Sanjay Agrawal
Editor

Obesity, Bariatric and Metabolic Surgery

A Practical Guide

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Foreword by President of British Obesity and Metabolic Surgery Society (BOMSS)

Obesity has become a pandemic, with billions of people across the globe now overweight or obese. This not only affects the health and longevity of each overweight person, but it also impacts massively on the economy and healthcare system in each and every country affected. As such, the management of this crisis is one of the greatest challenges facing the healthcare profession across the world.

No really successful pharmaceutical treatment currently exists and preventive measures seem just a pipe dream. This leaves bariatric surgery as the most effective tool that we have at the present time. The clinical value of such surgery is without question, and the number of bariatric operations performed has increased exponentially in recent years and continues to increase year on year.

Many different surgical procedures have been tried in the management of morbid obesity, and many different variations of each operation exist. *Obesity, Bariatric and Metabolic Surgery: A Practical Guide* is a major new surgical textbook, covering all aspects of obesity and its surgical management.

The book deals with the obesity epidemic, the underlying science of obesity and its health consequences. Non-surgical management of obesity is outlined, prior to an in-depth discussion of all aspects of bariatric and metabolic surgery. It describes the historical perspectives of obesity surgery, followed by a detailed discussion of patient selection and perioperative management. All of the different surgical techniques and variations of technique are described, each written by world experts in the field. It deals with the metabolic effects of bariatric surgery, and contains chapters dealing with the training, reporting and practice of bariatric surgery, finishing with many miscellaneous topics related to the field.

Not only is this textbook the perfect guide for the bariatric surgeon, but it will also act as a reference guide for physicians, family doctors and other healthcare professionals, such as dieticians and specialist nurses.

Sanjay Agrawal must be congratulated on putting together and editing what is undoubtedly the most modern and comprehensive textbook on the subject of the surgical treatment of obesity. He has bought together an amazing array of world renowned experts, each of whom has contributed chapters to the book. Looking at the list of authors is like reading a list of Who's Who in Obesity Surgery across the globe!

This book is set to become the worldwide reference guide to obesity and bariatric and metabolic surgery.

Roger Ackroyd, MD, FRCS
Consultant Upper GI and Bariatric Surgeon
Sheffield, UK

Foreword by President of International Federation of Surgery for Obesity and Metabolic Disorders (IFSO)

It is a great honor for me as the current President of the International Federation of Surgery for Obesity and Metabolic Disorders (IFSO) to be requested to write the foreword for this book *Obesity, Bariatric and Metabolic Surgery: A Practical Guide*.

Obesity has been declared a worldwide epidemic. The etiology of obesity is highly complex and multifactorial encompassing genetic, environmental, physiologic, cultural, political, and socioeconomic factors. This makes it a challenge to develop effective interventions to prevent and manage obesity. The key solution for this epidemic is the prevention of obesity. However, once morbid obesity develops, bariatric or metabolic surgical intervention is the most effective and long-lasting treatment.

The editor of the book, *Mr. Sanjay Agrawal* from Homerton University Hospital, London, United Kingdom, has been able to collaborate with and motivate a large number of experts from around the world to contribute for the contents of the book. He has organized the time-limited submission and painstakingly reviewed all chapters to give the book its final shape.

A total of 152 authors from across the globe with practical experiences in the surgical and endoscopic treatment of obesity have elaborated upon the different aspects of obesity and its surgical management. The ever-increasing number of publications from across the world in the field of metabolic or bariatric surgery is an indicator of the rapid growth of this field of modern medicine.

Through 78 chapters, spread across 14 sections, this book offers a concise summary of obesity and its surgical management for a wide range of healthcare professionals involved within a multidisciplinary team such as surgeons, anesthetists, physicians, dietitians, psychologists, radiologists, and nursing staff. The 14 sections were edited mainly by surgeons and scientists from the United Kingdom. The chapters themselves were written by international experts in the field from 20 countries covering five different continents. This makes the book an excellent reference guide for physicians, surgeons, and general practitioners.

Besides the basic fundamentals, pathophysiology and surgical techniques for morbid obesity, other important practical aspects are also discussed in detail. These include the credentials for training in the field of metabolic surgery, the quality control of bariatric surgery services, and the data management and reporting systems used worldwide. Medico-legal issues that play an important role in metabolic surgery are described in a special chapter. The spectrum of actual procedures in the field of bariatric and metabolic surgery is completely represented in this book. Online videos for many of the procedures make this book an excellent training tool as well.

The well-documented therapeutic effects of metabolic/bariatric surgery on several obesity-related diseases, the increased life expectancy after weight-loss surgery and the fact that surgery is more cost-effective than nonsurgical management are likely to change the indications for such surgeries in the future.

Surgery for morbid obesity involves surgical manipulation of normal body parts to get a biological result that can potentially cause weight loss and arrest weight regain. Hence, such surgery is considered as metabolic surgery. The actual body weight and the body mass index are not the sole indications for surgery. Henry Buchwald, who first coined the term *metabolic surgery* said, "Metabolic surgery is cognitive surgery." The realization that bariatric surgery is actually metabolic surgery is, however, relatively new. The term *bariatric* is expected to be changed to *metabolic* surgery in the future. The future of this field is extremely bright and rapid advancements likely to happen. Therefore, we can expect a second edition soon.

Rudolf A. Weiner, MD, PhD
Professor of Surgery at University of Frankfurt am Main, Germany

Head of the Obesity Center Sana-Klinikum Offenbach am Main, Germany

Foreword by Pradeep Chowbey

Obesity is the modern-day scourge of mankind. The obesity epidemic is sweeping across nations, regions, and continents. There are enormous implications of the obesity pandemic for the affected population and health care delivery systems globally. Increasingly large segments of obese population have to contend with declining health parameter, poorer quality of life, and increased costs of health care.

The management of obesity is complex and involves several medical and surgical disciplines. Bariatric is an area of health care that epitomizes importance of teamwork and synergy in providing optimal health care delivery. Bariatric surgery today has evolved into a highly specialized surgical discipline in the short span of a few decades. Bariatric surgeons worldwide are a busy lot and the tribe is expanding in an effort to keep pace with demand.

On browsing through the list of contents of Dr. Agrawal's textbook, it is apparent that this is a textbook that is comprehensive, broad based, and yet exhaustive. The initial section of the textbook comprises an introduction to the problem of obesity and metabolic syndrome, the rationale and case for bariatric surgery, preoperative assessment, anesthetic considerations, and perioperative management of the bariatric patient. The subsequent sections describe the standard bariatric surgical procedures in elaborate detail as also different approaches like single incision bariatric surgery. Also included are complex situations like revisional surgery and some less commonly performed bariatric procedures. Newer endoscopic approaches and pure metabolic surgical procedures are described.

The expanse and scope of this textbook is immense. I cannot think of an important and relevant subject in bariatric surgery that has not been covered. I think this textbook would serve as a useful reference book for the armchair academic, the novice, and the experienced bariatric surgeon. I am impressed with the list of contributors that includes several leading practitioners in bariatric surgery.

I believe Dr. Agrawal's textbook will provide a reference and insight into the state-of-art information and knowledge on bariatric surgery as it exists today. I wish him the best for the current and all future endeavors.

Dr. Pradeep Chowbey
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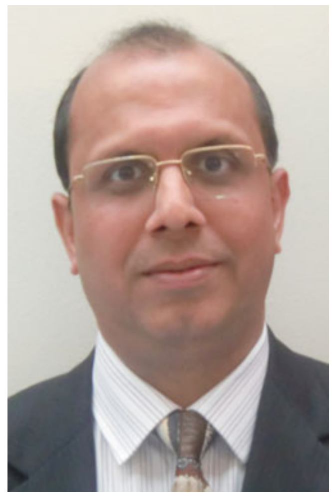
President– International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) 2012–2013

Asia Pacific Chapter of IFSO (IFSO-APC) 2011–2013

Asia Pacific Metabolic & Bariatric Surgery Society (APMBSS) 2010–2012

Obesity & Metabolic Surgery Society of India (OSSI) 2006–2010

Preface



Obesity has become an epidemic worldwide. Bariatric and metabolic surgery is in a state of continuing flux. For the clinicians and other health-care professionals involved in the care of an obese patient, keeping up with all these changes is a challenging task. This new book will offer a comprehensive yet concise summary about obesity and its surgical management, making it an ideal guide for all.

The book's 78 chapters are spread across 14 sections, each with an Honorary Section Editor. Each lead author was carefully selected and is an expert in their chosen subject. Over 150 experts from 20 countries across five continents have contributed to the content of the book.

The book covers all the aspects of bariatric and metabolic surgery including perioperative management, surgical techniques of common as well as newer procedures, complications, and outcomes. There are dedicated sections on revisional surgery, single-incision surgery and innovative endoscopic procedures. The book is well illustrated with photographs and video clips along with step-by-step guidance for a complete range of bariatric procedures. Medical aspects of obesity and metabolic syndrome are included in the introductory sections, and the last two sections cover diverse topics in this exciting field of bariatric and metabolic surgery.

I would like to express my deep appreciation and gratitude to the many people involved in the preparation of this book. First and foremost, the authors, for their timely submission of a high quality content within each chapter of the book. I would like to thank all the Honorary Section Editors who selflessly have invested enormous amounts of their time and energy in this project. I wish to record my special thanks to all the reviewers for their independent review of every chapter in the book. I would also like to mention Dr Natasha Das whose! careful attention to detail as copy editor has been critical to the quality of the finished book. Finally, I would like to thank my family, especially my wife and children who missed me greatly during this time-consuming endeavour and for their encouragement in completing this book.

The book will serve as an excellent manual for a wide range of healthcare professionals including bariatric surgeons, general surgeons, trainees, physicians, anaesthesiologists, dietitians, psychologists, radiologists and nursing staff.

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Section I

Obesity and Metabolic Syndrome

Honorary Section Editor - Rachel L. Batterham

Obesity is one of the greatest twenty first century public health challenges. It is responsible for approximately 5 % of all deaths a year worldwide. Its global economic impact amounts to roughly $2 trillion annually, which equates to 2.8 % of global gross domestic product. Currently, more than 2.1 billion people, approximately 30 % of the global population, are overweight or obese. More worryingly if the prevalence of obesity continues on its current trajectory, almost half of the world's adult population will be overweight or obese by 2030.

The chapters in this section summarise how obesity is defined and assessed, provide an overview of the biology of energy regulation, the health and economic consequences of obesity and its medical management. Chapter 1 outlines the epidemiologic and economic burdens of obesity, how overweight and obesity are classified and the current methodologies used to assess the degree of adiposity and its distribution. Chapters 2 and 3 summarise the biological basis of energy homeostasis. Chapter 2 outlines the main peripheral short and long-term signals that regulate energy balance, the central homeostatic and reward brain regions upon which these act and the key neurotransmitters implicated. This chapter also summarises how genetic and environmental factors influence body weight regulation. Chapter 3 reviews the physiological effects of the gut-derived orexigenic hormone, ghrelin, and the enteroendocrine L-cell derived satiety hormones peptide YY (PYY), glucagon-like peptide (GLP-1) and oxyntomodulin (OXM). Emphasising how an increased understanding of the biology of enteroendocrine cells may hold the key to novel therapeutic approaches for treating obesity and type 2 diabetes. Chapter 4 summarises the health consequences, societal and economic burdens of obesity and the complex bidirectional interplay between medical problems causing obesity and obesity causing medical problems. The final chapter in this section reviews the medical management of obesity, which aims to reduce morbidity and mortality while improving psychological well-being and social function. This chapter summarises the clinical assessment of obesity, available treatment options and how to target limited resources to those who will gain the greatest health benefits. It also highlights the importance of combined dietary and physical activity interventions, the utility of behavioural interventions for weight loss maintenance and the health benefits of modest (10 %) weight loss.

There is optimism that with continued advances in our understanding of the biology of energy regulation, in particular the mechanisms by which bariatric surgery mediates its beneficial weight loss and metabolic effects that non-surgical therapies, rivalling the health benefits of surgery are on the horizon.

1 Introduction to Obesity

Imran Alam and Sanjay Agrawal

Abstract

Obesity is defined as an abnormal or excessive accumulation of fat that may impair health. According to World Health Organization (WHO), any individual with a body mass index (BMI) greater than or equal to 30 kg/m^2 is obese and severe or class III obesity is defined as a BMI equal to or greater than 40 kg/m^2; this term is also used for individuals with a BMI between 30 and 39.9 kg/m^2 who have significant comorbidities. National Institute of Clinical Excellence (NICE) has recommended bariatric surgery for such individuals. The prevalence of severe obesity has increased significantly in the last two to three decades. Mexico and United States of America have highest prevalence in the world and United Kingdom is leading in Europe. BMI is used as a surrogate for adiposity. There are other methods like bioimpedance analysis, dual-energy x-ray absorptiometry (DEXA), hydrometry, computed tomography (CT), magnetic resonance imaging (MRI) and others but for all clinical and interventional purposes, BMI is used as a measure of obesity.

Fat is the main source of stored energy and it also secretes number of hormones and cytokines. Excess central fat deposition is associated with increased risk of morbidity and mortality. Overweight (BMI of 25 kg/m^2 to 29.9 kg/m^2) is associated with increased risk of comorbidities such as type 2 diabetes mellitus, cardiovascular diseases, respiratory disorders, infertility, certain forms of cancers, psychological and social problems; and the risk of these comorbidities increases significantly with further increase in BMI. The cost of treating obesity and associated comorbidity is causing significant burden on the health system. Conservative treatment has a high failure rate. Bariatric surgery performed primarily for weight reduction also causes resolution/remission of associated comorbidities.

Keywords

Severe Obesity • Prevalence • Body Mass Index • Waist and Hip Circumference • Fat • Adipose Tissue • Morbidity • Mortality

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1.1 Obesity Definition

Obesity is defined as an excess of body fat (increased fat cell size and number) relative to lean body mass [1]. Clinically, obesity is defined on the basis of BMI. Any person with BMI between 25 and 29.9 kg/m^2 is termed overweight and any individual with BMI 30 kg/m^2 or more is classified as obese (see Table 1.1) [2]. Severe or class III obesity is defined as BMI 40 kg/m^2 or more with or without significant comorbidity. This term is also used for individuals with a BMI between

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30 and 39.9 kg/m^2 who have significant comorbidities [3]. Any individual with BMI equal to or greater than 50 kg/m^2 is termed super obese [4]. However, super obesity is not officially recognized as a weight category by classification systems that are designed to stratify various treatment regimens [5]. Based on the BMI, obesity is divided in to class I, II and III and risk of comorbidities increases from classes I to III (discussed in more details below).

1.2 Prevalence of Obesity

The prevalence of obesity among adults (defined as people aged 16 years and over) has been increasing over the last 30 years in virtually every country in the world (see Fig. 1.1). It has increased between 1980 and 2013 from approximately 29–38 % in men and from 30 to 39.0 % in women. Mexico and United States of America (USA) were among the countries with the highest prevalence of obese population until recently, but now according to a recent report in adults, estimated prevalence of obesity has exceeded 50 % in men in Tonga and in women in Kuwait, Kiribati, Federated States of Micronesia, Libya, Qatar, Tonga, and Samoa [6, 7].

The prevalence of severe obesity in England has more than doubled in the last 25 years. The prevalence of adult obesity rose from 13 % of men in 1993 to 25 % in 2011 and from 16 % of women in 1993 to 26 % in 2011 (see Fig. 1.2). The prevalence of severe obesity has increased from 1.4 % in 1993 to 3.2 % in 2011 among women and from 0.2 % in 1993 to 1.7 % in 2011 among men (see Fig. 1.3) [8]. As the prevalence of obesity in England increases, it has become a major public health concern due to its association with serious chronic diseases and related morbidity and mortality.

According to National Obesity Observatory (NOO), prevalence of obesity varies in different social classes. Women living in more deprived areas are more likely to be obese than residents of affluent areas. Obesity prevalence rises from 18.3 % in the least deprived quintile to 24.5 % in the most deprived quintile (see Fig. 1.4). There is no clear pattern for men. Similarly, prevalence also varies in different ethnic groups, for example women from black African groups appear to have the highest prevalence of obesity and men from Chinese and Bangladeshi groups the lowest. Women seem to have a higher prevalence in almost every minority ethnic group, with a significant difference between women and men among the Pakistani, Bangladeshi, and Black African groups (see Fig. 1.5).

The number of recorded hospital admissions in the National Health Service (NHS) in England related to obesity rose by more than 30 % in 1 year, from nearly 8000 in 2008/09 to nearly 10,600 in 2009/2010 and rising again by almost 10 % in 2010/2011 to 11,600. The number of prescription items dispensed in the community in England specifically to treat obesity also increased from 1.28 million in 2008 to 1.45 million in 2009, a rise of 13 %.

Table 1.1 Primary classification of obesity

Grade of obesity	BMI (wt. in kg/ht. in m^2)	Risk of co-morbid diseases
Underweight	BMI < 18.5 kg/m^2	Low risk of co-morbid disease
Normal	BMI between 18.5 and 24.9 kg/m^2	
Overweight	BMI between 25 and 29.9 kg/m^2	+
Obese	BMI > 30	
Class I	BMI between 30 and 34.9 kg/m^2	+ +
Class II	BMI between 35–39.9 kg/m^2	+ + +
Class III	BMI between >40 kg/m^2	+ + + +

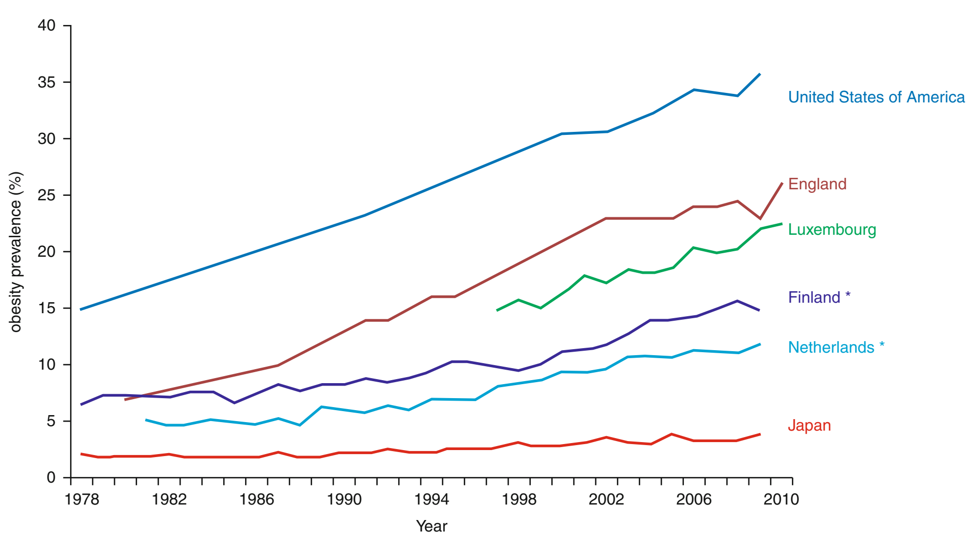

Fig. 1.1 Trends in adult prevalence of obesity in a selection of countries (Source: OECD Health Data 2011—Version: November 2011) *Self reported data (prevalence rates for the other countries are based on measured data) Source: Public Health England (http://www.noo.org.uk/NOO_about_obesity/adult_obesity/international)

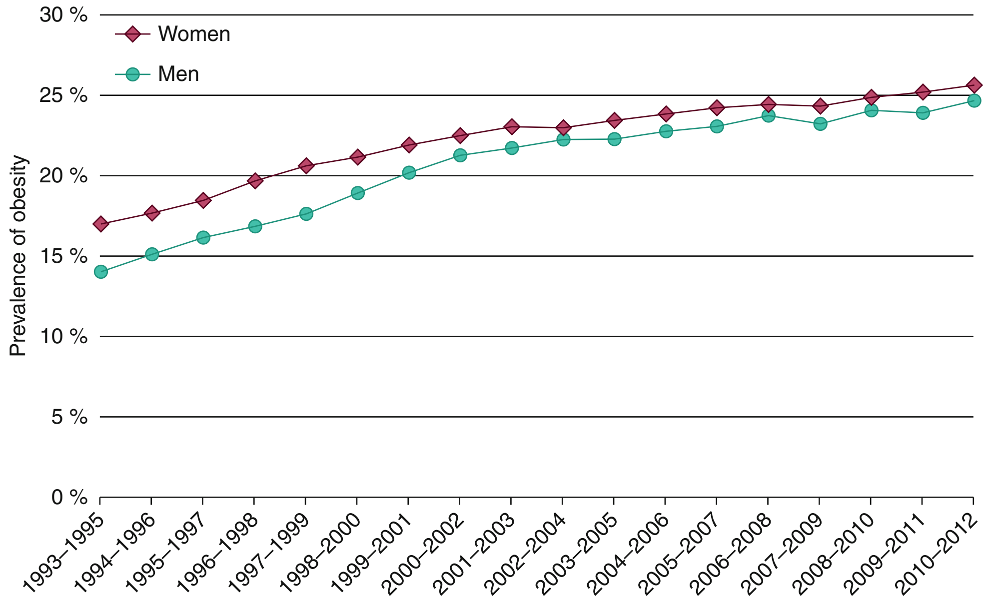

Fig. 1.2 Trends in adult prevalence of obesity in England (Source: HSE, 1993–2012) Adult (aged 16+) obesity: BMI ≥30 kg/m². Three-year average of published prevalence figures. Source: Public Health England (http://www.noo.org.uk/NOO_about_obesity/adult_obesity/international)

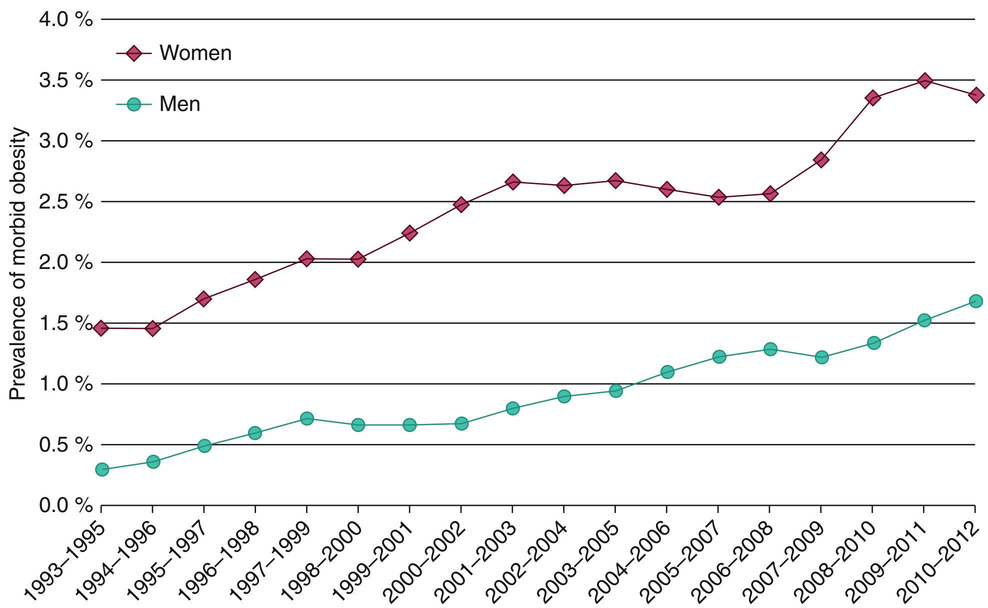

Fig. 1.3 Trends in adult prevalence of morbid obesity in England (Source: HSE, 1993–2012). Source: Public Health England (http://www.noo.org.uk/NOO_about_obesity/severe_obesity)

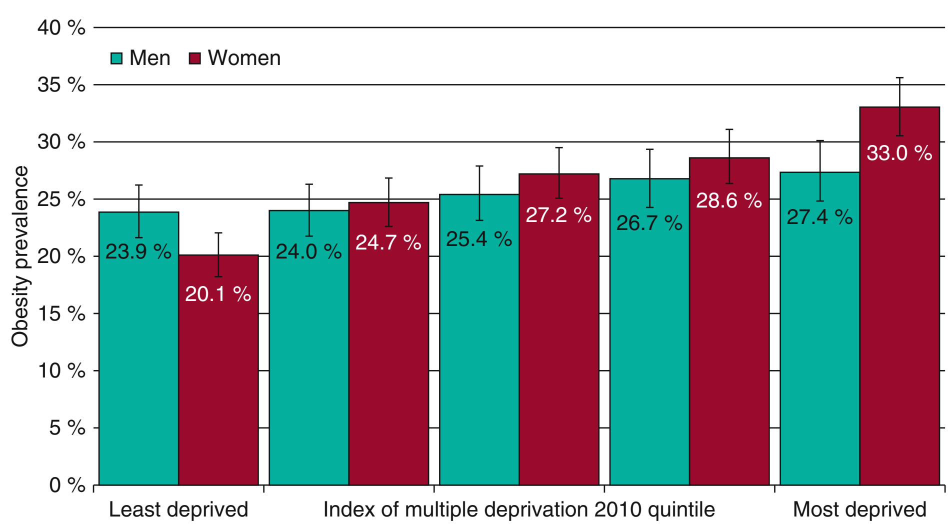

Fig. 1.4 Prevalence of obesity in adults (aged 16 and over) by deprivation quintile based on IMD 2010, 2011–2012 (Source: Public Health England. Adult obesity and socioeconomic status data factsheet. August 2014)

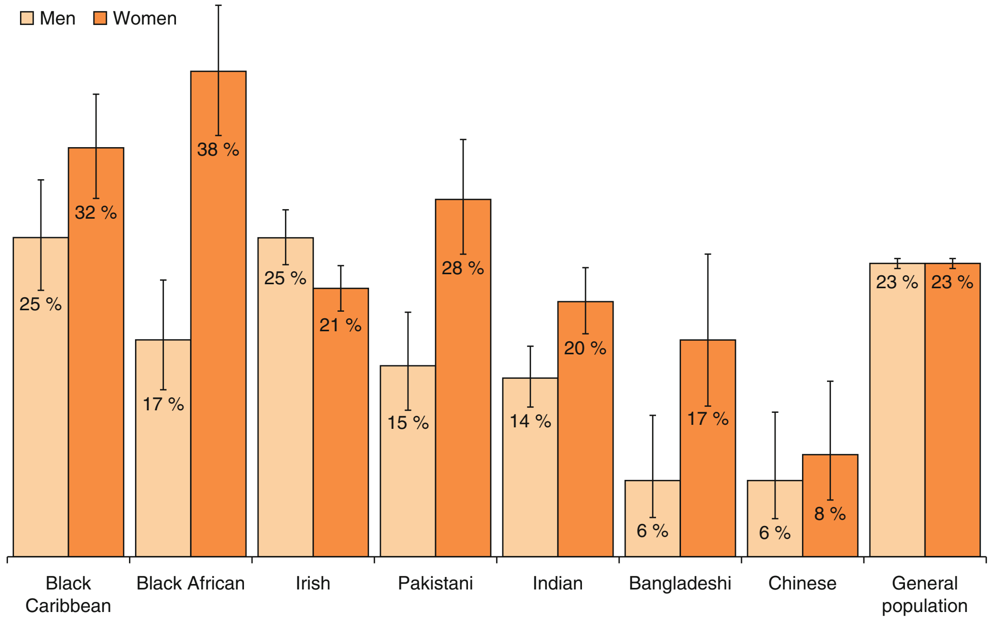

Fig. 1.5 Prevalence of obesity in adults (aged 16 and over) by ethnic group and sex, 2004 (Source: Public Health England (http://www.noo.org.uk/NOO_about_obesity/inequalities))

In 2007, estimates of direct NHS costs of treating obesity and associated comorbidities in England were 4.2 billion pounds estimated to be 6.3 billion pounds in 2015. By 2050, obesity is predicted to affect 60 % of adult men and 50 % of adult women [9]. The NHS costs attributable to overweight and obesity are projected to double to 10 billion pound per year by 2050. The wider costs to society and business are estimated to reach 49.9 billion pound per year (at today's prices) [9].

The United Kingdom as a whole had the highest proportion of deaths attributable to obesity in Europe; it is 8.7 %, compared to 7.7 % of all deaths across the European Union [10]. It is difficult to measure obesity related deaths in a population because of number of reasons, for example there is general approach of documentation that tends to underestimate the proportion of obesity related deaths; a recent study has shown that obesity was mentioned only on 0.23 % of all death certificates during 2006 [10].

According to calculation of National Audit Office (NAO) in 1998, 6 % of all deaths in UK were caused by obesity. This is compared to 10% caused by smoking and 1% caused by road traffic accidents [11]. NAO also estimated that each individual whose death was attributed to obesity, lost approximately Nine years of his/her life. Since the prevalence of obesity has increased significantly since 1998, at present it is difficult to estimate the trends because a lot of effort has been made to create awareness and also to treat obesity.

1.3 Measurement of Obesity

The common methods for assessment of obesity are BMI, waist circumference (WC), waist-to-hip ratio (WHR), and skin fold thickness. The methods of analysis are discussed below.

1.3.1 Body Mass Index

Body mass index (BMI) was devised in the 1830s by Lambert Adolphe Jacques Quetelet, a Belgian mathematician. BMI is the most commonly used method to measure obesity. This measure makes no specific measurement of body fat but records total weight relative to height (see Table 1.2). No specialized equipment is required; so it is easy to measure accurately and consistently across different countries and regions. Therefore, it has been accepted as an international standard for the measurement of obesity [12]. It is calculated by dividing weight (in kilograms) by square of height (in meters). BMI has some limitations; it does not take in to account body fat distribution, muscle mass, bone density, overall body composition, racial sex differences, or ethnicity; which influences the correlation between BMI and health.

Kidney, liver, and heart are more severely affected by abdominal fat than by the fat around the bottom or hips. In addition, very high muscle mass skews the BMI measures.

Muscle is denser and weighs more than fat (a cubic centimeter of muscle weighs more than a cubic centimeter of fat). Therefore, well built, athletic people will inevitably be classed as fatter, by BMI, than they really are. A BMI calculation of an 1.83 meter (m) tall Olympic 100 m sprinter weighing 90 kg (200 lbs) will be same as that of sedentary individual of the same height and weight; and both will be classed as overweight. The athlete's waist circumference, at 86 cm, is well within "healthy weight," if his height is 1.83 m, his waist is less than half his height. However, the sedentary person's waist of 102 cm is more than half his height.

Research has shown that for the same BMI, people of African ethnicity are likely to carry less fat while people of south Asian ethnicity carry more fat than the general population [13]. This indicates that BMI overestimates obesity among Africans and underestimates obesity in South Asians. Using adjusted thresholds for these ethnic groups could improve obesity estimates.

At present the primary classification of obesity is based on BMI (see Table 1.1), and the risk of comorbid diseases increases exponentially from a BMI more than 30 kg/m^2 (see Fig. 1.4). Of note, the relationship between BMI and disease varies among the individuals and its limitation under various circumstances must be recognized. It is possible for an individual to have high BMI but low body fat (very muscular and well exercised sportsman) or low BMI and high body fat (females and individuals with lost muscle mass such as elderly person) [12].

National Institute of Clinical Excellence (NICE) has recommended the use of BMI in the management of overweight and obesity in adults. NICE has also recommended use of BMI to classify the degree of obesity and to determine the health risks. Obesity has been divided into class I (BMI between 30 and 34.9 kg/m^2), class II (BMI between 35 and 39.9 kg/m^2) and class III (BMI more than 40 kg/m^2); the risk of comorbidities increases with higher BMI (see Table 1.1).

Table 1.2 Formula for calculation of BMI, IBW, EW and %EWL

BMI = Weight in kg/height in m^2 (kg/m^2)
IBW Adult Female: 5 feet tall = 119 lb. Adult Male: 5 feet tall = 135 lb. (for each additional inch, add 3 lb.) 1 foot = 30.4 cm; 1 inch = 2.54 cm Divide lb. by 2.2 to change to kg
EW = Actual Weight − Ideal Weight
%EWL = [(Operative Weight − Follow-up Weight)/Operative Excess Weight] × 100
%EBMIL = (Preoperative BMI − current BMI/preoperative BMI − 25) × 100

Formula corresponds to mid-point of medium frame of the Metropolitan Table, with accuracy within 1 %. To convert to IBW for small or large frame decrease or increase the result by 10 %. BMI = body mass index; IBW = Ideal body weight; EW = Excess weight; %EWL = Percent excess weight loss; %EBMIL = Percent excess body mass index loss.

Studies have shown BMI is a good predictor of an individual's risk of death. There is a J-shaped relationship between BMI and risk of death, demonstrating high and low BMI are associated with higher risk of death than the BMI in the middle range (see Fig. 1.6) [14]. NICE, in the current guidelines, recommends the use of BMI in conjunction with waist circumference as the method of measuring overweight and obesity and determining health risks, specifically.

1.3.2 Ideal Body Weight, Excess Weight

The Metropolitan Life Insurance Company, founded on March 24, 1868 [15], is among the largest global providers of insurance, annuities, and employee benefit programs, with 90 million customers in over 60 countries [16, 17]. The Metropolitan Life Insurance Company introduced their standard height-weight tables for men and women in 1943; revised 20 years later in 1983. They are called desirable weights, indicating individuals with the lowest mortality rates [18]. However, the phrase ideal weight gradually became associated with these tables in common usage, even though the word ideal was not specifically published with the tables.

A person's ideal body weight (IBW) is based on the Metropolitan Life Insurance Company standard height and weight tables for men and women [19]. Excess weight (EW) is the weight above IBW (see Table 1.2).

1.3.3 Percent Excess Weight Loss and Percent Weight Loss

Percent of excess weight loss (%EWL) is calculated by using a formula described in Table 1.2. %EWL is widely accepted and used as a measure of successful outcome or failure of bariatric surgery in an individual. Percent of excess BMI lost (%EBMIL) has also been used to compare the treatment of

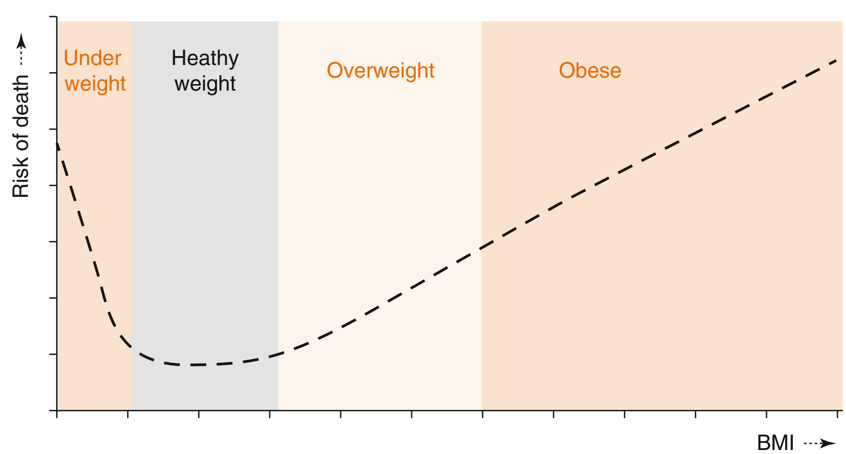

Fig. 1.6 Schematic illustration of the association between mortality and BMI (kg/m^2) (Source: Public Health England (http://www.noo.org.uk/NOO_about_obesity/mortality)).

moderate and severe obesity [20]. %EWL is now recognized as a better measure as least affected by starting BMI and has now been used as an outcome measure of obesity surgery [21].

A percentage, is used rather than the absolute number of pounds or kilograms lost to allow comparison of weight loss between persons or between types of bariatric procedures [22]. It is more widely accepted and is a better marker now (see Table 1.2).

1.3.4 Waist Circumference and Waist-to-Hip Ratio

Waist circumference (WC) and waist-to-hip ratio (WHR) are simple and the most commonly used indicators of body fat distribution. WC is a valid measure of abdominal fat mass and disease risk in individuals with a BMI less than 35 kg/m^2. If BMI is 35 kg/m^2 or more, WC adds little to the absolute measure of risk provided by BMI. Therefore, WC and WHR are not routinely measured in patients with BMI greater than 35 kg/m^2.

A raised waist circumference is defined as greater than 102 cm in men and greater than 88 cm in women [23]. WC and WHR are correlated with risk factors for cardiovascular disease, hyperglycemia and blood lipids [24]. Changes in WC reflect changes in risk factors for cardiovascular disease [25]. Thus, because of its greater simplicity WC has been recognized as useful measure of obesity. It has been shown that WC of more than equal to 102 cm in men and more than equal to 88 cm in women carries the same risk as a BMI of 30 kg/m^2 [26].

WHR is an inexpensive method. Studies have shown that development of disease and death in adults can be predicted by waist-to-hip ratio. WHR has good correlation with body fat when measured by the most accurate methods. However, it is less accurate and adds little value to risk prediction in individuals with a BMI of 35 kg/m^2 or higher. It is difficult to measure and is prone to measurement errors as it requires more than one measurement. Measuring hip circumference is more difficult than measuring waist circumference and it is more complex to interpret hip circumference than waist circumference, since increased waist-to-hip ratio can be caused by increased abdominal fat or decrease in lean muscle mass around the hips, turning the measurements into a ratio leads to a loss of information as two people with very different BMIs may have the same WHR.

The use of BMI cut-offs as generally proposed seems to be somewhat limited, if we accept that the diagnosis of visceral obesity is more important than overall obesity. Therefore, it is probably much better to consider both BMI and WC, and to diagnose visceral obesity when this is more than equal to 102 cm in males and 88 cm in females (see Table 1.3) [27].

Table 1.3 Waist circumference range in men & women

	Men (cm)	Women (cm)
Normal	<94	<80
Moderate risk	95–102	80–88
High risk	>102	>88

1.3.4.1 Waist and Hip Circumference Measurements

The waist and hip measurements are performed in a standing position with arms at the side, legs placed one foot apart with the weight equally divided over both legs.

Waist Circumference

The lowest rib margin and the iliac crest are located (by palpation) and marked. The same procedure is performed on the opposite site. The tape measure is placed horizontally midway between the marked sites on both side and wrapped firmly around the abdomen (approximately at the level of umbilicus). The subject is asked to breathe normally and the measurement is taken when the subjects breathes out (the patients are not informed about the timing of measurement). Three measurements are required and all are recorded to 0.1 cm.

The mean of the three measurements are recorded with a precision of 1 %cm.

Hip Circumference

This measurement is taken at the point yielding the maximum circumference over the buttocks. The tape measure is placed horizontally. The tape is placed horizontally, touching the skin but not indenting the soft tissue. Three measurements are taken and all recorded to 0.1 cm. The mean of the three measurements are recorded with a precision of 1 cm.

Waist-to-Hip Ratio

Waist-hip ratio is calculated by dividing WC with HC. A WHR of 0.7 for women and 0.9 for men has been shown to correlate strongly with general health. Abdominal obesity is defined as a waist–to-hip ratio above 0.90 for males and above 0.85 for females [28].

1.3.5 Skin Fold Thickness

Skin fold measurement is inexpensive, easy to do, and a portable method. However, the results, being dependent on technician's skills and site measured, are subjective. Additionally, this method has inherent short comings as it is based on two assumptions; one is that the thickness of the subcutaneous fat reflects a constant proportion of the total body fat (contained on body cavities), and the second is that the site selected for measurement represents the average thickness of the measured fat. To have a greater precision of the results the calipers that are to be used must be accurately calibrated and should have a defined constant pressure.

In large population studies often only one site is measured to reduce the time involved. If more than one site is measured then a calculation is used to derive a body fat percentage based on the sum of the measurements. This test should only be used for rough estimate of obesity.

1.3.6 Bioimpedance Analysis

Bio-electrical impedance analysis (BIA) measures the impedance to the flow of an electric current through the body fluids. Impedance is low in lean tissue, where intracellular and extracellular fluid and electrolytes are primarily contained, but high in fat tissue. Consequently, impedance is proportional to body water volume (TBW). BIA is a good alternative for measurement of percentage body fat (%BF) when subjects are within normal body fat range. BIA tends to overestimate %BF in lean subjects and underestimate %BF in obese subjects [29].

1.3.7 Other Methods Used for Obesity Measurement

1.3.7.1 Dual Energy X-Ray Absorptiometry (DEXA)

Dual energy x-ray absorptiometry (DEXA) scanning is a useful and accurate method for assessing body composition. Currently, DEXA scans take approximately 5–20 min and use standard software for analyses [30]. Its ability to study body composition in the whole body and individual body segments is also helpful for determining body fat distribution and regional bone mineral density (see Fig. 1.7). The equipment is relatively expensive, cannot be moved and it cannot accurately distinguish between different types of fat (fat

Fig. 1.7 DEXA scan showing whole body fat composition in a morbidly obese individual (Hologic DXA body composition image ©[copyright] Hologic; used with permission).

under the skin, also known ast "subcutaneous" fat versus fat around the internal organs, or "visceral" fat). It cannot be used in pregnant women, since it requires exposure to a small dose of radiation [31].

The maximum weight limit is 136 kg (300 lb) and width of scanning area is approximately 60 cm but with the introduction of iDXA (GE Lunar Medical Systems, Madison, WI), the weight limit has increased to 181.5 kg (400 lb) and scanning width has increased to 66 cm [25]. There is an excellent correlation between DEXA predicated abdominal fat and CT measured total abdominal adipose tissue [30].

1.3.7.2 Hydrometry (Dilution Method)

Hydrometry involves drinking isotope-labeled water and sampling of body fluid. The isotope level is measured in body fluid sample, which is subsequently used to measure total body water, fat free body mass, and in turn, body fat mass [32]. This method is relatively inexpensive, safe, and accurate. It can be used in individuals with a BMI of 40 or higher and is most accurate method of assessment in very obese (more than 200 kg or 440 lb) children and pregnant women [10]. The accuracy decreases as the ratio of body water to fat free mass changes e.g. during illness, dehydration, or weight loss.

1.3.7.3 Underwater Weighing (Densitometry)

Underwater weighing is usually used in research settings where individuals are weighed in air while submerged in a tank. Formulas are used to estimate body volume, body density, and body fat percentage. Fat is more buoyant (less dense) than water, so an individual with high body fat will have a lower body density than someone with low body fat [33]. It is accurate but time consuming and requires individuals to be submerged in water. It is generally not a good option for children, older adults, and individuals with a BMI of 40 kg/m^2 or higher.

1.3.7.4 Air Displacement Plethysmography

In air displacement plethysmography, air is used instead of water. Individual is made to sit in an empty chamber wearing a bath suit and the body volume is calculated by means of pressure difference between the empty and occupied chamber. It is less time consuming, less troublesome, and relatively better choice for children, pregnant women, and older people with a BMI of 40 kg/m^2 or above. Air displacement plethysmography is an expensive but a safe and more accurate option for subjects.

1.3.7.5 Computed Tomography or Magnetic Resonance Image

Computed tomography (CT) or magnetic resonance image (MRI) scanning, have useful clinical and research application. They can give accurate results and organ specific adiposity levels. However, access is limited to a few specialized centers and information is gained at the expense of increased radiation exposure. They are however helpful to calibrate other more accessible methods of fat mass assessment for example hydrometry using isotope radio labeled water [12]. CT scans cannot be used with pregnant women or children due to the high amounts of ionizing radiation used. Some MRI and CT scanners may not be able to accommodate individuals with higher body weights (upper weight limit of 200 kg or 440 lb) but the greatest issue with MRI is the limited bore size.

1.4 Importance of Assessing Abdominal Fat

Excess abdominal fat or adipose tissue represents central body fat distribution (between thorax and pelvis, central obesity or apple shaped obesity). It is an independent predictor of risk factors and morbidity [34]. Abdominal fat is composed of three compartments which are visceral, retroperitoneal, and subcutaneous. The relative contribution of the different component of abdominal wall to overall risk remains uncertain. Several studies have shown that visceral fat component is most strongly associated with risk factors for cardiovascular disease [32]. Similarly, the size of the deep truncal subcutaneous component may be linked with insulin resistance (IR) and Type 2 diabetes mellitus [24, 35]. The presence of central obesity appears to be an independent risk factor even when BMI is not markedly increased [36]. It is important to measure the waist and BMI for initial assessment of obesity and as guide to the efficacy of weight loss [37].

Key Learning Points

- Mexico and USA have the highest prevalence of morbid obesity in the world and UK is leading in Europe.
- BMI and waist/hip measurements are most simple practical means of measuring obesity in the individuals with BMI 35 kg/m^2 or less.
- Based on BMI obesity is divided in to class I, II and III and risk of comorbidities increases from class I to III.

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Etiopathogenesis of Obesity

2

Surya Panicker Rajeev and John Wilding

Abstract

Obesity develops in an individual when energy intake exceeds energy expenditure over a prolonged period and the excess is stored as triglyceride, predominantly in adipose tissue. The rising prevalence of obesity is a worldwide problem and to understand the pathogenesis, it is important to understand regulation of energy balance, which although very tightly regulated, is subject to biological variation and easily overwhelmed by societal pressures and marketing influences. Control pathways for food intake and energy expenditure during as well as between meals include short-term mechanisms that operate from gastrointestinal tract to the central nervous system, as well as long-term signals that regulate the 'set point' for body weight, which are dominated by leptin, an adipocyte derived hormone. These pathways converge in the central nervous system, notably the hypothalamus, which plays a vital role in controlling food intake, energy expenditure and other aspects of metabolism. Various genetic and environmental factors can influence these energy homeostasis mechanisms. Foods that are high in sugars and fat are potent rewards that promote eating even in the absence of absolute energy requirement, particularly in modern societies where food is available in abundance, contribute to the obesity epidemic. Single gene disorders that result in obesity such as leptin deficiency and mutations in the pro-opiomelanocortin gene are rare but demonstrate the biological importance of these systems. Other etiological factors in some people may include drugs that increase appetite through central or peripheral mechanisms and structural damage to the hypothalamic areas involved in control of appetite. However, the recent increase in the prevalence of obesity is predominantly due to adverse environmental factors that are able to override these regulatory systems. These include widespread availability of high-energy foods, coupled with an unprecedented decline in levels of physical activity.

Keywords

Obesity • Appetite • Genetics • Ghrelin • Leptin • Pro-opiomelanocortin • Metabolic rate • Energy balance • Diet • Physical activity

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2.1 Introduction

If energy intake from food and drink exceeds that expended by the body through metabolism and physical activity the excess is stored as fat; this will eventually result in obesity if the imbalance persists over time. A complex interplay of genetic and environmental factors determines the age of onset and the severity of obesity. Knowledge of the regulation

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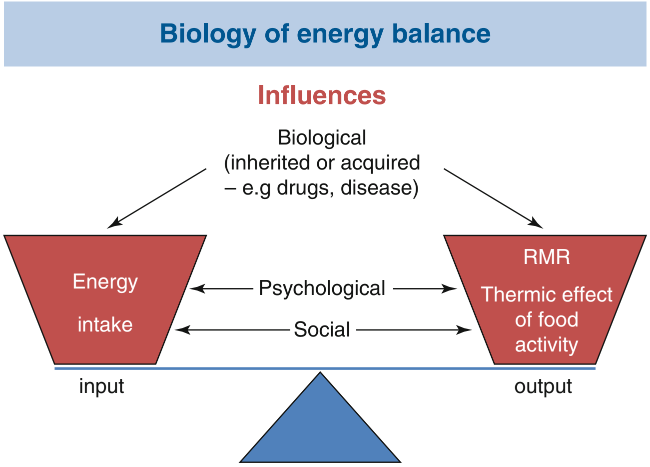

Fig. 2.1 Explains the energy balance mechanisms. *RMR* Resting Metabolic Rate

of energy balance (see Fig. 2.1) is essential to understand the pathogenesis of obesity.

2.2 Regulation of Energy Balance

There is tight regulation of energy balance in humans; however, there is a tendency to gain weight throughout adult life of about 1 kg per year, reflecting the fact that energy balance mechanisms evolved to protect against weight loss rather than preventing weight gain.

Food intake and energy expenditure are under the control of the central nervous system. There are afferent signals arising from the gastrointestinal tract, liver and adipose tissue, which regulate energy intake as well as efferent neurohormonal signals influencing the digestion and metabolism of food. Signals from adipose tissue, mostly hormone leptin, also influence long-term regulation. Recent research has shown that there is a small capacity to metabolize excess energy through uncoupling of mitochondrial oxidation in brown adipose tissue in non-obese young adults.

2.2.1 Role of the Central Nervous System

Central nervous system (CNS) regulates energy balance by sensing metabolic status from various neurohumoral signals and thereby controls energy intake. However, sight, smell, texture and memory of foods as well as the social situation also influence these systems. There are at least 50 different neurotransmitters in the CNS responding to the circulating nutritional and neurohormonal signals. These determine feelings of hunger and satiety as well as influence the metabolic rate. In general, signals that increase food intake tend to lower metabolic rate and vice versa. Table 2.1 shows some key neurotransmitters and Table 2.2 shows peripheral signals that influence appetite and energy expenditure.

Table 2.1 Neurotransmitters involved in food intake

Neurotransmitters that increase food intake	Neurotransmitters that decrease food intake
Dopamine	α[alpha]- MSH
Agouti related peptide	Cholecystokinin
Neuropeptide Y	GLP-1
Melanin concentrating hormone	Calcitonin gene related peptide
Orexin	Bombesin
Galanin	Serotonin
Nitric oxide	Corticotrophin-releasing factor
Nor-adrenaline	Neurotensin
Opioids	
GABA	

GABA gamma aminobutyric acid, ∝− *MSH* ∝− melanocyte stimulating hormone, *GLP-1* glucagon-like peptide −1

Table 2.2 Peripheral signals

Ghrelin
Glucose
Serotonin
Catecholamines
Cholecystokinin
Glucagon-like peptide 1
Peptide YY 3–36
Insulin
Nutrients
Leptin

Dopamine is a key neurotransmitter modulating reward and it acts mainly through its projections from the ventral tegmental area (VTA) to nucleus accumbens (NAc). On first exposure to a food reward, the firing from dopaminergic neurons in the VTA increases, resulting in increased dopamine release in NAc. With such repeated exposures, the response habituates and is gradually transferred on to stimuli associated with the reward (for example, the sight or smell of food), which is then processed as a predictor of the reward.

Centers localized in hypothalamus that are involved in control of feeding behavior include:

- The arcuate nucleus
- The paraventricular nucleus
- The ventromedial hypothalamic nucleus
- The lateral hypothalamic nucleus
- The perifornical area

However, brain circuits other than these are involved in regulation of food consumption and obesity. These include:

- The nucleus of tractus solitarius and area postrema in the brain stem
- Parts of the limbic system—Nucleus accumbens, amygdala and hippocampus
- Cortical brain regions—Orbitofrontal cortex, cingulate gyrus and insula.

These centers integrate neural (vagal) and circulatory signals (nutrients and hormones) related to the control of food intake. Many of these regions are polymodal and integrate sensory aspects.

2.3 Regulation of Food Intake

Food intake is under short-term as well as long-term control. This is through nutrients, hormones and neurotransmitters (see Fig. 2.2).

2.3.1 Short-Term Mechanisms

Hunger develops partly in response to decreasing concentrations of certain nutrients like glucose, fatty acids and amino acids as well as to changes in circulating concentrations of hormones. Ghrelin secreted predominantly by the stomach in between meals stimulates food intake. Ghrelin was identified in rat stomach as a factor that stimulated growth hormone (GH) secretion, hence the name [1]. Ghrelin may be an important hunger signal. Following a meal, the concentration of nutrients as well as certain satiety hormones including cholecystokinin, glucagon like peptide-1, pancreatic polypeptide, oxyntomodulin and peptide YY increase and hunger signals diminish resulting in switching off hunger and stimulate a feeling of fullness by acting on the brain directly or indirectly via the vagus. These endocrine signals from the gut form a part of the gut-brain axis that plays a part in appetite regulation (see Fig. 2.3).

2.3.2 Long-Term Mechanisms

This is mainly mediated by leptin, an adipocyte derived hormone; circulating leptin concentrations reflect adipose tissue stores. Leptin was discovered in mice with an inherited syndrome of severe obesity by positional cloning; these mice have a defect in the gene encoding leptin, so are unable to make the hormone in fat [2]. The downstream signaling pathways for leptin are in the hypothalamus. Leptin is transported actively into the CNS, where it binds to the long-form of its receptor (OB-Rb), predominantly in the arcuate nucleus of the hypothalamus [3]. When adipose tissue mass is low and leptin concentration decreases, secretion of neuropeptide Y (a 36 amino acid peptide that is found in high concentrations in the hypothalamus) is increased [4] and α[alpha]-melanocyte-stimulating hormone, derived from pro-opiomelanocortin gene (POMC), is decreased. This results in stimulation of food intake and reduction of thermogenesis. Although, in response to energy excess, body switches off some hunger signals and increases dietary thermogenesis, the reverse mechanisms are relatively weak. Hence, there are strongly biased energy homeostasis mechanisms that promote weight gain; while there is little evolutionary pressure to reduce food intake or burn off excess calories as heat once energy stores are replete.

Leptin also acts on the neural circuits of the human brain and increases the response to satiety signals while reducing the perception of food reward. Functional magnetic resonance imaging studies in patients with congenital leptin deficiency showed activation of dopaminergic mesolimbic centers (nucleus accumbens and caudate nucleus) to visual

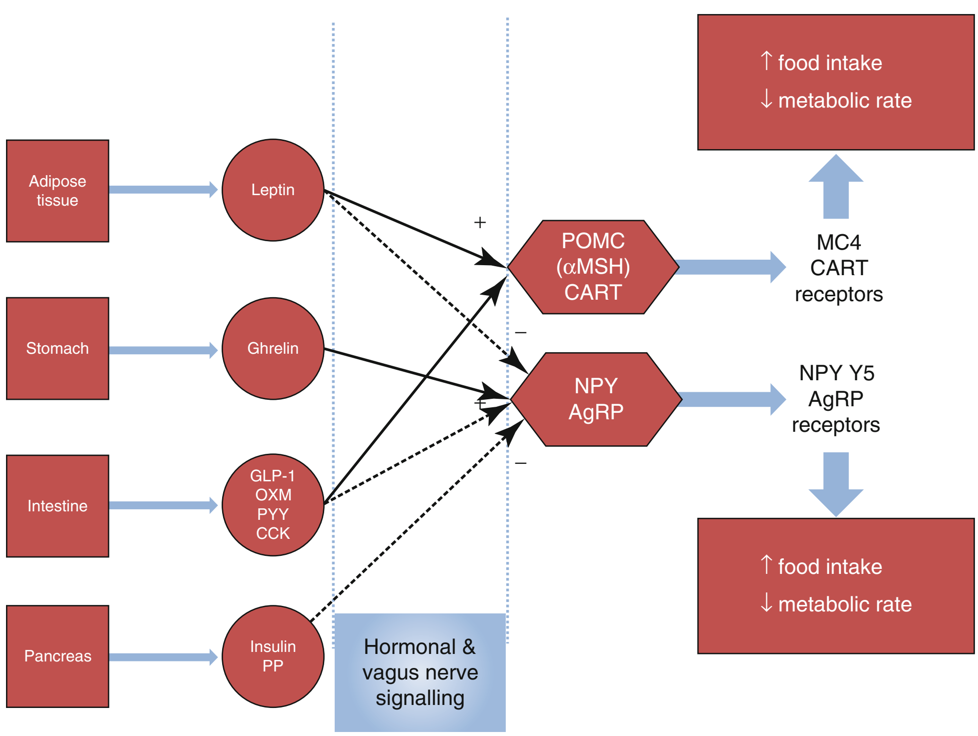

Fig. 2.2 Illustrates the various neurotransmitters and hormones involved in the regulation of food intake. Peripheral signals involved in energy homeostasis. + denotes stimulatory and – denotes inhibitory effect. *GLP*-1– glugagon-like peptide 1; *OXM* Oxyntomodulin; *PYY* peptide YY; *CCK* cholecystokinin; *NPY* neuropeptide Y; *AgRP* Agouti-related peptide; *CART* cocaine and amfetamine-related transcript

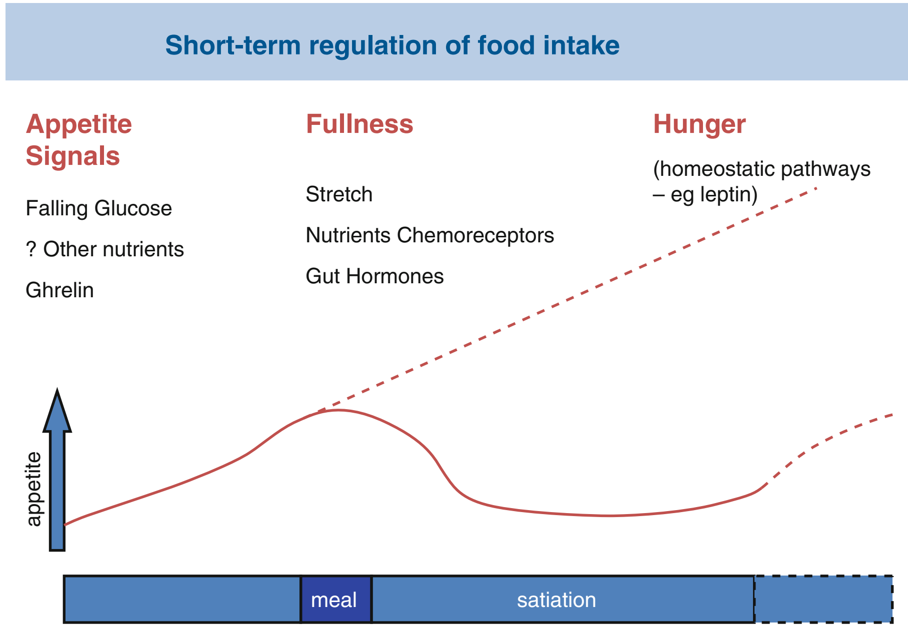

Fig. 2.3 Demonstrates short-term regulation of food intake

food stimuli, which was associated with food wanting although the subject had recently eaten. However, activation of these mesolimbic targets did not occur after 1 week of leptin treatment [5].

Insulin and glucocorticoids may also act as modulating factors in this process. Glucocorticoid administration stimulates appetite while its deficiency reduces appetite and causes weight loss. Insulin has been found to reduce appetite when injected directly into the CNS in experimental animals, but is anabolic in peripheral tissues, resulting in net weight gain.

Glucagon like peptide-1 (GLP-1) is one of the incretin hormones secreted by the gut in response to a meal. It is unclear whether GLP-1 at physiological levels decreases food intake in humans [6]; still various GLP-1 analogues used in the treatment of type 2 diabetes, have resulted in significant weight loss in patients.

Peptide YY (PYY) belongs to the pancreatic polypeptide family and circulates as PYY1–36 and PYY3–36. It is expressed throughout the small intestine and is secreted in response to a meal. PYY stimulates gastrointestinal absorption of fluids and electrolytes, reduces gastric and pancreatic secretions and delays gastric emptying. Studies have shown that infusion of PYY reduces hunger and calorie intake in healthy subjects as well as obese patients.

Neurotransmitter systems like dopaminergic, serotoninergic and endocannabinoid systems (CB1 and CB2 receptors) have a role in appetite regulation. Blockade of CB1 receptor suppresses appetite and gives a feeling of satiety. It has several other beneficial metabolic changes in addition to weight loss. However, rimonabant, an inverse agonist at the CB1 receptor, was withdrawn due to its neuropsychiatric side effects.

2.4 Regulation of Metabolism

The total energy expenditure (TEE) constitutes three components: basal metabolic rate (BMR), diet-induced thermogenesis (DIT) and physical activity (PA).

BMR represents the basal energy costs of keeping the body alive; it represents energy used during respiration, cardiac pumping, protein turnover etc. Though the question of reduced BMR contributing to obesity has always been a matter of debate, BMR is higher in obese people than in lean individuals, both at rest and at times of physical activity. This is because the obese have greater lean body mass than their lean counterparts and lean body mass is the major determinant of BMR [7]. However, some patients often have difficulty in accepting this fact and the myth that obesity results from low BMR persists. BMR represents 65–70 % of TEE in sedentary people.

In rodents, excess energy dissipates as heat in brown adipose tissue (BAT) due to uncoupling of oxidative phosphorylation within mitochondria. This is an important component in response to the cold and may help resist weight gain in response to overfeeding. This may also occur in some humans, but the magnitude of the effect is not clear.

Dietary thermogenesis, which represents only 5–10 % of TEE, is the energy used in the digestion, absorption, transport, interconversion and storage of the energy within any meal. Dietary thermogenesis is highest for meals that are rich in protein, moderate for meals rich in carbohydrates and least for fat rich meals. This could partly explain why excessive intake of fatty meals leads to weight gain, although higher energy density and a reduced satiating effect compared to protein may also contribute [8].

Variable amounts of energy are required for different physical activities. Obese people, however, generally have much higher, not lower, energy expenditure during physical activity, as is the case for BMR [9]. Obese people have higher body mass and require considerably more energy to move especially in weight bearing activities.

Non-exercise activity thermogenesis (NEAT) in describes spontaneous and sub-conscious physical activities such as fidgeting; research suggests that people with low levels of NEAT may be more likely to become obese.

2.5 Etiology of Obesity

Genetic changes more likely influence obesity developing at a young age. Adult onset obesity is more likely to have a strong environmental component. The complex interaction between individual factors (as determined by genetics) and environmental factors (the way in which an individual relate and respond to food especially when it is widely available) play a pivotal role in the development of obesity.

2.5.1 Inherited Causes

Studies of families, twins and adoptees suggest contribution of genetic factors to the development of obesity with an overall heritable contribution of 20–70 % to the variance between individuals [10]. Rankinen and co-workers reviewed evidence from single-gene mutation obesity cases, Mendelian disorders exhibiting obesity as a clinical feature, transgenic and knockout murine models relevant to obesity, quantitative trait loci (QTL) from animal cross-breeding experiments, association studies with candidate genes and linkages from genome scans and published the 12th update of the human obesity gene map; this includes 176 human obesity cases due to single gene mutations in 11 different genes, 50 loci related to Mendelian syndromes relevant to human obesity and 253 QTLs for human obesity-related phenotypes from 61 genome-wide scans [11].

Genetic factors influence obesity in two ways; there may be single gene defects or there may be susceptibility genes. Single gene defects causing obesity are rare in humans. There has been significant progress in identifying single gene defects leading to obesity in the last decade. Congenital leptin deficiency was the first monogenic obesity syndrome reported [12]. Affected individuals are markedly hyperphagic, develop severe obesity at a young age, and show therapeutic response to treatment with recombinant leptin. Other single gene disorders include defects in POMC gene and melanocortin-4 receptor deficiency. Such inherited causes are extremely rare and are not associated with the common forms of obesity or body fat distribution in the general population. However, melanocortin-4 receptor mutations, may account for up to 1 in 20 cases of severe early-onset childhood obesity [13].

The second mechanism is through susceptibility genes, on which environmental factors act to cause obesity. Genetic epidemiology studies have led to the discovery of variants in FTO-linked gene (fat mass and obesity-associated gene), which is strongly associated with obesity-related traits in different populations. Variant alleles of FTO gene are relatively common (about 16 % of the population has one variant allele). On an average, the body weight of people who have this gene allele increases by 1.5 kg [14]. Even the most powerful gene variants do not contribute much to the inheritance of body weight.

Recent research has identified the potential role of Kinase suppressor of Ras 2 (KSR2) gene and shown that carriers of a polymorphism in this gene exhibit hyperphagia in childhood, reduced metabolic rate and severe insulin resistance [15].

Severe obesity is also a feature of several inherited syndromes and Prader-Willi syndrome is the most common of these (see Table 2.3). Affected children typically present with failure to thrive in the first 2 years of life, but then develop a voracious appetite, leading to severe obesity and related complications such as type 2 diabetes and obstructive sleep apnea. Other features include learning difficulties,

Table 2.3 Inherited obesity syndromes

Condition	Clinical features	Genetic defect
Prader-Willi syndrome	Short stature, small hands and feet, almond-shaped eyes, learning difficulties, hypogonadism	Chromosome 15
Bardet-Beidl syndrome	Mental retardation, renal dysplasia, polydactyly, hypogonadism	Chromosomes 4,11,15,16
Leptin deficiency	Severe hyperphagia, hypogonadism	Leptin gene (autosomal recessive)
Leptin receptor mutations	Severe hyperphagia, hypogonadism	Leptin receptor gene (autosomal recessive)
Pro-opiomelanocortin (POMC) defects	Moderate obesity, red hair	POMC gene (autosomal dominant)
Melanocortin-4 receptor defects	Severe early onset obesity	Melanocortin-4 receptor gene (autosomal dominant)
Pro-hormone convertase 1 deficiency	Failure to process insulin and POMC	Pro-hormone convertase 1 deficiency (autosomal recessive)
Neurotropin receptor (TrkB) deficiency	Hyperphagia, impaired speech and nociception	TrkB (autosomal recessive)

short stature, almond-shaped eyes, small hands and feet. The putative genetic locus has been identified and is due to a mutation in a paternally imprinted gene on chromosome 15, but the biological explanation for the increased appetite and obesity remains unknown.

Other rare genetic disorders associated with obesity include Albright hereditary dystrophy, Alstrom-Hallgren syndrome, Cohen syndrome, Carpenter syndrome, Grebe syndrome, Beckwith-Wiedemann syndrome, Adiposogenital dystrophy syndrome, Kleine-Levin-Critchley syndrome, Young-Hughes syndrome, Laron dwarfism, X-linked mental retardation-hypotonic facies syndrome, Borjeson-Forssman-Lehmann syndrome and pseudohypoparathyroidism type 1a.

2.5.2 Environmental Causes

Adverse environmental influences play an important part in the development of obesity in an at-risk individual. Food marketing and social pressure readily overcome the subtle hypothalamic regulation of appetite. The availability and palatability of cheap, energy dense food combined with the drop in levels of physical activity, is one of the major contributors to this epidemic.

2.5.2.1 Dietary Factors

There has been a considerable change in the dietary pattern in many western countries over the past few decades with increase in the supply and consumption of energy-dense foods as well as fat and sugar rich soft drinks. Epidemiological data has shown diet high in fat to be associated with obesity [16]. There has been a profound increase in the proportion of dietary fat consumption at the expense of carbohydrate intake. High fat diets produce a less powerful satiety response compared to carbohydrate rich foods and this leads to passive overconsumption. There has also been an increase in fast food consumption with an associated, anticipated fall in household food consumption. Less regular eating patterns, shorter meals and increased snacking may be other contributing factors. However, under-reporting by obese subjects greatly confound studies that estimate food consumption.

2.5.2.2 Physical Activity

There has been a marked decline in physical activity over the last 50 years. The use of energy-sparing devices at home as well as the work place, better transportation facilities and sedentary leisure-time pursuits, especially watching television and computer games have all been implicated as the cause of the drop in levels of physical activity of adults and children alike. Data from various observational studies show that of all sedentary behaviors, television watching appears to be the most predictive of obesity and diabetes risk [17].

2.5.2.3 Other Lifestyle Factors

Sleep deprivation is a lifestyle change that may have negative metabolic consequences. Sleep deprivation causes decrease in leptin and increase in ghrelin levels contributing to increase in hunger and appetite [18]. Smoking cessation is often associated with an average weight gain of 4–5 kg and hence it is important to offer appropriate dietary and exercise advice to people who are planning to quit smoking.

Obesity is more prevalent in the lower socioeconomic groups and the reasons for this are unknown, but may reflect food availability and marketing practices. Ethnicity also influences the incidence of obesity; white men and black women are more obese than their corresponding counterparts are. Individuals from Indian subcontinent, especially South Asians have high prevalence of abdominal obesity as well as truncal subcutaneous fat, even with a BMI of <25, an important correlate of insulin resistance. Abdominal obesity, due to its proinflammatory, prothrombotic, dyslipidemic and insulin resistant state has been implicated as a significant contributory factor in the pathogenesis of glucose intolerance and atherosclerotic cardiovascular disease in this population.

2.5.3 Endocrine Causes

Previously undiagnosed endocrine disease is almost never the cause of obesity. Hypothyroidism is a rare cause, and causes only modest weight gain (due to slowing of metabolic activity), but treatment does not appear to be associated with weight loss. Cushing's syndrome is another rare cause and is associated with progressive, centripetal obesity. GH deficiency in adults is associated with an increase in body fat and reduced lean body mass and this can be corrected by GH replacement. Obesity is also a feature of polycystic ovarian syndrome (PCOS), but not a consequence of polycystic ovaries. About 50 % of females with PCOS are obese. However, these endocrine conditions are usually diagnosed before causing significant weight gain due to various other signs and symptoms. Nevertheless, ruling out these causes is an important part of the assessment of a subject with obesity.

2.5.4 Hypothalamic Obesity

It is a rare syndrome in humans and is due to injury to the ventromedial or paraventricular regions of the hypothalamus where integration of metabolic information regarding nutrient stores takes place. When trauma, tumor (craniopharyngiomas and pituitary macroadenomas with suprasellar extension), inflammation, surgery or increased intracranial pressure, damage these regions; hyperphagia develops and obesity follows. These patients also have autonomic imbalance leading to hyperinsulinaemia, which exacerbates weight gain by promoting fat deposition. There may be reduction in physical activity due to somnolence or other neurological sequelae. Endocrine abnormalities like GH deficiency and hypogonadism may contribute to an unfavorable morphological distribution of body fat, increasing the metabolic risk in this group of patients [19].

2.5.5 Drugs

Drugs promoting weight gain include psychoactive drugs, antiepileptics, oral hypoglycemic agents and hormones (see Table 2.4). This could be due to central effects on appetite (for example psychoactive drugs and antiepileptics) and peripheral metabolic effects (for example, oral hypoglycemic agents (OHA) and insulin). Hence, patients who are on such drugs should be aware of the side effects so that they can take appropriate dietary as well as physical activity measures, and wherever possible consider alternative agents.

2.5.6 Pregnancy and Menopause

Pregnant women tend to gain weight and there is postpartum weight retention when compared to nulliparous women. Menopause and the associated decline in female sex hormones may cause changes in adipocyte biology, which can lead to weight gain. Females may have a higher preponderance to obesity than males due to the above reasons and also there are gender differences in brain's response to hunger and obesity [20].

Table 2.4 Drugs associated with weight gain

Class of drugs	Examples
Anticonvulsants	Sodium valproate, carbamazepine, gabapentin
Antidepressants	Citalopram, mirtazepine, amitriptyline, clomipramine, doxepin, imipramine
Antipsychotics	Clozapine, olanzapine, risperidone, lithium, chlorpromazine
Beta blockers	Atenolol
Corticosteroids	Prednisolone, dexamethasone
Insulin	All formulations
Migraine relieving drugs	Pizotifen
Oral hypoglycemic agents	Glibenclamide, Gliclazide, Repaglinide, Pioglitazone
Protease inhibitors	Indinavir, ritonavir
Sex steroids	Medroxyprogesterone acetate, combined oral contraceptives

2.5.7 Eating Disorders and Psychological Causes

Bulimia nervosa can be associated with obesity through episodes of binge eating. Psychological factors, especially stress is associated with increased food consumption, in particular, high-energy foods [21]. This may be due to increased glucocorticoid levels. Anomalous eating habits of families and parental conflicts can lead to overeating in children due to unsatisfactory personal relations and lack of confidence and self-esteem, which can extend to adulthood.

Key Learning Points

- Obesity develops when excess energy is stored as fat. Most human obesity is associated with increased food intake rather than reduced energy expenditure.
- The fundamental cause is a change in environment with easy availability of energy dense foods and reduced opportunities for physical activity.
- The development of obesity in the modern environment is most likely in those with increased genetic susceptibility.
- Single gene defects causing obesity are rare, but demonstrate the importance of appetite-regulating pathways in control of human energy balance. Many genes may contribute to the susceptibility of individuals to obesity.
- Other causes include drugs that affect appetite and damage to appetite regulating areas of the brain.

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Gut-Derived Hormones and Energy Homeostasis

3

Wui-Hang Cheung, Andrea Pucci, and Rachel L. Batterham

Abstract

The gut is the largest endocrine organ of the body producing multiple hormones that are implicated in regulating glucose and energy homeostasis. While the mechanisms promoting the sustained weight loss and amelioration of type 2 diabetes mellitus (T2DM) after Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) remain incompletely understood, gut hormones are proposed as key potential mediators. This chapter will review the known effects of the enteroendocrine L-cell derived hormones, peptide YY (PYY), glucagon-like-peptide-1 (GLP-1) and oxytomodulin (OXM), and the P/D1-type cell (X/A-like in rodents) produced hormone, ghrelin, on energy homeostasis. Recently, transgenic advances have enabled the isolation and characterization of the previously enigmatic L-cells and X/A-like cells revealing a complex array of receptors that act to modify hormone secretion and these will be summarized. PYY, GLP-1 and OXM exert broad ranging pleiotropic actions but here we will limit our focus to their effects on energy and glucose homeostasis. We will also discuss the impact of obesity *per se* and the effect of non-surgically induced weight loss upon their circulating levels. Of note, these peptides are also produced within the central nervous system (CNS). However, the focus of this chapter is on the gastrointestinal (GI) tract, as the major source of circulating hormones and the key site impacted upon by bariatric surgery. We have limited our review to PYY, GLP-1, OXM and ghrelin to provide biological contextual background for Chaps. 54 and 55. However, this does not decreases the contributions of other gut derived factors to nutrient homeostasis and body-weight regulation.

Keywords

Peptide YY • Glucagon-like-peptide-1 • Oxyntomodulin • Acyl-ghrelin • Des-acyl ghrelin

3.1 Hormones Secreted by the Enteroendocrine Cells

Historically enteroendocrine cells have been difficult to study due to their scattered distribution throughout the GI tract. However, over the last 5 years the development of transgenic enteroendocrine reporter mice has enabled these somewhat elusive cells to be isolated, purified and studied providing novel insights into their biology. In particular, the accepted dogma that enteroendocrine cells express and secrete peptides derived from one, or very occasionally two, peptide precursors has been debunked. It is now clear that enteroendocrine cells throughout the GI tract are capable of expressing a broad

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repertoire of peptide hormone precursors [1, 2]. Importantly, it is now also clear that the number, density and secretory profile of enteroendocrine cells can also be modified.

3.1.1 L-Cell Secretion

Gut hormone secretion from L-cells in response to nutrient ingestion is mediated by a combination of nutrient, neural and hormonal activated pathways. Circulating plasma levels of PYY, GLP-1 and OXM exhibit an early rise followed by a prolonged plateau phase [3]. Studies in rodents have shown that the proximal activation of the vagus nerve indirectly mediates the early L-cell response. In addition, humoral factors are implicated in modifying the early L-cell secretion. Indeed, recently high ghrelin levels have been shown to 'prime' L-cells [4]. Nutrients in the gut lumen, acting directly on L-cells through a variety of mechanisms, prolonged the secretory phase. Figure 3.1 summarizes factors known to impact upon L-cell secretion [1]. Of particular note is the recent finding that the melanocortin-4 receptors (MC4Rs) are present on L-cell and that these act to regulate the

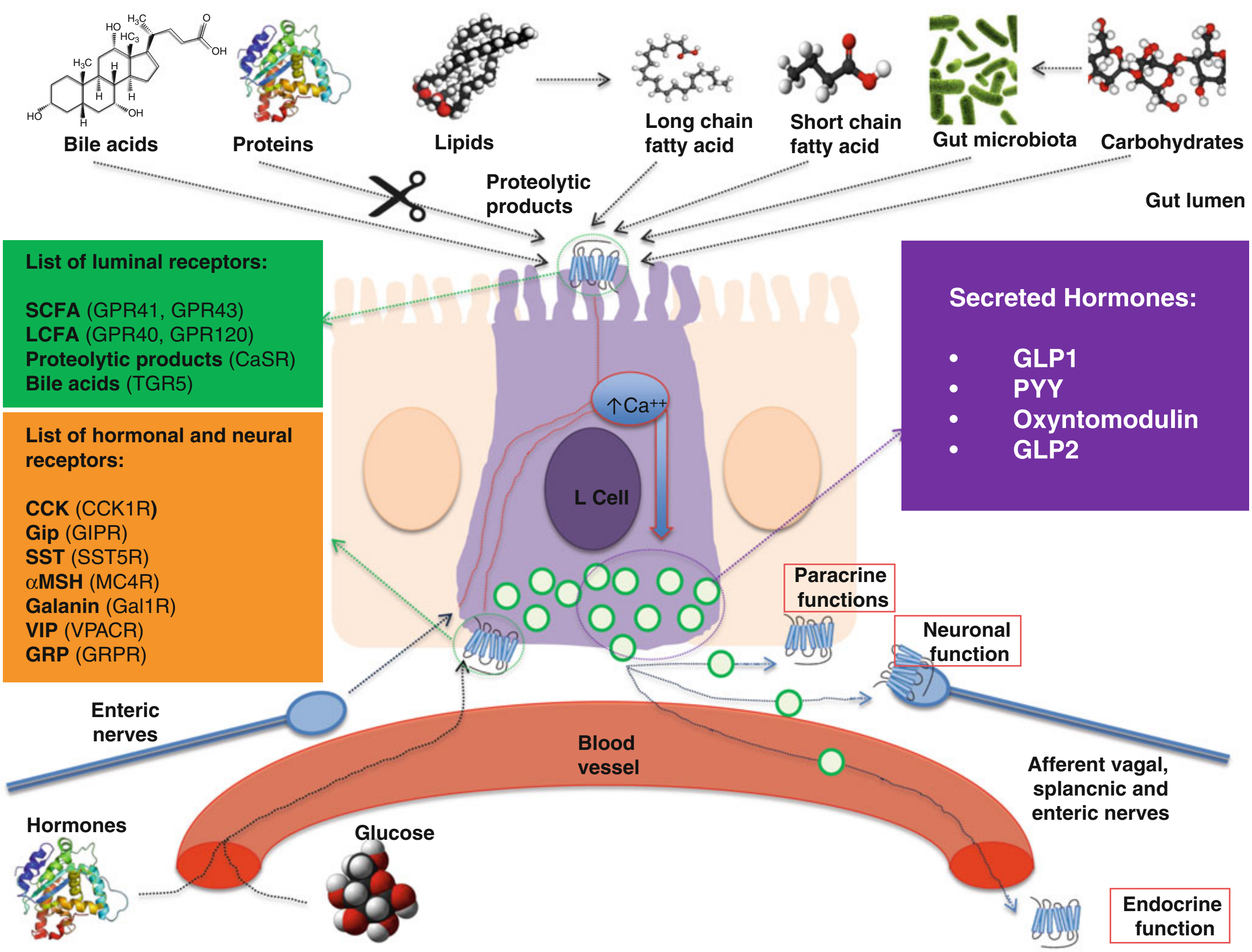

Fig. 3.1 Schematic overview showing the main factors known to impact upon enteroendocrine L-cell secretion. An L-cell (*purple*), containing peptide filled secretory granules, lies between enterocytes (*light brown*). The L-cells's apical microvilli are exposed to the gut luminal contents. The main known food components and metabolites that regulate hormone secretion are listed (*LCFA* long-chain fatty acids). The gut microbiota are responsible for degrading complex polysaccharides to the main short chain fatty acids (*SCFAs*). Bile acids can also affect enteroendocrine function. In the *green box* there is a list of the main known luminal receptors. In the *orange box* there is a list of the main known hormonal and neural receptors that can modulate L-cell hormonal secretion. L-cells are also impacted upon by neural factors from enteric nerves (in *blue*) and circulating factors such as glucose and hormones from bloods vessels. PYY, GLP-1, GLP-2 and OXM are secreted from L-cells and can act in an autocrine, paracrine, endocrine and neuronal. *α[alpha]-MSH* alpha-melanocyte-stimulating hormone, *CCK* cholecystokinin, *GIP* gastric inhibitory polypeptide, *GLP-1* glucagon-like-peptide 1, *GLP-2* glucagon-like-peptide 2, *GRP* gastrin-releasing peptide, *LCFA* long-chain fatty acids, *MC4R* melanocortin-4 receptor, *PYY* peptide YY, *SGLT-1* sodium-glucose cotransporter-1, *SST* somatostatin, *VIP* vasoactive intestinal peptide

secretion of PYY and GLP-1 [5]. Understanding the factors that modify L-cell secretion is of particular potential therapeutic importance as stimulation enhanced L-cell release of PYY, GLP-1 and OXM in response to nutrient intake offers the most promising "knifeless" bariatric surgery option.

3.1.1.1 Peptide YY

Peptide YY (PYY) was so named due to the presence of a tyrosine residue (amino acid abbreviation Y) at each terminus of the polypeptide. The first two amino acids are cleaved from the N-terminal end of the 36-amino-acid peptide (PYY1-36) by di-peptidyl peptidase-4 (DPP-4) to produce PYY3-36, the predominant circulating form in both the fed and fasted states. Importantly, PYY1-36 and PYY3-36 exhibit differential selectivity for the five Y-receptor subtypes (YR); PYY1-36 binds to all five YRs with equal affinity whereas PYY3-36 is Y2R selective. Consequently, PYY1-36 and PYY3-36 exhibit divergent effects on feeding behavior and glucose homeostasis [6].

PYY expressing enteroendocrine cells are present throughout the small and large intestine. Circulating PYY levels are low and progressively fall in the fasted state. In response to nutrient ingestion PYY plasma levels increase proportionate to the caloric content and with differential responses according to the specific macronutrient composition of the meal. In 2002, Batterham et al. were the first to identify a role for PYY3-36 in regulating feeding behavior by showing that peripheral PYY3-36 administration, mimicking the post meal state, reduced caloric intake in rodents and humans [6]. This anorexigenic role for PYY3-36 has now been firmly established through multiple human and animal studies. Moreover, the finding that *pyy*-null mice are hyperphagic and obese and that PYY3-36 replacement reverses their obese phenotype suggests a key physiological role for PYY3-36 in regulating bodyweight [6].

Studies in mice lacking the Y2R coupled with pharmacological approaches using a selective Y2R antagonist have identified a crucial role for the Y2R in mediating the anorectic effects of PYY3-36. Robust evidence from translational studies indicate that PYY3-36 mediates its anorectic effects predominantly by acting upon central appetite-regulating circuits with the hypothalamic arcuate nucleus and brainstem regions identified as key areas.

In addition, brain functional magnetic resonance imaging (fMRI) studies undertaken in human subjects have markedly enhanced our understanding of neural circuits modulated by circulating gut hormones. In 2007, Batterham and colleagues employed a novel study paradigm combining infusion of PYY3-36/placebo with fMRI brain scanning, physiological and behavioral measures to investigate the central effects of PYY3-36. In accord with rodent studies they found that PYY3-36 modulated neural activity within the hypothalamus and brainstem. However, the greatest effects of PYY3-36 were observed within the orbitofrontal cortex (OFC), a polymodal region implicated in reward processing. In addition, PYY3-36 modulated neural activity within addition brain reward regions namely the ventral tegmental area, limbic system and ventral striatum. In the low-PYY state (fasted state) change in signal within the hypothalamus predicted subsequent food intake. In contrast, under conditions of high plasma PYY concentrations, mimicking the fed state, changes in neural activity within the OFC predicted feeding behavior. Thus, the presence of postprandial levels of PYY3-36 switched food intake regulation from a homeostatic to a hedonic, corticolimbic area [7]. Subsequently, two additional groups, one using fMRI brain scanning and the other employing positron emission tomographic (PET) measurements of cerebral blood flow have confirmed that circulating PYY levels modulate neural activity within key brain reward regions [6]. Moreover, a recent elegant rodent study that employed c-fos immunohistochemistry (a marker of neuronal activation) to identify brain regions activated by PYY3-36 increments within the hepatic portal vein (HPV) corroborated the human imaging studies with activation observed in the hypothalamic and brain reward regions [8].

While the anorectic actions of PYY3-36 are well established, there is a paucity of studies examining the effect of PYY3-36 on energy expenditure. However, there is limited evidence that PYY3-36 has beneficial effects on energy expenditure, including fuel partitioning. In rodent studies, chronic PYY3-36 administration altered substrate partitioning in favor of fat, and transgenic mice that over-express PYY had increased basal temperature indicative of increased thermogenesis. In humans, no correlation has been reported between fasting PYY levels and 24 h resting energy expenditure and Sloth et al. demonstrated that peripheral PYY3-36 infusion increased energy expenditure and fat oxidation rates in obese and lean subjects [6].

In addition to being expressed in the GI tract, PYY is also coexpressed in the pancreatic islets with glucagon and somatostatin in α[alpha]- and δ[delta]-cells respectively. Studies undertaken on isolated islets from mice have shown that PYY1-36 reduces glucose stimulated insulin release whereas PYY3-36 has no effect; a finding that is in keeping with the detection of islet Y1R but not Y2R expression. In contrast, peripherally administered PYY1-36 does not impact upon glucose tolerance whereas PYY3-36 improves glucose tolerance via a peripheral Y2R-dependent mechanism. Furthermore, the finding that post meal peripheral Y2R antagonist administration impairs glucose tolerance suggests that PYY3-36 also plays a physiological glucoregulatory role [9].

3.1.1.2 Glucagon-Like-Peptide-1

The proglucagon (GCG) gene encodes preproglucagon which undergoes tissue specific posttranslational processing to generate glucagon in the α[alpha]- cells pancreas and

GLP-1, GLP-2 and OXM in L-cells. GLP-1 is synthesized by intestinal L-cells in two forms: GLP-11-37 and GLP-11-36 amide. Further cleavage at the N-terminus is required to produce biologically active fragments GLP-17-37 and GLP-17-36 amide which bind to and activate the GLP-1 receptor (GLP-1 R). Once secreted, active GLP-1 is almost immediately degraded by DPP-4 [10].

The role of GLP-1 in regulating glucose homeostasis is well established. GLP-1 is an incretin hormone that enhances glucose dependent insulin secretion, increases insulin sensitivity of α[alpha]- and β[beta]-cells, stimulates insulin biosynthesis and, in rodents, promotes β[beta]-cell proliferation while inhibiting apoptosis. In addition, GLP-1 exerts glucoregulatory actions by delaying nutrient absorption through inhibition of gastric emptying and intestinal motility and by glucose dependent inhibition of glucagon secretion [3, 10]. GLP-1 also enhances insulin sensitivity at the level of both the liver and peripheral tissues, although the majority of its effects on glycemia seem to be mediated through changes in islet hormone secretion. These glucoregulatory effects of endogenous GLP-1 have been confirmed using transgenic and pharmacological approaches.

In contrast, a physiological role, as opposed to pharmacological role for gut derived GLP-1, in regulating energy homeostasis is less clear. Peripheral administration of GLP-1 and its analogues reduce caloric intake in normal and obese rodents and humans, as well as in patients with type 2 diabetes mellitus (T2DM) [10]. The reported effects of GLP-1 administration on energy expenditure in rodents and humans are inconsistent suggesting that the major effect on bodyweight is via reducing caloric intake [11]. The very short circulating half life of GLP-1 suggests that some of the physiological actions of GLP-1, are mediated indirectly by local effects on GLP-1Rs expressed in the hepatoportal region of the liver and/or vagal sensory afferent neurons [11]. These nerve fibers have their cell bodies in the nodose ganglion where abundant GLP-1R mRNA has been demonstrated. The neurons subsequently project to the nucleus tractus solitarius (NTS) in the brainstem. Moreover, peripheral GLP-1 administration induces c-fos expression within the NTS neurons, which in turn project to the vagal dorsal motor nuclei and the hypothalamus (arcuate and paraventricular nuclei). In addition, there is also evidence that GLP-1 may act directly in the brain to regulate feeding behavior. In direct comparative studies, the requirement for sensory afferents in the actions of GLP-1 on both insulin release and food intake in mice was observed at low, but not high, doses of GLP-1. By contrast, the pharmacologic actions of GLP-1 and long acting GLP-1R agonists seem to be exerted, at least in part, through direct effects on the GLP-1R in β[beta]-cells and the brain. Indeed, brain fMRI scanning in healthy normal weight volunteers has shown that exogenous intravenous GLP-1 administration modulated neural activity within brain reward regions in response to viewing pictures of food [11].

3.1.1.3 Oxyntomodulin

Oxyntomodulin (OXM), a 37-amino-acid peptide that contains the 29-amino-acid sequence of glucagon followed by an 8-amino-acid carboxyterminal extension, activates both the GLP-1Rs and glucagon receptors (GCGR) [12]. Similarly to GLP-1, OXM is also inactivated by DPP-4. Peripheral administration of OXM reduces caloric intake in rodents, lean and obese human subjects. Subcutaneous administration of OXM three times daily for 4 days to overweight/obese humans proved to be effective on reducing caloric intake and increasing energy expenditure while an administration over a 4 weeks period resulted in an average weight loss of 2.3 kg [13]. Studies on *Glp-1r* null and *Gcgr* null mice have identified that the anorectic effects of OXM require the GLP-1R and are thought to involve both vagal and direct CNS activation [12, 14]. However, despite mediating its anorectic effects via the GLP-1R, peripheral administered OXM and GLP-1 produce differential c-fos activation patterns within the hypothalamus suggesting that their mechanisms of action are indeed different. Increased energy expenditure is a known effect of GCGR agonism, thus it is likely that the stimulatory effects of OXM on energy expenditure are mediated by the GCGR. Importantly, despite its known agonism of the GCGR, OXM does not adversely impact upon glycemia. In fact, similar to GLP-1, OXM causes glucose dependent insulin secretion and improves glucose tolerance in mice and humans with T2DM. Intravenous infusion of OXM has been shown to reduce gastric emptying in humans and this may contribute to its effects on appetite, thus improving glucose tolerance.

3.1.1.4 P/D1-Type Cells and Ghrelin

Ghrelin is a 28-amino-acid octanoylated peptide hormone secreted from P/D1-type cells in humans, X/A like-type cells in rodents, which are a distinct population of endocrine cells located within the gastric oxyntic mucosa. Ghrelin producing cells are also present throughout the small intestine with the greatest numbers in the duodenum. Of note, majority of the proximal P/D1-type cells are closed-type and are not in contact with the gastric lumen, and hence they are not regulated directly by dietary components present in the stomach [3]. In contrast, ghrelin producing cells in the duodenum and jejunum are open type. The only naturally occurring peptide modified by Ser3 O-octanoylation is ghrelin; the reaction is catalyzed by the enzyme ghrelin O-acyl transferase (GOAT). This posttranslational modification is essential for the binding of acyl-ghrelin to and thereby activation of its specific receptor, the growth hormone secretagogue receptor type 1a (GHSR1a). Acyl-ghrelin is absent in GOAT null mice indicating that GOAT is the only enzyme capable of activating ghrelin in vivo.

Circulating ghrelin levels increase before spontaneously initiated meals and decreases rapidly after nutrient ingestion through molecular mechanisms that are poorly characterized [15]. The magnitude of ghrelin reduction is in proportion to the caloric load and macronutrient content with ingested lipids being the least effective suppressor. Neither gastric nutrient infusion nor gastric distention, mediate a reduction in circulating ghrelin levels. In contrast, intraduodenal and intrajejunal nutrient administration reduce circulating ghrelin levels. These findings are in keeping with closed type nature of the ghrelin cells in the stomach and the open type nature of those in the duodenum and jejunum. In vivo and in vitro studies have shown that epinephrine, norepinephrine, endothelin and secretin increase ghrelin release, whereas hyperglycemia, insulin, gastrin releasing peptide, PYY3-36, OXM, GLP-1, cholecystokinin, glucose dependent insulinotropic polypeptide and somatostatin decrease ghrelin release. However, it remains unclear whether these factors act directly on ghrelin cells or indirectly via neighboring cells and for many the physiological relevance remains unclear. Figure 3.2 summarizes factors known to impact upon ghrelin secretion [2].

In rodents, peripheral acyl-ghrelin administration increases caloric intake and repeated administration results in increased adiposity. Similarly in humans, peripheral acyl-ghrelin administration increases hunger and caloric intake in lean, obese, healthy and malnourished individuals. The orexigenic effect of ghrelin is specifically modulated through GHSR1a, as ghrelin fails to promote food intake in mice lacking this

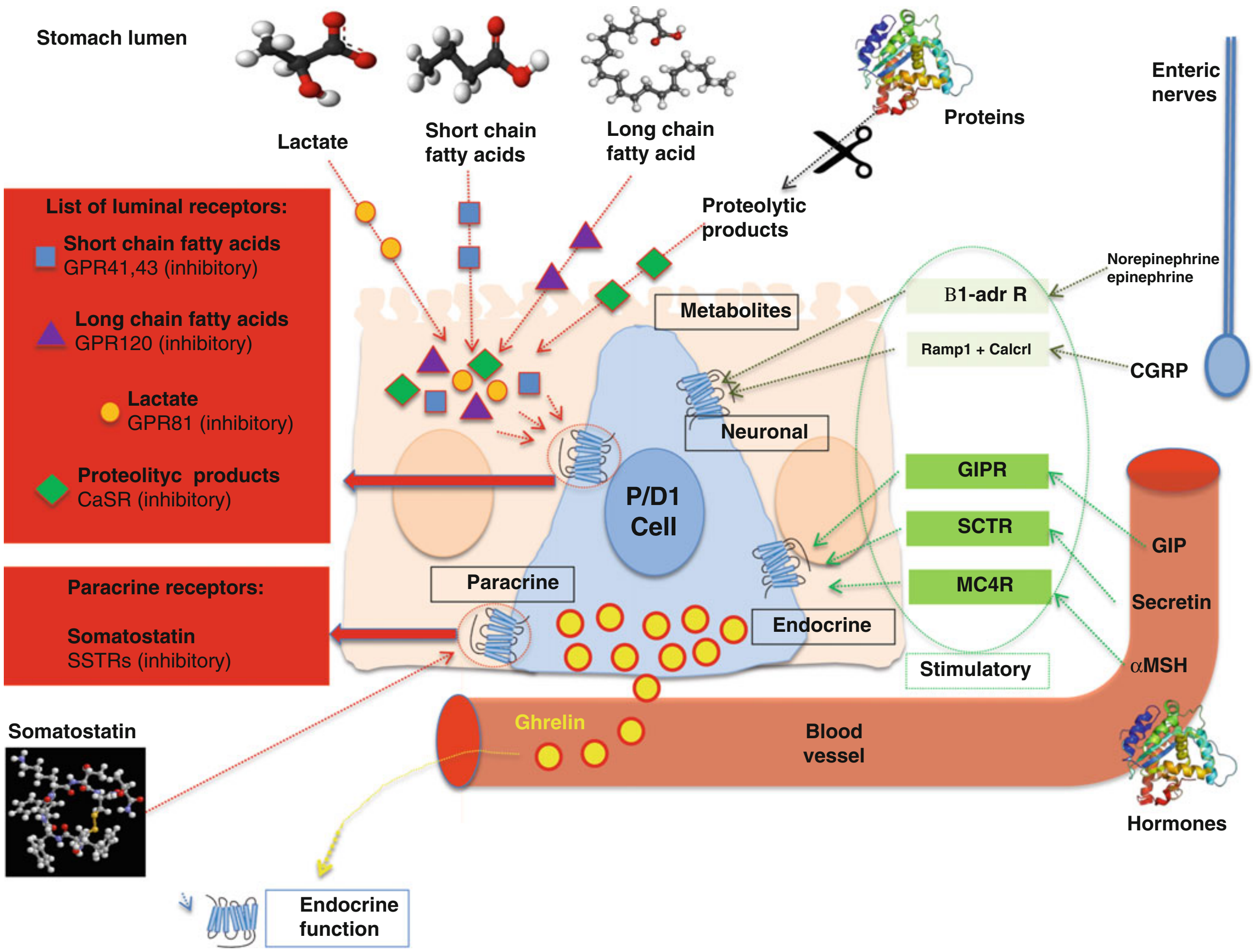

Fig. 3.2 Schematic diagram showing the main known molecular mechanisms regulating P/D1-type cell secretion of orexigenic-glucoregulatory hormone ghrelin by the stomach. P/D1-type cells (*light blue*) of the stomach contain peptide hormone-filled secretory granules (*yellow and red dots*) lie between gastric cells (*light brown*). Stomach P/D1 type cells are closed type that do not contact the gastric lumen and are not regulated directly by dietary components present in the stomach. The main known food components and metabolites that regulate ghrelin secretion acting either on open-type P/D1 type cells in the intestine or indirectly via processing by the other gastric cells are listed. Inhibitory metabolites are their receptors are listed in the *red box*. On the *right hand side* of the figure there is a list of known neural (*light green*) and hormonal (*dark green*) factors that can stimulate the P/D1-type cell hormonal secretion. The enteric nerves (in *blue*) provide the neural factors and the main circulation is the source of hormones. *α[alpha]-MSH* alpha-melanocyte-stimulating hormone (α[alpha]MSH), *CGRP* calcitonin gene-related peptide, *GIP* gastric inhibitory polypeptide

receptor. There is evidence that ghrelin acts directly upon CNS appetite regulating circuits, in particular the arcuate nucleus of the hypothalamus and also indirectly via the vagus.

In addition to its role in mediating meal-to-meal food intake, ghrelin also plays a role in long term energy balance regulation, serving to defend against prolonged energy deficiency. In humans, circulating ghrelin levels are inversely associated with adiposity and increase with weight loss induced by exercise, low caloric diet, mixed life style modification or anorexia nervosa and cachexia. In contrast, patients with Prader-Willi syndrome are hyperphagic and have very high circulating ghrelin levels [15].

Translational studies have shown that in addition to stimulating increased caloric intake of freely available food, administration of acyl-ghrelin shifts the food preference toward fat rich diets and also increases consumption of palatable saccharin solution. Indeed, while initially ghrelin was viewed as a regulator of homeostatic feeding there is increasing evidence that ghrelin's main feeding effect, especially in our current 'obesogenic environment,' is on 'reward based/hedonic' feeding. This notion is further supported by the phenotypes of the *ghrelin* knockout and *goat* knockout mice. These knockout mice are indistinguishable from wild type mice while on a normal chow diet, however, they are protected from diet induced obesity and display reduced hedonic feeding [16]. Furthermore, ghrelin administration to human subjects during fMRI brain scanning increases the neural response to food pictures in several brain regions implicated in hedonic feeding [17]. More recently, attenuated post meal acyl-ghrelin suppression and altered CNS responsivity to circulating acyl-ghrelin have been implicated as drivers of the increased appetite and hedonic food preferences observed in people with the *FTO*-linked obesity risk single nucleotide polymorphism rs9939609 [18].

Approximately 80 % of the ghrelin in circulation is desacyl ghrelin. Initially des-acyl ghrelin was viewed as just a degradation product of acyl ghrelin [19]. However, there is increasing evidence that des-acyl ghrelin acts independent of acyl-ghrelin. It is only at supraphysiological concentrations that des-acyl ghrelin binds and activates the GHSR1a. This low affinity interaction rules out the role of GHSR1a as a mediator of des-acyl ghrelin activities at physiological concentrations. Several human studies report a positive relationship between des-acyl ghrelin and insulin sensitivity [19]. The effect of des-acyl ghrelin on glucose metabolism might, at least in part, be triggered indirectly via modulation of lipid metabolism, as transgenic mice over expressing des-acyl ghrelin have lower body fat mass and less body weight gain while insulin sensitivity is improved as compared to wild type controls. However, the role and mechanism of action of des-acyl ghrelin remains to be clarified.

The glucoregulatory role of ghrelin is somewhat complex, in that depending on the experimental conditions ghrelin can either stimulate or inhibit insulin secretion. There is emerging evidence that the insulin sensitivity is dependent upon the acyl/desacyl ghrelin ratio as acyl-ghrelin promotes insulin desensitization, while desacyl ghrelin neutralizes the insulin desensitizing effects of acyl ghrelin. In addition, acyl-ghrelin stimulates hepatic glycogenolysis/neoglucogenesis and prevents the insulin suppression of glucose production leading to increased glucose levels. On the other hand, desacyl ghrelin inhibits liver glucose production in a dose dependent manner. In light of these findings it is not surprising that GOAT inhibition leads to improved glucose tolerance [20] and that GOAT inhibitors are being developed as treatment option for patients with T2DM.

3.2 Effect of Obesity on PYY, GLP-1 and OXM

Obesity *per se* is associated with a state of relative circulating PYY and GLP-1 deficiency coupled with decreased circulating ghrelin concentrations [6, 10, 15]. Translational studies have revealed a progressive reduction in circulating PYY, active GLP-1 and ghrelin concentrations with the development of obesity in mice fed a high-fat diet [21]. Similarly, obese adults exhibit reduced fasted and nutrient stimulated circulating PYY, active GLP-1 and ghrelin levels together with reduced satiety compared to their normal weight counterparts. The mechanisms resulting in reduced circulating PYY, GLP-1 and ghrelin with the development of obesity are unclear. Importantly from a therapeutic perspective, obese subjects remain responsive to the anorectic and glucoregulatory effects of PYY3-36 and active GLP-1. To date, there have been no reports comparing circulating OXM levels in obese compared to normal weight subjects. Reduced circulating PYY, GLP-1 and ghrelin levels in obese subjects compared to normal weight subjects have not been universally reported. However, strict subject standardization protocols and stringent sample collection procedures are required to accurately measure circulating PYY, GLP-1 and ghrelin levels [22]. Thus, methodological differences most likely underlie these discrepancies.

3.3 The Effect of Diet Induced Weight Loss and Exercise on PYY, GLP-1 and OXM

In 2002, Cummings et al. were the first to demonstrate that diet-induced weight loss led to a marked increase in circulating ghrelin levels [23]. More recently, in overweight and obese humans a 10-week very low calorie diet (VLCD) was shown to adversely impact appetite, circulating PYY and ghrelin levels. At the end of a 10-week VLCD program hunger was increased, fasted and nutrient-stimulated PYY levels were reduced and fasted and nutrient stimulated ghrelin levels were increased compared to pre-diet. More importantly, these adverse appetite and gut hormone changes persisted 1 year after the end of the VLCD despite subjects regaining weight [24]. Given the known effects of PYY3-36 and ghrelin on appetite and food reward it is highly likely that these hormonal changes contribute to the failure of weight loss maintenance following dietary restriction. The effect of intermittent dietary restriction, in the form of the 5:2 diet, on appetite and gut hormone profiles is unknown.

In contrast to the already mentioned adverse effects of caloric restriction, acute energy deficit induced by exercise, albeit in normal weight individuals, reduces appetite, suppresses acyl-ghrelin concentrations and increases circulating PYY3-36 levels [25]. The mechanisms underlying the beneficial effects of exercise on these hormones are unclear. Furthermore, the effects of an exercise program and whether similar beneficial effects are seen in obese individuals remain to be determined.

3.4 Gut Hormone Cross-Talk and Combination Therapies

There is increasing evidence for "cross-talk" between gut hormones. PYY3-36, active GLP-1 and OXM have all been shown to decrease circulating acyl-ghrelin levels and indeed this reduction may in part contribute to the appetite reducing effects of these hormones [6, 14]. GLP-1 exhibits a negative feedback effect on L-cells leading to reduced GLP-1 and PYY secretion, while PYY3-36 administration has recently been shown to increase active GLP-1 levels within the hepatic portal vein [9]. Recently, high ghrelin levels have been shown to "prime" L-cell secretion of GLP-1 [4]. Taken together these findings illustrate the intricate cross-talk that exists between gut hormones which needs to be taken into account when designing therapeutic strategies targeting one or more hormones. Indeed, the majority of pharmaceutical efforts are now focused on combination therapies or on stimulating L-cell secretion.

Key Learning Points

- Enteroendocrine cells throughout the GI tract are capable of expressing a broad repertoire of peptide hormones.
- Understanding the factors that modify L-cell secretion is of key potential therapeutic importance as stimulation enhanced L-cell release of PYY, GLP-1 and OXM in response to nutrient intake offers the most promising "knifeless" bariatric surgery option.
- PYY3-36, active GLP-1 and acyl-ghrelin modulate homeostatic and brain reward regions to regulate feeding behavior in humans.
- PYY3-36, active GLP-1, OXM and ghrelin regulate glucose homeostasis.
- Circulating PYY3-36, active GLP-1 and acyl-ghrelin levels are reduced in obese subjects compared to normal weight subjects. However, VLCD adversely impact upon appetite and circulating ghrelin and PYY levels.

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Health Consequences–Obesity Associated Comorbidities

4

Julian J. Emmanuel and Simon W. Coppack

Abstract

Severe and complex obesity is associated with multiple medical problems. The lines of causality are often complex with (a) medical problems causing obesity and obesity causing medical problems as well as (b) 'third' factors (such as sedentary lifestyle or poor diet) causing both the medical problem and obesity.

The chapter seeks to outline the main medical and psychological comorbidities, to indicate the frequency and impact on morbidity and mortality of these comorbidities. The clinical rationale and financial justification for obesity treatment is very dependent on these comorbidities and the extent to which they are reversed by successful weight loss.

The major comorbidities include type 2 diabetes, increased vascular deaths, thromboembolism, sleep disordered breathing, and cancer. Comorbidities that contribute to poor quality of life include psychological, esophageal, gynecological, urological, and musculoskeletal problems.

Insulin resistance is an important mechanism for type 2 diabetes, dyslipidemia, and hypertension all of which lead to vascular disease. Aromatization of androgens is an important mechanism in gynecological problems and some neoplasia.

Obesity is currently the largest cause of lost quality adjusted life years (QALYs) in the United States of America and it is the only major risk factor from which the total loss of QALYs is currently increasing year on year.

Keywords

Obesity • Quality adjusted life years • Comorbidities • Cardiovascular disease • Mortality

4.1 Introduction

Large scale long term epidemiological studies have shown obesity to be strongly associated with an increase in cardiovascular, cancer, and all-cause mortality (Fig. 4.1) [1]. In such studies, it is difficult to distinguish the effects of obesity *per se* and the influences of low physical activity and psychosocial factors that promote obesity. Thus it may be that low physical activity is responsible for some increase in the mortality. Furthermore, it might be that primary psychological problems *per se* may cause obesity and increase mortality. Low levels of education may have similar effects. Such issues may not affect the epidemiological view of the association(s), but are relevant to physicians and surgeons

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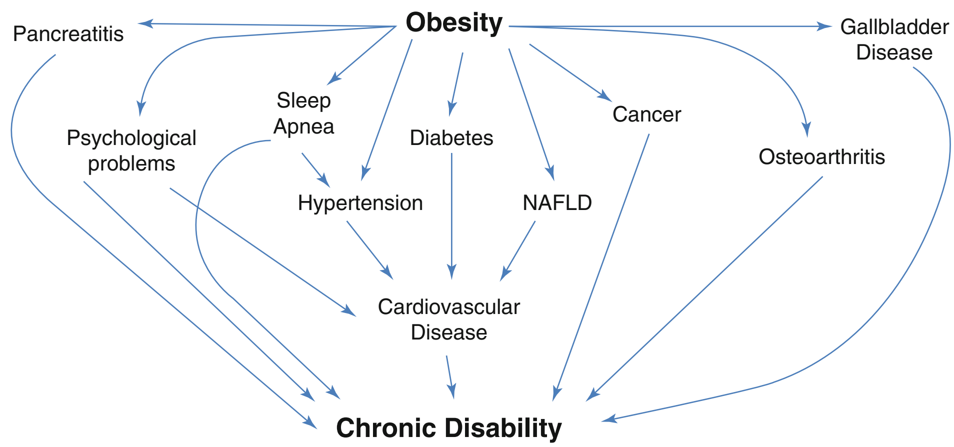

Fig. 4.1 Overview of disability caused by obesity. *NAFLD* non-alcoholic fatty liver disease

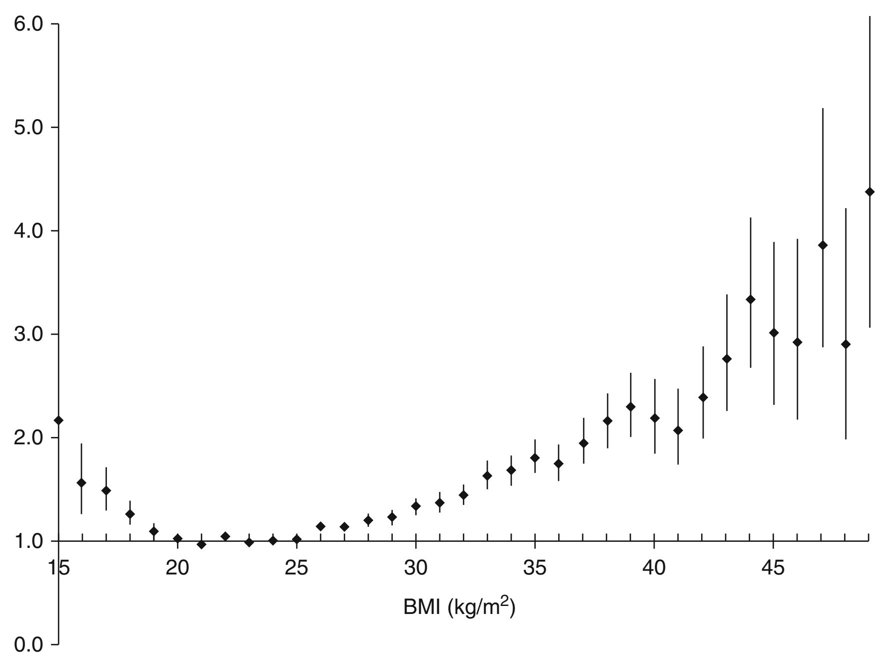

Fig. 4.2 Relationship between body mass index and mortality. Estimated hazard ratios adjusted for age, gender and education (& 95 % confidence intervals) for all-cause mortality according to BMI (BMI 24 kg/m^2 was set at reference value) in healthy never-smoking white adults (Data from Berrington de Gonzalez A, et al. [25])

seeking to improve patients' outcomes. In this chapter, we shall talk about effects of obesity but the caveat is that it may, or more usually may not, be possible to distinguish the effects of these other factors.

A related issue is that to understand the biological effects of adiposity, one would wish to have a better index of fatness than body mass index (BMI). Although, World Health Organization (WHO), and hence most public health documents and guidelines, use BMI as their predominant index of obesity, the severe limitations of BMI itself have been widely and repeatedly reported. The use of BMI is especially problematic if one wishes to discriminate between adiposity and muscularity since BMI is increased by both fatness and muscularity.

However using simplistic indices of obesity such as BMI, since 2008 in the United States population, obesity has been the single greatest cause for loss of QALYs (quality adjusted life years), having overtaken smoking. Although in 2008 smoking still caused more QALYs to be lost due to death, obesity caused more QALYs to be lost through morbidity. Moreover, while all other major risk factors (smoking, cholesterol, hypertension, and others) that contribute to loss of QALE (quality adjusted life expectancy) in the population show a declining temporal trend, obesity is increasing (Fig. 4.2).

Obesity is associated with an increased prevalence of type 2 diabetes mellitus (T2DM), hypertension, elevated serum cholesterol, gallbladder disease, coronary heart disease, cerebrovascular disease, obstructive sleep apnea, certain types of cancers and osteoarthritis leading to functional impairment, reduced quality of life, serious disease and greater mortality. Figure 4.3 outlines diseases with direct and indirect association and obesity.

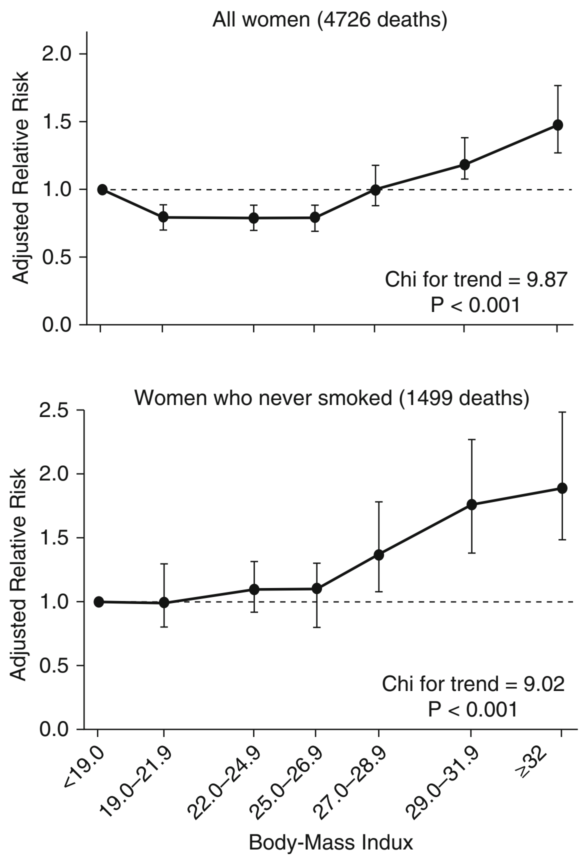

Fig. 4.3 Relationship between body mass index and mortality in relation to smoking. Deaths amongst US nurses according to BMI. *Upper panel* all deaths. *Lower panel* deaths in subject who had never smoked (Data from Manson JE, et al. [26])

4.2 Causes or Consequences of Obesity

It is not the main aim of this chapter to consider in detail the causes of obesity. The etiopathogenesis of obesity is described in Chap. 2. But if one is discussing 'medical risks of obesity' it is relevant to consider factors that cause obesity. As indicated in Chap. 2, factors that cause obesity often have their own medical risks independent (totally independent or partially independent) of obesity. Extreme examples would be obesity caused by steroid excess or alcohol. These both cause obesity and have their own medical risks. Importantly, there are characteristics of obese subjects that may be the causes of obesity, or consequences of obesity, or both (Fig. 4.4). Although the association may be clear, the mechanistic relation may not be. It is also crucial to recognize factors that cause obesity as they are very relevant to decisions about treatment, especially decisions about surgical treatment.

Fortunately some studies show that bariatric surgery leads to a reduction in cardiovascular risk factors and in mortality which clearly suggests the direction of causality. A recent metanalysis of 12 trials suggested a reduction in global mortality [2]. Conversely, no such benefit was reported in the respected Veterans Affairs (VA) study of patients with existing cardiac disease which suggests that such causal relations can be complicated and may even change as patients become sicker [3].

4.3 Characteristics of Obese Subjects

Obesity is more common in certain ethnic groups, in low socioeconomic groups, and in those with lower educational attainment. Obese subjects have low levels of employment and are more likely to have prolonged unemployment. Social stigmatization from obesity can lead to low employment and low social class; however, it is more common to find low social class as a cause of obesity.

Generally, obese people have lower rates of marriage and higher rates of divorce than the general population. Obese subjects report higher levels of previous sexual abuse. In women, obesity is associated with greater parity and short duration of breast feeding.

Obese subjects tend to smoke, drink alcohol and use recreational drugs less often than their non-obese peers. Obese subjects may use laxatives and other over the-counter medication more commonly than non-obese peers. These characteristics probably contribute to the development of obesity and do not usually change with weight loss.

4.4 Psychological Illness and Obesity

Multiple psychological abnormalities are associated with obesity [4]. These psychological abnormalities may sometimes be the cause and sometimes the effect of obesity. They have major effects on the quality of life. Despite higher frequency of psychological abnormalities in obese populations, it scarcely needs to be said that each patient is an individual with a unique personality and social background. It is necessary to consider the different psychological issues separately even though they co-segregate (personality disorders are linked with depression) and one psychological disorder can lead to others (post traumatic syndromes can lead to anxiety).

The relation between self esteem and obesity varies considerably with historical and social mores, but currently in Western societies obesity is not favored.

Personality disorders (axis two) are common in obese subjects. Personality disorders seem to be intractable, difficult to treat and respond poorly to intervention by mental health professionals. The interplay between different personality disorders, obesity and various modalities used to treat obesity are little studied and poorly understood. One might

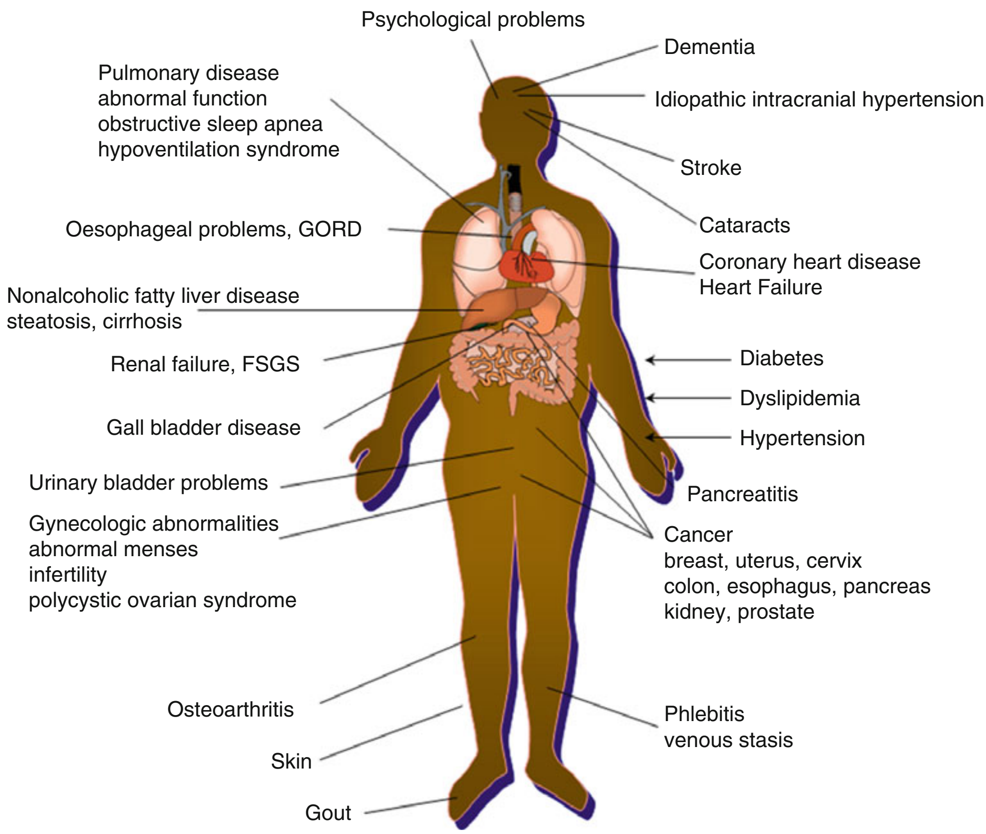

Fig. 4.4 Cartoon of main co-morbidities of obesity by site in body (Please see text for further details). *GORD* gastro-oesophageal reflux disease, *FSGS* focal segmental glomerulo-sclerosis

speculate that patients with obsessive compulsive disorder (OCD) might respond well to psychological intervention while malabsorptive surgery might be the only effective treatment for obesity in those with psychopathic tendencies. But hard data from large studies is lacking.

4.4.1 Depression

There are complex relations between obesity and depression. Some patients lose weight during depressive episodes but others gain weight. For some patients obesity is the dominant cause of depression. Many antidepressant drugs cause weight gain. There are associations between BMI and mood, anxiety, and personality disorders.

4.4.2 Psychotic Illness

Patients with psychotic illness are more likely to be obese than non-obese. Antipsychotic drugs (especially the atypical antipsychotic drugs) commonly cause weight gain. Most would consider that psychotic illness causes obesity rather than obesity causing psychotic illness, but mental illness of all types may be exacerbated by obesity related ill health such as sleep apnea.

4.4.3 Psychological Effects of Dieting Weight Loss and Weight Gain

This is a complex area that may or may not be separable from the effects of 'stable obesity.' Obese subjects are often under considerable psychosocial pressure to diet and lose weight. Dieting (especially severe calorie deficit) may cause adverse psychomotor changes. Successful weight loss may improve self esteem, although this often destabilizes interpersonal and sexual relationships/networks. Weight gain/regain often has adverse psychological effects (Table 4.1).

4.5 Type 2 Diabetes Mellitus and Metabolic Syndrome

Diabetes, insulin resistance and 'metabolic syndrome' are the medical complications most intimately linked to obesity (and even to overweight). The etiology of insulin resistance is probably multifactorial. Bjorntorp [5] and Stewart [6] have described abnormalities of stress hormones (notably cortisol, but also sympathetic activity) that contribute to insulin resistance. The Randle Cycle [7] and the cellular satiety hypothesis demonstrate that over-availability of metabolic fuels (usually lipid fuels) in cells can reduce insulin action on glucoregulation. More recently, it has been recognized that the multiple endocrine actions of adipose tissue, like the release of leptin, adiponectin, and interleukin-6 [8], are changed in obesity and this has thus revealed further mechanisms whereby an expanded adipose tissue mass affects insulin resistance.

Insulin resistance is clearly one of the main problems that lead to T2DM [9], full blown diabetes appearing once pancreatic ß[beta]-cell compensation can no longer cope. Insulin resistance probably also underpins other elements of the metabolic syndrome, such as dyslipidaemia and hypertension.

The risk of developing T2DM proportionately doubles with every 5–7.9 kg gain in weight (Fig. 4.5). The converse also holds true. T2DM exacerbates other weight-related problems, notably heart failure, obstructive sleep apnea (OSA) and hypogonadism. A subnormal free testosterone is noted in up to a quarter of obese T2DM patients, and is associated with a three-fold increase in cardiovascular risk. Treatment with testosterone leads to improved insulin sensitivity.

Many treatments for T2DM, such as insulin, thiazolidinediones and sulphonylureas, cause weight gain.

Weight loss (by a variety of methods) can have powerful 'antidiabetic' effects [10].

Also, in the Look AHEAD trial, weight loss was associated with improved diabetes control and intensive lifestyle intervention reduced hospital and medication costs [11]. Analysis of the associations between risk factors for metabolic syndrome in diabetic and non-diabetic subjects did show a significant association between BMI and metabolic syndrome, and weight loss is associated with a significant reduction in the prevalence of this syndrome.

Table 4.1 Psychological associations of severe obesity and its treatment

Associated with obesity per se	Associated with treatment of obesity
Low self esteem	Changes with success or otherwise with treatment
Interpersonal relationships	May change positively or negatively with weight change
Personality disorders	
Agoraphobic trait	
Addictive behavior	'Substitution' of addiction may complicate treatment
'Histrionic behavior'[a]	
Post traumatic stress disorder	
Anxiety	
Depression	Antidepressant drugs affect weight
Previous sexual abuse	Problem may be 're-ignited' by weight loss
Psychomotor retardation seen with depression, obstructive sleep apnea (OSA)	Seen with severe acute undernutrition
Eating disorders	Patients may abuse laxatives
Disordered body image	Redundant skin folds may be problematic
Psychotic illness	Antipsychotic drugs affect weight

[a]Term used by Prather & Williamson

4.6 Hypertension and Obesity

The link between obesity and hypertension is well established [12–14]. Visceral obesity driven hypertension is only treated to target in one-third of the patients. Humoral, renal autonomic, OSA and insulin resistance are all thought to contribute to its pathogenesis. The major consequences of poorly controlled hypertension manifest in chronic kidney disease and cardiovascular morbidity and mortality through heart failure and coronary heart disease, atrial fibrillation and sudden cardiac death. An increased systemic blood volume seen in obesity and a redistribution of this volume to the cardiopulmonary area with an increase in cardiac output and an inappropriately high peripheral vascular resistance leads to cardiac adaptations of hypertrophy and electrophysiological changes. These are thought to mediate the adverse cardiac consequences. However, the relationship between obesity,

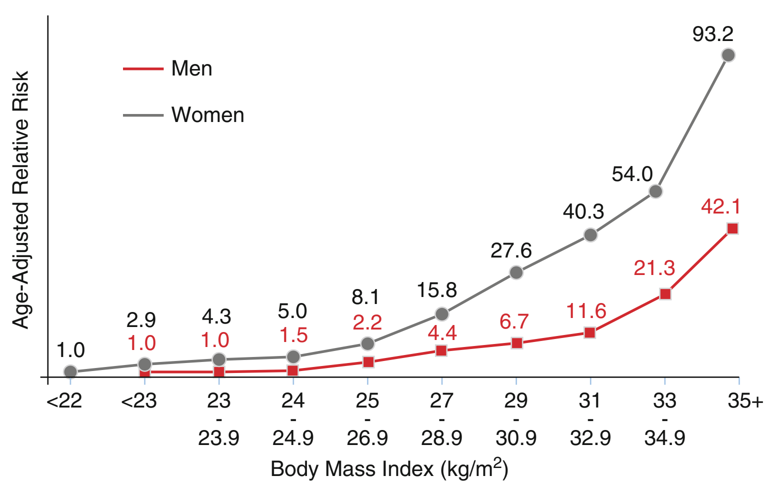

Fig. 4.5 Relationship between BMI and risk of Type 2 diabetes. Relative risk of developing Type 2 diabetes by BMI categories. BMI category <2224 kg/m^2 was set at reference value (Data from Chan J, et al. [27] and Colditz G, et al. [28])

hypertension and heart failure is not established. The 'obesity paradox' whereby obesity increases survival after the onset of heart failure has been shown to be a statistical misinterpretation based on ascertainment bias and survivor effect [15].

Chronic kidney disease and microalbuminuria has been linked to the metabolic syndrome and obesity. In the Framingham cohort, a unit increase in BMI was associated with a 1.2-fold increase in the risk for kidney disease. Sympathetic over activity and changes in the renin angiotensin aldosterone system (RAAS), insulin resistance and leptin resistance, lead to salt retention alongside changes to blood flow and vascular resistance. Hypertension is correlated with salt intake in subjects thought to be sodium sensitive, and this is believed to be an inherited trait. The resultant hyperperfusion and hyperfiltration, focal segmental glomerulosclerosis (FSGS), tubulointerstitial inflammation and fibrosis has been confirmed on biopsy or post mortem. Obese subjects have high rates of proteinuria, usually reflecting FSGS.

A reduction in salt intake alongside pharmacotherapy is desirable in view of the dietary habits in these patients. Though studies with weight reduction alone have also shown promising results, on the whole the reduction in blood pressure is proportional loss of weight. Exercise is also a key agent in the treatment of obesity related hypertension. Other associated comorbidities such as alcohol intake have also to be considered when managing hypertension in this group. The angiotensin converting enzyme inhibitors and angiotensin receptor blockers are the agents of choice in view of their positive effects on cardiac and renal organ dysfunction. Diuretics are thought to be the best add on therapy. OSA has been linked to hypertension and its treatment has led to a reduction in blood pressure and cardiovascular events.

4.7 Dyslipidemia

Obesity is associated with some increase in total cholesterol, but has greater and arguably more pernicious effects on lipid composition including reduced high density lipoprotein (HDL) cholesterol, increased very low density lipoprotein (VLDL), small dense low density lipoprotein (LDL) and triglycerides [1]. The increase in cardiovascular risk from such changes may be difficult to separate from the associated risks of insulin resistance and T2DM. However, some risk calculators include either HDL or total: HDL cholesterol suggesting that these risks can be partially enumerated.

There are multiple mechanisms whereby increased energy intake, alcohol intake, low physical activity, insulin resistance and/or glucose intolerance and/or obesity per se alter lipid metabolism. The prime common factor would be secretion of overproduced VLDL from fatty liver. This overproduction of VLDL requires an increased consumption of HDL [16]. There is evidence that high fructose (and alcohol) consumption is especially likely to lead to fatty liver and hence overproduction of VLDL (compared to other iso-caloric carbohydrates or lipids).

4.8 Cardiovascular Diseases

Obesity is an independent risk factor for coronary heart disease, myocardial infarction, angina pectoris, congestive heart failure, stroke, hypertension, and atrial fibrillation. In severe obesity, classical exertional angina is not common. The clinical picture of exertional dyspnea is more usual. Myocardial infarctions are more often silent in obese than in lean subjects (Fig. 4.6).

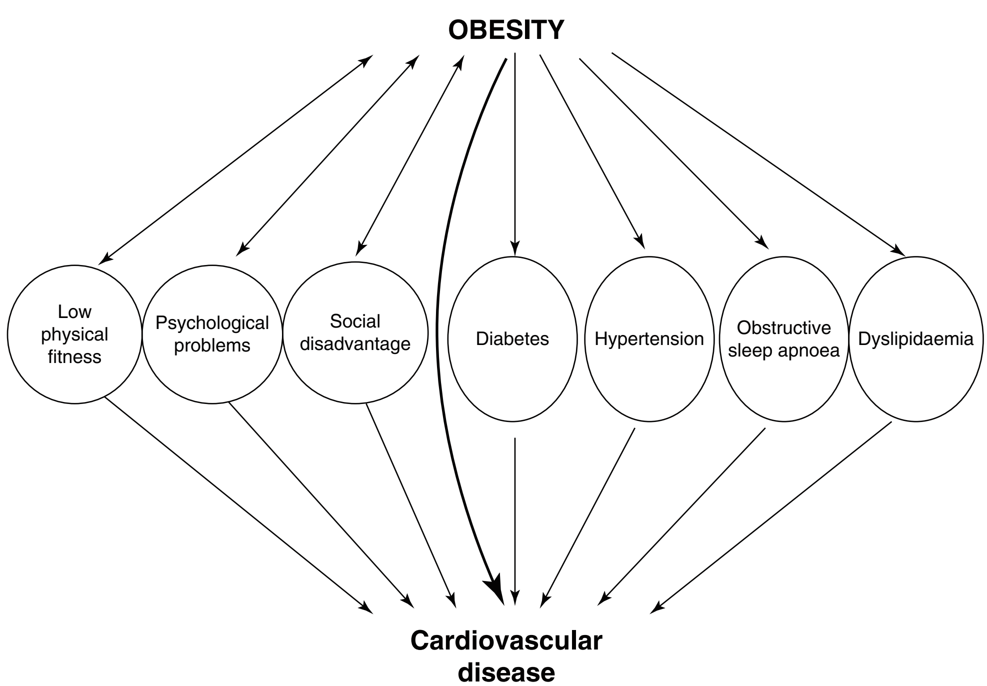

Fig. 4.6 Mechanistic links between obesity and cardiovascular disease. Note that for factors on *left side* of diagram, e.g. low physical fitness, there is a reciprocal causal link with obesity

In the patients with exertional dyspnea, there can be multiple causes or components responsible, such as physical deconditioning, asthma, pulmonary emboli and sleep disordered breathing as well as cardiac dysfunction. Echocardiography shows that diastolic dysfunction (rather than systolic abnormalities) is more common in severe obesity. Diastolic dysfunction seems to contribute to symptoms and overall mortality, but may be less of a concern in relation to perioperative mortality.

The 'obesity paradox' in which obese subjects with heart failure survive longer [13, 15] seems to be an artifact. In some studies this is attributable to statistical problems such as selection bias. In other studies there may be an issue of obese patients presenting with severe functional impairment and symptoms (and hence high New York Heart Association (NYHA) grade) even while their systolic function is relatively well preserved.

4.9 Obesity and Gynecology

Childhood obesity is linked to early onset puberty. This is thought to be mediated through insulin resistance and other endocrine pathways. The risk of ovulatory disorders is proportional to the degree of obesity. The adiposity related rise in leptin and decline in adiponectin leads to poor folliculogenesis; in addition to this the conversion of androgens to estrogen in adipose tissue inhibits gonadotropin secretion. Further, hyperinsulinemia causes hyperandrogenemia, and granulosa cell apoptosis. Phosphorylation of the insulin receptor prevents signal transduction and insulin resistance. Ovarian androgen production is facilitated by insulin, through Insulin-like Growth Factor 1 IGF1 in the presence of luteinizing hormone (LH) mediated steroidogenesis in the theca cell. The increased aromatization of androgens to estrogen in peripheral adipose tissue may underlie many of the reproductive abnormalities seen in women and may as well increase the risk of gynecological cancers (see below).

Obesity is associated with longer irregular cycles and perimenopausal bleeding. The relative hyperestrogenic state related to obesity can be linked to fibroid growth or endometrial polyps. Obesity and increased waist circumference are associated with stress urinary incontinence through raised intra-abdominal pressure. Pelvic floor dysfunction is proportional to the degree of obesity, and is thought to be irreversible; with this there is also proportional exacerbation of cystocele, rectocele and uterine prolapse.

4.10 Female Fertility

Fertility seems to decline in women with increasing obesity, whether they have or do not have, polycystic ovarian syndrome (PCOS). The rise in infertility does seem to plateau above a BMI of 35 kg/m^2. In addition, there is a high incidence (30–70 %) of obesity among women with PCOS with consequential anovulation, infertility, and miscarriage [17]. Weight loss is helpful in treating PCOS. Bariatric surgery can lead to complete resolution of menstrual irregularities and PCOS, and improved fertility at an appropriate time to plan conception.

Obesity and insulin resistance are predictors of treatment failure with gonadotropins in assisted reproduction. Obese females also have lower pregnancy rates, and significantly higher risk of miscarriage regardless of the method of conception.

4.10.1 Obesity in Pregnancy

In America, one in every five antenatal patients is clinically obese. Obesity is known to significantly increase maternal risk through diabetes, hypertension, thromboembolic disease, mood disorders, infection, fetal macrosomia, stillbirth, fetal anomalies, post-term pregnancy and labor related complications such as abnormal presentation, fetal distress, increased instrumentation and cesarean section and dystocia [18]. There is also an increase in complications associated with administering regional anesthesia, and postoperative complications after cesarean section. Obesity is associated with three-fold increase in gestational hypertension, and there is linear risk association between preeclampsia and obesity. Some also suggest a linear risk between gestational diabetes mellitus (GDM) and obesity. Obesity leads to fetal abnormalities through GDM and independently in proportion to BMI. Prematurity and increased neonatal and infant mortality, with risks to severely obese mother and baby are also well recognized. However, contraceptive use remains low in this group, likely due to a complex relationship between obesity and socioeconomic factors.

Despite the anxieties related to weight gain, there is little evidence to link significant weight gain with combined oral contraception. There is also increased risk of oral contraceptive failure with obesity.

Antenatal intervention can limit weight gain by up to 6.5 kg without adverse impact on neonatal outcomes. Bariatric surgery before the conception has also been shown to improve pregnancy outcome by decreasing preeclampsia, GDM, cesarean section rates and macrosomia. However, there is an increase in small for gestational age babies, especially in women losing weight rapidly. In line with this, pregnancy should be avoided in the first 12–18 months after bariatric surgery. It is also important to ensure that nutritional supplementation is undertaken when conception is planned after Roux-en-Y gastric bypass surgery. Any mechanical obstruction following bariatric surgery may be masked by hyperemesis associated with pregnancy and therefore, a high index of suspicion should be maintained.

Postpartum thromboprophylaxis for about a week, along with encouragement to breastfeed, to reduce risk of T2DM after GDM, and earlier screening for GDM, T2DM and pre-eclampsia would enable targeted early intervention and risk modification.

4.11 Male Sexual Dysfunction

Erectile dysfunction and reduced male fertility are associated with obesity and are thought to be mediated by low testosterone levels and a pro-inflammatory milieu [19]. As in women, excess conversion of androgens to estrogens by adipose tissue aromatization seems to be an important mechanism. Obesity has been linked to reduced sperm count, increased DNA fragmentation in sperm and reduced sperm motility in proportion to the degree of obesity. Weight loss may improve male infertility, though the impact on sperm quality is yet to be determined.

4.12 Knee Osteoarthritis

The risk of knee osteoarthritis is strongly and proportionally associated with BMI, but not with hip osteoarthritis [20, 21]. This is known to adversely influence exercise capacity and daily function; weight loss reverses the symptoms and functional consequences of knee osteoarthritis. The etiology is thought to involve a combination of genetic, humoral and mechanical factors. However, whether these factors are reversible with weight loss remains to be proven. Obese patients are also at increased risk of distal extremity injuries and tendinopathies.

4.13 Gallstones

BMI is independently linked to hospitalization from symptomatic gall stone disease, and acute pancreatitis. Further, obese subjects have a higher incidence of systemic complications and mortality related to acute pancreatitis.

4.14 Esophageal Disorders

Obesity is a major risk factor for gastroesophageal reflux disease (GERD). The higher prevalence of GERD may be linked to Barrett's esophagus and thence to adenocarcinoma. A weight loss of around 3.5 kg resulted in significant decrease in the frequency of symptoms of gastroesophageal reflux disease.

4.15 Nonalcoholic Fatty Liver Disease

Obesity is independently associated with nonalcoholic fatty liver disease and consequently with the metabolic syndrome, it is not yet clear if weight loss may reduce the risk of NAFLD in obese patients.

4.16 Obstructive Sleep Apnea

Obesity increases the prevalence of sleep disordered breathing tenfold. This rise in incidence is proportional to weight gain. This leads to daytime sleepiness, hypoxemia/hypercapnia, pulmonary hypertension, right heart failure, drug resistant hypertension, stroke, arrhythmias, and cardiovascular complications. Weight loss leads to a reduction in OSA (Fig. 4.7).

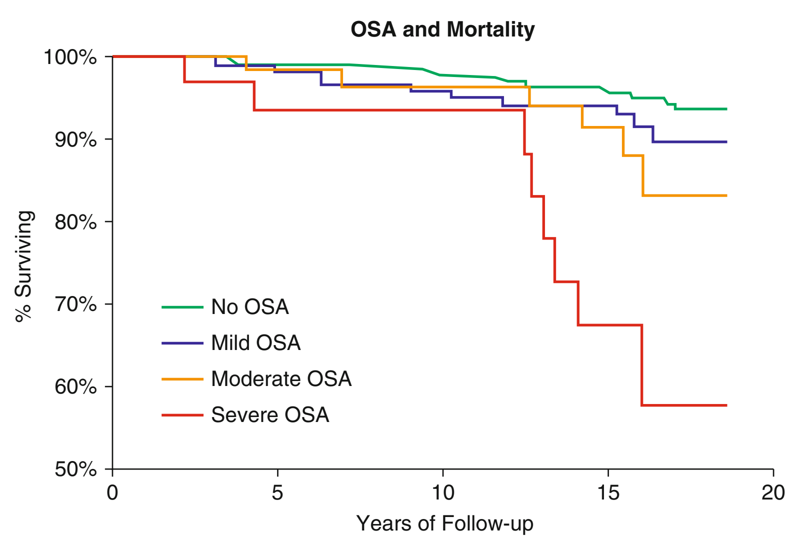

Fig. 4.7 Survival of patients by presence and severity of Obstructive Sleep Apnoea (OSA) (Data from Young T, et al. [29])

4.17 Bladder

Bladder dysfunction with urgency and incontinence are common in severe obesity, often unrelated to previous obstetric history. The mechanisms are often poorly understood.

4.18 Obesity and Cancer

There is a strong association between elevated BMI and cancer risk, and between BMI and cancer mortality related to esophageal, colon, rectum, liver, gallbladder, pancreas, kidney, non-Hodgkin lymphoma, multiple myeloma and prostate cancer (Table 4.2). Obesity leads to 20–35 % of all the cancers [22]. When broken down, obesity as a cause is linked to 11 % of colon cancer, 9 % of postmenopausal breast cancer, 39 % of endometrial cancer, 25 % of kidney cancer, and 37 % of esophageal cancer. Obesity is also related to mortality from liver, pancreatic cancer, non-Hodgkin's lymphoma, and myeloma. Obesity increases risk for aggressive prostate cancer.

Humoral mechanisms are thought to underlie these processes; obesity related estradiol can explain the breast and endometrial cancer risk.

Growing evidence points to insulin signaling pathways mediating the effect of BMI on colon and prostate cancer risks, however these effects may be counteracted by higher levels of estrogen in women. The role of insulin pathway has been identified through expression of insulin and IGF receptors in colon cancer.

A rise in BMI between ages 30–50 leads to a parallel rise in risk of colorectal cancer. In men, it has found that weight loss is associated with reduced risk of colonic cancer, and the converse of it also holds true. Roux-en-Y gastric bypass leads to reduction in mortality and incidence of obesity related cancers. Metformin therapy in diabetics is associated with lower total cancer incidence and associated mortality.

4.19 Mortality

There is an increased mortality associated with obesity (see Fig. 4.2) [23]. Total QALYs lost to obesity (and low physical activity) is reflected in the changes in lifetime medical costs and years of life lost [24]. Obesity leads to a disproportionate rise in life years lost when compared to anorexia. However, the Swedish Obesity Study has shown that cardiovascular, cancer and all-cause mortality associated with obesity can be significantly reduced by surgical intervention for morbid obesity.

There has been some heterogeneity in the strength of the associations between BMI and mortality. In general there is a J-shape curve of association between BMI and mortality, but the BMI at the nadir of the J varies. Some of the heterogeneity may relate to whether the study is carried out in general populations or in more homogeneous groups. One

Table 4.2 Cancer risks with obesity

Cancer type	Relative risk men	Relative risk women	Suggested causal mechanism
Endometrium		1.59	Estrogen excess
Adenocarcinoma esophagus	1.52	1.51	GERD, Barrett's esophagus
Thyroid	1.33	1.14	
Adenocarcinoma colon	1.24	1.09	Hyperinsulinemia and/or IGF-1
Renal	1.24	1.34	Hypertension partly
Hepatoma	1.24	1.07	NAFLD, cirrhosis
Breast, estrogen receptor positive		1.18	Estrogen excess
Malignant melanoma	1.17	0.96	
Multiple myeloma	1.11	1.11	Inflammatory cytokines, e.g. IL-6
Rectum	1.09	1.02	
Gall bladder	1.09	1.59	Gall stones
Leukemia	1.08	1.17	Inflammatory cytokines, e.g. IL-6
Pancreas	1.07	1.12	
Non-Hodgkin's	1.06	1.07	Inflammatory cytokines, e.g. IL-6
Breast, estrogen receptor negative		1.03	Inflammatory cytokines, e.g. IL-6
Ovary		1.03	
Prostate	1.03		
Stomach	0.97	1.04	
Lung	0.76	0.80	Negative association with smoking
Squamous esophageal	0.71	0.57	Negative association with smoking

Modified from data in Renehan et al. [30]
Relative risks are per 5 kg.m^{-2} increase in BMI. Mechanisms suggested for one cancer probably contribute to other cancer risks

example is whether one considers a mixed population including subjects who have lower BMI but high mortality rates, such as recent immigrants from East Africa, then this will affect the apparent nadir in the J. Likewise other characteristics, like smoking, will affect the relationship between BMI and mortality. This was elegantly shown by subgroup analysis of nonsmokers in the Nurses Health Study (see Fig. 4.3). A related problem is the effect of age on the consequences of obesity. Obesity causes a higher relative mortality rate in younger adults than it does in older adults. In people of over 70 years, the standardized mortality ratio of obese people is often not significantly different from lean people, but it is unclear whether this represents a 'survivor effect.'

Key Learning Points

- There are multiple medical comorbidities of obesity, some of which reduce quality of life, others increase mortality.
- T2DM, heart disease and cancer are the biggest 'killing' comorbidities. Obstructive sleep apnea and arthritis are other important comorbidities.
- Key mechanisms for obesity comorbidities seem to be insulin resistance causing T2DM and dyslipidemia and aromatization causing gynecological and neoplastic problems.
- On a population scale, obesity is already the biggest single loss of QALYs and its impact is increasing.

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Medical Management of Obesity

5

Robert C. Andrews

Abstract

The term obesity implies an excess of adipose tissue and excess adiposity is a health risk. Patients with obesity are at increased risk of many medical and psychiatric diseases, they have reduced life expectancy, and are also subjected to unwanted social, psychological, and physical disadvantages. As a result of these factors the cost to individuals and society due to obesity is huge. For these reasons prevention and treatment of obesity is now widely recognised as a chief priority.

The aim of treatment is to reduce morbidity and mortality while improving psychological well-being and social function. Interventions are costly and time consuming and thus should be targeted at patients who at the most risk (BMI >30 or BMI >27 + serious co-morbidities of obesity) and motivated.

Overeating and decreased activity are the fundamental problems underlying the development of obesity, thus any therapy aimed at helping the obese patient must have a dietary and physical activity (PA) component. Initially patients should be encouraged to increase their PA to 60 min 5 days per week and reduce their total energy intake by 500–1000 kcal/day. The aim is to lose 5–10 % of weight at a rate of 0.5–1 kg/week. If after 6 months significant weight-loss has not been achieved then obesity drugs can be added.

Encouraging patients to loss and maintain weight loss can be difficult. Using behavioural techniques and helping patients to identify their barriers to change and providing them with tools to overcome this will improve adherence and aid with weight loss and maintenance of this.

This chapter covers the clinical assessment of obesity, what treatment options are available and how to use these.

Keywords

Activity • Diet • Barriers • Behavioural therapy • Obesity drugs • NES • BED

5.1 Introduction

The term obesity implies an excess of adipose tissue and excess adiposity is a health risk. Even mild obesity increases the risk of type 2 diabetes mellitus, hypertension, dyslipidaemia and coronary heart disease as well as osteoarthritis, polycystic ovarian syndrome, obstructive sleep apnoea (OSA) and many psychiatric diseases. Obesity also significantly shortens life expectancy, the risk from premature death increases with each increment in BMI. Patients with obesity are also subjected to unwanted social, psychological, and physical disadvantages. The combination of these factors inevitably creates negative impacts on the individual's quality of life.

As a result of these factors the cost to society due to obesity is huge, in the UK the current cost to the National Health

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Service is estimated to be £4.2 billion and this is forecasted to more than double by 2050 [1]. For these reasons prevention and treatment of obesity is now widely recognised as a chief priority.

This chapter covers the clinical assessment of obesity, what treatment options are available and how to use these.

5.2 Aims of Treatment

The ultimate aim of treatment is to reduce morbidity and mortality while improving psychological well-being and social function. As well as reducing weight, risk reduction may also require other interventions such as lipid lowering, blood pressure and diabetes medication. In addition psychological therapies may be required to help with both weight loss and to improve well-being and social function. Thus input from a wide variety of health care professionals may be needed to obtain this aim.

5.3 The Team

A team approach is required for the successful management of obesity. The core team includes a physician, a dietitian and an exercise therapist. Behavioural therapists, psychologists, psychiatrists and other secondary care teams may also be required. Managing an obese patient often necessitate the full co-operation of the family and can involve managing the whole family as well. For these reasons GPs are frequently best placed to manage obesity.

5.4 The Principles of Treatment

In order to have a successful outcome in obesity, treatment has to target changing patients' behaviours more than providing recommendations and education. This is because patients on the whole, know what changes they need to make, but lack the impetus or support to make these changes.

Ideally care workers dealing with obesity should be trained in behavioural techniques as these have been shown to improve outcomes. If this is not available then minimal intervention strategies such as the 5As (ask, assess, advise, agree, and assist) can guide the process of counselling a patient about behavioural change [2].

An overview of the 5As is shown in Fig. 5.1. In brief you should start by asking permission to discuss weight. If they agree then in the ensuring conversation you should be non-judgmental and explore the drivers of the obesity and the patient's readiness for change (see Table 5.1). Next you should assess body mass index, waist circumference, obesity stage and complications of excess weight. You should then advise the patient about the health risks of obesity, the benefits of modest weight loss, the need for a long-term strategy, and the treatment options. Then agree on a realistic weight target and how this target will be obtained. Finally at future appointments you should assist in identifying and addressing barriers and provide the resources to help overcome these.

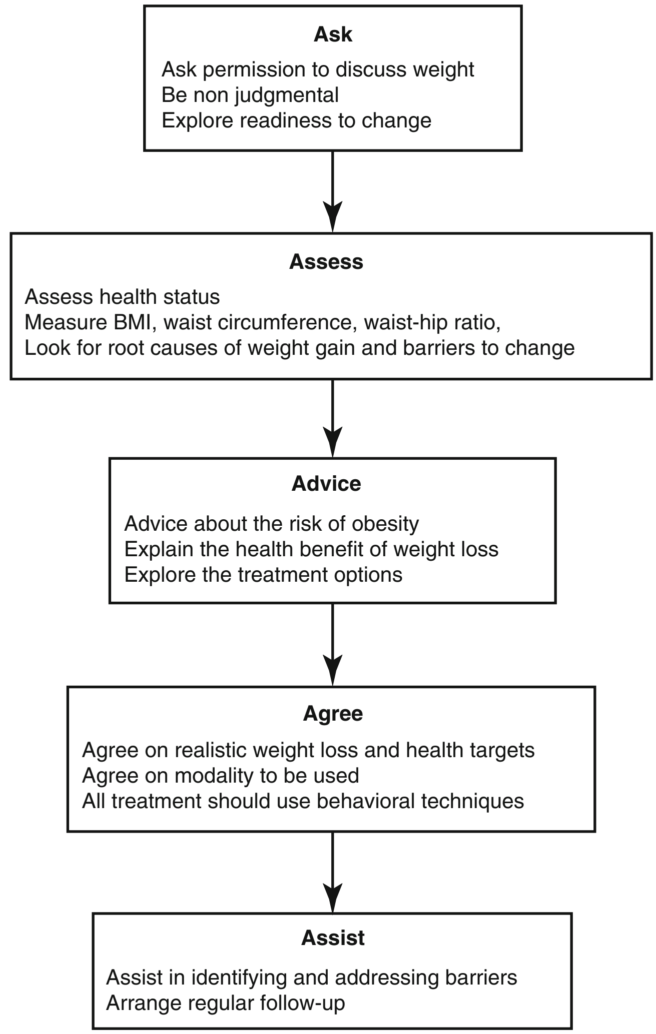

Fig. 5.1 The 5As for obesity counselling (Adapted from Vallis et al. [2])

5.5 Overview of Assessment and Treatment

Obesity interventions are time-consuming and costly, they therefore should be offered to a select group of patients who are likely to benefit from them. In general treatment is targeted at patients who are at the greatest risk, as the greater the risk, the greater should be the benefit from an intervention.

Table 5.1 Question to assess stage of change in terms of weight loss

Which of these statements best describes where you are	Stage
At the moment I'm not doing anything to lose weight and I have no intention of doing anything over the next 6 months	Pre-contemplation
At the moment I'm not doing anything to lose weight but I'm thinking about doing something over the next 6 months	Contemplation
During the last year I haven't done anything to lose weight but I'm planning to do something over the next 30 days	Preparation
I've been making an effort to lose weight (by dieting and/or exercising) for less than 6 months	Action
I've been making an effort to lose weight (by dieting and/or exercising) for more than 6 months	Maintenance

There are numerous methods of identifying increased risk; the two most commonly used are the BMI and the waist circumference. A BMI >30 kg/m^2 is associated with a 7.1 year reduction in life expectancy in men and a 5.9 year reduction in life expectancy in women compared to a person with a normal BMI (<25 kg/m^2)[3]. Similarly a waist circumference greater than 102 cm in men and 88 cm in women is associated with an increased risk of diabetes and cardiovascular disease [4]. As a result of this most guidelines suggest that obesity should be actively treated in patients with a BMI >30 kg/m^2 and/or waist circumference greater than 102 cm in men and 88 cm in women. If however diabetes, sleep apnoea or cardiovascular disease is present, then treatment should be offered to patients who have a BMI >27 kg/m^2 [1]. Figure 5.2 shows an algorithm for the treat and assessment of obesity.

5.6 Initial Assessment

When first meeting a patient with obesity, it is important to schedule sufficient time to allow a thorough history and examination, and to ensure exploration of any salient features that arise. It is best to think of obesity as a symptom of calorie excess and, like you would do with water excess (oedema), use the history and examination to try and identify the underlying causes [5]. In many cases the cause may simply be 'too large portions' and 'too little activity,' but sometimes features found during this consultation may alter the initial treatment strategy that you come up with (see Fig. 5.2 and Table 5.2).

Charting out weight over time can be very insightful into the likely cause of weight gain. In the majority of patients there is a gradual increase in weight (see Fig. 5.3a), the cause of weight gain here will tend to be a simple misbalance between energy in (food intake) and energy burnt (too little activity). In others there can be a sudden rapid increase in weight (Fig. 5.3b), this can be due to development of a disease that limits exercise (cardiorespiratory disease) or reduces metabolism (Cushing's disease), commencement of a drug that promotes weight gain (see Table 5.3) or a serious life event (abuse or death of a relative). In others there can be quite fluctuant weight with periods of rapid weight loss followed by periods of rapid weight gain (Fig. 5.3c), in these individuals eating disorders and self-sabotage behaviour should be considered. Finally in a small subset of patients, weight gain will have started in early childhood with the child's weight moving away from the centile line that they started on (Fig. 5.3d), here genetic causes should be considered.

During this initial assessment the causes that need to be looked for are:

5.6.1 Genetic Causes

An early onset of obesity (before age of 5), hyperphagia, developmental delay, short stature, diarrhoea and a strong family history of obesity can all point to a genetic cause of obesity (see Table 5.4). If patients have any of these key features they should be referred to secondary care for further investigation.

Prader-Willi syndrome (PWS) is probably the most frequently recognised syndrome of childhood obesity. It is characterised by behavioural problems, food foraging and hyperphagia leading to early-onset childhood obesity; mental retardation and hypogonadism are also features [6].

Currently there are no specific therapies for the majority of these conditions, although there is evidence that some genetic diseases respond better to certain treatments and in some cases certain options should not be tried. For example there is clear evidence that PWS patients do not do well with obesity surgery.

5.6.2 Eating Disorders

Eating disorders may accompany obesity and are frequently overlooked by families, carers and even health-care workers. Importantly, their presence often reduces the effectiveness of long-term obesity management. Eating disorders should therefore be actively sought, and their treatment form part of the overall obesity management plan. The two commonest eating disorders are Binge Eating Disorder (BED) and Night-time Eating Syndrome (NES).

BED is characterised by recurrent binge eating, but without the inappropriate compensatory weight-control methods—e.g. self-induced vomiting, excessive exercise—that are

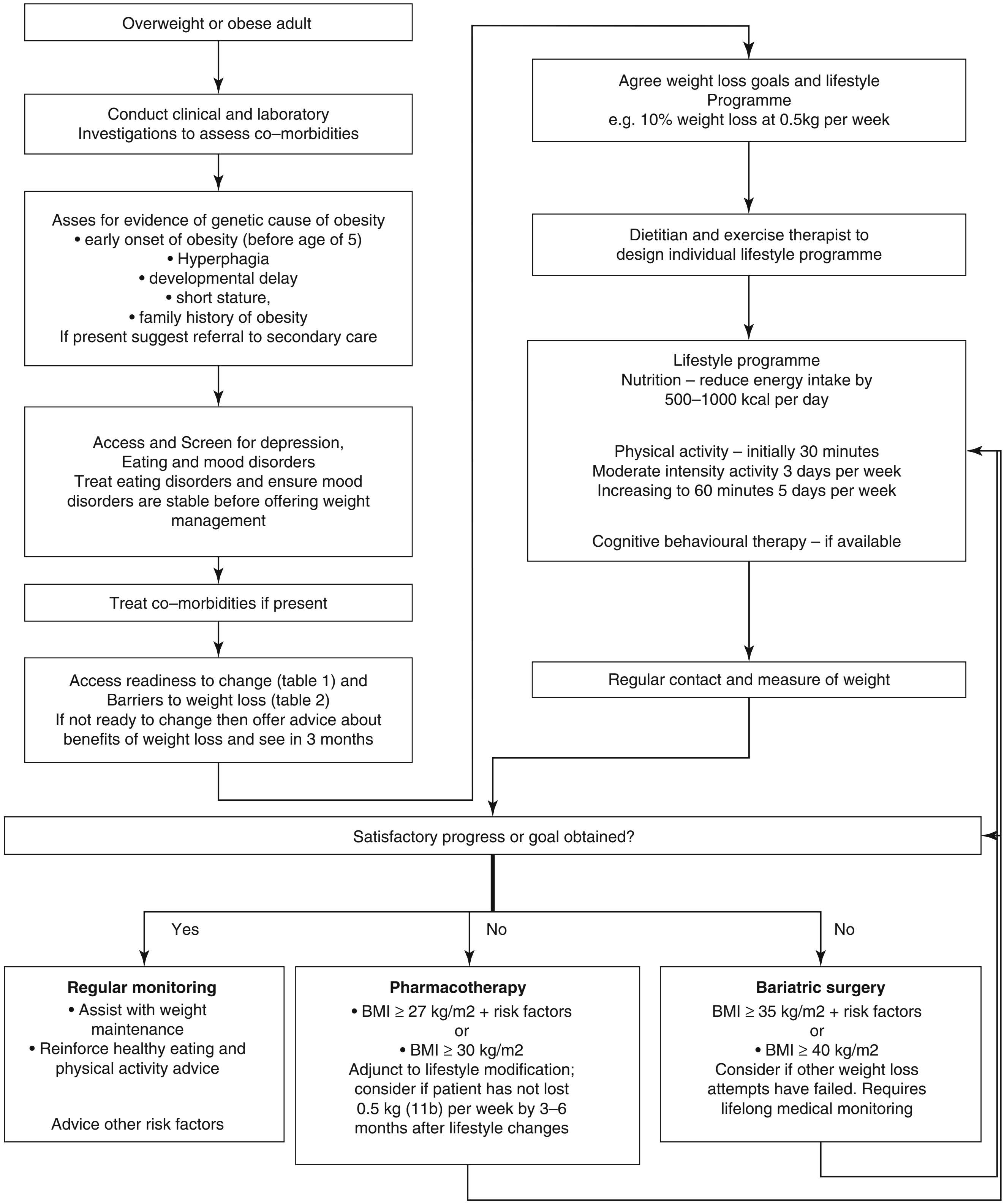

Fig. 5.2 Algorithm for the assessment and stepwise management of the overweight or obese adult

Table 5.2 Barriers to weight loss

Barrier		Intervention	Rationale
Acceptance of obesity as a chronic disease		Education of patients and health care providers	Obesity treatment requires lifelong management to maintain weight loss
Time constraints		Assess motivation and readiness for change Adapt strategy to patient's schedule Use of meal replacements Flexible exercise schedule	Offers portion control, availability, portability, ease of preparation Practical and sustainable
Saboteurs		Identification of problem Counselling, support and motivation	Support systems are essential to long-term weight maintenance
Co-morbidities	Mental health	Recognition and concomitant treatment of depression and attention deficit disorder (ADD)	Improvement of depression and impulsive behaviour facilitates adherence to obesity treatment
	Eating disorders	Recognition and referral for specific intervention of binge eating disorder (BED) and night time eating syndrome (NES)	Cognitive behavioural therapy (CBT) focusing on binge eating and associated psychopathology facilitates adherence to lifestyle habits
	Sleep	Evaluation and treatment of obstructive sleep apnoea (OSA)	Reduction of cardiovascular risk and risks of accidents. Improved sleep may positively impact adherence to lifestyle changes and physical activity.
	Pain	Pain management	Allows patient to be more physically active
	CV disease	Management of symptoms of cardiovascular disease	Allows patient to be more physically active
	Respiratory disease	Accurate diagnosis and treatment of the cause of dyspnoea	Allows patient to be more physically active
	Digestive disease	Recognition and treatment of reflux symptoms	Avoidance of using food to relieve reflux symptoms.
	Endocrine disorders	Recognition and treatment of insulin resistance, hypothyroidism, Cushing and hypogonadism	Investigation of endocrine disorders is only justified when historical and clinical evidence supports the diagnosis.
Medication		Choose medication with less propensity for weight gain	Prevent weight gain
Alcohol and substance abuse		Assessment and treatment of addictions	Improve adherence to obesity treatment

Adapted from Mauro et al. [5]

found in bulimia nervosa [7]. It affects about 5 % of the general population, rising to 17 % among the obese and to 30 % in those participating in weight-reduction programmes [8].

NES is characterised by morning anorexia, evening hyperphagia and insomnia. Its prevalence in obese individuals is reported to be as high as 27 %, compared with only 1.5 % in non-obese individuals [9].

5.6.3 Medical Conditions

Although rare, hypothyroidism, hypogonadism and Cushing's disease need to be considered, as treatment of these will help the patients to loose weight and will reduce their cardiovascular risk. If the thyroid function has not been check in the last year then this should be done. Tests for hypogonadism and Cushing's disease only needed to be done if signs of these diseases are present or there had been a sudden change in the rate of weight gain.

Complications of obesity such as diabetes, sleep apnoea, respiratory disorders and osteoarthritis should be looked for and treated. Their presence should indicate a more aggressive approach to the treatment of obesity. Treatment of these conditions may also help to alleviate barriers to weight loss (see Table 5.2).

5.6.4 Psychiatric Disorders

Obesity can cause a negative emotional affect and is linked with disorders including low self-esteem, body image dissatisfaction, depression, anxiety disorders, self-harm and borderline personality symptomatology. It is thus crucial that warning signs and symptoms of psychological and psychiatric disorders are recognised and treated without delay as part of the general management of obesity. Most people would not recommend trying to treat obesity whilst a patient's psychiatric disorder is unstable.

5.6.5 Medication

Certain medication can stimulate appetite or reduce the metabolic rate thus hampering attempts to lose weight. Where

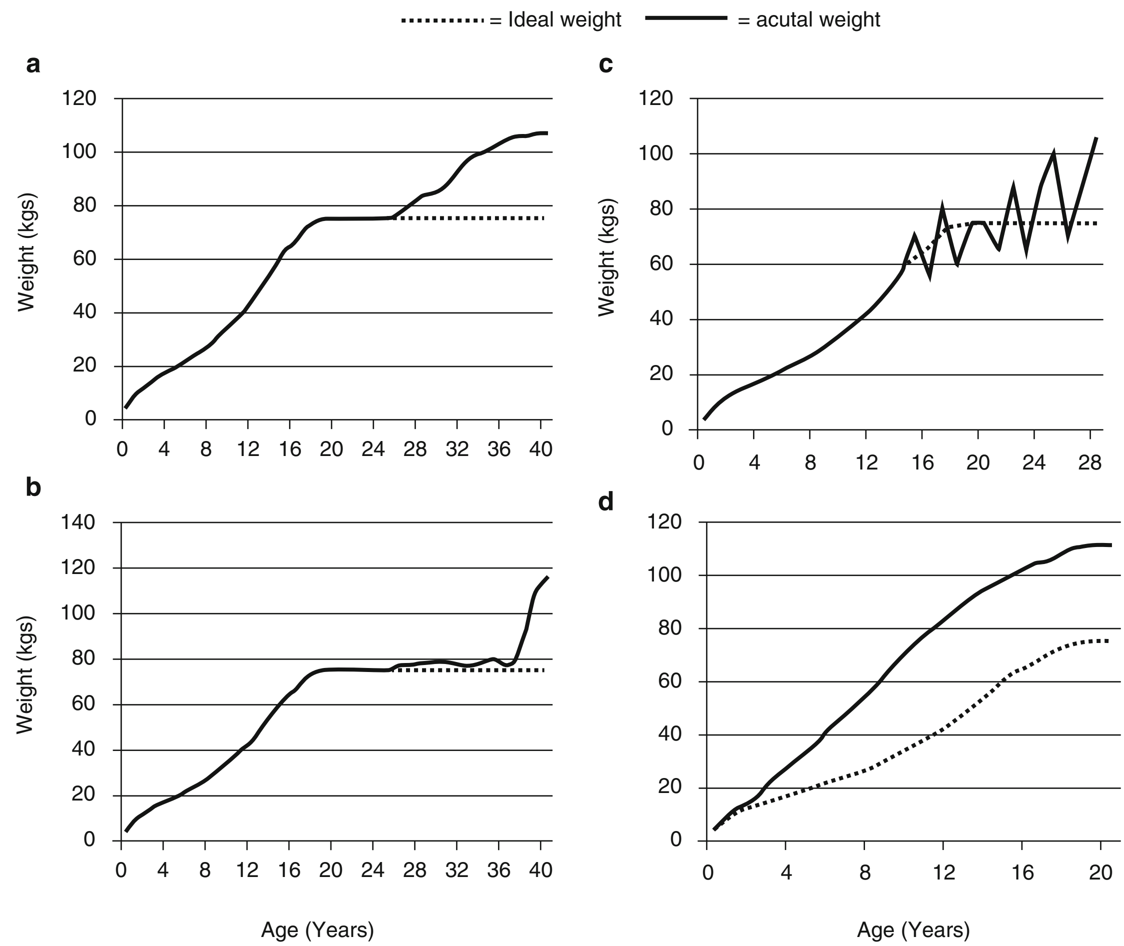

Fig. 5.3 Different weight charts. Shown here are four different weight gain patterns. Graph (**a**) shows a gradual increase. Graph (**b**) shows a sudden increase in weight. Graph (**c**) shows rapid fluctuation in weight. Graph (**d**) shows weight gain from an early age

possible these should be swopped to drugs that are weight neutral or that will help to promote weight loss (Table 5.3) [5].

5.7 Treatment

Established obesity is very difficult to treat with the currently available medical treatment and often the effects are not long lasting. Where possible, barriers to weight loss found at the initial assessment should be dealt with (Table 5.2) and the patients should be motivated to change (Fig. 5.2) before treatment is offered.

5.7.1 Assessing Readiness to Change

According to the multi-dimensional transtheoretical model (TTM) [10], there are five stages of changes that people pass through when making behavioural: (1) Precontemplation: the individual has no intention to change diet and activity behaviour(s); (2) Contemplation: the individual intends to change his or her behaviour within the next 6 months; (3) Preparation: during which the individual tries the new behaviour and intends to change it within the next month; (4) Action: in which an individual has adopted a new behaviour less than 6 months ago, and finally, (5) Maintenance: the individual has successfully changed and maintained from a poor behaviour for more than 6 months. There is some evidence that working with patients in stage 3 and 4 improves the outcomes. A simple questionnaire (see Table 5.1) can be used to help identify which stage they are in.

5.7.2 Barriers to Weight Loss

Even in patients who are clearly motivated to change it is important to recognise potential barriers that will make weight loss difficult as management of these barriers can save resources and increase the changes of long-term success [5]. In some patients these barriers may be too difficult to overcome, in these the focus should be on the prevention of further weight gain rather than on weight loss. Table 5.2 highlights the common barriers that are seen. Mood disorders should be stabilised and eating disorders treated before offering treatment to help with weight loss.

Table 5.3 Weight gain and tablets

Drug class	May cause weight gain	Less weight gain, weight loss or weight neutral
Antipsychotics	Clozapine Risperidone Olanzipine	Ziprasidone Aripiprazole
Antidepressants and Mood stabilizers	Citalopram Lithium MAOIs TCAs Venlafaxine Mirtazapine Paroxetine	Bupropion Sertraline Fluoxetine
Anticonvulsants	Carbamazepine Gabapentin Valproate	Lamotrigine Topiramate
Diabetes Drugs	Insulin Sulphonylureas Thiazolidinediones	Metformin Acarbose GLP-1 DDPIV
Antihypertensives	Alpa blockers Beta blockers	ACE inhibitors Calcium Channel Blockers
Oral Contraceptives	Progesterone only pill Combination pill with progesterone	Barrier method IUDs

5.7.3 Treatment of Eating Disorders

Patients who manage to stop binge-eating lose more weight and are able to maintain their weight loss for longer than those who fail to stop [11, 12]. For this reason BED should be treated as part of the management package for patients with obesity. There are three main treatments for BED: cognitive behavioural therapy (CBT); interpersonal psychotherapy (IPT), and drug therapy.

CBT aims to improve and maintain motivation, self-monitoring and problem-solving and is usually administrated on a one to one basis at regular intervals as part of a weight management programme. CBT is regarded as the best intervention for BED [13, 14], however there is no good data confirming that it promotes weight loss on its own.

IPT focuses on problem resolution within four social domains: grief, interpersonal role disputes, role transitions, and interpersonal deficits. It can be as effective as CBT in stopping binges and thus helps to maintain weight loss, but again has not been shown to decrease weight in its own right [15].

In studies, antidepressants (both SSRIs and monomine oxidase inhibitors) or topiramate have demonstrated a reduction in the frequency of binge episodes and weight loss of 2–7 kg, [16, 17]. However, these studies were small and under 6 months' duration; meaning that the use of these drugs remains limited to specialist clinics.

Whether bariatric surgery should be offered to patients with BED is debatable. Surgery does not cure the underlying eating disorder and in some cases has been reported to

Table 5.4 Genetic causes of obesity

Syndrome	Developmental delay	Short	Impaired Satiety and/or increased hunger	Other features
Prader-Willi syndrome	Yes	Yes	Yes	Hypotonia, small hands and hypogonadism
Down syndrome	Yes	Yes	No	Hypotonia, flat facies, slanted palpebral fissures, small ears
Bardet-Biedl syndrome	Yes	Yes	No	Retinal pigmentation, polydactyly, hypogonadism, renal disease
Turners syndrome	Yes	Yes	No	Female phenotype, broad chest, wide-spaced nipples, congenital lymphedema, webbed neck
Cohen syndrome	Yes	Yes	No	Hypotonia, prominent incisors, narrow hands and feet, decreased visual acuity
Carpenter syndrome	Yes (mild)	Yes	No	Acrocephaly, polydactyly, lateral displacement of inner canthi
Albright hereditary osteodystophy	Yes	Yes	No	Pseudohypoparathyroidism, rounded facies, hypocalcaemia, short metacarpals
Borjeson-Forssman-Lehmann syndrome	Yes (severe)	Yes	No	Large ears, hypogonadism, coarse facies
Killian-Teschler-Nicola syndrome	Yes (severe)	Yes	No	Sparse scalp hair, seizures, coarse facies, accessory nipples, streaks or hyperpigmentation and hypopigmentation
Pro-opiomelanocortin deficiency	No	No	Yes	Red hair, pale skin, adrenal insufficiency
MC4R mutations	No	No	Yes	None

Used with permission from Kramer and Daniels [6] worsen BED. However, the average weight loss after surgery in patients with BED is similar to that seen in unaffected obese subjects. An exception is patients with powerful cravings for sweet food, who lose little weight [18]. If surgery is offered to patients with BED then they should be closely monitored and offered CBT if overconsumption of sweetened, energy-dense drinks occurs.

Treating patients with NES can be more difficult. Both CBT and IPT are used, but are less effective than they are in the treatment of BED. High-dose sertraline (50–200 mg) reduces eating in the evening and can induce an average weight loss of 3 kg [19, 20]. These studies were small and larger studies are needed before the routine use of this drug can be recommended.

A few studies have found that patients with NES after bariatric surgery have similar weight loss to obese patients without NES. There also seems to be an improvement in nocturnal eating postoperatively, possibly due to improvements in both sleep quality and symptoms of depression [21]. More studies are needed to confirm this.

5.7.4 Lifestyle Modification

Lifestyle modification is essentially the first line treatment for all cases of obesity. The initial goal is to achieve a 5 % weight reduction over a 6-month period, with a further 5 % weight loss over the next 6 months. There are clear health benefits from achieving a 5 and 10 % weight loss (see Table 5.5).

Caloric reduction is the most important component in achieving weight loss whereas increased and sustained physical activity is particularly important in maintaining weight loss [22]. Weight loss is primarily dependent on reducing total caloric intake, not the proportions of carbohydrate, fat, and protein in the diet, with no diet having been shown to be more effective than any other [23]. With the help of dietitian the macronutrient composition (i.e. proportion of calories from carbohydrate, fat and protein) will ultimately be determined by the patient's taste preferences, cooking style, culture metabolic profile and risk factors. Incorporating meal replacements, foods that have a fixed caloric value and take the place of meals and snacks can be useful [24]. An alternative strategy is referral to commercial weight loss programmes that have demonstrated good weight loss outcomes [25, 26].

Table 5.5 Benefits of 5–10 % weight loss

Factor	Amount of weight loss needed (%)
Improved insulin sensitivity	>5
Reduced Risk of IGT progression to Type 2 diabetes	>5
Lower blood pressure	5–10
Decreased total cardiovascular risk	5–10
Reduction all cause mortality	5–10
Reduction in triglycerides	>5
Reduction in LDL cholesterol	>10

As well as reducing caloric intake, patients should be encouraged to burn more calories. Both PA and exercise should be encouraged. PA consists of any bodily movement that increases energy expenditure, e.g. activities of daily living like walking, climbing stairs and gardening. Exercise on the other hand is defined as planned, structured, and repetitive bodily movement carried out to improve or maintain one or more components of physical fitness [27]. Studies have demonstrated that increasing PA through increasing lifestyle activities is as effective as structured exercise programmes in improving cardiorespiratory fitness and weight loss [28]. Initially patients should aim to increase their activity to 30 min of moderate activity 3 days a week, increasing overtime until they are doing 60 min of moderate activity on 5 days per week [28].

In order to help patients achieve their lifestyle goals they should be encouraged to record their food intake, PA, and weight [29]. Recording dietary intake helps patients to plan meals and to reflect on their intake, it also helps to limit intake and provides information for the medical team. Recording PA through pedometers or other means that record time or steps have been shown to increase PA.

However, lifestyle change can be difficult to adhere to in the long run and long-term weight loss can be quite minimal with meta-analysis showing weight loss of 4.5–7.5 kg at 1 year and 3–4 kg at 4 years [30]. As a result some patients may require other medical intervention to achieve the weight loss they want or need to improve their health.

5.7.5 Weight Loss Drugs

When weight reduction is not achieved through lifestyle modification alone, anti-obesity medications (Table 5.6) are often considered. These are available for obese individuals who have been on lifestyle modification for at least 6 months duration with minimum weight reduction.

Currently only one drug, orlistat, has been approved for use in both the USA and Europe for chronic weight management. Since 2012, lorcaserin and phentermine/topiramate have been licenced for use in the USA but are not licenced in Europe and they are many new obesity agents in the pipeline. More specialised, but unlicensed, anti-obesity agents such as metformin, SSRI and topiramate are often tried in specialist obesity clinics if patients fail to achieve weight loss with licenced medication (see Table 5.6).

Orlistat, a lipase inhibitor, blocks the digestion and absorption of ~30 % of dietary fat. In randomised control trials the mean weight loss is ~2.7–3.19 kg greater than placebo treated

Table 5.6 Drugs used to treat obesity

Name	Average weight loss (kg)	Patients selection	Side effect	Where licenced for treatment of obesity
Orlistat	2–3.2	Used in patients with or without diabetes	Gastrointestinal symptoms & Steatorrhoea	World wide
Lorcaserin	2–3.6		headache, dizziness, fatigue, nausea, dry mouth, and constipation	USA only
Phentermine and topiramate combinations	8.9–9.6		headaches, constipation, dry mouth, dizziness, insomnia, depression, anxiety, blurry vision, and irritability.	USA only
Metformin	0.5–4	In patients with diabetes mellitus only	Gastrointestinal symptoms	World wide
GLP-1 analogues	2–3		Gastrointestinal symptoms	World wide
Pramlintide	4–6		Gastrointestinal symptoms and hypoglycaemia	World wide

patients [31–33]. In the UK orlistat is the first line treatment after lifestyle modification. It is only continued if patients have achieved the required weight loss, 3 % weight loss at 3 months or 5 % at 6 months whilst on treatment [1].

In humans, serotonin, acting through 5-HT receptors reduces appetite and hence food intake. Lorcaserin is a selective 5-HT2C receptor agonist. This selectivity means that it can reduce appetite without the risk of hallucinations due to 5-HT2A activation and the risk of cardiovascular side effects, including valvulopathy and pulmonary hypertension, through 5-HT2B receptors. Both of which were reason why previous 5-HT receptors agonists were withdrawn (fenfluramine and dexfenflurame). In clinical trials Lorcaserin shows a 2–3.6 % additional weight loss over and above the placebo treated patients [34, 35].

Weight loss with single agents has been disappointing; as a result of this drug companies have started to look at combining drugs. One combination that has recently been approved for treatment of obesity is phentermine/topiramate extended-release formulation.

Phentermine, through modulation of catecholamines in brain, reduces appetite. Topiramate, a licenced drug, which is primarily used to treat convulsive disorders and migraines, induces weight loss by decreasing food intake and increasing energy expenditure. Together these drugs in clinical trials have shown a 8.6–9.6 % additional weight loss over and above the placebo treated patients [36, 37] (Table 5.5).

Future drugs in the pipeline aim to target hormonal circuits that regulate energy intake and metabolism, as well as combining drugs for reduced side-effects and increased effect, through synergism.

5.8 Who and When to Refer for Bariatric Surgery

Bariatric surgery should be considered in patients with severe obesity who have not responded to the measures discussed above. Criteria for surgery vary from country to country. In the UK, the National Institute for Health and Care Excellence (NICE) currently state that bariatric surgery should be offered to patients with a body mass index (BMI) of 35–40 kg/m^2 who have obesity-related conditions such as Type 2 diabetes or obstructive sleep apnoea, or in those with a BMI of 40 kg/m^2 or greater, regardless of weight-related co-morbidities [38]. However, research is emerging that suggests bariatric surgery could be appropriate for those with a BMI of 35–40 with no comorbidities or a BMI of 30–35 with significant comorbidities and this may lead to lowering of the BMI cut offs recommended by NICE.

The decision to recommend bariatric surgery must be based on risk–benefit ratio along with other factors including psychosocial health, adherence, expectations and cost. There is not enough predictive information available to differentially select one procedure over another for an individual patient or to predict which patients will successfully lose weight and/or see an improvement of their co-morbidities.

Contraindications to surgery include an extremely high operative risk, active substance abuse or a major unstable or uncontrolled psychopathological condition such as major depressive disorder, schizophrenia or bulimia. Patients who have recently have had a serious life-events such as death of a family member, should have their surgery delayed until they have had a chance to deal with this.

All patients who are considering weight loss surgery should undergo a comprehensive assessment by the multidisciplinary weight management team. During the preoperative process, patients should be given advice on healthy eating and physical activity patterns and behavioural strategies to implement these lifestyle changes. Management of co-morbidities should also be optimised and patients screened for nutritional deficiencies.

Postoperatively patients will need to be seen regularly for dietary advice, nutritional surveillance, and alteration in medication for management of their co-morbidities. Evidence-based recommendations for "Best Practice" patient care have been recently been published [39].

Conclusion

Obese individuals can present with a wide range of medical and psychosocial problems, which can promote weight gain. These problems also provide important indications for treatment, but in some cases, also pose significant barriers to management. It is thus essential that a thorough history and examination is undertaken and that treatment is as far as possible targeted at the underlying problems and deals with the barriers to success.

Key Learning Points

- Obesity management aims to reduce morbidity and mortality, while improving well-being. Interventions are costly and time consuming and thus should be targeted at patients who at the most risk (BMI >30 or BMI >27 + serious co-morbidities of obesity) and motivated.
- Lifestyle improvement, with healthy eating and increased physical activity (PA) forms the basis of all weight management. Patients should be encouraged to increase their PA to 60 min 5 days per week and reduce their total energy intake by 500–1000 kcal/day. The aim is to lose 5–10 % of weight at a rate of 0.5–1 kg/week.
- Weight loss of 5–10 % improves blood pressure, blood lipids and blood glucose. Modest weight loss can reduce cardiovascular risk and the risk of developing diabetes as well as improve life expectancy.
- Adherence to weight management programmes is generally poor. Using behavioural techniques and helping patients to identify their barriers to change and providing them with tools to overcome this will improve adherence and weight loss.
- Anti-obesity drugs are not a cure, but with lifestyle changes can improve weight loss. They can be considered in patients with a BMI >30 or BMI >27 + serious co-morbidities of obesity who have not lost sufficient weight with lifestyle attempts.

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Section II

Introduction to Bariatric Surgery

Honorary Section Editor - Mervyn Deitel

Bariatric surgery had its origin in the 1960s. Prior to that, severe obesity was a rare problem and general surgery was still in early stages. Obesity surgery commenced with operations entailing short bowel syndrome – the various intestinal bypasses. These morphed into gastric procedures – bypass (malabsorptive) and plasty (restrictive). Through the ingenuity of surgeons, various operations were proposed, developed, and superseded. Their progress is described in the historical perspectives of this section, and lead now to laparoscopic and endoscopic technologies.

With many of these operations, the weight loss has been significant, and has had a duration of a number of years. During this time, the weight loss has been accompanied by resolution of the major morbidities of the metabolic syndrome – type 2 diabetes, hypertension, coronary heart disease, dyslipidemias, fatty liver, urological and gynecological sequelae, cancers, etc.

It was realized that there were situations where a gastric restrictive weight-loss operation was indicated – banding and sleeve, and where a malabsorptive, more strategic weight loss operation with various bypasses of bowel were indicated. In general, the bypasses are accompanied by greater weight loss of a greater duration, but with occasional complication. However, all procedures require patient cooperation in eating properly, and in taking vitamin and mineral supplements, more strategic with the bypass malabsorptive operations. It is germane that the patients understand the operation and the need for cooperation and lifelong follow-up. Patients must understand that there are potential complications of the procedure, which may be painful, and which require attendance and management for success.

It is with these important considerations in mind that I find that the four chapters in this section cover the topic magnificently.

Historical Perspectives of Bariatric Surgery

6

Simon P.L. Dexter and Mervyn Deitel

Abstract

Surgery for severe obesity started in the 1950s. The development of different operations, including variants of jejuno-ileal bypass, gastric bypass, gastric restrictive surgery and biliopancreatic diversion are discussed. Laparoscopic surgery, and novel approaches including endoscopic procedures and neuromodulation are also presented.

Keywords

Bariatric surgery history • Jejuno-ileal bypass • Gastric bypass • Sleeve gastrectomy • Gastric banding • Duodenal switch • Mini gastric bypass • Laparoscopic bariatric surgery • Endoscopic weight loss interventions • Neuromodulation for obesity

6.1 Early Approaches: Jejuno-Ileal Bypass

The earliest meaningful attempt to treat morbid obesity surgically was by Henrikson of Gothenberg in 1952 [1]. Having observed that extensive small bowel resections resulted in weight loss, he treated a female with obesity and constipation by resection of 105 cm of small intestine. However, due to adaptations in the remaining intestine, she did not have a successful lasting weight loss outcome.

Two years later, in Minneapolis, Kremen et al. [2] performed the first intestinal bypass for obesity, although in the same hospital, Varco may have set the precedent in the previous year [3]. Kremen's work on dogs established that sacrifice of the distal small bowel, and not proximal bowel, was instrumental in fat malabsorption and hence weight loss [2]. The experiments were initially designed to study the impact of small bowel resection for malignancy, ischemia and other pathologies, but the impact on weight loss was so profound that it led to the development of surgical obesity treatments.

Between 1956 and 1961, Payne from Los Angeles undertook a series of ten jejunocolic bypasses or "shunts" in patients with uncontrolled obesity. In these procedures, jejunum was divided 15 in. distal to the ligament of Treitz, and the proximal jejunum was implanted into the mid-transverse colon. Weight loss was excellent, but side-effects included intractable diarrhea, electrolyte disturbances and liver fibrosis on biopsy. Payne planned reversal of the shunt between 6 months and 2 years after the initial surgery. In six of the ten patients, normal anatomy was restored, but in three patients a jejuno-ileal bypass (JIB) was fashioned by re-anastomosing the bypassed bowel to the side of a variable length of distal ileum. Of the JIB patients, only one, who had a 15 in. jejunum to 10 in. ileum reconstruction, maintained the weight loss [4]. The authors then reported the contemporary world experience of JIB, citing 19 further cases by five other investigators, including one by N. Tanner from Charing Cross Hospital.

Between 1956 and 1968, Payne's group performed 80 intestinal bypasses and settled on JIB with a standardized 14 in. (35 cm) of jejunum to 4 in. (10 cm) of ileum (see Fig. 6.1). They noted that some patients whose weight loss stalled had reflux of intestinal content into the bypassed segment [5].

In 1971, Scott from Nashville presented 12 patients in whom an *end-to-end* JIB had been fashioned, in order to

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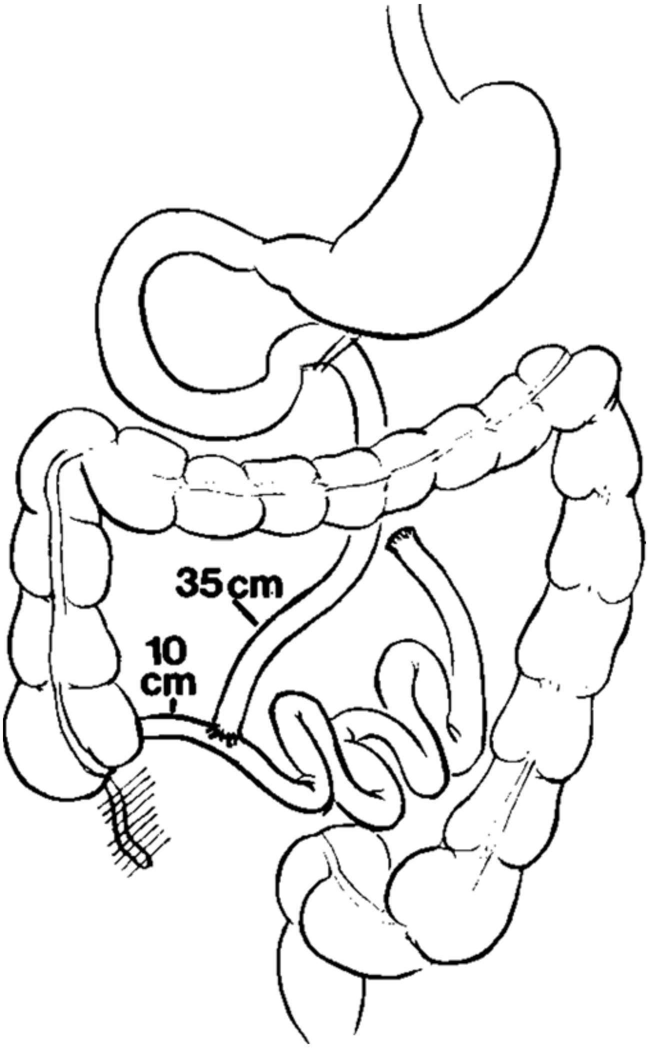

Fig. 6.1 Jejuno-ileal bypass of Payne—end-to-side 35–10 cm [5]. In all jejuno-ileal bypasses, the appendix was removed

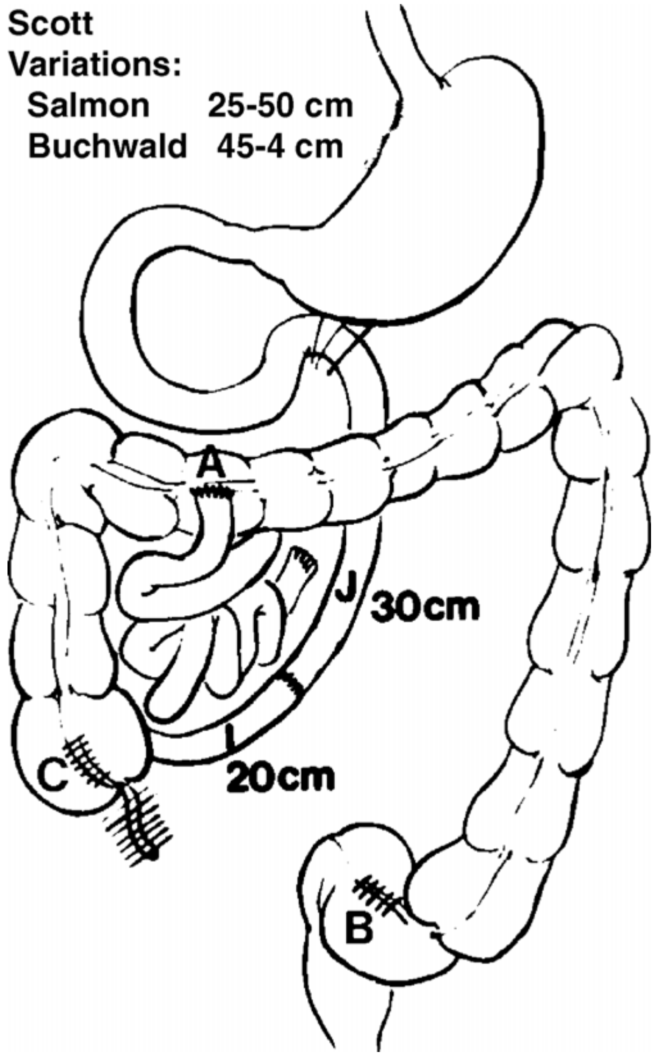

Fig. 6.2 End-to-end jejuno-ileal bypass of Scott, with anastomosis of bypassed bowel to transverse colon (*A*) or sigmoid (*B*) or caecum (*C*) [6]

obviate the problem of retrograde reflux. The distal end of the bypassed segment of small bowel was drained into the transverse or sigmoid colon (see Fig. 6.2) [6]. Other authors utilized similar bypass with variations in the point of drainage (Buchwald used caecum) and in the relative lengths of jejunum and ileum.

Variation of the end-to-side JIB by creating a valve at the anastomosis was used to prevent reflux (see Fig. 6.3) [7]. Cleator joined the end of the defunctioned ileum to the stomach in order to reduce backwash and overgrowth of bacteria in the bypassed bowel which were responsible for a number of complications after JIB (see Fig. 6.4) [8].

Complications of JIB were due to the bypassed small bowel. Bacterial overgrowth within this segment led to abdominal distention with bloating and also absorption of bacterial antigens resulting in migratory arthralgia. Furthermore, fatty acids were poorly absorbed and became bound to ingested calcium, so that dietary oxalate was absorbed instead of being bound to calcium and excreted. This resulted in oxalate kidney stones. In addition, protein malabsorption resulted in liver failure in some patients [7]. A modification to avoid stasis in the bypassed bowel was to drain the gallbladder into the proximal end of the bypassed jejunum [9].

Enthusiasm for the JIB was replaced by concern for the complications, and the procedure was abandoned. What remained was the recognition that obesity was a disease entity and that surgical reversal of severe obesity led to improvement in comorbidities.

6.2 Gastric Bypass

Edward Mason observed that those patients who underwent high gastric resection with Billroth II reconstruction lost weight and struggled to regain weight. In 1966, he developed the loop horizontal divided gastric bypass (see Fig. 6.5)

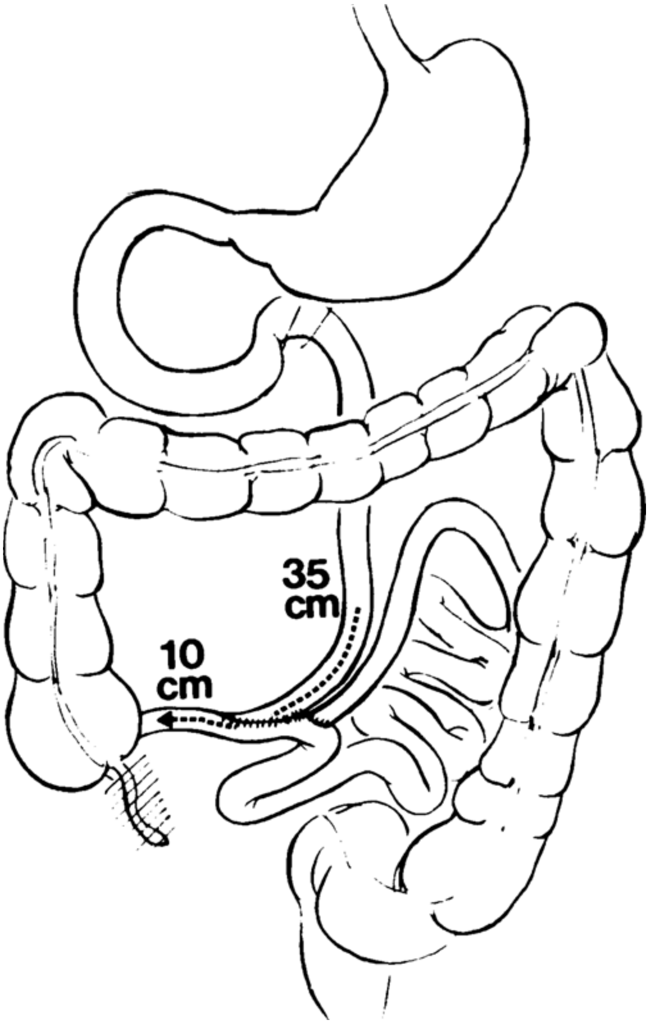

Fig. 6.3 Jejuno-ileal bypass of Palmer and Deitel, with Y-shaped anastomosis and local suturing, directing contents to caecum [7]

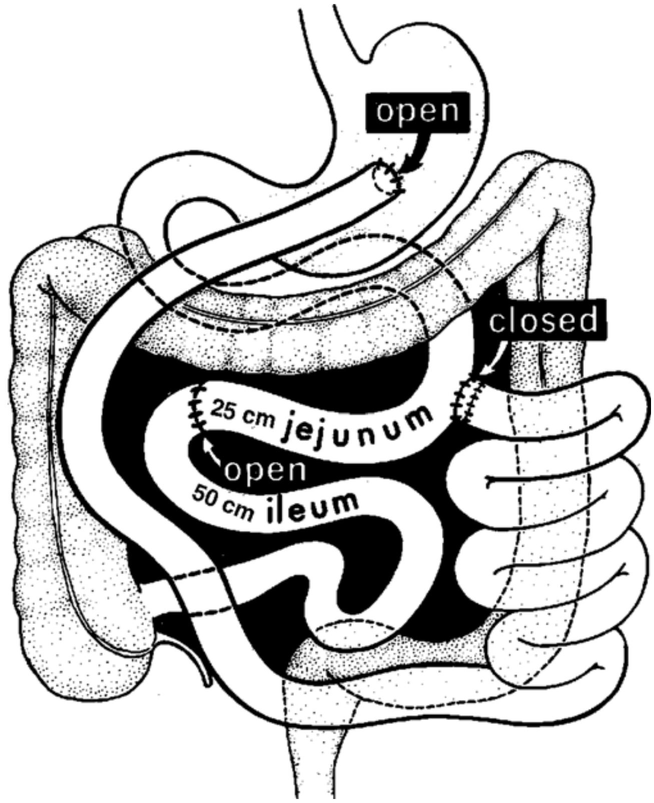

Fig. 6.4 Jejuno-ileal bypass with ileogastric drainage of bypassed bowel (Cleator) [8]

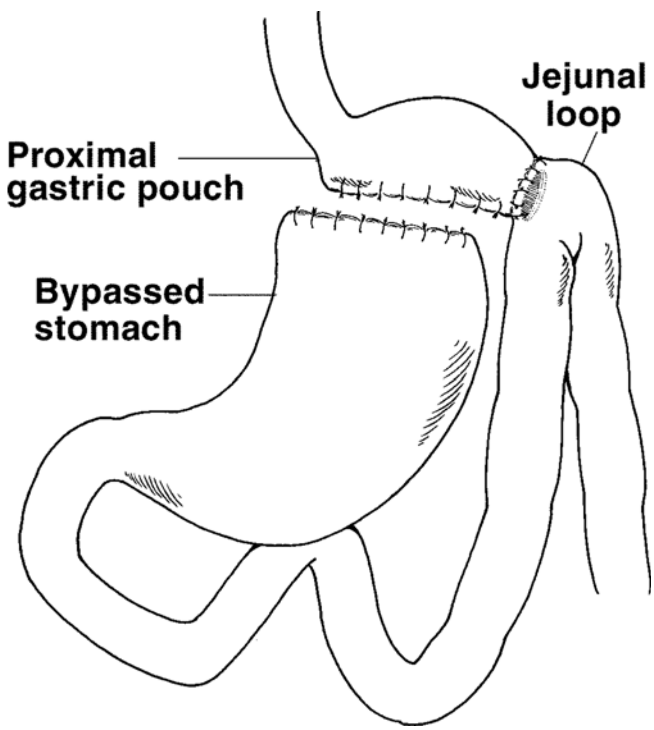

Fig. 6.5 Loop horizontal divided gastric bypass of Mason [10]

[10]. A loop of jejunum was anastomosed to the greater curve aspect of the gastric pouch and a gastro-jejunostomy was performed. The procedure was challenging because of frequent tension on the anastomosis. In due course, greater weight loss was achieved by a smaller fundus, the tension on the anastomosis was reduced by dividing the short gastric vessels, and a narrower gastro-jejunostomy was constructed.

In 1977, Alden constructed the anastomosis between the jejunal loop and the upper stomach first, and then cross-stapled the stomach below the anastomosis without dividing the stomach; he had a low complication rate with no deaths [11].

Anastomotic leakage from the Mason loop bypass was dangerous, because the leaking fluid comprised both gastric and activated duodenal secretions. Griffen introduced Roux-en-Y reconstruction, which diverts bile and duodenal secretions away from the proximal anastomosis, and renders a gastro-jejunal anastomotic leak into essentially a salivary fistula [12, 13]. In Roux-en-Y gastric bypass (RYGB), the Roux-limb decreases tension on the gastro-jejunal anastomosis (see Figs. 6.6 and 6.7).

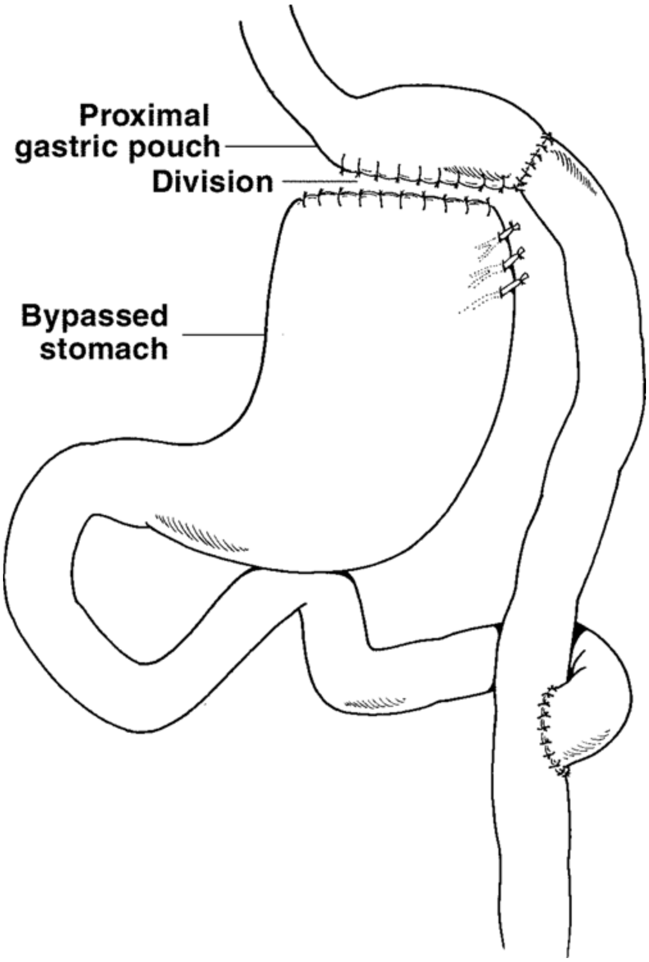

Fig. 6.6 Roux-en-Y gastric bypass of Griffen [12]

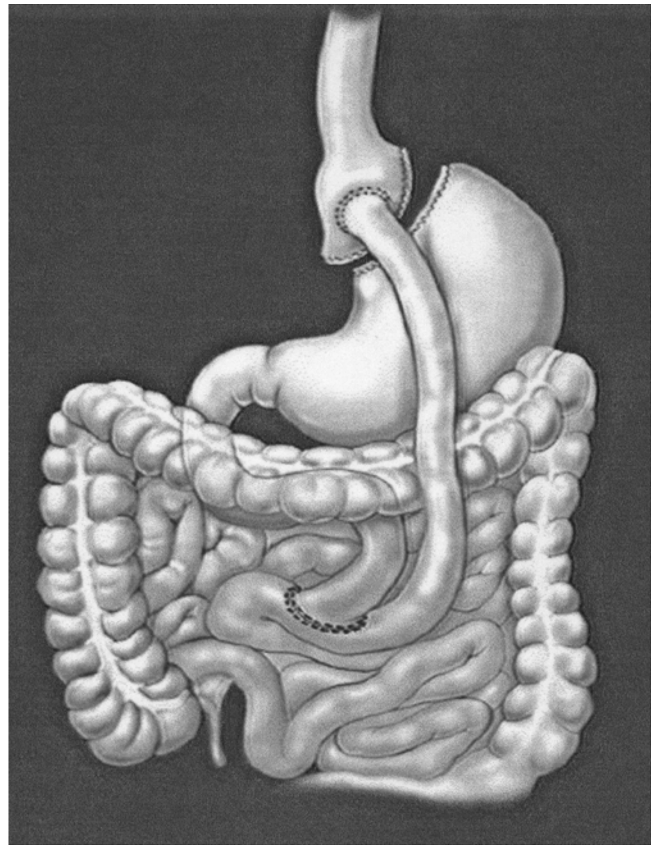

Fig. 6.7 Modern Roux-en-Y gastric bypass with divided tiny proximal pouch on lesser curvature, performed by laparoscopy

With increasing follow-up, it became apparent that late weight regain could still occur after gastric bypass. Attempts were made to enhance long-term weight loss. Torres took the view that combining gastric restriction with malabsorption would provide sustained weight loss. The Torres distal RYGB employed a 50 cc *lesser curve* gastric pouch, an average common channel length of 5 ft (152 cm) with a 3 ft (90 cm) alimentary limb. There was a 7 % protein-malnutrition rate in the Torres RYGB, not including initial patients with short limbs who required revision. The weight loss was impressive, with an average excess weight loss (EWL) of 82.5 % at 5 years [14].

Fobi's approach differed and was based on the finding that the gastrojejunostomy stoma distends over time. This is often due to dilatation of the pouch and stoma, resulting in late weight regain. Linner banded the gastroenterostomy with a non-absorbable suture, but this resulted in a high erosion rate [15]. Fobi placed a silastic ring around the pouch above the gastroenterostomy (see Fig. 6.8) [16]. The ring was placed loosely to prevent dilatation rather than apply restriction. Other elements of the Fobi pouch included interposing the Roux-jejunal loop between the divided pouch and the bypassed stomach to prevent a

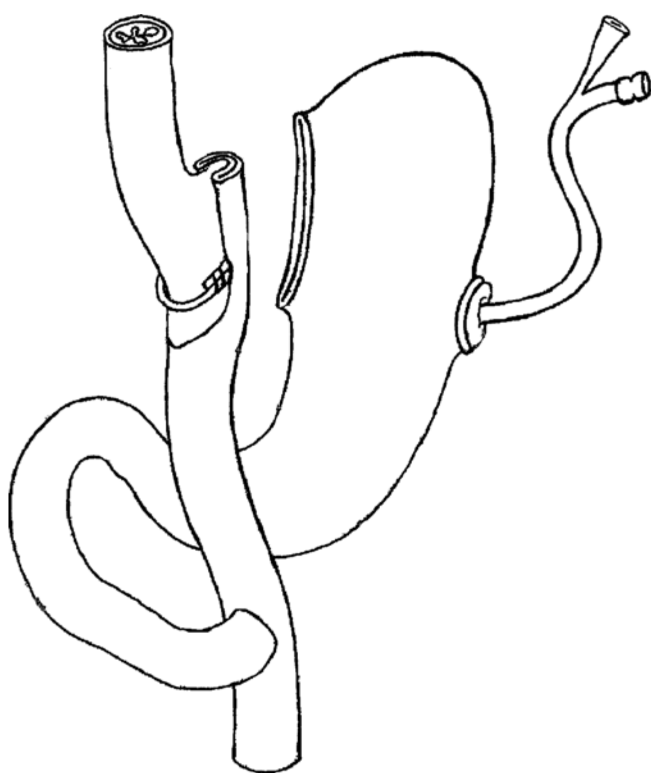

Fig. 6.8 Fobi pouch Roux-en-Y gastric bypass: ring about pouch, interposed Roux-loop, temporary gastrostomy [17]

Fig. 6.9 Two great pioneers—*left* Nicola Scopinaro; *right* Edward E. Mason

gastro-gastric fistula, and placement of a temporary gastrostomy into the bypassed stomach to avoid postoperative gastric dilatation and provide a potential portal for feeding [17]. The results of the Fobi RYGB appear to be better than those of non-banded RYGB, with 10–20 % higher long-term EWL.

6.3 Biliopancreatic Diversion

The malabsorption of the jejuno-ileal bypass had been an effective mechanism for weight loss, but with problematic complications. Accordingly, in 1976 Scopinaro in Genoa (see Fig. 6.9) developed the biliopancreatic diversion (BPD) (see Fig. 6.10). The BPD involves gastric reduction by a subtotal gastrectomy (which avoids ulcer formation) and a lengthy bilio-pancreatic limb to cause malabsorption. Unlike the JIB, there is no blind end to the small bowel. The biliopancreatic limb is diverted distally and anastomosed to the ileum 50 cm proximal to the ileo-caecal valve. Initial weight loss is contributed by the gastric reduction, but the ultimate excellent weight loss and maintenance result from fat and starch malabsorption from the diversion [18]. After the first few months, the volume of food which can be eaten returns to pre-operative levels, but the malabsorption maintains the weight loss.

The excellent outcomes of BPD have been documented for more than 20 years of detailed study by Scopinaro and his team. The optimal stomach size and limb lengths were adjusted to achieve best results and fewest complications, in particular protein-calorie malnutrition. Some cohorts of patients during the experimental process had an incidence of protein-calorie malnutrition as high as 30 % when a small stomach was used. The high incidence of potential metabolic complications and requirement for close and prolonged follow-up make BPD an uncommon operation when compared to other weight loss operations, despite excellent long-term outcomes for weight control and resolution of co-morbidities.

6.4 Duodenal Switch

Hess developed the duodenal switch (DS) operation as a hybrid procedure between Scopinaro's BPD and the duodenal switch described by DeMeester [19]. DeMeester's operation was designed to treat troublesome duodenogastric bile reflux, and divert bile away from the stomach. Hess had used BPD as a revisional procedure for patients with poor weight loss, and who were also troubled by marginal ulcers. DeMeester had shown that preserving a short length of duodenum protected against anastomotic ulceration at the duodenojejunal anastomosis, and Hess employed this principle. Gastric reduction was achieved by vertical parietal gastrectomy, a procedure now commonly termed as sleeve gastrectomy. The greater curvature gastrectomy reduced both volume and parietal cell mass, helping to minimize the incidence of anastomotic ulcer. The first case was performed in 1988 as a revision in a patient who had regained weight after staple-line disruption following a transverse gastroplasty 9 years earlier. The limb lengths of the Hess DS were based on small bowel length, the length of the alimentary limb was

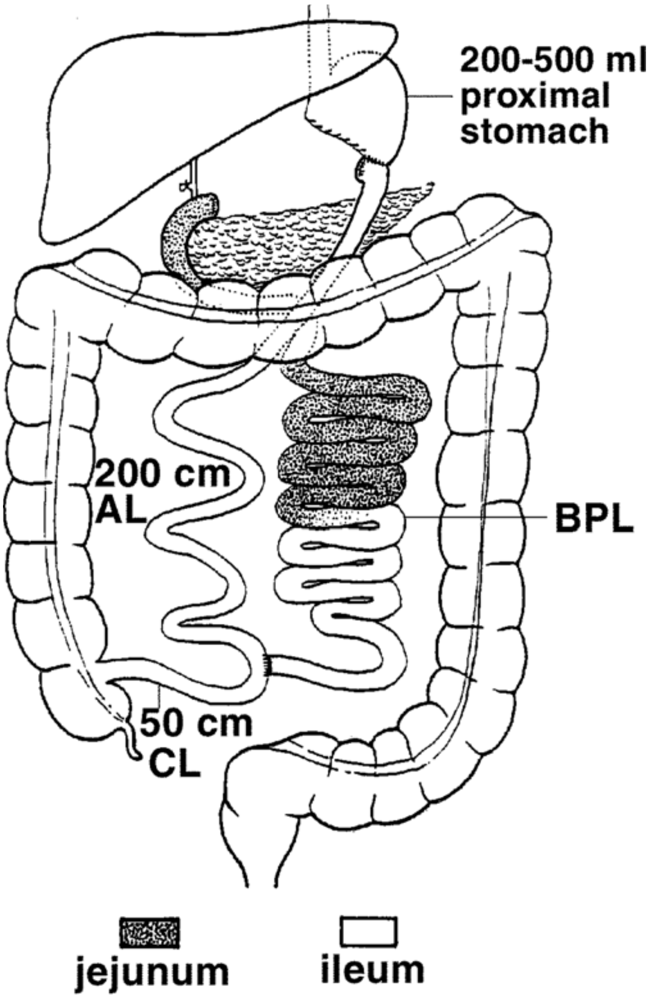

Fig. 6.10 Scopinaro biliopancreatic diversion [18]. *BPL* biliopancreatic limb, *CL* Common limb, *AL* alimentary limb

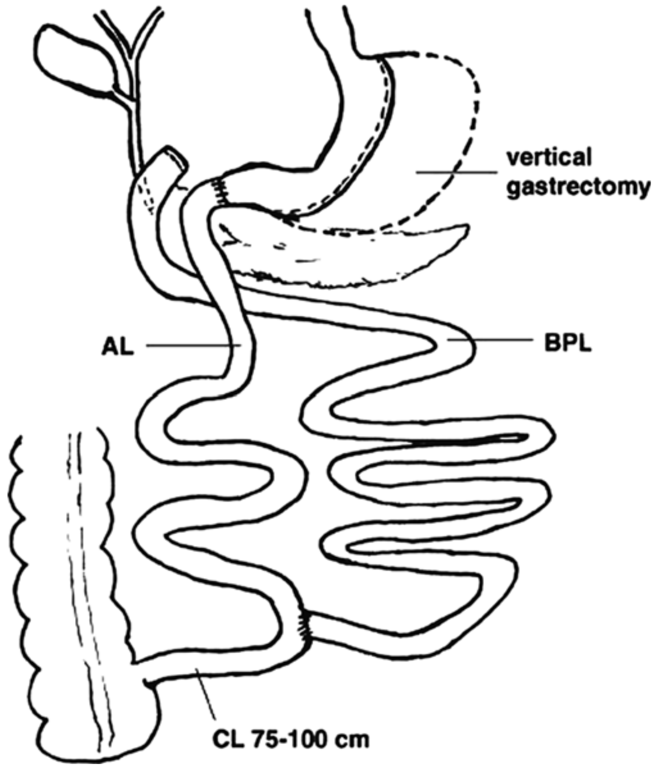

Fig. 6.11 Duodenal switch of Marceau [20]. *BPL* biliopancreatic limb, *CL* Common limb, *AL* alimentary limb

approximately 40 %, while that of common channel was approximately 10 % of small bowel length. The outcomes were excellent with 80 % EWL maintained at 8 years. The metabolic impact of the BPD was maintained for diabetes and dyslipidemia, and preservation of the pylorus avoided dumping and marginal ulcers.

Marceau in Quebec in 1990 also carried DeMeester's principles forward in adapting the classical BPD, resulting in a DS which he initially called "modified BPD." [20] The operation differed slightly from that of Hess in two respects. The duodenum was cross-stapled and not divided, and an end-to-side ileo-duodenostomy was fashioned proximal to the duodenal staple-line. The limb lengths were also fixed rather than adjusted to bowel length, with a common channel of 100 cm and an alimentary limb length of 250 cm. After the first 2 years, duodenal cross-stapling was abandoned, as some patients re-canalized through the staple-line, and an end-to-end duodeno-ileostomy became standard (see Fig. 6.11).

6.5 Gastric Restrictive Procedures: Gastroplasty and Banding

Various gastric partitionings (staplings) were developed in an attempt to reduce the morbidity of gastric bypass. In 1977, Gomez reinforced the channel between the fundus and distal stomach at the greater curvature, using a continuous imbricating polypropylene suture over a 12-mm bougie (see Fig. 6.12) [21]. Weight was lost, but gastric dilatation resulted in later regain of weight. Also, breakdown of undivided staple-lines led to regain of weight. Because the lesser curvature was more muscular and less likely to distend, Long in 1978 in Australia constructed a vertical lesser curvature tube and reinforced the outlet with a polypropylene suture [22].

In 1980, Edward Mason designed a vertical lesser curvature channel encircled at the outlet by a Marlex mesh band, passed through a window created by a circular stapler (see Fig. 6.13) [23]; the vertical banded gastroplasty (VBG) became very popular for 10–15 years, especially in the United Kingdom (UK).

Meanwhile, in the early 1980s, Wilkinson [24] and Molina [25] performed gastric restriction by external non-adjustable gastric banding. Gastric banding was adopted by Kuzmak in United States of America (USA) [26] and Forsell in Sweden [27], who independently developed an adjustable silicone band (see Fig. 6.14). Both bands employed a subcutaneous

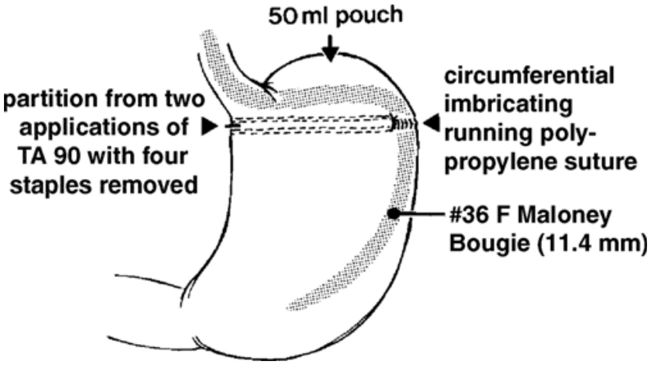

Fig. 6.12 Gomez gastroplasty [21]. TA 90® (Instrument)

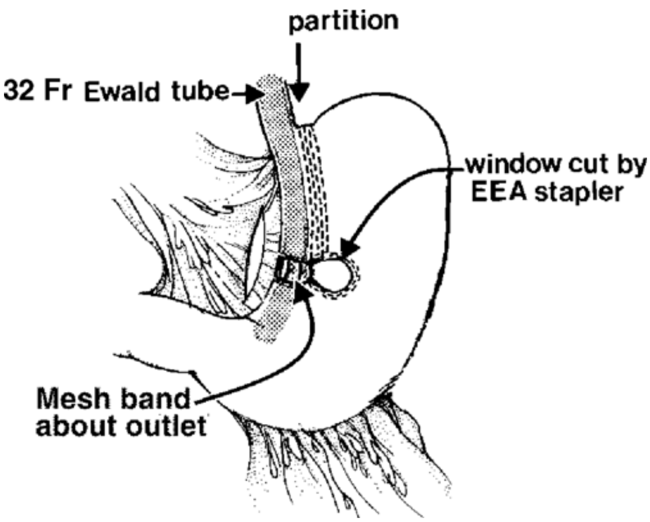

Fig. 6.13 Vertical banded gastroplasty of Mason [23]. EEA® (End-to-End)

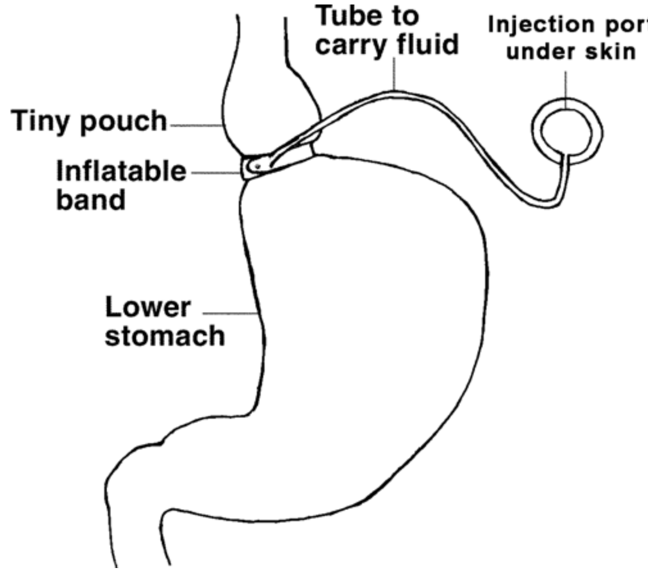

Fig. 6.14 Adjustable gastric banding, with the band size controlled via a tube connected to a percutaneously-accessable saline reservoir [26, 27]

reservoir, which could be used to introduce saline via a tube connected to the band in order to control the band's diameter.

Gastric banding lent itself readily to laparoscopic surgery because of its simplicity. Laparoscopic banding was reported by Catona et al. [28], Forsell et al. [29] and Belachew et al. [30], all in 1993. Initially, the band was placed closely around the stomach by *peri-gastric* dissection; this was later changed to a *pars flaccida* technique which reduced the incidence of band slippage and remains the standard technique for band placement [31].

6.6 Sleeve Gastrectomy

A pouch along the lesser curvature is less likely to distend over time; such a pouch became standard for gastric bypass and gastroplasty.

The construction of a long vertical lesser curve restrictive gastric tube was championed by Johnston from Leeds. He was concerned with complications of VBG (predominantly stenosis, food intolerance, and erosion) due to the band. His Magenstrasse and Mill (M&M) operation created a gastric tube fashioned against a 36 F (or smaller) bougie on the lesser curve, without inserting a band. The gastric channel (Magenstrasse) preserved the antral (Mill) action. Early results were encouraging [32], but there was later weight regain. In 1999, McMahon performed the M&M operation laparoscopically in Leeds, and in 2000 he performed the first laparoscopic sleeve gastrectomy [33].

Hess and Marceau had both used a vertical lesser curve sleeve with a parietal gastrectomy as part of the duodenal switch, but it had not been intended as a stand-alone operation. A small number of patients from Anthone's group were considered too high-risk for a full DS, which was their operation of choice. Between 1995 and 2002, 21 patients had an isolated longitudinal gastrectomy intended as an interim procedure for high-risk patients [34].

At the same time, Gagner decided to break down laparoscopic duodenal switch and gastric bypass operations into two phases in very high body mass index (BMI) patients, because of high morbidity of performing the total procedure in one sitting. He thus performed laparoscopic sleeve gastrectomy (LSG), intended as a first step of a staged procedure (see Fig. 6.15) [35]. However, the initial weight loss after LSG alone was often found to be adequate and maintained. Complications consisted of high gastric leaks postoperatively in 3.5 % of primary LSGs [36] and gastro-esophageal reflux in up to 1/3 of patients at 3 years. Furthermore, after LSG, late dilatation of the sleeve results in weight regain in some patients. However, the late dilatation of the sleeve and weight regain can be managed by addition of a Fobi ring to limit dilatation of the sleeve, or by a second stage operation [37].

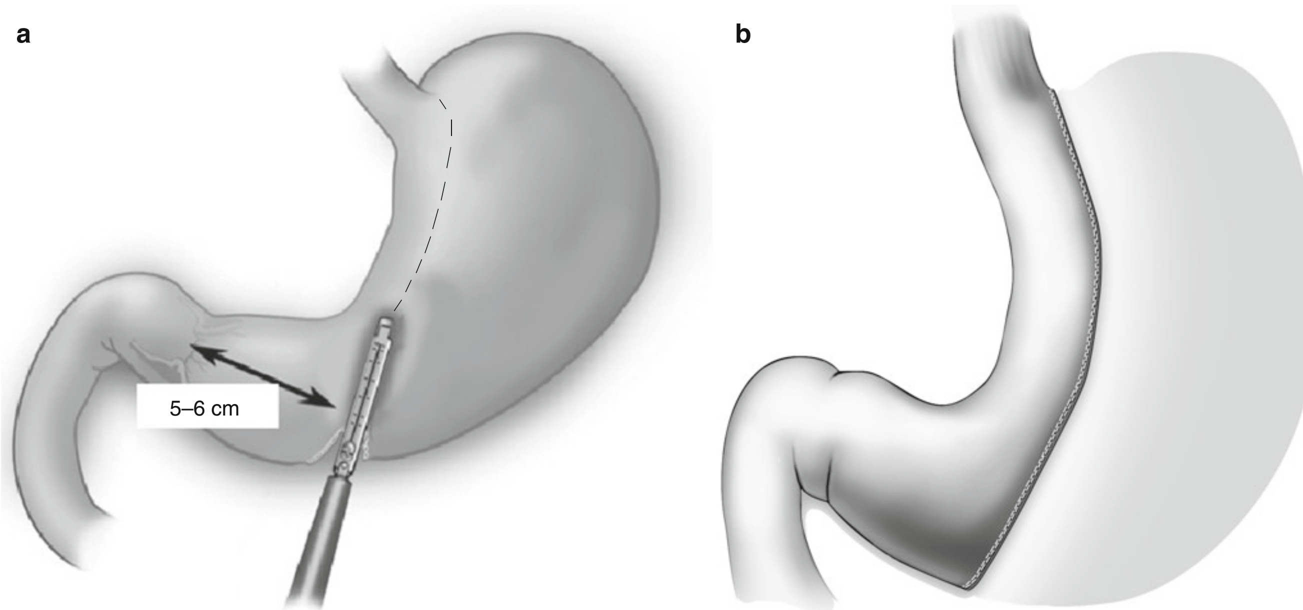

Fig. 6.15 Sleeve gastrectomy. (**a**) Stapled-division across antrum and up lesser curvature. (**b**) Completed sleeve [35, 37]

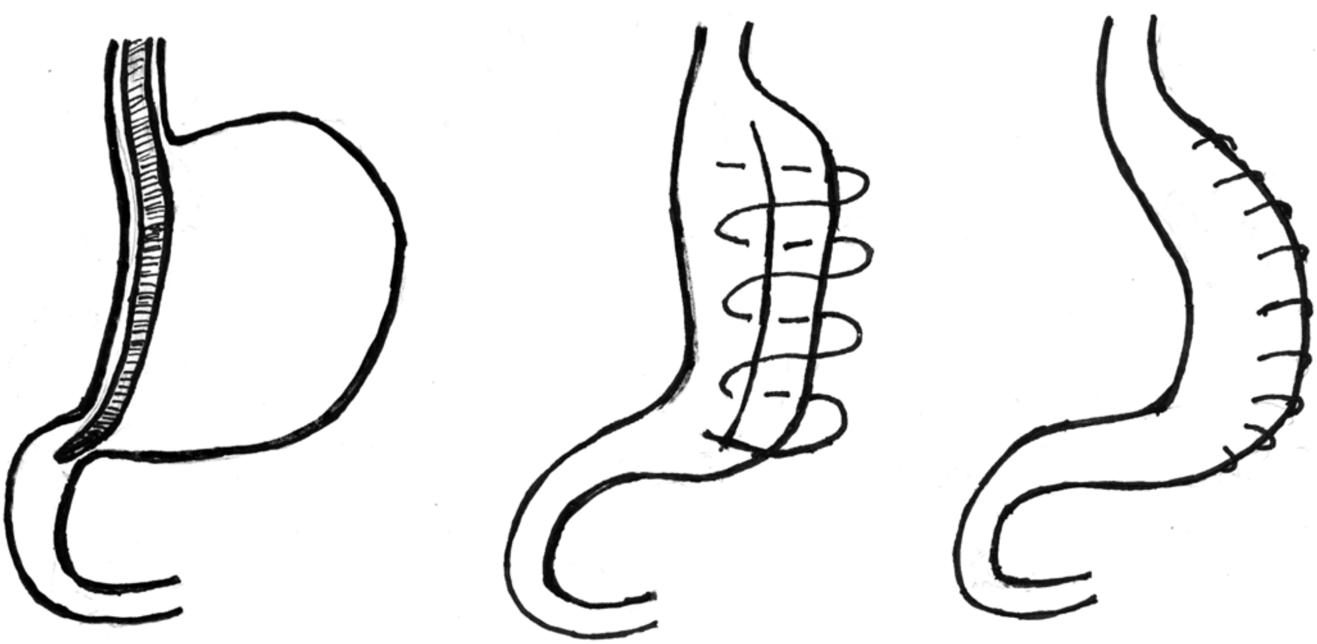

Fig. 6.16 Steps in gastric plication [38]

6.7 Gastric Plication

Gastric plication (GP) has gained recent interest. It involves imbrication of the mobilized greater curve without resection, to achieve gastric restriction (see Fig. 6.16). GP has minimal risk of leakage, which is regarded by some as the Achilles heel of sleeve gastrectomy. GP was developed by Talebpour in Iran in 2002, and a detailed analysis of the first 800 cases had been published [38]. However, there is fear of early channel dilatation with regain of weight.

6.8 Mini Gastric Bypass

The mini gastric bypass (MGB, or *one-anastomosis gastric bypass*) was originated by Rutledge in USA in 1998 (see Fig. 6.17) [39]. There was prejudice in USA against this rapid, safe operation by those who performed the more complex RYGB, although both Peraglie and Hargroder, who were trained by Rutledge, have each performed more than 1400 MGBs, with no deaths. This laparoscopic operation creates a long non-obstructive lesser curvature conduit down

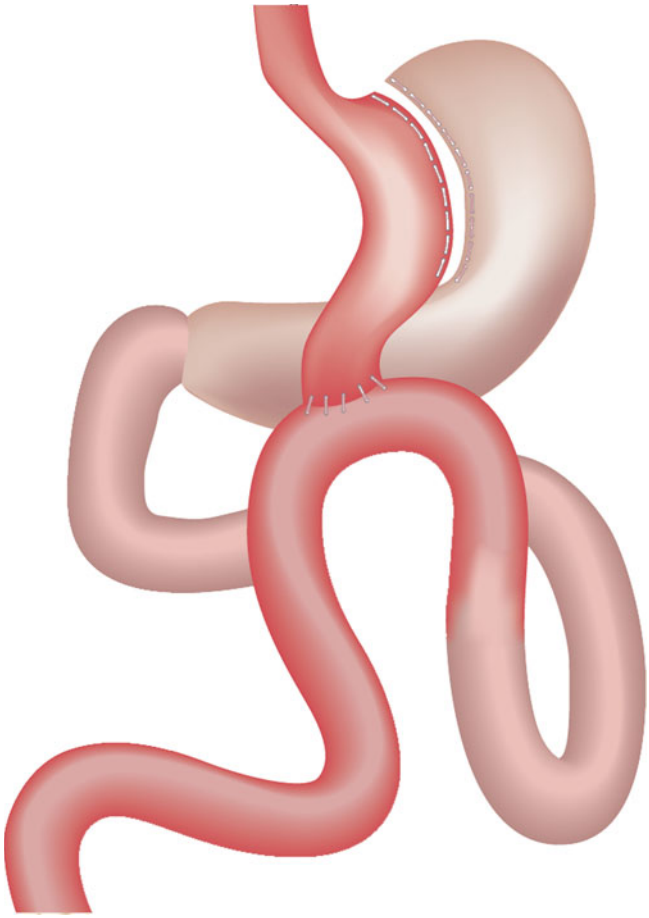

Fig. 6.17 Mini-gastric bypass. Mini-gastric (one-anastomosis or omega-loop) bypass, with long gastric channel down to crow's foot [39]

to crow's foot (that is, to the incisura), which is anastomosed antecolic end-to-side to a loop of jejunum approximately 200 cm distal to Treitz' ligament (depending on the BMI or height), providing safe malabsorption. In Malaga, Spain, the operation adds an anti-reflux suture at the junction of the afferent limb with the gastric tube [40].

There was a concern for the development of carcinoma from bile in the distal gastric tube, but so far carcinoma has not developed in humans. In rat investigations, application of bile has been found to cause hyperplasia and neoplasms in the proximal two-thirds of the rodent's unique stomach which is *squamous cell*, but *not* in the distal third which is *glandular* like the human stomach [41]. However, surgeons revising the LSG to an MGB must adhere to the *long* channel. Salicylates and smoking must be avoided, just like after RYGB, even though the incidence of marginal ulcer with the MGB appears to be slightly less than after RYGB.

The MGB is increasing internationally, because multiple comparative studies have revealed superiority of the MGB in resolving diabetes and the metabolic syndrome, weight loss durability, quality of life, and ease of revision or reversal if ever required [42].

6.9 Laparoscopic Surgery

Most bariatric operations require access to the upper stomach as well as other areas within the peritoneal cavity. It can be difficult to clearly access and operate high up on the stomach even in individuals without obesity, and complications such as inadvertent splenectomy or leaks from difficult high anastomoses have been a feature of open bariatric operations, because of difficulties in exposure.

Initially regarded a *tour de force*, laparoscopic surgery for major obesity has almost completely replaced open surgery. In part, this is because, once the specific techniques of laparoscopy in obesity have been mastered, the access afforded by laparoscopic surgery is far more superior to open surgery. In addition, early recovery and mobilization are much easier after laparoscopic surgery, and wound-related complications are both fewer and less disabling. For all these reasons, laparoscopic bariatric surgery has resulted in safer operations with better outcomes [43].

Gastric banding was unsurprisingly the first laparoscopic bariatric operation, but Hess performed a VBG laparoscopically in 1993 [44]. Later in 1993, Wittgrove performed the first laparoscopic RYGB [45]. Gagner initiated a series of 40 laparoscopic BPD-DS in 1999 [46] and 6 months later Scopinaro's group applied laparoscopic techniques to the classical BPD [47]. This was soon followed by LSG, as an isolated operation, in 2000, by McMahon and Gagner. Since that period, most bariatric operations have been performed via laparoscopy.

The quest to make bariatric interventions even less invasive has continued. Single incision laparoscopic surgery was introduced in 2008 [48]. The technical restrictions and the small margin of cosmetic advantage over conventional laparoscopic surgery have limited the growth of this approach.

6.10 Endoscopic Approaches

The concept of an endoscopic bariatric intervention remains attractive. However, to date there has been no permanent endoscopic approach that achieves anything like the durable success associated with conventional bariatric surgery. Intragastric balloons have been around since the 1980s, but remain a temporary intervention, the balloon have to be removed, usually after 6 months [49].

Endobarrier™, or the duodenojejunal sleeve device, was developed following observation of resolution of diabetes in obese diabetic rats subjected to duodenal exclusion [50]. Implantation of the impermeable sleeve device within the duodenum was as effective as surgical duodenal bypass for resolution of diabetes. Human devices were placed endoscopically for the first time and achieved 26 % EWL and remission of diabetes in all patients within 12 weeks, with no direct intervention to the stomach [51]. As with the balloon, however, the device needs to be removed, albeit after 12 months.

Endoscopic suturing and stapling devices have been under development for many years, and endoscopic platforms are starting to reach a point where a permanent endoscopic solution is achievable. One such example is endoscopic fundal plication or the POSE (Primary Obesity Surgery, Endoluminal) procedure, which has shown promising initial results with approximately 50 % EWL at 6 months [52] and is currently being assessed against a sham procedure in multicenteric 'Essential' trial.

6.11 Other Approaches

Neuromodulation of the stomach and vagus nerve have both been used to modify appetite and satiety. There is a complex relationship between hunger, food intake and the autonomic nervous system. Gastric myoelectrical stimulation is associated with delayed gastric emptying. Cigaina was the first to consider this option and after initial successful experiments in pigs, undertook the first human gastric neuromodulation studies [53]. However, the results of the multicentric SHAPE study, a randomized trial, resulted in no difference in weight loss between the treatment and control arms [54]. Other devices which deliver the electrical stimulus in relation to food intake are under evaluation (Abiliti™ and Tantalus™).

Direct vagal nerve blockade from an intra-abdominal stimulator has been explored in the EMPOWER study. There was no difference in weight loss between controls and treatment arms at 6 months. The investigators concluded that control patients may have benefited from electrical safety checks, accounting for parity between the two arms [55]. A further study (ReCHARGE) is in progress to provide further details.

Conclusion

Bariatric surgery began in the 1950s with JIB, which proved that weight loss by surgery in the severely obese reduced obesity-related co-morbidities. The modern malabsorptive and gastric restrictive operations developed from attempts to reduce the side-effects of JIB. Laparoscopic bariatric surgery started in the early 1990s and has now become the usual approach for weight loss surgery. The emphasis on current investigations in bariatric surgery, including endoscopic procedures, is towards reducing the impact of surgery.

Key Learning Points

- Bariatric surgery began in the 1950's, with the jejuno-ileal bypass (JIB) as the first sustainable operation.
- JIB proved that bariatric surgery could work, and reduce obesity related comorbidities.
- The common modern operations were developed from attempts to reduce the risks and side effects of JIB.
- Laparoscopic surgery for obesity started in the early 1990's and has now become standard of care for weight loss surgery
- The emphasis on current developments in bariatric surgery is towards reducing the impact of surgery, including endoscopic procedures.

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Evidence Base for Bariatric Surgery

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Abstract

Bariatric surgery is recognized worldwide as a cost-effective treatment for morbidly obese patients. In recent years, the role of these procedures has been revised following the impressive postoperative outcomes from a metabolic and functional viewpoint. These outcomes have given rise to further possible indications for bariatric procedures that could be applied to non-obese patients in the near future. This chapter summarizes the evidence collected following bariatric procedures, both in terms of weight loss and remission of co-morbidities. We still need to clarify the concepts of "ideal weight" and "success" in bariatric surgery and moreover the exact interaction between gut hormones, pancreatic endocrine function and adipose cell signaling needs further investigations to predict a possible outcome or a possible relapse of a metabolic condition.

Keywords

Morbid obesity • Bariatric surgery • Metabolic surgery • Surgical treatment for type II diabetes mellitus • Gastric bypass • Sleeve gastrectomy • Duodenal switch • Adjustable gastric band

7.1 Introduction

The relationship between severe obesity and disease was evident many hundreds of years ago, though at that time limited resources favored an association between mild obesity and wealth. Hippocrates, in his Corpus Hippocraticus, first stated that "corpulence is not only a disease itself, but it is the harbinger of others," suggesting therefore to avoid any form of obesity through a healthy diet (i.e. avoiding pig meat), exercise and through warm baths [1]. Four centuries later Galeni published a book, Peri leptynouses diaites, about how to lose weight by changing eating habits [2]. Thus, despite having most of the suggestions provided by ancient scholars, there was a complete lack of understanding of the reasons why obesity and increased mortality were so entangled.

The treatment of obesity continued throughout the Middle Ages, during which being overweight or obese was strictly associated with vice and therefore hardly condemned [3]. This moral understanding of obesity continued despite the enlightenment and the development of medicine as a new science rather than an art or a philosophy. In the 1960s, most of the failures of dietetic treatment were ascribed to the weak will of the patient rather than to a lack of understanding of the mechanisms that lead to the control of body weight. Consequently, treatments for obesity began to gather momentum when society and the scientific community started to look for a drastic solution for the problem through the application of simple, scientifically sound principles to a different field of treatment, namely bariatric surgery. In particular, the evidence that people affected by short bowel syndrome developed severe malabsorption with consequent

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weight loss triggered the development of the first jejuno-ileal bypass in 1954. In addition, the observation that patients submitted to subtotal gastrectomy due to peptic ulcer disease were able to decrease their weight led to the development of gastric bypass surgery in 1967 [4]. The mechanisms involved in the postoperative weight loss are still under investigation and several landmark studies in this field have added to our understanding of obesity as well as the development of new techniques for the medical management of obesity and metabolic complications. Moreover, the proven efficacy of bariatric surgery has raised several key questions:

- What is the target of bariatric surgery? Is it the overweight or the complications of the overweight? Is there a cut-off age below which surgery should be avoided?
- What is the role of the surgeon? Since he/she cannot reverse the primary cause of obesity, the operation is not a definitive answer and a patient could experience weight re-gain if not compliant?
- Taking into consideration the first two points, when should surgery be proposed? Are the National Institute of Health (NIH) criteria of 1991 still valid?
- How to evaluate the success of the weight loss?
- When should obesity be considered a disease? Bariatric surgery is no longer perceived as an asthetic procedure and the risks of the surgery are low. Are such risks paid back by the reduction of the risk derived from developing obesity related metabolic diseases?

Several studies have provided strong evidence that bariatric surgery is currently the best answer to the management of morbidly obese patients, despite the need for elucidating the mechanisms involved in the weight loss. In fact, prospective controlled trials such as the Swedish Obesity Study (SOS) are still confirming the good outcomes in the surgically treated patients when compared with the matched population treated with conventional therapies [5]. The SOS study was born in 1987 as a survey registry including an ongoing interventional study. It was designed to offer a controlled prospective long term instrument to investigate the effects of bariatric surgery and weight loss on mortality (primary end-point) and on cardiovascular complications of obesity, Type 2 diabetes improvement/resolution, quality of life and the cost-effectiveness of bariatric surgery compared with the medical management of obesity and its complications. The volunteers enrolled in the study were matched in a surgical or a medical group, but they were not randomized (in 1987 randomization was considered unethical by the commission because of the risks related with surgery). This surgical cohort (2010 patients) contained the highest BMI patients, with the most severe degree of obesity related complications compared to the control group (2037 patients). Moreover, the patients were matched aiming to obtain the minimal difference possible at baseline (a computed algorithm identified the patients suitable for being enrolled in the cohorts) in the period between 1987 and 2001. The last SOS review presented in 2013 reported a range of follow up of 12–25 years. The results in term of weight loss were not only better for the surgical group but it was sustained during the long period of follow up. It is to be noted that the drop out at follow-up ranged from 24.6 to 40 % at 10 years follow up as reported in the last series. Despite the high numbers, a specific survey on the patients who did not attend their follow up appointments at 10 years did achieve similar results in term of weight loss and remission of co-morbidities in the surgical arm [5]. These good results were achieved even though the operations proposed at that time were carried out through a laparotomy in 89 % of cases, and were mainly adjustable gastric banding, vertical banded gastroplasty (VBG) and Roux-en-Y gastric bypass. In particular VBG is now considered an obsolete procedure due to the poor weight loss provided to patients compared with the new surgical techniques developed over the last 10 years and thus the high percentage of revisions required. The difference between the control cohort and the bariatric surgery cohort was impressive. While the control group experienced only a fluctuation of 3 % from the baseline weight, the surgical group had a more significant weight loss after 2 years (32 ± 8 % SD for gastric bypass, 25 ± 9 % SD for VBG, 20 ± 10 % SD for the adjustable gastric band) and experienced only a mild weight re-gain in the last report at 20 years follow up. The evidence collected from the sub-studies of the SOS were the basis for validating the efficacy of weight loss surgeries and of the weight loss itself in reducing mortality while improving the quality of life in the morbidly obese population. Evidence based studies also witnessed the cost effectiveness of bariatric surgeries, which could represent cost saving procedures in the management of morbid obesity in most countries.

Even if studies such as the SOS provide evidence that bariatric surgery is more effective than medical treatment in the management of morbid obesity there is a real need globally to describe the efficacy of bariatric surgery using standardized language. In fact, describing weight loss as a percentage of starting weight as per the SOS does not allow us to know whether the patients reached their goal with the surgery.

7.2 Outcomes of Surgery and Pre-operative Expectations

Bariatric procedures do not act on the primary causes that lead to obesity. The role of the bariatric surgeon is to provide tools that the patient needs to use in order to reach their own target weights and treat metabolic problems associated with obesity. The anthropometric tools a bariatric surgeon requires are:

- Weight (W), with a simple international system scale (in kg)
- Height (H), in meters
- Body mass Index (BMI) defined as: weight (kg)/ height^2 (meters)
- Percentage excess body weight (% EBW) defined as [(W-I)/I] × 100, where W is actual weight and I is ideal weight.

This important formula introduces the concept of ideal weight. There are different ways to calculate it

- Broca formula
  I = H (in cm) − 100 (males)
  I = H (in cm) − 103 (females)
- Metropolitan life insurance tables (used especially in United States)

Each method has favorable aspects for its application as well as drawbacks. The first method obtains a univocal value for each patient. Therefore, it may be particularly helpful when auditing the results of several patients at once in order to get a reproducible standardized tool. The drawback of the formulae is that they do not consider the congenital habitus of the single patient, which is overcome using the Metropolitan Insurance Tables [6]. These tables provide weight intervals for the patients determined upon sex, constitution (endomorph, mesomorph, and ectomorph) and age. Despite introducing the concept of body composition, this system has the limitation of not getting a precise value but a range of about 10 kg, which is broad enough to confuse the results in term of weight loss. Moreover, these tables were derived from primarily an insured Caucasian population who were presumably healthier than the general population and other ethnicities were not taken into consideration. A final drawback, which should be emphasized is that the average class of weight identified in such tables were identified upon self-reported measures (in up to the 90 % of cases), which is a major limitation to the use of such a value for scientific purposes [7]. The calculation of the ideal weight is vital for monitoring the efficacy of the bariatric procedures, since it will be used in the course of follow up to calculate the percentage of excess weight loss (EWL% = (start weight − actual weight)/(start weight − ideal weight) × 100) which is the main objective criteria to evaluate the success rate after bariatric surgery which should be at least > 50 %.

There are other criteria for evaluating the success of bariatric procedures in the long term but all of them have limitations in their application to current practice.

Reinhold's criteria [8] were based upon the residual excess of weight, so that the result is:

- Very good: residual excess of weight <25 %
- Good: residual excess of weight 26–50 %
- Fair: 51–70 %
- Insufficient: 71–100 %
- Very bad: >100 %

Christou et al. [9] proposed a different classification based upon the evidence that patients with greater starting body mass index (BMI), also termed the super morbid obese, struggle to reach the same results in term of weight loss as the leaner morbidly obese patient. Success criteria for weight loss/reduction in BMI were defined as:

- Final BMI <35 kg/m^2 for starting BMI <50 kg/m^2
- Final BMI 35–40 kg/m^2 for starting BMI >50 kg/m^2

The pattern of weight loss after bariatric surgery is similar despite differences in efficacy. In general the weight loss is dramatic within the first 6 postoperative months, then decreasing and stabilizing progressively at 18–24 months follow-up. Within the first 2 postoperative years the weight loss is not constant, and often the patients could have concerns noticing sudden changes of 3–5 kg alternating with periods of steady weight. The patients should therefore be reassured about the pattern of weight loss, explaining that a short period of plateau in terms of weight loss does not necessarily imply a failure of the procedure.

7.2.1 Predictors of Outcomes

7.2.1.1 Types of Procedure

Laparoscopic Adjustable Gastric Banding

This is the simplest and safest bariatric surgery procedure. Its' mechanism of action is consistent with the creation of a sensation of satiety due to food stretching a small gastric pouch above the band. There is strong evidence confirming that poor compliance could lead to failure with insufficient weight loss (in case of liquid diet or sweet eaters) or to constant vomiting in case the patient cannot modulate the food intake upon the sensation of satiety (binge, compulsive or emotional eating). The expected average weight loss is about 45–55 % of the overall excess weight at 2 years, and patients who comply can easily maintain such a result long term (at least more than 15 years, as already reported) [10]. However, despite poorer results in the medium term due to the lack of a metabolic action, when compared with other bariatric procedures, gastric banding permits long term results similar to other more effective procedures, according to several reviews

[10]. However there is a not insignificant risk of long term complications such as band slippage, band erosion, or infection of the reservoir port used to adjust the band.

Laparoscopic Roux-en-Y Gastric Bypass

This operation is still considered the gold standard for the treatment of morbid obesity. It combines a restriction in food intake through the creation of a small gastric pouch with a metabolic action achieved by bypassing the foregut and allowing the enhanced passage of the food bolus to the hindgut. Such an effect is still under investigation for its possible implications in term of remission of type II diabetes while also being associated with a dramatic decrease in the blood levels of ghrelin within the first postoperative year [11]. Interestingly, the gastric bypass provides a greater weight loss compared with purely restrictive procedures (%EWL—65–70 %), but 15 % of patients experience a progressive weight re-gain years after surgery with the weight loss comparable in some series to the average levels reported after gastric band surgery (%EWL 48–60 %). Possible reasons for this evidence could be related to a progressive adaptation of the metabolic changes with reduction of symptoms related to dumping syndrome and consequent changes in eating habits. Moreover, patients report a complete lack of appetite within the first year postoperatively (when the ghrelin levels are suppressed) while appetite returns after 2 years from surgery (when the ghrelin levels start to increase again).

Gastroplasties

These were the first restrictive procedures introduced into clinical practice. The concept of reducing the size of the stomach allowing an early and prolonged satiety led the pioneers of bariatric surgery to alter the gastric anatomy using different sutures to create a partition of the stomach. Whereas in the gastric band the restriction is achieved by a band encircling the stomach from the outside, gastroplasties are consistent with a more invasive alteration of the native anatomy. The first procedure was developed by Printen and Mason in 1971 with a horizontal pouch. Despite further changes in the shape and reinforcement of the gastric outlet proposed by several authors such as Gomez et al. and Kroyer et al., this conformation was abandoned due to the high incidence of kinking with pouch dilatation or suture line disruption. Fabito et al. first proposed a vertical shaped pouch to reduce the incidence of outlet kinking, but the weight loss was affected by dilatation of the gastro-gastric outlet. Eckout et al. proposed to reinforce the gastric outlet with a silastic ring and finally Mason developed a vertical banded gastroplasty reinforcing the outlet with a non-absorbable Marlex band in 1981 [12]. The results in term of weight loss reported in the long term were between the gastric band and the gastric bypass with an average excess weight loss ranging from 43 to 62.9 % in the most recent review of 2009. However, even the vertical banded gastroplasty has been almost abandoned worldwide since it has a wide spectrum of long term complications including pouch dilatation, suture line disruption, outlet kinking or stenosis and also because it represented a challenge as the laparoscopic approach became the standard approach in bariatric surgery [13]. Moreover, while being as difficult as the gastric bypass when performed with the laparoscopic approach, gastroplasties did not have any metabolic mechanism that could play an additional role in terms of weight loss and remission of co-morbidities.

Laparoscopic Sleeve Gastrectomy

Laparoscopic sleeve gastrectomy was developed as the first stage of a two stage duodenal switch with the intention to reduce the risks of this complex technique. It was established as a stand-alone procedure after it demonstrated to be so effective in terms of weight loss that most patients did not require a second stage procedure. Short term follow up demonstrated better results in term of weight loss when compared with other purely restrictive procedures such as gastric banding or VBG. The weight loss in some studies is comparable with the gastric bypass, with a %EWL of 65–70 % achieved at 2 year follow-up [14]. The discovery of ghrelin as a trigger of appetite, produced mainly in the portion of the stomach (fundus) which was resected as part of sleeve gastrectomy, suggested the presence of other metabolic mechanisms that lead to weight loss. This was confirmed by long term studies that showed the presence of low levels of ghrelin even after 2 years whilst patients treated with gastric bypass were experiencing an increase in ghrelin levels. Further evidence that ghrelin has the potential to increase insulin resistance was achieved following the observation that sleeve gastrectomy had the same potential to induce a decrease in blood glucose levels before significant weight loss (as seen in gastric bypass) [15]. Hence, sleeve gastrectomy is a metabolic-restrictive procedure similar to gastric bypass. Moreover, recent studies about gastric sleeve emptying show an accelerated transit through the antrum and duodenum, so that some authors consider the procedure as a "functional duodenal bypass" [14]. It is still unclear why some patients experience weight re-gain following the first 2 postoperative years. The dilation of the sleeve could be responsible for an increased capacity and greater calorie intake. The procedure is still not standardized; it is unclear what should be the ideal distance from the pylorus to start making the gastric sleeve and there is still no consensus about the precise size of bougie that should be used to size the sleeve. This variation could lead to different results mainly in the long term follow up as patients experience possible increases in the sleeve volume. Greater steps have been taken in the reduction of early complications such as sleeve leak since the risk of leak has progressively reduced from 10–15 % in 2002 to 2 % in 2012 [16]. Recently, the incidence of leak was shown to be between 0.6–2.38 % when using a bougie size greater than 40 Fr in diameter [17]. Gagner et al. in a systematic review analyzed the leak rate associated with the use of buttressed sutures. Whilst the overall incidence of leak was 2.1 %, it increased to 3.3 % when buttressing the staple lines with bovine pericardium and was significantly lower when absorbable polymer membrane (e.g. Seamguard) was used with an incidence of 1.09 % [18]. An incidence of sleeve staple line leak of 3.6 % was recently reported in one series from a high volume bariatric center in Belgium [19]. The main reason for the reduction in leaks is possibly due to the efforts done to identify their causes. At present, stapling too close to the esophago-gastric junction (with possible ischemia of the upper suture line) and narrowing at the mid-portion of the sleeve at the incisura (increasing the endo-luminal pressure) are well recognized risk factors for an increased incidence of leaks. Since the formation of the sleeve must exclude the fundus, careful dissection of the left crus must be done and often a concomitant hiatal hernia repair is necessary. In fact it has been proposed that disruption of the lower esophageal sphincter mechanism may explain the propensity of sleeve patients to develop acid reflux or even a sliding hernia with most of the sleeve herniating into the chest [20, 21]. The risk of leak and unknown outcomes in the long term limits the widespread practice of this technique compared to the gold standard procedure, gastric bypass.

Laparoscopic Mini-Gastric Bypass

Mini-gastric bypass (MGB) was developed by [22] and is consistent with an omega, single anastomosis technique. In this procedure the gastric pouch must be longer than in traditional RYGB and narrower, and the anastomosis with the afferent limb is measured at 200 cm from the Ligament of Treitz which means there is a long bilio-pancreatic component of the bypass [23]. Several concerns limited the initial uptake of this technique. Most surgeons felt bile reflux, reportedly experienced in up to 70 % of patients who underwent the first Mason's horizontal bypasses with omega-loop, would be a significant problem. Quality of Life (QOL) surveys completed postoperatively showed that the creation of a long, narrow lesser curvature based gastric pouch with the gastro-jejunal anastomosis at its bottom-end reduces the risk of bile reflux and alkaline esophagitis. Currently there is a lack of evidence about the long term results following this procedure though it seems there is a lesser propensity for weight re-gain after the second postoperative year compared to laparoscopic Roux-en-Y gastric bypass (LRYGB). The presence of just one anastomosis and the shorter operation time makes the MGB appear attractive. In addition to the good results reported in term of weight loss, which are similar or slightly better than that obtained with the established LRYGB. Some concerns about possible long term anastomotic complications still need to be clarified, in particular, whether the presence of a greater acid pocket related with the longer shape of the pouch could increase the incidence of marginal ulcers and whether bile reflux could have a carcinogenic effect on the gastric/esophageal mucosa.

Laparoscopic Bilio-Pancreatic Diversion and Duodenal Switch

This operation is derived from the bilio-pancreatic diversion (BPD) and is currently the most effective bariatric surgery procedure in terms of weight loss. It combines the volumetric restriction of the stomach with metabolic effects achieved through the bypass of the foregut and a selective malabsorption for fats which is determined by measuring the alimentary limb and common channel as ratios of the overall length of the small bowel. Recent evidence shows an average % excess weight loss of 75–85 % which is usually sustained in the long term [24]. Despite the good results in term of weight loss, the technical challenges and the risks of severe postoperative complications (anastomotic leak, protein calorie malnutrition, vitamin and mineral deficiencies) as well as the unclear impact in terms of quality of life limit the widespread practice of this procedure. There is still a consensus for proposing this procedure in super obese patients (BMI >50 kg/m^2) with several metabolic co-morbidities difficult to control with medical therapy in specialized bariatric centers. In addition it can be done as a two staged procedure with the sleeve gastrectomy being the first step. Interestingly, the bilio-pancreatic diversion with duodenal switch (BPD-DS) is the only bariatric procedure which provides excellent weight loss in the long term without the tendency to weight re-gain and at the same presents a low rate of recurrence of Type 2 diabetes mellitus (T2DM) and other metabolic diseases.

If the patient should be the central figure complying with the mechanism of the operation for reaching the best possible result, it is also true that a bariatric procedure should ideally be tailored upon the expectation of patient and upon the need to correct specific metabolic co-morbidities and to avoid any major risks. So, for example, the evidence based treatment for a morbidly obese patient with a reasonable starting BMI (in particular BMI <50 kg/m^2) without co-morbidities could be either a gastric band, or a sleeve gastrectomy or a gastric bypass, while a BPD-DS would probably represent an overtreatment that could expose the patient to an excessive risk.

7.2.1.2 Other Predictors of Outcomes

Despite bariatric surgery being developed primarily to decrease weight, the secondary endpoint in the SOS was to reduce co-morbidities and risk factors for mortality associated with obesity (type II diabetes, hypertension, dyslipidemia, sleep apnea) and to improve the functional status, the depression/anxiety state, and the overall quality of life of the patient [5, 25–27]. The evaluation of these outcomes in the long term started several years ago, representing the key to compare medical versus surgical treatment of obesity. Unfortunately, this comparison is missing some fundamental scientific elements. Firstly the medical and surgical cohorts in the SOS were different in terms of preoperative features, with very different starting weight levels (which was much greater for the surgical cohorts) and a different functional and psychological status (which was much worse in the surgical cohorts). The follow up was established in a different way and there was much more data pertaining to medical treatment groups, compared with the surgical groups. Randomization of patients could reduce the differences and bias in the selection process, but it was considered unethical by several commissions that reviewed the design of such studies. Upon the latest evidences, there is a generalized consensus that bariatric surgery is more effective than medical therapies to induce a weight loss (an overall 16–23 % of overall body weight at 10–20 years in the Swedish Obesity Study Group) [5, 25–27]. Studies performed comparing the mortality in obese patients reported a significant decrease in mortality in the long term follow-up among the group of obese patients treated with bariatric surgery compared to the outcomes with patients treated with medical therapies. Nevertheless bariatric surgery can lead to better control of blood glucose in the mid-long term but cannot reverse the possible microvascular damage already done. Studies analyzing changes in the cholesterol deposits in the internal carotids in surgically or medically treated obese patients did not show any significant difference. Whilst it is possible to observe the efficacy of bariatric surgery on blood sugar levels even in the first postoperative month before any significant weight loss, improvements in the lipid profile takes a longer time. Recent evidence shows that a longer course of type II diabetes, need for insulin administration to control blood glucose levels and a lower pre-operative BMI could be associated with a poorer postoperative outcome [28]. This is due to the fact that all these factors are usually an expression of compromised β[beta]-cell function. Despite the weight loss favoring an improvement in the insulin resistance, this outcome could be affected by whether the diabetes is already established or not. Recent studies reported that the Roux-en-Y surgeries, such as the LRYGB or BPD-DS could lead to an increase in the number of pancreatic islet cells within the first postoperative months [29]. This would suggest an improved effect in terms of blood glucose control after such procedures when compared with primarily restrictive procedures such as adjustable gastric banding.

Obstructive sleep apnea (OSA) is frequently associated with obesity. In particular, its severity increases with the increase in neck circumference. A long history of obstructive sleep apnea is usually responsible for persistently high blood pressure levels, and if not treated, could lead to eccentric hypertrophic cardiomyopathy [30]. Dyslipidemia and a sodium-rich diet are also risk factors for essential hypertension. If risk factors are not corrected, they can produce a hypertrophy of the arterial tunica media and consequent sustained high blood pressure [31]. Recent evidence suggest that obesity is also related to adrenal resistance. Thus lipolysis is limited in these subjects, while higher levels of catecholamines act on the heart (with positive chronotropic and inotropic effects) and kidneys (stimulating sodium uptake) and increase the blood pressure [31].

Insulin resistance is frequently associated with obesity. Morbidly obese patients often have high blood insulin levels. According to recent studies, insulin plays a role in increasing the cardiac output and determining the contraction of the muscular layers of microvascular net [32].

Some outcomes are strictly related to the weight loss itself. A generalized remission of OSA has been reported in 90–98 % of the cases within few months postoperatively. At the same time, the decrease in the load on the lower limbs led to a reduction in the dose of pain relieving drugs to control joint pain in most patients. The mobility and the functional status of patients also improved in proportion with the amount of weight loss.

Two year analysis of the changes in the health-related quality of life showed a dramatic improvement when considering changes in terms of mood, overall health perception, improvement of psychological problems due to obesity and social interaction. In particular, the depression scale improves usually after significant weight loss whilst anxiety does not improve with the weight loss [33].

The constant efforts to elucidate the mechanisms involved in weight loss after bariatric surgery is producing evidence based treatments focused on the specific patient. Despite the impressive results obtained with bariatric surgery, the surgical treatment should not overcome the medical therapies, which still have a role in the management of severe obesity. The greatest achievement so far is the understanding that the best treatment for such patients requires a multidisciplinary team to tackle the different aspects of morbid obesity which should be considered not only as a “condition” but, potentially, as a complex metabolic syndrome.

7.2.2 Evidence Base for Bariatric Surgery in Morbidly Obese Patients with Type 2 Diabetes Mellitus

The prevalence of obesity has increased throughout the developed and developing world. Currently, the prevalence of obesity (BMI >30 kg/m^2) is 26 % in the United Kingdom (UK), with predictions of an increase to >50 % by 2025 [34]. Prevalence of morbid obesity (BMI >40 kg/m^2) has also increased, and is currently estimated at 2 % of the UK population. The Type 2 diabetes mellitus (T2DM) epidemic has also increased in parallel to the rise in obesity throughout the world with high incidences in North America, North Africa, the Middle East, and the Indian subcontinent. It has been estimated that the current prevalence of T2DM among UK adults is 4.45 % [35]. Projections for 2025 suggest an estimated five million patients with T2DM in UK compared to the current 2.9 million patients [35].

Medical weight loss through diet and exercise remains the simplest measure for treating T2DM and weight loss in individuals with impaired glucose tolerance is capable of delaying/reversing these disease states. However, the durability of medical weight loss over the long term has been shown to be poor compared with surgical weight loss through bariatric surgery, especially in morbidly obese individuals [5]. Pharmacotherapy agents, such as Orlistat do not provide significant and sustained weight loss, even when combined with diet and regular aerobic exercise. Bariatric surgeries, primarily Roux-en-Y gastric bypass (RYGB) have been shown to be associated with reductions in insulin resistance before significant weight loss has occurred. Currently, RYGB, laparoscopic sleeve gastrectomy (LSG) and bilio-pancreatic diversion and duodenal switch (BPD-DS) are the primary bariatric surgeries well known to have high rates of resolution of T2DM [36].

The evidence supporting the role of bariatric surgery in the treatment of T2DM in obese and morbidly obese has primarily been based on meta-analyses and cohort studies. Buchwald et al. in a meta-analysis of studies on bariatric surgeries in patients with T2DM found an overall 78 % remission rate of hyperglycemia with remission rates of nearly 50 % in LAGB patients, 80 % of gastric bypass patients and 90 % of BPD patients [37]. Numerous studies have shown clear economic benefits of bariatric surgery in obese and morbidly obese patients with T2DM [38, 39]. Recently two randomized controlled trials from the USA and Italy have provided Level I evidence for the role of bariatric surgeries in the treatment of T2DM [40, 41]. In addition a sub-group analysis of the effect of bariatric surgery on T2DM prevention as a secondary end point from the Swedish Obesity Subjects study has provided further evidence supporting the role of bariatric surgery [5, 25]. However, relapse of T2DM has been reported in around 25 % of patients, but it usually appears in a milder form when compared to the pre-operative pattern, so that most of authors still consider the result as a success. It is still not clear whether the relapse is simply due to weight re-gain or whether there could be different mechanisms responsible which are not yet identified.

7.2.2.1 Randomized Controlled Trials

The STAMPEDE trial (Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently) which was published in 2012 was a randomized, non-blinded single center trial based at the Cleveland Clinic, Ohio, USA [40]. The trial involved block randomization of 150 patients between the ages of 20–64 years with a BMI from 27 to 43 kg/m^2 all with poorly controlled type 2 diabetes (based on a HbA1c level of >7.0 %) to one of three groups. Fifty patients were randomized to intensive medical treatment of their T2DM as defined by the American Diabetes Association (ADA) guidelines of a HbA1c level of ≤6 %. This included lifestyle counseling, weight management, frequent patient home glucose monitoring and the use of the newer diabetic therapies approved by the Food and Drug Administration (FDA) such as the incretin analogues. Fifty patients were randomized to intensive medical therapy with laparoscopic Roux-en-Y gastric bypass (LRYGB) and a further 50 patients to intensive medical therapy with laparoscopic sleeve gastrectomy (LSG). The mean HbA1c amongst the 150 patients was 9.2 ± 1.5 %. The primary end point of the trial was the percentage of the treatment group achieving HbA1c level of ≤6 % at 1 year after treatment. Ninety-three percent patients were followed up at 1 year and the proportion of patients achieving the primary end point was 12 % (5/41 patients) in the medical treatment group, 42 % (21/50 patients) in the LRYGB group and 37 % (18/49 patients) in the LSG group. The difference between both the LRYGB and the medical treatment group as well as between the LSG and the medical treatment were statistically significant. Mean HbA1c in all three groups significantly improved after 1 year with levels of 7.5 ± 1.8 % in the medical therapy group versus 6.4 ± 0.9 % in the LRYGB group and 6.6 ± 1.0 % in the LSG group. Weight loss was greatest in the LRYGB compared to the LSG group (29.4 ± 9.0 kg versus 25.1 ± 8.5 kg). Utilization of anti-diabetic, anti-hypertensive and lipid lowering drugs significantly decreased in the surgical patients but increased in the medical therapy group. Indeed more than 50 % of patients in each of the surgical groups were off anti-diabetic medications at 12 months. There was one serious complication (staple line leak after LSG) but no deaths in the surgical group.

This is the first randomized controlled trial comparing the 'gold standard' bariatric operation, LRYGB, with intensive medical therapy in obese and morbidly obese patients with T2DM. The study demonstrated the superior effect of surgery compared to medical management in this patient population at 12 months follow up. In view of this short duration of follow up, the STAMPEDE trial patients, as per the study protocol, will be followed up for a further 4 years to ascertain the long term safety profile and efficacy in the maintenance of the remission of T2DM in each group. The study is based in a single bariatric surgery center and the lead author and principal investigator is the sole surgeon in the trial. There was one serious complication (staple line leak after LSG) in this study but no deaths in the surgical group. Four patients (8 %) in the surgery groups required further surgery within the follow up period.

Mingrone et al. from the Catholic University in Rome, Italy have also published their results of a single center, non-blinded, randomized control trial comparing bariatric surgery with intense medical therapy for T2DM [41]. All 60 patients in this study had a BMI ≥35 kg/m² with T2DM for at least 5 years and a HbA1c level of 7.0 %. The patients were between 30 and 60 years of age and were computer randomized into three groups:

1. medical (intense medical therapy),
2. laparoscopic gastric bypass (LRYGB)
3. biliopancreatic diversion (BPD).

The primary endpoint was the proportion of patients whose T2DM resolved at 2 years as defined by a fasting blood glucose of less than 5.6 mmol/L and a HbA1c level of less than 6.5 % in the absence of pharmacological therapy. The mean baseline HbA1c level in this study was 8.65 ± 1.45 %. All the patients undergoing bariatric surgery had their diabetic medications stopped within 15 days of surgery based on home blood glucose readings. At the 2 years follow up, none of the patients in the medical therapy group had remission of their diabetes compared to 75 % in the LRYGB group and 95 % in the BPD group. The mean HbA1c level at 2 years improved in all three groups with the surgical group showing the most significant improvement from baseline. The mean HbA1c level was 4.95 ± 0.49 % in the BPD group, 6.35 ± 1.42 % in the LRYGB and 7.69 ± 0.57 % in the medical treatment group. This study confirms the significant benefit of bariatric surgery in the amelioration of T2DM in patients with a BMI ≥35 kg/m² at 2 years follow up. Patients in the surgical group also had greater weight loss compared to the medical group and lipid profile was significantly improved in patients undergoing open BPD compared to both LRYGB and medical therapy alone. There were no significant complications or deaths in the surgical group. The limitations of this study include the short duration of follow up of 24 months as well as the small sample size with only 20 patients in each of the three groups. The study was not powered to determine the safety profile of the different interventions (medical and surgical treatments) or to detect differences in long term morbidity, cardiovascular events and death rates between the two surgical groups.

Dixon et al. published the first randomized controlled trial comparing LAGB versus conventional drug treatment for T2DM in 2008 [42]. The aim of this non-blinded study was to evaluate the efficacy of glycemic control following primary LAGB surgery and best medical treatment compared with best medical treatment alone in patients with a BMI of 30–40 kg/m² with T2DM. All participants were diagnosed with T2DM within 2 years of randomization and had no evidence of diabetic nephropathy or retinopathy. The study was conducted over a 4-year period with all 60 patients (age 20–60 years) recruited within the 2-year period from December 2002 to November 2004. The medical treatment group included individualized dietary regimens and an exercise program combined with regular assessment and follow up with the diabetic team consisting of a general physician, nutritionist, diabetic nurse and diabetic counselor. Each patient saw one of these team members every 6 weeks for 2 years. Diabetic medications were managed by an experienced diabetologist. The surgical group included patients randomized to undergo LAGB, as well as all the components of the medical treatment group. Band adjustments were conducted according to the investigators' usual protocol. The primary endpoint was remission of T2DM as defined by the American Diabetic Association (ADA) criteria of fasting glucose of less than 126 mg/dL, HbA1c of less than 6.2 % and no glycemic therapy. The secondary endpoints were percentage change in HbA1c, weight loss, changes in blood pressure, abdominal waist circumference, triglycerides, and total, LDL, and HDL cholesterol levels. Mean preoperative BMI in this study was 37.1 kg/m² and 13 patients had a BMI <35 kg/m² (6 in the surgery group and 7 in the medically treated group). A significant difference in the remission of T2DM at 2 years was found in 22 patients (73 %) in the surgical group and 4 patients (13 %) in the medical group. Mean weight loss at 2 years was 20.7 % in the surgical group compared with 1.7 % in the medical group. This corresponded to 62.5 % excess weight loss (% EWL) in the surgical group compared with 4.3 % EWL in the medically treated group. Remission of T2DM was significantly associated with greater % EWL and lower baseline HbA1c levels. In the surgical group at 2 years, the fasting plasma glucose levels and mean levels of HbA1c were significantly less than in the medical group. At the completion of the study, 80 % of patients in the surgery group had HbA1c levels of less than 6.2 % compared with only 20 % in the medical group. This was mirrored by a significant reduction in use of antidiabetic medications at 2 years in the surgical group compared with the medical group. Complications in both treatment groups were analyzed. In the medical treatment group, side effects related to the antidiabetic medications (requiring discontinuation of the medication) were observed in five patients. Seven complications occurred in the surgical group, including a superficial reservoir port site infection (n = 1), gastric pouch dilatation requiring elective revisional band surgery (n = 2), persistent food regurgitation necessitating band removal (n = 1), unexplained febrile illness (n = 1), minor gastrointestinal side effects (n = 1), and a hypoglycemic attack (n = 1).

In this landmark study, Dixon et al. demonstrated that surgical weight loss after laparoscopic gastric banding was more effective than the best medical management for obese patients diagnosed with T2DM in terms of weight loss, glycemic control, and T2DM remission rates. Resolution of components of the metabolic syndrome, as well as reductions in the anti-diabetic, anti-hypertensive, and cholesterol-lowering medications were also seen in the surgical arm. The study, however, only included newly diagnosed T2DM patients (within the last 2 years). Thus, the generalization of the results to patients who have had longstanding T2DM is questionable.

7.2.2.2 Non-randomized Controlled Trials

The Swedish Obesity Subjects (SOS) study, a nonrandomized, prospective, controlled intervention trial was the first trial demonstrating the effectiveness of bariatric surgery in terms of sustained weight loss [5, 27]. It included patients of 37–60 years of age with a BMI of ≥34 kg/m^2 in men and ≥38 kg/m^2 in women. The SOS study also showed a clear benefit of bariatric surgery in terms of diabetes remission compared to a contemporaneously matched control group who had their T2DM treated by lifestyle changes and medical treatment. Carlsson et al. in an analysis of data from the SOS study determined that bariatric surgery had a profound anti-diabetic effect compared to a control group in which none had T2DM at baseline [43]. This study analyzed the effect of bariatric surgery on T2DM prevention and compared 1658 patients who underwent bariatric surgery with 1771 obese matched controls. At base line none of the patients in either group had T2DM. The majority of patients in the surgical group (69 %) underwent the vertical banded gastroplasty (VBG), 19 % underwent LAGB and 12 % underwent LRYGB. It also analyzed the incidence of T2DM in both the groups and included up to 15 years of follow up. In this period there were 392 patients in the control group versus 110 in the bariatric surgery group who had developed T2DM. This translated into an approximate 4-fold increased incidence of T2DM in the control group compared to the surgery group. The postoperative mortality in the surgical group was 0.2 % with a 2.8 % serious complication rate. It must be noted that the dropout rate from the original cohort at 15 years was high at 36.2 % and nearly 31 % of patients had not reached their 15-year follow up examination. The study demonstrated clearly that bariatric surgery induces a 78 % remission of T2DM compared to conservative/medical treatment for the same. This risk reduction was despite the baseline characteristics of the surgical group being more unfavorable in terms of a higher BMI, random blood glucose, blood pressure, total cholesterol, smoking incidence and less physically active during leisure time. There was an 87 % risk reduction in the development of T2DM in patients who underwent bariatric surgery despite impaired fasting glucose at baseline. This rate of remission was noted to be higher after LRYGB compared to LAGB.

The limitations of this non-randomized control trial are related to the high dropout rate at follow up and the high proportion of patients who underwent the VBG operation which has since become obsolete due to the high incidence of staple line dehiscence and subsequent weight re-gain. However the SOS study still remains a landmark study in terms of long term follow up outcomes of bariatric surgery [5, 27].

7.2.2.3 Cohort Studies

Cohen et al. recently evaluated the role of LRYGB in 66 patients with BMI 30–35 kg/m^2 and T2DM [44]. Median follow up was for 60 months with the primary endpoints of surgical complications/deaths and remission of T2DM as defined by a HbA1c level of <6.5 % without pharmacotherapy. All participants had poorly controlled T2DM with a mean disease duration of 12.5 years and HbA1c of 9.7 ± 1.5 % despite all patients taking insulin and/or oral hypoglycemic medications. Diabetes remission was noted in 88 % of patients up to 6 years postoperatively with an improvement in T2DM in a further 11 % of patients. Mean HbA1c significantly decreased to 5.9 ± 0.1 % despite the majority of patients being off medication. The remission/improvement in T2DM occurred independent of significant weight loss presumably through the changes in gut hormones as a consequence of diversion of nutrients from the foregut. There was clear evidence of improvement in β[beta]-cell function as shown by increase in C peptide levels in response to a glucose load. Improvements in hypertension and hyperlipidemia were noted with a reduction in predicted cardiovascular or cerebrovascular risk of 50–84 % at 10 years. There was no significant morbidity or mortality in the study. This study confirms the safety of gastric bypass surgery and its clear beneficial effects in terms of remission of T2DM even at 6 years with 100 % follow up.

7.2.3 Recommendations from International/National Consensus Statements on Bariatric Surgery in Patients with Type 2 Diabetes Mellitus

The International Diabetes Federation (IDF) Taskforce on Epidemiology and Prevention of Diabetes consisting of eminent diabetologists, endocrinologists, bariatric surgeons, and public health experts in December 2010 established clear guidelines for the role of bariatric surgery in patients with T2DM [45]. The group recommends bariatric surgery in T2DM patients with a BMI ≥ 35 kg/m^2. In addition, surgery is recommended in patients with a BMI of 30–35 kg/m^2 with poorly controlled T2DM despite appropriate lifestyle changes and pharmacotherapy. This should be the case especially if the patient has additional cardiovascular risk factors such as hypertension, hyperlipidemia or a history of coronary heart disease. Patients of Asian origin with T2DM should be considered for bariatric surgery with a BMI ≥32.5 kg/m^2 or if they have poorly controlled T2DM with additional risk factors considered for surgery at a BMI ≥27.5 kg/m^2.

The American Society of Metabolic and Bariatric Surgery (ASMBS) also endorses the IDF guidelines and has released a position statement recommending bariatric surgery should be offered in patients with a BMI 30–35 kg/m^2 who do not achieve substantial and durable weight and co-morbidity improvement with non-surgical methods [46]. All three commonly practiced bariatric surgeries (LRYGB, LAGB and LSG) have now been shown in randomized, controlled trials to be safe and effective treatment for patients with BMI 30–35 kg/m^2 in the short term. These guidelines have also been partially adopted by the American Diabetes Association (ADA) with bariatric surgery to be considered in patients with a BMI ≥35 kg/m^2 with T2DM especially if poorly controlled with conservative/pharmacological therapy [46]. These patients must be followed up lifelong and require close monitoring for vitamin and mineral deficiencies, osteoporosis and reactive hypoglycaemia. The ADA however does not recommend bariatric surgery in T2DM patients with a BMI <35 kg/m^2 except within a research protocol.

7.2.4 Strategy for Managing Type 2 Diabetes Mellitus in the Morbidly Obese

It must be appreciated that surgery is not a single answer—not all diabetic patients are suitable for surgery (and not all would contemplate surgery). In addition, the capacity of surgical provision is far outweighed by the numbers of potential patients. However surgery should be given as a treatment option by those involved in the care of obese and diabetic patients. An effective strategy would integrate bariatric surgery as a standard treatment option in obese patients with T2DM, recognize obesity and its related comorbidities as a chronic health problem and build the resources, knowledge and skills in primary care to manage these patients effectively within the community. The positive evidence in term of blood glucose control achieved following weight loss procedures has triggered the development of a different surgical speciality, namely "metabolic surgery," aiming to treat diabeti and not just morbidly obese patients. At the same time, the burden of evidence about the possibility to interact with gut hormones to improve the number of medications available to treat the T2DM has led to the development of several effective drugs, as the GLP-1 analogues. It seems reasonable to state that in the future there will invariably be a change in treatment strategies for patients with T2DM.

Key Learning Points

- Bariatric surgery is effective in treating not only obesity but also obesity related co-morbidities such as T2DM.
- There are several surgical procedures currently in practice with different efficacies in terms of weight loss, co-morbidity reduction and complication profiles. The choice of a procedure should be tailored to the specific patient.
- Some surgeries (LRYGB, LSG, BPD-DS) have a particular metabolic action which lend them to be the preferred choice when treating patients with metabolic co-morbidities such as T2DM.
- With ongoing clinical and molecular research, there is a possibility that in future there may be different indications for surgery, and also there may be development of new surgical techniques.

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Patient Selection in Bariatric Surgery

8

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Abstract

Appropriate patient selection is one of the key steps to the success of any bariatric surgery. In 1991, the National Institutes of Health (NIH) put in a consensus statement about the indications for bariatric surgery. Over time, these have been repeatedly revalidated and reinforced. The evidence derived from national databases is helping to refine the criteria for patient selection. However, a significant number of the recommendations made by NIH are based on majority consensus rather than being based on evidence. There are no reliable indicators which predict success of one operation over another in any individual patient neither is there any irreversible absolute contraindication to bariatric surgery. However, certain factors identified during the preoperative patient assessment may influence the type of bariatric operation possible in that patient. For a successful outcome, all individual complicating factors should be dealt with prior to any surgical intervention. The importance of a multidisciplinary team approach to patient selection and management is now well established. In this chapter, we discuss the relevant factors that would affect the suitability of any patient for bariatric surgery.

Keywords

Bariatric surgery • Patient selection • Multidisciplinary approach • Contraindications • Comorbidities

8.1 Introduction

Bariatric surgery is currently the only effective treatment for morbid obesity. The need for this treatment has escalated dramatically over the last two decades as the obesogenic environment has affected a whole generation of patients, of all ages, simultaneously. Patients present to their bariatric physicians and surgeons at all stages of this progressive and relentless disease process.

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Morbidly obese patients present a complex population with a particular set of perioperative problems. Devastating complications in the perioperative period can lead to disastrous outcomes. In recent years improved and standardized techniques, along with increasing experience of surgeons, has resulted in a dramatic fall in the morbidity and mortality from bariatric surgery [1]. Surgical excellence, appropriate operations, and patient selection are also the keystones to maintaining an optimum risk-benefit balance. The benefits of treating existing comorbidities and preventing future ones must outweigh any risks arising from the perioperative complications and postoperative morbidity and mortality.

Bariatric surgery is currently a target of much political, media, and social scrutiny. Since complications of such surgeries are often poorly tolerated, we can improve the services by collecting data and relating the outcomes to presenting comorbidities and contributing to ongoing databases.

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While the optimal operation, if there is one, is still being debated, the evidence derived from these databases is helping to refine the criteria for patient selection which, although complex, are becoming clearer. Decisions are rarely taken in isolation and the importance of a multidisciplinary team approach to patient selection and management is now well established as these are a complex group of patients who need a multifaceted input from the very start of their treatment pathway.

8.2 Patient Selection Criteria

The initial indications for bariatric surgery were first laid down in the National Institutes of Health (NIH) consensus statement of 1991 and have stood the test of time being repeatedly revalidated and reinforced with an ever increasing evidence base (see Table 8.1) [2, 3]. There have been few modifications in the subsequent 20 years other than to extend the indications even further, especially for the treatment of recent onset type 2 diabetes mellitus (T2DM). There is evidence that the uptake of bariatric surgery within these guidelines varies from country to country. Compared to guidelines in other countries, in the United Kingdom, there is greater emphasis on treating patients at a higher body mass index (BMI) and those with more comorbidities (see Table 8.2) [4].

According to large databases, when patients are selected using NIH criteria, bariatric surgery results in an operative mortality in the order of 0.1 % and a major complication rate of approximately 4 %. However, such surgery also results in a significantly enhanced overall life expectancy, an improvement in T2DM in the order of 90 % and a reduction in the mortality from cancer and coronary disease by approximately 60 % [5, 6].

NIH clinical criteria are accepted with very minor variations by most western countries including National Institute for Health and Care Excellence (NICE) [3] and Scottish Intercollegiate Guidelines Network (SIGN) in the United Kingdom [7], American Society for Metabolic and Bariatric Surgery (ASMBS) in the United States of America [8] and by International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) [9] internationally. These clinical criteria have been repeatedly reinforced and further validated on health economic and cost grounds [10].

Inherent differences in the body constitutions of Asian, Caucasian and Afro Caribbean populations have been recognized for a long time. Asian Pacific Bariatric Surgery Group (APBSG) was founded in 2004 to address these discrepancies and thereafter establish modified criteria for surgery in accordance with the physiological difference in these populations. Asian Pacific Metabolic and Bariatric Surgery Society (APMBSS), previously called APBSG, held a consensus meeting in 2005 and modified the indication for bariatric surgery for the Asian population. The modified criteria are laid out in Table 8.1.

The remission of T2DM is one of the most remarkable features of bariatric surgery, with remission rates in excess of 80 % being frequently reported [11, 12]. These data have prompted the American Diabetes Association and the International Diabetes Federation (IDF) to advocate surgery as an option in morbidly obese patients with T2DM. APBSG not only modified the indications for bariatric surgery but

Table 8.1 National and international variation of Nih guideline—indication for bariatric surgery in adult population

Eligibility criteria	NIH guideline [2]	NICE guidelines [3]	Asia Pacific guidelines
BMI only	BMI ≥40	BMI ≥40	BMI >37
BMI with comorbidities	BMI ≥35 and <40	BMI ≥35 and <40 BMI ≥35 who have recent-onset T2DM[a] BMI 30–34.9 who have recent-onset T2DM[a]	BMI ≥32[b]
Additional limitations	Previous failed weight loss attempts (such as nonsurgical interventions: diet control, behavioral modification, exercise). Patients are motivated and well informed and are free of significant psychological disease.	All appropriate non surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months. The person has been receiving or will receive intensive management in a specialist obesity service. The person is generally fit for anesthesia and surgery. The person commits to the need for long term follow up.	Have been unable to lose or maintain weight loss using dietary or medical measures.
Age	NA	NA	>18 years, <65 years[c]
Recommended		First line treatment for BMI ≥50	

NIH National Institutes of Health, *NICE* National Institute for Health and Care Excellence, *BMI* body mass index, *T2DM* type 2 diabetes mellitus, *NA* not applicable

[a]As long as they are also receiving or will receive assessment in a tier 3 service or equivalent.

[b]Presence of diabetes or two significant obesity related comorbidities

[c]Under special circumstance and in consultation with a pediatrician, bariatric surgery may be used on children under 18

Table 8.2 The comorbid conditions associated with morbid obesity

1. Type 2 diabetes mellitus
2. Obstructive sleep apnea
3. Asthma
4. Hypertension
5. Hypercholesterolemia
6. Hypertriglyceridemia
7. Metabolic syndrome (Syndrome X)
8. Coronary artery disease
9. Congestive heart failure
10. Gastroesophageal reflux disease (GORD)
11. Gallstones and gallbladder cancer
12. Urinary stress incontinence
13. Dysmenorrhea or amenorrhea
14. Infertility
15. Osteoarthritis
16. Deep venous thrombosis
17. Depression
18. Stroke
19. Colon cancer
20. Breast cancer
21. Endometrial cancer

also emphasized its role in diabetic treatment, thereby becoming the first bariatric guideline in the world to establish a focus on T2DM. The growing number of bariatric operations performed for metabolic resolution is on the rise in Asian countries. NICE recently recommended that patients with BMI between 30 and 34.9 who have recent onset T2DM should be considered for assessment [3].

Ongoing studies produced from database interrogation further reinforce and inform the clinical and cost economic basis for offering bariatric surgery.

Ideally the process of patient selection would be purely based on clinical requirements and evidence base. In reality however, political and social pressures are often reflected in commissioning guidelines, especially where funding is state or insurance based. In the UK for example, the majority of bariatric surgery is state funded and commissioned by NHS England who place additional criteria for eligibility for obesity surgery in the National Health Service. These stipulate that in addition to the clinical criteria, patients must demonstrate a defined commitment to non-surgical weight loss and that they are formally evaluated in this commitment. In so doing the approach is to regard obesity as a chronic disease with stepwise progressive interventions, known as tiers of treatment, with surgery for morbid obesity only available as the final possible option [13]. Exceptions are made for patients with a BMI of over 50 and it remains to be seen how clinically or cost effective this will prove to be in the overall public health strategy against obesity, but there is no doubt that obesity is a chronic illness and long term interventions will be required with or without surgery.

Table 8.3 Factors associated with complications and mortality after bariatric surgery

Age
Male gender
History of prior VTE or thromboembolic disease
Mobility limitations/poor functional status
Coronary artery disease previous cardiac interventions
Smoking history
Open surgery
Operation performed
Hypertension
Stage and severity of obesity

VTE venous thromboembolism

For the patients with BMI more than 40 and no comorbidities, surgery may be considered prophylactic, reducing the long term risk of the complications of obesity, most notably the onset of type II diabetes mellitus and early mortality. There is a wealth of data to support this, but at least 70 % of the patients present preoperatively with at least one comorbidity and in over 50 % there are three or more comorbidities present. These comorbidities will affect the overall risk from surgery and judging them is an important, imprecise and ongoing science. Several major retrospective and some prospective data exists but the conclusions are sometimes conflicting. However, several factors associated with complications and mortality after bariatric surgery have been clearly identified (see Table 8.3).

Prospectively combining postulated risk factors may be used to derive a composite risk score as proposed in the Obesity Surgery Mortality Risk Score (OS-MRS) which is a useful but not perfect tool [14, 15]. Data is constantly emerging in this field. For example the prospective bariatric outcome longitudinal database (BOLD) from America and the British National Bariatric Surgical Registry (NBSR) identify more precisely independent risk factors for adverse surgical outcomes. Currently the only definite independent risk factors are a history of sleep apnea, a previous history of deep vein thrombosis (DVT) or pulmonary embolism (PE) and functional status. BMI alone may not be an independent risk factor but adverse outcomes were increasingly seen with patient BMIs above 50 kg/m^2 and especially above 73 kg/m^2. More data is anticipated. Pre-operative scoring and databases are discussed further in Chap. 14.

A significant limitation of database results is that they analyze retrospectively the risk factors for patients who have been selected for and undergone bariatric surgery. They do not include those who were deemed unsuitable for surgical intervention or who chose not to pursue this route. It can tell us retrospectively when we might not have chosen bariatric surgery but not always prospectively when we should. A further pressure on the bariatric surgeon in selecting the patient for surgery is the knowledge that should the risk for surgery be deemed too high, there are no other effective alternative treatments particularly if that patient is super obese.

It is the responsibility of the multidisciplinary team to assess and optimize all risk factors wherever possible. Not all decisions however are evidence-based and a significant number of recommendations are based on majority consensus. In addition, the factors identified in the preoperative patient assessment may influence the type of bariatric operation possible in that patient but so far there are no reliable indicators which predict success for one operation over another in any individual patient.

8.3 Contraindications to Surgery

In the setting of a multidisciplinary team environment, there are few absolute contraindications to bariatric surgery. Patient factors as well as local expertise and experience will however determine the nature and timing of surgical intervention in individual patients.

8.3.1 Physiological Factors

8.3.1.1 Extremes of Age

The original NIH guidelines specified adult age limit of 18–60 for surgical intervention, but this has been subsequently relaxed.

Children and Adolescents

With the rising obesity epidemic, increasing numbers of adolescents are now accepted as candidates for bariatric surgery [16, 17]. These operations should only be undertaken in specialist units and only after the patients have reached skeletal maturity. The same criteria as in adults are used as a basic minimum but with an even greater emphasis on a multidisciplinary team approach and lifelong follow up. One of the important factors that could influence the decision is the maturity in the children to understand the lifelong commitment to long term modification that is required of them following surgical intervention. This group of patients therefore require mandatory and intensive psychological support throughout the process. Surgery in this age group is discussed in detail in Chap. 77.

Elderly

The elderly inevitably carry greater risks for surgery and have less opportunity to enjoy the benefits, particularly when they present with end stage chronic diseases. It is known that for some comorbidities such as diabetes, arthritis and others, the longer the disease is present, the less reversible it will prove to be. There has also been concern that the elderly may adapt less well to life after bariatric surgery, but this has not been verified, and it may actually enhance the quality of life in appropriately selected patients. The risk benefit profile needs to be scrutinized for individual patients to determine their operative suitability and also the optimum procedure. Advancing age alone is considered to be a major independent risk factor for poor outcome in bariatric surgery although common sense and caution are required. Certain units have successfully operated on patients in their seventh decade with no difference in morbidity and mortality compared to the general population [18, 19].

8.3.1.2 Body Mass Index

It has been long held that greater the BMI, the greater the degree of technical difficulty, but this linear association is lost in the laparoscopic era. Various studies have indicated a rise in risk of operative mortality and perioperative complications with increased BMIs [20]. It has been noted that the abdominal wall can be relatively thick in comparison to a small abdominal cavity especially in men, thereby increasing the risk of intra abdominal complications. This category of patients are also at increased risk of developing thromboembolic complications after surgery. Evidence regarding preoperative weight loss is inconclusive. The general consensus is that achievement of successful weight reduction preoperatively reduces the above mentioned perioperative risks [21, 22].

8.3.2 Medical and Surgical Factors

8.3.2.1 Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a recognized obesity related condition and an independent risk factor for postoperative complications after bariatric surgery. It increases the relative risk for surgical complications approximately threefold. Up to 80 % of bariatric patients may have sleep apnea, which maybe previously undiagnosed [23]. Sleep apnea is not a contraindication for bariatric surgery. However, all patients should be screened for sleep apnea and if it is present or suspected, treatment should be established before surgery by consulting a respiratory physician.

8.3.2.2 Diabetes, Hypertension and Cardiovascular Problems

It is good practice to involve the diabetologist at an early stage in the perioperative management of patients with T2DM as good glycemic control is associated with better outcomes after bariatric surgery [24].

Hypertension is prevalent in morbidly obese and may be associated with diabetes as part of the metabolic syndrome. It should be pharmacologically controlled preoperatively.

Patients with cardiovascular diseases should not be refused surgery. Assessment and optimization of both stable and unstable cardiovascular conditions by a cardiologist perioperatively often leads to successful intra as well as post operative outcomes [25].

8.3.2.3 Malignancy

Obesity is a risk factor in the etiology of many cancers. However, there is an understandable concern when offering bariatric surgery to patients with a history of cancer. Clearly, the type, stage and prognosis of the initial cancer are key questions, but there are numerous reports of bariatric surgery being successful in this group of patients and the history of a previous malignancy need not be an absolute contraindication to surgery.

8.3.2.4 Thromboembolic Risk

While mortality is uncommon after bariatric surgery, approximately 20 % of deaths after bariatric surgery result from pulmonary embolism, three quarters of which occur after discharge from hospital [26, 27]. All patients should receive appropriate in-hospital thromboembolic prophylaxis as per the local protocols. A previous history of clots increases the risk of mortality approximately threefold and these patients may therefore benefit from prolonged prophylaxis. Overall risk of morbidity and mortality following consideration of individual risk of venous thromboembolism will determine the suitability and nature of surgical intervention.

8.3.2.5 Smoking

There is an association between smoking and the development of postoperative marginal ulceration after gastric bypass. Smokers are advised to stop smoking before surgery. Some units would not operate on patients until there is evidence of smoking cessation [28].

8.3.2.6 Functional Status and Mobility

Functional status is a recognized risk factor for immediate surgical outcome, complications and mortality following bariatric surgery. It is also an important factor in determining the ultimate result from surgery. A wheelchair or housebound patient will lose less weight than an able bodied individual and some surgeons regard this as an absolute contraindication to surgery. Overall functional activity improves markedly after bariatric surgery. At the very least, a thorough multidisciplinary approach is required with a deep understanding of the causes for immobility in order to set clear achievable objectives. This is of particular interest when considering surgery in the extremes of age. Lesser degrees of immobility are measured either by distance walked (BOLD) or the ability to climb stairs (NBSR).

8.3.2.7 Previous Abdominal Surgery, Intestinal Disease and Abdominal Wall Hernia

The diseases that needed previous abdominal surgery and the actual procedure performed have a bearing on the options available to the patient. Previous surgery would determine not only the feasibility of any surgical procedure following risk assessment but also determine the actual procedure itself. For example Crohn's disease itself is not an absolute contraindication to bariatric surgery, however bowel resection for Crohn's disease would be a relative contraindication for a malabsorptive procedure. Caution should certainly be exercised and these patients will require an extensive risk assessment process. Previous intra-abdominal or pelvic operations and repair of large incisional hernias will also influence the practicality and applicability of the laparoscopic approach. Residual adhesions may totally preclude access to the infra-colonic compartment and therefore laparoscopic small bowel surgery. Prior knowledge about the patient's previous surgical history could therefore sway the risk benefit scenario in favor of conservative treatment, open surgery or sleeve gastrectomy as the latter does not involve the small bowel.

Patients with early or established cirrhosis present a difficult problem, particularly if the cirrhosis is obesity related [29]. There are reports of progression and worsening of liver disease after successful bariatric surgery and caution should be exercised.

8.3.3 Psychological Factors

8.3.3.1 Active Psychiatric Disease

Patients with active psychiatric disease, a recent suicide attempt, personality disorders or drug/alcohol dependency are not suitable candidates for surgery until appropriately treated [30, 31]. While untreated, these are absolute contraindications to surgery. Once resolved they are not contraindications, with good and even excellent results sometimes seen in these patients. However, most units would offer increased support to these patients in the postoperative period.

8.3.3.2 Eating Disorders

All patients should be screened for eating disorders and seen and assessed by a dietitian as part of the multidisciplinary process. There are a multitude of eating disorders and these are associated with a suboptimal outcome after surgery [30–33]. However, when appropriately assessed, these need not be absolute contraindications for bariatric surgery. Information about eating disorders can help to choose an appropriate bariatric procedure for the individual. Patients who cannot comply sufficiently with preoperative programs may fare less well with certain procedures [34].

8.3.3.3 Intelligence, Understanding, and Mental Capacity

Bariatric surgery imposes a lifelong commitment to discipline in oral intake, either by complying with restrictive diets or supplementing or adjusting diets in the case of malabsorptive operations. Patients who cannot comply with the dietary changes required after bariatric surgery may develop dangerous complications or malnutrition and therefore patients who are unable to comply are probably unsuitable candidates. However, the decision about adequate mental capacity should be carefully measured against available familial and social support before the risk benefit ratio can be appropriately evaluated.

Conclusion

Bariatric surgery is complicated by a myriad of factors that on occasion contribute to the obesity itself and at other times is contributed by the disease process. It is therefore of utmost importance to assess individual patients in a multidisciplinary setting to enable appropriate patient selection. There is no irreversible absolute contraindication to bariatric surgery. However, for successful outcome, all individual complicating factors should be dealt with prior to any surgical intervention.

Key Learning Points

- The complexity of a bariatric surgical procedure itself is further complicated by disease and patient related factors.
- There is no irreversible absolute contraindication to surgery. However, presence of a combination of factors can tip the risk benefit balance towards a nonsurgical approach.
- Active psychological disorders and psychiatric diseases must be resolved prior to consideration for surgery.
- A multidisciplinary approach to the individual patient is of paramount importance in achieving the best and desired postoperative outcome.

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Procedure Selection in Bariatric Surgery

9

Neil A. Jennings and Peter K. Small

Abstract

This chapter discusses the complex decision-making involved in performing a bariatric procedure on the individual patient. It provides an overview of the benefits and pitfalls of the most commonly performed bariatric surgeries and examines how factors related to the individual patient as well as surgical and regulatory factors affect the selection of the surgery.

Keywords

Bariatric surgery • Obesity • Procedure selection • Risk stratification

9.1 Introduction

There is no ideal bariatric procedure. Clinicians around the world debate not only on which procedure is superior but also on which is better for an individual patient. An understanding of the "ideal" operation should be developed in order to understand how a selection may be tailored to an individual patient. An ideal bariatric procedure would be safe, easy to perform, have minimal short- and long-term complications, and allow patients to eat a wide variety of foods while still controlling volume and/or absorption. It will require minimal or no ongoing maintenance, be acceptable to the patient and finally, should be easily reversible if necessary.

This chapter focuses on patient selection for the most commonly performed bariatric procedures which include laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (LRYGB), laparoscopic duodenal switch (DS) and mini-gastric bypass (MGB). The operations should be assessed and discussed in an experienced multidisciplinary team (MDT), so that optimal recommendations are made to the patient. The MDT is discussed elsewhere in this book.

9.2 Patient Factors

In many ways the most complex and variable component of a bariatric pathway is the patient. All National Health Service (NHS) units should ensure that patients meet current National Institute for Health and Care Excellence (NICE) guidance [1]. While most established units have a preferred procedure and established protocols, each new patient enters their journey with preconceived ideas and expectations. Most patients in UK are referred to a surgical centre via their general practitioner (GP). The UK is currently changing its referral criteria requiring all patients to undertake a medical weight management programme prior to referral to a surgical weight management specialist centre. . Each patient often attends the first surgical appointment with their own idea of which surgical procedure is best for them. They base their opinion on a variety of information sources including popular magazines, patient support groups, commercial websites and discussion with postoperative patients or occasionally with their own GP. Thus, the surgeon will encounter patients with variable knowledge.

Though all patients requiring bariatric surgery currently require a body mass index (BMI) higher than 35 to meet

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NICE criteria, there may be a considerable range in the degree of obesity seen. Similar variations may be observed in the prevalence of comorbidities, medication, age and mobility of the patients. Further, the patient's dietary history should be considered to assess the source of excess calorie intake. Variations in the texture and type of food consumed as well as the volume and timing of meals or snacks could ultimately influence the choice of procedure. While current guidelines expect all patients to have gone through a psychological assessment before referral, in reality there are insufficient psychologists to deliver this to everyone. A significant proportion of bariatric patients require psychological input prior to surgery, and some method of screening needs to be included in the patient assessment. Various tools exist to help with the preoperative psychological assessment, and this varies from unit to unit [2, 3]. Psychosocial pathology may have implications with regard to the potential success of bariatric surgery. In our unit, psychology service believes that restrictive and malabsorptive procedures place different psychological stresses on individual patients. As such, some patients may be more suited for a particular procedure. A temporary gastric balloon may be utilised to assess the stress response to more permanent biological restriction, although this approach has little supporting data [4].

9.3 Surgical Factors

Bariatric surgery is no different from other fields of abdominal surgery in terms of planning operative intervention. The surgeon needs to ensure that adequate access can be obtained, the blood supply remains sufficient for anastomotic healing, and that no damage occurs to adjacent structures. The surgeon must assess the likelihood of encountering intra-abdominal adhesions which may prevent adequate access to the surgical field. Ventral hernias may compromise access. In cases of previous gastric surgery, careful attention must be paid to how the gastric blood supply has been compromised and ensure that no part of a subsequent bariatric procedure is exposed to ischaemia-related complications.

In many cases, previous adhesions may be dealt with laparoscopically following careful insufflation and port insertion and thus may not limit surgical options. However, even adhesiolysis may be associated with morbidity. Extensive adhesiolysis exposes the patient to the risks of prolonged surgery as well as an increased risk of iatrogenic enteric injury. A more successful strategy may be to defer to an alternative operation, as well as considering conversion to open surgery. Ideally, such situations can be predicted preoperatively and a suitable strategy discussed with the patient.

Ventral abdominal wall hernias are relatively common in the obese population. These can affect bariatric surgery, either by preventing adequate visualisation of the operative field or by limiting the mobility of the small bowel required to restore gastrointestinal (GI) continuity. If possible, we prefer to leave a ventral hernia untouched at primary surgery and to repair it once the patient's weight loss has stabilised. If reduction of the hernia sac is essential, for example, if it contains small bowel loops or has a narrow neck, then a formal hernia repair should be undertaken as part of the bariatric procedure. Such a strategy exposes the patient to the same problems as undertaking extensive adhesiolysis. Simple reduction of the contents of the hernial sac with no subsequent hernia repair exposes the patients to the possibility of early postoperative obstruction. In the presence of a new GI anastomosis, this can lead to postoperative distal small bowel obstruction causing anastomotic leak.

In cases of previous gastric surgery, an adequate review of the original operative notes can yield much useful information. For example, the surgeon can gain a clear understanding of which vascular pedicles, if any, have been divided and this knowledge can help plan staple or suture lines and avoid compromising the blood supply of the remaining stomach. A history of previous anti-reflux surgery with division of the short gastric arteries poses particular problem. In this case, the surgeon has to deal with the possibility of rendering the gastric fundus ischaemic, which may result in leak from the gastric remnant. A similar situation may be encountered in patients with a previous vertical banded gastroplasty (VBG) where parallel staple-lines could result in ischaemia.

9.4 Local/Regulatory Factors

The range of operations for patients may be limited by government regulation, insurance regulations or limitations of the bariatric unit. UK regulations covering bariatric surgery are set out by NICE and the Clinical Commissioning Policy Guidelines covering England published in 2013 [5]. These guidelines outline the criteria for patients to qualify for publically-funded bariatric surgery within the NHS but leave the choice of procedure to the individual bariatric units. This approach is different to the Medicare or Medicaid programmes in the USA, where, initially in 2006, sleeve gastrectomy was not covered as a primary bariatric procedure [6]. To date there remains limitation of the procedures available via Medicaid in certain states, with a strong preference for gastric bypass [7]. In UK, there are very few centres which offer gastric banding, sleeve gastrectomy, gastric bypass surgery and duodenal switch or biliopancreatic diversion, i.e., the entire spectrum of bariatric procedures to their patients. Additionally, most centres have a strong preference for one particular procedure, with some only offering patients the choice of the single procedure.

9.5 Laparoscopic Adjustable Gastric Banding (LAGB)

LAGB (Chap. 30) using the pars flaccida technique is one of the world's most popular bariatric procedures and is the predominant operation performed in Australia. On an average, patients lose 40–60 % of their excess weight [8], but frequently there is weight regain at 5 years. LAGB has the advantage of being a short, simple operation, and has the lowest postoperative mortality. Worldwide, there has been a decrease in the number of gastric bands being inserted. Some groups, including the authors' unit [9], have questioned the long-term durability of LAGB [10]. Patients undergoing LAGB require follow-up at least on a three-monthly basis in the first postoperative year. Additionally, band patients require lifelong band surveillance, with inflation or deflation of the band with saline via the port site depending on the course of their weight. Band slippage with obstruction seen in 2–4 %, erosion in 1–2 %, and tubing problems are potential complications of the procedure [11, 12]. Gastric banding is a purely restrictive procedure. Less vitamin supplementation is necessary, although there can be deficiencies due to the need for tiny soft meals to be chewed well and taken slowly; furthermore, although the duodenum is present, anaemia can occur because of difficulty getting red meat through the band [13]. LAGB is a readily reversible bariatric procedure with the band usually removed laparoscopically.

9.6 Laparoscopic Sleeve Gastrectomy (LSG)

In LSG (Chap. 26), the greater curve of the stomach is resected adjacent to a lesser curve on a 30–40 Fr bougie, leaving a long lesser curve gastric sleeve. LSG was initially conceived as the first step in a two-stage management of high-risk or super-obese patients, who were intended subsequently to undergo conversion to a gastric bypass or a duodenal switch. Excellent results from this first step led to LSG being performed as a standalone procedure [14]. LSG appears to be technically simple, with a short operating time, which has led to a rapid increase in the number of LSGs being performed in UK and worldwide. However, LSG is more technically demanding than many surgeons first realised [13]. Although there may be increased intestinal transit time, LSG is mainly a restrictive procedure. However, dietary supplements are necessary, and vitamin B12 deficiency may develop in 3–5 years unless B12 supplementation is done [14, 15]. Weight loss observed with LSG appears to lie somewhere between that with LAGB and gastric bypass. However, due to dilatation of the sleeve, weight regain is common after 4 years [16]. A major drawback of LSG is frequent gastro-oesophageal reflux, occasionally necessitating conversion to a gastric bypass [17]. Many feel that a hiatus hernia or significant reflux preoperatively is a contraindication to LSG. The most challenging complication is a postoperative leak rate of 2–4 % (due to the dissection along the cardia and left crus to achieve a small pouch or due to pouch obstruction at the incisura). These leaks necessitate emergency drainage, nutritional support and often stents, and may be prolonged and problematic for the surgeon and the patient [18, 19]. While postoperative staple-line leaks in the mid-pouch are rare, they can also be difficult to manage.

9.7 Laparoscopic Roux-en-Y Gastric Bypass (LRYGB)

LRYGB (Chap. 19) is currently the most commonly performed bariatric operation both in the UK and worldwide, and has more than 50 years of experience to draw on. LRYGB involves creation of a 15–30 ml proximal gastric pouch that is separated from the remnant stomach. The proximal GI tract is bypassed by anastomosing a Roux loop of jejunum to the tiny gastric pouch. GI continuity is restored by a jejuno-jejunostomy. LRYGB is both restrictive and somewhat malabsorptive. Many units consider LRYGB to be the "gold-standard" operation to which other procedures are compared. Patients require lifelong vitamin and mineral supplementation and surveillance [13]. The internal hernia spaces are generally closed, but there still remains a lifelong risk of intestinal obstruction due to internal hernia. Marginal ulcer remains a potential complication, salicylates and non-steroidal anti-inflammatory drugs should be forbidden and patients encouraged to stop smoking. LRYGB offers consistent favourable weight loss, but some long-term studies reveal variable weight gain, at least partly related to dilatation of the pouch and stoma [20, 21].

9.8 Duodenal Switch (DS)

DS (Chap. 44) has been shown to lead to best results in terms of both excess weight loss and resolution of obesity-related co-morbidities [22], but also has the highest incidence of early and late postoperative complications. It is technically demanding to perform. The procedure involves a sleeve gastrectomy. Then, the first part of the duodenum is divided, with the distal end of the divided duodenum closed. The ileum is divided 250 cm proximal to the ileocaecal valve; the distal end of the divided ileum is anastomosed to the proximal end of the first part of the duodenum, to restore alimentary continuity. The proximal end of the divided ileum is anastomosed end-to-side to the ileum 75–100 cm proximal to the ileocaecal valve (leaving a long bilopancreatic limb and short common channel). Leak on the sleeve does not occur (unlike in the LSG operation), because the cardia is not dissected. The sleeve acts mainly as a conduit for food, as DS is predominantly a malabsorptive operation. DS is thus more prone to long-term vitamin, mineral and protein deficiencies, which mandates surveillance [13]. This has led many units to consider DS too drastic an operation for most patients.

9.9 Mini-Gastric (One-Anastomosis) Bypass (MGB/OAGB)

MGB started 16 years ago, but its popularity has increased recently. A long gastric sleeve is created along the lesser curve of the stomach. The cardia is not dissected. The sleeve extends to at least the crow's foot. The gastric sleeve is anastomosed end-to-side to the jejunum 200 cm distal to the ligament of Treitz, although this distance can be shortened or lengthened depending on the patient's BMI. If a hiatal hernia is present, it is not repaired at this time, as the traction by the gastro-jejunostomy is said to reduce the cardia into the abdomen. MGB is a rapid and safe malabsorptive procedure [23, 24]. The long gastric sleeve inhibits significant bile reflux, and the projected fear of development of gastro-oesophageal cancer appears to be unwarranted. Weight loss and resolution of comorbidites are excellent [25, 26]. Marginal ulceration may be a problem postoperatively and again salicylates and non-steroidal anti-inflamatory drugs must be avoided and smoking cessation advised. Vitamin and mineral supplementation is mandatory.

9.10 Balancing Risks Versus Outcome

It is impossible to predict how much weight an individual patient will lose from a specific bariatric procedure and whether particular comorbidities will resolve. The more technically difficult, higher risk operations offer the best chance of significant weight loss and resolution of comorbidities. LAGB or LSG can be performed initially to reduce weight in high-risk super-obese patients, who could subsequently tolerate a more durable malabsorptive procedure after initial weight loss. However, this strategy exposes the patient to a higher risk of revisional bariatric surgery and has significant financial consequences, which must be considered. A gastric balloon has also been used for preoperative weight loss in the super-obese.

9.11 Patient Choice

When discussing the selection of procedure both the surgeon and the patient should be aware of the biased opinions they both bring to the discussion. Patients may base their choice of procedure on what friends or family have experienced, viewing the situation as a transaction as opposed to a consultation. In units that only offer one bariatric procedure, this dilemma is avoided as consent to surgery has only one option. However, many bariatric surgeons and commissioning bodies are critical of units that only offer one modality of surgery. This may cause an ethical dilemma for surgeons or units that only recommend a particular procedure when faced with a patient only willing to consent to a different operation. Patients who feel that they are forced into a particular operation may be less likely to attend follow-up or blame the fact that they did not achieve their desired outcome on the operation they received. The commonest conflict encountered within our unit occurs when a patient requests a gastric band or a sleeve gastrectomy. If a proven hiatus hernia or reflux disease (which we consider to be significant contraindications for these procedures) is found during workup we offer these patients a LRYGB or referral to a neighbouring unit for a second opinion.

9.12 Co-existing Medical Conditions

The patient may sometimes present with medical disorders that are not related to obesity but may still influence the choice of procedure. An existing history of anaemia or vitamin deficiency would preclude many units from undertaking a malabsorptive procedure and to opt instead for a gastric band or LSG. A history of Crohn's disease is considered a contraindication to performing an LRYGB, DS or MGB, due to risk of fistula formation at anastomotic sites. It would also be best to leave the small bowel undisturbed, given the lifetime risk of subsequent small bowel resection in such patients.

Several medications are dose sensitive, for example, antiepileptics, psychotropic medication, warfarin and immunosuppressants. If the patient requires such medications, an argument can be put forward for a purely restrictive procedure where the pharmacokinetics should remain unaltered. Patients at increased risk of upper GI malignancy may be advised to undergo surgery which allows ongoing surveillance of the upper GI tract, while in the presence of Barrett's oesophagus, sleeve gastrectomy is contraindicated.

Conclusions

Matching the correct patient to the correct procedure is a challenge in bariatric surgery. The answer to a large extent depends on individual dedicated surgeons and units knowing their own outcomes, the characteristics of their patient population and the limitations of both the surgeon and the individual patient. All patients deserve a service that is tailored to their needs. In UK, patients considered for bariatric surgery should be discussed within a multidisciplinary team to ensure that all aspects of their management are addressed. In many cases, units will have a preferred procedure and must ensure that if what can be offered by their service is not the best option for the patient, then referral to another unit is made.

Key Learning Points

- Procedure selection in bariatric surgery should be tailored to the individual needs of the patient.
- There is no ideal bariatric procedure that is suitable for all patients.
- Bariatric units should be able to offer a range of procedures to their patients.
- Close follow up is essential for any procedure to be successful.
- Significant differences in bariatric practice exist in various countries around the world with new techniques currently being developed.

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Section III

Perioperative Assessment for Bariatric Surgery

Honorary Section Editor - Cynthia-Michelle Borg

The number of bariatric operations performed worldwide has increased dramatically. The morbidity and mortality associated with surgery have however decreased due to careful patient selection, pre-operative amelioration, improved surgical techniques and peri-operative care. This section discusses the pre-operative assessments and decision-making involved prior to performing a bariatric procedure.

There is no one ideal bariatric operation. Matching the correct patient to the correct procedure is the ultimate challenge in weight loss surgery. This is probably best achieved within a multidisciplinary team (MDT) setting to ensure that all aspects of patient management are addressed. Members of the bariatric team vary from centre to centre and this is discussed in Chap. 15.

Medical co-morbidities are common in morbidly obese patients and at times are only diagnosed during pre-operative assessments. Medical evaluation and management of bariatric patients are discussed in Chaps. 10 and 17. Associated co-morbidities and previous operations not only determine suitability and fitness for surgery but may help to decide which operation is best suited for an individual patient.

Scoring systems have been devised to identify patients who may be at higher risk of adverse outcomes. These are discussed in detail in Chap. 14. There is no single ideal scoring system and most tend to overestimate risk. They, however, can be a useful adjunct in planning a customized approach to allow patients to be better counselled pre-operatively.

Bariatric anaesthesia has become very safe however the margin for error in this patient group is still small. An experienced bariatric anaesthetist is crucial to ensure safe care and management. Chapter 13 highlights areas where care may differ from standard anaesthetic practice.

Most patients being considered for bariatric surgery have had previous unsuccessful attempts at non-surgical forms of weight reduction. Despite these, numerous patients still make inappropriate food choices, have little knowledge about portion sizes and calorie intake and may have unrealistic expectations regarding the outcome of surgery. Chapter 11 highlights the specialist dietetic assessment required prior to surgery. Mineral and vitamin deficiencies are relatively common and so preoperative screening is important. The specialist dietician also has a key role in educating the patient regarding eating after bariatric surgery.

Higher rates of psychological morbidity have been found amongst obese patients. Most units include a psychological assessment or the use of screening tools as part of the pre-operative workup. Chapter 12 outlines key areas that should be included in this evaluation.

The provision of specialized nursing care will impact positively on the patient's journey. Chapter 16 highlights the roles of the bariatric specialist nurses.

Many units have designated inpatient protocols and pathways. The feasibility and safety of early discharge following laparoscopic bariatric surgery are discussed in Chap. 18.

Careful patient assessment is important prior to bariatric surgery as this identifies pre-existing medical, surgical, nutritional and psychological problems that may impact on successful postoperative outcome and long-term results. This pre-operative workup helps to tailor individualized plans, quantify the risks and benefits, improve patient education and identify the operation that is best suited for the patient.

Preoperative Medical Evaluation of the Bariatric Surgery Patient

10

Christopher James Grocock, Senthil Natchimuthi, and Conor J. Magee

Abstract

Obese patients must be thoroughly assessed before undertaking any bariatric procedure. Medical comorbidities are common, yet complications are relatively rare. This makes it difficult to identify those who will develop a perioperative complication, even with the help of validated scoring tools.

After thorough clinical assessment, patients should be discussed at a bariatric multidisciplinary team meeting, ideally one involving motivated individuals from the full range of medical and allied professions who can contribute to providing best possible pre-, peri- and postoperative bariatric care.

This chapter will focus on the evidence base behind the pre-operative medical evaluation process and how comorbidities and other potential pitfalls should be managed once they have been identified.

Keywords

Bariatric • Preoperative • Medical • Comorbidity • Assessment

10.1 Introduction

Patients with morbid obesity often have coexisting medical problems [1], accordingly, successful bariatric surgery requires careful patient selection and optimization, combined with meticulous surgical technique and lifelong follow up.

The growing acceptance of a bariatric multidisciplinary team (MDT) allows the detailed assessment of patients and a coordinated approach to complex problems.

We will consider the preoperative assessment process, including risk stratification and preoperative investigations, before focusing on preoperative management of medical conditions.

10.2 Initial Medical Assessment

The latest United States guidelines state that all the patients should undergo preoperative evaluation for obesity related comorbidities and causes of obesity. Special attention should be directed to those factors that could affect the indications of bariatric surgery [2].

10.2.1 Medical Causes of Obesity and Obesity Associated Conditions

There is growing recognition that obesity is much more complex than the result of excessive caloric intake and sedentary lifestyle; the interplay between genetic polymorphisms and environmental influences on obesity cannot be overstated. Furthermore there are specific and drug induced types of obesity which need to identified during the initial

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medical assessment (Tables 10.1 and 10.2). The role of bariatric surgery in obesity associated with genetic conditions, such as Prader-Willi syndrome, remains undefined. Case series have been reported [11] but long term outcomes remain unproven.

Bariatric surgeons also need to be aware of the consequences of obesity. Obesity related comorbidities such as type 2 diabetes mellitus (T2DM) and obstructive sleep apnea (OSA) are well known, but rarer problems such as benign intracranial hypertension can also be successfully treated with bariatric surgery [12] making it imperative that these comorbidities are recognized at the initial preoperative assessment (Table 10.3).

Table 10.1 Some obesity related syndromes and identified causative or associated genetic abnormalities

Obesity associated syndromes	Prader-Willi syndrome
	Bardet-Biedl syndrome [3, 4]
	Alström syndrome [5, 6]
	Börjson-Forssman-Lehman syndrome [7] Albright hereditary osteodystrophy
Causative or obesity associated genetic abnormalities	Leptin deficiency [8]
	Leptin receptor deficiency
	Melanocortin-4 receptor mutations [9]
	Peroxisome proliferator-activated receptor mutations
	Pro-opiomelanocortin mutations
	Prohormone convertase 1 deficiency
	β[beta]3 adrenergic receptor [10]

Table 10.2 A summary of potential pharmacological causes of obesity

Antidepressants	Mirtazapine Monoamine oxidase inhibitors Selective serotonin reuptake inhibitors (Paroxetine) Tricyclic anti-depressants
Antidiabetic agents	Insulin Sulfonylureas Thiazolidinediones
Antiepileptic drugs	Carbamazepine Gabapentin Valproate sodium
Antihistamines	Cyproheptadine hydrochloride
Antihypertensive agents	α[alpha]1 and β[beta] adrenergic receptor blockers
Antipsychotic agents	Clozapine Olanzapine Phenothiazine Risperidone
HIV protease inhibitors	
Mood stabilizers:	Lithium
Steroid hormones	Corticosteroids Progestational steroids

10.2.2 Preoperative Assessment

Once patients are referred for surgery, a formal assessment takes place. This is usually protocol driven to allow detailed

Table 10.3 A summary of obesity related comorbidities

System	Condition
Cardiovascular	Cardiomyopathy Cerebrovascular disease Congestive cardiac failure Cor pulmonale Diastolic dysfunction Dyslipidemia Endothelial dysfunction Hypertension Ischemic heart disease Peripheral vascular disease
Pulmonary	Asthma Obesity hypoventilation syndrome Obstructive sleep apnea
Venous thrombo-embolic	Deep vein thrombosis Lymphedema Peripheral edema Pulmonary embolism Venous stasis
Endocrine excluding reproductive	Diabetes mellitus types 1 & 2 Gestational diabetes Insulin resistance Metabolic syndrome
Gastro-intestinal	Cholelithiasis Constipation Hepatic steatosis Nonalcoholic steatohepatitis Cirrhosis Hiatus hernia Irritable bowel syndrome Esophageal dysmotility Esophageal reflux
Dermatological	Acanthosis nigricans Alopecia Cellulitis Diaphoresis Hidradenitis suppuritive Hirsutism Intertriginous dermatitis Striae Telangiectasia Tinea corporis
Genitourinary & reproductive	Amenorrhea Dysfunctional uterine bleeding Infertility Menorrhagia Polycystic ovarian syndrome Preeclampsia Testicular atrophy Urinary incontinence
Musculoskeletal	Fibromyalgia Gout Hernia Musculoskeletal back pain Osteoarthritis

(continued)

Table 10.3 (continued)

System	Condition
Neoplastic	Breast Colon Endometrial Gallbladder Esophageal Pancreas Prostate Renal cell carcinoma Thyroid
Nephrological	Chronic renal insufficiency Primary nephrotic syndrome
Neurological	Idiopathic intracranial hypertension Meralgia paresthetica
Psychological	Anxiety Body dysmorphic syndrome Depression Eating disorders Insomnia
Miscellaneous	Chronic fatigue syndrome

analysis of each patient and provide information for clinical records and databases. A structured proforma ensures that all areas are covered, including comorbidities and their management. It is useful to subdivide the proforma into sections that are completed by the relevant specialists. Section headings and core content are shown in Table 10.4.

There is currently no consensus on age limits, although there are obvious concerns regarding suitability and consent in adolescent patients and a trade-off between risk and benefit as patients become more elderly.

Risk assessment can be supplemented by the use of validated scoring tools that assess operative risk, complexity of obesity and presence of comorbidities (see Table 10.5). Scoring tools provide objective evidence to supplement clinical judgment and can be used to guide the choice of procedure. For example, patients with an Obesity Surgery Mortality Risk Score (OS-MRS) of more than or equal to four may be offered an initial sleeve gastrectomy as part of a planned two stage gastric bypass [16]. These scoring systems are discussed in more detail in Chap. 14.

Other factors, including the presence of malignancy, significant portal hypertension or cirrhosis of liver, may amount to a contraindication for bariatric surgery. Gastrointestinal tract diseases such as inflammatory bowel disease may be either a relative contraindication or affect the choice of procedure, where a restrictive rather than a malabsorptive procedure may be more appropriate.

Table 10.4 A summary of the sections that should be included within a basic proforma, with minimum suggested content for each section

	Information fields (including current treatment)
Personal	Personal details, age and gender; next of kin; referral source
Bariatric Indices	Body mass index (BMI); ideal and excess weight
Metabolic	Diabetes mellitus & treatment, thyroid disease, polycystic ovary syndrome
Cardiovascular	Hypertension & dyslipidemia; angina, myocardial infarction & arrhythmias; thromboembolic events & anticoagulation
Respiratory	Sleep apnea, with STOPBANG screening; asthma; chronic obstructive pulmonary disease (COPD)
Other co-morbidity	Gallstones; previous abdominal surgery & scars, arthritis; reflux; infertility; smoking & alcohol
Psychiatric/Psychology	Major mental health problems; psychological issues (e.g., binge eating disorder, previous anorexia); previous drug abuse
Scoring of surgical risk & severity of obesity	Obesity Surgery Mortality Risk Score (OS-MRS); Edmonton Obesity Severity Score (EOSS)
Compliance with local and national guidelines	NICE[a] compliance; completion of medical weight management program
Aims & Expectations	Record patient aims & expectations
Surgical Options	Discussion supplemented with PowerPoint presentation & written material, including estimated excess weight loss for each procedure

[a]National Institute for Health and Care Excellence

Table 10.5 Bariatric scoring tools

Scoring tool	Description
Edmonton Obesity Scoring System [13]	Provides functional staging of obesity with suggested management based on clinical stage.
Assessment of Obesity Related Co-morbidities Scale (AORC) [14]	A scoring system for obesity related comorbidities, which are scored 0–5. A significant reduction was observed in several of the co-morbidities following bariatric surgery.
Obesity Surgery Mortality Risk Score (OS-MRS) [15]	The presence of each of 5 variables (BMI >50 kg/m2; male gender; hypertension; a novel thromboembolic risk variable; and age >45 years) is awarded one point. The presence of ≥4 risk factors gives an overall mortality risk of 7.56 %, compared to mortality risks of 0.31 % and 1.90 % for scores of 0–1 and 2–3 points respectively

10.2.3 The Role of Investigations

Bariatric units may differ in their assessment process, particularly regarding preoperative investigations. In 2005, the European Association for Endoscopic Surgery recommended laboratory tests, as well as polysmonography, for all the patients at high risk of sleep apnea [6]. Furthermore, a gas-

Table 10.6 Preoperative investigations for bariatric patients

	All patients	Selective
Bloods	Full blood count & electrolyte profile; Liver function tests & bone profile; Clotting screen: Hematinics:–iron, ferritin, folate, vitamin B12 Fasting glucose and lipids Thyroid function 25-OH vitamin D3 and PTH	HbA1c Micronutrients Zinc
Cardiac	Blood pressure ECG	Catheter studies Echocardiogram
Respiratory	Oxygen saturation	Arterial blood gas Polysomnography Spirometry
Imaging		Chest x-ray Computed tomography Ultrasound

troscopy (or barium study) was advised, particularly before a gastric bypass. A chest x-ray, electrocardiography (ECG), spirometry, and abdominal ultrasonography may also be used although definitive evidence is lacking [17].

Many patients undergoing bariatric surgery are healthy; however, they may have significant occult pathology. A suggested set of baseline investigations are shown in Table 10.6.

A thorough assessment often identifies undiagnosed comorbidities. In Paris, a group of scientists assessed the preoperative cardiopulmonary investigations of 77 patients undergoing bariatric surgery [18], and detected ECG abnormalities in 62 % of these patients, with Doppler echocardiography detecting left ventricular hypertrophy in 61 %. Assessment of respiratory function yielded a diagnosis of obstructive sleep apnea-hypopnea syndrome (OSAHS) in 40 % when assessed by polysomnography, with over half of these being started on preoperative continuous positive airway pressure (CPAP).

Undiagnosed medical problems are therefore common in obese; the challenge is to develop a rational strategy to determine which are clinically significant and how to detect them preoperatively. Although the Paris group [18] recommended routine polysomnography, this is expensive and it is likely that a busy bariatric unit (more than 500 cases per year) would swamp the local sleep investigation service.

10.2.4 The Bariatric Multidisciplinary Team

All patients should be discussed by the bariatric multidisciplinary team (MDT). This is an open forum similar to that used for cancer services. The ideal MDT should include surgeons, anesthetists, specialist nurses, dieticians, bariatric physicians and psychologists. On occasion, the MDT may be supplemented by other specialties, such as cardiology. The MDT can recommend further assessment or investigations, can decide on which bariatric procedure is to be performed or can recommend discharge if the patient is not a candidate for surgical intervention. This process is summarized in Fig. 10.1. The MDT can also be used to assess problems in previously operated patients, for example those with weight regain.

10.3 Management of Common Medical Conditions in the Preoperative Bariatric Patient

The remainder of this chapter will focus on aspects of management of specific medical conditions which are commonly detected in bariatric patients during the pre-operative medical evaluation and present specific management difficulties.

10.3.1 Management of Cardiovascular Comorbidities

It is essential that the presence and severity of conditions such as hypertension, coronary artery and possible valvular disease are documented as the association between obesity and cardiovascular disease is clear (Table 10.3). Following history and examination, the simplest way to assess the heart is to perform an ECG. In bariatric patients, clinically significant ECG changes include abnormalities in the heart rate, the QRS interval and the corrected QT interval (QTc) [19]. Other detectable abnormalities of lesser clinical significance include: changes in the PR interval, QRS voltage and QT dispersion; ST-T abnormalities, ST depression and flattening of the T wave; also left axis deviation and left atrial abnormalities [19]. Indeed, the range and frequency of ECG changes in the bariatric population makes it difficult to identify those at greatest risk. A preoperative ECG will identify ST-T wave changes in as many as 62 % [18] but these changes do not predict 90-day mortality [20]. Routine echocardiography is not performed, although there is good evidence that epicardial fat pad size is a marker of cardiovascular and metabolic disease [21].

One area of potential difficulty for the MDT is the management of those who have had coronary revascularization with a drug eluting stent (DES). A systematic review has shown that it remains prudent to avoid elective surgery for the first 12 months following DES placement [22] and existing guidelines should be followed [23]. There is no doubt that cardiology input into the MDT can help in such complex cases.

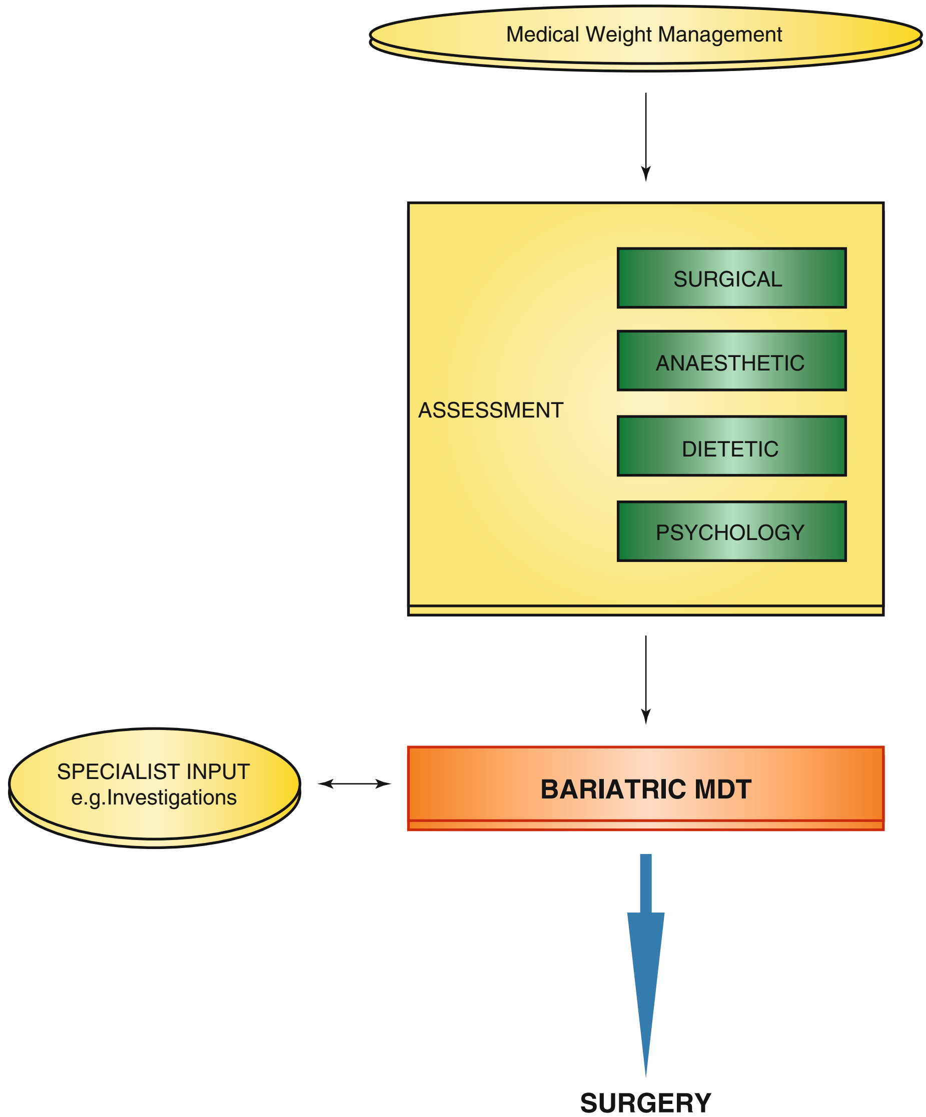

Fig. 10.1 A stylized preoperative assessment pathway for each bariatric patient. The process starts with a period of medical weight management before the structured pre-operative assessment process and discussion at the bariatric MDT. Following this discussion, further investigations may be requested to minimize risks before suitable patients are listed for surgery

10.3.2 Respiratory Disease

The risk of postoperative pneumonia and subsequent respiratory failure has been reduced through the adoption of the laparoscopic approach for bariatric surgery. However, prolonged surgery in morbidly obese patients can be complicated by the presence of preexisting respiratory disease.

Obstructive sleep apnea (OSA) and obesity hypoventilation syndrome (OHS) are particularly important. OSA is present in almost half of bariatric patients [1]. It was thought to be associated with poorer outcomes and requirement for critical care beds [24–26], although more recent work has disputed this [27, 28].

A useful screening tool for OSA is the STOPBANG questionnaire [29], which identifies those who should be referred for sleep studies. This is a simple eight point questionnaire with the first four elements picking out those with symptoms or signs associated with OSA (Snoring louder than talking, Tiredness in the daytime, having been observed to have stOpped breathing during sleep, and a diagnosis of high blood Pressure). The last four elements pick out those in particularly high risk groups (BMI more than 35 kg/m^2; Age more than 50 years; Neck circumference more than 40 cm; and male Gender). The use of the four point STOP questionnaires across all patients has a positive predictive value (PPV) of 78.4 %, with patients being classed as high risk for OSA if they meet more than or equal to two of the criteria. The PPV increases with use of the full eight point questionnaire, with patients identified as high risk if they score more than or equal to three points. If patients belong to several of the high risk groups identified by the BANG element of questionnaire, the overall PPV can reach 100 % [29].

An alternative to STOPBANG is the Epworth Sleepiness Scale; however, this tool cannot predict the severity of OSA [30].

If the sleep studies confirm OSA, patients should commence CPAP, which is normally delivered via a face mask. There is no definitive evidence on the best interval between initiating CPAP and proceeding to surgery. Local practice is to defer surgery until patients have had 6 weeks of CPAP treatment. Patients with facial hair are encouraged to shave prior to admission for surgery to optimize the mask seal.

Patients must stop smoking and they should be encouraged through counseling and support groups for the same. Smoking has strong associations with both postoperative pneumonia [31] and gastrojejunal anastomotic ulceration. Traditionally, a 6 weeks interval between smoking cessation and surgery was recommended but this was not supported by a recent metaanalysis. Urinary cotinine testing for occult smoking has not gained widespread acceptance and surgeons need to be aware that patients may continue to smoke until admission for surgery.

10.3.3 Management of Thromboembolic Risk

Venous thromboembolism (VTE) is associated with obesity and all the patients should be considered to be at high risk. Historically, death from venous thromboembolism after bariatric surgery was not uncommon. Today the incidence of postoperative VTE is much reduced, principally through improvements in surgical technique (laparoscopic surgery with shorter operating times) and the use of effective prophylaxis. Clinicians should be conscious that despite these preventative measures, the incidence of thromboembolism remains at 0.4 %, with almost three quarters of these events occurring in the 30 days following surgery [1].

To counter this risk, numerous regimes involving high dose low molecular weight Heparin, intraoperative sequential compression devices and aggressive, early postoperative mobilization have been proposed. These regimes were recently assessed in a systematic review [32]. A paucity of controlled studies made definitive recommendations difficult although the authors determined that it was reasonable to use unfractionated heparin (5000 IU subcutaneously every 8 h) or enoxaparin (30–40 mg subcutaneously every 12 h) for VTE prophylaxis. They recommended starting this the day before the surgery and to continue it for 3–4 weeks postoperatively. This should be combined with sequential compression devices and early ambulation. There is an obvious trade-off between minimizing the risk of a thromboembolic event and increasing the chance of bleeding. Bleeding rates have been calculated at approximately 3 %, although the majority of them are treated non-operatively [33]. Our unit uses an extended postoperative thromboprophylaxis regimen. Patients receive dalteparin 2500 IU before surgery and then 5000 IU per day for up to 3 weeks after discharge [34]. Other bariatric centers differ in the dosage and type of low molecular weight heparin administered. At present, level 1 evidence recommending one protocol above all others is lacking.

Patients with a history of thromboembolic disease or thrombophilia are at even greater risk. Some centers, including our own [34], use caval filters, although the evidence base is limited [31, 35, 36]. As caval filters can cause serious complications, including death [37], their use should be carefully considered by the MDT and advice from a hematologist may be required. Caval filters should be placed by an experienced vascular radiologist, with audit of outcomes. In practice, filters are rarely required and are used in less than 1 % of our caseload [34].

10.3.4 Type 2 Diabetes Mellitus

Type 2 diabetes mellitus (T2DM) is extremely common in preoperative bariatric patients. Diabetic control should be optimized prior to bariatric surgery, ideally by a specialist diabetologist working closely with the bariatric team. The plethora of diabetic medication (metformin, sulphonylureas, glitazones, glucagon like peptide-1 (GLP-1) analogues, dipetidyl peptidase-IV (DPP-IV) inhibitors and insulins) makes this input invaluable. A number of patients will have occult T2DM and screening for diabetes with fasting/random blood glucose or a serum HbA1c level (more than 6.5 % or 48 mmol/mol) can be diagnostic.

In the perioperative period, patients need their blood sugars to be monitored regularly. In practice glucose, potassium and insulin (GKI) infusions and formal sliding scales are rarely required for type 2 diabetic patients. Both insulin and oral antidiabetic drug requirements reduce immediately following a gastric bypass, duodenal switch and sleeve gastrectomy (although not after a band) and many patients can be discharged without regular T2DM medication. Even if the patients are not on any antidiabetic medication after surgery, it is imperative that blood sugar monitoring is continued, with regular follow up by the diabetic team [38, 39].

Guidance on perioperative management of T2DM is covered in the latest American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines [2]. There is Grade A evidence to recommend the determination of fasting blood glucose concentrations on a periodic basis. Finger stick blood glucose testing should be encouraged before and after food, before bed time or if symptoms of hypoglycemia occur (Grade A). Further guidance has been issued, albeit with a lower grade of supporting evidence. Grade D recommendations (i.e., two thirds consensus could not be reached) have been issued regarding:

- Discontinue insulin and insulin secretagogues (sulfonylureas and meglitinides) preoperatively, and make dose adjustment postoperatively to minimize the risk of hypoglycemia;

- Following bariatric surgery, if the T2DM is in remission, antidiabetic medications may be withheld, but metformin can be continued postoperatively till the demonstration of prolonged clinical resolution of diabetes;
- In the patients hospitalized in nonintensive care unit, basal-bolus insulin therapy, using a rapid acting insulin analogue (insulin lispro, aspart, or glulisine) before meals and a basal long acting insulin analogue (insulin glargine or detemir) should be used to attain glycemic targets (140–180 mg/dL);
- In the patients hospitalized in intensive care unit, intravenous insulin should be used;
- In the outpatients not reaching glycemic targets, antidiabetic medications that improve insulin sensitivity such as metformin, as well as incretin based therapies, should be considered. Endocrinology consultation should be considered for patients with uncontrolled hyperglycemia.

It is crucial to ensure that patients do not have type 1 diabetes mellitus (characterized by an absolute insulin deficiency) as opposed to type 2 diabetes mellitus (characterized by insulin resistance). This is a clinical decision based on age and speed of onset of diabetes mellitus (DM), the current treatment regimen and the degree of control this brings. A history of diabetic ketoacidosis is indicative of type 1 DM. Decision making can be informed by serum blood tests including C-peptide and antibody testing but there is no absolute diagnostic test to differentiate between the two types. Misclassification of a type 1 diabetic as a type 2 diabetic, with cessation of insulin, can lead to a rapid decline into potentially fatal diabetic ketoacidosis, therefore if the MDT is uncertain whether a patient has type 1 or type 2 diabetes, the input of a diabetologist should be sought.

10.3.5 Cholelithiasis

Gallstones are associated with both obesity and bariatric surgery. A Cochrane review showed that following bariatric surgery, male bariatric patients have 5.4 times increased incidence of cholecystectomy [40]. There is good evidence that postoperative ursodeoxycholic acid (at least 300 mg daily in divided doses) significantly decrease gallstone formation [41] and its use is suggested in the latest ASMBS guidelines [2].

Pragmatically, it is sensible to perform a transabdominal ultrasound if the patient has symptoms suggestive of gallstones. If gallstones are present, patients can have a cholecystectomy at the time of their bariatric procedure, although the MDT may recommend that this be deferred until significant weight loss has taken place.

The clinical quandary for the MDT is whether to recommend synchronous cholecystectomy for asymptomatic gallstones. Clinicians must balance the risk of adding a potentially unnecessary cholecystectomy to the bariatric procedure against the risk of complications of gallstone disease. This is particularly relevant in those having a procedure where endoscopic access to the biliary tree is lost, for example, gastric bypass. At present there remains no consensus opinion to guide surgeons [2, 42].

10.3.6 Management of Gastroesophageal Pathology

Obesity is associated with both gastroesophageal reflux disease (GERD) and the presence of a hiatus hernia. A large hiatus hernia can complicate bariatric surgery. Furthermore, severe GERD, often associated with a large hiatus hernia, is a relative contraindication for sleeve gastrectomy. Simply put, prewarned is prearmed. If a hiatus hernia is diagnosed before surgery, the surgeon can discuss the options with the patient; for example, gastric bypass might be preferable to a sleeve gastrectomy.

Gastroesophageal reflux is a very common symptom in the morbidly obese. Symptomatic patients should undergo esophagogastroduodenoscopy (EGD) to assess for active ulceration, the presence of a hiatus hernia, Barrett's esophagus and the exclusion of Helicobacter pylori and malignancy prior to surgical intervention. In many cases, severe reflux can be successfully treated by gastric bypass and this may be an important factor in the procedure offered to the patient.

Following gastric bypass, the remnant stomach is inaccessible by endoscopy. There is concern that an occult cancer could develop in the gastric remnant and a potential combination of reduction of symptoms, misappropriation of symptoms to bariatric surgery and inaccessibility of the remnant may lead to a delay in diagnosis of what remains a highly lethal cancer.

Zeni reported the results of preoperative upper gastrointestinal (GI) endoscopy in 169 patients who went onto gastric bypass [43]. Just one third of EGDs were normal. Findings included three (2 %) patients with gastric ulceration, one (0.7 %) with duodenal ulcer, two (1.3 %) with Barrett's esophagus, and one (0.7 %) with GI stromal tumor (GIST). There were a total of 56 hiatal hernias (35.2 %), of which nine altered the planned upcoming surgery. Esophagitis was present in 28 (17 %), with five Schatzki's rings. Gastritis was present in 43 (27 %), with gastric polyps in eight (5 %), and duodenitis in nine (6 %). No investigation is risk free, and the authors reported a case of duodenal microperforation diagnosed on CT 9 days following endoscopy. The authors recommend a preoperative EGD but level one evidence is lacking. The latest ASMBS guidelines [2] recommend a preoperative EGD in symptomatic patients (Grade D).

The concern about cancer risk after bariatric surgery may be overstated. A recent systematic review [44] found only five cases of remnant stomach cancer reported in the literature. Rather than increasing the overall cancer risk, bariatric surgery reduces the risk posed by obesity related cancers. However, it remains prudent to have a low threshold for endoscopy in bariatric patients with dyspeptic and other upper gastrointestinal symptoms, particularly when endoscopic access to these areas of the GI tract will be lost following surgery.

10.3.7 Medication

Bariatric surgery will alter how medication is taken and absorbed, particularly in the immediate postoperative period. Following surgery, patients have a significantly reduced stomach size (gastric bypass more than sleeve gastrectomy) with potential for malabsorption (duodenal switch much more than gastric bypass).

General rules to optimize absorption of medication include replacing modified-release/sustained release preparations with standard preparations. Capsules should be replaced with tablets that can be crushed. Soluble tablets are preferred to syrups as these often have a high sugar content, which can induce dumping in gastric bypass patients. Liquid preparations are significantly more expensive than tablet alternatives, but are only required for the first 6–8 weeks following surgery.

Nonsteroidal anti-inflammatory drugs (NSAIDS) or bisphosphonates should be avoided due to the risk of gastrojejunal ulceration. This may have an impact on bone health and on pain control in those with obesity associated osteoarthritis.

Physicians caring for bariatric patients should be aware that as weight loss progresses in the months following surgery, other obesity related comorbidities, such as hypertension, may resolve or require dose adjustment. Careful follow up by the bariatric team and effective liaison with primary care is essential.

10.3.8 Pregnancy

Obesity is associated with both polycystic ovarian syndrome (PCOS) and infertility. Indeed, the desire to have a child may be the trigger for a patient to enter the assessment process for bariatric surgery. A discussion regarding pregnancy is essential in women of child bearing age. It should form a part of the initial assessment and is the opportunity to counsel the patient about the need to avoid pregnancy in the postoperative period.

The evidence regarding the duration of contraception following surgery is not clear but the latest ASMBS guidelines [2] give a grade D recommendation of 12–18 months; the period of most dramatic weight loss. Oral contraceptives may be less effective following surgery (due to malabsorption or vomiting) and patients should be counseled to use alternative contraceptive methods. Patients who become pregnant should be monitored for appropriate fetal weight gain and health, with special attention given to nutritional deficiencies. Iron, folate, vitamin B12, calcium and fat soluble vitamin levels should be checked in each trimester.

In addition to the nutritional risks to maternal and fetal health, there have been reports of strangulated internal hernias, in patients who have had gastric bypass, during pregnancy, presumably through increased abdominal pressure and organ displacement caused by the gravid uterus.

10.3.9 Previous Surgery

Adhesions from any previous surgery can make bariatric surgery more difficult and increase the operative time. Dense adhesions (or a complex incisional hernia) may require an intraoperative change in the plan with, for example, a sleeve gastrectomy performed instead of a gastric bypass. Rarely adhesions may even result in conversion to an open procedure. Surgeons need to discuss these issues with their patients and document them clearly on the consent form.

A growing proportion of patients have had previous anti-reflux surgery. In these cases, take down of the wrap with conversion to gastric bypass would be an appropriate procedure.

Revisional bariatric surgery may be required in those with weight regain, poor weight loss or complications of previous surgery. Careful evaluation of these patients is paramount. This will include obtaining old clinical and operation notes, specialized investigations and review by the bariatric MDT. Revisional surgery should only be undertaken in a specialist unit by an experienced surgeon. In particularly complex cases, the patient may benefit from a second consultant surgeon in theatre. This helps not only with the technical aspects of the case, but also with intraoperative decision making.

Conclusion

Patients undergoing bariatric surgery require a comprehensive evaluation to allow the identification and optimization of medical problems. This is best achieved by following a multidisciplinary, protocol based process with decisions taken through the bariatric MDT prior to the surgical intervention. Protocols allow vital information to be collated and also permit research orientated practice which will enable the delivery of the best possible care to patients.

Key Learning Points

- All patients should be assessed using a proforma covering the areas set out in Table 10.4.
- Decision making should be supplemented by validated scoring systems.
- Medical comorbidity is an important factor in choice of operation.
- All cases should be discussed by a bariatric MDT setting.
- Further work is required to develop definitive evidence based guidance on preoperative assessment.

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11 Preoperative Dietary Evaluation of the Bariatric Surgery Patient

Mary P.M. O'Kane

Abstract

As an essential member of the bariatric multidisciplinary team (MDT), the dietitian has a key role in assessing, evaluating and preparing the patient for bariatric surgery. Patients presenting for surgery generally have a long history of unsuccessful attempts at losing weight or in maintaining a clinically significant weight loss. Careful assessment and evaluation of the patient is essential to determine the current nutritional status, eating patterns, disordered eating, socioeconomic status and lifestyle, along with the patient's understanding of the surgery and the anticipated results. This assessment will aid the MDT in assessing if the surgery is suitable for the patient. It will also assist in the preoperative planning and preparation, if surgery is scheduled.

This chapter covers the key points in the dietary and nutritional assessment and evaluation of the patient scheduled for bariatric surgery, including the preoperative blood tests and dietetic preparation of the patients for surgery.

Keywords

Weight and dieting history • Diet history • Nutrition assessment • Eating disorders • Food cravings • Dietitian • Preoperative diet • Multidisciplinary team • Preparation for surgery

11.1 Introduction

The majority of patients who opt for bariatric surgery will usually have a long history of dieting over many years. Many will state that they were successful at losing weight however experience difficulties in maintaining the weight loss; hence, bariatric surgery seems to be the only hope. It is essential for patients opting for bariatric surgery to have a complete and comprehensive assessment by a specialist dietitian. This will help determine:

- The suitability of the surgery for the patient
- The patient's readiness for surgery including realistic expectations of outcomes and the weight loss journey
- The preparation needed for surgery
- The support mechanisms required.

The specialist dietitian should be skilled in weight management, possess a good knowledge of bariatric surgery and the impact on nutrition, and should be able to provide behavioral and motivational counseling for lifestyle changes.

11.2 Weight and Dieting History

In the United Kingdom (UK), to be eligible for bariatric surgery on the National Health Service (NHS), patients must have failed to achieve or maintain a clinically beneficial weight loss, by all non-surgical means [1]. Patients may have tried a variety of methods including self-administered diets,

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dietetic consultations, slimming clubs and fad diets. Gibbons et al. [2], in a study involving 83 candidates reported a mean total of 4.7 weight loss attempts, and a mean total weight loss of 61 kg. One third had used weight loss medications and a quarter had used very low calorie diets or weight loss medications.

Ideally, the referral should include a verified report of weight and dieting history. During the dietetic consultation, further information is collected from the patient about their previous weight loss attempts. Occasionally, some patients, especially the younger with less comorbidities and lower BMIs, will report that they have never been on a diet or used weight loss medication [2]. Given that successful results from bariatric surgery are accrued only in combination with dietary modification, it is important that patients do try other approaches before opting for the surgical route [3]. Patients who have not tried to lose weight previously may need additional preoperative support and preparation before undergoing bariatric surgery [3].

11.2.1 Diet History

A diet history is important for assessing the nutritional quality and adequacy of the diet, eating pattern, food frequencies and an insight into the thoughts and perceptions about food. It is a well-known fact that obese individuals are more likely to underreport their food intake than lean people [4]. Individuals are often embarrassed to report their diet to a healthcare professional, for fear of being judged. It should be made clear that this information will be used to assess how best to support them, in order to get the best results from surgery. A diet history of a typical day helps in assessing the usual routine (or lack thereof) of the patient, and where food fits in. The dietitian will be interested in learning about the structure (if any) of the day, meal patterns, cues for eating, frequency of consumption of fast foods, takeaways and snacks, and any other issues around food such as food cravings, night time eating, and binges. Using "a typical day" approach helps in collecting information, including the social circumstances of the patient and where food fits in. Other factors like financial circumstances, employment status, circadian shift patterns, and influences and support from other family members should be considered.

Perceptions about the impact of surgery on diet, hunger and appetite are important. Some patients believe that following surgery, they will no longer experience hunger or food cravings, and that the surgery is a magic cure, whereas in reality, patients may continue with similar eating patterns, for instance missing meals or consuming snacks such as crisps or biscuits [5]. The ability of patients to cook may affect their ability to consume a nutritionally balanced diet before or after surgery. In addition to food groups, information should also be collected about intake of liquids. Some patients may be consuming a high calorie intake in the form of fluids such as milk, milky drinks, soft drinks, fruit juice, smoothies and alcohol. Active alcohol and substance dependence are seen as contraindications for bariatric surgery [6]. Stevens et al. [6] recommend that patient's totally abstain or control the use of alcohol and other substances for at least 12 months before surgery is considered.

Any additional information about medical conditions such as type 2 diabetes mellitus (T2D) and relevant medications, celiac disease, inflammatory bowel disease and irritable bowel syndrome which may influence diet should also be considered. Patients may have food allergies or intolerances that affect their ability to manage a balanced diet. Patients may dislike swallowing medications or might have a needle phobia, and hence, may face difficulties in complying with the recommended vitamin and mineral supplements.

Although this discussion focuses mainly on diet, additional information on the physical activity of the patient should also be collected.

11.2.2 Nutritional Assessment

As part of the dietetic assessment, the nutritional quality of the diet will be evaluated. The patient, although obese, may be suffering from nutritional deficiencies, which need to be corrected prior to surgery.

Within the UK, iron deficiency anemia is seen in 4.7 % of the adult women, and low vitamin D levels have been observed in both men and women [7]. Higher levels of vitamin D deficiency have been reported in the morbidly obese individuals [8], and several studies have reported other nutritional deficiencies in patients presenting for bariatric surgery [9–11]. Multiple factors such as limited knowledge regarding diet, financial constraints, and disordered eating may cause nutritional deficiencies. It is essential to correct any nutritional deficiencies that the patient may have in advance, in order to ensure an optimum nutritional status prior to surgery. Although preoperative nutritional screening should be performed to determine any preexisting nutritional problems [12], this is not always done as a routine examination [13, 14]. The recommended baseline laboratory examinations are listed in Table 11.1.

The quality of the diet is important, because nutritional intake will be compromised in the early stages following surgery. It is essential to discuss with patients the impact of surgery on their diets, with respect to meal patterns, and the type and texture of food, that can be managed after surgery, to fit into their lifestyle. Many studies report deterioration in diet following surgery [5, 15, 16].

Since it is difficult to eat a wide variety of food in the early postoperative stages, any concerns about the nutritional

Table 11.1 Preoperative blood tests

Blood urea and serum electrolytes
Liver function tests
Fasting blood glucose, HbA1C
Lipid profile (fasting)
Complete blood count, serum ferritin, serum folate, and vitamin B12
Serum calcium, 25-hydroxyvitamin D, parathyroid hormone

quality of the diet should be addressed prior to surgery. An adequate protein intake is difficult to maintain following surgery [17] and there are chances that this might deteriorate further [16, 18]. Roasted and grilled meat and poultry are often poorly tolerated in the early stages postoperatively, and hence, alternative methods of cooking and sources of protein should be discussed. For those patients with vitamin D insufficiency or deficiency, the National Osteoporosis Society "Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management" includes treatment schedules for the correction of vitamin D levels [19]. Iron deficiency anemia may be of dietary origin; nevertheless, other causes of chronic blood loss must be excluded. Iron deficiency is best corrected using supplements rather than diet alone, and patients should be counseled on ways to maintain a good oral intake of iron.

11.3 Eating Disorders

Eating disorders are extensively dealt with in Chap. 12, and should be a part of the overall assessment. Depending on the MDT, there may be a complete psychological assessment by a psychologist/psychiatrist, or a mutually agreed screening tool may be used to identify those patients with eating disorders that require further evaluation.

Binge eating is characterized as a loss of control on eating, with the consumption of large volumes of food within a short time period. Patients who suffer from binge eating disorders should be encouraged for bariatric surgery; however, the importance of adhering to the prescribed diet and maintaining the overall weight loss after surgery should be discussed [20]. For some, cognitive behavioral therapy should be offered [3].

11.4 Knowledge of Bariatric Surgery

Many patients would have researched on their own on the different types of bariatric surgery procedures, and may have already decided which procedure they prefer. Some patients may have very limited knowledge of the surgery. Hence, patients should be encouraged to discuss the surgical procedures, their expectations about weight loss, its impact on their diet and lifestyle, and the steps for managing these changes after surgery. Written information should be provided, and patients should be encouraged to attend patient support group meetings. Any misconceptions about surgery should be cleared.

Discussions should focus on the different surgical procedures, their impact on eating patterns, nutritional intake and absorption of micronutrients and macronutrients. The need for nutrition monitoring and nutritional supplements should also be discussed at this stage. Patients should be aware that hypoglycemia and dumping syndrome are more frequently associated with gastric bypass and the duodenal switch requires compliance with a high protein, low fat diet and high doses of fat soluble vitamins. Patients need to be fully informed to help with their decision making process regarding surgery.

11.5 Preparation for Surgery

Although surgery is often viewed as the last option by patients who have failed to lose or maintain a significant weight loss, dietary and lifestyle changes remain the key factors that influence successful postoperative outcomes. Patients will still require lifestyle changes that they would have implemented before. Prevailing diet and nutritional intake issues may persist. Although food cravings may initially decrease after surgery, the possibility that they may return exists [21]. Patients may also expect improved satiety after surgery, and although this is possible, triggers for eating such as boredom should be analyzed along with advice for handling these issues.

As part of the preoperative counseling, the patient should be provided with details about both the rate and amounts of weight loss, and the differences in procedures, due to which there may be variations in results from patient to patient. The gastric band, for instance, will result in slower and steady weight loss than the sleeve gastrectomy and gastric bypass procedures, where the rate of weight loss is dramatic in the first few months. The patient should be aware that following the initial period of weight loss, the focus will be entirely on weight maintenance. It has been reported that many patients overestimate the amount of weight they will lose by surgery, expecting a weight loss of greater than 70 % of excess weight loss [22]. In the same study, nearly one third of patients thought that surgery prevented overeating, rather than facilitated improvements in diet and physical activity. Among the various bariatric surgery techniques, excess weight loss expectations are greatest with the biliopancreatic diversion/ duodenal switch, but even with this technique patients rarely achieve a 100 % excess weight loss.

Optimizing the patient's diet is essential prior to surgery. Whilst there is debate as to whether losing weight prior to surgery is a good indicator of postoperative compliance, Sarwer et al. [18] suggest that the ability to restrict food intake prior to surgery is an indicator of compliance to post-operative guidelines, thus resulting in a greater weight loss. Patients should also be aware that the self monitoring techniques used prior to surgery are also useful following surgery [23]. These include maintaining a food diary, in which they record all that they eat and drink, along with their weight record.

Preoperative sessions have been found to be beneficial to patients in preparing for surgery [24]. There should be a discussion about the phases of the diet following surgery. The meal patterns and types of food textures that may affect compliance should also be discussed along with other factors. High fat snack foods such as crisps, biscuits and chocolate are still easy to consume following surgery.

Postoperatively, there will be a phased approach with the patient being encouraged to start on a liquid diet, before moving on to blended food, a soft diet and more normal textures. Other topics that should be included are the importance of hydration, common problems following surgery and techniques to manage weight on a long term basis [25]. Patients need to be aware that they must eat slowly and chew their food well. Some patients may struggle with this because of poor dentition or lack of cooking skills. Foods which are more likely to get stuck especially in the early postoperative stages include roasted or grilled meats and poultry, bread and pasta [23]. This will lead to discomfort and subsequently vomiting in an attempt to dislodge the food. For some patients, this may result in the development of food intolerances or avoidance of certain types of food. Adequate counseling prior to surgery on the rationale behind the phased approach to diet may help reduce such events postoperatively. Patients should be advised that vomiting or regurgitation of food after surgery is not normal and can ultimately lead to malnutrition. Patients should be forewarned of the risks of maladaptive eating. Soft foods such as ice cream and chocolate or crispy foods such as biscuits and crisps are easily tolerated following surgery, and some people may be tempted to choose these foods as an easier option to a more balanced diet.

In the initial stages, consumption of food and fluids together should be strictly avoided, because of the small stomach pouch, and later because the drinking action may help to push the food, thereby allowing the patient to eat more. Encouraging the patient to practise some habits prior to surgery can be helpful.

The preoperative advice should include preparation on how to manage the diet especially during the early post-operative phases, with a focus on achieving good protein intake. The vitamin and mineral supplements needed and the importance of compliance with these lifelong should also be covered. Patients should be aware that they are making a commitment to complying with long term postoperative nutritional monitoring.

11.6 Dietetic Input into the Multidisciplinary Team

The specialist dietitian, as an essential MDT member, should share the nutritional assessment and evaluation with the team and this should be used as part of the decision making process with regard to the patient's suitability for surgery. If there are concerns about the current nutritional status or ability to comply with the diet following surgery for any patient, these should be discussed. This will help in the decision as to whether surgery is appropriate and when it is most appropriate.

11.6.1 Preoperative Diet

Many bariatric centers will advise patients to follow a low calorie, low carbohydrate diet immediately prior to surgery to reduce the liver volume, and hence facilitate the surgery [26, 27]. González-Pérez et al. [27] reported a significant decrease in the liver size when patients followed a six-week preoperative very low calorie diet. Colles et al. [28] reported an 80 % of the reduction in liver volume within the first 2 weeks. The recommended length of time on a preoperative diet will vary between centers; however, the decrease in the liver size is during the first 2 weeks on the diet [28]. While preoperative diets significantly decrease liver volume, there is only very limited evidence that they improve outcome, or that they reduce the incidence of early complications [29]. There may also be concerns regarding cost, compliance and the catabolic effects of a prolonged diet. T2D patients will usually need reduction of their T2D medications while on such diets, and should therefore be cautioned.

In the UK, a review of current practice demonstrated a lack of consensus, and variability on the types of preoperative diet that are currently used. Baldry et al. recommended that further research was needed to compare outcomes for preoperative diets [30].

Conclusion

A comprehensive assessment, evaluation and patient education by an experienced specialist bariatric dietitian is an essential part of the overall MDT assessment and is summarized in Table 11.2. While surgery acts as a tool for accelerated weight loss, diet, physical activity and lifestyle changes are important for long term weight maintenance. Patients need appropriate support and preparation for bariatric surgery.

Table 11.2 Preparation for surgery

Topics	Dietitian to discuss
Meal pattern and frequency of meals	Importance of regular meals
Types of meals, snacks and drinks	A balanced low-fat diet. Reduced consumption of high fat, high sugar snacks. Avoidance of fizzy drinks and high-sugar drinks.
Binge eating or disordered eating and impact on diet	Control of binge eating. Discuss whether further support/counseling is needed
Nutritional content	Optimizing the nutritional content of the diet prior to surgery. Discuss importance of nutrition following surgery
Triggers for eating	Emotional eating, eating for boredom, food cravings
Behavioral changes	Importance of behavioral changes in weight loss and weight maintenance. Increasing physical activity wherever possible. Achievable goals
Nutritional supplements	Appropriate vitamin and mineral supplements before and after surgery
Introduction of food and drinks following surgery	Discuss the phased approach to diet, food texture progression and portion sizes required. Discuss common problems experienced in initial stages for example, regurgitation and how to avoid it
Cooking skills	Consider cooking skills in discussions regarding dietary changes
Support network	Discuss the various support networks available to the patient following surgery
Lifestyle, including work and shift patterns	How will this impact on the ability to manage diet following surgery? What needs to change?
Impact of bariatric procedure and preparation specific to that procedure	Consider specific recommendations for the bariatric procedure in addition to the general advice. This includes macronutrient and micronutrients, rates of weight loss and expectations around weight loss
Importance of follow up and keeping in contact	Ensure contact number is given and emphasis on keeping in contact and attending review appointments

Key Learning Points

- In the UK, to be eligible for surgery on the NHS, patients must have attempted all non-surgical methods of losing weight, and failed to achieve or maintain a clinically beneficial weight loss.
- Patients must have a comprehensive dietary and nutritional assessment preoperatively, to identify nutritional deficiencies or dietary concerns, including eating disorders.
- Nutritional deficiencies must be addressed prior to surgery, and the patient should be counseled to improve eating patterns and quality of the diet.
- Surgery affects postoperative nutrition, and patients need support in preparing for surgery.

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12 Psychological Assessment of the Bariatric Surgery Patient

Denise Ratcliffe

Abstract

Psychological assessments are often part of the bariatric surgery process and it is important to clarify the purpose and function of these assessments. The purpose of the psychological assessment has shifted from identifying contraindications for surgery and evolved towards assessing psychological and behavioural readiness. Whilst there are higher rates of psychological morbidity amongst bariatric candidates, no single preoperative psychological predictor of outcome has been identified. It is important to assess for psychological readiness for bariatric surgery as the weight loss outcomes are highly dependent on the individual implementing and maintaining significant behaviour changes. Whilst there is significant variability in the methods and outcomes of these assessments, there is general consensus about the domains that should be covered. The chapter will provide an outline of the key areas that should be included in a preoperative bariatric psychological assessment. The psychologist undertaking the assessment needs specific experience and knowledge of bariatric surgery as well as the preoperative and postoperative issues that may arise. The assessment should lead to individualised recommendations and possible psychological interventions in order to minimise the impact of psychological risk factors on outcomes. The psychological assessment may generate useful clinical information for other members of the multidisciplinary team. The assessment is an opportunity to help individuals make informed decisions about bariatric surgery. It also helps to raise their awareness of the presurgery preparatory behavioural changes they are recommended to make to optimise their postoperative outcomes.

Keywords

Preoperative psychological assessment • Psychological contraindications • Psychological readiness and preparation • Treatment recommendations

12.1 Rationale for Psychological Assessment in Bariatric Surgery

There has been a significant increase in the number of individuals seeking bariatric surgery in the recent years. This is due to a combination of increased rates of morbid obesity as well as increasing evidence that bariatric surgery is the only very effective treatment for severe obesity and its comorbidities [1]. Psychological assessments are often included in the assessment of individuals requesting bariatric surgery for various reasons. Whilst bariatric surgery is the most effective means of losing weight and maintaining weight loss in the severely obese, weight loss outcomes are dependent on the individual making and maintaining long term, restrictive behavioural changes. The individual's weight and dieting history would imply that these behavioural changes are likely to be uncongenial or difficult to maintain.

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Aside from the specific challenges of implementing and maintaining required behavioural changes, there are higher rates of mental health difficulties amongst this population [2, 3]. A psychologically vulnerable group are being assessed for a psychologically challenging surgical procedure. Although the weight loss outcomes of surgery are generally positive, there are individual variations with at least 20 % of individuals experiencing weight regain or poor weight loss [4]. It is likely that these individual variations in outcomes are partly attributable to psychological or behavioural factors and therefore, identification and management of these factors is important.

Psychological assessment in bariatric surgery can be challenging because of the lack of evidence-based guidelines regarding the process, content and outcomes of such assessments. This has led to significant variation. Furthermore, there are different views on the purpose of preoperative psychological assessments and this clearly influences the assessment focus and process as well as possible outcomes.

12.1.1 First Generation Psychological Assessments: Identification of Contraindications

12.1.1.1 Empirical Evidence Regarding Psychological Contraindications

Historically, the underlying driver for these assessments has been the identification of psychological factors which facilitates identification of suitable and unsuitable candidates and enables better prediction of weight loss outcomes. Despite the high rates of psychological morbidity amongst individuals seeking bariatric surgery, clear psychological or psychiatric predictors of weight loss outcomes have not been identified [5]. The reasons for the lack of empirical evidence regarding clear psychological predictors include an overemphasis on psychiatric diagnoses rather than behavioural factors, as well as variation in methodological approaches and measurement of constructs leading to difficulties in making meaningful comparisons.

12.1.1.2 Consensus Evidence: Clinician's View of Psychological Contraindications

An alternative source of information about potential psychological contraindications comes from studies where data has been collected from clinicians who conduct these assessments. Bauchowitz et al.[6] reported data on psychological evaluations from over 80 bariatric programs in the USA and identified a number of psychological disorders that were considered to be "definite" contraindications by the vast majority of the mental health professionals participating. These included current substance misuse, active or unmanaged symptoms of serious mental illness (for example, psychosis, bipolar disorder, etc.), suicide attempts, severe learning difficulties and poor knowledge about surgery. However, there was wide variation in opinions regarding other commonly occurring conditions (such as depression and binge eating disorder) with many clinicians indicating that they would consider these to be "possible" contraindications. In another study, Fabricatore et al. [7] found that the most commonly identified contraindications were similar to those reported above although no specific condition was considered a definite contraindication by more than 45 % of respondents. A significant proportion also identified non-psychiatric contraindications such as non-adherence, lack of knowledge about surgery and unrealistic expectations. It is interesting that clinicians seem to emphasise the importance of behavioural factors in their assessments and recommendations whereas the empirical literature has tended to focus primarily on psychiatric disorders as potential contraindications. The assessment should focus on whether the psychiatric condition is likely to impact on the individual's ability to adhere to postoperative recommendations rather than just the absence or presence of the psychiatric condition. This could partially explain the lack of predictive power of psychiatric diagnosis on outcomes.

12.1.2 Second Generation Psychological Assessments: Psychological and Behavioural Readiness

Some have interpreted the lack of consistent psychological contraindications to bariatric surgery as evidence that psychological assessments are unwarranted [8]. However, others have clarified and redefined the purpose of the preoperative psychological assessment as moving beyond information gathering to create an opportunity for increasing awareness and providing psychoeducation [9, 10]. The assessment is conceptualised as an opportunity to identify psychological factors that may facilitate or hinder the individual's weight loss outcome and offer recommendations and where appropriate, interventions to counteract these. While specific psychiatric conditions are not necessarily considered to be absolute contraindications, there is some evidence that these may be risk factors for suboptimal outcomes [2, 9]. Explaining the hypothetical pathway by which the risk factor may impact upon the weight loss outcome is likely to improve understanding and engagement since patients are usually highly motivated to lose weight. Identifying these risk factors and offering interventions to minimise their impact on outcomes is a more helpful, constructive and collaborative model of preoperative assessment. This approach to assessment also takes into account the significant physical benefits that individuals are likely to derive from bariatric surgery and the ethical dilemma associated with denying severely obese individuals access to surgery when clear evidence about psychological contraindications is not available [7]. A further advantage of this approach is that it generates clinical information that may influence the way other team members work with the patient. In this chapter we will focus on the latter approach to psychological assessment whereby the psychological assessment is positioned as an integrated aspect of the bariatric surgery process rather than an antecedent.

It is important that these assessments are provided by a qualified mental health professional who can contextualise, formulate and understand the significance and potential implications of the psychological information provided and generate individualised, meaningful treatment plans. These preoperative psychological assessments go beyond a generic psychological assessment to incorporate aspects which are specific to bariatric surgery such as knowledge of surgery, risks and benefits of surgery, and expectations for weight loss [10]. This means that clinicians undertaking such assessments need skills and experience which allow them to straddle mental health and behavioural medicine as well as specific knowledge and experience of bariatric surgery, obesity and eating issues that arise pre and post-surgery [11]. In light of the variation in practice and the ethical implications of denying or deferring surgery, regular clinical supervision is essential in order to have a mechanism for reviewing the recommendations and outcomes of assessments.

12.2 The Assessment Process and Content

12.2.1 Methods of Assessment

The vast majority of clinicians utilise clinical interviews which are supplemented with psychological questionnaires and tests [7, 12]. Comprehensive reviews of the supplementary questionnaires and tests that have been widely used in preoperative psychological assessments have been previously published in the literature [13, 14]. Assessments usually take place over a series of appointments as the clinician is likely to want to review the individual's capacity to implement recommendations arising from the assessment.

12.2.1.1 Semi-structured Interviews

In order to address the variation in assessment methods, a number of semi-structured interviews have been developed that provide a framework to standardise the information gathered. The Weight & Lifestyle Inventory [14]) is a self-report instrument designed for obesity rather than bariatric surgery although it has been successfully used with this patient group. There are also a couple of interviews and assessment tools which have been developed specifically for the preoperative psychology assessment [11, 15].

Key Areas Included in the Clinical Interview

There are a number of sources of information about the key areas to assess in a preoperative psychological assessment, including American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines [16], consensus evidence [7, 10, 12] and emerging empirical evidence highlighting the importance of certain psychological factors [9, 17, 18].

Reasons for Seeking Surgery

It is important to understand the context and rationale for the patient's decision to request bariatric surgery. This includes obtaining information about specific reasons for the request, their rationale for why they wish to have bariatric surgery at this particular time-point and their expectations regarding how surgery will address the current problems that are driving their request.

Weight and Dieting History

It is helpful to obtain a timeline and trajectory of the individual's weight, particularly focusing on any significant weight gains and losses and their interaction with significant life events. Identifying the patient's attributions about their weight difficulties may provide an insight into their engagement with future changes. Information on the rapidity of weight losses and gains may be helpful in assessing whether the individual is prone to all-or-nothing approaches which are likely to be unsustainable or unhelpful. This also provides an insight into ways in which the individual has previously attempted to manage their weight, including any tendencies to choose radical, short-term options. There is a continuum from healthy weight loss approaches to extreme approaches to dieting, to eating disordered approaches (see below). Identifying factors which may have been associated with the individual abandoning their diet or behavioural changes can highlight vulnerability factors that could lead to future lapses.

Eating Patterns

Gaining an insight into the individual's daily eating patterns and habits is helpful. In particular, their food preferences and dislikes which may affect their ability to adhere to postoperative guidelines. Gathering information about their current meal pattern plus their ability to organise and maintain a meal structure is important. Other factors such as their ability to identify hunger and satiety and to identify longstanding beliefs and rules (for example, "you should always clear your plate") which may impact on their eating, are important. Requesting information about changes which the individual has introduced to prepare for surgery can give an insight into their understanding of the importance of behavioural change for those undergoing bariatric surgery.

Current and Past Eating Disorders

Binge eating disorder (BED) is the most common eating disorder in candidates for bariatric surgery with approximately 25 % fulfilling the diagnostic criteria [19]. BED is characterised by episodes during which the individual objectively eats large quantities of food. Such episodes are accompanied by a subjective feeling of loss of control over eating and some other signs such as guilt after eating, secret eating, rapid eating, and the absence of compensatory behaviours seen in bulimia nervosa. It is important to identify if binges are triggered by uncontrolled hunger which arises through irregular, chaotic eating or if they are emotionally triggered. Whilst BED is not necessarily considered to be a contraindication for surgery, it is important to carefully assess for its presence as some individuals may require preoperative treatment or, at the very least, will require active monitoring postoperatively [17]. Individuals with preoperative binge eating difficulties are more likely to experience postoperative "loss of control eating" (in theory postoperative patients would be unable to meet BED diagnostic criteria) and self-induced vomiting for weight and shape reasons. Whilst this is not the case for all individuals who have preoperative binge eating disorder, it is not currently possible to predict which individuals will have a recurrence of this problem and therefore education is very important, particularly as postoperative loss of control over eating is associated with suboptimal weight loss [17, 20].

Bulimia nervosa is differentiated from binge eating disorder by the presence of compensatory or purging strategies, most commonly vomiting or laxative misuse, following eating. Chen et al. [21] found that 8.5 % of pre-surgery individuals used compensatory strategies but this was not related to weight loss outcomes 1 year following surgery. The authors note that their findings differ from clinical guidelines and opinion whereby current use of compensatory strategies is considered a cause for concern. It is important to ensure that the individual has alternative coping strategies in order to avoid postoperative recurrence when they experience potential triggers such as weight loss plateaus. The individual should engage in psychological treatment to address this prior to surgery because ongoing purging can lead to physical complications (such as nutritional deficiencies, dehydration, cardiac arrhythmias, etc.) following surgery. Aspects of surgery such as spontaneous vomiting or 'dumping' syndrome can offer people novel methods of purging or make it easier to return to pre-existing purging.

Night eating syndrome (NES) is defined as the consumption of more than quarter of daily calories after the evening meal, poor sleep and morning anorexia. Some individuals will also wake during the night and eat. While prevalence rates vary widely, it is clear that this problem is more common in bariatric candidates than the general population [22]. The impact on weight loss outcomes is not clear currently although the presence of NES appears to be a marker of psychological co-morbidity and complexity [23].

Many patients present with eating difficulties which do not meet diagnostic criteria for an eating disorder but can potentially lead to postoperative difficulties. Emotional eating, which involves eating in response to specific emotions (for example, stress, boredom, and sadness) is problematic if it is the individual's main way of coping with these feelings, particularly as surgery will not necessarily address the factors that trigger these feelings. The eating pattern described as "grazing" involves individuals eating small amounts of food repetitively in a mindless and unplanned manner. It is important that patients are aware that mindless eating is a risk factor for poorer outcomes [24].

Eating Disorder History

In addition to assessing for current eating disorders, it is helpful to enquire about previous eating disorders as some individuals migrate across diagnoses over time. Data is not widely available regarding the prevalence of this in bariatric populations but recent work has shown that individuals who developed a postoperative eating disorder were more likely to have had a history of other eating disorders [25].

Understanding and Knowledge of Their Role in Surgery

Patients are asked to describe their understanding of the surgery, the pre- and postoperative guidelines that they need to follow and their view of how surgery may work for them. It is helpful to assess the individual's understanding that bariatric surgery is a "tool" that they need to work with rather than a cure. Caution is also needed if the patient tends to over-rely on the surgery as the catalyst for change or to create some kind of 'threat' based motivation. It can be useful to gather information about other lifestyle changes that individuals have made and whether these were maintained (for example, smoking cessation). Adherence with other medical recommendations and regimes such as adherence to the use of continuous positive airway pressure (CPAP) for sleep apnoea can be used as an approximate gauge of how well the individual listens and responds to guidance from healthcare professionals as this is crucial following bariatric surgery.

Expectations of Outcome

It is important to gather information about the patient's expected outcomes following bariatric surgery; this includes expected and acceptable weight loss outcomes as well as other relevant domains such as changes in mobility, pain, and appearance. Individuals are usually given an estimate of the typical weight loss they could expect following bariatric surgery and it is helpful to assess whether their expectations converge or diverge. In addition to the amount of weight loss, it is important that patients have realistic expectations about weight loss plateaus and the potential for weight regain.

It may be important to assess the patient's understanding and awareness of excess skin resulting from massive weight loss, especially when funding for body contouring surgery may be limited. Excess skin is a significant source of distress for many postoperative patients. Individuals should make an informed decision about bariatric surgery based on realistic information [26].

Mental Health

As outlined previously, there are higher rates of psychiatric disorders amongst bariatric candidates but simply looking at whether an individual has a specific mental health diagnosis does not predict outcomes. However, those individuals who have two or more psychiatric diagnoses (regardless of the type) have significantly worse outcomes [27]. In the assessment, past and current mental health difficulties must be considered in so far as they may impact on the individual's ability to understand and implement the behavioural change required. If an individual has severe mental health problems (for example, severe depression that impacts on motivation, volition and memory) that may impact on their ability to implement change, they may need specific treatment for these difficulties first. In terms of current mental health problems, it is important to obtain information about their manifestation, stability, duration, psychotropic medication (particularly ones which affect appetite and weight), psychological therapy (particularly evidence-based therapy and whether therapy has helped). It is important to ascertain if the individual has a history of deliberate self-harm or suicide attempts as well as the time elapsed since the most recent episode. There is emerging evidence of increased suicide rates following bariatric surgery [28] and a history of suicide attempts is known to be a predictor of future attempts. Clearly, the psychologist assessing a person prior to bariatric surgery should liaise with professionals already providing the individual with mental health treatment. They should obtain their perspective on the stability and complexity of the individual's mental health and ascertain their future plans regarding support.

It is important to carefully consider the balance between the potential benefits of recommending further treatment for mental health problems versus the physical costs associated with delaying bariatric surgery, particularly in light of the fact that patients who are deferred are less likely to return for surgery [11]. It is important to recognise that psychological and/or psychiatric treatment may not necessarily lead to the greatest improvement in the individual's mental health [29].

Substance Misuse

One study [2] reported that 32.6 % of candidates undergoing bariatric surgery had a history of substance use disorders; yet, very few (<2 %) met the criteria for a diagnosis at the preoperative stage. There is increasing evidence of postoperative alcohol problems, particularly amongst those who have a gastric bypass and personal histories of alcohol problems [30]. The assessing clinician needs to ensure that the individual has adequate coping skills and resources to avoid this, particularly in those who have had recent difficulties. It is widely accepted that individuals who have current substance misuse problems should be deferred from surgery and referred onwards to a substance misuse service in order to help them reduce their dependency or become abstinent.

Trauma and Abuse

There are higher rates of abuse and traumatic experiences in the bariatric population [31] and individuals often disclose this for the first time during the preoperative psychology assessment. While this is not relevant in terms of assessing suitability or predicting outcomes, it is important to consider whether it has any relationship with the individual's eating (such as eating in response to flashbacks or to self-soothe) or weight (for example, higher weight is used to avoid reactivation of trauma memories associated with the lower body weight). Furthermore, it is important to consider the impact that rapid and significant weight loss may have on the individual's sense of vulnerability or how they may cope with increased attention from others following surgery.

Weight Stigma

Many obese individuals report experiences of being stigmatised and ostracised because of their weight. It may be helpful to enquire about this as studies have shown that those who have experienced weight stigma are at significantly increased risk of binge eating disorder [32]. This can also lead to avoidance of social situations and exercise and reinforce isolation, all of which are related to binge eating and mood disorders.

Relationships and Support

It is important to consider the support systems available to the individual and whether the key individuals in their life support or oppose their request for bariatric surgery. Those people will also be affected by changes in the individual's eating habits and it is important that they provide support and encourage adherence rather than sabotage the postoperative regime. The potential impact of bariatric surgery and weight loss on interpersonal relationships should be discussed with the individual. It is helpful to consider the individual's relationship to the bariatric team including attendance, engagement and functional communication, especially given the power imbalance and potential for anger, hurt and frustration on both sides and impact of pre-existing mind-sets such as previous experiences of weight stigma from health professionals. Recommendations can be provided to the patient and team about how helpful effective communication can be fostered.

Stability and Stressors

Obtaining information about the stability of the individual's life circumstances and potential for major stressful life events is important when considering whether this is the most appropriate time for bariatric surgery. The assessment should not just focus on the identification of problems and vulnerability factors but should also highlight the individual's strengths and protective factors such as personal resilience, support network, stable job, etc.

12.3 Outcome of Assessments

There are a number of possible outcomes and recommendations which may arise from the psychological assessment. Walfish et al. [12] reported that overall less than 15 % of individuals were delayed or denied access to bariatric surgery following psychological assessment, however there was significant variation in these rates with 4 % of participating clinicians delaying or denying more than 50 % of candidates. Interestingly, one study [7] found that clinicians with more experience of conducting assessments deferred or denied fewer individuals. Heinberg et al. [10] reported that following assessment, 3 % of candidates were not considered suitable for bariatric surgery and 26 % required additional psychological intervention prior to surgery a figure similar to that reported by Fabricatore et al. [7]. Overall the number of patients declined surgery is very low but a significant proportion are recommended to have further psychological input prior to surgery. The type of recommendations for psychological input ranges from self-help using recommended books and leaflets, guided self-help and attendance at support groups to formal psychological therapy. The clinician may also highlight circumstantial or lifestyle issues which could be problematic following surgery—for example, it may be useful for the individual to try and negotiate changes in work patterns if they have an erratic shift pattern or irregular breaks.

Conclusion

The psychological assessment has moved beyond simple information-gathering and identification of contraindications to surgery. The preoperative psychological assessment should lead to the identification of psychological factors which may facilitate or jeopardise weight loss and other psychosocial outcomes from bariatric surgery. The assessment should lead to the generation of individual recommendations and possible psychological interventions in order to minimise the impact of psychological risk factors on outcomes. The psychological assessment generates useful clinical information for other members of the multidisciplinary team. The assessment is an opportunity to help individuals make informed decisions about bariatric surgery and raise their awareness of preparatory behavioural changes to work on prior to surgery to optimise their outcomes. The preoperative psychological assessment should be integrated into the bariatric surgery pathway and should be routine for all patients seeking bariatric surgery.

Key Learning Points

- While there are no single preoperative psychological factors that are considered to be contraindications, there are certain psychological and behavioural risk factors that may be associated with poorer outcomes.
- The preoperative psychological assessment should focus on identifying the individual's psychological and behavioural readiness for bariatric surgery rather than "gate-keeping."
- The assessment should lead to the generation of recommendations and possible psychological interventions to ameliorate the impact of psychological risk factors that could lead to suboptimal psychological and weight loss outcomes.
- The assessment needs to go beyond a generic psychological assessment to incorporate issues that are specific to bariatric surgery. These assessments should be conducted by psychologists who have specialist knowledge of bariatric surgery and the pre- and postoperative issues that can arise.
- In addition to generating information which is useful to the multidisciplinary team, the preoperative psychological assessment generates information which can assist patients in making informed decisions about bariatric surgery as well as helping them prepare for future issues that could jeopardise their goals for surgery

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Anesthesia Considerations in the Obese Patient for Bariatric Surgery

13

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Abstract

Provision of bariatric surgery in the United Kingdom (UK) has grown exponentially since the turn of the century with consequent increase in the requirement of anesthesia for morbidly obese patients. In this chapter we outline key considerations for safely managing this challenging patient group and highlight areas where care may differ from standard anesthetic practice. Particular consideration is given to the importance of specialist anesthetic involvement in a multidisciplinary team (MDT) working at the pre-assessment clinic and the value of a team-based approach throughout the care pathway. We outline the importance of ensuring the availability of basic equipment such as large chairs, patient gowns, high-weight theatre tables and electric beds.

Effective preoperative assessment and investigations are outlined with discussion of determining appropriate levels of postoperative care. Particular mention is made the importance of identifying and optimizing obstructive sleep apnea, heart failure and metabolic disease. Anesthetic techniques are discussed including correct positioning of patients prior to anesthesia, pre-oxygenation and determining appropriate drug regimes aiming for short acting agents with sparing opioid use. Morbidly obese patients are at higher risk of venous thromboembolism than the general population. Suggestions are made for minimizing the risk.

Anesthesia for bariatric surgery in the UK is very safe, but the margin for error is small. Patient safety is best assured by meticulous attention to detail, appropriate training and care delivered by experienced staff.

Keywords

Anesthesia • Multidisciplinary Team (MDT) • Venous Thromboembolism (VTE) • Preoxygenation • Drug dosing in obese patients • Continuous positive airway pressure (CPAP) • Total intravenous anesthesia (TIVA) • Obstructive Sleep Apnea • Risk stratification

13.1 Introduction

Obesity is an increasingly worrying public health and economic burden for the United Kingdom (UK). The development of bariatric surgery offers both individual patients and health commissioners an effective option for long term treatment of morbid obesity. The popularity of bariatric surgery has increased as it has been shown to be effective not only in producing long term weight loss but also in helping to

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ameliorate chronic metabolic conditions including Type 2 Diabetes (T2D). Since the turn of the century, provision of the UK bariatric surgery has grown exponentially [1, 2]. As a result, a large number of anesthetists are practicing anesthesia for bariatric patients. Whilst much of the management of this patient group is consistent with the careful provision of anesthesia to any obese patient, there are specific strategies that will avoid common problems and allay many of the concerns.

As an overall principle, anesthesia for bariatric surgery is best practiced by anesthetists, with a specialist interest, who conduct anesthesia for morbidly obese patients on a regular basis. The added value of the regular anesthetist is more than in-theatre clinical expertise; it is the specialist involvement in the preoperative assessment and multidisciplinary team (MDT) management.

13.2 UK Bariatric Anesthesia

The sustained growth in requirement for bariatric surgery has led to commissioners, specialist societies and providers recommending standards of care which encompass the whole surgical patient pathway. The overall safety profile of bariatric surgery in the UK is excellent [3, 4]. In addition, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) reported on bariatric surgery in 2012 [5]. Among the key recommendations in this report were:

- Specialist associations involved with bariatric surgery should provide guidance on the number of procedures surgeons and hospitals need to perform to optimize patient outcomes.
- All patients must have access to the full range of specialist professionals appropriate for their needs in line with NICE guidelines.
- There should be greater emphasis on psychological assessment and support at an early stage in the care pathway.
- A deferred two-stage consent process must be in place so benefits and risks can be clearly spelt out, and not carried out on the day of surgery.

Although there are currently no recommended minimum numbers of cases per year for anesthetists, the available guidance suggests that all specialist units should have specialist anesthetists with experience in bariatric anesthesia. Anesthetist attendance at the multi-disciplinary team (MDT) process should be mandatory. It is not recommended that anesthetists with little experience of bariatric anesthesia undertake anything other than the most straightforward cases.

The subspecialty, bariatric anesthesia, had led the anesthetic community to develop safe practice in anesthesia for morbidly obese patients, in all other specialties. The Society for Obesity and Bariatric Anaesthesia (SOBA) (www.sobauk.com) was established in 2008 to provide a forum and representation for bariatric anesthetists, as well as to provide comprehensive education in the management of morbidly obese patients for non-specialist anesthetists.

13.3 Preoperative Care

Patient assessment prior to bariatric surgery is important to inform the planning of the anesthetic technique, anticipate potential problems and importantly to build rapport and educate patients about the surgical process. Many morbidly obese patients are aware that they are at higher risk for anesthesia and are consequently often quite anxious [6]. Preoperative assessment should ideally be carried out as a part of the MDT assessment. Many hospitals operate a 'one stop' clinic approach, enabling the team to discuss and plan care, for each patient at a single clinic. MDT working is now a mandatory part of UK NHS bariatric surgical practice [7]. The structure and membership of the MDT is according to local agreement, but should certainly include a specialist anesthetist [4]. This is discussed further in Chap. 15.

Clinical evaluation by an anesthetist should focus particularly on the following aspects (Fig. 13.1):

13.3.1 Cardiovascular Disease

Obesity itself constitutes an important cardiovascular risk factor. Arterial hypertension, ischemic heart disease (IHD), atrial fibrillation, and heart failure are more frequent in the morbidly obese than in the general population.

Fig. 13.1 Measurement of abdominal circumference

Fig. 13.2 Forearm blood pressure cuff measurement

13.3.1.1 Arterial Hypertension

Arterial hypertension is very common and should be managed in the same way as in non-obese subjects. In our experience, non-invasive blood pressure measurement using forearm blood pressure measurement is sufficient in most cases (Fig. 13.2). While an arterial line may be necessary on occasion, it is very rarely required.

13.3.1.2 Ischemic Heart Disease

Signs and symptoms of ischemic heart disease in the obese patients are similar to those in patients with normal weight. In the presence of established disease, the decision whether to advise for or against revascularization therapy prior to bariatric surgery can be very delicate. An important consideration is that coronary artery stenting prior to bariatric surgery will necessitate postponement of weight loss surgery for many months and in case of drug eluting stents, even a year. Any perioperative risk reduction that might be achieved by coronary stenting is not easy to quantify and has to be balanced very carefully against the risks of withholding bariatric surgery for a prolonged period of time.

13.3.1.3 Heart Failure

The incidence of heart failure (HF) increases with increasing body mass index (BMI) and advancing age. In a study following up nearly 6000 Framingham Heart Study participants over 14 years, the age-adjusted cumulative 10-year incidence of HF was 6.8 % in obese women and 10 % in obese men, while the risk of developing heart failure increased five percent in men and seven percent in women with every 1 kgm^{-2} increment in BMI [8]. The study population did not include any super- or mega-obese subjects, in whom the incidence of heart failure can be expected to be considerably higher.

Obesity cardiomyopathy, as the term suggests, is a form of global heart failure that arises as a consequence of obesity and its associated conditions along common pathophysiological pathways. This situation is frequently compounded by the presence of arterial hypertension. The increased cardiac workload renders the morbidly obese prone to develop left heart failure. Obstructive sleep apnea (OSA) and especially the much under-diagnosed obesity hypoventilation syndrome (OHS) also predispose to right heart failure.

13.3.1.4 Cardiovascular Assessment

Morbid obesity not only places the patients in a high risk cohort, but also renders them unsuitable for many forms of cardiac investigations as they are often severely restricted in their mobility. This means that it is often not possible to assess functional cardiac reserve or identify coronary flow limitation on clinical grounds and the range of cardiovascular investigations that can be expected to yield useful information is limited. Echocardiography is often of little value due to poor image quality. Scanners (Computed tomography (CT), Magnetic resonance imaging (MRI)), tables and cameras are often subjected to weight and spatial restrictions. Cardiopulmonary exercise testing (CPET) [9] has been validated in that a reduced anaerobic threshold of <11 ml/kg/min has been shown to be associated with an increased risk of postoperative morbidity and length of stay. However, CPET tends to be only suitable for the minority of patients who are actually able to exercise, and therefore usually fall in a lower risk stratum anyway. A shuttle walk test may provide an alternative method of assessment. All patients should have a preoperative electrocardiography (ECG) (See Table 13.1).

Many morbidly obese patients are short of breath on exertion; however, this is not necessarily due to a pathological cause. Whether or not it reflects heart failure can be a difficult question that requires the input of experienced clinicians. Echocardiography may be of some use but may be difficult due to body habitus. In patients with suspected or proven OSA, signs of left or right heart failure should be actively sought.

Table 13.1 Suggested pre-operative investigations

System		Tests to consider pre-op
Cardiovascular	IHD	ECG, angiography
	Heart failure	Echo
Respiratory	OSA	STOP Bang questionnaire, sleep studies
	OHS	Arterial blood gas
Functional status		Shuttle walk test
		CPEX testing
Endocrine	Diabetes	Finger prick blood sugar level
		HbA1c or fasting glucose

13.3.2 Obstructive Sleep Apnea (OSA) and Obesity Hypoventilation Syndrome (OHS)

OSA is very common in the obese, and is particularly dangerous because it predisposes to airway obstruction and respiratory arrest in the postoperative period. Diagnosis of OSA should be actively sought. Many questionnaires and scoring systems exist to help identify these patients. SOBA recommend using the STOP BANG score [10]. The commonly used EPWORTH [11] score is a sleepiness assessment and not a specific for diagnosing OSA. Patients with suspected OSA should be investigated preoperatively, with sleep studies or overnight oximetry to diagnose OSA or the more serious OHS. The latter is characterized by the persistence of hypercapnia during the daytime (See Table 13.2). Many bariatric MDTs would advise treating patients with confirmed OSA or OHS with non-invasive ventilatory support (NIV) for a few weeks prior to bariatric surgery, although there is limited evidence as to whether this decreases the postoperative morbidity.

Many morbidly obese patients appear to suffer from 'asthma'. Whilst undoubtedly some patients do have pure asthma, a percentage of patients wheeze due to small airways collapse, which is related to obesity. This is not reversible with bronchodilators. Often the wheeze improves with weight loss and it is worth questioning the diagnosis of asthma in morbidly obese patients, particularly if the onset has been later in life as the patient's weight increases.

13.3.3 Fat Distribution

Although body mass index is the most commonly encountered measure of obesity, it is useful to make an assessment of the fat distribution pattern for an individual. Typically fat distribution has been described as 'apples' if the majority of the weight is distributed centrally around the abdomen and 'pears' if the weight is distributed predominantly around the thighs. Central obesity has been associated with increased risk of co-morbidities, such as the metabolic syndrome (dyslipidemia, hypertension and T2D) and may lead to greater difficulties with anesthesia due to impaired ventilatory mechanics [12]. Patients thought to be at particularly increased risk are those with a waist circumference of over 88 cm in women or 102 cm in men. Mortality risk stratification in bariatric surgery is discussed in Chap. 14.

Table 13.2 Diagnostic criteria for obesity hypoventilation syndrome

BMI >30 kg/m^2
Awake arterial hypercapnia ($PaC0_2$>45 mmHg)
(Rule out) other causes of hypoventilation
Polysomnography reveals sleep hypoventilation with nocturnal hypercapnia with or without obstructive apnea/hypopnea events

13.3.4 Airway

Morbid obesity constitutes a major risk factor for airway complications. Most of the reasons are common and well recognized, however it is worth bearing in mind that obesity can be associated with rare conditions (for example, acromegaly and genetic abnormalities) which are liable to further compound the difficulty in airway management. In the UK, the fourth National Audit Project of the Royal College of Anaesthetists (NAP4) [13] has demonstrated that morbidly obese patients are four times more likely to suffer severe airway-related morbidity (Intensive care unit (ICU) admission, surgical airway formation, hypoxic brain damage) or mortality than the general population.

Important considerations for preoperative planning as well as the conduct of anesthesia are:

- Obesity is a risk factor for developing T2D, hiatus hernia and gastro-esophageal reflux.
- Hypoxemia under anesthesia occurs much faster in obese patients than in non-obese subjects, thus dramatically shortening the safe apnea time, during the induction of anesthesia. Due to their cranially displaced diaphragm and associated basal lung atelectasis, obese patients typically have very small functional residual capacity, which is often exceeded by their closing capacity. Available oxygen stores are therefore diminished and gas exchange is impaired. On the other hand, basic metabolic demand and oxygen consumption are increased and contribute to rapid desaturation, allowing the anesthetist little time to achieve adequate ventilation. It follows that pre-oxygenation is of fundamental importance and has to be performed absolutely meticulously every time.
- Difficulty in facemask ventilation is more common in obese patients. Apart from the presence of obesity itself, independent predictors of difficult or impossible facemask ventilation that are distinctly associated with obesity are: a large neck circumference and the presence of a positive snoring history or OSA. Factors that are not necessarily associated with obesity, but nevertheless compound difficulty in facemask ventilation are: poor Mallampati score, limited jaw protrusion, male gender and the presence of a beard.
- Difficulty in laryngoscopy is not more common in the obese than in the general population, provided patients are correctly positioned with their torso elevated (sometimes called head-elevated-laryngoscopy or simply "ramped" position). The hallmark of this position is that the jugular notch and the tragus of the ear should be on the same horizontal level.

- While there is currently no indication to suggest that failed tracheal intubation occurs more frequently in the obese compared to the non-obese population, the published evidence with regard to intubation difficulty is conflicting. NAP4 indicates that the incidence of difficult or delayed intubation is indeed higher in the obese (13.2 %) versus the non-obese (10 %).

13.3.5 Preoperative Optimization

Patients should be encouraged to change any modifiable risk factors prior to surgery.

Smoking: Smoking is associated with lower survival rates following obesity surgery [14] and impaired postoperative wound healing. Patients should be strongly advised to stop smoking for several weeks preoperatively.

T2D: It is more common in the obese population. Good diabetic control is represented by glycosylated hemoglobin, HbA1c, of less than 69 mmol/mol (8.5 %). Referral to a specialist diabetic team for optimizing diabetic control preoperatively may be useful for patients not meeting the target [15]. T2D frequently improves dramatically after bariatric surgery, often within days. Postoperatively, patients with T2D need careful follow up and advice about diabetes management. Frequently, medications can be stopped completely or significantly reduced. Patients with uncontrolled diabetes achieved a significant improvement in diabetic control with both bariatric surgery and medical management than compared to medical management alone [16].

OSA: Treating OSA preoperatively with continuous positive airway pressure (CPAP) is recommended, although evidence for its efficacy is lacking. There is evidence that both anesthetists and surgeons regularly miss the signs that a patient may suffer with OSA [17].

Patient expectations: Discussing patient expectations at the preoperative assessment clinic can improve the patient experience by emphasizing the importance of early mobilization, an analgesic strategy minimizing the use of opioids and highlighting the potential for difficult venous access.

Dignity: This is a very important consideration in the obese patient group. It is important to ensure that all patients have access to an appropriately sized theatre gown. There should also be floor mounted toilets and appropriately sized patient chairs (Fig. 13.3), wheelchairs and hoists in all clinical areas (13.4 and 13.5).

13.4 Perioperative Care

Anesthetizing the morbidly obese patient is a challenge for the entire theatre team. All team members need to be aware of the difficulties and understand the processes and equipment to minimize risk. The Preoperative safety brief should include details of the patient's weight (See Fig. 13.6), BMI and any medical problems which may be relevant. Key points for the team to focus on are manual handling, patient transfers, induction of anesthesia including failed intubation planning and safe patient positioning. Recovery staff also needs to be briefed regarding specific requirements such as CPAP therapy and postoperative care level should be clarified. Sufficient staff must be immediately available for the

Fig. 13.3 Waiting area with chairs suitable for morbidly obese patients

Fig. 13.4 Bariatric wheelchair

Fig. 13.5 Floor mounted weighing scales

Fig. 13.7 Bariatric patient being weighed preoperatively

Fig. 13.6 Floor mounted toilet

duration of the operation, should the patient need to be moved in an emergency.

Appropriate equipment must be available to safely manage the patients with raised BMI. The theater table (See Fig. 13.9) should be checked for its maximum weight capacity and consideration should be given to the positioning of the patient as the weight limit may be reduced for certain table positions. Table attachments should be available in order to enable the patient to be easily placed in the ramped position (Fig. 13.7, 13.8, 13.9 and 13.10). Foot supports are particularly helpful and arm boards may be needed to provide additional width. In order to position the patient correctly for extubation and to assist with postoperative care, all morbidly obese patients should have an electric bed. An inflatable air cushion transfer mattress. Hover mattress (Fig. 13.11) is helpful to assist with the transfer of the patient from the theatre table back to the bed.

If possible, the patient should be anesthetized in theatre to minimize manual handling during transfers and ideally should be asked to position themselves on the theatre table. It is useful to fix the table in the ramped position prior to positioning. The ramped position has been demonstrated to give improved glottis views when the tragus of the ears is level with the sternum and assists with effective pre-oxygenation [18, 19]. There are currently several bespoke devices on the market that are specifically designed to help achieve; This although in our

Fig. 13.8 Operating table in steep head up bariatric anesthesia induction position

Fig. 13.9 Patient on operating table pre- induction in head up position

Fig. 13.10 Bariatric surgical patient positioned on operating table preoperatively, showing head up position, arm supports and foot supports to prevent slippage

Fig. 13.11 Moving obese patient with hover mattress from operating table to bed

experience, correct positioning can be achieved by appropriate adjustment of the theatre table and pillows. We advise strapping or bandaging the knees to the theatre table (Fig. 13.12 and 13.13) to keep them straight and prevent slippage or knee flexion when the patient is in a head up position.

Correct positioning on the theatre table is critical. Meticulous attention to detail will help prevent overhanging tissue becoming damaged or crushed. Morbidly obese patients are at risk of gluteal muscle rhabdomyolysis during long procedures (more than 4 h) [20, 21].

Securing intravenous access can be challenging. We recommend that two functioning cannulae should be in situ prior to induction. In very challenging patients, central venous access may be necessary.

13.4.1 Induction of Anesthesia

For reasons listed previously, all morbidly obese patients should receive pre-oxygenation to end-tidal oxygen concentration of 90 %, ideally, or as high a steady state as achievable. Pre-oxygenation should always be performed in the head up/ramped position in order to prolong safe apnea time [19].

Fig. 13.12 (**a**, **b**) Bariatric surgical patient, legs supported and knees strapped to prevent flexion and slippage

Standard intubation drugs may be used SOBA "Single Sheet Guideline" for current recommendations (www.sobauk.com) (See Fig. 13.14). The dose of most drugs can be based on ideal body weight (BMI 22–25) with the expection of the exception of suxamethonium and neostigmine.

The weight to use for dosing in total intravenous anesthesia (TIVA) is also not well defined and some practitioners use a "hybrid" weight of IBW plus 40 % of excess body weight (IBW+40 % (ABW- IBW)). We do not recommend the use of TIVA in morbidly obese patients by practitioners who are not highly experienced in the technique, and depth of anesthesia monitoring should be used. Due to issues with the software algorithms in commonly used TIVA pumps in the UK, extreme caution should be exercised if using TIVA in patients with BMI >36 in women and>42 in men. The reader is referred to current literature on the subject of drug dosing in the obese patient, but an easy up to date reference is the SOBA "Single Sheet Guideline" (www.sobauk.com) (See Fig. 13.14).

Ideal induction for obese patients should minimize the apnea time as patients may desaturate very rapidly. Whilst many anesthetists advocate the use of rapid sequence induction (RSI) in all obese patients, the risk of regurgitation is no higher than in the normal population and indications for RSI in the obese patient are no different to normal weight patients. Suxamethonium has been shown to increase oxygen consumption during fasciculation [22] thus reducing the time to desaturation. Rocuronium may be preferable particularly as it is easily reversible with sugammadex. Although the incidence of intubation difficulty, with correct positioning, may be no higher than for the general population, NAP4 has shown that rescue techniques for failed intubation (facemask, supraglottic airway ventilation and cricothyroidotomy) are more difficult in the obese and are associated with a higher failure rate than in the non-obese. Turning a patient quickly into the left lateral head down position is also fraught with difficulty and trying to ventilate a morbidly obese patient in this position is almost impossible. These considerations illustrate why skilled, atraumatic and effective airway management is of utmost importance (Fig. 13.14).

13.4.2 Maintenance of Anesthesia

There is no optimum technique of choice for the maintenance of anesthesia in the obese patient. A survey, conducted by the SOBA in 2012, showed that around 70 % of the bariatric anesthetists use volatile agents and 30 % use TIVA. The most important consideration is to ensure that the chosen technique and agents are short acting, with rapid offset, allowing a quick recovery from anesthesia. Remifentanil may be useful as an adjunct to either of the techniques.

13.4.3 Analgesia

Anesthetic techniques involving significant doses of opioids, particularly long acting opioids, may result in postoperative hypoventilation and reduced level of consciousness. Both are particularly dangerous in patients with diagnosed or likely OSA, as the risk of hypoventilation and respiratory arrest is significantly increased. Optimal pain management in the morbidly obese patient should involve multimodal regional and local techniques to minimize the use of opioids postoperatively. Preoperative management of patients' pain expectation is also important and should be addressed at the pre-assessment meeting.

THE SOCIETY FOR OBESITY AND BARIATRIC ANAESTHESIA GUIDELINES

ANAESTHESIA FOR THE OBESE PATIENT: BMI>35KG/M^2

Preoperative Evaluation

S	**Snoring**: Do you snore loudly (louder than talking or heard through a closed door?	
T	**Tired**: Do you often feel tired fatigued or sleepy during the daytime?	
O	**Observed**: Has anyone observed you stop breathing during sleep?	
P	**Blood Pressure**: Do you have or are being treated for high blood pressure?	
B	**BMI**: BMI > 35kg/m^2	
A	**Age**: Age > 50	
N	**Neck**: Neck circumference >40cm (16 inches)	
G	**Gender**: Male	

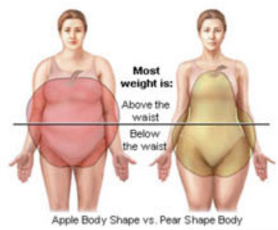
Any of:
Poor functional capacity
Abnormal ECG
Uncontrolled BP/IHD
SpO_2 <94% on air
Poorly controlled asthma/COPD
Previous DVT/PE
STOP-BANG ≥ 5

YES →
Consider:
Bloods gases/Sleep Studies
Preoperative CPAP
Echocardiogram
Cardiorespiratory referral

Need experienced anaesthetic team
If major surgery consider HDU

NO →
Maybe suitable as Day case surgery
SEE BELOW

Central Obesity (waist > half height)
Difficult airway /Ventilation problems more likely
Greater risk of CVS disease, thrombosis
↑Risk of Metabolic syndrome:
Central Obesity plus Hypertension
Dyslipidaemia, Insulin resistance



Peripheral Obesity
(Fat outside body cavity)
Less co-morbidity

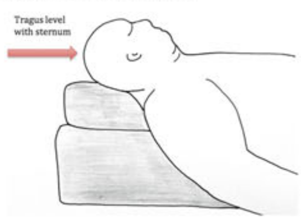
Intra Operative Management

Suggested Equipment

Suitable bed/trolley & operating table
Gel padding, wide strapping, table extensions/arm boards
Forearm cuff or large BP cuff
Ramping device, step for anaesthetist, difficult airway equipment, ventilator capable of PEEP and pressure modes.
Hover mattress or equivalent.
Long spinal, regional and vascular needles.
Ultrasound machine.
Depth of anaesthesia and neuromuscular monitoring.
Enough staff to move patient.

Ramping

Ear level with sternum. Reduces risk of difficult laryngoscopy, improves ventilation.



Anaesthetic Technique

Consider premed antacid & analgesia, careful glucose control & DVT prophylaxis.
Self-position on operating table.
Preoxygenate & intubate in ramped position +/- CPAP. Minimize induction to ventilation interval to avoid desaturation. Commence maintenance anaesthesia promptly.
Tracheal intubation is recommended.
Avoid spontaneous ventilation. Use PEEP.
Use short-acting agents e.g. desflurane or propofol infusion. short-acting opioids, multimodal analgesia. PONV prophylaxis.
Ensure full NMB reversal.
Extubate and recover in head up position.

Drug dosing- what weight to use?

Induction agents: titrate to cardiac output- this equates to lean body weight in a fit patient.
Competitive muscle relaxants: use lean body weight.
Suxamethonium use adjusted body weight to a maximum of 200mg
Neostigmine: Increase dose
Opioids: Use Lean body weight. Care with obstructive apnoea!
TCI propofol: IBW plus 40% excess weight

If in doubt, titrate and monitor effect!

Lean Body Weight this exceeds Ideal body weight in the obese and plateaus ≈100kg for a man, ≈70kg for a woman.
Ideal Body Weight in Kg - Broca formula
Men: height in cm minus 100 Women: height in cm minus 105

Suggested dosing regimes for anaesthetic drugs

Lean Body Weight Males 100Kg Females 70Kg	Adjusted Body Weight Ideal plus 40% excess
Propofol induction	Propofol Infusion
Thiopentone	Suxamethonium (Max 200mg)
Fentanyl	Alfentanil
Rocuronium	Lidocaine
Atracurium	Neostigmine (5mg)
Vecuronium	Sugammadex (see package insert)
Morphine	Antibiotics
Paracetamol	Low Molecular weight Heparin
Bupivacaine	

Post Operative Management

PACU discharge: Usual discharge criteria should be met. In addition, SpO_2 should be maintained at pre-op levels with minimal O_2 therapy, without evidence of hypoventilation.
OSA or Obesity Hypoventilation Syndrome: Sit up. Avoid sedatives and post-op opioids. Reinstate CPAP if using it pre-op. Additional time in recovery is recommended, only discharge to the ward if free of apnoeas without stimulation. Patients untreated or intolerant of CPAP who require postoperative opioids are at risk of hypoventilation and require continuous oxygen saturation monitoring. Level 2 care is recommended. Effective CPAP reduces this risk to near normal.
Ward care: Escalation to Level 1, 2 or 3 care may be required based on patient co-morbidity, the type of surgery undertaken and issues with hypoventilation discussed above. General ward care includes: multimodal analgesia, caution with long-acting opioids and sedatives, early mobilisation and extended thromboprophylaxis.

See www.SOBAuk.com for references Updated July 2014

Fig. 13.13 Society for Obesity and Bariatric Anaesthesia (SOBA) “One Page Guideline”

Fig. 13.14 Adjunct for difficult intubation. An Airtraq optical intubating laryngoscope

13.4.4 Extubation

Patients benefit when they are sat steeply head up for extubation as it improves ventilatory mechanics. This is best achieved following transfer onto an electric bed. Safe transfer of a morbidly obese patient requires the assistance of a sufficient number of adequately trained staff members. They need to be present in the theatre during transfer and until the patient has been extubated, in case the patient needs to be moved urgently.

13.4.5 Recovery

Patients should continue to be nursed in the head up position. Analgesia should be titrated to effect, opioids should be given cautiously and the patient should be closely monitored for signs of airway obstruction and respiratory depression. Early mobilization, as soon as possible, after surgery should be encouraged.

Most patients undergoing bariatric surgery in experienced units do not require either level three (intensive care) or level two (high dependency care) postoperatively. Many units send most of the postoperative bariatric surgical patients to a designated level one care area [23]. In units without significant experience of managing morbidly obese patients, thought must be given to the level of postoperative observation required. In the author's opinion, patients who score four or five on the obesity surgery mortality risk score (OSMRS) [24] and those with sleep apnea, or who have had significant amounts of perioperative opioids should be managed in a level two environment postoperatively.

13.5 Postoperative Care

13.5.1 Venous Thromboembolism (VTE) Prophylaxis

There is evidence that increase in BMI increases the risk of VTE and death from pulmonary embolism [25]. Before considering therapeutic options it is worth emphasizing on early mobilization. Enhanced recovery techniques that facilitate mobilization should be used routinely in bariatric surgery.

Thromboprophylaxis is indicated for bariatric surgical procedures, but there is no consensus on any of the following:

- Type of prophylaxis (mechanical, drug, compression stockings)
- When to start
- Duration of treatment
- Dosages of drugs given

National Institute for Clinical Excellence (NICE) has guidelines for bariatric surgery (See Table 13.3) [7] prophylaxis. In essence, the recommendations are to use prophylaxis but to adapt local protocols. Duration of pharmacological treatment varies from one dose to 3 weeks treatment. There is an incidence of late pulmonary embolus, after 14 days [26] and some units advocate 3 weeks of postoperative treatment.

Venacaval filters may be used as prophylaxis in very high-risk patients, and can be placed preoperatively. The evidence

Table 13.3 NICE guidance on venous thromboembolism for bariatric surgery

1.5.7 Offer VTE prophylaxis to patients undergoing bariatric surgery
Start mechanical VTE prophylaxis at admission. Choose any one of the following:
Anti-embolism stockings (thigh or knee length)
Foot impulse devices
Intermittent pneumatic compression devices (thigh or knee length)
Continue mechanical VTE prophylaxis until the patient no longer has significantly reduced mobility
Add pharmacological VTE prophylaxis for patients who have a low risk of major bleeding, taking into account individual patient factors and according to clinical judgement. Choose any one of the following:
Fondaparinux sodium
Low-molecular-weight heparin (LMWH)
Unfractionated heparin (UFH) (for patients with renal failure)
Continue pharmacological VTE prophylaxis until the patient no longer has significantly reduced mobility (generally 5–7 days)

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for efficacy is equivocal and they need to be placed and removed by interventional radiologists.

Anti-embolic stockings must be of the correct size and fitting—several companies now cater for this patient group. There are still some instances where appropriate fitting is not possible in some patients due to the size and shape of the legs, in these cases alternative types of prophylaxis should be used.

Conclusions

Bariatric surgical services must have experienced and specialist anesthetists involved to lead them in the preoperative assessment and MDT processes. Specific knowledge and experience of preoperative assessment and perioperative patient safety can inform a holistic approach to the morbidly obese patient.

Many patients are straightforward but some are very challenging, particularly for the occasional practitioner.

UK bariatric surgery and anesthesia is very safe, but the margin for error is small when anesthetizing morbidly obese patients. Patient safety is best assured by meticulous attention to detail every time, appropriate training and care delivered by experienced staff.

Key Learning Points

- Inexperienced anesthetists should not undertake anything but the most straightforward bariatric surgical work.
- Obese patients are at high risk and a comprehensive assessment of co-morbidities needs to be undertaken preoperatively on all patients.
- Anesthetists must be involved in all the bariatric surgical MDT meetings.
- Airway management in the morbidly obese can be very challenging and should therefore be the domain of the experienced bariatric anesthetist. Morbidly obese patients desaturate very quickly; so attention to detail at all stages of anesthesia is vital.
- Patients with central fat distribution and those with obstructive sleep apnea are particularly at high risk, both perioperatively and postoperatively.

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Preoperative Risk Scoring Systems in Bariatric Surgery

14

Irfan Halim and Yashwant Koak

Abstract

Surgery on the morbidly obese patient can carry a high risk of peri-operative morbidity and mortality due to the unusual stress placed on the physiology of such patients. This risk is often increased because of pre-existing medical cardiorespiratory and metabolic comorbidities. This chapter discusses the preoperative risk scoring systems that are currently used in bariatric surgery, in order to identify and evaluate the morbidity and mortality risks for each patient. These risk scoring systems include the Obesity Surgery Mortality Risk Score (OSMRS), the Bariatric Mortality Risk (BMR), the Edmonton Obesity Staging System (EOSS), the Metabolic Acuity Score (MAS) and the Nomogram for predicting surgical complications. Other useful scoring or classification systems used include the Cardiac Risk Assessment for non-cardiac surgery system and the American Society of Anesthesiologists (ASA) physical status classification system. While there is no single ideal risk scoring system that caters to every patient, preoperative risk scoring systems are useful tools in planning a customized approach for each patient.

Keywords

Risk scoring systems • Mortality prediction • Morbidity prediction • Obesity Surgery Mortality Risk Score (OSMRS) • Bariatric Mortality Risk (BMR) • Edmonton Obesity Staging System (EOSS) • Metabolic acuity score (MAS) • Nomogram for predicting surgical complications

14.1 Introduction

Morbid obesity was once a relative contraindication for most elective surgical operations [1] and was considered only when the risk of not operating for a condition outweighed the high risk of complications due to multiple comorbidities, especially the cardio-respiratory and metabolic comorbidities. In current times, surgery offers a potential treatment for obesity in addition to the improved metabolic and physiological conditioning that the body undergoes. Surgery in the obese, however is not without risks and the risks are greatest in the peri-operative period.

Body mass index (BMI) on its own is not a good predictor of peri-operative risk in morbidly obese patients and this has led to the development of scoring systems that estimate or predict postoperative morbidity and mortality. These risk-scoring systems have been used in patients electing for bariatric surgery, in order to reliably identify high-risk patients in the preoperative phase. Determining the extent of the risk is critical in guiding the surgical team regarding the appropriate surgical procedure, preoperative optimization

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of comorbidities [2] and the need for enhanced perioperative vigilance.

While there is no single ideal risk scoring system that assesses every patient with great accuracy, there are a handful of popular systems that have been developed over the years that provide a reasonable estimation of risk. The ideal risk scoring system, if one existed, would provide an accurate risk score of both morbidity and mortality taking into account the surgical risk of the proposed procedure, the overall risk of anesthesia, and most importantly the individual risk factors of the patient.

The main risk scoring systems used currently are:

- Obesity surgery mortality risk score (OSMRS) [3]
- Bariatric Mortality Risk (BMR) classification system [4]
- Edmonton Obesity Staging System (EOSS) [5]
- Metabolic Acuity Score (MAS) [6]
- Nomogram for predicting surgical complications

Other systems used in the literature include:

- Cardiac risk assessment for non-cardiac surgery [7]
- American Society of Anesthesiologists (ASA) physical status classification system [8]

14.2 Obesity Surgery Mortality Risk Score (OSMRS)

The OSMRS was originally developed by DeMaria et al. [3] in the United States of America, from a multivariate analysis of prospectively collected data of various preoperative risk factors of 2075 patients. All these patients underwent primary open or laparoscopic gastric bypass surgery between 1995 and 2004 in a single institution.

Although previous studies in bariatric surgery had addressed mortality risk based on particular preoperative characteristics, this was the first paper to assign a true scoring system that correlated with a quantified mortality risk over a 90-day period. The OSMRS indicated that mortality risk could be analyzed by stratifying five main independent variables (Table 14.1).

Patients with a total summative score of 0–1, 2–3, and 4–5 were assigned to Class “A” (low risk), Class “B” (intermediate risk), and Class “C” (high risk), respectively. The mortality figures from the original paper indicated a significant statistical difference between the three classes (Table 14.2).

Since the original publication, OSMRS has been independently validated [9–11], in both North America as well as Europe in over 9000 patients and is now well recognized as a simple and effective classification system for the preoperative identification of high-risk patients undergoing gastric bypass surgery.

Although initially, OSMRS was applied to all primary gastric bypass patients with mortality as the end-point, Sarela et al. [10] utilized the scoring system to assess all laparoscopic bariatric operations and included a composite end-point of adverse events as well as mortality. A systematic review of the OSMRS was published by Thomas et al. [12] in 2012. A simple nomogram (Table 14.3) was constructed using the results of various international studies and this also confirmed the widespread validation of the OSMRS and statistical significance of the differences in 90-day mortality rate between each of the three classes.

The OSMRS is a quick and easy tool to assess gross mortality risk in patients undergoing bariatric surgery.

Table 14.1 Obesity Surgery Mortality Risk Scoring (OSMRS) System

Variable	Score if present
BMI >50 kg/m^2	1
Age >45	1
Male gender	1
Hypertension	1
Risk factors for pulmonary embolus (previous DVT, PE, IVC filter, right heart failure or obesity hypoventilation)	1

Each patient is given a score from 0 to 5 based on the presence of any of the features listed above. This enables the calculation of mortality risk as shown in Table 14.2

Table 14.2 OSMRS mortality risk calculator

Class (score)	90-day mortality risk
A (0–1)	3/957 (0.31 %)
B (2–3)	19/999 (1.9 %)
C (4–5)	9/119 (7.56 %)

Patients are scored based on variables in Table 14.1 are assigned to one of 3 classes (A, B or C)

Table 14.3 Normogram depicting the 90-day mortality risk from various studies

Class	DeMaria et al. [3]	DeMaria et al. [9]	Efthimiou et al. [11]	Dimitrios et al. [13]	Sarela et al. [10]	Agrawal [14]	Total
A	0.31 %	0.23 %	0.36 %	0 %	0 %	0 %	0.26 %
B	1.9 %	1.17 %	1.49 %	0.69 %	0 %	0 %	1.33 %
C	7.56 %	2.4 %	3.08 %	0 %	6.67 %	0 %	4.34 %
Total	1.49 % 31/2075	0.74 % 33/4431	0.8 % 17/2121	0.33 % 1/300	0.26 % 1/381	0 % 0/74	0.88 % 83/9382

Adapted from Thomas et al. [12]

14.2.1 Limitations of OSMRS

Since its introduction in 2007, the OSMRS has become popular due to its simplicity; however, there are several limitations of OSMRS in clinical practice. The following considerations need to be addressed with individual patients when calculating a score and mortality risk.

- The calculated risk may be an overestimation as most procedures are now performed through laparoscopy. The OSMRS used a combination of both open and laparoscopic procedures. Open procedures have been shown to significantly increase the mortality risk compared to laparoscopic procedures.
- OSMRS does not take into account all the bariatric procedures such as gastric banding and sleeve gastrectomy, which are considered less risky than gastric bypass surgery and thus, the calculated risk may again be an overestimation for these procedures [5].
- The endpoint of the original OSMRS study was only limited to mortality and risk stratification for morbidity was not calculated [3].
- It is important to note that of the five risk factors mentioned in the OSMRS, only the BMI is modifiable preoperatively.

The OSMRS was the very first risk scoring system to be developed and with emerging technologies and enhanced surgical skills and experience, the tool may seem to be a bit outdated [15]. General mortality risk for a bariatric surgical patient in 1995 undergoing an open gastric bypass operation would be significantly different from one undergoing a laparoscopic bypass in the present day.

14.3 Bariatric Mortality Risk (BMR) Classification System

The BMR classification system was developed in 2013 by Nguyen et al. [4] using a large volume of nationally compiled data from the University Health System Consortium database that included an impressive 105,287 patients who underwent bariatric surgery between 2002 and 2009.

The purpose of the BMR classification study was to determine mortality trends after bariatric surgery over an 8-year period, as well as to determine independent preoperative variables that predicted in-hospital mortality. Thereafter, the aim was to develop a system that could be incorporated into routine clinical practice to predict in-hospital mortality, by overcoming some of the limitations of the widely accepted OSMRS.

Six independent variables were identified by multiple regression analyses, and were given a weighted score (Table 14.4); the total score falling into one of four classification categories each with an established mortality risk (Table 14.5).

Table 14.4 Bariatric Mortality Risk (BMR) study scoring system

Variable	Points
Age 60 and over	0.5
Diabetes	0.5
Open surgery	1
Gastric bypass surgery	1
Medicare payer	1
Male gender	1

In the BMR study, each patient is assigned a score depending on the presence of specific listed variables. A total score is then calculated and the patient assigned to one of four categories (Table 14.5) and assigned a mortality risk

Table 14.5 Bariatric Mortality Risk calculator

Classification category	Mortality risk (%)
Class I (0–0.5)	0.1
Class II (1.0–1.5)	0.15
Class III (2.0–3.0)	0.32
Class IV (3.5 and above)	0.7

The Bariatric Mortality Risk calculator gives an indication of mortality risk based on the resulting score from patient variables as derived from Table 14.4

At present, the BMR classification system is the most recently published system using a large patient group in order to improve accuracy. Like the OSMRS, this system only looks at mortality risk and has its own set of limitations.

14.3.1 Limitations of BMR Classification System

- It is important to note that the vast volume of data used for performing the calculations did not include any BMI data as the complete dataset was not available for inclusion in the study. The OSMRS had already identified BMI as an important and statistically significant component in calculating the overall mortality risk. Specifically, the BMI represented 20 % of the overall score calculation in the OSMRS. [16]
- The complete data on particular comorbidities such as sleep apnea were also not available in the initial dataset. The omission of these datasets in regression analyses weakens the overall strength of the study.
- Another limitation of the study is the presence of the significant variable "Medicare payer" which is only applicable in the USA health system and hence this scoring system may not be accurately extrapolated internationally.
- Although BMR scoring system shows promise, at present, a validation study is warranted to confirm the findings.

14.4 Edmonton Obesity Staging System (EOSS)

The Edmonton Obesity Staging System [5] (Fig. 14.1) categorizes obese patients into one of five stages (Stage 0 to Stage 4) based on parameters such as BMI, adiposity, underlying comorbidities (diabetes, hypertension, and dyslipidemia), and functional status (Table 14.6). Once a patient was categorized, the EOSS system could be utilized as a management guide towards potential treatments for obesity including counseling, lifestyle changes, behavioral, pharmacological and surgical treatments based on staging.

Given the simplicity of the system, a retrospective study by Padwal et al. was conducted using the EOSS to predict mortality associated with obesity in 2011 [17]. The dataset used here was acquired from National Health and Human Nutrition Examination Surveys (NHANES) from 1988–1994 to 1999–2004 on patients with obesity and mortality follow-up to the end of 2006. The study revealed that higher stages with EOSS correlate with higher mortality; stages two and three were shown to be associated with hazard ratios of 1.57 and 2.69 respectively when compared to a score of zero to one.

The EOSS is quick and easy to use. It may be used to prioritize bariatric surgery for patients who are at increased risk of mortality from their obesity (Stage 2 and 3) in an era when national healthcare is facing huge economic constraints.

14.4.1 Limitations of EOSS

The classification system is somewhat subjective and symptoms are categorized in to 'none', 'mild', 'moderate', 'significant' and 'severe' categories. This spectrum makes the assessment difficult to verify from patient to patient and is open to inter-operator variability.

Comorbidities such as diabetes and osteoarthritis are arbitrarily assigned to be equivalent in terms of their burden of illness. At present, it is unclear whether different illnesses should hold a particular weighting.

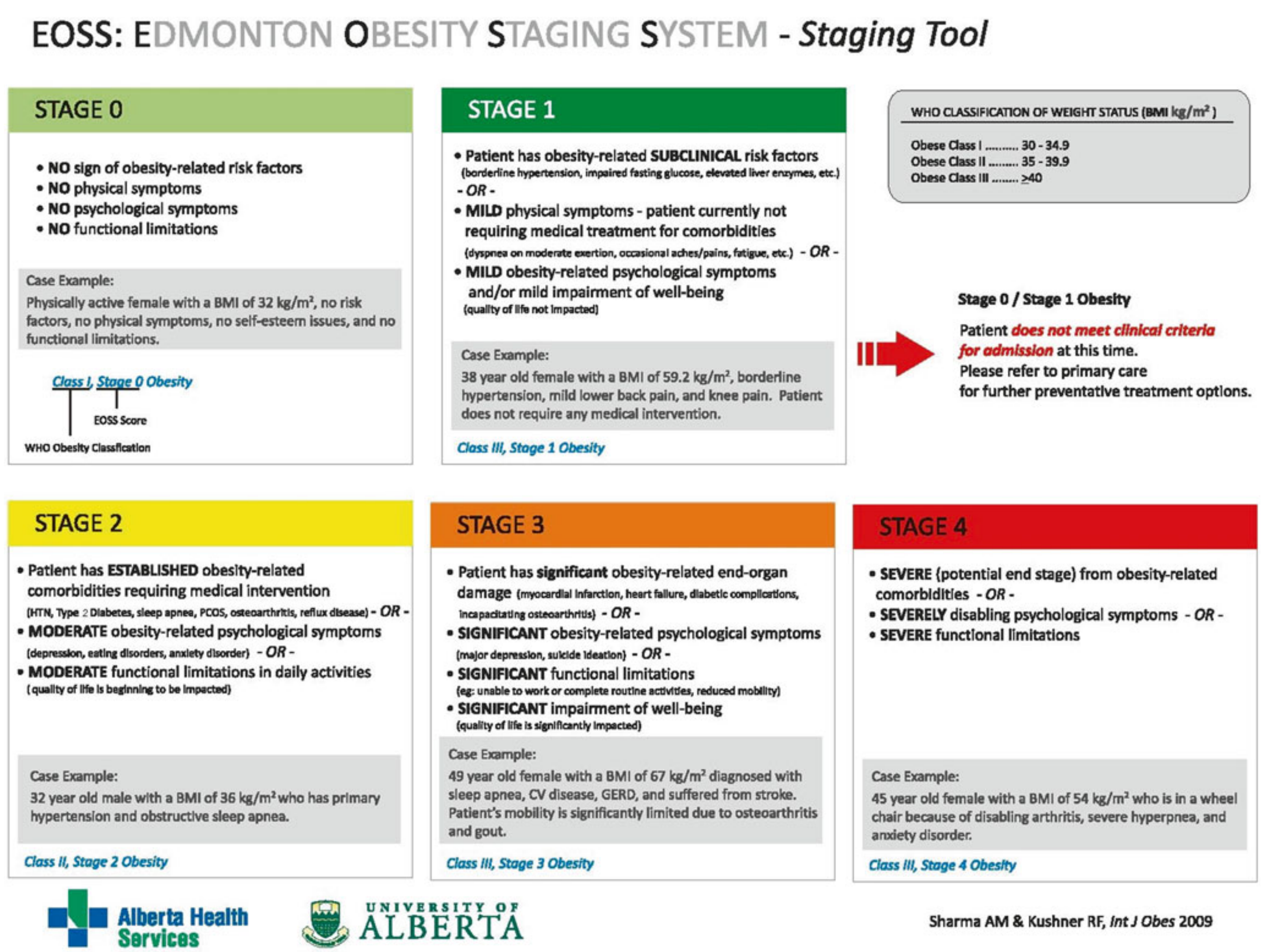

Fig. 14.1 Edmonton Obesity Staging System

In the retrospective study by Padwal [17]:

- Staging of level 4 could not reliably be assigned a mortality risk because specific data elements were lacking.
- Certain data elements such as psychological functioning were unavailable due to the retrospective nature of the study

Some co-morbidities were self-reporting or inferred, thus increasing the risk of bias when compared to direct measurements.

Only mortality was examined. Morbidity and other endpoints such as quality of life and costs which are so important in this chronic disease were not examined.

To date, there are no studies about the postoperative morbidity and mortality outcome of the patients in the different EOSS groups.

Health economists and managers may use this system to deny or delay bariatric surgery in patients with EOSS 0 and 1 patients as they have low mortality risk from their obesity. The impact on quality of life and on risk of obesity in future generations is not taken into account. This may negatively affect young morbidly obese females of child bearing age who may not get surgery until they are much older and sicker.

The EOSS is used widely in clinical practice by most hospitals in UK despite its limitations.

14.5 Metabolic Acuity Score (MAS)

Blackstone and Cortes devised the MAS [6] in 2010 using data from 2416 patients who underwent either gastric banding or Roux-en-Y gastric bypass surgery (RYGB) by a single surgeon in a private bariatric center between November 2001 and November 2008. Patients were classified into one of four categories (Acuity 1 to Acuity 4) based on their comorbidities with a score of one being the least severe and a score of four being the most severe. Data on variables such as age, gender, previous abdominal scars (only for patients undergoing RYGB), BMI, weight, history of deep vein thrombosis or pulmonary embolism, sleep apnea, diabetes, hypertension, immobility, heart disease and psychological classification were collected in order to minimize postoperative complications, and thus, ensure an optimum use of healthcare resources (Table 14.7). The study compared prospective outcomes from 1072 patients, divided into the four MAS groups, with each other as well as with 1344 patients who had undergone treatment before MAS was introduced.

When the MAS was used as a preoperative tool, there was a statistically significant reduction in postoperative complications and readmission rates as a preoperative tool as higher risk patients were identified and managed.

Although the implementation of the MAS clearly showed its usefulness in pre-operative patient, a handful of limitations within the study were acknowledged.

Table 14.6 Criteria for assigning EOSS score

Variable	EOSS score assigned			
	0	1	2	3
Fasting glucose (mmol/l)	<5.6	5.6–6.9	7.0 or self-report of diabetes or treatment with insulin/ anti-diabetic medication	
Blood pressure (mmHg)	BP <130/85 not known hypertensive or BP <125/75 with diabetes or chronic kidney disease	SBP 130–139.9 or DBP 85–89.9. For individuals with diabetes or chronic kidney disease SBP 125–129.9 or DBP 75–79.9	Known hypertension or on medication. If not BP >140/90. For diabetes or chronic kidney disease patients BP> 130/80	
LDL cholesterol (mmol/l)	<3.4	3.4–4.0	>4.0	
Total cholesterol (mmol/l)	<5.2	5.2–6.1	>6.1	
HDL cholesterol (mmol/l)	>1.6	1.0–1.6	<1.0	
Triglycerides (mmol/l)	<1.7	1.7–2.3	>2.3	
Liver disease	None with normal LFTs	Elevated LFTs with no known liver disease	Known liver disease and elevated LFTs	
Kidney disease: GFR (ml/min/m^2)	GFR > 90	GFR 60–90	GFR 30–59.9	GFR <30
Osteoarthritis	No reports of back or joint pains	Occasional back or joint pains	Known osteoarthritis	
Physical Health	No functional or ADL limitations	Functional impairment but no ADL limitations	ADL limitations	

Subjects with a history of angina, coronary artery disease, congestive heart failure or cerebrovascular disease were automatically assigned to Stage 3
ADL activities of daily living, *GFR* glomerular filtration rate, *HDL* high-density lipoprotein, *LDL* low-density lipoprotein

Table 14.7 Metabolic Acuity Score

Variable	Acuity 1	Acuity 2	Acuity 3	Acuity 4
Age (year)	<60	<60	60–64	>65
BMI (kg/m^2)	<50	51–54	55–69	>70
Weight (lb)	<350	351–424	425–599	>600
History of DVT/PE	No	No	Previous history or 4 out of 8 risk factors	Currently taking anticoagulation therapy (other than aspirin)
OSA (cm H_2O)	CPAP < 10	CPAP ≥ 10–14	CPAP ≥ 10 plus asthma	CPAP >15 or BiPAP with or without asthma
T2DM	Pre-T2DM or taking metformin	HbA1c ≤ 7	HbA1c >7	Insulin-dependent T2DM
Hypertension	One medication	Yes	Yes	Yes
Immobile	No	No	No	Use of aids such as walker or wheelchair
History of CAD (stent or CABG)	No	No	No	Yes
Psychological classification	1, 2	1, 2, 3A	3B	3B

The Metabolic Acuity Score assigns patients into one of four acuities as shown in Table 14.7. This is done in the preoperative phase in order to stratify risks, ameliorate pre and peri operative care hence minimizing operative comorbidity. Patients are placed into the highest acuity category based on the listed variables. Modifiers include male gender, which add +1 score to the Acuity as well as previous upper abdominal scars only for patients about to undergo laparoscopic Roux-en-Y gastric bypass surgery

BMI body mass index, *DVT/PE* deep vein thrombosis/pulmonary embolus, *OSA* obstructive sleep apnoea, *CPAP* Continuous positive airway pressure, *BiPAP* Bi-level positive airway pressure, *T2DM* Type 2 diabetes mellitus, *HbA1c* Hemoglobin A1c, *CAD* coronary artery disease, *CABG* coronary artery bypass graft

14.5.1 Limitations of the MAS

The authors noticed an improvement in their operative technique and learning curve over the study period which may have accounted, at least, in part, for the improved results. Advances in technology during the same time period may also have had a similar effect.

- Psychological factors make the scoring system more subjective and may weaken the study through observational bias.
- At present, most bariatric units examine comorbidities to assess and optimize preoperative comorbidities risk, and thus inadvertently, use the principles of the MAS.

14.6 Nomogram for Predicting Surgical Complications in Bariatric Surgery Patients

In 2011, Turner et al. published a retrospective study based on 32,426 bariatric patients treated between 2005 and 2008 from the American College of Surgeons National Security Quality Improvement Program (NSQIP) database [18]. A predictive model using preoperative variables (Table 14.8) was developed and the primary outcomes in the study were defined as a composite 30-day morbidity in a wide range of conditions (Table 14.9) as well as morbidity. Detailed statistical analyses to check the validity of the predictive nomogram model revealed that the greatest predictors of morbidity and mortality were a lower serum albumin, body mass index, age and functional dependence.

Table 14.8 Summary of baseline predictor variables for 32,426 US bariatric surgery patients treated between 2005 and 2008 in the Nomogram Study

Factor	Percent missing	Statistics[a]
Age (years)	–	45.0 ± 11.5
ASA classification	0.05 %	2.7 ± 0.5
Preoperative albumin (g/dL)	31.22 %	4.1 ± 0.4
Body mass index (kg/m^2)	–	45.2 [41.2, 50.7]
Diabetes mellitus	–	8501 (26.2)
Functional dependence prior to surgery	–	223 (0.7)
History of COPD	–	539 (1.7)
Hypertension requiring medication	–	17,062 (52.6)
Race		
Caucasian	–	23,781 (73.3)
African American	–	4135 (12.8)
Hispanic	–	1855 (5.7)
Asian	–	177 (0.5)
Other	–	2478 (7.6)
Female gender	–	25,899 (79.9)
Current smoker (within 1 year)	–	
3974 (12.3)		

[a]Statistics presented as mean ± SD for symmetrically distributed continuous predictors, median [1st and 3rd quartiles] for asymmetrically distributed continuous predictors, and N (%) for factors

The nomogram (Fig. 14.2) assigns points to each of the demographic, morphometric and pre-operative variables. A sum of the total points is then calculated and used to determine the predicted probability of a 30-day event occurring.

Table 14.9 Frequency of individual outcomes in Nomogram Study

Outcome	N (% of patients with composite outcome)
Pneumonia	157 (13)
Unplanned intubation	105 (8)
Pulmonary embolism	61 (5)
Ventilator dependence >48 h	106 (9)
Acute renal failure	39 (3)
Stroke/CVA with neurological deficit	8 (1)
Coma >24 h	4 (0)
Cardiac arrest requiring CPR	26 (2)
Myocardial Infarction	7 (1)
Bleeding requiring 5+ units of transfusion	76 (6)
Any infections	972 (79)
Systemic infections	314 (25)
Total wound infections	835 (67)
Superficial surgical site infection	527 (43)
Deep incisional wound infection	97 (8)
Organ space infection	206 (17)
Wound disruption	48 (4)
Mortality	45 (4)

This is an additional tool for preoperative risk scoring in patients scheduled for bariatric surgery. However, it does have a few limitations.

- The study and scoring system need large scale external validation in order to be validated as an accurate model.
- The initial study had pre-operative albumin level data missing from 31.22 % (10,123 patients) of its overall dataset. Although a statistical tweak was used to overcome the missing data and smooth out the end calculations, this is significant given that low pre-operative albumin levels have been shown in this study to be the greatest single predictor of 30-day mortality.
- Multiple operations within the 30-day period were not included in the composite endpoints.
- When selecting bariatric patients from the database, there was no mention of the procedural distribution or whether the patients had an open or laparoscopic procedure. This study gives a prediction score from any bariatric procedure and not a specific procedure.

Overall, the study is generally comprehensive and useful in predicting the likelihood of morbidity in a patient under-

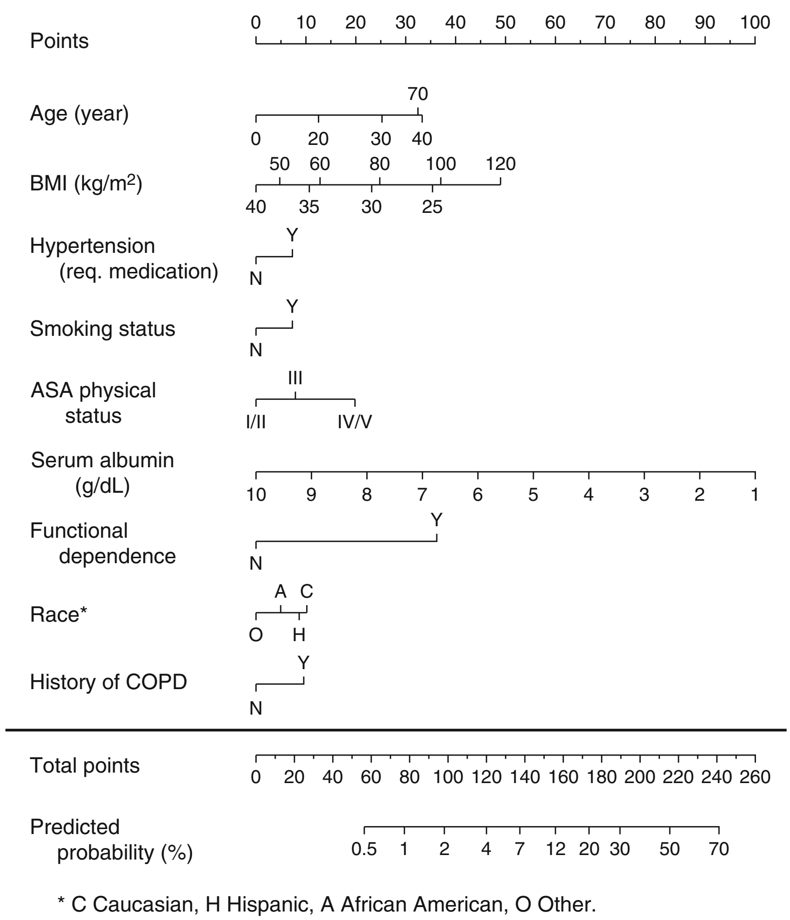

Fig. 14.2 Nomogram for predicting surgical complications within a 30-day period in bariatric surgery patients

going bariatric surgery. The identification of particular modifiable risk factors such as low serum albumin concentration can allow for pre-operative correction and minimization of morbidity and mortality risk.

14.7 American Society of Anesthesiologists (ASA) Physical Status Classification System

The ASA score is universally known and requires little introduction to surgeons and anesthetists [8]. It is probably the most widely utilized classification system of comorbidities and risk in any surgical patient, and it is easy to calculate the overall risk for each patient.

The ASA system grades patients into one of five classes below according to their systemic status at the time of surgery (Table 14.10).

Most bariatric patients fall into ASA II or III category. ASA is a useful tool in guiding patient selection and timing of surgery, both of which affect overall risk of morbidity and mortality for the patient. It is useful to know that ASA status can change in the same patient with time and with status of co-morbid conditions. A young and fit man with no comorbidities presenting for elective surgery, for example, would be classed as ASA I; however, the same individual with a delayed presentation of sepsis with an esophageal perforation and requiring emergency surgery would be classified in ASA category-IV.

14.7.1 Limitations of the ASA

- The ASA is generally a crude marker of overall risk and subjective to a certain extent.
- The ASA does not distinguish between individual or compounded co-morbidities which would affect bariatric patients.
- The BMI has no particular significance or weighting in the scoring system and this has been shown in the key studies to be a significant parameter.
- The usefulness of the ASA is limited to timing of surgery and calculating high risk only. It is not useful for optimizing individual co-morbidities.

Table 14.10 ASA classification

I. Patient is a completely healthy and fit
II. Patient has mild systemic disease
III. Patient has severe systemic disease that is not incapacitating
IV. Patient has incapacitating disease that is a constant threat to life
V. A moribund patient who is not expected to live for 24 h with or without surgery

- The ASA is a dynamic score and can change quickly in emergency situations. It is, therefore, only useful in showing current physiological status and not past status.

14.8 Cardiac Risk Assessment for Non-cardiac Surgery

The cardiac risk assessment for non-cardiac surgeries (including bariatric surgery) is a useful tool for anesthetists in predicting outcome in the perioperative stage [7]. Although not a true scoring system per se, it deserves mention because it uses different scoring systems in order to predict the preoperative risk.

This assessment is based on a combined guideline issued by the European Society of Cardiology (ESC), the American College of Cardiology and American Heart Association (ACC/AHA) that follows a step-wise systematic approach in each patient regardless of their cardiac disease status.

The following criteria are considered:

- Assessment of urgency of surgical procedure,
- Assessment of presence of active cardiac disease,
- Assessment of surgical risk,
- Assessment of functional capacity,
- Re-assessment of surgical risk,
- Assessment of cardiac risk factors using Framingham score,
- Consideration of non-invasive testing, and
- Interpretation of stress test results

Some anesthetists and physicians use the Framingham coronary heart disease prediction score for risk assessment to predict outcomes in obese patients with New York Heart Association (NYHA) Classes II and III of heart failure undergoing bariatric surgery. By using this tool for preoperative risk assessment, the bariatric surgery outcomes showed more than 40 % and 42 % reduction in cardiac events and cerebrovascular accidents, respectively, after gastric bypass surgery.

In addition, after gastric bypass surgery, the 5-year risk of mortality from cardiovascular disease decreased by 18 %; and the risk of developing kidney disease, and intermittent claudication and diabetic retinopathy decreased by 45 % and 47 %, respectively. These results are useful in assessing the risk-benefit ratio for individual high-risk patients and aid in the decision-making process by the multi-disciplinary team [7].

Most bariatric patients will benefit from such a comprehensive multi-disciplinary team assessment regardless of whether they have cardiac disease or not. The score from the each of the various steps allows for an overall risk assessment, and it is very useful tool in selecting the appropriate procedure for each patient. It can be combined with other scoring systems in order to provide a more global assessment of risk outside of the peri-operative phase.

14.9 Longitudinal Assessment of Bariatric Surgery (LABS), National Bariatric Surgery Registry (NBSR) and Scandinavian Obesity Surgery Registry (SOReg)

Regional and national registries of patients who underwent bariatric surgery in the USA, United Kingdom and Scandinavian countries are currently collecting data on the outcomes, and in future, may be helpful in developing predictive models to assess risk profiles of individual patients. The National Institutes of Health (NIH)-funded Longitudinal Assessment of Bariatric Surgery (LABS) [19] is a consortium of six clinical centers in the USA that collects data that helps in the planning, development, and conduct of coordinated clinical, epidemiological, and behavioral research in bariatric surgery. The National Bariatric Surgery Registry (NBSR) in the UK and the Scandinavian Obesity Surgery Registry (SOReg) in Sweden and Norway are national registries that collect prospective data and are similar to LABS. The NBSR also includes risk factors from the OSMRS for outcome assessment.

The SOReg [20] outcome data shows that postoperative complications in bariatric patients decreased by more than 50 % over the last decade, and the mortality rate reduced from 0.1 to 0.04 % (same as that of elective cholecystectomy) with an incidence of around 1 death in 2500 cases.

The NBSR data shows a similar trend and an improvement of >50 % was observed in patients with comorbidities such as Type 2 diabetes mellitus, hypertension and sleep apnea. On the basis of the NBSR data, the UK Office of Health Economics in 2012 suggested that £1.3 billion could be saved over a period of 3 years, if even a quarter of eligible bariatric patients underwent surgery. Currently, less than 0.5 % suitable patients in UK undergo bariatric surgery. With the use of appropriate preoperative risk scoring systems, further reductions in healthcare can be envisaged.

Conclusion

Preoperative risk scoring systems in bariatric surgery are useful in tailoring a personalized approach for each individual patient. Better preoperative counseling enables the patient to make informed decisions about their own care. Despite the use of advanced statistical algorithms, no single predictive model appears to be ideal for health care providers and individual patients, and hence, a combination of models is often required. A combination of OSMRS, BMR, EOSS and cardiac risk assessment for non-cardiac surgery are useful tools that can guide individual patient care planning.

These scoring systems are based on data collected some years ago and as such may not take into account learning curves, improved training methods, operative skills and technological advances in medical device and support monitoring [15].

Mortality risk calculators [20, 21] and risk scoring systems have not only been devised with retrospective center data but also from data derived from national registries. With rapid advances in bariatric surgery, while these systems can identify high risk patients, they tend to overestimate the risks associated with surgery in this patient group [16, 22, 23].

It might be preferable to devise a more robust preoperative risk scoring system based on outcome measures, which includes current global data pooled from various national registries and high volume centers. A pilot project has recently been set up under the auspices of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) to create a global registry by merging and analyzing bariatric and metabolic surgery datasets from different countries. This may be used for the development of an up-to-date scoring system that predicts the morbidity and mortality risk in patients scheduled for bariatric surgery.

Key Learning Points

- Preoperative risk scoring systems in bariatric surgery may be useful in tailoring a personalized approach for each individual patient.
- Despite the use of advanced statistical algorithms, no single predictive model appears to be ideal for health care providers and individual patients, and hence, a combination of models may be required.
- Mortality risk calculators and risk scoring systems have so far been devised with retrospective center data only.
- It might be preferable to devise a more robust preoperative risk scoring system based on outcome measures from more current global data pooled from national registries and high volume centers.

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The Structure and Role of the Multidisciplinary Team in Bariatric Surgery

15

Omar Khan, Gul Bano, and Marcus Reddy

Abstract

Over the last decade, there has been increasing awareness of the importance of the multidisciplinary team (MDT) in the management of a number of conditions which have traditionally been considered as surgical conditions. This is particularly true in bariatric surgery where the complex multifactorial nature of obesity combined with the need for regular follow-up and monitoring after the surgery means that this specialty lends itself to following an MDT approach. Members of the bariatric MDT vary according to circumstances but should have as its core members an obesity physician, specialist surgeon, dietitian, psychologist and anesthetist with the expertise of additional members (for example, plastic surgeons) available when needed. Although there is limited prospective data on the efficacy of the MDT in bariatric surgery, given the trends with respect to the rising incidence of high-risk surgical candidates and revisional surgery, it is likely that the MDT will have an increasingly important role in the future in managing pre- and post-bariatric patients.

Keywords

Multi-disciplinary team • Team work • Obesity physician • Bariatric surgeon • Dietitian • Psychologist • Anesthetist • Bariatric Nurse Specialist

15.1 Introduction

Over the last 20 years, the role of the multidisciplinary team (MDT) has expanded to encompass diseases which were previously thought to be under the purview of surgeons. This is particularly true in cancer surgery. In the United Kingdom, Cancer Networks have made the MDT an integral and mandatory part of the management of all cancer patients. Similarly, in the context of bariatric surgery, there has been a growing emphasis on a multidisciplinary approach towards the management of morbid obesity. In this chapter, we discuss the rationale for the MDT approach in bariatric surgery, the role of the key members of the MDT and the future trends in MDT management of morbid obesity.

15.2 Obesity and the MDT

Traditionally, most branches of surgery have relied on a paradigm of direct referrals from either primary care or specialist physicians to surgeons, with the latter acting as the final arbiter for deciding the management of the patient. Although this model still persists in private practice in the UK and indeed throughout the world, over the last few decades, there has been an increasing appreciation of the role of the MDT in determining the management of patients with what would traditionally be thought of as "surgical problems." While this trend has initially been seen in many surgical oncology disciplines, bariatric surgery is arguably a branch of surgery which

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requires and benefits to a great extent from the adoption of a multidisciplinary approach. The reasons include:

1. Multifactorial nature of obesity: Unlike many other surgical diseases such as gastrointestinal cancers where there is often a focal and well-defined pathology, morbid obesity is a complex, multifactorial condition with disturbances in psychology, physiology and pathology. In addition, morbid obesity is itself associated with a number of medical conditions including type 2 diabetes, ischemic heart disease and hypertension. The optimum management of both obesity and its related comorbidities requires the input of experts from multiple domains to manage the different medical, psychological, and surgical aspects of this condition.
2. In comparison to for example surgical oncology patients where the mainstay of treatment tends to be surgical resection, obesity management represents a different clinical paradigm. In particular, patients suffering with morbid obesity often do not suffer any short-term life-threatening complications associated with this condition. The decision to offer surgery, with its inherent risks, is often more finely balanced as compared to, for example, gastrointestinal tumors where treatment without surgical resection can often be fatal.
3. Unlike oncosurgery where complete resection of the tumor is often the definitive (albeit not always successful) treatment for the underlying pathology, patients undergoing bariatric surgery require continued input to maintain weight loss. In addition, patients undergoing bariatric surgery may present both acutely and chronically with treatable postoperative complications related to the bariatric surgery such as metabolic disturbances following malabsorptive procedures which require management by a multidisciplinary team.

15.3 Members of the Multidisciplinary Team

Although there are no set criteria as to who should be part of the MDT that manages patients undergoing bariatric surgery, in our institution, the following are core members of the team:

1. Metabolic physician or a physician with a special interest in obesity is central to the management of morbid obesity. This physician should:
   - Undertake the primary assessment of the patient;
   - Assess the presence or absence of any obesity related comorbidities
   - Exclude any endocrine or neurological abnormality which may be contributing to the obesity (example, hypothyroidism or hypothalamic obesity)
   - Ensure that the patient's comorbidities are being optimally managed.

   In most cases, the metabolic physician also acts as a "gatekeeper" for the bariatric surgical service and refers patients on to a bariatric surgeon only when he/she is convinced that surgical weight loss management is both appropriate and likely to be effective.
2. Bariatric surgeon: The role of the specialist bariatric surgeon in the MDT is to provide a general assessment of the patient's fitness for surgery as well as their overall suitability for surgery. In particular, the surgeon must ensure that patient is clearly informed of the risks and benefits of bariatric surgery and provided a detailed account of the different surgical procedures and their relative advantages and disadvantages with respect to perioperative and long-term outcomes. The surgeon also advises the patient about the overall surgical journey they will be undertaking. He or she educates the patient on the need for a preoperative liver reducing diet, explains the complications of surgery and the importance of engaging with the bariatric team following surgery. Although the decision about the type of operation that is best suited for the patient should be made by the whole MDT, it is often during the surgical consultation that this issue is most explored. Patients may sometimes present with a fixed idea as to which surgical operation they wish and it is up to the surgeon to ensure that their choice is fully-informed. In addition, there are certain circumstances (example, where patients had previous major abdominal surgery or those who have inflammatory bowel disease) where the surgeon needs to emphasize on the benefits and risks of one particular bariatric operation over another.

   Finally, patients referred for bariatric surgery often have other surgical pathologies (example abdominal wall hernia or gallstone disease) which require treatment and it is important for the surgeon to advice on the optimum timing and treatment of these conditions in relation to any bariatric operation.
3. Dietitian: The role of the dietitian is crucial to the preoperative assessment and postoperative management of all bariatric surgical patients. Prior to surgery, the role of the dietitian is to assess the calorific and nutritional intake of potential surgical candidates. This is particularly important as although morbidly obese patients, by definition consume an excess of calories, a significant proportion have micronutrient abnormalities secondary to the quality of food consumed. In addition the role of the dietitian is to give patients an insight into their eating habits as well as encouraging them to commence a calorie-restricted

diet in the months prior to surgery. In addition, dietitians have an important role in educating patients about their proper dietary intake including the need and rationale for a liver-reduction diet immediately prior to surgery as well as managing the expectations of what they are able to eat in the immediate postoperative period. Dietitians also have a crucial role to play in long-term maintenance of weight loss following the surgery as well as in monitoring and detecting any potential micronutrient deficiencies in patients who undergo malabsorptive procedures. The role of the dietitian is discussed further in Chap. 11.

4. Psychiatrists or psychologists with an interest in obesity management have an important role in identifying patients with problematic eating patterns (for example binge eaters) as well as those with significant patterns of comfort eating. In addition, patients undergoing bariatric surgery often have high levels of psychiatric diseases and psychiatrists may have an important role in managing these conditions prior to surgery as well as in assessing whether patients are psychologically and physiologically fit for surgery.

   It should be noted that although psychiatrists or psychologists are an integral part of the MDT, unlike the surgeon, physician, surgeon and dietitian, not all patients necessarily require review by a psychiatrist or psychologists. In our institution, all patients undergo a preoperative validated psychological questionnaire screening test and only those with significant abnormalities are referred on to psychiatrist for further assessment and evaluation. (For further information about the role of the psychologist in the bariatric MDT refer to Chap. 12).
5. Anesthetists: Given that bariatric patients often have significant levels of medical comorbidities, specialist anesthetists have a central role in ensuring patients are optimally assessed and investigated prior to surgery and medically-optimized, if necessary. In addition the anesthetist has a central role in the acute perioperative period. The anesthetist may advise on the potential suitability of a patient to be managed either in the ward or in the High Dependency Unit in the immediate postoperative period. (The role of the bariatric anesthetist is discussed in more detail in Chap. 13).

   In addition to these core members of the MDT, there are number of additional personnel who often have an important role in the multidisciplinary management of bariatric patients. These include:
6. Clinical nurse specialist: In many units, the nurse specialist has a role in assessing patients prior to surgery; conducting postoperative clinical reviews, and acting as a first port of call for any patient with a problem following their bariatric surgery.
7. Plastic surgeons: Following bariatric surgery, a significant number of patients have excess skin as a result of weight loss which can have significant functional impairment as well as significant esthetic consequences. As a consequence, the input of the plastic surgeon may be useful in appropriately managing these patients and their expectations.
8. Administrative staff: Patients having bariatric surgery undergo a complex clinical pathway involving multiple assessments by different personnel. In addition, patients require close monitoring following surgery and hence, the input of the administrative team is required to co-ordinate these services.

15.4 Evidence Base for Multidisciplinary Team Approach

Although the MDT approach to most branches of general surgery has become standard over the last decade, there has been very little research on this subject. Perhaps the most obvious reason for this is that it is very difficult to perform randomized control trials on the impact of the multidisciplinary working given the obvious ethical issues associated in allocating patients to a treatment pathway which does not include input from different specialties. Despite this, a number of cohort studies have been done in the field of cancer surgery examining the role of the MDT on outcomes. Martin-Ucar et al. [1] demonstrated that in patients with non-small cell lung cancer, the involvement of a specialist surgeon and an MDT were associated with an increased rate of patients undergoing a lung resection and an increase in the number of extended resections. Similarly Stephens et al. [2] demonstrated that the MDT approach in the management of the esophageal cancer led to a significant improvement in perioperative mortality rates and 5 year survival rates. The impact of the MDT on clinical outcomes is almost certainly multifactorial, but probably related in part to number of factors including:

- Centralization of services—One feature of the MDT approach is that it tends to result in patients treated in high volume specialist centers and managed by high volume specialist surgeons. These two factors have been shown to improve clinical outcomes in bariatric surgery [3] as well as in upper GI cancer surgery [4].
- Previous studies have demonstrated that physicians tend to overestimate the morbidity and mortality associated with surgery [5]. Hence by involving surgeons in the management of all cases, it is possible that patients who ordinarily would not have been referred by their physician for surgery, when managed through an MDT approach may in fact undergo surgery and potentially derive a better clinical outcome.

Unlike cancer surgery, which for many years occurred without the involvement of a formal MDT, bariatric surgery is a relatively new specialty. As such, the vast majority of the publicly-funded units in the UK which have been formally commissioned to provide bariatric surgery have utilized the MDT as an integral part of bariatric surgical pathway from the very beginning of their activity. Currently there is no prospective or retrospective cohort study data on the impact of the MDT in the literature. Indeed the only UK based study on this subject was an experience of University College Hospital, London [6]. In this study, the authors analyzed the impact of MDT case discussion and found that the MDT rejected a total of only 3.6 % of the patients for surgery due to either severe medical or psychological problems. Although the study demonstrated that MDT had a limited role in filtering the patients for surgery, this study did not calculate how many patients had their management altered by the MDT (example by initiating investigations or interventions prior to surgery).

15.5 International Guidelines

Several guidelines now recommend the service of a multidisciplinary team for the care of a patient undergoing bariatric surgery. For example in

England, the National Health Services (NHS) Commissioning Board Clinical Reference Group for Severe and Complex Obesity [7] states that surgery can be considered as a treatment option for morbidly obese patients only if there is a formalized MDT led process for screening of comorbidities, preoperative management of comorbidities, conservative treatments and life-long follow–up care.

Similarly the National Institute for Clinical Excellence (NICE) clinical guideline (CG43) on obesity recommends that bariatric surgery should be undertaken only by an MDT [8]. The MDT is required to provide preoperative assessment with risk-benefit analysis, information on the procedure, regular postoperative dietetic care and assessment, and management of comorbidities. It should also be able to provide psychological support both before and after the surgery as well as information about and access to plastic surgery, if needed. Young people who undergo bariatric surgery should be cared for by an MDT that has sufficient pediatric experience.

The Endocrine Society Clinical Practice Guideline for management of the post-bariatric surgery patient recommends that all patients must receive care from an MDT that includes an experienced primary care physician, endocrinologist, or gastroenterologist [9]. The patient should also consider enrolling in a comprehensive program for nutrition and lifestyle management following the surgery.

Conclusions

Multidisciplinary team involvement is now considered an integral part to successful patient outcomes in bariatric surgery. Although primary role of the MDT is to assess and optimize patients for primary bariatric surgery, there has over the last few years been an increase in the number of complex cases referred for bariatric surgery. There is an increasing workload of patients who present particular technical challenges (example, the super-super obese), patients with complex underlying medical conditions and "special" categories of patients (example, morbid obesity in the extremely young and old). In addition, there has been a steady increase in the number of referrals for revisional bariatric surgery either for weight regain or for complications related to primary bariatric surgery such as acid reflux and stomal ulceration. As bariatric surgery becomes more common and the incidence of these revisional and high-risk surgical cases increases, the MDT will become even more central in ensuring high quality short and long-outcomes.

Key Learning Points

- There is an increased acceptance of the importance of a multi-disciplinary (MDT) approach in bariatric surgery.
- Core member of the MDT include an obesity physician, bariatric surgeon, dietitian, psychologist, and anesthetist.
- Additional members of the MDT may include plastic surgeons, nurse specialists and administrators.
- Although there is limited direct evidence of the efficacy of the MDT in bariatric surgery, the increasing number of revisional and high risk surgical cases means the MDT is likely to have an increasingly important role in managing these patients

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16 Nursing Care of the Bariatric Surgery Patient

Tamara Puplampu and Susan Simpson

Abstract

Bariatric surgery offers an effective method of long term weight loss for the obese patient. The increase in the number of bariatric patients undergoing surgery means that an understanding of how to provide high quality nursing care to this challenging group of patients is vital. The provision of specialized nursing care, based on up to date research and knowledge will have a positive impact on the patient's journey. This chapter deals with multidisciplinary approach to the preparation of the patient for surgery and the prevention and early recognition of perioperative/postoperative complications.

Keywords

Communication • Multidisciplinary approach • Perioperative care • Teamwork • Patient positioning • Surgical complications • Protocols

16.1 Introduction

Specialized and empathic bariatric nurses as well as trained hospital staff play a key role in the care of bariatric patients. Understanding morbid obesity and the surgical treatment of obesity enables nurses to provide evidence-based quality care as these patients may be at high risk and also have various co-morbidities. Coordinating and delivering holistic, high quality and competent care for bariatric surgical patients is imperative [1]. The role of bariatric nurses is to ensure coordinated care for the patient while in hospital. Liaising with the supporting staff, ensuring availability of appropriate equipment and trained staff to care for bariatric surgical patients are critical to safe and effective care of the bariatric patient and prevention of caregiver injuries [2].

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Bariatric patients need to be well prepared and optimized for surgery in order to minimize risks. Hence, decision making for bariatric surgery needs a multidisciplinary approach. Effective communication is a crucial part of the process. It enables team members from different disciplines to share their valued, and sometimes different, opinions and collaborate for the best interest of the patient. Spending time to listen to the patients, collecting information from them, and updating the multidisciplinary team may promote patient safety [1].

16.2 Preparation for Surgery

The bariatric nurse's involvement in patient care commences at the patients' first appointment at the bariatric center. The bariatric specialist nurse assesses the individual needs of each patient and begins their education about the types of bariatric procedures available. It is important that the patients understand their own vital role in the preparation for the surgery especially in relation to the preoperative changes that may be required, their postoperative management and the eventual outcome of the surgery. The bariatric specialist nurses are involved in the multidisciplinary

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discussion of each patient, where they share the information they have gathered about the patient with the team and help the team to decide the overall suitability of the patient for surgery. The bariatric nurse will also ensure that patients who are on medication such as anticoagulants follow the preoperative protocol. Patients who require nutritional optimization through supplementation are informed in writing about the specific instructions. Their general practitioner (GP) is also informed so that they can prescribe any needed supplements or medication. The bariatric nurse specialist will see the patient again at the education sessions and at pre admission visit. The patient is informed about the ward experience, medication, pregnancy, diet and physical activity post-surgery.

16.2.1 Preparation Includes

- Assessment of height, weight and body mass index (BMI),
- Education (individual or group sessions)—about the required pre- and postoperative changes,
- Blood tests—full blood count (FBC), liver function test (LFT), thyroid function test (TFT), lipids, glucose, HbA1c, urea and electrolytes (U&E), vitamin B12, folate, ferritin, calcium, 25 hydroxy-Vitamin D and parathyroid hormone levels. C-reactive protein (CRP) levels may also be checked at some centers [3].
- Electrocardiography (ECG) is done as a reference point to detect any later abnormalities,
- Surgical review to examine the patients' fitness and suitability for surgery and to discuss the different types of surgeries available,
- Multidisciplinary team discussion with a decision on whether to proceed with surgery. This discussion will also highlight any areas for optimization,
- Sleep studies, if indicated,
- Psychological evaluation and therapy if needed,
- Review by the bariatric specialist physiotherapist to educate the patient about the importance of physical activity.

16.3 Intraoperative Care of the Bariatric Patient

Every patient's journey through the operating theatre involves some degree of risk. Morbid obesity increases those risks and presents many challenges to the operating theatre team [4]. Preoperative assessment by the surgeon and the anesthetist will provide the team with important information.

At the time of preoperative nursing assessment, the sequence of events for the day of surgery can be discussed and any outstanding questions from the patient answered. It has been identified that one of the most distressing times for patients is waiting to go to operation theatre followed closely by not being allowed to drink [5]. With a thorough and honest explanation of the process involved, the anxiety may be reduced. This is not only important for the patient's wellbeing but may also decrease the complications and improve the recovery and the success of surgery [6]. Elevated anxiety levels have been shown to increase the need for postoperative analgesia [7]. Patients who are in pain will not mobilize as quickly and are therefore at greater risk of postoperative complications such as the formation of deep vein thrombosis or pulmonary embolism. The healing of surgical wounds may also be affected by anxiety [8]. Once the preoperative assessment has been completed, the information gathered can be shared at the team briefing prior to the surgery in accordance with the World Health Organization surgical safety checklist [9]. The team brief allows everyone involved with the patients' surgery to discuss and formulate a plan of care appropriate to that specific patient's needs, ensuring that the operating list runs safely and smoothly. The following are areas for consideration when planning the intraoperative care of the obese patient.

16.3.1 Teamwork

In the past, a hierarchical approach to operating theatre teams was commonplace. The surgeon instructed and the team carried out those instructions, creating a sometimes stressful environment for the surgeon who perhaps worked with different personnel every week and therefore needed to check that the theatre team of the day was aware of his/her and the patients' needs. The more recent collaborative specialist team approach allows theatre practitioners to work towards being part of a dynamic, interactive professional team with the shared goal of high quality patient-centered care, where all team members are valued for their contribution. Creating an open and mutually supportive workplace environment encourages inter-professional learning and better understanding of other team members' roles. Such an environment has also been shown to improve communication and professional practice, and reduce conflict [10]. The overall and most compelling reason to commit to effective inter-professional teamwork is that this should improve patient outcomes, increase safety, and reduce risks. The services provided are consultant-led and as such even in a collaborative team, the consultant still assumes ultimate responsibility for the patients' overall care [11]; however, using such a collaborative team approach, surgeons and anesthetists may be better supported by a motivated, knowledgeable and informed team of theatre personnel.

Fig. 16.1 Operating table showing width extensions

Fig. 16.2 Padded leg support

Fig. 16.3 Padded arm board

16.3.2 Patient Positioning

Positioning the patient safely begins with ensuring that the right equipment is available. It is important to have operating tables that are specifically designed to carry the weight of bariatric patients together with the relevant table attachments. There are many models on the market, some holding weights of up to 450 kg. At the higher end of the weight spectrum, table movement is limited; table tilting to the reverse Trendelenburg position and from side to side are unlikely to be an option above the 350 kg mark. These types of operating tables are also available in wider widths and have the option of extending that width using table attachments for the super obese (Fig. 16.1).

Well padded extra large leg and arm boards as well as foot boards, security straps and table clamps may be needed (Figs. 16.2 and 16.3).

Ward beds and patient trolleys should also be checked to ensure their weight capacity is adequate. Special bariatric beds may need to be provided for super obese patients and may be hired in if existing ward beds are not suitable or unavailable at the time.

Obese patients are at increased risk of injury due to the extra weight and pressure on their musculoskeletal system and nerves [4]. The comorbidities associated with obesity including type 2 diabetes, vascular disease and osteoarthritis all greatly increase the risk of tissue, nerve or joint damage through poor positioning techniques [4]. It is safer for the patient and the theatre team when the bariatric patient is able to get onto the operating table and position themselves comfortably before the start of the anesthesia Where this is not possible, equipment is needed to assist with positioning, for example a hover mattress. This device may be placed under the patient prior to anesthesia and when needed, can be inflated with air. It makes the patient more maneuverable and positioning simpler and safer. The use of these air mattresses also reduces trauma to the skin due to shear force [12]. All movements for proper positioning of the patient should be well coordinated, with adequate manpower to achieve the move and with the anesthetist as the lead. The team of theatre personnel will require training in positioning the obese patient. Staff may be concerned about injuring themselves [13], but gaining familiarity with the techniques and equipment used to move the bariatric patient will build confidence in the team and ensure safety of the patient.

Many bariatric surgeons prefer to have their patients in the French position during surgery [14]. This is essentially a supine position with the legs abducted on flat leg boards allowing room for the surgeon or assistant to stand between the patients' legs (see Fig. 16.4).

If reverse Trendelenburg position is preferred during surgery, it necessitates the use of well-padded and securely

Fig. 16.4 French position

Fig. 16.6 Padded foot board showing leg strapping

Fig. 16.5 Padded leg board showing foot support

fixed footboards to stop the patient from sliding down the operating table during surgery (see Fig. 16.5).

Strapping should be applied to the legs to ensure that they are supported when the reverse Trendelenburg position is used and to prevent the patient from sliding or moving [14]. The knees also need to be secured to avoid flexion during steep head-up tilt (see Fig. 16.6a).

Additional padding and cushioning of pressure points should be used as necessary to reduce the risk of pressure sores and nerve damage [15]. The patient's arms should be placed on padded arm boards and hyperextension avoided as it may result in brachial plexus injury (Fig. 16.6b) [16]. The arms should be secured to the boards or wrapped by the patient's sides to prevent him/her from sliding when the reverse Trendelenburg position and sideways tilt are employed. The theatre team should check the patients' position during surgery, especially after a change in position of the operating table. Although the patient is covered with sterile drapes, it is still possible to see any gross change in position and the scrub practitioner may be able to feel through the drapes to ensure limbs are still on the boards.

Other positions used for bariatric surgery include the supine position with both the legs lying together. This position may be used when the patient is super or mega obese and manipulating the legs is not possible. Lloyd Davis or modified Lloyd Davis position is not recommended in the morbidly obese as raising the legs in this way increases intra-abdominal pressure which may affect respiration and ventilation [17]. Evidence also shows that there is an increased risk of compartment syndrome when using one of these positions [18].

Whichever position is used, it is important to ensure that the patients' body is not overhanging the operating table and does not make contact with any metal as there is a risk of burning the skin if diathermy is used. Any overhanging tissue is at risk of compression from table attachments so these should be attached to the operating table with the utmost care. At the end of the procedure, an inspection of the patient's skin is useful to determine if there are any new breaks or areas of obvious pressure damage.

16.3.3 Prevention of Deep Vein Thrombosis in the Operation Theatre

Venous thromboembolism (VTE) is a major cause of morbidity and mortality in all surgical patients. Pulmonary embolism is a leading cause of death for bariatric patients as they are at an increased risk of developing this due to

Table 16.1 Points to remember while using stapling devices

How does the stapler work?	Involve the company representative to teach the staff Have regular updates
Familiarity with handling the staple gun	Have unsterile sample staplers available so that staff can practice loading and unloading the staples in a stress free environment. Staple line reinforcement products may also be required and these often are loaded directly onto the jaws of the stapler. Having the opportunity to practice this maneuver is also useful for the scrub team
Keep a preference folder of each surgeon's choices	The operating list will run much more smoothly if the correct equipment is immediately available in theatre for the surgeon who is operating As surgeons' preferences may change, it is good practice to ensure that the folders are regularly updated
Supervise and support junior staff	It takes time to learn how to use the staple devices safely and to gain the experience to be able to trouble shoot problems. Supervising and supporting inexperienced staff prevents mistakes for example, opening the wrong stapler or reloads. These are expensive items and mistakes have cost implications
Clear communication	Clear communication between the surgeon and the scrub practitioner is vital to ensure the correct staple cartridge is available when needed

their weight, reduced mobility and venous stasis. Those with a history of previous VTEs, hypercoagulation and recurrent spontaneous abortions are at an even higher risk [19].

According to the National Institute of Clinical Excellence guidelines, every patient should have a preoperative assessment for the risk of developing VTE [20] Local protocols should be followed based on that assessment to employ strategies to reduce the risks of VTE. These may involve the use of graduated compression stockings (unless contraindicated), intermittent pneumatic compression (IPC) devices and the use of subcutaneous low molecular weight heparin (LMWH).

The patient needs to be measured for the stockings to ensure the correct size is applied. Once worn, the stockings need to be checked on a regular basis to avoid wrinkling around the knees and ankles where the bunching of the material may restrict circulation and cause tissue damage. If the stocking are too small, there may be increased risk of compartment syndrome [21].

The correct application of IPC devices is vital. The manufacturers' instructions need to be followed particularly in reference to the contraindications for use, which include patients with vascular or neurological impairment, edema or areas of fragile or broken skin on the lower limbs [21]. It is important to ensure that table attachments and any strapping used for positioning do not interfere with the function of the IPC device. Assessment of the patient's legs must be made postoperatively as continued use of the IPC device, especially in the presence of active patient warming, may cause skin irritation [22].

16.3.4 Stapling Devices

Stapling devices are available from many companies, all differ slightly in design and each surgeon will have their own preferences. Table 16.1 illustrates some points to remember when dealing with stapling devices.

16.4 Postoperative Care of the Bariatric Surgery Patient

To improve and optimize the patients' quality of care, clinical protocols and guidelines for the peri- and postoperative care of the bariatric patients should be in place. These reflect patients' needs at different time points during their stay and allow staff to follow a structure of care, delivering safe and effective care to the patients, reducing their hospital length of stay and thereby reducing the overall financial costs [23].

Careful monitoring of the cardiovascular and respiratory status is essential in the postoperative period. Being able to identify early signs and symptoms of complications, acting on them and escalating to the surgical team are vital skills required by nursing staff managing the bariatric surgery patient [24, 25].

16.4.1 Pain Management

It is crucial to effectively manage postoperative pain after bariatric surgery as it allows early mobilization, increases overall levels of activity, allows sitting up and out of bed, promotes deep breathing exercises and coughing and the use of the incentive spirometer. It also allows the patient to interact more fully with the physiotherapy team. All of this will aid in getting the patient back to normal function and reduce postoperative complications [26].

Nursing staff should regularly assess patients' pain and encourage them to communicate their needs freely. Opioid sparing analgesics, such as paracetamol, are preferred as they reduce the risk of respiratory depression and airway compromise especially for patients with obstructive sleep apnea.

Avoiding opiates may have the additional advantage of not masking the signs of postoperative complications [25, 26]. There will be consultations with the bariatric pharmacist to convert postoperative analgesia from intravenous to oral form (this can also be part of the bariatric inpatient protocol). The pharmacist will also ensure other medications such as antihypertensive and antidiabetic agents are available in soluble or crushable form. Following surgery, it is usually recommended that patients avoid whole tablets for a period of 4–6 weeks.

16.4.2 Respiration

Obese patients are at higher risk for hypoxemia; therefore, supplemental oxygen should be administered as prescribed to maintain acceptable oxygen saturation levels. Patients with obstructive sleep apnea should restart continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) support as soon as feasible after surgery in order to minimize postoperative atelectasis and respiratory failure [27].

Patients should be advised to bring their CPAP/BiPAP devices when coming to hospital for bariatric surgery. Concerns about the use of CPAP and BiPAP in the postoperative period have been shown not to be significant and studies have not shown any increased risk of anastomotic complications following RYGB [28, 29]. However, postoperative instructions about the use of CPAP/BIPAP devices, as mentioned in the surgical postoperative notes, should always be followed.

Deep breathing, coughing, and the use of incentive spirometers are encouraged postoperatively. Patients are nursed at a 45° angle in bed to improve pulmonary function by the use of gravity to assist the downward movement of the diaphragm facilitating an increased tidal volume.

Adequate pain control with minimal use of opioids will aid breathing exercises and is also optimal to their care [23, 30].

16.4.3 Venous Thromboembolism

Early and frequent mobilization is the key in the prevention of VTE or pulmonary complications. Nurses must encourage deep breathing, leg exercises, and mobilization on the day of surgery and while the patient is in hospital [2, 29].

As discussed above, hospital protocols for the administration of low molecular weight heparin and the use of IPC should be followed as these interventions decrease the risk of VTE formation in the postoperative period [19, 31].

A bariatric physiotherapist may be helpful to educate the patients about the importance of activity pre- and postoperatively and to work with patients to optimize their activity levels.

16.4.4 Detecting Early Postoperative Complications

16.4.4.1 Wound Infection

Surgical site infection is the most common complication of bariatric surgery, more so in open surgery, but less in laparoscopic procedures [32]. Wounds should be observed for signs of infection, redness, swelling, and tenderness. Wound dressing should be assessed for any bleeding and wounds should be covered with a sterile dressing. Skin and skin folds should be kept clean and dry as there is a high risk of skin breakdown.

16.4.4.2 Nausea and Vomiting

Nausea and vomiting can be common problems following bariatric surgery. Prescribed antiemetic should be given to the patient as required. Patients are usually allowed sips of water postoperatively unless otherwise instructed by the surgical team. Nurses should ensure patients are well hydrated and a strict fluid chart balance maintained [1, 23].

16.4.4.3 Postoperative Hemorrhage

Postoperative hemorrhage is usually at the site of the staple line or at the site of anastomosis. Bleeding can manifest itself as a gastrointestinal bleed with melena or hematemesis. It may also present as an intraperitoneal bleed with abdominal distension and bloody drain output, if a drain is present. Caution should be applied as the drain can get blocked with clots. Bleeding can also present with evidence of hypovolemic shock. Signs may include hypotension, tachycardia and oliguria [2, 30].

16.4.4.4 Anastomotic Leak

Clinical observations remain the most reliable means of diagnosing a leak. Nurses need to be aware of the signs and symptoms of an anastomotic leak and be vigilant while nursing patients. Patients should be observed for tachycardia, tachypnea, hypotension, increasing abdominal and shoulder pain as these raise the suspicion of a leak or a bleed. Prompt action by escalation to the surgical team is required if these signs or symptoms occur.

16.4.5 Intensive Care Input

Bariatric patients with multiple comorbidities or those that develop complex postoperative complications may require the input of the critical care team. The assistance of cardiologists and respiratory physicians in particular may be needed. If patients require ventilation the right equipment must be available with appropriately trained staff to use it [29]. Nursing bariatric patients in such settings may require the addition of extra staff and equipment for the safe moving and handling of the patient. At this stage, communication between the multidisciplinary team and the family is vital. Dignity, privacy, and care without prejudice and inequality must be maintained throughout the patient's stay in hospital [29, 30].

16.5 Discharge

Depending on the type of surgery, medications on discharge may include analgesics, laxatives, multivitamins, calcium supplements, proton pump inhibitors and low molecular weight heparin. The nurse should review all the medications with the patient prior to discharge. Written and verbal dietary information and postoperative instructions including wound care, diabetes care, signs and symptoms of late complications are given to the patient and are explained to them to ensure the patients have complete understanding. Advice regarding physical activities or a review by a bariatric physiotherapist prior to discharge is also required. Patients need to be given information about what to do if they become unwell or are not tolerating oral intake.

Patients are advised about the importance of follow up support by the bariatric team. Follow up appointments to see the bariatric specialist nurse, dietician and surgeon should be arranged prior to discharge. Most bariatric specialist nurses conduct telephone follow up consultations 24–48 h following discharge to support the patient at home.

If the patient has had gastric band surgery, the initial adjustments of the band are often carried out with radiology support but following this the bariatric surgery nurse specialist will usually carry out any further adjustments if trained and competent to do so.

Patients are encouraged to attend the support groups facilitated by the bariatric surgery nurse specialists. This forum gives additional support to both patients who have had surgery and also those considering it in the future.

Conclusion

Nursing morbidly obese patients in hospital is becoming more and more frequent due to the rise in obesity. Adequate education and training of nurses to deliver evidence based nursing care throughout the journey of the bariatric surgery patients along with adherence to policies and protocols will result in safer nursing practice, more confident staff and satisfied patients. Educational opportunities can also challenge negative attitudes held by nurses towards obese people and potentially improve them. The bariatric surgery nurse specialist can play a vital role in this process by supporting and educating nursing staff regarding issues that affect obese patients [33].

Key Learning Points

- Nursing morbidly obese patients in hospital has become more prevalent due to the rise in obesity.
- Bariatric specialist nurses have an important role in the bariatric surgery team as they help to evaluate the patients considering bariatric surgery and educate them about the pre-, peri- and postoperative changes required. Specialist nurses often lead patient support groups and provide a link between the patient and the rest of the bariatric surgery team.
- Nursing staff treating patients undergoing bariatric surgery need a thorough understanding of the disease, the operations performed and the possible complications.
- Adequate education and training of nurses to deliver evidence based nursing care throughout the patient's bariatric surgery journey and the adherence to policies and protocols will result in safer nursing practice, more confident staff and satisfied patients.

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17 Perioperative Management of the Bariatric Surgery Patient

Sean A.A. Woodcock

Abstract

The perioperative care of the bariatric surgical patient is provided by the multidisciplinary bariatric team with patient safety being paramount. Patients should be adequately assessed and risk factors identified and managed prior to surgery to optimize patient outcomes. Such care can be divided into preoperative, perioperative and immediate postoperative care, up until the patient is discharged from the bariatric unit. Apart from addressing the medical and psychological issues of the patients,' the in-hospital experience of the patients should also be taken care of. Units should have adequate equipment and fully trained staff to look after the morbidly obese, with enough space to care for and ensure patient dignity and respect. Good communication between the surgical, medical, allied health professional and primary care is essential at this time of the patients' pathway to promote the high standard of care that bariatric surgery patients need. This chapter deals with these issues and is illustrated with the practical aspects of care that is offered at the author's place of work.

Keywords

Perioperative • Preoperative • Postoperative • Assessment • Multidisciplinary • Bariatric • Obesity • Surgery

17.1 Introduction

There are no quick fixes or easy solutions to patients who suffer from morbid obesity and associated illnesses. By the time a patient is listed for bariatric surgery they would have undergone several assessments in the community and hospital to identify and treat their complex medical, psychological and social needs. In England, patients need to have successfully completed a community adult weight management program (AWM), demonstrating a satisfactory level of commitment, motivation and understanding before being considered for surgery [1]. Community AWMs are called Tier 3 and are either funded by local authorities or clinical commissioning groups (CCGs). They have now become mandatory in England since April 2013 and are a prerequisite of bariatric surgery itself. Patients will have their cases discussed at Tier 3 multidisciplinary team (MDT) meetings or a Tier 4 (hospital) bariatric MDT. This process can take anywhere from 6 to 24 months to complete depending on local arrangements.

The bariatric procedure itself is only a part of the total bariatric care offered by a comprehensive bariatric service. Perioperative management includes all care delivered before, during and after the bariatric procedure and like most aspects of care is delivered by an MDT to ensure best patient outcomes.

17.2 Preoperative Issues

The purpose of the preoperative assessment is to stratify risk, identify patient specific factors and optimize patient outcomes using a multidisciplinary approach. The National Institute

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for Health and Care excellence (NICE) criteria states that the patients have to be fit for surgery [2] but obesity is associated with higher anesthetic complications. Obese patients are twice as likely to have airway problems [3]. In an audit of 6773 patients who underwent noncardiac moderate or major surgery, postoperative complications were seen in 33 % of obese patients and 15 % of morbidly obese patients. Obese patients had a five times higher rate of myocardial infarction. The morbidly obese had a postoperative death rate of 2.2 % compared to 1.2 % in the nonobese [4].

Dedicated preoperative assessment clinics that are jointly run by specialist nurses and anesthetists allow such patients to be identified and adequately discussed. Such assessment should take place several weeks prior to any intended surgery to allow time for adequate work up and more specialized investigations if required. Up to date blood tests, electrocardiograms (ECGs) and echocardiograms and carbon monoxide evaluation in "ex"-smokers are performed in our unit. We provide our patients with written and verbal details of the liver reduction diet at this stage. If patients are found to have put on weight since their last visit, then the surgery may be postponed after discussions with the consultant bariatric surgeon. In our unit, we take the consent for surgery in the outpatient clinic, weeks before the actual surgery and prefer a family member to be with the patient at that time. In our opinion, it is not appropriate to take the consent for such complex elective surgeries on the day of surgery as patients need time to consider all that has been discussed with them and the risks involved.

17.2.1 Respiratory Considerations

Respiratory problems are common in this patient group, in particular obstructive sleep apnea (OSA). This is associated with obesity and is seen in up to 77 % of the patients [5].

OSA should be considered if:

- Neck circumference is more than 43 cm in men and more than 40 cm in woman, and there is a history of snoring,
- There is a history of witnessed apneas and occurrence of morning headaches.

Symptoms alone are a poor predictor of OSA in obese patients as excessive daytime sleepiness is common in those who do not suffer OSA. This is why the Epworth Sleepiness Score (ESS) is not a particularly sensitive screening tool [6]. There are many scoring systems described that use anthropometric measurements [neck circumference, waist-hip ratio, and body mass index (BMI)] along with clinical and biochemical markers. The STOP-Bang questionnaire is one such scoring system in common use with scores of five to eight predicting patients with moderate to severe OSA [7]. Following a positive screening a referral to the local respiratory unit for formal sleep studies is made. Positive studies are associated with an apnea: hypopnea index more than five an hour and patients are commenced on nocturnal continuous positive airway pressure (CPAP) or bi = level positive airway pressure (BiPAP) using a device which can deliver air via different face/nasal masks depending on patient preference. The optimal time for treatment is unclear but we suggest a minimum of 6 weeks. Patients are reminded to bring their CPAP devices in for surgery.

Obesity hypoventilation syndrome (OHS) is seen in 10–20 % of obese patients with OSA and is defined as a triad of obesity, daytime hypoventilation, and sleep disordered breathing without an obvious significant lung or respiratory muscle disorder [8]. OHS is associated with higher rates of congestive cardiac failure, cor pulmonary and pulmonary hypertension. When untreated, it has a mortality of 46 % within 50 months of diagnosis [9]. Early recognition is essential with CPAP being the main stay of treatment.

Routine chest x-rays are of limited value due to poor penetration in the obese. Tests for arterial blood gases to determine PaO_2, $PaCO_2$ and bicarbonate levels can be used selectively.

17.2.2 Cardiovascular Considerations

Cardiovascular disease and its complications are not uncommon following bariatric surgery. Taking a reliable cardiac history is difficult given most patients are sedentary. Similarly, physical signs of cardiac disease are often missed due to the patients' body habitus. Hypertension is common and reported in up to 53 % of the patients with Class III obesity [10].

There exists a relationship between OSA, obesity and left ventricular failure (LVF). Obesity complicated by OSA can lead to hypoxia, hypercapnia, pulmonary arterial hypertension, pulmonary venous hypertension and LVF. Pulmonary arterial hypertension can also lead to right ventricular enlargement and hypertrophy resulting in right heart failure (RHF). Obesity is also associated with increased circulatory volume, increased stroke volume and an increase in cardiac output. An increase in cardiac output can lead to RHF or LVF via left ventricular hypertrophy and left ventricular systolic and diastolic dysfunction that in turn leads to obesity cardiomyopathy. These effects are all made worse by the coexistence of hypertension and ischemic heart disease.

We always ask for an up to date cardiac opinion for those patients with a known or significant cardiac history who are being considered for surgery. The revised Cardiac Risk Index can be used to assess cardiac risk in patients undergoing bariatric surgery. Parameters scored for are:

- High risk surgery,
- Ischemic heart disease,
- Congestive cardiac failure,

- Cerebrovascular disease,
- Insulin dependent diabetes mellitus and
- Renal Insufficiency

We do not use this routinely in our bariatric unit. Where used patients performing poorly should be considered for more formal cardiac function tests arranged by their cardiologist. Such provocation tests are not without their own problems with poor image quality and physical limits to the size of patient who can be studied. Such specialist tests may include single photo emission computerized tomography (SPECT) and cardiac positron emission tomography (PET), pharmacological stress testing and cardiac catheterization (the gold standard for investigating coronary heart disease).

The heart and the lungs however do not function independently and to investigate them as such gives limited information. Cardiopulmonary exercise (CPEX) testing has been used in those patients who can exercise although its use in bariatric patients is by no means widespread. Straight away we can appreciate the limitations of this investigation in our population of patients and currently it is not used in our unit. When used, this test helps to calculate the mean maximum oxygen uptake (VOmax). Peak VO_2 less than 15.8 ml/kg/min has been shown to be associated with higher mortalities and morbidities. Obesity, male sex and the presence of diabetes but not OSA were found to predict poor functional capacity [11] and preoperative CPEX has been reported to predict length of stay following laparoscopic gastric bypass [12].

17.2.3 Smoking

Cardiovascular disease is the leading cause of mortality in the obese population. It does seem perverse to offer bariatric surgery, with a view to treating diabetes, hypertension, and dyslipidemias, to patients who continue to smoke but this is controversial. Cigarette smoking is an independent risk factor for postoperative complications following bariatric surgery. Smoking more than 20 pack years is associated with a difficulty in weaning from a ventilator [13]. Smokers have a longer length of hospital stay compared to non-smokers [14]. Anastomotic ulcers and staple line erosions are also more common. Evidence suggests that by stopping smoking at least 4 weeks prior to surgery such risks are reduced [15]. Our unit policy is not to offer bariatric surgery to patients who continue to smoke. We perform carbon monoxide assessments at preassessment visit and on the day of surgery. If carbon monoxide levels are in keeping with continued cigarette smoking then the surgeries are postponed. These carbon monoxide detectors are inexpensive. All our patients are made aware of our unit's policy with respect to smoking at the initial seminar and are offered smoking cessation advice and support. To date, we have postponed two patients out of the 1200 treated. We acknowledge that this is not a universal practice at present.

17.2.4 Endocrine

All patients should have had their thyroid function tests performed and were screened for type 2 diabetes mellitus (T2DM). Because of its extremely low pick up rate we no longer screen for Cushing's disease using the dexamethasone suppression test.

Patients that are found to be hypothyroid at assessment are commenced on thyroxine replacement therapy. Often patients believe that the thyroxine therapy will lead to sustained weight loss. Unfortunately this is rarely the case and patents continue on the bariatric care pathway. A euthyroid state is desirable; however, the relationship between obesity and thyroid status is complex as obesity is associated with an increase in thyroid stimulating hormone (TSH) and T3 compared to non-obese patients [16].

T2DM is common amongst our patients and good glycemic control is the aim preoperatively. We recognize that many type 2 diabetics are commenced on insulin in order to achieve better glycemic controls. This often leads to a static weight or more commonly a weight regain. This must be taken into consideration when listing patients for surgery if their motivation and commitment is being questioned.

Care needs to be exercised during the period when the patient is on the preoperative liver reduction diet. Diabetic patients often have hypoglycemia attacks as their insulin and oral hypoglycemic medication need to be decreased with weight loss and hepatic glycogen depletion. This is usually an early indicator of the likelihood that the patient might come off diabetic medications all together. It is suggested that insulin secretagogues are discontinued at this stage, premix and rapid acting insulins are reduced by 50 % and long acting analogues by 30 %. All other oral medications should be maintained until surgery [17]. Good communication between the patient, their diabetologist, and their general practitioner is important with clear guidelines for medication reduction.

17.2.5 Blood Tests

All patients need full hematological and biochemical profiles prior to surgery (see Table 17.1).

There is a 48–91 % prevalence of vitamin D deficiency in the morbidly obese [18]. The reasons given are variable. We screen all our patients at initial assessment and treat accordingly with high dose 20,000 U vitamin D taken three times a week for 6 weeks and then followed up with further supplements long term.

17.2.6 Endoscopy

The need for preoperative gastroscopy is controversial. Some units perform upper GI endoscopy prior to all types

Table 17.1 Routine screening blood tests

Full blood count
Ferritin
B12
Folate
Urea and electrolytes
Liver function tests
C-reactive protein
Thyroid function tests
Vitamin D
Calcium
Parathyroid hormone
Fasting lipids and cholesterol
Fasting Glucose

of bariatric surgeries, others selectively and some none. We routinely endoscope all our patients scheduled for gastric bypass and all the potential sleeve patients with a history of reflux disease. In the bypass patients, we want to know that we are excluding a healthy stomach and also to test for Helicobacter pylori using the Campylobacter Like Organism (CLO) test. Stomal ulceration at the gastrojejunostomy is multifactorial and the presence of H.pylori remains controversial in causation. Our policy is to treat all patients found to be CLO positive at the time of their preoperative endoscopy [19].

Gastroscopies are performed using throat spray only, usually 8 weeks prior to the surgery to allow for treatment of unsuspected ulcers and to have time to re-scope prior to definitive surgery.

17.2.7 Liver Reduction Diet

The purpose of the liver reduction diet is to reduce the size of the liver by using up a vast majority of its glycogen stores [20]. This diet, in its most extreme forms, consists of skimmed milk and yogurt, but in fact a very low fat and low carbohydrate diet will suffice. Other units describe the use of Optifast® as a meal replacement regime. One study has shown that the use of the liver reduction diet is associated with a decrease in postoperative complication rates [21]. The diet is usually started 10–14 days prior to the date of operation. Care must be taken with diabetic patients on medication, as hypoglycemic events may occur if medication doses are not adjusted accordingly. The resulting liver is softer and easier to retract during laparoscopy. Patients are warned that if they do not adhere to the diet, their surgeries may be abandoned. It is an interesting observation that most of our patients ask about the state of their livers at the time of their surgery.

17.2.8 Diet

Patients need to be informed about their new diets and eating patterns that will follow surgery. Experience has taught us that this information should be offered several weeks prior to the surgery, allowing the patients adequate time to prepare. Written information about food choices, suggested menus, explaining differing textures, portion size and fluid intake is given either individually or during a group session and any questions that come up are answered. Our dietitians lead seminars on postoperative diets for patients who are within a month of their surgeries. They make good use of visual aids to reinforce portion size following all of the three commonest procedures namely bypasses, sleeves, and bands. Since the introduction of these dietitian led events preoperatively, we have had a significant reduction in phone calls and queries postoperatively compared to when such information was provided only postoperatively. One of the simplest and most effective aide memoire is the "Rule of 20s." This trains our patients to chew their food well and eat slowly by chewing each mouthful of food 20 times, allowing a 20 s hiatus between each mouthful and after 20 min any food on the plate has to be discarded.

17.2.9 Pharmacy

Many patients are on polypharmacy prior to bariatric surgery and many of the medications are unsuitable to be taken in tablet form immediately postoperatively. The role of the bariatric pharmacist is to go through the patients medication several weeks preoperatively and convert them either into liquid medications or identify those medications that can be crushed or dissolved. Effervescent medications and non-steroidal anti-inflammatory drugs should be avoided. Medication with high sugar content should be avoided post gastric bypass in order to avoid dumping syndrome. Drug charts are written out prior to admission. There are many medications for which it is may be impossible to predict their bioavailability post bypass and sleeve gastrectomy. For other medications blood levels can be measured to help dose accurately, for example anti-epileptics and Lithium. The need for these medications in the long term may affect the choice of operation that the patient is counseled to have. Good communication is important in primary care so that general practitioners (GPs) are aware of the short term need of a different form of medication, thus preventing excess costs and waste and also educating both GP and patients with respect to the possibility of staggering doses throughout the day.

There is no published evidence that disease modifying antirheumatic drugs (DMARDs) used for immunosuppression need to be stopped prior to bariatric surgery [22]. Most such studies have been performed in relation to orthopedic surgery. However, it is difficult to make similar conclusion with respect to bariatric surgery. It is advisable to develop a close liaison with the patients' rheumatology team and provide individualized treatment plans.

17.3 Preoperative Care

On the day of admission most patients will be apprehensive and anxious. Many have been waiting for several years for the opportunity to undergo such surgery. Most morbid obese patients are self conscious and care, as for all patients, should include respect and dignity.

17.3.1 Furniture

When looking after bariatric patients it is vital that the ward and operation theatre are appropriately equipped with staff trained and familiar on how the equipment works. Suitable bed space that allows for a bariatric chair and bed needs to be made available, if required. A space of 14 ft by 15 ft has been recommended with patient controlled room temperature and toilet and bidet facilities with room to maneuver [23]. Most standard National Health Service (NHS) hospital beds take a weight of 30–35 stone (220 kg). However, investment should be made for dedicated bariatric beds that allow patients to "sit" in their beds. Bariatric chairs, commodes, zimmer frames and wheelchairs also need to be available. Thought should be given to make available blood pressure cuffs and theatre gowns that fit.

Unless wheelchair bound, the patients are allowed to walk to the theatre and get themselves up onto the operating table themselves. This reduces the amount of manual handling required by staff and so reduces the risk of injury to patient and staff alike. Neuropraxias to the brachial plexus can be decreased by patients positioning their arm themselves before being anaesthetized. The use of Hovermatts® (HoverTech International Bethleham PA USA) are ideal to transfer the obese patients safely back onto their bed (Figs. 17.1 and 17.2). Many patients have chronic back conditions that can be exacerbated by prolonged immobilization at the time of surgery. We make use of vacuum beanbags that support the arch of the back when the patient is awake. Once in the correct position the vacuum is applied and the bag molds the shape of the spine in the awake patient. With the spine now supported the patient is anaesthetized and muscle relaxants given. We have noticed decreased length of stays in our patients with existing severe mechanical spinal problems when using such devices. All patients are home within 1–2 days of their surgery, patients with exacerbated back problems had delayed discharges, which may extend even up to 7 days.

Potential pressure points are identified and protected by jelly pads [24]. Patients are best operated either in the supine position with full reverse Trendelenburg or in the beach chair position. In the first position, the patient's weight is supported by foot pads and the thighs are prevented from bowing using straps. This offers a great position, however, in prolonged surgeries ankle injury can occur (Fig. 17.3). We have adopted the beach chair position in our unit. The thorax is at 45° with the patient hips flexed to 90° and abducted (Fig. 17.4). This keeps the entire patient's weight in the seat of the table and is very stable with no excess strain on ankle joints or chuck devices. This also allows for a shorter rectus muscle length which in turn for the anaesthetized patient will give a greater intra abdominal space for any given intraabdominal pressure [25]. For large breasted patients we retract the breast cephadaly using adhesive tape but the nipple area is protected. This exposes the left upper quadrant perfectly for trocar insertion. Pressures of 12–15 mmHg usually suffice. A World Health Organization (WHO) check list is performed.

The vast majority of patients do not need high dependency unit (HDU) or intensive therapy unit (ITU) facilities routinely (more than 98 % in our practice).

17.3.2 Airway

Intubation of the morbidly obese patient is not without problems and an anesthetist should be well versed with the skills and techniques required to manage such airways.

Predictors of difficult tracheal intubation are:

- Neck circumference of 40 cm
- Mallampati score more than three
- Thyromental distance more than 6 cm
- Large tongue
- Presence of sleep apnea
- Respiratory

Respiratory physiology is significantly affected by obesity (see Table 17.2); general anesthesia and laparoscopy will exacerbate these respiratory variables further. Morbidly obese patients desaturate alarmingly quickly at induction.

Intravenous access is not without its difficulties in this group of patients and central line access may occasionally be required.

For all cases we prescribe antibiotics, intravenous proton pump inhibitors for our sleeve and bypass patients and combination of antiemetic medications. Specifics of surgery are discussed elsewhere in this book.

Fig 17.1 Operating table in Full Trendelenburg position with foot plates (**a**) from the right; (**b**) from the left

On the day of surgery, oral hypoglycemics can be omitted but some T2DM patients may require sliding insulin scales and this is discussed with the anesthetist. Regular blood glucose monitoring postoperatively helps predict when this can be stopped. We have a policy of stopping insulin the day following the surgery but maintaining oral hypoglycemics if required. If patients are on oral hypoglycemics only, the oral hypoglycemics may usually be stopped, however, this should be discussed with the obesity physician and an individualized plan made for each patient.

17.3.3 Deep Vein Thrombosis Prophylaxis

Morbidly obese patients are 2.5 times more likely to have a deep vein thrombosis (DVT) than nonobese patients [26]. There is 1–2 % risk of developing deep venous thrombosis and pulmonary emboli in this group of patients. A recent study observed that 74 % of events occurred after discharge and were more common in patients who are males, aged over 55 years, smokers and have a past history of previous DVTs [27]. There are no clear antithrombotic guidelines with respect to what to give,

Fig. 17.2 Inflated Hovermatt (**a**) from the right; (**b**) from the left

at what dose and for what duration. Our policy is to give low molecular weight heparin preoperatively and to continue for 7 days following a gastric band and 14 days following a gastric bypass or sleeve. In the hospital all the patients get antiembolism stockings and while in the operation theatre they get intermittent pneumatic compression boots. Early mobilization is recommended. Postoperatively, it may be difficult to distinguish between an early anastomotic or staple line leak and a pulmonary embolus. A high index of suspicion is required to recognize such problems and to perform appropriate investigations.

17.4 Postoperative Care

Following the WHO sign out checklist, patients are transferred back to their beds using the Hovermatts® and nursed upright to minimize atelectasis.

Patient data and operative information is placed on the National Bariatric Surgical Registry (NBSR) at this stage. The NBSR is an internet based surgical registry that resulted from the collaboration between Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI), Association

Fig. 17.3 Deflated Hovermatt (**a**) from the left; (**b**) from the right

of Upper Gastrointestinal Surgery (AUGIS), British Obesity & Metabolic Surgery Society (BOMSS) and Dendrite Clinical Systems. The objective of the registry is to accumulate data to allow the publication of a comprehensive report on outcomes following bariatric surgery in the United Kingdom. Input of NHS patient data onto the NBSR is now compulsory and has led to surgeon and unit specific data being made available in the public domain since June 2013.

Patients are allowed to sip water once they recover from the anesthesia and move on to free clear fluids as their recovery continues on the day of surgery. Other units may have different oral protocols depending on the surgeon's preference and experience.

Regular four-hourly observations are performed including Boehringer Mannheim blood glucose tests (BMs) in our diabetic patients and CPAP devices applied to our patients with OSA. The ward nurses and doctors are instructed to call the bariatric surgeon directly if patients develop a persistent tachycardia as this may be the only indication of an anastomotic leak or a bleed postoperatively. Early relaparoscopy is the management of choice if a nonsurgical cause cannot be easily identified.

Fig. 17.4 Operating table in the "Beach chair" position. (**a**) from the left; (**b**) from the right

Table 17.2 Effect of obesity on respiratory physiology

Increased basal oxygen consumption
Increased basal carbon dioxide production
Decreased chest wall and lung compliance
Increased airways resistance
Decreased functional residual capacity
Increased risk of atelectasis
Increased risk of ventilation/perfusion mismatch
Impaired oxygenation

Initially the pain relief is usually achieved by the use of opioids but analgesia via different pharmacological pathways is preferred. Patients who are on multiple classes of analgesics due to chronic pain conditions preoperatively present postoperatively as a challenge to the anesthetist and to the surgical teams alike and one must remember that 'forewarned is forearmed.' In such a situation a thorough preoperative assessment is recommended. It is also recommended to explain to the patient about the expected pain and what drugs can be used and their modes of administration including patient controlled analgesia (PCA) and dermal patches. It was of interest to note that younger patients, male patients and those patients with a history of hospitalization for psychiatric disorders had higher use of opioids in the immediate postoperative period in a study by Weingarten et al. [28]

Physiotherapist should be available if required to educate on breathing exercises and mobility.

On the day following the surgery, we offer yogurt as a first meal and clear soups. Patients are encouraged to mobilize but asked to keep their thigh length anti-embolism stockings (TEDS) on. They are taught how to self-administer their subcutaneous heparin. Our diabetic patients are reviewed by the diabetic nurse specialist and given clear instruction with respect to BM monitoring and a schedule to decrease their medication once discharged.

17.4.1 Discharge

Gastric band surgery and gastric balloon insertion is usually performed as a day case. Most gastric bypass and sleeve patients are discharged 1–2 days postoperatively. Our patients get clear written advice and have already attended a postoperative diet information seminar prior to their surgery so they are fully aware of what their diet will be like in the forthcoming weeks. Routine patients are discharged with liquid paracetamol, sublingual proton pump inhibitors (PPIs), Low molecular weight heparin and chewable multivitamins. Their usual medication is converted to a more appropriate form, if required. Patients receive a telephone call from a member of the team within 2 days of discharge and are given a contact number for further advice and support. A routine outpatient appointment is made with the specialist nurses for 6 weeks postoperatively. The NBSR database is updated on discharge and subsequent outpatient visits.

Key Learning Points

- A Multidisciplinary team approach is essential in the management of the obese patient undergoing bariatric surgery
- All care should be patient centered and provide by experienced personal
- The appropriate management of patient comorbidities optimizes patient outcomes
- The well-being of our patients involves an understanding of their physical, emotional and psychological needs

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18 Enhanced Recovery after Bariatric Surgery

Sherif Awad

Abstract

Enhanced recovery after surgery (ERAS) pathways integrate multimodal perioperative interventions. They aim at reducing metabolic stress, facilitating recovery after major surgery and maintaining bodily functions, and thereby allow early discharge from hospital. Much of the evidence in support of ERAS pathways originates from colorectal surgery. Morbidly obese patients undergoing bariatric and metabolic surgery characteristically have significant medical co-morbidities and a significant proportion have impaired mobility. Even then, a few studies have demonstrated the feasibility and safety of early discharge, on day one postoperatively, following laparoscopic bariatric surgery. There remains a paucity of data providing evidence in support of enhanced recovery after bariatric surgery pathways, with data originating from a few case series and one randomized study. However, many of the interventions utilized within generic ERAS pathways are now considered standard of care. In the absence of randomized studies in bariatric patients, these interventions may be implemented within enhanced recovery pathways designed for this patient group.

Keywords

Enhanced recovery • Fast track • Morbid obesity • Laparoscopic • Bariatric surgery • Length of stay • Complications • Readmissions • Compliance

Abbreviations

BMI	Body mass index
CP	Clinical pathway
ERABS	Enhanced recovery after bariatric surgery
ERAS	Enhanced recovery after surgery
LMWH	Low molecular weight heparin
LOS	Length of hospital stay
LRYGB	Laparoscopic Roux en-Y gastric bypass
LSG	Laparoscopic sleeve gastrectomy
OSA	Obstructive sleep apnea
PONV	Postoperative nausea and vomiting

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18.1 Introduction

The concept of enhanced recovery after surgery (ERAS) or 'fast-track' surgery originated following pioneering work in the mid-90's, by Kehlet and others [1, 2], who challenged traditional anesthetic and surgical practice employed during colonic surgery. ERAS pathways were developed to integrate multimodal interventions [3] that aimed to ameliorate physiological and metabolic stress perioperatively, facilitating early return of body function and reducing length of hospital stay (LOS). Numerous studies and subsequent meta-analyses [4] provided robust evidence that ERAS pathways, when utilized in patients undergoing colorectal surgery, improved surgical outcomes. Almost two decades on from the origin of the concept [5], ERAS pathways are now utilized in a number of surgical disciplines including colorectal, oesophagogastric, hepatobiliary, vascular, urological,

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orthopedic, and gynecological surgery, and furthermore are now considered standard of care [3]. International guidelines and consensus documents have been developed to guide and standardize enhanced recovery practice in the various disciplines. Constrained national healthcare budgets have provided impetus for implementation of these programs due to associated healthcare cost savings. While data supporting use of ERAS in bariatric surgery are limited [6], many of the components of ERAS pathways may be successfully applied in the setting of bariatric and metabolic surgery. This chapter provides a succinct review of the key ERAS interventions that may be utilized in an enhanced recovery after bariatric surgery (ERABS) pathway and reviews the existing evidence base in support of ERABS.

18.2 Components of ERAS

A number of multidisciplinary interventions (Fig. 18.1) employed in the pre, intra and postoperative settings aim to facilitate recovery by reducing the stress response to major surgery and attendant functional decline.

Fig. 18.1 Multimodal interventions which may be utilized within an enhanced recovery after bariatric surgery (ERABS) pathway. Abbreviations: *intraop.* intraoperative, *LPP* low pressure pneumoperitoneum, *NG* nasogastric, *PONV* postoperative nausea and vomiting, *preop.* preoperative

18.2.1 Preoperative

- Preadmission counselling: This helps in setting appropriate patient expectations and facilitating postoperative pain relief and recovery [3]. Explanation of what the patient will experience during their inpatient stay and the daily goals/milestones of the ERAS pathway helps empower the patient to achieve these goals. At this appointment, it is also important to explore the patient's social support structure, to ensure that measures are in place to enable postoperative care of the patient, thereby facilitating timely hospital discharge. These preadmission patient education sessions are normally provided by means of oral and written information sheets. Video animation may be used to increase patient understanding of the procedure to be performed. DVDs may be used to introduce patients to members of the multidisciplinary team and inpatient facilities [7] thereby helping to reduce their anxiety.
- Bowel preparation: Preparing the bowel preoperatively using oral agents is not a routinely used process in bariatric surgery.
- Shortened preoperative fasts: Nowadays, most anesthetic societies recommend shortened preoperative fasts permitting a light meal (dry toast and clear liquid) not less than 6 h preoperatively and unrestricted clear liquids (water, fruit juice without pulp, carbonated drinks, clear tea and coffee) until 2 h before surgery [8]. A Cochrane review [9] demonstrated no differences in residual gastric volumes (RGV) and occurrence of pulmonary aspiration between a shortened preoperative fast and traditional 'nil by mouth' from midnight regimens (Grade A evidence). Furthermore, two studies have demonstrated that in comparison to lean patients, RGV and pH were either reduced in obese patients following an overnight fast [10] or no difference was noted following ingestion of clear oral fluids 2 h before anesthesia [11].
- Preoperative metabolic conditioning: Oral carbohydrate-based drinks are utilized [12] to reduce patient anxiety and the occurrence of postoperative insulin resistance (Grade A evidence). These iso-osmolar drinks contain sufficient carbohydrate to induce an insulin response similar to that after a meal while having an osmolality that permitted rapid gastric emptying (within 2 h). Human studies demonstrated that undergoing surgery in a 'metabolically-fed' state, achieved when these drinks are ingested 2 h before surgery, was associated with a 50 % reduction in development of postoperative insulin resistance [8, 12, 13]. Furthermore, a recent meta-analysis [13] of seven studies that included 762 patients undergoing major abdominal surgery demonstrated preoperative conditioning using carbohydrate based drinks to be associated with significant reduction in LOS of one day. Two studies have utilized preoperative carbohydrate conditioning in the bariatric population as an intervention incorporated within ERAS pathways [14, 15]. In a randomized study comparing ERAS to standard care in patients undergoing laparoscopic sleeve gastrectomy (LSG), no differences in complications were reported between the groups [14]. However, it should be noted that only 15 % of the ERAS group (6 of 40 patients) received these preoperative drinks. Another study reported the use of carbohydrate conditioning drinks preoperatively in 65 patients that were part of an ERAS clinical pathway [15]. However, the aforementioned study did not report compliance with this intervention, nor describe in detail the nature of pulmonary complications that were encountered. Further data on preoperative carbohydrate conditioning are therefore needed in bariatric patients. As these carbohydrate-based drinks are administered in the evening before and 2 h prior to surgery (a total of 150 g carbohydrate), it is unlikely for their use to interfere with preoperative 'liver-shrinking' diets.
- Antithrombotic prophylaxis: There is grade A evidence from meta-analyses [16] supporting the use of low molecular weight heparin (LMWH), for example, enoxaparin, in major abdominal surgery to reduce occurrence of deep venous thrombosis, pulmonary embolism and mortality. Compared to unfractionated heparin regimens, LMWH is preferable due to the ease of the once-daily dosing and lower risk of occurrence of heparin-induced thrombocytopenia (HIT). Mechanical thromboprophylaxis should also be employed using anti-embolism stockings and intermittent pneumatic compression calf/foot pumps (example Flowtron®, Arjohuntleigh, Malmö, Sweden). However, in bariatric surgery, a consensus is yet to be reached on the optimal perioperative regimen and the duration of thromboprophylaxis. ERAS guidance on thromboprophylaxis in other surgical disciplines recommends adoption of an evidence-based local policy.
- Antimicrobial prophylaxis: Administration of a single dose of prophylactic antibiotics 1 h prior to skin incision is recommended to reduce occurrence of infective complications (Grade A evidence).

18.2.2 Intraoperative

- Standardized anesthetic practice: An optimized bariatric anesthesic protocol [7] may include ramped head-up intubation and extubation, utilizing short-acting opioids (for example, remifentanil) and multimodal analgesia (such as use of intravenous paracetamol, diclofenac and tramadol). Volume controlled ventilation with high PEEP (6–8 cm/H_2O) and permissive hypercapnea (end tidal CO_2 >6.5 kPa) may be used, the latter utilized due to its vasodilatory effects (to allow intra-abdominal bleeding to be detected intraoperatively). As most bariatric procedures are now performed via a minimal access approach, epidural analgesia is not routinely required in bariatric patients.

- Avoidance of intraoperative hypothermia: This can be achieved by using forced air warming blankets (example Bair Hugger®, 3 M, Bracknell, UK) and has been shown in randomized studies [1] to reduce occurrence of wound infections, cardiac complications, bleeding and transfusion requirements (Grade A evidence).
- Minimal access surgery: This is now routinely utilized worldwide to perform bariatric procedures [17]. Laparoscopic surgery is associated with reduced incidence of postoperative pain, wound infections and intraabdominal adhesions. It also allows earlier hospital discharge and is associated with reduced incidence of postoperative incisional hernias when compared to traditional open approaches. Use of low pressure pneumoperitoneum has been shown to reduce postoperative pain and analgesic requirements [18]. Similarly, there are data in support of wound infiltration and intraperitoneal local anesthetics to reduce postoperative pain and analgesic requirements [19].
- Humidification and warming of insufflated CO_2 during laparoscopic surgery (e.g., HumiGard™, Fisher & Paykel Healthcare, Auckland, NZ): This has been associated with reduced development of intraoperative hypothermia and postoperative pain [20]. Additionally, there were reports of reduced laparoscopic lens fogging thereby enhancing surgical efficiency [7]. It should be noted, however, that a previous Cochrane review [21] failed to demonstrate the aforementioned benefits. However the latter included small, heterogenous low-quality studies.
- Attenuating postoperative nausea and vomiting (PONV): Reduction of PONV can delay time to mobilization and oral ingestion thereby delaying hospital discharge. Specific patient groups are more prone to developing PONV and these include females, history of motion sickness, non-smokers and patients who receive opioids. Patients with ≥2 risk factors should receive PONV prophylaxis at induction with dexamethasone or a serotonin receptor antagonist at the end of surgery [3]. Additionally, regular prophylactic administration of antiemetic agents for the first 24 h (especially following sleeve gastrectomy where a high incidence of PONV is encountered) may also reduce occurrence of PONV [7].
- Nasogastric drainage, urinary catheters and surgical drains: A Cochrane review [22] of 33 studies that included >5000 patients demonstrated fewer pulmonary complications and earlier return of gut function in patients who did not have nasogastric decompression (Grade A evidence). Similarly, as epidural analgesia is not routinely utilized in laparoscopic bariatric surgery, there is no requirement for urinary catheterization. Indeed, the need to void urine often provides an incentive for early mobilization in bariatric patients postoperatively. Finally, meta-analyses have demonstrated no decrease in the incidence or severity of anastomotic leaks with the routine use of drains in colonic surgery [3]. In bariatric surgery, data from meta-analyses are lacking but there are those for [23] and against [24] routine use of abdominal drainage. Benefits include permitting drainage of abdominal wash fluid used during surgery, early detection of anastomotic leak (when an oral methylene blue postoperative leak test is utilized) and postoperative bleeding (although a blocked drain may provide false assurance that the patient is not bleeding). However, the aforementioned potential benefits need to be weighed against increased occurrence of postoperative pain, both locally at the drain exit site and due to diaphragmatic irritation (if the drain tip is positioned in the left upper quadrant), both of which could delay mobilization.

18.2.3 Postoperative

- Postoperative analgesia: There are no data suggesting gender differences in pain scores or analgesic requirements following bariatric surgery. As up to a third of bariatric patients may suffer from obstructive sleep apnea, avoidance of opiates, and their deleterious effects of respiratory depression and delayed gut function, are key to successful ERAS pathways. Multimodal opiate-sparing analgesia (example combination of paracetamol and tramadol) is therefore the preferred option. These may be administered by the intravenous or sublingual routes pending initiation of postoperative oral intake. The use of regular NSAIDs postoperatively is discouraged due to the attendant increased occurrence of anastomotic erosions and ulcers [25].
- Incentive spirometers: When appropriately utilized postoperatively, incentive spirometers encourage patients to deep breathe thereby reversing basal atelectasis and reducing pulmonary complications. This is of importance in morbidly obese patients in whom respiratory morbidity accounts for a significant proportion of complications encountered.
- Early mobilization: Within 4–6 h of completion of laparoscopic bariatric surgery, early mobilization may be successfully achieved [7]. Prolonged bed rest is associated with development of insulin resistance, decreased muscle strength, pulmonary complications and delayed gut function. Bariatric patients are also at increased risk of rhabdomyolysis and pressure sores; therefore, early mobilization is vital to avoiding significant postoperative morbidity.

- Avoidance of fluid overload: The patient is often administered liberal perioperative intravenous fluid infusion regimens. Restricting fluid intake to that which will maintain balance, as guided by body weight, results in earlier return of gut function [26], improved wound and anastomotic healing as well as improved tissue oxygenation thereby resulting in reduced postoperative complications and LOS (Grade A evidence). The safest way to manage fluid balance postoperatively is to stop intravenous fluids and allow patients to regulate their own fluid intake orally. In ERABS pathways, patients may be permitted sips of water on the evening of surgery and commence oral liquid diet on the first postoperative day.
- Postoperative nutrition: ERAS protocols encourage early nutritional intake via the enteral route. There is Grade A evidence that supports early enteral nutrition (versus '*nil by mouth*') following major abdominal surgery. There is reduced risk of infection, reduced LOS and no increased incidence of anastomotic dehiscence [3]. In the first few days following bariatric surgery, a multimodal regime of opiate-sparing analgesia, prophylactic anti-emetics, prokinetics and daily laxatives can increase tolerance of liquid diet and facilitate early discharge from hospital [7].
- Discharge and follow-up plans: Informing patients of the discharge criteria that need to be met, may help allay their fears and anxiety and promote cooperation with the ERABS pathway. Following bariatric surgery these criteria should include: adequate pain control with oral analgesia, tolerance of liquid diet, fluid intake of more than one l per day, adequate mobility to the same level prior to admission and presence of an adult at home to help care for the patient postoperatively. It is also important to issue written discharge information sheets to guide patients on symptoms encountered during the early postoperative course as well as alarm signs and symptoms that mandate hospital attendance. Provision of an emergency out of hours bariatric telephone number may also increase patients' confidence in the discharge process [7].

18.3 Advantages and Disadvantages of ERAS Pathways

Implementation of ERAS pathways has challenged traditional anesthetic and surgical practice leading to benefits for patients and healthcare providers. Patients report feeling more empowered and involved in their recovery process leading to increased satisfaction. Functional recovery is improved as a result of earlier mobilization, commencement of oral diet and earlier discharge from hospital. For healthcare providers, adoption of ERAS pathways has streamlined anesthetic and surgical pathways resulting in increased capacity, clinical efficiency and reduced healthcare costs. The benefits of ERAS pathways *versus* conventional perioperative care were demonstrated in a meta-analysis of six non-blinded randomized studies ($N=452$ patients) of patients undergoing major elective open colorectal surgery [4]. ERAS pathways were associated with significantly reduced LOS [weighted mean difference (95 % confidence interval): −2.55 (−3.24, −1.85)] days and complication rates [relative risk (95 % confidence interval): 0.53 (0.44, 0.64)]. There were no differences between groups in readmission or mortality rates [4], in contrast to other reports of readmission rates up to 22 % in ERAS patients [27]. Numerous weaknesses were identified in randomized studies of ERAS, including poor reporting of compliance with the individual elements of ERAS pathways, non-uniform methodology for reporting complications and individual studies being underpowered to report various clinical outcomes.

The major drawbacks of ERAS pathways, when applied outside the research setting, are firstly, compliance with the various elements of the pathway [27]; which unless enforced by a dedicated ERAS nurse tends to be non-uniform. Secondly, it is unclear which of the numerous components of ERAS are associated with clinical benefit. This concept is of importance, for example, when a laparoscopic approach is utilized as this may negate the need for epidural analgesia (which reduces development of physiological stress via blockade of the sympathetic nervous system). Finally, high re-admission rates [27] of ERAS patients are associated with financial penalties in some healthcare systems; therefore potentially negating economic benefits associated with early postoperative hospital discharge.

18.4 Evidence Base Supporting ERABS

There is relative paucity of evidence in support of ERABS practices. While there are no published randomized trials of ERABS in laparoscopic Roux en-Y gastric bypass (LRYGB) patients, numerous case series demonstrated that early discharge is feasible and safe in this group. A consecutive series of 2000 LRYGB patients (mean BMI 49.3 kg/m^2) demonstrated successful 23-h discharge in 84 % of cases [28]. This was associated with a 1.7 % 30-day readmission rate. Another series of 406 patients undergoing 'fast-track' LRYGB demonstrated the effects of the learning curve on LOS [29]. After the learning curve had been reached, it was possible to discharge 65 % of patients on the first postoperative day. It should be noted, however, that a formal ERABS pathway was not utilized in the aforementioned two series [28, 29]; which in effect demonstrated proof of principle that early postoperative discharge was feasible in LRYGB patients. Another study (published in abstract form) examined outcomes pre and post implementation of an ERABS pathway in 150 LRYGB patients [30]. Utilizing an ERABS pathway permitted standardization of pre and intraoperative care which improved the efficiency of the operating theatre (reduction in the time from arrival at theatre to arrival in the recovery area). Furthermore, the ERABS cohort had reduced LOS and no differences were noted in occurrence of postoperative complications. Finally, systematic review of 23-h laparoscopic gastric bypass surgery that included over 2200 patients demonstrated 84 % could be discharged within 23 h [31].

The only randomized controlled trial of ERABS undertaken to date, examined outcomes of laparoscopic sleeve gastrectomy (LSG) within an ERABS pathway ($N=40$) *versus* a control group ($N=38$) of patients that received standard care [14]. Median hospital stay was significantly shorter in the ERABS group (2 *vs* 1 day, $P<0.001$) and there were no differences in development of postoperative complications. Overall compliance rate with the ERABS protocol was 85 % but there was a 29 % crossover between ERABS and control study groups. It was also of note that both groups had a 30-day hospital readmission rate of 20 % [14].

Two further cohort series described outcomes of ERABS in patients undergoing bariatric surgery (LRYGB, LSG, laparoscopic gastric banding or biliopancreatic diversion with duodenal switch). The first study examined the effects of implementation of a clinical pathway (CP) that incorporated ERAS interventions in 65 consecutive patients who underwent laparoscopic bariatric surgery [15]. These patients were compared to a historical cohort at the same centre. Implementation of the CP resulted in earlier removal of the urinary catheter, improved mobilization on the day of surgery, increased use of incentive spirometers and shortened LOS. However, 75 % of patients in the aforementioned series received epidural analgesia and hospital discharge was planned on day 6 postoperatively. The perioperative protocol utilized therein was, therefore, at odds with publications from other bariatric centres that demonstrated shorter LOS in patients undergoing laparoscopic bariatric surgery [7, 28, 29]. The second was a feasibility study that described 226 consecutive patients undergoing primary bariatric surgery [LRYGB (66 % of patients), LSG (21 %) and laparoscopic gastric banding (13 %)] within an ERABS pathway [7]. The mean LOS for gastric bands, bypasses and sleeve gastrectomy was 0.69, 1.88 and 2.3 days respectively. Many patients had a successful discharge on the first postoperative day (37 % undergoing bypasses and 28 % undergoing sleeve gastrectomy). In 48 % of patients, gastric bands were performed as a day-case procedures. There was a 4 % complication rate and a 2.7 % readmission rate in this series. However, the authors did not describe compliance with the individual elements utilized within their ERABS pathway [7]. Finally, a systematic review of same-day laparoscopic adjustable gastric band surgery that included over 2500 patients demonstrated over 99.4 % of patients could be discharged on the same day [32].

18.5 Future Research

Future studies in patients undergoing bariatric and metabolic surgery should address the following:

- The safety of preoperative conditioning drinks administered 2 h prior to-induction of anesthesia in morbidly obese patients. Specifically, data should be sought on occurrence of pulmonary complications (e.g., aspiration) and preoperative glucose control in diabetic, morbidly obese patients.
- The beneficial effects of individual ERABS interventions on postoperative recovery should be studied. This approach is difficult, however, as thousands of patients would be needed to demonstrate differences in clinical outcomes that arise from use of individual elements in the ERAS pathway.
- The optimal perioperative analgesic regimen in morbidly obese patients is worthy of further study.
- Determine the minimum number and type of interventions that need to be utilized within an ERABS pathway to improve compliance and achieve clinical benefits.
- Factors (patient, surgeon and hospital specific) that predict successful outcomes following adoption of an ERABS pathway.

Key Learning Points

- Enhanced recovery after surgery (ERAS) pathways integrate multimodal interventions designed to reduce metabolic stress and facilitate rapid recovery after surgery.
- There is strong evidence base in support of ERAS pathways following major elective abdominal (mainly colorectal) surgery.
- Morbidly obese patients characteristically have significant medical co-morbidities and a significant proportion have impaired mobility. Having said that, principal studies have demonstrated the safety of early discharge, on day one postoperatively, following laparoscopic bariatric surgery.
- Many of the interventions utilized within generic ERAS pathways are now considered standard of care and may be implemented within enhanced recovery pathways designed for bariatric patients.

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Section IV

Laparoscopic Roux-en-Y Gastric Bypass (LRYGB): Techniques, Complications, Outcomes, and Controversies

Honorary Section Editor - Avril A.P. Chang

The original open Roux-en-Y gastric bypass was described by Mason and Ito [1] in 1966 and it was almost 30 years later in 1994 when Wittgrove and Clark first reported their experience with the laparoscopic Roux-en-Y gastric bypass (LRYGB) [2]. In the two decades since, surgeons around the world have made further modifications to the LRYGB in an effort to improve efficacy and decrease complications. The details of the LRYGB are well described in subsequent chapters on operative techniques.

In Chap. 25, Professor Higa discusses some of the controversies and questions surrounding the LRYGB, including whether the different types of anastomotic reconstruction, the different limb lengths and pouch sizes have any significant impact on outcomes.

The different types of anastomoses and their variations are described by experienced surgeons who give us the benefit of their detailed operative techniques, their peri-operative management strategy and their unit's results. Within each chapter, the surgical team has presented their work in full, and this has resulted in some duplication across chapters in this section. However, it has the advantage of each chapter being a complete entity, taking the reader through an operative technique from start to finish.

Chapter 19 describes the linear stapler technique for the gastro-jejunostomy with slight variations in the placement and formation of the alimentary limbs. In Chap. 20, the circular stapler technique for the gastro-jejunostomy is described with different methods of placing the anvil of the stapler into the stomach pouch. The hand-sewn technique requires more advanced laparoscopic suturing skills and is well described in Chap. 21. In addition, in Chap. 22, a completely standardised fully stapled technique is described, which, according to Professor Dillemans, offers a fast, reproducible, safe and easy technique to impart to trainees.

Chapter 23 provides a comprehensive overview of the complications that can occur with the LRYGB, along with preventative measures to lessen the likelihood of them occurring and helpful algorithms and management plans to lessen the impact of the complications if they do occur.

Finally Chap. 24 reports on the outcomes after LRYGB, including a brief mention on possible adverse outcomes to put things into perspective. However it is the therapeutic outcomes specific to LRYGB that is important and the authors have provided us with the knowledge to inform us why the LRYGB is currently still considered the 'gold standard' and the most popular bariatric procedure worldwide [3].

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LRYGB: The Linear Technique

19

Irfan Halim, Dimitri J. Pournaras, Sanjay Agrawal, and Yashwant Koak

Abstract

The evolution of the linear technique of laparoscopic Roux-en-Y gastric bypass for obesity is described. The two different approaches of the linear technique—reverse technique and the omega-loop, including the operative steps, are described here. The theatre set-up, intra-operative considerations and the postoperative treatment are included.

Keywords

Bariatric Surgery • Gastric Bypass • Laparoscopy

19.1 Introduction

The Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) procedure or "gastric bypass" is now one of the most popular procedures in bariatric surgery worldwide. There is considerable variation in the way this procedure is performed. In the first reported LRYGB a circular stapler technique was used [1]. Subsequently a linear stapler technique was described [2]. The first reported laparoscopic gastric bypass in Europe was performed with a variation of the linear staple technique which utilises an omega loop [3]. A hand-sewn technique for the gastrojejunostomy was also described [4]. There is considerable debate on the optimal technique for gastrojejunostomy anastomosis.

The debate regarding the most appropriate technique for creation of the gastrojejunal anastomosis is not new [5, 6] and there is considerable variation in the technique between individual surgeons [7]. It was reported in the United Kingdom in 2010 that of the 3817 gastric bypass operations performed. In 22.4 % of operations the circular stapling technique, 36.2 % the linear stapling technique, and in 33.4 % a hand-sewn technique was used. The method was not specified in 8 % [8]. It is widely accepted that the individual choice of approach is due to surgeon's preference and usually determined by previous training. Familiarisation with all the techniques is advised especially with the ever-increasing number of patients who have undergone gastric bypass surgery and present in the emergency setting. Knowledge and familiarity of other techniques will equip the surgeon with confidence in dealing with emergency or unexpected intra-operative situations such as stapler misfire, failed leak test or unusual operative anatomy which may not favour the technique being deployed by the surgeon.

This chapter discusses the linear technique and its variations in performing LRYGB and gives an overview of the procedure with detailed description of the key components of the operation. It is based on the authors' preference for the execution of particular techniques, however possible variations are also mentioned. Regardless of surgical preference, the overall procedural success is dependent on methodically

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following the main principles and key steps rather than debating over the superiority of one technique variation over another.

19.2 Pre-Procedural Setup

In performing the LRYGB, appropriate surgical preparation with setup and positioning of the patient is essential before commencing the surgery. Preoperative planning is described in more detail in another chapter in the book, however it is briefly mentioned again as this step is critical to the success of the operation as a whole. This consists mainly of:

- Liver shrinkage diet
- Informed consent
- Thromboprophylaxis
- Prophylactic antibiotics
- On-table setup and positioning

The liver shrinkage diet commences 2–4 weeks prior to surgery. This consists of a low calorie or low carbohydrate diet with the objective to reduce the liver size, improve intra-operative exposure and minimise abdominal wall splinting.

Thromboprophylaxis measures include the routine use of stockings for 30 days postoperatively, low molecular weight heparin preoperatively and then for 7–14 days postoperatively. Lower limb pneumatic compression devices are also used intraoperatively and during the immediate postoperative period.

Prophylactic broad-spectrum intravenous antibiotics are routinely given at induction and also continued for a further two postoperative doses.

Informed consent is obtained by the operating surgeon with risks, benefits, and alternative options to treatment explained to the patient. Details regarding the procedure and the postoperative course are discussed. At the same time patients are also consented for alternative procedures such as sleeve gastrectomy, if the bypass cannot be carried out. Patients are also informed that rarely neither procedure is feasible following diagnostic laparoscopy leading to abandoning of the operation.

During the consent process, complications mentioned include those specific to the bypass procedure such as bleeding, infection, port-site hernia, visceral injury, need for conversion to open procedure, anastomotic or staple line leakage, internal herniation, dumping syndrome, gastric or stomal ulceration, anastomotic stricture, malnutrition with the need to be on vitamin and elemental supplements lifelong with regular blood tests. General risks of surgery and anaesthesia such as deep vein or pulmonary thrombosis, atelectasis, pneumonia, myocardial infarctions, stroke, anaesthetic complications and mortality risk (less than 1 in 300) are also mentioned.

The patient then walks to the operating table and lies down on the operating table comfortably prior to anaesthesia.

After anaesthetic induction, the patient is placed in a reverse Trendelenburg position with the split-leg approach. The operating surgeon stands on the right side of the patient with the assistant between the legs, or vice versa and the scrub nurse on the left side of the patient. Dr Koak prefers standing centrally between the legs position with the assistant on either side. The laparoscopic equipment including the monitor is positioned just above the patient's head in the midline or just to the right of it. An orogastric tube (30 Fr) is inserted by the anaesthetist to decompress the stomach. Note that the withdrawal of this tube into the oesophagus is essential prior to any stapling in the stomach.

19.3 Procedural Set-Up

The procedure commences with skin preparation and draping of the patient. A pneumoperitoneum is created with the insertion of a Veress needle in the left mid-clavicular line just below the costal margin and insufflation to an intra-abdominal pressure of 15 mmHg is commenced.

Tip: Pressures between 12 mmHg to 20 mmHg may be used depending on the surgeon's preference and patient factors. A pressure higher than 15 mmHg is not generally recommended unless for short periods of time to overcome a difficult step in the operation after which the original pressure is resumed.

Four 10/12 mm trocars and a liver retractor are inserted (Fig. 19.1).

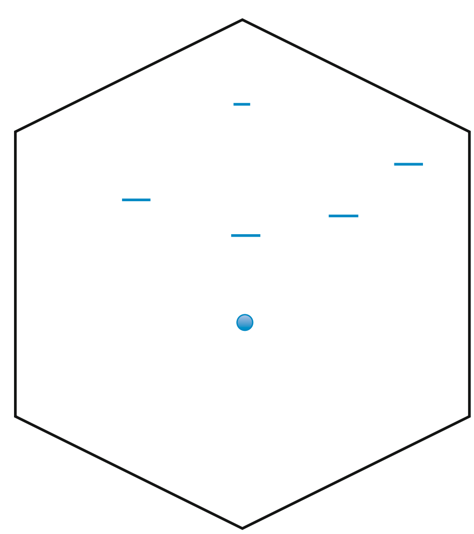

Fig. 19.1 Abdominal trocar/ports setup (see above)

The first trocar is inserted in the midline, 15 cm below the xiphisternum. We utilise an optical non-bladed trocar for the first entry to minimise haemorrhage and port-site hernia occurrence. Some surgeons prefer a position left of midline at the highest point of dome during insufflation for the first trocar, in line with hiatus, to decrease port site hernia issues.

The second trocar is inserted in the left flank usually one hand's breadth to the left and slightly cranial to the first port.

The third trocar in the right upper quadrant usually at the midpoint between the first port and right costal margin.

The last trocar is inserted in the left upper quadrant inferiolaterally to the Veress needle insertion site or just under the costal margin. The four trocars are like a smiling face position and provide the necessary triangulation required.

A 5 mm incision in the sub-xiphisternal midline is used for the insertion of the liver retractor.

Tip: There is considerable variation in exact port placement between surgeons and with different patients. Thus an individual surgeon may not necessarily use the same port sites depending on the patient's particular anatomy. Our recommendation is to place the first trocar as per the surgeon's individual preference and then assess the abdomen under direct vision for the optimal placement of the remaining ports.

An initial diagnostic laparoscopy is performed with inspection of the hiatus and with the objective to ensure that no abdominal adhesions are present so that the procedure is feasible. Any hiatus hernia seen is repaired as a cruroplasty prior to formally commencing the bariatric part of the operation. A very large hiatus hernia may require insertion of a mesh and the operation can be performed as a 2-step procedure to reduce the risks associated with long operative time. Simple visceral or abdominal wall adhesions may be divided to allow the LRYGB to progress. In difficult cases it is advisable to check if the bowel is free enough to allow mobilisation to the stomach. At this stage, a decision can also be made to proceed with a sleeve gastrectomy or other procedure if a bypass is deemed to be challenging or risky based on laparoscopic findings or not to proceed at all.

19.4 Laparoscopic Roux-en-Y Gastric Bypass

Once appropriate setup and diagnostic laparoscopy have been completed and a decision to proceed with gastric bypass is made, the surgeon must proceed with the main steps in performing the operation.

The four main steps in performing any LRYGB are:

- Formation of the gastric pouch
- Creation of a gastrojejunal anastomosis (GJA)
- Creation of the jejunojejunal anastomosis (JJA)
- Other essential steps such as closure of hiatus hernia, closure of hernia defects and leak test.

Note that the main steps are not performed in any particular set order and is subject to variation and individual surgeon's preference. We describe the two main variations of the linear stapled technique below in this chapter. The first variation—REVERSE LRYGB—creates a JJA first and then a gastric pouch followed by a GJA (Video 19.1). The second variation which uses the omega loop approach commences with the creation of the gastric pouch and the GJA followed by the JJA. The omega loop technique utilises the gravity traction afforded by the gastrojejunostomy and favoured by many surgeons. The mesenteric or Peterson's hernial defects may be closed as they are created or at the end of the procedure. Any hiatus hernia closure if required is usually done as the first step and the leak test is the final step. One of the key steps is dividing the omentum to prevent undue traction on the anastomosis. This step is essential to prevent omental traction. The omentum is divided longitudinally up to the transverse colon. Care must be exercised to prevent omental ischaemia or necrosis. This step can be avoided if the omentum is very thin.

There are three main areas in which variations to the LRYGB are noted.

- Anastomosis technique
  - Linear stapled
  - Circular stapled
  - Hand-sewn
- Alimentary limb configuration
  - Antecolic or retrocolic
  - Antegastric or retrogastric
- Length of both biliopancreatic (BP) and alimentary limbs
  - BP limb 25 cm/50 cm/100 cm (longer lengths are favoured for type 2 diabetes melitus, T2DM)
  - Alimentary limb 100 cm/150 cm/200 cm (longer lengths are favoured for T2DM)

The authors' preference is to use an antecolic, antegastric configuration with the linear stapled technique [9, 10] while Dr Agrawal prefers a retrocolic antegastric technique with limb lengths being adjusted to the patient's particular co-morbidity. In this chapter, we describe two variations upon this technique. The circular stapler technique and the hand-sewn technique will be described in detail in following chapters.

19.5 First Variation by Sanjay Agrawal

The main steps of this procedure in order are:

- Jejunojejunal anastomosis with closure of the JJA mesenteric window
- Creation of gastric pouch
- Gastrojejunal anastomosis with leak test

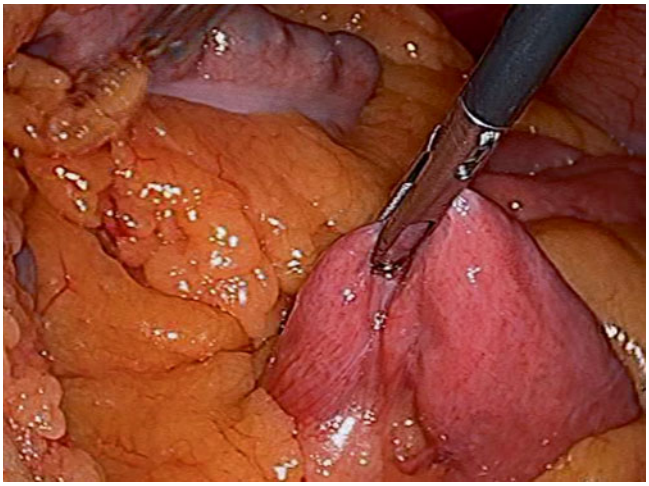

Fig. 19.2 Duodeno-jejunal flexure

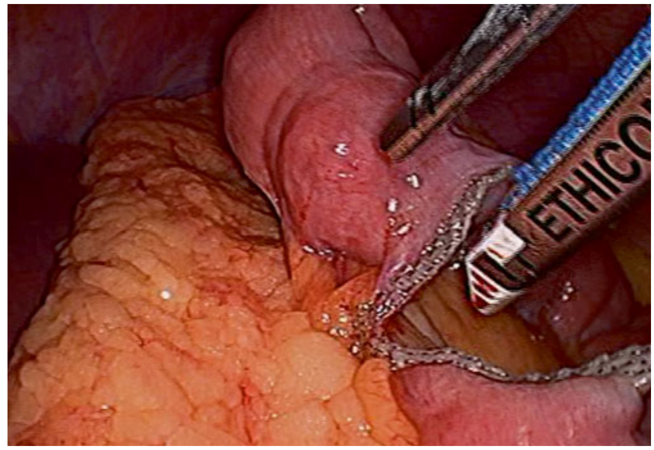

Fig. 19.3 Stapled division of small bowel

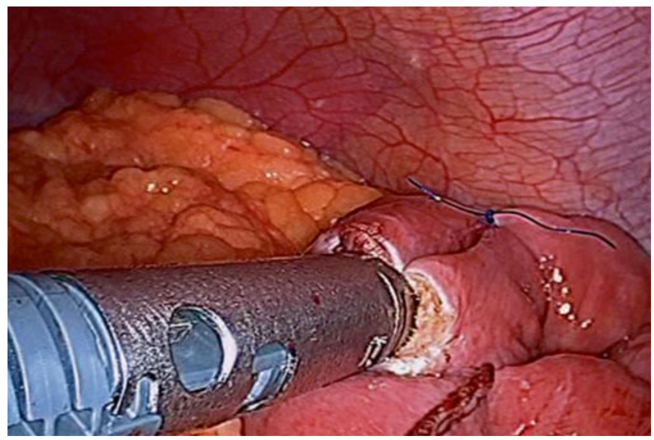

Fig. 19.4 Stapled jejuno-jejunostomy with approximation suture visible

19.6 Jejuno-Jejunal Anastomosis with Closure of the JJA Mesenteric Window

After performing a diagnostic laparoscopy we commence the LRYGB procedure with displacement of the omentum cephalad and identification of the duodeno-jejunal (DJ) flexure (Fig. 19.2) at the ligament of Treitz. The BP limb is measured to 25 cm from the DJ flexure and divided with a 45 mm 2.5 mm (Ethicon™ white cartridge) linear stapler (Fig. 19.3) and the mesentery is divided with an energy device (Harmonic ACE ®—Ethicon ™). From the distal stapled end the alimentary or Roux limb is measured accordingly. Dr Agrawal routinely uses a 100 cm alimentary limb for patients with a BMI of 40 kg/m^2 or less and 150 cm for patients with BMI of more than 40 kg/m^2.

The two limbs (BP limb and measured alimentary limb) are approximated with a 2/0 monofilament suture at the antimesenteric borders. Two enterotomies are performed using the energy device. The jejuno-jejunostomy is formed with one firing of a 45 mm 2.5 mm linear stapler in a side-to-side fashion (Fig. 19.4) and the enterotomy is closed with a continuous 2/0 absorbable monofilament suture.

Tip: Dr Agrawal's preferential technique is to use 2 × Monocryl ® (Ethicon ™—poliglecaprone 25) continuous sero-muscular sutures from either end of the enterotomy and meet in the middle with the tying of both sutures to each other. A second interrupted layer of a few sutures can also be used to reinforce and reduce tension on the suture line.

The internal hernial defect created by the JJA is closed using a continuous purse-string non-absorbable braided suture (Ethibond Excel ®- EthiconTM) or Autosuture device® (CovidienTM)(Fig. 19.5) depending on the surgeon's preference. The omentum is then split in a cranio-caudal direction with the use of the harmonic scalpel to minimise any tension on the Roux limb and GJA.

19.7 Gastric Pouch Formation

The liver retractor is placed prior to pouch formation in order to assist visualisation of the anterior gastric wall and lesser curve. The creation of the pouch commences with the creation of a window on the lesser curve just on the perigastric border at the level situated between the 2nd and 3rd gastric vessels (Fig. 19.6). Dissection occurs using a combination of energy device and blunt manipulation and continues along the posteromedial wall of the stomach until the lesser sac is reached. Care should be taken to avoid entering the stomach by mistakenly dissecting its fibres.

A lesser curve based gastric pouch is created with firings of a 45 mm 3.5 mm (Ethicon™ blue cartridge) linear stapler to create a reverse-L shape (Fig. 19.7). The orogastric tube is removed from the stomach prior to any stapling and the first firing of the stapler is horizontal from the lesser curve. At this

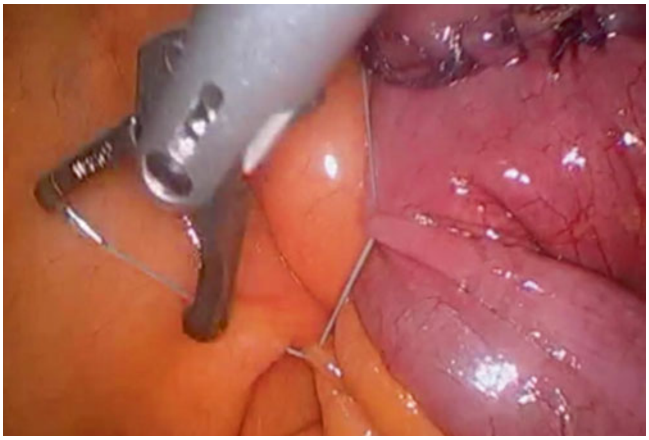

Fig. 19.5 Closure of jej-jej mesenteric window to prevent internal hernia

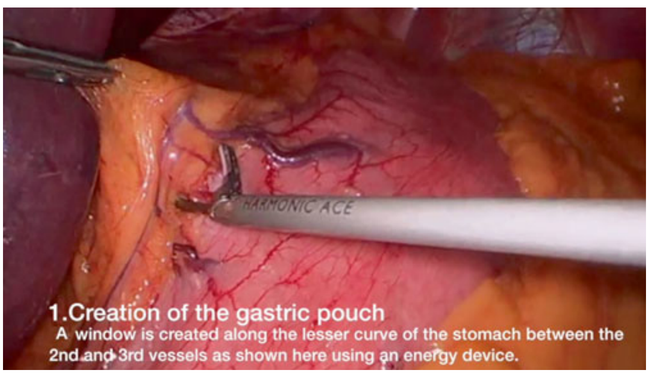

Fig. 19.6 Gastric pouch creation

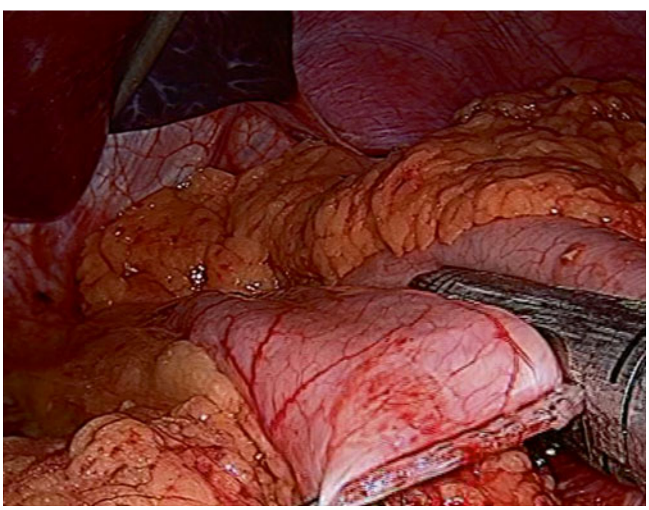

Fig. 19.7 Stapling to create gastric pouch in reverse-L shape

point, the orogastric tube is re-inserted and aimed towards the newly created first staple line. The subsequent staples are fired in a cephalad direction alongside the orogastric tube for calibration and directed towards the angle of His. The aim is

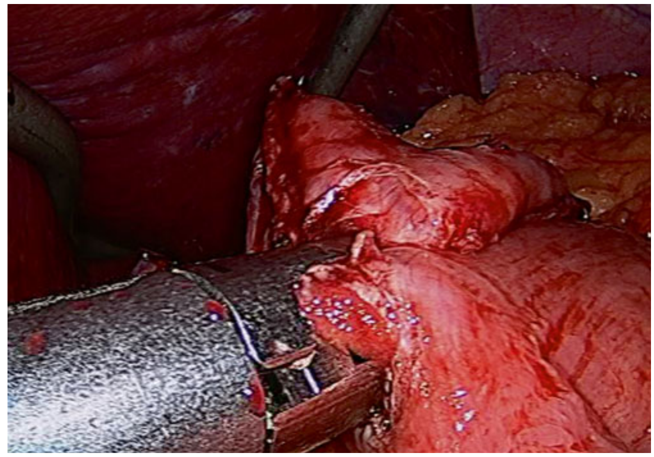

Fig. 19.8 Stapled Gastrojejunostomy

to create a pouch for a volume of no more than 20 ml. A combination of sharp and blunt dissection may be required at the angle of His in order to separate the stomach from the diaphragmatic adhesions and allow the final stapler cartridge to fully divide the gastric pouch and remnant stomach into separate entities.

19.8 Gastrojejunal Anastomosis and Leak Test

A gastrotomy is created which allows the linear stapler to be inserted for the GJA. We prefer to make the gastrotomy at the right-angle junction between the horizontal and first vertical staple lines. It is presumed that removal of this least vascular area will minimise the subsequent risk of leakage from ischaemic breakdown and prevent the formation of future marginal ulcers.

The alimentary limb staple line is brought to the pouch in an antecolic fashion. A jejunotomy is performed using the energy device and the gastojejunal anastomosis is formed with the single firing of the 45 mm 3.5 mm (Ethicon™ blue cartridge) linear stapler (Fig. 19.8). The enterotomy is then closed in two continuous sero-muscular layers over a 30 Fr oro-gastric tube with 3/0 monofilament absorbable sutures similar to the JJA. A leak test with 50–100 ml of methylene blue dye via the orogastric tube is routinely performed. If this is satisfactory, the procedure is completed with checking for haemostasis, suctioning any residual fluid and the insertion of a Robinson's 20 Fr drain in the left upper quadrant. All ports are removed under vision and skin incisions closed with 3/0 monofilament absorbable sutures.

Postoperatively all patients are encouraged to mobilise as much as possible as well as to perform extensive bed-side exercises taught to them preoperatively. Special medications given usually just for the postoperative period include intravenous antibiotics, fluids, omeprazole, analgesia, ondansetron, saline nebulisers, sips of water by straw only for immediate postoperative period. On the first postoperative day further free fluids are encouraged to be sipped by straw only and 20 ml of peppermint water every 6 h to reduce abdominal discomfort. Daily enoxaparin and thromboembolic device (TED) stockings are commenced from the date of surgery. The Robinson's drain is removed usually within 36 h and the patient discharged home usually within 48 h if all vital signs and blood results are within expected parameters.

19.9 Second Variation by Yashwant Koak

The omega loop, a very popular technique described below is favoured by Dr Koak [3].

The procedure commences with the establishment of a pneumoperitoneum as before and trocar insertion. The first trocar is inserted 2.5 cm to the left of the midline in-line with the oesophagogastric hiatus one handsbreadth or 15 cm below the xiphisternum. The remaining ports are placed as previously described. A diagnostic laparoscopy is performed initially with the closure of any hiatus hernia found.

The main steps of this procedure in order are:

- Creation of the gastric pouch and splitting of the omentum
- Gastrojejunal anastomosis
- Jejunojejunal anastomosis
- Closure of hernia defects and leak test

This technique commences with the formation of the gastric pouch as described earlier in this chapter and the liver retractor is required to be setup from the time of trocar insertion. In difficult cases Dr Koak first checks if the bowel is mobile and able to reach the stomach pouch before commencing the formation of the gastric pouch. After fashioning a small gastric pouch a gastrotomy is also performed at this stage as preparation for the GJA (EndoGIA™—Covidien™ staplers tan 45 mm for horizontal and 60 mm for linear part). Dr Koak utilises an antecolic antegastric approach.

The greater omentum is divided in a cranial direction with the energy device aiming to shorten the distance between the jejunum and the gastric pouch and reduce any tension on the anastomosis. Note that this step can be excluded if the omentum is very thin. Care must be taken to prevent omental ischemia or necrosis.

Similar to the first technique, the alimentary limb is measured to a distance of 50 or 100 cm depending on the surgeon's preference. Dr Koak prefers to use a 50 cm BP and 150 cm Roux limb for most patients except those with T2DM in which a 100 cm biliary limb and 200 cm Roux limb are used.

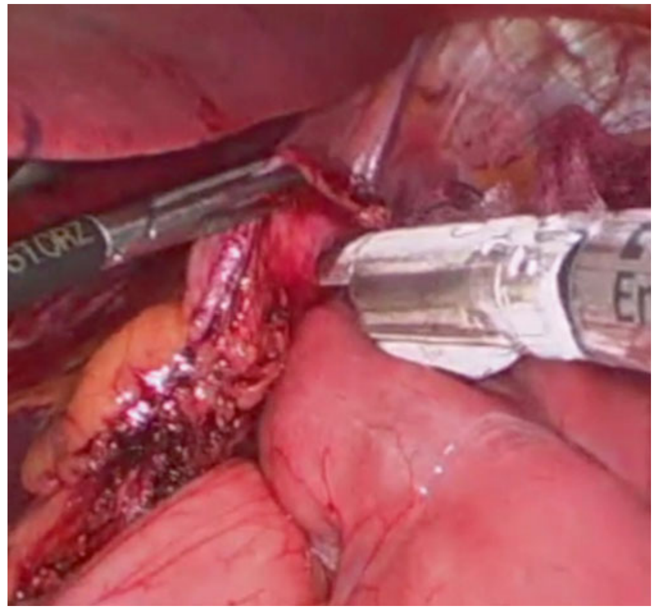

Fig. 19.9 Stapled loop gastrojejunostomy for Omega-loop technique

The measured BP limb is brought up to the gastric pouch gastrotomy and a further enterotomy is created at the measured length. A tan linear 45 mm stapler (EndoGIA™—Covidien™) is used to create the GJA (Fig. 19.9) and the resulting enterotomy is closed in a single layer of continuous absorbable 2/0 braided absorbable (Vicryl®—Polyglactin 910 Ethicon™) suture. Care must be taken to tighten each suture insertion to prevent leak as braided suture can't be pulled at the end.

The remaining distal limb length used to create the alimentary or Roux limb is measured from the GJA distally and an enterotomy made on the anti-mesenteric border at the appropriate measured distance. An enterotomy is then made on the BP limb a few centimetres proximal to the GJA loop anastomosis and a tan (EndoGIA™—Covidien™) stapled 45 mm anastomosis is made in a side-to-side fashion through both enterotomies (Fig. 19.10). The resulting defect is stapled across using the same stapler and the BP limb is divided using the stapler just proximal to the loop GJA to leave a very short hockey stick (Fig. 19.11). Another variation is using a totally stapled jejuno-jejunal anastomosis in an H-shaped configuration which Dr Koak favours, utilising 2 × 45 and 1 × 60 mm staplers.

The mesenteric defects (Petersen's and JJA mesentery) are closed using 0 non-absorbable braided (Ethibond Excel ®- EthiconTM) sutures in a purse-string manner with an anti-kinking suture. A methylene blue leak test is performed using 50 ml of diluted dye under pressure to check for leakage. Any pooled fluids from surgery are suctioned to dryness and drains are not routinely placed unless there is intraoperative concern or patient factors dictate a high risk of bleeding. The liver retractor and all ports are removed under

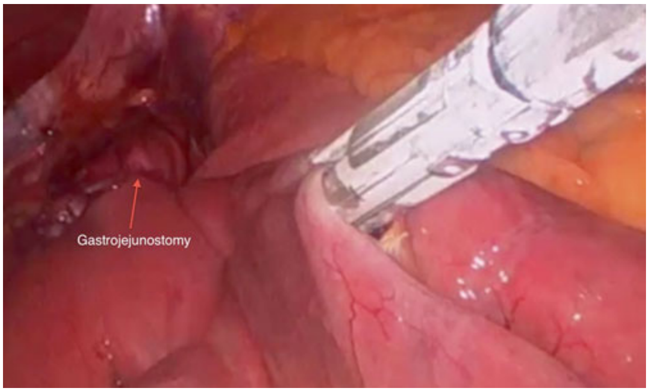

Fig. 19.10 Stapled jejunojejunal anastomosis to create Omegaloop

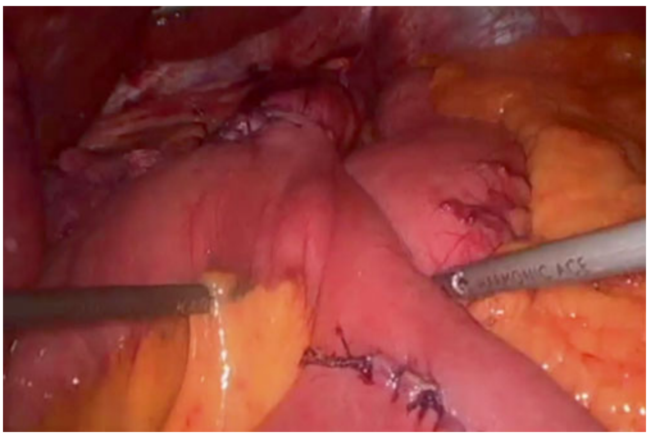

Fig. 19.11 Completed Omega-loop with gastrojejunal anastomosis and jejunojejunal anastomosis visible before separation of alimentary and pancreaticobiliary channels by stapled division of small bowel between the two anastomoses

vision. The skin closed with absorbable monofilament 3/0 sutures or skin clips and local anaesthetic (30 ml 0.5 % Chirocaine) infiltrated into the wounds and fascia.

The postoperative care remains similar to that described in the first variation.

Following the enhanced recovery principles, no nasogastric tube is left in place postoperatively. Drains and urinary catheters are not routinely used. Free clear fluids (30 ml/h) by straw are allowed on the day of surgery using an enhanced recovery protocol. The patient is prescribed breathing and leg exercises/h and early mobilisation is commenced. Liquid diet is introduced on the first postoperative day and for the rest of the first postoperative week. For the next 2 weeks thicker liquid is commenced. Subsequently a soft diet is suggested with the objective of an intake of 1,000–1,200 kcal per day by the fifth postoperative week for 2 weeks. Solid food diet can then commence. Patients are warned that this may vary between individuals.

Mobilisation starts on return to the ward. A proton-pump inhibitor is prescribed for 3 months with the objective to reduce the risk of anastomotic ulcers. The patient is discharged home on the first postoperative day unless there are concerns related to patient recovery, blood test results or home circumstances. Early relaparoscopy is favoured if surgical concerns warrant further assessment.

Key Learning Points

- The linear stapled technique may be used to perform a Laparoscopic Roux-en-Y Gastric Bypass operation for the treatment of morbid obesity
- Essential preoperative preparations are necessary for a successful outcome with the bypass procedure
- Variations in technical setup and operative procedure can be used depending on surgeon preference. We introduce the "reverse technique" and the "omega-loop technique".
- The importance in good procedure execution lies in following the principles and key steps in a logical order.
- Postoperative protocols should be utilised to ensure a good outcome and safe discharge with minimal complications.

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LRYGB: The Circular Stapler Technique (Includes Transoral as well as Transabdominal Anvil Placement)

20

Corinne E. Owers and Roger Ackroyd

Abstract

The gastrojejunal anastomosis is arguably the most challenging and crucial step of the laparoscopic Roux-en-Y gastric bypass. Either hand sewn or stapling devices can be used to good effect. Both hand sewn and linear stapled techniques can take time and are not easy. This is a quick, easy and safe method of performing this anastomosis. We describe the circular stapler technique employing different placement methods, and its advantages and disadvantages.

Keywords

Roux-en-Y gastric bypass, laparoscopic, gastrojejunal anastomosis • Trans-oral • Transgastric • Circular stapler

20.1 Introduction

Constructing the gastro-jejunal anastomosis is one of the most challenging, technically demanding and critical steps of performing a Roux-en-Y gastric bypass procedure. Although many techniques exist, none have been shown to have a clear advantage over the other, and therefore the choice between hand sewing, linear stapling or circular stapling, as described in this chapter, is usually determined by cost, operative time, and surgeon preference.

The circular stapler technique for creating the gastrojejunal anastomosis during laparoscopic Roux-en-Y gastric bypass surgery was originally described by Wittgrove et al. using the orogastric technique [1], and is one of the most common techniques in bariatric practice. It creates an end-to-end (EEA) anastomosis between the stomach and small bowel, thereby reducing the need for closure of a common opening as created by a linear stapling device. This technique may be seen as an advantage, possibly reducing the risk of an anastomotic leak or necrosis of any remaining redundant bowel distal to the anastomosis. This procedure can be performed using a transabdominal or transgastric technique.

20.2 Patient Positioning and Port Placement

The patient is usually placed legs apart in a steep reverse Trendelenburg position; the surgeon standing between the legs with the first assistant on the patient's left and the scrub nurse on the patient's right. Alternatively, the patient can be placed on the table with the legs together, still in steep reverse Trendelenburg positon, with the surgeon and assistant on the patient's left side (Fig. 20.1).

The first 12 mm port is placed under direct vision in the left subcostal region. Following CO_2 insufflation, the camera port is placed in the midline approximately one and a half hand breadths below the xiphisternum. A Nathanson liver retractor is placed in position through a small sub-xiphoid incision. The final three ports are placed in the left upper

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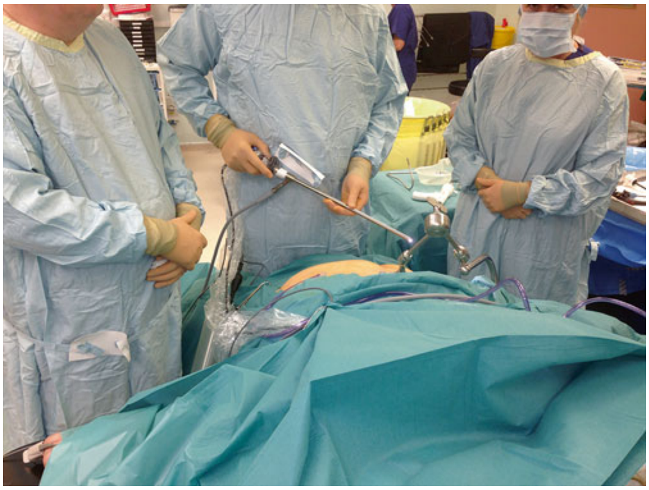

Fig. 20.1 Position of surgeon, assistant and scrub nurse

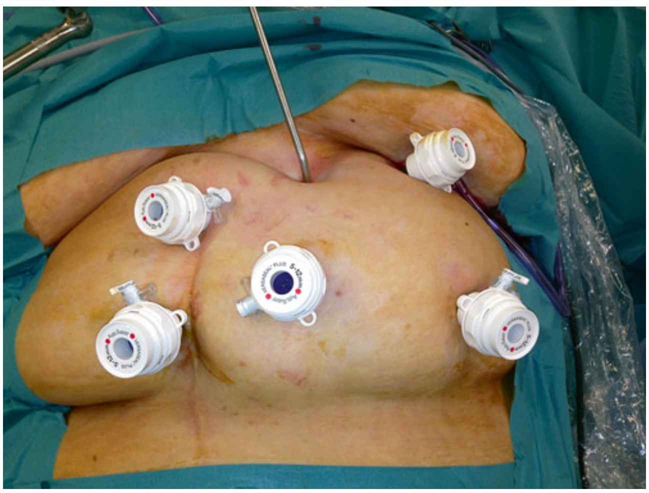

Fig. 20.2 Port positions

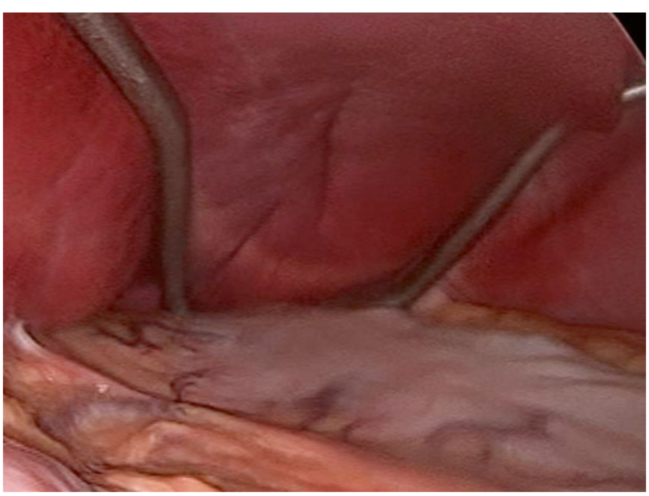

Fig. 20.3 Nathanson liver retractor

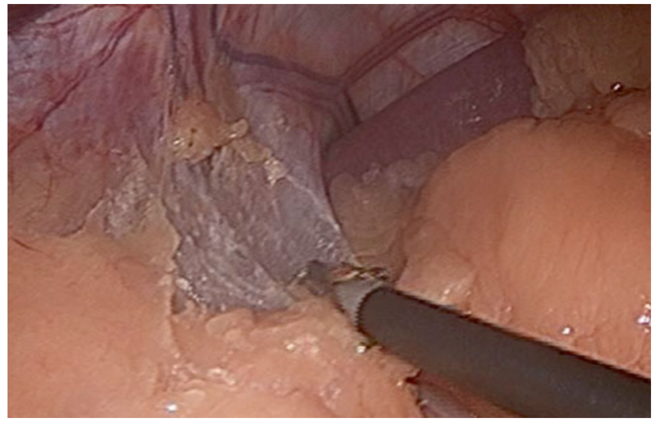

Fig. 20.4 Dissection at the Angle of His

quadrant, approximately 1–2 cm below the camera port in the mid-axillary lines (Figs. 20.2 and 20.3).

20.3 Jejuno-Jejunostomy

Following initial division of the greater omentum to allow better visualization of the small bowel, the duodeno-jejunal flexure is identified. After measuring 100 cm down the small bowel, a suture is placed at this point and the bowel is divided. A further 100 cm is measured down the small bowel and this loop of bowel is brought up to lie adjacent to the divided bowel. A side-to-side anastomosis is fashioned at this point using a triple-stapled technique. Following creation of this anastomosis, the distal end of divided small bowel is brought up to create the anastomosis with the gastric pouch.

20.4 Gastric Pouch Creation

Before creating the pouch, it is often beneficial to incise the peritoneum over the angle of His in order to mobilize this area and help with the subsequent pouch creation (Fig. 20.4).

The lesser curve is mobilized by opening the pars flaccida, approximately two centimeters below the gastroesophageal junction to allow placement of a Covidien blue (or tan tri-staple) 45 mm linear stapler, cutting the stomach transversely. If using a transoral technique, the pouch is completed at this stage with two or three subsequent fires of a blue (or tan tri-staple) 60 mm linear stapler vertically, aiming for the angle of His. If a trans-gastric technique is used, the pouch is completed after placement of the anvil, which is described below (Fig. 20.5).

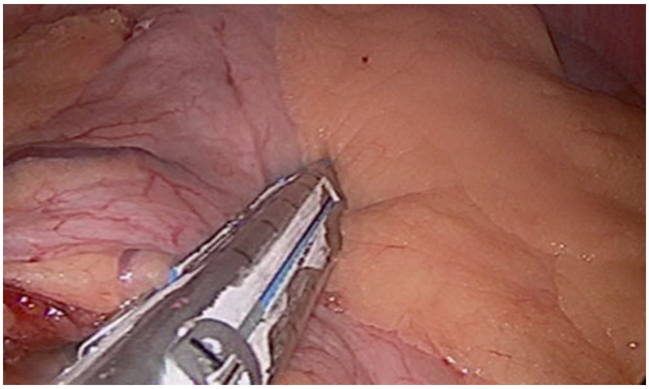

Fig. 20.5 Pouch creation

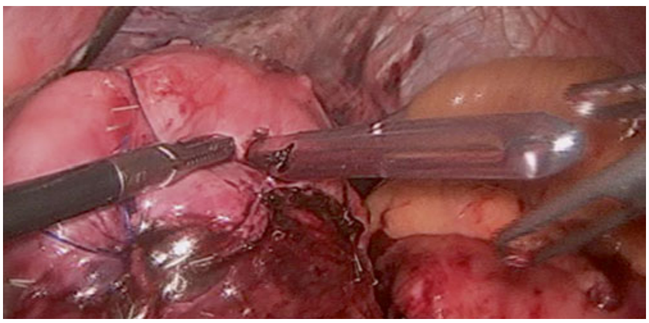

Fig. 20.6 Feeding the orogastric tube through the esophagus

20.5 Trans-oral Technique

The orogastric technique involves the use of the circular stapler with a detachable anvil head (Covidien EEATM) The anvil head is pulled down the esophagus and maneuvered into position within the gastric pouch, reducing the need for a further gastrotomy.

The pre-tilted anvil head is attached securely to the distal end of an orogastric tube (18 F). The proximal tip of the tube is fed down through the mouth and into the esophagus under vision by the anesthetist, and then down into the newly created gastric pouch. A small opening is made in the anterior surface of the stomach, around 1 cm proximal to the pouch staple line and the tip of the orogastric tube fed through this opening into the abdominal cavity (Fig. 20.6).

The orogastric tube has 5 cm markings along its length to help guide passage of the anvil head past the endotracheal cuff. The surgeon and anesthetist gently guide the anvil down the esophagus, pulling the orogastric tube through the wall of the gastric pouch into the abdominal cavity, until the anvil trocar appears. Here, the surgeon grasps the trocar, cuts the sutures that bind the trocar to the orogastric tube, and removes the redundant tubing out of the abdominal cavity via one of the laparoscopic ports. This method sometimes causes enlargement of the pouch aperture, and therefore a prolene or PDS purse string suture is occasionally placed before the stapling device is fired (Fig. 20.7).

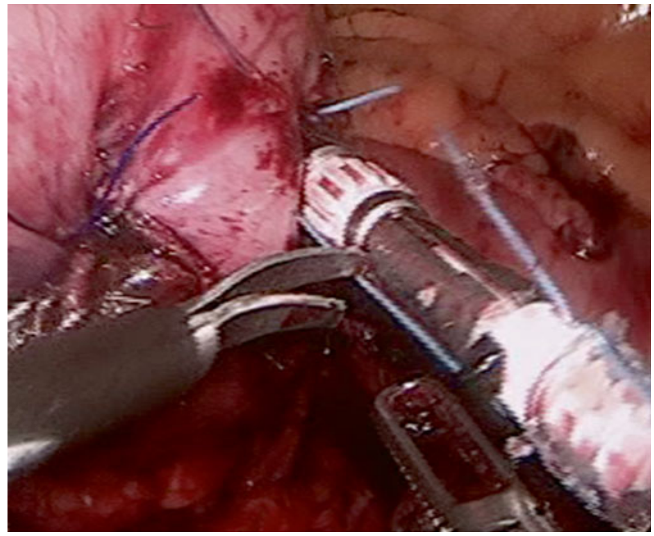

Fig. 20.7 Pulling the anvil trocar through the esophagus

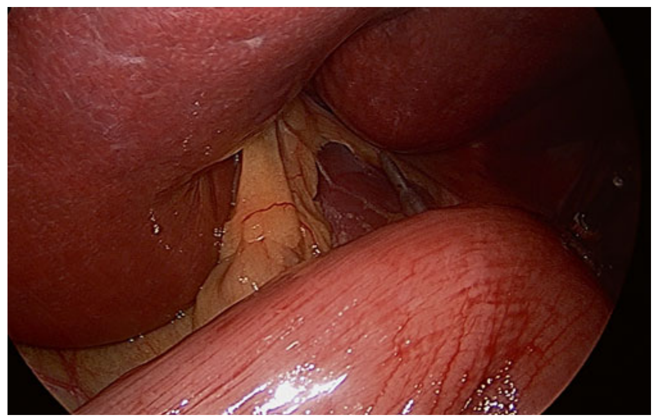

Fig. 20.8 Spike protruding through jejunum

The blind end of the jejunum is then brought into the upper abdomen by the surgeon and the body of the stapling device is introduced into the abdomen via one of the port sites (usually the lower left). The spike used for anvil attachment is retracted and the device is fed into the open end of jejunum. It is important to feed the jejunum onto the device, rather than pushing the device blindly up the loop of bowel in order to reduce the likelihood of forming tears or enterotomies, which then need repair after the anastomosis has been created. At approximately 5–10 cm from the end of the jejunum, the spike is extended and pushed through the wall of the jejunum on the antimesenteric border (Fig. 20.8).

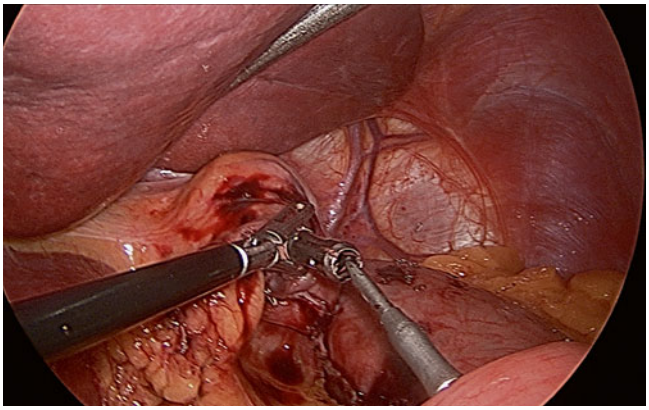

Fig. 20.9 Connecting stapling device

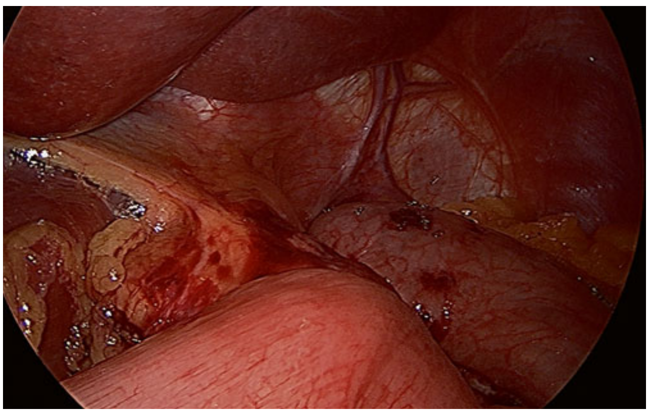

Fig. 20.10 Completed anastomosis

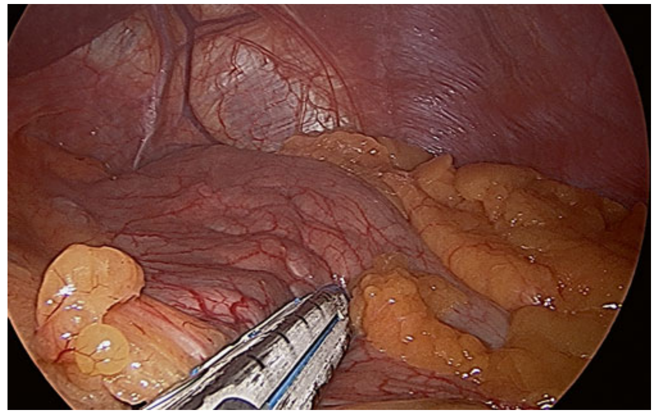

Fig. 20.11 Pouch creation

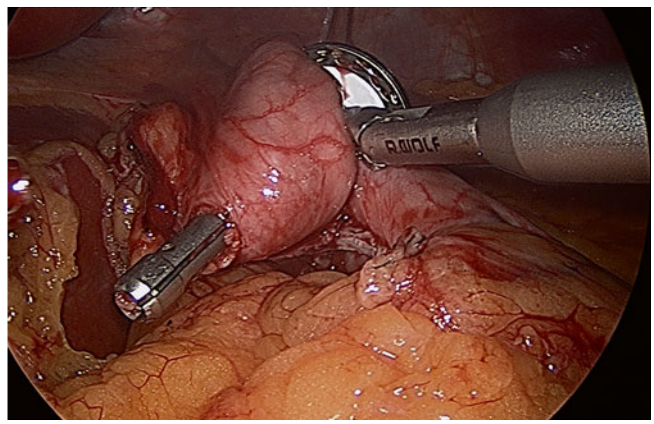

Fig. 20.12 Placement of anvil head into pouch

The anvil trocar is grasped securely and fed onto this spike (Fig. 20.9).

The spike, with the anvil head attached, is then retracted so that the stomach and bowel are opposed and the stapling device fired. The whole device is then removed via the open end of jejunum. A linear staple device is then used to close this blind end of jejunum (Fig. 20.10).

20.6 Transabdominal Placement

Although the transoral approach was the original technique described, a variation on this approach is to place the anvil into the pouch via a transabdominal/ transgastric route, removing the need for orogastric insertion. We describe the technique used in our practice, although slight variations may exist.

As described in the gastric pouch creation, the surgeon staples transversely across the stomach with the blue (or tan tri-staple) 45 mm linear stapler (Fig. 20.11).

A tiny but full-thickness hole is made in the pouch just above the staple line. A larger gastrotomy (approximately 15–20 mm) is then made in the remnant stomach below this position; large enough to admit the anvil head below and to the patient's left, from the staple line. The stapling device with the anvil head attached is introduced into the abdominal cavity by an enlarged port site (approximately 25 mm) in the left side of the abdomen. The anvil is detached from the circular stapler and the body of the device can then be removed leaving the anvil head within the abdomen. The surgeon then feeds the trocar through the large gastrotomy, and out of the small hole in the pouch, until the anvil head is flush with the inside wall of the stomach (Fig. 20.12).

With the anvil safely in position, the pouch is then completed by two or three vertical firings of a blue (or tan) 60 mm linear stapler across the remaining portion of the stomach. This leaves a closed pouch with the anvil trocar 'poking out.' The large gastrotomy on the now redundant stomach can then be closed using the linear stapler (Fig. 20.13).

The rest of the anastomosis is created in the same manner as when using the transoral circular stapling device.

With either technique, the 'donuts' of stomach and bowel created by the circular stapler should be inspected for their integrity (ensuring they are a complete ring), and/ or a leak test performed. Any leak detected should be repaired or reinforced using hand sewn sutures.

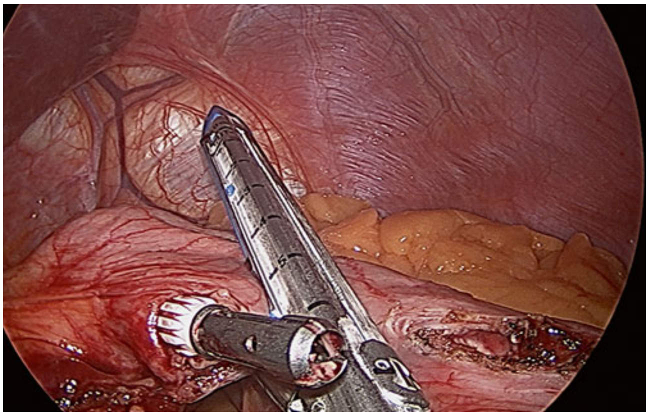

Fig. 20.13 Pouch completion

20.7 Advantages and Disadvantages

As with any stapling device, there are advantages and disadvantages to the circular stapler. The size of the anvil head results in a pre-determined anastomotic aperture, lending uniformity to each gastric bypass operation. Some studies have shown an increased risk of anastomotic stricture with smaller sized staplers [2, 3] such as the 21 mm stapler which provides an inner aperture diameter of 11.8 mm, when compared to the 25 mm circular stapler, which creates an inner diameter of 15.3 mm [3]. Other authors have failed to show any difference between the anvil size, although their follow up was for 12 months only and did not mention any investigation of patients with nausea, dysphagia and vomiting [4].

The detachability of the anvil head makes the device more maneuverable when compared to a linear stapler, which can be an advantage in the confined space of the abdomen, especially if the liver is large or adhesions are present. It does however require more laparoscopic skill, as the device needs some assembly within the abdominal cavity before the anastomosis can be created. The anastomosis can be reinforced with hand sutures, but this is rarely necessary and may decrease the size of the stoma, possibly increasing the risk of a gastro-jejunal (GJ) anastomotic stricture.

A slightly increased incidence of postoperative complications using the circular stapling technique when compared to the linear stapler has been demonstrated by one study, although this was statistically insignificant, and the re-operation rate for anastomotic leak following surgery was higher in the linear technique group than in the circular stapler [5]. The authors of this study noted that using the circular stapler via the orogastric route increased their operative time and wound infection rate. In our practice, using the transabdominal/ transgastric route, we have not found this to be the case.

An advantage of the orogastric anvil placement technique is that it requires fewer laparoscopic skills to maneuver the anvil head into the pouch. This may be advantageous to the trainee surgeon as they learn to create the anastomosis. Disadvantages may be increased risk of esophageal trauma [6], and increased rate of intra-abdominal as well as wound infection [7], as the anvil head is passed through the oropharynx down the esophagus and out into the abdominal cavity, where it is removed via one of the laparoscopic ports. In cases where there is an esophageal stenosis, placement of the anvil head using this technique may be impossible, and the surgeon will have to revert to intra-abdominal placement, which could be difficult if the pouch has already been created. Under these circumstances a linear stapling or hand sewn technique may become necessary. The anvil during esophagogastric placement is pre tilted to minimize esophageal trauma, and this anvil tilt needs to be corrected before stapling so that the head is 90° perpendicular to the trocar. Maneuvering the anvil to correct the tilt is done when the trocar has been passed through the opening in the pouch, and therefore can be tricky to accomplish, especially during the learning curve. This maneuver can often increase the opening diameter, necessitating the need for a purse string suture, thereby increasing the time taken for the operation and requiring more technical skills of the surgeon.

Although rare, the complication of stapling an nasogastric (NG) tube into the anastomosis during GJ anastomotic construction has been reported [8]. A distinct advantage of the circular stapling technique using the orogastric placement technique is that this is impossible, providing only the tube attached to the anvil has been placed. With the transabdominal route, there is no need for NG tube placement until the leak test, thereby negating the chances of stapling an NG into the anastomosis.

In either technique, the abdominal wound, through which the handle of the circular stapling device is inserted, needs to be enlarged, as it will not fit down a standard 12 mm port. Although many small port sites do not need individual closure after finishing the procedure, it is imperative that this particular incision is closed in order to prevent documented complications such as wound infection, scarring and incisional herniae.

20.8 Postoperative Management

The post operative management required for a patient who has had the GJ anastomosis constructed with a circular stapling device is no different from that of a patient who has had an anastomosis created using the hand sewn or linear stapler techniques. There is a slightly increased risk of bleeding after using a stapling device when compared to a hand sewn anastomosis [9]. Serosal surface bleeding can be controlled using sutures. If an intraluminal bleed is suspected an upper gastrointestinal endoscopy may be performed.

If there is any suspicion about the integrity of the anastomosis, a nasojejunal tube can be placed, although in most cases, this is not necessary. Patients can be allowed to sip water within hours of the procedure, and then can gradually be allowed to increase their fluid intake. The anastomosis usually heals quickly, and although the GJ anastomosis is the most common site for postoperative leaks after laparoscopic bypass surgery (approximately 80 % [10]), the actual incidence of any leak is low, at around 1.7 % of all cases.

Conclusion

The learning curve for performing Roux-en-Y gastric bypass surgery is estimated to be between 75 and 100 cases [11, 12], the most challenging part of which is learning to create the GJ anastomosis. The decision as to which operative technique to use for its creation is down to a number of factors including surgeon's preference, skill (learning curve), and economic factors. Either the transoral or transabdominal approaches using the circular stapler are known to be successful and quicker than hand sewing an anastomosis. Further long-term studies are needed to see if there is a true difference between the transoral or transabdominal approaches. It is useful for the surgeon to be familiar with both techniques, as complications such as esophageal stenosis or strictures can make the orogastric technique difficult, and surgical ability may confer an advantage to one technique over the other.

Key Learning Points

- The GJ anastomosis is the most technically demanding and potentially risky step during a Roux-en-Y gastric bypass, and extra care should be taken to ensure it is performed properly.
- The most common site for anastomotic leaks is at the GJ anastomosis, so this should be checked intraoperatively with a leak test and/or by checking the integrity of the tissue donuts on the circular stapler, to ensure the anastomosis is intact.
- The surgeon and anesthetist need to communicate in order to successfully introduce the anvil during orogastric placement.
- A 25 mm diameter circular stapler is the optimum size to use for this anastomosis.
- Use of the transgastric technique eliminates and potential risk of contamination with oral flora.

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LRYGB: The Hand-Sewn Technique

21

Javed Ahmed and Waleed Al-Khyatt

Abstract

Laparoscopic Roux-en-Y gastric bypass (LRYGB) results in sustained long-term weight loss and reduced mortality. Several techniques have been described to perform this procedure. In this chapter, the technical steps and tips of performing a supracolic retrocolic hand-sewn LRYGB (LRYGB-HS) approach are described.

Keywords

Laparoscopic Roux-En Y • Gastric bypass • Hand-sewn • Supra-colic, retro-colic

21.1 Introduction

Roux-en-Y gastric bypass surgery is a well established modality for the treatment of morbid obesity [1, 2]. It has gained more popularity with the introduction of the laparoscopic approach [3, 4]. In fact, laparoscopic Roux-en-Y gastric bypass (LRYGB) surgery is considered one of the few bariatric operations that provides significant magnitude and duration of weight loss, with reasonably low perioperative and long-term complication rates [5]. The main principle of performing LRYGB includes the formation of a small gastric pouch using a stapling device. Then, a loop of small bowel (alimentary limb) is divided at some point distal to the ligament of Treitz and anastomosed to the gastric pouch. Finally, the loop of small intestine draining gastric, pancreatic, and biliary secretions (biliopancreatic limb) is joined to the alimentary limb in a Roux-en-Y fashion to restore continuity [6, 7]. Several techniques have been described to achieve these steps. For instance, the formation of Roux limb and jejuno-jejunostomy can be created in the supra- or infracolic compartment. The gastro-jejunostomy anastomosis may be performed via the retrogastric or antegastric route. Moreover, the anastomosis can be completed either using a stapling device (circular or linear) or by hand-sewing. In this chapter, we describe the steps involved in performing a supracolic retrocolic hand-sewn LRYGB (LRYGB-HS) technique.

21.2 LRYGB-HS: Technical Pearls

21.2.1 Patient Selection

Wittgrove and Clark were the first group to publish their preliminary results of LRYGB where the gastro-jejunal anastomosis was completed in the retrocolic passage [8]. However, the full description LRGBY-HS was first reported by Higa et al. in 2000. In our center, LRYGB-HS was first introduced in 2009, and it has been offered to patients who fulfill the regional commissioning criteria. These include a body mass index (BMI) more than equal to 50 kg/m^2 or BMI more than equal to 45 kg/m^2 with obesity related comorbidities). Patients are assessed by a multi-disciplinary team consisting of bariatric surgeons, anesthetists, metabolic physicians, dieticians, bariatric nurse specialists, and psychologists. Those patients deemed appropriate to undergo LRYGB are counseled to implement the appropriate lifestyle and dietary changes. A preoperative two week low carbohydrate, low

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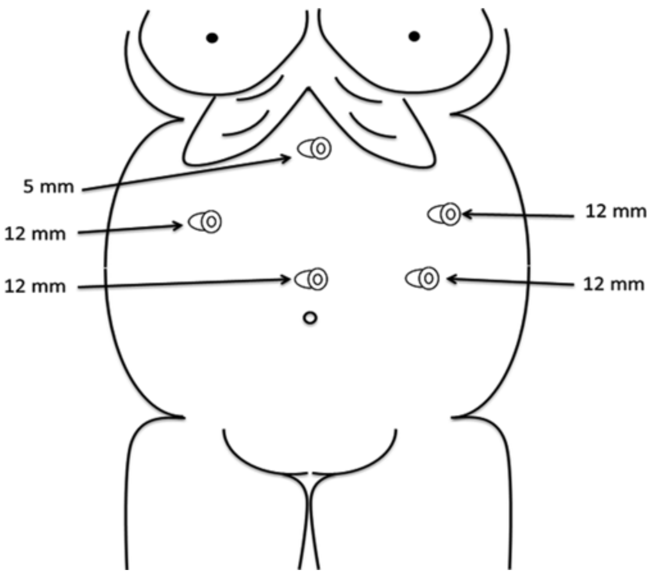

Fig. 21.1 Schematic presentation of port placement of in a patient undergoing supra-colic retro-colic LRYGB-HS

calorie (800 kCal/day) diet is utilized to reduce liver size and improve intraoperative exposure.

21.2.2 Positioning and Placement of Ports

The patient is placed in a supine position with a slight reversed Trendelenburg position of 15–20° and a 10–15° tilt to the right. The patient is secured to the operating table using a strap around the pelvis and another one around the legs. The surgeon stands on the right side of the patient with the assistant surgeon on the patient's left. Venous thromboembolic prophylactic measures are used intraoperatively. We employ both mechanical and pharmaceutical methods, namely anti-embolism compression stockings and pneumatic compression devices, and intraoperative enoxaparin (40 mg), respectively.

LRYGB-HS is performed using a five-port approach (see Fig. 21.1). Proper adjustment of location and configuration of ports are essential in this procedure. They are placed in a fashion that allows simultaneous access to both the stomach and the small bowel thereby avoiding difficulties such as failing to reach targets, or falling too short and facing a "sword-fighting" phenomenon.

Abdominal entry is achieved under direct vision using a 12 mm Optiview™ trocar (ENDOPATH® XCEL™, Ethicon, USA) which is placed in the left upper quadrant along the mid-clavicular line (MCL). This allows direct visualization of the liver, falciform ligament, and umbilical region. It also helps to plan the insertion sites for subsequent working ports. Intra-abdominal pressure is maintained at 15–18 mmHg. Another 12 mm bladeless trocar is placed above the umbilicus. At this stage, the camera is placed into this port, and three further ports are placed as follows: a 12 mm bladeless trocar in the left flank in the MCL, a 12 mm bladeless trocar in the right upper quadrant in the MCL, and lastly, a 5 mm trocar in the epigastric region for the liver retractor. This last trocar is placed later during the procedure for the creation of the gastric pouch.

21.2.3 Laparoscopic Assessment

LRYGB-HS is a technically demanding procedure and the creation of an adequate pneumoperitoneum for direct visualization and dissection is a crucial prerequisite. It is also essential to carry out full laparoscopic examination to assess whether the procedure is possible, as there must be enough space to permit access to the gastro-oesophageal hiatus to allow formation of the gastric pouch. For instance, the presence of a huge hepatomegaly will render the LRYGB-HS technically difficult to achieve. It is also vital to search for the presence of any significant hiatus hernia as its identification and repair is considered an essential step towards a successful outcome [9].

21.2.4 The Formation of Roux Limb: Technical Tips

The principle of the supracolic approach in LRYGH-HS is to create a window in the mesentery of the transverse colon. This window will facilitate the identification of the ligament of Treitz and to mobilize a 150 cm small bowel loops into the supracolic compartment. Therefore, unlike the infracolic approach, there is no need for cephalad displacement of the omentum, which can be difficult in patients with previous abdominal surgery or dense pelvic adhesions.

Firstly, the gastrocolic omentum is lifted up by the assistant surgeon using a laparoscopic grasper placed through the left upper quadrant port. Another laparoscopic grasper is placed through the right upper quadrant port to provide counter-traction. The Harmonic ACE (Ethicon™) is placed through the left flank port and used to divide the gastrocolic omentum approximately 5 cm from the greater curve of the stomach to allow access to the lesser sac (see Fig. 21.2a). Any retrogastric adhesions are taken down. The inferior border of the pancreas is identified and the transverse mesocolon is divided approximately 5 cm to the left of the mid-colic vessels (see Fig. 21.2b, c). This allows access to the infra-colic compartment for the identification of the duodeno-jejunal (DJ) flexure (see Fig. 21.2d). Subsequently, the jejunum is mobilized into the supracolic compartment such that the DJ flexure is at the 11 o'clock position with the jejunum extending distally in an anticlockwise manner (see Fig. 21.2e). The jejunum is divided using Endo GIA™ 60 mm articulating medium/thick (tan) stapler with Tri-Staple™ technology (Covidien™) fashioning a 30 cm biliopancreatic limb (see Fig. 21.2f). The distal end of the divided jejunum is mobilized to fashion a 100 cm Roux

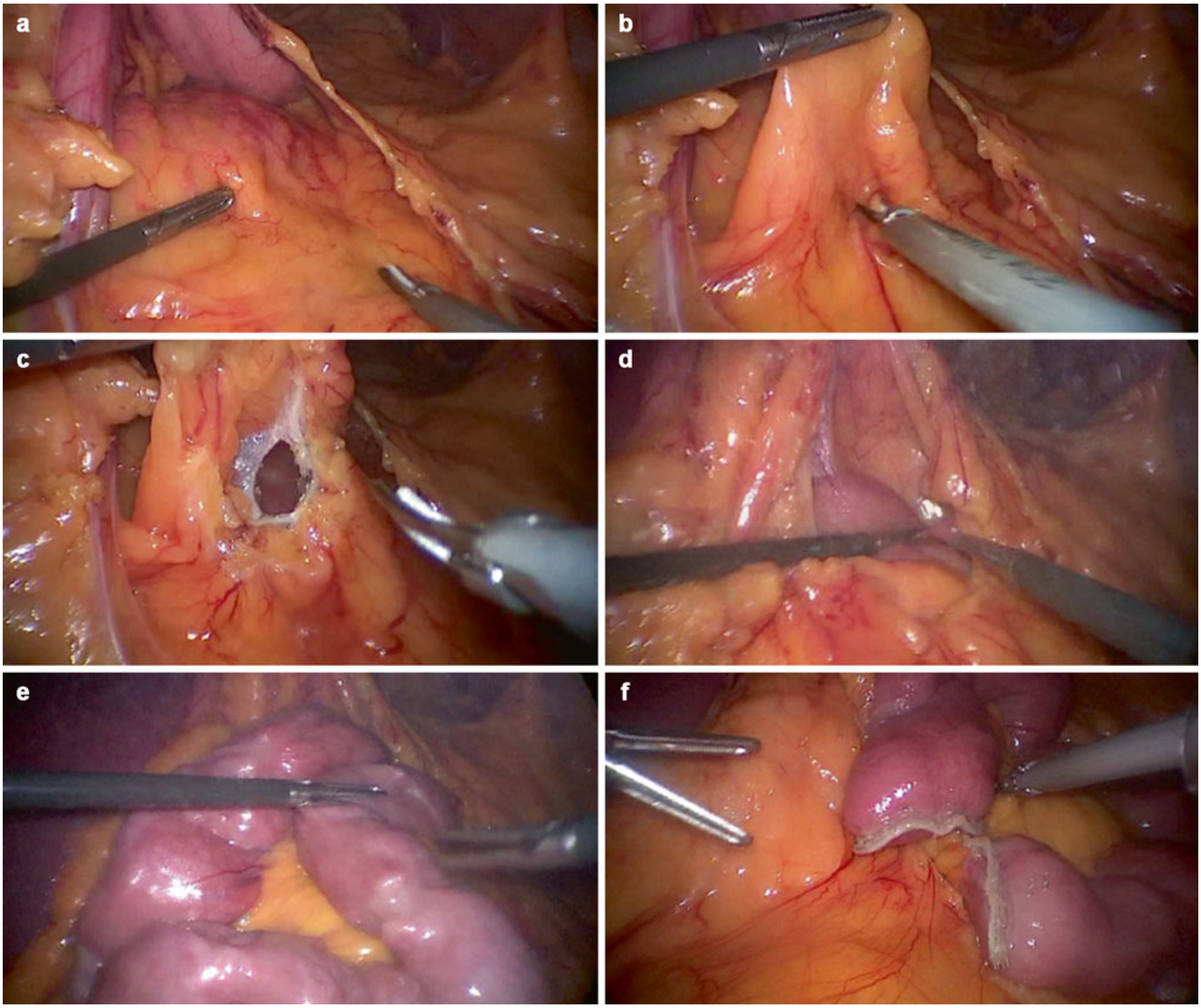

Fig. 21.2 The creation of a window in the gastro-colic omentum and mesentery of transverse colon to mobilize small bowel loops into the supra-colic compartment

limb. A side-to-side jejuno-jejunostomy is created using a single firing of Endo GIA™ 60 mm articulating medium/thick (tan)s stapler with Tri-Staple™ technology (Covidien™) followed by closure of the resultant enterotomy using 2/0 Vicryl™ (see Fig. 21.3a, c). The jejuno-jejunal mesenteric defect is closed with 1/0 Ethibond (Ethicon™) sutures and the jejuno-jejunal anastomosis and Roux limb are returned to the infra-colic compartment (see Fig. 21.3e). The mesocolic and Petersen defects are closed using 1/0 Ethibond (Ethicon™) sutures (see Fig. 21.3d, f).

21.2.5 The Formation of Gastric Pouch

At this stage, a fifth port is placed in the sub-xiphiod space for the insertion of a liver retractor. The gastro-esophageal junction fat pad is excised for proper identification of the angle of His. In the case of the presence of a concomitant hiatus hernia, the hernia is dissected and reduced (see Fig. 21.4a, b). Size1 Gore-Tex™ interrupted sutures are placed posteriorly for the approximation of the crura (see Fig. 21.4c). A window is created in the gastro-hepatic ligament close to the lesser curve of the stomach approximately 5 cm from the gastro-esophageal junction. A vertical lesser-curve based gastric pouch (approximately 25–30 mL) is constructed using multiple firings of Endo GIA™ articulating medium/thick reloads with Tri-Staple™ technology (Covidien™) and sized using a 34 F orogastric bougie (see Fig. 21.5). The first fire of Endo GIA™ 60 mm (purple) is made horizontally and lies perpendicular to the longitudinal axis of the stomach. Two essential steps should be taken at this stage before any further stapling. Firstly, all retrogastric adhesions must be divided. Secondly, a laparoscopic retractor should be used to retract the excess stomach left laterally

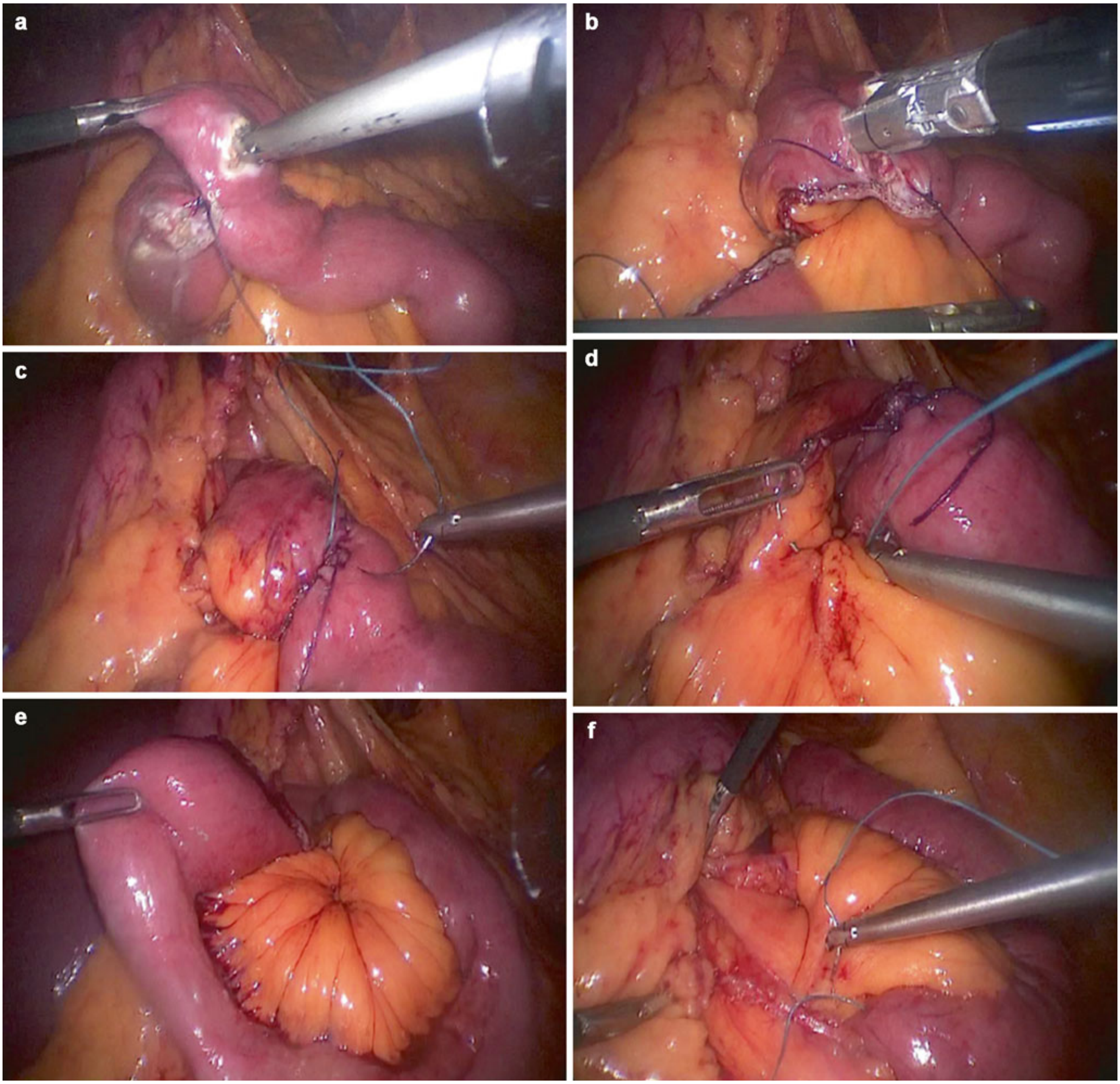

Fig. 21.3 The formation of jejuno-jejunostomy anastomosis and closure of small bowel mesenteric and Petersen's defects

(see Fig. 21.5). These two steps are fundamental for proper sizing of the gastric pouch, and avoid leaving an excess posterior wall behind. Finally, two applications of the Endo GIA™ 60 mm (purple) are aimed towards the angle of His for completion of the gastric pouch.

21.2.6 The Formation of Gastro-Jejunostomy: The Hand-Sewn Technique

There are several advantages of LRYGB-HS. Firstly, it provides direct access to fully examine the anastomosis line. Hence, the risk of anastomotic bleeding which may occur using stapling techniques is avoided. Secondly, the hand-sewn technique can be adjusted according to the tissue thickness as in the case of performing a revisional gastric bypass. Thirdly, it provides an alternative option for completion of the gastro-jejunal anastomosis if the stapling device misfires during the procedure.

In LRYBG-HS, the gastro-jejunal anastomosis is performed entirely in a hand-sewn fashion and sized over a 34 F bougie. Hence, advanced laparoscopic suturing skills, such as mounting of the needle at various angles, are required for neat and sound completion of the anastomosis. Initially, the

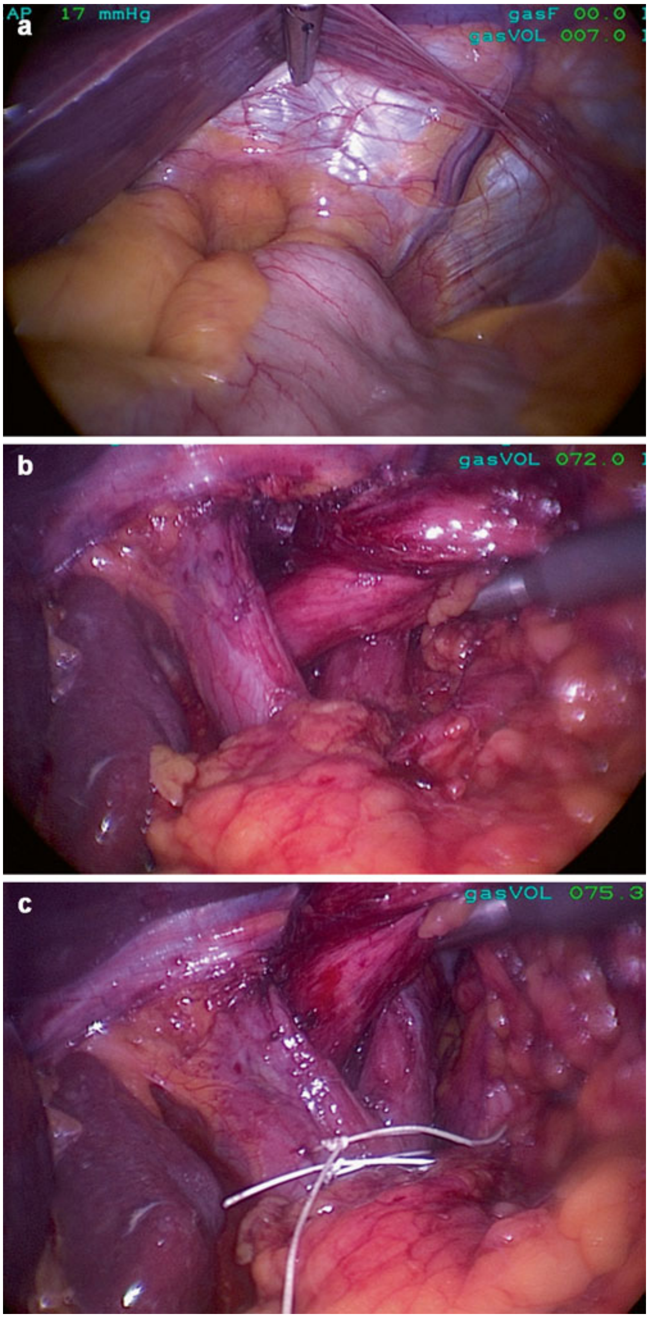

Fig. 21.4 Concomitant hiatus hernia is dissected and reduced. Crural repair is performed by applying multiple interrupted sutures posteriorly using a size 1 Gore-Tex®

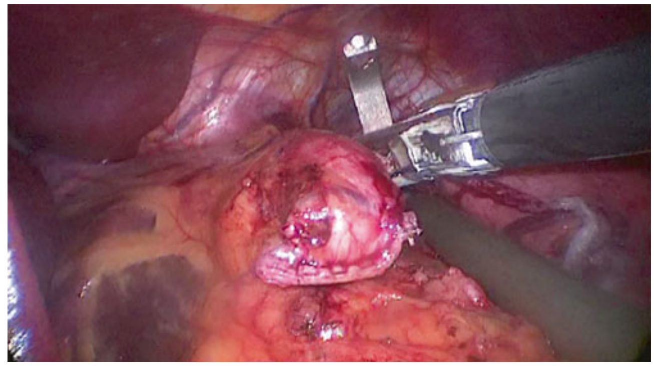

Fig. 21.5 The vertical lesser curve based gastric pouch (approximately 25–30 ml) is constructed

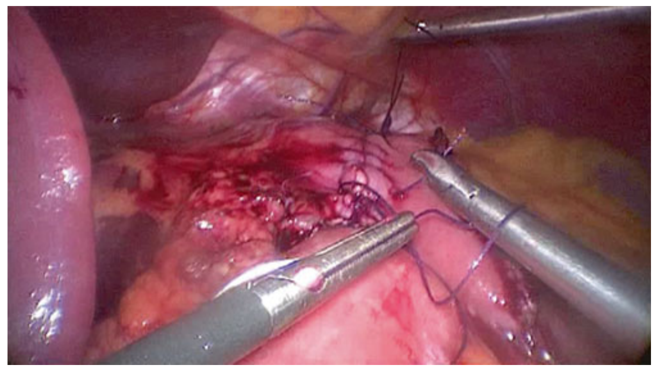

Fig. 21.6 A hand-sewn gastro-jejunostomy anastomosis is constructed

distal end of the Roux limb is held by a laparoscopic grasper and placed next to the gastric pouch to construct an end-to-side gastro-jejunostomy. Posterior (outer) seromuscular running stitches are placed using 2/0 Vicryl™ to bring both sides together starting at the midpoint of the left vertical length of the gastric pouch, and finishing at the right end of the inferior border of the pouch. Subsequently, a hook diathermy is used to create a gastrostomy and enterotomy in the gastric pouch and jejunal end respectively. A second inner, full-thickness layer of posterior running sutures are placed using 2/0 Vicryl™, starting at the left lateral corner and working towards the right corner of the anastomosis. Anterior running (full thickness) single layer sutures are placed using two lengths of 2/0 Vicryl™ for completion of the anastomosis. The placement of first length of 2/0 Vicryl™ starts at the far left corner and continues towards the middle of the anastomosis. The second length of 2/0 Vicryl™ is placed at the medial corner of the anastomosis and continued until it reaches the middle of the anastomosis. At this point, the 34 F bougie is advanced to allow the tip to sit in the jejunal lumen. Finally, both ends of the suture lines are tied together. This result in a gastroenterostomy diameter of approximately 12–14 mm (see Fig. 21.6). An intraoperative air/methylene blue leak test is performed at the end of the procedure and additional sutures placed in the presence of an abnormal intra-operative leak test. Surgical drains, nasogastric tubes and urinary catheters are not utilized (See Video 21.1).

21.3 Postoperative Care

Postoperatively all patients are nursed on a dedicated bariatric ward that utilizes an enhanced recovery program. This includes mobilization four hours postoperatively, oral sips on the evening of surgery, and hourly use of an incentive spirometer. Majority of the patients are discharged on the first or second postoperative day if they are clinically stable (normal postoperative physiological observations and blood tests), tolerating adequate oral fluids and liquid diet, and are fully mobile. Patients are discharged with a proton pump inhibitor, multivitamins and mineral supplements. The postoperative follow-up schedule includes a telephone interview by a specialist nurse during the first week, and joint medical and dietetic reviews at 6 weeks, 3 months and 12 months postoperatively, with additional dietetic reviews at 6 and 9 months.

21.4 The Outcome of LRYGB-HS Technique

The main aim of the surgical management of morbid obesity is to establish a sustained weight loss and resolution of comorbidities like diabetes. In our experience, LRYGB-HS provides excess weight loss (EWL) of 70 % at 1 year follow up. More than 80 % of patients with diabetes had either complete remission or reduced used of anti-diabetic medications [10]. In our unit, nearly 25 % of patients are 55 years or older with a mean BMI of 52 kg/m^2. In our experience, we found that older patients with morbid obesity undergoing LRYGH-HS have comparable very low complications rates, and high efficacy in achieving excellent EWL, and diabetes control [11].

21.5 Complications and Potential Difficulties

As described before, the creation of a window in the gastrocolic omentum and the mesentery of the transverse colon are essential for performing LRYGHB-HS using the retro-colic supracolic passage. Sometimes, it is not possible to perform LRYGB-HS using this approach because there are dense adhesions in the retro-colic space, or there is a short and dense transverse mesocolon. In these circumstances an ante-colic passage is an alternative available option to complete the procedure.

LRYGB-HS is considered a safe procedure with a very low mortality risk and postoperative complication rates. LRYGB-HS like other techniques of LRYGB may be associated with small risks of bleeding requiring transfusion or re-operation, infection (wound or chest), marginal ulcer, thromboembolism, and port-site or internal hernias. Another specific complication of LRYGH-HS is stenosis of the gastro-jejunal anastomosis. The incidence of anastomotic stricture in LRYGB-HS is relatively comparable to its incidence following using linear or circular stapler techniques [12]. It responds very well to endoscopic balloon dilation, and surgical revision is very rarely required.

Key Learning Points

- LRYGB-HS provides excellent and prolonged excess weight loss and resolution of comorbidities like diabetes.
- It is considered a safe procedure with low risk of anastomotic bleeding.
- It is an excellent approach for a patient undergoing revisional gastric bypass.
- It requires advanced laparoscopic suturing skills.
- Adequate pneumoperitoneum and appropriate placement of ports are essential for completion of procedure.

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LRYGB: The Fully Stapled Technique

22

Bruno Dillemans and Bert Deylgat

Abstract

In this chapter, we describe the fully stapled laparoscopic Roux-en-Y gastric bypass as performed at our center. The entire procedure has been described in detail, beginning with the patient preparation until the normal postoperative course and follow up. Key steps of the procedure are illustrated with photographs. We have also discussed possible pitfalls and points of interest.

Keywords

Fully stapled Laparoscopic Roux-en-Y gastric bypass • Bariatric surgery • Roux-en-Y gastric bypass • FS-LRYGB • Standardization • Obesity

22.1 Introduction

In 2004, we introduced the fully stapled laparoscopic Roux-en-Y gastric bypass (FS-LRYGB) to our list of services. Due to the increasing number of patients (Fig. 22.1) at our hospital, we needed a fast, reproducible, and safe procedure that was easy to teach the residents and those pursuing fellowship. Therefore, we revised our institutional practice to perform a fully stapled technique that was completely standardized. In 2009, we reported data of 2,606 patients who underwent the completely standardized FS-LRYGP with minimal morbidity and mortality; thus, proving that the technique was feasible [1], and in 2011, one of our fellows used this technique at a second hospital with good perioperative outcomes, thereby confirming the reproducibility of this technique [2]. We have been continuously improving our technique ever since, and have additionally introduced the stapled closure of the mesenteric gaps. Given the increasing demand for revisional bariatric surgery, we used the same technique for these surgeries, and reported the compared outcomes of the vertical banded gastroplasty to gastric bypass in 2013 [3]. Our experience with conversion of gastric banding to FS-LRYGP will be published soon, thus proving that it is feasible to perform even the most complex laparoscopic bariatric procedures quickly and safely, if one adheres to the basic principles of bariatric surgery.

Electronic supplementary material The online version of this chapter (doi:10.1007/978-3-319-04343-2_22) contains supplementary material, which is available to authorized users.

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22.2 Preoperative Assessment

22.2.1 Nutritional Evaluation

This has been dealt with in detail in Chap. 11.

22.2.2 Medical Evaluation

Please refer to Chap. 10 for details.

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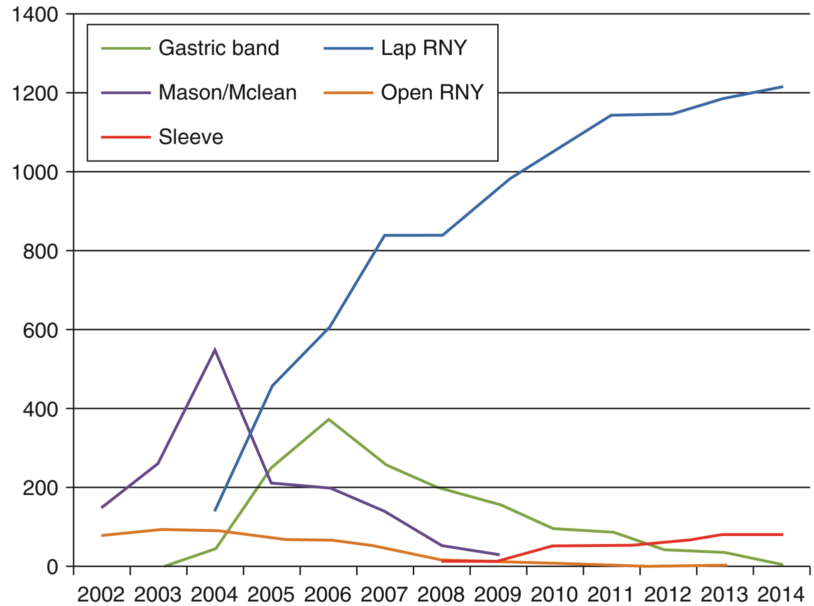

Fig. 22.1 Frequency of different bariatric procedures between 2002 and 2014 at our center

22.2.3 Psychological Evaluation

Chapter 12 covers this topic in detail.

22.3 Operative Technique

22.3.1 Material List

- Knife no 11 blade
- Veress needle (Covidien, USA)
- Trocars: 1 × 5 mm, 3 × 12 mm, 1 × 10 mm
- Insufflation tubing
- Suction device
- Gastric tube 34 French. (Kendall gastric lavage set)
- 30° laparoscope
- Light cable
- Ultrasonic dissecting device
- Three laparoscopic clamps (Conmed, USA)
- One Babcock (Conmed, USA)
- 10 mm fan liver retractor (Storz, DEU)
- Laparoscopic needle holder (Ethicon, USA)
- Stapling devices
- Echelon™ flex 60 mm blue (3.5 mm): 3 cartridges; white (2.5 mm): 4 cartridges (Ethicon, USA)
- DST SERIES™ circular EEA™ stapler 25 mm blue (3.5 mm) (Covidien, USA)
- Two towel clamps
- One polydioxa-none suture (PDS) 3/0 cut at 22 cm (Ethicon, USA)
- Three PDS 4/0 cut at 15 cm (Ethicon, USA)
- ENDOPATH Endoscopic Multifeed Stapler (EMS) ™ (Ethicon, USA)
- Endo Close™ (Covidien, USA)
- One Polysorb 1 suture (Covidien, USA)
- Easyflow drain (Dispomedica, Germany)

22.3.2 Patient Positioning and Trocar Placement

After induction and intubation with a 34 French orogastric tube, all patients receive a dose of prophylactic antibiotic (1 g Cefazoline). The patient is placed in a 30° reverse Trendelenburg beach-chair position with split-legs. This position not only allows optimal access to the upper part of the abdomen, but also increases the abdominal workspace. [4] After disinfection, and draping of the patient, the surgeon stands between the legs, the first assistant, holding the camera, on his left, the second assistant on his right, with the video monitor placed at the level of the patient's head. After installation of insufflation, suction, camera, and ultrasonic device, a horizontal 1.5 cm incision is made approximately 7.5 cm below the xiphoid. Abdominal insufflation with carbon dioxide (CO_2) begins after insertion of the Veress needle. Intra-abdominal pressures are set at 15 mmHg and changed if necessary (increased or decreased) based on workspace. After introduction of a 10-mm scope trocar, the 30° angled scope is introduced, and four additional working trocars are placed under direct vision; a 5-mm port high in the epigastric area in the midline, a 12 mm port in the right upper quadrant, and two 12-mm ports in the left upper quadrant. The latter two ports are placed in the same line as the 10 mm port, while the former 12 mm port is placed higher (subcostal) (Fig. 22.2). Once the insertion of trocars is completed, the abdomen is inspected for abnormalities and the procedure begins with the creation of the gastric pouch.

Trocars	Instruments
1 (12 mm)	Liver retractor, Graspers, Linear stapler
2 (5 mm)	Graspers
3 (10 mm)	Scope
4 (12 mm)	Graspers, Ultrasonic device, Suction, Linear stapler, Scissors
5 (12 mm)	Graspers, Scissors, Circular stapler

Fig. 22.2 Schematic overview of trocar positioning, trocar sizes and overview of the different instruments used by each trocar

22.3.3 Creation of the Gastric Pouch

The 34 French stomach tube that is introduced for evacuating any intragastric air is retracted into the esophagus. A Babcock forceps is inserted via the left lateral trocar, and exerts traction on the lesser curvature at the level of the antrum. The lesser sac is accessed 4–5 cm below the gastro-esophageal junction by creating a small window in the lesser omentum (Fig. 22.3a) using a blunt dissection knife and the ultrasonic device. Introduction of the linear stapler occurs through this window, perpendicular to the lesser curvature. The stomach is horizontally cut over 60 mm (Fig. 22.3b), taking care not to completely transect the stomach. Usually, a blue cartridge is used, but cartridges with higher stapler height are employed when deemed necessary, based on tissue thickness. Posterior gastric adhesions are divided. A second linear 60 mm stapler is introduced through the left medial trocar, and positioned towards the angle of His starting from the most lateral point of the horizontal transection line. Guided by the 34 French orogastric tube, the stapler is closed and fired making sure not to leave a posterior sac (Fig. 22.4a). The next step consists of dissecting the angle of His. Anteriorly, the dissection extends as deep as possible by using the suction device as a blunt dissector, whilst applying traction at the fundus with the Babcock (Fig. 22.4b). Posteriorly, the window is opened just lateral to the left crus by blunt dissection, using the Babcock and the inserted gastric tube for traction. Finally, the pouch is created by vertically firing one or two 60 mm cartridges in the direction of and through the created window, along the gastric tube (Fig. 22.4c). Upon completion, the orogastric tube is pulled back into the esophagus.

22.3.4 Creation of the Gastro-jejunostomy

A small portion of the lower left corner of the pouch is excised using the ultrasonic device (Fig. 22.5a). The opening is stretched and a 3/0 PDS purse-string suture is sewn in (Fig. 22.5b). After extending the left lateral port site incision up to 2.5 cm, the interior opening in the abdominal wall is bluntly dilated with a scissor and two fingers. A blue 25 mm DST SERIES circular EEA stapler is then introduced intra-abdominally, and the anvil is introduced into the gastric pouch opening (Fig. 22.6). The pouch construction is completed by closing the purse-string around the anvil. A final inspection is performed to ensure that the tissue is tight around the anvil, excess mucosa and fat are removed, and veins or arteries running towards the future anastomotic site are excised to prevent bleeding. Thereafter, the greater omentum is lifted, and the transverse colon is visualized. The omentum is split longitudinally on the left side of the midline (Fig. 22.7a). Next, the ligament of Treitz is located (Fig. 22.7b). Using the ligament, the inferior mesenteric vein, and the root of the transverse mesocolon with the mesentery as landmark, the loop of jejunum is stretched up from this point in an anti-clockwise and ante-colic direction to the gastric pouch. The length of the biliary limb can be maximally 100 cm, depending on the degree of tension on the gastroenterostomy. In our experience, the mesentery becomes shorter if one extends beyond this point. If a sufficient length cannot be obtained, a retrocolic-retrogastric pull-up has to be performed.

An enterotomy is created 5–10 cm proximal to the designated anastomotic point, and the circular stapler is introduced into the jejunal loop in a distal direction (Fig. 22.8a).

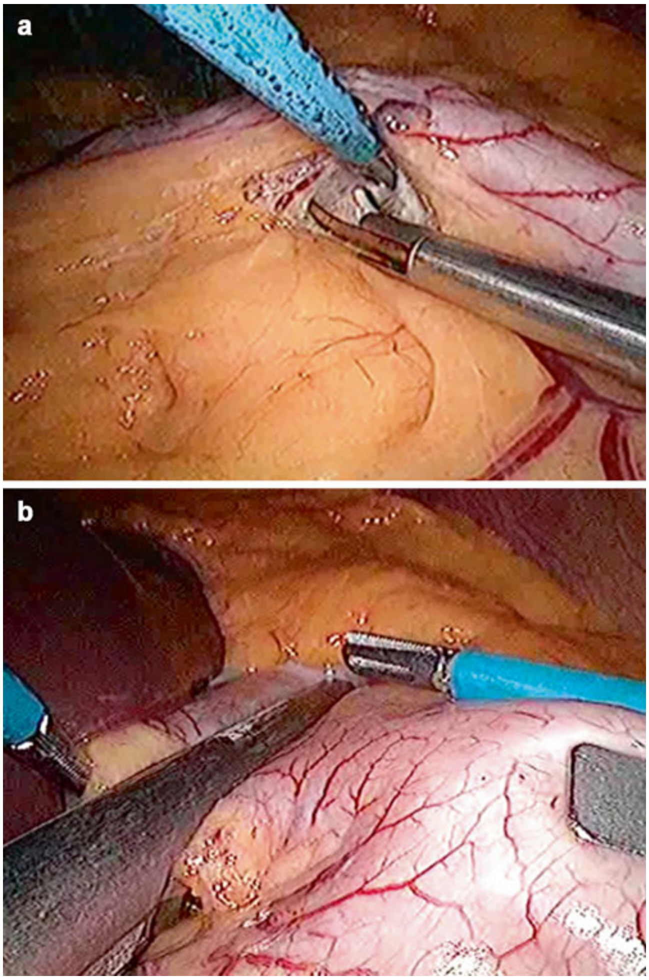

Fig. 22.3 Creation of the gastric pouch. (**a**) Start of the dissection at the lesser curvature 5–6 cm below the gastro-esophageal junction. (**b**) The first linear stapler cuts the stomach horizontally

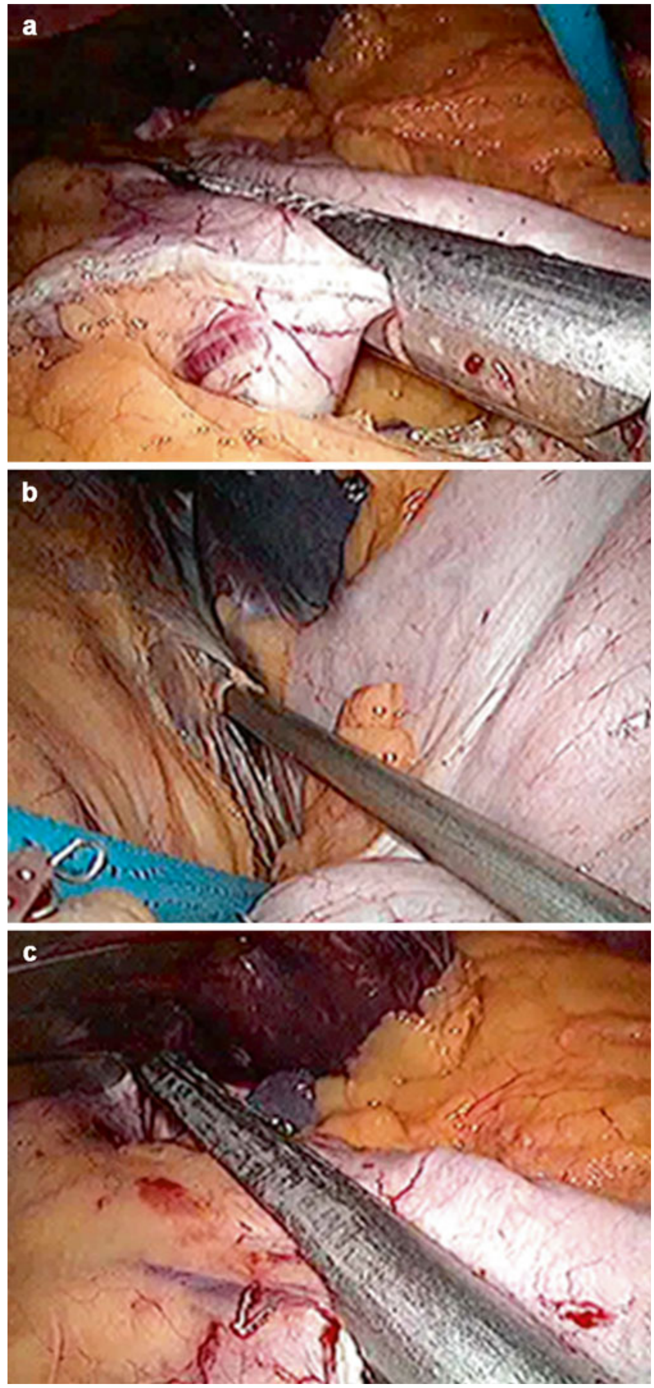

Fig. 22.4 (**a**) Vertical transection of the stomach along a 34 French. orogastric tube. (**b**) Opening of the angle of His, (**c**) Final stapling at the angle of His

The jejunum is prone to perforations with even a slight traction with the spike; hence, it is necessary to exercise caution in order to avoid perforations in the bowel wall, in an anti-mesenteric direction. Next, the stapler is connected to the anvil (Fig. 22.8b) and the anastomosis is completed by closing and firing the stapler. The superfluous 5–10 cm long small bowel segment, remaining from the previously created opening, is then transected 1 cm proximal to the gastro-jejunostomy using a linear stapler with a 60 mm white cartridge, thus, avoiding a long blind loop of jejunum (Fig. 22.9).

22.3.5 Creation of the Jejuno-jejunostomy

An alimentary limb of 130 cm (or 200 cm when body mass index [BMI] is above 50 kg/m^2) is marked, and an anti-mesenteric opening is created in the jejunum (Fig. 22.10a). A clamp introduced in the left lateral trocar site, is placed just distal to this opening as a reference point. Similarly, the biliopancreatic limb is accessed at a distance of 10 cm proximal to the enterotomy (Fig. 22.10b). A linear 60 mm stapler with a white cartridge is introduced via the right trocar, first in the biliopancreatic limb, then in the alimentary limb by aiming towards the pelvis (Fig. 22.10c). After positioning the stapler in the small bowel, the stapler is brought up in the direction of the costal margin and opened again, whilst holding the small bowel in place, before firing. This

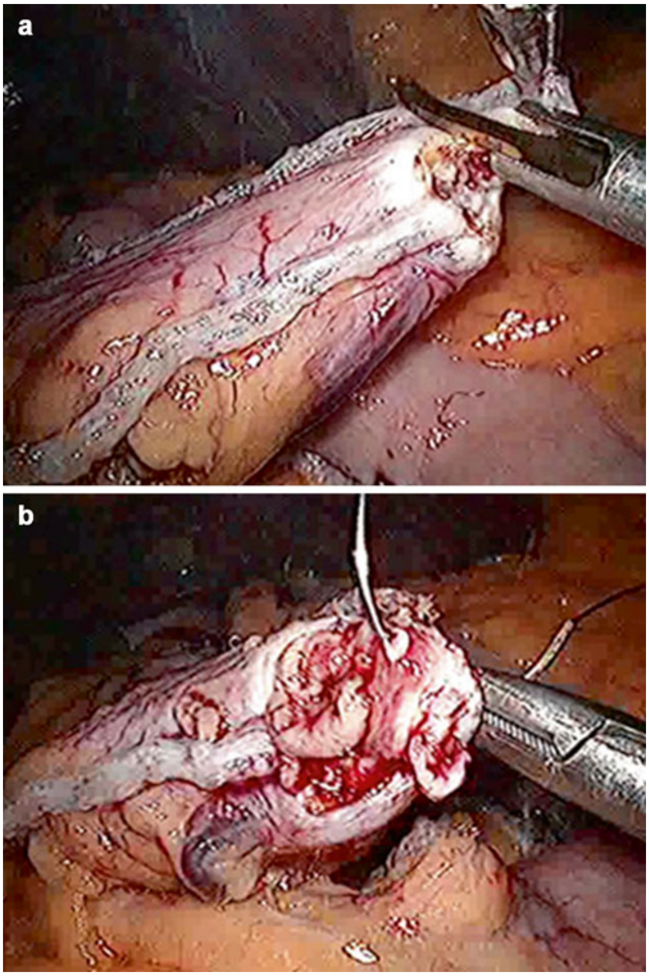

Fig. 22.5 Creation of the gastro-jejunostomy. (**a**) Opening of the gastric pouch in the lower left corner. (**b**) Purse-string suturing with PDS 3/0

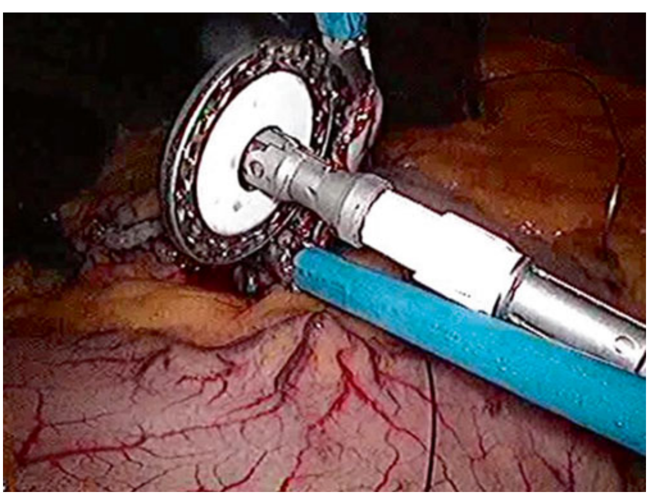

Fig. 22.6 Introduction of the anvil of the circular stapler and tying of the purse string

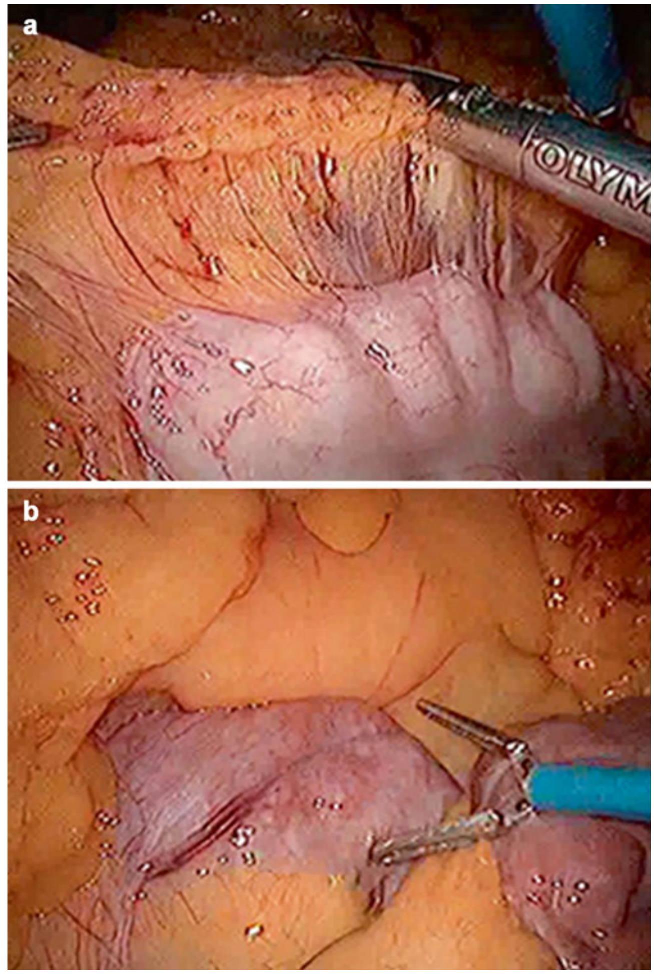

Fig. 22.7 (**a**) Division of the greater omentum, (**b**) Identification of the ligament of Treitz

maneuver makes sure that the side-to-side anastomosis is anti-mesenteric. The resulting enterotomy defect is lifted by three PDS 4/0 holding stitches, and then longitudinally closed using a similar stapler inserted through the right trocar (Fig. 22.11a). In this step, care is taken not to reduce the diameter of the alimentary limb too much, as this can lead to small bowel obstruction. If any problem such as kinking is anticipated, an aligning stitch can be placed, approximating both ends of the stapler line which closes the enterotomy. In the final step, the remaining blind loop of the biliopancreatic limb is transected with a linear stapler through the right trocar (Fig. 22.11b). Afterwards, this resected piece of bowel is removed via the left lateral trocar.

22.3.6 Testing of the Gastrojejunostomy

After positioning of the orogastric tube at the level of the gastrojejunostomy, leakage is checked by forcefully injecting 60 mL of methylene blue and air on an occluded anastomosis. If any leakage is present, the gastro-jejunostomy is reinforced with some additional stitches of an absorbable monofilament suture (Fig. 22.12).

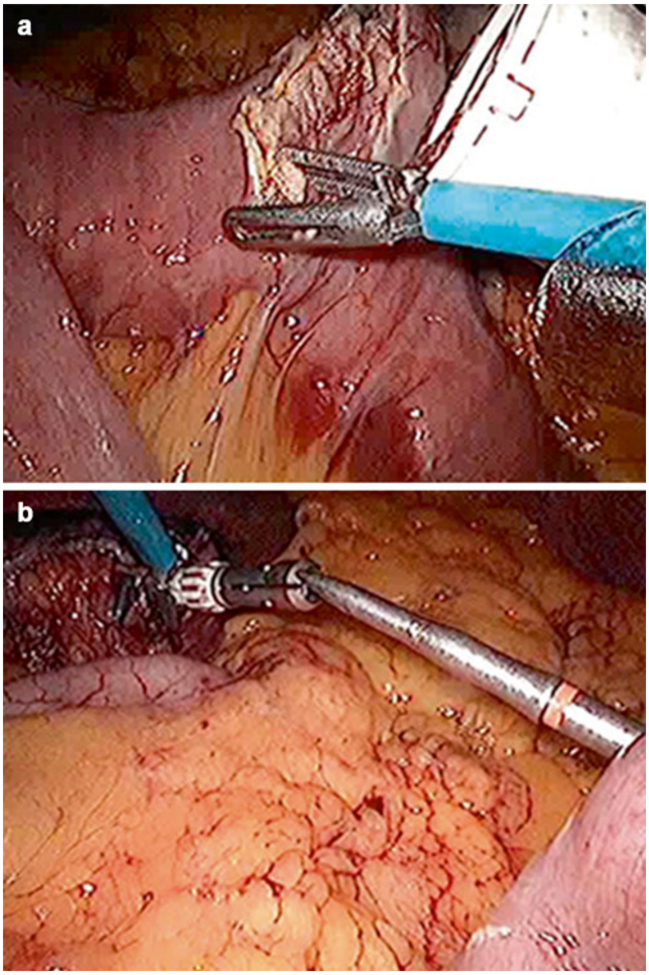

Fig. 22.8 (**a**) Enterotomy 30–50 cm from the angle of Treitz. (**b**) Antimesenteric perforation of the jejunum with the spike after introduction of the circular stapler

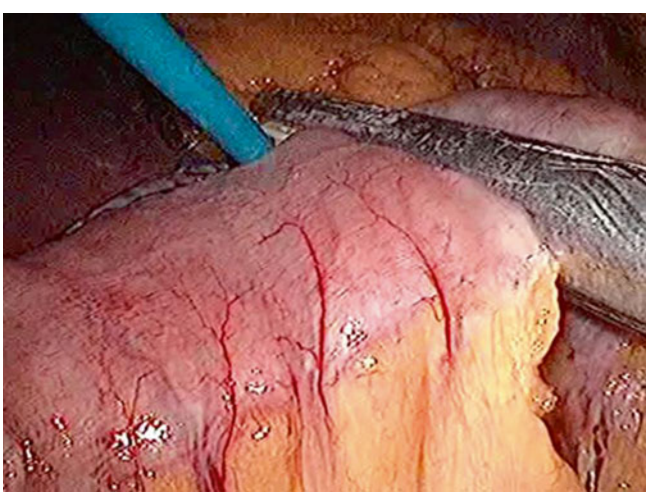

Fig. 22.9 Finalization of the anastomosis by transection of the remaining small bowel 1 cm proximal to the gastro-jejunostomy

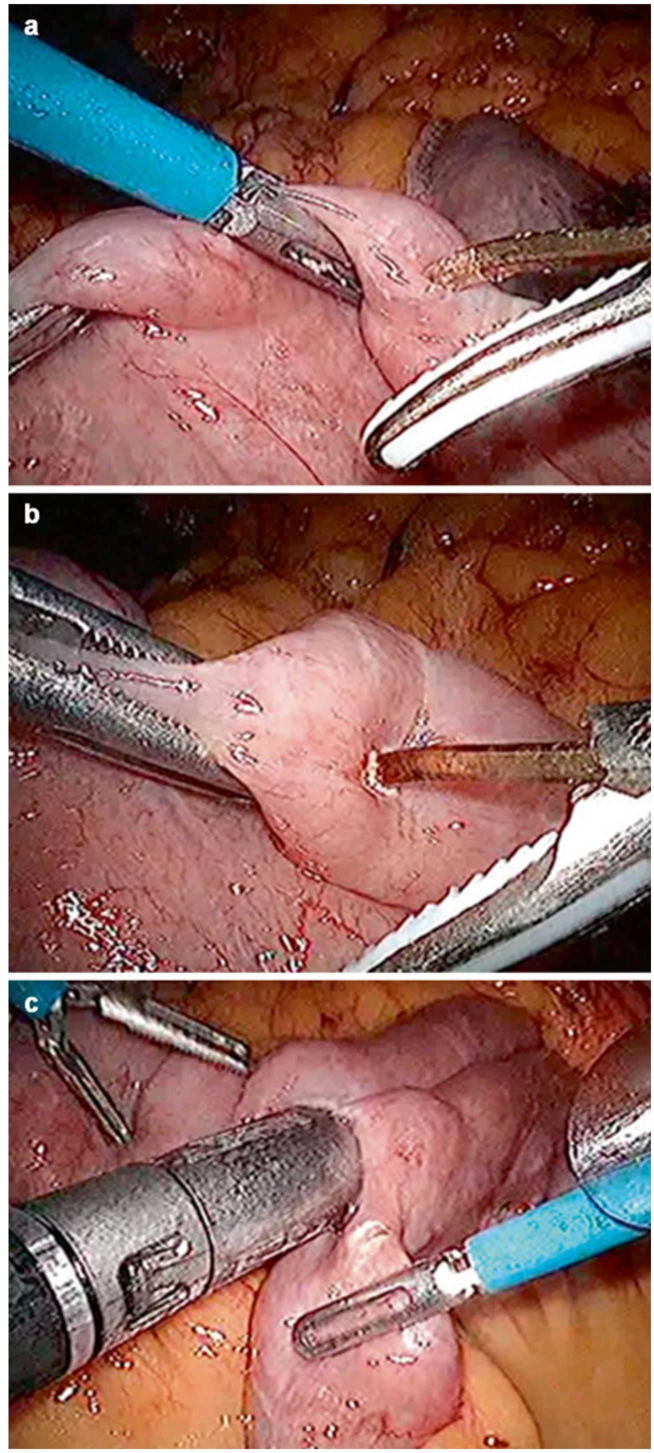

Fig. 22.10 Creation of the jejuno-jejunostomy. (**a**) Antimesenteric opening in the alimentary limb. (**b**) Antimesenteric opening in the biliopancreatic limb. (**c**) Side-to-side anastomosis with a linear 60 mm stapler

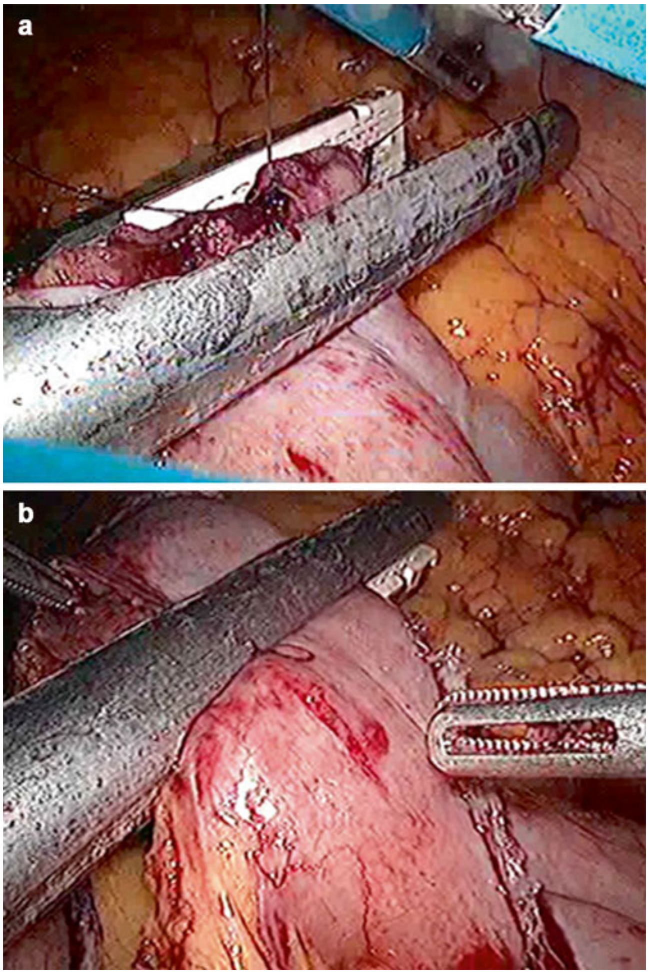

Fig. 22.11 Creation of the jejuno-jejunostomy. (**a**) Closure of the enterotomy defect using three stay sutures. (**b**) Transection of the remaining blind loop of the biliopancreatic limb

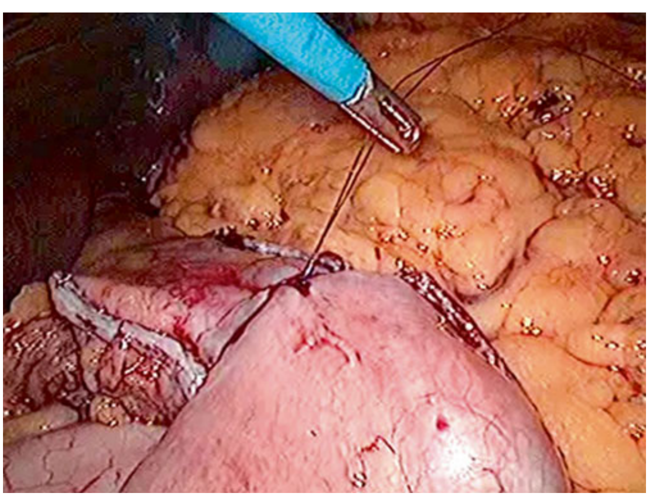

Fig. 22.12 Additional reinforcement stitch at the level of the gastro-jejunostomy

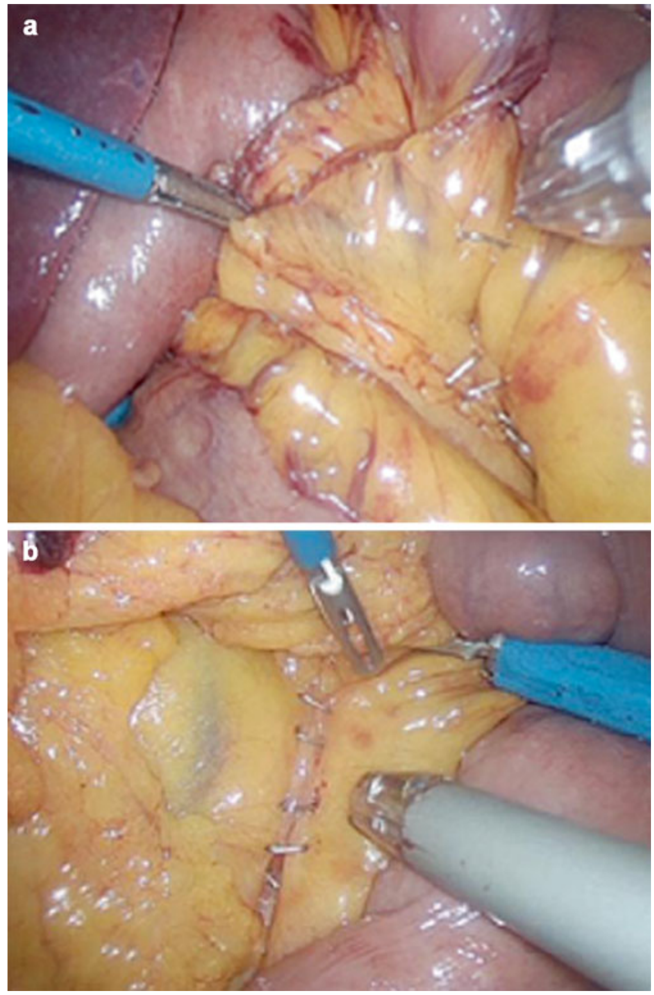

Fig. 22.13 Closure of the mesenteric gaps with EMS™ stapler. (**a**) Mesenteric gap at the entero-enterostomy. (**b**) Petersen's space

22.3.7 Closure of Petersen's Space and Mesenteric Gap During Entero-enterostomy

Although the antecolic-antegastric technique has the lowest incidence of internal hernias, and closure of the defects have their own advantages and disadvantages [5–7], we close the Petersen's space and the mesenteric gap using an EMS™ stapler since August 2013. The mesenteric gap is closed starting from the blind loop downwards, whilst keeping the alimentary limb aside (Fig. 22.13a). It is advisable to exercise caution, by avoiding a closure of the gap too close to the mesentery of the alimentary limb, because of the risk of bleeding and tension at the gastroenterostomy site. Pushing up the transverse colon with the Babcock from the left lateral trocar and pulling the omentum to the right exposes the

Petersen's space (Fig. 22.13b). One EMS™ device (20 staples) is usually sufficient to close both gaps.

22.3.8 Completion

To prevent postoperative bleeding, all staple lines are inspected at an elevated systolic arterial pressure above 130 mmHg [8] and any detected bleeding points are clipped. The entero-enterostomy is buried underneath the omentum, and the left lateral trocar port site is closed with the help of the Endo Close™ trocar site closure device, in order to prevent lateral entrapment or hernia formation (Fig. 22.14). The left lateral incision is infiltrated with a long-acting local anesthetic and a drain is passed through the incision, so that it lies next to the gastric pouch. The drain is fixed cutaneously with a Polysorb stitch.

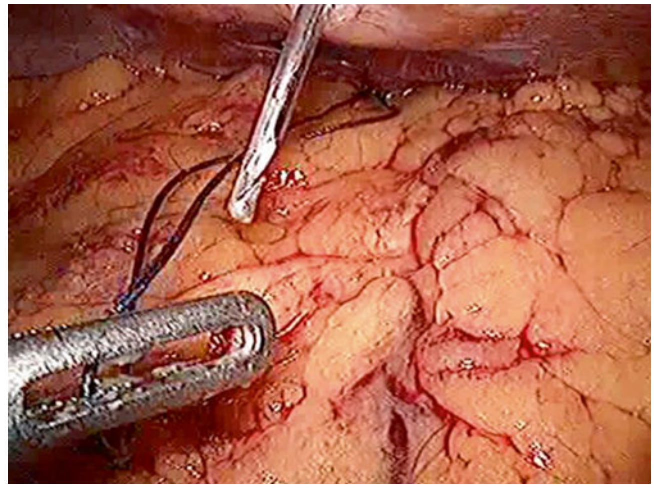

Fig. 22.14 Closure of the left lateral trocar port site with the Endo Close™ trocar site closure device

22.4 Advice for the Initial Cases

In order to get used to the FS-LRYGB, it is advisable to choose patients without an extreme BMI, and with a female fat distribution (mainly extra-abdominal fat) for allowing a good learning curve for the initial cases. Patients should be prescribed a preoperative high protein diet for 14 days to reduce the size of the liver (a 5–10 % reduction in weight should be achieved). It is preferable to seek highly experienced assistance, even if it entails a delay for the operation. Peroperatively, after insufflation and appropriate (high enough) trocar placement, evaluate all important anatomical landmarks, including the angle of His. Surgery may be initiated by splitting the omentum and identifying the ligament of Treitz. Pull up the small bowel, evaluate the mesenteric length, and check if an antecolic gastroenterostomy can be safely constructed without traction. By using the stepwise approach as described earlier, a safe Roux-en-Y gastric bypass can be performed successfully, with favorable outcomes.

22.5 Postoperative Care

On the first postoperative day, oral intake is resumed, and the drain and any intravenous infusions are removed. Upper gastrointestinal imaging is not routinely performed. Generally, patients are discharged on the second postoperative day with specific dietary instructions. To prevent deep venous thrombosis patients receive a daily subcutaneous injection with low-molecular-weight heparin for 10 days. In addition, a proton pump inhibitor (omeprazole 20 mg) is prescribed for 3 months to prevent marginal ulcer formation. A double dose is prescribed in patients who smoke or patients on anticoagulants or non-steroidal anti-inflammatory drugs. The first follow-up visit is scheduled at 6 weeks postoperatively. Thereafter, patients visit at 6, 12, and 24 months postoperatively.

Conclusion

The FS-LRYGB is a safe and easily reproducible surgical weight-loss procedure. Maximum standardization of the operation and high surgical volumes contribute to low 30-day morbidity and mortality rates.

Key Learning Points

The Fully Stapled Laparoscopic Roux-en-Y Gastric Bypass Technique

- allows complete standardization
- is reproducible, fast and safe
- is associated with minimal morbidity and mortality
- can be used in complex revisional bariatric surgery

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LRYGB: Complications—Diagnosis and Management

23

Susannah M. Wyles and Ahmed R. Ahmed

Abstract

Several significant and potentially catastrophic complications can occur after a laparoscopic Roux-en-Y gastric bypass (RYGB). Early complications include anastomotic leaks and hemorrhage, followed by internal herniation with possible small bowel ischemia, fistulation, ulceration, and nutritional and metabolic complications. Other complications include deep venous thrombosis and pulmonary embolism, skin and neurological complications, and cholelithiasis. Bariatric patients may have elusive and non-specific clinical signs and their weight may restrict the types of imaging investigations available. All these factors may make it difficult to detect complications when they occur. Hence, it is important that the treating surgeon have a high index of suspicion for complications in any bariatric patient, both when postoperative progress does not appear to be following the usual course, and in those presenting with unmanageable pain, fever or tachycardia. It is also important for the patient to be educated of the potential changes in a normal postoperative course. They should be advised that they or any other treating clinician should contact the primary bariatric surgeon in case of any untoward symptoms in the postoperative period, as these may be related to their operation, even if not obvious in the first instance. In the early postoperative stage, if there is any doubt about potential abdominal complications, a diagnostic laparoscopy should be performed without further delay, since these patients can deteriorate very quickly, and abdominal scans may often be unhelpful and/or falsely reassuring.

The complications of RYGB, their incidence, presentation, diagnosis and management are discussed in this chapter, and in addition, some tips for their prevention are provided.

Keywords

Leak • Internal hernia • Complication • Laparoscopic Roux-en-Y gastric bypass • Ulcer • Pulmonary Embolism • Fistula • Stenosis • Gastro-Intestinal bleed • Dumping syndrome

23.1 Introduction

Worldwide, there are currently more than 340,000 bariatric procedures performed annually, of which the Roux-en-Y gastric bypass (RYGB) remains the most common operation (46.6 %). Approximately 80 % of these operations are performed laparoscopically, and is termed a laparoscopic Roux-en-Y gastric bypass (LRYGB) [1]. Given the technical complexity of the LRYGB there are associated complications at a rate of approximately 21 % (12–33 %), and a re-operation rate of 3–20 % [1, 2]. There is a perioperative

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(<30 days post LRYGB) and postoperative (>30 days post LRYGB) mortality rate of approximately 0.38 % and 0.72 % respectively [2]. In the early postoperative period, these complications tend to be related to technical issues. Later, they can include metabolic or nutritional problems, though these may be minimized by ensuring good patient compliance with pos-operative care and the provision of lifelong regular follow-up in clinic. It is important to note that bariatric surgery patients do not behave in the same way as the average post-surgical patient during the postoperative period. Furthermore, bariatric surgery patients may exhibit fewer symptoms and signs of complications such as peritonitis, and may consequently deteriorate rapidly and suddenly. This stresses the importance of early diagnosis in this patient population. A bariatric surgeon, therefore, should be able to utilize diagnostic laparoscopy early in the postoperative course if a patient is not progressing satisfactorily and there is concern about an intra-abdominal complication. Laparoscopy enables a surgeon to make not only a prompt diagnosis, but also, in the most part, manage complications effectively, thus saving the patient from the surgical stress and further complications associated with a laparotomy. The fear of a negative diagnostic laparoscopy should not deter the surgeon from offering this potentially disaster-averting and life-saving treatment. Most bariatric surgeons, when it comes to recognizing postoperative complications, are very familiar with the expression, "delay is the deadliest form of denial" [3].

There have been some attempts to develop a pre-operative risk predictor score (Obesity Surgery Mortality Risk Score [OS-MRS]), which has recently been customized to make it applicable to the LRYGB, and the use of this tool may affect future outcomes and reduce complication rates [4]. The OS-MRS assigns points to patients for certain preoperative variables. These include: male gender, body mass index (BMI) >50 kg/m^2, age >45 years, hypertension and known risk factors for pulmonary embolism [4]. Patients who score 0–1 fall into the lowest risk group (A), 2–3 into intermediate group (B), and score 4–5, into high risk group (C) [4]. Nevertheless, it is wise to suspect every postoperative patient who is not progressing normally of having a complication. In general, it is suggested that the patient should be diagnosed within 4 h, and an intervention should be administered within 6–12 h.

Table 23.1 outlines the complications, their incidence and their time course that are considered in this chapter. The following complications are discussed in detail: bleeding, leak, ulcers, gastro-gastric (GG) fistula formation, bowel obstruction, deep vein thrombosis (DVT), and pulmonary embolism (PE); skin complications, nutritional, metabolic and neurological complications, cholelithiasis, and rarer complications. Weight gain following gastric bypass will be discussed in a separate chapter. For each complication, a description of the more common symptoms and signs, the investigations, management, and steps for prevention are defined. Table 23.2 summarizes the main clinical features found with these complications.

23.2 Early Complications

23.2.1 Gastrointestinal Bleeding

The current incidence of postoperative gastrointestinal (GI) bleeding is 0.8–4.4 %. It is more common in those patients who have been heavy users of non-steroidal anti-inflammatory drugs (NSAID) pre-operatively, particularly if they have not ceased taking them 7–10 days prior to surgery [5]. The problem is further compounded by the use of low molecular weight heparin (LMWH) prophylaxis for venous thromboembolic events (VTE). Most patients undergoing surgery receive a dose before or during surgery, which is then continued daily until they leave hospital, or in some centers, for even longer after discharge.

23.2.1.1 Types of Gastrointestinal Bleeding

Bleeding may arise from anywhere, including the bypassed (remnant or excluded) portion of the stomach. It may present

Table 23.1 Incidence and timings of postoperative complications after LRYGB

Complication	Incidence (%)	Timing (early <1 week, intermediate 1 week – 1 month, or late >1 month)
GI bleed	1–2	Early
Leak	1–2	Early/intermediate
Ulcers and GG fistula	4	Late
GI obstruction	5	Late but may occur early/intermediate
Thromboembolism	0.1–1.3	Early/intermediate
Skin complications	variable	Late
Nutritional complications (of some degree)	variable	Late
Metabolic complications	variable	Intermediate/late
Cholelithiasis	7–10	Late

GG gastro-gastric, *GI* gastrointestinal, *LRYGB* laparoscopic Roux-en-Y gastric bypass

Table 23.2 "Symptom sorter": a list of the common symptoms and their causes to aid diagnosis

Tachycardia	Hypotension	Abdominal pain	Pyrexia	Nausea and vomiting
GI bleed	GI bleed	GI bleed	Leak	Ulcer/fistula
Leak	(Leak)	Leak	Pneumonia/sepsis	Intestinal obstruction/internal hernia
PE		Ulcer/fistula		Cholelithiasis
		Intestinal obstruction/internal hernia		"Hockey stick" syndrome
		Cholelithiasis		
		"Hockey stick" syndrome		

It should be remembered that in bariatric patients symptoms and signs may be elusive so this table should be considered to be a guide rather than a definitive list
GI gastrointestinal, *PE* pulmonary embolism

clinically as a GI bleed with hematemesis or melena, or covertly as intraperitoneal bleeding, or both. If a GI bleed occurs within the first 48 h, a staple line bleed should be suspected. The most commonly affected site is at the gastro-jejunal (G-J) anastomosis, which usually represents an inadequate hemostasis (intra-abdominal or intra-luminal). Other staple lines that may bleed include those of the gastric remnant, gastric pouch, or jejuno-jejunal (J-J) anastomosis. If the hemorrhage occurs from the gastric pouch itself, it tends to present as hematemesis; a per-rectal (PR) bleed can be indicative of bleeding from any of the sites intra-luminally [4]. If the bleeding occurs more than 48 h postoperatively, it is most likely from a G-J marginal ulcer. Occasionally, bleeding can also be due to an alternative intra-abdominal source such as a tear in the mesentery or spleen. General oozing or even a more significant hemorrhage can be due to the use of low molecular weight heparins after the induction of anesthesia. It must also be borne in mind that a GI bleed can result in a blood clot blocking the jejuno-jejunostomy, thus resulting in bowel obstruction and abdominal distension. Bleeding into the gastric remnant may not present with overt PR bleeding, but instead can present with acute gastric distension if the blood stays within the gastric remnant.

23.2.1.2 Symptoms and Presentation

The most commonly observed symptoms are as follows:

- Tachycardia (early) and hypotension (later), with or without pallor and collapse
- Hematemesis or bleeding per rectum (PR) in the form of melena or bright red blood
- Abdominal pain or abdominal distension
- Frank blood arising from any intra-abdominal drainage (note that lack of blood in drainage fluid does not indicate an absence of internal bleeding)

23.2.1.3 Management

The key steps in the diagnosis and management of a postoperative bleeding episode are outlined in Fig. 23.1.

23.2.1.4 Immediate Steps

- Promptly resuscitate with intravenous fluid
- Discontinue heparin or LMWH
- Correct any coagulopathy
- Check serial measurements of hemoglobin levels and hematocrit
- Commence transfusion of blood products as per the clinical findings, and in line with the local hospital guidelines
- Administer tranexamic acid and coagulation products as appropriate

An upper GI endoscopy should be considered; however, accessing the excluded stomach and the Roux limb is not usually possible with a direct esophagogastroduodenoscopy (EGD), and it may be necessary to perform a gastrostomy to enable the insertion of a scope into the stomach [5]. Unfortunately, due to the high vasculature in the stomach, angiography with embolization is often not useful. Surgical intervention, such as diagnostic laparoscopy, may be required in the first instance in about 40 % of the cases. This depends on the rate of blood loss, the hemodynamic stability of the patient, and extent of bleeding [5]. During repeat laparoscopy, it is recommended to oversew the bleeding points and staple lines, decompress the remnant stomach and to place a gastrostomy tube [5]. Extra-luminal bleeding is best managed by performing a repeat laparoscopy, followed by evacuation and washout of the clot (because leaving the clot adjacent to a staple line may increase the risk of a leak), oversewing of all staple lines, and using other hemostatic agents, if deemed necessary. A drain should be left to monitor the area for further bleeding.

23.2.1.5 Prevention

There are several measures that can be adopted to prevent GI hemorrhage. One is to oversew the staple lines. Although not routinely recommended, persistent intraoperative ooze from a particular site may warrant oversewing. It is important to select the correct staple height, as short staples may help prevent bleeding, but if the staple height is too short, it will lead to the incorrect staple formation and hence predispose

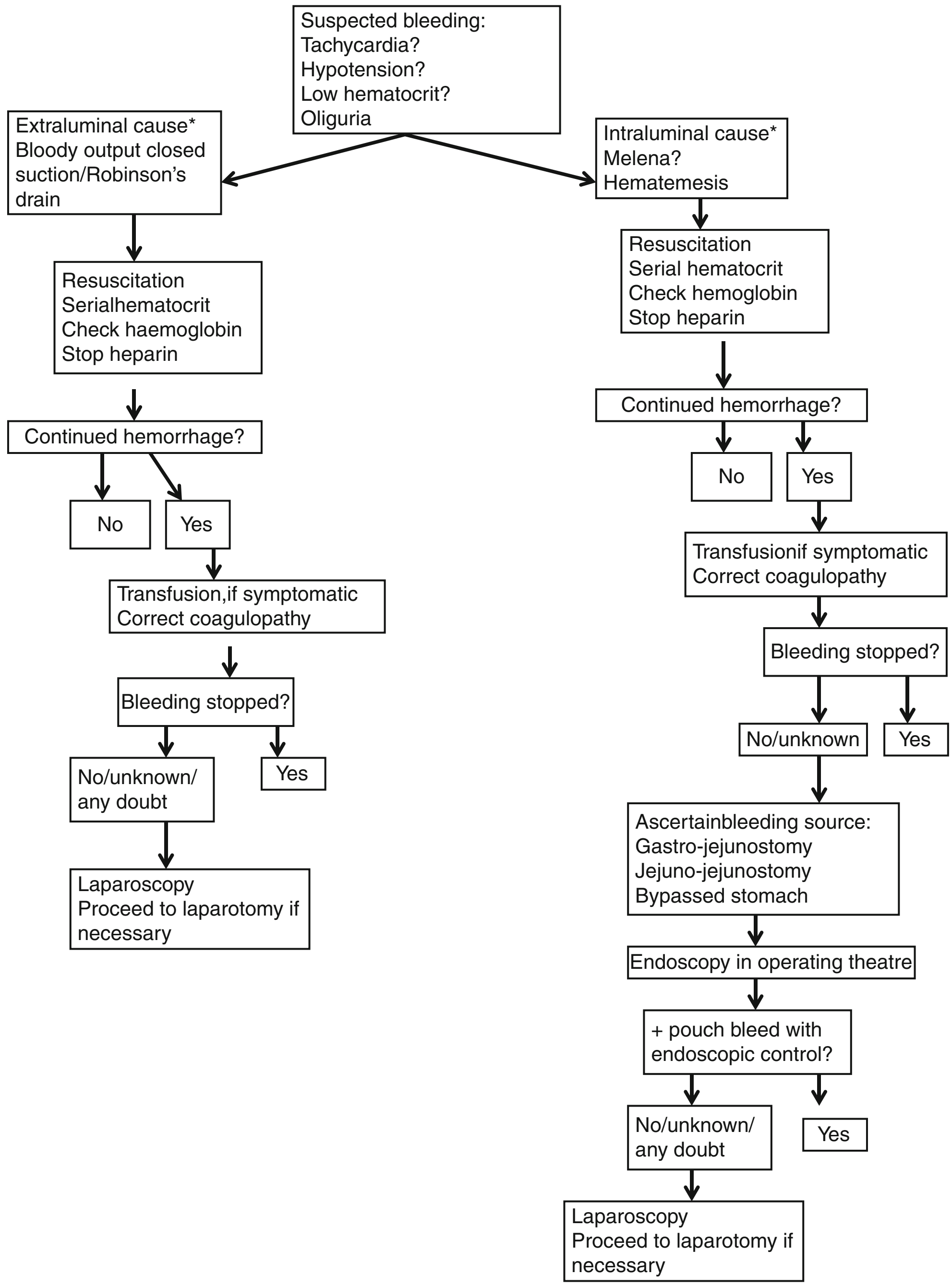


Fig. 23.1 Diagnosis and management algorithm for gastrointestinal bleeding post gastric bypass (Adapted Mehran et al. [5])

the patient to a risk of leak. The stapler gun should be fired as directed by the manufacturer; for example, clamping and maintaining pressure on the tissue for a period of time prior to firing, helps to enable hemostasis.

There have been reports of a significant reduction in the number of bleeding sites following the division of gastric, jejunal, and mesenteric tissue, and the overall intra-operative blood loss, by using staple-line reinforcement (SLR), especially those made of absorbable material [6]. The advantages of these reinforcements must be weighed against their potential disadvantages, which include high cost and the additional time required to load the SLR onto the stapler [6]. Fibrin glues have also been used to manage leaks, and may be beneficial in preventing bleeding; however, although they are easy to use, they are also expensive and can induce patient immunological reactions since they are derived from blood products [7].

The risk of postoperative bleeding complications can be minimized further by performing a final careful inspection of all staple lines, the divided mesentery and omentum, to ensure hemostasis prior to exiting the abdomen, once the blood pressure has returned to normal [8].

23.2.2 Leak

Anastomotic and staple line leaks occur after approximately 2–4.4 % of LRYGB operations, and can result in significant morbidity, cutaneous fistula, peritonitis, abscess formation, sepsis, multi-organ failure, and eventually death [9]. Leaks occur most commonly from the G-J anastomosis. They occur less commonly from staple lines, more dangerously from the J-J anastomosis, the remnant stomach, and from an unrecognized iatrogenic intestinal injury. Early detection has been proven to reduce morbidity and mortality. This may be challenging, however, both due to the physical effects of obesity itself rendering it difficult to elicit the usual clinical signs, and with the weight limits of the computed tomography (CT) table [8], restricting the ability to obtain good postoperative scans.

23.2.2.1 Symptoms and Presentation

The most commonly observed symptoms are as follows:

- Tachycardia, with or without hypotension
- Tachypnea
- Pyrexia
- Abdominal pain, although they seldom present with overt peritonitis
- Excessive abdominal pain, shoulder tip pain, and hiccups are ominous symptoms, especially in the presence of a persistent tachycardia; a leak should be suspected when the heart rate is more than 120, until proven otherwise

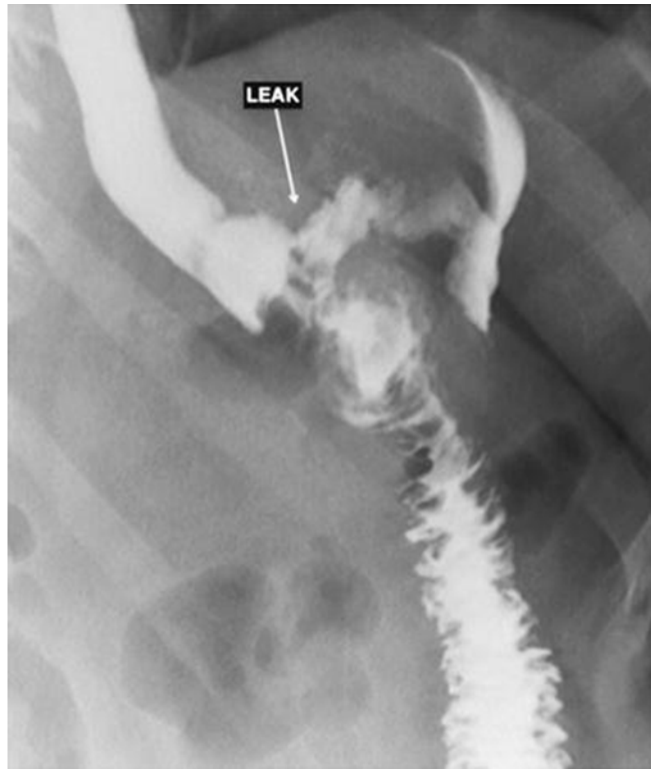


Fig. 23.2 Typical leak from the gastrojejunostomy 24 h after surgery (Reproduced with kind permission from Springer from: Trenkner [56])

23.2.2.2 Diagnosis

Intra-operative Diagnosis

Leak must be ruled out intra-operatively after completion of the G-J anastomosis, with either a methylene blue dye test, or by using air insufflation under saline via the orogastric tube [9]. The air test is preferred for several reasons: first, it is thought to be more sensitive as it tests the entire anastomosis and not just the visible area (the methylene blue test may miss a leak on the anastomosis back wall); second, it is faster; third, it is cheaper, and fourth, it does not color all areas if there is a leak [10]. An alternative approach is to perform an on-table endoscopy to check the anastomosis for both its lumen size and for any leaking points. However, this can be expensive and time consuming to perform and needs to be done carefully to avoid traumatizing the newly formed gastric pouch and anastomosis.

Postoperative Diagnosis

Upper gastrointestinal (UGI) contrast studies are frequently used to evaluate the gastric pouch for leaks, stenosis or obstruction (Fig. 23.2.). However, routine imaging during the early postoperative care is neither necessary nor cost-effective [11]. Review of the published literature [11] suggest that most leaks occur between postoperative day 2 to day 5, and are more likely to be detected using a CT scan with oral contrast (Table 23.3), (Fig. 23.3). The sensitivity of UGI studies can be influenced by the experience of the radiologist, the size of the leak, and the contrast material used, and is the preferred study for detecting alimentary limb obstruction such as stenosis [11, 12]. Though there is minimal patient-associated risk, this investigation cannot reliably detect a leak; reports indicate true-positive rates of only 1 in 9 [12, 13]. It also does not rule out a leak at the jejunojejunostomy site or in the remnant stomach. It is suggested that a routine postoperative UGI contrast study should be avoided, as it is unreliable, and should only be performed selectively when a patient demonstrates clinical signs and symptoms of a leak [11, 14, 15].

The routine practice of placing a surgical drain is advantageous in detecting an increased sanguineous or abnormal drain output that may aid in the diagnosis of a bleed or leak, respectively [9]. Those who argue against the use of drains suggest that they can be falsely reassuring if there is no output, and the drain may be blocked or in the wrong position. Some suggest that the drains themselves may cause a leak or obstruction and result in a route for infection [16]. Yet there is some

Table 23.3 Representation of the timelines when common complications occur

Time after surgery	Complication				
Day 1–2	GI bleed (staple line)				DVT/PE
Day 3–5	GI bleed (ulcer)	Leak			
Day 5–10				GI obstruction	
1–6 months			Ulcer/fistula		
6–12 months					
12–24 months					
24–36 months					

DVT deep vein thrombosis, *GI* gastrointestinal, *PE* pulmonary embolism

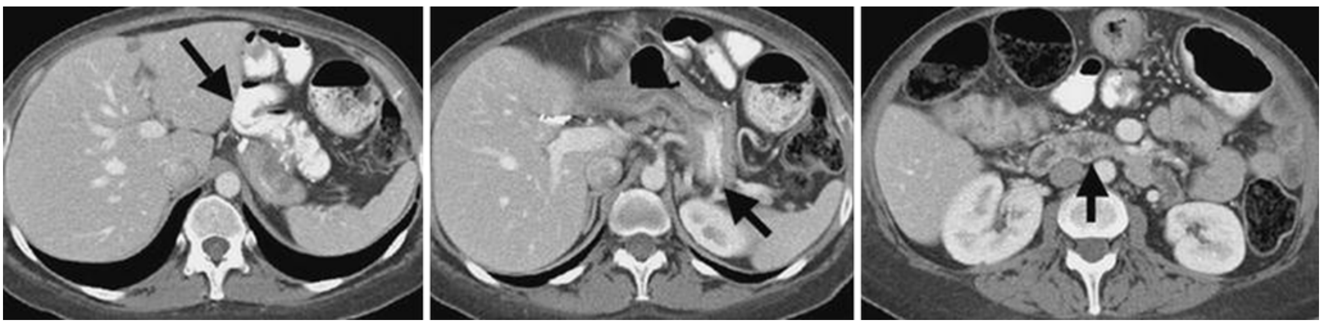


Fig. 23.3 Leak across the staple line into the bypassed stomach diagnosed by computed tomography. In the first image note the contrast in the Roux limb (*arrow*). In the second image note the contrast in the excluded stomach (*arrow*). On the final image no contrast is seen in the duodenum (s) (Reproduced with kind permission from Springer from: Trenkner [56])

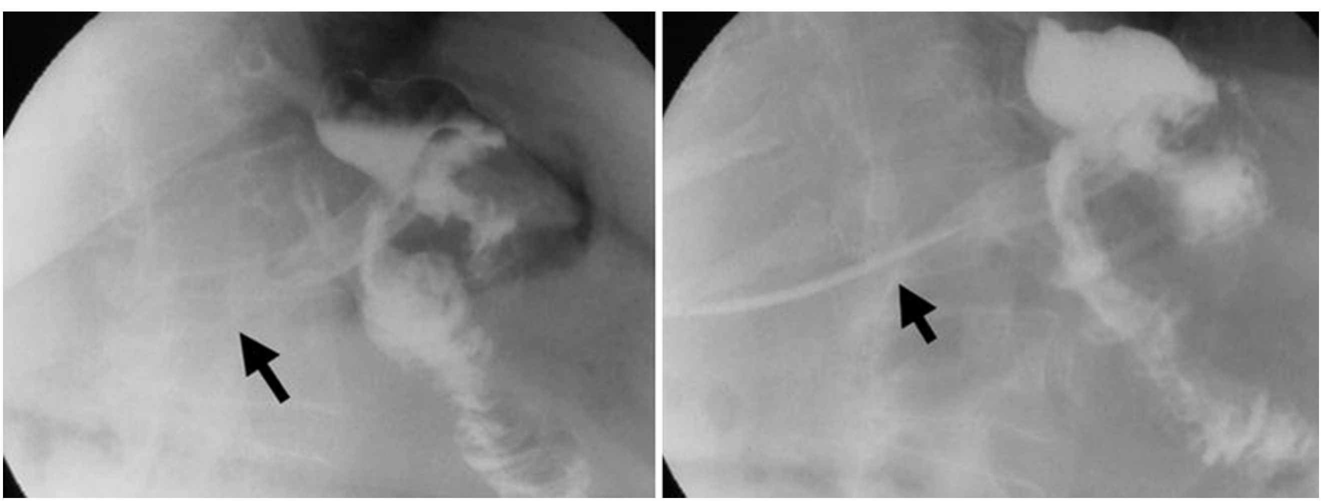


Fig. 23.4 Leak diagnosed only by presence of contrast in the drain (*arrows*). The first image is early in the study and the second is later (Reproduced with kind permission from Springer from: Trenkner [56])

evidence to show that sometimes a leak is only diagnosed by UGI studies or in the presence of a drain (Fig. 23.4) [17, 18].

If an anastomotic leak is suspected in a patient, a prompt diagnostic laparoscopy remains the gold standard approach, as it provides the ability to accurately diagnose the problem as well as providing prompt treatment. ACT scan can be helpful in making a diagnosis when the patient is stable, but it has limited feasibility as patient weight and girth can exceed the parameters of the imaging equipment. Additionally, it can sometimes be falsely reassuring, if interpreted incorrectly.

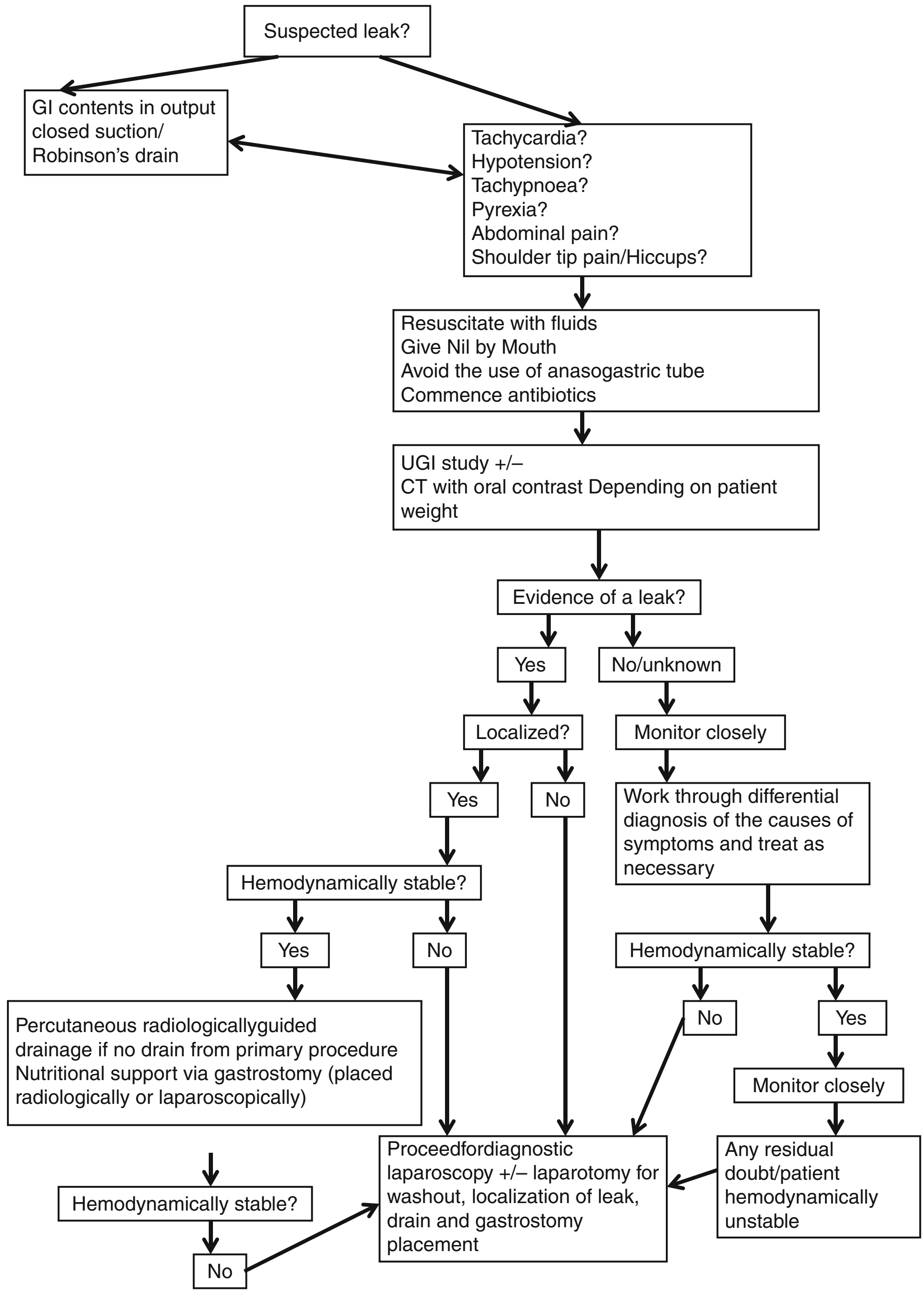


Fig. 23.5 Diagnosis and management algorithm for anastomotic leak post gastric bypass

23.2.2.3 Management

Immediate steps to be adopted in the management of a leak are as follows:

- Fluid resuscitation
- Nasogastric tube placement
- Commence antibiotics
- Definitive treatment strategies, such as diagnostic laparoscopy in unwell patients
- CT scan in stable patients (Fig. 23.5)

Conservative management includes drainage, either via a drain placed at the primary procedure site or through a radiologically guided percutaneous drain, intravenous antibiotics, and nutritional support (nil by mouth and feeding parenterally or via a radiologically placed gastrostomy tube), may be sufficient for treatment of patients who are hemodynamically stable [19, 20]. If the patient is unstable and unwell, or if there is an uncontrolled leak, then the patient should proceed to the operating room immediately. The operative procedure would usually start with a laparoscopy, but the surgeon may have to perform a laparotomy. The aim of surgery is to drain and washout all the contamination and any intra-abdominal GI contents, followed by an attempt to localize the site of the leak in order to repair it or ensure well-placed drains for controlling the leak. A fresh leak may be amenable to being oversewn and/or patched. A leak that is over 24 h old usually has friable edges that will be difficult to approximate. The key maneuvers are to place drains and establish a method for enteral feeding if appropriate (e.g., remnant stomach gastrostomy or feeding jejunostomy tube), or central venous access for parenteral nutrition.

Non-healing leaks and fistulas may develop, and endoscopic placement of covered self-expandable stents (SES) may be a minimally invasive treatment option for the management of such postoperative leaks, even in patients with acute symptoms [19, 21]. SESs are a relatively well-tolerated, safe and effective means of achieving leak closure, with success rates of up to 87 % [19, 21]. Stent migration is the most common complication of SES placement, which may require endoscopic stent repositioning, retrieval or replacement [19]. In some circumstances, surgical retrieval is necessary [19]. Further additional drawbacks associated with migration are the need for both X-ray surveillance to assess possible stent migration, and for repeated endoscopic procedures [19]. At present, however, the stents being used are not designed specifically for this purpose, and with further modifications, there may be an improvement in the migration risk, and consequently the morbidity rates associated with this technique.

23.2.2.4 Prevention

Three simple ways to help prevent leaks include (i) avoiding excess tension at the gastro-jejunal anastomosis, (ii) avoiding devascularization of the gastric pouch through meticulous dissection and identification of the anatomy, and (iii) using the correct size endostapler cartridge for the tissue being divided or anastomosed.

It has been reported that the use of staple-line reinforcement is associated with a reduced leak rate in LRYGB [7]. It is crucial to select the correct staple size as the reinforcement gives additional tissue thickness, which can result in staple-gun misfiring [6]. There is an associated mortality in patients who have post-bypass leaks. In those who do not succumb, the recovery is often prolonged and complicated. Therefore, it cannot be understated that every measure should be taken to prevent a leak.

23.2.3 Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)

The risk of developing a DVT or a PE after bariatric surgery is between 0.1 and 1.3 %, although recent studies suggest this to be grossly under-reported. It should be considered as one of the strongest independent factors for perioperative mortality [22–24]. It is most common in the first 2 weeks after surgery when patients are least ambulant [22–24]. There are certain risk factors for venous thromboembolism, which include hypercoagulability, increased BMI (>50), history of thrombosis, surgical interventions at the pelvis, heart failure, venous insufficiency, supplementary hormonal therapy, male gender, expected long operative time, smoking, and obstructive sleep apnea [22–25]. Extreme body weight, high intra-abdominal pressure and reverse-Trendelenburg positioning in laparoscopic surgery reduce venous backflow, but creation of the pneumoperitoneum has not been shown to be an independent risk factor for the development of thromboembolism despite the potential for increased venous stasis [22].

Table 23.4 Differential diagnosis of chest pain after LRYGB

<48 h after surgery	>48 h after surgery
PE	PE
MI	MI
Retained gas from pneumoperitoneum	Pneumonia
Abdominal compartment syndrome	Leak

LRYGB laparoscopic Roux-en-Y gastric bypass, *MI* myocardial infarction, *PE* pulmonary embolism

23.2.3.1 Signs and Presentation

DVT: Pain or swelling involving the lower extremities (though not always observed in obese patients)

PE: Hypoxia, tachypnea, and tachycardia. The patient may also complain of chest pain. It can be difficult to distinguish a PE from a leak or sometimes from atelectasis and pneumonia (Table 23.4).

23.2.3.2 Investigations and Management

Diagnosis of a DVT can be made using a Duplex ultrasound, and the patient should be treated with anti-coagulants [22]. A PE can be diagnosed with a CT angiogram, or a V/Q scan. If the weight of the patient restricts the use of CT, then it is advisable to initiate anti-coagulation therapy for these patients and accept the small risk of potential postoperative hemorrhage rather than risk the consequences of a possible PE.

23.2.3.3 Prevention

The American Society for Metabolic and Bariatric surgery currently recommend mechanical calf compression devices and compression stockings, early ambulation and anticoagulation, wherever possible [25]. The risk for DVT is reduced by 62 % with intermittent pneumatic compression, by 47 % with anti-thrombotic stockings, and by 48 % with low-molecular weight heparin [22]. There is a 2.4 % risk of developing a DVT if chemoprophylaxis is not administered [22]. However, the optimal approach for reasonable prophylaxis is unknown since a balance should be drawn between

Fig. 23.6 Normal gastrojejunostomy as seen on postoperative endoscopy in a patient who underwent Roux-en-Y gastric bypass patient (Reproduced with kind permission from Springer from: Narula et al. [57])

reducing the risk of a clot versus that of postoperative bleeding [22, 25]. There is no consensus on the dosage, application mode or duration of therapy [22, 25, 26]. For high-risk patients, defined as those patients in a hypercoagulable state, BMI >60, medical history significant for DVT or PE and venous stasis; the use of intraoperative 1000 IU heparin per hour intravenously and an IVC filter is recommended [22, 26]. Although the filter has been shown to reduce, but not eliminate, the risk of venous thrombosis, placement is not without serious risks. These include filter migration, vessel rupture, and IVC thrombosis [27]. The risk of these complications is reduced when the filter is only placed temporarily, and it should therefore ideally be removed at approximately 6 weeks, or once the patient is fully ambulant [27]. Others recommend that those patients at a high risk for VTE should undergo a period of extended prophylaxis with low molecular weight heparin for a suggested 14–28 days post operation. This is the current practice of most bariatric surgeons to reduce the risk of VTE in their patients.

23.3 Late Complications

23.3.1 Ulcers and Fistulas

The overall incidence of marginal ulcers and fistulas is approximately 4 %, with a reported range of <1–36 %. There is an increased incidence of fistulas in patients who undergo revisional surgery, which has an associated mortality of 8–37.5 % [28]. The ulcers usually occur at the gastrojejunostomy (GJ) anastomosis, often on the intestinal side, between 1 and 6 months post surgery. The etiology of ulcers is not entirely clear, but suggested mechanisms include increased acid production in an oversized pouch, the presence of Helicobacter pylori, ischemia of the pouch or alimentary limb, staple-line disruption, and/or the presence of staples and suture material within the pouch [29]. Fistulas may result from an untreated leak, a marginal ulcer perforating into the remnant stomach, or iatrogenically from an incompletely divided pouch. Marginal ulcer risk seems to be increased with the use of NSAIDS, and in smokers, and decreased with the use of proton pump inhibitors (PPI) [29, 30].

23.3.1.1 Symptoms and Presentation

- Abdominal pain, especially post-prandial
- Nausea, vomiting
- GI bleed
- Asymptomatic (occasionally)
- Weight regain or plateau in weight loss

23.3.1.2 Diagnosis

The usual diagnostic investigation is an upper GI endoscopy or an upper GI contrast study (Figs. 23.6 and 23.7).

23.3.1.3 Management

Medical management can be through the use of proton-pump inhibitors and sucralfate, treatment of H. pylori infection, and the cessation of any exacerbating factors such as smoking or the use of NSAIDs (Fig. 23.8) [29, 31]. It is not

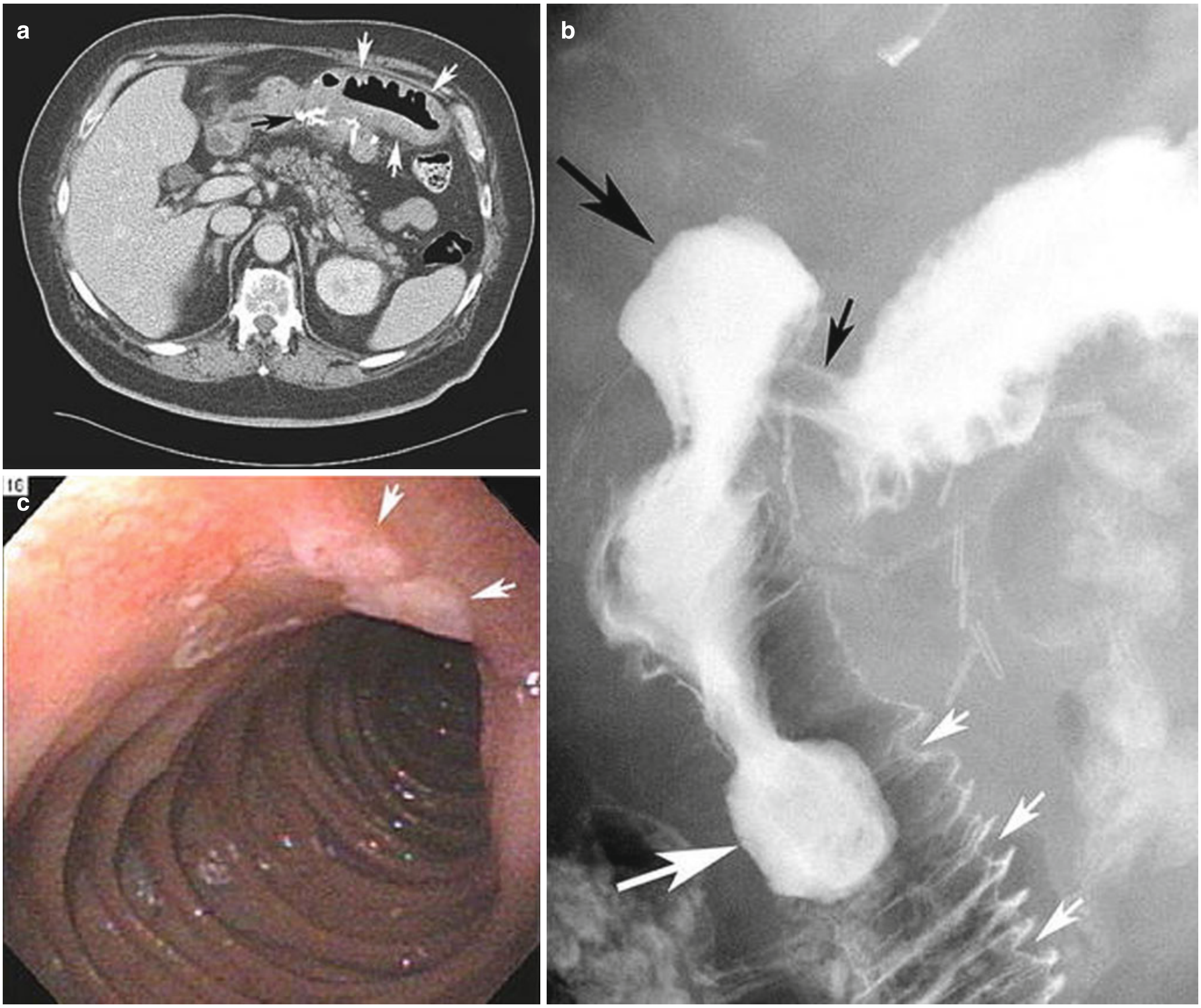


Fig. 23.7 Giant jejunal ulcers in a 66-year-old man with abdominal pain and melena after Roux-en-Y gastric bypass. (**a**) Intravenous contrast-enhanced axial computed tomography scan through upper abdomen shows thickening of the bowel wall (*white arrows*) in the Roux limb of proximal jejunum abutting the gastrojejunal anastomosis (*black arrow* denoted staples at anastomosis). Note how jejunal folds are thickened along the anterior wall of this abnormal loop of jejunum. (**b**) Right posterior oblique spot image from single-contrast upper gastrointestinal tract barium study showing a 3-cm diameter ulcer (*large black arrow*) in the Roux limb on the jejunal side of the gastrojejunal anastomosis (*small black arrow*), and a 2.5 cm diameter ulcer (*large white arrow*) more distally in the Roux limb. Thickened folds (*small white arrows*) are also seen in the proximal jejunum in the region of the more distal ulcer. (**c**) Upper endoscopy shows a giant ulcer (*arrows*) in the jejunal Roux limb distal to the gastrojejunal anastomosis. Note the appearance of the jejunal folds (Reproduced with kind permission from: Ruutiainen et al. [58])

necessary to proceed immediately to surgery, unless there is evidence of perforation. The operative approach should involve exploration; excision of the fistula and ulcer, and revision of the G-J anastomosis; and reduction in the size of the pouch if it is oversized as necessary. If there is tension in the Roux limb and mucosal ischemia, then the Roux limb should be mobilized. If the ulcer is associated with a foreign body such as suture material, this should be removed [29, 32]. The difficulty with the surgical repair of fistulas is the tissue quality; it is hard to suture due to the excessive contamination and inflammation.

It has been reported that a conservative approach is useful, prior to reoperation, in these very high-risk patients [33]. Endotherapy with the use of SESs, and particularly self-expanding metal stents (SEMS), are a management option [19, 33]. Advantages of endoscopy are that it is less affected by BMI, is less invasive than surgery, and does not induce local inflammation that can have a negative impact on healing [28]. There is an ongoing concern regarding the feasibility of removal of these stents and possible migration. There has been some improvement in this with the use of self-expanding plastic stent (SEPS)

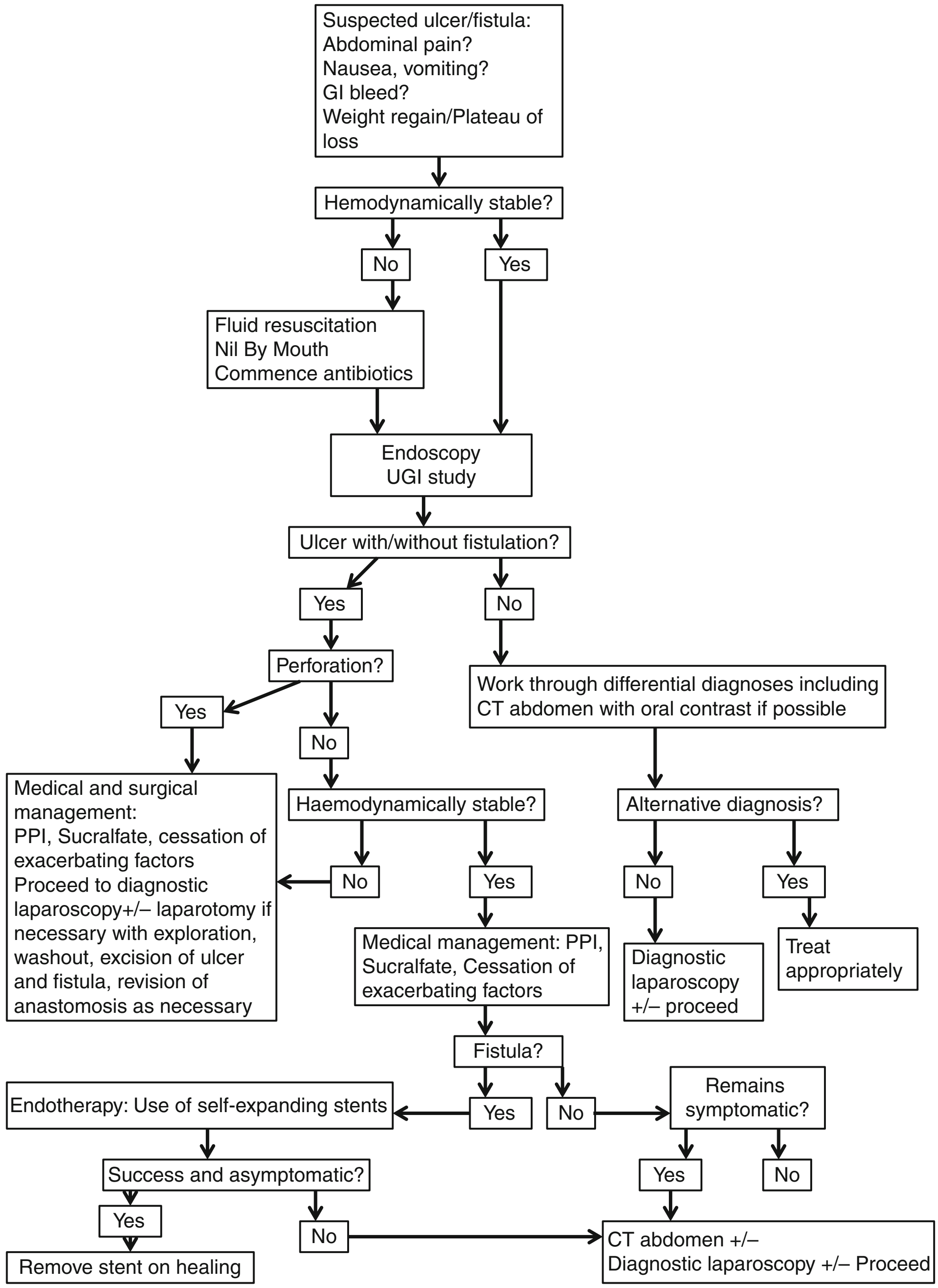


Fig. 23.8 Algorithm for the diagnosis and management of gastrojejunostomy ulceration and fistula after gastric bypass

with the subsequent extraction of both stents together. Endoscopy is currently applied more imaginatively, such as in the drainage and washout of the peri-fistula debris, along with debridement if necessary using the natural orifice translumenal endoscopic surgery (NOTES) procedure, placement of a stent with or without use of clips and/or glue with collagen plugs to close the fistulous trajectory [28]. The evidence is not yet conclusive enough to define specific management guidelines using these techniques; however, they will almost certainly play a more significant role in future.

23.3.1.4 Prevention

These measures include those advised for preventing a leak. Further, more the use of PPI postoperatively is strongly recommended [30].

23.3.2 Gastrointestinal Obstruction

Yet another complication specifically related to the LRYGB is gastrointestinal tract obstruction. This is the commonest complication after a LRYGB with a reported incidence of

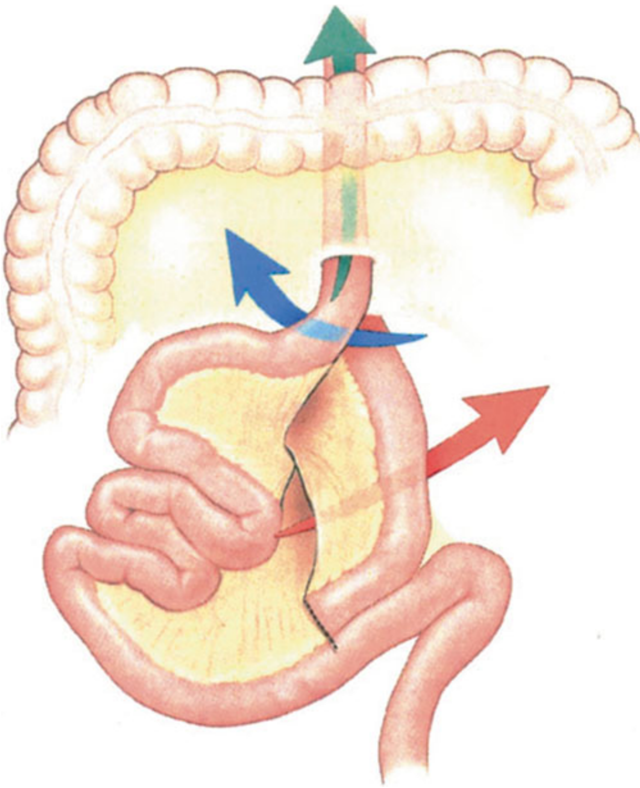


Fig. 23.9 Sites of retroanastomotic or transmesenteric internal hernias, including mesocolic window or retrocolic tunnel (*green arrow*) mesenteric defect, Petersen's mesenteric defect (*blue arrow*), and enteroenterostomy or distal anastomosis mesenteric defect (*red arrow*) (Reproduced with kind permission from Springer from: Comeau et al. [59])

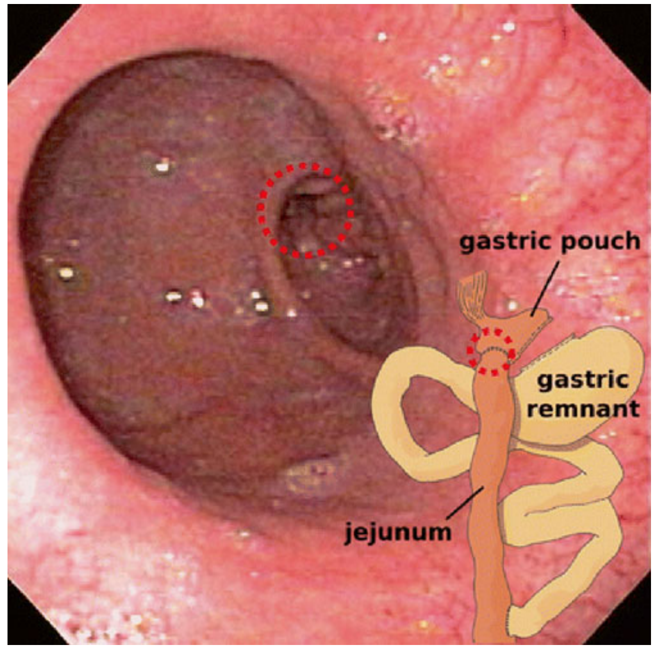


Fig. 23.10 Stricture at the site of gastrojejunal anastomosis. An endoscopic view from the esophagus into the gastric remnant is shown. Marked narrowing of the gastrojejunal anastomosis (*dotted circle*) was noted at the time of endoscopy. The inset depicts the surgical anatomy following gastric bypass (Reproduced with kind permission from Springer from: Limketkai and Zucker [60]).

small-bowel obstruction ranging from 1.5 to 5 % (Table 23.1) [34]. The majority of cases present within the first 12 months, however, this can range up to at least 42 months post surgery [34]. Depending on the method adopted for the surgical construction of the gastric bypass, the altered anatomy can result in blockages from scarring at the various anastomoses or by kinking of the loops of small intestine, secondary to it getting stuck in spaces within the peritoneal cavity that did not exist before the surgery (internal hernia) (Fig. 23.9). A blockage can occur at the GJ anastomosis from a postoperative stricture (1 %) or food bolus obstruction (Figs. 23.10, 23.11, and 23.12). More distally, small bowel obstruction (SBO) may be related to internal hernia formation (1–2 %) (Figs. 23.13 and 23.14). A further complication, more specifically, of the retrocolic LRYGB, is Roux limb obstruction caused by narrowing within the transverse mesocolic defect (Figs. 23.15 and 23.16). This tends to present earlier than internal herniation, and is usually caused by scar formation and extrinsic circumferential compression of the Roux limb. Other possible causes of SBO in this population include intussusception; adhesions; port site hernias; and obstruction at the jejuno-jejunostomy from kinking, stricture, blood clot or bezoar (Table 23.5) (Figs. 23.17, 23.18, and 23.19) [34]. An iatrogenic cause that should not be ignored in the immediate post-surgical setting, particularly with the

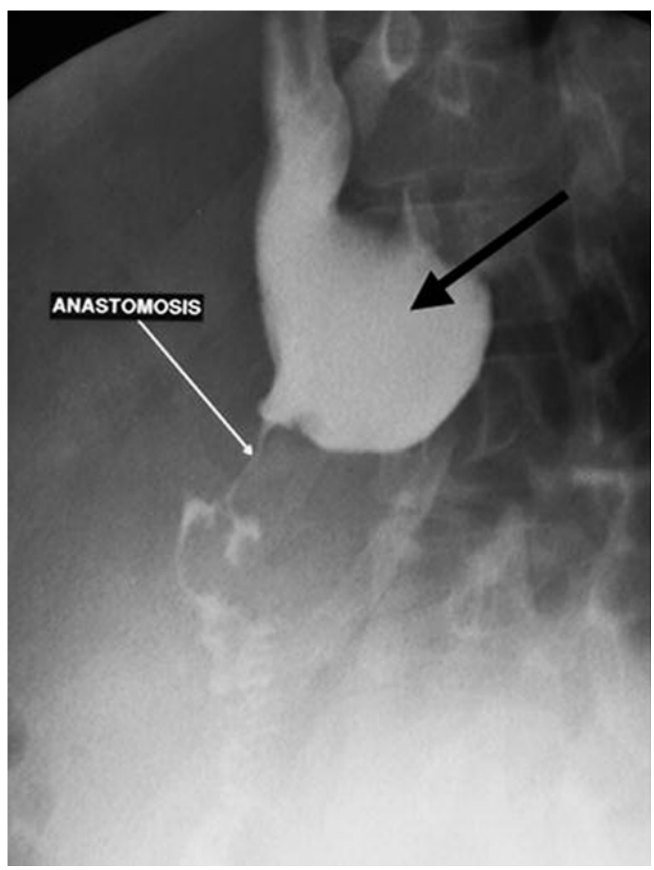


Fig. 23.11 Stenotic gastrojejunostomy. Note the dilated pouch (*arrow*) (Reproduced with kind permission from Springer from: Trenkner [56])

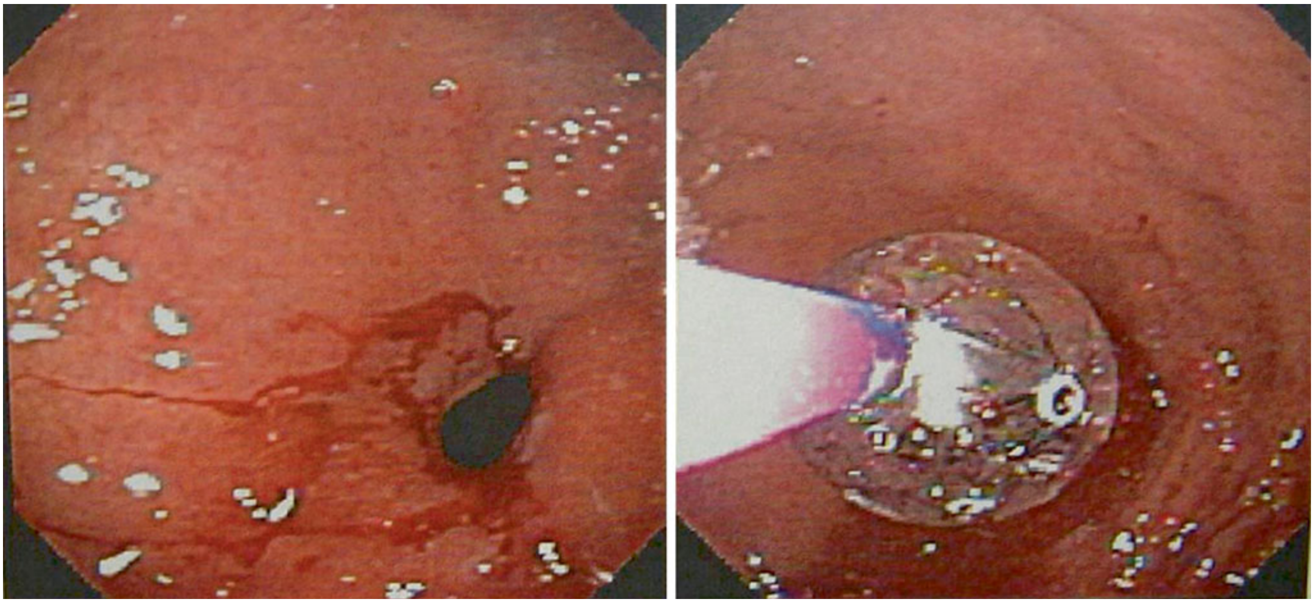


Fig. 23.12 Dilating a strictured gastrojejunal anastomosis in a postoperative Roux-en-Y gastric bypass patient (Reproduced with kind permission from Springer from: Narula et al. [57])

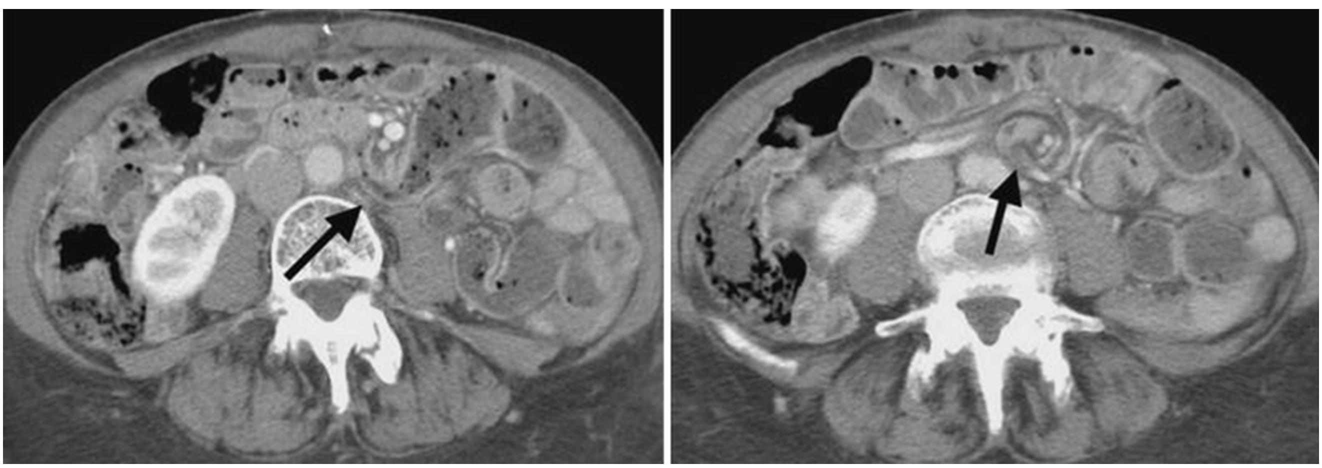


Fig. 23.13 Internal hernia through the mesenteric defect at the jejunojejunostomy. In the first image note the point of obstruction (*arrow*). In the second image the mesenteric swirl is seen (*arrow*) (Reproduced with kind permission from Springer from: Trenkner [56])

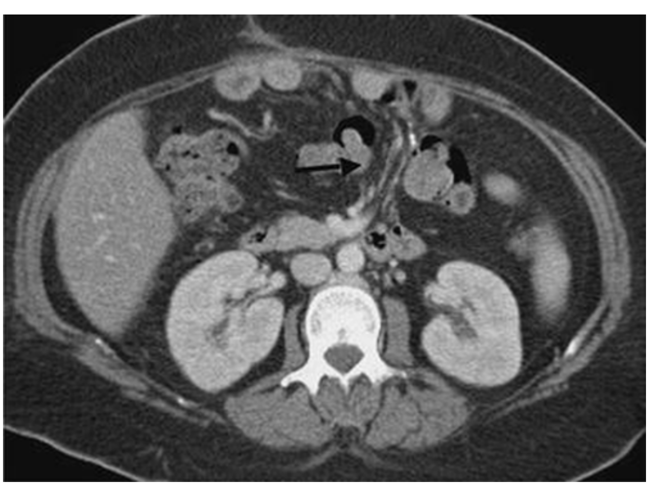


Fig. 23.14 Internal hernia through the transverse mesocolon (*arrow*) (Reproduced with kind permission from Springer from: Trenkner [56])

laparoscopic approach, is a Roux-en-O formation where the small bowel becomes a closed loop (Fig. 23.20).

Interestingly, the laparoscopic approach results in a higher incidence of postoperative bowel obstruction. In a review that included 3464 patients, a higher frequency of both early and late obstructions were reported in LRYGB when compared to open cases [35]. One reason attributed to this is that very few adhesions are formed allowing small bowel loops freedom to move and become ‘stuck’ in spaces that did not exist before the surgical ‘re-organization’ of anatomy that occurs with the gastric bypass [36, 37].

23.3.2.1 Symptoms and Presentation

It should be remembered that unlike the usual symptoms in patients with small bowel obstruction, large volumes of vomit are rare due to the small size of the gastric pouch, and

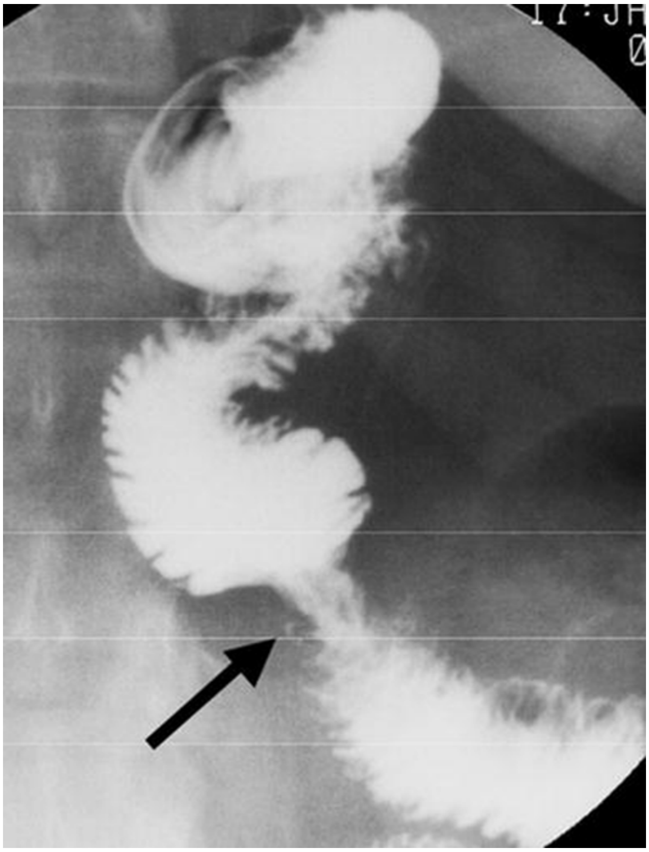


Fig. 23.15 Narrowing of the Roux limb where it passes through the transverse mesocolon (Reproduced with kind permission from Springer from: Trenkner [56])

nausea or retching may in fact be more significant [34]. Small bowel obstruction can present in these patients as an acute event with severe colic and complete obstruction or as vague abdominal discomfort after eating (Table 23.2).

The presenting symptoms vary according to the site of obstruction in the LRYGB. Vomiting of undigested food and abdominal cramps are present when the obstruction is proximal to the common channel. When the obstruction is at the level of, or distal to the jejuno-jejunostomy, bilious vomiting, fullness, tachycardia, nausea, retching, hiccups, shoulder pain (if GI contents decompress into excluded remnant stomach) are usually present. The differential diagnosis is a gastro-gastric fistula, which is rare. Fullness due to the stomach distending with fluid, with a sense of impending doom, is observed in cases of an obstructed bilio-pancreatic limb proximal to the common channel.

23.3.2.2 Investigations

Small bowel obstruction may sometimes be diagnosed using a standard plain abdominal radiograph, but a CT scan with oral contrast is the most helpful. A barium meal (UGI study) or follow through may also be helpful. With a barium meal, it is easier to diagnose a stricture than an internal hernia. Subtle radiological signs more usually seen on CT indicating bowel obstruction after LRYGB include an abundance of small bowel in the left upper quadrant, dilatation of the stomach remnant and duodenum, mild dilatation of bowel without obstruction, increased Roux limb contrast transit time, increased Roux limb redundancy, and thickened bowel loops.

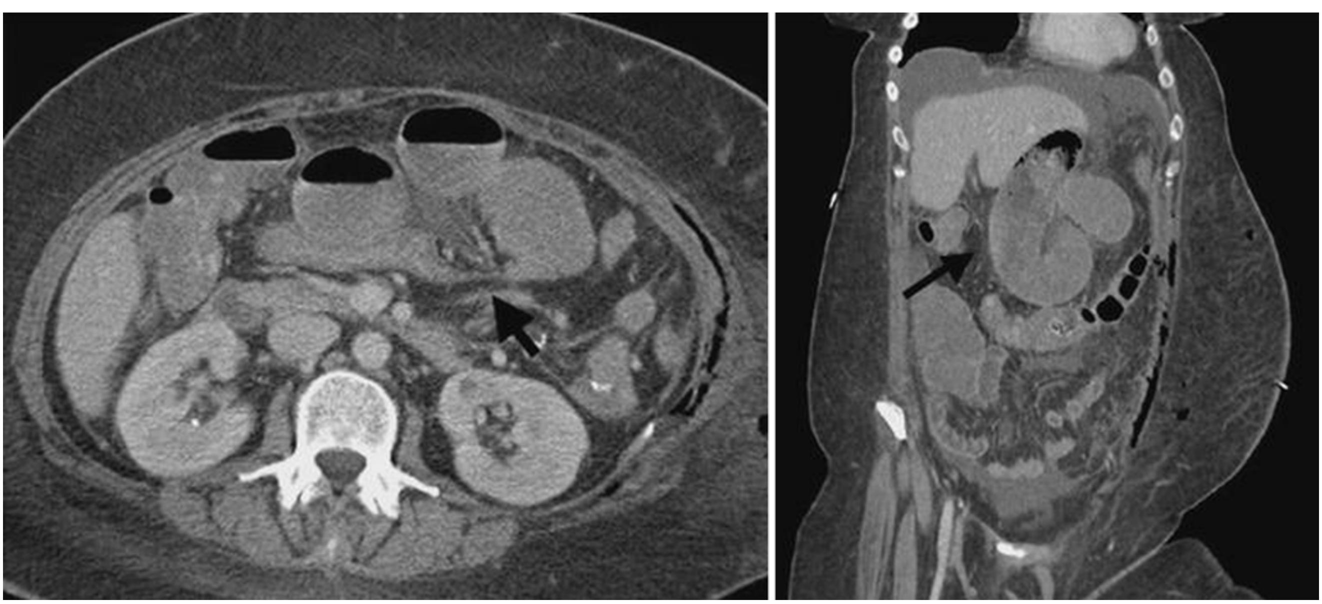


Fig. 23.16 High-grade obstruction at the defect in the transverse mesocolon 6 days after Roux-en-Ygastric bypass. The point of obstruction is seen on the axial image (*arrow*). On the coronal image note the dilated Roux limb (*arrow*) superior to the transverse colon (Reproduced with kind permission from Springer from: Trenkner [56])

Table 23.5 Incidence of the different causes of SBO after LRYGB [34]

Cause	Incidence (%) of all SBO
Internal hernia	53.9
Roux limb stricture	20.5
Adhesions	13.7
Angulation at entero-enterostomy	6.8
Port-site hernia	1.9

LRYGB laparoscopic Roux-en-Y gastric bypass, *SBO* small bowel obstruction

Fig. 23.17 Non-enhanced axial computed tomography of the abdomen showing a characteristic target sign in the left upper quadrant in the region of the jejunojejunostomy consistent with an intussusception (Reproduced with kind permission from: McAllister et al. [61])

In actuality, the precise cause of the obstruction can sometimes not even be determined by a skilled expert radiologist. Regardless, the decision to re-operate should not be delayed in order to exclude an internal hernia. This is different from the postoperative general surgical patient where the commonest cause of obstruction is from adhesions, which often resolve with a non-operative approach (Fig. 23.21).

23.3.3 Internal Hernia

From the review of a case series of over 2500 patients with retrocolic Roux limb placement, the internal hernia site, in order of frequency, was transverse mesocolon (46 %), entero-enterostomy (41 %) followed by Petersen's space (13 %), (the area between the posterior aspect of the mesentery of the Roux limb and the transverse mesocolon). Patients usually present after approximately 14 months, by which stage they have experienced good weight loss (59 % excess body weight loss [EBWL]) [36, 38]. This may be a consequence of reduced intra-peritoneal fat secondary to overall weight loss, which can result in larger mesenteric defects [36]. Unsurprisingly, there is a higher incidence of internal herniation with a retrocolic vs. antecolic Roux limb placement (Fig. 23.9) [36]. This is relevant because an antecolic approach removes the need to create a window in the transverse mesocolon, thus eliminating this as a site for potential herniation (Fig. 23.14) [36].

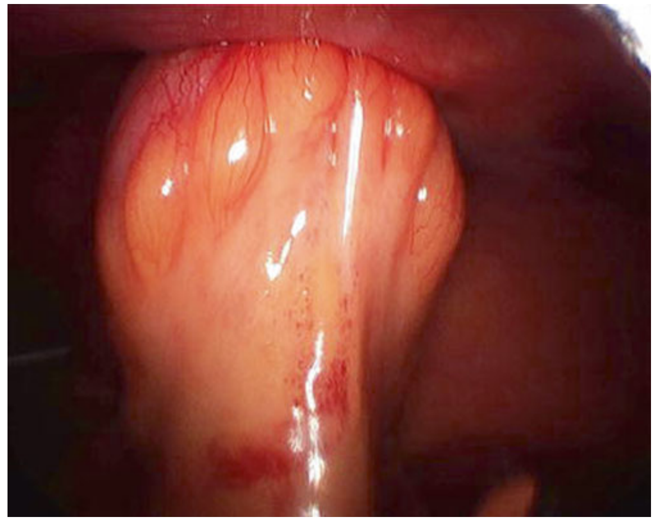


Fig. 23.18 A 5 mm port site containing small bowel (Reproduced with kind permission from Springer from: Thapar et al. [62])

The consequences of an untreated internal hernia may include closed loop obstruction, leading to bowel strangulation, as well as gastric remnant dilatation, which may go on to cause bowel perforation [37]. Patients presenting with recurrent episodes of colicky abdominal pain with or without nausea and vomiting should raise a high index of suspicion of internal hernia. The differential diagnosis would include infectious gastroenteritis, pregnancy, biliary tract disease, ulcers and appendicitis.

23.3.3.1 Management

A careful history and the usual baseline blood tests and plain AXR may be helpful in making the diagnosis but if possible a CT scan should be obtained [36]. A diagnostic laparoscopy should be performed if the diagnosis of an internal hernia is suspected, irrespective of normal investigations [36–38]. At surgery, the whole small bowel should be traced and inspected, and any mesenteric defect(s) checked and closed and any non-viable bowel segments resected [36].

23.3.3.2 Prevention

Closure of all mesenteric defects does not avoid this complication, so some bariatric surgeons leave all spaces wide open thus allowing bowel loops to freely move in and out of these

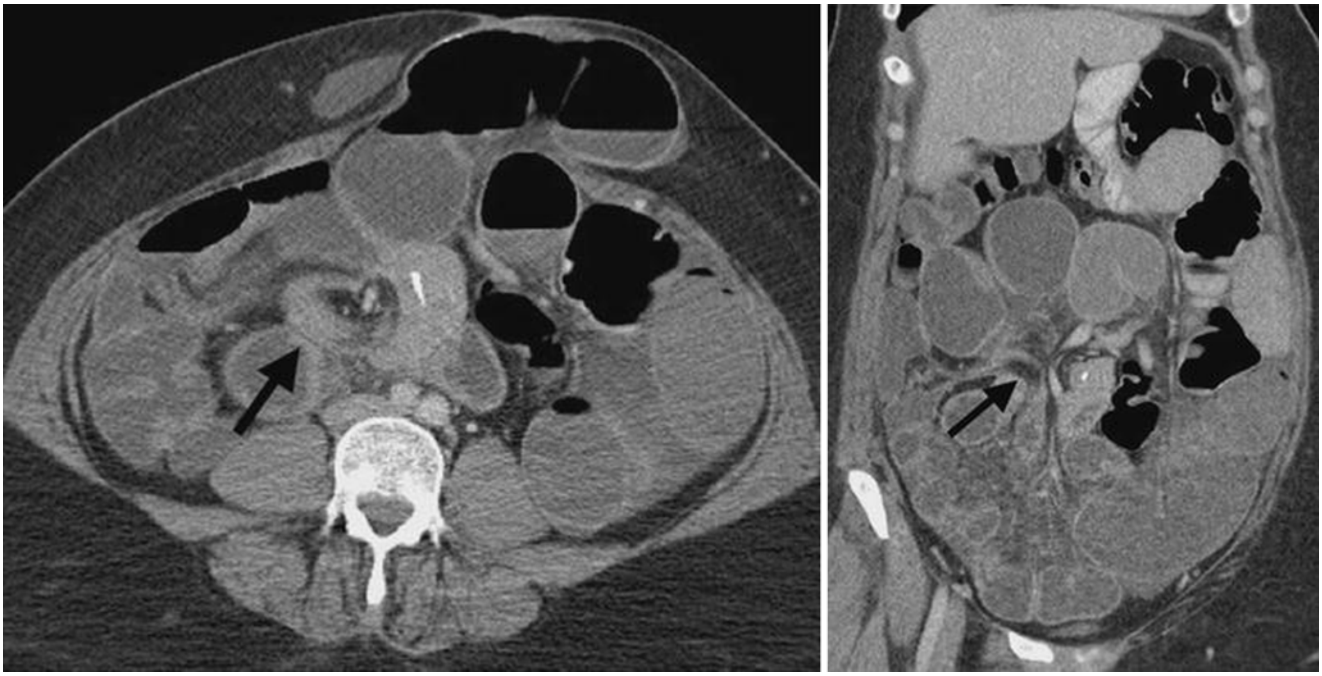


Fig. 23.19 Patient referred for a small bowel obstruction secondary to a ventral hernia. The actual obstruction is due to an internal hernia through the mesenteric defect at the jejunojejunostomy. Note the swirl (*arrow*) on the axial image and pinch (*arrow*) on the coronal image (Reproduced with kind permission from Springer from: Trenkner [56])

spaces. Others suture and close all mesenteric defects meticulously, using a running, non-absorbable suture. An antecolic Roux limb is also associated with a lower risk of internal hernias so should be the preferred approach where the surgeon has a choice [36]..

23.3.4 Port-Site Hernia

Port-site hernias tend to occur at the sites where a 10 mm port was used rather than a 5-mm port. The diagnosis should be considered in the patient who presents with focal pain near port sites, with or without colic [39]. These patients may or may not have a palpable lump. CT or laparoscopy can be helpful in making the diagnosis (Fig. 23.18) [39]. The hernia should be reduced and the defect closed. To help prevent such hernias, or Richter hernias from occurring, the use of blunt-tipped dilating trocars that separate the muscle and fascia obliquely as the device is inserted is advocated [39], and the use of sharp cutting trocars discouraged. Blunt dilating ports, in the most part, remove the need for fascia closure and additionally reduce some of the risks involved with other techniques of creating a pneumoperitoneum [39]. The use of these ports, have decreased port site hernia rate to 0.2 %, at some centers [39]. The fascia at the midline or umbilical port sites should still be closed due to the lack of musculature at this site, and if there is any difficulty then a specific laparoscopic fascia-closing device can be used [39].

23.3.5 Stricture

There is an approximate 5 % incidence of stricture at the GJ anastomosis post LRYGB. There is an observed increased risk of the incidence of stricture with the use of a circular stapler (especially with 21 mm diameter), in the presence of scarring from a healing marginal ulcer, or if there was undue tension or evidence of ischemia at the anastomosis at the index operation [40]. Patients usually present with nausea, vomiting, and dysphagia for solids progressing to liquids, within the first year after surgery. UGI studies using barium can be helpful, although the diagnosis is usually confirmed during endoscopy, particularly if a 9 mm endoscope cannot be passed through the anastomosis [11, 41]. Furthermore, the presence of a concurrent marginal ulcer can be identified during endoscopy (Figs. 23.7, 23.10, 23.11, and 23.12). The management consists of endoscopic balloon dilatation of the anastomosis, which can be stretched to approximately 15 mm without any apparent impact on weight regain, or on the development of dumping syndrome (Fig. 23.12) [41, 42]. An anastomotic stricture has an associated recurrence rate of 17 %, however there is a success rate of approximately 95 % after two separate dilatations for patients who present early (within the first 3 months post-surgery). There is also the associated risk of perforation, which may be reduced by gradual dilatation [43]. For those presenting with symptoms later than 3 months postoperatively, it may still be possible to dilate the stricture; however, up to one third may require

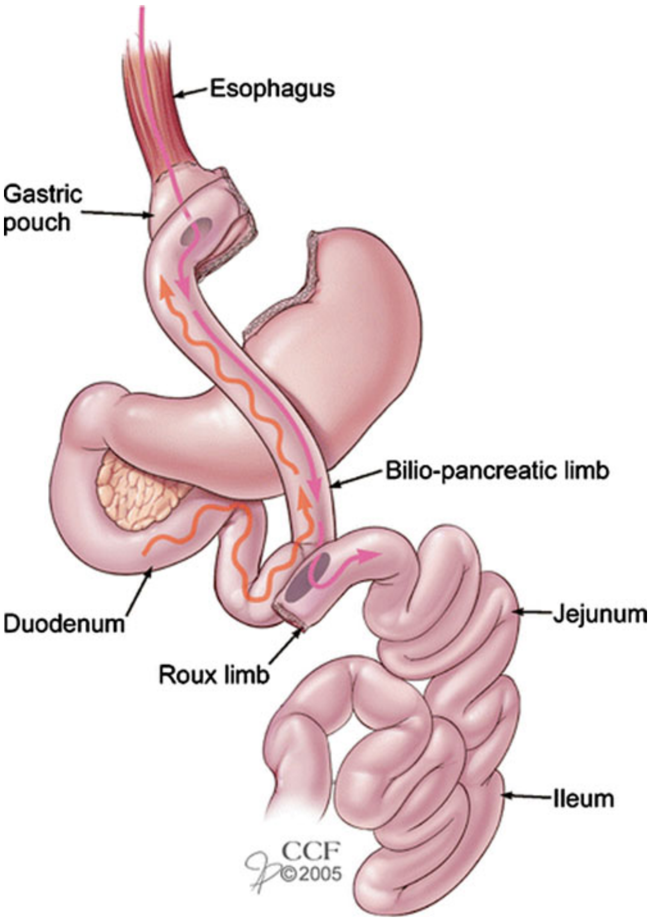


Fig. 23.20 The Roux-en-O configuration. The bilio-pancreatic limb is inadvertently anastomosed to the gastric pouch. The *wavy line* represents peristalsis and flow of bile. The *solid line* represents movement of a food bolus (Reproduced with kind permission from Springer from: Sherman et al. [63])

operative revision [44]. Surgery involves refashioning of the anastomosis. The rate of stricture can be reduced by creating a tension free, well-vascularized anastomosis, and by avoiding the use of 21 mm circular staplers for the anastomoses. Furthermore, any of the measures that prevent ulcer formation should also minimize the risk of strictures.

23.3.6 Acute Gastric Dilatation (of the Gastric Remnant)

This is unusual but can be very serious as it can lead to rapid clinical deterioration and hemodynamic instability due to blowout of the gastric remnant staple-line. It usually occurs after the biliopancreatic limb (or occasionally the common channel) has been obstructed, and can be diagnosed by evidence of gastric dilatation on a plain abdominal radiograph or CT in the postoperative patient with severe epigastric pain (Fig. 23.22). Gastric dilatation can also be caused by bleeding within the gastric remnant. Treatment is through percutaneous gastrostomy tube decompression and the subsequent management of the underlying biliary limb obstruction or bleeding point.

23.4 Long-Term Complications

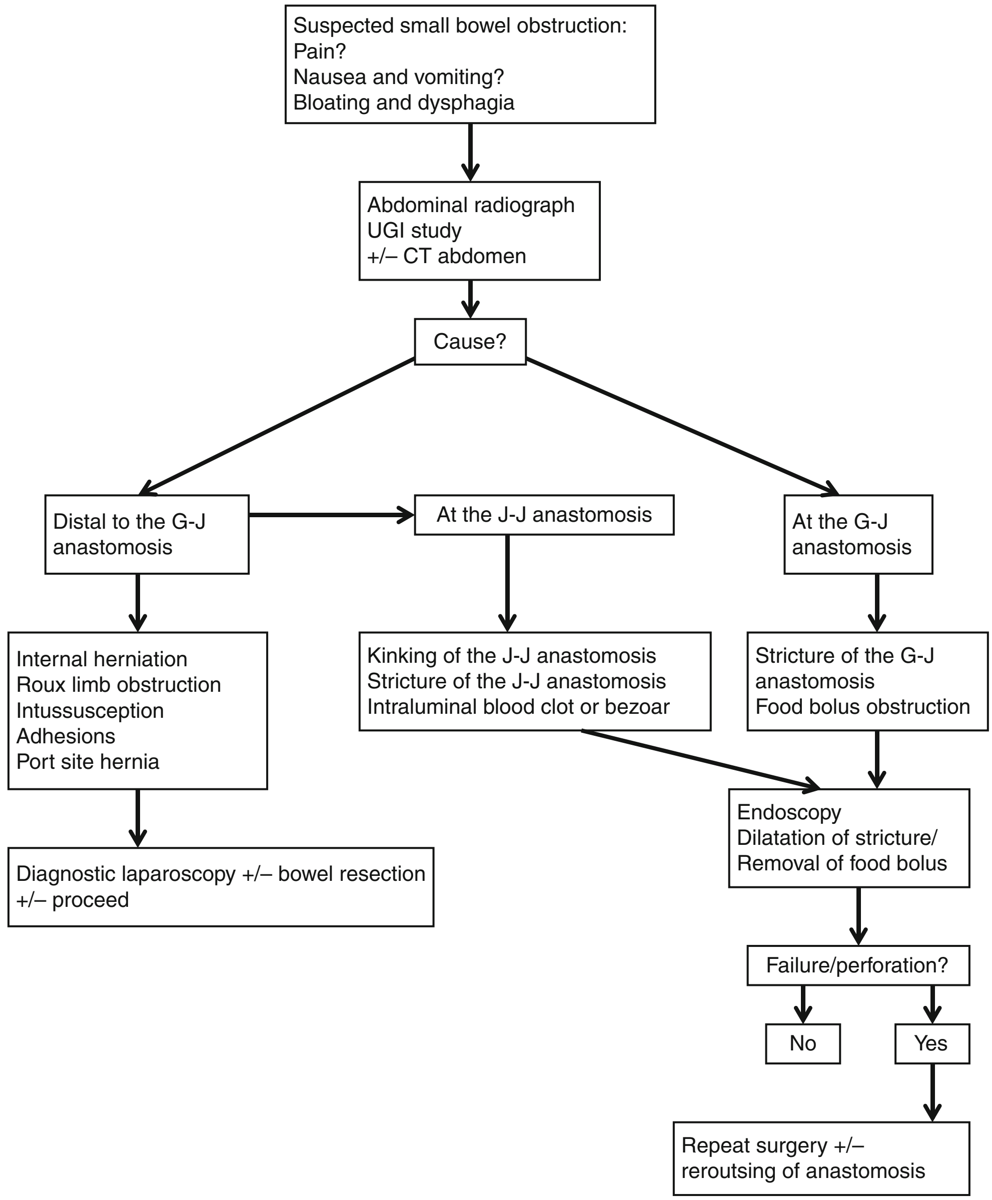
23.4.1 Intussusception

Intussusception in general is uncommon. It is usually seen in children secondary to lymphoid hyperplasia in the distal ileum, and less frequently in adults due to a pathological process that acts as a lead point, and the proximal segment invaginates into the distal one (antegrade intussusception). It can also occur after LRYGB, with a prevalence of between 0.07 and 0.6 %. Different etiologies are possible with the most common being retrograde intussusception of the common channel into the jejuno-jejunostomy. It is not understood why it occurs; it is suggested that it is possibly due to the disruption of the usual anatomy and therefore the peristalsis pathway. This causes abnormal ectopic pacemaker potentials to occur in the Roux limb, thus altering the direction of the peristaltic flow. It also tends to be more common in women, which may be due to an underlying hormonal cause. The patients can present with recurrent abdominal pain and obstruction, with or without bowel ischemia and necrosis. However, they usually present with acute abdominal pain, with approximately 70 % experiencing nausea with or without vomiting. The mean time of occurrence is 3.6 years after LRYGB (range, 5 months–24 years), after a mean weight loss of 64.1 kg. A plain AXR or CT can demonstrate signs of small bowel obstruction (dilated loops or air-fluid levels), and additionally, a target sign can be viewed on CT (Fig. 23.17). Conservative management is discouraged since it is hard to ascertain the absence of necrosis from the clinical and radiological signs alone. Laparoscopic exploration followed by surgical reduction of the invaginated segment, and if indicated, subsequent bowel resection, should be performed. A reconstruction of the J-J anastomosis, and intestinal plication might also be necessary [45].

23.4.2 Bezoars

Food bezoars occur more commonly after gastric banding, but can still occur after LRYGB, particularly as an early postoperative complication. The patients tend to present with dysphagia, nausea, and vomiting. The simplest diagnostic and therapeutic technique is endoscopy, as the bezoar can be broken up and removed, and any associated G-J anastomotic stenosis can be dilated during the same procedure.

Fig. 23.21 Diagnosis and management algorithm for small bowel obstruction post gastric bypass



23.5 Skin Complications

Postoperatively, with progressive weight loss, patients can complain of loose and hanging skin as skin may not contract with volume loss, and this cannot always be adequately resolved with non-surgical measures such as exercise, creams, lotions or diet [46, 47]. The surgical options include body contouring, where excess tissue is removed, and approximately a quarter of bariatric patients elect to undergo such surgery [46]. Some people are so affected by the impact of the excess skin that they retrospectively state that they would rather not have undergone a bypass [47]. Despite pre-operative concerns of body image, some patients felt even worse about themselves after their bariatric surgery and pre-contouring surgery [48]. This surgery is not available to everyone and requires careful planning [46]. The patients' weight is required to be stable for a minimum of 6 months, to avoid further skin laxity [46]. Most patients are suitable for a panniculectomy, as it is the panniculus that often causes the most functional disturbances. These include skin rashes, sub-pannicular itching and intertriginous dermatitis, difficulty with exercise, finding clothes that fit, and sexual dysfunction [46–48]. Other areas of skin contouring tend to be reserved for those patients who have achieved a BMI of 35 or less. It is important to warn patients that it can be difficult to secure funding for such operations, and that they are not without side effects [46]. For example, they should be aware of the significant scarring that occurs with such procedures, which can make people feel self-conscious and have reduced sensation over these scars. They might need a staged approach with multiple surgeries, and they must be diligent with their intake of multi-vitamins and proteins to maximize

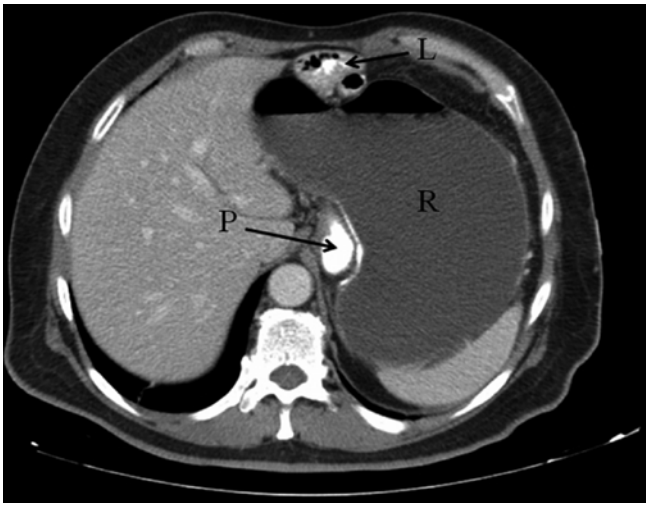


Fig. 23.22 Bypass obstruction. Note the distended, fluid-filled gastric remnant (R) surrounding the contrast-filled gastric pouch (P), and posterior to the antegastric, antecolic Roux limb (L), also filled with contrast. (Reproduced with kind permission from Springer from: Pieracci et al. [64])

wound healing [46–48]. Likewise, they should be dissuaded from smoking [46].

23.6 Nutritional, Metabolic, and Neurological complications

Within the first 12 postoperative months, almost 50 % of patients experience metabolic and nutritional deficiencies, particularly if they do not take the prescribed multivitamin daily supplements [49].

23.6.1 Post-prandial Hypoglycemia and Nesidioblastosis

LRYGB patients can present with some specific post-prandial symptoms termed as ‘dumping syndrome, which may occur in some to a variable degree and may be absent in others. Dumping syndrome is a normal and advantageous side effect of surgery with the following characteristics:(i) vasomotor symptoms of weakness, diaphoresis, dizziness and flushing in the early phase (30 min after eating), and (ii) reactive hypoglycemia and accompanying symptoms and signs later. This dumping syndrome is attributed to the rapid emptying of gastric contents into the small intestine initially causing a fluid shift due to the hyperosmolality in the intestine, and later causing hypoglycemia triggered by an insulin response, especially if after the consumption of a carbohydrate-rich meal. A small proportion of patients may suffer from exaggerated responses to meal or fluid intake. The development of documented, severe hypoglycemic episodes after a LRYGB is quite rare (<1 %). Similarly, the development of autonomic instability after a meal is even rarer (Potts Syndrome). Such patients can present with postprandial symptoms after achieving satisfactory weight loss. The management of these patients can be challenging and should be addressed using a multi-disciplinary team approach. Early involvement of endocrine specialists is recommended. In the first instance, it is necessary to exclude patients with insulinoma or nesidioblastosis [50]. Investigations include an oral glucose tolerance test as well as continuous glucose monitoring. Occasionally, if any autonomic dysfunction is suspected, then table tilt testing may aid diagnosis [50].

Non-operative management, with dietary therapy such as the avoidance of high-glucose dense foods, and pharmacologic therapy (e.g., diazoxide, calcium channel blockers, acarbose, octreotide) should be administered in the first instance. Nevertheless, some patients do not respond to these non-operative approaches, and the neuroglycopenic symptoms persist, thereby, exposing them to a dangerous and even potentially life-threatening risk. A temporary solution involves the placement of a gastrostomy tube, and feeding via this route almost always relieves symptoms. Overall, subsequent definitive surgical correction is usually necessary, and occasionally even involves the reversal of the bypass [50].

23.6.2 Protein Malnutrition

Total body protein is monitored by checking patients’ albumin levels, and deficiency after a standard LRYGB is extremely rare. It may result from a short common channel leading to malabsorption, or from an extreme restriction due to pouch outlet obstruction. Protein supplements and oral pancreatic enzymes can improve absorption when the deficiency is mild. Sometimes, after a period of prolonged starvation, an acute hypophosphatemia with cardiac failure can occur approximately 72 h after feeding is restarted (refeeding syndrome). Thiamine administration prevents this syndrome, and hence, it must always be considered after surgery when reinstating nutrition in a patient who has previously been chronically under-nourished [51]. The treatment for protein malnutrition depends on the underlying cause.

23.6.3 Vitamins and Trace Elements

Patients may experience iron deficiency after an LRYGB; the estimated prevalence is 30–40 %. However, 20 % of the obese patients may have pre-existing iron deficiency prior to surgery. It occurs due to multiple reasons, and should be investigated with an EGD or colonoscopy, as appropriate. It is advisable for patients to take regular iron replacement, with vitamin C, which aids absorption. Calcium supplements are suggested, particularly in post-menopausal women. Although there is no obvious evidence that there is a benefit of zinc supplementation, zinc levels are commonly low in post bypass patients and supplementation can be recommended in those patients who suffer from hair loss, weak nails or wounds.

Vitamin B12 deficiency may take years to manifest, due to its long half-life and entero-hepatic circulation [49]. Rarely, thiamine related polyneuropathy, and occasional encephalopathy can occur. This presents at 6–12 weeks after surgery, following persistent nausea and vomiting, with severe weakness of the lower limbs [51]. In the outpatient clinic, patients should be monitored annually with certain blood tests that should include micronutrient levels (vitamin B6, vitamin B12, thiamine, vitamin D, vitamin E, folate, calcium, magnesium, phosphorus, selenium and copper) [49]. It should be ensured that the patient is well-educated about the benefits of micronutrient replacement through the use of a daily broad spectrum multivitamin and mineral supplement, and maintaining a high protein diet [49, 51].

23.7 Neurologic and Musculoskeletal Complications

Neurologic complications include compression mononeuropathies from poor positioning on the operating table and neurologic damage from micronutrient depletion as mentioned above [49]. Symptoms may include anesthesia, tingling paresthesia, severe pain, and can particularly affect the feet causing a burning sensation [49]. Signs may include tenderness on palpation of muscles, hyporeflexia, sensory impairment involving pain and light touch in a glove-and-stocking distribution, distal vibratory and proprioception loss, and foot drop [49].

Early or immediate musculoskeletal complications include rhabdomyolysis or myonecrosis [49]. This is more common in the super-obese due to the increased risk of compression, but should be considered if there are any signs of impaired renal function, as there is a significant associated morbidity. Blood should be checked for creatinine kinase levels. The prevention of compression injuries and rhabdomyolysis is aided by the careful positioning of the patient on the operating table and through the avoidance of a prolonged operating time [49].

23.8 Cholelithiasis

Morbid obesity and rapid weight loss are both risk factors for gallstone formation, and there is an approximate 7 % risk of cholelithiasis in patients who undergo LRYGB [52]. For simple gallstones, a laparoscopic cholecystectomy can be performed [52]. However, common bile duct stones are more difficult to treat using the conventional endoscopic retrograde cholangiopancreatography (ERCP). Given the surgical alteration in the anatomy after a LRYGB, there is no longer direct access to the duodenum, and different techniques have been devised to address this issue. One technique is the combination of laparoscopy and ERCP. A gastrostomy is performed in the remnant stomach after inserting a laparoscope. The endoscope can then be passed via a laparoscopic port through the gastrostomy and into the stomach and duodenum and the bile ducts accessed in the conventional manner [53].

23.9 Hockey Stick/Blind Limb/Candy Cane Syndrome and Other Causes of Postprandial Pain

A long, non-functional Roux limb tip, or "hockey stick" may cause persistent nausea, and postprandial epigastric pain. This may be relieved after vomiting an unexpectedly large volume of food. The patients may also complain of a lack of satiety and even weight gain, and their symptoms tend to get worse with time. The differential diagnoses for these symptoms include transient food intolerance, over-eating, marginal ulceration and G-J strictures. Investigations include an UGI study and endoscopy, and the management involves re-operation and removal of the excess tip [54]. A summary of the other causes are listed in Table 23.6 [55].

Table 23.6 Causes of abdominal pain after gastric bypass

Pouch, remnant stomach disorders	Small-intestine disorders	Behavioral, dietary disorders	Functional disorders	Biliary disorders	Other
Ulcer disease	Abdominal wall hernias: ventral, trocars	Overeating, rapid eating	Constipation, diarrhea, flatus	Cholelithiasis: colic, cholecystitis	Omental infarction
Gastrogastric fistula	Adhesions	Food intolerance	Irritable bowel syndrome	Choledocholithiasis: cholangitis, pancreatitis	SMA syndrome
GERD	Internal hernia	Micronutrient deficiencies	Esophageal motility syndrome	Sphincter of Oddi dysfunction	Bezoar
Hiatus hernia, gastrojejunostomy stenosis	Intussusception, jejunojejunostomy stenosis	Micronutrient supplementation	Dumping syndrome		

Modified from Greenstein and O'Rourke [55]
SMA superior mesenteric artery syndrome

Conclusion

Although the LRYGB has become increasingly common as a procedure, it can have numerous medical and surgical complications, both in the immediate and longer postoperative period. It is, therefore, prudent to have a high-level suspicion of the worst-case scenario for these patients, in order to maximize the detection of complications, and to give the patient a chance of the best possible outcome.

Key Learning Points

- Patients undergoing bariatric surgery often present with subtle signs when there is a serious complication; hence it is best to avoid any delay, and in case of any doubt, perform a re-laparoscopy (Table 23.7)
- A routine postoperative UGI study is not recommended, but may be helpful for specific situations when there is clinical suspicion of a complication
- Hemostatic, well-vascularized, tension free, antecolic, correctly orientated anastomoses and staple lines help prevent leaks, ulceration, fistulas and bleeding
- The patients should regularly consume multivitamins especially Vitamin B12 or thiamine and also a PPI, calcium supplement, along with a high protein diet

Table 23.7 Summary of important surgically reversible complications

	Signs/symptoms	Differential characteristics	Investigations/actions
Early complications	Persistent tachycardia (>120 beats/min) Supportive features: Fever, tachypnea, raised CRP or WCC, drop in Hb	Anastomotic or staple line leak Significant bleeding	Diagnostic laparoscopy/laparotomy ?EGD + diagnostic laparoscopy/laparotomy CT angiogram may be considered in stable patients for diagnosis of bleeding
	Bilious vomiting	Roux-en-O configuration Obstruction distal to JJ anastomosis	CT scan with oral contrast, diagnostic laparoscopy and revision
	Abdominal pain and vomiting, sense of impending doom	?Internal hernia/small bowel obstruction	Small bowel follow through, diagnostic laparoscopy
Late	Colicky abdominal pain after meals Excessive weight loss	?Internal hernia/	EGD, CT scan +/– diagnostic laparoscopy
	Profound weight loss and vomiting, colicky pain	?anastomotic stricture at GJ or JJ	EGD +/– dilatation, small bowel follow through studies, ?diagnostic laparoscopy

CRP C-reactive protein, *CT* computed tomography, *GJ* gastrojejunostomy, *Hb* hemoglobin, *JJ* jejuno-jejunal, *EGD* esophago-gastro duodenoscopy, *WCC* white cell count

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LRYGB: Outcomes

24

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Abstract

Roux-en-Y Gastric Bypass (RYGB) is the most commonly performed bariatric procedure worldwide. This chapter discusses the outcomes from RYGB for weight loss and co-morbidity resolution and compares them to those from other procedures. The early and late morbidity and mortality associated with RYGB is compared to other procedures and the argument is made as to why many believe RYGB to be the "gold standard" bariatric procedure.

Keywords

Roux-en-Y gastric bypass • Weight loss • Diabetes • Mortality • Morbidity • Marginal ulcers

24.1 Introduction

Roux-en-Y Gastric Bypass (RYGB) has become the gold standard bariatric operation performed worldwide, accounting for nearly half of all procedures (Table 24.1) [1]. This popularity is because RYGB has consistently achieved effective weight loss and comorbidity resolution with acceptable complications and mortality rates. The first report of the National Bariatric Surgery Registry (NBSR) demonstrated this popularity reporting that 3817 from a total of 7045 (54.7 %) procedures were RYGB [2]. The journey from Mason's open loop bypass to the many different techniques of laparoscopic RYGB in use today has been associated with gradual improvement in safety and efficacy of this procedure. This evolution is continuing as variations such as the "banded bypass" and "mini bypass" have become more widely performed.

Defining success after a bariatric operation is not straightforward. An ideal bariatric procedure must achieve durable weight loss and co-morbidity resolution with low rates of complications and mortality. Although excess weight loss is the widely used measure to compare outcomes between different procedures, it is not ideal. Success or failure after bariatric surgery requires consideration of a number of variables including weight loss, effect on co-morbidities and impact on quality of life and complication rates. The following discussion will demonstrate the benefits of RYGB and why many believe it to be the ideal bariatric procedure.

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24.2 Adverse Outcomes

24.2.1 Early (<30 Day) Mortality and Morbidity

An early mortality rate of 0.2 % is widely accepted for Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) [3, 4]. Flum presented a comparison of adverse outcomes comparing Laparoscopic adjustable gastric banding (LAGB) to LRYGB and open RYGB [4]. Death rates of 0.2 % were noted for LRYGB compared to 0 % with LAGB and 2.1 % with open RYGB. Thromboembolic events were noted in 0.4 % for LRYGB, 0.3 % for LAGB and 1.1 % for open RYGB. Likewise reoperation was required within 30 days for 3.2 % LRYGB, 0.8 % for LAGB and 3.4 % for open RYGB. This was also reflected in the failure to be discharged by 30 days postoperatively which was 0.4 % for LRGB, 0 %

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Table 24.1 Percentage distribution of metabolic bariatric procedures worldwide

Procedure	Number	Percentage
Roux-en-Y gastric bypass	158,729	46.6
Sleeve gastrectomy	94,689	27.8
Adjustable gastric band	60,677	17.8
Biliopancreatic diversion/ duodenal switch	7,595	2.2
Mini gastric bypass	5,250	1.5
Vertical banded gastroplasty	2,297	0.7
Electric pacers	34	0.01
Others and revisions	11,497	3.4
Total procedures	340,768	

Buchwald and Oien [1]

for LAGB and 0.9 % for open RYGB. Whilst LAGB may appear to have a better safety profile this is offset by less weight loss, co-morbidity resolution and band related complications and failure. High volume centers have shown that complication rates from RYGB can be reduced further through standardized operative approaches and prompt management of complications. In a series of 2606 RYGB, Dillemans reported 5.8 % early complication rate, including gastrointestinal hemorrhage in 3.4 % patients, intestinal obstruction in 0.35 %, and anastomotic leak in 0.19 % [5]. There was one death from pneumonia. High body mass index (BMI) and age, male sex, hypertension, and factors predisposing to DVT/PE are recognized as risk factors for adverse events [6].

Postoperative hemorrhage is a common early complication with varying incidence in the literature. Staple lines, surgical anastomoses, retrogastric/short gastric vessels and port sites are all possible sources. Anastomotic leak has been reported to occur between 0.1 and 5.3 % and is dependent on surgical expertise and on the technique chosen for the anastomosis [7].

24.2.2 Late (>30 Day) Mortality and Morbidity

RYGB is associated with a number of late complications, which, if not managed appropriately, can result in significant morbidity and even mortality. With increasing follow up data now available readmission rates of 0.6–6.6 % have been reported [8]. Three main areas of concern persist resulting in the need for further intervention and occasionally emergency surgery, namely marginal ulceration, stomal stenosis and internal herniation. Gallstones and nutritional deficiencies are also longer-term issues that require consideration. Further details on the management of these complications are covered elsewhere in this book.

24.3 Therapeutic Outcomes

24.3.1 Weight Loss

The most compelling data supporting RYGB came from Buchwald's meta-analysis published in 2004 in which RYGB was the most commonly performed procedure and resulted in 62 % excess weight loss and a 30-day mortality rate of 0.5 % [3]. This compared favorably to other procedures, providing marginally less weight loss than the duodenal switch but at less than half the mortality rate (1.1 %). Alternative procedures suffer with adverse safety record (example, duodenal switch, biliopancreatic diversion), lack of long-term data (example, gastric band, sleeve gastrectomy and mini-bypass), poorer weight loss and co-morbidity resolution (example, gastric band, sleeve gastrectomy) or "controversy" amongst surgeons regarding bile reflux and potential risk of malignancy (mini-bypass).

24.3.1.1 Comparison with Other Procedures

It is worth noting that although many authors have reported sustained weight loss with LAGB, long-term complication rates with LAGB are high, requiring conversion to RYGB [9, 10]. The longest running randomized controlled trial comparing RYGB and LAGB presented 10 year follow up data recently showing superior excess weight loss with RYGB compared to LAGB (76.2 % vs. 46.2 %) [11].

Since 2004 laparoscopic sleeve gastrectomy (LSG) has become increasingly popular and the subject of several recent trials which have reached conflicting results [12, 13]. The largest comparison of these procedures showed that weight loss at 1, 2 and 3 years were not significantly different although a trend towards superior weight loss with RYGB was suggested (Fig. 24.1) [14]. Quality adjusted life year (QALY) scores between the procedures were not significantly different nor was the rate of nutritional deficiencies. Troublesome de novo reflux symptoms often occur following sleeve gastrectomy necessitating conversion to RYGB and many authors regard pre-existing reflux disease to be a contra-indication to sleeve gastrectomy or an indication for RYGB [14–16]. Long-term data from randomized trials comparing RYGB and laparoscopic sleeve gastrectomy (LSG) is not available.

Mini gastric bypass (MGB) is an increasingly popular procedure involving a single anastomosis loop jejunostomy instead of the Roux-en-Y reconstruction. The only randomized clinical trial comparing MGB and RYGB showed slightly superior weight loss results with MGB but no difference in comorbidity resolution [17]. However, experience with MGB is limited and more long-term experience is needed before it can challenge the current status of RYGB. A recent systematic review of MGB showed it to be

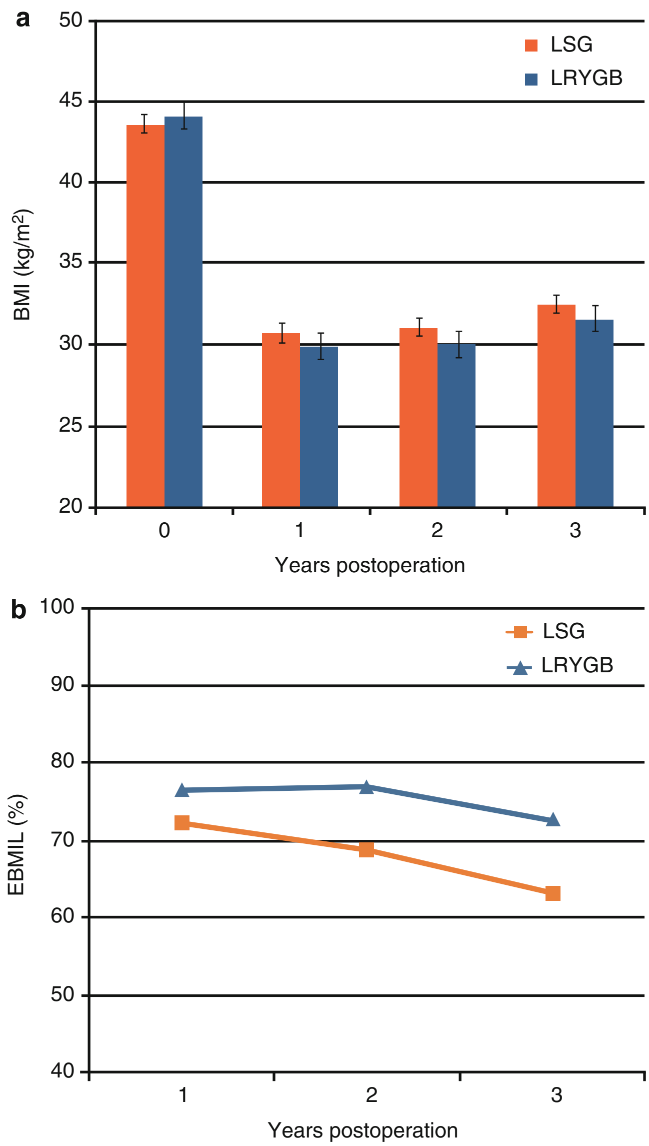


Fig. 24.1 Results of RCT comparing LRYGB and LSG. (**a**) Change in BMI. (**b**) Excess BMI loss [14]

an equally safe alternative with comparable short term results [18].

The first report of NBSR suggests that for patients with co-morbidities, RYGB is the procedure of choice within the UK [2]. Although the registry is unable to determine why the authors hypothesize that this is reflection of the belief that RYGB will produce quicker and more effective improvements in co-morbidities.

24.3.1.2 Weight Loss Outcomes with RYGB

RYGB results in significant early weight loss, which is maintained in the longer term. Most patients can expect to lose more than 50 % of their excess weight and an average excess weight loss of more than 70 % can be expected in the first 12 months after surgery. The Swedish Obese Subjects (SOS) Study [19]. provides the longest matched prospective follow up data comparing surgical intervention against non surgical management and shows open RYGB to be superior to vertical banded gastroplasty surgery (VBG) and LAGB throughout the study period in terms of weight loss (Fig. 24.2). Weight loss with RYGB was maximal at 2 years at 32 % before decreasing slightly to 25 % at 10 years and maintaining this up to 20 years post op [19]. This modest weight regain is not unique to RYGB.

These results have been replicated in the UK. The first report of the NBSR reported excess weight loss of 67.8 % for RYGB compared to 43.2 % for gastric banding and 54 % for sleeve gastrectomy.

The addition of banding the bypass has been shown to improve early weight loss compared to the traditional bypass. However longer-term studies looking at the safety and effectiveness on banding the bypass are awaited and there appears to be a risk of band related complications [20, 21]. Trials comparing different lengths of gastric bypass have not shown significant differences in weight loss outcomes [22].

Despite excellent weight loss figures reported in Buchwald's meta-analysis, there are still a percentage of patients who fail to lose 50 % excess weight loss or reach a BMI of less than 35 kg/m^2. This figure for failed bypass is between 5 and 40 % [23–25]. For the super obese acceptable weight loss may be achieved with a final BMI remaining in excess of 35 kg/m^2.

24.3.2 Effect on Comorbidity

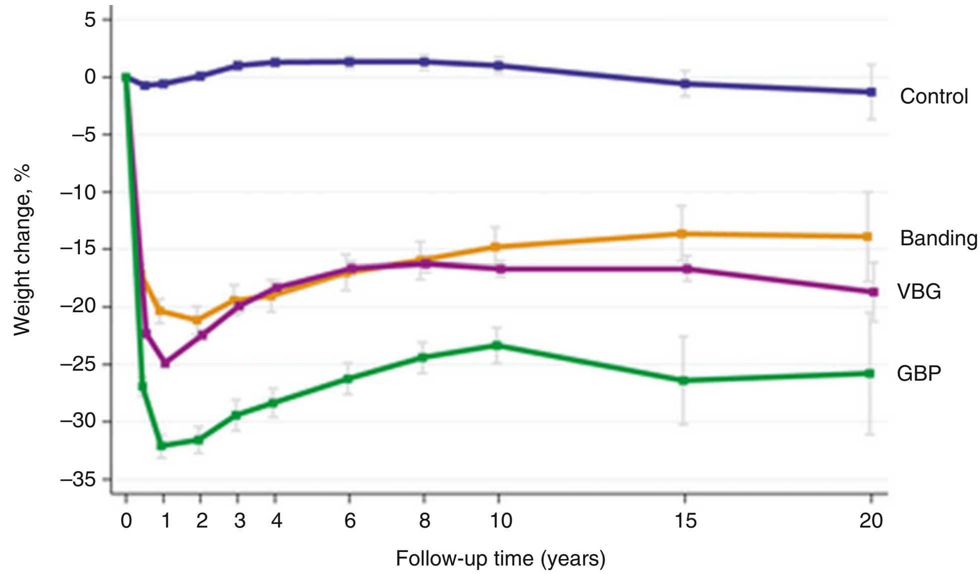
Improvements in obesity-related co-morbidities tend to be in proportion to weight loss. For example in Buchwald's review resolution of hypertension was 43.2 % after LAGB, 69.0 % after VBG, 67.5 % after RYGB and 83.4 % after BPD and DS. The postoperative decrease in hyperlipidemia and sleep apnea syndrome follows a similar trend.

Furthermore a recently published systematic review comparing LSG and RYGB has shown that RYGB is significantly better at resolving type 2 diabetes, hypertension, hypercholesterolemia, and arthritis [26]. The NBSR 1st report provides an insight into the resolution of co-morbidities over a 12 month period following RYGB. In summary, sleep apnea rates fell by 63 %, dyslipidemia rates by 61 %, the proportion of patients able to climb three flights of stairs increased from 26.9 to 70.4 % whilst type 2 diabetes and gastro esophageal reflux disease (GERD) fell by 56 %.

24.3.2.1 Sleep Apnea/ Respiratory Problems

Sleep apnea remains a recognized risk factor for complications following bariatric surgery. A recent randomized trial

Fig. 24.2 Long term weight loss from the Swedish Obesity Study [19]



No. examined

Control	2037	1490	1242	1267	556	176
Banding	376	333	284	284	150	50
VBG	1369	1086	987	1007	489	82
GBP	265	209	184	180	37	13

has demonstrated the effect RYGB has on obstructive sleep apnea [27]. Compared against intensive lifestyle intervention, RYGB patients had a 66 % remission rate while the control group had 40 % remission rate. On further analysis, these benefits were directly attributable to weight loss alone. A further systematic review has, however, suggested that despite significant improvements in the apnea hypopnea index induced with surgery, there will still be a need for many patients to continue treatment to minimize its long term complications [28].

24.3.2.2 Type 2 Diabetes Mellitus

Within Buchwald's meta-analysis, diabetes remission occurred in 80 % of RYGB patients compared to 57 % after banding, but was less than for duodenal switch (DS) (95 %). (LSG was not included in the analysis) [3]. Given that the meta-analysis clearly shows that the benefits of RYGB in terms of weight loss and diabetes remission are greater than all other procedures except DS it is worth considering why DS is not so widely accepted

In 2012, Mingrove presented the results of a randomized controlled trial (RCT) comparing the effects of bariatric surgery on 60 diabetic patients [29]. At 2 years, diabetes remission had occurred in no patient in the medical group, 75 % in the RYGB group and 95 % in bilio-pancreatic diversion group. A similar effect was seen for improvements in lipid profile and hypertension with BPD showing better results than RYGB. Weight loss from the two groups was however not significantly different. Even in this small group of patients the intestinal malabsorption after bilio-pancreatic was noted in 10 % of patients compared to none in the RYGB group. These findings were confirmed in another RCT comparing bypass against DS in which 60 patients with a BMI >50 were randomized to RYGB or DS. Whilst QALY and cardiovascular risk improved equally with both procedures the rate of adverse events was nearly double for DS (62 %). Adverse nutritional events only occurred after duodenal switch.

Diabetes is perhaps the most important comorbidity associated with obesity and Buchwald's meta-analysis showed RYGB to be the most effective procedure after DS. However given that early weight loss is comparable between RYGB and LSG, it is important to note that RYGB is more effective in inducing diabetes remission than LSG and other purely restrictive procedures, an effect thought to be related to duodenal exclusion. Lee et al. conducted a randomized controlled trial comparing diabetes resolution in diabetic patients with BMI of 25–35 kg/m^2, showing that RYGB was associated with significantly better diabetes remission at 12 months after the surgery when compared to LSG (93 % vs. 43 %) [30]. This effect was also noted in obese patients with BMI >35 kg/m^2 [31]. More recently, the Stampede Trial reported 3 year results comparing RYGB to LSG and medical treatment for poorly controlled type 2 diabetes [32]. They found that an HBA_{1c} level of less than 6.0 % was achieved in 5 % of medical patients, compared with 37 % of RYGB and 24.5 % LSG, with less use of glucose lowering medication in the surgical patients.

RYGB appears therefore to have an additional effect on diabetes remission that is superior to restrictive procedures alone and given this success, it has now been incorporated into management guidelines for patients with class 1 obesity if their type 2 diabetes mellitus is proving difficult to manage.

24.3.2.3 Cardiovascular Risk Factors

The Diabetes Surgery Randomized Control Trial demonstrated the added effects of RYGB over lifestyle and medical management in patients with a BMI 30–39.9. With surgery, 49 % of patients achieved the composite endpoint of HBA_{1c} less than 7 %, low density lipoprotein cholesterol less than 100 mg/dL and systolic blood pressure less than 130 mmHg compared to 19 % in the control arm [33] This was achieved with three fewer medications.

The 6-year follow up data of Adams comparison of outcomes from RYGB and non surgical management paper showed sustained improvements following RYGB in major cardiovascular and metabolic risk factors including diabetes remission, reduced incidence of dyslipidemia and hypertension while there was worsening of these parameters in the control (nonsurgical) group [34]. This study showed a diabetes remission rate of 62 % at 6 years showing the effects noted by many at 2 years persist. Sustained increases in HDL-C (and hence reduction of cardiovascular risk) were also noted. In a previous publication, Adams had already noted that RYGB leads to a 40 % reduction in all cause mortality compared with non-surgical management, a result replicated elsewhere [34–37]. Improvements in cardiovascular risk profile and type 2 diabetes, and increased physical mobility are likely to account for most of the beneficial effects seen.

24.3.2.4 Polycystic Ovarian Syndrome

Polycystic ovarian syndrome (PCOS) is relatively common (5.5 %) in obese females. Nevertheless, RYGB has been shown to achieve excellent amelioration of PCOS manifestations and improvement in fertility rates in up to 100 % of patients desiring pregnancy after surgery [38].

24.3.2.5 Non-alcoholic Fatty Liver Disease (NAFLD)

Chronic liver disease caused by obesity is becoming increasingly common. For NAFLD patients, RYGB has been shown to reduce the grade of steatosis, hepatic inflammation, and fibrosis in majority of patients [39]. With up to 74 % of obese patients suffering with NAFLD, this is an important disease process in which the exact role of bariatric surgery is not fully elucidated. NAFLD alone is not currently an indication for RYGB.

24.3.3 RYGB and Reduced Mortality

Despite significant improvements in obesity associated comorbidities that have shown to persist over longer-term follow-up, this has not been shown to reduce mortality rates until over 10 years postoperatively. In Swedish Obese Subjects trial the mortality benefits of weight loss surgery with different procedures did not become apparent till 13 years after the surgery [19]. This was also noted in the high risk patient study in the Veterans Affairs study [40]. Conclusive data showing long-term mortality benefits between procedures are not available and is unlikely to be significant until many years after the surgery. At the same time, it is worth noting that mortality due to accidents and addictions may increase. There is also long-term mortality related to RYGB specific surgical complications such as internal hernia, marginal ulcer and gastro-gastric fistula.

24.3.4 Quality of Life

The Swedish Obese Subjects trial provides long term evidence of improvements in Health Related Quality of Life (HRQoL) [19]. At baseline, the patients in the surgery group had generally worse HRQoL than those in the non-surgical treatment group. At 2 years follow up, surgical patients had significant improvements in all HRQoL measures compared to patients receiving non-surgical treatment. These changes were significantly related to the magnitude of the weight lost which was greatest with RYGB. The improvements peaked one year after surgery followed by a gradual decline till the sixth year after surgery, remaining stable till 10 years after surgery. All HRQoL measures were improved at 10 years compared with baseline for the surgery group, but in the non-surgical group some had improved while others had worsened. Other studies have shown that over longer term follow up, general health perceptions and vitality are the most likely to be improved after RYGB [41].

24.3.5 Effect on Cancer Risk

Whilst cardiovascular risk reduction is an important outcome from bariatric surgery, SOS study noted that that more patients died from cancer than myocardial infarction (76 versus 38) during the study period [42]. This trial also demonstrated that weight loss reduced the risk of cancer, particularly female cancers (Fig. 24.3). This risk reduction is not exclusive to RYGB although this procedure resulted in the most sustained weight loss.

24.4 Cost-Effectiveness

Cost-effectiveness of any intervention is a significant factor in any healthcare system and few operations can truly be regarded as cost saving. There are significant upfront costs with RYGB but it is widely acknowledged that this cost is recovered after surgery through reduced expenditure on

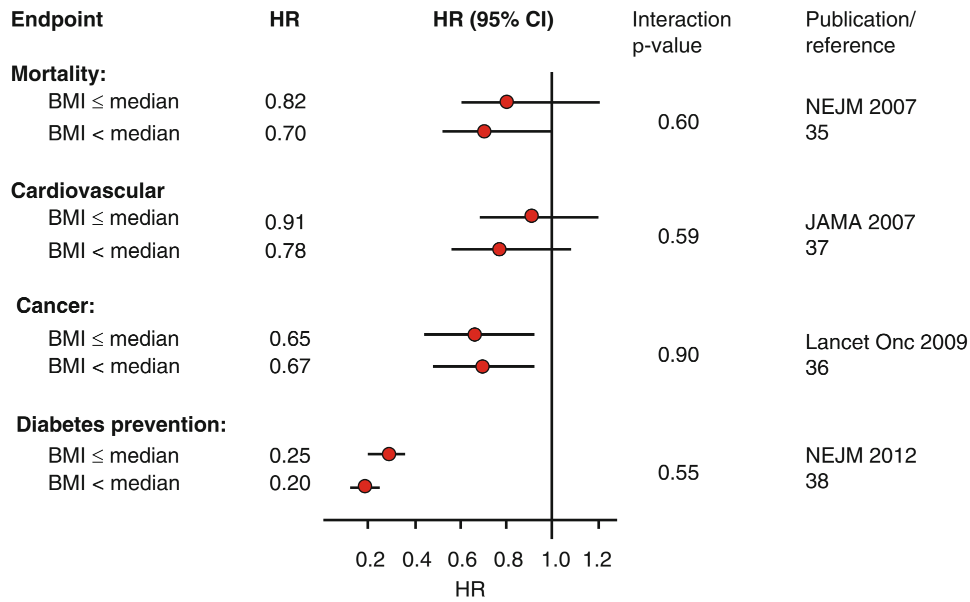


Fig. 24.3 Surgical treatment effects (Hazard ratio) on indicated endpoints in subgroups below and above the median BMI at baseline as well as BMI–treatment (surgery vs. control) interactions (interaction P-value) for each endpoint. The treatment effect was not significantly related to BMI (interaction P-value nonsignificant) for any of the analyzed endpoints [19]

healthcare and gains in economic productivity of individuals. The time taken to achieve this is perhaps longer than initially predicted [43, 44] With gradual improvements in availability and safety profile of surgery, cost effectiveness is likely to further improve. Cost benefits are also probably highest in those with most severe forms of obesity and this has led many funding bodies to prioritize bariatric surgery for these individuals.

24.5 Revision and Reversal

Not all patients will achieve satisfactory weight loss with any bariatric procedure and some may gain weight in the long term. Moreover, some patients need complete reversal of their procedure for one reason or the other. RYGB is no exception in this regard. Revision of RYGB to add a longer bypass limb to promote weight loss has been described and associated with increased risk of nutritional deficiencies [45] Surgeons have also tried to add an adjustable band to a failed RYGB with variable success [46]. How to manage poor weight loss following RYGB remains a controversial issue which lacks a commonly accepted solution; which is perhaps testament to the accepted reliability of good outcomes following RYGB as first line treatment.

24.6 Summary

RYGB has been the subject of multiple studies from which long-term outcome data is now becoming available. With the exception of malabsorptive procedures, which are less commonly performed due to high rates of nutritional deficiencies, RYGB provides superior weight loss to gastric banding and similar weight loss to LSG. However RYGB is the preferred procedure for patients with GERD and diabetes as both of these improve the most with RYGB. Modifications to RYGB by banding the bypass may further improve weight loss at the expense of band related complications, whilst the mini bypass may eliminate internal herniation and shorten operative time but at the expense of bile reflux with uncertain long-term implications. Long-term studies of LRYGB have identified that marginal ulceration and internal herniation affect a small minority of patients in the long term although these remain the Achilles heel of RYGB. Nevertheless, the low complication rate, excellent weight loss and co-morbidity resolution mean RYGB remains the gold standard bariatric procedure for most patients. For the super morbidly obese undergoing RYGB 60 % excess weight loss may still leave the patient with a BMI of over 35. Long-term trial data comparing RYGB with a staged LSG+/−DS in these patients has not been performed.

Key Learning Points

- RYGB remains the most commonly performed bariatric procedure worldwide.
- RYGB is the procedure of choice for patients with pre-existing reflux disease.
- Weight loss, comorbidity resolution and improvements in mortality have now been published in long term follow up studies after RYGB.
- Modifications of RYGB with banding or the mini bypass are becoming increasingly popular.
- Revision of the RYGB for poor weight loss remains a challenging area with no consensus regarding the optimal approach.

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LRYGB: Current Controversies

25

Kelvin D. Higa and Amit K. Taggar

Abstract

The laparoscopic gastric bypass technique, invented 20 years ago, is currently the benchmark for all other operations. It has the advantages of long-term success and direct metabolic activity, but it is one of the most difficult operations to master. Consensus on the optimal anatomic construct remains elusive; many controversies exist regarding the achievement of optimal results.

Keywords

Laparoscopic gastric bypass • Controversies • Internal hernia • RYGB • Complications

25.1 Introduction

The year 2013 marks the 20th anniversary of the first laparoscopic gastric bypass performed by Drs Wittgrove and Clark in San Diego, California [1]. This remarkable accomplishment was not a random act of genius as many assume, rather the result of careful planning and novel utilization of existing technologies and techniques without the need for creation of new instrumentation. The procedure did not violate contemporary principles of sound surgical technique or anatomic construction. This was in contrast to many other innovative procedures that usually compromise on safety, efficiency or efficacy in the hope that the potential benefits of less invasiveness and patient acceptance would offset the other shortcomings. This operation is currently performed exactly as it was designed 20 years ago. It remains a testimony of the pioneering vision of those who invented it and is exemplified in the message of Dr. Carlos Pelligrini in his Presidential Address at the American College of Surgeons Convocation Ceremony in 2013, "The Surgeon of the Future: Anchoring Innovation and Science with Moral Values." [2]

Ironically, the long learning curve and transient increase in complications did not deter the patients from undergoing this operation nor the surgeons from adopting this technique. The increase in volume brought along new insights into the pathophysiology of the procedure, as many of our non-surgical colleagues gained interest in the metabolic aspects of the operation [3]. The success of the laparoscopic gastric bypass heralded a paradigm shift in the minimal approach to complex gastrointestinal problems and a new generation of minimally invasive surgeons was born.

Long-term issues such as nutritional deficiencies, weight recidivism, or inadequate weight loss led many surgeons to ponder not only how to perform a safe gastric bypass, but also how to optimize long-term weight and metabolic results. Prior to the discovery of gut hormone alteration by the procedure, most investigators concentrated on the anatomic construct rather than the biological implications of the procedure. For example, a modification of the now defunct vertical-banded gastroplasty was in the use of prosthetic material to permanently prevent the gastric pouch from dilating [4]. Superior weight loss and weight maintenance have been observed with the banded gastric bypass without an increase in early or late complications [5].

The laparoscopic gastric bypass has undergone subtle changes over the last couple of decades, but these changes were not because of randomized, prospective, double-blinded

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studies. The procedure has been refined through the observations made by numerous surgeons, who diligently compared their results not only with published series, but also by mutual collaboration. This is quite understandable as it would be impossible to analyze the data of a heterogeneous patient population with multitudes of confounding variables. This chapter will discuss many of the current controversies and pseudo-controversies such as issues that are often the subject of heated debate but are rarely clinically significant.

25.2 Mechanism of Action of the Gastric Bypass

Perhaps the biggest controversy surrounding gastric bypass is the lack of clarity on its mechanism of action for weight loss and its profound metabolic effects [6]. A reduction of only 400 kcal/day compared to controls does not account for the magnitude of sustained weight loss, and additionally, significant carbohydrate malabsorption is absent [7]. Although some researchers feel that the metabolic effects are primarily due to weight loss, substantial evidence proves otherwise. Whether these changes are impacted by sustained incretin effect, altered bile acid metabolism, or microbiotic changes, the observed early metabolic effects or the sustained weight maintenance cannot be explained by imposed dietary changes alone [8–11]. While the pathophysiology of the gastric bypass remains unresolved; the discussion of incretins is an exciting academic exercise, although, with little clinical significance at this time.

25.3 Role of Open Gastric Bypass

Another controversy surrounding gastric bypass is whether it should be performed open. Surprisingly, there are a few surgeons who still prefer the open gastric bypass. It is even more surprising that there are patients willing to undergo these procedures. In our opinion, gastric bypass is currently a laparoscopic procedure and surgeons unwilling or unable to learn these techniques should refer their patients to an appropriate center. The laparoscopic gastric bypass has established itself as the standard of care in terms of outcomes and cost compared to open surgery [12, 13]. Incredibly, there are some countries that provide insurance cover only for open gastric bypass procedures; but this is probably more a political issue than an economic or scientific debate.

25.4 Prefered Anastomotic Technique for the Gastro Jejunostomy

The three primary methods of performing gastrojejunostomy are the hand-sewn technique, linear stapler technique, and circular stapler technique [14]. Anastomotic leaks after gastrojejunostomy is one of the most serious complications of this procedure. Apart from patient safety, surgeons are also concerned about operation time and cost. The circular stapler technique as proposed by Wittgrove and Clark [15] used an endoscopically retrieved guidewire to pull the anvil of the stapler transorally into the pouch, and this was later adopted by Jacob and Gagner [16] using only a modified anvil and nasogastric tube without the need of an endoscope. Another modification by Scott and de la Torre [17] was the use of transgastric placement of the anvil. All these techniques were successful, reproducible, and safe. However, the major drawbacks were the need for an entry port larger than 12 mm to accommodate the stapler, the cost of the stapler, and an increase in wound infections if the entry site was unprotected while withdrawing the contaminated tip [18].

The linear-stapled anastomosis technique popularized by Williams and Champion [19], and Schauer et al. [20] avoided the issues faced with the circular-stapled anastomosis, but required manual suturing to complete the enterotomy procedure. In addition, it was more difficult to calibrate the size of the anastomosis. The completely hand-sewn technique avoided many of the issues of the stapled anastomosis, but admittedly was the most difficult to master, with the longest learning curve [21].

Clearly, no single technique emerged as the best, since all the techniques are currently in use, with excellent results [22]. However, when one considers the increasing number of reoperations for complications and weight loss failures inherent when treating a chronic disease, the need for manual suturing skills is readily apparent.

25.5 Pouch Size and Surgical Outcomes

Restriction and malabsorption are important concepts in bariatric surgery education, for both the surgeon and the patient. The gastric bypass technique combines the elements of both the purely restrictive LAGB procedure and the highly malabsorptive procedures such as the bilio pancreatic diversion and additionally, it was consistent in its perceived performance by being more effective than the band, but less than the BPD. However, with increasing success in operating much smaller pouches by using laparoscopic techniques and the discovery of incretins, physiological changes after the operation gained more interest than structural ones. The eating behavior of a patient with a mature 5–10 mL pouch is not restrictive, and it was observed that gastric emptying was faster in gastric bypass patients than in control subjects [23]. Dumping syndrome (reactive hypoglycemia), a relatively common phenomenon after gastric bypass appears to be due to the rapid egress of food into the small bowel which is an opposite effect [24].

Pouch volume has been difficult to study because traditional contrast material used in computed tomography assessments leaves the pouch so rapidly that consistent distension is rarely achieved [25]. Sporadic reports of investigations using barium meals have not been validated. This further reinforces that the concept of restriction is inadequate to explain the reduction in calorie acquisition commonly seen in patients with a successful gastric bypass. A recent study by Heneghan found no correlation with pouch volume and weight maintenance, but did find a correlation with anastomotic diameter [26].

Consistent with Heneghan's findings, numerous studies have confirmed weight reduction with anastomotic size manipulation [27]. Unfortunately, these studies suffer from lack of power because of inadequate sample size and follow-up. Another deterrent is the lack of intermediate data, due to which the results are suspected because either permanent anastomotic reduction is difficult to achieve or, it simply is not the primary mechanism of weight maintenance after gastric bypass. This has been our observation as well as other surgeons [28].

The goal of gastric bypass has been to make the pouch smaller, with the exclusion of a distensible gastric fundus. This has had little effect on long-term weight loss, especially when compared with open and laparoscopic series (assuming that smaller pouches are managed laparoscopically), but we hope this would lead to fewer complications such as marginal ulceration or gastroesophageal reflux disease [29–31]. Proponents of the banded gastric bypass technique argue that pouch stability is an important factor in influencing both initial and sustained weight loss as indicated in O'Brien's systematic review of medium-term weight loss [32] and Schauer's short term comparative trial [5]. However, the randomized controlled study reported by Herrera's on banded versus non-banded gastric bypass failed to support this hypothesis [33].

25.6 Optimal Limb Lengths

Critical discussions regarding limb lengths are hampered by the inability to accurately and consistently measure the size of the small bowel which is as elastic as much as the stomach is distensible. In situ measurements are rarely reproducible, even when measured by the same surgeon. However, several studies have been conducted that compared the Roux and bilio-pancreatic limb lengths. With the exception of extreme distal bypasses in patients with a BMI >50, there appears no significant difference among Roux or bilio-pancreatic limbs of 100 cm ± 50 cm length, with respect to weight loss or nutritional deficiencies [34]. However, there appears to be an issue with bile reflux gastritis in patients with short Roux limb lengths [35].

25.7 Closure of Potential Hernia Spaces

Small bowel obstruction after gastric bypass is particularly a troublesome issue because of the vulnerability of the isolated gastric remnant that is prone to distension and possible ischemic necrosis. As opposed to bowel infarction due to adhesions, which is often limited, the entire small bowel and right colon can be at risk with an internal hernia. This phenomenon has also been reported in patients who underwent the open gastric bypass, but much more infrequently due to a greater degree of post surgical adhesions preventing volvulus of the intestine. Delay in treatment and diagnosis has led to disastrous consequences emphasizing the need for formal education of general surgeons who may encounter post-gastric bypass patients.

Our initial experiences were based on open gastric bypass surgeries performed by us, where we closed potential internal hernia spaces (except for Petersen's) with absorbable sutures. We soon realized that this was inadequate, and therefore, we decreased the incidence of internal herniation to <1 % using continuous permanent sutures [36]. Others surgeons eliminated the meso colic defect that is usually seen after the traditional retro colic bypass by routing the Roux limb ante colic, but this did not eliminate the need to close the jejunal and Petersen's defects [37]. Most authorities agree that closure of mesenteric defects with non-absorbable suture material is highly advisable, but conclusive evidence for prevention of internal hernias is still lacking.

25.8 Gastric Bypass: The Current Scenario

Although the complete mechanism of action of gastric bypass is unknown, the observed metabolic effects and long-term weight maintenance are far superior to other medical alternatives [38, 39]. Nutritional deficiencies and anatomic derangements such as internal hernias and marginal ulcers do occur rarely, thus, demonstrating a substantial risk/benefit ratio. Among all the procedures, only the biliopancreatic diversion and duodenal switch procedures have demonstrated superior long-term weight loss results [40], but they are fraught with severe drawbacks in terms of nutritional consequences and the need for supplementation; however, these are only secondary to flatulence and diarrhea after surgery exacerbated by dietary indiscretion [41]. The laparoscopic adjustable band procedures are increasingly unpopular among patients, probably due to the maintenance schedule, lower effectiveness, and the relatively high reoperation rate. In contrast, the vertical sleeve gastrectomy (VSG), has gained acceptance globally, and is all set to supersede the gastric bypass procedure by the time this book is published [42]. Although metabolically active with short-term weight maintenance similar to the gastric bypass, the mid-term weight recidivism and potential reflux issues of the VSG will need further evaluation. As the VSG is an irreversible procedure, it is unclear if the enthusiasm is more patient or surgeon driven. It is clear that the VSG is an easier procedure to master despite the peculiar challenges of leaks and stenosis of the sleeve.

The gastric bypass is not the panacea for morbid obesity. However, increased longevity and minimal side effects make this operation a standard by which all others are compared. It remains one of the few stapled procedures that can be reversed, modified and/or optimized depending on the individual patient. However, the learning curve is long and arduous, and may take as many as 500 cases to become proficient surgeon [43].

Key Learning Points

- The mechanism by which the gastric bypass exerts its effects is unknown.
- The size of the gastric pouch and/or stoma has little effect on long-term weight maintenance or control of metabolic syndrome.
- Differing methods of gastro jejunal anastomosis have similar safety statistics.
- The open gastric bypass should not be offered as a routine operation in favor of laparoscopic solutions.

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Section V

Laparoscopic Sleeve Gastrectomy (LSG): Technique, Complications, Outcomes, and Controversies

Honorary Section Editor - Sandeep Aggarwal

Laparoscopic Sleeve Gastrectomy (LSG) has established itself as a definitive weight loss proce-dure across the globe. Recently, it has taken over the number one position from the current 'gold standard'—Roux-en-Y Gastric bypass (RYGBP). However the growth of sleeve gastrectomy has been accompanied with more than its fair share of criticism. The initial argument of the critics (and there are many vehement critics still!) is that weight loss is not sustained. They compared it to Vertical banded gastroplasty (VBG) and predicted that LSG will meet the same fate as VBG! The consistently good medium and long term weight loss results as well as metabolic impact of LSG have been discussed in detail in the chapter on outcomes after sleeve gastrectomy.

Today, the technique of the procedure is more or less standardized. Like most other surgical pro-cedures, there are bound to be some variations based on individual preferences. The only contro-versy of significant importance is whether staple line reinforcement decreases leak rate. Though there are numerous randomized studies comparing the various techniques of reinforcement, the sample size is too small to reach any meaningful conclusion. In the chapter on technique, which has been co-authored by none other than the originator of sleeve gastrectomy—Dr Gagner, we have focused on the standard steps of surgery leaving the discussion of controversies in tech-nique to another chapter.

The fear of leak and it problematic management is definitely an important issue. However the good news is that the leak rate is decreasing. In a recent article Dr Gagner reported that the leak rate has decreased from earlier average of 2.5–1.1 % based on an analysis of >46,000 patients (*Surg Obes Relat Dis*. 2014 Jul-Aug;10(4):611–2.). The Chapter on complications has been au-thored by Dr Himpens in which the authors have presented probably the largest series of late post-LSG complications. I believe that detailed discussion of late complications, which has gen-erally received scant attention, would be of immense benefit to the reader.

The Gastro-esophageal reflux (GER) remains an important unresolved problem. There are a number of studies showing that GER worsens after sleeve. Appearance of de-novo reflux in some patients after surgery is another pitfall. However, there are an equal number of studies re-porting improvement of GER after LSG. All these studies and other relevant issues have been discussed lucidly in the chapter on Controversies by Dr Borg and Dr Adamo.

It has been our endeavor to present a comprehensive overview of this exciting procedure. The chapters reflect the experience of eminent surgeons along with inclusion of most recent and rele-vant literature. There is an explosion of literature about LSG and I am sure that this would help consolidating the relevance of sleeve gastrectomy. We might see sleeve gastrectomy being la-beled as the new "gold standard" surgery for morbid obesity in not so distant future.

Finally I would welcome any comments and criticism which would only help us in improving the section in future editions.

26 LSG: The Technique

Sandeep Aggarwal, Pratyusha Priyadarshini, and Michel Gagner

Abstract

Sleeve gastrectomy is presently considered as effective as the current gold standard operation, the Roux-en-Y gastric bypass. The only absolute contraindication to this procedure is presence of Barrett's esophagus. Comprehensive preoperative work-up, optimization of co-morbidities, and adequate preoperative preparation are of paramount importance. Preoperative patient counseling should focus on caution about variable impact of surgery on symptoms of gastro-esophageal reflux, if present. Though technically less complex than the gastric bypass, meticulous technique and avoidance of certain pitfalls are essential to achieve an optimal outcome and minimize serious complications including leaks. It is recommended to adopt an unhurried approach during stapling to avoid narrowing at incisura angularis and other complications.

Keywords

Sleeve gastrectomy • Bariatric surgery • Obesity surgery • Laparoscopic technique • Operative steps

26.1 Introduction

Bariatric surgery is superior to medical therapy for weight loss, survival, and treatment of comorbidities [1–4]. Among the various procedures, laparoscopic Roux-en-Y gastric bypass (LRYGB) has generally been considered as the gold standard. Laparoscopic sleeve gastrectomy (LSG) originated as a part of the duodenal switch procedure. It was not used as a separate procedure for weight loss, until it was pioneered by Gagner as a first stage procedure for the two-stage duodenal switch (DS) in super-obese patients, since the risk of operative mortality for these patients undergoing a prolonged procedure was very high [5]. The second stage of the surgery is usually carried out in another setting, once the patients have lost some weight. However, majority of patients had significant weight loss during this interval, and hence, the second stage surgery was deferred or not required. Hence, with some further modifications laparoscopic sleeve gastrectomy was established as an effective stand-alone bariatric procedure.

Copious published data suggest that long-term weight loss following LSG is equal to laparoscopic RYGB [6, 7]. LSG results in superior weight loss and better appetite control 3 years post -surgery compared with LRYGB [8] LSG reduces ghrelin levels and hence, apart from the reduced capacity of stomach, one of the important mechanisms of weight loss is decreased appetite and enhanced satiety [9].

Various advantages of the LSG include its technical simplicity, shorter operative time, maintenance of normal continuity of bowel, along with preservation of the pylorus [10]. Long-term problems associated with LRYGBP, including internal hernias and small bowel obstruction are avoided with LSG. Patients who underwent LSG had fewer nutritional deficiencies than that in patients who underwent LRYGB. The LSG procedure can later be modified

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if required, to a LRYGB or laparoscopic Duodenal Switch (DS) configuration in patients who develop severe reflux symptoms or weight regain.

The only major disadvantage of the procedure is development of leak along the long gastric staple line, which is often more difficult to treat than that following LRYGB, and may lead to formation of chronic fistula. One of the other concerns about the non-availability of long-term results following this procedure has been put to rest by recent data that have re-established its efficacy [11]. Also, long term studies on DS shows a stable sleeve.

26.2 Indications and Contraindications

LSG, a multi-purpose operation, is suitable for almost all morbidly obese patients fulfilling the National Institutes of Health (NIH) criteria for bariatric surgery [12, 13]. It is specifically indicated for super-obese patients, either as a first stage or as a stand-alone option. LSG is a safer option in high-risk patients and those with poor intra-operative conditions. Specific contraindications for LSG are few and include the Barrett's esophagus. It is generally agreed that LRYGB is superior to LSG in patients with long-standing diabetes, although recurrent diabetes is easier to treat after sleeve than bypass. Other general contraindications apply, as for any bariatric surgical procedure, and include the American Society of Anesthesiologists (ASA) grade 4 patients not likely to withstand the surgery, patients with end-stage organ dysfunction of the heart, lungs, or both that are unlikely to improve, patients with malignancy, and cirrhotic liver with severe portal hypertension.

The patients should be counseled about the variable impact of LSG on reflux symptoms and possibility of de novo reflux in future. As with any other procedure, they must understand about the nature of surgery and accept the risks of surgery. The patient must be motivated enough to comply with long term dietary changes, lifestyle and behavior modification.

26.3 Diagnosis and Management

26.3.1 Work Up /Preoperative Evaluation

A comprehensive preoperative work-up is necessary for careful selection of patients and risk stratification. A detailed history and physical examination of all patients is mandatory before performing any investigations with special emphasis on comorbid conditions. History should include detailed questioning of reflux symptoms. If the patient complains of suggestive symptoms, details about the nature and frequency of each symptom as well as the requirement of medication should be obtained. We routinely use a symptom questionnaire devised by the gastroenterology department at our Center. We perform an upper gastrointestinal endoscopy in all patients to evaluate the extent of reflux esophagitis, hiatal hernia, gastric and duodenal ulceration, and Helicobacter pylori status. Some patients may need 24 h pH studies, esophageal manometry, and esophageal biopsies in associated Barrett's esophagus [14].

Morbidly obese patients need additional investigations to identify hidden comorbidities. It requires a multidisciplinary team to investigate these patients, and includes a surgical team, nutritionist, anesthesiologist, psychologist, cardiologist, pulmonologist, endocrinologist, gastroenterologist, orthopedician, and other specialists [15].

Patients should be asked about any history of recent chest pain and dyspnea. Patients with cardiovascular diseases should undergo preoperative evaluation by a cardiologist. Echocardiography, stress testing, and cardiac catheterization may be indicated in some patients.

Morbidly obese patients with a history of loud snoring or excessive daytime sleepiness and fatigue should be checked for respiratory insufficiency and obstructive sleep apnea (OSA). Evaluation includes baseline oxygen saturation measured by pulse oxymeter, room air arterial blood gases (ABG), pulmonary function tests, and polysomnography. Patients with significant OSA should be treated with nasal continuous positive airway pressure preoperatively. Often these patients are at high risk for developing pulmonary complications in the postoperative period, which are occasionally life-threatening like acute upper airway obstruction and pneumonia. Hence, patients with OSA, or severe asthma should be properly evaluated by a pulmonologist [16, 17].

Ultrasound of the abdomen is performed in all the patients prior to surgery, mainly to assess the status of liver and to rule put any intra-abdominal pathology. Morbidly obese patients have high incidence of non-alcoholic steatohepatitis, and the liver is soft and bulky in these patients. Venous Doppler of both lower limbs is performed in all the patients to rule out the stigmata of previous/existing deep vein thrombosis.

A dedicated nutritionist should be involved early in the work up of these patients. The dietitian will help in counseling the patients regarding necessary changes in postoperative eating habits and food choices.

26.3.2 Preoperative Preparation

Preoperative preparation involves optimization of risk factors and other routine preoperative preparation applicable to upper gastrointestinal surgery. Preoperative incentive spirometry is encouraged as it improves pulmonary function, and ensures good compliance for chest physiotherapy in postoperative period. In patients with severe OSA who are not on any prior treatment, preoperative continuous positive airway pressure (CPAP) application during sleep is initiated at least 5–7 days prior to surgery.

In many patients, a very low calorie diet is advised for 2 weeks prior to surgery and patients are encouraged to lose some weight prior to surgery in order to decrease the liver size.

26.3.3 Operating Room Setup

Operating room set-up and instrumentation have been discussed in Chap. 13. Briefly, a suitable operating table for heavy patients with facility for steep reverse Trendelenberg position, foot boards, and straps is mandatory. Long instruments, telescopes and a good self-retaining liver retractor [Nathanson Liver Retractor (Cook Medical Inc., Brisbane, QLD, Australia)] should be available.

Preoperative antibiotic is given at the time of induction, which is usually a second generation cephalosporin-such as Cefuroxime at a dose of 1.5–2 g intravenously. Intra-arterial line is routinely placed by the anesthetist for monitoring and an oro-gastric tube is placed to decompress the stomach.

26.3.4 Positioning of Patient

Proper positioning and securing the patient to the operating table is important, because this surgery is done in a steep reverse Trendelenberg position. The patient is positioned supine with both arms extended on the armboard. Patient is positioned in split leg (French) position. Sequential compression device and graduated compression stockings are applied to the lower extremities as prophylaxis for deep venous thrombosis. The patient is secured to the table using footboards, straps, and bandages.

26.4 Operative Steps

Videos 26.1 and 26.2 illustrate operative steps in the procedure.

26.4.1 Creating Pneumoperitoneum

Closed method using Veress needle is our preferred method for establishing the pneumoperitoneum. The Veress needle is inserted in supraumbilical region in most cases. In patients with previous operations, Veress is inserted at Palmer's point; a point two- fingers breadth below the subcostal margin in left midclavicular line. Intrabdominal pressure is maintained between 15 and 20 mm. Use of two insufflators is helpful.

In patients where the Veress cannot be inserted safely or has failed, optical entry using a zero degree telescope is used for insertion of the first port. The Hasson technique is also used in the morbidly obese in the upper umbilicus, and is the safest method of entry.

26.4.2 Port Placement

Port positions, most commonly used when the surgeon is operating from the right side, are as shown in Fig. 26.1. Normally two 12-mm and two 5-mm ports are used. However, in difficult situations extra ports may be required. The first port is inserted in the upper abdomen about 15 cm below the xiphisternum for the camera. A 45° telescope is preferred as it enables an excellent visualization of the Angle of His and hiatus. The working ports for the operating surgeon include a 12-mm port placed in right midclavicular line and a 5-mm port in right anterior axillary line. The other 5-mm port is inserted in left midclavicular line for the assisting surgeon. In some cases with severe adhesions in the right upper quadrant of abdomen (for example, previous open cholecystectomy), working ports are placed on the left side of abdomen and operations is carried out with some modification in operative steps.

26.4.3 Placement of Liver Retractor

A quick diagnostic laparoscopy to identify any inadvertent injury is carried out. If found normal, Nathanson hook liver

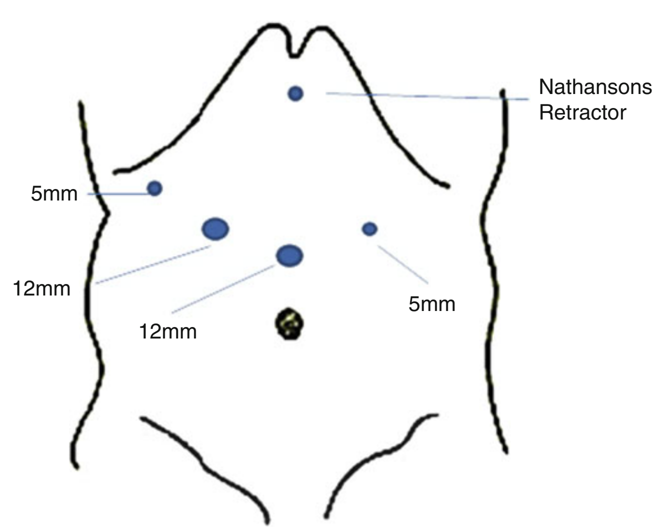

Fig. 26.1 Port position

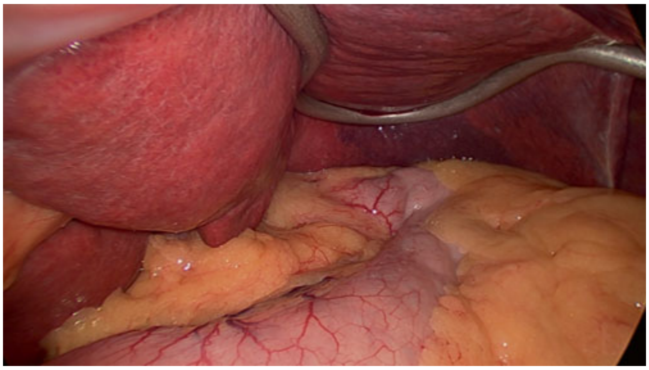

Fig. 26.2 Nathansons hook liver retractor placed to elevate the left lobe of liver

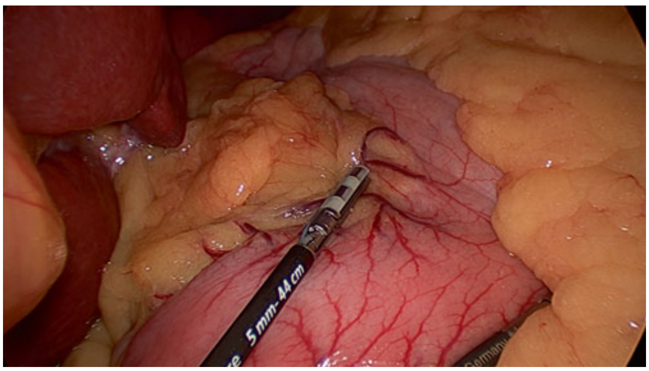

Fig. 26.3 Identification of incisura angularis

retractor (Cook Medical Inc., Brisbane, QLD, Australia) is placed through a 5 mm incision in the subxiphoid region to elevate the left lobe of liver (Fig. 26.2 and Video 26.3). At this stage, the hiatus is assessed for any laxity or hiatal hernia. In patients with hiatus hernia, the crural repair is performed usually before commencing the original procedure. However, some surgeons would prefer to do the crural repair after completion of sleeve gastrectomy (Videos 26.4 and 26.5).

26.4.4 Mobilization of Greater Curvature

A 36-French bougie is inserted under vision at this stage. It helps in decompression of the stomach, and is easier to insert at this stage rather than later when the patient is in steep reverse Trendelenberg position. The bougie is then withdrawn up to the GE junction. The incisura is identified (Fig. 26.3). A window is created in the lesser sac at a point on the greater curvature that is almost midway as it is easier to enter the omental bursa at this location (Fig. 26.4). A 5-mm bipolar vessel sealing device or ultrasonic shears is used. After entering the lesser sac, the omentum is detached from the greater curvature proximally by staying close to the gastric wall. The dissection proceeds cranially and great care is taken while taking down short gastric vessels (Fig. 26.5, Videos 26.1 and 26.6).

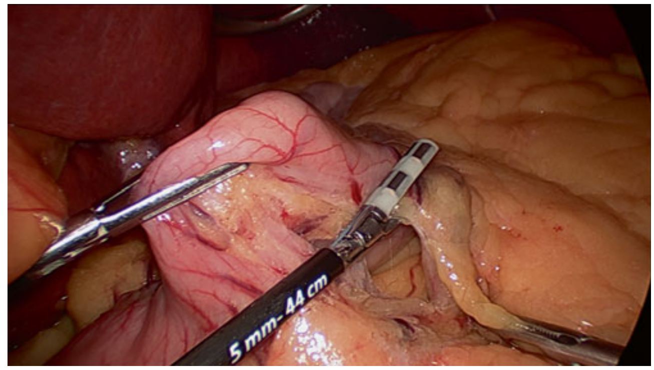

Fig. 26.4 Creation of window on greater curvature

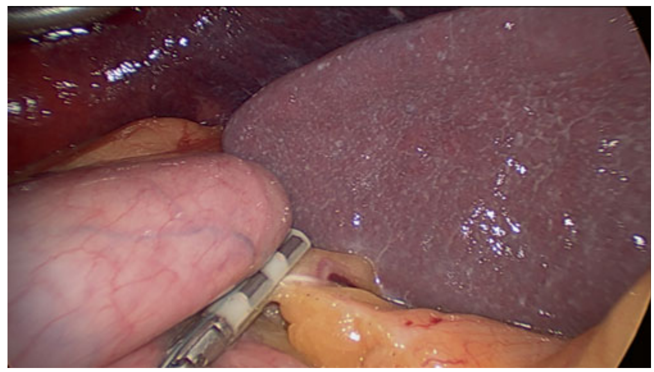

Fig. 26.5 Short gastric vessels being taken down close to gastric wall

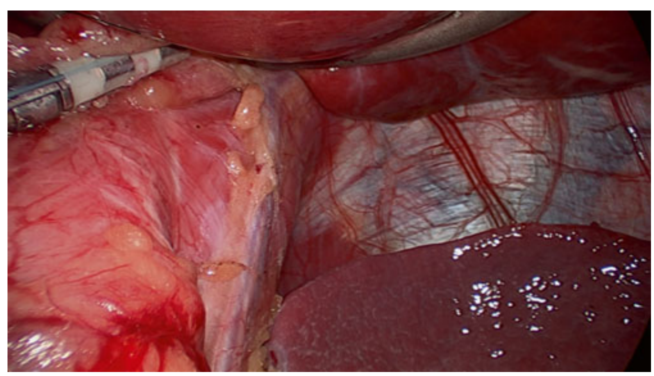

Fig. 26.6 Entire Left Crura exposed

26.4.5 Dissection Near Angle of His

The fundus is completely mobilized by detaching all adhesions. The left crura is exposed completely up to its medial border (Fig. 26.6 and Video 26.7). The left phreno-esophageal membrane is an important anatomical landmark that defines the cranio-medial limit of dissection. Anteriorly, the gastroesophageal fat pad is mobilized to guide the correct placement of stapler. Any overzealous dissection near the GE junction is best avoided, to prevent bleeding as well as injury to the esophagus.

Posterior attachments are taken down as the next step (Fig. 26.7). While taking down posterior attachments, care should be taken to avoid injury to the left gastric artery as it is the main vascular supply for the remnant sleeve of stomach.

Next, the caudal part of greater omentum is taken down, which becomes thicker and vascular closer to the pylorus. Usually two distinct layers of omentum are encountered in this area, which may need to be taken down individually. Dissection is stopped 3–5 cm away from the pylorus (Fig. 26.8a, b, Videos 26.2 and 26.8). This distance is variable and there are controversies on the amount of antrum to be left behind [18–20].

26.4.6 Creation of Sleeve

First, it is ensured that all the tubes are placed in the stomach except the bougie (e.g., temperature probe and orogastric tube) have been taken out by the anesthetist. Preplaced bougie is then advanced up to the first part of duodenum under vision, and it is ensured that its alignment is straight. It can be a tricky step sometimes, and atraumatic graspers may be required to guide and push the bougie through the pylorus (Fig. 26.9a, b and Video 26.9). Hence, some surgeons prefer to place the bougie after firing the first stapler. A good communication between anesthetist and surgeon is essential during this step, as forced placement can lead to injury of the esophagus or stomach during this vital step. A gastroscope can also be used instead, to calibrate and guide the creation of sleeve.

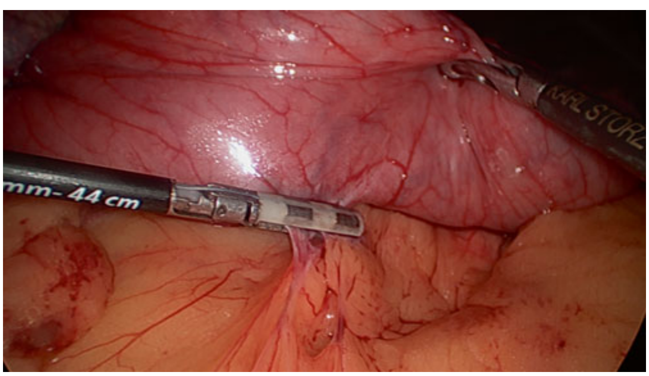

Fig. 26.7 Detachment of Posterior attachments

There is a great variation in the size of gastric calibration tube being used to create the sleeve, which ranges from 32 to 60 French. Technically, there appears to be no short-term weight loss difference as a result of the choice of bougie size used to create the sleeve [21, 22]. On the contrary creating a sleeve using a bougie of smaller size may result in greater effective weight loss, but at the expense of higher stricture and leak rates [23]. At our center, the sleeve is created over a 36-French bougie. For the first fire, the Endo GIATM stapler is placed 3–5 cm away from pylorus. We usually prefer the Purple cartridges (TristaplerTM Technology, Covidien Tyco Healthcare Private Limited) for the first two firings. In patients with thick stomach, a black cartridge can be used. The Endo GIATM stapler is inserted through the right 12-mm port, with the left hand surgeon retracting the greater curvature laterally, and placing the stapler close to the bougie. The assisting surgeon may help in the correct placement of first stapler close to the bougie by retracting the greater curvature of stomach laterally. The stapler should be angled away from the incisura (Fig. 26.10a, b, Videos 26.4 and 26.10). Before firing the first staple, the distance of stapler from incisura angularis is reassessed. The stapler is placed slightly away from bougie at this point to avoid any narrowing that can result in a leak in the post-operative period. There have been studies suggesting that the chances of leak are less if the diameter of sleeve at the incisura is maintained around 40 French [19, 23]. After ensuring that the stapler is placed correctly, we wait for about 30 s before firing the stapler.

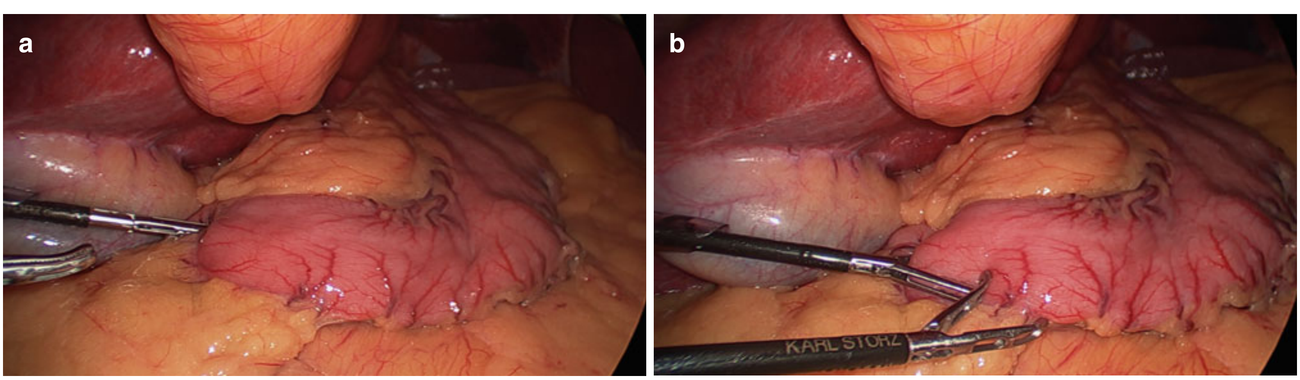

Fig. 26.8 (**a**) Dissection is stopped 3–5 cm away from pylorus. (**b**) Measuring the distance from pylorus

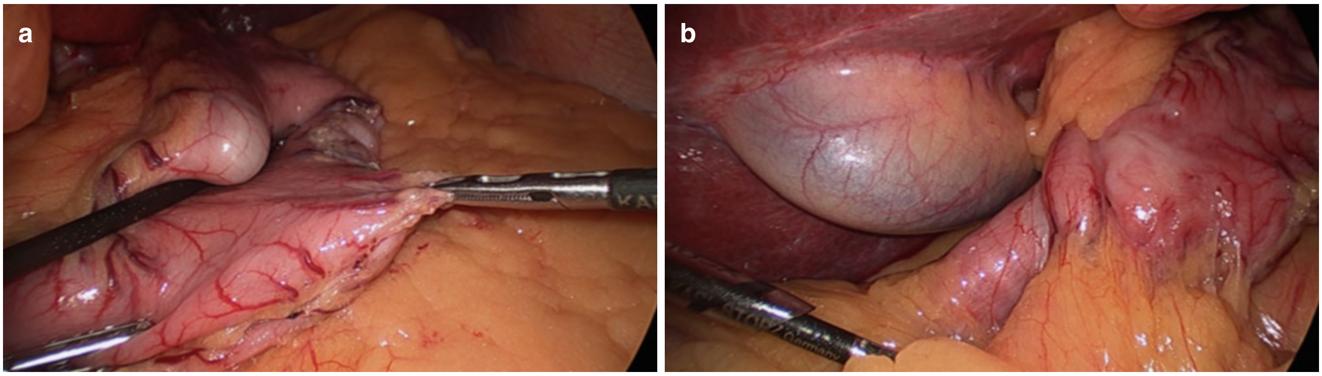

Fig. 26.9 (**a**) Atraumatic graspers guiding the placement of bougie. (**b**) Bougie has been pushed through the pylorus to the first part of duodenum

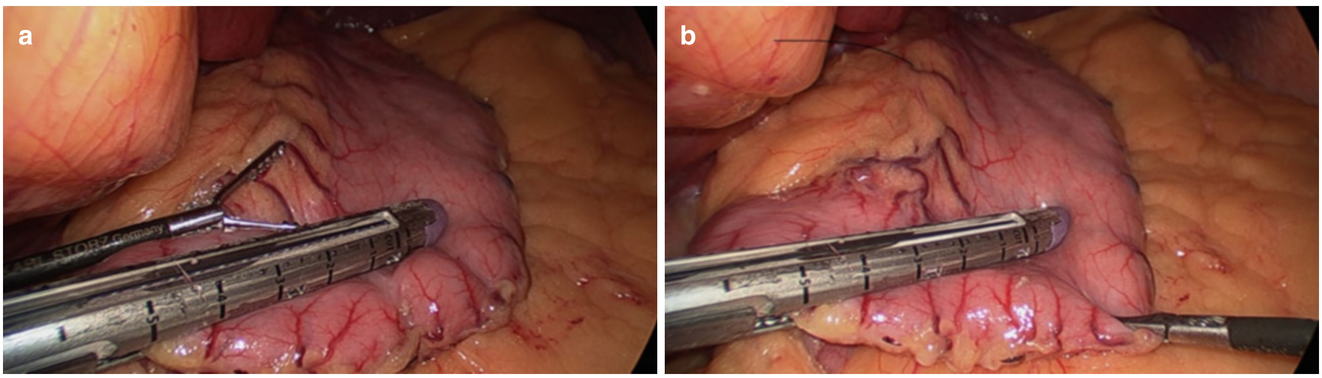

Fig. 26.10 (**a**) Measuring the distance from incisura to guide the correct placement of first stapler. (**b**) The first stapler should be angled away from the incisura to prevent narrowing

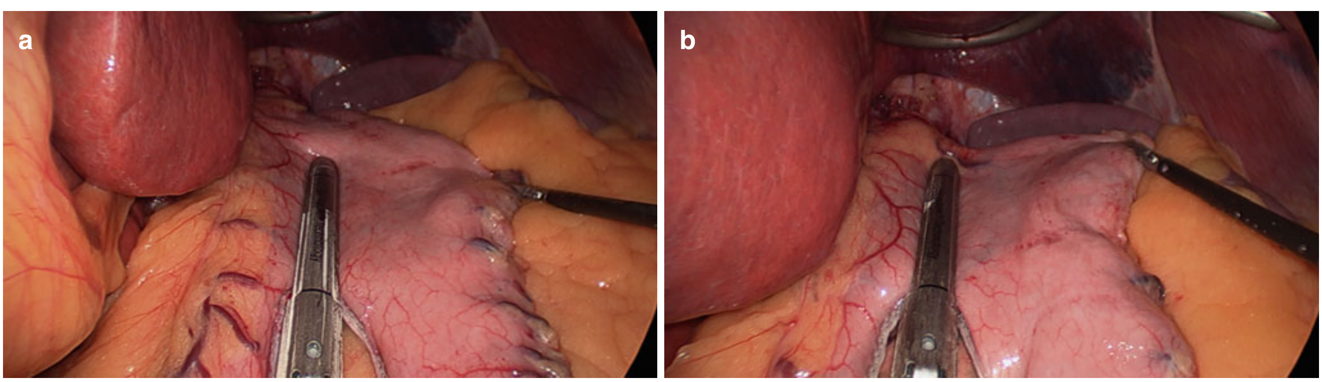

Fig. 26.11 (**a**, **b**) Creation of gastric sleeve using sequential firings of the stapler

The sleeve is created by sequential firings of the Endo GIATM stapler using the purple cartridges (Fig. 26.11a, b, Videos 26.4 and 26.11). After each placement, the stapler should be rotated to check that the excessive posterior stomach is not left behind (Fig. 26.12). After each fire, the staple formation should be checked for proper staple formation and any loose staples (Fig. 26.13) should be removed. Care should be taken to avoid bunching of tissues. While retracting the stomach, the assistant should hold the greater curvature and not the anterior or posterior wall, as it may cause twisting of sleeve. Excessive traction should also be avoided.

The last fire should be properly planned. Again, an articulating instrument such as Goldfinger (Fig. 26.14) can be used to define the angle of His. The fundus should be retracted appropriately to avoid bunching of tissues. Care should be taken to include whole of the fundus in the resected part, as remnant fundus can lead to poor long-term outcome. The stapler should be angled away from the Angle of His to avoid

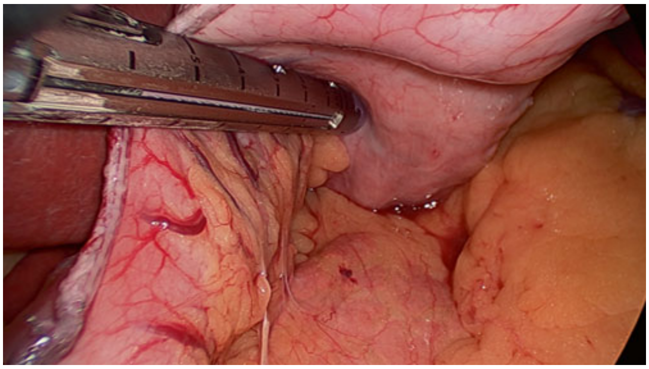

Fig. 26.12 Rotating the stapler to check that excessive posterior stomach is not left behind

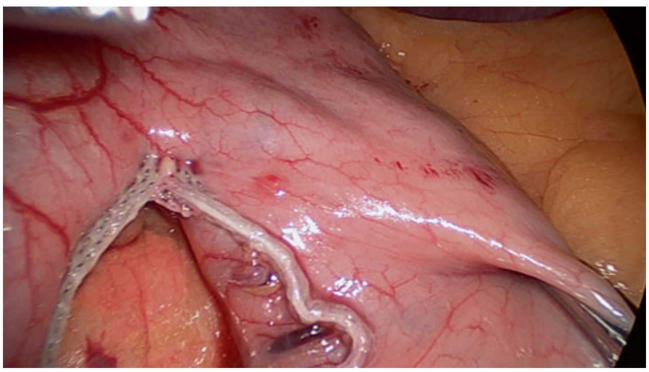

Fig. 26.13 Checking for proper staple formation and loose staples at the crotch

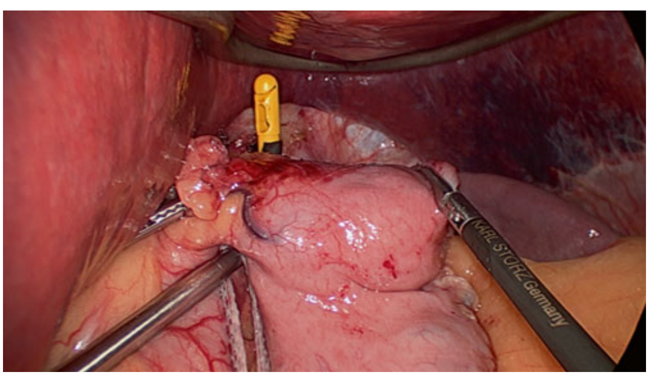

Fig. 26.14 Using articulating instrument/Goldfinger to define the angle of His

any narrowing at the gastroesophageal (GE) junction or inclusion of esophagus in the stapler (Fig. 26.15, Video 26.12). Another important precaution is to avoid the temptation of saving on a cartridge by trying to push the stapler all the way through and cause bunching. It is safer to fire for a lesser distance and use another cartridge if one is unsure that the entire tissue will fit in the stapler during the last fire.

An alternative approach used by few surgeons involves creation of a small window at 2–3 cm from the pylorus, com-

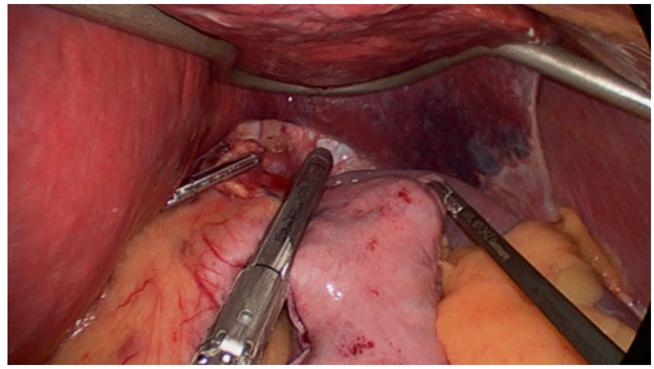

Fig. 26.15 The stapler should be angled away from the Angle of His to avoid injury to esophagus

plete the sectioning of stomach first to create the sleeve, and then do the omentolysis.

26.4.7 Hemostasis and Reinforcement

The bougie should be withdrawn until the GE junction before checking for hemostasis. The stapled end of the sleeve is inspected carefully for any bleeders (Fig. 26.16a, b). Most often, they can be secured using small clips. Rarely figure of eight sutures may be required to invert the bleeding edge of the stomach.

Staple line reinforcement (SLR) has been used to decrease bleeding and leaks. There are various methods for reinforcement of staple line such as oversewing, placing omental flap, using buttressing material over stapler, and spraying fibrin glue along the staple line. A number of buttressing materials are commercially available to reduce the rate of bleeding from the staple line. These include glycolide trimethylene carbonate copolymer (Videos 26.2 and 26.4) (Gore Seamguard, W.L. Gore and Associates), bovine pericardium strips (Synovis Surgical Innovations) or porcine small intestinal submucosa (Surgisis Biodesign, Cook Medical) [24]. However, it is controversial if the use of buttressing material reduces the rate of bleeding. Albanopoulos and colleagues, could not find a significant difference in the rate of postoperative bleeding between patients with staple line suturing or buttressing with Gore Seamgard [25]. In a prospective randomized trial, Dapri et al. compared the rate of staple line bleeding after LSG using three different techniques: no SLR, reinforcement with either suturing, or buttressing with Gore Seamguard. They observed a significantly lower rate of bleeding with the use of buttressing material but there was no difference in the incidence of leaks [26]. A systemic review of various methods of staple line reinforcement after sleeve gastrectomy concluded that use of absorbable polymer membrane (APM) as a buttressing material is most effective in decreasing the leak rate [27].

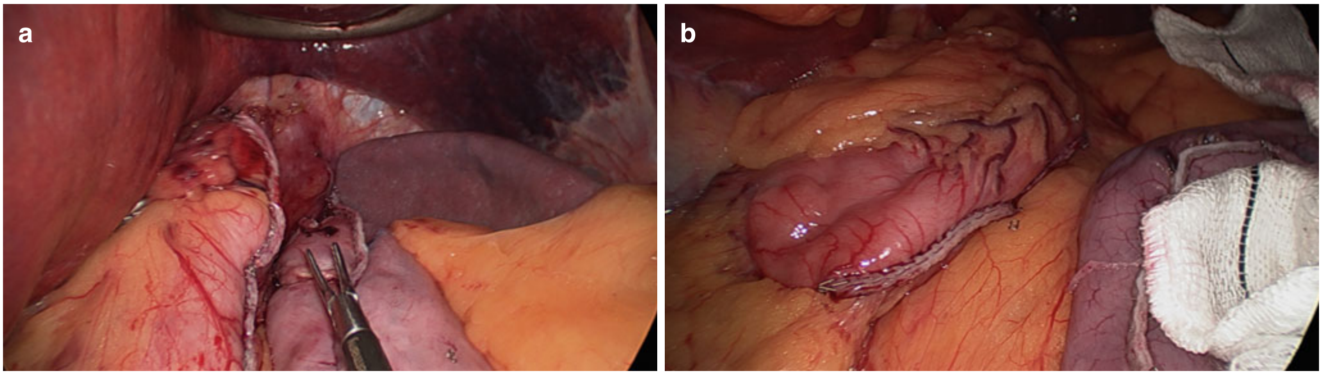

Fig. 26.16 (**a**) Completed sleeve (**b**) The stapled end of the sleeve should be inspected carefully for bleeders

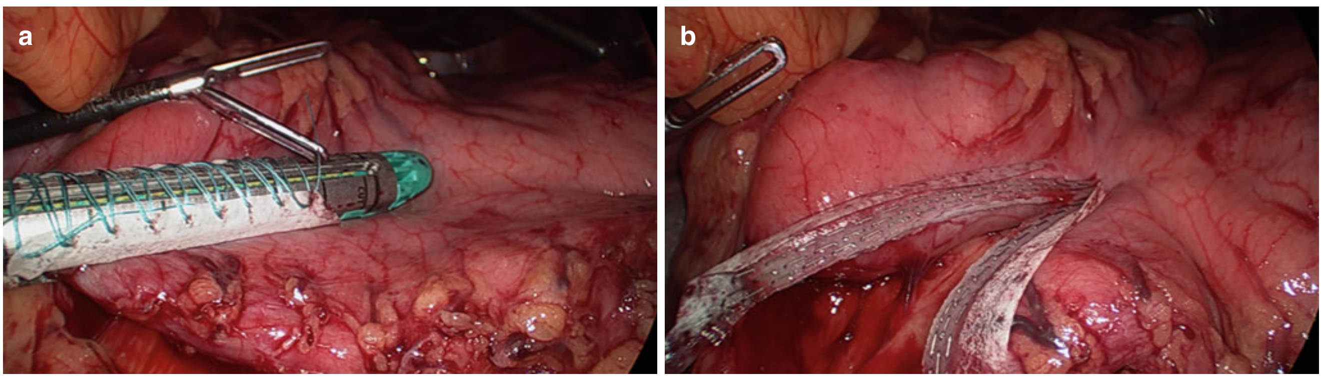

Fig. 26.17 (**a**, **b**) Reinforcement using Gore Seamguard

At our institution reinforcement using Gore Seamguard (Fig. 26.17a, b) is used in some selected patients such as super-obese patients, patients on anticoagulants and patients of OSA who require high pressure CPAP. The high cost of buttressing material appears to be prohibitive to recommend its routine use.

26.4.8 Leak Test and Organ Retrieval

Leak test can be done by air insufflation or by instilling methylene blue dye. We perform the leak test for all our cases by instilling methylene blue dye in the created sleeve through the bougie (Fig. 26.18 and Video 26.13). Some surgeons may like to omit the leak test based on the presumption that the staple line appears good. However, we strongly recommend a routine leak test for all cases [28].

The specimen is retrieved from the right 12-mm port after dilating it (Fig. 26.19). We avoid using any bag. A Jackson Pratt 14-French flat drain is placed near sleeve through left port (Fig. 26.20). The right 12-mm port is closed using trans-fascial sutures using an endoclosure device. Subcuticular monocryl stitches and dermabond are used for skin approximation.

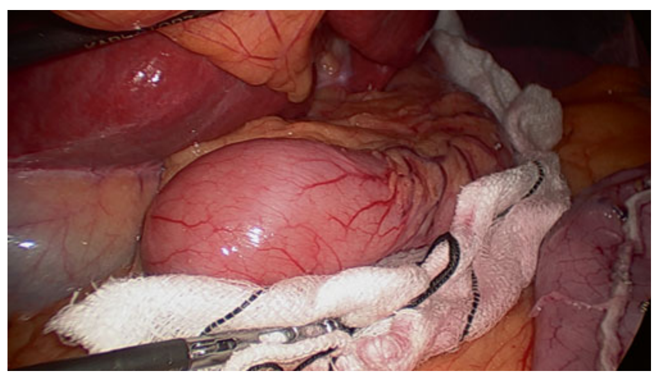

Fig. 26.18 Leak test being done by instilling methylene blue dye

26.5 Postoperative Care

Patients are monitored overnight in a high-dependency unit. Early ambulation of patients, sequential pneumatic compression device, and subcutaneous heparin are used for DVT prophylaxis. Patients are ambulated as early as possible, often after 4–6 h of surgery. Incentive spirometry and deep breathing exercises are encouraged to prevent atelectasis. Patients are permitted to sip clear liquids after 24 h. We do not recommend a dye study after surgery, although some surgeons may prefer performing a routine gastrograffin test before allowing oral intake.

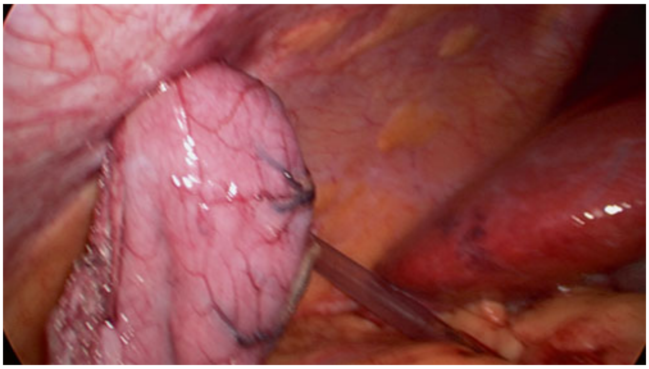

Fig. 26.19 Retrieval of Specimen from Right 12 mm port

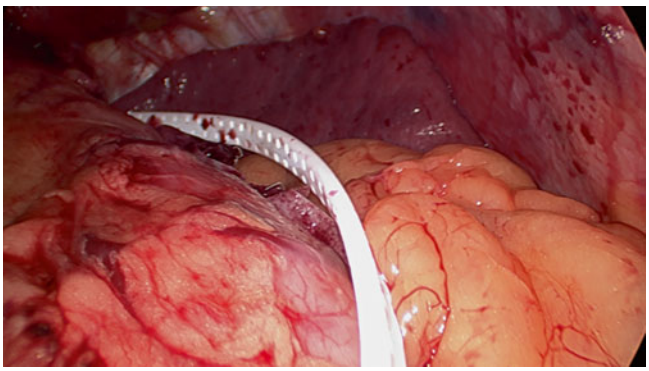

Fig. 26.20 Jackson- Pratt drain placed near sleeve through left port

Patients are discharged on the second or third postoperative day if they are afebrile, ambulatory, tolerate oral liquid diet, and do not require oral analgesics.

26.6 Complications

A detailed discussion of the complications is outside the scope of this chapter, and can be found elsewhere. A few important complications are discussed below:

26.6.1 Hemorrhage

The incidence of hemorrhage after LSG is reported to range from 1 to 6 % [29]. The hemorrhage can be extraluminal or intraluminal. The causes of extraluminal hemorrhage are bleeding from the staple line, omental vessel, spleen injury, liver laceration or trochar sites. Intraluminal bleeding is uncommon, and is a result of staple line bleed. Patients with extraluminal hemorrhage ususally experience tachycardia, sudden hypotension, and sanguineous drain output, with a drop in hematocrit. Patients are resuscitated and serial monitoring of pulse rate, blood pressure, and haematocrit is done. An urgent relaparoscopy or laparotomy should be done if bleeding results in hypotension, especially within 12 h after LSG. In our experience, most patients can be managed conservatively if they are hemodynamically stable. Anticoagulants should always be discontinued in such cases.

26.6.2 Leak

The most dreaded complication after bariatric surgery is a leak from the staple line [29, 30]. Leak can be classified as early or late, depending upon the time interval of presentation after surgery. Early leak is defined as a leak that is diagnosed within 3 days after surgery. Late leaks are those diagnosed a week after surgery. The presentation of leak is often varied ranging from absence of symptoms to diffuse peritonitis. The earliest signs of leak are tachycardia, agitation, tachypnea, and fever. Pulse rate is the single most reliable parameter to diagnose leak in obese patients. Any tachycardia or fever warrants further evaluation by contrast enhanced computer tomography of the abdomen and/or gastrograffin study to diagnose the leak. If the leak is diagnosed or suspected within 48–72 h, relaparoscopy is done. At the time of relaparoscopy, the leak is repaired, peritoneal lavage is done, a drain is placed, and a feeding jejunostomy is done. After 72 h, repair of leak is not recommended because of the extensive inflammatory changes. If the patient presents with a leak after this narrow therapeutic window and is stable, conservative management is an excellent alternative to surgery, and includes image-guided drainage of infected collections, parenteral antibiotics, naso-jejunal feeding, and insertion of stents (two types are available-silicon and covered). However, if the patient has toxemia and has signs and symptoms of diffuse peritonitis relaparoscopy is mandatory. The important point is to avoid any delay in the management of such patients. The sepsis should be drained at the earliest, after the diagnosis.

Chronic fistula will eventually require a surgical intervention, usually a Roux-En-Y fistula-jejujunostomy, which should be performed after 3 months of initial surgery.

26.6.3 Stricture

The incidence of stricture following LSG is reported to be 1–2 % [29]. The presentation of stricture may be either acute or chronic. The most common site of stricture is incisura angularis that may be due to luminal narrowing or kink. The stricture manifesting in an acute setting is mainly due to tissue edema and settles with conservative management, which comprises of keeping the patient off any oral intake along with administration of intravenous fluids. Earlier, when we routinely oversew the entire staple line, early postoperative vomiting was a common occurrence. Ever since we discontinued oversewing, this situation has not recurred. Alternatively, chronic stricture needs multiple endoscopic balloon dilatations. Patients with persistent stricture who do not respond to endoscopic dilatation often require surgical intervention, mostly conversions to LRYGBP.

26.6.4 Reflux

The relationship between LSG and gastroesophageal reflux is not clear, and regarding whether LSG increases or decreases the symptoms of GE reflux is debatable [31]. Our experience shows that there is a significant decrease in objective symptom scores, as well as endoscopic grade of esophagitis, despite a dramatic increase in scintigraphic reflux [32]. Additionally, a routine check for hiatal hernia and prompt hiatal hernia repair decreases the incidences of postoperative reflux.

26.6.5 Nutritional Deficiency

The incidence of nutritional deficiency following LSG is comparatively lower than LRYGBP [33]. However, nutritional surveillance is important during follow-up for early detection and management of nutritional deficiencies. The deficiencies commonly seen after LSG are thiamine, Vitamin B12, Vitamin D3, zinc, and folic acid.

26.7 Follow Up

Patients are called for follow up at regular intervals. The first follow up visit is usually a week after surgery. Subsequent visits are scheduled at 1 month, 3 months, and at quarterly intervals thereafter, in the first year. After the first year, we recommend a half-yearly follow-up for the next 2 years, and annually thereafter. As stated earlier, nutritional monitoring is an important aspect of follow-up. Importance of dietary compliance and physical activity should be stressed at each visit. Regular support group meetings are an important component of an effective weight loss program.

Conclusion

The LSG has already been established as a safe and effective primary weight-loss procedure. Its popularity has risen exponentially to the extent that it is being investigated as a metabolic procedure for inducing remission in Class I obese patients with type 2 diabetes. Despite some technical variations, the basic steps of surgery remain the same and have been continually standardized in the last decade. Further, a series on long-term results and research on the problem of de novo reflux will help establish LSG as a gold standard procedure in the future.

Key Learning Points

- Although LSG is technically less complex than LRYGBP, the following points are noteworthy:
- Special attention is required during the first and the last stapler firings to avoid excessive narrowing.
- It is extremely important to avoid rotation of sleeve by ensuring equal traction on both walls of stomach, and avoiding excessive traction.
- Caution should be exercised to avoid including too much tissue into the stapler to preclude bunching of tissues.
- There is no substitute for hemostasis. The entire staple line should be inspected for bleeding after withdrawing the bougie up to the GE junction. Staple line hematoma has often lead to leak.
- Even though the surgery seems simple, these procedures should be performed only by experienced surgeons, and in a facility where a multidisciplinary team is available for perioperative management.

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LSG: Complications—Diagnosis and Management

27

Rudolf A. Weiner, Islam A. El-Sayes, and Sylvia R. Weiner

Abstract

Laparoscopic Sleeve Gastrectomy (LSG) is currently one of the most common obesity procedures performed worldwide. Initially described as the first component of more complex procedures, it is now accepted as a stand-alone intervention. Although theoretically a simple procedure, it can be followed by life-threatening complications. Prevention and management of these complications require the adoption of a standardized perioperative protocol and timely interpretation of abnormal postoperative findings. Deviation from the normal postoperative clinical course or abnormal blood tests (elevation of inflammatory parameters or a drop in hemoglobin) should raise the suspicion of complications. An integrated teamwork approach is necessary to interpret abnormal signs, blood or radiology results and to instigate prompt management. Diagnostic laparoscopy yields highly specific results.

Postoperative complications can present either early or late. Early complications include staple line leakage and bleeding. Endoscopic stenting and/or surgical revision are usually required to manage leakage. Haemodynamic instability secondary to staple line bleeding necessitates surgical revision. Late postoperative complications include leakage (which may present as free intra-peritoneal leakage, abscess formation or development of fistula), sleeve stenosis (which may be associated with other complications including leakage) or perigastric hematoma. Late leakage may respond to endoscopic stenting, drainage or conversion to Roux-en-Y gastric bypass (RYGB). Stenosis can be managed with dilatation and/or conversion to RYGB. Malnutrition after LSG is another serious complication.

This chapter will analyze early and late post-LSG complications, highlighting our standardized perioperative protocol to prevent, diagnose and manage complications in a timely manner. Relevant algorithms are also discussed.

Keywords

Laparoscopic sleeve gastrectomy • Early and late complications • Leak • Stenosis • Staple line bleeding • Conversion to Roux-en-Y gastric bypass • C reactive protein • Tachycardia • Pyrexia • Endoscopic stenting

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27.1 Evolution of Sleeve Gastrectomy

Worldwide, sleeve gastrectomy is becoming increasingly popular within the field of obesity surgery. The modern procedure of longitudinal gastric resection or sleeve gastrectomy was incorporated quite late in the repertoire of obesity surgery. In 1993, Marceau and co-workers [1] modified the biliopancreatic diversion (BPD), which had been introduced by Scopinaro et al. [2], and replaced the horizontal gastric resection with a longitudinal gastric resection along the greater curvature preserving the pylorus. In addition, they doubled the length of the "common tract" to 100 cm. In 1999, the first laparoscopic BPD/DS and therefore the first LSG was performed [3]. A high frequency of complications in patients with a body mass index (BMI) exceeding 60 kg/m^2 was noticed, leading to the staged procedure concept: LSG first and the second step after reasonable weight loss, assuring better safety profile for the patient and less hostile operative field for the surgeon. Unexpectedly, some patients did not require the second procedure as weight loss and results were good enough for the patient and even for the surgeon. These experiences in United States of America (USA), Belgium and Germany were the basis for the introduction of LSG as single-stage procedure into the spectrum of obesity procedures.

The current value of stand-alone sleeve gastrectomy within the spectrum of surgical weight-reducing and metabolic procedures is still under discussion. LSG may not be the desired universal procedure for bariatric surgery but it is certainly an attractive treatment option. It should be performed in a standardized manner and with due regard to future long-term results, which are currently lacking.

In LSG, up to 90 % of the stomach reservoir is removed, leaving a sleeve of not more than 100 mL capacity. It also removes the fundus with its ghrelin hormone-producing cells. Gastric restriction and the associated hormonal changes, together with postulated changes in alimentary tract motility, seem to explain the outcome of the procedure. The capacity of the resected specimen is variable among patients and can exceed 3 l (Fig. 27.1).

27.2 LSG Complications

Although theoretically LSG is a simple procedure, it requires thorough understanding of the associated anatomical and physiological changes. It is, therefore, better performed by a highly experienced team, who can diagnose and timely manage any deviation from the normal postoperative course. Otherwise, potentially devastating outcomes can occur. Recent data from the USA reported postoperative complication rates

Fig. 27.1 Capacity of the resected stomach specimen can exceed 3 l

ranging between 2.2 and 10.8 % [4–6]. Retrospective analysis of our unit's data revealed an early postoperative morbidity rate of 7.1 % [7].

Complications can be divided into intraoperative, early postoperative and late postoperative complications. Early postoperative complications include, primarily, leakage and bleeding. Deep vein thrombosis is another potentially life-threatening complication. Late postoperative complications include delayed postoperative leakage with fistula or abscess development and sleeve stenosis. Nutritional complications, although not specific to sleeve gastrectomy, require specific attention. Other less common complications including trocar-site herniation and adhesive intestinal obstruction have also been reported. Post-LSG mortality is a rare event but could occur after any of these complications.

In order to prevent and timely manage the LSG complications, a triad of adequate preoperative preparation, adoption of standardized operative technique and meticulous postoperative care is strongly recommended.

27.3 Standard Perioperative Protocol

Our experience with LSG commenced in 2001 and since then we have developed a more or less standardized technique for the procedure [8]. When discussing the issue of LSG complications and their management, it is necessary to outline our perioperative protocol which, in our opinion, helps to prevent, detect and manage potential complications.

Patients are instructed to follow a liquid low-calorie diet preoperatively, aiming to achieve preoperative weight loss. This helps to reduce hepatic and intra-abdominal fat leading to better exposure of the operative field. Additionally, initial weight loss may prepare the patient for future gastric restriction.

Upper gastrointestinal endoscopic study, assessment of pulmonary function, checking of cardiac state, anesthetic consultation and routine laboratory investigations are mandatory for all patients. Enoxaparin sodium (CLEXANE®, Sanofi-Aventis®, 40 mg once-daily subcutaneous injection) together with anti-embolic compression stocking usage starts the day before operation until the day of discharge.

A third-generation cephalosporin is infused intravenously intraoperatively. Muscle splitting trocars are routinely used. A 42-Fr orogastric bougie is inserted and linear green (and blue, if needed) staple loads are used. Overriding (migratory) staples are removed at the point of transition between staple loads because leaving them may cause a misfire of the next staple load.

Peri-Strips Dry® with Veritas® Collagen Matrix (Synovis®) reinforces the staple line as needed. In our experience, the use of buttressing materials decreases the rate of complications after LSG [9]. Based on that experience, we recommend staple-line reinforcement during LSG, where a long stapling distance and cutting through a relatively thick antrum may adversely affect the integrity of the stapled tissues.

In a meta-analysis, Sajid et al. [10] associated the use of buttressing materials with decreased operative times and leakage rate. Lower bleeding rate along the staple line is reported with the use of Bioabsorbable Seamguard® in LSG [11]. The use of staple buttressing in LSG is discussed in more detail in Chap. 29.

We use hemostatic sutures or ultrasonic coagulation to assure hemostasis. Methylene blue testing, to check the integrity of the sleeve, is not a standard practice in our unit. The use and choice of intraoperative leak tests are a matter of debate and most authors have emphasized the benefit [12, 13]. Air insufflation using intraoperative endoscopy is preferred by some authors as this can check for luminal integrity of the constructed sleeve at the same time [14, 15]. Others, however, prefer methylene blue injection through the inserted gastric bougie or orogastric tube [16]. We routinely place a drain in the vicinity of the staple line.

Patients are admitted to the postoperative overnight intensive care unit (ICU) for adequate hemodynamic and hourly urinary catheter output monitoring. Early postoperative ambulation is recommended for all patients. Oral sips are encouraged on the first postoperative day, progressing gradually to soft food by the time of discharge.

Persistent unexplained tachycardia of more than 100 beats/min, fever (≥38.5 °C), abdominal pain, tachypnea (>20 breaths/min) or decreased urinary output despite good hydration are handled with a high index of suspicion. Laboratory findings of C-reactive protein (CRP) >150 mg/L or leukocytosis >11,000 cells/μ[mu] L also suggest the development of complications. CRP level and complete blood count are routinely checked on the first and fifth postoperative day. Diagnostic radiological and endoscopic tools are readily available but are not used routinely in uncomplicated cases. In our center, all patients are discharged on the fifth postoperative day, as long as the postoperative course is smooth. Some centers discharge their patients as early as the first postoperative day [17] while others report a postoperative hospital stay of 2–3 days in the absence of complications [18, 19]. Our experience suggests that postoperative hospital stay of up to 5 days ensures adequate perioperative patient assessment, unless postoperative complications necessitating a prolonged hospital stay are encountered. Governmental health insurance routinely covers the costs of the procedure, as long as an operative indication is present.

27.4 Intraoperative Complications

Like other bariatric procedures, LSG is performed in a patient group with markedly limited intra-abdominal compartment space due to intra-abdominal fat deposition and an enlarged fatty liver. These together with a thick abdominal wall, which adds the burden of limited trocar manipulation and further increase in the intra-abdominal pressure, increase the risk of intraoperative complications. As previously discussed, we recommend preoperative liquid low-caloric diet which helps to reduce the amount of intra-abdominal fat and liver size with a subsequent better exposure of the operative field. Complications including inadvertent vascular, hollow or solid organ injury can be encountered and require immediate intervention. Decision of conversion into conventional open techniques should never be delayed.

Staple-line bleeding is a common intraoperative event which should be managed with meticulous care. Absolute hemostasis should be ensured intraoperatively. Otherwise, acute or delayed postoperative bleeding and hematoma formation can be anticipated. Peri-Strips Dry® with Veritas® Collagen Matrix (Synovis®) proved, in our experience, to reduce the risk of bleeding [9]. Additionally, over-sewing, clip application and ultrasonic coagulation may be used to achieve satisfactory intraoperative results.

Technical controversies regarding sleeve gastrectomy are discussed in Chap. 29.

27.5 Diagnosis and Management of Post-LSG Complications

Accurate diagnosis and timely management of post-LSG complications can be highly challenging. Particular care must be given to this high-risk patient group, where results of laboratory parameters may be misleading. Reliable clinical evaluation and interpretation of radiological studies pose another challenge. Thus, diagnosis and management of post-LSG complications require an integrated teamwork approach which analyzes the triad of clinical suspicion, altered laboratory profile and abnormal radiological studies. More importantly, to date, we lack a consensus for sound management of those complications. Currently, results about different management options for these patients are limited to case series and personal experience from high volume centers.

27.5.1 Diagnosis of Post-LSG Complications

27.5.1.1 Laboratory Parameters

Routine postoperative check of patient's laboratory profile (full blood count and CRP) should be a standard practice. Any deviation from the normal values should be strictly monitored. CRP and leukocyte count play a major role in the early detection of postoperative complications, especially staple line disruption and leakage [20]. Elevated serum CRP levels show higher sensitivity and specificity for these early complications than the leukocyte count [20]. Analysis of our data showed that elevated CRP and leukocytosis were detected in 18 patients (36.5 %) out of 49 patients with early postoperative complications, including all 12 patients (100 %) who developed early postoperative leakage [7].

Postoperative check of hemoglobin level is also mandatory. A drop of more than 2 g/dL should warrant further work up, especially if combined with tachycardia, gastrointestinal bleeding or excessive bloody drain effluent.

27.5.1.2 Clinical Symptoms and Signs

Abdominal pain, nausea and vomiting requiring excessive analgesic or antiemetic requirements raise the suspicion of possible complications. Hypotension, tachycardia, fever, tachypnea, dyspnea, low urinary output and abnormal color or increased volume of drain effluent should also be handled with a high index of suspicion [21]. Additionally, haematemesis or melena raise the possibility of staple line bleeding. To date, the sensitivity and specificity of these parameters have not well studied. Tachycardia seems to be correlated with the highest sensitivity and specificity amongst the other parameters [22, 23]. However, one study claimed that fever is the most accurate diagnostic sign for gastric leaks [23]. In our center, tachycardia was found in five patients (42 %) and seven patients (37 %) who developed early postoperative leakage and bleeding respectively [7].

27.5.1.3 Radiological Studies

Extravasation of gastric contents outside the sleeve lumen can be diagnosed radiologically by contrast-enhanced computed tomography (CT) scans with oral contrast (Fig. 27.2) or gastrografin swallow studies (Fig. 27.3). The

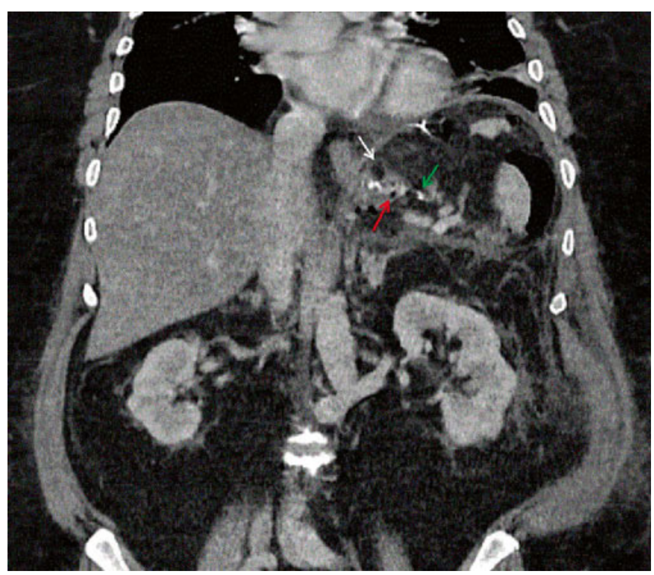

Fig. 27.2 Acute post-LSG leakage detected by contrast-enhanced CT scan. Note the sleeve lumen (*white arrow*), the trickling of contrast material outside the sleeve lumen (*green arrow*) and the air foci in the vicinity of the constructed sleeve (*red arrow*)

presence of an abscess cavity, air foci (Fig. 27.2) in the vicinity of operative field or stranding in the mesentery on CT scans raise the possibility of leaking sleeve. Pleural effusion or pneumonia may also be suggestive of an underlying leak [24].

Intra- as well as extra-luminal bleeding can be diagnosed by CT scans [25, 26]. The same applies to abdominal wall bleeding and intraoperative solid organ injury. However when intra-peritoneal bleeding is suspected, it is often safer for the patient to undergo an exploratory laparoscopy rather than wait for cross-sectional imaging.

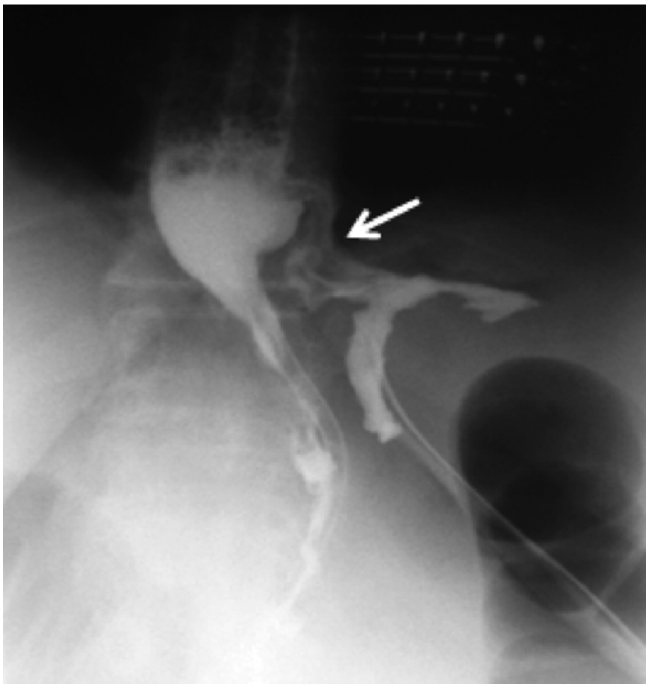

Fig. 27.3 Post-LSG leakage can be detected by gastrografin upper GI swallows (*arrow*)

Radiological studies are the corner stone in the diagnosis of postoperative pulmonary embolism.

Some authors perform routine postoperative gastrografin upper GI series for all their patients due to simplicity and relatively low cost of the procedure [27]. Negative studies should not however mislead the surgeon in the presence of a strong clinical suspicion [21]. Mittermair et al. [28] reported complete failure of gastrografin series to detect leakages in their patients. Such data together with the resulting radiation exposure attributed to those modalities raises the question of the necessity of its routine postoperative use.

27.5.1.4 Diagnostic Laparoscopy (DL)

DL is the most reliable tool to confirm or exclude serious postoperative complications namely leakage, extra-luminal bleeding and trocar-site hernia in patients with suspicious clinical, laboratory or radiological findings. In our personal series, we have observed a 100 % specificity for DL in 23 patients with complicated LSG; DL confirmed their unsatisfactory post-LSG course (13 patients with bleeding, nine with leakage and one with trocar-site hernia). This is compared with a specificity of only 70 % in 33 patients with suspected complications after laparoscopic Roux-en-Y gastric bypass (RYGB) where DL confirmed complications suspected by routine postoperative check in only 23 patients (12 patients with leakage, seven with bleeding, three with trocar site hernia, and one with small bowel obstruction) and it was negative in 10 patients (Table 27.1). It could be attributed to the fact that DL can miss some complications such as transient internal herniation, twisted gastro-jejunal or entero-enteral anastomotic reconstruction, intussusception or anastomotic

Table 27.1 Value of diagnostic laparoscopy (DL) in patients with a suspicious (*) postoperative course after LSG VS. LRYGB

First detected indication for DL	LSG N=23 Diagnosis confirmed by positive DL	LSG N=23 Negative DL	LRYGB N=33 Diagnosis confirmed by positive DL	LRYGB N=33 Negative DL
Elevated CRP	Leakage: 7	0	Leakage: 9 Trocar site hernia: 2	4
Tachycardia	Bleeding: 9 Leakage: 1	0	Bleeding: 6 Leakage: 3	4
Abdominal pain	Bleeding: 3 Trocar site hernia: 1	0	Bleeding: 1 Trocar site hernia: 1 SBO: 1	2
Suspicious CT scan	Bleeding: 1 Leakage: 1	0		0
Total number (%)	23 (100 %) ($p<0.05$)	0 (0 %)	23 (70 %)	10 (30 %)

Values refer to number of patients in whom DL was done and confirmed or excluded a suspected acute post-LSG complication
LRYGB laparoscopic Roux-en-Y gastric bypass, *SBO* small bowel obstruction
*Suspicious means: Persistent unexplained tachycardia of more than 100 beats/min, fever (≥38.5 °C), a more than routinely-encountered postoperative abdominal pain, tachypnea (>20 breaths/min), or decreased urinary output despite good hydration, C-reactive protein (CRP) >150 mg/1, leukocytosis >11,000 cells/μ[mu] l or a suspicious CT scan

ulcer post-RYGB. These factors can lead to transient deviation from normal post-RYGB course but are not encountered after LSG. The results are currently under further analysis for future publication.

27.5.2 Management of Post-LSG Complications

27.5.2.1 Early Post-LSG Complications

Leakage

Post-LSG leakage is a serious complication defined as extravasation of gastric contents outside the sleeve lumen. Arbitrarily leaks are divided into: acute leaks (within the first postoperative week), early leaks (within 6 weeks), late leaks (after 6 weeks) and chronic leaks (after 12 weeks) [29]. Acute leakages are the most hazardous complication with potentially fatal outcome without timely management. The leak usually occurs at the proximal or the distal ends of the staple line. Proximal gastric leaks, however, represent more than 90 % of post-LSG leaks [30]. Possible mechanisms of post-LSG leaks are classified into mechanical, tissue and ischemic causes [13]. Mechanical causes are attributed to high intragastric pressure in the constructed sleeve due to the mechanical obstruction by L-shaped sleeve, physiologic pyloric obstruction, haematoma or oedema formation, too small bougie size or reinforcing sutures causing excessive narrowing [31]. They are responsible for leaks in the first two postoperative days. Tissue causes represent excessive gastric stretching exceeding the tensile strength of the proximal thin walled stomach or encroachment onto the lower esophagus. This can be avoided by leaving an island of 1–2 cm lateral to the angle of His. The ischemic theory is attributed to the development of critical ischemic area corresponding to the gastro-esophageal junction just at the angle of His [32]. Tissue causes are responsible for leaks up to the sixth postoperative day. Recent reports documented an average incidence of 1.1 % for post-LSG leaks [33]. Analysis of data of more than 680 patients who underwent LSG in our clinic, in the last 3 years, revealed a slightly higher incidence of 1.7 % (12 patients). Others reported leakage rates ranging from zero percent to 3.9 % [29].

Management strategies described for acute leaks can be broadly classified as surgical and endoscopic. Surgical management starts with thorough abdominal lavage and drainage [34, 7]. Suturing of the leak site has also been described [34] but may be of limited value due to friable tissue at the site of the leak [35]. Early suturing of the leak has been associated with better results in one study when compared with delayed suturing [34]. We think that early suturing of the leaking site, when accompanied with suction drainage, can be a suitable option [7].

Chour et al. [36] studied the efficacy of anastomsing the leaking site to a Roux limb. This technique resulted in healing in all six patients. Early use of the procedure in two patients significantly reduced the length of hospital stay and its costs when compared to the four patients who had delayed Roux limb placement in this study [36]. Trials implementing a gastrostomy tube or a T-tube at the leaking site have also been performed. It may be appropriate to insert a feeding jejunostomy during the diagnostic laparoscopy if a leak is confirmed as this enables enteral feeding directly into the small bowel [25, 37]. However, large-sized series are needed to confirm the efficacy of the practice.

Some recent reports show that aggressive surgical approaches [35] are being abandoned in favor of more conservative management [34] which are centered on adequate drainage. It can be achieved by drain placement either with image-guided techniques or leaving the same drain that was inserted during initial surgery (if still present and if located in an adequate position) [34]. Although intraoperative drain placement is practiced only in 39 % of cases [34], it is a standard practice in all our LSG patients [7]. Endoscopic stenting (as a sole procedure or combined with other surgical or percutaneous procedures) plays a considerable role in managing post-LSG leaks. Endoscopic stents are thought to promote healing by bypassing the leaking site, allowing for undisturbed healing and enabling enteral nutrition at the same time. The success rate of stenting has been reported as varying between 50 and 100 % [38–40]. Lower success rate in some studies may be related to stent migration (Polyflex (polyester, silicone) stents) [41]. On the other hand, Nitinol stents have less tendency to migrate but have higher propensity for marginal mucosal growth [42]. Therefore, these endoscopic stents need to be removed or replaced within 6 weeks after insertion [43]. Stent-related discomfort (nausea, vomiting and retrosternal discomfort) is also commonly reported [44].

Other endoscopic modalities have also been tried with varying success. Papavramidis et al. [45] showed excellent results for endoscopic fibrin glue injection in three patients (50 %) who developed post-LSG leakage and did not respond to parenteral nutrition and somatostatin. Conio et al. [46] described the efficacy of using an over-the-scope clip for managing early post-LSG leakage. Pequignot et al. [43] described the use of endoscopically placed pigtail drain and reported that this was tolerated better and safer than endoscopic stenting. They also reported shorter healing time with this modality when compared to endoscopic stenting. Other treatment modalities such as endoscopic pneumatic dilatation of distal narrowing or pylorus are also reported [33]. Further studies are warranted to confirm the efficacy of these endoscopic treatment modalities and to compare the results.

Percutaneous radiologically guided drainage was also tested as a temporary procedure before implementing definitive surgical or endoscopic modalities [16, 43]. It should be balanced against its potential risk of future fistulous tract development.

In our experience, a combination of surgical intervention (over-sewing (Fig. 27.4), suction drainage) and endoscopic stenting (Niti-S Fully Covered Esophageal Stent®, Taewoong Medical Co., Ltd.) assures better control of early leakage after LSG (Table 27.2) [7]. Patients should be kept well nourished (we prefer the use of parenteral nutrition) and covered with intravenous broad spectrum antibiotics to control sepsis. Return to oral intake should be under strict clinical monitoring, with confirmation of healing by gastrografin upper GI studies or contrast enhanced CT scans if clinically indicated. We recommend that stents are removed within 6 weeks of insertion for further patient evaluation as to whether stenting has achieved closure of the leak [29]. Figure 27.5 shows our recommended diagnosis and management plan for patients with suspected acute post-LSG leakage.

Bleeding

The incidence of bleeding after obesity surgery ranges from 0.6 to 4 % [47, 48]. Stapling through a thick, highly vascular gastric wall can be followed by considerable amount of intra- as well as extra-luminal (intra-peritoneal) bleeding. We reported a post-LSG bleeding rate of 2.7 % (19 among 686 patients) (Table 27.3) [7]. Bleeding should be controlled by surgical intervention (hematoma evacuation, over-sewing, and drainage) in hemodynamically unstable patients. In hemodynamically stable patients, we usually resort to conservative methods with fluid resuscitation, blood transfusion (if necessary) and careful observation. We do not recommend withdrawal of prophylactic anticoagulation in patients who encounter post-LSG bleeding as we believe that post-LSG bleeding can be adequately controlled (conservatively or surgically) in the presence of prophylactic parenteral anticoagulation [7]. Lack of postoperative prophylaxis carries 2.4 % risk of developing fatal thromboembolic accidents [49]. Mechanical compression alone does not achieve the intended anticoagulant efficacy [50]. High intra-abdominal pressure may momentarily tamponade the sites of intraoperative bleeding. The effect is exaggerated if an abnormally high intra-abdominal pressure is encountered. It is typically seen in patients with history of anterior abdominal wall operations, especially who underwent abdominoplasty. Particular care is advised in that patient group. Absolute intraoperative haemostasis and blood pressure control are a must.

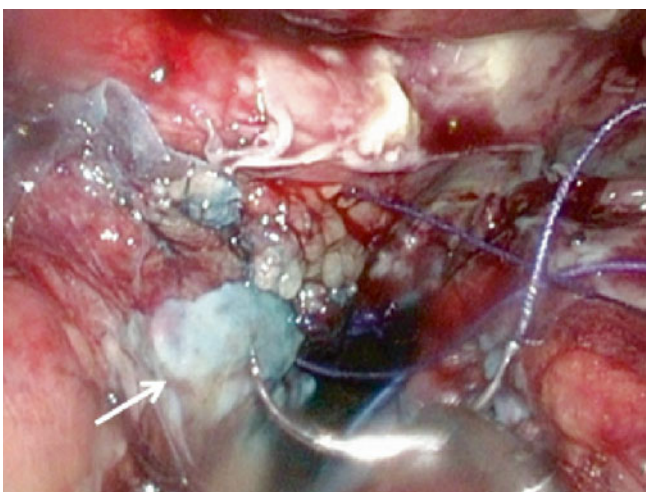

Fig. 27.4 Acute post-LSG leakage (*arrow*) was detected during DL by methylene blue testing and over-sewing was successfully performed in this case

Trocar-Site Hernia

Trocar-site herniation should always be kept in mind in patients presenting with abdominal pain or obstructive symptoms. Some surgeons dilate the trocar site to facilitate the extraction of the gastric specimen. Additionally, the thick subcutaneous fatty layer in these patients makes the timely diagnosis challenging. Unexplained trocar site pain or swelling in addition to clinical or laboratory evidence of bowel or mesenteric incarceration are helpful for diagnosis. The average reported incidence for the complication is 1 % [51]. We encountered only one case of trocar-site herniation (0.14 %) in our patient group which necessitated laparoscopic revision [7].

Venous Thromboembolism VTE (Deep Venous Thrombosis and Pulmonary Embolism)

Although it is not specific to LSG, VTE can be a life-threatening event. Adequate prophylactic anticoagulant

Table 27.2 Different modalities of intervention for acute post-LSG leakage in our clinic

Intervention			Patients with acute post-LSG leakage (N = 12/686)	Range of time to healing of leakage (days)
Reoperation (over sewing, lavage and suction drainage)	Laparoscopic	Plus stenting	6	21–33 (one patient who died)
		Without stenting	3	11–20
	Open	Plus stenting	2	50–92
		Without stenting	–	
Endoscopic stenting only			1	37

Values refer to number of patients in whom the corresponding technique was used

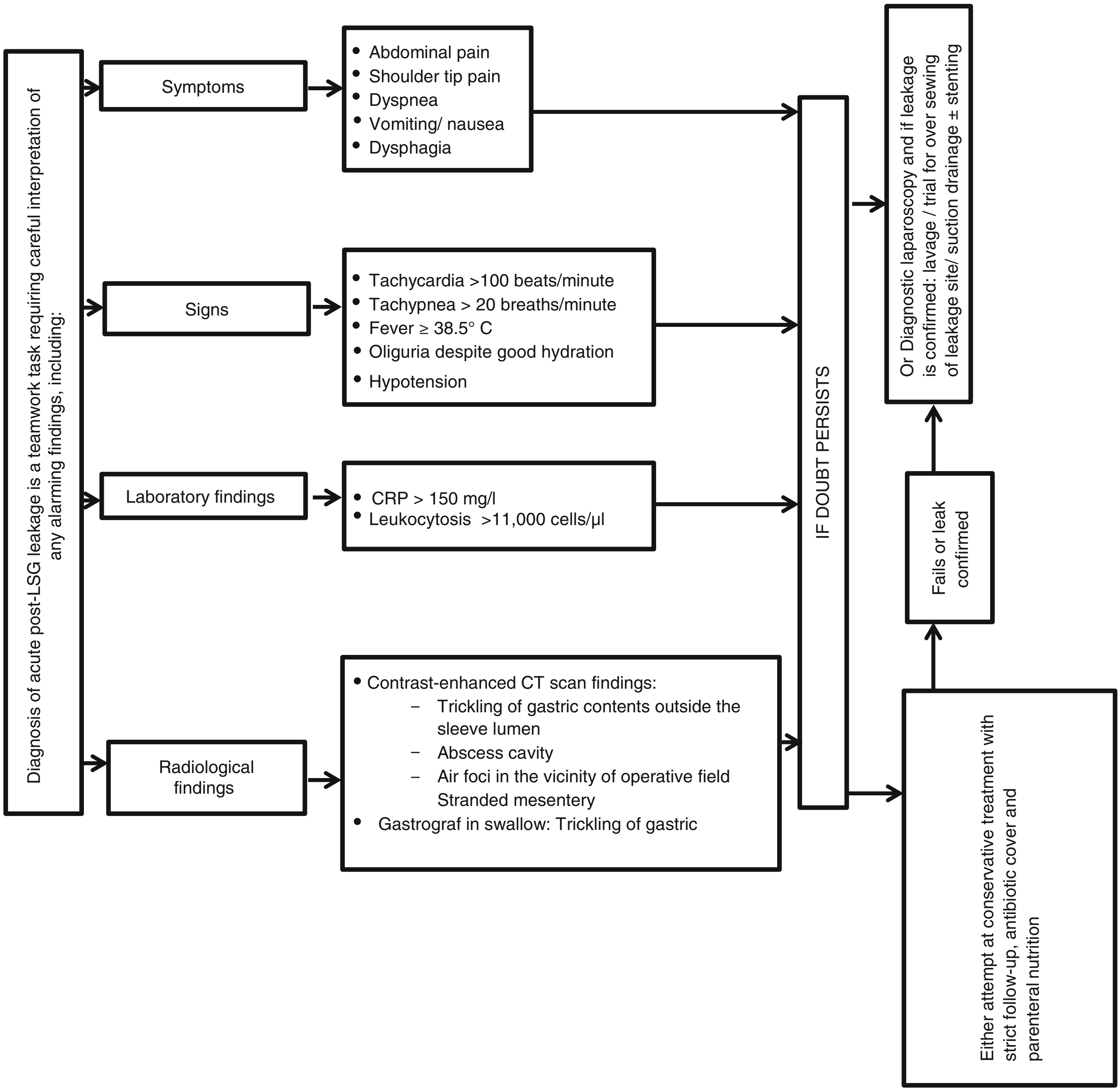

Fig. 27.5 Management of patients with suspected acute post-LSG leakage

Table 27.3 Different sites of post-LSG bleeding in our clinic by sex and BMI [7].

	Number of patients with acute post-LSG bleeding				
	Males		Females		Incidence
BMI (kg/m²)	<50	>50	<50	>50	
Bleeding (total)	4	4	6	5	2.7 % (19/686)
Extraluminal	4	3	4	4	
Intraluminal	0	0	0	0	
Combined	0	0	1	0	
Abdominal wall	0	1	1	1	

measures and early ambulation should be implemented to guard against its development. Prompt diagnosis and therapeutic management should be practiced to avoid fatal outcome. The incidence of VTE after RYGB has been reported to be between 0 and 1.3 % [52]. To our knowledge, we have had only one clinical case (0.14 %) of deep venous thrombosis which was diagnosed by lower limb Duplex study. Medical management was successful in the case and the patient made an uneventful recovery [7].

27.5.2.2 Late Post-LSG Complications

Late Post-LSG Leakage

Late leaks may result from delayed ischemic changes associated with mobilization of the greater curvature or from delayed manifestation of thermal damage. The exact mechanism, however, is not well studied. Just like acute post-LSG leakage, delayed leakage may present with classical symptoms and signs of peritoneal irritation. Diagnosis is based on the same steps as for diagnosing an acute leakage (Fig. 27.5). It may also present with atypical clinical manifestations such as upper abdominal pain, food intolerance or gastroesophageal reflux. When a late leak is suspected, patients should be thoroughly investigated by endoscopy, gastrografin upper GI studies and CT scans.

Late post-LSG leakage can present as: a free intraperitoneal leakage, an encapsulated abscess cavity (Fig. 27.6) or a fistulous tract starting from the gastric wall and extending to the skin (Fig. 27.7), internal abdominal organs or even the bronchial tree [53, 54]. Sometimes the tract can end blindly in a sinus form (Fig. 27.8). While management of acute leakage is mainly centered on the elimination of septic state due to the friability of involved area, the tissues in cases of delayed leakage are much more tolerant for ultimate cure. Clearance of septic foci must be attempted—this can be achieved by conventional, laparoscopic approaches or radiological guidance. Over-sewing of the leakage site can also be attempted. Drainage of post-LSG leakage should be under

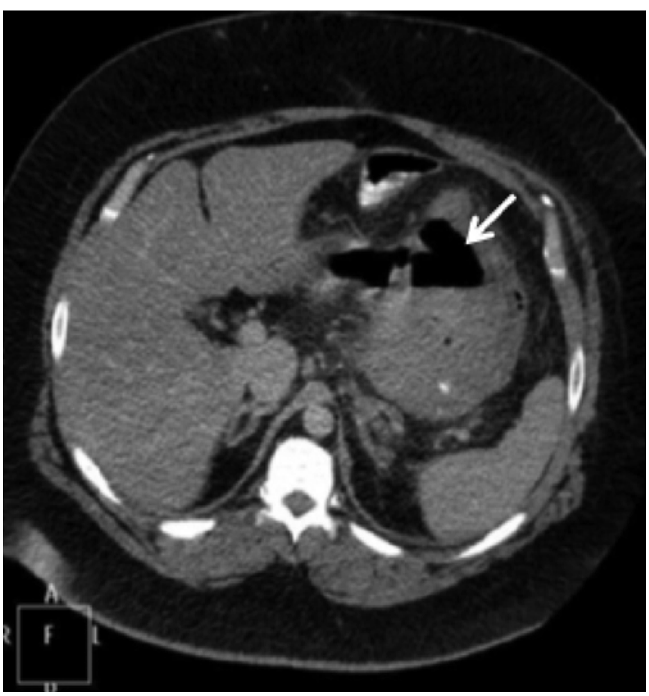

Fig. 27.6 Delayed post-LSG leakage presenting as an abscess in CT scan (*arrow*)

Fig. 27.7 Post-LSG gastro-cutaneous fistula (*arrow*) following delayed post-LSG leakage

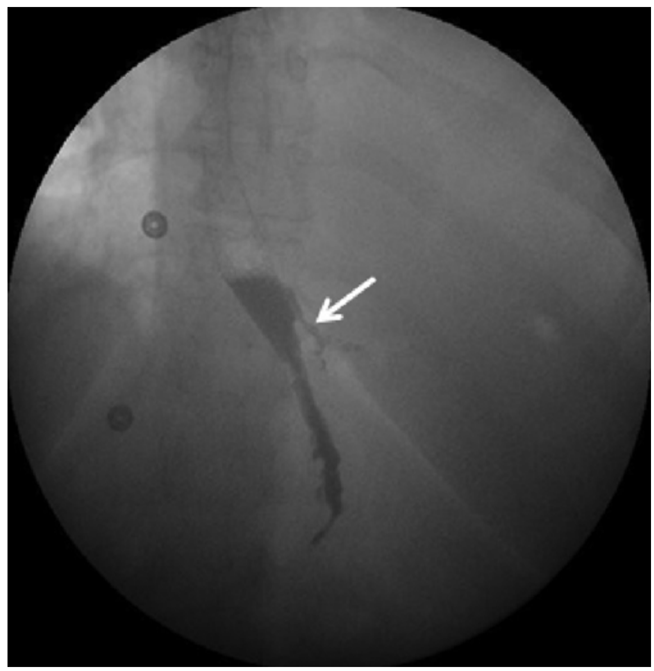

Fig. 27.8 Delayed proximal post-LSG leakage presenting as a blind sinus (*arrow*) of gastrografin upper GI swallow

negative suction as it allows immediate drainage of any septic content. We recommend gradually withdrawing the drain, over days, allowing healing of the leaking site. Endoscopic stenting plays a major role in post-LSG leakage. We avoid metallic stents (Fig. 27.9) and use self-expanding covered stents (Niti-S Fully Covered Esophageal Stent®, Taewoong Medical Co., Ltd.) in this setting instead. Stents should be removed within 6 weeks after insertion as leaving one in situ for more than 6 weeks will not have any additive benefit. Additionally, gastric mucosal overgrowth and creeping on the stent hinder its future removal. Another treatment option

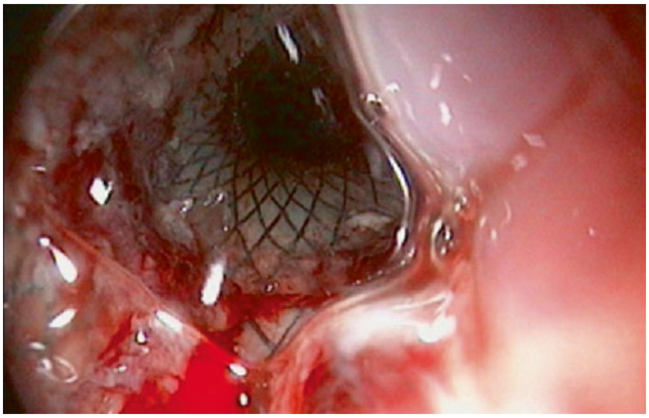

Fig. 27.9 Use of metallic stents can be hazardous, especially when left in place for a long time. This endoscopic picture refers to a patient who presented to us with post-LSG fistula, which was unsuccessfully managed by endoscopic stenting. Use of this stent was associated with severe dysphagia and epigastric pain requiring a high opioid consumption. In addition, endoscopic removal of the stent failed due to strong attachment to the overgrowing mucosa. The sleeve was converted into an open roux-en-Y gastric bypass and the stent was removed during the operation

is conversion to RYGB through refashioning of the leakage site and anastomosing it to Roux limb. This converts the leakage site into a point of anastomosis with Roux limb, allowing resumption of the oral intake which flows directly through the leaking point into the constructed roux limb. In addition, it accelerates the healing process at the leakage site by relieving the high pressure of constructed sleeve. We suggest that patients with post-LSG leakage should be put on broad spectrum antibiotics and nourished parenterally till adequate resumption of oral intake.

To date, there is paucity of literature regarding management of delayed post-LSG complications. Table 27.4 [24, 37, 55–61] summarizes some of the published studies.

Post-LSG Stenosis

Sleeve stenosis is a rare but serious complication which can lead to severe malnutrition unless properly managed. Parikh and colleagues [62] reported a 3.5 % incidence of post-LSG stenosis and quoted 0.26–4 % incidence in the world literature. Vilallonga et al. [63] reported 1.8 % incidence of post-LSG stenosis. The three main predisposing

Table 27.4 Some of the published studies in literature dealing with the management of delayed post-LSG leakage

Study	Year	Number of patients	Complication	Management	Outcome/mortality
De Aretxabala et al. [24]	2011	6	Late leak	Percutaneous drainage (1 patient) Laparoscopic re-operation (2 patients) Open re-operation (2 patients) Open re-operation with stent (1 patient)	Healing in 100 % of patients
Sakran et al. [55]	2012	2	Splenic abscess	Percutaneous then laparoscopic drainage (1 patient) Open splenectomy (1 patient)	Recovery in both patients
Dakwar et al. [56]	2013	1	Late leak presenting with inflammatory syndrome and abdominal pain	CT guided drainage and a 10 mm over-the-scope metallic clip	Healing
El Hassan et al. [37]	2013	5	Late leak (including entero-cutaneous fistula in 1 patient)	Jejunostomy tube and drainage Laparoscopic T tube at leak site if possible Resection of enterocutaneous fistula (1 patient)	Healing in 100 % of patients
Moszkowicz et al. [57]	2013	18	Late leak (including gastro-esophageal fistula in 2 patients and gastrobronchial fistula in 1 patient)	Total gastrectomy (6 patients) Gastrojejunostomy en-Ω [omega] after gastric division (3 patients) Endoscopic covered stent/ clipping/ sealing	1 patient died (5.5 %)
Vilallonga et al. [58]	2013	15	Chronic fistula	Laparoscopic Roux limb placement	Healing
Nedelcu et al. [59]	2013	8	Chronic fistula	Gastrojejunal lateral anastomosis (4 patients) RYGB (2 patients) Gastrectomy with esophago-jejunal anastomosis (2 patients)	No mortality was reported
Shimizu et al. [60]	2013	2	Chronic fistula	Conversion in RYGB	Healing
Ben Yaakov et al. [61]	2014	4	Persistent leak (gastrocutaneous fistula in one patient)	Operative suturing (1 patient) Endoscopic stenting (2 patients) Over-the-scope clip (3 patients) Percutaneous drainage (3 patients) Biological glue (2 patients)	Healing was achieved only after laparoscopic total gastrectomy with esophago-jejunostomy

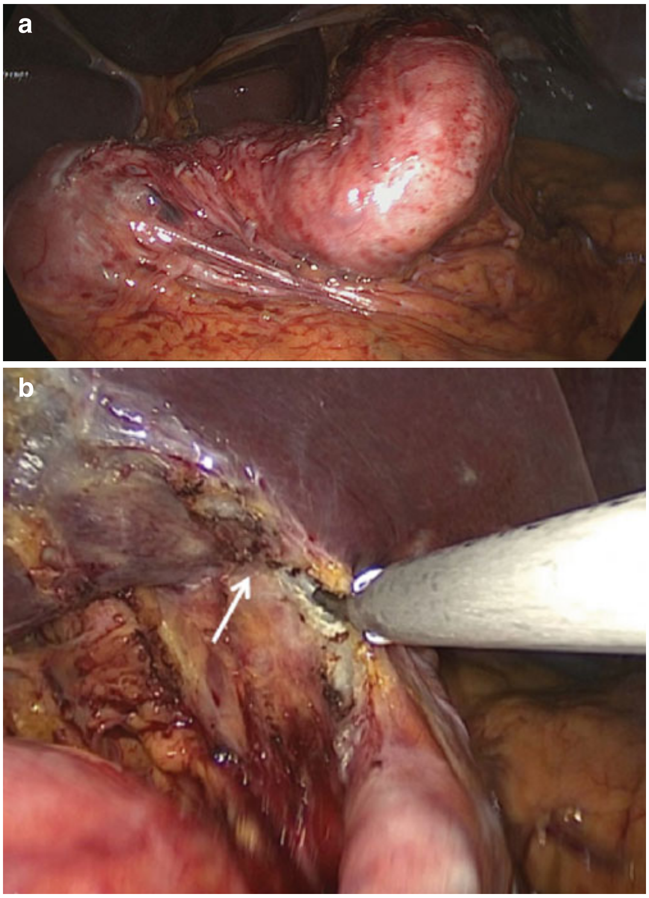

Fig. 27.10 Post-LSG adhesions (*arrow* in Fig. 27.12) as a cause of sleeve lumen stenosis

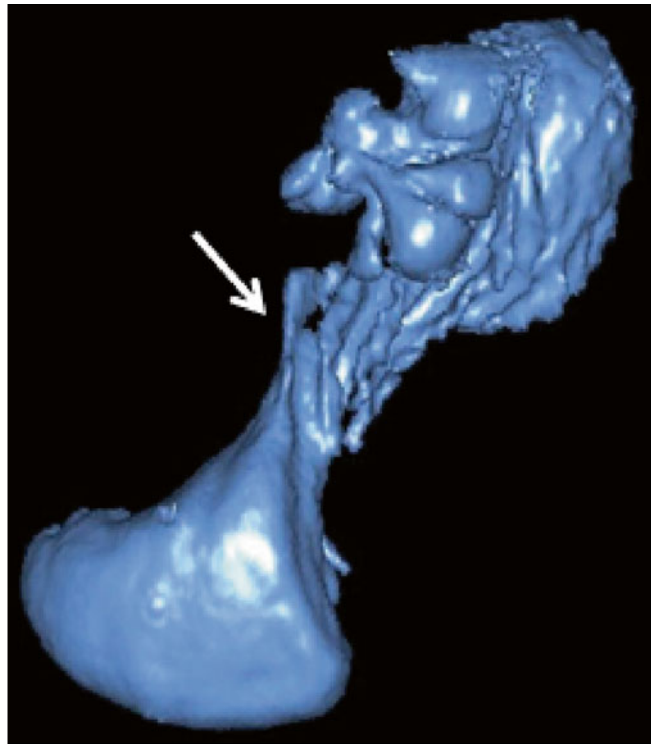

Fig. 27.11 Post-LSG adhesions may also cause twisting (*arrow*) of the sleeve with resultant stenosis of the sleeve lumen

factors are: asymmetrical lateral stomach traction, bougie size and extrinsic factors including adhesions (Figs. 27.10 and 27.11) or perigastric hematomas. Asymmetrical stomach traction seems to be a common problem that can give rise to this complication. Data regarding the effect of bougie size on the future incidence of stenosis is conflicting. We routinely use 42 Fr orogastric bougie during LSG and the stenosis rate low (0.8 %). Lalor et al. [64], despite using a 52 Fr bougie, reported a more or less similar stenosis rate (0.7 %). Therefore, we believe that bougie caliber is not the only predisposing factor. An interaction of all three predisposing factors seems to determine the development of stenosis.

The most common site for post-LSG stenosis is at the incisura angularis (Fig. 27.12) [63]. Patients with stenosis usually present with proximal obstructive symptoms ranging from intermittent vomiting and reflux symptoms to complete obstruction with a dramatic picture of severe weight loss and malnutrition. Diagnosis can be accomplished by gastrografin upper GI studies (Fig. 27.13) or contrast enhanced CT studies of the upper abdomen (Fig. 27.14). In our opinion, radiological imaging has higher accuracy than endoscopic assessment because the stenosed site may be passable with the endoscope, leading to false negative result.

Due to the paucity of literature regarding this complication, there is lack of standardized algorithms regarding management of post-LSG stenosis. We recommend endoscopic balloon dilatation as the first line of treatment. This may require multiple sessions over several weeks and should also be associated with a change to a liquid diet, ensuring adequate calorie intake and nutritional supplementation [62, 63]. Failure of balloon dilatation, tight sleeve stenosis, long-segment stenosis (Fig. 27.14c) or stenosis associated with other pathology (proximal fistula, abscess or delayed leakage) is usually an indication for surgical intervention.

In our opinion, conversion of the stenosed LSG to RYGB is followed by an excellent outcome and it also allows the management of the associated pathologies discussed above.

An important technical point to remember during conversion from a complicated LSG to RYGB is that the patient who previously had sleeve gastrectomy has already lost the gastric blood supply running along the greater curvature (gastroepiploic and short gastric vessels). The constructed sleeve thus depends mainly on the right and left gastric vessels. Therefore, when the sleeve in divided into the proximal and distal parts for RYGB construction, the blood supply of future proximal gastric pouch will be from the left gastric vessels. Extreme caution is therefore required during pouch construction to safeguard these vessels, especially where

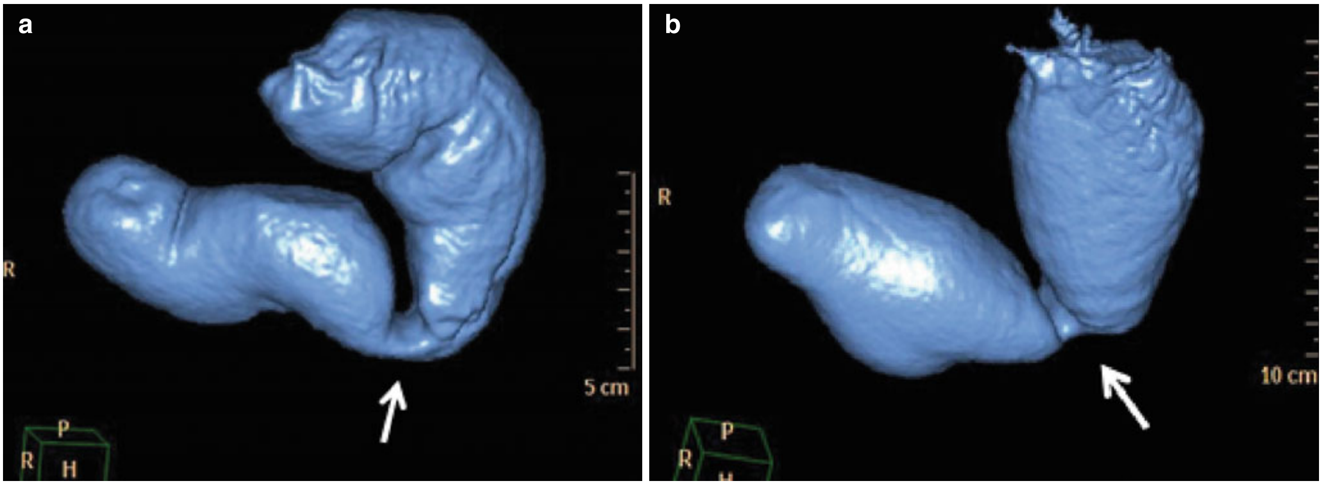

Fig. 27.12 Post-LSG angular stenosis (*arrows*)

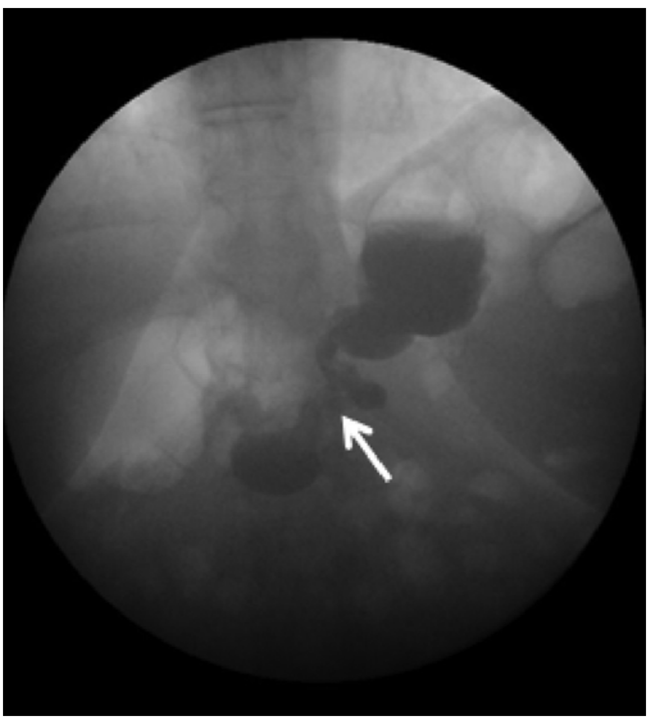

Fig. 27.13 Post-LSG stenosis (*arrow*) in a gastrografin swallow

extensive adhesions might be encountered. An alternative reasonable option is to place a roux limb proximal to the stenotic site without gastric division. It will achieve symptomatic resolution and also weight loss with the least possible intervention (Fig. 27.15).

Parikh et al. [62] reported ten patients with post-LSG stenosis; eight patients were managed conservatively by endoscopic dilatation and two patients required surgical conversion to RYGB. Burgos et al. [65] reported five cases; four of them were managed by endoscopic balloon dilatation and one patient required conversion to RYGB. All patients reported resolution of their complaints. Vilallonga et al. [63] studied the effect of seromyotomy and wedge resection of the stenotic area as the primary intervention modality in 16 patients (seromyotomy in 14 patients and wedge resection in 2 patients). Leakage (short term failure) of seromyotomy was reported in five patients (35.7 %), CT guided drainage was needed in two patients and second look laparoscopy was required in three patients. Long-term recurrence of the stricture was encountered in five patients (31.2 %) after seromyotomy, with wedge resection required in two patients and conversion to RYGB in three patients.

We postulate that sleeve stenosis can be divided into five main types, based upon the cause and the presentation:

- Type 1: Stenosis due to extra-gastric pathology example axial hiatal herniation (Fig. 27.16), peri-gastric hematoma or adhesions (Fig. 27.10b). This is best treated by managing the underlying cause of sleeve stenosis.
- Type 2: A short stenotic segment (Fig. 27.17) or stenosis which is amenable for endoscopic dilatation.
- Type 3: A long stenotic segment (Fig. 27.14c) or stenosis which is not amenable for endoscopic dilatation (Fig. 27.14d).
- Type 4: A completely obliterated sleeve lumen. This may result if a sleeve gastrectomy is performed without the use of a calibrating gastric bougie/endoscope (Fig. 27.18). Conversion to RYGB is the best treatment option.
- Type 5: A combination of the above causes (Fig. 27.14b). It is managed according to the underlying pathology and will often need surgery.

Types 2 and 3 can be managed by seromyotomy or endoscopic stenting. However, in our opinion, the short- and long-term results are not encouraging. Conversion to RYGB seems to be a better treatment option in those patients.

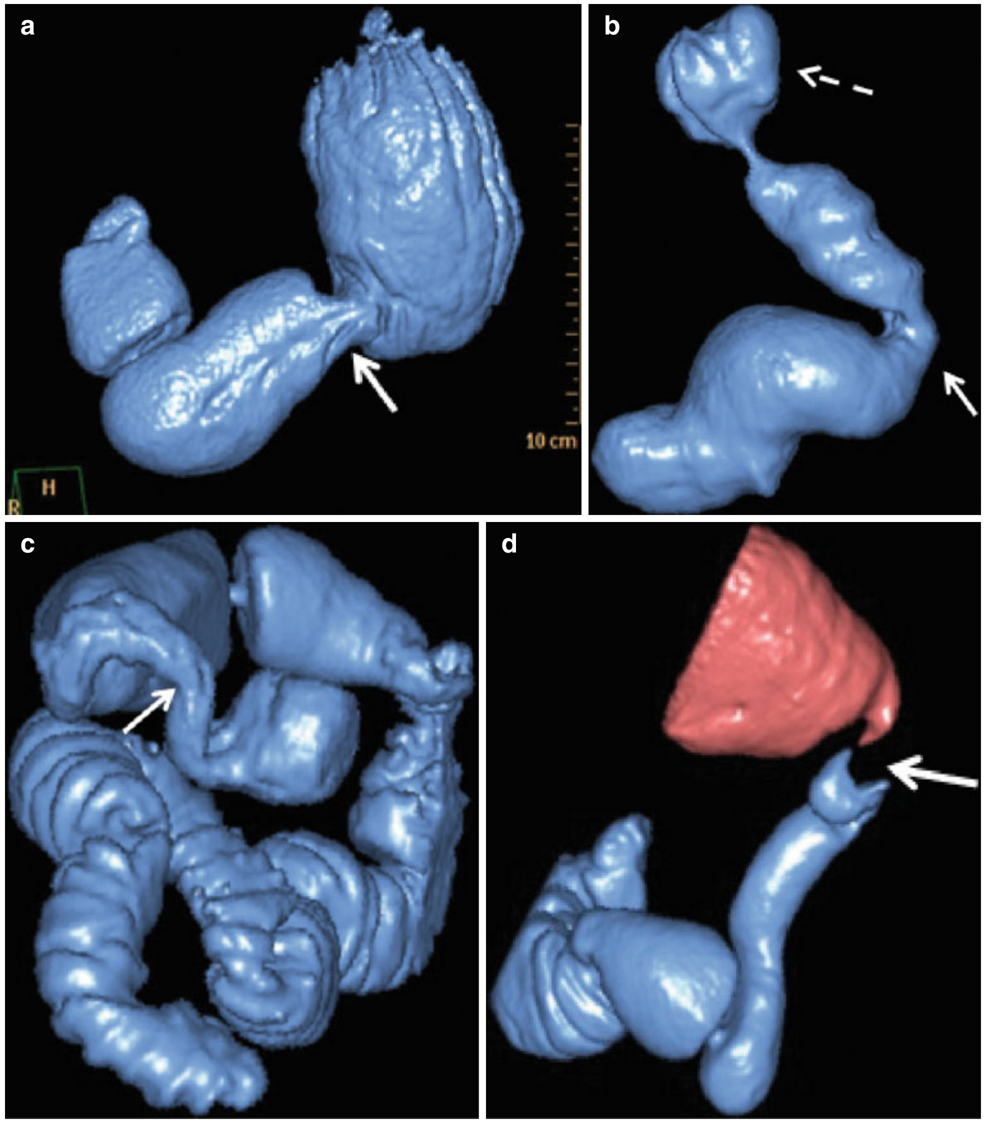

Fig. 27.14 (**a**) Contrast-enhanced CT studies are very diagnostic for post-LSG stenosis (*arrows*). Note the axial hiatal herniaion (*dashed arrow*) in (**b**), the long stenotic segment in (**c**) and the pre-stenotic gastric dilatation in (**d**) (*red colored*)

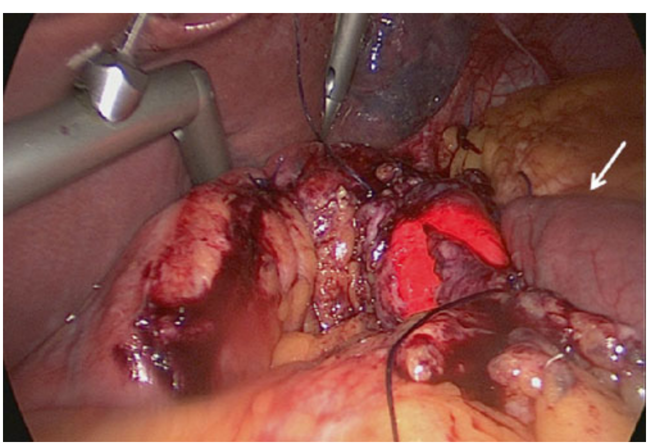

Fig. 27.15 Roux limb construction (*arrow*) without division of the stomach

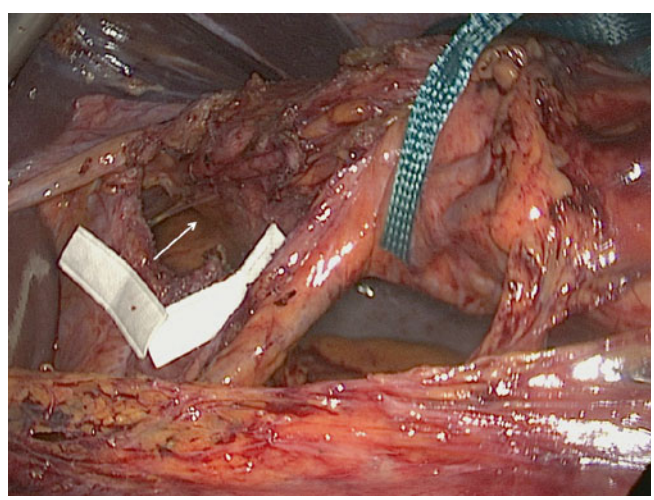

Fig. 27.16 Axial hiatal herniation (*arrow*) after sleeve gastrectomy may lead to sleeve stenosis

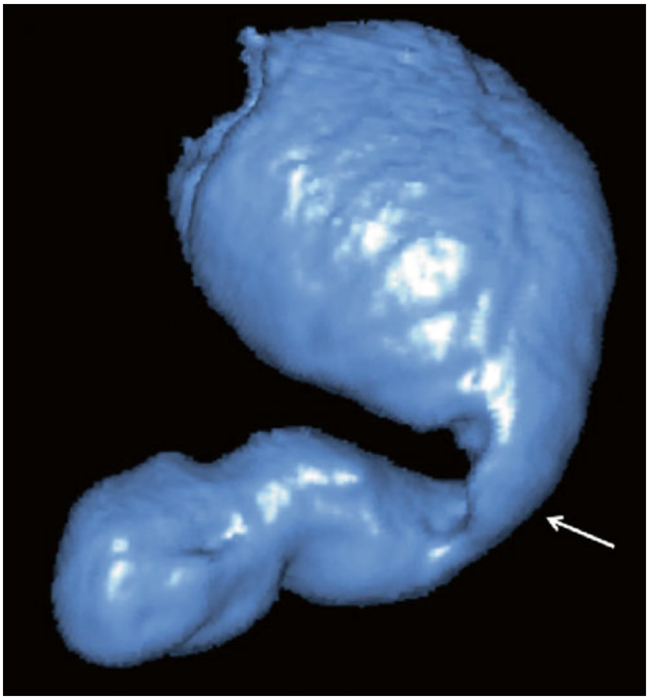

Fig. 27.17 A short post-LSG stenotic segment (*arrow*) can be amenable for endoscopic dilatation

In contrast to RYGB, LSG is a high pressure system due to gastric contraction against a contracting pylorus. The intra-gastric pressure increases even further if sleeve stenosis develops often leading to a proximal high pressure system which prevents sound healing of the staple line with the potential development of delayed complications (leakage, abscess or fistula).

Post-LSG Hematoma

Post-LSG haematoma can cause extrinsic pressure on the sleeve lumen leading to a presentation similar to post-LSG stenosis. Diagnosis depends on clinical, radiological and endoscopic assessment. Two patients presented to us with delayed post-LSG perigastric hematoma. Drainage of hematoma was satisfactory in these patients. However, patients should be monitored for recurrence.

To summarize, delayed post-LSG complications can be difficult to handle and may present with mixed pathologies. Managing a previously operated patient, sometimes referred from another medical facility, can be challenging as the patient may be septic (in cases of leakage) or malnourished (in cases of stenosis). We recommend that these complex

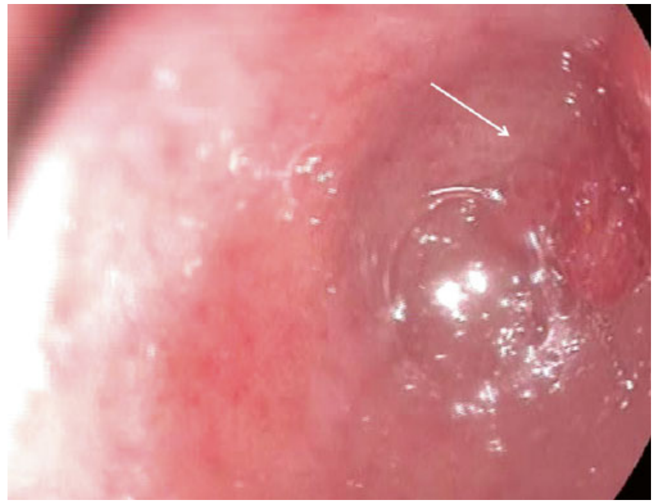

Fig. 27.18 A completely obliterated sleeve lumen (*arrow*) due to absent bougie

patients are managed in medical facilities with experienced personnel who not only can carry out different bariatric procedures but also can also perform other intervention modalities (endoscopy and interventional radiology). We propose our algorithm to manage late post-LSG complications (Fig. 27.19). This algorithm is based on an experience extending over more than a decade with about 50 patients who presented to us with the above mentioned late post-LSG complications.

Post-LSG Nutritional Complications

Nutritional support and follow-up is an integral part of post-LSG management program. Postoperatively, 89 % of the surgeons recommend supplements for their patients; of these, 72 % advice vitamin B_{12} preparations [33]. We recommend that all patients must follow a multivitamin replacement program identical to those who undergo RYGB.

Patients may suffer from severe malnutritional deficiencies resulting in Wernicke's encephalopathy, severe osteoporotic states and profound hair loss (Fig. 27.20) due to the neglect of postoperative nutritional supplement replacement. Patients at increased risk include those who have additional pathologies, mainly sleeve stenosis (Fig. 27.21). Patients presenting with clinically evident severe malnutritional status should be handled on an emergency basis with liberal parenteral multivitamin replacement in high doses, with particular attention to vitamin B1, vitamin B12, calcium and vitamin D_3 supplementation.

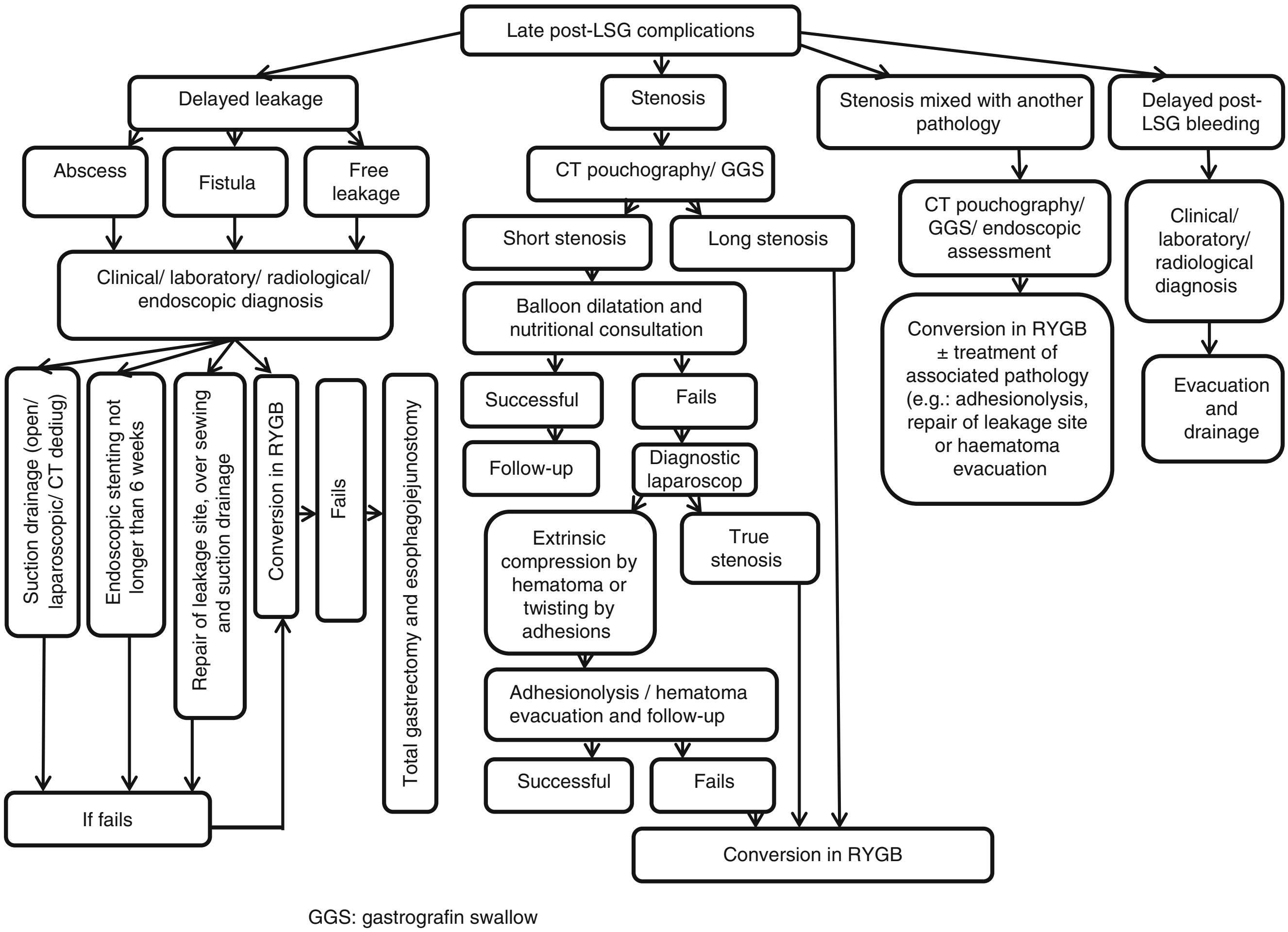

Fig. 27.19 Management of patients with late post-LSG complications

Post-LSG Mortality

Data from the Michigan Bariatric Surgery Collaborative showed no post-LSG mortality [5]. Analysis of the data of a large prospective national registry in Spain reported 0.36 % post-LSG mortality rate among 540 patients who were operated in 17 centers. It corresponded to two deaths (one due to multiple organ failure after reoperation due to port-site postoperative bleeding and the other due to respiratory failure with pneumonia) [66]. Data of the American College of Surgeons reported postoperative mortality rate of 0.11 % [4]. Recently, analysis of data of 46,133 patients who underwent LSG reported 0.33 % postoperative mortality [33]. In our published series, there was one case of post-LSG mortality (0.14 %) [7], where the patient succumbed from uncontrolled, fulminant sepsis following an early post-LSG leakage.

Fig. 27.20 Profound hair loss due to neglected nutritional replacement after LSG

Key Learning Points

- Although sleeve gastrectomy is theoretically a simple procedure, thorough understanding of the associated anatomical and physiological changes is mandatory. It is best performed by a highly experienced team who can diagnose and timely manage any deviation from the normal postoperative course.
- A triad of adequate preoperative preparation, adoption of standardized operative technique and meticulous postoperative care is essential.
- Diagnosis and management of post-LSG complications require an integrated teamwork approach which analyzes a triad of clinical suspicion, altered laboratory profile and abnormal radiological studies.
- Conversion of a complicated sleeve gastrectomy to RYGB can be a lifesaving procedure. The bariatric surgeon attempting this procedure must however have the operative skills required for RYGB and revisional surgery.
- Adequate nutritional supplementation, after sleeve gastrectomy, should be prescribed routinely for all patients.

Fig. 27.21 Dry gangrene of the extremities due to a severe state of malnutrition after LSG due to combined post-LSG stenosis and fistula development. This patient was treated by open conversion to RYGB

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28 LSG: Outcomes

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Abstract

Laparoscopic sleeve gastrectomy (LSG) is gaining widespread use and has displaced gastric banding in popularity. Short, medium, and long-term data regarding the weight loss associated with LSG and its durability are encouraging. Resolution of comorbidities and improvement in health-related quality of life are comparable or better than other bariatric procedures. In the long term, weight regain is a natural course in a proportion of patients who may undergo a second procedure. It is used as a first stage in a two-stage duodenal switch procedure for weight loss in the super-obese group. Gastroesophageal reflux disease (GERD) is a concern following LSG, but concomitant hiatal hernia repair may prevent this problem.

Keywords

Laparoscopic Sleeve Gastrectomy • Obesity • BMI • Outcome • Weight loss • Comorbidity • Quality of life

28.1 Introduction

Laparoscopic sleeve gastrectomy (LSG) has gained popularity in recent years around the world. It constitutes up to one-third of all the bariatric procedures performed in the USA [1, 2]. It also ranks as a leading procedure in Asia, Middle East, and Australia where obesity is prevalent and rising. The relative ease of technique, avoidance of insertion of a foreign body, and the immediate restriction of caloric intake led to its adoption by many bariatric centers throughout the world. LSG does not alter the gastrointestinal continuity. The procedure does not involve any anastomosis, thus eliminating the possibility of anastomosis related complications as seen to be associated with gastric bypass.

LSG also has the advantage of fewer perioperative complications, especially in the high-risk group. The long-term nutritional complications are low. Patients with inflammatory bowel disease, previous abdominal surgery, recurrent peptic ulcer disease, and protein-losing enteropathy are considered suitable for this procedure.

28.2 Technical Factors Affecting Outcome

Laparoscopic sleeve gastrectomy is an evolving procedure. Variations in technique such as the distance from the pylorus where the greater curvature resection begins, sizing of the antrum, ideal bougie size, completeness of resection of fundus, and identification and repair of hiatus hernia will make standardization of the technique difficult. This lack of standardization in the surgical technique has a bearing on the complications, efficacy, and durability reported in different studies. This has been discussed in detail in Chap. 29.

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28.3 Short-Term Weight Loss

Factors affecting the degree and duration of weight loss in LSG are not fully understood. Many published retrospective studies and a systematic review has shown that the excess body weight loss (EBWL) at 1–2 years after LSG can vary from 47 to 76 % [3–6]. This variation in outcomes is seen mainly because of a lack of standardization of the surgical technique.

Weight loss achieved after LSG is variable, but most studies report that it is comparable to that achieved by gastric bypass and better than the weight loss achieved following gastric banding [7, 8]. A single surgeon experience with 500 sleeve gastrectomy with 3-year follow-up showed that the mean EBWL was 76 %, 71 %, and 73 % at 12, 24, 36 months, respectively [9]. Short-term weight loss achieved by other surgeons is shown in Table 28.1. A study comparing LSG with laparoscopic adjustable gastric banding (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGB) found that weight loss at one year following LSG was 13 % lower than that after LRYGB, but 77 % higher than the weight loss achieved through gastric banding [17]. A comparative study between LSG and LRYGB showed that LSG is associated with fewer complications and similar weight loss after one year. Prospective and case-matched studies have claimed that LSG is safer with similar weight loss at 2 years when compared to LRYGB [18–20].

The first report from the American College of Surgeons Bariatric Surgery Center Network has placed LSG between band and bypass in terms of weight loss at one year. For LSG patients, the average reduction in body mass index (BMI) is 11.87 kg/m^2 at 1 year. In comparison, LAGB has a BMI reduction of 7.05 kg/m^2 and the LRYGB 15.34 kg/m^2 [21].

A review article including 24 studies and a total of 1749 patients showed a mean percentage EBWL of 60.7 % with the follow-up period ranging from 3 to 36 months after LSG [22].

Single anastomosis gastric bypass and laparoscopic greater curve plication are procedures that are increasingly being offered to patients. According to a report from India which compared single anastomosis gastric bypass (mini gastric bypass, Omega loop bypass) with LSG, the percentage EBWL was 63 % vs. 69 % at one year and 68 % vs. 51.2 % at five years [23]. Postoperative GERD was a less common finding with single anastomosis gastric bypass (2.8 %) than with LSG (21 %).

28.4 Long-Term Weight Loss

Studies with follow-up of 5 years or more after surgery are considered to be long-term at this point. This definition is likely to change as we follow patients up for a longer duration in the future. The technique used in all these studies show variation with regards to the size of bougie, distance from pylorus to the first staple, and use of staple-line reinforcement.

One study, in which the surgeon created a narrow sleeve with a gastroscope as bougie and started transection at 3 cm from the pylorus, had a follow-up rate of 90 % at 5-years [24]. The study showed an EBWL of 86 %. A recently published randomized trial quoted a greater weight loss in antral resecting-LSG than in the antral preserving-LSG group in one year though there was no significant statistical difference. There is an urgent need for more studies comparing antral preserving-LSG and antral resecting-LSG focusing on long term outcomes [25].

Another retrospective study revealed more than 50 % EBWL in 40 % of patients at five years and 10 % of patients had a second procedure [26]. Another study showed a 57 % EBWL in 77 % of patients at five years [13]. A comparative study between LSG and LRYGB with five years follow-up showed similar percentage of EBWL [27], but a randomized controlled trial from China showed a 76 % EBWL with LRYGB and 63 % EBWL for LSG at five years [28]. There was no difference in resolution of comorbidities. In a published series of 53 patients who had LSG, the follow-up rate was 78 %. At 3 and 6 years, the EBWL was 73 % and

Table 28.1 Percentage of excess body weight loss up to 4 years after LSG

Article	1 year (n)	2 years (n)	3 years (n)	4 years (n)
Himpens et al. 2006 [10]	58 % (40)		66 % (40)	
Jacobs et al. 2010 [3]	78 % (131)	75 % (33)		
Himpens et al. 2010 [11]			73 % (41)	
Lee et al. 2011 [12]	76 % (30)			
Gluck et al. 2011 [5]	70 % (77)	62 % (34)	62 % (9)	
Gibson et al. 2013 [9]	76 % (258)	71 % (102)	73 % (12)	
Kehagias et al. 2013 [13]			71 % (90)	
Sieber et al. 2013 [14]	61.5 % (68)	61.1 % (66)		
Catheline et al. 2013 [15]		57.1 % (45)		
Hoogerboord et al. 2014 [4]	54 % (NA)	64 % (NA)		
van Rutte et al. 2014 [16]	68.4 % (866)	67.4 % (342)	69.3 % (163)	70.5 % (62)

n number of patients, *y* year(s), *NA* not available

Table 28.2 Percentage of excess body weight loss at 5 years and beyond following LSG

Study (year of publication)	% EBWL in 5 years (n)	% EBWL in 6 years (n)	% EBWL in 7 years (n)	% EBWL in 8 years (n)
Santoro et al. 2007 [29]	55 %			
Weiner et al. 2007 [30]	40 % (8) EBMIL			
Bohdjalian et al. 2010 [31]	55 % (21)			
Himpens et al. 2010 [11]		53 % (30)		
D'Hondt et al. 2011 [32]	71 % (27)	56 % (23)		
Strain et al. 2011 [33]	48 % (23) EBMIL			
Sarela et al. 2012 [34]				69 % (13)
Eid et al. 2012 [35]		52 % (19)	43 % (13)	46 % (21)
Abbatini et al. 2012 [36]	56 % (13)			
Braghetto et al. 2012 [37]	57 % (60)			
Saif et al. 2012 [38]	48 % (30) EBMIL			
Kehagias et al. 2013 [13]	58 % (21)			
Zachariah et al. 2013 [39]	64 % (6)			
Catheline et al. 2013 [15]	51 % (45)			
Brethauer et al. 2013 [40]	50 % (23)			
Sieber et al. 20123 [14]	57 % (54) EBMIL			
Rawlins et al. 2013 [24]	86 % (49)			
Lim et al. 2014 [27]	57 % (14)			
van Rutte et al. 2014 [16]	58.3 % (19)			

EBWL excess body weight loss, *n* number of patients, *EBMIL* excess BMI loss

57 %, respectively [11]. Many studies now have consistently reported more than 50 % weight loss at five years and beyond as listed in the Table 28.2. A recent review of results of 16 studies analyzing a total of 492 patients post LSG, % EBWL was 62.3 %, 53.8 %, 43 %, and 54.8 % at 5, 6, 7, and 8 or more years [41]. These long-term results support LSG as a bariatric procedure achieving weight loss that can be defined as success based on Reinhold criteria [42] and are durable.

28.5 Diabetes Resolution/Remission after LSG

The greater the weight loss, the better is the resolution of type 2 diabetes mellitus (T2DM) [43]. While it was initially thought that the effects of weight loss and glucose regulation were only caused by restriction and malabsorption, a multitude of evidence show that there are many physiological changes that mediate the above effects. Along with alterations in gut hormones such as glucagon-like peptide-1 (GLP-1), leptin, ghrelin, peptide YY (PYY), glucose-dependent insulinotropic peptide (formerly, gastric inhibitory peptide) (GIP), etc., both LSG and LRYGB seem to cause alterations in bile acid levels, its composition, and bile acid signaling pathway as well as alteration in gut microbiome [44]. These seem to play a collective and coordinated role in initiating favorable metabolic changes that help with weight loss and diabetes resolution. It has been difficult to conclude on the exact diabetes resolution rates after LSG mainly because of the different criteria used and changes in the definition of diabetes over time (Table 28.3).

According to many studies, diabetes resolution after LSG is achieved in about 60–80 % of patients and the average number of diabetic medications reduced from two to less than one [52, 53].

A study involving 23 patients with a mean follow-up for six years after LSG showed that 74 % of patients had a HbA1c of <7, and another study involving 35 patients with a median follow-up of 73 months showed improvement and remission of diabetes in 77 % of patients [35, 40].

A randomized controlled trial that compared LSG, LRYGB, and intensive medical therapy for diabetes mellitus found no statistically significant difference in patients between the LSG and LRYGB groups. The medically treated group did worse than the surgically treated groups. There was higher glycemic relapse in the LSG group when compared to LRYGB group, though it was not statistically significant, and also a higher proportion of patients in the LSG group needed glucose lowering medications [50].

According to studies, which used higher cut-off levels of hemoglobin A1c (HbA1c) due to older definitions of diabetes, a HbA1c level of 6.6 or less was achieved in 56 % of patients in as early as three months. At three years 80 % of patients achieved HbA1c of 6.6 % or less [50].

In a systematic review with a mean follow-up of 13.1 months (range 3–36 months), diabetes mellitus had resolved in 66.2 % of the patients, improved in 26.9 %, and remained stable in 13.1 % of patients [6].

Another systematic review and meta-analysis of outcomes after LRYGB and LSG for type 2 diabetes involving 33 studies (1375 patients), showed that the remission rates following LSG and LRYGB were 56 % and 67 % at three months, 68 % and 76 % at one year and 80 % and 81 % at

Table 28.3 Diabetes remission rates following LSG, using different HbA1c levels

Author, Year	Patients n/total	Follow-up (months)	HbA1c (%)	T2DM remission (%)	Comments
Nocca et al. 2011 [45]	25/33	12	7.0	76	
Vidal et al. 2008 [46]	33/39	12	6.5	85	
Lee et al. 2011 [12]	10/20	12	6.5	50	Patients BMI:25–35 kg/m^2
Nosso et al. 2011 [47]	24/25	12	6.5	96	
Pournaras et al. 2012 [48]	5/19	12	6.0	26	
Schauer et al. 2012 [49]	18/49	12	6.0	37	
Schauer et al. 2014 [50]	12/49	36	6.0	24	
Abbatini et al. 2012 [51]	22/26	36	6.0	85	
Abbatini et al. 2013 [36]	10/13	60	6.0	77	
Eid et al. 2012 [35]	27/35	73	NA	77	Remission & improvement
Brethauer et al. 2014 [40]	17/23	72	7.0	74	

LSG, Laparoscopic sleeve gastrectomy; *HbA1c*, hemoglobin A1c; *T2DM*, type 2 diabetes mellitus; *BMI*, Body mass index

three years, respectively [54]. As more studies are reported the initial enthusiasm of LRYGB having a better outcome for remission of type 2 diabetes is being challenged.

Factors that predict failure of remission of diabetes include a longer duration of T2DM, a higher pre-surgical glycated hemoglobin level, insulin treatment at baseline, and a lower EBWL. A strong predictor of remission or resolution is the percentage of EBWL. Insulin use before surgery, an older age, and weight regain predict recurrence of diabetes [55]. Natural progression of diabetes in patients may lead to recurrence of diabetes after remission and also development of diabetes de novo after surgery.

Early decrease of circulating levels of metabolites such as fetuin-A, retinol binding protein 4, and several other metabolites were demonstrated after GBP compared to LSG, preceding significant weight loss [56]. This may contribute to higher T2DM remission observed following foregut bypass procedures.

28.6 Comorbidity Resolution

LSG leads to a dramatic improvement of several other comorbidities. These include obstructive sleep apnea (88 %), hypertension (75 %), hyperlipidemia (83 %), stress incontinence (90 %), and musculoskeletal disorders. There is no significant difference in the comorbidity resolution between LSG and LRYGB in the short term [50, 53, 57].

Patients with metabolic syndrome consisting of central adiposity, dyslipidemia, insulin resistance, and hypertension are at higher risk of postoperative complications. Bariatric Outcomes Longitudinal Database (BOLD) study comparing different bariatric surgery outcomes in patients with metabolic syndrome showed higher perioperative complications with LRYGB [58]. LSG is a low-risk option in this group of patients with comparable resolution of comorbidities.

A 5-year study showed excellent resolution of the following comorbidies in the super-obese patients after LSG: hypertension (95 %), T2DM (100 %), hyperlipidemia (100 %), and obstructive sleep apnea (100 %) [24].

The effect of weight loss on chronic kidney disease progression is not well established. Obesity and diabetes lead to renal impairment and end-stage renal disease. Obese patients with end-stage renal disease are referred for weight loss surgery. Successful weight loss will optimize these patients for subsequent transplant. In patients who have undergone bariatric surgery, an improvement in creatinine clearance and microalbuminuria has been reported [50, 59]. This improvement is likely to be weight loss dependent.

A meta-analysis of studies comparing LSG and LRYGB in patients with BMI more than 30 did not show statistically significant difference in improvement of levels of triglycerides and low-density lipoproteins, but LRYGB showed a better reduction of total cholesterol and increase in high density lipoproteins [60]. Another meta-analysis of randomized controlled trials comparing LSG and LRYGB for morbid obesity and or T2DM reported that T2DM remission was higher in LRYGB. So was the weight-loss and reduction in levels of LDL, triglycerides, homeostasis model assessment index and insulin levels [61]. However, patients treated with LRYGB had a higher incidence of complications and reoperations than those treated with LSG. Though this paper concluded that LRYGB is more effective than LSG for the surgical treatment of T2DM, LSG produces comparable results and is safer due to reduced complications.

28.7 Quality of Life After LSG

Health-related quality of life (HRQOL) is assessed using the Bariatric Analysis and Reporting Outcome System (BAROS), the Medical Outcomes Study Short Form questionnaire (SF-36) and the Impact of Weight on Quality of Life-Lite questionnaire (IWQOL-Lite). The BAROS assesses percentage of EBWL, improvement and/or resolution of comorbid conditions, five aspects of quality of life (self-esteem, physical activity, social activity, work, and sexual activity), complications, and reoperations [62] and shows good outcomes after LSG.

A prospective study with two quality of life (QOL) questionnaires: SF36 and IWQOL-Lite showed significant improvement in the scores for all domains of SF-36, but there was no significant correlation to the amount of weight loss. But patients who had more than 50 % EBWL showed better scores for self-esteem. Postoperative complications had a negative impact on the scores [63]. A randomized controlled trial comparing LRYGB and LSG showed similar improvement in Moorehead-Ardelt (M-A) II QOL at five years follow-up [28]. Long-term follow-up studies are lacking but with more than 50 % EBWL at 5 years being the norm after LSG, one would expect sustained improvement in QOL.

28.8 Super Obesity and LSG

Super-obese patients are defined as those with a BMI of more than 50 kg/m^2. They are an important group with a higher incidence of comorbidities [19]. The weight loss achieved in the short term from an LSG is lower than that achieved following an LRYGB [64] although there is a retrospective study showing excellent results [24]. Super-obese patients have a higher risk of failure to lose weight with all types of bariatric surgery and more chance of weight regain. In a single institution retrospective study of super-obese patients, the EBWL at one year was 39 % (interquartile range: 34–51), and 41 of the 61 patients proceeded to have the planned second-stage procedure [65].

A prospective database review of 74 super-obese patients with 93 % follow-up, six to eight years after LSG, who did not have a second-stage procedure showed a 48 % EBWL and 77 % resolution or remission of diabetes [35].

LSG offers the opportunity to add a second procedure later and the choices available are duodenal switch, re-sleeve, or LRYGB. This second procedure depends on the indication and the preference of the patient and surgeon. It is discussed in great detail in the Chap. 41.

28.9 LSG in the Elderly

It is known that weight loss in the elderly is less when compared to young adults. This is due to the slower metabolism, less calorie requirement and limitation of physical activity. Age is an independent factor in the mortality and morbidity after bariatric surgery. LSG results show better weight loss when compared to gastric banding and is believed to have fewer postoperative complications when compared to LRYGB [66] and is safe in the >65 years age group [67]. In a large study from National Surgical Quality Improvement Program (NSQIP) database, in patients aged >65 years, LSG was not associated with significantly different 30-day outcomes compared to LRYGB [68]. Comparison between patients aged >60 years and those aged 18–50 years showed that EBWL was higher in the younger group (75 % vs. 62 %). Older patients had a significantly higher rate of a concurrent hiatal hernia repair (23 % vs. 1.9 %) and postoperative minor complication rate was higher in the older group (25 % vs. 4.8 %) [69].

28.10 Late Re-operation Following LSG

Unlike LRYGB, where re-operations were mostly due to complications of the procedure, late re-operations or second operations for standalone LSG are mainly for insufficient weight loss, weight regain, refractory GERD, and stricture. The International Sleeve Gastrectomy Expert Panel Consensus Statement revealed that there is consensus among 90 % of the experts that even if 30 % of patients need a second operation, LSG is an excellent procedure [70]. In a systematic review, the re-operation rate range was 0.7–25 % in patients who were offered LSG as a standalone procedure. In patients who have LSG as a planned first-stage procedure, 9.6–28.5 % had a second operation [71]. This rate is dependent on the duration and completeness of follow-up.

Conclusion

LSG has established itself as a standalone procedure due to the relative simplicity of the technique, short learning curve, less morbidity and durable medium to long-term results. It is a serious alternative to LRYGB, which is a demanding, and complex procedure compared to LSG. At present, there is no consensus on the procedure of choice and surgeons should choose the procedure after carefully assessing the requirements of the patients and discussing the benefits and risks of each procedure. Longer-term data from quality studies will further define the role of LSG in managing the complex obesity disorder.

Key Learning Points

- There is a variation in outcomes among different studies because of a lack of standardization of the surgical technique for LSG.
- Short- and medium-term data in terms of weight loss and diabetes resolution associated with LSG are comparable to that of LRYGB.
- Long-term results of 5 years and beyond show more than 50 % EBWL though the published data is very limited.

- Patients who have failed to lose weight or had weight regain have the option of a revision operation.
- Health-related quality of life (HRQOL) in patients following LSG shows significant improvement.

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LSG: Current Controversies

29

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Abstract

Laparoscopic sleeve gastrectomy (LSG) is still a new procedure with many technical variations. Sleeve volume, bougie size, stapling technique and distance from pylorus may affect medium- and long-term weight loss and metabolic outcomes. Further data and larger series will be needed to draw definitive conclusions. The only technical point beyond controversy and now universally accepted is that an orogastric bougie should always be inserted during stapling.

The controversies regarding level of hiatal dissection and staple line reinforcement are more related to perioperative and short term outcomes such as staple line leak rate and postoperative gastroesophageal reflux disease (GERD). Most recent meta-analysis and reviews are in favor of more aggressive hiatal dissection with synchronous hiatal hernia repair and staple line reinforcement; however no consensus has been reached yet.

Keywords

Sleeve gastrectomy • Controversies • Indications • Stapling distance from pylorus • Bougie diameter • Stapling distance from GEJ • Hiatus hernia and reflux • Staple line reinforcement • Banded sleeve gastrectomy

29.1 Introduction

Laparoscopic sleeve gastrectomy (LSG) has been used as a stand-alone procedure for the management of morbidly obese patients for more than a decade.

As it reduces gastric capacity, LSG is often thought of as a purely restrictive technique. However it also reduces the levels of fasting and post-prandial ghrelin [1, 2]. Ghrelin, which is mainly secreted from the gastric fundus, is the only known circulating orexigenic (appetite-stimulating) hormone. LSG has also been shown to increase gastric emptying and intestinal motility [3], influencing the rate of food reaching the small bowel and thus affecting circulating levels of other gut hormones including peptide YY (PYY) and glucagon-like peptide-1 (GLP-1) [1]. These changes may account for the increased satiety, decreased appetite and amelioration of the glycemic profile often seen after LSG.

In UK, the sleeve gastrectomy is considered as technical evolution of the Magenstrasse & Mill gastroplasty. Doug Hess is credited to have performed the first open sleeve gastrectomy in 1988 as part of the duodenal switch procedure in an attempt to reduce marginal ulceration and dumping associated with the Scopinaro biliopancreatic diversion [4]. Almogy [5] described a series of 21 open sleeve gastrectomy performed between 1997 and 2001 in high risk super-obese patients. These were planned as the first part of a two stage procedure in nine patients and terminated at the gastrectomy stage due to unforeseen intraoperative difficulties in the remaining 12 patients. Follow-up showed that this was a safe option and was associated with significant weight loss.

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The first laparoscopic approach to the duodenal switch in humans was performed by Michel Gagner [6]. A higher complication rate was noticed in the super-obese patients [6] and so a staged approach was developed with LSG as the initial operation. Due to its sustained and significant weight loss even in these super-obese patients, the operation developed into a single stage option for patients with lower body mass index (BMI). Now more than 90 % of LSGs are intended as a sole bariatric operation [7]

LSG has continued to gain popularity, becoming the most commonly performed bariatric operation in several countries including France and the United States. There are however still certain aspects of the technique, pre- and peri-operative care that are debated at length and these differences may, at times, make it difficult to compare publications regarding LSG outcomes and results. This chapter aims to discuss these controversies with a review of current literature.

29.2 Preoperative

29.2.1 Patient Selection

Patient selection for bariatric surgery is discussed in detail in Chap. 8.

LSG is very useful in management of super-obese patients (BMI of 50 or more). In these patients, LSG may be planned as the first part of a two stage procedure, although whether the second stage takes place depends on the results in terms of weight loss, resolution of co-morbidities and the patient's expectations. LSG may also be useful in the management of high risk patients including those candidates awaiting kidney and liver transplant [8, 9] Sleeve gastrectomy has a shorter operative time thereby reducing procedural and anesthetic time when compared to Roux-en-Y gastric bypass (RYGB). It also maintains access to the biliary tree and does not involve the creation of a Roux loop; this is especially useful in patients awaiting liver transplantation and in those with ongoing chronic biliary pathology.

Sleeve gastrectomy is the operation of choice in the management of morbidly obese patients with inflammatory bowel disease and in patients who require regular endoscopic surveillance for chronic gastric pathology. LSG may also be helpful in patients who have had previous lower abdominal surgery and in whom dense small bowel adhesions are suspected or found intra-operatively [10]. In the authors' practice, LSG is also recommended for patients who are on long term medications including anti-epileptic and anti-retroviral drugs which may be absorbed in the small bowel as their serum level might alter if a gastric bypass is performed instead.

Many bariatric surgeons would regard GERD [11] and Barrett's esophagus as a contraindication for sleeve gastrectomy with most citing Barrett's esophagus as an absolute contraindication [8]. To date, there are no animal and human studies suggesting increased risk of transformation of Barrett's esophagus into high grade dysplasia or adenocarcinoma after LSG. However, most bariatric surgeons would caution against LSG use in the presence of Barrett's esophagus. Should lower esophageal cancer develop, the stomach cannot be used as a conduit, as the fundus and greater curvature would have been excised during LSG. Controversies relating to hiatus hernia, GERD, and LSG are discussed in detail in Sect. 29.3.5.

Duodenal switch has been associated with the best results for remission of type 2 diabetes mellitus (T2DM). Controversies exist as to whether gastric bypass and LSG have similar outcomes with respect to T2DM remission or amelioration. A recent meta-analysis by Zhang et al. [12] suggests that gastric bypass may be better; however more long term data is required.

Revisional surgery for patients who have inadequate weight loss or develop complications after gastric banding is becoming increasingly common. Some surgeons advocate two step revisional surgery (removing band first and then doing the next bariatric operation at a later date) as safer than a one step approach. Controversies exist as to whether there are differences in safety and long-term outcomes between conversion from band to LSG or from band to gastric bypass. Most studies have shown that both operations are adequate and effective as revisional procedures; however, complication and re-operation rates tend to be higher than primary procedures [13, 14] The gastrogastric plication sutures, if present, need to be removed. If the definitive revisional procedure is going to be done at the same time, it is strongly recommended to remove the fibrous capsule created by the band. This step may not be necessary if the LSG is done a few months after band removal, as the capsule tends to be absorbed.

In our opinion, revisional operations should be performed by surgeons who are experienced in both operations (LSG and bypass) and who are able to tailor the surgery depending on the patient's preoperative characteristics and the intraoperative findings. A one step approach is usually more difficult and is certainly not recommended in the case of band erosion. The authors' personal preference is not to use LSG as revisional procedure after failed gastric band, due to the reported increase in leak rate. If no other options are available, the two step approach is preferred.

LSG as a revisional procedure after failed bypass (as first step of duodenal switch) is technically feasible and few cases have been described.

The prevalence of obesity in adolescents has increased dramatically over the last 30 years with the associated decreased quality of life and increased morbidity and mortality. Bariatric surgery may be considered in morbidly obese adolescents with BMI more than 40 or BMI more than 35 with serious comorbidities. This is more effective than diet and exercise alone and leads to improvement or resolution of both physical and psychological problems associated with morbid obesity [15–17]. Bariatric surgery in adolescents however remains controversial not only with the public at large and but also with medical and pediatric colleagues. At this stage, the literature does not suggest that one bariatric operation offers considerable advantages over others in terms of long term outcome in this patient group [15–18].

LSG is becoming increasing popular amongst bariatric units treating adolescents. This partly reflects the global trend of LSG becoming the commonest procedure performed. There are theoretical advantages of LSG that make it particularly suited to this group of patients. These include the perceived reduced need of long term mineral and vitamin supplementation (although not yet proven) together with lower incidence of long term surgical and nonsurgical complications (including internal hernia, intussusceptions, and hypoglycemia) when compared to the gastric bypass, making LSG a very attractive option for adolescents. Probably the greatest advantage of LSG in these young patients is the intrinsic versatility of the procedure that can be easily converted at later stages to more aggressive alternatives (duodenal switch, single anastomosis duodeno-ileal bypass, single anastomosis gastric bypass) should these be required for weight regain.

Case reports of LSG being done in children are probably referring to extreme cases in very specific circumstances as "life saving" procedure [19]. These cases are to be considered exceptional and raise multiple questions. Currently, there is no indication for LSG as treatment for obese children.

We believe that adolescents being considered for bariatric surgery need to be evaluated by a tailored adolescent bariatric multidisciplinary team including specialist pediatric endocrinologists, child psychologists and social workers.

It is controversial whether pediatric surgeons should be involved in this patient group. The main criticism is that, because of the relatively small number of teenagers undergoing bariatric surgery, they may lack in the required procedure specific annual caseload and therefore could have poorer outcomes than a fully trained bariatric surgeon.

Follow-up arrangements in this patient group are particularly important and should also reflect the logistical challenges posed by teenagers.

One of the authors routinely performs LSG in the adolescent group (age range 14–19) and has a dedicated adolescent bariatric team and facilities.

29.3 Intraoperative—Technical Controversies

29.3.1 Bougie Size

Most bariatric surgeons agree that standardization of LSG diameter and hence volume with a bougie or orogastric tube is important [8]. There is, however, no universal agreement regarding the ideal size of this bougie.

Any comparison of outcomes detailed below, has been carried out in the, sometimes wrong, assumption that the bougie has been employed as a true caliber of the sleeve, with the operating surgeon applying the stapler tightly to it. Clearly any technique involving stapling "loose" on the bougie will grossly underestimate the volume of the gastric sleeve and make the caliber of the bougie used not relevant for comparisons. An estimation of the tightness of stapler to the bougie, and conversely on the level of standardization of the technique, can be extrapolated from the number of 60 mm stapler cartridges used for completing the procedure, which should not exceed five or six.

When used as part of duodenal switch (DS), it is generally agreed that wide bougies are used for LSG as patients need to be able to eat enough to ensure adequate protein intake. When the operation is planned as a standalone procedure, there has been a tendency towards the use of narrower bougies as most surgeons believe that these sleeves need to be narrow enough to induce restriction, limiting food ingestion and thus resulting in weight loss and weight maintenance. Narrowing the LSG will result in higher intraluminal pressure in an already high pressure system thereby increasing the chance of leak usually from the proximal part of the sleeve.

Most studies have found little difference in weight loss using bougies of different diameters in the short and medium term. Spivak et al. found no significant difference in BMI, excess weight loss or change in co-morbidities at 1 year post-operatively when retrospectively comparing a group of patients who had LSG with a 42 French versus those who in whom a 32 French bougie was used [20].

Data from the Spanish Registry revealed that a smaller bougie size (32–36 French) had initial better weight loss outcomes compared with 38–60 French up to 12 months after LSG, without a difference in complication rate [21]. However there was no significant impact on weight loss beyond 12 months in the two groups [21].

In a large meta-analysis, there was no significant difference in weight loss in the first 36 months when patients who had LSG calibrated with bougies size less than 40-French were compared to those with bougie size of more than or equal to 40-French [22]. It was noted that patients who had a LSG with a bougie less than 40-French had more rapid weight loss in the first 6 months but both groups had similar weight loss at 36 months postoperatively. This meta-analysis however showed that the leak rate decreased from 2.5 % when a bougie less than 40-French was used; to 1.7 % for a bougie size 40–49-French to 0.9 % for bougies of 50-French or more [22]. The authors of this study thus recommended the use of bougies more than or equal to 40-French size as this may decrease the leak rate without impacting percentage of excess weight loss (%EWL) up to 3 years.

The commonest size bougie used by surgeons responding to the 4th International consensus summit on LSG was a 36 French bougie [7] while the panel of experts at the International Sleeve Gastrectomy Expert Panel Consensus Statement [8] concluded that the optimal bougie diameter is 32–36 French. This consenus panel expressed concerns that larger bougie diameters may result in dilatation of the sleeve and hence long term weight regain. They, however, also agreed that tighter the sleeve the greater the incidence of leaks [8].

There is currently a paucity of data with regard to the influence of bougie diameter on long term weight loss and rate of LSG failure. On one hand, there is a concern that the wider the initial LSG, the more likely it is to stretch, resulting in long term sleeve dilation and weight regain. Theoretically with a wider bougie, a larger part of gastric fundus, with its content of ghrelin producing cells, may be retained. Currently, however, there is no scientific evidence showing lower satiety scores and increased hunger scores associated with wider diameter boogies.

On the other hand, smaller sized bougies causing greater restriction may result in maladaptive eating and adoption of increased intake of sweets, high calorie liquids and meltable calories making it more likely that the patients regain weight in the long term.

In conclusion, although there seems to be no difference in weight loss in the short and medium term with bougies less than or more than 40 French in diameter, the effect of bougie size on long term weight loss and weight maintenance is unclear and warrants longer term studies with adequate follow up. The authors of this chapter use bougies of 32–34 French and staple close to the bougie.

29.3.2 Distance from Pylorus

There are deferring opinions amongst bariatric surgeons as to the extent of antral resection required when performing LSG and how this affects patients' outcome. The antrum is the thickest part of the stomach and hence thought to be less likely to stretch than the fundus or the body [23].

Some surgeons believe that starting the resection more than 4 cm from the pylorus will improve gastric emptying via antral preservation, decreasing intraluminal pressure and hence the risk of a leak. Others believe that narrower the LSG, the better the long term weight loss. In the International Sleeve Gastrectomy Expert Panel Consensus Statement, 32 % of surgeons reported that they start the resection at 4–5 cm from the pylorus, 27 % at 3–4 cm while 23 % at 5–6 cm [8].

In a prospective randomized study by Abdallah et al., there was a significantly higher %EWL at 6, 12 and 24 months in the group where gastric division was started at 2 cm from pylorus compared to those where division was started at 6 cm [24]. In this study, there was no difference in improvement in comorbidities, in weight regain after 2 years and in the incidence of complications between the two groups. The study however was not powered sufficiently to detect significant changes in the incidence of complications including leak [24].

Sánchez-Santos et al. reported that Spanish groups who begin LSG closest to the pylorus obtained significantly better weight loss results at 3, 6, and 12 months postoperative follow up with no difference in postoperative complications [21]. However, there was no difference in weight loss at 24 and 36 months when these were compared to groups that did not resect the antrum.

A study by Michalsky et al. showed that four patients who had LSG with antral resection at 2.5 cm from pylorus had faster gastric emptying on scintigraphy at 3 months postoperatively compared to preoperatively [25]. However this study did not perform the test in patients who had LSG with antral preservation.

In a large meta-analysis by Parikh et al., there was no significant difference in leak rate or weight loss between patients who had LSGs that was started less than 5 cm from pylorus compared to those where it was started 5 cm or more from pylorus [22].

Currently, there does not seem to be any difference in early complication rates and in medium term weight loss results between groups who preserve the antrum and those who resect it. More research is required to investigate the influence of antral preservation and resection on long term results in terms of weight loss and weight regain. If the antrum is resected, surgeons should make sure that the correct staple height should be used for this thicker tissue and use of green (closed staple height: 2 mm) or black (closed staple height: 2.3 mm) cartridges is commonly recommended.

The authors begin their LSG resection at about 4 cm from the pylorus, thus attempting to decrease the antral volume while preserving part of its function. We however pay particular attention to avoid stenosis or strictures at this point by making sure that the bougie is correctly positioned at the time of the first firing. We believe that decreasing antral volume and partially reducing its function as antral pump might contribute to reduce intraluminal pressure in the sleeve. While there is no evidence that this would prevent or reduce leak rate, it is reasonable to assume that a reduced intraluminal pressure would be beneficial in the event of a leak.

29.3.3 Staple Line Reinforcement

To date, the thickness of different parts of the stomach and their vascularity has not been studied in great detail in the medical literature.

Staple line reinforcement includes oversuturing and invagination of the staple line with interrupted or continuous sutures, the application of sealants or tissue glue and the use of absorbable or nonabsorbable buttressing material. Buttressing materials include bioabsorbable polyglycolic acid and trimethylene carbonate (SeamGuard®), bovine pericardium (Peri-Strips Dry®), and small intestine submucosa (Surgisis®). Buttressing material needs to be preloaded onto the stapler gun and the material gets incorporated into the staple line on firing. Ideal buttressing material should enhance the strength of the staple line during the healing process but also be flexible and thin enough in order to be easily cut by the stapler's blade. Ideally it should also not be costly and avoid creating adhesions.

In the 4th International consensus summit on LSG, 75 % of surgeons reported that they reinforced the staple line, 57 % of these using buttress material while and 43 % oversutured [7].

Several studies have shown that reinforcement decreases the risk of bleeding from the staple line [8, 26]. Most bariatric surgeons would however regard the development of a leak as the worst complication after LSG as it is associated with increased morbidity and it is often difficult to treat requiring multiple endoscopic and/or surgical interventions. The incidence of staple line leaks after primary LSG ranges between 0 and 5.5 % for primary surgery [27] with higher rates in revisional procedures. About 90 % of leaks appear near the gastro-esophageal junction (GEJ) [28]. The etiology of leaks is poorly understood, however, mechanical, tissue and ischemic factors may play a role [29]. A high intraluminal pressure due to the intact pylorus and/or antrum may also contribute and lead to delayed healing.

Till date, there are three randomized studies comparing different reinforcement techniques in LSG. The only randomized controlled study comparing the outcome in three groups (no reinforcement, buttressing with Gore Seamguard® and staple line suturing with polydiaxone) was published by Dapri et al. [26] In this study, surgery was longest in the group where the staple line was oversutured while blood loss was significantly lower in the group in whom buttressing with Seamguard® was used. The authors commented that the use of Seamguard® added between 640 and 896 Euros (depending on amount of cartridges used) to the operation cost at the time when the paper was written. In another study where patients were randomized between buttressing of the last staple firing at the GEJ with Seamguard® (48 patients) versus suturing of the whole length of the staple line with PDS 2.0 (42 patients), no significant difference between bleeding and leak rates were found [30]. In another study, Gentileschi et al. also found no significant differences when 120 patients were randomized to LSG with oversewing versus buttressed transection with a polyglycolide acid and trimethylene carbonate versus staple line roofing with a gelatin fibrin matrix [31].

These three studies were underpowered to detect the differences in leak rate and studies with large number of patients are required to identify any changes in the rate of early complications with these different techniques to reinforce the staple line. A recent systematic review of the subject by Gagner et al., which included over 8,900 patients, showed that the leak rate was lowest when absorbable polymer membrane was used (1.1 %) [27]. The leak rate was 3.3 % when nonabsorbable bovine pericardial strips were used compared to 2.6 % when no reinforcement was used and 2 % when staple line was oversutured. The overall leak rate in this study was 2.1 % and the mortality rate 0.1 %.

It may be difficult to organize large enough randomized studies to investigate the impact of different types of staple line reinforcement. However, it has to be highlighted that there are no reported adverse events associated with the use of Seamguard® in reinforcing the staple line and therefore the only controversy on its routine use is related to the obvious added cost.

Both authors currently use staple line reinforcement with Seamguard® routinely as they believe it reduces incidence of leaks by mechanical strengthening of the staple line with equal distribution of the tissue compression exerted by the three rows of staplers. The added intraoperative costs are accepted because any sleeve leak is not only a difficult management problem for the surgeon and the patient but also a highly costly issue for the hospital [32].

29.3.4 Proximity to the Gastro-Esophageal Junction (GEJ)

One of the theories of proximal leak and fistula formation is the vascular/ischemic theory [29]. Complete dissection of the fundus requires division of the short gastric vessels and of the posterior gastric artery and the phrenic branches if present. A watershed area of vascularization may arise on the left posterolateral side just at the esophagogastric junction. Some surgeons suggest that in order to avoid a potential leak at this area, a resection line leaving 1–2 cm of gastric remnant at the gastroesophageal junction is required [33].

Other groups are not in favor of this maneuver as it will anyway lead to devascularization with complete fundal mobilization but retains potentially more ischemic tissue in situ. Particular attention is required in patients who previously had adjustable gastric band.

Of all the expert surgeons participating in the International Sleeve Gastrectomy Expert Panel Consensus meeting, 96 % agreed that it is important to stay away from the GEJ on the last firing [8].

It should be noted that the dissection near the GEJ is very similar, if not identical, to that undertaken during gastric pouch formation in gastric bypass, in which the occurrence of a staple line leak near the GEJ is exceptionally rare. This is the main criticism against the vascular/ischemic theory, which is currently not accepted by many surgeons.

The authors' preference is to dissect the fundus entirely, exposing the GEJ up to the base of the left diaphragmatic crus and dividing posterior gastric and phrenic branches, if present. Stapling is near but not onto the GEJ making sure that any esophageal tissue is carefully avoided. With regards to the gastroesophageal or Belsey fat pad, this is not routinely dissected as it can be easily compressed by the stapler, if correct compression time is applied before stapling. In exceptional circumstances, when the fat pad is so bulky that it would interfere with the placement of the stapler, this is carefully and partial dissected so it can be displaced medially. We do not recommend routine and complete dissection of the Belsey's fat pad due to the added risk of thermal injury to the GEJ, which could affect incidence of leaks.

There seems to be a consensus on the caution with which to perform the last section at the gastroesophageal junction, thereby avoiding contact with the esophagus and minimizing as much as possible the occurrence of complications at this level.

29.3.5 Management of Coexisting Hiatus Hernia and Reflux

The management of coexisting hiatus hernia (HH) and the prevalence of gastroesophageal reflux disease (GERD) after LSG remain controversial.

GERD is present in up to half of morbidly obese patients. The development of symptomatic GERD is associated with increased transient lower esophageal sphincter relaxations, hypotensive lower esophageal sphincter (LES), HH and increased intra-abdominal pressure. These are found more frequently in obese patients and morbidly obese patients have increased prevalence of reflux symptoms [34], esophagitis [34] as well as a higher incidence of lower esophageal and junctional adenocarcinoma when compared to the general population [35].

Of the expert surgeons participating in the International Sleeve Gastrectomy Expert Panel Consensus meeting, 83 % agreed that aggressive identification of HH intraoperative is required and this should be repaired if found [8]. In the 4th International Consensus on LSG, 69 % of the surgeons questioned actively looked for a HH with the rest only looking for one if patients had preoperative symptoms of GERD or if a HH was visualized preoperatively [7]. If a HH was identified intraoperatively, the majority of surgeons (89 %) said that they would repair it [7].

There have been numerous conflicting studies regarding the incidence of de-novo or worsening GERD symptoms after LSG. It is difficult to evaluate the literature regarding this debate as different studies use different criteria to diagnose GERD, different diagnostic tests (endoscopy, pH studies, manometry—standard or high resolution, radiology and histology) and vary in their length of postoperative follow-up. Studies also differ in their inclusion/exclusion criteria with some including and others excluding patients with preoperative GERD. Others do not differentiate between persistent symptoms in patients with preoperative symptomatic GERD and 'de-novo' symptoms in patients who were asymptomatic preoperatively. Surgical technique including bougie size, experience of the operating surgeon and learning curve and postoperative use of antireflux medication also vary between papers.

The current medical literature gives opposite and differing outcomes about the effects of LSG on reflux. Some of the studies and their findings are discussed in Tables 29.1 and 29.2. Of note most studies that have been published over the last 12 months show improvement in GERD post-LSG [36, 45–49]; this can possibly be explained by changes and evolution of LSG technique.

Differences in esophageal physiology and postoperative manometric findings have also been described after LSG with some studies showing a decrease in LES pressure [56] and others showing no change [57] or an increase [58].

Possible causes of increased GERD after LSG include loss/blunting of the angle of His, the creation of a high pressure, non-compliant gastric tube, damage to the sling fibers when the phrenoesophageal junction is dissected, and thoracic migration of the sleeved stomach. On the other hand, improved gastric emptying and the decreased gastric parietal cell mass should result in decreased incidence of GERD. Long term weight loss with its associated decrease in abdominal pressure should also help to decrease the incidence of GERD.

The issues of reflux after sleeve and the management of HH are still hotly debated at length in surgical meetings. Most surgeons would repair moderate or large HH when present at surgery. If the patient has very symptomatic GERD and/or a large HH diagnosed preoperatively, most surgeons would caution against LSG and may offer the patient a Roux-en-Y gastric bypass if technically possible. Both Daes et al. [46] and Soricelli et al. [51] found that searching for and repairing a HH at the LSG operation significantly decreased GERD. On the other hand, a study by Santonicola found that LSG and concomitant HH hernia repair was associated with increased postoperative symptoms of GERD in patients who

Table 29.1 Studies showing increase in GERD symptoms

Author	Number of patients	Modality used	Length of follow-up	Results
Vage et al. [36] 2014	117	Symptoms	24 months	Statistical increase in the prevalence of reflux symptoms from 12.8 % preoperative to 30.4 % at 12 months to 27.4 % at 24 months.
Tai et al. [37] 2013	66	Pre- and postoperative symptoms questionnaire and endoscopy	12 months	Increased prevalence of GERD after SG, from 12.1 to 47 %. Increased incidence of esophagitis from 16.7 to 66.7 % Increased incidence of hiatal hernia from 6.1 to 27.3 %.
Braghetto et al. [38] 2012	167	24 h pH monitoring and endoscopy (patients with preoperative GERD excluded)	Not reported	Significant increase in patients with GERD symptoms after SG (27.5 %)
Carter et al. [39] 2011	176	Pre- and post-op GERD symptoms	Not reported	Increase in the prevalence of GERD from 34.6 % preoperatively to 47.2 % post-op. Medications use also increased. Patients who had pre-op symptoms were more likely to have persistent symptoms post-op.
Howard et al. [40] 2011	28	Symptoms based questionnaires Medication usage Upper GI swallow	8–92 weeks	New onset GERD symptoms in 22 % of the patients at 4 weeks post-op despite being on daily anti-reflux medications
Lakdawala et al. [41] 2010	50	Symptoms and medication usage	12 months	4 % increase in GERD prevalence
Arias et al. [42] 2009	130	Symptoms (patients with pre-op GERD excluded)	24 months	2.1 % of patients had new onset symptoms of GERD
Nocca et al. [43] 2008	163	Symptom reporting	24 months	Increase in prevalence of GERD after LSG from 6.1 % pre-op to 11.8 % post-op
Himpens et al. [44] 2006	40	Symptom reporting	Up to 72 months	Incidence of denovo GERD post LSG 21.8 % at 1 year, 3.1 % at 3 years 75 % of patients who had pre-op GERD were asymptomatic at 3 years.

SG sleeve gastrectomy, *LSG* laparoscopic sleeve gastrectomy, *GERD* gastroesophageal reflux disease, *Post-op* postoperative, *Pre-op* preoperative, *GI* gastrointestinal

had a HH diagnosed intraoperatively compared to those who only had LSG (no intraoperative HH diagnosed) even though the prevalence of preoperative GERD symptoms was similar in the two groups [48]. In view of their findings, these authors warn against a very aggressive attitude towards HH management especially in small HH.

The problem of GERD after LSG is a complex issue. Careful attention to technique may be important. The differences in the postoperative prevalence of GERD symptoms may be due to different surgical techniques or complications including creation of twists in the sleeve, retention of the fundus, development of a neofundus, relative stenosis in the antrum and the use of smaller diameter bougie size [46, 57]. Incorrect surgical technique/early learning curve has to be taken in account as a dilated upper third of the sleeve with redundant fundus is often seen in patients complaining of new onset of GERD.

If reflux occurs post LSG, most patients can initially be treated with proton pump inhibitors (PPIs). In case of persistence of the GERD symptoms after several years, conversion of LSG to RYGB could abolish GERD symptoms as reported in patients submitted to primary RYGB and affected with GERD symptoms [11, 59].

In authors' own experience, approximately 5 % of LSG patients required conversion to RYGB for demonstrated severe GERD refractory to PPI treatment. In all cases reflux symptoms disappeared after conversion.

29.3.6 Banding the Sleeve Gastrectomy

Banding of LSG has been proposed by some surgeons in an attempt to minimize potential long term dilatation. There are few small published studies using nonadjustable bands [60]. adjustable bands [61] and biological tissue [62].

In a recent study comparing 25 patients with a banded sleeve (MiniMizer ring ® Bariatric Solution) with 25 matched patients who had standard LSG, there was similar excess weight loss at 12 months but a significant increase in vomiting episodes in the banded group [60]. Reoperation and band removal was necessary in two patients. While the follow up period in this study may be too short with regards to weight

Table 29.2 Studies showing decrease or no change in GERD symptoms

Author	Number of patients	Modality used	Length of follow-up	Results
Burgerhart et al. [45] 2014	20	Pre and post-op high resolution manometry, 24 h pH and impedance studies and symptom questionnaires	3 months	No change in GERD symptoms but increased upper GI symptoms (belching, epigastric pain, vomiting) Significant increase in acid exposure in lower esophagus at 3 months post-op Significant decrease in LOS pressure at 3 months post-op
Daes et al. [46] 2014	373	Symptoms and medication use	6–22 months	Pre-op GERD diagnosed in 44.5 % of patients Intra-operative HH diagnosed in 37.2 %. These were repaired. Only 2.6 % of patients had GERD post-op 94 % of patients with pre-op GERD were asymptomatic post-op
Pallati et al. [47] 2014	585	Symptoms and medication use (patients who would have been eligible for anti-reflux surgery or who had concomitant hiatal repair excluded)	6 months	41.7 % improvement in GERD scores post-op
Santonicola et al. [48] 2014	180	Symptom questionnaire	6 months	78 found to have intra-op hernia underwent LSG + HH repair, 102 did not have an intra-op HH. Both groups had similar rates of GERD symptoms pre-op 38.4 % versus 39.2 %. Patients who only had LSG had a significant decrease in GERD symptoms post-op. This was not the case in patients who had LSG + HH.
Sharma et al. [49] 2014	32	Pre and post-op symptom questionnaires, EGDs and radionuclide scintigraphy	12 months	Decreased GERD symptom scores at 12 months post-op. Increased incidence but decreased severity of esophagitis on EGD Increased evidence of asymptomatic reflux on post-op scintigraphy
Rawlins et al. [50] 2013	49	Symptoms	60 months	Pre-op prevalence of GERD 30.6 %, post-op prevalence 26.5 % GERD resolved in 53 % of patients with pre-op symptoms and occurred 'denovo' in 11 % of patients
Soricelli et al. [51] 2013	378	Symptoms, EGD	18 months	97 patients (25 %) had a hiatal hernia (posterior) crural repair intra-operatively GERD remission in 73.3 % of patients with pre-op GERD who also had HH repair. Denovo GERD in 22.9 % of patients undergoing LSG alone compared to no new cases in those undergoing SG+ HH repair
Chopra et al. [52] 2012	174	Symptoms	At least 6 months	GERD resolution in 45.92 % of symptomatic patients
Melissas et al. [53] 2007	23	Symptoms, gastric emptying	6 and 12 months	8 patients had pre-op GERD 33 %, symptoms improved/disappeared in half of these post-op. De-novo GERD in 2 patients (13 % of asymptomatic pre-op patients) Significantly faster gastric emptying post-op
Weiner et al. [54] 2007	120	Symptoms	12 months	Pre-op prevalence of GERD 35 %, improved in 43 % of patients and resolved in 57 %, no worsening of symptoms reported
Rebecchi et al. [55] 2014	65	Symptoms, upper GI endoscopy, barium swallow, 24 h pH studies, stationary manometry	24 months	Patients (n = 28) with pre-op symptomatic reflux improved (symptoms, deMeester score and total acid exposure decreased), De novo GERD occurred in 5.4 % of patients (n = 37) who were asymptomatic pre-op. Patients with large HH or previous gastric surgery were excluded from this study.

SG sleeve gastrectomy, *LSG* laparoscopic sleeve gastrectomy, *GERD* gastroesophageal reflux disease, *Post-op* postoperative, *Pre-op* preoperative, *HH* hiatus hernia, *EGD* esophago-gastro-duodenoscopy loss and weight maintenance, patient intolerance to rings is certainly an issue even in banded gastric bypass. Larger studies are required to identify any difference in leak rate as a result of the placement of a band on an already high pressure system and the incidence of long term erosion. Intraoperative problems that have been reported with the use of such rings include bleeding from the lesser curvature blood vessels. The potentially negative effects of such rings on the beneficial effects of LSG that occur secondary to the faster pyloric and gastric emptying have not been studied.

The authors believe that at this stage, routine use of bands on sleeves cannot be recommended or advocated. Addition of a silastic ring or a band around a gastric sleeve has no proven benefits and can potentially increase short and long term morbidity. Banded LSG should only be considered, inserted and evaluated as part of long-term, larger randomized controlled trials with the appropriate arrangements around the patient consenting process.

Key Learning Points

- LSG is still new procedure with many technical variations. The lack of a standardized technique suggests that we may have different types of LSG completely different from a functional and endocrine perspective.
- Sleeve volume, bougie size, stapling technique and distance from pylorus can all affect medium and long term weight loss and metabolic outcomes.
- The only technical point beyond controversy and now universally accepted is that an orogastric bougie should always be inserted during stapling.
- The controversies regarding level of hiatal dissection and staple line reinforcement are more related to perioperative and short term outcomes such as staple line leak rate and postoperative GERD.
- Most recent meta-analysis and reviews are in favor of more aggressive hiatal dissection with synchronous hiatal hernia repair and staple line reinforcement; however no consensus has been reached yet.

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Section VI

Laparoscopic Adjustable Gastric Banding (LAGB): Technique, Complications, Outcomes and Controversies

Honorary Section Editor - Sally A. Norton

The chapters in this section describe the technique of laparoscopic gastric banding, the diagnosis and management of complications, the outcomes, and current controversies surrounding this long-established weight-loss operation.

The worldwide trend in gastric banding over the last decade has shown an interesting shift. In 2003, banding represented 24 % of all bariatric procedures performed; this rose to 42 % in 2008 and in 2011 dropped to 18 %. Reasons for the decline in gastric banding are likely to include emergence of alternative procedures (notably sleeve gastrectomy), concern regarding the perceived long-term complications of the technique, overall effectiveness for weight-loss and resolution of co-morbidities—and media effect and popular trends.

However, the following chapters illustrate that the decline in popularity of this technique should not be seen as evidence that it is no longer a viable option for weight loss. I encourage upcoming bariatric surgeons to keep an open mind about this tried and trusted procedure; offering a spectrum of operations rather than trying to find a 'one size fits all' operation when the evidence does not currently exist to justify such a stance.

The number of bariatric operations currently performed is less than 1 % of those eligible. We are barely touching the tip of the iceberg, let alone the submerged mass. This does not simply reflect a lack of funding; it also reflects patient choice. Many patients do not want to undergo major surgery when they do not see an urgent need. Such patients are unlikely to request gastric bypass or resectional procedures, which are generally perceived as more invasive. As the least invasive, reversible and lowest risk operation, as well as one that is quick, easily reproducible and easy to learn, gastric banding may be the most appropriate for a mass weight-loss intervention. Complications occur but are rarely severe and often simple to rectify laparoscopically.

Obesity is a chronic disease, of mind as well as body. It is unlikely that any one operation will achieve long-term success for the lifetime of every patient. As such, a step-wise approach offering the ability to move from one operation to another may be appropriate.

It is difficult to conceive that a better alternative to surgery will not be identified over the next 20 years. Should that occur, gastric band removal is feasible but for other weight-loss operations, reversal is somewhat more complex or impossible. We may be leaving an unnecessary legacy of adults with nutritional deficiencies.

So, gastric banding has its problems, like all weight loss operations but for many patients, it provides a quick, easy and safe weight-loss solution. We await, with interest, a definitive trial to compare our current surgical options.

With current evidence showing very little to choose between outcomes of the different operations, the combination of a motivated patient, a technically proficient surgeon performing a familiar operation, and a focus on good postoperative support is likely to be a winning recipe for health improvement. Perhaps we should be more focused on the destination rather than the route.

LAGB: The Technique

30

Chris S. Cobourn and John B. Dixon

Abstract

Laparoscopic adjustable gastric banding (LAGB) surgery, developed to address the shortcomings of the vertical banded gastroplasty and fixed gastric band procedures, is now established as a safe and well-standardized bariatric-metabolic surgical procedure. The safety and complication profiles are well known: complications are often prevented and long-term sustained weight loss is documented. Standardization and reproducibility are attributes of all quality interventional care programs, and these attributes should be the signature of a successful LAGB practice.

Surgical access is optimized with the use of preoperative weight loss, careful patient positioning and excellent liver retraction. The diaphragmatic hiatus is explored and repaired when indicated. The pars flaccida technique is used to generate the retrogastric tunnel and the band is positioned accurately in relation to the gastro-esophageal junction. Fixation of the band to prevent anterior gastric prolapse is recommended and the access port is fixed to fascia to allow easy access.

LAGB surgery can be used to enhance the outcomes of vertical banded gastroplasty, Roux-en-Y gastric bypass and sleeve gastrectomy if weight regain or poor weight loss is experienced, and a suitable abnormality of gastric anatomy is present. Meticulous band placement and aftercare are the essential requirements of all LAGB programs.

Keywords

Severe obesity • Metabolic • Surgical technique • Minimally invasive • Weight control • Bariatric surgery • Laparoscopy • Gastric banding

30.1 Introduction

Laparoscopic adjustable gastric banding (LAGB) surgery was independently developed by Kuzmak and Hallberg to overcome the shortcomings of fixed gastric banding and fixed vertical banded gastroplasty restriction respectively [1]. The initial procedures were performed via open laparotomy prior to the widespread acceptance of laparoscopic surgery. The first laparoscopic procedure on humans was performed by Dr Belachew in Belgium in 1993 [1]. Since that time the laparoscopic approach has become the standard technique used for this procedure. Rarely, the open laparotomy approach is used for difficult revision procedures where significant intra-abdominal adhesions may be encountered. Even with the previous open procedures, majority of gastric bands can be placed with laparoscopic surgery.

The initial surgical approach to LAGB surgery (perigastric technique) involved creating an opening in the lesser curve omentum and another opening in the gastrosplenic omentum or angle of His, on the upper part of the stomach with the band often passing through the lesser sac. Due to the

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high incidence of posterior prolapse, this approach has now been abandoned and replaced with the pars flaccida technique which will be described below [2].

In this chapter, the technique of LAGB placement will be described as used in our practice since 2005. Over time, the technique has evolved but the changes have been subtle and we have not substantially changed how the procedure is performed. A key feature of the LAGB procedure is that the technique has become standardized worldwide based on long-standing experience and reported results. Any substantial changes to the accepted technique should be based on evidence rather than surgeon preference.

30.2 Preoperative Preparation

The preoperative preparation of the LAGB patient generally involves short term use (1–3 weeks) of a very low calorie diet (VLCD) and a meal replacement product that is low in carbohydrate and high in protein. The purpose of the VLCD is to reduce fatty infiltration of the liver prior to surgery. This makes elevation and retraction of the liver safer and less likely to lead to hepatic injury or bleeding.

Other preoperative preparation is determined by the patient's underlying health status and associated comorbidities. Routine evaluation for obstructive sleep apnea is not necessary if the anesthesia protocol minimizes the use of postoperative narcotics to reduce respiratory depression. Patients are encouraged to consume large amounts of water for 2–3 days prior to surgery. This helps reduce the postural hypotension that may result when patients are placed in deep reverse Trendelenburg position. On the morning of the procedure, preferably at least 4 h prior to induction, all the patients receive a combination of acetaminophen (1000 mg), gabapentin (200 mg) and celecoxib (200 mg) orally with a sip of water. These medications reduce the need for postoperative analgesia by blocking pain pathways on a prophylactic basis [3].

30.3 Our Surgical Technique

In our practice, patients are placed on the operating room (OR) table in the supine position, with the monitor at the head of the bed and the surgeon on the patient's right side. A footboard at the end of the bed and two straps keep the patient from sliding when placed in deep reverse Trendelenburg position. Other surgeons may choose the lithotomy position, with the surgeon between the legs. This positioning requires a "butt-stop" device to keep the patient from sliding. This position may require more time for the positioning and remains a matter of surgeon's preference. Meticulous care in the positioning and support of the morbidly obese patient is essential to avoid injuries from slipping, pressure and traction on limbs and joints during surgery.

All the patients receive prophylactic antibiotic coverage with 2 g of cefazolin and anti-thrombotic prophylaxis with subcutaneous (s.c.) dalteparin (10,000 IU) and sequential compression stockings. The use of a large caliber oro-gastric tube that is supplied with the gastric band device is optional. This tube is helpful for decompression of the stomach and aspiration of the gastric contents. It is also helpful as a bougie type device across the gastro-oesophageal junction if crural approximation for crural laxity is performed.

Proper trocar replacement aids in the comfortable and efficient conduct of the operation (see Fig. 30.1). The Veress needle is used to access the peritoneal cavity via a small incision in the left subcostal space. We have found this to be a very safe area to gain initial access, even in patients who have had previous upper abdominal surgery. Some surgeons prefer to use the clear trocar which advances mechanically until the peritoneal cavity has been entered. This may require a zero-degree scope which would mandate a change of scopes at this point in the procedure. We have not found this to be necessary and the disposable ports add to the cost.

Once adequate CO_2 has been inflated, we insert a 5-mm trocar at this site which will act as the camera port. We prefer a 5-mm 30° laparoscope that allows maximum flexibility to move the scope to other sites as needed. After an initial evaluation of the upper abdomen, further trocars are introduced under direct vision as outlined in Fig. 30.1. It is important that during insertion, all the trocars are angled towards the GE junction to avoid torque on the instruments which can increase the difficulty of the procedure. The port in the right mid abdominal area can be a 5 or 10 mm depending on the size of the device being used to create the retrogastric tunnel.

At this point the patient is placed into the maximal reverse Trendelenburg position. The use of the footboard and secure strap fixation of the lower body, especially in the area of the knees is essential to prevent unsafe movement of the patient on the OR bed. The Nathanson retractor is attached to a support anchored to the OR bed (for example Iron Intern® by Automated Medical Products Corp.) and is used to elevate the left lateral segment of the liver. This step is important in order to achieve optimal visualization of the upper stomach, diaphragm and gastro-oesophageal junction. It is important not to allow the Nathanson retractor to rest in the notch where the falciform ligament enters the liver. Elevating the liver with the retractor in this space may lead to laceration of the left lateral segment of the liver and bleeding. Reduction of intrahepatic fat with the VLCD is important to make liver elevation easier and to reduce the risk of bleeding from tearing of the retractor into the hepatic parenchyma.

Laparoscopic evaluation of the upper abdominal parenchyma including the liver and stomach is performed to make

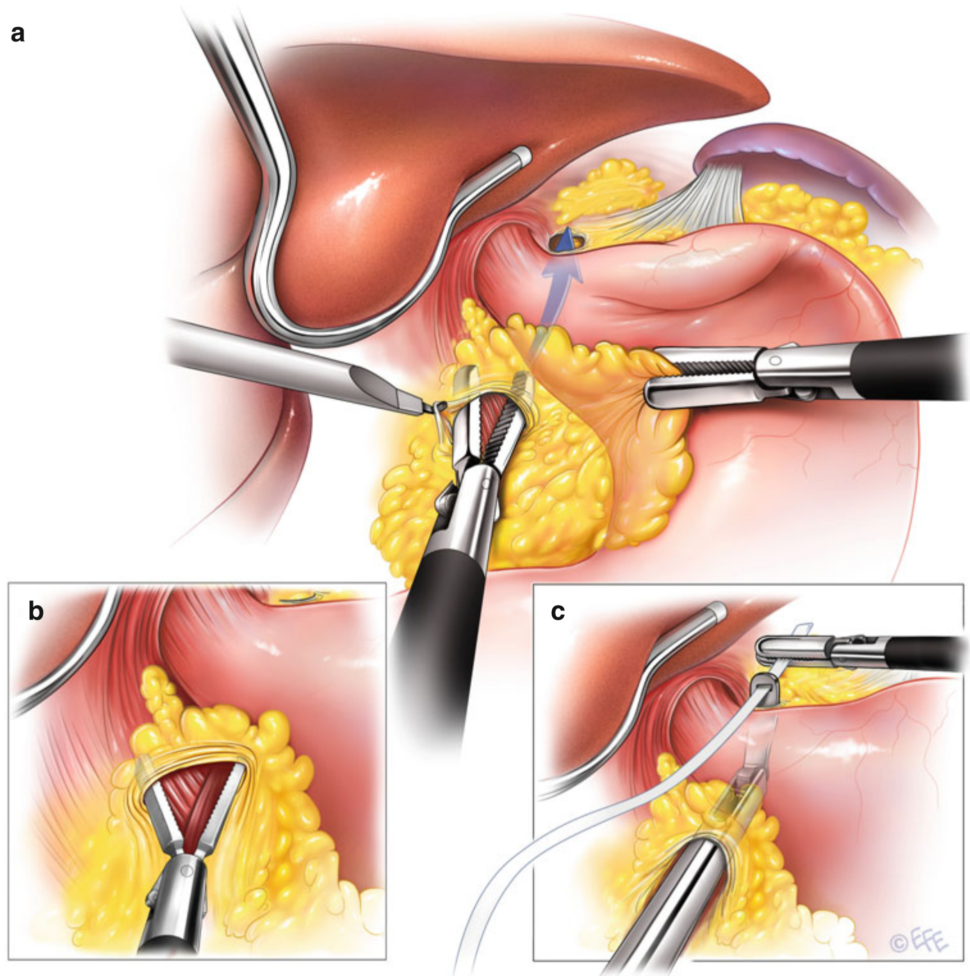

Fig. 30.1 Creation of tunnel posterior to upper stomach, through pars flaccida. (**a**) Dissection of plane through pars flaccida above lesser sac. (**b**) Opening of pars flaccida membrane. (**c**) Gastric band is grasped and pulled through tunnel

sure there are no unanticipated or unusual findings. There may be adhesions from previous abdominal surgery such as cholecystectomy or inflammatory processes such as pancreatitis. These adhesions should be released to the extent necessary to place trocars and perform the procedure.

30.3.1 Diaphragmatic Hiatus

At this point the diaphragmatic hiatus can be examined for evidence of crural laxity or a sliding hiatus hernia. There has been considerable debate recently as to how aggressive the surgeon should be when it comes to approximating the crura. If a true sliding hiatus hernia or significant crural laxity is identified, then the recommended approach is anterior crural approximation with a non-absorbable suture. Very large defects with a significant herniation of stomach into the mediastinum may require posterior crural fixation. We prefer to avoid posterior dissection as much as possible in order to avoid disruption of the retrogastric space above the lesser sac. There is concern that dissecting this area may increase the risk of posterior gastric prolapse. The use of prosthetic mesh to close the crural defect is rarely necessary and should be avoided unless absolutely necessary. There was enthusiasm for approximation of the crura as a mechanism to reduce the incidence of dilatation of the gastric pouch, but the recent publication of a large case matched series failed to demonstrate a protective relationship [4]. The current approach is to perform crural approximation if there is obvious laxity, or if the patient requires medication for heartburn or reflux symptoms prior to surgery. This issue is further discussed in Chap. 33.

30.3.2 Band Placement

The next step is to evaluate the area of band placement. We begin by identifying the angle of His at the junction between the left crus of the diaphragm and the greater curve of the stomach. Blunt dissection can be used to peel the fat from left crus freeing up the stomach. Electrocautery may be necessary to aid in this dissection. The fat pad from the greater curve of the stomach below the angle of His is removed with electrocautery. Thermal energy devices such as the Harmonic

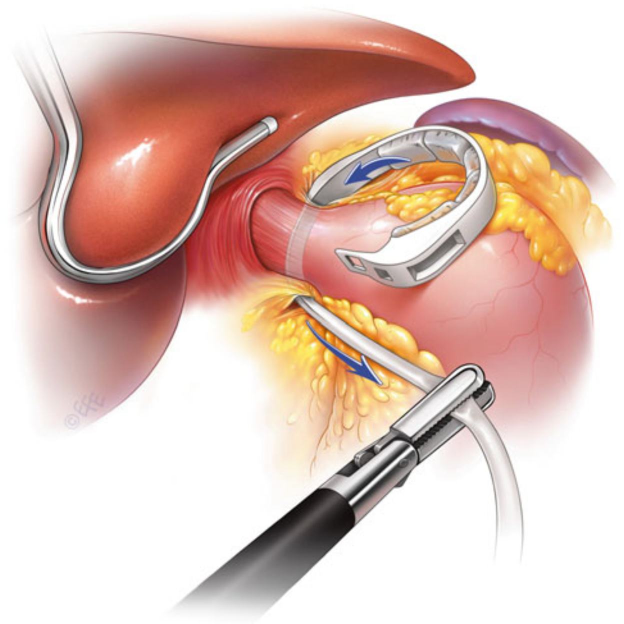

Fig. 30.2 Gastric band device is placed around upper stomach

ScalpelTM (Ethicon Endosurgery, USA) or LigaSureTM (Covidien, Ireland) can be used if the fat pad is particularly large; although this is rarely necessary. Care must be taken to avoid thermal injury to the serosa of the stomach. It is important to dissect this fat pad to ensure optimal placement of the gastro-gastric plication sutures and to minimize the risk of the band being too tight which may lead to postoperative dysphagia. Some surgeons feel this step is not necessary but our preference is to remove the fat pad routinely.

Next, the thin tissue of the gastrohepatic omentum (pars flaccida) is opened (see Fig. 30.2) and the right crus is identified. It is important to assess the amount of fat present on the lesser curve side of the stomach. This is the most helpful factor when deciding on the size of gastric band to be used, if there is a choice of sizes available. Care must be taken not to mistake the nearby inferior vena cava for the right crus. In higher BMI patients, especially men, the right crus may be hidden behind a significant amount of fat. If there is doubt about the identification of the right crus, it can be followed up to the diaphragm where the continuation of the right crus into the diaphragm can be confirmed. Care should be taken when dividing the most superior part of the pars flaccida, to avoid bleeding from the hepatic branch of the left gastric artery which can lead to troublesome bleeding.

A thin layer of fat crosses the base of the right crus and a relatively consistent venous branch can be identified. Cautery is used to make a small defect in the peritoneum over the right crus in this area. A blunt grasper is then passed from the right side port (5 or 10 mm), in the retrogastric space, angled towards the angle of His on the greater curve and the left crus. The grasper should pass with minimal resistance through this plane. The distance between the entry and exit point of the grasper is very short. It is important to ensure that the plane is above the lesser sac to avoid problems with posterior gastric prolapse. Once this plane has been confirmed, a specially designed grasper such as the Greenstein or Goldfinger grasper is passed from the right to the left crus emerging at the angle of His. Some surgeons use the standard grasper but this can be a little more difficult due to the inability to angulate the grasper. Care must be taken not to force the chosen instrument against resistance as this may lead to injury to the posterior wall of the stomach or esophagus. An injury in this area is difficult to detect at the time of the procedure and can lead to significant morbidity in the postoperative period.

The appropriate sized gastric band is determined by the surgeon and prepared by the scrub nurse. The band is introduced into the abdomen through the 15 mm port using either a specially designed introducing device or a grasper. The end of the tubing of the band is brought through the retrogastric tunnel and the band device is closed (see Figs. 30.3 and 30.4). At this point, the orientation of the band should be checked. The band should be oriented obliquely from 2 to 8 o'clock position. There should be a very small pouch of stomach above the band and the serosa of the anterior wall of the stomach should be visible. If the band is too tight it will tend to migrate towards the gastro-esophageal junction and be too high. If necessary, some of the fatty tissue on the lesser curve of the stomach can be divided. Care must be taken to avoid troublesome bleeding from the branches of the left gastric artery. Thermal energy devices may be helpful in this area. Time spent at this stage to ensure proper positioning of the band is critical to optimize the results in the postoperative period. If the band remains too tight, a larger size band can be substituted if available. Alternatively, the band can be evacuated of all fluid prior to connecting the port at the end of the procedure.

30.3.3 Band Fixation

At this point, a series of interrupted and non-absorbable plication sutures are placed between the anterior wall of the fundus of the stomach and the visible anterior wall of the stomach above the band (see Fig. 30.5). Attempts should be made to avoid full thickness sutures if possible. The purpose of the plication sutures is to help ensure proper positioning and to prevent anterior prolapse of the band, especially in the early postoperative period. The number of sutures used depends on the space available but generally varies between two and four (see Fig. 30.6). Some authors have used a continuous suture. Care should be taken to ensure that the stomach overlapping the band is not too tight, in order to avoid ischemic injury to the stomach.

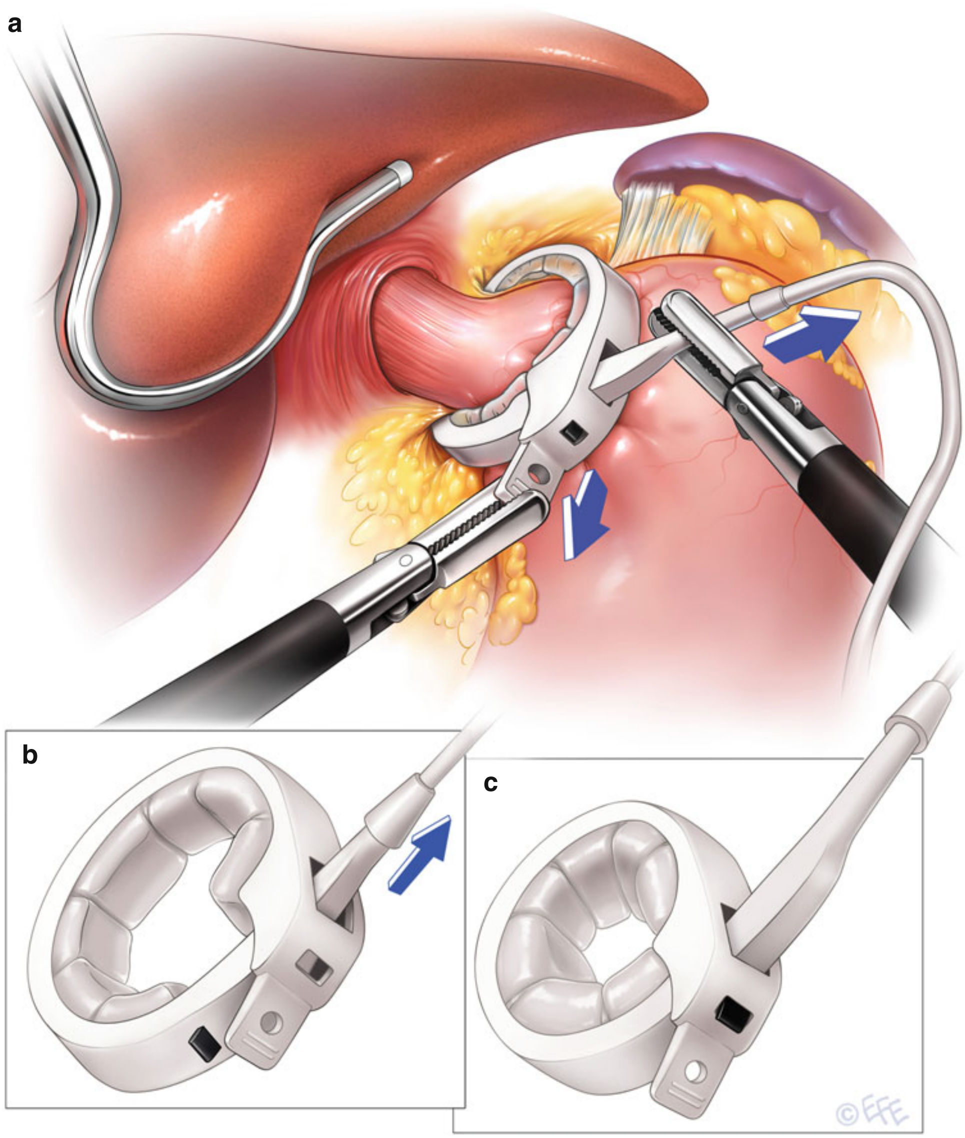

Fig. 30.3 Gastric band is closed and locked. (**a**) Gastric band is closed around upper stomach. (**b**) Closure mechanism. (**c**) Band is closed and locked in place

Some authors have recommended a suture anchoring the plication to the diaphragm (Birmingham stitch) in an attempt to minimize late gastric prolapse [5], while others place a lesser curve plication stitch to reduce the risk of lesser curve gastric prolapse. Some authors and band manufacturers feel that band fixation is unnecessary as it does not reliably prevent band slippage. This issue is discussed further in Chap. 33.

30.3.4 Port Placement

Once the plication sutures have been placed, the tubing of the band can be brought out through one of the ports in preparation for connection to the adjustment port. We prefer to bring the tubing out through the 15 mm port close to the midline. Care must be taken to ensure that the tubing is extracted without knotting. The peritoneal cavity is checked for bleeding or other unusual findings, and the Nathanson liver retractor along with the ports can be removed.

A subcutaneous plane is then generated for the adjustment port. Fixation of the port to the fascia is important to prevent flipping or twisting of the port which can make subsequent band adjustment challenging—although some surgeons prefer a subcutaneous port placement (see Chap. 33).

Some authors have advocated the use of synthetic mesh attached to the port, to enhance fixation to the fascia [6]. The standard approach is to use four non-absorbable sutures placed in the fascia and then through the holes in the port. Mechanical devices have also been designed to fix the port to the fascia [7]. The orientation of the port in relation to the incisions should be consistent within each practice in order to minimize difficulties with accessing the port in patients with substantial abdominal wall fat. Local anesthesia is

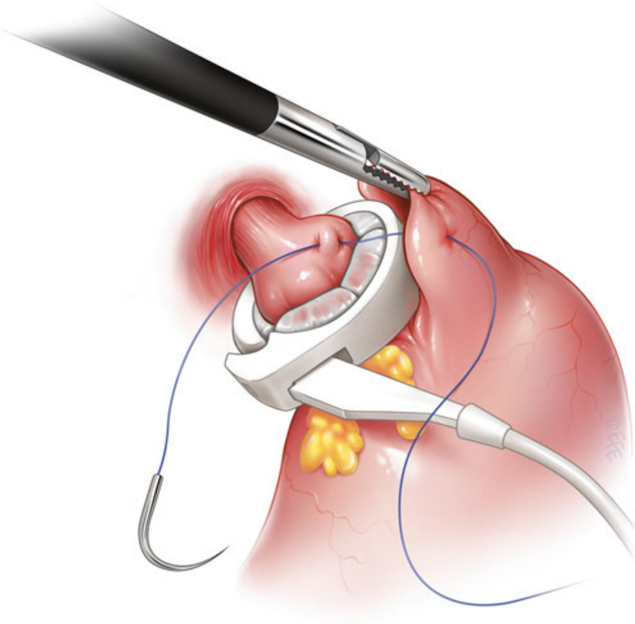

Fig. 30.4 Plication of stomach around anterior aspect of the gastric band

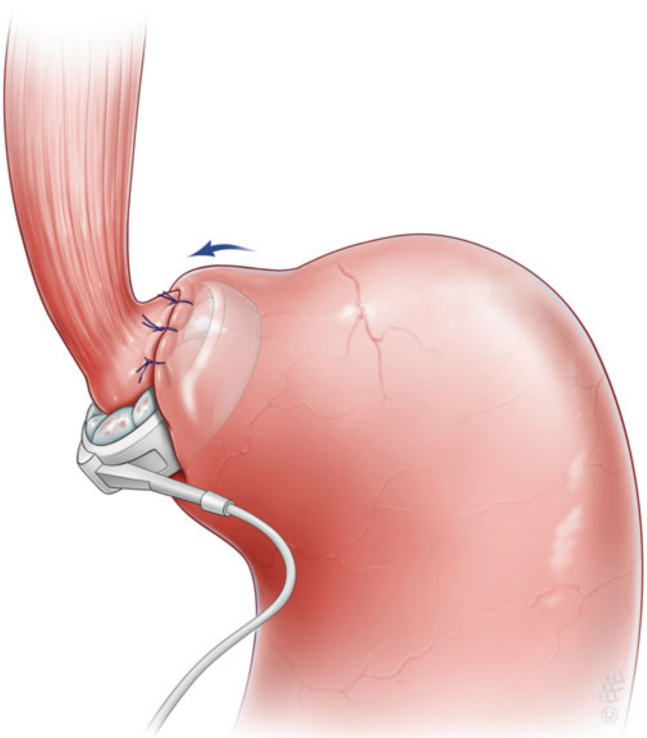

Fig. 30.5 Completed procedure with gastric band closed and anterior plication completed

infiltrated into the incisions to reduce the need for postoperative narcotic analgesia (See Video 30.1).

The use of postoperative narcotic analgesic is limited in order to minimize respiratory depression and to aid in same day discharge [3]. Non-sedating anti-emetics are preferable if necessary. Once appropriate discharge criteria are met, patients can be discharged in the care of a responsible adult. All same day discharge patients are followed up by the clinic staff the next day.

30.4 Special Circumstances

30.4.1 Portal Hypertension

Patients with evidence of significant portal hypertension should be managed very carefully. Elevation of a firm cirrhotic liver with the Nathanson retractor may be difficult and potentially leads to hepatic laceration. Dissection in the area of the gastro-esophageal junction may lead to significant venous bleeding that can be very difficult to control.

30.4.2 Revision Procedures

Patients undergoing gastric band procedures after previous bariatric surgery are more challenging. If the original procedure was carried out with a laparotomy, significant adhesions are likely to be encountered. This is less of a problem with laparoscopic primary procedures. Meticulous dissection and the avoidance of cautery injuries to the stomach, spleen and liver are critical for success. Creation of the retrogastric tunnel is usually less problematic than dissection of the anterior stomach and identification of relevant structures and planes. Band placement is possible after previous vertical banded gastroplasty [8], roux-en-Y gastric bypass [9] and gastric sleeve with low morbidity and good results.

30.4.3 Single Incision Laparoscopic Surgery (SILS)

There has been recent interest in applying the technique of SILS to gastric band surgery [10]. This is discussed further in Chap. 37.

30.5 Postoperative Care of Gastric Band Patients

30.5.1 Immediate Postoperative Care of Gastric Band Patients

Optimal care begins in the recovery room when patients should be treated with limited narcotics to avoid respiratory depression and complications associated with obstructive sleep apnea. With the appropriate use of analgesics and non sedating anti-emetics such as Ondansetron, early postoperative complications should be minimal, occurring in less than

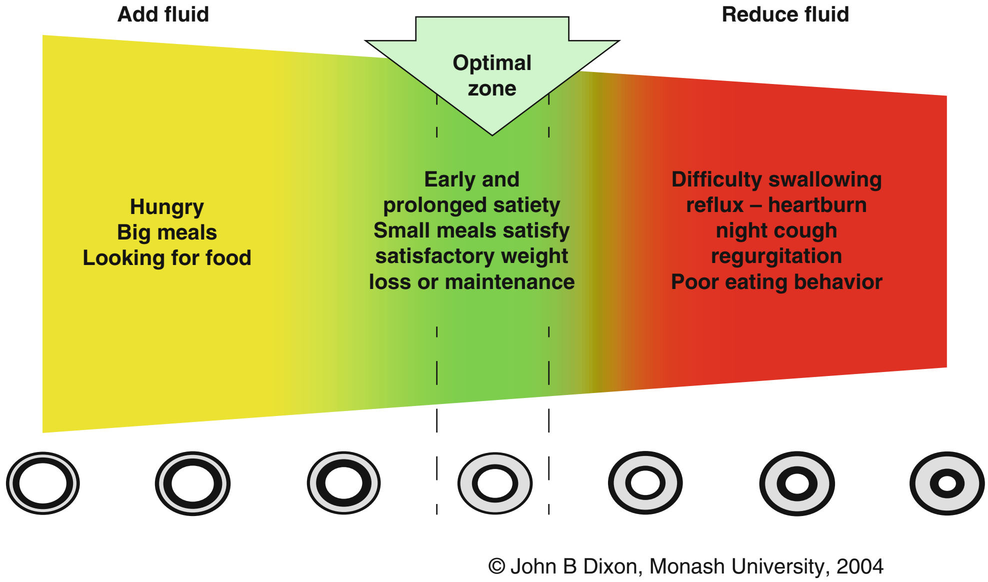

Fig. 30.6 Green Zone chart depicting ideal band adjustment

1 % of patients. Attentive wound care and early ambulation are important and ensure that the majority of gastric band patients can be safely discharged from the surgical facility on the day of surgery. Access to staff after hours is reassuring for patients and allows for early detection if there are any rare issues with dysphagia or bleeding.

Appropriate dietary progression is critical to ensure the presence of gastric band in the optimal position. Postoperative edema of the gastric mucosa may narrow the lumen. Patients are started on liquids and progress through pureed, soft and solid food over a 3–4 week period. These dietary guidelines should be given to patients in written form with the support of the dietitian at the clinic if there are any questions. Patients may feel hungry during this period, and may not be necessarily losing weight because the band may not yet be providing the sensation of satiety. They will often need reassurance that they will begin losing weight once they start eating solid foods.

30.5.2 Postoperative Follow Up

One of the unique features of the gastric band procedure is that the device is adjustable. This allows the effectiveness of the band to be tailored to the individual patients and their progress during the follow up. The band is adjusted by adding saline to the adjustment port, which is anchored to the fascia of the abdominal wall. The technique of accessing the port has been well described and is performed as an office procedure without sedation and generally without local anesthesia. It is important that the port is placed in a standardized position on the abdominal wall, so that the nurse or physician can find the adjustment port even when the abdominal wall is very deep in high BMI patients.

The goal of band adjustments is to encourage the sensation of satiety with small portions. Each follow up visit with the clinic staff should involve a review of the eating habits, pattern of weight loss or gain and a review of symptoms that may be related to the gastric band. Based on the assessment, patients should have their band adjusted so that they enter the "Green Zone" as described by Dr John Dixon (see below). When the band is not optimally filled, patients are in the "Yellow Zone" where they remain hungry and small meals do not satisfy them. They are unlikely to lose weight when in the "Yellow Zone" unless they are "dieting" and are not making optimal use of the gastric band device.

If the band has too much fluid, patients may enter the "Red Zone" where the band is too tight. When in the "Red Zone," patients are unable to consume solid food no matter how well they chew. They become fearful of solid food and generally resort to soft or liquid calories which will pass across the band more easily. These foods do not cause the stimulation of the receptors in the proximal gastric pouch; so satiety is not achieved. Patients will tend to consume large amounts of these types of food, when in the "Red Zone," and may even gain weight. Being in the "Red Zone" for prolonged periods of time can lead to vomiting when solid food is eaten. Prolonged vomiting in the presence of a band that is too tight may lead to dilatation of the gastric pouch and the necessity of band repositioning. Unfortunately, many physicians and patients have been given the idea that the band should cause a feeling of "restriction." This concept is no longer valid and may lead to patients remaining in the "Red Zone" thinking that this is how the band works best.

Any patient who is having difficulty consuming solid foods should contact the clinic for reassessment and if the band is too tight, an appropriate amount of fluid should be removed at the earliest convenience.

Optimal band adjustments are performed in small increments (0.5 cc or less) once the patient is approaching the "Green Zone." This will minimize the risk of bands being too tight. Patients are encouraged to follow up regularly with the clinic staff. This helps to assess the progress and to determine whether a band adjustment or patient behavior adjustment is required. The adjustable nature of the gastric band should promote regular contact with the entire multidisciplinary team. This enhances success with the band both in the short and long term. Patients should never feel any resistance to contact the clinic if they have any issues or concerns.

30.5.3 Long-Term Management of Gastric Band Patients

Education on the mechanism of action of the band is important to ensure patient compliance and enhance the long-term effectiveness. Realistic expectations should be established before surgery and reinforced by the entire team with each visit. Patients will benefit from understanding that the gastric band is a device, which enables a feeling of satiety after consuming smaller portions of food. Patients are encouraged to choose good quality food and to chew it well as the band creates a narrowing of the upper stomach, which acts like a funnel. Food that is poorly chewed will not pass through the band and may be regurgitated. In addition, patients are counseled to eat slowly (45–60 s between bites). This allows intermittent filling and emptying of the gastric pouch, which stimulates the stretch receptors in the gastric pouch and thus provokes satiety.

Patients are encouraged to choose a small portion of food by using a side plate or dessert plate rather than dinner plate and to sit at the table to eat. They are advised to stop eating BEFORE reaching the uncomfortable feeling of being "full." If the patient remains truly hungry or hunger returns in a short period of time, then we encourage them to return to the clinic to have the band adjusted. The key message is that the gastric band does not stop them from eating, but rather allows them to be satisfied with a smaller portion. Reinforcement of these key messages is critical for success with the gastric band and should be the mantra of the entire support team.

Unlike other bariatric surgical procedures such as gastric bypass, the gastric band does not lead to malabsorption. As such, patients generally do not require special nutritional supplements. Any pre-existing deficiencies should be identified and treated but other than a basic multi-vitamin (chewable) and folate for women of childbearing age, gastric band patients simply require a healthy variety of foods. Patients are encouraged to eat the same foods as the rest of their family, but in smaller portions.

Weight loss with the gastric band is slower than with other bariatric procedures. We counsel patients that weight loss of 1–2 pounds per week is optimal. This rate of weight loss allows loss of fat mass, without compromising loss of muscle mass that can occur if weight loss is more rapid. When patients find their weight loss is in a plateau phase, or if they start to feel hungry with the smaller portions, they should be reassessed for the appropriateness of a band adjustment. Typically, as they get better at eating slowly and chewing well, and as they lose some of the perigastric fat that is within the band device, they will benefit from a small band adjustment that return the feeling of satiety with small portions.

Key Learning Points

- Established perioperative protocols including very low calorie diet, preoperative preemptive analgesia, thrombotic prophylaxis and antibiotics enhance the safety within a busy outpatient LAGB practice.
- Visualization of the upper abdomen is optimized with patient positioning and liver retraction.
- Consideration should be given to exploration and repair of the diaphragmatic hiatus.
- Positioning and fixing of the gastric band in place is an established technique. Any change in practice should not be undertaken without thorough evaluation.
- Standard positioning and fixation of the access port allows for optimal office band adjustment.

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LAGB: Complications–Diagnosis and Management

31

Paul Constantine Leeder

Abstract

Gastric Band Complications are relatively common but rarely serious in nature. Complications can be classified as general or specific to band surgery. General complications are rare and gastric band surgery remains one of the safest forms of weight loss surgery available.

Over the lifetime of a band, approximately 10 % of patients should expect to have their surgery revised. Problems that develop over the long term include pouch dilatation, band slippage, erosion and port related problems. A reduced risk and appropriate management of complications is dependant on good long-term follow-up. Major complications occur a median of 33 months after band surgery and outside most bariatric centres' regular follow-up programmes.

Gastric band patients can rarely present acutely with complete obstruction that requires immediate attention to avoid potentially life-threatening sequelae.

Keywords/Phrases

Gastric band complications • Erosion • Pouch dilatation • Band slippage • Maladaptive eating • Band intolerance • Port related problems

31.1 Introduction

With appropriate patient selection, meticulous operative technique and a commitment to long-term follow-up, excellent results can be achieved with gastric band surgery [1]. As with other operative techniques, gastric band surgery should be routinely performed laparoscopically and with support and careful patient selection can be performed as a day case procedure [2].

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31.2 Classification of Complications

Morbid obesity can generally be considered an incurable, chronic medical condition. As such, a patient with a gastric band is a patient for life. Band patients require long-term follow-up and are likely to require adjustments to the band on a regular basis. It is estimated that, even in the most experienced units around 12 % of gastric bands will require some form of re-operation over their lifetime [3]. Most revision surgery is likely to be for minor adjustments such as port replacement or reposition. Reviews of complications post weight loss surgery put the rate of re-operation after band surgery as the highest compared to all of the commonly performed bariatric procedures [4]. It should be emphasised however that these procedures are generally minor and rarely life threatening [1].

It is interesting that the efficacy of gastric band surgery does provoke passionate views both for and against. Gastric band placement was one of the most commonly performed

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bariatric procedures up to 2010 [5]. In the first National Bariatric Surgery Registry report, band surgery accounted for 33 % of primary bariatric procedures in the UK and Ireland between 2009 and 2010. The latest registry report in 2013 has shown a significant reduction in band insertions overall, particularly within the National Health Service. It appears that this drift away from the gastric band is reflected worldwide. Despite this, over 3000 bands were still placed in the UK between 2011 and 2013 [6] and it is estimated that there are approximately 500,000 gastric bands currently placed worldwide.

One of the potential problems with gastric band surgery is not the technique per se, but rather that most bands are currently placed by private providers. Patients often travel abroad, or some distance from their local hospital for a mixture of privacy, cost-effectiveness and surgeon renown. Where the patient and surgeon are separated by both distance and cost, the follow-up received is likely to be less than ideal and patients will invariably arrive at their local healthcare provider once a problem is experienced. The gastric band patient is likely to be an increasingly regular user of public hospital services for the foreseeable future.

Whatever a surgeon's personal feelings are regarding the gastric band, all general, upper GI and bariatric surgeons, and gastroenterologists should be aware of the potential complications that can occur following gastric band placement. Physicians need to be particularly astute, as patients may not make the connections between their presenting symptoms and their previous surgery and may not even admit to having had a previous gastric band. Patients may have feelings of guilt that they have gone abroad for 'cut price' surgery, they may also be embarrassed if the surgery has not been as successful as hoped. It is important to treat all patients with respect and not be critical of their previous health choices, but to manage their symptoms appropriately. All patients are owed a duty of care to have their acute problem managed expeditiously. There are obvious financial implications for the provision of ongoing, elective healthcare for gastric band patients, but this needs to be a joint decision between the local provider and the financial authority as to whether longer-term care can be offered. It does make economic sense to ensure patients have access to appropriate follow-up, to optimise the success rates of surgery.

31.3 General Complications

Complications can be classified as those that are common to all surgical procedures and those that are specific to the gastric band placement. It is important to be aware that all surgery on the morbidly obese patient is high risk and potentially life-threatening. The average BMI of patients undergoing bariatric surgery in the UK public sector is 50.6 [5]. Most patients at this BMI level would be refused alternative routine surgery because of their operative risk. There are risk assessment scores available to help quantify this risk [7]. Even though it can be a day-case procedure, gastric band placement should never be considered minor.

31.3.1 Infection

Infection is common to all surgical procedures. Infection can occur locally, either in the wound or around the band itself. Infection is perhaps most common distant from the procedure site in the form of a chest infection, secondary to postoperative respiratory depression and secretion retention. Respiratory infection can be greatly reduced by insisting on smoking cessation prior to surgery and adopting an enhanced recovery/early mobilisation programme post surgery.

It is important to note that both local and wound infections are rare following gastric band surgery. The surgery should be considered a clean procedure. A foreign body is placed and therefore most teams would recommend administering a single dose of prophylactic antibiotics during the procedure. The band should be handled with care, to avoid unnecessary contact with the patient's skin and particularly the umbilicus. Local infection should be considered to be secondary to an early gastric perforation until proven otherwise (see Sect. 31.4.1).

31.3.2 Bleeding

Bleeding can occur either at laparoscopic port insertion or around the stomach during band placement. It is possible to experience bleeding from neighbouring organs such as the liver or spleen, but this should be extremely rare for the experienced bariatric surgeon unless dense adhesions are encountered. Bleeding during band placement can be kept to a minimum using a minimal dissection of gastric attachments [8]. Meticulous attention should be paid to both technique and haemostasis, particularly if the patient has been on anticoagulants.

31.3.3 Perforation of Viscus

Although visceral perforation is possible in any laparoscopic procedure, most perforations occur as a result of damage to the wall of the gastric cardia. Injury can occur during dissection or can be delayed, secondary to thermal injury or local ischaemia, after band and suture placement. The most widely used and recommended technique for band placement does involve blind passage of an instrument behind the gastric cardia. A blind technique will always place the posterior cardia at potential risk of damage during retro-gastric band placement. Use of an oesophago-gastric bougie or calibration balloon can, in addition, risk direct trauma to the oesophagus during positioning [9].

If perforation is identified at the time of surgery, this should be repaired immediately, normally without significant consequence. Suspicion of a perforation in the postoperative period should be raised in the presence of a pyrexia, tachycardia or need for continued opiate analgesia 12 h post surgery. The abdomen may be soft and pain poorly localised. The classical signs of peritonitis may be absent in the postoperative bariatric patient and should not be relied upon. If in doubt, early re-laparoscopy should be the investigation of choice. A negative laparoscopy will delay patient discharge by only a day; a delay in diagnosis of perforation can lead to a greatly increased mortality risk.

31.3.4 Venous Thrombo-Embolism

Blood clots are a serious, life-threatening complication after any surgical procedure. The risk of thrombo-embolism is increased in the morbidly obese population. The risk can be reduced by early postoperative mobilisation, including day (outpatient) surgery. The use of graduated compression stockings is recommended, although these need to be fitted properly to avoid tight bands behind the knee or mid-calf. Pneumatic calf compression is a preferred alternative in many specialist bariatric centres, used both at the time of surgery and during the early postoperative period.

Most specialist centres recommend the use of thromboprophylaxis in the form of heparin or low molecular weight fractionated heparin (LMWH), as a daily injection. There is however no consensus as to whether this should be started pre-operatively, during, or immediately after surgery and whether it should be continued after hospital discharge. A U.K. survey from 2010, found that 86 % of units administer LMWH at a higher prophylactic dose (e.g. Enoxaparin 40 mg) once daily during hospital stay [10]. Our unit also continues LMWH for 2 weeks after surgery, as a self-administered injection.

31.4 Specific Complications

Most laparoscopic gastric band insertion procedures go without complication. It has the lowest early complication rate of all bariatric procedures and by far the lowest mortality risk [11]. It is for this reason that it is likely to remain popular amongst patients who are offered a choice of surgical procedure.

Longer term, between 6 and 60 % of patients will run in to a problem with their gastric band, that will require re-operation [1, 12]. Although some of these problems may result in band removal, it is important that this is not considered a default for all long-term band problems. In our experience many patients do become very attached to their bands and simple maintenance may be all that is required to keep the band working properly for that patient. A summary of specific gastric band complications can be found in Table 31.1.

31.4.1 Band Erosion

It is possible that any foreign material placed against a mobile viscus, may eventually migrate or erode into a neighbouring organ. Erosion is a phenomenon that was well known with the ‘Angelchick’ prosthesis placed around the lower oesophagus in the 1970s and 80s for the control of reflux [13]. Similar problems have been reported since the first bands were placed in 1990s [14]. What is surprising is how relatively rare erosion remains as a complication.

The incidence of erosion following gastric band surgery remains currently at around 1 % [15]. The reported incidence has reduced significantly since the widespread adoption of the ‘pars flacida’ placement technique [15].

Table 31.1 Management of gastric band complications

Complication	Symptoms	System aspiration	X-ray	Contrast swallow	Gastroscopy	Treatment
Band erosion	Dyspepsia, lack of satiety	Turbid fluid	Satisfactory 2–8 o’clock	Oral contrast both sides of Band	Erosion on retroflexion	Band removal
Pouch dilatation	Dysphagia, reflux	Clear fluid	Horizontal band	Concentric pouch	Large pouch, oesophagitis	Deflation, education
Band slippage	Dysphagia, reflux, regurgitation	Clear fluid	‘O’ or vertical band	Eccentric pouch on AP and lateral views	Difficult identifying pouch exit, oesophagitis	Band removal or reposition
Band intolerance	Intermittent vomiting	Clear fluid	Satisfactory 2–8 o’clock	Normal	Normal	Band removal
Port tilt	Port pain	Unable to access	Tilt on lateral X-ray	Normal	Normal	Port reposition
System leak	Lack of satiety	Less fluid aspirated	May see tubing disconnection	Leak of contrast from band system	Normal	Port or tubing replacement

Presentation of gastric band erosion can be either early or late after surgery. Erosion occurring within a few weeks of surgery is likely to be due to a microperforation of the gastric wall caused either during band placement or as a consequence of local gastric ischaemia secondary to a tight band. Presentation in this circumstance is similar to a gastric perforation and is likely to require emergency surgery to both remove the band and repair the erosion.

Most gastric band erosions present a median of 31 months after band placement [16]. The aetiology is less convincing. Direct irritation or ischaemia of the gastric cardia leads to a gradual ‘cheese wiring’ of the band into the stomach. Whether an overtight band increases the chance of erosion is not proven. Most erosions occur from the greater curve, leaving the band buckle, at the lesser curve, to erode last. This may be due in part to the ‘pars flacida’ protecting the lesser curve. The incidence of early erosion is related to surgeon experience, while that of late erosion remains static throughout a surgeon’s band career [17].

Symptoms of band erosion vary between pain, dyspepsia, and lack of satiety to a solitary port site infection. All port site infections beyond the early postoperative period should be considered to be due to band erosion until proven otherwise. In our experience, all infections have been eventually identified as erosions, although some have taken many months to become visible.

The investigation of choice in suspected band erosion should be a gastroscopy. Careful assessment should be made of the cardia with endoscope retroflexion and air insufflation (Fig. 31.1). If the patient is unwell, further imaging with Computerised Tomography can be useful to both identify the site of erosion and any associated collection (Fig. 31.2). Careful aspiration of the band contents via the port will yield turbid, yellow fluid. If the port needling was not difficult, discoloured band fluid is diagnostic of erosion. Caution should be given to compete band deflation if erosion is suspected as this can potentially lead to a leak of gastric contents along the deflated band track.

Treatment of gastric band erosion will require removal of the gastric band. The timing of removal and route will depend on both the patient’s symptoms and the local surgical expertise. Initial gastroscopy will allow assessment of the degree of erosion. If symptoms are relatively minor, it is better to wait for at least half of the band to erode into the gastric lumen. There are reports of small bowel obstruction if the band has eroded completely and is allowed to travel distally into the bowel lumen [18]. The limit of travel is dependant on the length of the attached gastric band tubing.

Once at least half of the band has eroded, or if symptoms dictate earlier intervention, the band can be removed. Access to the eroded band is best from the gastric lumen. If local facilities and expertise exist, then the band can be removed endoscopically. The technique requires specialist endoscopic tools to both divide and retrieve the band endoscopically. The port has to be removed and tubing divided as a separate procedure. Both procedures are normally carried out together under a general anaesthetic [19].

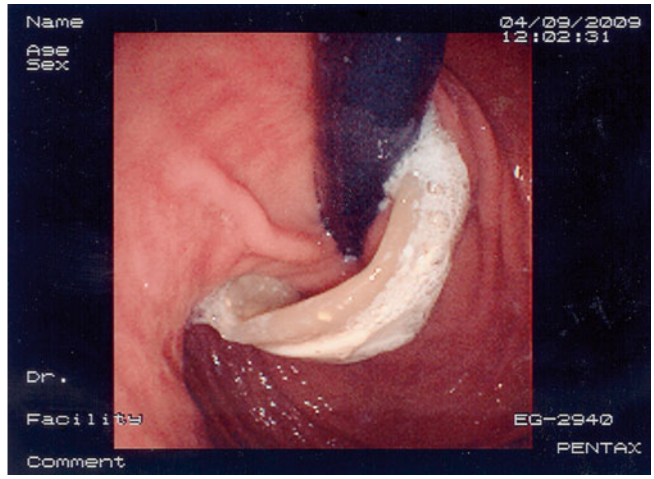

Fig. 31.1 Endoscopic view of a partially eroded gastric band

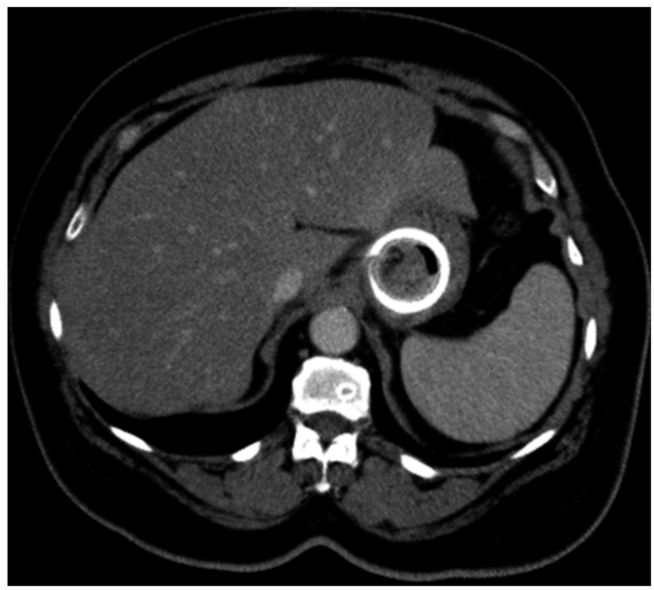

Fig. 31.2 CT scan of a gastric band partially eroded into the proximal stomach

If endoscopic management is not possible, then the eroded band can be removed laparoscopically. Various techniques have been described. With established erosion, it is not usually possible to see the band within the peritoneal cavity, because of the dense adhesions encountered. In the author’s experience, the most successful technique involves making an anterior gastrotomy through uninvolved gastric body. The band is then divided and removed via the gastric lumen, following division of the band tubing. The gastrotomy can be closed primarily with sutures or staples. If there is a concern regarding a leak from the gastric band site, this can be covered with an omental patch [20].

The gastric band port can then be removed and if infected, the wound will have to be left to heal by secondary intention.

Most patients' symptoms will settle completely following band removal, but may require a course of treatment with both proton pump inhibitors and broad spectrum antibiotics. Most centres would not recommend further surgery after band erosion but some authors have published successful re-banding or gastric bypass after previous erosion [15].

31.4.2 Tight/Loose Band

Poor band follow-up can be considered a specific complication of Gastric Band surgery. If a service is not able to provide, or a patient not able to commit to, a lifelong follow-up programme then band problems are more likely to occur. In these circumstances a gastric band perhaps should not be considered the weight loss procedure of choice.

A word of warning should be mentioned when presented with a patient with symptoms of an over tight band. If the patient has not been seen for over a year, or is not known to the department, then a baseline contrast swallow is recommended to ensure that the band is in a satisfactory position for adjustment. If one is satisfied with the band position, adjustments should be minor only (less than 1 ml of saline). The recommended volumes for adjustment are dependent on the band type and are beyond the scope of this publication. If large volumes of fluid are aspirated from a band system, patients often experience extreme refractory hunger and rapid weight regain. The patient will lose confidence in both you and the band and it can be extremely difficult to get the band back to optimal adjustment.

31.4.3 Pouch Dilatation

Gastric pouch enlargement, proximal to the gastric band can be either due to a distal migration of the gastric band or due to a stretching, or dilatation, of the proximal gastrointestinal tract. Accurate diagnosis and classification can be made by a combination of a good history and contrast study findings.

A dilatation of the stomach proximal to a gastric band is known as a pouch dilatation. Pouch dilatation usually develops chronically between 2 and 5 years post band placement [21]. This emphasises the need for long-term follow-up after gastric band surgery. Pouch dilatation is thought to be a result of either an over tight band or chronic overeating. More often than not, both problems are present. The incidence of pouch dilatation is probably underreported in the literature as it is often mislabeled as band slippage.

Patients may present with symptoms relating to an over-tight band, particularly nighttime reflux and occasional food regurgitation. The symptoms are not specific to a pouch dilatation that can only be diagnosed on an X-ray contrast study. A plain Antero-posterior non-contrast X-ray may show a flat band, compared to the optimal 2–8 o'clock angle of an appropriately positioned gastric band (Fig. 31.3) [22]. A contrast X-ray swallow test will identify the concentric gastric pouch enlargement, diagnostic of a pouch dilatation (Fig. 31.4). An endoscopic examination is not normally necessary in this circumstance, unless the patient develops red flag symptoms such as haematemesis. It is difficult to accurately assess the size of a gastric pouch and correct band position on endoscopy, but inflammatory changes such as gastritis or even oesophagitis may be identified.

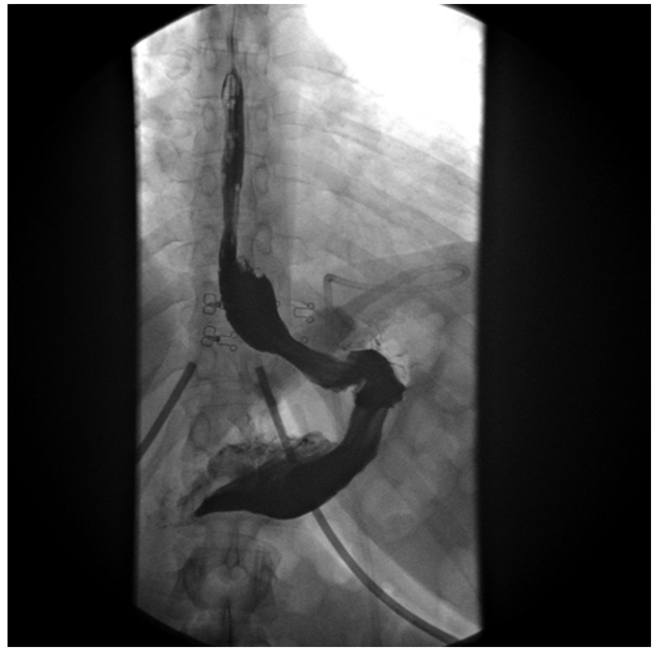

Fig. 31.3 X-ray contrast swallow demonstrating an optimally positioned gastric band pointing toward the 2 and 8 O'clock positions

Management of a pouch dilatation should consist of initial band deflation, using a non-coring needle. Most people recommend removing all but 1 ml of saline from the band system, to allow some continued cushioning around the band. The patient should be advised that pronounced hunger may be an issue and to work hard to avoid significant weight regain during this period. A repeat contrast swallow is recommended after a period of 6–8 weeks to check for pouch resolution. Although dietary change is not normally recommended, a prescription of a proton pump inhibitor to reduce gastric acid secretion is normal to heal any associated mucosal inflammation.

If caught early enough, a pouch dilatation may resolve without the need for surgical intervention. If the pouch has resolved with conservative measures then a period of intense patient re-education and judicious band adjustment is required to help prevent a re-occurrence. It is important that the patient learns to recognise the feeling of satiety and to use this to control eating rather than the feeling of obstructive symptoms that may previously have been the case. The support of a clinical psychologist may also be useful in this circumstance.

Fig. 31.4 Concentric gastric pouch dilatation above a horizontal lying band

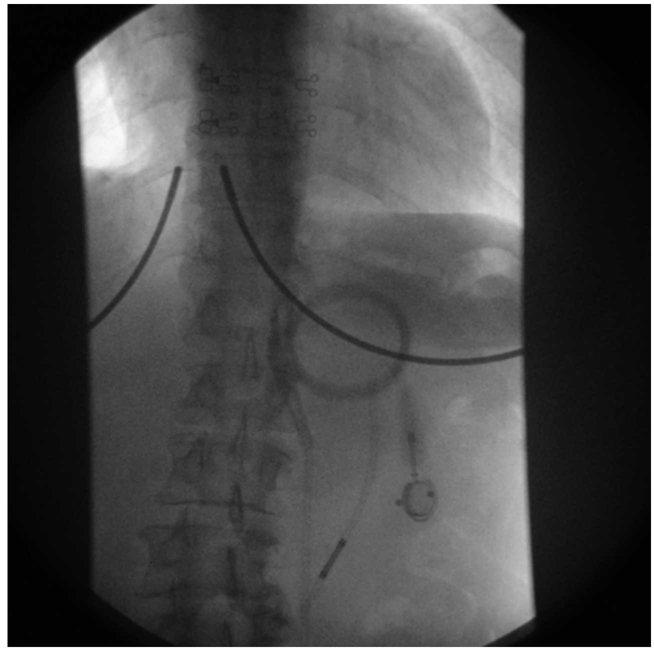

Fig. 31.5 The 'O' sign gastric band position, indicative of an anterior band slippage

31.4.4 Band Slippage

A gastric band can migrate distally along the stomach, or the stomach proximally above the band. A band slippage can present either chronically or acutely and can involve either the anterior of posterior gastric wall. If a band slippage occurs within the first 6 months of gastric band placement, it is likely to be a technical problem relating to the surgical procedure [23].

31.4.4.1 Anterior Slippage

Most gastric band slippages are anterior and present chronically, up to 45 months after gastric band placement [23]. The symptoms and mode of presentation are very similar to that of a concentric pouch dilatation.

Most chronic gastric band slippages present with symptoms of night reflux and regurgitation. An X-ray may show a classical 'O' sign with the gastric band pushed inferiorly and posteriorly, secondary to the eccentric anterior pouch dilatation (Fig. 31.5) [22]. A contrast X-ray swallow will aid diagnosis and help differentiate anterior slippage from other complications (Fig. 31.6). Once diagnosed, the acute management includes band deflation and use of a proton pump inhibitor. A full slippage will not settle with conservative measures alone, although symptoms should resolve with deflation. The problem is likely to return as soon as fluid is put back into the band system.

Anterior slippages can present acutely with symptoms of intractable vomiting. If left, a significant gastric band slippage can act like a gastric volvulus. The risk of dehydration or aspiration secondary to complete obstruction can be severe. There is also a rare risk of gastric necrosis or perforation if prolonged, or the diagnosis delayed. The author recalls a patient with a significant slippage being managed by the psychiatrist for misdiagnosed bulimia, before eventually presenting to hospital in acute renal failure secondary to their intractable vomiting.

In the acute situation a significant band slippage should be managed with band deflation and intravenous fluid rehydration. If contrast studies confirm a complete obstruction at the level of the band despite deflation then emergency surgery is warranted in order to prevent gastric necrosis (Figs. 31.7 and 31.8). An experienced anaesthetist should be available and fully aware of the risk of aspiration from a distended gastric pouch so that the airway is fully protected.

Options for surgical intervention of slippage include band removal, unbuckling or repositioning. Although an alternative weight loss procedure can be contemplated after band slippage, most units would not recommend this at the same time as band removal in the acute situation. The choice of procedure does require careful thought and the patient should be counselled regarding these options. The ultimate choice will be influenced by local expertise and the viability of the stomach after band unbuckling.

Fig. 31.6 Eccentric pouch secondary to an early anterior gastric band slippage

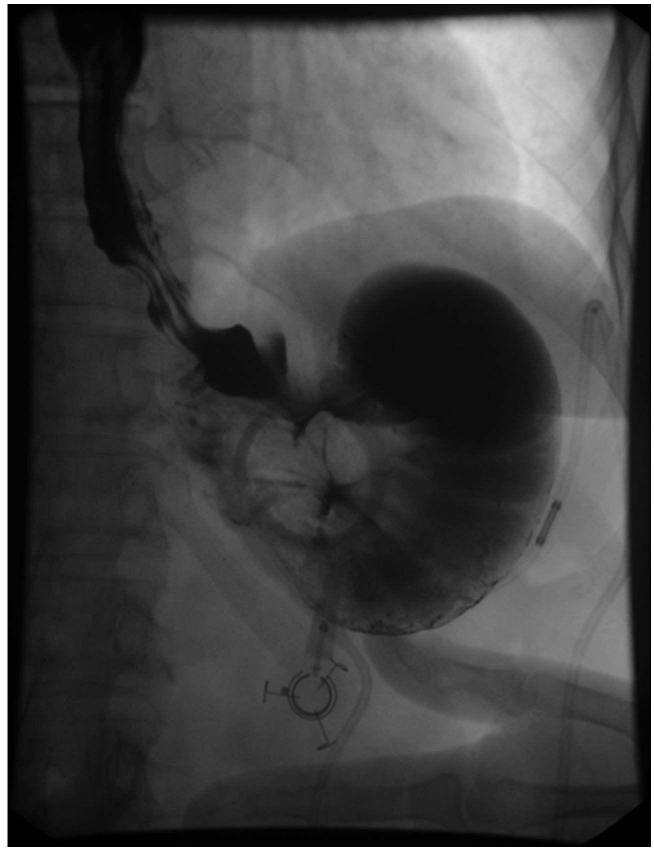

Fig. 31.7 Acute anterior band slippage resulting in complete obstruction to flow of X-ray contrast

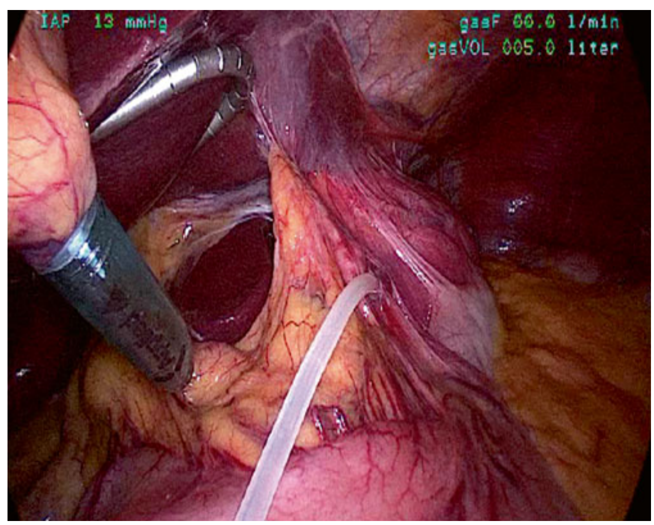

Fig. 31.8 Anterior gastric band slippage seen at laparoscopy

The operative approach should involve dissection on to the band buckle, unbuckling, followed by releasing the band from it's anterior attachments. The site of previous sutures can help to guide the anterior dissection. Once the band has been released, it is advisable to also divide the thick capsule that often forms between the band and stomach. If not divided the capsule can act as a persistent stricture and prevent resolution of symptoms.

If the patient has had good results previously with the band and the stomach is healthy, then band reposition should be considered. If there is no evidence of posterior slippage then a proximal, anterior reposition and re-suture is straightforward.

One of the potential associated factors in both anterior slippage and pouch dilatation is the presence of a sliding hiatus hernia (Fig. 31.9). Whether the hiatus hernia is causative or consequential is controversial [24], but there is some evidence to suggest that hiatus hernia repair at the time of initial band placement can lower the risk of future slippage [25]. At the time of re-operation it is important to look specifically for a hiatus hernia and perform a repair, particularly if reposition is contemplated.

31.4.4.2 Posterior Slippage

A posterior band slippage is rare, but can occur if the gastric band has been placed within the lesser sac of the stomach. The pars flaccida technique should be used together with a tunnelling technique to place the band securely within the retro-cardiac plane. The combination of these

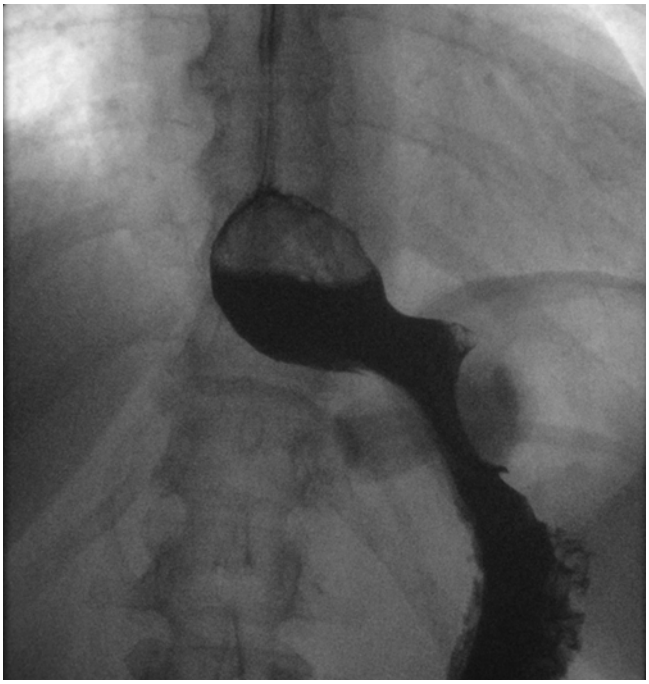

Fig. 31.9 Hiatus hernia identified at X-ray contrast swallow. Note the gastric pouch dilatation above the left hemi-diaphragm

Fig. 31.10 Posterior gastric band slippage with associated abnormal band position

techniques should help to prevent posterior slippage from occurring.

Symptoms of a posterior band slippage are indistinguishable from other types of slippage, but like anterior slippages can present acutely with obstructive symptoms. The investigation of choice is X-ray. Plain abdominal X-ray can be diagnostic with a classical vertical band position. A contrast swallow may need to be performed at a lateral angle to confirm the posterior slippage in relation to the anterior band (Fig. 31.10).

The acute management will involve band deflation but ultimately the band will need to be repositioned or removed.

31.4.5 Oesophageal Dilatation

Oesophageal dilatation can occur in association with a proximal gastric pouch dilatation. Oesophageal dilatation is part of the spectrum of significant pouch dilatation, but is possibly secondary to oesophageal hypo-motility. If left, the condition can resemble a pseudoachalasia. X-ray contrast swallow will demonstrate a dilated oesophagus, with poor peristalsis (Fig. 31.11). Food residue is often seen present within the oesophageal lumen, with the oesophagus acting as a food reservoir after eating.

Gastric band deflation may help to resolve the problem of oesophageal dilatation, but it is likely to recur once the band's high-pressure zone is re-established. Patient re-education and support around appropriate eating behaviour is required to reduce the risk of persistent dilation.

The inevitable treatment for persistent dilatation will involve band removal [26]. Careful consideration will need to be given to alternative weight loss procedures, in order to avoid further proximal gastric high-pressure.

31.4.6 Maladaptive Eating

One of the under-reported risks of the gastric band is the development of poor eating habits post surgery. It is well known that a textured food diet is optimal for most bariatric procedures. The resultant proximal gastric peristalsis produces afferent vagal nerve stimulation that results in early, prolonged satiety [27]. Softer food choices and liquid calorie foods pass easily through the proximal gastric restriction provided by the band. As a result, larger quantities of low texture foods can be ingested at a higher rate. Patients with a gastric band will find it a lot easier to ingest soft food choices that can lead to poor weight loss or weight regain.

Paradoxical weight gain can occur in the presence of a tight gastric band, mainly as a result of softer food choices. This condition has been named maladaptive eating. The condition is associated with poor postoperative follow up and an over tight band. It is often associated with an episode of anxiety or psychological stress.

Treatment should be aimed at initial loosening of a tight gastric band to allow the ingestion of solid, textured foods.

Fig. 31.11 Proximal pouch dilatation with associated oesophageal dilatation. Note evidence of food residue within the oesophagus

This management should be closely supervised, with re-education toward an appropriate eating pattern. Once a balanced eating habit is established, judicious band adjustment can take place.

Overall, once a maladaptive eating pattern is established, achieving success with a gastric band can be very difficult and it may be better to look at alternative procedures.

31.4.7 Band Intolerance

The existence of true band intolerance is probably overestimated. Most authors do admit that intolerance is an entity in itself, but is often over-diagnosed in place of pouch dilatation or maladaptive eating [28]. There will be circumstances where, early in the life of the band, a patient can develop obstructive symptoms, despite investigations demonstrating lack of restriction.

If a patient develops symptoms of dysphagia and regurgitation of solid foods, it is important to exclude one of the complications already listed above. X-ray contrast swallow and gastroscopy should be performed to confirm a satisfactory band position, lack of restriction at the level of the band and healthy gastric mucosa. If no other cause can be identified then it is appropriate to give a diagnosis of band intolerance. Oesophageal manometry may identify a hypomotile lower oesophagus, but more often than not motility is not affected. Despite this it is suggested that the intolerance may be due to poor oesophago-gastric motility and hiatal hernia development [24]. Intolerance may simply be due to the patient failing to develop an appropriately slow eating habit to work with the band.

Conservative measures are not useful in the management of true band intolerance. Resolution of symptoms can only be achieved with permanent removal of the gastric band.

31.4.8 Port Site Infection

With the use of standard precautions and an aseptic technique, wound infections after band placement should be rare. Equally, gastric band adjustment should not present an infection risk. Most adjustments can be performed safely in an outpatient clinic setting, although the use of a standard aseptic non-touch technique is recommended.

If a port site infection occurs within the first week of surgical placement, it is likely to be secondary to a wound infection. An early gastric perforation must always be suspected, particularly if microbiological culture yields a gut rather than cutaneous infection source. If a perforation is excluded, early infections can be treated with appropriate broad-spectrum antibiotics. If the infection persists the port may have to be removed and the band tubing placed within the peritoneal cavity, away from the site of infection. Once healed, the tubing can be retrieved laparoscopically and a new port placed at an alternative site. Even if the infection has resolved completely, replacement at the original site is not advised, as the scarring will make future adjustments very difficult.

Most port site infections are late and occur at a time after the wounds have completely healed. Any infection should be treated in a standard fashion with incision and drainage and microbiological culture taken to help identify the source of infection. Most infections will not heal without the temporary removal of the gastric band port.

All late port site infections should be investigated thoroughly for evidence of gastric band erosion. Gastroscopy is mandatory in this circumstance. In the author's experience all late port infections will eventually be identified to be secondary to gastric band erosion, although initial investigations may be clear.

31.4.9 Port Site Pain

A relatively common complication after gastric band surgery is that of pain or tenderness at the gastric band port site.

Pain may be due to proximity to the costal margin, partial rotation of the port or secondary to pouch dilatation.

The port site should be examined for signs of infection and to identify any area of tenderness. The patient may complain of port pain, where the tenderness is actually some distance from the port and due to an unrelated cause.

If problematic, port site pain can be treated with replacement of the port away from the ribs, although patients should be cautioned that this might not help. Local anaesthetic and steroid injections around the port have been used with varying degrees of success, ensuring the injection needle does not damage the port itself. Pain secondary to a pouch dilatation can be alleviated by band deflation.

31.4.10 Port Rotation

Gastric band port rotation or tilting can occur at any time post placement. While port fixation can help to reduce the incidence of rotation, a poorly positioned port can result in pain and damage secondary to repeated difficulty with adjustment. Most rotated ports are partial and can be manipulated to allow adjustment. X-ray can help to locate an awkwardly placed port. Reposition is required if the port is painful or completely tilted so that it is no longer accessible. While port reposition can be performed under local anaesthetic, it is probably better repositioned under a general anaesthetic. This allows re-tunnelling of the tubing if appropriate, which often requires laparoscopy, prior to port replacement or reposition.

31.4.11 Band/Tubing Leaks, Disconnection, Migration

The gastric band system is designed to remain in situ for the patient's lifetime. Despite this, system failures can occur. One study suggests the incidence of port related revisions to be around 6 %, the majority of these for the management of leaks [29]. All bands that are currently available are made of solid silicon. Silicon is inert and but can develop leaks. A leak in the band system can be most commonly due to needle trauma during difficult adjustment or as 'wear and tear' damage as the tubing traverses the abdominal wall. A leak is very rarely due to damage during initial band placement or secondary to a manufacturing defect. Occasionally the silicon tubing can come apart from its metal port connector. Leaks can occur as a result of gastric band erosion, but the presentation and management in this circumstance would be for erosion rather than leak.

Most band system leaks present as a gradual or sudden loss of restriction relating to the band. The patient feels as if 'the band isn't there any more'. The patient may notice that restriction only lasts for a few days following each gastric band adjustment. With this history, it is important to carefully record the total volume and colour of fluid within the gastric band system. If turbid in colour, one must immediately consider band erosion. If clear, the next step is to instil a measured volume of fluid into the system and see if the same volume can be aspirated. If a reduced volume is immediately present there is likely to be a leak in the band system. If fluid can be instilled but not aspirated, it is likely that there is a complete tubing disconnection or fracture.

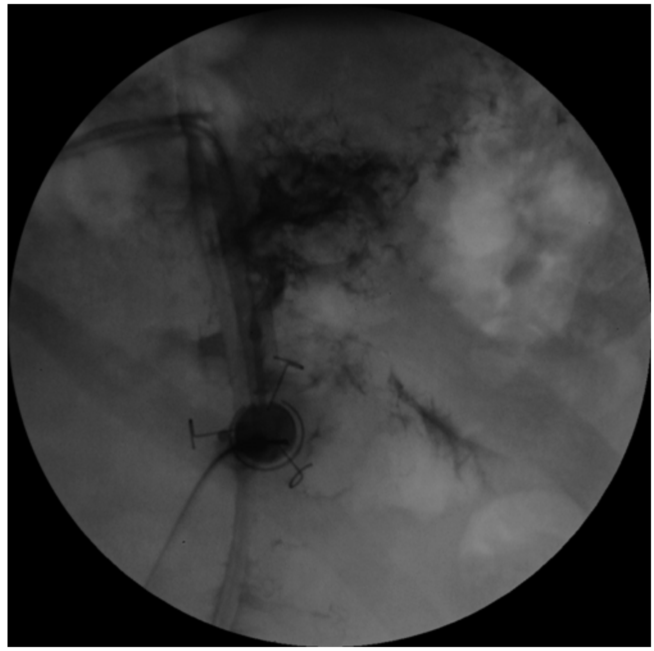

Fig. 31.12 Gastric band tubing fracture resulting in leak of injected X-ray contrast

If a leak is suspected, the next step is to arrange an X-ray and contrast injection to identify the site of leak (Fig. 31.12). If the leak is slow it may not be obvious immediately. One should accurately note the volume of fluid in the band system & arrange to measure it again after 1 or 2 weeks. If the volume is reduced at follow-up visit, it is likely to represent a leak. The exact site of the leak may remain mysterious if very minor. In this circumstance, it is reasonable to arrange a replacement of the gastric band port and nearby tubing, as being the most likely site of leak. If this fails to address the problem but there is convincing evidence of fluid leak, a laparoscopic procedure can be performed to replace the gastric band. This is best done by attaching the new band to the disconnected old band, which is then used to pull the new band into the existing retro-gastric tunnel as it is removed.

It is important that all potential gastric band leaks are managed as a matter of urgency, to prevent the patient gaining weight and as a result losing faith in the band.

31.4.12 Weight Loss Failure/Weight Regain

Failure due to poor weight loss is probably the most common and contested complication relating to gastric band surgery.

Whether it should be considered a complication can be debated. Failure to achieve an acceptable level of weight loss following gastric band surgery has been reported in up to 50 % of patients [30]. As a result, many units have abandoned the use of the gastric band as a primary weight loss procedure. With appropriate band placement and regular follow up, some centres have reported long-term results equal to gastric bypass surgery [1].

31.5 Prevention of Band Complications

The following criteria may help to prevent complications and produce long-term successful results with a gastric band:

1. Patient Selection. A motivated, mobile, young patient is more likely to do well with gastric band surgery [31]
2. Patient Preparation. A focus on changing lifestyle and eating habits and managing expectations pre-operatively can help with postoperative success.
3. Operative technique. Most authors recommend the pars flaccida dissection technique as gold standard in band placement [32]. There is increasing evidence that hiatus hernia repair can help to prevent slippage in the future [25]. Most authors would recommend gastric sutures to secure the band in position, many now preferring a plication or 'Birmingham Stitch' to prevent complications, however, this is controversial (see Chap. 33) [33].

   Securing the gastric band port with suture, staples or mesh is recommended although some authors cite fewer complications with subcutaneous placement [34]. The umbilicus should be avoided to reduce infection.
4. Regular follow-up. A regular follow-up programme is mandatory to optimise the function of the band and identify complications at an early stage [35].

   A low threshold for investigation with X-ray contrast studies or endoscopy is also recommended. Christine Ren has devised a useful algorithm for the management of adverse symptoms related to the gastric band. This is reproduced by kind permission (Fig. 31.13).

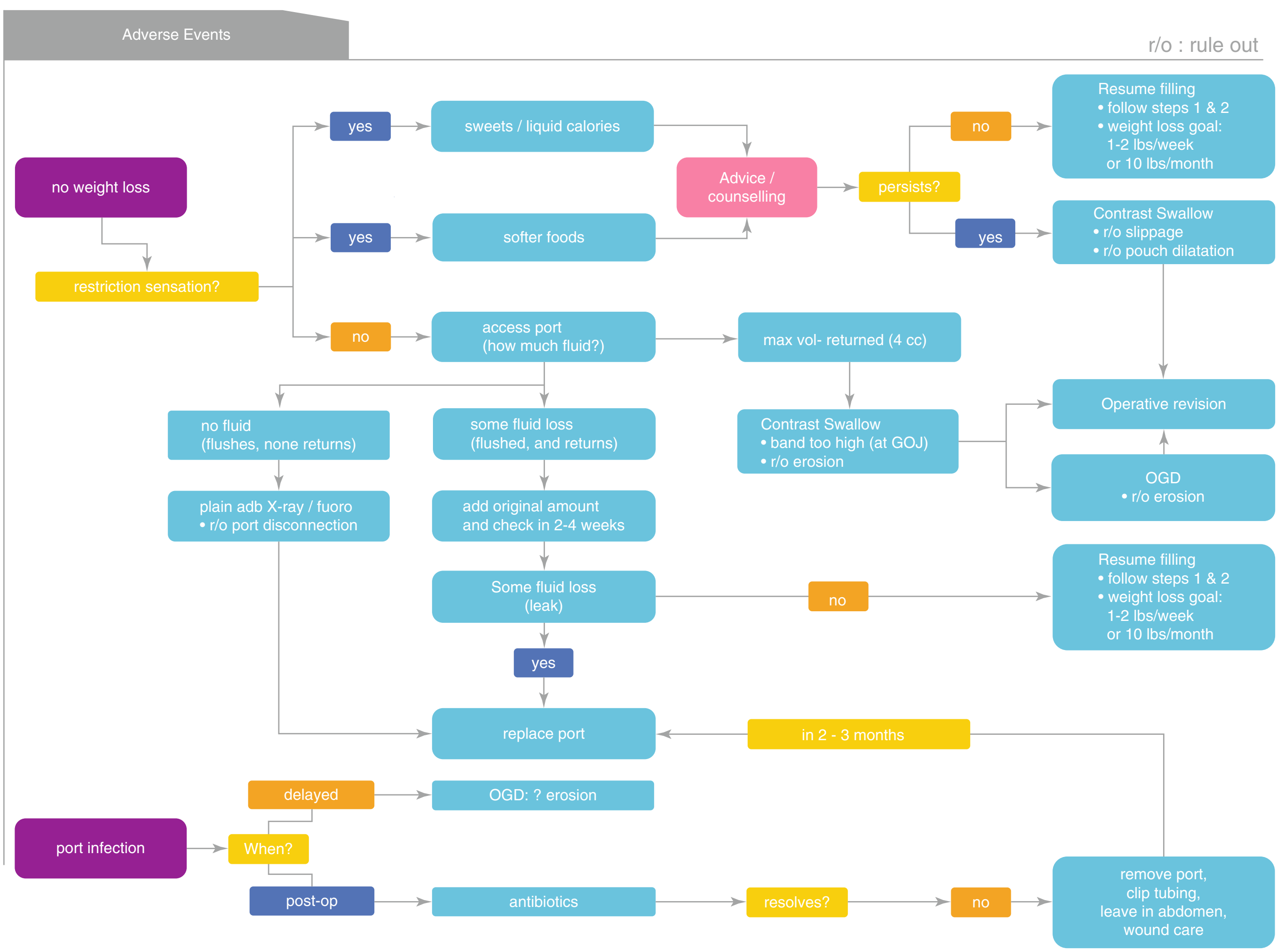

Fig. 31.13 Algorithm for the management of adverse events relating to the gastric band (Adapted with permission by Bariatric Times: Ponce et al. [36]. Copyright © 2013. Matrix Medical Communications. All rights reserved)

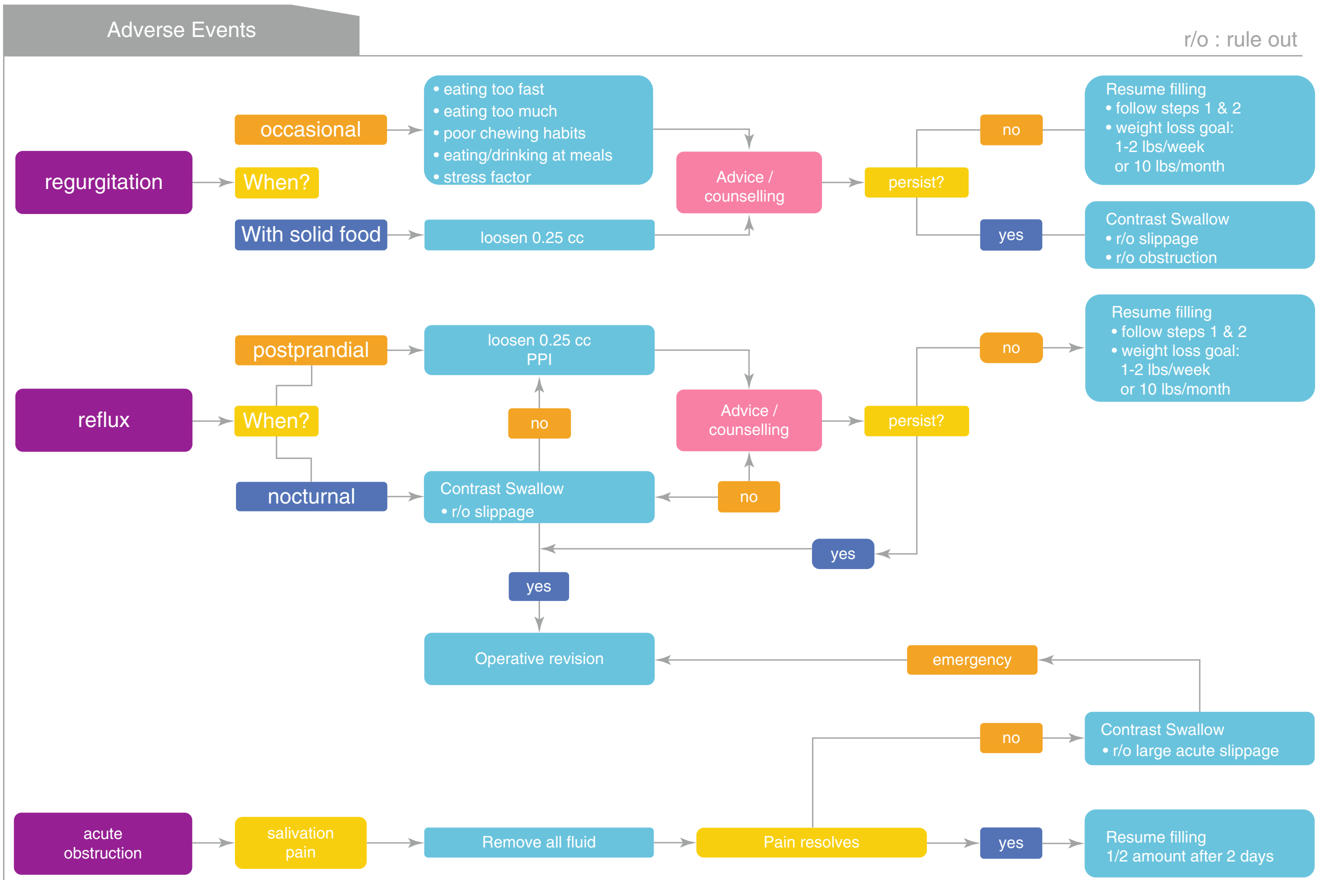

Fig. 31.13 (continued)

Although laparoscopic gastric band surgery may have fallen out of favour in a lot of bariatric surgery units, it still deserves a place in the surgeon's armamentarium in their fight against obesity. There is general consensus that following a high standard of care can help to reduce the risks of complications and failure with gastric band surgery in the future.

Key Learning Points

- Regular follow-up can help prevent complications
- Most gastric band complications can be managed acutely by band deflation
- Early investigation can often identify an easily reversible problem
- Late port site infections are due to a band erosion, unless proven otherwise
- Vomiting that persists post band deflation requires emergency operative management in a specialist bariatric centre

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32 LAGB: Outcomes

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Abstract

Laparoscopic adjustable gastric banding (LAGB) continues to be the second most prevalent procedure in the United States of America (USA)/Canada and the third most prevalent procedure in Europe. Unfortunately, most of the bariatric surgical literature contains data on short-term follow-up only (<3 years). There are limited reviews on medium-term follow-up but large volume, long-term, follow-up data regarding most bariatric surgical procedures are still lacking. LAGB, besides having the lowest mortality, also has comparable results regarding weight loss and comorbidity resolution. Furthermore, recent randomized controlled trial data suggests that complications following other bariatric procedures may be unacceptably high.

Keywords

Gastric banding • Weight loss • Metabolic outcome • Patient satisfaction • Morbidity • Mortality • Quality of life

32.1 Introduction

It is important to be clear on outcome measures following any procedure. For many years, the outcome of bariatric surgery focused purely on weight loss. However, it is now clear that several outcome measures must be included in any study related to bariatric procedures. These include:

- Weight loss outcomes
- Metabolic outcomes
- Patient satisfaction
- Morbidity and mortality

32.2 Weight Loss Outcomes

The efficacy of laparoscopic adjustable gastric banding (LAGB) in producing weight loss is comparable to other bariatric procedures. The systematic review by Buchwald et al. [1] yielded good quality results relating to 22,094 procedures. The review compared the results of gastric banding, gastric bypass, gastroplasty and biliopancreatic diversion. The analysis quoted excess weight loss of 47.5 % for LAGB compared to 61.6 % for Roux-en-Y gastric bypass (RYGB), 68.2 % for gastroplasty and 70.1 % for biliopancreatic diversion (BPD).

Equivalent medium-term weight loss, following LAGB, has also been confirmed in systematic reviews. A review by Chapman et al. [2] confirmed that for the first 2 years, LAGB resulted in less weight loss than RYGB; however from 2 to 4 years there was no significant difference between LAGB and RYGB. Similar results were also seen in a systematic review published by O'Brien et al. [3] The authors of the study noticed that BPD had the maximal effect on weight loss, with a mean medium-term 74.4 % excess weight loss (EWL). When compared with LAGB, RYGB caused significantly greater weight loss at years one and two, but there were no differences in the medium-term weight loss (3–10 years).

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There are limited studies comparing LAGB and laparoscopic sleeve gastrectomy (LSG). Himpens et al. [4] compared LAGB to LSG, randomizing 40 patients for each treatment group. Compared to the LAGB, the LSG reported statistically significant difference in weight loss, reduced body mass index (BMI) and higher percent EWL (57.7 % vs. 48 %) at 1 and 3 years. Two patients in the LSG group required re-operation as compared to none in the LAGB group. On the contrary, a recent study comparing LAGB and LSG (20 patients in each group) confirmed comparable weight loss at 2 years (Excess percent BMI loss: LAGB—45 ± 23 kg/m^2; LSG—48 ± 22 kg/m^2) [5]. A meta-analysis published in 2013 concluded that LSG is more effective than LAGB, with higher percentage weight loss and greater improvement in type 2 diabetes [6]. It is to be noted though that the meta-analysis commented only on the weight loss at 6 and 12 months.

Weight loss results following gastric banding are variable. Our review of 1140 patients, published in 2008, demonstrated an excess percent BMI loss of 43.7 % and 58.9 % at 24 and 36 months respectively [7].

One of the major criticisms of LAGB has been the long-term band removal rates and lack of significant weight loss. However, most of the claims were challenged when O'Brien et al. [8] published their long term results, 15 years following LAGB. The authors noted a mean of 47 % EWL (n = 714; 95 % CI = 1.3) for all patients who were at or beyond 10 years follow-up. This data thus challenges some of the best weight loss results obtained for RYGB and LSG.

32.2.1 Determinants of Effective Weight Loss Following LAGB

It cannot be disputed that good follow up is essential for success following any bariatric surgery, including LAGB. However, there are numerous other factors that improve weight loss outcomes following this procedure.

32.2.1.1 Meticulous Surgical Technique

Reducing the rates of complications such as slippage and erosion not only reduces the need for explantation, but also promotes steady weight loss by providing reliable restriction. A meta-analysis published in 2010 confirmed the relationship between slippage and erosion [9]. The authors of the study noticed that units with low slippage rate also had low erosion rate and vice versa. It was concluded that slippage and erosion probably shared a common pathophysiology and that surgical techniques which help to eliminate/reduce slippage should also reduce rates of erosion.

32.2.1.2 Fluoroscopy Guided Band Adjustments

Radiological adjustments ensure an appropriate and optimal band fill and patient satiety. In addition, inappropriate band fills are largely avoided if radiological imaging detects esophageal dilatation and pouch enlargement as the reasons for lack of satiety. Maintaining an optimal restriction enables steady weight loss, whilst avoiding some of the much publicized complications of the procedure, usually related to over-restriction when bands are too tight.

32.2.1.3 Follow Up

Ideally, all patients would be followed up indefinitely. However, the number of clinic appointments increases exponentially with time. There is good evidence that patient management program led by specialist dieticians (or nurses) is an effective way to manage large numbers of patients after LAGB, while maintaining comparable weight loss to surgeon/nurse-led follow-up [10].

32.3 Metabolic and Other Co-morbidity Outcomes

Metabolic outcomes are equally important endpoints following any bariatric procedure. Gastric banding has comparable results, in some studies, with regards to resolution of co-morbidities. The systematic review by Buchwald et al. [1] demonstrated strong evidence for improvement in type 2 diabetes and impaired glucose tolerance for all surgery types. However, the reported results for resolution of diabetes were only 47.9 % for LAGB, compared to 98.9 % for BPD, 83.7 % for RYGB and 71.6 % for gastroplasty. Improvement in hypertension and sleep apnea was consistent across all the procedures, demonstrating improvement in at least 70 and 85 % of the cases, respectively.

LAGB has been confirmed to be superior to the conventional treatment of diabetes. A randomized controlled trial by Dixon et al. [11] in 2008 concluded that patients randomized to surgical therapy were more likely to achieve remission of type 2 diabetes through greater weight loss.

Our data on metabolic outcomes, following LAGB, in 122 diabetic patients [12] confirmed that 93.1 % of the patients experienced an improvement in fasting glucose levels and 75.4 % of the patients experienced an improvement in glycated hemoglobin (HbA1c) levels at the end of 1 year. All the patients experienced decrease in insulin requirements and 36.6 % were able to totally discontinue using it. Furthermore, 100 % of the patients demonstrated improvement in their triglyceride level and 90.9 % showed improvement in their total cholesterol level. The mean arterial pressure improved in 87.5 % of the patients.

Most of the studies have included all obese diabetics, however it is conceivable that such results would be difficult to mirror in insulin dependent diabetics. We recently published our data in 69 insulin dependent diabetics, following LAGB [13]. It was noticed that at 3 years, 80 % of patients who were taking insulin preoperatively were able to discontinue it. Other metabolic benefits which were observed in our previous study [12] were also noticed.

A recent analysis of our data, for 175 type 2 diabetics, confirmed mean excess BMI loss of 33.8 ± 17.9, 39.6 ± 20.3, and 41.2 ± 23.2 % at the end of first, second and third years respectively [14]. More importantly, we noted that there was no statistically significant correlation between the duration of diabetes and changes/improvements in any of the parameters measured (i.e. diabetes, hypertension, dyslipidemia). The analysis reconfirmed our previous finding that an improvement in those parameters was not statistically related to weight loss. This is in contradiction to published evidence from other centers [15].

32.3.1 Re-emergence of Metabolic Complications

An issue that is frequently overlooked is the long-term metabolic remission following bariatric surgery. The pro-bypass surgeons argue that the metabolic improvements after LAGB are primarily due to weight loss and perhaps calorie restriction rather than the hormonal effect produced by the bypass component of RYGB. Hence it is unlikely to be effective as a metabolic procedure [16].

There is some research regarding long-term re-emergence of diabetes, following RYGB. DiGiorgi et al. [17] found re-emergence of diabetes in up to 24 % of the patients following RYGB. The authors of the study believe that attenuation of the foregut or hindgut hormonal effect, over time, perhaps by receptor downregulation on the beta cell or within the peripheral tissues might be the cause for re-emergence. The natural progression of the beta cell dysfunction, which contributed to the preoperative diabetic state, might also play a role. Another recent review suggested that, following RYGB, of all individuals who experienced an initial complete diabetes remission, 35.1 % redeveloped diabetes within 5 years [18]. Other experts believe that the continual increased stimulation of beta cells, by incretins, leads to their loss, over time, and thus the re-emergence of metabolic syndrome.

Thus, an operation that solely relies on restriction, to cause weight loss, (i.e. LAGB) may be more likely to maintain metabolic improvements if weight loss can be maintained in the longer term. The recent study by O'Brien et al. [8] is a testimony to the possibility.

32.4 Patient Satisfaction and Quality of Life

Patient satisfaction is as important as weight loss or metabolic outcomes when evaluating bariatric procedures. Obesity significantly limits quality of life (QoL) and thus QoL measurements have been the focus of numerous research groups. The main tools to currently measure QoL, following bariatric surgery, are: Short Form-36 (MOS SF-36, Rand SF-36 or SF-36), Bariatric Analysis and Reporting Outcome System (BAROS) and the Impact of Weight on Quality of Life-Lite (IWQoL-Lite).

O'Brien and colleagues [19] compared SF-36 scores before and after LAGB at 1 and 2 years, with the Australian general community, and found highly significant improvements in QoL following LAGB.

Hell et al. [20] tested the ability of BAROS to compare the outcomes following different bariatric operations. Groups of 30 matched patients underwent vertical banded gastroplasty (VBG), LAGB and RYGB and were followed from 3 to 8 years. Although RYGB patients had greater percent of EWL, VBG and LAGB patients benefited from greater improvement in co-morbid conditions and QoL. Chevallier and colleagues [21] also used BAROS in their prospective study of 500 consecutive patients undergoing gastric banding. They concluded that quality of life significantly improved with the excess weight loss as early as 6 months in 76 % of their patients.

On the contrary, a recent systematic review that compared banding and bypass, concluded that approximately 80 % of the patients in RYGB group reported being very satisfied with the procedure, and no patients in the group were unsatisfied or regretted having had the procedure. In contrast, only 46 % of the patients in the LAGB group reported being very satisfied with the procedure, and 19 % of the patients were unsatisfied or even regretted having undergone the procedure [22].

Weiner et al. [23] found that 99 % of patients following LAGB were satisfied with the results of their surgery and 96 % stated that they would be willing to have the operation again.

32.5 Morbidity and Mortality

With long-term weight loss and metabolic outcomes being comparable in few of the long-term studies available, one of other the important measures following bariatric surgery is morbidity and mortality. A recent meta-analysis by Chang et al. [24] illustrated the effectiveness and risks of bariatric surgery. The authors concluded that complication rates were lowest following LAGB. Complication rates following LAGB were 13 % compared with 21 % following RYGB.

There has been limited randomized controlled trail (RCT) evidence comparing the morbidity and mortality of different types of bariatric surgery. Angrisani et al. [25] recently published the results of RCT of 10 years, following laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass. The authors of the study concluded that RYGB exposed patients to higher early complication rates than LAGB (8.3 % vs. 0 %) and potentially lethal long-term surgical complications (internal hernia and bowel obstruction rate: 4.7 %).

Buchwald et al. [26] published a meta-analysis, in 2007, on the trends in mortality following bariatric surgery. A superficial analysis of the results shows that the 30 day mortality following RYGB is twice that of LAGB (0.2 % vs. 0.1 %). RYGB did not also compare well when the medium term mortality data was taken into consideration (RYGB 0.1 % vs. LAGB 0 %). Similar results have also been echoed in the recent meta-analysis by Chang et al. [24]. The perioperative and postoperative mortality rate following LAGB was 0.07 % and 0.21 % respectively. The same rates following RYGB were 0.38 % and 0.72 % respectively. Thus, upon comparison, LAGB is probably the safest bariatric procedure with respect to perioperative and postoperative mortality up to 2 years.

Conclusion

Laparoscopic adjustable gastric banding is a safe and effective bariatric procedure. It provides an acceptable weight loss with comparable resolution in co-morbidities. Meticulous surgical technique and good follow up program is the cornerstone to the success of this minimally invasive and potentially reversible bariatric procedure.

Key Learning Points

- An excess weight loss of up to 50 %, at 10 years, can be achieved with gastric banding in a good follow up program.
- The resolution in co-morbidities is comparable besides diabetes which is better resolved with foregut bypass procedures.
- Morbidity and mortality following LAGB is the lowest, compared to any other bariatric procedure.
- Randomized controlled trials suggest that although better weight loss can be achieved with RYGB, it exposes patients to higher early complication rates and potentially lethal long-term surgical complications.

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LAGB: Current Controversies

33

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Abstract

Laparoscopic adjustable gastric banding (LAGB) is a safe and effective option for weight loss surgery, but is still subject to controversies. This chapter aims to address some of these issues.

Surgical technique is as yet not standardized. This chapter discusses the current opinions regarding gastric band placement and fixation, hiatal hernia repair and port fixation. The newer technique of single incision laparoscopic surgery (SILS) is also covered.

The decision regarding which weight loss procedure best suits each patient should be made on an individual basis. This chapter discusses what factors should be taken into consideration for different patient groups including adolescents, the elderly, those with binge eating disorder (BED), the pregnant patient, and those undergoing revisional surgery.

LAGB has lower perioperative risks than other surgical options and long-term follow up is essential to optimize results. Gastric banding remains an important method of weight loss surgery but the finer details of the procedure continue to stimulate controversy. In future, well designed studies will help to improve outcomes.

Keywords

Gastric band • Controversies • Technique • Patient selection • Hiatus hernia • Complications

33.1 Introduction

Laparoscopic adjustable gastric banding (LAGB) is well established as a safe and effective weight loss operation. Shorter learning curve and duration of operating time, potential reversibility, and low operative morbidity even in high-risk patients, have been hailed as the main advantages of this procedure. However, certain aspects of the operation divide the bariatric community and stimulate fierce debate.

While gastric banding is by no means the only bariatric operation that attracts controversy, addressing some of the more contentious issues with good quality research would help informed decision-making in the expanding specialty of bariatric surgery.

This chapter aims to inform the reader of the main areas of controversy relating to gastric banding. Some of these areas will be addressed in more detail elsewhere in the book.

33.2 Technical Controversies

33.2.1 Banding Technique

Two techniques for gastric banding have been described in the literature; the peri-gastric and the pars flaccida technique. The peri-gastric technique involves dissection between the lesser curve of the stomach and the lesser omentum creating a passage along the apex of the lesser sac to the angle of His. The pars flaccida technique makes use of a natural window in the lesser omentum and involves minimal dissection from

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the base of the right crus of the diaphragm up along the left crus to the angle of His. A randomized controlled trial comparing these two techniques showed they were equally efficacious for weight loss but that there was a significantly higher slippage and erosion rate with the peri-gastric technique [1]. As a result, this approach has been largely abandoned in favor of the pars flaccida technique [2].

33.2.2 Hiatal Hernia Repair and Endoscopy

Hiatus hernias are common in the obese population, particularly in those patients who are at the upper extremities of the body mass index range. Exact incidence is difficult to establish due to inconsistent reporting and criteria used, but can be as high as 52.6 % [3]. How to manage the incidental hiatus hernia found while performing the procedure, and whether to dissect the hiatus to identify a small defect, remains a contentious issue. Some take the view that in asymptomatic individuals, repairing the defect adds little value, increases the risk of the procedure and can lead to postoperative dysphagia whilst others who advocate repair comment on more accurate placement of the band on the stomach as the true gastro-esophageal junction can be identified [4]. Closure of the hiatus also prevents the potential for a pouch dilatation within a lax hiatus and may also increase the efficacy of the band. A retrospective study compared LAGB alone to LAGB with simultaneous hiatus hernia repair [5]. The reoperation rate over a period of 2 years was 5.6 % in the LAGB group and 1.7 % in the LAGB with hiatus hernia repair group. Reoperations were for slippage, hiatus hernia, and pouch dilatation [5]. Azagury et al. reported a series of 12 patients who had revisional surgery after gastric banding (primary surgery performed in their unit) due to the development of significant hiatus hernia which was not present at the original operation [6]. All the patients had preoperative imaging and intraoperative assessment. They concluded, as did the other groups [7], that gastric banding may in fact cause a hiatus hernia by chronic over pressurization of the gastric pouch and lower esophagus on phreno-esophageal ligament, and the consequent stretching of the phreno-esophageal ligament [6, 8]. However, it is still unclear whether the repair of a small, asymptomatic hiatus hernia at the time of original surgery reduces the risks of symptomatic hiatus hernia at a later stage or not.

Pre-operative endoscopy is not universally performed, with many units feeling that it is unnecessary. However, other centers feel that it is valuable in identifying hiatal hernias and other gastro-esophageal pathologies [9]. In addition, endoscopy can exclude asymptomatic esophageal carcinoma. Whilst rare, it is more likely to occur in the morbidly obese population which has a higher incidence of gastro-esophageal reflux. Furthermore, delay in diagnosis could occur as symptoms of esophageal carcinoma may be misinterpreted as band-related symptoms [9].

33.2.3 Gastro-Gastric Fixation Sutures

Anterior fixation of the gastric band via gastro-gastric sutures is another area of controversy. Proponents of suturing feel that this reduces band slippage. However, those that advocate non-suturing report that suturing does not prevent slippage and has similar rates of band related complications with the added benefits of reduced operative time. In addition there are fewer adhesions and potentially a reduced risk of perforation if revisional surgery is required. It is also possible that suturing can increase the risk of erosions due to tension on the stomach around the band, though a very large study would be required to determine this. A prospective randomized controlled study from Paris which divided the patients into two groups (fixation with gastro-gastric sutures versus no fixation) had to be abandoned early due to three early slips in the no-fixation group [10]. Those patients that were followed up showed no difference in complication rate at 2 years between the two groups but the numbers were small. Another prospective randomized trial that did reach completion, showed no significant difference in slippage, erosion or pouch dilatation rates [11]. The study commented on a statistically significant reduction in operating time, concluding that the concept of mandatory fixation should be revisited. Modifications to the standard two or three gastro-gastric tunneling sutures have been reported, such as a gastropexy suture to the diaphragm and a gastric plication below the band [12]. Again, until prospective randomized trials with longer term follow up are conducted, individual surgeons are likely to practice techniques that are familiar, comfortable and acceptable based on their own unit outcome data (see Fig. 33.1).

33.2.4 Access Port Fixation

The access port is integral to the functioning of the LAGB as optimum volume in the adjustable component will lead to maximum weight loss and patient satisfaction. The location of the access port is therefore crucial. If the port is inaccessible or difficult to puncture the risk of an inadvertent tube puncture and subsequent leakage, or hematoma and infection is higher. Also emergency staff may be unable to deflate a band in a timely manner if the port is inaccessible, leading to potential gastric ischemia. Conversely a port that is too superficial, particularly after weight loss, may cause patient discomfort and poor cosmesis.

Various locations have been used for access port fixation including anterior to the rectus sheath, sub-fascial to rectus sheath, sub-xiphoid, left subcostal margin and subcutaneous. A study looking at 619 patients using the infra-mammary incision and placing the port on the left pectoral fascia confirm high patient satisfaction. However, they reported nine cases of inaccessible ports, three requiring ultrasound to locate and the remaining six needing surgical relocation. They also reported four tube punctures and subsequent leakage [13]. Thirty patients had persistent discomfort and in seven of these cases revisional surgery was required to relocate the port. A study comparing sub-fascial port placement with subcutaneous placement in age, sex and body mass index (BMI) matched patients reported more pain during sub-fascial port adjustments and more port site hernias. There was no difference in port site infections or skin erosions [14].

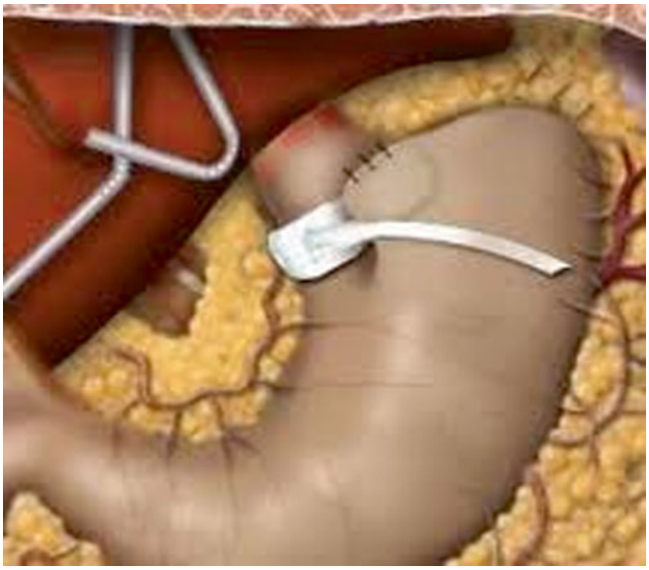

Fig. 33.1 A diagrammatic representation of three gastro-gastric sutures (Picture courtesy of Dr R. K. Mishra, World Laparoscopy Hospital, Gurgaon, India)

Fixation methods include sutures, retractable hooks integral to the port. Proponents of fixation report that the port is in a reproducible location for every adjustment but acknowledge that it adds time to the total operative length. Proponents of no formal fixation of the access port report no adverse outcomes and a mobile port that can be easily manually rotated as necessary (see Fig. 33.2) [15].

33.2.5 Choice of Band

There are many band manufacturers in the market and the choice of band is often down to surgeon's preference. There is very little evidence to suggest that one band is superior to another. A recent retrospective study looking at outcomes between matched patients using four different manufacturers (LAP-2BAND Adjustable 2Gastric Banding System VGTM, Allergan-LAGBTM, LAP-2BAND APTM Standard, LAP-2BAND APTM Large, Realize 2BandTM, and Realize-C 2BandTM) concluded that outcomes were similar in term of excess weight loss, co-morbidity reduction and band related complications [16]. Port related complications, however were significantly lower in the RealizeTM group. In another prospective, randomized, multicenter study, the Cousin Bioring™ was compared to Allergan LAPBAND™ and out-

Fig. 33.2 A device designed to fix the access port to the rectus sheath (Picture courtesy Ethicon Endosurgery)

comes were similar in terms of safety and effectiveness [17]. This was a useful study as the mechanics of these two varieties are different; Bioring™ has been developed to be low pressure, large surface area contact whilst the LAPBAND™ is deemed a high pressure band. Ultimately, the choice of band will be made based on a combination of available evidence, familiarity and cost.

33.2.6 Single Incision Laparoscopic Surgery

Single incision laparoscopic surgery (SILS) involves the use of one incision with a multichannel port as opposed to a traditional four or five port technique via separate incisions. The presumed benefit is better cosmesis. This technique is well established for cholecystectomy and appendectomy and is now being performed for gastric banding. A study looking at SILS gastric band confirmed that the procedure was possible but reported a prolonged operating time and noted that postoperative pain was associated with the duration of procedure and that this association was strongest in the male patients [18]. Umbilical wound infection, with resultant infection of the band system, and herniation remain a potential concern but, as yet, long term follow up data is not available. More experience and trials in this area are required before safety can be confirmed.

33.3 Patient Selection and Other Issues

33.3.1 High Risk Patients

Gastric band placement has the lowest peri-operative risk as compared to all the other surgical procedures that are currently available. In theory, this should be the best procedure for the highest risk patients, that is those with the highest BMI and most extensive comorbidity profiles. However, these are the patients that would benefit from losing maximum excess weight, and average excess weight loss with banding is lower than that of sleeve and bypass. This provides a dilemma for the surgeon and reinforces the importance of decision making through multidisciplinary teams including anesthetists. With the high-risk patient group, even a 10 % excess weight loss has been shown to improve comorbidity and so the option of gastric banding should be explored. The outcome in the long term can be optimized by careful follow up.

Fifteen year follow up data has recently been reported by an Australian unit with compelling evidence to maintain close supervision of the patients in the postoperative term [19]. They reported a 47 % excess weight loss at 10 years and beyond surgery and have a strict intensive follow up regime. In the United Kingdom, follow up is often funded for a 2 year maximum term and some private institutions offer no follow up as a part of the surgery package. This may explain disparity in long-term results. Performing a procedure in which the patient is dependent on lifelong band adjustments and support without the facilities or economic infrastructure to provide this, is unlikely to achieve optimal results—and yet such support is relatively cheap to provide compared to life-long management of co-morbidities.

33.3.2 Adolescent Surgery

Bariatric surgery in adolescents is a difficult issue that is covered in detail in Chap. 77. A recent meta-analysis on the subject concluded that although many studies show a sustained reduction in body mass index, they do not report satisfactory long term complication or health related quality of life data which, at this stage, makes it more difficult to quantify the true benefits of surgery in this group. It would seem pragmatic that an easily reversible operation, that is LAGB, would be the operation of choice, if considered essential after multidisciplinary assessment, until the long term outcomes are firmly established [20].

33.3.3 Elderly

Considered to be a lower risk operation, LAGB should be the operation of choice for the elderly; but is it effective? A retrospective analysis of over 5000 banding patients from 26 European centers looked at the outcomes for those over 60 years old and compared them to those less than 60 years [21]. The mortality, morbidity and revisional surgery rates were comparable but weight loss was significantly lower in the elderly patients. However, at 1 year follow up, there was significant improvement in 100 % of patients with diabetes, 67 % of patients with sleep apnea and 34 % of patients with arthritis, thus validating its use in this group of patients. As mentioned previously, improvement in comorbidities is not always dependent on drastic degrees of weight loss and an individualized approach tailored to the patients' needs and expectations may be required.

33.3.4 Binge Eating Disorder

This is an area of contention and the diagnosis of binge eating disorder (BED) was originally thought to be a contraindication to gastric banding. An Italian study looking into 5 year outcomes of two matched cohorts, one with binge eating disorder and one without, showed that although the excess weight loss was similar between the two groups, the complication rate was significantly higher in the BED group.

The BED group required more intensive follow up with more band adjustments and the average fill volume was also significantly higher. Despite concluding that banding was safe for BED patients, caution must be exercised and psychological treatment must be incorporated into the process. Other forms of bariatric surgery have been performed in BED patients with equivalent results [22]. Bulimia remains a concern as forced vomiting following banding may result in slippage with its inherent problems.

33.3.5 Pregnancy

The majority of LAGB patients are female of whom many may be in the fertile age group. Fertility also increases as weight reduces and comorbidity improves. This raises a unique challenge in managing these patients during pregnancy. The nausea and vomiting associated with the first trimester of pregnancy increases the risk of band slippage and the rising intra-abdominal pressure during the later stages also theoretically increases the risk of gastric herniation through the band. Other concerns include lack of adequate nutrition for the developing fetus if a gastric band remains inflated. Lack of maternal weight gain during pregnancy can result in intra-uterine growth retardation (IUGR) regardless of maternal body mass index. Conversely, excessive maternal weight gain during pregnancy, which may result from gastric band deflation, can increase other complications such as gestational diabetes and increase the risk of cesarean section [23]. Dixon et al. analyzed a cohort of 22 pregnancies in women with gastric bands and described an active band management program [24]. They adjusted band fill volumes and tailored each band individually so that there was an appropriate maternal weight gain (average 8.3 kg). In this way, there were minimal obstetric complications and no premature or low birth weight babies. Weiss et al. adopted a prophylactic decompression of all bands in pregnancy and reported a higher than average spontaneous abortion rate and two serious band erosions requiring operation [23]. There is a lack of randomized controlled trials in this area and a recent Cochrane Systematic Review failed to identify any valuable studies that met the inclusion criteria [25]. Despite this an individualized approach seems to be most appropriate to ensure the correct balance between sufficient maternal weight gain and avoidance of slippage.

33.3.6 Revisional Surgery

There is controversy surrounding the management of failed gastric bands as there are many different operative strategies. A new tunnel can be created, the band can be unclipped and re-clipped at a later occasion or the band can be removed and converted to a sleeve gastrectomy or a Roux-en-y gastric bypass. The reasons for the failure of the band must be identified and involvement of the multidisciplinary team is mandatory. Revisional surgery after gastric banding is covered in detail in Chap. 42.

Conclusion

Gastric banding remains an important part of the armamentarium of the bariatric surgeon. The operation has many controversial aspects, both in terms of techniques, patient selection and follow-up, and is likely to continue to cause debate amongst bariatric professionals for the foreseeable future. Many of the controversies surrounding gastric banding will not be settled until formal long term prospective randomized studies are carried out. The By-Band multicenter randomized controlled trial is in its recruitment phase and is designed to compare gastric banding to other techniques [26]. The results of this and other well-conducted studies are eagerly awaited.

Key Learning Points

- The peri-gastric technique is now largely historical due to the higher rate of slippage. Pars flaccida remains the technique of choice.
- Preoperative endoscopy can be useful to exclude erosive disease and incidental adenocarcinoma.
- Fixation of concomitant hiatus hernia can help prevent pouch dilatation and allows more accurate placement of the band.
- Gastro-gastric fixation sutures are designed to minimize slippage but do not obviate the risk completely and may not be necessary.
- LAGB remains useful in high risk or elderly patients as operative time and potential for peri-operative complications are minimized.

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Section VII

Advances in Minimally Invasive Bariatric Surgery

Honorary Section Editor - Yashwant Koak

In this section, several international authors describe their experience with reduced-port, single-port or single incision bariatric surgery and detail the benefits, challenges and techniques for performing the operations. In the last chapter in the section authors describe adoption of Da Vinci robot for bariatric surgical operations.

Professor Alan Saber from New York gives an overview of evolution of reduced-port approach. He gives details of advantages and techniques of using this approach for a number of bariatric procedures. To make this approach successful Prof Saber gives specific contra-indications, details of achieving adequate triangulation, liver retraction techniques, methods to overcome limitations of movement, umbilical port closure technique and use of TAP block analgesic control. He concludes the chapter by detailing some early complications and need for randomized studies.

Dr Saurav Chakravartty and Senior author Prof Ameet Patel, from London, give details of benefits, challenges and technique for performing “scarless” (scar hidden in umbilicus) gastric band operation. They note that there is a slower adaptation of single-port technique in bariatric surgery – mostly related to port problems and surgical challenges encountered. The authors describe the different ports that are available and details of the technical aspects to address surgical challenges, including emphasis on having an experienced assistant. They conclude by mentioning that though enough data is not available of benefits of this technique over conventional laparoscopic surgery, nevertheless it is well liked by the patient.

Prof Giovanni Dapri, from Brussels, addresses the technical challenges and cost of performing sleeve gastrectomy by single incision. Prof Dapri details the various techniques used for liver retraction, the equipment, setup and technique of surgery – using reusable and curved instruments and postop patient management. He concludes the chapter by mentioning benefits of less operating time and less pain after SILS technique.

Dr Chih-Kun Huang and co-authors from Taiwan, in their chapter on single incision laparoscopic Roux-en-Y gastric bypass, concentrate on describing their technique of performing the gastric bypass operation. The authors give technical tips on using omega-shaped umbilical incision, multi-port use at umbilicus, T-shaped liver retraction and intra-corporeal suturing. They conclude the chapter by mentioning that there is almost no difference in the outcomes comparing traditional laparoscopic and single-incision gastric bypass surgery, except for higher patient abdominal scar satisfaction.

In the last chapter in this section, Dr Ranjan Sudan and coauthors from Durham, North Carolina, write about adoption of the Da Vinci robot in performing bariatric surgery. The advantages of robotic surgery, including increased dexterity, decreased operating time and usefulness in complex bariatric operations are discussed. They conclude by mentioning that clear advantages of robotic surgery, in terms of outcomes, have yet to be proven.

Reduced Port Laparoscopic Bariatric Surgery

34

Alan A. Saber

Abstract

Reduced port laparoscopic surgery (RPLS) is a new surgical approach in bariatric surgery that minimizes abdominal wall trauma. It has the potential to cause reduced postoperative pain and improved cosmesis without compromising the outcome. It is useful for a selected group of patients, especially women with a short distance between the xiphoid process and umbilicus. RPLS bariatric approach is contraindicated in patients who have undergone upper abdominal open surgery or upper abdominal ventral hernia mesh repair and in super obese patients. Postoperative weight loss with this approach is similar to that occurring after conventional multiport laparoscopic procedures. More importantly, no major intraoperative or postoperative complications have been reported. However, the data is scarce, early intraoperative and postoperative experience with RPLS bariatric surgery has shown that RPLS sleeve gastrectomy, adjustable gastric banding, and gastric bypass procedures are feasible and associated with reasonable degree of safety.

The present chapter presents the technical considerations and strategic modifications for reduced port laparoscopic bariatric surgery.

Keywords

Bariatric surgery • Laparoscopy • Reduced port • Postoperative pain • Cosmesis

34.1 Introduction

With the recent advances in minimally invasive surgery, there is an increasing interest in surgical techniques that minimize abdominal wall trauma. This facilitated the development of a new concept, reduced port laparoscopy (RPL) with decrease in either the number of ports or the size of ports, or a combination of the two.

In 2008, we described the technique of reduced port laparoscopic (RPLS) sleeve gastrectomy (SG). The approach has been applied to a wide variety of procedures, both bariatric as well as non-bariatric, including appendectomy, cholecystectomy, colectomy, and, more recently, bariatric surgery [1–5]. The technique is particularly attractive for the placement of an adjustable gastric band, which requires an incision large enough to insert the band and the port, and for the sleeve gastrectomy to allow retrieval of the gastric specimen.

Having acquired extensive experience with RPLS for primary bariatric surgery, we, recently, started exploring RPLS for its use in revisional procedures, mainly for the revision of the adjustable gastric band (AGB) to SG.

34.2 Indications and Contraindications of Reduced Port Laparoscopic Bariatric Surgery

Initially, morbid obesity was considered as a contraindication for reduced port laparoscopic bariatric surgery (RPLS), but currently the RPLS approach is being used successfully

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in morbidly obese patients also. We have found that it is particularly useful for a selected group of patients, especially women with a short distance between the xiphoid process and umbilicus.

The contraindications for the RPLS bariatric approach include patients who have undergone upper abdominal open surgery or upper abdominal ventral hernia mesh repair and patients who are superobese.

34.3 Preoperative Preparations

Preoperative work up for RPLS is the same as for conventional laparoscopic bariatric surgery. This includes medical, psychological, pulmonary, and nutritional evaluation. Preoperative education is crucial for good postoperative outcome. It includes advice on preoperative low calorie diet intake for 2–4 weeks, in order to shrink the liver, and evaluate the patient's compliance.

Prophylaxis of deep vein thrombosis (DVT) is achieved using both chemical and mechanical modalities. Surgical wound prophylaxis is achieved by intravenous antibiotic administration just before making the skin incision.

34.4 Operative Strategy and Technical Considerations

The feasibility of RPL and single port laparoscopic surgery (SPLS) depends on the individual's body habitus. We performed transumbilical SPLS in patients with relatively low body mass index (BMI), peripheral obesity, small liver, and short umbilicus to xiphoid distance. The hidden intraumbilical single incision provided a cosmetic advantage. The umbilicus also provides a safe area for accessing the abdomen, while minimizing the torque effect of the thick abdominal wall of an obese patient. However, for patients with a greater BMI, central obesity, a large liver, and a long umbilicus to subxiphoid distance, we proceed with reduced port laparoscopic approach with extraumbilical trocars placement. A gradual reduction in the number of ports is advocated, to make the transition, from multiple ports to reduced port approach, smooth.

34.5 Single Port Versus Reduced Port Approach

We have found that the single port laparoscopy could be challenging for certain patients and certain procedures. The approach required certain set of skills with possible prolonged learning curve. However, the concept of reduced port laparoscopy is a reproducible approach. Apart of stapling and endobag, all laparoscopic procedures could be performed with reduced size laparoscopic port of 5 mm or even more recently 3 mm ports with 3 mm laparoscopic instruments. This approach is easier to learn than single port laparoscopy. In addition, reduced port laparoscopy avoids the technical challenges of single port approach and maintains the principles of multiport conventional laparoscopic approach.

34.6 Technical and Physical Challenges in Reduced Port Approach

There are several technical challenges that can be encountered during reduced port laparoscopy [1].

34.6.1 Lost Triangulation and Trocar Placement Strategy

Triangulation is a basic principle of traditional multiportlaparoscopic surgery. Trocars can be directed from multiple points of entry, guiding instruments towards the target organ, where adequate manipulation can be easily achieved (see Fig. 34.1a).

Operating through a single incision with only rigid instruments would be challenging, because the surgeon would either implement a co-axial positioning of instruments (see Fig. 34.1b) or a 'crossing' arrangement (see Fig. 34.1c). In the co-axial technique, both instruments emerge through the umbilicus and are parallel to one another; thus, controlling both instruments outside the abdomen would pose a challenge, because the surgeon's hands would be in close proximity. On the other hand, when rigid instruments are crossing, there would considerably be more comfortable range of movement on the outside. On the inside, however, the left hand controls the right instrument and vice versa, posing a challenge for first-time SPL adopters.

Flexible instruments restore the triangulation during single port laparoscopy by steering the tip of the instrument towards the target organ. This overcomes the triangulation issues without sacrificing external maneuverability (see Fig. 34.1d, e)

34.6.2 Conflict of Instruments

When multiple instruments are inserted in close proximity through a common port of entry, there is limitation of movement both inside and outside. Advanced procedures involve frequent switching of the instruments, which could compromise the pneumoperitoneum. These challenges have led to the development of multichannel ports to maintain the

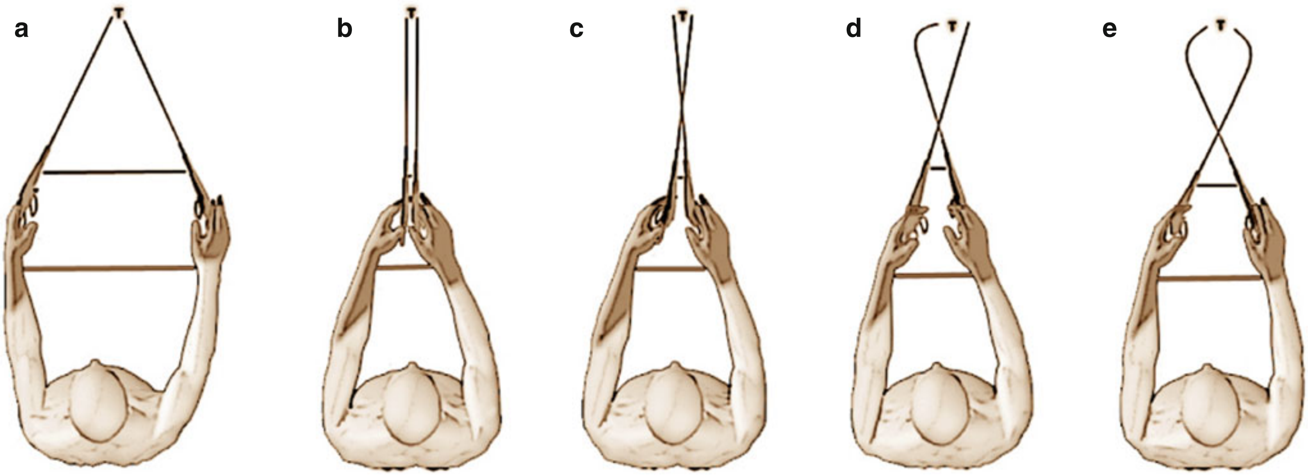

Fig. 34.1 Trocar/Instrument placement strategy (**a**) conventional laparoscopic surgery; (**b**) co-axial placement of instruments with SILS; (**c**) crossing rigid instruments with SILS; (**d**) crossing flexible and rigid instruments with SILS; (**e**) crossing flexible instruments with SILS (Reproduced, with permission, from El-Ghazaly et al. [6])

pneumoperitoneum and avoid the clinching of laparoscopic instruments diverting from a common point. If multichannel ports are not available, we can insert three trocars through the same umbilical skin incision but with different fascial incisions and at different levels in a triangular fashion. Using a flexible tip scope minimizes the external conflict of instruments, as its cable exits through the instrument's back end, thus keeping it away from the operative field.

34.6.3 Abdominal Wall 'Torque Effect'

The umbilicus is the thinnest part of the abdominal wall. This minimizes the torque effect on umbilical trocars inserted at such close proximity. This provides a wider range of motion in different directions for the instruments and trocars.

34.6.4 Umbilical Recession

In morbidly obese patients with central obesity, the umbilicus displaces inferiorly. This reduces the feasibility of the transumbilical approach. In such situations, we either add extraumbilical trocars or we place the main port in the epigastric area to ensure that the gastroesophageal junction is within the comfortable reach of laparoscopic instruments.

34.6.5 Retraction of Large Liver

Retraction of fatty liver in the morbidly obese presents unique difficulties during retraction. Fatty liver can be retracted by internal retraction (through sutures) (see Fig. 34.2), external retraction (by subxiphoid or transumbilical liver retractor) (see Fig. 34.3) or by using the mobilized portion of the stomach.

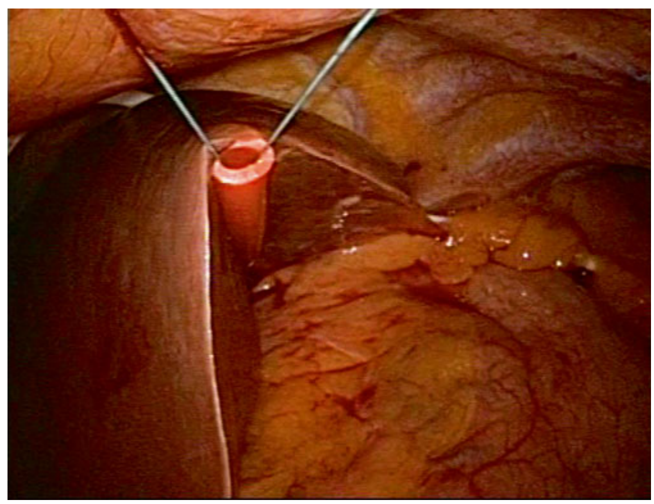

Fig. 34.2 Suture liver retraction

34.7 Operative Strategy for RPL Sleeve Gastrectomy

The location of entry incision and the method of liver retraction are both tailored according to the patient's body habitus discussed in the previous sections. For the transumbilical approach a 2.5 cm intraumbilical skin incision is created and deepened to the linea alba. Either three separate fascia incisions for three trocars or a single fascial opening up to a length of 2 cm is established (see Fig. 34.4).

Larger incisions can result in a loose port, promoting gas leakage and thus inadequate pneumoperitoneum. Single port is

Fig. 34.3 Transumbilical liver retraction

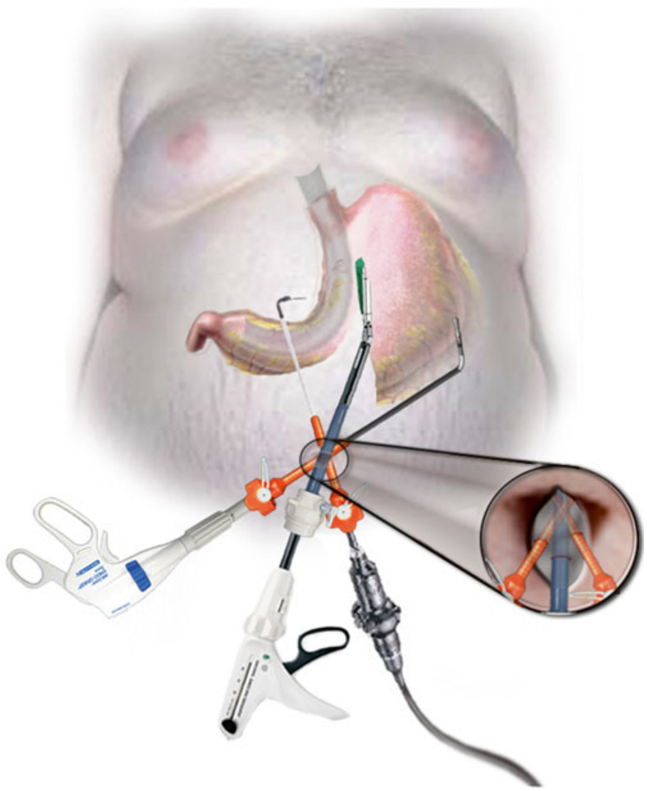

Fig. 34.4 For laparoscopic sleeve gastrectomies, trocars are placed through the same skin incision, but different fascial incisions on different levels in a triangular fashion

advanced under direct vision into the abdomen. Two 5-mm trocars and one 15-mm trocar are introduced through the access channels. The pneumoperitoneum is initiated to a pressure of 15 mmHg and a 5-mm flexible tip laparoscope is inserted [1, 4].

The mobilization is begun from a point 6 cm proximal to the pylorus and extended all the way up the greater curvature to the angle of His, staying close to the wall of the stomach, dividing both gastrocolic and gastrosplenic ligaments. This is followed by liver retraction, as described, according to each patient's body habitus and liver size.

Mobilization of the angle of His to expose the left crus of the diaphragm. This will facilitates complete resection of the fundus. LigaSure is used to take down retrogastric adhesions. This allows complete stomach mobilization, excludes the fundus from the gastric sleeve, and eliminates any redundant posterior wall of the sleeve.

Once the stomach is completely mobilized, a 34 French orogastric tube is inserted orally into the pylorus and placed against the lesser curvature. This calibrates the size of the gastric sleeve, prevents constriction at the gastroesophageal junction and incisura angularis, and provides a uniform shape to the entire stomach.

Six centimeters proximal to the pylorus, gastric transection is started, thus preserving gastric emptying; antrum is left behind. A long laparoscopic reticulating 60 mm XL endo-GIA stapler with green cartridge 4.8 mm staples and a buttressing material is inserted through the 15 mm trocar in a cephalad direction. Until the angle of His is reached, the stapler is fired consecutively along the length of the orogastric tube. Care must be taken to not to narrow the stomach at the incisura angularis. Stomach should be inspected anteriorly as well as posteriorly to ensure that no redundant posterior stomach is left behind. Approximately 80 % of the stomach is separated during this procedure. The entire staple line is inspected for bleeding and tested for leakage.

The integrity of the staple line is checked with methylene blue leak test. The resected stomach is extracted through the entry port incision without endobag. The fascial defect of the port site is closed with a figure-of-eight 2–0 nonabsorbable suture to prevent port site hernia. The skin incision is closed with 4/0 absorbable suture in a subcuticular fashion.

34.8 Operative Technique for Reduced Port Laparoscopic Other Bariatric Surgery Procedures

A similar approach has been utilized for port laparoscopic adjustable gastric band and for Roux en Y gastric bypass.

34.9 Operative Technique for Single Incision Laparoscopic Revision of Adjustable Gastric Band to Sleeve Gastrectomy

The surgeon stands between the legs of the patient with the assistant on the left side.

Both the location of the single incision and the method of liver retraction are tailored according to the operative strategy

Fig. 34.5 Gel point (applied medical) inserted in the umbilicus

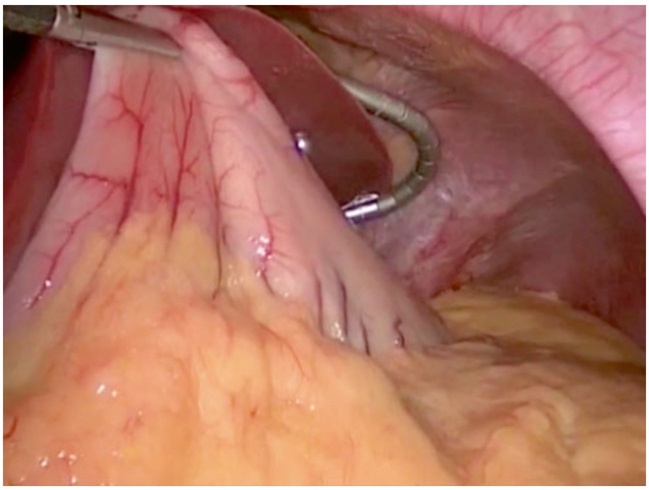

Fig. 34.6 Retraction of the greater curvature of the stomach

discussed in the previous section. If the subcutaneous port is in the vicinity of the umbilicus, we choose a transumbilical approach, Gel point placement, to conduct the procedure and in the end to remove the subcutaneous port.

A 2.5 cm intraumbilical skin incision is created and deepened to the linea alba. A fascial opening up to a length of 3 cm is established. This large fascial incision minimizes fighting between instruments and laparoscope. The Gel point Port (Applied medical, Rancho Santa Margarita, CA) is placed. Three 10 mm trocars are introduced through the Gel point (see Fig. 34.5). The pneumoperitoneum is initiated to a pressure of 15 mmHg. A long 45° 5 mm laparoscope with L connection is inserted.

Using a 5-mm Ligasure and 5-mm flexible grasper, the greater curvature of the stomach is retracted (see Fig. 34.6) and then mobilized (see Fig. 34.7), beginning from a point 6 cm proximal to the pylorus, staying close to the wall of the stomach, all the way up the greater curvature to the angle of His, dividing both gastrocolic and gastrosplenic ligaments. This is followed by liver retraction with flexible liver retractor inserted through the gel point.

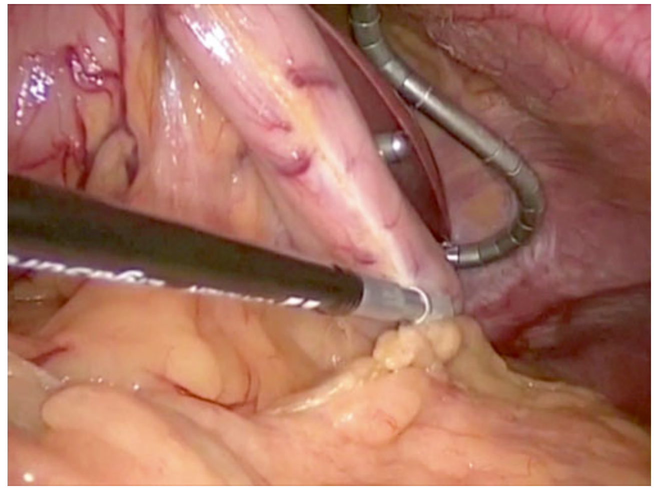

Fig. 34.7 Mobilization of the greater curvature of the stomach with Ligasure (Covidien)

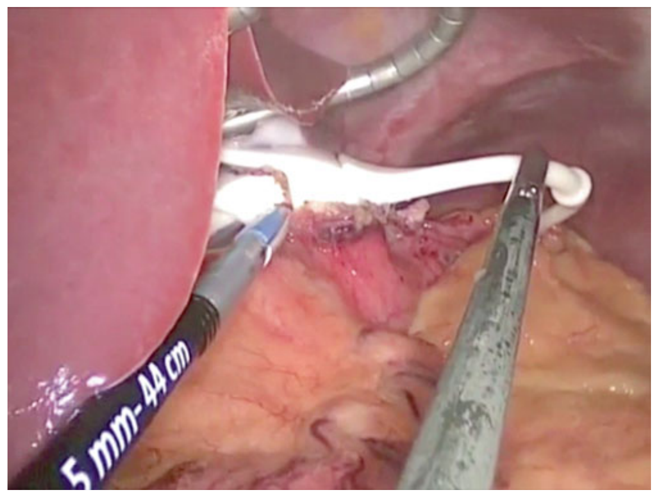

Fig. 34.8 Taking down the fibrous capsule around the AGB

Taking down the fibrous capsule over the band (see Fig. 34.8). The band used as a retractor then cut & retrieved (see Fig. 34.9).

The gastrogastric plication is taken down with laparoscopic scissor. In case of dense adhesions at the gastrogastric plication, linear stapler is used to take down the plication. The gastric transection, leak test, specimen extraction, and incision closure is done as described above (see Figs. 34.10 and 34.11).

34.10 Transversus Abdominis Plane Block (TAP Block)

This involves selective blocking the nerves supplying the anterior abdominal wall periumblical area. This is achieved by either ultrasound or laparoscopic-guided transversus abdominis plane (TAP) block (see Fig. 34.12). In our

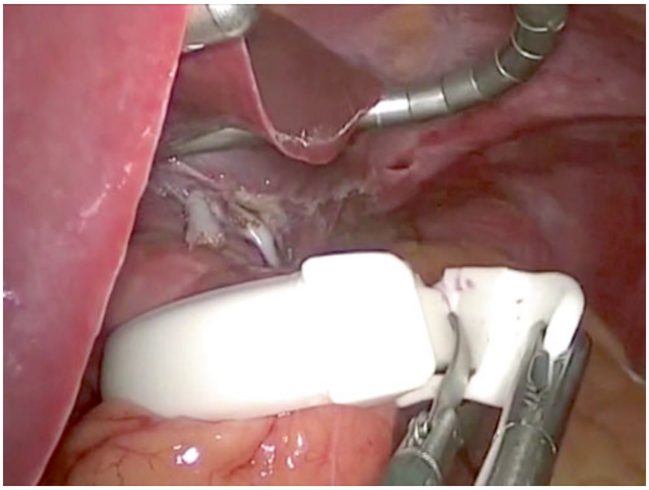

Fig. 34.9 Cutting the AGB

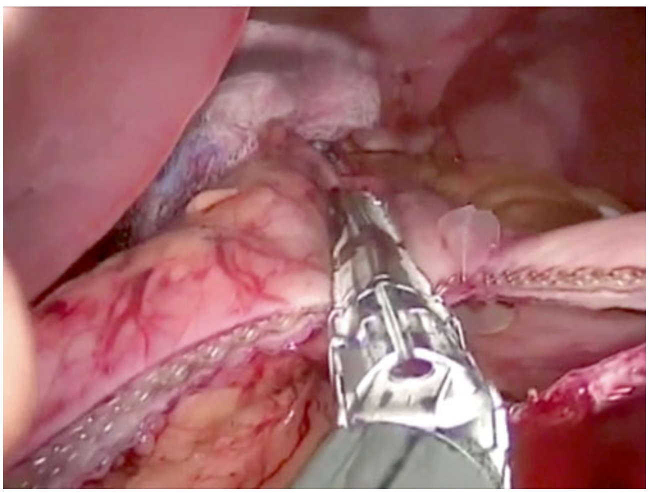

Fig. 34.10 Gastric stapling along 34 French orogastric tube

Fig. 34.11 Removal of SG specimen

experience, if the block is performed correctly, the reduced the postoperative pain in surgical incisions, allowing subsequent reduction of the requirement for pain medications and a faster recovery for the patient.

Fig. 34.12 laparoscopic-guided transversus abdominis plane (TAP) block

34.11 Postoperative Care

Patients are started on bariatric clear liquid diet on the same operative day. Prophylaxis for deep vein thrombosis is achieved using anticoagulants, an intermittent venous compression device and early ambulation. Postoperative gastrografin swallow is not done routinely. The patient is discharged once she or he is hemodynamically stable, afebrile, ambulating, tolerating a bariatric full liquid diet, and pain can be managed with oral analgesics.

34.12 Complications

Minor early postoperative complications have been described, like hematoma. However, long-term follow up is needed to rule out port site hernias, weight regain and others.

34.13 Results

Literature review revealed that RPLS sleeve gastrectomy, adjustable gastric banding, and gastric bypass procedures are safe and feasible compared to conventional laparoscopic approach [1–5].

Postoperative outcome including weight loss and improvement of comorbidities are similar to those occurring after conventional multiport laparoscopic sleeve gastrectomy and adjustable gastric banding.

In addition, no major operative or perioperative complications have been reported. The potential advantage of the RPLS approach, include cosmetic advantage, a shorter hospital stay and a reduced need for analgesia.

Prospective randomized studies comparing conventional laparoscopic bariatric procedures with their RPLS counterparts in large number with long-term follow up are needed to confirm these initial results.

Key Learning Points

- In expert hands, RPL bariatric surgery is a safe and feasible option in selected patients.
- The approach is particularly attractive for procedures that require a 2–3 cm incision to retrieve or insert the AGB and the port as in AGB, or to retrieve a big specimen as in SG. The use of a singleport device would be helpful in that task.
- RPLS approach has many potential advantages over the conventional laparoscopic approach, including less postoperative pain, less need for analgesia, and a shorter hospital stay. In addition, it improves cosmesis and body image, an important outcome to consider in the bariatric population where there is a predominance of young women.
- The RPLS approach has outcomes similar to those of its conventional multiport counterparts in terms of morbidity, mortality, reoperation, readmission, weight loss, and comorbidity improvement.
- However, some technical challenges are encountered during RPLS bariatric procedures, including lost triangulation, conflict of instruments, umbilical recession, and large fatty liver. These could be overcome by using long flexible instruments, a flexible tip scope, multichannel access ports, and a liver retractor.
- If any difficulties are encountered during the procedure, do not hesitate to add more trocars to achieve the same operative goal.

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Single Incision LRYGB

35

Chih-Kun Huang, Jasmeet Singh Ahluwalia, Po-Chih Chang, and Ming-Che Hsin

Abstract

Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) has emerged as a gold standard bariatric procedure. In the pursuit of scarless surgery, the concept of single incision laparoscopic surgery (SILS) was born and implicated in bariatric surgery. To hide the scar, umbilicus serves as the main orifice for entry of all ports in SILS. However, this small incision leads to change of basic laparoscopic principles of port placement and makes procedure exceptionally difficult. To perform single incision transumbilical (SITU) LRYGB, proper case selection important. Extremely obese patients (BMI >50 kg/m^2) and very tall patients (>180 cm in height) should be avoided because of abundant visceral fat and the long distance between umbilicus and gastric pouch. Previous abdominal surgery is a relative-contraindication because of lost advantage of cosmesis. During early learning curve stage, the 4.5 cm skin incision can be enlarged to 6 cm omega shaped incision, to get extra room for instrument maneuverability. Umbilicoplasty can be done to decrease this to 3.5 cm at the end of the procedure. Furthermore, in morbidly obese patients, the hypertrophic liver usually hinders the surgeon's view of upper stomach and liver retraction plays a pivotal role in the success of surgery. Liver suspension technique provides good exposure. After adequate experience, all steps of multi-port LRYGB can be readily replicated in SITU-LRYGB, without increased complication rate but with improved cosmetic result.

This chapter describes the technique of SITU-LRYGB, along with variations in technique, complications and some technical tips.

Keywords

Single incision LRYGB • Scarless RYGB • SILS bariatric surgery • SITU-LRYGB • SILS

35.1 Introduction

The introduction of laparoscopy has greatly impacted the acceptance of bariatric surgery among morbidly obese patients. It has dramatically increased the prevalence of such procedures all over the world. Nowadays, laparoscopic Roux-en-Y Gastric Bypass (LRYGB) has emerged as gold standard bariatric procedure. Additional weight loss of 60–70 % has been reported after LRYGB and long-term weight loss over 10 years is also well maintained [1]. However, it is also one of the most complex bariatric procedures that has a steeper learning curve, than many other advanced laparoscopic surgeries [2]. Since the first LRYGB reported by Wittgrove et al. [3] in

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1994, the procedure has become hugely popular and the incidence of immediate surgical complications has gradually decreased [4].

With increasing experience in advanced laparoscopy, surgeons have pushed the limits further. In their pursuit of scar-less surgery, the concept of single incision laparoscopic surgery (SILS) was born and implicated in bariatric surgery. It obviates multiple incisions needed for conventional laparoscopy and has gained tremendous attention in the past few years. SILS decreases trocar numbers and has a cosmetic advantage. Hence, SILS operation results in better patient satisfaction as compared to standard multiport laparoscopy [5].

To hide the scar, umbilicus serves as the main orifice for entry of all ports in SILS. However this small incision leads to change of basic laparoscopic principles of port placement and loss of triangulation for manipulation. This makes the procedure exceptionally difficult, especially in initial period of learning curve. Furthermore, in morbidly obese patients, the hypertrophic left liver usually hinders the surgeon's view of upper stomach and liver retraction plays a pivotal role in the success of surgery.

The popularity of SILS has also led to development of various special and commercial devices, to help surgeons in different steps of this challenging procedure. Many new access devices, specialized instruments, and imaging devices are now available for SILS, but it can also be performed using conventional trocars and instruments. We have reported the later technique since first case of single incision transumbilical (SITU) LRYGB in 2008 [6].

35.2 Case Selection

The indications for SITU-LRYGB are the same as for multi-port surgery in morbidly obese patients. However, extremely obese patients (BMI >50 kg/m^2) and very tall patients (>180 cm in height), should be avoided because of abundant visceral fat and the long distance between umbilicus and gastric pouch. Previous abdominal surgery is a relative contraindication because of lost advantage of cosmesis.

35.3 Surgical Technique

See Video 35.1. All patients should receive prophylaxis against deep vein thrombosis and antibiotics as per the policy of the hospital for other bariatric procedures.

A bariatric operating table providing at least 45° of reverse Trendelenburg position should be used. A footboard is essential to prevent patient slippage while tilting the table. All kinds of extra-long instruments must be kept ready.

35.3.1 Room Setup

Patient lies supine on the table with arms extended. Adequate padding is ensured and patient is fastened to the table. Surgeon stands on the right side while the camera man and the first assistant are on the left side of the patient. Set-up of monitor and instrument trolley are shown in Fig. 35.1.

35.3.2 Port Placement

At least three ports are required to perform SITU-LRYGB. A 4.5 cm transverse incision is made along upper margin of the umbilicus (Fig. 35.2). A space is created over the linea alba to insert the ports by limited dissection in the subcutaneous plane. Pneumoperitoneum is created using Veress needle and a 12 cm port is inserted in the center of the incision. This port is fixed to the skin with a suture to prevent air leakage due to slippage. A 5-mm port is inserted on the right side of the first port for the left hand instrument. Another 5- or 10-mm port is inserted on the left side for the telescope (10 mm 30°). These three ports are arranged in a triangular fashion (Fig. 35.3).

35.3.3 Liver Retraction

The left lobe of liver is elevated using T-shape liver suspension technique [7]. A silicon or rubber drain attached to 2-0 polypropylene suture on a long straight needle is used (Fig. 35.4). Usually two such suspensions are used but more can be used in a difficult case. Once inside the abdomen, the needle is grasped while the left lobe of the liver is gently raised. The needle is then passed into the inferior surface of the liver so as to exit at the superior surface. The tip of the needle is exteriorized by piercing the anterior abdominal wall and pulled out. The thread is clamped close to the abdominal wall. This maneuver helps to lift the left lobe of the liver and provide good exposure of the surgical field.

35.3.4 Gastric Pouch

A gastric calibration tube is inserted and the balloon is inflated to 25 cc. The pouch is marked using a cautery. Dissection is started on the lesser curvature of stomach at the marked site using an electrocautery hook (alternatively, ultrasonic shears or Ligasure V™ can be used). The dissection is deepened to free the posterior adhesions of the stomach. Laparoscopic stapler (Endo-GIA roticulator 45–3.5, Covidien, Norwalk, CT) is fired according to the marked line. Further staplers are fired towards the angle of His, and great care should be taken to exclude the fundus of the stomach from the pouch.

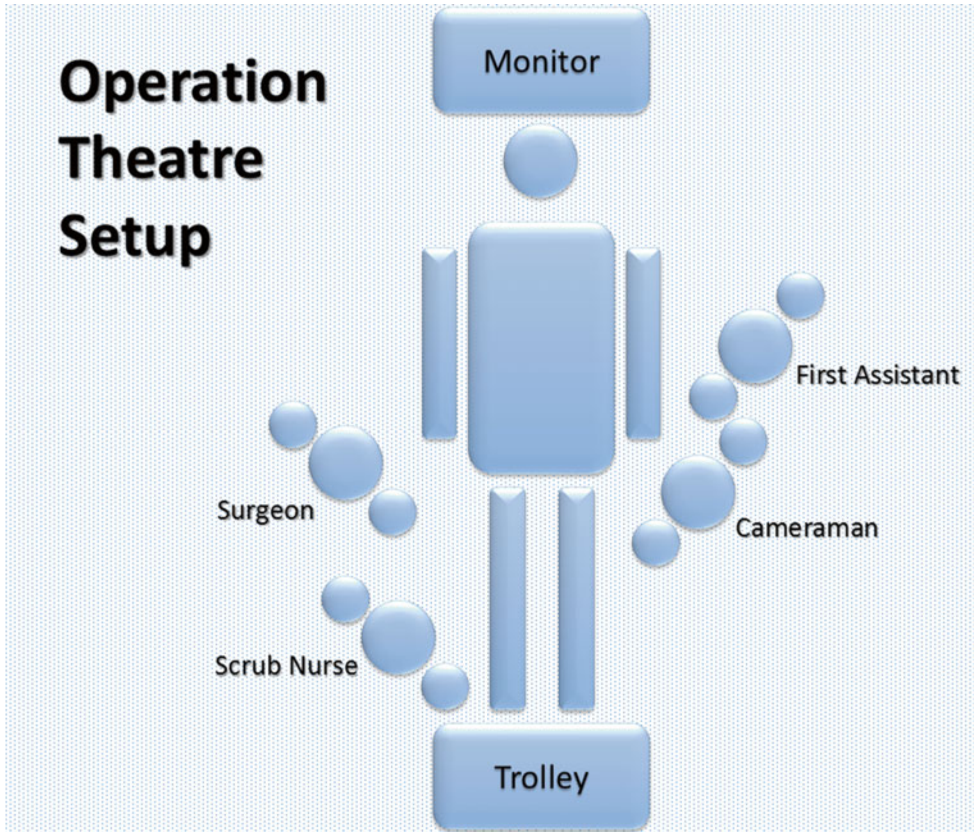

Fig. 35.1 Operation theatre set-up

Fig. 35.2 4.5 cm skin incisionin made at upper edge of umbilicus according to the natural skin crease

35.3.5 Gastro-Jejunostomy

A small opening is made in the pouch after inserting calibration tube. The entry into the lumen must be ensured at this point by inserting a blunt instrument and observing the mucosa. Then the ligament of Treitz is identified, jejunum is measured for 100 cm by using marked bowel graspers, and a small opening is made at its antimesenteric side. Then 2 cm antecolic, antegastric gastro-jejunostomy is created with 45 mm purple stapler. The defect of gastro-jejunostomy is closed using intra-corporeal suturing (3-0 Monosyn, Braun).

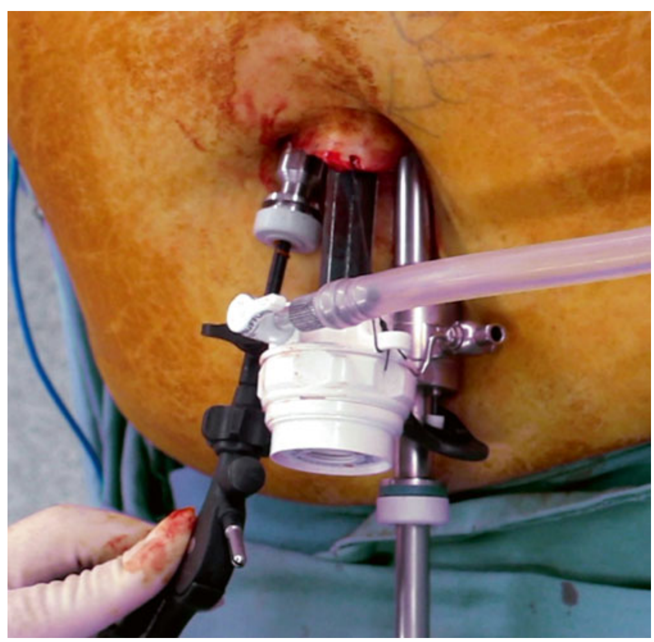

Fig. 35.3 Port positioning. (**a**) Diagrammatic representation of triangular position of three trocars

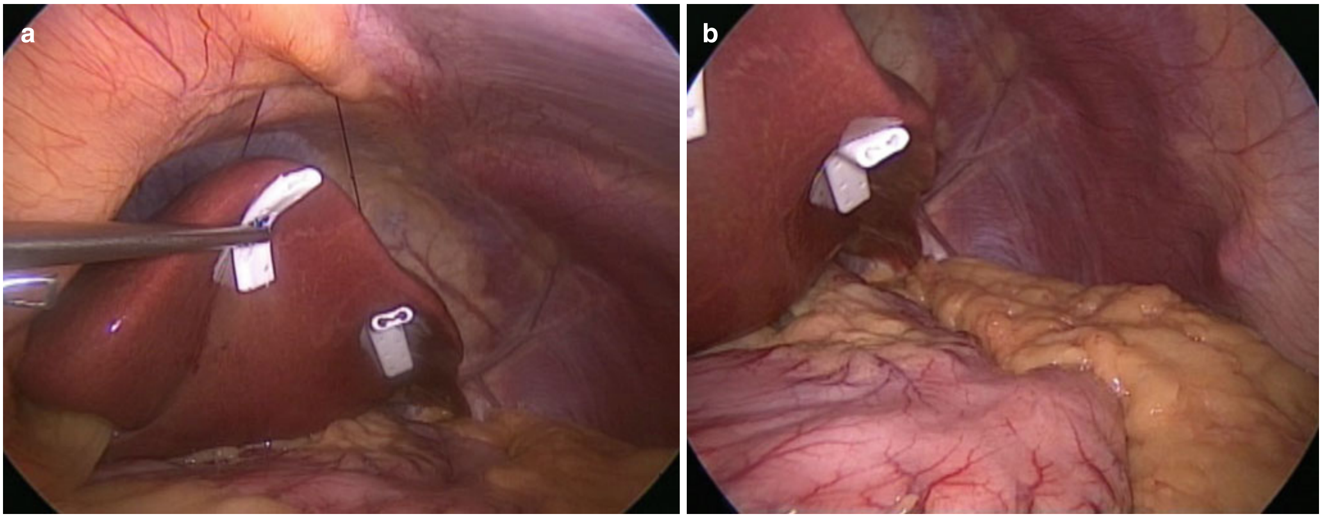

Fig. 35.4 Liver suspension. (**a**) Liver being suspended using suture attached to a drain. (**b**) After completion of liver suspension

35.3.6 Jejuno-Jejunostomy

Then division of jejunal loop is done just distal to gastro-jejunostomy using white linear stapler (Endo-GIA, Covidien). Jejunum is measured 100 cm from gastro-jejunostomy and again a small opening is made at its antimesenteric border. A 45 mm- stapler (Purple, Tri-staple, Covidien) is used to create jejuno-jejunostomy and the defects are closed using intracorporeal suturing (3-0 Monosyn, Braun).

35.3.7 Mesenteric Defect Closure

Both Peterson's defect and intermesenteric defect must be routinely closed using non-absorbable running suture (2–0 Ethibond, Ethicon), to prevent internal hernia.

35.3.8 Liver Suspension Removal

Liver suspensions are removed and the puncture sites are coagulated with electrocautery.

35.3.9 Wound Closure

The ports are removed and all the fascial defects are closed with sutures (1-0 Prolene, Ethicon). Subcutaneous space is closed with care to prevent seroma formation. The skin is closed with subcuticular sutures (4-0 Monocryl, Ethicon). The final scar is hardly noticeable (Fig. 35.5).

Fig. 35.5 Wound after closure at the end of the procedure

35.4 Variations in Technique

35.4.1 Incision

During early learning curve stage, the 4.5 cm skin incision can be enlarged to 6 cm omega shaped incision (Fig. 35.6a), to get extra room for instrument maneuverability. Umbilicoplasty can be done to decrease this to 3.5 cm at the end of the procedure (Fig. 35.6b–e). This could decrease the technical difficulty in early learning curve. But this technique causes more postoperative pain and possible seroma

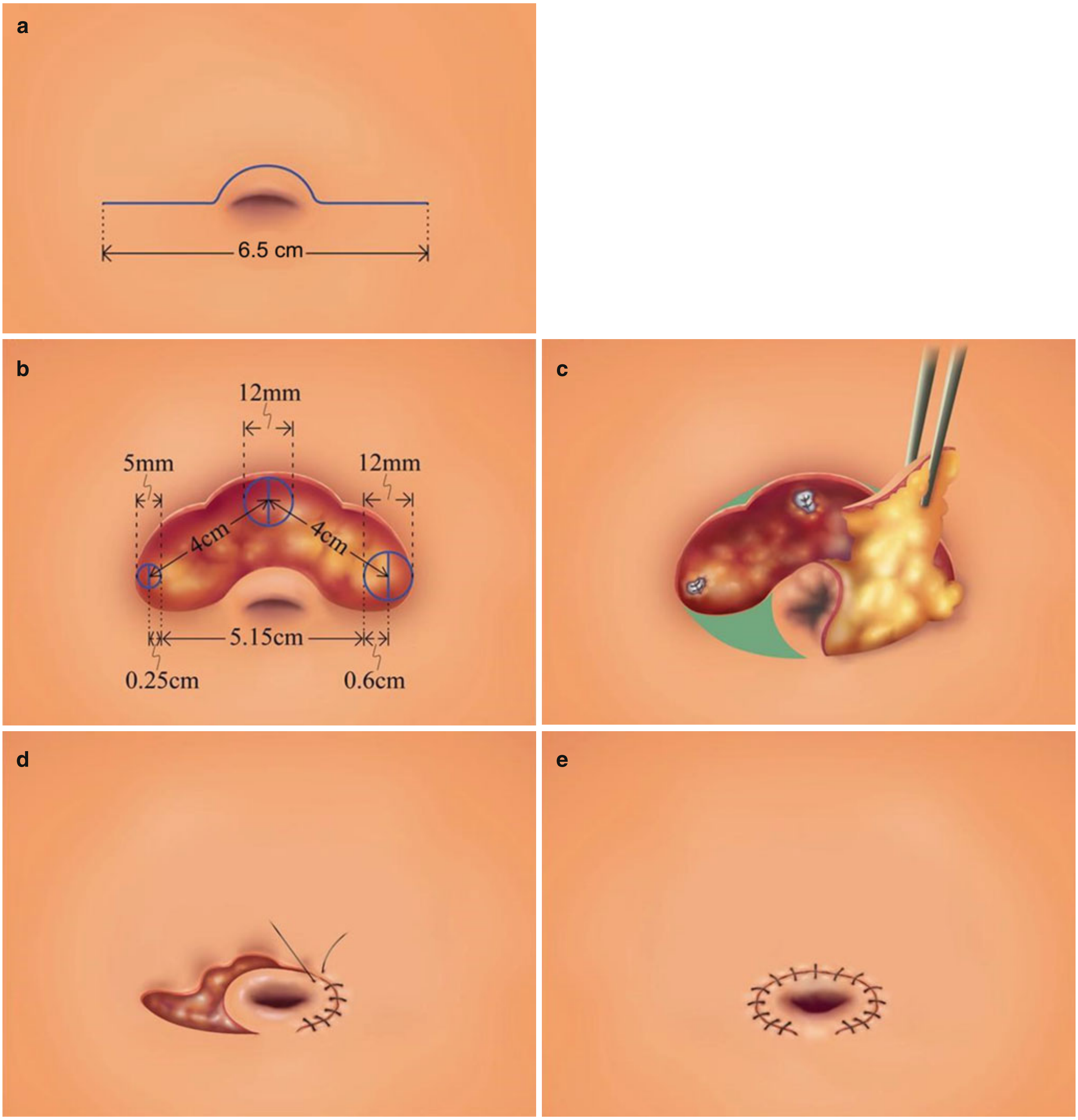

Fig. 35.6 (**a**) 6 cm omega shaped skin incision, (**b**) umbilicoplasty procedure, (**c**) repair the fascial defects, (**d**) umbilicoplasty, (**e**) circular wound repair decreases wound length to 3.5 cm

and keloid formation. When overcoming the learning curve, a 4.5 cm incision would be enough to decrease extent of dissection in subcutaneous plane and chances of seroma formation [5].

35.4.2 Port Placement

After subcutaneous dissection is done, open technique or optical trocar can be used for initial abdominal access.

35.4.3 Special Devices

Many specialized devices (TriPort™ or SILS-port® etc.) can also be used. Roticulating instruments have been used by some authors to decrease in-fighting between the instruments [8].

35.4.4 Liver Retraction

Liver retraction can also be done by hanging it with umbilical tape or taking a suture in the right crus. In the liver puncture technique, instead of using silicon drain, gauze or a corrugated drain can also be used.

35.4.5 Pouch Calibration

Alternative techniques include using a calibration balloon to size the pouch—to start dissection 5 cm inferior to the angle of His or to start between first and second vessel on the lesser curvature.

35.4.6 Pouch Creation

If peri-gastric technique is found too difficult, complete section of the lesser omentum and stomach by *pars-flaccida* method can be tried to avoid intra-operative injury of the stomach.

35.4.7 Limb Length

Various limb lengths have been described for RYGB. These can be varied according to the surgeon's choice and the condition of the patient. We routinely bypassed 100 cm biliopancreatic and 100 cm Roux limb.

35.4.8 Leak Test and Drain

Leak test can be done using air or methylene blue after finishing the anastomosis. Drain is not recommended routinely.

35.5 Complications

Complication rate after SITU-LRYGB has been found to be similar to that of multi-port LRYGB [5].

Complication reported particular to SILS procedure is related to the wound. A single larger wound with subcutaneous dissection and abrasions from port stretch, calls for a more careful wound care than in multi-port technique. If seroma is formed, it usually resolves by itself or by needle aspiration.

No higher incidence of incisional hernia in SITU-LRYGB is found, if the surgeon routinely repairs all defects in the fasciae.

There is almost no difference in the postoperative hospitalization, pain, and weight loss, when comparing multi-port and SITU-LRYGB. But satisfaction about abdominal scar is definitely better in SITU group [5].

35.6 Technical Tips

Some authors have described this procedure without using any liver retraction. However, we feel, using liver retraction improves visualization and ease of surgery. Puncturing liver has not resulted in any major complication.

Because of the longer-than-normal working distance between the gastric pouch and umbilicus, we used 43-cm-long instruments, including the endoscope, graspers, and a long endocutter.

Intra-corporeal suturing also becomes very challenging in SITU-LRYGB. Using curved tipped instruments and making vertical rather than horizontal movements can make this task easier. Grasping and positioning the needle with a single hand, could make suturing more efficient and faster. Using one long and one short instrument can also be helpful in preventing instrument in-fighting for the handler. Alternatively, EndostitchTM (Covidien) may be used in unexperienced hands in the beginning.

By using conventional ports and instruments, the cost of SITU-LRYGB can be almost equal to multi-port laparoscopy and it can be made more widely acceptable.

This procedure requires considerable skill and we recommend that it should be performed only by experienced bariatric surgeons. Because of the increased operative time and technical difficulty, this procedure should be regarded as an optional approach to those with great concern about the cosmetic results.

35.7 Redo Surgery After SITU-LRYGB

Another SITU laparoscopic procedure has been reported to be safe, technically feasible, and reproducible, for patients requiring second surgery after SITU-LRYGB. It included cholecystectomy, revision of gastro-jejunostomy, and repair of mesentery defect and so on. It revealed reasonable operation time, quick recovery, but without creating new scars [9].

Key Learning Points

- Proper case selection is important in this advanced laparoscopic procedure.
- Omega shaped skin incision of 6 cm can be employed especially during initial learning curve and subsequent umbilicoplasty can offer the same cosmetic result.
- Routine straight instruments can be used for SITU-LRYGB.
- Liver suspension technique provides good exposure.
- Developing intra-corporeal suturing techniques with vertical and fro-back skill is a boon to perform this procedure.

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Single Incision LSG

36

Giovanni Dapri

Abstract

Sleeve gastrectomy (SG) was initially performed as the first part of a two stage bariatric procedure for duodenal switch. However, its success in achieving significant weight loss on its own was soon recognized. SG is now increasingly gaining popularity throughout the world, especially in Asia and USA. This procedure is generally performed using 5–7 abdominal trocars, but can also be done through a single-incision laparoscopy (SIL) performed at the umbilicus. A proper selection of patients is required. In this chapter, a specific developed technique of trans-umbilical SILSG using complete reusable material (except for linear stapler) and curved instruments is described.

Keywords

Laparoscopic sleeve gastrectomy • Single-incision • Single-port • Single-access • Single-site

36.1 Introduction

Sleeve gastrectomy (SG) was initially performed as the first part of a two stage bariatric procedure for duodenal switch. However, its success in achieving significant weight loss on its own was soon recognized. SG is now increasingly gaining popularity throughout the world, especially in Asia and USA [1, 2]. In the last decade it has become increasingly popular as a standalone bariatric procedure [3]. It is projected to overtake the gastric bypass as the commonest bariatric procedure overall in the near future.

This procedure is generally performed using 5–7 abdominal trocars, but can also be done through a single-incision laparoscopy (SIL) at the umbilicus. This incision is in line with the axis of the stomach. This allows the optical system and instruments to be inserted at the same access site (umbilicus), and access the target (stomach) without much difficulties. Moreover, the access site can be enlarged to remove the resected stomach from the abdomen with relatively better cosmesis as the scar remains at the umbilicus.

A past problem working through a SIL has been the establishment of the conventional working triangulation needed in laparoscopic surgery. The introduction of the curved instruments has helped solve this issue to some measure. Another potential problem was the exposure of the hiatal region and the retraction of the liver. It helps if a liver shrinkage preoperative diet can offer a hypotrophic liver parenchyma. In literature, several different options of liver retraction have been reported:

- insertion of a classic 5-mm liver retractor [4],
- insertion of a penrose drain at the triangular ligament [5],
- fixation of a penrose drain to the abdominal wall by endo-hernia stapler [6] or sutures [7],
- placement of an expandable sponge under the left liver lobe [8],

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- use of cyanocrylate between the left liver lobe and the diaphragm [9],
- use of a bulldog anchored at the falciform ligament [10],
- use of magnet forceps and external magnets [11],
- insertion of percutaneous transhepatic sutures [12] or superficial hepatic sutures [13, 14],
- insertion of percutaneous Cerrahpasa retractor [15],
- insertion of boxing glove retractor [16],
- retraction and central fixation of the left triangular ligament [17],
- use of liver vacuum retractor [18].

In this chapter, a specific developed technique of transumbilical SILSG is described.

36.2 Technique

36.2.1 Material

- Sutures: one polydiaxone (PDS) 1, four polyglactin (Vicryl) 1, three polyglactin (Vicryl) 2/0
- One reusable 11-mm metallic trocar (Karl Storz-Endoskope, Tuttlingen, Germany)
- One reusable 13-mm metallic trocar (Karl Storz-Endoskope, Tuttlingen, Germany) or disposable 12-mm trocar (Ethicon Endosurgery, Cincinnati, OH or Covidien, New Haven, CT)
- One reusable 6-mm flexible trocar (Karl Storz-Endoskope, Tuttlingen, Germany)
- One straight 10-mm, 30° and regular length scope (Karl Storz-Endoskope, Tuttlingen, Germany)
- One straight 5-mm, 30° and long length scope (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI bicurved reusable grasping forceps (Fig. 36.1a) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI monocurved reusable coagulating hook (Fig. 36.1b) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI monocurved reusable RoBi bipolar grasping forceps (Fig. 36.1c) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI monocurved reusable RoBi bipolar scissors (Fig. 36.1d) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI monocurved reusable needle holder (Fig. 36.1e) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI monocurved reusable scissors (Fig. 36.1f) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One DAPRI 1.8-mm reusable trocarless grasping forceps (Fig. 36.2) (Karl Storz-Endoskope, Tuttlingen, Germany)
- One straight reusable grasping forceps
- One reusable suction and irrigation cannula
- One reusable Veress needle
- One disposable roticulator linear stapler 60 (green/black loads) (Ethicon Endosurgery, Cincinnati, OH or Covidien, New Haven, CT)
- One disposable orogastric bougie (36-Fr).

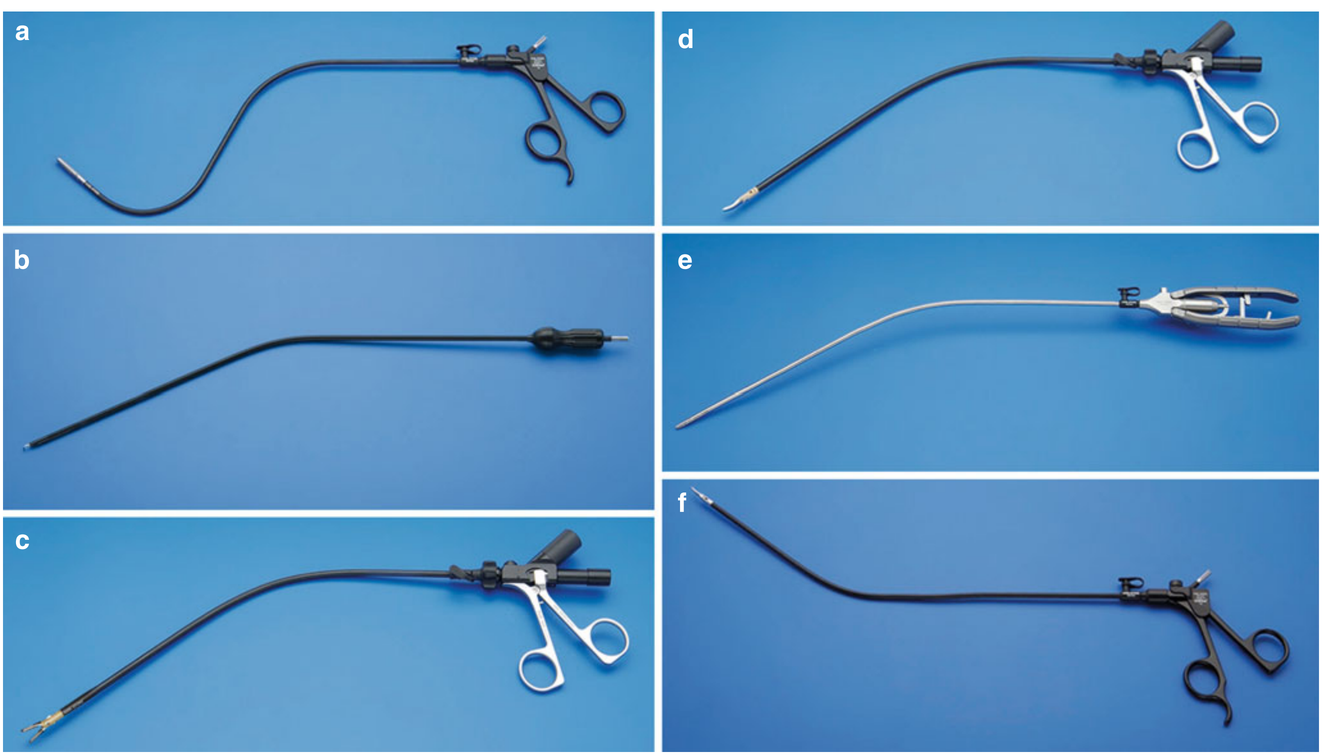


Fig. 36.1 (**a**–**f**) DAPRI curved reusable instruments (Karl Storz—Endoskope, Tuttlingen, Germany): bicurved reusable grasping forceps (**a**), monocurved reusable coagulating hook (**b**), monocurved reusable RoBi bipolar grasping forceps (**c**), monocurved reusable RoBi bipolar scissors (**d**), monocurved reusable needle holder (**e**), monocurved reusable scissors (**f**)

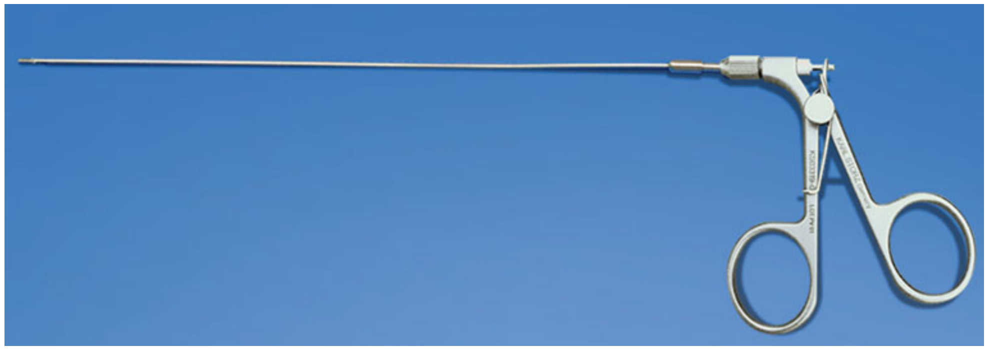


Fig. 36.2 DAPRI 1.8-mm reusable trocarless grasping forceps (Karl Storz—Endoskope)

36.2.2 Patient and Team Positioning

The patient is placed in a supine position, with the arms alongside the body and the legs apart. The surgeon stands between the patient's legs, the camera assistant to the patient's right and the scrub nurse to the patient's left. The video monitor is placed at the patient's head end, in front of the surgeon and camera assistant (Fig. 36.3).

36.2.3 Technique

The umbilicus is everted and incised for 2.5 cm (Fig. 36.4). The central fatty tissue is found and enlarged in order to directly get access to the peritoneal cavity. A purse-string suture using PDS 1 is placed in full-thickness method in the umbilical fascia and peritoneum at 1, 3, 5, 6, 7, 9, 11 and 12 o'clock positions (Fig. 36.5); this suture is maintained externally by a Kelly grasper.

A reusable 11-mm metallic trocar or a disposable 12-mm trocar is inserted into the peritoneal cavity inside the purse-string suture, and once the pneumoperitoneum is created, the 10-mm scope is introduced as well.

The bicurved grasping forceps (Fig. 36.1a) is inserted without a trocar through a separate fascia window, created by a 6-mm trocar's wire 5 mm outside the purse-string suture at 10 o'clock position. The insertion of this grasping forceps is done following its curves at 45° with respect to the abdominal wall (Fig. 36.6).

The other instruments, like the monocurved coagulating hook (Fig. 36.1b), the monocurved RoBi bipolar grasping forceps and scissors (Fig. 36.1c, d), the monocurved needle holder (Fig. 36.1e), the monocurved scissors (Fig. 36.1f), the straight 5-mm grasping forceps and the suction and irrigation cannula are introduced through a 6-mm flexible trocar positioned at 2 o'clock position 5 mm outside the purse-string suture (Fig. 36.6).

The operative room table is positioned in a reversed Trendelenburg position.

The distal curve of the bicurved grasping forceps is used to retract the left liver lobe but if an insufficient exposure of the hiatal region is noted, a 1.8-mm trocar-less grasping forceps (Fig. 36.2) is percutaneously inserted through a skin puncture created under the xyphoid, accessed by a Veress needle (Fig. 36.7), or a simple sponge is placed between the left liver lobe and the lesser curvature of the stomach.

The procedure starts with the identification of the spared antrum, placing some marks by the monocurved coagulating hook on the anterior gastric surface at the vessels' termination in the direction of the pylorus (Fig. 36.8). The lesser sac is opened 3–5 cm laterally to these scores using the monocurved coagulating hook, or the monocurved bipolar forceps and scissors (Fig. 36.9). The greater omentum is then dissected from the greater curvature in the direction of the pylorus until the marks.

The reusable 11-mm trocar is replaced by a reusable 13-mm metallic trocar (if a disposable 12-mm is used, this change is not needed), in order to accommodate a 60 mm roticulator linear stapler. The 10-mm scope is switched to a 5-mm long scope and inserted through the 6-mm flexible trocar at 2 o'clock position (Fig. 36.10a). A 36-Fr orogastric bougie is pushed down by the anesthesiologist and the stapler is fired (Fig. 36.10b). Before the last two firings, a right-sided tilt of the operative room table is increased, and the angle of His is freed from bottom to top in order to create a retrogastric tunnel by a straight grasping forceps (Fig. 36.11). Then, the last firings of linear stapler are performed as well (Fig. 36.12a, b).

The reusable 13-mm trocar is replaced by the reusable 11-mm trocar, together with the change of the scope into 10-mm. The resected stomach is freed from the greater omentum using the monocurved coagulating hook, or the monocurved bipolar forceps and scissors (Fig. 36.13a).

The curves in the instruments reduce the instrument clash intracorporeally and the conflict between the surgeon's hands externally (Fig. 36.13b).

Some sutures using Vircyl 2/0 are placed between the firings of linear stapler (Fig. 36.14a) or at the bleeding site.

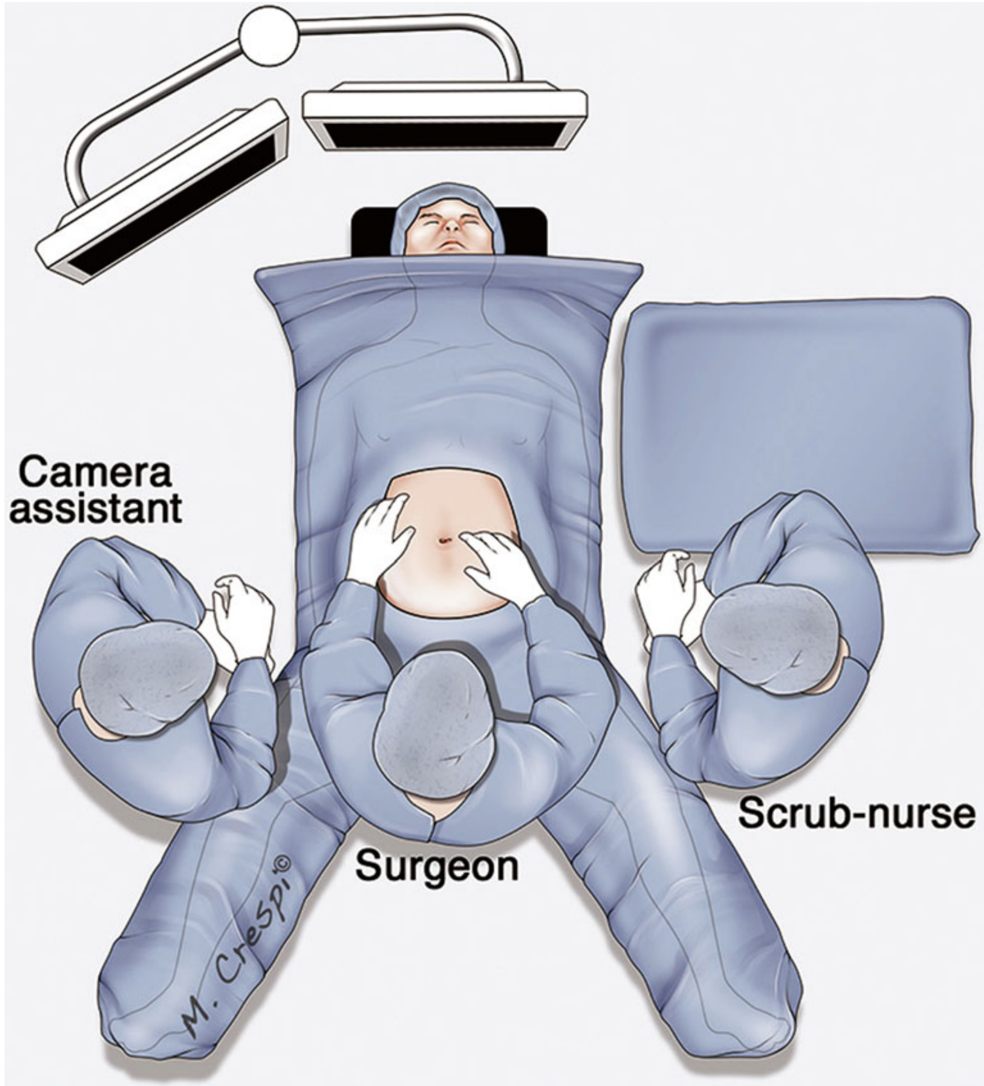


Fig. 36.3 Patient and team positioning for SILSG procedure

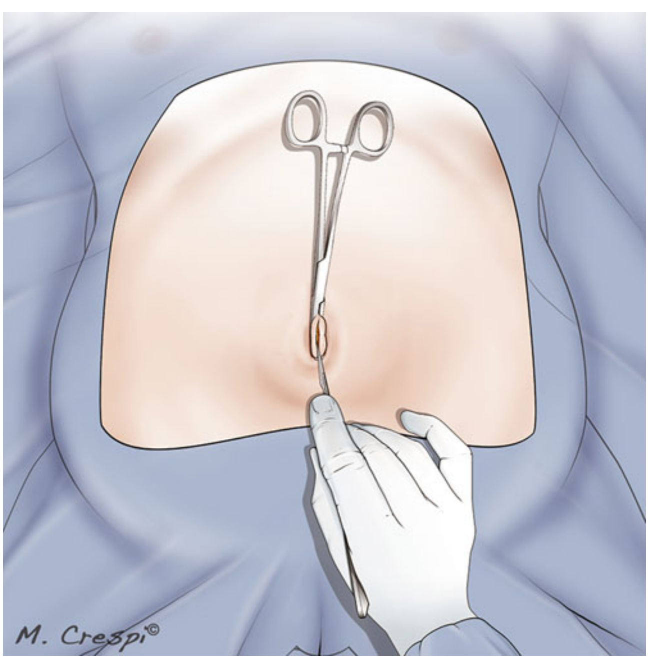


Fig. 36.4 Umbilical incision for SILSG procedure

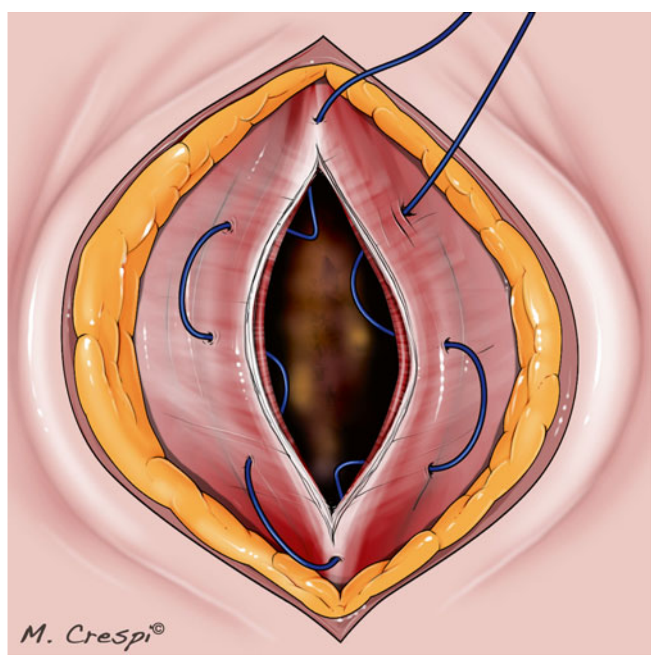


Fig. 36.5 Placement of a purse-string suture in the umbilicus

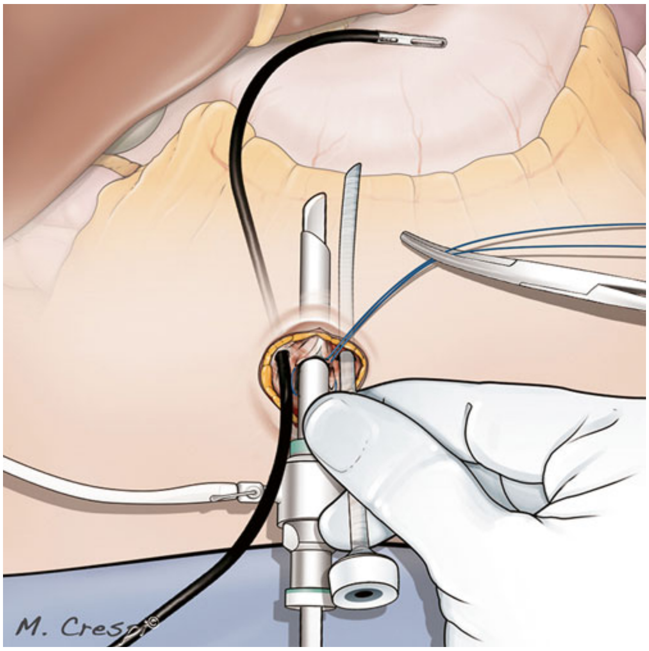


Fig. 36.6 Placement of the instruments and trocars through the umbilical scar during SILSG procedure

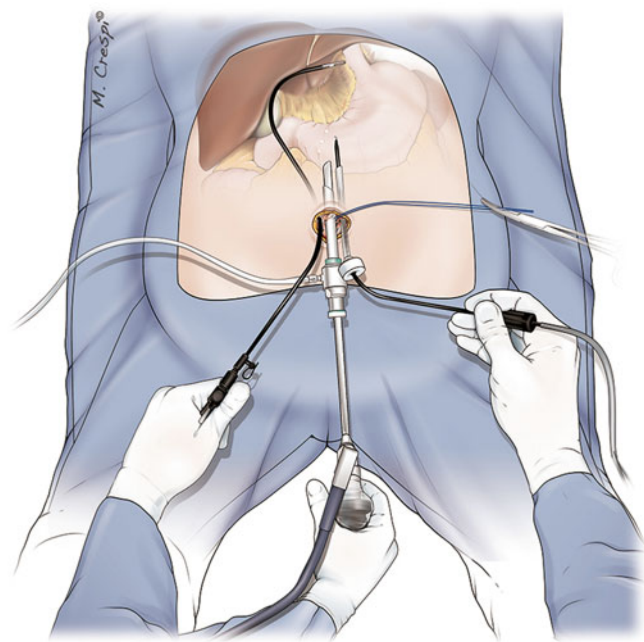


Fig. 36.8 Identification of the spared antrum marking the gastric wall with the coagulating hook

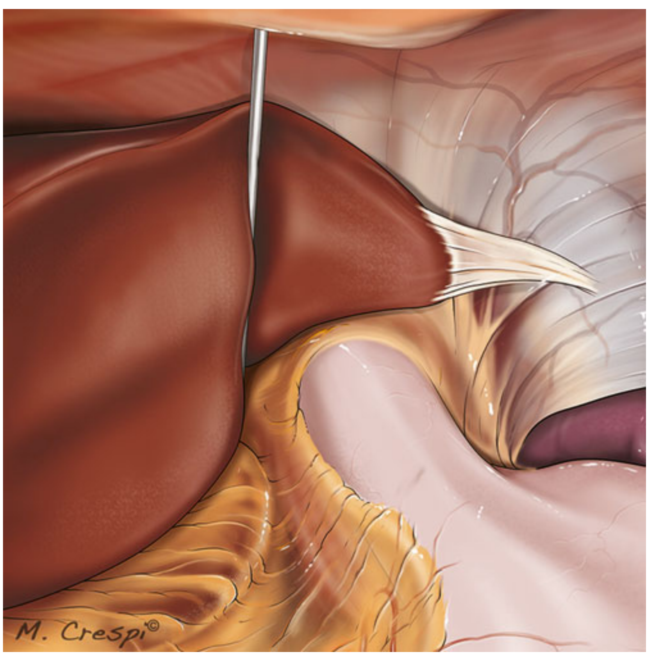


Fig. 36.7 Percutaneous insertion of DAPRI 1.8-mm reusable trocarless grasping forceps under the left liver lobe

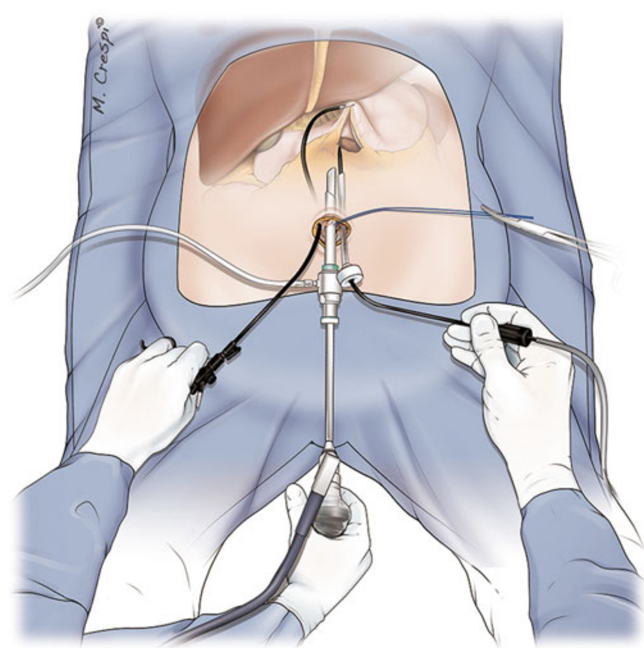
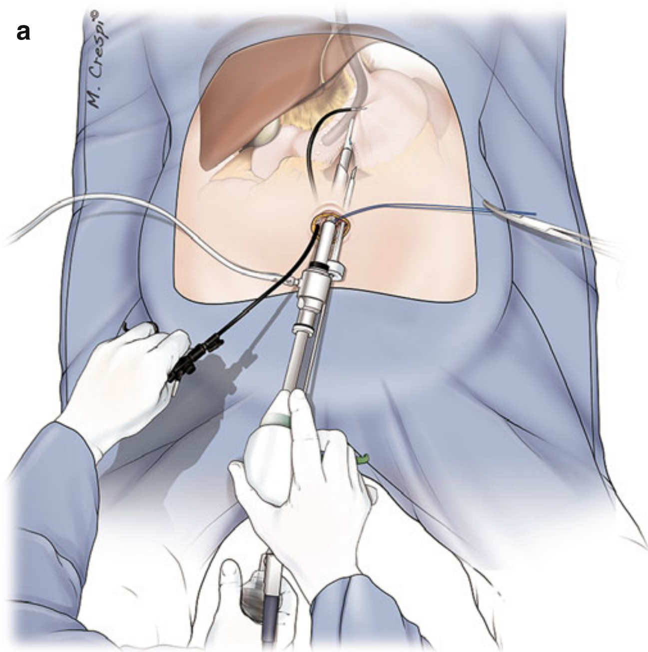


Fig. 36.9 Opening the lesser sac some centimeters laterally to the spared antrum

Surgeon continues to work under ergonomic positions, without clashing of the instruments' tips (Fig. 36.14b).

No drain is left in the abdominal cavity. A nasogastric tube is positioned under laparoscopic view and maintained for 24-h. The bicurved grasping forceps is retrieved following its curves at 45° with the abdominal wall. The resected stomach is grasped by a straight grasping forceps (Fig. 36.15) and removed transumbilically, after joining together the fascia openings of both trocars and bicurved grasper at the umbilicus (Fig. 36.16a, b).

Vicryl 1 sutures are placed as a figure of 8 to close the umbilical fascia, taking care to close the fascia openings used for the bicurved grasping forceps and 6-mm flexible trocar (Fig. 36.17a, b). The cutaneous scar is stitched.



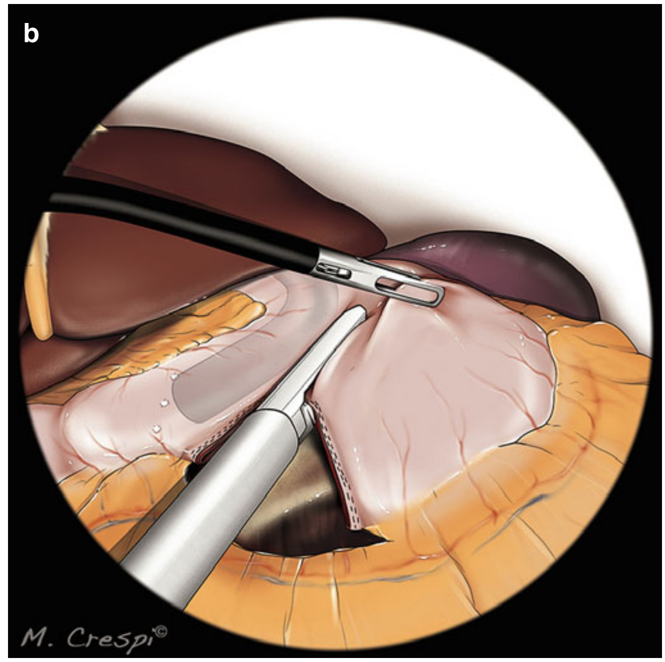


Fig. 36.10 (**a**, **b**) Insertion of the roticulator linear stapler under 5-mm laparoscopic view

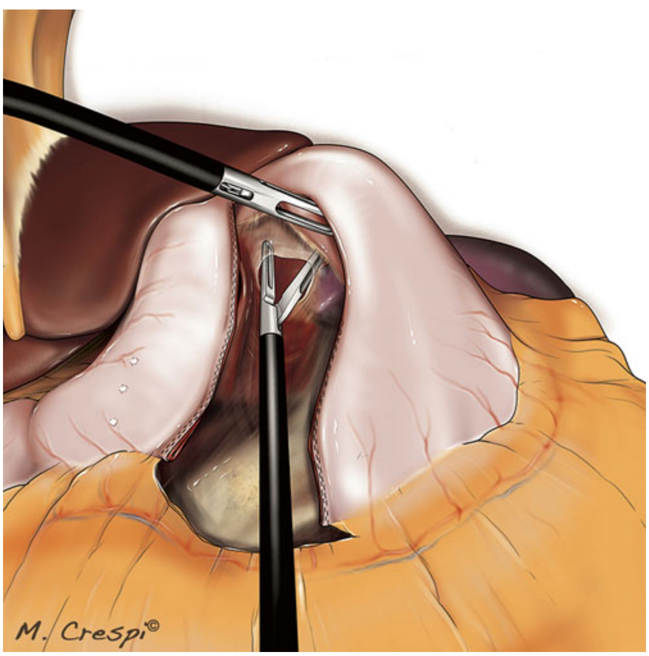


Fig. 36.11 Mobilization of the angle of His from bottom to top creating a retrogastric tunnel

36.3 Postoperative Management

One gram paracetamol is given intravenously (IV) at the end of the surgical procedure. Postoperative analgesia is given following the WHO visual analog scale (VAS) for pain. In the recovery room, the following scheme is followed: for VAS between 1 and 3, 1 g paracetamol IV. is pushed; for VAS between 4 and 8, 100 mg tramadol IV. is used; for VAS greater than 8, 1 mg piritamide IV. is given.

After the patient leaves the recovery room, pain is assessed every 6 h. One gram of paracetamol is administered IV. if VAS is between 1 and 3, and 100 mg of tramadol is administered IV if VAS is between 4 and 8.

Venous thromboprophylaxis is prescribed until the discharge of the patient from the hospital. The nasogastric tube is maintained in place for the first 24 h. Then, the patient is allowed to drink water on the second postoperative day and may tolerate a liquid diet from the third postoperative day. If there are no complications, the patient is discharged from the hospital on the fourth postoperative day.

Upon discharge, 1 g paracetamol orally or 50 mg tramadol orally are prescribed only if needed. This is prescribed besides 40 mg proton pump inhibitors and multivitamins.

Ambulatory visits are scheduled at 10 days and 1 month. Then, visits are scheduled together with the nutritionist and the psychologist, every 3 months for the first year, every 6 months for the second year, and then once every year.

36.4 Specific SILS Based Complications and Management

During SIL, the operative field's exposure is mandatory and different options as reported above are available [4–18]. The advantage of inserting a millimetric trocarless grasper is that it permits not only retraction of the left liver lobe but also

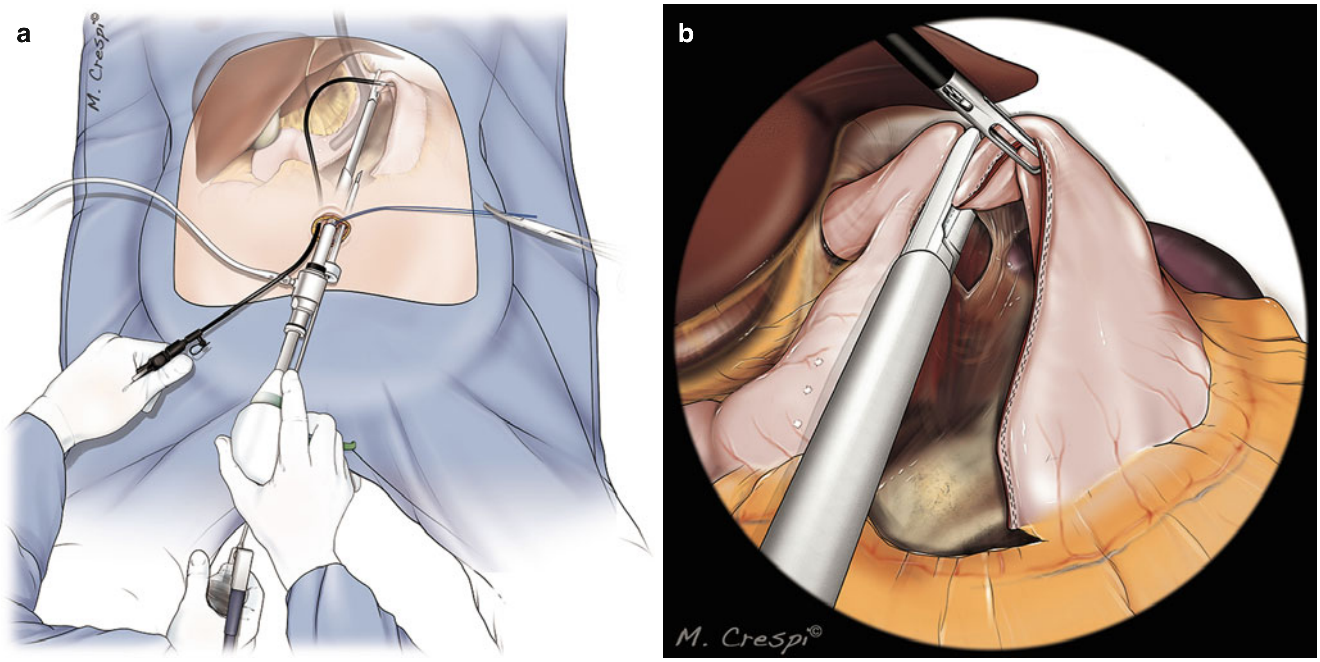


Fig. 36.12 (**a**, **b**) End of the gastric tubulization with the last firings of linear stapler

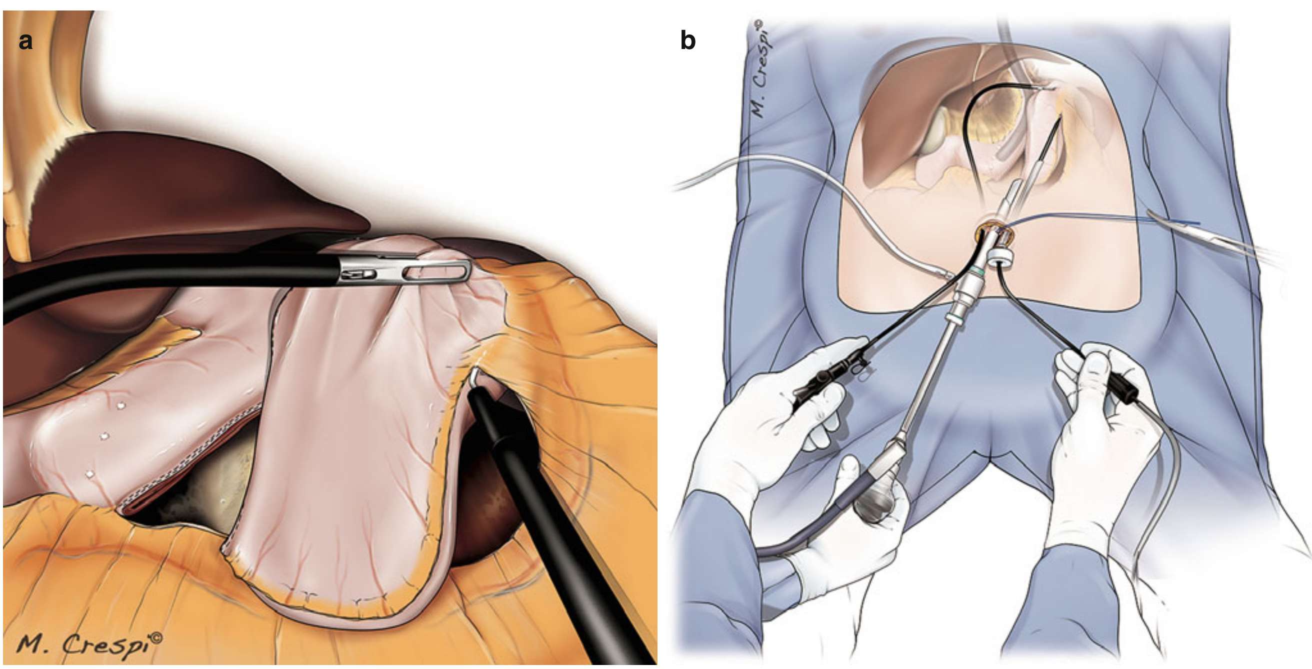


Fig. 36.13 (**a**, **b**) Mobilization of the resected stomach from the greater curvature (**a**) under surgeon's ergonomic positions (**b**)

helps in grasping the greater omentum or the gastric wall when necessary. For example, when bleeding occurs, an additional grasping forceps can be inserted to control bleeding and reduce the risk of conversion to multi-trocar laparoscopy.

A proper patient selection for SIL is required to maintain the feasibility of this technique, an acceptable operative time, and low conversion rate. Hence, we recommend that male patients with a body mass index more than 40 kg/m^2 and those with a distance between the xyphoid process and the umbilicus more than 20-cm be excluded from consideration for SIL. Patients with previous surgery at the umbilicus or upper abdominal quadrants are not good candidates for

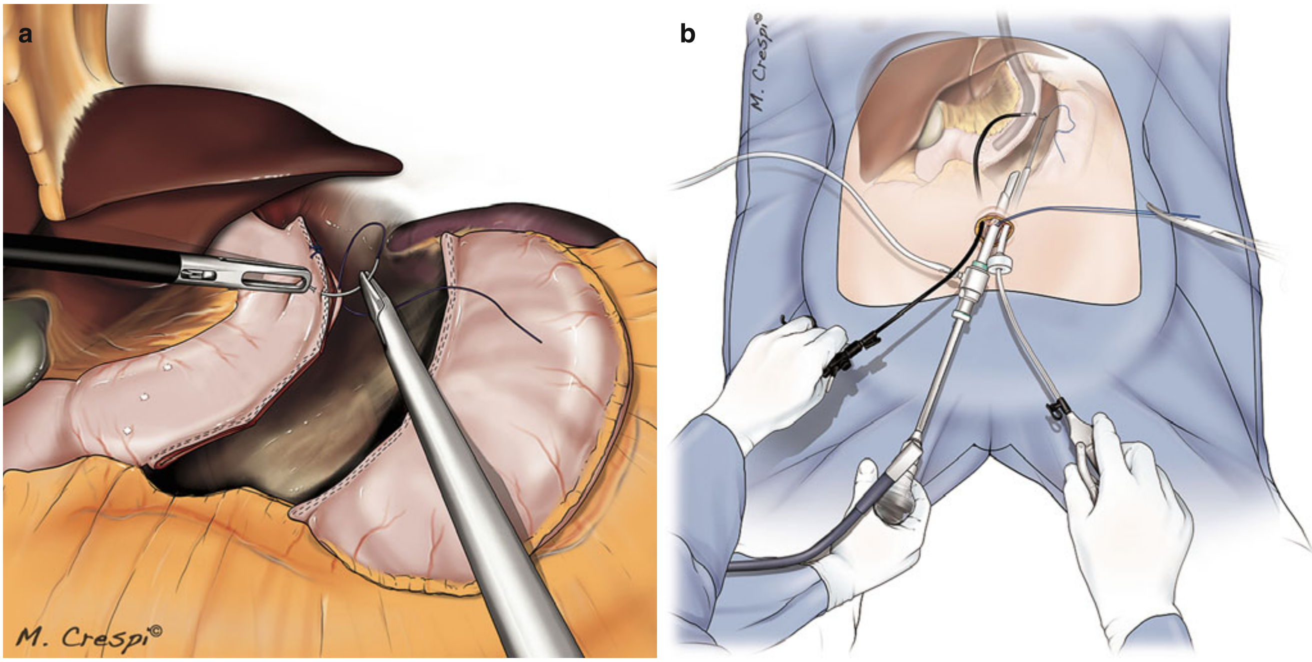


Fig. 36.14 (**a**, **b**) Placement of some sutures between two firings of stapler (**a**) and surgeon's ergonomy (**b**)

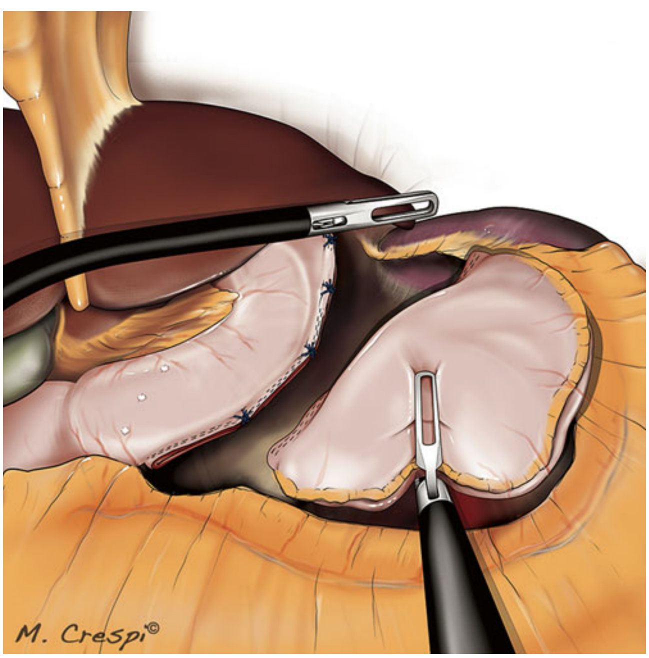


Fig. 36.15 Removal of the specimen using a straight 5-mm grasping forceps to keep the resected stomach

this technique either. Obviously, the general indications and contraindications for the procedure of laparoscopic sleeve gastrectomy (LSG) have to be respected.

If an abdominal drain needs to be left in the abdominal cavity, a different scar in an abdominal quadrant beyond the umbilicus has to be used to avoid the risk of incisional hernia. Moreover, this scar can be used for the insertion of an additional instrument during the SIL procedure, hence the rationale to start immediately the SIL procedure with an additional tool and to perform the so-called Reduced Port Laparoscopic Surgery (RPLS) [19].

Technically, different port devices, scopes, and instruments are available on the market and can be used. The choice depends on the surgeon's experience and habits, and also on the equipment availability. In the technique reported here, specific curved instruments were adopted to allow the surgeon to work in ergonomic positions, respecting the rule of conventional multi-trocar laparoscopy, which poses the optical system in the center of the two ancillary tools [20].

36.5 Outcomes

After the first report of LSG performed through SIL [21], other bariatric procedures like gastric banding, gastric bypass and biliopancreatic diversion have been described.

The additional trocar insertion rate varies between 0 and 21.6 % [22, 23]. The operative time [24] and the postoperative pain [22] were showed to be significant less after SIL technique.

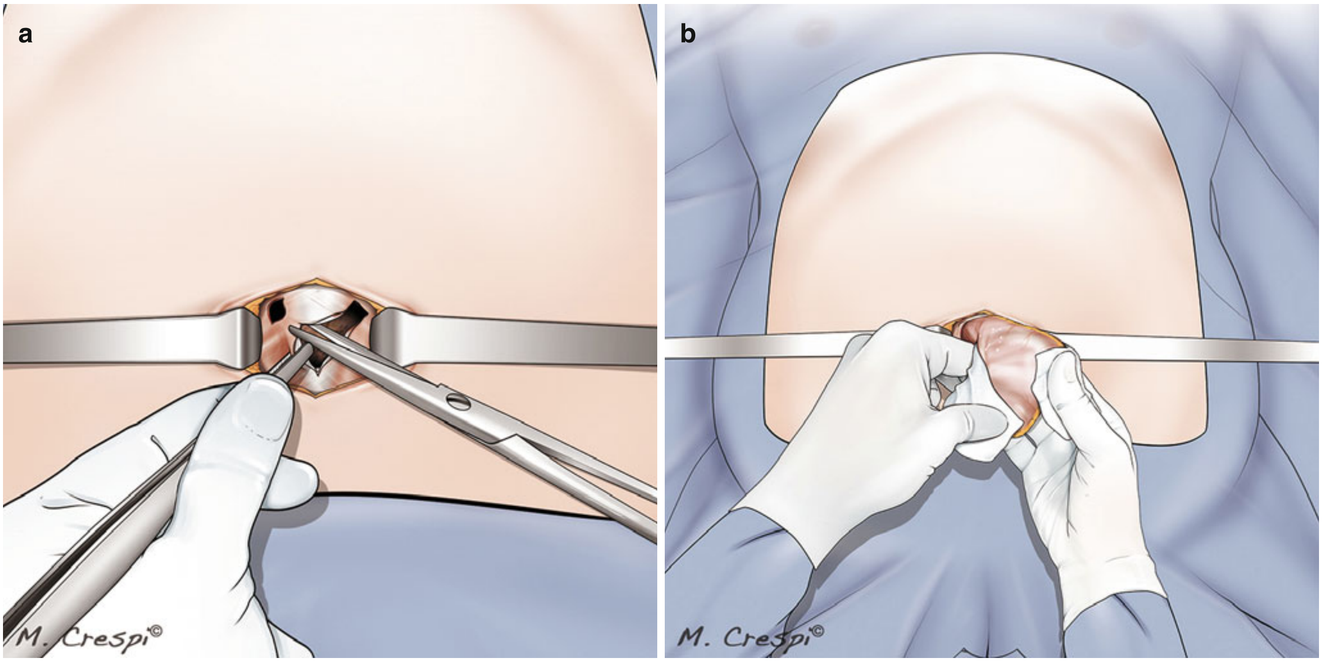


Fig. 36.16 (**a**, **b**) The fascia openings of both trocars and bicurved grasper are joined together, permitting the removal of the specimen

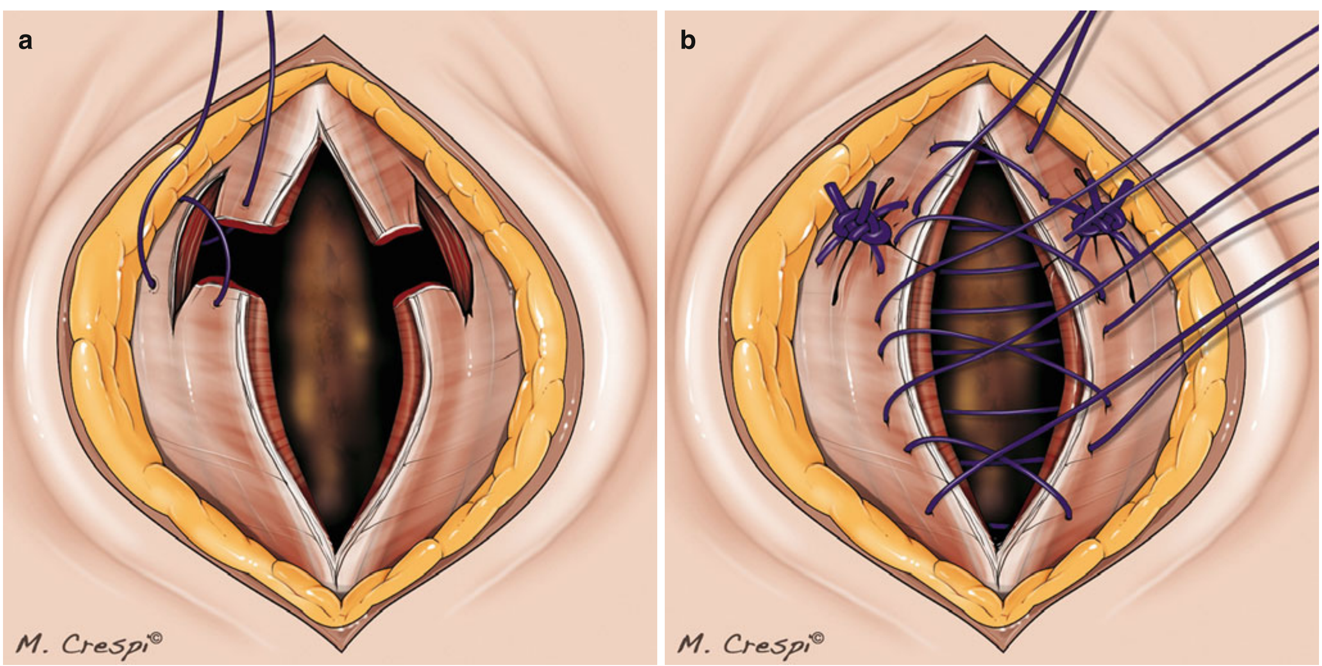


Fig. 36.17 (**a**, **b**) 'Figure of 8' sutures are used to meticulously close the umbilical fascia, taking care of the openings for the bicurved grasper and 6-mm flexible trocar

Conclusions

LSG remains a procedure that can be performed through SIL, but the importance of patient selection cannot be overstated. Adequate mastery of multitrocar LSG is required prior to embarking on SIL technique application to LSG.

Key Learning Points

- SILSG can be performed after appropriate learning curve and knowledge of conventional multitrocar LSG
- Experience in general SIL is fundamental to perform bariatric SIL
- Intracorporeal working triangulation during SIL can be established by the use of curved instruments
- Also, surgeon can work under ergonomic conditions in SIL thanks to the use of the curved instruments
- Intracorporeal knotting technique is finally feasible by SIL

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Single Incision LAGB

37

Saurav Chakravartty, Beth Murgatroyd,
and Ameet G. Patel

Abstract

Laparoscopic gastric band surgery is a popular choice amongst obese patients; the challenges this patient group present to the surgeon include central adiposity and hepatomegaly. Single incision laparoscopic surgery (SILS) adds to those challenges with difficulty in maneuverability of instruments in a limited space. Recent evidence suggests that SILS is a suitable technique for gastric band insertions with the potential of causing less pain and resulting in better cosmetic appearance than conventional multiport surgery. In this chapter, we describe a successful technique to accommodate all patients, consider the limitations for certain patient groups, and address the surgical challenges with practical tips to successfully perform single incision gastric band insertion.

Keywords

Single incision bariatric surgery • Gastric band • Triport

37.1 Introduction

Over the last 20 years, minimal access surgery has evolved and been adopted in all surgical specialities. The benefits of minimal access approach have been seen to outweigh the traditional open surgery [1]. Scarless approach was seen as a natural progression of minimal access promising further benefits. In the pursuit of scarless surgery, technical advances and surgical innovations have led to the development of single incision laparoscopic surgery (SILS) as a more practical application than Natural Orifice Transluminal Endoscopic Surgery (NOTES) has proven to be [2]. In addition to the possibility of better cosmetic scar, SILS offers less abdominal trauma, less pain and early discharge from hospital than conventional laparoscopic surgery [3]. However, SILS in bariatric surgery has been slower to take off presenting unique challenges with large abdomens, hepatomegaly and adiposity. With the first reported SILS cholecystectomy, in 1997, it was over a decade later that bariatric SILS emerged [4]. In 2008, renewed interest in SILS was seen as laparoscopic surgeons became more competent with skills and techniques, and with industry developing single incision ports and specially designed instruments. It led to a surge in bariatric SILS, especially with gastric bands, and a number of case series emerged in the literature [5–8].

One of the main challenges that SILS presents results from the multiple instruments accessing the abdominal cavity through a single incision. It results in limited external triangulation as required in laparoscopic surgery. Instead, the surgeon's instruments must work in parallel or, alternatively, create internal triangulation. Another challenge is providing internal retraction without additional ports or external puppeteering. Refined techniques and practice help overcome these problems.

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37.2 Patient Selection

Most of the patients who chose to have gastric band can be operated using SILS approach. For the majority of patients, single incision approach presents no greater risk than traditional laparoscopic gastric band insertion. However, in our experience, we have identified groups of patients who present greater surgical challenge and have higher chance of intraoperative difficulty [6]. Surgery was more challenging, as demonstrated by longer operative times, in patients with body mass index (BMI) >45 kg/m^2 and in male patients. We also found that there was a greater need for the placement of an additional port, to safely fit the band, in men than in women. Therefore patients who are female and with BMI <45 kg/m^2 prove to be the better candidates, early in learning curve. Previous laparotomy would be considered as contraindication to SILS gastric band.

37.3 Equipment

37.3.1 Ports

There are a number of ports on the market which have been specially designed for SILS including the Tri-Port (Olympus Keymed, Southend-on-Sea, United Kingdom), SILS Port (Covidien, Mansfield, Massachusetts), X-Cone (Karl Storz), or Gelpoint (Applied Medical, Santa Margerita, California). Multiple individual ports can also be used successfully through the same incision but with different fascial entries. It allows 3–4 ports to be placed in the same incision with greater degree of freedom for movement. However, each surgeon develops one's own preference. In our experience, the original Triport (Olympus Keymed, Southend-on-Sea, United Kingdom) was found to provide the greatest maneuverability and its design easily accommodated different abdominal wall depths.

37.3.2 Instruments

Seeking to recreate laparoscopic triangulation via single incision, a number of reusable and disposable curved instruments with flexible tips and streamlined handles have been developed. However, rather than recreating laparoscopic approach with SILS, developing a unique SILS technique enables the surgeons to use their already familiar long and straight instruments. Practicing the operation with instruments in parallel using 'to and fro' motion rather than side to side, and most importantly tying sutures with restricted maneuverability is essential to achieve single incision gastric band. Extra-corporeal knot tying instruments can be used; however we have not adopted this technique. When considering the instruments to be used, we would suggest using a combination of longer bariatric length and shorter instruments to avoid hand clash externally.

37.3.3 Camera/Scope

A small or streamlined camera head is preferable for the assistant which allows greater room for movement outside the abdomen and avoids clashing with other instruments. Some may prefer the vision provided by 10 mm laparoscope. However, it uses valuable single incision space and therefore 5 mm scope is advisable. Again, surgeons develop their own preference. However, we have found that a 45 degree, 5 mm scope provides the optimum view for safe band insertion when operating from a single site. Usually 30 cm long laparoscopes are used; however, for SILS, 45 or 50 cm scope can also be of value in larger abdomens.

37.4 Operative Technique

37.4.1 Positioning

Patients are best placed in supine position with reverse Trendelenburg tilt of 30 degree. With single incision approach, it is preferable that the operating surgeon stands to the right with the assistant on the left of the patient. Whilst some may find it easier with the assistant positioned behind the surgeon, it results in less room externally when working through a single incision. The scrub nurse is placed at the patient's feet and the monitor is placed above the left shoulder of the patient (See Fig. 37.1).

37.4.2 Incision

In majority of patients, 2 cm transverse skin incision positioned half-way between the xiphisternum and umbilicus, to the right of the midline, provides optimal access to most of the large abdomens and to the operative site at the correct angle. In the super obese, attention should be paid to the size of the abdomen as the umbilicus may be positioned low within an overhanging belly. It is important to keep the incision high for the success of the operation.

About 1.5 cm incision in the linea alba, opening the peritoneum, allows access to the abdominal cavity; it is confirmed by inserting the surgeon's index finger. We use an independent 5 mm trocar, preferably low profile, which is inserted to the left of the fascial opening and pneumoperitoneum is established. A single port (Triport) is then placed adjacent to the 5 mm port within the same single skin incision.

37.4.3 Preparation

The prepared gastric band is placed into the abdomen via the casing of the Triport, maintaining optimum sterility, following which pneumoperitoneum is re-established keeping the pressure high at 15 mmHg.

The original triport housed three working channels. The newer version has four entry sites. With either port we found that one additional 5 mm trocar, within the same incision, allows the optimum movement of four required instruments including laparoscope, liver retractor and two working instruments (See Fig. 37.2).

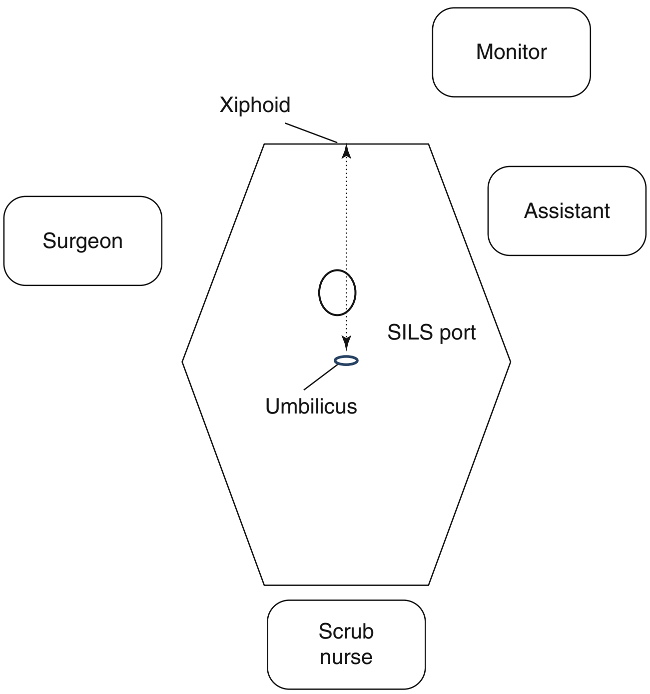

Fig. 37.1 Patient positioning and port placement

37.4.4 Liver Retraction

A number of different techniques for retracting the liver are found in the literature [8–10]. Some of those involve additional incisions or puncture sites into the abdomen, detracting from the pure SILS. We found that the flexible ('snake') retractor used though the single port ensures a truly single incision approach; it can accommodate all sizes of the liver and provides the required space for the operating surgeon to safely place the band.

37.4.5 Band Placement

The SILS gastric band is placed using the 'Pars Flaccida' technique, identical to the laparoscopic approach. Before starting, however, ensure the band is placed where you can reach it with the band tubing located below the diaphragm. A diathermy hook is used for the dissection of the angle of His. If hiatus hernia is present then it can, with practice, be repaired with crural plication using SILS approach prior to the band placement. Hook diathermy is then used to open a window into the lesser sac. The right crus is identified and a small window is opened at the base of the right crus; a straight grasper can be gently inserted behind the stomach, through that small window, reaching for the positioned band tubing and pulled through. With instruments working in parallel, the band tubing is fed through the band and then locked into place.

37.4.6 Suturing

The band is secured in position with 3–4 anterior fixation sutures (zero Ethibond). Again surgeons have their own preferences; however, we prefer a straight 5 mm Wolf needle

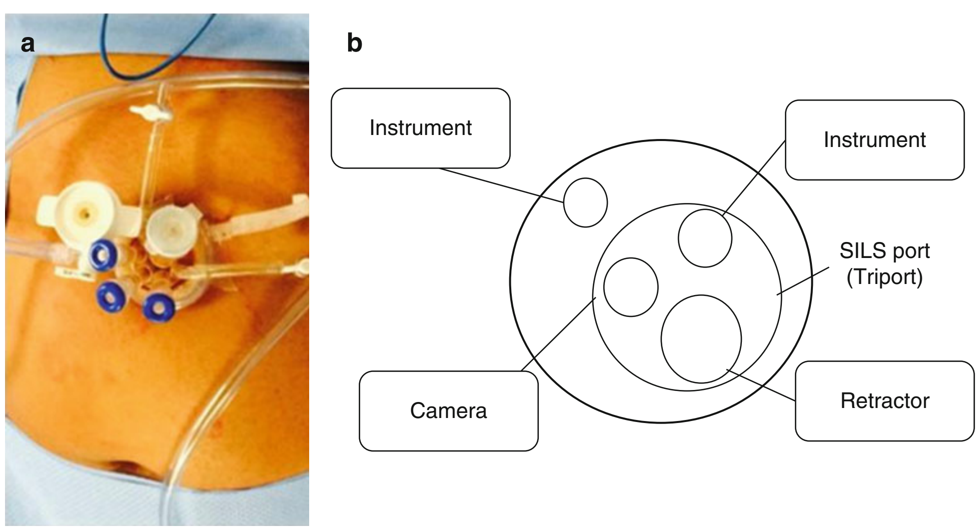

Fig. 37.2 SILS port. (**a**) Port position (**b**) schematic diagram of SILS port

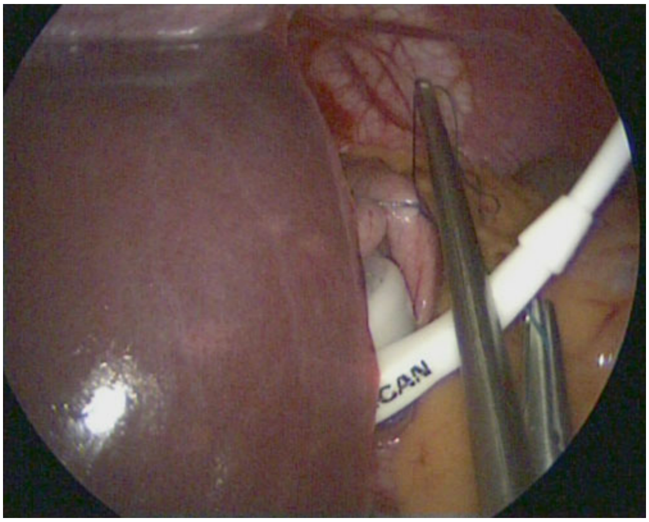

Fig. 37.3 Suturing with "to and fro" movement

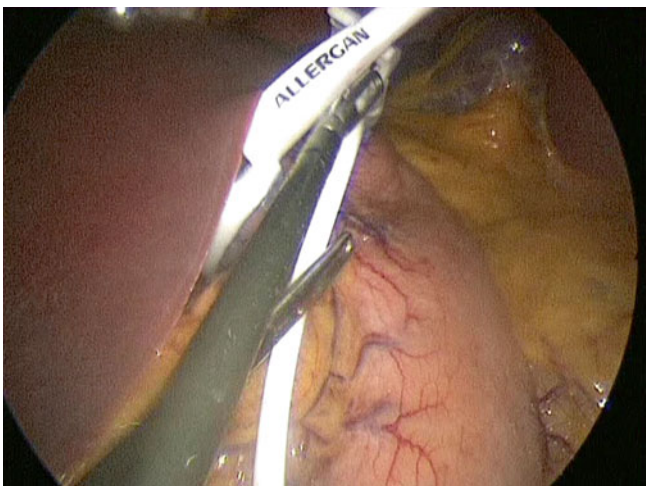

Fig. 37.4 Crossing of instruments

holder (Richard Wolf Medical Instruments Corporation, Illinois, United States of America) with sutures tied intracorporeally. Utilizing the curved tip of the needle holder, sutures are tied adopting a 'to and fro' motion, with instruments in parallel, securing each of three throws in an 'up/down' direction rather than laparoscopic 'left/right' direction. Extra long scissors are carefully used to cut the sutures (See Fig. 37.3).

37.4.7 Access Port Placement

Finally the band tubing is brought out of the single incision and the SILS port is removed. The gastric band port is attached to the tubing, as in laparoscopic band placement. Prior to securing the port to the anterior rectus sheath, the facial incision is closed using a one-loop polydioxanone suture (PDS) to minimize the risk of abdominal hernia in the future. The 2 cm skin incision is extended to 3 cm to accommodate the access port. Once secured, the subcutaneous tissue is approximated with 2/0 Vicryl and the skin is closed with subcuticular 3/0 monocryl, or preferentially 3/0 V-Loc (Covidien, Massachusetts, United States of America).

37.5 Challenges

Single incision surgery, in any operation type, presents a number of challenges that only experience can help overcome. As discussed above, becoming skilful in the art of parallel operating and manipulating your instruments safely in a confined and restricted manner is difficult. Adapting your hand-eye co-ordination to accommodate crossed or curved instruments and working comfortably without the luxury of triangulation can be achieved (See Fig. 37.4). It is beneficial to the trainee SILS surgeon to have a dedicated assistant, as you learn to work together rather than against each other when sharing one operative port. A heavy handed assistant can limit the surgeon's freedom of movement. Similarly, the surgeon understanding that the assistant cannot always 'stay still,' would result in a more harmonious operative experience. It is not always possible, for the assistant, to hold the perfect screen centered picture; however, safety must never be compromised and team work is crucial in single incision operation.

Patient's anatomy can sometimes work against you and results in difficulty in placing the band. Early within our series [5], the most common reason for the placement of an additional port is patient's anatomy such as the presence of hiatus hernia, the need for extra omental retraction, and the left hepatic artery arising from the left gastric vessel. If even after 60 min the band is not safely locked in place, then we advocate insertion of additional ports to facilitate the surgery. Our initial experience showed that any benefit gained from single incision approach was lost with prolonged operation [5].

Conclusions

The single incision approach for gastric band insertion, although challenging, can be safely performed with high success rate and low complications. Male patients and those with BMI >45 kg/m^2 do present a greater challenge. Whilst not yet widely adopted, and the benefits to the patient not yet determined, it is a surgical approach that is popular with patients and an emerging technique that the bariatric surgeons should keep in their armamentarium. Further refinement of single incision operative techniques is essential for SILS to be widely adopted.

Key Learning Points

- SILS gastric band insertion is safe and may cause less pain and better cosmetic scars compared to conventional multiport surgery.
- The procedure is more challenging in male patients and those with BMI >45 kg/m^2.
- Operating with instruments in parallel, to and fro movement during suturing and dedicated surgical assistants help to overcome the challenges of single incision surgery.

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Robotic Assisted Bariatric Surgery

38

Ranjan Sudan, Brandon V. Henry, Vivek Bindal, and Erica Podolsky

Abstract

Intuitive Surgical, Inc., United States of America obtained Food and Drug Administration approval in 2000 and introduced the da Vinci™ robot system in the United States providing an alternative platform for performing minimally invasive surgery. The system offers enhanced three-dimensional vision and wrist-like articulating instrumentation providing ergonomic and technical advantages to the surgeon. Soon after its introduction, we used the da Vinci™ system, for complex abdominal operations including bariatric procedures. Its use has now been described for adjustable gastric band, sleeve gastrectomy, Roux-en-Y gastric bypass and biliopancreatic diversion with or without duodenal switch.

Keywords

Robot • Robotic surgery • Bariatric surgery • Adjustable gastric band • Sleeve gastrectomy • Roux en y • Biliopancreatic diversion • Duodenal switch

38.1 Background

Bariatric surgery has undergone a major transformation since the first description of laparoscopic Roux-en-Y gastric bypass (RYGB) in the 1990s [1], and it is estimated that more than 100,000 procedures are now performed annually in the United States alone [2]. The major types of laparoscopic bariatric procedures currently being performed include adjustable gastric band (AGB), Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG) and biliopancreatic diversion with or without duodenal switch (BPD ± DS). A laparoscopic vertical banded gastroplasty has also been described but appears to have declined in popularity.

Conventional laparoscopy has reduced hospital length of stay, pain, and other complications such as wound infections compared to laparotomy [3], but it also has certain technical drawbacks including two dimensional visualization, loss of tactile sensation, counterintuitive movement, and instruments with restricted degrees of freedom [4].

Laparoscopic bariatric operations are technically advanced procedures often performed in the context of considerable anatomical challenges. Morbidly obese patients can have hepatomegaly and significant intraperitoneal adiposity which can obscure anatomy. The use of conventional laparoscopic instruments on patients with thick abdominal walls may require large amounts of torque. This can make precise maneuvers, such as those required for laparoscopic intracorporeal suturing, more challenging. Male gender and increasing body mass index (BMI) have also been associated with higher rates of complications such as leaks and mortality possibly due to such difficult anatomy [5]. The risk of complications increases with increasing complexity of the procedure from a laparoscopic adjustable gastric band, to a sleeve gastrectomy, followed by the RYGB and finally, the biliopancreatic diversion with

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duodenal switch (BPD/DS). The learning curve to perform Roux-en-Y gastric bypass is about 75–100 cases [6, 7]. The even more complex BPD/DS procedure carries the highest risk of complications and may have a steeper laparoscopic learning curve [8, 9]. Decreasing the learning curve and increasing the safety of the procedure is paramount in bariatric operations as these are elective procedures in a high risk population.

In July 2000, the da Vinci™ system was approved by the Food and Drug Administration for use in general surgery with the expectation that enhancements such as three-dimensional vision and instruments with a wrist-like action would reduce the learning curve for surgeons and increase safety for patients. Soon after its introduction, the robotic system was used for advanced procedures. The first da Vinci™ bowel resection in the world was performed in a patient with Crohn's disease in August, 2000 followed by the first BPD/DS in October, 2000 [4]. Since then, the adjustable gastric band, the Roux-en-Y gastric bypass and the sleeve gastrectomy have all been performed robotically. The purpose of this chapter is to present key technical points in performing the various bariatric operations and review their outcomes.

38.2 Setting Up the Operating Room for Robotic Bariatric Surgeries

Although there are technical differences in how each of the bariatric operations are performed, we set up the operating room similarly for all robotic bariatric operations (Fig. 38.1). This setup can be adapted based on the space considerations of other operating rooms.

The anesthesia cart is to the patient's left side. The instrument table is set up on the patient's right side. The video monitor and robot tower is also positioned on the right and more towards the head of the patient. The surgeon's console is positioned on the right side of the patient in the farthest corner of the room allowing for direct communication with the scrub assistant. This also keeps the operating table within easy viewing distance of the console surgeon. The robot is docked over the patient's head ensuring that the robot arms have adequate clearance from the operating room table or the patient. Slight variation in the orientation of the robot may be required depending on the specific bariatric operation by bringing it over the patient's right or left shoulder or over

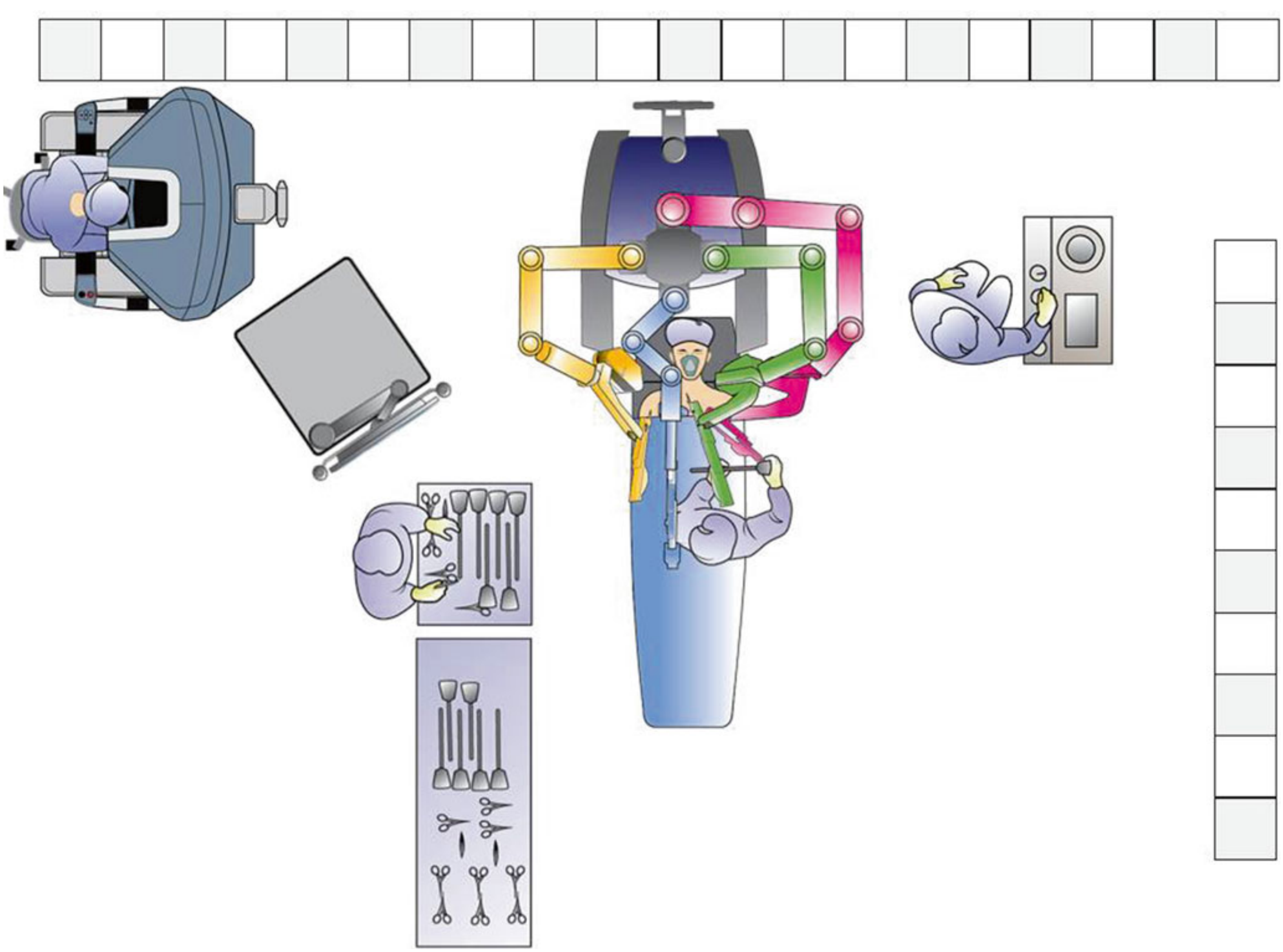

Fig. 38.1 Operating room configuration

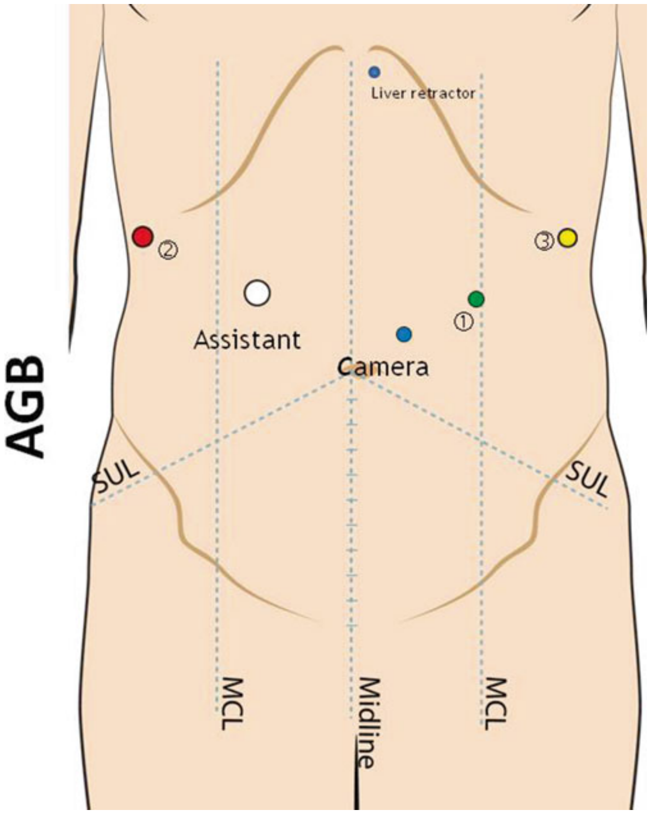

Fig. 38.2 AGB Trocar arrangement

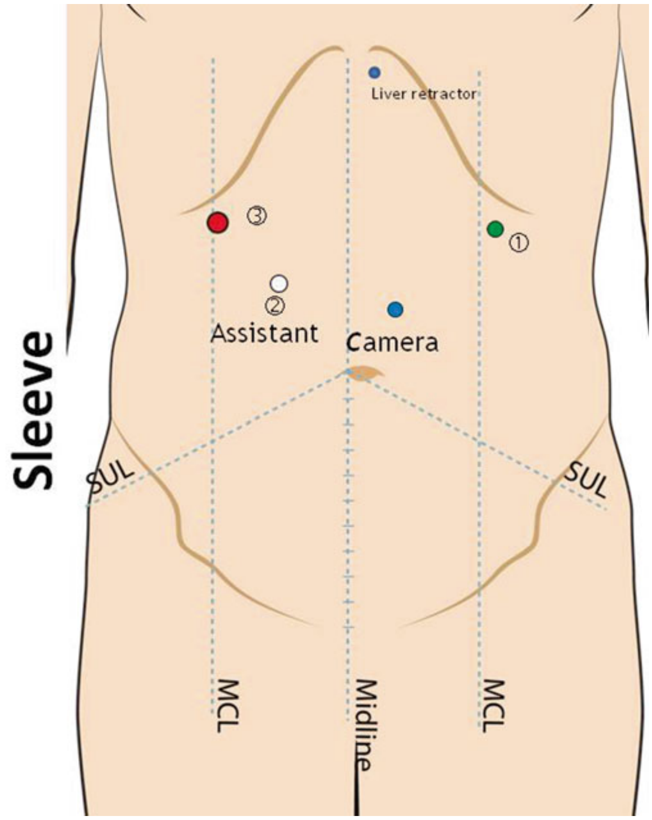

Fig. 38.3 Sleeve Gastrectomy trocar arrangement

the head. Each of the robot-assisted bariatric operations will next be discussed individually.

38.3 Adjustable Gastric Banding (AGB)

As early as 2003, three surgeons were using the da Vinci™ to perform adjustable gastric band procedures [10]. The AGB is encircled around the proximal stomach to create a 30 mL pouch. The outlet of this pouch is adjusted by injecting saline in a subcutaneous port. The robot is docked at the head of the patient, usually slightly over the left shoulder. The trocars are arranged to allow for instruments to reach the hiatus (Fig. 38.2). A 15 mm assistant port is placed in the right midclavicular line above the umbilicus to allow for the passage of the band device. The camera port is slightly on the left of the midline and is about 15 cm inferior to the xiphoid. Two additional robot trocars are placed in the each subcostal area for instruments. The pars flaccida is incised with hook cautery along the right crus of the diaphragm to allow for dissection posterior to the fundus of the stomach. The band is then passed through this path posterior to the stomach and buckled to itself. The band is secured in place by imbricating the stomach over the band anteriorly to prevent slippage. The robot is then undocked and the subcutaneous port is secured to the anterior abdominal fascia at the 15 mm port site.

Early in the use of the robot for banding, Muhlman et al. [11] evaluated their initial experience with 20 patients and compared outcomes in patients who had undergone adjustable gastric band placement either laparoscopically or with robot assistance. They found that the duration of the operation was significantly longer and cost higher in the robotic group. A more recent study by Edelson et al. [12] compared their robotic AGB cases (N = 287) with conventional laparoscopy (N = 120) and found that although the overall duration of operation was similar between the two groups, there was a distinct advantage in favor of the robot for patients with a preoperative BMI ≥50 kg/m^2.

38.4 Sleeve Gastrectomy (SG)

Sleeve gastrectomy has been gaining in popularity every year since its introduction and has become one of the most common bariatric procedures. The setup for performing a robotic sleeve gastrectomy is similar to that of the adjustable gastric band. The assistant port (12 mm) for the sleeve gastrectomy is in the same position as the 15 mm port for the AGB and is used to pass a laparoscopic stapler when performing the sleeve gastrectomy (Fig. 38.3). A robotic trocar may be placed within this 12 mm trocar in a “port-in-port” configuration making it possible to alternate between the robot arm and conventional laparoscopic instruments by the bedside assistant. The robot is used to retract the stomach and the ligaments of the greater curvature of the stomach. The short gastric vessels are then divided using a robotic energy device (Harmonic scalpel®, Ethicon, Cincinnati, USA). This technique uses four arms of the robot, giving the operator enhanced control of the operation and reduces reliance on the bedside assistant. Alternately, three robotic arms can be used and, the bedside assistant can either retract or use the energy source for coagulating and dividing the short gastric vessels. After complete mobilization of the stomach, a 34 French Bougie is placed within the stomach lumen for sizing the stomach tube and then the bedside assistant uses conventional laparoscopic staplers to divide the stomach. Typically long leg length staplers (Covidien® purple or black loads) are used more distally where the stomach is thick, transitioning to medium leg length staplers (Covidien® tan or purple with reinforcement) proximally where the stomach is less thick. Staple line reinforcement using either buttress material or robotic suturing can be performed at the discretion of the surgeon. The stomach is removed from the midline port site. A suture is attached to one end of the stomach and is used as a handle to pull the stomach out of the peritoneal cavity The sleeve gastrectomy can be performed as part of the BPD/DS or as a standalone bariatric operation.

The first robotic sleeve gastrectomy, as part of the BPD/DS, was performed in 2000 [4], but the first series of standalone robotic sleeve gastrectomies was reported in 2011 [13]. The duration of the operation in the robotic group (N = 30) was 135 min, and was longer by a mean of 21 min, than the laparoscopic sleeve gastrectomy procedures (N = 39) [13]. In the robotic group, the staple line was oversewn and likely contributed to the increase in operative duration. In another study by Diamantis et al. [14], 19 patients underwent a primary sleeve operation with a mean operating time of 95 min and no complications.

The robot is particularly useful when performing complex dissection such as complex adhesiolysis because of three-dimensional vision and tremor-free precise movements. These features are highlighted in a report of a sleeve gastrectomy after liver transplantation [15] and in another patient with achalasia who underwent a sleeve gastrectomy with a simultaneous Heller myotomy [16].

One of the serious complications of a sleeve gastrectomy is stricture formation. Robotic strictureplasty has been utilized to widen the lumen of the gastric tube in patients with strictures. In the robot-assisted strictureplasty, an incision is made along the long axis of the stomach and sutured along the transverse axis in a single layer [17]. Conversion to RYGB has also been described, but a strictureplasty maintains the intent of the original sleeve operation.

38.5 Roux-en-Y Gastric Bypass (RYGB)

The Roux-en-Y gastric bypass is the most frequently performed bariatric operation. In the RYGB, a small stomach pouch measuring 15–30 mL is created using a medium leg length (Covidien® tan loads or equivalent) laparoscopic stapler and a jejuno-jejunostomy is performed to create a Roux limb of 75–150 cm. Alimentary tract continuity is restored by performing a gastrojejunostomy using a variety of different techniques such as using the circular stapler, linear stapler or hand-sewn technique. In the robot-assisted operation the trocars are positioned to permit access both to the oesophageal hiatus in the diaphragm and the mid-abdomen (Fig. 38.4). Although the robotic operation can be performed in an identical fashion to the laparoscopic version, we first create a small stomach pouch and then perform a robot-assisted hand-sewn omega loop gastrojejunostomy using two layers of absorbable 3–0 barbed sutures. The jejunum is then divided with a medium leg-length (tan load) stapler to separate the biliary limb from the gastrojejunostomy. This is followed by the creation of a side to side 60 mm medium leg-length stapled or sutured jejunojejunostomy. This allows all of the robotic procedure to be performed in a single quadrant (See Video 38.1). The extent to which the robot is used

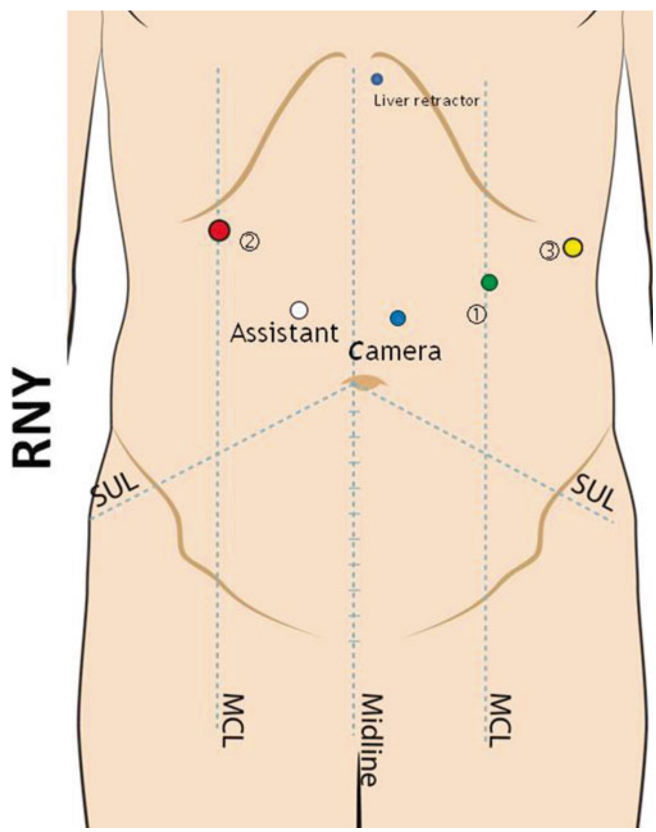

Fig. 38.4 RNY trocar arrangement

in performing a RYGB varies from closing enterotomies for stapled anastomosis to performing all of the anastomoses robotically thereby minimizing the number of staple loads that are used for the operation.

The robotic RYGB procedures have been performed in both academic and community settings with a mean operative time of 155 min with no mortality or conversions and a low leak rate (0.09 %) [18–20]. Others have found no difference in operative time, anastomotic leak, or length of hospital stay, and a significantly reduced stricture rate in the robotic group compared to conventional laparoscopy [21].

A study by Buchs et al. has also shown that the learning curve for novices may be shorter for performing a Roux-en-Y gastric bypass with the robot and may be as few as 14 cases [22]. In another study Sanchez et al. [23] have demonstrated that novice laparoscopic fellows randomized to laparoscopic or totally robotic Roux-en-Y gastric bypass, had a significantly shorter mean operating time for robotic group, and the difference was more marked with increasing BMI of the patient [23].

38.6 Biliopancreatic Diversion with Duodenal Switch (BPD/DS)

The biliopancreatic diversion with duodenal switch is technically the most advanced bariatric procedure requiring skilful dissection and intracorporeal suturing. It consists of a sleeve gastrectomy and a distal bypass. The first robotic BPD/DS was performed in October, 2000 soon after the introduction of the da Vinci™ system [4].

The robot is docked over the patient's right shoulder. Two 12 mm laparoscopic ports are needed to accommodate laparoscopic staplers (Fig. 38.5). The assistant port on the right side of the abdomen is also used for robotic instruments using a port-in-port configuration. Caution must be exercised with the port-in-port configuration as thermal injury can occur by creation of a dielectric. We do not use this configuration for electrical energy. The robotic port is withdrawn when needed to allow the assistant to use conventional laparoscopic instruments and staplers. A sleeve shaped stomach is created and the duodenum is transected about 4 cm distal to the pylorus. A two layer robot-assisted hand-sewn duodeno-ileostomy is then created followed by a distal ileo-ileostomy. We also perform a cholecystectomy as part of the procedure (See Video 38.2).

The results of the first 47 robotic BPD/DS patients demonstrated no mortality, but the duration of the operation, which included an appendectomy and a cholecystectomy, was long [4]. The learning curve of the more complex robotic BPD/DS is about 50 cases for complications to stabilize [24] and is influenced by difficult anatomy such as increased

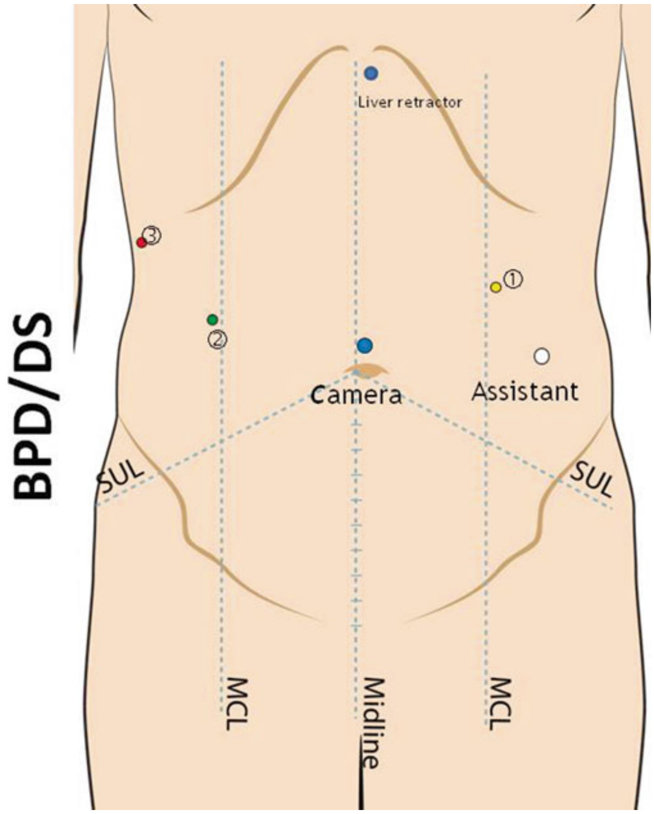

Fig. 38.5 BPD/DS trocar arrangement

abdominal wall torque, hepatomegaly and significant intraperitoneal adiposity. Lysis of adhesions increased the duration of the operation, but did not increase the complication rate. Male gender and increasing BMI was not associated with complications suggesting that the robot may have an advantage with more difficult operations. In the last 13 years we have not had any 30-day or 1-year mortality and the operative times have decreased to about 3 h for an uncomplicated operation. The robot has also been employed for revisional operations such as conversion of a laparoscopic adjustable gastric band or a vertical banded gastroplasty to a BPD/DS [25, 26]. A BPD/DS in the presence of malrotation of bowel has also been described [27], as has the expanded use of the robot on weekends and for emergencies to deal with postoperative complications of the BPD/DS [28].

Conclusion

Since the introduction of the da Vinci ™ robotic system in 2000, its use has gained popularity and the robot has been used to perform all major bariatric operations. Although the capital expenditure to purchase a robot and the investment of time in learning a new technology may make the initial deployment of the system challenging, its use can enhance a surgeon's ability to perform technically advanced procedures. The ergonomics of the robot including three-dimensional view, wrist-like instrumentation, availability of a third operative arm, and surgeon comfort offer advantages unlike any other available laparoscopic technology. Clear advantages in terms of outcomes have yet to be proven when compared to laparoscopy, but the feasibility of performing all bariatric operations including revisions with robotic assistance has been demonstrated.

Key Learning Points

- Initial attention to the room setup is crucial. Once the robot is docked, patient position cannot be altered without undocking.
- Trocar placement varies for each individual bariatric procedure.
- The accessory trocar for the bedside assistant must be strategically located to allow the assistant to function without impediment from the robot arms. The trocar size depends on the material that will need to pass through it. An extra-long 12 mm port is used for the robot camera.
- The robot may offer enhanced ergonomics for the surgeon especially when performing bariatric surgery. In some patients, the abdominal wall may add significant torque on the laparoscopic instruments limiting freedom of movements and increasing operator fatigue. The robotic arms negate the effects of such abdominal torque to a large extent offering an advantage in the super obese.
- When performing procedures that require intracorporeal suturing or complex dissection, the robot offers an advantage over two-dimensional laparoscopy.

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Section VIII

Revisional Bariatric Surgery

Honorary Section Editor - Andrew C.T. Wan

Unlike conditions that have one definitive surgical operation, bariatric patients have a variety of procedures available to them. The techniques involved in such procedures also differ considerably from center to center and surgeon to surgeon. Ill-defined criteria for procedure selection, lack of standardization of the procedure and the inherent learning curve of the surgeons invariably culminate in a cohort of patients with unsatisfactory weight loss, and to a lesser extent, metabolic recidivism and chronic complications that would require rectification. All the chapters in this section emphasized the importance of careful reevaluation of these patients, with investigations targeted at the respective procedure and involvement of the multi-disciplinary team before revisional surgery is considered.

Suter gave a comprehensive account in Chap. 39 on how to manage individuals who had the historical procedure of Vertical Banded Gastroplasty (VBG), presenting with weight issues or complications. He detailed the options available including reversal or conversion, paying particular attention to the technical aspects on how to avoid pitfalls during revision of the already stapled stomach. Although Laparoscopic Adjustable Gastric Band (LAGB) became one of the most popular bariatric procedures in the past decade, failure with the device is not uncommon. In Chap. 42, Angrisani et al. described how to manage nonemergent complications, whether to stage the conversion and detailed rationale behind the choice of procedures for conversion of the LAGB in failures. For many, Laparoscopic Roux-en-Y Gastric bypass (LRYGB) is the gold standard bariatric operation with a proven track record with weight loss and its metabolic effects. However, like many 'bypasses', there are drawbacks associated with the LRYGB construct. Higa outlined in Chap. 40 how to tailor the revisional procedure to the needs of the individual and punctuated the importance of surgeons using a variety of arsenal to resolve anatomical and metabolic flaws, and address weight issues. As Laparoscopic Sleeve Gastrectomy (LSG) gathers momentum in becoming one of the favorite bariatric procedures, more complications are emerging as results on longer term outcomes become available. The pendulum may have swung to using LSG as a primary solution for the morbidly obese and the super-obese, its historic companion, the Duodenal Switch (DS) is always lurking in the background awaiting the failed sleeve for conversion. In Chap. 41, Himpens and Wan gave a balanced overview on the options available for weight regain following LSG and dealing with 'reflux disease', with also interesting proposals to tackling strictures in sleeved stomachs.

"Who would have thought it?" A statement made on the effect of bariatric surgery on diabetes may seem premature at the time, but as bariatric surgery continues to thrive, its momentum is unlikely to be hindered. As other bariatric operations are also being performed more frequently, complications and failures with these are also inevitable. Further thoughts need be put in place on the criteria for revisional surgery, balancing improvement in quality of life against achieving satisfactory weight loss, otherwise in the forthcoming decade, the question that needs to be answered would be none other than, "When do we stop?"

Revisional Surgery after Vertical Banded Gastroplasty

39

Michel Suter

Abstract

With the abandonment of jejuno-ileal bypass and despite the development of gastric bypass, several surgical groups preferred less aggressive options such as vertical banded gastroplasty (VBG), for the treatment of morbid obesity, in order to reduce early morbidity and avoid bypassing any segment of the digestive tract. Long-term complications requiring redo surgery are common after the VBG.

Patients who develop long-term complications after VBG need to be fully evaluated by a multidisciplinary team before anything is undertaken. This includes the precise anatomy of the former procedure, which can be assessed by endoscopy and upper gastrointestinal (GI) series. Patients should be prepared if any reoperation is necessary, especially if they have regained weight, in order to optimize the results of the redo procedure.

Reoperation can consist of reversal, restoration of the normal VBG anatomy, or conversion to another bariatric procedure. While reversal inevitably leads to weight regain, restoration is associated with many further complications. Therefore, conversion to another procedure is the best option in most cases and conversion to Roux-en-Y gastric bypass (RYGBP) is the most popular.

The indications for and the technical aspects of RYGBP, after VBG, are discussed in detail in the chapter. A prefect understanding of the anatomy is essential before any division of the stomach is done. Pitfalls are described and published results are discussed. In most cases, conversion to RYGBP can be performed by laparoscopy, by a well trained and experienced bariatric surgeon.

Keywords

Vertical banded gastroplasty • Reoperation • Roux-en-Y gastric bypass • Complication • Failure • Surgical technique • Revisional surgery

39.1 Introduction

The jejuno-ileal bypass was abandoned because of its association with high rate of long term, severe, and occasionally devastating complications. Later, despite the development of gastric bypass, which rapidly proved to be both safe and effective for weight loss, several surgical groups opted for more conservative approaches involving various forms of gastroplasties. This is to provide alimentary restriction and weight loss, but avoiding bypassing any portion of the alimentary tract and its possible malabsorptive

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consequences. While horizontal gastroplasty was shown to result in rapid weight regain after the first 1 or 2 years, vertical banded gastroplasty (VBG) proved to be more durable in its effects, especially regarding longer-lasting weight loss and maintenance. VBG has been used extensively around the world, and was the most popular procedure in Europe for almost 15 years (1980–1995), until it was largely replaced by laparoscopic adjustable gastric banding. In the Swedish Obese Subjects (SOS) study, more than two thirds of the patients included in the surgical group were submitted to VBG [1].

Unfortunately, long-term complications are common after VBG. Too narrow a band or fibrotic stricture at the outlet of the gastric pouch, often induced by the band, results in progressive food intolerance, repeated regurgitation and vomiting. Even if the outlet of the gastric pouch is large enough to allow passage of a regular endoscope, VBG frequently results in too much functional restriction, important limitations in food selection or gastroesophageal reflux with its complications. It often prompts the patients to switch diet and prefer liquid or semi-liquid food. It obviates vomiting, but usually results in higher caloric intake, and eventually weight regain, a common phenomenon after purely restrictive bariatric procedures. Staple line disruption is another anatomical long-term complication, after undivided VBG, which has been reported in up to 48 % of cases [2]. Progressive dilatation of the gastric pouch is not uncommon, especially in patients with too long a gastric pouch or in whom the vertical staple line has been placed at a distance from the angle of His. Both of these anatomical variants could result in a loss of restriction, greater food intake before satiety and eventually weight regain.

Long-term results after VBG show that, overall, more than 50 % of the patients eventually require some form of revisional surgery [2–4] because of complications and/or weight regain. The aim of any reoperative procedure in bariatric surgery is to deal with the complication of the index procedure and its associated symptoms, provide further weight loss and/or prevent weight regain.

39.2 Preoperative Patient Evaluation

Before any consideration is given to reoperate on a bariatric patient, a complete and detailed evaluation of both the patient and the former procedure must be done. The multidisciplinary team, here, is even more important than before the first procedure. Patients with failed VBG were often operated on, several years ago, when preoperative patient education was almost non-existent and follow-up was often of poor quality. While failure can be linked exclusively to a technical defect, weight regain very often results, at least in part, from poor eating habits, poor choices of food (liquid and solid) and insufficient exercising. Eating behavior, type of diet and eating capacities must therefore be assessed in detail by a dietician as well as a psychologist. Symptoms like regurgitation, vomiting, heartburn, cough, or symptoms of laryngeal irritation may suggest stenosis at the outlet of the gastric pouch and/or pouch dilatation. Increase in meal size or loss of restriction are typical of vertical staple line disruption. Reliable anthropometric data from the patient before the initial operation must be obtained as well as data about how the patient did after it. Not only initial weight and lowest weight attained after VBG are important but also details about food tolerance over the years, nature and timing of the development of complication associated symptoms, type of diet used, eating behavior and history of weight regain are important. The latter is common to all bariatric procedures and results not only from complications of a former operation, but also and mostly from recurrent poor eating habits and/or inappropriate choices of food.

The anatomy of the VBG must be assessed in detail in order to plan and facilitate the redo procedure. It would be useful to ascertain the type of VBG previously performed, be it the standard Mason or a divided Mc-Lean type (See Fig. 39.1). Preoperative endoscopy as well as preoperative contrast study is mandatory. They are essential to localize the hiatus and the gastro-esophageal junction. They also help to delineate the length and width of the gastric pouch, the position of the band and that of the vertical staple line, as well as the integrity of the latter. All the information gathered would be invaluable in helping to identify the essential anatomical landmarks needed at the time of revisional surgery. These studies also serve to rule out any other abnormality of the upper digestive tract that may interfere with the redo procedure or its expected results. Functional tests such as manometry and pH studies may help to objectively assess esophageal motility and reflux, and can therefore play a role in the choice of the redo procedure. *Helicobacter pylori* infection must be screened for and eradicated if present.

39.3 Preoperative Patient Preparation

In order to limit the risks of repeated failure, all patients should be reminded about the changes they need to make after reoperation. It not only includes information about frequency and sizes of meals, choice of food and what a balanced diet represents, but also stresses the importance of regular exercising. Patients whose eating habits are clearly inadequate must receive additional dietary education before redo surgery. Grazers and snackers should benefit from psychological counseling and be submitted to cognitive-behavioral therapy. Patients with a tight stricture may have difficulties to adjust their diet before reoperation but the more information they receive before it, the more likely they are to make the necessary adjustments afterwards.

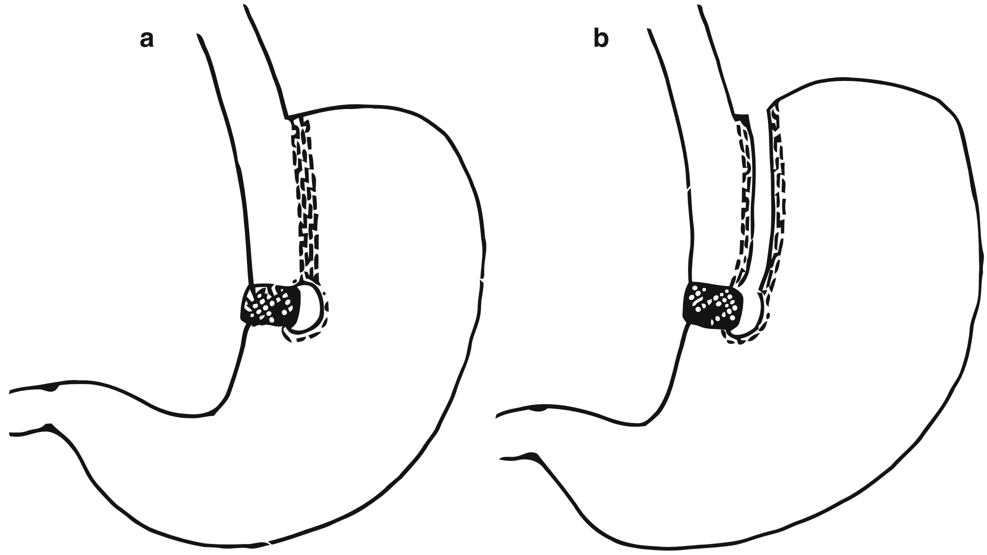

Fig. 39.1 Mason-type standard VBG (**a**), and divided Mc-Lean-type VBG (**b**)

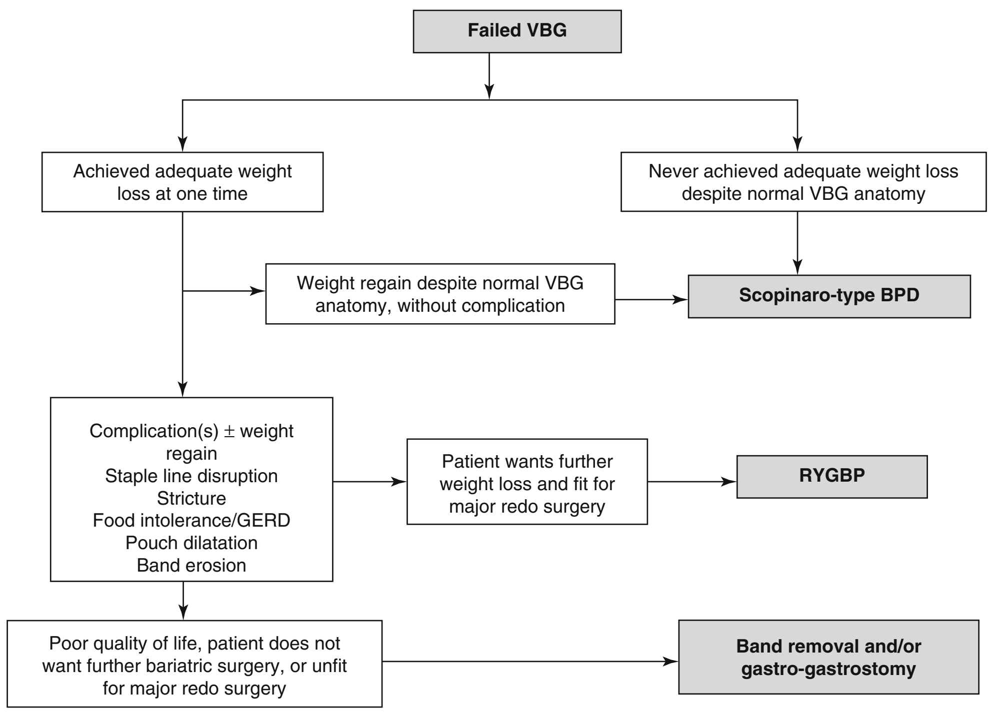

Fig. 39.2 Algorithm for reoperation after failed VBG

Preparation can often be done during the phase of evaluation. In many cases, the need for reoperation can be foreseen early and delaying it too long is unfair to the patient.

39.4 Choice of Procedure

The choice of procedure must be made carefully, only after complete evaluation by the multidisciplinary team. It depends on the initial and current Body Mass Index (BMI), the weight loss history after the first procedure, the type of complication from the latter and the patient's capacity to increase his/her physical activity. As a general rule, if VBG as a restrictive procedure never provided acceptable weight loss, then a malabsorptive procedure should be considered. This is especially true for patients in whom the indication for redo surgery is insufficient weight loss or weight regain alone. On the contrary, if adequate weight loss had been achieved and maintained for a period of time, after VBG, a primarily restrictive procedure may again be elected. In any case, existing VBG related complications must be addressed and the associated symptoms must be permanently relieved. Options for reoperation include restoration of the normal anatomy of VBG, reversal or conversion to another bariatric procedure. Figure 39.2 provides an algorithm for reoperations after failed VBG.

39.4.1 Restoration of the VBG Anatomy

Because some of the common complications arising after VBG such as stenosis or staple line disruption are of purely anatomical nature, it is tempting to consider re-establishing the normal anatomy of the VBG as a viable option. Replacing the band by a larger one, sometimes in association with intra-operative dilatation of the outlet of the gastric pouch, may improve food tolerance sufficiently. For staple line disruption, simple vertical re-stapling is an option. But completely dividing between the pouch and distal stomach as suggested by McLean is intuitively more attractive as it avoids recurrence. The literature unfortunately does not provide a lot of data about the results of the redo procedures. With an open approach, complications rates were in the range of 30 % and weight loss was not always satisfactory [4, 5]. Furthermore, morbidity was not different from that associated with conversion to Roux-en-Y gastric bypass (RYGBP) and more patients required further redo surgery [4, 5]. As a result, restoration of the VBG anatomy should not be offered anymore.

39.4.2 Reversal

There are two indications for simple reversal after VBG. The first is the presence of an anatomical or functional stenosis at the outlet of the gastric pouch, usually associated with fibrosis around the band and complicated by severe food intolerance and/or intractable GERD, in a patient who does not accept another bariatric procedure. The second is the same complication in a patient who is unfit to undergo major redo surgery. Quality of life improvement is the main driver to reoperate in those patients. They must, however, be clearly informed about the high risk of weight regain, even if the initial procedure has been performed years before and weight has been maintained for a prolonged time.

For reversal, removable bands such as silastic rings or silicone bands should be removed. A Marlex mesh is usually imbricated in the gastric wall and therefore should not be removed. In cases with mesh or removable ring and with severe fibrotic stenosis at the outlet of the gastric pouch, gastro-gastrostomy, consisting of a large anterior anastomosis between the gastric pouch and the anterior part of the fundus, should be done.

39.4.3 Conversion to Another Bariatric Procedure

Theoretically, one could convert VBG to any other bariatric procedure. However, placing an adjustable gastric band in the correct position is not easy and is unlikely to provide adequate weight loss, if the primary restrictive procedure failed to do so. Furthermore, it exposes the patients to possible further band related complications. In my opinion, sleeve gastrectomy after VBG carries significant risks for leaks in the upper portion of the staple line and should not be done. Although there are anecdotal reports on both the options, the most common procedure is conversion to RYGBP.

For patients who never achieved sufficient weight loss after a functioning VBG and for those who regained a large amount of weight without any anatomical complication, conversion to malabsorptive procedure, such as Scopinaro-type bilio-pancreatic diversion, should also be considered [6, 7]. Indeed, a second restrictive procedure is unlikely to provide sufficient weight loss if the first one failed. Additionally, this option obviates dissection in the upper portion of the stomach and allows for stapling in healthy unscarred tissue [7]. As there is a lack of long-term results with that option in the literature, both regarding morbidity and results, the choice should be made individually only after careful evaluation and full patient information about the possible advantages and risks of malabsorption.

Conversion to RYGBP has been shown, by different authors, to carry no additional operative risk than restoration of VBG. Furthermore, it results in better weight loss and maintenance, alleviates symptoms related to VBG complications and is associated with fewer late complications requiring further redo surgery [4, 5, 8–11]. When food intolerance and reflux are predominant symptoms, conversion to RYGBP has been shown to very efficiently alleviate those problems [12]. Conversion to RYGBP in the era of open surgery was associated with high morbidity in the range of 30–50 % [4, 5, 8–11]. Despite the fact that the procedure remains a difficult one, using laparoscopic approach has reduced overall morbidity, especially the major complication rate [13–18]. It is likely due to the magnification provided by the laparoscope which allows more precise and safer dissection.

39.4.3.1 Technical Aspects of Conversion from VBG to RYGBP

Even if an open access has been used at the time of VBG, the current approach of choice for conversion is laparoscopy. Antibiotic and thrombo-embolic prophylaxes are routinely used. Access to the abdominal cavity must be obtained away from potential adhesions or from a solid organ. Using the Verres needle in the left upper quadrant just below the costal margin is successful in most cases and very safe; but alternative sites may be used. The first trocar is then placed away from previous incisions. Alternatively, an open Hassan technique can be used or the first trocar can be placed under direct optical view. The second trocar is placed under vision usually on the left side of the abdomen. It is used to free adhesions between the abdominal content and the anterior abdominal wall, using scissors or some energy source, taking care to avoid intestinal injuries. Three or four additional

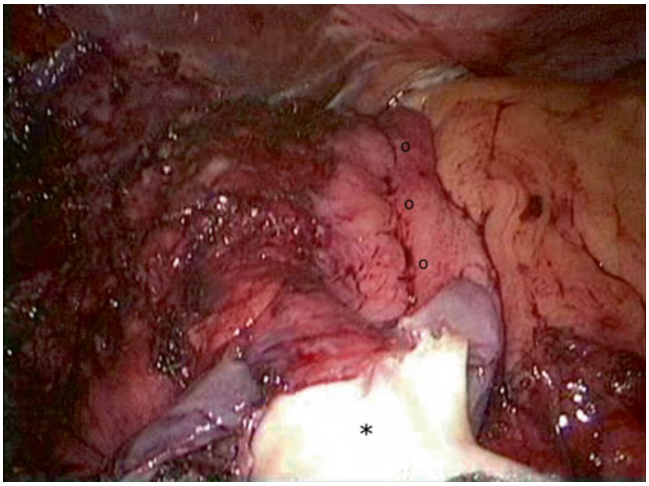

Fig. 39.3 Intraoperative view with former staple line on the anterior aspect of the stomach. * location of the former band with fibrosis. *o* former staple line

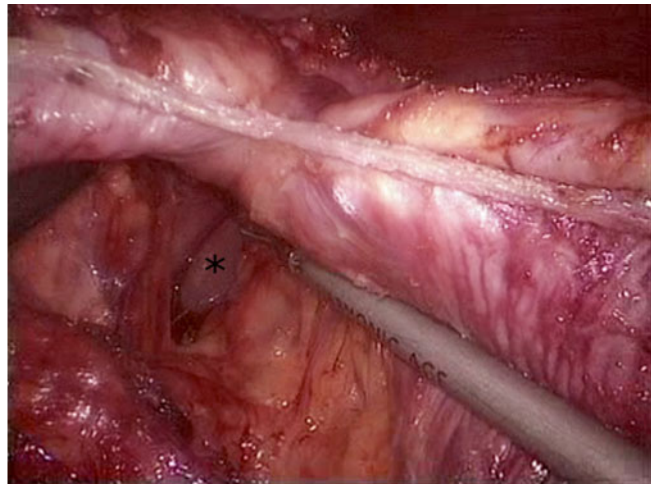

Fig. 39.4 Intraoperative view after horizontal division of the stomach 3–4 cm below the cardia and posterior dissection up to the angle of His. * spleen seen through window at the angle of His

trocars can then be placed and lysis of adhesions is pursued between the left lobe of the liver, the anterior aspect of the stomach and the lesser omentum. Both the right and left crura of the diaphragm must be identified and the angle of His must be freed from the diaphragm. The band is usually visualized during the dissection (See Fig. 39.3). It is removed unless consisting of a Marlex mesh which is imbricated in the gastric wall and best left untouched. The lesser sac is then accessed by dissecting between the lesser curve and the lesser omentum, usually above the band; although sometimes starting below is easier, especially if the pouch is relatively short. Dissection along the lesser curvature is pursued proximally and the posterior wall of the stomach is dissected free from the pancreas. If the patient has had a regular Mason-type VBG, the next step is to identify the former vertical staple line both anteriorly and posteriorly (See Fig. 39.3). At this time, division of the stomach to form the new gastric pouch can start. It is initiated by transecting the stomach horizontally with 45 mm long linear stapler. Care is taken to remain away from the previous vertical staple line in order to allow drainage of the secretions, from the remaining portion of the former gastric pouch into the stomach remnant. Dissection between the posterior aspect of the stomach and the left crus is best completed after the first division because vision is improved. After exposure of the left crus and the spleen (See Fig. 39.4), transection of the stomach can then be completed with the linear stapler, always taking care to remain away from the previous staple line so that no blind pouch is created (See Fig. 39.5). As tissues are usually thicker and more fragile in redo cases than in primary cases, taller staple height should be used than for primary RYGBP, especially for the vertical portion of the staple line. Although there is no evidence in the literature about its real effects, we now routinely use absorbable reinforcement material such as Seamgard® for the vertical part of the division. If despite all efforts, the new staple line lies in too close vicinity of the former one, or even crosses it, re-stapling closer to the lesser curve is necessary on the side of the gastric pouch. On the remnant side, the upper portion of the fundus must be resected if there is any doubt about possible blind pouch or proper drainage into the remnant (See Figs. 39.6 and 39.7). If the patient has had divided McLean-type VBG and the VBG pouch is not dilated, the RYGBP pouch can be created by simply dividing the former gastric pouch above the band. If the VBG pouch is dilated, it must be completely resized as described above. It devascularizes the upper portion of the former pouch which needs to be resected.

If dissection or division of the upper stomach is impossible due to too much scarring or fibrosis, and instead of dividing the stomach too low, with the risk of forming too large a gastric pouch, the esophagus can be prepared and transected just above the gastro-esophageal junction. We have shown that it does not affect the results [17]. Once the gastric pouch has been created, the RYGBP is completed as usual and according to the surgeon's preference, 100–150 cm Roux limb is created. Methylene blue or air test can be performed to check for leaks at the gastrojejunostomy, although we do not use it routinely. All mesenteric defects must be closed with running non-absorbable sutures.

Patients with previous laparotomy are likely to have one or more midline incisional hernia. After the lysis of adhesions, there is risk of postoperative incarceration into the hernia, especially if the Roux limb is brought up antecolic; this is because, in this case, the Roux limb is in direct contact with the abdominal wall whereas with the retrocolic technique, the omentum remains between the small bowel and the abdominal wall. Although some suggest immediate laparoscopic repair with non-absorbable mesh, we prefer to

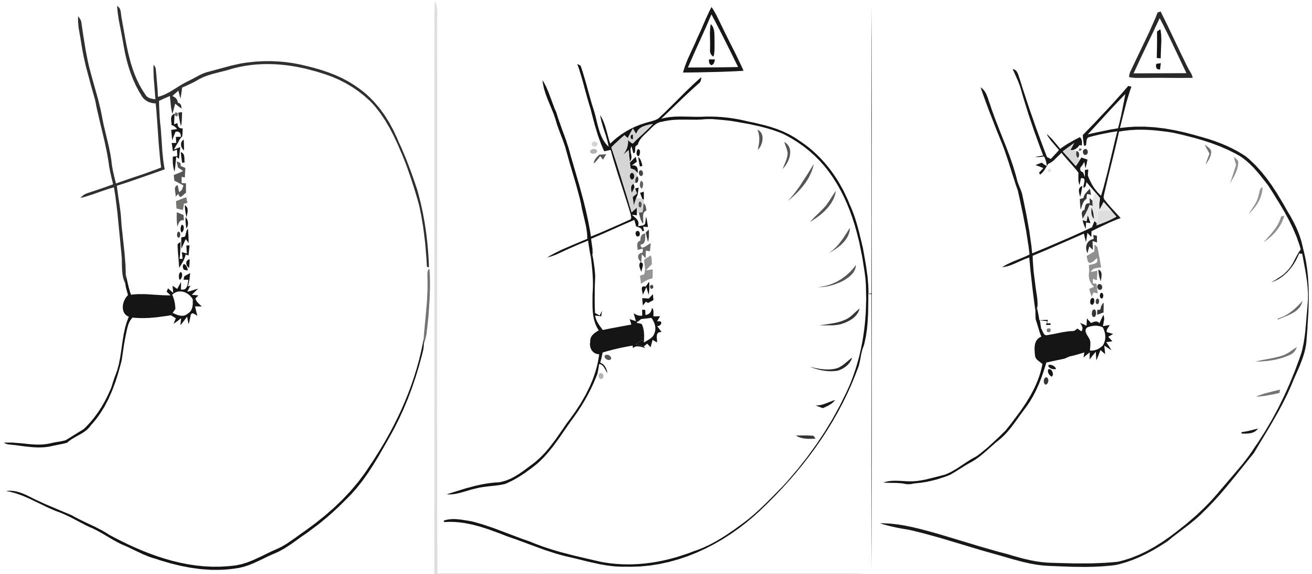

Fig. 39.5 Ideal placement of staple lines and places at risk from which a minimal distance must be preserved in order to avoid constructing a blind pouch (Reprinted with permission from Suter et al. [17]/Springer Verlag)

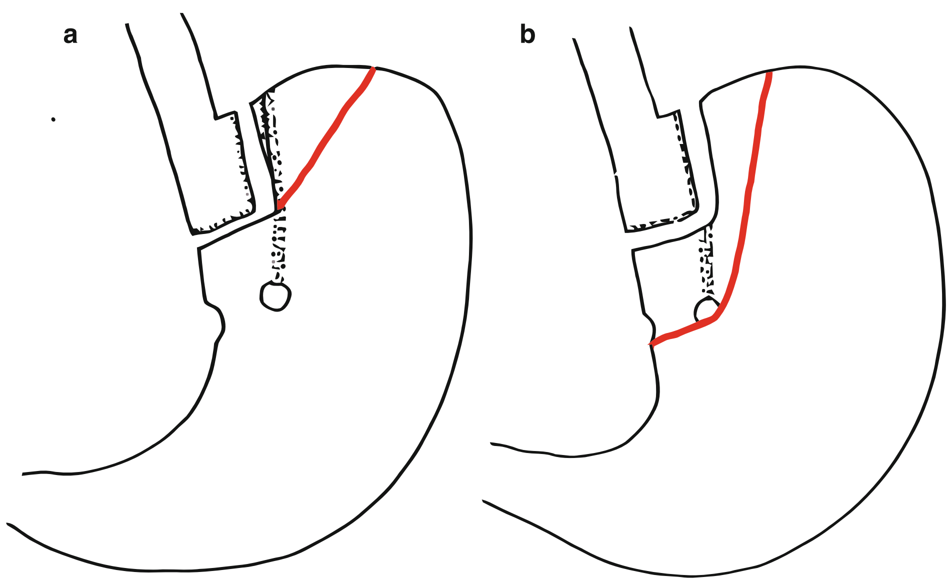

Fig. 39.6 Other options for the construction of the gastric pouch when the vertical staple line is not readily identifiable, or if the new staple lines interfere with the former ones, with partial resection of the fundus (see Fig. 39.3). (**a**) Resection of the upper portion of the staple line with part of the fundus, (**b**) resection of the entire former staple line with part of the fundus

refrain from it due to the risk of mesh infection, and perform a secondary repair. Small defects, however, should be suture closed while larger defects can be left wide open as the risk of incarceration is minimal. High index of suspicion of incarceration must be kept in mind if the postoperative course is not straightforward (See Video 39.1).

RYGBP for Failed VBG: Results

The largest series reporting on conversion from VBG to RYGBP includes 205 patients over a 20-year period. They were operated openly, except for two patients, with major postoperative morbidity of 26 % [9]. It mirrors the relatively high morbidity reported in other smaller open series [4, 5, 8]. In more recent laparoscopic series, 30 day or in-hospital morbidity varies from 11.8 to 22 %, with major complications in 4.5–11.1 %, and mortality ranges from 0 to 0.5 % [16, 17, 19–21]. Early results with respect to weight loss are acceptable. As is common in bariatric surgery, there is unfortunately paucity of long-term results in the literature. Nesset et al. [10] reported an average long-term satisfactory weight loss, in patients primarily revised for weight loss failure, with 13 BMI units decrease after a mean of 7.5 years when

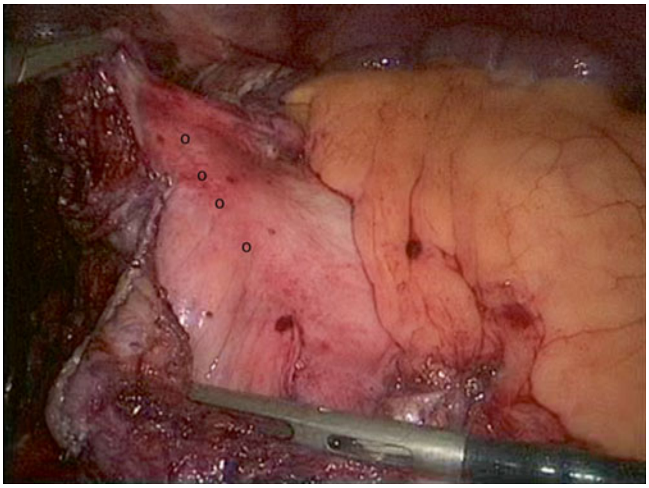

Fig. 39.7 Intraoperative view after complete division of the stomach, with new staple line in close relationship with the previous one. *o* former staple line. In this case, partial fundectomy as pictures in Fig. 39.6a is indicated

compared to pre-revisional BMI. In our series including 203 patients [17], the mean BMI was 43 before VBG, 37.5 before revision and maintained below 30 as of the first postoperative year and up to 10 years post revision. Twenty four out of the 27 patients, who had at least 8 years of follow-up, were available for evaluation. Twenty two (91.7 %) of them achieved BMI < 35, with 12 below 30. The results compare favorably with those obtained after primary RYGBP.

Conclusions

VBG is associated with high long-term risk of complications which interfere with quality of life and/or lead to weight regain. More than 50 % of the patients need revisional surgery at some point. Complete anatomical and clinical evaluation is essential before decision to reoperate can be made. Furthermore, if the long-term failure rate is to be maintained as low as possible, many patients need some form of education and preparation before redo surgery such as dietician and/or psychological counseling. The best option for revision is to convert from VBG to RYGBP. The procedure can be difficult due to previous changes in the anatomy and adhesions and should only be done by experienced bariatric surgeons. It can be done laparoscopically with acceptable morbidity and mortality. If the upper portion of the stomach is too difficult to dissect or transect, esophago-jejunostomy can be done with results similar to those of usual RYGBP. Another option is conversion to Scopinaro-type bilio-pancreatic diversion with its malabsorption-associated risks. After conversion to RYGBP, weight loss is acceptable and comparable to that obtained after a primary procedure, and symptoms associated with complications of the VBG are satisfactorily relieved.

Key Learning Points

- Long-term complications requiring reoperation are common after VBG
- Conversion to RYGBP is the procedure of choice in most cases
- A complete evaluation of the patients is mandatory before redo surgery
- During redo, anatomical landmarks need to be identified before construction of the gastric pouch
- Results of revisional gastric are good in general

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Revisional Surgery after LRYGB

40

Kelvin D. Higa and Steven S. Chang

Abstract

Laparoscopic gastric bypass has proven long-term results and benefits. Our lack of understanding as to the pathophysiology of the operation underscores the variable response curve observed. It is unreasonable to assume patients who do not do well after surgery are merely "non-compliant." In addition, there are inherent drawbacks to the anatomic construct that can lead to significant complications. Therefore, bariatric/metabolic surgeons should be prepared to restore, correct, augment, or reverse this operation depending on the needs of each individual patient.

Keywords

Gastric bypass • Revision gastric bypass • Reversal gastric bypass • Weight loss failure after gastric bypass • Weight recidivism after gastric bypass • Gastrogastric fistula after gastric bypass • Marginal ulcer • Reactive hypoglycemia

40.1 Introduction

Over the years, laparoscopic Roux-en-Y gastric bypass (RYGB) has been shown to have favorable long-term outcome and benefits [1]. However, morbid obesity, similar to many other chronic diseases, may require additional treatment depending on the response of the individual patient. The need for interventions after RYGB can be for complications such as marginal ulceration (MU) or gastrojejunal (GJ) stricture, inadequate response in terms of initial weight loss or weight recidivism, or for suboptimal treatment of the metabolic syndrome. At times, intolerance of the procedure, characterized by excessive weight loss or malnutrition, reactive hypoglycemia or psychological issues may require reversal or conversion to another procedure. There is a role for endoscopic or other novel procedures; the reader is advised to understand the spectrum of options available and to use his/her judgment in designing a treatment algorithm appropriate for the problem at hand, given the resources available. These concepts apply to "open" RYGB as well; although laparoscopic intervention after open surgery has its own challenges, it offers significant advantages in making the learning curve worthwhile.

The strategy of revisional surgery is to optimize, repair or significantly change the current anatomy in order to address a problem that has failed non-operative management. Clearly, if a marginal ulcer can be treated with medications; there is no need for reoperation. Reversal of RYGB or reactive hypoglycemia would only be advised when dietary and medical treatments fail. It is understood that revisional surgery is associated with higher surgical risk and that the results are often difficult to predict, especially in terms of weight management. Therefore, surgeons must have a realistic understanding of their capabilities and level of expertise as well as that of his/her institution.

The literature on this subject is sparse and based on fewer patients with short-term results. Patient heterogeneity and

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the inability to control confounding variables make comparative studies nearly impossible. Therefore surgeons must evaluate their results on an individual basis and not interpolate across a large demography. Therapy must be based on the individual patient with a clear understanding of the objectives desired and the risks involved.

40.2 Preoperative Evaluation

Prior to intervention, it is important to understand the current anatomy as much as possible. Oral contrast studies and endoscopy can be complimentary; delineating the current anatomic construct as well as motility issues. Reviewing the operative note of primary procedure and discussion with the primary surgeon, when available is often helpful. In addition, it is important to have an understanding of the patient's history, compliance, participation in support groups and expected outcomes. As the perioperative risks of revisional surgery are greater than the primary operation, potential benefits must be significant. Further psychological counseling is advisable, regardless of whether patients originate from your own institution or referred from other centers. Dietary input is also a prerequisite, irrespective of whether further revisional surgery takes place or not. Hence, a multi-disciplinary team approach is required to ensure that revisional surgery is the best option (see Figs. 40.1 and 40.2).

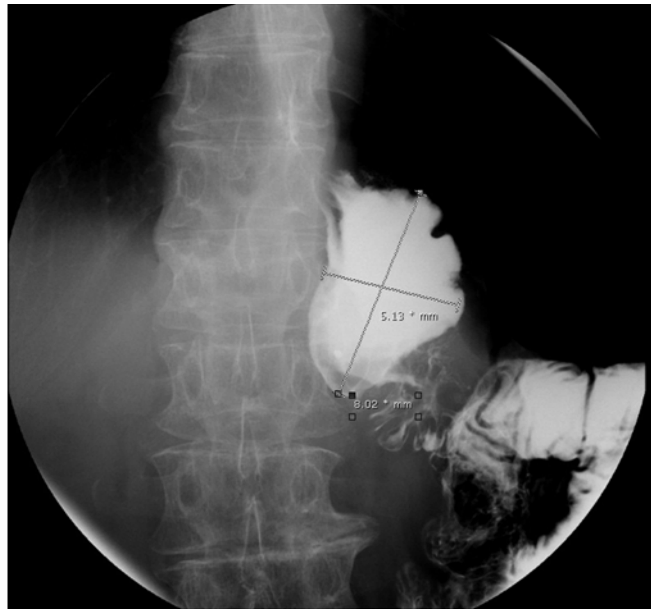

Fig. 40.1 Large gastric pouch

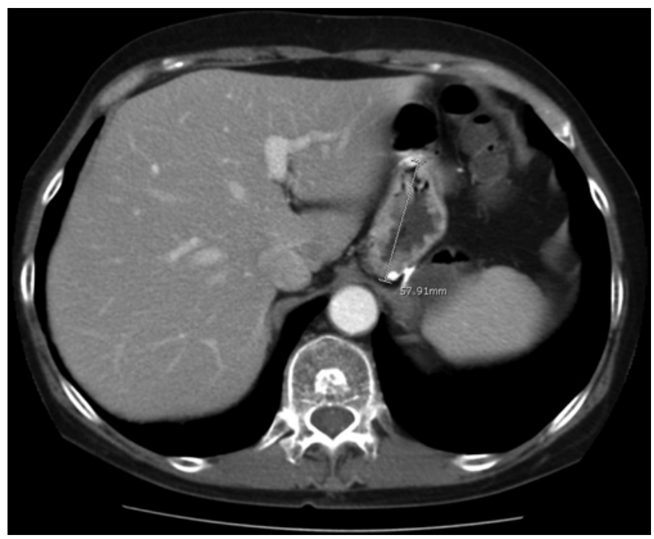

Fig. 40.2 Compurized Tomography scan underestimates the true size of the pouch

40.3 Restorative/Corrective Surgery

"Restorative" surgery assumes a change in the original anatomy requiring repair or restoring the bypass to its optimal state. A dilated gastric pouch and/or anastomosis can lead to weight gain, inadequate initial weight loss, MU or exacerbation of reactive hypoglycemia. Gastrogastric (GG) fistula, either de novo, or due to chronic MU, when symptomatic, requires intervention. Stenosis of the gastrojejunostomy, often due to chronic MU or ischemia may require reoperation when not responsive to endoscopic balloon dilation. The latter examples would be classified as "corrective"; that is, addressing complications of the primary procedure and/or a suboptimal anatomic construct after a primary procedure.

A "dilated" gastric pouch assumes that there is consensus that a "normal" gastric pouch exists. However, neither "normal" gastric pouch exists nor there is convincing evidence that a dilated pouch is responsible for weight gain or inadequate initial weight loss [2–4]. In fact, there are a few series that report short-term weight loss with pouch revision. Lanneli demonstrated in a series of 20 patients, followed for a mean of 20 months, variable weight loss with pouch resizing (without revision of the gastrojejunostomy), but his data also showed a trend toward recidivism six months after revision and a 15 % leak rate [5]. A small study in 2011 described 'gastrojejunal sleeve reduction' for weight loss failure with insignificant further weight reduction [6]. In a retrospective study, O'Connor found no correlation with weight loss and the number of staple firings at the time of pouch creation—a surrogate for pouch size [7]. Nonetheless, enlarged pouches can lead to food intolerance due to food trapping in the 'neo'-fundus, MU and chronic pain.

Downsizing the pouch often requires revision of the gastrojejunal anastomosis, depending on the orientation of the anastomosis. The pouch can be enlarged either lengthwise or widthwise or both; the true dimensions are difficult to estimate by routine contrast studies or endoscopy. Most pouches empty so rapidly, that distension is only possible by clamping the Roux limb operatively. Some studies have shown that larger pouches, 45–60 mL, are associated with weight loss failures [8, 9]. Muller showed significant weight loss in five patients followed for 12 months after pouch and GJ anastomosis resizing [10]. Interestingly, Heneghan, found no correlation with gastric pouch volume, but only with GJ anastomotic diameter when she compared two disparate patient populations [11].

GJ diameter is difficult to measure and revise in isolation without affecting the gastric pouch except by endoscopic techniques. Sclerotherapy [12], endoscopic fasteners [13], and endoluminal suturing devices have been shown to have an initial effect, yet most commercially available devices are no longer available [14]. Thompson reported a correlation between stoma size and weight regain in 165 patients [15]. "Corrective" surgery is necessary for GJ stenosis [16], chronic MU [17] and GG fistula [18] when symptomatic and/or not amenable to non-surgical therapy. In general, early postoperative GJ stenosis almost always responds to endoscopic balloon dilation [19] and rarely requires operative revision [20]. Chronic GJ stenosis is often associated with MU; hence therapy is directed toward causation, in this case, the marginal ulcer—associated with a dilated pouch, tobacco, nonsteroidal antiinflammatory drug (NSAID) use or the presence of a GG fistula. GG fistulas only need to be addressed when symptomatic [18].

Operative strategy mandates a high degree of skill, knowledge and understanding of the esophageal hiatus and related structures (Video 40.1). Laparoscopy is infinitely more desirable to the open approach as it affords better visualization and less chance of splenic injury. The gastric pouch-jejunal complex should be separated to exclude posterior and lateral fistulation of a marginal ulcer into the gastric remnant as even a combination of endoscopic evaluation and contrast studies can miss a small GG fistula. Transection of the Roux limb close to the GJ anastomosis, early in the course of the operation, allows for free mobility of the gastric pouch and accurate delineation of the anastomosis through visualization of the ischemic Roux limb. With a chronic GJ stenosis, the gastric pouch is invariably dilated; hence the gastric pouch should be downsized as well. Identifying healthy tissue is paramount to prevent re-stricture formation. Circumferential dissection of the esophageal hiatus often reveals a hiatal hernia, which should be repaired posteriorly. Care must be taken to preserve the lesser curve vessels and not to indiscriminately staple the existing pouch in a manner that can lead to ischemic necrosis between staple lines. Intraoperative endoscopy is mandatory to help delineate anatomy and evaluate the reconstruction.

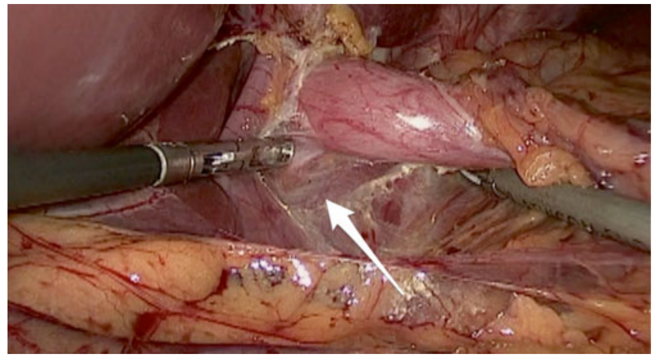

Fig. 40.3 Hiatal hernia (*arrow*) dissection

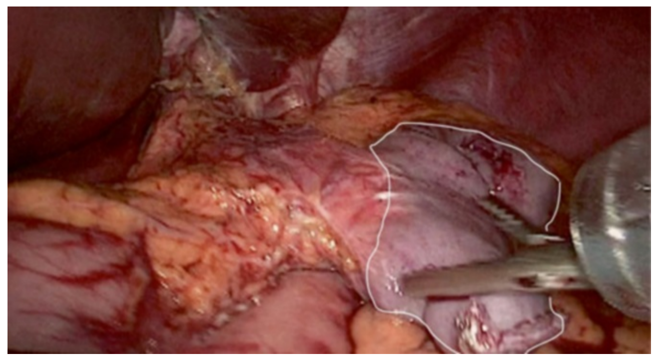

Fig. 40.4 Line delineates ischemic Roux limb after transaction

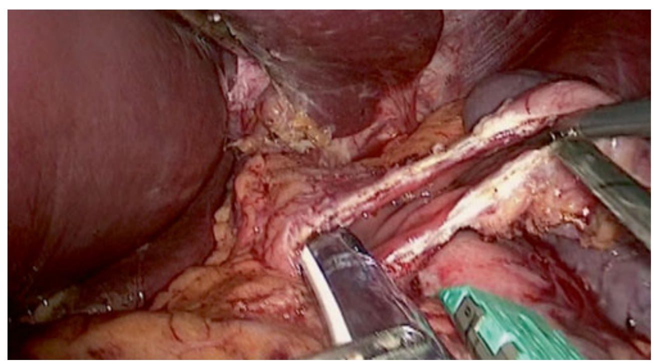

Fig. 40.5 Interior of gastric pouch prior to downsizing, demonstrating viability

Reconstruction of the GJ anastomosis in these instances can be done by a combination of stapling and suturing but many surgeons may prefer to reconstruct this by a totally sutured technique to avoid stapling thickened tissues. If stapling were used, it would be wise to use taller staples to accommodate the thickened or edematous tissue. Like intraoperative endoscopy, laparoscopic suturing skill is a prerequisite for these procedures. Postoperative closed suction drainage and gastrostomy tube decompression of the gastric remnant is advisable, but it is left to the surgeon's discretion based on individual experience (see Figs. 40.3, 40.4, 40.5, and 40.6).

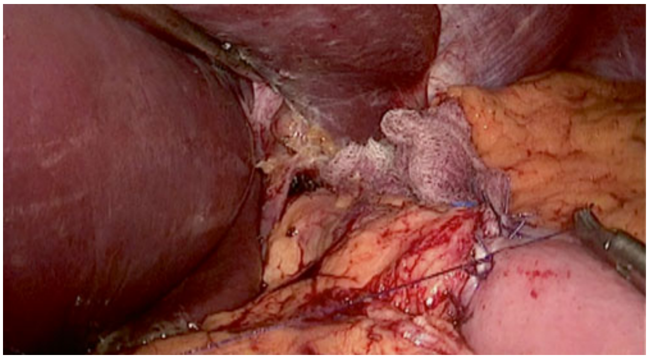

Fig. 40.6 Interrupted, hand-sewn gastrojejunal anastomosis

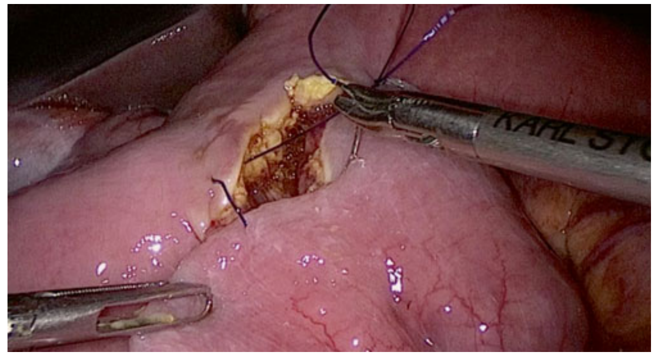

Fig. 40.7 Distalization of Roux-en-Y gastric bypass—single layer continuous monofilament absorbable suture

40.4 Augmentation

Incompletely or partially treated obesity or related comorbidities after RYGB may require enhancement of the procedure depending on the initial response. This can take the form of either altering the gastric pouch, with adjustable or nonadjustable prosthetic devices, or lengthening or shortening the alimentary, bilio-pancreatic or common channel limbs.

"Augmenting" the gastric pouch after gastric bypass by the use of adjustable gastric bands or static prosthetic rings has been shown to be safe and effective as a salvage operation after failed RYGB [21]. In a 2012 review article, Vijgen cites seven studies (all but one study were adjustable gastric bands) where a total of 94 patients achieving 55.9–94.2 % excess body mass index loss with 12–42 months follow-up. Complications were acceptable, with no 30-day morbidity in the non-adjustable band series, with only 2 reported erosions in all the studies but 16 % required re-revision. Although there is compelling evidence in primary procedures that the non-adjustable banded bypass yields superior long-term weight loss, especially in the superobese population [22, 23], patient tolerance, as a salvage procedure is less understood. Our personal experience with primary banded bypasses has been similar to that reported, but despite adequate weight control, most of the bands that were placed as a revision needed to be removed because of dysphagia; whereas none of the primary bands required removal.

Altering limb lengths has been shown to be both effective and dangerous. In a 1997 publication, Sugerman revised 27 super-obese patients from a standard RYGB, to what was termed a "distal" bypass consisting of a common channel of 50 cm or 150 cm and an alimentary limb of approximately 150 cm. The authors found that a common channel of 50 cm was unacceptable (as there were two deaths due to hepatic failure; all the surgeries had to be revised due to malnutrition) and a common channel of 150 cm yielded an acceptable 14 % revision rate [24]. The "distal" RYGB should not be confused with the "long-limb" RYGB as described by Sugerman [25] and the "distal" RYGB as described by Brolin [26]. Both Sugerman and Brolin use the term long-limb to describe a Roux limb of 150 cm and a relatively short biliopancreatic limb. However, Brolin's distal bypass consists of a short 15–25 cm biliopancreatic limb, a common channel of 75 cm and a long Roux limb. Despite Sugerman's conclusion that the distal RYGB should not be used as a primary procedure in the obese or super-obese patient because of unacceptable nutritional complications, its use as a salvage operation can be considered [27, 28]. Clearly, "distalization" of a RYGB for inadequate weight loss or control of metabolic syndrome has additional benefits of duodenal switch or classic Scopinaro biliopancreatic diversion. Unfortunately, the small gastric pouch imparts a variable in protein and calorie availability that can lead to greater malnutrition than the primary procedures [28].

In addition to limb lengthening or distalization, Ferraz described other novel techniques of addition of a silicone band as well as pouch plication [29] but the numbers in this series were small and for many patients follow up was much too short to allow for any suitable conclusion to be drawn (see Fig. 40.7).

40.5 Conversion

Because of the non-standard approach to obesity management, individual surgeon bias and patient preference, the RYGB may not have been the optimal procedure from the onset. Also, unforeseen complications such as intractable marginal ulcers or reactive hypoglycemia may require reversal or conversion to either sleeve gastrectomy (SG) or duodenal switch (DS). Alternatively, reversal may be considered.

Conversion of RYGB to SG as a single stage procedure in our center has been associated with an unacceptably high fistula rate. Upon review of 12 consecutive patients, we experienced a 42 % fistula and 25 % stenosis rate [30]. The highest

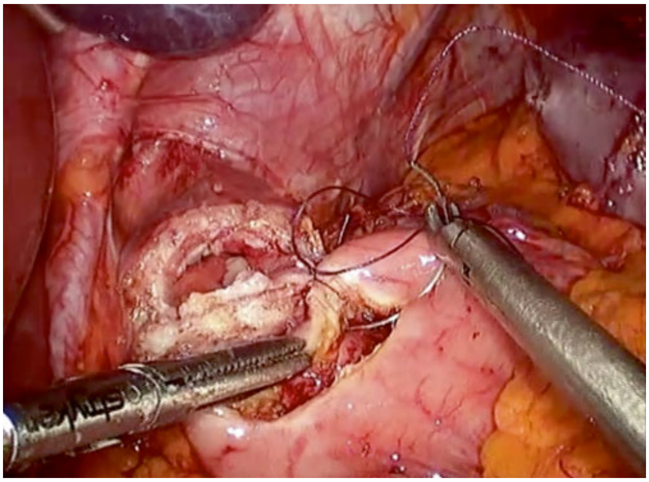

Fig. 40.8 RYGB reversal—gastrogastrostomy

rate of fistula was found when conversion was done for chronic MU due to tobacco use. Dapri reported a 25 % fistula rate with 4 patients [31]. Keshishian reported 4 leaks (15 %) when converting RYGB to DS as a single stage open procedure, but only half of this required reoperation [32]. Gagner reported no leaks in 12 patients who had RYGB converted to DS, of which 42 % had SG as the first stage of a staged conversion and one patient had conversion to SG only [33].

Our personal experience invites caution when considering conversion of RYGB to SG in one stage, especially in the case of chronic MU. Moreover, single stage conversion from RYGB to DS is not recommended considering the added complexity and knowing many surgeons prefer a staged approach even for primary procedures [34]. Ironically, many patients will experience satisfactory weight loss with just the conversion to SG; not requiring the intestinal bypass [35].

40.6 Reversal

Reactive hypoglycemia [35, 36], psychological intolerance and chronic MU may be reasons to reverse a RYGB (Video 40.2). The operative strategy should be one of complete restoration of the stomach, especially if there is a potential for SG in the future. A number of techniques can be employed. Dapri described restoration of gastrogastric continuity by either hand-sewing or linear stapling of gastric pouch to gastric remnant without excision of the Roux limb [37]. Campos described the excision of the alimentary limb and restoring the gastric pouch-remnant continuity with circular stapling [36]; this latter technique potentially allows for single stage conversion to a SG or as a staged procedure. Furthermore, if there is question of vagal nerve injury, either from the primary or secondary procedure, a pyloroplasty may be necessary (see Fig. 40.8).

40.7 Algorithm for Revision Gastric Bypass: A Personal Approach

Complications of the RYGB such as uncontrolled malnutrition, reactive hypoglycemia and alcoholism can be effectively treated with reversal or conversion to SG. Chronic MU due to continued tobacco or NSAID use would likely recur, so simply revising the GJ anastomosis and excising the ulcer would not be optimal. Unfortunately, in our experience, conversion to SG has resulted in a very high leak rate in one stage; therefore we have adopted a two-stage approach when conversion to SG from RYGB is desirable. If tobacco or NSAID use can be avoided, then downsizing the gastric pouch and excision of the ulcer is satisfactory and incurs lower risk.

Revision for weight-related issues, either inadequate initial weight loss or weight recidivism after RYGB, can be one of the most challenging scenarios of our specialty. Unlike weight related issues after the vertical-banded gastroplasty or adjustable gastric band that has satisfactory response in conversion to RYGB; solutions aimed at increased "restriction" have yielded only short-term results. Our observations are consistent with current theories regarding the biologic and genetic nature of the disease of obesity and the mechanism of action of RYGB [38]. Patients respond to a varying degree; those who have long-term success are able to "self-regulate" their weight. In contrast, those who do not respond are often labeled as "non-compliant," which may be a convenient, but inaccurate description. Patients that do not achieve satiety after surgery will likely have a suboptimal response regardless of individual determination.

If satiety is achieved, then the operation is successful and weight issues can be attributable to behavior or psychological dysfunction. If satiety is not achieved, then evaluation of the anatomic construct is done to check whether the construct is in order. If a GG fistula is encountered, the bypass is essentially bypassed and restoration is indicated. If the pouch was created too large, by intent or miscalculation, optimization of the pouch size (less than 20 mL) may be of benefit. Distalization as described by Sugerman [24], shortening the total alimentary tract can have a remarkable effect on both diabetes and satiety, possibly through similar mechanisms [39]. Although not advised for primary patients, revision candidates have already proven themselves resilient to intervention. Caution must be taken, as the patient's ability to process protein is different after a standard RYGB, than after SG, so distalization of a RYGB may incur higher rates of protein-calorie malnutrition than seen after DS.

Distalization is a fairly straightforward procedure after RYGB. Assuming a Roux limb length of approximately 100 cm, the jejunum is transected just proximal to the jejuno-jejunal anastomosis and attached to the distal small bowel approximately 300 cm proximal to the ileocecal valve, thus

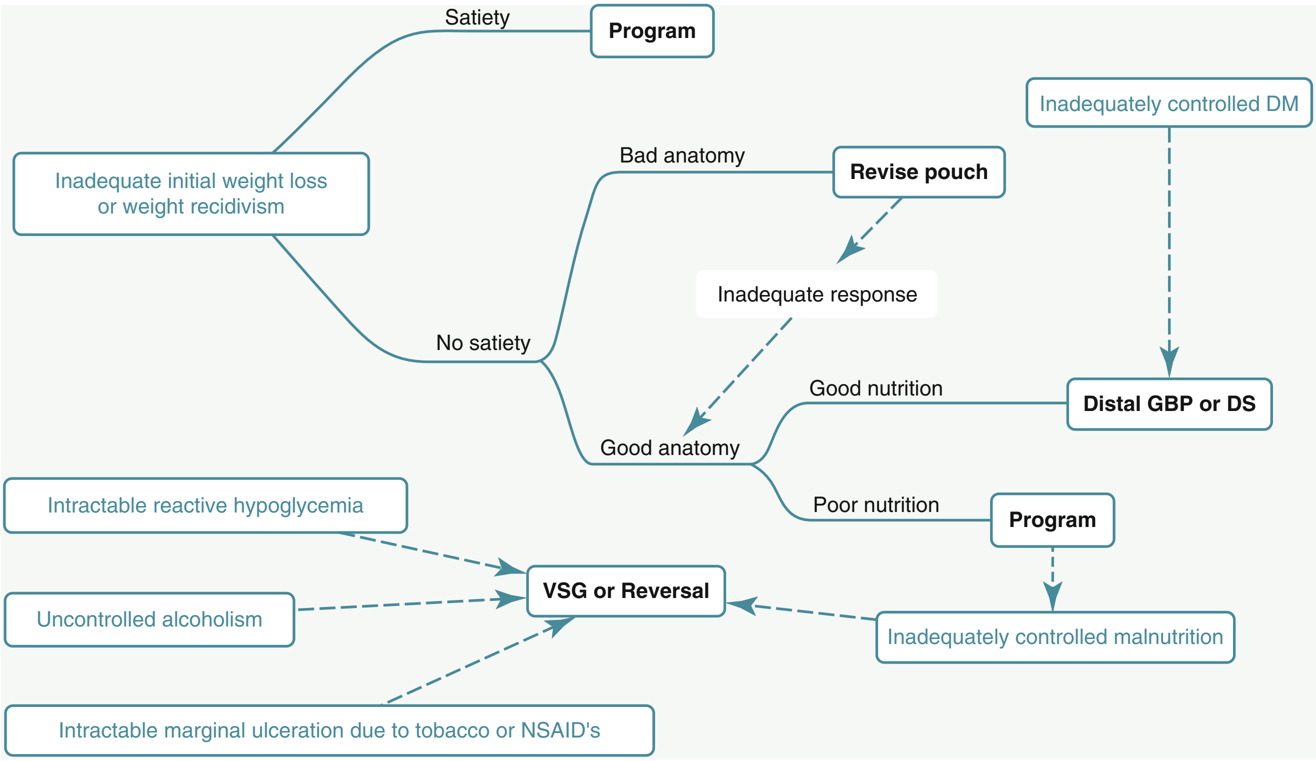

Fig. 40.9 Algorithm for revision of Roux-en-Y gastric bypass

achieving a 400 cm total enteric length. Others have described 250 cm [40] or 300 cm [27] total alimentary length, but we have found this to be too short, requiring revision to lengthen the bowel due to uncontrollable diarrhea (see Fig. 40.9).

Conclusion

Bariatric/Metabolic surgeons must embrace the concept that obesity is a chronic disease and as such, there will be a varying degree of response/success to our interventions [41]. Failures should not be judged as patient non-compliance, more accurately it should be considered as a result of our ignorance of the pathophysiology of this disorder. Revisional procedures will become more frequent as with the growing number of primary operations. Unfortunately, we can ill afford the higher complication rates associated with random interventions based on archaic notions of "proper" anatomic constructs [42]. In some respects, contemplating a revisional procedure allows us to reflect on the patient's response to the original procedure so that the next procedure will have less uncertainty. If there was a partial or incomplete response, then augmentation may be in order; and if there was no response, then conversion to a different procedure should be considered. Unfortunately, this is often not the case: it is imperative that surgeons inform prospective patients of realistic outcomes, despite their optimistic expectations.

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41 Revisional Surgery after LSG

Jacques M. Himpens and Andrew C.T. Wan

Abstract

The laparoscopic sleeve gastrectomy has become a popular procedure in the armory of bariatric surgery. However, failures with this procedure are often difficult to manage in the absence of any single defined pathway; complications that emerge are often debilitating and frequently demand prompt corrective surgery.

Operations aimed at improving weight loss include the restoration of the original sleeve in case of anatomical deformation, the addition of malabsorption or hormonal effects by augmenting the sleeve with several variations of bypasses, and the revision of the sleeve gastrectomy in those with severe reflux in conjunction with poor weight loss. Other revisional procedures address typical complications with the rectification of anatomical or functional blemishes in the sleeve and the hiatus, and infrequently, dealing with chronic fistula.

Reoperation on a sleeve gastrectomy is a delicate endeavor because of the risk of leaks and further failures. It demands advanced laparoscopic skills and specific technical precautions. All patients require careful preoperative evaluation, and expectations should be addressed before further surgery is offered.

Keywords

Sleeve gastrectomy • Failed sleeve • Weight regain • Weight loss • Duodenal switch • Re-sleeve gastrectomy • Plication • Gastric bypass • Complications • Stenosis • Stricture • Gastroesophageal reflux disease • GERD • Seromyotomy • Wedge resection • Hiatal hernia • Chronic fistula • Roux limb

41.1 Introduction

In the last decade, laparoscopic sleeve gastrectomy (LSG) has become a fashionable primary procedure in the armamentarium of bariatric surgeons. However, like all other bariatric procedures, it has failures as well as complications. Despite its increasing popularity, management of failed and complicated LSG can be a challenge, even to the most seasoned surgeon. Although some LSG series have showed reasonable maintenance of weight loss in excess of 5 years [1], LSG would appear to be characterized by weight (re)gain at least in the medium term [2]. Historically, duodenal switch (DS) has always been the "natural" complement to LSG to improve weight loss outcome and sustainability. LSG is

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sometimes performed in the superobese as part of a staged procedure [3] to reduce morbidities associated with single stage procedures, but infrequently LSG does not progress to DS as planned [4]. Over the years, many centers have utilized the gastric bypass as a rescue option for the failed sleeve [5]. More recently, other operations have emerged as revision alternatives for the sleeve gastrectomy (SG). These include retrimming/reresection; invagination; and a number of other diversion/bypass-like procedures to restore the sleeve; and augmenting malabsorption and/or adding hormonal effect to the existing sleeve. Although the open approach was adopted in revisional surgery in the early years [6], the majority of these corrective procedures are now carried out laparoscopically.

Another important area to address is the common complications linked with altered or defective anatomy. Many, if not most, of the complications that have an anatomical basis after SG are characterized by the common condition of gastroesophageal reflux disease (GERD), presenting as a variety of upper gastrointestinal symptoms secondary to an anatomical or functional abnormality at the hiatus or in the sleeved stomach. All these symptoms may prove very debilitating to the patients, and invariably give rise to an altered eating behavior or often result in cachexia. Reoperations aimed at alleviating these symptoms are targeted at correction of the aberrant anatomy usually by a restoration of the girth or luminal diameter of the sleeve by resection and reanastomosis, widening or diversion; most of which are difficult to perform and are fraught with complications of their own. Finally, some patients who present with chronic leaks after LSG and with numerous failed nonsurgical interventions will require more definitive treatment with diversion or radical resection.

It goes without saying that all revisional procedures should be addressed in bariatric units experienced in dealing with failed procedures and complications. The appropriate teams involved need to have realistic goals and appreciation of their levels of expertise before offering patients these treatments.

41.2 Patient Evaluation

Individual bariatric units usually have their own follow up policies. Although patients may not be requested to adhere to follow up beyond a set time, because weight loss results appear to deteriorate with time, some bariatric units offer bariatric check-up visits indefinitely. Nevertheless, respective units should have their own follow up protocol depending on resources available. Patients who experience weight regain or insufficient weight loss would often request repeat treatment. Obviously, conservative and dietary measures should be attempted first, and only patients who are deemed appropriate during their reevaluation should qualify for reexploration. The actual body mass index (BMI) is not an absolute indication or contraindication for revisional surgery; patients should fulfill national and/or local criteria based on individual unit's policy. Aside from the indication pertaining to weight issues, a substantial number of individuals will require further surgery for non—weight-related problems, mostly caused by anatomical flaws. GERD is thus an essential element in the diagnosis of immediate or late anatomical abnormalities of the sleeve construction, and may mandate reoperation. Even though BMI is not a key point in GERD, there appears to be a definite link between GERD and weight regain after LSG [2]. Other patients may present with intermittent dysphagia, regurgitation or vomiting, also secondary to these anatomical abnormalities. Patients who require reoperation due to persistent leaks or excessive weight loss, often with an element of malnutrition, should receive mandatory nutritional augmentation prior to reexploration.

41.3 Preoperative Work Up

When the decision has been made for revisional surgery, the classic work up should be done as for any primary bariatric procedure. This means that all patients should be reevaluated by a psychologist or psychiatrist to rule out psychological conditions, such as eating disorders [7] that may interfere with the renewed bariatric construction. The dietitian should reassess the patient and try to detect any abnormal eating pattern that the patient had developed. Patients may often be categorized into frequent eaters (polyphagia) or volume eaters (hyperphagia) [2]. Though the categories are controversial to some these may help in deciding the type of revisional surgery that should be performed. A good radiological investigation is equally important. Computed tomography (CT) scan, and more pertinently, a barium swallow and meal (semisolids with contrast) may review a hiatal hernia (HH) or irregularities on the sleeved gastric body such as stenosis, 'kink,' twist or too limited a diameter overall. Although gastroscopy can sometimes be complimentary to barium studies, it may be less important in the subset of patients being studied here because endoluminal visualization often fails to detect functional abnormalities, especially in cases with a subtle twist(s) or an elusive stenosis mistaken as a sharp angulation, especially at the level of incisura. Thorough blood tests can help rule out any condition that may have a repercussion on the gastric function. Such tests can also identify conditions that may be a result of poor dietary choices made by the patient to accommodate the difficulty in eating, for example vitamin B12 deficiency because of the reduction of meat intake. Blood tests can also be done to identify poor dietary choices that could have caused weight gain. This includes an abuse of carbohydrates and sugar that may lead to low fasting plasma glucose levels.

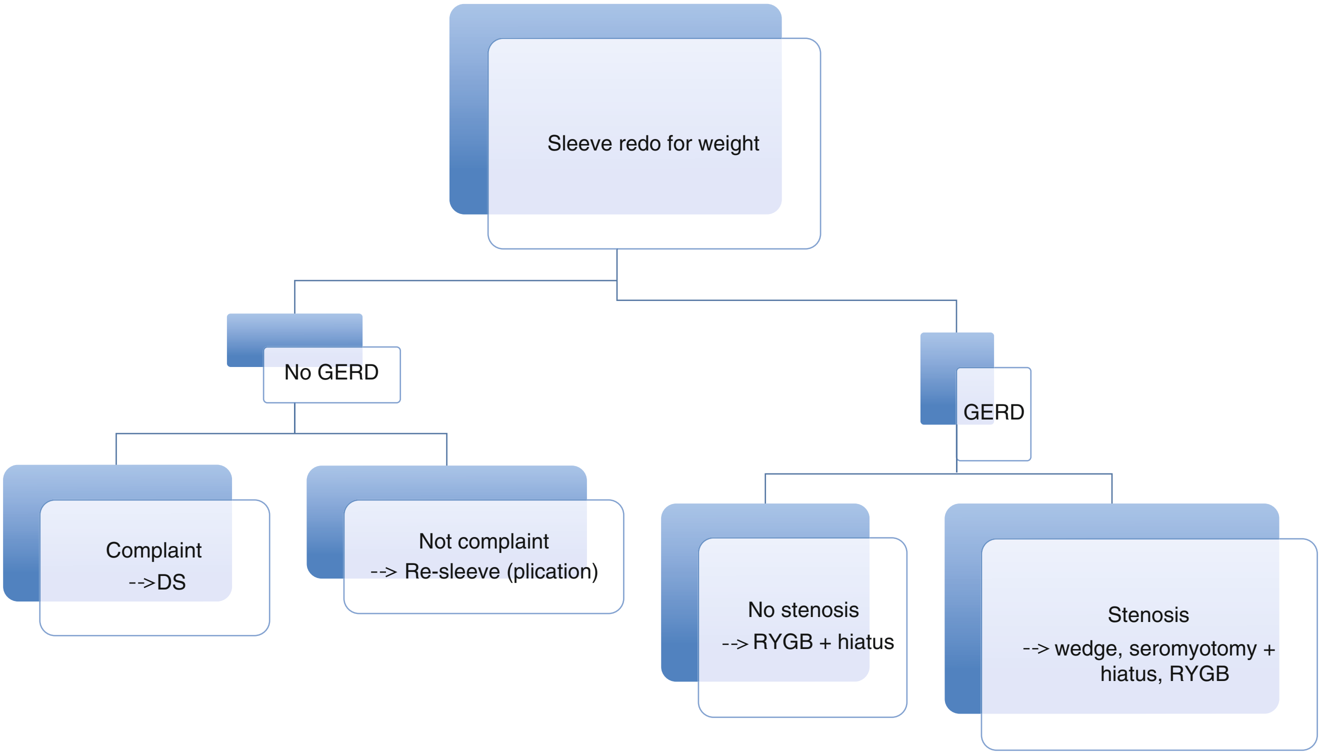

Fig. 41.1 Algorithm: redo surgery for weight issues following sleeve gastrectomy

41.4 Reoperation for Weight Issues

There is limited guidance and little consensus to the selection of corrective procedure after LSG for those who regain weight or endure poor weight loss. However, a proposed revisional surgery algorithm may be helpful (see Fig. 41.1). Traditionally, after LSG, many patients undergo DS if there is no evidence that the sleeve construction was flawed, usually indicated by the appearance of a neofundus (see Fig. 41.2). If sleeve construction was flawed, reresection or laparoscopic re-sleeve gastrectomy (LRSG), may be an option.

In order to adequately select patients for LRSG, individuals who regained weight after LSG should be advised to undergo barium swallow and meal for evaluation of a possible aberrant shape of the sleeve. An interesting study aiming at establishing a link between LSG with complications and radiological appearance of the sleeve showed irregular shapes of the sleeve in patterns of 'inferior pouch' (antral preservation) and 'superior pouch' (residual fundus), with the latter often mistaken as a leak, thus confirming difficulty with interpretation and correlation with clinical picture [8]. CT scan with 3-dimensional reconstruction had been used to evaluate the post sleeved stomach where intrathoracic migration of the staple line could be detected; this condition often correlates with regurgitation [9]. There is some evidence that a 'high residual gastric volume' of the sleeve found on CT volumetry plays a significant role in the phenomenon of weight regain after SG [10] and alternatively, a proposal that a critical volume of stomach that should be resected should be at least 250 mL, under which the sleeve resection is considered to be inadequate [11]. Endoscopy, when performed,

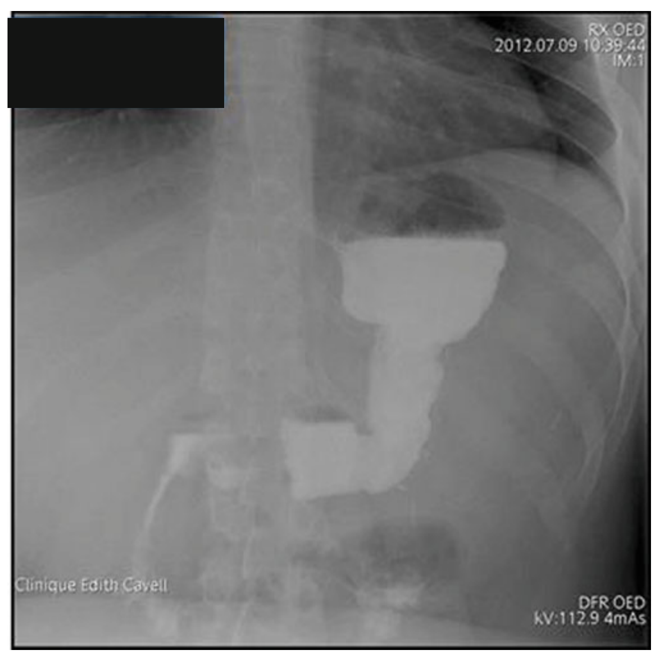

Fig. 41.2 Neo-fundus—dilatation of the proximal sleeve on Barium studies

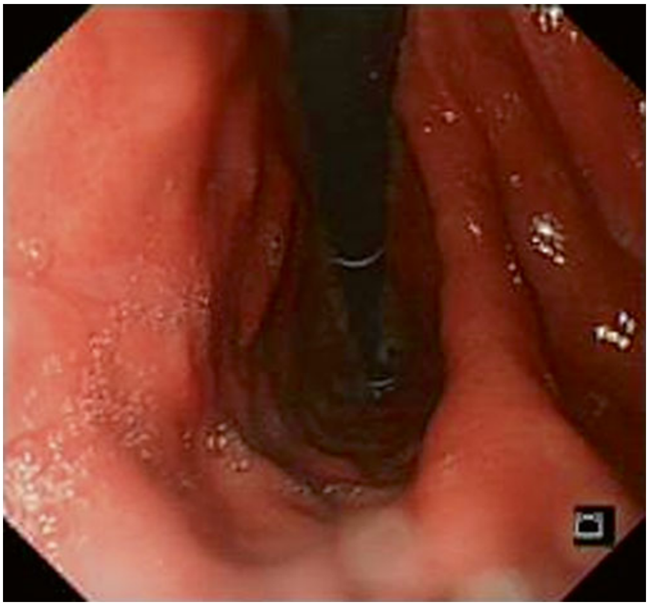

Fig. 41.3 Dilated sleeve-endoscopic view

often confirms a voluminous sleeved stomach (see Fig. 41.3). Interestingly, Braghetto found a small increase in the sleeve volume early in the postoperative period compared with intraoperative measurement but did not observe any significant weight gain in patients where there was volume increase up to approximately 250 mL, with the sleeve a few years after LSG [12]. Various types of dilatation of the sleeves have been described, with primary dilatation (upper posterior gastric pouch) and secondary dilatation (homogeneous dilated gastric tube) being the commonest findings, but nonetheless the mechanisms involved are still unknown, with narrowing at the incisura and incomplete dissection of the posterior fundus as possible reasons for the sleeve dilatation [13].

Some patients could experience the recovery of the capacity to eat large meals (hyperphagia), while others deny the ability to eat large meals, but by consuming too frequent small meals (polyphagia); it was suggested that the former group of patients would most likely benefit from a LRSG [14]. This solution with LRSG was originally proposed by Gagner as revision of the sleeve after a DS [15], and by Baltasar as part of a conversion to the DS, sleeve diameter in excess of 4 cm [16]. However, it was shown in the past that LRSG is not characterized by a similar good weight loss as after the DS [14]. This is hardly surprising, considering the fact that restrictive procedures treated by a new resection usually are less effective. Nevertheless, LRSG has since been reported by several authors, some with no morbidities [17] and others with higher complication and fistula rates [13, 18], but all with promising results in the early stages of follow up. In general, leaks or fistulas appear to occur twice more frequently with revisional than with primary cases [19], which in itself is not astounding. The gastric defect where the leak originates is almost invariably located at the level of angle of His, a notoriously unfavorable location. Hence, even in cases of volume regain after SG, one should bear in mind the possibility of performing a DS, which may cause complications as well, but these complications are usually easier to manage [14].

There is little data to support banding of a primary sleeve, hence, using an implantable ring device on a dilated sleeve as a revisional procedure, solely following reresection or in combination with another maneuver, is not recommended without further supporting evidence. Similarly, greater curve plication or gastroplasty, whether laparoscopic or endoscopic, is still in its infancy as a primary procedure. Hence, without the larger case series or randomized studies reporting on its efficacy on failed sleeve, this too is unlikely to become a mainstream procedure.

Furthermore, Chevallier's group published their short series of 23 patients with poor weight loss, requiring conversion from SG to minigastric bypass (MGB) using predominantly the laparoscopic approach with reasonable excess weight loss [20]. Information is currently lacking on MGB as a revision option on this group of patients. Other choices including the addition of malabsorption or augmenting hormonal effects to the sleeve are few and far between. In conjunction with the sleeve, single anastomosis duodenojejunal (SADJB-SG) [21] or duodenoileal (SADI-S) [22] bypasses are very much in vogue as primary operations with good short term results. Adding hormonal effects with 'bipartition type' as described by Santoro [23] or ileal transposition as described by De Paula [24], to the sleeve in those patients with significant metabolic derangements work well with good metabolic response as single stage primary procedures. All these novel techniques could be adjuncts for the failed sleeve, but until more evidence is available in the foreseeable future, they cannot be considered with equal footings or as possible alternatives to the DS.

GERD is a peculiar symptom after LSG. In many patients without anatomical abnormality of the sleeve, SG appears to increase reflux during the first postoperative year without reflux associated complications. GERD, or at least a condition that is experienced as such by the patients, is an important complaint beyond the third postoperative year [2]. The senior author demonstrated that GERD regressed within 3 years after LSG and persisted in only 3.1 % of patients [25], but with time, a substantial number of patients started complaining of reflux [2]. There is also a striking correlation between the emergence of GERD and the increase of BMI [2]. In this context, GERD may thus be considered a secondary phenomenon caused by food intake exceeding the volume of the stomach and its emptying capacity. Although there is conflicting evidence with regard to gastric emptying after LSG [26, 27], this condition is most probably caused by a stasis phenomenon and should primarily be addressed by dietary measures. Many authors favor a laparoscopic Roux-en-Y gastric bypass (LRYGB) as the corrective procedure for a failing LSG, independent of the presence or absence of GERD. Schauer's team demonstrated in a group of 126 extremely obese patients that most of the patients did well with LRYGB after LSG [28]. Similarly, Rosenthal and coworkers showed that in patients complaining of GERD after LSG, Roux-en-Y gastric bypass (RYGB) is a good option [29]. According to the literature, RYGB is indeed considered the preferred treatment for GERD after a previous restrictive bariatric procedure [30]. However, weight loss figures for RYGB after LSG are poorer compared to RYGB after laparoscopic adjustable gastric banding (LAGB) [31]. In addition, patients often complain of bloating after a revisional RYGB from LSG. Bloating is a common symptom after stomach surgery. In RYGB, the limited volume of the bypassed stomach can constitute a smaller than usual expansion bellows, creating uncomfortable sensations when pressure increases in the system [32]. Hence, in the proposed treatment algorithm (see Fig. 41.1) we suggest limiting conversion of LSG to LRYGB to those few patients who, besides weight regain or insufficient weight loss, suffer from GERD without evidence of alteration of the sleeve anatomy. Although LRYGB is popular, it was never intended as the first choice to correct weight loss in post SG patients. Conversely, in patients presenting with GERD and weight loss issues after LSG, it may be preferable to explore the hiatus to cure a possible hernia and to perform a DS rather than a RYGB. Exploring the hiatus is mandatory. Interestingly, the senior author demonstrated that GERD does not evolve well after simple DS [14]. Contrary to believe, GERD is not always cured in patients submitted to corrective RYGB. These findings highlight the complexity of GERD and of the anatomy of the hiatal region especially in redo bariatric surgery.

41.5 Reoperation for Stenosis

A number of patients complain of severe GERD or even regurgitations and slime vomiting during midterm follow up after LSG. This condition may occur after a leak, but most often the patients had an uneventful postoperative course. Typically, patients suffering from this condition complain of GERD and vomiting of slime but often, not food. Usually these patients are unable to consume solid foods even after six months following the surgery and are often treated with proton pump inhibitors even though they do not suffer from esophagitis. At gastroscopy, the findings are unimpressive; the gastroscope most often finds its way without substantial hindrance and subtle anatomical abnormalities are easily missed. Diagnosis is best made following barium swallow, preferably with semisolids, such as barium coated marshmallow or mashed potato, suggesting that stenosis in most cases is functional. Usually a midcorpus stenosis (see Fig. 41.4) can be found. Alternatively, a cork screw deformity may be the culprit (see Fig. 41.5). Based on the findings of more than 12,000 patients, an international sleeve gastrectomy expert panel stated in its consensus statement that stenosis occurred in only up to 1.4 % of cases in all the high volume centers [33]. Nevertheless, whatever the cause, symptoms can be disabling and warrant swift intervention.

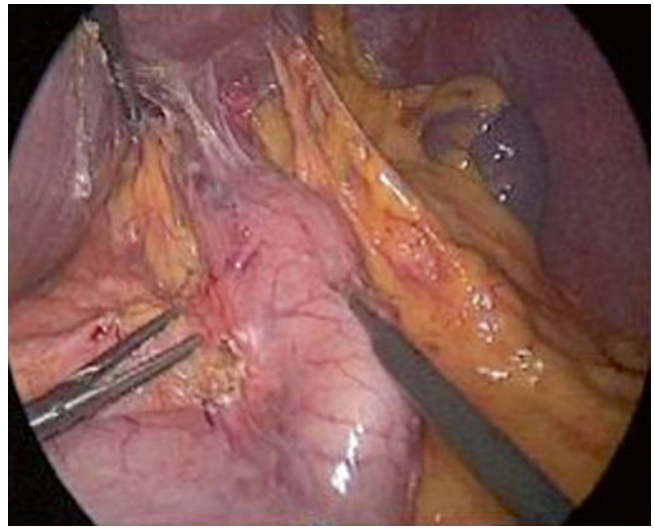

Fig. 41.4 Preoperative aspect of a severely stenotic sleeved stomach

Fig. 41.5 Cork-screw sleeve—Barium appearance of a twisted sleeve stomach

Endoscopic balloon dilatation appears to provide reasonable functional outcomes for 'early' strictures [34], but invariably it is not therapeutic for kinking of the sleeved stomach. Other endoscopic therapy such as stenting has been

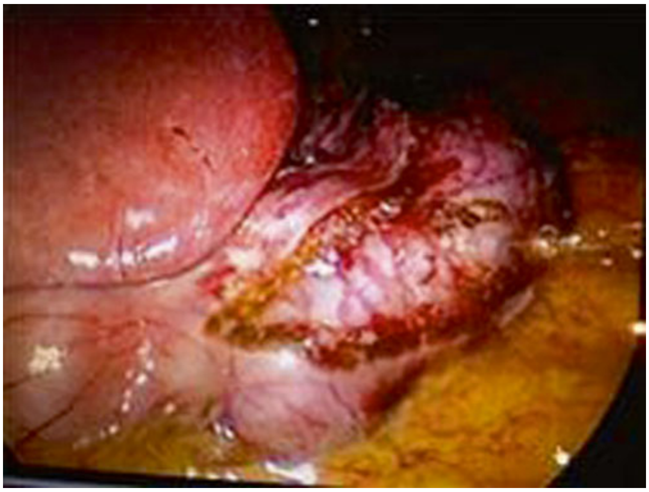

Fig. 41.6 Seromyotomy—appearance of mucosa bulging through after procedure was completed

used in chronic anatomical strictures with little success [35] and is unlikely to be useful in functional stenosis.

The author published the outcomes of 14 individuals who were treated by seromyotomy (see Fig. 41.6) for invalidating reflux and dysphagia [36]. The stenotic area is located by insufflating air into the stomach via an orogastric tube. The stenotic zone usually is located around the mid-section of the body of the stomach and may extend over some 5–15 cm. Just like cardiomyotomy for achalasia, the seromyotomy must be complete in its entirety, both in length (addressing the complete stenotic zone) and in depth (all the layers superficial to the mucosa must be transected). The complication rate in this patient population was alarmingly high, with a substantial number of leaks (35 %), most likely because of burn wounds inflicted to the mucosa during the transection of the deeper muscular layers overlying the mucosa. In addition, some patients did present again with recurrent symptoms and required further revisional procedures.

An interesting strategy also used was to resect the stenotic area by cutting out a wedge of stomach tissue (see Fig. 41.7) comprising the stenosis [36]. Transection of the stomach was performed either by using a linear stapler, or by scissors transection, leaving the gastric lumen wide open. Reanastomosis was performed either by linear stapling technique or more often by manual one layer anastomosis (see Fig. 41.8) with monofilament absorbable sutures. This laparoscopic procedure was well tolerated and there were no leaks in the small cohort. The number of patients in this study was probably too small to prove its efficacy as a revision option for strictures.

Another alternative in treating stenosis is the stricturoplasty. This technique is well known in treating stenotic areas in Crohn's disease and was first described by Gagner at the Bariatric Endoscopy and Surgery Treatment (BEST) meeting in Bruges in 2013 [37]. When using this technique, the stenotic area is incised until the gastric lumen is opened. The full thickness defect is then closed transversely, hereby substantially increasing the diameter of the gastric tube. A word of caution is that even with adequate mobilization of the sleeve, the rigidity of the tissue may occasionally preclude closure of the gastrotomy without undue tension, putting the approximated tissue at risk of leakage.

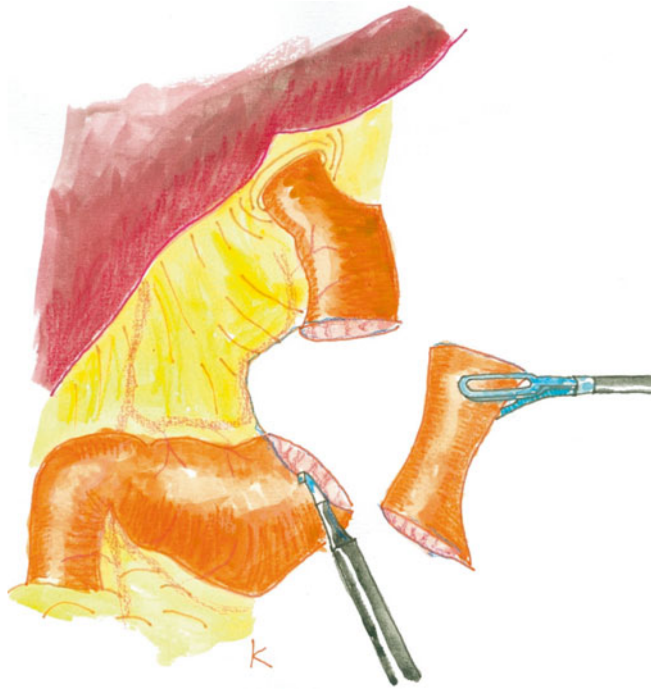

Fig. 41.7 Wedge resection—central resection in substantial stenosis of sleeve gastrectomy (artist impression)

Fig. 41.8 Wedge resection—single layer anastomosis (artist impression)

Lacy described revision of sleeve stricture to RYGB by dividing the stomach just proximal to the stricture [38]. The authors suggest the use of intraoperative endoscopy with insufflation of the sleeved stomach; this may assist in localizing the strictured segment and enable the transection of the sleeve more accurately for the bypass. Despite successful treatment of stenosis or strictures with some novel techniques, the consensus of International SG Expert Panel in 2011 was that reintervention for chronic stricture should be a Roux-en Y reconstruction [33].

41.6 Reoperation for Persisting Leaks

Leaks constitute the Achilles heel of the SG procedure. Leaks after LSG are reported at rates varying from less than 1 % to over 7 %. Leaks may be classified as acute (within the first postoperative week), early (the first four weeks after the operation), late (between the first and the third postoperative month), and chronic (beyond the third month) [33]. Whereas conservative methods, including drain placement and endoscopic methods such as glue, sponges and stents, are preferred for the earlier leaks, chronic leaks mandate a specific surgical approach. Some surgeons prefer to address the issue by radical surgery such as laparoscopic proximal gastrectomy with Roux-en-Y esophagojejunal reconstruction, especially to deal with fistulas occurring proximally and adjacent to the gastroesophageal junction; these locations often render pouch reconstruction impossible [39]. The utilization of a Roux limb for remedial surgery was originally described by Baltasar using open surgery with access through a supraumbilical transverse incision [40]. More recently, the author has so far succeeded in treating chronic leaks by a laparoscopic intervention consisting of placement of a Roux limb on the defect [41]; the technique was elaborated by the senior author [42], describing a side to end Roux anastomosis with a mucosa to mucosa appositioning to create an internal sump, leaving the stenosis that is usually present immediately distal to the defect untouched. Iannelli detailed a technique using a Roux limb without using mucosa to mucosa anastomosis to cover the chronic defect [43].

41.7 Reoperation for Hiatal Hernia with GERD

As mentioned above, GERD is a frequent symptom during midterm follow up following LSG [3] and DS [44]. When work up demonstrates a HH, reoperation must be considered (see Video 41.1). The best treatment for HH is prevention: when performing LSG one should never hesitate to dissect the left crus, and, when indicated, the entire hiatus. Not seldom, a prehernial lipoma found during primary LSG must be reduced to avoid the genesis of a true hernia postoperatively. When a HH does develop, we recommend performing dissection from left to right, in an effort to avoid damaging the blood supply coming from the right. This technique includes the creation of a retroesophageal window from a usual position, but is easily achievable after clear identification of the base of the right crus. Further dissection will reveal the caudate lobe indicating that the retroesophageal window has indeed been created. An essential part of the dissection is the intramediastinal freeing of the esophagus, and importantly, identification of the aorta (see Fig. 41.9) to allow good approximation of bites in the pillars when performing the posterior cruroplasty.

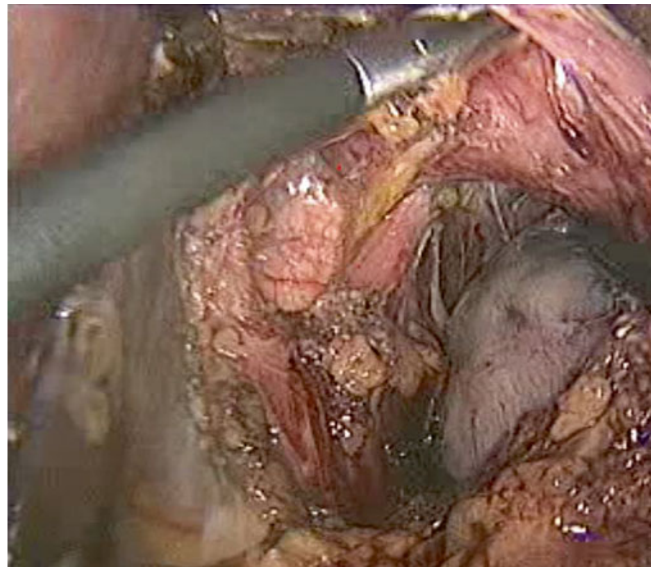

Fig. 41.9 Hiatal dissection—identification of aorta prior to crura approximation

Usually, the left lateral upper part of the sleeve is adherent to the base of the left crus. Dissection should be performed extremely carefully because it involves the most dangerous area of the sleeve construction. The authors believe closure of the hiatus should be performed posteriorly. Non-absorbable suture material should be used for approximation of the crura. Additionally, one should not hesitate to use pledgets for reinforcing the knots in order to reduce the risks of the suture material cutting through the crural muscle fibers. One can use Teflon patches or better still, patches of absorbable material such as Surgicel (see Fig. 41.10), because it is biodegradable and has bacteriostatic and hemostatic properties.

41.8 Reoperation for Excessive Weight Loss

There is a paucity of literature on this issue. In exceptional cases, patients suffer from excessive weight loss after LSG. This condition may have to do with too small diameter of the gastric tube, or with a stenosis preventing adequate nutrition. Before these two conditions are corrected, the nutritional status of the patient must be addressed because restorative surgery performed on a malnourished patient may

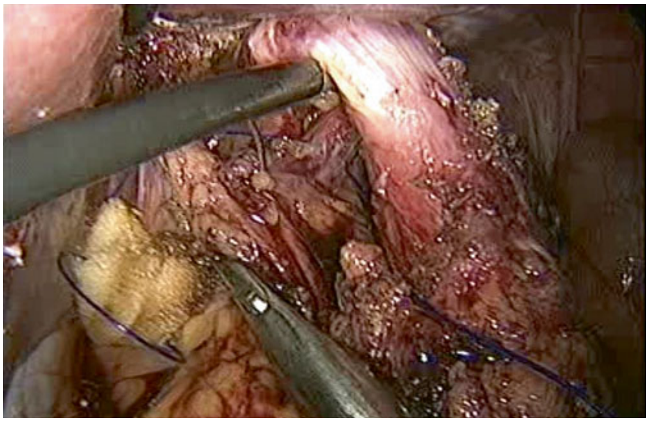

Fig. 41.10 Hiatal hernia repair using pledgets to buttress crura during suture approximation of crura

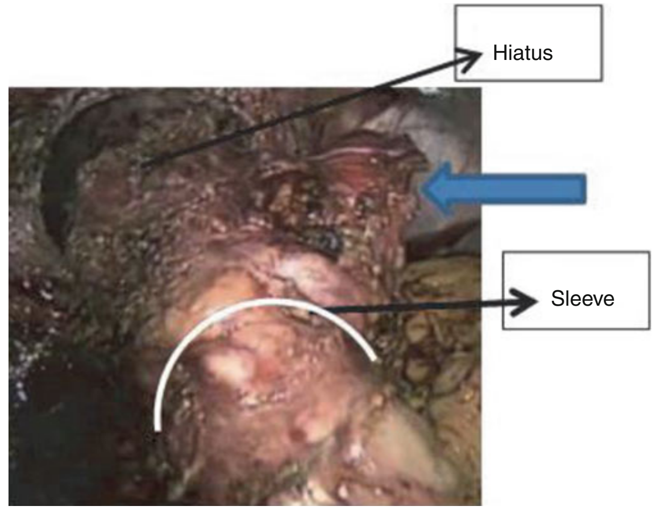

Fig. 41.11 Post-reduction of a mediastinal migration of an expanded fundus

prove to be dangerous. Enteral feeding is the preferential route of feeding. It is done by either starting to feed the patient via a nasojejunal tube or by performing laparoscopic jejunostomy followed by tube feeding rather than using parenteral nutrition. Parenteral nutrition is more expensive and exposes the weakened patient to potential infectious complications. Once the patient achieves an adequate nutritional state, corrective surgery can be undertaken. Stenosis is rectified as mentioned above. In case of too narrow a sleeve, it is sensible to transform the sleeve in to an RYGB. Another option is to perform seromyotomy, but, as mentioned above, this procedure probably carries too significant risks for leaks to be considered in this context.

41.9 Techniques for Reoperation After Sleeve Gastrectomy

Except for the DS, all reoperations on the gastric sleeve should involve full dissection of the hiatus. This is essential because quite often the upper part of the staple line will have migrated inside the mediastinum. We have encountered many cases where the angle of His had indeed migrated in to the chest, because of which the fundus expanded inside the mediastinum (see Fig. 41.11). This evolution causes marked dysphagia as well as reflux and regurgitations. In cases where the gastroesophageal junction is difficult to reduce into an intraabdominal position, we recommend transecting the anterior vagus nerve to obtain more slack in repositioning the entire cardia.

When performing dissection of the sleeve body, attention must be paid to minimize unnecessary dissection at the lesser curvature because this part of the stomach harbors all the remaining blood supply to the sleeve. Hence, when the stomach is transected as for wedge resection of the sleeve, it is advisable to dissect the greater curvature side and perform the staple transection from left to right. With this technique, the lesser curvature is dissected posteriorly, which is easily achievable by lifting the transected proximal part of the stomach anteriorly, and stays in very close vicinity of the serosa. We believe that this strategy avoids undue damage to the vasculature and indeed to Latarjet's nerve or the posterior nerve of the lesser curvature because dissection can be carried out primarily in the lesser sac that usually shows few, if any, postoperative adhesions. According to some, not damaging Latarjet's nerve may be important in preserving the pyloric function.

Another important area to be cautious in the dissection is the staple line. The staple line is usually quite hidden because of omental adhesions and also because of fibrous changes overlying this region. Obviously, one must avoid the staple line when performing seromyotomy because it will hinder incision and may cause convection burn wounds if electrical energy is used. When the decision is made to cross staple, a sufficiently larger staple height (green/purple/black load) must be chosen in order to accommodate thicker gastric tissue or scar.

The last important element to take into account in revisional surgery after LSG is the gastric antrum. Sometimes, the residual antrum is too large, because surgeons preserved a substantial part of this area in the earlier years of sleeve resection. Resecting part of the antrum may however prove hazardous, not only because of the inherent thickness of the gastric wall at that level, but also because quite often the greater curvature part of the antrum will be even thicker secondary to postoperative fibrous changes. Moreover, sometimes the antrum will be covered by the end of the suture line that may have been placed by the previous surgeon. We recommend that if resection is the preferable option, taller staple heights should be used. On the other hand, a novel alternative is to plicate a substantial part of the lateral aspect

Key Learning Points

- Weight regain is frequent after sleeve gastrectomy (SG) and may be addressed by duodenal switch, resleeve (in case of anatomical abnormality), or Roux-en-Y gastric bypass (in case of severe reflux without significant hiatal hernia).
- Severe stenosis occurs in up to 3 % of the cases after laparoscopic sleeve gastrectomy (LSG) and may be corrected surgically by a seromyotomy, by a wedge resection of the stomach, or a Roux-en-Y gastric bypass.
- Hiatal hernia with gastroesophageal reflux (GERD) is a frequent condition in the long term follow up after sleeve gastrectomy and may require reoperation.
- Chronic leaks after LSG are best treated by the placement of a Roux limb on the defect.
- Reoperations after SG warrant special technical measures to avoid ischemic incidents. The lesser curvature should be avoided as much as possible.

of the antrum rather than resecting it. However, care should be taken not to be too radical when performing plication because the invaginated part of the stomach is often very bulky and may obstruct the gastric lumen, so the use of a bougie during plication would be sensible.

Conclusion

Over a period of time, a substantial number of patients will require revisional surgery after LSG because of complications or weight loss issues. The favored revisional procedure for weight loss issues is currently DS, the only procedure that provides a statistically significant additional weight loss overall. However, the potential nutritional deficiencies associated with the procedure and also the limited experience with it at some centers must also be borne in mind. DS may only fit selected group of patients who could commit to long term follow up, otherwise the RYGB may be more appealing to some. A selected group of patients may benefit from other revisional procedures including reresection, such as resleeve or wedge resection, but either of rescue techniques is associated with high rates of complication. Although novel single anastomosis and bipartition procedures are gaining popularity as primary bariatric procedures, there is little data so far to support them as revision or rescue procedures for weight issues with SG. RYGB, despite being used by some centers successfully for revising the sleeve, is often reserved to cases of weight issues complicated by severe GERD. Significant, symptomatic stenosis is best addressed by a Roux-en-Y reconstruction, but wedge resection of the stomach may be utilized as a novel approach in experienced hands. However, it is best not considered as the primary option until there are case series with larger number of patients to support its efficacy. Seromyotomy nowadays is only used to correct the unduly small diameter of the sleeve in some malnourished patients, but once again in the less experienced hands, RYGB should be the preferable option. In case of persisting leaks after LSG, we recommend decompressing the sleeved system and laparoscopically suturing the defect to a Roux limb. Reoperation on a sleeved stomach, however, demands some specific techniques to avoid ischemic damage and special attention must also be paid to the hiatus to rule out hiatal hernia.

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Revisional Surgery after LAGB

42

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Abstract

Laparoscopic adjustable gastric banding (LAGB) is generally safe and well tolerated but complications are not infrequent. As with all other bariatric procedures, there are patients who experience poor weight loss or even weight regain at long term follow up. Some of these complications require prompt management whereas more chronic problems require careful work up involving the multidisciplinary team. All complications require a resolution and revision tailored to the individual. Revision of failed or complicated LAGB should be performed by an experienced bariatric team. A wide range of endoscopic and laparoscopic procedures can be offered to patients with LAGB complications. Management of these issues often requires explanting the device, with or without proceeding to more definitive measures. Invariably, there will be a subgroup of patients with interval weight regain, especially if the gastric band is removed without any immediate salvage or replacement procedure. Redo surgery for LAGB is still a gray area of bariatric surgery. Large experiences with long follow up are lacking and high grade level evidence based experiences are also absent. Overall, outcomes in terms of weight loss and complications are controversial according to different experiences.

Keywords

Laparoscopic adjustable gastric band • Roux-en-Y gastric bypass • Sleeve gastrectomy • Weight loss failure • Weight recidivism • Band complications • Revisional surgery • Band repositioning • Band removal

42.1 Introduction

Laparoscopic adjustable gastric banding (LAGB) is one of the most popular bariatric surgery procedures performed worldwide and has been shown to provide long term weight loss in the morbidly obese [1]. Although LAGBs are generally innocuous and well endured, complications are not unusual (see Chap. 31). Complications are generally device related and broadly categorized into primary failure with poor patient compliance or, not infrequently, mechanical or iatrogenic in origin. Complication rates are variable and differ from one institution to another [1–3]. There is also a significant subset of patients who experience very poor weight loss or even weight gain at long term follow up [4–6]. All these issues require revisions customized according to the complications that are associated with weight regain (recidivism).

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As surgery for morbid obesity becomes more accepted and commonplace, failure of bariatric procedures requiring further surgery will too. Reintervention is thus becoming an important public health issue, with serious health and financial implications [5, 7]. However, failure with gastric banding remains a poorly investigated area of surgical practice with no level one evidence available to help in decision making. Therefore, this is an emerging subspecialty within bariatric surgery and the best available evidence is discussed here.

Redo bariatric surgery can be differentiated into 'conversion' surgery or 'revisional' surgery. Conversion surgery is usually defined as the exchange from one bariatric procedure to another. Revisional surgery is defined as the modification of the primary bariatric procedure without major anatomical alteration. At this time, these terms are interchangeable and freely used to indicate a redo procedure, independently from their specific reasons.

42.2 Presentation and Preoperative Patient Evaluation

To a large extent, the preoperative evaluation of a patient with any LAGB complication, including failure to lose weight or weight recidivism, depends on the clinical scenario. Some patients will present as an emergency while other may be identified at a routine clinical review. In a stable or elective patient there is more time to investigate their symptoms.

Typical symptoms related to band complications are summarized in Table 42.1. Weight regain may be seen as a consequence of a loss of restriction (from a band erosion or damage to the band) and therefore increased appetite. It can also be due to maladaptive eating, making inappropriate food choices usually high in sugar and fat which easily pass through the band. This behavior may be psychological but may also indicate that the band is too tight or has slipped. The standard investigations to evaluate most band related symptoms are a gastrografin or barium contrast swallow and upper gastrointestinal endoscopy. Contrast can be injected into the gastric band port to detect fault in the device (Fig. 42.1).

Some patients may develop nutritional problems secondary to the complication which may render them unfit for revisional surgery before a period of dietary input and may require tubefeeding to augment their nutritional status if required. An algorithm is a useful guide on how to manage non-emergent complications (Fig. 42.2).

42.3 Preoperative Patient Preparation

The decision process has to be made in accordance with the local set up in a multidisciplinary setting. As with primary bariatric surgery, best practice should have the involvement of the full multidisciplinary team in this decision. It should be considered whether there are patient factors that have led to the failure of the gastric band, because this may influence the choice of the procedure that needs to be performed.

Nonemergent complications, especially those involving a mechanical fault, do not often involve maladaptive eating behavior, but nevertheless, psychological counseling may be required to address expectations as repeated failures could occur and infrequently patients would have developed maladaptive eating behavior to 'eat through the band.' Patients with poor weight loss or weight recidivism will most certainly benefit from having psychologic or psychiatric input; revision surgery itself is generally more risky, but patients are often willing to accept 'any risk' to pursue further weight loss. Once the multidisciplinary assessment has been completed, a decision of the most appropriate approach can be made with the patient. In order to give informed consent, the

Table 42.1 Symptoms and investigations of gastric band problems

Diagnosis	Typical symptoms	Investigations
Food bolus obstruction	Vomiting/regurgitation, dysphagia, abdominal/chest discomfort, suggestive history	Band defill, gastrografin x-ray, +/− upper GI endoscopy
Slippage/pouch dilatation Esophageal dysmotility	Vomiting/regurgitation, dysphagia, abdominal pain/discomfort, heartburn/volume reflux, chest pain	Gastrografin x-ray, +/− upper GI endoscopy
Intragastric migration (band erosion)	Asymptomatic >50 %, loss of restriction, weight regain, abdominal pain, evidence of intraabdominal sepsis, adjustment port infection	Gastrografin x-ray, upper GI endoscopy, +/− CT
Damaged band	Loss of restriction—may be gradual after a band fill, weight regain	Gastrografin x-ray, radiological band fill (introducing contrast into the system)
Maladaptive eating	Weight regain, patient's admission	Rule out anatomical concern: gastrografin x-ray, upper GI endoscopy, then dietetic evaluation
Failure to lose weight	Minimal weight loss	As above

GI gastrointestinal, *CT* computerized tomography

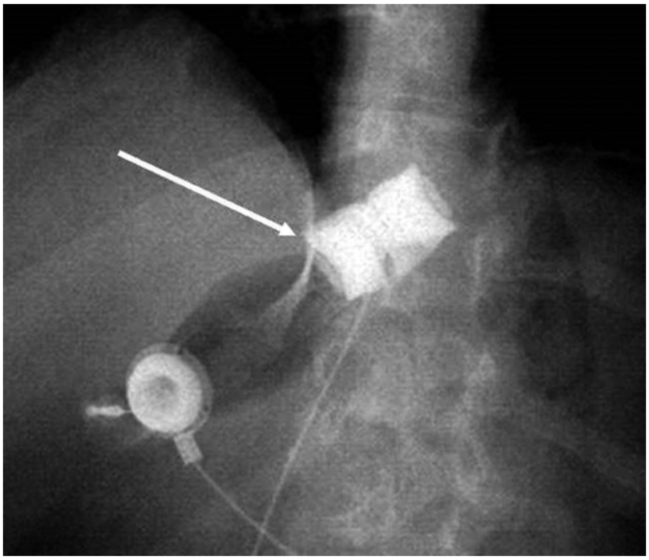


Fig. 42.1 X-ray showing leakage of contrast (*arrow*) from gastric band

patient should understand the available options and the reason why certain procedures are being recommended over the alternatives. The discussion should also explain that redo bariatric surgery conveys a higher surgical risk in terms of morbidity and mortality and may be less effective in terms of weight loss or comorbidity resolution than a primary bariatric procedure.

Redo surgery should be offered in centers with established multidisciplinary team used to deal with this cohort of patients. It is recommended that only surgeons with extensive bariatric experience and specialist training should undertake such work.

42.4 Redo Surgery: The Choice of the Best Procedure

Once the diagnosis is determined, the process can start to establish what intervention is required. In some cases, when patients have successfully lost weight or have maintained the weight loss in absence of life threatening complications, the primary band can be preserved and repositioned using the pars flaccida route [8, 9] but most cases of band failure will require its removal. It should not be forgotten that band removal often results in rapid weight regain [10].

For patients who have experienced good weight loss prior to developing a gastric band complication, especially if associated with resolution of any comorbidities, repositioning or replacing the band is an attractive option [8–12]. In cases of band slippage or gastric pouch dilatation, this can be a relatively straightforward procedure in expert hands but has a recurrence rate of around 10 % [1, 7]. If the original band requires removal, the decision on whether the band should be replaced immediately or delayed by several weeks will be determined by the mode of presentation, the diagnosis, patient factors and surgeon choice [12–15].

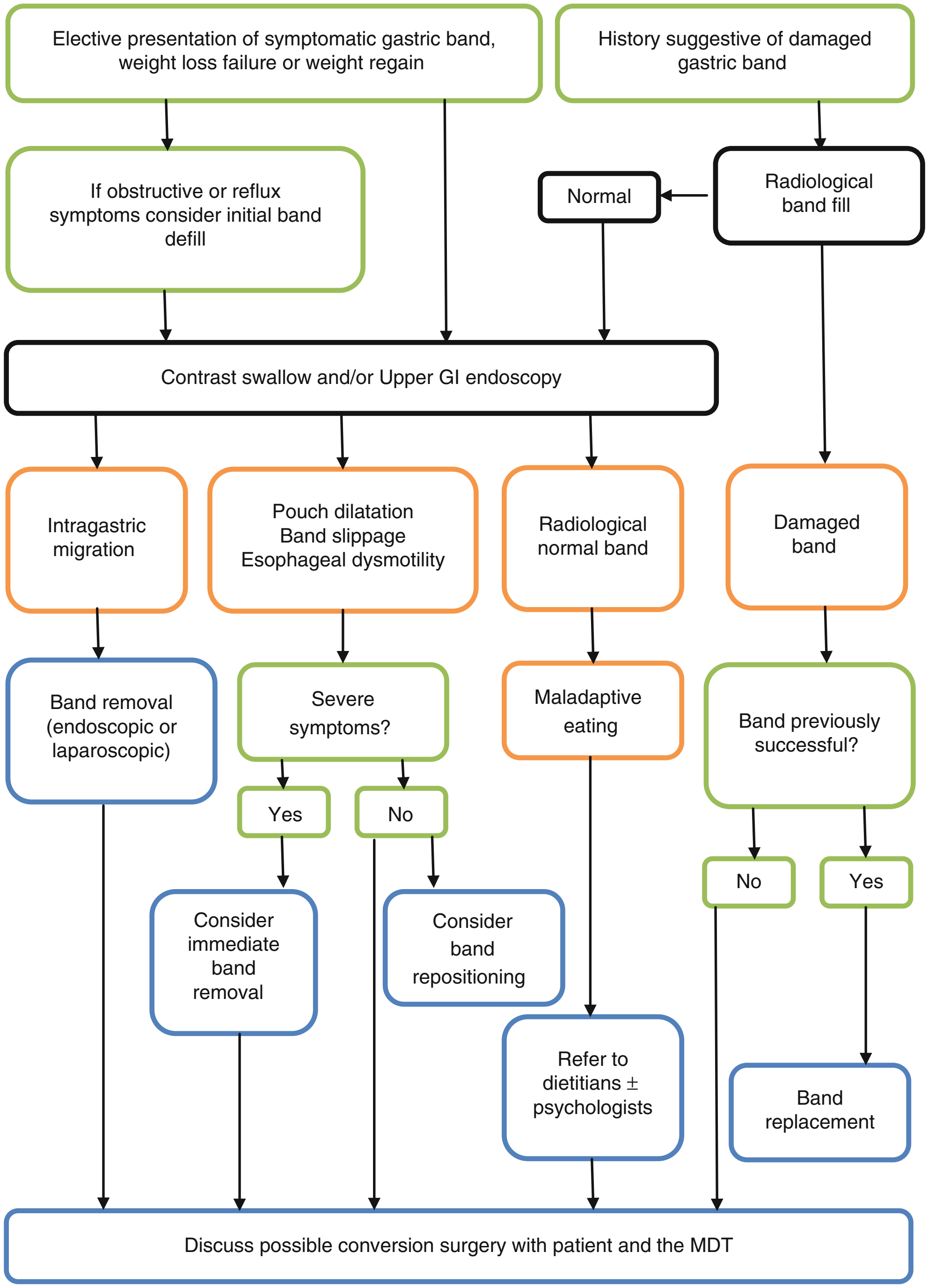
The management of intragastric migration of the primary band needs careful planning with band removal performed either endoscopically or laparoscopically (see Chap. 31). Intragastric migration is not an absolute contraindication for replacement of the band, although the reported success of this intervention is variable, with recurrence rates between 9 and 40 % [12, 16]. The risk of recurrence can be reduced by delaying the replacement, so that it is not performed at the same time as the removal. Also the best outcomes have been seen in patients who initially had the gastric band inserted with a perigastric approach, with the pars flaccida approach utilized for the revisional operation [8, 10, 12].

For patients who never experienced successful weight loss with a gastric band, its replacement is unlikely to yield better results and most surgeons would advocate an alternative approach [7]. This is also the case for patients who have already had a gastric band replaced once and then develop a subsequent complication. Since there is limited literature available on which revisional surgery should be chosen for a failed gastric band, the decision should be made by the surgical team largely based on their own experience and expertise [17, 18]. Randomized controlled trials in this field are lacking, and the majority of reported experience present a low patients number and limited follow up. In a systematic review, Elnahas et al. indicated that failed LAGB is best managed with conversion to another bariatric procedure [4]. Stable weight loss was achieved with salvage procedures, and following 12–24 months from revision, the mean percent excess weight loss (%EWL) was: 22 %, 57.8 %, and 47.1 % in laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (LRYGB), and bilio-pancreatic diversion with duodenal switch (BPD-DS), respectively.

42.5 Open Versus Laparoscopic Surgery

In experienced hands a vast majority of revisional bariatric surgery can be performed laparoscopically, even for those who initially had an open operation. This approach is associated with a lower mortality and complication rate compared to laparotomy. Though there may be circumstances where a minimally invasive approach is unsuccessful or unfeasible, an initial laparoscopy should be considered first for the vast majority of patients [19, 20]. Gagner et al. [21] converted 24 patients with primary bariatric surgery to gastric bypass via laparoscopy with only one patient converted to laparotomy. There was no report of mortality and only six (22 %) experienced complications [21].

Fig. 42.2 Suggested protocol for investigating gastric band patients with potential complications. *MDT* Multidisciplinary team



42.6 One Stage/Two Stage Surgery

An important consideration when performing redo surgery after gastric banding is whether to perform the band removal and the subsequent intervention as one or two steps. There are some instances where the decision is simple, such as replacing a broken band, which can be done as a 'railroad' technique (Figs. 42.3 and 42.4) by coupling a new band onto the old one and pulling it through the tunnel [22]. A few surgeons would choose to immediately continue with another procedure after removing a band for intragastric migration.

Although single stage approach with concomitant band removal and sleeve gastrectomy is feasible [23], evidence generally seems to favor a two stage approach for conversion to a LSG [24], with several weeks delay between removing the band and performing the sleeve gastrectomy. This will be discussed later in the LSG section. There is a divide in opinion about the optimal approach to band replacement and LRYGB. The benefits of a single stage approach are that it

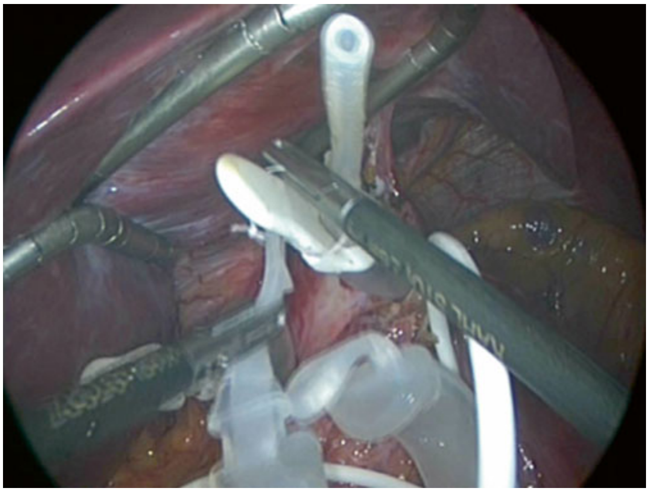


Fig. 42.3 Linking a new gastric band to an old device to facilitate replacement

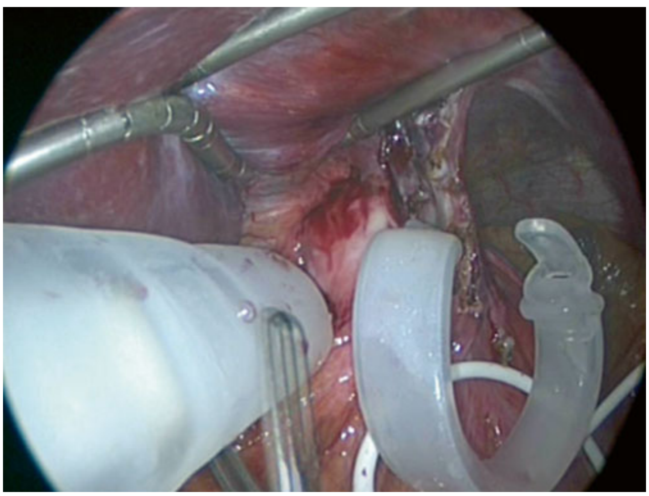


Fig. 42.4 Pulling a new gastric band through the retro-gastric tunnel after coupling to an old gastric band

involves a single general anesthesia and avoids weight regain between the two procedures. It also avoids the formation of adhesions in the interval between the two procedures that may make the subsequent operation more difficult or even impossible to perform safely. If a one stage procedure is chosen, the surgeon is not obliged to adhere to this plan if removing the band proves to be more complicated than expected, thus changing to a two stage approach to minimize unnecessary risks is perfectly acceptable.

Proponents of a two stage approach are often concerned about the impact of the fibrous capsule that forms around the gastric band distorting the anatomy or making the tissues excessively thick. This could potentially compromise the safety of the operation when converting to a gastric bypass or sleeve gastrectomy and may increase the risk of stricture formation at the gastroenterostomy of a gastric bypass [6]. Delaying the second procedure may allow the capsule to soften and permit the tissues to "normalize' between the two stages. The surgeon needs to decide whether to fully mobilize the gastrogastric tunnel during the primary procedure, allowing use of the band as a guide to this dissection but potentially leading to the formation of new, unpredictable adhesions or to deal with this during the second stage having allowed the capsule to soften but potentially making this dissection less straightforward.

Another reason why surgeons may opt for a two stage procedure is time pressures on the operating list, with a single stage redo procedure being less predictable in terms of operating time. If the operation is split into two stages, it can allow the surgeon to assess the feasibility and estimate the time required for the second stage more accurately to make best use of their resources [6, 12, 25]. Overall, a recent systematic review found it difficult to draw any definitive conclusion about the preferable number of stages for revisional bariatric surgery [26].

42.7 Laparoscopic Sleeve Gastrectomy

Long term results from primary laparoscopic sleeve gastrectomy (LSG) have demonstrated that weight loss and comorbidity improvements comparable to those seen in LRYGB patients are possible [27, 28]. In addition, LSG is free from the risks of an anastomosis, internal herniation, dumping syndrome or marginal ulceration [29]. The success with this procedure has led to the use of LSG as a conversion operation after LAGB failure, but there is currently very little published evidence on this emerging discipline.

The first reported LSG following a gastric band was published in 2005 by Baltasar [30]. This has been followed by several small cohort studies and case series. The indications for LSG over other options are yet to be fully determined [24] but are broadly similar to that for LRYGB. Patient's choice and surgeon's experience should perhaps be the main criteria when choosing a surgical option after gastric band failure. Given the likelihood of developing postoperative gastroesophageal reflux disease (GERD) following LSG, the 'relative' contraindications for conversion to LSG include the presence of a hiatus hernia, symptomatic GERD or reflux esophagitis on endoscopy. LRYGB is the preferred procedure in such patients [31].

Several small studies initially demonstrated that LSG is a feasible operation following removal of a gastric band and can be performed with a low mortality rate [23, 32–34]. Conversion to open procedure and 30 days mortality was usually absent [34]. However, there is a tendency towards a higher rate of stapleline leakage (0–33 %) and more complications related to bleeding (0–20 %) than following a primary LSG [26, 32–35]. Single stage gastric band removal and concomitant sleeve gastrectomy is certainly feasible with acceptable morbidities [36]. One way to reduce potential complications is to adopt a two stage strategy for conversion from LAGB to LSG. Noel et al. reported a series of 300 patients who underwent laparoscopic sleeve gastrectomy after gastric band failure [35]. They observed a primary complication rate of 2 %, a leak rate of 1.6 % and a mean percentage of excess weight loss (%EWL) of 62.6 ± 22.2 %. More recent series have demonstrated a much lower leak rate of less than 1 % with a two stage procedure [24, 33–35, 37] so this should currently be considered the best approach for conversion to LSG.

The weight loss seen after conversion to LSG varies between series and is generally inferior to that seen after a primary LSG [35]. More recent data, from larger series and using both one-stage and two stage techniques, have shown more acceptable EWL between 65 and 80 % [35–37]. However, data from the reported studies are on an intention to treat basis that will include patients who have required further intervention, perhaps conversion to a gastric bypass.

Technical aspects such as optimal bougie size, stapling distances from the pylorus and the cardia, and whether to use stapleline reinforcement still require investigation. However, it would be logical to use taller staples for stapling thicker stomach tissues, particularly adjacent to the previous gastric band location. It is also sensible to avoid an overly narrow sleeve in an attempt to reduce the risk of stapleline leak in this group of patients. Further large scale studies are required to fully determine the optimal approach.

42.8 Laparoscopic Roux-en-Y Gastric Bypass (LRYGB)

Due to its familiarity, generally reliable weight loss and positive effect on comorbidities, laparoscopic Roux-en-Y gastric bypass (LRYGB) has naturally become the most popular choice in revisional surgery after gastric banding. The lower pressure in the gastric pouch as compared to a sleeved stomach also makes LRYGB a more sensible choice for patients who have significant reflux symptoms or evidence of esophageal dysmotility [27, 28].

As with other options, there is little evidence to determine the optimum configuration of the bypass in terms of limb length, pouch size, stoma size, and others. However, pooled data demonstrates LRYGB to be a safe procedure following gastric banding, with a very low mortality and a conversion to laparotomy rate of less than 2 %. The most frequently quoted morbidity data relate to anastomotic leak and bleeding, with respective rates around 1 and 2 % being reported [17, 18, 26, 36, 38].

Coblijn et al. in their systematic review reported the absence of perioperative mortality in patients who underwent LRYGB as revisional procedure after LAGB [26]. Of 588 patients in this review the rate of conversion to laparotomy was 2.4 %, and the rate of reoperation was 6.5 %.

In terms of configuration, there appears to be no reason to recommend a change from the surgeon's standard approach to a primary gastric bypass when performing revisional surgery (Video 42.1). The common area where deviation may be needed is in creating the gastric pouch. Adhesions, the gastrogastric tunnel and the capsule formed around the band usually make the tissues around the hiatus thickened and sometimes distorted or friable. It is advisable to excise part of the capsule to reduce the thickness of the tissues before stapling, and if in doubt, taller staples should be used. It is important to fully mobilize the gastrogastric tunnel to avoid stapling across a folded fundus, that equates to four layers of tissue, which would result in leaving an ischemic portion of fundus within the stapleline. Once the tunnel is mobilized, if there is any concern about the quality of the tissues, it is prudent not to take risks and leave either a wider or longer pouch to avoid an anastomosis or stapleline across damaged tissue. Whether the gastrojejunal anastomosis should be placed above, across or below the gastric band capsule should be left to the individual surgeon's preference, but once again bearing in mind the thicker gastric tissue adjacent to the capsule. The hiatus should be dissected in case of concomitant hiatal hernia and be repaired at the time of band removal using nonabsorbable sutures for the cruroplasty.

Martin-Perez et al. in a retrospective study involving 59 patients, who underwent revisional LSG or LRYGB after LAGB and showed both procedures to be safe and feasible, however, more superior for further weight loss was LRYGB [38]. Excess weight loss is often inferior to that seen after primary surgery and it may be that these technical issues explain the inferior results seen after revisional LRYGB compared to primary procedures. Sleghtenhorst et al. compared the effects of LRYGB as primary procedure to the same procedure as a revisional approach after LAGB after 1 year of follow up with no mortality in either group, but significantly greater weight loss with the primary procedures (71.6 % ± 20.8 % versus 48.4 % ± 26.8 %) [39]. However, some authors have hypothesized that the differences seen may be more behavioral, with patients perhaps adopting maladaptive eating habits such as increased caloric or 'smell food' intake, due to their band failure. These habits may not be reversed by conversion to LRYGB, thereby diminishing its effects [39], although failure of weight loss with a gastric band does not necessarily predict failure of weight loss after an LRYGB [18].

42.9 Laparoscopic Biliopancreatic Diversion with Duodenal Switch

Another option that some surgeons have adopted for patients after failed gastric banding is converting to a biliopancreatic diversion with duodenal switch (BPD-DS). There is very little data available on this option, but advocates propose it as an option for patients with a body mass index (BMI) over 45 kg/m^2 while others prefer a BMI of more than 50 kg/m^2. Duodenal switch was first used as a revisional procedure in 2001 to treat a patient who had undergone a vertical banded gastroplasty with failed weight loss and nonresolution of diabetes [40]. The use of BPD-DS in failed gastric banding was first described by Gagner's group in 2002 in two patients [41]. From the limited literature, BPD-DS appears to offer superior weight loss to LRYGB but this is at the expense of a significantly higher complication rate (62 % compared to 12.5 % in one small series) [42, 43]. Dapri et al. reported laparoscopic conversion from LAGB to BPD-DS in one step in 31 patients [44]. Despite one mortality in this series, they stated that this surgical redo option can be considered feasible and effective in LAGB failure. Until more evidence is available, this should only be considered an option in units that have suitable experience of BPD-DS as a primary procedure.

42.10 Other Procedures

Laparoscopic mini gastric bypass (MGB), a sleeved gastric tube with Billroth-II anastomosis, has also been proposed as an alternative to Roux-en-Y gastric bypass for morbid obesity. In 2006, Rutledge reported three patients with LAGB converted to mini gastric bypass [45]. This conversion was considered safe, with high patient satisfaction, rapid recovery and valid weight loss. Noun et al. provided the only other published report of using MGB as a revisional operation after failed restrictive procedures and confirmed feasibility, minimal morbidity with reasonable fall in BMI, but only very short follow up was provided in this small series [46]. At present, larger series, comparative studies with other redo option after LAGB, and longer follow up data are lacking.

Recently, gastric plication as used by Talebpour and Amoli, was described in a novel case report for failed gastric banding [47], and subsequently it has been used in conjunction with gastric banding as a synchronous primary procedure with reasonable short term success [48, 49]. However, so far there has been no further published reports on its usage as a revision procedure for failed gastric banding, hence, it cannot be recommended at this junction as a revisional option.

Conclusion

Laparoscopic gastric banding is a popular and important bariatric operation. For many patients it offers good weight loss with the associated benefits on their comorbidities. However, there are a significant percentage of gastric band patients that will encounter difficulties due to failure of weight loss, weight recidivism or complications specific to the procedure, such as slippage or intragastric migration. It is important for a bariatric surgeon to recognize the symptoms of these complications, which can occasionally be life threatening, and to investigate them appropriately.

Inevitably, most of these difficulties will lead to a need for the gastric band to be removed. Bariatric surgeons, therefore, need a strategy to deal with those who have not lost weight and those who regain weight when the band is explanted. There is no consensus of opinion about the ideal management of these patients but the most widely used options are gastric band replacement, conversion to LRYGB in one stage and conversion to LSG in two stages.

Although mortality is low, all these options are associated with higher morbidity when compared to primary bariatric surgery. There also appears to be a trend towards a lower excess weight loss, however, longer follow up is required to really understand the long term outcomes of revisional surgery for LAGB. There is also a need for a large scale, randomized controlled trial to determine the best option for these patients.

As this involves higher risk and is more specialized surgery, it should be ideally performed only in high volume specialist centers within the context of a supportive multidisciplinary team.

Key Learning Points

- Nonemergent complications of gastric bands are not infrequent and should be managed in the multidisciplinary setting after careful evaluation.
- Gastric band replacement is an acceptable option for patients who have device-related failure but previously had good results.
- There is limited evidence for the 'best' revisional procedure after gastric band failure, so any further surgery should be carried out in a setting experienced in dealing with revisional surgery, balancing benefits to the patients against the risks with an understanding that revisional procedures may offer less weight loss than primary procedures.
- Staging the operations with an interval may reduce risks associated with immediate revision or conversion to another procedure.
- Minor technical modification may be necessary during revisional procedures to avoid having an anastomosis across the capsule or stapling across extra thick tissues, and the usage of taller staples would be advisable when staplers are utilized.

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Section IX

Other Operations for Obesity

Honorary Section Editor - Conor J. Magee

Bariatric surgery remains an imperfect solution to the problem of morbid obesity. Furthermore, the ideal bariatric procedure does not exist. This is not surgical nihilism, but rather an appreciation of the complexity of the problem facing us. Fortunately, we surgeons are a redoubtable profession and recognise that improvements and innovation can provide real benefits for our patients.

Novel operations, or modifications of the "standard" bariatric procedures seek to address their shortcomings (such as weight regain, risk of leak) and may become more established as long-term results are published.

I am pleased that this section concerning "Other operations for obesity" has attracted world renowned authorities to present their thoughts regarding the role of less well-known procedures (such as the bilio-pancreatic diversion with or without duodenal switch), modifications to conventional procedures (the banded gastric bypass, mini-gastric bypass, single anastomosis duodeno-ileal bypass) and more novel procedures (gastric plication, gastric pacing). The authors provide an overview of each procedure with technical details for those who may be faced with patients who have had these operations. Each chapter will include a synopsis of the available evidence, as well as learning points for the reader.

The role of many of these procedures still remains undefined. It is important that any surgeon wishing to introduce these procedures is appropriately mentored and be prepared to publish their results. It is only through transparent presentation of our experiences with more novel techniques that we can make evidence based decisions on their safety, effectiveness and durability.

43 Laparoscopic Mini-Gastric (One-Anastomosis) Bypass Surgery

Robert Rutledge, Kuldeepak S. Kular, and Mervyn Deitel

Abstract

The mini-gastric bypass (MGB) consists of a long, narrow lesser curvature gastric pouch beginning below crow's foot, extending lateral to the esophagogastric (EG) junction, with a wide anastomosis to an antecolic jejunal loop at a point about 200 cm distal to Treitz' ligament, providing malabsorption. The operation is brief, simple and safe, has provided reliable weight loss, and is now being increasingly performed. If needed, the anastomotic site can be easily adjusted for body mass index (BMI). The technique, complications and results are reported.

Keywords

Mini-gastric bypass • One-anastomosis gastric bypass • Omega-loop gastric bypass

43.1 Introduction

Since the first mini-gastric bypass (MGB) in 1997, the operation is becoming more and more popular, due to increasing reports supporting the operation as a short, straightforward procedure with low complication-rates and excellent outcomes [1–19]. This chapter includes a brief review of the physiology of the MGB (also called the *one-anastomosis gastric bypass* [OAGB] and the *omega-loop gastric bypass*). The information presented is formed by the combined experience of Rutledge and Kular with about 9,000 MGBs.

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In India, Kular and Manchanda started MGB and documented that the MGB can be performed in a consecutive series of more than 1000 patients with extremely low risk and excellent outcome in a community hospital [17]. The emerging international reports of success with the MGB including controlled prospective randomized trials by Lee et al. have added to the current interest [5, 12].

With widespread use of the gastric band, the sleeve gastrectomy (SG) and the Roux-en-Y gastric bypass (RYGB), the question arises of "Why consider MGB?" The MGB overcomes some limitations of the other operations and offers many features of an ideal bariatric operation [1]. The MGB is a short, simple, low-risk operation. It is easily reversed or revised as needed. It has now been shown in short- and long-term studies that MGB results in excellent weight loss, good resolution of co-morbidities and high levels of patient satisfaction [14–19]. In addition to the above advantages, it also offers the advantage of the ease of revision or reversal of the MGB [10, 11, 20, 21].

The power of the MGB comes from the fact that it has restrictive and malabsorptive components; additionally it produces hormonal changes and also lowers the patient's bile acid pool. Studies show that a bariatric operation which includes a gastric and intestinal component outperforms purely gastric restrictive procedures like the band and sleeve gastrectomy [12, 14, 15, 18, 22, 23].

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43.2 History of the Mini-Gastric Bypass

Historically, the horizontal "Mason loop" bypass for morbid obesity was a modification of the high subtotal gastrectomy with Billroth II reconstruction, but being anastomosed high near the esophagogastric (EG) junction, it had the potential for dreadful postoperative leaks due to tension on the high gastrojejunostomy (GJ) and the possibility of bile reflux. Thus, the Roux-loop (RYGB) was introduced by Griffin to overcome these concerns [24, 25]. The RYGB is not an ideal procedure, because of issues such as technical demand, internal hernia, gastrojejunal stricture, late weight regain, and difficulty reversing and revising [26–28]. These factors led to the development of the gastric band and sleeve gastrectomy.

The MGB was designed to overcome limitations of the RYGB and improve its outcomes [12, 29]. The goal was to create a powerful operation that was simple with minimal complications, a short learning curve, a high degree of efficacy, and also that was easily reversed or revised [28, 29]. The Billroth II with antrectomy has been performed continuously since the late 1800s, as a standard general surgery operation for peptic ulcer or antral carcinoma. Unlike the Mason loop, the MGB constructs a lesser curvature gastric conduit to or below "crow's foot."

An erroneous objection to the MGB has been the potential development of gastro-esophageal cancer from bile reflux. Data show, the Billroth II gastrectomy is not associated with increased cancer rates [30–33]. Likewise, one of the authors (MD) has performed more than 1000 vagotomy and pyloroplasties (V & P) in the 1960/1970s, where bile moved proximal to pylorus, but gastric cancer did not develop after V & P. Furthermore, experiments with bile applied to the rodent's unique stomach found that proliferative lesions develop in the *proximal 2/3 which is squamous-cell,* but *not* in the *distal 1/3 which is glandular* and corresponds to the human stomach [34, 35]. Following all the other bariatric operations, more than 43 cases of gastric and esophageal carcinoma have been reported; however, after MGB, no carcinoma of the gastric channel or esophagus has been reported [36–39].

43.3 Technical Details in Performing the Mini-Gastric Bypass

This chapter describes our operative technique of MGB (Fig. 43.1). There exist various variations to the operation which are good, in particular the so-called one-anastomosis gastric bypass (OAGB) with an anti-reflux afferent limb described by Drs. Garcia-Caballero and Carbajo of Spain [2, 4, 13]. This chapter specifically focuses on the widely adopted technique of MGB developed by the authors.

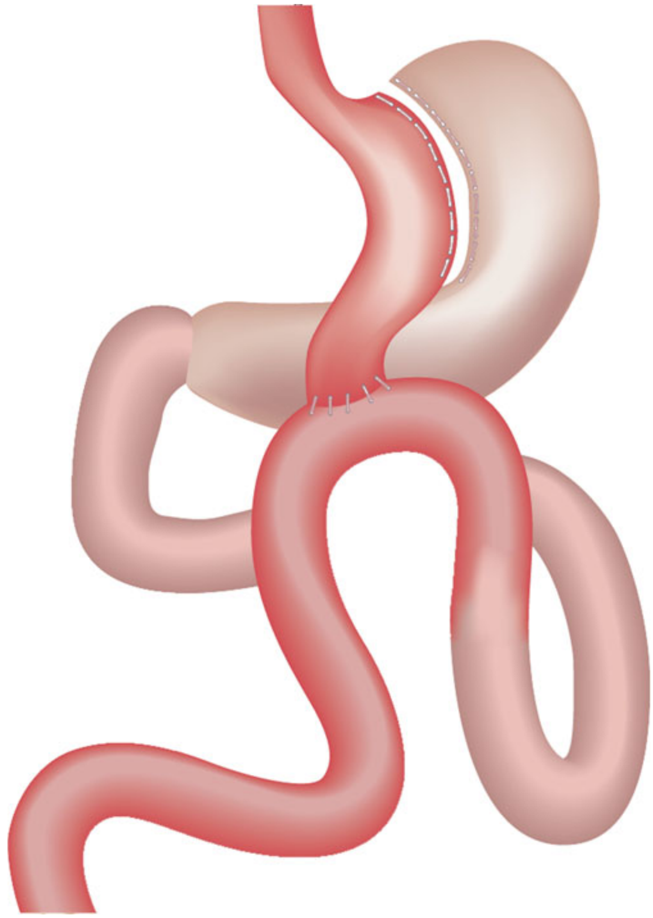

Fig. 43.1 Diagram of the mini-gastric bypass (one- anastomosis gastric bypass)

43.3.1 Patient Positioning

The patient is placed on the operating table, which is inclined to maximum reverse Trendelenburg and maximum left side up. This requires secure patient immobilization. The team should slowly test this position prior to draping the patient, to confirm the security of the positioning and the stability of the vital signs.

43.3.2 Ports

Five ports are placed in a "diamond-shaped" pattern in the upper abdomen:

- 12-mm camera port in the midline approximately two handbreadths below the xyphi-sternum (ignoring the location of the umbilicus).
- 12-mm port in between the right midclavicular and anterior axillary line, 2–3 fingerbreadths below the right costal margin.

- 12-mm midline port (the surgeon's left hand working port), 2–3 fingerbreadths below the xyphi-sternum.
- 12-mm port in the left midclavicular line two to three fingerbreadths below the patient's left costal margin is the surgeon's right hand working port.
- 5-mm assistant port in the left anterior axillary line, 2–3 fingerbreadths below the left costal margin.

43.3.3 Constructing the Gastric Tube

The goal of this step is to eliminate the reservoir function of the stomach and to convert it into a non-obstructive extension of the esophagus. The mesentery at crow's foot (the junction between the antrum and the body) on the lesser curvature is dissected for 3–5 cm, making a window into the lesser sac, cleaning the stomach to the gastric serosa in preparation for the later gastrojejunostomy.

The first staple firing is critical in the creation of the gastric pouch. From the epigastric port angling down and toward the left lower quadrant, a 45-mm stapler is fired perpendicular to the lesser curvature. It is common for new MGB surgeons to perform this step incorrectly, as they often come from a RYGB background. The pouch in the RYGB is designed to be small and "tight," which is an underlying mechanism of action of the RYGB. However, the gastric tube of the MGB is not designed to be "obstructive"; although it does have some restrictive effect on intake, it is explicitly designed to allow the patient to eat comfortably. The MGB needs to have a very long gastric pouch that is non-obstructive. To re-emphasize, the first stapler firing is critical; it needs to be *perpendicular* to the lesser curvature and far down on the lesser curvature to create a long pouch, keeping the daily stream of bile well away from the esophagus.

Using the left hand working port or the patient's right side port, a second stapler is fired. Where the first stapler was fired from superior to inferior perpendicular to the horizontal lesser curvature of the stomach, this next firing begins to turn the staple-line to *now run parallel* (not perpendicular) to the lesser curvature in the proximal antrum.

A bougie is advanced under direct vision. The surgeon maintains attention on the left upper quadrant to report to the anesthesiologist if he/she can see any problems. Similarly, the anesthesiologist will continually describe the distance that the bougie has advanced as he proceeds.

Then, through the patient's left subcostal (surgeon's right hand working) port and *parallel* to the lesser curvature, the 60-mm stapler is repeatedly applied well lateral to the esophagogastric (EG) junction to reach the top of the stomach.

To restate, this technique is opposite to SG surgeons who advocate a medial dissection into the area of the cardia, esophagus and crura. While dissection of the EG junction may be necessary in the sleeve gastrectomy (SG) to remove medial fundus, reported leak rates for the SG procedure indicate that 3.5 out of every 100 primary cases may face the devastating and deadly complication of a *high* peri-esophageal leak [23, 40]. In the MGB, the EG junction is explicitly avoided and *not* dissected.

As to the use of the bougie in the MGB, beware of an attempt to get greater weight loss by the error of tightly applying the stapler to the bougie. Tension next to the bougie as it closes can lead to an insecure staple-line along the tube and the feared complication of leak. Thus, with attention to meticulous handling of the tissue, try to make a relatively narrow pouch but *never* a tight pouch.

The goal of the gastric pouch in the MGB is to remove the reservoir function of the stomach and convert to a purely transport tube, that is to convert the stomach into a non-obstructed extension of the esophagus, where food does not stay in a reservoir but is dumped into the lumen of the jejunum.

43.3.4 Running the Bowel and Construction of the Gastrojejunostomy

Attention is turned to the left abdominal gutter. The omentum is retracted medially, and the ligament of Treitz is identified. The bowel is run to a distance of approximately 200 cm distal to the ligament of Treitz. The length of the bypass is related to the amount of weight loss. The new MGB surgeon may be tempted to offer longer and longer bypasses; however, experience has shown that as the length of the bypassed jejunum increases, the risk of excess weight loss and malnutrition increases [41].

The Harmonic scalpel is used to create a gastrotomy and jejunostomy. A linear 45–60 mm stapler is used to create the gastrojejunostomy, and the stapler defect is closed using either hand-sewn or stapled techniques. A methylene blue leak test is advised for newer surgeons. As experience reaches 1000 cases, the test becomes superfluous as the leaks are now not found at surgery. No nasogastric tube or abdominal drains are used (Figs. 43.2, 43.3, 43.4, 43.5, 43.6, 43.7, 43.8, 43.9, 43.10, 43.11, and 43.12).

43.4 Critical Factors in Use of the Staple-Gun in Mini-Gastric Bypass

43.4.1 How to Prevent Staple-Line Bleeds

To prevent bleeding and obtain ideal form of the staple "B" formation, "go slow to go fast." How to stop bleeding: direct pressure. Warnings: select a stapler with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation. Do not attempt

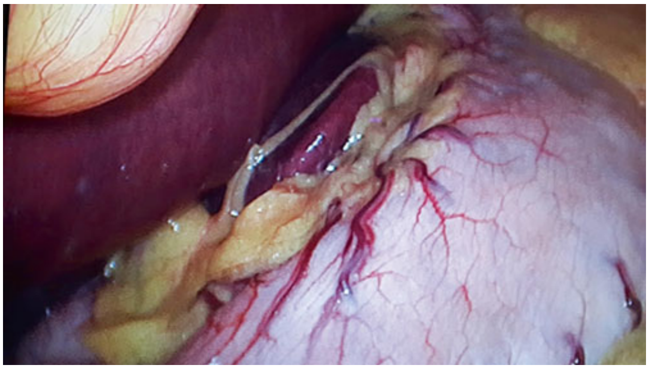

Fig. 43.2 Expected view of the abdomen using the ports described for the MGB. *On the left* is the *blue* retractor on the liver. *On the right* is the spleen. *On the lower left* is the omentum, *on the lower right* is the body of the stomach, and in the upper mid-portion of the picture is the inferior surface of the patient's left hemidiaphragm. The instrument on the left is passed via the midepigastric port using the left hand

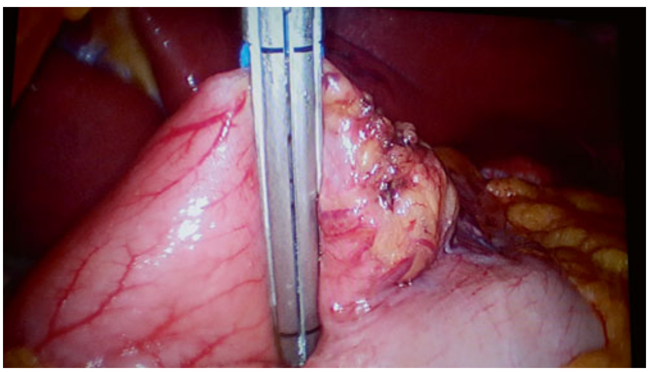

Fig. 43.3 The lesser curvature of the stomach has been skeletonized at the junction of the body and the antrum of the stomach and the first stapler is in place. Important, note the angle of the stapler, as it enters from the left upper corner of the screen and passes diagonally towards the right lower portion of the screen perpendicular to the lesser curvature

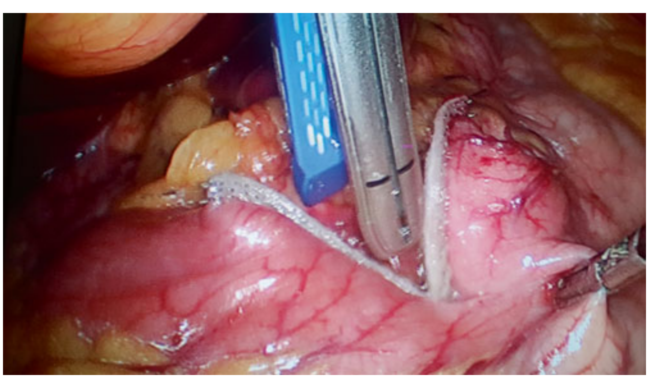

Fig. 43.4 The first stapler has been fired. This creates the new base of the gastric pouch and will be the location of the gastrojejunostomy. The stapler is passed via the midepigastric port using the left hand for this one and only staple firing

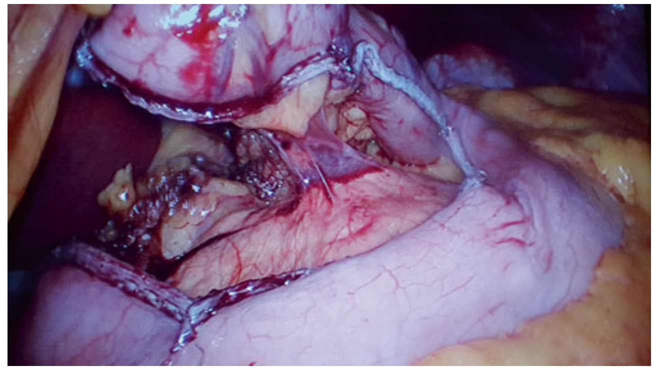

Fig. 43.5 The stapler is moved to the patient's left midclavicular line port and fired repeatedly parallel to the lesser curvature up towards the EG junction

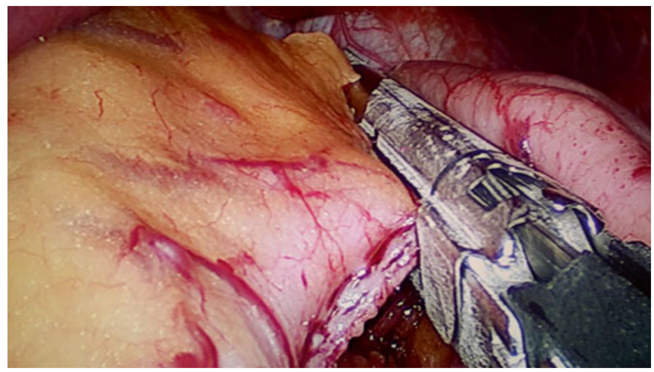

Fig. 43.6 Extreme care is used to avoid the junction and stay well away from this dangerous area as the stomach is divided completely

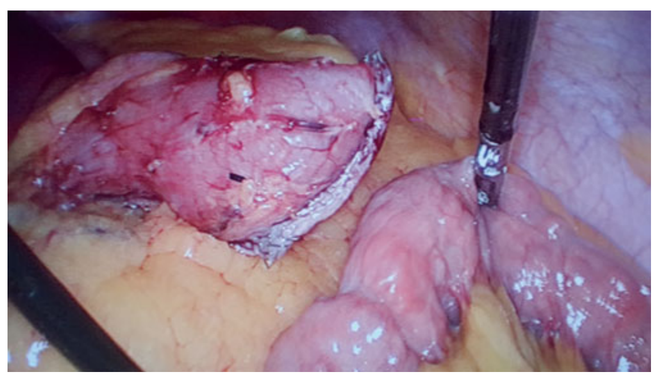

Fig. 43.7 The bowel is run to a distance of 2 m distal to the ligament Treitz and the loop brought up along the left gutter to the tip of the gastric pouch. It is never necessary to divide the omentum

to remove the shipping safety wedge until the stapler is loaded into the instrument. Do not squeeze the handle while pulling back the black retraction knobs. Do not attempt to override the safety interlock—doing so will render the stapler non-operational. Failure to completely fire the stapler

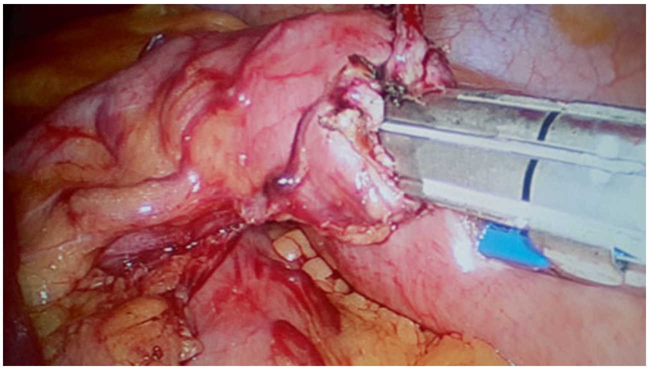

Fig. 43.8 A gastrotomy and enterotomy are created and a gastro-jejunostomy is created. Care is used to avoid a "twist" of the bowel loop

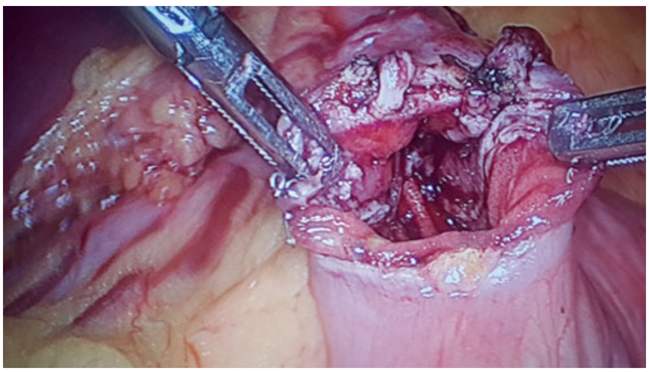

Fig. 43.9 The interior and exterior of the gastro-jejunostomy is inspected for bleeding and security of the anastomosis. The bougie is very slowly and gently passed across the anastomosis into the efferent limb in preparation for closure of the defect

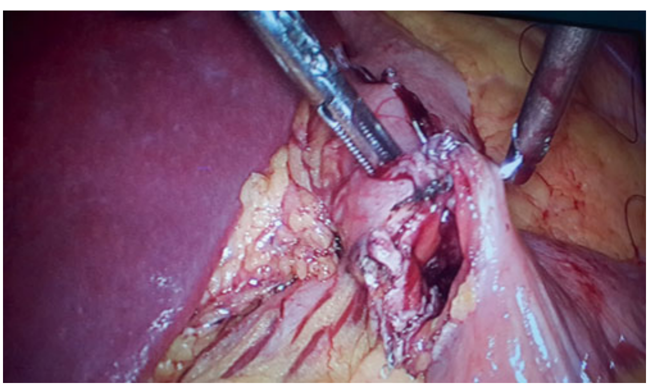

Fig. 43.10 The GJ is closed with staples or hand-sewn.

will result in an incomplete cut and incomplete staple formation, and may result in poor hemostasis.

By slow meticulous application of the staple-gun, the procedure is actually performed in a more rapid manner, and the staple-line is secure and less likely to leak. This "slower" technique saves the time that could be required to deal with a bleeding staple-line.

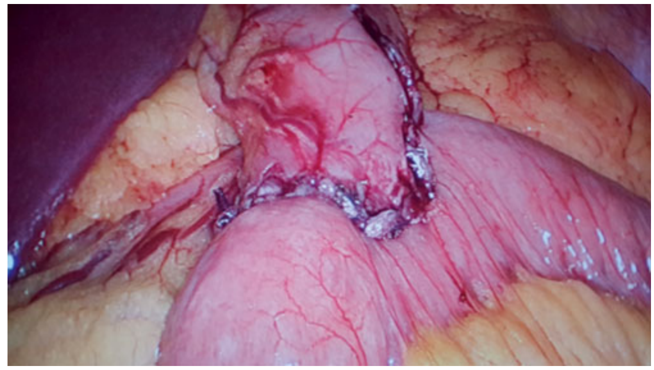

Fig. 43.11 The completed mini-gastric bypass

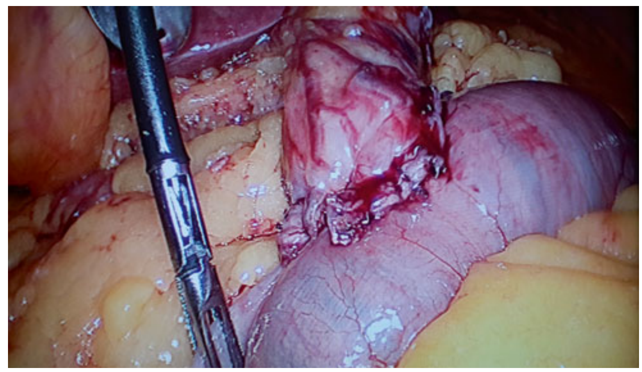

Fig. 43.12 Another view of the completed MGB with the loop inflated. Note routinely the MGB table does not include clips or clip applier; no suction is used and no irrigation is on the OR table for this case. In more recent cases, no sutures are used

43.4.2 Avoiding a Twist in the Pouch

Be careful not to cause a twist during creation of the gastric pouch. As the surgeon advances the staple-line, there is a tendency to pull on the anterior wall of the gastric pouch and the staple-line can rotate posteriorly, creating a spiral towards the back wall of the stomach and around towards the lesser curvature. This can cause obstructive symptoms and failure of the operation, especially if not carefully managed at the time of the gastro-jejunostomy.

43.4.3 Postoperative Period and Follow-Up

Patients are ambulated within 1–2 h of the operation. Oral clear liquids are started in a few hours when the patient is awake. Patients are usually discharged in 1–2 days. The first postoperative follow-up is done on the seventh or eighth day. The next follow-up visits are at 1, 3, and 6 months and then yearly. Patient information on length of stay, late complications (more than 30 days), resolution of the co-morbidities, weight regain and revision is recorded [42]. Patients' bloodwork in the form of hemoglobin (Hb), glycosylated Hb, blood sugar, renal function tests, liver function tests, lipid profile, and serum calcium, iron, vitamin D3, and vitamin B12 can be performed on follow-up visits and recorded. Multivitamin, iron, and calcium supplements are routinely prescribed for all postoperative patients.

Follow-up upper GI endoscopy is done in symptomatic patients only.

43.5 Complications and Management

43.5.1 Immediate Postoperative Complications

MGB has shown low complication rates compared to the other operations [5, 14, 17]. Early intra- and postoperative bariatric surgery complications can occur, and would require a standard management as with bariatric or general surgical procedures.

43.5.2 Leak

Early leak, diagnosed in first 48 h, often can be closed with a suture repair.

Late leak, diagnosed after 48 h, is a dangerous situation, and we recommend not attempting repair but instead dividing the gastrojejunostomy and performing a gastro-gastrostomy recreating the preoperative anatomy [17].

43.5.3 Management of Late Complications

Late complications can occur in the form of some deficiency. A commonly seen deficiency like in other forms of bariatric surgery is vitamin B_{12}, mostly seen in pure vegetarians. These patients can be treated with sublingual vitamin B_{12} or injections of the same. Iron deficiency can be commonly seen in young menstruating females. This can be treated with iron supplements or oral iron porphyrin or iron infusions [43].

43.5.3.1 Marginal Ulcer

The incidence of marginal ulcers is 1–6 % which is similar to the RYGB [3, 5, 17, 26, 27, 44]. These ulcers are acid-peptic in origin which are routinely managed by stopping smoking, removing ulcerogenic medications such as NSAIDs, steroids and others, and prescribing proton pump inhibitors, H2 blockers and probiotics. Regarding the fear of bile reflux, no anti-bile therapy is prescribed. Kular and Manchanda reported very low incidence of ulcers in the state of Punjab, probably owing to the fresh vegetarian diet and very minimal incidence of smoking [17]. In the case of intractable marginal ulcer or a perforation in smokers who refuse to quit, the operation can easily be reversed [29, 41].

43.5.3.2 Malnutrition—Hypoproteinemia

MGB is a powerful form of weight loss surgery. This impact on the patient's nutrition is good in those who are massively obese, but can be too powerful in others. In such cases, the decreased intake of calories and nutrients can lead to excess weight loss or nutritional deficiencies. Routine follow-up is necessary for the patient's lifetime, and in the event of excess weight loss or a specific deficiency, treatment such as extra supplements may be instituted. However, in some cases (0.5–1 % in Dr. Rutledge's series) significant specific or nonspecific excess weight loss and deficiencies have been treated by reversal of the MGB [17, 29, 41]. Fortunately, it is a very simple procedure involving a division of the gastrojejunostomy and gastro-gastrostomy, which usually is a very easy and simple procedure requiring less than 45–60 min in the operating-room. This is one of the real advantages of the MGB: it has an "Exit Strategy."

43.5.3.3 Internal Hernia

Internal hernia has been widely recognized in RYGB patients, and all surgeons are alert to this complication [25]. However, at the Paris World Consensus of MGB experts in October 2013 with an experience of more than 16,000 MGBs, no internal hernias had been experienced [45]. Nevertheless, the patient and surgeon should be warned to look for the signs and symptoms that might indicate bowel obstruction [17].

43.5.3.4 Dumping Syndrome

Dumping syndrome can happen in anyone via a rapid and high volume of high osmolar food bolus or a large and rapid intake of sugars. The gastrojejunostomy of the MGB means that the patient is likely to be much more sensitive to rapid and large intakes of sugary foods or to boluses of food delivered to the small bowel. In general, these patients find that sweets and liquid calories are very hard to handle, so that sodas, ice cream and candy are difficult for MGB patients except in small volumes, taken slowly. High volume fatty foods are also very poorly tolerated and lead to bloating, diarrhea and steatorrhea. Thus, the MGB has been shown to induce the patient to eat a very healthy diet that mimics in most ways the ideal Mediterranean diet. MGB patients report increased intakes of yogurt, fresh fruits and vegetables and a marked decrease in fatty foods, soda, and processed meats.

The symptoms of dumping syndrome with MGB can usually be controlled with simple dietary modifications and has never required surgical intervention.

43.5.3.5 Diarrhea

In all MGB cases, the reported frequency of bowel movements increases from preoperative levels. In Dr. Rutledges's series, it was found that the number of preoperative bowel movements increased from a mean of 0.5 per day to around two per day postoperatively, with a marked variation depending upon the dietary fat content. Significant diarrhea was seen in 4–5 % of cases. This is often related to lactose intolerance in a patient who does not recognize the issue and takes in high dairy volumes. This can be managed by decreasing or stopping the dairy products, choosing fermented dairy such as yogurt, choosing low lactose dairy and/or giving lactase enzyme orally.

43.5.3.6 Steatorrhea and Flatulence

The MGB is a powerful fat malabsorptive procedure and interferes with fat absorption to a significant degree [17]. This means that if a fatty food diet is consumed, patients have more or less steatorrhea as direct evidence of the decreased absorption of fat after MGB. This is simply managed by decreasing the fat in the diet and by adding high fiber.

43.5.3.7 Bile Reflux

About 1–2 % of patients complain of bilious vomiting once in 2 or 3 months. The underlying cause of bile reflux in MGB can be an ulcer or an abnormal short-length gastric pouch. The most important intervention in these patients is the addition of probiotic foods such as yogurt and avoiding inciting foods such high fat or high volume meals. Often the bile reflux indicates the presence of a marginal ulcer of acid-peptic origin. In these cases, as descried above, the treatment is routine for the treatment of any acid-peptic ulcer. In refractory cases (less than 1 %) that do not respond to medical management, a side-to-side Braun jejuno-jejunostomy can be performed.

43.5.3.8 Cholelithiasis

As is seen with all forms of weight loss surgery, the incidence of cholelithiasis can be anywhere from 4 to 10 %. Ursodeoxycholic acid can be routinely used to prevent the cholelithiasis for the first 6 months.

43.5.3.9 Weight Regain in Mini-Gastric Bypass

No bariatric procedure is perfect, as we are dealing with human beings of different eating behaviors and different genetic make-up. MGB has the strength to be tailored easily. The length of the bypass can be adjusted easily, in case the dietary modifications do not help [20, 29].

43.6 Reported Results of the Mini-Gastric Bypass

43.6.1 Weight Loss

Mean excess weight loss (EWL) at 12 months is reported to be from 55 to 91 % [46]. In the study by Kular's group [17], the average EWL at 2 years was 91 %. Weight loss was well maintained over 5 years, with less than 5 % of patients regaining more than 10 kg. A mean EWL of 85 % was maintained over 6 years of follow-up [17]. Noun et al. reported a mean EWL of 69.9 % at 1 year, which persisted at 5 years (68.6 %) [10]. Lee et al. reported 72.9 % EWL [5]. Carbajo et al. reported a mean EWL of 75 % at 1 year and greater than 80 % at 18 months [4]. Piazza et al. reported a % EWL of 65 % at 1 year and 80 % at 2 years [11].

43.6.2 Co-Morbidity Resolution

Kular and Manchanda found remission of type 2 diabetes (T2DM) in 93 % of their patients, hyperlipidemia in 91 %, shortness of breath in 94 %, sleep apnea in 92 % and hypertension in 74 % [17]. Rutledge and Walsh reported resolution or marked improvement of gastro-esophageal reflux in 85 % of patients, shortness of breath in 96 %, T2DM in 83 %, sleep apnea in 87 %, hypertension in 80 %, hypercholesterolemia in 89 %, and urinary incontinence in 82 % of patients [3]. Noun et al. reported complete resolution of co-morbidities in 85 % of patients at 1 year [10]. Piazza et al. reported resolution of T2DM in 90 % of patients, hypertension in 80 %, dyslipidemia in 70 %, and sleep disorders in 90 % [11]. The Italian experience found higher T2DM remission and significant additional weight loss with mini-gastric bypass (MGB) after failed SG [14]. Moskowicz et al. also showed a higher T2DM remission rate following MGB than sleeve gastrectomy [15]. Coskin's group found a T2DM remission rate with MGB of 78 % [19]. Lee reported higher resolution of T2DM with MGB than RYGB and there was also higher postop rise of GLP-1 [12, 47]. Interestingly, Garcia-Caballero and co-workers performing one-anastomosis gastric bypass in diabetics with BMI 24–29 found resolution of T2DM in 77 %, as well as significant decrease in hypertension and hyperlipidemia [13].

Conclusion

There are many satisfactory choices for operations for morbid obesity. There are growing numbers of MGB advocates. The MGB has been shown to be a very safe and effective operation with very durable weight loss and very high levels of patient satisfaction. It is simple to reverse or revise and has a short learning curve for new surgeons who wish to adopt this operation. Although simple and straightforward, there are tricks and traps in the performance of the MGB. This chapter has identified these issues, the mechanism of action, and ways to avoid these traps.

Key Learning Points

- The MGB is a simple, rapid, and quite safe bariatric operation, which is mainly malabsorptive.
- It consists of a long conduit from just below crow's foot extending up to the left of the angle of His (the cardia is not dissected). An antecolic loop of jejunum 200 cm distal to Treitz' ligament is anastomosed antecolic. Bile reflux is generally not a problem, and fear of cancer is unwarranted.
- Excess weight loss is durable at about 80 %, but the anastomosis can be constructed more distally for super-obesity, and the anastomosis can later be moved if rarely necessary.
- Diabetes type 2 resolves in 90 %, and resolution of other co-morbidities has also been found to be higher than with other bariatric operations.
- The MGB originated with Robert Rutledge in 1997, but it has now become mainstream due to increasing published series showing advantages over other bariatric operations.

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Laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD-DS) Surgery

44

David D. Kerrigan, Luca Leuratti, Haris A. Khwaja, and Charlotte E. Harper

Abstract

Biliopancreatic diversion with duodenal switch (BPD-DS) produces unmatched weight loss and superb resolution of comorbidities, particularly type 2 diabetes; however BPD-DS remains a controversial procedure that polarises opinion in both surgeons and patients. It combines surgical bypass of the majority of the small intestine with a sleeve gastrectomy in an attempt to produce greater weight loss and improved remission of comorbidities compared to that seen after Roux-en-Y gastric bypass (RYGB), whilst reducing the incidence of common side effects of a standard BPD such as marginal ulceration and dumping syndrome. With careful patient selection, meticulous technique and attentive follow-up, BPD-DS offers patients outstanding long-term clinical results, a surprisingly good quality of life and an effective revisional option when other procedures have failed. Done badly, it is a recipe for protein-calorie malabsorption and a return to the bad old days of bariatric surgery from the 1970s. In this chapter we explore the essentials of how to use this powerful tool- the nuclear option in the bariatric surgeon's armamentarium- safely and effectively.

Keywords

Biliopancreatic diversion • BPD • Biliopancreatic diversion with duodenal switch • Duodenal Switch • DS • RYGB • Type 2 diabetes

44.1 Introduction

Despite producing unmatched weight loss and superb resolution of comorbidities such as type 2 diabetes, the biliopancreatic diversion with duodenal switch is something of an unloved child in the bariatric community that polarises opinion in both surgeons and their patients. This article attempts to explore this enigma, dispel some of the myths that surround the operation and take a critical look at its role (if any) in the bariatric armamentarium. To begin, we need to understand what the procedure is and where it came from.

44.2 Biliopancreatic Diversion

The biliopancreatic diversion (BPD) was originally described as an open operation by Nicola Scopinaro and his team in Genoa almost 40 years ago [1]. It combined surgical bypass of the majority of the small intestine with a subtotal gastrectomy (see Fig. 44.1) and its rationale was that greater weight loss following BPD would result in improved remission of comorbidities compared to that seen after more established procedures such as the Roux-en-Y gastric bypass (RYGB) [2]. However, concerns

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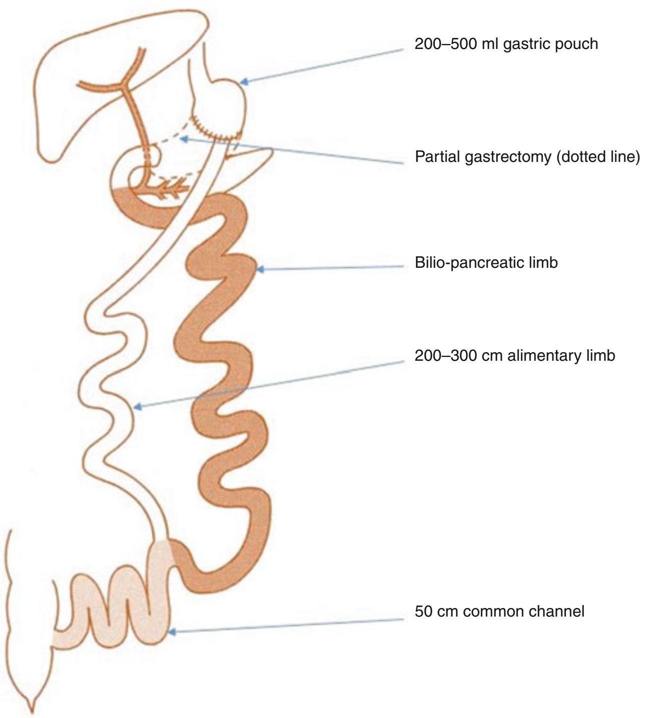

Fig. 44.1 Biliopancreatic diversion

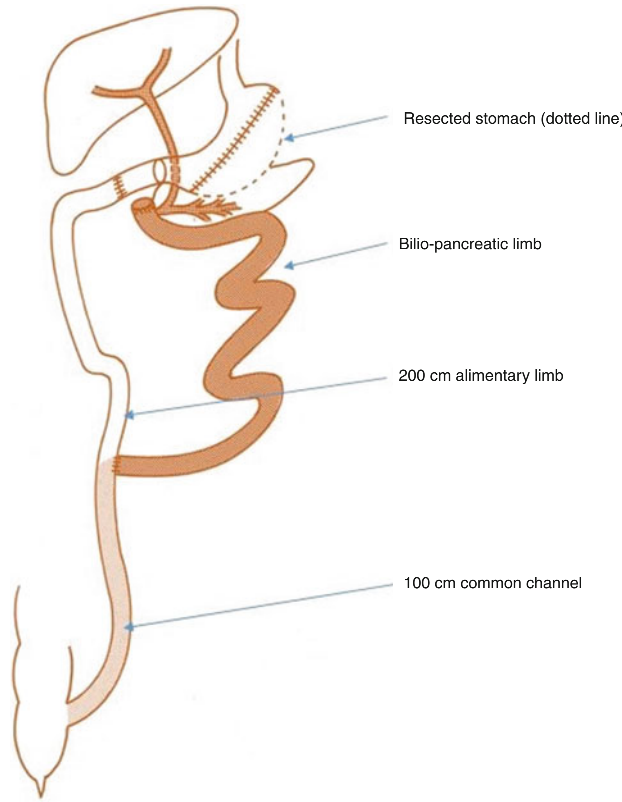

Fig. 44.2 Duodenal switch

related to the partial gastrectomy (such as marginal ulceration and dumping syndrome) together with the real risk of troublesome symptoms of malabsorption and the potential for surgically induced malnutrition hampered widespread adoption of the BPD. Marginal ulcers occurred in about 10–15 % of BPD patients [3–5], although Scopinaro himself managed to reduce the incidence in his unit from 12.5 to 3.2 % through modifications such as resecting more of the stomach and using prophylactic H2-receptor antagonists [6].

In 1998, almost 20 years after the introduction of the BPD, Douglas Hess (USA) [7] and Picard Marceau (Quebec) [8] independently published their experience of treating morbid obesity with a hybrid procedure called the biliopancreatic diversion with duodenal switch (BPD-DS, often abbreviated to just DS). The duodenal switch was originally developed by Tom DeMeester as a surgical solution for chronic duodenogastric reflux [9] and combines the small intestinal bypass of a BPD with a vertical 'sleeve' gastrectomy, resulting in a narrow banana shaped gastric pouch based on the lesser curvature. The duodenum is transected a few centimeters beyond the pylorus and an ileoduodenal anastomosis formed to divert food into the alimentary limb of the intestinal bypass (see Fig. 44.2). Unlike a standard BPD, the DS preserves more normal physiological function by retaining the pylorus and most of the antrum.

44.3 Biliopancreatic Diversion Versus Biliopancreatic Diversion with Duodenal Switch

This new configuration resulted in a dramatic reduction in the incidence of marginal ulceration and preservation of the pylorus virtually eliminated dumping syndrome. The exceptionally low rate of marginal ulceration is thought to result from a combination of lower acid production, (there is less residual parietal cell mass after sleeve gastrectomy) and alkaline mucus production by Brunner's glands in the duodenum protecting the otherwise vulnerable ileal mucosa from acid attack. Marceau reported just one case of marginal ulceration in a 15 year audit of 1000 patients [10], similar to the 0.3 % incidence of marginal ulceration reported by Hess after more than 10 years of follow up [11].

Preservation of more normal gastric physiology and a short segment of duodenum also reduced the severity of vitamin and mineral deficiencies compared to standard BPD, particularly calcium [12–14], iron [15–17], zinc [12, 13, 17], magnesium [12] and vitamin B12 [15, 17]. By avoiding a conventional subtotal gastrectomy, after DS the vagus nerves are spared; consequently there is less disturbance of bowel motility and less disruption to the physiologic splanchnic signaling to the pancreas that regulates insulin release [18, 19]. Short term weight loss after the two procedures is similar [12, 20]; although long term results favor the DS, with 25 % greater mean weight loss than BPD and with fewer patients (1.3 %) failing to lose less than 25 % of their excess weight [10, 21].

44.4 Patient Selection

Rigorous patient selection is crucial; more so than with any other bariatric procedure. The potential adverse consequences of a failure to adhere to a strict postoperative protocol involving a high daily intake of protein, minerals and vitamins are potentially so severe it is imperative that all patients undergo a trial of this dietary protocol as part of their preoperative assessment; only then can both physician and patient take a reasoned view on the likely ability of the patient to successfully adapt to life after a DS. It is an operation that mandates an exceptionally high degree of patient compliance, which in turn limits its widespread applicability in patients who for economic, psychological, intellectual or occupational reasons are unable to meet these requirements. This major drawback, along with the DS's technical complexity and the perceived severity and frequency of side effects are amongst the reasons why, along with the BPD, the DS has not being widely adopted. A recent review of the patient registry of the American Society for Bariatric and Metabolic Surgery showed that between 2007 and 2009 only 517 (0.9 %) of the 57,918 registered patients underwent either a BPD or a DS and most of them were performed using open surgery [22].

The main indications for DS are based on the degree of weight loss it can induce (particularly in the very heaviest patients in whom other operations may fail) and its remarkable effect on diabetes remission.

44.5 Weight Loss

It is often claimed that super obesity, a body mass index (BMI) more than 50, is the main clinical indication for DS, but this should not be the only consideration as many super obese patients would be unable to adhere to the postoperative regime. However it is true that RYGB is less effective in the super obese, with 1 in 5 patients failing to reach or maintain expected target weight loss [23]. It is also true that weight loss after DS compared favorably with that after RYGB in a randomized controlled trial of super obese patients, with a percentage excess weight loss (%EWL) of 75 % versus 54 % respectively after 12 months [24]. Others have reported similarly superior results at 2 years in a study of super obese patients undergoing both DS and RYGB (%EWL 72 % and 60 % respectively) [25].

Late weight regain is also uncommon because the malabsorptive element of the duodenal switch provides a more durable long term result [25] with 90 % EWL maintained between 2 and 5 years postoperatively in our own series [17].

The unrivaled weight loss of DS in the heaviest of patients has led some to propose it as the treatment of choice for the super-super obese (BMI more than 60 kg/m^2), but the same limitations in patient selection must apply. Furthermore, there are several studies highlighting a significantly increased mortality in this particularly heavy subgroup (see mortality section below) if they undergo a lengthy and technically difficult laparoscopic operation as a single stage procedure. For this reason, we and others recommend two stage surgery for patients with a BMI more than 60 kg/m^2, carrying out the sleeve as an initial step, followed by completion of the DS 12 months later [26].

44.6 Remission of Comorbidities

Diabetes remission and correction of hyperlipidemia are more likely to occur after DS than after any other type of bariatric surgery and so some consideration should be given to the potential of the DS to benefit patients with these metabolic complications of obesity when discussing surgical options with them [17, 21, 26]. In our own practice no fewer than 90 % of type 2 diabetics were rendered euglycaemic after surgery [17], a finding echoed by others [26, 27]. In a comparison of matched patients with a mean BMI of 50 undergoing either RYGB or DS, Dorman et al. reported 82 % diabetes remission after DS compared to just 64 % after RYGB. The same study noted 69 % resolution of hypertension in the DS group (39 % in RYGB) and an 81 % resolution of hyperlipidemia (51 % RYGB) [27]. A randomized trial comparing relatively small numbers of diabetic patients undergoing DS and RYGB confirmed significantly lower HbA1c levels at 1 and 3 years postoperatively in the DS group, in addition to superior weight loss [28].

44.7 Quality of Life

However, in practice the main indication for DS in our unit is patient preference. Prospective DS patients tend to be very well informed; they have a clear idea as to why they think the DS is the best operation for them, particularly in terms of quality of life (QOL) after surgery and have balanced the potential advantages of a DS against its drawbacks. A common perception amongst patients is that they will be able to eat 'normally' after a DS compared to RYGB, but this has not always been borne out in several studies [29–31]. The rate limiting factor for portion size (at least in the early years) will of course be the sleeve and so there is no reason why DS patients would be at any advantage here. What is true is that unlike RYGB, the absence of dumping allows unfettered carbohydrate consumption and a more 'normal' food intake.

In a small randomized controlled comparison of DS and gastric bypass patients from a low volume unit, QOL was actually slightly worse in the DS group with only five out of eight SF36 domains showing significant improvement at 2 years (compared to seven out of eight after RYGB) [32]. This is in contrast to our own experience in which 98 % of respondents to a bariatric surgery-specific QOL score (BAROS) reported improvement, with 85 % reporting 'very good' or 'excellent' outcomes [17].

44.8 Technical Tips and Operative Considerations

The laparoscopic approach is now the recommended method of performing a DS. It can be a very demanding and challenging operation for the surgeon as well as the patient. It is our practice to give a standard dose of both low molecular weight heparin and tranexamic acid at induction of anesthesia. A pneumoperitoneum is established with a left upper quadrant Veress needle (or through a direct vision cannulation technique) and sustained at 15–17 mmHg. Usually seven trocars are necessary to perform the surgery. Their exact positions will vary with individual patients' abdominal shape; Figs. 44.3, 44.4, and 44.5 serve as a guide.

We start with the creation of the common channel using the active ports shown in Fig. 44.3. With the surgeon and camera holder standing on the patient's left, and the operating table in a neutral flat position with slight left tilt, the ileocecal valve is identified and from this point a 100 cm common channel of terminal ileum carefully measured on the stretched anti-mesenteric border of the bowel. A suture is placed at this point to mark the site where the ileo-ileal anastomosis will be constructed. Measurements then continue proximally from the suture mark for a further 200 cm, at which point the ileum is transected with a linear stapler. An ileoileal anastomosis is then constructed using the bowel proximal to the point of transection (the biliopancreatic limb) and the point at which the terminal ileum had been marked with the suture, 100 cm from the ileocecal valve.

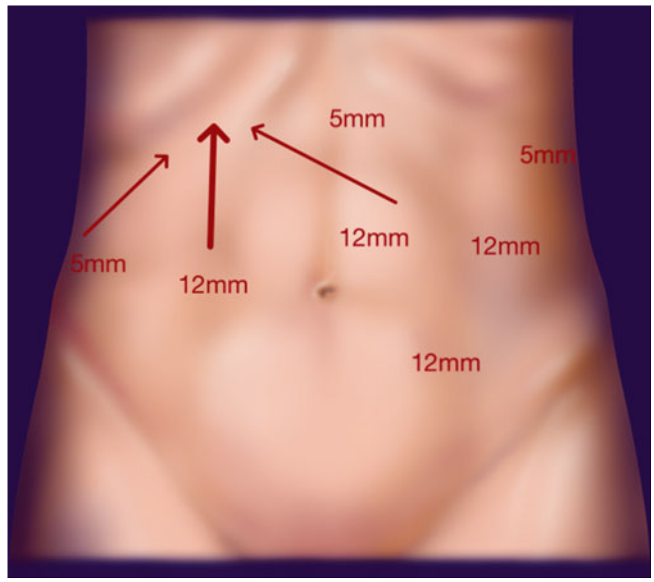

Fig. 44.4 Ports used in creation ileo-duodenal anastomosis

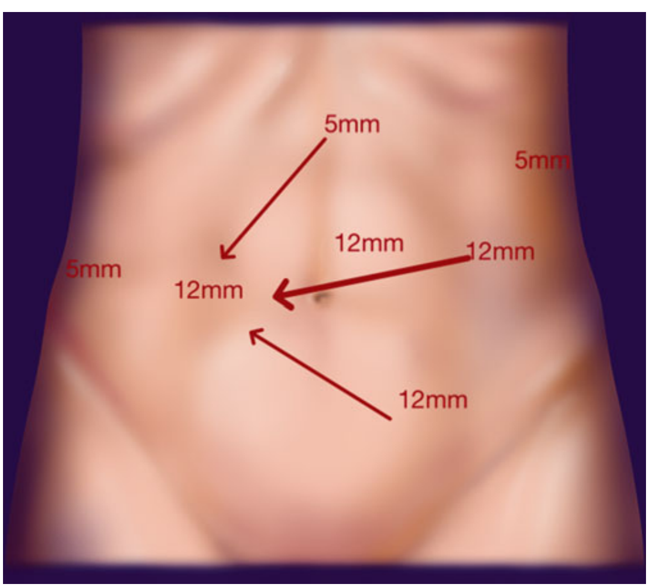

Fig. 44.3 Ports used in creating common channel

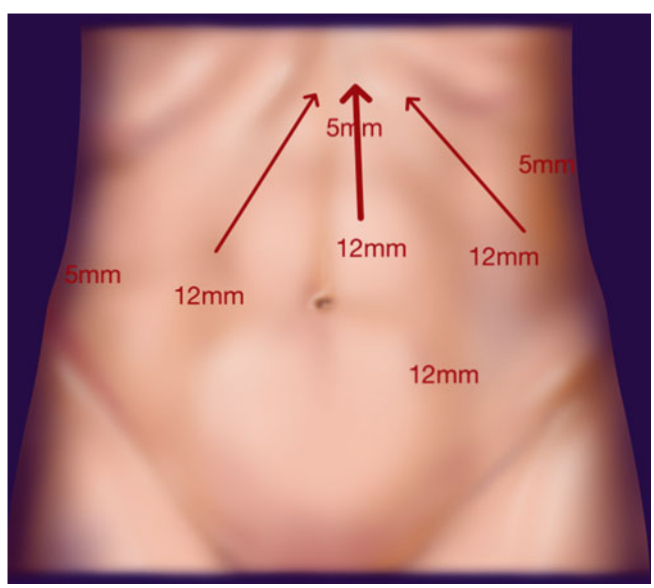

Fig. 44.5 Ports used in creation sleeve gastrectomy

Care must be taken not to twist the mesentery of the small bowel when aligning the bowel limbs in preparation for this anastomosis which can be done using a hand sewn technique, or (as in our unit) using a totally stapled method. This involves bidirectional linear stapler firings, with transverse stapled closure of the enterotomy. Finally, the ileoileal mesenteric defect is closed with a non-absorbable running suture.

The patient is then positioned in reverse Trendelenburg and with the surgeon now standing between the patient's legs and using the active ports shown in Fig. 44.4, careful dissection along the inferior border of the duodenal bulb is commenced approximately 4–5 cm distal to the pylorus by gently coagulating the very fine connecting vessels between the head of the pancreas and the posterior wall of the duodenum. The aim is to create a small window between the duodenum and pancreatic head wide enough to admit a linear stapler cartridge. Care should be taken not to damage the gastroduodenal artery as it passes behind the duodenal bulb or significant bleeding can occur. A flexible angulating instrument can be useful when completing this posterior tunnel, which should result in a second window at the superior edge of the duodenal bulb, lateral to the hepatoduodenal ligament. The first part of the duodenum is then transected with the stapler. We do not routinely oversew the duodenal stump of the biliopancreatic limb. An alternative method of mobilizing the duodenal bulb that we used early in our experience involves lifting the antrum and approaching the gastroduodenal artery by dissecting posterior to the pylorus via the lesser sac.

We share the view that prophylactic cholecystectomy at the time of DS is unnecessary [33]. Indeed, in our experience, the combination of DS and cholecystectomy may cause problems by exacerbating postoperative diarrhea. We do not use it routinely and instead reserve delayed cholecystectomy for symptomatic individuals only. In practice this amounts to fewer than 10 % of patients. Ursodeoxycholic acid 300 mg twice a day is effective in preventing gallstone formation in patients with dramatic weight loss, although this benefit has to be balanced with the increased cost and added inconvenience to the patient. Furthermore the value of ursodeoxycholic acid in long-term gallstone prevention is questionable. Our 10 % late cholecystectomy rate is remarkably similar to the 8.7 % late cholecystectomy rate reported by Bardaro and Gagner in DS patients who had also been treated with 6 months of ursodeoxycholic acid [33].

After transection of the duodenal bulb, the alimentary limb is pulled upwards in an antecolic fashion, (after division of the greater omentum if this is necessary to reduce tension on the transposed small bowel) and an ileoduodenal anastomosis is constructed 3–5 cm beyond the pylorus. There are several means of achieving this; some prefer a transoral circular stapled (Gagner) technique which has the advantage of speed and is less technically challenging than a totally hand sewn anastomosis. However, it can be difficult to maneuver the tip of the nasogastric tube and/or the anvil of the stapler through the pylorus. Additional problems can arise if the narrow caliber alimentary limb cannot easily accommodate the staple gun; there is a risk of tearing the ileum at this point. Use of a smaller (21 mm) anvil can help circumvent these problems, albeit with a higher risk of anastomotic stricture. An alternative (the preferred technique in our unit) is to perform a single layer ileoduodenal anastomosis by hand, using a continuous seromuscular posterior suture to approximate the sealed ends of the duodenal bulb and alimentary limb, before creating an enterotomy in each and closing the corners and anterior wall of the anastomosis with a second continuous serosubmucosal stitch. Since the alimentary and biliopancreatic limbs are much longer than in a gastric bypass, it is possible to inadvertently perform a duodenoileal anastomosis with the wrong limb (loop bypass) or to twist the mesentery of the alimentary limb. This can be avoided by marking and carefully checking the position of the limbs prior to performing the anastomosis. Early symptoms of small bowel obstruction suggest the need for an oral water soluble contrast study and/or a diagnostic laparoscopy.

Now that the more challenging parts of the procedure are complete it is usually a relatively straightforward matter to complete the DS by carrying out a standard sleeve gastrectomy (using the ports indicated in Fig. 44.5). The lesser sac is easier to enter at the midpoint of the greater curvature (less experienced surgeons tend to start too distally). After creating a window in the greater omentum close to the stomach wall with an energy device, dissection is continued proximally, dividing the short gastric vessels and the phrenosplenic ligament until the left crus is reached. The crurae are dissected and exposed to rule out the presence of a hiatus hernia, which must be repaired if present [34]. After taking down any posterior lesser sac adhesions, the greater curvature is then mobilized distally in a similar fashion until the mid-antrum is reached, several centimeters distal to the incisura. It is important not to be over-zealous in this distal dissection as the right gastroepiploic vessels must be preserved; they form part of the blood supply to the duodenal bulb. Division of posterior adhesions is an important technical point, as otherwise they could prevent the stapling device being applied close enough to the lesser curvature posteriorly, risking an unduly wide sleeve or excess fundus being inadvertently included within the proximal portion of the sleeve, both of which could result in sleeve failure.

We fashion the sleeve using a linear stapler placed lateral to a 36–40 French bougie, starting about 4–6 cm from the pylorus and progressing cranially snug with the bougie, ensuring that each staple firing crosses the last slightly. The choice of the staple cartridges depends upon the thickness of the gastric wall. A thicker 4.5 mm or greater cartridge is advised in the gastric antrum to prevent serosal splitting, bleeding or leakage, whilst in the absence of staple-line reinforcement, a 3.5–4.5 mm cartridge is usually sufficient when progressing across the gastric body and fundus. Counter-traction with instruments accurately placed on the greater curvature of a properly mobilized stomach reduces the risk of creating a spiral effect in the cylindrical sleeve during the stapling process, a well-recognized cause of postoperative functional obstruction [35, 36]. It is particularly important that the last firing of stapler does not sit too close to the gastroesophageal junction and that any thick fat pad at this site is reflected medially to reduce the depth of tissue the stapler has to fire through. Anastomotic leakage at the proximal end of the sleeve is the most feared and most common perioperative complication of DS. The value of staple line buttressing with bovine pericardium or other bioabsorbable material, while effective in reducing staple line bleeding, is still debatable with respect to the prevention of early postoperative leaks [34, 37, 38].

Finally, Petersen's defect is closed from the patient's right, as this allows better exposure of the mesentery of the alimentary limb and transverse mesocolon. It is advisable to start the closure from the lower end of the defect and progress upwards, so that the last bite incorporates the inferior taenia of the colonic wall.

44.9 Inpatient Care and Complications

An enhanced recovery protocol that eschews the routine use of urinary catheters, arterial and central venous lines and nasogastric tubes is adopted, although patients do undergo close postoperative monitoring to detect hypoxia, unexplained tachycardia (which may indicate a leak) and hypotension. Two additional doses of tranexamic acid are prescribed 12 h apart during the first 24 h after surgery; this has been shown to reduce the requirement for blood transfusion after elective surgery without convincingly increasing the risk of venous thromboembolism (VTE) [39, 40].

Given the longer operative time associated with DS (and its suitability for heavier patients) it is important to be alert to the possibility of rhabdomyolysis and myoglobinuria, particularly if the patient complains of severe buttock pain. It is also vital that a VTE prevention protocol adequate for the needs of high BMI patients who have undergone prolonged surgery is in force. We have previously reported a 0 % VTE rate in 735 bariatric patients treated using our extended low molecular weight heparin protocol [41].

An early (day 1) water-soluble contrast study is unnecessary as it will not pick up a leak that develops the following day. Indeed, given the low sensitivity of this test in ruling out a leak [42], in the presence of symptoms and signs of sepsis we simply adopt a very low threshold for diagnostic re-laparoscopy in those with clinically suspicious findings.

In patients who have an uneventful postoperative course, a liquid diet can be commenced within hours of surgery and patients are discharged on postoperative day three, after appropriate dietetic counseling. Normal solids can usually be started 4–6 weeks postoperatively. Some authors suggest supplementation with liquid protein shakes to prevent protein malnourishment until the patients achieve their target protein intake of 100–140 g/day.

44.9.1 Operative Mortality

Laparoscopic DS is perceived by some as a high risk procedure, but this has not been borne out in several large cohort and individual institution studies that have reported a 30 day mortality of 0–0.7 % [17, 24, 43–46], closely matching that of laparoscopic gastric bypass. However, an all-cause mortality (that is including deaths unrelated to surgical complications) of 7.2 % was noted in a report from the University of Southern California [43]. What is clear from the literature is that the super-super obese (BMI more than 60 kg/m^2) represent a subgroup with high perioperative mortality. Fazylov's group reported a 0 % mortality in patients with BMIs less than 60, but a 7.8 % mortality in the super-super obese [47]. Ren and Gagner also reported a similarly higher mortality in this group [48] as did Kim (7.6 %) [49]. This observation is the rationale for performing the DS as a two-stage procedure in patients with a BMI more than 60 kg/m^2 [26, 50].

Data on longer term mortality is more difficult to come by but Marceau's group reported 4.7 % mortality (67 out of 1423 patients) at 15 years. A breakdown of these data showed a 1.1 % perioperative mortality with a further 0.7 % of patients dying from late surgical complications such as malnutrition, obstruction and delayed operative deaths. The remainder died of seemingly unrelated causes such as cancer (0.9 %), suicide (0.4 %) and trauma. Less than 1 % of the patients in this study died of late medical complications such as cardiopulmonary disease or a cerebral vascular accident (CVA) [10].

44.9.2 Staple Line/Anastomotic Leak

Anastomotic leakage is the most feared complication of bariatric surgery. Once again, there is a perception that leak rates are higher after DS than other procedures, but in fact the majority of leaks come not from the malabsorptive part of the operation, but from the construction of the gastric sleeve. Small intestinal leaks are relatively rare in most series. The risk of leak arising from the long gastric staple line has progressively reduced with increasing awareness of the technical details of performing sleeve gastrectomy (see Chap. 26). In a comprehensive analysis from Mason's group in California there was no evidence of a higher rate of serious perioperative complications (including anastomotic leakage) in matched groups of patients undergoing laparoscopic duodenal switch and laparoscopic gastric bypass [43]. There is undoubtedly a steep learning curve that surgeons undertaking DS have to negotiate which probably explains the high leak rates reported in some early studies of open and laparoscopic duodenal switches performed 10 or more years ago (0–6.6 % leak rate) [12, 46, 48, 51, 52], and more recent low volume studies (6.8–8 % leak rate) [24, 53]. Higher volume, recent studies consistently report leak rates of 0–3.5 % [27, 45, 54]. We reported our own learning curve with the laparoscopic DS in 2011. At that time, our sleeve leak rate was 1.6 % (2 out of 121 patients), with one duodenal stump leak and another patient with an ileoduodenal leak. These serious complications occurred in our first 50 cases and the overall leak rate fell to 1.4 % (a sleeve leak) in the next 71 patients treated [17].

Leaks can be managed conservatively with surgical or radiological drainage of any collections and intravenous antibiotics. However, management of the catabolic state resulting from this complication is more difficult because of the presence of significant surgically induced malabsorption. Enhanced nutritional supplementation is usually required and this is best achieved by inserting a laparoscopic feeding jejunostomy into the proximal part of the bypassed jejunum (the biliopancreatic limb), thus making most of the length of the small bowel available for nutrient absorption. An alternative would be TPN, but our preference is always to use the enteral route if feasible.

Possible risk factors for anastomotic leakage include high BMI, use of a circular stapled ileoduodenal anastomosis [55] and cases performed at the beginning of surgeon's learning curves [17, 24, 48, 53].

44.10 Outpatient Care and Complications

This is perhaps the most critical part of the patient's management. It must be thorough, frequent and carried out to an uncompromisingly high standard for the patient's lifetime, with involvement of a comprehensive multidisciplinary team of bariatric surgeons, dieticians, physicians and psychologists. Failure to closely monitor and manage a DS patient is a recipe for disaster, but when properly cared for, majority of patients achieve a safe, durable and highly effective outcome.

44.10.1 Vitamin and Micronutrient Deficiency

After DS the need for closely monitored vitamin and mineral supplementation is paramount because of the degree of malabsorption, particularly with respect to fat soluble vitamins (A, D, E, and K), which must be supplemented in high doses, the exact dosage being adjusted according to the results of regular serum assays including vitamin D3 and vitamin A. Vitamin E levels have not been shown to differ from levels in RYGB patients during the first 12 months after surgery [56] and so we do not routinely assay vitamin E. An indirect measure of vitamin K activity can be deduced by checking the patient's international normalized ratio (INR).

Our current baseline maintenance regime is Vitamin D3 10,000 IU daily, together with vitamin A 10–25,000 IU daily in non-pregnant individuals. Unabsorbed fatty acids may form complexes with minerals such as calcium, thus inhibiting absorption and increasing the risk of long term deficiency, although ingestion of medium chain triglycerides that are easily assimilated by the body (for example coconut oil) can ameliorate this effect, enhancing absorption of minerals and fat soluble vitamins [57]. Nevertheless, calcium supplements (at least 2 g per day) are mandatory, preferably given in the citrate form. Calcium citrate is better absorbed than carbonate preparations in the more alkaline milieu that follows sleeve gastrectomy and because citrate is an inhibitor of calcium salt renal stone formation, it has the added advantage of lowering the risk of troublesome calcium or oxalate calculi [58, 59]. Careful dosing of calcium and vitamin D levels is necessary to prevent bone demineralization (a rare but serious complication of malabsorptive procedures). We do not routinely perform DEXA scans (indeed these are often abnormal preoperatively in the morbidly obese), but a good indication for a DEXA scan is persistent elevation of alkaline phosphatase and parathormone levels, despite appropriate supplementation.

Most other trace elements (such as copper, zinc, magnesium and selenium) can be maintained by taking a good quality complete multivitamin and mineral preparation twice daily, but it is common to require additional iron (particularly in premenopausal women) [12, 15]. Some patients fail to respond to oral iron and require iron infusions from time to time. There is a clear interaction (either synergistic or antagonistic) between different trace metals and minerals that can influence effective absorption of supplements after DS, particularly in the relationship between iron, zinc and calcium [60] and similarly between copper and iron absorption [61]. It is thus unusual for a single nutrient deficiency to develop exclusively; other deficiencies or excesses are often involved.

The combination of a subtotal sleeve gastrectomy and the short terminal ileal common channel of a DS clearly poses a risk of vitamin B12 deficiency and close monitoring is required. Having said that, we do not routinely supplement with parenteral vitamin B12 after DS and noted an incidence of deficiency of just 5 % in each of the first 2 postoperative years, thereafter falling to 1 % [17]. Although vitamin B2 and B6 levels are similar after DS and RYGB [56], within the first few months after DS there is a greater risk of thiamine (B1) deficiency compared with the gastric bypass, but this difference seems to correct spontaneously within 6 months [56]. In a review published in 2008, of the 84 cases reported with Wernike's encephalopathy (WE) after bariatric surgery, 80 were associated with gastric bypass or other restrictive procedures (95 %) and this was almost always associated with vomiting [62]. A rare but concerning incidence of WE (0.18 %) was reported within 3–5 months of surgery in a large historical series of 1,663 biliopancreatic diversion (BPD) patients [63]; however, this finding has not been confirmed after DS, suggesting that it may be more related to the high incidence of stomal ulceration (and thus vomiting) after BPD than to any malabsorption.

The importance of close and meticulous outpatient follow up after DS cannot be over emphasized. Patients are seen with an up to date nutritional blood screen at least four times a year for the first 2 years, although the frequency of appointments can be reduced to 6 monthly after this if all is well. In addition to a full blood count (FBC), liver function tests (LFT), urea & electrolytes, and a bone profile, regular blood screens include; magnesium, zinc, serum iron, vitamin B12, red cell folate, vitamin A, INR (as a marker of Vitamin K status), vitamin D and parathormone.

44.10.2 Protein Calorie Malnutrition

The short common channel of a DS reduces the opportunity for pancreatic enzymes to digest food. Older malabsorptive operations affect absorption of fat, protein and carbohydrate equally. What is different about the DS is that it selectively protects protein absorption to a degree. Pepsinogen and acid are still produced in the sleeve and trituration can occur in the near-intact antrum, so it is likely that a degree of protein pre-digestion in the stomach occurs, which would allow peptide absorption not just in the common channel, but also in the 200 cm alimentary limb. Nevertheless, as the rate of protein loss from the gut is five times greater than normal after the very short 50 cm common channel of a BPD [2], it is prudent that DS patients adhere to a high protein intake indefinitely [12]. Given the careful preoperative selection and counseling we employ for DS patients it is unusual to see severe protein calorie malnutrition in the course of follow up, with a peak 3–5 % incidence of hypoalbuminemia (less than 30 g/1) about a year postoperatively, decreasing to 1–3.7 % at 2 years and 0–1 % thereafter [17, 46].

The majority of DS patients can easily maintain serum albumin with diet alone, but they have reduced reserve should they develop a severe intercurrent or diarrheal illness. For this reason, we recommend DS patients consume more than 100 g of protein daily choosing high biologically valued proteins; meats, fish, nuts, eggs, milk, cheese, yogurts and oral protein supplements such as bars or food additives. If a decrease in albumin levels is identified, protein shakes and/or high protein (semi-elemental) prescription nutritional supplements should also be used, with the addition of pancreatic enzyme replacement (Creon® 10–40,000 units two to four times a day) if required. Another key to managing hypoalbuminemia after DS is to control any diarrhea by vigorous and prompt treatment of underlying causes such as infection, bacterial overgrowth and bile salt irritation of the colon.

In the rare instance of protein calorie malnutrition that cannot be managed using the above conservative measures, ambulatory enteral feeding using a laparoscopically placed feeding jejunostomy tube (positioned in the proximal part of the biliopancreatic limb) is a useful technique. If at all possible we try to avoid the use of total parenteral nutrition (TPN). In cases of persistent protein malnutrition, or if a lack of compliance is suspected, reversal or revision of the procedure must be considered. The reported incidence of this in early series of open DS procedures was quite high (2–12 %) [7, 20, 64], but in more recent reports runs at about 1.5 % [46].

44.10.3 Small Bowel Obstruction

In a study of 805 DS patients, Biertho reported a 2.4 % incidence of intestinal obstruction, with 1.6 % requiring further surgery [46], findings that are similar to those reported after RYGB. Intestinal obstruction after laparoscopic DS can result from simple adhesions, port site hernia, incorrect anastomotic technique (twisting or narrowing) or ischemic stenosis. However the most dangerous causes are internal herniation of the bowel and organo-axial rotation of the very long alimentary limb [65]. Meticulous attention must be paid to the closure of the ileoileal mesenteric and Petersen's defects. We have encountered several cases of infarction of the alimentary limb after organo-axial twisting and entrapment in Petersen's defect [65]. Early re-laparoscopy should be considered in any DS patient presenting with bouts of severe abdominal pain for which there is not an obvious alternative explanation.

44.10.4 Chronic Diarrhea/Steatorrhea

Contrary to common wisdom, chronic diarrhea is not typical after DS although steatorrhea (fatty, offensive stools) can be a notable problem, particularly if patients choose not to adhere to a low fat diet. Most DS patients pass two to three semi-formed stools per day [8, 17] and less than 1 % ever require hospitalization to manage severe diarrhea [46]. In a comparison between DS and RYGB patients, no significant difference was noted in stool frequency over a 14 day period (average of 23.5 movements after DS versus 16.5 after RYGB) [66]. A sudden increase in bowel frequency, loosening of stool and flatulence is usually due to bacterial overgrowth (which often follows a course of antibiotics taken for an unconnected condition). A stool culture should be taken if possible (to exclude causes of infective gastroenteritis such as Campylobacter) and the patient started on empirical treatment with metronidazole 400 mg thrice daily for 10 days, followed by a further 10 days of ciprofloxacin 500 mg twice daily if the diarrhea has not cleared. During this time, patients are encouraged to consume probiotics or live natural yogurt products [67].

Loose stools that are steatorrheal in nature can be managed with pancreatic enzymes supplements such as Creon®

(10.000 to 40,000 units with each meal), while simple antidiarrheals such as loperamide and codeine are also valuable in controlling frequent or loose bowel movements. Consideration should also be given to the possibility of bile salt malabsorption causing colonic irritation (particularly in patients who have also had a cholecystectomy, in whom bile acids can be delivered into the short terminal ileum between meal-times before passing unbound into the colon). This can be difficult to manage, but our current regime using colesevelam appears to be better tolerated than older products such as cholestyramine. Only rare refractory cases of severe diarrhea, usually related to poor dietary compliance, may require a reversal of the procedure or conversion to a gastric bypass.

Conclusion

The duodenal switch offers patients, particularly very high BMI patients, a powerful option in the fight against diabetes and obesity. It is an operation that is much maligned, usually by those with little first-hand experience of the technique. In practice, as with most branches of bariatric surgery, with careful patient selection, meticulous surgical technique, good patient compliance and excellent multi-disciplinary follow-up the DS can produce outstanding, long-term clinical results without having a major negative impact on patient safety or quality of life. Mortality, complication rates and even the incidence of diarrhea are comparable with those seen after more mainstream procedures such as the sleeve gastrectomy and the Roux-en-Y gastric bypass. The main obstacles to its widespread adoption are the shortage of surgeons with suitable training and the shortage of patients for whom the rigors of the postoperative protocol are suitable.

Key Learning Points

- The duodenal switch (DS) is the most effective bariatric procedure in terms of weight loss and diabetes remission.
- Unlike RYGB and sleeve gastrectomy, the DS retains its efficacy even in patients with super super obesity (BMI > 60).
- There is a common misconception that the DS is associated with higher rates of peri-operative and postoperative complications compared to RYGB, but this view is not supported by the published literature.
- Rigorous patient selection is essential for safe DS surgery – it is not a procedure that is widely applicable to the general bariatric patient population.
- The patient and their bariatric team must both commit to close lifelong follow-up if long-term nutritional sequelae are to be minimized

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45 Laparoscopic Biliopancreatic Diversion (BPD) Surgery

Roberto Maria Tacchino

Abstract

This chapter describes the pathophysiology, surgical technique, complications and results of biliopancreatic diversion. The laparoscopic and single incision approaches, with different technical variations, are described. The physiological role of pouch size and bowel limb lengths in determining weight loss and maintenance are detailed. The early surgical complications as well as nutritional sequelae of the operation are also discussed.

Keywords

Biliopancreatic diversion • Single incision • Bariatric surgery • Obesity • Metabolic surgery • Diabetes

45.1 Introduction

Scopinaro originally described biliopancreatic diversion (BPD) in 1976 [1]. The original procedure consisted of an upper midline incision extending from the xiphoid process to just above the umbilicus. The first maneuver was the measurement of the small bowel, on the antimesenteric border, starting from the ileocecal valve (ICV) with the intestinal wall fully stretched. Marking sutures were placed at 50 and 250 cm from the ICV. The ileum was divided at 250 cm and an end-toside ileoileal anastomosis was made at 50 cm from the ICV. The gallbladder was then removed. The next step was that of distal gastric resection adjusted according to the patient's initial weight, sex, age, eating habits, and expected degree of compliance. The average residual gastric volume was around 300 mL. A gastroileal end to-side retrocolic anastomosis completed the procedure (see Fig. 45.1).

The key points of the BPD, from the physiological point of view, are the gastric volume and the lengths of the bowel limbs: biliary, alimentary and common channel.

These factors determine the mechanism of action of the operation and the final weight of the patient.

45.2 Physiology

45.2.1 Pouch Size

A larger gastric volume allows the patient to eat larger meals and reduces the rapid emptying of the stomach into ileum. The large gastric volume is responsible for the postoperative change in eating habits and preserves some gastric digestion and consequently minimizes the risk of malnutrition. On the other hand, a smaller gastric pouch enhances the postcibal syndrome, sense of fullness and satiety immediately after eating, and the patient eats considerably less for a longer period of time [2].

45.2.2 Bowel Limb Length

The bowel limbs lengths determine the maximum absorptive capacity of the patient. Metabolic studies have shown that the average BPD patient can absorb no more than 1800 kCal when eating a balanced diet [3]. A common channel shorter than 50 cm has been considered to be incompatible with

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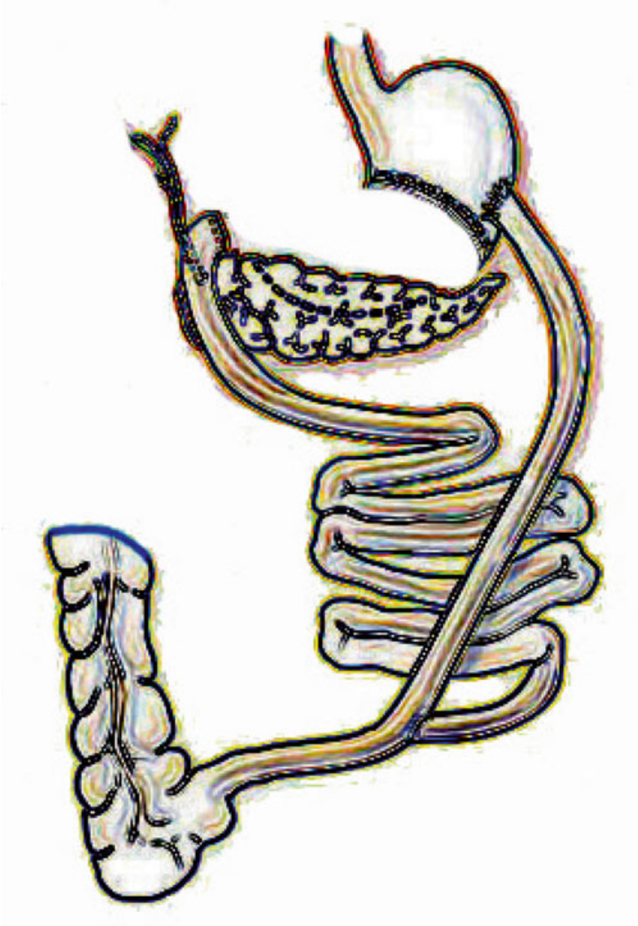

Fig. 45.1 Schematic illustration of biliopancreatic diversion according to original description by Scopinaro: residual gastric volume 200–400 ml, gastroileal anastomosis (c) with Roux-en-Y reconstruction (d) (1: alimentary limb = 200 cm, 2: biliary limb, 3: common limb = 50 cm). The operation included a distal gastric resection and a prophylactic cholecystectomy

normal nutrition. On the other hand, the length of the alimentary limb can influence the total amount of calories and protein absorbed. A longer alimentary tract will affect calorie absorption and weight loss significantly but can protect the noncompliant patient from the risk of protein calorie malnutrition. Usually, the alimentary limb is considered to be the bowel between gastroenteric anastomosis (GEA), and the ileoileal anastomosis (enteroenteric anastomosis). This is typically 200 cm in BPD. The common channel is the bowel from this latter anastomosis to the ICV. All the rest, between the ligament of Treitz and the enteroenteric anastomosis (EEA), is the biliary limb.

We would like to correct this definition as physiologically and semantically the alimentary limb is the length of bowel between the GEA and ICV. This definition is very important in the case of revisional surgery. The so-called "lengthening" to correct protein malnutrition consists of dividing the continuity of the alimentary limb and creating a new EEA 150 cm proximally to the biliary limb. This is described as lengthening of the common tract. Indeed the common channel length increases from 50 to 200 cm, but more important the total alimentary length increases from 250 to 400 cm allowing a significantly higher absorption of calories.

The alimentary limb length thus appears to be most important for adequate nutrition and successful weight loss.

To summarize, a typical BPD should have a large pouch with no food restriction, a common limb of 50 cm and an alimentary limb of 250–300 cm. Revision consists of adding 150 cm to the common limb in order to obtain alimentary limb of 400–450 cm length.

45.3 Biliopancreatic Diversion

The biliopancreatic diversion as described by Scopinaro [1] has undergone several modifications that have not altered the fundamental working principle: limited absorption of fat and carbohydrates. The typical procedure consists of creating a large gastric pouch, with a volume between 300 and 500 mL, such that it will not limit food intake in any manner (see Fig. 45.2). There should not be any permanent restriction and part of the digestive capacities of the stomach will be maintained. The distal gastric remnant can be removed, as originally described, or preserved, as many authors, including us, prefer [4–6]. Prophylactic cholecystectomy is not considered necessary. The advantage of preserving the distal stomach is the full reversibility, less surgical trauma, and earlier recovery. However, there may be an increase in marginal ulceration.

The reconstruction of the alimentary tract is performed as an antecolic Roux-en-Y with an alimentary limb of 200–250 cm and a common limb of 50 cm.

Several authors have modified the limb lengths. If you elongate the "total" alimentary limb (distance between the stomach and the ICV) you reduce the risk of protein malnutrition, but you compromise on the weight loss result. Interestingly, the need for a Roux-en-Y reconstruction can also be questioned. A Billroth II reconstruction at 300 cm from the ICV is feasible, safe and effective [7] (see Fig. 45.3).

The patient is placed in supine position with the right arm abducted and left arm along the body. The laparoscopic tower is placed near the patient's left shoulder. The surgeon operates by standing on right side of the patient while the assistant holds the camera standing behind the surgeon. Access is through an optical port Visiport™ 12 mm in the left hypochondrium. Under vision two 5-mm trocars are placed in the umbilicus and in the right hypochondrium. The intervention starts with the dissection with LigaSure™ 5 mm blunt tip 44 cm at the level of the lesser curvature of the stomach that is carried out at about 10 cm from the gastro-esophageal junction (see Video 45.1). Once the opening is made the stomach is transected transversally with two appli-

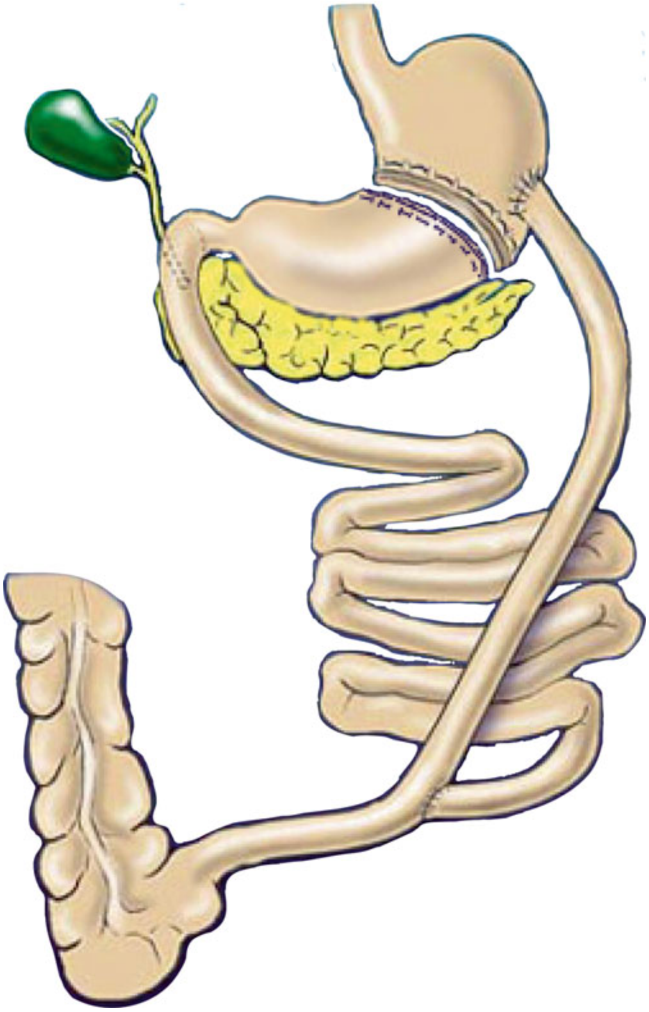

Fig. 45.2 Schematic illustration of biliopancreatic diversion: residual gastric volume 200–400 ml, gastroileal anastomosis (c) with Roux-en-Y reconstruction (d) (1: alimentary limb = 200 cm, 2: biliary limb, 3: common limb = 50 cm). The food is separated from the biliopancreatic secretions and mixing can happen starting from the common limb where absorption is possible

cations of Endo GIA™ articulating 60-mm purple Tristaple reload. Before dividing completely the stomach accurate hemostasis of the gastro-epiploic vessels is obtained (see Video 45.2). The gastric pouch volume is about 350 ml as measured at the time of methylene blue test for assuring integrity of the anastomosis. A gastrotomy is performed on the anterior surface of the stomach pouch near the lesser curvature and the hole is enlarged with a small bowel clamp to facilitate the future introduction of the stapler (see Video 45.3) The surgeon moves to the left side of the patient and the patient is put in an almost horizontal position; the omentum is shifted upward and to the right hypochondrium and the ICV is identified; two enterotomies are opened at 50 and 250 cm from the ICV (see Video 45.4). Measurement of the bowel is done coupling a straight small bowel clamp with the articulated grasper and the enterotomies are opened with coagulating scissors and marked with a stitch. An antecolic gastroenteric anastomosis is made using an Endo GIA™ articulating 45 tan Tristaple cartridge. The patient is put back into an reverse Trendelenburg position and the gastric remnant is retrieved with the grasper; the anvil is placed in the jejunum at 250 cm from the ileocecal valve, then the stapler is closed, shifted up and gastric pouch is approached while the direction of the joint is changed presenting the cartridge of the stapler in proximity of the gastrotomy (see Video 45.5) The defect is closed with a double layer handmade suture with the Endo Stitch™ (see Video 45.6). At about 10 cm from GEA along the afferent limb another enterotomy is made for the next enteroenteric anastomosis at a point 50 cm from the ICV that is found easily on the efferent limb. We use an Endo GIA™ articulating 60 mm tan Tristaple reload for the EE anastomosis and the final closure of the gap is performed with a double layer handmade Polysorbate™ 2/0 suture. The last step of the procedure consists of dividing the small bowel with an articulating 60-mm tan Tristaple between the two anastomosis to create the Roux-en-Y reconstruction (see Video 45.7). The patency of the GEA anastomosis is tested with methylene blue. We do not place drains. The operation ends with the release of the pneumoperitoneum and the removal of ports. The fascia is closed with an absorbable suture and the umbilicus is reinstated in its original position.

Our experience with BPD dates back to 1986, when we performed our first case using open surgery. In the beginning of 2000 we performed our first laparoscopic BPD according to the original Scopinaro's technique. In 2009 we introduced the single incision laparoscopic BPD (SIL-BPD) that has become our standard approach.

The potential advantage of single incision is the reduced postoperative pain while maintaining the same steps of laparoscopic procedure. The benefits are cosmetic, the happiness expressed by the patients of not having a visible scar and the psychological advantage of not having to disclose to others the fact that they underwent weight loss surgery.

Apart from the use of a single port, the technical steps for SIL-BPD and laparoscopic BPD are similar [8].

Prophylactic anticoagulants are given to all patients (Calciparine 5000 U bid or Enoxaparin 4000 U qd, subcutaneously, preoperatively as well as postoperatively until discharge).

Short term prophylactic antibiotic are used (2 g of cefazolin at operation time, followed by four doses of 1 g six hourly).

Daily multivitamin, iron and calcium oral supplements are prescribed to every patient.

The patients are followed in the clinic at 2, 6, and 12 months and yearly thereafter, as well as whenever the attending physician or the patient feels it necessary. At each visit medical his-

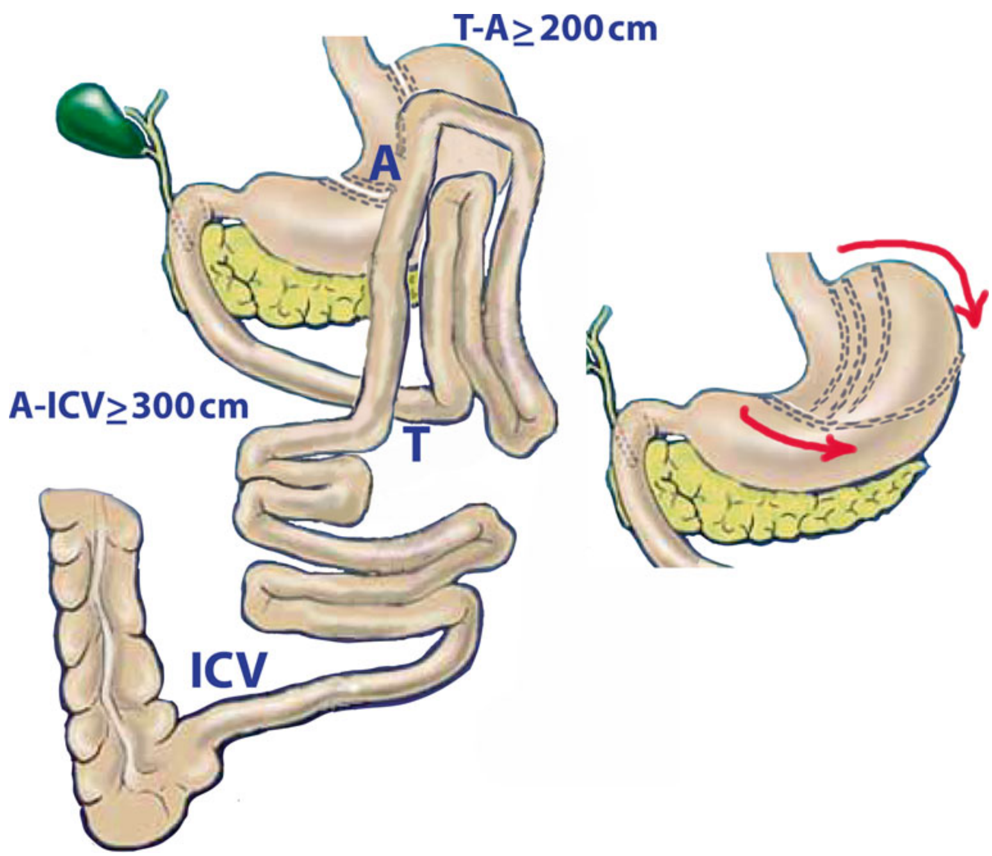

Fig. 45.3 Schematic illustration of Billroth II biliopancreatic diversion: residual gastric volume 200–400 ml, gastroileal anastomosis (c) with Billroth II reconstruction (d) (1: alimentary/common limb = 300 cm, 2: biliary limb = approximately 400 cm). Pouch shape and size can be adapted

tory is taken (compliance to prescriptions, dietary interview), a complete medical examination and laboratory tests are performed (urine, blood chemistry, hematology, coagulation).

Serum levels of alkaline phosphatase, vitamin D, parathyroid hormone (PTH), vitamin B12, folate, iron, zinc, copper, and magnesium are particularly monitored.

45.3.1 Indication for Surgery

We have performed BPD in a wide range of age, from the second to the seventh decade of life. Of course, these extremes were due to exceptional indications such as Prader-Willy syndrome. As a general rule, the widely accepted 18–60 years range should be used. Our patient population body mass index (BMI) ranges from 17 to 110 kg/m^2.

We stress the fact that low BMI is not a contraindication for BPD and that high BMI is not the preferred indication.

The threshold of absorption after BPD is 1800 kCal. If the patient is introducing any caloric intake above 1800 kCal the effect will be similar to that of a diet of 1800 kCal. Regardless of the initial weight they will tend to progress towards weight stabilization corresponding to an intake of 1800 kCal.

If their intake is lower there will practically be no malabsorption and weight loss. This is the reason why BPD can be used in low BMI diabetic patient with positive effect on glucose metabolism without weight loss [9].

A relatively low BMI patient, between 40 and 50 BMI, will have the best results from BPD without significant side effects. This patient is not eating an excess of fat and carbohydrate so the side effects due to malabsorption and fermentation will be limited.

On the other hand patients in the 30–40 BMI range will not benefit from a significant weight loss as their preoperative intake is probably not much higher than 1800 kCal.

45.4 Results

The result that we present below are from a group of 360 BPD patients with at least 10 years of follow up

45.4.1 Side Effects

Postoperative postprandial symptoms (early satiety, epigastric pain, vomiting) improve rapidly. Eight to twelve months after surgery the appetite is fully restored, patients can eat large meals, and on the average they eat more than before the operation [10].

The patients are instructed about the absorptive capacity of their bowel and are aware that they will absorb almost no fat, little starch, enough proteins but all monosaccharides and disaccharides and alcohol. They must learn to modulate the relative intake of nutrients in order to maintain a stable long term weight.

When patients resume a normal food intake the number of bowel movements increases. The incidence of foul smelling stools and flatulence vary depending on eating habits, fat and starch intake. Diarrhea, present in the early phase due to the rapid gastric emptying, decreases over time. It is rarely reported as frequent after 1 year and in 80 % of these cases, is related to lactose intolerance.

Many patients complain of poor cold tolerance after weight loss. There may be metabolic reasons for this but loss of insulating fat is the most likely explanation.

Rarely, patients request restoration because they do not tolerate the normal side effects of BPD, particularly the foul-smelling stools.

45.4.2 Complications

45.4.2.1 Early Postoperative Complications

Many complications (see Table 45.1) may cluster in the same patient; for example, protein malnutrition is often associated with vitamin and iron deficiency. Thus, when analyzing results, it is important to consider the overall complication rate in the total number of patients experiencing clinically significant complications (see Table 45.2). Leak is rare after BPD compared to other procedures; in this series, it was seen in one in 360 cases. This is probably related to the fact that the anastomosis is done on the body of the stomach, without tension and good blood supply. Revision is easier compared to other surgeries as intact stomach is available. The incidence of early nonspecific complications is comparable with other types of bariatric surgery and the rate can be considered acceptable for an abdominal surgical procedure.

In our experience perioperative mortality directly or indirectly related to the procedure is 0.3 % [10].

Table 45.1 Early, late complication, reoperations and causes of death (%)

Early (less than 30 days) postoperative complications	
Pneumonia	0.6
Intrabdominal bleeding[a]	0.3
Small bowel obstruction[a]	0.3
Leak[a]	0.3
Myocardial infarction[b]	0.3
Late complications	
Secondary hyperparathyroidism	8.5
Anemia	6.6
Protein malnutrition	3.1
Anal fissure	1.4
Peptic ulcer	1.4
Severe bone disease	0.8
Night blindness	0.8
Reoperations	
Protein malnutrition: elongation	2.5
Biliary limb obstruction	1.1
Reversal	0.8
Alimentary limb obstruction	0.3
Deaths	
Pulmonary embolism	0.3
Myocardial infarction	0.3

[a]Early reoperations: (0.8 %)
[b]Postoperative mortality: (0.3)

Table 45.2 Cumulative complication rate (%)

Early postoperative complications	1.6
Early reoperations	0.8
Postoperative mortality	0.3
Nutritional sequelae	6.6
Late reoperations	4.7
Total	7.2

Table 45.3 Incidence of abnormal values (%)

	Preoperative	Postoperative
Alkaline phosphatase	5.7	14.2
Vitamin D3	80.0	45.8
Parathyroid hormone	0.4	12.2
Vitamin B12	19.0	33.8
Folate	1.3	25.9
Iron	9.0	15.6
Iron binding capacity	12.5	14.6
Hemoglobin	23.6	27.2
Mean corpuscular volume	0.95	11.6
Zinc	30.7	38.2
Copper	45.5	25.0
Magnesium	2.8	5.6
Albumine	9.6	7.8

45.4.2.2 Nutritional Complications

Rapid weight loss, whether induced by diet, gastric restriction or malabsorption is associated with a variety of nutritional problems and deficiency states (see Table 45.3). Metabolic problems are more frequent when patients have inadequate knowledge or education about nutrition and when compliance is poor. Close follow up is essential.

Vitamins

Deficiency of water soluble B complex vitamins, a few weeks or months after BPD, may produce severe symptoms including encephalopathy with confusion, ataxia or coma [11], acute visual loss [12], peripheral neuropathy [13] and death unless rapid vitamin replacement by intravenous route is initiated. This can be associated with rapid weight loss, excessive vomiting, and inadequate vitamin intake due to poor advice or poor compliance and inadequate follow up by the family doctor. In our series we did not observe any case, the key being prevention.

Lack of standard test for evaluating vitamin A status [14] leads to an underestimation of true incidence of vitamin A deficiency. The cases of night blindness probably represent only the clinically evident cases, while many subclinical deficiencies are not diagnosed. Therefore, periodical administration of parenteral vitamin A should be advocated.

Episodes of hair loss are common during the first 6 months following BPD. Possible explanations include lack of protein, vitamin or zinc [15]. The problem has been termed "telogen effluvium." The cause may simply be severe caloric restriction that affects the hair matrix where there is a high cell turnover. It is well tolerated as long as patients are warned that it may happen and reassured when it does occur.

Bone Metabolism

The duodenum and proximal jejunum are sites for calcium absorption. Deficiency of fat soluble vitamins and metabolic bone disease were reported following jejuno-ileal bypass [16] as well as in patients with severe obesity without surgical treatment [17]. The bone demineralization following BPD [18] does not seem to differ from that reported after distal gastrectomy with duodenal exclusion for ulcer [19] and after gastric bypass surgery for obesity [20].

An increase in alkaline phosphatase usually indicates osteomalacia that is associated with abnormal PTH and decreased plasma vitamin D activity (not included in Table 45.3). Osteomalacia is important because of the increased risk of fractures. Treatment and prevention are possible with vitamin D and calcium supplements.

Although all patients were encouraged to maintain daily oral intake of calcium citrate to around 2 g and to supplement vitamin D by mouth, a significant incidence of secondary hyperparathyroidism was documented. This can be attributed both to a poor compliance to calcium intake and also to the inadequacy of oral vitamin D preparations. Our current protocol includes periodical intramuscular vitamin D and intravenous treatment of all subclinical cases documented by laboratory tests.

Decreased magnesium levels have been reported years after gastrectomy [21] and gastric bypass [22].

Zinc deficiency can be observed during prolonged starvation or parenteral nutrition and is associated with diarrhea, dermatitis and alopecia [23]. A decrease in serum zinc is associated with immunological problems [24].

Anemia

Obese patients are subject to the usual causes of anemia before and after surgery. Excessive menstrual bleeding in younger females, hemorrhoids or stomal ulceration may be a contributing factor to iron deficiency. The most frequent cause of anemia is iron deficiency followed by vitamin B12 and folic acid deficiency. Understandably, exclusion of the primary site of iron absorption in the alimentary tract causes an unavoidable incidence of iron deficiency. Vitamin B12 deficiency although rare is caused by the gastrectomy with loss of intrinsic factor while folic acid deficiency is explained by a degree of malabsorption. The strict follow up of the patients and the supplementation with iron and folate has kept the incidence of anemia, requiring further treatment, to less than 7 % [10].

Protein Malnutrition

The degree of weight loss tolerated by patients is often surprising. Patients may lose as much as 100 kg in the first year without apparent clinical or biochemical side effects. On the other hand some patients develop protein calorie malnutrition with anemia.

Two different types of malnutrition can be recognized, early and late.

The early episodes occurring during the first year are caused by a prolonged reduction of food intake or insufficient intake of proteins.

Late malnutrition can be related to concomitant diseases that cause diarrhea (protozoal infections, bacterial gastroenteritis) or reduction of food intake (for example peptic ulcer). Cases of recurrent protein malnutrition can be attributed to excessive malabsorption or permanent reduction of food intake. The former are corrected by lengthening of the common alimentary tract while for the latter full reversal is advisable. From personal experience and data in literature [2] despite the revision these patients do not regain significant weight as they reach an adequate balance between food intake and absorption.

45.4.3 Effects

45.4.3.1 Weight Loss

Weight loss after BPD is excellent (see Fig. 45.4). The final mean BMI is around 30 kg/m^2. This means that on an average patients are not "morbidly" obese anymore. The final result can also be viewed as a function of the initial overweight category (see Fig. 45.5).

After 5 years all of the super obese patients (initial BMI more than 50 kg/m^2) reached a BMI below 50 kg/m^2 and less than 20 % had a BMI between 40 and 50 kg/m^2. Of those patients with initial BMI between 35 and 50 none of them is above 30 kg/m^2. That means a "cure" rate of 100 % for obese and of 70 % for super obese patients.

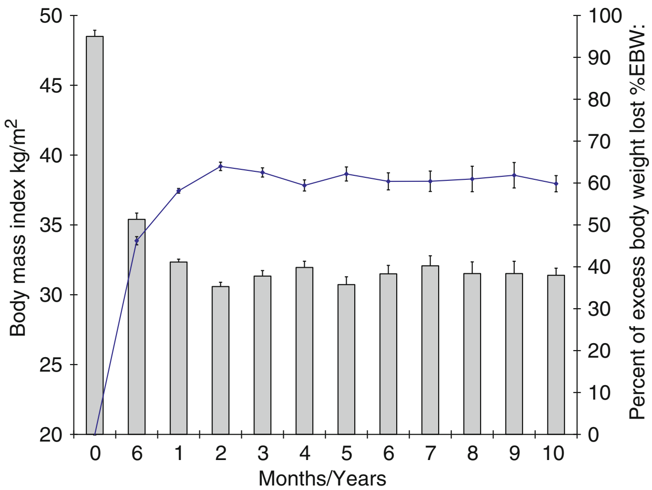

Fig. 45.4 Weight loss after biliopancreatic diversion. BMI and % of Excess Body Weight Lost: mean values ± SEE in 360 patients with at least 10 years of follow up. Percentage of patients attending follow-up: Pre: 100; 2 months: 91; 6 months: 91; 1 year: 87; 2 years: 87; 3 years: 85; 4 years: 83; 5 years: 88; 6 years: 87; 7 years: 81; 8 years: 71; 9 years: 87; 10 year: 86

This practically means that while one can predict weight loss to almost normal levels in all the obese patients, the super obese will lose only a percentage of the initial excess weight, and will not return to the normal levels.

Weight maintenance is the strength of BPD and long term weight results confirm the stability of weight loss with no tendency to regain.

45.4.3.2 Comorbidities

The beneficial effects of BPD on comorbidities (see Table 45.4) derive not only from the weight loss but also from reduced nutrient absorption and hormono-metabolic modifications.

Substantial changes in sex hormones have been found after weight loss and we observed return of regular periods in many women. The return of ovulation is associated with an increased chance of pregnancy.

Pregnancy early after BPD can be hazardous to both mother and child because of the poor nutrition, a consequence of rapid weight loss. Pregnancies after this time have

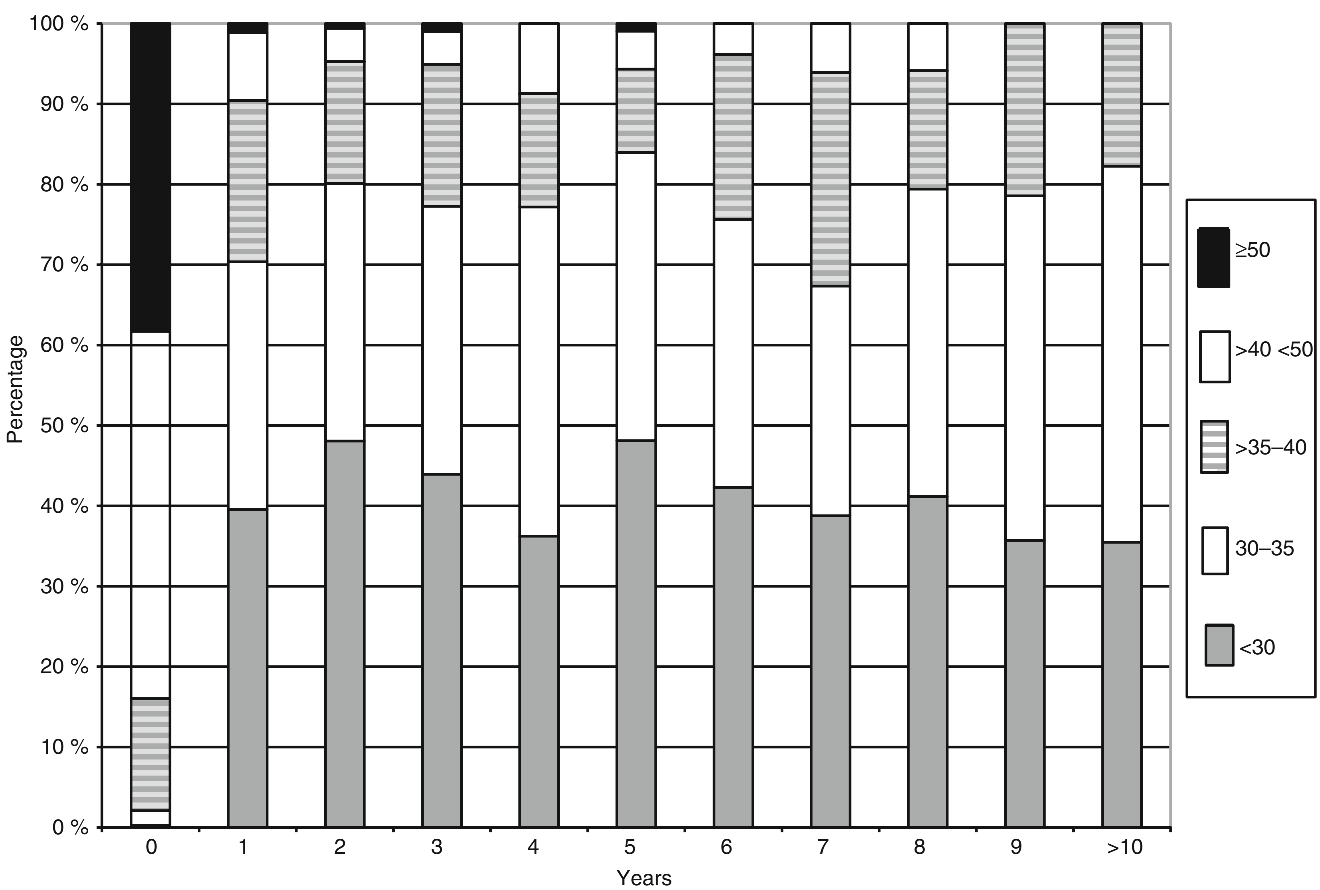

Fig. 45.5 Distribution of patients in BMI categories preoperatively, 1, 5 and over 10 years after biliopancreatic diversion

Table 45.4 Incidence of medical comorbidities before and after BPD (%)

	Preoperative	1 year	<10 years
Hyperglycemia (oral antidiabetic therapy)	23	0	0
Type II diabetes (insulin therapy)	2	0	0
Hypercholesterolemia	53	3	0
Hypertriglyceridemia	17	4	5
Hyperuricemia	21	0.9	0
Respiratory Insufficiency	44	0	0
Pickwick syndrome	3	0	0
Hypertension	36	3	3

been uncomplicated and represent an extra benefit to the previously infertile obese women.

The decrease in cholesterol serum levels exceeds the simple reduction of intestinal absorption. The partial interruption of bile salt enterohepatic circulation enhances bile acids synthesis and can explain part of the phenomenon. Serum cholesterol levels decrease both in patients with normal and elevated (greater than 200 mg/dL) preoperative values. Low and very low density lipoproteins cholesterol levels decrease, but high density lipoprotein cholesterol levels remain unchanged.

Elevated uric acid values return to normal in most patients and a significant decrease is observed in those with normal preoperative values.

The most striking metabolic effect of BPD is on insulin resistance. The normalization of blood glucose levels with restoration of normal insulin sensitivity is the rule following biliopancreatic diversion. This effect is evident independently of weight loss and thus a specific action of BPD must be postulated. Hypotheses have been made on the role of plasma free fatty acids levels [25] and on the interruption of enteroinsular axis [26] caused by the operation [9, 25].

Conclusion

The results demonstrate the efficacy of BPD in weight loss, long term weight maintenance and resolution of comorbidities. The biliopancreatic diversion is very effective particularly in high risk superobese patients where this technique is easier, safer and presents less surgical complications compared to other bariatric procedures. The Billroth II approach further simplifies the procedure while preserving the effectiveness of limited absorption technique.

Most metabolic changes are beneficial rather than harmful. For most patients, the postoperative course is uneventful in spite of the profound weight loss. Careful patient selection, instruction and close postoperative follow up can prevent problems.

Key Learning Points

- BPD is ideal for patients who will not be able to accept food restriction.
- The procedure must not produce any restriction.
- Resolution of comorbidities and weight maintenance is excellent.
- Compliance to supplements is mandatory.
- The procedure can be safely done on low BMI subjects: they will resolve comorbidities without weight loss.

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Laparoscopic Banded Gastric Bypass Surgery

46

Mathias A.L. Fobi and Mohit Bhandari

Abstract

The laparoscopic banded gastric bypass is a modified gastric bypass operation with a controlled reservoir formed by placing a ring or band around the gastric pouch. The placement of the ring prevents the formation of the neo-pouch that forms after gastric bypass operations, when the pouch, stoma and proximal jejunum dilate over time. Control of the reservoir size has been reported to result in more weight loss and better weight loss maintenance by enhancing the restriction and full sense mechanisms that decrease caloric intake and result in weight loss. A report of a series of 167 patients with 3–5 years follow up is presented; the patients had laparoscopic banded gastric bypass as a part of the Food and Drug Administration (FDA) clinical trials where GaBP Ring™ is used to band the pouch in the banded bypass. The results corroborate the results of more weight loss and weight loss maintenance reported with banded gastric bypass.

Keywords

Laparoscopic • Banded Gastric Bypass • Ring • Reservoir • GaBP Ring™

46.1 Introduction

The banded gastric bypass (BGBP) is a modified gastric bypass operation which creates a tubular gastric pouch (See Video 46.1). A ring is placed around the pouch to control the reservoir capacity of the patient [1]. The gastro-intestinal continuity is completed by forming a gastro-intestinal anastomosis with a Roux-en-Y limb 2 cm distal to the ring (See Fig. 46.1) [2].

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The gastric bypass operation is currently known to affect weight loss, weight maintenance, and metabolic effects by eight mechanisms [3–5].

1. *Restriction mechanism*: Small reservoir capacity of the stomach—small pouch and small stoma.
2. *Full sense mechanism*: Stretching of the gastro-esophageal junction after oral intake causes neuro stimulation that signals fullness to the brain.
3. *Malabsorption*: Bypassing of the proximal gastrointestinal tract—decreasing the digestive and the absorptive ability of the gastro-intestinal tract results in decreased caloric absorption.
4. *Decreased ghrelin secretion*: Excluding or removing the gastric fundus and antrum results in decreased ghrelin secretion thus minimizing the desire to eat. It results in decreased caloric intake.
5. *Dumping*: Neurotensin effect—entrance of caloric dense and/or a large volume directly into the small bowel causes pulling of fluid into the small bowel with resultant diaphoresis, tachycardia, hyper motility of the small bowel

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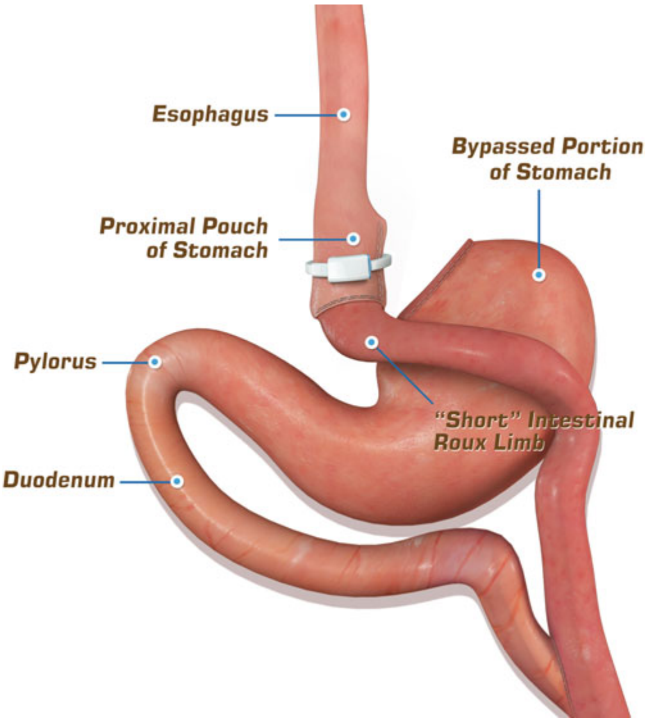

Fig. 46.1 Banded gastric bypass

and somnolence. It alters the eating habit of patients in favor of less caloric dense foods.

6. *Foregut and hindgut incretins release*: Neuro-hormonal changes alter the choice of foods, sensitivity to various nutrients particularly sugars, and other cognitive changes.
7. *Changes in the microbiota of the gut*: Alteration of the microbiota of the gastrointestinal tract, with neuro-hormonal stimulation, alters the sense of satiety, choice of foods and sensitivity to various nutrients. It results in decreased caloric intake.
8. *The compliance mechanism*: It is patient dependent, very important but not predictable.

46.2 The Banded Gastric Bypass

The premise for the banded gastric bypass is that placing a ring/band around the pouch of the gastric bypass operation, stabilizes the restriction and full sense mechanisms.

The thought had always been that the restrictive and full sense mechanisms of the gastric bypass are due to the size of the pouch and/or the size of the stoma. It is now known that the size of the gastric reservoir, after the gastric bypass operation, is the important component of both the mechanisms. Initially after any gastric bypass operation, the gastric reservoir size is same as the gastric pouch. However, with time, the pouch, the stoma and the proximal jejunum stretch or dilate and it results in dilated pouch and dilated jejunum [1]. The larger neo-reservoir formed allows for less restriction and increased caloric intake before the full sense signal is registered in the brain. The larger neo-reservoir, depending on its size, results in inadequate weight loss and/or weight regain after the gastric bypass operation (See Figs. 46.2, 46.3, and 46.4). It is now known that banding the pouch of the gastric bypass operation prevents the formation of the reservoir that is made up of dilated pouch, stoma and proximal jejunum (See Figs. 46.5, 46.6, and 46.7). The small and stabilized reservoir formed by placing a ring/band around the gastric pouch, is responsible for the better restriction and full sense mechanisms after banded gastric bypass. It results in better weight loss and weight loss maintenance.

Various materials have been used to band the pouch (See Table 46.1). We prefer to use the GaBP Ring™ which is a prefabricated, standardized and auto-locking device that comes in various sizes ranging from 6.0 to 7.5 cm (See Fig. 46.8). Animal studies by Bozbora [6] showed silicone to be the least reactive material for banding the pouch. Erosion of the silicone ring is easily treated by endoscopic extraction [7].

46.3 Surgical Technique

46.3.1 Formation of the Banded Pouch

The operation is done laparoscopically with the patient in the semi-Trendelenburg position. Four to six trocars are used (See Fig. 46.9). The light source is placed through a trocar at or just above the navel depending on the patient's pannus. A trocar is placed at the xyphoid for the liver retractor, two subcostal trocars are placed at the para-costal line for retraction and exposure, and one or two trocars are used for operating and passage of the stapling devices and the ring/band (See Fig. 46.9).

After the trocars are in place, the first step is either to perform laparoscopic exploration of the abdominal cavity to determine if there is any pathology that may be addressed at the time of the operation or to make a note to monitor and address later. Inspection of the small bowel is made to ascertain that there are no extensive adhesions, of the small bowel, that may prevent bringing it up to establish the gastrointestinal continuity.

Liver retractor is placed to expose the gastro-esophageal junction. A gastric tube of size 34–40 is inserted to decompress the stomach, removing any contents that are still in the stomach.

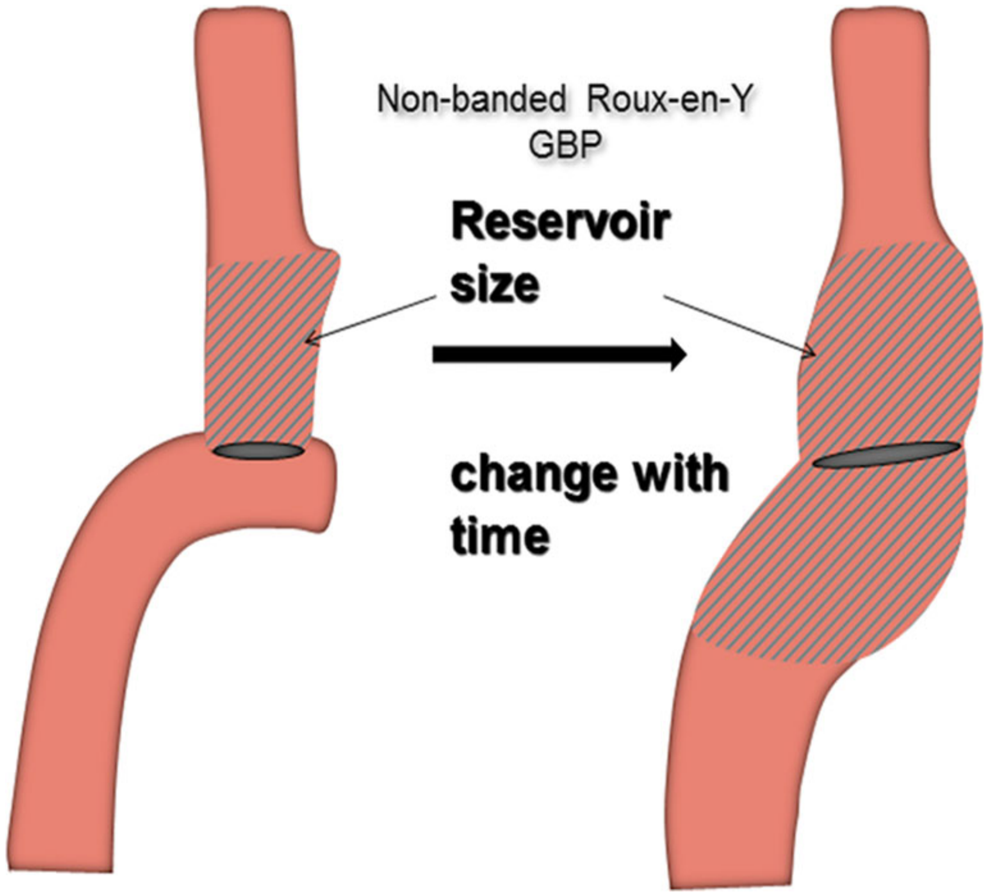

Fig. 46.2 New gastric reservoir of dilated pouch and dilated proximal jejunum

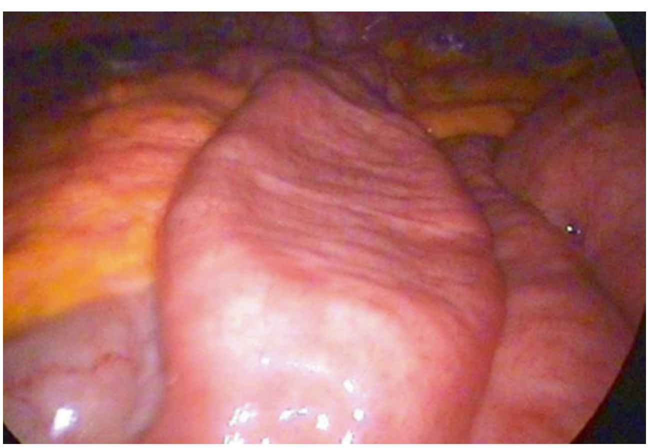

Fig. 46.3 Dilated proximal small bowel that becomes part of the gastric reservoir

The left gastro-esophageal junction is mobilized and exposed (See Fig. 46.10). A peri-gastric window is made on the lesser curvature of the stomach at a point 5–6 cm from the gastro-esophageal junction. A stapler is passed through that window and used to transect the stomach horizontally. With the gastric tube in place, the gastric transection is then carried out vertically to the gastro-esophageal junction coming out at least 1 cm on the stomach side of the gastro-esophageal line (See Fig. 46.11a–e). Hemostasis on the cut edge of the staple lines is controlled with sutures and/or clips.

46.3.2 Placement of the GaBP Ring™

Once the vertical and tubular pouch is formed, a peri-gastric window is then made on the lesser omentum at a point at least 2 cm from the distal transected end of the pouch. Through that window a ring is passed, placed around the pouch and locked. A non-absorbable suture is used to anchor the ring in place at the anti-mesenteric border of the pouch (See Fig. 46.12a–f). With the ring stabilized in place by the lesser curvature omentum and the suture, a membrane will form around the ring within 3 weeks to stop it from slipping. The ring needs to be loose around the pouch and it should not compress the wall of the pouch (See Fig. 46.13). We use GaBP Ring™ of size 6.5 cm with 2 cm diameter because it gives the optimum stoma for controlling the reservoir and allows more food tolerance [8, 9].

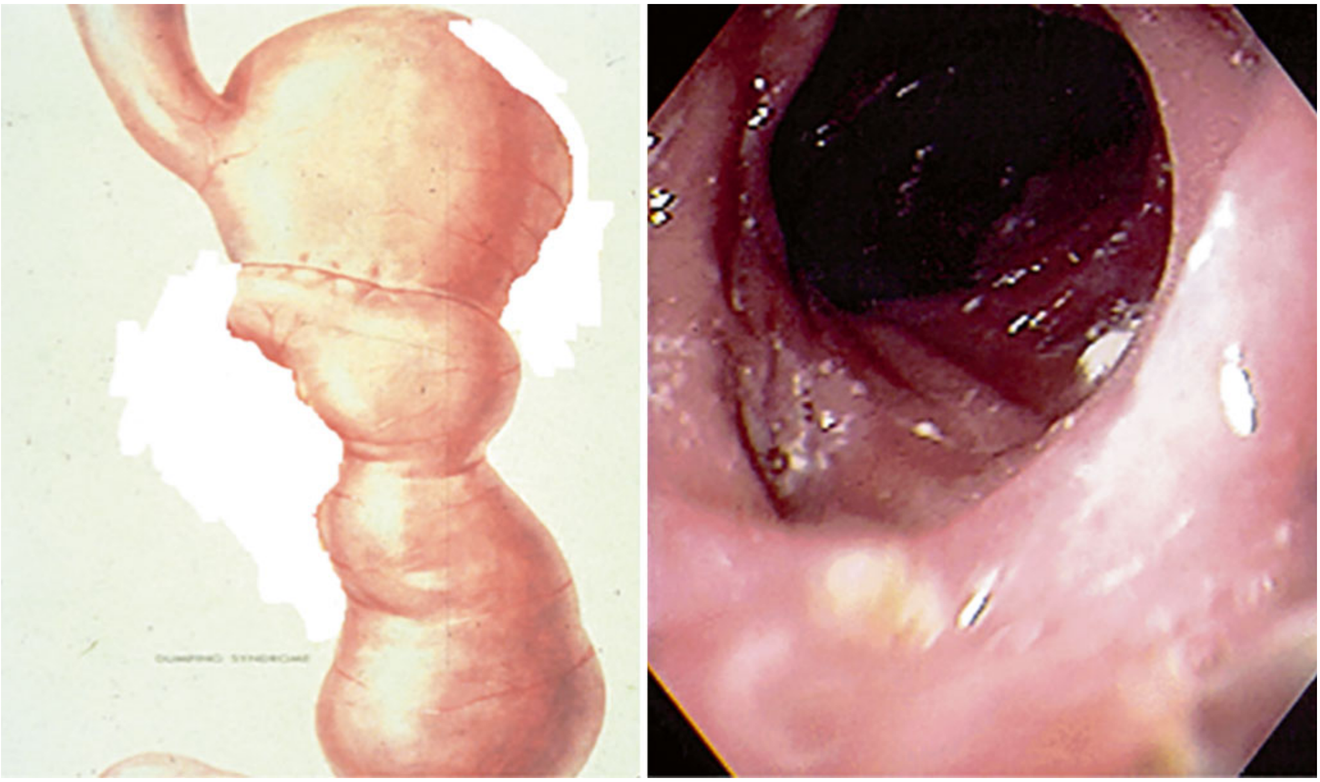

Fig. 46.4 New gastric reservoir made up of the dilated pouch and dilated jejunum

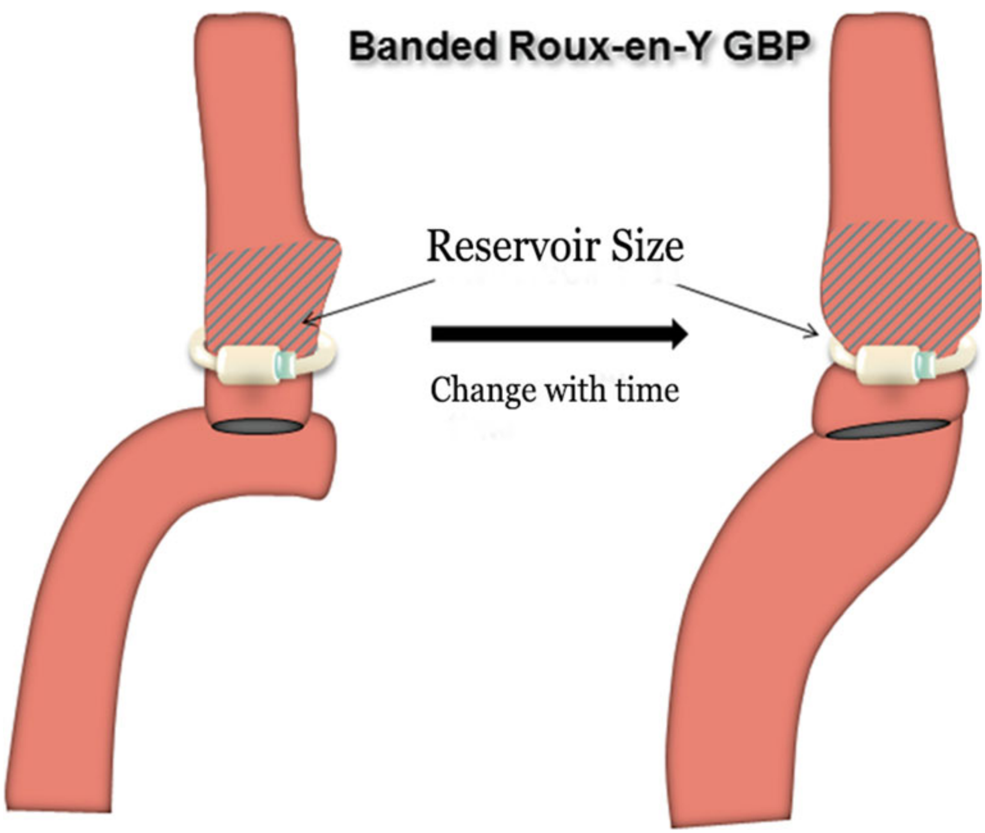

Fig. 46.5 Putting a ring around the pouch prevents formation of the new reservoir

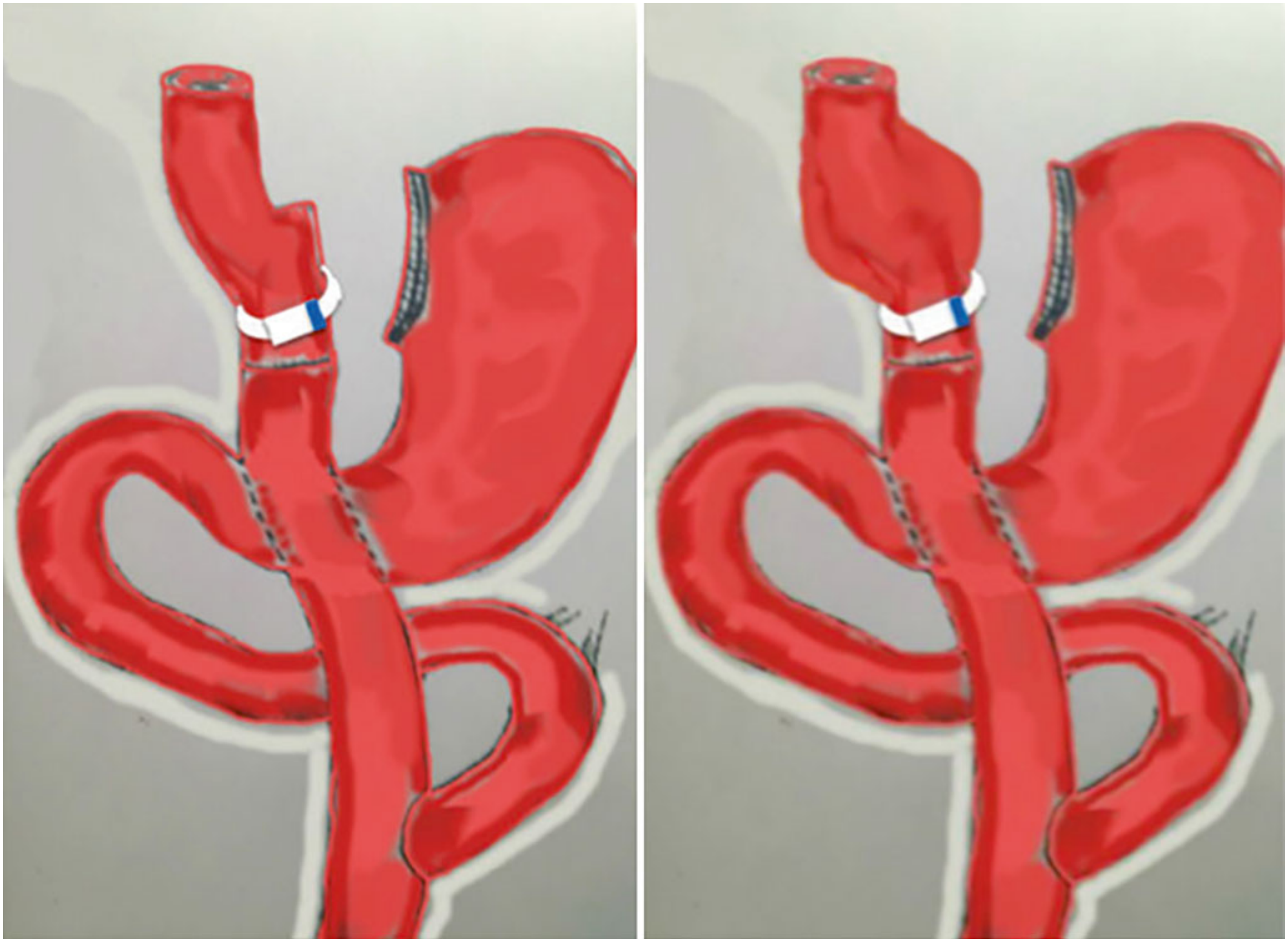

Fig. 46.6 A banded gastric bypass with limited increase in reservoir size

46.3.3 Formation of the Roux-en-Y Limb

The omentum is retracted cephalic exposing the ligament of Treitz. The small bowel is transected 35–60 cm from the ligament of Treitz where there is good mesentery arcade to vascularize the Roux limb, thus creating the biliopancreatic limb. The Roux limb is measured to a point of 75–100 cm where the biliopancreatic limb is anastomosed side-to-side using a gastro-intestinal anastomotic stapler with hand sewn closure of the enterostomy (See Fig. 46.14a–e). The mesenteric defect is closed with non-absorbable suture to prevent internal hernia formation (See Fig. 46.15a, b).

46.3.4 Formation of Gastro-jejunostomy

The omentum is divided to facilitate bringing up the Roux limb ante colic and ante gastric to anastomose to the pouch. The end of the gastric pouch is anastomosed to the side of the small bowel either hand sewn, with a circular stapler or by using a gastro-intestinal anastomotic stapler. The gastro-enterostomy is closed with hand sewn sutures. We prefer to do the hand sewn gastro-jejunostomy (See Fig. 46.16a–c).

46.3.5 Closure of Petersen's Defect

Petersen's defect, which is present in all gastric bypass operations, is sought and closed with non-absorbable suture to prevent internal hernia formation. A purse string suture encompassing the omentum, the small bowel mesentery and the retroperitoneal mesentery is usually adequate (See Fig. 46.17a–c).

46.4 Results

A total of 215 patients had the GaBP Ring™ (See Fig. 46.8) placed during the banded gastric bypass in the US Food and Drug Administration (US FDA) clinical trials, from April 2003 to September 2006, at the Center for Surgical Treatment of Obesity, California, United States of America (U.S.A). 48

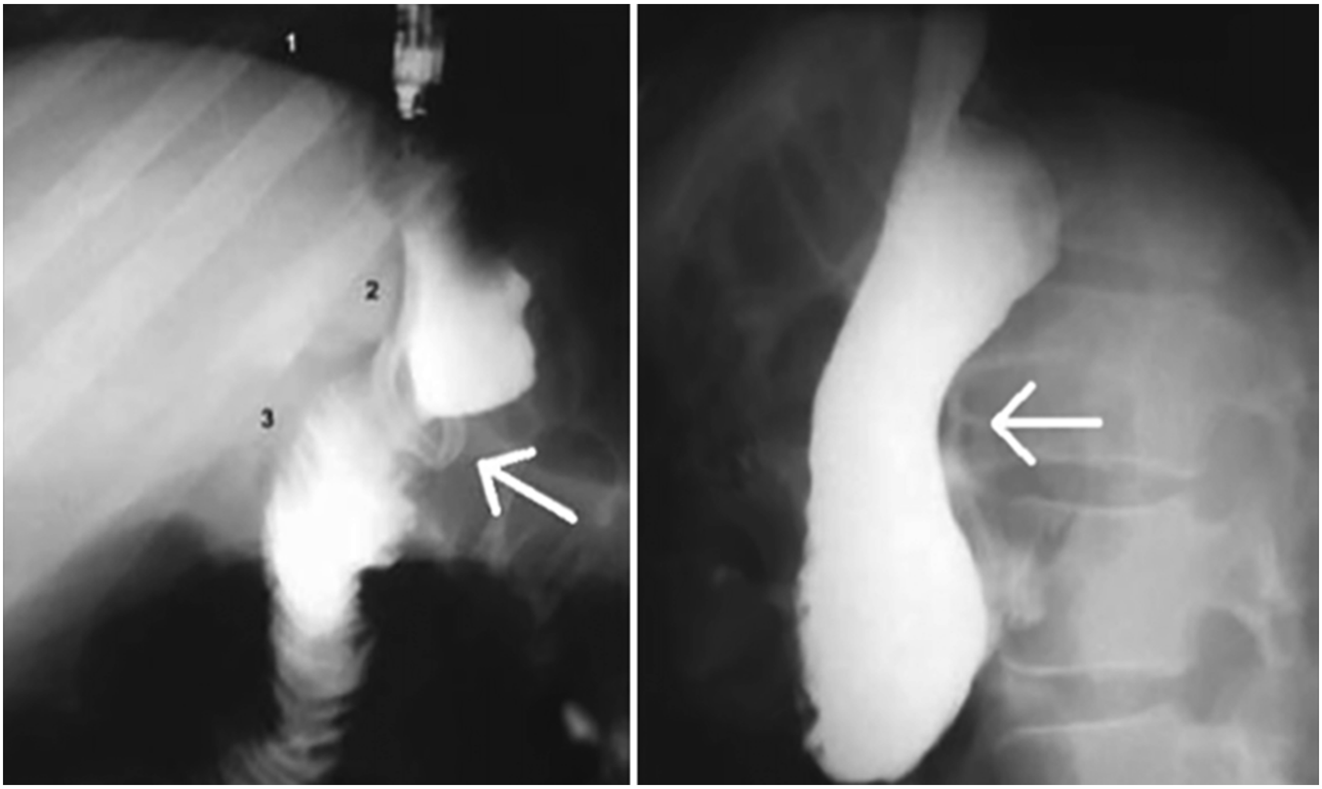

Fig. 46.7 X-rays of banded gastric bypass pouch with controlled reservoir VS. Non-banded gastric bypass with dilated pouch, stoma and proximal small bowel with a large reservoir. The *arrow* on the left is pointing to the new stoma created by the GaBP Ring. The *arrow* on the right is pointing to the dilated gastro-enterostomy that used to be the out let or stoma. *1* Diaphragm, *2* Liver no significance (*Arrow* pointing to) GaBP Ring providing a fixed pseudopyloris or stoma, *3* Liver no significancs (proximal dilated small bowel to the right)

Table 46.1 Band types

Marlex mesh
Porcine graft
Bovine graft
Silastic tubing
Linea alba fascia
Various non-absorbable sutures
GaBP RingTM (designed for the Gastric Bypass)
IOC band
Lap-band
Pericardial patch

patients had the operation through open laparotomy and 167 patients had the operation using laparoscopic approach. Tables 46.2, 46.3, 46.4, 46.5, 46.6, and 46.7 detail the outcome from the 167 patients who had the laparoscopic banded gastric bypass with up to 5 years follow up. The patient demographics are summarized by gender, age and initial body mass index (BMI) in Table 46.2.

The preoperative co-morbidities including arthritis, asthma, diabetes, gastro-esophageal reflux disease (GERD), high blood pressure, hypercholesterolemia, sleep apnea and urinary incontinence are summarized in Table 46.3.

Postoperatively, for the patients who completed follow-up visits at the time the report was written, the follow-up data at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years is

Fig. 46.8 GaBP RingTM devise used for banding the banded gastric bypass

Fig. 46.9 Trocar sites for laparoscopic banded gastric bypass

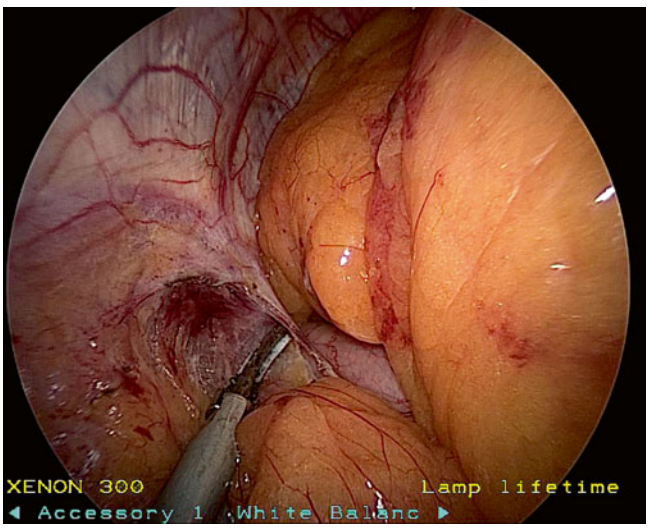

Fig. 46.10 Mobilization and exposure of the left gastro-esophageal angle

presented in Table 46.4. Not all patients had reached 3 or more years after operation, and thus were not eligible for longer postoperative follow-ups.

The early postoperative complications (within 30 days of the operation) are summarized in Table 46.5. Five (3 %) leaks required re-exploration. The three patients with gastric outlet stenosis required one endoscopic dilatation each. The patient with deep venous thrombosis required re-admission to hospital for anticoagulation and the patient with marginal ulcer was treated with medications.

The late postoperative complications included the five small bowel obstructions requiring surgical exploration, the three ring slippages requiring laparoscopic ring removal, the two cases of excessive weight loss requiring ring removal and the one case of penetrating ulcer requiring revisional surgery with ring removal because of ring erosion (See Table 46.6). Out of 167 patients, seven patients (4.2 %) have had the GaBP Ring™ removed, one patient due to contamination from leaks and six patients due to slippage, erosion or excessive weight loss. There were no early or late postoperative deaths.

The percentage of excess weight loss at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years is summarized in Table 46.7. The patients with successful weight loss with >50 % excess weight loss are derived from the patient population who completed their postoperative follow-up visit for the time period described in the Table 46.4.

46.5 Discussion

Laparoscopic banded gastric bypass is currently the preferred and most commonly used method of performing the banded gastric bypass [10–16]. A study of the outcome of prospective randomized comparison of laparoscopic banded gastric bypass vs. laparoscopic non banded gastric bypass by Bressler [17], in super obese patients, showed superior weight loss and weight loss maintenance with the laparoscopic banded gastric bypass with no mortality and no difference in the incidence of morbidities. Henegan [18] also reported better weight loss with laparoscopic banded gastric bypass, in the comparative study of laparoscopic banded gastric bypass to a cohort of laparoscopic non banded gastric bypass. The difference was found to be more in the super-obese. Zarate [19], however, reported no difference in the outcome between laparoscopic banded vs. non banded gastric bypass. There was no mortality and no difference in the incidence and types of morbidities. Several reports in the literature show weight loss and weight loss maintenance after laparoscopically placing a ring or band, to control the gastric reservoir, around the pouch of a failed gastric bypass operation [20–25].

The occurrence of the early and late postoperative complications in our series is the same as reported in the above reports [17–23] and as reported in the literature using the "surgeon-fashioned" rings/bands [3, 10, 11]. The incidence of ring-related complications, ring erosion, ring slippage and gastric outlet stenosis is within the range of what is reported in the literature with the "surgeon-fashioned" devices in open or laparoscopic banded gastric bypass [10–13]. The success rate at all intervals in our series is identical to what is reported in the literature after banded gastric bypass and is higher than in the regular gastric bypass [10–15, 17, 18]. Subjectively, it is easier and desirable to have a ring/band that is prefabricated, standardized, sterile and ready to use in the laparoscopic banded gastric bypass. The auto-locking mechanism of the GaBP Ring™ highly enhanced the placement of the ring, thus decreasing surgical trauma and reducing surgical time [16].

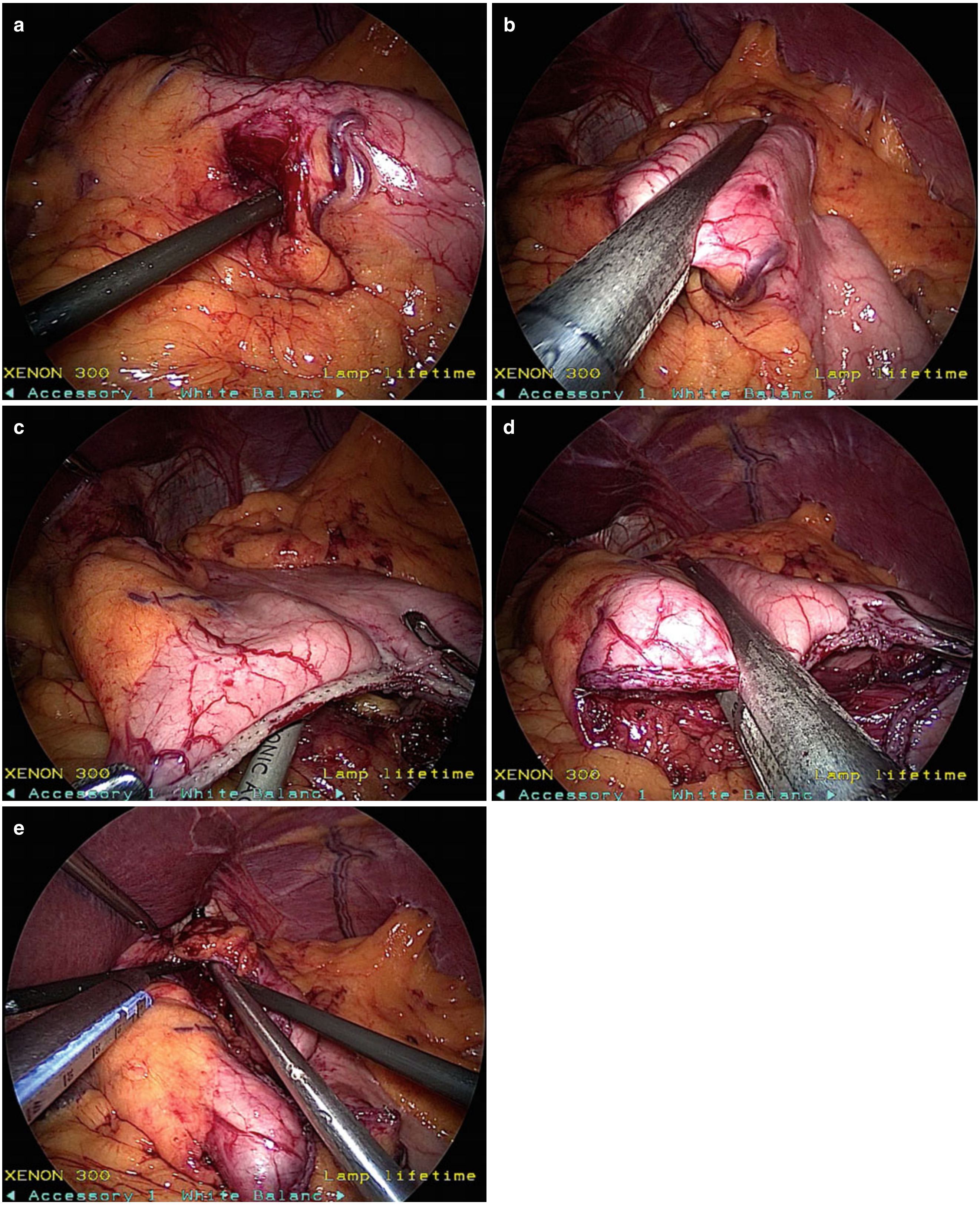

Fig. 46.11 Creation of vertical tubular pouch. (**a**) Perigastric window 5–6 cm from gastro-esophageal junction. (**b**) Horizontal gastric transection to form pouch. (**c**) Partially transected stomach. (**d**) Vertical gastric transection to form pouch. (**e**) Created tubular pouch of 15–25 cc

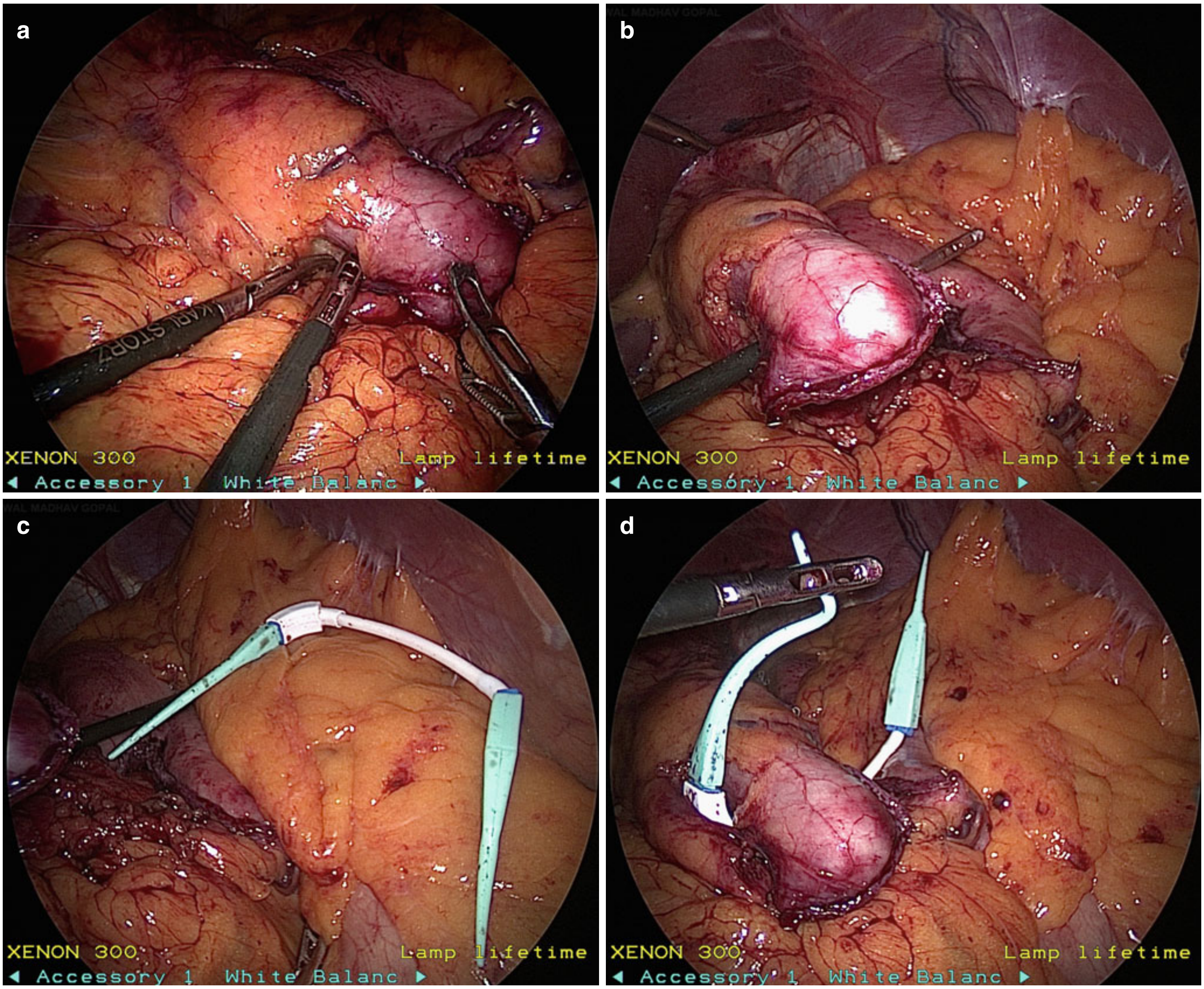

Fig. 46.12 Implantation of the GaBP RingTM. (**a**) Creation of a peri-gastric window 2 cm from the cut end of pouch. (**b**) Pass a grasper though the window to grab the GaBP RingTM introducer. (**c**) Insert GaBP RingTM into the peritoneal cavity through a 10–12 trocar. (**d**) Place the ring around the pouch. (**e**) Remove introducer and latch cover to expose both the locking ends of ring. (**f**) Engage the ends of the ring, lock it with a click and test to make sure it is locked

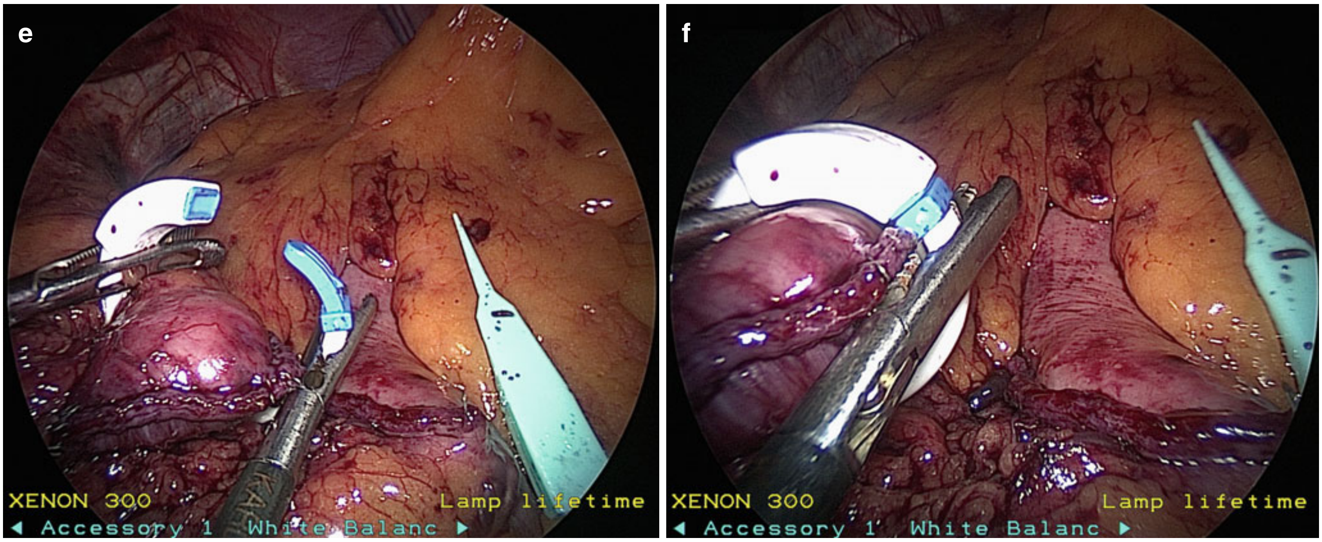

Fig. 46.12 (continued)

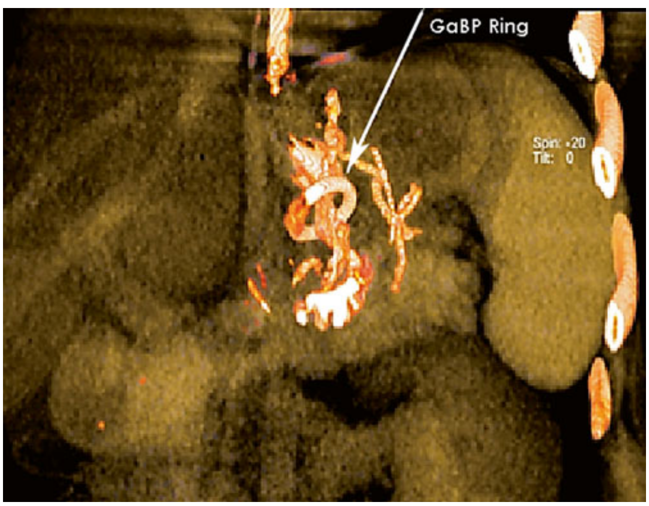

Fig. 46.13 3D Recon image of GaBP RingTM loose around the pouch

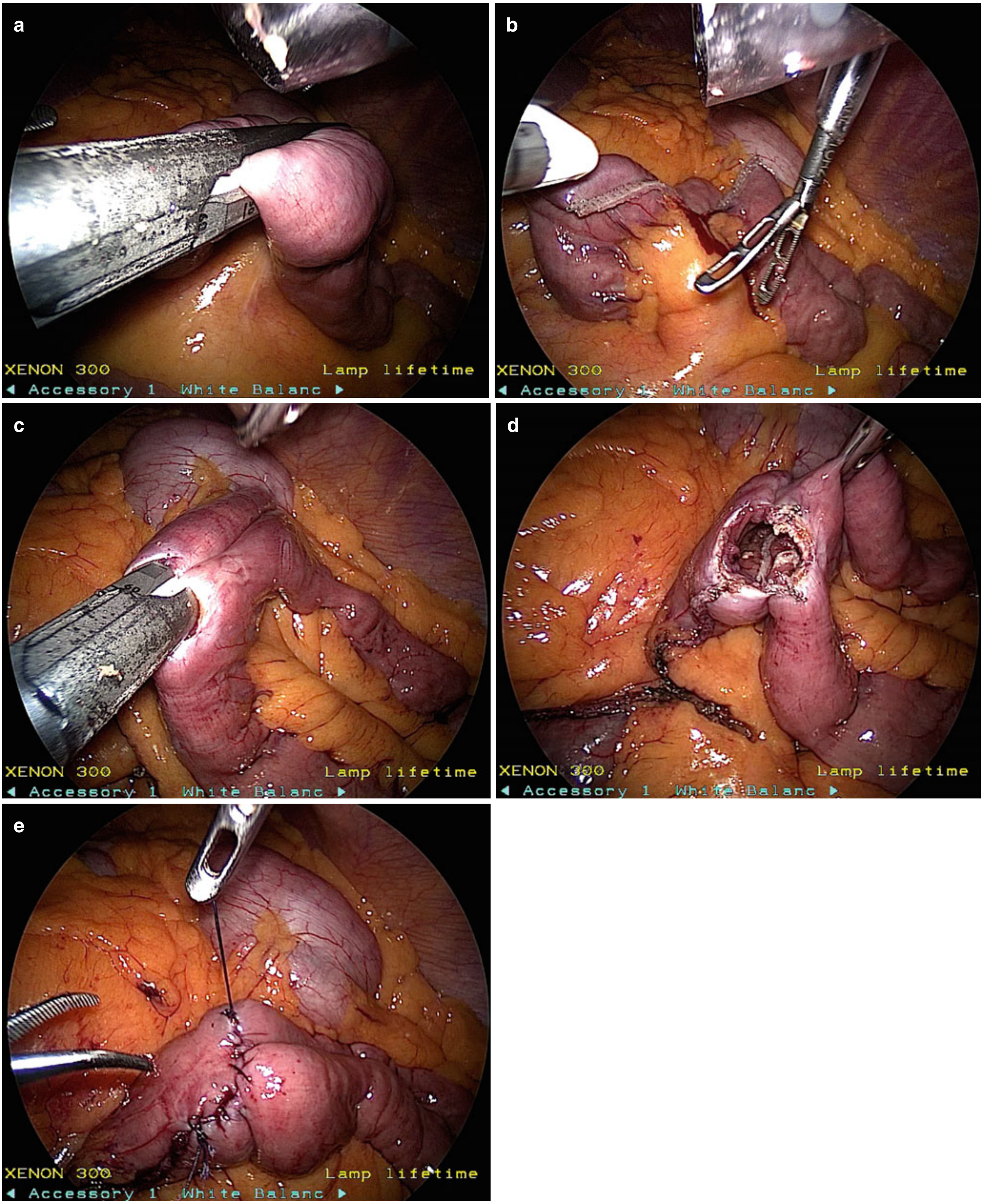

Fig. 46.14 Creation of entero-enterostomy. (**a**) Jejunal transection with stapler. (**b**) Transected jejunum. (**c**) Side to side enterostomy with linear stapler. (**d**) Entero-enterostomy. (**e**) Hand sewn closure of enterostomy

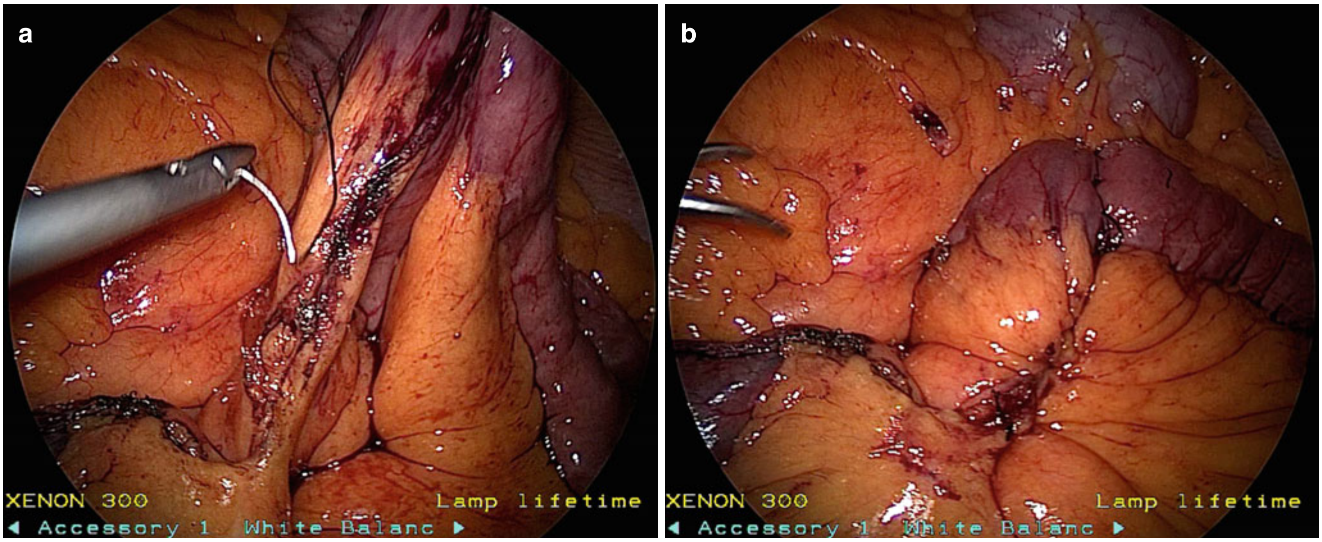

Fig. 46.15 Mesenteric defect. (**a**) Mesenteric defect at entero-enterostomy. (**b**) Closed mesenteric defect

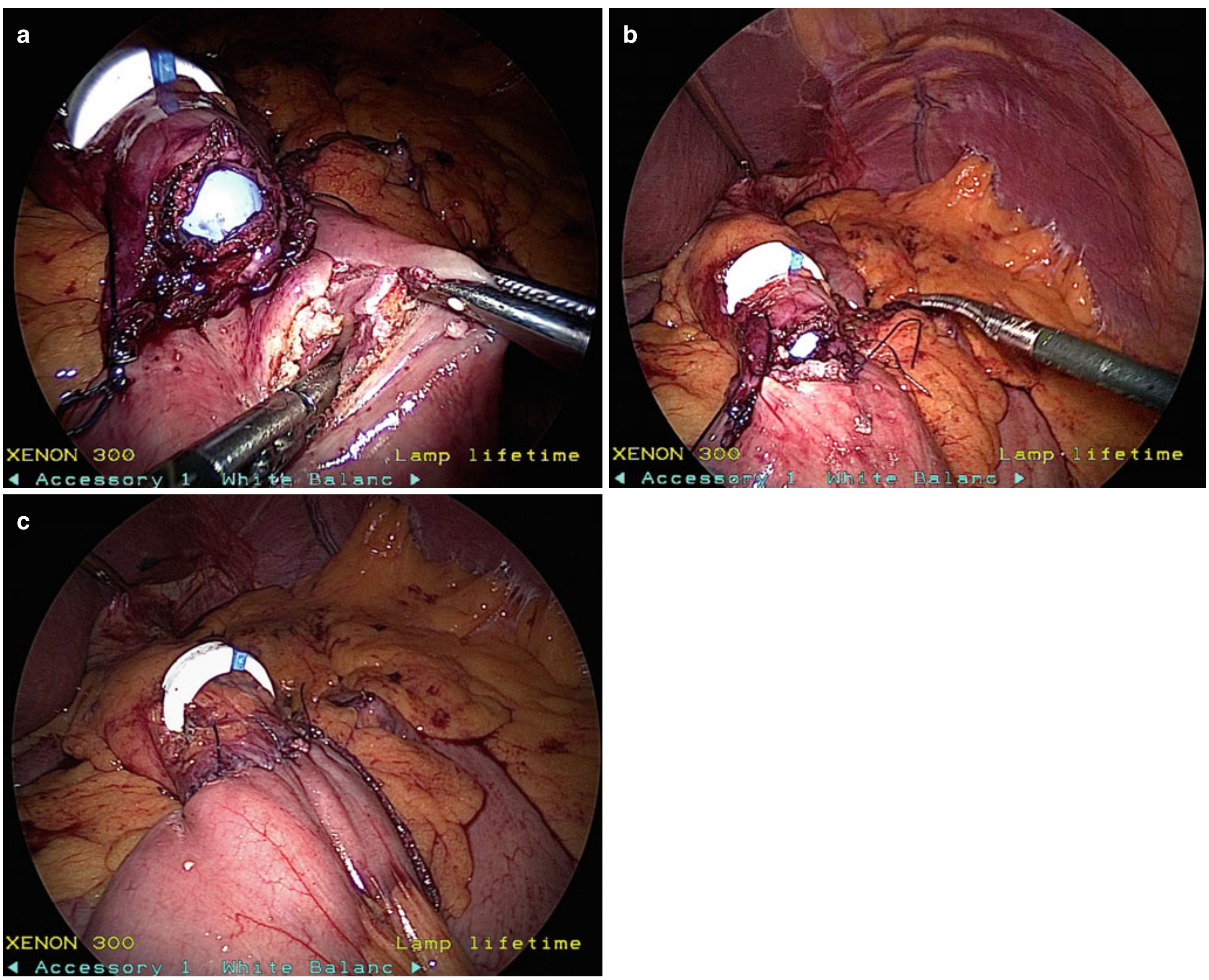

Fig. 46.16 Formattion of gastro-jejunostomy. (**a**) Posterior wall sutured with opening made in the pouch and the small bowel. (**b**) Anterior wall closure over gastric tube. (**c**) Completed gastro-jejunostomy

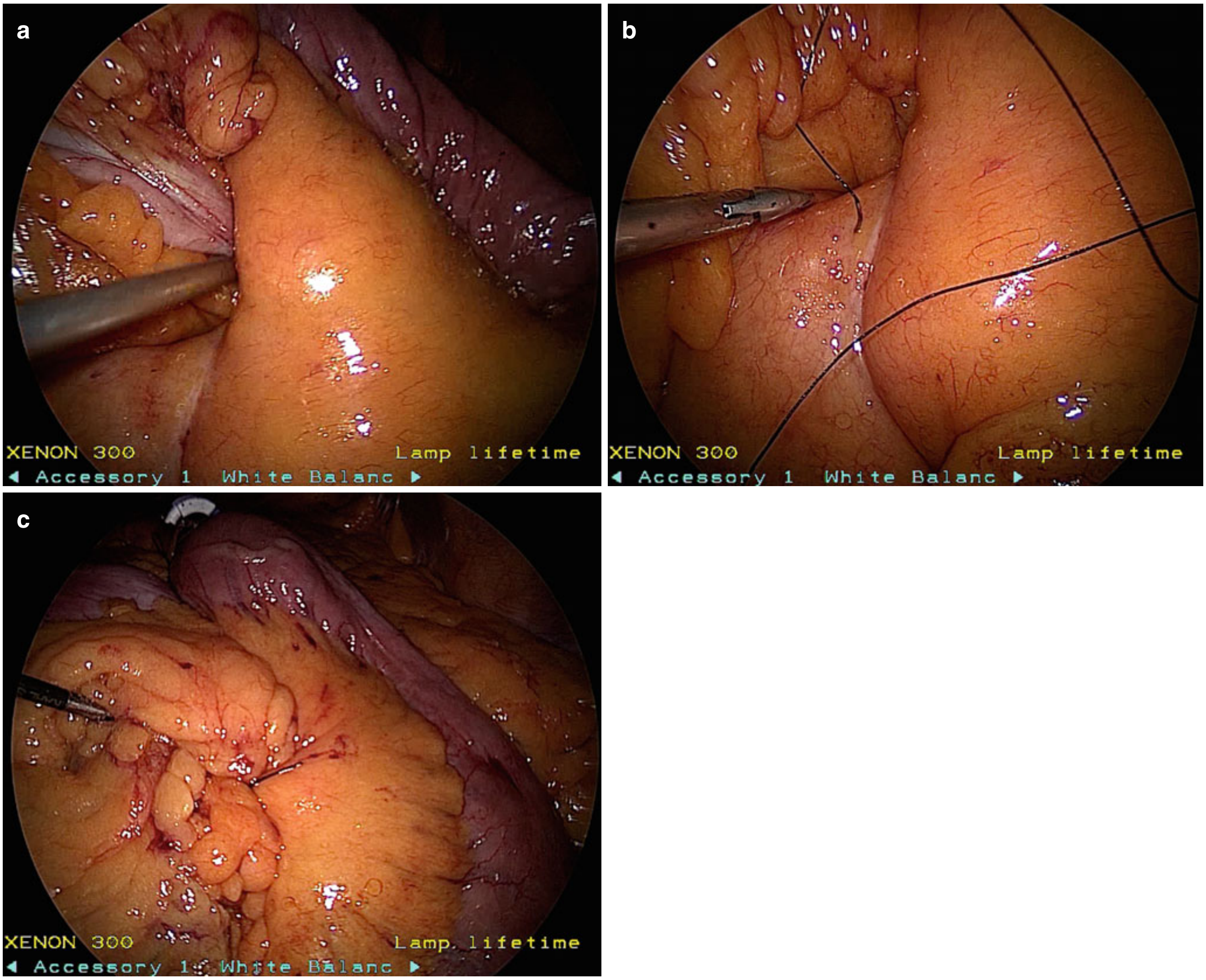

Fig. 46.17 Closure of Petersen's defect. (**a**) Petersen's defect. (**b**) Placement of sutures to close Petersen's defect. (**c**) Closed Petersen's defect

Table 46.2 Patient demographics

Parameter	
Gender	N (%)
Females	139 (83.2 %)
Males	28 (16.8 %)
Total	167 (100 %)
Age (in years)	
Mean	40
Minimum	12
Maximum	71
BMI	
Mean	48.16
Minimum	31.61
Maximum	82.18

Table 46.3 Preoperative co-morbidities

Number of patients receiving surgery (N)	
Parameter	
Co-morbidity groups	167 Pts. (100 %)
0 conditions	12 (7.2 %)
1–2 conditions	38 (22.8 %)
3–5 conditions	99 (59.2 %)
>5 conditions	18 (10.8 %)
Co-morbidities relating to higher risk of complications	418 (100 %)
Arthritis	86 (20.5 %)
GERD	75 (17.9 %)
High blood pressure	70 (16.6 %)
Diabetes mellitus	51 (12.4 %)
Hypercholesterolemia	51 (12.4 %)
Sleep apnea	43 (10.2 %)
Urinary incontinence	26 (6.2 %)
Asthma	16 (3.8 %)

Table 46.4 patient visit accountability

Number of patients with follow-up visits (N)		
Postoperative time period	# Eligible	# F/U N (%)
6 months	167	162 (97.0 %)
1 year	167	159 (96.2 %)
2 years	167	135 (80.8 %)
3 years	138	103 (74.2 %)
4 years	71	53 (74.7 %)
5 years	12	10 (83.3 %)

Table 46.5 Early postoperative complications

Number of patients with complication (N)	
Complication	N (%)
Leaks	5 (3.05 %)
Gastric outlet stenosis	3 (1.7 %)
Deep venous thrombosis	1 (0.6 %)
Marginal ulcer	1 (0.6 %)

Table 46.6 Late postoperative complications

Number of patients with complication (N)	
Complication	N (%)
Small bowel obstruction	5 (3 %)
Ring slippage	3 (1.8 %)
Excessive weight loss	2 (1.2 %)
Ring erosion/penetrating ulcer	1 (0.6 %)

Table 46.7 Percentage excess weight loss and success rate

Postoperative time period	Mean PEWL	Range PEWL	Success rate (%)[a]
6 months	55.8	17.1–108.8	95/162 (58.4 %)
1 year	74.8	33.3–142.9	144/159 (90.6 %)
2 years	79.6	31.9–136.9	129/135 (95.5 %)
3 years	79.1	20.8–136.9	97/103 (94.2 %)
4 years	75.4	32.2–124.4	49/53 (92.6 %)
5 years	74.3	40.9–117.9	9/10 (90.0 %)

[a]Success rate ≥50 PEWL

Conclusions

Laparoscopic banded gastric bypass is a modified gastric bypass operation. It enhances the restrictive and the full sense mechanisms of the gastric bypass operation by controlling the size of the gastric reservoir, thus resulting in more weight loss and enhancing the weight loss maintenance. Laparoscopic banded gastric bypass is well documented, less invasive and has fewer perioperative complications. It also provides quicker recovery rate than open banded gastric bypass.

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47 Single-Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S) Surgery

Andrés Sánchez-Pernaute, Miguel Ángel Rubio, and Antonio J. Torres

Abstract

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-s) is a novel one loop duodenal switch with a 250 cm common limb. A sleeve gastrectomy over a large bore bougie (54 French) is initially performed and the duodenum is transected 2–4 cm from the pylorus. An ileal loop, 200–250 cm from the cecum, is ascended antecolically and anastomosed to the duodenum in an end-to-side fashion. One-hundred and eighty patients have been consecutively operated upon. Mean initial body mass index (BMI) was 45 and 60 % of the patients were diabetic. Mean excess weight loss was 90–95 %, with only 3 % of the patients failing to reach a 50 % excess weight loss. Glycemia and HbA1c values normalized in the early postoperative periods, with 85 % of the diabetic patients showing levels of HbA1c below 6 %. The overall conversion rate for malnutrition is 3.8 %, but this fell to 2.3 % for patients with a 250 cm common limb.

Keywords

One loop duodenal switch • Biliopancreatic diversion • Malabsorptive surgery • SADIs

47.1 Introduction

Malabsorptive bariatric techniques were initially derived from the metabolic outcomes of massive intestinal resection (usually following mesenteric infarction). The first bariatric procedures were the jejuno-ileal bypass and jejuno-colic bypass, techniques which gave good weight loss and improvement/remission of the metabolic conditions accompanying obesity. Unfortunately, these procedures were associated with severe late nutritional complications that caused them to be abandoned. [1, 2] In an attempt to deal with these nutritional complications, Nicola Scopinaro developed the biliopancreatic diversion with the intention of maintaining malabsorption but avoiding major uncontrolled malabsorption, disruption of the enterohepatic cycle, and the presence of a long blind loop. [3] One of the features of Scopinaro's technique was the concept of "the three limbs": the alimentary limb, biliopancreatic limb and the common channel. Over the years, a number of different groups have demonstrated different results based on the varying length of these limbs. Hess [4, 5] then pioneered the biliopancreatic diversion with duodenal switch (BPD-DS). This technique offered two advantages over previous operations:

- The performance of a sleeve gastrectomy as a restrictive component, with preservation of the pylorus
- Anastomosis of the alimentary limb to the first part of the transected duodenum and a common channel of 100 cm. Almost two decades after the description of Hess' technique, our group introduced a further modification of the BPD-DS—the single anastomosis duodeo-ileal bypass with sleeve gastrectomy, SADI-S (Fig. 47.1). [6–8]

Electronic supplementary material The online version of this chapter (doi:10.1007/978-3-319-04343-2_47) contains supplementary material, which is available to authorized users.

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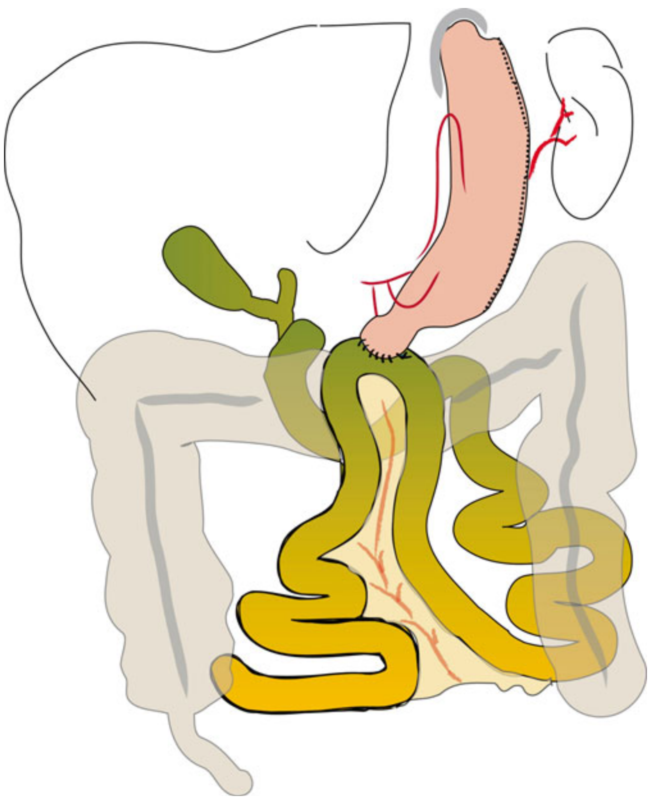

Fig. 47.1 Scheme of the technique. Sleeve gastrectomy plus one loop duodenal switch with a 250 common channel

SADI-s was designed to simplify the BPD-DS while maintaining the principles of biliopancreatic diversion. The reduction to one anastomosis would theoretically shorten the operation time and the risk of anastomotic leak. Additionally, since the small bowel mesentery would not be opened this may potentially reduce the incidence of internal hernias.

In this chapter, we review our experience of this technique and the outcomes achieved by our group.

47.2 Surgical Technique

A standard laparoscopic approach is performed with four ports, with the surgeon positioned between the patient's legs and the patient remaining in an anti-Trendelenburg position (Video 47.1).

1. The optical port is placed 2–3 finger breadths above the umbilicus in the left paramedian line. A left-subcostal port is placed for the surgeon's right hand, a subxiphoid one is utilized to retract the liver, and a right paramedian port is used for the linear stapler and the surgeon's left hand.
2. The initial step is to divide all the short gastric vessels and branches of the gastroepiploic arteries to completely dissect the greater curvature of the stomach, and from the duodenum to the left crus of the diaphragm.
3. The duodenum is totally mobilized posteriorly until the gastroduodenal artery is exposed. The duodenal dissection is completed by opening the peritoneum over the hepatoduodenal ligament; the duodenum is then encircled from behind taking care not to damage the right gastric artery.
4. A large bore (54 French) intragastric bougie is introduced, and the sleeve gastrectomy is completed with sequential shots of a linear stapler (purple, gold, green or black cartridge) usually protected with Seamguard ® patches.
5. Then the duodenum is divided with a 60-mm purple/blue linear stapler (EndoGIA, Covidien/Echelon, Ethicon, Johnson & Johnson).
6. Once both the sleeve and duodenal division are completed, the patient is placed in the horizontal position and the surgeon moves to the left hand side of the patient. The laparoscope is moved to the left subcostal port, and the ileo-cecal junction is identified. Two-hundred and fifty centimeters are measured proximally along the ileum.
7. At this point, the loop of bowel is lifted cranially in an ante-colic fashion to the duodenal stump and an isoperistaltic end-to-side duodenojejunal anastomosis is completed. This can be performed either semi-mechanically with a 30-mm linear stapler [9] or hand sewn with sequential running sutures of a 3/0 polydioxane suture (PDS) or V-LocTM. A methylene blue leak test is then performed and a suction drain is left behind.
8. The stomach is removed through an enlarged port. A suction drain is left behind at the end.

47.3 Postoperative Management

Patients start on oral liquids 6 h after the operation; on the second postoperative day, a very low caloric liquid diet is initiated, the drain is removed, and the patient is typically discharged.

47.4 Lessons Learnt in SADI-s

Initially, our technique consisted of a one-loop duodenal switch with a 200 cm common channel. This was based on analysis of outcomes of BPD variants. The SADI-s with a 200 cm efferent limb, carried an 8 % incidence of clinical malnutrition, and 4 % of our patients had to be re-operated to lengthen the common channel. Although these lengthening procedures were considered to be secondary to poor dietary compliance, after this experience we chose to we considered that it was better to perform a safer procedure by enlarging the common channel to 250 cm. Furthermore, a more rigorous selection of patients was introduced with added weight being given to psychosocial aspect of the patients (such as their ability to comply with the high protein requirement)

From May-2007 we have performed SADI-s on 180 patients. The initial cohort of 50 patients underwent SADI-S with a 200 cm common channel and the rest with a 250 cm common channel. In 21 cases, the operation was performed as a second step after a sleeve gastrectomy. SADI-s was performed, in 4 cases after a failed vertical banded gastroplasty and in one case after a failed Roux-en-Y gastric bypass (in which case the gastric bypass was reversed preserving the alimentary limb and the SADI then performed in one stage).

For SADI-s as a primary surgery, operative times have been decreased from a mean of 210–240 min, to 75–120 min. The mean age of the patients was 47 years (22–71) and mean weight 119 kg with a mean BMI of 44.6 kg/m^2. Sixty percent of the patients were diabetics or presented insulin resistance (IR); 40 % of them were under insulin treatment, and mean history of the disease was almost 10 years. Mean preoperative glycemia was 178.2 mg/dL, and mean glycated hemoglobin 7.9 % (5.4–13). Seventy-two percent of diabetic patients had an initial glycated hemoglobin over 6.5 %. Mean preoperative C-peptide was 2.12 ng/mL (0.4–7) and mean preoperative HOMA was 7.9 (0.66–22.10). Fifty-seven percent of our patients had dyslipidemia, 27 % of them had obstructive sleep apnea and 57 % hypertension.

There were no intraoperative complications and no postoperative mortality. There was one gastric leak (0.5 %) and two anastomotic leaks (1.1 %). Only one patient with an early anastomotic leak was submitted to reoperation and the leak was sutured without further complications. One patient suffered gastric tube hemorrhage successfully treated endoscopically, two patients had re-laparoscopy because of intraperitoneal hemorrhage and two patients suffered a herniation through a portal orifice.

Mean excess weight loss was 95 % in the first 12 months and it was maintained through the following 5 years (Fig. 47.2), without significant differences between SADI-S 200 and SADI-s 250. Three percent of the patients have failed to reach a 50 % excess weight loss.

Metabolic results have been excellent, similar to those reported after any of the previously described biliopancreatic diversions. Mean glycemia of diabetic patients decreased to 94.7 mg/dL in the first postoperative year, and to 93.1, 91.09 and 79.6 in the following years, and mean postoperative HbA1c came down to 5.3 %, 5.2 %, 5.4 % and 5 % respectively. Eighty-five percent of the patients maintained HbA1c levels below 6.5 %. A longer history of diabetes, a worse control of the disease, higher glycemia and higher HbA1c, and the need of insulin therapy were all related to a worse evolution of the disease after surgery.

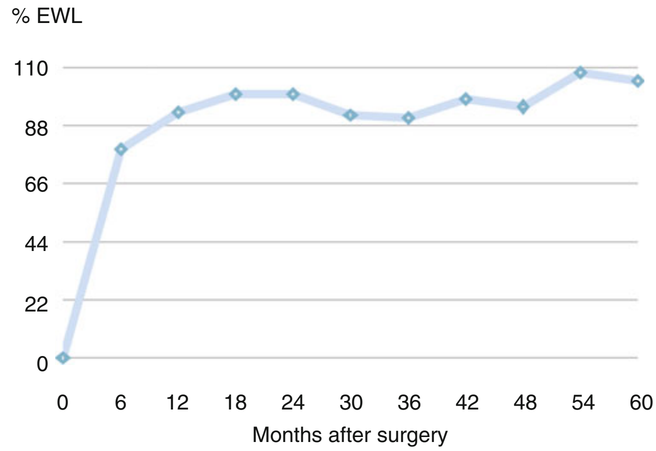

Fig. 47.2 Excess weight loss percentage of the series of patients who underwent SADI-S operation

Dyslipidemia remitted in 73 % of the cases, obstructive apnea in 88 % and hypertension was controlled in 98 % with complete remission in 58 % of the patients.

The mean number of bowel movements was 2.5 per day. A short number of patients presented more than four movements per day, and occasionally they were treated with oral antibiotics, bismuth salts or cholestyramine.

The greatest problem after a biliopancreatic diversion is hypoproteinemia, which we have seen in 16 % of the patients. We also see secondary hyperparathyroidism due to deficient absorption of vitamin D (mean PTH 92 pg/mL, with >40 % showing abnormally high levels).

Four patients submitted to SADI-S 200 (8 % in 7 follow-up years) and 3 patients submitted to SADI-s 250 (2.3 % in 5 follow up years) have undergone revisional surgery to lengthen the common channel. Different techniques have been performed for revisional surgery, e.g. duodeno-duodenostomy, with almost complete reversal of the operation; proximalization of the SADI-S by dismantling the duodeno-ileostomy and performing a new duodeno-enterostomy 1–1.5 m proximally; or conversion into a Roux-en-Y duodenal switch with a longer common channel by dividing the efferent limb just distal to the duodeno-ileostomy and anastomosing it 1–2 m proximally in the afferent limb, leaving an antiperistaltic intestinal segment.

47.5 Advantages and Drawbacks

SADI-s is a malabsorptive technique, derived from the biliopancreatic diversion. It is based on the same principles. It has an intestinal diversion with a known and short common channel which is expected to cause fat malabsorption while preserving the enterohepatic cycle, and a moderate gastric restriction, as the stomach is calibrated with a large bore bougie. However, SADI-S is a versatile technique, and depending on the preferences of the surgeon or on the patient's characteristics, it can be performed as a gastric bypass with a narrow gastric tube and a duodeno-jejunal bypass with more than 3 m of common channel, or stay as a malabsorptive operation with a short common limb (200–250 cm) and a wider gastric tube.

47.5.1 Advantages Over Scopinaro's Procedure

The sleeve gastrectomy and the pyloric preservation are potential major advantages of duodenal switch over classical biliopancreatic diversions: There is also a potentially decrease incidence of postoperative dumping, as there is a preserved (albeit reduced) gastric secretion with no defunctioned remanent stomach. The sleeve gastrectomy performed in this procedure results in fundal removal thereby reduces gherhelin secretion which increases the metabolic potential of the operation. A possible limitation could be the presence of gastroesophageal reflux disease, but if the gastric tube is wider than the esophagus there should not be an increase in gastric pressure and a problem with esophageal emptying. Nonetheless Barrett's esophagus is considered a relative contraindication for the performance of this operation.

47.5.2 Advantages Over Duodenal Switch

As SADI-s is a one-loop duodenal switch, the advantage of the technique is the elimination of one anastomosis. Although Roux-en-Y diversion was introduced to avoid alkaline reflux. After a post-pyloric division of the duodenum, there may not be a need to build up a Roux-en-Y reconstruction- indeed we have demonstrated using the Bilitec system that SADI-s does not cause dudenogastric reflux. The reduction to one anastomosis has three direct advantages: the operation is shortened, there is a lower risk of anastomotic leak, and the mesentery is undisturbed which is expected to reduce the incidence of internal hernias (in our hands, we have not seen any symptomatic internal hernia on follow up).

47.5.3 Advantages Over Gastric Bypass

The weight loss after SADI-s procedure is greater, as the rate of co-morbidity resolution is more pronounced than that seen in published series of gastric bypass surgery. The reduction to one anastomosis simplifies the procedure, and the sleeve gastrectomy can be considered to be more physiological than the minimal pouch of gastric bypass. Although some authors equate this procedure to that of the mini-gastric bypass [10], this is incorrect. Although the stomach is larger than after the mini gastric bypass, the pylorus is still not preserved and hence the mini-bypass is prone to alkaline reflux [11].

Conclusions

SADI-s is a malabsorptive operation, derived from Scopinaro's and Hess' procedures. It is a simplified biliopancreatic diversion, which shortens surgical duration, decreases the possibility of postoperative complications and maintains the same metabolic and weight loss results. It is our current preferred malabsorptive technique both as primary surgery or a second-step operation. After a failed sleeve gastrectomy, we prefer SADI-s to gastric bypass as we believe the failure of an essentially restrictive procedure requires the addition of a malabsorptive component. Furthermore, it is easier for the surgeon to perform a one-loop duodeno-ileal bypass in "virgin territory" than to revise a gastric pouch or gastrojeunal anastomosis in a potentially hostile area. Moreover SADI-s is a versatile operation, in which we can change the volume of the sleeve and the length of the common limb adapting those to the patient's characteristics or to the surgeons' preferences.

Finally, as with all biliopancreatic diversions, it is of paramount importance to carefully select patients for this operation. More large scale multicentre studies, are needed with a longer follow-up period to properly evaluate this new operative approach to morbid obesity.

Key Learning Points

- SADI-s should be performed with a wide sleeve gastrectomy.
- The duodenum should be dissected from behind, at the level of the gastroduodenal artery taking care not to damage the vascularization from the hepatic artery.
- There is no need to close the retroanastomotic space.
- A common limb shorter than 250 cm is not advised, as the rate of malnutrition raises exponentially.
- Careful selection of the patients results in a successful postoperative result.

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Laparoscopic Gastric Plication

48

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Abstract

Bariatric operations classified as restrictive such as laparoscopic sleeve gastrectomy (LSG) and laparoscopic greater curvature plication (LGCP) are gaining more attention in bariatric surgery environment, as they are considered technically simpler since there are no anastomosis. However, in sleeve gastrectomy a significant portion of the stomach is resected resulting in impossibility to reversion of the procedure. LGCP is an alternative reversible bariatric procedure, which is similar to LSG, without the need of gastric resection, but it is still an experimental technique. The main advantages of this new procedure are: absence of foreign body (band or ring); no intestinal bypass; no gastric or intestinal resection; it can be augmented with more extensive procedures; no need for staples and the potential reversibility. However, hospital stay may be longer because of nausea and vomiting after the procedure that can interfere in diet acceptance, which can increase the costs. The outcomes in terms of weight loss are inferior than those achieved with LSG; percentage of excess weight loss (EWL) in LGCP is comparable to adjustable gastric band.

Keywords

Laparoscopic bariatric surgery • Greater curvature plication • Morbid obesity • Sleeve gastrectomy • Restrictive procedure

48.1 Introduction

Morbid obesity has grown in severity over the past several decades and now can be considered a worldwide public health priority. Bariatric surgery has proven to be effective in treating primary obesity and its comorbidities according to long-term results. The underlying technical mechanisms for weight loss following bariatric surgery are either decreased intake of food or decreased absorption of ingested foods or both [1]. More recently several other mechanisms based in hormonal changes, signaling and metabolic improvement have been described.

The most commonly used restrictive approaches in obese patients are Adjustable Gastric Banding (AGB) and Laparoscopic Sleeve Gastrectomy (LSG) with LSG presenting worldwide increasing numbers and progressively decreasing numbers of AGB. These procedures are good options for selected patients, however they have their own complications, like erosion or slippage of the gastric band or leaks and strictures in LSG.

The placement of an implantable device or the irreversible resection of gastric tissue could limit the acceptance of AGB and LSG. LSG also has high costs because of the use of staplers, motivating the search for an effective, possibly safer technique, with reduced need of staplers and/or no

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Table 48.1 Studies involving patients submitted to LGCP: analysis of clinical and surgical aspects

Author	Year	Number	Age (years)	OR time (min)	LOS (days)	FU	N	%EWL
Talebpour and Amoli [2]	2007	100 (76 F)	32	98 (70–150)	1.3 (1–4)	6 12 46	72 56 11	54 61 57
Ramos et al. [3]	2010	42 (30 F)	33.5 (23–48)	50 (40–100)	1.5 (1–4)	6 12	20 15	48 60
Brethauer et al. [4] Anterior plication Greater curvature plication	2011	9 6	42 (26–58) 42 (26–58)	89 (68–147) 72 (48–106)	1.5 1.5	6 12 6 12	6 5 6 6	28.4 23.3 49.9 53.4
Pujol Gebelli et al. [5]	2011	13 (7 F)	(31–59)	N/A	5 (4–7)	N/A		
Skrekas and Antiochos [6]	2011	135 (104 F)	36	58 (45–80)	1.9 (1–6)	6 12 24	——	51.7 67.1 65.2
Talebpour et al. [7]	2012	800 (648 F)	27.5 (12–65)	72 (49–152)	3 (1–45)	1 6 12 24 60 120	779 615 491 356 134 35	20 60 67 70 55 42
Taha et al. [8]	2012	55 (44 F)	38.5 (22–55)	55 (40–80)	1.8 (1.5–5)	12	–	35
Huang et al. [9]	2012	26 (16 F)	30 (18–52)	87.3 ± 22.6	1.1 ± 1.2	1 3 6 9 12	26 24 18 10 5	21.9 31.9 41.3 55.2 59.5
Shen et al. [10]	2013	19 (14 F)	33.9 ± 5.7	95 ± 17.4	4.2 ± 1.9	12	11	58.8
Niazi et al. [11]	2013	53 (53 F)	36.3	95 (82–120)	3 (1–5)	1 3 6 12 18 24	53 48 41 30 19 10	25.6 40.7 54.2 70.2 71.7 74.4
El-Geidie et al. [12]	2013	63 (54 F)	34.2 (20–48)	N/A	N/A	3 6 12	63 63 63	41 52 60
Atlas et al. [13]	2013	44 (40 F)	40 (18–72)	106 (60–180)	0.75 (0.5–7)	1 6 12	40 24 13	30.6 57.0 50.7

implants. For that, laparoscopic greater curvature gastric plication (LGCP) may be an option in the treatment of morbid obesity. LGCP appears to present results close to LSG with fewer complications (see Table 48.1). However, in case of LGCP, the neuroendocrine mechanisms that affect weight loss and help in the resolution of comorbidities are yet unexplored.

Bradnova et al. studied the influence of LGCP on type 2 diabetes mellitus (T2DM), glucose homeostasis, serum lipids and gut hormones in obese, diabetic women and concluded that LGCP, during the initial 6 months postoperatively, induces significant weight loss and improves the metabolic profile of morbidly obese T2DM patients, while it also decreases circulating postprandial ghrelin levels, and increases the meal-induced gastrointestinal peptide (GIP) response [14]

The main advantages of LGCP can be: no foreign body (band or ring); no intestinal bypass; no gastric or intestinal resection; it can be augmented with more extensive procedures; no need for staples and the potential reversibility.

48.2 Technique

The current technique of LGCP consists of infolding the greater curvature to reduce stomach volume by the placement of rows of non-absorbable sutures (see Fig. 48.1). However, there isn't a standardized technique and the surgical systematization may vary according to different authors. For all that and looking for more uniforms results, in the last few years, there is a tendency towards more standardization.

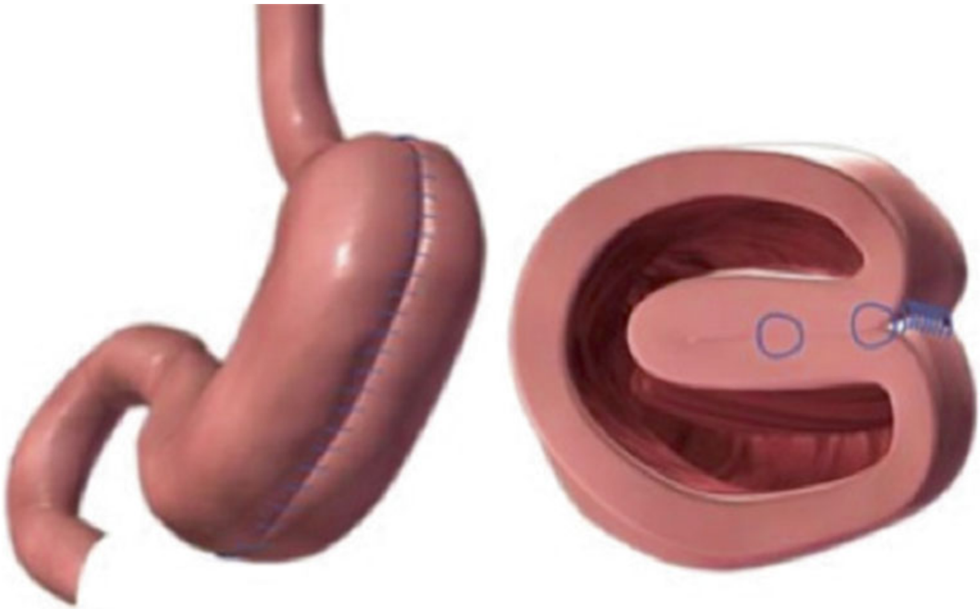

Fig. 48.1 Schematic view of the final aspect of LGCP procedure

Patient positioning on the operating table is an anti-Trendelenburg position at 30-degree, with the operator between legs and two assistants, one in each side of the patient [15].

Various authors have described placement of four to five trocars in the upper abdomen [3]. One 10-mm trocar above and slightly at the left side of the umbilicus for the 30 degree laparoscope; one 10-mm trocar in the upper left quadrant (ULR), in the mid clavicular line for the surgeon's right hand, for and passing the needle holder, suturing; one 5-mm trocar also in the ULQ below the 10-mm trocar at the anterior axillary line for the surgeon's assistant; one 5-mm trocar below the xiphoid appendices for liver retraction; and one 5-mm trocar in the patient's right side (Upper Right Quadrant URQ) for the surgeon's left hand (see Fig. 48.2).

There are two possible approaches regarding how and where to start the greater curvature dissection. Ramos et al. preferred starting at the angle of His and continue towards the pylorus, whereas in the larger studies of Skrekas et al., Andraos et al. and Fried et al. it, the esofagogastric junction was the final step of the dissection of the greater curvature of the stomach [3, 6, 16]. These authors suggest starting the dissection about 3–5 cm above the pylorus and continuing cephalead. Some authors perform dissection of the entire fundus, up to the angle of His, exposing the left diaphragmatic crus, similar to sleeve gastrectomy. However, Fried et al. (and others) advocate leaving the last 2–3 short gastric vessels intact [17]. The main reasons for not dissecting last couple of short gastric vessels are as follows:

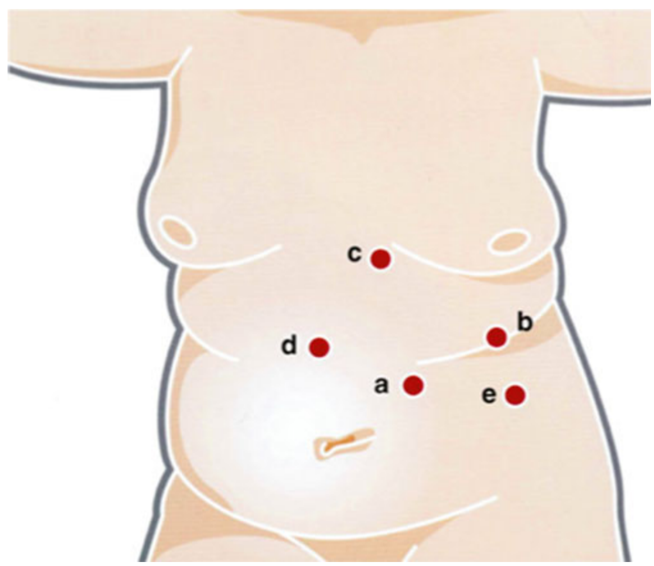

Fig. 48.2 Trocar position: (*a*) 10 mm above the umbilicus slightly to the right; (*b*) 10 mm in ULQ; (*c*) 5 mm below xiphoid's appendices; (*d*) 5 mm in the ULQ; (*e*) 5 mm on the ULQ at the axillary line

- To preserve the vascular supply to the part of the fundus that is most vulnerable to ischemia. In contrast to sleeve gastrectomy (in which the entire fundus is removed), in LGCP the fundus stays in place and is plicated. Such invagination contributes to impaired vascular supply of the uppermost fundus region, and if total devascularization is done by means of complete dissection of the fundus, could induce some risk of necrosis, namely of the anterior fundus area. Preservation of the first two short gastric vessels does not interfere with fundus invagination and can avoid this complication.
- To keep the angle of His intact. By this means, the physiological anti-reflux mechanism of the angle of Hiss is maintained. Preserving the physiology of angle of His contributes to very low postoperative gastro esophageal

reflux (GERD) symptoms that can be reported after LGCP.
- Prevent possible fundal herniation towards the lumen of the esophagogastric (EG) junction. This may happen in case the invaginated fundus was too floppy (thus entirely dissected from the surrounding attachments). Such condition could partially/intermitently obstruct the EG junction, resulting in signs of pseudo-obstruction and subsequent need of reoperation.

The use of a bougie is recommended for final calibration of the gastric tube and the most commonly used is the 36 F bougie. Bariatric surgeons use different bougies diameters, ranging from 32 to 48 F. Using smaller bougies than 36 F is associated with potentially higher risk of gastric obstruction. The reason is that, in contrast with sleeve gastrectomy (in which the greater curvature is resected and removed); in LGCP the bulk of gastric greater curvature tissue is infolded into the stomach lumen and in the first days after the procedure some edema will happen.

Hence if the calibration bougie will be too small, the actual stomach lumen will be small also and once the bougie will be removed, the invaginated stomach tissue will expand into the lumen, and cause obstruction. Thus, in LGCP the stomach lumen should be created larger enough to accommodate the infolded greater curvature and, at the same time additional space should be left for food passage. Intra-operative upper gastrointestinal endoscopy (UGE) has being used by Brethauer et al. in order to have the additional benefit of visualizing the imbricated fold intraluminally [4].

Different energy sources are described for greater curvature mobilization, including Harmonic scalpel® (Ethicon Endo-Surgery, Cincinnati, OH), Ligasure Vessel Ligation System® (Covidien, MA) or even diathermy, initially by opening the gastric omentum at the transition between the gastric antrum and gastric body [18]. An important safety aspect to be taken into consideration during the greater curvature dissection is prevention of thermal injury. This is another, major difference between sleeve gastrectomy and the LGCP dissection technique.

LGCP dissection has to be carried out at least in distance of 1–2 cm from the stomach wall, leaving an intact "strip" of fatty tissue between the dissecting instrument and the stomach wall. The main reason is to prevent any possible thermal injury caused either by direct contact of the tip of the dissecting instrument with stomach serosa, or mediated via collateral thermal damage. In sleeve gastrectomy, there is no need for such precaution, as this, dissected part of the stomach is resected at the end of the operation. However, in LGCP the stomach tissue is inverted/infolded and left in place. If thermal damage is present, the necrosis related leak is almost inevitable to occur in the early postoperative period.

The gastric plication is initiated by imbricating the greater curvature by applying a first row of extramucosal interrupted stitches, with subsequent rows of extramucosal running suture lines (see Fig. 48.3). Some authors suggest a continuous suture line for creation of the first row also. Using a non-absorbable monofilament suture (such as 2/0 polypropylene) could be beneficial for continuous suturing. The first row stops three centimeters from the pylorus, this reduction results in a stomach shaped like a large sleeve gastrectomy (see Fig. 48.4). The choice of suture material (e.g. absorbable versus nonabsorbable) as well as the choice of suturing technique (interrupted versus running sutures) varies among surgeons but non-absorbable clearly is the preference [15].

Fig. 48.3 Intraoperative picture and schematic view of initial suture line with interrupted non-absorbable suture

The sutures (applies to running sutures as well) should be placed approximately 1–2 cm apart, the suture bites not being larger than 2 cm from the greater curvature median. This is to avoid risk of stomach wall herniation/prolapse between the sutures. The three bites technique – posterior, middle, anterior – for the stitches is gaining the preference of the surgeons regarding the evidence of presenting less nausea and vomit. An intraoperative methylene blue leak test was performed in most studies, without drain placement [15].

48.3 Complications

Laparoscopic greater curvature plication (LGCP) is an emergent bariatric procedure and the short follow-up rate of several published series may imply in a selection bias, and the complications rate may be underreported.

Mild complications include: prolonged nausea, vomiting, and sialorrhea. These may require more days of hospitalization or even readmission for intravenous administration of anti-emetics, prokinetics, and hydration [6, 18]. Reported major complications include gastric obstruction, bleeding (intraluminal upper GI bleeding or intraperitoneal), leaks, and perforations.

Talebpour and Amoli, each one reported a case of a gastric leak associated with a more aggressive version of LGCP, which the authors attributed to excessive vomiting in the

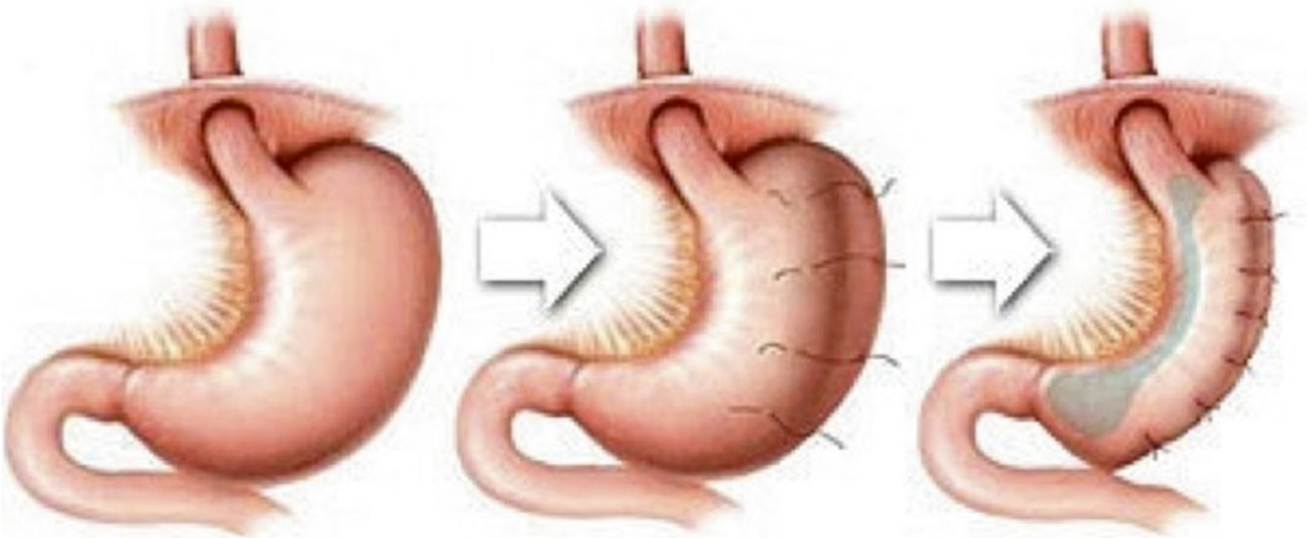

Fig. 48.4 Schematic image of alimentary path after gastric plication

early postoperative period [2]. In the study by Ramos et al. the adverse events described by patients were minor, such as nausea, vomiting, and hypersalivation, which were resolved quickly [3]. These events may be related to the severity of the restriction induced by the invagination of the greater curvature and/or the edema caused by venous stasis.

A key difference between LGCP and LSG is the presence of the endoluminal invaginated greater curvature. Qualitative endoscopic findings suggesting that the greater curvature fold gets smaller overtime and this may be related with the resolution of the initial edema or some grade of fold's atrophy occurring over time in the postoperative. The radiological findings did not reveal significant dilation of the gastric lumen at 6 months [3].

In the systematic review done by Abdelbaki et al. eight percent of the patients developed complications, with individual author complication ranging from 7 to 15.3 %. Nausea and vomiting occurred in all studies, ranging from mild to moderate, usually resolving within 1–2 weeks. Twenty patients (6.5 %) were readmitted, of whom 14 (4.6 %) required reoperation, mostly due to gastric obstruction [18].

Skrekas et al. had three cases of acute gastric obstruction, in a series of 135 patients [6]. In one of them, the fundus prolapsed in between the sutures, which was reduced and reinforced with sutures. The other two had serious fluid collection within the cavity formed by the gastric plication, both were treated with reversal of plication. The overall complication rate in this case series was 8.8 % (12/135), including vomiting (n = 4), GI bleeding (n = 2), and abdominal pain attributed to a micro-leak from the suture line (n = 2), one patient had a portomesenteric thrombosis leading to partial jejunal necrosis. Brethauer et al. had to reoperate the first patient in their series due to a gastric obstruction 2 days after surgery [4].

In an analysis of early complications in the 120 patients submitted to LGCP, the major intraoperative complication was bleeding, with hemostasis achieved in all cases without the need for blood transfusion (n = 13). During the first postoperative week, nausea, vomiting, sialorrhea, and minor hematemesis occurred in 40, 25, 22, and 15 % of patients, respectively. Symptoms disappeared spontaneously within 4–5 days and patients returned to normal activities within 5–7 postoperative days. In the first postoperative month, complications were mainly due to the complete obstruction of the residual gastric pouch by fold edema (5 %), extrinsic compression by intramural gastric hematoma (2 %) and gastric tube distortion (0.8 %). Peritonitis, which occurred in one patient on day three from a gastric leak, was managed laparoscopically by suturing the defect and cleaning the whole peritoneal cavity [16].

Fried et al. described a gastric perforation in a patient with a prior Nissen fundoplication (not taken down during LGCP procedure) [17]. This occurred immediately after discharge due to noncompliance with suggested food restrictions, with the patient developing gastric leak and peritonitis. In the same study, another major complication was seen in a patient who had a gastric band and underwent LGCP to correct weight regain.

An abundance of fibrous tissue adherent to the band and scarring surrounding the band area were observed. The band was removed and plication performed below the affected region. Three days following discharge patient returned with symptoms of peritonitis. On reoperation an area of partial stomach wall necrosis below the original band site was found. The authors suggest that previous surgery may be limited to resolve the uncontrolled vomit, and should be considered a relative contraindication to subsequent LGCP in the same procedure [17].

48.4 Postoperative Management

In the postoperative period, patients were discharged as soon as they were able to have a liquid diet without vomiting and received a prescription of a daily proton-pump inhibitor (PPI; single dose) for 60 days; ondasentron and the anti-spasmodic hyoscine were prescribed for 7 days. The use of corticosteroids is also recommended for a couple of days in order to reduce the edema inside the stomach and alleviate nausea and vomit.

The postoperative diet was prescribed as follows: a customized liquid diet for 2 weeks, followed by a progressive return to solid foods in a stepwise fashion, with the dietary restrictions removed at 4–6 weeks, depending on patient acceptance.

Follow-up visits for the assessment of safety and weight loss were scheduled for 1 week and at 1, 3, 6, 12, 18, and 24 months in the postoperative period. Endoscopic evaluations were scheduled for 1, 6, and 12 months.

48.5 Outcomes

In a systematic review involving seven published articles, encompassing 307 patients who underwent LGCP, the mean operative time was 40–150 min. Median length of hospital stay ranged from 1.3 to 1.9 days. In respect to excess weight loss (EWL), at 6 months it ranged from 54 to 51 %, while at 12 months it ranged from 67 to 53.4 %. The longest follow-up in this series was 3 years [2–6, 18–20].

Universal exclusion criteria varied with pregnancy, previous bariatric or gastric surgery, hiatal hernia, uncontrolled diabetes, cardiovascular risks, history of eating disorders, and medical therapy for weight loss within the previous 2 months, or any other condition that constitutes a significant risk of undergoing the procedure [15]. A BMI more than 50 was defined as an exclusion criterion for the Brethauer et al. and Skrekas et al. series [4, 6].

In the study by Ramos et al., 42 patients were operated, with a mean operative time of 50 min, and a mean hospital stay of 36 h. No intraoperative complications were documented. Mean percentage EWL was 20 % EWL at 1 month (42 patients), 32 % EWL at 3 months (33 patients), 48 % EWL at 6 months (20 patients), 60 % EWL at 12 months (15 patients), and 62 % EWL at 18 months (9 patients). In the first postoperative week, however, nausea, vomiting and sialorrhea occurred in 20 %, 16 % and 35 % of patients, respectively. In all cases, these symptoms were resolved in no more than 2 weeks. No weight regain was recorded during the follow-up period of 18 months [3].

Talebpour et al. published a case series in 2012, involving 800 patients, with an average time of follow up of 5 years (range 1 month—12 years). Different techniques of plication were used; one-row plication was performed during the first 6 years, followed by two-row plication for the next 6 years. The mean excess weight loss was 70 % (40–100 %) after 24 months (n = 356), and 55 % (24–100 %) after 5 years (n = 134). Weight regain was a complaint in 31 % of cases after the 12 year follow up.

The main failure and weight regain group consisted of cases with wrong selection of technique, mainly males without good motivation. Reoperation was required in 8 patients (1 %), due to complications like: micro perforation, obstruction and vomiting following adhesion of His angle. Complications were more common with the one-row plication technique. The authors concluded that the percentage of EWL in LGCP is comparable to other restrictive methods as AGB and vertical banded gastroplasty, with 1.6 % of complications, 31 % weight regain, with a lower financial cost [7].

In a study focused on weight loss and type 2 diabetes outcomes, LGCP was performed in 55 morbidly obese diabetic patients, with a 1 year follow-up. BMI ranged from 35 to 52 kg/m^2 (mean 43.5 kg/m^2). Mean EWL was 35 % (30–65 %) after 12 months, with a mean BMI of 38 kg/m^2. A total of 23 % of patients stopped losing weight 6 months after the procedure, and 11 % began regaining about 14 % (12–20 %) of their EWL 9 months after the procedure. Mean HbA1c was 7.5 % (5.5–8 %) after 12 months. All patients were on oral antidiabetic medications preoperatively, and none had more than 5 years of disease. No patients stopped their diabetes medications after surgery. These results may indicate that LGCP has a weaker metabolic effect compared with other restrictive procedures [8]. However, recently published multicenter, international study on influence of LGCP on T2DM suggests that metabolic effects of LGCP are positioned in between adjustable gastric banding and sleeve gastrectomy. Thus, LGCP appears to be more effective on T2DM than gastric banding, however slightly less effective than sleeve gastrectomy [14].

Gastric plication should be selected for cases with potential for continuous diet and exercise after operation, BMI less than 45 and with early T2DM. In cases with less motivation, high BMI or severe metabolic disease, sleeve gastrectomy, gastric bypass or a malabsorptive technique should be chosen.

Key Learning Points

- LGCP is technically simpler since there is no anastomosis stapling or resection. However, hospital stay may be longer because of nausea and vomiting after the procedure that can interfere in diet acceptance, increasing the cost of the surgery. It is not a leak proof procedure.
- LGCP is an alternative reversible bariatric procedure without gastric resection. It is still considered an experimental technique.
- The neuroendocrine mechanisms that affect weight loss and help in the resolution of comorbidities after LGCP are yet unexplored.

- The main advantages of LGCP are: absence of foreign body (band or ring); no intestinal bypass; no gastric or intestinal resection; it can be augmented with more extensive procedures; no need for staples and the potential reversibility.
- The results in terms of weight loss are lower than those achieved with sleeve gastrectomy; percentage of EWL in LGCP is comparable to adjustable gastric band. In long-term can be observed insufficient weight loss, weight regain and dilatation of the gastric pouch.

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Laparoscopic Gastric Pacing

49

Karl Miller

Abstract

Laparoscopic gastric pacing (LGP) is a minimally invasive technique that is performed for the treatment of obesity. LGP was first developed in the early 1990s for gastroparesis, and was also found to be effective in the treatment of obesity. The application of electrical current to the stomach alters gastric myoelectrical activity, without any changes in the gastrointestinal anatomy. The exact mechanism of LGP remains to be elucidated. However, potential mechanisms to assess the success of LGP might include an increased feeling of satiety as the result of reduced gastric emptying, or changes in neuropeptide levels.

LGP is a minimally invasive technique that is potentially safe and effective for treating obesity; nevertheless, the selection of patients for gastric stimulation therapy appears to be an important determinant of the outcome of this treatment.

This article reviews the current status, potential mechanisms of action, operating techniques, complications, postoperative management and outcomes, and possible future applications of gastric stimulation in obesity management.

Keywords

Gastric pacing • Obesity • Neuromodulation • Surgery • Outcomes

49.1 Introduction

Currently, obesity is growing to epidemic proportions; hence, there is a clear need for minimally invasive therapies with few adverse effects, which enable sustained weight loss. Weight loss that is not supported by behavior and lifestyle modifications is of limited value in sustaining the durability of weight loss. Conventional surgery results in guaranteed weight loss in the long run, but it is associated with morbidity and mortality. Laparoscopic gastric pacing (LGP) is a minimally invasive technique, which was first developed in the early 1990s for gastroparesis and was also found to be effective in the treatment of obesity [1]. The application of an electrical current to the stomach region alters gastric myoelectrical activity, but does not change the gastrointestinal anatomy. With gastric pacing, there is an impairment of the gastric slow waves postprandially. It may delay the gastric emptying, thereby giving rise to a satiated feeling, and hence, may reduce the intake of food [2].

49.2 Methods of Gastric Stimulation for the Treatment of Obesity

49.2.1 Gastric Pacing with Short Pulse Width and High Frequency Electric Current

The first studies of gastric electrical stimulation as a treatment for obesity were performed using the Transcend™ Implantable Gastric Stimulator. The stimulus parameters were an

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amplitude of 3–10 mA, a pulse width of 208 ms, and a frequency of 40 Hz with 2 s "on" and 3 s "off", 3–10 mA of current, and a short pulse duration of 0.18–0.4 ms. Thereafter, different modifications of the stimuli parameters were investigated in clinical trials [2–5]. The Transcend™ device blocks vagal efferent activity and delays gastric emptying.

49.2.2 Gastric Pacing with Long Pulse Width and Low Frequency Electric Current

In a study conducted in 12 healthy volunteers, Yao and associates adjusted the gastric slow waves to nine cycles per minute. The symptoms of satiety, bloating, discomfort, and nausea correlated linearly with increase in energy stimulation. Food intake decreased by 16 % and gastric retention of solids increased by 15 % during this retrograde pacing. These changes were accompanied by tolerable symptoms of dyspepsia [6].

49.2.3 Stimulation of Stomach Muscles During the Electrical Refractory Period

The TantalusTM system (MetaCureLtd., Germany) has a pulse generator and three bipolar leads. Two pairs of electrodes are implanted in the gastric antrum and two pairs in the gastric fundus [7]. The electrodes in the gastric fundus sense the beginning of a meal and signal the pulse generator to stimulate the antral electrodes during the absolute antral refractory period. This enhances spontaneous gastric contractions and sends a signal through the afferent vagus that the stomach is distended. The gastric stimulation begins when food enters the stomach; hence, this is a postprandial stimulation. The phased antral contractions are enhanced by stimulation parameters such as a frequency of 80 Hz, a pulse width of 1–2 s, and a current of 0.5–1 mA. Because the stimulation is a high-energy activity, the device must be recharged weekly by an external charger.

49.2.4 Surgical Technique

The most widely used gastric pacing device was the Transcend™ Implantable Gastric Stimulator (IGS) [8]. Patients are administered general endotracheal anesthesia and positioned in the lithotomy position in approximately 20° reverse Trendelenberg position. The surface of the abdomen is cleansed with an antiseptic solution and covered with a sterile drape. The abdomen is insufflated with 12 mmHg CO_2. A minimum of three trocars are inserted (Video 49.1). The optical system and the stomach grasper are introduced through the midline supraumbilical port and the right upper quadrant port, respectively. The lead and subsequently the needle-driver are introduced through the left subcostal port, in the anterior axillary line. This port is 10 mm in diameter. The needle is then brought out with the back end of the lead through the left subcostal port at the completion of the operation. If necessary, a fourth trocar is used to introduce a liver retractor; the location is at the discretion of the surgeon and depends upon the type of liver retractor used. The next step is the identification of the region where the electrodes will be implanted. Centers are evaluating different electrode positions, and are also assessing the possibility of using two leads. However, all these positions are on the lesser curvature of the stomach. One useful landmark to describe the location is the distance from the junction of the lesser curvature of the stomach with the fat of the neurovascular bundle. Another easily identifiable landmark is the *pes anserinus* (the position where the motor nerve of the vagus to the antrum, the nerve of Latarjet, crosses onto the serosa of the stomach). Using electrocautery, the entry and exit points for the 3-cm recommended tunnel length are marked. A ruler (such as the open jaws of a grasper), a metal ruler or a portion of a cut plastic ruler may be used to accurately define the distance. Next, the lead is prepared. The suture sleeve is securely ligated to the lead that is immediately proximal to the proximal line and electrode. Care must be taken to ensure that the sleeve does not slide on to the lead. The lead is then introduced into the abdomen. It is important to minimize traumatic damage to the insulating sheath around the lead because damage may render the lead useless for a subsequent operation. The lead is inserted into the muscle tunnel (Fig. 49.1). Appropriate counter-traction on the stomach is helpful. Needle insertion in to the stomach is facilitated by retracting it in the opposite direction. An adequate length of the tunnel is mandatory, to ensure that both of the electrodes are buried within the tunnel wall. When the electrodes have

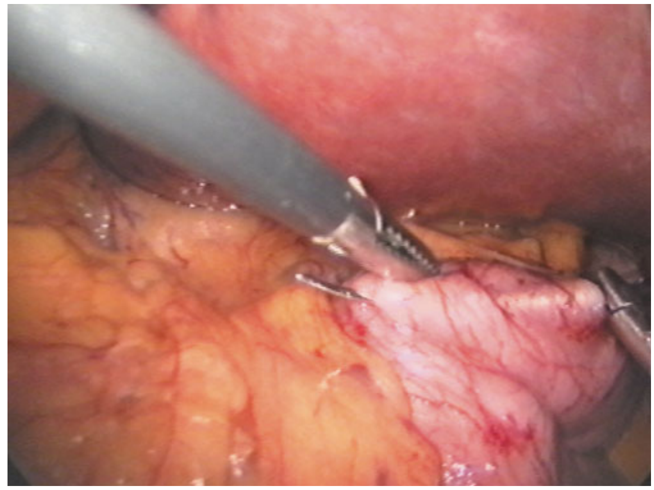

Fig. 49.1 The lead is inserted into the muscle tunnel of the stomach wall with an adequate length of tunnel to ensure that both of the electrodes are buried within the tunnel wall

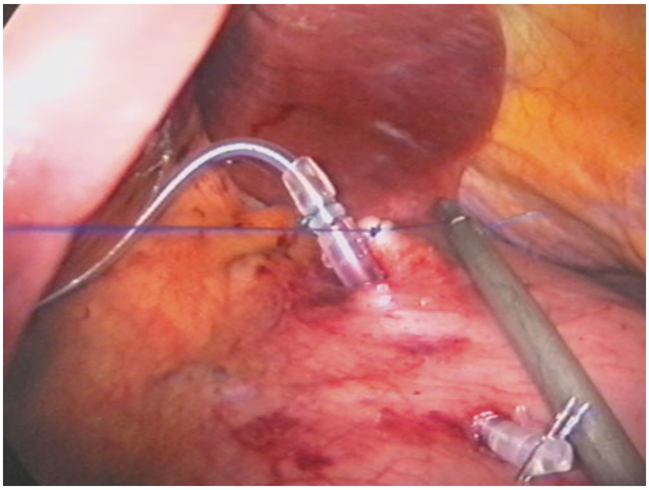

Fig. 49.2 After removal of the needle, the lead is secured in position with separate non-absorbable sutures into the underlying serosa and muscle

been inserted, gastroscopy is carried out to check if the needle has inadvertently perforated the lumen of the stomach. If the electrodes are visualized within the lumen of the stomach, they are removed.

The needle is then inserted in an adjacent location in the immediate vicinity of the initial tunnel. It has not been found necessary to suture the entry and exit site of an abandoned first tunnel. There have been no reports of immediate or delayed complications, such as infection or gastric fistula. When a perforation is detected at the time of implantation, it is immediately corrected.

Once satisfactorily implanted, the lead is secured in position. Separately, each of the eyelets on the suture sleeve is used to pass a non-absorbable suture into the underlying serosa and muscle (Fig. 49.2). Care is taken to avoid displacing the electrodes from their tunnel during this suturing. Following fixation, the proximal end of the lead is withdrawn from the abdomen through the left sub-costal port.

The pocket where the generator will remain is then prepared. The location should be on the anterior abdominal wall beneath the fat. It is often helpful to outline the desired location of the pocket as well as the location of the skin incision with a sterile marking pen. The skin incision itself should always be away from the location of the pocket, so that a suture does not overlie the generator itself. The posterior wall of the generator pocket rests on the anterior aspect of the anterior rectus fascia. The header is gently cleaned, with sterile water (not saline), to remove traces of any tissue debris. It is then fully inserted into the header on the generator. The surgeon should visually confirm that the tip of the lead is at the back of the header cavity. Confirmation of an adequate connection is necessary because incomplete insertion may result in an electrical open or short circuit. The device that controls the settings (wand) is covered with a sterile cover and the system impedance is checked. If the impedance is within acceptable limits, the generator is inserted into its pocket and the skin is closed with a running subcutaneous absorbable suture. Sutures are avoided in the fat layers of the abdominal wall. The abdomen is then reinflated and visually checked for the presence of any electrodes that may have dislodged during external manipulation with the generator. The redundant residual lead is left in the abdominal cavity lying in a gentle curve to allow movements of the patients without tension on the lead. The trocars are removed under direct visualization. The skin over the 5-mm incisions is sealed with Steristrips™.

49.2.5 Postoperative Management

Following Surgery, the stimulation is in the OFF mode to permit healing of the gastric tunnel. An upper gastrointestinal gastrografin study was performed prior to discharge to confirm the absence of leak and to document the immediate postoperative lead location. The stimulation parameters were activated 1 month after operation. Patients are advised to follow standard dietary and lifestyle modification programs. The recommended duration after which the generator has to be replaced is 5 years.

49.2.6 Safety

A total of four randomized controlled trials (RCTs) and 13 case series (redundant papers not included) associated with LGP across centers in the United States and Europe were reviewed (Table 49.1). Overall, adverse events and device-related adverse events were low (i.e. ≤0.05 events/patient/year) and there were no life-threatening or fatal complications in the RCTs and case series of LGPs. Safety outcomes were pooled (see Table 49.1). The rates of overall and device related adverse events were low (i.e. ≤0.05 events/patient/year). Most common complications included lead dislodgement (22.7 % of patients), abdominal discomfort (20.6 %), pain at the incision site (18.0 %), stomach lumen penetration (14.1 %), abnormal abdominal sensations (11.4 %), and gastrointestinal symptoms (32.4 %).

49.3 Efficacy

The efficacy of LGP was proven in a multicenter European double-blind study with 48 patients (Table 49.2). This was followed by the Laparoscopic Obesity Stimulation Survey (LOSS) study, which was a multi center European surveillance study across 16 hospitals, wherein 91 patients have undergone implantation to date [9]. All 91 patients from

Table 49.1 Summary of safety data comes from 4 randomized controlled trials and 13 case series

	Number of patients[a]	Proportion of patients (95 % CI)	Mean event rate (number of events/patient/year)[b]
Adverse events			
Overall	24/323	7.4 % (5.0–10.8 %)	0.05
Device-related	3/323	1.9 % (0.8–4.2 %)	0.01
Deaths	0/334	0	0
Complications			
Lead dislodgement	42/185	22.7 % (17.2–29.3 %)	0.25
Abdominal discomfort	65/315	20.6 % (16.5–25.4 %)	0.40
Incision site pain	32/178	18.0 % (13.0–24.2 %)	0.20
Stomach lumen penetration	47/334	14.1 % (10.8–18.2 %)	0.13
Abnormal abdominal sensations	21/184	11.4 % (7.6–16.8 %)	0.30
Gastrointestinal symptoms[c]	58/179	32.4 % (26.0–39.6 %)	0.56

CI confidence interval
[a]Denominator (total number of patients) different as not all studies reported all outcomes
[b]Assuming a constant risk over time
[c]Including diarrhea, dyspepsia, nausea, vomiting, reflux and constipation

Table 49.2 Multicenter European double-blind study with implantable electrical gastric stimulation in 48 patients

Follow-up	% Excessive weight loss
1 month	3.7 ± 7.1
3 months	8.7 ± 9.3
6 months	15.1 ± 13.0
12 months	23.5 ± 21.1
15 months	32.0 ± 22.1

Source: Miller et al. [13]
Mean ± Standard deviation
Investigators: Cigaina V.(1), Dargent J.(2), Belachew M.(3), Melissas J.(4), Miller K.(5), Favretti F.(6), Dietl K-H. (7), Horber F.(8)
Hospitals: (1) Ospedale Umberto I, Mestre-Italy; (2) Polyclinique de Rilleux, Lyon–France; (3) CHRH de Huy-Belgium; (4) University General Hospital Heraklion-Greece; (5) KrankenhausHallein-Austria; (6) Ospedale S. Bortolo, Vicenza-Italy; (7) UniversitätsklinikMünster-Germany; (8) KlinikHirslanden, Zurich-Switzerland

the LOSS study showed a mean excess weight loss (EWL) of 20 % at 12 months after surgery, and about 25 % at 2 years after implantation. Patients with an initial body mass index (BMI) less than 40 kg/m^2 prior to the operation experienced a significantly higher weight loss after 21 months than the group with BMI over 40 kg/m^2. They showed an EWL of 32 % and 20 %, respectively. In a retrospective patient selection study [10], patients who passed the Baroscreen ($n = 50$) achieved a EWL of 31.4 % than those who failed the screening algorithm ($n = 37$), where the EWL was 15 % ($p < 0.01$), and the overall EWL after 24 months was 25 %. Baroscreen (a screening algorithm) was used to predict IGS weight loss from pre-implant assessment data, such as age, gender, BMI, and SF-36 questionnaire responses [10]. Interestingly, data suggest that the Tantalus™ system for gastric electrical stimulation can potentially improve glucose metabolism and induce weight loss in obese diabetic patients whose glucose levels are not well controlled on oral antidiabetic therapy [11]. Mizrahi et al. discussed that patient selection for gastric stimulation therapy is an important step in determining the treatment outcome [12].

Conclusions

Laparoscopic gastric pacing appears to be promising therapy for promoting short-term weight loss in selected patients. Furthermore, LGP is a relatively safe technique particularly when compared to other forms of bariatric and metabolic surgery. Currently, there is a paucity of evidence for LGP. The use of LGP in the treatment of obesity is potentially useful because the different pacing strategies impact obesity through different physiologic mechanisms. Different pacing mechanisms could be applied by combining with diverse therapeutic strategies for greater efficacy in weight loss and metabolic disorders in obese patients.

Key Learning Points

- Laparoscopic Gastric Pacing is a promising, minimally invasive, safe, and effective method for treating obesity.
- Selection of the appropriate patients for gastric stimulation therapy is an important determinant of treatment outcome.
- Various methods of gastric stimulation are gastric pacing with short pulse width and high frequency and stimulation during the electrical refractory period of the stomach.
- Gastric pacing with long pulse width and low frequency are not used in clinical practice.
- Various applications include Transcend™ that uses gastric pacing with short pulse width and high frequency, and Tantalus™ that stimulates during the electrical refractory period of the stomach.

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Section X

Endoscopic Approaches in Obesity and Bariatric Surgery

Honorary Section Editor - Dan R. Titcomb

In the following four chapters, the authors set out to describe the role of endoscopic therapies to act as a primary means of tackling obesity, an adjunct to the management of severe and complex obesity, endoscopic treatments of complications after surgical procedures in Bariatric patients and what the future of endotherapy might hold for both the bariatric surgeon and patient.

Some of the techniques described are tried and tested with appropriate long term follow up data and outcomes, some are novel and may never enter into wide stream clinical practice. What is certain is that the techniques described in the following pages should be considered when bariatric patients are being assessed and their management plans formulated by both surgeon and endoscopist.

The chapters describing some of the newer endoluminal techniques currently available for the management of obesity are both insightful in their conclusions. Although these techniques may show promise, the authors are careful to mention that the aspiration of any new technique should be equivalence in terms of long term benefit when being compared with the laparoscopic techniques that are widely available. Long term follow up data from clinical trials must be sought for validation.

Bariatric surgeons should be aware of the contents of the chapter on the endoscopic management of complications after surgery. Although complications are relatively uncommon after bariatric surgery compared with other type of upper gastrointestinal surgery, they can be catastrophic and lead to significant morbidity. Less invasive techniques for managing these potentially fatal complications are a valuable adjunct to more traditional surgical therapy and may well be associated with less morbidity in the long term.

Intragastric Balloon Treatment for Obesity

50

Alfredo Genco, Roberta Maselli, Giovanni Casella, Massimiliano Cipriano, and Adriano Redler

Abstract

The first intragastric balloon was launched in the market 30 years ago. From then, different intragastric prosthesis have been presented and used worldwide. There are, now, one billion overweight/obese persons worldwide. Only some of those patients express the desire or are able to undergo surgical operation. At present there is no medical cure for obesity. Despite the numerous dietary treatments, the natural course of obesity is characterized by an ongoing and sometimes unstoppable weight gain. In patients with first degree obesity, the intragastric balloon interrupts the ongoing and inexorable weight gain, and improves the relevant co-morbidities. In super-obese patients, where there are numerous co-morbidities, the weight loss obtained with the balloon represents a chance to reduce the surgical and anesthesiologic complications deriving from bariatric surgery.

Different balloons (filled with fluids, gas or air) are present in the market, but the BioEnterics® Intragastric Balloon (BIB) is still the most used and known. Therefore, the chapter is mainly focused on it. However in some patients, especially overweight patients, there is doubt on the placement due to the post-placement discomfort. The Obalon® Gastric Balloons (OBG) (Obalon Therapeutics, Carlsbad, California) is a fully repeatable and reversible intragastric balloon; compared to other balloons it is totally swallowable, does not need endoscopy for its placement and has low rate of post-placement symptoms.

The chapter explores the history of intragastric balloons, the indications, technical notes and complications of intragastric balloon treatment with particular attention to the state-of-the-art long term results.

Keywords

BIB • Intragastric balloon • Endoscopic treatment • Endoluminal treatment • Device • Obalon

50.1 Introduction

The natural history of pathological obese patients is chequered with the repeated diet failures. The indications of surgical treatment are strictly specific and, even today, far from acceptable to the patients [1].

In the last decades, obesity surgery has increasingly spread. Its users, as well as the operators, are constantly looking for minimally invasive (for the procedure itself, complications and discomfort rate) and at the same time massively effective (weight loss results) treatment [2, 3].

In 1986 Pasulka et al. [4] demonstrated how a modest preoperative weight loss (10–20 %) reduced surgical

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Table 50.1 Ideal intragastric balloon characteristics

Efficacy
Variable volume
Spherical shape
Soft surface
Filled with liquid
Radiopaque valve

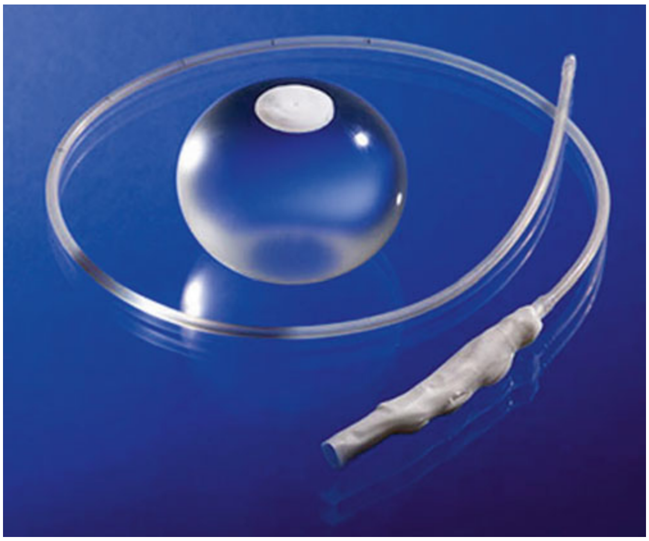

Fig. 50.1 The BioEnterics® Intragastric Balloon (BIB®, courtesy of Apollo Endosurgery)

complications resulting from bariatric surgery. Consequently the interest has turned to the remedies which help patients to maintain restrictive diets. Those remedies make diet more effective and thus lead to greater control of the co-morbidities from the point of view of surgery.

The concept of intragastric balloon emerged in the early 1900 when patients with bezoars (partially digested agglomerates of hairs or vegetable fibers) often complained of postprandial fullness, nausea and vomiting. It led to the idea of contriving a device which would imitate an intragastric bezoar.

The first intragastric balloon to be marketed was the Garren-Edwards Gastric Bubble, a cylindrical, polyurethane contrivance, inflated with air. It was then followed by different types of intragastric balloons, but all of them showed lack of safety and efficacy [5].

In 1987, a team of experts defined the ideal intragastric balloon (See Table 50.1). The BioEnterics® Intragastric Balloon system (BIB®, Apollo Endosurgery) (See Fig. 50.1), in accordance with their indications, is made up of soft and transparent silicone balloon connected, by means of a radiopaque valve, to a placement catheter. Three fundamental factors distinguish the BIB® from the 1980s bubbles: the liquid content which makes it definitely more effective, the self-sealing radiopaque valve, the spherical form and silicone structure which render the complication of ulcers extremely rare.

Up to now, the intragastric balloon has been shown to be less invasive, being a removable device, with a high safety and efficacy profile [6, 7]. To the patients asking for a temporary weight loss device, especially overweight patients, still some doubts remain on its placement and removal due to the endoscopic approach and the post-placement discomfort. A new swallowable intragastric balloon, "Obalon," and other commercially available devices have strong safety profile and low rate of post-placement symptoms.

50.2 BIB® Intragastric Balloon

50.2.1 How It Works?

The efficacy of the BIB® in inducing weight loss is not due to the placebo effect but due to the characteristics which make it effective 'in itself.' How it works depends on the following:

- Weight: The weight of the BIB, filled with liquid, stimulates the baroreceptors of the gastric wall. Baroreceptors, through the brain-gut axis, stimulate the satiety center located at the hypothalamic level.
- Delayed gastric emptying: An ultrasonographic study showed that in patients without the balloon, food was visualized in the antrum 32 min after the consumption of solid meal. In the same patients, 30 days after the placement of BIB®, food was visualized after 300 min.
- Reduction of gastric volume: The presence of the device reduces the unoccupied gastric volume.
- Discomfort: The nausea, precocious sense of satiety, vomiting and epigastric pain suffered during the first 24–30 h post-placement and if the patient fails to adhere to the prescribed dietary regime.
- Hormonal mechanisms: During the first 3 months of treatment with the BIB®, significant increase in the plasma ghrelin levels was observed, followed by gradual reduction until the basal levels reached, after removal [8].

50.2.2 Indications

The BIB® is indicated in association with specific diet treatment in patients with a history of obesity (at least 5 years), after numerous failures of dietary treatment only.

Present indications suggest BIB® placement in patients with:

- <35 Body Mass Index (BMI) with obese-related co-morbidities whose resolution or improvement require mandatory weight loss

- >35 BMI, as a pre-surgery role in patients with co-morbidities, before any other type of surgery, or in patients who refuse surgery

At the moment, there are no specific limitations regarding age. The device can, therefore, also be used for children.

50.2.3 Placement and Removal Technique

BIB® placement and removal can be performed in conscious sedation, in unconscious sedation or with orotracheal intubation. The balloon is positioned under the cardia and filled with 500–700 ml of physiological solution and 10 ml of methylene blue. BIB® removal is carried out after 6 months. The procedure uses gastroscopy to see the balloon and deflate it with a specific device. The BIB® is removed with a dedicated 'grasper' when the balloon is completely deflated (Video 20.1). Stomach observation is necessary to exclude possible mucosal lesions.

50.2.4 Post-placement Pharmacological Treatment

Due to the secondary effects (nausea, regurgitation or vomiting, epigastric pains) derived from the presence of the BIB® and from the almost total impossibility of eating during the first 24–36 h, all the patients must receive support treatment such as infusion of electrolytic solutions, proton pump inhibitors, antispasmodic and antiemetic drugs.

50.2.5 Post-placement Diet

On the first day, the patient receives only liquid diet. From the second and up to the sixth day, semi-liquid diet is followed. The dietetic regime from the seventh day until the removal is daily intake of 1000–1200 Kcal (68 g protein, 18 g lipids, 146 g glucids, at least 1 g protein/kg ideal weight), consumed over three main meals and two snacks.

50.2.6 Follow-up

For the first 7 days, all patients are contacted by phone every day. On the eighth day patients undergo clinical-nutritional examination. Later, the patient undergoes clinical-nutritional examination every 2 weeks.

When there are signs (such as blue urine) or symptoms indicating possible complication, immediate clinical evaluation of the patient is essential.

Table 50.2 BIB (bioenterics intragastric balloon) post-placement symptoms

Nausea	87 %
Vomit	51 %
Epigastralgia	61 %
Meteorism	36 %
Diarrhea	5 %
Halitosis	12 %

Table 50.3 Results of the 1353 patients who have undergone BIB (Bioenterics intragastric balloon) placement

	BMI	EWL%
BIB placement	38.9	—
BIB removal	31.8	34.4 %

Table 50.4 GILB results on the 2515 patients using BIB (Bioenterics intragastric balloon) system

	BMI	EW%/EWL%
BIB placement	44.4	59.5 EW%
BIB removal	35.4	33.9 EWL%

EWL excess weight loss, *EW* excess weight, GILB [9]

At the end of the sixth month, the BIB® is removed and the following alternatives are then evaluated: (a) 'maintenance' diet program; (b) placement of second BIB® (multiple treatments); (c) previously planned bariatric surgery.

50.2.7 Results

50.2.7.1 Secondary Post-placement Effects

In our personal experience (data not published), the secondary post-placement effects are: nausea for 24–36 h in 87 % of the patients; vomiting (a mean two episodes) in 51 %; slight epigastralgia in 61 %, regressed with antispasmodic drugs; increased intestinal meteorism in 36 %; diarrhea (5–6 episodes/day) in 5 %; and halitosis in 12 % (See Table 50.2).

50.2.7.2 Weight Loss

From March 1998 to May 2011, our case histories (data not published) recorded 1436 placements of BIB® in 1353 patients. The mean age was 36.5 and mean BMI was 38.9. At the end of the treatment the patients presented: BMI of 31.8 and excess weight loss (EWL) of 34.4 % (See Table 50.3). The results can be superimposed on those reported by the Italian LAP-BAND® and BIB® group (GILB) in 2,515 cases with a mean weight-loss of 9.0 BMI and 33.9 % EWL (See Table 50.4) [9]. Our study [10] compared the weight loss achieved by the BIB® + diet to that achieved by the diet therapy alone at 6 months, when the balloon was removed, at

12 months after the BIB® removal. The experimental group (BIB®+diet) consisted of 122 obese patients (mean BMI 41.8±6.8). The control group (diet alone) consisted of 128 patients (mean BMI 42.0±6). At 6 months, weight loss was significantly higher in patients treated with BIB®+diet when compared to the patients treated with diet alone (weight loss of 16.2 vs 6.6 kg, BMI decrease of 5.7 vs 2.5 kg/m^2). The difference was still significant at the follow-up (12 months) but to a lesser degree. Both the groups showed a tendency to regain weight at the follow-up: in the BIB®+diet group, the average weight loss from the baseline was reduced to 11.2 kg and the BMI loss was reduced to 3.5 kg/m^2; in the diet control group, weight loss from the baseline was reduced to 5.5 kg and BMI loss was reduced to 2.0 kg/m^2. The results demonstrate that intragastric balloon combined with dietary instructions induces significantly higher weight loss than the simple dietary therapy, in the first 6 months of treatment and persists at 12 months of follow-up

50.2.7.3 Long-term Results

It is difficult to observe the long-term efficacy of a device such as the intragastric balloon which is created for temporary treatment. In almost all morbid obese patients, the weight loss is followed by subsequent weight regain. Several authors have reported successful weight loss in the short term but only few studies have investigated the long-term results after removal [7, 11, 12].

Within the framework of our experience from 1998 to 2006 (613 patients), we retrospectively evaluated patients with 60 months post-removal follow-up (n=45) (patients who had undergone bariatric surgery or who had sequential BIB® placement were excluded) [data in press].

EWL at the BIB® removal was the cutoff: patients (69 %) who lost ≥25 % of their excess weight (EW) were classified as successes, while patients (31 %) who lost 0–21 % of their EW were categorized as failures. At 60 months follow-up, 30 % (9/30) of the success group had EWL percent of ≥25 and 70 % (21/30) of them had EWL percent of <25. We evaluated the association between results and three factors: initial BMI, age and gender. Statistical analysis confirmed the associations: female gender, age <35 years and initial BMI of 35–40 are long-term success predictive factors. The results also confirm the short-term efficacy of the BIB®: at 6 months, about 70 % of the patients lost at least 25 % of their EW. At 60 months follow-up, 30 % of the patients were able to control their weight loss.

We also investigated the efficacy of multiple balloon treatment, in the long term (6 years), with respect to weight loss, influence on co-morbidities and quality of life in patients refusing surgery [6]. The multiple treatment consists of placing two balloons one after the other, with an interval of at least 30 days between the first balloon removal and the second balloon placement. The interval allows the patient to 'get the feel' of the balloon again. We evaluated 83 patients, with BMI >40, who are good candidates for surgery but refusing it. After removing the first balloon, second balloon was placed when the patients had regained ≥50 % of the weight loss achieved with the previous balloon. Weight, co-morbidities and quality of life were recorded until the 76 months follow-up.

Table 50.5 Weight loss effects on co-morbidities

	Cleared up (stopped drug treatment)	Improved (reduction of drug treatment)	Unchanged
Hypertension	38 %	52 %	10 %
Diabetes	36 %	45 %	19 %
Dislipidemia	58 %	28 %	14 %
Joint diseases	61 %	–	39 %
Respiratory function	80 %	–	20 %
Hyperinsulinemia	56.6 %	–	43.4 %

All patients experienced the second balloon and 22.2 % had the third balloon placed. Only one patient had the fourth balloon. At 76 months follow-up, mean BMI was 37.6 Kg/m^2 and weight cycling periods were observed. Significant difference was recorded regarding the presence of co-morbidities at the baseline (80 % of the patients) and at the follow-up (30 % of the patients). Quality of life test, in the follow-up, showed better scores than those at baseline. The results demonstrate that, in patients refusing surgery, multiple intragastric balloon is the recommended treatment allowing the patients to achieve better weight loss, better control of co-morbidities and better quality of life than those at the baseline.

The BIB® has been used only as a short-term treatment. Our study suggests utilizing the BIB® as a possible long-term treatment in selected patients, especially to prevent obesity.

50.2.7.4 Effects of the Weight Loss on Associated Diseases; Pre-operative Strategy

In our series (data not published) the weight-loss induced by the BIB® drastically affects the progression of obesity-related diseases, thus determining the suspension or reduction of the pharmacological therapy (See Table 50.5). The dyslipidemic values improved in 58 %. There is significant hypertension control in 38 %. Joint diseases improved in 61 %. In 80 %, the weight loss led to the prompt improvement of respiratory function and sleeping difficulties with the disappearance of apnea attacks. After the BIB® treatment, the apnea index ranged from 33–5 episodes/h. Furthermore, weight loss induced by the intragastric balloon led to significant reduction in the intestinal fat and the liver volume. In Busetto's study [13], the pre-LAP-BAND® treatment together with the BIB® induces weight loss that reduces the operating time, the

Table 50.6 Busetto's study data on the operating time, hospital stay, conversion rate and intraoperative complications

	BIB-LAPBAND (case pts)	LAPBAND (control pts)
Operating time	82.5 ± 20.9	102.6 ± 35.1
Hospital stay	3.0 ± 0.2	3.3 ± 0.8
Conversion rate	0/43 (0 %)	7/43 (16.3 %)
IO complications	0/43 (0 %)	3/43 (7.0 %)

hospital stay, the intraoperative complications and the conversion rate for patients subsequently subjected to gastric banding,, when compared to the patients submitted directly to the LAP-BAND® (See Table 50.6).

Recently, a multicenter study was conducted on the patients who underwent BIB® with subsequent Laparoscopic Adjustable Gastric Banding (LAGB) [14]. After balloon removal, patients were allocated into: group A with >25 % EWL and group B with <25 % EWL. Patients from both the groups underwent LAGB. Totally, 1357 patients were enrolled in the study (mean initial BMI of 44.9). After 6 months, at the time of removal, mean BMI was 39.4. According to the cut-off, patients were allocated into group A (n = 699) and group B (n = 658) and at that time the mean BMI was 36.4 and 42.7 respectively. After LAGB, at 1 year follow up, mean BMI was 35.8 and 40.0 in group A and B respectively. The significant difference was also confirmed at 3 and 5 years of follow up. The results showed that satisfactory results with the BIB® are predictive of positive outcome with LAGB at 1, 3 and 5 years of follow up, while negative results are not inevitably indicating negative outcome with gastric banding.

The findings of the GILB group [9], in a study on 2515 patients, indicate that the use of the intragastric balloon induced normalization of the co-morbidities in 44.3 % and an improvement in 44.8 %. In only 10.9 % of the cases, the co-morbidities showed no positive effects whatever from the balloon treatment

It is evident that such changes are related to the weight loss and not to the use of the BIB® *per se*.

50.2.8 Complications

50.2.8.1 Minor Complications

In the Italian BIB® study with 3252 patients (data not published), the incidence of minor complications was 2.1 % (71 patients). The intragastric balloon was removed due to intolerance in 13 patients (0.39 %). Breakage of the device occurred in 19 patients (0.58 %) and, except in two cases, always after the period advised by the company (6 months). Oesophagitis was diagnosed after the removal of the BIB® in 39 patients (1.2 %), probably due to the discontinuous use of the proton pump inhibitors (See Table 50.7).

Table 50.7 BIB (bioenterics intragastric balloon) minor complications in 3252 patients

BIB intolerance	0.39 %
BIB breakage	0.58 %
Esophagitis	1.2 %

Table 50.8 BIB (Bioenterics intragastric balloon) major complications in 3252 patients

Gastric obstruction	0.58 %
Gastric ulceration	0.15 %
Gastric perforation	0.15 %

50.2.8.2 Major Complications

In the Italian BIB® study with 3252 patients, the incidence of major complications was 0.9 % (32 patients). In 19 patients (0.58 %) the device caused gastric obstruction and it was resolved with medical treatment in three cases, but 16 cases required removal of the BIB®. Gastric ulceration occurred in five patients (0.15 %) (See Table 50.8). Gastric perforation, the most frightening complication, occurred in five patients (0.15 %); four of them had already undergone surgery: three at the gastric level (Nissen fundoplication, vertical gastroplasty complicated by fistula, gastric banding removed because of intragastric migration) and one due to prior thoracic–abdominal trauma. In three patients, gastric perforation was surgically treated. The other two patients died; one during surgery and the other during diagnostic tests.

50.3 Obalon Balloon

The Obalon balloon has received Conformite Europeenne (C.E.) mark approval and was launched in the market, initially to a limited number of centers, in Europe since July 2012. The balloon is designed to be swallowed in gelatin capsules and inflated with 250 cc of gas without the need for endoscopy or sedatives. To increase the gastric volume occupied, it is possible to place more than one balloons (up to three) over the entire treatment period of 3 months in order to stimulate further loss of weight. All balloons are intended to be removed at the end of 3 months by using short endoscopy and standard tools available on the market.

50.3.1 Indications for Use

The Obalon balloon is indicated for temporary use in treatments aimed at weight loss in overweight and obese adults with BMI of ≥27 and who have not achieved satisfactory results in previously supervised weight control program. It is intended for use in combination with diet and behavior modification program. Up to three balloons can be placed in the stomach during the 3 months (12 weeks), depending on the progress in weight loss and the levels of satiety in the patient. The maximum period of use is 3 months (12 weeks), within which all the balloons must be removed.

50.3.2 Study Outline

In our study (in press), we aimed to prospectively evaluate the safety and efficacy of the new device (Obalon), focusing on its side effects and complications.

After a general work-up (lab test, physical examination) and signed informed consent, the Obalon was placed in the patients. Accordingly to the patient's BMI, one or two Obalons were placed for 3 months: if the initial BMI was <39.9 Kg/m^2, one balloon was paced; if the initial BMI was ≥40 Kg/m^2, two balloons were placed together in the same session. The patient was discharged the same day with dietary instructions (glucids, 146 g; lipids, 68 g; proteins, 1 g/kg ideal weight) and therapy prescription (Esomeprazole—40 mg/daily for 1 month followed by Esomeprazole—20 mg/daily for 2 months, Butylscopolamine bromide—20 mg if needed, Ondansetrone—8 mg if needed). The visual analogue scale (VAS) score was evaluated at the baseline, 1, 2 and 3 months (balloon removal).

The VAS is a measurement scale, here used for pain intensity; the scale is most commonly anchored by "no pain" (score of zero) and "pain as bad as it could be" or "worst imaginable pain" (score of 10).

Together with the epigastric pain, specific items were also evaluated such as satiety (zero = no satiety, 10 = totally "full" sensation) and vomit (zero = no nausea/vomit, 10 = daily vomit). If and when the satiety score was ≥5, second balloon was placed. VAS score, minor (intolerance, esophagitis, gastritis, ulcer) and major (perforation, bowel occlusion, death) complication rate as well as weight parameters were evaluated. Post-placement pharmacological symptomatic therapy (type and timing) was also recorded and evaluated.

Patients were evaluated at the first post-placement day (VAS score, therapy, complication), at 1 month (weight, VAS score, therapy, complication), at 2 months (weight, VAS score, therapy, complication) and at 3 months (removal, weight, VAS score, therapy, complication)

50.3.3 Obalon Intragastric Balloon: Device and Placement/Removal Techniques

The Obalon is a 250 cc gas-filled device with less than 6 g of weight. It is composed of strong, light, multilayer, smooth and bio-resistant nylon and polyurethane material. The balloon has a small self-sealing, smooth and flush radiopaque under x-ray valve to check the balloon position.

The patient swallows a capsule attached to a micro catheter; the balloon is inside the gelatin capsule. Once in the stomach (verified by fluoroscopy and by the inflation system gauge), the balloon is remotely inflated with gas (nitrogen) using the microcatheter that is 71 cm, 2 French (Fr) and without any endoscopy and/or anesthesia. After the inflation, the micro catheter (extended from the stomach to the mouth) is detached and removed, leaving the balloon in the stomach.

After the 3-month treatment period, all the balloons are retrieved by upper gastro-intestinal endoscopy under conscious sedation, using standard and commercially available endoscopic tools (injection needle and endoscopic grasper/foreign body grasper). The balloon/balloons are punctured by endoscopic injection needle and the gas is aspirated. The balloon is finally removed with rat tooth/foreign body forceps or with polypectomy snare.

50.3.4 Results

From May 2013 to December 2013, 62 patients (20/42 M/F, mean age 41.3 ± 14.9 years, mean BMI 38.2 ± 7.3 Kg/m^2) received Obalon balloons. Five of them (8 %) received two balloons in the same session (mean BMI 43.8 Kg/m^2) (data in press).

After mean 40 days from the first placement, 21/62 (33.9 %) received second balloon and 6/62 (9.7 %) had three devices.

50.3.4.1 Obalon Placement/Removal

Among the 62 patients, 4.8 % (3/62) were unable to swallow the capsule even after several attempts: in two patients (3.2 %), the Obalon was endoscopically placed and one patient (1.6 %) refused the endoscopic placement and was excluded from the final analysis. Totally 59 patients (95.2 %) were successful in swallowing the device. After 3 months, all the balloons were endoscopically removed. All the balloons were found in the stomach after 3 months.

50.3.4.2 Post-placement Symptoms and Therapy

Mean satiety score was 8/10 on the first post-placement day and it gradually decreased during the 3 months. Mean nausea and epigastric pain scores were 1.5/10 and 3.4/10 respectively on the first post-placement day and they dramatically decreased in 3 days. Mean vomit score was zero.

Twenty one patients (33.9 %) had two devices in two different sessions. Figure 50.2 shows the course of post-placement symptoms in those patients.

Only 6/62 patients (9.7 %) needed post-placement therapy; four of them used a single dose of 20 mg

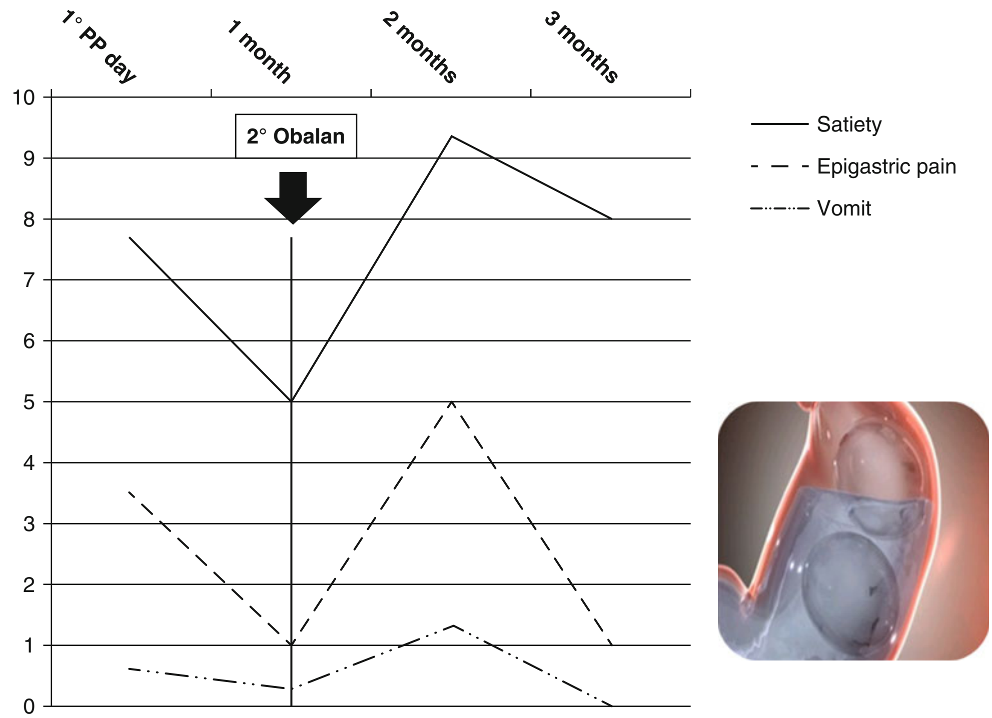

Fig. 50.2 Weight loss results in subgroups of patients (1 balloon, 2 balloons, 3 balloons and 2 balloons placed in the same session) (With permission of Obalon Therapeutics, Inc., San Diego, CA). *BMI* body mass index, *EWL%* percentage of excess weight loss, *BMIL%* percentage of BMI loss, *1* 2nd balloon placement for "2 Obalon" subgroup, *2* 3th balloon placement for "3 Obalon" subgroup, *3* Removal time

butylscopolamine bromide on the first and the second postoperative day. Those patients received two Obalons in the same session. The remaining two patients needed a single dose of 20 mg butylscopolamine bromide on the first postoperative day (second Obalon placement). None of them required ondansetrone. As per protocol, esomeprazole/daily was given to all patients for the entire treatment period (3 months), except four patients who voluntarily discontinued the therapy.

50.3.4.3 Weight Loss

At the time of balloon removal, mean BMI was 33.6 ± 6 Kg/m^2, mean EWL percent was 23.3 ± 8, mean BMIL percent was 9.8 ± 3.6 ($p = 0.03$). Different weight loss results have been reported in the three subgroups of patients (1, 2, 3 Obalon balloons or directly 2 Obalon placed in the same session).

50.3.4.4 Placement/Post-placement Complications

No complications occurred during the placement/removal. Four peptic lesions (superficial gastric erosions) were noted at the removal and those patients discontinued post placement Proton Pump Inhibitor (PPI) therapy. No major complications were registered. In four patients (6.4 %), who did not come back for removal after 3 months, the devices were not found in the stomach at the removal time (mean 160 days, range 188–153); they were spontaneously evacuated and no bowel obstruction was present.

50.4 Discussion and Conclusions

The BIB® is a safe and effective device. Even though the incidence of major complications is less than one percent, its use for cosmetic purposes is not advisable because 4/5 perforations occurred in patients with previous gastric surgery, the contraindication of this factor is absolute [9].

The placement and removal procedures are easy. Physicians must, however, take great care to follow-up their patients very closely, particularly in the first 7 days. It permits timely diagnosis and treatment of possible dangerous complications.

In morbid obese patients, who are to control their diet and who are candidates for bariatric or other types of surgery, the intragastric balloon is the only non-surgical procedure able to induce consistent weight-loss which positively affects the obesity related co-morbidities and reduces the risks of surgery and anesthesia.

The unexpected results derived from the evaluation of patients with 6 year follow-up [6], led us to think that the BIB® plays an important role in the prevention of super-obesity.

There are one billion overweight or obese persons worldwide but only some of those patients express the desire or are able to undergo surgery. In this context, the intragastric balloon plays a role in interrupting the ongoing and inexorable weight gain and in achieving positive control or resolution of the relevant co-morbidities.

Obalon is also a safe and effective device and due to its low rate of post-placement symptoms, it is indicated for overweight patients. The low discomfort can influence the patients' perspective and experience, as well as the post placement management and costs. In our initial study (in press), only 6/62 patients (9.7 %) required therapy for epigastric pain and they were the only patients in whom two Obalons were placed in the same session. Although cost analysis was not performed, we also found a lesser therapy request (in terms of dose per day and in terms of total days of therapy) compared with our personal balloons experience (data not published). With the other balloons, often the patients need an overnight control after the placement and they are unable even to drink for the first 24 h due to the pain and nausea. It means that the hospital stay increases and more therapy is needed, thus increasing the cost. But with swallowable Obalon, no endoscopy is required for placement and it also reduces the hospital stay, the placement therapy and thereby the total cost.

The impact on the weight loss was statistically significant at 3 months, similar to that achieved in 3 months with other balloons. Some authors reported that the intragastric balloons that remain in the stomach for 3 months reached satiety plateau after 3–4 months post insertion. As Obalon remains in the stomach for a shorter time, it is not possible to find the satiety plateau with the Obalon. Obalon is smaller (250 cc) than the other (500 cc) balloons and a slow decrease in satiety has been reported from our patients (data in press). In patients who had satiety score of less than five, we easily placed a second device and the so called "obalon therapy" was repeated as needed. They immediately reported high sense of satiety and started losing weight [data in press].

The Obalon also shows very low complication rate. In our initial series, only four (4/62, 6.4 %) minor complications were noted in low-compliance patients, who discontinued the PPI therapy. No device malfunction occurred. Though the first Obalon generation was approved and tested only for 3 months, the device is already highly safe.

Obalon could be the ideal device to treat overweight patients, due to its less invasiveness, low discomfort and complication rate. Therefore, it should be optimized such that the length of stay reaches at least 6 months and to compete and be compared with other balloons.

Key Learning Points

- The intragastric balloon concept arose from the observation that patients with bezoars often complained of postprandial fullness, nausea and vomiting. It led to the idea of contriving a device which would imitate an intragastric bezoar.
- The efficacy of the intragastric balloon in inducing weight loss is not due to the placebo effect but due to the characteristics which make it effective 'in itself.'
- BIB® is a safe and effective device as the incidence of major complications is less than one percent.
- The intragastric balloon is the only non-surgical procedure able to induce rapid and consistent weight loss which positively affects all the obesity related co-morbidities and reduces the risks of surgery and anesthesia.

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51 Endoscopic Duodeno-Jejunal Bypass Sleeve Treatment for Obesity

Rodrigo Muñoz and Alex Escalona

Abstract

Bariatric surgery has experienced a dramatic evolution over the last years. The search for less invasive procedures to improve the benefit/risk ratio and to expand the benefits of these interventions to a larger group of patients has led to the development of primary endoscopic procedures for the treatment of obesity and its associated diseases. The duodenal-jejunal bypass liner (DJBL) is a highly flexible and impermeable tube that can be endoscopically implanted and explanted. It is specifically designed to create a duodenal-jejunal exclusion. The DJBL treatment has now become a primary intervention for the treatment of morbid obesity and to improve glycemic control in obese patients with type 2 diabetes mellitus (T2DM). Available evidence supports the role of DJBL in treating obesity and improving glycemic control in a significant proportion of severely obese diabetic patients. Early removal and a higher rate of serious adverse events in clinical practice are the most important limitations in terms of safety. Randomized clinical trials are needed to evaluate the safety/efficacy ratio of the procedure and its clinical use in future.

Keywords

Obesity • Diabetes • Bariatric surgery • Weight loss • Glycemic control

51.1 Introduction

There has been a dramatic evolution in the field of bariatric surgery over the last few years. The search for less invasive interventions to improve the benefit/risk ratio and to expand the benefits of these interventions to a larger group of patients has led to the development of endoluminal procedures for the treatment of obesity and its associated diseases [1]. Initially conceived as an alternative for preoperative weight loss before a definitive surgical procedure [2], duodenal-jejunal bypass liner (DJBL) treatment has now become a primary intervention for the treatment of obesity and to improve glycemic control in obese patients with type 2 diabetes mellitus (T2DM) [3]. Over the last few years, over 2000 patients have been treated with DJBL worldwide and this number is expected to increase in the upcoming years as more and more physicians are being trained for this procedure.

In this chapter, we will provide an overall description of DJBL device and discuss technical aspects of device placement and explantation as well as patient selection. We will also describe the mechanism of action of this procedure and its outcomes.

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51.2 Duodenal-Jejunal Bypass Liner

DJBL is a 60-cm long, highly flexible and impermeable tube that is anchored endoscopically at its proximal end in to the first portion of the duodenum (Fig. 51.1). All parts of the device are designed to permanently withstand the acid and base environment of the proximal gut. The device consists of two components: (1) the anchor, and (2) the liner. Located at the proximal end of the device, the anchor has two important roles. First, it maintains the position of the liner within the intestinal wall. Second, it creates a seal to ensure that all chyme passes through the liner, and does not come in contact with the intestinal mucosa. The anchor is made of nitinol, a nickel-titanium alloy from which many vascular stents are made. This super elastic metal is biocompatible and can be compressed into a small diameter to enable endoscopic delivery. The anchor contains proximal and distal barbs that engage the duodenal wall to prevent movement of the anchor in either direction. Silk drawstrings on the proximal end of the anchor are used to remove the DJBL at the desired point of time. When grasped and withdrawn, they act to purse string the proximal opening of the anchor and collapse it for endoscopic withdrawal. Upon placement of the device, the anchor slowly expands such that the barbs are pushed into the wall. The highly flexible and nutrient impermeable tube liner permits normal peristalsis to push chyme through the liner. After the DJBL device is placed inside the duodenum with the help of an endoscope, chyme from the stomach moves through the liner and exits into the jejunum. The chyme thus bypasses the entire duodenum and the proximal jejunum. In addition, the DJBL prevents the mixing of bile and pancreatic enzymes with the chyme until they join in the jejunum partially digested.

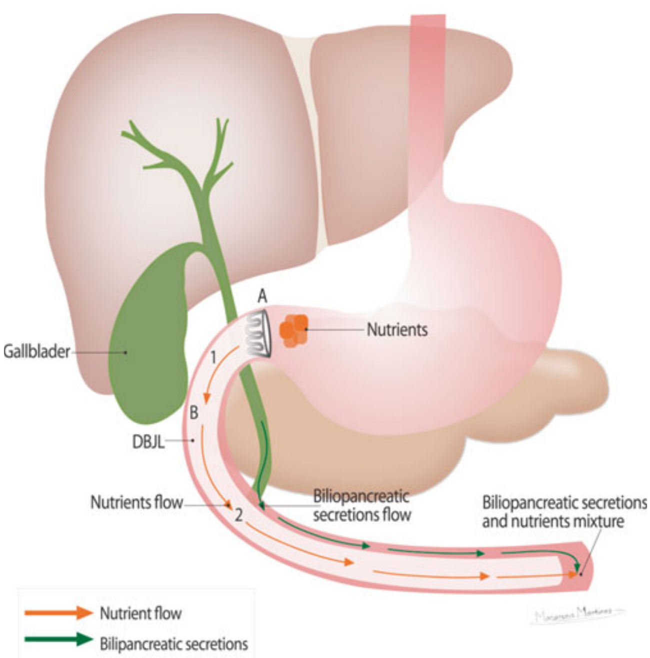

Fig. 51.1 Duodenal-jejunal bypass liner

51.3 Technique

51.3.1 DJBL Placement

Patients are usually admitted to the hospital on the morning of device placement following 10–12 h of fasting. The patient is placed in the left lateral decubitus position. While the patient is under general anesthesia, endotracheal intubation is done under endoscopic and fluoroscopic guidance and the DJBL is implanted [4]. However, there are reports of the use of conscious sedation for device placement in a group of patients [5, 6]. A standard gastroscopy is used to advance a guide wire into the duodenum. Over it, the encapsulated device on a custom catheter is passed. The capsule at the distal end holds the sleeve and anchor. The catheter has a ball which is advanced through the intestine deploying the sleeve behind itself. After full extension of the sleeve, the anchor is deployed in the duodenum distal to the pylorus (see Video 51.1).

51.3.2 Management of Patients After Implantation

After the implantation, patients are instructed to consume a liquid diet during the first week, a puree diet during the second and third week, and a normal diet (1200–1500 kcal/day) thereafter. This should be combined with exercise and behavior modification. Patients are normally discharged the same day or the day after the implant, provided they are able to tolerate the liquid diet. Patients are on proton pump inhibition (omeprazole 40 mg BID) 3 days before the implant and 2 weeks after the device is removed. Daily multivitamin and oral iron supplements are recommended and maintained during DJBL treatment. Helicobacter pylori, if present, needs to be eradicated in all subjects before DJBL implantation.

51.3.3 DJBL Explantation

Prior to DJBL removal, patients should beput on liquid diet for 3 days and should be fasting for 12 h. Explantation is performed under general anesthesia with endotracheal intubation and endoscopic visualization and fluoroscopic guidance as was previously described [4]. Removal is achieved with a custom grasper that grasps the suture on the anchor. In order to avoid trauma to the stomach or esophagus, a retrieval hood is use at the tip of the endoscope. In majority of the cases, device explantation is scheduled according to study design length or patient preference. However, there are reasons for early device removal. The rate of early device removal differs from study to study, but on an average it ranges from 16 to 40 % [2, 3, 7, 8]. The most frequent reasons for early removal are symptomatic or asymptomatic device migration, persistent abdominal pain, device related upper gastrointestinal hemorrhage, and device obstruction. In our experience, all these adverse effects can be managed successfully through endoscopic device explantation. In our clinical experience in almost 200 patients we observed a lower rate of early explantation but a higher rate of serious adverse events including 6.5 % of gastrointestinal bleeding and 1.5 % of liver abscess.

51.4 Patient Selection

Safety and efficacy of the DJBL device has been evaluated in morbidly obese patients (BMI >40) and also in obese subjects with BMI lower than 40 with associated co-morbidity, especially poorly controlled T2DM. There are many good candidates for bariatric surgery not interested in an irreversible operation and such patients are potentially candidates for DJBL treatment [9].

Absolute contraindications are anticoagulant use, severe coagulopathies or previous gastroduodenal surgery. Inflammatory bowel disease is considered a relative contraindication.

51.5 Mechanism of Action

The DJBL was designed to mimic key anatomical components of Roux-en-Y gastric bypass (RYGB) procedure–nutrient exclusion from duodenum and proximal jejunum, and early delivery of partially digested nutrients to midjejunum leading to distal gut stimulation. This is thought to mediate weight loss and glycemic control [10, 11]. After DJBL placement, the ingested nutrients flow through the device lumen and do not contact duodenal mucosa, keeping the biliopancreatic secretions external to the device. Additionally, ingested nutrients that are only partially digested are delivered into the midjejunum earlier. Thus, DJBL mimics both the RYGB components in isolation [4].

Weight loss following gastrointestinal surgical procedures such as RYGB cannot be explained only by reduced food intake, and/or nutrient malabsorption. Weight loss after RYGB results from the additive effects of reduced food intake, and increased total (TEE) and resting (REE) energy expenditure in diet-induced obese (DIO) rats [12, 13]. In contrast, weight loss after isolated gastric procedures such as vertical sleeve gastrectomy (VSG) primarily results from decreased food intake, as this procedure does not increase energy expenditure [14]. Recently, these findings have been supported by experiments performed in a group of morbidly obese patients who underwent RYGB and VSG [15]. Similarly, weight loss after implantation of an endoluminal sleeve (ELS) device in DIO rats also results from reduced food intake and increased TEE and REE [16]. The average percentage of excess body weight loss (%EBWL) has been demonstrated to be higher in DJBL-treated patients (19–22 %) compared to patients under dietary restriction (5.3–6.9 %) [7, 17]. This suggests that increased energy expenditure after DJBL placement can mediate greater weight loss than diet restriction alone.

In addition, nutrient stimulated secretion of the gut-derived peptides involved in food intake regulation such us glucagon like peptide-1 (GLP-1) and gastric inhibitory polypeptide (GIP) are increased after DJBL placement [18].

In terms of diabetic control, remission after RYGB in morbidly obese patients occurs before any significant weight loss has occurred, suggesting the existence of weight loss independent mechanisms for glycemic control [12, 13, 19]. Moreover, the better glycemic control effect observed after RYGB in comparison to the glycemic control obtained after a comparable weight loss obtained with diet, supports the weight-loss independent effect of RYGB on diabetes control [20]. Among proposed mechanisms of glycemic control, increased levels of incretin, the hormone GLP-1, has been considered to play an essential role in mediating this effect [20, 21]. Conversely, the glycemic control after isolated gastric procedures including laparoscopic adjustable gastric banding (LAGB) parallels the induced weight loss and the GLP-1 levels remain unchanged after surgery [22], indicating that weight loss dependent mechanisms are primarily mediating improvement of glycemic control [23].

After DJBL placement, obese patients with T2 DM experience a significant improvement in different parameters of glucose homeostasis [3, 8, 24]. Similarly, ELS-treated rats improved fasting glycemia, fasting insulin levels, and oral glucose tolerance [25]. To determine whether complete duodenal exclusion with the ELS was necessary to improve glycemic control, ELS of different lengths was implanted in a group of DIO rats to induce partial or complete duodenal exclusion. Interestingly, DIO rats treated with complete duodenal exclusion had a greater glycemic control and significantly elevated GLP-1 levels when compared to controls—and rats implanted with shorter ELS devices did not completely exclude the full length of duodenum [16]. Moreover, rats treated with ELS that covered the entire length of duodenum and proximal jejunum had a greater glycemic control than rats showing the same weight loss induced by calorific restriction alone.

Recently, the effect of the DJBL on fasting and nutrient-stimulated levels of different gut derived peptides and hormones involved in glucose and energy balance regulation was characterized in a group of obese T2DM patients treated with the DJBL [18]. Plasma levels of GLP-1, GIP, and glucagon were determined at baseline, 1 week after DJBL placement, 24 weeks later and 1 week after device explant. Twenty-four weeks after DJBL placement, mean percentage of EBWL was 29.8 ± 3.5 %. Also, fasting glucose during oral nutrient stimulation test were significantly lower compared to baseline values. DJBL treatment augmented GLP-1 secretion in response to oral nutrient stimulation. In addition, levels of the glucose raising hormone, glucagon, were significantly reduced after DJBL treatment. Interestingly, the endocrine changes observed occurred only 1 week after DJBL placement, when minimal weight loss had occurred. Together, these findings suggest that glycemic control observed in T2DM patients after DJBL placement results from entero-endocrine effects induced by complete duodenal exclusion, and cannot be explained by simple calorific restriction and weight loss.

51.6 Outcomes

51.6.1 Weight Loss

Several studies have demonstrated an EBWL that ranged from 11.9 to 23.6 % over 12 weeks in patients who underwent DJBL [2, 7, 17, 26]. After 12 weeks, patients treated with DJBL had an average EBWL of 19 to 22 % compared to a mean EBWL of 5.3 to 6.9 % in those treated with diet alone [7, 17]. Studies designed to maintain the device for 1 year demonstrated that greater weight loss could be achieved. Two studies have evaluated the effect of DJBL after 52 weeks of treatment. In a single arm prospective open label study, the average EBWL in 24 patients that completed the study was 47 ± 4.4 % [3]. Similarly, in a group of 22 morbidly obese patients, the EBWL after 52 weeks was 39 ± 3.9 % [27]. Weight loss after 1 year of DJBL treatment exhibits a normal distribution. The majority of patients lose the expected amount of weight with few patients on either side of the mean [28].

In terms of the pattern of weight loss, it has been determined that the most significant weight loss occurs during the first 3 months after device placement, continuing up to 8 months after implantation. Thereafter, patients maintain their body weight within a narrow range. With respect to body weight gain after device explantation, data indicates that within 6 months, patients regain an average of around 4–5 kg [3].

51.6.2 Glycemic Control

Several early studies have shown that in addition to its weight loss effect, in patients with T2DM, DJBL improved glucose homeostasis [2, 7, 17]. In all these studies, patients had a decrease in fasting glucose levels, insulin resistance, and HbA1c levels. These results were seen despite little or no hypoglycemic treatment. The studies were conducted on T2DM patients that were in remission 12 weeks after DJBL therapy [2, 11, 29]. However, these early studies were not designed to study the effect of the DJBL on T2DM treatment and included few diabetic patients. Despite this selection bias, the observed results were encouraging.

The first study designed to determine the effect of DJBL in diabetic treatment included 54 T2DM patients that were treated for 26 weeks [30]. Glycemic control improved in all patients and was demonstrated by reductions in HbA1c levels. However, T2DM patients with baseline HbA1c levels above 9 % were not able to decrease HbA1c below 7 %, suggesting that longer treatment may be necessary to improve glycemic control in patients with more aggressive disease.

A prospective open- label clinical trial of 52 weeks duration included 22 morbidly obese T2DM patients aged 46.2 ± 10.5 years with a baseline BMI of 44.8 ± 7.4 kg/m^2 [27]. Of these, only 13 patients completed the 52-week study. Fasting glucose and Hb1Ac levels decreased from 179 ± 68 to 142 ± 57 mg/dl ($p < 0.05$) and from 8.9 ± 1.7 to 6.6 ± 1.4 % ($p < 0.05$) respectively. Similarly, fasting insulin levels were reduced from 19.5 ± 14.7 to 9.4 ± 10.5 lU/mL ($p < 0.05$) which are indicative of augmented insulin sensitivity. The average EBWL was 39 ± 0.9 % after 52 weeks. The improvement in glycemic control was also accompanied by improvement in the lipid profile.

To determine whether DJBL treatment can improve glycemic control in T2DM patients who are not severely obese, 20 subjects with T2DM of less than 10 years of duration, and HbA1c levels between 7.5 and 10 %, were enrolled in a prospective 52 week, single-center, open-label clinical study [8]. Sixteen (80 %) patients implanted with the DJBL completed the entire 52 weeks. The average preimplant BMI in these patients was 30 ± 3.6 kg/m^2. At 1 year follow up, fasting glucose levels had decreased significantly from 207 ± 61 mg/dL to 155 ± 52 mg/dL. Baseline HbA1c levels also declined from 8.7 ± 0.9 % to 7.5 ± 1.6 %. Importantly, 62.5 % (10/16) of patients at the end of the study had Hb1Ac levels below 7 % which is indicative of an appropriated glycemic control [31]. DJBL-treated patients had lost approximately 14 kg on average at conclusion of the study. These results indicated that in majority of patients with T2DM, placement of the DJBL yielded a significant improvement in glycemic control. When the device is removed early, the available data show that the benefits of treatment extend to 6 months, HbA1c levels remaining lower compared to baseline, but somewhat higher compared with the levels after a year of treatment [27].

Conclusion

Available evidence supports the role of DJBL in treating obesity and improving glycemic control in a significant proportion of severely obese diabetic patients. Early removal and a higher rate of serious adverse events in clinical practice are the most important limitation in terms of safety. These results need to be further supported by long-term data from randomized controlled clinical studies.

Key Learning Points

- DJBL is an impermeable tube that mimics RYGB in nutrient exclusion from duodenum and proximal jejunum distal gut stimulation.
- DJBL implant is performed under GA with patient in left lateral decubitus.
- After the implantation, patients are instructed to consume liquid diet in the first week, puree diet in the second and third weeks and normal diet thereafter.
- The most frequent reason for early removal is device migration.
- Criteria for patient selection is morbidly obese patients (BMI more than 40), severe obesity and associated diseases (BMI more than 35) and obese with less than 35 with uncontrolled type 2 diabetes

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52 Newer Endoluminal Interventions for Obesity

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Abstract

At present, several primary endoluminal weight loss procedures are under investigation, all of which aim to reproduce more invasive, restrictive or malabsorptive operations. They are in various stages of development and clinical application, in the United States of America (USA) and the rest of the world. They have been designed to address refractory obesity for patients with Body Mass Index (BMI) in the range of 30–35, as well as for those individuals who currently are candidates for more traditional bariatric surgery (BMI >35).

Although nearly all of those devices have been developed in the USA, most of the clinical trials have been performed outside of the USA, since the regulatory pathways in regions such as Europe and South America are much less stringent than those set by the Food and Drug Administration (FDA). This chapter will discuss the results of those trials, along with descriptions of devices and procedures still in the preclinical phase of development.

Keywords

Endoluminal surgery • Endoluminal suturing • Bariatric surgery • Morbid obesity • Endoscopic surgery • Gastroplasty

52.1 Introduction

The recent development of endoluminal upper gastrointestinal (GI) procedures over the last few years is a natural consequence of the evolution of surgery from an open approach to laparoscopic, single-port and natural orifice platforms. Endoluminal techniques can be applied to anti-reflux surgery as well as to the correction of gastric pouch and/or gastrojejunal stomal dilatation after gastric bypass in patients experiencing weight regain or refractory dumping. They are also used to expand the pool of obese patients who might benefit from invasive treatments, after failing to lose weight with dietary and other conservative regimens.

Primary endobariatric operations are still considered investigational by the Food and Drug Administration (FDA) in the United States of America (USA). The FDA has recently set certain goals for investigational endoscopic weight loss devices. For approval of short-term implantable devices or reversible procedures, the FDA has established the need for a 6 month trial demonstrating 25 % excess weight loss (EWL) in fifty per cent of the patients, and on average 15 % more EWL than sham [1] controls. For 1 year device or non-reversible therapies, the FDA has established the need for a 2 year trial showing 25 % EWL in 50 % of the patients, and on an average 25 % more EWL than sham controls [1].

These procedures are, however, currently performed in Europe and South America, both within and outside the clinical trial settings.

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Most of the primary "endobariatric" procedures are restrictive; they aim to decrease the volume of the stomach and reduce ghrelin production by closing off the fundus and greater curvature [2–7].

52.2 Clinically Tested Endoluminal Interventions

52.2.1 The EndoCinch™ device (C. R. Bard Inc., Murray Hill, New Jersey)

The first primary endoluminal bariatric platform to be developed was the EndoCinch™ device. The EndoCinch™ device was originally designed for the treatment of gastroesophageal reflux disease. It was subsequently applied to the revision of failed gastric bypass procedures and then used for the primary treatment of obesity.

The device features a hollow capsule that is fitted onto the endoscope tip, and utilizes suction for tissue acquisition. A hollow needle is delivered through the acquired tissue, to pass the suture material back-and-forth. Fogel et al. [2] first described the use of the Bard® EndoCinch™ suturing system as a primary bariatric operation. Seven sutures were deployed in a continuous and cross-linked fashion from the proximal fundus to the distal body, thereby limiting gastric distension. This simple procedure was typically completed in approximately 45 min, with patients discharged home on the same day. The study followed up 64 patients for 12 months and demonstrated both promising efficacy (EWL of 58.1 %, decreasing BMI from 39.9 to 30.6 kg/m^2) and safety (no report of serious adverse effects).

A more recent iteration of the device (the Restore Suturing System: RSS) allowed for the creation of deeper, full-thickness plication's and eliminated the need for device withdrawal for suture reloading, as was required by its predecessor. The Transoral Gastric Volume Reduction as an Intervention for Weight Management (TRIM) trial used the RSS to place four to eight plication's, approximating the anterior and posterior gastric walls to achieve restriction of the upper stomach. The first study of 18 patients showed the procedure to be safe, well tolerated and without serious complications, with an average procedure time of 125 min. Unfortunately, the procedure was not durable at 12 months follow up as on endoscopy, 13 patients had partial or complete loss of their plication's [3].

52.2.2 TransOral Gastroplasty—TOGa™ (Satiety Inc., Palo Alto, California)

The next generation of endoluminal weight loss procedure was typified by the trans-oral gastroplasty or the TOGa™ procedure. The TOGa™ stapler had a flexible 18-mm diameter shaft and was introduced over a guidewire. The device accommodated a standard endoscope to provide retroflexed visualization of the procedure. A septum from the device spread and positioned the anterior and posterior gastric walls, which were then apposed using vacuum suction. Two successive vertical staple lines were deployed to create a partial sleeve, approximately 8–9 cm in length. A "restrictor" stapler was then used to staple pleats of tissue, at the inferior end of the sleeve, to create a restrictive "pouch."

Deviere et al. (2008) reported the first multi-center trial of TOGa with a pilot study of 21 patients [4]. No serious adverse events were reported during any of the procedures. The authors reported that transient pain, nausea and vomiting were the most common procedure-related adverse events. Eighteen out of 21 patients (85.7 %) received two stapled sleeves. One patient received a single sleeve, while two other patients had a partial sleeve due to technical difficulties during the procedure. A proximal staple line gap (between the angle of His and proximal staple line) or mid gap (between the proximal and distal staple lines) was observed, via endoscopy or on contrast radiography, in 11 patients before discharge (eight patients had fully intact sleeves, two patients had partial sleeves). At 6 months follow-up, staple line gaps were visible in 13 out of 21 patients; three patients had incomplete distal sleeves, while five patients had fully intact sleeves and staple lines, and no results were provided for the remaining five patients. At 1, 3 and 6 months, mean EWL was 16.2 %, 22.6 % and 24.4 % respectively, corresponding to absolute mean weight losses of 8.0, 11.1 and 12.0 kg. The average body mass index (BMI) was decreased significantly from 43.3 to 38.5 kg/m^2, 6 months post treatment. After some technical improvements were made to the device, the same group conducted another study on 11 patients [5]. At 1, 3 and 6 months, mean EWL was 19.2 %, 33.7 % and 46 % respectively, corresponding to absolute mean weight losses of 9.9, 17.5, and 24 kg. The average BMI was decreased significantly from 41.6 kg/m^2 to 33.1 kg/m^2 at 6 months after treatment. Both the studies demonstrated that TOGa™ was feasible and safe.

Chiellini et al. examined nine glucose normo-tolerant obese patients, both at baseline and at 3 months after undergoing the TOGa™ procedure [8]. The primary aim of the study was to evaluate the effect of TOGa™ on insulin sensitivity and secretion. Three months after the TOGa™, analysis of the oral glucose tolerance test (OGTT) data revealed that insulin levels were significantly lower with the fasting baseline sample and the 2-h sample. Meanwhile, C-peptide levels were significantly lower with 2 h and 2.5 h samples; glucose levels did not change. Three months after the TOGa™, insulin secretion decreased significantly whereas insulin sensitivity increased significantly.

In spite of initial encouraging results, the long term data after TOGa™ failed to show sustained efficacy due to a high rate of progressive failure of the staple line as well as dilatation of the stoma (at the bottom of the staple line). The critical multi-center US/European pivotal trial of TOGa™ (192 TOGa™ patients vs. 93 sham patients) showed poor response data: based on the definition of response as weight loss of ≥25 % EWL, the European site data demonstrated responses of 63.2 % vs 9.1 % for TOGa *vs*. sham,; whereas the American site data showed responses of 41.6 % vs 22.2 % for TOGa *vs*. sham [9]. Sadly, the inability of the procedure to achieve the efficacy milestones set by the FDA, forced the manufacturer to abandon production of the device in January 2011 after the company withdrew its FDA application in November, 2010.

52.2.3 Primary Obesity Surgery Endolumenal (POSE) Procedure Using the Incisionless Operating Platform™ (USGI Medical Inc., San Clemente, California)

More promising than the TOGa is the POSE procedure (Primary Obesity Surgery, Endoluminal) which includes a large (33 mm) endoscopic grasper to place suture anchors that permanently affix full-thickness plication's in the stomach. The system employs a <6 mm pediatric scope for visualization. The POSE procedure involves invagination of the fundus using these plication's, as well as a narrowing of the distal body at the antral inlet. The POSE procedure requires the placement of approximately 12 plication's and is performed under general anesthesia in the O.R. or procedure suite. Procedure time averages 30–45 min and perioperative safety appears to be similar to endoscopy with biopsy. Video 52.1 is an intra-operative movie clip of an actual POSE procedure. The hypothetical mechanism of action is a combination of reduction in gastric capacity, rapid movement of food to the antrum inducing early satiety and prolonged total gastric emptying time leading to loss of appetite.

POSE was evaluated in a prospective European trial of 45 patients with a mean preoperative BMI of 36.7 [6]. At 6 months follow up, there was 49.4 % EWL and 15.5 % total body weight loss (TBWL), without mortality or significant morbidity. Long term follow up data from a sufficient number of patients, undergoing POSE, is yet to be obtained. The procedure (which takes 2 h or more to perform) cannot, therefore, yet be recommended as an effective and durable endoluminal treatment for refractory obesity; although, it has been performed (commercially) in several thousand patients in Europe (mainly in Spain and in the UK).

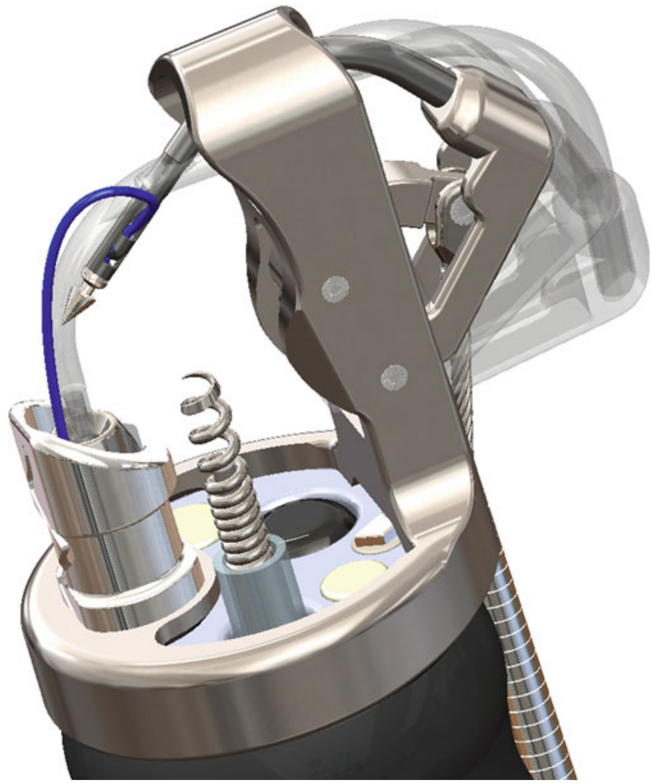

Fig. 52.1 The Apollo OverStitch device (showing the curved needle holder)

52.2.4 Apollo OverStitch™ (Apollo Endosurgery Inc., Austin, Texas)

The Apollo OverStitch™ device is a generally applicable endoluminal suturing device employing a curved needle holder which fits over the end of a standard (10 mm) therapeutic gastroscope. It can be used to place running or interrupted sutures under direct endoscopic vision through the full thickness of the wall of the esophagus, stomach and colon (see Fig. 52.1).

The Apollo OverStitch™ platform has been used for several purposes such as to reduce gastric pouch and/or stoma size after gastric bypass surgery, close fistulae in the esophagus and in the stomach, oversew bleeding peptic ulcers and to close full thickness colonic wall defects after colonoscopic polypectomy. The Apollo OverStitch™ platform shares many characteristics with the USGI IOP system, but is generally considered to be more operator friendly, thereby enabling procedures to be performed in less than half the time when compared to the IOP system. A pilot study of four patients recently demonstrated the technical feasibility of performing a gastroplasty with the OverStitch device, using it to collapse down the fundus and greater curvature [7]. Thompson and co-investigators [10] are currently employing the Apollo Overstitch device to perform primary restrictive bariatric surgery, in patients with BMI ranging from 30 to 35, with the placement of at least eight sutures along the greater curvature. No data is currently available from this trial protocol.

52.3 Devices in the Early Phase of Development

All of the devices and procedures described above have progressed to at least clinical trials; some are currently in general clinical use. There are several devices which are still in the early stages of development, as exemplified by the following innovative approaches.

52.3.1 Gastric Aspiration Using the AspireAssist™ (Aspire Bariatrics Inc., King of Prussia, Pennsylvania)

The AspireAssist™ device works by allowing a patient to aspirate his or her gastric contents, 20 min after eating, through a percutaneous endoscopic gastrostomy, thereby limiting absorption from the stomach. The AspireAssist™ was examined in a randomized pilot study comparing 10 patients who used aspiration and life style modifications, to four patients who used only life style changes [11]. At 1 year follow up, the study group lost 18.6 % of mean TBWL and 49.0 % of mean EWL vs 5.9 % of mean TBWL and 14.9 % of mean EWL in those within the control group. There were no significant changes in eating habits or adverse events after the procedures. However, greater long term follow-up and a larger patient sample size will be required to prove durable weight loss efficacy as well as to demonstrate that certain long term physiological sequelae, such as electrolyte imbalance, will not result from the daily postprandial gastric aspiration.

52.3.2 SatiSphere™ (EndoSphere Inc., Columbus, Ohio)

SatiSphere™ is a C-shaped implant composed of a nitinol double pigtail stent with several polyethylene terephthalate spheres attached along its length (see Fig. 52.2). It is deployed endoscopically, sitting in the duodenum with its proximal end anchored just proximal to the pylorus. It produces satiety by delaying the transit time of food down the duodenum, thereby stimulating the production of incretins such as Glucagon-like peptide-1 (GLP-1), by increasing insulin secretion and target cell sensitivity to insulin, and by stimulating the satiety center of the brain. In a German

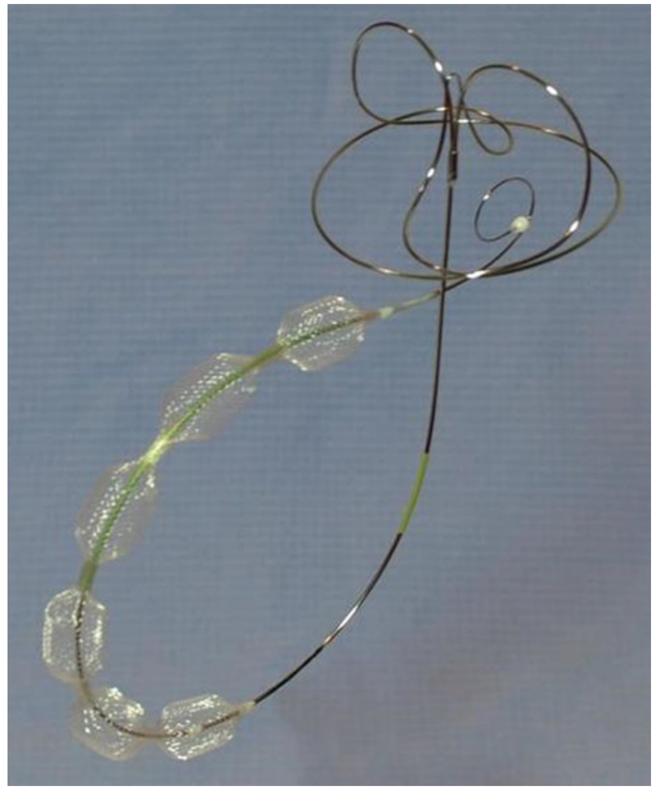

Fig. 52.2 The SatiSphere (showing its 1 mm nitinol wire and polyethylene terephthalate spheres)

study, 21 patients implanted with SatiSphere™, completed the three–month implantation treatment and had a EWL of 18.4 % in comparison to 4.4 % in the control group of 10 individuals. However, migration of the device in 10 out of 21 patients led to the termination of the trial, with two patients requiring emergency surgery to extract the migrant devices [12]. The high rate of migration led the manufacturer to redesign the device's anchoring system. The second generation device is currently being evaluated in Europe, with promising early results showing a significantly lower rate of migration.

52.3.3 TransPyloric Shuttle (TPS) (BAROnova Inc., Goleta, California)

The TransPyloric Shuttle (TPS) is an endoluminal device comprising of a large sphere with a flexible connection to a smaller cylindrical bulb (see Fig. 52.3). The TPS does not require any anchoring and relies on normal gastric physiology to function. During peristalsis, the smaller bulb migrates into the duodenum, pulling down the larger sphere to engage and intermittently obstruct the pylorus. This produces delayed gastric emptying and early satiety. The safety and

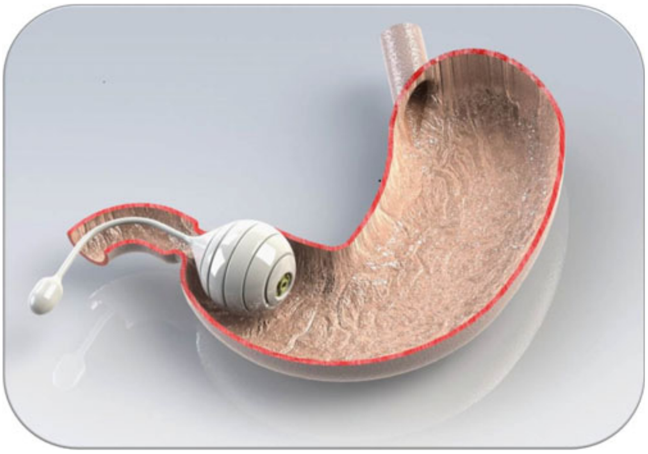

Fig. 52.3 A schematic diagram showing how the Transpyloric shuttle sits in the stomach

efficacy of the TPS was studied prospectively in 20 patients with 3 months and 6 months follow up [13]. The TPS produced a mean EWL of 31.3 % at 3 months and 50.0 % at 6 months. Two patients experienced mucosal ulcerations necessitating early retrieval of the device.

52.3.4 Biliary Diversion

Biliary shunting is an interesting concept that can theoretically amplify the satiety factor and incretin production by the gut, mimicking some of the effects of gastric bypass. Kohli et al. postulated that the outcomes of bariatric and metabolic surgery can be reproduced by "short-circuiting" the biliary circulation [14]. This hypothesis was tested in a rat model with a biliary diversion group, a sham group, and a non-operative "naïve" group. The biliary diversion group received a catheter shunting bile from the common bile duct directly to the mid jejunum; the sham group underwent common bile duct dissection alone; the control group underwent no intervention. The three groups were all fed a high fat diet for 5 weeks.

Biliary diversion not only induced significant weight loss, but also induced a decrease in fasting serum glucose, a reversal in hepatic steatosis, an increase in serum GLP-1 and an elevation in fasting serum bile acid levels. Interestingly, these effects were not dependent on the length of the small bowel bypassed. Several companies (such as Satiogen in the USA and EndoBetix in Israel) are in the process of developing endoscopically placed biliary shunts, to divert bile from the duodenum to the jejunum, thereby inducing weight loss and treating type 2 diabetes [15]. No clinical safety and efficacy data is yet available for those prototype biliary shunts.

Conclusion

Driven by the increasing global prevalence of obesity, as well as the need for less invasive operations, several endoluminal weight loss devices and procedures are currently under development. Presently, there is a lack of compelling evidence to support these procedures as durable modalities of treatment. None of the available evidence has yet satisfied the criteria set by the FDA either for short term or long-term weight loss implants and procedures. When laparoscopy evolved out of open surgery, it had to demonstrate that the efficacy and safety of the traditional approach would not be sacrificed on the altar of progress, for the sake of greater patient comfort and convenience. Similarly, as we consider even less invasive, incision-free, surgical approaches to obesity, we should always strive towards the ultimate goal of attaining results similar to those of laparoscopy. Clearly, endoluminal techniques are presently far from achieving this goal. Perhaps they never will. However, even if they can never demonstrate the long-term durability of their more invasive predecessors, they can at least occupy an intermediate position within our weight loss armamentarium, offering short-term and moderate weight loss (as defined by the FDA) for individuals who are moderately obese (BMI 30–35), have failed dietary and medical treatment plans and who currently do not meet the qualifying criteria for standard weight loss surgery. If these procedures are safe, relatively inexpensive and repeatable, then they may yet have something of value to offer both to the physicians and the obese patients.

Key Learning Points

- FDA goals for investigational endoscopic procedures:
  - For short term implantable or reversible devices: 6 month trial showing 25 % EWL in >50 % of the patients and on an average 15 % more EWL than sham controls
  - For 1 year device or non-reversible endoscopic therapy: 2 year trial showing 25 % EWL in >50 % of the patients and on average 25 % more EWL than sham controls
- The majority of newer endoluminal devices for primary obesity treatment are based on restrictive mechanisms.
- Level I data with long term follow up is still needed to validate the efficacy of all of those devices/procedures for primary obesity treatment.
- Biliary diversion is a novel concept that can potentially replicate the metabolic effects of bariatric surgery using reversible endoluminal techniques.

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Endoscopic Treatment of Complications after Bariatric Surgery

53

Josemberg M. Campos, Patrícia Souza de Paula, and Almino C. Ramos

Abstract

With increasing incidence of obesity and its related comorbidities, there has been a steep rise in the number of bariatric procedures throughout the world. Clearly, this has resulted in a rise in the number of complications unique to bariatric surgical procedures. Given the fact that almost all current procedures revolve around the esophagus and stomach, there is a push (or need) to attempt resolve these complications endoscopically. Thus technically advanced endoscopic procedures have come into practice to help treat complications related to bariatric surgery. We collectively call this new methodology as 'bariatric endoscopy.' This could be considered as an interface between bariatric surgery and advanced therapeutic endoscopy.

Surgical therapy could result in other complications and is therefore being replaced by minimally invasive endoluminal endoscopic procedures, especially in the control of conditions such as infection, fistula, stenosis, food impaction, ring and band erosion, bleeding and choledocholithiasis.

Keywords

Bariatric surgery • Sleeve gastrectomy • Gastric bypass • Adjustable gastric band • Stenosis • Gastric fistula • Bariatric endoscopy

53.1 Introduction

With increasing incidence of obesity and its related comorbidities, there has been a steep rise in the number of bariatric procedures throughout the world [1]. Clearly, this has resulted in a rise in the number of complications unique to bariatric surgical procedures. Given the fact that almost all current procedures revolve around the esophagus and stomach, there is a push (or need) to attempt resolve these complications endoscopically. Thus technically advanced endoscopic procedures have come into practice to help treat complications related to bariatric surgery. We collectively call this new methodology as 'bariatric endoscopy.' This could be considered as an interface between bariatric surgery and advanced therapeutic endoscopy [2].

This chapter aims to present briefly the role of endoscopy in the treatment of complications that may arise after the procedures such as laparoscopic adjustable gastric band (LAGB), laparoscopic Roux-en Y gastric bypass (LRYGB) and sleeve gastrectomy (SG).

The technical details of endoscopic surgery in its role as therapeutic intervention to manage complications are discussed in this chapter [2].

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53.2 Laparoscopic Adjustable Gastric Band (LAGB) Complications

53.2.1 LAGB Erosion

Intragastric band erosion can occur in about 1.5 % of patients (0.23–32.65 %) commonly reported to occur 12 months after device placement [3].

Clinical presentation may be characterized by epigastric pain radiating to scapula, shoulder or retrosternal pain, subcutaneous port infection or weight regain. Diagnostic upper gastrointestinal (GI) endoscopy has been the investigation of choice in gastric erosion. It has the advantage of being able to facilitate treatment in most cases. On retroflexion you can directly view the eroding prosthesis in the gastric lumen, at the level of gastric cardia.

In asymptomatic patients with minimal erosion, patients should remain under close supervision due the risk of gastrointestinal bleeding or intraabdominal infection [4, 5]. It is safe to prescribe proton pump inhibitor (PPI) to minimize further gastric acid damage until the band is removed.

Endoscopic removal of gastric band is less invasive and is therefore increasingly preferred to surgical removal [6, 7]. Division of the LAGB can be performed with a gastric band cutter (GBC; Agency for Medical Innovations, a.m.I. GmbH, Götzis, Switzerland), facilitating endoscopic removal of the band (Video 53.1), followed by surgical removal of the subcutaneous port (see Figs. 53.1 and 53.2) [7].

53.2.2 LAGB Slippage

When the prosthesis is displaced distally, there is subsequent dilation of the proximal gastric pouch, hindering the passage of food. These patients present with vomiting, dysphagia, heartburn or halitosis. Endoscopy and or contrast swallow imaging is required to confirm the diagnosis [5].

It is important, that the band should be deflated immediately in all the patients with a suspected slippage. In principle, this allows the stomach to return to its normal anatomical position and negate the need for emergent surgery in most patients.

Should this fail to resolve symptoms, an upper GI endoscopy could be performed to evaluate if the prosthesis still remains slipped? If the prosthesis happens to remain slipped then hyperinflation of the stomach helps force proximal displacement of the band; thus repositioning the band to its usual site. This procedure is performed with the patient in lateral decubitus position under conscious sedation. This maneuver also allows temporary relief of obstructive symptoms.

In cases where this maneuver fails, the band needs be surgically removed [8]. We should anticipate an increased risk of aspiration at the time of endotracheal intubation. It is important to note that this is a temporary measure that allows definitive management by surgical removal of the band in an elective setting in the future.

53.3 Laparoscopic Roux-en-Y Gastric Bypass Complications

53.3.1 Food Impaction

Food impaction may occur after LRYGB. It may be associated with the use of surgically implanted restrictive ring due to ring slippage or erosion, dietary malcompliance, gastric pouch or gastrojejunostomy stenosis. Clinical presentation is consistent with upper GI obstruction, involving nausea, retrosternal pain, epigastric discomfort or postprandial vomiting [5]. Endoscopy allows both diagnosis and its immediate treatment (see Fig. 53.3).

Endoscopic retrieval basket is commonly used accessory for foreign body removal. It is often difficult to remove all the fragments orally. Retained fragments instead can sometimes

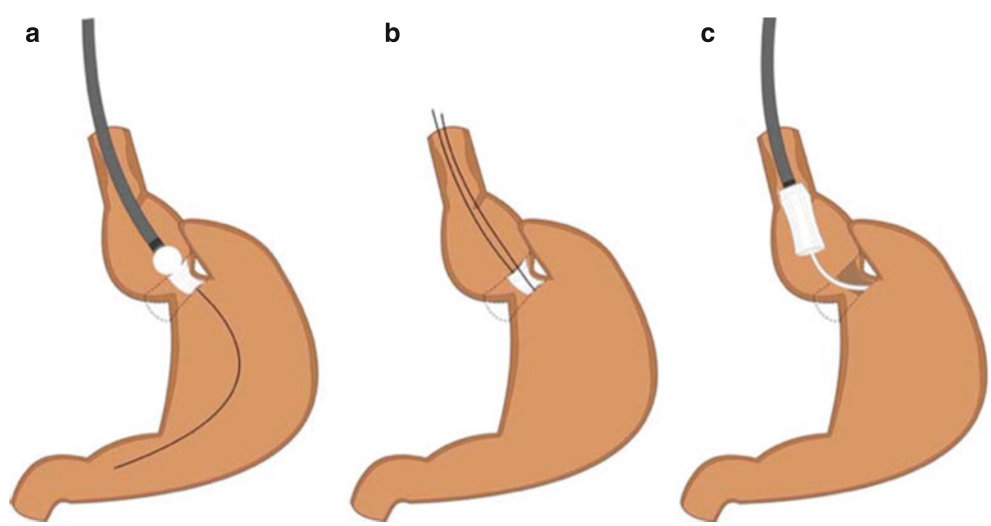

Fig. 53.1 Schematic images describing band removal with gastric band cutter. (**a**) Passage of metallic thread in between eroded band and gastric wall. (**b**) Recovery of thread by endoscope. (**c**) Oral removal of band after cutting it

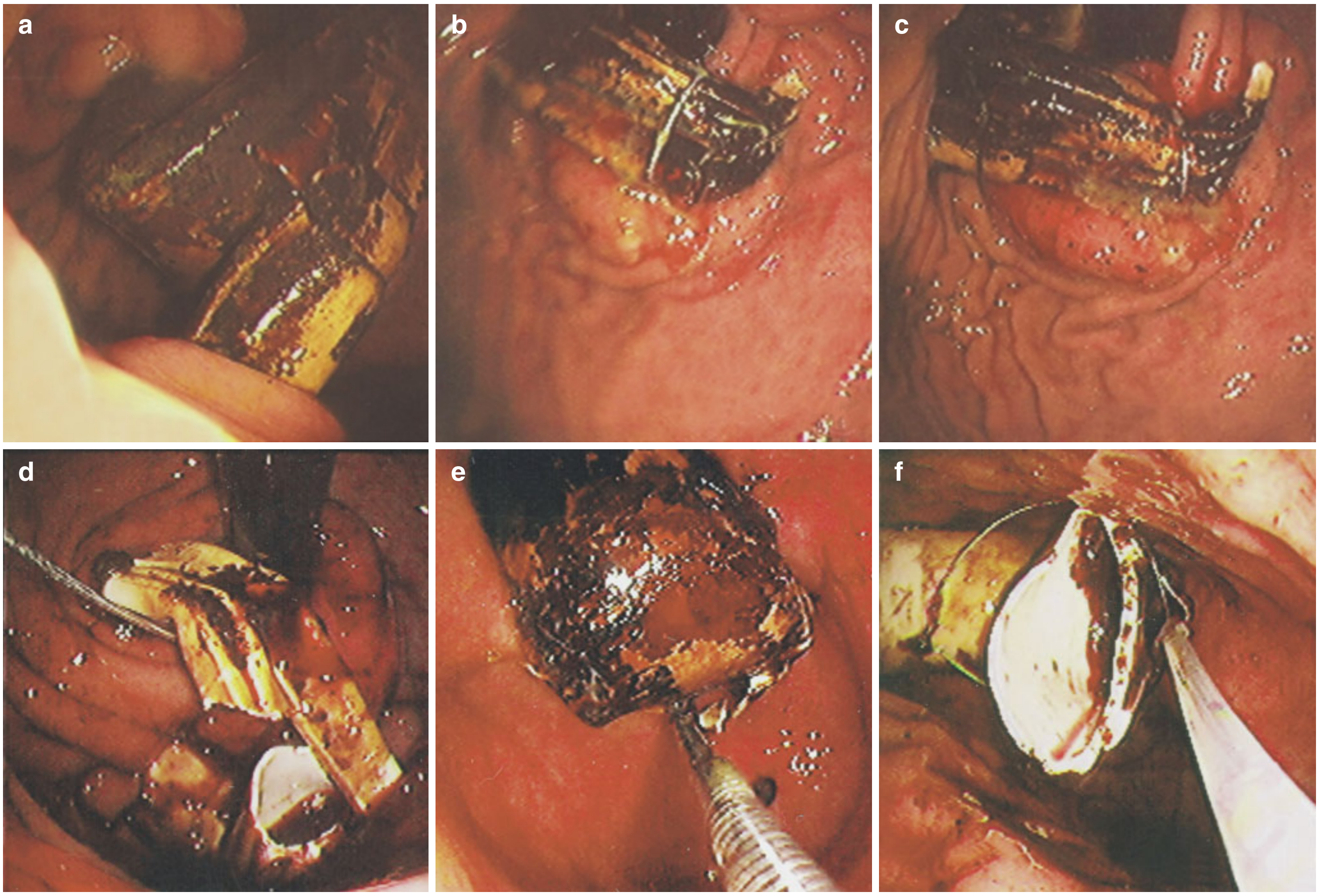

Fig. 53.2 Endoscopic images of band removal. (**a**) Eroded band. (**b**) Metallic thread over band. (**c**) Metallic thread "hanging" band. (**d**) Transected band pulled into antrum by polipectomy snare. (**e**) Band removal with polipectomy snare

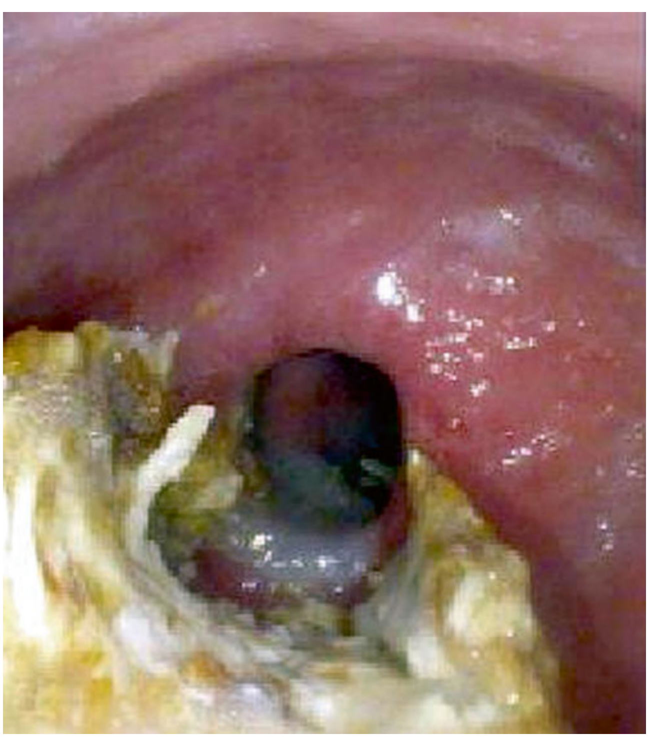

Fig. 53.3 Endoscopic image of food impaction in gastrojejunal anastomosis

be pushed gently into the distal jejunal loop, distal to the restriction point (ring or gastrojejunostomy). It is strongly advisable that after resolution of symptoms, the etiology of the narrowing should be investigated. The causes include stenosis and reinforcing ring complications. It is advisable to use minimal sedation during the procedure due to a potentially increased risk of aspiration of gastric contents. Alternatively, endotracheal intubation negates this risk. This can also be prevented by undertaking the procedure under general anesthesia after endotracheal intubation with or without the use of an overtube. An overtube is a device through which the endoscope is passed, serving to protect cardiac sphincter, esophagus and airways during removal of foreign body [9, 10].

53.3.2 Marginal Ulcer

Marginal ulcers occur as either an early or late complication of surgery. Its etiology post bariatric procedure is still not completely understood. Hence there is no established treatment protocol [11, 12]. It is found in 27–36 % of symptomatic patients. Interestingly, it is also incidentally detected in up to 6 % of asymptomatic patients after surgery [13]. When appearing as an early postoperative complication, this issue is thought to be associated with the surgical management itself. In the late phase it may be secondary to the existence of large or long gastric pouch (greater number of parietal cells) or presence of nonabsorbable sutures or staples [14].

The development of a marginal or anastomotic ulcer after LRYGB may be explained by the preservation of the antrum and the vagus nerve, causing hypergastrinemia and increased gastric acid production. They are often located in the jejunal mucosa just below the gastrojejunal anastomosis and may involve the entire circumference of the small bowel [11].

Symptoms include epigastric pain and obstructive symptoms caused by edema. Upper GI endoscopy is the investigation of choice. Findings include injury to the gastrojejunal anastomosis, varying in size and depth, commonly on the lesser gastric curvature side of the pouch and with a fibrin covered ulcer base.

Prophylaxis with acid suppression after surgery is increasingly being used with an aim to prevent marginal ulcer formation. However, no consensus exists about the duration of its usage [15]. Its routine use postoperatively varies from 30 days to 2 years, with some recommending its use lifelong. Treatment should include high dose PPI therapy (for at least 2 months) and sucralfate (10 days). Upper GI endoscopy should be repeated to ensure healing.

53.3.3 Anastomotic Stricture

A stricture is diagnosed when the lumen at anastomosis is less than 10 mm in diameter making it difficult for a standard endoscope (9.8 mm in diameter) to pass through (see Fig. 53.4). The patients' main presenting symptom is dysphagia [16]. This is believed to be caused by ischemia, gastric hypersecretion, foreign body reaction to staples and anastomotic surgical technique [16].

Initial treatment with TTS (through the scope) balloon dilation is indicated, up to a maximum diameter of 15 mm when inflated (see Fig. 53.5). Subsequent balloon dilations up to 20 mm may be used as needed. Studies indicate that a small number of dilations, between one and two, are often enough to resolve the stricture. Persistent stenosis after two dilations or presence of gastrojejunostomy fibrosis is managed by division of the fibrous stenosis, which may be performed using a needle-knife [5]. Complication rates can be as high as 2.5 %, perforation being the most common, occurring in upto 1.86 % of patients; although this can be treated by conservatively [5].

Upper GI endoscopy is the diagnostic and therapeutic method of choice, for early stenosis occurring within the first week after surgery, when initial administration of corticosteroids to reduce anastomosis edema fails to improve symptoms. Balloon dilatation could be used in such cases with caution to allow low inflation pressures, as the risk of rupture otherwise is high [17].

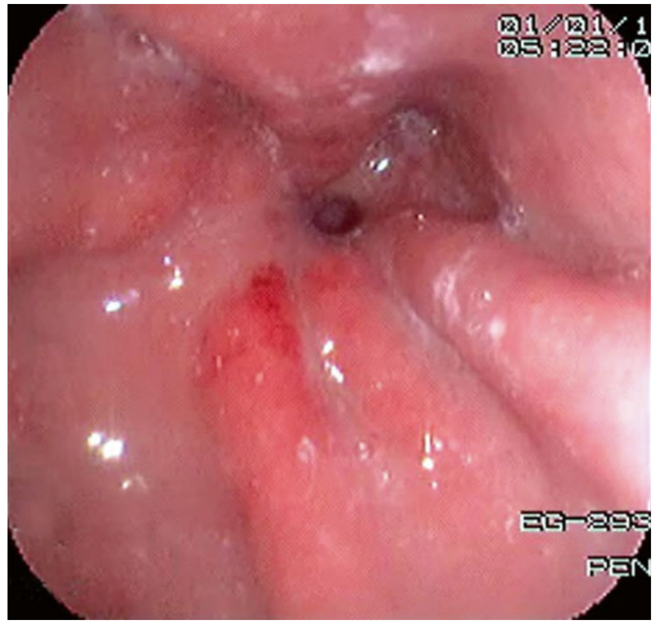

Fig. 53.4 Endoscopic image of gastrojejunal anastomosis stenosis, not allowing endoscope free passage

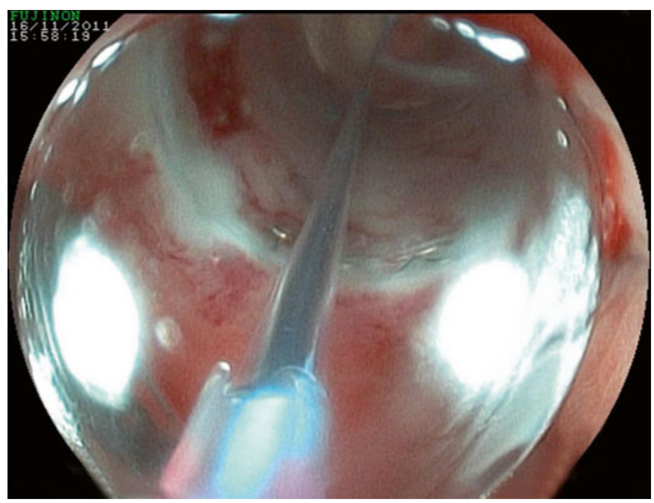

Fig. 53.5 Endoscopic image showing balloon dilation of anastomotic stricture

53.3.4 Choledocholithiasis

It is well known that the incidence of gall stone disease is increased after gastric bypass (LRYGB). Management of choledocholithiasis in these patients however can be technically difficult due to difficulty in accessing common bile duct (CBD) as a result of surgically altered anatomy of the stomach in LRYGB [8]. A combination of laparoscopy and endoscopy can be used wherein a transgastric endoscopic retrograde cholangiopancreatography (ERCP) (see Fig. 53.6) is performed along with laparoscopic cholecystectomy.

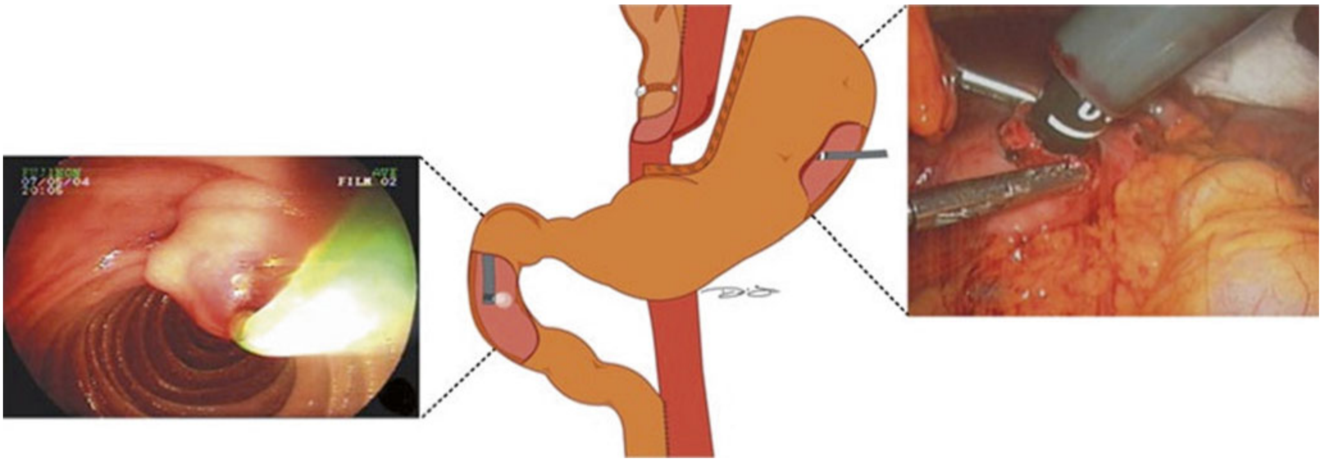

Fig. 53.6 ERCP procedure: insertion of the duodenoscope in the gastrotomy; schematic drawing of access to the duodenum through the remnant stomach; endoscopic view via cannulation of the papilla

Access is via a 1 cm incision in the anterior wall of the remnant stomach through which a duodenoscope (introduced laparoscopically) is passed. The rest of the procedure follows conventional ERCP [18].

In those cases where this is technically challenging, an alternate technique wherein access to CBD via jejunum is facilitated using double balloon enteroscope is used. This technique has a successful biliary cannulation rate of upto 60 % [19].

53.4 Banded Laparoscopic Roux-en-Y Gastric Bypass Complications

53.4.1 Erosion

With evolution of newer modifications of standard bariatric procedures, there has been a push to use a band or silastic ring implanted around the gastric pouch at the time of LRYGB. This technique presents a new array of complications, significant among which is gastric erosion. The intragastric erosion incidence varies from 0.9 to 7 %, occurs slowly with an inflammatory capsule formation around the ring. This prevents the leak of gastric contents in to the abdomen. Hence the clinical presentation is nonspecific as upto 15 % of the patients are asymptomatic. When symptoms do occur, they include weight regain, epigastric pain and obstructive symptoms, and upper gastrointestinal bleeding [5, 20].

At diagnostic endoscopy, the eroding prosthesis is often seen directly in the lumen of the gastric pouch (see Fig. 53.7). An early endoscopic finding may be an ulcer at the site of ring deployment. While these patients should be started on high dose PPI, there is evidence to suggest that migration of the band is found in more than 50 % of such patients [20].

It can be removed with a standard one channel endoscope utilizing an endoscopic scissor [21]. Should that fail due to the rigidity of the ring, an endoscopic lithotripter (or gastric band cutter) could be used.

Fig. 53.7 Endoscopic image of intragastric (pouch) ring erosion in RYGB

A dual channel device can also be used if the ring has only a small area of intragastric erosion and is adherent to the gastric pouch wall. The use of a dual channel endoscope allows the introduction of foreign body grasping forceps for traction, allowing better ring exposure. The other channel can then be utilized to pass an argon ablation catheter to divide the ring [21].

53.4.2 Slippage/Intolerance/Stenosis

Postprandial vomiting, dysphagia and other obstructive symptoms after a gastric band and banded gastric sleeve/

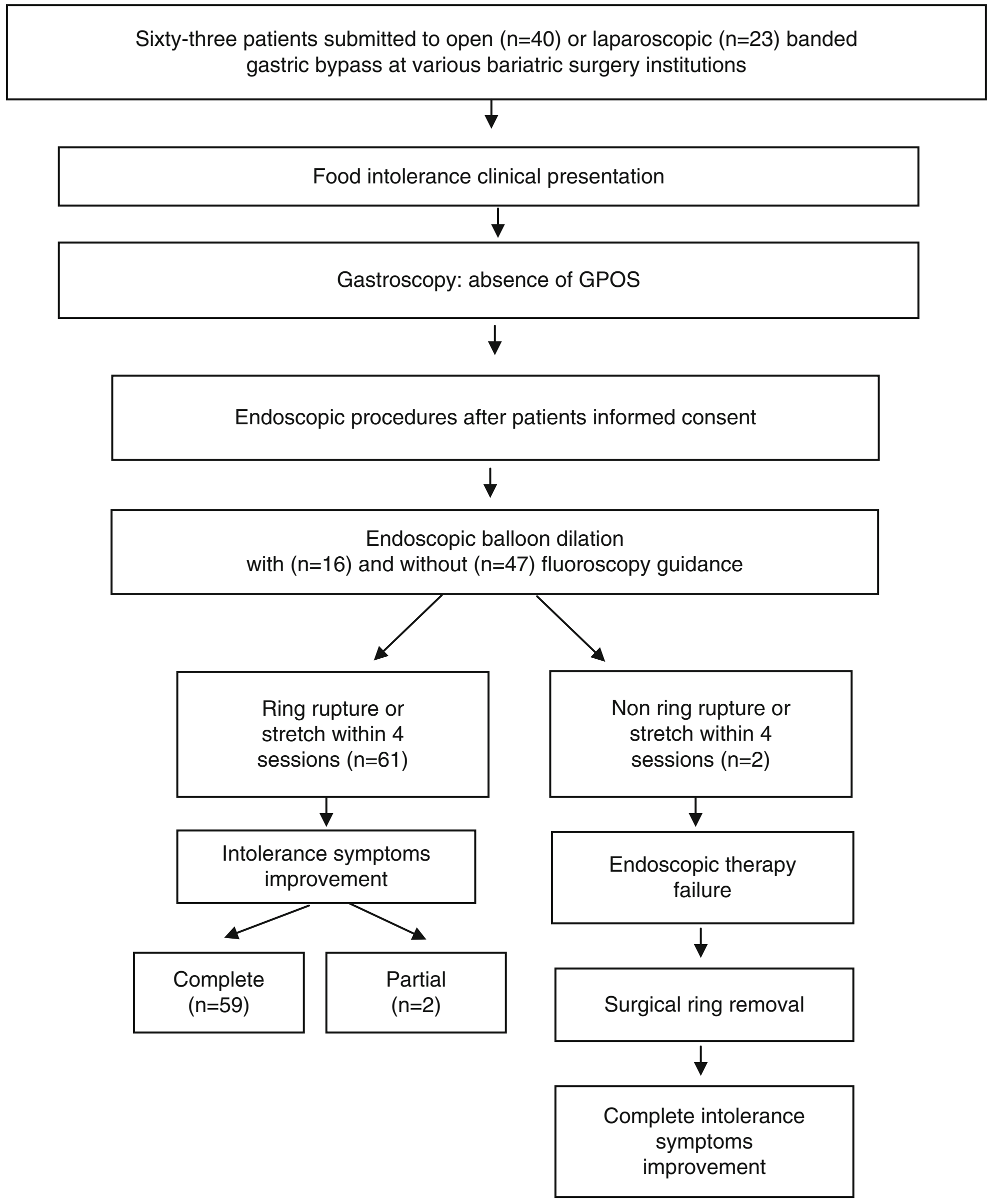

Fig. 53.8 Flowchart of food intolerance treatment by endoscopy

bypass procedure should always be investigated. Slippage corresponds to the prosthesis being displaced from the gastric pouch, subsequently causing obstructive symptoms. If there has been a complete slip, there can be signs of esophagitis from excessive vomiting, gastric pouch dilatation or formation of gastric "neofundus." [22] Food residue can also be seen in the pouch and a site of stenosis seen in the jejunal folds distal to the anastomosis.

Some patients may have frequent episodes of vomiting with no evidence of stenosis, a condition quoted by the authors as "food intolerance secondary to the presence of the ring" (see Fig. 53.8) [23].

Dilation with a 30 mm balloon (Rigiflex ®—Boston Scientific, Natick, MA) promotes stretching or rupture of the internal fibrotic band caused by the presence of the ring, which can relieve symptoms (see Fig. 53.9). If symptoms persist, a self expanding plastic stent, which promotes intragastric ring erosion allowing endoscopic oral removal, may be used [22].

53.5 Gastric Fistula After LRYGB and Sleeve Gastrectomy

This is one of the most feared complications after bariatric surgery and may present with variable symptoms corresponding to the site of the fistula [24, 25].

The incidence has decreased in recent years (approximately 1 %), due to the recognition of its etiology and improved surgical technique. It is more common in the first few weeks after surgery. However, it is still associated with high morbidity [2].

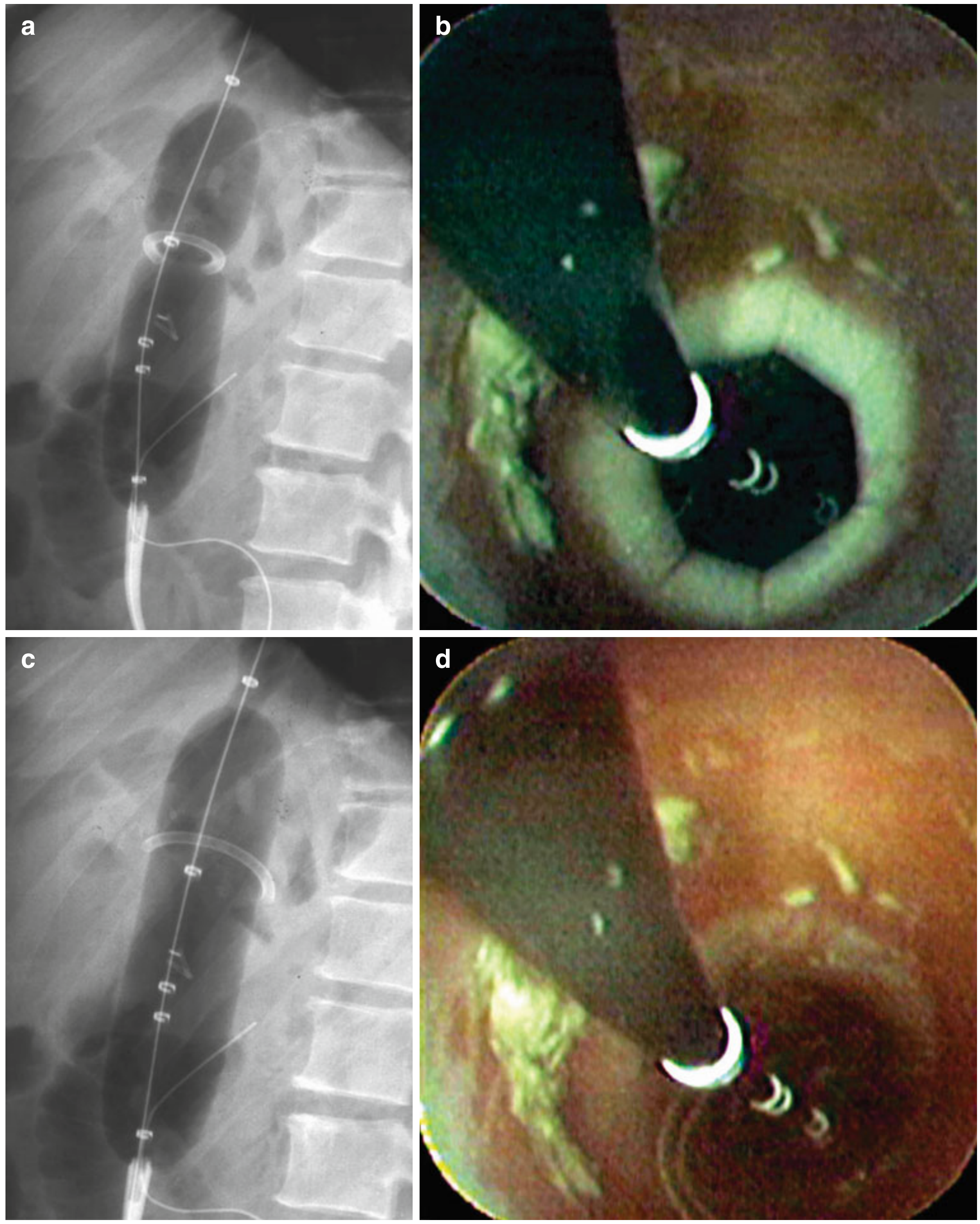

Fig. 53.9 X-ray (**a**) and endoscopic image (**b**) of gastric pouch evidencing Rigiflex® balloon inflated revealing ring compression. X-ray (**c**) and endoscopic image (**d**) evidencing ring opened ring after few minute dilation

The risk factors are male sex, increasing age, body mass index (BMI) more than 50 kg/m^2, the presence of comorbidity, revisional surgery and early learning curve [2]. The pathogenesis can be explained in some cases by ischemia of the angle of His, increased intraluminal pressure after surgery and staple line or suture failure [26].

The fistula may be difficult to control and, in some cases, does not heal after conventional treatment (reoperation, intraabdominal drainage and feeding distal to the fistula) [27]. When external drainage is not adequate, a chronic internal fistula (gastrocutaneous, gastrogastric, gastrojejunal, gastrocolic and gastrobronchial) may develop [28].

Increased pressure in the gastric pouch or tube, secondary to distal stricture or stenosis prevents fistula healing by direct surgery alone. Surgery is recommended in selected cases for abscess drainage and should always be performed in case of peritonitis [29].

Upper GI endoscopy facilitates diagnosis and simultaneous minimally invasive therapy. A stenosis can usually be identified distal to the fistula, for both sleeve gastrectomy or LRYGB. The resulting increased pressure leads to its delayed healing. Stricturoplasty and balloon dilatation can relieve distal stenosis (see Figs. 53.10 and 53.11) allowing the pouch or tube to resume a normal function by facilitating gastric pouch or tube emptying, reducing intragastric pressure and decreasing fistula output [29]. Also, occlusion of the internal opening of the fistula is possible with implantation of a removable stent.

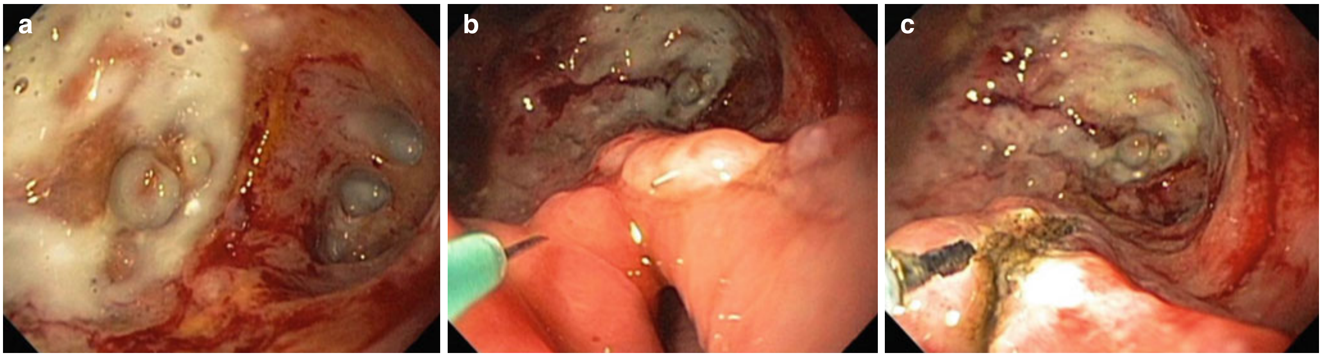

Fig. 53.10 Endoscopic septotomy: (**a**) perigastric cavity partially clean; (**b**) Begining of septotomy using needle-knife catheter (**c**) Sectioned septum

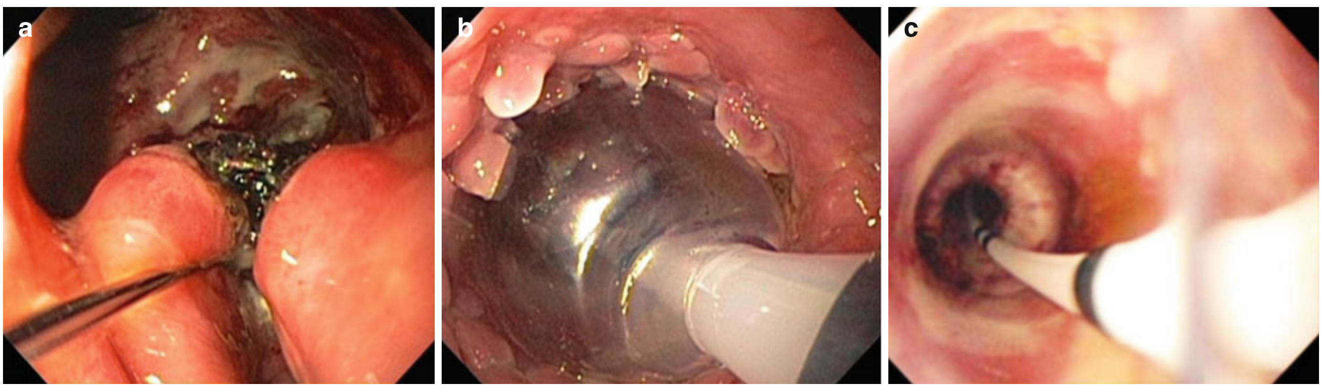

Fig. 53.11 Balloon dilation procedure: (**a**) Savary guide wire passage in stenosis area (**b**) Inflated balloon – Rigiflex (Boston) ® (**c**) Sectioned septum and removed edges after dilation

Acute (less than 7 days) and early (7–45 days) fistulas are treated with stents with good results [24]. In the late (1.5–3 months) and chronic (more than 3 months) stages balloon dilation and septotomy with electrocautery or argon plasma could be used. Options available to treat chronic fistula after sleeve gastrectomy are: open/laparoscopic reoperations or endoscopic procedures. There is still no standard of care for these conditions. Often, the redo surgery tends to be complex. Hence therapeutic endoscopy, a minimally invasive procedure, such as: stricturotomy and dilation with 30 mm balloon proves valuable [30].

In addition to the incision of the fibrotic band, a pneumatic balloon dilatation of up to 30 mm is performed aiming to correct its anatomical and functional changes. These procedures are repeated on a weekly basis in an outpatient setting until the digestive secretion flow and pouch axis are corrected, encouraging permanent fistula healing [8, 31].

Some other procedures such as clip placement and endoscopic application of sealents have also been described. Mercky et al. described clip placement with promising results [32].

53.6 Twisted Gastric Tube After Sleeve Gastrectomy

Twisted gastric tube after sleeve gastrectomy is a possible complication, rarely described in the international literature. It may lead to a leak or perforation. Its diagnostic investigations of choice are plain or contrast x-ray, computerized tomography (CT) scanning and or endoscopy. X-ray images may be difficult to interpret as there is radiological evidence of a stenosis in the absence of stricture on endoscopic examination (see Fig. 53.12).

At endoscopy, twisted gastric folds with an axis deviation are pathognomonic of twisted gastric tube. Endoscopic treatment can be attempted by balloon dilation with a 30 mm balloon. If it persists, open incision of the great curvature including the first muscle layer, followed by balloon dilatation, is indicated. This procedure can be performed with argon plasma or electrocautery (Needle knife®, Cook), being comparable to the gastric seromyotomy reported by Himpens [33] and is relatively less invasive, that appears to be safe and effective.

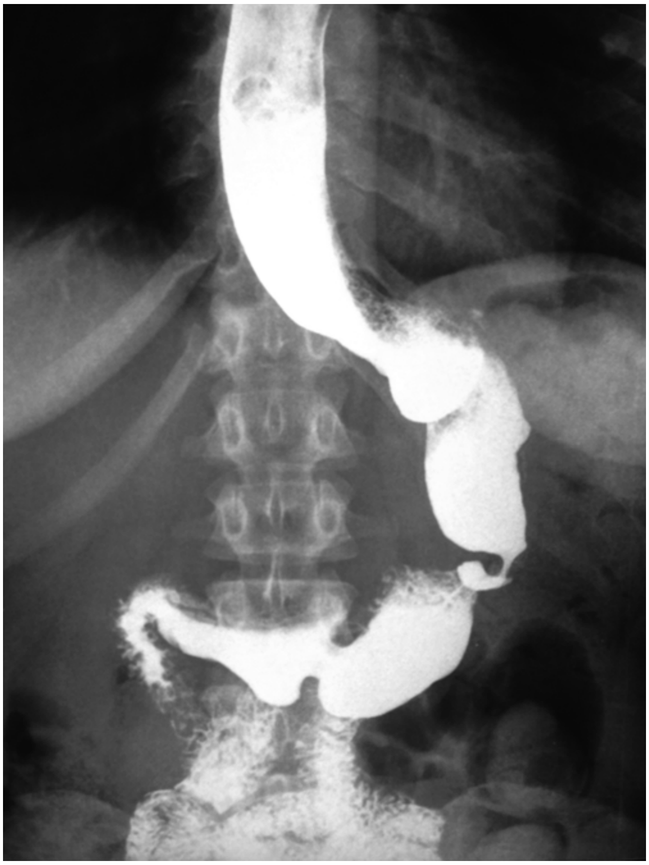

Fig. 53.12 X-Ray image showing gastric twist twists

53.7 Secondary Treatment for Obesity

Some patients undergoing LRYGB may regain approximately 30 % of their excess weight loss; around 20–30 % of these patients regain a large proportion of their lost weight. This leads to a negative impact on quality of life clearly negating the expected long term benefits of surgery for management of obesity [34]. Several factors may be related to regain, such as detrimental nutrition, fistula, poor surgical technique, and implant complications. Poor eating habit is one of the main factors associated with this complication. Increased caloric intake can be related to esophageal, gastric or anastomotic dilation, with subsequent weight regain. It is important that dietary and behavioral habits such as volume and quality of the meal and anxiety disorders are always evaluated when there is inadequate weight loss.

Weight regain in the late postoperative period after LRYGB should be reviewed by a multidisciplinary team as well as endoscopic or radiologic evaluation to study the surgical anatomy. When there is dilation of the anastomosis after LRYGB, endoscopic diameter reduction methods

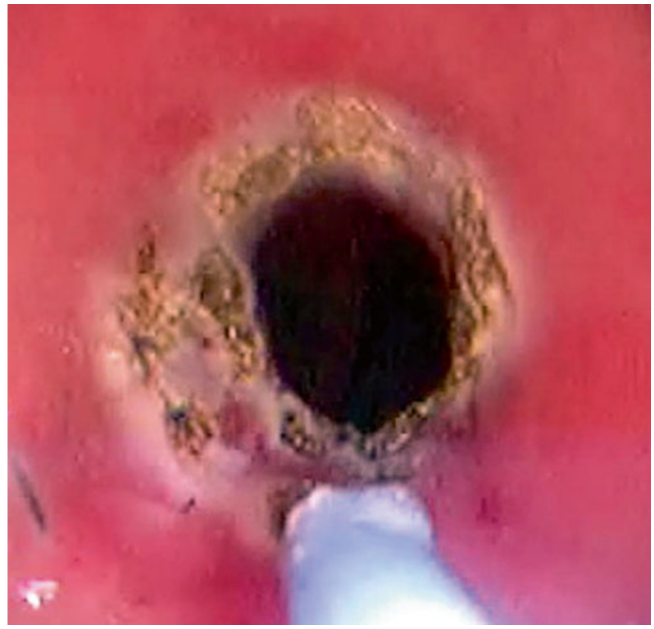

Fig. 53.13 Endoscopic argon plasma application at gastrojejunal anastomosis

(as described below) may be tried. Reoperation has been the most traditional option, but it is high risk procedure with high morbidity and mortality [34].

There are good results reported after injection of sclerosing substances into a dilated anastomosis [35]. Application of argon plasma has been reported as a way to induce the formation of fibrotic scar and consequent anastomotic diameter reduction (see Fig. 53.13) [34]. Significant dietary restrictions should be observed post procedure due to anticipated anastomotic edema and a local inflammatory response. Subsequently, the edema is replaced by fibrosis. This procedure may have to be repeated to achieve satisfactory results.

Endoscopic suturing devices, such as Apollo ® EndoCinch have been presented as minimally invasive alternatives, and may be used alone or in association with argon plasma [27]. The procedure involves suturing the internal mucosa with flexible endoscope thereby restricting the gastric lumen. The sutures are performed under direct vision, with the aid of curved needle [27].

Key Learning Points

- Endoscopic removal to treat band erosion is a safe, effective and minimally invasive procedure; it has been replacing the surgical approach.
- Abdominal pain is the main complaint of patients with marginal ulcers; healing usually occurs with the prolonged use of PPI and sucralfate.

- Upper digestive endoscopy is the best diagnostic and therapeutic method to manage stenosis of gastrojejunal anastomosis. Endoscopic balloon dilation is a safe and effective approach with a low morbidity rate.
- In order to treat choledocholithiasis after gastric bypass, combined management (laparoscopic and endoluminal procedures) can be performed by transgastric endoscopic retrograde cholangiopancreatography (ERCP); enteroscopy has been performed as a minimally invasive approach, recently.
- Gastrojejunal anastomotic leak after RYGB has been treated by autoexpandable metallic stent.
- Gastrobronchial fistula after sleeve gastrectomy can be due to clinical conditions such as chronic fistula, recurrence of subphrenic abscess and absence of abdominal drain.

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Section XI

Metabolic Effects of Bariatric Surgery

Honorary Section Editor - Francesco Rubino

A significant body of evidence has accumulated demonstrating that bariatric/metabolic surgery can achieve sustained weight loss, excellent metabolic control and reduction of cardiometabolic risk. Randomized clinical trials also show that surgery is more effective than conventional medical therapies in the treatment of obese patients with Type 2 Diabetes Mellitus (T2DM). In this section, leading international experts discuss clinical and mechanistic aspects of bariatric/metabolic surgery and provide the reader with a state-of-the art review of the latest research in this field.

Research on the mechanisms of action of these surgical procedures have revealed a critical role of the gastrointestinal (GI) tract in the regulation of glucose metabolism, satiety/hunger and lipid metabolism, providing a biological rationale for the use of GI-based interventions as a treatment for metabolic syndrome. Metabolic surgery has been one of the fastest growing fields of medical research in the last decade. In their chapter, Drs Neff and le Roux discuss mechanisms of weight loss and glucose homeostasis after the most commonly performed bariatric operations.

Lifestyle interventions and drugs have relatively little impact on CVD risk in patients with fully blown diabetes. In contrast, long-term case-controlled studies document a significant reduction of cardiovascular disease (CVD) and mortality after bariatric/metabolic surgery. Drs Elliott and le Roux have reviewed the effects of various bariatric procedures on CVD risk factors.

Drs Olbers and Johannson reviewed the effect of bariatric/metabolic surgery on various metabolic conditions, including T2DM, hypertension, sleep apnea and metabolic syndrome; emphasizing how the health benefits of these GI operations go well beyond weight loss.

Although the indications for bariatric/metabolic surgery are still based on body mass index (BMI)-centric criteria, studies in animals and humans show that many of the metabolic effects of GI surgery are independent of weight loss. Such evidence has led to the hypothesis that surgical treatment for T2DM could be offered to less obese and non-obese patients. Dr Cohen and co-workers discuss the results of metabolic surgery for the treatment of type 2 diabetes in patients with BMI below 35 kg/m^2.

The recognition that alteration of GI anatomy can exerts weight-independent effects on metabolism and that different anatomical manipulations can exert distinct physiologic effects has fueled interest toward the development of new surgical procedures and endoluminal devices specifically designed for the treatment of metabolic disease. Such novel approaches have the intent to mimic at least some of the metabolic effects and possibly reduce the nutritional side effects of conventional bariatric surgery. Dr Ugale presents the results of laparoscopic ileal interposition with sleeve gastrectomy, an experimental procedure for T2DM and other metabolic conditions.

The reader will find the chapters that follow both informative and stimulating as they provide a critical appraisal of the available evidence, including current gaps in knowledge and a view of how research in metabolic surgery may shape the future care of obesity and diabetes.

Mechanisms of Action of Bariatric Surgical Procedures

54

Karl J. Neff and Carel W. le Roux

Abstract

Bariatric surgery can effectively induce durable weight loss and can reduce the risk of obesity-associated complications, including type 2 diabetes mellitus (T2DM). Bariatric procedures fundamentally alter physiology, and in those with diabetes, bariatric surgery can affect insulin sensitivity and insulin secretion, resulting in remission of diabetes in many recipients. The action of each procedure differs, and the mechanisms by which each procedure produces weight loss and alters physiological mechanisms, such as glucose homeostasis, are multiple and often integrated. The known mechanisms include gut hormone mediated changes affecting appetite, insulin dynamics, food preferences, and energy expenditure. In this review, we outline the current knowledge on the putative mechanisms of weight loss and glucose homeostasis after the most commonly performed bariatric operations.

Keywords

Appetite • Energy expenditure • Stomach size • Malabsorption • Bariatric surgery • Mechanisms • Diabetes mellitus • Obesity • Metabolic surgery

54.1 Introduction

Bariatric surgery effectively reduces body weight, and is the only intervention that maintains weight loss in the long-term. In the Swedish Obese Subjects study, a cohort study of obese patients with a body mass index (BMI) >34 kg/m^2 and a follow-up of more than 20 years, the surgical group achieved up to a 23 % reduction in total body weight as compared to patients receiving conventional non-surgical treatment [1]. Bariatric surgery is also an effective treatment for obesity-associated comorbidities such as type 2 diabetes mellitus (T2DM). Randomized controlled trials have demonstrated that in obese patients with T2DM, bariatric surgery results in better glycemic control than intensive medical therapy alone [2–4].

Previously, bariatric surgery was considered to produce these effects simply by restricting meal size by altering stomach volume, and by macronutrient malabsorption. However, it is now recognized that the effects of bariatric surgery include changes in gut hormones favoring improved insulin dynamics, reduced hunger, increased satiety, and increased energy expenditure [5]. The main hormones that are implicated originate from the endocrine L-cell in the gut and include glucagon-like-peptide 1 (GLP-1), oxyntomodulin (OXM), and peptide YY (PYY). Other hormones such as ghrelin have also been identified as having a role in the post-operative changes in appetite and insulin secretion.

GLP-1, OXM and PYY are synthesized by the L-cells, which are located mainly in the ileum. They are released after food intake and differences have been observed between nor-

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mal weight and obese individuals [6]. GLP-1 is an incretin and stimulates the insulin release in response to nutrient ingestion. It exerts its glucose-lowering effects through enhanced insulin secretion in the postprandial state, inhibition of gastric emptying, which blunts postprandial glycemia, and inhibition of glucagon secretion. It also plays a significant role in the regulation of energy homeostasis as it acts on the central nervous system to induce satiety and decrease food intake.

PYY is a peptide released into the circulation with GLP-1 following food ingestion. PYY is released in proportion to the calories ingested and has an inhibitory effect on gastrointestinal mobility. It increases satiety, reduces food intake and delays gastric emptying, but does not affect glucose homeostasis [6].

Similarly, OXM has very little direct influence on glucose levels, but can reduce food intake while increasing energy expenditure [7, 8]. This can result in weight loss. It is cleaved from proglucagon like GLP-1, and can act at the GLP-1 receptor [8]. However, it also has GLP-1 receptor independent activity [8].

Ghrelin is a peptide mainly produced from the X/A-like cells in rodents and P/D1 cells in humans in the fundus of the stomach and acts on the hypothalamus to regulate appetite. It is an orexigenic hormone and stimulates appetite and food intake. Ghrelin also stimulates insulin counter-regulatory hormones, suppresses the insulin-sensitizing hormone adiponectin and inhibits insulin secretion, all of which acutely elevate blood glucose levels. Circulating ghrelin concentrations increase with fasting and decrease following nutrient ingestion in normal weight subjects, but in obese populations the dynamic responses are attenuated [6].

We will review the potential mechanisms involved in weight loss and glucose homeostasis in the four major bariatric procedures: Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion (BPD), adjustable gastric banding (AGB), and vertical sleeve gastrectomy (VSG).

54.2 Mechanisms of Weight Loss

54.2.1 Malabsorption and Reduction of Stomach Size

As was the case with other bariatric procedures, RYGB was initially designed to combine malabsorption and restriction. However, over the decades since its introduction, it is now established that serum albumin levels remain normal, and levels of fecal fat are minimally altered after RYGB [9, 10]. Patients after RYGB usually complain of constipation and the reduction in combustible energy absorption is low [9]. Therefore, calorie malabsorption is not a major mechanism of weight loss in RYGB and other mechanisms play a greater role (Fig. 54.1). However, malabsorption may become more important in those with shorter lengths of the intestinal limbs or in those who maintain high-fat diets post-RYGB.

RYGB does reduce stomach volume, but food is usually not present within the smaller stomach pouch as it progresses rapidly to the small bowel. In those cases with gastrojejunal stenosis, food in the pouch may result in early gastric distension and subsequently lead to early discomfort and reduced meal size [11]. In the absence of a pylorus, gastric pouch emptying is fast after RYGB. The expectation could reasonably be that reduced stomach volume would result in a compensatory increase in appetite for calorie-dense food to counter weight loss, but this does not appear to be the case.

RYGB recipients report reduced hunger, increased satiety, and a lower consumption of energy dense foods as compared to their preoperative state [12]. Therefore, it is not simply a matter of gastric pouch size; randomized controlled trials have shown that vertical banded gastroplasty (VBG) with reduction in pouch size for example, results in less weight loss and less change in food preferences as compared

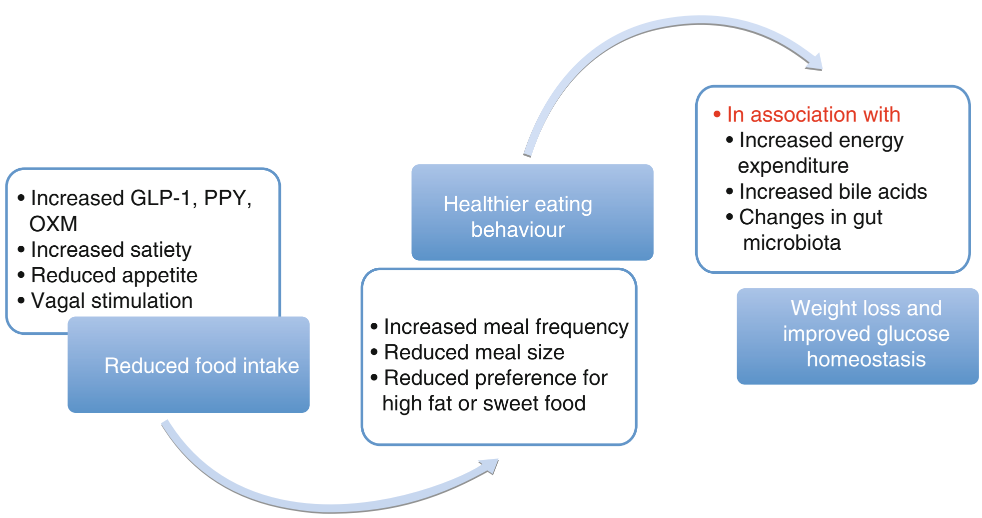

Fig. 54.1 Roux en Y Gastric Bypass (RYGB): The design of RYGB reduces stomach volume but food does not usually rest in the gastric pouch, instead moving rapidly into the small bowel. Modern procedures do not produce significant malabsorption, however, shorter intestinal limbs can limit absorption and result in nutrient deficiency. Key features of this procedure include exclusion of the duodenum and increased delivery of nutrients to the ileum. Transection of vagal fibers during gastrectomy may also be important

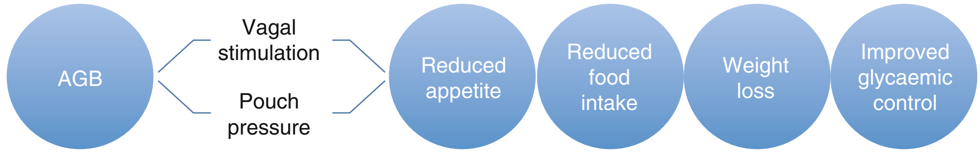

Fig. 54.2 Adjustable Gastric Banding (AGB): This procedure limits the rate of food emptying from the esophagus to the stomach by applying pressure to the stomach inlet. This pressure can be adjusted by inflation or deflation of the band, and may modulate neural signalling producing effects on satiety

to RYGB [13]. This supports the notion that other mechanisms are responsible for the effects of RYGB.

AGB reduces the rate of food emptying from the esophagus to the stomach by regulating the stomach inlet. The pressure on branches of the vagal nerve in the upper gastro-esophageal junction can lead to early satiety (Fig. 54.2) [12]. The lack of compensatory, high calorie seeking behavior in the majority of patients after AGB suggests that the pressure on the upper gastro-intestinal junction alone may not be the only mechanism in weight loss and that other mechanisms may be involved to modulate appetite and food preference. However, this remains to be proven.

Gastric emptying is not altered after AGB, and the rapid weight regain seen after reversal of AGB argues for the physiological attenuation of appetite when the band is optimally adjusted [12]. Much work currently focuses on the role of the vagus nerve in AGB and the associated changes in appetite and satiety. Altered neural signaling is likely to have a role, as gut hormone secretion is not affected by this procedure. This has yet to be conclusively demonstrated in humans [14]. There are no data that demonstrates malabsorption in AGB.

BPD has a malabsorptive effect. BPD recipients can consume over 3000 kcal daily and still maintain weight loss in the long-term [15]. The accompanying high incidence of hypoalbuminemia after BPD confirms the risk of malabsorption [15].

Stomach size is reduced after BPD, but not to the same extent as RYGB. Gastric emptying can be marginally accelerated compared to the non-operated state but is not nearly as fast as after RYGB. Gut hormones such as PYY and GLP-1 are also increased in the post-prandial state [16]. This may reduce the hyperphagia caused by the calorie malabsorption. Multiple mechanisms are likely to be important in mediating the effects of BPD (Fig. 54.3).

In VSG, a non-significant increase in fecal caloric density has been demonstrated in animal models [17]. However, this has not been replicated in humans. Consequently, the contribution of caloric malabsorption to the weight loss after VSG is currently considered to be minimal (Fig. 54.4). There is significant controversy as to whether the gastric sleeve volume in VSG correlates with food intake and body weight reductions. Some studies have shown that larger gastric pouches or stomas result in less weight loss [18, 19]. Others do not find any relationship between these variables [20–22].

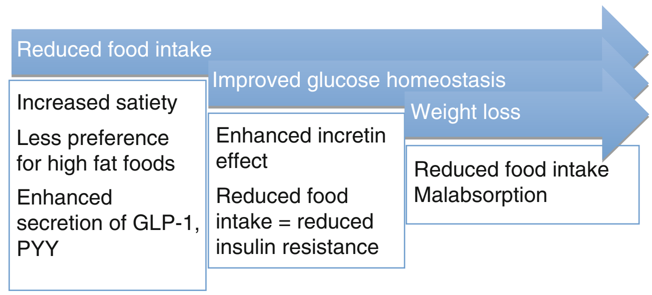

Fig. 54.3 Biliopancreatic Diversion (BPD): BPD is a complex procedure involving many physiological mechanisms, but is the only modern major form of bariatric surgery that could be considered a malabsorptive procedure due to the extensive intestinal bypass central to its design

Similarly, the data on the effect of gastric sleeve volume on weight loss after VSG are inconsistent [23–26]. These inconsistencies may be due to the variation in the measurement of gastric volume. Nonetheless, the lack of a clear association between gastric volume and weight loss to date suggests that the physiological consequence and not the anatomical size of the reduced stomach is important.

Counter to the initial hypotheses of the VSG causing restriction to gastric emptying, intestinal transit appears to be faster postoperatively [27–30]. This may not be the case in surgery where the antrum is preserved [31]. The mechanisms underlying this are unclear but may include the generation of very high intraluminal gastric remnant pressures, the excision of the gastric pacemaker at surgery, and neural signaling (Fig. 54.4). The rapid gastric emptying and intestinal motility may explain why the release of anorexigenic gut hormones after VSG is very similar in magnitude to RYGB.

54.2.2 Changes in Hunger and Satiety

Increased satiety and decreased hunger occur within days following RYGB [32–34]. The changes in the postprandial levels of gastrointestinal hormones that induce satiety, such as GLP-1, OXM and PYY have been proposed as one of the possible contributors to the reduced food intake after RYGB. Increased postprandial PYY, OXM, and GLP-1 responses are observed from the second postoperative day after RYGB, prior to any significant weight loss, and correlate with differ-

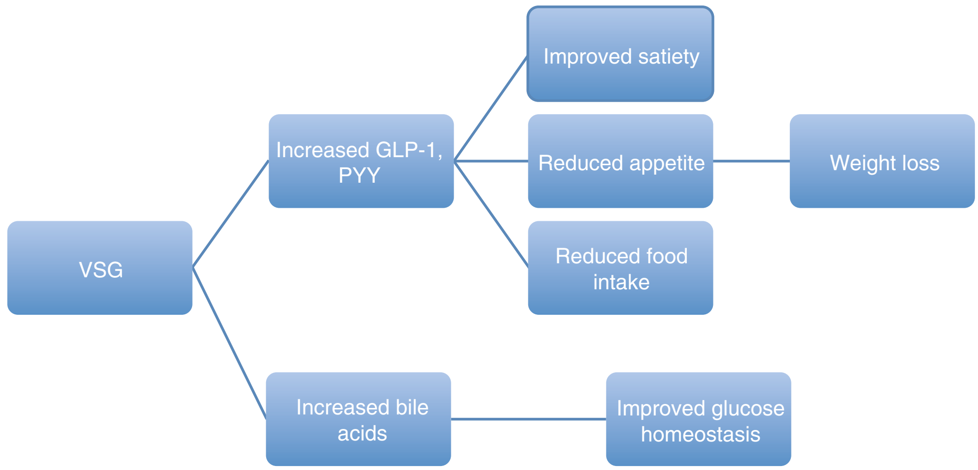

Fig. 54.4 Vertical Sleeve Gastrectomy (VSG): This procedure reduces stomach volume, but does not alter nutrient flow. The contribution of caloric malabsorption is considered to be minimal. It may be that physiological changes, such as gut hormone secretion for example, are more important than the reduction in stomach volume. VSG does not appear to cause restriction, but instead increases intestinal transit time, potentially due to the generation of high intraluminal gastric remnant pressures, the excision of the gastric pacemaker at surgery, and neural signalling

ent levels of weight loss [17]. Moreover, inhibition of the gut hormone responses with a somatostatin analogue (octreotide) in patients after RYGB results in an increase in food intake, suggesting that gut hormones are important in mediating the reduced calorie consumption seen after RYGB [33].

Changes in appetite are also reported following AGB [32–34]. The changes in the postprandial levels of gastrointestinal hormones that induce satiety, such as GLP-1 and PYY, are not seen in AGB, and inhibition of the gut hormone responses with octreotide does not affect food intake in AGB recipients [33, 34]. The vagal nerve plays an important role in the regulation of food intake and body weight, and it is likely that AGB exerts its effects on satiety by neural signaling arising from the upper gastro-esophageal junction [12]. This is suggested by data that show increased satiety associated with increased pouch pressure [35]. Pouch emptying rates and changes in pouch pressure are not associated with satiety. Therefore, the dilatation or pressure effect on the gastric pouch produces a satiation effect in the absence of any consistent change in gut hormones [34].

The vagal nerve also plays an important role in the regulation of food intake after RYGB [36]. Vagal afferents are activated by the presence of nutrients in the stomach and the intestine, and the preservation of vagal fibers during surgery leads to greater and more sustained body weight loss in animal models of RYGB [36]. Similarly, pressure generated in the proximal alimentary limb of the RYGB by a 20 mL balloon appears to predict the meal size of a patient. Thus, the rapid entry of food from the esophagus, through the small gastric pouch and the larger gastro-jejunostomy, may trigger neural signals in the alimentary limb, which may contribute to the long-term weight maintenance after RYGB [22, 37].

Satiation is increased in BPD recipients for up to 2 years postoperatively [38]. There is also a change in food preference with an increased aversion to sweet tastes [39]. While there are very little data on these mechanisms after BPD, similar changes to the gut hormone profiles and mediation of vagal activity are likely to be involved as in RYGB (Figs. 54.1 and 54.3).

54.2.3 Changes in Energy Expenditure

Chronic caloric deprivation as observed after RYGB normally produces a decrease in resting energy expenditure [40]. However, resting energy expenditure has been shown to increase after RYGB in rodents, and this may contribute to the postoperative weight loss [40, 41]. The data on energy expenditure in humans are controversial and inconsistent. In patients with a normal preoperative metabolic rate, resting energy expenditure decreases over time, whereas patients who have low metabolic rates before RYGB can exhibit increases in their resting energy expenditure postoperatively [40]. These changes occur after RYGB despite the very low-calorie diet. Other studies have found lower resting energy expenditure after RYGB [42]. These discrepant results may be a result of the difficulty in measuring energy expenditure in humans, and a reliance on indirect calorimetry as the primary measurement method.

Energy expenditure over 24 h appears to be increased up to 9 years postoperatively [43]. Much of this effect is due to increases in postprandial energy expenditure, which is associated with postprandial increases in GLP-1 and PYY. GLP-1 would be expected to reduce energy expenditure, but may affect an increased rate of energy use in conjunction with glucagon in humans [44]. Therefore, changes in energy expenditure after bariatric surgery may not be attributable to one single hormonal change, but to a combination of changes. The increase in small bowel mass and metabolism after RYGB in rodents, and potentially humans, may explain the changes in postprandial energy change, and to some extent, the basal metabolic rate.

Measurements of energy expenditure in VSG or AGB rat models, in which the only anatomical alteration is the reduction of stomach size, do not reveal significant changes in energy expenditure [45, 46]. Resting energy expenditure after VSG has only been assessed in rodent models which have demonstrated either stability [45] or a trend for a decrease [17]. In studies of AGB, a decrease in energy expenditure at rest has been demonstrated [47, 48]. However, the data is not consistent and other results report an increase in expenditure when corrected for body weight [49]. These discrepancies likely arise from the variability in the methodologies used to quantify body composition, and the inherent limitations of indirect calorimetry and the assessment of subjects with different food intake at different time points after surgery.

Resting energy expenditure in humans decreases significantly after BPD to the level of normal weight controls [50]. However, energy expenditure related to physical activity increases after BPD compared to the preoperative level [50, 51]. There are also increases in diet-induced thermogenesis and carbohydrate oxidation after BPD [51]. The increased energy expenditure is likely to contribute towards sustained weight loss in BPD recipients. As with other procedures, the mechanisms to explain this are not defined, but the increase in small bowel mass, which is more pronounced after BPD than RYGB, may play a role.

54.2.4 Changes in Food Preferences

The orbitofrontal cortex, hypothalamus, brainstem and corticolimbic areas in the brain co-ordinate the processing of sensory information and energy homeostasis, and regulate food searching, sensing and reward. Higher cortical centers are implicated in psychological and emotional factors, which can influence food intake beyond homeostatic requirements [52]. Neuroimaging studies show that this reward network is dysfunctional in obese cohorts [53].

RYGB recipients tend to have reduced meal size but increased meal frequency postoperatively [54]. In randomized controlled experiments, VBG recipients consumed a higher proportion of fat and carbohydrates compared to RYGB recipients, who preferred fruit and vegetables instead of high-fat food [13]. RYGB recipients consume less solid and liquid sweets and less dairy products compared to VBG recipients, consequently producing an avoidance of calorie dense foods, and a preference for high glycemic index foods [29, 55]. The reward areas of the brain are activated in response to high calorie food to a lesser extent after RYGB [56, 57]. Animal models of RYGB report an avoidance of sweet and high-fat foods compared to sham animals [58–60].

The data on food preferences after AGB suggest that there may be a reduction in appetite for palatable foods (hedonic drive) after AGB [61]. However, specific data on preferences for fats or carbohydrates are not available. In VSG, there are no human data, and the rodent data are conflicting. In these results, rats exhibit either no change in food constituent preference or changes which are comparable to RYGB [17, 60, 62]. Further work is needed in non-RYGB bariatric surgery to define the effect on food preferences in these procedures.

54.3 Mechanisms of Improved Glucose Homeostasis After Bariatric Surgery

54.3.1 The "Hindgut and Foregut" Theories

Maintained weight loss clearly plays an important role in the improved glucose homeostasis after RYGB. This is evident in the restoration of glucose tolerance and improvement of insulin sensitivity by all types of bariatric surgery. The enforced caloric restriction reduces hepatic insulin resistance after all bariatric procedures. The ability of acute caloric restriction to transiently improve glycemia in T2DM is well established, and by the time patients return to an unrestricted diet, they begin to experience the peripheral insulin-sensitizing effects of weight loss [63]. However, if caloric restriction played the only role in mediating changes in glucose homeostasis, then improvements in glucose homeostasis would be equivalent after all types of bariatric surgery. RYGB produces greater effects in glucose homeostasis than AGB and VSG, and these effects are independent of weight loss [64, 65].

The "hindgut" hypothesis postulates that the improved insulin secretion after RYGB is due to increased rapid delivery of nutrients to the distal gut, which causes enhanced secretion of gut hormones such as GLP-1 and PYY. This theory could partially explain the significant effectiveness of VSG and RYGB on glucose homeostasis from the early postoperative period. Support for this hypothesis comes from experiments involving ileal interposition [63, 66]. In this operation, a segment of the L-cell-rich ileum is transplanted into the upper intestine, near the duodenum-jejunum boundary, thereby increasing its exposure to ingested nutrients [66]. This operation significantly increases the postprandial GLP-1 response and results in improved glycemic control without any malabsorption or gastric restriction [66].

According to the "foregut hypothesis," bypass of the proximal small bowel reduces the secretion of unknown gastrointestinal factors that decrease insulin secretion and promote insulin resistance. Therefore, duodenal exclusion could reduce production of these putative 'anti-incretins' leading to an increase of insulin secretion [67]. Duodenal exclusion and correction of the anti-incretin dysfunction, may explain the improvement of T2DM after RYGB. Additional evidence supporting the foregut hypothesis comes from studies examining the effects of preventing nutrient contact in the proximal gut by inserting a duodenal jejunal bypass liner into the duodenum which extends into the jejunum and results in early improvement in glucose homeostasis after insertion [68].

54.3.2 Bile Acids

Alterations in the levels or types of bile acids in the gut or the circulation after bariatric surgery have been implicated in the improvements in glucose homeostasis observed after RYGB. Bile acids levels, both total and sub-fractions, in the plasma are increased after RYGB [47, 69–71]. Plasma bile acids are also elevated in animal models of VSG [72]. This is in contrast to AGB, where plasma bile acid levels are unaffected. The level of bile acid fractions in plasma negatively correlates with glycemic excursions, implicating bile acids as agents in glucose homeostasis [69].

Bile acids can directly or indirectly affect glycemic control through the TGR5 receptors or nuclear FXR receptors and the release of fibroblast growth factors. There may be a central effect on food intake and appetite, as bile acids can cross the blood–brain barrier and act on receptors in the hypothalamus [73–77]. This could conceivably contribute towards improved glycemic control. In the absence of detailed mechanistic studies, the exact role of bile acids as mediators of weight loss and glycemic control after RYGB is unclear.

54.3.3 Gut Microbiota

Gut microbiota in the context of obesity and weight loss have also been identified as important metabolic mediators after bariatric surgery. Bacteria that are more efficient in extracting energy from nutrients and storing it as fat have been implicated as contributing towards the development of obesity [78]. A depletion of Prevotellaceae, Archea, Firmicutes, Bacteroidetes colonies, and an increase in the Bacteroidetes/Prevotella ratio and Gammaproteobacteria of this flora has been observed after RYGB [79–81]. These alterations may be due to changes in dietary macronutrient composition, anatomical manipulations and pH, but altered bile flow may also be a major determinant of change in gut microbiota.

The microbiota may change as a result of surgery, but they also affect the surgical recipient. The transfer of the gut bacteria from RYGB to un-operated germ free mice leads to weight loss, and this may be the result of increased energy expenditure [82]. However, the exact mechanisms through which gut bacteria contribute to weight loss remain to be determined.

Conclusion

There are multiple mechanisms that contribute to weight loss and improvements in glucose homeostasis after bariatric surgery (Figs. 54.1, 54.2, 54.3, and 54.4). Many of these are due to the anatomical rearrangements of the gut, which produce powerful physiological changes and which may alter gut microbiota. Each procedure utilizes these mechanisms to different extents, and therefore can produce different clinical outcomes and side-effect profiles. A full understanding of these mechanisms may lead to the optimization and personalization of these procedures but also the development of more effective and safe pharmacotherapy for the treatment of obesity and T2DM.

Key Learning Points

- Bariatric surgery is the most effective treatment for long-term weight loss and to optimize glycemic control in type 2 diabetes mellitus.
- Each major procedure acts through various mechanisms including reduction in hunger, increase in satiation, changes in food preferences, increasing energy expenditure, altering bile acid, gut hormone and vagal signaling.
- The contribution of each of these mechanisms varies with procedure.
- Understanding the mechanisms of action of these procedures may accelerate their optimization and the development of medical and surgical therapies for obesity and type 2 diabetes mellitus.

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55 Glycaemic Control and Reduction of Cardiovascular Risk Following Bariatric Surgery

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Abstract

Obesity in combination with type 2 diabetes mellitus (T2DM) is associated with excess cardiovascular (CV) morbidity and mortality. Weight loss of more than 15 % has the potential to attenuate this phenomenon. Bariatric surgery effectively induces significant and sustained weight loss in morbidly obese patients with T2DM. In addition, bariatric surgery can produce improvements in, as well as remission of T2DM, hypertension, dyslipidemia, inflammation and renal impairment. Improvement in CV risk factors following bariatric surgery reduces the incidence of fatal and non-fatal CV events. This chapter will outline the differential effects of each of the current most common bariatric procedures on CV risk factors.

Keywords

Cardiovascular disease • Hypertension • Diabetes • Hyperlipidemia • Inflammation

55.1 Introduction

Obesity along with the metabolic syndrome or diabetes is associated with increased morbidity and mortality, with an estimated 70 % of this excess mortality attributed to cardiovascular disease (CVD) [1]. As such, cardiovascular (CV) risk reduction constitutes a major consideration in the management of patients with morbid obesity and type 2 diabetes mellitus (T2DM). Bariatric procedures were originally designed to achieve substantial and sustained weight loss, but it is now acknowledged that, in addition to weight loss, these procedures lead to improved management of blood glucose levels, blood pressure, lipid metabolism, and inflammation [2, 3]. Although there is an established association between weight loss and improved CV risk factors in the short term [4, 5], this has not always translated into reduced CV mortality in epidemiological studies [6] or randomized controlled trials using non-surgical weight loss therapies [7]. Whether incremental changes in CV risk following bariatric surgery result in a significant reduction in CV events and mortality compared with intensive medical therapy has recently been reported in the 20-year outcomes of the non-randomized cohort-controlled Swedish Obese Subjects (SOS) study [8]. In this cohort, surgery was associated with a long term reduction in overall mortality (adjusted hazard ratio [HR] = 0.71), myocardial infarction (HR = 0.71), and stroke (HR = 0.66) compared with best medical management. Body mass index (BMI) was not a predictor of benefit after surgery and only those patients with fasting insulin levels above the median appeared to have had a survival advantage after surgery. Evidence of significant improvements in morbidity and survival following bariatric surgery confirms that bariatric surgery is a valid treatment for patients with metabolic disease, and thus necessitates reassessment of the traditional indications for surgery in overweight and obese patients, particularly those with T2DM.

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Table 55.1 Excess body weight loss and total body weight loss outcomes following bariatric surgery

Weight loss	RYGB		VSG		BPD		AGB	
	%EBWL	%BWL	%EBWL	%BWL	%EBWL	%BWL	%EBWL	%BWL
1 year	50–60	38	58	–	55–85	–	55	21
2 years	55–70	35	60	–	75	–	41–54	22
3 years	55–75	–	55–60	–	80	–	39–47	–
5 years	60–70	30	45–55	–	80	–	48–73	15–20
10 years	50	25–30	–	–	72	–	31	15
≥14 years	–	–	–	–	75	–	16 (14 years) vs 43 (12 years)	–
20 years	–	25–30	–	–	–	–	–	15

All values are approximate, based on the available literature
%EBWL percentage excess body weight loss, *%BWL* percentage body weight loss, *RYGB* Roux-en-Y gastric bypass, *VSG* vertical sleeve gastrectomy, *BPD* biliopancreatic diversion, *AGB* adjustable gastric banding

The following section will discuss the differential effects of the four most common bariatric procedures, Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB), vertical sleeve gastrectomy (VSG), and biliopancreatic diversion (BPD) [9], upon each of the major CV risk factors.

55.2 Weight Loss Following Bariatric Surgery

The extent of weight loss following bariatric surgery varies between different procedures. Much is known about early weight loss outcomes after bariatric surgery; however, the durability of weight loss is not well established for all procedures due to the lack of long term follow-up data [10]. Weight loss after bariatric surgery is usually presented in the surgical literature as percentage of excess body weight loss (%EBWL), rather than the more intuitive percentage total body weight loss (%BWL). For the purposes of this review, it is easier to use %EBWL to compare studies. In terms of short-term outcomes, %EBWL is highest after BPD with an average of approximately 70 %, followed by RYGB and VSG, which produce similar early %EBWL of 55–65 % [4, 10]. AGB may result in a mean %EBWL of approximately 50 % [11, 12].

The trajectory of weight loss also differs with different types of operations. RYGB, VSG, and BPD result in rapid weight loss reaching a nadir around 18 months postoperatively. AGB induces slower weight reduction, with continued losses occurring up to 3 years postoperatively [10]. Table 55.1 summarizes differential weight loss outcomes over time following bariatric surgery.

While most procedures seem to result in sustained weight loss, many patients experience some recidivism over time, and about 10–20 % of patients experience significant weight regain with long term follow-up [2, 13]. After RYGB, weight regain may begin after the second postoperative year, although most patients appear to stabilize over time [2]. Less data are available for VSG, but observational data suggest that the majority of patients regain weight after 2 years [14, 15]. Current data regarding weight regain after bariatric surgery is insufficient, due to a paucity of studies reporting long term outcomes, related at least in part to high attrition rates. Factors that may predispose patients to postoperative weight regain can be divided into biological factors affecting patient behavior and procedure-specific factors. Some factors that have been highlighted are: (a) loss of reduction in appetite causing dietary non-compliance (in particular "grazing" behavior that involves eating small amounts of food steadily over prolonged periods), (b) persistent or incident disordered eating related to altered central appetite and reward processing, and (c) patients' inability to increase physical activity [13].

In some studies, AGB has been associated with higher rates of weight regain than other bariatric procedures. After AGB, the most common procedure-specific causes of weight regain are band slippage, explantation, and gastric pouch dilatation, which can occur in up to 50 % of patients at around 4 years postoperatively, and may be prevented by meticulous follow-up and careful band management. Current best practice suggests the patient should be assessed every 4–6 weeks during the first year after AGB, then at 3–6 month intervals for 2 further years. Yearly assessments are recommended thereafter, provided the patient's weight and symptoms remain stable, and regular assessments must continue as long as the band remains in situ [11]. Symmetric gastric pouch dilatation (GPD) after AGB may be conservatively managed in the majority of patients, with temporary deflation, but persistent GPD or band slippage with weight regain usually requires surgical re-intervention [12, 16]. The role of gastric pouch and/or stoma dilatation in the pathogenesis of weight recidivism after RYGB remains controversial [17]. Gastro-gastric fistula is a cause of weight regain, occurring in 1–2 % of post-RYGB patients in recent series, and may indicate a previous subclinical leak, or marginal ulcer [18, 19]. Some reports patients with weight regain after VSG have higher rates of sleeve dilatation compared with patients who maintain their postoperative weight loss [13]. The mechanisms through which these changes are associated with weight regain are unclear. While some authors suggest that loss of a tight sleeve may alter food intake and satiety [13], it is possible that these anatomical features are secondary to an impaired perception of satiety, resulting in long term increased food intake and hence intra-sleeve pressure. This theory is potentially supported by the findings of Bohdjalian et al. who showed an inverse association between weight regain and ghrelin levels, albeit in a small group of patients, following VSG [15]. However ghrelin levels were not correlated with endoscopic findings in this study and at present the mechanisms underlying weight recidivism after bariatric surgery remain elusive.

Finally, weight loss after bariatric surgery comprises loss of fat, loss of bone mass, and loss of lean mass (about 5–30 % of initial lean body mass). While retention of lean body mass may be desirable, loss of lean body mass does not seem to result in differential changes in inflammation, insulin resistance or lipid disturbances, compared with those who retain lean body mass postoperatively. In fact, higher preoperative lean body mass has been shown to be the strongest predictor of lean body mass loss implying that body composition seems to equalize with less lean subjects after bariatric surgery [3]. The majority of body weight loss after bariatric surgery is due to loss of fat (approximately 15–30 %) [20].

55.3 Glycemic Control Following Bariatric Surgery

In addition to sustained weight loss, bariatric surgery can also significantly improve glycemic control, reduce the requirement for diabetes medications, induce remission of T2DM, and prevent the incidence of diabetes in baseline non-diabetic patients [21]. Improvements in glycemic control vary depending on the procedure, with BPD producing the most profound effects on glycemia, followed by RYGB, and VSG. The efficacy of AGB in the treatment of T2DM is significantly lower compared to other procedures. Reported rates of remission from diabetes vary in published literature for any given procedure, due to differences in definition of remission [22, 23], and as such data on remission of diabetes must be interpreted with some caution.

The effects of bariatric surgery on glycemic control have been best characterized following RYGB. RYGB results in remission from T2DM in approximately 40 % of patients in the short term [21, 24], but remission rates decrease over time with many patients subsequently relapsing over a 10–15 years follow-up period [25, 26]. Initial improvements in glycemia occur within days after RYGB and similar procedures, prior to significant weight loss [27, 28]. The weight loss-independent effects of RYGB on glucose metabolism, although controversial, have been a key driving force behind the investigation of postoperative changes in gut hormone and vagal signaling. It is hypothesized that initial improvements in glycemia after RYGB are partly mediated by increased glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP) secretion from enteroendocrine L- and K-cells, which is induced by rapid delivery of nutritious content into the small bowel [27]. Duodenal exclusion could also influence glycemic control, either by increasing bile acid absorption, or upregulating unknown factors, which could increase insulin secretion, increase hepatic insulin sensitivity, inhibit glucagon secretion, and stimulate satiety [27]. The endoscopically-placed endoluminal duodenojejunal liner can replicate some of the glycemic effects of RYGB [29]. In the medium to long term, the role of gut hormone signaling may be overshadowed by improved peripheral insulin sensitivity that occurs secondary to sustained weight loss. These mechanisms are further discussed in Chap. 54.

Short-term outcomes are similar with both VSG and RYGB in terms of remission of T2DM [30, 31]. However, there is a paucity of data on the long term durability of remission of T2DM after VSG. It is noteworthy that the exaggerated postprandial gut hormone response is similar among patients post RYGB and VSG at 3–4 years postoperatively [30].

An initial improvement in T2DM is observed in up to 80 % of patients who undergo AGB, with many patients achieving remission of disease at 1 year [4, 32]. Outcomes in terms of remission at 2 years vary widely across studies. However, the majority of studies reported significant improvement in glycemic control at 2 years [32]. Long term data for remission of T2DM after LAGB are less encouraging. Himpens et al. [33] showed that at 12 years after LAGB, several patients who did not have diabetes prior to surgery subsequently developed diabetes postoperatively, despite a mean 12-year %EBWL of 43 %. It should be noted that 50 % of patients in this study underwent band removal, and %EBWL was 48 % among those who remained banded at 12-year follow-up. Unfortunately, this study does not specifically report band-related outcomes for the diabetic patients within the cohort. Therefore, while AGB may induce remission of T2DM in some patients, and halt progression of abnormal glucose metabolism, the results are not enough to completely neutralize the high risk of progression to T2DM in this population.

In contrast, BPD results in the highest 1-year remission rate for patients with T2DM [4, 34], albeit at the expense of increased rates of postoperative nutritional deficiency. Additionally, diabetes remission after BPD appears to be constant at 10 years as demonstrated by Iaconelli et al. [34] In this study, mean glycated hemoglobin (HbA1c) levels dropped below 5 % at 1 year post BPD, and remained significantly lower than that in patients who were medically managed (control group) throughout the follow-up period.

Patients with more advanced diabetes preoperatively are at increased risk of postoperative relapse, presumably owing to impaired pancreatic β-cell function at the time of intervention. Higher preoperative HbA1c, preoperative insulin requirement, and time since diagnosis of T2DM are associated with increased risk of relapse [25, 30]. Patients who lose more weight postoperatively are less likely to experience relapse than those with a more modest weight reduction; and weight regain is associated with increased risk of relapse [30, 35]. Whether bariatric surgery can prevent progression to T2DM has recently been addressed in the SOS study. In this study, bariatric surgery reduced the incidence of T2DM by 96 %, 84 % and 78 % at 2, 10 and 15 years postoperatively [21]. Thus, although a significant proportion of patients with T2DM who initially achieve remission will subsequently relapse, the efficacy of bariatric surgery for the prevention of T2DM is clear.

55.4 Other Cardiovascular Risk Factors Following Bariatric Surgery

55.4.1 Changes in Lipid Metabolism

Bariatric surgery alters lipid metabolism, typically reducing triglyceride levels, increasing high-density lipoprotein (HDL) levels, and modestly reducing or causing no reductions in low-density lipoprotein (LDL) levels, with total cholesterol remaining relatively stable in both the short and long term [8]. The reduction in triglyceride levels appears to be associated with improved glycemic control, while the effect on HDL is unclear, but may be related to increased hepatic insulin sensitivity. Interestingly, deteriorations in lipid profile have not been observed following postoperative weight regain, implying that changes in lipid metabolism may occur through a weight-loss independent mechanism [36].

Unsurprisingly, BPD produces the greatest changes in lipid metabolism with a propensity for lowering total cholesterol, triglycerides and LDL. Increases in HDL after BPD are modest, with mean increases of about 0.07 mmol/L reported in the meta-analysis by Buchwald et al. [4] This study reported a 99.5 % rate of improvement of hyperlipidemia after BPD. RYGB has a similar, albeit less pronounced, effect producing significant reductions in triglycerides and modest increases in HDL [4]. VSG and RYGB have a similar effect on triglyceride levels. The SOS study reports greater increases in HDL levels after RYGB than banding.

55.4.2 Changes in Blood Pressure

While the effects of bariatric surgery on weight, glycemia and lipid metabolism are relatively well-established, postoperative changes in blood pressure are not well elucidated. Bariatric surgery results in overall improved rates, and in some cases resolution, of hypertension. Data suggest that BPD is most effective at normalizing blood pressure followed by RYGB and VSG. Proportionally, fewer patients experience resolution of hypertension after AGB, but improvements are seen in many [4].

In terms of the stability of blood pressure changes, the SOS study suggests that changes in both systolic blood pressure (SBP) and diastolic blood pressure (DBP) occur early after surgery, while only DBP shows significant improvements at 10 years [8]. While reductions in blood pressure were significantly higher in the surgery group than that in the control group in this study, overall reductions in blood pressure were modest. Indeed, the RYGB group in the SOS study demonstrated reductions in SBP and DBP of 4.7 and 10.4 mmHg, respectively, which were associated with increased urinary sodium excretion [37]. These changes were more pronounced than the changes in the much larger vertical banded gastroplasty and AGB groups [37]. As such current evidence suggests that while all procedures result in initial improvements in blood pressure, significant and sustained changes occur only after RYGB and BPD [34, 37].

55.4.3 Changes in Inflammation

The association between the metabolic syndrome, obesity, and inflammation is well documented with low-grade systemic inflammation due to the secretion of pro-inflammatory adipokines, thought to contribute to the pathogenesis of CV and renal pathologies in metabolically deranged obesity. Bariatric surgery attenuates low-grade systemic inflammation with sustained reductions in C-reactive protein and other inflammatory markers postoperatively [3, 38]. Increased production of the predominantly anti-inflammatory adiponectin, which is positively associated with insulin sensitivity, is also seen following bariatric surgery [36]. Reductions in systemic inflammation seem to occur as a result of massive weight loss, whether surgical or non-surgical and are possibly related to reduction in the total adipose tissue mass [36]. Whether changes in gut hormone signaling might further down-regulate systemic inflammation after RYGB, VSG, and BPD is yet to be established, but the anti-inflammatory effects of GLP-1 receptor agonists suggest that enhanced endogenous GLP-1 levels after some bariatric procedures may contribute to improvements in the inflammatory milieu.

55.4.4 Changes in Renal Function

Renal impairment is a recognized presentation of metabolic syndrome and is associated with increased mortality in the context of T2DM [39]. In addition, mild reduction in renal function is associated with increased CV morbidity and mortality [40]. There is increasing evidence indicating that bariatric surgery can prevent, halt and even reverse the progression of renal impairment secondary to obesity and T2DM [41–44]. The mechanism through which bariatric surgery ameliorates renal impairment remains unclear. It is possible that RYGB exerts its effects on the kidney through the combination of weight loss, improved glycemic control, normal blood pressure, reduced lipid levels, and reduction in systemic inflammation. A study by Seyfried et al. suggests that the effect of RYGB on renal damage is independent of weight loss, as demonstrated by early normalization of urinary pro-inflammatory cytokines preceding dramatic weight reduction [41]. Further exploration of the effects of bariatric surgery on renal impairment will help elucidate the cellular, molecular, and genetic mechanisms involved in the pathogenesis of renal injury in diabetes and obesity.

Conclusion

Obesity, T2DM, and metabolic syndrome are associated with excess CV morbidity and mortality. Bariatric surgery results in significant reductions in CV risk through weight loss, and improvements in glycemic control, hypertension, dyslipidemia, inflammation and renal impairment. Changes in CV risk factors after bariatric surgery result in a reduced 10-year CV-mortality risk, both predicted [38] and observed [8]; however, those with diabetes or pre-diabetes may benefit the most. BPD, RYGB, and VSG produce greater improvements in CV risk factors than AGB. In particular, achievement and maintenance of remission of T2DM are less frequent after AGB, compared with other procedures. Given the significant reduction in CV risk and mortality after bariatric surgery, reconsideration of current practice guidelines is required to optimize selection of patients at a risk of morbidity and mortality from CVD who, in turn, will benefit most from surgery.

Key Learning Points

- Bariatric surgery results in significant improvements in CV risk factors
- Bariatric surgery reduces long term overall and CV mortality
- The different bariatric procedures result in varying degrees of weight loss and weight recidivism
- Bariatric surgery can induce remission of T2DM, but many patients relapse over 10 years
- Bariatric surgery can prevent the development associated with T2DM
- Bariatric surgery can improve end organ damage of T2DM

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Resolution of Obesity Associated Comorbidities (Diabetes, Hypertension, Sleep Apnoea, and Metabolic Syndrome) Following Bariatric Surgery

56

Torsten Olbers and Suzanne Hedberg

Abstract

In modern medicine, one of the most exciting and unexpected findings is that a number of metabolic diseases appear to be effectively treated with gastro-intestinal surgery. Several publications over the last decades demonstrate profound effects, with improvements and even resolution of comorbidities in obese patients following bariatric surgery.

Further investigation shows that there appears to be substantial improvements in comorbidities, even when the patients treated have only modest obesity. This suggests weight-loss independent mechanisms, and that altering of the gut may thus be used to treat metabolic disorders, regardless of obesity. This has led to an increased interest in searching for the mechanisms of action to understand, and thereby find alternative ways to alter signaling from the gut, i.e., medicines and devices.

By using the term "metabolic surgery" we are addressing an aim beyond weight loss for patients suffering from diseases such as; type 2 diabetes mellitus, sleep apnea, hypertension and dyslipidemia. Interestingly, there are also recent data demonstrating a favorable impact on unexpected morbidities following bariatric surgery, including asthma, gout, and psoriasis as well as cancer in women.

In this chapter, we will strive to summarize the current evidence of the effects of bariatric and metabolic surgery on the metabolic comorbidities, namely type 2 diabetes mellitus, hypertension, sleep apnea and the metabolic syndrome.

Keywords

Obesity • Metabolic • Surgery • Bariatric • Type 2 diabetes • Hypertension • Obstructive sleep apnea • Metabolic syndrome

56.1 Introduction

Bariatric and metabolic surgeries not only reduce the weight of the patient but also seem to affect various comorbidities associated with obesity. In this chapter, we present the current evidence about the effects of bariatric and metabolic surgery on some of the obesity-associated comorbidities such as type 2 diabetes mellitus (T2DM), hypertension, sleep apnea, and the metabolic syndrome.

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56.2 Type 2 Diabetes Mellitus (T2DM)

There is a strong association between increasing body mass index (BMI) levels, secondary to increased body fat predominantly around visceral organs and the prevalence of T2DM. A strong contributing factor to the increased risk is a greater insulin resistance, which is associated

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with visceral adiposity. Until quite recently T2DM has been regarded as a progressive chronic disease that requires an escalation of medical treatment over time.

Already in 1984 Herbst et al. demonstrated positive effects on T2DM among bariatric patients [1]. The effect was mainly considered to be attributable to the weight loss, which was not farsighted as there was obviously a loss of visceral adipose tissue along with other regional fat stores and thereby reduction in insulin resistance.

In 1995 Pories et al. presented a seminal paper in Annals of Surgery with the provocative title- “Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus”[2]. The observation was that most patients with T2DM undergoing gastric bypass surgery improved. Actually it appeared, as the normal case was that T2DM went into remission and remained under control for long time.

Large studies assessing the impact of bariatric surgery on T2DM have subsequently demonstrated substantial positive effects. In the Swedish Obese Subjects study Sjöström et al. in 2004 could demonstrate that diabetes was effectively brought under control and effectively prevented by bariatric surgery [3]. Buchwald et al. demonstrated consistent results with improvements and reversal of diabetes after all variations of bariatric procedure, with gastric bypass and BPD being most effective [4].

Two randomized clinical trials between best medical therapy and bariatric surgery were published in the same issue of *New England Journal of Medicine* in 2012. The trials demonstrated superiority of bariatric surgery in terms of diabetes control after 1 and 2 years respectively. The Rome study, led by Dr. Mingrone, showed that, 75 % of patients with poorly controlled T2DM were in remission of their diabetes 2 years after Roux-en-Y gastric bypass (RYGB) surgery. In the intensely treated medical group, none of the patients were in remission. The results in patients undergoing biliopancreatic diversion (BPD) were even more spectacular, showing a 95 % resolution rate [5]. The other trial, led by Dr. Schauer, used somewhat different criteria for remission, showing a 42, 37, and 12 % remission rate in RYGB, vertical sleeve gastrectomy and intensively medically treated patients respectively [6].

Dixon et al. demonstrated that the remission rate of recently diagnosed T2DM with a BMI between 30 and 35 kg/m^2 was superior in patients treated with adjustable gastric banding compared to intense conventional treatment (73 vs. 13 %) [7]. In this study patients were recruited directly from the community.

A 2013 JAMA publication from a multicenter international consortium led by Dr. Ikramuddin demonstrated that in patients with poorly controlled T2DM and a BMI between 30 and 35 kg/m^2, the addition of RYGB to an intensive lifestyle intervention and medical treatment, was associated with a greater rate of reaching the primary composite end-point of metabolic normality (49 and 19 % respectively) [8]. We are awaiting results of long term follow up in this and other ongoing randomized trials having slightly different design and endpoints in patients with T2DM being randomized to intense medical treatment or bariatric surgery.

The protective effect for patients having undergone bariatric surgery against the risk of developing T2DM may be even more impressive. Another publication from the Swedish Obese Subject (SOS) study in *New England Journal of Medicine* 2012 Carlsson et al. demonstrated that the risk of developing T2DM was reduced by 78 % in pre-diabetics over a 10–15 years period [9].

Few studies address the outcome regarding hard end points such as macro- and micro-vascular complications in patients with T2DM after bariatric surgery. However, results from the SOS study indicate that the reduction in cardiovascular events in the bariatric group was related only with high baseline fasting insulin levels but not to the level of BMI [10], reinforcing the role of insulin resistance due to increased adiposity as a risk factor for cardio-vascular events rather than BMI, an indicator which is a ratio of weight to height rather than the state of adiposity.

The International Diabetes Federation recommends that metabolic surgery should be considered for diabetic patients with a BMI >35 kg/m^2 and suggests that surgery might be an option for diabetic patients with BMI 30–35 kg/m^2 that do not attain diabetic control with medical treatment [11].

56.3 Hypertension

There are relatively few studies concerning outcome of hypertension after bariatric surgery. However, most studies indicate improvements in systolic as well as in diastolic blood pressure after bariatric surgery. Methodologically, it is problematic to determine the true effect of surgery on blood pressure, as any improvement in blood pressure needs to be assessed with regard to medications used as well as to the surgery performed.

The bariatric procedure having the strongest documented impact on hypertension is the RYGB. In 2003 in *Annals of Surgery*, Sugerman et al. demonstrated that 51 % of the approximately 1000 patients included in their study had hypertension prior to RYGB [12]. They subsequently found a 69 % resolution of hypertension at 1 year and a 66 % resolution 5–7 years postoperatively, with the limitation of the study having a 50 % follow up rate. A cohort study from Adams et al. demonstrated a remission rate of hypertension of 53 % and 42 % after 2 and 6 years respectively following RYGB [13].

The overall long-term effect on hypertension was modest in the SOS study [3]. This study was, however, dominated by restrictive surgery. Significant improvements in both resolution and incidence of hypertension were demonstrated at 2 and 10 years after surgery, but in comparison to the effects on other cardio-vascular risk factors such as T2DM, the effects were limited. In a subgroup analysis study of SOS-data Hallersund et al. showed a weight independent reduction in blood pressure after RYGB but not after banding [14]. The significant effect on blood pressure after RYGB remained also after 10 years and was associated with a larger secretion of sodium and increased diuresis indicating a possible specific mechanism for lowering blood pressure after RYGB. This effect on blood pressure and urinary sodium secretion after RYGB has also been demonstrated in a rat model [15].

In the JAMA paper from the Longitudinal Assessment of Bariatric Surgery (LABS) consortium in 2013, Courcoulas et al. demonstrated a 38 % and 17 % remission rate of hypertension after 3 years following RYGB and gastric banding respectively [16]. However, there was also a substantial risk of newly onset hypertension over the 3 years (12 % after RYGB and 18 % after lap band surgery).

56.4 Sleep Apnea

Obstructive sleep apnea not only induces biological changes of intermittent hypoxia, intermittent hypercapnia and sympathetic activation but can also cause widespread metabolic dysregulation affecting multiple organs. Patients with sleep apnea are more predisposed to cardiovascular events, ischemic heart disease due to endothelial dysfunction, hypercoagulation and sympathetic system activation. Resolution of sleep apnea following bariatric surgery is associated with marked improvement in cardiovascular morbidity and mortality in addition to the quality of life of the patient.

The origin of sleep apnea is considered multi-factorial. There are weight related factors when excessive soft tissue in pharynx creates a blockage of the airways when relaxing during sleep. In severe cases, hypoventilation due to the weight of the body hinders respiration, especially when lying down (Pickwick syndrome). There are, however, most likely also effects on the respiratory center in the brainstem related to metabolic dysregulation, which in turn may also be related to obesity.

In a recent systematic review it was found that in 75 % of patients with sleep apnea had at least an improvement in their sleep apnea after bariatric surgery. BPD was the most successful procedure in improving or resolving obstructive sleep apnea, with laparoscopic adjustable gastric banding being the least. Improvements were seen regardless of the specific type of sleep apnea [17].

In a randomized controlled trial Dixon et al. assessed the outcome in sleep apnea between patients having conservative weight loss therapy or gastric banding surgery [18]. They demonstrated substantial improvements in both groups although there was a significant difference in weight loss (greater in surgical patients). There was a greater improvement in the surgically treated group. However, the difference regarding apnea-hypopnea index, which was the primary endpoint, did not reach statistical difference.

In the SOS study 1592 individuals completed a 2-year follow-up with sleep apnea symptom questionnaires. They could demonstrate that, compared with the conservatively treated control group, surgical patients reported significantly fewer symptoms of sleep apnea and a significant reduction in the persisting apnea episodes (27.9 % vs. 71.3 %) and snoring (21.6 % vs. 65.5 %) postoperatively [19].

Although the limitation that there is only one randomized controlled study comparing lifestyle changes and surgical weight loss that focuses on sleep apnea endpoints, we can conclude that there are improvements in apnea-hypopnea index in patients undergoing bariatric surgery. There is, however, a great heterogeneity in study outcomes, diagnostic criteria and selection for analysis of sleep apnea after bariatric surgery.

56.5 Metabolic Syndrome

The many differing definitions of the metabolic syndrome make it difficult to compare the outcome of studies. Nevertheless, the impressive improvement in a broad range of metabolic risk factors (mainly hypertension, impaired glycemic control, dyslipidemia and increased abdominal circumference) commonly seen after bariatric surgery may be the reason for the reduced mortality in surgically treated obese patients.

In the LABS cohort, approximately 80 % of patients undergoing bariatric surgery fulfilled the National Cholesterol Education Program criteria for the metabolic syndrome. The presence of metabolic syndrome did not in itself confer a higher risk for short-term perioperative complications [16].

A meta-analysis of randomized controlled studies by Gloy et al. in *British Medical Journal (BMJ)* 2013 show that the chance of obtaining remission of the metabolic syndrome after bariatric surgery was 2.4 times higher (RR 1.6–3.6) than with conservative treatment [20].

56.6 Mechanisms for Metabolic Improvements

The positive effects of weight loss on T2DM are well known. In addition to these, studies indicate that there are direct physiological effects, primarily after RYGB, leading to diabetes remission and control, suggesting effects that are weight loss neutral. Resolution of sleep apnea following bariatric surgeries and associated weight loss can be a major contributory factor as recent studies have shown that CPAP improves glycemic control in T2DM with sleep apnea.

Although the effects on diabetes are the best studied, there are substantial improvements in sleep apnea, hypertension, and hyperlipidemia as presented above. Studies also indicate positive effects regarding polycystic ovarian syndrome [21], asthma [22], psoriasis [23], pseudotumor cerebri [24], non-alcohol steatosis of hepatitis/non-alcohol fatty liver disease [25] and gout.

The cancer incidence is reduced by 50 % in women who have undergone bariatric surgery compared to controls. This appears to be true for all types of cancer, although the mechanism is largely unknown [26, 27].

The dominating part of improvements in metabolic diseases following bariatric surgery appears to be weight loss related. Bariatric surgery is from this viewpoint unique as it is the only treatment associated with long-term weight control. However, there may be some additive physiological effects not only secondary to weight loss and reduced caloric intake.

The mechanisms of action after RYGB surgery have shed light on the complexity of the interaction and signaling between the gut and the brain, also known as "the gut-brain axis." It would appear that surgery "resets" what the body believes to be the optimum weight, as if the surgery had "turned down the thermostat." This new "set-point" will strive to maintain a lower weight, but can be altered by surrounding factors, such as pregnancy. It is also safe to assume that it may be changeable by other factors of which we are not fully aware, and that the same factors that influence our original "set-point" may influence the new one (i.e., dieting, exercise etc.) [28].

Further studies of the mechanisms of action of the RYGB are interesting not only to understand better what surgery does, but also to eventually replicate these mechanisms in non-surgical treatments.

56.7 Future Directions

By introducing the concept of "metabolic surgery" we are clarifying that the goal of treatment should not focus on weight reduction in order to be slim but instead on being healthy.

In the future, we believe that gastro-intestinal surgery will be used specifically to treat various metabolic conditions. Emphasizing metabolic status and not only weight in choosing surgery will mean "metabolic surgery." From this aspect metabolic surgery for T2DM is already a reality. Patients undergoing metabolic surgery may not accept and tolerate negative side effects to the same extent as patients suffering from severe obesity.

In the future we envision the formation of metabolic clinics organized with collaboration between bariatric surgeons and physicians specialized in metabolic disorders. Collaborating physicians and surgeons could agree on which patients are the most suitable candidates for surgery and have a common strategy for follow-up. In a "metabolic clinic," patients with both weight problems and metabolic diseases can be managed together by physicians and surgeons, and deliver tailored interventions in order to give each patient a treatment that will benefit him or her most.

Key Learning Points

- The prevalence of metabolic diseases is strongly associated to increase in BMI.
- Bariatric surgery has a positive impact on metabolic conditions like diabetes type 2, hyperlipidemia, hypertension, sleep apnea and metabolic syndrome.
- Metabolic surgery, on the mildly or moderately obese, is associated with diabetes resolution, and provides a model for the future of metabolic surgery.
- Bariatric surgery is associated with decrease in overall mortality.
- Studies of the mechanism of action of bariatric surgery may lead to a greater understanding and, possibly eventually new non-surgical treatments.

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Metabolic Surgery for Type 2 Diabetes Mellitus in Patients with BMI <35 kg/m²

57

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Abstract

Bariatric surgery was initially developed as a tool for weight reduction only, but it is gaining increasing popularity because of its remarkable effect on glucose metabolism in morbidly obese and less obese patients. Recent publications have shown the superiority of metabolic surgery over medical treatment for diabetes, creating a new field of clinical research that is currently overflowing in the medical community with outstanding high quality data. Metabolic surgery is effective in treating diabetes, even in non-morbidly obese patients. In this chapter the authors present a review of the relative benefits and results associated with metabolic surgery for treating type 2 diabetes mellitus (T2DM) in patients with body mass index (BMI) below 35 kg/m².

Bariatric surgery, although developed primarily for weight reduction, has been gaining popularity due to its significant effect on plasma glucose levels and glucose metabolism both in morbidly obese as well as those with less obesity. Recent studies have proven the superiority of metabolic surgery in controlling blood sugar over medical treatment, thus paving way for further clinical research in this field especially when the medical community is overflowing with outstanding high quality data. Bariatric/metabolic surgery is effective in treating diabetes, not only in morbidly obese but also in non-morbidly obese patients.

Keywords

Type 2 diabetes mellitus • Metabolic surgery • Bariatric surgery • Obesity • Gastrointestinal surgery

57.1 Why Should We Address Low Body Mass Index Diabetic Patients?

It is estimated that 333 million individuals will be affected by type 2 diabetes mellitus (T2DM) by 2025. T2DM is a major cause of death in the United States given its relation to kidney failure, blindness, amputations, heart attacks, and other conditions such as erectile dysfunction and gastroparesis [1].

The therapeutic cornerstones for T2DM are dieting, exercise and medications. Long term success rates of lifestyle modifications can be disappointing, and despite new drug therapies continue to improve medical therapy for this disease, the majority of patients never reach the defined targets for success and are susceptible to the severe effects of this disease [1].

In cases where lifestyle interventions and medical treatment fail to promote adequate glycemic control, gastrointestinal surgery has been advocated as a powerful alternative in less obese patients, mainly due to previous experience with bariatric surgery and favorable outcomes in morbidly obese patients. However, this practice remains controversial.

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Bariatric surgery leads to significant weight loss and improvement of obesity related diseases in patients with body mass index (BMI) above 35 kg/m^2. In this population, procedures such as Roux-en-Y gastric bypass resulted in better glucose control and massive weight loss at 1 or 2 years when compared to clinical intervention. Approximately 80–85 % of morbidly obese patients who undergo bariatric surgery experience full remission of T2DM, lowering diabetes related deaths as well as overall mortality. Furthermore, metabolic amelioration occurs in a few days or weeks, long before significant weight loss, suggesting that the mechanisms behind such changes are independent of weight loss [2]. Metabolic surgery can be defined as any intervention over the gastrointestinal tract that can put under control glycemic and other metabolic syndrome components initially through weight independent mechanisms and weight loss.

Such encouraging results observed after bariatric surgery in diabetic morbidly obese patients, along with mounting evidence that surgery engages weight independent antidiabetic mechanisms, prompted considerations of these operations in less obese individuals with T2DM as well.

The majority of the T2DM persons fall in Class I obesity (BMI between 30 and 35 kg/m^2). Despite lifestyle modifications and pharmacotherapy, millions of obese people suffer from poorly controlled T2DM. Moreover, these group of patients do not satisfy the current criteria for bariatric surgery [1]. Additionally, the medical community is still skeptical when it comes to accepting surgery as a treatment modality for T2DM, particularly in less obese patients.

The full risk benefit ratio of surgical versus medical treatments for T2DM was not adequately ascertained until recently.

57.2 Results of Metabolic Surgery Over Glycemic Control in Low Body Mass Index Diabetic Patients

57.2.1 Laparoscopic Adjustable Gastric Banding (LAGB)

Dixon et al. published in 2008 a randomized controlled trial with 60 patients with early onset (less than 2 years) T2DM and a BMI range of 30–40 kg/m^2 assigned to medical/lifestyle treatment or LAGB plus conventional diabetes care [3]. After 24 months, T2DM remission, defined as fasting plasma glucose (FPG) level below 126 mg/dL and HbA1c less than 6.2 %, was observed in 73 % of patients in the LAGB groups while only 13 % in the purely medical group achieved remission. As expected after a pure restrictive procedure, weight loss was the major driver of glycemic improvement, since few participants achieved T2DM remission when loss in the body weight was less than 10 % of the initial weight. However, the efficacy of this procedure in achieving T2DM remission should be analyzed carefully because all patients in this study had early onset T2DM, were taking only oral antidiabetics, and were followed for a short time.

O'Brien et al. published a randomized controlled trial of 80 patients with a BMI of 30–35 kg/m^2 assigned to LAGB versus an intensive medical treatment intervention [4]. Although both groups lost similar amount of weight (13.8 %) by 6 months, the surgical group continued to lose weight during the following 18 months, while the medical treatment group regained much of the weight initially lost. Metabolic syndrome was initially present in 15 (38 %) patients in each group and was present in 8 (24 %) nonsurgical patients and 1 (3 %) surgical patient at the completion of the study.

57.2.2 Sleeve Gastrectomy (SG)

Recently, SG has been widely used as a standalone procedure for treating obesity, even in patients with T2DM. However, limited data regarding T2DM resolution with considerable time of follow up are available.

Many published studies verify the superiority of SG when compared with medical treatment and pure restrictive procedures, such as LAGB [3]. Indeed, there may be some hormonal background that underlies the early postoperative improvement in insulin sensitivity, but other confounding factors such as calorie restriction may play a role for improved metabolic outcome.

In a randomized controlled trial by Lee et al. compared the mini gastric bypass versus the sleeve gastrectomy, 47 % of poorly controlled diabetic patients with BMI between 30 and 25 kg/m^2 achieved T2DM remission of the 60 patients enrolled, all completed the 12-month follow-up. Remission of T2DM was achieved by 28 (93 %) in the gastric bypass group and 14 (47 %) in the sleeve gastrectomy group (remission defined as FPG less than 126 mg/dL and HbA1c more than 6.5 %, without any medication) [5]. Such patients were less likely to achieve T2DM remission when compared to gastric bypass, demonstrating an important role of duodenal exclusion in order to achieve better T2DM control.

57.2.3 Roux-en-Y Gastric Bypass

Roux-en-Y gastric bypass (RYGB) was first associated to T2DM remission in morbidly obese patients. Based on the favorable outcomes, some authors proposed this type of treatment for low BMI patients with uncontrolled T2DM, most surgeries performed under Internal Review Board protocols.

We recently published the largest and longest term study till date, examining the efficacy and safety of RYGB to treat uncontrolled T2DM in patients with class I obesity (BMI 30–25 kg/m^2). All patients had severe, long standing T2DM, with mean disease duration of 12.5 years and a mean HbA1c of 9.7 % despite insulin and/or oral antidiabetic medication use. In the follow up period of 6 (1–6) years, 88 % of patients achieved complete T2DM remission (HbA1c less than 6.5 %, without any antidiabetic medication), with improvement in an additional 11 % (HbA1c less than 7.0 %, under oral antidiabetic therapy). Moreover, postoperative changes in c-peptide and glucose response to test meals demonstrated improvement in beta-cell function, suggesting that RYGB can reverse the progressive beta-cell failure in diabetic patients.

Such results were accompanied by other significant improvements, such as substantial reductions in hypertension and dyslipidemia, yielding major improvements in predicted cardiovascular disease risk from fatal and nonfatal coronary heart disease and strokes. No mortality or significant surgical morbidity, excessive weight loss or malnutrition was observed in this series [1].

Lee et al. reported T2DM remission rate of 80 % (HbA1c less than 6.5 %) in 62 patients with a BMI of 23–35 kg/m^2 at 2 years of follow-up [6]. Mean HbA1c decreased from 9.7 to 5.9 %. The authors also documented a significant decrease in insulin resistance as measured by the homeostatic model assessment (HOMA) index and an increase in early insulin secretion, as determined by the insulinogenic index.

Shah et al. reported the effects of RYGB in 15 diabetic patients with a BMI of 22–35 kg/m^2 [7]. At 3 months and thereafter, 100 % were euglycemic and no longer required medication (mean HbA1c of 6.1 %). The predicted 10-year cardiovascular disease risk calculated by the United Kingdom Prospective Diabetes Study (UKPDS) risk engine decreased substantially for fatal and nonfatal coronary heart disease and stroke. There was no mortality, major surgical morbidity, or excessive weight loss.

Well designed randomized controlled trials (RCT) are required to provide additional data showing the benefits of metabolic surgery over conventional treatment. They are also required to test the efficacy and safety of metabolic surgery in treating low BMI diabetic patients.

Schauer et al. in a RCT not powered for lower BMIs (mean BMI of 37 kg/m^2, slightly higher than the upper limit of this chapter target population) showed better glycemic control and better weight loss in the surgical groups (RYGB and SG) than the medical group [8]. T2DM control, defined as HbA1c less than 6.0 % with or without medication, was achieved by 42 % of patients receiving gastric bypass and 37 % of patients receiving SG, compared with only 12 % of patients in the medical arm. Although the surgical arms had similar results on glycemic control, there was a potential trend toward better outcomes in the RYGB group. That was reflected by three times less use of antidiabetic medications in the RYGB group when compared to the SG one.

More recently, Kashyap et al. published an extended follow-up of 24 months of the previous study [9]. The authors report a more durable glycemic control in the RYGB group, with a substantially greater number of patients achieving HbA1c levels below 6.0 %, despite similar weight loss compared with SG group. Insulin sensitivity measured by the Matsuda index and insulin secretion determined by the insulinogenic index were both higher in the RYGB group. This adds another important piece of knowledge that backs up the importance of food rerouting metabolic procedures.

So far, many studies have observed that the remission rate of diabetes after RYGB in patients with low BMI is comparable to the reported rates of 80–85 % after RYGB in morbid obese diabetic patients. Similarly, RYGB in low BMI patients seems as safe as it is in more obese patients, and although excessive weight loss is a theoretical concern for less obese patients when undergoing weight loss surgery, it did not occur in any of the previous studies. It is our belief that RYGB for less obese diabetic patients is as efficient as or even more efficient than expected in morbid obese patients.

57.2.4 Biliopancreatic Diversion

Available data support that remission of metabolic complications is highest with biliopancreatic diversion (BPD), in morbidly obese patients. However, because of higher incidence of mid/long term nutritional complications with BPD, it has not gained too much acceptance as a treatment modality for low BMI diabetic patients. So far only two studies, evaluating the role of BPD in low BMI diabetic patients, have been published. Scopinaro et al. reported the outcomes of 30 diabetic patients with a mean BMI of 30.6 (25–35) kg/m^2 after BPD and found that 83 % reached an HbA1c less than 7 % without medication, while the remaining patients had improvement in their HbA1c levels [10]. No significant nutritional deficiencies were reported in the first 12 months, although a longer follow up in this type of patients should be attempted to identify potential severe nutritional complications.

Chiellini et al. reported the metabolic outcome of five diabetic patients with a mean BMI of 30.9 kg/m^2 after BPD. At 1 year, the HbA1c levels were reduced from 8.5 to 5.6 %. There was also a significant increase in insulin mediated glucose uptake as measured by euglycemic-hyperinsulinemic clamping, showing that the rapid postoperative remission of diabetes is primarily related to improved insulin sensitivity [11].

BPD seems to have a positive effect on glucose metabolism, even in patients with low BMI, without causing excessive weight loss. However, larger clinical studies are needed to verify the long-term efficacy and safety.

57.3 A Quick Note on Investigational Procedures

Based on the metabolic results following "traditional" operations, efforts were directed toward operations that reroute the food through the gastrointestinal tract, without creating significant restriction. These operations led to no or mild weight loss and followed some anatomical and pathophysiological patterns to achieve metabolic control in a population that in theory does not need massive weight loss. These procedures include ileal transposition and its variations, duodenal jejunal bypass with or without sleeve gastrectomy.

57.3.1 Ileal Transposition

Several ileal transposition (IT) techniques were developed: IT alone, IT with sleeve gastrectomy (IT+SG) and IT with sleeve gastrectomy and duodenal exclusion (IT+SG+DE).

In an RCT comparing IT+SG with IT+SG+DE, De Paula et al. found that both operations promoted significant T2DM remission however lower HbA1c levels were observed in the duodenal exclusion subtype of surgery [12]. They reported that foregut exclusion plays an important role in T2DM remission, as duodenal exclusion was the only variant between the two studied groups.

In a more recent report, the same author published the outcomes of 202 diabetic patients with a mean BMI of 29.7 kg/m^2 submitted to either procedure. Mortality rate was 1 %, and major complications occurred in 11.9 % of patients. Mean HbA1c decreased from 9.7 to 6.2 %, and 90 % of the patients had HbA1c less than 7 % at 39 months [13].

Although improvement in metabolic diseases has been reported following IT, complication rates are higher than those of other procedures and some of them are specific to this type of procedure, such as ischemia of the transposed ileum and higher incidences of intestinal obstruction due to internal hernias. Such complications lead to a higher mortality rate compared with standard bariatric procedures.

57.3.2 Duodenal Jejunal Bypass

The largest "classic duodenal jejunal bypass (DJB)" cohort was published in 2012 by Cohen et al., in which 36 nonmorbidly obese diabetic patients (mean BMI of 28.5 kg/m^2) were submitted to classic DJB [14]. We reported T2DM remission (HbA1c less than 7 % and FPG less than 126 mg/dL) in 40 % of patients at 1 year follow-up. There was no relation between the variation of BMI and the decrease of HbA1c. We further assessed ß [beta] cell response to oral glucose load and found that DJB improved beta cell function, although it did not normalize it. These findings suggest that altering the intestinal site of delivery of ingested nutrients has therapeutic effects, mainly when there is duodenal exclusion.

Conclusion

Every new T2DM treatment must be safe and effective. It must not only correct hyperglycemia, but also prevent or mitigate the complications of this chronic disease. The continuing morbidity and mortality in individuals with T2DM diabetes and lack of control of diabetes even with new medications is a sign that the best management in terms of maximizing metabolic control remains elusive. Given this scenario, the option of metabolic surgery must be considered in appropriately selected individuals. So far, while more data is needed to determine the place of metabolic surgery in lower BMIs, it is important to highlight that all operations should be done under internal Revue Boards investigational protocols.

Key Learning Points

- Bariatric surgery is a highly effective treatment for obesity and its related comorbities
- Some of the antidiabetic effects of metabolic procedures are weight loss-independent, prompting consideration for surgery in less obese diabetic patients
- Recent data from randomized controlled trials show that metabolic surgery is highly effective, with greater rates of diabetes remission when compared to medical therapy

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Ileal Interposition with Sleeve Gastrectomy for Type 2 Diabetes Mellitus and Metabolic Syndrome

58

Surendra M. Ugale and Alper Celik

Abstract

"Diabesity," ie a combination of type 2 diabetes mellitus (T2DM) and obesity, is increasing in epidemic proportions. Medical management of diabetes mellitus requires that patients remain compliant to their medication regimen and monitor the condition closely; patients are also required to make changes in lifestyle and diet. However, over time the pancreatic B cell function deteriorates and this leads to increased requirement of medications and may also lead to introduction of insulin based therapy. Laparoscopic ileal interposition (II) with sleeve gastrectomy (SG) is an evolving procedure that offers good control of type-2 diabetes and other metabolic derangements and also helps in weight reduction without causing significant malabsorption. In this chapter, the two versions of this procedure, jejunal (non-diverted) and duodenal (diverted) ileal interposition, along with patient selection criteria, mechanisms of action, postoperative care and follow up, and its advantages are described. This is a promising procedure for control of type 2 diabetes, hypertension, obesity, and associated metabolic abnormalities in obese but also in non-obese.

Keywords

Type-2 diabetes • Metabolic syndrome • Co-morbidities • Ileal interposition • GLP-1 • Incretins • Ileal brake • Remission

58.1 Introduction

The combination of type 2 diabetes mellitus (T2DM) and obesity—"Diabesity"—is increasing to epidemic proportions. In 2013, the estimated worldwide prevalence was 347 million, including 63.5 million in India. Effective medical management of diabetes mellitus requires changes in lifestyle and diet, coupled with good compliance with medication regimens and close monitoring. However over time, pancreatic B cell function deteriorates and this may lead to increased requirement of medications and introduction of insulin based therapy [1, 2].

Bariatric surgery performed as a treatment for morbid obesity is associated with improvements in blood glucose control and resolution of T2DM, along with significant weight loss. The mechanisms for these improvements are under investigation and include caloric restriction through behavioral and hormonal changes, alterations in gut hormone release and gastrointestinal physiology and through malabsorption [3]. For non-obese patients with T2DM, the standard bariatric techniques may not be applicable, given that malabsorption and significant weight loss is not a desired or acceptable side effect in this patient group.

In view of this, Aureo DePaula from Brazil pioneered the development of ileal interposition combined with a variable BMI adjusted sleeve gastrectomy in 2003 [4, 5]. This operation was devised particularly for patients with T2DM with a

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lower body mass index (BMI) in the non-morbidly obese (BMI less than 35 kg/m^2).

After the initial publication of successful outcomes in 2005, this procedure was also taken up in various centers worldwide. Moreover, extensive animal studies have been conducted in Cincinnati, USA to aide understanding. Studies have confirmed that ileal interposition with sleeve gastrectomy (II + SG) induces remission of T2DM in patients with BMI 23–34 kg/m^2, and is also effective in ameliorating other components of the metabolic syndrome [6–9].

58.2 Ileal Interposition with Sleeve Gastrectomy

Ileal interposition with variable sleeve involves transposing a 170 cm segment of terminal ileum to the jejunum or the duodenum, along with variable gastroplasty depending on the BMI of the patient (see Fig. 58.1).

There are two versions of the procedure:

- the jejunal ileal interposition with sleeve gastrectomy (JII + SG), when the ileal segment is interposed into the proximal jejunum, at 20–50 cm from ligament of Trietz, without any bowel exclusion
- the duodenal ileal interposition with sleeve gastrectomy (DII + SG) where the duodenum and proximal 50 cm of jejunum are excluded and bypassed [4, 6].

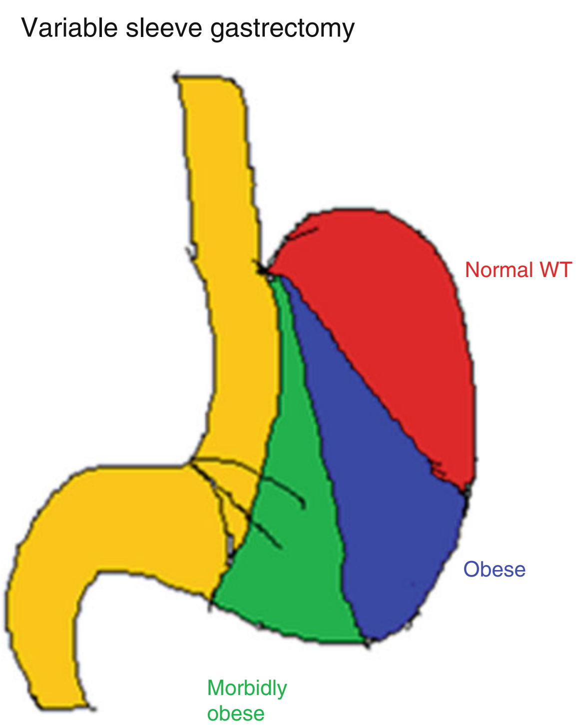

Fig. 58.1 BMI-adjusted sleeve gastrectomy

DePaula et al. reported the results of a randomized clinical trial (RCT), comparing these two versions and showed that DII + SG is more effective, even in severe disease [10].

58.2.1 Mechanisms of Action

The anatomical modifications after II + SG are thought to lead to resolution of T2DM through multiple actions, postulated in both foregut and hindgut theories [10]. Changes occur in gut microbiota, bile acid absorption and gut hormone release [11]. Increased post prandial glucagon like peptide-1 (GLP-1) release is thought to be a major factor responsible for the same (see Fig. 58.2) [12].

58.2.2 Selection of Patients

The indications for II + SG include

- Worsening T2DM of more than 1 year duration, with or without additional risk factors and comorbidities (microvascular or macrovascular complications)
- Diabetes with mild to moderate complications like nephropathy/retinopathy/nonhealing ulcers
- Diabetes with strong family history of complications
- Poor glycemic control despite optimum medical management
- Age between 20 and 70 years
- Stable weight for last 3 months (variation in weight less than 3 %)
- BMI more than 20 kg/m^2
- Fluctuating glycemic control with comorbidity despite good HbA1c levels
- Stimulated C-peptide level more than 1 ng/mL.

58.2.3 Exclusion Criteria

- Type 1 diabetes mellitus, latent autoimmune diabetes of adult (LADA) or maturity onset diabetes of the young (MODY) – through estimations of glutamic acid decarboxylase (GAD) antibody/islet cell antibody (ICA)/insulin auto-antibody (IAA2) and clinical course evaluation by the endocrinologists
- Undetectable fasting C-peptide and stimulated C-peptide less than 1 ng/mL
- Positive urine ketones
- Pregnancy
- Coexisting severe hepatic, pulmonary, renal (glomerular filtration rate (GFR) less than 30 mL/min), cardiovascular, neurological and psychiatric diseases

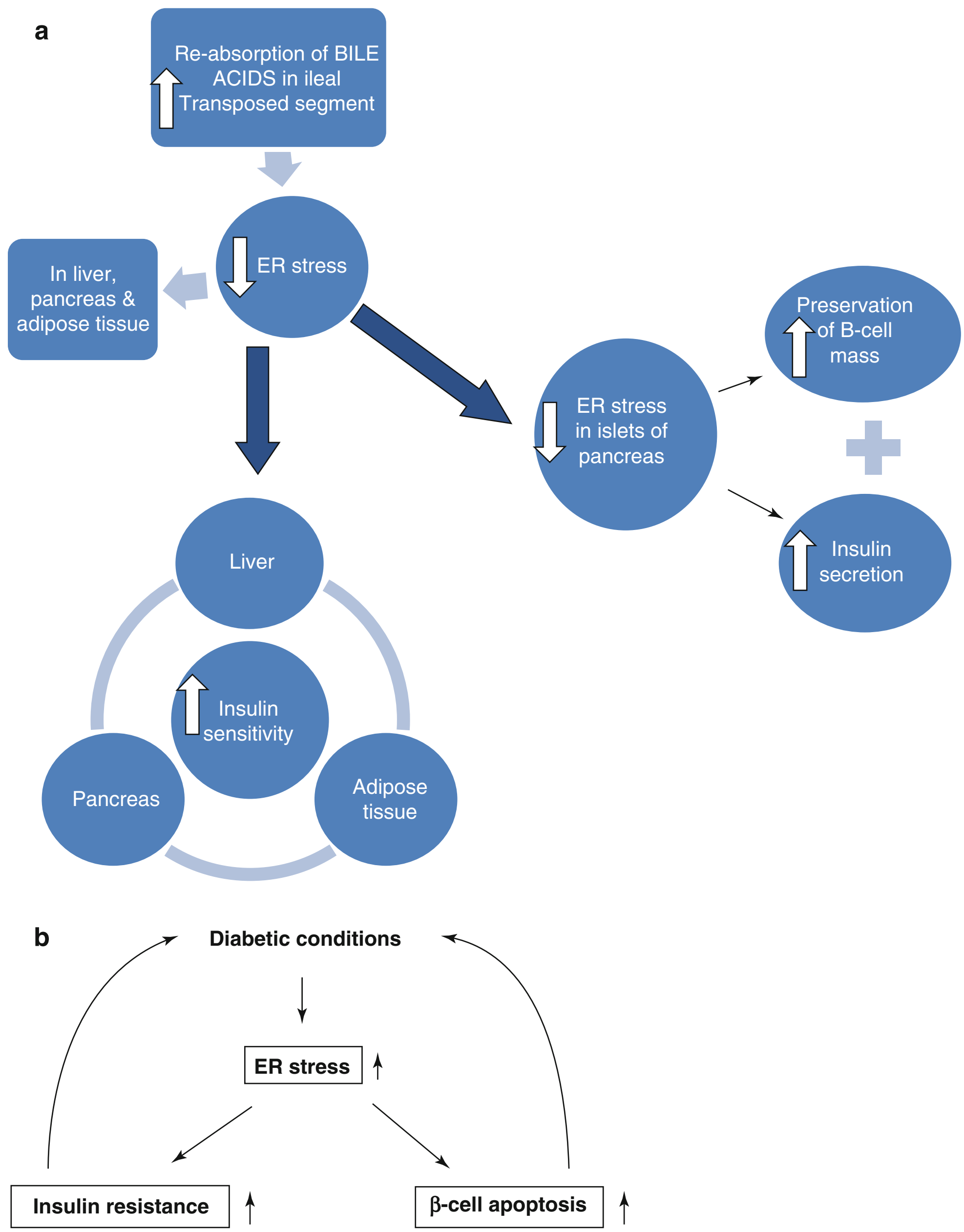

Fig. 58.2 (**a**) Major Role of the Transposed Ileal Segment – Reabsorption of Bile Acids causing Decreased Endoplasmic Reticulum Stress. (**b**) Continued Worsening of Diabetes due to Increased Endoplasmic Reticulum Stress

- Obesity due to organic illness
- Addiction to alcohol or illicit drugs

58.3 Preoperative Evaluation

Evaluation includes clinical history of T2DM, comorbidities and complications and thorough physical examination. Pancreatic B-cell function was estimated by measurement of serial serum C-peptide levels in response to a mixed meal test or OGTT, glucose load of 75 g. Patients with well-preserved B-cell function are more likely to benefit from surgery.

A 'Diabetes Severity and Remission Score' (DSRS) has been developed to determine which type of surgery was more likely to benefit the patient [13]. JII+SG was performed in patients with less severe disease and higher BMI, while DII+SG was used for those with higher DSRS and lower BMI (Table 58.1).

58.4 Procedure

These operations can be performed totally laparoscopically, by a hybrid method or by combining laparoscopic and robotic surgery. When introducing the technique, the hybrid operation may be employed (laparoscopic sleeve gastrectomy, followed by small bowel surgery by mini-laparotomy). This allows the surgeon to understand the anatomical changes

Table 58.1 Diabetes severity & remission score

	Score	
Parameters	1	2
Age (years)	30–60	>60 or <30
BMI (kg/m^2)	>27	≤27
Duration of diabetes (years)	<10	≥10
Microvascular involvement (Nephro/retino/neuropathy)	Absent	Present
Macrovascular involvement (Cardio/cerebro/peripheral vascular)	Absent	Present
Mandatory insulin usage	No	Yes
Stimulated C-peptide (ng/ml)	≥4	<4

Grading of diabetic severity
Grade I diabetes if total score is 7–8
Grade II = 9–11
Grade III Severe diabetes if total score is 12–14

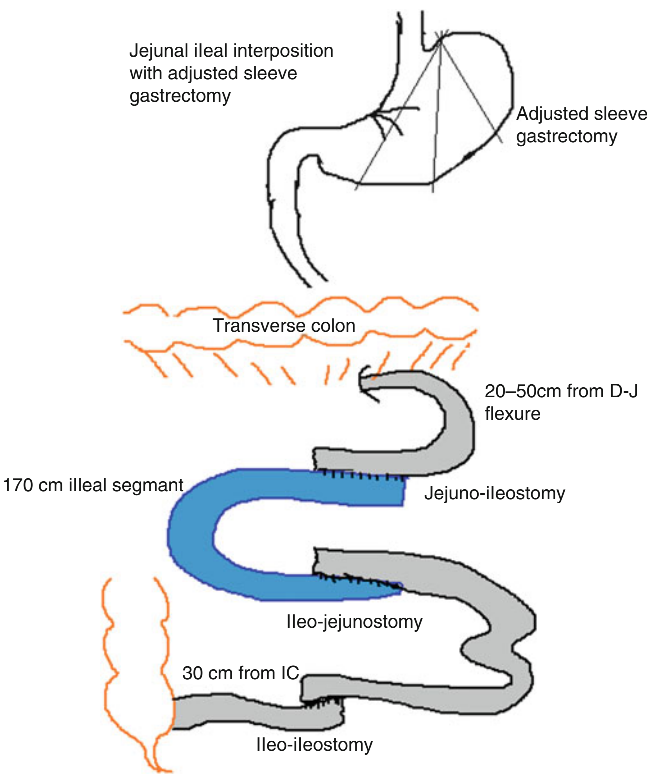

Fig. 58.3 Jejunal ileal interposition with sleeve gastrectomy

more clearly, including the nature of the mesenteric defects created during ileal interposition which must be closed after each anastomosis.

The operation is performed under general anesthesia with a standard six port laparoscopic technique. Once the greater omentum is disconnected from the greater curve of stomach, from antrum to fundus, a variable sleeve gastrectomy, adjusted to the BMI, is performed first (see Fig. 58.3, which depicts diagrammatic representation of the procedure)

58.4.1 Jejunal Ileal Interposition (Non-Diverted) with Variable Sleeve Gastrectomy

1. Sleeve gastrectomy is followed by staple line reinforcement with continuous sutures of 3-0 polydiaxanone, or reinforcement, with glue.
2. Transection of jejunum between 20 and 50 cm from ligament of Trietz with suture marking of the proximal and distal margins for identification. If BMI is more than 35, transection is done at 50 cm, to give a greater ileal brake effect, for better weight control.
3. Second small bowel transection at 30 cm proximal to ileo-caecal valve (ICV), with sufficient division of mesentery for freedom of movement for a relaxed anastomosis, with marking of the transected ends.
4. Third transection at 200 cm proximal to ICV, creating the ileal segment of 170 cm. The ileal segment is run through to reconfirm correct placement of marking sutures and also the base of mesentery is checked to ensure it is broad-based with good vascular supply for the whole segment (see Video 58.1).
5. Distal anastomosis is created first (ileo-ileal) to reestablish continuity, with endostapler using white 45 mm cartridge, and 3-0 polydiaxanone single layer suture closure for the stapler opening. The mesenteric gap is closed with 3-0 polypropylene interrupted sutures (see Videos 58.2 and 58.3).
6. The second anastomosis is the proximal one (jejuno-ileal) and is performed as above.
7. The third anastomosis (ileo-jejunal), in similar fashion, is made after retracing the bowel to confirm the appropriate limbs.
8. After hemostasis is secured, the resected gastric tissue is removed. Drain placement is at the surgeon's discretion.

58.4.2 Duodenal Ileal Interposition (Diverted) with Variable Sleeve Gastrectomy

In this technique the duodenum is transected 3–4 cm distal to pylorus, and the ileal segment is interposed from that point, to 50 cm distal to D-J flexure, so that food bypasses the duodenum and proximal jejunum (Fig. 58.4).

1. The lumen of the stomach is cannulated with a 36–60 French calibrator. Non-obese patients undergo fundectomy, leaving a good volume of residual stomach. Division of the greater omentum along the greater curvature of the stomach is continued onto the duodenum, 3–4 cm beyond the pylorus.
2. After posterior duodenal dissection is done, identifying the gastro-duodenal artery and pancreatic tissue, the

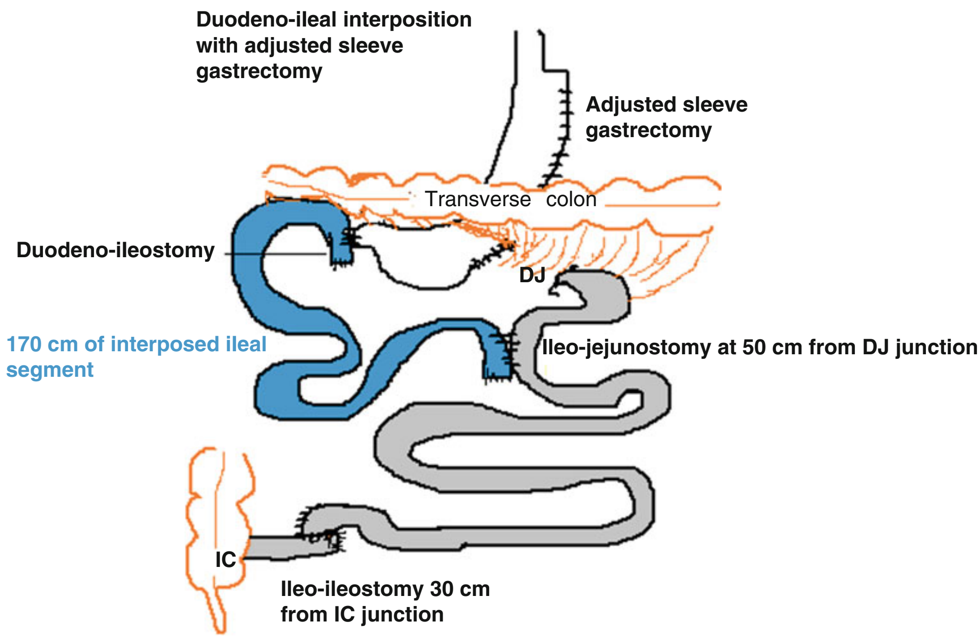

Fig. 58.4 Duodenal ileal interposition with sleeve gastrectomy

duodenum is transected using a linear stapler usually with articulation. The gastric sleeve and proximal duodenum are then transposed to the lower abdomen through an opening created at the root of mesocolon (see Videos 58.4 and 58.5), after dividing the gastro-hepatic attachments.
3. A distal ileal segment of 170 cm is created.
4. Continuity of small bowel is restored by ileo-ileal anastomosis.
5. The proximal end of the transected ileal segment is interposed and anastomosed in iso-peristaltic manner, to the proximal duodenum. This anastomosis is done end-to-side in one or two layers using intracorporeal suturing with 3-0 polydiaxonone (see Videos 58.6 and 58.7).
6. A point in the jejunum, at 50 cm from the ligament of Treitz is measured, and anastomosed to the distal part of the interposed ileum, in a side to side fashion, using stapler and 3-0 polydiaxonone sutures (see Video 58.8).
7. All anastomoses are performed functionally using linear staplers with care taken to close the mesenteric defects using interrupted 3-0 polypropylene sutures (see Video 58.9).
8. Since the endoscopic access to the bile duct is lost, a concomitant cholecystectomy is always done if gallstones are present (even if they are asymptomatic) or whenever signs of cholecystitis are seen, and also for all patients from non-urban areas; this makes up 40–80 % of the patients.
9. The 10 and 12 mm trocar openings are closed with 1-0 polydiaxonone sutures using a suture passing instrument, after removing the gastric specimen ± the gallbladder, and placing a flat penrose drain along the sleeve and the duodenal stump.

58.5 Postoperative Regimen

Postoperatively, the plasma glucose levels are to be measured three hourly, with insulin used according to sliding scale. The patients are kept on a liquid diet, started 24–36 h after surgery, for 5–7 days. This is followed by semisolid diet for another 7 days, and finally a solid diet. The patients are discharged between the third and fifth postoperative day with vitamin supplements including B1, B12, D, high protein drinks and calcium and iron supplements. Upper gastrointestinal endoscopy is performed for patients with symptoms of dysphagia to check for gastric stricture. Routine follow up visits, including clinical and laboratory evaluation, are scheduled at 1, 3, 6, 9 and 12 months and every 6 months thereafter and following parameters checked:

- Fasting and postprandial glucose
- HbA1c
- diabetes medication usage (agents, doses and frequency)
- weight loss (expressed in BMI and percentage of weight loss), and
- resolution or improvement of associated metabolic abnormalities and complications.

In addition screening test for malabsorption including estimation of iron (serum ferritin, total body stores, saturation), vitamin B12, proteins with liver function tests, serum parathormone (PTH), vitamin D3 and calcium are also performed at 3 monthly intervals.

58.6 Results from Our Series (of 490 Patients Operated in India and Istanbul; 10.2 % Had Jejunal II and 89.8 % Underwent Duodenal II)

Within our two centers a total of 490 patients underwent surgery between February 2008 and December 2013. The mean age of the patients was 43.5 years, and the mean BMI was 29.5 and 63 % of patients had BMI less than 35. The mean duration of diabetes prior to surgery was 9.5 years and the mean preoperative HbA1c was 9.8 %. The duration of operation ranged from 240 to 360 min while duration of hospital stay was between 4 and 6 days. Patients were followed up for 10–72 months, with a mean of 24 months; complete remission, HbA1c less than 6 without any medication, was achieved in 72 % of the cases, while partial remission, HbA1c <6.5 % without any medication, was achieved in 81.5 % of the patients. Mean weight loss was 23.5 % (18–28 %). Resolution of hypertension was seen in 92.5 % (blood pressure less than 130/80 mmHg), dyslipidemia in 89.5 % and microalbuminuria in 80 %. At 2 years mean fall in HbA1c (26.5 %) was more than the reduction in BMI (21 %; range between 15 and 25 %).

58.7 Complications (Encountered in Our Series of 490 Patients)

The major problems were food intolerance, with difficulty in drinking liquids or eating solids (e.g. water, rice, spicy foods), food getting stuck at mid-chest level, dislike for some food items or vomiting after any intake, was seen in 12 % and diarrhea and abdominal pain seen in 4 %. Total complication rate in this series of patients was 7.75 %, 38 out of 490, and mortality rate from procedure was 0.2 %.

58.7.1 Postoperative Problems

58.7.1.1 During Hospital Stay

During the hospital stay, anastomotic leaks occurred in five patients from either the ileo-ileal (four patients) or the ileo-jejunal (one patient) anastomosis (they were all reoperated and the leaks were sutured laparoscopically). Bile leak from duodenal stump occurred in two patients and was managed conservatively. Four patients had intra-luminal bleeding with malena – all settled completely with transfusions and conservative treatment. Three patients had intra-peritoneal bleed; they were re-operated successfully – 1 re-laparoscopy and 2 had laparotomy. One patient underwent a diagnostic laparoscopy for abdominal pain on fourth postoperative day (POD), which was negative; this same patient underwent laparotomy 3 days later, as X-ray showed free gas under diaphragm, wherein an ileal perforation was found proximal to a loop adherent to uterine fundus and this was sutured followed by uneventful recovery. Intraabdominal abscess seen in one patient was treated with percutaneous drainage; there were two patients with wound infections which were treated with dressings and one patient developed atelectasis which was managed with Continuous Positive Airway Pressure (CPAP), mucolytics and pulmonary physiotherapy.

58.7.1.2 After Discharge

The major reason for readmission was food intolerance (manifested as poor intake, vomiting, weakness, rapid weight loss) in 26 patients, or diarrhea and abdominal pain. All were given parenteral nutrition for 1–2 days, mostly daycare, ± antibiotics and probiotics, and they all improved.

Abdominal exploration (laparoscopic/open) was done for recurrent abdominal pain; ventral incisional hernia; gastric stasis following only ileal interposition without a sleeve gastrectomy (he developed repeated vomiting, which did not settle with conservative treatment and so a sleeve gastrectomy was added after 2 weeks). Anastomotic ulcer, (duodeno-ileal), was seen in a smoker and it healed with medication and stoppage of smoking. Gallstones in 46 patients and renal stones in two patients (treated with calcium citrate to prevent further oxalate stone formation) were also encountered. Coronary stenting, tuberculosis, esophageal fungal infection and postoperative depression were the other complications seen.

Procedure related mortality took place in one patient who developed biliary peritonitis and sepsis due to leak from the ileo-jejunal anastomosis; the other causes that resulted in mortality were diarrhea with poor intake and anuria leading to metabolic acidosis in two patients while severe urinary tract infection leading to septicemia lead to death in one patient

Recurrence of diabetes after complete remission occurred in six patients and four patients had to resume insulin, after 1 year of stopping it.

58.8 Nutritional Stability

All patients were given supplements for 6 months postoperatively and subsequently only if there was a deficiency, which was quite rare to find and required in 15 patients. There is minimal/no malabsorption after this procedure. It is postulated that jejunalization of interposed ileum occurs, where the absorption is enhanced for all nutrients (there is hypertrophy of the mucosal absorptive surface along with an increase of GLP-2, as an adaptive response), while the enteroendocrine function is retained (Table 58.2).

58.9 Long Term Results

The biliopancreatic diversion with duodenal switch (BPD-DS) gives the highest remission of diabetes, even in the long term of more than 10 years (excluding the very severe diabetics), with a recurrence rate of 5–10 % [14].

With gastric bypass, recurrence of diabetes, in comparable groups, is between 30 and 45 % within 5 years; [15, 16] for the sleeve gastrectomy it is between 50 and 55 %; in the other procedures it is still not documented clearly.

With ileal interposition, our 5 year follow up appears to indicate a recurrence rate of less than two percent.

Studies confirm that ileal interposition with sleeve gastrectomy (II+SG) induces remission of T2DM in most patients, even with a BMI between 23 and 34 kg/m^2, and is effective in ameliorating other components of the metabolic syndrome [6–9].

DePaula et al. reported the results of a randomized clinical trial (RCT), comparing these two versions and showed that DII+SG is more effective, even in severe disease [10] (Tables 58.3 and 58.4).

Table 58.2 Nutritional Stability at 1 year post-surgery (without supplements)

Nutritional data	Pre-op	Post-op
Total proteins	7.03 ± 0.48	6.46 ± 0.69
Se albumin	4.4 ± 0.35	3.69 ± 0.55
Se calcium	9.42 ± 0.63	9.4 ± 1.03
Vit D	17.49 ± 14.65	20.33 ± 13.8
Vit B-12	430.2 ± 183.2	413.9 ± 209.9
Se iron	98.55 ± 55.6	82.47 ± 47.6

58.10 Advantages of Ileal Interposition

In the nonobese T2DM, insulin resistance is not essential to the development of diabetes, implying an essential role for impaired insulin secretion. This operation re-regulates the body's own mechanism in such a way that more insulin is produced in the body at the required time, in conjunction with food intake, so as to mimic the normal pattern of insulin secretion. This is achieved through GLP-1 from the ileum; this mechanism is still intact in these diabetics. The proportionate incretin response does not cause post prandial hypoglycemia. Hence, this operation would be effective in type 2 diabetics with enough pancreatic B-cell reserve.

The transposed segment retains its ability to absorb nutrients, in fact some report an increase in absorbance capacity; this helps to ensure nutritional stability, which is a great

Table 58.4 Comparison with other procedures

Procedure	Remission [partial] of diabetes (%) [HbA1c <6.5 without medication]
Adjustable gastric banding	40–50
Sleeve gastrectomy	50–70
Roux-en-Y gastric bypass	50–90
Biliopancreatic diversion/ duodenal switch	90–98
Ileal interposition with sleeve gastrectomy	70–90
Sleeve with duodenojejunal bypass	25–70
Minigastric bypass	80–90
Gastric plication	Uncertain

Refs. [11, 17, 18]

Table 58.3 Comparison of results from different centers

Published data	2-Center Ugale & Celik	Tinoco	Aureo DePaula	Ramen Goel	Kota & Ugale
Number of patients	490	30	454	5	43
Gender ratio (male/female)	320/170	10/20	322/132	2/3	25/18
Mean age (years)	43.5	49.7 ± 8.9	53.6	47.4	47.2
Mean BMI	29.5	30.8 ± 5.1	29.7	29.4	33.2
Duration (years)	9.5	9.9 ± 4.4	10.8	8.4	10.1
HbA1c	9.8	9.5 ± 1.7	8.8	9.6	9.6
Follow up (months)	24	13.0 ± 3.3	39.2	6	20.2
Complete remission (%)	72		60.1		
Partial remission (%)	81.5	80	86.4	80	78.6
Mean weight loss (kg)	23.5			23.2	22.5 %
Hospital stay (days)	5	3.17 ± 0.79	3.3	8.33	4.1
HbA1c		6.2 ± 0.8	6.2	6.22	6.4
Remission HTN	92.5		87.5	100	90
Remission dyslipidemia	89.5		87		
Remission microalbuminuria	80		71.1		

BMI body mass index, *HTN* hypertension advantage as compared with other bariatric procedures. Since the main emphasis is on the ileal interposition and not the sleeve, the preserved gastric volume can be tailored according to the BMI; hence lower BMI patients can have a good capacity of stomach. It is important to note that any procedure causing increased GLP-1 will require a gastric resection, to prevent gastric stasis which is caused by GLP-1; hence the ileal interposition should not be done alone, without at least an adjusted sleeve gastrectomy.

58.11 Future Trends

It is likely in the future that greater utilization of procedures, which combine the advantages of different mechanisms, to address all the different pathophysiological aspects of a complex disease like diabetes, are more likely to be used. While extensive research goes on to find easier solutions to treat type 2 diabetes (including stem cells and pancreatic transplantation), the surgical trends may shift more towards least malabsorptive with better efficacy; procedures relying on mechanical restriction partly or primarily, which seem to have higher recurrences, may be replaced by those with mainly functional restriction (through better hormonal action and feedback) [12].

Key Learning Points

- This procedure is another modification of gastrointestinal anatomy, resulting in multiple metabolic benefits
- Duodenal (Diverted) Ileal Interposition with a BMI-adjusted Sleeve Gastrectomy is a very effective metabolic procedure where malabsorption/malnutrition is minimal or absent
- This operation combines the advantages of the Sleeve with that of the Ileal transposition
- It is a challenging procedure, but technically feasible, with morbidity and mortality comparable to other bariatric procedures; it is seemingly very effective even in severe diabetes and the only hope for lower BMI diabetics at present

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Section XII

Training, Reporting, and Practice in Bariatric Surgery

Honorary Section Editor - Nagammapudur S. Balaji

Over the past two decades the field of bariatric and metabolic surgery has seen significant advances in the aspects of technical innovations and in understanding of the physiological basis of disease and how different treatment work.

Parallel to the above developments, we have witnessed the formation and establishment of professional organizations around the world in the field of Bariatric and metabolic surgery. They have lead the way in making an attempt to set standards of practice and form guidelines for training and research which serve as a quality control/improvement check posts to ensure safety and quality of care to patients. The ASMBS and IFSO have both individually and collaboratively spearheaded these initiatives globally. "Centre of excellence" programs and pre-requisites for accreditation to centres worldwide have been developed and evolved over the past decade. The BOMSS in the UK has been equally active and contributory in the development of practice and training guidelines that are easily extendable beyond the UK.

Emergence of national and organizational registries from across continents has shed light on the epidemiology and prevalence of different surgical approaches and their results on the global epidemic of Obesity and the associated metabolic syndrome.

Over the same period hand locked with the innovations and advances mentioned above, the medicolegal aspects of surgical treatment of obesity and the metabolic syndrome has also been of increasing importance which is not surprising at all.

Hence it was felt appropriate that a dedicated section be allocated to the non-clinical aspects of equal importance.

Mr Hewin in his chapter has given a broad overview of the training guidelines that have been adopted in the UK, USA and Europe based on the recommendations from the BOMSS, ASMBS and IFSO. He also highlights the facilities, opportunities and the available methods for training for trainees to pursue while embarking on a career in the specialty.

Dr Mellisas and his team have summarized the guidelines, and requirements for a centre of excellence program accreditation from the IFSO that is globally recognized with specific focus in Europe – (EAC – BS) (European Accreditation council) for Bariatric surgery.

Dr Saber and Dr Hutcher detail the requirements for the establishment and accreditation to obtaining recognition as a centre of excellence based on the previous Surgical research corporation (SRC) and ASMBS initiative and the recently joint initiative from the ASMBS and American College of surgeons (ACS) – MBSAQIP (Metabolic and Bariatric surgery accreditation and quality improvement program).

Mr. Welbourn and Mr. Singhal with their experience in the establishment of the NBSR registry in the UK have highlighted the importance, information gained and limitations of large registries in the UK, USA and Europe.

Mr. Reddy and Mr. Khan who have an extensive background in medical law explore the medicolegal aspects to which the bariatric surgeon is increasingly faced. They highlight the current and potential future medicolegal issues with some advice on avoiding these pitfalls.

We profoundly thank all the contributors for their expertise and time spent to building this very important non-clinical surgical section for the bariatric surgeon.

59 Training in Bariatric Surgery

David F. Hewin

Abstract

This chapter describes the current status of postgraduate training in bariatric surgery in the United Kingdom and United States. Resources available for training are discussed including the variety of practical courses, the range of simulation techniques, web-based and e-learning facilities, and preceptorships.

Keywords

Bariatric surgery training • ISCP • Courses • Fellowships • Simulation

59.1 Introduction

The provision of bariatric surgery services requires the surgeon to develop multidisciplinary skills. Technical ability, specialist knowledge, communication skills, and team working are all essential qualities of a bariatric surgeon. Although these are characteristics that any surgeon must possess, these must be developed to the highest standards, in order for a surgeon to lead an effective bariatric surgery multidisciplinary team. The National Institute for Health and Care Excellence (NICE) [1] have specified:

> The surgeon in the multidisciplinary team should have undertaken a relevant supervised training programme, have specialist experience in bariatric surgery and be willing to submit data for a national clinical audit scheme.

Traditional surgical training followed an apprenticeship model, where a junior surgeon worked as part of a surgical firm, led by one or two consultants, and developed skills through observation, practice and one-to-one tuition in the operating theatre and clinic. At the end of an often long period of training, the trainee surgeon would appear in an exit exam and become a fully qualified "General Surgeon."

The development of sub-specialization in surgery, together with changes in working time practices, educational theory and the recognition of the inefficiencies of the old system has led to a dramatic change in the way surgeons are trained. A junior surgeon now can expect to undergo multiple assessments of performance with a range of educational tools in a structured, well-defined training program. Continuous review of progress, formalized teaching and a defined career path form the characteristics of a modern training program, at the end of which a surgeon may undergo further sub-specialist training after appointment as part of a team of surgeons providing a specialist service.

59.2 Training in Bariatric Surgery in the UK

Bariatric surgery is now recognized as a subspecialty of upper gastrointestinal (GI) surgery with a dedicated national organization, the British Obesity and Metabolic Surgery Society (BOMSS), as well as a representation in the Association of the Upper GI Surgeons and the Association of Laparoscopic Surgeons. These organizations provide a national forum for bariatric surgery research and training and an advisory role for organizations such as the Department of Health.

The intercollegiate surgical curriculum program (ISCP) [2] recognizes bariatric surgery and includes aspects of bariatric surgery in the curriculum. Junior surgeons must

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Table 59.1 UK Bariatric and metabolic surgery fellowships

North Tyneside Hospital, Northumbria
Sunderland Royal Hospital, Sunderland
Luton and Dunstable Hospital, Luton
Imperial Weight Centre, Imperial College Healthcare NHS Trust, London
University College Hospital, London
Musgrove Park Hospital, Taunton
Countess of Chester Hospitals NHS Foundation Trust, Chester
Aintree University Hospitals NHS Foundation Trust, Liverpool

complete this in order to achieve a certificate of completion of specialist training. However, specific dedicated training in bariatric surgery is often sporadic and dependent on the particular interests of the surgical unit.

Bariatric surgery training can be classified according to the level of the trainee:

1. Basic training, undertaken by all general surgery trainees.
2. Specialist training only undertaken by those trainees who have particular interest in upper GI surgery and who have specified that bariatric surgery will be part of their consultant surgical practice.
3. Post-Certificate of Completion of Specialty Training (CCST) training which comprises fellowships in recognized centers of excellence (Table 59.1). The latter training is normally performed at a consultant or senior trainee level as a final step in training before independent practice. The current steps in training were outlined in an article published in the journal BMJ Careers [3].

BOMSS have produced a Professional Standards document which specifies the characteristics of a bariatric surgeon in the UK (Table 59.2) [4].

Surgical training has traditionally followed an apprenticeship model, whereby a trainee surgeon would observe and be taught surgical techniques and patient management by direct observation and supervised teaching in a clinical setting. While this is still largely the case, training methods have been supplemented by a range of formal educational training tools and a specified curriculum. Thus the extent and range of knowledge of a surgical trainee at each stage in the training program is now prescribed by the Joint Committee on Surgical Training (JCST) [5] which is an advisory body to the four Royal Colleges of Surgery of the UK and Ireland. The content of the curriculum is specified in the ISCP [2]. Continuous assessment of training occurs through workplace based assessments (WPBAs). The WPBAs consist of Case-based Discussions (CBD), Multisource Feedback (MSF), Clinical Evaluation Exercises (CEX), Procedure-based Assessment (PBA) and Direct Observation of Procedural Skills (DOPS).

Table 59.2 British obesity and metabolic surgery society professional standards

Perform at least 40 bariatric cases per annum
Be able to offer patients a range of procedures, including gastric banding, Roux en Y gastric bypass and Sleeve Gastrectomy according to individual patient's needs and circumstances
Be adequately trained and experienced in the recognition and management of bariatric surgery complications
Be able to carry out revisional bariatric surgery
Be involved in the training of less-experienced bariatric surgeons and trainees
Be committed to multidisciplinary team working with other healthcare professionals to best meet the needs of individual patients
Be committed to the long-term follow-up of his/her patients
Maintain a log of procedures, results and complication rates, ideally via a dedicated Bariatric database, preferably the National Bariatric Surgery Registry (NBSR)
Regularly audit their individual and Unit's/Centre's results
Be an active member of a Specialist Bariatric Professional Society, preferably BOMSS
Have appropriate certification to perform General Surgery (CCT) and have had training in Upper Gastrointestinal, Laparoscopic and Emergency surgery
Have completed a period of participatory training at a bariatric institution (not simply observing surgery)
Have testimonials by mentors/proctors of satisfactory bariatric training
Have a log book/maintain a database (preferably the NBSR) of bariatric cases during training
It is recognised and recommended that for a surgical trainee an additional (post-CCT) fellowship for 6 or 12 months in a specialist bariatric unit or centre may be the best way of achieving the above skills and experience skills for independent bariatric surgical practice, e.g. those accredited by the Royal College of Surgeons according to the ISCP

In General Surgery, the latest version of the curriculum was published in 2013 [2] and for the first time, specifically details knowledge, clinical skills, and technical skills required by all general surgical trainees at an intermediate level and by those with a declared interest in Upper GI Surgery at an advanced level (Table 59.3).

59.3 Training in Bariatric Surgery in the USA

Bariatric surgery is seen in the USA as a growing subspecialty of minimally invasive-laparoscopic surgery [6]. Although, it is recognized + that laparoscopic bariatric procedures are some of the most technically challenging operations, it is also clear that exposure of residents to bariatric surgery varies depending on the particular training program. The American Board of Surgery requires an experience of a minimum number of basic (60) and advanced (25)

Table 59.3 Intercollegiate surgical curriculum programme—morbid obesity—basic level

Objective
Basic management of the patient who is morbidly obese and an understanding of the surgical treatment of morbid obesity including early and late complications. A knowledge of the different patterns of presentations complications
Indications for surgery in morbid obesity
Therapeutic options for morbid obesity. Types of operations performed
General principles of the management of the obese patient perioperatively
Long term management of the bariatric patient post surgery
Clinical skills
History and examination of the obese patient
Assessment of the post operative bariatric patient
Interpretation of Investigations in the obese patient
Management decisions for early and late complications of morbid obesity
Technical skills
(Strongly recommended as an area in which simulation should be used to develop relevant skills)
Laparoscopic access in the morbidly obese
(Desirable as an area in which simulation should be used to develop relevant skills)
Aspiration of lap band port
Emergency release of lap band for slippage
Insertion of lap band
Repair of internal hernia after gastric bypass
Roux en Y gastric bypass
Revisional gastric surgery for obesity
General surgery for the super morbidly obese patient

Table 59.4 Fellowship council accreditation guidelines and definitions

Bariatrics A Bariatric Fellowship provides exclusively or predominantly bariatric surgical training. The institution sponsoring the fellowship must be certified as a Center of Excellence by either the American Society for Metabolic and Bariatric Surgery (ASMBS) or the American College of Surgeons (ACS), or be actively engaged in the application process. Fellows finishing bariatric fellowships should have completed the minimum number of cases required to allow them to be "certified" as bariatric surgeons at the completion of their training. Current ASMBS guidelines require a minimum of 100 cases with 51 as primary surgeon, and must include a combination of restrictive procedures (bands and sleeves) and malabsorptive procedures. In addition, fellows must have demonstrable experience in the pre-operative evaluation and assessment as well as postoperative follow up and assessment of patients
Advanced MIS/Bariatric An Advanced MIS/Bariatric fellowship consists of a mixture of bariatric surgery training and broad advanced MIS training. In order to be dually accredited as an MIS/Bariatric program, the bariatric experience must meet the requirements for a pure bariatric fellowship (See guidelines for *Bariatrics*), and must also provide exposure to broad-based advanced MIS training as evidenced by performance of an additional 150 advanced MIS cases. Basic MIS procedures do not count towards these minimum requirements, and these excluded procedures include laparoscopic cholecystectomy, appendectomy, and diagnostic laparoscopy; and ventral hernias should not represent a preponderance of the cases. Single incision, robotic, or NOTES basic MIS procedures as defined above will be counted as advanced MIS procedures and should be identified accordingly in the case log system. Credit for minimally invasive bariatric procedures is allowed for up to 50 of these required 150 procedures — thus the minimum total number of cases required for Advanced MIS/Bariatric accreditation ranges from 200 to 250 bariatric and/or advanced MIS cases

laparoscopic procedures [7]. The advanced procedures do not specify particular bariatric procedures, but these are included with other advanced laparoscopic cases in the minimum number. Several publications, however have suggested that the learning curve for an operation such as gastric bypass is 75–100 cases as the primary surgeon [8, 9]. This kind of experience can only be obtained in a fellowship within a busy dedicated bariatric surgery unit. Many insurance companies require surgeons and hospitals providing bariatric surgery to obtain Centre of Excellence accreditation for coverage and reimbursement.

In order to obtain a bariatric fellowship, it is necessary for a trainee surgeon to complete a general surgery residency program. The Minimally Invasive Surgery MIS fellowship council provokes high quality fellowship training in minimally invasive surgery including bariatric surgery. They are more than 130 program in the US which have received accreditation from this council [10]. These programs range from those that with little or no bariatric training through to those that are considered advanced bariatric fellowships. Most of these fellowships are of 1 year duration. The characteristics of bariatric and advance bariatric fellowships are outlined in Table 59.4. At present, there is no board certification in bariatric surgery. As in the UK, there are professional societies dedicated to the promotion of bariatric surgery. These include the American Society for Metabolic and Bariatric Surgery (ASMBS) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).

59.4 Facilities for Training in Bariatric Surgery in the UK and Europe

59.4.1 Practical Courses

The requirement for training in advanced laparoscopic techniques, an understanding of multidisciplinary team working and complex decision making skills has resulted in the development of a range of practical courses for both surgeons and non-surgical members of the bariatric Multidisciplinary team MDT.

Some courses are sponsored by the industry, such as the Surgery for Obesity—Registrar Training and Educational

Development (SORTED) course in the UK.[11] This modular course consists of lectures, practical skills, wet lab, and animal model simulation. It is aimed at the bariatric surgery trainee in the final years of training. Many other courses are provided by large dedicated laparoscopic training centers such as Institute de Recherche contre les Cancers de l'Appareil Digestif (IRCAD) in Strasbourg, as part of their advanced laparoscopic surgery portfolio.

The Royal College of Surgery of England (RCS) recognized the need for the provision of training in bariatric surgery and in 2011, appointed the first Specialty Tutor in Bariatric Surgery to develop courses and training at the college in London. In collaboration with the Specialty Tutor in Minimally Invasive Surgery, the RCS provides courses in basic and advanced laparoscopic skills, in the care of the gastric band patient, in practical gastric band follow up and in gastric bypass surgery techniques.

Several large laparoscopic/bariatric centers in the UK provide a range of courses aimed at trainees and consultants wanting to develop their bariatric surgical skills.

In addition to the courses mentioned above, the three national organizations associated with bariatric surgery BOMSS, the Association of Upper Gastrointestinal Surgeons (AUGIS), and the Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI) provide training days attached to their annual scientific meetings, which include practical skills training, as well as lectures, mock viva voce, and interactive discussions. These training days include bariatric surgery exclusively (BOMSS) or as part of a wider program of education (AUGIS, ALSGBI).

59.4.2 Simulation

Laparoscopic surgery is ideally suited for training through simulation, both in reality and virtual. All bariatric surgery trainees will experience simulation training at some stage in their training program and the increasing refinement of optical technology as well as virtual reality platforms has resulted in a vast range of simulation techniques available to the trainee.

59.4.2.1 Animal Tissue (Wet Lab) Models

Following basic laparoscopic skills training on dry (black box) models (Fig. 59.1), the simplest form of practical bariatric surgical skills training using tissue involves the use of wet labs, in which animal organs (esophagus, stomach, and small bowel) are operated on by the trainee using normal instruments, laparoscopes, cameras, and monitors. Such models allow dissection techniques, anastomoses, stapling techniques, and suturing to be practiced on real tissue.

Fig. 59.1 "Black box" laparoscopic training model. Pyxus Pro. Image courtesy of Inovus Surgical Solutions, St Helens, UK

59.4.2.2 Human Cadaveric Models

The next step towards an accurate reproduction of reality is the use of human cadavers to allow trainees to perform actual bariatric operations on human tissue. The accurate reproduction of organ size, anatomical relationships, and tissue handling characteristics allows a realistic representation of the operative environment. This lends itself to specific procedure based training on a one-to-one basis with the trainer. The development of tissue preserving techniques such as fresh freezing has, in recent years, allowed a degree of realism and tissue handling previously unknown with chemical preservation methods. Several anatomical science centers in the UK now have fresh frozen cadaveric facilities and provide a range of bariatric surgery courses.

59.4.2.3 Live Animal Models

Operative surgery training on live animals is forbidden by the law in UK but there are many centers in the rest of Europe which provide training on live anaesthetized animals, particularly pigs. While lacking the anatomical reality of human cadaveric models, the live animal provides a more realistic environment with respiratory and cardiac movement, arterial pulsation, and bleeding. It is possible for the trainee sequentially to perform gastric band placement, gastric band removal, sleeve gastrectomy and gastric bypass on this model.

59.4.2.4 Virtual Reality Models

The development of computer simulation has led to a range of laparoscopic virtual reality training tools. These allow precise measurement and analysis of movement, pressure and timing.

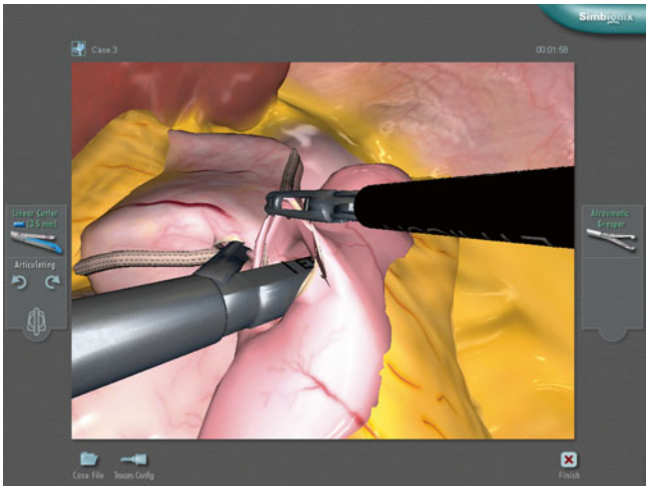

Fig. 59.2 Virtual reality gastric bypass simulation. Image courtesy of 3D Systems Inc, Airport City, Israel

The most sophisticated models provide a virtual reality reconstruction of the laparoscopic view, together with haptic feedback through the instruments. Procedure specific modules have been developed to allow trainees to practice the sequence of steps involved in a range of operations, including bariatric procedures (Fig. 59.2). The digital platform allows a high degree of interaction between the operator and computer system. Thus, it is possible to pause and save part way through a procedure, to replay and undo previous movements, to compare performances and to offer a score of parts or all of the performance, giving an objective measurement of performance and progression (Fig. 59.3) [12].

59.4.3 Webbased Study and E-Learning

The use of webbased training programs has developed considerably over recent years. These programmes allow remote access to online training courses and resources for bariatric surgery training. Courses may result in the award of certification in some aspect of bariatric patient management. They often form part of a bigger course including practical skills training. A fee may be charged for course enrolment or they may be sponsored by industry. Examples of such resources are given in Table 59.5.

59.4.4 Preceptorships

It is recognized that limitations on trainee working hours, together with relatively small numbers of centers offering training in advanced bariatric surgery means that many trainees who reach completion of their specialist training in upper GI surgery will not have the experience to start a practice in

Fig. 59.3 Advanced virtual reality laparoscopic simulator. Image courtesy of 3D Systems Inc, Airport City, Israel

Table 59.5 Web-based courses in bariatric surgery

IASO- International Association for the Study of Obesity. SCOPE-Specialist Certification of Obesity Professional Education http://www.iaso.org/scope/
WebSurg http://www.websurg.com/
ASMBS – Certified Bariatric Nurse (CBN®) Online Review Course http://asmbs.org/cbn-program/
SAGES Webinars http://www.sages.org/residents_courses/free_courses/
SAGES postgraduate courses: complications in bariatric surgery and how to manage them https://cine-med.com/index.php?id=MS1113
MedScape bariatric surgery CME learning centre http://www.medscape.org/resource/bariatric-surgery/cme

bariatric surgery independently. This is also true of consultant surgeons wishing to introduce bariatric surgery into their practice. To address this issue post-certification fellowships in bariatric surgery have been developed, alongside the concept of preceptorships. The principle of such preceptorships is that an experienced surgeon (the preceptor) acts as a mentor to the trainee or inexperienced surgeon (the preceptee) who visits the home unit of the preceptor to perform a number of cases under the preceptor's direct supervision. The preceptor then visits the preceptee's unit to supervise the preceptee performing a number of operations in their home environment. After completion of this program the preceptor "signs off" the preceptee as capable of performing that operation independently to an acceptable standard. This concept of supervised final training and certification is endorsed by the major bariatric surgery organizations worldwide (including BOMSS, IFSO and ASMBS)

59.5 Conclusions and Future Training

The rise of bariatric surgery as a major surgical subspecialty has occurred rapidly and with minimal regulation. The worldwide epidemic of morbid obesity and associated comorbidity has led to increasing demands for bariatric surgery services. Concurrently with this rise in demand, there has been the recognition that traditional methods of surgical training are no longer fit for the purpose. The reduction in training hours, the demand for increased productivity, the advances in technology, and the ever-increasing demand for surgical interventions have resulted in the need for focused, streamlined training using a range of existing and novel training opportunities.[13] The national organizations involved in bariatric surgery together with the Colleges of Surgery will need to coordinate training programs to satisfy the needs of bariatric surgery patients.

Key Learning Points

- Bariatric surgery training involves the development of advanced laparoscopic and multidisciplinary team working skills.
- These skills are usually acquired in post-basic training fellowships provided by bariatric surgery centers of excellence.
- The standards and characteristics of an accredited bariatric surgeon are described by national specialist organizations.
- Many postgraduate courses offer a range of training opportunities in bariatric surgery.
- A range of training techniques, especially simulation, are used to develop bariatric surgical skills.

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Bariatric Surgery Data Management and Reporting Worldwide

60

Rishi Singhal and Richard Welbourn

Abstract

The prevalence of overweight and obesity is increasing globally. The total number of bariatric procedures being performed worldwide has increased exponentially. There is an increasing need to develop strategies for effective data collection and analysis to provide benchmarks for surgical outcomes and reassurance for patients. Clinical registries serve as a portal that can facilitate this process.

In this chapter, we discuss the importance of clinical registry and how a registry can be set up. We review the pitfalls in registry-based data and the lessons learnt from previous or historical bariatric registries.

Keywords

Registry • Data management • National Bariatric Surgery Registry (NBSR) • Clinical registry

60.1 Introduction

Evidence-based practice is defined as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research" [1]. Evidence in different forms has thus led to many of the changes in practice of medicine that we see today.

For many disease processes and interventions, national and international registries have evolved as a preferred means of collecting data that contribute to this evidence. Clinical registries can be defined as "prospective, observational cohort study of patients with a particular disease and/or receiving a particular treatment/intervention" [2]. Registries thus provide a long-term opportunity to generate important disease-based and treatment-based information. As the available infrastructure for information technology develops, together with increasing demand for quality improvement and transparency, analysis of the data by statistical techniques can thus change the basis of surgery [3].

Clinical registries are considered the gold standard of observational data [4] although by their nature, they are inferior to randomized clinical trial (RCT) data, systematic reviews or meta-analyses. One of the main advantages of RCT data over registry data is that confounding variables that might lead to biased treatment effects have been formally accounted for by randomization.

60.2 Advantages and Lessons Learnt from Using Registries

One of the earliest registries in the management of obesity was the International (formerly National) Bariatric Surgery Registry that began collecting data in January 1986. It was created by Dr Edward Mason in the United States of America, and was active from 1986 to 2001. It contained data on 38,000

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patients with a 30-day mortality rate of 0.24 % [5]. One of the first reports from this registry confirmed that the increasing weight of candidates for surgical treatment mandated earlier use of operative treatment before irreversible complications of obesity could develop. It further confirmed that the risk of obesity surgery was low and there was good evidence towards decreasing postoperative hospital stay. These impressive findings contributed to the evidence supporting the development and expansion of bariatric surgery [6].

Despite the increase in availability of bariatric surgery there are very few reports of long-term follow up. Published follow up reports after bariatric surgery are at best inadequate. A report by Higa et al. in 2011 confirmed that despite all reasonable attempts to make contact, only seven percent of patients were available to have their data recorded at 10 years after gastric bypass [7]. Similar follow up rates have been recorded from various units internationally. One of the aims of a registry therefore is to bridge the gap between good practice and good data maintenance. Not all good databases, however, have originated from registries. One of the best follow up programs in bariatric surgery is not based on a registry. O'Brien et al. recently published their 10 year series of over 3,000 gastric banding patients in which they achieved follow up in 81 % [8]. The collection of follow up data into registries, if appropriately funded, resourced and optimized could provide invaluable globally relevant data. There is a golden opportunity for publicly funded health services to collect such data. The example of cancer registries, where the infrastructure to collect basic observational data on quality of services is deeply embedded, is an obvious parallel. In contrast, it probably will always be especially challenging for countries that do not have publicly funded health services to collect registry-level data on bariatric surgery.

One of the mechanisms by which worldwide data collaboration can drive changes in practice is the generation of research questions that can lead to a better understanding of the problems based on the information obtained from the registries. Buchwald et al. published a review of the trends in bariatric surgery worldwide in 2011 [9]. This review identified the total number of bariatric procedures upto 2011 as 340,768 and the total global number of metabolic/bariatric surgeons as 6,705. The most commonly performed procedures were Roux-en-Y gastric bypass (RYGB) 46.6 %; sleeve gastrectomy (SG) 27.8 %; adjustable gastric banding (AGB) 17.8 %; and biliopancreatic diversion/duodenal switch (BPD/DS) 2.2 %. However, a limitation of this type of review is the lack of data on variables such as patient body mass index (BMI) ranges, sex, age and co-morbidities—data that can greatly affect the choice of procedure and the outcomes. For instance the burden of comorbidity between different bariatric surgery populations and the types of operations done for comorbidities such as type 2 diabetes are unknown. Such data can only be reliably obtained from an international collaborative registry.

60.3 The 'Hawthorne' Effect

The Hawthorne effect is a form of reactivity whereby subjects improve or modify an aspect of their behavior, which is being experimentally measured, in response to the fact that they know that they are being studied [10, 11]. Henry A. Landsberger, in 1950, coined the term Hawthorne effect [12] when he was analyzing older experiments from 1924 to 1932 at the Hawthorne Works (a Western Electric factory outside Chicago). The original purpose of the experiments was to study the effects of physical conditions on productivity. They were conducted for the most part under the supervision of Elton Mayo, an Australian-born sociologist who eventually became a professor of industrial research at Harvard.

Two groups of workers in the Hawthorne factory were used as guinea pigs. One day the lighting in the work area for one group was improved dramatically while the other group's lighting remained unchanged. The researchers were surprised to find that the productivity of the workers who had better lighting increased much more than that of the control group. The employees' working conditions were changed in other ways too (their working hours, rest breaks and others), and in all cases their productivity improved when a change was made. Indeed, their productivity even improved when the lights were dimmed again. Although at the end of the experiment everything had been returned to the way it was before the changes had begun, productivity at the factory was at its highest level and absenteeism had plummeted.

The experimenters concluded that it was not the changes in physical conditions that were affecting the workers' productivity. Instead, it was the act of active observation that was responsible for the reported changes. Thus, in the context of registries, it is assumed that widespread adoption of data collection can encourage a higher level of effort from all personnel involved, thus potentially improving the overall results and the quality of the service provided.

60.4 Current National Bariatric Surgery Registries

60.4.1 Bariatric Outcomes Longitudinal Database (BOLD)

As a result of a previous collaboration with the American Society for Metabolic and Bariatric Surgery, the Surgical Review Corporation developed the Bariatric Outcomes Longitudinal Database (BOLD) [5], to provide observational data as a part of center of excellence initiative, with the intention to improve and optimize bariatric surgical care. The BOLD bariatric database is the world's largest and most comprehensive repository of clinical bariatric surgery patient information, with data from more than 500,000 patients.

60.4.2 Michigan Bariatric Surgery Collaborative

Since this initiative was set up in 2006 [13], rates of venous thromboembolism have reduced by half. According to Blue Cross Blue Shield of Michigan actuaries, quality improvement in bariatric surgery saved Michigan payers $15 million between 2008 and 2010. This is an excellent example of changes in practice driven by a system of data collection in which there is independent verification of data entry and accuracy.

60.4.3 Scandinavian Obesity Surgery Register (SOReg)

Scandinavian Obesity Surgery Register: SOReg was first proposed by Hedenbro in 2000. It was ready for data entry trials in 2004 and became fully functional in 2007. Since then, the registry has recorded over 35,000 cases from over 40 centers in Sweden and Norway, and collects data on more than 9,000 annual procedures.

60.4.4 Ontario Obesity Bariatric Registry

The Ontario-based Bariatric Registry project aims to improve the care of the obese patients and increase the effectiveness of health care dollars. It consists of creation of a centralized referral process, to collect standard referral data on all patients, and direct their referral to their nearest bariatric center.

60.4.5 Italian National Registry

The Italian registry is one of the largest bariatric registries in the world. A study of data from an Italian national registry of 13,871 morbidly obese adults who underwent bariatric surgery between 1996 and 2006 demonstrated that the type of procedure significantly influenced mortality risk [14]. The risk ranged from 0.1 % for adjustable gastric banding to 0.8 % for biliopancreatic diversion.

60.4.6 Europe

In Europe there are several examples of national registries with limited follow up data. The International Federation of Surgery for Obesity (IFSO) European Chapter has also set up a Centre of Excellence program with a linked registry—the IBAR (International Bariatric Registry).

60.4.7 National Bariatric Surgery Registry (NBSR-UK)

The National Bariatric Surgery Registry was the result of a collaboration between Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI), Association of Upper Gastrointestinal Surgery (AUGIS), British Obesity & Metabolic Surgery Society (BOMSS), and Dendrite Clinical Systems Ltd. The key objective of the registry was to accumulate sufficient data to allow the publication of a comprehensive report on outcomes following bariatric surgery. This would include reportage on weight loss, co-morbidity and improvement of quality of life. The NBSR was set up in 2009 and by the ending of the year 2013 approximately 33,000 patient records have been accumulated. The first report of the surgeon-anonymized outcomes of over 8,000 patients was published in April 2011 [15].

60.5 Registries in Other Specialties

The Society for Cardiothoracic Surgery in Great Britain & Ireland has been actively involved in collecting, analyzing and benchmarking the data since 1977, and has been recognized as an international leader in this field; having published data down to individual surgeon level since 2005. Intermittent comprehensive reports of trends and outcomes in cardiac surgery (The Blue Books) are also published. The most recent Blue Book (Demonstrating Quality) was published in 2009.

On a Europe-wide level, the European database project was established in 2003 to collect, merge, and present cardiac surgical data throughout Europe. Over the last 10 years, the contributors towards this database have increased from 12 countries to 29 countries with over one million patient records.

60.6 Setting up a Clinical Registry and Sensitivities of Data Ownership

Information governance is the framework that brings together all the legal rules, guidance and best practice to ensure that the personal information is collected and stored safely. Thus an understanding of information governance is paramount before establishing any clinical registry. The European Data Protection Directive [16] regulates the transfer of personal data from an EU member state to a third country that has an adequate level of data protection. Understanding of these directives is essential when setting up an international registry.

Since a large number of organizations are usually involved in maintaining a registry, managing the intellectual property within it is a very complex process [17]. Also, if a registry is to be mandated post-hoc as a means of discriminating between the performances of individual surgeons or units, particular sensitivity needs to be used to encourage 'buy-in' to the process.

In 2013, there was a heated debate about the ownership of the bariatric surgery data that had been collected voluntarily by surgical teams into the UK National Bariatric Surgery Registry (NBSR). The Secretary of State held the view that data concerning National Health Service (publicly funded) patients should be available in the public domain even though there had been no administrative support or infrastructure available within the provider units for registry maintenance. Thus there was no way to ensure there were no missing/incomplete records or data inaccuracies. The resulting challenge to gain consent for data publication highlights the complexities of handling and storing large amounts of data on behalf of contributors whose view was near unanimous that the right to publish the data on their practice should remain with the surgeon, in the absence of public funding for data collection [15].

The resulting mandated report covered 106 consultant surgeons contributing to the NBSR for the financial year 2012/2013. One hundred and one surgeons (95 %) consented to have their individual outcomes for primary surgery published and the results showed no potential statistical outliers for mortality or length of stay. Using Hospital Episode Statistics codes, it was estimated that there were 138 NHS surgeons doing bariatric surgery in the 11 months between April 2012 to February 2013, and 5,656 operations were recorded. Most bariatric surgeons (77 %) were entering data and the great majority of NHS patients (up to 78 %) were being recorded into the registry.

There were three recorded deaths for an in-hospital mortality rate of 0.07 %, equivalent to an in-hospital survival rate of 99.93 %. The average length of hospital stay for all operations was 2.5 days.

The latest report from the National Bariatric Surgery Registry (NBSR) published on November 10, 2014. Following on from the success of previous years, this registry compiled information from 161 surgeons at 137 hospitals and reported figures on 16,956 primary operations and more than 1,327 planned follow-up procedures. Once again, excellent results with regards to the observed in-hospital mortality rate after primary surgery were notes (0.07 % overall).

60.7 Designing the Registry

60.7.1 Dataset Design and Collection

A well-designed and concise dataset design is central to the success of any clinical registry. Small datasets facilitate high participation rates and maximize rates of complete records. Registries with too many data fields are prohibitively time consuming and are inevitably limited by missing data points or inaccurate data entry. An example of the measures that can be used to analyze this is the proportion of records that are complete. For instance in the first report of 1 and 2 years outcome in 8,000 patients from the UK NBSR in 2011 it was found that 85 % of records had zero or only one baseline comorbidity data entry points missing [15]. The commonest comorbidity question that was missing was one that required a specific question to be asked that could not be gleaned already from the patient record—that is the functional status ('how many flights of stairs can be climbed without resting?'). The use of traffic lighting to indicate missing data entry, incomplete or outstanding data can be very useful, as can the use of hover prompts and intuitive progression through the pages of data entry. It is also imperative that the terminology for each data point is defined, so as to avoid confusion between, for example, primary and revision surgery.

60.7.2 Data Validation

After collection, data validation is essential to ensure that the data are accurate for reporting and research purposes [18]. External cross checking can be performed by comparing events such as mortality reported by the registry to the Hospital Episode Statistics (HES) database. HES codes were analyzed in conjunction with the surgeon-level reporting described above and it was estimated that the overall in-hospital mortality rate for bariatric surgery was 0.11 % for the four financial years 2009–2013, equivalent to a survival rate of 99.89 %. This validated the very low mortality from bariatric surgery recorded by the consultant surgeons contributing to the NBSR.

60.8 Minimum Datasets and Definition of a Bariatric 'Success'

There is currently no agreed minimum clinical outcomes dataset for bariatric surgery. To add to the ambiguity and lack of uniformity, there is currently no international agreement on how to calculate the excess weight loss or whether it should be completely replaced by excess BMI loss. There also needs to be increased emphasis on the accurate capture and reporting of complications and collation of patient-reported outcomes. Most importantly, there is no uniform definition of success of a bariatric procedure despite several decades of bariatric surgery and hundreds of thousands of patients it is still not known whether the outcome measures used should be weight loss, comorbidity outcomes, quality of life, or a varying combination of all these.

60.9 Data Pre-Processing

Clinical registries inevitably have unclean data. This is defined as an accumulation of transcription errors, logical inconsistencies, missing information, duplicate records and others. However, simply removing these data will potentially lead to an increase in bias and variance for any subsequent analysis conducted using the registry [19]. Thus appropriate resources should be allocated to this process which will usually require a close collaboration between clinicians and database managers.

60.10 Self Reporting vs. Independent Reporting?

The ideal data collection should be performed by an independent body which is not involved directly with the care or outcomes of bariatric patients. This would ensure that the collected data are not biased. It would also detach data collection from the clinical sources of funding thus making it more independent and credible.

Of the current registries, only the Michigan Bariatric Surgery Collaborative maintains a registry with independent reporting, and such quality assurance may currently be unique. The University of Michigan Health System serves as the Coordinating Centre and is responsible for collecting and analyzing comprehensive clinical data from the participating hospitals. It uses these analyses to examine practice patterns, generate new knowledge by linking processes of care to outcomes and by identifying best practices and opportunities for quality and efficiency improvement. The Centre further supports participants in establishing quality improvement goals and assists them in implementing best practices. The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSASQIP) of the ASMBS and the American College of Surgeons similarly aim to maintain and improve standards of data collection in the USA [20]. Currently, due to reasons such as lack of funding or resource, all or most of the other bariatric registries are based on self-reporting and are thus open to potential bias.

60.11 Using the Registry: Strengths and Limitations

National and international registries can be used for audit purposes, development of risk-prediction models, epidemiological and scientific research. They have also promoted significant developments in statistical methodology. Risk models are commonly developed and validated using registry data and are necessary when the data are used for assessment of performance of individual units or surgeons against statistical means for governance purposes.

One of the main concerns of large registries is that the analysis of results is only as good as the data entered. Thus, one of the major pitfalls in registries is the presence of incomplete data. This situation can be retrievable in certain circumstances, especially when duplicate data are being collected by other disciplines that share patient's care. However, records with inaccurate data are more difficult to identify and verify, and if the patient had a poor outcome such as mortality because then the resulting error means that the whole dataset is misrepresentative. The available methods for correcting erroneous data entry are limited and ultimately the responsibility for accurate data entry lies wholly with the surgical team, assuming it is properly resourced.

60.12 Device Monitoring and Relevance to Bariatric Surgery

Several implantable devices are presently being used in bariatric patients. Adjustable gastric banding is the third commonest bariatric procedure performed worldwide with its market share currently being 17.8 % of all bariatric procedures performed. This represented 60,677 procedures in 2011 alone [9]. The intragastric balloon device procedure is done infrequently in individual countries but still potentially represents a large number of bariatric procedures when analyzed worldwide. The recent case of the Poly Implant Prothèse breast implant highlights the importance of device monitoring. These implants were shown to have a significantly higher rupture rate than other implants after 5 years [21]. Registries for such devices would have possibly led to earlier detection of the unacceptable failure rates of these implants.

Conclusion

In the past, bariatric surgery registries have attempted to capture data of clinical significance but more efforts need to be put in this aspect of bariatric surgery. Had we as surgeons participated in such programs from the beginning, the landscape would have been potentially very different than what it is today. The creation of bariatric registries internationally is a positive step towards a unified global bariatric database. Inferences from such a powerful tool will provide payers and patients with reassurance that quality control is evident in bariatric surgery. It could provide a basis for generating research questions and provide important observational data on differences in practice in bariatric surgery worldwide. More powerful data would be generated from the adoption of an internationally accepted clinical outcomes dataset, when one is published. "Knowledge is gained by gathering data, whereas, wisdom is earned by going through actual life experiences."

—Master Jin Kwon

Key Learning Points

- The Hawthorne effect is a psychological phenomenon that produces an improvement in human behavior or performance as a result of increased attention from superiors, clients or colleagues. Thus in the context of bariatric surgery registry, it is conceivable that the overall results may improve by the act of active data collection and monitoring
- Registries can provide a long-term opportunity to generate important disease-based and treatment-based information
- A well-designed and concise dataset design is central to the success of any clinical registry. Smaller datasets facilitate high participation rates and maximize rates of complete records. The data from registries is only as good as the data entered. Thus, one of the major pitfalls in registries is the presence of incomplete data.

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61 Surgical Review Corporation (SRC) Center of Excellence Program for Bariatric Surgery

Neil E. Hutcher

Abstract

Within a decade, bariatric surgery emerged from the brink of extinction to being recognized as the safest and most effective treatment for severe obesity and its life-threatening comorbidities. An integral component of this resurgence was the creation of a Center of Excellence program, which was first conceived by the leadership of the American Society for Metabolic and Bariatric Surgery and developed and administered by Surgical Review Corporation (SRC).

The guiding principle of the Center of Excellence program is that exceptional care results from fostering a culture of continuous improvement rather than earning a certificate. The program was designed accordingly, and provides surgeons and hospitals with a framework for elevating bariatric surgical care. The program requirements, which address the needs of both patients and providers, are coupled with an objective evaluation process and supported by a central outcomes database. Long-term data collection on a diverse patient population yields the information necessary to evaluate the safety and efficacy of bariatric procedures, as well as establish best clinical practices for the surgical treatment of obesity and related comorbidities.

Since the inception of the Center of Excellence program, there has been a significant reduction in the incidences of morbidity and mortality associated with bariatric surgery and a complete change in the public perception of the procedure's safety and effectiveness. SRC's Center of Excellence program, central outcomes database model is now benefiting other specialties as well.

Keywords

Center of Excellence • Surgeon of Excellence • Accreditation • Certification • Designation • Quality • Safety • Outcomes data/database • Surgical Review Corporation • COEMBS • BOLD

61.1 Introduction

Bariatric surgery demonstrates the difference a decade can make like no other. Just 10 years ago, there was no consensus on patient selection criteria, surgical techniques or procedure methods, even though the annual number of bariatric surgeries exceeded 100,000 [1]. Outcomes were vastly inconsistent, and public opinion held that the procedure was unsafe. Surgeons had no data to defend themselves, and the specialty was in danger of extinction.

To sustain the profession, the American Society for Bariatric Surgery (now the American Society for Metabolic and Bariatric Surgery) founded Surgical Review Corporation (SRC) in 2003 as an independent, nonprofit organization dedicated to advancing the safety, efficacy, and efficiency of bariatric surgical care. SRC's objective was to develop a patient safety and quality improvement program for the

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specialty, supported by a centralized outcomes database. The result was a "Center of Excellence" program that would identify surgeons and facilities providing exceptional patient care, and promote optimal levels of performance. Data collection from these providers on their diverse patient populations would yield the information necessary to evaluate the benefits and risks of bariatric procedures as well as establish best clinical practices for the surgical treatment of obesity and its comorbidities [2].

The success of the Center of Excellence program spurred the formation of other bariatric surgery accreditation programs, which were modeled after the original. SRC's Center of Excellence program is currently the only internationally recognized certification, available to all bariatric surgeons and facilities around the world. A region-specific program is offered in the United States and Canada by the American College of Surgeons together with the American Society for Metabolic and Bariatric Surgery [3]; and in Europe, the Middle East and Africa by the European Accreditation Council for Bariatric Surgery [4, 5].

61.2 Program Methodology and Guiding Principles

The methodology adopted by SRC emphasizes the interdependence of a Center of Excellence program and outcomes database. At a basic level, this approach creates a Hawthorne effect, whereby program participants improve the quality of care simply by entering data that will be subject to evaluation [6].

Certification requirements are established through a collaboration between SRC and the specialty's stakeholders (e.g., leading surgeons, hospital administrators, allied health professionals, medical society leadership, patient advocates, payers). This ensures the requirements are balanced and meet the needs of patients and providers. The requirements are coupled with an objective evaluation process that enables a thorough review of each candidate, and a periodic renewal process verifies ongoing compliance.

Regardless of specialty, the following principles guide the development of each program:

- Participation is about creating a culture, not earning a certificate.
- The program must benefit all stakeholders, but the benefit to patients is paramount.
- Excellence has no geographic or specialty boundaries.
- There are no levels of excellence.
- Even the best can get better.
- Competence requires experience.
- The surgeon is central to a surgical quality program but must be supported by an interdisciplinary team and facility administration.
- Outcomes data is essential. It must be accurate, secure and used for improvement.
- The surgeon's data is their data, and it will never be released to a third party without permission.
- Trust, but verify. Comprehensive, independent inspection of each applicant leads to credible recognition.
- The benefits of participation begin as soon as the commitment to pursuing certification is made.
- Accreditation is a transformative process that results in improved safety and efficacy, decreased costs, increased patient awareness and satisfaction, actionable program data and competitive differentiation.

61.3 Certification Requirements

The requirements of SRC's Center of Excellence in Metabolic and Bariatric Surgery™ (COEMBS™) program recognize the unique roles that surgeons, their interdisciplinary teams and facility administration play in delivering high-quality perioperative care. A commitment to long-term patient safety and success necessitates that they be comprehensive, research-based and verified through a rigorous site inspection and review process. The requirements are designed to promote quality improvement while being practical, concise and easy to understand.

The COEMBS program comprises 10 "pillars of excellence" (certification requirements):

- Institutional commitment to excellence
- Surgical experience
- Program director and interdisciplinary team
- Consultative services
- Equipment and instruments
- Surgeon dedication and qualified call coverage
- Clinical pathways and standardized operating procedures
- Surgical team and support staff
- Patient education
- Continuous quality assessment

The full text of the requirements is available at www.surgicalreview.org.

61.4 Accreditation Process

The COEMBS certification is available to surgeons, hospitals, and ambulatory surgery centers around the world that perform bariatric and metabolic surgery procedures. Surgeons do not have to be a member of a medical society to participate. The COEMBS designation is awarded to both the facility and its associated surgeons who successfully complete the accreditation process.

For a new participant, the process consists of the following steps:

- Register online as a user in SRC's account management system
- Create accounts for the facility, surgical practice and each applicant surgeon (these three entities form the Center of Excellence)
- Pay annual participation fee ($3,975 for the facility, $650 for each surgeon), which includes use of the BOLD™ outcomes database
- Complete and submit surgeon and facility applications and BOLD Participation Agreement
- Review site inspection preparation materials
- Return required documentation and pay site inspection fee ($1,850) [7]
- Schedule and prepare for site inspection
- Hold site inspection (typically 1 day for a facility with ≤5 applicant surgeons)
- Await Review Committee's certification decision or request for additional information
- Receive certification approval and marketing materials

The certification is valid as long as the center complies with program criteria. A formal re-evaluation is conducted every 3 years to verify compliance.

61.4.1 Site Inspection

The program application is supplemented by a site inspection, which is conducted to verify the applicant's compliance with the certification requirements. The surgeon, surgical practice and facility are all involved in the inspection, and it is scheduled with SRC at a mutually agreeable date to ensure that everyone has plenty of time to prepare.

The site inspection is similar to an open-book exam, where the applicant is provided with detailed preparation materials that identify exactly what will be reviewed and what is needed for compliance. The site inspector and SRC support staff are available to answer questions and help the applicant prepare. Site inspections are consultative as much as they are evaluative, and they are not graded pass or fail. If any deficiencies are noted during the inspection, the applicant is given an opportunity and guidance to correct them.

Providers who meet certain criteria are eligible to have their inspection performed using a virtual approach. In a virtual inspection, the applicant submits documentation electronically and provides a digital video to demonstrate compliance with the certification requirements. Virtual inspections save participants time and money while maintaining the integrity of the review process.

Whether on-site or virtual, the inspection process often motivates participants to critically evaluate their bariatric surgery program and identify areas for improvement beyond the certification requirements.

61.5 Outcomes Data

The BOLD™ outcomes database was launched in 2007 to help ensure participants' ongoing compliance and support quality improvement in bariatric surgical care. Today, BOLD contains nearly 600,000 patients, making it the world's largest and most comprehensive clinical repository of patient information [8].

61.5.1 Data Collection and Entry

Program participants are required to enter data prospectively on all of their bariatric surgery patients. Retrospective data entry is optional. Data are collected for each phase of surgery (preoperative, intraoperative and postoperative):

Patient registration includes basic demographic information, payer/insurance information and surgical and medical history.

Preoperative visits include anthropometric measurements, status of 10 comorbidities, medications and risk factors. The initial visit serves as the baseline for the patient's health status prior to beginning a preoperative nutrition and exercise regimen. The visit immediately before the bariatric surgery procedure serves as the baseline to compare postoperative changes in the patient's health status.

Facility stays include basic operative information, intraoperative or pre-discharge complications, and discharge information for the primary bariatric procedure or revision.

Post-discharge encounters (i.e., follow-up visits) include postoperative changes in weight, comorbidity status, medications and risk factors; attendance at support group meetings; and any complications the patient experienced as a result of bariatric surgery. Other types of post-discharge encounters/follow-up visits can also be documented.

The data collected is comprehensive but not cumbersome. Each data element provided pertinent patient information and avoided adding unnecessary components either in the database or in the participant workflow. SRC regularly evaluates the data elements to ensure they remain relevant.

Data entry for the participating surgeon is not restricted to a single user, and enables entry by multiple staff members. BOLD is web-based, and hence, it is accessible in a secure manner from authorized users who have access to the Internet, 24–7. Maximum data entry time is usually 2 min or less per patient per encounter, although this may vary based on patient complexity and user proficiency. BOLD is user-friendly, and provides explanation of data elements, helpful tips as well as forms that contain the information collected during each encounter to expedite the data entry process, reduce errors and eliminate the need to retrieve information from charts.

61.5.2 Use of Data

BOLD data is collected for two reasons: (1) verifying ongoing compliance with the requirements of the Center of Excellence program and (2) research.

61.5.2.1 Compliance

All data collected in BOLD is monitored for ongoing compliance with the requirements of the Center of Excellence program. However, compliance entails more than SRC periodically reviewing data to ensure participants meet the required surgical volume and are up to date with their data entry. Participants are expected to use the BOLD data to drive quality improvement in their respective bariatric surgery programs.

Surgeons and their staff gain real-time access to individual patient information through BOLD to support their clinical decisions. Program-specific reports provide an insight into practice performance; aggregate reports enable participants to compare their individual outcomes with benchmark data and guide them to the appropriate approach and care. To accommodate a variety of provider needs, reports can be exported into several file formats, including Excel and PDF.

Although information from BOLD is readily available to those participating in the Center of Excellence program, surgeon-specific data is never disclosed without consent.

BOLD data is also used to refine the Center of Excellence program requirements. For example, it yielded the evidence necessary to reduce the annual hospital volume requirement from 125 to 80 cases and added surgical outcomes benchmarks for mortalities, complications, readmissions and reoperations [9]. SRC then conducted a review of the metrics used in payer-based quality programs to validate the findings.

61.5.2.2 Research: The BOLD Study

BOLD participants are required to enter the data of their bariatric surgery patients for a minimum of 5 years following the procedure. Collecting such a long-term follow-up information of a large cohort of patients enables evaluation of the efficacy and safety of bariatric surgery.

When BOLD data is used for research, it is referred to as the "BOLD Study." This study involves analyzing BOLD data to evaluate the relationship between surgical outcomes and patient demographics and comorbidities; clinical and surgical characteristics; as well as preoperative, perioperative and postoperative treatment regimens. Under the United States (U.S.) law, this is research on human subjects and requires oversight by an institutional review board (IRB) or ethics committee.

The Copernicus Group Independent Review Board (CGIRB) granted approval for SRC to engage in research using BOLD data with a waiver for documentation of informed consent (IRB Tracking #SRC1–10–037). CGIRB concluded that the BOLD Study poses minimal risk to patients, and SRC has adequate safeguards in place to ensure confidentiality of the protected health information described in the study protocol. As a result, patients are not required to sign an informed consent document to participate in the BOLD Study. Instead, they must be provided with a Patient Information Sheet [10].

Information from the BOLD Study is available to program participants as well as researchers, payers, government and other third parties. SRC encourages these stakeholders to use BOLD data to answer their questions about bariatric surgery. Anyone who requests information from BOLD must submit a formal data request, which is available at www.surgicalreview.org.

In 2010, the first analysis of BOLD data, which validated the safety of bariatric surgery performed by participants in the Center of Excellence program, was published in Surgery for Obesity and Related Diseases [11]. Since then, the database has been a source for numerous bariatric surgery studies on topics such as patient demographics, impact of surgical intervention on obesity-related comorbidities [12], long-term efficacy and emerging procedures. Inspira Health Network in New Jersey, USA, has used BOLD data for resident research papers, resulting in nine accepted publications and 10 others in progress [13]. SRC collaborated with investigators at Duke University to develop a risk stratification model to predict composite adverse events related to Roux-en-Y gastric bypass surgery [14]. As participation in BOLD increases internationally, the database will be able to provide key information on different patient populations, procedures and care options around the world.

61.6 Certification Benefits

Regardless of how experienced surgeons are or how established the department is, the accreditation process can be a transformative experience for the entire patient care team. It challenges participants to establish and maintain a systemic culture of excellence instead of simply earning a certificate.

Center of Excellence program participants begin to experience benefits as soon as they commit to pursuing certification. Surgeons, hospitals and ambulatory surgery centers can

Table 61.1 Improvements in mortality: center of excellence participants [2–15]

	2006	2008–2012
Patients	55,567	425,753
In-hospital mortality	.14 %	.05 %
30-day mortality	.29 %	.11 %
90-day mortality	.35 %	.13 %

Table 61.2 Improvements in outcomes: hospital designee in Virginia, USA [16]

	2003–2005 Before center of excellence certification	2005–2008 After center of excellence certification
Patients	1,582	2,445
Complications	11.10 %	3.10 %
Reoperations	5.70 %	1.10 %
Readmissions	9.80 %	3.10 %
30-day mortality	0.56 %	0.00 %

expect to gain the following benefits that reinforce the value of participation:

- Improved outcomes
- Decreased complications and morbidity
- Reduced costs
- Increased surgical volume and referrals
- Standardization of patient care through clinical pathways/protocols
- Professional recognition and distinction
- Marketing advantage and competitive differentiation
- Improved surgeon, staff, and patient satisfaction
- Access to central outcomes database
- Clinical decision support
- Measurement and comparison of program performance
- Longitudinal data to evaluate long-term efficacy
- Sample size to analyze high- and low-frequency occurrences

Quality improvements that resulted from Center of Excellence certification and translated into cost savings are presented in Table 61.1 [2–15] for all program participants and from an individual designee in Table 61.2 [16].

61.7 The Evolution of Excellence

As surgical care evolves, so must the Center of Excellence program to ensure that the needs of patients and providers continue to be met.

One of the most significant changes made was the introduction of a surgeon-only certification option. Just as there is not a one-size-fits-all approach to improving care delivery and patient safety, there should not be a one-size-fits-all approach to accreditation. Having more than one certification option affords the flexibility to support how different bariatric surgery providers provide patient care.

The Surgeon of Excellence in Metabolic and Bariatric Surgery™ (SOEMBS™) program is ideal for surgeons who practice at more than one facility, want to move forward with certification before their hospital or are interested in multiple designations. It differs from the Center of Excellence program in two primary ways:

No hospital co-certification requirement. The hospital does not have to meet the Center of Excellence requirements or pay fees, but it must agree to participate in the site inspection for the surgeon.

The surgeon must perform at least 100 qualifying bariatric surgeries each year instead of 50 [17].

The full text of the Surgeon of Excellence requirements is available at www.surgicalreview.org.

The certification process is faster, simpler, and more straightforward. The surgeon and facility registrations have been streamlined, and site inspections are now conducted using a virtual approach for applicants who meet certain criteria. In a virtual site inspection, the applicant submits documentation electronically and provides a digital video to demonstrate compliance with the certification requirements. Virtual inspections save time and money while maintaining the integrity of the review process.

The BOLD outcomes database continues to evolve based on user feedback and evaluation of data for usefulness and relevance. Improvements to the data set and data entry process are ongoing. Modifications have included new features to facilitate faster data entry, a more intuitive workflow that aligns with how providers deliver care and manage their practice, as well as enhanced reporting capabilities. BOLD is the largest and most advanced bariatric surgery outcomes database in the world, and SRC is committed to keeping it that way.

61.7.1 Global and Multispecialty Expansion

Following the success of the Center of Excellence program in the U.S. and Canada, SRC launched an international accreditation in 2008 to enable the delivery of safe and high-quality care to bariatric surgery patients worldwide, regardless of where they chose to have their procedure performed. SRC's Center and Surgeon of Excellence programs are now available to all bariatric surgery providers, heralding the arrival of a truly global quality improvement initiative.

While initially focused on bariatric surgery, SRC has expanded its efforts for advancing safety, efficacy, and efficiency of surgical care into other specialties.

The Center of Excellence in Minimally Invasive Gynecology™ (COEMIG™) program is designed to expand patient awareness of and access to minimally invasive gynecologic procedures performed by surgeons and facilities that have demonstrated excellence in these advanced techniques. SRC manages the program worldwide on behalf of the AAGL, the leading professional society for minimally invasive gynecologic surgery. As of February 2014, nearly 200 hospitals and 600 surgeons from 14 countries that includes 38 states from the US, are participating in the COEMIG program.

The Center of Excellence in Hernia Surgery™ (COEHS™) and Surgeon of Excellence in Hernia Surgery (SOEHS™) programs support global initiatives on quality improvement in hernia repair and abdominal wall reconstruction. These programs are endorsed by the Asia Pacific Hernia Society, which represents more than 1,100 hernia surgery specialists. The endorsement indicates that the programs meet the Society's standards for improving modern hernia treatment and providing a professional forum for the exchange of information and education regarding current and future methods of diagnosis and treatment.

In October 2014, SRC launched a Center of Excellence program and BOLD database in robotic surgery on behalf of the Clinical Robotics Surgery Association (CRSA). This program transcends multiple specialties that use robots in their surgical approach.

SRC's Center of Excellence program, BOLD database model is also being considered for such specialties as anesthesia for obese patients, diabetes mellitus, hand surgery, obstetrics, orthopedics, and pulmonary hypertension.

Key Learning Points

- A Center of Excellence program provides a framework for quality improvement that yields tangible benefits for surgeons, facilities and patients. Participation is focused on creating a culture, not earning a certificate.
- A Center of Excellence program and a database that monitors results are interdependent. Outcomes data must be accurate, secure and used for improvement.
- Accreditation is a transformative process that results in improved safety and efficacy, decreased costs, increased patient awareness and satisfaction, actionable program data and competitive differentiation.
- There is no one-size-fits-all approach for improving care delivery and patient safety, and there should not be a one-size-fits-all approach to accreditation. Certification options must be flexible to support how bariatric surgeons provide care.
- SRC has more than 10 years of experience developing and managing patient safety and surgical quality programs worldwide for multiple specialties.

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International Federation for Surgical Obesity (IFSO) Center of Excellence Program for Bariatric Surgery

62

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Abstract

The rapid increase in bariatric surgery has stimulated much effort to improve the quality of the service provided, by setting standards of care for these patients.

The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)-endorsed Centre of Excellence (COE) program, for Europe, Middle East and Africa, provides guidelines, and defines the reference requirements for surgeons and institutions in order to safely manage patients with morbid obesity.

The COE program is overseen by the European Accreditation Council for Bariatric Surgery (EAC-BS). Senior members of IFSO form the EAC-BS Scientific Board and the Accreditation Review Committee.

Surgeons and institutions who fulfil the IFSO guidelines and requirements, are welcome to apply to get recognised as an IFSO—Accredited Centre of Excellence in Bariatric and Metabolic Surgery.

Participating surgeons are required to submit data of patient care prospectively in the International Bariatric Registry (IBAR™), including operative outcomes, complications, re-admissions, mortality and follow-up. Once the required number of patients have been submitted to the IBAR, the institution can apply for final evaluation as a COE. An experienced auditor will visit the institution in order to verify the reported data. The auditor's report will be submitted to two reviewers who will express their opinion to the EAC-BS Scientific Board. The board will make the final decision to bestow COE designation to the institution.

Keywords

Bariatric surgery • Centre of Excellence (COE) • Quality in bariatric and metabolic surgery • Patient's safety • IFSO-endorsed COE program

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62.1 Introduction

In Europe, the prevalence of obesity has increased three-fold in the past two decades. Obesity currently affects 150 million adults and 15 million children and is responsible for approximately one million deaths annually [1]. Within in the countries covered by the IFSO-European Chapter (IFSO-EC), the rising levels of morbid obesity has reached epidemic levels and the number of patients undergoing bariatric surgery has risen exponentially. In turn, the number of surgeons and institutions offering bariatric surgery has increased, in response to the high demand.

The safe and effective delivery of bariatric surgery services requires experienced surgeons, with excellent technical skills and clinical expertise, practicing in a supportive institution, committed to providing high quality multi-disciplinary support and resources [2, 3].

The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) is dedicated to improving the quality of surgical services offered to patients with morbidly obesity. IFSO have endorsed a number of Centres of Excellence (COE), where the services meet a number of proposed benchmarks. These criteria define the minimal acceptable standards, in terms of individual surgeon's credentials and institutional facilities. IFSO has proposed that these standards be applied worldwide and are considered to be of the utmost importance if bariatric surgery is to be practised safely, with adequate and consistent quality assurance [2, 4].

62.2 History of the COE Program in the Region of IFSO-EC

In September 2007, at the IFSO Council meeting in Porto, an official document was unanimously accepted indicating IFSO's views on surgeon's credentials and institutional requirements for safe and effective bariatric surgery practice [4].

In the official document published at Obesity Surgery (2008; 18:497–500), the intention of the Federation to support and endorse centre of excellence programs around the world was clearly stated:

In an effort to improve the quality of service offered to bariatric patients worldwide, IFSO elected to form an international board that would advise and endorse national and regional 'centre of excellence' programs.

In the region encompassing Europe, Middle East and Africa, (the geographic region of IFSO -EC) the creation of a COE program was considered essential because of:

- The absence of similar programs for bariatric and metabolic surgery in the region in contrast to well-structured programs that have been successfully implemented in the USA towards standardizing and improving the quality of care [5–9]
- The realisation that a network of centres of excellence in bariatric (and other disciplines) surgery, in Europe, would benefit the patient and the health care system aiming towards improving safety and quality in care.

As a result, in Capri Italy May 2008, during the General Assembly of IFSO-EC members, the representatives of all European National Bariatric Societies who were present then, unanimously accepted the idea of a regional COE program.

Shortly thereafter, four past presidents of the IFSO from the geographic region of Europe, Middle East and Africa (N. Scopinaro, M. Fried, A. Baltasar and J. Melissas) and the president of IFSO European Chapter (Luc Lemmens) decided to proceed in forming the European Accreditation Council for Bariatric Surgery (EAC-BS).

Many leading bariatric surgeons from the region have participated voluntarily. Most of the Presidents and General Secretaries of IFSO–EC National Bariatric Societies are now either members of the Scientific Board or of the Accreditation Review Committee of EAC-BS, having approved the need for a Centre of Excellence (COE) program in the geographic area of IFSO-EC.

The program was endorsed by IFSO at the 13th World Congress of IFSO in Paris, 2009.

62.3 Mission

The European Accreditation Council for Bariatric Surgery (EAC-BS), as an organisation, examines the institutional infrastructure and the surgeon's credentials, training and experience in order to ensure the safe and efficient management of morbidly obese and patients with surgically treatable metabolic disorders (for example, type 2 diabetes).

Members of the Scientific Board and the Accreditation Review Committee achieve this, through several means such as analysis of the number and outcomes of procedures performed by each institution and individual surgeon as well as personal reviews. Measures of the performance of each surgeon and outcome data are obtained from the International Bariatric Registry (IBAR) where patients' data are entered prospectively on a mandatory basis. On-site visits by experienced auditors are an integral part of the certification process. Contribution to scientific programs, and publications in peer review journals help in the award of the IFSO COE accreditation.

62.4 Process of Application to COE Program

Applications for enrolling in the Centre of Excellence program in Bariatric and Metabolic Surgery can be submitted online for evaluation to EAC-BS at www.EAC-BS.com provided both the institution and the surgeon(s) meet majority of the following requirements:

62.4.1 Surgeon's Qualifications, Training and Experience

- Appropriate certification to perform general surgery
- Training and experience in performing open and laparoscopic gastrointestinal surgery
- Successful completion of a training course in bariatric surgery
- Testimonials, by mentors (proctors), of satisfactory skills in bariatric surgery
- Evidence of a prospective database of all bariatric patients and surgery, including outcomes
- Commitment to postoperative life-time follow-up of the patients
- Skills to perform revisional surgery
- Attendance of bariatric surgery scientific programs on a regular basis and subscription to at least one bariatric surgery journal
- Performance of at least 25 bariatric cases per year including a number of revisional cases. (50 cases are required when Adjustable Gastric Banding is most commonly utilised)
- Involvement in the training and the accreditation of less-experienced bariatric surgeons
- Possession of follow-up data of at least 75 % of the operated patients

62.4.2 Institutional Requirements

- Ensure that surgeons performing bariatric surgery have the appropriate certification, training and experience
- Provide ancillary services such as specialised nursing care, dietary counselling, clinical nutrition, endocrinology and psychological assistance if and when needed
- Have readily available consultants in cardiology, pulmonology, psychiatry and rehabilitation with previous experience in treating bariatric surgery patients
- Have trained anaesthesiologists with experience in treating bariatric surgery patients
- Ensure that a recovery room capable of providing critical care monitoring and treatment to morbidly obese patients after surgery and an intensive care unit with similar capacity is available
- Ensure that radiology department facilities can perform emergency chest x-rays with portable machinery, abdominal ultrasonography and upper gastrointestinal (GI) series
- Ensure that blood tests can be performed on a 24-h basis
- Ensure that blood bank facilities are available and blood transfusion can be carried out at any time
- Have comprehensive and full in-house consultative services required for the care of the bariatric surgical patients, including critical care services
- Have the complete line of necessary equipment, instruments, items of furniture, wheel chairs, operating room tables, beds, radiology facilities such as computed tomography (CT) scan and other facilities specially designed and suitable for morbidly and super obese patients
- Have a written informed consent process that informs each patient of the surgical procedure, the risk for complications and mortality rate, alternative treatments, the possibility of failure to lose weight and his/her right to refuse the treatment
- Maintain details of the treatment and outcome of each patient in a digital database
- Have experienced interventional radiologists available, to take over the non-surgical management of possible anastomotic leaks and strictures
- Perform at least 50 bariatric surgical cases per year including revisional surgery. The peri-operative care and the surgical procedures have to be standardised for each surgeon
- Provides lifetime follow-up for the not less than 75 % of all bariatric surgical patients. Patients' data should be available on request by EAC-BS authorities

The completed application form is reviewed by the EAC-BS Scientific Board and a provisional acceptance is granted within 1 week. In case the board members require additional information, the application will be placed on "monitoring" status until appropriate details have been submitted to satisfaction of the board.

62.5 Procedure for the Final Accreditation as Centre of Excellence

Following the acceptance of the application of the institution and the surgeon(s), by the Scientific Board and the payment of the provisional fees, access codes to the International Bariatric Registry (IBAR) database will be provided to the surgeon(s) and/or institution to prospectively enter the data of patients. IBAR is an online database constructed and owned by EAC-BS. The information in IBAR allows evaluation of the performance of each institution and surgeon, and also provides a useful survey of activity in the COEs across Europe, the Middle East and Africa. Demographic, metabolic, preoperative, surgical, outcome and follow-up data are monitored for every participating surgeon and institution.

Once adequate number of patients with sufficient follow-up have been analysed from the IBAR, the participants can apply for final evaluation. This allows the accreditation board to reach a conclusion on the safety and efficacy of the service offered. This is followed by an on-site visit to verify the reported data, facilities and surgeons' certification. The auditor's report is then examined by two members of the Accreditation Review Committee. Both the members forward their reports to EAC-BS Scientific Board for a final decision. The Scientific Board, in conjuction with the President and Officers of IFSO-EC, make the decision to award COE designation to the institution and the surgeon(s). A diploma is issued, signed by the chairman of EAC-BS Scientific Board and the President of IFSO-EC (see Fig. 62.1).

62.6 Current IFSO COE Participation

A total of 72 centres and 110 surgeons from 22 countries, in the area of Europe, Middle East and Africa (IFSO-EC), were participating in the COE program by the end of August 2012.

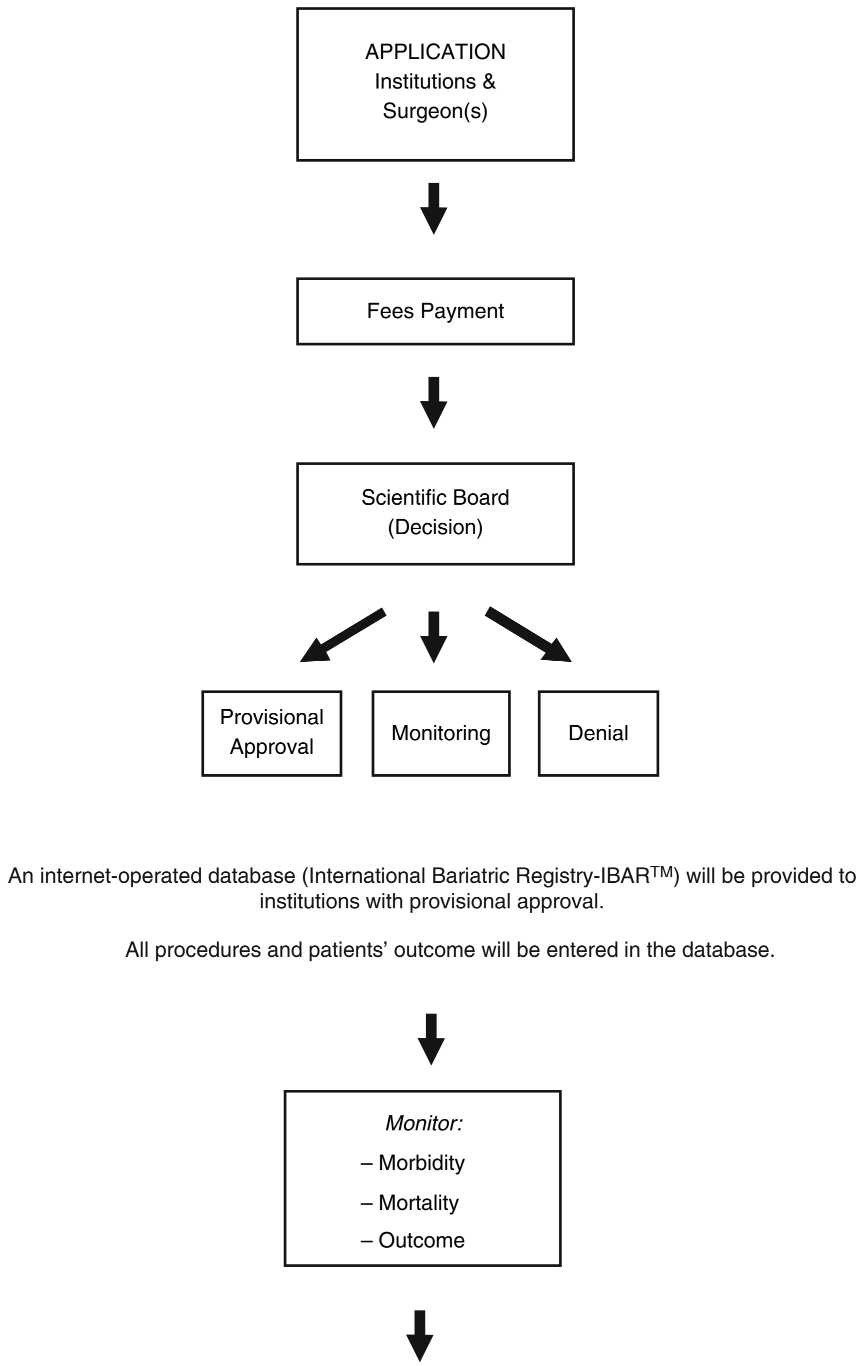
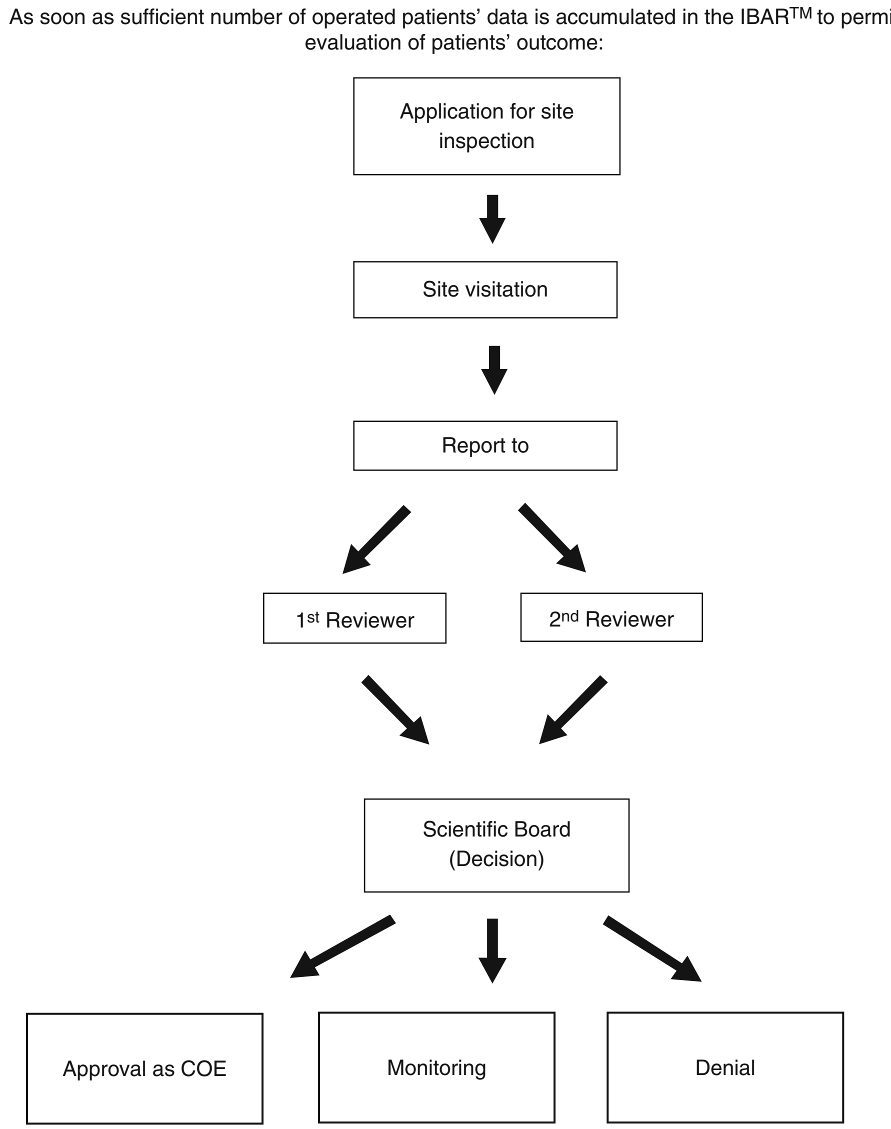


Fig. 62.1 Steps from the application to the final designation as Centre of Excellence

Fig. 62.1 (continued)



Twenty-five centres and 35 surgeons had already been evaluated and granted the COE designation. Forty-seven centres and 75 surgeons were still under evaluation. The COE certificates were granted to the first batch of fully certified centres at the 16th World Congress of IFSO in Hamburg, the fifth European Congress of IFSO-EC in Barcelona, the 18th World Congress of IFSO in Istanbul and the recent 6th European Congress of IFSO-EC in Brussels.

62.7 Current Database—IBAR Statistics

By the end of September 2013, 18,512 patients were entered prospectively into the IBAR™. From those operated patients, 85.5 % were subjected to primary bariatric procedures; 8.35 % were subjected to revisional surgery and the rest 6.15 % were subjected to two-stage operations.

In the area of IFSO's European region, the primary procedures performed were: gastric bypasses (57 %), sleeve gastrectomies (21.22 %), adjustable gastric banding (13.05 %), biliopancreatic diversion Scopinaro (0.81 %), biliopancreatic diversion with duodenal switch (BPD-DS) (2.46 %) and other bariatric procedures (5.46 %). The reported overall mortality rate was 0.06 % for primary operations. The very low mortality rate must be viewed with caution as all data were self-reported by participating COEs. Independent verification of data was performed for 22 fully accredited institutions.

Conclusions

The very low documented mortality for patients undergoing bariatric surgery in the IFSO EAC-BS COE program indicates that adherence to IFSO guidelines and standards in bariatric surgical practice is beneficial.

The establishment of a network of Centres of Excellence for bariatric and metabolic surgery allows standardisation of care pathways, defines standards of care and is associated with consistently excellent outcomes, across a wide range of participating centres [10–13].

Key Learning Points

- International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) endorses the 'Centre of Excellence' (COE) program to improve the quality of service offered to bariatric surgery patients.
- Applications are submitted online to the European Accreditation Council for Bariatric Surgery (EAC-BS), by the institution and the surgeon(s) meeting certain requirements.
- EAC-BS Scientific Board accepts the application, after evaluation of the declared institutional infrastructure and the surgeons' credentials, training and experience, and provides access codes of the International Bariatric Registry (IBAR) database to the surgeon(s) and/or institution to prospectively enter the data of patients.
- The participants apply for final evaluation when adequate number of patients with sufficient follow-up period have been analysed from the IBAR. An auditor visits the institution, to verify the reported data, and submits a report to two reviewers of the Accreditation Review Committee.
- The reviewers further forward their reports to the EAC-BS Scientific Board which, along with IFSO, finalises the decision to grant the COE designation to the institution if appropriate.

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Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) By American Society for Metabolic and Bariatric Surgery (ASMBS) and American College of Surgery (ACS)

63

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Abstract

Metabolic and bariatric surgery procedures provide highly effective solutions for durable weight loss. This helps in resolving obesity-related comorbidities and reducing mortality in the morbidly obese population. Therefore, more and more healthcare facilities are gearing up to meet the increasing demand for such services. In order to achieve a single national accreditation standard for bariatric surgery centers in the United States and Canada, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) was started by combining the accreditation programs of the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS).

Accreditation is for a period of 3 years. Depending on the criteria fulfilled, the center may be designated as low acuity center, comprehensive center, comprehensive center with adolescent qualifications, band center, or adolescent center. Better outcomes are seen in morbidly obese patients who undergo bariatric surgery at accredited centers than those who undergo such procedures at nonaccredited centers.

Keywords

Metabolic Surgery • Bariatric Surgery • Quality Improvement Program • Center of Excellence • Outcome

63.1 Introduction

Metabolic and bariatric surgical procedures have been shown to be highly effective in achieving durable weight loss with resolution of obesity-related comorbidities and improving mortality. As a result, an increasing number of hospitals and surgery centers are interested to provide this service to their morbidly obese patients. However, metabolic and bariatric surgery involves a uniquely vulnerable population in need of specialized resources and ongoing multidisciplinary care.

The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) is a conjoint effort of the American College of Surgery (ACS), and the American Society of Metabolic and Bariatric Surgery (ASMBS) working together with the health care facilities and professionals who provide care to morbidly obese patients. It is the only nationwide accreditation and quality improvement program for metabolic and bariatric surgery in the United States of America (USA).

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Table 63.1 MBSAQIP core standards

Standard	Title	Definition
Standard 1	Case volume, patient's selection & approved procedures	Case volume, patient selection and approved procedures are different according to the level of designation
Standard 2	Commitment to quality care	The facility must provide the structure, process, and personnel to maintain the quality standards of the MBSAQIP
Standard 3	Appropriate equipment and instruments	The center must maintain appropriate equipment and instruments for the safe delivery of patient's care
Standard 4	Critical care support	The facility must maintain critical care support and various consultative services required for patient's care. The MBS Committee must develop selection guidelines relative to the available resources and experience
Standard 5	Continuum of care	The center must utilize protocols to facilitate the standardization of perioperative care
Standard 6	Data collection	All metabolic and bariatric operations and interventions must be entered into the online MBSAQIP Data Registry Platform
Standard 7	Continuous quality improvement process	The MBS Committee must demonstrate a continuous quality improvement process with data analysis and implement strategies to maximize perioperative patient care

Table 63.2 MBSAQIP accredited centers

Designation level	Definition	Facility volume	Required standards	Patient age selection
Low acuity center	Perform primary and revisional bariatric stapling and band procedures on a minimum volume of low acuity patients	25	1–7	≥18
Comprehensive center	Perform complex primary and revisional bariatric stapling and band procedures on a high volume of patients at all acuity levels	50	1–7	≥18
Comprehensive center with adolescent qualifications	Perform complex primary and revisional bariatric stapling and band procedures on a high volume of patients at all acuity levels	50	1–7, 9	All patients
Band center	Perform complex primary and revisional bariatric band procedures on a minimum volume of patients at all acuity levels	25	1–8	≥18
Adolescent center	Perform complex primary and revisional bariatric stapling procedures on all acuity levels	<25	9	<18

63.2 Levels of Designation

MBSAQIP aims to move toward risk-adjusted outcomes metrics to assess centers, rather than primarily relying on the volume of bariatric surgery cases done at the center. High-quality data is critical to provide information about quality improvement and to determine accreditation. Data about each bariatric procedure, whether primary or revisional as well as complications and reoperations related to the procedure, must be submitted into the MBSAQIP Data Registry Platform.

MBSAQIP has issued a document titled "Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2014" which outlines both the standards and the pathways for healthcare facilities to follow when seeking accreditation [1].

Seven MBSAQIP Core Standards are required for any accredited center (See Table 63.1). There are six categories of designations that centers are offered by the MBSAQIP. These are grouped into two main categories:

1. Data Collection Centers are non-accredited in the USA or internationally and collect all outcomes data in a reliable and streamlined format. These do not require site visits from MBSAQIP. The data collections centers in the USA must intend to apply for accreditation within 12 months of participation.
2. Accredited Centers: Currently, MBSAQIP accreditation applies to centers only in the USA and Canada. Centers are accredited for a period of three years. The accreditation ensures the facilities offer high-quality care and support efforts inherent to patient safety and excellent clinical outcomes. They require MBSAQIP site visits for approval of their level of designation. Accredited centers may be designated as:
   - Low Acuity Center
   - Comprehensive Center
   - Comprehensive Center with Adolescent Qualifications
   - Band Center
   - Adolescent Center

Detail requirement criteria for all designation centers are included in Table 63.2.

63.3 Onsite Visits

Accredited programs are evaluated with frequent site visits conducted by a trained MBSAQIP metabolic and bariatric surgeon surveyor. However, data collection centers do not required site visits.

During the visit, metabolic and bariatric surgery centers are verified against set criteria for each designation level. Under the leadership of metabolic and bariatric surgery director, a multidisciplinary metabolic and bariatric surgery committee is in charge of monitoring the care of metabolic and bariatric surgical patients.

In order to ensure appropriate experience and competency of the surgeon and center, the annual facility and individual surgeon volumes and outcome specific to stapling and non-stapling procedures are reviewed.

Thirty-day morbidity, mortality, readmission, and reoperations as well as long-term follow-up outcomes, reported to a national data registry, are reviewed to inform the center of its performance and help the center identify areas of focus for continuous quality improvement. Appropriate infrastructure, equipment, and patient care pathways to accommodate the specialized needs of morbidly obese patients are evaluated.

63.4 Discussion

Since 2004, the American College of Surgeons and the American Society of Metabolic and Bariatric Surgery have accredited numerous bariatric hospitals. In 2014, both the societies collaborated to form the MBSAQIP. MBSAQIP provides guidance for facilities to build the infrastructure, process, and outcome expertise with a mutidisciplinary approach with a focus on quality and safety of the care of metabolic and bariatric surgery patients. The MBSAQIP accredits inpatient and outpatient metabolic and bariatric surgery centers in the United States and Canada that have undergone an independent and rigorous peer evaluation in accordance with nationally recognized metabolic and bariatric surgical standards [1].

Maintenance of accreditation requires continual monitoring of quality of care with periodic review of outcomes, pathways, and protocols to ensure that the center is providing a safe and competent metabolic and bariatric surgical care. Timely best-practice updates require close collaboration between the members of a multidisciplinary team to identify new risks, develop strategies to address them, and optimize treatment for the growing numbers of morbidly obese patients [2].

Several studies have evaluated the impact of hospital accreditation upon outcomes of bariatric surgery. These show improved outcomes associated with accredited bariatric centers [2–5].

In one such study, accreditation in bariatric surgery was associated with more than a threefold reduction in risk-adjusted in-hospital mortality [3]. Multivariate analysis showed that non-accredited centers had higher risk-adjusted mortality for bariatric procedures compared to accredited centers (odds ratio [OR] 3.1, $P < .01$) [3].

In another study, a total of 72,615 (61.8 %) weighted discharges, corresponding to 145 (61.7 %) American Heart Association (AHA) identifiable hospitals were included [4]. Among the 145 hospitals, 66 (45.5 %) were unaccredited and 79 (54.5 %) accredited. Incidence of any complication was higher at unaccredited centers than at accredited centers (12.3 % vs. 11.3 %, $P = 0.001$), as was mortality (0.13 % vs. 0.07 %, $P = 0.019$). Multivariable logistic regression analysis identified unaccredited status of healthcare facilities as a positive predictor of incidence of complication [odds ratio (OR) = 1.08, $P < 0.0001$], as well as mortality (OR = 2.13, $P = 0.013$). Hospital accreditation status was associated with safer outcomes, shorter lengths of stay at hospital, and lower total charges after bariatric surgery [4].

The MBSAQIP proposed an annual threshold volume of 50 stapling cases. Hospital accreditation was found to have an impact on surgical outcomes for bariatric surgery greater than that of volume of cases [5].

In conclusion, significant differences in morbidity and mortality are documented between patients treated at non-accredited and accredited metabolic and bariatric centers. Resources established for bariatric surgery accreditation have the benefit of improving outcomes for morbidly obese patients undergoing bariatric surgery. The MBSAQIP is just the beginning of a high quality care to the morbidly obese patient for whom surgery is being considered.

Key Learning Points

- The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) is a conjoined effort between the accreditation programs of the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS).
- Better outcomes are seen in morbidly obese patients who undergo bariatric surgery at accredited centers.
- MBSAQIP aims to move toward risk-adjusted outcomes metrics to assess centers rather than primarily relying on the volume of bariatric surgery cases done at the center.
- Seven MBSAQIP Core Standards are required for any accredited center.

- There are six categories of designations that centers are offered by the MBSAQIP (Low Acuity Center, Comprehensive Center, Comprehensive Center with Adolescent Qualifications, Band Center, and Adolescent Center).
- Site visits provide centers with feedback and reviews whether or not it is up to standards with ASMBS/ACS guidelines. The center is evaluated on whether it has enough support and staff to provide high quality of care to morbidly obese patients.

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Medico Legal Issues in Bariatric Surgery

64

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Abstract

There is an increasing incidence of litigation associated with bariatric surgery. The reasons for this increase are multifactorial and include a rise in the number of patients undergoing surgery and hence potential litigants, the need for long-term follow up and the relative novelty of this specialty. Although the principles and case law governing medico-legal practice vary across jurisdictions, as a general rule for a case to be successful there must be a breach of duty of care leading to actionable harm. In order to avoid medico-legal pitfalls, it is important to ensure that the consenting process is robust and that every complication is appropriately investigated and dealt with in a timely fashion. There are chances that in the near future number of litigations will increase with respect to the management of the patients presenting as an emergency with long-term complications related to bariatric surgery and also due to the patients who do not qualify for bariatric surgery for financial reasons due to rationing within public-funded health systems.

Keywords

Breach of duty of care • Negligence • Litigation • Emergency surgery

64.1 Introduction

Bariatric surgery procedures, although being novel in nature, have established themselves as providing significant prognostic and functional benefits to patients suffering with morbid obesity. Despite the obvious benefits of surgery there has been a steady increasing in the incidence of litigation following bariatric surgery- a fact reflected in the escalating medical insurance premiums for this surgical subspecialty. In this chapter we explore reasons for this increase in litigation. In addition we discuss the underlying legal principles underpinning case laws in bariatric medico-legal cases. Finally, we analyze the scientific literature on bariatric litigation and discuss the options available for avoiding the obvious medico-legal pitfalls.

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64.2 Bariatric Surgery and Litigation

Randomized controlled trials have shown that bariatric surgery provides significant functional and prognostic benefits to the patients suffering with morbid obesity. In particular, bariatric surgery has been demonstrated to improve co-morbidities such as hypertension and diabetes mellitus as well as increasing patients' overall lifespan. In the United Kingdom, over the last decade, there has been a steady fall in the complication rates associated with bariatric surgery. The latest National Bariatric Surgical Register shows a mortality rate of only 0.07 % for bariatric surgery [1]. Despite the potential benefits associated with bariatric surgery and its low perioperative mortality rate, the medical insurance fees is steadily rising which suggests that there must be a significant increase in the litigations following these procedures. In the United Kingdom, bariatric surgery and cosmetic surgery are the surgical subspecialties with the highest insurance premiums. The reasons underlying this rise in litigation are multifactorial. For a start, over the last two decades there has

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been an increasing tendency in many Western countries for patients to seek legal redress following any medical complication. While this increase in so-called “compensation culture” has affected all medicine and surgery it should be noted that medical negligence claims associated with bariatric surgery have grown much more than with other surgical specialties. The particular reasons for this increased litigation in bariatric surgery are:

64.2.1 Increasing Volume of Cases

Over the last decade, there has been large rise in the incidence of obesity and obesity-related diseases particularly in the Western countries. In addition there is now greater awareness of the potential benefits of bariatric surgery, both within the medical community and in the population at large. As a consequence of this, there has been an increase in the number of bariatric procedures performed that in turn means that the overall numbers of potential litigants has increased.

64.2.2 Bariatric Surgical Population

Patients with morbid obesity tend to be a vulnerable population in terms of psychiatric and psychological co-morbidities. In addition, unlike cancer surgery where patients are undergoing surgery to combat an immediate and life-threatening condition, bariatric patients are often relatively young and healthy and are undergoing surgery ‘only’ to prevent future medical complications. As such there is a very poor tolerance of adverse outcomes.

64.2.3 Restrictions in Access to Bariatric Surgery

Due to financial restrictions in many publicly-funded healthcare systems, there is significant rationing of access to bariatric surgery. As a consequence of this many patients end up funding these operations in the private health sector, essentially to overcome this hurdle to surgery. These patients are therefore potentially more likely to complain if, after having paid for their surgery, they suffer significant complications.

64.2.4 Long Term Complications Following Surgery

Unlike traditional resectional gastrointestinal surgery, bariatric surgical patients are prone to complications many years after their original operation. For example gastric band patients can present with obstruction or band erosion whilst gastric bypass patients can present with internal herniation. These conditions can be overlooked or misdiagnosed by non-specialists and the morbidity associated with a failure to diagnose these late complications can potentially be a further source of litigation.

64.2.5 Surgical Training

Given the relatively novel nature of bariatric surgery, it is only recently that formal fellowship programs have become established to train surgeons in these techniques. As a consequence of this, a significant proportion of bariatric surgery is still performed by surgeons who are trained principally in esophago-gastric cancer surgery and these surgeons may not appreciate the nuances associated with bariatric surgery. Furthermore, for those trained in the era when cancer resections were exclusively performed through an open approach, these surgeons may not have the laparoscopic skill set necessary to perform what is complex and technically-demanding surgery.

64.3 Principles of Medical Law

Although the principles and case law governing medico-legal practice vary across jurisdictions, broadly-speaking legal complaints following bariatric surgery fall into the two categories:

64.3.1 Criminal Law

In rare case where alleged gross misconduct results in the death of the patient, criminal charges of manslaughter may be brought against the operating surgeon and members of the team.

64.3.2 Civil Law

This represents the bulk of bariatric medico-legal cases which essentially involve litigants seeking monetary redress from the surgeon or hospital for perceived errors in their medical management. Although the legal mechanics and standards vary from jurisdiction to jurisdiction, in most English Commonwealth dominions, medical negligence falls under the purview of Tort Law. Under Tort law, for litigants to be successful, they must demonstrate that:

- The surgeon and/or institution had a duty of care to the litigant.
- That this duty of care was breached.
- That this breach led to some material damage or loss.

In most of the cases the key issue revolves around the duty of care. Whether the duty of care was breached or not, by the virtue of litigant's clinical care falling below the standard expected, remains an important issue. In the United Kingdom the principles governing what is deemed to be the expected standard of care have been developed through case law. Under the so called "Bolam principle" this standard is deemed to be that which would be expected by a responsible and respectable body of medical practitioners skilled in the relevant field [2]. This has been further extended following the case of Bolitho to include the requirement that the doctor or medical team should also have behaved in a way that 'withstands logical analysis'; with the determination of 'logical analysis' being the responsibility of the Court [3]. It should be noted that in many countries the courts apply a higher standard.

64.4 Medicolegal Literature in Bariatric Surgery

Medical literature has limited information about bariatric surgery in spite of the importance of medicolegal claims in bariatric surgery. The case files of 49 Spanish medicolegal bariatric surgery cases presented to the Professional Liability Department of the Catalonian Medical Colleges Council from 1992 to 2009 were reviewed by Bruguera et al. [4] Complete recovery was seen in 21 % of the cases, death in 47 % and residual impairment in the remainder of cases. Peritonitis, due to suture line dehiscence (48 %), and respiratory complications were the two most common causes of death. Malpractice was considered to have occurred in 20 % of cases and, importantly, in 6 % of the cases the surgeons were convicted in criminal courts of criminal negligence. Cottam et al. reviewed the case notes of 100 consecutive North American bariatric surgery lawsuits [5]. The most common adverse events initiating litigation were anastomotic leaks; followed by intra-abdominal abscess, bowel obstruction, major airway events, organ injury and pulmonary embolism. In terms of clinical outcomes, 32 patients had a documented intra-operative complication and 72 required additional surgery. A total of 53 of the patients died and 28 had a full recovery with the remainder having minor or major disability. When a medical malpractice lawyer analyzed the cases, he found that potential negligence was present in 28 % of cases—delay in diagnosis of a complication or misinterpretation of vital signs being the most common one. Importantly the majority of lawsuits involved surgeons with a low level of experience (that is less than 1 year of experience in bariatric surgery). However, it should be noted that this analysis was of cases performed between 1997 and 2005 and included a significant number of operations which are no longer routinely undertaken—such as vertical banded gastroplasty and open gastric bypass. In addition, none of the patients in the cohort underwent gastric band insertion which, again, reflects the timeframe during which this study was conducted. The finding of negligence, in both of these studies, was typically based on a failure to detect complications in a timely fashion as opposed to the complications themselves. Moreover, it should also be noted that both studies focused on early postoperative complications associated with bariatric surgery and did not analyze litigation associated with late complications.

In an attempt to quantify the current burden of litigation in the United Kingdom, we reviewed all bariatric medicolegal cases referred to the authors over a 1 year period between 2012 and 2013. This comprised a total of 40 cases of which 17 had early complications (the most common being anastomotic failures and significant bleeding events) and 23 had late complications (the most common being intestinal obstruction secondary to internal herniation following gastric bypass and band slippage and erosion). In total there were ten cases where it was considered that there was a breach of the duty of care leading to actionable harm. An important finding from our series was a significant incidence of litigation against non-specialist centers providing emergency care to post-bariatric surgery patients. While such facilities would not be expected to provide expert bariatric care, they would be expected to be able to diagnose a patient and to discuss the management with an appropriate bariatric center. Indeed an important principle is that these patients should be discussed with a bariatric unit (ideally the institution where the surgery was originally performed) at the earliest opportunity and, where possible and appropriate, early transfer of the patient should be arranged. However, this should not delay treatment as the majority of complications after bariatric surgery are general surgical complications such as intestinal obstruction, the management of which should be well within the remit and capacity of any general surgeon covering the emergency service. Failure to recognize these problems early and intervene in a timely fashion is sub-standard provision of care and is one of the most common causes of preventable, major, long-term disability or death in bariatric surgical patients.

64.5 Avoiding Medicolegal Pitfalls

Given the rising incidence of medico-legal cases, it is important for clinicians involved in the care of bariatric patients to ensure that they avoid the obvious medico-legal pitfalls. The keys areas which need to be addressed are:

64.5.1 Appropriate Consenting

A significant portion of bariatric medico-legal complaints revolve around inadequate consent. In order to avoid such issues, it is essential that the consenting process is carefully documented with evidence that patients are given the options of both conservative treatment and surgery. With respect to surgical options, it is important that the serious and significant risks associated with surgery are emphasized (for example for sleeve gastrectomy and gastric bypass the possibility of leaks, bleeding and mortality). In addition the long term potential consequences of surgery should also be emphasized (for example gastric band slippage and erosion and gastric bypass strictures and internal herniation). There is also the possibility of weight regain and there will be excess hanging skin which should be specifically mentioned along with the need for regular follow-up in the case of patients undergoing gastric bypass surgery. Some units now rely on pre-printed consent sheets in an attempt to address these issues but consenting is a process as opposed to an event-simply documenting a list of complications on a pre-printed form will not prevent successful claims if there is no evidence that there was a full discussion with the patient prior to surgery, often on more than one occasions, and that the patient had been given an appropriate "cooling-off period" before surgery.

64.5.2 Follow Up

Unlike traditional excisional or resectional surgery, bariatric patients require life-long follow-up. Additionally, patients who undergo gastric bypass require vitamin supplementation and monitoring of their micro-nutrient levels. Although this follow up does not necessarily need to be performed by the original Bariatric Team it is important that on discharge from the Bariatric Service there are clearly documented instructions to the patient and his primary physician regarding the intervals and type of follow-up required.

64.5.3 Emergency Presentation

Bariatric patients may present acutely many years following surgery with complications related to the original operation. These patients pose a particular problem when they present to a hospital with limited bariatric experience, but, while such a facility will not be expected to provide expert bariatric care, it would be expected to be able to diagnose a patient and to discuss the management with an appropriate bariatric center and failure to do so, as discussed above, is a growing area for litigation.

64.6 Conclusion

Bariatric surgery is a new surgical paradigm with respect to the types of procedures performed and the need for long-term monitoring and management. As a consequence, we are seeing increasing litigation which is not confined to the performance of the operations alone. With appropriate multidisciplinary involvement and robust protocols for the pre-, intra- and post-operative management of these patients this can be mitigated. Finally it should be noted that the authors have focused exclusively, in this chapter, on the medico-legal aspects of patients enrolled on bariatric surgical programs. But in countries such as the United Kingdom, with predominantly state-funded health care systems, thcere is a growing problem with access to publically-funded bariatric surgery and it is likely that this rationing of bariatric surgery will also become a significant source of medicolegal claims in the future.

64.7 Case Presentations

64.7.1 Case Number 1

A 35-year old female with a body mass index (BMI) of 47 kg/m2 was referred for bariatric surgery. The patient had been obese since the age of 16 years and had multiple diets. The patient had been diagnosed with type 2 diabetes 5 years previously and she also had hypertension (which was well-controlled with pharmacological monotherapy). Her case was discussed by the multidisciplinary team and she was listed for a laparoscopic gastric bypass. The procedure was performed at a regional bariatric surgical center and following an uneventful 2-day hospital stay, the patient was discharged with the plan for outpatient review in 6 weeks.

Two weeks following surgery, the patient presented as an emergency at her local hospital with vomiting and abdominal pain. The client was managed over the weekend in her local hospital and then transferred to bariatric center on Monday. Two days following transfer she underwent diagnostic laparoscopy which revealed peritonitis over all four quadrants of the abdomen. Her procedure was converted to laparotomy and during dissection of the gastro-jejeunostomy, a splenic laceration was noted. The spleen was removed, the peritoneal cavity was washed out, and intra-abdominal drains were inserted. Following a prolonged period in the intensive care unit the patient was transferred to the ward and eventually to the community rehabilitation service.

64.7.1.1 Medicolegal Analysis

The patient's solicitors originally submitted a letter of claim alleging the following:

- the patient was inappropriately discharged following her gastric bypass.

- following admission to her local hospital, there was an inappropriate delay in the transfer to the bariatric center.
- the fact that the patient had a splenectomy was evidence of sub-standard performance of repeat surgery

However, the experts felt that the initial operation was satisfactory as was the decision to discharge the patient. With respect to the issue of transferring back to the bariatric center, there was good documentary evidence that the bariatric center was called following admission and appropriate advice given and enacted. In the experts' opinion urgent transfer to the bariatric center would not have led to a change in management. Similarly, the experts felt that the decision to perform a laparoscopy and then convert to laparotomy was reasonable and the splenic injury, whilst unfortunate, was not evidence of negligence.

However, on closer examination of the complete medical clinical entries, it was noted that the patient presented to her general practitioner (primary physician) 7 days following discharge with tachycardia and pyrexia. From the clinical records it appears that her primary physician was under the impression that the patient had undergone a gastric band insertion and treated her conservatively. The patient then represented 10 days after the surgery to the primary physician with pyrexia and abdominal pain. The patient was reassured by the primary physician who did not contact the bariatric team or the on-call surgeons at the local hospital. This failure to appreciate the severity of the client's symptoms was deemed to be a breach of duty of care and the delay in diagnosing the leak was deemed to be significant as on the balance of probabilities an earlier diagnosis would have lessened the severity of the sepsis and peritonitis and enabled a faster recovery.

64.7.1.2 Learning Points

This case illustrates the importance of the non-specialist in the management of bariatric complications. In particular, while the primary physician would not necessarily have been expected to diagnose the patient's leak, his failure to contact the bariatric center for advice was deemed to be a materially significant breach of duty of care.

64.7.2 Case number 2

A 42-year old female with a BMI 46 kg/m2 self-referred to a surgeon working in the private sector for consideration of bariatric surgery. Following discussion at the outpatient clinic, the client consented for a laparoscopic gastric bypass which was performed uneventful. Three months following surgery the patient was noted to have excellent weight loss but persistent nausea and abdominal pain. The patient's symptoms persisted and she underwent an Upper gastrointestinal (GI) endoscopy and gastrograffin swallow which showed no abnormalities. One year following surgery the patient was discharged from the care of her private surgeon as per her agreed package of care with instructions to contact her primary physician if she had any problems. The patient still had persistent malaise and nausea and saw her primary physician who referred her to the gastroenterology outpatient clinic for further investigations. On review in the clinic, she was noted to have had excellent weight loss with a BMI of 20 kg/m2. Routine blood tests revealed deranged liver function tests and a low albumin. An ultrasound revealed a gallstone within a thin walled-gallbladder. A magnetic resonance imaging of the biliary tree was then arranged which revealed no abnormalities. A percutaneous liver biopsy was then undertaken which revealed non-alcoholic steatosis. She was scheduled for a further outpatient review but prior to this, she was admitted as an emergency (15 months after her initial surgery and 3 months after being first reviewed by the gastroenterologists) with peritonitis. Laparotomy revealed an internal hernial defect in the Petersens space with gross dilatation and perforation of the blind-end ("hockey stick") of the bilio-pancreatic limb consistent with a long-standing obstruction. The bilio-pancreatic "hockey stick" was resected but the patient had a prolonged period on the intensive care unit and unfortunately died 2 weeks after surgery.

64.7.2.1 Medicolegal Analysis

The patient's solicitors submitted a letter of claim alleging the following:

- the presence of an internal hernia was a direct consequence of the negligent failure of the surgeon to close the mesenteric defects intra-operatively.
- the failure of the bariatric surgeon to diagnose the presence of an internal hernia of the bilio-pancreatic limb in the initial year following surgery was a breach of duty of care

Similarly, the failure of the gastroenterologists to diagnosis the presence of an internal hernia of the bilio-pancreatic limb was a breach of duty of care

Expert opinion was supportive of the decision not to close the mesenteric defects at the first operation on the basis that this action fulfilled the "Bolam test" (that is, a body of surgeons faced with the same clinical scenario would reasonably choose not to close the mesenteric defects as this practice is of questionable efficacy). However, the experts were very critical of the failure of the bariatric surgeon not to diagnose an internal hernia of the bilio-pancreatic limb. Although the bariatric surgeon did perform an Upper GI endoscopy and gastrograffin swallow, these investigations do not adequately delineate the anatomy of the bilio-pancreatic limb. In the opinion of the experts, in the context of a patient presenting with nausea and abdominal pain following gastric bypass, the failure to consider the diagnosis of internal herniation of the bilio-pancreatic limb and to arrange a CT scan or diagnostic laparoscopy to exclude this possibility was a breach of duty of care. In addition, the lack of clear written advice given to the primary physician by the surgeon following the patient's discharge from the surgeon's care (particularly in the context of a patient who was known to have on-going symptoms) was deemed to be fall below the expected standard. Although the experts were more sympathetic towards the gastroenterologists, their overall opinion was that their failure to appreciate the severity of the patient's symptoms and her malnourished status and to either make a timely diagnosis of internal herniation of the bilio-pancreatic limb, or failing that, to urgently refer the patient on to a bariatric surgeon for an opinion about the cause of her malnutrition was a breach of duty of care. Overall, the collective negligence of the medical teams looking after the patient meant that that she suffered from a potentially treatable pathology which directly led to her demise.

64.7.2.2 Learning Points

This case illustrates the importance of initiating timely and appropriate investigations for postoperative bariatric patients. In addition, although bariatric patients are often discharged from the care of their primary surgeon, there is a responsibility on the surgeon to ensure that there is appropriate handover to the team taking over the patient's care. Similarly, any team accepting responsibility for the management of bariatric patients needs to be competent in the management of post-bariatric complications, or at the very least, have access to a specialist bariatric service to which they can refer for advice and support.

Key Learning Points

- There is a rising incidence of medicolegal claims following bariatric surgery.
- the underlying reasons for this is multi-factorial including high patent expectations, increasing volume of surgery and the incidence of long-term complications following surgery.
- the majority of medicolegal cases fall under civil law and the expected standard of care can vary across jurisdictions
- with appropriate multidisciplinary involvement and robust protocols for the pre-, intra- and postoperative management of bariatric patients, medicolegal risks can be mitigated

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Section XIII

Miscellaneous Topics

Honorary Section Editor - Omar Khan

As bariatric surgery becomes an established mainstream treatment for morbid obesity, there is an increasing focus on the impact of surgery on factors beyond simple weight loss. These chapters explore some of the wider effects of bariatric surgery on physiological function as well as general health and wellbeing.

In terms of physiological function, Menon and Bhowmik review respiratory function in patients undergoing bariatric surgery. They emphasise the importance of pre-operative screening in these patients particularly for obstructive sleep apnea (OSA), obesity hypoventilation syndrome (OHS), pulmonary hypertension and asthma. In addition they discuss the beneficial role of bariatric surgery on respiratory function and pathology in general- an area which coming under increasing attention. In terms of reproductive function, Khan reviews the literature surrounding issues of female reproductive function and bariatric surgery. Khan concludes that although bariatric surgery does cause weight loss, which in turn reduces infertility rates, surgery should not be thought of as a primary treatment for infertility. There is however some evidence to suggest that women who have undergone bariatric procedures have safer pregnancy with fewer complications as compared to than those with morbid obesity. However she cautions that reliable contraception (preferably non-oral) is advised to delay pregnancy for approximately 12 months following bariatric surgery.

In terms of nutritional status following bariatric surgery, Pinnock, in her chapter on nutritional aspects of bariatric surgery points out there is a high incidence of nutrient deficiencies following both malabsorbative and non- malabsorbative procedures and hence long term follow-up is imperative in order to minimise potential micronutrient problems and to ensure patients make the necessary dietary and lifestyle changes to achieve a healthy and sustained weight loss. In terms of more general health outcomes, Snowdon-Carr discusses the psychological aspects of bariatric surgery. As she points out the complex relationship between mental health and obesity makes quantifying the importance of psychological factors following bariatric surgery very difficult. Part of this difficulty lies in the absence of validated tools to assess quality of life following bariatric surgery- an issue discussed in depth by Ogden in her chapter. She concludes that despite its obvious importance, there is no one measure of health- related quality of life that meets all research and clinical needs for use following bariatric surgery. Finally in their chapter Somers and Carter explore the challenge of the super-super obese- a growing problem in contemporary bariatric practice. They demonstrate that surgery in this high-risk cohort is feasible within specialist units but thorough, surgically-led multidisciplinary assessment is essential. They emphasise that no one operation is preferred for these patients, but two stage procedures are often required and body contouring surgery should be an essential part of the management path.

What these chapters illustrate is the impact of bariatric surgery on a wide range of physiological and psychological functions. Indeed as Olbers argues in his excellent chapter, there is a need to stop viewing bariatric surgery as a solution to weight problems but rather as a complex metabolic intervention which both corrects and prevents dysfunction.

Nutritional Management after Bariatric Surgery

65

Gail L. Pinnock

Abstract

Despite benefits to health, long-term problems such as nutritional deficiencies have been reported in patients following bariatric surgery. Deficiencies may occur after any of the procedures and are usually a consequence of non-compliance with diet and supplement recommendations, food intolerances, reduced dietary intake and malabsorption. The most commonly encountered deficiencies are those of iron, vitamin $B_{12,}$ calcium, vitamin D and folate. However, deficiencies in protein, fat-soluble vitamins, thiamine, zinc or copper may also occur. Patients need to follow a balanced diet that is low in fat and sugar, adopt new eating behaviours that will minimise gastrointestinal problems and take a complete multivitamin and mineral supplement. After all bariatric procedures, routine biochemical monitoring should be carried out and deficiencies treated accordingly. Long-term follow-up is imperative in order to minimise potential problems. The dietitian has an important role in supporting the patient, both short and long term, to make the necessary dietary and lifestyle changes that will achieve a healthy and successful weight loss.

Keywords

Nutritional deficiencies • Routine monitoring • Vitamin and mineral supplements • Staged diet progression • Postoperative diet • Eating behaviours • Food intolerance • Compliance • Dietetic assessment

65.1 Introduction

Despite considerable benefits to health offered by bariatric surgery, some long-term problems have been reported. These include nutritional deficiencies, metabolic bone disease and renal stones [1–3]. It is therefore imperative that patients have access to long-term follow-up in order to minimise these potential complications. However, patients should be encouraged to share responsibility for their health and commit to long-term follow-up.

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Frequency of follow-up depends on the type of procedure and the severity of any pre-existing co-morbidities. A key recommendation from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was the need for long-term follow-up; it was also felt that patients should have access to clear postoperative dietary guidance [4]. Attendance at regular follow-up appointments is associated with better weight loss [5].

The dietitian is an essential member of the multidisciplinary team [6] whose expertise is paramount in managing the long-term nutritional support and weight loss of the bariatric patient [7]. A pilot study by Sarwer [8] showed regular post surgical follow-up carried out by a registered dietitian led to the consumption of a healthier diet, fewer episodes of gastrointestinal symptoms and better weight loss.

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Table 65.1 Checklist for dietary assessment after surgery

Check list for dietary assessment	Additional comments
Anthropometry	Weight, Body Mass Index (BMI), Excess Weight Loss (EWL) to date, waist circumference
Medications and multivitamin and mineral supplements	Record any change in medications/dosage Check compliance with supplements
GI symptoms/bowel habit/any other symptoms or health changes	Check for reflux/heartburn, nausea, vomiting, pain/discomfort, dumping, constipation, diarrhoea, steatorrhoea
Diet recall	Meal pattern, eating behaviours, snacking/grazing, protein intake, iron and calcium intake, fruit/vegetables, inappropriate foods, fluid intake, alcohol, food textures appropriate for the stage after surgery, portion size, speed of eating and drinking
Physical activity	Level and frequency compared to pre-surgery
Biochemistry	Review most recent results
Lifestyle/miscellaneous	Changed behaviours, support network, cooking ability, cooking facilities, financial situation, coping strategies, etc.

65.2 Overview of Nutritional Management

The nutritional management of the bariatric patient, following surgery, serves a number of purposes. In the short term, it ensures the diet is adequate to promote wound healing, preserve lean body mass (LBM) and to establish eating behaviours that will minimise vomiting and reflux. In the long term, it is to monitor nutritional status, minimise complications and maximise weight loss.

Frequently, the dietitian is the first point of contact for patients after surgery. Using a combination of motivational interviewing and behaviour change techniques the dietitian can support the patient to make the necessary dietary and lifestyle changes that will lead to a successful outcome. Any unrealistic expectations about surgery and weight loss need to be addressed, preferably before surgery, but some patients may need continued support (see Chap. 11).

Cultural and religious influences on food choice and intake should be recognised and supported. In addition, a patient's economic status will impact food choice; this must be sensitively handled and appropriate alternatives should be suggested. Patients should also be offered advice on healthier cooking methods and meal planning.

See Table 65.1 for more information on the dietetic assessment after surgery.

65.3 Short-Term Nutritional Management

In the immediate period after surgery, it is important to ensure that the patient is adequately hydrated and they should be encouraged to aim for at least 1.5 l of sugar-free fluids a day [5]. They need to sip slowly rather than gulp liquids in order to avoid discomfort. Carbonated drinks should be discouraged because they may also cause discomfort and bloating. Melting ice on top of the tongue may help to enhance hydration.

There is some evidence of an increased risk of renal stones following Roux-en-Y gastric bypass (RYGB) [3, 9]. Although the exact mechanism is unclear, it is thought that increased excretion of urinary oxalate and decreased urine output are significant. Dehydration should, therefore, be avoided following RYGB.

Adequate energy and protein is needed to promote healing and preserve LBM during the initial period of rapid weight loss [7]. This may be difficult to achieve in the early postoperative stage because of the physical restrictions imposed by reduced stomach capacity.

65.3.1 Staged Diet Progression

Practice varies considerably between bariatric centres, but usually the patient progresses from fluids to textured foods over a period of some weeks. Some centres follow a conservative management plan and commence patients on liquids, while other centres prefer to start their patients on puréed foods. Although there is limited evidence for the use of such transition diets, many bariatric centres, internationally, recommend the gradual introduction of textures. An audit of dietetic members of the American Society for Metabolic and Bariatric Surgery (ASMBS) revealed that multiple phase diets are commonly used with a "normal" textured diet being achieved in 8 weeks for a RYGB and 6–8 weeks for an Adjustable Gastric Band (AGB) [7].

It can be difficult to meet nutritional requirements during the liquid and purée stages of the postoperative diet. Patients should be encouraged to have milk and milk-based products (which have a high biological value) and smooth sieved soups. Advice should be given on methods of fortifying liquids and on appropriate protein supplements. It is worth noting that some patients may develop temporary lactose intolerance after surgery and alternative non-dairy products such as soya milk or lactose free milk should be suggested.

Table 65.2 Stages of diet progression after surgery

Stage 1 approximately 2 weeks	Stage 2 approximately 2 weeks	Stage 3 approximately 2 weeks	Stage 4 approximately 2 weeks
Free fluids only Encourage 1.5–2.0 l/day	Purée or blended food 2–3 tablespoons/meal	Soft foods and some crispy textures	Low fat, low sugar balanced diet—increasing to small tea plate size over time

When patients progress to purée foods, they should be encouraged to have protein foods of high biological value such as eggs, fish, etc. Some non-fibrous vegetables and fruit can be included provided they purée easily. All foods need to be blended with additional fluid in order to achieve a smooth consistency.

Some bariatric surgeons prefer sleeve gastrectomy patients to be on free fluids for 4 weeks rather than 2 weeks. This is because the narrow gastric remnant is vulnerable to anastomotic leaks.

Table 65.2 highlights the dietary stages after surgery but it is worth noting that the practice at any individual bariatric centre will be the personal preferences of the surgeon and dietitian.

Even during this very early postoperative stage, it is important to remind patients of the new eating behaviours they need to adopt in the long-term such as eating slowly, keeping food and drinks separate and stopping before feeling full (see Sect. 65.4.1).

65.4 Long-Term Management

Ideally, patients will have been counselled on the general principles of healthy eating during their assessment prior to surgery and this should be continued afterwards for re-enforcement. All patients, no matter what procedure they have had, should be encouraged to follow a balanced, low fat and low sugar diet. They should choose protein of high biological quality, and complex wholegrain carbohydrates rather than simple carbohydrates and aim for the recommended five portions of fruit and vegetables a day. They should avoid sugary foods and drinks, which will have a detrimental effect on weight loss and may also cause dumping syndrome.

Reduction in stomach capacity after surgery can sometimes encourage patients to graze throughout the day. This should be discouraged in favour of a regular meal pattern consisting of three small meals a day with appropriate healthy snacks between meals, if needed. Some textures such as tough meat, bread and fibrous vegetables and fruit are not well tolerated after surgery. This may lead some patients into maladaptive eating, where they choose soft or sloppy foods of poorer nutritional quality that are better tolerated. It is unfortunate that chocolate, ice cream, biscuits and savoury snacks such as crisps are easier to eat than more nutritious foods.

Patients who report following recommended postoperative dietary advice, once they have resumed a normal diet, have better weight loss in the long term [10].

It is recommended that patients should take a complete multivitamin and mineral supplement in the long term in order to minimise potential nutritional deficiencies (see Sects. 65.5.1 and 65.5.2).

65.4.1 Eating Behaviours After Surgery

After surgery, the smaller stomach capacity imposes some dietary restrictions that require a change in eating behaviours [11]. Patients are no longer able to eat large quantities of food and it is also difficult for them to eat and drink at the same time. The following eating behaviours are usually recommended:

- Have a regular meal pattern.
- Eat slowly. Take approximately 20–30 min to eat a meal.
- Take small bites of food.
- Chew really well before swallowing.
- Stop eating before feeling full.
- Use a small plate or bowl in order to control portion sizes.
- After eating, leave at least 30 min after eating before drinking [5].
- Sip fluids slowly rather than taking large mouthfuls.
- Mindful eating—concentrate on your meal rather than watching television or working while eating.

Patients may sometimes notice a change in appetite following some surgeries such as the sleeve gastrectomy, RYGB and biliary pancreatic diversion with duodenal switch (BPD/DS) because of a change in gut hormones. They may also experience a change in taste acuity especially with sweet foods and drinks [12].

65.4.2 Gastrointestinal Symptoms After Surgery

Changes in gut anatomy and physiology after surgery increase the likelihood of food intolerances and gastrointestinal symptoms such as reflux, nausea, vomiting and dumping syndrome [11]. In the majority of cases, these symptoms are exacerbated by noncompliance with new eating behaviours, eating foods whose textures are poorly tolerated or progressing too quickly through the staged eating plan (see Sects 65.4.1 and 65.3.1). Poorly tolerated foods tend to be dry, doughy or stringy and fibrous. The most frequent complaints are about red meat, chicken breast, bread, other starchy foods such as pasta and rice and fibrous fruit and vegetables. Some food intolerances improve with time but some patients can still experience problems many years after surgery. Dumping syndrome tends to be associated with RYGB but similar symptoms have also been reported following sleeve gastrectomy (SG) [11]. Consumption of simple sugars that are rapidly absorbed and high fat foods are the usual cause of dumping syndrome.

Constipation may also be a problem, especially in the early stages, because of low fibre intake; patients should be advised about appropriate high fibre foods, adequate fluid intake and laxatives. Some supplements such as calcium and iron may exacerbate constipation. Persistent nausea, vomiting, reflux, diarrhoea, constipation and abdominal pain should be investigated [5]. If intractable steatorrhoea occurs after BPD and BPD/DS, then the patient should be screened for nutritional deficiencies. In addition, their diet should be assessed for fat content and they should be advised accordingly.

65.4.3 Disordered Eating

Disordered eating such as binge eating disorder, emotional eating, grazing etc. is frequently encountered in obese patients. Although it is not a contraindication to surgery, it is preferable to address the disordered eating before surgery so that patients are equipped to cope with their changed relationship with food. It is important for the dietitian to look out for a return to old habits that may jeopardise successful weight loss. Patients who cannot cope with their changed relationship with food should be referred for psychological input.

65.4.4 Weight Loss and Weight Regain

Poor weight loss or weight regain have been reported in 20–30 % of patients within the first few years of surgery [13] and this possibility should be discussed in detail with the patient prior to surgery (see Chap. 11). Frequent causes of weight regain are:

- Slipping back into old habits
- Not following dietary and lifestyle recommendations
- Not following new eating behaviours—maladaptive eating
- Not engaging in physical activity
- Psychological problems.

In the first instance, patients should be supported with dietary and lifestyle modifications, behaviour change techniques and encouragement to increase their physical activity [14]. If these prove to be unsuccessful then investigations should be carried out to establish whether there is any physical or surgical problem such as:

- Pouch enlargement
- Anastomotic dilation
- Inadequate band restriction

Revisional surgery, which carries increased risk, should be considered only as a last resort [5].

65.4.5 Alcohol

Patients should be warned that alcohol frequently has a more potent effect after surgery. Accelerated alcohol absorption and longer time for alcohol clearance from the blood have been shown to occur after RYGB; similar findings have been demonstrated following SG [5]. In addition, lower body weight and rapid gastric emptying are also contributing factors.

Some patients may struggle after surgery when their relationship with food changes and they may resort to substitution behaviours; alcohol is often used as a substitute. Conason [15] reports a significant increase in substance use following surgery; in particular, RYGB patients are more likely to be at risk of increased alcohol use. The dietitian needs to discuss alcohol consumption with patients, both pre- and post surgery.

65.4.6 Exercise

Although not directly connected to nutritional management, the importance of increasing physical activity both as a means of improving general health and as an aid to weight loss should be discussed with patients. Patients should also be aware that physical activity plays an equally important role in weight maintenance.

Patients should be encouraged to engage in moderate intensity aerobic exercise for a minimum of 150 min/week but to aim for 300 min/week. In addition, to preserve LBM, patients should engage in strength training two–three times a week. Physical activity after bariatric surgery is associated with better weight loss [16].

65.5 Nutritional Considerations

There is a risk of developing nutritional deficiencies following any of the bariatric procedures. These may be a consequence of non-compliance with dietary and supplement recommendations, inability to tolerate some foods, reduced dietary intake or malabsorption. Some nutritional deficiencies are associated with specific procedures and in the case of malabsorptive procedures, the length of intestinal bypass is directly related to the risk of nutritional deficiencies [5].

65.5.1 Monitoring

Routine monitoring should be carried out, after any procedure, on a regular basis [5, 7]. These results can then be compared to nutritional baseline markers collected prior to surgery, to highlight any change in nutritional status [17]. However, there is some evidence that pre- and postoperative monitoring is not carried out in a large number of patients [18]. An audit conducted amongst members of the British Obesity and Metabolic Surgery Society (BOMSS) revealed some areas of good practice but also considerable diversity regarding routine monitoring and vitamin and mineral supplementation [19].

Routine postoperative screening should include the following:

- Full blood count (FBC)
- Urea and electrolytes (U&E)
- Liver function test (LFT)
- Ferritin
- Folate
- Vitamin B_{12}
- Calcium
- Vitamin D
- Parathyroid hormone (PTH)
- Zinc (after malabsorptive procedures)

Routine screening should also include glucose and glycosalated haemoglobin (HbA1C) if there is evidence of type II diabetes prior to surgery.

Noncompliance can be an issue in some bariatric surgery patients with respect to vitamin and mineral supplementation. Edholm [20] found compliance with supplementation to be as low as 24 %. It should be impressed upon patients, both pre- and post- surgery, how important it is, for long-term health, to comply with recommendations regarding supplements and follow-up appointments.

65.5.2 Supplementation

Guidelines pertinent to the management of bariatric surgery patients have been reviewed [5, 7, 21, 22] and used to write this section. The aim of supplementation is to maintain nutritional parameters within the normal range without giving excess doses of supplements. However, there are currently no guidelines in the United Kingdom (UK) regarding monitoring and supplementation. A recent audit shows diversity of practice and work is continuing on the development of peer reviewed BOMSS guidelines [19].

See Table 65.3 for details of minimal supplementation. Please note the following:

- Some patients (RYGB, BPD/DS) may need double the adult dose of complete multivitamin and mineral supplement daily.
- The dose of elemental calcium supplement should be divided throughout the day.
- Calcium and iron supplements should not be taken within 2 h of each other.
- Vitamin D supplement should be titrated to give 1,25 dihydroxy-vitamin D levels >30 ng/mL.
- Sufficient B_{12} should be given to maintain normal range.

However, it should be noted that clinical practice is likely to vary depending on local or national guidelines. In case of doubt, healthcare professionals should refer to current literature. Routine monitoring of nutritional status is, however, always necessary in order to determine whether supplementation is adequate.

Table 65.3 Minimal supplementation post surgery

Micronutrient	LAGB	SG	RYGB	BPD/BPD-DS
Complete multi-vitamin and mineral supplement (containing Fe, folate, thiamine)	Yes	Yes	Yes	Yes
Calcium and vitamin D supplement	Depends on baseline levels of D and PTH	Yes	Yes	Yes
Iron (from multivitamin/mineral supplement and/or additional supplement)	Consider in pre-menopausal women	Yes	Yes	Yes
Vitamin B_{12}	As needed for normal range	As needed for normal range	As needed for normal range	As needed for normal range

LAGB laparoscopic adjustable gastric banding, *SG* sleeve gastrectomy, *RYGB* roux-en-Y gastric bypass, *BPD* biliary pancreatic diversion, *BPD-DS* biliary pancreatic diversion with duodenal switch, *PTH* parathyroid hormone

65.5.3 Significant Nutrients to Be Monitored

65.5.3.1 Protein

Adequate protein intake is important, following surgery, in order to preserve LBM of patients. However, this may be difficult to achieve because of reduced intake or malabsorption. Some individuals may struggle with the texture of meat, especially in the early stages after any of the bariatric procedures, resulting in poor dietary intake. In those situations, patients should be counselled about alternative forms of protein such as dairy, eggs, fish, pulses or soya that may be better tolerated. In addition, they should be reminded to take small mouthfuls and chew food very well to facilitate the digestive process.

Decreased levels of hydrochloric acid following RYGB limit the conversion of pepsinogen to pepsin, which starts the breakdown of protein; therefore patients who have had RYGB may be at risk. Of particular concern are those who have had malabsorptive procedures such as the BPD/DS; about 25 % of protein is malabsorped following BPD/DS. Although uncommon, protein malnutrition (PM) or protein-energy malnutrition (PEM) may occur. Patients with severe malnutrition should be admitted to hospital and enteral or parenteral nutrition started according to local clinical guidelines [5].

Protein intake should be patient-specific with respect to age, gender and weight. A minimum of 60 g/day or 1.5 g/kg ideal body weight (IBW)/day should be adequate [5]. Frequently, 60–80 g protein/day is suggested, but after the early postoperative stage this is likely to exceed metabolic requirements [7]. Greater intakes of 2.1 g/kg IBW/day should be assessed on an individual basis only [5]. About 30 % extra protein is needed for those patients who have had BPD/DS to compensate for malabsorption; this equates to approximately 90 g/day [7]. Protein intakes of 80–90 g/day are associated with lower LBM loss [5].

It should be noted that consumption of excessive quantities of protein will limit intake of other macronutrients because of the small stomach capacity [7].

65.5.3.2 Iron

A number of factors, such as food intolerances, reduced intake, non-compliance with supplements and malabsorption, are implicated as causes of iron deficiency following bariatric surgery. Red meat is frequently poorly tolerated after all bariatric procedures and patients tend to exclude it from their diet thereby limiting their intake of heme iron. For those who can eat meat, iron deficiency is less common [7]. Absorption of iron mainly takes place in the duodenum and proximal jejunum and therefore patients who have undergone RYGB are at more risk of developing iron deficiency anaemia; it is reported to range from 20 to 49 % [7]. In addition, decreased levels of hydrochloric acid limit the amount of dietary iron that can be reduced from the ferric state to the more easily absorbed ferrous state. Although AGB, SG and BPD/DS patients are considered to be at less risk, there is evidence of iron deficiency, low iron stores and anaemia following these procedures, so they should also be routinely monitored.

It should be noted that iron deficiency is common in the general population especially in menstruating women; deficiencies should be rectified before surgery.

A complete multivitamin and mineral supplement should usually be adequate although menstruating women and adolescents may require additional supplementation following surgery. Mechanick [5] suggests 45–60 mg after SG, RYGB and BPD/DS and Aills [7] recommends 50–100 mg for menstruating women. Patients should be advised about sources of heme and non-hame iron in the diet. Having a food or drink that is high in vitamin C at the same time as the iron supplement will improve absorption of iron. Patients should be advised not to take an iron supplement within 2 h of taking a calcium supplement because they have similar absorption pathways and may interfere with each other's absorption.

Iron deficiency should be supplemented with 100–200 mg elemental iron daily.

65.5.3.3 Vitamin B_{12}

Vitamin B_{12} (hydroxycobalamin) is considered to be the most common deficiency with a prevalence of 11 % 1 year after surgery [23]. There is a greater risk of deficiency after RYGB (26–70 %) because of decreased hydrochloric acid, which is needed for the release of B_{12} from protein foods. In addition, there is decreased availability of Intrinsic Factor, which is required for the absorption of B_{12} in the terminal ileum. Although it is considered to be of less risk with other procedures, Gudzone [18] found that B_{12} deficiency occurred after all surgeries.

Low intake of B_{12} containing foods such as meat and poultry, which are not well tolerated by patients, and malabsorption are the major causes of B_{12} deficiency. Patients following a vegan diet may also be at risk. The use of medication that reduces gastric acid secretion such as H_2-receptor blockers and proton pump inhibitors can also contribute to vitamin B_{12} deficiency [23]. Body stores of B_{12} can last for many years but deficiency may occur over time if not routinely supplemented.

Routine screening should occur after RYGB and BPD, but healthcare professionals need to be aware that deficiencies may also occur after SG and BPD/DS. Mechanick [5] suggests oral supplementation with B_{12} of 1000 μg (micrograms) daily should maintain levels within the normal range. Intramuscular formulations are rapidly absorbed and considered to be the "gold standard"; 1000–3000 μg intramuscularly every six to 12 months was also suggested. In the UK, it has become more common to routinely supplement after

RYGB with 1 mg (milligramme) of vitamin B_{12} every 3 months. If supplementation is not routinely given to SG and BPD/DS patients, then they should be closely monitored and supplemented as needed.

65.5.3.4 Folate

Although folate deficiency is thought to be less common than B_{12} deficiency after surgery there is evidence that it increases after all surgeries but especially after the RYGB [7, 18]. Deficiency is usually a consequence of poor diet (main source is green vegetables) and non-compliance with vitamin and mineral supplementation. In normal circumstances the folate present in a complete multi-vitamin and mineral supplement is sufficient to meet requirements. High levels of folate can mask the haematologic symptoms associated with B_{12} deficiency.

Folic acid deficiency is associated with an increased risk of neural tube defects during pregnancy and women of child-bearing age should be routinely monitored (see Sect. 65.5.4).

65.5.3.5 Thiamine

Thiamine deficiency (beriberi) can cause irreversible damage and patients may present with peripheral neuropathy, Wernicke's encephalopathy or Korsakoff's psychoses. Most cases of thiamine deficiency are likely to occur in the early postoperative period if protracted vomiting is an issue. Aasheim [24] reports that 94 % of such cases occurred within 6 months of surgery although the range was 3 weeks to 18 months. Rapid weight loss, anorexia, food intolerance and non-compliance in the early postoperative period may also contribute to thiamine deficiency [24]. If the patient becomes dehydrated and is admitted to hospital, the dextrose/saline drip further exacerbates the problem. Any period of prolonged vomiting or suspicion of thiamine deficiency should be treated immediately with oral, intramuscular or intravenous thiamine in order to avoid further depletion of body stores.

It is worth noting that thiamine deficiency may also occur at a later stage as a consequence of poor dietary intake, non-compliance with multivitamin and mineral supplementation, excessive alcohol intake or maladaptive eating [7].

Most complete multivitamin and mineral supplements usually provide the recommended daily amount. Routine screening is not necessary but should happen in patients with rapid weight loss, protracted vomiting, excessive alcohol use or on parenteral nutrition (PN).

65.5.3.6 Calcium and Vitamin D

Absorption of calcium takes place mainly in the duodenum and proximal jejunum while vitamin D (cholecalciferol) absorption occurs in the jejunum and ileum. Vitamin D is required for the absorption of calcium and consequently low vitamin D levels will decrease the absorption of dietary calcium with a corresponding increase in parathyroid hormone levels. Secondary hyperparathyroidism is an indication that mobilisation of calcium from bone is occurring in order to maintain calcium homeostasis. There is evidence of an increased risk of metabolic bone disease, in the long term, following BPD/DS and RYGB [25, 26]. Patients who undergo malabsorptive procedures and experience steatorrhoea will be at greater risk of vitamin D (and other fat-soluble vitamin) deficiencies compared to those who undergo RYGB [18]. Deficiency after AGB is usually the result of poor compliance with dietary recommendations and reduced diary intake. Calcium, vitamin D and PTH levels should be monitored routinely and supplemented accordingly.

It is worth noting that the incidence of vitamin D insufficiency is relatively high (90 %) in the morbidly obese population [27, 28] and should be rectified before surgery.

There is some evidence that calcium citrate is more readily absorbed than calcium carbonate and is therefore the preferred supplement, combined with vitamin D, to minimise the risk of secondary hyperparathyroidism [5, 7]. Absorption is improved if supplements are taken with food but they should not be taken within 2 h of taking an iron supplement.

There is no consensus of opinion regarding supplementation levels; calcium doses range from 500 to 1500 mg and vitamin D doses range from 800 to 5000 International Units (IU)/day [7]. Mechanick [5] suggests 1200–1500 mg of calcium and 3000 IU of vitamin D. In the UK, patients are usually supplemented with 1000–1200 mg calcium and 800 IU vitamin D [19]. If severe vitamin D deficiency occurs, oral vitamin D2 or D3 may be necessary with 50,000 units one to three times a week or daily [5].

Some patients may become intolerant to dairy products in the early stages after surgery and this leads them to avoid calcium-containing foods; alternative non-dairy sources of calcium should be suggested. In addition, many patients believe that dairy products are high in fat and calories and therefore should be avoided. Low fat dairy products are acceptable alternatives because they are low in calories but still have good calcium content.

65.5.3.7 Fat-Soluble Vitamins—A, E and K

Fat soluble vitamin deficiencies are more likely to occur after malabsorptive procedures such as the BPD because fat absorption is decreased by 72 % [7].

Slater [2] found evidence of vitamin A deficiency (69 %), vitamin K deficiency (68 %) and vitamin D deficiency (63 %) in patients after BPD/DS. There is also evidence of vitamin A deficiency after RYGB [7]. Mechanick [5] recommends routine screening for vitamin A after malabsorptive procedures such as BPD/DS, although there is insufficient evidence for the routine monitoring of vitamin E and K after surgery. Because of this evidence of vitamin A deficiency after RYGB, routine monitoring should be considered. In the case of vitamin A deficiency, it may be necessary to supplement alone or in combination with other fat soluble vitamins [5].

Table 65.4 General supplementation during pregnancy and breastfeeding

Micronutrient	Level of supplementation (daily)	Additional comments
Folic acid	400 μg (in addition to 300 μ[mu]g from diet)	Prior to conception and for the first trimester. Can then be reduced to 350 μg
Vitamin D	10 μg	Needed during pregnancy and breastfeeding
Calcium	700 mg	Needed during pregnancy. Additional 500 mg needed during breastfeeding
Iron	14.8 mg	

65.5.3.8 Zinc, Copper and Selenium

Zinc relies on fat for absorption and therefore deficiencies may occur after BPD/DS and should be monitored routinely. Incidence of zinc deficiency has been shown to range between 42 % in RYGB to 92 % in BPD/DS after 12 months of surgery; 9 % of patients were zinc deficient prior to surgery [29]. There is conflicting evidence for zinc deficiency after SG [17, 30]. Mechanick [5] suggests routine screening of zinc after both RYGB and BPD/DS but routine supplementation of zinc only after BPD/DS. Zinc deficiency should be suspected in patients with hair loss [5].

Patients having a zinc supplement for hair loss or deficiency should also receive 1 mg of copper for every 8–15 mg of zinc [5]. Many of the divalent cations share a common absorption pathway and zinc replacement can therefore cause copper deficiency.

Copper is released from food by the action of stomach acid and therefore deficiencies may occur following procedures that reduce gastric acid secretions [31]. In addition, zinc supplements can also cause copper deficiency because they share a common absorption pathway [5, 31]. Low levels of copper have been seen in RYGB [32] and two cases of copper deficiency were reported 10 years after RYGB [31]. Ernst [32] suggested that, as well as bypassing of the duodenum and proximal jejunum, high levels of iron, zinc and calcium supplementation may result in copper deficiency. Routine screening for copper may not be necessary but healthcare professionals should be aware of the potential for copper deficiency following RYGB and BPD/DS [31]. Mechanick [5] suggests that copper should be screened in patients who have evidence of poor wound healing and anaemia that is not related to iron deficiency. A complete multivitamin and mineral supplement containing 2 mg of copper should be sufficient.

For patients with zinc and/or copper deficiency, an additional 8–38 mg of elemental zinc and/or 1.6–7.5 mg of copper is needed daily to restore normal levels [33].

There is some evidence of selenium deficiency after BPD/DS and Aills [7] recommends using supplements that are complete in all minerals. However, Mechanick [5] believes that there is insufficient evidence to routinely screen and supplement for selenium, but it should be checked in those patients who have unexplained anaemia following malabsorptive procedures.

65.5.4 Nutrition in Pregnancy

Although pregnancy is not contraindicated after bariatric surgery, it is not encouraged within the first 12–18 months, which is the period of rapid weight loss [5]. This should be discussed with women of childbearing age before surgery.

Thereafter, women who intend to become pregnant should be counselled on the importance of preconception nutrition, especially with respect to folic acid. Once pregnant, they may need to change their usual multivitamin and mineral supplement to one specifically designed for pregnancy that does not contain vitamin A in the retinol form [34]. However, women who have had BPD/DS may need to continue with fat soluble vitamins throughout pregnancy and their bloods should be monitored accordingly. Patients who become pregnant post-AGB should have band adjustments as necessary for appropriate weight gain for foetal health [5]. All women should be counselled about appropriate weight gain during pregnancy and the need for a healthy balanced diet. See Table 65.4 for more details.

Conclusion

There is substantial evidence that nutritional deficiencies frequently occur following bariatric surgery, with some procedures carrying a greater risk of deficiencies compared to others. Routine monitoring of the patient's nutritional status and appropriate supplementation is imperative to minimise the potential deficiencies. The dietitian plays an important role in managing the long-term nutritional support and weight loss of the bariatric patient.

Key Learning Points

- Despite the considerable benefits to health, some long-term nutritional deficiencies have been reported in bariatric surgery patients.
- Patients should be monitored regularly and deficiencies supplemented accordingly.
- Better weight loss is achieved when patients have long-term follow-up with a registered dietitian.
- Compliance with diet, lifestyle modifications and supplements can be an issue with some patients.

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Management of Extreme Obesity (BMI > 60 kg/m²)

66

Shaw Somers and Nicholas C. Carter

Abstract

The management of extreme obesity (BMI >60) is becoming a modern necessity. A significant proportion of these patients may not be suitable for surgical intervention, and need palliative management. Those thought suitable for surgical intervention will require thorough specialist multidisciplinary team assessment led by the bariatric surgeon. Assessment should include input from the bariatric physician, psychologist, dietitian, and anesthetist.

Preparation for surgery must take account of the operating and ward environment. Many of these massive patients will require bespoke environmental and handling solutions.

The choice of surgical procedure should be determined by an experienced bariatric surgeon confident in undertaking treatment of such patients. Any procedure will achieve weight loss, the imperative is for a safe and straightforward perioperative course.

Post operatively, specific adjustments to the general course of post-op bariatric care are required for this group. The need for long-term dietetic, psychological, and plastic reconstructive input is established.

Keywords

Obesity • Morbid Obesity • Super Obesity • Super Morbid obesity • Super-super obesity • Extreme obesity

66.1 Introduction

The rise in prevalence of morbid obesity worldwide has been matched by an increase in the incidence of extreme obesity (BMI >60). These complex individuals present specific challenges to their healthcare professionals and demand significant experience and resource allocation for their treatment. It is imperative to undertake a full multi-disciplinary team (MDT) assessment, and to accept that for some patients in this category, active intervention will not result in improved quality of life and treatment should be with palliative intent only.

It should be remembered that in this patient group, achieving weight normality is a very unlikely goal. For some, substantial weight loss may be achieved, but at the cost of gross disfigurement from excess skin. For the majority of patients, weight loss can be significant enough to restore function and improve comorbidities.

While the principles described in other sections of this book have relevance to this patient group, it is important to understand one vital precept—patients with extreme obesity can tolerate appropriate and uncomplicated bariatric surgery. However, any complication of surgery can place life-threatening strain on their limited physiological reserve. The prevention, avoidance, and active management of complications is paramount to prevent perioperative mortality.

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Table 66.1 Nomenclature for morbid obesity

BMI	Class	Alternatives
40+	Morbid obesity	–
50+	Super obesity	Super morbid obesity
60+	Extreme obesity	Super super obesity

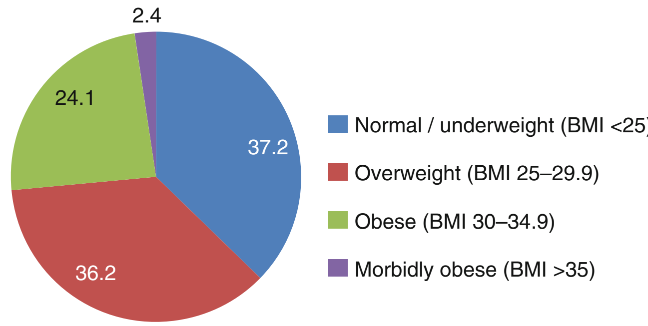

Fig. 66.1 BMI adult (>16 years) proportions in the UK 2012 [1]

66.2 Nomenclature

The onset of morbid obesity has been defined by international convention. However, nomenclature for the gradation of increasing levels of morbid obesity remains unclear. We suggest a nomenclature classification (See Table 66.1) to provide clarity in discussion of cases and reporting of data.

Clearly, patients with morbid obesity can be subdivided into simple and complex groups depending on the number of comorbid and concomitant conditions. In the extreme obese population, these additional factors must be individually assessed and management determined by analysis of the specifics of each case.

For data analysis, there should be accurate reporting of terms used to describe groups of obese patients.

The use of percent excess weight loss (%EWL) as a measure of surgical success is questionable in this patient group. As body weight increases, the percent excess weight that can be reasonably lost without significant nutritional compromise decreases. For an average 200 kg patient, 40 % EWL still equates to over 50 kg. Acceptance of percent total body weight loss as the universal measure of bariatric surgical results is therefore recommended.

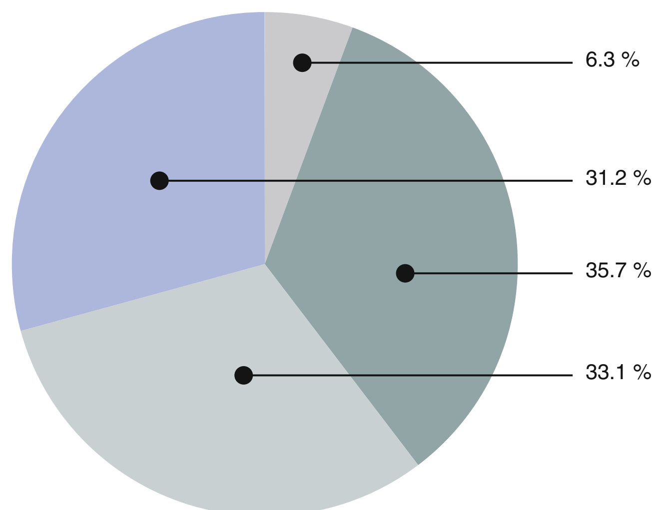

Fig. 66.2 BMI adult proportions in the USA [2]. Normal weight or underweight (BMI under 24.9). Overweight (BMI of 25–29.9). Obesity (BMI of 30+). Morbid obesity (BMI of 40+)

66.3 Prevalence

Analysis of the 2007 Health Survey for England data revealed 728,571 (1.8 %) adults were morbidly obese with a BMI >40 [1]. Subset analysis showed that 51,000 (7 %) of these were super obese (SO) with a BMI >50. The most recent available Health Survey for England data is for the year 2012 (Fig. 66.1) and shows that the number of adults with morbid obesity has risen to 1,065,000 (2.4 %) [1]. Assuming the same proportion has a BMI >50 as in 2007, then some 74,500 fall into the super obese category [1]. Public Health England has estimated that the cost to the UK economy of overweight and obesity for 2007 was £15.8 billion [1]. There is no available national data on the number of patients with extreme obesity.

For comparison, in the United States of America (USA), the latest figures from the Centre for Diseases Control and Prevention reveal that some 6.3 % of adults are morbidly obese [2] (Fig. 66.2). If we assume that like the United Kingdom (UK), 7 % of these are super obese then there are just over a million adults in the USA with super obesity although this is well known to be a conservative estimate [2, 3]. Healthcare costs attributable to obesity in the USA have been calculated to be in the region of $147 billion for 2008 [4].

66.4 Assessment of the Extremely Obese Patient

Assiduous preparation of the extremely obese patient is vital. There is no scope for shortcuts or error of judgment in this patient group. Issues concerning the assessment of the extremely obese patient are summarized in Table 66.2. A truly multidisciplinary approach with a bariatric physician, specialist dietitian, specialist nurse, psychologist, bariatric anesthetist and bariatric surgeon is mandatory. This is the crux of making sure these patients are managed appropriately. In this group especially, the decision making and care should be led by the bariatric surgeon.

Table 66.2 Assessment considerations for extreme obesity

Nutritional deficiencies:
Vitamins B1, B6, B12, D
Folate, Iron
Protein (hypoalbuminaemia – usually secondary)
Trace elements
Psychological:
Feeder dependence, emotional eating, stress eating, sabotage eating, overt eating disorder
Physical:
Immobility, shortness of breath, lymphoedema, pressure ulcers, proximal muscle wasting.

Patients with extreme obesity have a complex multifactorial etiology for their obesity. Environment, psychology, genetics and comorbidites all play their part. Many of these patients cannot attend hospital appointments easily, and therefore some of the preoperative preparation and work up may need to be performed in the home or local care environment. Similarly, some centers would arrange for the extremely obese patients to be admitted onto the ward to perform adequate preoperative preparation and perhaps stay for their preparatory liver reducing diet.

The MDT must be aware of the paradoxically high prevalence of nutritional deficiency in this patient group. The commonest are micronutrient and vitamin deficiency, but true malnutrition may also be evident from blood assessment. Chronic lymphedema of the legs and abdominal apron is common. Repeated cellulitis can lead to amyloidosis and other protein and nutrient losing pathologies. These must be adequately managed if any active intervention is to be contemplated.

Mobility and optimization of proximal muscle strength is vital in this patient group, especially if the subject is immobile. Involvement of physiotherapy in the pre-operative assessment of this group of patients is essential. Pre-coaching of respiratory exercises, especially in those with obesity hypoventilation can help minimize the possibility of respiratory compromise that can occur in the event of complications.

66.5 Assessment of the Treatment Environment

Extremely obese patients require specific support within the environment for bariatric treatment. It is not thought appropriate for these patients to be treated within the same environment as general patients. Dignity and privacy must be respected and segregation offered to prevent derision and comment from the general public.

Furniture and physical environmental considerations should be made well in advance of patient admission. Bariatric beds must be adequately specified to carry the weight of the patient and allow movement (Fig. 66.3). Similarly, there should be bariatric chairs of sufficient size and rating. Toilet facilities should be adequate to allow dignity and privacy in safety. Specialized toilet seat-support frames are available to protect standard toilets (Fig. 66.4). When surgery is planned, adequately rated operating tables must be sourced. The ability of such tables to tolerate the patient's weight while tilting is important—some are rated differently depending on the anticipated patient positioning (Fig. 66.5.). Consideration should also be given to floor loading. Patients with weight in excess of 300 kg may require loading assessment for the ward and operating room floor. Combined weight of the patient, operating table, surgical team, and laparoscopic kit may exceed local area load tolerance. Supporting the floor from below has been required on occasion.

Patient handling must be carefully considered and rehearsed. Staff should be aware of limitations to manual handling, and understand which handling aids are appropriate. Specialist lifting and transfer equipment should be available, especially in theatre. Devices such as the hover-matt and hover-jack [Hovertech International, Bethlehem, PA, USA] are indispensible for these patients.

66.6 The Specialist MDT

66.6.1 Bariatric Physician

Screening of comorbidites is part of every bariatric patient's preparation for surgery. In extreme obesity it must be conducted with thoroughness. Comorbidities are present much more frequently in extreme obesity (93.5 %) compared to morbidly obese patients (56.7 %) [5]. Lopez et al., for example, found that the incidence of obstructive sleep apnea was 95 % in extreme obesity [6]. The specialist bariatric physician needs to perform careful screening and investigation of all obesity related co-morbidities. Any identified co-morbidities need to be vigorously treated before considering surgery in order to minimize perioperative morbidity and mortality.

Special consideration must go into investigating and treating lymphedema. Bilateral lower limb lymphedema may actually be a physical manifestation of cardiac failure and as such all patients should have an echocardiogram as part of their work up. Lymphedema should be aggressively treated with compression, diuretics, and elevation as appropriate before surgery.

Given the complexity of the cases, they should normally be nursed in a high dependency care (level 2) area postoperatively. This group of patients has much less reserve to cope with any surgical complications and as such preoperative preparation needs to be fastidious and the surgery itself meticulous.

Fig. 66.3 Bariatric high-care ward

Fig. 66.4 Commode support and corner hi-weight scales

66.6.2 Dietitian

The extremely obese patient is the most likely of bariatric patients to be nutritionally deficient and as such, full dietetic assessment needs to be performed. Vitamin levels need to be analyzed and deficiencies corrected and supplemented accordingly. Some centers recommend a longer preoperative liver reducing diet, which may need to be supervised at home or with the patient as an in-patient to ensure adequate compliance. Patients also need to have significant preoperative dietetic counseling to discuss the pre- and postoperative diet and how they are going to manage so that they are ready at the time of surgery.

66.6.3 Psychologist

These patients often have complex psychological issues that need specialist attention from clinical psychologists and psychiatrists. Considered analysis by the psychology team is essential. Patients need to make progress dealing with their issues well before they come to surgery. The psychologist perhaps plays the most important role preoperatively in making sure that patients are suitable to undergo surgery and are prepared for the psychological impact of surgery. Surgery must be delayed until the psychologist is sure the patient is ready. Equally important is the fact that these patients will need more psychological input after surgery than standard

Fig. 66.5 Extreme obese subject set up for surgery

bariatric patients and there needs to be adequate service capacity to help patients both in the short and long term following surgery.

66.6.4 Anesthetist

Once assessed and appropriately prepared by a bariatric physician, patients need a dedicated anesthetic work up. At extreme obesity, the demand on the cardiovascular system and response under anesthesia can be difficult to manage. The anesthetist will be careful to ensure adequate management of obesity hypoventilation and sleep apnea before agreeing to undertake anesthesia. Liaison with the critical care facility is important for the first perioperative night stay, in order to monitor ventilator function.

66.6.5 Surgeon

The operating surgeon should lead the pathway for all patients considered for bariatric surgery. They will need to carefully assess the extremely obese patient with regards to the choice of operation they wish to perform. Consideration needs to be given to the size of the skeletal frame, abdominal wall thickness, and previous surgery. Each may influence the choice of the procedure. The consenting process needs to start early in the pathway to give patients adequate time to understand and agree. In some patients. their mobility can be significantly limited not only by their overall size but also by the presence of a pudendal and abdominal apron. In certain circumstances an apronectomy of the pudendal apron may be required before bariatric surgery to ensure that patients are mobile enough to comply with postoperative physiotherapy and mobilization.

66.7 Surgical Options

Much has been written regarding the optimum surgical approach in Extreme Obesity. Each patient presents with an individual number of risks and determinants that govern the best management strategy. MDT analysis and consensus greatly assist appropriate management.

66.7.1 Preoperative Weight Loss

This patient group presents most perioperative risk. Any preoperative weight loss is advantageous from every perspective. The method employed to achieve this can be with outpatient or inpatient Very Low Calorie Diet (VLCD) and/or intragastric balloon. There should be no arbitrary target set for this. Care should be taken to minimize nutritional depletion during this period. The aim is to reduce hepatic and omental fat mass.

66.7.2 Choice of Procedure

The choice of procedure should be guided by the whole MDT; especially the dietitian, the physician, and the psychologist. The surgeon must temper operative enthusiasm for weight loss with an understanding of how each procedure will impact on the individual patient and their circumstances. It would be mindless to offer a duodenal switch to an immobile patient, unless the surgeon is offering to clean the bed linen regularly!

66.7.2.1 Staged Procedures

There continues to be controversy regarding single or staged procedures.

Single stage procedures tend to be more major, and may enable significant short to medium term weight loss. However, in the long term, a significant proportion of extremely obese patients may experience weight regain or weight loss arrest. These patients may request revision or conversion surgery to increase weight loss. Depending on the complexity of the original surgery, this may or may not be feasible.

Multi-staged procedures accept that the initial surgery will not be the final procedure. The first procedure should be of lesser risk that enables sufficient weight loss to improve mobility and reduce co-morbidities. Further procedures can then be undertaken to achieve further weight loss and can be tailored to suit the patients improved circumstances. The exact sequence of procedures should be carefully judged with the MDT for a planned pathway for the patient. Care should be taken to gain commissioning (funding) approval for this strategy, to avoid the patient being 'stranded' with a lesser procedure.

66.7.3 Review of Publications on Extreme Obesity Bariatric Surgery

There are many published articles reporting results of bariatric surgery on super obesity. However, most do not publish results of patient with super obesity and extreme obesity separately. Those that do report specific results on extreme obesity bariatric surgery often only report short term surgical outcomes and omit long term weight loss data. There is hardly any robust paper report on patient satisfaction or quality of life for patients with extreme obesity undergoing bariatric surgery.

In general, the procedure of choice will be one that the surgeon has great experience in and technical confidence on. There is no place for a 'try-out' in this patient group.

66.7.3.1 Duodenal Switch

Duodenal switch (DS) is reported to provide consistent excess weight loss in the region of 70–80 % in the super obese [7]. Despite this there are only a handful of papers reporting results in extreme obesity. Hamoui et al. in 2007 showed a 75 % EWL at 3 years follow up but did not state the number of patients [8]. Dapri et al. in 2011 showed a 54.8 % EWL at 2 years in 31 patients [9].

66.7.3.2 Laparoscopic Adjustable Gastric Band (LAGB)

There is a lack of universal support for LAGB in extreme obesity. There are three good series published reporting good results. Fielding showed 61 % EWL at 2 years in 76 patients [10]. Weiner et al. showed 53 % EWL in 28 patients at 2 years follow up [11]. Torchia has managed to show 82 % EWL at 4 years follow up with 5 patients and 69.7 % in 55 patients at 2 years follow up [12]. Proponents of banding in extreme obesity draw attention to the near absence of mortality and morbidity when compared to LRYGB or LVSG; they also claim LAGB needs shorter operating times and length of hospital stay [13].

66.7.3.3 Sleeve Gastrectomy

Laparoscopic vertical sleeve gastrectomy (LVSG) is rapidly gaining in popularity, especially in the case of extreme obese patients due to the perception that it is a technically easier operation together with its weight loss results and comorbidity resolution. It has been used as the first step in a dual stage approach for extreme obesity and also as a standalone procedure. Cottam et al. showed a 46 % EWL at 1 year in 126 patients undergoing LVSG as the first stage of a LRYGB [14]. Catheline et al. showed a 51 % EWL at 3 years but with only 45 % follow up [15]. Six patients at 18 months had not had sufficient weight loss and so underwent either a re-sleeve or conversion to LYRGB [15]. Gagner et al. showed in 20 patients, the BMI dropped from a mean of 68–50 after 1 year [16]. Magee et al. showed a 40 % EWL in 68 patients with an initial mean BMI of 58 [17].

66.7.3.4 Laparoscopic Roux Y Gastric Bypass

There are considerable number of papers published on outcomes in LRYGB in extreme obesity. Regan et al. in a two-stage procedure demonstrated a 46 % EWL at 14 months in 7 patients [18]. Date showed a 53 % EWL at 1 year in 28 patients and Helling et al. showed a 61 % EWL in 34 patients with an initial BMI > 70 [19, 20]. Sanchez-Santos et al. showed that at 5 years, 80 % patients still had >50 % EWL in 70 patients [5]. Farkas et al. showed only 53 % EWL at 1 year in 46 patients [21]. Taylor et al. showed 38.3 % EWL at 1 year [22].

Early reports of bariatric surgery for extreme obesity suggested higher morbidity and mortality rates compared to the non-extreme obesity population [23, 24]. More recent reports have suggested that morbidity and mortality rates are comparable in patients [21, 22, 25, 26]. Length of hospital stay seems to be increased by around a day in extreme obesity compared with non-extreme obesity [5, 27, 28]. These differences may indicate that as surgeons progress along their learning curve with increasing experience, the mortality and morbidity rates associated with surgery in the extreme obesity may begin to approach standard bariatric surgery outcomes.

66.7.3.5 Mini-Gastric Bypass

This procedure is gaining popularity due to the relative ease in technique involved in the single anastomosis. However, proximal gastric dissection is still required in the construction of the long gastric pouch, and may be difficult to access due to hepatomegaly and difficult body habitus. In addition, the anastomosis is no less 'at-risk' than that in a standard RYGB. The procedure is none the less a gastric bypass variant and is an appropriate option.

66.7.4 Technical Aspects

Surgery in extreme obesity is challenging with difficulties from the abdominal wall leading to port site problems especially with torque and operator fatigue and problems with distribution of intra-abdominal visceral fat. While there are conflicting results for each type of surgery in extreme obesity it is probably fair to say that banding is likely to have the lowest morbidity and mortality [10–13]. Banding centers of excellence with intensive follow up have reported good results in the short term. With increasing complexity of operation comes increasing morbidity and mortality as previously described especially in extreme obesity [23, 28]. In order to cope with the increasing complexity due to body habitus, some surgeons recommend a two-stage procedure with a LVSG first followed by either conversion to a DS or LRYGB [1, 14, 18, 20]. Other surgeons maintain that a primary LRYGB or DS should be performed. Many published results have shown that surgery in extreme obesity is worthwhile and can produce good weight loss results and comorbidity resolution [5, 8–14, 17, 18, 21, 23, 25].

66.8 Specific Post-discharge Issues for the Extreme Obese Patient

66.8.1 Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) Prophylaxis

Extremely obese patients are at significantly increased risk of DVT/PE. Postoperative prophylaxis should extend for at least 1 month, or longer if the patient is immobile. Most patients can be taught to self administer injectable prophylaxis at home.

66.8.2 Mobilization/Occupational Therapy

Once successfully through the surgical procedure, patient physiotherapy should continue to encourage mobility. Bed bound patients should especially continue to build proximal muscle strength in anticipation of sufficient weight loss to begin weight bearing.

66.8.3 Psychological Care

Patients with extreme obesity will often have significant issues relating to body image and behavior. Dependence on others for daily activities and essentials must be managed to increase independent living. The relationship with feeding individuals may require others to also accept psychological counseling.

66.8.4 Enforcing Dietary Change

While the aim of bariatric surgery is to 'reinforce' dietary change on a patient, patients must accept this and be bound to a program of dietary rehabilitation if long term weight loss is to be achieved. Regular dietetic consultation is vital to manage this rehabilitatory process.

66.8.5 Redundant Skin/Personal Hygiene

Extremely obese patients commonly have problems maintaining personal hygiene. This is commonly associated within skin folds, and the urogenital areas. Intertrigo can be foul-smelling and on occasion, frank tissue inflammation and breakdown can occur. Care to these areas must commence pre-operatively if any serious skin problems are to be avoided in the postoperative period (Fig. 66.6).

Following massive weight loss, redundant skin can be remarkable. It is unethical and trite to refuse such patients remedial body contouring surgery. Their skin causes functional problems, often with personal hygiene and toileting issues (Fig. 66.7). An experienced plastic surgeon can often deal with these problems and improve functionality.

Conclusion

The incidence of extreme obesity is increasing in line with morbid obesity. There is an increasing body of quality evidence demonstrating that bariatric surgery is an effective treatment of extreme obesity. Morbidity and mortality rates are increased in extreme obesity surgery and patients should therefore have a thorough pre-operative work up and preparation for surgery. The surgery should be performed in units with experience in managing these patients. The MDT should give careful consideration to the choice of procedure, but the lead for this must be taken by the bariatric surgeon in charge of the case.

Fig. 66.6 Pre-op bariatric patient with multiple aprons

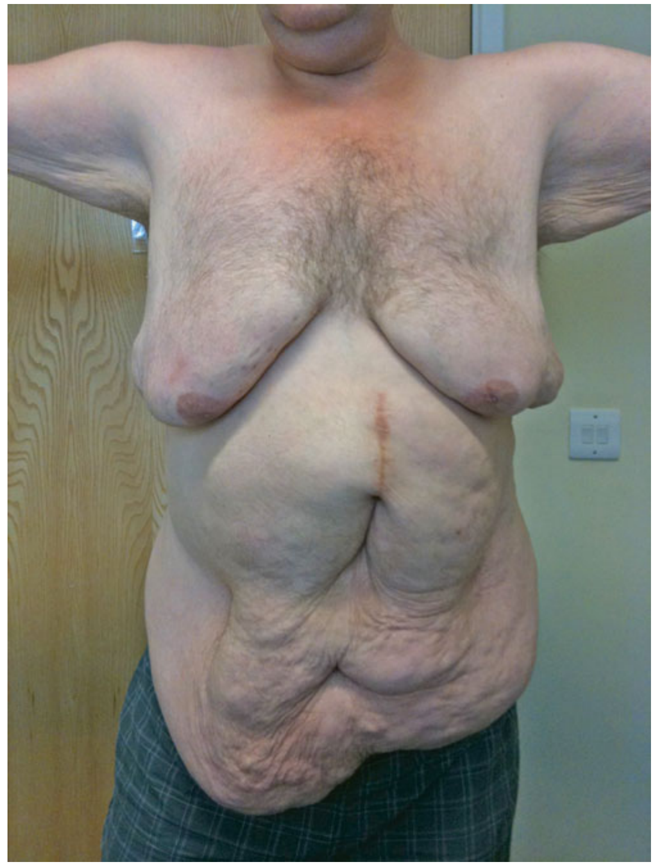

Fig. 66.7 Post massive weight loss redundant skin fold in a 38 year old man

Key Learning Points

- Surgery for extreme obesity is feasible within specialist units.
- Thorough surgically-led multidisciplinary assessment is essential.
- Surgery requires 360° planning.
- Postoperative care requires long term MDT input/
- Body contouring surgery should be an essential part of the management path

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Respiratory Considerations and Effect of Bariatric Surgery in the Obese Patient

67

Manoj K. Menon and Angshu Bhowmik

Abstract

Pulmonary function abnormalities are quite common in obesity. Consequently, in this population, a number of respiratory comorbidities are seen, which have to be identified and treated prior to bariatric surgery. The most commonly occurring conditions are obstructive sleep apnea (OSA), obesity hypoventilation syndrome (OHS), pulmonary hypertension and asthma. Preoperative assessment includes a detailed history and clinical examination, followed by appropriate investigations to detect these comorbidities. OSA is highly prevalent in the population undergoing bariatric surgery and should be considered in all patients during the preoperative evaluation. Screening tools and questionnaires are useful to identify patients with OSA, although there are suggestions that all patients presenting for weight-loss surgery should have a preoperative sleep study. Continuous positive airway pressure (CPAP) is the treatment of choice in moderate to severe OSA, and should be instituted prior to surgery in order to reduce the risk of perioperative complications. Bariatric surgery can result in significant improvements in pulmonary function and resolution of some of the respiratory co morbidities such as OSA.

Keywords

Bariatric Surgery • Obesity • Obstructive Sleep Apnea • Obesity Hypoventilation Syndrome • Epworth Score • Sleep study • CPAP • Asthma • Pulmonary Embolism

67.1 Introduction

Obesity can have an adverse impact on normal respiratory physiology and function. This occurs via multiple mechanisms and can be associated with a number of respiratory comorbidities such as obstructive sleep apnea (OSA), obesity hypoventilation syndrome (OHS), asthma, and pulmonary hypertension. The recognition and management of these conditions prior to bariatric surgery is important to minimize the risk of perioperative complications.

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67.2 Impact of Obesity on Respiratory Function

67.2.1 Altered Respiratory Mechanics

Alterations in respiratory system compliance and resistance are seen in obese individuals. Total respiratory system compliance is reduced, primarily due to a decrease in chest wall compliance and stems from excess fat accumulation around the ribs, diaphragm and abdomen [1]. To a lesser extent, lung compliance is also reduced and is thought to be related to increased pulmonary blood flow. In addition, both total respiratory resistance and airway resistance are significantly elevated [2]. Consequently, subjects have to overcome not only the excessive load placed on the respiratory system from reduced compliance, but also the increased airways resistance resulting from lower lung volumes of obesity.

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67.2.2 Respiratory Muscle Dysfunction

While measures of expiratory and inspiratory respiratory muscle strength are preserved in simple obesity, the latter may be impaired in patients with obesity hypoventilation syndrome (OHS) [3]. This might be a consequence of the overstretched diaphragm (the main inspiratory muscle) being placed at a mechanical disadvantage in extreme obesity, resulting in decreased inspiratory muscle strength and efficiency, particularly when the subject is in the supine position [4]. Reduced maximal voluntary ventilation (MVV), an index of respiratory muscle endurance, has also been demonstrated in obese individuals [3].

67.2.3 Increased Work and Energy Cost of Breathing

Because of the excess load placed on the respiratory system from the combined effects of increased total respiratory resistance and reduced compliance, the work and energy cost of breathing is elevated in obesity. When compared to normal controls, morbidly obese patients devote a disproportionately higher percentage of their oxygen consumption (VO_2) on respiratory work during quite breathing [5]. This increase in energy expenditure suggests a limited energy reserve, and could predispose these individuals to respiratory failure in the face of acute pulmonary or systemic illnesses.

67.2.4 Spirometry and Lung Volumes

The effect of obesity on lung function tests is influenced by a number of factors such as age, severity of obesity and nature of fat distribution (central or peripheral). Spirometry is usually normal in mild obesity. A restrictive defect is seen with increasing BMI, with proportional reductions in both the forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC), while the FEV1 to FVC ratio is either normal or increased [3]. In morbidly obese subjects, additional reductions in mid-expiratory flow rates have been observed, which may represent true airflow obstruction due to early small airway collapse as a result of breathing at low lung volumes [6].

Reduced expiratory reserve volume (ERV) is the most common lung function abnormality seen in obesity [7]. Displacement of the diaphragm into the chest by the obese abdomen reduces functional residual capacity (FRC), while residual volume remains unchanged. The net effect is a decline in ERV, and is particularly worse in the supine position, when the weight of the lower thorax and abdomen presses on the lungs [8]. Measures of dynamic lung volumes such as vital capacity (VC) and total lung capacity (TLC) are generally maintained in obesity, although the former may be reduced in cases of extreme obesity.

67.2.5 Gas Exchange

Carbon monoxide diffusion capacity of the lung (DLCO), a measure of gas exchange is increased in obesity [7]. DLCO corrected for alveolar volume is also increased, and is thought to be the result of increased pulmonary blood volume and flow in obese subjects. Since DLCO is directly related to the lung volume at which it is measured, it follows that any reduction in lung volumes will also decrease DLCO. Therefore in healthy obese adults, DLCO values are expected to be higher than predicted, and the presence of a low to normal DLCO or ratio of DLCO to alveolar volume, may indicate a loss of pulmonary bed as seen in atelectasis.

67.2.6 Ventilation and Perfusion

Regional distributions of ventilation and perfusion may be altered in obesity. There is data to show that in obese individuals with reduced ERV, the distribution of a normal tidal breath is predominantly to the upper lung zones, whereas perfusion is mainly to the lower zones [9]. Under ventilation of the lung bases is thought to occur as a result of airway closure and alveolar collapse.

67.2.7 Ventilatory Responses

Obesity is associated with enhanced neural respiratory drive [10]. However, subjects with obesity hypoventilation syndrome (OHS) appear to have impaired ventilatory responses to hypoxia and hypercapnia when compared to obese individuals without sleep disordered breathing [3]. However, it is not clear whether this loss of ventilatory drive is a primary phenomenon that precedes obesity, or is secondary to chronic hypoxia and hypercapnia that develops once obesity has been established.

67.2.8 Inflammatory Responses

Obesity may be associated with low-grade systemic inflammation. Increased concentrations of various circulating inflammatory markers such as C-reactive protein (CRP), tumor necrosis factor-alpha (TNF-α[alpha]) and interleukin-6 (IL-6) have been observed [11]. Airway smooth muscle tone can be altered by these inflammatory mediators, and potentially contribute to abnormal pulmo-

Table 67.1 Effects of obesity on respiratory function

Respiratory physiology
Decreased respiratory system (chest wall and lung) compliance
Increased airway resistance
Respiratory muscle dysfunction
Increased work and energy cost of breathing
Altered gas exchange
Ventilation-perfusion mismatch
Impaired ventilatory responses (mainly in patients with OHS)
Lung function tests
Proportional decrease in FEV_1 and FVC (greater reduction in FEV_1 in severe obesity)
Reduction in ERV and FRC
TLC and VC generally maintained (may be reduced in severe obesity)
DL_{CO} usually normal or elevated

nary function in obesity. Airway reactivity can also be increased by the adipocyte-derived hormone leptin, levels of which have been noted to be elevated in obese subjects. Table 67.1 gives a summary of the effect of obesity on pulmonary function.

67.3 Respiratory Diseases Associated with Obesity

The mechanical and inflammatory insults imposed on the respiratory system by obesity can contribute to the development of a number of co-morbidities which are described below:

67.3.1 Obstructive Sleep Apnea (OSA)

OSA is defined as recurrent partial or complete closure of the upper airways during sleep, resulting in multiple apneic and hypopneic events. The partial pressure of oxygen (PaO_2) decreases while that of carbon dioxide ($PaCO_2$) increases during these events. This leads to increased ventilatory effort and triggers recurrent arousals during sleep, and sleep is therefore fragmented. Patients present with symptoms such as excessive daytime sleepiness, tiredness, heavy snoring and witnessed apneas. The combination of daytime symptoms with OSA is referred to as obstructive sleep apnea-hypopnea syndrome (OSAHS). The recurrent arousals during sleep may be accompanied by cardiac arrhythmias, increased sympathetic tone, eventually leading to systemic and pulmonary hypertension if left untreated.

Obesity is the major risk factor and is present in 50–70 % of patients with OSA [12]. Conversely, the prevalence of OSA in the obese population is estimated to be around 40 % [12], but may be as high as 70 % among those evaluated for bariatric surgery [13]. Therefore OSA should be actively sought for in patients presenting for bariatric surgery.

67.3.2 Obesity Hypoventilation Syndrome (OHS)

OHS, also known as Pickwickian syndrome, is defined as the presence of daytime hypercapnia ($PaCO_2$ more than 45 mmHg) in obese subjects (body mass index (BMI) more than 30 kg/m^2) with sleep disordered breathing in the absence of other causes for hypoventilation such as coexisting lung or neuromuscular disease [14]. It is estimated to be present in as much as 30 % of hospitalized obese patients [15]. While obesity-related factors such as impaired pulmonary mechanics, airway resistance and respiratory muscle dysfunction may contribute to the development of diurnal hypercapnia in OHS, decreased ventilatory drive may have an important role to play in some patients [16]. OSA is present in the vast majority of patients with OHS, although the mortality and morbidity in the latter is worse due to associated respiratory and cardiac complications [17]. However, the long term survival on noninvasive ventilation (NIV) is excellent when compared to untreated controls [18].

67.3.3 Asthma

A large body of evidence exists to show that the prevalence of asthma is increased in overweight and obese individuals [11]. Moreover, the presence of obesity appears to enhance asthma severity, making it more difficult to treat. At the same time, weight loss seems to improve various asthma-related outcomes such as symptom control, medication use and hospitalizations. Multiple factors including elevated obesity-related inflammation and chronic aspiration from increased gastro-esophageal reflux may increase airway reactivity, hence predisposing to asthma [19].

67.3.4 Pulmonary Embolism

The risk of venous thromboembolism (VTE) in obesity seems to be twice that of normal weight subjects [20]. Despite the routine use of pre and postoperative anticoagulation prophylaxis, pulmonary embolism continues to be a leading cause of death following bariatric surgery. The reported incidence is between 0.84 and 0.95 %, with over a third of cases being diagnosed only after hospital discharge and up to 30 days postoperatively [21]. A hypercoagulable state exists in obesity and is thought to be related to a combination of increased coagulation cascade activity, decreased fibrinolysis and endothelial dysfunction [20]. Additional factors such as increased intra-abdominal pressure of obesity, and increased venous stasis caused by the artificial pneumoperitoneum induced during bariatric surgery, all increase the risk of postoperative deep vein thrombosis and pulmonary embolism.

67.3.5 Pulmonary Hypertension

The true prevalence of pulmonary hypertension in the obese population is unknown. It is likely that multiple mechanisms and common risk factors act synergistically in these patients leading to pulmonary hypertension. Examples include OSA, OHS, chronic thromboembolic disease, obesity-associated cardiomyopathy, and the use of anorexic agents [22]. Retrospective reviews have shown that pulmonary hypertension is present in about 5 % of otherwise healthy individuals with body mass index (BMI) more than 30 kg/m^2 [23], and in nearly half of all obese post-menopausal women [24].

67.4 Pre-operative Respiratory Considerations

67.4.1 Assessment

Candidates for bariatric surgery are assessed by a multidisciplinary team to identify and treat obesity-associated comorbidities prior to surgery. In particular it is important to optimize preoperative respiratory and sleep status to minimize the risk of perioperative and postoperative complications. Respiratory assessment includes a detailed history, physical examination and investigations targeted towards identifying common obesity-associated conditions such as OSA and OHS. Relevant points in the history would include snoring, witnessed apneas, gasping and choking at night, nocturia, unrefreshed sleep, and excessive daytime sleepiness and headaches.

Physical examination may reveal important clues. Neck circumference more than 40 cm in men and more than 36 cm in women is associated with an increased risk of OSA [25], and so is the presence of a crowded oropharynx. The latter can be assessed clinically by inspecting the anatomy of the upper airways and posterior pharynx using the Mallampati classification (see Fig. 67.1). Mallampati scores between one

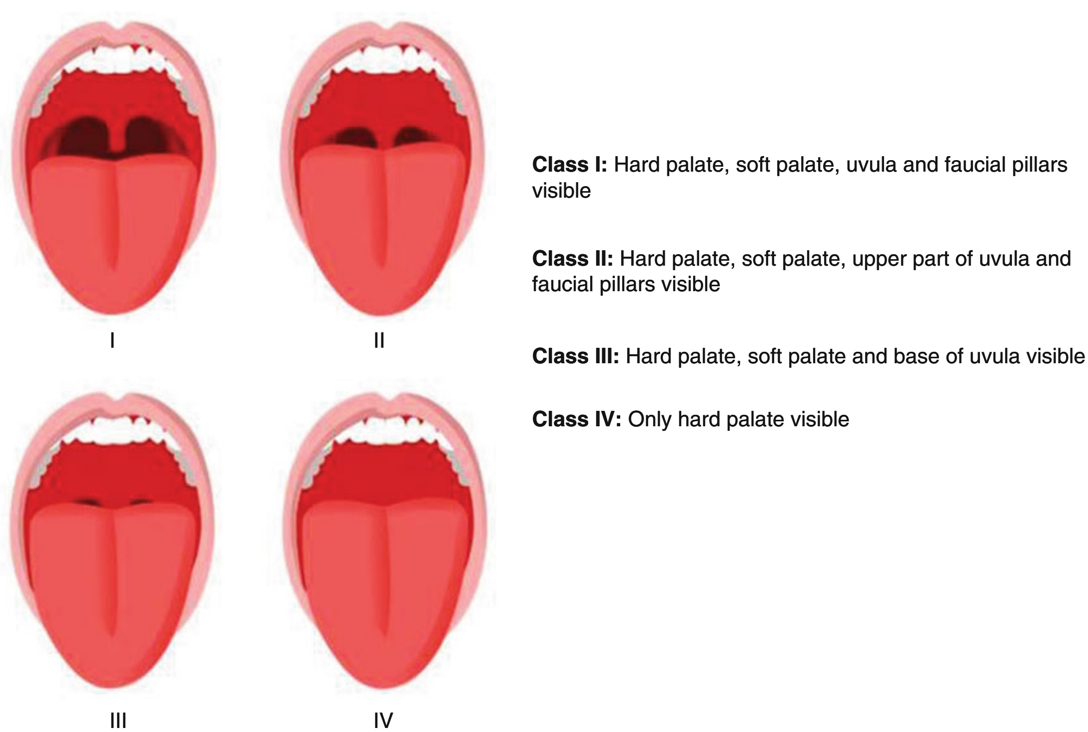

Fig. 67.1 The Mallampati Classification: *Class I*: Hard palate, soft palate, uvula and faucial pillars visible. *Class II*: Hard palate, soft palate, upper part of uvula and faucial pillars visible. *Class III*: Hard palate, soft palate and base of uvula visible. *Class IV*: Only hard palate visible

and four are given based on the visibility of the base of the uvula, faucial pillars, and soft palate, with scores more than three predictive of difficult intubation and higher incidence of OSA [26]. Craniofacial abnormalities affecting the airways, enlarged tonsils and nasal obstruction may also be the contributing factors. Oxygen saturation less than 92 % may be indicative of hypoxia and nocturnal hypoventilation, suggesting the need for further investigations such as arterial blood gases, chest x-ray, transthoracic echocardiogram and sleep studies. Because of the high prevalence of sleep disordered breathing in the bariatric population, there are suggestions that preoperative sleep studies should be performed in all patients [27]. Pulmonary function tests may be useful to predict the risk of complications after bariatric surgery [28].

A number of screening questionnaires and clinical prediction tools have been developed to help identify patients at high risk of OSA. Commonly used questionnaires include the Epworth Sleepiness Scale (ESS) score, the STOP-Bang questionnaire, and the Berlin questionnaire. The latter two scoring systems have been validated for preoperative use in the general surgical population, with the STOP-Bang questionnaire being specifically validated in obese and morbidly obese surgical patients [29]. The STOP-Bang questionnaire (see Table 67.2) is probably the most frequently used screening tool in surgical patients. It has eight "yes/no" items, with each "yes" answer scoring one point, each "no" answer scoring zero points, giving a total score of between zero to eight. A score of more than equal to three puts the patient at high risk of having OSA. The questionnaire is self-administered, simple to use in a busy clinical setting, and demonstrates high sensitivity (84–100 %) and negative predictive value (61–100 %) in the surgical population [30].

The Berlin questionnaire has ten items divided into three categories, with five questions on snoring, three on excessive daytime sleepiness, one on sleepiness while driving, and one inquiring about a history of hypertension. If patients are positive in at least two symptoms categories, they are considered as high risk of having OSA. In surgical patients, the Berlin questionnaire has a moderately high level of sensitivity (68.9 %) [31].

The Epworth Sleepiness Scale (ESS) score is a validated method of assessing the likelihood of falling asleep in various situations. It is a self-administered questionnaire consisting of 8 questions and the subject is asked to rate their chances of falling asleep on a 4-point scale ranging from 0 to 3 (0 = would never doze; 1 = slight chance of dozing; 2 = moderate chance of dozing; 3 = high chance of dozing). The maximum score is 24 [32]. The score can be used to clinically divide patients into the normal range (ESS less than 11), mild subjective daytime sleepiness (ESS 11 to 14), moderate subjective daytime sleepiness (ESS 15 to 18), or severe subjective daytime sleepiness (ESS more than 18). Ideally, the scale should be completed by the patient as well as their partner, since the patient may underestimate the severity of their sleepiness due to its insidious onset, or in order to hide concerns about driving ability. However, the ESS does not correlate with the severity of OSA in patients undergoing bariatric surgery [33], but can be used to predict the likelihood of long term compliance with nasal CPAP [34].

The gold standard test to evaluate for OSA is a full laboratory polysmonography (PSG) [35]. It includes a comprehensive recording of the electroencephalogram (EEG), electrooculogram (EOG), and chin electromyogram (EMG) to identify the various sleep stages. Additional channels include airflow, respiratory effort, body position, limb movements, electrocardiogram (ECG) and oxygen saturation. An apnea is defined as cessation of airflow for at least 10 s, and a hypopnea is defined as a more than equal to 10 s reduction in airflow associated with an EEG arousal or oxyhemoglobin desaturation. The apnea-hypopnea index (AHI) is the number of apneas and hypopneas occurring per hour of sleep. It is a key measure used for quantifying the severity of OSA into mild (AHI: 5–15/h), moderate (AHI: 16–30/h) or severe (AHI: >30/h) categories, although it must be appreciated when assessing patients that these cut offs have been arbitrarily set. Increasingly, portable sleep monitoring systems that record a minimum of airflow, respiratory effort and oximetry have been developed and used for the diagnosis of OSA. Portable monitors are in widespread use in many countries and have been shown to be clinically equivalent to full in-lab PSG as well as demonstrating additional benefits including improved access to testing, reduced cost, and assessing patients in their own environment [36]. Figure 67.2 shows an example of a multichannel portable sleep study of a patient with severe OSA with frequent apneas, while Fig. 67.3 illustrates an example with hypopnea. Figure 67.4 is the sleep study of a patient with predominant hypoventilation, but no evidence of OSA.

67.4.2 Treatment

Guidelines are available for the management of OSA in patients planning to undergo bariatric surgery [37]. Continuous positive airway pressure (CPAP) is the treatment of choice for patients with moderate to severe OSA. It consists of a flow generator which delivers air under pressure via a tubing and nasal or face mask, to produce a fixed positive pressure in the upper airways. This splints open the upper airway, preventing repeated collapse and closure, stabilizes overnight oxygen saturation, and reduces sleep fragmentation. CPAP has been shown to significantly reduce AHI and oxygen desaturation during sleep, and also improves sleep efficiency, sleepiness and cognitive function [38]. The use of CPAP preoperatively reduces the risk of perioperative complications. The optimal or minimal time of preoperative treatment with CPAP has not

Yes ○	No ○	**S noring?** Do you **Snore Loudly** (loud enough to be heard through closed doors or your bed-partner elbows you for snoring at night)?
Yes ○	No ○	**T ired?** Do you often feel **Tired, Fatigued, or Sleepy** during the daytime (such as falling asleep during driving)?
Yes ○	No ○	**O bserved?** Has anyone **Observed** you **Stop Breathing** or **Choking/Gasping** duringy our sleep?
Yes ○	No ○	**P ressure?** Do you have or are being treated for **High Blood Pressure**?
Yes ○	No ○	**B ody Mass Index more than 35 kg/m²?**
Yes ○	No ○	**A ge older than 50 year old?**
Yes ○	No ○	**N eck size large? (Measured around Adams apple)** For male, is your shirt collar 17 inches/43 cm or larger? For female, is your shirt collar 16 inches/41 cm or larger?
Yes ○	No ○	**G ender = Male?**

Table 67.2 The STOP-Bang questionnaire
Scoring Criteria**:**
For general population
Low risk of OSA: Yes to 0–2 questions
Intermediate risk of OSA: Yes to 3–4 questions
High risk of OSA: Yes to 5–8 questions
or Yes to 2 or more of 4 STOP questions + male gender
or Yes to 2 or more of 4 STOP questions + BMI >35 kg/m^2
or Yes to 2 or more of 4 STOP questions + neck circumference
(17″/43 cm in male, 16″/41 cm in female)
Modified from Chung et al. Anesthesiology. 2008; 108:812–21, Chung et al. Br J Anaesth. 2012; 108:768–75, Chung et al. J Clin Sleep Med. 2014
With permission from University Health Network, www.stopbang.ca

been established, but usually 2–3 weeks is required to reduce AHI and improve symptoms [39].

Non-invasive ventilation (NIV) may be required in patients with OHS in whom CPAP therapy alone is inadequate to control nocturnal hypoventilation and daytime hypercapnia, rarely supplementary oxygen is required in order to achieve acceptable control of sleep disordered breathing [40]. In the postoperative period, CPAP, NIV, or oxygen therapy may be required to minimize complications such as atelectasis and respiratory failure. Patients are therefore usually advised to bring their own CPAP machine and mask to hospital when attending for surgery, so that the equipment is readily available for use in the postoperative period [37]. Although there remains some debate regarding

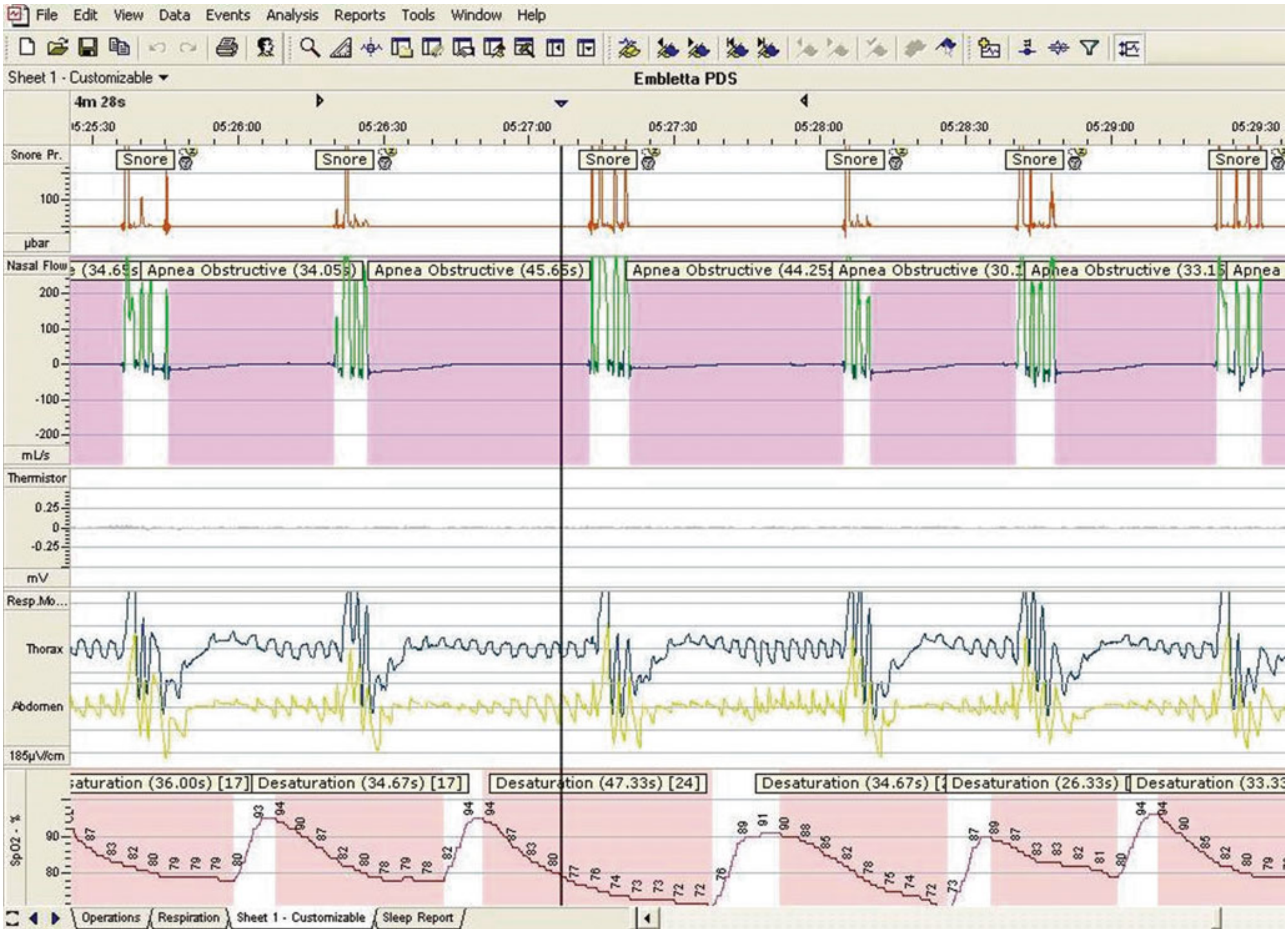

Fig. 67.2 Sleep study of a patient with severe OSA (apneas)

the use of CPAP in the acute postoperative period due to perceived pressure applied to the surgical sites there are reliable data demonstrating no additional complications and the association with improved physiological parameters [41].

Surgical interventions such as uvulopalatopharyngoplasty (UVPP) are available to treat OSA, but are generally not recommended as first line therapy as they can interfere with the acclimatization and long term adherence to CPAP therapy which has demonstrably superior outcomes. In patients with mild OSA, or those intolerant of CPAP, mandibular advancement splints can be considered, although they are less effective in reducing the AHI when compared to CPAP. Lifestyle modifications such as avoiding excess alcohol consumption prior to bed time may reduce the severity of OSA. Positional sleep apnea, especially in the supine position is quite common in patients with mild OSA, and can be managed by avoiding supine position during sleep using the "tennis ball technique," [42] or newer position monitoring and supine alarm devices [43].

Patients with asthma should have their treatment optimized prior to surgery. Bariatric surgery patients are deemed to be at high risk of perioperative venous thromboembolism. Hence primary prevention is the key to reducing mortality and morbidity from pulmonary embolisms (PEs). Various prophylactic regimens that have been recommended include the administration of subcutaneous heparin before and after surgery, use of sequential compression devices, and early ambulation [44].

67.5 Impact of Bariatric Surgery on Respiratory Comorbidities

Significant increases in lung volumes and arterial oxygen saturation, with reduction in $PaCO_2$ have been observed following bariatric surgery [45]. Improvements in ventilation/perfusion mismatching and reduction in the work of breathing is also seen as a result of weight loss [46]. There is ample evidence to show that weight loss surgery improves symptoms of OSA, with a reduction in AHI seen in the vast majority of cases [47], although it is uncommon to achieve a complete cure [48]. Bariatric surgery has also been performed exclusively as a treatment modality for OSA in patients who either did not tolerate CPAP or for whom CPAP was unavailable, with significant positive effects on indices of sleep apnea [49].

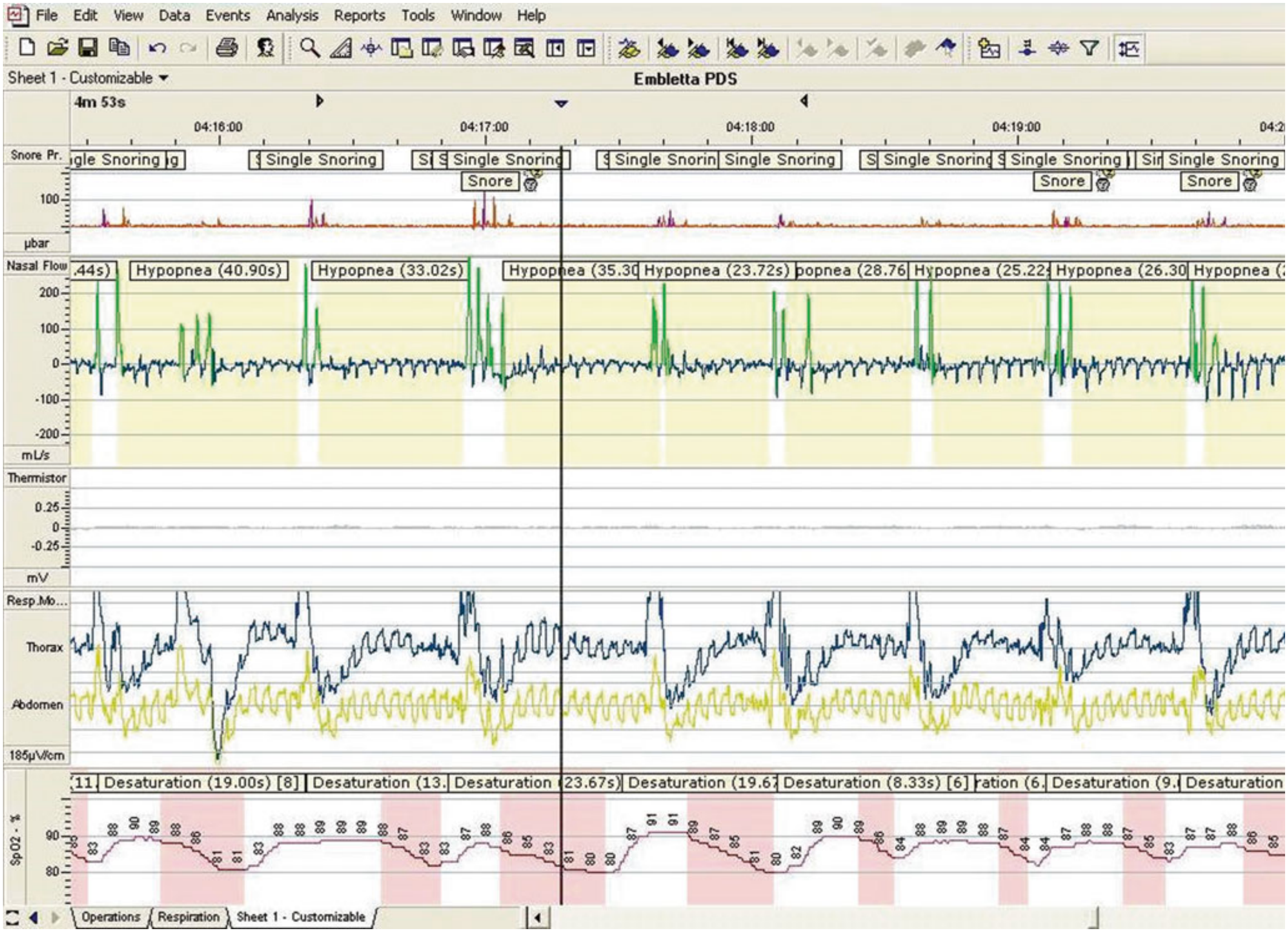

Fig. 67.3 Sleep study of a patient with severe OSA (hypopneas)

Reduced pulmonary artery pressures have been demonstrated following weight loss surgery in patients with OSA [50] and OHS [51]. In obese asthmatic patients who undergo bariatric surgery, the vast majority experience significant improvements in symptom control [52].

Conclusions

In patients undergoing bariatric surgery, pulmonary comorbidities such as OSA and OHS are quite prevalent, and can lead to perioperative complications. Multidisciplinary preoperative evaluation should include a detailed history, physical examination and investigations such as a sleep study. A number of screening tools are available to identify subjects who may have sleep disordered breathing. Patients diagnosed with moderate to severe OSA should be established on CPAP prior to surgery, and advised to bring the equipment to hospital in case it is required in the postoperative period. Venous thromboembolism including PE is the primary cause of mortality following bariatric surgery, and adequate anticoagulant prophylaxis should be instituted to minimize this risk. Weight-loss surgery in the bariatric population can lead to significant improvements in lung function, asthma control and pulmonary hypertension.

Key Learning Points

- Obesity can have a detrimental effect on normal pulmonary physiology and function.
- OSA is highly prevalent in bariatric surgery patients and should be considered in the preoperative evaluation.
- CPAP is the treatment of choice in patients with moderate to severe OSA, and should be instituted in the preoperative period.
- Pulmonary embolism remains the leading cause of death in patients undergoing bariatric surgery.
- Weight-loss surgery can significantly improve both lung function and various respiratory comorbidities seen in the bariatric population.

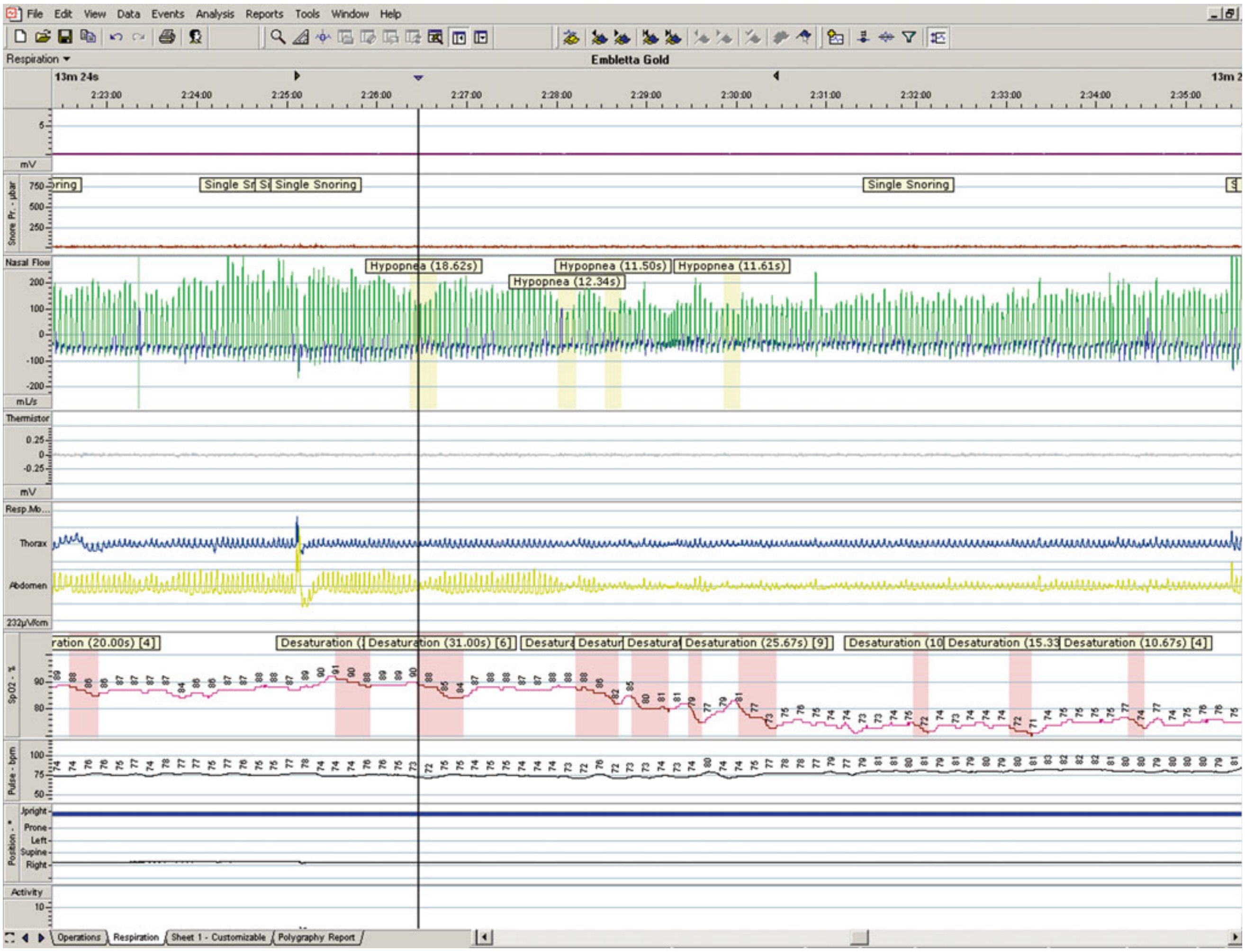

Fig. 67.4 Sleep study of a patient with OHS

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Infertility, Pregnancy, and Bariatric Surgery

68

Rahat Khan

Abstract

A large number of obese women of childbearing age are opting for bariatric surgery and require information and proper guidance regarding the effect of such surgeries on reproductive health. In this chapter we outline the safety, advantages and limitations of bariatric surgery procedures in relation to maternal and neonatal outcome. A multidisciplinary team comprising of surgeons, primary care clinicians, obstetricians, anesthetists, fertility specialists, nutritionists, psychologists, as well as patients themselves is required to ensure healthy maternal and neonatal outcomes. Women who have undergone bariatric procedures have safer pregnancy with fewer complications than those with morbid obesity, however, patients should be strongly advised to avoid getting pregnant for at least 12–18 months post this surgery. With regard to infertility, bariatric surgery should not be performed with the intention of treating infertility; however, fertility may improve with rapid postoperative weight loss.

Keywords

Bariatric surgery • Infertility • Pregnancy • Malnutrition • Surgical complications • Neonatal outcome

68.1 Introduction

Bariatric surgery (or weight loss surgery) has become an increasingly effective approach for reducing morbidities associated with severe obesity. Bariatric surgery is commonly performed in morbidly obese women of child bearing age, for example, between 2003 and 2005, 49 % of all inpatient bariatric procedures in the United States of America were performed in women aged 18–45 years [1]. The United Kingdom (UK) Centre for Maternal and Child Enquiries (2006–2008) reported that 49 % of women who died during childbirth were either obese or overweight. [2] In the UK, the prevalence of obesity among women of reproductive age is expected to rise from 24.2 % in 2005 to 28.3 % in 2015 [3]. Obesity increases the risk of obstetric complications (see Table 68.1). The National Institute for Health and Care Excellence (NICE) recommends bariatric surgery as an option in morbidly obese patients (BMI >40 kg/m^2) where lifestyle and/or medications have been found to be ineffective [9].

68.2 Bariatric Surgery in Women of Child-Bearing Age

The obstetrician should be aware of the type of bariatric procedure a woman has undergone in order to be able to counsel her regarding the complications and issues that may arise during pregnancy as well as possible interventions that may be required. The literature reporting on pregnancy outcome after bariatric surgery is limited but encouraging. A literature review of 75 observational studies by Maggard et al. reported that rates of adverse maternal and neonatal outcomes are lower following laparoscopic adjustable gastric banding (LAGB) and gastric bypass as compared to other bariatric

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Table 68.1 Maternal and fetal risks to obese women

Risks	Study	Odds ratio (OR) 95 % confidence interval (CI)
Spontaneous abortion	Meta-analysis [4]	3.5 (1.03–12.01)
Gestational diabetes	UK [5]	3.6 (3.3–4.0)
Hypertensive disorders	UK [5]	2.1 (1.9–2.5)
Emergency cesarean section	UK [5]	1.8 (1.7–1.9)
Thromboembolism	Denmark [6]	9.7 (3.1–30.8)
Wound infection	UK [5]	2.24 (1.9–2.64)
Postpartum hemorrhage	UK [5]	1.4 (1.2–1.6)
Congenital anomalies	Australia [7]	1.6 (1.0–2.5)
Macrosomia	UK [5]	2.4 (2.2–2.5)
Shoulder dystocia	Sweden [8]	3.14 (1.86–5.31)
Admission to neonatal unit	UK [5]	1.3 (1.3–1.4)
Stillbirth	Meta-analysis [4]	2.79 (1.94–4.02)

surgery procedures [10]. Few studies have assessed pregnancy outcomes following biliopancreatic diversion (BPD) [11, 12]. Shekelle et al. reviewed the evidence on the impact of bariatric surgery on fertility and subsequent pregnancy and found that fertility improves, and maternal as well as fetal outcomes are acceptable with LAGB and gastric bypass [13].

68.3 Ideal Timing for Conception Following Bariatric Surgery

Current recommendations advise delaying pregnancy for at least 1 year following bariatric surgery because this is when rapid weight loss occurs [14]. In addition, it is during this period that nutritional deficiencies or electrolyte imbalance can arise. However, data validating this recommendation are limited and confounding. A study by Dao et al. [15] found no difference in outcomes between pregnancies within the first year versus pregnancies occurring more than 1 year after gastric bypass surgery. A retrospective study of 104 pregnancies by Sheiner et al. [16] concluded that pregnancies conceived during the first postoperative year had comparable short-term perinatal outcomes compared with pregnancies conceived after the first postoperative year (1.9 % versus 1.3 %; $P=0.485$). No significant differences were noted regarding hypertensive disorders (15.4 % in the early versus 11.2 % in the late postoperative group; $P=0.392$) or diabetes mellitus (11.5 % versus 7.3 %; $P=0.392$). Marceau et al. found no difference in miscarriage rates between pre- BPD and post-BPD pregnancies (21.6 % pre-BPD versus 26 % post-BPD) [11]. A lower mean birthweight was found in the post- BPD group compared with obese controls (3 kg versus 3.5 kg, $P<0.001$). Dixon et al. reported lower maternal gestational weight gain (GWG) in early post-surgery pregnancies [17]. In light of the available evidence, patient education and prepregnancy counseling regarding benefits of delaying pregnancy for at least 12 months following weight loss surgery is pivotal in morbidly obese women who are considering pregnancy after bariatric surgery.

68.4 Fertility and Bariatric Surgery

A retrospective analysis by Gosman et al. of 1538 women who were offered bariatric surgery (mean $BMI=47.2\ kg/m^2$) showed that women who reported obesity by 18 years of age also had some related reproductive comorbidity [18]. These women were more likely to report polycystic ovaries and were less likely to have ever been pregnant. Case–control studies demonstrate increased fertility following bariatric surgery; however, these studies lack complete data and statistical significance due to small sample sizes. One study found that after bariatric surgery, the need for fertility treatment is low (6.7 %) but exceeds that of the community (2.3 %, $P<0.001$) [10]. Data suggest that weight loss surgery can result in normalization of hormones in patients with polycystic ovaries and can improve anovulation and endocrine fertility [13].

Little is published on the impact of surgical weight loss on spontaneous or in vitro fertilization-treatment related pregnancy rates [19]. Studies evaluating safety and effectiveness of various contraceptive measures in women with a history of bariatric surgery showed no decrease in either the safety or effectiveness [20]. More such randomized trials comparing women who have previously undergone weight loss surgery versus control groups are required to assess the efficacy and safety of contraceptive methods following bariatric surgery.

68.5 Nutritional Deficiencies

Sheiner et al. [15] demonstrated favorable outcomes in pregnant women who were put on multivitamins and mineral supplementation following different types of bariatric surgery. Special consideration should be given to prenatal supplementation in women considering pregnancy following bariatric surgery. Mild nutritional deficiencies are frequent after bariatric surgery. Women will require additional levels of iron, calcium, folate, vitamin B12, protein and fat-soluble vitamins alongside diagnosis and treatment of other nutritional deficiencies [14].

Dumping syndrome can be provoked by an excessive carbohydrate diet as well as the standard 75 or 50 g glucose tolerance test. Nausea and vomiting of pregnancy exacerbate the poor nutritional status of the mother [21].

68.6 Optimal Gestational Weight Gain

In several case–control studies, a significantly lower gestational weight gain (GWG) is observed in women who had undergone prior bariatric surgery compared with a BMI-matched control group or compared with pregnancies prior to the surgery ($P<0.009$) [17, 22, 23]. A review by Guelinckx et al. showed no difference in GWG after restrictive and malabsorptive procedures [23]. LAGB is considered more 'physiologic' since the banding can be adjusted to increase the patient's food intake. A recent retrospective study by Sheiner et al. ($n=449$) reported higher weight gain during pregnancy in the LAGB group (13.1 ± 9.6 kg) as compared with Vertical Banded Gastroplasty (VBG) (8.5 ± 8.0 kg) and Roux-en-Y Gastric Bypass (RYGB) (11.6 ± 9.6 kg, $P<0.001$) [24]. The interval between surgery and conception influences GWG. Dias and colleagues reported high GWG and various co-morbidities among women who conceived within 24.2 ± 21.6 months following RYGB [25]. However, the neonates were born in good condition.

68.7 Surgical Complications During Pregnancy

Pregnancies following bariatric surgery procedures are not without complications. For example, in patients with gastric banding, severe vomiting may precipitate band slippage and migration. Post-RYGB pregnant women are at risk of nutritional deficiencies, intestinal hernia (most commonly reported), intestinal obstruction, perforation, and death [10, 11]. Most cases of intestinal obstruction are due to adhesions from previous surgery. However, diagnosis can be a problem, since the symptoms of epigastric pain or vomiting are common in pregnant women and although computed tomography scan with contrast may be helpful, an exploratory laparotomy might be necessary [24].

68.8 Maternal Outcomes

68.8.1 Gestational Diabetes (GDM)

Most studies report a reduced incidence of GDM in patients following bariatric surgery [10, 15, 17, 22]. Ducarme et al. showed that the incidence of GDM (0 % versus 22.1 %, $P<0.05$) and pre-eclampsia (0 % versus 3.1 %, $P<0.05$) were lower in the LAGB group than in the obese comparison group [26]. GDM screening in malabsorptive patients, however, requires special considerations. In order to prevent the induction of dumping syndrome, obstetric physicians may choose to screen them for GDM by monitoring home fasting and 2-h postprandial blood glucose levels for a week at 26–28 weeks of gestation [27].

68.8.2 Pre-eclampsia

Incidence of pregnancy induced hypertension (PIH) and pre-eclampsia is lower in post-bariatric surgery pregnancies than that in obese women and the risk may approach community levels [10].

68.8.3 Cesarean Delivery

There is no evidence that cesarean delivery complications are higher in the post-surgery group but data are limited [13]. Overall, bariatric surgery does not appear to reduce the risk of cesarean delivery. In the review by Maggard et al. rates of cesarean delivery ranged from 0 to 65.8 % for post-surgery pregnancy and from 5.6 to 64.5 % for comparison groups [10]. Caregiver bias might have contributed to this elevated rate, as there was no known physiological reason necessitating more cesarean delivery in women who had previously undergone weight loss surgery. Another study showed higher labor induction rates as compared with non-obese comparison groups (23.8 % versus 10.9 %, $P<0.001$) [12]. Obstetricians need to be aware of caregiver bias and avoid surgery without clear and definitive indications. The presence of large areas of redundant skin can result in loss of landmarks and make access difficult intraoperatively. Postoperatively, wound infection rates can be increased because of the warm and moist area underneath the pannus. Early mobilization, chest physiotherapy, thromboprophylaxis and adequate pain control are essential components of effective postoperative care. Antenatal and postnatal thromboprophylaxis should be considered in accordance with the Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline No 37 [28].

68.8.4 Breastfeeding

Morbid obesity is associated with a reduction in breastfeeding frequency because of positional difficulties and a reduced prolactin response to suckling. Significant malabsorption in the mother can affect the energy content of breast milk and may affect the postnatal growth of the baby [29]. Therefore, specific supplementation of micronutrients may be indicated prenatally and during pregnancy to overcome these problems.

68.9 Perinatal Outcomes

The incidence of spontaneous miscarriage reported after RYGB and BPD was 34.7 % and 4 % respectively [23]. There is no strong evidence that adverse neonatal outcome rates are higher following LAGB and gastric bypass procedures as compared with obese groups. Sheiner et al. showed no statistically significant difference in preterm delivery ($P = 0.720$) and perinatal mortality rates (6.6/1000 versus 14.8/1000 in their obstetrical population) between restrictive and malabsorptive groups [24].

68.9.1 Birth Weight

There were no statistical differences in low birthweight (<2.5 kg, $P = 0.789$), macrosomia (>4 kg, $P = 0.851$) or umbilical artery pH (7.28 ± 0.089, $P = 0.111$). Low Apgar scores (<7 at 1 min, $P = 0.884$; <7 at 5 min, $P = 0.996$) were noted [24]. However, a French retrospective study of 24 pregnancies showed that RYGB surgery was associated with reduced birthweight as compared with normal BMI and BMI- matched control groups (2.948 kg versus 3.368 kg versus 3.441 kg, respectively, $P < 0.0001$) [30]. This was suggestive of possible nutritional growth restriction in these pregnancies.

68.9.2 Congenital Malformations

Guelinckx et al. reported higher congenital malformation rates following BPD, including diaphragmatic hernia, intestinal obstruction and rectal atresia (0.4 %), and neural tube defects (NTDs; 0.8 %) [23]. Folic acid supplementation is required in all women who have undergone weight loss surgery to prevent NTDs. They should be screened for NTDs through second trimester alpha-fetoprotein and ultrasound. Further research is needed to establish the correct preconception dosage of folic acid in women who have undergone weight loss surgery. Sheiner et al. did not show an increased risk of congenital malformations after controlling for diabetes and hypertensive disorders [12]. The positive association between premature rupture of membranes (PROM) and bariatric surgery was shown in one study [12]. A retrospective review by Dias et al. revealed higher incidence of postmaturity and PROM following RYGB [25]. They also reported good infantile growth 1–3 years post-delivery. Overall, there is no strong evidence that adverse neonatal outcomes are higher following gastric bypass procedures compared with obese groups [10].

68.10 Cosmetic Surgery Following Bariatric Surgery

More than 80 % of post-bariatric surgery patients' state a desire for body contouring but as few as 12 % undergo plastic surgery [31]. Women considering body contouring surgery post bariatric surgery should wait till they have completed their family as future pregnancies can reverse the effects of cosmetic surgery

Key Learning Points

- Preconception counseling—Reliable contraception (preferably, non-oral) is advised to delay pregnancy for approximately 12 months after surgery
- Antenatal care should be managed in a multidisciplinary setting to optimize pregnancy outcome. Keep the bariatric surgeon in the loop. Assess for thromboprophylaxis
- Even if there is slight suspicion of intestinal obstruction, perform clinical examination and imaging studies. Surgical exploration may be required. Active band management following LAGB provides the best results concerning GWG
- There is no medical reason that pregnant women post bariatric surgery requires CS.
- Postpartum: Adequate pain control, early mobilization, thromboprophylaxis, physiotherapy. Encourage breast feeding.

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Non-alcoholic Fatty Liver Disease (NAFLD) and Bariatric Surgery

69

Shlok Balupuri, Angela C. Cheung, Kamal K. Mahawar, and Quentin M. Anstee

Abstract

Morbid obesity is associated with debilitating conditions that adversely affect quality of life and increase the risk of premature death including the metabolic syndrome (hypertension, hypercholesterolemia, type 2 diabetes mellitus (T2DM)) and non-alcoholic fatty liver disease (NAFLD). Insulin resistance is almost a universal finding in patients with NAFLD with majority suffering from T2DM. NAFLD was found to be present in more than 67 % of overweight patients (body mass index (BMI) more than 25 kg/m^2) and nearly in 94 % of obese patients (BMI more than 30 kg/m_2). NAFLD is a common cause of chronic liver disease worldwide. Simple fatty liver disease (steatosis) is a benign condition, reversible by weight loss. Inflammatory cell infiltration leading to non-alcoholic steatohepatitis (NASH) is a more aggressive condition, which is present in up to 10 % of cases and may lead to varying degree of fibrosis and cirrhosis or hepatocellular cancer (HCC) in up to 2 % of this at risk population. However, NASH and hepatic fibrosis short of cirrhosis cannot be reliably diagnosed clinically, radiographically, biochemically or even on gross examination intraoperatively, making liver biopsies the only reliable way to evaluate the liver status. Bariatric surgeons encounter NAFLD in 85–95 % of morbidly obese patients and thus have the unique opportunity to diagnose and assess severity of NAFLD by conducting an intraoperative liver biopsy in morbidly obese patients.

Keywords

Non alcoholic fatty liver disease • NAFLD • NASH • Bariatric surgery • Liver biopsy • Steatosis • Steatohepatitis • Liver fibrosis, cirrhosis

69.1 Introduction

Non-alcoholic fatty liver disease (NAFLD) is considered as the hepatic manifestation of the metabolic syndrome, ranging from benign steatosis to steatohepatitis (NASH), which can progress to fibrosis, cirrhosis and subsequent predisposition to hepatocellular carcinoma (see Fig. 69.1). By definition, the diagnosis requires exclusion of excess alcohol consumption (more than 20 g per day for females and or 30 g per day for males). In many countries, up to 30 % of the adult population have NAFLD, rising to 75 % of obese adults [1]. Moreover, NAFLD is on its way to becoming the most prevalent cause of chronic liver disease in developed nations [2].

Bariatric surgery has proven to be one of the most effective weight loss treatments [3] and improves survival [4] in those with morbid obesity. Given the high prevalence of NAFLD in the morbidly obese, this disease is frequently encountered by surgeons while performing bariatric procedures. Type 2 diabetes mellitus (T2DM) improvement and even remission, if not cure, is well documented after bariatric

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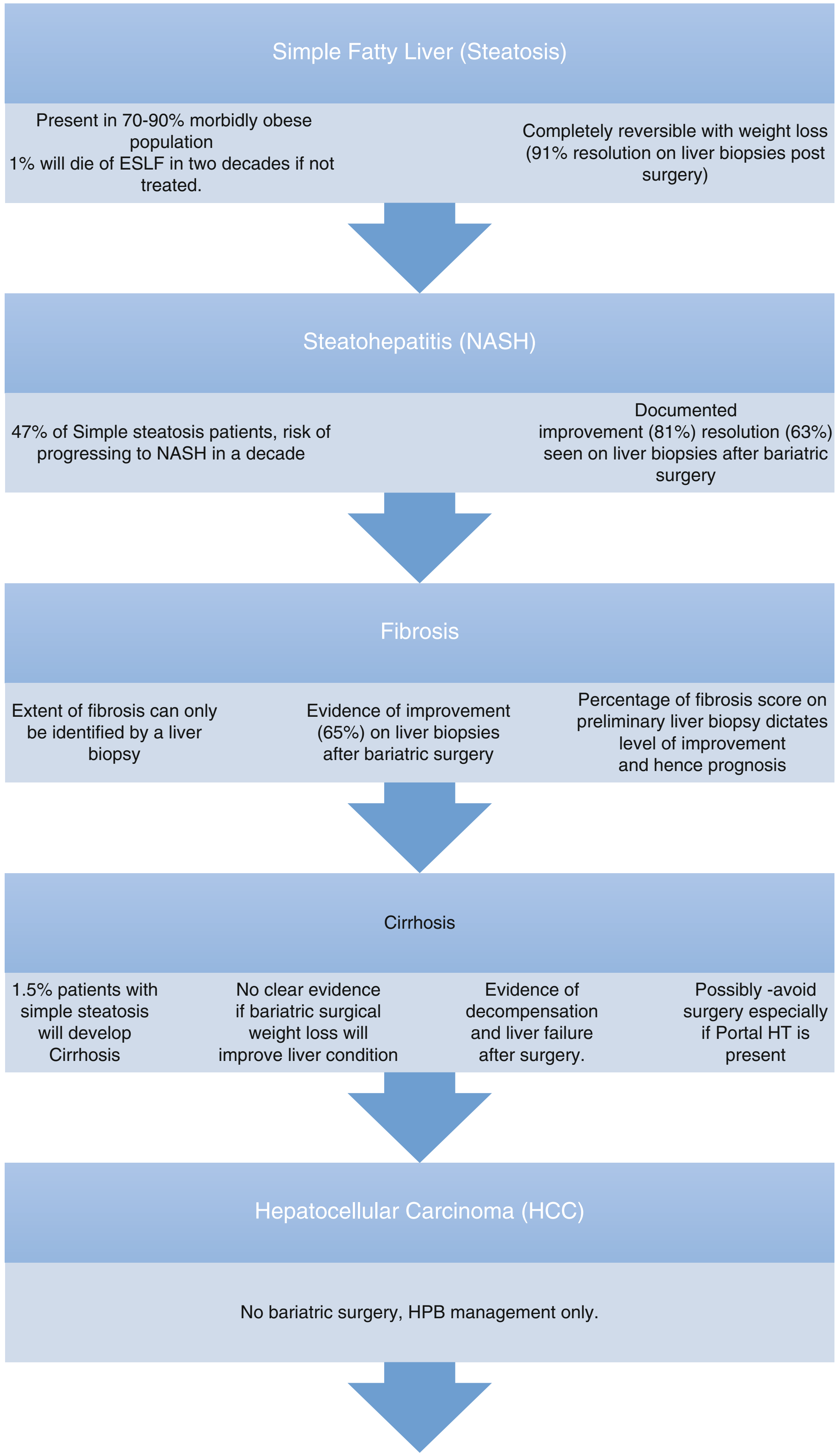
Fig. 69.1 Flow chart



procedures. Interestingly approximately 50–80 % of patients with T2DM have NAFLD, with T2DM being associated with more advanced disease including steatohepatitis and fibrosis. The diagnosis and management of patients with NASH who undergo bariatric surgery poses a unique, and growing challenge to gastroenterologists, hepatologists and bariatric surgeons since routine clinical blood tests cannot detect NAFLD or accurately determine the severity of disease. For this reason, the "gold standard" both for diagnosis and distinguishing simple steatosis from NASH remains histological [2].

69.2 Natural History of Non-alcoholic Fatty Liver Disease

Prevalence of Non-alcoholic fatty liver disease (NAFLD) is increasing with rising population obesity and T2DM. NAFLD occurs on a background of insulin resistance and obesity when influx or synthesis of fatty acids (FFA) in the liver exceeds export/fatty acid oxidation. Although steatosis has in the past been considered directly toxic, it is likely that hepatocyte triglyceride accumulation is itself not directly harmful, but is a surrogate marker for histologically invisible increased hepatocyte FFA flux that is driving disease pathogenesis [5, 6]. The various histological subgroups of NAFLD progression are:

69.2.1 Simple Fatty Liver (Steatosis)

Excess triglyceride builds up within the hepatocytes. Complete resolution can be expected with weight loss. There are usually no symptoms although some patients may complain of a right upper quadrant dull aching pain. It is frequently diagnosed as an incidental finding on ultrasound scan due to increased echogenecity of the liver (see Fig. 69.2).

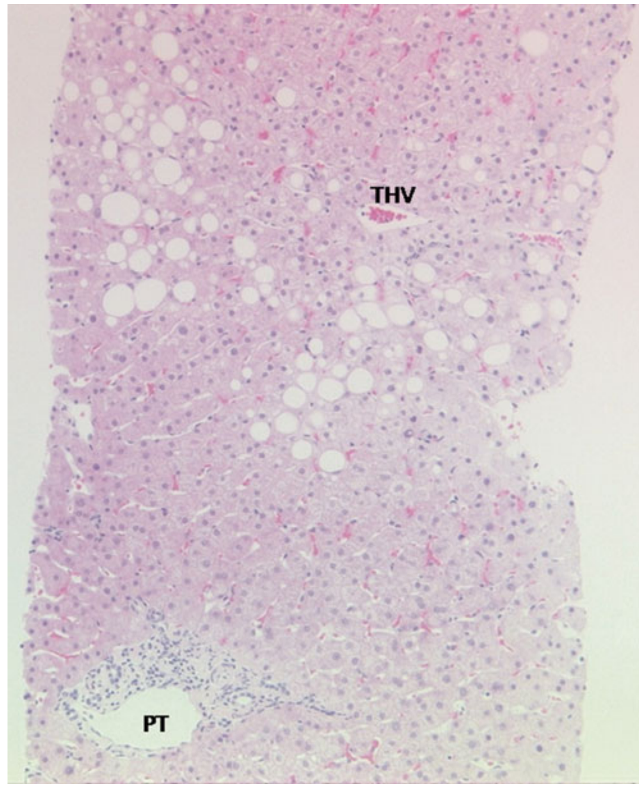


Fig. 69.2 Fatty liver (Steatosis)—Pale appearance of blunted edged liver on gross inspection and simple fat infiltration with no inflammatory cells on histological examination. Defined as fat accumulation exceeding five percent of fat laden hepatocytes identified histologically [Courtesy of Dr Dina Tiniakos (Newcastle University)] *THV*: Hepatic vein, *PT*: Portal Tracts

69.2.2 Non-alcoholic Steatohepatitis (NASH)

This is a more aggressive form of the condition characterized by an inflammatory cell infiltrate into the liver parenchyma and as a result hepatocyte damage occurs, called 'ballooning degeneration' (see Fig. 69.3).

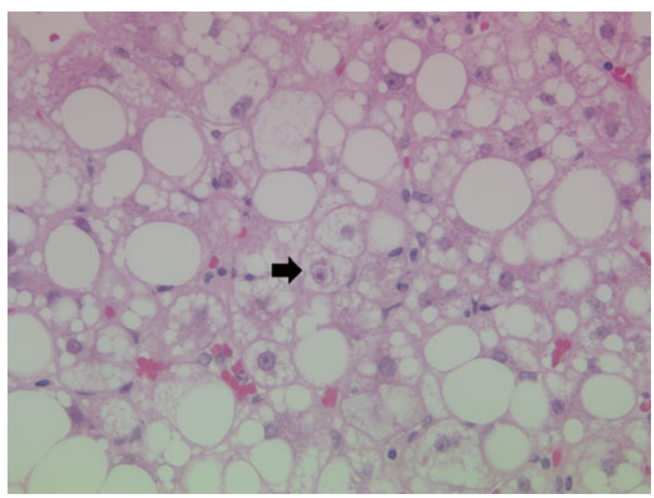


Fig. 69.3 Steatohepatitis (NASH)—inflammatory cell infiltration [Courtesy of Dr Dina Tiniakos (Newcastle University)]

69.2.3 Fibrosing-NASH

Some NASH progresses to fibrosis, due to persistent inflammation of hepatocytes. There is generation of fibrous scar tissue around the liver cells and blood vessels with fibrous tissue replacing some of the healthy liver tissue. Due to natural redundancy of hepatocellular function, there are enough hepatocytes to maintain liver function. Therefore completely normal liver function tests may be present, even in the presence of active inflammation and progressive fibrosis.

69.2.4 Cirrhosis

Even at this stage blood tests may be normal however they deteriorate as hepatic damage accumulates and hepatic decompensation occurs (see Fig. 69.4).

Standardization of the histological diagnosis of NASH is achieved by using validated Kleiner NAFLD activity score (NAS), (see Fig. 69.3) which defines steatohepatitis by grading the degree of steatosis, lobular inflammation and hepatocyte ballooning degeneration and quantifies fibrosis [7].

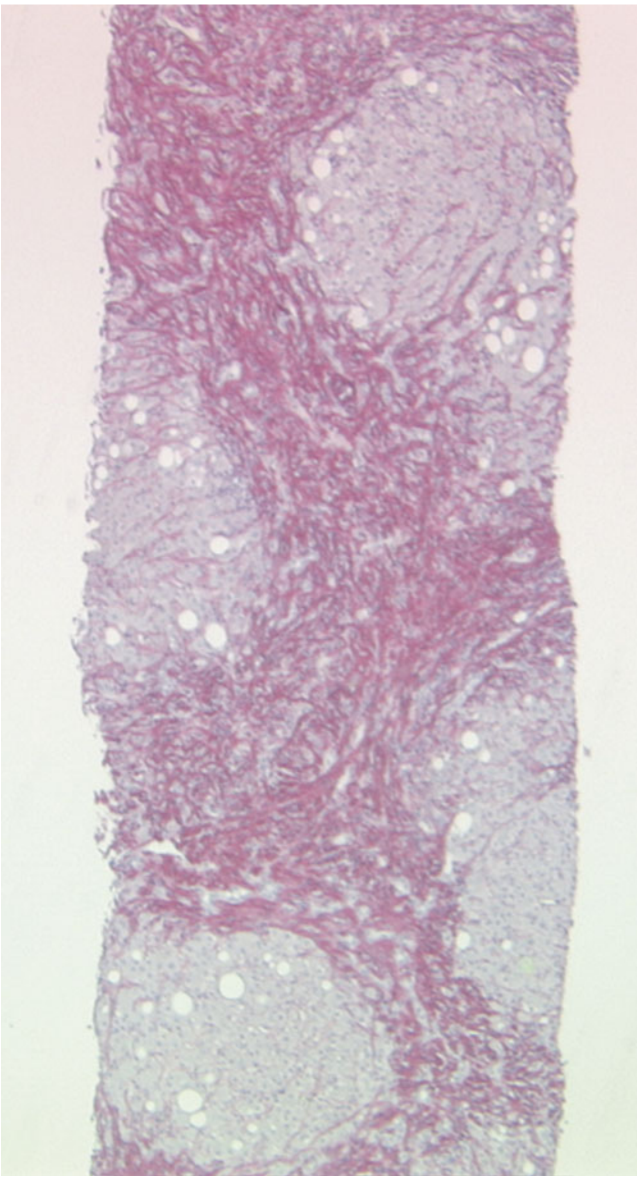


Fig. 69.4 Cirrhosis—Shrunken nodular liver with substantial fibrosis on histology [Courtesy of Dr Dina Tiniakos (Newcastle University)]

69.3 Clinical Presentation and Diagnosis

Since NAFLD may be asymptomatic, a high index of suspicion is needed in patients with metabolic syndrome (T2DM and/or insulin resistance, abdominal obesity, elevated triglycerides, reduced HDL cholesterol and hypertension). However the diagnosis cannot be made on clinical grounds alone [8, 9]. Liver enzymes may be normal in more than 75 % cases, making them insensitive in detection of NAFLD. In the absence of cirrhosis, an aspartate aminotransferase (AST) to alanine aminotransferase (ALT) ratio of less than 1 (AST less than ALT) may be seen in NAFLD patients however this ratio reverses (AST more than ALT) as disease progresses towards cirrhosis. Gamma glutamyltransferase (GGT) is found to be elevated frequently in NAFLD and has been shown to be associated with advanced fibrosis [10] and increased mortality [11]. However it cannot be used as a solo marker for diagnosis of NAFLD when elevated in isolation. NAFLD is frequently detected on imaging performed for other conditions. However, ultrasound scan (USG), magnetic resonance imaging (MRI) or computerized tomography (CT) scan cannot differentiate benign steatosis (fatty liver) from the more aggressive NASH and importantly; these modalities are unable to quantify degree of fibrosis within the liver.

Since it is steatohepatitis (NASH), rather than steatosis that is associated with progression to cirrhosis, those with NASH require hepatological follow-up. The risk of NASH progressing to cirrhosis is estimated to be between 8 and 15 %, while the risk of developing hepatocellular carcinoma (HCC) is 1–2 % [2]. Currently, about 13 % diagnosed HCC are directly related to NASH cirrhosis, with end stage NAFLD accounting for 5–10 % of liver transplant activity [12].

In an attempt to reduce the need for liver biopsies, several non-invasive tests for fibrosis have been proposed. These include the BARD score [13], the fibrosis-4 (FIB4) index [14–16], the NAFLD fibrosis score [17, 18], the aspartate aminotransferase to platelet ratio index (APRI) [19, 20] and the AST/ALT [21, 22].

The plethora of proposed scoring systems indicates an inherent difficulty in identifying a good non-invasive modality to diagnose and prognosticate liver disease. While non-invasive testing is reasonably accurate at identifying patients at extremes of fibrosis, there has yet to be a single test, which can accurately stage intermediate degrees of fibrosis. This is particularly true in morbidly obese population. Hence, liver biopsy is the only reliable modality available to accurately diagnose NASH and the degree of fibrosis.

69.4 Bariatric Surgery and Non-alcoholic Fatty Liver Disease

It is widely acknowledged that the patients undergoing bariatric surgery have high rates of NAFLD. Steatosis is thought to be present in approximately 90 % of morbidly obese patients and steatohepatitis in 13–56 % [23]. Up to 13 % of patients may have cirrhosis [24], which is associated with increased perioperative morbidity and mortality [25] and also increases the risk of developing hepatocellular carcinoma. It is therefore, likely that morbidly obese bariatric patients could derive significant benefit from a diagnostic/staging liver biopsy at the time of surgery [14].

The two important questions in managing patients with NAFLD are therefore: (1) Does the patient have simple steatosis or NASH? and (2) What is the stage of fibrosis?

Bariatric surgeons have the unique opportunity and ability to address these questions via an intraoperative liver biopsy. Intraoperative liver biopsy can help differentiate between simple steatosis, NASH and varying degrees of fibrosis [8]. However its use is not without controversy, as it may be subject to sampling error and can lead to complications. A morbidity rate of 1–5 in 100 and a mortality rate of 1 in 1000–10,000 [26, 27] have been quoted for transcutaneous liver biopsy.

The risk of intraoperative liver biopsy under direct vision is considered to be much lower than percutaneous approaches. Of the studies that have examined the use of routine intraoperative liver biopsies, none have reported an increase in intraoperative complications secondary to liver biopsy [14, 24, 28, 29]. Furthermore, these studies show that macroscopic examination of the liver by 'visual inspection' during surgery cannot reliably distinguish steatosis from steatohepatitis or assess degree of fibrosis (or even cirrhosis) [14, 24, 29, 30].

Of the two methods of intraoperative liver biopsy, wedge biopsy and core needle biopsy, the latter provides greater accuracy, with no increase in procedural risk. Wedge biopsies, however, due to subcapsular fibrosis, demonstrate 30 % more fibrosis than needle biopsies. Despite these histological differences in extent of the fibrosis, the steatosis assessment appears to stay consistent, irrespective of biopsy modalities [28].

69.5 Liver Biopsy During Bariatric Surgical Procedures to Differentiate Simple Steatosis from NASH and Fibrosis

A study by Powell et al demonstrated that gross evaluation of livers had a sensitivity of 52 %, specificity of 52 %, Net Predictive Value (NPV) of 76 % and Positive Predictive Value (PPV) of 22 % in diagnosing NASH [23]. 48 % of the patients with biopsy proven NASH had normal appearing livers of these normal appearing livers, 24 % had NASH. Furthermore, of those with fibrosis, 40 % had a macroscopically normal looking liver. Unfortunately, the stage of fibrosis was not reported in the study.

Shalhub et al compared 68 consecutive patients with routine liver biopsies and 86 patients with selective liver biopsies (86 of 174, 49 %) from 242 patients intraoperatively, undergoing either open or laparoscopic Gastric Bypass Roux en y [24]. the routine biopsies were from 68 consecutive patients irrespective of visual impression of liver status intraoperatively. a further 86 liver biopsies were taken selectively only from those patients where NAFLD was suspected during the bariatric operation. They found significantly more patients diagnosed with NASH in the setting of routine (consecutive) liver biopsy (37 % versus 32 %, p less than 0.01). There was also a significant difference in patients discovered to have moderate or severe steatosis (15 % versus 6 % and 4 % versus 1 % respectively) but there was no difference in patients found to be cirrhotic (7 % versus 8 %). in this study, neither body mass index (BMI) nor liver enzymes were able to predict the presence or severity of NASH.

These data would suggest that intraoperative liver biopsy may be a useful additional test during bariatric procedures so that extent of liver damage can be formally assessed and patients with established cirrhosis can be referred for hepatological review and ongoing surveillance for hepatocellular carcinoma.

69.6 The Effects of Bariatric Surgery on Liver Histology

Despite NAFLD being associated with obesity, T2DM and insulin resistance, it is not yet included in the criteria as an indication for bariatric surgery. At present national consensus bodies do not advocate the use of bariatric surgery as a treatment for NAFLD alone [8, 31]. While there have been studies demonstrating a statistically significant decrease in steatosis following bariatric surgery in patients with biopsy-proven NASH [32–35], a recent Cochrane review concluded that without a randomized control trial, bariatric surgery for NASH alone could not be recommended [36]. Further evidence is therefore needed to determine the utility of bariatric surgery for this indication however the available evidence suggests that it is highly effective.

Mummadi et al in a systematic review and meta-analysis of effect of bariatric surgery on NAFLD, reported a total of

15 studies consisting of 766 paired liver biopsies performed during bariatric surgery [37]. They found steatosis only in 637 of 766 (83.15 %) initial biopsies. Postoperatively, improvement/resolution in steatosis was demonstrated in 91.6 % with the interval between biopsies ranging from 2 to 111 months.

Furthermore, NASH was present in 299 of 555 (53.87 %) initial biopsies, with improvement or resolution documented in 81.3 % (95 % CI, 61.9–94.9 %) of cases. This meta-analysis showed a complete resolution in histopathologic changes of NASH in 69.5 (95 % CI, 42.4–90.8 %) post surgery. Fibrosis was present in 300 of 460 (65.21 %) biopsies. Improvement post-surgery or resolution of fibrosis was demonstrable in 65.5 % (95 % CI, 38.2–88.1 %) of cases.

The following year, a key study by Mathurin et al involved 381 patients who had a liver biopsy pre-operatively, then at 1 and 5 years postoperatively [32]. Once again, there was significant improvement in steatosis, ballooning and even resolution of NASH at 1 year, although no further changes at 5 years. Thus, the improvement conferred by bariatric surgery is likely to be maximal within the first postoperative year however established cirrhosis is unlikely to get completely resolved.

Systematic review of bariatric surgery in obese patients with NASH by Chavez-Tapia et al showed that many of the studies have been of a small size and hence difficult to accurately determine the extent of benefit from bariatric surgery in NAFLD [36]. To address this, there needs to be more rigorous investigation and documentation of the effects of surgery on the histological manifestations of NAFLD.

69.7 The Effect of Type of Bariatric Operation on Hepatic Function

So far, there is no evidence to guide, what is the ideal bariatric procedure that would provide NAFLD patients with the most benefit and least harm. [8] There is a lack of data on the risk factors for hepatic decompensation in patients undergoing modern bariatric procedures [24, 29, 32, 38]. the various types of bariatric surgery procedures are each associated with varying degrees of weight loss, with techniques that combine malabsorptive and restrictive mechanisms leading to greater weight loss on average than restrictive surgeries alone [39]. There is also evidence that a bariatric procedure may be harmful in some patients with NASH and advanced fibrosis, as rapid weight loss may lead to worsening of fibrosis and even liver failure [38]. Combined restrictive and malabsorptive procedures such as the very long limb Roux-en-Y gastric bypass (distal RYGBP), biliopancreatic diversion (BPD), and duodenal switch (DS) appear to convey higher risks of hepatic complications due to their ability to precipitate rapid weight loss [24]. While large cohort studies do not demonstrate significant early or delayed postoperative complications from liver disease [40, 41], data is limited by empiric definitions of liver disease, the absence of histological follow-up and the inherent limitations of retrospective data collection.

Conclusion

Non-alcoholic fatty liver disease (NAFLD) is an increasingly recognized, common cause of chronic liver disease worldwide. It is a silent and slowly progressive disease with significant associated morbidity. It is clear from the evidence that NAFLD cannot be reliably diagnosed clinically, radiographically, biochemically or on gross examination intraoperatively. This makes liver biopsies during surgery, the only reliable way to evaluate disease status. Hence, the true number of patients with significant fibrosis or cirrhosis undergoing bariatric surgery remains unknown.

The limitations of currently available diagnostic testing for NAFLD makes it difficult to develop any conclusions about the risks and benefits of bariatric surgery on this patient population although it would appear to be beneficial in the majority. While there are clear guidelines for nutritional and psychosocial management of patients undergoing bariatric surgery, there is a dearth of recommendations with regards to preoperative assessment of liver disease although unidentified NAFLD, may have a significant impact on postoperative complications and mortality. There is increasing evidence to support the use of intraoperative liver biopsy to detect NASH and determine the severity of associated fibrosis to guide postoperative care. Finally, although bariatric surgery is likely to significantly improve NASH, we need to understand better the role of bariatric surgery in this condition.

Key Learning Points

- Non -alcoholic liver disease: NAFLD is part of the metabolic syndrome affecting obese patients. NAFLD is estimated to be present in more than 67 % of overweight patients (body mass index (BMI) more than 25 kg/m^2) and nearly in 94 % of obese patients (BMI more than 30 kg/m^2)
- Bariatric surgery: Bariatric surgery leads to overall improvement in metabolic syndrome associated with obesity. It also reverses the fatty infiltration within the liver and arrests simple fatty liver progression to NASH
- Liver biopsy: Possibly liver biopsy is the only reliable way to diagnose NASH and accurately distinguish

steatosis from steatohepatitis. Liver biopsy reveals degree of fibrosis and its stage.

- Non-alcoholic steatohepatitis: Steatohepatitis is reportedly seen in 50 % of morbidly obese patients on histological analysis of liver biopsies. Most studies, though small numbers, show marked improvement in NASH after weight loss post surgery. Visual appearance of liver is mostly unreliable in evaluating NASH and its progression.
- Liver cirrhosis/hepatocellular cancer: Up to 13 % of morbid obese patients may have cirrhosis; this is associated with increased perioperative morbidity and mortality. The degree and stage of progression of fibrosis on liver biopsy is predictive of developing cirrhosis and in 1–2 % of the cases developing hepatocellular carcinoma.

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Cancer, Obesity, and Bariatric Surgery

70

Duff M. Bruce

Abstract

Since the 1950s, healthcare workers have recognized an increased risk of some malignancies associated with high body weight. A number of epidemiological studies have confirmed the association of high body mass index with increased cancer incidence and mortality rates and poorer outcomes. There appears to be significant variation in these risks depending on the severity of obesity, tissue origin of the malignancy, ethnicity, menopausal status and smoking habits.

There is little evidence to suggest limitation of risks with decrease in weight. Some long term studies have revealed that, for some cancer types, weight reduction has a beneficial impact. The academic community increasingly explores the mechanisms behind this association. A number of factors seem to be related. At a holistic level, obesity may impair the ability of patients and clinicians to recognize the early signs of cancer development or influence uptake of screening resources. Similarly, the severely overweight patient may neither be fit nor suitable for all the usual treatment modalities. At the tissue level, metabolic and endocrine factors of carcinogenesis have an impact on inflammation, cell repair and tumor genesis. Such factors include insulin metabolism, sex steroids and fatty-tissue related proteins such as leptin and adiponectin.

The significant and consistent long term weight loss resulting from bariatric surgery may have an impact on some cancer risks in this patient group. This now gives clinicians and sufferers the intriguing hope that weight loss surgery may have a role in affecting the health of populations by modifying their risk for some cancers.

Keywords

Obesity • Overweight • Weight loss • Bariatric surgery • Weight loss surgery • Cancer • Cancer risk • Cancer surveillance • Tumor genesis

70.1 Introduction

Increased awareness of the poor health outcomes associated with adiposity focuses on associated illnesses with obvious health economic impacts, such as type 2 diabetes mellitus (T2DM). The story of obesity's association with malignancy risk and poor cancer outcomes has been slower to develop. As a result, an increasing number of patients in our clinics are concerned about the impact of weight gain on the cancer risk or the ability to fight cancer. Similarly, oncologists have started to seek help with aspects of cancer care thwarted by

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physical aspects of obesity. This chapter explores the relationship between obesity and cancer and the potential for modifying risk and outcomes by traditional weight loss and bariatric surgery.

70.2 Relationship Between Obesity and Cancer

Obesity's relationship with cancer was recognized in the 1950s and was first described by Lew and Garfinkel, examining a US population, in 1979 [1]. By 2007, The World Cancer Research Fund was convinced by the evidence, that overweight and obesity were associated with increased risk of esophageal (adenocarcinoma), pancreatic, colorectal, breast (postmenopausal), endometrial and renal cancer, with a possible association with gallbladder cancer [2]. Renehan, more recently, undertook a systematic review and metaanalysis of body mass index (BMI) and cancer incidence and described congruent and further findings suggesting that a 5 kg/m^2 increase in body weight was associated with increased risk [3]. In men, increased BMI was clearly associated with esophageal adenocarcinoma (relative risk (RR) 1.52, $p<0.0001$), thyroid (RR 1.33, $p=0.02$), colon (RR 1.24, $p<0.0001$) and renal (RR 1.24, $p<0.0001$) cancers. In women, an increase was associated with esophageal adenocarcinoma (RR 1.51, $p<0.0001$), endometrial (RR 1.59, $p<0.0001$), gallbladder (RR 1.59, $p=0.04$) and renal (RR 1.34, $p<0.0001$) cancers. The author noted weaker associations with leukemia, multiple myeloma and non-Hodgkin lymphoma in both the sexes, rectal cancer and malignant melanoma, in men and post-menopausal breast, pancreatic, thyroid and colon cancer, in women. Lung cancer risk, conversely, decreased with increasing BMI. This is almost certainly confounded by the association of tobacco smoking with both low BMI and lung cancer. The study also examined ethnicity, and showed similar associations with cancer risks worldwide, apart from increased risk for pre- and post-menopausal breast cancer in Asia-Pacific populations [3]. The United Kingdom based Million Women Study revealed a similar pattern as above [4]. This study also examined mortality, and found that mortality rates very much mirrored incidence rates. For endometrial cancer (RR 2.46) and esophageal adenocarcinoma (RR 2.24), in particular, high weight represents a major modifiable risk factor.

More recently, Bhaskaran et al. examined links between BMI and 22 common cancer types in a prospectively collected UK general practice database and adjusted them for age, sex, smoking status, alcohol use and diabetes [5]. They showed that each 5 kg/m^2 increase in BMI was roughly linearly associated with cancer of the uterus, gallbladder, kidney, cervix, thyroid and leukemia. Cancer risk increased overall with higher BMI for liver, colon, ovarian and post menopausal breast cancers but there was variation between groups categorized as above. Prostate and pre-menopausal breast cancers were estimated as slightly protective (see Table 70.1) [5].

In terms of prospective studies, nine hundred thousand United States adults, who were free of cancer in 1982, were followed prospectively [7]. The risk of death was calculated

Table 70.1 Cancer incidence risks in relation to obesity: key findings

	Renehan, et al. [6] male RR, 95 %CI	Renehan, et al. [6] female RR, 95 %CI	Reeves, et al. [4] female RR, 95 %CI	Bhaskaran, et al. [5] HR, 99 % CI
Esophageal (adenocarcinoma)	1.52, 1.33–1.74	1.51, 1.31–1.74	2.38, 1.59–3.56	
Uterus				1.62, 1.56–1.69
Pancreatic		Weak association	1.24, 1.03–1.48	
Gallbladder		1.59, 1.02–2.47		1.31, 1.12–1.52
Kidney	1.24, 1.15–1.34	1.34, 1.25–1.43	1.53, 1.27–1.84	1.25, 1.17–1.33
Cervix				1.10, 1.03–1.17
Thyroid	1.33, 1.04–1.70	Weak association		1.09, 1.00–1.19
Leukemia	Weak association	Weak association	1.50, 1.23–1.83	1.09, 1.05–1.13
Liver	1.24, 0.95–1.62			Variable association
Colon (all)	1.24, 1.20–1.28	Weak association		Variable association
Colon (premenopause)			1.61, 1.05–2.48	
Rectum	Weak association			
Ovarian			1.14, 1.03–1.27	Variable association
Endometrial		1.59, 1.50–1.68	2.89, 2.62–3.18	
Post-menopausal breast		Weak association	1.40, 1.31–1.49	Variable association
Non-Hodgkin lymphoma	Weak association	Weak association	1.17, 1.03–1.34	
Multiple myeloma			1.31, 1.04–1.65	
Malignant melanoma	Weak association	Weak association		

RR relative risk, *CI* confidence interval, "weak association" = RR < 1.20, *HR* hazard ratio, "variable association" = positive association but affected by individual-level characteristics (such as smoking, age). Renehan et al. described risk gradients categorized at 5 kg/m^2 change, Reeves et al. at 10 kg/m^2 gradient and Bhaskaran examined linear gradients of change

16 years later, for those with BMI more than 40 kg/m^2. The combined death rates were 52 % higher for men and 62 % higher for women when compared with the cohort of normal weight. In both men and women this BMI was associated with higher risk of death due to cancer of the esophagus, colon, rectum, liver, gallbladder, pancreas, kidney, non-Hodgkin lymphoma and multiple myeloma. The authors estimated that overweight and obesity accounted for 14 % of deaths from cancer in men and for 20 % in women [7]. Bergstrom et al. found more conservative but still significant findings in a European cohort, suggesting that excess body mass accounts for 3 % of cancer in men and 6 % in women [8].

There is also some evidence of association between obesity and premalignant disease. Stronger association has been shown with larger, rather than smaller, colonic adenomas in the obese [9]. Barrett's esophagus is a condition associated with an increased risk of esophageal adenocarcinoma, and related to gastroesophageal reflux disease (GERD). While some studies show no relationship between high BMI and the risk for Barrett's esophagus when stratified for reflux symptoms, others show an association between increased BMI and risk for Barrett's esophagus when compared with population based controls, suggesting indirect effects of GERD as key to risk of malignancy [10].

70.3 Weight Loss and Cancer

While it is evident that obesity increases the incidence of cancer and relates to poorer outcomes, it is more difficult to show weight loss associated benefits. It is difficult to retrospectively identify which patients lost weight intentionally, and most documentation is of self-reported weights. Also, some weight loss in such patient population is secondary to malignant disease. The key challenge is the absence of reliable nonsurgical methods to maintain significant weight loss in more than a tiny portion of this population. The sustainable weight loss following bariatric surgery has created populations that may be studied; however, the effects of nonsurgical weight loss may differ.

In 2012, a systematic review conducted by Birks et al. identified 34 publications that reported weight loss in relation to cancer incidence or mortality [11]. About half of these papers were inconclusive and the other half of them showed improvements in the incidence and mortality associated with obesity, after successful weight loss. When papers only studying intentional weight loss were examined, five out of six showed this benefit which was greater for "obesity related" cancers and in women. They concluded that intentional weight loss results in decreased incidence of cancer, particularly in female obesity related cancers [11].

Only a small body of evidence has prospectively studied nonsurgical weight loss and cancer risk. One study documented significant decrease in the mortality from all cancers in those losing more than 0.5 kg. However, this was primarily in women with preexisting, nonmalignant, illness [12]. These authors calculated 39–53 % decrease in mortality for obesity related cancers. In men, no significant differences in the risk of cancer mortality were seen with intentional weight loss [13].

70.4 Mechanisms of the Effect of Obesity on Cancer Risk and Outcomes

In 2002, the International Agency for Research on Cancer reviewed international literature on increased weight and cancer. They recommended that people avoid weight gain to reduce the risk of cancer of the colon, breast (in postmenopausal women), endometrium, kidney and esophagus (adenocarcinoma).

Increased weight has an impact on cancer outcomes in a variety of ways. Regardless of the menopausal status and the stage and treatment of cancer, severe adiposity may be related to poorer survival and increased risk of recurrence for breast and gynecological malignancy [14].

Research continues to examine what links weight gain to cancer development. Key factors appear to be metabolic and endocrine effects with subsequent impact on inflammation, cell repair and tumor genesis [15]. This is a complex multifactorial process. In health, adipose tissue is an active organ that stores and releases energy in the form of free fatty acids and contributes to lipid metabolism. Aspects of this system play a role in carcinogenesis.

70.4.1 Role of Insulin Metabolism

Increased release of proinflammatory proteins and peptide hormones and decreased production of adiponectin, associated with obesity, result in increased insulin resistance. Resultant attempts to produce more insulin cause chronic hyperinsulinemia. Amongst other mechanisms, this results in increased production of insulin like growth factor (IGF) and decreased production of its binding proteins 1 and 2. Insulin and IGF both also stimulate availability of male and female sex hormones. This nurtures an environment that promotes cell proliferation, inhibits apoptosis (programmed cell death) and results in the potential for tumor growth [10, 16].

70.4.2 Role of Chronic Inflammation

Excess body weight results in chronic low- grade inflammation, evidenced by increased levels of proinflammatory markers and cytokines, such as C-reactive protein, interleukin-6, and macrophage inhibitory factor. Many of these have tumorigenic effects and others stimulate inflammatory cells. There is also an association of chronic inflammation with obesity and insulin resistance, in the metabolic syndrome [10].

70.4.3 Role of Sex Steroids

Obesity alters availability of sex hormones such as androgens, estrogens and progesterone through a number of mechanisms. This alteration of circulating sex hormones may explain the associations between obesity and risks of cancers of the postmenopausal breast and endometrium. Also, estrogen and progesterone regulate aspects of cell differentiation, proliferation and apoptosis [16].

70.4.4 Role of Adipokine

Adipokines are cell signaling proteins secreted by fatty tissue. Leptin is one such hormone that regulates the amount of fat stored in the body and is related to satiety. Its levels increase with obesity and it has mitogenic activity in intestinal epithelium. In vitro evidence links this with colorectal cancer promotion. Adiponectin is an insulin sensitizing hormone, which regulates glucose levels and fatty acid breakdown. Its levels are inversely proportional to body fat percentage. In vitro it reduces some gastrointestinal tumor growth. These hormones, with others, may have a role in the obesity cancer story but the association remains unclear [10].

70.4.5 Role of the Intestinal Microbiome

The relationship between the gut flora and obesity is a novel and topical area of study. Changes in the abundance of some gut commensals may relate to the story of chronic inflammation and link to colorectal adenoma risk. This is an active area of research [10].

Other clinical cancer outcomes may be affected by biological factors and obesity related differences in recognition, diagnostic investigation, stage at presentation and management of the disease [7]. For example, women with a BMI above 40 kg/m^2 have almost three times the breast cancer death rate of lean women. This may represent different biology, differences in seeking mammographic screening, or poorer self detection rates [16].

Also, women with the highest measures of central obesity had poorest outcomes for colorectal cancer survival, with 37 % increased risk of cancer death. A further study revealed a 20 % reduction in colorectal cancer specific survival for every 10 cm greater waist circumference. This is almost certainly a combination of increased surgical morbidity mixed with poorer metabolic outcomes. There is also a worse overall survival in overweight patients receiving adjuvant chemotherapy [10].

70.5 Bariatric Surgery and Cancer

A recent systematic review and metaanalysis, identified 13 studies with 54,257 participants (primarily from Europe and USA) [6]. Examination of four controlled studies, in this group, concluded that bariatric surgery is associated with reduced cancer risk in morbidly obese people [odds ratio (OR) from 0.12 to 0.88] and incidence between 1.06 to 1.08 per 1,000 person-years. These levels are similar to those in nonobese individuals and about half that described in obese patients globally [6]. Interestingly, the higher the preoperative BMI, the lower the cancer risk following the procedure (beta coefficient −0.2, $p<0.05$). Absence of randomized controlled trials was highlighted and several potential areas of bias in surgical and nonsurgical groups should encourage conclusions to be viewed with care [17].

Three key studies showed decreased incidence of breast, uterine, hematopoietic cancers and melanomas following surgical weight loss [18–20]. These should be considered in the context of the consistent evidence of improved overall long term survival benefits of bariatric surgery [21]. The mechanism for such benefits is unclear and may relate to metabolic changes following bariatric surgery, associated benefits of improved lifestyle or earlier diagnosis [22].

It is difficult to determine if all surgical interventions and all patient subgroups have similar effects. There is a suggestion that there may be increased risk of colorectal cancer after bariatric surgery. Some potential mucosal biochemical markers of colorectal cancer risk and mucosal proinflammatory gene expression were increased at least three years after gastric bypass surgery [10]. A Swedish study compared colorectal cancer incidence ratios in an obesity surgery cohort. They showed continuously increasing risk in the postbariatric surgery group with a standardized incidence ratio of 2.00 (95 % confidence interval (CI) 1.48 to 2.64) by ten years compared to 1.26 (95 % CI 1.14–1.40) in the nonsurgical obese group. They suggested that the risk was greater for men and did not relate to the procedure type. Further research should be directed at colonoscopic surveillance of postsurgical patients [23]. We must reflect that all potential bariatric surgery patients have highlighted themselves at increased risk of metabolic, psychological and malignant diseases and we should consider screening as appropriate.

Conclusions

In our day to day practice, obese patients increasingly challenge routine clinical pathways. Wards and intensive care units require special equipment to facilitate supportive care and enable moving and handling of obese patients. Physical size may affect the ability to offer certain diagnostic modalities and may require specialist knowledge or equipment to facilitate procedures in the operating room. It is the responsibility of healthcare organizations to ensure that bariatric surgeons have the resources to overcome such issues while maintaining patient safety and dignity.

Obesity increases individual and population risk of developing malignant disease. In worldwide populations affected, it contributes to a significant proportion of cases. There are factors such as age, sex, BMI and ethnicity that modify this effect. Weight loss by either nonsurgical or surgical means improves cancer risk and for women, in particular, may reduce it to near that of people in the normal weight range. Mechanisms, which cause this association, are a mix of physical, metabolic, endocrine and cellular processes. Avoidance of obesity is clearly the most desirable solution but currently, bariatric surgery remains the only treatment offering predictable, long term effective weight loss and, therefore, has a key role in minimizing obesity related cancer risk.

Key Learning Points

- Increasing weight above usual levels is related to higher cancer incidence and mortality for a range of tumors; including cancer of the esophagus, uterus, gallbladder, kidney, thyroid, liver, colon, endometrium and the postmenopausal breast and hematopoietic malignancy.
- There is variability in the risk of cancer associated with obesity, related to individual factors such as body mass index, sex, ethnicity, menopausal status and smoking.
- Traditional weight loss appears to decrease the risk of some cancers; particularly female obesity related tumors and may decrease related mortality.
- The mechanism of obesity related increased cancer risk appears to be multifactorial but probably includes combinations of metabolic and endocrine effects that adversely impact inflammation, cell repair and tumor genesis.
- Bariatric surgery related weight loss seems to decrease the incidence of some cancers; including breast, uterine, hematopoietic and melanomas though further studies are required.

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Psychological Issues Before and After Bariatric Surgery

71

Vanessa Snowdon-Carr

Abstract

Bariatric surgery is an extremely effective treatment for severe and complex obesity. However, changes are dramatic and rapid and therefore it is a psychologically demanding intervention even for patients who experience very positive outcomes. A person's weight and eating history, past attempts to lose weight, and self efficacy will influence the decision to have weight loss surgery. Past dieting "failure" can result in desperation and the belief that weight loss is not possible by any other means. The complex relationship between mental health and obesity also has an impact on a person's ability to make lifestyle changes. There are a wide range of adjustments to be made postoperatively as a result of the significant changes to eating, weight, identity, and coping. Difficulties can occur with each of these issues and therefore appropriate detection and provision of psychological support is required. Better understanding of factors which previously led to, and maintained obesity and postoperative issues may help to improve outcome for the significant minority of patients who either regain weight or have other adjustment difficulties. Health professionals need to have a greater understanding of the range of psychological and social factors influencing outcome.

Keywords

Psychological • Dieting • Self efficacy • Adjustment • Transitional • Coping • Mental health • Eating disorder • Alcohol • Body image

71.1 Psychological Issues Before and After Surgery

71.1.1 Pre-surgical Issues

Obesity is the end point of a complex set of interactions both in terms of the underlying causes and maintenance of the state involving dietary, medical and psychological issues. Despite the tendency to regard all ranges of obesity as an 'obese population' this is not a homogenous group. For example the range from the start of the obese body mass index (BMI) categorization (BMI more than 30) to the highest weights we see within the specialist clinics (BMI more than 90) demonstrates a much wider spread of BMI points than the rest of the narrow "healthy" BMI range bands even when mild or modest obesity is included. There is a corresponding substantial variation in psychological and physical wellness within this range of BMI. By focusing on the over simplified and often ineffective message of 'eat less, move more' many health professionals have limited their approach when working with obesity. The subsequent "failure" to lose weight then increases the stigma experienced by the patients. We know that physiology, environment, past learning and current functioning all play a part in why losing weight for an individual is so difficult.

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71.1.1.1 Experience of Dieting and Impact on Eating

The majority of people will consider weight loss surgery (WLS) after years of dieting. For National Health Service (NHS) patients in the United Kingdom, National Institute for Health and Care Excellence (NICE) [1] guidelines require that prior to referral "all appropriate nonsurgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months." Typically patients who wish to have WLS may be categorized into two groups with regards to their past dieting experience; those who are successful with weight loss but who are unable to maintain the loss; and those who struggle to lose any weight. While physiological factors significantly influence eating behavior, these two populations also have differing psychological presentations.

Self efficacy is the confidence a person has over his/her ability to make change [2] and this influences a person's beliefs about weight loss in three ways:

The Impact of Dieting

If a person has repeated experiences of "failed" dieting attempts they are likely to have developed internal narratives or beliefs that s/he will "never" succeed. Each of these unsuccessful attempts is self re-enforcing and strengthens the beliefs that the person has. Thus future attempts may become increasingly more difficult.

The Impact of Health Conditions

Health conditions (for example genetic conditions, polycystic ovary syndrome, Cushings disease and chronic pain) may also have an impact on beliefs about weight loss success and will often be cited as the reason weight loss is not possible. These beliefs may exist for a person regardless of whether they are medically 'accurate' or whether they are only part of an explanation for the cause/maintenance of obesity.

The Impact of Ambivalence

There may be complex psychological barriers to weight loss. These may be conscious or unconscious. Examples of barriers include the role of weight as protection, food as a means of managing affect and relationship dynamics; this can lead to considerable ambivalence about change. Whilst people are able to list the positive reasons for health change possible with weight loss, they may be less aware/able to articulate the losses associated with weight loss, for example losing the secondary gains associated with eating behavior and/or weight. Clinicians should recognize that for the patient there may be both positive and challenging aspects to weight loss. Identification of unconscious barriers is yet more complex and may be resisted by the patient. Literature from the Motivational Interviewing perspective would suggest the exploration and resolution of ambivalence to change (either to begin or maintain weight loss) is essential for change to occur [3].

Many studies have found dieting itself causes difficulties with weight management. Ogden suggested that it is the process of self-control and denial which makes particular foods more attractive and consequently there is an increase in preoccupation with eating [4]. This translates to ideas of "being good" and "being bad" with food and the subsequent shame, frustration and hopelessness when diets lapse. Narratives of WLS candidates highlight multiple previous weight loss attempts, reduced self efficacy as a result of believing weight loss is not possible and the impulsive/unconscious preoccupation with food [5]. Self monitoring and conscious intent to change behavior require considerable effort which is 'above and beyond' the effort required to complete a task and therefore psychologically demanding. If overwhelmed these changes are difficult to sustain resulting in a sense of internal conflict, perceived loss of control and shame [6].

When sustained weight loss has not been possible, individuals can feel as if they need to be 'treated,' believing change can only occur as a result of outside intervention, for example by medications or WLS. This is referred to as an external locus of control. As WLS requires an individual to make behavioral changes to improve the outcome, having an external locus of control can interfere with the belief that nothing a person does will make a difference and thus impacts upon engagement with lifestyle change. Believing that WLS will solve a person's obesity can lead to thoughts of it being a 'quick fix' or that it is 'cheating' [7]. The sense of desperation and urgency for change to occur has been found to influence the decision to have WLS over a nonsurgical weight management intervention [8].

71.1.1.2 Eating Disorders

Men and women who are obese have an 11–20 times higher risk of eating disturbances compared to normal weight BMI 18–25 [9]. The prevalence for binge eating disorder (discussed in Chap. 12), for pre WLS candidates is estimated to be between 17 % [10] and 48 % [11]. This may be an over estimate as more recent research using stricter definitions (full DSM-TR criteria) estimated a much lower prevalence of binge eating disorder of 4.2 % with a further 1.4 % who binge at least once a week [12].

Perhaps due to the different criteria used within research for diagnosis, the presence of binge eating prior to surgery results in differing opinion as to its impact post surgery for weight loss. Furthermore, binge eating disorder is associated presurgically with higher levels of mood disorder, anxiety disorder, greater symptoms of depression and lower self esteem and is greater than the levels noted for obese people not seeking WLS [13].

Night-time eating syndrome, characterized by the absence of morning hunger and significant evening hyperphagia, is

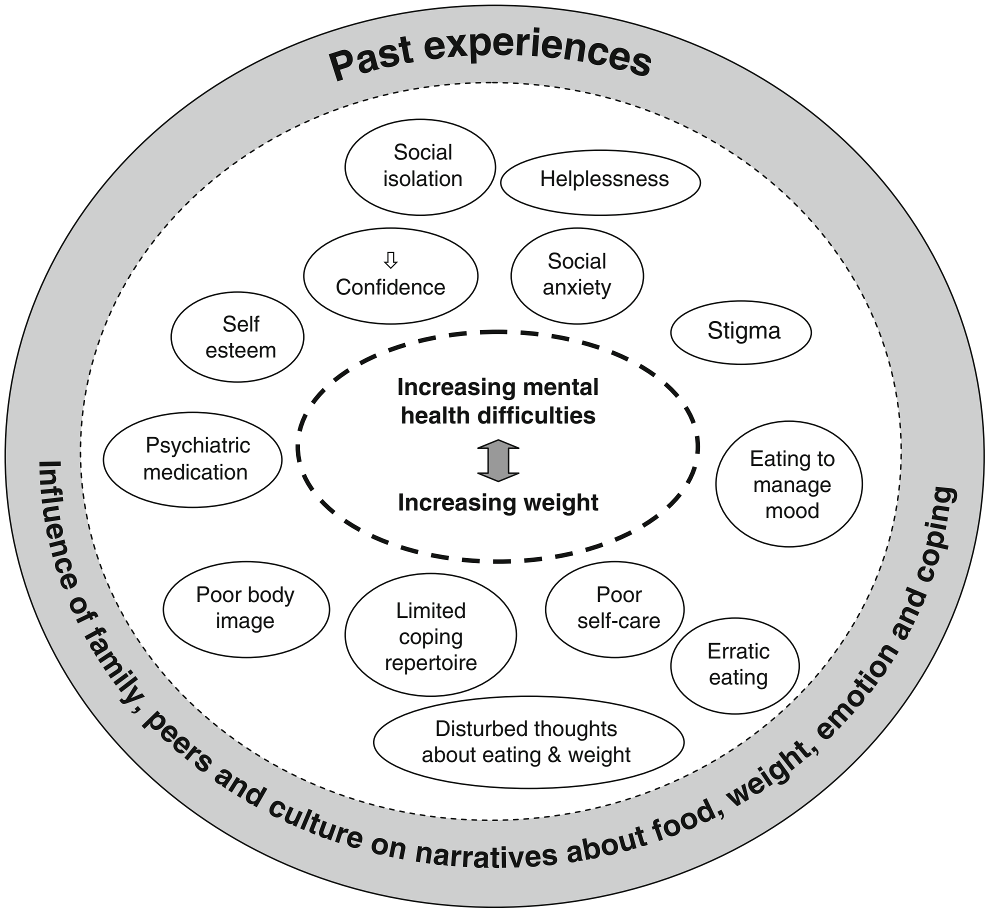

Fig. 71.1 Relationship between obesity and mental health

found in between 1.9 and 8.9 % of WLS candidates, again depending on the definition criteria used [12].

Many more patients binge eat or have binge-fast patterns of eating and whilst not meeting criteria for diagnosis of binge eating disorder or night-time eating syndrome, this pattern of eating makes weight loss extremely difficult.

For patients seeking WLS, a high proportion (66 %) of them have been found to have a lifetime history of an eating disorder [13]. Research which looked at the breakdown between eating disorders preoperatively, found a higher prevalence of lifetime binge eating disorder than bulimia nervosa [14]. There is very little evidence to support the evolution from a restrictive eating disorder to binge eating disorder for obese individuals but this is noted clinically with patients describing themselves as "burnt out anorexics."

71.1.1.3 Mental Health

The relationship between obesity and common mental health disorders is complex and bidirectional. A systematic review of obesity and depression concluded that the risk of developing depression over time for obese people was 55 %, whereas those who were depressed had a 58 % increased risk of becoming obese [15]. There are also recognized links between psychiatric medication and weight gain, particularly with antipsychotic treatments [16].

Links between trauma and weight have noted that both sexual [17] and physical abuse [18] were related to increased BMI in adults. Increased severity [19, 20] and frequency of trauma [21–23] have been linked to increased weight and higher BMIs.

Food can be a powerful means of managing mood in terms of distracting from, soothing or of anesthetizing distressing and/or overwhelming emotions. It has been suggested that food may be used to modulate the neurotransmitters involved in affect control [24]. The continual use of this strategy will lead to a reduction in alternative strategies and an increase in weight. The experience of being overweight, particularly for obese people can lead to weight related stigma and discrimination [25] which in turn can lead to anxiety in social situations, reluctance to participate in activities, poor body image and lowered mood, all factors which may compound the cycle of using food to bolster mood. Figure 71.1 highlights the complexity of the relationship between obesity and mental health, and puts these issues within the context of past, familial and cultural influences. For example, individuals may struggle with erratic eating

Table 71.1 Summary of presurgical issues and opportunities for intervention

Pre-referral (Specialist weight management service)	Preoperative (Bariatric surgery service)
Weight and eating Weight & dieting history Function of weight and eating Individual's beliefs about cause of weight gain/loss Locus of control Self-efficacy, beliefs about capacity to change	Meaning of surgery Motivation for surgery Expectations of outcome
Mental health Recognizing links: weight, eating, mood Stabilization of mental health Management of trauma, substance misuse Deliberate self harm Suicidal ideation	Understanding of: Procedure Behavioral changes required Dietary requirements immediately postoperatively and long term
Eating habits Habitual eating Disturbed eating Current and past eating disorders	Physical health Appropriate assessment of physical health stability
Physical health Recognizing links between weight and health conditions Appropriate management of health conditions	Mental health Appropriate assessment of mental health stability
	Planning Appropriate care planning based on individual need

without it always leading to deterioration in mental health and the reverse is true. It does not suggest causality but instead demonstrates the issues which when considered together can provide a useful formulation of the interplay between an individual's mood and weight.

Further exploration of the complexity of the obesity-mental health dyad can be found in a review by Taylor et al. [24].

There is a difference in mental health functioning between obese people who are seeking WLS and those who are not [26]. Compared to the general population candidates for WLS demonstrate higher rates of personality disorders [26], suicide attempts [27] and past experience of physical, sexual and emotional abuse [28].

71.1.1.4 Working with Issues Before Surgery

Increased insight into the psychological issues which have maintained obesity, particularly the thoughts and beliefs previously sabotaging weight loss attempts will strengthen a person's ability to manage these thoughts should they reemerge after surgery. Thus, using a weight loss target for referral to surgery can provide a therapeutically useful focus during which time a multidisciplinary exploration of barriers to change can occur. There is emerging evidence that weight loss prior to surgery can also improve weight loss at a one year follow up [29].

In advance of WLS the stability of clinical presentation is an important consideration; it is unrealistic to believe the issues causing and maintaining obesity could be completely resolved presurgery, but if unstable they may indicate the need for further intervention. Understanding patients' perception of obesity, eating behavior and willingness to engage in treatment may be an integral element to improving surgical outcome [30].

Table 71.1 summarizes the range of issues to consider in advance of a surgical referral (as not all patients will want or will be suitable for WLS) and when the referral has to be made.

71.1.2 Issues Following Weight Loss Surgery

It is widely recognized that WLS leads to substantial weight loss and major secondary health benefits [31]. While most studies report psychosocial improvements after WLS, some patients have difficulties adapting to the various psychosocial consequences [32]. Adjustment difficulties post operatively can coexist with success in terms of weight loss but if the focus of the service is only on weight loss, these may be missed. For many, difficulties can be transient but without awareness of the potential for management and improvement they can be distressing and anxiety provoking.

71.1.2.1 Eating Behaviors

Patients appropriately supported by a bariatric service pre WLS will have an expectation that their eating behavior will need to be substantially different after surgery. This starts with the eating regime recommended immediately post operatively and depending on the type of surgery may extend for the first six weeks. For the majority of patients this adjustment in eating behavior continues for much longer.

The effects of surgery may enforce dietary self regulation. Vomiting may occur if too much is swallowed or eaten too quickly with the gastric band. The 'dumping syndrome' is often reported if high sugar/fat food is eaten after the gastric bypass. These symptoms continually act as reminders that eating behavior needs to be different. For many people the symptoms are an aversive deterrent and eating behavior settles over time. There is often enjoyment with the opportunity to relearn how their body responds to food. The term 'paradox of control' has been used to describe the increased sense of being in control of eating, typically associated with the reduction in hunger cues after surgery and a decrease in preoccupation with food and eating [33].

Recent research has highlighted the impact of the different surgical procedures on activation of regions of the brain associated with reward systems, noting gastric bypass patients had lower reward system activation in response to food, found high fat food less palatable, rated high-calorie foods as less appealing and had healthier eating behavior than gastric band patients [34]. This is a further demonstration of the relationship between physiology and habit; the above changes in eating behavior are likely to impact on self efficacy and increase confidence in being able to manage weight.

71.1.2.2 Emotional Eating

If the use of food to manage mood has been a primary coping strategy for an individual, it is unsurprising that during periods of increased stress or emotional upset there will be a return to old behaviors, albeit post weight loss surgery this may manifest differently. Graze eating is suggested to be one such way emotional eating can change [35]. Where there is high emotional eating post WLS suboptimal weight loss is noted [36].

There is evidence that cravings will change after WLS, however, in one study 34 % of post-surgery patients who described themselves as 'emotional eaters' had cravings for particular food as early as six weeks postoperatively [37].

Post surgery, when physical hunger cues are less intense there is further opportunity to develop alternative coping strategies building on work which can usefully start pre surgery.

71.1.2.3 Weight Management: Loss and Regain

Poor weight loss and weight regain has been noted for some patients [38]. Weight regain can occur for a variety of physiological factors, discussed elsewhere in this book, but also likely to influence weight regain is a return to preoperative eating and lifestyle behaviors [39] and maladaptive eating behaviors [40].

A very useful systematic review of weight regain [41] highlighted the variability in how weight regain is assessed and the impact this has on reported outcome. It also summarizes five principle etiologies of weight regain:

- Nutritional indiscretion
- Mental health issues (including eating disturbance/disorder)
- Endocrine/metabolic alterations
- Physical inactivity
- Anatomic surgical failure

Monitoring psychosocial functioning during routine multidisciplinary follow up within the surgical team may help to ameliorate weight regain after surgery particularly if self efficacy is also considered in addition to mood [42]. Separating self efficacy as a single issue has conflicting evidence post operatively with some studies showing an improvement in weight loss [42] while in others no difference was noted [43]. The frequency of support from bariatric surgery teams is linked to outcome. Patients who had no follow up visits were 4.6 times more likely to regain weight than those who attended four to five follow up clinic visits per year [44].

Mental health presentation has been found to influence weight postoperatively. In one study, self reported low wellbeing was linked to patients being 21.5 times more likely to experience significant weight gain, compared to those reporting good wellbeing [44]. Those with two or more psychiatric conditions were approximately six times more likely to regain weight [45].

There seems to be a relationship between social support and weight loss after surgery but as yet literature does not reveal a consistent picture [46]. In the early stages postoperatively, people who feel ashamed about their decision to have WLS, and who have not told others about their surgery will reduce their access to social support. Difficulties can also occur if the patient is 'hiding' WLS and trying to been seen to eat 'normally.'

A systematic review found that behavioral management for lifestyle changes and support post WLS led to significantly greater weight loss than for patients who received usual care or no treatment [47] but as yet there are no standardized guidelines for treatment as to how frequent, with what focus or delivered by which professionals.

71.1.2.4 Psychosocial Functioning

There is an improvement in psychosocial functioning, particularly within the first two postoperative years when the majority of weight is lost [48]. Suggestions that psychosocial improvements are noted immediately after surgery, even before weight loss has occurred, highlights the benefits of hope, optimism and a patient taking an active role in changing their life [48].

However, there are patients for whom the psychosocial improvements do not reach the levels of a non-obese reference population [49] and for whom improvements diminish over time [50]. When weight stabilizes or increases, quality of life may diminish [30]. Up to 40 % of patients do not improve psychologically following WLS [51] which may reflect the diversity of the population and the multiple causes of psychosocial difficulty. Strong interpersonal feelings of anger, embarrassment, uncharacteristic assertiveness and at times euphoria are all experiences described postoperatively [52].

Depression can continue to be a problem for people postoperatively and this can be linked to differences in the way people manage the intense changes in lifestyle especially eating behavior and body image [53].

There is a growing literature which suggests an increased risk of suicide post WLS. The most recent systematic review estimates prevalence at 4.1 per 10,000 person-years post WLS which is higher than the general population [54]. There would appear to be a range of factors which contribute to increased risk of suicide, a detailed review of the literature is provided by Mitchell et al. [55] and highlights the following:

- Persistence or recurrence of medical comorbidities following WLS
- Increased sensitivity to alcohol following absorption changes postoperatively
- Hypoglycemia and impact on social functioning
- Psychosocial, weight and eating factors
- Weight and eating outcomes
- Health related quality of life
- Physical activity and mobility
- Sexual functioning and problems within relationships
- Low self esteem
- Depression
- Pre-morbid vulnerability factors such as early trauma/maltreatment

71.1.2.5 Impact on Relationships

Actual or prospective weight loss can have significant effects on relationships. Within intimate relationships the role weight has played to attract or distance the partner or avoid intimacy can act as a barrier to weight loss. The impact after surgery can often be very unsettling. Equally, people can feel threatened and insecure about their partners' dramatic weight loss. A useful overview of these issues has been written by Applegate and Friedman [56]. Rather than surgery causing the destabilization of relationships, results from large scale research indicate that relationships already fragile can become even more strained because of the changes associated with WLS [57].

Magdeleno noted that women who face fear, jealousy and envy, as weight and social circumstances change, can present with significant emotional challenges post WLS [58]. Other people criticizing the decision to have WLS, the change in dynamics when the patient is no longer the 'bigger friend' and others insecurity with the patient's new body shape are some of the experiences people describe post WLS and can result in losing friendships [7]. Comments from others may be complimentary but they can still feel intrusive, judgmental or sexually charged [58].

71.1.2.6 Eating Disorders

The presence of eating disorders following WLS was for a long while disputed but more recently there has been a greater understanding of the difference in presentation pre and post WLS.

However, the distinction between expected eating behavior postoperatively and an eating disorder is at times unclear and in fact the symptoms after WLS can lead to compensatory or restrictive behaviors often associated with eating disorders [59]. An example of this is 60 % of post operative patients report vomiting regularly, 12 % of whom have a clear goal of influencing weight and shape [59] but this intent behind vomiting may not be routinely discussed and instead is assumed to be linked to the way food is eaten postoperatively.

Binge Eating

Estimating the prevalence of postoperative binge eating is difficult because of the variation in criteria used for assessment. WLS has a positive impact in reducing binge eating regardless of binge severity [43]. However, the decrease in symptoms noted in the early stages postoperatively, do not persist; 46 % reporting binge eating at a 24 month follow up [60]. Meeting the diagnostic criteria for binge eating disorder is rarely achieved because of the difficulty in eating the quantity of food required for formal diagnosis. However, perceived loss of control is considered the most useful criteria to identify postoperative binge eating and has been found to predict less weight loss at 12 months [61].

Post Operative Eating Avoidance

The presence of anorexia post WLS is a much rarer occurrence mainly because diagnosis requires a BMI within the underweight range. However significant anxiety about eating can occur. Post surgical eating avoidance (PSEA) was termed by Segal and colleagues [62] and is characterized by: fear of appetite; fear of weight regain; fear of physical reaction and typically involves the obsessive monitoring of food and preoccupation with achieving a 'healthy BMI.' The question of whether this is an eating or anxiety disorder remains unclear. It is most frequently observed after gut altering procedures rather than the gastric band. It is also inadvertently reinforced by the intense focus on weight reduction and regular weighing associated with follow up support [63].

71.1.2.7 Perception of Self

WLS has a powerful effect on self-image [64]. If perception of self is very much bound to weight and physical appearance, with significant weight change the sense of identity is questioned resulting in feelings of uncertainty and anxiety [7]. Patients describe not knowing who they are for a while after surgery and report others comment that their 'personality has changed.' It would appear that the change in perception of self is connected to the postoperative journey: success, complications and adjustment.

71.1.2.8 Body Image and Excess Skin

Patients who have repeated experiences of significant weight loss know what it is like to inhabit a smaller body but for many weight regain, pre surgery, was also very rapid and so there was little time to adjust to a different body size. After WLS some patients take significantly longer to emotionally accept the difference in their body size despite recognizing objective measures of change such as weight and clothing size.

Excess skin post WLS is an issue which impacts to some degree on approximately 70 % of patients [65] usually on their stomach, arms, breasts and thighs and is associated with dramatic weight loss [66]. It can have an impact on personal hygiene and ability to exercise; most difficulties are associated with abdominal excess skin [67]. People can lack confidence about their body and can feel very differently about themselves clothed versus naked, as often support clothes are used to disguise excess skin. Intimate relationships can be distressing either in terms of changing physical intimacy within existing relationships or increasing anxiety about the possibility of developing new ones; patients describe not knowing at what point to 'disclose' their WLS prior to a new partner seeing them naked.

People respond differently to excess skin and responses can change over time. For some there is significant shame, disappointment and humiliation [68] and descriptions of feeling as if they "no longer fit" their body. For others it is an expected cost of surgery which is outweighed by the benefits.

71.1.2.9 Substance Misuse

A significant increase in the use of alcohol particularly following gut altering procedures, for example gastric bypass, has been noted compared with the gastric band [69, 70]. However, no associations have yet been found between preoperative depressive symptoms, binge eating, mental health or past year treatment for psychiatric or emotional problems [69]. King highlighted factors predictive of alcohol use disorder post WLS: being a younger male smoking, regular alcohol use preoperatively, recreational drug use and a lower sense of interpersonal support [70].

There is very little research which explains the psychological function of substance misuse post WLS. However, switching to an alternative substance when food can no longer be used to manage affect may explain the increased use of alcohol. The increased sensitivity to alcohol noted post operatively may also influence the problematic use of alcohol [71].

71.1.2.10 Working with Issues after Surgery

The majority of difficulties experienced after WLS are a result of adjustment to the changes in eating, body shape, identity, coping and relationships rather than diagnosable mental health disorders and therefore patients will not always be able to access psychological support from mental health services. Many of these adjustment issues are transitional but early access to support and greater understanding of the lived experience for patients after surgery is likely to prevent difficulties becoming more severe and enduring. It is also essential to acknowledge usual life stressors and events continue and therefore the trigger for difficulties may be unrelated to WLS but have an impact on the outcomes monitored by bariatric services.

There is evidence to suggest that psychological services designed to support postoperative adjustment may have the effect of optimizing weight loss [46] and indeed the combination of WLS and psychological support result in better postoperative weight loss than WLS alone [72].

Within United Kingdom bariatric services there is considerable variability in the support offered postoperatively. Many services are commissioned to provide support for only two years following the surgery and access to psychological support is limited [73]. Psychological support post surgery within the UK is mainly provided on an ad-hoc basis rather than through systematic planning [74]. (The Division of Clinical Psychology within the British Psychological Society is currently writing guidance to highlight psychological interventions for weight management including WLS and will provide a detailed summary of the intervention literature both pre and post surgery. This document in combination with greater understanding of the range of difficulties experienced may encourage more considered planning of services based on patient volume and psychological need.)

Table 71.2 contains a summary of issues discussed within this section, separating out issues noted in the early stages postoperatively with those occurring in the longer term.

Conclusion

A person's journey of reaching the decision for WLS is very individual. A combination of factors leading to and maintaining obesity, experiences of being obese and previous weight loss attempts will all influence the decision. Adjustment after WLS is significant and complex as change occurs on so many different levels some of which are directly a result of weight loss and some a ripple effect. For the majority WLS is a positive experience with favorable outcomes both physically and psychologically. However there is potential for significant disturbance in a significant minority. An improvement therefore in patients' and health professionals'

Table 71.2 Summary of issues and opportunities for intervention after surgery

Up to two years postoperatively (Bariatric surgery service)	After two years postoperatively (No formal Bariatric Surgery provision, instead Primary Care and/ or Specialist Weight Management service)
Surgical after care Regularity and engagement with follow up Appropriate monitoring to highlight difficulty (surgical, medical, nutritional, behavioral, emotional)	Self care Maintenance with nutritional supplementation Ability to manage lifestyle change
Transition Fluctuations in mood and mental health Reflections on decision for surgery Adjustment to dietary change Fear of failure Fear of appetite	Weight change Increase in appetite and portion capacity Eating disturbance and disorder Self-efficacy regarding ability to manage weight in the long term
Appetite Management of limited appetite Emotional or habit hunger versus physical hunger Management of cravings	Coping strategies Substitution—alcohol, substance misuse Reliance on eating to manage mood Eating disturbance and disorder Impact of life events
Impact of weight loss on: Confidence Self-worth Self-identity Body image Intimate relationships Family, friends, colleagues, strangers Functional status Physical and mental health status Occupation	Changes to: Health conditions Mental health Fitness and physical activity Occupation Relationship status Social networks
Coping strategies Substitution—alcohol, substance misuse Reliance on eating to manage mood Eating disturbance and disorder Impact of life events	Body image Adjustment to body size and shape Excess skin

understanding of issues pre surgically and experiences postoperatively is likely to support the management of change throughout. This area of work requires that we hold a holistic perspective which includes medical, surgical, psychological, social and environmental or a 'biopsychosocial' position. Failing to do so would prevent us from viewing the outcomes of WLS within the context of a person's life, and thus taking an overly narrow focus may miss some of the significant adjustment challenges for the patient.

We also have to develop understanding of when further intervention is required and ensure that adequate service provision is systematically planned. Qualitative research is helping us to consider the lived experience for patients post WLS, which highlights clinical themes, areas to target intervention and will over time help to shape the way we conduct research.

Key Learning Points

- Obese population is heterogeneous and so patients and professionals need to understand the cause and maintenance of obesity as well as understand the blocks to behavioral change as these may be important factors impacting upon outcome following WLS.
- The belief a person has in his/her ability to make change (self efficacy) will impact the outcome.
- Bariatric surgery has significant psychological impact which can be both positive as well as challenging for patients.
- There are many issues which emerge post WLS some of which are transitional adjusting to dramatic change.
- There are multiple issues which may require support and/or intervention and so coordinated services providing long term support are essential.

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Health-Related Quality of Life Before and After Bariatric Surgery

72

Jane Ogden and Amelia Hollywood

Abstract

Over recent years it has become increasingly clear that health related quality of life (HRQoL) is an important outcome for assessing the effectiveness of bariatric surgery. HRQoL can be measured using uni dimensional tools to assess factors such as mobility, mood, self esteem or eating behavior or multidimensional tools which assess health status in the broadest sense. This chapter will present these different measurement tools and describe their use across a range of studies in the context of bariatric surgery. It will then evaluate the pros and cons of each tool and consider the issues relevant for identifying the best tool for any given situation. Finally, the chapter will conclude that there is no one measure of HRQoL that meets all research or clinical needs for bariatric surgery and that the choice of measure should take into account the definition of HRQoL being used, the function of the measure being used and the practicalities of the data collection process.

Keywords

Health related quality of life • Bariatric surgery • Health status • Outcomes • Assessment tools

72.1 Introduction

To date, all trials exploring the effectiveness of bariatric surgery use weight loss as the primary outcome variable and clinics generally assess the impact of each individual operation for each patient in terms of weight change from before to after [1]. Over the past few years, however, it has become increasingly clear that weight change alone is not a sufficient index of whether or not surgery has been a success and both researchers and clinicians have turned their attention to Health Related Quality of life (HRQoL) [2]. This chapter will explore what HRQoL is, how it can be measured and the ways in which it has been measured in the context of bariatric surgery. It will provide an evaluation of the different tools available in terms of what they do and do not include and then offer some recommendations of appropriate tools for use in either the clinic or as part of research studies.

72.2 What is HRQol?

Quality of life has been defined in a multitude of ways. For example, the World Health Organization used the following definition: 'a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships and their relationship to the salient features in their environment' [3]. In contrast, the Rand Corporation health batteries operationalized quality of life in terms of 'physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, energy/vitality, pain and general health perception' [4]. In addition, while some researchers treat the concepts of quality of life, health status, health related quality of life or subjective health status as inter- changeable, others argue that they are

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separate. For the purpose of this chapter the term HRQoL will be used. Measures will be assessed that are of relevance to bariatric patients.

72.3 How Can HRQoL Be Measured?

The different terms and definitions cited above are reflected in the many different ways in which HRQoL has been measured. In general, however, HRQoL can be considered as the individual's own assessment of their health status and the multitude of different available measures can be defined as either unidimensional or multi dimensional. These can either be used for specific patient groups or patients regardless of their condition.

72.3.1 Unidimensional Measures

Some measures of HRQoL focus on one particular aspect of health such as level of functioning, mood, pain, self esteem, life satisfaction or eating behavior. From this perspective they can be considered to be unidimensional.

72.3.1.1 Level of Functioning

Measures of functioning ask the question, 'To what extent can you do the following tasks?' and are generally called activity-of-daily-living scales (ADLs). Some measures have been designed to be completed by an observer. For example, Katz et al. [5] designed the index of activities of daily living for caregivers to assess levels of functioning in the elderly and covers key activities such as bathing, dressing, continence and feeding. Other ADLs are self report measures and have been developed for individuals themselves to complete and include questions such as, 'Do you or would you have any difficulty: washing down/cutting toenails/running to catch a bus/going up/down stairs?'

72.3.1.2 Mood

There are several measures of mood or emotional state or trait. Goldberg [6] developed the general health questionnaire (GHQ), which assesses mood by asking questions such as 'Have you recently: been able to concentrate on whatever you're doing/spent much time chatting to people/been feeling happy or depressed?' The GHQ is available as long forms, consisting of 30, 28 or 20 items, and a short form, which consists of 12 items. While the short form is mainly used to explore mood in general and provides results as to an individual's relative mood (i.e. is the person better or worse than usual?), the longer forms have been used to detect 'caseness'. Other mood measures include the Hospital Anxiety and Depression Scale (HADS) [7], the Beck Depression Inventory 11 (BDI-11) [8] and the Mood Adjective Check list (MACL) [9].

72.3.1.3 Pain

A commonly used measure of pain is the McGill pain questionnaire (MPQ) which assesses pain levels [10] and involves patients rating their pain in terms of its three dimensions: sensory (for example, 'flickering', pulsing); affective (for example, punishing, cruel) and evaluative (for example. annoying, miserable).

72.3.1.4 Self-esteem

There are several measures of self-esteem that measure general esteem such as the Rosenberg self-esteem scale [11] or are specific to body esteem such as the Body Shape Questionnaire [12] and the Body Discrepancy Scale [13].

72.3.1.5 Life Satisfaction

There is also a very brief scale which measures the patient's general satisfaction with life [14].

72.3.1.6 Eating Behavior

Researchers also use a number of different measures to assess aspects of eating behavior which is of particular relevance to research in bariatric surgery. For example, the Three Factor Eating Questionnaire (TFEQ, [15]) assesses restrained eating, disinhibition and hunger; the Dutch Eating Behaviour Questionnaire (DEBQ, [16]) assesses emotional eating, external eating and restrained eating and the emotional eating scale (EES) just focuses on emotional eating [17]. Furthermore, the Questionnaire on Eating and Weight Patterns (QEWP, [18]) and the Binge Scale [19] measure binge eating.

72.3.2 Multidimensional Measures

Other measures are multidimensional in that they take a more global approach to health status and assess health status in the broadest sense. Some of these are single item scales, some are composite scales and some are individual quality of life scales.

72.3.2.1 Single Item Scales

Measuring quality of life does not have to be a long and complicated process and some scales use a single item such as, 'Would you say your health is: excellent / good / fair / poor?,' 'Rate your current state of health' on a scale ranging from 'poor' to 'perfect' or from 'best possible' to 'worst possible' [20]. Further, researchers have also developed single item self report measures of fitness which ask 'would you say that for someone your own age your fitness is . . . ' with the response options being very good/good/moderate/poor/very poor [21]. These scales have been shown to correlate highly with other more complex measures and to be useful as an outcome measure. They have also been shown to be good predictors of mortality at 16.5 years follow up [21].

72.3.2.2 Composite Scales

Researchers have tended to use mainly composite scales. Because of the many ways of defining quality of life, many different measures have been developed. Some focus on particular populations, such as the elderly or children while others focus on specific illnesses, such as diabetes or HIV. Generic measures of quality of life have also been developed, which can be applied to all individuals. The most commonly used ones are: the Nottingham Health Profile (NHP) [22], the short form 36 (SF36) [23] the Sickness Impact Profile (SIP) [24] and the WHOQoL-100 [25].

The items in composite scales are chosen by the researcher and may not reflect the patient's own priorities. Researchers have, therefore, developed individual quality-of-life measures, which not only ask the subjects to rate their own health status but also to define the dimensions along which it should be rated. One such measure, the schedule for evaluating individual quality of life (SEIQoL) [26], asks subjects to select five areas of their lives that are important to them, to weigh them in terms of their importance and then to rate how satisfied they currently are with each dimension.

Quality of life can therefore be defined in a number of different ways. It can also be measured using unidimensional scales which address individual domains or multidimensional scales which take a broader perspective. So how has it been measured in the context of bariatric surgery?

72.4 Measuring HRQoL in the Context of Bariatric Surgery

Research exploring the impact of bariatric surgery on quality of life has used a range of unidimensional and multidimensional scales which include both generic, obesity specific and bariatric specific approaches. A summary of the scales commonly used together with an outline of their pros and cons can be found in Tables 72.1 and 72.2.

As can be seen from Table 72.1, a number of measures have been used in bariatric research to assess individual domains of quality of life such as mood (for example, MACL, HADS), eating behavior (for example, DEBQ and TFEQ), binge eating (for example. Binge Scale and EES) and self esteem (for example, RSE). Similarly, from Table 72.2, it can be seen that research has also used multidimensional measures which are either generic such as the SF-36 or the NHP, obesity specific such as the Obesity Psychosocial State Questionnaire OPSQ or specific to bariatric patients such as the QoL of The Bariatric Analysis and Reporting Outcome System BAROS or the Bariatric Quality of Life Index BQL. Different measures have different pros and cons as they vary in terms of their focus, what they include or omit, their length, how simple they are to complete, whether they can be easily completed by all participants or whether they may be too 'pathology' focused for some patients. Further, some measures have been more widely used than others enabling comparisons between studies to be made either across obese patients or between obese patients and those with other chronic conditions. However, research exploring the impact of bariatric surgery has most often used composite structured questionnaires with the items developed by researchers rather than individual measures of quality of life whereby the patients define their own domains. Further, studies have tended to use multi-item scales rather than the simple single item measures of health status or fitness. In addition, few to date have focused on body dissatisfaction and several do not include measures of eating behavior or binge eating.

72.5 Some Recommendations for Practice and Research

Quality of life has therefore been defined in different ways and can be measured using a range of unidimensional or multidimensional measures. To answer the question 'which measure shall I use'? with a straightforward answer would be to miss the complexity of the concept and the fact that one size certainly does not fit all. Therefore, for the purpose of this chapter, we will take a highly pragmatic approach and suggest that a measure of quality of life should be chosen in terms of the following criteria and should fit (i) the definition of QoL being used; (ii) the function of the measure and (iii) the practicalities of the data collection process.

(i) The definition of QoL: If QoL is being defined in a broad generic sense to include physical, emotional and social functioning then a generic measure such as the SF-36 or NHP would be appropriate. But, if the focus is on outcomes specific to bariatric surgery then it would be better to use an obesity specific measure such as the OPSQ or a bariatric specific measure such as the BQL. Alternatively, it would also be feasible to use a generic measure and add in extra unidimensional measures of factors such as eating behavior, binge eating or body dissatisfaction. Further, if the focus of the research is more on emotional function then well validated measures of mood such as the GHQ could be included or if the focus is on functioning then an ADL could be added. Therefore the first step is to define QoL in line with the focus of the clinic or research and choose the measure or set of measures that best operationalizes the desired aspect of QoL.

(ii) The purpose of the measure: Researchers and clinicians use measures for different reasons. Some need to know the outcome of a large randomized trial and need data that will stand up to scientific scrutiny. Some may also

Table 72.1 Unidimensional measures

Name	No. of items/examples of use	Domains	Pros/Cons
Mood adjective check list (MACL) [9]	38 items/[2]	3 major bipolar dimensions of mood: (i) pleasantness; (ii) activation; (iii) calmness.	Pros: Specific to mood, simple Cons: Unusual aspects of mood covered
Hospital anxiety and depression scale (HADS) [7]	14 items/[2]	(i) anxiety; (ii) depression	Pros: Specific to mood; designed not to use physical items (for example shaking) to avoid confounding mood and health Cons: Items are complex to read; linguistic idioms; validity?
Beck Depression Inventory (BDI) [8]	21 items/[27–29]	The presence and severity of depressive symptomatology.	Pros: Frequently used Cons: Some items are highly sensitive; superseded by BDI-II
Sickness Impact profile (SIP/SI) [24]	20 items/[2]	Quality and quantity of social interaction within the family, among friends and in the community.	Pros: Captures impact of illness Cons: Narrow definition of impact
Three Factor Eating Questionnaire (TFEQ) [15]	51 items/[27, 28]	(i) Dietary restraint; (ii) disinhibition of dietary control; (iii) perceived hunger.	Pros: Commonly used in eating research Cons: Time consuming to complete
Binge Scale Questionnaire [19]	9 items/[30, 31]	Frequency, intensity, and accompanying feelings and perceptions of binge eating episodes.	Pros: Simple to complete Cons: Uncomfortable to complete for non bingers
Emotional Eating Scale (EES) [17]	25 items/[27]	The extent to which subjects eat in response to: (i) anger; (ii) anxiety; (iii) depression	Pros: Can be completed by everyone. Cons: Does not measure amount eaten; much EE is outside awareness so people can't report it (completing the questionnaire implies in itself a degree of emotional awareness)
Dutch Eating Behavior Questionnaire (DEBQ) [16]	33 items/[32]	(i) Emotional eating; (ii) external eating; (iii) restrained eating.	Pros: Easy to complete, can be completed by everyone Cons: Does not measure amount eaten
Questionnaire on Eating and Weight Patterns-Revised (QEWP-R) [18]	28 item/[27, 33, 34]	Components, duration, and frequency requirements for the proposed DSM IV Binge Eating Disorder diagnosis.	Pros: Specific to BED Cons: Some items are sensitive
Rosenberg Self-Esteem Scale (RSE) [11]	10 items/[27]	Measures overall self-esteem.	Pros: Simple to complete, can be completed by everyone Cons: Not specific to body esteem

want data that will enable comparisons to be made with other studies on either similar or different patients. In contrast, some might just want to know whether their own patients are feeling better after their operations. The measure chosen therefore needs to fit its purpose. If the measure is for a large scale randomized controlled trial then use those most frequently applied such as the QoL component of the BAROS or the BQL. But these measures have only been used in bariatric surgery. Further, they are relatively new. Therefore if comparisons are needed with other studies and/or other patient groups then use generic measures such as the SF-36 or the NHP and if necessary, add in unidimensional measures to capture the specific changes found in bariatric patients such as body dissatisfaction or binge eating. If, however, the measure is just to audit how patients in a clinic feel after their surgery, then simple single item measures of health status would suffice.

(iii) The practicalities of the data collection process: The final factor to consider is the practicalities of the data collection process. Some measures are very time consuming and can lead to high levels of non responders, particularly if they are sent by post. In addition, some measures contain quite sensitive items which may alienate patients again leading to non completion and the questionnaire ending up in the bin. The measure therefore needs to be chosen bearing in mind factors such as location, timing, patient energy, patient commitment and

Table 72.2 Multidimensional measures

Name	No. of items/examples of use	Domains	Pros/Cons
Generic measures			
SF-36 Health Survey (SF-36) [23]	36-item/[27, 29, 35]	(i) physical functioning; (ii) role-physical; (iii) bodily pain; (iv) general health; (v) vitality; (vi) social functioning; (vii) role-emotional; (viii) mental health.	Pros: Good for general QoL, simple Cons: No measure of eating behavior, body satisfaction, sexual activity, symptoms specific to surgery
Nottingham Health Profile Part I (NHP-I) and part II (NHP-II) [22]	Part I: 38 items Part II: 7 items [36]	Part I: (i) physical mobility; (ii) pain; (iii) energy; (iv) sleep; (v) social isolation; (vi) emotional reaction. Part II: (i) paid employment; (ii) jobs around the house; (iii) social life; (iv) personal relationships; (v) sex life; (vi) hobbies and interests; (vii) holidays.	Pros: Broad measure of QoL Cons: No measure of eating behavior, body satisfaction,
Obesity specific measures			
Obesity Psycho-social State Questionnaire (OPSQ) [37]	43 items/[38]	(1) physical functioning, (2) mental well-being, (3) physical appearance, (4) social acceptance, (5) self-efficacy toward eating and weight control and (6) intimacy, (7) social network.	Pros: Tailored for the obese, includes body satisfaction and eating control Cons: Does not assess amount eaten
Obesity-related problems scale (OP; SOS) [39]	8 items/[2]	How bothered they are by their obesity in a broad range of social activities.	Pros: Brief and quick to complete Cons: Only addresses social interactions; limited scope.
Bariatric specific measures			
The Bariatric Analysis and Reporting Outcome System (QoL Part of BAROS) [40, 41]	5 items/[35, 42, 43]	(1) self-esteem, (2) physical activity, (3) social life, (4) work conditions, (5) sexual activity.	Pros: Quick and simple to complete Cons: Does not measure physical symptoms, eating behavior
Gastrointestinal Quality of Life Index (GIQLI) [44]	36 items/[45]	(i) gastrointestinal symptoms; (ii) emotional situation; (iii) physical status; (iv) social performance	Pros: Broad measure of QoL, some obesity specific items Cons: Not specific to bariatric patients
Bariatric Quality of Life Index (BQL) [43]	19 items/[45]	(i) psychological well-being; (ii) social functioning; (iii) physical functioning; (iv) problems and symptoms related to obesity surgery and obesity-related co-morbidity.	Pros: Quick and simple to complete, specific to bariatric patients Cons: No validated section on eating behavior

the number of other measures they are also being asked to complete. Thus, if the patient is tired and ready to leave the clinic, then use a brief single item measure or a shorter scale such as the 5 items from the BAROS. But if they have more time, use a composite scale but always monitor response rates whatever scale you use.

Conclusion

It is increasingly clear that weight is not the only outcome of bariatric surgery and that attention should be paid to quality of life and the ways in which surgery influences the patient's life across a number of different domains. There are numerous unidimensional and multidimensional measures available which vary in their focus and complexity. This chapter has offered a summary of the ways in which quality of life can be defined and measured and offered a pragmatic answer to the question 'which measure shall we use?'

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Section XIV

Special Topics

Honorary Section Editor - Vinod S. Menon

It gives me great pleasure to provide an overview on this well written and enlightening section of *Special Topics*; these chapters deliver a fascinating insight to professionals of all disciplines interested in the management of the morbidly obese patient. The simple diagrams and photographs add to the value of each chapter.

Even though bariatric surgery is undertaken in a few selected centers, patients present as emergency admissions to all hospitals and A&E units. Different specialties and professionals will find the chapter on management of bariatric emergencies very helpful; it provides a systematic and concise approach to detection, investigation, and initial management of potential complications of different bariatric operations, placing great emphasis on establishing timely contact with specialist units. Sharing of agreed management protocols following surgery among the wider professional groups has been adequately emphazised

Multi-disciplinary care is key to successful outcomes in bariatric surgery; the chapter on the role of radiology and the specialist radiologist makes very easy reading. Interpretation of normal and abnormal anatomy and the relevance of different tests (including their application in complex situations) are well described. Simple and easy-to-understand radiological images are well presented.

Obesity and particularly bariatric surgery in adolescents is a very emotive and sensitive issue. The authors have articulated the varied effects on different body systems while making a clear case for surgery in the right patient based on clear guidelines. They also stress the importance of thorough medical examination, multi-disciplinary discussion, effects of different types of surgery, long term follow up after surgery, and monitoring nutritional parameters. This chapter will be particularly relevant to pediatric specialists and the endocrinologist with an interest in childhood obesity.

The success of bariatric surgery, including the positive physical and psychological impact, is now well established. People embark on a new life and body contouring surgery has become more relevant and widely available. This chapter provides fantastic literature review and clearly articulates the wide choice of procedures available. Also included are discussion of complications and funding streams.

The natural history of non-alcoholic liver disease, role of liver biopsy in bariatric surgery, and the impact of bariatric surgery on liver histology and function is clearly described in the chapter that follows. This is very enlightening reading, not only for the surgeon but for all of us interested in the concept of metabolic syndrome and the positive impact of surgery on reversing many of these changes. The authors make an important point about the relative paucity of appreciating liver problems prior to surgery which could have an impact on postoperative outcomes.

The final chapter on the role of primary care nicely puts into context the role of general practitioners in supporting bariatric surgery including referral, education, supporting perioperative care, and—most importantly—ensuring optimal long term nutritional follow-up. Integrated care in the community including diet, exercise, drugs, and education is well described. The close relationship with specialist units in terms of sharing protocols and timely communication is also emphasized.

Management of Bariatric Emergencies by the General Surgeon

73

Christopher Peters, Gianluca Bonanomi, and Evangelos Efthimiou

Abstract

The epidemic of obesity affects almost all countries of the developed world and has led to a dramatic increase in the number of bariatric procedures worldwide. In the United Kingdom (UK), the adoption of weight loss surgery has been via dedicated regional bariatric centres, and there is a drive for shorter stays in hospital after surgery. Both these factors make it inevitable that almost every doctor sooner or later will encounter a patient who has undergone bariatric surgery, even if they do not work in a bariatric centre. Although safe, bariatric surgery has potential complications, which if recognised early and treated promptly can minimise the negative impact on outcomes.

It is important that the non-bariatric general surgeon has at least a working knowledge of bariatric procedures and the complications that can arise so that they are vigilant for them and understand the necessity for early intervention. The basic principles of management must always include early discussion with a bariatric centre and transfer if possible. Bariatric patients often have high anaesthetic risks and low reserves; therefore, deterioration can be rapid and interventions fraught with difficulties.

This chapter aims to assist doctors and health care professionals who wish to increase their awareness and confidence in dealing with bariatric emergencies. It also provides them with some advice on what to do when faced with such a patient. It will cover the important complications for the major bariatric procedures namely, gastric band, gastric bypass, sleeve gastrectomy and intra gastric balloon.

Keywords

General surgeon • Gastric band emergencies • Intra-gastric balloon emergencies • Gastric bypass emergencies • Sleeve gastrectomy emergencies • Leak • Obstruction • Dilatation • Bleeding

73.1 Introduction

The epidemic of obesity affects almost all countries of the developed world and has led to a dramatic increase in the number of bariatric procedures worldwide. In the United Kingdom (UK), the adoption of weight loss surgery has been via dedicated bariatric centres, which means that many patients have to travel to regional bariatric units for surgery. With the current drive for day case surgeries, average hospital stay for a gastric band patient is one night. Most of the laparoscopic gastric bypass and sleeve gastrectomy patients spend only two nights in hospital. Although safe, bariatric

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surgery has potential complications which if recognised early and treated promptly can minimise the negative impact on outcomes.

It is inevitable that almost every doctor, sooner or later, will encounter a patient who has undergone bariatric surgery. Doctors involved in acute care may have to receive a patient presenting with a complication, some of which if not treated promptly can be life threatening. This chapter aims to assist doctors and health care professionals who wish to increase their awareness and confidence in dealing with bariatric emergencies; it also provides them with some advice on what to do when faced with such a patient. In the preceding chapters, the specific complications that can arise following each procedure have been detailed in great depth. This chapter aims to summarise, in a practical manner, the important bariatric emergencies that may present to a general surgeon in a non-bariatric centre.

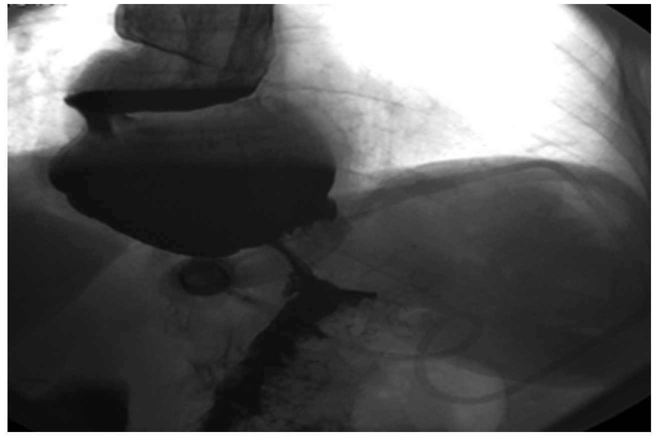

Fig. 73.1 Pouch and oesophageal dilatation

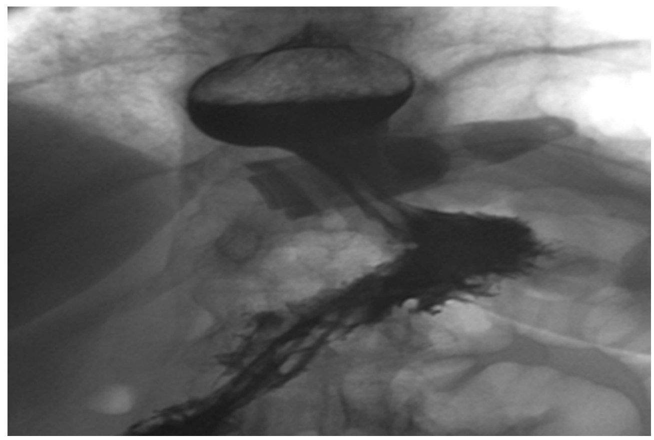

Fig. 73.2 Pouch dilatation

73.2 Laparoscopic Gastric Band Emergencies

73.2.1 Gastric Pouch and Oesophageal Dilatation

73.2.1.1 Presentation

A gastric band that is too tight can, over a prolonged period, lead to the dilation of both the pouch above it and the oesophagus itself. Patients may present with food intolerances, heartburn, vomiting and reflux or even episodes of aspiration when lying flat, particularly at night.

Some degree of dilatation above the gastric band is common and may occur in up to 25 % of the patients [1].

73.2.1.2 Diagnosis

A tight band and/or gastric pouch dilatation and oesophageal dilatation can be diagnosed via barium contrast studies. A delay is seen in the movement of the contrast dye through the band. In addition, there is significant uniform and symmetric dilation of the gastric pouch and oesophagus proximal to the band (See Figs. 73.1 and 73.2).

73.2.1.3 Management

The band should be deflated using a Huber needle, under radiological guidance if needed. Patients should be rehydrated if necessary. A repeat contrast study, after 3 months, ensures whether the dilation has resolved or not. The band should be re-inflated at a slower rate (less volume, less frequent adjustments) with careful assessment to ensure there is no recurrence of the symptoms and of the dilation. If it fails, removal of the band and conversion to gastric bypass or gastric sleeve may become necessary.

In situations where vomiting started after a band fill, rather than completely deflating the band, it may be possible to partially deflate the band and assess whether swallowing has improved. Advice regarding the situation may be obtained from a bariatric centre.

73.2.2 Band Erosion

73.2.2.1 Presentation

Band erosion is the phenomenon where the band erodes into the stomach. This occurs in 1 % of the patients [2]. It can occur either early (less than 6 months) or late (after 6 months) of band placement. It can present as recurrent port site infection, lack of sense of restriction to eating in a previously working band or a failure to adjust the band. The first sign may be either a failure to lose weight or weight regain. Pain can sometimes be a feature.

73.2.2.2 Diagnosis

Diagnosis is most accurately made via gastroscopy where the band is visible in the stomach during retro-flexion of the gastroscope. Alternatively, a barium swallow contrast study may show the contrast dye passing both through and outside the band (See Fig. 73.3).

73.2.2.3 Management

The band should be removed either endoscopically, if more than 50 % of the band is intra-gastric with concomitant surgical port removal, or more commonly laparoscopically.

73.2.3 Band Slippage

73.2.3.1 Presentation

Band slippage may occur in 5–20 % of the gastric band cases [1] and presents with vomiting, reflux, dysphagia, inability to tolerate liquids, coughing or choking episodes, regurgitation and epigastric pain (ominous sign).

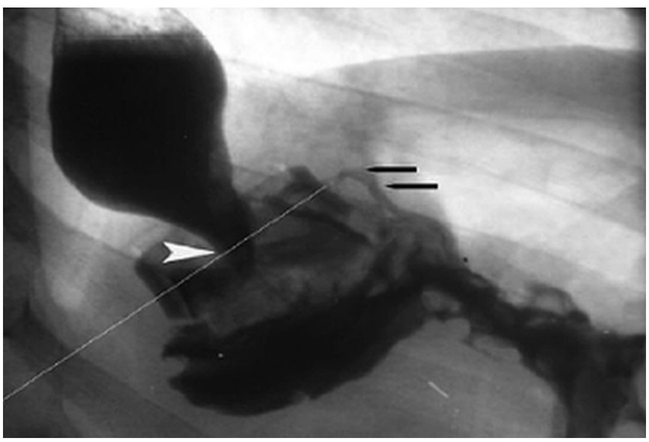

Fig. 73.3 Barium study shows contrast flowing through (*white arrow*) and outside the band (*black arrows*) suggesting band erosion

73.2.3.2 Diagnosis

Diagnosis is made via barium swallow contrast study which shows either anterior slippage with the band in a more horizontal position, or posterior slippage with the band in a more vertical position or even beyond the vertical position with the inferior part of the band lying to the left (See Fig. 73.4). Sometimes a plain X-ray alone is enough to determine the inadequate position of the band.

73.2.3.3 Management

The first line of treatment involves accessing the port with a Huber needle and deflating the band. It can help to buy time until definitive surgical treatment. If the patient is complaining of epigastric pain at rest, stomach wall ischaemia should be suspected and the patient should be taken to theatre immediately.

If feasible, the slippage is reduced and the band is re-sutured with gastro-gastric sutures. If that is not possible, the band is replaced either at the same time or later depending on the acuteness of presentation. Both the procedures are performed laparoscopically but in acute situation with gastric wall ischemia and imminent gastric perforation, if a laparoscopic surgeon is unavailable, laparotomy for open removal of the band is an acceptable option to prevent perforation and peritonitis that can cause catastrophic consequences.

73.2.4 Infected Band

73.2.4.1 Presentation and Diagnosis

Band infection is relatively uncommon occurring in less than 1 % of cases.) [2]. It presents as purulent discharge from the port site wound or with the tube protruding through the

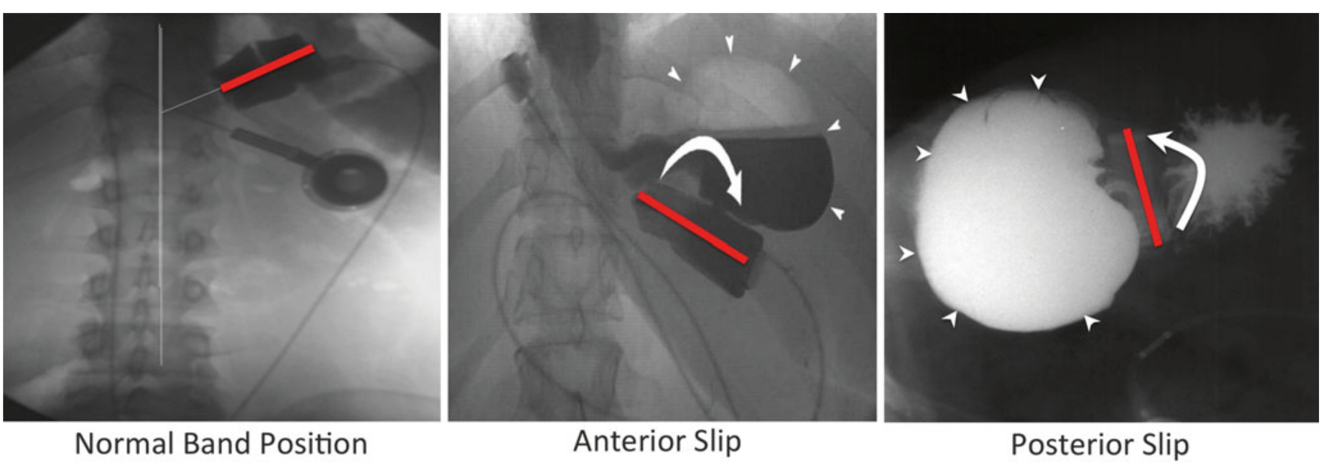

Fig. 73.4 the two types of slippage and the characteristic shift in the orientation of the band which normally lies tilted from 7 to 1 o'clock. Band position demonstrated by the *red line*. The band movement by the *white arrow* and the dilated pouch by the *small arrow heads*

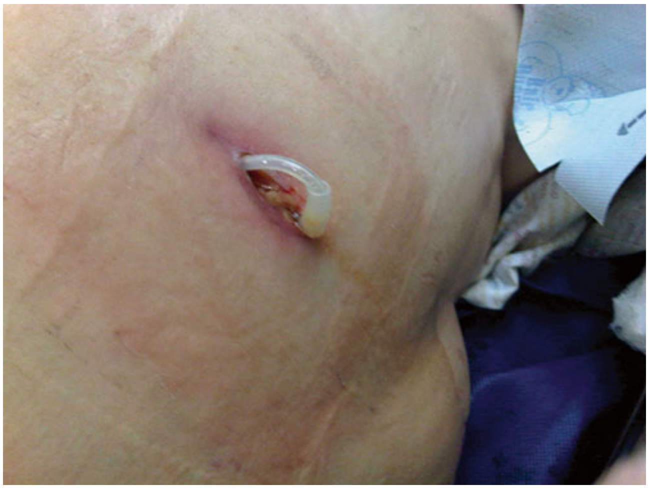

Fig. 73.5 Gastric band tubing protruding through skin due to gastric band infection

wound if the infection occurs early (See Fig. 73.5), or as port site pain and erythema if the infection occurs late. It often occurs during the first 2 weeks after band insertion or after a band adjustment. If recurrent, band erosion (see Sect. 73.2.2) should be considered.

73.2.4.2 Management

Antibiotics are required and the whole band needs to be removed. It should be replaced after a few months, only if the infection has fully resolved. Some believe that wound wash and antibiotics with only port removal, leaving the band in situ with the tubing in the peritoneal cavity, can be tried if there is no evidence of peritoneal contamination upon laparoscopy. However, the safest option is to remove the whole band.

73.2.5 Other Early Complications

The other early complications following gastric band surgery that are usually picked up by the operating centre are discussed below. However, with the growing popularity of day case laparoscopic gastric bands, there is an increased chance that these complications can occur after the patient has left the bariatric centre, returned home, and subsequently presents to their local hospital.

73.2.5.1 Gastric/Oesophageal Perforation

Gastric or oesophageal perforation is an early complication of gastric band surgery and occurs in approximately 0.2 % of the patients [3]. Diagnosis is usually evident from the leakage of gastric contents at the time of surgery or by the patient becoming severely unwell and presenting with upper abdominal pain in the first few hours after the operation. Diagnosis is with gastrografin swallow or computed tomography (CT) with oral contrast which reveals extravasation of the contrast. This is a serious complication and should be managed with the removal of band and repair of perforation, either by laparotomy or laparoscopy based on the availability of expertise. The patient is placed on nil by mouth and prolonged enteral feeding with careful observation. A repeat gastrografin swallow after 3 days confirms the sealing of perforation. Delays in surgery can have catastrophic effects.

73.2.5.2 Tight Band

A tight band, early after insertion, is normally a result of the band being too tight when inserted or as a result of haematoma developing at the oesophago-gastric junction when the gastro-gastric sutures are placed. It usually settles by removing some of the priming fluid from the band. If symptoms do not settle, band slippage or malposition (see Sect. 73.2.3) should be suspected and a contrast study is required.

73.3 Laparoscopic Gastric Bypass Emergencies

As described in earlier chapters, the gastric bypass procedure involves surgery to both the stomach and the small bowel, including two anastomoses (gastro-jejunal and jejuno-jejunal), multiple staple lines and a new anatomical configuration creating a small new stomach (the pouch) whilst the remaining stomach (the remnant) is defunctioned. There are three bowel limbs named the biliopancreatic [variable length from 25 to 150 cm, depending on the technique and patient's Body Mass Index (BMI)], the alimentary limb or Roux loop (usually 100 cm but may be longer) and the common channel which constitutes the remaining small bowel (See Fig. 73.6). It is important for the general surgeon to be prepared to face great variability in the biliopancreatic and Roux limb lengths.

The anatomical configuration of the bypass and particularly the position of the Roux or alimentary limb in relation to the transverse colon and remnant stomach are critical in the interpretation of CT findings and operative planning. Figure 73.7 shows the four potential configurations of the Roux limb (most commonly antecolic-antegastric, less commonly retrocolic-antegastric, and far less commonly retrocolic-retrogastric or antecolic-retrogastric) in gastric bypass surgery. All of these combinations can place the patient at risk of developing any one of the number of complications which may present as an emergency to a non-bariatric centre. This section outlines how the centre should manage the complications, but early involvement of the original bariatric team is clearly the gold standard.

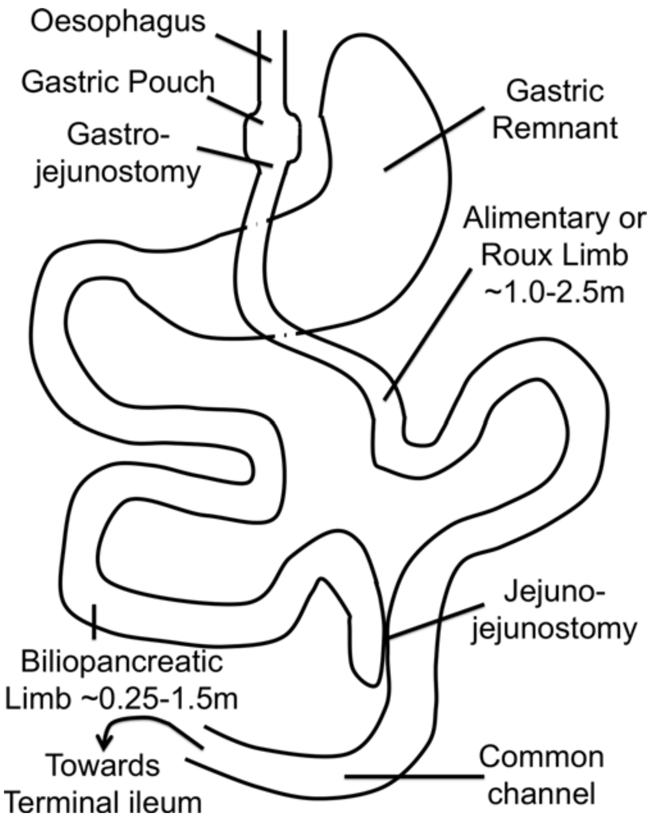

Fig. 73.6 Schematic of the Roux-en-Y gastric bypass operation

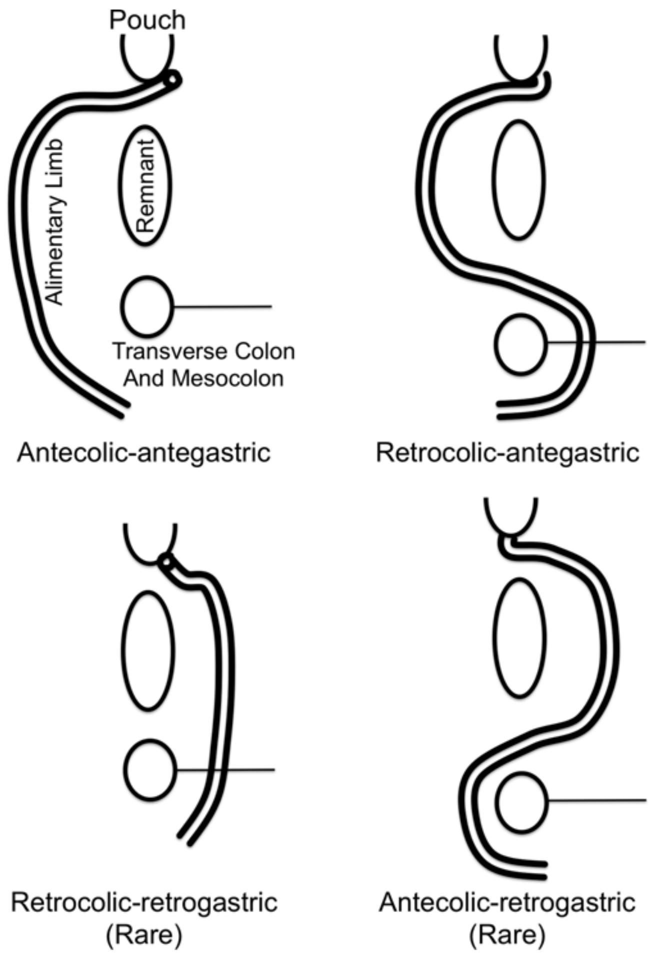

Fig. 73.7 The four anatomical configurations of the Rou-en-y gastric bypass as viewed in the coronal plane; antecolic-antegastric, retrocolic-antegastric, and the far less common retrocolic-retrogastric and antecolic-retrogastric

73.3.1 Intraluminal Bleeding

73.3.1.1 Aetiology

Bleeding occurs in about 2–3 % of the laparoscopic gastric bypass cases [4] and can be intraluminal [within the gastrointestinal (GI) tract], or extra-luminal (outside the GI tract). Intraluminal bleeding in the early postoperative stages tends to occur along the staple lines and anastomoses (jejuno-jejunal and gastro-jejunal). In the order of descending frequency, it can occur from the gastric pouch staple lines, the gastro-jejunostomy staple lines, the jejuno-jejunostomy staple lines and from the gastric remnant staple line.

Rarely, patients may bleed from an acute marginal ulcer or from a previously undiagnosed duodenal ulcer. The later is difficult to manage as the duodenum is no longer endoscopically accessible.

73.3.1.2 Presentation

Patient with acute intraluminal bleeding may present with either bright red haematemesis (indicating bleeding from the pouch staple line, gastro-jejunostomy or a marginal ulcer) or may have rectal bleeding or melaena (indicating bleeding from the gastric remnant or jejuno-jejunostomy). Patients may be tachycardic, hypotensive or have orthostatic hypotension or fainting episodes.

73.3.1.3 Management

Management should be along the lines of standard resuscitation—Airway, Breathing and Circulation (ABC). Intravenous (IV) access should be obtained early, as the bariatric population may be difficult to cannulate. IV fluids should be commenced and anticoagulants should be stopped. Blood samples should be sent for full blood count, clotting screen and blood products should be made available (packed cells, fresh frozen plasma (FFP) and platelets as required). Patients may require a high-dependency bed and urine output should be monitored. Nasogastric (NG) tubes should not be placed as the small gastric pouch is at significant risk of perforation with a blind NG tube insertion in the early stages. The majority (75 %) of cases settle with conservative management either with or without a blood transfusion [4].

If there is haemodynamic instability, or the patient is unresponsive to fluid resuscitation or blood products, then urgent intervention is required. The bleeding may necessitate combined endoscopic and laparoscopic interventions; therefore, endoscopy should ideally take place in the operating theatre. It should be performed under general anaesthesia ensuring safe airway and comfortable patient. Attempts to arrest the bleeding in the endoscopic suite, with the patient sedated, should be resisted as loss of airway, over sedation, aspiration, and patient distress can occur and have disastrous aftermaths. All equipment needed for the procedure including haemostatic modalities should be transported and made available in the operating theatre. A trained endoscopy nurse familiar with the use of such equipment should be present. Arresting the bleeding staple lines endoscopically employs standard techniques such as clipping, diathermy application, adrenaline injection, glue application etc.

The limitation of endoscopic management is that it only allows evaluation of the gastric pouch, gastro-jejunal anastomosis and jejuno-jejunal anastomosis. After gastric bypass, the remnant stomach and duodenum are not accessible by conventional endoscopic techniques. Occasionally, there is a need to combine diagnostic endoscopy with laparoscopy in order to achieve control of bleeding.

73.3.2 Extraluminal Bleeding

73.3.2.1 Aetiology

Extraluminal bleeding is most commonly caused because of the intra abdominal bleeding from the staple lines at the stomach transection or small bowel mesentery. But occasionally, a trocar injury or occult splenic injury at the time of pouch construction can lead to intra-abdominal bleeding.

73.3.2.2 Presentation

Similar to intraluminal bleeding, patients with extraluminal bleeding may present with tachycardia, hypotension or orthostatic hypotension/fainting. In addition, there may be bloody fluid in either the drains or the port sites, but generally drains are unreliable as they tend to clot early.

73.3.2.3 Management

Initial management is performed similarly as with intraluminal bleeding. Again, usually the bleeding settles with conservative management either with or without blood transfusion. As with intraluminal bleeding, if there are signs of haemodynamic instability immediate surgery is indicated. Laparoscopic access is used and the bleeding points are identified. The blood clots are suctioned and dealt with using conventional techniques such as clipping, under-running, diathermy and glue application. Occasionally, no bleeding point is identified and after all the clots are removed and the abdominal cavity is thoroughly irrigated, the procedure is terminated and the patients are monitored with serial estimation of haemoglobin and blood products are transfused as necessary.

73.3.3 Leaks

73.3.3.1 Presentation

Leaks usually occur from the gastro-jejunal anastomosis, the jejuno-jejunal anastomosis or the oesophago-gastric junction at the angle of His (where the gastric pouch has been created), or at any point of the staple line. Iatrogenic injury to another unrelated segment of the bowel should also be considered. Eighty-five per cent of the leaks occur within 2 weeks of surgery and late leaks tend to be contained and amenable to radiological guided drainage. Leaks are rare complications of bypass surgery occurring in less than 1 % of the cases [5].

73.3.3.2 Management

Leaks should be highly suspected in bariatric patients who are unwell. Patients should be carefully examined and blood tests (arterial and venous), chest x-ray and contrast studies (either water soluble swallow or CT with oral contrast) should be performed immediately. It should be remembered that patients are able to drink only 100–200 mL of contrast due to the small gastric pouch. CT scan of the chest should also be considered to rule out alternative causes of deterioration, especially because pulmonary embolism (PE) and leaks may present with an identical clinical picture. Patients should be started on broad spectrum antibiotics and given IV fluid boluses. If the patient is clinically unwell or there is a sense of impending doom, then early surgical exploration is required.

In the event of surgical exploration, peritoneal cavity should be washed out and all the anastomoses should be inspected and tested. Any leaks should be repaired and an omental patch placed, if possible. Drains should be carefully placed to achieve adequate drainage and to act as warning sign if the leak reoccurs. If there is delayed presentation or the patient is critically unwell, feeding gastrostomy should be considered to provide an enteral route for feeding. If there are no signs of leak from any of the anastomoses or staple lines, the whole bowel should be carefully inspected to look for another occult cause. If the patient has increased intra-abdominal pressure or a delayed diagnosis, laparostomy should be considered to prevent abdominal compartment syndrome.

As an alternative, percutaneous drains may be considered in a stable patient with contained leak. Stenting of the leak may be employed at a later stage once sepsis is controlled and adequate drainage has been achieved.

In the patient who is unwell or who is going to be managed for a prolonged period without enteral feeding, total parenteral nutrition (TPN) should be started early to avoid malnutrition and assist healing.

The traditional teaching involves suspecting a leak if the patient has sustained tachycardia >120/min and pyrexia >38.50C over 4 h. But these are late signs of leak and ideally leaks should be suspected and treated before the end stage signs develop.

73.3.4 Abdominal Pain or Colic >4 h

Abdominal pain should always be taken seriously in gastric bypass patients, especially in the presence of vomiting, as it may be a sign of obstruction. Closed loop obstruction and internal herniae are unique to gastric bypass and can lead to dead bowel and fatal complications. An alternative cause of obstruction may be pre-existing distal adhesions that may become clinically relevant after the manipulation and repositioning of the bowel during surgery. Radiological investigation with abdominal films and CT are usually negative and should not be relied upon.

There is no place for NG tubes as there is only a small gastric pouch and the remnant stomach is at risk of a closed loop obstruction. Conservative management is not appropriate in gastric bypass patient, if obstruction is present.

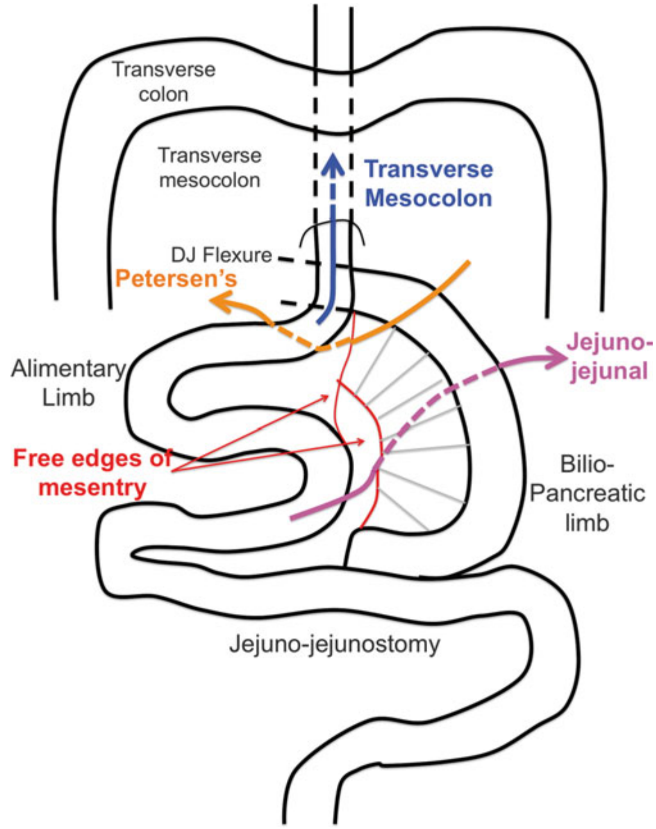

Fig. 73.8 Possible locations of internal hernias; Petersens defect (*orange*), transverse Mesocolon (*blue*) and Jejuno-jejunal (*purple*)

73.3.5 Internal Herniae

73.3.5.1 Presentation and Diagnosis

In gastric bypass patients, there is an up to 5 % lifetime risk of internal herniae [6]. Internal herniae can occur at any time after surgery but are more common after 6 months, particularly when the patient has lost significant weight and the mesenteric spaces have increased in size due to fat loss. They present as postprandial colicky pain often radiating to the back and occasionally associated with nausea and vomiting. A differential diagnosis would be gallstones, which are also common in this population. Altered liver function test can be seen in cases where the obstructed loop is the biliopancreatic limb and can cause confusion with gallstones. Abdominal films and CT scans are often negative and urgent referral to a surgical team is advised. If there is a suspicion of internal hernia, it is safer to laparoscopically explore the patient early. The diagnosis of an internal hernia is always confirmed on the operating table.

73.3.5.2 Management

Diagnosis is critical in internal herniae and often causes frustration due to negative radiological results. The diagnosis is essentially confirmed at exploration and wherever possible, attempts should be first made to determine the configuration of the bypass (antecolic vs retrocolic, antegastric vs retrogastric) which aids in diagnosis. Details of the previous surgery are essential for both the surgeon and the anaesthetist. The principles of exploration involve identification of the ileocaecal valve and then working backwards along the small bowel to determine the presence or absence of a cut off. Care should be taken to assess both the biliopancreatic limb and the alimentary limb, after jejuno-jejunostomy has been identified. Once the internal hernia has been identified, it should be reduced and the bowel viability carefully inspected. Bowel resection may become necessary in delayed cases. The defect should then be closed with non–absorbable sutures to prevent recurrence. Figure 73.8 demonstrates the possible locations for internal hernias.

73.3.6 Acute Gastric Dilatation

An acute dilatation of the gastric remnant may be visible on abdominal X-ray (AXR) even though the patient may or may not present with pain. In such cases, the surgeon should consider a biliopancreatic limb obstruction if there is a closed loop picture. Patients should be explored as above and the jejuno-jejunal anastomosis should be assessed. Venting gastrostomy can be performed percutaneously with CT guidance, to buy time, if surgery is delayed for some reason.

73.3.7 Nausea and Vomiting for >4 h

73.3.7.1 Presentation

Nausea and vomiting are common complaints in bypass patients. They may represent a failure of the patient to adhere to the dietetic education. The patient may be having too large portions of food, eating too fast, or consuming wrong types of food and drink. Inability to tolerate any oral intake, especially liquids, however, presents the risk of dehydration. If nausea and vomiting is accompanied by pain, it may be a sign of an internal hernia (see Sect. 73.3.5).

73.3.7.2 Management

Patients with ongoing vomiting should be admitted for IV rehydration and IV thiamine replacement. However, dextrose should be avoided as it may exacerbate any thiamine deficiency resulting from prolonged vomiting (thiamine is depleted from human stores within 2 weeks).

Gastrografin swallows should be performed to assess for stenosis at the gastro-jejunostomy site and the patients should be commenced on IV proton pump inhibitors (PPI) and IV thiamine (100 mg twice a day) replacement therapy.

If gastro-jejunal anastomotic narrowing is diagnosed, oesophago-gastro duodenoscopy (OGD) should be performed and the anastomosis dilated with a balloon. If the patient can tolerate oral fluids, then dilation of the gastro-jejunal anastomosis should be avoided during the first 6 weeks following surgery because there is a good chance that postoperative oedema will settle and the anastomosis will widen when tissue remodelling is completed. Also, there is a risk of perforation on dilation of the anastomosis during this period.

73.3.8 Marginal Ulceration

The incidence of marginal ulcers after gastric bypass is approximately 1–3 % [7] and can present as iron deficiency anaemia, haematemesis or melaena. It may also present as epigastric pain that radiates to the back and is worse after eating and following perforation. Marginal ulcers are usually associated with ingestion of nonsteroidal anti-inflammatory drugs (NSAIDs) as well as smoking. Sometimes they can occur in the absence of these two contributing factors and a gastro-gastric fistula between the pouch and the remnant stomach should always be sought using barium contrast study with the patient in the left decubitus position.

Fig. 73.9 Perforated marginal ulcer of the gastro-jejunal anastomosis

Management is with high dose PPIs (at least for 3 months and for long term in cases where no cause is found), discontinuation of NSAIDs, smoking cessation and, in case of gastro-gastric fistula, referral to the centre for surgical excision of the fistula.

In cases of acute presentation with perforation, standard techniques applied to perforated duodenal ulcer should be employed either with an open or a laparoscopic approach (See Fig. 73.9). An adequate vascularised omental patch should be placed and the perforation closed over the patch with interrupted absorbable sutures. Copious washout and abdominal drainage is paramount. The repair should be tested with water soluble contrasts and oral intake should be instituted after 48–72 h.

Long term PPIs may be necessary. The possibility of an occult gastro-gastric fistula should be investigated either with an OGD or a contrast study, 2–3 months after the surgery.

73.3.9 Retrograde Intussusception

This is a rare but important complication of gastric bypass where small bowel obstruction is caused by retrograde intussusception of the small bowel. The entry point is just below the jejuno-jejunostomy and there is a characteristic absence of any identifiable leading point [8]. The CT scan will normally reveal the classical target sign of intussusception (See Fig. 73.10). The mainstay of management is early surgical exploration where the affected segment of small bowel is excised and the anastomosis is reconstructed (See Fig. 73.11). The underlying cause of retrograde intussusception is unclear.

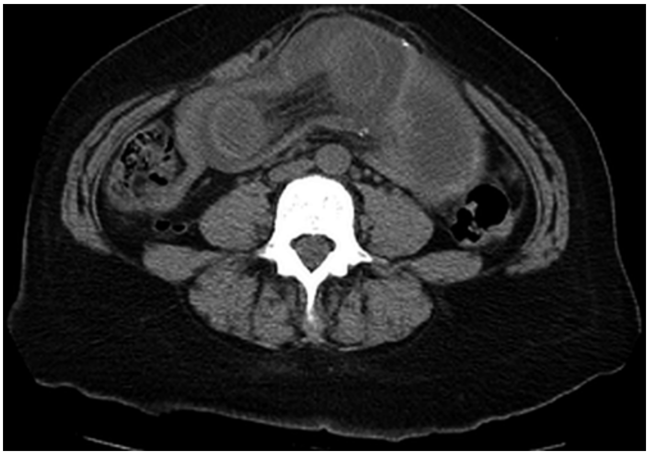

Fig. 73.10 Typical "target sign" in abdominal CT characteristic of intussusception

Fig. 73.11 Common channel with retrograde intussusception in the Jejuno-Jejunal anastomosis

73.4 Laparoscopic Sleeve Gastrectomy Emergencies

While surgically and anatomically more straightforward than the gastric bypass, the sleeve gastrectomy presents its own specific complications and difficulties to the general surgeon. This section shall outline the potential complications of sleeve gastrectomy and their management.

73.4.1 Intra-luminal Bleeding

73.4.1.1 Aetiology

As with gastric bypass, any bleeding following sleeve gastrectomy may be either intra-luminal or extra-luminal. Intraluminal bleeding tends to occur along the long staple line used to create the gastric sleeve though gastroduodenal ulcers must also be considered.

73.4.1.2 Presentation

Sleeve gastrectomy patients with an intragastric bleed present with either haematemesis or melaena. They may have signs of haemodynamic instability or exhibit a reduction in their haemoglobin concentration. Chronic low volume bleeds may be occult and present with an iron deficiency anaemia. Acute bleeds can occur in 1–6 % of the cases [9].

73.4.1.3 Management

The management is very similar to that for gastric bypasses. Patients should be appropriately resuscitated. Initial management is conservative which is usually successful. If the patient has ongoing bleeding or is haemodynamically unstable, then endoscopy should be performed, again preferably in theatre and under general anaesthesia, to protect the patient and allow for a greater range of therapeutic options including surgery. The simplifying factor for sleeves versus bypasses is that the whole operative site is endoscopically accessible. It increases the chances of the bleed being managed endoscopically. Standard endoscopic haemostatic techniques are employed to arrest the bleeding.

73.4.2 Leak

73.4.2.1 Aetiology

Leak from the sleeve is a troublesome and awkward problem that is associated with great deal of morbidity and indeed sometimes, mortality. It tends to occur from the corner at the top of the staple line at the angle of His, and may present some time after surgery. The overall incidence varies greatly between the published literature but is approximately 3 % [10].

73.4.2.2 Presentation and Diagnosis

Sleeve patients with a leak are generally unwell with raised temperature, tachycardia and pain and may not have clear localising signs. There should always be a high suspicion of leak in any sleeve patient who unexpectedly deteriorates. If suspected, a contrast study should be performed. The leak can be confirmed with demonstration of contrast outside of the gastric tube with the CT often demonstrating a localised collection.

73.4.2.3 Management

Sleeve gastrectomy leaks are very difficult to treat and the mainstay of management for the non-bariatric surgeon should be urgent referral back to the operating bariatric centre. Patients should be kept on nil by mouth and started on high dose IV PPIs to try and decrease gastric secretions.

Total parental nutrition should be considered early, to avoid malnutrition. Surgical options are often frustratingly unsuccessful as the irritant nature of the gastric contents impairs healing. Possible interventions include laparoscopy and repair of the leak, insertion of a T-tube in an attempt to create controlled fistula to the skin which then closes slowly, or endoscopic stenting across the leak, though the location of many of the leaks close to the gastro-oesophageal junction can make it troublesome. If the patient has a collection, then radiologically guided drainage should be considered.

73.4.3 Nausea and Vomiting for >4 h

73.4.3.1 Aetiology and Presentation

Nausea and vomiting are frequent complaints of patients following sleeve gastrectomy. It is often due to either large portion size, high speed of eating or the wrong textures being consumed in the early postoperative period. Often the situation may improve with dietetic advice. However, prolonged or troublesome vomiting may be a symptom of an anatomical problem such as a tube stricture, which usually occurs at the level of incisura angularis on the lesser curve. The reported incidence of tube strictures varies but is probably around 1 % [11].

73.4.3.2 Management

Regardless of the cause, the initial management of recurrent vomiting should be IV rehydration (avoiding dextrose), and IV thiamine. Investigation of vomiting should include gastrografin swallow, to assess the sleeve and to look for hold up. If there is a cut off in the sleeve itself, endoscopy with dilatation should be utilised to try and improve swallowing. It should be done preferably in operation theatre under general anaesthesia. In extreme circumstances of sleeve narrowing, not amenable to dilatation, patients are sometimes converted to gastric bypass.

73.5 Intra-gastric Balloon Emergencies

The intragastric balloon is a technique involving the endoscopic placement of balloon in the stomach, to reduce the quantity of food that can be consumed in one sitting. While a conceptually straightforward procedure, it is not without its complications which may present to a non-specialist.

73.5.1 Nausea and Vomiting >4 h

73.5.1.1 Aetiology and Presentation

Nausea and vomiting are common symptoms following gastric balloon placement. Vomiting may be particularly pronounced in the first 2 weeks following insertion of the balloon. Occasionally however, vomiting may be so pronounced that it leads to dehydration, electrolyte disturbance, thiamine deficiency or the risk of malnutrition.

73.5.1.2 Management

Initial conservative measures are rehydration with IV fluids, IV thiamine and electrolyte correction and the use of multiple IV antiemetics in rotation. Patients should be encouraged to drink slowly and have protein shakes to avoid malnourishment. Radiological studies such as gastrografin swallow can make sure that the balloon has not migrated into the duodenum. Still if the balloon is not tolerated, then it should be removed but this requires specialist endoscopic equipment, including, the balloon aspiration needle and the correct grasping forceps. For this reason, referral back to the original bariatric centre is preferable.

73.5.2 Balloon Leak and Obstruction

73.5.2.1 Aetiology and Presentation

The manufacturer's guidance and device approval states that the most commonly placed balloon (Orbera, Allergan) should be replaced every 6 months due to the continued degradation of the balloon material by the stomach acidity. If it does not get replaced in a timely manner and becomes compromised, there is a risk of spontaneous deflation. The first sign maybe either the patient reporting that urine has turned green or blue (as the balloon is filled with blue dye to warn of leak) or there is a sudden increase in the size of portions that can be consumed.

73.5.2.2 Management

If there are signs of balloon leakage, then endoscopy should be done immediately to remove the balloon before it passes through the stomach and into the small intestine where, in theory, it may cause obstruction. If the balloon is not present in the stomach and the patient is exhibiting signs of obstruction, then contrast CTs can be used to identify the location of the balloon and therefore the site of blockage. At this point, surgery may be required to remove the balloon, but as balloons are often used in the super obese population, it is anaesthetically very risky and balloon removal should probably take place in a bariatric centre. It should be noted that it is not uncommon to find a balloon that has deflated and passed through the gastrointestinal tract without the knowledge of the patient, while attempting to remove the balloon which was not followed up. So even if the balloon does leak, obstruction is relatively rare [12].

73.5.3 Bacterial Overgrowth in the Balloon

73.5.3.1 Aetiology and Presentation

If the fluid filling the balloon becomes infected with bacteria, then, when it is punctured during the removal, patients may

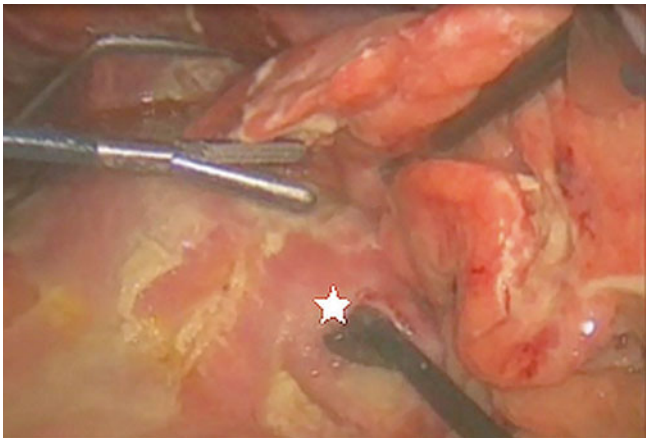

Fig. 73.12 Anterior stomach wall perforation (*white star*) from an intragastric balloon

develop severe acute signs of gastroenteritis with cramps, fever and diarrhoea.

73.5.3.2 Management

The mainstay of management is conservative and the infection is usually self-limiting but care must be taken to avoid dehydration and, in extreme circumstances, organ impairment. Rehydration with fluids and antiemetics are normally required.

73.5.4 Stomach Perforation due to Intragastric Balloon

Gastric perforation following the insertion of balloon-in-balloon (BIB) is a rare but serious and life-threatening complication. To date, there are only five case reports describing this major BIB complication and our group has published one of these case [13].

Management is done with laparoscopic or open approach, depending on the availability of expertise. The balloon should be removed and gastric perforation closed in two layers with continuous absorbable sutures, following which there should be adequate irrigation of the abdominal cavity and drains should be placed (See Fig. 73.12).

Conclusion

Increasingly, patients will be discharged from bariatric centres earlier after surgery and to homes further away from the operating centre. It is important that the non-bariatric general surgeon has at least a working knowledge of bariatric procedures and the complications that can arise so that they remain vigilant with such complications and understand the necessity for early intervention. The basic principles of management must always include early discussion with a bariatric centre and transfer, if possible. Bariatric patients often have high anaesthetic risks and low reserves; therefore, deterioration can be rapid and interventions fraught with difficulties.

Key Learning Points

- Bariatric patients often have high anaesthetic risks and low reserves. Therefore, deterioration due to complications can be rapid making interventions difficult.
- General surgeons must have at least a working knowledge and understanding of bariatric procedures and their complications so that they remain vigilant about such complications and understand the need for early intervention.
- Even patients who have been eating and drinking well with a certain band fill volume may suddenly develop emergencies due to LAGB surgery. In such patients, the band position should be assessed and the band emptied, if needed.
- Band slippage is a surgical emergency requiring urgent removal of the band.
- In patients who had laparoscopic gastric bypass, complaints should always be taken seriously; the patient should never be discharged without consulting a bariatric surgeon.
- There should always be a high suspicion of leak in sleeve gastrectomy patient who is unwell. Water soluble contrast imaging should be employed early to locate the leak, if any.
- Gastric balloons are generally well tolerated but persistent vomiting can occur. Deflation and obstruction can be a serious complication in a patient who is at high anaesthetic risk.
- A bariatric centre should be consulted for all cases showing signs and symptoms suggestive of complications following bariatric surgery, and if possible, the patient should be transferred to the centre early.

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The Role of Primary Care in Bariatric Surgery

74

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Abstract

The primary care physician plays an important role in early identification and engagement of the overweight or obese individual and in managing their weight in association with global risk. Should first-line measures fail to induce sufficient weight reduction or adequate risk control or amelioration of comorbidities, the primary care provider is in a position to assess eligibility, suitability, and willingness for surgery, discuss the options with the patient, and make an informed, appropriate referral. Postoperatively, the General Practitioner (GP) should anticipate an urgent communication from the tertiary care center to alert them that a patient with rapidly changing physiology is residing under their care in the community. In the long term, the role of the GP is the lifelong monitoring and management of the individual who has undergone bariatric surgery. For this, the GP is guided by an awareness of the nutritional and metabolic sequelae of bariatric surgery as well as the enhanced risk status many of these patients remain under.

Keywords

Obesity • Primary Care • General Practice • Bariatric Surgery

74.1 Introduction

Bariatric surgery, in any form, is a brief technological interlude within a lifetime of obesity management which occurs predominantly in the primary care setting [1]. It begins with the identification, engagement, screening, and motivation of the obese patient—arguably the most challenging part of the entire obesity management program, and unique to primary care—and ends with the patient's death, hopefully, as an elderly citizen. Access to obese individuals in primary care is not an issue—the majority of patients carry excess weight [2], and those who are obese will use healthcare services more than their lean counterparts [3]. Many present asking for help to lose weight. Others may present with weight related comorbidities and may or may not have made the connection. However, most present with conditions unrelated to their weight, ranging from travel vaccinations to influenza. Even in these instances, it is important to 'make every contact count' and engage the individual with regard to their weight and general health regardless of their presenting complaint. A brief intervention in the final moments of an unrelated appointment can represent best practice in obesity management and is arguably the most important few moments of the entire lifelong program, as a patient can be engaged or alienated at that point. The simple question 'Is your general health being looked after?' easily broaches the subject and allows basic weight, height and blood pressure screening. The offer of screening blood tests and the assurance of prompt follow up, may avoid any semblance of blame or discrimination directed toward the patient. Height, weight, Body Mass Index (BMI) and waist circumference are all essential measurements, but if a person appears to the naked eye as if they have a weight problem, they have a weight problem; and regardless whether their BMI falls marginally under the 'obese' threshold, they merit treatment.

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74.2 Obesity Management in Primary Care

Cornerstones of obesity management in primary care are diet and physical activity regimes which permanently underpin any obesity management strategy.

74.2.1 Diet

In most countries, a food pyramid or 'Eatwell' Plate is often misunderstood and perceived as a weight loss program, when in fact, it is a means of helping maintain a healthy weight. Even when used in this context, they are highly questionable as they promote, excess quantities of carbohydrate intake in all the macronutrient layers or segments and with no water in sight. Time-limited diets are not recommended, as returning to old habits post-dieting will cause weight gain, just as they did the first time. Nutrition changes must be sustainable in the long term. For many individuals a low-carbohydrate approach is the superior approach, although for others a traditional Mediterranean style approach may succeed [4]. The benefits of low-fat diets and calorie counting appear limited. In children, the combination of high protein and low glycemic index (GI) carbohydrate has been shown to be beneficial [5].

74.2.2 Physical Activity

Although '10,000 pedometer-recorded steps per day' is held up as the ideal degree of exercise, any increase in activity is beneficial especially on starting from a low baseline. Building physical activity into the daily routine is effective and sustainable, although resistance exercises are equally effective at reducing cardio-metabolic risk.

74.2.3 Other Integrated Approaches

Behavioral therapy is considered to be the third basic facet of weight management, but in practice, techniques such as motivational interviewing and stimulus control are very important. They are naturally built into dietetic and general advice on obesity, rather than involving separate sessions, although patients with binge eating disorder, night eating syndrome, or emotional eating may need specialist psychological input.

Integrated service models such as the Rotherham obesity management system have shown that a multi-disciplinary primary care model succeeds in inducing weight loss across a population. Models like this have embraced community based commercial weight loss programs such as Weight Watchers, Slimming World and very low calorie diets (VLCDs) such as the Cambridge Diet which are evidence based [6], and have an important role to play (Fig. 74.1).

Numerous trials such as Counterweight [7], and Camwel [8] have demonstrated that high levels of weight loss in primary care are difficult to achieve and maintain. However, engagement of obese individuals into a weight management program, and screening for, and management of comorbid risk factors means that weight management is more than just a measure of pounds lost, but a chance to apply global risk management in otherwise anonymous obese people. The Look Ahead [9] study of weight management in patients with type 2 diabetes demonstrated impressive weight reduction over an extended period, alongside improvements in lipid levels and blood pressure, proving that weight management across a population can succeed, if only in study conditions.

74.2.4 Drug Therapy

Drug treatment should be initiated in primary care, although only orlistat is universally available and only moderately successful [10]. In some countries, other agents such as Qsymia® (phentermine and topiramate extended-release), and Belviq (lorcaserin) are licensed, and phentermine is widely used outside the UK, but rarely in the UK. Pharmacotherapy can be used to sustain weight loss following a VLCD or other successful dietary regime [11].

Primary care physicians' role in obesity management, therefore, is the identification, engagement, motivation and screening of relevant individuals, the initial management strategies of diet, activity, behavioral therapy and pharmacotherapy, and management of comorbidities. However, those obese individuals who fail to achieve necessary targets or goals need to be assessed for eligibility, suitability, and fitness for bariatric surgery and their willingness, motivation and understanding of the concept. Men and racial minorities are less likely to have considered bariatric surgery and are less likely to be recommended for surgery by their GP [12].

74.2.5 Surgery

Once traditional weight management techniques have been exhausted, the role of primary care with regard to surgery is:

- Identification of individuals for whom bariatric surgery is a viable option:
  - Obese people who are medically fit for anesthesia and surgery, and are able to fully understand the nature of the process and comply with it may be considered for

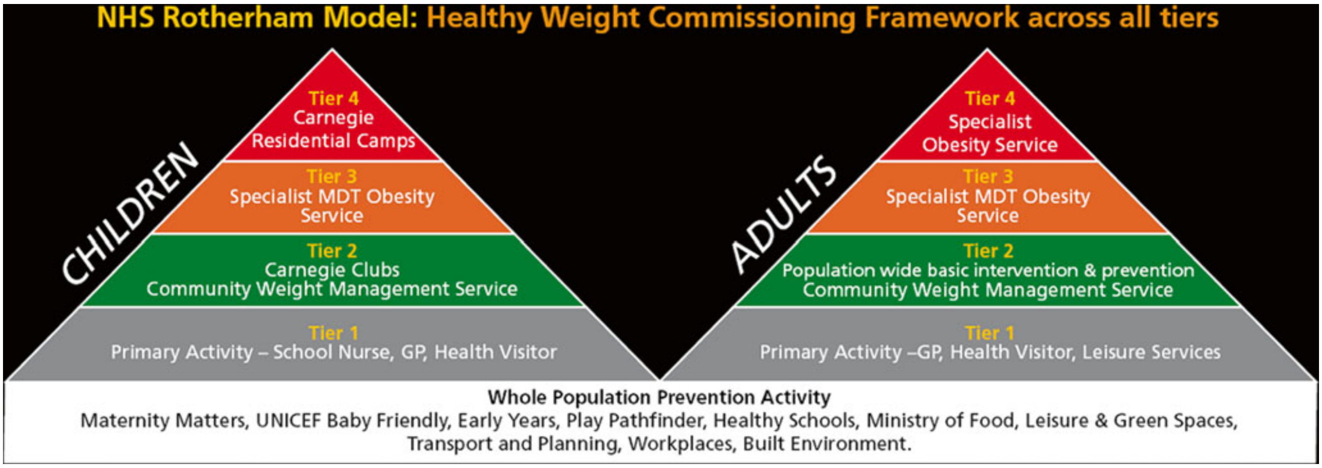

Fig. 74.1 Diagram of the Rotherham weight management service

bariatric surgery. Individuals with abnormal eating patterns such as comfort eating, binge eating or night eating need to be identified and offered psychological assessment and therapy prior to referral. Psychological implications of a bariatric procedure on an individual are enormous. A patient's temperament and psychological robustness to cope with the ramifications including changes in their body size and image are critically important for a successful outcome. A full medical assessment including broad-based hematology and biochemistry should take place; obstructive sleep apnea although easily screened for, is often overlooked and if left undiagnosed is a barrier to surgery

- Knowledge of the various surgical techniques:
  – The primary care physician should have knowledge of various surgical techniques, mainly Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy and gastric band, and be able to explain the pros and cons of each in the context of the individual patient.
  – Knowledge of the ramifications of surgery to the individual post-surgery; how their eating behavior will be altered after the surgery and how psychological adaptation and lifestyle change is essential. They should also be able to discuss what effect surgery will have on family and social life and how their medical conditions will change.
- Assessment of who is likely to benefit the most from surgery:
  – This may not be the most obese patient but may be a moderately obese individual with severe and worsening obesity related comorbidity such as type 2 diabetes. The Edmonton Obesity Staging System can be a useful guide [13]. It is discussed in detail in Chap. 14.
- Understanding of the eligibility criteria for bariatric surgery:
  – Different regions and countries apply different criteria for selecting patients who are eligible for bariatric surgery depending on the specific commissioning of services. Commonly criteria are BMI >40 or BMI >35 with significant co-morbidities. The primary care physician needs to have an understanding of the eligibility criteria applicable for the patient.
  – Knowledge about the contraindications to surgery, which include untreated eating disorders, excess cardiovascular or other anesthetic risk, certain learning difficulties, genetic causes of obesity, and certain hormonal syndromes.
- What the referral pathway is and what a local provider should offer**,** including full multi-disciplinary assessment at an experienced specialist tertiary center, including psychological assessment for all patients, and adequate follow-up including unscheduled care

Other unsuitable patients might include:

- Adolescents or young adults, who wish to be thinner but would reject necessary changes in lifestyle that would prevent them binging on food and alcohol to fit in with their social life.
- Those with personality disorders or learning difficulties who may not understand the commitment required to permanently alter their lifestyle and relationship with food.
- Individuals who mistakenly believe that their depression is caused by their weight, when actually it relates to multiple factors (for example, unresolved childhood trauma or abuse), which will not be resolved by weight loss. The realization, postoperatively, that weight loss has made no improvement to their physical or mental wellbeing can induce such a profound reassessment of their own status that it can lead to severe depression and even suicide [14].

- Patients who eat for reasons other than hunger, especially those with binge eating disorder or night eating syndrome or comfort eaters who will require psychological assessment and management prior to consideration for surgery

74.3 Immediate Postoperative Care

Ultimately all patients who undergo bariatric surgery will be discharged and be cared for in the primary care setting. This is irrespective of, whether they are discharged from a UK National Health Service (NHS) bariatric unit or equivalent, or following a procedure in the private sector at home or as a medical tourist.

The first days and weeks postoperatively are a crucial period, especially following RYGB when diabetes may be in the process of resolving rapidly, while patients may still be on glucose lowering medication including insulin. Down-titration of glucose lowering agents does not come naturally, and some guidance from the bariatric physician during the process of resolution is appreciated. GPs should expect an urgent communication on discharge alerting them to the fact that bariatric surgery has taken place and that vulnerable patients especially those with diabetes, are residing back in the community. No routine postoperative care by a GP should be necessary, but primary healthcare professionals should be aware of the signs of possible early surgical side effects and ensure rapid referral back to the tertiary specialist center, not the local general hospital which may not have healthcare professionals with adequate skills and knowledge in the bariatric field.

74.4 Long Term Care

Medical review, and dietitian involvement where possible, is important as is monitoring of physical activity. Regular reassessment of cardio-metabolic risk factors should take place, remembering that conventional risk engine formulae are not valid after bariatric surgery; a re-appraisal of need for drug therapy is important. Many patients will merit apronectomy or other plastic surgery procedures for excess skin folds, which can be unsightly and lead to loss of morale in addition to causing severe and uncomfortable rashes and skin eruptions. The primary health care professional (HCP) should be aware of the appropriate clinical and commissioning pathways.

Once the relatively brief follow up in tertiary care has ceased, the HCP fulfills the role of long term care. Surgery dramatically improves co-morbidities in obese individuals, and reduces the risk of premature death. Long term cardiovascular events are reduced postoperatively regardless of baseline BMI and degree of weight lost [15]. Hypertension, type 2 diabetes mellitus (T2DM), hyperlipidemia [16], and obstructive sleep apnea [17] resolve in many patients. Given that other methods of weight reduction are almost inevitably followed by weight regain to similar or higher levels than baseline, surgery has created a new, hitherto unknown category of patient—The Permanent Post-Obese individual—with their own unique management problems for primary care physicians to oversee.

Although studies such as the Swedish Obese Subjects (SOS) study [15] clearly show that cardiovascular events, deaths, particularly those due to myocardial infarction (MI) and cancer are significantly reduced postoperatively, the mortality rate is still considerably higher than in the background population. There remains residual increased cardio-metabolic risk because of the previous obese state. If two patients have the same weight and build, only one having previously been morbidly obese and undergone bariatric surgery, the formerly obese individual has the higher cardio-metabolic risk. This is important in deciding whether to continue or initiate lipid-lowering or antihypertensive agents based on 10 year coronary heart disease (CHD) risk score, or conversely whether to stop such pharmacotherapy as body weight and other cardio-metabolic parameters improve postoperatively. There is little supportive evidence, but it is a safe and sensible assumption that just as pre-treatment blood pressure is used in Risk Engine calculations, so should the pre-treatment weight, thereby a post-obese individual should still undergo multiplication of their CHD risk score by a factor of 1.5 in view of their former obesity.

It is now common consensus that anyone with a preoperative diagnosis of T2DM whose condition enters remission with bariatric surgery should remain on the diabetes register in order to ensure regular monitoring for retinopathy, nephropathy, neuropathy and the likely eventual return of the condition. Similarly it is generally considered that drugs which don't increase risk of hypoglycemia especially metformin, should be continued. Previously, by general consensus, resolution of diabetes was defined as normoglycemia, off all medication [18]. This is now often considered flawed, as medication may have been stopped prematurely or unnecessarily despite the long term risk of diabetes returning.

Various metabolic changes occur as a result of surgery such as increased insulin sensitivity, increased adiponectin levels and a reduction in pro-inflammatory cytokines [19]. The PHP should be aware that conditions such as obstructive sleep apnea, gastro-esophageal reflux [20], and urinary incontinence [21] are likely to improve or resolve with weight loss; mobility may improve with reduction in joint pain.

74.4.1 Gastric Bypass and Sleeve Gastrectomy

The HCP should be aware of the specific risk of iron, B12 and calcium deficiency after gastric bypass [22] as well as the risk of early and late dumping syndrome [23]. Early dumping syndrome may occur if hypertonic material such as sugar sweetened beverage or sugary foods leave the gastric pouch rapidly, resulting in sudden rise of glucose followed by rebound hypoglycemia. This may lead to nausea, sweating, and faintness. Rapid transit through the gut may then cause diarrhea. With sleeve gastrectomy, as the stomach architecture–in particular the cardiac and pyloric sphincters—is preserved, problems with nutrition and dumping are not encountered. However, nutritional deficiency, particularly B12 deficiency is not uncommon after sleeve gastrectomy.

74.4.2 Gastric Band

Gastric bands do not interfere with digestion or absorption. The nutritional status should therefore, be maintained with a well-balanced diet but commonly occurring problems such as iron, vitamin D and calcium deficiency may still develop. Medications may need to be given in liquid or dispersible form as capsules and tablets may become lodged in the stricture.

74.4.3 Biliopancreatic Diversion

Patients are more likely to show overt features of malabsorption, diarrhea and offensive stools. The range of potential long term effects is similar to that following RYGB but more so.

74.5 Changes in Drug Therapy After Bariatric Surgery

The primary HCP is largely responsible for prescribing and monitoring drugs for the long-term care of patients who have undergone bariatric surgery. A review of pharmacotherapy in 114 patients following gastric bypass showed the greatest changes in medication use occurred for diabetes and hypertension [24]. Twenty-two of twenty-eight patients using insulin preoperatively discontinued it by 2 years. The use of metformin and sulfonylurea was reduced from 25 to 4 cases, and 27 to 1 case respectively from pre-operative to 2 years postoperatively. However, whether stopping metformin postoperatively is considered as best practice is now open to conjecture. Thiazolidinedione use was halved; angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) use was reduced from 33 to 15 subjects, β[beta]-blocker use from 21 to 11, calcium channel blockers from 21 to 10 and diuretics from 54 to 19 at 2 years, mostly occurring by the 3 month review. With regard to mental health problems, selective serotonin reuptake inhibitors (SSRI) use was reduced from 49 to 35 subjects, and tricyclic antidepressants and benzodiazepine reduced from 19 to 6 cases. The use of nonsteroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-2 (COX-2) inhibitors for osteoarthritis was reduced from 59 to 33 cases at 2 years. Surgery related pharmacotherapy increased histamine (H2) receptor antagonists and proton-pump inhibitors fourfold. More studies are needed to study postoperative pharmacokinetics and drug usage in order to determine best practice in this area [25].

74.6 Metabolic Complications After Bypass

The major postoperative macronutrient deficiency following gastric bypass is protein malnutrition. Therefore, intake of dietary protein should be encouraged. Deficiencies in micronutrients, including trace elements, essential minerals, water- and fat-soluble vitamins, are commonplace prior to surgery and may persist postoperatively, despite recommendations on multivitamin and mineral supplements. Other disorders, including small intestinal bacterial overgrowth, can cause micronutrient deficiencies, especially in patients with T2DM. Recognition of micronutrient deficiencies is important, to enable early intervention and minimize long-term adverse effects. The relationship between vitamin D deficiency and the development of metabolic bone diseases, such as osteoporosis or osteomalacia is a major clinical concern; metabolic bone diseases may explain the increased risk of hip fracture in patients after RYGB [26]. Electrolyte deficiencies may include calcium (Ca), potassium (K), magnesium (Mg), sodium (Na), and phosphorus (P), and may lead to myopathy, or arthralgia. Metabolic acidosis, metabolic alkalosis, and even starvation ketoacidosis may occur in rare cases [27].

The surgical team should give guidance on the diet to be followed in stages after surgery. By the time of full-time return to primary care at 2 years' postoperative, a healthy balanced diet is selected from adequate protein sources, fruits, vegetables and whole grains. Use of small plates may help to control portion size. The energy (calorie) needs are based on height, weight and age. Since total food intake is relatively low, a vitamin and mineral supplement must be taken daily for an indefinite period.

74.7 Supplements

Although regimes vary, the following is a guide for postoperative and long term supplementation (Tables 74.1, 74.2, and 74.3).

- Multivitamin/mineral, for example. Forceval, Sanatogen Gold
- Calcium (1200–2000 mg)/vitamin D (400–800 IU) examples Calcichew-D3 or Seven Seas Ca + vit D

- Iron (40–65 mg) example, ferrous fumarate
- Folic acid (400 mcg)
- Vitamin B12 3 mg given intramuscularly once in 3 months
- Fat soluble vitamins after biliary pancreatic diversion (BPD) or duodenal switch [28]

74.8 Diabetes Pharmacotherapy

After the patient has a gastric band surgery, oral glucose lowering agents should be continued at the preoperative dose; then adjusted, according to the levels of markers of glycemic control. Drugs which induce hypoglycemia, such as sulphonylureas and insulin, should be targeted for early reduction and cessation. During weight loss, the patient should be in close contact with the PHP, who must be made fully aware of the patient's surgical timetable. As nutritional energy intake falls, drugs which cause hypoglycemia should be reduced and stopped first whereas metformin, incretin agents, pioglitazone and sodium dependent glucose transporter (SGLT-2) inhibitors may remain in place for longer, depending on medium to long-term control. Glucagon-like peptide (GLP-1) analogues and related drugs may sometimes be discontinued at the time of surgery. The default strategy is to keep the patient on metformin. The patient should remain on the diabetes register to benefit from long term monitoring which includes retinal screening.

Following gastric bypass or BPD, all oral glucose lowering agents may often be stopped at the time of surgery and the need for them to be re-instated judged later. Patients on insulin should reduce dose according to blood glucose response; a substantial drop in requirement is anticipated with reduction in dietary intake following surgery, and alterations in intrinsic gut hormone levels. Diligent glucose monitoring and close contact with the PHP is essential and primary care should be fully appraised of responsibility to supervise patients during this down-titration phase.

74.9 Hypertension

Blood pressure lowering agents should be continued after surgery unless reduction of dose is indicated by repeated measurements, hypotension, or where electrolyte measurements suggest reduction of diuretics is appropriate. β[beta]-blockers may be reduced or stopped at the time of surgery, especially if they are considered to be limiting physical activity, subject to satisfactory blood pressure readings. Gastric bypass is associated with a sustained blood pressure reduction and an increased diuresis [29].

74.10 Drugs Affecting Lipid Profile

Total cholesterol, low density lipoprotein (LDL) and triglycerides may improve after surgery, but the effect may be transient—often not sustained in the long term [30].

Table 74.1 Postoperative nutritional considerations

Complication	Clinical features	Management
Acid-base disorder	Metabolic acidosis, ketosis Metabolic alkalosis	Oral bicarbonate Check water & salt load
Bacterial overgrowth	Abdominal distension, diarrhea	Antibiotics (metronidazole) Probiotics (evidence level?)
Electrolyte abnormalities	Low Ca, K, Mg, Na, P Myopathy, arthralgia	Replete enterally or parenterally
Iron deficiency	Anemia or low ferritin	Ferrous fumarate
Vitamin B12 deficiency	Anemia, neuropathy	Measure methylmalonic acid, give vit B12 i/m
Thiamine deficiency (B1)	Dry beriberi (peripheral neuropathy), Wernicke-Korsakoff encephalopathy	High dose thiamine i/v then high dose oral thiamine
Osteoporosis	Fractures	DXA scans, give oral calcium, vitamin D, consider biphosphonates
Secondary hyperparathyroidism	Low vitamin D levels, negative Ca balance, osteoporosis	DXA scans, measure PTH and vit D levels. Give calcium and vitamin D orally
Oxalosis	Kidney stones	Low oxalate diet, give potassium citrate, probiotics (evidence level?)

Adapted from Mechanick et al. [28]

Table 74.2 Postoperative blood tests

Method	Roux-en-Y gastric bypass (and duodenal switch)	Gastric Bband
Laboratory tests on blood	Full blood count	Full blood count
	Electrolytes	Electrolytes
	Glucose, and HbA1C	Glucose, and HbA1C
	Iron, ferritin	Iron, ferritin
	Liver function tests	Liver function tests
	Lipid profile	Lipid profile
	Vitamin D, calcium	Vit D, calcium
	Vitamin B12, methylmalonic acid	
	Thiamine	
	Selenium	
	PTH	
Scans	DEXA[a]	

Adapted (in part) from Mechanick et al. [28]
For biliopancreatic diversion (BPD) an extended list of investigations is suggested (see the AACE/TOSA/ASMBS guidelines)
[a]The frequency of DEXA scans should be annual after BPD but the frequency after gastric bypass is not yet determined (every 2—3 years?)

Table 74.3 Supplementation

Supplement	Dosage	Product examples
Multivitamin/mineral	1–2 daily	Forceval (prescribable) Centrum (OTC) Sanatogen Gold (OTC)
Calcium and vitamin D	1200—2000 mg/day 400—800 IU/day	Calcichew (prescribable) Seven Seas Ca &vitD (OTC) Osteocare (OTC)
Iron	40–65 mg/day*	Fe fumarate or feredetate (prescribable)
Folate	400 µ [mu] g/day	Within forceval& centrum
Vitamin B12	1 mg i/m/month or 3 mg i/m/3 months*	Prescribable
Fat soluble vitamins	After biliopancreatic diversion or duodenal switch only	AquaADEK

Adapted from Mechanick et al. [28] and from material prepared by Ella Segaran of NLOSS for BOSS Dietitians November 2008

A conservative approach is to leave lipid-lowering therapy in place and re-assess lipid profile 3 and/or 6 months later.

74.11 Drugs for Gastric Hyperacidity

Proton pump inhibitors and H_2 receptor antagonists may usually be continued at preoperative doses. With weight reduction, reflux may be diminished, but evidence for reducing risk of esophageal carcinoma should be considered before stopping therapy. After surgery there may however, be a greater need for proton pump inhibitors.

74.12 Other Effects of Weight Loss

Gallstones are common in overweight and obese individuals and during weight loss the lithogenicity of the bile may increase [31]. Surgically-induced weight loss may perturb physiological dietary fat induced gall bladder filling and draining cycle. PHPs should be aware, and patients warned of the increased risk of developing gallstones. Blood uric acid levels tend to be raised in association with overweight and obesity; losing weight may raise uric acid further. Ketosis during postoperative weight loss may additionally reduce renal excretion of uric acid, further predisposing patients to episodes of acute gout.

74.13 Vitamin D Status

Vitamin D deficiency is common amongst the population. Many individuals embarking upon the surgical pathway will be vitamin D deficient or have low-normal levels possibly due in part to repeated weight-loss attempts with dietary regimens that provide insufficient vitamin D intake. Furthermore, in countries such as the UK, vitamin

D is not synthesized in the skin during October to March. Vitamin D status should therefore be checked where possible after surgery.

74.14 Re-referral Criteria

A patient should be considered for referral back to the tertiary center if there is:

- Excessive or unusual weight regain
- Suspicion of nutritional deficiency including chronic hypoglycemia
- Suspicion of complications
- Abnormal nausea or vomiting
- Symptoms suggestive of bowel obstruction
- Pregnancy: Fertility may be increased during weight loss; contraception should be diligent for the first year and subsequently pregnancy should ideally be overseen by an obstetric unit at a hospital with bariatric expertise.

Conclusion

Primary care has a crucial role in the bariatric process, prior to, during, and following the tertiary multidisciplinary process. PHPs should be closely involved with the patient journey at all stages and be fully appraised of the different elements of treatment. A particularly crucial phase is immediately after hospital discharge, when communication between the tertiary care center and primary care center is paramount. PHPs should be aware of the long term ramifications of surgery and appropriate referral pathways.

Key Learning Points

- Patient identification, engagement, and initial screening is crucial, and unique to primary care.
- Diet and lifestyle plus pharmacotherapy and behavioral input should be managed in primary care before consideration for referral.
- Primary care should be versed in judging eligibility, willingness, and suitability for bariatric surgery.
- GPs should expect an urgent communication on discharge after surgery, and anticipate, recognize and manage rapidly changing metabolic status of the patient.
- Primary care should treat their permanently post-obese patients as having elevated long term cardiometabolic risk, and manage them accordingly.

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Intensive Care and Obesity

75

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Abstract

The incidence of obesity is rising throughout the world. The likelihood of a morbidly obese patient being admitted to an intensive therapy unit (ITU) either electively or as an emergency is increasing (Pieracci et al., Crit Care Med 34(6):1796–1804, 2006). In the UK around 25 % of the population are obese and just over 3 % of men are classed as morbidly obese. The prevalence in women is slightly lower at around 1.6 % (Public Health England Obesity Knowledge and Intelligence Team 2013). In a meta-analysis of obese patients admitted to ITU, 25 % of the pooled population was obese (Akinnusi et al., Crit Care Med 36(1):151–158, 2008). The care of this population on ITU brings with it challenges and uncertainties as the use of conventional treatments in ITU cannot necessarily be extrapolated to very overweight patients. The mortality and morbidity of ITU admission of bariatric patients is not necessarily increased in comparison to the non-obese population. However, a raised body mass index (BMI) is associated with an increased risk of ITU admission. Overall there is a scarcity of evidence from large, randomized trials to support the care of this patient group and as a result many questions remain unanswered.

Keywords

Intensive care • Critical care • Obesity • Ventilation • Drug dosing • Renal replacement therapy • Nutrition • Equipment

75.1 Introduction

The incidence of obesity is increasing throughout the world and this has made the likelihood of admission of obese patients to intensive care units more likely [1], which in turn has had a significant impact on healthcare spending. In the UK obesity related healthcare spending has increased from £479.3 million to £4.2 billion in the decade from 1998 to 2007. A further rise to £27 billion has been projected for the following decade [2]. The decision to admit an obese patient to a critical care setting should be made based on the same criteria as for any other patient, i.e., morbid obesity itself should not be a contraindication to critical care admission. Once a decision has been made to admit a morbidly obese patient, there are several factors that need to be considered. These include medical considerations such as drug dosing and provision of care that is often weight based (for example, ventilation and renal replacement therapy), nursing including staffing levels, and equipment-related issues.

For the purposes of this chapter it is presumed that most intensive care units are used to dealing with patients with a BMI of up to 35. The content of this chapter will therefore concentrate on the care of patients who are classified as morbidly obese (BMI >35) or greater. Around 1 % of patients undergoing bariatric surgery require intensive care postoperatively. Risk factors that increase the likelihood of admission to ITU include male sex, age >50 years, pre-existing lung disease and re-operation [3]. Morbidly obese patients

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may also be admitted for other reasons including acute medical and surgical presentations, trauma and elective non-bariatric surgery.

Several studies have found an increased mortality risk in obese patients including peri-operative mortality and mortality related to trauma [4]. Studies of critical care outcomes in obese patients have conflicting results: some studies have demonstrated an increased length of stay and an increase in mortality, other studies have not demonstrated this. In fact, some studies looking at critical care admission of obese patients suggest a protective effect with a reduction in mortality [5]. Obese patients are however more likely to have an increased length of stay on ITU and are more likely to require mechanical ventilation [6]. Meta-analysis [7, 8] has shown that there is no overall increase in critical care mortality associated with obesity; however, there is a paucity of research.

75.2 Medical Considerations

Morbidly obese patients may be admitted to ITU for problems associated with obesity or for obesity-related comorbidities, but it is important to remember that obese patients may be admitted due to other medical conditions unrelated to obesity. In this chapter, we will concentrate on reviewing the medical problems associated with obesity in particular, although there may be some overlap with medical illnesses not necessarily related to obesity.

Obesity has multi-system effects [1]. These include an increase in blood volume, increased intra-thoracic and intra-abdominal pressures, a likely increase in atherosclerotic disease and a greater susceptibility to thrombotic events. There is a significant association between obesity and obstructive sleep apnea (OSA), with a 40–90 % likelihood of its occurrence in patients with a BMI of >40. Obstructive sleep apnoea is also much commoner in males and is more likely to occur in patients with central obesity [9]. The cardiovascular conditions commonly seen in association with obesity include right-sided cardiac problems and hypertension. In addition, there may be problems related to musculoskeletal stress such as osteoarthritis and patients may have longstanding issues such as pressure areas and chronic infections in skin folds. Diabetes is very common in obese patients, with an incidence of 10–28 % in morbidly obese patients, with a further 10–30 % of morbidly obese patients having impaired glucose tolerance.

75.2.1 Airway

The airway of an obese patient may appear somewhat daunting however the likelihood of encountering a difficult intubation grade is not necessarily any higher than in the rest of the population [1]. There is some evidence linking a larger neck circumference with a more difficult intubation but other studies have suggested no such association. Some studies have shown that as long as adequate preparation and positioning of the patient is undertaken, intubation is no more likely to be difficult just because a patient is obese. However, the presence of other indicators of difficult intubation, such as a high Mallampati score, should be treated with the same degree of expectation as they would be in any patient. The process of intubation is discussed in Chap. 13 and will therefore not be repeated here. However, it is important to ensure that appropriate equipment is immediately available in the intensive care unit in case of an airway emergency. The equipment includes a difficult airway trolley (as recommended in the National Audit Project 4 for all intensive care units) and appropriate equipment to position the patient correctly [10]. Staff should be aware of the potential difficulties of an emergency intubation in this patient group to appropriately plan for this situation. In particular, it should be remembered that oxygen desaturation in this patient group is likely to occur much faster due to changes in their respiratory physiology, so senior clinical involvement and good planning is vital. The use of intubation aids, such as the Glidescope© may be of benefit, and easy access to a fibreoptic bronchoscope should be ensured. The use of a pre-intubation checklist may be helpful.

If prolonged ventilation or gradual weaning from the ventilator is required, the placement of a tracheostomy tube may be indicated. In obese patients, there may be a need for longer than normal tracheostomy tubes (often adjustable flange tubes) to accommodate the patient's increased neck girth [4]. The tracheostomy tube can be placed surgically or percutaneously and the latter approach has not been shown to be associated with increase in complications in obese patients [11]. In the case of surgical placement, transfer of the patient to an operating theatre, provision of anesthesia and surgical technique should all be considered in the context of a sedated, morbidly obese patient. It is particularly important to ensure that a stock of appropriate sized tracheostomy tubes is available. Tracheostomy insertion in morbidly obese patients should not be undertaken lightly, as these patients can decompensate very rapidly if there are any airway problems [9].

75.2.2 Ventilation

Obesity is linked with a restrictive ventilation pattern due to chest wall size and an increase in pulmonary blood flow. In addition, the presence of a raised intra-abdominal pressure will exert upward pressure from below the diaphragm. The result of all of this is that there will be a decrease in total lung capacity and functional residual capacity as well as expiratory reserve volume [9]. Tidal volume should be calculated according to ideal body weight (IBW) to prevent volu- or barotrauma. The use of a higher positive end expiratory pressure (PEEP) is likely to be beneficial and reduce the occurrence of atelectasis [1]. Because of this increased chance of pulmonary collapse, the threshold for the use of non-invasive ventilation (NIV) may be lower in the unintubated obese patient [12]. Published studies have not shown any evidence of an increase in anastomotic leaks with the use of postoperative NIV for bariatric surgical patients requiring it [13]. Nursing ITU patients in a head-up position is standard practice in most ITUs to reduce the incidence of ventilator-associated pneumonia and is particularly helpful in obese patients, since it reduces work of breathing and improves ventilation/perfusion (V/Q) mismatch. Target saturations for oxygenation should be in most instances no different than in any other patient group, particularly bearing in mind the increased metabolic requirements of the obese patient. Obesity is also associated with OSA [14]. Severe OSA may be associated with hypoventilation and hypercapnia, which is referred to as obesity hypoventilation syndrome (OHS). Although the reason for the development of this syndrome is unclear, these patients are particularly high risk for airway obstruction, hypoventilation and heart failure, and need very careful monitoring [15].

The presence of OSA may have some implication for a patient on extubation. Patients may need NIV after extubation and are at greater risk of airway compromise, particularly if they are still sedated. Such patients will need closer monitoring in ITU for longer post extubation. A proportion of patients suffering from OSA/OHS may not have been diagnosed previously [16], especially if they are presenting as an emergency. In these previously undiagnosed cases, the early use of NIV may be beneficial and patients should be referred for further assessment once they are discharged from the intensive care.

75.2.3 Cardiovascular Assessment

Cardiovascular changes associated with obesity include an increase in blood volume, increased vascular tone, hypertension, and left ventricular hypertrophy. The chronic hypoxia of OSA can lead to pulmonary hypertension and subsequent right-sided heart failure and arrythmias. An electrocardiogram may reveal very small size complexes due to the depth of the chest wall. For non-invasive blood pressure monitoring, larger cuff sizes are available, and measuring forearm blood pressure is effective if the upper arm is too large. Occasionally an invasive arterial line may be necessary to facilitate accurate blood pressure measurement. The use of ultrasound for placement of this line may be extremely helpful, and a longer cannula should be considered [1].

The use of cardiac output measurements from devices that are based on algorithms, such as the Oesophageal Doppler Monitor©, may be of limited use in such patients (although the assessment of trends and response may still be possible) and other systems such as pulse contour analyzers may be more informative.

Venous and arterial vascular access may prove challenging. The use of ultrasound may be of great benefit. Consideration should also be given to the length of the lines being used since the depth of vessels (both peripheral and central) may be significantly greater than in other patients. Although the indications for central venous access insertion should be no different than in any other patient group, early consideration should be given to this form of access in patients with difficult peripheral vasculature.

Table 75.1 Drug dose adjustments in morbid obesity

Drug	Weight adjustment
Propofol	IBW and titrate to response
Benzodiazepines	IBW and titrate to response
Opiates (incl Remifentanil)	IBW and titrate to response
Muscle Relaxants	IBW
Vasopressors	IBW or ABW
Digoxin/Phenytoin/Theophyllines	IBW
Aminoglycosides	ABW

75.2.4 Sedation and Drug Dosing

Drug dosing in the morbidly obese patient is based on a variety of calculations dependent on the drug in question and its pharmacology [17]. The most common adjustments of dose relate to IBW, total body weight (TBW) and adjusted body weight (ABW) and their use in common drug groups are shown in Table 75.1. Adjusted body weight is a function of the patient's excess weight and can be calculated based on the formula:

- $$\mathrm{ABW} = 0.4\left(\mathrm{TBW} - \mathrm{IBW}\right) + \mathrm{IBW}$$

Table 75.1 indicates the adjustments for common drugs used in ITU.

Although the ABW calculation is used for aminoglycoside, dosing levels should be checked additionally. In fact, the dosing of all drugs with a narrow therapeutic window should be monitored with regular levels [9]. Drugs that fall into this category include digoxin, phenytoin and theophyllines and these should be administered according to IBW.

Both the intramuscular and the subcutaneous routes for drugs should be avoided if at all possible [18]. It is unlikely that the muscular layer will be reached by standard needles used for intramuscular injection. Blood supply to subcutaneous tissues may be chronically reduced, making the use of subcutaneous administration routes unpredictable. Likewise, transcutaneous routes may be of limited use due to reduced

Table 75.2 Effects of obesity on drug metabolism

Physiological change associated with obesity	Effect on drug pharmacokinetics and pharmacodynamics
Increased glomerular filtration rate	Increased clearance of renally excreted drugs
Altered function of cytochrome P_{450}	Altered clearance of hepatic excretion of drugs
Increased adipose tissue compartment	Altered volume of distribution and elimination half life

cutaneous blood supply. There are several other changes in pharmacodynamics and pharmacokinetics associated with obesity that are summarized in Table 75.2.

75.2.5 Renal Assessment and Renal Replacement Therapy

The risk of developing an acute kidney injury as an intensive care patient is increased in obesity although there is no increase in the risk of subsequent mortality. Some studies show a survival benefit in obese patients with both chronic and acute renal disease. Chronic renal disease is directly associated with obesity as well as other disease processes, especially diabetes. Glomerular filtration rate is probably not the most accurate measurement of renal function in morbidly obese patients due to changes in the glomerular blood flow, but at present no other test has been validated in this patient group. The criteria for renal replacement therapy should be the same in this patient group as they are in any other patients in the critical care unit. The dosing of therapy is unclear. According to limited evidence available, treatment should be commenced based on IBW and adjusted subsequently based on biochemical parameters [19].

75.2.6 Thromboembolic Prophylaxis

Thromboembolic prophylaxis is of great importance in obese patients since obesity is a pro-thrombotic state [4]. Both pharmacological and non-pharmacological treatments can be employed [20]. Intermittent compression devices and preventative stockings may be used, depending on local guidelines with regard to skin integrity. However, it must be ensured that these devices are sized correctly for the patient prior to use. National Institute for Health and Care Excellence (NICE) guidelines suggest that pharmacological deep vein thrombosis (DVT) prophylaxis can be achieved using low-molecular weight heparin, unfractionated heparin or Fondaparinux. There is no clear evidence as to the correct dose of any of these agents in obese patients. There is some evidence that a dose of 0.75 mg/kg of enoxaparin is therapeutic but the lack of evidence base makes the provision of standardized guidelines difficult [21].

75.2.7 Nutrition

Nutrition in critical illness is a contentious area. In the routine postoperative bariatric patient, dietary advice should be sought from the local multi-disciplinary team and this patient group will not be discussed in this chapter. However, for the bariatric patient admitted to intensive care for emergent reasons, decisions regarding nutrition are less clear. There is evidence that enteral feeding is beneficial compared to other routes of nutrition, provided there are no contraindications. There is also a suggestion that targeting a full caloric feed early in critical illness may not be beneficial to patients [22]. NICE has published guidelines that state that nutrition for seriously ill patients should be started at a maximum of 50 % of their requirements and be increased over 24–48 h. Patients who have suffered a complication following bariatric surgery can be considered to be at high risk of malnourishment, and total parenteral nutrition can be considered if enteral feeding is not possible. There should be a high level of vigilance with regard to re-feeding syndrome in these patients [23]. Patients presenting with non-bariatric surgery-related emergencies should be managed as any other patients but since their nutritional requirements may be unusual (in particular a high protein, hypocaloric diet), early involvement of a dietician is recommended [24].

75.2.8 Resuscitation

The medical decisions around resuscitation and treatment escalation remain individual to each patient. Good practice mandates that these decisions should be discussed with the patient if possible and be relayed to their kin if the patient lacks capacity. Obesity is not a reason to change this practice nor is it a reason not to undertake treatment escalation or resuscitation per se. Although there have been some suggestions that chest compressions are less efficacious in obese patients, there is no demonstrable evidence to suggest that Basic or Advanced Life Support should be carried out any differently in this patient group [25].

75.3 Nursing Considerations

Nursing bariatric patients on intensive care poses some significant challenges. There are very practical considerations such as staffing levels, equipment storage, and manual handling concerns. Additionally, these patients also have significant privacy and dignity needs that may require additional arrangements beyond those normally undertaken in critical care units. Close liaison with the multi-disciplinary team for patients admitted following bariatric surgery will help to elucidate the patients' needs and aims [26]. Patients who have undergone uncomplicated surgery need early mobilization and attention on postoperative symptoms such as nausea, pain and early complications such as constipation or dumping syndrome.

75.3.1 Staffing

The admission of a morbidly obese patient to ITU may necessitate additional staffing to care for them. The staff involved in their care must be familiar with local and national manual handling guidance and staff should not be asked to act outside this framework. However, increasing staffing levels significantly solely in order to be able to provide additional support for one patient may not be practical. It may therefore be useful to consider cross cover from other areas in the hospital on a pre-arranged basis or similar schemes that are appropriate locally. There are also some types of equipment that may be helpful in the care of these patients, for example beds that turn the patient without requiring significant nursing input and a hoist to help with patient positioning. The use of a HoverMatt© transfer mattress can also aid greatly in patient transfer.

75.3.2 Hygiene Needs and Skin Care

Bariatric patients may have specific hygiene needs and skin care requirements. Relative immobility places these patients at significant risk of skin breakdown. Hence, strict vigilance with regard to skin integrity should be adhered to and early involvement of tissue viability teams if required should be considered. The care of skin and hygiene is particularly crucial around skin folds such as those seen in the lower abdomen and under arms. The cleanliness of these areas is important both for the comfort of the patient and to help prevent the development of localized skin conditions and yeast infections.

75.3.3 Privacy and Dignity

One of the psychological sequelae of morbid obesity is that patients may be reluctant to engage with medical services and feel uncomfortable in the hospital [26]. They may also be dealing with a long history of psychological problems related to their weight that can impact on how they interact with staff.

The provision of adequate equipment and resources to be able to ensure privacy for the patient may be challenging. In order to ensure privacy for the patient in all situations, the use of additional measures such as extra curtains or screens may be required.

The patient's dignity must be maintained at all times. This includes the provision of appropriate clothing (e.g., bariatric hospital gowns) and equipment so that the patient is not made to feel an exception and maintenance of an open and non-judgmental attitude by the staff. The patients should be involved in as many decisions about their care as possible and their opinions should be valued.

75.4 Equipment

Throughout this chapter there has been a mention of various types of equipments and the potential problems encountered with bariatric patients. It is important that there is advance consideration, if possible, of how services, investigations and monitoring will be delivered for this patient group [27]. Equipment can be divided into two categories:

Delivery of personal care: Examples of such equipment include appropriately sized gowns and wrist bands, weight-appropriate mattresses and beds, equipment such as HoverMatt© mattresses for patient transfer and seating, and appropriately sized physiotherapy devices. Scales that are able to accurately weigh the patient should be available.

Delivery of hospital-wide care: An understanding of the weight limits of radiology gurneys and operating tables is important so that alternative arrangements can be made if necessary. Consideration should be given to the use of structural arrangements such as maximum weights in lifts and width of door frames that may affect patient transfer and monitoring capabilities e.g., blood pressure cuffs. Sufficient storage also needs to be provided for any additional equipment required for patient care.

Conclusion

The likelihood of admission of morbidly obese patients to ITU is increasing and evidence suggests that mortality in this group of patients is no greater than any other population. The practicalities of the care of these patients requires an extrapolation of current best practice and there is a lack of evidence base to direct this at present. Possibly the greatest challenge with these patients is the delivery of care with dignity and every effort should be made to try and provide this. This requires a team-based approach to care and should involve appropriate staffing levels and specialist referral at the earliest opportunity.

Key Learning Points

- The admission of bariatric patients to critical care is increasing.
- The management of these patients is challenging as there is limited evidence to support treatment decisions.
- The nursing needs of bariatric patients need to be considered early since they are complex in this patient group.
- Specialist equipment may be required.

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Radiological Imaging in Bariatric Surgery

76

Kamini Patel

Abstract

Radiology is an important component of the multidisciplinary team caring for the patients undergoing bariatric surgery. The radiologist must understand the surgery performed and be cognizant of the appearances of the normal postoperative appearances upon imaging. The radiologist must be aware of the specific complications that arise from the common bariatric surgical procedures. These mainly include band slippage, erosions, and tube leakage and dis-association in patients with gastric band insertion; anastomotic leaks, strictures, bleeds, ulcers, gastric remnant dilation, and internal hernias in patients with Roux-en Y gastric bypass; perforations, strictures, gastric dilatation and in the long term, gastro-esophageal reflux and failure to achieve weight loss in patients who underwent sleeve gastrectomy.

Computer tomography and fluoroscopy are the imaging modalities of choice when evaluating postoperative complications in a patient following bariatric surgery.

Keywords

Bariatric surgery • Normal post surgical appearances • Radiology • Complications

76.1 Introduction

Radiology is an important and integral component of the multidisciplinary care that must be available to those undergoing bariatric surgery.

The National Institute of Health and Care Excellence (NICE) recommends bariatric surgery for individuals considered morbidly obese, i.e. adults with a body mass index (BMI) of 40 kg/m^2 or more, or between 35 and 40 kg/m^2 in the presence of other significant co-morbidities

The commonest procedures performed in the recent years include laparoscopic adjustable gastric band (LAGB), Roux en Y gastric bypass (RYGB), sleeve gastrectomy, and duodenal switch in the morbidly obese as a two-stage operation [1].

Globally, there has been an increase in the number of obesity surgical procedures performed in the last 10 years. In England, the number of RYGB procedures has increased from 858 in 2006–2007 to 5407 in 2011–2012. Over the same period (2007–2012) LAGB procedures have increased from 715 to 1316 [2]. With a surge in the number of interventions, there is an increasing need for trained radiologists, who are experts at advising appropriate investigations and their interpretation within the clinical context.

Radiology plays an important role in the management of these patients, in both the early and late postoperative periods. It is important for the radiologist to have adequate knowledge of the surgical procedures performed at their institution, and the expected postoperative anatomical presentations. This is particularly important when the patient undergoes imaging for symptoms unrelated to obesity surgery, and care is necessary to avoid misinterpreting normal postoperative findings as abnormal. As with any other surgery there are general complications, however the radiologist also has to be aware of specific complications that arise from the various surgical interventions used to manage obesity.

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There is no role of imaging in the pre-operative assessment of the patients undergoing obesity surgery; the detection rate for significant abnormalities is very low.

In the postoperative period, imaging plays an important role in the diagnosis or assessment of complications in both the early (within the first 30 days) and in the late (after 30 days) postoperative period, which includes weight gain. Computer tomography (CT) and upper GI studies (UGI) are the mainstay imaging modalities.

The surgical techniques for the above procedures have been described elsewhere. Below are the commonest complications for these procedures, and the role of imaging in their diagnosis.

76.2 Laparoscopic Adjustable Gastric Band (LAGB)

The normal position of the gastric band is just to the left of the spine in the upper abdomen. It is angled about 45° to the vertical (normal range 8–58°) (Fig. 76.1) [3, 4]. The gastric pouch is normally 15–20 mL and may measure up to 4 cm. The stoma is normally approximately 4 mm [3].

76.2.1 Early Complications in Laparoscopic Adjustable Gastric Band

These include gastroesophgeal perforation, inappropriate band placement, early band slippage, and stomal stenosis.

Perforation occurs in 0.1–0.8 % of cases, because of trauma during stomach mobilization or imbrication [3]. The presentation is variable and can be a vague abdominal pain, signs of sepsis, etc. CT is the modality of choice, when looking for signs of perforation and abscess. Signs include free air (greater than that expected for the postoperative period) and fluid collection in the left upper quadrant near the gastric band.

Stomal stenosis in the very early postoperative period is usually due to edema or a food bolus. In the later stages, stomal stenosis may be due to over filling. Patients usually present with pain, nausea and vomiting. An upper gastrointestinal (UGI) study (using water soluble contrast in the early postoperative period) will show the position of the band, mild pouch dilatation, stomal narrowing (less than 4 mm) [5, 6], and slow passage of contrast through the stoma. In this situation, the band is deflated and patient managed conservatively.

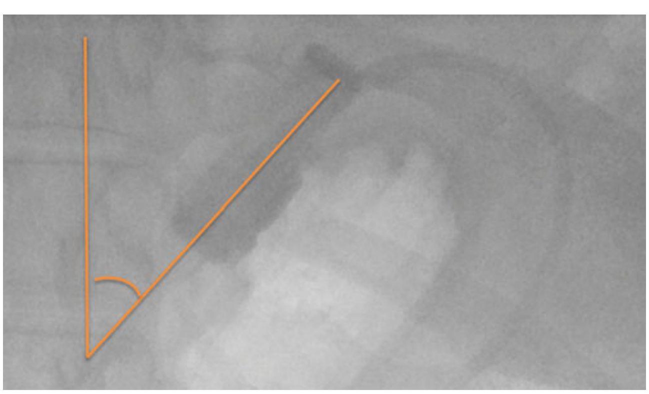

Fig. 76.1 Normal position of the gastric band

Gastric obstruction at the level of the band in the early postoperative period may also be due to an inappropriate size of the band, and/or secondary to the surgical technique, with too much fat included around the band. Imaging cannot assess these causes [3].

76.2.2 Late Complications

76.2.2.1 Gastric Pouch Dilatation

Pouch dilatation may be concentric or eccentric. Concentric dilatation may result from over inflation of the band. This may occur as an acute presentation following the band fill. The patient will experience pain, reflux, and vomiting. An UGI study usually reveals a dilated pouch with a narrowed stoma of less than 4 mm. Generally, a dilated pouch is greater than 4 cm in diameter [4–6]. Deflation of band is required to increase the size of the stoma and rectify the condition.

Another cause of pouch dilatation can result from poor dietary compliance with over-eating. The stoma is normal or widened. This may present with reduced weight loss. Other complications of poor dietary compliance include esophageal dilatation, gastroesophageal reflux, and esophageal dysmotility. This occurs in 3–8 % of patients. These changes can be easily assessed by performing an UGI study. The management in this situation requires strict dietary control and deflation of the band to allow the esophagus to recover.

Eccentric pouch dilatation is usually due to band slippage. Gastric band slippage maybe caused by overeating or overfilling of the gastric pouch, over inflation of the band, or recurrent vomiting. It occurs in approximately 24 % of patients who undergo bariatric surgery. Faulty surgical technique is less likely to be a cause, especially with surgical modifications such as, introduction of the pars flaccid technique and reduction in the pouch size [7]. There are two main types of slippage, anterior (upward movement of the lesser curve) caused by insufficient fixation of band, and posterior slippage where the posterior wall moves superiorly above the band. Posterior slippage is believed to be caused by band misplacement in the lesser curve. Concentric dilatation can also occur occasionally with complete displacement of the band [3–6]. Slippage maybe asymptomatic but may be accompanied with food intolerance, epigastric pain, early satiety, vomiting, and gastroesophageal reflux. A plain radiograph will show the band to be in an abnormal orientation, outside the range of 8–58° to the vertical or may appear as a ring (Fig. 76.2). An UGI contrast study will demonstrate the band position, pouch size and orientation, any filling defects, stomal size, and any obstruction to the flow of contrast through the stoma.

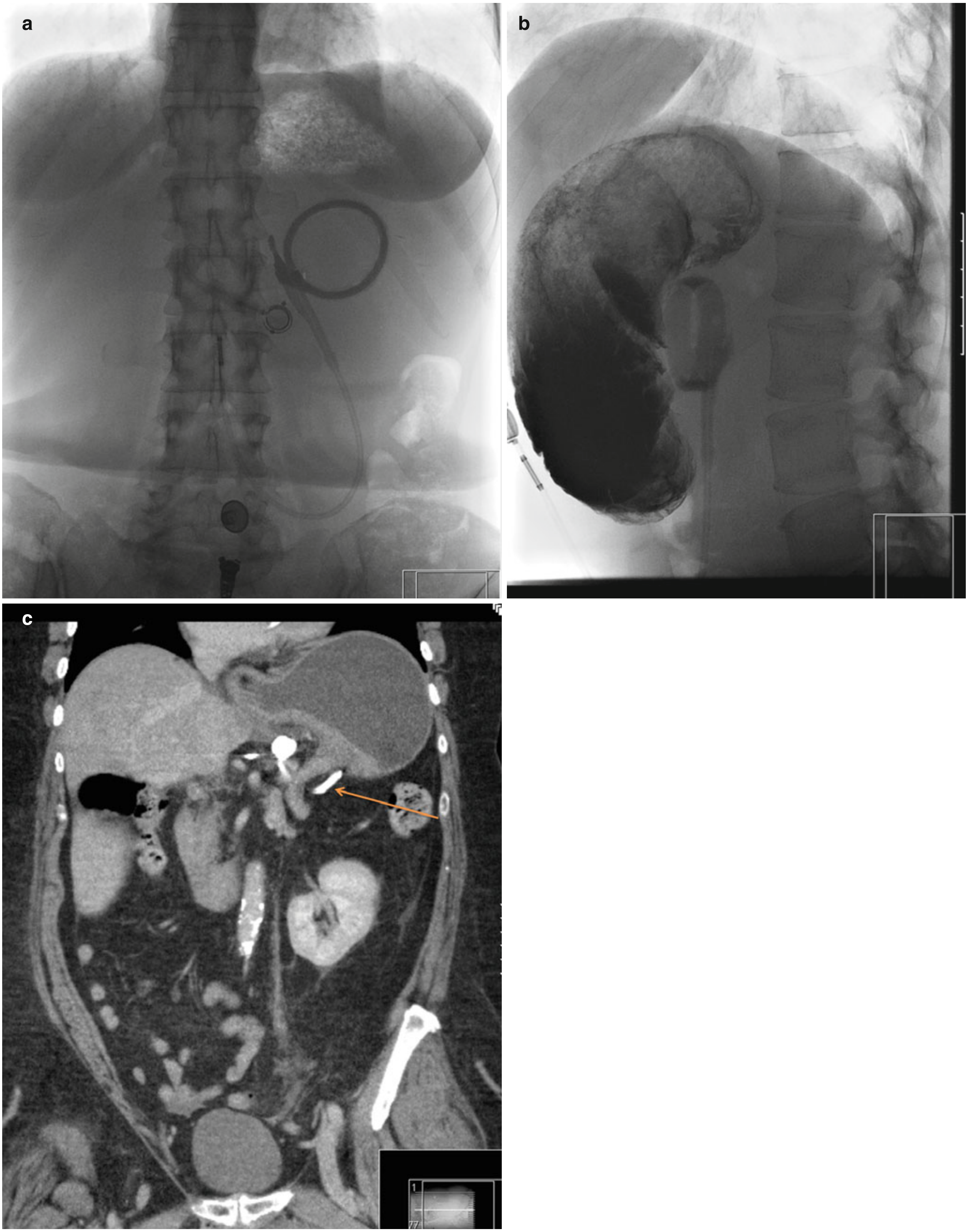

Fig. 76.2 Slipped gastric band. (**a**) An abnormal orientation of the band. (**b**) Slipped band causes moderate obstruction. (**c**) Different patient, Computed tomography showing slipped gastric band (*arrow*) with proximal dilatation

76.2.2.2 Band Erosion

Band erosion is a more serious late complication and occurs in approximately 3 % of patients with gastric bands [4]. It is thought to be related to pressure necrosis of the gastric wall with migration of part or the entire band into the gastric lumen. Band erosions are also associated with smoking and use of non-steroidal anti-inflammatory drugs [7]. Patients with band erosions may present with hematemesis, infection, pain, and vomiting. Both CT and UGI studies are useful. The results of an UGI study are characteristic with contrast outlining the band as a partial filling defect (Fig. 76.3). Usually no contrast is found extravasating outside the gastric lumen, presumably, as the inflammatory response contains the perforation that occurs with the gradual erosion. Very early erosion can be missed in a contrast-enhanced UGI study. A CT investigation is recommended if clinically an associated infection or fluid collections are suspected. CT is also superior in demonstrating the small pockets of air, if present around the band.

76.2.2.3 Other Complications

Other band related complications include inversion of the port (Fig. 76.4), kinking or damage to the tube resulting in leakage of injected contrast and loss of restriction (Fig. 76.5) or detachment of the tubing (Fig. 76.6). These can be assessed fluoroscopically and with injection of a water-soluble contrast into the port.

76.2.2.4 Infection

Infection occurs in about 1 % of the patients [4]. This may remain superficial around the port but may spread along the tubing to cause deep-seated infection and fluid accumulation (Fig. 76.7). CT with oral and IV contrast is the investigation of choice and this will enable the detection of any other complications such as band erosions.

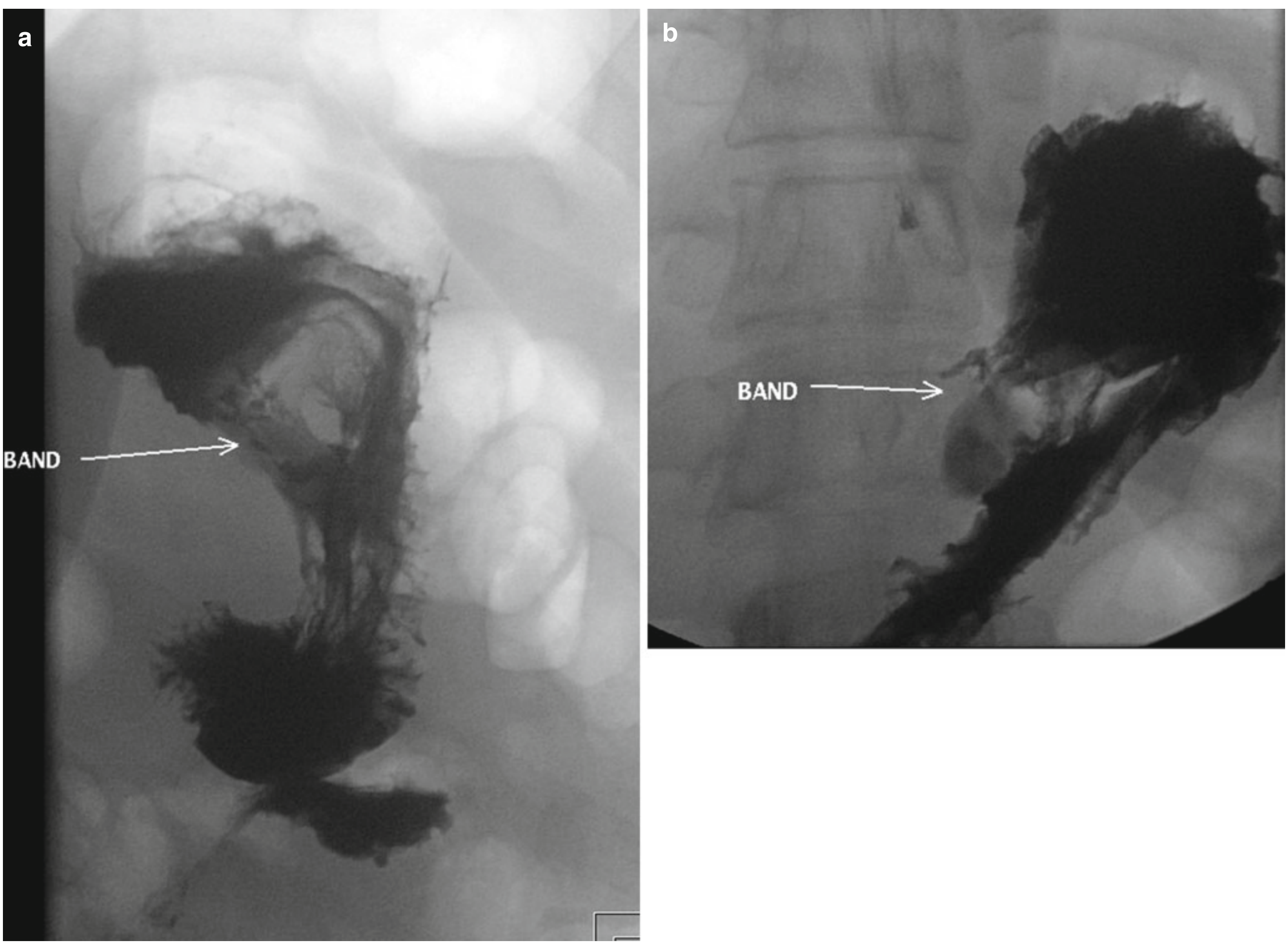

Fig. 76.3 (**a**, **b**) Band erosion. Barium seen around the band

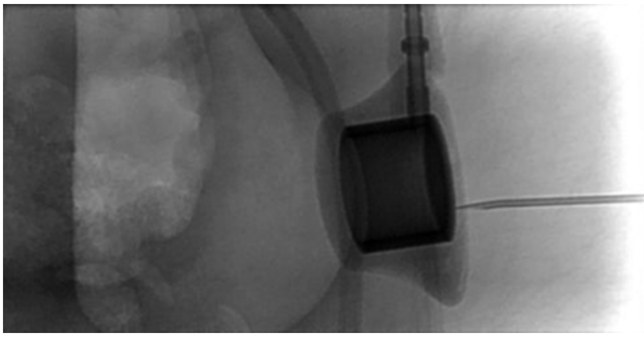

Fig. 76.4 Port inversion precluding the band filling

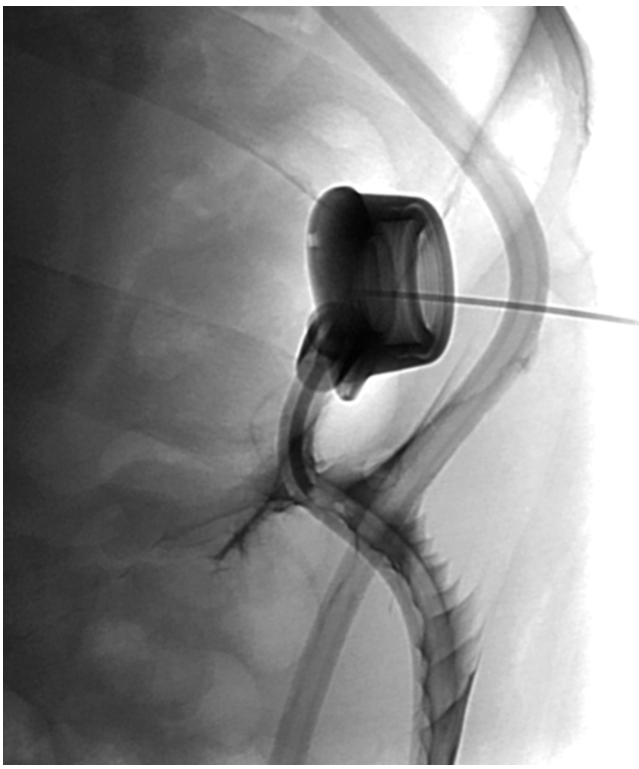

Fig. 76.5 Damage to the tubing just proximal to the junction with the port associated with leak of injected contrast

76.3 Gastric Band Fill

This can be performed in the clinic either in a stepwise fashion (0.5–1 mL) or as an ultrasound-guided procedure. However, fluoroscopy-guided port cannulation using a non-coring needle such a Huber needle is preferred. During fluoroscopy, the pouch size is assessed and any complications may be detected, e.g. esophageal dilatation etc. There is no clear consensus on the steps adopted for filling. Past studies report that 20 mL of oral contrast when administered, should clear from the gastric pouch in 15–20 min [6]. This is however impractical in a normal fluoroscopy list; we prefer to titrate the band fill until the

Fig. 76.6 Detached port from the tubing

flow of contrast is restricted through the stoma. An adequate fill is achieved when the esophagus and gastric pouch empties after two peristaltic waves.

76.4 Roux-en-Y Gastric Bypass (RYGB)

The size of the gastric pouch is normally around 30 mL, which will be similar to the size of the adjacent lower thoracic or upper lumbar vertebra, as seen on fluoroscopy (Fig. 76.8). The contrast should flow reasonably freely through the gastrojejunal anastomosis. The normal caliber of the roux loop is generally less than 2.5 cm. The anastomosis is usually an end-on-side anastomosis, and care must be taken not to mistake the contrast filling of the blind side loop as a sealed leak.

In the early postoperative period, the following complications may present:

76.4.1 Bleeding

Intraluminal bleeding usually originates from the anastomotic site and presents as, hematemesis or malena [3]. This is best investigated with endoscopy. Extraluminal bleeding into the peritoneum is usually caused by damage to either the regional vessels such as the short gastric vessels, or adjacent

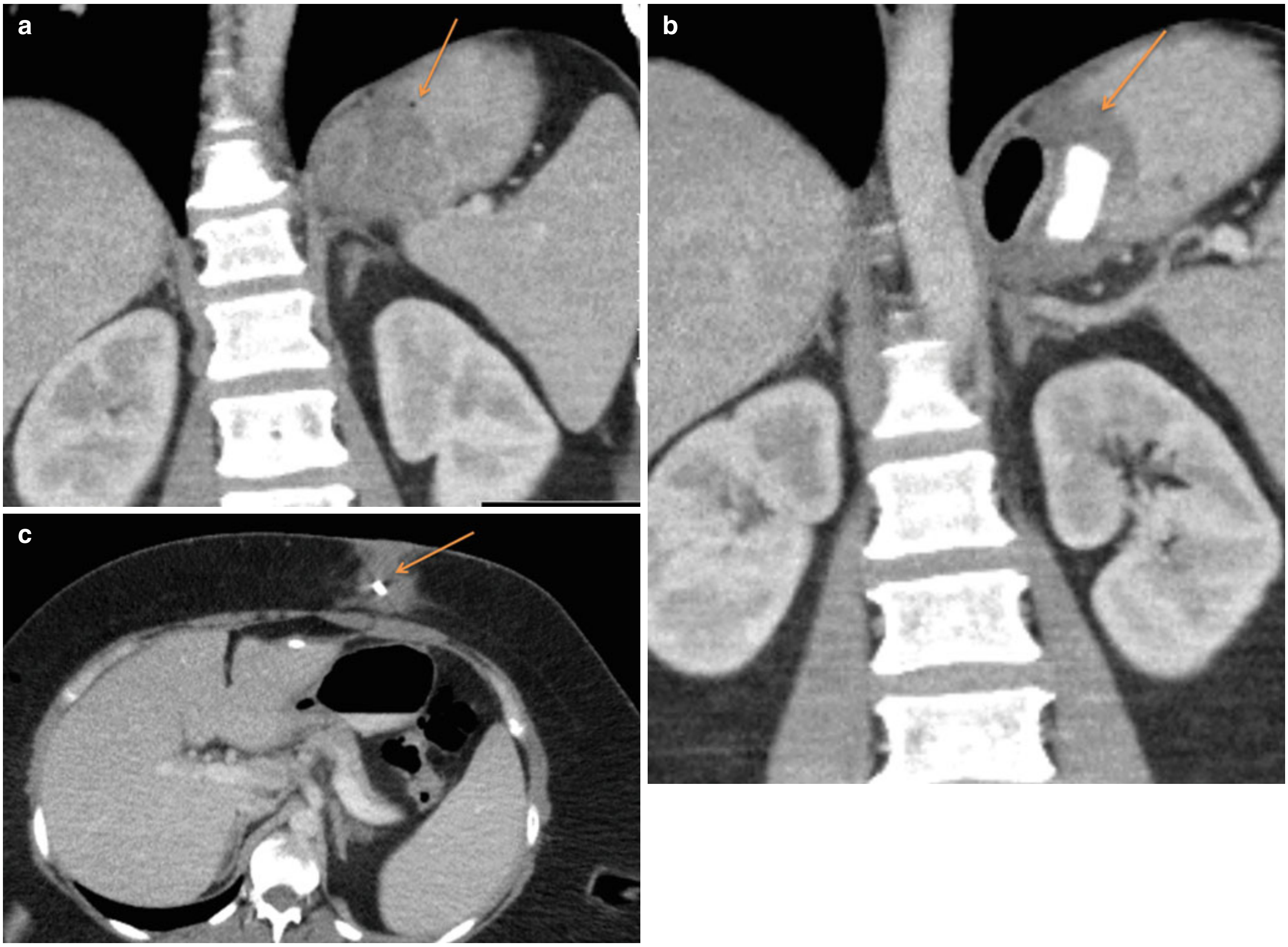

Fig. 76.7 (**a**–**c**) Infection tracked from the port to the gastric band seen as soft tissue or fluid density around the tubing and band. Tiny pocket of air is seen in fluid around the band in (**a**) (*arrow*)

organs including the spleen [8]. If an extraluminal bleed is suspected, CT is the modality of choice, because the hemorrhage will be seen as a high-density fluid collection (Figs. 76.9 and 76.10).

The bleed may be small or large, contained or diffuse. The presentation varies from very few symptoms to life threatening events.

76.4.2 Anastomotic Leak

Anastomotic leak is observed in 2–5 % of patients [5, 6]. In some centers, a routine UGI study is performed at 24–48 h following surgery to assess for anastomotic leak. This is however, not routinely done at all centers. In our center, the anastomoses are checked for leaks using methylene blue at the time of surgery. The commonest site for a leak is at the gastrojejunal anastomosis [5–7, 9]. Other sites include the gastric pouch, jejuno-jejunal anastomosis, and gastric staple line. Both UGI study and CT with oral contrast can be used to detect the presence of a leak. However, UGI study may miss a small leak. In addition, detection of any associated collections is difficult to identify in an UGI study. CT is capable of detecting extravasation, by tracking the presence of oral contrast and/or air outside the bowel lumen (Figs. 76.11 and 76.12).

Leaks from slipped sutures or clips from the closed side limb at the proximal anastomosis (Fig. 76.13) are less common. CT is useful in revealing the size and location of any associated fluid collections, and feasibility of percutaneous drainage. In the very early postoperative period, care must be taken, as air outside the bowel lumen may simply be postoperative from the time of the surgery [3].

76.4.3 Gastric Pouch Dilatation

Dilatation of the gastric pouch may occur due to stomal stenosis that is secondary to edema in the early postoperative period, which requires conservative treatment.

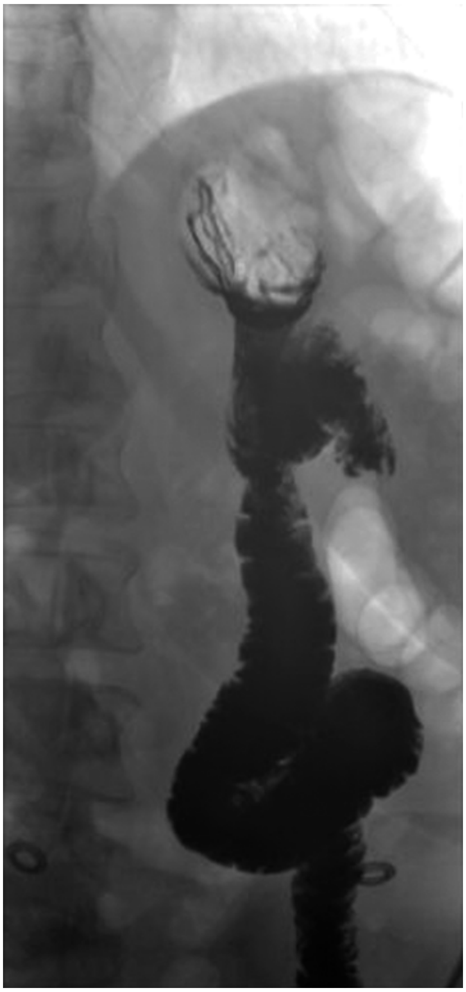

Fig. 76.8 Normal fluoroscopic appearances following gastric bypass (*GP* gastric pouch, *RL* Roux loop, *SB* side branch)

76.4.4 Dilatation of the Gastric Remnant and Duodenum

This is an uncommon occurrence and presents with acute abdominal pain and electrolyte imbalance. A fluid-filled dilated stomach with or without duodenal dilatation is generally visible on CT. The management is usually conservative, but occasionally percutaneous drainage may be required to decompress the stomach. Obstruction of the stomach and duodenal loop can be secondary to a stenosis at the biliopancreatic-jejunal anastomosis [9]. These two findings can be difficult to differentiate during the initial CT examination. Water soluble contrast follow through via the gastrostomy tube maybe helpful (Fig. 76.14).

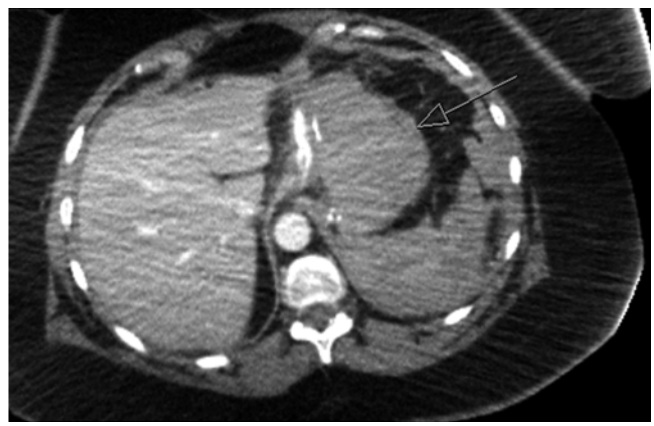

Fig. 76.10 Hemorrhage (*arrow*) adjacent to the gastric pouch

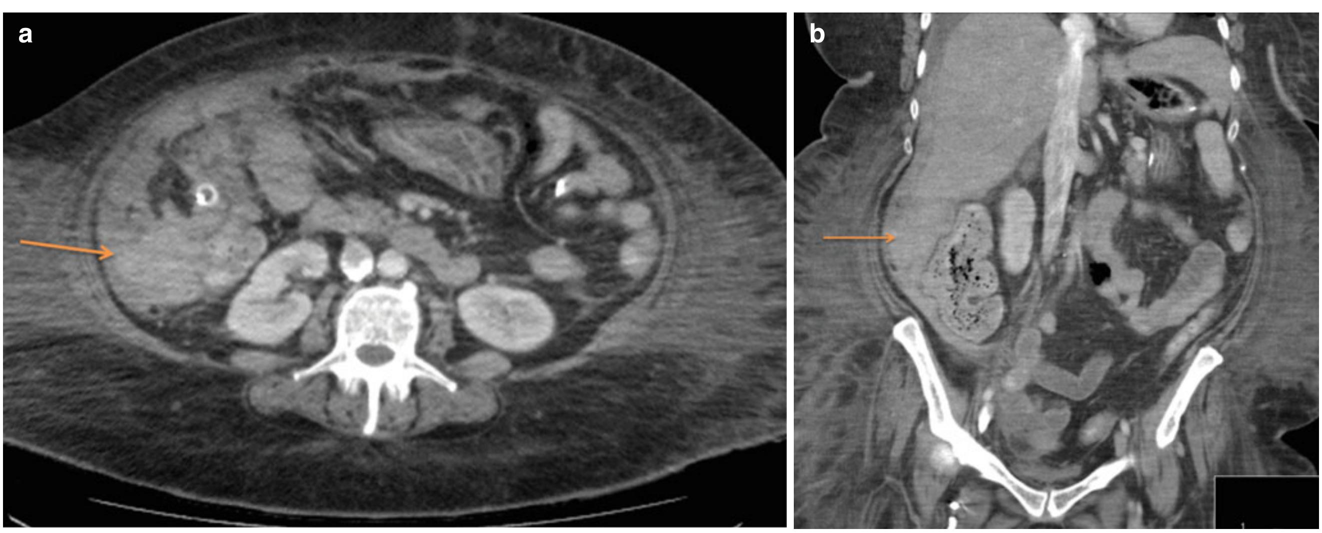

Fig. 76.9 (**a**, **b**) High density fluid (*arrows* pointing towards hemorrhage) is seen in the right paracolic gutter that is tracked from the region of the proximal anastomosis

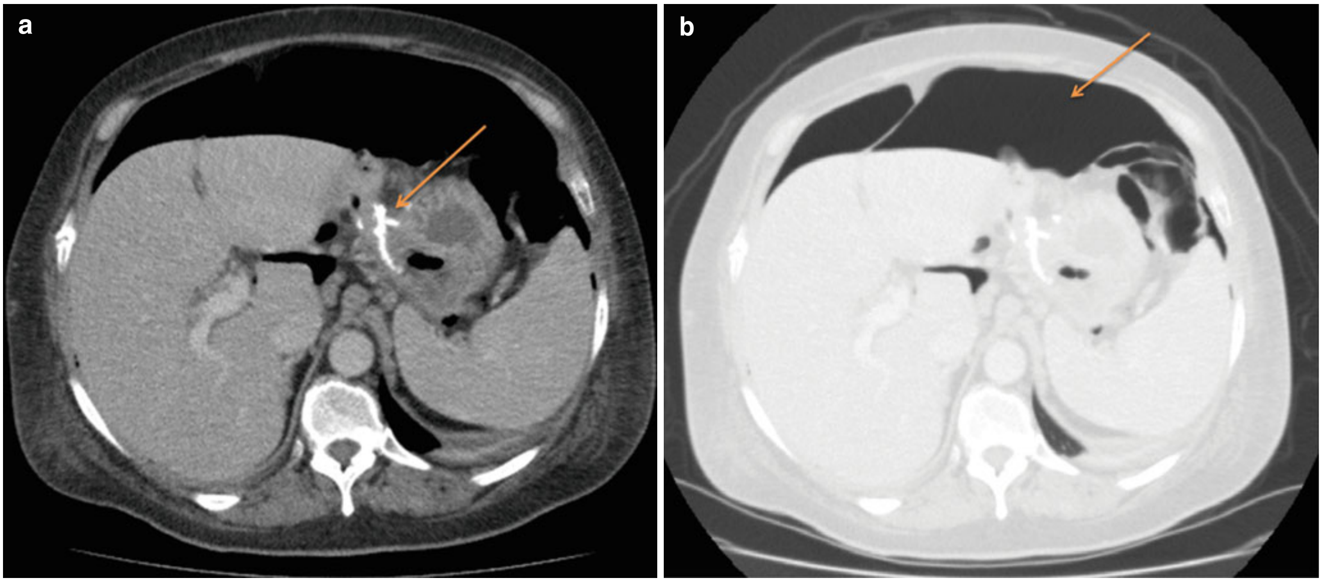

Fig. 76.11 Perforation at the gastrojejunal anastomosis (*arrow* **a**) with large volume of free peritoneal fluid (*arrow* **b**)

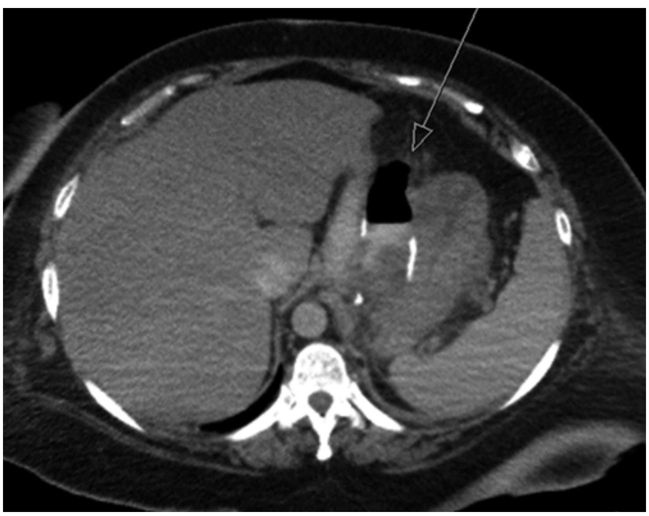

Fig. 76.12 Small collection between the gastric pouch and gastric remnant containing oral contrast and air. *Arrow* indicates a collection containing air and oral contrast indicating a leak

76.4.5 Infection

As with any other abdominal surgery, postoperative infection, such as sub phrenic collection or port site infection are common complications (Fig. 76.15). CT is helpful to monitor fluid collection, and if percutaneous drainage is feasible.

76.4.6 Ischemia

Tension on the surgically-mobilized roux loop may lead to ischemia, which is often self-limiting [9]. This is seen as thickening of the valve conniventes in a barium study, and bowel wall thickening on CT. Chronic ischemia will lead to jejunal strictures or ulceration [9].

76.4.7 Late Complications

76.4.7.1 Obstruction

The commonest site of obstruction is the gastrojejunal anastomosis with stomal stenosis that is secondary to fibrosis. This occurs in 69–77 % of patients with obstructive symptoms [9]. Both endoscopy and UGI study are useful in the assessment of a gastro-jejunal anastomosis, with endoscopy having the advantage of being able to dilate the stenosis at the time of the procedure (Fig. 76.16). These strictures may be managed with dilatation during endoscopy. However, the dilatation itself may also lead to complications (Fig. 76.17).

Other causes include stenosis at the jejuno-jejunal anastomosis and internal hernias. e.g. defect made in the transverse colon mesentery in the retrocolic procedure, small bowel mesentery and in the Peterson's space. CT is the modality of choice in assessing patients with obstruction arising due to causes other than stenosis of the gastro-jejunal anastomosis.

With jejuno-jejunal stricture, the gastric pouch and the roux loop will be dilated (roux loop diameter of greater than 2.5 cm); this is uncommon and may present in the late postoperative period.

Internal hernias, occurring in about 3 % of patients [9], can be difficult to diagnose on CT and are often missed [8].

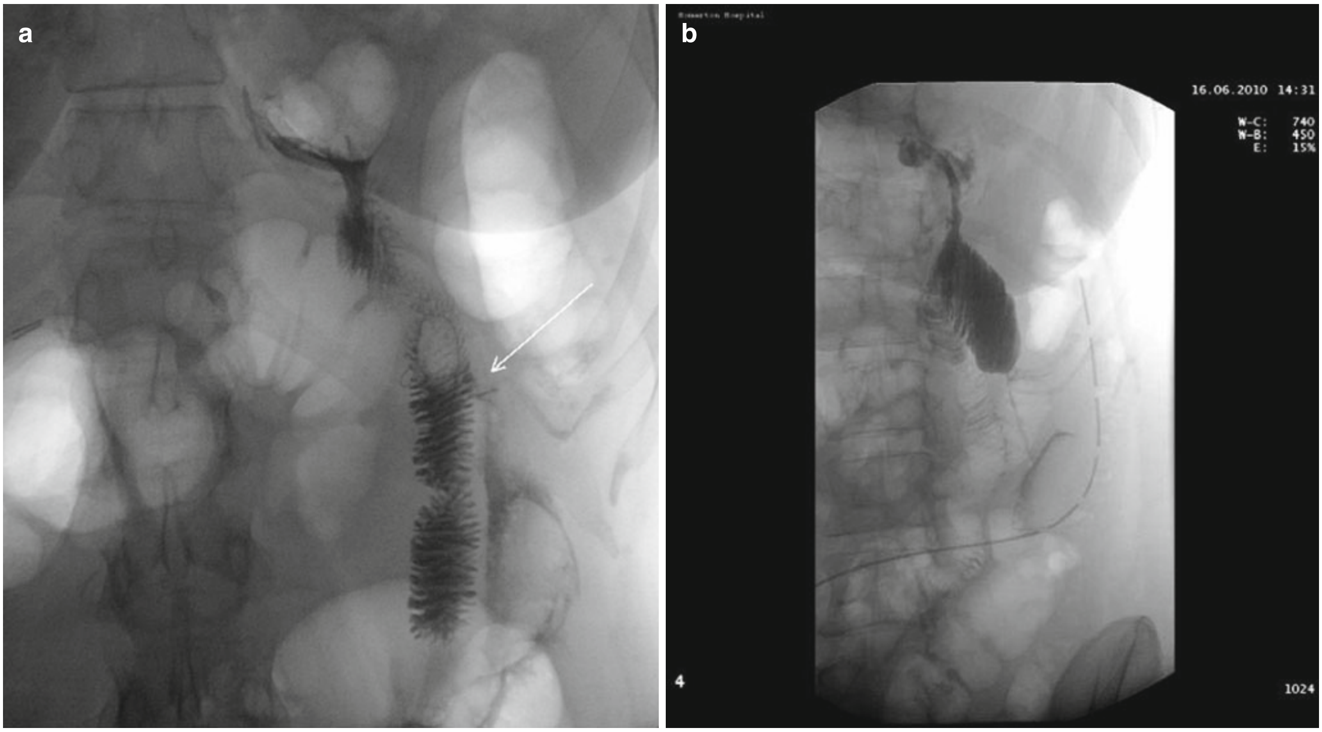

Fig. 76.13 (**a**, **b**) Two images taken 3 days apart showing persistent leak from the closed end of side branch (*arrow*) at the gastrojejunal anastomosis

The features to look for are a cluster of small bowel loops, often in the left upper quadrant or adjacent to the anterior abdominal wall associated with proximal dilatation, displacement of J-J suture line and vessel engorgement (Figs. 76.18 and 76.19) [5–10]. Occasionally, a mushroom sign is seen, where the afferent and efferent limbs of the herniated bowel loop are seen adjacent to each other at the presumed hernial orifice [10]. If the hernia is through the transverse colon mesentery, the bowel loops extend posterior to the gastric remnant that is displaced anteriorly. Weight loss following surgery results in reduction of intra-abdominal fat and subsequent increase in the size of the mesenteric defects, thereby giving rise to internal hernias. With advances in surgical techniques e.g. antecoloic rather than retrocolic placement of roux loop, the incidence of internal hernias has decreased; in most of cases, urgent surgery is indicated.

Adhesions are less common in patients undergoing laparoscopic surgery compared to those undergoing open surgery, although there is an increased risk of port site hernias (Fig. 76.20). On rare occasions, volvulus and intussusception (Fig. 76.21) can also occur.

76.4.7.2 Staple Line Dehiscence Leading to Gastro-gastric Fistula

Dehiscence along the staple line occurs in approximately 3.5 % of patients [5, 9], most often during the early postoperative period, further to an anastomotic leak. In the late postoperative period, the gastro-gastric fistula may be asymptomatic or the patient may experience either poor weight loss or weight gain. It is thought to occur secondary to inadequate dietary control and anastomotic stenosis, which puts a strain on the suture or staple line (Fig. 76.22).

A UGI study is the best modality, since contrast will be visible in the gastric remnant in the early images. The fistula site is often undetectable; however, a large defect maybe seen on endoscopy. On CT, reflux of oral contrast through the jejuno-jejunal anastomosis may result with contrast in the duodenum and the gastric remnant. Care must be taken not to misinterpret this as a gastro-gastric fistula. The possibility of a fistula should be considered if contrast is seen in the gastric remnant but not in the duodenum or pancreatobiliary loop.

76.4.7.3 Gastro-jejunal Marginal Erosion and Ulcers

These are considered as secondary to bile and acid refluxes [3, 9], and are best diagnosed by endoscopy. CT and UGI study have limited role in assessing for erosions as these are poorly seen [3]. Occasionally ulcers may be seen if they are large enough and fill with contrast (Fig. 76.23). The ulcers and strictures are often secondary to reflux, and endoscopy must always be performed to exclude malignancy (Fig. 76.24).

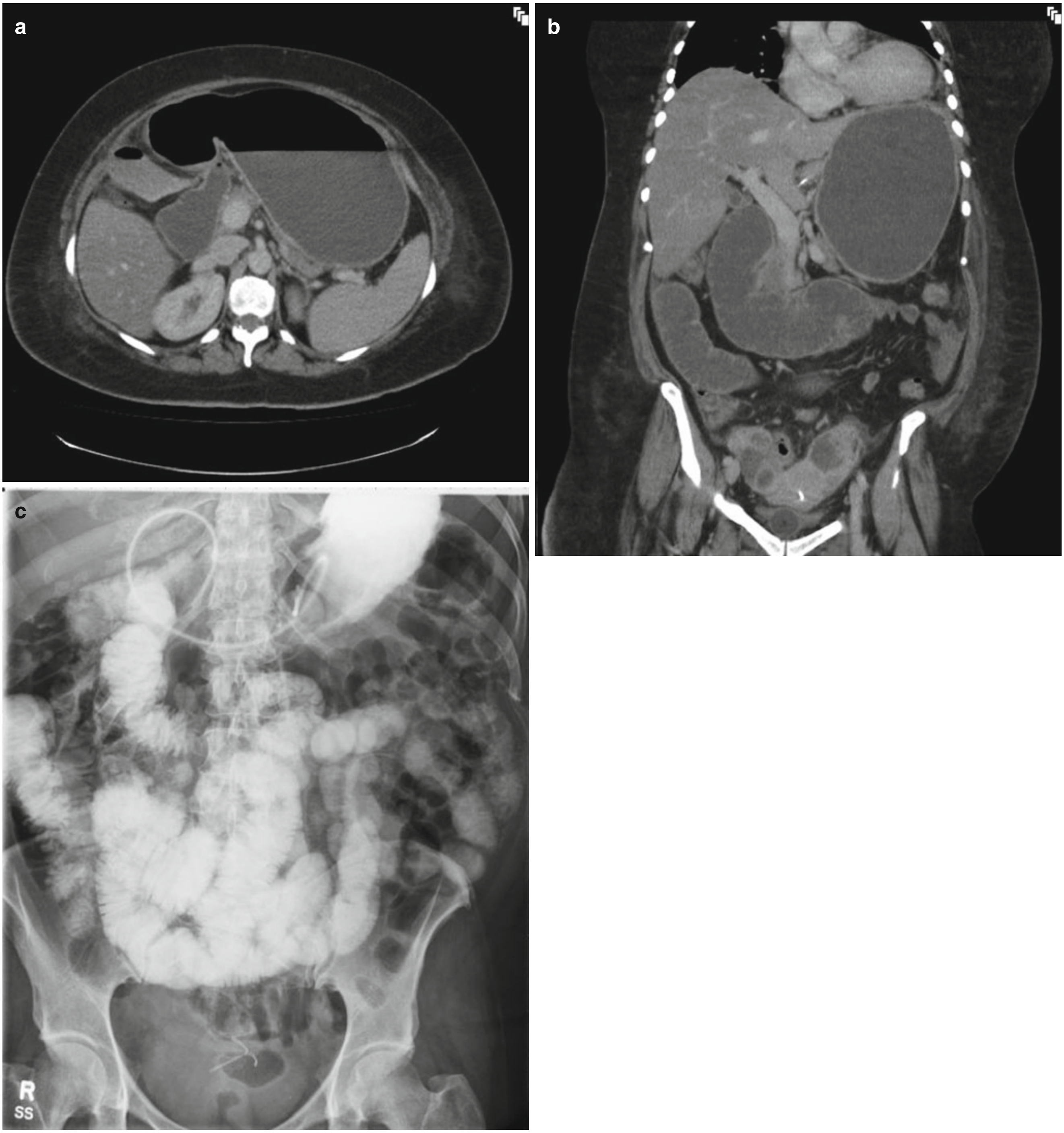

Fig. 76.14 (**a**, **b**) Showing acute dilatation of the stomach and duodenum in the early postoperative period that required decompression with gastrostomy tube. (**c**) Contrast administered via the gastrostomy tube passing into the distal small bowel confirming the presence of acute dilatation and not obstruction (*GR* gastric remnant, *D* duodenum)

Fig. 76.15 Left port site infection (*arrow*)

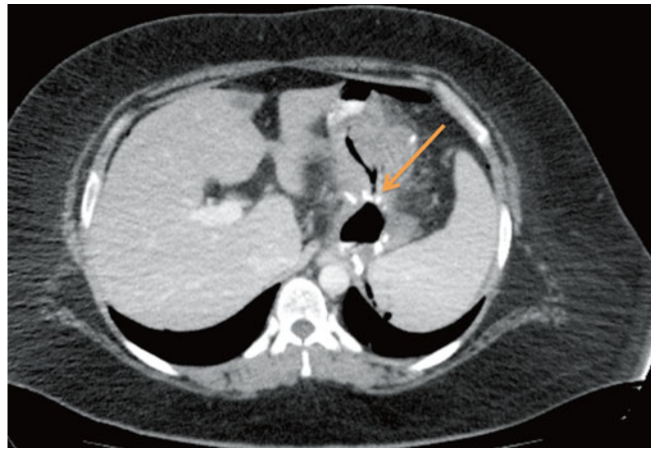

Fig. 76.17 Perforation following endoscopic dilatation of a gastrojejunal anastomosis stricture (*arrow*)

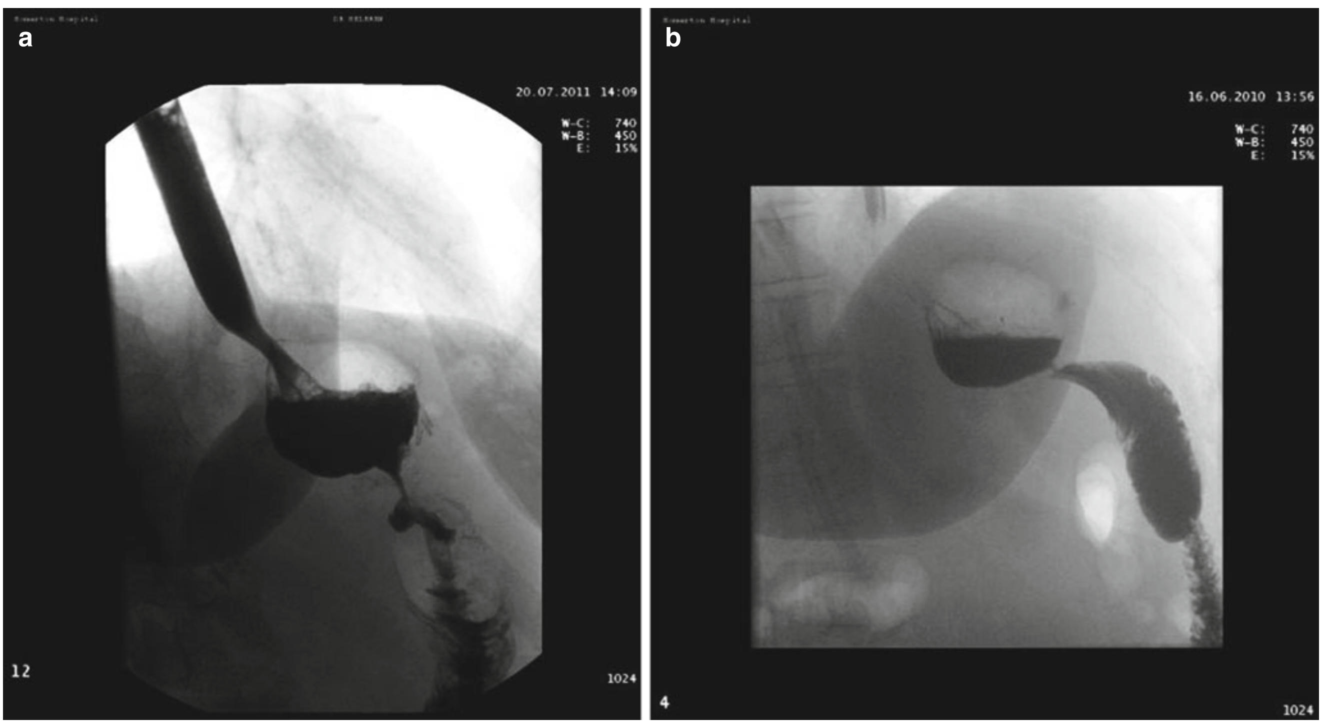

Fig. 76.16 (**a**, **b**) Stricture at the gastro-jejunal anastomosis in different patients

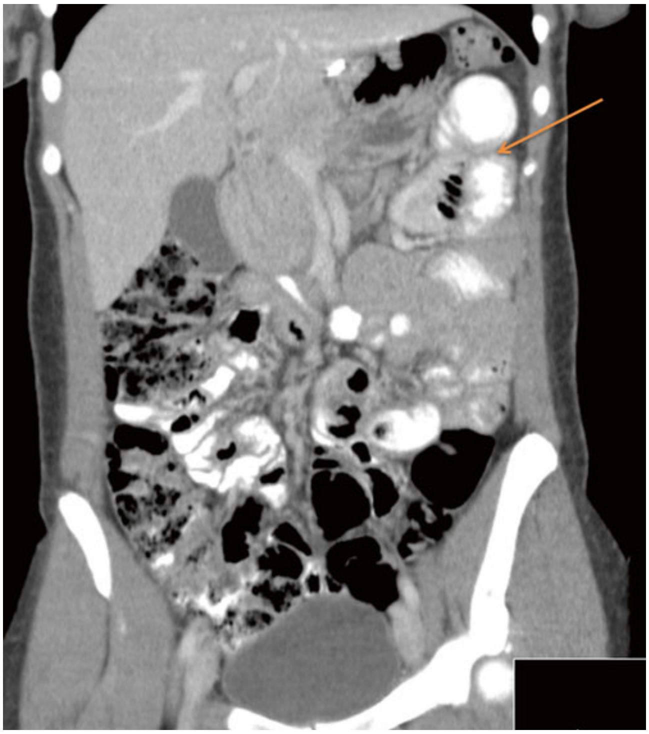

Fig. 76.18 Dilated loop of bowel (*arrow*) in the left upper quadrant, representing an intermittent hernia that recurred 3 years after gastric bypass

Fig. 76.19 Obstruction secondary to an internal hernia showing displace proximal Roux loop (*1*), dilated distal Roux loop and small bowel (*2*), distended vessels (*3*) and transition point at the orifice (*4*)

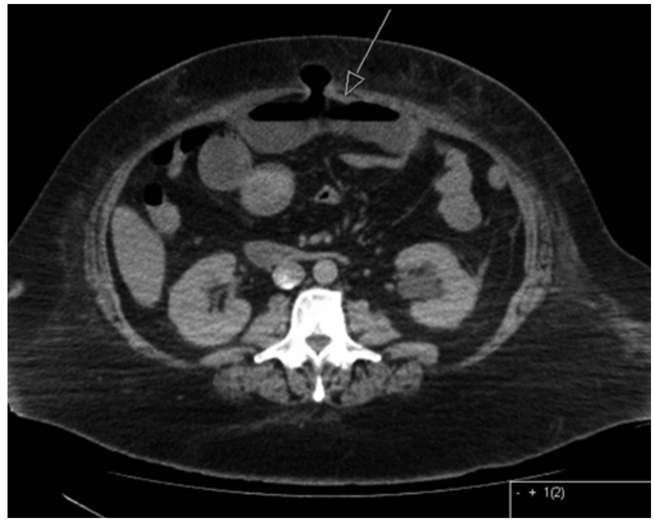

Fig. 76.20 Port site hernia containing the distal Roux loop causing obstruction. The collapsed efferent loop is indicated (*arrow*)

Fig. 76.21 Intussusception at the jejuno-jejunal anastomosis

76.5 Laparoscopic Sleeve Gastrectomy (LSG)

During LSG the gastric volume is reduced to 30–50 mL and appears tubular in shape (Fig. 76.25).

Early complications in patients undergoing LSG are bleeding, wound or suture dehiscence, leaks (Fig. 76.26), infection/collections, gastric dilatation, and port site hernias, which are common complications after any other surgery. CT with oral and IV contrast is the best modality to evaluate these situations (Fig. 76.27).

Late complications are usually related to poor weight loss, and patients are referred for UGI contrast studies to

Fig. 76.22 Gastro-gastric fistula. Contrast is seen in the gastric remnant in the early images of the barium study (*GP* gastric pouch, *GR* gastric remnant)

Fig. 76.23 Large ulcer crater seen at the gastro-esophageal junction in a patient who underwent sleeve gastrectomy

assess the gastric volume. The volume of the stomach is reduced surgically to about 30–50 mL (Fig. 76.25). However, following surgery poor dietary control results in an increase in the volume of the residual stomach. This can be significant with eventual loss of the intended restrictiveness of the procedure resulting in weight gain. This requires re-operation in 4.5 % of patients [5, 9].

In patients with nausea and vomiting, UGI studies are useful to detect complications such as strictures, etc. that can lead to alteration of the shape and volume of the residual stomach.

The gastric shape, volume, and presence of any strictures can be assessed on UGI studies. The normal appearance is a tubular shape. Werquin et al. [11] have described various patterns and shapes of the stomach. These shapes include a tubular shape (the most common and expected shape), superior pouch, inferior pouch, the inferior-superior pouch, and the pseudodiverticular pattern. The extent of resection, and thus the suture line determine these shapes. The tubular pattern describes the shape assumed by the oral contrast. The superior pouch shows a widening of the lumen of the sleeve near the gastro-esophageal junction (Figs. 76.28 and 76.29), and inferior pouch shows a widening of the sleeve in the antral region. The inferior-superior pattern shows widening at both ends of the sleeve as the name suggests. In the pseudodiverticular pattern, there is a diverticular dilatation of the lesser curve.

Gastric emptying maybe a problem, which in some patients may lead to gastro-esophageal reflux. Gastroesophageal reflux is more common in patients with a superior pouch pattern [12, 13].

76.6 Duodenal Switch

This is the second part of the operation following sleeve gastrectomy. Good weight loss has been observed with sleeve gastrectomy, and because of the significant metabolic problems encountered with duodenal switch, this procedure is not commonly performed and is reserved for the super obese patients. There is very little published literature on the radiological findings after this procedure; however, similar complications as with any surgery would apply to this procedure. Wherever possible, CT would be the modality of choice to assess for complications.

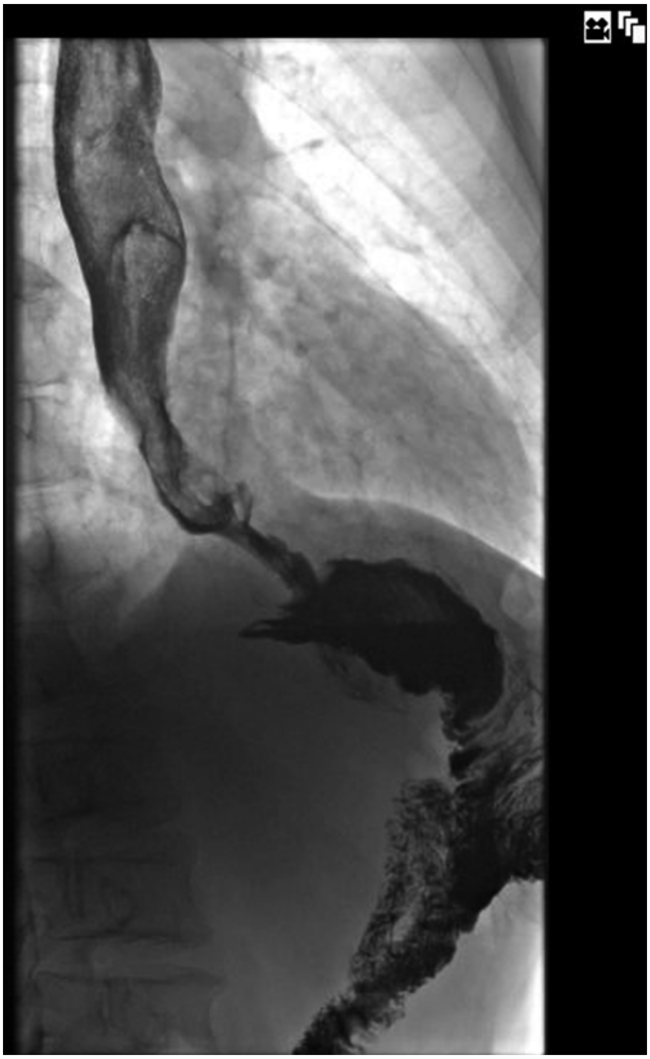

Fig. 76.24 The stricture at the gastro-esophageal junction with irregularity of the distal esophagus proved to be a tumor during endoscopy

Recently, there has been a move to combine procedures. In patients with a deemed failed sleeve gastrectomy or gastric bypass, some patients have been fitted with a gastric band (Fig. 76.30). There is little evidence in the published literature relating to radiological evidence on these combination procedures.

Conclusion

Radiology plays an important part in the management of patients scheduled for obesity surgery. Imaging helps in the diagnosis of both early and late complications, and the investigation and monitoring of postoperative abdominal pain and weight gain, respectively in patients. CT and UGI studies are the primary modalities used. Good communication between surgeon and radiologist is essential for optimum results in patient management.

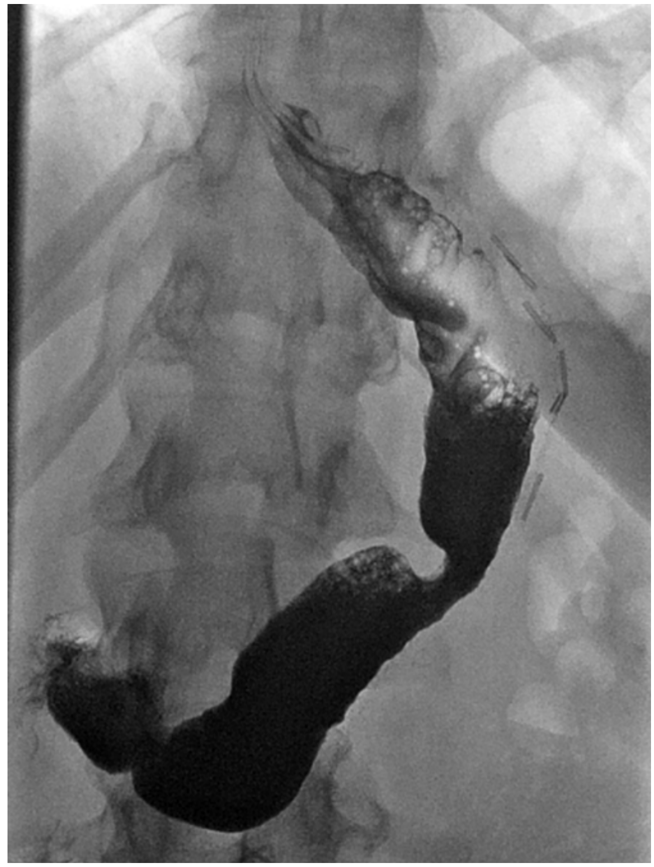

Fig. 76.25 Normal fluoroscopic appearances of residual stomach following sleeve gastrectomy (spot image from a barium meal study)

Key Learning Points

- Increased awareness of the 'normal' post operative anatomy following the common bariatric procedures on radiological imaging.
- To learn the specific complications of the various procedures and the best imaging modality to demonstrate the complication and the extent of the complication.
- Good communication is key between the multidisciplinary team looking after the bariatric patients.

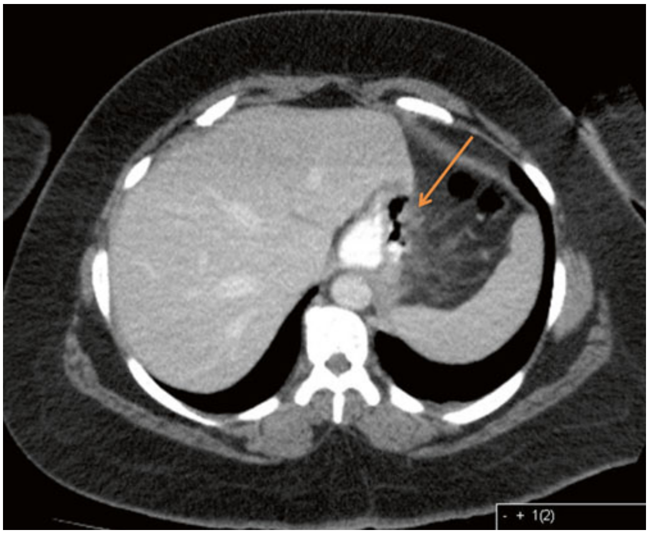

Fig. 76.26 Anastomotic leak after a large meal, a week following sleeve gastrectomy. *Arrow* is indicating the leak resulting in air and contrast collection

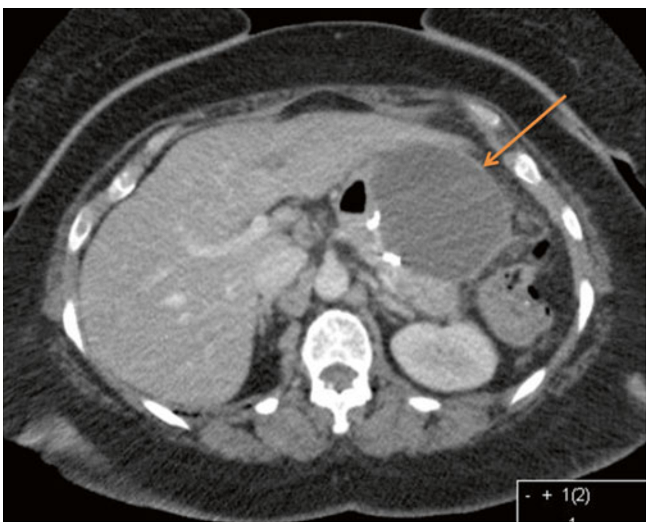

Fig. 76.27 Postoperative collection (*arrow*) adjacent to the gastric remnant following a sleeve gastrectomy

Fig. 76.28 Sleeve gastrectomy with a superior pouch pattern

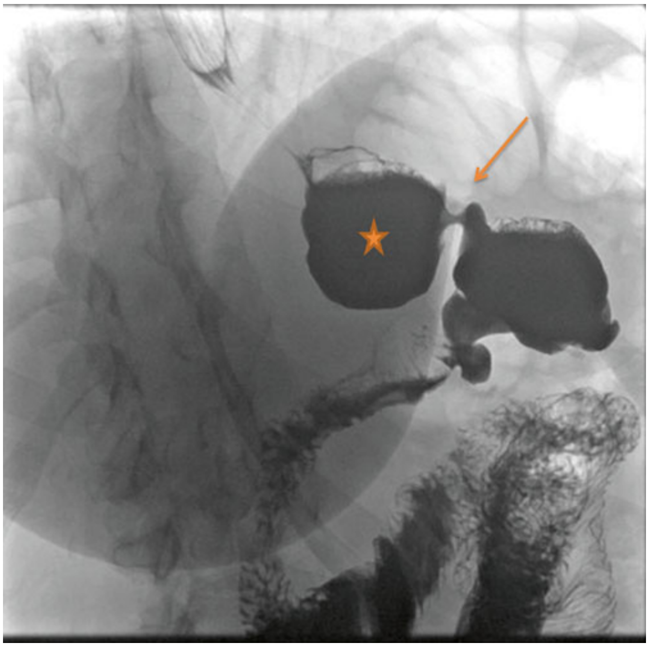

Fig. 76.29 Irregular dilatation of a sleeve gastrectomy with a stricture in the upper stomach associated with a dilated superior pouch. The gastric pouch is *starred* and *arrow* indicates the stricture

Fig. 76.30 Patient who experienced weight gain despite a gastric bypass, was fitted with a gastric band

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Adolescent Bariatric Surgery

77

Bradley C. Linden and Sean J. Barnett

Abstract

The stark increase in global obesity encompasses not only adult population but also pediatric and adolescent population. Morbidly obese adolescents are highly likely to suffer from obesity as adults; enduring some of the same obesity related comorbid disease states with little to no medical options for long term weight loss. These comorbidities tend to have already had a significant impact on their health even as young adults. There are specific guidelines that have been set up for the surgical treatment of morbid obesity in adolescents, which readily align with adult recommendations. The timing of surgery is important given the multitude of medical as well as psychosocial issues that need to be addressed. Recent prospective trials have demonstrated that bariatric surgery in the adolescent population is safe and effective. Roux-en-Y gastric bypass remains the gold standard. The advent of vertical sleeve gastrectomy has supplanted the adjustable gastric banding procedure as the second most commonly performed procedure and is quickly gaining favor amongst many adolescent bariatric surgeons. The general postoperative management of these patients is similar to their adult counterparts with particular attention paid to psychosocial support, frequent follow up, vitamin supplementation, and birth control. As the pool of knowledge regarding bariatric surgery in this population of patients continues to grow, especially the long term response of adolescent to bariatric surgery, the surgical treatment for the morbidly obese adolescent will continue to gain credence as a front line treatment.

Keywords

Adolescent • Bariatric surgery • Obesity • Comorbidities • Bariatric recommendations

77.1 Introduction

As the prevalence of obesity in the adult population has continued to rise significantly over the past decade, these increases are also seen in the pediatric population. It is estimated that in the time frame of 2009–2010, 16.9 % of children and adolescents in the United States were considered overweight based on body mass index (BMI) [1], and as many as 4 % can be considered to be extremely or morbidly obese based on defined criteria [2]. The National Child Measurement Program in England measures every child for height, weight, and BMI at reception (age 4–5) and year 6 (age 10–11). According to figures available in 2012–2013, 33.3 % of children in year 6 (age 10–11) are considered overweight or obese with a prevalence of 18.9 % [3]. The National Health Service of England further estimates that three in ten boys and girls aged 2–15 years are considered overweight or obese [4]. The inherent risk of becoming obese as an adult for obese children is roughly 77 % with all of the accompanying medical complications and socioeconomic ramifications [5]. In morbidly obese adolescents, durable, sustained

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weight loss by conventional means has shown little to no success, leading to the advent of bariatric surgery for their ultimate treatment.

77.2 Definitions

Categorizing obesity in children requires correction for age and sex. Consequently, the nomograms developed using the National Health and Nutrition Examination Survey (NHANES) data have been extrapolated to define morbid obesity as body mass index (BMI) greater than 99th percentile for age and sex [6]. There are fine technical arguments about the statistics used to make these assumptions, however, the use of 99th percentile as a BMI cutoff for morbidly obese children has persisted and is reasonably valid.

In adults, weight loss operations are indicated in patients with BMI greater than 35 when associated with major comorbidities such as diabetes, moderate to severe obstructive sleep apnea, pseudotumor cerebri and severe nonalcoholic steatohepatitis (NASH). Patients with BMI greater than 40 qualify for weight loss operations when comorbidities such as mild obstructive sleep apnea, hypertension, insulin resistance, glucose intolerance, dyslipidemia and impaired quality of life, are present [7]. Adolescent obesity is now defined by these same criteria [8], however, there is growing evidence that indications such as psychosocial isolation are under appreciated as important operative indications [9–11]. The use of weight loss operations to optimize the child's ability to meet important psychosocial developmental goals could substantially contribute to improved overall societal contribution and wellness.

The majority of adolescent weight loss surgery candidates are in their mid to late teens, and, as a prerequisite for having a weight loss operation, they have reached near-adult stature. Consequently, the use of BMI directly, rather than BMI percentile could be functionally adequate.

77.3 Consequences of Adolescent Morbid Obesity

77.3.1 Obesity Related Chronic Disease in Adolescents

Obese adolescents suffer from many of the same chronic obesity related medical conditions as their adult counterparts and are not immune to their effects merely because of their young age. The relative increase in prevalence of these conditions reflects the significant increase of obesity in the young patient. Their onset at a relatively young age can carry lasting ramifications later on into adulthood [12].

77.3.2 Glucose Impairment

Childhood obesity has been linked to many abnormalities of glucose regulation. The most prominent of these is hyperinsulinemia (60–80 %), which could be manifested by insulin resistance due to the ongoing low grade chronic inflammation seen in obese patients [13]. This can in turn lead to impaired glucose tolerance (12–15 %) and ultimately type 2 diabetes mellitus (1–6 %) [13]. The recent paper from the teen longitudinal assessment of bariatric surgery (Teen-LABS) study found that 13.6 % of patients undergoing bariatric surgery were diagnosed with diabetes prior to intervention [14]. As the obesity epidemic continues to rise in the pediatric population, the center for disease control (CDC) predicts that 33–50 % of all Americans born in the year 2000 will eventually develop type-2 diabetes sometime within their life span [14]. A recent study, although with a relatively small sample size, of obese diabetic adolescents who underwent Roux-en-Y gastric bypass (RYGB) showed that 10 of 11 were able to discontinue oral hypoglycemic medications following surgery [15]. This data in adolescents supports numerous studies in adults demonstrating the significant benefit of bariatric surgery in combating the effects of glucose impairment.

77.3.3 Cardiovascular Effects

Although the prevailing thought is that cardiovascular risk factors manifest themselves later in life, almost 60 % of obese children in the Bogalusa Heart Study had one risk factor for cardiovascular disease and 20 % had two or more [5]. Significant cardiovascular risk factors are found in obese adolescents including the aforementioned glucose impairments [13, 14], increased serum lipids, and hypertension [15]. Bariatric surgery, namely RYGB, has been demonstrated to reduce hypertension from 46 to 20 %, 1 year after surgery [13]. There is also a significant reduction in left ventricular mass (LVM), due to remodeling of the posterior ventricular wall and reduced septal thickness, thus improving overall cardiac function [16].

77.3.4 Nonalcoholic Fatty Liver Disease

Multiple studies have demonstrated significant improvement or complete resolution of steatohepatitis and subsequent fibrosis in adults following bariatric surgery; however, there is little data in the adolescent population. Biopsies from morbidly obese adolescents undergoing bariatric surgery have revealed nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) in up to 83 % of patients [17], demonstrating that this is a significant issue in this population.

77.3.5 Obstructive Sleep Apnea

Children with chronic obstructive sleep apnea (OSA) demonstrate development and significant progression of both right and left ventricular hypertrophy and subsequent dysfunction [16]. Although an European epidemiological study investigating childhood obesity has documented OSA rates as high as 46 % in obese children [18], bariatric surgery has shown to effectively treat this disorder and allow for the reversal of cardiac abnormalities.

77.3.6 Menstrual Irregularities and Polycystic Ovarian Syndrome

In a recent study looking at menstrual concerns and contraceptive use in obese female adolescents undergoing bariatric surgery, 84 % of patients demonstrated some form of menstrual irregularity (menorrhagia, oligomenorrhea, or dysmenorrhea) and 36 % had a diagnosis of polycystic ovarian syndrome (PCOS), much higher than the general population [19]. These findings are not surprising as in obesity there is increased aromatization of testosterone to estradiol in fat tissues resulting in elevated levels of free androgens.

77.3.7 Psychological and Quality of Life Issues

There is significant evidence demonstrating a link between those who are obese as adolescents and the development of depression [20] and the risk of suicide [21]. There is also a significant association between obese children and the development of depression well into adulthood [20]. Following gastric bypass, adolescents show improvement in both depression as well as quality of life scores [22].

77.4 Guidelines

The guidelines for the use of bariatric surgery for the treatment of adolescent obesity have been evolving over the past three decades. The original National Institutes of Health Consensus Development Statement deferred making a recommendation for adolescent operative criteria due to lack of adequately powered data on adolescent outcomes [7]. Subsequently, there is increasing volume of data to suggest that the indications for adolescent weight loss operations are very similar to those for adults and there are even more evolving criteria that are unique to adolescents [8, 23].

Since the proposal of early adolescent program constructs, several consistent themes are seen. These include requirements for a multidisciplinary approach to operative candidate assessment, patient and family psychological evaluation, obligatory attempts at medically supervised weight loss and assessment of the family and home environment [24, 25].

Importantly, adolescent bariatric surgery programs require institutional commitment to the development and maintenance of a robust multidisciplinary program rather than simply focusing on the performance of operations and procedures for morbidly obese patients.

Long term follow up is central to obtaining the best outcomes after bariatric surgery. Achieving good long term follow up in adults is difficult, and even more so for adolescents [26]. Consequently, adolescent bariatric surgery programs must have substantial resources committed to ensuring that the patients follow up regularly so that optimal weight loss is achieved, nutritional needs are met and metabolic complications are avoided, identified early and intervened upon.

In England, the National Institute for Health and Clinical Excellence (NICE) has approved surgery as an accepted treatment modality on exceptional circumstances. Guidelines issued in 2006 are similar to National Institute of Health (NIH) consensus statement and emphasizes need for specialist multidisciplinary team, need for psychological assessment and long term follow up [27]. Similar guidelines are also approved by Scottish Intercollegiate Guidelines Network (SIGN) in 2010 [28].

77.5 Timing of Operation

As a general rule, the earliest ages at which adolescents can be considered for operations are 13 years for girls and 15 years for boys [24]. These ages are largely based on the patient having achieved around the 95th percentile for mid-parental height (skeletal maturation nearly complete) and having entered into puberty. These criteria were developed largely due to concerns over postoperative bone mineralization in the setting of changes in the absorption of calcium and vitamin D [29], as well as the effects of weight loss on the normal rate of development of secondary sexual characteristics [24].

Once a child presents to a bariatric surgery program, he or she needs to meet several milestones before proceeding to the operating room. This is where the multidisciplinary team in an adolescent bariatric surgery program is fully utilized. It routinely takes up to 6–12 months for an adolescent to successfully meet the milestones in a fashion that leads to unanimous team opinion that the child is ready to have a weight loss operation [22].

A full medical evaluation needs to be performed to identify undiagnosed and untreated comorbidities of morbid obesity [30]. A complete psychosocial evaluation of patient and parents must be performed. The child's physical activity, nutritional habits and home nutritional environment need to be ascertained. Once this comprehensive evaluation has been completed, identified medical, psychosocial, nutritional and exercise interventions need to be instituted. Major psychological disorders, including eating disorders, are identified and treated. The presence of eating or psychiatric disorders does not preclude proceeding to an operation, however, their effects must be substantially mitigated through medication, psychotherapy or both [31].

While there is an initial intake evaluation for all of the varied subspecialists within the multidisciplinary adolescent bariatric surgery program, the team's understanding of the complex psychosocial, nutritional, and physical activity aspect of an adolescent's daily life are substantially augmented by ongoing regular monthly follow ups [25]. It is during these subsequent visits that subtle psychological and interpersonal needs between the patient and their parents are teased out. Additionally, the follow up visits are used as an attempt to institute habits and behaviors that will make the adolescent successful at achieving their health goals after having had a weight loss operation. Finally, the relationships that are established during the 6–12 month period are thought to increase the probabilities of patient compliance with long term follow up.

77.6 Types of Operations

77.6.1 Surgical Options and Outcomes for Bariatric Surgery in Adolescents

Roux-en-Y gastric bypass (RYGB) continues to be the most commonly performed bariatric procedure in the adolescent population. With the introduction of the vertical sleeve gastrectomy (VSG) as a primary operation, the number of adjustable gastric band (AGB) operations has significantly decreased [32]. Although the duodenal switch has been performed in limited numbers in the past, it is generally avoided in this population of patients given the significant nutritional and malabsorptive complications. The most recent landmark publication from the teen longitudinal assessment of bariatric surgery study group has demonstrated that bariatric surgery in adolescents with morbid obesity and significant comorbidities has a favorable short term safety profile similar to or better than the majority of adult studies [14].

77.6.2 Roux-en-Y Gastric Bypass

Roux-en-Y gastric bypass (RYGB) has long been considered as the gold standard operation for weight loss in the United States for over five decades. There have been numerous small, retrospective publications that have examined the experience with bariatric surgery in adolescents where the predominant operation performed was the RYGB and demonstrated a sustained reduction in excess body mass and significant improvement in the majority of comorbidities similar to their adult counterparts [33]. As previously stated, those undergoing RYGB have shown significant improvement in hypertension [15], diabetes [13, 15], cardiac abnormalities [16], menstrual irregularities [19], and psychosocial issues [22]. A more recent publication looking at RYGB over a range of body mass indexes has demonstrated a fixed ceiling for weight loss (BMI reduction of approximately 37 % at 1 year), irrespective of preoperative weight [34]. This, coupled with the recent excellent safety profile data demonstrated through Teen-LABS [14], has lead to the avocation of earlier operation for the morbidly obese adolescent.

77.6.3 Vertical Sleeve Gastrectomy

The use of vertical sleeve gastrectomy (VSG) has been steadily on the rise and has recently outpaced the AGB [32]. A recent publication by Nguyen et al. utilizing the University Health System Consortium database demonstrated a rapid increase in the use of VSG and decrease in AGB over a 2 year period with the morbidity, mortality, and costs settling out between those of RYGB and AGB [35]. Data for the use of VSG in the pediatric population is modest with the largest retrospective review published by Alqahtani from Saudi Arabia. His most recent retrospective review of 108 severely obese children demonstrated an average excess weight loss of 65.8 % at 12 months with significant resolution of dyslipidemia (70 %), hypertension (75 %), OSA (90.9 %) and diabetes (93.8 %) [36]. With a safety profile similar to or better than adults [14, 36], excellent efficacy similar to RYGB [36], and less issues with vitamin deficiency when compared to RYGB, VSG is rapidly becoming the procedure of choice for morbid obesity in the adolescent.

77.6.4 Adjustable Gastric Banding

Since the adjustable gastric band (AGB) is a device, its use is governed by the Food and Drug Administration (FDA) and remains approved for use only in those patients that are 18 years of age or older. The most comprehensive study for its use in the adolescent population originates from Australia in which AGB was compared to medical treatment alone in a prospective randomized controlled trial. Over a 2 year period, 50 morbidly obese adolescents were randomized into either group. The average weight loss over that time period was roughly 79 % in the AGB group compared to only 13.2 % in the medical group. Of note there was a 33 % re-operation rate in the AGB group, mainly due to proximal pouch dilation [37]. Given the plummeting numbers of ABG in favor of VSG in the United States, it is unlikely that an adequate study will be performed to gain FDA approval in those under the age of 18.

77.7 Postoperative Management

Initial postoperative management is similar to adult bariatric surgery including particular attention to early warning signs of gastrointestinal leak. Once patients are discharged they are advanced to a high protein liquid diet and slowly advanced during follow up. The diet advancement is similar to adult programs. Given the significant needs of the adolescent patient, including but not limited to psychosocial issues, patients are seen on a more regular basis than their adult counterparts. As an example, at a large pediatric institution specializing in adolescent bariatric surgery, patients are seen at 2, 6 weeks, 3, 6, 12, 18, 24 months, and then yearly following surgery. All of these visits generally involve a visit to a social worker who monitors the psychosocial make up of the patient.

Postoperative vitamin supplementation typically consists of two pediatric chewable multivitamins, a calcium/vitamin D supplement, and an iron supplement for menstruating females (see Table 77.1) [38]. Serum chemistries, complete blood count and representative B-complex vitamin levels are obtained at 6 and 12 months postoperatively and then yearly.

The American College of Obstetricians and Gynecologist (ACOG) recommends postponing pregnancy for 12–18 months following bariatric surgery [39]. These recommendations coupled with changes in self esteem and increased fertility after bariatric surgery leading to an increase in unplanned pregnancies among adolescent females following bariatric surgery [40] has lead many programs to offer intrauterine device (IUD) placement at the time of surgery. IUD placement in the adolescent population is well accepted and serves as a viable option among this population of patients [19].

Conclusion

Adolescent bariatric surgery has evolved from a rare and controversial intervention to a potent, safe and valuable modality in the treatment of childhood morbid obesity. The argument has been made that it is unethical to perform these operations for children. Mounting data clearly indicate that early intervention is critical to prevent the long-term consequences of morbid obesity and, consequently, it may now be unethical to not perform these operations for those that need them.

Table 77.1 Recommended nutritional supplementation following weight loss surgery

Supplement	Recommendation
Multivitamin (with folic acid)	One to two daily
Calcium citrate with vitamin D	1500–1800 mg/day
Vitamin D	1000 IU/day (if deficiency found preoperatively)
Vitamin B12	500 mcg/day oral or 1000 mcg/month intramuscular
Elemental iron	65 mg elemental iron for menstruating females
Vitamin B1	Consider 50 mg daily in first 6 months
Vitamins A and K	Treat if symptomatic

Labs are checked at 6 months postoperatively and then yearly unless symptoms arise

Adapted from: Barnett [41]. With permission from Elsevier

Key Learning Points

- Roughly 17 % of children in the United States and the United Kingdom are considered obese and approximately three forth of those will be obese as adults
- Consequences of adolescent obesity are similar to adults including glucose impairment, cardiovascular issues, sleep apnea, NAFLD, menstrual irregularities, and psychosocial issues
- Indications for weight loss surgery in adolescents mimics those for adults with prerequisite multimodal, team approach
- Bariatric surgery in the adolescent has been shown to be safe and effective

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Body Contouring Surgery after Bariatric Surgery

78

Mark Soldin, Charles Jack Bain, and Maleeha Mughal

Abstract

Bariatric surgery leads to massive weight loss (MWL) in patients resulting in heavy folds of redundant skin and contour irregularities. The resultant functional problems have raised concerns about the quality of life of these patients. As a direct consequence, this has led to an increasing uptake of body contouring surgery, to manage the complex problems associated with redundant skin. Body contouring surgery in this context, is thus reconstructive surgery performed after massive weight loss. This is the final part of the MWL patient journey.

Keywords

Massive weight loss • Body contouring surgery • Abdominoplasty • Brachioplasty • Thigh lift • Total body lift

78.1 Introduction

The bariatric treatment of the worldwide obesity pandemic has created the fastest growing field in plastic surgery—body contouring surgery (BCS). Around 70 % of massive weight loss patients are left with redundant folds of tissue that impact on their quality of life. These folds are heavy and cumbersome, and present functional and esthetic problems (Fig. 78.1). The techniques used to correct these severe deformities are reconstructive modifications of well-established esthetic procedures. This differential in terminology and purpose is important to emphasize as healthcare funding for cosmetic surgery is restricted, whereas BCS usually falls well within the reconstructive remit because of the debilitating manifestations for example, intertrigo, blisters, attrition ulcers of the skin folds, limited mobility, difficulty with clothing, continued social isolation and relationship issues. This chapter reviews the preoperative assessment of the MWL patient, the common body contouring procedures, potential complications, and pitfalls in management thereof.

78.2 Preoperative Assessment of the MWL Patient

The physiological and psychological effects of obesity and subsequent MWL can be profound and may significantly impact upon recovery from body contouring surgery. The initial consultation with the patient explores their functional disabilities, perception of body image, likely expectation of surgical outcome as well as their fitness for surgery.

78.2.1 Nutritional Considerations

Nutritional deficiencies are thought to be present in 50 % of MWL patients, and this is not limited to those undergoing malabsorptive procedures [1]. Patients with restrictive surgery may also develop nutritional deficiency resulting from emesis. Those who have lost weight through diet and exercise alone have often followed a poorly balanced dieting

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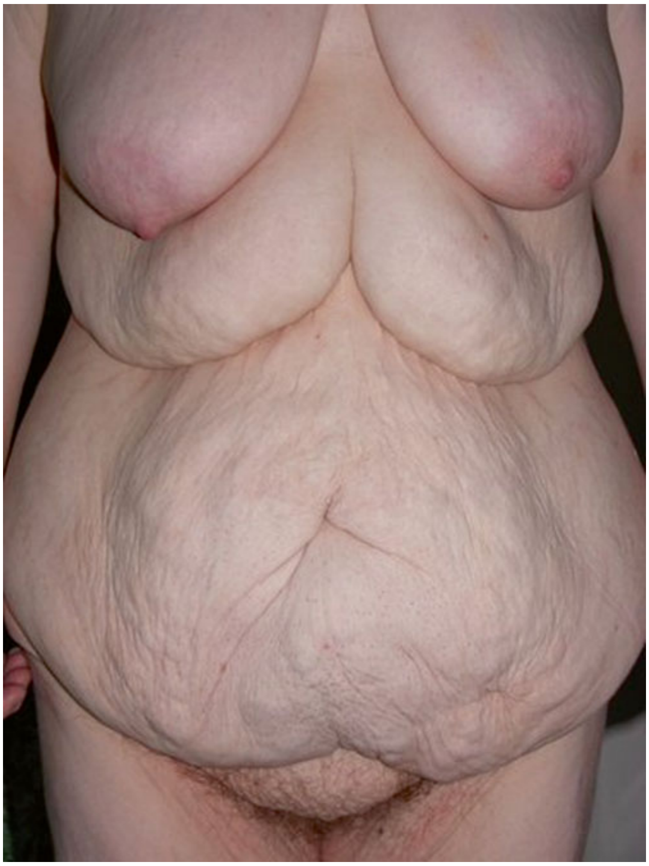

Fig. 78.1 Appearance of anterior trunk post massive weight loss

regime and neglected their general health. Anemia should be identified preoperatively as body contouring surgical procedures involve removal of large amounts of vascularized tissue resulting in significant blood loss. Folate or Vitamin B 12 deficiency is also possible, and correction of anemia preoperatively is of paramount importance [2].

Albumin deficiency may also be evident in those who have undergone malabsorptive bypass procedures and will impair wound healing and recovery unless identified and addressed prior to surgery [3].

78.2.2 Weight Loss and Weight Stability

Rapid and continued weight loss places the patient in a 'catabolic' state. Wound healing is poor and elective surgery is therefore postponed until the weight has been stable for at least 6–12 months [3, 4]. Weight stability indicates a return to an anabolic state and improved surgical safety.

It is of note that a high body mass index (BMI) at the time of surgery directly correlates with a higher incidence of peri-operative complications [5–7]. The term 'fully deflated' is commonly used to describe the ideal body-contouring patient and this state is usually reached when the BMI is less than 30 kg/m^2. This sometimes leads to mixed patient messages with the bariatric team emphasizing that 50 % excess weight lost (EWL) is considered a success, and plastic surgeons being concerned about surgical complications when performing BCS on patients still obese.

78.2.3 Medical and Surgical History

A thorough medical history must be taken preoperatively. Diabetes and hypertension are associated with obesity, which may persist after weight loss and compound wound healing problems [8]. Autoimmune conditions, steroid or anti-inflammatory usage, and some endocrine conditions, such as hypothyroidism, can also impair wound healing [8].

A drug history must include information on use of herbal medications, which are known to be associated with coagulopathy [9–11]. Assessment for increased risk of thromboembolic events should be performed in the preoperative period and hematological advice should be sought in high-risk patients [12]. The incidence of venous thromboembolism however seems to be low with a recent study quoting the overall rate of risk at 1.96 % [13].

Past surgical history should also be discussed in the pre-operative assessment as previous surgery may compromise the vascularity of skin flaps in subsequent contouring procedures [14]. Previous lymphadenectomy will have particular relevance in limb contouring, as there may be a higher risk of postoperative lymphedema and hence wound breakdown [8]. Smoking should be discouraged in patients undergoing body-contouring surgery, as smokers are at an increased risk of wound healing complications [15, 16].

78.2.4 Psychological Considerations

Bariatric surgery may not address the psychology and emotional well being of the obese patient. The same psychological frailty exists in these patients after weight loss, and may be made worse by the weight loss sequelae. Depression and other psychopathologies are common, and patients should continue to get psychological support throughout their recovery where necessary [1]. Establishing a clear plan and balancing expectations from the outset is paramount. MWL patients are usually happy to accept significant scarring in exchange for removal of redundant tissue and restoration of function and comfort, but the common complications such as wound healing, seroma and the need for revisional operations need to be explained. Use of diagrams here is extremely beneficial to aid patient understanding of scar placement and the necessary staging of operations.

78.2.5 Multidisciplinary Team Approach

Given the physiological and psychological challenges presented by the MWL patient, a multidisciplinary team approach should be used with close collaboration between the bariatric team and the plastic surgeon [17].

78.3 Techniques in Body Contouring Surgery

As there are numerous body areas requiring contouring it is not advised to perform all the contouring in a single operation. A staged approach is taken to optimize safety. The author's practice combines abdominoplasty (or lower body lift/belt lipectomy) with the brachioplasty. The upper trunk reconstruction is combined with an inner thigh lift, thus completing the reconstruction in two operations, which balances surgical risk and number of admissions well. Separating body areas prevents excessive interference with regional blood supply, and allows for optimal tissue resection without competing vectors for wound closure. Combining abdomen/arms and breasts/thighs allows for the common areas of concern to be addressed in two 5–6 h operations. The MWL patient may also experience facial fat atrophy and skin laxity, which renders an aged appearance. The face is often the last area to be addressed in the MWL patient, and a variety of rejuvenation techniques, including rhytidectomy, can be used, but these are beyond the scope of this chapter.

78.3.1 Contouring of the Trunk

The trunk is further subdivided into the upper trunk (which includes the breast, flank and upper back rolls), and the lower trunk (which includes the abdominal pannus, buttocks and mons pubis). The abdominal pannus causes most concern to patients and is usually addressed primarily. Surgical strategy is tailored depending on BMI and fitness. In the obese patient, a simple, time-efficient procedure is indicated in the form of an apronectomy. A full abdominoplasty or a lower body lift is performed on patients only when their weight is optimized, depending on whether circumferential contouring is required.

78.3.1.1 Upper Body Lift

The upper body lift (UBL), like the lower body lift (LBL), is a circumferential procedure [18]. Goals in both sexes include excision of back rolls, re-balancing of nipple areolar complex (NAC) vector and correction of breast parenchymal ptosis. In women, augmentation of the breasts can also be performed with autologous tissue or implants.

78.3.1.2 Female Upper Body Lift

The female upper body lift comprises excision of back rolls, sometimes to the midline posteriorly, and mastopexy. The goals of the mastopexy are to 'obtain a youthful, well-contoured breast with upper pole fullness and appropriate nipple positioning, yielding an overall balanced and long-lasting result [19]. Inverted-T mastopexy tends to be the technique of choice in patients with sufficient breast volume. In this technique, the NAC is elevated on a pedicle and the breast parenchyma reshaped beneath it and secured to the chest wall to its new, elevated, youthful position (Fig. 78.2). Excess skin is excised and the remaining tissue reconfigured to restore the 'breast cone.' (Fig. 78.3) [20].

Autologous tissue can be used to augment breast volume. This can be excess tissue from the lateral chest wall and back, which is de-epithelialized and rotated anteriorly [21], or tissue from the upper abdomen (the reverse abdominoplasty) which is de-epithelialized and moved superiorly [22].

Implant placement has also been described to augment the breast after mastopexy in the MWL patient. However, it is generally accepted that the implant should be of relatively small volume, deployed in addition to autologous tissue, and placed at a later stage than the mastopexy to ensure that viability of skin flaps and the NAC are not compromised [23, 24].

78.3.1.3 Upper Body Lift in Males

Contouring of the male chest presents unique challenges. The surgical goals here are to excise excess fatty tissue and skin, correct the position of the ptotic NAC and to masculinize the chest (make it flat and broad). While it is geometrically difficult to conceal scars in this population, patients tolerate them if the end objectives are achieved. Techniques include simple liposuction for mild ptosis or excess adiposity, inverted T mastopexy with the NAC lifted on a pedicle, or breast amputation with nipple transposition on a pedicle or grafting of the NAC in the new, elevated position (Fig. 78.4) [25–29].

78.3.1.4 Lower Body Lift

The first circumferential lower body lifting (LBL) technique or belt lipectomy was described by Gonzalez-Ulloa in 1960 [30]. It was Lockwood's pioneering work on the superficial fascial system (SFS) that again improved outcomes in trunk contouring [31, 32]. Historically, surgeons had performed amputative panniculectomy in obese patients in an attempt to address functional and esthetic concerns but had not addressed the lower back rolls present in the MWL patient or successfully tackled recurrence of ptotis in the long term. With lifting and suturing of the fascial layer, ptosis of the mons and lateral thighs can be addressed at the same time as excision of redundant tissues anteriorly and posteriorly, and with durable results.

Various authors have described techniques for autologous buttock augmentation at the time of circumferential lower

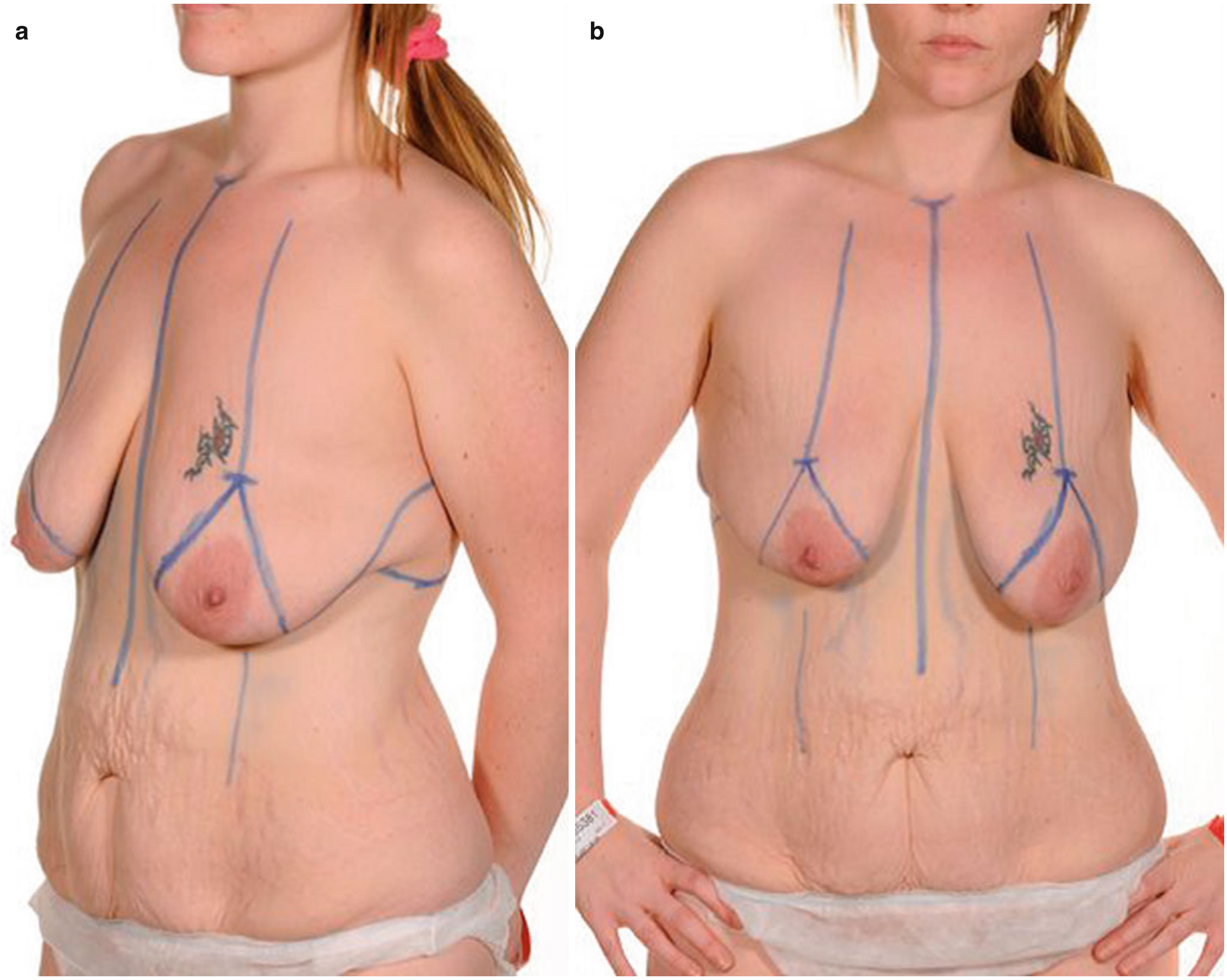

Fig. 78.2 Female massive weight loss patient with asymmetrical ptotic breasts – pre op. (**a**, **b**) Pre-operative markings for upper body lift with autologous breast augment using tissue from the back

body lifting as the buttock area can appear flat after weight loss, and the tightened skin envelope can serve to accentuate this appearance [8, 25, 33]. Shermak and Kenkal describe similar relatively simple techniques whereby the gluteal region is augmented by means of tissue already in situ on the lower back/upper buttock, which can be de-epithelialized, sculpted, partially undermined (with care to preserve arterial perforators) and sutured into place to give better buttock projection before the skin envelope is lifted over it and anchored with an SFS suture technique [8, 25]. Fat transfer may well be a safer alternative. Implant placement is not in common usage in the MWL population [25].

78.3.2 Brachioplasty

Brachioplasty is a surgical technique to remove excess skin or adipose tissue from the upper arms. In the MWL patient, this deformity can be severe and involve the lateral chest wall. Thorek first described the procedure in 1930 and Correa-Iturraspe and Fernandez later popularized it in 1954 [34, 35].

The redundancy may comprise hanging skin, adipose deposits or a combination of the two, and the surgical plan should be adapted to account for these anatomical abnormalities. If there is significant fat excess, liposuction can be deployed prior to excisional surgery. The traditional brachioplasty is essentially the excision of a longitudinal ellipse of tissue from the medial arm with the final scar lying in the bicipital groove. In the MWL patient, an 'extended brachioplasty' may be required to address the redundant tissue on the lateral torso. In these cases, the ellipse on the upper arm is designed as usual and an additional short vertical ellipse is taken on the lateral torso to include the excess tissue there. Some surgeons advocate placing a z-plasty in the axilla to avoid scarring contractures, but the author feels that this is unnecessary.

Fig. 78.3 Post op – mastopexy and autologous augmentation with flaps from back. (**a**, **b**) Breast appearance improved with better symmetry, larger volume, and lift of nipple areolar complex. Trade off is unsightly scar on back

Care must be taken to preserve the medial ante brachial and brachial cutaneous nerves that pierce the brachial fascia at around 14 and 7 cm proximal to the medial epicondyle respectively [36]. The cephalic vein is also preserved if possible but may need to be sacrificed in the excision. Gentle compression sleeves are worn for 3 weeks postoperatively.

78.3.3 Medial Thigh Lift

Patients with MWL experience functional difficulties due to excess medial thigh tissue. The excess deflated skin often hangs in folds and is in contact with the folds on the contralateral thigh leading to chafing, rubbing and even blisters. This also interferes with everyday activities such as walking, hygiene and can be complicated with intertrigo. For these reasons, it can be argued that removing this tissue lends both functional and esthetic improvements [37].

Lewis introduced the concept of the cosmetic thigh lift in 1957 [38]. This technique involved the excision of horizontal ellipses of tissue superiorly in the medial thighs with the resultant scars hidden in the groins bilaterally. While this method and subsequent refinements addressed some of the excess dermal and adipose tissue, recurrent ptosis frequently led to scar-stretch and distortion of the labia in women. The horizontal ellipse also proved insufficient to correct more marked tissue excess, such as that seen in the MWL population. These patients generally require a T-shaped excision to address circumferential laxity and to remove tissue from the entire length of the medial thigh. Patients with excess adipose tissue who are not fully deflated may require adjunctive liposuction.

To combat labial distortion and recurrent ptosis, Lockwood described a fascial anchoring technique whereby the thigh flap is lifted and anchored to the relatively inelastic deep layer of the superficial fascia (Colles' fascia) of the

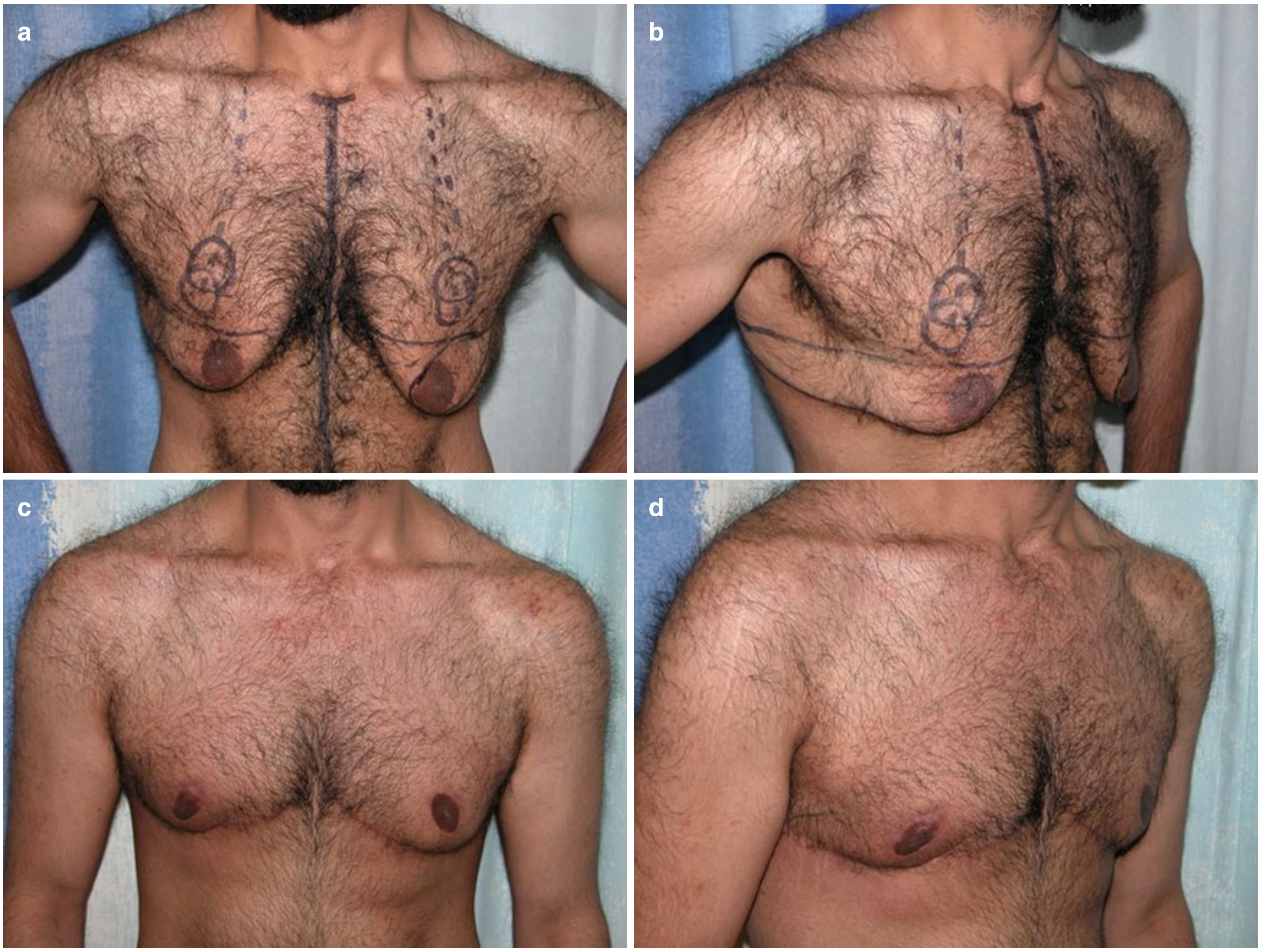

Fig. 78.4 Male massive weight loss patient (now normal BMI) with empty ptotic breasts pre-op and –post op following excision of redundant tissue and elevation of the nipple on a supero-lateral pedicle. (**a**, **b**) reveal ptotic asymmetrical pseudo-gyanecomastia with the pre-operative markings. (**c**, **d**) show the post operative appearance with improved symmetry, smaller nipple areolar complex in a more anatomical position

perineum [31]. Secure repair of the superficial fascial system (SFS), as described by Lockwood, is now a central tenet of all body contouring techniques [31, 32].

Excision in the groin area and anterior to adductor longus is carried out at the subcutaneous level to avoid damage to lymphatics, whereas more inferiorly and posteriorly the dissection can be carried down almost to the fascia. Care is taken to preserve the great saphenous vein, as its ligation or division can result in prolongation of lower limb edema [8, 39]. Gentle compression garments are worn for 6 weeks postoperatively.

78.3.4 Total Body lift

This novel technique combines UBL, LBL, brachioplasty and medial thigh lift in a single operation, and has been described by Hurwitz in a small number of patients [40]. This is a physically demanding procedure for the patient and the surgical team alike, and is performed only on patients who are 'energetic [and] accomplished' with good general and psychological health and BMI <35 kg/m^2. The total body lift is an attractive proposition in principle, but the potential for serious complications, financial constraints and staffing issues within the NHS have limited its application.

78.4 Complications of Body Contouring Surgery

Body contouring surgery is a major undertaking. Complications of surgery are common and must be promptly identified and corrected. The literature highlights that complication rates are amplified with high BMI [5–7]. Outcome data is better for trunk contouring than for limb contouring, probably due to the fact that limb surgery is associated with risk of long-term lymphoedema whilst this is unheard of in

Table 78.1 Complication rates for published trunk contouring series

Study	No. of study participants	Overall complication rate (%) (% major in brackets)	Seroma rate (%)	Wound dehiscence (%)	Infection (%)	Blood transfusion (%)	DVT/PE %/%
Nemerofsky et al. [43]	200	50(?)	16.5	32.5	3.5	15.5	2/1
Huizem et al. [44]	21	38(0)	0	29	14	19	0/0
Buchanan et al. [45]	35	? (0)	25	69	60	0	0/0
Kolker et al. [46]	24	? (4)*	17	0	0	0	0/0
Iglesias et al. [47]	69	42(3)	27	18	3	25	? /1.5
Al Aly et al. [26]	32	? (?)	37.5	9	9	?	0/9.3

Key:
*—1 patient requiring evacuation of hematoma
?—Figure not given and not possible to work out

trunk surgery. In addition the potential for major complications such as deep vein thrombosis (DVT)/pulmonary embolism (PE) is higher and the procedures more extensive with an inherent, prolonged recovery period. However, the data may be non-specific as limb contouring is often performed at the same time as trunk contouring in the MWL population. Complication rates in the largest trunk contouring series are shown below (Table 78.1) [26, 41–47].

The commonest complications in limb contouring again tend to be seroma and wound dehiscence, along with scar hypertrophy. Major complications are extremely rare [37, 42–45].

78.5 Funding

In the United Kingdom, healthcare funding for bariatric surgery allows morbidly obese patients to have access to care on the NHS, but funding for reconstructive body contouring has been varied and restricted such that patients in certain areas obtain the needed surgery, but in other areas do not. The British Association of Plastic Reconstructive and Aesthetic Surgeons and the Royal College of Surgeons of England have recently established national guidelines for this surgery in the hope that access to this surgery will be fairly and more widely distributed [46].

78.6 Summary

Body contouring surgery offers esthetic, functional and psychological benefits. Studies have shown that the improvement in quality of life after bariatric surgery is further enhanced by subsequent body contouring procedures, and that this effect is long-lasting [47–54]. The obese patient's journey is not complete until the redundant tissue is removed with reconstructive body contouring surgery, and the life quality of the patient is optimized. Plastic surgeons should therefore form an integral part of the bariatric team.

Key Learning Points

- Bariatric surgery patients have a high chance of having bio clinical abnormalities; it is imperative that before embarking on body contouring surgery a full pre operative assessment is carried out. Nutritional parameters are essential; therefore this surgery should be undertaken with close liaison with the local bariatric surgical team in the form of an MDT.
- The mind of the bariatric patients has not changed and great care must be taken in the explanation of the surgery to generate realistic expectations.
- There are multiple areas of the body that frequently need contouring, simultaneous multi site surgery has been proven in our institution to minimize number of complications, reduce in patient stay and decrease out patient follow up.
- The senior author does abdominoplasty and brachioplasty together and upper body lift with inner thigh reduction.
- It is important to remember that body contouring surgery is associated with a high incidence of complications. These are wound related and the wound healing problems do not detract from the satisfaction and improved life quality in these patients.

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