The SAGES University Masters Program Series
Editor-in-Chief: Brian Jacob

The SAGES Manual of Bariatric Surgery

Kevin M. Reavis
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Second Edition

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SAGES University MASTERS PROGRAM

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This book is dedicated to the SAGES family of surgeons committed to excellence in the care of the bariatric patient. I am most grateful to my amazing wife Kelly, to our wonderful sons Nathan and Andrew, and to my dedicated partners and professional friends whose collective support allowed this book to become a reality.

~Kevin M. Reavis, MD, FACS

For Michael, whom I love more than words can say.

~Allison M. Barrett, MD, FACS

This book is dedicated to the health-care professionals of all variety who care for our patients and, in particular, to my colleagues around the world. And a dear thanks to my wife Jean and our three children for their love and support.

~Matthew D. Kroh, MD, FACS, FASMBS, FASGE

Preface

"If I have seen further, it is by standing on the shoulders of giants," expressed by Isaac Newton, paid homage to the accomplishments of those before him for providing the foundation upon which his many contributions to society were able to materialize.

The SAGES Manual of Bariatric Surgery, Second Edition, likewise benefits from a solid foundation regarding the care of the bariatric patient. *The SAGES Manual: A Practical Guide to Bariatric Surgery* pioneered the SAGES offerings in this field in 2008, and, as with all surgical disciplines, tremendous advancements have prompted us to reassess, update, and bring forth a manual reflecting those changes over the past decade.

The SAGES Manual of Bariatric Surgery, Second Edition, covers each of the fundamental components of care for the bariatric patient, and we have extended the list of topics to include highly relevant but rarely published issues such as domestic and international surgical tourism, pregnancy, and innovative devices in the premarket setting, among others. This second edition also aligns with the novel SAGES Masters Program Bariatric Pathway, and, as such, the reader will appreciate an innovatively organized text reflecting this.

We are very excited to have garnered the contributions of many founding members in our field alongside those of mercurially rising stars. This manual is designed as a reference for surgeons, residents, medical students, and allied health members who provide comprehensive preoperative evaluations along with medical, endoscopic, and surgical interventions and long-term care for the bariatric patient. We would like to thank the contributing authors for their selfless efforts, along with Springer Science and SAGES for helping to make this manual a reality. We anticipate the knowledge shared will prompt the next generation to further the advancements we have enjoyed thus far.

Portland, OR, USA — Kevin M. Reavis
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Part I
SAGES Masters Program

Chapter 1
Introduction: SAGES Masters Program Bariatric Pathway

Daniel B. Jones, Linda Schultz, and Brian P. Jacob

Introduction

The Masters Program organizes educational materials along clinical pathways into discrete blocks of content which could be accessed by a surgeon attending the SAGES annual meeting or by logging into the online SAGES University (Fig. 1.1) [1]. The SAGES Masters Program currently has eight pathways including acute care, biliary, bariatrics, colon, foregut, hernia, flex endoscopy, and robotic surgery (Fig. 1.2). Each pathway is divided into three levels of targeted performance: competency, proficiency, and mastery (Fig. 1.3). The levels originate from the Dreyfus model of skill acquisition [2], which has five stages: novice, advanced beginner, competency, proficiency, and expertise. The SAGES Masters Program is based on the three more advanced stages of skill acquisition: competency, proficiency, and mastery. *Competency* is defined as what a graduating general surgery chief resident or MIS fellow should be able to achieve; *proficiency* is what a surgeon approximately 3 years out from training should be able to accomplish; and *mastery* is what

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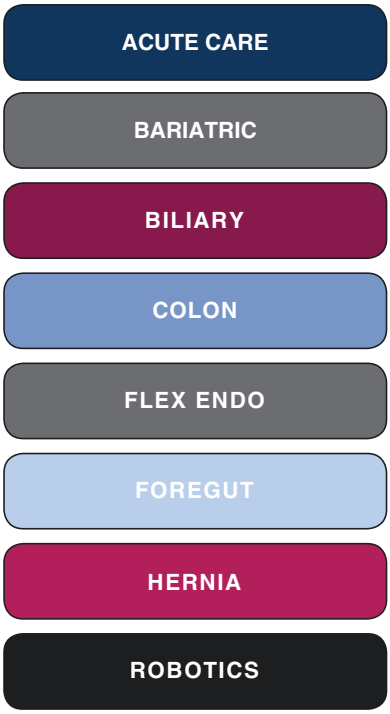
Fig. 1.1 Masters Program logo

Fig. 1.2 Masters Program clinical pathways



more experienced surgeons should be able to accomplish after several years in practice. Mastery is applicable to SAGES surgeons seeking in-depth knowledge in a pathway, including the following: areas of controversy, outcomes, best practice, and ability to mentor colleagues. Over time, with the utilization of coaching and participation in SAGES courses, this level should be obtainable by the majority of SAGES members. This edition of The SAGES Manual of Bariatric Surgery aligns with the current version of the new SAGES University Masters Program bariatric surgery pathway (Table 1.1). SAGES has included the American Society of Metabolic and Bariatric Surgery Essentials (www.Essentials.ASMBS.org) in the Masters Competency Curriculum. The ASMBS Essentials outlines the preoperative assessment, intraoperative considerations, and postoperative management for the most commonly performed operations and procedures.

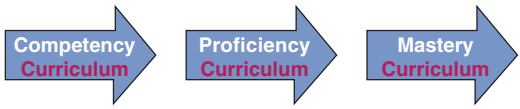


Fig. 1.3 Masters Program progression

Why Engage in the SAGES Masters Program?

The SAGES Masters Program is a more engaging, more valuable, more enjoyable continuing educational tool that will revolutionize postgraduate learning. Since it is often difficult for a practicing surgeon – after residency and fellowship – who has trained in one focus area to gain new expertise in another area of focus, additional options for ongoing training are needed. Traditionally, surgeons have taken postgraduate courses and industry courses and have gone online to watch and learn from videos and other peers and colleagues. The SAGES Masters Program establishes a curriculum the learner can follow that goes from simple to more complex while incorporating the many educational products of SAGES. It is hoped that this will be an inexpensive, fun, engaging, and valuable way to track progress over time. We envision that 1 day, the SAGES Masters Program will replace the ABS MOC requirements. The curriculum along each pathway is sensible and incorporates all elements of adult learning. Completion of the program will also eventually help surgeons optimize their online profiles.

Bariatric Surgery Curriculum

The key elements of the bariatric surgery curriculum include core lectures for the pathway, which provides a 45-min general overview including basic anatomy, physiology, diagnostic work-up, and surgical management. As of 2018, all lecture content of the annual SAGES meetings are labeled as follows: basic (100), intermediate (200), and advanced (300). This allows attendees to choose lectures that best fit their educational needs. Coding the content additionally facilitates online retrieval of specific educational material, with varying degrees of surgical complexity, ranging from introductory to revisional surgery.

SAGES identified the need to develop targeted, complex content for its mastery-level curriculum. The idea was that these 25-min lectures would be focused on specific topics. It assumes that the attendee already has a good understanding of diseases and management from attending/watching competency- and proficiency-level lectures. Ideally, in order to supplement a chosen topic, the mastery lectures would also identify key prerequisite articles from *Surgical Endoscopy* and other journals, in addition to SAGES University videos. Many of these lectures will be forthcoming at future SAGES annual meetings.

The Masters Program has a self-assessment, multiple-choice exam for each module to guide learner progression throughout the curriculum. Questions are submitted

Table 1.1 Masters Program bariatric curriculum outline

Curriculum elements	*Competency*
Anchoring procedure – competency	2
Core lecture	1
Core MCE 70%	1
Annual meeting content	3
Guidelines	1
SA CME hours (ASMBS electives, SAGES, or SAGES endorsed)	6
Sentinel articles	2
Social media	2
SAGES top 21 video	1
FLS®	12
Pearls	1
ASMBS essentials in bariatric surgery web-based application essentials.ASMBS.org	3
Credits	*35*
Curriculum elements	*Proficiency*
Anchoring procedure – proficiency	2
Core lecture	1
Core MCE 70%	1
Annual meeting content	5
Fuse™	12
Outcome database enrollment	2
SA CME hours (ASMBS electives, SAGES, or SAGES-endorsed)	6
Sentinel articles	2
Social media	2
SAGES top 21 video	1
Pearls	1
Credits	*35*
Curriculum elements	*Mastery*
Anchoring procedure – mastery	2
Core lecture	1
Core MCE 70%	1
Annual meeting content	6
Fundamentals of surgical coaching	4
Outcomes database reporting	2
SA CME credits (ASMBS electives, SAGES, or SAGES-endorsed)	6
Sentinel articles	2
Serving as video assessment reviewer and providing feedback (FSC)	4
Social media	7
SMART™ enhanced recovery	1
FES™	9
Credits	*45*

by core lecture speakers and SAGES annual meeting faculty. The goal of the questions is to use assessment for learning, with the assessment being criterion-referenced with the percent correct set at 80%. Learners will be able to review incorrect answers, review educational content, and retake the examination until a passing score is obtained.

The Masters Program bariatric surgery curriculum taps much of the SAGES existing educational products including FLS®, FES™, FUSE™, SMART™, top 21 videos, and Pearls (Fig. 1.4a–f). The Curriculum Task Force has placed the aforementioned modules along a continuum of the curriculum pathway. For example, FLS®, in general, occurs during the competency curriculum, whereas the Fundamental Use of Surgical Energy (FUSE™) is usually required during the proficiency curriculum. The Fundamentals of Laparoscopic Surgery (FLS®) is a multiple-choice exam and a skills assessment conducted on a video box trainer. Tasks include peg transfer, cutting, intracorporeal and extracorporeal suturing, and knot tying. Since 2010, FLS® has been required of all US general surgery residents seeking to sit for the American Board of Surgery Qualifying Examinations. The Fundamentals of Endoscopic Surgery (FES™) assesses endoscopic knowledge and technical skills in a simulator. FUSE™ teaches about the safe use of energy devices in the operating room and is available at FUSE.didactic.org. After learners complete the self-paced modules, they may take the certifying examination.

The SAGES Surgical Multimodal Accelerated Recovery Trajectory (SMART™) Initiative combines minimally invasive surgical techniques with enhanced recovery pathways (ERPs) for perioperative care, with the goal of improving outcomes and patient satisfaction. Educational materials include a website with best practices, sample pathways, patient literature, and other resources such as videos, FAQs, and an implementation timeline. The materials assist surgeons and their surgical team with implementation of an ERP.

Top 21 videos are edited videos of the most commonly performed MIS operations and basic endoscopy. Cases are straightforward with quality video and clear anatomy.

Pearls are step-by-step video clips of ten operations. The authors show different variations for each step. The learner should have a fundamental understanding of the operation.

SAGES Guidelines provide evidence-based recommendations for surgeons and are developed by the SAGES Guidelines Committee following the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine standards (formerly the Institute of Medicine) for guideline development [3]. Each clinical practice guideline has been systematically researched, reviewed, and revised by the SAGES Guidelines Committee and an appropriate multidisciplinary team. The strength of the provided recommendations is determined based on the quality of the available literature using the GRADE methodology [4]. SAGES Guidelines cover a wide range of topics relevant to the practice of SAGES surgeon members and are updated on a regular basis. Since the developed guidelines provide an appraisal of the available literature, their inclusion in the Masters Program was deemed necessary by the group.

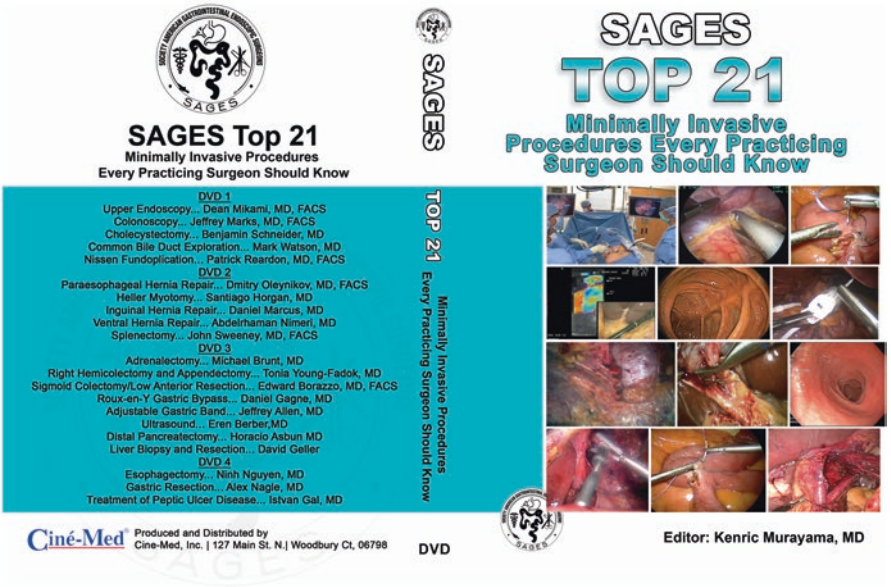
a

b

c

d

e



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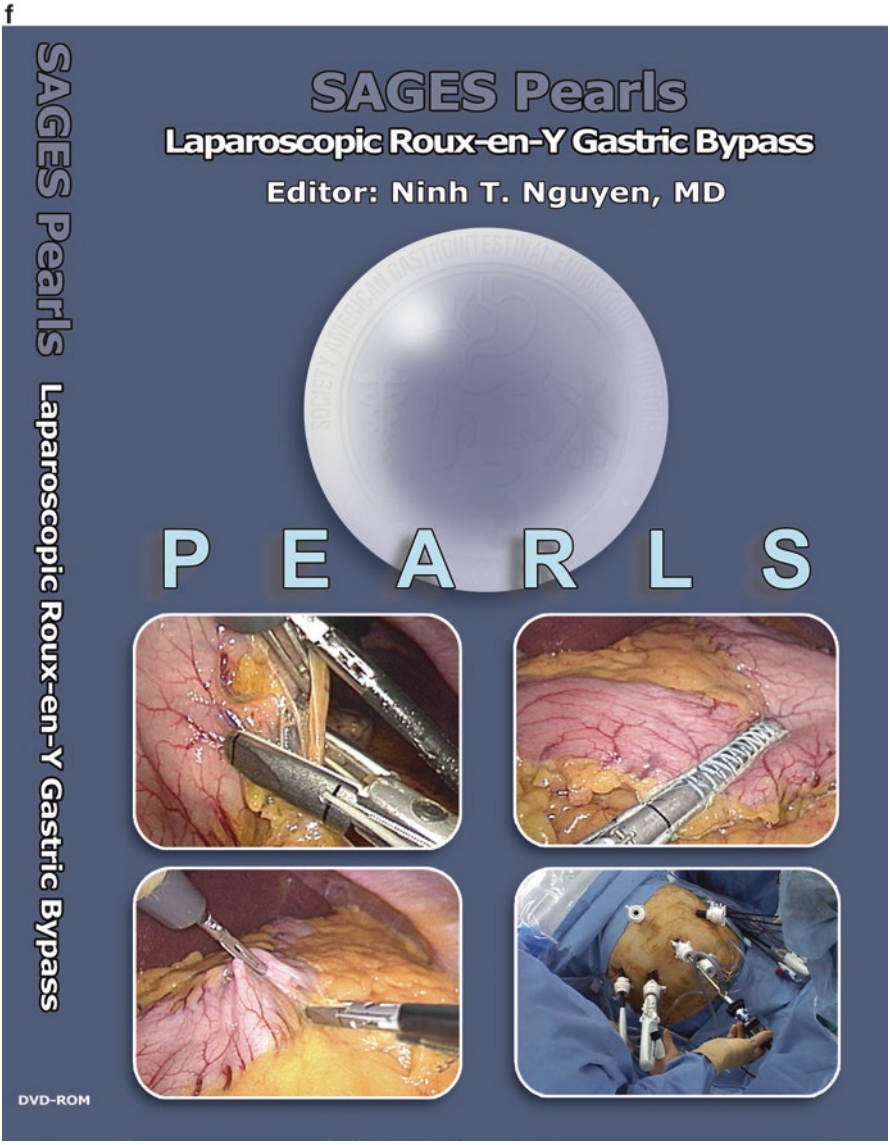

Fig. 1.4 (**a**–**f**) SAGES educational content: FLS® (**a**), FES™ (**b**), FUSE™ (**c**), SMART™ (**d**), top 21 videos (**e**), Pearls (**f**) (Trademarks and registered trademarks by SAGES)

The Curriculum Task Force identified the need to select required readings for the Masters Program based on key articles for the various curriculum procedures. Summaries of each of these articles follow the American College of Surgeons (ACS) selected reading format.

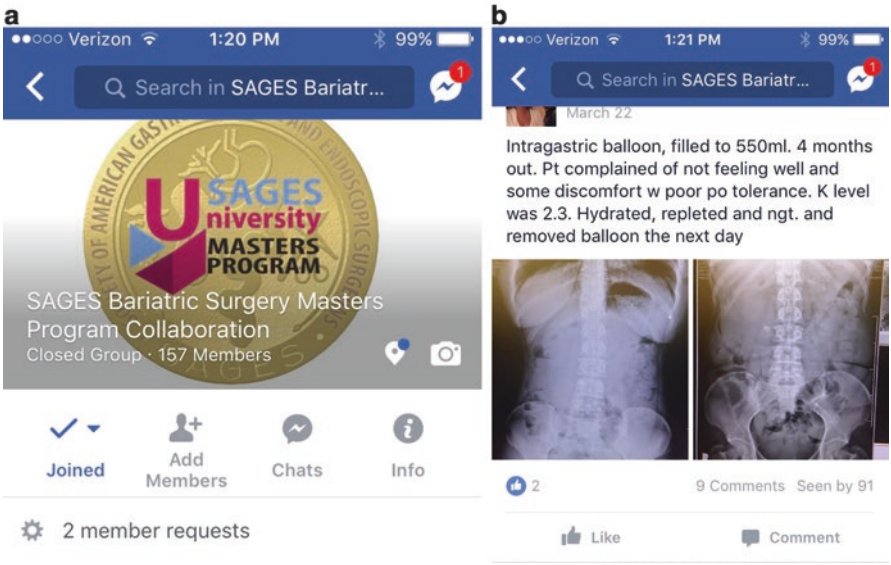

Fig. 1.5 (**a**, **b**) Bariatric Facebook™ group

Table 1.2 Bariatric surgery anchoring procedure by pathway

Anchoring procedure by pathway	Level
Bariatric surgery	
Lap sleeve gastrectomy	Competency
Lap Roux-en-Y gastric bypass	Proficiency
Lap revisional surgery	Mastery

Facebook™ Groups

While there are many great platforms available to permit online collaboration by user-generated content, Facebook™ offers a unique, highly developed mobile platform that is ideal for global professional collaboration and daily continuing surgical education one example being our newly formed SAGES Masters Program Bariatric Facebook(tm) Group (Fig. 1.5a, b). Proof of concept was demonstrated by the wide adoption of the International Hernia Collaboration closed Facebook™ group, started by Dr. Brian Jacob in 2012. Since then, the use of many different closed Facebook™ groups has allowed for video assessment, feedback, and coaching as a tool to improve practice.

Based on the anchoring procedures determined via group consensus (Table 1.2), participants in the Masters Program will submit video clips on closed Facebook™ groups, with other participants and/or SAGES members providing qualitative feedback. For example, for the bariatric surgery curriculum, surgeons would submit the critical views during a laparoscopic gastric bypass with a demonstration of a leak

test by methylene blue saline infusion or endoscopic air insufflation. Using crowdsourcing, other surgeons would comment and provide feedback.

Eight, unique vetted membership-only closed Facebook™ groups were created for the Masters Program, including a group for bariatrics, hernia, colorectal, biliary, acute care, flexible endoscopy, robotics, and foregut. The Bariatric Surgery Facebook™ group is independent of the other groups and will be populated only by physicians, mostly surgeons or surgeons in training interested in bariatric and metabolic surgery.

The group provides an international platform for surgeons and healthcare providers interested in optimizing outcomes in a surgical specialty to collaborate, share, discuss, and post photos, videos, and anything related to a chosen specialty. By embracing social media as a collaborative forum, we can more effectively and transparently obtain immediate global feedback that potentially can improve patient outcomes, as well as the quality of care we provide, all while transforming the way a society's members interact.

For the first two levels of the Masters Program, competency and proficiency, participants will be required to post videos of the anchoring procedures and will receive qualitative feedback from other participants. However, for the mastery level, participants will submit a video to be evaluated by an expert panel. A standardized video assessment tool, depending on the specific procedure, will be used. A benchmark will also be utilized to determine when the participant has achieved the mastery level for that procedure.

Once the participant has achieved mastery level, he will participate as a coach by providing feedback to participants in the first two levels. Masters Program participants will therefore need to learn the fundamental principles of surgical coaching. The key activities of coaching include goal setting, active listening, powerful inquiry, and constructive feedback [5, 6]. Importantly, peer coaching is much different than traditional education, where there is an expert and a learner. Peer coaching is a "co-learning" model where the coach is facilitating the development of the coachee by using inquiry (i.e., open-ended questions) in a noncompetitive manner.

Surgical coaching skills are a crucial part of the Masters curriculum. At the 2017 SAGES annual meeting, a postgraduate course on coaching skills was developed and video recorded. The goal is to develop a "coaching culture" within the SAGES Masters Program, wherein both participants and coaches are committed to lifelong learning and development.

The need for a more structured approach to the education of practicing surgeons as accomplished by the SAGES Masters Program is well recognized [7]. Since performance feedback usually stops after training completion and current approaches to MOC are suboptimal, the need for peer coaching has recently received increased attention in surgery [5, 6]. SAGES has recognized this need, and its Masters Program embraces social media for surgical education to help provide a free, mobile, and easy-to-use platform to surgeons globally. Access to the Masters Program groups enables surgeons at all levels to partake in the Masters Program Curriculum and obtain feedback from peers, mentors, and experts. By creating surgeon-only private groups dedicated to this project, SAGES can now offer surgeons posting in these

groups the ability to discuss preoperative, intraoperative, and postoperative issues with other SAGES colleagues and mentors. In addition, the platform permits transparent and responsive dialogue about technique, continuing the theme of deliberate, lifelong learning.

To accommodate the needs of this program, SAGES University is upgrading its web-based features. A new learning management system (LMS) will track progression and make access to SAGES University simple. Features of the new IT infrastructure will provide the ability to access a video or lecture on demand in relation to content, level of difficulty, and author. Once enrolled in the Masters Program, the LMS will track lectures, educational products, MCE, and other completed requirements. Participants will be able to see where they stand in relation to module completion, and SAGES will alert learners to relevant content they may be interested in pursuing. Until such time that the new LMS is up and running, it is hoped that The SAGES Manual of Bariatric Surgery will help guide learners through the Masters Program Curriculum.

Conclusions

The SAGES Masters Program bariatric surgery pathway facilitates deliberate, focused postgraduate teaching and learning. The Masters Program certifies completion of the curriculum but is *not* meant to certify competency, proficiency, or mastery of surgeons. The Masters Program embraces the concept of lifelong learning after fellowship, and its curriculum is organized from basic principles to more complex content. The Masters Program is an innovative, voluntary curriculum that supports MOC and deliberate, lifelong learning.

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Chapter 2
Masters Program Bariatric Pathway: Adjustable Gastric Band

Andrea S. Bedrosian and Christine J. Ren Fielding

Abbreviations

LAGB	Laparoscopic adjustable gastric band
LRYGB	Laparoscopic Roux-en-Y gastric bypass
LSG	Laparoscopic sleeve gastrectomy

Introduction

Since 2001 upon FDA approval of the Lap-Band® (now Apollo Endosurgery Lap-Band®, Apollo Endosurgery Inc., Austin, TX, USA) in the United States, the laparoscopic adjustable gastric banding system (LAGB) has been an effective option for treatment of severely obese patients. As a purely restrictive modality, LAGB relies on proper placement of a circumferentially adjustable, saline-filled band just below the gastroesophageal junction. The band effectively restricts passage of food into the distal stomach, resulting in early satiety and slowed gastric emptying. When appropriately positioned and with adequate restriction, the patient should feel diminished hunger, early satiety with small meals, and minimal dysphagia with certain foods, such as dry meats, fibrous vegetables, or bread. Success is dependent on two main factors: a standard surgical technique that has been refined to result in fewer band-related complications like prolapse and erosion and intensive long-term follow-up with a dedicated, experienced bariatric team. This chapter will focus on the details of appropriate surgical technique and outcomes of LAGB.

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Technique

Initial technique utilized the perigastric approach, which resulted in an unacceptably high rate of band prolapse (band "slip"), or herniation of the gastric wall up through the band proximally, with distal migration of the band [1]. This was later refined into the currently accepted "pars flaccida" technique, which utilizes the avascular retrogastric plane to tunnel the band posteriorly [2–4]. This approach ensures proper angulation of the band at the superior-most aspect of the stomach and significantly lower rates of band slippage. This was demonstrated in a prospective randomized controlled trial done by O'Brien and Dixon, showing a 16% slip rate with the perigastric approach versus a 4% slip rate with the pars flaccida approach [5]. With the pars flaccida approach being universally accepted, there are few controversies these days involving technique of band placement and mostly involve suturing of the band in place, gastro-gastric plication, and the so-called "anti-slip" stitches. None have been shown definitively to prevent band prolapse, and therefore we will not delve into their respective details. The following will delineate our own technique, refined in the course of thousands of laparoscopic adjustable gastric banding procedures and standardized in our practice with low complication rates.

The surgeon stands on the patient's right and the assistant opposite. The patient is positioned supine on the operating room table with both arms outstretched and padding to all pressure points. A perpendicular foot rest is helpful for bariatric patients that will be in steep reverse Trendelenburg. Appropriate antibiotic and venous thromboembolism prophylaxis is administered, and general anesthesia is induced. The abdomen is entered in the left upper quadrant just below the costal margin, utilizing the cut-down approach, Veress needle entry, and/or an optical entry-type trocar. Once access to the peritoneal cavity is confirmed, the other trocars are placed along the same level of the abdomen: a 15 mm working trocar in the epigastrium and 5 mm trocars in the right abdomen at the decussation of abdominal muscle fibers (for the surgeon's left hand), and another in the left mid-abdomen (for the assistant). A Nathanson liver retractor is placed percutaneously in the subxiphoid region in order to fully expose the gastroesophageal junction. The table is positioned in steep reverse Trendelenburg.

A 30-degree angled laparoscope is used, either 10 mm or 5 mm depending on surgeon's preference. The first step is to prepare the lap band and port, the most commonly used being the Apollo AP-Standard and AP-Large, the latter being preferable in men due to their preponderance of intra-abdominal fat. Less commonly used is the Ethicon Realize Band. The prepped band can then be placed into the abdominal cavity via the 15 mm trocar, being careful to protect the balloon side from the port valve.

The assistant retracts the fundus by gently sweeping the omentum from the left upper quadrant downward. This simple retraction maneuver is maintained until the band is placed, allowing for excellent exposure of the angle of His and the left crus. The hook electrocautery is then used to dissect the peritoneum above the angle of

His, exposing the left crus at the diaphragm. The fundus should be completely dissected free of the diaphragm in order to facilitate placement of the band through a retrogastric tunnel. At this point, with the left crus completely exposed, the thickened peritoneal reflection over the esophagus can be gently pushed superiorly, and the anterior crural confluence exposed. This is key in identifying the presence of a true hiatal hernia or paraesophageal hernia, in which case a formal circumferential crural dissection and posterior repair should be performed. In most cases, the hernia can be repaired with one or two nonabsorbable figure-of-eight sutures. If there is tension, pledgets may be used. If the hernia defect cannot be adequately closed with sutures alone, mesh reinforcement should be considered. There should be generous room for the diameter of one laparoscopic instrument through the hiatus once the repair is complete. To ensure the repair is not too tight, a 50-French bougie may be placed prior to suture repair. Finally, if there is no distinct hiatal hernia, but rather a dimpling or weakness of the crus over the esophagus, an anterior cruroplasty using figure-of-eight nonabsorbable suture should be considered.

Next, the thin, diaphanous gastrohepatic ligament (the "pars flaccida") is opened using hook cautery in order to expose the right crus at its posterior confluence with the left crus (there is usually a small fat pad just at this point). The peritoneum at the medial edge of the right crus is opened here, and a long blunt grasper in the surgeon's left hand is gently placed through the opening pointing toward the angle of His. At the correct angle, which is in a horizontal plane with the crura, the grasper can be gently pushed with minimal pressure and no resistance until it emerges just anterior to the left crus. If there is resistance, usually it is because the angle of the instrument is incorrect, fundal retraction is insufficient, or the fundus has not been completely mobilized off the diaphragm. The tubing end of the band is then brought up to this grasper and pulled through the esophagogastric tunnel just created. The band is then locked, with the buckle lying directly anterior to the stomach wall.

Our practice is to then place a running, gastro-gastric plication suture over the band using 2–0 Prolene suture. The plication is run for just a few bites, leaving the buckle of the band uncovered. The end of the tubing is then exteriorized through the 15 mm trocar and connected to the port. Ensure that the band is empty of saline and free of any air bubbles by accessing the port with a specialized, noncoring band needle. The port is then secured flat to the anterior fascia of the abdominal wall with four nonabsorbable sutures. Any redundant tubing is then replaced into the peritoneal cavity in order to avoid kinking at the port connection. The fascial opening at the 15 mm port site often requires closure in order to avoid port-site hernias.

Once recovered from anesthesia, most patients can be discharged the same day on a liquid diet for 10–14 days. An esophagram may be performed to assess baseline band position and patency, and the first adjustment is done at about 4–6 weeks postoperatively. The patient follows up monthly for the first year after surgery, with adjustments done until they are in the "green zone" of band tightness – adequately sated with small meals, with hunger well controlled, and no dysphagia with proper chewing and food choices.

Outcomes

A common evaluation of many bariatric procedures is its comparability to the laparoscopic Roux-en-Y gastric bypass (LRYGB), widely considered the "gold standard" among weight loss surgeries for its long-term effectiveness in percentage of excess body weight lost (%EWL), resolution of comorbidities, and safety. Retrospective series analyzing mid- to long-term weight loss in gastric bypass patients have shown, for the most part, significantly greater weight loss and BMI reduction in LRYGB compared to LAGB [6]. Our practice's experience has shown favorable, durable weight loss outcomes similar to other bariatric procedures, with low surgical risk and very low mortality [7] – certainly an endorsement of the procedure over higher-risk procedures like the gastric bypass or duodenal switch, whose serious early and late complications include intestinal leak, malnutrition, obstruction/stenosis, and internal hernia. In a recent multicenter, retrospective, and matched cohort study comparing the laparoscopic sleeve gastrectomy (LSG), LRYGB, and LAGB, Dogan and colleagues showed no statistically significant difference in %EWL or BMI between LAGB and LRYGB at 5 years (though the LRYGB had lower BMI and %EWL at earlier time points) [8].

Some medium and long-term outcome series of adjustable gastric banding have shown wide variation in %EWL [9, 10] reflecting the variability in band outcomes seen among bariatric surgery centers. It is our impression that practitioners without much band experience, and who do not have an established support system and postoperative follow-up program available to patients, generally see poorer weight loss and possibly even more complications. LAGB is indeed a surgery that requires a long-term commitment from both medical professionals and patients in order to ensure long-term success.

In general, we tell patients that with appropriate follow-up, expected EWL can be anywhere from 40–60%. Weight loss is more gradual compared to other operations; 0.5–1 kg per week is a reasonable goal for many patients. The most successful patients have a good working relationship with bariatric nutritionists, who will provide advice and support and can prevent many gastronomic misadventures in the inexperienced band patient – and more importantly, guide long-term band patients away from maladaptive eating behaviors. In the first year after surgery, monthly visits are typical, where the band is variably adjusted in order to optimize prolonged satiety with small meals, hunger control, and minimal dysphagia. Behavioral guidelines are strongly reinforced at every visit, namely, thorough chewing of each bite, slow and deliberate eating, and avoidance of mixing solids with liquids at meals. It is the marked slowness in eating that is the key to minimizing dysphagia with properly fitted bands. After the first year, and once patients have found their "green zone" of appropriate band tightness, they are seen on an annual or semi-annual basis. We generally perform esophagrams annually to assess the position of the band as well as any esophagogastric dilatation that may be contributing to reflux symptoms or maladaptive eating. Prompt correction of these sometimes silent findings (band slip, esophageal dilation, and gastric pouch formation – all reversible in

most cases with temporary band decompression) can help prevent future complications.

With weight loss after LAGB, obesity-related comorbidities show improvement and, in some cases, complete resolution. Compared to conventional medical therapy, there is a clear benefit to surgery in diabetic patients, with remission seen in 40–73% [11, 12]. Improvements are seen in insulin sensitivity and pancreatic beta cell function [13]. Hypertension, dyslipidemia, and other components of metabolic syndrome are seen to improve after even modest weight loss with LAGB. Obstructive sleep apnea and other disturbed sleep conditions similarly get better. So too do non-alcoholic fatty liver disease, gastroesophageal reflux disease, joint pain, and fertility related to polycystic ovary disease.

Reduction in these medical complications of chronic disease, and even simply reduction in the number of medications a person takes, dramatically improves quality of life, not to mention life expectancy. Using a modified obesity staging system to evaluate in severity stages of physical, psychological, socioeconomic, and functional disease, Neff and colleagues showed improvement in all scores in patients who underwent LAGB [14]. It follows that long-term mortality is improved in these patients.

The issue of revisional surgery after laparoscopic adjustable gastric banding is an important one and will be addressed in detail in a later chapter. Band slippage, persistent concentric gastric pouch enlargement, band erosion, port and tubing complications, and failure of weight loss/weight regain are all reasons for surgical revision. In O'Brien's 15-year follow-up series of 3227 patients [10], the need for revision after LAGB ranged up to 60%; however, this included the era preceding the pars flaccida approach and the modern AP bands, which dramatically reduced incidence of band prolapse. After 2006, the rate of band revision was much lower (most series put this number at up to 30%). O'Brien showed similar weight loss in the revision group compared to the overall group beyond 10 years.

Summary

While laparoscopic adjustable gastric banding has seen a downtrend in popularity in the last few years, dedicated surgeons have shown durable long-term results in weight loss, reduction of comorbidities, and improvement in quality of life, all with excellent perioperative and long-term safety and mortality outcomes. The standardized pars flaccida technique, with repair of hiatal hernia when present, should be mastered by the surgeon performing LAGB. A long-term postoperative care program should be maintained to provide the following key components:

- Close long-term follow-up by an experienced team that includes bariatric surgeons, advanced care practitioners, and nutritionists
- Access to support groups including other bariatric patients and nutritionists
- Accessibility of practitioners for frequent adjustments and follow-ups

- Practitioners' familiarity with abnormal esophagram findings
- Sensitivity and quick response to symptoms and findings such as reflux, dysphagia, esophageal dilation, lack of weight loss, etc., in order to prevent more serious complications
- Ready availability of surgeons trained in revisional procedures to deal with band complications

These components are essential to a successful laparoscopic adjustable gastric banding program, which can be life changing to the severely and morbidly obese patient.

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Chapter 3
Masters Program Bariatric Pathway: Laparoscopic Sleeve Gastrectomy

Michel Gagner

Introduction

According to the World Health Organization (WHO) report on obesity and diabetes, worldwide prevalence has doubled over 30 years, to reach over one billion patients [1]. During this interval, a precipitously growing body of evidence has driven bariatric and metabolic surgery to the forefront of decisive efforts directed toward this growing epidemic and its health-related after effects. Having undergone a swift evolution from an effective two-stage procedure for high-risk patients to a stand-alone procedure, laparoscopic sleeve gastrectomy (LSG) – a left "parietal cell" gastrectomy of the fundus, body, and proximal antrum – creates a longitudinal, partly vertical, cylindrical gastric conduit constructed along the lesser curve of the stomach. It is presently the most performed bariatric/metabolic intervention in the United States and worldwide by a ratio of 3 to 1 when compared to Roux-en-Y gastric bypass, the previous standard [2]. This is impressive given that this intervention began in 2000, by serendipity, after an incomplete attempted laparoscopic duodenal switch in a patient with a high body mass index (BMI) [3].

As a relatively "physiological" option that doesn't drastically alter GI anatomy, sleeve gastrectomy (SG) offers an array of advantages over other bariatric procedures. The stomach is reduced in volume (by an almost tenfold reduction, i.e., 1000 ml to less than 100 ml) but tends to function normally so most nutritional items can be consumed, in small amounts. Vagus branches are kept intact, vascular supply comes from the left and right gastric arteries, and the lower antrum should be sufficient to propel food distally through the pylorus. It removes the major portion of the stomach that produces the hunger-stimulating ghrelin while preserving the pylorus to prevent less severe dumping syndrome. Gastric emptying occurs faster and as a result increases the early release of GLP-1 and PYY 3–36 [4]. Being

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a technically simpler operation that does not require intestinal anastomotic procedures, the incidences of intestinal obstruction, peptic ulcers, anemia, calcium, protein, and vitamin deficiencies after LSG are negligible (except for vitamin B12), making it an attractive option for patients with prevailing anemia, inflammatory bowel disease, transplant candidate, heart failure, and other comorbidities that make them too high risk for intestinal bypass procedures. Examining one of the largest databases for bariatric procedures, the American College of Surgeons Bariatric Surgery Center Network longitudinal database compared 1-year outcomes of laparoscopic SG, gastric banding, and Roux-en-Y gastric bypass (LRYGB) performed in 28,616 patients. This study found that LSG was associated with higher risk-adjusted morbidity, readmission, and reoperation/intervention rates compared to the gastric banding but lower reoperation/intervention rates compared to LRYGB. There were no differences in mortality between groups, in spite of LSG patients having a higher BMI and higher risk profile than gastric band patients [5]. Another recently conducted systematic review found that in 12,129 patients, there was no difference in excess weight loss (EWL) associated with SG compared with RYGB at the time point of 24 months [6].

Technique

Patient position and room setup are addressed. The patient may be placed in the so-called French position, a split-leg position with thighs and legs abducted or supine. Footplate attachments permit steep reverse Trendelenburg positioning during surgery. The surgeon stands between the patient's legs or on the patient's right side (Fig. 3.1a, b).

Each surgeon may have a slight modification of trocar placement, and it also has to be adapted to body habitus and previous abdominal surgery. In our institution, I classically use five to six trocars (Fig. 3.2): a 12 mm trocar at the umbilicus with an open technique to access the peritoneal cavity (and in lower BMI patients, this will be the main camera port and the extraction site), a 10 mm trocar in the left epigastria paramedian (optics), a 5 mm Nathanson retractor in the epigastrium (left hepatic lobe retraction), a 5 mm trocar in the right paramedian area, a 12 mm trocar four fingerbreadths inferior to the costal margin in the left midclavicular line, and a 5 mm lateral port in the left anterior axillary line.

The patient is placed in steep reverse Trendelenburg position, and the table is tilted right-side down to optimize visualization of the gastroesophageal junction. The 10 mm 30 degree laparoscope is utilized for optics (or 5 mm alternatively). A 3–5 mm Nathanson liver retractor (curved hook) is placed through the epigastrium to retract the liver's superior and anterior, to expose the gastroesophageal junction. First, dissection begins along the distal greater curvature by dividing the branches of the gastroepiploic artery near the gastric wall with the ultrasonic shears (Fig. 3.3). An assistant retracts the omentum laterally with a bowel grasper through the 5 mm left lateral port, but this can be avoided in smaller patients. The greater curvature is

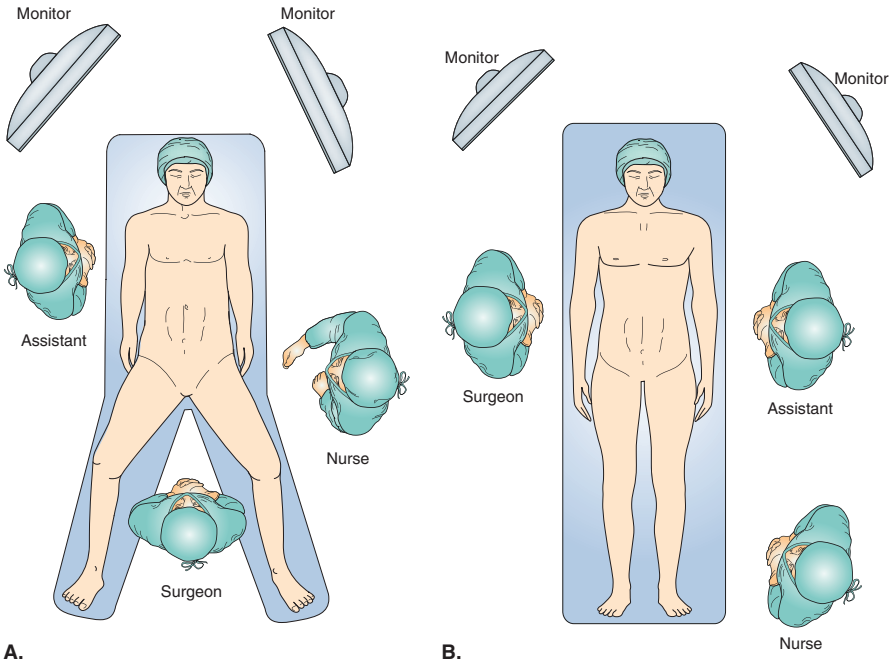

Fig. 3.1 (**a**, **b**) Surgical setup. The surgeon stands between the patient's legs (**a**) or on the right side of the patient (**b**)

devascularized in this manner toward the pylorus, a distance of about 2–3 cm proximal to this landmark. The assistant's grasper is frequently repositioned on the stomach, elevating the stomach away from the pancreas, to maximize retraction. All posterior attachments to the pancreas must be freed, taking care not to injure the splenic artery and branches. It is important to divide these attachments prior to stapling because these attachments can tear and create significant bleeding. However, one must not be too aggressive near the lesser curvature because the blood supply to the sleeve originates solely from the lesser curvature vasculature. The short gastric vessels are next, going upward, and different strategies maybe employed to completely secure the spleen from the stomach. Sometimes, I will divide vessels closer to the mid-posterior fundus first in order to leave the corner of the spleen last, as it will expose them. Rarely, stapling will be initiated first, and vessels (short gastric) taken last.

The left crus and gastroesophageal junction must be completely exposed, not only to eliminate a hiatal hernia but also to make sure that all fundus tissue has been dissected and none are left behind (Fig. 3.4). Exposure in this area can be difficult; helpful maneuvers include to place the assistant's grasper on the lateral fold of the omentum (in the mid-gastrosplenic ligament) and retract this laterally toward the spleen, temporarily increase the pneumoperitoneum to 20 mm Hg, place the patient in maximal reverse Trendelenburg position with a tilt toward the right side, ask the

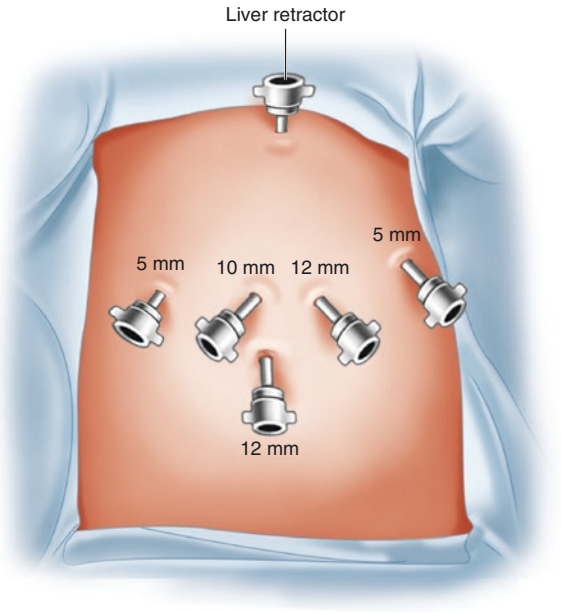

Fig. 3.2 Trocar position

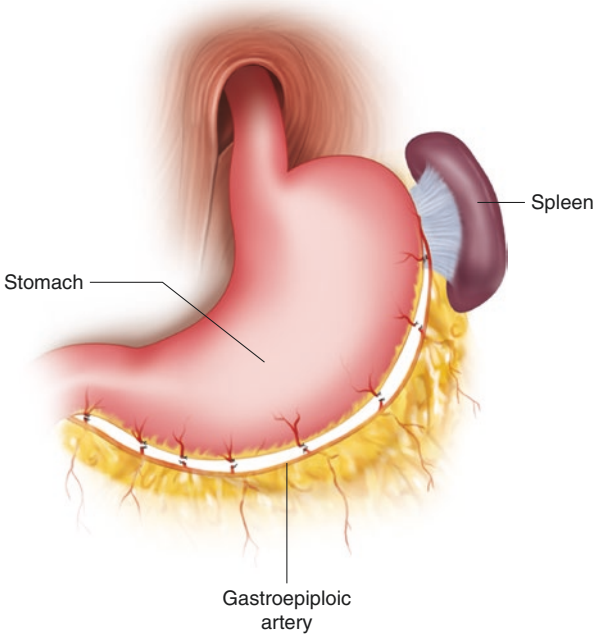

Fig. 3.3 Taking down branches of the gastroepiploic vessels and short gastric

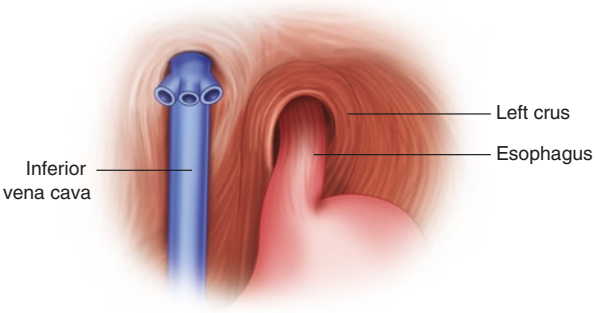

Fig. 3.4 Exposure of the left crus

anesthesiologist to give an additional dose of paralytics, position the assistant's grasper on the posterior fundus, and retract this toward the contralateral patient's right side or add an additional 5 mm trocar to retract the perigastric fat and adequately expose the gastroesophageal junction.

I routinely clear the anterior perigastric fat just to the left of the gastroesophageal junction to minimize tissue thickness during stapling, minimize bleeding from vessels underneath, and identify correctly the gastroesophageal junction. If there is laxity behind the esophagus or dimpling of the phrenoesophageal ligament indicating potential hiatal hernia, the hiatus should be completely dissected by opening the lesser omentum and freeing the right crus, the esophagus should be mobilized into the abdominal cavity, and the crural defect repaired with permanent sutures. Failure to recognize and repair a hiatal hernia at the time of initial operation may lead to reflux, transthoracic migration of the upper sleeve (and with a potential for a bronchopleural fistula if a leak occurs on the superior staple line).

Instrument palpation is used to confirm the anatomic position of the pylorus, and if adhesions make this identification more difficult, a posterior dissection may help. There is significant debate regarding optimal distance from the pylorus to initiate the sleeve gastrectomy. We prefer to initiate the sleeve at 4 cm proximal to the pylorus to preserve the distal antrum, as there is some evidence that a shorter distance is not predictive of greater weight loss. The bougie has been advanced by the anesthesiologist and should not bow toward the greater curvature (Fig. 3.5). Some operators use a gastroscope; however, I discourage this since the scope can bring unwanted air/carbon dioxide into the stomach and bowel and again may bow toward the greater curvature, and the covering sheath of the endoscope can be caught in the staple line. The first two firings of the stapler are via the umbilical trocar (Fig. 3.6). I mostly use the Echelon 60 with a black cartridge (closed staple height of 2.3 mm) (Ethicon EndoSurgery, Cincinnati, OH, USA) buttressed with bioabsorbable SEAMGUARD® (Gore, Flagstaff, AZ, USA) for most firings. On thinner stomachs, the cartridge size may need to downsize to green or gold. The buttressing material is sandwiched between, over, and below the anterior and posterior gastric wall and reduces staple-line hemorrhage and leakage rate [7].

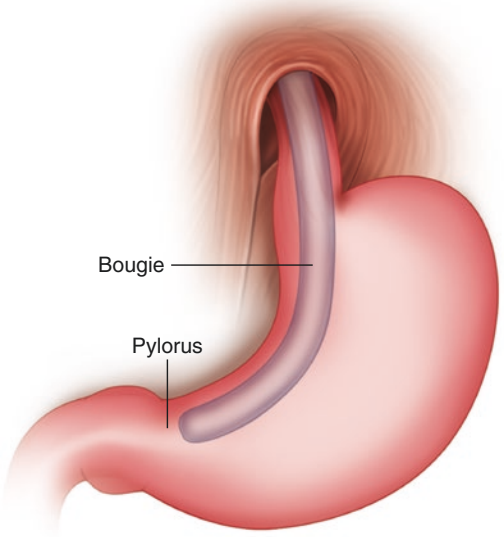

Fig. 3.5 Bougie against the lesser curvature

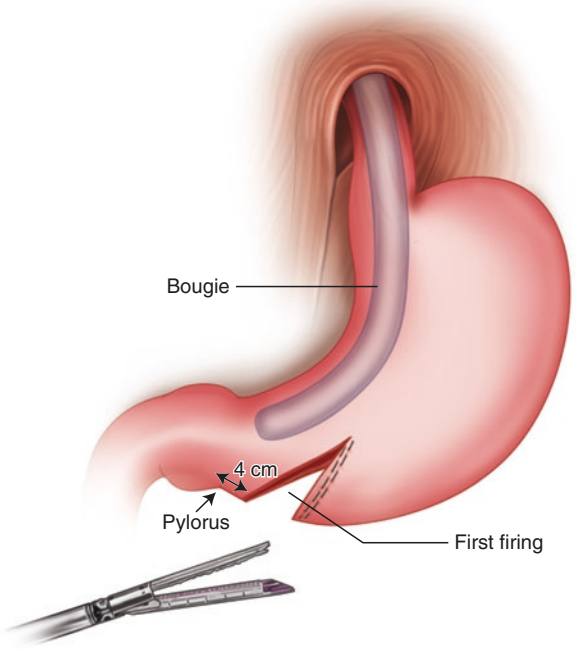

Fig. 3.6 Stapling 4 cm from the pylorus avoiding narrowing of the incisura

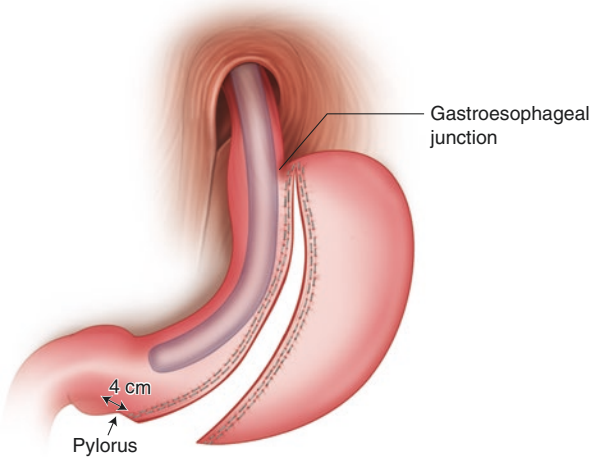

Fig. 3.7 Stapling the fundus

The assistant retracts the body of the stomach toward the patient's left side. The stapler should be positioned such that at least 2 cm of anterior stomach serosa is visible between the stapler and lesser curvature at the incisura. The first two firings of the stapler are performed, aiming approximately 2 cm away from the lesser curvature. The anesthesiologist inserts the bougie after the first two stapler firings to help align the bougie along the lesser curvature (Fig. 3.4). For first-stage LSG (as part of duodenal switch cases), we routinely use the 60 Fr bougie (to ensure enough gastric volume to permit adequate protein intake). For primary sleeve gastrectomy, we use a 40 Fr bougie.

The remainder of the sleeve gastrectomy is completed by sequential firings of the linear stapler along the bougie toward the angle of His (Fig. 3.5). Although we have used the 3.5 mm linear stapler in the past, it is safest to use a higher staple height for the entire sleeve gastrectomy due to the thick stomach in these morbidly obese patients. The differences in hemostasis between the two staplers are no longer seen with the routine use of the buttressing SEAMGUARD material. A total of 5–6 staple firings are typically required to complete the sleeve (Fig. 3.7). The anesthesiologist must pay careful attention that the bougie does not retract during stapling to prevent the tip of the bougie from being incorporated into the staple line or staple with a too narrow lumen.

Next, the anesthesiologist removes the bougie. We routinely place figure-of-eight 3–0 monofilament absorbable sutures at the apex of the sleeve gastrectomy (the area most prone to developing leak) and at the most distal end of the staple line (thickest part of stomach) (Fig. 3.8).

I routinely perform methylene blue test to assess the integrity of the staple line, and estimate grossly the volume, and determine areas of strictures or kinking. The anesthesiologist inserts an 18 Fr orogastric tube. The surgeon clamps near the

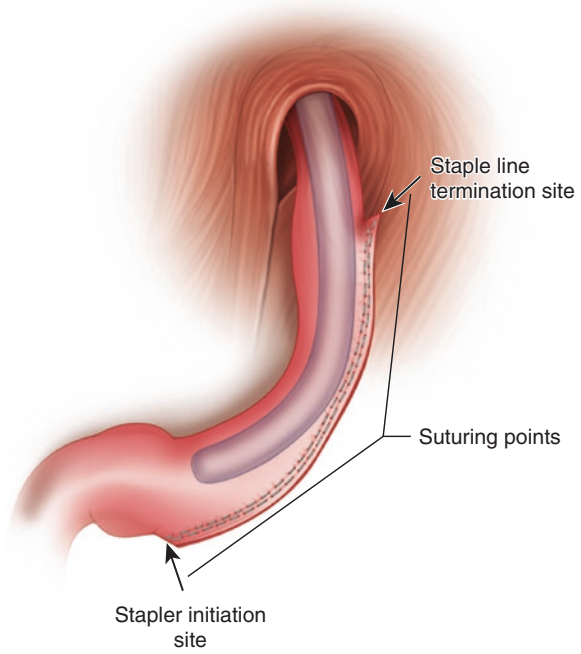

Fig. 3.8 Suturing the staple line

pylorus, and the anesthesiologist instills methylene blue mixed with saline through the tube. Approximately 60–120 cc is required to distend a sleeve. Another option is to insert a gastroscope and check for leak (and intraluminal bleeding) via air insufflation; this latter option is used less often because of the tendency of air to pass through the pylorus and distend the small bowel. The umbilical site is slightly stretched with an atraumatic clamp and a laparoscopic forceps grasper in the distal part of the sleeve specimen for extraction.

Outcomes

LSG has shown to be quite effective in weight loss, very similar to Roux-en-Y gastric bypass in the first 5 years, reaching 60–70% of EWL in morbidly obese patients. Several studies have shown effectiveness up to 10 years but with some weight regain, similar to Roux-en-Y gastric bypass [8]. It is most effective in patients with BMI less than 50 kg/m^2, as those above are treated with two-stage procedures (any intestinal combination, usually a duodenal switch or one of it's variant). Conversion of sleeve gastrectomy to Roux-en-Y gastric bypass is less effective for weight regain and tends to be reserved for severe gastroesophageal reflux disease (GERD) [9].

The most frequent contraindication has been the presence of Barrett's esophagus, because the progression to dysplasia may increase the need for resection and esophageal replacement with stomach. Hence, if a sleeve gastrectomy had been done, this may compromise the use of stomach and necessitate colon interposition, a much more complex endeavor. Nevertheless, it is strongly recommended to perform endoscopic surveillance every 5 years, with biopsies. Preoperative GERD has been a recent topic of controversy, as some surgeons tend to favor Roux-en-Y gastric bypass, as seen to be more effective; however, 10 years later, 30% of patients suffer from GERD with bypass, a problem difficult to treat, perhaps associated with a pouch enlargement or migration of the gastric pouch, transthoracic [10]. After sleeve gastrectomy, acid production is greatly diminished, and 2/3 of patients experience relief from GERD symptoms for several years. There has been a hint that presence of a hiatal hernia should be corrected in the same setting, as there has been less GERD in the postoperative period [11]. De novo GERD is about 5–10%, and patients may have to be medicated with PPI or H2 blockers for prolonged period of time. There has been a resurgence of localized treatment to decrease GERD associated with sleeve gastrectomy, like radiofrequency treatment to the lower esophageal sphincter, which increases the LES pressure, or adding a magnetic collar have been successful [12]. Some are even advocating partial fundoplication or pexy to the crus as part of a routine sleeve gastrectomy or as part of revisional strategies, but have not been tested in a randomized fashion and cannot be fully recommended at the moment.

Sleeve gastrectomy has proven its proficiency as a metabolic procedure capable of resolving type 2 diabetes mellitus (T2DM) [13–15]. Remission rates of T2DM after LSG are typically reported between 60% and 80% depending on the patient population and length of follow-up. In a systematic review that examined 27 studies and 673 patients with a mean follow-up duration of 13 months, T2DM had completely resolved in 66% of patients who had undergone SG and improved in 27%, with a mean decrease in blood glucose of −88 mg/dL and a mean decrease in HbA1c of −1.7% [16]. Moreover, the duration of T2DM seems to be of paramount importance as a prognostic factor, with 10 years representing a cutoff between high rates of remission and significantly lower rates [17].

While the metabolic mechanisms of action of SG continue to be an active area of research, they may be related to neurohumoral changes resulting from gastric resection or expedited nutrient transport into the small bowel. As glycemic control can be observed with bariatric procedures earlier than weight loss, it has been suggested that T2DM could be regulated by mechanisms involving a group of gastrointestinal hormones known as incretins, which account for 50–70% of the insulin response. This has led to a variety of technical modifications that have been introduced to the SG, including procedures that allow premature exposure of nutrients to an interposed ileum (II), stimulating incretin-producing cells without disrupting intestinal transit or absorption. In a study that included 30 patients diagnosed with T2DM for a mean period of 10 years, combining SG with II resulted in resolution of DM in 80% of the patients and improvement in 20% at a mean follow-up of 13 months [18].

For weight recidivism or failure, patients are now subjected to a second stage procedure or re-sleeve depending on the volume of the present sleeve. Many studies point out that after volumetric studies by CAT scan, 400 ml and above constitute a good indication for re-sleeve, especially the upper half [19]. However, if no increase in volume of the sleeve is noted, then added hypoabsorption may be proposed. Either classic duodenal switch or one of its variant such as SADI (single anastomosis with duodenoileostomy) or SIPS (stomach intestinal pylorus sparing) can be considered options [20]. All three options have the potential to provide more than 70% EWL.

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Chapter 4
Master's Program Bariatric Pathway: Roux-En-Y Gastric Bypass

Zubaidah Nor Hanipah and Philip R. Schauer

Introduction

Gastric bypass was first introduced by Mason and Ito in 1967 when they recognized that patients who underwent partial gastrectomy had difficulty gaining weight [1]. The original operation consisted of a 150-ml gastric pouch and a loop gastrojejunostomy. Over the last four decades, the operation has been modified significantly, including addition of a Roux-en-Y construction to reduce the incidence of bile reflux and a small (15–30 ml) divided gastric pouch. Some surgeons place a fixed band around the pouch to reduce pouch dilation and augment satiety.

Wittgrove and Clark demonstrated the feasibility of the laparoscopic Roux-en-Y gastric bypass (LRYGB) in 1994 [2]. Later they reported significant reduction in perioperative morbidity compared to the open approach, with excellent weight loss and comorbidity resolution [3]. Currently, more than 95% of bariatric procedures are performed laparoscopically worldwide [4, 5]. The laparoscopic approach has been shown by others to have a significant reduction in perioperative morbidity, mortality, recovery time, and cost [6]. Over the years, the physiologic effects of gastric bypass, particularly those related to improvement in diabetes, have been the focus of much research and discussion. The term "metabolic surgery" has been added to our vernacular to emphasize the important effects that gastric bypass and other bariatric procedures have on diabetes, other metabolic comorbidities, and cardiovascular risk [7–9]. The resolution of metabolic comorbidities along with excellent long-term weight loss explains why RYGB remains one of the most common bariatric procedures in the world [10, 11].

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Table 4.1 DSS II guidelines for metabolic surgery for type 2 diabetes

Recommended in	Considered in
T2D patients with class III obesity (BMI ≥40 kg/m^2) regardless of glycemic control with glucose-lowering agents	T2D patients with class I obesity (BMI 30–34.9 kg/m^2) with inadequate glycemic control despite optimal medical treatment (either oral or injectable medications including insulin)
T2D patients with class II obesity (BMI 35–39.9 kg/m^2) with inadequate glycemic control despite lifestyle and optimal medical treatment (either oral or injectable medications including insulin)	

T2D type 2 diabetes, *BMI* body mass index
Data from Rubino et al. [9]

Patient Selection

Indications for Bariatric/Metabolic Surgery

If obesity is the primary indication for surgery, patients are considered candidates if they have a body mass index (BMI) ≥ 40 kg/m^2 or a BMI ≥ 35 kg/m^2 with obesity-related comorbidity [12, 13]. However, classifications of "obesity" depend on the patient's ancestry: in Asians, the BMI threshold should be reduced by 2.5 kg/m^2. New guidelines which endorse metabolic surgery for the management of type 2 diabetes (T2D) were released following the Second Diabetes Surgery Summit (DSS-II). In these guidelines, metabolic surgery was recommended in the treatment algorithm for T2D based on the class of obesity and adequacy of glycemic control with optimal medical treatment. These guidelines have been widely endorsed by more than 50 diabetes and medical organizations worldwide, including the American Diabetes Association [9] (Table 4.1).

Indications and Contraindications for LRYGB

LRYGB is suitable for patients who meet eligibility criteria for bariatric/metabolic surgery. Patients with severe gastroesophageal reflux disease (GERD) or T2D are particularly suitable for LRYGB. See Table 4.2 for contraindications for RYGB and LRYGB.

Table 4.2 Contraindication for RYGB

Relative contraindications for RYGB	Contraindications for LRYGB
Patients with severe iron deficiency anemia	Patients who require concurrent open abdominal surgical procedures
Patients with Barrett's esophagus with severe dysplasia	
Patients with gastric or duodenal neoplasia that need surveillance endoscopy	

Operative Technique of LRYGB

Access and Exposure

Patient Position

- Patient is in the supine position with the feet together on a footboard.
- Heavy tape and straps are used to secure the patient's legs to the bed above and below the knees to prevent the knees from bending when the patient is in full reverse Trendelenburg position.
- The operating surgeon stands on the patient's right side and the assistant on the left (Fig. 4.1).
- Alternate: supine position with split legs, also called the French position

Pneumoperitoneum Creation

- Pneumoperitoneum is established with a Veress needle through a left upper quadrant incision (Palmer's point).
- Insufflate up to pressure of 15 mmHg for adequate visualization (usually at least 4 L of initial insulation before trocar insertion).

Port Placement

- Visual access to the peritoneal cavity is obtained using a 5-mm optical viewing trocar, and the remaining ports are placed under direct vision after needle localization and infiltration of local anesthetic (Fig. 4.2).
- If there are adhesions to the abdominal wall from prior surgery, an additional 5-mm trocar can be placed in the left lower quadrant to create an adequate working space for the remaining ports.

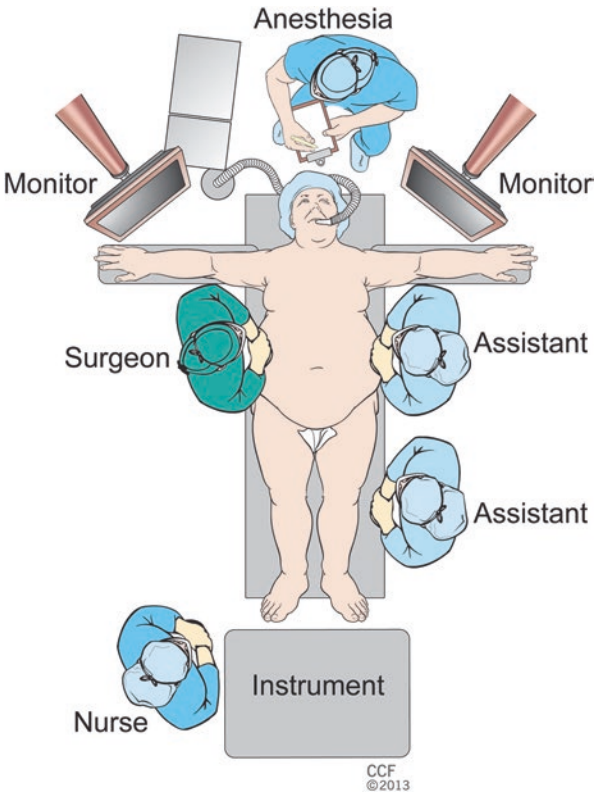

Fig. 4.1 Laparoscopic setup in the operating room (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

Liver Exposure

- A 5-mm liver retractor is placed through the right lateral port and anchored to the bed with a self-retaining device.
  - *Alternate*: A Nathanson liver retractor can be used in the subxiphoid position.
- For very large patients with an extremely large or floppy left hepatic lobe, both retractor systems can be used simultaneously to achieve adequate exposure of the gastroesophageal junction and hiatus.

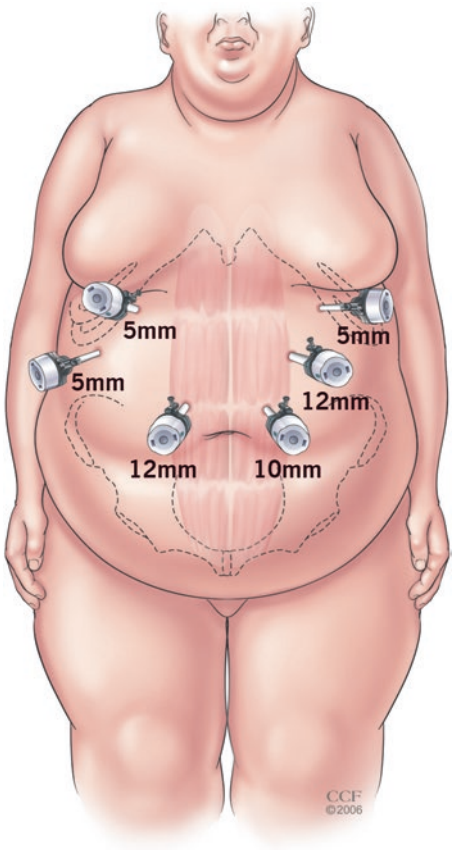

Fig. 4.2 Port placement for laparoscopic gastric bypass (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

Jejunojejunostomy and Roux-Limb Creation

Proximal gastric bypass is the most common version of RYGB and has been loosely defined as a Roux-limb length of ≤150 cm and BP limb length of ≤50 cm. Variations of these lengths have been assigned various terms, including long-limb bypass and distal bypass, but they generally come with a higher risk of micronutrient and macronutrient deficiencies [14].

Technique

- The transverse colon and omentum are reflected superiorly to the upper abdomen, and the ligament of Treitz is identified.
- The assistant holds the mesocolon anteriorly and cranially with a grasper to maintain adequate exposure during creation of the jejunojejunostomy.

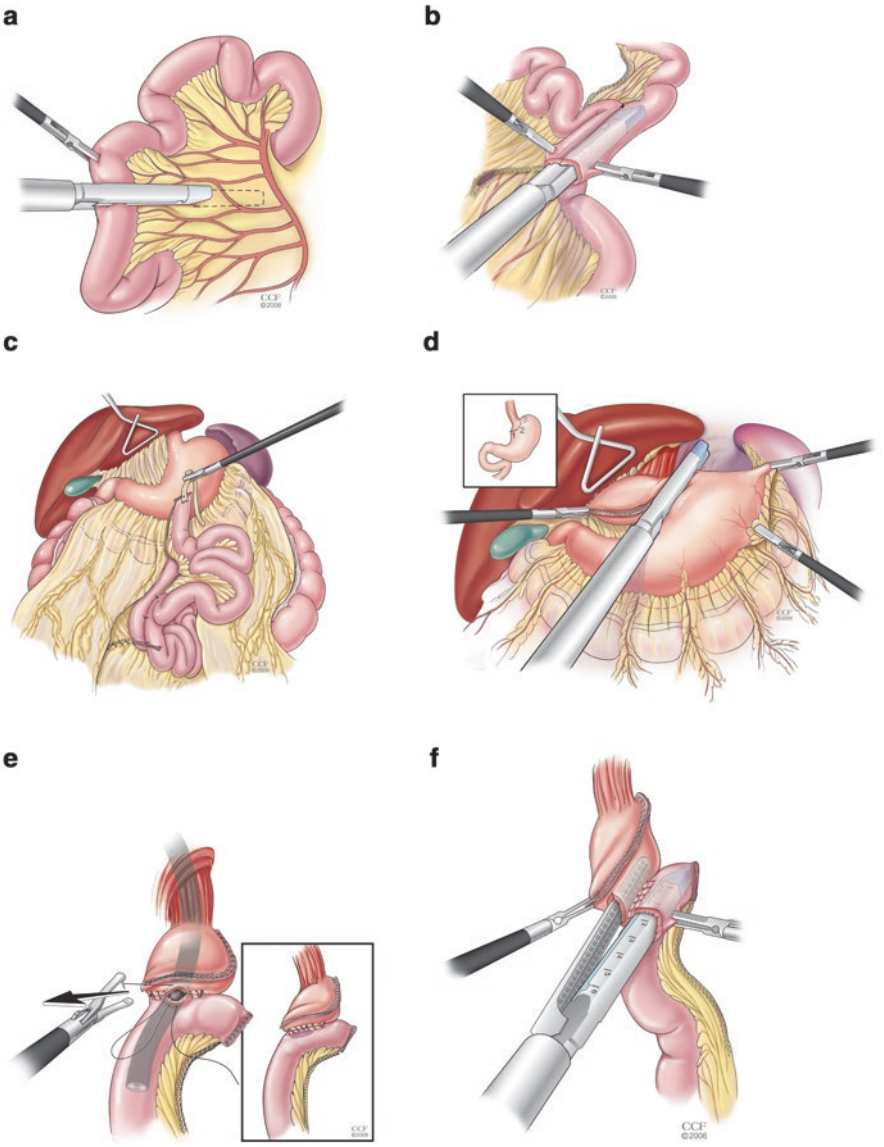

Fig. 4.3 (**a**-**i**) Steps of laparoscopic Roux-en-Y gastric bypass operative techniques. (**a**) Jejunojejunostomy and Roux-limb creation. (**b**) Jejunojejunostomy (J-J) anastomosis. (**c**) Roux limb brought into the upper abdomen. (**d**) Gastric pouch creation. (**e**) Hand-sewn gastrojejunostomy anastomosis. (**f**) Linear stapled gastrojejunostomy anastomosis. (**g**) Transoral circular stapler method to create the GJ anastomosis. (**h**). Banded RYGB. (**i**) Final anatomy following RYGB (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

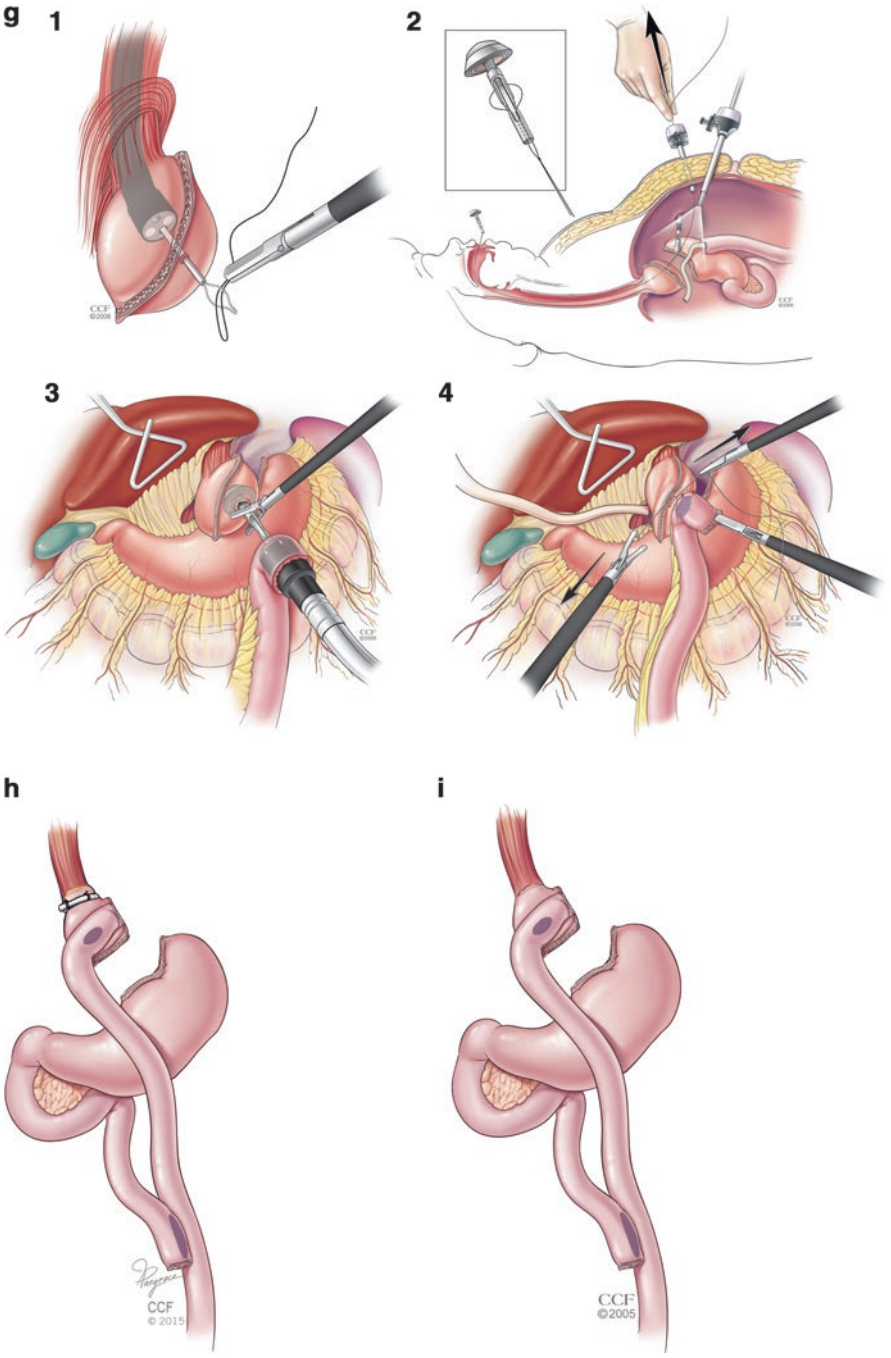

Fig. 4.3 (continued)

- "C" configuration of the proximal jejunum toward the camera helps in orientation of the proximal and distal segments.
- The jejunum is divided 50 cm from the ligament of Treitz with 1 × 60 mm load stapler (Fig. 4.3a).
- Mesentery is divided using a Harmonic scalpel, ligasure, or vascular load stapler, so as to reduce tension on the Roux limb when it is brought cranially to create the gastrojejunal anastomosis.
- The Roux limb is measured distally from the cut end for a distance of 150 cm. The bowel should be straightened (not stretched) against a rigid measuring device such as a marked grasper to determine proper limb length.
- At the appropriate point, a suture is placed to approximate the biliopancreatic limb and the Roux limb in side-to-side fashion.
- With the assistant holding upward the stay suture, the Harmonic scalpel is used to create small enterotomies on adjacent aspects of the two limbs, about 20 mm in length.
- A side-to-side jejunojejunostomy (JJ) anastomosis is created with a 60-mm, medium-height stapler cartridge (Fig. 4.3b). The remaining common enterotomy is then closed with another firing of the linear stapler.
  - *Alternate technique*: The JJ anastomosis can be performed using a hand-sewn method. Once the appropriate length is measured, a suture is placed to approximate the biliopancreatic limb and the Roux limb. A side-to-side jejunojejunostomy is made with the Harmonic scalpel about 20 mm in length. A single-layer 25–30-mm anastomosis is created with 2–0 absorbable sutures.
- The length of the JJ anastomosis should be approximately 20–30 mm. A wider anastomosis has less chance to develop anastomotic stricture, but has a higher incidence of malabsorption and ulcer formation.
- The jejunal mesenteric defect is closed with 2–0 nonabsorbable suture.
- The omentum is split in a cranial-caudal direction using the Harmonic scalpel to reduce tension on the Roux limb and gastrojejunal anastomosis.
- The Roux limb is brought into the upper abdomen (Fig. 4.3c).

Roux Limb: Antecolic Versus Retrocolic

The Roux limb can be brought up to the gastric pouch in either antecolic or retrocolic orientation. The retrocolic technique ensures less tension on the gastrojejunal anastomosis, but does require creation of a defect in the transverse mesocolon, providing a third location for potential internal hernia. Techniques are discussed in Table 4.3.

Table 4.3 Roux limb: antecolic versus retrocolic

Antecolic	Retrocolic
The omentum is divided with the ultrasonic shears down to the midportion of the transverse colon to provide a "valley" for the antecolic Roux limb	The Roux limb is placed in the retrocolic, retrogastric position through a defect created in the mesocolon
In some cases, the gastrocolic fat is very thick and this can be divided as well to avoid tension on the gastrojejunostomy	This technique minimizes tension on the Roux limb and gastrojejunal anastomosis
The Roux limb is passed upward between the leaves of the divided omentum to the gastric pouch in the antecolic and antegastric position	When the retrocolic technique is used, the mesocolic defect and space between the mesocolon and Roux limb mesentery (Peterson's space) should be closed with a nonabsorbable suture, as the chance of internal hernia is higher

Creation of the Gastric Pouch (Fig. 4.3d)

Technique

- A window is created in the gastrohepatic ligament with the Harmonic scalpel. The retrogastric space is dissected bluntly to accommodate the stapler.
- After the anesthesiologist removes all intragastric devices, a 60-mm, medium-height staple cartridge is fired across the stomach from the lesser curvature toward the greater curvature.
- The retrogastric space is dissected bluntly in a cranial direction until the diaphragm and left crus are visualized and free of adhesions to the stomach.
- Stapler loads of medium height are fired in a cranial direction across the cardia to create a gastric pouch of approximately 15 mL in size.
- Staple lines are examined and hemostasis is confirmed.

Creation of the Gastrojejunostomy (GJ) Anastomosis

The gastrojejunostomy (GJ) anastomosis can be created using various techniques: hand-sewn, linear stapler, or circular stapler. The learning curves for these techniques vary according to expertise and availability of equipment.

Gonzalez and co-workers [15] conducted a review of these three techniques in creation of the GJ during LRYGB. The hand-sewn technique resulted in lower operative cost with lower postoperative stricture and wound infection rates compared to the other two techniques. The incidence of stenosis and marginal ulcer was significantly lower in the linear stapler technique compared to circular stapler technique [16].

Hand-Sewn GJ Anastomosis Technique (Fig. 4.3e)

- The end of the Roux limb is sutured to the posterior aspect of the gastric pouch using 2–0 nonabsorbable suture.
- Enterotomies are made in the gastric pouch and the Roux limb with the Harmonic scalpel.
- End-to-side gastrojejunostomy (GJ) anastomosis is performed with 2–0 absorbable suture.
- The enterotomy is closed with the endoscope or bougie in place to avoid catching the back wall of the anastomosis with a suture.

Linear Stapled GJ Anastomosis Technique (Fig. 4.3f)

- Once the gastric pouch is created and the posterior aspect of the gastric pouch is sutured to the end of the Roux limb, a small gastrotomy and an enterotomy are created.
- A medium-height linear stapler is placed in the adjacent openings, but deployed only partially so as to limit the size of the anastomosis.
- The common enterotomy is closed in two layers over an endoscope or bougie.
- The anastomosis is checked for bleeding and leaks using the endoscope.

Circular Stapled GJ Anastomosis Technique (Fig. 4.3g)

A circular stapler (EEA) can be used for creating the gastrojejunostomy. There are two methods for delivering the anvil into the gastric pouch: transoral and transgastric. Earlier methods required the use of an endoscope and guidewire to deliver the anvil transorally. Currently, most surgeons utilize a system in which a 21-mm or 25-mm anvil is already attached to the end of an orogastric tube.

- After the gastric pouch is created, a posterior gastrotomy is created in the pouch. An orogastric tube with the anvil attached is passed by anesthesia down the esophagus and is withdrawn through the gastrotomy. As the orogastric tube is withdrawn from the abdomen through a trocar, the anvil is seated into place within the pouch. The tube is then detached from the anvil and removed through a trocar.
  - *Alternate*: Transgastric method – The anvil is delivered directly into the stomach. A gastrotomy is created in the body of the stomach and the anvil is placed into the gastric lumen. The anvil is then moved and seated proximally in the cardia prior to creation of the gastric pouch. After the pouch has been formed, a posterior pouch gastrotomy is created and the end of the anvil withdrawn through it. The remnant gastrotomy is closed with a linear stapler. This technique does allow the use of larger-diameter staplers, as the anvil does not have to pass through the oropharynx and cricopharyngeus.

Table 4.4 Endoscope versus bougie for GJ creation

Endoscope	Bougie
The endoscope sizes the anastomosis to 30 French	Bougie size variable, depending on surgeon's preference (26–30 French)
Allows inspection for anastomotic bleeding at the time of the procedure	It provides only a stenting effect at the time of the procedure
Provides insufflation for leak testing	Provides a channel for instillation of methylene blue into the gastric pouch to test the anastomosis

- The end of the Roux limb is cut open using the Harmonic scalpel.
- The circular stapler is passed directly through the abdominal wall and placed into the open end of the Roux limb and advanced several centimeters. The spike is deployed through the antimesenteric aspect of the Roux limb. The anvil and spike are joined, and the EEA is fired to create the anastomosis.
- The open end of the Roux limb is divided with a linear stapler.
- The anastomosis is reinforced with sutures.

Endoscope Versus Bougie for GJ Creation

A sizing tube should be used during creation of a hand-sewn or linear-stapled GJ to ensure that the back wall is not captured during sewing. Different devices can be used for this purpose, as discussed in Table 4.4.

Banded RYGB (Gastric Pouch Ring)

If the patient has a BMI > 55 kg/m^2, placement of a gastric pouch ring can be considered to minimize gastric pouch dilatation and weight regain. We selectively place a silastic ring around the gastric pouch for super obese patients to provide additional long-term restriction.

Technique

- A 10-cm 8F silastic band (2 mm wide) is used. We place a silk suture 1.75 cm from each end of the silastic tubing, which leaves 6.5 cm of the band to encircle the pouch.
- After the gastrojejunostomy has been completed, a small opening is created in the peritoneum overlying the base of the right crus, and an instrument is passed posteriorly using the pars flaccida technique.
- The silastic ring is grasped and pulled into place around the upper pouch with the endoscope still seated in position across the gastrojejunostomy.

- The surgeon and the assistant grab the ends of the tubing and bring the two sutures together over the anterior pouch. Clips are placed across the overlapping tubing to hold the ring in place. The sutures are then tied together.
- The ring should be approximately 2 or 3 cm above the gastrojejunostomy. This can be confirmed endoscopically (Fig. 4.3h).

Role for Remnant Gastrostomy

Insertion of gastrostomy tube in the remnant is not routine in RYGB. In cases of revisional bariatric surgery or a difficult procedure, placement may be considered. Indications for placement include revisional surgery with thickened gastric tissue, severe adhesions, expected postoperative ileus, or revision to correct a gastro-gastric fistula, leak, or stenosis. Gastrostomy insertion can either be for feeding or decompression. See Fig. 4.3i for final anatomy following RYGB.

Intraoperative Leak Test

Regardless of the method used to create the gastrojejunostomy, leak testing should be performed at the end of the case:

- The GJ anastomosis is checked for leaks by occluding the Roux limb distal to the GJ with a bowel clamp, submerging the anastomosis in saline, and insufflating the proximal Roux limb and gastric pouch with air through an endoscope. Any area of the anastomosis that bubbles with insufflation should be carefully inspected and oversewn.
- Alternatively, methylene blue can be instilled through a calibration or orogastric tube.

Closure of Mesenteric Defects

The mesocolic defect, jejunal defect, and space between the mesocolon and Roux limb mesentery (Petersen's space) should be closed with a nonabsorbable suture as these are two potential sites for internal hernia formation.

Cholecystectomy

Cholecystectomy is performed if the patient is found to have symptomatic cholelithiasis during the preoperative evaluation. We do not prophylactically remove the gallbladder unless symptomatic. Patients with an intact gallbladder should be considered for ursodiol treatment for 6 months postoperatively.

Liver Biopsy

A core needle liver biopsy should be considered during bariatric procedure to document the severity of nonalcoholic fatty liver disease.

Port Site Closure

Port sites 10 mm or greater should be closed with absorbable suture using a suture passer. Prior to removing the ports and desufflating the abdomen, a final inspection is performed and a safety checklist (Table 4.5) is verbally completed.

Single-Anastomosis Gastric Bypass

The single-anastomosis gastric bypass (SAGB) sometimes referred to as mini-gastric bypass (MGB) is a variant of the original loop gastric bypass first described by Mason and Ito in 1967. It consists of a long gastric pouch (50–75 ml), an end-side gastrojejunostomy, and a 200-cm biliopancreatic (afferent) limb (Fig. 4.4). SAGB has a shorter operative time due to its single anastomosis, compared to RYGB which has two anastomoses. However, SAGB does subject the patient to the potential risk of bile reflux gastritis and esophagitis. Also, due to the longer biliopancreatic limb, this operation increases malabsorption. Both these procedures have relatively similar weight loss and improvement in comorbidities. Lee et al. [17] showed significantly higher percent excess weight loss (%EWL) at 5 years postoperatively MGB compared to RYGB (72.9 vs. 60.1%, $p < 0.05$). A recent meta-analysis comparing the MGB with RYGB showed that MGB is more effective for weight loss ($p = 0.0008$) [18]. The overall remission rate for T2DM was greater for MGB as compared to RYGB (93.4% versus 77.6%, $p = 0.006$) [18]. Parmar and co-workers [19] compared MGB to RYGB in patients with BMI $\geq$ 60 kg/m2 and found that T2DM remission was 42.9% vs. 59.1% ($p = 0.45$). SAGB has a higher incidence of micronutrient deficiencies due to its longer malabsorptive bypass component [17, 20].

Table 4.5 LRYGB safety checklist prior to removing ports

On-table checklist
Jejunojejunostomy done, mesentery closed
Gastrojejunostomy done, mesentery closed
Silastic band placed (optional)
Leak test negative
Omental covering for gastrojejunostomy done
Drain (optional)
Liver biopsy (optional)
All specimens removed, labeled, and sent
Ports 10 mm or larger are closed
Sponges out, counts correct
Hemostasis confirmed
Additional procedures completed (hernia, gallbladder)
Equipment problems identified and noted for repair
Anesthesia plan for extubation noted

As SAGB is a relatively new procedure, long-term outcomes are not well known. It is not regarded as a standard bariatric procedure in the United States, and at the time of writing this chapter, SAGB/MGB is not approved by insurance companies.

Technique

- Long gastric tube creation: creation of long gastric tube similar to that of a sleeve gastrectomy. Volume 50–75 mL.
- The jejunum is measured 200 cm distal to the ligament of Treitz.
- An antecolic/antegastric Billroth-II loop gastrojejunostomy is created in end-to-side fashion (Fig. 4.4).

Outcomes of RYGB

RYGB results in significant improvement and resolution of obesity-related comorbidities. Table 4.6 lists the ranges for resolution rates of major comorbidities in large published series of laparoscopic RYGB [6, 7, 21–26].

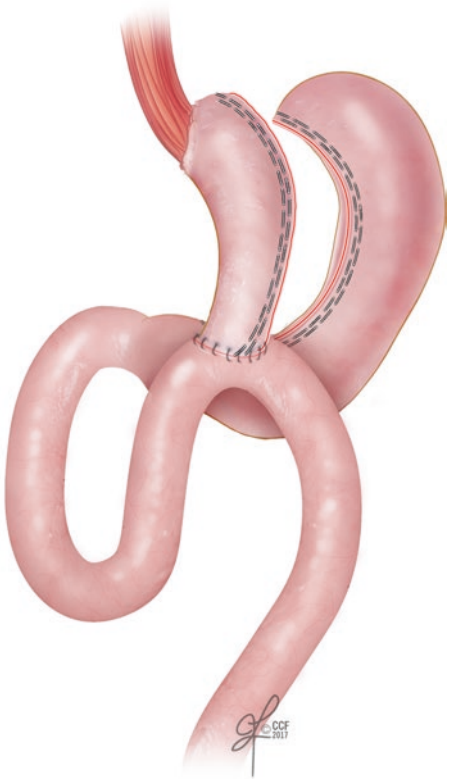

Fig. 4.4 Single-anastomosis gastric bypass (SAGB) with end-to-side anastomosis (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

Resolution of T2DM after RYGB is well established [7, 8, 27]. In morbidly obese patients seeking bariatric surgery who have T2DM (mostly mild disease), remission rates average around 78% [24]. Recently, 12 RCTs [7] involving patients with T2DM and obesity (874 patients with follow-up from 6 months to 5 years) showed that bariatric surgery (mostly RYGB) was significantly superior to medical treatment in achieving glycemic control or remission ($P < 0.05$), with the exception of one study involving laparoscopic adjustable gastric band (LAGB) patients [28]. Out of these 12 RCTS, 9 studies involved RYGB patients. A systematic review of long-term outcomes (involving 73 studies with 19,543 patients) showed significant remission or improvement of hypertension (63%), hyperlipidemia (65%), and T2DM (73%) [22].

Excess weight loss at 1–5 years after RYGB ranges from 68% to 80% [3, 6–8, 21, 23]. A meta-analysis involving 136 studies of short-term weight loss outcomes after more than 22,000 bariatric procedures showed that the overall mean %EWL after RYGB was 61.6% (56.7%–66.5%) [23]. In the STAMPEDE trial, Schauer and colleagues [8] reported on patients with T2DM and obesity, and identified a significant change in body weight from baseline to 5 years postoperatively in the RYGB group, compared to sleeve gastrectomy and intensive medical therapy (−23%, −19%, and −5%; p = 0.01) [8].

Table 4.6 Outcomes after Roux-en-Y gastric bypass

Percent excess weight loss (%EWL)	65–80%
Obesity-related comorbidities	Resolution outcome (%)
Diabetes	73
Hypertension	63
Hypercholesterolemia	65
Metabolic syndrome	90
Gastroesophageal reflux	72–90
Sleep apnea	45–78
Degenerative joint disease	41–76
Migraines	57
Pseudotumor cerebri	92
Depression	55
Venous stasis disease	95
Polycystic ovarian syndrome	96
Urinary incontinence	44–88
Nonalcoholic fatty liver disease (NAFLD):	
NAFLD inflammation/fibrosis	37/20
NAFLD steatosis	90 (improvement)

A study which prospectively evaluated 2410 patients showed that at 4-year follow-up period, there were significant variations in weight loss depending on the procedure: 27.5% for RYGB, 17.8% for sleeve gastrectomy, and 10.6% for LAGB. Between 2% and 31% regained weight back to baseline: 30.5% for LAGB, 14.6% for SG, and 2.5% for RYGB [29]. These studies suggest that RYGB is an effective procedure leading to significant long-term weight loss and comorbidity improvement.

Conclusion

Obesity and diabetes are major public health threats throughout the world. RYGB is an effective bariatric procedure, and it is mostly performed laparoscopically. It has excellent long-term weight loss, good remission and improvement of comorbidities, and improved life expectancy. The neurohumoral and hormonal effects of this operation are still not well understood but likely contribute to the rapid improvement in diabetes and the durability of the operation. LRYGB has a longer learning curve regardless of the specific anastomosis technique used. Advanced training is recommended to achieve optimal outcomes.

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Chapter 5
Master's Program Bariatric Pathway: Revision of Adjustable Gastric Band

Wayne S. Lee and Miguel A. Burch

Introduction

In 2001, the Lap Band® (Allergan, Dublin, Ireland) became the first FDA-approved laparoscopic adjustable gastric band (LAGB) in the United States. The procedure was considered a significant innovation in bariatric surgery due to its adjustability, reversibility, and lack of invasiveness. Initial studies demonstrated excellent weight loss with low morbidity and mortality [1, 2]. Compared to other bariatric procedures, the LAGB resulted in no anatomic alteration, had a low malnutrition rate, and required a shorter hospital stay [3].

However, this initial enthusiasm has waned as patients with LAGB had lower excess weight loss (EWL) compared to other procedures. This is thought to be the result of a lack of hormone effect, as there was no division of the stomach or small intestine. As such, there is no decrease in ghrelin exposure or effects from duodenal exclusion. Furthermore, as experience with the procedure and follow-up care increased, long-term complications were revealed, such as gastric prolapse, band erosion, obstruction, and port malfunction. As a result, rates of gastric band placement decreased from 35% of all bariatric procedures performed in 2011 to less than 10% in 2014 [4]. Because of this, in 2016 Johnson & Johnson (New Brunswick, NJ, USA) discontinued the sales of the Realize® band, the second FDA-approved LAGB.

In patients experiencing inadequate weight loss, weight regain, or other complications associated with the LAGB, management options include gastric band removal, band revision, and conversion to another bariatric procedure, such as Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), or biliopancreatic diversion-duodenal switch (BPD-DS).

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Workup

In patients with prior LAGB, a thorough history should be obtained to assess symptom presentation, dietary habits, and food choices. Persistent heartburn may be due to food stasis and an overly tight band. Reflux may be symptomatic after overeating or may present as a cough or bitter taste in the back of the mouth. Obstruction may present as solid or liquid dysphagia or odynophagia, requiring urgent band deflation and/or removal. During the physical examination, the clinician should assess for skin discoloration and signs of inflammation at the port site (erythema, induration, tenderness, discharge), which may indicate seroma, port infection, band infection, or band erosion.

Subsequent workup should be based on presenting symptoms. Imaging should be compared against baseline radiographic studies to assess for any change in the band axis, port position, and esophageal/gastric anatomy. Plain x-ray, upper GI study, and computed tomography may be done to investigate abnormal symptoms. On plain films and upper GI study, the normal shape and position of the band are a rectangle lying in an oblique angle, which should be less than 58 ° from the vertical axis. A prolapsed band may be suspected when imaging shows the angle is greater than 58 °. A horizontal position is commonly associated with an anterior prolapse [5]. The "O sign," delineated by an O-shaped appearance on anterior-posterior view, may be seen in a posterior prolapse, in which the band rotates vertically [6]. Oral contrast on upper GI study may further delineate the anatomy of the pouch and serves as a functional study in evaluating the passage of contents through the band. Endoscopy may be necessary if there is concern for erosion or to assess for esophagitis, gastric ulcer, and gastritis [3].

Indications for Revision/Conversion

Revisional surgery may be performed in patients after LAGB for failure of weight loss, weight regain, or comorbidity recurrence. Complications that may lead to revision or conversion include band/port infection, gastric perforation/erosion, obstruction, gastric prolapse, pouch dilation, esophageal dilation, or pseudoachalasia.

Band and port infections may be early or late in the postoperative course. In the early postoperative period, port site erythema and fluctuance may indicate a seroma. Any draining fluid should be cultured. Diagnostic laparoscopy may be performed to assess for intra-abdominal infection and to obtain cultures. Removal of the band is warranted if it looks grossly infected or if the tubing culture is positive for infection. Infected ports without band involvement may have an attempt at salvage by port removal alone (leaving the band and tubing in the peritoneal cavity), with port replacement at a different site 3 months later. After band removal for infectious etiology, gastric perforation should be ruled out by either leak test or intraoperative endoscopy. Bands may be replaced in 3 months if an infection was present [3].

Gastric perforation is a rare complication (<1%) which may present early postoperatively after unrecognized iatrogenic injury during placement [7]. Perforations may also occur after emesis from a tear at the gastro-gastric plication [3]. Although rare, gastric perforation is the most common technical cause of mortality after LAGB [8]. Rarely, delayed perforation may occur with band erosion into the gastric lumen. As a capsule forms over time around the foreign body, the erosion is usually walled off and presents subclinically. The most common symptoms of erosion, if any, are the loss of resistance to food passage and weight regain. This occurs as the band no longer offers restriction because it has completely transected through the wall of the stomach. Gastric prolapse may also present with perforation, as the results of ischemia and transgastric necrosis. Emergent operative intervention is necessary and consists of band removal, repair or resection of the perforation if possible, omental patch, and wide drainage.

Obstruction after LAGB occurs in 0.5–11% of patients [7]. Early presentation may occur with an overfilled band, postoperative hematoma/edema, or food impaction. This should be treated with prompt band deflation. Severe or refractory cases may require band removal or endoscopic removal of impacted food. A band that is too small for the size of the patient or placed over a large gastroesophageal fat pad may be replaced with a larger band (AP-L for Lap Band®). Removal of the fat pad should be performed with the Realize® band.

Acute gastric prolapse may also cause obstruction, with an incidence of 0.4–8% [7]. This is characterized by the herniation of a portion of the stomach with caudal migration of the band. Either the anterolateral fundus or posterior fundus may herniate. Classic presentation includes symptoms of severe abdominal pain and vomiting. Conservative management starts with band deflation and institution of liquid diet. If the prolapsed gastric segment reduces, as manifested by improved tolerance of liquid diet, the band may be reinflated in 2–4 weeks. If abdominal pain persists after fluid removal, urgent surgical removal should be performed to prevent gastric necrosis. For those not tolerating a liquid diet challenge, UGI would confirm failure of reduction and subsequent need for urgent or emergent band removal. Band revision with repositioning may be able to salvage refractory patients. Conversion to another bariatric procedure may also be indicated [7].

Pouch dilation is distinguished from gastric prolapse as a concentric stretching of the gastric pouch. It rarely leads to obstruction and is treated conservatively with band deflation.

Chronic obstruction from the LAGB is associated with persistent dysphagia and GERD. Transient swelling associated with a band inflation typically resolves over a period of 24–48 h. In contrast, chronic difficulties with deglutition are usually due to chronic overfilling of the band, which can lead to esophageal dilation and esophageal dysmotility over time. Early incidence of esophageal dilation ranges from 6% to 15%, with longer-term studies reporting rates up to 68% [9]. Dysmotility after LAGB is acquired and seems to not be associated with preoperative abnormal manometry. Mild dilation >35 mm with poor esophageal emptying should be treated with temporary removal of fluid from the band and frequent evaluations. Severe dilation with esophageal dysmotility, or failure of resolution with band deflation,

should be followed by prompt band removal [9]. Band removal early in the process may reverse the esophageal dysmotility [10]. To prevent weight gain in these patients, conversion to RYGB or SG may be considered. However, caution should be used to ensure return of esophageal function by esophageal manometry prior to conversion to SG, as failure to do so could result in continued esophageal emptying issues secondary to high intragastric pressure from the SG, causing resistance to flow [11].

Revision of Gastric Band

Re-banding in patients with increasing body mass index (BMI) and band-related complications has been found to be associated with worse weight loss compared to conversion to RYGB after 3-year follow-up. Average BMI change in the re-banding group actually increased by 1.5 BMI points, likely due to patients initially presenting with obstruction. In addition, 45% of re-banding patients had secondary failure requiring additional surgery [12]. In a case-matched study with 81 patients who underwent re-banding for slippage, there was no difference in the percentage failure of weight loss compared with primary banding patients. Subgroup analysis of patients with unsuccessful weight loss prior to re-banding demonstrated poor long-term outcomes [13].

Conversion to Roux-en-Y Gastric Bypass

Conversion of LAGB to RYGB may be performed with complication rates that are similar or slightly higher than primary RYGB [7]. Systematic review of 15 studies with 588 patients undergoing LAGB conversion to RYGB had an overall complication rate of 8.5% [14]. This is comparable to primary gastric bypass complication rates of 7–17% [15]. Studies report an overall anastomotic leak rate of 0.9% and bleeding complications in 1.8% of patients [14]. Two-stage operations (band removal with interval RYGB after 3–6 months) or single-stage operations may be performed. Medium-term weight loss has been comparable to the index operation [7]. Percent EWL at mean 4-year follow-up ranged from 23% to 74%, with the majority of patients reporting at 10-point BMI decrease [14]. By comparison, %EWL following a primary RYGB at 4 years postoperatively ranges from 49% to 94% [15]. In a recent meta-analysis, at 24 months, LAGB conversion to RYGB has significantly greater EWL (48–70%) compared to EWL with conversion to SG (28–66%; $p = 0.03$) [16].

Conversion to Sleeve Gastrectomy

The most common indication for conversion of LAGB to SG is failure of weight loss. Low rates of morbidity and good weight loss have been demonstrated following revision. However, some studies demonstrate higher staple line leaks than primary SG procedure, thought to be associated with inadequate release of scar tissue at the angle of His [7]. A systematic review of eight studies reported an overall complication rate of LAGB to SG as 12.2%, with a 5.6% leak rate. The conversions were performed in 78% as a single-stage operation [14]. This is comparable to complication rates for primary SG, which is reported at 5–13% [15]. A more recent meta-analysis of 1034 patients undergoing conversion to SG reported a leak rate of 2.2%, compared to 1.8% in 1583 patients with RYGB. These conversions were performed as single-stage in 47% and 80% of patients in the SG and RYGB groups, respectively [17]. Other meta-analyses demonstrated no significant difference in complication rates between LAGB conversion to RYGB and to SG [16]. Percent EWL after follow-up of 6–36 months ranged from 31% to 60% [14]. By comparison, %EWL following primary SG at 3 years postoperatively is reported to be 48–71% [15].

Conversion to Duodenal Switch with Biliopancreatic Diversion

In general there is a paucity of data regarding conversion of LAGB to DS-BPD; however, higher complication rates have been reported. In one study, only 38% had an uneventful postoperative course after conversion. There was a major complication in 33% of patients, with 14% leak rate. Percent EWL (66.2%) was found to be similar to a primary malabsorptive procedure [18].

Two-Stage Versus One-Stage

The rationale behind a two-stage operation for LAGB conversion is that it allows time for resolution of perigastric inflammation after removal of the band, therefore improving the safety profile of interval bariatric surgery. However, histopathologic changes of acute and chronic inflammation have been found to be present at least 3 years after band removal [19]. Some studies have demonstrated fewer leaks in a staged approach [20]. However, in two-stage operations, there is a propensity for interval weight gain, which may increase the complication risk for the secondary operation. By contrast, one-stage revisional surgery has been well described and carries several advantages. For the patient, it avoids two separate operations, admissions, and recoveries.

In a single institution study looking at one-stage revision from LAGB to RYGB or SG, patients had overall complication rates of 18.8% and 12.5%, respectively. Reoperation rates were 9.3% and 2.8%, respectively [21]. A systematic review of one- and two-step revisional LAGB surgeries (both SG and RYGB) demonstrated no significant difference in the rates of complications, including abscess, bleeding, leak/fistula, and anastomotic strictures. Mortality was also similar between one- and two-stage RYGB/SG [19]. In patients undergoing conversion due to complications, planning for a two-stage operation may create a situation wherein there is a potential lack of insurance approval if BMI criteria are not met for the second operation.

Technical Considerations

LAGB revision and conversions to RYGB or SG should be performed by experienced bariatric surgeons. As with any preoperative case, prior scarring may obliterate planes and make identification of anatomy difficult. Tracing the tubing may facilitate identification of the band and buckle. Careful lysis of adhesions between the liver, omentum, stomach, and hiatus should be performed. Sharp dissection should be used around the stomach and esophagus to prevent thermal injury. Initial identification of the caudate lobe and right crus of the diaphragm may be a foundation on which to elucidate the rest of the anatomy. Intraoperative endoscopy is often helpful to delineate the anatomy.

Limited dissection of the band capsule may be necessary in patients presenting with band erosion, as there may be significant inflammatory reaction. After the band is transected, it may be slipped out along the track in the capsule for removal. Any gastric perforations should be closed and buttressed with omental flap repair. Leak test should be performed with intraoperative endoscopy or instillation of air by the anesthesiologist through a gastric tube. Drain placement around the anastomotic staple lines can be used liberally.

In conversions, our approach involves complete dissection of the capsule in the planned areas for stapler division. All prior sutures and clips should be removed. EGD may be performed to ensure that the gastro-gastric plication is completely taken down. Mobilization of the greater curvature should also be undertaken to aid in complete lysis of the capsule posteriorly.

Prior to conversion to RYGB or SG, the gastric serosa should be carefully examined to identify any deep serosal tears. If this is present, closure with braided absorbable suture is indicated and strong consideration should be given for a two-stage procedure. Seprafilm® (Genzyme Corporation, Cambridge, MA, USA) adhesion barrier should be considered for any staged procedure. This is anecdotally associated with minimal adhesions found during the second procedure.

Staple lines for RYGB and SG should be placed in an area with less scarring, away from the prior capsule if possible. Failure to do so may increase the risk of staple line leaks. Selection of the staple height should be determined by the amount of gastric edema and thickness after complete dissection. Early leaks within

2–3 days postoperatively are usually technical. This may be due to poor tissue handling with unidentified injury or stapler misfiring through scar tissue. Later leaks between 5 and 7 days are usually due to ischemia and devascularization; identification and preservation of the left gastric pedicle are crucial.

If converting to SG, routine hiatal interrogation should be performed to identify any hiatal hernias, which should be repaired to prevent postoperative GERD. Due to the higher leak rate, staple line reinforcement or oversewing should be considered. A meta-analysis demonstrated decreased incidence of postoperative leak and overall complications with the use of either staple reinforcement or oversewing, compared to nonuse of reinforcement [22]. A randomized controlled study found no significant difference between staple reinforcement and oversewing the staple line, although suturing was more time-consuming but lower cost [23].

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Part II
Bariatric Programs in 2018

Chapter 6
Bariatric Surgery: A Historical Perspective

Adam C. Celio and Walter J. Pories

Introduction

Obesity. A problem that has plagued mankind for centuries. Hippocrates once wrote, "corpulence is not only a disease itself, but the harbinger of others" [1]. The World Health Organization has described obesity as one of the most blatantly visible yet most neglected public health problems [2]. Obesity continues to be a health problem today with 20% of Americans having a body mass index (BMI) >35 kg/m^2 [3]. While surgeons have been refining the role of gastrointestinal operations for the treatment of obesity for more than 60 years, this year, for the first time, the American Diabetes Association 2017 Standards of Medical Care included specific guidelines that make metabolic surgery part of the standard of care of diabetic patients [4]. This is a historic moment of the surgical specialty of metabolic surgery that has been a long time in the making. It is remarkable that the breakthroughs accomplished with bariatric surgery are only recently being recognized for a disease that has been a problem for so long. In this chapter we will discuss the beginnings of the field of bariatric surgery, development of historic and current operations, development of surgical societies, and the acceptance of metabolic surgery into the mainstream.

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Operative Evolution

Over the last several decades, the failure of medical therapy for obesity and the success of surgery have produced a remarkable series of new techniques for the treatment of obesity and its comorbidities. The bariatric operations are classified as malabsorptive, restrictive, or a combination of the two. Malabsorptive procedures produce weight loss by interference with normal digestion and absorption. Restrictive procedures induce weight loss by limiting one's intake. Mixed malabsorptive and restrictive procedures produce malabsorption and limit intake [5]. There are, probably, no true restrictive operations. The gastric band, for example, in restricting intake, also prevents gastric distension and, accordingly, also interferes with the secretion of gastrin.

Unfortunately, the following discussion can only provide an overview on the lengthy history of bariatric surgery. There are multiple variations of each of the operations that has been performed over the last 60 years. For example, there has been variation in the size of gastric pouches, length of limbs, types and sizes of anastomoses, and vagotomy use. Additionally, many operations were developed and are no longer or rarely used but are of historical interest.

Malabsorptive Procedures

Intestinal Bypass

The first operations developed were of the malabsorptive type. The earliest application of these observations for the surgical treatment of obesity and its comorbidities was in 1952 by Henriskson. This Swedish surgeon recognized that small bowel resections performed for other disease processes than obesity usually produced no change in the patient's general status but in some cases resulted in significant weight loss [6]. Years of clinical observation had shown surgeons that shortened gut led to massive weight loss [7]. He applied these observations and resected 105 cm of small intestine from a 32-year-old obese female who was unable to complete a weight loss program. Interestingly, she lost only a small amount of weight but experienced an improvement in her quality of life [6]. While this was the first reported operation specifically for improving obesity, it was not adopted for treatment in other patients because it was not reversible. It would take the later development of a reversible procedure for the widespread use of a malabsorptive procedure.

In the United States, around the same time, surgeons were investigating ways to shorten the intestines as a treatment for obesity, and they created the intestinal bypass. Varco performed the first jejunoileal bypass (JIB) in 1953 [7]. One year later, his colleague, Kremen, published a report describing the effects of small intestinal bypass on dogs [8]. He bypassed various portions of small bowel and found that removing 50% of distal small bowel from the intestinal stream was associated

with weight loss. The procedure was done by diverting the proximal intestine to the terminal ileum. Kremen postulated that bypassing much of the small intestine could be used to induce weight loss in the severely obese and referenced the one human patient that had undergone the procedure [8]. The procedure consisted of an end-to-end jejunoileostomy and an ileocecostomy.

Other surgeons began developing variations of operations that bypassed small bowel. One of these was a diversion of the proximal small bowel to the colon. In 1963, Payne published a series of ten patients that had jejuno-colonic shunts performed [9]. In his procedures, the bypassed intestine included the jejunum, ileum, and right colon with an end-to-side jejuno-transverse colostomy. At the time, this was the largest published series of patients undergoing an operation to treat obesity. Initial results showed patients were able to lose weight and have improvement in their comorbidities. The operation was performed as a temporary measure, allowing time for weight loss to occur then the bypass would be reversed. However, after reversal, patients experienced significant weight gain, so the procedure began to be used a long-term option with the option of reversal if needed [9].

After the initial success of Payne, the intestinal bypass procedures increased in popularity. However, over the next decade, results showed that while there was significant weight loss, the patients suffered from severe diarrhea, electrolyte disturbances, and nutritional deficits. More importantly, there was a reported death rate of up to 10% [10]. These complications lead to modification by Payne to preserve the ileocecal valve [11]. This consisted of anastomosing the first 14 inches of the proximal jejunum to the side of the terminal ileum 4 inches from the ileocecal valve (Fig. 6.1). This "14+4" procedure became more popular, but despite the modification, the complications continued. Scott found that the proximal jejunal segment had elongated in several patients to almost 20 inches, and there was evidence of

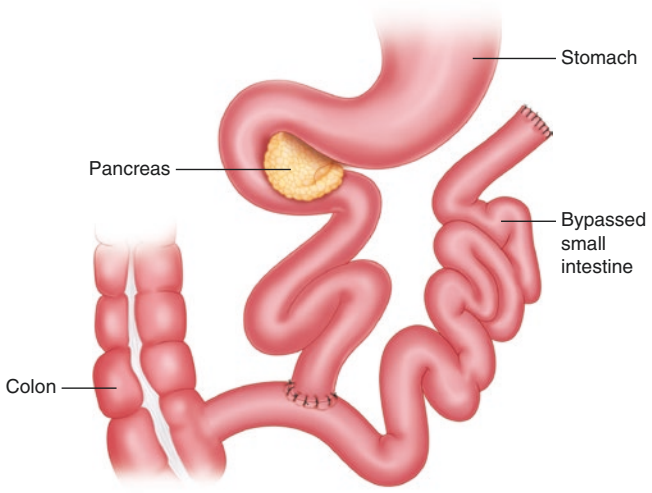


Fig. 6.1 Jejunoileal bypass

barium reflux into the bypassed ileum. This reflux allowed reabsorption of the contents and subsequent weight gain. He concluded that the procedure was still too experimental and not ready for widespread therapeutic application [12, 13].

The JIB and its variations were popular in the 1960s and early 1970s, and some patients had happiness with their results, but the procedure continued to have serious postoperative ramifications that ultimately were insurmountable. Without any food or bile passage through the bypassed limb, the environment was favorable for bacterial overgrowth and the condition bypass enteritis. JIB patients presenting with abdominal pain were found to have small bowel pneumatosis on radiograph from a passage of gas through the bowel wall. Unfortunately, some patients underwent unneeded operations for this problem as it was later found that antibiotics could resolve the bacterial overgrowth [14]. Among the most serious complication of the JIB was liver disease from protein deficiency, often progressing to liver failure and death [15]. Other complications included malabsorption of vitamins and nutrients, electrolyte imbalance, renal calculi, arthritis, significant diarrhea, cholelithiasis, colonic pseudo-obstruction, and osteomalacia [16]. JIB patients needed very close surveillance, diet modifications, and antibiotics to avoid complications. Many patients underwent reversal of the operation [17]. For these reasons, surgeons offering the procedure were not well received, and many advocated for its end. The JIB was replaced and since abandoned by less morbid operations [18, 19]. This period remains one of the darkest in modern surgery; more than 30,000 intestinal bypass operations were performed before recognition that the complications were unacceptable [5].

Partial Ileal Bypass

One intestinal bypass, introduced by Buchwald in 1963, has, however, stood the test of time. The operation consisted of the division of the ileum 100 cm from the ileocecal valve with implantation of the proximal loop into the cecum, a procedure that, in essence, excluded the distal ileum from contact with food. In the NIH-sponsored trial, the Program on the Surgical Control of Hyperlipidemias (POSCH), the procedure reduced plasma cholesterol, in particular LDL, with concomitant retardation of atherosclerotic disease and increased life expectancy. A 30-year follow-up documented that the operation also afforded partial protection from the onset of type 2 diabetes [20].

Combined Malabsorptive and Restrictive Procedures

Gastric Bypass

With the troublesome results of the intestinal bypass procedures, surgeons continued to search for safer bariatric operations. There was a major breakthrough in 1967 when Mason developed the gastric bypass, the first malabsorptive and restrictive

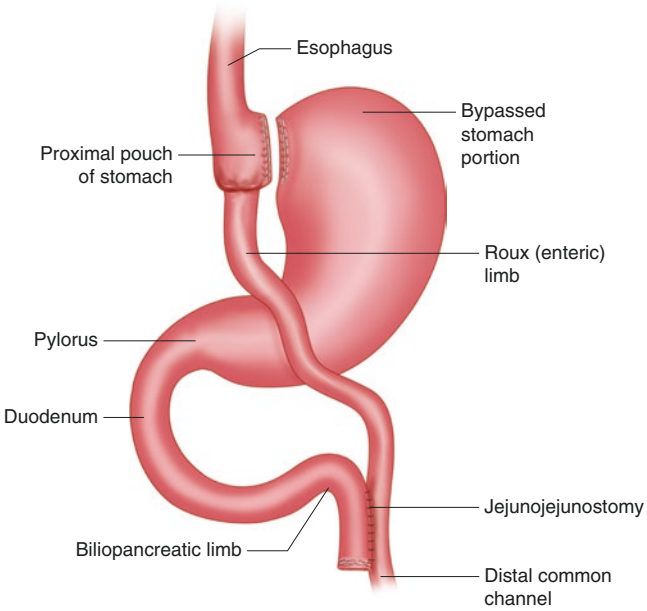


Fig. 6.2 Roux-en-Y gastric bypass

procedure (Fig. 6.2). Mason observed that weight loss was common in patients after undergoing gastrectomy for ulcer disease. His team studied this on dogs, performing a gastroenterostomy and concluded that a subtotal gastric bypass could be used for the treatment of obesity in humans [21]. In 1969, Mason reported a series of 24 patients that underwent the procedure that was essentially a modification of a Billroth II with a different goal [22].

Surgeons were already skilled in gastric resection for the treatment of ulcer disease which helped grow the popularity of the operation more quickly than a novel operation. The loop gastric bypass offered the possibility of reversal with the use of the excluded stomach. Despite the familiarity with the gastric resection, the operation proved difficult in this patient population with operating times in excess of 5 h. Alden published a series in 1977 that compared JIB patients to gastric bypass patients and concluded that the gastric bypass had fewer comorbidities, was equally safe, and resulted in equal amounts of weight loss [23, 24]. Also, in 1977, Griffen noted that the largest technical difficulty of the Mason loop gastric bypass was obtaining the correct positioning of the stomach and small bowel loop. Several of his early patients had postoperative bilious emesis prompting the change from a loop to a Roux-en-Y type anastomosis [25].

The Greenville gastric bypass developed at East Carolina University included 837 consecutive patients, all treated with an identical operation (30 cc gastric pouch, 10 mm handsewn gastroenterostomy, 60 cm alimentary jejunal segment) with a 95% follow-up from 1980–1986, with a mean duration of 9.2 years. This study documented that the procedure could be done safely, achieved a long-term mean weight loss of 102 lbs., and, most importantly, produced long-term remission of

type 2 diabetes in 83% of the diabetic patients [5, 25]. From the same series, MacDonald was also the first to document the reduction in the mortality of diabetics by 78% [26]. The study highlighted that patients lost to follow-up were treatment failures and that any new operative procedure requires thorough evaluation before widespread use [27]. The addition of the Roux-en-Y was important because it eliminated bile reflux and provided less tension on the gastroenteric anastomosis.

Additional experimentation and modifications followed in an effort to improve the operation over the following decades [28]. While the gastric bypass had good results compared to the available options, it had its own set of new complications. Patients could suffer from dumping syndrome if too high of a carbohydrate load was eaten. Although, some argued this was beneficial from weight loss as a deterrence to overindulgence. More importantly, marginal ulcers presented as a potential serious complication. As seen in the prior malabsorptive procedures, iron, B12, and calcium supplements were necessary. In 1994, Wittgrove first described the technique of the laparoscopic Roux-en-Y gastric bypass [29]. This proved to be a major advancement for the field of bariatric surgery as one of the most difficult abdominal operations could be performed with laparoscopy safely. Laparoscopy offered patients a shorter hospital stay and an earlier return to activity, among other benefits and over time replaced the open technique completely [5].

Biliopancreatic Diversion and Biliopancreatic Diversion with Duodenal Switch

Meanwhile, another operation, the biliopancreatic diversion (BPD), also a malabsorptive and restrictive procedure, was described only shortly after the gastric bypass by Scopinaro (Fig. 6.3). After success with animal models, in 1979, the Italian surgeon published a report of 18 patients that had underwent BPD with 1-year follow-up. The operation consisted of a partial gastrectomy with closure of the duodenal stump, transection of the jejunum 20 cm distal to the ligament of Treitz, and a gastrojejunostomy performed with the distal portion of the transected jejunum creating a limb about 250 cm long. The proximal portion of the transected jejunum was anastomosed to the distal ileum forming a common channel of 50 cm with a preserved terminal ileum. This arrangement was created to keep the bypassed bowel from developing stasis and blind loop syndrome seen in earlier intestinal bypass procedures. The results from the initial case series showed that the procedures were a safe alternative [30].

The BPD procedure proved to be safe and very successful. Scopinaro reported his experiences with the BPD over a 21-year period in 1998. The results from over 2000 patients showed that the BPD was the most effective procedure in terms of initial weight loss and maintenance of weight [31]. The procedure had excellent reduction in comorbidities as well. As seen with other new operations, potentially dangerous complications were found including diarrhea, foul-smelling stools, increased flatulence, anemia, stoma ulceration, protein malabsorption, dumping

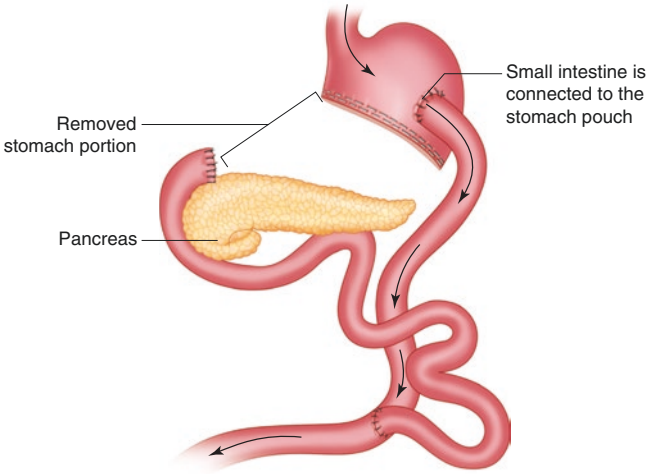


Fig. 6.3 Biliopancreatic diversion

syndrome, peripheral neuropathy, Wernicke encephalopathy, and bone demineralization. Among these, protein deficiency was the most serious complication and the most common cause of late mortality after the operation. Surgeons recognized that very careful lifelong follow-up was needed for surveillance and prevention of these complications [32].

While the BPD produced excellent weight loss, the long-term morbidity inspired others to attempt to improve upon the positive results. In 1998, Hess described the BPD combined with a duodenal switch (DS) (Fig. 6.4). The operation was essentially a hybrid of the BPD and an experimental operation initially used for duodenogastric reflux [33]. The BPD with DS preserved the pylorus with a gastrectomy performed along the greater curvature. After 9 years of follow-up, reported weight loss and comorbidity resolution was similar to the BPD data. The advantages of the BPD with DS over the BPD alone were less liver failure, renal failure, and electrolyte disturbances due to the longer common channel. Additionally, with the preserved pylorus, marginal ulcers and dumping syndrome were much less common. The BPD and the BPD with DS are difficult and long operations both open and laparoscopically that have a long learning curve. Another complication, an internal hernia, is a problem that may need immediate surgeon attention to avoid bowel incarceration and necrosis. The complication was rarely seen in the days of primarily open surgery but has become more common since the advent of laparoscopic surgery, as the approach produces fewer intra-abdominal adhesions [34]. These reasons along with the potential morbidity if not followed properly have hindered the popularity of these operations despite the excellent weight loss results.

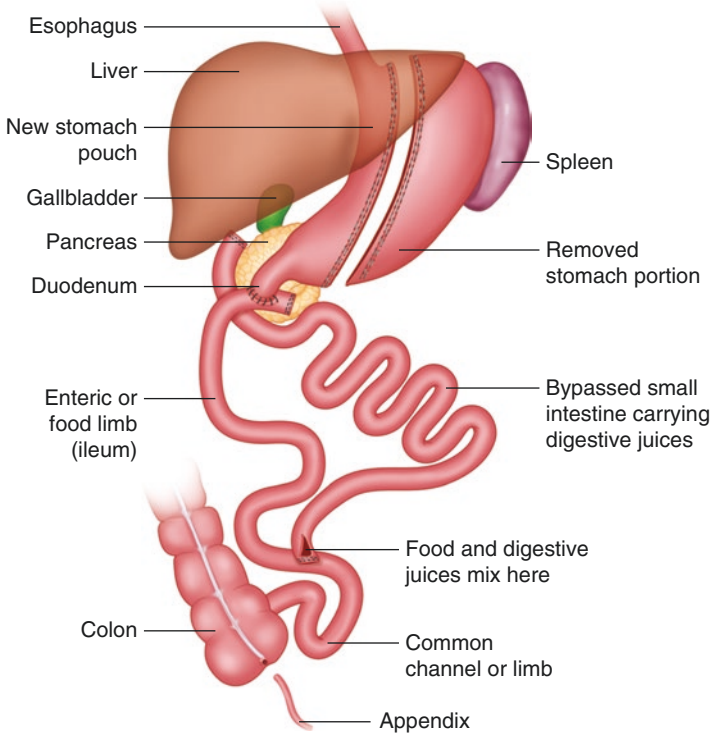


Fig. 6.4 Duodenal switch

Minigastric Bypass

The minigastric bypass, sometimes also known as the omega bypass or single anastomosis bypass, remains a controversial operation in spite of increasing evidence of efficacy in terms of weight loss and remission of comorbidities. The operation, as described by Rutledge in 2001, is in theory less technically difficult than a Roux-en-Y gastric bypass and consists of a single gastrojejunal anastomosis between a long gastric pouch and a jejunal omega loop of 150–250 cm [35] (Fig. 6.5). There is a lack of reliable randomized clinical trials on the minigastric bypass, but available studies suggest a similar weight loss and metabolic improvement comparted to the Roux-en-Y gastric bypass [36]. However, the minigastric bypass remains controversial due to concerns of increased biliary reflux leading to dysplastic changes of the gastric and esophageal mucosa. Questions about higher complication rates, need for reoperation, and the lack of reliable randomized clinical trials vs. the accepted operations continue to limit its evaluation and acceptance [37].

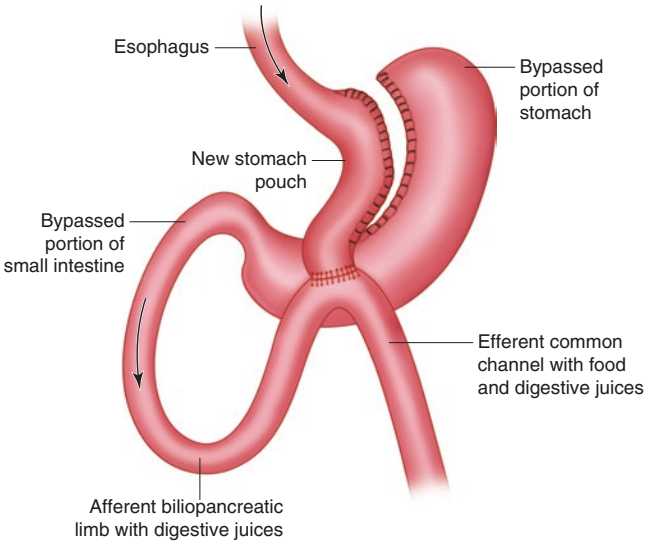


Fig. 6.5 Minigastric bypass

Restrictive Procedures

Vertical Banded Gastroplasty

Other surgeons sought additional methods to provide an operation that did not involve an enteric or a gastric bypass. Gastroplasty was first reported in 1973; from the observation that extensive gastric resection with a Billroth II anastomosis produces weight loss, Printen and Mason wanted to find a simpler procedure than the loop gastric bypass that would not have the risk associated with bowel anastomoses [38]. They proposed a partial horizontal transection of the stomach leaving a small upper gastric remnant with a narrow channel between the upper and lower gastric pouches. Their procedure consisted of stapling across the stomach to create a functional gastric transection with a greater curvature conduit of 1.0–1.5 cm between the upper and lower pouches. The gastroplasty resulted in less weight gain compared to the gastric bypass. The common channel could be stretched with excessive eating and become widened, and the integrity of the staple line remained a problem over time. In an effort to keep the gastric pouch from widening, Laws added a silastic ring around the newly created gastric outlet after a vertical gastric partition in 1981 [39].

With these modifications, a series of 42 patients underwent a vertical banded gastroplasty (VBG) with Mason in 1982 [40]. The procedure included creating a vertical gastric partition to create a small, <50 mL pouch, and banding of the lesser curvature pouch outlet with polypropylene mesh. He noted that with horizontal stapling, the retaining sutures and staples often failed over time and left a larger stoma. The small gastric pouch had been shown to put the patient at risk for reflux esophagitis. But with the vertical partition, the incidence was less as the angle between the

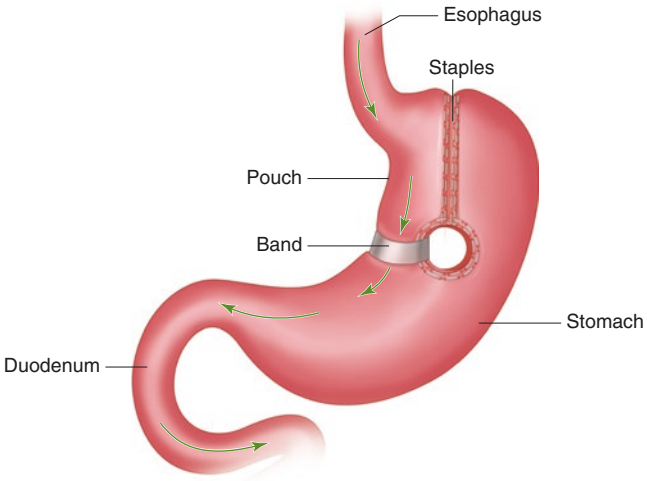


Fig. 6.6 Vertical banded gastroplasty

stomach and the esophagus was maintained [41]. The long-term data showed that the silastic ring created stenosis of the gastric outlet in some patients and contributed to food intolerance and reflux esophagitis and had high rates of reoperation. Other surgeons used Marlex mesh to reinforce the gastric outlet, and this proved to be the superior material for the VBG [42] (Fig. 6.6).

The VBG had advantages compared to the other available weight loss operations available in the early 1980s and 1990s. First, it was not as technically challenging as the bypass procedures. Additionally, it avoided the potential complications of dumping and marginal ulcers. The VBG was easier to reverse as well, if needed. However, over several years, patients began to regain their lost weight. Studies comparing the VBG to the gastric bypass with long-term results began to surface in the mid-1990s. The Roux-en-Y gastric bypass proved to be a better weight loss operation. The reports pointed out that the stapled partition would break down over time creating a larger stoma and causing weight gain [43]. Many patients underwent revisions to other bariatric procedures. The VBG slowly fell out of favor and was rarely performed once the laparoscopic adjustable gastric band was widely available.

Adjustable Gastric Bands

In the mid-1970s, Wilkinson was searching from other means to surgically achieve early satiety and reduced caloric intake. He wanted to develop a more physiologic operation without disturbing the continuity of the gastrointestinal tract. He conducted canine experiments in which he tied prolene suture around the greater curvature with a 1 cm bougie in the stomach. The dogs lost weight, but after 3–4 months

the stomach dilated back to its normal size, so he began using a polypropylene mesh wrap around the stomach. His first human patient underwent a similar operation with a polypropylene mesh stomach wrap in 1976. The patient was pleased with their weight loss in the first year but became discouraged at 1 year and underwent a gastric bypass. Later, he published a series of 100 patients that underwent Nissen fundoplication and gastric wrapping with polypropylene mesh. The fundoplication was performed to prevent post op reflux. He found that this procedure has satisfactory weight loss and gave the patient early satiety without any metabolic or physiologic changes [41, 42].

As the operation gained popularity, different sizes and materials of mesh were used to decrease inflammation and the potential for erosion. Fewer surgeons would wrap the entire stomach as Wilkinson initially did and began using 1–2.5 cm bands placed across that stomach to create a small upper pouch and narrow channel to the remaining stomach. Among the most used material was Marlex mesh. A series with 7–12 years follow-up from Sweden, the Marlex gastric band was not successful at long-term weight loss. Half of the patients underwent revision due to severe emesis, esophagitis, and weight gain [44]. Other surgeons used silicone bands with better results. Despite this, the nonadjustable banding procedures were difficult in creating the correct stoma size, and reoperations were done frequently due to obstruction. Additionally, the gastric pouch could dilate over time and contribute to reflux esophagitis [45]. With further developments, the band was made to be adjustable. The adjustable bands were originally developed in Austria by work done on rabbits. The goal was to develop a reversible gastric band that could be adjusted to the individual needs of the patient. A liquid-filled silastic cuff placed around that stomach adjacent to the cardia was used. The cuff diameter was adjusted by filling or draining fluid from a subcutaneous valve access by percutaneous needle puncture [46].

The adjustable band provided patients with a variable size stoma that could be altered based on their individual symptoms. The procedure proved to be better at weight loss than the nonadjustable band and had fewer complications [45]. The adjustable bands easily displaced the nonadjustable bands in popularity. Around the same time in the early 1990s, laparoscopy was beginning to offer alternative means to traditionally open surgery. In 1993, Belchew described the laparoscopic adjustable gastric band placement [47]. The laparoscopic gastric band became the most common bariatric operation in Europe and the United States (Fig. 6.7). This procedure was able to provide a significant loss of excess weight with few complications and a reduction in comorbidities. The procedure provided a less invasive and reversible operation than a gastric bypass with similar short-term weight loss but with long-term potential risks of band slippage, erosion, and foreign body infection [48]. While the operation has fallen out of favor in recent years with the popularity of the sleeve gastrectomy, the adjustable gastric band remains a current option for obese patients. One of the challenges of the adjustable gastric band is that, in practice, it is not easily adjustable due to the requirement to return to the surgeon for adjustment. Perhaps the addition of a valve from the reservoir that could be adjusted with an external magnet could again make this operation attractive, especially in children and adolescents.

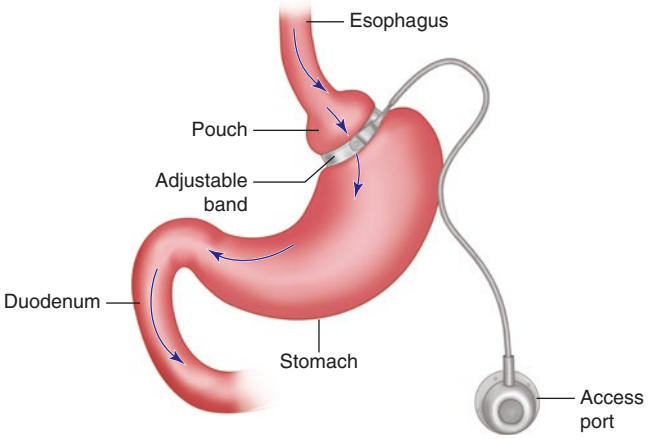


Fig. 6.7 Adjustable gastric band

Sleeve Gastrectomy

The sleeve gastrectomy (SG) was originally described as a staging procedure for super obese patients to bridge them to a more definitive weight loss operation. After observing a high morbidity and mortality rate after BPD and DS in the super obese, Regan and Gagner developed the two-stage approach. Their patients underwent an initial SG over a 60 F bougie, and then in 6–12 months after a plateau of weight loss, the patients would undergo a second-stage BPD with DS or gastric bypass [49]. The SG procedure separates the greater curve from the antrum. Many patients that underwent SG as a bridge operation lost enough weight with the SG alone that the secondary operation was no longer necessary (Fig. 6.8). The first laparoscopic sleeve gastrectomy (LSG) was reported in 1999, and the first report of LSG as a standalone operation was in 2003 [50]. Gagner later published a comparison of LSG and adjustable gastric band patients and showed that short-term 1 year weight loss was comparable and the LSG had a decreased need for reoperation and decrease in ghrelin production [50].

The standalone LSG has increased in popularity in the last several years and is now the most common bariatric operation performed in the United States [51]. The LSG has many advantages over other current operations. The LSG is less technically demanding than the gastric bypass or the BPD, has minimal morbidity, and is without marginal ulcers, dumping syndrome, internal hernias, or nutritional deficiencies. Complications seen with the LSG include staple line leaks and strictures. Over time, the leak rate has decreased with improved technique and staple technology. The LSG's favorable weight loss results, significant remission of comorbidities, and very low rates of postoperative mortality and morbidity have contributed to its rise in popularity [52]. The LSG is still as relatively new operation and is without much long-term data; we will have to wait and see with the further holds for this promising operation.

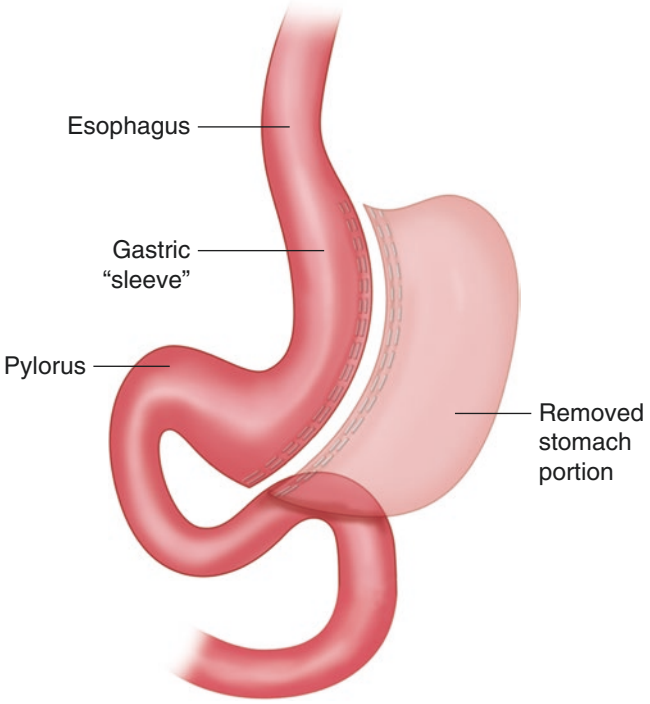
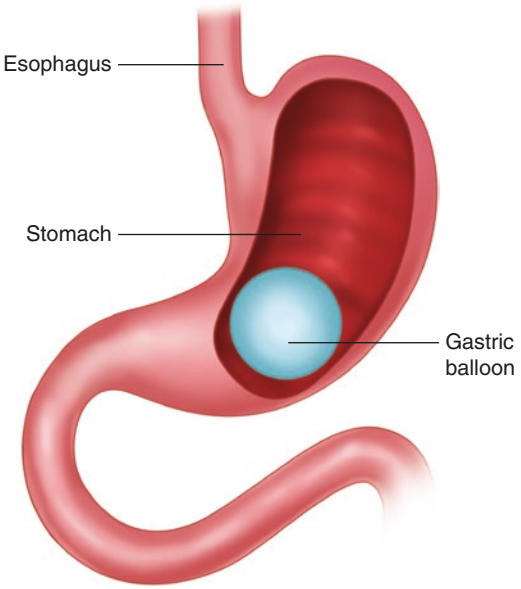


Fig. 6.8 Sleeve gastrectomy

Gastric Balloon

Many patients are reluctant to undergo any of the bariatric operations despite the knowledge associated of comorbidities associated with morbid obesity. An option for these patients is the newly developed intragastric balloon. This provides a temporary, reversible, and repeatable treatment alternative (Fig. 6.9). The balloon is placed endoscopically, and typically the balloon is filled with 500 mL of saline and removed after 6 months [53]. Newer balloons can be placed without endoscopy; others have two chambers to prevent migration. The therapy has been found to have a temporary effect up to 3 years, despite repeat balloon placement [54]. The weight loss experienced does improve obesity-related comorbidities, but typically the weight is regained, and the positive effect is lost [53]. The balloon, along with diet and exercise, has demonstrated better weight loss compared to diet and exercise alone in a prospective randomized trial [55]. The balloon does not solve the patient's obesity problem, and only with multiple placements can it control obesity in the long term, but in patient who declines surgery, it is a treatment option that should be strongly considered [53]. Interestingly, up to 32% of patients that undergo gastric balloon placement eventually go on to have bariatric surgery [53, 54].

Fig. 6.9 Gastric balloon



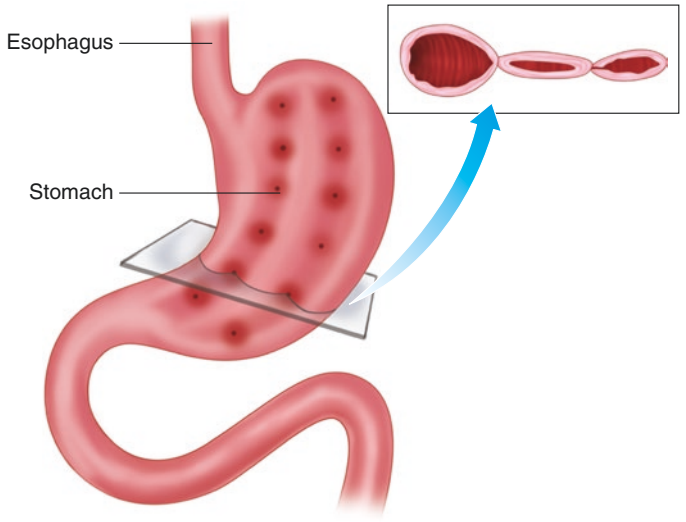


Fig. 6.10 Endoscopic gastroplasty

Endoscopic Gastroplasty

Endoscopic plication to produce and reduce the stomach into a gastric sleeve has some favorable reports but is not ready for wide adoption. The procedure is incisionless and reduces gastric capacity by creating a restrictive sleeve through a series

of endoluminally placed full-thickness triangular sutures extending from the prepyloric antrum to the gastroesophageal junction (Fig. 6.10). In a study of 248 patients from three centers, Lopez-Nava reported total body weight loss at 6 and 24 months of 15.2% and 18.6%, respectively, with five serious adverse events (2%). The loss of 33 and 35 patients, respectively, for follow-up, raises more questions [56].

The Rigorous Documentation of Outcomes, Safety, and Societal Development

One important innovation that advanced the field of bariatric and metabolic surgery was the emphasis on rigorous quality control and documentation that operations could be performed with minimal mortality and morbidity. Our studies on gastric bypass, the Swedish Obese Subjects (SOS) study, and the NIH/NIDDK "Longitudinal Assessment of Bariatric Surgery" (LABS) all demonstrated the importance of long-term studies. The SOS study was a prospective controlled trial of 4047 obese patients with 2010 undergoing bariatric surgery including gastric bypass, banding, and vertical banded gastroplasty and 2037 in matched control group undergoing conventional treatment. The patients were followed over a period of up to 15 years, with average of 10.9 years of follow-up for 99.9% of patients. The SOS results showed that compared to conventional treatment, the surgery group was associated with a long-term reduction in overall mortality, decreased incidence of diabetes, myocardial infarction, stroke, and cancer [57].

The NIDDK-sponsored Longitudinal Assessment of Bariatric Surgery (LABS) study was established to analyze the risks and benefits of bariatric surgery and its impact on the well-being of patients with obesity [58]. The consortium started collecting data in 2005. LABS first evaluated the 30-day outcomes after bariatric surgery, with data from 4776 bariatric surgery patients, with an overall 30-day mortality of 0.3% and low rates of adverse outcomes, comparable to a laparoscopic cholecystectomy [59]. LABS also evaluates the long-term safety and efficacy of bariatric surgery, and these data have led to multiple publications and newfound knowledge in bariatric surgery.

Bariatric surgery, perhaps to gain credibility in view of the disbelief that an intestinal operation could cure diabetes and other expressions of the metabolic syndrome, has been the leader in the improvement of surgical safety with the development of Centers of Excellence (CoE). Confronted with reports of disastrous clinical outcomes in hospitals with limited experience, an increase of malpractice suits, and unaffordable insurance premiums, the leadership of the American Society for Metabolic and Bariatric Surgery (ASMBS) created a program for the certification of CoE in 2003 [5]. To assure total independence, the ASMBS delegated the process to a separate nonprofit organization, the Surgical Review Corporation, led by Mr. Gary Pratt. The certification required standardization of care paths, training of hospital personnel, well-equipped hospitals capable of managing very obese

patients, and registering all patients and following their outcomes. In addition, all sites were inspected at least once every 3 years, often with unannounced visits [60].

Outcomes were recorded with the Bariatric Outcomes Longitudinal Database (BOLD) in the program that eventually included 425 hospitals in the United States as well as other centers in 22 countries. The BOLD software provides a medical record that does not allow dictation but requires the entry of all relevant data with tablet-touch multiple choice questions. That approach not only assures the completeness of all data but overcomes the inability to search dictated histories. Due to immediate entry on a national server, it allows real-time analysis of the entries. For example, the approach allowed the determination of how many patients were seen that day who were hypertensive and over 65 years old. BOLD collected patient demographics and surgical outcomes for up to 2 years after their operation. BOLD provided information for providers to learn and provide better patient care. In 2006, the Centers for Medicare and Medicaid Services (CMS) restricted coverage for bariatric operations for Medicaid patient to CoE hospitals [61]. In 2012, the program was absorbed by the American College of Surgeons which had developed its own CoE program to assure there would be only one set of standards for bariatric surgery. In an interesting development, centers that were not certified were forced to produce the same excellent outcomes to continue reimbursement by insurance carriers. This "the tide lifts all boats" phenomenon has led to the CMS to stop requiring center certification in 2013 [61, 62]. Despite the CMS decision, private insurers continue to support accreditation and restrict coverage to only high-volume centers.

A major factor in the progress and acceptance of bariatric surgery has been the development of two, trusted, high-impact journals, Surgery for Obesity and Associated Diseases (SOARD) and Obesity Surgery (OBSU).

Acceptance into Mainstream

Currently in the United States, there is a failure for the medical community as a whole to take full advantage of bariatric surgery. More than one third of Americans suffer from obesity, and approximately 20% have a BMI > 35 kg/m^2 [3]. Furthermore, there are 29.1 million Americans with type 2 diabetes and close to 2 million newly diagnosed cases annually [63]. Despite this, there were only 179,000 bariatric operations performed in 2013 [64]. Less than 1% of possible patients underwent a treatment that could cure them of diabetes, not to mention an improvement in their other comorbidities. There are several prospective randomized studies showing patients that undergo bariatric surgery compared to a matched control group without surgery have lower all-cause mortality and decreased deaths from type 2 diabetes, heart disease, and cancer [65–70]. Despite the benefits and the supporting data, patients remain afraid of surgery, and many physicians are not convinced that traditional treatments are ineffective.

Unfortunately, this delay in acceptance of a revolutionary treatment has been seen many times throughout medicine. Alexis Carrel developed the basic principles of vascular surgery in 1894, but the first vascular surgery procedure did not occur until 1962 [71]. Additionally, laparoscopy was used in 1901 by Georg Kelling on dogs [72], but it was not until 1981 that Kurt Semm performed the first laparoscopic appendectomy [73]. Along those same lines, in the 1940s, Gerhard Kuntshcer developed and used the first intramedullary nail in Europe during World War II. The procedure was described in a 1945 Time magazine article "Amazing Thighbone," but American surgeons remained skeptical of his methods. It wasn't until the 1970s that the closed nailing technique was revisited and is now the standard of care for femoral shaft and tibial fractures requiring operative stabilization [74].

With the current obesity epidemic and the associated increasing prevalence of associated comorbidities, more work needs to be done to educate patients and other physicians of the lifesaving benefits that bariatric surgery provides.

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Chapter 7
The Obesity Epidemic

Laura Mazer and John M. Morton

Introduction

Early in history, humanity feared food shortages, malnutrition, and starvation. The accumulation and storage of excess fat in the body was a potential survival advantage. The first sculptural representations of the human body were idolizations of obese women carved in the Stone Age (Fig. 7.1). But the recognition of obesity as potentially undesirable also has its roots in antiquity: the Ancient Greeks sought an equilibrium between the excessive thinness of starvation or malnutrition and excessive heaviness of obesity which carried its own potential long-term consequences. Socrates apparently danced every morning to maintain his figure; physicians of his era encouraged the overweight to eat less, work more, and avoid baths [1]. Hippocrates wrote that "corpulence is not only a disease itself, but the harbinger of others," a quote referenced by William Harvey in his 1872 book *On Corpulence in Relation to Disease* [2]. The establishment of obesity as a cause of ill health was not well accepted, however, until the mid-nineteenth century, and the pathophysiology of excess weight loss on chronic illness was not understood until the early twentieth century [3].

The cultural and economic implications of obesity have also changed over time. Traditionally, obesity was a problem of wealth, and it is still true that high-income countries have greater rates of obesity than middle- and low-income countries and that on the national level obesity rates correspond to economic growth [4]. Within high-income countries like the United States, however, people living closest to the poverty line are the most prone to obesity [4, 5]. There are numerous factors underlying the relationship between obesity and poverty within the developed world, including education, income, access to food, and occupation. Socioeconomic status not only impacts obesity, but the converse is also true: the perception of obesity carries a stigma, and discrimination can limit upward socioeconomic mobility [6].

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Fig. 7.1 Venus of Willendorf, Austrian example of the Venus figurines from the Paleolithic era (Source: http://donsmaps.com/willendorf.html. Photo by Don Hitchcock. Licensed under the Creative Commons Attribution-Share Alike 3.0 Unported License)

In the developing world, low- and middle-income populations face a double burden of disease. Children in these countries often have inadequate prenatal, infant, and early childhood nutrition, while being exposed to high-fat, high-sugar, and nutrient-poor foods later in life. The result is an increase in childhood obesity in the same households still fighting the specter of malnutrition [7].

Obesity has become a worldwide epidemic, impacting almost every country and socioeconomic group. Health-care workers are increasingly required to manage the consequences of an overweight population. Understanding the epidemiology of obesity is becoming an essential element of clinical practice. This chapter will provide a brief overview of the current status of the obesity epidemic.

Defining the Terms

Obesity refers to the accumulation of excess body fat, although the specific percentages of body fat that differentiate normal from overweight from obese are somewhat arbitrary. These definitions can change depending on genetic and cultural norms. Body weight is the most common proxy of adiposity, although weight does not correlate directly with percentage of body fat. There are also numerous factors beyond either weight or percentage of body fat, including muscle mass, frame size, and distribution of adiposity, that impact overall health. Central adiposity, along with a constellation of other risk factors including serum cholesterol, elevated blood pressure, and impaired fasting glucose, defines metabolic syndrome, a group of conditions that dramatically increase the risk of chronic disease.

The presence of metabolic syndrome, or its components, is a better indicator of morbidity and mortality than weight alone, but it is more challenging to identify and

Table 7.1 WHO adult BMI classifications

Weight class	BMI (kg/m^2)	Risk of comorbidities
Underweight	<18.5	Low[a]
Overweight	>25	Average
Obese class 1	30–35	Increased
Obese class 2	35–40	Moderate
Obese class 3	>40	Severe

Used with permission of WHO from http://www.euro.who.int/en/health-topics/disease-prevention/nutrition/a-healthy-lifestyle/body-mass-index-bmi

[a]Risk of obesity-related comorbidities is low, although risk of other health problems is increased

record. Health-care workers and epidemiologists have sought an objective metric that can be easily and reproducibly applied in a clinical setting. Historically, body weight and height have been used as proxy indicators of increased metabolic risk. In 1959, the Metropolitan Life Insurance Company produced life tables indicating the range of weights and heights at which mortality was lowest for policy holders. For decades thereafter, "overweight" was defined as a body weight greater than 20% above the midpoint weight range for a medium frame size on the Metropolitan Life Tables [8]. In 1995, the World Health Organization (WHO) accepted body mass index (BMI, weight divided by height squared) as the best method for determining degrees of under- or overweight (Table 7.1) [9]. The WHO chose 25 as the upper limit of normal, although some regional societies have argued for slightly different cutoffs: Asian countries use 23 instead of 25 as a cutoff for normal BMI, and some physicians in the United States have argued for 28 an upper limit [9]. In childhood and adolescence, obesity is defined as the 85th–95th percentile of sex-specific BMI-for-age in a reference population [8].

As BMI increases around the world, researchers and commentators are increasingly referring to the prevalence of excessive adiposity as an "epidemic." Classically used to refer to the spread of infectious diseases, epidemics are widespread occurrences or outbreaks within a community. The term has been extended to refer to noninfectious health-related events that are in excess of normal expectations [10]. Given the current worldwide prevalence and lack of geographic constraints, the current obesity distribution can be more accurately viewed as a pandemic.

Health Implications

Obesity carries both individual and public health burdens. Obesity is associated with an increased risk of type 2 diabetes [11], cardiovascular disease [12], several forms of cancer [13], and numerous other conditions including osteoarthritis, asthma, sleep apnea, liver disease, and kidney disease (Fig. 7.2) [14, 15]. In addition, obesity raises risks of surgical complications and decreases effectiveness of medical interventions like chemotherapy. Increasing BMI carries an increased burden of chronic illness

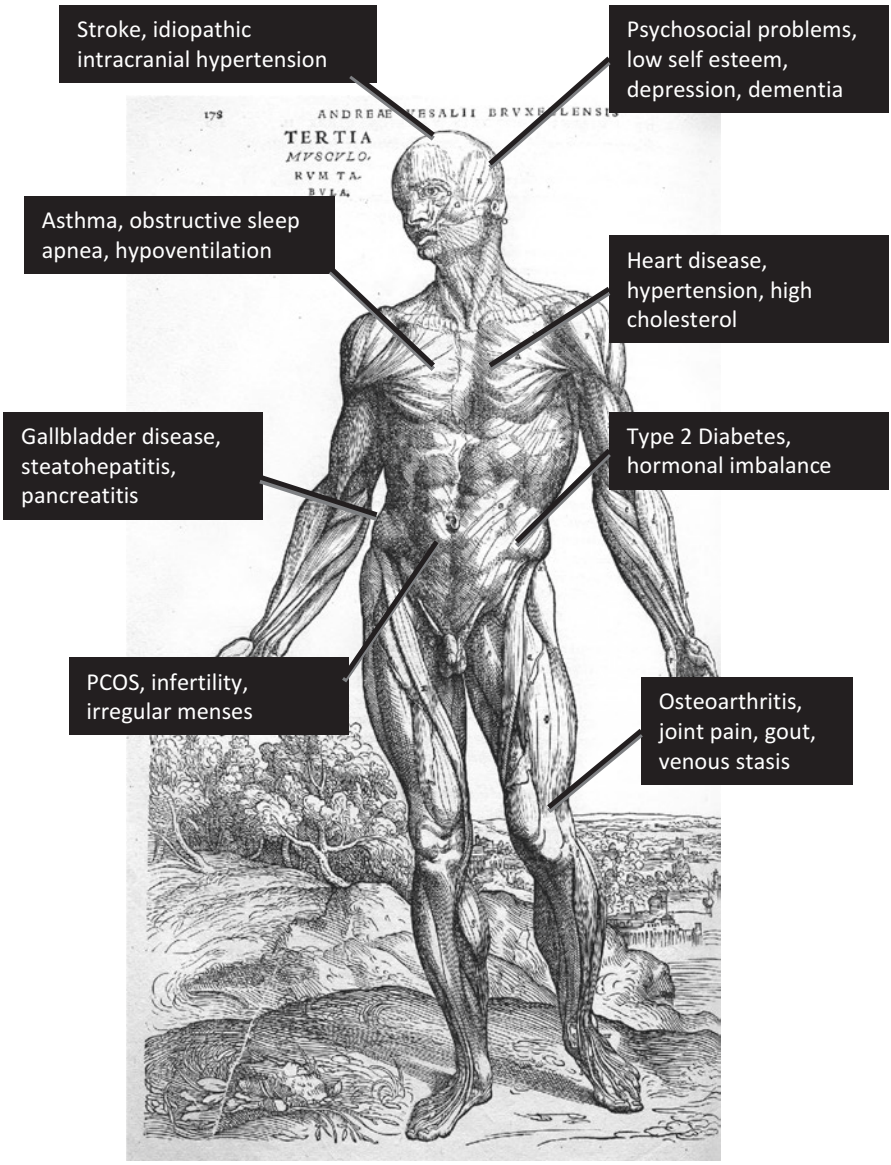

Fig. 7.2 Consequences of obesity

and disability, with associated decrease in quality of life [16]. Obesity also decreases life expectancy, especially among younger adults who can lose on average more than 20 years of life compared with normal BMI controls [17, 18]. Along with the physical complications, obesity also carries psychosocial burdens including depression, eating disorders, and poor self-esteem, especially among obese children and adolescents [19]. Even in the absence of comorbidities, overweight and obese BMI is associated with decreased quality of life [16]. The converse is also true: weight loss has been shown to improve numerous health risk factors. Even without reaching an ideal weight, a moderate amount of weight loss can result in improved blood pressure, fasting blood sugar, and cholesterol panels [8].

Rising obesity rates also carry significant public health implications. Obese patients incur 46% greater inpatient costs, 27% more outpatient visits, and 80% more prescription drug spending than non-obese patients [20]. The annual extra medical costs of treating obesity in the United States account for up to 7% of total health-care expenditures with similar values in other countries around the world [14]. A hypothetical reduction of 1% in BMI across the entire population would avoid 2 million cases of diabetes and over 100,000 cancers [14]. The estimated direct medical costs of obesity in the United States were more than $92 billion in 2002 [21]. Americans spend more than $30 billion dollars annually on weight loss programs and products [8]. However, these costs focus on health care alone, ignoring the economic impact of loss of productivity from disability- and obesity-related diseases.

The Numbers: Prevalence and Trends

In the United States, most long-term epidemiologic studies of obesity rely on data from the National Health and Nutrition Examination Survey (NHANES). NHANES is a program of studies designed to record the health and nutritional status of adults and children in the United States from a combination of interview and physical examination data. From 1960 to 2004, the percentage of overweight or obese adults in the United States increased from 45% to 66%, and the percentage of obesity alone increased from 13% to 33% during the same time period [8]. By 2014, 38% of the adult population in the United States was obese [22]. While adult obesity continues to rise in the United States, the rate of rise has slowed slightly in recent years (Fig. 7.3). Obesity rates are also high for children and adolescents in the United States, with up to 17% of children at or above the 95th percentile on sex-specific growth charts. Although there seems to be no reversal of the trend in sight, the incidence of obesity in the adolescent population has leveled off, with no change in prevalence between 2003–2004 and 2009–2010 [23]. Rates continue to vary depending on gender and ethnicity, ranging from a 5% prevalence of obesity in Asian girls to a 25% prevalence in Hispanic boys.

Around the world, over half of all adults are overweight, and 18% of the population is obese. Prevalence varies by country. In Mexico, New Zealand, and the United States, more than one in three adults are obese; in Australia and Canada, one in four

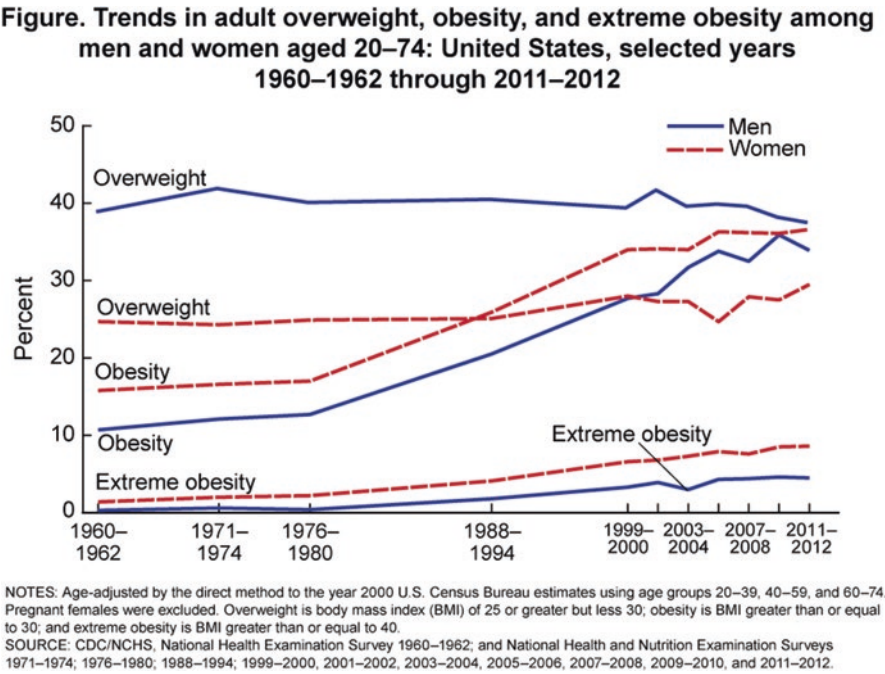

Fig. 7.3 Trends in adult overweight, obesity, and extreme obesity among men and women aged 20–74: United States, selected years 1960–1962 through 2011–2012. Notes: Age-adjusted by the direct method to the year 2000 US Census Bureau estimates using age groups 20–39, 40–59, and 60–74. Pregnant females were excluded. Overweight is body mass index (BMI) of 25 or greater but less 30; obesity is BMI greater than or equal to 30; and extreme obesity is BMI greater than or equal to 40 (Data Source: CDC/NCHS, National Health Examination Survey 1960–1962; and National Health and Nutrition Examination Surveys 1971–1974; 1976–1980; 1988–1994; 1999–2000, 2001–2002, 2003–2004, 2005–2006, 2007–2008, 2009–2010, and 2011–2012; Reprinted from: Fryar et al. [24])

are obese. In Asian countries, less than 1 in 20 adults is obese [25]. Many countries have seen similar trends to the United States, with a slower rate of increase or even a leveling off in obesity rates in recent years [25].

As discussed earlier, obesity is multifactorial. Epidemiologic studies focus almost entirely on body weight and BMI because these metrics are objective, easy to measure in the clinical setting, and easy to compare between studies or databases. A more complete picture involves an analysis of the consequences of obesity, which are also rising. From 1994 to 2014 in the United States, the prevalence of diabetes mellitus type 2 in adults increased from 8% to 12%, hyperlipidemia increased from 23% to 27%, and hypertension from 25 to 30% [22]. In adolescents, the presence of metabolic syndrome findings is dramatically increasing, from 4.2% in 1994 to 9.4% in 2002 [26, 27].

Determinants of Obesity

Genetics certainly play a role in obesity, with adoption and twin studies suggesting that genetic factors explain anywhere between 20% and 80% of observed variance in BMI [28]. There are even specific genes that have been implicated in causing childhood obesity [29], although it is unlikely that a single obesity gene accounts for more than a small fraction of the disease [19]. Ethnicity also plays a role, with the rate of increase in obesity differing in different ethnic groups. In the United States, prevalence has increased more than twice as fast in African American and Hispanic groups compared to Caucasian or Asian cohorts [19]. Even the impact of diet is filtered through genetic mediators; the results of a high-sugar diet differ depending on ethnicity [19].

Diet may be the most important overall driver of the obesity epidemic, with drastic increases in the availability of processed, affordable, calorie-dense, and nutrient-poor food [30]. Processed foods take less effort to obtain and are higher in energy density. Portion size is also a factor, as food becomes more affordable and overconsumption becomes increasingly common [30]. Beyond these obvious culprits, the ideal macronutrient balance for weight maintenance is a topic of continued debate. Fat, the most energy-dense nutrient, is not always linked epidemiologically with increased adiposity [19]. High glycemic index foods, including sugar-sweetened soft drinks, likely play a greater role in overall adiposity than absolute fat consumption. It is likely that changing fads in dietary regimens have contributed to the obesity epidemic by demonizing high-fat intake and unwittingly encouraging carbohydrate-dense alternatives [31]. In recent years, low-carbohydrate and high-protein diets have shown increasing promise for weight loss and resolution of obesity-related comorbidities [32, 33].

Socioeconomic disparities are inexorably linked to obesity. Once a problem of overnutrition and affluence, obesity is increasingly becoming a disease of poverty. In 2008, the world faced a record economic crisis with a resulting decrease in food budgets in almost every country. A direct correlation emerged in first world countries between decreased spending on food and increased weight [25]. Obesity rates increase as families began to rely on cheap, energy-dense, and nutrient-poor food. Regardless of overall income or absolute food budget, people who experience periods of financial hardship are at an increased risk of developing obesity [34]. Individuals living in impoverished regions often have poor access to food, resulting in "food deserts" that force reliance on processed food [4]. There is also a consistent inverse correlation between education level and obesity [25]. Finally, socioeconomic disparities and obesity create a negative feedback loop. Obesity results in increases in personal health-care costs, disability claims, and trouble finding work. Stigmatization of obese individuals can impede social mobility [35].

Epigenetics and prenatal nutrition also play a role in determining obesity risk. Whitaker and Dietz propose a hypothesis by which maternal obesity increases transfer of nutrients across the placenta and induces life-long changes in appetite, neuroendocrine functioning, and endocrine metabolism [36]. This hypothesis potentially explains the reduced risk of obesity in children born after maternal bariatric surgery.

Table 7.2 Sample articles from popular press describing the "obesity epidemic"

Year	Title	Source
2017	"U.S. obesity epidemic at a standstill, CDC says"	CBS News
2016	"The global crisis of obesity"	The economist
2015	"Obesity rises despite all efforts to fight it, U.S. health officials say"	New York Times
2014	"Obesity epidemic costs world $2 trillion a year, study says"	Wall Street Journal
2010	"Beating obesity"	The Atlantic
2006	"Obesity explosion may weigh on China's future"	National Geographic
2003	"How can America end its obesity epidemic?"	Time Magazine
1999	"Waging war on obesity"	New York Times

Kral and colleagues compared age-matched siblings born to obese mothers before and after substantial weight loss from biliopancreatic bypass. After surgery, obesity in offspring decreased by 52%, reaching population norms [37]. Follow-up analyses showed that the decrease in obesity was accompanied by improvement in cholesterol levels and insulin resistance and that changes were sustained into adolescence [38].

Preventative Efforts

The "obesity epidemic" has been on the front page of newspapers and the covers of medical journals since the 1990s. *The New York Times* has published over 700 articles on obesity between 1990 and 2001 [39], and the popular press coverage has only increased since that time (Table 7.2). A search for "obesity epidemic" returns almost 8000 articles in PubMed. Despite the widespread attention, no country to date has successfully reversed its obesity epidemic [40].

In 2013, the World Health Organization proposed a Global Action Plan for the prevention and control of noncommunicable diseases, including obesity targets and indicators to track progress. The first goal was zero increase in obesity prevalence between 2010 and 2025 [41]. In pursuit of this goal, governments, nongovernmental organizations, and international agencies have proposed and enacted a wide range of food policies to promote healthier eating and weight loss. The core targets for policy and public health interventions are summarized in the "NOURISHING" framework developed by the World Cancer Research Fund [42]. The framework (Fig. 7.4) identifies key domains of policy areas to promote healthier eating and proposes a framework for reporting, categorizing, and monitoring worldwide preventative efforts in the fight against obesity. Finally, prevention may take the form of treatment through tertiary prevention, which is the prevention of future progression of disease. Treatment of obesity can provide tertiary prevention. Treatment and prevention of obesity must be intertwined and needs to become a priority for all health-care systems and providers.

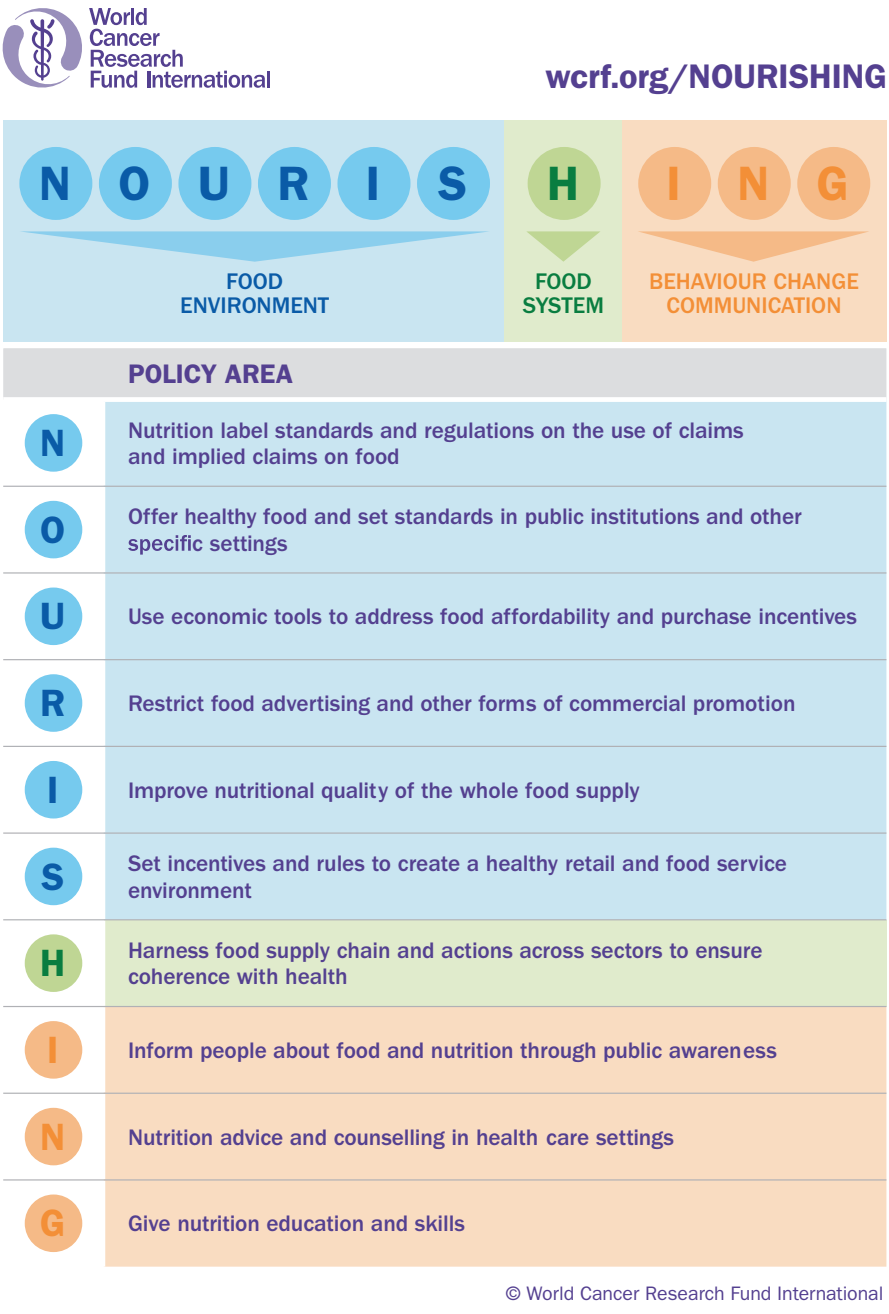

Fig. 7.4 A food policy package for healthy diets and the prevention of obesity and diet-related noncommunicable diseases: the NOURISHING framework (This material has been reproduced with permission of the World Cancer Research Fund International NOURISHING framework. www.wcrf.org/NOURISHISHING)

Conclusions

Obesity is a multidimensional problem, stemming from a number of biologic, cultural, and economic factors. The prevalence of obesity continues to increase, and rates remain high. The associated comorbidities, health-care costs, and years of life lost emphasize the importance of understanding and fighting this trend. Epidemiologists focus almost exclusively on body weight and BMI to report the incidence of obesity, and public health interventions rely mostly on mandating nutritional guidelines. The history of the epidemic warns against an overly narrow focus. BMI alone does not describe the true cost of the disease. Government-mandated nutritional recommendations are also an imperfect solution, in part because nutritional education is not an effective method of weight change and in part because our understanding of an ideal diet still remains incomplete. The food pyramid of the 1950s has, if anything, served as a driver of the epidemic rather than a successful preventative strategy. Overall, obesity remains one of the most critical health challenges of the modern era, and clinicians will be increasingly called upon to care for these patients. Clinicians must answer this challenge through empathy, prevention, and treatment.

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Chapter 8
Patient Selection Prior to Bariatric Surgery

Armando Rosales, Emanuele Lo Menzo, Samuel Szomstein, and Raul J. Rosenthal

Introduction

Obesity has reached epidemic proportions in the United States, where 66% of the population is overweight or obese [1]. The statistics of worldwide obesity continue to trend upward, based on the 2013 Guidelines for the Management of Overweight and Obesity in Adults released by the American College of Cardiology, the American Heart Association, and the Obesity Society, and 140.2 million American adults are recommended for weight loss treatment. Of these, 53.4% of adults could receive pharmacologic therapy in addition to lifestyle therapy, and up to 14.7% could undergo bariatric surgery [2].

According to the National Health and Nutrition Examination Survey, more than two thirds of Americans older than 20 years are overweight or obese, and more than 5% are morbidly obese with a BMI >40 kg/m^2 [3]. During 1998 and 2000, the prevalence of body mass index (BMI) of 30 or greater doubled, BMI of 40 or greater quadrupled, and BMI of 50 or greater increased fivefold [1].

Obesity has been associated with multiple comorbidities such as type 2 diabetes, cardiovascular disease, cancer, osteoarthritis, nonalcoholic fatty liver disease, polycystic ovary syndrome, sleep apnea, depression, and reduced life expectancy [1]. Type 2 diabetes and obesity are recognized as public health threats in Western countries [4, 5].

Medical management of obesity includes calorie restriction, exercise, behavioral changes, and pharmacotherapy. Changes in lifestyle result in loss of 5–10% of initial body weight, though a high percentage of patients will regain the weight in 1–2 years.

Currently, the most effective treatment option for management of obesity is bariatric surgery. Weight loss varies depending on the type of surgery, though this is significant and durable [1]. The estimated weight loss at 10 years is 16.1% [6]. Also, there is a significant improvement in obesity-related comorbidities, in particular type

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2 diabetes [1]. Based on the National Institutes of Health (NIH) consensus conference, candidates for bariatric surgery are either patients with a body mass index (BMI) between 35 and 40 kg/m^2 with comorbidities such as diabetes, hypertension, and obstructive sleep apnea or patients with a BMI greater than 40 kg/m^2 with or without comorbidities. However, Livingston and Ko demonstrated that African-Americans, lower-income groups, less educated groups, and publicly insured patients were underrepresented among the bariatric surgery population [7]. On the other hand, Santry and colleagues [8] reported that bariatric surgery patients usually are more likely to be female, privately insured, and from the highest income bracket.

Indications

Currently, bariatric surgery remains the only intervention that results in significant and durable weight loss, causing improvement or resolution of comorbidities and a decrease in mortality [6]. As previously mentioned, the current indications for bariatric surgery based on the NIH criteria are the following:

1. Patient with a BMI > 40 kg/m^2 without coexisting medical problems and to whom bariatric surgery would not pose an excessive risk [9]
2. Patients with a BMI > 35 kg/m^2 and one or more severe obesity-related comorbidities including type 2 diabetes, hypertension, hyperlipidemia, obstructive sleep apnea (OSA), obesity hypoventilation syndrome (OHS), Pickwickian syndrome, nonalcoholic fatty liver disease, or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux (GERD), asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life [10, 11]

Pories and colleagues [12] in 1992 reported for the first time the 10-year follow-up of diabetic patients after undergoing a gastric bypass, with an 86% resolution rate. One of the main contributing factors for these outstanding results was attributed to the improvement of insulin sensitivity secondary to the decrease in fat tissue [12]. Additionally, an improvement in beta-cell function was demonstrated [13].

In a meta-analysis comparing Roux-en-Y gastric bypass with sleeve gastrectomy, Wan and colleagues [14] reported that there was no significant difference between these two procedures, though cardiovascular risk did significantly decrease in the gastric bypass group.

The STAMPEDE randomized trial compared bariatric surgery versus intensive medical therapy for diabetes. The 5-year outcome data showed that in diabetic type 2 patients with a BMI of 27–43 kg/m^2, bariatric surgery plus intensive medical therapy was more effective than intensive medical therapy in decreasing or resolving hyperglycemia [15]. Based on these significant metabolic changes post-bariatric surgery, many authors have advocated expanding the indications of bariatric surgery to lower BMIs. However, in spite of the robust body of literature on the matter, the extended indications remain part of well-scrutinized research studies.

The main contraindications of bariatric surgery are related to prohibitive cardiovascular and respiratory risk of undergoing general anesthesia. Although liver cirrhosis was once considered an absolute contraindication to bariatric surgery, sleeve gastrectomy is now been evaluated before or in concomitance with liver transplant to improve organ longevity. Other contraindications to bariatric surgery include active malignancy and uncontrolled psychiatric illnesses. Although some controversy exists, in general the presence of Barrett's esophagus is considered a contraindication to sleeve gastrectomy.

Sleeve Gastrectomy

This procedure is a partial gastrectomy of the fundus and body that results in the creation of a tubular stomach, causing both restriction and also neurohormonal changes [16]. This procedure was introduced as the first step of the duodenal switch. Currently the American Society for Metabolic and Bariatric Surgery has recognized sleeve gastrectomy as an acceptable bariatric procedure [1]. The estimated weight loss (EWL) at 3 years is 77.5% or 13.3 kg/m^2 BMI and at 6 years or greater is 55.3% or 8.8 kg/m^2 BMI [17].

Gastric Bypass

Mason first introduced this procedure more than 40 years ago. Since then the procedure has undergone modifications and improvements in technique, approach, equipment, and outcomes [1]. The Roux-en-Y-gastric bypass (RYGB) entails a reduction of the gastric volume to a 15–30 ml gastric pouch and also rerouting of the nutrients' flow from the stomach to the proximal jejunum through a gastrojejunal anastomosis. As a result, the procedure creates three distinct intestinal limbs: the biliopancreatic limb (from ligament of Treitz to jejunojejunostomy) carrying bile and pancreatic enzymes to the jejunojejunostomy, a 100–150 cm alimentary limb (jejunal Roux-en-Y limb anastomosed to gastric pouch), and a common channel (enteroenterostomy to ileocecal valve) [18].

Preoperative Screening

Psychological Evaluation

In 1991, the NIH Consensus Development Conference Panel issued a statement that all patients undergoing bariatric surgery require a comprehensive, multidisciplinary assessment, including mental health evaluation, in order to determine psychological

and surgical contraindications or postoperative care obstacles [19]. No psychosocial factors have been identified that contraindicate surgery. ASMBS consensus states that evaluation by mental health professionals is not routinely needed but should be available if indicated [20]. Currently the need for a psychological evaluation is also mandated by certain insurance companies as part of the initial qualification screening.

Bauchowitz and coworkers [21] reported definitive psychological contraindications for bariatric surgery such as illicit drug use, active psychosis, severe mental retardation, current heavy drinking, multiple and recent suicide attempts, active symptoms of uncompensated bipolar disorder, current depressive symptoms, and symptoms of obsessive-compulsive disorder.

During the informed consent process, a physician should review the procedure and its risks and benefits, as well as clarify weight loss expectations [22, 23].

Nutritional Evaluation

Preoperative nutritional counseling is a key step in initial patient screening. Patients have to be familiarized with the significant dietary changes required postoperatively to avoid complications and promote success of the operation. Appropriate nutritional counseling has been linked to a higher rate of postoperative success, higher initial weight loss, improvement of patient's perception of ability to lose weight, early identification of dietary derangements and eating disorders, and, finally, increased overall weight loss [24, 25]. Also, it has been shown that a reduction of 5–10% body weight in the preoperative period can result in a reduced risk of death [26].

Magno and coworkers [25] assessed the nutritional status of patients and characterized the consumption of healthy nutrients through a multidisciplinary approach in both the treatment of morbidly obese patients and in the preoperative phase of bariatric surgery candidates. The authors showed that with the progression of the number of appointments, there was a decrease in caloric intake, and by the fifth appointment, patients had lower weight, and more than 50% of them were consuming six meals daily. Also, food choice dramatically changed, with a 72% increase in fruit consumption, vegetables, and whole wheat products. They concluded that there was a decrease in body weight, decrease in BMI and waist circumference, and quantitative as well as qualitative improvement of food consumption. These positive nutritional changes constitute a solid base in preparation for the surgical intervention.

Preoperative Clinical Evaluation

All candidates for bariatric procedures should undergo a preoperative evaluation for obesity-related comorbidities, mainly those that can affect postsurgical outcomes. The preoperative evaluation should include a comprehensive medical history, psychosocial history, physical examination, and patient-specific laboratory, radiographic, and procedural evaluations to assess surgical risk [2].

Glycemic Control

Glycemic control should be optimized preoperatively using a comprehensive care plan that includes healthy dietary patterns, medical nutritional therapy, and physical activity, and, if indicated, pharmacotherapy should be considered. The glycemic control parameters that have shown outcome improvement are hemoglobin A1C less than 7%, fasting glucose level less than 110 mg/dL, and a 2-hour postprandial blood glucose of less 140 mg/dL [6, 27, 28].

Smoking

In patients with a history of smoking, tobacco should be stopped at least 6 weeks before bariatric surgery and should be avoided postoperatively, as it has been shown to increase the risk of poor wound healing, pneumonia, and anastomotic ulcer [28, 29].

Cardiopulmonary Evaluation

Morbid obesity is usually associated with comorbidities, particularly hypertension, type 2 diabetes, sleep apnea, and pulmonary hypertension [30]. Therefore, this patient population has a higher incidence of coronary artery disease and left ventricular systolic dysfunction. The evaluation of the cardiac function and the diagnosis of coronary artery disease might, however, be limited by the inability to perform routine diagnostic tests secondary to weight and body size limitations [31]. Currently, there are no specific guidelines for the preoperative evaluation of morbidly obese candidates for bariatric surgery.

Depending on the patient's history and physical exams findings, noninvasive studies beyond electrocardiogram should be considered. In general, a higher percentage of such patients compared to the non-obese population will warrant a formal cardiology consult, and beta-blockade should be considered [32, 33].

Bhat and coworkers [31] assessed seven morbidly obese patients (mean BMI 67.7 m/kg^2) with transesophageal dobutamine stress echocardiography. Of these, one patient had an abnormal transesophageal dobutamine stress echocardiography, which showed inferior ischemia. All of the patients underwent surgery without cardiac complications. The mean follow-up was 11 months, and there were no cardiac events in any of the patients.

Catheline and colleagues [34] performed a preoperative cardiopulmonary assessment in patients undergoing bariatric surgery. After clinical evaluation, all patients underwent resting electrocardiography, Doppler echocardiography, exercise stress test, Epworth sleepiness scale and polysomnography, spirometry, blood gases, and chest X-ray. The electrocardiography demonstrated in 62% either conduction or ST-T wave abnormalities and in 17% QT interval prolongation. The stress test was negative in 73% and not interpretable in 27%. Doppler echocardiography showed hypertrophy

of the left ventricular posterior wall in 61% without perioperative consequences. Polysomnography showed obstructive sleep apnea hypopnea syndrome in 40%, of which 22% required continuous positive airway pressure. Chest X-ray was abnormal in 13%. Spirometry demonstrated an obstructive syndrome in 17% and restrictive syndrome in 6%. The gasometry showed hypoxemia <80 mmHg in 27% and hypercapnia >45 mmHg in 8%. The authors concluded that in morbidly obese patients, preoperative assessment should be by clinical evaluation, ECG, and polysomnography.

Obstructive sleep apnea has been associated with increased mortality and adverse effects in bariatric surgery patients. Therefore, preoperative screening with polysomnography should be considered, with further testing tailored to each patient, and be managed with continuous positive airway pressure (CPAP) [35, 36].

Conclusion

Bariatric surgery has become the preferred approach for weight loss due to its high effectiveness and low complication rate. Stronger evidence now exists of the superior metabolic ameliorative effects of surgery as compared to other weight loss interventions. In order to increase the likelihood of success and preserve the safety profile, bariatric surgery candidates must be evaluated by a multidisciplinary team. It is foreseeable that in the near future, metabolic surgery indications will be extended to lower BMI patients.

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Chapter 9
The Role of the Advanced Practice Provider in the Management of the Bariatric Patient

James B. Wooldridge Jr and Mellanie Merrit

Introduction

The role of advanced practice providers (APP) has increased significantly in the last 10 years. Practicing physician assistants (PAs) tripled from 1998 to 2008 [1], and the number of nurse practitioners (NPs) in training increased 61% from 1995 to 2006 [2]. Their presence in the medical setting has been shown to decrease costs and increase revenue for multiple specialties. These savings are based on several factors. The most obvious is salary. On average, an APP's salary is less than half of a primary care physician's salary. That gap increases when the physician is a surgeon, therefore increasing the benefit. There are also noted decreased overhead costs, and some studies have suggested a lower cost of care in primary care settings [3]. One of the most important advantages is that adding an APP can increase access to more patients [4]. There have been reports of increasing surgical volume by up to 30% by using APPs in the clinical setting.

Along with these cost benefits, there are studies that show at least a comparable level of care in primary care settings [5]. There are also data that the addition of APPs can increase patient satisfaction [6]. This is increasingly important as patient satisfaction plays a more major role in reimbursement.

Another added benefit is decreasing the physician workload. As work-life balance becomes more important to providers, APPs may alleviate some work-related stress. Control over schedule and work hours has been shown to be the best predictor of a healthy work-life balance and the ability to avoid burnout, two factors strongly associated with career satisfaction [7]. Adding an APP may increase schedule flexibility and therefore job satisfaction.

The advantages of the APP in the bariatric setting are extensive. There are several ways to use APPs in a practice, and their use will vary based on individual needs.

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The obvious uses are in the clinic, hospital, and operating room. It is important to note that APPs roles will vary based on each state's regulations.

Nurse Practitioner and Physician Assistant Distinction

NPs complete a master's or doctoral degree in nursing and are regulated through state nursing boards, whereas PAs complete a master's degree in a medical school-based curriculum and are regulated through state medical boards [8]. One of the key differences between these two professionals is that PAs must practice in collaboration with a supervising physician. Based on a study published in the Society of Hospital Medicine in 2014, inpatient NPs and PAs performed similar tasks despite their differences in training [8].

Some differences were noted between the two professions. PAs were twice as likely to perform procedures, twice as likely to teach nonphysician students, and significantly more likely to work weekends and federal holidays [8]. PAs also performed more history and physicals and worked more often with hospitalists than did NPs. NPs had a higher perception of inpatient and discharge care coordination, which may be due to their background in nursing [8]. Based on the findings of this particular study, PAs and NPs can perform the same tasks. It may be preferred for NPs to focus on inpatient care coordination and for PAs to focus care in the OR and perioperative setting.

Salaries for NPs and PAs are similar, but, according to a Clinical Advisor survey, the average PA salary of $108,743 is higher than the average NP salary of $101, 989, based on a 2015–2016 survey [9]. The highest salaries are in the Western United States and in urban settings versus suburban.

APPs in the Hospital Setting

The use of APPs in hospital care varies widely depending on practice and hospital needs. Their use can include rounding on patients postoperatively, which allows the surgeon to focus their time in the operating room. In addition, APPs can evaluate patients, order and interpret necessary testing, and prescribe medications as needed. They may also assist with discharges and patient education. Having the APP review discharge instructions and write discharge orders may allow for decreased length of stay and increase compliance on discharge.

APPs in the Operating Room

One of the greatest benefits of having an APP on your staff is their ability to first assist in surgery. With a continuity of care in the operating room and the technical skills in surgery, they can help increase the surgeon's case load. APPs can also bill as a surgical first assistant to help increase revenue. In teaching hospitals, this can help decrease surgery resident work hours and improve resident work outlook [10]. In 6 months of PAs arrival, 60% of residents reported less stress, 100% of residents reported decrease in workload, and 40% reported spending less time in the hospital since the PA's arrival [10]. Surgical residents' workload decreased 15 h, equating to a 1:1 ratio of resident work hour decrease to PA work hour completed [10].

The APP can decrease the surgical workload throughout the entire perioperative process, functioning in the same role as surgical residents. Roles include discussing with anesthesia preoperatively and coordinating with operating room staff and surgical equipment sales representatives to ensure that the required tools and instruments are available for the procedure. They can position, drape, and prepare the patient before surgery, allowing the surgeon to come in and focus on the surgery alone. They perform first assistant surgical duties, and their continuity and experience during surgery can assist the surgeon in reducing operative time. They close surgical incisions and escort the patient, along with anesthesia, to the postanesthesia care unit. All of these duties can contribute to decreasing OR time and increasing surgery volume for the program.

APPs in the Clinical Setting

The use of APPs in the clinic may be the most helpful for some practices. APPs are able to practice independently. PAs practice under a supervising physician, but they operate with their own patient schedule in the office. They can treat and diagnose patients, making it easier for the surgeon to focus his or her time in the operating room. They also have prescriptive authority, which differs by state [11]. They are able to spend more time with patients increasing education and patient satisfaction. They contribute to education outside the office through support group meetings and preoperative surgery seminars. Often the bariatric surgery coordinator role is filled by a PA or NP.

A major advantage in the office setting is the improved patient satisfaction scores seen with APPs and equal or improved care. Improved patient satisfaction scores and quality care are increasingly important for reimbursement in the current healthcare climate. The current Affordable Care Act and future possible plans being presented all include these metrics as a major part of their reimbursement structure. APPs have shown the ability to improve satisfaction scores in the office setting, thought in part to be from increased time spent with patients [6]. All of this improved satisfaction with equal and, in some cases, improved clinical outcomes. These data

have been shown in several studies that have demonstrated equivalent outcomes associated with clinical measurements, improvement in conditions, and utilization of health services (ER visits and hospitalizations) [5, 6, 12].

Conclusion

The roles of APPs have significantly increased, and they have become an essential part of patient care. Each practice can tailor the role of the APP to meet their needs. With their ability to provide continuity of care in the clinic, operating room, and hospital, they are essential to providing optimal patient care.

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Chapter 10
The Role of the Social Worker in the Management of the Bariatric Patient

Shaina Eckhouse

Introduction

A visit with a bariatric social worker is not currently mandatory as part of the patient's preoperative assessment or postoperative recovery. However, the input of a social worker is highly recommended as he or she can assist patients with the many psychosocial challenges faced during the bariatric surgery process [1]. Social workers are licensed mental health providers who help patients address their own needs, including familial, social, environmental, economic, and behavioral needs. In fact, social workers are the largest group of mental health providers in the United States, where they outnumber psychologists, psychiatrist, and psychiatric nurses combined [2]. Therefore, these professionals may be of significant utility in improving bariatric surgery patient outcomes pre- and postoperatively. Several studies suggest that standard psychiatric interviews are insufficient for a preoperative bariatric psychology evaluation; therefore, obtaining a psychosocial evaluation that includes the expertise of a social worker should be considered to assess bariatric patients familial, environmental, economic, and behavioral support needs [3].

Preoperative Assessment

Like psychologists, social workers perform patient interviews prior to bariatric surgery to assess potential issues that may hinder a successful outcome. Their role in the preoperative management of bariatric patients helps ensure postoperative success. The National Institutes of Health (NIH) 1991 Consensus Guidelines, the current American Society of Metabolic and Bariatric Surgery (ASMBS) Guidelines for

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psychosocial evaluation, and the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) require that a psychosocial evaluation of a candidate bariatric patient be performed by a credentialed individual, which includes licensed social workers [4, 5]. When a social worker participates in the preoperative evaluation by conducting a one-on-one interview, the topics that should be considered are next discussed.

Knowledge of Bariatric Surgery

It is important to spend time ensuring that patients understand and are able to verbalize the risks, benefits, and outcomes of bariatric surgery. Importantly, a social worker interview is an ideal opportunity to evaluate the expectations of candidate patients. While it will be discussed later on in this chapter, patients frequently have unrealistic assumptions regarding the outcomes of bariatric surgery. A realignment of these can aid in the patient's accurate understanding of what to expect postoperatively. Specifically, patients should expect that they will need to take an active role in their care to ensure optimal outcomes and understand the importance of follow-up care with their bariatric team. An active role in their follow-up care, which should include dietary evaluations, surgical evaluations, and postoperative support groups, can help ensure optimal use of safe behavioral changes in dietary habits and overall lifestyle [5, 6].

Patient Motivation

The most common motivation reported by patients undergoing weight loss surgery is health concerns from comorbid conditions. However, other patient motivators toward weight loss surgery include embarrassment, appearance, physical fitness, and physical limitations [7, 8]. More specifically, the psychological and social concerns of patients motivate them toward bariatric surgery in combination with their physical and medical limitations. However, when patients are asked about the impact of bariatric surgery, they focus almost exclusively on the psychosocial changes rather than the medical benefits [6]. The motivation of a patient should be questioned and discussed to ensure realistic expectations of bariatric surgery.

Quality of Life

The impairments caused by obesity are multiple, but one of the most important to patients is a diminished quality of life. Unlike other chronic illnesses, obesity creates social and physical impairments that affect their personal satisfaction. Most

frequently, preoperative patients report significant concern with the public distress of obesity that leads to social stigma, which can motivate them to undergo bariatric surgery [6, 8]. Indeed, when interviewed postoperatively, bariatric surgery patients note significant improvement in social stigmatization and discrimination after losing weight. Furthermore, patients with obesity secondarily report concerns that physical limitations cause decreased function and activity. These limitations can act as a motivator to undergo bariatric surgery [8, 9]. Despite the motivation, a multitude of studies demonstrated improved quality of life postoperatively for patients. With the help of a social worker, patients can identify what constitutes an improvement in their quality of life that is realistic, attainable, and sustainable postoperatively.

Familial and Social Support

Previously, a lack of familial or social support for bariatric surgery was not considered a contraindication for bariatric surgery [3]. However, the need for social support from partners, family, and other patients is well known to potentiate the success of a bariatric surgery patient. Considering the dramatic change that bariatric patients can experience, preoperative evaluation and education is imperative. The available social support for patients should be assessed during their initial psychosocial evaluation by both the surgeon and the social worker. A preoperative interview with a social worker provides an opportunity to further inform and educate the patient on the importance of familial and social support. Not only do the patients themselves experience changes in their day-to-day lives but so do their spouses, partners, and family. A social worker can educate them on how bariatric surgery may affect their familial and social support. Lastly, support between patients can be a significant help in understanding the changes that will occur after bariatric surgery. In fact, many bariatric programs recommend patients participate in a support group preoperatively as part of the evaluation process [3].

Environmental Stressors

Patients with the disease obesity and the field of bariatric surgery continue to be misunderstood by the general public. Specifically, obesity is often considered one of the last safe prejudices, and frequently obesity surgery is deemed to be an easy way out. There is a general lack of community understanding about how difficult lifestyle changes, including dietary and exercise changes, can be to initiate and maintain. The necessary lifestyle changes for long-term success after bariatric surgery are not consistently identified as a safe and effective intervention by the outside community. Data from social work literature document the general misinformation that exists regarding this field and the need for improved advocacy for both patients

with the disease obesity and bariatric surgery. A better understanding of this concept can help social workers in their preoperative assessment of patients [6, 10]. The social worker can advocate for their patients by educating them on how to overcome community stressors pre- and postoperatively.

Economic Stressors

Both obesity and unemployment are negatively associated with quality of life, depression, and overall health outcomes [11]. The combination of the two can lead to a deleterious cycle for patients. Bariatric surgery can positively affect both issues. An evaluation by a social worker preoperatively can help patients plan for their economic needs during the perioperative period.

Substance Use and Abuse

A screening for substance use and abuse, whether illicit or prescription drugs, should occur prior to bariatric surgery as part of the preoperative psychosocial assessment. This evaluation is often performed by a social worker. If there are concerns for current, recent, or remote use of drugs, then a toxicology screen is recommended. Ongoing substance use and abuse, commonly referred to as substance use disorder (SUD), can increase the risk of surgical complications. For instance, patients using marijuana are at increased risk for marginal ulcer and wound infection, and patients taking cocaine are at increased risk of cardiovascular complications and overall mortality. Also, recent or ongoing SUD preoperatively may increase risk of alcohol use disorders (AUD) and other addictive behaviors. Thus, one contraindication to bariatric surgery is ongoing substance use and abuse, and the patient should be postponed until durable abstinence can be achieved with the assistance of behavior counseling focusing on addiction [5, 12]. Because the highest risk of relapse in the setting of SUD is within the first-year postoperatively, durable remission of SUD needs to occur for 1–2 years prior to a patient undergoing bariatric surgery.

However, a remote history of substance abuse should not deter patients from bariatric surgery, which would be defined as durable remission from SUD for over 1–2 years. Interestingly, patients who achieve durable remission from SUD are at no higher risk of relapse after bariatric surgery. Several studies have demonstrated greater postsurgical weight loss in the setting of a preoperative history of treatment and successful abstinence of substance use and abuse [12, 13]. Therefore, patients with a remote history should be able and allowed to move forward with the bariatric surgery process.

Similar to SUD, active and ongoing AUD is a contraindication to bariatric surgery [14]. However, a history of AUD is not a contraindication to bariatric surgery.

If a patient suffers from alcohol use disorder, whether abuse or dependence, he or she needs to demonstrate a period of uninterrupted abstinence with concurrent treatment before bariatric surgery can be considered safe. Specifically, screening, assessment, and preoperative education and preparation may help decrease the risk of AUD after bariatric surgery. Importantly, patients with a history of AUD that stop drinking alcohol need to be made aware of the postoperative risk for recurrence of AUD after undergoing bariatric surgery [14].

Tobacco Use

Smoking cessation is recommended prior to surgery by most bariatric surgery programs. Tobacco use increases the risk of bariatric surgical complications, which include leak, wound healing, infection, and marginal ulcers. Several studies also demonstrate an increased 30-day mortality risk in patients that smoke within a year of surgery [15, 16]. Education regarding smoking cessation is imperative, and it is important for patients to understand that the side effects of smoking in the setting of bariatric surgery persist postoperatively.

Eating Behaviors

It is well studied that an average of 13–16% of preoperative bariatric patients suffer from binge eating disorder (BED). Moreover, up to 50% of patients experience disordered eating behaviors that do not meet Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), criteria for diagnosis of BED. BED and disordered eating prior to bariatric surgery can lead to less weight loss postoperatively [17]. For this reason, a preoperative assessment of eating habits, as part of the psychosocial evaluation, is important for bariatric surgery candidates. Historically, a diagnosis of eating disorders was a contraindication for bariatric surgery. Currently, disordered eating and BED is not a contraindication but should lead to a more intensive preoperative psychosocial evaluation, which may include behavioral modification with continued therapy postoperatively.

Treatment of eating disorders can be difficult, but recent studies described safe weight loss as a key adjunctive treatment modality. Indeed, weight loss in patients who suffer from BED and disordered eating can lead to improvements in body satisfaction and overall well-being and quality of life [18]. Furthermore, weight loss utilizing pharmacologic and surgical interventions does not increase risk or symptoms of eating disorders. Since bariatric surgery produces significantly more weight loss than lifestyle changes or pharmacologic intervention, it is a useful tool to consider in the management of patients with obesity, BED, and disordered eating. If utilized, continued postoperative follow-up, including effective behavioral therapy and support, can maximize the outcomes of bariatric surgery.

Psychologic Testing

It may be beneficial to incorporate psychologic testing as a standardized assessment tool if a licensed social worker is performing the patient's preoperative psychosocial evaluation. In combination with a detailed interview, psychologic testing can be an effective tool [4, 5]. Please refer to Chapter 14, The Role of the Psychologist, for more information regarding specific tests.

Postoperative Recovery

Social workers have multiple qualifications to assist the postoperative bariatric surgery patient. They can help patients, while in the hospital immediately following bariatric surgery, and promote patient wellness, patient autonomy, communication, and resource planning for discharge. Social workers can further ensure a safe and supportive environment as the patient transitions to caring for oneself at home. This may include help from the patient's family and community, which can also be monitored long term and serially evaluated by a social worker. Lastly, support groups led by social workers can provide a lasting, positive influence to provide information and answer questions for the postoperative patient. This support may become most important 1–3 years postoperatively, as a patient's weight stabilizes or even increases. When a bariatric social worker is facilitating care for a patient postoperatively, the support structures and special concerns that need to be evaluated and addressed are discussed next.

Familial Support

Family support postoperatively improves obesity rates within the whole family unit, as evidenced by improved food choices, increased activity, and weight loss in family members of the bariatric surgery patient [19]. Consequently, familial relationships also improve as the patient continues to lose weight [6]. If a family member has already undergone weight loss surgery, the patient typically has increased weight loss and an overall better recovery due to the support from a loved one who understands the postoperative bariatric surgery process [19]. For example, couples who undergo bariatric surgery together have an overall lower risk of weight regain as they are able to continuously support each other over time. There is a suggestion in the literature that a family-based approach, where multiple supportive family members undergo bariatric surgery, will also improve post-surgery outcomes [19, 20].

Social Support

Bariatric surgery is a "tool" performed in conjunction with lifestyle changes, which include long-term behavioral changes in eating practices and activity [21]. However, the self-motivation of patients to continue these lifestyle changes weakens with time even with initial success. Accordingly, ongoing social support after bariatric surgery should be offered. Long-term postoperative social support correlates with improved weight loss [22]. Resources utilized to maintain long-term success include bariatric surgery support groups, online blogs and support groups for patients, and continued follow-up with the bariatric surgical team [21]. Online blogs and support groups offer an opportunity for patients to share their experiences, obtain advice, and give support. When discussed with patients, these opportunities are most helpful in the first year [22]. However, long-term support, especially when the weight loss slows and stabilizes, is important so that post-bariatric surgery patients continue to be successful.

Economic Support

There is a measurable change in the economic opportunities offered to bariatric surgery patients postoperatively. Twenty-five percent of previously unemployed patients are able to go back to work after surgery due to improvements in their overall health and quality of life [11]. Postoperatively, patients report an increase in the number of employment opportunities available. After bariatric surgery, patients use less sick days and short-term disability. Hence, they are more reliable members of the general workforce. A social worker can aid in identifying both stressors and opportunities to optimize either the process of returning to work or obtaining gainful employment.

Substance Use

Postoperative bariatric surgery patients are at a higher risk of alcohol use disorders (AUD) compared to the general population. The Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) demonstrated a twofold increased risk for AUD and an increased risk for SUD after bariatric surgery [23]. Increased risk of AUD and SUD postoperatively may be associated with decreased social support. Thus, postoperative bariatric patients should regularly be screened and counseled for alcohol and substance use and abuse long term. Furthermore, patients are encouraged to regularly participate in support groups led by social workers or other mental health providers if available.

A theory currently undergoing evaluation called addiction transfer hypothesizes that bariatric surgery patients substitute one addictive behavior for another one. Specifically, abnormal eating habits, loss of control over food intake, or food addiction preoperatively increases a bariatric surgery patients risk of AUD and SUD postoperatively because both addictions create a similar neurologic effect [24]. Food and illicit drugs are demonstrated to stimulate similar addictive behaviors and therefore facilitate addiction transfer. Most bariatric patients who develop negative behaviors with alcohol or illicit drug use postoperatively never experienced AUD or SUD preoperatively. This raises concern that a link exists between patients undergoing bariatric surgery and the risk of AUD or SUD. However, this concept of addiction transfer has never been directly tested, and the results of correlative studies are variable [12, 23]. Importantly, because of the increased risk of AUD and SUD after bariatric surgery, patients require long-term follow-up and support.

Eating Disorders

As mentioned earlier in this chapter, patients who suffer from BED or disordered eating behaviors preoperatively are at higher risk for insufficient weight loss, weight regain, and poorer outcomes long term following bariatric surgery [3]. Previous studies demonstrate no disordered eating behaviors in patients with a preoperative history of BED during the first year after bariatric surgery. However, disordered eating behaviors can occur long term (over 1 year postoperatively). Up to 50% of patients more than 2 years after bariatric surgery demonstrate disordered eating behaviors. To try and reduce this risk, regularly scheduled follow-up is recommended with the multidisciplinary team. Specific disordered eating habits that occur can include skipping meals, consuming larger portions and becoming nauseated or needing to vomit, binge eating, grazing, or frequent consumption of small amounts of food in an unplanned manner. Resources, such as visits with a licensed social worker, a dietician, and utilization of support groups, can help patients minimize the risks of disordered eating, insufficient weight loss, or weight regain. Nevertheless, the fear of weight regain in a patient can lead patients to engage in restrictive or compensatory disordered eating. For example, patients may purposefully skip meals or adopt vomiting to reduce food intake and accelerate weight loss. These behaviors can make it challenging to distinguish what is considered normal postoperative dietary changes or disordered eating after bariatric surgery. If disordered eating behaviors are identified, then consistent follow-up should be planned with a psychologist or behavioral health expert along with the bariatric surgery team.

Unrealistic Expectations

A body of literature exists which consistently demonstrates that many patients have unrealistic expectations about weight loss after bariatric surgery. Currently, it is recommended that patients' postsurgical weight loss expectations be discussed as part of their preoperative evaluation. Expectations should then be realigned through education regarding realistic weight loss and outcomes of bariatric surgery. Furthermore, the risk of weight regain needs to be discussed. This is particularly important for those patients who demonstrate low self-esteem and increased emotional angst related to body image [3, 5]. Postoperatively, bariatric patients should be followed regularly to ensure safe weight loss and realistic expectations.

Conclusion

Personal, familial, societal, economical, and environmental factors impact patients considering bariatric surgery. If not addressed and treated appropriately, these all can lead challenges and possible failures before and after surgical intervention to treat obesity. A licensed social worker is uniquely qualified to address these broad and diverse factors. While not a required member of the team, the social worker can be a crucial contributor to optimize the quality of care patients receive throughout the bariatric surgery process.

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Chapter 11
The Role of the Registered Dietitian in the Management of the Bariatric Patient

Vasanth Stalin and Megan Hammis

Introduction

The Registered Dietitian or Registered Dietitian Nutritionist (RD or RDN) is the lynchpin coordinating the nutritional care of the bariatric surgery patient. The RD assumes a central role in all aspects of the patient's care, including preoperative assessment of the patient, counseling in the immediate postoperative inpatient phase, and long-term follow-up postoperatively. The dietitian provides evidence-based nutrition education and counseling to patients during each phase before and after surgery. He/she is the interdisciplinary team's nutrition expert and will help patients to understand the role of diet and nutrition in each phase.

Preoperative Period

The Registered Dietitian will play many roles during the preoperative period. While the main role will be performing a comprehensive nutrition assessment and providing nutrition education and counseling, the dietitian may lead informational sessions and support groups. For many patients, getting ready to have bariatric surgery begins with attending an informational session. Often these sessions are led by the Bariatric Surgeon, bariatric center manager, or a Registered Nurse. The RD can also

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lead these sessions and may provide a unique perspective for patients at these meetings. These informational sessions help educate patients on the different types of bariatric surgery, risks, and benefits of each procedure, as well as providing introductory information on diet and lifestyle changes that will need to occur. Patients will also learn about insurance requirements and what steps they must take to begin the path towards surgery.

Comprehensive nutritional assessment is the cornerstone of the RD's role in the preoperative period. Many insurance companies as well as the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) require a comprehensive nutrition assessment performed by a Registered Dietitian. The RD is able to expand on information required by insurance companies in order to obtain approval for surgery, such as height, weight, body mass index, and history of weight loss attempts. This assessment also gives the medical team vital information about the nutritional status of the patient in the preoperative period. The assessment will include anthropometric information, such as height, weight, body mass index, and other body composition information such as body fat percentage and waist circumference, if available. The RD will also assess the patient's nutrient intake, which includes not only the food that the patient is eating but also beverages that are being consumed and the nutritional supplements that he or she is taking. He or she will evaluate the patient's laboratory values for nutritional deficiencies and may provide recommendations to the surgeon or patient's primary care provider for supplementation. The patient's eating patterns and behaviors will be discussed, such as frequency and timing of meals, where meals are consumed, whether the patient is preparing his or her own meals or eating away from home frequently, how fast or slow meals are eaten, and the RD will gather information about potential disordered eating patterns such as binge eating, cravings for certain foods, hiding or hoarding foods, night eating, etc. Physical activity levels will also be evaluated in order to provide an accurate estimation of the patient's energy requirements. The RD may also perform a nutrition-focused physical exam, looking for physical signs of nutrient deficiencies or needs for any other condition-specific dietary recommendations. The patient will provide the RD with his or her medical history so that nutrition education and counseling can be tailored to any specific medical conditions, if necessary.

Many insurance companies also require patients to complete a medically supervised weight loss program prior to surgery, usually ranging from 3 months to 12 months in duration. Some insurance carriers require that the programs be directed by a physician, while others do not specify who must direct the weight loss program. In many cases, the RD is the ideal person to lead these supervised weight loss programs as the nutrition expert of the team. Insurance companies may require patients to lose a specified amount of weight during these weight loss programs, prior to having weight loss surgery. Meeting with the dietitian at regular intervals as part of a supervised weight loss program can help patients to achieve this goal, as the RD is able to not only provide further nutrition counseling and education but also is able to hold the patient accountable. These programs allow the Registered Dietitian to focus deeper on individualized nutrition counseling for each patient.

Studies have shown that patients are most successful with weight loss when keeping food records [1]. The RD can work with patients to figure out what type of food log will work well for them. He or she can walk the patient through some of the newer technologies, such as smart phone apps, wearables, and websites that help patients keep track of the foods they are eating and the physical activity that they are participating in. The dietitian can then use this information to evaluate that patient's readiness for change and comprehension of nutrition education.

Dietitians use several different counseling techniques during their patients' medical nutrition therapy visits. One effective method is motivational interviewing, a counseling approach used by psychotherapists. This method uses open-ended questions and has the patient directing the forward motion of the counseling session. Perfecting this technique can prove to be challenging for the dietitian, especially with bariatric surgery patients. It isn't the patients themselves that make this technique challenging; rather, it is the amount of nutrition education needed for successful outcomes after bariatric surgery that makes it difficult. Sometimes, patients are limited to few visits with the dietitian prior to surgery, and so the RDs may feel like they are overwhelming the patients with information.

Providing nutrition education is an important role of the dietitian in the preoperative period. Patients typically come to bariatric programs with differing levels of learning ability and comprehension of nutrition concepts. It is the RD's role to evaluate the patient's nutrition knowledge and readiness to change, in order to provide adequate nutrition education. It can be challenging for the dietitian not to overwhelm the bariatric patient with all of the dietary requirements before and after surgery. The Nutritionist will help patients learn how to read food labels and measure out food, teaching them about how their portion sizes will change once they have had bariatric surgery. The patient will learn how to look for certain ingredients on food labels that may cause tolerance issues, such as added sugars and fats. The dietitian teaches patients the importance of each macronutrient in the diet and appropriate macronutrient distribution for each patient, based on their individual medical history and goals. He or she will help the patient evaluate protein supplements before and after surgery. In some programs, patients are encouraged to purchase a diet kit prior to surgery for the pre- and postoperative periods. Typically, these diet kits are designed to help patients lose weight prior to surgery and also may help decrease the size of the patient's liver. Other programs may design their own "liver-shrinking" diets, and the RD plays a vital role in assessing these diets for nutritional adequacy. The dietitian educates bariatric patients on the importance of vitamin and mineral supplementation for life. He or she will provide patients with the resources to obtain these supplements and may even be able to provide the patient with samples in some cases. The RD will also help patients in understanding how to take their nutritional supplements, as they often times interact with certain medications and some of these supplements may need to be taken separately for optimal absorption.

While the role of the dietitian in providing evidence-based nutrition information to bariatric patients is very important, another essential role the RD plays is that of a supporter. If the dietitian does not build rapport and establish a relationship with

the bariatric patient, he or she can provide nutrition education but may not be able to make any appreciable progress with their patient. The dietitian may also be viewed as a safe person to share information with; so, it is vital to the team that the dietitian builds trust with patients. For example, during a nutrition counseling session, the patients may reveal to the RD pertinent medical information that they did not feel comfortable sharing with their physicians. Dietitians often observe signs of eating disorders, addiction problems, and other psychological conditions during their one-on-one sessions with patients and are able to report these findings back to the interdisciplinary team and refer the patient to other medical professionals as needed.

Role of the Dietitian in Postoperative Nutrition Management

Even though every surgeon, dietitian, and program has their own individual preferences or algorithm as far as advancing the patient's diet goes, there are certain general guidelines that are usually recommended. At this time there are no standardized diets for after bariatric surgery. However, it is important to understand that huge variations in food tolerance are to be expected, depending on the individual patient and the type of surgery that they have had. The Registered Dietitian shepherds the patients through various dietary stages so that nutritional support is adequate for postsurgical healing and also for ongoing long-term, durable weight loss.

Bariatric Stage I Diet: Clear Liquid Diet

The Stage I diet is a very short-term, clear liquid diet that is usually used in the immediate postoperative period (first couple of days post-op). A typical practice that is seen in many bariatric surgery centers is for an upper GI study to be ordered on post-op day 1, followed by initiation of the clear liquid diet. A low-sugar, clear liquid meal program can usually be initiated within 24 h after any of the bariatric procedures, but this diet and meal progression should be discussed with the surgeon and guided by the Registered Dietitian (RD) *(Grade C, BEL 3).* A consultation for postoperative meal initiation and progression should be arranged with a dietitian who is knowledgeable of the postoperative bariatric diet *(Grade A, BEL 1)* [2]. Initially, most patients start with small sips of clear liquids that are low in calories and sugar while avoiding caffeinated, carbonated, and alcoholic beverages. The dietitian will make sure that the patients are well-instructed to continue sipping liquids in incremental amounts throughout the day, placing specific emphasis on hydration and maintaining adequate urine output. Patients are encouraged to take in at least 48–64 ounces of fluid orally in a 24-h period. Dehydration is one of the key challenges in the immediate postoperative phase, and the Registered Dietitian helps play an integral role in preventing dehydration-related ER visits and hospital

readmissions. The Registered Dietitian will also review educational materials provided to the patient that reinforce diet advancement concepts and will help patients with making healthy choices as they are shopping for foods and beverages and customizing their meal choices.

Bariatric Stage II Diet: Full Liquids

The Stage II diet is a full liquid diet that is usually started on postoperative day 2 or 3 and is continued for up to 2 weeks after the operation. During this phase, the patient is instructed by the Registered Dietitian to maintain hydration status by consuming at least 48–64 oz. fluids daily. Patients are encouraged to sip on very small amounts of fluid regularly throughout the day. The registered dietitian instructs patients to monitor for signs of dehydration, such as decreased urine output, dark urine, dizziness and lightheadedness, confusion, etc. Foods that are often introduced in this stage are full liquid or semi-liquid and provide additional protein and calories. Patients are advised to avoid high-sugar fluids and foods (less than 25 g sugar per serving; many programs will encourage keeping sugar grams in "single digits" or less than 10 g per serving), and patients are encouraged to focus on fluids that are high-protein sources, such as low-fat dairy products and liquid protein supplements. It is also important for the Registered Dietitian to help the patient to recognize that protein shakes contain less free water than clear liquids, thus providing less overall hydration than clear liquids. At this point, the patient should aim to make up 50% of their goal intake with full liquids, while the other 50% should be met with clear liquids to maintain proper hydration status. As always, inter-patient variability is quite normal, and while some patients may be able to consume the recommended target volume right from the get-go, others may take their time in getting to the recommended target, with small incremental steps. The registered dietitian emphasizes to the patient the importance of separating full liquid and semi-solid foods from clear liquids by at least 30 min. The RD will ensure that patients habitually look at food labels, reinforcing what ingredients to look for, so that they avoid added sugars which can precipitate dumping syndrome. The Registered Dietitian will also help patients to choose appropriate full liquids that do not provide more than 30 g protein per serving as consumption of small servings of protein at each feeding seems to be metabolically more effective than consuming large amounts at one time [3]. The RD also reviews patients' choice of protein sources and will recommend high-bioavailability proteins (whey, egg white, casein, milk, and soy) [4, 5]. Proteins lacking essential amino acids, such as collagen and gelatin, are not ideal for the weight loss surgery patient. Also, proteins that have a better effect on satiety should be recommended after bariatric surgery [3].

Bariatric Stage III Diet: Soft Solid Food Diet

The Stage III diet is started approximately 2 weeks after surgery. At this time, the diet is advanced to include soft, semi-solid foods and in some programs may start with a pureed or blended consistency. The Stage III diet will emphasize continuing to include adequate protein sources while introducing fruits and vegetables that provide a better balanced vitamin and mineral content. Pureed, soft, or diced proteins are introduced in addition to pureed or soft fruits and vegetables. Starches are not particularly recommended at this stage, although some programs may start introducing whole grains at this time. The Registered Dietitian will continue to emphasize the importance of taking vitamin and mineral supplementation as portion sizes will remain small and nutritional adequacy will not be met with oral diet alone. Eating behavior concepts such as chewing food thoroughly and eating slowly will be emphasized by the RD. Patients are reminded to separate solid and semi-solid foods, as well as high-protein full liquids, from clear liquids by at least 30 min to prevent postoperative dumping syndrome or overeating. If patients experience a "stuck" feeling, the registered dietitian will encourage helpful strategies such as walking rather than drinking liquids which can precipitate regurgitation and discomfort. Food tolerance varies significantly among patients. The RD will continue to help guide patients to making educated food choices while taking into consideration what the patient is or isn't tolerating. The RD emphasizes the need to follow the diet plan as a nutrition prescription, irrespective of whether the patient is hungry or not, as most patients will experience different sensations of hunger and satiety after bariatric surgery. Most patients will learn to recognize the feeling of "fullness" secondary to the small gastric volume. Overeating can result in nausea, retching, and vomiting, so it is important that the Registered Dietitian continues to emphasize small portion sizes. Guidance by an experienced bariatric Registered Dietitian is strongly advised during the transition between diet stages, as per the clinical practice guidelines [6]. As always, avoidance of dehydration is of paramount importance, and the Registered Dietitian will support patients by providing education and counseling to maintain proper hydration.

Bariatric Stage IV Diet: Regular Long-Term Diet and Lifestyle

The Stage IV diet is started as the patients begin to tolerate more foods in each meal, but the amount varies based on each individual's ability to adhere to a healthy diet, willingness, and motivation. Foods to avoid initially may include stringy vegetables, pasta, untoasted bread, and dry foods. The RD will continue to emphasize post-bariatric eating habits such as separation of solid foods from liquids. Liquids leave the stomach very quickly, and it is unlikely that they affect satiety or cause dumping syndrome before meals; however, drinking with meals or within 30 min

after eating is still discouraged because it can cause dumping syndrome [7]. Though there is some speculation that the abovesaid behavior can allow the patient to eat more, strong evidence is lacking for the assertion. Patients are still encouraged to avoid consumption of alcoholic, caffeinated, and carbonated beverages. The RD will help patients by recommending vitamin and mineral supplements catered to their individual needs that are available locally or online. Some patients may experience lactose intolerance after bariatric surgery, and it is the dietitian's role to help patients understand how to read food labels to avoid foods that contain lactose and to help them with choosing good lactose-free sources of calcium and protein.

Long-Term Postoperative Follow-Up

The Registered Dietitian will often follow up with postsurgical patients on a regular basis after their procedure, more frequently in the immediate postoperative phase and then possibly yearly after that. In the more immediate postoperative phase, the Registered Dietitian may field concerns about adequate weight loss, hair loss, and other physical changes that patients may go through. The dietitian may field complaints of hair loss in the months immediately following bariatric surgery and should be able to reassure the patient that it is normal and rarely secondary to a nutritional deficiency. He or she will also help patients understand what the expected weight loss rate will be for each procedure and that weight loss is maximal in the first 3 months after surgery. The dietitian will provide comfort to patients by reassuring them that weight loss plateaus are expected and will be interspersed between periods of more rapid weight loss. The Registered Dietitian plays an important role in driving home the point that the goal is to lose weight in the safest, healthiest way possible and not necessarily as quickly as possible. Patients also benefit from the RD's guidance in not weighing themselves obsessively but rather focusing on other physical changes such as change in clothing size or ability to perform activities with lesser effort or strain. Patients may become panicked as they find that they are able to eat larger portions after surgery, and it is the role of the dietitian to explain that this is expected and necessary for good health. At these meetings the dietitian will continue to reinforce good eating habits, emphasizing high-protein and whole foods that are abundant and vitamins and minerals. The RD may adjust supplementation recommendations with the assistance of the primary care physician or bariatric surgeon based on laboratory values, if available. If patients are unable to have regular visits with their bariatric dietitian due to insurance restrictions, they may have access to him or her through Group support meetings. Registered dietitians are qualified to be bariatric group support leaders or may often times be asked to be a guest speaker at these meetings. Again, it is important that the RD builds trust and rapport with patients so that they will continue to seek out his or her guidance years after their surgery.

About 12–18 months after a Roux-en-Y gastric bypass or a sleeve gastrectomy, the weight of most patients has stabilized [8, 9]. The RD helps the patients understand

this and addresses their concerns with additional education so that they aren't discouraged with the process. If the patient demonstrates significant weight regain (Recidivism), the RD is able to pick up on that quickly and make the surgeon aware so that appropriate workup can be initiated. Apart from their scheduled annual visits with the multidisciplinary team, these patients may benefit by meeting up with the dietitian more frequently, to help stop negative habits and behaviors. Management of women who become pregnant after bariatric surgery is more complex than what a RD alone can accomplish, and a multidisciplinary team should be involved [10].

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Chapter 12
The Role of the Physical Therapist in the Management of the Bariatric Patient

Alex Ordonez

Introduction

It has been well known for decades that obesity is a major health concern in the United States and even worldwide. This has led to a continued rise in the number of bariatric surgical procedures being performed. More than 60% of the population in the United States is overweight; over 30% is obese. Obesity is an epidemic that will continue to increase.

In regard to the ethology, obesity has been associated with psychological, environmental, social, behavioral, and genetic factors. However, an excessive caloric intake coupled to a sedentary lifestyle is the primary culprit of the rapid increase in obesity during the past several decades.

In 2011 it was estimated that over a million patients worldwide were experiencing the benefits of bariatric operations such as gastric bypass, and laparoscopy has revolutionized bariatric surgery across the globe [1].

Obesity affects people of all ages, socioeconomic strata, and races. It is associated with more than 40 different chronic medical conditions and is directly associated with early death [2].

One of the most common comorbidities is osteoarthritis which usually affects knees, ankles, and back. It contributes to pain secondary to increased stress from the excess weight on the joints, muscles, and vertebral disks. Obese patients commonly have low energy levels which, coupled with pain, can lead to inability to perform regular activities such as walking, climbing stairs, and multiple other household and work responsibilities [3].

Technology and industrialization have enabled humans to evolve from hunters and gatherers to highly sedentary individuals, especially in the United States and

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other developed nations [4–6]. The increasing use of technology, including video games and smartphones, has replaced in large part outdoor recreational and physical activities for children and adolescents. The high reliance on automobiles, escalators, elevators, etc. has further increased the sedentary behaviors. The result is a growing generation of individuals who start a sedentary lifestyle at an early age, with many of them remaining obese as adults [7].

Even though the number of health clubs and other resources as well as the focus on fitness and health have increased substantially during the past several years, it is not enough to match the sedentary nature of the population as well as the excessive caloric consumption [6]. Furthermore, those who participate in formal, regular physical activities comprise the minority of the population. It has been reported that only about 20% of the population engage in regular physical activity and exercise, with a larger percentage of adults adopting a complete sedentary life [8]. In this setting, physical therapy can provide assistance, educating the population and in particular bariatric patients about the correct type and amount of physical activity.

Since obesity can directly affect movement and patient's ability to perform physical therapy, an adequate assessment of the limitations could reveal the need to modify therapy. This is important from the therapist point of view, since tailoring therapeutic regimens could help meet the specific needs of obese patient.

Objective

Physical therapy can assist patients who suffer from obesity to engage in pain-free physical activities aiming to lose fat, burn calories, preserve muscle, and avoid injuries especially in joints which are typically affected in this population. Exercise should include aerobic and anaerobic activities such as weight lifting which will enhance weight loss and conditioning [8].

The therapist will recommend specific activities including passive and active movements designed to restore the normal joint movement, improve posture, and maintain adequate flexibility.

Initial Evaluation

In ideal circumstances a bariatric patient should undergo a preoperative assessment performed either by a licensed physical therapist or an exercise physiologist. This will allow for a better understanding of the patient's baseline status as well as the establishment of long-term goals dependent on each individual's condition.

Physical therapy is an excellent tool that can be used to prevent potential muscle mass loss as a consequence of rapid weight loss in the bariatric postsurgical patient.

The initial evaluation is very similar to a regular history and physical exam. The physical therapist will conduct a thorough evaluation that includes taking the health

history: medical comorbidities, surgeries, prior injuries, medications, diet, level of activity, etc.

With regard to the level of activity, the physical therapist will focus on potential physical impairments and the physical condition during the hospitalization. Special attention will be focused in the following parameters [9]

- Ability to walk
- Gait difficulties
- Bed mobility and transfers
- Pain related to chronic conditions and/or recent surgery
- Fall risk
- Limited respiratory capacity with subsequent dyspnea and inability to perform physical activities
- Musculoskeletal deficits
- Gait and coordination disturbances
- Prior level of function
- Medications which could affect the patient's mobility
- Prior use of assistive devices

During the initial physical examination, the physical therapist will focus on the patient's weight (significantly elevated BMI could require a different approach), pain level, posture and alignment, strength, flexibility, endurance, sensation, and physical limitations, if any [1, 3, 9].

Obese patients have a higher risk for skin complications such as skin breakdown associated with diabetes and higher body temperature, as well as inadequate blood supply to the adipose tissue. Other skin conditions such as wounds, ulcers, and lymphedema should also be evaluated since these could limit the type of activity [10–12].

When assessing the aerobic capacity and endurance, the physical therapist will focus on the appropriate test based on the patient's prior level of function, strength, balance, range of motion, pain, and the presence of cardiovascular and respiratory conditions which would impair the patient's ability to perform physical activities. The following tests are usually performed by physical therapists during the initial evaluation [13–17]:

- The six-minute walk test (used to quantified aerobic impairment)
- Timed stair climbing: evaluates and addresses functional impairment
- Two-minute assessment of vital signs recovery in patients who do not tolerate other standardized tests
- Untimed four-flight stair climbing: reports symptoms and also addresses functional impairment
- RPE (rate of perceived exertion): evaluates exercise intensity in obese women

Hospital Care

During the postoperative period, physical therapy is used to prevent sequelae associated with morbid obesity including but not limited to back pain, osteoarthritis, thrombotic events, plantar fasciitis, and muscular pain [11].

In the acute care setting, the physical therapist will encourage early mobilization to prevent complications from bedrest as well as to promote patient independence. This will also include avoiding injuries to the patient and hospital personnel and addressing equipment needs.

The most commonly used bariatric equipment includes commodes, scales, tilt table, walkers, beds, chairs, bath bench, wheel chairs, plastic boards, HoverMatt® (Hovertech International, Allentown, PA, USA), and AirPal® (AirPal Inc., Coopersburg, PA, USA) [9, 10].

For patients undergoing bariatric surgery such as sleeve gastrectomy and gastric bypass, the usual length of stay is between 1 and 3 days. Patients undergoing more complex procedures such as revisional surgery may require a longer hospital stay. During this time period, the physical therapist will start working with the patient as soon as the surgeon has requested to proceed or according to a hospital protocol if one exists. Commonly established goals may include [9, 10, 17, 18]:

- Getting out of bed on postoperative day zero. This includes independent bed mobility as well as independent transfers with assistive devices (if indicated)
- Independent ambulation greater than 100 feet (with assistive device if indicated)
- Achieve independent mobility to transfer or negotiate stairs
- Presence of adequate respiratory (maintaining normal oxygen saturation) and cardiovascular response
- Patient demonstrates a clear understanding of the therapy goals and activity progression once he or she is discharged

Inability to achieve these objectives or to demonstrate adequate support systems upon discharge should prompt to consider outpatient physical therapy including home PT or even extended care facility if deemed necessary [10, 18].

Patients with more complicated hospital courses—including patients who required more extensive bariatric procedures, patients who had complications from the initial procedure, or patients with functional impairment and decreased endurance—may require inpatient rehabilitation [19, 20].

Treatment Options

Multiple different approaches can be used before and after bariatric surgery. These will be tailored depending on the patient's initial clinical condition, comorbidities, musculoskeletal disorders, and response to the recent surgery.

The American College of Sports Medicine recommends at least 150 minutes per week of moderate intensity exercise (50–70% of maximum heart rate). In the presence of obesity, a gradual increase in physical activity to 200–400 min per week is recommended to achieve a higher (100% increase) weight loss per week (11–16 lbs) [19].

Commonly used exercises include elliptical, walking program or treadmill, swimming, stationary, or conventional bike, etc.

Results

It is well known that prompt initiation of physical therapy and exercise in bariatric patients will lead to a significant improvement in quality of life, increased energy levels, better function, and decreased chronic pain [20, 21].

Osteoarthritis is the leading cause of disability and low quality of life in the United States. Obese patients are at a significantly higher increased risk [22]. Weight loss significantly reduces pain related to osteoarthritis as well as postoperative complications after knee replacement. Bariatric surgery has continued to be used as an adjunct therapy prior to knee or hip replacement [23].

Ultimately, the prognosis of the patient will depend on the type of program, the patient's comorbidities, and the patient's ability to tolerate exercise. However, most patients will adapt to and actively participate in the recovery program since weight loss leads to an improvement in the functional status and energy levels, a decrease in pain, and an increase in aerobic capacity.

Encouragement from the entire bariatric staff and a well-established exercise program will positively affect the patient's recovery.

Hospitals taking care of bariatric patients should have on staff physical therapists with experience in treating obesity, its potential joint complications, and postsurgical patients. In some cases, patients may benefit from an outpatient evaluation with a physical therapist that has experience in orthopedic and sports medicine [13].

Discharge

Upon discharge, it is important that the patient has a clearly delineated plan since a well-designed outpatient program can improve weight loss and BMI reduction and improve energy levels and aerobic capacity [21].

A daily exercise program (i.e., walking) of 20–50 min per day is recommended to start the process.

Resistance training 4–5 times/week is also recommended since it has shown to reduce free-fat mass loss and accelerate fat burning [21].

The active involvement of the family in the recovery process is very important.

Conclusion

In summary, physical therapy has clearly demonstrated to be a critical component during the early postoperative period as well as during the entire weight loss process. Hospital and surgeons performing weight loss surgery should consider incorporating physical therapy as part of any bariatric protocol.

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Chapter 13
The Role of the Obesity Medicine Physician in the Management of the Bariatric Patient

Vamsi Alli and Ann M. Rogers

Introduction

The rapid rise in the prevalence of obesity and its resultant health consequences mandates a comprehensive approach to treatment. Medical and surgical care of the bariatric patient has changed dramatically over the past 60 years. Just as bariatric procedures have continued to evolve since the initial operations specifically intended for weight loss in the 1950s, the medical management of obesity has also progressed substantially. With improved understanding of gastrointestinal (GI) physiology and pharmacology, the increasingly large body of knowledge pertinent to the field of medical weight loss has led to the existence of training and certification standards in the field of obesity medicine. Since 1997 there has been a formal certification process for medical bariatricians through the auspices of the American Board of Bariatric Medicine. In 2011 an educational curriculum and a nationally administered certification examination was created, leading to certification through the American Board of Obesity Medicine. The existence of a distinct medical board underscores the unique knowledge base and skill set required for the effective practice of obesity medicine [1].

The focus of the field of obesity medicine and the obesity medicine physician (OMP) is the comprehensive care of individuals with overweight and obesity. This includes medically supervised weight management, either prior to weight loss surgery (WLS) or as sole therapy for patients who do not wish to undergo surgery or who may not meet the criteria for surgical treatment of clinically severe obesity. Thus the scope of the OMP may be considered to be even broader than that of the bariatric surgeon, who generally treats only those patients who are candidates for WLS or endoscopic therapies. The OMP

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could well manage the entirety of the patient's weight-related comorbidities individually or as a function of their obesity, including type 2 diabetes (T2DM), hypertension (HTN), dyslipidemia, coronary artery disease (CAD), asthma, obstructive sleep apnea (OSA), nonalcoholic fatty liver disease (NAFLD), osteoarthritis (OA), chronic kidney disease (CKD), infertility, and a myriad of other weight-related issues.

Though the breadth of practice of an OMP may be considerable, for purposes of scope, this chapter will deal specifically with the OMP who works as an integral member of a surgical weight loss program (SWLP). An OMP contributes many unique elements to a multidisciplinary SWLP, through the spectrum of preoperative, postoperative, and long-term post-bariatric care. Along with their crucial medical role, OMPs can provide many other key services to a WLS program. This might include community outreach, public speaking, holding in-person information seminars, moderating support groups, and contributing to the research endeavors within a program. There is a significant literature [2] suggesting that family doctors are frequently uncomfortable discussing weight with patients or may even feel such a discussion is a waste of valuable visit time.

The Obesity Medicine Physician in Context

As the OMP and the bariatric surgeon both play unique roles, their relationship should be complementary and collaborative in a SWLP. Such a partnering approach is comparable to that between medical and surgical oncologists for the better care of patients. More commonly, multidisciplinary WLS programs have been likened to transplant programs, where the nonsurgical specialty arms provide adjunctive treatment modalities that ultimately result in improved patient care. Collaborative care discussions between various WLS team members can be extremely productive, and the input of the OMP is invaluable.

Within a SWLP, one of the primary functions of the OMP is to provide initial assessments that encompass medical, social, and functional consequences of a patient's excess weight and medical comorbidities. The OMP employs a holistic evaluation to determine indications for treatment, using tools such as the Edmonton obesity staging system [3], rather than relying on body mass index (BMI) and comorbid conditions alone. Treatment modalities are then data-driven and allow for individualized plans with patient-specific advice on nutrition, physical activity, and behavioral interventions. Such personalized treatment plans make allowances for patient variability, rather than the simple binary decision of whether weight loss surgery (WLS) will or will not be offered to a given patient. After initial assessment, the OMP is then able to offer the choice of a medical or surgical treatment arm, or both, depending on patient preference and medical criteria.

Optimization of Presurgical Patients

Patients seeking WLS who are not yet deemed medically optimized as surgical candidates can pursue an appropriate work-up as outlined by the OMP. The OMP can make recommendations regarding current medications that may be known to promote weight gain and may discuss and facilitate medication changes with a patient's primary care provider (PCP). The OMP therefore acts as an integral patient navigator; a specialist who can interpret the various consultation reports and coordinate care in this way facilitates progression through a WLS program [4].

For patients in medical weight management, the OMP, in consultation with the registered dietitian, can recommend patient-prepared meal plans or can recommend commercial meal plans or supplements. Availability of commercial products in a multidisciplinary weight loss programs can be a great convenience for some patients and can improve the business side of the program. Similarly, an exercise regimen, in consultation with an exercise physiologist, can be recommended and followed. Digital applications exist to help patients track their progress, and these can be accessed by the program as well. Body composition tools may also be helpful in measuring progress and motivating patients. An additional benefit is the OMP's ability to recommend, prescribe, and follow the effects of the various FDA-approved weight loss drugs, including those that suppress appetite, those that inhibit fat absorption, and those that increase metabolic rate.

Management of the Nonsurgical Patient

The presence of an OMP within a SWLP is invaluable for patients who either are unable or unwilling to pursue surgical therapies, allowing the endpoint of therapy to be defined as meaningful weight loss, rather than completion of a bariatric surgical procedure. Patients may not be surgical candidates due to the state of their comorbidities, significant or imperfectly controlled psychological issues, social issues, or lack of insurance coverage. The ability of the OMP to support and treat patients who are not in a surgical track still keeps patients engaged in the SWLP. Should the patient's medical, social, or psychological situation change or if coverage for WLS is later attained, such patients will have remained active participants within the program and can more seamlessly be prepared and scheduled for WLS.

Coordination of Care

The OMP serves an integral role in the coordination of care between the patient, the SWLP, PCPs, health insurance plans, and the surgeon when indicated. Their unique knowledge of both the medical and surgical components of the care of the obese

patient allows them to triage and address many urgent patient calls and issues and assign patients to office-based care or emergency department referral for complaints. Unlike the bariatric surgeon who may spend a significant portion of time in the inpatient setting, the OMP treats patients for the most part in the clinic. This key difference in availability and access is another core benefit of an OMP within a SWLP. The OMP is a more accessible resource for patients and their PCPs to contact for guidance. This may take the form of consultation regarding medication options to avoid weight regain, micronutrient repletion guidelines, or recommendations regarding laboratory testing for patients who have undergone malabsorptive bariatric procedures.

An example of such collaboration would be in the optimization of a patient with poorly controlled T2DM. Many WLS programs mandate good preoperative glycemic control, as reflected in glycated hemoglobin (HbA1c) levels below a certain standard. Some patients, while in the process of controlling their glucose levels, find that this also increases their weight [5]. This can be extremely frustrating for patients, particularly those whose program or insurance requires a certain amount of preoperative weight loss. The conundrum of using insulin to treat patients in a state of insulin resistance and intrinsic hyperinsulinemia has been previously noted [6]. In addition, not all hypoglycemic medication regimens are equally effective for a given patient, and communication between the OMP, the dietitian, and the endocrinologist can facilitate achieving better control while still allowing for ongoing weight loss.

In a more acute context, post-WLS patients who develop issues can call or come to the office and be personally triaged by the OMP. This could include advice regarding wound care, antiemetics, pain medications, or ways of increasing oral fluid intake or making a diet more tolerable. In some outpatient clinics, administration of intravenous fluids is available and can prevent expensive and time-consuming visits to an emergency department. Ordering and coordinating the delivery of enteral nutrition or antibiotics may be necessary, as may referral to other specialists.

Management of Bariatric Complications

Imperfect nutrition or frank malnutrition can still be commonly seen, even in the overweight population. The OMP can determine if micro- or macronutrient deficiencies exist before or after surgery and can initiate correction of such deficiencies. Repletion of some nutrients, such as copper, can be extremely complicated and may require a plan of care over the course of several months. Iron deficiency anemia is quite common after gastric bypass and the duodenal switch procedure [7]. The OMP can make recommendations that help prevent this complication or when it is discovered can initiate or coordinate treatments that allow patients to avoid unnecessary blood transfusion.

Functional difficulties are amenable to work-up by the OMP. Chronic abdominal pain after gastric bypass is a frequent complaint and requires diligent

evaluation and sometimes multimodal treatment. Similarly, sphincter of Oddi dysfunction or biliary dyskinesia can be troubling after bypass and may require significant time spent in evaluation and counseling. The evaluation and management of hyperinsulinemic hypoglycemia, which may be referred to as neuroglycopenia or nesidioblastosis, would also fall under the purview of the OMP. This syndrome can be extremely distressing for patients and PCPs, and appropriate management by a specialist may prevent unnecessary referral for pancreatic resection [8].

As noted previously, another potentially valuable role of the medical bariatrician is in the management of patients with adjustable gastric bands. The OMP can assess a patient's weight trajectory, calculate body composition, discuss food choices and symptoms, make a determination as to the need for band adjustment, and then perform such adjustments. In addition, they may determine the need for acute or interval imaging studies depending on timing or patient complaints.

Role in Diagnostic and Therapeutic Endoscopy

OMPs with advanced training in gastrointestinal (GI) endoscopy are well positioned to provide this diagnostic tool for those programs that request it routinely in the preoperative phase. Postoperatively, such an OMP would be available to offer various endoscopic therapies such as stricture dilation, pyloric Botox application, fluoroscopic examinations, stenting, clipping, gluing, and other treatment modalities for certain complications. An OMP capable of placing intragastric balloons, following such patients, offering dietary advice to prevent nausea and vomiting, prescribing antiemetics, and ultimately removing those balloons that are not intended to pass spontaneously provides a valuable adjunctive therapy.

Evaluation of the Revisional Surgery Candidate

As the field of WLS expands, more and more patients are presenting with the need for surgical revision or conversion. This may be on the basis of either weight regain or technical complications. The evaluation of patients requesting revision or conversion to another form of WLS can be complex and requires a skilled practitioner and a sensible algorithm. One complex issue is that patients who underwent procedures in the past may have no idea what operation was actually performed. The hospital where it was performed may be closed, the surgeon may no longer be living, and records could be unavailable. When this is the case, the OMP will likely initiate an evaluation that could include radiologic imaging, functional studies, and endoscopy. All this will help clarify current anatomy so that the bariatric surgeon can enter into a detailed discussion of revisional surgery with a clearer understanding of what to expect.

Conclusion

Long term follow-up of WLS patients may be facilitated by the availability of an OMP [9]. We have discussed the use of weight loss medications, and OMPs should be comfortable with how they are prescribed, in what setting they are used, and how such patients are followed. In addition, some PCPs are uncomfortable or unwilling to manage the laboratory assessment and micronutrient repletion of such patients. A specialized physician with the knowledge and time to attend to these aspects of care may not only improve patient follow-up but may encourage more medical providers to refer patients for WLS. Overall, an understanding of the myriad contributors to overweight and obesity, such as biology, genetics, socioeconomic factors, and psychological issues, positions the OMP as the ideal physician for the care of patients who struggle with weight.

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Chapter 14
The Role of the Psychologist in the Management of the Bariatric Patient

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Introduction

It has been well-established that obesity is the result of complex interactions among biological, environmental, behavioral, and psychological factors. To be effective, strategies to treat obesity should address as many components as possible. Bariatric surgery is accepted as the most efficient, effective, and durable treatment for morbid obesity, as it produces significantly better weight loss and improvements in medical comorbidities compared to lifestyle intervention [1–5]. However, long-term maintenance of results is not guaranteed, and outcomes are highly dependent on individual, behavioral, and psychological factors associated with overall adherence [6, 7].

Mental health professionals were initially recommended to be part of the bariatric surgery evaluation team in the 1991 National Institutes of Health Consensus Development Conference Statement. The purpose of the entire team was to help select patients who were candidates for bariatric surgery [8]. Updated clinical practice guidelines from the American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery (ASMBS) also state that an assessment of psychological factors should be part of the comprehensive evaluation to assess for surgical risk [9]. As such, a psychosocial evaluation is a routine part of the preoperative process in the majority of bariatric surgery programs in the United States and is often required by third-party payers [10]. In this constantly evolving area of behavioral health in bariatric surgery, the role of a psychologist is key in evaluating presurgical patients but has also extended to facilitate psychosocial interventions and long-term management during the postoperative time period [10–12].

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Qualifications of a Bariatric Psychologist

Psychologists study the mind and behavior and work with patients throughout the developmental spectrum [13]. Those working in the field of bariatrics typically have earned a doctorate in clinical or counseling psychology, have completed a clinical internship, and hold a valid license to practice. Many psychologists have additional fellowship training with specialized populations. Psychologists provide initial assessments for mental and behavioral health problems, long-term or short-term therapy, and psychoeducation. They are also trained to administer and interpret psychological testing or questionnaires and to conduct research. While psychologists do not typically prescribe medications, they can currently be granted the right to prescribe a limited number of psychotropic medications with appropriate training in five states [14].

While the current chapter will examine the role of a psychologist in the field of bariatrics, it is important to note that other mental or behavioral health professionals also provide similar services. These include clinical social workers, clinical counselors, psychiatrists, and psychiatric nurses [15]. Thus, the term psychologist in this chapter will also encompass behavioral health professionals in the field of bariatrics. A 2010 survey of ASMBS members suggested that behavioral health providers in the field of bariatrics should have extensive specialized knowledge and experiences in the treatment of obesity and weight loss surgery and that standards could be regulated by a formal credentialing process. However, this has yet to be formalized as several concerns were also noted, including the possibility of the process becoming burdensome, unnecessary, or creating a barrier to treatment [15]. The psychologist or behavioral health professional should also be available postoperatively to address long-term complications and provide continuity of care [11].

The Presurgical Evaluation

The purpose of the evaluation is to assess for psychosocial contraindications and adherence factors, to formulate a treatment plan that utilizes the patient's strengths, and to identify and address challenges to long-term success after bariatric surgery [10, 12, 16–18]. A guiding question is, "Do the potential benefits of the patient having surgery outweigh the potential risks?" Complicated cases will require consultation with the surgeon, medical providers, dieticians, and nurses on the bariatric treatment team [9, 11]. While there are no set standards on how presurgical psychological evaluations should be conducted, there is a general consensus regarding the domains that should be addressed, which are beyond the scope of standard psychopathology [10, 17, 19].

The role of the psychologist and the purpose of psychological evaluation should be described to the patient, as well as a description of what is going to take place during the interview. Patients are often anxious about "saying the right thing" in

order to "pass the evaluation" and subsequently engage in positive impression management [20]. The initial evaluation provides the evaluator a chance to establish rapport and develop a relationship with the patient [21]. The typical evaluation involves a semi-structured or structured face-to-face interview, review of the medical chart, along with psychological testing, and/or symptom inventory [10, 12]. Common components of a comprehensive presurgical evaluation include knowledge about bariatric surgery and its risks and benefits, motivations and expectation for weight loss, weight and diet history, current eating and exercise behaviors, adherence to pre- and postoperative lifestyle changes, psychiatric history, past and current disordered eating, past and current substance use, stress and coping, and social support.

Knowledge, Motivations, and Expectations

Patient education and knowledge play an important role in weight loss surgery, and the information that patients are expected to know is often complex and extensive [22]. These areas are routinely addressed in the initial portions of most psychological evaluations. Patients should be able to describe the surgical procedure, risks, and benefits of surgery. Additional information can be gathered objectively. For example, Bauchowitz and colleagues [23] developed a measure that assesses knowledge about medical, behavioral, and psychological factors associated with bariatric surgery. Results from a study using this scale suggested that 65% of patients overestimated the degree of weight loss, and only 25% of patients maintained accurate expectations of weight loss. Patients who do not demonstrate adequate knowledge and/or realistic expectations are required to complete additional intervention.

While motivation for pursuing surgery has not consistently been linked to surgical results, several studies demonstrate that lack of knowledge contributes to unrealistic and inaccurate expectations, which in turn are a key predictor of patient self-efficacy and patient satisfaction. Most patients cite reasons for pursuing surgical weight loss that are related to improved health, decreased need for medications, improved mobility and fitness, and living longer, along with improvements in body image and self-esteem [24]. Unrealistic motivations (e.g., "so my husband won't leave me") and expectations ("I'd like to be pain-free" or "I'd like to weigh the same as I did before I had children.") provide a degree to which patients presume their lives to change after surgery [17, 23]. Sufficient data suggest that patients seeking surgical [25, 26] and nonsurgical [27] weight loss tend to have unrealistic expectations. These unrealistic expectations may lead patients to accept a greater level of surgical risk. Patients also need to understand that the outcome is highly dependent on their own behavioral efforts and adherence to postoperative eating and exercise recommendations.

Body image is a multifaceted construct involving the internal representation of one's outer appearance or the way one perceives and responds to his or her body and physical appearance [28]. Body image concerns are often noted at this time and may

be related to the anticipation of dealing with excess skin as a result of significant weight loss. On the other hand, some patients are surprised or distressed to hear this may be an issue. Most patients experience improvements in body image, but improvement in body image and self-esteem are not guaranteed following weight loss surgery. Assessing the domains of knowledge, motivation, and expectations gives the evaluator an idea about a patient's capacity to provide informed consent, and a chance to provide education and correct misinformation [23]. We encourage patients to adopt various measures of success beyond weight loss that encompass improvements in quality of life (i.e., "Non-scale victories"). Examples include changes in clothing size, being able to cross your legs, improvements in fitness, riding on a roller coaster, and getting off of medications [29].

Weight and Diet History

Assessing the patient's weight and diet history is important. Gibbons and colleagues [30] found that patients who sought bariatric surgery reported an extensive history of dieting attempts, often beginning in adolescence, but weight loss was never maintained. This area of inquiry includes learning about weight gain trajectories, description of childhood weight/size compared to peers, lowest adult weight, highest adult weight, and factors associated with weight gain over the years (e.g., poor eating habits, inactivity, side effect of medications, pregnancy, smoking cessation, etc.). Number and types of major diet attempts (e.g., diet, exercise, medications etc.) should also be documented, as this is often required by third-party payers and provides the evaluator with a sense of adherence and challenges faced. Maladaptive weight loss attempts, including vomiting, laxative/diuretic use, starvation, and excessive exercise, should also be assessed.

Current Eating, Exercise, and Health Habits

The psychologist assesses for maladaptive eating patterns such as skipping meals, emotional factors affecting food choices, and environmental factors (e.g., night shift schedule, responsibility of shopping and cooking) associated with poor weight management. Discussion of frequency of eating out at restaurants and eating fast food, favorite/problematic foods, caffeine intake, consumption of juice, sugar-sweetened beverages, and carbonated beverages also provides opportunity for education, problem-solving, and potential early intervention. Most programs ask patients to keep a food diary, as this has consistently been shown to be a key factor in predicting initial weight loss and long-term weight maintenance [31–33].

Information should be obtained about current exercise habits, sleep habits, compliance with medication regimens, adherence to blood glucose monitoring, and compliance with treatments for sleep apnea. Some of this information can be

gathered while reviewing medical history, surgical history, current medications, and drug allergies [21]. Many patients take multiple medications, and while they may not remember all the names of their medications, some will provide a list. This shows the ability to problem-solve and adapt, which are positive prognostic indicators for postoperative compliance.

Past and Current Disordered Eating

A discussion of eating habits leads to the assessment for diagnosable eating disorders and other problematic eating behaviors found in the *Diagnostic and Statistical Manual-Fifth Edition* (DSM-5) [34]. During the clinical interview, it is best to ask questions using diagnostic criteria rather than closed-ended questions such as "Have you ever binged?" or "Are you a binge eater?" Information can also be corroborated using objective assessment measures.

Binge Eating Disorder (BED)

BED has been recently included in the *DSM-5* as a diagnosis [34]. Key features include recurrent and persistent intake of an objectively large amount of food, subjective loss of control with eating during a binge episode, and three or more associated symptoms (e.g., eating more rapidly than normal, eating until one is uncomfortably full, eating large amounts when one is not physically hungry, eating alone out of embarrassment, or feeling disgusted, depressed, or guilty after eating). Diagnosable behaviors typically involve distress. Current frequency of binges is once a week for the past 3 months. BED is more common in patients seeking bariatric surgery than in community samples, and current prevalence rates range from 10.1 to 23.3% [35–37]. While binge eating disorder is not a contraindication to having bariatric surgery, untreated symptoms (with loss of control as a key predictor) may lead to poorer outcomes. Patients treated with a brief four-session group treatment show improvements in eating behaviors and attitudes after the treatment, and responders to treatment had enhanced surgical outcomes across different bariatric procedures [38].

Bulimia Nervosa (BN)

Bulimia Nervosa is characterized by (1) recurrent episodes of binge eating (i.e., eating, in a discrete period of time, an amount of food that is definitely larger than more people would eat during a similar time period and under similar circumstances, accompanied by a sense of lack of control while eating); (2) recurrent compensatory behavior to prevent weight gain (e.g., self-induced vomiting, misuse of laxatives or diuretics, fasting, or excessive exercise); (3) self-evaluation being unduly influenced

by body shape and weight concerns; and (4) behaviors occurring at a frequency of once a week for 3 months [34]. Symptoms of BN tend to be rare among bariatric surgery candidates and should be considered a contraindication to these surgical procedures. Lifetime prevalence of BN was reported between 0.0% and 6.8%, while current prevalence has been reported between 0.0% and 1.0% [36, 37, 39, 40].

Anorexia Nervosa (AN)

A history of anorexia nervosa is also rare in this population but should be evaluated, nonetheless.

Night Eating Syndrome (NES)

Night eating syndrome was first identified in 1955 by Stunkard and colleagues [41] as a stress-related eating disorder characterized by a disproportionate consumption of calories at night and/or waking up from sleep to eat, morning anorexia, and insomnia [42]. The relationship between night eating and weight is inconsistent and is listed in the *DSM-5* as part of the "Feeding and Eating Disorder, Not Elsewhere Classified." Prevalence of NES ranged from 6% to 64% in patients seeking weight loss treatment and from 8% to 42% for those seeking bariatric surgery [43]. Symptoms that should be addressed prior to surgery include general timing of eating and beliefs about eating that are related to sleep.

Graze Eating

Graze eating is defined as "repetitive, unplanned eating of small amounts of food throughout the day" and is also referred to as nibbling, picking, or unplanned snacking. Approximately 33% of bariatric surgery candidates endorse graze eating, and 32% experience loss of control [44, 45]. Although less research has been done in this area, graze eating has been found to lead to suboptimal weight loss and ultimately can lead to weight regain [45]. Patient may engage in graze eating following surgery, as this behavior is easier to engage in compared to binge eating, and it can serve as a maladaptive coping/avoidance strategy [44]. Patients should be educated about the occurrence and consequences of graze eating postoperatively, and loss of control should be addressed.

Other Problematic Eating Behaviors

Another subclinical problematic eating behavior is emotional eating, or eating that occurs in the absence of hunger cues and is influenced by emotions, both positive and negative. Emotional eating is often used to self-soothe or to provide relief from

difficult feelings [46]. Subclinical problematic eating patterns tend to lead to poorer weight loss. Finally, meal skipping should also be addressed, as many patients have an erroneous belief that they will lose weight as a result. In most cases, patterns of meal skipping lead to overconsumption later in the day.

Psychiatric History and Current Mental Health Symptoms

Psychiatric comorbidities are prevalent among bariatric surgery patients, with estimates ranging from 23% to 68% of patients affected preoperatively [35, 36, 47]. Accurate prevalence rates are difficult to capture due to social desirability on the patient's end, sample sizes, and differing methods of assessment [20, 35]. Results examining the association between psychopathology and weight loss after bariatric surgery are mixed [48–50]. Fisher and colleagues [51] presented findings from a recent study of more than 8000 bariatric surgery patients that found no significant differences for changes in weight or BMI in patients with and without preoperative mental illness. However, those with preoperative mental illness had greater use of acute care (specifically ED visits and hospital days) between 3 months after surgery through 2 years of follow-up [51]. These findings support the importance of focusing on stability of mental health illnesses and symptom management more than the diagnosis type [12], as the functional impact of specific symptoms can vary among individuals with similar diagnoses. It is also important to differentiate between genuine symptoms of depression, and those that are secondary to medical conditions (e.g., fatigue, changes in appetite, poor sleep, anhedonia vs limited physical function, etc.)

The following areas of interest provide insight into the patient's mood stability and openness to seeking treatment: past and current psychiatric diagnoses, symptom frequency, duration, and impact on life are reviewed, and family mental health history. A patient is typically asked about past and current mental health treatment with counseling from a psychologist, therapist/counselor, social worker, or other mental health provider. Further questions are asked about the concerns addressed in treatment, duration, frequency, modality, and the usefulness of therapy. Summary of treatment notes within the past 6 months are routinely requested, with a signed release of information from the patient. Consider more intense postoperative follow-up for patients with risk factors.

Information is also gathered about past and current psychotropic medication use. Details about doses, formulations, how often the patient takes PRN medications, frequency of missed doses, and the usefulness of medications for symptom management can also be addressed. Patients and their prescribing providers should be educated about the possible changes in effectiveness of psychotropic medications after malabsorptive procedures, due to changes in pharmacokinetics. The patient should be encouraged to consult with their physicians about modifying the formulation (i.e., standard release medications are recommended over extended release

medications) or increasing doses postoperatively to achieve similar benefits of symptom management seen before surgery [52, 53].

Finally, information about past and current suicidal and homicidal ideation, plan, intent, and attempts is gathered, along with information about self-injury behaviors and psychiatric hospitalizations. Information regarding dates, duration, reason for admission, and discharge recommendations can provide insight into the nature and severity of psychopathology. The evaluator should request a copy of the discharge summary for any psychiatric hospitalization within the past year.

Depression and obesity have been linked to suicide [54]. Results of systematic review found that patients undergoing bariatric surgery are four times more likely to commit suicide compared to people in the general population [55]. Patients who have a diagnosis of self-harm before surgery (especially in the 2 years preceding surgery) are at an increased risk of post-surgery self-harm, or hospitalization for depression in the first 2 years after surgery. Routine postoperative screenings of depression and suicidal ideation are warranted for this vulnerable subset of patients [56].

Trauma

A brief screening of trauma history is typically conducted, as adverse childhood events are associated with adult obesity [57–59]. A study of bariatric surgery candidates found that 16% of the sample reported a history of sexual abuse [60]. It is not necessary to ask for or to document a detailed account of the abuse, and this line of questioning should be done in a nonjudgmental and supportive way. Because trauma history can affect the development and maintenance of chronic health conditions, the purpose of this inquiry is to provide perspective on the patient's perceptions of the relationship between abuse and current body weight [61]. Patients with unresolved trauma run the risk of re-experiencing negative feelings. Referral to a mental health provider with expertise in the treatment of trauma is recommended for patients who become distressed when discussing a history of abuse, or if the "experience of a 'barrier weight'" is identified [17, 61].

Substance Use

Past and current use of alcohol, nicotine products, and illicit and prescription drugs is also an important area of assessment. In addition to the clinical interview, brief screening tools (see below) can be used to obtain objective measures to distinguish between abuse and dependence. Guidelines for alcohol consumption from the National Institute of Alcohol Abuse and Alcoholism (NIAA) suggest no more than 4 standard drinks on an occasion or 14 standard drinks per week for men and no more than 3 drinks on an occasion or 7 standard drinks per week for women.

Approximately 2 in 100 people who drink within these limits have alcohol use disorder. Frequency and quantity of alcohol consumption should be assessed to rule out binge drinking [62]. All patients should be informed about the risks for alcohol use prior to surgery, as well as potential changes in sensitivity, faster absorption, reduced volume of stomach, decreased alcohol dehydrogenase (an enzyme that partially metabolizes alcohol), rapid emptying of gastric pouch, and "addiction transfer" after surgery [63, 64]. Further information on conducting an alcohol history in the bariatric presurgical patient is presented in Heinberg and colleagues [65].

Frequency, duration, and amounts of past and current nicotine use with cigarettes, cigars, chew, snuff, hookah, vapor, and e-cigarettes should be assessed. Recent ASMBS guidelines [9] recommend cessation of tobacco at all times by all patients and state that "Patients who smoke cigarettes should stop, preferably at least 6 weeks before bariatric surgery." Education about avoiding nicotine after surgery should be provided, given the increased risk of poor wound healing, anastomotic ulcer, and overall impaired health. Information for tobacco cessation should be provided in writing, along with contact information for a Quit Line.

Current use of illicit drugs is a contraindication for surgery [9]. Toxicology screening should be ordered for patients who are suspected to be using nicotine and illicit drugs, or misusing prescription drugs. A brief review of legal, social, and occupational problems as a result of substance use should be determined, along with treatment history.

Stress and Coping

Chronic and/or acute stress is unavoidable and can negatively affect a patient's weight management efforts. Identifying ongoing stress and expected stressors can be helpful for treatment planning. Stressors can impact timing of surgery. Patients should plan ahead for the preoperative requirements and for taking time off after surgery to recover. While not ideal, the recommendation to delay surgery may be made in cases where significant life stressor may actually put a patient at risk for poor surgical outcomes [66]. Discussions on ways to cope with stress without using food can also be helpful for patients.

Family History and Social Support

In addition to general background information that is assessed during a standard psychological evaluation (e.g., marital status, highest education attained, difficulties in school, and employment), information about a patient's support network is key. The decision to have bariatric surgery often affects partners, family members, and friends. In some cases, these people can be against bariatric surgery and may even try to sabotage weight loss efforts [66].

Relationship dynamics can be impacted positively or negatively. Factors such as comparing one's weight to that of a partner or to sociocultural norms can lead to weight competition, weight envy, sabotage, negative weight talk, and disputes over food choices [67]. This may prompt further weight evaluation, body dissatisfaction, and conflict between partners [68]. When positive support between couples is lacking during the preoperative stage, the relationship strain postoperatively is exacerbated. Negative responses from one's partner may be related to anxiety or jealousy. Tension can ensue as the patient may be losing weight, gaining confidence, and engaging in a wider variety of activities, which alters the dynamic of the relationship. For the partner who did not undergo surgery or is not losing weight, insecurity and fear of abandonment can develop [69].

Patients can identify positive sources of support, learn ways to improve adherence to eating recommendations, and discuss their needs with people in their lives. They often must make changes in their daily routines, including limiting eating out, attending potluck events without overeating, and sometimes cooking separate meals for themselves and their families. Interventions targeted at helping patients learn stimulus control techniques, how to plan ahead for high-risk situations, and addressing concerns and barriers to healthy eating prior to surgery can help improve outcomes.

Psychological Testing

Objective psychological testing is utilized in 50–66% of bariatric surgery programs [10, 16]. Standards for psychological testing do not exist at this time, but common measures typically assess symptoms of mood disorders, eating disorders, cognitive function, and general psychopathology [16, 70–72]. ASMBS guidelines for psychological testing advise consideration of psychometric information, availability of bariatric norms, validity indices to assess the degree of over- or underreporting by the patient, burden of time and cost for the patient, added value of the assessment measure to information gathered in the clinical interview, and finally the utility of measures related to bariatric surgery outcomes [12]. For a comprehensive review of commonly used measures, the reader is directed to LeMonte [70], Heinberg [71], and Marek and colleagues [72]. Discrepancies between results of objective measures and the clinical interview should be discussed with the patient. A referral for neuropsychological testing may be indicated to better characterize the etiology and nature of a patient's cognitive deficits if found during brief cognitive screening. Table 14.1 summarizes commonly used measures in bariatric evaluations.

Table 14.1 Commonly used psychological assessments in conjunction with bariatric evaluations

	Name	Abbreviation	Domain assessed
Mood disorders	Beck Depression Inventory-II [73]	BDI-II	Depression
	Patient Health Questionnaire 9 [74]	PHQ-9	Depression
	Beck Anxiety Inventory [75]	BAI	Anxiety
	Generalized Anxiety Disorders-7 [76]	GAD-7	Anxiety
	Mood Disorder Questionnaire [77]	MDQ	Bipolar disorder
Eating behaviors	Binge Eating Scale [78]	BES	Binge eating
	Eating Disorder Examination-Questionnaire [79]	EDE-Q	Overeating vs. binge eating
	Master Questionnaire-Revised [80]	MQR	Stimulus control, hopelessness, motivation, physical attribution, and energy balance knowledge in weight loss
	Night Eating Questionnaire [81]	NEQ	Night eating syndrome
	Questionnaire on Eating and Weight Patterns [82]	QEWP	Binge eating, bulimia, and body image concerns
	Three-Factor Eating Questionnaire [83]	TFEQ	Dietary restraint, disinhibited eating
	Yale Food Addictions Scale-Version 2.0 [84]	YFAS 2.0	Addictive-like eating behavior
	Brief Symptom Inventory [85]	BSI	Psychological distress and psychopathology
Personality and psychopathology	Millon Behavioral Medicine Diagnostic [86]	MBMD	Psychosocial factors that support or interfere with a patient's course of medical treatment
	Minnesota Multiphasic Personality Inventory-2 [87]	MMPI-2	Psychopathology, personality, and social adjustment
	Minnesota Multiphasic Personality Inventory-2-Revised [88]	MMPI-2-RF	Personality and psychopathology
	Personality Assessment Inventory [89]	PAI	Psychopathology
	Symptom Checklist 90 [90]	SCL-90	Psychopathology
	Mini Mental Status Exams [91]	MMSE	Brief cognitive screening

(continued)

Table 14.1 (continued)

	Name	Abbreviation	Domain assessed
Cognitive function	Montreal Cognitive Assessment [92]	MOCA	Mild cognitive impairment
	Alcohol Use Disorders Identification Test [93]	AUDIT	Alcohol use/dependence
Alcohol use	Alcohol Use Disorders Identification Test-Consumption [94]	AUDIT-C	Alcohol use/dependence
	36-Item Short Form Health Survey [95]	SF-36	Physical and emotional health
Other	Adverse Childhood Events [96]	ACE	Childhood trauma
	Impact of Weight on Quality of Life-Lite [97]	IWQOL	Impact of weight on psychosocial quality of life-lite
	Marlowe-Crowne Social Desirability Scale [98]	MC-SDS	Social desirability
	Moorehead-Ardelt Quality of Life Questionnaire [99]	M-A QoLQ	Quality of life
	Multidimensional Body Image Self-Relations Questionnaire [100]	MBSRQ	Body image domains
	University of Virginia Gastric Bypass Knowledge Scale [23]	UVGBKS	Knowledge about medical, behavioral, and psychological factors

Contraindications for Surgery

Research has not identified standard psychosocial contraindications to bariatric surgery, and studies on predictive outcomes show mixed findings [10, 16]. Differences among study results are likely related to methodological differences in survey instruments. Table 14.2 provides a list of definite psychosocial contraindications from survey results of 81 bariatric programs [10] and relative psychosocial contraindications from the 2013 updated clinical guidelines [9]. The most common recommendation resulting from psychosocial contraindications is to delay surgery in order to improve a condition (e.g., improve knowledge, referral for treatment of bipolar disorder, address untreated binge eating). Studies suggest that bariatric programs do not immediately approve patients due to psychosocial reasons up to 25% of the time [16]. Rates for denial of weight loss surgery for psychological reasons range between 2 and 6% [16, 52, 101–103].

Table 14.2 Definite and relative psychosocial contraindications for bariatric surgery

Definite psychosocial contraindications[a]	Relative psychosocial contraindications[b]
1. Current illicit drug use	1. Impaired intellectual capacity or the inability to comprehend the surgical intervention or the lifelong behavior changes necessary to ensure success and safety
2. Active psychosis	
3. Severe mental retardation (IQ < 50)	
4. Current heavy drinking	2. Lack of ability, willingness, or motivation to comply with postoperative lifestyle changes, dietary supplementation, and follow-up
5. Lack of knowledge about surgery	
6. Significant medical noncompliance	
7. Unrealistic expectations for weight loss	3. Active drug or alcohol abuse
8. Multiple suicide attempts	
9. Active symptoms of bipolar disorder	4. Untreated severe psychiatric illness
10. Suicide attempt within the past year	

[a]The top ten of 37 items are listed for brevity from Bauchowitz et al. [10]
[b]2013 updated clinical guidelines from Mechanick et al. [9]

Summary of Evaluation Results

The psychologist should be able to provide a provisional *DSM-5* and/or ICD-10 diagnosis and clinical impression at the end of the evaluation [21]. A summary of the evaluation and testing results, along with treatment requirements and recommendations, should be discussed with the patient and, ideally, provided in writing. Additionally, these results should be communicated to the members of the multidisciplinary team [10, 12].

The Preoperative Preparation Stage

Information gathered from the clinical evaluation helps to identify treatment recommendations that will improve short- and long-term outcomes. The time leading up to surgery provides an opportunity for intervention through individual or group counseling. Limited research has been done in this area but some bariatric programs have protocols to provide education for preparing for life after surgery. These may be offered as a one-time education session or as a multiple-session treatment to address a specific area of need. For example, at our institution, we offer two structured four-session Cognitive-Behavioral Therapy (CBT)-based group treatment interventions. The first program addresses eating pathology and patients completing

treatment have reported improvement in binge eating behaviors, cognition, and binge eating episodes [104]. The second program has been shown to increase knowledge and improve coping skills in patients who were found at their initial evaluation to have poor knowledge or substandard understanding of postoperative lifestyle changes [105]. We also refer at-risk patients to a one-session group intervention that provides psychoeducation on substance abuse prevention [106]. Results of the latter intervention showed that patients reported increased knowledge about the negative effects of substance use and abuse after surgery. Common session topics of CBT-based treatment groups include the importance of self-monitoring, stimulus control, how to identify and challenge negative thought patterns, stress management, relapse prevention skills, and education about adjusting to life after surgery.

Currently in progress is a randomized controlled trial in the Netherlands, investigating if the delivery of a preoperative ten-session CBT intervention will strengthen the effect of bariatric surgery [107]. The aim of these interventions is to improve problematic behaviors that have been shown to correlate with poor outcomes. Preoperative weight loss is not always related to long-term outcomes. However, recent studies have associated preoperative weight loss with a number of positive outcomes, including shorter operation times [108] and reduced risk of major complications [109].

The Postoperative Period

Postoperative Follow-Up

Patients attend follow-up appointments with their providers after bariatric surgery to address overall adjustment [21]. The focus of the initial postoperative appointments is on medical and nutritional concerns. Surgery programs also encourage attendance at support groups as this is associated with improved outcomes [110, 111]. Less well-defined is the role of psychology in the postoperative process. This may stem from the erroneous belief from a patient perspective that the preoperative psychological evaluation is a one-time hurdle to surgery, and they only need to return if they are having problems. It is recommended that bariatric programs utilize behavioral and mental health services and inform their patients of the availability, role, and importance of continuity of care to improve overall success. In addition to individual and shared medical appointments, patients at the Cleveland Clinic attend shared psychological appointments at different time points postoperatively. The group format offers peer support, accountability, and the benefit of sharing ideas and suggestions.

Weight Regain and Nonadherence

Weight regain after bariatric surgery is the most common reason for patients to return to treatment. A systematic review of weight recidivism by Karmali [112] found that postoperative weight regain varies according to duration of follow-up and the type of surgery performed. Factors leading to weight regain are multifactorial [113]. Several studies show that regain tends to occur between 2 and 10 years after bariatric surgery, and some patients may regain up to 15% of their initial body weight [114–116]. Long-term data from the Swedish Obese Subjects trial demonstrated that weight regain was seen in all surgical subgroups in the years following surgery, but the relapse curves leveled off after 8–10 years [117].

Adherence to postoperative diet had been directly associated with weight loss. For patients enrolled in lifestyle interventions, variability in weight loss outcomes appears best accounted for by adherence to their respective diet plans [118, 119]. Data from the Swedish Obese Subjects showed that participants decreased their daily calorie intake from 2800 at baseline to 1500 calories at 6 months after surgery. By 10 years postoperatively, patients increased their intake to 1800–2000 calories [116]. Weight regain is likely related to increased energy intake from factors such as grazing eating [45, 120], increased food urges/cravings [121], and increased snacking [122, 123]. Types of snacks were more likely to be high in calories, such as potato chips, crackers, and high-fat microwave popcorn. Snack foods were also more convenient, required little preparation, and emptied quickly from the gastric pouch.

Patients also experienced changes in food tolerance [124, 125]. In addition to experiencing an increase in pouch size, gastric bypass patients may experience gastrointestinal adaptation, increased food tolerance, and a decrease in the unpleasant symptoms of dumping syndrome. Food tolerance was found to be comparable to controls by 5 years postoperatively [125].

Lack of exercise tends to be the most frequently reported noncompliant behavior post-surgery [122]. Not surprisingly, adherence to exercise has been found to be a strong predictor for weight maintenance [126–128]. Other behaviors related to successful weight maintenance include self-monitoring [33, 113], attendance at support groups [129, 130], adherence to follow-up visits [131], and positive response to binge eating treatment [38]. A multidisciplinary and systematic approach to addressing weight regain should also focus on dietary, psychosocial, medical, and surgical factors [113].

Other Reasons for a Postoperative Referral to Psychology

Davidson [132] discussed the following topics, in addition to weight regain, that warrant a referral to a psychologist or mental health provider:

- Problematic eating behaviors including mindless eating, emotional eating, graze eating, binge eating, night eating, or purging
- Reoccurrence of depression or anxiety
- Suicidal thoughts
- Negative feelings including shame, guilt, fear of failure, or fear of relapsing/weight gain
- Poor body image or self-esteem
- Self-sabotage behaviors
- Poor treatment compliance
- Stress management
- Reemergence of addictive behaviors or "addiction transfer" including drug use/abuse, alcohol use/abuse, cigarette use, or any nonsubstance-related behavior such as pathological gambling, high-risk sexual behavior, impulsive or compulsive shopping, etc.
- Relationship/support network concerns
- Intimacy concerns

Summary

Psychologists and other mental health providers are considered an essential part of the multidisciplinary team in most bariatric surgery programs. These practitioners should have a thorough understanding of the biological, environmental, behavioral, and psychological contributors and consequences of morbid obesity, weight loss after bariatric surgery, and long-term maintenance of treatment effects [12, 21]. This chapter provided an overview of the role of a psychologist on the preoperative evaluation, preoperative preparation stage, and postoperative period. While no clear standards exist for psychological assessment and treatment of a bariatric surgery patient, generally accepted guidelines for assessment and treatment were reviewed. The role of mental health in a surgical process has evolved over the past few decades and will likely continue to progress as additional information is gathered to help optimize long-term medical, psychological, and behavioral outcomes.

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Chapter 15
Preoperative Checklist for Bariatric Surgery

Abdelrahman A. Nimeri

Abbreviations

BMI	Body mass index
MDT	Multidisciplinary team
OSA	Obstructive sleep apnea
STOP BANG	Snoring, tiredness, observed apnea, previous history of HTN, BMI > 35, age > 55, neck circumference > 35 cm females and 40 cm in males, and gender male
Type II DM	Type II diabetes mellitus

Patient Education, Informed Consent, and Setting Realistic Expectations

Patients, their families, and the general public often are unaware of the relationships of obesity, bariatric surgery, and the association between obesity and type II DM [1]. In addition, many consider obesity a social problem and bariatric surgery a cosmetic procedure [2]. This lack of knowledge is only compounded by the prejudice toward obesity among many individuals and health care professionals [3]. Furthermore, many patients approach bariatric surgeons to help them with their weight without an appreciation of the need for preoperative physical and psychological evaluation, knowledge of endoscopic and surgical options, potential perioperative complications, the need for vitamin supplementation, lifelong follow-up after bariatric surgery, and with unrealistic weight loss expectations.

The lack of patient education leads to patient frustration with the process of preparation for bariatric surgery and the preoperative requirements proposed by the multidisciplinary team. In addition, patients may have unrealistic expectations

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regarding the possible perioperative complications and weight loss expectations after bariatric and metabolic surgery. Furthermore, some patients, especially in regions where bariatric surgery is not well regulated, leave established bariatric programs and undergo bariatric surgery by less qualified bariatric surgery teams willing to offer surgery without adequate preoperative evaluation leading to poor patient outcomes [4].

It is critical for the bariatric surgeon and the members of the multidisciplinary team (MDT) to inform patients about some of the known data about obesity and bariatric and metabolic surgery. These include that obesity is a serious medical condition not a social problem. In addition, patients need to know that obesity often has associated medical conditions, including type II DM. Furthermore, patients and their family need to know the risk-benefit ratio of obesity and bariatric surgery. This includes complex decision-making needed before embarking on bariatric surgery and gauging the potential benefit in the first year compared to the perioperative risk in the first month [5–12]. Finally, patients and their families need to know the importance of evaluation by an MDT and not a surgeon alone, the need for thorough preoperative evaluation, potential perioperative complications, and the setup of the facility where they will have their bariatric surgery. One of the possible ways to inform patients and their families about these facts is through educational seminars that the bariatric surgeon and the MDT can offer to the community.

If patients, their families, and the general public are well informed about the dangers of obesity and the obesity-related medical problems, they will likely be in a better position to understand the risks and potential benefits of undergoing bariatric surgery. In addition, their acceptance and expectations for weight loss and potential perioperative complications will become more realistic. This knowledge may aid patients and their families in the preoperative decision-making and in making objective choices about bariatric surgery programs.

The Multidisciplinary Team (MDT)

The MDT includes core members central to optimizing care of patients with obesity. In addition, many other support services are needed. The core members include the bariatric surgeon, bariatric physician, dietician, psychologist, anesthesiologist,and bariatric nurse coordinator [13]. These core members need the support of a cardiologist, pulmonologist, smoking cessation specialist, physiotherapist, interventional radiologist, critical care physicians, gastroenterologist, operating room team, and perioperative nursing staff. The MDT works best when the message delivered to patients, their families, and referring physicians is consistent. This consistent effort is developed by constant communication among the MDT members. In addition, educational sources help in cementing this common message. The MDT needs to meet on regular intervals to discuss the logistics of the bariatric program and review the processes and outcomes of the comprehensive program. Though variable in frequency, these MDT meetings are led and facilitated by the bariatric surgeon and the

bariatric nurse coordinator. All MDT members are engaged to work toward a common vision, with input from all members representing different fields.

Core Members of the Multidisciplinary Team (MDT)

Bariatric Dietician

The bariatric dietician is an important member in the team because many patients with obesity seeking bariatric surgery have nutritional and vitamin deficiencies. In addition, many patients are not aware of the components of a healthy diet [14, 15]. Furthermore, all patients undergoing bariatric surgery need specific instructions before bariatric surgery, including low-calorie diet after bariatric surgery, on how to achieve the best results and avoid weight regain after bariatric surgery. For example, monitoring of muscle mass through regular evaluation of body composition analysis is commonly needed to ensure that patients are not disproportionately losing their muscle mass. In addition, regular follow-up appointments after surgery with the bariatric dietician are important to affirm consumption of three small meals and two snacks, including protein with each meal and drinking more than two liters of water per day [14–16].

Bariatric Psychologist

Routine evaluation by an experienced bariatric psychologist is essential to make sure that patients are appropriate candidates for bariatric surgery [17]. In addition, this evaluation allows the bariatric surgeon to know a patient's ability to consent, expectations for weight loss, ability to deal with complications after surgery, social support, stress coping mechanisms, alcohol dependence, eating behavior, and adherence to previous diet programs. It is important that the psychological gives the bariatric surgeon and the rest of the MDT an overall impression rather than clearance for surgery. This impression can include eight main areas in a Likert scale 1–5 (1 poor, 2 guarded, 3 fair, 4 good, and 5 excellent). These eight areas include ability to consent, patient weight loss expectations, social support, mental health, chemical/alcohol/tobacco dependence, eating disorders (binge eating, grazing, high-calorie/beverage consumption), adherence to previous diet programs, and coping with stressors in life [17].

The American Society of Metabolic and Bariatric Surgery has recommended routine psychological evaluation since 2004 [18]. In addition, in a survey of 188 US bariatric surgery, 81% of US bariatric surgery programs require routine psychological evaluation, and almost half require formal standardized psychological assessment [19]. Furthermore, studies have linked post-bariatric surgery patients to higher rates of self-harm and suicide. Hence, it is strongly recommended for patients to undergo psychological screening prior to bariatric surgery and to address specifically

depression, emotion eating, binge eating, self-shame, and low self-esteem in these patients prior to having bariatric surgery [20]. Furthermore, the trust developed between the patient and the psychologist before surgery may facilitate patient's acceptibility of psychological care if needed after surgery. Finally, the psychologist will help identify high-risk patients who need monitoring by the MDT.

Obesity Medicine Specialist/Bariatric Physician

The obesity medicine specialist or bariatric physician is a recognized subspecialty in internal medicine with its own fellowship programs and board examination and certification [20]. The obesity medicine specialist has several roles in the multidisciplinary team. These roles include the workup of patients before surgery, management of patients who don't meet the criteria for bariatric surgery, follow-up of patients after bariatric surgery, and the management of patients with weight regain after bariatric surgery. For example, the obesity medicine specialist evaluates patients before surgery either because they don't meet the criteria to undergo bariatric surgery and subsequently may undergo medication therapy or because the patient needs evaluation of medical conditions as part of the workup prior to bariatric surgery. The obesity medicine specialist is needed to follow up patient in the immediate postoperative period as well as long-term follow-up at 3–6 month intervals during the first year after bariatric surgery after surgery and yearly afterward.

Bariatric Nurse Coordinator

The bariatric nurse coordinator is influential in many different aspects of the bariatric team and the overall function of multidisciplinary team. The American Society of Metabolic and Bariatric Surgery has a certification program for bariatric nurse coordinators. This program details the roles and responsibilities, qualification, and certification for a certified bariatric nurse coordinator [21]. These roles include informing patients and providing them with educational materials (brochures, booklets, flyers). In addition, he/she helps in organizing and calling for the monthly or quarterly team meeting. Overall, the most important role is to coordinate the care of the patients and help the patients navigate the evaluation by the multidisciplinary team.

Bariatric Anesthesiologist

Morbidly obese patients represent a challenging patient population for the anesthesiologist for several reasons. Obese patients pose several challenges to the anesthiologist, these challenges include unique challenges in patient positioning, airway management (intubation and extubation process), intraoperative management of paralytic agents, emergence from anesthesia, and moving the patient off the

operating room table [22]. In addition, pain management after surgery without excessive use of narcotics is implemented to avoid over sedation, especially in the presence of obstructive sleep apnea. The anesthesiologist is an integral component in an effective enhanced recovery after bariatric surgery program (ERABS) [23].

Preoperative Patient Evaluation

The preoperative evaluation for patients considering bariatric surgery varies depending on body mass index (BMI), age, gender, history of previous bariatric or other surgeries, and comorbid medical and psychiatric conditions. Due to these considerations, the length and complexity of the preoperative workup will vary for one patient to another. To simplify the process of preoperative evaluation for patients and the MDT, our practice is to group patients into moderate-risk patients, high-risk patients, adolescent patients, patients with previous history of bariatric surgery, and patients who do not meet criteria for bariatric surgery. This grouping can streamline the process of preoperative evaluation and clarify expectations about the length and the complexity of the preoperative evaluation needed. The following summarizes our specific practice pattern and is not mandated or endorsed by any particular organization:

A. *Moderate-risk patients*: this category includes patients who are >18 and <45 years of age, BMI > 40 without medical or psychological problems, no history of smoking, and STOP BANG questionnaire for obstructive sleep apnea (OSA) <3/8. These patients need evaluation by the bariatric surgeon, bariatric dietician, and bariatric psychologist.
B. *High-risk patient*: this category includes patients more than 60 years of age or patients more than 45 years of age with medical or psychiatric problems. These patients will need to have evaluation by respiratory if STOP BANG > 3, cardiology if age more than 45 years, history of chest pain, shortness of breath, or previous history of coronary artery disease. In addition, they might need colonoscopy if age over 50 years for history of anemia or history of inflammatory bowel disease. Furthermore, they might need further evaluation by psychology and psychiatry if they have previous history of psychiatric or psychological problems and smoking cessation specialist if they smoke.
C. *Adolescent patients*: this category includes patients <18 years of age, BMI > 40 and STOP BANG questionnaire for OSA <3 (If the patient has previous bariatric surgery, medical problems, or psychological problems, then follow high-risk or revisional pathway as well.) These patients and their families need to be evaluated by a center with known outcomes in adult bariatric surgery by a pediatric endocrinologist, pediatric dietician, and pediatric psychologist as well as an experienced bariatric surgeon. In addition, the MDT needs to evaluate the adolescent and the family to ensure they obtain consent from the family but assent from the adolescent in the absence of the family.

D. *Revisional bariatric surgery patients*: this category includes patients with previous bariatric or foregut surgery. They might need reversal, conversion, or correction of the previous bariatric surgery. These patients will need upper gastrointestinal radiographic series and upper endoscopy to evaluate the esophagus and stomach for postsurgical anatomy. In addition, patients with reflux as the main symptom may need a 24-h pH testing and esophageal manometry (if they have medical or psychological problems or STOP BANG > 3, then follow the high-risk pathway).
   In contrast, routine upper endoscopy in average-risk asymptomatic patients without previous history of bariatric surgery is optional as most of these studies will have results that lead to a change in medical management in 2.5% of patients and change in surgical management in less than 1% of patients [24]. Similarly, routine upper gastrointestinal series evaluation in patients without previous history of bariatric surgery has a low yield and is typically not necessary [25]. However, once exception to this rule is sleeve gastrectomy due to recent reports linking this procedure to a higher incidence of reflux, and Barretts esophagitis long term after sleeve gastrectomy [26, 27].
E. *Patients who do not meet criteria for bariatric surgery*: this category includes patients with BMI > 27 < 35 with obesity-related medical problems or patients with BMI > 30 < 40 without obesity-related medical problems [28–30]. These criteria vary widely, and different centers in geographically distant regions may have other criteria, reflecting metabolic disease burdens that may affect populations differently. These patients are typically seen by the bariatric physician and bariatric dietician.

Screening for Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is common among morbidly obese patients, especially males [31]. Many patients are not aware that they have OSA [32]. Patients with OSA are at a higher risk for morbidity and mortality. For these reasons, it is important to screen all patients for OSA before embarking on bariatric surgery. One of the validated screening methods for OSA is the STOP BANG questionnaire [33]. This questionnaire is simple and can be administered as part of the history and physical examination. The STOP BANG questionnaire includes eight items including snoring, tiredness, observed apnea episodes at night, previous history of hypertension, body mass index more than 35 kg/m^2, age more than 50, neck circumference more than 35 cm in females and 40 cm in males, and male gender. All patients with more than three items in the STOP BANG questionnaire may benefit from referral to pulmonology for a sleep study.

Screening for Colon Cancer, Breast Cancer, and Prostate Cancer

Obese and morbidly obese patients are at a high risk for developing colorectal, breast, and prostate cancer [34]. This is an opportunity for all patients undergoing bariatric surgery to also receive the recommended screening during preoperative workup: for example, screening colonoscopy at age 50 or in all patients with anemia, severe constipation, or signs of inflammatory disease; screening mammogram for females over 40 years of age; and prostate-specific antigen (PSA) as well as digital rectal examination for males over 50 years of age [35–37].

Smoking Cessation

Smoking accentuates the effects of obesity on the cardiovascular system especially in males over 45 years of age [38]. In addition, smoking is as detrimental to health as obesity [39]. Furthermore, smokers are at a higher risk of pulmonary complications, marginal ulceration, and infectious complications after bariatric surgery [40]. For all these reasons, it is important for patients who smoke to be enrolled in a smoking cessation program prior to undergoing bariatric surgery.

Infrastructure, Program Setup, and Program Accreditation

The initial setup of the bariatric program can be a hurdle to developing bariatric surgery programs because of the initial investment needs to establish the necessary infrastructure [41]. This setup includes outpatient and inpatient facilities, appropriate alterations or updating of operating rooms, education and equipment for the intensive care unit, specific expertise, and any unique supplies for the radiology department. Such considerations include aspects that might be overlooked, such as making sure that the furniture is appropriate for morbidly obese patients in regard to weight and size. Furthermore, hospital equipment such as gowns, blood pressure cuffs, and devices to move patients from the operating room table, wheelchairs and trolleys, need to be appropriate for morbidly obese patients [42].

Anesthesia Pathway

Morbidly obese patients undergoing bariatric surgery have several unique anesthetic issues that need to be addressed in a dedicated pathway [22]. These issues include airway management during induction and extubation at the end of surgery,

intraoperative neuromuscular blockage management and reversal at the end of surgery, intraoperative fluid management, and making sure all tubes are removed from the stomach before gastric transection is started. In addition, several processes of enhanced recovery after bariatric surgery (ERABS) are within the domain of anesthesia [23]. These processes include allowing clear liquids 2 h before surgery, oral carbohydrate loading, management of postoperative nausea and vomiting (PONV), judicious intraoperative fluid management, limiting the use of narcotic medications, and reversal of neuromuscular blockage, neuromuscular monitoring during bariatric surgery, and the use of multimodal therapy for pain [22, 23].

Enhanced Recovery after Bariatric Surgery (ERABS)

The protocol of enhanced recovery after bariatric surgery involves preoperative, intraoperative, and postoperative components. The preoperative components include allowing clear liquids 2 h before surgery, oral carbohydrate loading, and management as well as admission on the day of surgery. The intraoperative components include avoiding the use of drains and urinary catheters, management of postoperative nausea and vomiting (PONV), judicious intraoperative fluid management, limiting the use of narcotic medications, and reversal of neuromuscular blockage and neuromuscular monitoring during bariatric surgery. Postoperative components include the use of multimodal therapy for pain, early ambulation after surgery, the use of incentive spirometry, and allowing clear liquids once the patient is awake and alert [23].

Inpatient Pathway

The process of patient care after bariatric surgery needs close collaboration between the nursing and surgical teams. A dedicated inpatient pathway allows for the consistent orders to be carried out, dissemination of instructions to patients, triggers to call the surgical team, and expected milestones for progression of activity: diet and oral hydration are all clearly outlined. It is best to develop this pathway closely with the nursing team that will take care of the patients after surgery.

Prevention of Venous Thromboembolism

Patients undergoing bariatric surgery are at moderate risk, high risk, or very high risk for venous thromboembolism (VTE) [43]. Hence, the use of chemoprophylaxis in addition to sequential compression devices is needed in all patients. Studies have shown that low-molecular-weight heparin is more effective than subcutaneous

heparin without an increased risk of bleeding [43]. Furthermore, studies have shown that using LMWH 40 mg once a day is sub-therapeutic for morbidly obese patients with BMI > 40 kg/m^2. Hence, most patients need risk stratified into moderate risk, high risk, and very high risk for VTE based on BMI, age, previous history of VTE, or pulmonary embolism [44]. In our experience, we have found the Caprini scoring system an excellent tool for risk stratification of these patients. We give patients with a score of 3 (BMI less than 40 kg/ m^2), score of 4–5 (LMWH 40 mg twice a day), score 6 or more (LMWH 60 mg twice a day), and we measure anti-factor Xa after the 3rd dose to make sure it is between 0.2 and 0.4. All patients with score 5 or more have continued the hospital dose for 2 weeks [45–47].

Discussion of Perioperative Risks, Benefits, Alternatives, and Potential Complications of Bariatric Surgery

Discussion of different options of bariatric surgery with the patients and their families is an essential component of the preoperative evaluation. In addition, patients and their families need to be aware of the perioperative risks and potential complications after bariatric surgery. Furthermore, this discussion with the patients and their families helps in building trust and avoiding medicolegal malpractice law-suits [48].

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Chapter 16
Postoperative Care Pathways for the Bariatric Patient

Katherine M. Meister and Stacy A. Brethauer

Care Pathways

The primary goal of implementing a standard postoperative care protocol is to improve patient outcomes by adhering to evidence-based practice recommendations. Utilizing a routine postoperative care pathway within an institution decreases variability for the caregivers involved in patient care. Standardization of postoperative care pathways in bariatric surgery has been shown in multiple studies to decrease length of stay, improve resource utilization, and improve patient outcomes [1–4].

While the American Society of Metabolic and Bariatric Surgeons (ASMBS) and Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) require an institution to maintain and adhere to a clinical pathway [5], a recent study demonstrated significant variability in management of six key perioperative variables: preoperative nutritional evaluation, preoperative psychological evaluation, intraoperative venous thromboembolism prophylaxis, antiemetic utilization in the postoperative period, a dedicated perioperative pain plan, and obtainment of postoperative laboratory values [6]. Given such variability, the ASMBS has recently published an evidence-based clinical pathway for the perioperative management of patients undergoing a laparoscopic sleeve gastrectomy [7].

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Enhanced Recovery After Surgery

Enhanced recovery after surgery (ERAS) pathways were first described by a group of academic surgeons in Europe with the basic premise that the quality of recovery could be improved by implementation of an evidence-based, multidisciplinary, perioperative approach aimed at limiting issues that delay postoperative recovery [8]. ERAS pathways attempt to reduce perioperative surgical stress, maintain preoperative physiologic organ function, reduce pain and nausea, enhance early mobilization, and encourage early oral nutrition; this results in substantial improvements in clinical outcomes while overall reducing healthcare costs [8]. The key elements of ERAS protocols include preoperative counseling, optimization of nutrition, standardized multimodal analgesic and anesthetic regimens, and early mobilization [8]. Recently, these principles have been introduced to bariatric care pathways, though there is currently no consensus on the optimal perioperative care pathway [9].

General Guidelines for Postoperative Hospitalization and Monitoring

Following the PACU recovery, most patients are suitable for admission to a general surgical care unit. Routine vital signs and strict documentation of intake and output should be recorded every 4–8 h, according to institution policy. Notable changes in vital signs, including fever greater than 38.5 °C, sustained tachycardia above 110 beats per minute, oliguria, or atypical pain, should prompt a phone call to the surgical team for further evaluation. Fever, tachycardia, and abdominal pain are the most common signs of a leak after bariatric surgery. As the abdominal exam in an obese patient is unreliable, even in the presence of peritonitis, a benign exam does not rule out an intra-abdominal complication. Changes in the vital signs should prompt evaluation for possible complications.

Respiratory Care

Patients should be closely monitored for postoperative respiratory complications including hypoxemia, hypercarbia, atelectasis, and pneumonia. Oxygen supplementation is routinely used to prevent hypoxemia in the postoperative period. Routine use of continuous pulse oximetry is recommended in all bariatric patients with a history of obstructive sleep apnea or other underlying pulmonary conditions that require oxygen [10]. However, due to the incidence of frequent desaturations in the postoperative period, there should be a low threshold to use continuous pulse oximetry in all postoperative bariatric surgery patients. In addition, the use of incentive

spirometry and aggressive pulmonary toilet has been shown to reduce postoperative pulmonary complications [11].

If patients have the diagnosis of obstructive sleep apnea and require continuous positive airway pressure (CPAP) at home, they should be advised to bring their mask with them to the hospital on the day of surgery. This ensures the availability of a properly fitted mask. It is safe for CPAP to be initiated in the recovery room, immediately after extubation, without increasing the risk of anastomotic leak [12]. Furthermore, patients should be advised to wear the CPAP whenever sleeping to prevent life-threatening hypoxia in the postoperative period.

Glucose Monitoring

Patients with known diabetes mellitus or those with elevated perioperative glucose should undergo routine glucose finger-stick testing in the inpatient postoperative period. This is typically performed every 6 h in a patient who is NPO or on a clear liquid diet, though frequency may vary according to hospital protocols. Due to the immediate metabolic effects of bariatric surgery, insulin regimens need to be evaluated and adjusted frequently to avoid life-threatening hypoglycemia [13]. Additionally, there should be a low threshold for consulting a diabetic management team or endocrinologist for assistance with inpatient management of persistent hyperglycemia and recommendations for diabetic management upon discharge.

Drains and Tubes

Nasogastric Tubes

Primary bariatric procedures do not warrant the routine use of nasogastric decompression. Depending on surgeon technique, orogastric or nasogastric tubes are sometimes placed intraoperatively, after the stapling is complete, to insufflate the stomach with air and perform a leak test. However, these tubes should be removed, while the patient is still in the operating room. Postoperative nasogastric tube placement is generally not recommended due to the risk of injury to the staple line or anastomosis.

Intra-Abdominal Drains

Several studies have demonstrated that the routine use of a closed suction abdominal drain after primary bariatric surgery is not necessary. These studies found no difference with regard to leak, postoperative bleeding, abscess formation, or reoperation rates [14–16].

Urinary Catheters

There is insufficient evidence for the routine use of indwelling urinary catheters after bariatric surgery. The use of urinary catheters is a known risk factor for the development of urinary tract infection. In addition, catheters may lead to patient discomfort and limit ambulation after surgery. If a urinary catheter is placed during surgery, it should be removed as soon as possible to decrease the risk of urinary tract infection [17].

Postoperative Diet

While there is little evidence to specifically direct the dietary progression after bariatric surgery, programs should have a routine institutional protocol. It is recommended that a bariatric clear liquid diet be initiated within 24 h of surgery, as early as the night of postoperative day zero [13]. The bariatric clear liquid diet consists of non-carbonated, low-calorie, non-concentrated clear liquids. Once a patient is tolerating adequate oral intake, this is progressed to a full liquid diet to include protein shake supplementation. Patients are typically able to progress to a full liquid diet in the first 1–3 days postoperatively. They then remain on a full liquid diet until evaluated by the surgeon at the first postoperative visit, typically 1–2 weeks. Patients then progress to a pureed diet, blended food-baby food consistency. After 1–2 weeks on the pureed diet, patients then start a soft diet for 1–2 weeks and finally, a regular diet.

Patients should be counseled on their daily oral requirements. Patients are advised to drink at least 64 ounces of fluid and a minimum of 60 grams of protein, or up to 1.5 g/kg of ideal body weight, per day [13]. In addition, patients are advised to start their daily multivitamin regimen. Further information on nutrition is provided elsewhere in this manual (Chap. 26).

Imaging

The use of routine upper GI (UGI) contrast studies after bariatric surgery remains controversial. Postoperative UGI can provide anatomic information on possible complications following bariatric surgery, including anastomotic narrowing secondary to postoperative edema, stricture of either the gastrojejunal anastomosis or jejunojejunostomy, abnormal dilation of the gastric remnant, or stenosis of a sleeve gastrectomy [18]. Some surgeons use clinical predictors to guide the selective use of postoperative UGI imaging. Other surgeons, however, advocate the routine use of UGI, though there is little evidence to support this practice.

The accuracy of UGI may vary depending on a number of factors, including the size of the patient, the ability to stand and swallow, the experience of the radiologist, the size of the leak, and the contrast material used [19].

In addition, early postoperative UGI contrast studies have very low sensitivity to detect an early leak, as many leaks are reported to occur after hospital discharge [20]. As such, a negative UGI on postoperative day, one may give the surgeon a false sense of security regarding the possibility of a leak.

Several studies support the use of selective UGI, rather than routine UGI, based on operative finding and the clinical status of the patient [21–23]. A study evaluating routine versus selective use of UGI found no statistical differences between the two groups and concluded that routine UGI does not significantly contribute to postoperative care [21]. In a separate study, selective UGI has been found to decrease the mean hospital stay without any adverse effects on morbidity or mortality [23].

As noted above, there are several factors that can lead to a surgeon's decision about whether or not to obtain routine or selective postoperative UGI. Included among those factors are the experience of the surgeon, factors related to the system of care in place, and characteristics of the patient. Ultimately, the decision to utilize routine versus selective UGI in evaluation for a postoperative leak should be left to the discretion of the surgeon [24].

Pain Management

A multimodal analgesic plan should be the standard of care for postoperative bariatric surgery patients, as this patient population can be more susceptible to the depressive respiratory effects of opioids [25]. The use of a multimodal pain regimen, including preoperative and intraoperative modalities, has been shown to provide superior analgesia, shorter recovery room stay, lower opioid requirements, earlier ambulation, and shorter hospital stays [26].

The preoperative protocol currently in use at our institution includes the routine use of acetaminophen, celecoxib, and gabapentin, unless there are patient-specific contraindications. Patients receive these medications with a sip of water, upon arrival to same day surgery. A scopolamine patch is placed upon arrival to same day

surgery to begin pretreating expected postoperative nausea. Additionally, a single dose of intravenous dexamethasone is given upon induction of anesthesia, as this regimen has been found to significantly reduce postoperative nausea and vomiting without increasing adverse events in patients undergoing elective bowel surgery [27].

Intraoperative modalities include local and regional anesthesia and the use of systemic lidocaine. The regional anesthetic modality most frequently utilized is the transversus abdominis plane block, which can be performed using ultrasound or laparoscopic guidance. This block has been shown to reduce opioid requirements, improve pain scores, decrease sedation, and promote early ambulation, resulting in greater patient satisfaction [28]. A randomized controlled trial found that patients who received 1.5 mg/kg lidocaine bolus followed by a 2 mg/kg/h lidocaine infusion for the duration of the surgical procedure had improved pain scores and decreased opioid requirements than patients randomized to placebo [29].

The postoperative regimen at our institution includes scheduled acetaminophen, scheduled ketorolac (up to 48 h), and oral narcotics as needed. Intravenous narcotics are available on an as needed basis, for breakthrough pain only. Compared to a multimodal regimen, the use of patient controlled analgesia PCA is associated with increased narcotic requirements and increased need for antiemetic rescue medication [30]. Within our institution, the use of PCA is limited, as most patients are controlled on the multimodal regimen described above including pretreatment, regional nerve block, and scheduled nonnarcotics postoperatively.

Here is the institution multimodal pain protocol for bariatric surgery:

Preoperative regimen:

Acetaminophen 1000 mg PO
Celecoxib 200 mg PO
Gabapentin 600 mg PO
Dexamethasone 8 mg IV upon induction

Intraoperative regimen:

Bupivacaine laparoscopic transversus abdominis plane block

Postoperative regimen:

Acetaminophen 650 mg PO every 6 h
Ketorolac 15 mg IV every 6 h for 8 doses
Oxycodone elixir 5–10 mg PO every 4 h, as needed

Hydromorphone 0.2 mg every 4 h, as needed, breakthrough pain

Antibiotics

Routine use of preoperative antibiotics is recommended for prophylaxis of superficial surgical site infections. Both the laparoscopic sleeve gastrectomy and the Roux-en-Y gastric bypass are classified as clean-contaminated cases. Current recommendations are based on other clean-contaminated gastroduodenal procedures, as there is limited Level 1 evidence specific to bariatric surgery. In addition, there is little evidence on the optimal dosing for obese patients. Most commonly, weight-adjusted first-generation cephalosporins are administered as a bolus within 60 min of incision-cefazolin 2 g IV for weight less than 120 kg and cefazolin 3 g IV for weight greater than 120 kg. An alternative antibiotic (i.e., vancomycin, clindamycin) can be utilized for patients with allergies. As with other clean-contaminated cases, there is no level 1 evidence to support routine continuation of antibiotics in the postoperative period [31].

Deep Vein Thrombosis Prophylaxis

Although the overall incidence is low, venous thromboembolism (VTE) remains a leading cause of morbidity and mortality after bariatric surgery. Bariatric surgery patients are considered at least moderate risk of VTE, with many patients at high risk for VTE complications. All bariatric patients should receive at least one form of prophylaxis, in addition to early ambulation [32, 33]. Most institutions utilize routine use of mechanical prophylaxis by placing sequential compression devices preoperatively and continuing therapy postoperatively while the patient is sedentary until discharged home. Low-molecular-weight heparin is more effective than unfractionated heparin for the prevention of postoperative venous thromboembolism among patients undergoing bariatric surgery and does not increase the risk of bleeding [34]. There is currently no consensus regarding the optimal dosing of low-molecular-weight heparin in the bariatric patient.

Routine post-discharge pharmacoprophylaxis should be considered for high-risk patients. Personal history of venous thromboembolism, evidence of venous stasis, known hypercoagulable state, congestive heart failure, paraplegia, dyspnea at rest, and reoperation are risk factors associated with the highest risk of post-discharge VTE [35]. A risk calculator can be utilized to identify high-risk patients who may benefit from post-discharge pharmacoprophylaxis [35]. There is currently no consensus regarding the optimal protocol, including pharmacologic regimen or duration of therapy.

Criteria for Discharge

Length of Stay

Patients should be counseled preoperatively on the expected length of stay. Most patients are able to meet discharge criteria within 1–2 days after surgery. It is safe to discharge patients on postoperative day one without an increase in hospital readmissions. A large, multicenter, outcomes analysis demonstrated that patients with a stay of 3 days were twice as likely to be readmitted than patients discharged on postoperative day 1 [36].

Prior to discharge, patients should meet the following criteria:

- No signs of ongoing or evolving complication (fevers, unexplained tachycardia or tachypnea, increased oxygen requirements, increasing leukocytosis, etc.)
- Tolerate a liquid diet with adequate volume to maintain hydration
- Adequate pain control with an oral regimen
- Safe ambulation
- Adequate glucose control

Discharge Instructions

Prior to discharge from the hospital, patients should receive education from the bariatric team on what to expect after leaving the hospital. While this education most frequently begins in the preoperative setting, it should be reiterated with the patient and their families prior to discharge. Patients should be counseled on the signs and symptoms of possible postoperative complications, including anastomotic leaks, strictures, dehydration, and venous thromboembolism. They should receive reinforcement of the importance of dietary compliance and diet progression, instructions on the expected activity level and restrictions, as well as incision and drain care. A list of medications should be reviewed with the patient, as there are often changes from their presurgery routine. The postoperative follow-up appointment with the bariatric surgeon should be confirmed, and patients should be encouraged to follow-up closely with their primary care physicians for further medication adjustments. A written copy of all discharge instructions and medications should be provided to the patient upon leaving the hospital.

Appendix: Sample Post-Laparoscopic Gastric Bypass Order Set

The following is a sample order set used as a framework for bariatric postoperative ERAS protocol:

Admission

Admit to inpatient
Diagnosis: morbid obesity s/p LRYGB/LSG
Condition: stable
Expected length of stay: for surgical procedure
Principle admitting diagnosis: morbid obesity
Location: regular nursing floor

Non-ICU continuous cardiac monitoring, routine, continuous
Vital Signs every 4 h for 24 h, then every shift
Activity

Up with assistance
Mobilization frequency: minimum of five times per day.
Head of bed position: 30 degrees
Up walking the day of surgery POD#0, every 2–3 h.

Diet

Bariatric Phase 1, starting the night of surgery
Bariatric Phase 2, on POD1 advance as tolerated from Phase 1 to Phase 2

Nursing Orders

Use mouth swab for oral care
Foley catheter; connect to constant drainage
Discontinue Foley catheter on POD#1
Record intake and every 4 h
Oxygen by nasal cannula, wean to SpO2 greater than 92%
Incentive spirometry ten times per hour while awake, please encourage
Maintain elevated head of bed 30 degrees or greater
Place intermittent sequential compression devices
Continuous pulse oximetry
Patient may be transported off unit without telemetry monitoring
Notify physician for:

Temperature greater than 101.5° F
Heart rate greater than 110 BPM
Systolic BP greater than 180 mmHg
Systolic BP less than 90 mmHg
Diastolic BP greater than 90 mmHg
Urine output less than 250 ml/8 h.

Pulse Oximetry less than 92%
Respiratory Therapy
CPAP/BiPAP for sleep apnea, if required

Labs

CBC, BMP morning of POD#1

Imaging

(Optional) esophagram with gastrografin, then barium on POD#1

IV Fluids

Lactated Ringers at 100 ml/h

IV Antibiotics

(Optional) cefazolin 2 g IV every 8 h for two doses
(Optional) vancomycin 1.5 g IV every 12 h for one dose, for PCN allergy

Medications

Ondansetron 4 mg IV every 6 h PRN nausea
Scopolamine 1.5 mg transdermal (1 mg over 3 days)
Acetaminophen 650 mg PO every 6 h
Ketorolac 15 mg IV every 6 h for eight doses
Oxycodone 5–10 mg PO every 4 h PRN nausea
Hydromorphone 0.2 mg IV every 4 h PRN breakthrough pain
Lovenox 40 mg SQ BID

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Chapter 17
The MBSAQIP (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program) Comprehensive Bariatric Program (MBSAQIP-ASMBS/ACS)

Julietta Chang and Matthew M. Hutter

Introduction

With the introduction and widespread adoption of laparoscopic techniques, the number of bariatric procedures performed increased tenfold from the late 1990s to the early 2000s [1]. With this exponential growth, there were significant concerns from the media and the public about the safety of bariatric surgery. Several publications in select high-risk patients showed mortality rates of nearly 2% [2]. Headlines like "Gastric Bypass Surgery Gone Bad: 1 in 50 People Die within a Month of Surgery" from CBS News (1/21/05) and others shortly followed. Bariatric surgeons knew that bariatric surgery could be done safely by well-trained surgeons, at high-volume centers with appropriate resources. In late 2004 and early 2005, the American Society of Bariatric Surgery developed the Centers of Excellence Program for Bariatric Surgery, and the American College of Surgeons developed an accreditation program for bariatric surgery – the Bariatric Surgery Center Network. Accreditation programs seek to improve patient safety through determining standards of care, assuring the sites have the right infrastructure, providing accurate data collection, and verifying programs through data monitoring and site visits.

The Centers for Medicare and Medicaid Services (CMS) responded to these concerning mortality rates by convening a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in November 2004 which made a noncoverage proposal for bariatric surgery in November 2005. Following numerous comments, CMS reversed the noncoverage proposal on February 2006 with the National Coverage Decision where they stipulated that CMS *would* cover bariatric surgery *only if* performed at a site accredited by either the ASBS or the ACS. Many other payers and insurers soon followed suit with the requirement for accreditation.

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In March of 2012, the ASMBS and ACS unified the two bariatric surgery accreditation programs and created the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). This allowed for standardized data collection from all participating centers with well-defined data definitions modeled on ACS National Surgical Quality Improvement Program (NSQIP) standards while instituting 100% case reporting [3]. The second version of MBSAQIP standards went into effect on October 2016 and can be found at www.facs.org/quality-programs/mbsaqip/standards.

Retrospective studies demonstrate significantly improved outcomes at accredited centers. One review compared 71 accredited centers with 43 nonaccredited centers over a 2-year period [4]. They found that nonaccredited centers were associated with a 3.5-fold increase in in-house mortality, longer hospitalizations, and increased procedural costs. In addition, sicker patients, i.e., those requiring ICU admissions, had significantly better outcomes in accredited centers. Another retrospective longitudinal study examining perioperative outcomes between accredited and nonaccredited centers in the state of New York over a 6-year period found that perioperative morbidity and mortality were significantly reduced in accredited centers [5]. Specifically, postoperative respiratory complications including pneumonia and prolonged ventilator requirements were significantly increased in the nonaccredited group, as well as early (30-day) mortality. Although long-term (>30-day) mortality approached significance, there was no difference between nonaccredited and accredited hospitals. Similar to the prior paper, accreditation was associated with shorter hospital stay as well.

In June 2013, CMS decided to no longer require accreditation for bariatric surgery, stating that bariatric surgery is now sufficiently safe that accreditation is no longer required. The ASMBS membership voted whether to continue this accreditation program, and over 80% felt that it was important to assure high-quality care and to promote continuous quality improvement.

Currently there are more than 800 programs within the MBSAQIP accreditation program, capturing more than 190,000 bariatric cases annually.

The MBSAQIP accreditation recognizes five designations: (1) comprehensive center, (2) low-acuity center, (3) adolescent center, (4) comprehensive center with adolescent qualifications, and (5) ambulatory surgery center. This chapter will focus on the components of accreditation for maintaining designation for a comprehensive center.

Designations

Comprehensive centers require compliance with all MBSAQIP core standards with successful site visits and must maintain a minimum of 50 approved bariatric stapling procedures annually. These centers are allowed to perform all approved procedure types, including primary and revisional procedures. A Metabolic and Bariatric Surgical (MBS) Clinical Reviewer enters data into the data registry, and these centers are approved to provide care for patients 18 years or older.

Low-acuity centers, similar to comprehensive centers, meet all core standards. However, due to lower volume (minimum 25 stapled bariatric procedures), they may perform only primary procedures within low-acuity restrictions. Low-acuity restrictions include age > =18 and <65, males with a BMI <55 and females with a BMI <60, patients without organ failure or an organ transplant and not currently a candidate on an organ transplant list, and patients without significant cardiac or pulmonary impairment, and they must be ambulatory. Low-acuity centers are not accredited to perform elective revisional procedures.

Adolescent centers are those that comply with Standard 9 (adolescent standards) and core standards but do not necessarily perform >50 stapled bariatric procedures annually. Those with fewer than 25 stapling procedures annually require a MBSAQIP-verified bariatric surgeon as a co-surgeon on each case, and these centers may perform all approved procedure types

Comprehensive centers with adolescent qualifications meet criteria as above but also comply with Standard 9 and are thus approved to provide care to patients of all ages.

Ambulatory surgery centers meet criteria similar to low-acuity centers, with regard to volume and patient selection, but are freestanding nonhospital-based centers.

Full documentation of the *nine standards* can be found at www.facs.org/quality-programs/mbsaqip/standards. A brief summary follows:

- *Standard 1*: Volume criteria for comprehensive centers are at least 50 stapled bariatric cases annually. These cases include any procedure involving the use of a surgical stapler for the anastomosis or resection of any part of the gastrointestinal tract. Procedures involving a hand-sewn anastomosis (e.g., gastric bypass) are included in this category. This is verified by site review and/or chart review. By maintaining high volume and review of cases and data during site visits, comprehensive centers are allowed to provide care to all patients regardless of age, BMI, and comorbid conditions. In addition, comprehensive centers may perform all approved procedures including revisional bariatric procedures. Approved procedures include adjustable gastric banding, biliopancreatic diversion with or without duodenal switch, Roux-en-Y gastric bypass, sleeve gastrectomy, and vertical banded gastroplasty. Investigational procedures are only to be performed under IRB-approved protocol.
- *Standard 2*: The second standard ensures the proper infrastructure and medical staff to provide quality standardized care for the bariatric patient. This includes the creation of a MBS committee with a director, the involved surgeons and proceduralists, a coordinator, a clinical reviewer, and institutional administration representatives. The committee is the primary forum for continuous quality improvement, and thus there must be a minimum of three meetings annually. At least one should focus on quality initiatives, procedural volumes, outcomes, and the center's compliance with MBSAQIP standards at which all surgeons and proceduralists should be in attendance:

  (a) The director is an actively practicing MBSAQIP-verified surgeon. Responsibilities include overseeing continued compliance with requirements and contacting MBSAQIP within 30 days should the center fall out of compliance.

(b) The coordinator is required to be a licensed health-care professional or a registered dietitian and serves as a liaison between the center and MBSAQIP. The coordinator and clinical reviewer may be the same individual as long as the clinical reviewer does not document in patient medical records. The coordinator assists in center development while supporting the development of written protocols and education of nurses to minimize delays in the recognition and treatment of serious adverse events.
(c) The clinical reviewer is not approved to be participating in patient care or charting in the record and must be given unrestricted access to patient medical records for timely data entry. They must complete yearly certifying exams to ensure appropriate clinical knowledge and expertise in data collection. The hospital itself must be licensed by the appropriate licensing authority as required by state law.
(d) The center must have at least one actively practicing, credentialed bariatric surgeon. This requires the surgeon to be American Board of Surgery (or equivalent) certified or eligible trained in a bariatric fellowship or with documentation of previous bariatric surgery experience. In addition, surgeons must attend at least two quality meetings per year, must document at least 100 lifetime stapling cases (75 stapling cases from an accredited fellowship may count toward this), and must maintain at least 75 stapling cases per 3-year reaccreditation cycle. They are also required to maintain CME credit hours as detailed in the MBSAQIP standards manual.
(e) The center must provide 24/7 call coverage for all bariatric patients. If general surgeons are covering bariatric call, they must receive formal training regarding a basic understanding of the center's commonly performed bariatric procedures, postoperative complications, and the management and care of bariatric patients. Transfer agreements do not substitute for call coverage.
(f) Comprehensive centers must maintain a dedicated bariatric surgery floor or group of beds as well as nursing and ancillary staff. Personnel include nurses, physician extenders, dietitians, psychologists, psychiatrists, social workers, and physical or exercise therapists. The staff must complete three training sessions, which cover (1) signs and symptoms of postoperative complications, (2) sensitivity training in order to provide compassionate care for the obese patient, and (3) patient transfer and mobilization.

- *Standard 3* outlines proper equipment in the care of bariatric surgical patients. Examining and operating room tables, beds, chairs, etc. must be weight and size appropriate. Surgical instruments including staplers, retractors, and trocars must be available in longer sizes to accommodate thicker abdominal walls. The areas where bariatric patients receive perioperative care must have appropriately sized doorways, etc.
- *Standard 4* defines appropriate critical care support must be available at comprehensive centers. The facility must maintain immediate on-site availability of personnel capable of administering advanced cardiovascular life support (ACLS)

and advanced airway management. Comprehensive centers must provide anesthesia services, critical or intensive care unit services, diagnostic and interventional radiology services, and endoscopy services on-site. Low acuity, ambulatory, and adolescent centers, for example, do not need to have these services on-site but must have transfer agreements in place that detail plans for transfer to higher level of care if they lack such capabilities. Endoscopic services include both diagnostic and therapeutic endoscopy. Radiologic procedures include percutaneous drainage and other interventional procedures.

- *Standard 5* ensures detailed preoperative, perioperative, and postoperative patient follow-up. A standardized preoperative patient education curriculum should be developed regarding diet, exercise, postoperative vitamin/mineral supplementation, as well as warning signs of postoperative complications such as fever and tachycardia. Each center should have well-defined selection criteria encompassing psychosocial and nutritional evaluations. There must be a standard postoperative bariatric surgery order set that addresses (1) diet progression, (2) deep vein thrombosis prophylaxis, (3) respiratory care, (4) physical activity, (5) pain management, and (6) thresholds for notifying the staff surgeon in order to recognize early the warning signs of postoperative complications. To prevent losing patients to follow-up, there must be a plan to follow long-term progress. At minimum, bariatric patients should been seen at 1 month, 6 months, 1 year, and yearly thereafter by a physician or physician extender or nurse with training in the care of a bariatric patient. At least two documented efforts (including a phone call and a letter) must be made if a patient is lost to follow up. In addition, support groups must be offered at least quarterly; these may be in person or via web or teleconferenced.
- *Standard 6* defines the data collection requirements. Prospectively maintained data in a timely fashion is critical in identifying areas for improvement and maintaining accreditation. The MBSAQIP requires 100% case reporting of all bariatric procedures performed. This includes primary and revisional surgeries as well as endolumenal therapies for weight loss (e.g., intragastric balloons or endolumenal stapling). Data are collected at 30 days, 6 months, 1 year, and annually thereafter. Unadjusted outcomes reports are available to centers via the MBSAQIP Data Registry Platform in real time, while risk-adjusted reports are available on a semiannual basis to participating centers who maintain a 30-day follow-up rate of at least 80%.
- *Standard 7* describes the requirement for Continuous Quality Improvement (CQI). Inherent to participating in the MBSAQIP is continuous effort toward improvement of patient outcomes. To this end, the center must develop a process to identify adverse events and develop corrective action plans to improve quality outcomes. The MBS committee reviews adverse events (such as readmissions, morbidities, and mortalities), and individual surgeons review their data as they compare to national averages. The center, under guidance of the MBS Director, should undertake at least one quality improvement initiative or project each year. These should focus and improve upon on a process of care, and its outcome should be data that are reliably collected and valid. Examples include projects

focusing on decreasing rates of surgical site infections or deep vein thrombosis. Centers that are outliers when compared to national data with regard to a particular outcome should focus on factors contributing to the outlier when developing a CQI. As a final measure of maintaining a culture of safety, all in-house and 30-day postoperative mortalities must be reported to the MBSAQIP.

- *Standard 8* describes the requirements for ambulatory surgery centers.
- *Standard 9* describes the Adolescent Center Accreditation requirements which can be either a stand-alone children's hospital or a comprehensive center which meets the additional adolescent requirements including a pediatric medical advisor and a pediatric behavior specialist

Summary

Accreditation programs in bariatric surgery grew out of necessity because of concerns about safety when the field grew exponentially in the early 2000s. The ASBS and the ACS each developed programs which unified into one program in 2012: the MBSAQIP. The founding principles of accreditation programs include setting the standards, building the right infrastructure, collecting robust data, and verifying through a third party with monitoring and site visits. Retrospective data has shown decreased mortality and postoperative morbidity in bariatric surgery in accredited centers compared to nonaccredited centers. With the implementation of future quality initiative projects within the MBSAQIP, we anticipate continued improvement in patient safety and outcomes.

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Chapter 18
Establishing a Comprehensive Bariatric Surgery Program

Manish Parikh

Navigating Your Way to Creating a Successful Program

The most critical factor for success in starting a new bariatric surgery program is an institutional commitment at the highest level (medical and administrative) [1]. If you are being interviewed for a position to create a program, take notice regarding who specifically (i.e., what level administrator) is conducting the interview. Ideally, you should meet face-to-face with the Chief Medical Officer and/or Chief Executive Officer to ensure the hospital is fully committed (including requisite resources) to creating a new bariatric surgery program.

Next, create a taskforce or a "steering committee" that oversees the various aspects of creating a program. This committee should be charged with fulfilling the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) criteria for "comprehensive center" accreditation [2]. These criteria serve as a useful "blueprint" to establish a bariatric program. The process of going through the requisite needs to meet each MBSAQIP criterion is invaluable for the entire multidisciplinary team since part of the accreditation process includes a site visit which includes evaluating the equipment, meeting the team, and going over the pathways. Therefore, do a "walk-thru" of the entire hospital. Determine the weight capacity for all the equipment in the hospital including all radiology machines, stretchers, hospital beds, etc. Since the MBSAQIP accreditation criteria are clearly published, there should be no question about the "up-front" hospital commitment of resources; this commitment ensures adequate infrastructure and personnel support for the bariatric surgery program.

It is important to also meet with a member of the finance department (ideally the Chief Financial Officer) to ensure that billing/reimbursement is appropriate and that

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Table 18.1 ICD-10 Bariatric surgery procedure codes

ICD10 procedure code	Code description
0D16079	Bypass Stomach to Duodenum with Autologous Tissue Substitute, Open Approach
0D1607A	Bypass Stomach to Jejunum with Autologous Tissue Substitute, Open Approach
0D1607B	Bypass Stomach to Ileum with Autologous Tissue Substitute, Open Approach
0D160Z9	Bypass Stomach to Duodenum, Open Approach
0D160ZA	Bypass Stomach to Jejunum, Open Approach
0D160ZB	Bypass Stomach to Ileum, Open Approach
0D16479	Bypass Stomach to Duodenum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1647A	Bypass Stomach to Jejunum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1647B	Bypass Stomach to Ileum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D164Z9	Bypass Stomach to Duodenum, Percutaneous Endoscopic Approach
0D164ZA	Bypass Stomach to Jejunum, Percutaneous Endoscopic Approach
0D164ZB	Bypass Stomach to Ileum, Percutaneous Endoscopic Approach
0DB60Z3	Excision of Stomach, Open Approach, Vertical
0DB60ZZ	Excision of Stomach, Open Approach
0DB63Z3	Excision of Stomach, Percutaneous Approach, Vertical
0DB63ZZ	Excision of Stomach, Percutaneous Approach
0DB64Z3	Excision of Stomach, Percutaneous Endoscopic Approach, Vertical

Source: International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS). Baltimore, MD: US Government, Centers for Medicare and Medicaid Services. Public Domain

the financial implications for the initial and ongoing program costs are fully understood by the hospital administrators [3]. Ideally a business plan should be created that accounts for the hospital reimbursement, the costs associated with the surgeries, and projected growth of the program. Be realistic about the growth. It is better to underestimate the growth than overestimate the growth.

The finance department (in close collaboration with the surgical leader) should be able to generate business models based on the anticipated revenue for commonly performed procedures for obesity, taking into account the current hospital payor mix as well as standard costs associated with the procedures. Tables 18.1 and 18.2 contain the ICD-10 procedure and diagnosis codes, respectively, that finance can utilize to generate the revenue model. As the program meets specific targets/outcomes, additional dedicated personnel and bariatric supplies/equipment can be added and funded by the revenue associated with the increased cases.

Another reason the institutional commitment is so important is that the bariatric team will likely need to tap into existing hospital resources to get the program started. These resources include psychiatric/psychological personnel (for preopera-

Table 18.2 ICD10 morbid obesity diagnosis codes

ICD10 procedure code	Code description
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.8	Other obesity
Z68.35	Body mass index (BMI) 35.0–35.9, adult
Z68.36	Body mass index (BMI) 36.0–36.9, adult
Z68.37	Body mass index (BMI) 37.0–37.9, adult
Z68.38	Body mass index (BMI) 38.0–38.9, adult
Z68.39	Body mass index (BMI) 39.0–39.9, adult
Z68.41	Body mass index (BMI) 40.0–44.9, adult
Z68.42	Body mass index (BMI) 45.0–49.9, adult
Z68.43	Body mass index (BMI) 50.0–59.9, adult
Z68.44	Body mass index (BMI) 60.0–69.9, adult
Z68.45	Body mass index (BMI) 70 or greater, adult

Source: International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS). Baltimore, MD: Centers for Medicare and Medicaid Services. Public Domain

tive evaluations), social workers, nutritionists, medicine personnel (for preoperative medical assessments), gastroenterologists for potential preoperative endoscopies and postoperative endoscopic treatment for bariatric complications, and physical therapists. Other departments that should be engaged include Radiology (including Interventional Radiology), Respiratory Therapy, and Plastic Surgery. The ASMBS Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient is a useful resource that may help standardize the preoperative workup and postoperative care [4].

Patient selection is another significant aspect of starting a bariatric program successfully. Avoid operating on high-risk patients until a critical volume of patients have undergone surgery at your hospital. (Although the surgeon may be familiar with high-risk patients, chances are that the hospital is not familiar with this, and it is very important to get the entire hospital clinical team through the "learning curve" of caring for bariatric surgery patients).

Consider the following guidelines regarding patient selection during the early phases of the program, as most hospital administrators are risk-averse and their

tolerance for bariatric surgery complications may not be comparable to that for other complex surgical operations:

1. Start with laparoscopic sleeve gastrectomy, and avoid gastric bypass or more malabsorptive procedures (biliopancreatic diversion/duodenal switch, etc.) until the learning curve for the hospital has been reached.
2. Defer surgery on the super obese (body mass index > 50 or patients > 400 lbs) since this subset of patients has higher overall operative risk, they are more technically challenging, and they have a higher likelihood of sustaining a post-operative complication [5]. The patients who weigh > 400 lbs. may exceed the weight capacity of the existing hospital CT scanner, fluoroscopy machines, etc.
3. Defer surgery on patients > 65 years old.
4. Defer revision surgery: revision surgery is also associated with higher incidence of complications/mortality [6].
5. Place all patients on a very low calorie diet (e.g., Optifast®, Nestle HealthCare Nutrition, Bridgewater, NJ, USA) to decrease hepatomegaly and to make the surgery less technically demanding [7].
6. Consider who will be helping you in the OR (another attending, a resident, surgical tech, etc.). Plan accordingly especially for cases that you know may be difficult. It is always helpful if another surgeon can assist you during the early phases, to minimize operative complications.
7. Create a dedicated OR team (scrub techs, circulating nurses, anesthesiologists) in conjunction with the OR leadership, and identify one OR where the procedures will take place. Create a bariatric specialty cart that can be housed in the dedicated OR that contains common supplies utilized in bariatric procedures. Make sure the OR bed has adequate weight capacity and the laparoscopic instrumentation is adequate for laparoscopic bariatric surgery. The team also needs to ensure there are adequate supplies of bariatric blood pressure cuffs, binders, portable lifts, gowns, etc. Rental of some of these items may be reasonable at the outset of the program.
8. Meet with the team regularly and conduct regular education/in-services about:
   (a) Training to use lift devices and safely moving patients.
   (b) Obesity sensitivity.
   (c) Intraoperative details including patient positioning and surgical technique; show surgical videos, and discuss potential intraoperative complications to familiarize them with these types of procedures. The team focus should be on safe, efficient surgery that minimizes overall operative time.
   (d) Postoperative care and pathways.
9. If it is possible, designate a core group of nurses to obtain the Certified Bariatric Nurse accreditation [8].
10. Anticipate common complications, and establish a relationship with colleagues in Interventional Radiology, Advanced Endoscopy, perhaps Thoracic Surgery, etc. depending on the local practice patterns.

Outreach to potential referring providers is also important. Send letters to local providers letting them know of the new bariatric program. Include key landmark articles supporting the clinical benefits of bariatric surgery, particularly the survival benefit [9, 10]. Establish regular information seminars for prospective patients that describe the various types of bariatric procedures, the preoperative preparation required, and the postoperative expectations. The team also should focus on patient education, including preoperative preparation and standardized postoperative progression of the bariatric diet [11].

Conclusion

With the appropriate planning and resources (and commitment from the hospital administration), it is possible to establish a bariatric surgery program with high-quality outcomes. Patient selection at the outset is important. Building the program based on the MBSAQIP criteria is an effective method of ensuring adequate resources are in place to provide safe and effective care of the bariatric surgery patient.

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Chapter 19
Long-Term Follow-Up of Bariatric Patients

Kelly R. Haisley and Samer G. Mattar

Abbreviations

BPD	Biliopancreatic diversion
DS	Duodenal switch
EWL	Excess weight loss
Hgb A1C	Hemoglobin A1C
PCP	Primary care provider
PRN	As needed
RYGB	Roux-en-y gastric bypass

Introduction

Bariatric operations are powerful, life-altering procedures that deliver rapid, acute, and effective results in correcting metabolic dysfunction. However, the durability of these procedures inexorably hinges on a sustained commitment to lifestyle changes, health maintenance, and nutritional supplementation. These modifications must be enacted not just perioperatively but for life. Unlike most other common surgical procedures from which the patient recovers and moves on, the importance of long-term follow-up cannot be overstated in the success of bariatric patients. The underlying fundamental reason for this is that in addition to weight loss, bariatric operations result in significant changes in hormonal signaling and overall metabolism. These changes can continue to exert significant effects over the years and even decades following bariatric surgery. Such patients must be closely monitored and managed by teams familiar with the intricacies of the bariatric patient in order to optimize outcomes following surgery.

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Patterns of Follow-Up

Historically, follow-up after bariatric surgery has been imprecise, with patients frequently being lost to surgical follow-up shortly after their discharge from the hospital [1]. The causes for this are multifactorial. For one, bariatric patients frequently arrive from disparate, often rural geographic regions. And while they are willing to travel for the specialized surgery, they often, understandably, prefer to follow-up with primary care providers closer to home once the acute postoperative period has been traversed [2]. In fact, studies have shown that typical long-term follow-up (>10 years) with the surgical team after bariatric surgery in the USA is only around 10–15% [1, 3]. Such lack of postoperative follow-up affects not only our ability to track outcomes accurately but also fails to help patients achieve the best possible results after bariatric surgery [4].

Whose Job Is It Anyway?

Primary care physicians (PCPs) perform a vital role in maintaining the overall health of the postoperative patient. They play an integral role in the health maintenance and comorbidity management of bariatric patients in the years and decades after their operations. Patients are generally encouraged to be seen by their PCPs within a few weeks of their operation in order to establish their new baseline and make medication adjustments to account for the expected metabolic changes after surgery.

In recent years, however, there has been a growing recognition of the importance of multidisciplinary follow-up in the successful management of bariatric patients [1]. Unlike general practitioners, bariatric programs are able to provide enduring expertise in the prevention and management of the late complications of bariatric surgery. Their specialization allows them to pay focused attention to metabolic effects and bariatric specific challenges, allowing them to better anticipate and identify complications when they arise. Furthermore, bariatric centers are equipped with multiple care providers including nutritionists, psychologist, physical therapists, and bariatric nurses, providing a complete and broad approach, whereas the general practitioner may lack this multidisciplinary support system[2].

How Long? How Often?

While the frequency of office visits after bariatric surgery depends somewhat on the bariatric procedure performed and the severity of comorbidities, the care of a bariatric patient is a lifelong commitment that must be acknowledged by both patients and bariatric programs [5, 6]. Typically, visits in the early postoperative period tend to

Table 19.1 Sample long-term multidisciplinary follow-up schedule for bariatric patients

	Post-op (2–3 weeks)	3 months	6 months	1 year	Six-monthly or Yearly (for life)
Providers	MD Dietician	MD or NP Dietician	MD or NP Dietician	MD Dietician	MD or NP Dietician
Goals	Ensure surgical site healing Focus on maintaining hydration and nutrition	Weight check Encourage return to physical activity (joining a gym) Full labs Nutritional assessment and counseling Adjust supplements as needed	Weight check Nutritional counseling Full labs Adjust supplements as needed Specialist referrals PRN	Weight check Nutritional counseling Full labs Adjust supplements as needed Specialist referrals PRN Discuss hernia repair body contouring (if desired)	Weight check (watch for regain) Nutritional counseling Full labs Adjust supplements as needed Specialist referrals PRN
Primary care	Reestablish baseline	Medication titration Frequency varies based on comorbidities			Routine heath maintenance
Support groups	Postoperative support groups offered monthly Online support as needed				
As needed	Psychological support if displaying signs of emotional distress Physical therapy when physical limitations are hindering progress Additional office visits and labs as needed for acute new symptoms Routine imaging NOT required unless there is a clinical concern				

be more frequent and detailed. While office visits can be spaced out in the years following surgical recovery, there is no time point at which a patient should be discharged from their bariatric follow-up. While there may be subtle differences between programs, a general example of a lifelong bariatric follow-up protocol is available in Table 19.1, which outlines suggested intervals and general goals of bariatric visits.

Surgical Recovery and Anatomic Considerations

There is no doubt that the initial surgical recovery phase falls under the purview of the primary surgeon. An initial postoperative visit should occur within the first few weeks postoperatively. This visit centers on immediate surgical concerns such as wound healing, pain control, and diet tolerance to assure that there are no signs of operative complications.

It is important to recognize, however, that anatomic changes may continue for years after the initial operation as patients continue to lose weight. Problems with

marginal ulceration, gastro-gastric fistulas, anastomotic strictures, chronic abdominal pain, or internal herniation may present at any time postoperatively. [7–10].

Because of the nonspecific clinical picture frequently associated with such conditions, they may be missed by non-bariatric providers who are less familiar with the subtleties of bariatric complications. While such issues are rare, they can be life-threatening if not identified and managed appropriately and expediently. A keen clinical eye and routine follow-up with bariatric providers can help identify such problems at an earlier phase, and thus patients should be seen and evaluated at least every few months in their first year after surgery. Any new, concerning clinical symptoms at any point postoperatively should merit further workup.

Sustained Weight Loss

Weight regain is a common concern in all patients undergoing bariatric operations, both for patients and caregivers. Multiple longitudinal studies have shown that patients who are lost to follow-up are considerably more likely to regain a larger amount of weight than those who remain in a regimented system for nutritional, psychiatric, and exercise support [11]. Adherence with follow-up visits and attendance of support groups have also been associated with improved weight loss outcomes in a number of empirical studies and meta-analyses [12]. In order to maximize lasting weight loss success, patients should be encouraged to follow-up consistently with a designated bariatric team.

Nutrition

Nutritional management represents perhaps the most compelling need for long-term bariatric follow-up. While specific nutritional deficiency and supplementation will be discussed in detail in a later chapter, a basic understanding of micro- and macronutrient changes in the postoperative period are vital for establishing appropriate follow-up protocols. The involvement of a registered dietician familiar with bariatric nutrition protocols at all clinic visits helps assure this follow-up is meaningful, and interventions can be taken when needed (Table 19.1).

Nutritional Deficiencies

Many bariatric patients actually come into surgery nutritionally deficient in protein and vitamin stores [12]. While certain operations are more aggressive than others in terms of malabsorbtion (BPD/DS), some degree of nutritional deficiency may be expected in all bariatric operations [9, 13]. Non-compliance with nutritional

Table 19.2 Recommended long-term laboratory monitoring

Vitamins	B12 Folate Vitamin D Parathyroid hormone (PTH) Thiamine (vitamin B1)	
Blood counts	Complete blood count (CBC) Iron Ferritin Total iron-binding capacity (TIBC)	
Chemistries	Comprehensive metabolic panel (CMP)	
Special additions	Malabsorptive procedures (BPD/DS)	Fat soluble vitamins (vitamin A, E, D, K) Copper Zinc Niacin (vitamin B3) Pyridoxine (vitamin B6)
	Diabetics	Hgb A1C
	Hyperlipidemia	Lipid panel
Not required	Essential fatty acids Selenium	

guidelines is always a concern among this high-risk population. Patients who have been lost to follow-up are at risk of becoming non-compliant.

This may explain why nutritional deficiency is estimated to occur in 30–70% of patients following bariatric surgery [2]. Importantly, non-compliance with supplementation is known to worsen over time [14]. Unfortunately, while short-term studies evaluating macro- and micronutrient deficiencies are plentiful, long-term vitamin and nutrition changes in postsurgical populations are not entirely understood and thus must be closely followed [15].

Nutritional Monitoring

Because nutritional deficiencies can present months to years after the initial weight loss, patients must be monitored long-term in order to prevent the development of complications. The symptoms of vitamin deficiency are often nonspecific, with most characteristic physical findings only being seen very late in the course occasionally only after permanent complications have developed. Physical examination alone is not always reliable for early diagnosis, and therefore periodic laboratory monitoring is necessary, even in compliant patients [6]. Longitudinal studies have suggested that compliance with laboratory monitoring is greatly improved when patients have recently been seen by a surgeon compared to those being followed by their PCP's alone [2]. Appropriate monitoring involves a full set of labs including evaluation of vitamin and nutrient levels, blood counts, and blood chemistries

(Table 19.2). These should occur every six months for the first year, as well as yearly thereafter (Table 19.1). Labs should also be rechecked if a patient develops symptoms suggestive of a vitamin or nutrient deficiency at any point.

Nutritional Supplementation

Nutritional supplementation is important for the sustained health of bariatric patients but is one of the most frequently dropped therapies. However, like nutritional monitoring, adherence to multivitamin use is significantly improved when patients are being followed by a bariatric program [2]. Supplementation of vitamins and minerals (including a daily multivitamin, calcium, and B12) is generally recommended to avoid these deficiencies, some of which may not be revealed until years after the operation and can lead to irreversible damage (blindness, encephalopathy, osteoporosis) [16]. Additional deficiencies such as those of iron, folate, or other B vitamins should also be supplemented when deficiencies are identified on routine laboratory evaluation. These supplements must be considered a lifelong commitment after any and all metabolic operations.

Comorbidities

Much of the impetus for bariatric surgery rests in the remission of the comorbidities of obesity. These comorbidities can undergo dramatic changes in the months and years following a bariatric operation and must be closely monitored to avoid over- or under-medication as the body's homeostasis resets. In general, comorbidities such as type 2 diabetes, dyslipidemia, or hypertension should undergo continued surveillance and management as guided by current clinical practice guidelines for those conditions [5]. This management may be left to primary care teams. However, bariatric specialists must be aware of likely changes in metabolic physiology to counsel patients appropriately and ensure they are receiving the correct monitoring and medication titration postoperatively.

Diabetes

It is well documented that bariatric surgery can be more effective in treating type 2 diabetes than medical management [17, 18]. In patients with diabetes, the ability to achieve remission (defined as Hgb A1C <6.5 without pharmacologic therapy) has been reported to be as high as 75% following RYGB [1]. Alterations in insulin requirements can be dramatic and immediate and will continue to improve over time. Patients must be aware of the potential for significant changes in insulin needs

and monitor their blood sugar levels closely. This is critically important to avoid hypoglycemia due to excessive exogenous insulin dosing. Thus, it is imperative that in addition to explicit instructors on insulin and blood sugar management at the time of discharge, patients should be seen by their diabetes provider within a few weeks of their operation to establish a long-term monitoring and supplementation regimen. To track progress, Hgb A1C levels should be periodically monitored (Table 19.2). From there, personalized monitoring schedules can be customized based on the patient's success or struggles with postoperative glycemic control (Table 19.1) .

Hypertension

The ability to safely discontinue antihypertensive medications is an important benefit of surgical weight loss. Studies estimate an approximately 40% remission rate for hypertension following RYGB and just below that for other bariatric operations [6]. Because the effect of weight loss on blood pressure is variable, incomplete, and at times transient, the need for antihypertensive medications should be evaluated periodically [1]. However, according to current ASMBS guidelines, antihypertensive medications should not be stopped by bariatric teams unless clearly indicated, rather leaving this to primary care providers [5].

Hyperlipidemia

Data on hyperlipidemia remission are less clear with the majority of studies evaluating this outcome failing to report laboratory values or medication data. However, qualitative reports suggest remission rates for hyperlipidemia to be around 60% for RYGB [1]. The effect of metabolic surgery on lipids is similarly variable, incomplete, and at times transient. For those patients who have a history of hyperlipidemia, lipid levels should be closely monitored postoperatively. However, ASMBS recommends that bariatric teams should not stop lipid-lowering medications unless clearly indicated. Primary care personnel can and should titrate these medications off as patients cholesterol levels improve with weight loss [5].

Long-Term Support

Diet Counseling

While a majority of dietary changes occur in the first year postoperatively, patients are at risk for weight regain years after their operation, particularly if diet noncompliance sets in [19]. For this reason, all bariatric patients need to have a close and candid relationship with their dietitians. While these visits can become less frequent with time, they are necessary for monitoring reductions in compliance and assuring that patients remain on track with their caloric and nutrient intakes. To give patients the best change at nutritional compliance, they should see a registered dietician as part of every postoperative visit in their bariatric program (Table 19.1).

Exercise

In addition to diet, exercise should also be a lifelong commitment. While any level of regular activity is desirable, patients should be advised to incorporate moderate aerobic physical activity to include 150–300 min per week, including strength training two to three times per week [5]. As motivation may fade over time, support for exercise adherence can greatly improve long-term outcomes with regard to weight loss and comorbidities [20]. Having physical therapists available as part of the multidisciplinary bariatric team may assist with patients whose mobility may be impaired by fear or pain related to physical activity that developed while morbidly obese.

Medication Considerations

As discussed previously, lifelong vitamin supplementation is a cornerstone tenet in the management of bariatric patients. Additionally, acid-suppressing medications are frequently prescribed for the first few months after surgery. Ursodeoxycholic acid (ursodiol) is generally prescribed for the first 6 months after surgery to decrease the potential for developing gallstones during rapid weight loss. Nonsteroidal anti-inflammatory drugs should be avoided after bariatric surgery in post-RYGB patients, because they have been implicated in the development of anastomotic ulcerations/perforations [5].

Support Group Attendance

All patients should be encouraged to participate in ongoing support groups after discharge from the hospital [5]. Counseling patients in the setting of a group meeting or class has proven beneficial to both patients and program staff. This format has been shown to deliver quality counseling to patients in a practical and efficient manner that promotes discussion and group learning, especially in the realm of ongoing nutritional counseling. Involvement in such patient-centered bariatric support groups can improve compliance and optimization of the abovementioned outcomes [21, 22]. Individual, more focused, sessions can still be delivered on an ad hoc basis according to the needs of the patient. Unfortunately, attendance at such groups can be challenging for many patients due to travel or time restrictions. New forms of support utilizing the internet, social media, and teleconferencing may help increase the ease of access for patients seeking additional support who might otherwise be lost to follow-up [23].

Other Considerations

Adolescent Bariatric Surgery

With the extension of bariatrics into the field of adolescent medicine, we may find ourselves faced with new long-term challenges. The role of bariatric surgery in this patient population, while demonstrably rewarding, remains controversial. Recent data, however, have suggested that bariatric operations can be implemented safely and effectively in adolescents and will likely be performed with increasing frequency in the years to come [24, 25]. It is important to recognize that there is limited long-term outcome data on patients who are several decades out from surgery. In addition, the potential ramifications that the hormonal changes of bariatric surgery may have on growth and development in the adolescent are not entirely understood. Thus, long-term follow-up will be of particular importance and interest in this new population.

Hernia Repair

Abdominal wall hernias are frequent in bariatric populations and recurrence risk after repair is dramatically increased at higher weights. However, there have been conflicting studies evaluating the appropriateness of concomitant hernia repair at the time of bariatric surgery, versus postponing definitive repair until the patient's weight loss has plateaued [26]. Ultimately, the decision to proceed with hernia repair is at the discretion of the operating surgeon. However, it is reasonable to defer

if at all possible until after significant weight loss has occurred and postoperative weight has stabilized.

Body Contouring

Body-contouring procedures after bariatric surgery are associated with improved well-being and quality of life [27, 28]. However, as patients are unlikely to reach their new baseline of weight for at least a year postoperatively, procedures for removal of excess skin should wait until weight loss has stabilized.

Non-surgeon Bariatric Physicians

Increasingly, many bariatric surgery programs are incorporating non-surgeon physicians as integral members of the multidisciplinary team. Bariatricians are experts in this specialized area, many having received board recognition. These specialists provide additional and extended insight into the various facets of managing patients with this chronic disease and also provide the ability to offer additional combination therapy options, such as appetite suppressants and supervised dietary therapy when indicated.

Conclusions

Lifelong follow-up through a multidisciplinary bariatric program requires diligence, communication, and a team approach. When successful, long-term follow-up is associated with sustained weight loss, fewer nutritional deficiencies, and improved management of comorbidities. With a better understanding of the longitudinal effects of bariatric surgery, we are likely to continue to see an important role for the surgeon in the long-term management of bariatric patients. Thorough long-term follow-up is critically important and must be the goal of all bariatric programs.

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Part III
Treatment

Chapter 20
Medically Supervised Weight Loss Programs

Ricard Corcelles and Bartolome Burguera

Abbreviations

BID	Two times a day
BMI	Body mass index
CAD	Coronary artery disease
CHF	Congestive heart failure
ECG	Electrocardiogram
EMA	European medicines agency
FDA	Food and drug administration
GLP-1	Glucagon-like peptide 1
HTN	Hypertension
IGT	Impaired glucose tolerance
QD	Once a day
T2D	Type 2 diabetes

Introduction

Obesity is a growing epidemic in the USA affecting nearly 60 million adult Americans. Obesity is a multifactorial chronic disease defined as a body mass index (BMI) of greater than 30 kg/m^2 in adults [1, 2]. Excess body weight is recognized as a major risk factor for the development of type 2 diabetes (T2D), cardiometabolic disease, obstructive sleep apnea, nonalcoholic fatty liver disease, and certain types of cancer [1].

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Consequently, there is a determination to find solutions to this major health problem. Some clinical studies have demonstrated that modest weight loss of 5–10% of body weight is sufficient to reduce obesity-related health risks significantly among patients with overweight and obesity [3]. Magnitude of weight loss is associated with improvements in glycemia, hypertension, triglycerides, and HDL cholesterol. The risk reduction seems to be "weight related" as clinical improvements are greater with reduction of 10–15% of body weight [4]. In this chapter, we will provide an overview of the medications available for the treatment of obesity, in the context of lifestyle intervention programs. Of note is that bariatric surgery treats less than 1% of the eligible morbid obese population. Should all the subjects suffering this chronic disease solicit for surgery, we would not have the resources (economical and infrastructure) or health experts necessary to offer bariatric surgery to this population with obesity. Therefore, it is imperative to develop effective multidisciplinary medical therapies alternative and complementary to bariatric surgery.

Pharmacologic Therapy in Obesity

Obesity is a major public health issue that requires long-term broad treatment. Anti-obesity medications may have an important role in helping people to lose weight in the context of a lifestyle intervention program [5]. Obesity is a chronic disease; therefore, it is important that we develop long-term effective treatments. Patients need to be provided with the necessary therapeutic tools, which will allow them to become more accountable and to slowly obtain control over their weight, improving at the same time their general health [4].

We have identified five different areas that need to be addressed in detail and appropriately treated long term. In the first place, it is important to improve patient's dietary habits and make sure they slowly improve their eating habits. Different aspects related to quality, quantity, portion sizes, and type of drinks should be addressed. New behaviors are introduced to facilitate healthy habits. Patients also need to increase the level of physical activity. They need to receive a personalized physical activity plan [6]. We recommend that before significantly increase in the level of physical activity and based on their level of fitness and medical status, patients should be evaluated by a cardiologist for a detailed evaluation of their cardiac status. This personalized exercise program may consists of upper body exercises, water exercises, walking, jogging, bicycling, etc. [7].

It is also important to pay attention to a patient's sleeping patterns. Lack of sleep is associated to increased appetite [8]. Undiagnosed sleep apnea increases the risk of suffering a heart attack, a stroke, hypertension, and hypogonadism. Some patients may benefit from a detailed evaluation in the sleep clinic. The prevalence of eating disorders, anxiety, depression, and other psychiatric conditions is significant in the patients with morbid obesity [9]. Many of these patients may benefit from antide-

Table 20.1 Drugs FDA approved for treatment of obesity

Drug	Mechanism of action	Daily dosage[a]
Orlistat	Inhibits pancreatic and gastric lipase	120 mg three times a day with each main meal containing fat
Phentermine	Augments central norepinephrine release	5–37.5 mg once daily
Phentermine and topiramate CR	Augments central norepinephrine and gamma-amino butyric acid release	Phentermine 7.5 mg topiramate 46 mg once daily
Bupropion and naltrexone sustained release	Inhibits dopamine and norepinephrine reuptake; blocks opioid receptor	2 tablets twice daily bupropion 360 mg naltrexone 32 mg
Diethylpropion	Augments central norepinephrine release	25 mg 3 times a day
Lorcaserin	Activates serotonin 5-HT_{2C} receptor	10 mg twice a day
Liraglutide	Activates glucagon-like peptide 1 receptor	3 mg subcutaneously once a day

Average weight loss is about 5–10 kg by 1 year
[a]By mouth, except for liraglutide

pressant therapy. Psychotherapy may be helpful addressing issues related to food addiction, bulimia, and binge eating disorders [10].

Weight loss drugs used in conjunction with an interdisciplinary lifestyle intervention program may provide long-term weight loss [6]. Anti-obesity medications have shown to improve metabolic control in patients with obesity and T2D. Due to scarce accessibility to surgery for all obese patients, there is an imperative need for medical treatment options.

The history of anti-obesity medications is quite unsuccessful and associated with modest incremental progresses. The reason for this lack of progress is the paucity of our knowledge about energy homeostasis. The development of weight loss drugs represents a major research area and is a focus of investigation by pharmaceutical companies. Until recently, there were limited pharmacologic options approved to treat obesity. The drug regulatory agencies, the Food and Drug Administration (FDA) in the USA and the European Medicines Agency (EMA) in Europe, recommend a 5% weight reduction that should be maintained at least 12 months after treatment initiation. According to the 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults, weight loss medications can be considered if a patient has a BMI $\geq$ 30 kg/m^2 or a BMI $\geq$ 27 kg/m^2 with obesity-related comorbidities (hypertension, T2D, dyslipidemia, and obstructive sleep apnea) and have failed to achieve weight loss through diet and physical activity alone [11].

Despite the potential market, we still have a very limited armamentarium of drugs useful for the treatment of obesity (Table 20.1). Here we discuss the current pharmacologic therapies approved for the management of obesity.

Orlistat (Xenical®, Genentech, South San Francisco, CA, USA)

Orlistat is the only medication approved by the EMA/FDA for the treatment of obesity that acts outside the brain. It is a potent gastrointestinal lipase inhibitor that reduces intestinal fat absorption up to 30%. Xenical® was approved in 1997 for the treatment of obese adults and adolescents. The recommended dosage is one capsule (120 mg) TID with meals. It can be purchased over the counter in some countries at a lower dose of 60 mg (Alli®, GSK Group, London, UK). Data have demonstrated that orlistat has a dose-dependent effect: 120 mg decreases up to 30% fat intake, whereas half a dose (60 mg) decreases up to 25%.

The XENDOS study (XENical in the prevention of Diabetes in Obese Subjects) assessed the effect of orlistat in 3305 patients with obesity and impaired glucose tolerance (IGT). In this 4-year, double-blind, prospective study, patients were randomized to lifestyle changes plus either orlistat 120 mg or placebo, three times daily [12]. Primary endpoints were time to onset of T2D and change in body weight. The results of the study demonstrated that treatment with orlistat (plus lifestyle modification) resulted in a significant reduction in the cumulative incidence of T2D after 4 years of treatment (9.0% with placebo vs. 6.2% with orlistat), corresponding to a risk reduction of 37.3% ($p = 0.0032$). Mean weight loss at the end of the study was significantly greater in the orlistat group (5.8 vs. 3.0 kg with placebo; $p < 0.001$). Additional benefits of orlistat included a reduction in LDL cholesterol independent of the amount of weight loss. XENDOS was the first study to show that an anti-obesity medication (Xenical®) in combination with lifestyle changes was more effective than lifestyle changes alone facilitating patients to achieve long-term weight loss and improvements of their cardiovascular risk (CVR) factors [12]. A systematic review and meta-analysis of randomized controlled trials showed that orlistat produced an average reduction of 2.4 kg (95%CI −3.34 to −1.45) of body weight [13]. A reduction of total cholesterol, LDL cholesterol, fasting glucose, and blood pressure was also documented, more than expected by the decrease in body weight.

Limitations of the medication consumption included potentially significant gastrointestinal side effects. The most common adverse effects occurred after high-fat meal. The malabsorption of the fat can lead to abdominal cramping, flatulence, bloating, steatorrhea, and fecal urgency, being responsible of drug discontinuation in some patients [12]. Orlistat should be avoided in patients with chronic intestinal malabsorption, cholestasis, or known hypersensitivity. In the XENDOS study, decreases in fat-soluble vitamins (A, D, E, K) were reported in the orlistat group compared with placebo [12]. Therefore, fat-soluble vitamin supplements should be taken at least 2 h before or after the administration of orlistat. Severe but extremely uncommon adverse effects such as liver and kidney damage have been reported [14]. A recent study conducted in Canada (n = 953) suggests the relationship between orlistat and acute kidney injury [15]. The supposed mechanism is similar to enteric hyperoxaluria in which unabsorbed dietary fat binds enteric calcium and lowers its capacity to bind and sequester oxalate in the intestine. This leads in excessive absorption of free oxalate and consequent accumulation in the kidney. Therefore, kidney and liver function should be monitored while taking orlistat.

Instead of its gastrointestinal side effects, orlistat continues to be a useful medication to be prescribed in patients with obesity that are able to comply with a low-fat diet content.

Phentermine (Adipex®, Teva Pharmaceuticals, Petah Tikva, Israel)

Phentermine is a weight loss medication approved by the FDA in 1959. It is a central adrenergic agonist (activation of the sympathetic nervous system) that leads to early satiety and reducing appetite. Phentermine remains as the most widely prescribed medication in the USA for the short-term treatment of obesity (up to 12 weeks). The phentermine hydrochloride salt splits in the gastrointestinal tract, resulting in immediate release of phentermine and causing a powerful hunger suppressant effect. It is available in doses ranging from 8 mg to 37.5 mg daily by prescription only and is a schedule IV-controlled substance.

Phentermine has been shown to cause a 5–15% weight loss if given daily or intermittently [16]. However, phentermine is indicated only for short-term treatment, and tolerance often develops. In a recent 28-week randomized controlled trial ($n = 756$), phentermine monotherapy was associated with mean weight loss reduction of 5.1% [17]. Importantly, more than 42% of patients on phentermine achieved >5% weight loss from baseline to week 28. No long-term (>12 months) randomized controlled studies on the effectiveness of phentermine monotherapy have been published.

Common adverse effects associated with phentermine are dry mouth, insomnia, increased blood pressure, headache, and constipation. Other common side effects include hypertension and tachycardia [17]. Currently, there are no long-term data on the vascular effects of this drug. Phentermine is contraindicated in patients with uncontrolled hypertension, coronary artery disease (CAD), congestive heart failure (CHF), and stroke. In order to minimize side effects, all patients should be monitored closely for elevations in blood pressure and heart rate. This drug is contraindicated in pregnancy and during breastfeeding. In view of that phentermine is only approved for its short-term usage, this medication plays a limited role in the chronic management of obesity. However, it could be useful in patients with difficulties controlling their appetite and only be used as “jump start” in conjunction with lifestyle intervention programs.

Diethylpropion (Tenuate)

The FDA approved diethylpropion as anti-obesity medication, also in 1959. It is another central nervous system stimulant similar to bupropion in its molecular structure. Diethylpropion is a schedule IV drug used as part of short-term plan.

A randomized double-blind study evaluated the long-term efficacy and safety of diethylpropion 50 mg BID (n = 37) vs. placebo (n = 32) in obese patients for 6 months [18]. Subjects in the diethylpropion group lost an average of 9.8% of initial body weight vs. 3.2% in the placebo ($p < 0.001$). After this period, all participants received diethylpropion in an open-label extension for an additional 6 months. From baseline to month 12, the mean weight loss with diethylpropion was 10.6%. Patients in the placebo group who were switched to diethylpropion after 6 months lost an average of 7.0% of their initial body weight. No differences in blood pressure, pulse rate, ECG, and psychiatric evaluation were observed. In a meta-analysis of 13 studies lasting from 6 to 52 weeks, diethylpropion was associated with a 3.0 kg weight loss (95% CI 1.6–11.5) [18]. Very few studies have evaluated long-term use of diethylpropion. The most common side effects of diethylpropion include constipation, dry mouth, palpitations, headache, insomnia, and mild increases in blood pressure [19].

Phentermine and Topiramate (Qsymia®, Vivus Inc., Campbell, CA, USA)

The combination of phentermine and topiramate for the treatment of obesity was approved in 2012. The strategy of simultaneously targeting more than one regulatory pathway has become popular and potentially efficient to treat patients with obesity. Phentermine is a central noradrenaline-releasing drug previously described. Topiramate is an antiepileptic drug with weight loss benefits. Qsymia® is a combination of low doses of controlled release phentermine and topiramate in one capsule. The dosing of phentermine/topiramate (phen/top ER) requires titration, and the drug is available in four combinations (3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, and 15 mg/92 mg). This combination produces weight loss via complementary mechanisms (regulating various brain neurotransmitters), and each agent is used at a lower dose, resulting in enhanced weight loss compared with single-agent use.

The efficacy and safety of low doses phen/top ER were evaluated in several clinical trials. The EQUIP study was an early trial of the phen/top ER combination [20]. The EQUIP trial randomized 1267 patients with morbid obesity (average BMI 42 kg/m^2) into three arms: diet and placebo, diet and phen/top ER 3.75/23 mg daily, or diet and phen/top ER 15/92 mg daily. Dropout rates ranged from 47% in the placebo group to 34% in the high-dose medication group. In the primary analysis, patients in the phen/top ER 15/92 mg, phen/top ER 3.75/23 mg, and placebo groups lost 10.9%, 5.1%, and 1.6% of baseline body weight, respectively, at 56 weeks ($p < 0.001$ for each dose vs. placebo). The high-dose medication group had significantly greater changes vs. placebo for waist circumference, blood pressure, fasting glucose, triglycerides, total cholesterol, LDL cholesterol, and HDL cholesterol.

In the CONQUER trial, 2487 patients (BMI 27–45 kg/m^2) with two or more comorbidities (hypertension, dyslipidemia, diabetes, abdominal obesity) were included [21]. The EQUIP trial excluded patients with diabetes, but CONQUER allowed patients with T2D managed with lifestyle changes or metformin. The CONQUER study assessed the long-term efficacy and safety of two doses of phen/top ER (phen/top ER 7.5/46 mg and phen/top ER 15/92 mg) compared with placebo over 56 weeks. At 56 weeks, change in body weight was 9.8, 7.8, and 1.2% in the patients assigned to phen/top ER 15/92 mg, phen/top ER 7.5/46 mg, and placebo, respectively ($p < 0.001$ for each dose vs. placebo). Importantly, 70% of patients achieved at least 5% weight loss with phen/top ER 15/92 mg compared to 62% with phen/top ER 7.5/46 mg and 21% with placebo ($p < 0.001$ for each dose vs. placebo). Patients receiving either combination therapy also showed significant improvements in several cardiovascular and metabolic risk factors, such as waist circumference, systolic blood pressure, and total cholesterol/HDL cholesterol ratio. At 56 weeks, patients with diabetes and prediabetes receiving medication experienced greater reductions in their HbA1c levels compared to patients in the placebo group. Importantly, less prediabetes participants progressed to T2D [21].

The SEQUEL trial (an extension of the CONQUER) evaluated the long-term efficacy of lifestyle intervention and two doses of phen/top ER for an additional 52 weeks (total treatment duration of 108 weeks). Of 866 subjects, 676 (78%) completed the study, with similar retention rates between treatment arms [22]. The mean body weight change was significantly greater in the two treatment groups vs. placebo (10.5%, 9.3%, and 1.8% with phen/top ER 15/92 mg, phen/top ER 7.5/46 mg, and placebo, respectively; $p < 0.001$ for each dose vs. placebo). The percentage of patients who achieved 5% weight loss was greater than in the CONQUER study: 79% with phen/top ER 15/92 mg compared to 75% with phen/top ER 7.5/46 mg and 30% with placebo [21, 22]. The results of SEQUEL showed a 76% reduction in the progression to diabetes in subjects receiving phen/top ER 15/92 mg and a 54% reduction in patients taking phen/top ER 7.5/46 mg compared with placebo. Phen/top ER improved cardiovascular and metabolic variables and decreased rates of incident T2D in comparison with placebo. The medication was well tolerated over 108 weeks. Of importance, phen/top ER was less effective causing weight loss in the second year of the study, although most patients were able to maintain their weight loss [22].

The most common adverse effects include paresthesia (20%), dry mouth (19%), constipation (16%), upper respiratory infection (16%), metabolic acidosis (13%), nasopharyngitis (12%), and headache (11%). The FDA does not recommend the use of this drug combination in patients with recent stroke, CAD, HTN, glaucoma, hyperthyroidism, and patients receiving treatment with monoamine oxidase inhibitors. Because topiramate can cause renal stones, this combination should be used cautiously in patients with history of kidney stones. The ideal patient to prescribe phen/top ER is a patient with obesity who has low cardiovascular risk and refers substantial appetite. If a patient has a history of migraine or seizures, topiramate may provide an additional benefit.

In Europe, the combination of phen/top ER has not been approved yet. In 2013, the EMA refused again to grant approval for this drug in the European Union.

Lorcaserin (Belviq®, Eisai Inc., Tokyo, Japan)

Lorcaserin was approved for long-term use in the treatment of obesity in 2012 and has also been listed as a schedule IV drug. It is a selective 2C receptor agonist. Lorcaserin binds selectively to the serotonin 2C receptors in the hypothalamus, promotes hunger suppression, and increases satiety. Nonselective serotoninergic agents, including fenfluramine and dexfenfluramine, were associated with cardiac valvulopathy and withdrawn from the market in 1997 [23]. Lorcaserin is available as a 10 mg tablet, and the recommended dose is 10 mg twice per day. Lorcaserin has not been associated with valvular heart abnormalities.

Three randomized, double-blind, placebo-controlled trials evaluated the effects of lorcaserin [24–26]. The BLOOM was a 104-week, clinical trial to assess the safety and efficacy of lorcaserin in patients with obesity and at least one coexisting condition (hypertension, dyslipidemia, cardiovascular disease, impaired glucose tolerance, sleep apnea). A total of 3182 patients was randomized to receive lorcaserin 10 mg twice daily (BID) or placebo for 52 weeks, followed by a 1-year extension period [24]. All subjects participated in a behavioral interventional program. After 1 year, mean weight loss was higher in the lorcaserin group 5.8% compared to 2.2% in the placebo group ($p < 0.0001$). Approximately half of the patients remained in the study during the second year. Significantly, weight reduction was maintained in 68% of patients who continued to receive lorcaserin in comparison with 50.3% of patients who received placebo. The BLOOM study also demonstrated greater improvements in CVR factors and metabolic parameters in the lorcaserin group [24].

The BLOSSOM trial (n = 4008) evaluated two doses of lorcaserin, 10 mg BID and 10 mg daily [25]. This study was designed to evaluate the efficacy of a dose range of lorcaserin in conjunction with a lifestyle modification plan, in obese and overweight patients. After 1 year, patients in the lorcaserin 10 mg BID group lost more weight (5.8%) compared with those assigned to lorcaserin 10 mg daily (4–7%) and placebo (2.8%; $p < 0.001$ for each dose vs. placebo). Weight loss of at least 10% was obtained by 22.6% and 17.4% of patients receiving lorcaserin 10 mg BID and QD (one a day), respectively, and 9.7% in the placebo cohort [25].

A third lorcaserin trial BLOOM-DM was conducted in 604 T2D obese and overweight patients treated with metformin, a sulfonylurea, or both [26]. Patients were randomized to lorcaserin 10 mg BID ($n = 256$), lorcaserin 10 mg dosed QD ($n = 95$), or placebo ($n = 253$). At 1 year, patients treated with lorcaserin 10 mg once daily showed mean weight loss of 5%, compared to 4.5% and 1.5% in the lorcaserin 10 mg BID and placebo groups, respectively. Both lorcaserin treatment groups experienced significant reductions in HbA1c compared with placebo (1.0% with lorcaserin daily, 0.9% with lorcaserin BID). Differently to the dose effects observed

in the BLOSSOM study, the effects of lorcaserin on body weight and other parameters were not consistently dose related in the BLOOM-DM study [26].

The most common side events associated with lorcaserin were headache, dizziness, fatigue, nausea, dry mouth, and constipation. Clinical trials of lorcaserin included echocardiograms, which did not suggest an increase in cardiac valvulopathy compared with placebo. However, any patient with known valvulopathy or CHF should avoid taking this drug. Lorcaserin is contraindicated for use in pregnancy and lactating women.

The best possible patient to prescribe lorcaserin is a patient who necessitates weight reduction and reports difficulty with appetite control. It can also be an option for patients with diabetes as shown in the BLOOM-DM trial.

Bupropion SR/Naltrexone SR (Contrave®, Orexigen Therapeutics, La Jolla, CA, USA)

The combination of bupropion-naltrexone extended release (SR) was approved by the USA FDA in 2014 for chronic weight management. Naltrexone is an opioid receptor antagonist approved for the treatment of alcohol and opioid dependence [27]. Bupropion is a dopamine and norepinephrine reuptake inhibitor that increases dopamine activity in the brain [28]. Bupropion is approved for the treatment of depression and smoking cessation. The combination of the two medications has synergistic actions in the central nervous system and is thought to reduce food cravings.

The safety and efficacy of bupropion SR/naltrexone SR was studied in four 56-week randomized, double-blind, placebo-controlled, phase III clinical studies [29–31]. These trials included overweight and obese patients with weight-related comorbidities. The COR-I trial ($n = 1742$) assessed the weight loss effect of bupropion SR/naltrexone SR in patients randomly assigned to naltrexone 32 mg plus bupropion 360 mg daily, naltrexone 16 mg plus bupropion 360 mg daily, and placebo [29]. As expected, weight loss was significantly greater in the combination groups. Mean change in body weight was 6.1% in the naltrexone 32 mg plus bupropion 360 mg group and 5% in the naltrexone 16 mg plus bupropion 360 mg group compared to 1.3% in the placebo group ($p < 0.001$). Waist circumference, triglycerides, HDL cholesterol, blood pressure, and HOMA-IR were significantly increased in participants assigned in the combination treatment groups compared with placebo [29].

In the COR-BMOD study ($n = 793$), participants were randomly assigned in a 3:1 ratio to a fixed dose of naltrexone 32 mg plus bupropion 360 mg SR or placebo [31]. All patients were on an intensive behavioral modification program. At week 56 a significant greater weight loss was reported in the bupropion SR/naltrexone SR group compared with placebo (11.5% vs. 7.3%). The results of COR-BMOD study showed significant reductions with naltrexone 32 mg plus bupropion 360 mg SR plus behavioral programs compared to placebo plus behavioral programs in waist circumference, triglycerides, HDL cholesterol, fasting insulin, and HOMA-IR [31].

The efficacy of bupropion SR/naltrexone SR therapy in obese patients with T2D was evaluated in the COR-Diabetes trial [32]. In this study, 505 overweight or obese T2D participants (mean HbA1c = 8.0%) were randomized 2:1 to naltrexone 32 mg plus bupropion 360 mg SR or placebo. At 56 weeks, naltrexone 32 mg plus bupropion 360 mg SR daily resulted in significantly greater weight reduction compared with placebo (5.0% vs. 1.8%; $p < 0.001$). The percentage of patients achieving ≥5% weight loss was superior in the combination group compared with placebo (44.5% vs. 18.9%; $p < 0.001$). Additionally, bupropion SR/naltrexone SR therapy resulted in significantly better T2D metabolic control. The HbA1c reduction was greater in the bupropion SR/naltrexone SR group compared with placebo (0.6% vs. 0.1%, respectively), leading to a higher percent of patients achieving HbA1c < 7% (44.1 vs. 26.3%; $p < 0.001$). Improvements were also seen in other cardiometabolic risk factors, such as triglycerides and HDL cholesterol levels.

The most common side effect leading to medication discontinuation was nausea. Other adverse events included constipation, headache, vomiting, and dizziness. The bupropion SR/naltrexone SR therapy is contraindicated in subjects with history of seizures, anorexia nervosa/bulimia, or patients who have chronic pain or require opioids. However, this drug combination may increase in popularity due to primary care physicians are familiar with both medications.

Liraglutide (Saxenda®, Novo Nordisk Bagsværd, Denmark)

Liraglutide is a long-acting glucagon-like peptide 1 (GLP-1) receptor agonist used to treat T2D. It is an injectable drug with a 97% structural homology to human GLP-1. Liraglutide was approved in 2014 as an obesity treatment (only GLP-1 agonist approved for treatment of obesity). GLP-1 is a hormone secreted by the intestinal L cells following the consumption of fat and carbohydrate-rich nutrients. GLP-1 stimulates the release of postprandial insulin and suppresses any improperly elevated postprandial glucagon levels. Additionally to the effect of GLP-1 on the glucose homeostasis control, it also reduces appetite and delays gastric emptying [32].

Liraglutide comes in a multidose, for a daily subcutaneous injection (half-life of 13 h). The dose is increased to a maximum dose of 3 mg daily. Three randomized, double-blind trials examined the effect of liraglutide 3 mg on body weight reduction in overweight or obese patients. In the SCALE Obesity study ($n = 3731$, non-T2D patients), patients were randomized to receive liraglutide 3 mg daily or placebo [33]. At 56 weeks, patients in the liraglutide group lost 8.0% of their body weight compared to 2.6% of their body weight in the placebo group ($p < 0.001$). Data showed that 63.2% of the patients in the medication group achieved ≥5% of weight loss compared with 27.1% in the placebo group. Liraglutide was also associated with a reduction in HbA1c, fasting glucose, and other cardiometabolic risk factors. Moreover, T2D developed in more patients in the placebo group than in the liraglutide group during the course of the study. The SCALE Maintain study evaluated the efficacy of liraglutide in maintaining weight loss [34]. A total of 422 nondiabetic patients were randomized to liraglutide 3 mg vs. placebo as an adjunct to diet and

exercise; patients in the study had already lost at least 5% of their body weight. Mean weight loss on the initial diet plan was 6.0%, whereas by the end of the study, patients in the liraglutide group lost an additional 6.2% compared to 0.2% with placebo ($p < 0.001$).

The SCALE Diabetes study included 846 diabetic patients with an HbA1c 7–10% [35]. Participants were randomized to receive liraglutide 3.0 mg daily, liraglutide 1.8 mg daily, or placebo for 56 weeks. Liraglutide at a dose of 3.0 mg resulted in 6.0% weight reduction compared to 2.0% weight loss in the placebo group. Of patients receiving 3.0 mg, 54.3% achieved ≥5% weight loss at 56 weeks compared to 21.4% in placebo. Liraglutide also resulted in improvements in HbA1c (mean change 1.3% vs. 0.3% in placebo), fasting and postprandial glucose levels, and fasting glucagon levels. In the recently published LEADER trial ($n = 9340$ T2D patients), liraglutide has shown to significantly decrease rates of cardiovascular events (first occurrence of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) in patients with elevated CVR factors [36]. The results of the LEADER trial make liraglutide a favorable choice for high-risk patients with T2D, obesity, and cardiovascular disease.

The most commonly reported side effects of liraglutide are from the gastrointestinal system, with nausea and vomiting being the predominant symptoms. A good candidate for liraglutide is a patient with overweight and obesity who needs HbA1c reduction and appetite control.

Conclusion

Obesity is a growing global epidemic that requires long-term management. It is imperative that we define an optimal therapeutic plan alternative to bariatric surgery for patients with severe obesity. FDA-approved medications to treat obesity—especially drugs that lower the appetite set-point—should be considered in the context of an interdisciplinary lifestyle intervention. Pharmacotherapy must be individually tailored and based on patients' health risks, metabolic disturbances, and behavioral characteristics. Patients and healthcare providers need to keep in mind that obesity is a chronic disease that requires long-term treatment in order to maintain weight loss.

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Chapter 21
Index Endoscopic Restrictive and Other Devices in Obesity Treatment: Techniques and Outcomes

Bruce Schirmer and Peter Adams

Introduction

Endoscopic restrictive procedures include a variety of techniques that decrease gastric capacity and food intake. This chapter will deal with space-occupying devices as well as methods of decreasing gastric capacity through endoscopic suturing. These procedures should be offered to patients in the setting of a multidisciplinary group to address the underlying disease of obesity. Both medical and surgical expertise in treating obesity is optimal for such patients. In addition, procedures are best done with a team experienced and trained in caring for the obese patient and in performing the specific treatment. This chapter also includes discussion of a new type of device that uses the body's natural physiology to amplify, accelerate, and extend satiety.

Intragastric Balloons

In 1985, the Food and Drug Administration (FDA) approved the first intragastric balloon for use in the USA, but the Garren-Edwards balloon proved to be a major black eye for the FDA. There were an estimated 20,000 balloons placed during the first year after approval. By 1988, reports were already published noting a high incidence of complications from the device. By 1989, there were three prospective randomized controlled trials that failed to show any improvement in patient outcomes compared to diet and exercise programs [1]. The device was withdrawn from the market in 1992, and for many years, the FDA did not approve any further intragastric balloons.

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Table 21.1 Indications and contraindications for intragastric balloons

Indications
Patients with a BMI 30–40
May not want bariatric surgery
May not qualify for bariatric surgery
Bridge to another procedure such as transplant, joint replacement, etc
Contraindications
Previous gastric surgery
Hiatal hernia >5 cm
Coagulopathy
Bleeding lesion of UGI tract
Pregnancy or breastfeeding
Alcohol or drug addiction
Severe liver disease
Unreliable for follow-up

During the ensuing two decades, the use of intragastric balloons was performed in many other countries for the purpose of achieving short-term weight loss. In general, the indications for the balloon have been for patients with lower BMI (usually 30 to 40 kg/m^2). The BioEnterics® Intragastric Balloon (BIB®) (formerly Allergan Inc., now Apollo Endosurgery; Austin, TX, USA) was utilized and studied in several countries. The BIB was a spherical intragastric balloon that was inserted and removed endoscopically. It was filled to 400 ml with saline, and a blue dye was added to detect rupture. It produced short-term weight loss in a variety of trials and settings. In Italy, a series of over 2500 patients reported a 34% excess weight loss at 6 months upon balloon removal [2]. Sallet and colleagues [3] reported that almost 500 patients who had the BIB placed and removed in Brazil had an average 48% excess weight loss at device removal at 6 months and kept 90% of that weight off at 1 year follow-up.

The accumulated experience of many published balloon studies has been summarized in several review articles. Imaz and colleagues [4] reported on over 3500 patients from 14 studies in which the average weight loss was 32% of excess weight (%EWL), and the average actual amount of weight lost was 14.7 kg. Abbu Dayych and coworkers [5] recently reported a total of 6845 patients from the literature whose percent total body weight loss (%TBWL) at 6 months was 13.16% after BIB therapy. Adverse events have been uniformly low with the BIB, and this report detailed a 7.5% early removal rate, 18.3% GERD rate, 2% ulcer rate, 1.4% migration rate, 0.3% obstruction rate, 0.1% perforation rate, and a 0.08% death rate. Indications and contraindications for balloon placement are listed in Table 21.1.

In the summer of 2015, two intragastric balloons received approval for use in the USA. Since then a third has also received approval. These are described below, and all are currently available for patient use.

The Orbera® intragastric balloon (Apollo Endosurgery Inc.; Austin, TX, USA) is a saline-filled single spherical balloon with a volume of 550–650 ml (Fig. 21.1a, b). It is both placed and removed endoscopically. It is made by the same company

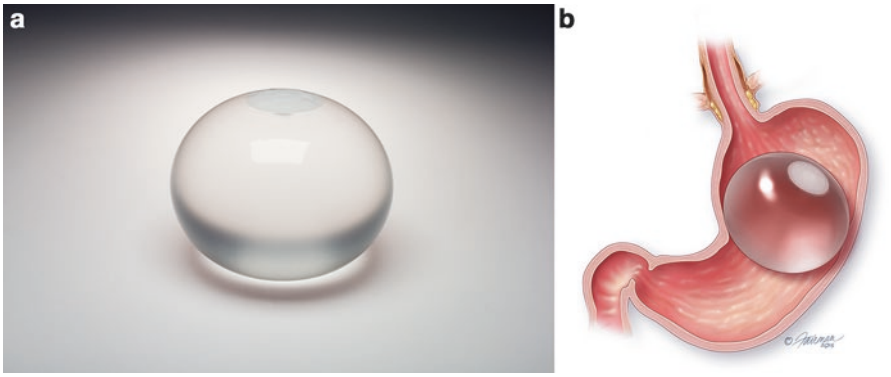

Fig. 21.1 Orbera® intragastric balloon. (**a**) Device. (**b**) Device in place (Used with permission of Apollo endosurgery, Austin, TX, USA)

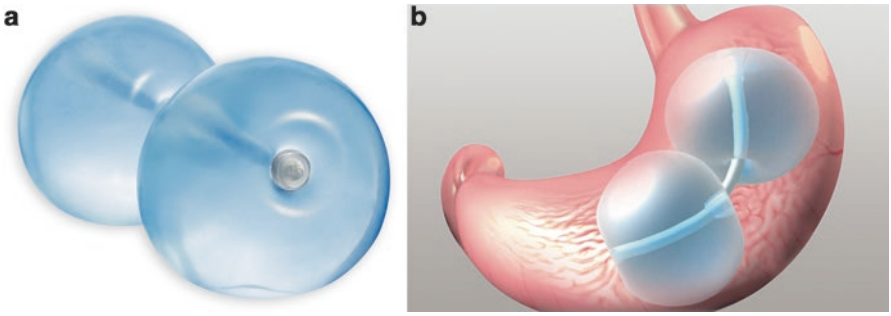

Fig. 21.2 Reshape™ integrated dual balloon. (**a**) Device. (**b**) Device in place (Used with permission of ReShape Medical, San Clemente, CA, USA)

that made the BIB and closely resembles it. Duration of balloon placement is 6 months. Data from the FDA trial of the Orbera balloon showed a 12-month %TBWL of 7.4% with the balloon versus 3.6% for the control group that utilized only diet and exercise. Nausea was reported in most patients (85%), as was abdominal pain (74%). GERD symptoms were reported in 26% of patients [6]. The Orbera is similar in design and features to the original BIB balloon, with modifications to improve symptoms and tolerance.

The Reshape™ integrated dual balloon (ReShape Medical Inc.; San Clemente, CA, USA) is a double-balloon system with each balloon containing 450 ml of saline (Fig. 21.2a, b). The balloon is promoted to be safer, since if one balloon accidentally deflates, the other will prevent balloon migration beyond the pylorus, which may require surgical removal. The Reduce Pivotal multicenter trial showed that the 6-month %EWL was 25.1% vs. 11.3% for the control group. Mean %TBWL was 7.6%, which was comparable to that seen with the Orbera balloon [7]. In the Reshape balloon's FDA trial, 264 enrolled patients had a 15% higher %EWL than controls if they completed the study. For patients that completed the study, 54.5% achieved a

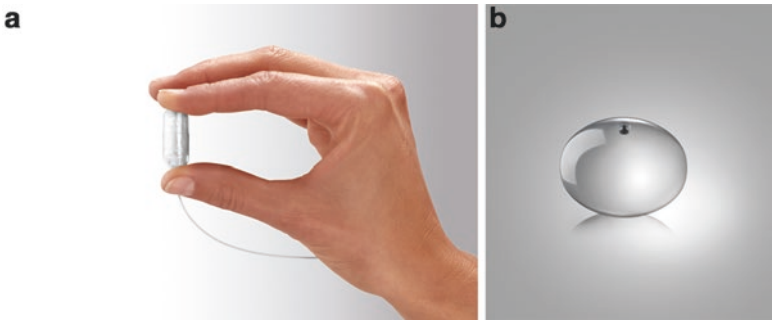

Fig. 21.3 Obalon® balloon system. (**a**) Capsule and catheter. (**b**) Inflated balloon (Used with permission of Obalon Therapeutics, San Diego, CA, USA)

greater than 25% excess weight loss. Adverse effects included vomiting in 87%, nausea in 61%, abdominal pain in 55%, gastric ulcers in 35%, and GERD in 7%. The incidence of gastric ulcers decreased to 10.3% with a modified balloon design [8]. Early removal of the device occurred in 9% of cases, whereas for Orbera it was 7.5%.

The Ullorex® balloon (Obalon Therapeutics, Carlsbad, CA, USA) was first described in 2003. In its initial design, this balloon was a capsule which was injected with citric acid then swallowed. It inflated to 300 ml after 4 minutes. The space-occupying device led to weight loss, and after 1 month, a plug on the balloon would degrade, allowing deflation and passage of the balloon. That model was revised to provide for placement of multiple air-filled balloons. All balloons are now removed endoscopically. Multiple balloons can be inserted, depending on patient tolerance and satiety. This new Obalon balloon was approved by the FDA in 2017. It is indicated for patients with a BMI of 30–40 kg/m^2. Patients can receive up to three balloons. Each balloon is introduced by swallowing a capsule attached to a catheter. The balloon can be then filled with 250 ml of the gas sulfur hexafluoride; then the infusion catheter is detached and removed (Fig. 21.3a, b). Manufacturer recommendations are that the balloons be removed within 6 months of placement. Recent data from a group of pediatric patients with BMI 30–35 showed efficacy with 16 patients losing an average of 12.2 kg, which represented %EWL of 20.1% [9].

The Spatz3 intragastric balloon (Spatz FGIA Inc., Great Neck, NY, USA) is not yet approved for use in the USA by the FDA (Fig. 21.4). It is a saline-filled intragastric balloon which is designed to stay in the stomach for 12 months. It also has a catheter attached to it which can be endoscopically accessed to allow further increase or decrease in balloon volume based on patient satiety or intolerance. This feature is promoted to [1] alleviate intolerance and avoid early balloon extraction and [2] enlarge balloon volume when balloon effect diminishes in the first 4–5 months. The Spatz 1 model from before 2012 had a rigid catheter and metal chain. Data from the UK on the Spatz 1 showed a mean weight loss of 21.6 kg or 45.7% of excess weight loss at 1 year. Catheter obstruction of 4%, intolerance without balloon adjustment of 5.5%, and early balloon deflation of 4% were also reported [10]. More recent data from a multicenter study with 206

Fig. 21.4 Spatz3 Adjustable Balloon System® (Used with permission of Spatz Medical FGIA Inc., Great Neck, NY, USA)

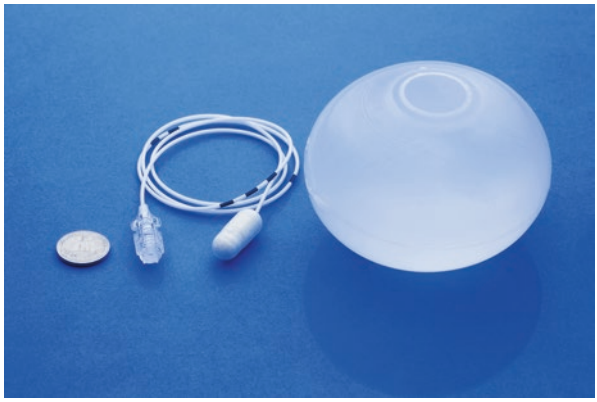

Fig. 21.5 Elipse® balloon system (Used with permission of Allurion Technologies, Natick, MA, USA)

patients with the Spatz 3 model (which has a soft catheter) reported weight loss of 14.5 kg with a mean 55.6% EWL and 15.2% total body weight loss [11].

The Elipse™ (Allurion Inc., Wellesley, MA, USA) is another device that is not yet FDA approved. This intragastric balloon is currently being tested in the USA and has shown efficacy in Europe. This balloon is swallowed as a capsule, with a small catheter attached, allowing for inflation of the balloon with 550 ml of saline (Fig. 21.5). A small portion of surface area of the Elipse is made from a material that dissolves in the presence of gastric acid after 4 months, and the balloon then passes out through the GI tract. Endoscopy is not needed for insertion or removal. The most recent publication of its efficacy in a group of 11 patients showed no adverse events, and at 4 months, patients experienced a 50.2% excess weight loss and a %TBWL of 14.6%. Eight months later, these numbers had fallen to 17.6% and 5.9% [12].

A recent review of eight randomized controlled trials of intragastric balloon efficacy since 2006 has shown a collective result of %TBWL of 9.7%. Subtracting the control group average weight loss, the efficacy was 5.6% TBWL. The authors point out that pharmacotherapy for weight loss with the drug qsymia has an efficacy of 6.6% at 6 months. The balloon studies showed an average serious adverse event rate

of 10.5% and an average cost of $8150 for the device, placement, and retrieval [13]. The FDA has also recently added pancreatitis as an adverse reported event for both the ReShape and Orbera balloons.

A recent FDA Disclosure on August 11, 2017, reported five deaths in patients who had undergone treatment with the Orbera or ReShape balloon systems [14]. The etiology of these deaths and the contributions of the balloons to these deaths are as yet unknown. One manufacturer, Apollo Endosurgery, posted a response statement emphasizing this unknown relationship, as well as the extremely low known mortality rate for patients undergoing balloon treatment over the past several decades. Further clarification of the role of the balloons in these cases is pending.

Based on the large body of evidence, with the understanding that weight regain is high and symptoms of nausea and abdominal pain are almost uniform, gastric balloon treatment has been shown to be effective for producing short-term weight loss with relatively good safety. As such, it is currently an option which should be offered to educated eligible patients, especially those adverse to more invasive surgical therapy, as an initial treatment option.

Gelesis 100

Gelesis 100 (Gelesis, Boston, MA, USA) is a capsule which is designed to help patients lose weight by occupying space within the alimentary tract. It is undergoing current FDA testing. The capsule, which is swallowed, contains thousands of tiny hydrogel particles. When these particles are released in the stomach, they absorb water and increase dramatically in size. The volume and elasticity of the gastric contents results in decreased gastric emptying, earlier satiety, and better control of glucose metabolism. Once the hydrated material passes into the small intestine, it continues to act as a bulk agent. Upon reaching the colon, the polymer is cleaved from some of its absorbed water, and the hydrogel is excreted.

In 2014, the Gelesis Corporation released data from their proof of efficacy study. Obese and overweight nondiabetic patients took a high or low dose Gelesis 100 pill or placebo before lunch and dinner for 12 weeks. Weight loss in the 2.25 gram Gelesis group, the 3.75 gm Gelesis group, and the placebo group was 6.1%, 4.5%, and 4.1% of total body weight after 12 weeks. The subgroup of patients who were prediabetic (fasting glucose 100–125 mg/dL) lost 10.9% body weight [15]. The product is currently undergoing FDA testing, and no other data are available as to its efficacy.

Endoscopic Gastric Suturing

One promising device for endolumenal bariatric surgery is the OverStitch™ (Apollo Endosurgery Inc.; Austin, TX, USA). This endoscopic suturing device allows a full thickness bite of tissue, providing more security for suture lines than previous

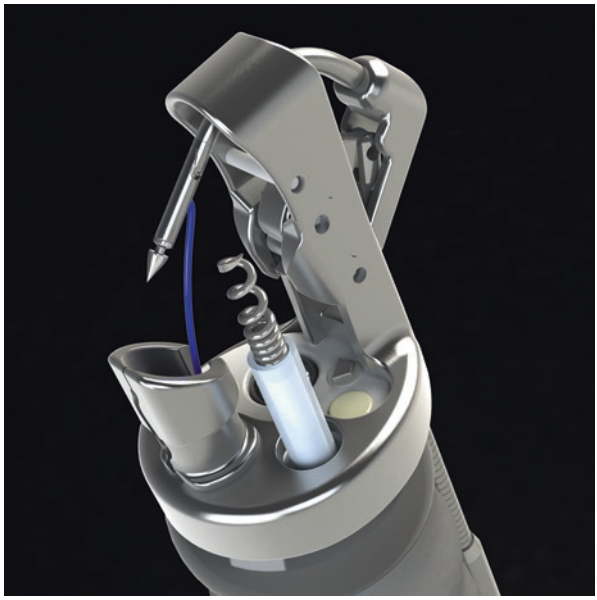

Fig. 21.6 OverStitch™ suturing device (Used with permission of Apollo Endosurgery, Austin, TX, USA)

devices, which typically only allowed mucosal bites via suction mechanisms. The EndoCinch (Bard; Murray Hill, NJ, USA) was such a device, and it has since been withdrawn from the market. The OverStitch (Fig. 21.6) has shown good efficacy for approximating gastric tissue, for which it has a device indication. It can be used for suturing gastric tissue defects, such as gastric fistulae from anastomotic or suture-line leaks and can anchor stents in place to prevent migration [16]. The instrument has been shown to be successful in narrowing the lumen of the gastrojejunostomy anastomosis in patients who have had previous Roux-en-Y gastric bypass and have been regaining weight [17].

Endoscopic Sleeve Gastroplasty

The OverStitch provides secure enough tissue approximation to allow for the creation of an endoscopic sleeve gastroplasty (ESG). In this procedure, the anterior and posterior surfaces of the stomach in the proximal antrum and body are sutured together, along with bites of the greater curvature, to collapse and suture closed the lumen of the stomach except the area along the lesser curvature. The main difference between an ESG and an operative sleeve gastrectomy, with respect to creation of the lumen, is that ESG does not suture the fundus completely closed (Fig. 21.7a, b). It was discovered early in the experience of creating the ESG that suturing the top of the fundus was associated with increased complications from full thickness tissue perforation, due to the thinness of the fundus.

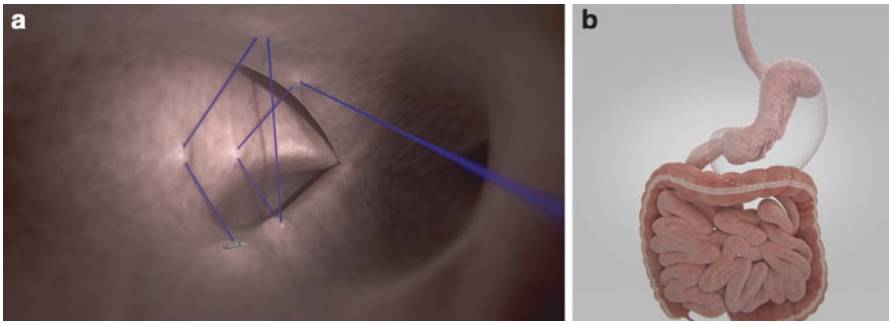

Fig. 21.7 (**a**) Suture locations for creating endoscopic sleeve gastroplasty (ESG). (**b**) Configuration of ESG (**a**, **b**: Used with permission of Apollo Endosurgery, Austin, TX, USA)

Indications for ESG have generally been for patients with a BMI of 30–40 kg/m^2, although some series have routinely included patients with a BMI over 40. The procedure is currently not approved by most insurance carriers, and it requires general anesthesia. In experienced hands, the procedure can be routinely done in 60–90 min. Outcomes for the procedure thus far have been encouraging both in their initial efficacy, as well as durability of weight loss. A multicenter series of 248 patients (213 with 2-year follow-up) showed that patients with an average preoperative BMI of 37.8 kg/m^2 experienced a mean %TBWL of 15.2% and 18.6% at 6 and 24 months postoperatively. Five adverse events (2%) were observed. These included two inflammatory perigastric fluid collections treated percutaneously, one pulmonary embolism 3 days postprocedurally, one extragastric hemorrhage requiring transfusion, and one pneumoperitoneum and pneumothorax requiring chest tube placement. All five patients recovered without surgery [18]. A single-institution study showed 91 patients with a mean BMI of 40.7 kg/m^2 had a 17.6% TBWL at 1 year, with significant reductions in systolic blood pressure, hemoglobin A1c, waist circumference, alanine aminotransferase, and serum triglycerides [19].

Space-Occupying Investigational Devices

Transpyloric Shuttle

The TransPyloric® Shuttle (TPS) (BAROnova; Goleta, CA, USA) is similar to the space-occupying devices, but is smaller in size, and is designed to intermittently occlude the pylorus (Fig. 21.8). The device is comprised of a 56 mm ball with a silicone skin connected to a smaller weighted ball by a 4 mm × 96 mm silicone tail [20]. The weight passes into the duodenum, positioning the device across the pylorus. This may create an intermittent seal across the pylorus, delaying gastric emptying, and inducing satiety. The TPS is delivered via endoscopy through an overtube. Once inside the stomach, the delivery device deploys a silicone coil, which coils

Fig. 21.8 TransPyloric Shuttle® in place (Used with permission of BAROnova, San Carlos, CA, USA)

inside the larger ball, assembling the TPS. In a feasibility study [21], 20 patients with a mean BMI of 36.0 kg/m [2] were assigned to have the TPS in place for either 3 or 6 months. The device was placed and retrieved in all patients without complication. Patients in the 3-month group had an average 31.3% EWL, and patients in the 6-month group had an average 50% EWL. There were persistent gastric ulcers in two patients, which resolved with device removal. In total, 50% of subjects developed gastric ulcers. The device has since been updated to address this issue. A pivotal US multicenter trial is underway [20, 22].

Full Sense

The Full Sense™ Bariatric device (BFKW; Grand Rapids, MI, USA) is a fully covered self-expanding nitinol esophageal stent connected to a gastric disc via two struts [22, 23]. The device is placed and retrieved endoscopically. The stent is positioned in the distal esophagus and the disc resides in the gastric cardia (Fig. 21.9a, b). The struts cross the lower-esophageal sphincter rather than a stent, which may preserve its function. The pressure in the distal esophagus and cardia may induce satiety. A feasibility trial in three patients reportedly resulted in 28.5% EWL at 6 weeks [22]. A 6-month follow-up trial of unknown design demonstrated a median EWL of 80%. Similar results were reportedly achieved in a randomized trial with crossover. These results have not yet been published in a peer-reviewed journal.

Vibrynt Prevail

The Vibrynt Prevail® (ExploraMed, Mountain View, CA, USA) (Fig. 21.10) is a space-occupying balloon placed in the abdomen through a small umbilical incision [24]. It is secured in the space between the stomach and the left rib cage, resulting

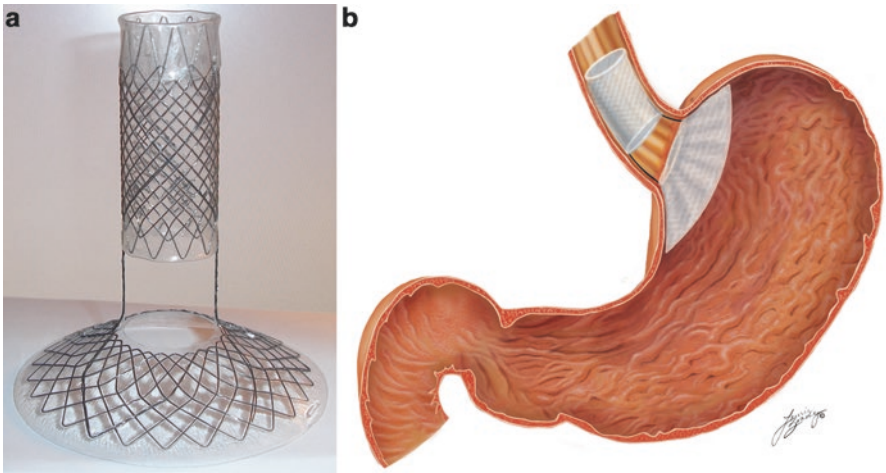

Fig. 21.9 Full Sense™. (**a**) Device. (**b**) Device in place (Used with permission of BFKW, Grand Rapids, MI, USA)

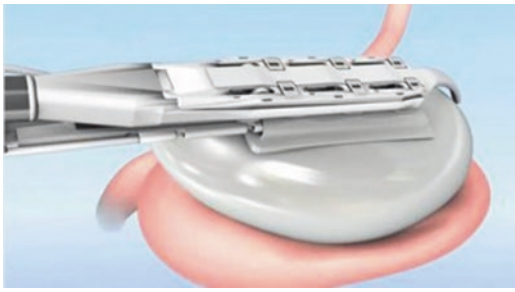

Fig. 21.10 Vibrynt Prevail® implant system in place (Used with permission of ExploraMed, Mountain View, CA, USA)

in external compression of the stomach. A port is left in the incision allowing for adjustment. A pivotal study was reportedly completed with 69 subjects, achieving a mean excess weight loss of 28.3% at 6 months [25]. These data are not currently published in a peer-reviewed journal.

Satisphere

The SatiSphere® (EndoSphere; Columbus, OH, USA) is an endoscopically placed series of mesh spheres mounted along a flexible nitinol shape-memory alloy insert which has a loop on the proximal end from which the duodenal insert hangs. The distal insert with attached spheres is released within the duodenum, and the proximal loop is released within the gastric antrum. The proximal loop floats freely within the gastric antrum, and the circumference of the loop exceeds the circumference of the pyloric valve, thereby serving a self-anchoring function without incisions or staples.

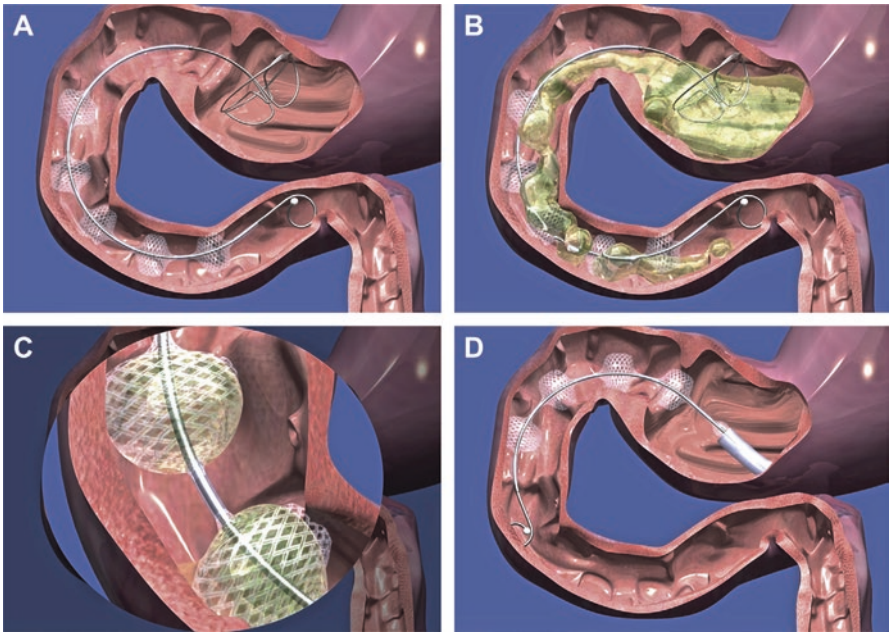

Fig. 21.11 SatiSphere.® (**a**) The device in situ once inserted endoscopically. (**b**) How the device amplifies the body's natural physiological responses to ingesta by increasing contact between ingesta and the neurons lining the duodenum as the ingesta passes through the duodenum. (**c**) A close-up view of how the ingesta grabs onto the porous spheres as it flows through the duodenum, prolonging the contact between the ingesta and the neurons lining the duodenum. (**d**) How the device is fully reversible by being easily pulled into the removal tube endoscopically for removal at the end of the treatment period (All: Used with permission of EndoSphere; Columbus, OH, USA)

See Fig. 21.11 a–d. The device slows duodenal transit, which may alter satiety and glucose metabolism [26]. A 3-month 2:1 randomized study including 21 subjects and 10 controls, whose results were published in 2013, showed a mean excess weight loss of 18.4% in completers. Device migration occurred in ten patients, and two required emergent surgery, which terminated the trial [27]. The device underwent modification following this study.

In 2016–2017, a multicenter prospective 1:1 randomized clinical study was initiated to test the safety and efficacy of the SatiSphere. The protocol called for device-treated patients to receive the device for a 90-day period, while control-arm patients underwent a diet and exercise program and a sham procedure. At the conclusion of the study period, two of the five device-treated patients completed the protocol. Among completers, device-treated patients (n = 2) achieved an average 36.3% excess weight loss, compared with control patients (n = 2) who achieved 2.85% excess weight loss. In three device-treated patients, the device migrated and was defecated without causing deleterious health effects. As a result of device migration, the study was terminated early [28]. At the time of publication, no additional data was available on this device.

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Chapter 22
Index Endoscopic Malabsorptive Procedures in Obesity Treatment: Techniques and Outcomes

Sabrena F. Noria, Sara A. Mansfield, and Dean J. Mikami

Introduction

The obesity epidemic continues since its first description in 1998 [1, 2]. According to the World Health Organization, there are more than 1.9 billion adults who are overweight, of which 600 million are obese [3]. Recently, Danesh and coworkers [4] demonstrated that the risk of mortality increased significantly throughout the overweight range (i.e., BMI of 25–<27.5 kg/m^2 = 7% higher risk of mortality, BMI of 27.5–<30 kg/m^2 = 20% higher risk, BMI of 30.0–<35.0 kg/m^2 = 45% higher risk) and within the obese range (BMI of 35.0–<40.0 kg/m^2) was related to a 94% higher risk. Additionally, every 5 units of higher BMI above 25 kg/m^2 was associated with ~31% higher risk of premature death. Finally, looking at the specific causes of death, the study found that, for each 5-unit increase in BMI above 25 kg/m^2, the corresponding increases in risk were 49% for cardiovascular mortality, 38% for respiratory disease mortality, and 19% for cancer mortality.

As is evidenced by the countless weight loss programs, most adults attempt to lose weight at some point in their life [5]. However, medically managed weight loss is ineffective for prolonged weight loss [6], and bariatric surgery is the only effective long-term weight loss therapy for obese patients [7]. Unfortunately, the number of people who get surgery is a small portion of those who need it. Between 2011 and

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2013, more than a half million people in the USA had bariatric surgery which represents ~1% of the estimated 18 million-plus adults who could qualify for surgery [8]. Therefore, due to the continued need for alternative therapy, transoral/endoscopic approaches to weight loss are gaining traction as they bridge the gap between need and eligibility. Specifically, considering endoscopic approaches are performed exclusively through the gastrointestinal tract, the value of this approach lies in the possibility of ambulatory weight loss procedures that may be safer and more cost-effective compared to laparoscopic approaches. By extension, this may allow bariatric procedures to be performed in those individuals who are currently precluded due to multiple comorbidities, older age, mild obesity (BMI 25–30 kg/m^2), atypical anatomy (e.g., adhesions secondary to previous abdominal surgery, a history of gastric resection, or bowel resection), or disease states that affect the bowel (e.g., Crohn's disease).

Given the surge in endoscopic therapies for obesity, the purpose of this chapter is to review the techniques and outcomes of specific malabsorptive procedures designed to induce weight loss and/or improve metabolic profiles.

Bypass Sleeve Procedures

Bypass sleeve procedures are designed to mimic malabsorptive surgical procedures (i.e., Roux-en-Y gastric bypass, biliopancreatic diversion with/without a duodenal switch) without the inherent risks associated with surgery. Two procedures currently being evaluated are the duodenal-jejunal bypass sleeve and gastroduodenal-jejunal bypass sleeve. These devices work by excluding the interaction of the nutrients with the foregut (i.e., stomach, duodenum, pancreatic, and biliary secretions), thereby decreasing absorption of food. Additionally, these sleeves may affect glycemic control either by exclusion of the duodenum (i.e., foregut hypothesis) or accelerated delivery of nutrients to the distal GI tract (i.e., hindgut hypothesis).

Duodenal-Jejunal Bypass Sleeve (EndoBarrier® Gastrointestinal Liner)

(FDA status: not approved)

The duodenal-jejunal bypass sleeve (DJBS, The EndoBarrier®, GI Dynamics Inc., Lexington, MA, USA) effectively bypasses the proximal small intestine using a 60-cm-long fluoropolymer liner anchored in the duodenum. Under general anesthesia, the device is delivered using both fluoroscopy and endoscopy. Using an over-the-wire catheter system, the implant is delivered contained within a capsule at the distal end of the catheter. Once in place at the duodenum, the inner catheter is pushed and the bowel negotiated with the aid of an atraumatic ball attached to the

Fig. 22.1 Duodenal-jejunal bypass sleeve (EndoBarrier® Gastrointestinal Liner, GI Dynamics, Boston, MA, USA) (Used with permission of Springer Nature from de Moura et al. [29])

distal end of the catheter. The sleeve, which is attached to the catheter, is pulled out of the capsule as the catheter is advanced. Once fully extended, a self-expanding anchor, positioned at the duodenal bulb, is deployed, and barbs engage the tissue to prevent movement. Contrast is flushed to ensure patency of the sleeve, and the sleeve and ball are detached from the catheter, which is removed from the bowel, leaving the implant in place [9] (Fig. 22.1).

Rodriguez-Grunert and coworkers [9] reported on the first prospective open-label single-center trial examining the safety and efficacy of the DJBS. A total of 12 patients were included. The mean implant and explant times were 26.6 and 43.3 min, respectively. The device remained in place for 12 weeks in 10 of 12 patients, with early retrieval (9 days) in 2 patients, related to intractable abdominal pain. Most adverse events related to implantation occurred within the first 2 weeks and included abdominal pain, nausea, and vomiting. During removal, complications included one partial pharyngeal tear and one esophageal tear, both of which were considered minor. Average percent excess weight loss (%EWL) at 12 weeks was 23.6%, with all patients achieving at least a 10% EWL. Finally, of the four diabetic patients, all had normal fasting plasma glucose levels for the entire 12 weeks, three of which had resolution within 24 h of implantation.

Tarnoff and coworkers [10] conducted an open-label, multicenter, prospective randomized control trial comparing the safety and efficacy of the DJBS plus low-fat diet to low-fat diet alone for 12 weeks. The device was implanted in 25 patients and 14 patients comprised the control arm. Both groups received counseling at baseline, consisting of a low-calorie diet, with advice on exercise and behavior modification. Twenty of 25 device subjects maintained the sleeve for 12 weeks. Five patients (20%) had to have the device explanted early due to upper GI bleeding ($n = 3$), anchor migration ($n = 1$), and sleeve obstruction ($n = 1$). The mean %EWL was 22% and 5% for the device and control groups, respectively ($p < 0.001$).

Schouten and colleagues [11] performed a multicenter, randomized clinical trial on the first European experience using the DJBS. Forty-one patients were recruited

of which 30 underwent sleeve implantation and 11 served as a diet control group. All patients followed the same low-calorie diet during the study period. The device was successfully implanted in 86% of patients. In four patients, the device was explanted prior to the protocol end because of migration, anchor dislocation, sleeve obstruction, and continuous epigastric pain. The remaining patients all completed the study without procedure-related adverse events. During the study period, all sleeve patients had at least one minor adverse event, specifically abdominal pain, and nausea during the first week after implantation. Initial mean body mass index (BMI) was 48.9 kg/m^2 and 47.4 kg/m^2 for the device and control patients, respectively. Mean %EWL was significantly greater after 3 months for the sleeve versus control patients (19.0% versus 6.9% [$p < 0.002$], respectively). The percentage of patients who had more than 10% excess weight loss at 12 weeks was 88.0% in the device group and 27.3% in the control diet group ($p < 0.05$). Type 2 diabetes mellitus (T2DM) was present at baseline in eight sleeve patients and improved in seven patients during the study period. At 12 weeks, glycated hemoglobin levels (HbA1c) decreased from 8.8% at baseline to 7.7%.

Gersin and colleagues [12] performed a prospective, multicenter, randomized sham-controlled trial to examine the difference in %EWL at 12 weeks between the experimental (DJBS patients) and control (sham endoscopic procedure) groups. Secondary endpoints included the percentage of patients achieving 10% EWL, total weight change, and device safety. Eight DJBL patients terminated early because of GI bleeding ($n = 3$), abdominal pain ($n = 2$), nausea and vomiting ($n = 2$), and an unrelated preexisting illness ($n = 1$). Thirteen DJBL patients and 24 control subjects completed the 12-week study. Percent EWL, percentage of patients that achieved ≥10% EWL and total weight change, was significantly improved in the DJBS arm compared to the sham group (11.9% versus 2.7% [$p < 0.05$], 62% versus 17% [$p < 0.05$], −8.2 kg versus −2.1 kg [$p < 0.05$], respectively).

Taken together, these preliminary studies demonstrated that the DJBS achieved significant preoperative weight loss compared with standard counseling in candidates for bariatric surgery. Additionally, the procedure was relatively safe in the short-term (12 weeks), but additional studies were warranted.

De Moura and colleagues [13] conducted a 52-week, open-label clinical trial that examined the effect of the DJBS on metabolic parameters in patients with T2DM. Twenty-two patients with T2DM and a BMI between 40 and 60 kg/m^2 were enrolled, and 13 completed the study (59%), with the average duration of the implant period for all subjects being 42 weeks. Reasons for early removal of the device included device migration ($n = 3$), gastrointestinal bleeding ($n = 1$), abdominal pain ($n = 2$), principal investigator request ($n = 2$), and discovery of an unrelated malignancy ($n = 1$).

Baseline fasting plasma glucose (FPG, 179.4 ± 68.8 mg/dL), fasting plasma insulin (FPI, 19.5 ± 14.7 l μU/mL), and HbA1c (8.9% ± 1.7%) were significantly improved by 52 weeks (FPG = −37.1 ± 11.8 mg/dL [$p < 0.01$], FPI = −2.3 ± 0.3 μU/mL [$p < 0.05$], HbA1c = −2.3% ± 0.3% [$p < 0.0001$]), demonstrating that the DJBS could be safely maintained in patients for 1 year and was effective for both weight loss and metabolic parameters in obese subjects with T2DM.

Finally, Koehestanie and colleagues [14] conducted a multicenter randomized controlled trial examining the safety and efficacy of treatment with the DJBS for 6 months and compared it to dietary intervention for obesity and T2DM. Seventy-seven patients were included in the study, 38 were randomized to 6 months' DJBL treatment in combination with dietary intervention (34 successfully implanted, 31 completed the study), and 39 received only dietary intervention (35 completed the study). Total study duration for both groups was 12 months, including 6 months of post-DJBL removal follow-up. Results demonstrated that after 6 months, %EWL and HbA1c levels were significantly improved in the DJBS compared to the control group (32.0% versus 16.4% [$p < 0.05$], 7.0% versus 7.9% [$p < 0.05$]). At 12 months, 6 months after removal of the sleeve, %EWL continued to be significantly improved for the experimental versus control group (19.8% versus 11.7% [$p < 0.05$]), although there was no significant difference in improvement in glycated hemoglobin (7.3% versus 8.0% in the experimental versus control group, respectively [p = ns]). This demonstrated that the DJBL was a valid alternative to invasive bariatric procedures, with effects on weight lasting well after removal of the device.

Interestingly, Maggi and coworkers [15] reported on a late complication of the DJBS, specifically the occurrence of liver abscesses. Their case report outlined the identification and treatment of a liver abscess 10 months after insertion of a DJBS that necessitated a left lobectomy. Indeed, final results from the now discontinued US pivotal clinical trial (ENDO Trial, $N = 325$ of the planned 500) demonstrated that while there was significant improvement in HbA1c, and reduction in body weight, the incidence of hepatic abscesses (3.5%) exceeded the previously established safety threshold of 2% and was much higher than the incidence in markets outside the USA (0.73%) with approximately 3000 units shipped commercially since 2009 [16]. Therefore, the ENDO Trial has been discontinued, and EndoBarrier is not approved for use in the USA. However, GI Dynamics is currently reapplying for FDA approval [17].

Gastroduodenal-Jejunal Bypass Sleeve (ValenTx Endo Bypass)

(FDA status: not approved)

The gastroduodenal-jejunal bypass sleeve (GDJBS; ValenTx Endo Bypass System, Inc., Hopkins, MN, USA) effectively bypasses the stomach, duodenum, and proximal jejunum using a 120-cm-long fluoropolymer sleeve anchored at the gastroesophageal junction, extended through the stomach past the pylorus into the proximal jejunum. As described by Sandler and coworkers [18], a long over-tube is placed through the pylorus, into the duodenal bulb. The GDJBS is delivered via a delivery catheter to the level of the first portion of the duodenum. The sleeve, with an attached polyester cuff on the proximal end, is deployed down through the pylorus using an endoscopic delivery method utilizing computer-regulated pressure and flow monitoring. Fluoroscopic guidance is also utilized to ensure adequate deployment of the sleeve through the duodenum, into the proximal jejunum. Once the

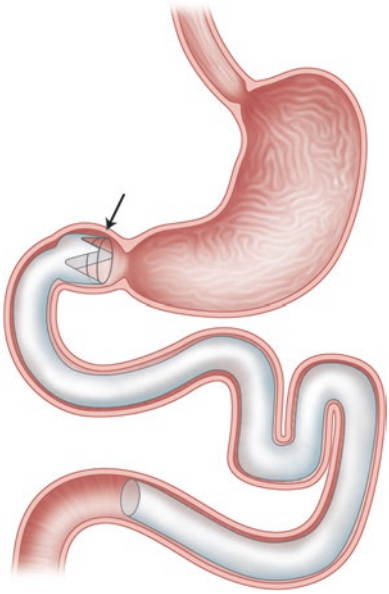

Fig. 22.2 The duodenal-jejunal bypass sleeve (EndoBarrier®, GI Dynamics, Boston, MA, USA) (Used with permission of Springer Nature from Narula et al. [28])

sleeve is adequately deployed downstream into the bowel, the delivery catheter is removed, and the over-tube is exchanged for a shorter one, in preparation for the proximal cuff attachment. The patient is then repositioned, and the abdomen is prepped and draped in standard surgical fashion in preparation for the laparoscopic portion of the procedure. After placement of one 12-mm and three 5-mm trocars, along with a liver retractor, the gastroesophageal junction is dissected circumferentially at the level of the diaphragmatic hiatus, and a Penrose drain is placed to assist with further gastroesophageal junction manipulation. The polyester cuff is then positioned endoscopically at the GE junction. The positioning is completed with the assistance of a removable stent helping to visualize the esophageal lumen at the GE junction. The attachment is performed with eight endoscopically delivered, nitinol-suture anchors, deployed circumferentially, with the assistance of laparoscopic visualization to ensure transmural anchor placement and to avoid any visceral injury. Once the cuff has been anchored, the stent is detached endoscopically and removed through the over-tube, via a drawstring at its proximal end. Following cuff attachment, the left and right diaphragmatic crura are laparoscopically approximated with suture closure (Fig. 22.2).

Sandler and coworkers [18] conducted a single-center prospective trial to examine the safety of the GDJBS with secondary outcomes including the %EWL and change in glucose control, use of antihyperglycemic medications, and changes in hemoglobin A1c levels. Twenty-four patients were enrolled in the study, and the device was successfully delivered in 22 of the 24 patients (92%) and retrieved successfully from all patients. Of the 22 patients who had the device implanted, 17 maintained it (77%) and completed the full 12-week trial. Five patients underwent explantation before 12 weeks due to pain with swallowing during the liquid and/or pureed phase of the

diet. The pain completely resolved at explantation of the device. Of the 17 that completed the study, average starting BMI was 42 kg/m^2 (range, 35.4–50.8 kg/m^2), and mean %EWL was 39.7% (range, 27–64%). In terms of change in comorbidity status, preexisting medical conditions included seven patients with T2DM, two with hypertension (HTN), and three with hyperlipidemia. After the procedure, all diabetic patients stopped using antihyperglycemic medication after 12 weeks, with HbA1c improved in four patients. Additionally, both patients with HTN and those with hyperlipidemia stopped all medications by completion of the study.

Sandler and coworkers [19] further examined outcomes after implantation of the GDJBS for 1 year by conducting a prospective, single-center trial. Thirteen subjects were enrolled, with devices placed in ten patients, all of whom reached the 12-month follow-up. Two early explantations were necessary due to dysphagia or odynophagia, which completely resolved upon device removal. For the remaining ten patients, average %EWL was 35.9%. However, for the six patients that had fully attached sleeves (observed at follow-up endoscopy), mean %EWL, at 1 year, was 54%. In the remaining four patients, partial cuff detachment was observed, and for this group, %EWL was lower. Of those who had comorbidities (four with T2DM, seven with HTN, five with hypertriglyceridemia), mean fasting plasma glucose (FPG) improved by 38%; average decrease in blood pressure was 15%, with five of seven patients off all antihypertensive medication, and there was a 26% decrease in triglyceride levels with four of five patients off all medications. Of the six patients that reached a year with a fully attached device, five were followed at an average of 14-month post-explant (26 months from the time of device implant). These five maintained an average percentage EWL of 30% at the 14-month post-explant follow-up.

These studies demonstrate that the DJBS is an effective and safe device for weight loss in morbidly obese individuals. The short-term weight loss at 1 year and improvement in related metabolic disorders are in keeping with more conventional bariatric surgical techniques. However, given that an endoscopic/laparoscopic approach is currently required to deliver the GDJBS, development of delivery tools that could enable a fully transoral, endoscopic procedure is required to facilitate adoption of this technique. This is currently the focus of investigation and will be the subject of future clinical studies. Continued clinical evaluation, including long-term data and device durability information, is important in establishing the effectiveness of this device in the treatment of morbid obesity.

Gastric Aspiration (A-Tube™ and AspireAssist® Bariatrics)

(FDA status: not approved)

Gastric aspiration involves endoscopic placement of a gastrostomy tube (A-Tube™) and the AspireAssist® siphon assembly (Aspire Bariatrics, King of Prussia, PA, USA) to aspirate gastric contents 20 min after meal consumption. The A-Tube is a thin tube that connects the inside of the stomach directly to a skin port on the outside of the abdomen. The skin port has a valve that can be opened or closed to control the

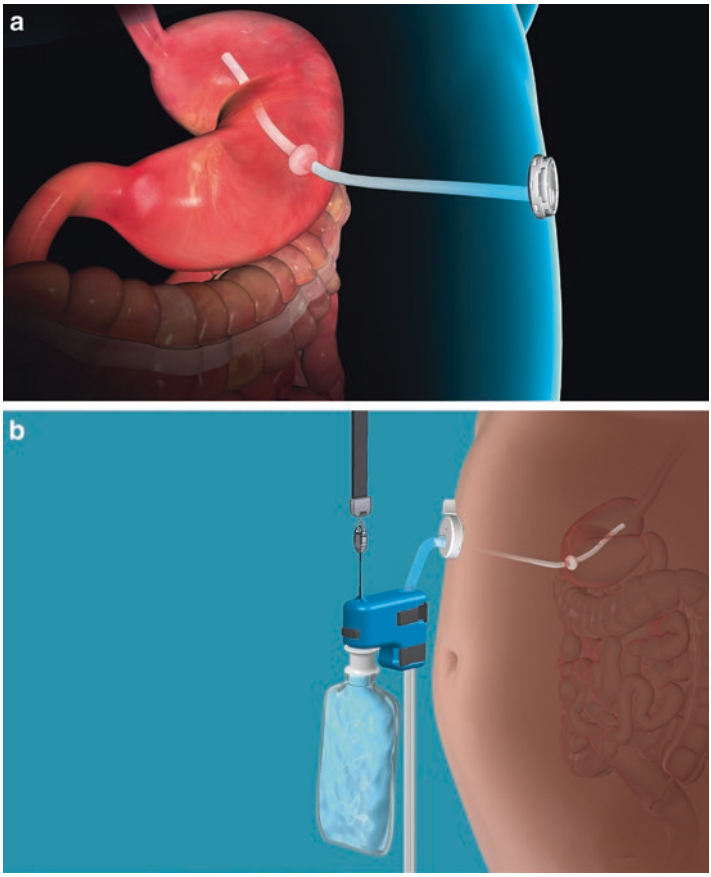

Fig. 22.3 Gastric aspiration (A-Tube™ and AspireAssist® Bariatrics). (**a**). A-Tube and skin port. (**b**) The connector attaches to the skin port and companion that allows two-way flow of fluid. The reservoir contains tap water that allows flushing of gastric contents (Used with permission of Aspire Bariatrics, Inc., King of Prussia, PA, USA)

flow of stomach contents. The patient empties a portion of stomach contents after each meal through this tube by connecting a small, handheld device to the skin port. The components of the system include (Fig. 22.3a, b) [20]:

1. The A-Tube, which has holes in the intragastric portion to allow aspiration of gastric contents.
2. The skin port, which is a flange 3.5 cm in diameter and 0.9 mm in height that connects to the external end of the A-Tube and contains a valve that is normally closed to prevent gastric leakage and is opened by engaging the connector.
3. The connector, which mates with the skin port and opens the skin port valve to allow aspiration of gastric contents. In addition, the connector contains a "counter" that tracks the number of times the connector is attached to the skin

port. When the count reaches 115 aspiration cycles (approximately 5–6 weeks of therapy), the connector locks, and the skin port can no longer be accessed for aspiration. The connector provides an additional safety measure against long-term unsupervised use, and the subject must return to the clinic to obtain a new connector to continue aspiration therapy.
4. The companion, which is a siphon that allows two-way flow of fluids (draining stomach contents and infusing water into the stomach).
5. The reservoir, which is a 600-mL soft water bottle that allows subjects to flush tap water into the stomach to facilitate aspiration.
6. The drain tube, which provides a clean exit of aspirated gastric contents into the toilet.

A-Tube installation is similar to placement of a percutaneous endoscopic gastrostomy tube. Specifically, after completing a full diagnostic upper gastrointestinal endoscopy, the A-Tube placement site is identified by both transillumination of the light from the endoscope and finger indentation in the left upper quadrant of the abdomen. The site is prepped and draped, and a 1-cm incision is made through which the A-Tube is pulled. Placement is verified by reintroduction of the endoscope. Ten to 14 days after placement of the tube, the proximal end of the A-Tube is cut to within 1 cm of the abdominal wall and attached to the skin port. Subjects are given instructions on how to aspirate after meals and proper care and cleaning of the device. Specifically, they are instructed to aspirate 20 min after breakfast, lunch, and dinner whenever the meal contained more than 200 kcal. Aspiration involves flushing food particles through the A-Tube by infusing water into the stomach from the reservoir in 150- to 200-mL increments and then reversing the flow by lowering the lever on the companion to allow contents to drain out of the stomach. This process is repeated as many times as necessary (typically 3–8 infusions) until food particles are no longer seen in the aspirate. This process takes 5–15 min to perform, depending on the size of the meal consumed. Patients are also treated with omeprazole (20 mg orally twice daily) and potassium chloride (20 mEq by mouth twice daily) to reduce acid loss and potential potassium depletion.

Sullivan and coworkers [20] performed a pilot study of 18 obese individuals who were randomly assigned (2:1) to groups that underwent aspiration and lifestyle therapy for 1 year (AT; $n = 11$, mean BMI = 42.6 kg/m^2) or lifestyle therapy alone (LT; $n = 7$, mean BMI = 43.4 kg/m^2). Lifestyle intervention involved a 15-session diet and behavioral education program. The primary endpoint was percent absolute weight loss (% AWL). Secondary study endpoints included % EWL and percentage of subjects achieving ≥25% EWL. After completion of the 12-month RCT, subjects in the AT group were invited to continue participation in the study if they met the goal of >25% EWL. Ten of 11 subjects in the AT group and 4 of the 7 in the LT group completed the first year of the study. After 1 year, %AWL and %EWL were significantly greater in the AT versus LT group (%AWL, 18.6% ± 2.3% versus 5.9% ± 5.0% [$p < 0.021$]; %EWL, 49.0% ± 7.7% and 14.9% ± 12.2% [$p < 0.036$], respectively). However, there was no significant change in weight loss or %EWL from week 52 to week 104 in the 7 subjects who continued aspiration therapy.

There were no serious adverse events in either the LT or AT group. The most common adverse events included parastomal pain after placement of the A-Tube, parastomal cutaneous infections (i.e., candida and presumed soft tissue infection), and nausea with or without emesis after placement of the A-Tube. One episode of hypokalemia occurred (serum potassium concentration of 3.4 mEq/L) due to patient noncompliance with potassium supplementation. Finally, five episodes of A-Tube blockage occurred during the 2-year trial. These were treated conservatively with an endoscopy brush in the outpatient setting. There were no adverse effects of aspiration therapy on eating behavior and no evidence of compensation for aspirated calories with increased food intake. No episodes of binge eating in the aspiration therapy group or serious adverse effects were reported.

Thompson and colleagues [21] performed a 1-year multicenter, randomized controlled trial designed to evaluate the efficacy and safety of AspireAssist for weight management obese subjects (Pivotal Aspiration Therapy with Adjusted Lifestyle [PATHWAY]). Eligible participants were randomized in a 2:1 ratio to 52 weeks of treatment with AspireAssist (aspiration therapy plus lifestyle counseling) or lifestyle counseling alone. Two prespecified co-primary endpoints included (1) mean %EWL at 52 weeks, with success defined as at least a 10% difference in %EWL between the AspireAssist and lifestyle counseling groups, and (2) the proportion of participants who achieved at least a 25% EWL at 52 weeks, with success defined as at least 50% of the AspireAssist group. Secondary endpoints included change in percent total body weight (%TBW) from baseline, proportion of participants who achieved a reduction in total body weight of ≥10%, percent change in systolic and diastolic blood pressures, change in HbA1c, percent change from baseline in serum lipids (triglyceride, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol), and change in the quality of life, assessed by using the Impact of Weight on Quality of Life questionnaire. Safety endpoints included the incidence of procedure-related, device-related, and therapy-related adverse events.

A total of 207 participants were randomized in a 2:1 fashion with 137 to AspireAssist and 70 to lifestyle counseling. However, due to patient withdrawal, the final number of patients was 82 in the AspireAssist group and 31 in the lifestyle counseling group. At 52 weeks, based on a modified intention-to-treat analysis (mITT analysis), mean %TBW loss was 12.1 ± 9.6% (14.2 ± 9.8% for completers only) in the AspireAssist group and 3.5 ± 6.0% (4.9 ± 7.0% for completers only) in the lifestyle counseling group. The difference in the mean %TBW loss between the two groups was 8.6% (95% CI: 6.2–10.9). A greater proportion of participants in the AspireAssist group lost 10% or more of their initial body weight (58.6% vs. 22.0% in the mITT analysis and 69.5% vs. 19.4% in the completer only analysis). Mean weight loss of the mITT population was 14.2 ± 11.3 kg in the AspireAssist group and 4.1 ± 7.2 kg in the lifestyle counseling group. Based on a mITT analysis, participants in the AspireAssist group had lost an average of 31.5% ± 26.7% EBW (37.2 ± 27.5% for completers only), whereas those in the lifestyle counseling group had lost an average 9.8% ± 15.5% EWL (13.0 ± 17.6%

for completers only). The difference in %EWL achieved between groups was 21.7% (95% CI 15.3, 28.1), which was greater than the 10% threshold needed to achieve the a priori definition of success ($p = 0.008$). A greater proportion of participants in the AspireAssist group than in the lifestyle counseling group lost at least 25% EBW (58.6% vs. 22.0% in a mITT analysis and 68.3% vs. 25.8% in a completer only analysis).

Regarding improvements in metabolic parameters, for the AspireAssist group, there was a clinically significant improvement seen in HbA1c (−0.36% relative to 5.7% baseline, $p < 0.0001$), triglycerides (−9.9%, $p = 0.02$), and high-density lipoprotein cholesterol (+8.1%, $p = 0.0001$) at 52 weeks compared to baseline. However, only modest improvements were seen in systolic blood pressure (−1.2%, $p = 0.38$), diastolic blood pressure (−2.6%, $p = 0.06$), low-density lipoprotein cholesterol (−4.2%, $p = 0.06$), and total cholesterol (−2.5%, $p = 0.07$). For the lifestyle counseling group, at 52 weeks, a moderate improvement was seen in HbA1c (−0.22% relative to 5.7% baseline, $p < 0.0001$), while modest or no improvement was seen in triglycerides (+0.1%, $p = 0.62$), high-density lipoprotein cholesterol (+1.7%, $p = 0.55$), systolic blood pressure (−2.5%, $p = 0.17$), diastolic blood pressure (+0.5%, $p = 0.83$), low-density lipoprotein cholesterol (−1.8%, $p = 0.72$), and total cholesterol (−2.5%, $p = 0.28$). The differences in improvement between the AspireAssist group and the lifestyle counseling group were not statistically significant except for glycated hemoglobin.

In terms of impact of weight on quality of life, scores increased in both treatment groups, across all five measures (physical function, self-esteem, sexual life, public distress, and work) with the AspireAssist group showing a greater increase in total score than the lifestyle counseling group ($p = 0.03$).

Finally, ~90% of the study-related adverse events (SAEs) in the AspireAssist group were those known to be associated with percutaneous endoscopic gastrostomy tubes, and approximately half of all SAEs occurred within the first 7 days after A-Tube placement (i.e., abdominal pain, nausea/vomiting). The development of parastomal granulation tissue occurred later, at 1–2 months after A-Tube placement. Most adverse events resolved spontaneously or with standard medical therapy, such as oral analgesics for abdominal pain, oral antibiotics for suspected or documented parastomal infection, and topical silver nitrate for granulation tissue. Five serious SAEs occurred in four participants in the AspireAssist group and included (1) severe abdominal pain treated with hospitalization and analgesia; (2) peritonitis, treated with intravenous antibiotics; (3) prepyloric ulcer; and (4) A-Tube replacement because of skin port malfunction.

Taken together, these results demonstrate that aspiration therapy results in considerable weight loss with minimal adverse events and no evidence of harmful effects on eating behaviors. Given the weight loss efficacy, safety profile, and ability for long-term use, the AspireAssist may help bridge the therapeutic gap between more conservative lifestyle modification and established bariatric surgical procedures for people with Class II and Class III obesity. However, more studies are needed.

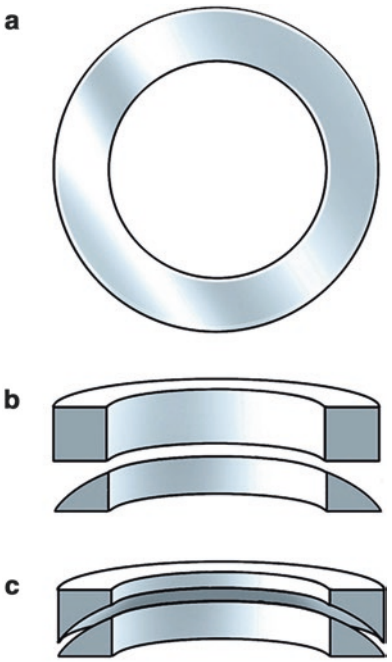

Fig. 22.4 Magnamosis. (**a**) Axial representation of magnamosis device. (**b**) Cross-sectional representation of gradient compression device. (**c**) Cross-sectional representation of uniform compression device (Used with permission of Dr. Michael R. Harrison and Elsevier. From Jamshidi et al. [22])

Incisionless Magnetic Compression Anastomosis [Magnamosis, Inc. (San Francisco, CA, USA) and EndoWindow, GI Windows™ (Bridgewater, NJ, USA)]

(FDA status: not approved)

Magnetic compression-induced anastomosis was designed to create a system that facilitated formation of a suture-less, full-thickness anastomosis that was strong, reproducible, and operator independent. The systems consist of a self-assembling magnetic device designed to create compression anastomoses between hollow viscera via transluminal attraction between the magnets.

Jamshidi and colleagues [22] performed the first feasibility study on pigs by designing a self-orienting device composed of two neodymium-iron-boron magnets affixed to polytetrafluoroethylene moldings. Two topologies were evaluated: one designed with "uniform" compression and the other with "gradient" compression (Figs. 22.4a–c, and 22.5). Sixteen adult pigs underwent laparotomy with creation of a magnetic side-to-side anastomosis. Animals were euthanized at 1, 2, and 3 weeks after operation, and anastomoses were compared on the basis of gross appearance, histology, functional radiography, and mechanical integrity. All magnetic devices formed patent anastomoses without leak. Comparison between device types revealed the gradient device trended toward greater strength and earlier patency (67% vs. 33% at 1 week). There was no evidence of stenosis, and histologic examination demonstrated tissue remodeling with mucosal and serosal apposition across the magnamosis.

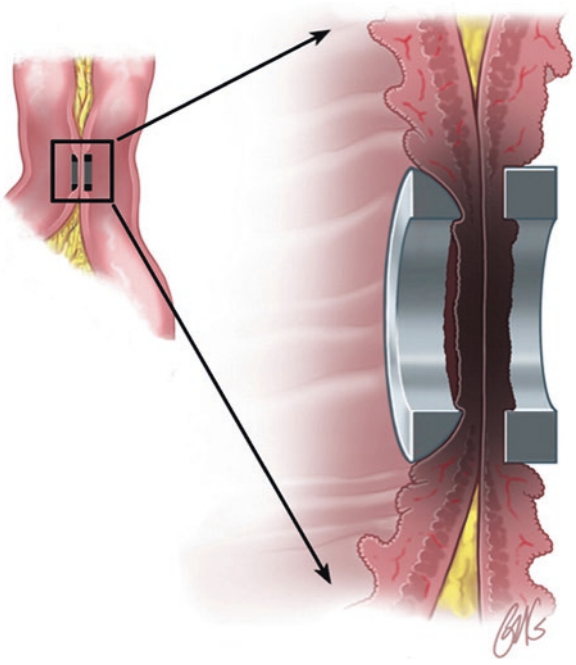

Fig. 22.5 Gradient magnetic device situated in the intestine, depicted in cross section. Greatest compression is applied along the inner circumference with nonlinear radial decrease toward the outer circumference (Used with permission of Dr. Michael R. Harrison and Elsevier. From Jamshidi et al. [22])

This group [23] further developed this technique by conducting experiments to test whether the two magnetic halves (donuts) could be placed and brought into magnetic proximity using minimally invasive techniques and whether the magnamosis could be opened to allow immediate patency. Features of the magnamosis device were (re)designed to incorporate three features: two convex-concave radially symmetric halves that magnetically self-align, a central channel for immediate patency, and specially engineered radial topography of the mating surfaces to promote gradual remodeling (Fig. 22.6). Twenty-one adult pigs underwent either magnetic gastrojejunostomy (GJ, $n = 13$) or jejunojejunostomy (JJ, $n = 8$). Animals were euthanized at 1, 2, 4, and 6 weeks after operation and anastomoses were studied with contrast radiography, burst pressure, and histology. Results for both GJ and JJ anastomoses showed patent, stable anastomoses (by contrast fluoroscopy), which were well-healed at time of sacrifice (by histologic examination), and showed excellent burst strength that equaled or exceeded that of traditional stapled anastomoses.

Finally [24], experiments were designed to further develop this technology to deliver two symmetrical magnetic rings into the upper and lower GI tracts and bring them into magnetic proximity using available endoscopic tools (Fig. 22.7). The device redesign involved creating a magnetic ring casing with a groove to accommodate an endoscopic snare. Using a pig model, colonoscopy was used to deliver one magnetic ring to the hepatic flexure, and upper endoscopy delivered the other magnetic ring into the duodenum. The two rings were brought into magnetic proximity under laparoscopic guidance which assured safe magnet mating of intestinal

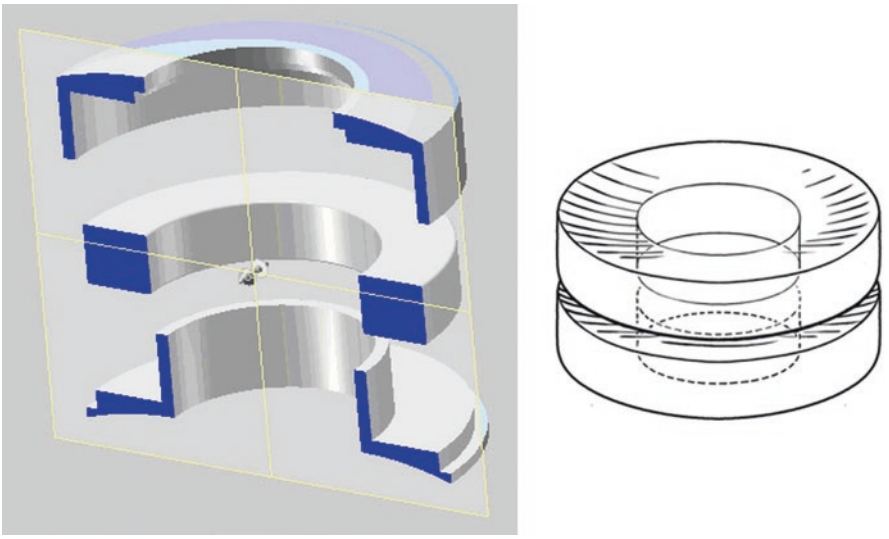

Fig. 22.6 Magnetic compression devices: magnetic donuts (Used with permission of Dr. Michael R. Harrison and Elsevier. From Pichakron et al. [23])

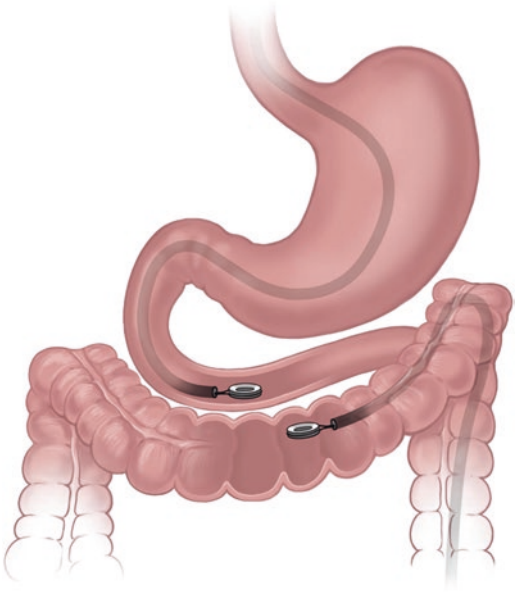

Fig. 22.7 Delivery of magnets using upper and lower endoscopy (Used with permission of Dr. Michael R. Harrison and Elsevier. From Gonzales et al. [24])

segments. The pigs were recovered and examined daily followed by sacrificing at 1, 2, 4, and 6 weeks. The duodeno-colonic anastomoses created with the snare yielded widely patent anastomoses. In vitro testing revealed excellent burst pressure. Histology revealed complete healing as early as 1 week.

Taken together, these studies demonstrate the feasibility of performing suture-less compression anastomoses laparoscopically and endoscopically using temporary magnetic attraction. Application of this technology in the bariatric population, via formation of a magnetic jejunoileal conduit, would create a "shortcut" for upper-gastrointestinal secretions to drain into the distal ileum as a means of increasing GLP, both inducing satiety through the "ileal-break" mechanism and affecting T2DM. Machytka and colleagues [25] conducted the first in-human clinical trial to assess the technical feasibility and durability of a jejunoileal side-to-side anastomosis using the incisionless anastomosis system (IAS). Dual-path enteral anastomoses, using enteroscopy and colonoscopy simultaneously, were performed, and IAS magnets were deployed in their respective lumens. Exact anastomosis location was determined laparoscopically. Ten out of ten anastomoses were created with an average procedure time of 115 minutes. At 2 weeks, upper gastrointestinal series confirmed flow though the anastomosis and expulsion of the magnets. Finally, upper endoscopy at 2 and 6 months demonstrated widely patent anastomoses with no evidence of ulceration. Evaluation of metabolic parameters demonstrated an average of 10.6% TBW loss or 28.3% EWL for the ten patients. Four of the ten subjects started the study with type 2 diabetes (average HgbA1c, 7.8%) and experienced a − 1.8% reduction in HgbA1c. Three of the ten subjects started the study with prediabetes (average HgbA1c, 6.1%) and experienced a normalization of their HgbA1c to 5.25% after 6 months. No SAEs occurred, but most patients had transient nausea and diarrhea that resolved without sequela [26].

These results suggest that suture-less anastomosis using magnetic devices, delivered endoscopically, can produce a clinically significant improvement in weight and diabetes control, with acceptable safety and tolerability. However, further examination of the long-term safety, efficacy, and durability of magnetic-induced anastomoses is required.

Duodenal Mucosal Resurfacing (Revita™ System Fractyl Laboratories, Inc.)

(FDA status: not approved)

Duodenal mucosal resurfacing (DMR; Fractyl Laboratories, Cambridge, MA, USA) uses superficial mucosal thermal ablation to reset diseased duodenal entero-endocrine cells and restore crucial signaling pathways. Rajagopalan and colleagues [27] conducted the first-in-human proof-of-concept study to assess procedural safety and glycemic indices at 6 months after DMR of various lengths. As described in this study, DMR is an endoscopic treatment consisting of intestinal

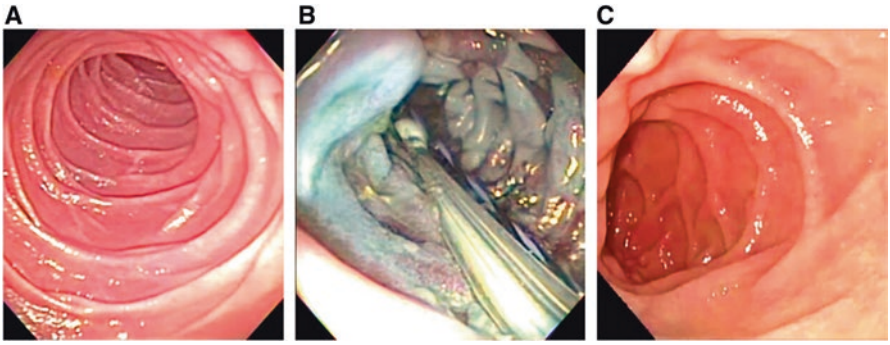

Fig. 22.8 The duodenal mucosa prior to DMR (**a**), immediately after hydrothermal ablation (**b**), and 1 month after the procedure (**c**) as seen during follow-up endoscopy

luminal sizing, submucosal expansion with saline (designed to provide a uniform ablative surface and a thermally protective layer of saline between the ablated mucosa and deeper tissue layers), and circumferential thermal ablation along a length of the duodenum. Polyethylene terephthalate balloon treatment catheters are introduced into the duodenum via a transoral endoscopic approach to determine the size of the duodenum and inject saline into the submucosal space via three vacuum-assisted needle injectors oriented at 120° from one another around the circumference of the balloon. Circumferential mucosal lift is performed along the length of the post-papillary duodenum from 1 cm distal to the ampulla of Vater (hepatopancreatic ampulla) to proximal to the ligament of Treitz. After removal of the initial catheter, a second balloon catheter is introduced to perform thermal ablation on the lifted area. Under direct endoscopic visualization, discrete circumferential thermal ablations of ~10 s each are applied at temperatures of ~90 °C to obtain up to five longitudinally separated ablations along the length of the post-papillary duodenum. Care is taken to avoid the ampulla of Vater to prevent damage to the biliary tree and to avoid treatment in or beyond the ligament of Treitz (Fig. 22.8a–c).

Thirty-nine patients with type 2 diabetes (screening HbA1c, 9.5% [80 mmol/mol]; BMI, 31 kg/m^2) were treated and included in the interim efficacy analysis. Twenty-eight had a long duodenal segment ablated (LS; ~9.3 cm treated), and 11 had a short segment ablated (SS; ~3.4 cm treated). Overall, DMR was well tolerated with minimal gastrointestinal symptoms post-procedure. Three patients experienced duodenal stenosis treated successfully by balloon dilation. HbA1c was reduced by 1.2% at 6 months in the full cohort ($p < 0.001$). A larger glycemic effect was observed among the LS cohort, who experienced a 2.5% reduction in mean HbA1c at 3-month post-procedure vs. 1.2% in the SS group ($p < 0.05$) and a 1.4% reduction at 6 months vs. 0.7% in the SS group ($p = 0.3$). This occurred despite net medication reductions in the LS cohort between 0 and 6 months. Among LS patients with a screening HbA1c of 7.5 ± 10% (58–86 mmol/mol) and on stable antidiabetic medication post-procedure, HbA1c was reduced by 1.8% at 6 months ($p < 0.01$).

These results suggest that a single-procedure DMR elicits a clinically significant improvement in hyperglycemia in patients with type 2 diabetes in the short-term, with acceptable safety and tolerability. Long-term safety, efficacy, and durability and mechanisms of action require further investigation.

Summary

Laparoscopic surgical therapies are effective in achieving significant weight loss and improving obesity-related comorbidities over the long-term. However, as is true of all surgical procedures, laparoscopic approaches to weight loss are not without patient restrictions (e.g., multiple comorbidities, older age, super-obesity, atypical anatomy) and procedural complications. Given the persistence of obesity and limitations of surgical interventions, there is a growing demand for less-invasive approaches. Primary endoscopic approaches are promising in this regard. Indeed, the major advantages of transoral techniques include (1) provision of ambulatory weight loss procedures that may be safer and more cost-effective compared with laparoscopic approaches and (2) circumvention of permanent surgical modification. Therefore, those patients who might be precluded for pathological/physiological or financial reasons may be candidates for weight loss procedures. Additionally, transoral techniques may also be used as a bridge for more definitive weight loss procedures. Specifically, using these techniques may provide a way of identifying those patients who are committed to a more definitive surgical intervention.

Endoscopic treatment for obesity is a rapidly evolving field that shows promising short-term results. However, these should not be viewed as a quick fix. Instead, it is important to remember that many of the preceding technologies are not FDA approved and are still under investigation. Evidence of their safety and long-term efficacy from appropriately designed trials are mandatory before they become part on the growing armamentarium of weight loss procedures.

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Chapter 23
Neurohormonal Procedures in Obesity Treatment

Sara A. Morrison and Sajani N. Shah

Abbreviations

BMI	Body mass index
DBS	Deep brain stimulation
DM	Diabetes mellitus
EWL	Excess weight loss
HbA1c	Hemoglobin A1c
HDL	High-density lipoprotein
LDL	Low-density lipoprotein
TWL	Total weight loss
Vbloc	Vagal nerve blockade

Introduction

While bariatric surgery is a promising option for many obese patients, the potential risks involved and permanent anatomic alterations may make this path prohibitive for some people. Additionally, the number of patients who regain weight after surgery and have exhausted all of these options is not insignificant. Novel approaches to weight loss and obesity-related comorbidities are needed. Safer, less invasive interventions may be ideal for high-risk patients to achieve weight loss as a bridge to bariatric surgery or in order to qualify for other procedures, such as transplants.

Neuroendocrine influences on gastrointestinal regulation and homeostasis have received closer scrutiny in the face of the exploding obesity crisis, particularly as successful bariatric surgery outcomes have been shown to be related to more than just the nutrient restrictions altered directly by the procedure [1]. Neuromodulation was developed on the premise that feeding behaviors largely responsible for phenotypic obesity result from dysregulation in the brain's reward pathway or aberrant

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responses to hormonally regulated sensations of hunger. In this chapter the authors present data from three developing neurohormonal approaches and their potential future applications in achieving sustainable weight loss.

Vagal Blockage

Pathophysiologic Rationale

The vagal blocking device, the vBloc® Maestro Rechargeable System (EnteroMedics, St. Paul, MN), was developed based on reports of weight loss following vagotomy, with the premise that intermittent vagal blockade achieved by arresting ascending and descending neural traffic would reduce sensations of hunger [2, 3]. Regulatory signals from the gastrointestinal tract direct responses from the central nervous system through either the release of hormones into the bloodstream or via afferent signaling from the vagus nerve [4]. Preclinical studies in animals and early clinical investigations in humans have demonstrated weight loss, enhanced satiety, and decreased food intake with vagal blockade that has been sustained over extensive follow-up periods [2].

The device works by delivering low-energy, high-frequency, intermittent, electrical pulses to the vagal trunks as they enter the abdomen, over a given period of time each day [3] (Fig. 23.1). Intermittent vagal blockade is used over permanent blockade to eliminate tachyphylaxis [2]. The device consists of a rechargeable neuroregulator

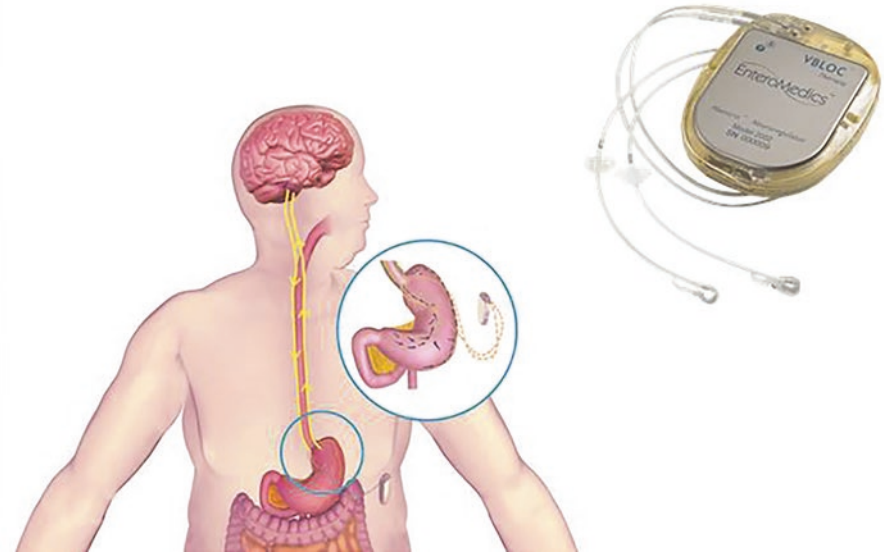

Fig. 23.1 The vBloc® device (Used with permission of EnteroMedics Inc., St. Paul, MN, USA.)

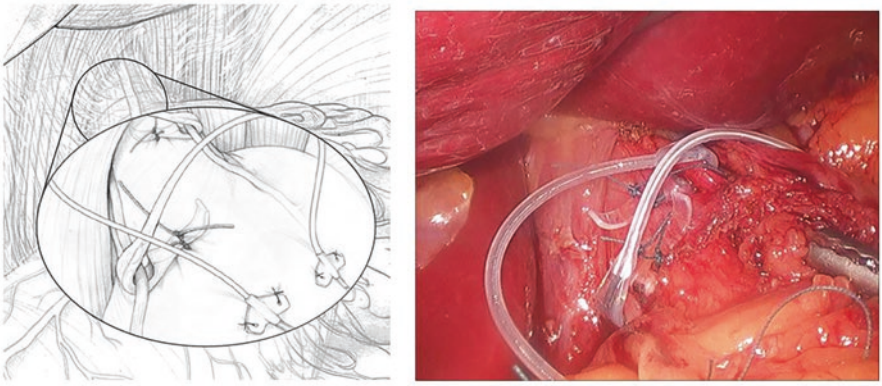

Fig. 23.2 Surgical placement of the vBloc® device (Used with permission of EnteroMedics Inc., St. Paul, MN, USA.)

which is positioned in the subcutaneous tissue on the anterior chest wall and two leads adjacent to the anterior and posterior vagal trunks as they cross over the gastroesophageal junction, which are implanted through a laparoscopic technique (Fig. 23.2). The device is recharged percutaneously [3].

Current Evidence

Clinical trials using the vBloc device have had promising results, demonstrating not only substantial and long-lasting weight loss but also an improvement in obesity-related comorbid conditions. Here we review the current data from the three published randomized controlled clinical trials on intermittent vagal blockage using this device (Fig. 23.3).

ReCharge Study

The ReCharge Study is the most recent publication of vBloc therapy. The study was a multicenter, double-blind, randomized controlled trial that compared the Maestro Rechargeable System to implantation of a sham device. Participants had either a BMI of 35–40 with a related comorbidity or a BMI of 40–45 with or without related conditions. Patients were followed for 2 years, with primary efficacy on weight loss, comorbid conditions, quality of life, and safety outcomes reviewed and published at 12, 18, and 24 months. Data from the final analysis at 24 months are presented here in summary. Devices were designed to deliver at least 12 h of therapy daily, with a goal amplitude of 6 mA, though these settings could be adjusted by investigators in order to tailor treatment to the desired effect or patient tolerability. The average

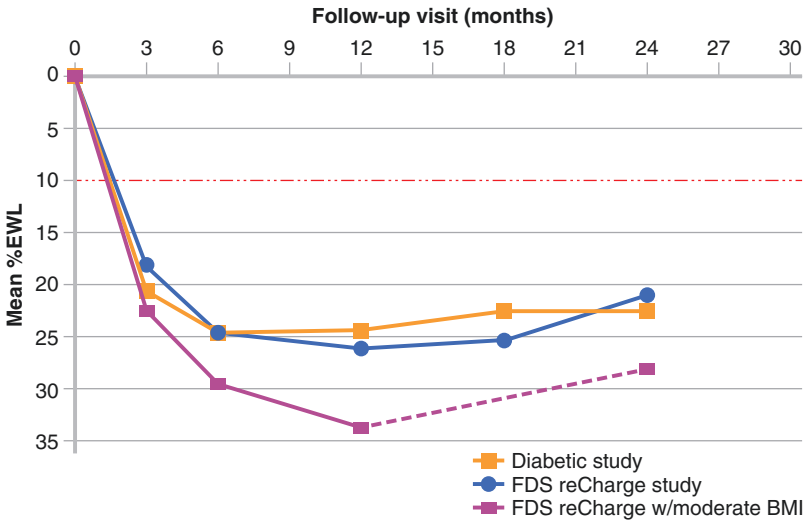

Fig. 23.3 Weight loss with vBloc® (Used with permission of EnteroMedics Inc., St. Paul, MN, USA.)

amount of therapy delivered over the study time period was 11.5 h daily (± 3.2 h), with an average altitude of 5.9 ± 1 mA.

At the 2-year visit, vBloc study patients ($n = 123$) had an average excess weight loss (EWL) of 21% compared to 4% in the sham arm ($n = 77$), though no longer considered to be a valid comparator as a large number of patients initially assigned to this arm had crossed over into the vBloc group by this time or withdrawn from the study. The mean percent total weight loss (TWL) in the vBloc group at 2 years was 8%, compared to 1% of remaining study participants in the sham arm. The vBloc arm saw statistically significant improvements in systolic and diastolic blood pressure (−11 and −10 mmHg), waist circumference (−8 cm), LDL cholesterol (−16 mg/dL), HDL cholesterol (+4 mg/dl), triglycerides (−46 mg/dL), and HbA1c (−0.3%), with the greatest improvements in patients whose baseline parameters were abnormal. Fasting glucose was the only parameter not significantly affected by vBloc therapy. However, at 2 years, 47% of vBloc study patients with metabolic syndrome had resolution of these diagnostic criteria, and 50% of patients identified on recruitment to be prediabetic had normal blood glucose levels at that time. Quality of life measures was significantly improved by vBloc therapy as assessed by the validated questionnaire, the Impact of Weight on Quality of Life-Lite. Significant changes in eating habits were also improved as measured by the Three-Factor Eating Questionnaire measuring cognitive restraint, disinhibition, and sensation of hunger.

The adverse event rate at 2 years was 4.3% with the most frequently reported events being implant site pain and dyspepsia [3].

EMPOWER Study

The EMPOWER study was a multicenter, prospective, randomized, double-blind, controlled trial. Enrolled patients had a BMI between 40 and 45 or a BMI between 35 and 40, with at least one obesity-related comorbidity. All study patients had a vBloc device implanted; however, only the treatment arm had its use activated. Patients were randomized to the treatment group (n = 192) or control group (n = 102). There were 35 serious adverse events reported in this study, though the majority of them were determined to be secondary to a pre-existing condition.

This study did not find significant differences in weight loss, quality of life, or blood pressure between treatment and control arms. However, analysis performed after the study demonstrated that system electrical safety checks resulted in low charges to the system and likely contributed to weight loss in the control arm. Additionally, duration of treatment each day was at the discretion of the individual patient, and there was a statistically significant EWL associated with longer hours of device usage, irrespective of the study group arm. vBloc was demonstrated to be a safe modality for therapy, though early results of weight loss were less promising compared to the control arm, likely secondary to a limitation in the study's design [2].

VBLOC DM2 Study

The VBLOC DM2 study was conducted as a prospective, multicenter, open-label, single-arm exploratory investigation examining the safety and efficacy of vBloc therapy in obese subjects with type 2 diabetes mellitus (DM). Study patients were obese patients with type 2 DM who had failed conventional weight loss measures, BMI between 30 and 40, HbA1c between 7 and 10, diabetes for 12 years or less, and an absence of any systemic complications.

At 2 years, EWL was 22%, and TWL was 6.9% ($p < 0.0001$). Patients had statistically significant reductions in HbA1c (0.6 percentage points), fasting blood glucose (15 mg/dL), systolic blood pressure (−10 mmHg), diastolic blood pressure (−6 mmHg), triglycerides (−64 mg/dL), and waist circumference (−7 cm). No surgical complications were reported. Two serious adverse events occurred, one relating to pain at the implant site and the other secondary to revision due to breakage of a lead [5].

Future Applications

The ReCharge study was a high-impact trial that demonstrated a meaningful therapeutic effect of a weight loss device and resulted in approval of the device by the United States Food and Drug Administration. The collected clinical trials presented here have established vBloc therapy as a safe and efficacious treatment for

obesity and related comorbid conditions, though with a lower EWL profile than that achieved through conventional bariatric surgery. Though TWL reported has been replicated to be about 7% at 2 years, sustained weight loss of even 5% has been demonstrated to have a significant effect on type 2 DM as well as other related comorbidities [6]. vBloc may offer a promising option for obese patients with modestly elevated BMIs associated with comorbid conditions that may not wish to pursue conventional surgical options or who have already failed other surgical approaches.

Deep Brain Stimulation

Pathophysiologic Rationale

An expanding body of literature suggests that eating patterns resulting in obesity may be associated with dysfunction of neural reward pathways. Our growing understanding of neurohormonal and behavioral influences in obesity, like other treatment refractory disorders, has led to an emerging interest in neuromodulation as a novel therapeutic approach [7]. Deep brain stimulation (DBS) is a technique based on implanted electrodes that deliver reversible electrical stimulation to neural targets and has previously been demonstrated to be a safe and effective intervention for a variety of disorders including Parkinson's, epilepsy, major depression, and obsessive compulsive disorder [8–11]. The lateral hypothalamus is traditionally characterized as the feeding center of the brain and regulates control over metabolism and the release of peptides regulating feeding behavior. Overexpression of these peptides has been shown in experimental models to correlate with obesity and insulin resistance, while deficient mice were found to be lean with lowered food intake [12]. Endogenous leptin signaling in the lateral hypothalamus has been shown to restrain the consumption of calorie-rich foods [13]. Animal studies and human genetic analyses have similarly shown that leptin deficiency is associated with a predisposition for obesity [14–16] (Figs. 23.4 and 23.5) .

The nucleus accumbens is at the epicenter of the brain reward circuit and has been the focus of investigation as a target for DBS as a potential therapy for a multitude of behavioral diagnoses including obsessive compulsive disorders, substance use disorders, eating disorders, and obesity [17]. Neural reward pathways are mediated by dopaminergic signaling and affect feelings of craving, reward anticipation, and consumption-driven behaviors. They also mediate the sensation of withdrawal symptoms. All of these converge on the nucleus accumbens [18, 19]. Rodents with chronic exposure to highly caloric palatable diets have increased dopaminergic signaling in the brain and demonstrate increased food consumption with loss of inhibitory regulatory pathways coupled with symptoms of withdrawal, noted by increased stress markers and decreased dopamine levels after removal of high-fat diets [20–23] (Fig. 23.6).

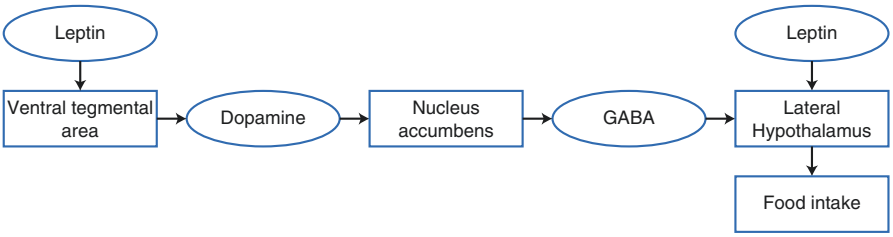

Fig. 23.4 Nucleus accumbens reward pathway

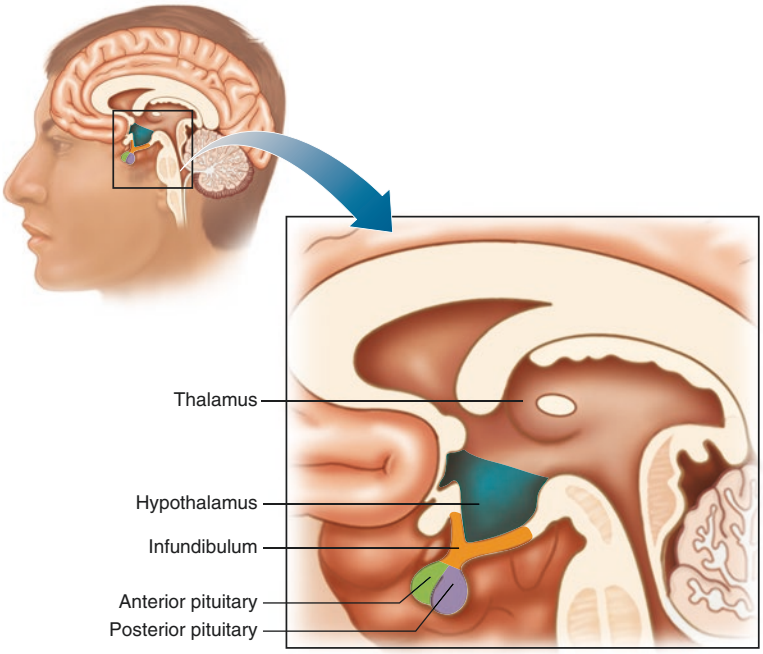

Fig. 23.5 Hypothalamus anatomy

Functional neuroimaging studies in humans following bariatric surgery have found decreased response of the nucleus accumbens to high-calorie food images and altered dopamine receptor binding potential. They have also identified patients at risk for future weight gain who demonstrated altered activation upon intake of richer foods [24–29]. These preliminary data lead the groundwork for clinical and preclinical studies targeting the nucleus accumbens pathway for DBS in the treatment of obesity.

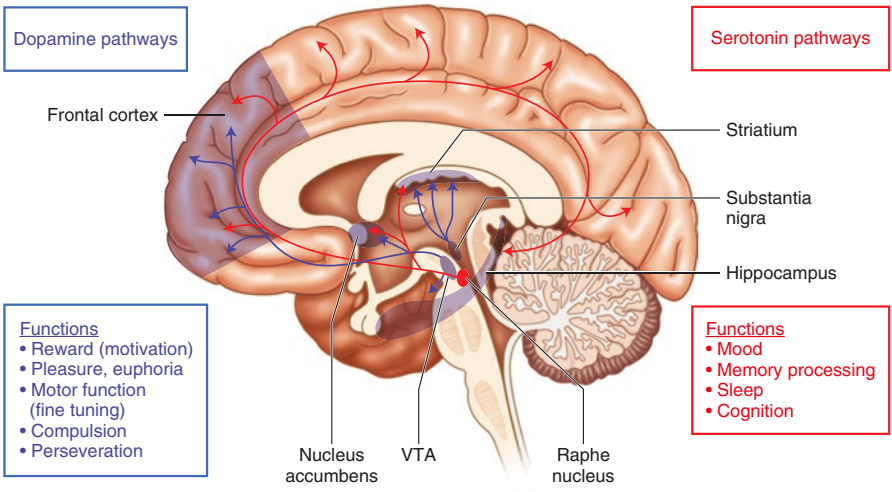

Fig. 23.6 Nucleus accumbens

Current Evidence

Data from early pilot clinical and larger preclinical studies have demonstrated the safety and efficacy of DBS in the treatment of obesity [30–34]. Most of the data in the literature on the use of DBS in the context of eating behavior are somewhat outdated and focus almost entirely on the hypothalamus as a target for therapy, given its dominant role in the maintenance of metabolic homeostasis [17]. Early studies on the lateral hypothalamus demonstrated that lesions of this area produced leanness in rats [35, 36], and data from Parkinson's literature indicated that DBS resulted in clinical effects similar to subthalamotomy [37]. Lesion studies on the nucleus accumbens in rats similarly set a foundation for later DBS studies. Rats given stereotactic 6-OHDA infusions into the nucleus accumbens experienced significant weight loss, and food hoarding behavior was essentially eliminated [38].

Out of 18 animal studies in the literature, mainly on rats, assessing the effect of DBS on food intake and weight, only two targeted the nucleus accumbens [39]. Halpern and colleagues demonstrated that activation of the nucleus accumbens by DBS in a murine model can significantly attenuate binge eating, decrease caloric intake, and result in sustained weight loss and improvements in features of type 2 diabetes [40]. Van der Plasse and colleagues demonstrated a decrease in food intake and sugar motivation [40, 41].

Studies targeting the lateral hypothalamus had mixed results, with stimulation largely resulting in increased food consumption and weight gain [39, 42–46]. One newer study, conducted in 2007, using bilateral stimulation of the lateral hypothalamus, did demonstrate a 16% weight loss in rats [30]. Stimulation of the ventromedial nucleus of the hypothalamus resulted largely in weight loss and decreased food consumption, though this approach too has had mixed results [32, 33, 39, 47–51].

The first pilot study in humans to test the use of DBS in the treatment of obesity was designed by Tomycz and colleagues [52]. This study used the lateral hypothalamus as its target. Preliminary results of this study confirmed that DBS could be used safely in humans to achieve weight loss in metabolically optimized settings [53]. A recent study of DBS of the lateral hypothalamus in three morbidly obese patients who had failed bariatric surgery demonstrated a sustained increase in resting metabolic rate with some weight loss and an absence of adverse consequences either medical or psychological [53]. Currently two clinical trials on DBS for the treatment of anorexia nervosa are ongoing [54].

Future Applications and Ethical Considerations

Further work in future clinical trials will be needed to establish where such approaches will fit within the treatment algorithm for refractory obese patients, develop qualifying criteria for therapy, and guide appropriate patient selection. Bariatric surgery remains the most effective long-term treatment for morbid obesity, and further investigations in postsurgical remodeling of brain reward circuitry and satiety signaling may help identify pivotal neural targets for future therapeutic modulation in obese patients. Emerging identification of biologic markers relating to obesity has been associated with neurocognitive skills [55]. Further characterization of such markers may contribute to identification and early intervention in high-risk individuals. Computational brain network models are also being developed that may be able to predict patient response to different therapies based on collected data from various neuroimaging modalities [56].

Genetic obesity syndromes associated with hyperphagia represent a particularly refractory subset of morbidly obese patients, notably with a concerning risk profile in the context of conventional bariatric surgery given the prevalence of related comorbidities in this population [7]. One such disorder, Prader-Willi syndrome, is the result of a genetic defect on chromosome 15 and creates a phenotype of cognitive disability and excessive hyperphagia, often with insatiable appetites [57]. Over a third of these patients are over 200% of their ideal body weight, and there have even been reports of stomach rupture from overconsumption [58]. Studies have shown that these individuals have dual dysregulation in their reward circuitry as well as subcortical hunger and satiety regions, thereby representing a patient subset that might uniquely benefit from approaches that target these neuromodulation pathways [7].

While early data are promising, the use of DBS in the context of obesity has largely been preclinical. The invasive nature of modulating neural reward pathways raises the concern for the possibility of an imperfect translation to human application on a larger scale [7]. Intervention in these pathways can modulate both conscious and unconscious functions, including self-control and decision making, which at its core is inherently distinct from previous therapies using DBS, for example, to alter motor pathways in the treatment of Parkinson's disease. Simply stated, artificially

altering brain activity is not a trivial undertaking and will likely be fraught with ethical considerations raised both by medical authorities and public opinion [17]. Proposed taxes on high-sugar foods have already been criticized as paternalistic and an "affront against freewill" [17], but neuromodulation proposes to go quite a step further. Rather than increasing the cost of high-calorie foods, it aims to decrease the hedonic value of these foods within a patient's brain [17]. It would follow that such a proposition will almost certainly spark debate in the public forum. Recent social movements promoting the acceptance of overweight and obese body types have also raised questions regarding consciousness of civil rights, free will, and discrimination in these patients [17] who may perceive developing neuroimaging and biomarker technology as stigmatizing and detrimental.

Any attempt at manipulation of the brain's reward circuitry carries a risk of unintended consequences that may not be fully anticipated. Early pilot studies have reported behavioral irregularities with treatment, ranging from emotional hyperactivity and increased impulsivity to suicidal ideation [59, 60]. Additionally, concerns arise for the preservation of a patient's autonomy in this setting. There are essentially four tenets to maintaining autonomy: the ability to understand, evaluate, appreciate, and control one's actions in context. The argument could be made that DBS does not fundamentally interfere with these processes. The aim of DBS treatment is to achieve enhanced self-control regarding food consumption, and it could be argued that the likely benefits of therapy outweigh the potential risks in a carefully selected patient population [7].

Bariatric Arterial Embolization

Pathophysiologic Rationale

Neurohormonal signaling triggers both long-term and short-term regulatory patterns in gastrointestinal homeostasis. Hormones that contribute to long-term regulation affect fat metabolism and energy expenditure and overall weight maintenance, whereas shorter-acting hormones modulate sensations of hunger and satiety and affect the initiation of meals [61]. Ghrelin has gained a substantial amount of attention for its function as the only known appetite-stimulating hormone; it induces hunger, suppresses insulin production, and increases gut motility [61]. Nearly 75% of ghrelin in the body is produced in the fundus of the stomach, in addition to a number of other hormones relating to sensations of hunger and satiety. The left gastric artery provides the primary blood supply to this area, and given the extensive collateral vascular bed serving the stomach, percutaneous, catheter-directed, trans-arterial embolization of the left gastric artery was hypothesized to be safe and well tolerated with the aim of inducing relative ischemia to the mucosa of the gastric fundus, thereby decreasing ghrelin production and ultimately leading to weight loss (Fig. 23.7). Early data on this intervention suggest weight loss results from a

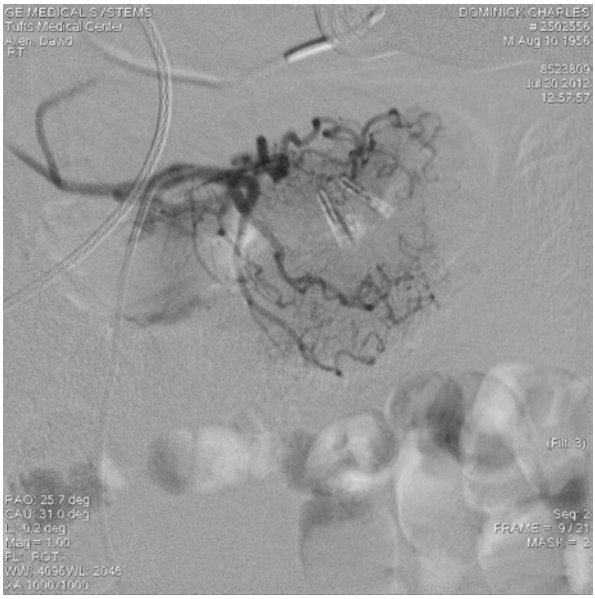

Fig. 23.7 Celiac angiogram

synergistic effect of physiologic and hormonal alterations, involving not only decreased ghrelin production but additionally acid production, gastric motility, and absorption [1].

Current Evidence

Arepally and colleagues [62–65] first explored left gastric embolization in a series of experiments targeting healthy pigs. Pilot studies demonstrated that ghrelin levels could be attenuated by gastric embolization and established a standard dose and sclerosing agent for later trials. Healthy swine underwent either gastric embolization using a sclerosing agent or sham embolization with normal saline. Animals were then allowed to feed freely, while ghrelin and weight levels were followed for 4 weeks following the procedure. Swine having undergone gastric embolization had a significant decrease in plasma ghrelin levels over the study period compared to sham pigs which did not have any change ($p < 0.004$) [63]. Toward the end of the study, ghrelin levels were noted to rise again, and follow-up angiography demonstrated that vessels supplying the fundus at that time had reconstituted. These healthy growing pigs gained less weight over the experimental period compared to their control counterparts ($p < 0.04$), laying groundwork for further investigation of this approach to weight loss.

Other animal studies replicated these results, using different embolic materials, demonstrating that dogs and swine undergoing gastric artery embolization had significantly decreased serum ghrelin levels and lower weight than their sham-matched controls. Safety profiles were similar among studies, without significant adverse events, but some findings of gastritis and delayed gastric emptying were noted. Shallow ulcerations found in the gastric body, though notably not in the fundus, were attributed to nontarget embolizations or possibly secondary to the stress of the procedure itself, as these were also found in sham animals. These findings highlighted the ability of this minimally invasive technique to modulate hormonal changes and weight likely in a collaborative fashion.

Clinical data are currently very limited on gastric arterial embolization. There have been two published studies in humans. The first study was entirely retrospective and reviewed all patients in a single institution who had undergone left gastric artery embolization for gastrointestinal bleeding and compared their weights over 12 years to control patients who had undergone embolization of other celiac branches for the same indication. This small limited study found that patients who had undergone left gastric artery embolization had a mean total body weight loss of 7.3% compared to 2% weight loss by control patients [66].

The only prospective human trial included five patients at a single institution. The left gastric artery was embolized using microspheres. Ghrelin levels and total body weight decreased significantly in this group from baseline. Three of the five patients complained of abdominal pain following the procedure; however, endoscopy performed on follow-up failed to demonstrate any appreciable change in the mucosa [1].

Future Applications

There is a long precedent on the safety profile of left gastric artery embolization for the treatment of gastrointestinal hemorrhage; however, the use of this procedure in an elective setting as an experimental approach to obesity would likely result in significant oversight from the Food and Drug Administration. Though initial data from clinical and preclinical trials are promising, larger clinical trials are needed. Several obstacles remain in the path of initiating this therapy for mainstream use in obesity. A consensus does not yet exist regarding which embolization materials would be ideal, whether small particle or liquid sclerosing agents would provide the best profile to achieve long-lasting vessel occlusion and penetrate smaller capillary vessels while avoiding nontarget embolization and its associated tissue injury. Additionally, concerns have been raised in early studies regarding delayed gastric emptying which can occur following this procedure. This would need to be more formally evaluated. The authors are aware of three small clinical trials currently enrolling patients in early studies to examine the safety and efficacy of gastric embolization for the treatment of obesity. Once an acceptable safety profile is established, larger multicenter prospective randomized controlled studies can proceed [1].

Conclusion

As the number of overweight and obese individuals continues to rise globally, novel approaches are needed in the armamentarium of therapeutic options for these patients to sustain meaningful weight loss and improvements in obesity-related comorbidities. Emerging evidence has demonstrated a strong influence of neurohormonal and behavioral pathways in the development of obesity. Early data from clinical and preclinical studies have demonstrated promising results in neuromodulatory approaches, specifically with regard to vagal blockade, deep brain stimulation, and gastric artery embolization. Larger randomized clinical trials are needed in addition to developing a consensus regarding a standard approach for delivery and ethical considerations of these techniques, but data from existing studies suggest that these methods may offer a safe and effective alternative for achieving weight loss in obese patients.

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Chapter 24
The Genetic and Microbial Influences in Obesity

Sarah Streett and Dan E. Azagury

Introduction

Patients have been told for decades that weight gain and weight loss were the product of a simple energy balance equation. The "calories in–calories out" model considers energy intake and expenditure to be independent parameters rather than interdependent variables, but this is not the case. Furthermore, this equation is missing a modifier that adjusts for individual characteristics in the complex pathways involved in energy intake, metabolism, and storage. The largest contributor to daily energy expenditure is resting energy expenditure (REE), the energy expended when not performing physical work. The primary determinants of REE are fat-free mass and to a lesser extent fat mass, as metabolically active tissues. However, fat-free and fat mass explain only 70% of the interindividual REE variability that is observed. Another 10% can be explained by differences in organ size; however, despite factoring in both body and organ size and composition, a 20% unexplained difference in resting energy expenditure exists between individuals [1, 2].

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Genetics

Genetic variation is undoubtedly an individual modifier in the energy balance equation. More than 140 genetic regions have been identified that influence adiposity, which illustrates the complexity and also the diversity of this disease. Genetic changes that predispose to an obese phenotype can exist in the gene sequence itself as genetic variants or in the variation of gene expression. Interestingly the genetic profiles of people with diffuse adiposity measured by elevated body mass index (BMI) are distinct from those associated with abdominal adiposity measured by elevated waist-to-hip ratio controlled for BMI (WHRadjBMI). Multiple studies have shown that the loci linked to an increased risk of generalized increased BMI do not overlap with the smaller number of loci associated with abdominal adiposity [3]. Regulation of BMI is associated with genes concentrated in the nervous system related to synaptic function, neurotransmitter signaling, and energy homeostasis. In contrast, genes linked to abdominal adiposity function in insulin sensitivity and adipose tissue development. While both types of obesity are associated with disease-related complications, this observed genotypic distinction between generalized obesity and abdominal obesity is an area of focus.

The rapidity of the global obesity epidemic cannot be explained solely by evolving genetic sequence changes. Rather, given the pace of the spread of obesity, the phenomena of epigenetic factors are implicated, where alterations in gene transcription and expression result in long-term changes in cellular or biologic functions. Environmental factors result in epigenetic changes through mechanisms of cell- or tissue-specific DNA methylation or alterations in RNA that influence gene expression and lead to obesity. Studies of epigenetic changes are more challenging than those of genetic sequence variations because they may be tissue or even cell specific and dynamic. While multiple potential triggers such as exposure to antibiotics, changes in dietary fiber intake, carbohydrate composition, food additives, and shifts in the microbiota have been raised, causality of these associations remains to be established. A number of lines of evidence also suggest that epigenetic modifications can occur in utero and may be heritable from either parent.

Other factors that underlie significant differences in the determinants of energy expenditure are now being elucidated. In the last decade, the distinction in mammals between different types of fat and their metabolic activity has come into focus. White fat cells store energy in a single oil droplet and are relatively inert, while brown fat cells have multiple fat droplets along with numerous thermogenic mitochondria. Brown fat was initially identified in infants but was recognized to be present in adults in 2009 [4]. It plays an important role in thermogenesis in response to cold stimuli, mediated largely by a unique protein called UPC1 found on the inner mitochondrial membrane [5]. In addition to increased thermogenesis, brown fat cells are able to mobilize triglycerides and glucose from the blood stream to use as fuel. In contrast, white fat cells store and release energy in the form of fatty acids [6]. If brown fat stores could be better maintained into adulthood, or white fat could

adapt properties of brown fat, so-called beige or brite fat, these would be potential therapeutic approaches to the treatment of obesity in the future.

The evolving understanding of the genetic/epigenetic influences in the development of obesity has involved studies in mouse models which have guided observations in humans. The *FTO* locus was the first genetic region associated with both elevated BMI and diabetes [7]. Studies have suggested that it takes more than one allele change in the *FTO* locus to affect a rise in BMI. Obesity-associated variants in the first *FTO* intron are associated with the increased expression of a nearby gene called *IRX*3. I*RX*3-deficient mice have body weight reductions of 25–30%, a loss of fat mass, an increase in basal metabolic rate, and a browning of white adipose tissue [8]. The mechanism of this was recently elucidated when a particular single-nucleotide polymorphism in the *FTO* region was shown to disrupt the binding of a repressor called $ARID_5B$, which leads to increased *IRX* expression. Increased *IRX* expression induces energy consuming beige adipocytes to become energy-storing white adipocytes [9].

Another compelling development in the role of epigenetics in the obese phenotype is the recent elaboration of an epigenetic switch involved in weight control in genetically identical mice. Mice with a mutation in the Trim28 region, felt to modulate gene expression, display an obesity phenotype in an "on/off" manner [10]. These mice exhibit a bimodal body weight distribution, with genetically identical animals randomly emerging as either normal or obese. The obese-"on" state was characterized by reduced expression of an imprinted gene network called IGN1. Independent targeting of alleles in IGN1 recapitulated the stochastic bi-stable disease phenotype. The investigators then analyzed adipose tissue transcriptomes in humans and found that people also cluster into distinct sub-populations of *Trim28* expression. Subjects with low Trim 28 levels exhibited a greater incidence of obesity and alterations in IGN1 dysregulation. Furthermore, analysis of monozygotic twins who are discordant in obesity showed reduced Trim28 levels and IGN1 gene expression in the obese twins.

Microbiome

Another frontier of exploration which may offer keys to the obesity equation is role of the intestinal microbiota. The mammalian gut microbiota belongs predominantly to four bacterial phyla: the Gram-negative *Bacteroidetes* and *Proteobacteria* and the Gram-positive.

Actinobacteria and *Firmicutes*. The microbiota of the gut rival the total number of human cells and influence the host in multiple ways: nutrient metabolism, maintenance of the intestinal barrier, and modulation of the gastrointestinal immune system. The intestinal microflora is estimated to contain 150-fold more genes than the human genome [11]. As in the field of genetics, much of what has been learned comes from work in rodent disease models. In mice, shifts in microbiota have demonstrated a causal role in the development of obesity. Over a decade ago, it was

shown that germ-free mice are protected from developing obesity in response to eating a Western diet [12].

The composition of the microbiota is unique for each individual and has both a heritable component and a significant environmental contribution. Across many aspects of health, gastrointestinal microbial diversity is associated with less risk for disease. The typical Western diet comprised of increased refined carbohydrates, processed foods, animal protein (potentially containing antibiotics), and low complex carbohydrate plant-based fiber, is associated with decreased microbial diversity. Decreased microbial diversity has been shown to be associated with obesity and type 2 diabetes [13]. Specific dietary intake has a profound influence on microbial composition. In mouse models, changing from a low-fat plant polysaccharide diet to high-fat and sugar diet has been shown to shift the structure of the microbiota in a single day, with ensuing alterations in metabolic pathways and increased adiposity [14]. Food emulsifiers such as carboxymethyl cellulose and polysorbate-80 which are common in processed foods have also been shown to have a deleterious impact on the microbiota in mice and associate with metabolic syndrome [15].

The interplay of environmental influences remains to be fully elucidated. Cho and Blaser showed that mice fed subclinical levels of antibiotics became fat and had alterations in lipid and cholesterol metabolism [16]. Work in the leptin-deficient ob/ob mouse model demonstrated that, compared with wildtype or ob/+ siblings fed the same diet, the ob/ob obese mice had a marked reduction in *Bacteroidetes* species and a proportional increase in *Firmicutes* [17]. This alteration was subsequently shown to be associated with an increased capacity to harvest energy from their diet. Furthermore, the obesity phenotype was transmissible to germ-free mice by fecal transplant from the microbiota of the ob/ob obese mice [18].

A compelling study by Ridaura and colleagues then asked if fecal transplant from humans with obesity could confer an obese phenotype in mice. They identified human twins discordant in obesity and found that fecal transplant from the obese twins caused obesity in germ-free mice, in contrast to FMT from the lean twins. This phenotype was also characterized by genetic and metabolic changes in the host including increased production of short-chain fatty acids. They then co-housed obese mice with lean and showed that invasion of the lean microbiota into the obese mice took place and protected them from becoming obese when fed a diet low in saturated fat and high in fiber. Interestingly this protection from the invasion of the lean microbiota was not conferred when a high-fat/low-fiber diet was given [19]. While *Bacteroidetes* were the predominant identified invading species, addition of a non-fecally derived culture collection of bacterial strains was not able to offer this protection against the obese phenotype.

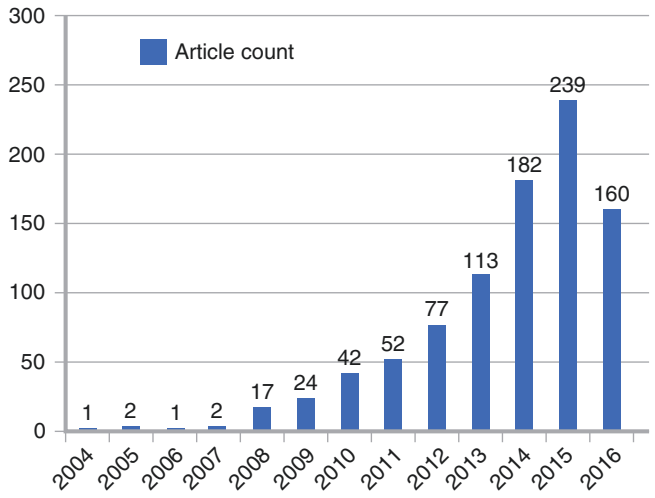

Fig. 24.1 Number of articles references in PubMed over time: "gut microbiota and obesity" in human subjects

Microbiome in Obese Humans and Patients Undergoing Bariatric Surgery

The influence of the gut microbiota on obesity has been an increasing area of study in human subjects over the last decade. While publications on the topic were nonexistent in 2003, PubMed references 239 publications in 2015 (Fig. 24.1). This very recent interest has been enabled by the ability to study these bacteria at a new level. Prior understanding of the microbiota was limited by the need to culture bacteria to identify organisms. Novel techniques allow the sequencing of all of the 16S RNA sequences, and even sequencing of entire genomes, allowing characterization of the microbiota [20]. Potential mechanisms by which microbial composition might influence the propensity for obesity in humans include dietary nutrient metabolism, production of microbial metabolites, hormonal signaling, and immunologic alterations of the human host.

While establishing a causal role of the gut microbiota in obesity remains to be determined, bariatric surgery has offered a unique research ground. The predictable shift between obesity and non-obesity has allowed researchers to study variations in the intestinal microbiome in this unique patient population. Similar to the animal model data discussed above, differences between the microbiome in lean and obese individuals seem to lie, at least in part, in the *Bacteroidetes* to *Firmicutes* ratio (B/F) and the increased capacity of the *Firmicutes* to harvest energy from our diet. Changes have been shown to significantly affect the *Proteobacteria* phyla as well. Some of the most important findings of these studies are summarized below.

Zhang and colleagues published a study in 2009 evaluating three normal weight, three obese, and three post-RYGB patients (8–15 months postop). In their study,

Firmicutes were dominant in normal weight and obese individuals but significantly decreased after RYGB, with a proportional increase of Gammaproteobacteria [21].

Graessler and colleagues studied six type 2 diabetic patients before and 3 months after RYGB using metagenomic sequencing. They observed a significant increase in *Proteobacteria* and decrease in both *Firmicutes* and *Bacteroidetes*. However, similarly to the B/F ratio mentioned in other studies, the *Proteobacteria to Firmicutes* ratio increased significantly after RYGB [22].

Damms-Machado and colleagues compared patients following laparoscopic sleeve gastrectomy (LSG) and very-low-calorie diet (VLCD), over 6 months. This showed a significant increase in B/F ratio following LSG and significant decrease after VLCD [23].

Ilhan and coworkers recently confirmed that changes in the microbiome differed among bariatric procedures. Approximately 3 years postop, patients' microbiome had greater diversity after RYGB than after gastric banding. Post-RYGB patients also had a significantly different microbiome compared to preoperative controls [24].

In a more comprehensive study, Tremaroli and coworkers studied alterations in the microbiota 9.4 years after Roux-en-Y gastric bypass (RYGB) and vertical banded gastrectomy (VBG). These patients were randomized to either procedure as part of a clinical trial and were compared to nonoperated morbidly obese subjects. They found significant differences in microbiota composition for RYGB versus obese controls samples but not for VBG versus controls. The difference resided in increased abundance of Proteobacteria in RYGB vs. controls. They then transplanted the fecal microbiota of each group into germ-free mice. Over the next 2 weeks, the RYGB and VBG microbiota colonized mice accumulated 43% and 26% less body fat, respectively, than mice colonized with microbiota from the control group [25].

The overall findings of these studies are still somewhat divergent. However, it seems clear that changes in microbiome are involved at some level in obesity. The influences of the presence of each bacterial type and changes in relative proportions are still unclear. However, these changes are present after bariatric procedures and at are at least in part dependent on the procedure type. They also appear to be different from the shifts seen after dietary modifications. This could in part explain the difference between weight maintenance and regain after surgery versus dietary modifications. Further studies are both expected and eagerly anticipated in this rapidly evolving field.

Therapeutic Targets and Future Treatments

Studying the effects of RYGB has allowed us to better understand hormonal aspects of both satiety and glucose homeostasis. Some of these findings have even translated into therapeutic agents such as GLP-1 agonists. As we investigate the effects of bariatric surgery on the microbiome, the hope is that novel findings could develop

into therapeutic targets. The first line of treatment envisioned is probiotics. It would make intuitive sense that providing the gut with bacteria associated with low inflammatory states or leanness could be a safe avenue for therapeutic weight loss.

At this time, trials aiming to change the gut microbiome using probiotics have not yet yielded results in terms of significant weight loss in obese individuals. Two recent reviews and meta-analyses concluded in favor of a "limited efficacy of probiotics," in the setting of low quality data. However, the clinical impact of these therapies was weak: the reported mean reduction in weight was 0.59 kg, and reduction in BMI was 0.49 and 1.77 kg/m^2[26, 27]. A study by Sharafedtinov and coworkers titled "Hypocaloric diet supplemented with probiotic cheese improves body mass index […}" concluded there was a statistically significant difference in BMI. However, the clinical significance was not evident: after a 3-week diet, baseline BMI decreased from 37.6 ± 4.3 to 35.7 ± 3.8 in the probiotic group vs. 36.3 ± 4.3 to 34.7 ± 4.2 in the control group [28]. Two larger randomized control trials studied have examined different probiotics. One study used *Bifidobacterium* in 137 patients over a 12-week period and demonstrated no change in weight or BMI but did show some reduction in visceral fat compared to placebo [29]. The other study used *Lactobacillus* in conjunction with energy restriction (reduction of ~500 kcal/day) for 12 weeks. This was followed by a weight maintenance phase for 12 weeks. They recruited 125 patients and 93 were available for analysis at the end of the 24 weeks. There was no difference in weight loss between the probiotic and placebo groups. However, there was an increase in weight loss and fat loss in women at both time points: at 24 weeks the average weight loss was −2.5 kg in the placebo group vs −5.2 kg in the probiotic group. Of note, there was no correlation with the abundance and prevalence of the *Lactobacillus* in feces between sexes [30].

Kadooka and coworkers used fermented milk containing another *Lactobacillus* strand in overweight Japanese patients (avg. BMI 27 kg/m^2). At the end of 12 weeks, mean BMI decrease was −1.6 kg/m^2 in the probiotic group vs. increase of 0.3 kg/m^2 in the control group. Of note, 4 weeks after the end of the treatment BMI decrease in the treatment group had shrunk from −1.6 kg/m^2 to −0.6 kg/m^2 [31]. One study was specific to bariatric surgery and also used a *Lactobacillus* sp. for a period of 6 months after RYGB. They demonstrated a short-term improvement in weight loss in patients given probiotics. At 3 months, the average excess body weight loss was 38.55% in the control group vs. 47.68% in the probiotic group. However, at 6 months, the difference was no longer statistically significant [32].

While some data have been encouraging, our knowledge of the microbiome is still evolving, as is its potential use as a weight loss therapy. As our understanding of the microbial "culprits" and mechanistic shifts are still unclear, finding the appropriate probiotic to study is the first challenge in designing future therapeutic trials. Even if the ideal bacterial agents are identified, not all species can be ingested and survive the proximal GI tract. Therefore, another avenue for exploration is to modify the microbiome already present using prebiotics, agents that induce change in the composition or the activity of the microbiome. Studies to date have demonstrated that these agents are able to modify the host microbiome. For example, Dewulf and colleagues have used inulin-type fructans in obese women for a 3-month

period. The prebiotic group had a significant increase in Firmicutes and Actinobacteria and a decrease in Bacteroidetes compared to placebo. Although there was a trend toward decreased fat mass in the prebiotic group, there was no significant impact on overall weight [33].

Fecal transplant is another means of altering the intestinal microbiome as a potential bariatric intervention, as demonstrated by the animal studies described above. The only human trial to date is a study by Vrieze and colleagues. They studied fecal transplant from lean humans to male recipients with metabolic syndrome. Six weeks after transplant, patients developed increased insulin sensitivity when compared to autologous infusion, along with a change in levels of butyrate-producing intestinal microbiota [34]. Clinicaltrials.gov currently lists approximately eight studies regarding obesity, metabolic syndrome, and fecal transplant, some still focusing on the safety of the procedure. It is therefore likely that substantial results won't be available for several of years.

Conclusion

The gut microbiome certainly plays a role in obesity. However, we still have divergent data as to what types of bacteria are implicated in both obesity and potentially weight loss. Furthermore, the mechanisms underlying how shifts in microbial composition impact energy metabolism have yet to be explained. Some attempts at modifying the microbiota have yielded encouraging preliminary results even if the impact was clinically limited. Early data point to a potential role in maintenance of weight loss that could be a valuable application for future therapies, both after diet or surgically induced weight loss.

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Chapter 25
The Role of Preoperative, Intraoperative, and Postoperative Diagnostic Endoscopy in Bariatric Surgery

Samantha R. Witte and Eric M. Pauli

Introduction

The increasing prevalence of morbid obesity worldwide has resulted in a steady rise in the number of surgical interventions designed to facilitate lasting weight loss. Procedures such as the Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), adjustable gastric band (AGB), and duodenal switch (DS) are among the surgical options currently available to patients. Each procedure varies in its indications, outcomes, and potential complications. Endoscopic evaluation of the bariatric patient is a necessary tool for patient and procedure selection, for intraoperative assessment of surgical integrity, and for the diagnosis and management of postoperative complications. This chapter reviews the role of diagnostic esophagogastroduodenoscopy (EGD) in the bariatric surgical patient.

Preoperative Endoscopy

The routine preoperative endoscopic evaluation of patients prior to a planned bariatric procedure remains a controversial topic in the literature. Debate exists between the clinical utility of routine screening endoscopy in comparison to selective endoscopic evaluation of those patients presenting with symptoms of a gastrointestinal disease (e.g., reflux, peptic ulcer disease, dysphagia) or with a history of gastrointestinal tract pathology (e.g., Crohn's disease, portal hypertension) or prior surgery (e.g., hiatal hernia repair and/or fundoplication) [1]. While endoscopy is generally safe in the bariatric population, it is important to consider that both sedation and

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general anesthesia in the morbidly obese patient carry a higher risk of procedure-associated adverse events, generally related to obstructive airway disease and aspiration (from higher intra-abdominal pressure leading to reflux) [2].

Over the last two decades, there has been an increase in the incidence of both gastroesophageal reflux disease (GERD) and esophageal adenocarcinoma, which some have proposed to be a result of the obesity epidemic [3]. A BMI of 25–30 kg/m^2 is associated with a 1.43-fold greater odds ratio of esophagitis and a 1.94-fold greater odds ratio of esophageal adenocarcinoma [3]. A BMI >30 kg/m^2 is associated with a 1.94-fold greater odds ratio of esophagitis and a 2.78-fold greater odds ratio of esophageal adenocarcinoma [3]. While an elevated cancer risk might be interpreted as an indication for routine preoperative screening endoscopy [4–6], several authors have demonstrated an overall low clinical benefit to such screening exams. While abnormalities are often apparent on endoscopic evaluation, only rarely do they delay or alter the original planned bariatric intervention [4–8]. A meta-analysis by Bennet and colleagues noted the proportion of findings which impacted surgical management to be 0.4%, once benign findings such as gastritis and hiatal hernias were excluded [7]. This results in a very high number of endoscopies that must be performed in order to diagnose a low number of truly clinically significant findings. In a recent series of patients being evaluated before bariatric surgery, only one major finding was noted in 523 consecutive patients [8].

Overall, there is poor correlation between the incidence of abnormalities detected endoscopically and clinical symptoms [9, 10]. For example, a patient with a small hiatal hernia diagnosed endoscopically may not undergo formal repair if the hernia is asymptomatic or too small to be detected laparoscopically [11]. In contrast, in the super morbidly obese, the esophageal fat pad can obscure an otherwise clinically significant hiatal hernia, and in these instances endoscopy can be a useful diagnostic tool to alert the surgeon of the need to do a more formal hiatal dissection and repair.

The reported incidence of abnormal findings impacting surgical planning varies greatly across the literature, with a range of 0.4–7.8% [7]. This broad range can best be explained by the variability in the definition of clinical significance between studies and whether or not medical therapies such as treatment of *H. pylori* are included. A series of 319 patients who underwent routine evaluation prior to undergoing RYGB had a 47% incidence of abnormal endoscopic findings but only a 3% rate of alteration of the surgical plan [12]. Other studies of screening EGD, by contrast, have shown up to a 22% rate of change in operative planning or technique as a result of the preoperative endoscopic findings [13]. The vast majority of these changes involved the decision to perform a RYBG rather than a SG in the setting of gastroesophageal reflux disease, the severity of which was not described.

When new medical management was instituted as a result of screening EGD, 76.4% of the time, it was related to the diagnosis and treatment of *H. pylori*, with the initiation of proton pump inhibitors being included in this positive sample [7]. However, since *H. pylori* can be detected, eradicated and confirmed to be eradicated without the need for endoscopy (by less invasive tests such as stool antigen and the urease breath test), this is not necessarily a clinically significant endoscopic finding.

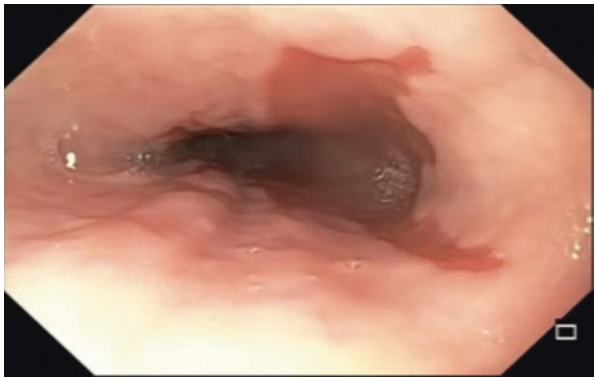

Fig. 25.1 Long-segment Barrett's esophagus seen on white light imaging in a patient undergoing selective endoscopic evaluation prior to bariatric surgery

The importance of a preoperative *H. pylori* diagnosis itself also can be debated. While there are some data to suggest that *H. pylori* colonization may contribute to postoperative complications such as marginal ulcer formation or erosive gastritis, other studies have demonstrated no relationship between *H. pylori* status and these conditions [9, 14]. The prevalence of *H. pylori* has been found to be similar between patients undergoing RYGB and the general population with a rate of 22.4% in the bypass population [14].

There may be a difference in preoperative management strategies for patients scheduled to undergo divided versus nondivided bariatric procedures. For patients in whom the planned operation involves complete division of the foregut, such as RYGB or DS, some consideration must be given to the technical limitations of postoperative diagnostic endoscopy (i.e., the excluded stomach and/or duodenum can no longer be easily evaluated endoscopically). As a result, the threshold for preoperative endoscopy in RYGB and DS patients should be lower than that for a patient scheduled to undergo SG or placement of an AGB [11, 15]. Arguably patients with known gastric, duodenal, or biliopancreatic pathology should not undergo divided bariatric procedures, as a result of these postoperative difficulties in reaching the excluded portions of the foregut without more complex means (such as balloon-assisted enteroscopy or laparoscopic-assisted endoscopy).

Additional consideration must be given to procedure selection in patients with a history of severe GERD, esophagitis, or known Barrett's metaplasia of the esophagus (BE) (Fig. 25.1). There are mixed data regarding the safety of performing SG in patients with severe GERD or esophagitis, as this procedure has been shown to both exacerbate preexisting reflux disorders and generate reflux de novo, possibly placing such patients at higher risk for the development of BE [16]. While the esophagus can continue to be surveilled regardless of the bariatric procedure performed, sleeve gastrectomy precludes future use of a gastric conduit for reconstruction following esophagectomy for adenocarcinoma. As such, some treat BE as a theoretical contraindication for SG [17]. However, the overall rate of progression of BE to esophageal adenocarcinoma is low, and with the modern advent of endoscopic therapy for BE

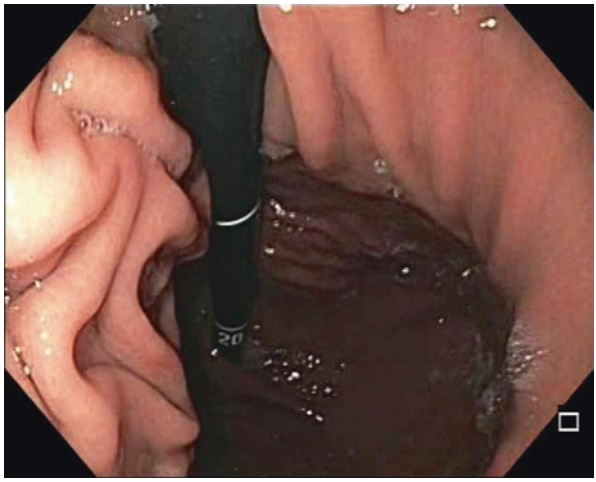

Fig. 25.2 Retroflexed view of the gastroesophageal junction demonstrates a large hiatal hernia in obese patients with reflux undergoing endoscopic evaluation prior to bariatric surgery

(including radiofrequency ablation, cryotherapy, endoscopic mucosal resection, and endoscopic submucosal dissection), this fear may be over exaggerated.

In contrast, RYGB has been shown to decrease the severity of GERD symptoms and so may be considered the preferred option for weight loss surgery in obese individuals with preexisting esophagitis or BE. The decision to pursue RYGB initially in patients with severe GERD may decrease the need for revisional surgery in these patients, who could otherwise return with worsened reflux following SG [18]. While conversion of SG to RYGB remains an option for management of severe reflux symptoms postoperatively, having an accurate preoperative endoscopic evaluation may help inform the decision-making process for both surgeon and patient. For example, some authors have reported the safety and efficacy of SG in patients with GERD who undergo concomitant repair of a hiatal hernia when present [19]. While endoscopy has been shown to potentially over-diagnose small hiatal hernias which are not clinically significant, it is accurate for the detection of moderate and large hiatal hernias [11]. Preoperative knowledge of the size of the hernia and any complications or reflux (e.g., esophagitis or BE) therefore becomes much more critical in these patients (Fig. 25.2).

While the use of routine screening endoscopy is not required prior to the performance of bariatric surgery, in patients with a history of GERD or other ongoing gastrointestinal complaints or with a known history of GI tract pathology, its selective use can be an effective tool to evaluate the primary complaints, as well as guide the decision of which bariatric procedure to perform. This is especially relevant in the case of a patient scheduled to undergo a divided bariatric procedure, where gastric and/or duodenal pathologies may otherwise be challenging to diagnose postoperatively.

Intraoperative Endoscopy

Intraoperative endoscopy is a useful adjunct to most, if not all, bariatric procedures. Endoscopy is commonly used to perform leak testing following creation of a gastric sleeve or a gastroenteric anastomosis (Fig. 25.3a, b). While leak tests can be performed by instilling the gastric pouch or sleeve with air or dye-colored fluid via an orogastric (OG) tube, endoscopy has specific advantages for this purpose. Alaedeen and colleagues demonstrated the superiority of intraoperative endoscopic evaluation by diagnosing twice as many intraoperative staple line leaks via endoscopic insufflation compared to OG tube insufflation. This resulted in a statistically significant decrease in the rate of their postoperative leaks in the endoscopy group (0.5% endoscopy vs 4% OG group, $p = 0.04$) [20]. The increased sensitivity of leak testing with endoscopy coupled with the therapeutic potential of endoscopic repair of identified leaks makes this a powerful tool. Intraoperative diagnosis of a leak allows for immediate correction, either via additional laparoscopic staple firings or suture placement or endoscopic management with the placement of clips or sutures (Fig. 25.4a, b).

Another benefit of intraoperative endoscopy is the ability to evaluate bariatric surgical anatomy in real time. Endoscopy can be used to assess the configuration of a sleeve to evaluate for kinks or strictures that may contribute to postoperative complications such as nausea or obstruction [21]. The incisura is a common point of stricture following sleeve gastrectomy, the risk of which may not be fully appreciated laparoscopically but may be more apparent on endoscopic interrogation [22]. In RYGB procedures, endoscopy can be used to assess the size of an anastomosis as well as its location in relationship to the natural lay of the tissue, again with a goal of decreasing potential postoperative complications [23]. Intraoperative evaluation of the size of the pouch in RYGB allows the surgeon to make necessary corrections at the time of the initial procedure. Endoscopy can also be used to evaluate for endolumenal bleeding along staple or suture lines, as well as offer a minimally invasive mechanism for management of bleeding when encountered, both at the time of the

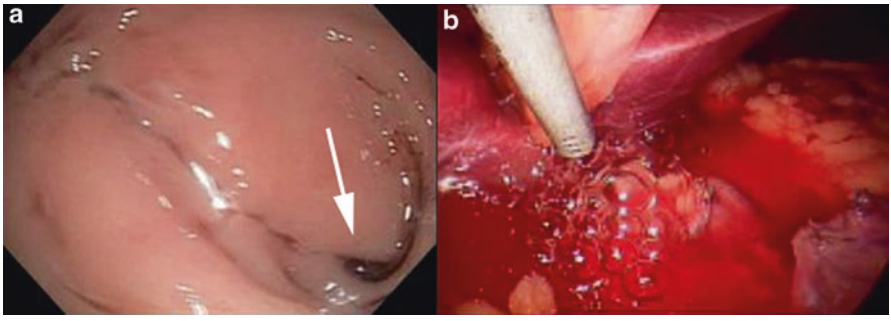

Fig. 25.3 (**a**, **b**) (**a**) Endoscopic view of a staple line leak (arrow) obtained during on-table endoscopy during a sleeve gastrectomy. (**b**) Laparoscopic view demonstrates bubbles emanating from the sleeve at the distal portion of the staple line

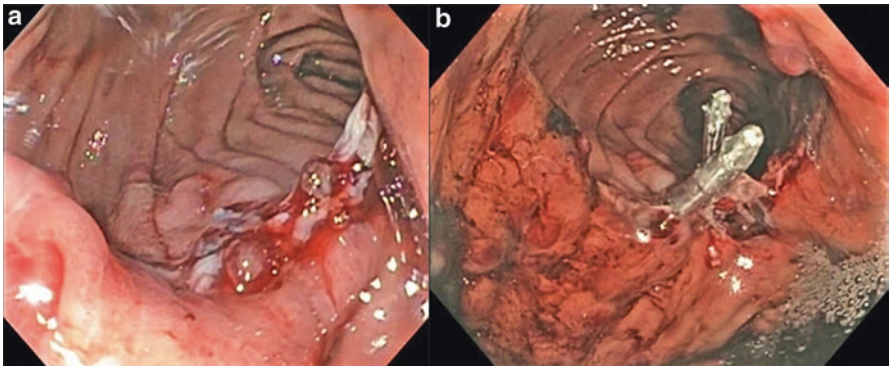

Fig. 25.4 (**a**, **b**) On-table endoscopic view of a gastrojejunal anastomosis with staple line bleeding. (**a**) Before. (**b**) After placement of endoscopic clips

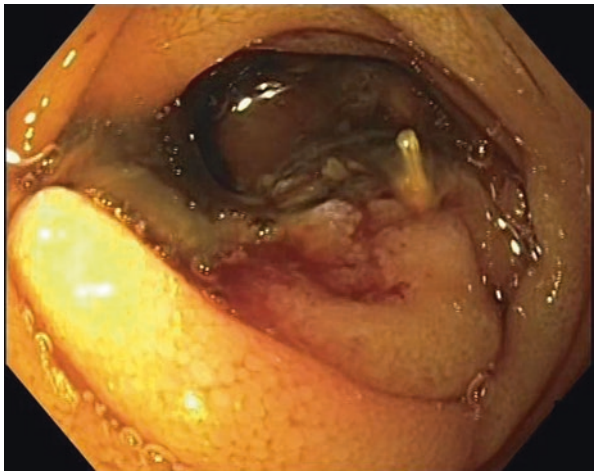

Fig. 25.5 On-table endoscopic view of a newly constructed jejuno-jejunal anastomosis

initial procedure and when diagnosed as a postoperative complication [21]. The endoscopic placement of clips or sutures can be used to control bleeding, potentially sparing the patient a more invasive procedure or the need for future interventions that become necessary when the diagnosis of bleeding is delayed until the postoperative period. In a DS, both the sleeve configuration and the duodenal-jejunal anastomosis can be evaluated. In the case of RYGB, a skilled surgeon can also assess the jejuno-jejunal anastomosis if any concerns exist regarding its construction (Fig. 25.5). Again, the real-time evaluation of this area allows for immediate intervention, should it be required.

In SG the gastroscope is routinely used to guide the staple line and help prevent the operator from creating too narrow of a sleeve, with a standard diagnostic scope diameter of 9.8 mm correlating to a bougie size of approximately 28–30 French. This method has been shown to be superior to the use of bougies for this purpose

[24, 25]. The scope can also be used to guide the creation of a hand-sewn anastomosis in the same manner.

During intraoperative endoscopy, including bariatric surgical procedures, we advocate for the use of carbon dioxide (CO_2) insufflation (rather than room air insufflation) for several reasons. First, in the event of a need for an endoscopic evaluation beyond a basic leak test, gas within the lumen will rapidly progress distally in the GI tract. This commonly results in dilation of the small intestine which obscures the operative field making the remaining portions of the surgical procedure more difficult to perform and visualize. Moreover, such small bowel distention may contribute to postoperative pain, nausea, and vomiting. Because CO_2 is rapidly absorbed from the GI tract, the bowel distention that occurs from intraoperative endoscopy done under CO_2 insufflation quickly dissipates, permitting the operation to continue without added difficulties and with minimal risk of postoperative patient complaints related to bowel distention.

Second, in the event of a positive leak test, the room air that traverses the leak during standard room air insufflation will remain in the peritoneal cavity for an extended period of time. Such pneumoperitoneum can make the postoperative management of the bariatric patient confusing as the surgeon will not know if the air present on any obtained imaging is a remnant of the positive intraoperative leak test or is the result of a new leak that has developed in the postoperative period. Because of the rapid absorption of CO_2 from the peritoneal cavity, any significant gas within the peritoneal cavity beyond the first 48 h should heighten suspicion for a postoperative leak.

Postoperative Endoscopy

Endoscopy plays a vital (and ever increasing) role in the diagnosis and subsequent treatment of symptoms and complications that occur following bariatric surgery [26–28]. Therapeutic endoscopic interventions will be discussed elsewhere in this text. Diagnostic endoscopic evaluation for complications of bariatric surgeries can be divided into two broad categories: early and late.

Early complications include leak, postoperative bleeding, and refractory nausea/vomiting. The use of endoscopy for the diagnosis of leaks is arguably more sensitive than radiographic tools such as CT scan or fluoroscopy, as an up to 20% false-negative rate has been reported in the literature with upper gastrointestinal fluoroscopy series (Fig. 25.6a) [29, 30]. Anticipated leak rates for bariatric procedures range from 1.7% to 2.5% after RYGB and between 1.5% and 7% after SG [26, 31, 32]. The sensitivity of endoscopy for leaks can be increased further by the concomitant use of selective radio-opaque contrast injection via the endoscope with subsequent real-time fluoroscopic image interpretation (Fig. 25.6b). If a leak is identified, a variety of endoscopic or combined laparoendoscopic approaches can be utilized. While it is our preference to now definitively manage small leaks in a totally endoscopic manner with a full thickness closure device, some patients may warrant a

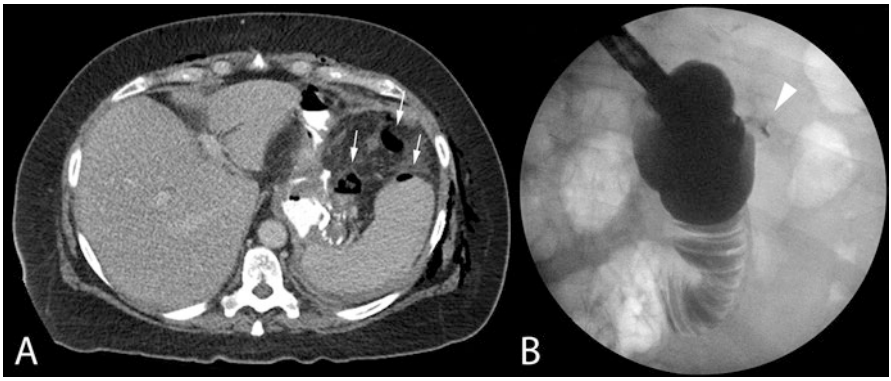

Fig. 25.6 (**a**, **b**) Following RYGB, this patient developed tachycardia. (**a**) CT scan was read as postsurgical changes with no oral contrast within extraluminal air collections (arrows). (**b**) Endoscopic contrast injection into the pouch demonstrated contrast leak (arrowhead) that was subsequently managed endoscopically

laparoendoscopic approach including washout of intraperitoneal contamination and placement of a covered endoscopic stent to prevent ongoing contamination [26, 27]. Care must be taken when performing diagnostic or therapeutic endoscopy in the setting of a suspected leak to monitor for the potential development of tension pneumoperitoneum. To this end, only low flow rate CO_2 should be used for insufflation, and the endoscopist should be ready to decompress the peritoneum in the event of sudden hemodynamic instability.

Evaluation of postoperative luminal bleeding is best performed endoscopically. There is an estimated incidence of bleeding of between 1% and 5% following RYGB and between 1% and 8% following SG [33, 34]. While in the case of divided procedures it may not be technically feasible to evaluate all areas of surgical anastomosis, the source of bleeding can be narrowed down by process of elimination endoscopically, as at least the gastric pouch, the gastrojejunal and (potentially) the jejuno-jejunal anastomoses will be accessible.

As with leaks, the advantage of endoscopic evaluation of bleeding is that it permits diagnosis and immediate therapy. Endolumenal bleeding can be managed endoscopically by a number of methods, including through the scope clips, over the scope clips, suturing devices, and hemostatic sprays. In general, early anastomotic bleeding responds to single modal therapy with a clip. Epinephrine injection and thermal therapy, the usual adjuncts to managing GI bleeding, should generally be avoided at a new surgical anastomosis due to concerns of subsequent ischemia and perforation.

Even in the event of endoscopic treatment failure, the endoscopic evaluation permits localization of the bleeding to guide surgical intervention. If bleeding is seen and treatment attempted but fails, further attempted interventions (either endoscopic or otherwise) can be initiated with a definitive target. If the bleeding is not visualized in the evaluated portions of the GI tract, further therapies can be directed to

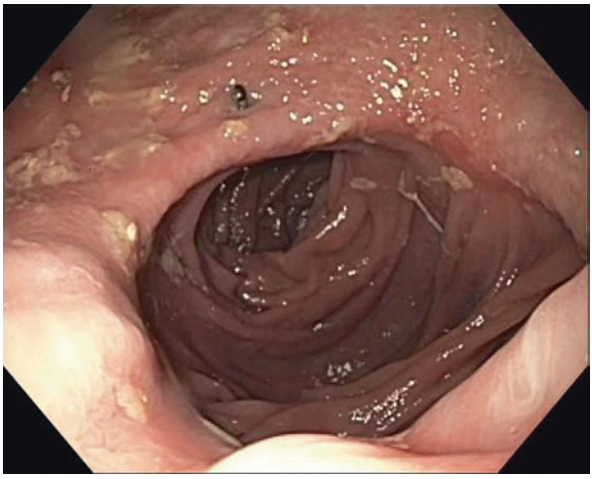

Fig. 25.7 Dilated (4 × 4 cm) gastrojejunal anastomosis in a patient with a poor sense of postprandial satiety and weight regain following RYGB

regions not accessible by the scope. Endoscopic-directed laparoscopic oversewing of bleeding has been successfully performed.

Refractory emesis is an uncommon early complication of bariatric surgery, with several possible etiologies that are best evaluated endoscopically. The cause is often obstruction, which can be the result of edema, a technical complication of an anastomosis or staple line or a space-occupying process such as a large blood clot or food bolus resulting from dietary indiscretion. Once diagnosed, necessary interventions can be undertaken, such as endoscopic relief of obstruction in the case of foreign material or placement of distal feeding access if a technical issue is diagnosed and not amenable to immediate correction with dilation or stent placement.

Symptoms of late bariatric surgical complications include abdominal pain, weight regain, GERD, vomiting, and dysphagia. The evaluation of all of these requires endoscopy as the cornerstone of diagnosis. The differential diagnosis for weight regain includes possible gastrojejunal anastomotic (GJA) dilation, pouch enlargement, the presence of a gastrogastric fistula (following RYGB), or retained fundus or sleeve enlargement (following SG) (Fig. 25.7).

Endoscopy permits rather exact measurement of the GJA and pouch and can be used to determine a patient's candidacy for a revisional endoscopic or surgical procedure. In RYGB patients, both dilation and narrowing of the GJA can produce symptoms. Endoscopic assessment of the GJA allows for an accurate measurement [35] and also provides options for therapeutic intervention. Balloon dilation and endoscopic stenting are two of the methods currently employed for management of stricture. In patients in whom balloon dilation does not provide the desired effect or does not produce durable results, stenting can be a second-line therapy [36]. The finding of a dilated GJA may explain dumping symptoms and weight regain after the procedure and can be managed with an endoscopic plication of the GJA itself.

The most common presentations of gastrogastric fistulae (GGF) are weight regain and abdominal pain with or without a concurrent diagnosis of a marginal

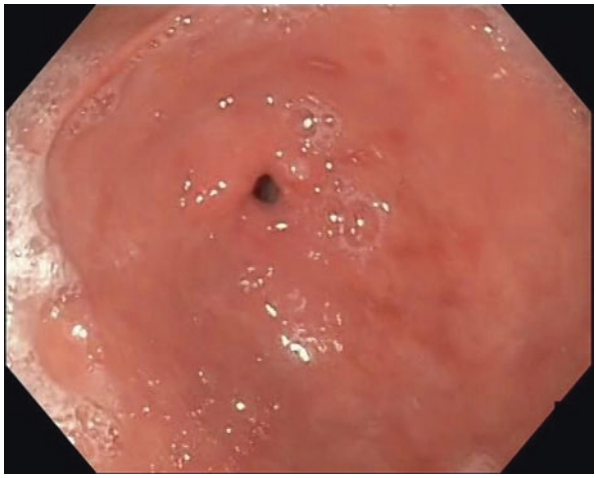

Fig. 25.8 Prepyloric intestinal metaplasia in the background of gastritis seen following sleeve gastrectomy

ulcer [37]. While GGF can be evaluated radiographically, small fistulae may be overlooked or missed on fluoroscopy alone [37]. Endoscopic evaluation offers not only the ability to visualize the fistula (either with endoscopy alone or with simultaneous diagnostic fluoroscopy) but also the ability to estimate its size and potentially render therapeutic endoscopic intervention. While surgical intervention remains the most definitive option for repair [38], as endoscopic techniques have continued to evolve, this minimally invasive approach may eventually supplant operative repair as the gold standard.

In patients presenting with chronic abdominal pain, nausea, dysphagia, or vomiting following bariatric surgery, endoscopic evaluation for a source of GI tract pathology should be undertaken. Following AGB, band slippage and erosion can both be diagnosed endoscopically. While the diagnosis of band slip or herniation can also be made radiographically, erosion is best evaluated for by careful endoscopic inspection. Significant band erosion can be managed primarily via endoscopy, with transgastric peroral removal of the band [2, 39].

In a subset of patients, endoscopic evaluation may be required for routine surveillance following bariatric procedures. In a series of 1555 patients who underwent SG, Safaan and colleagues reported a 48% rate of abnormal histopathology in the gastric sleeve specimens, ranging from chronic inactive gastritis to intestinal metaplasia (Fig. 25.8) to gastrointestinal stromal tumors [40]. Raess and colleagues also found a high rate of incidental histopathology in their sleeve specimens which necessitated routine follow-up endoscopy [41].

In nondivided bariatric procedures, the foregut remains easily endoscopically accessible; however, in patients with divided anatomy postoperatively, novel and advanced techniques may be required in order to perform adequate endoscopic evaluation, such as percutaneous access to the remnant stomach following RYBG or double-balloon endoscopy. Surveillance endoscopy is not just limited to evaluation of gastric metaplasia. Patients with a history of BE or in whom BE is diagnosed

postoperatively following their bariatric procedure should be surveilled for progression of their disease following guideline-based protocols.

Lastly, endoscopy plays an important role in preoperative planning for revisional procedures. In patients presenting with postoperative complications such as bile reflux and marginal ulcers, endoscopy can be used to assess the severity of disease, the length of the alimentary limb, and the presence of any additional anatomical characteristics which may play a contributing role. SG can exacerbate existing GERD or can cause GERD symptoms de novo in postoperative patients. In these patients it is important to continue to evaluate the esophagus endoscopically for evidence of progressive disease or development of BE or adenocarcinoma before performing a conversion to RYGB. In patients who present with weight regain or abdominal pain, an evaluation for pouch dilation, anastomotic dilation, sleeve dilation, or distal stricture (resulting in patient noncompliance and reliance on "slider foods") is critical prior to performing appropriate revision surgery. Knowledge of the presence or absence of band erosion is helpful and may drive the decision to perform a one-stage (band removal and immediate revisional weight loss surgery) vs a two-stage (band removal only with delayed revisional weight loss surgery) procedure.

Conclusion

While there are mixed data regarding the need for routine screening endoscopy prior to performing bariatric surgery, given the high rate of abnormal pathology identified on these exams, a discussion with the patient is warranted. In patients with a history of severe GERD in particular, upper endoscopy should be performed preoperatively. The intraoperative use of endoscopy can help prevent both early and delayed postoperative complications, as a skilled endoscopist may be able to not only diagnose these problems but also intervene on them immediately. Upper endoscopy in the postoperative setting is critical for the evaluation of common postsurgical complaints, both for accurate diagnosis and potential endoscopic intervention.

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Chapter 26
Long-Term Nutritional/Metabolic Sequelae of Bariatric Surgery

Milene Amarante Pufal and Konstantinos Spaniolas

The Birth of Metabolic Surgery

The obesity epidemic has expanded since the early twentieth century. Currently, more than one-third of the population in the United States is obese, and millions suffer from type 2 diabetes (T2D), heart disease, and other obesity-related comorbidities. Even highly specific weight loss programs designed to include low-calorie diet, exercise, medication, and behavioral change therapy have failed to sustainably treat severe obesity and its comorbidities.

Bariatric surgery was initially devised, in the middle of the last century, to promote weight loss in patients whose weight was deemed to be extremely abnormal. Even though weight loss was the primary focus of this field early on, metabolic alterations were common and originally attributed to the limited food intake and malabsorption associated with the aftermath of intestinal bypass [1, 2]. One of the most worrisome diseases, T2D, has gone into remission after weight loss procedures, often in a weight-independent manner, which has been supporting the metabolic usefulness of the surgery. Over time, therefore, the metabolic and hormonal effects associated with restrictive, hormonal, and/or malabsorptive surgical techniques have led to a transformation in the field and the advent of the term "metabolic" surgery.

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Type 2 Diabetes Mellitus

The normalization of blood glucose and HbA1c in the absence of antiglycemic medications defines T2D remission. Historically, remission has been rare when using medical therapy alone. However, immediately after bariatric surgery, patients seem to rapidly reduce their glucose levels despite not having yet lost significant weight. There is now a large body of evidence to demonstrate significant improvement in glycemic status with bariatric surgery (Table 26.1).

Table 26.1. The effect of bariatric surgery on diabetes remission and improvement in different bariatric procedures based on multiple studies with different research methodologies

Study	Procedure: n	Design	BMI (kg/m^2) at baseline	Follow-up (years)	Diabetes effect
LABS [3]	RYGB: 1738 (320 diabetics) AGB: 610 (98 diabetics)	Prospective, non-randomized	46.0	3	RYGB: 67.0% partial remission AGB: 28.6% partial remission
SOS [4]	AGB: 376 VBG: 1369 RYGB: 265 (323 diabetics)	Prospective, matched, non-randomized	42.4	2 10	72.0% 36.0%
Buckwald [5]	RYGB: 7074 AGB: 3873 VBG: 1568 DS: 4035 (2331 diabetics)	Meta-analysis	46.9	Variable	76.8% remission (AGB 47.9%, RYGB 83.7%, VBG 71.6%, DS 98.9%), 85.4% improvement
Utah obesity study [6]	RYGB: 418 (93 diabetics)	Retrospective	45.9	6	62.0% remission
East Carolina University [7]	RYGB: 608 (165 diabetics, 165 IFG)	Retrospective	49.7	Variable	82.9% remission 99.0% normalization of IFG
Virginia Commonwealth University [8]	RYGB: 1025 (154 diabetics)	Retrospective	51.0	Variable	83.0% resolution
Fresno, CA [9]	RYGB: 242 (45 diabetics)	Retrospective	NR	Variable	83.0% resolution/ improvement at 2 years 67.0% at 10 years

(continued)

Table 26.1. (continued)

Study	Procedure: n	Design	BMI (kg/m^2) at baseline	Follow-up (years)	Diabetes effect
University of Pittsburgh [10]	RYGB: 191 (177 diabetics, 14 IFG)	Retrospective	50.1	20 months	83.0% remission 17.0% improvement
San Diego, CA [11]	RYGB: 500 (85 diabetics)	Retrospective	NR	Variable	97% resolution
University of Oslo [12]	RYGB: 184 (49 diabetics)	Retrospective	46.0	5	67.0% remission 20.0% improvement
Cleveland Clinic [13]	RYGB: 50 SG: 41 (all diabetic)	Randomized controlled	36.0	1	42.0% remission for RYGB 27.0% remission for SG**
Universita Cattolica S. Cuore [14]	RYGB: 19 BPD: 19 (all diabetic)	Randomized controlled	45.0	2	75.0% remission for RYGB 95.0% remission for BPD
Monash University Medical School [15]	AGB: 30 (all diabetic)	Randomized controlled	37.0	2	73.0% remission with AGB vs 13.0% for MT
STAMPEDE trial [16]	RYGB: 49 SG: 47 MT: 38	Randomized, controlled, nonblinded, single-center	RYGB: 37.0 SG: 36.0 MT: 36.4	5	Remission (HbA1c $\leq$ 6.0%) RYGB: 22.4% SG: 14.9% MT: 0.0 Remission (HbA1c $\leq$ 6.5%) RYGB: 30.6% SG: 23.4% MT: 0.0
Mingrone et al. [17]	RYGB: 19 BPD: 19 MT: 15	Open-label randomized controlled trial	RYGB: 44.0 BPD: 44.7 MT: 45.4	5	ADA partial remission* RYGB: 37.0% BPD: 63.0% MT: 0.0

ADA American Diabetes Association. ADA partial diabetes remission definition: glycated hemoglobin <6.5% and fasting glucose concentration of 5.6–6.9 mmol/L without active pharmacological treatment for 1 year. *HbA1c* glycated hemoglobin, *AGB* adjustable gastric banding, *VBG* vertical band gastroplasty, *RYGB* Roux-en-Y gastric bypass, *DS* duodenal switch, *SG* sleeve gastrectomy, *MT* medical therapy, *BMI* body mass index, *IFG* impaired fasting glucose, *NR* non-reported

*No statistical difference between groups

A recent meta-analysis of 19 different studies [18] revealed that the overall bariatric surgery is associated with a 0.33 risk reduction for the development of T2D postoperatively, also underlining a significant difference in risk reduction between Roux-en-Y gastric bypass (RYGB)/ biliopancreatic diversion (BPD) and adjustable gastric banding (AGB) (0.26 vs 0.44, $p < 0.0001$). T2D remission at 48 months after surgery was significantly higher after RYGB (75%) and BPD (95%) compared to medical treatment (nil).

It is noteworthy that in most randomized trials comparing bariatric surgery to medical therapy, the intensity of the medical therapy is profound and often beyond common clinical practice. This is illustrated by the fact that intense medical therapy led to an 8% decrease in body mass index (BMI) and a discontinuation of antihypertensive medications in 70% of the group in the STAMPEDE trial. In the Swedish Obesity Subject (SOS) study, the adjusted odds ratio for new-onset T2D was 0.25 in the surgery group compared to the medically treated patients [19].

In 2017, Philip and colleagues [16] observed that the glycemic control relapse was not associated with weight regain. The RYGB group had impressive rates of patients of all diabetes medications at 5 years (45%) when compared to both 25% of the sleeve gastrectomy (SG) group ($P < 0.05$) and 2% of the medical therapy group ($P < 0.05$). In another recent 5-year controlled trial [17], authors commented that hyperglycemic relapse was observed in 53% of RYGB patients and 37% of the BPD group who had achieved 2-year remission. The Framingham Study addressed the question of the effect of medical weight loss on T2D prevention [20]. Overweight patients ($n = 618$) who lost at least 1 lb./year were compared to patients who had regained weight but were weight stable during that time period. After adjusting for years of follow-up, T2D occurrence in the weight-stable patients was 8.1 per 1000 person-years; sustained weight loss led to a 37% reduced risk of diabetes development (relative risk 0.63). Similarly, the Diabetes Prevention Program randomized over 3000 overweight and obese (mean BMI of 34 kg/m^2) patients with pre-T2D to intense lifestyle changes vs metformin vs placebo [21]. The incidence of T2D in this high-risk group at 10 years was 40%. Lifestyle modification (including low-calorie low-fat diet, moderate physical activity, and one-on-one education sessions) was associated with an important decrease in the prevalence of diabetes (OR 0.42), but this was to a lesser extent than what is achieved with bariatric surgery. Importantly, the downstream effects of T2D are markedly improved with bariatric surgery. The rate of development of both microvascular and macrovascular T2D complications was significantly reduced in the SOS study over a 20-year follow-up (hazard ratio 0.44 and 0.68, respectively, for bariatric surgery compared to medical therapy) [22].

In the recent consensus statement following the 2nd Diabetes Surgery Summit, which included mostly (75%) non-surgeon representatives of T2D organizations, summarized data from randomized controlled trials suggest that bariatric surgery was associated with a 2.0% decrease in HgA1c compared to a 0.5% decrease after medical therapy [23]. Based on this and other published scientific observations, the group concluded that surgery could achieve excellent control of hyperglycemia and

reduce cardiovascular risk factors. In addition, the consensus statement proposed that bariatric surgery should be a recommended option to treat T2D in appropriate candidates with BMI $\geq$ 40 kg/m^2, regardless of glycemic control status, and in poorly controlled T2D patients with lower BMI.

Bariatric surgery is more effective than medical treatment for the long-term remission of T2D in obese patients. The molecular basis for this improvement is not entirely yet elucidated. Nevertheless, continued monitoring of glycemic control should not be neglected due to a possible recurrence of hyperglycemia or other glucose-related pathologies.

Hypoglycemia

Despite the enormous range of benefits, bariatric surgery may lead to complications such as hypoglycemia. One of the severe complications of gastric bypass is delayed-onset hypoglycemia (1–2 h after a meal), which is different from early dumping syndrome (10–30 min after a meal). Hypoglycemic symptoms can be either autonomic (anxiety, palpitations, tremors) or neuroglycopenic (loss of consciousness, confusion), and they may occur when blood glucose levels are less than 60 mg/dL or 50 mg/dL, respectively [24]. The prevalence of hypoglycemia following bariatric surgery varies from 0.2% (patients requiring hospitalization) to 72% (reactive hypoglycemia after glucose tolerance test) [24]. According to Millstein and Lawler (2017) [25], differential diagnosis for hyperinsulinemic hypoglycemia after RYGB depends on the mean cause which includes (1) endogenous causes [insulinoma, dumping syndrome, post-gastric bypass hypoglycemia (PGBH)] or (2) exogenous causes [overuse of insulin secretagogue (sulfonylureas or meglitinides) or overuse of exogenous insulin administration] and should be properly identified. Although there are several hypotheses that explain hypoglycemia after meal, the exact mechanisms are still unknown [26]. It appears that glycemic variability, such as hypoglycemic events, transient postprandial hyperglycemia, and rapid circulating glucose drops, is commonly experienced after bariatric surgery, more so with RYGB than SG [27–29].

Although there are no established risk factors to predict the development of hypoglycemia postoperatively, patients may be able to control this adverse event by adhering to a strict diet that restricts consumption of carbohydrates as well as other foods with high glycemic indices. In addition, medical therapy with acarbose, calcium channel blockers of somatostatin analogues, can be tried; however, success is often limited, and efficacy is not well established [30].

Hypertension

The effect of bariatric surgery on hypertension is variable, but overall published literature suggests improvements after surgery. In a comparison analysis of 418 patients undergoing RYGB, hypertension remission was reported in 53% of the 169 hypertensive patients at 2 years after bariatric surgery and 42% at 6 years [6]. Using meta-analytic methods on almost 7000 bariatric patients, hypertension was resolved postoperatively in 65.6% and improved in 81.8% [5]. There was a significant difference between the stapling procedures [RYGB and BPD/duodenal switch (DS)] and AGB, with almost a twofold difference in the rate of hypertension remission after intervention. A more recent analysis reported similar findings with a 0.52 risk reduction for hypertension after bariatric surgery [18]. Similarly, another meta-analysis, with a total of 243 randomized bariatric patients and almost 17,000 observed non-randomized patients, found hypertension improvement or resolution in 75% and 74% of patients, respectively [31].

Prospective long-term data on hypertension remission show a less pronounced impact compared to diabetes. In the 3-year follow-up of the LABS study, 38.2% and 17.4% of the patients who underwent RYGB and adjustable gastric banding (AGB), respectively, were in remission for hypertension [3]. The SOS study showed that at 2 years after bariatric surgery (mostly vertical banded gastroplasty), hypertension resolution occurred in 34% of the patients; this number dropped to 19% at 10 years. Given the established relationship between advancing age and the prevalence of hypertension, this drop in hypertension resolution at 10 years after intervention should not be viewed as a failure of bariatric surgery but rather as an evolution of the natural process of aging.

Dyslipidemia

Abnormalities in lipids, lipoproteins, and triglycerides are common in obese patients. These are substantial components of the metabolic syndrome and represent a major risk factor for cardiovascular disease in T2D and non-T2D patients. Metabolic surgery improves the lipid profiles of the majority of patients. In a large meta-analysis from 2004, improvements in hypertriglyceridemia, hypercholesterolemia, and hyperlipidemia occurred in 92.8% (912 of 983), 86.6% (1777 of 2051), and 83% (846 of 1019), respectively [5]. These numbers for RYGB and BPD/DS exceeded 90% for all measures. A more recent meta-analysis evaluating overall cardiovascular risk reduction after surgery reported a hyperlipidemia risk reduction of 0.39 for patients undergoing bariatric surgery; RYGB and BPD/duodenal switch were associated with a risk reduction of 0.26 [18]. A second recent review of 25 bariatric studies reporting on lipid outcomes found

resolution or dyslipidemia improvement in 76% of patients participating in a bariatric surgery randomized controlled trial, and 68% of patients included in observational studies [31].

Long-term assessment of lipid profiles after RYGB demonstrates sustained improvement in dyslipidemia after surgery [6]. Normalization of HDLc, LDLc, and triglycerides 6 years after RYGB was seen in 67%, 53%, and 71% of patients, respectively. Again, there were minimal differences in these rates from year two to year six after RYGB. Recent data from the LABS study show that at 3 years from RYGB, the majority of patients normalize their LDLc (59.7%), HDLc (85.6%), and triglycerides (85.8%). Improvements, but to a lesser degree, were also seen after AGB (22.7%, 67.3%, and 62.1%, respectively) [3]. Long-term data are also available from the SOS study [4]. Normalizations of LDLc, HDLc, and triglycerides 10 years after bariatric surgery were found in 21%, 73%, and 46% of patients, respectively. There were no significant differences in the rates of HDLc and LDLc abnormality resolution between years 2 and 10 postsurgical intervention, suggesting that the benefit of bariatric surgery is evident early on and is long-lasting.

Cardiovascular Risk

The metabolic effect of surgery is translated to a significant improvement in cardiovascular risk. Kwok and colleagues [32] conducted a systematic review and meta-analysis to evaluate the impact of bariatric surgery on cardiovascular disease and mortality. The bariatric surgery cohort was made up of 29,208 patients and nonsurgical controls numbered 166,200. The authors demonstrated that bariatric surgery is associated with a reduced risk of myocardial infarction, stroke, and adverse cardiovascular events.

With long-lasting improvements in dyslipidemia, T2D, and hypertension, the cardiovascular risk of severely obese individuals is reduced after bariatric surgery. A single-institution study of 184 patients with a 5-year follow-up after RYGB reported that 112 patients met the criteria for having metabolic syndrome preoperatively [12]. At the end of the follow-up period, 67% of these patients no longer had metabolic syndrome. In this same cohort, the Framingham risk score significantly decreased with RYGB, representing an absolute risk reduction of 1% and relative risk reduction of 18.3%. Furthermore, the SOS study, with a median follow-up of 14.7 years, demonstrated that bariatric surgery is associated with a significantly lower incidence of cardiovascular events and cardiovascular-specific deaths [33].

Nutritional Sequelae

Necessity of Frequent Nutritional Assessments

Screening obese candidates for vitamin or mineral deficiencies is vital, as subclinical or clinical nutritional deficiencies are common preoperatively, possibly as a consequence of years of poor diet quality. Therefore, in order to reduce the severity of postoperative nutrient deficiencies, patients undergoing bariatric surgery must be monitored and aggressively treated when they demonstrate low levels of any nutrients. Because the combination of restrictive and malabsorptive procedures will affect both intake and nutrient absorption due to changes in the gastrointestinal tract, there is a need for a specific and frequent nutrition assessment where the importance of supplementation is reinforced. Supplementation will include multivitamins, minerals, and high protein intake in order to avoid nutritional sequelae. The patient must be made to understand the importance of nutritional status and of compliance with the center through regular follow-up (usually scheduled at 1–2 weeks, 4–6 weeks, 3 months, 6 months, 12 months, 18 months, 24 months, and annually after the procedure), prior to index bariatric surgery.

Malnutrition and Vitamin and Mineral Deficiencies

A micronutrient panel should be systematically conducted due to the broad evidences of deficiencies: vitamin D (up to 100%), vitamin A (up to 70%), thiamine (vitamin B1, <1–49%), vitamin B12 (4–20%), folate (up to 65%), iron (8–62%), zinc (up to 70%), copper (up to 90%) [34]. The main reasons why deficiencies may occur are due to the following practices/mechanisms:

1. Inadequate use of multivitamin and mineral supplements
2. Food intolerances or insufficient intake of foods that are good sources of the micronutrients
3. Bypassing of the primary sites of intestinal absorption (duodenum and proximal jejunum)
4. Rapid weight loss
5. Excessive alcohol use [35]

Common Nutrient Deficiencies

- *Vitamin D and calcium*: Vitamin D is mainly acquired by sun exposure. Many people spend most of the day indoors, so they do not produce vitamin D. When patients rely on ingesting vitamin D from foods, they may absorb limited

amounts because the sites of absorption are in the jejunum and proximal ileum. Patients with a vitamin D deficiency normally have hypocalcemia, which may lead to increased production of parathormone (PTH), which subsequently results in increased production of 1,25 dihydroxyvitamin D and increased release of calcium from bone. Calcium is then absorbed in the duodenum. So, patients who undergo bypass surgery tend to show deficiencies in both nutrients if not well supplemented. Daily nutritional supplementation of 1200–1500 mg of oral calcium citrate, taken in doses, and 3000–6000 international units (IU) of vitamin D is recommended [36]. One important issue for calcium supplementation among bariatric patients is its formula: calcium citrate is preferred over carbonate due to its solubility in the absence of acid in the stomach. Symptoms of deficiency often manifest as cramping. In cases of severe vitamin D malabsorption, doses as high as 50,000 IU taken one to three times per day or week may be necessary [36]. The diagnosis can be seen by dosages of 25-hydroxyvitamin D level and serum calcium.

- *Vitamin A*: As are all four fat-soluble vitamins (A, D, E, K), vitamin A is mainly absorbed in the jejunum and proximal ileum and is therefore at a high risk of becoming deficient after bypass procedures. For BPD or duodenal switch surgeries, 10,000 IU of vitamin A supplementation is required [37]. If deficient, patients may show night blindness, dry eyes, dry skin, and dry hair. It is diagnosed with a low serum retinol level.
- *Vitamin B1* (thiamine): This vitamin is primarily absorbed in the upper small intestine, so patients who do not comply with supplement intake are at increased risk for deficiency. Thiamine supplementation should be obtained from a daily multivitamin and mineral supplement [36]. Thiamine deficiency can occur within 6–15 weeks after the procedure. The mechanism is related to deprivation and can worsen with persistent vomiting. The result can be resting tachycardia and weakness; some people may develop Wernicke's encephalopathy. The diagnostic criteria of this disease require two of the four items: (1) dietary deficiency, (2) oculomotor abnormality, (3) cerebellar dysfunction, and (4) confusion or mild memory impairment [38]. Patients with severe thiamine deficiency should be treated with intravenous thiamine at a dose of 500 mg per day for 3–5 days followed by 250 mg per day for 3–5 days or until the total resolution of symptoms and thereafter with 100 mg per day orally until risk factors have resolved [36]. If thiamine levels are needed, laboratory confirmation should be measured.
- *Vitamin B9* (folate or folic acid): Folate deficiency occurs mainly in gastrointestinal surgeries because the bypass of upper small intestine reduces gastric acid. Its supplementation should be of 400 mcg daily [36]. Although folate deficiency is uncommon (occurs in 1% of patients) [39], the deficiency leads to anemia (i.e., fatigue, weakness, lethargy, shortness of breath). It is diagnosed by measuring serum folate levels and, if necessary, serum cobalamin.
- *Vitamin B12*: B12 requires intrinsic factor (IF) as a cofactor to be absorbed in the distal ileum; however, IF is produced by the parietal cells in the stomach. Because there is a gastrectomy in RYGB and LSG procedures, patients produce little IF and they end up developing a deficiency for this vitamin. Vitamin B12 storage is

larger than the nutritional daily needs: 2–5 years of reserve [40]. Oral supplementation with crystalline vitamin B12 at a dose of 1000 mcg daily is required [36]. However, its deficiency can be seen years after surgery as symptoms that range from anemia (fatigue, weakness, shortness of breath, pale skin) and/or tingling or numbness in fingers and toes to ataxia, mood changes, memory loss, and vision loss. To treat the deficiency, intramuscular or subcutaneous vitamin B12 supplementation of 1000 mcg per month to 1000–3000 mcg every 6–12 months is indicated when sufficiency is not achieved by oral methods [36]. Diagnosis is confirmed by serum vitamin B12 levels.

- *Protein*: Protein deficiencies are overall uncommon, mostly reported after distal or long limb bypasses and are normally due to intolerance for protein-rich foods [41] and/or failure to take protein supplements. Even in BPD/DS patients, protein deficiency is uncommon [42, 43]. A minimal protein intake of 60 g daily and up to 1.5 g per kg of ideal body weight per day should be adequate to avoid deficiency symptoms [36]. Protein intake needs to be higher in patients after procedures with long intestinal bypasses (e.g., long-limb RYGB or BPD/duodenal switch). Serum albumin, prealbumin, and creatinine can confirm this deficiency for the clinical symptoms of edema, weakness, thinning hair, and decreased muscle mass.
- *Iron*: Iron is a micronutrient that needs gastric acid to be reduced to its more absorbable form: ferrous. This nutrient is primarily absorbed in the duodenum and proximal jejunum, which are bypassed in RYGB and BPD/duodenal switch. Patients undergoing these procedures will be at higher risk of developing anemia. Iron supplementation should be 45–60 mg daily [36]. Vitamin C increases the absorption of iron, so consuming citrus fruits and/or taking a vitamin C supplement is recommended. In case of anemia, treatment should involve oral ferrous, sulfate, fumarate, or gluconate to provide up to 150–200 mg of elemental iron per day [36]. Symptoms of iron deficiency normally include anemia (fatigue, pale skin, palpitations). Deficiency is confirmed with serum iron and ferritin.
- *Zinc*: The primary site of zinc absorption is the small intestine. Its supplementation for hair loss requires a dosage of 8–15 mg for each 1 mg of copper due to the fact that zinc supplementation can cause copper deficiency [36]. So, bypass procedures can lead to a zinc deficiency, which results in hair loss, diarrhea, impaired immunity, and poor wound healing. Interestingly, obese and T2D individuals have a higher prevalence of hypozincemia at baseline. In severely obese patients being evaluated for nutritional parameters, zinc deficiency is found in 0–74% of patients at baseline [44–51]. In a study evaluating 324 morbidly obese patients undergoing bariatric surgery, 9% had zinc deficiency at baseline [48]. Zinc deficiency at 12 months was found in 41%, 92%, and 19% of patients following RYGB (n = 146), duodenal switch (n = 12), and sleeve gastrectomy (n = 16), respectively. In a study of 65 patients with BMI > 40 kg/m^2 undergoing evaluation for BPD, 74% of patients were zinc deficient at baseline, and this progressively increased during 4 years of follow-up [46]. A similar study of 64 patients followed for 3 years after BPD, demonstrated that the mean zinc level significantly decreased to almost half postoperatively (from 17.2 mM/l at

baseline to 9.1 mM/l at 3 years) [52]. At the end of follow-up, 54% of patients were zinc deficient. In 52 patients who underwent RYGB and 89 who underwent BPD/duodenal switch, the zinc levels were significantly different between the two operations [53]. All but one patient, after BPD/duodenal switch, had hypozincemia at least once during the 5-year follow-up, while zinc deficiency actually decreased the first 36 months after RYGB. At 2 and 5 years post-operatively, 46% and 45% of BPD/duodenal switch and 15% and 21% of RYGB patients had hypozincemia, respectively. Following sleeve gastrectomy, 10.7% and 14.3% of patients at 1 and 5 years follow-up had hypozincemia [54]. In a study comparing 50 and 86 patients who underwent sleeve gastrectomy and RYGB, respectively, with a mean follow-up of 24 months and 100% 1-year follow-up, there was no significant difference in hypozincemia between the two groups (34% vs 37%) [49]. Zinc absorption after RYGB appears to be altered. In a study of nine patients undergoing RYGB, evaluated with serial zinc levels for 4 h after zinc sulfate supplementation, there was a significant reduction in the plasma zinc response at 3 months postoperatively compared to baseline [55]. Using isotope analysis on 67 morbidly obese females undergoing RYGB, percent of absorbed zinc decreased dramatically from 32% to 14% at 6 months after surgery and remained impaired [56]. The diagnosis is done by measuring serum and urinary zinc levels.

- *Copper*: Copper is an essential trace element absorbed in duodenum. Copper is involved in enzyme systems related to hematopoiesis and catecholamine synthesis in addition to being a structural and functional component of the nervous system. Copper supplementation of 2 mg daily is necessary [36]. Deficiency, which is normally a late-onset complication, often 10–20 years after bariatric surgery [57], leads to weakness, skin sores, hair and skin discoloration, and neurological deficits. Neurological manifestations reported include myelopathy, peripheral neuropathy and/or optic neuropathy, and vision loss [58]. Routine copper screening should be implemented in patients with anemia, neutropenia, myeloneuropathy, and impaired wound healing. In cases of severe copper deficiency, treatment involves intravenous copper at a dosage of 2–4 mg per day for 6 days. After that, treatment should involve oral copper sulfate or gluconate 3–8 mg per day until levels normalize and symptoms resolve [36].

Most malnourished patients have no clinical symptoms. However, many bariatric patients report symptomatology suggestive of nutrient deficiencies. A study, including 49 RYGB patients, reported clinical symptoms of malnutrition in 59%, hair loss and/or dry skin in 39%, paresthesias in 12%, and myalgias in 16% [59]. These symptoms were reported despite a lack of measured deficiencies in iron, ferritin, calcium, vitamin B1, vitamin B6, folate, vitamin B12, vitamin C, vitamin A, or vitamin E, suggesting that protein or mineral metabolism was involved.

Although routine vitamin supplementation is essential to the postoperative long-term care of bariatric patients, this practice does not eliminate the risk of vitamin deficiencies. Thus, patients may require additional supplement amount of vitamin B12, iron, calcium/vitamin D, or folic acid [60]. At each follow-up

medical/dietitian appointment, the nutritional status should be assessed, and patients should be counseled about the importance of daily taking supplements after bariatric surgery.

Neuropathies

Post-bariatric surgery neuropathies are often serious complications with symptoms that vary from numbness and tingling to neuropathies and blindness. Most complications have been attributed to a variety of vitamin and mineral deficiencies, but the reports are isolated, therapies varied, and outcomes obscure. These neurologic complications, affecting any part of the neuraxis (brain, cerebellum, spinal cord, peripheral nerve, and muscle), have been observed in 5–10% of patients undergoing bariatric surgery. The bariatric team should be aware of the possibility of developing Wernicke's encephalopathy because it demands swift intervention [38]. A review [61] of 50 case reports of 96 patients showed that the most commonly reported neurologic complication was peripheral neuropathy (62% of patients) followed by encephalopathy (31%). The same review evaluated longitudinal series where 133 out of 9996 patients (1.3%; range: 0.08–16.0%) had neurological complications.

Although the clinical relevance of insufficient levels of zinc and copper are unclear in terms of neuropathies, some case report studies have been published [57, 62]. Every 6 months for the first 3 years after bariatric surgery and thereafter once every year, patients should have their zinc, copper, magnesium, ferritin, 25-hydroxyvitamin D, folate, thiamine, vitamin B12, and calcium levels checked [38].

Other Long-Term Effects

Obesity is one of the leading diseases in the United States that increases risk for diabetes, cardiovascular diseases, musculoskeletal diseases, pulmonary diseases, and cancers. Large epidemiologic studies have illustrated that obesity is associated with higher mortality rates. The first study to suggest a survival benefit for bariatric surgery retrospectively compared 154 patients who underwent RYGB with 78 patients who were evaluated for bariatric surgery but were denied the surgery by their insurance company [63]. With a mean follow-up of 9 years in the surgical group and 6.2 years in the controls, all-cause mortality was 9% and 28%, respectively. A more recent cohort study [64] compared almost 10,000 bariatric surgery patients with nonsurgically treated severely obese patients over 7.1 years. There was a 40% decrease in overall adjusted mortality in bariatric surgery patients. Cause-specific mortality for T2D and cardiac disease is decreased by 92% and 56%, respectively. Interestingly, cancer-specific mortality decreased by 60%. The SOS study verified the survival benefit of bariatric surgery with a large

prospective cohort [65]. With a mean follow-up of 10.9 years on over 4000 obese patients (split between surgery and the medical management of obesity), the hazard ratio adjusted for age, gender, and comorbidities was 0.71 for bariatric surgery. The most common causes of death were cardiac events and cancer. Both of these studies surprisingly illustrated a benefit in terms of cancer risk for bariatric surgery patients. An up-to-date review [66] highlighted that bariatric surgery is associated with improved long-term survival when compared to matched cohorts. They add that in the studies reviewed, the benefits of surgery can be noticed as early as 2.5 years post-operation in female and male cohorts, and there are no studies demonstrating an increase in all-cause long-term mortality after bariatric surgery compared to obese controls.

In a follow-up analysis of the SOS study, a significant reduction in cancer incidence was seen in bariatric surgery patients [67]. The overall cancer incidence in the surgery group decreased with an odds ratio of 0.67. In subgroup analysis, this effect was significant for female patients and was independent of weight loss. Similarly, using data from the Utah Cancer Registry, cancer incidence was assessed for a mean follow-up of 12.5 years in a bariatric surgery cohort [68]. Cancer incidence and cancer-specific mortality were significantly decreased in the bariatric surgery group (hazard ratio 0.75 and 0.54, respectively). Another observational study compared 1035 bariatric surgery patients with a control group matched for age and gender [69]. Cancer-related office and hospital visits were significantly lower in the bariatric surgery group (relative risk 0.22) over a 5-year follow-up period. A systematic review and meta-analysis [70] evaluated 11,087 surgery patients and 20,720 patients in the control group. The authors demonstrated that bariatric surgery was associated with a reduction in cancer risk (OR 0.42, 95% CI 0.24–0.73). Even though multiple theories exist to explain this effect, there have been no definitive studies to date to support the mechanism(s) behind it.

Conclusion

Current bariatric operations produce significant improvement and durable remission for the components of the metabolic syndrome (severe obesity, hypertension, type 2 diabetes, and hyperlipidemia) in addition to a broad array of related comorbidities such as sleep apnea, polycystic ovary disease, and pseudotumor cerebri as well as those that are due to excessive weight such as arthritis in weight-bearing joints. Now that the operations can be done with consistently low mortality and morbidity, metabolic surgery offers an effective, indeed the most effective, therapy for the most costly diseases of the developed world. Continued evaluation of nutritional metrics for patients, both before and after surgery, will optimize outcomes for patients in both short- and long-term periods.

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Chapter 27
Robotic Index Bariatric Surgery

Donald E. Yarbrough and Erika La Vella

Introduction

The obese surgical patient presents many challenges to minimally invasive surgery (MIS). Traditional laparoscopy is made difficult by a thicker abdominal wall that distorts trocar placement and adds torque to instrumentation. Obese patients have larger livers which obscure exposure, and there is more visceral and omental fat which reduce the internal working space. These factors leave the MIS surgeon in awkward, physically painful positions, sometimes shortening surgical careers due to injury [1]. Additionally, the obesity epidemic is worsening, and super obese patients presenting for surgical consultation is commonplace.

Robotic platforms have improved upon the limitations of laparoscopy offering a unique 3D immersive experience which allows for improved proficiency that mimics open surgery. The robotic platform employs wristed instruments, making intracorporeal hand-sewn anastomoses technically easier. Robotic surgical platforms have been demonstrated to be a safe and effective improvement upon laparoscopy, making once difficult MIS operations more feasible [1]. The surgeon gains an ergonomic benefit, and the patient gleans all of the benefits of MIS even at the extremes of BMI in experienced hands. Robotic index bariatric surgery is demonstrating generally comparable clinical outcomes to traditional laparoscopic bariatric surgery and, in some studies, a lower gastrojejunal anastomotic leak rate in robotic Roux-en-Y gastric bypass (RYGB) [1–4]. Surgeon experience and the learning curve to

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achieve such outcomes are highly emphasized, taking into consideration appropriate patient selection and mentorship. Cost analyses reveal mixed results [4, 5]. In this chapter, we discuss the past, present, and future of robotics in index bariatric surgery; robotic revision bariatric surgery will be considered in Chap. 40.

History of Robotic Bariatric Surgery

Minimally invasive surgery was introduced in the 1980s, and the benefits of decreased incisional pain, cosmesis, and faster return to activity and work soon became established. Traditional laparoscopy has many inherent limitations, unstable two-dimension vision, fixed point entry at the abdominal wall, limited degree of motion of instruments, and poor surgeon ergonomics resulting in musculoskeletal injuries [1]. Robotic surgery may offset some of the technical limitations of laparoscopy [6, 7].

In 1997, Belgian surgeons Himpens and Cadière reported the first case touting benefits of robotic-assisted surgery in obese patients, a cholecystectomy on a 72-year-old female with a BMI of 42 kg/m^2 [8]. The same authors, in 1998, described the first robotic-assisted laparoscopic gastric banding procedure in an obese patient emphasizing the surgeon's ergonomic comfort, the ease of endo-wrist manipulation, and the exemplary hand-eye coordination re-created by robotic operating system further promoting robotic surgery as an adjunct in bariatric surgery [9].

In America, the Da Vinci® robotic system (Intuitive Surgical, Sunnyvale, CA, USA) was approved by the Food and Drug Administration for general use in the year 2000. In the early days of robotic assistance, only portions of the operation were being performed robotically, such as the gastrojejunal anastomosis, and the remainder performed laparoscopically. More recently there has been a shift to totally robotic bariatric cases as efficiency and learning curve are achieved.

Review of Available Robotic Technology

Intuitive Surgical, Inc. (Sunnyvale, CA, USA) has been the major contributor to robotic surgical platforms, although several new competitive robotic platforms are reportedly forthcoming from press releases by Medtronic (Dublin, Ireland), Johnson & Johnson (New Brunswick, NJ, USA) with Google (Mountain View, CA, USA), and Titan Medical (Toronto, Canada), among others. The Da Vinci® robotic system will be reviewed here. The Da Vinci® robotic system encompasses a surgeon console(s), the patient trolley (robot), and the imaging system [6].

The surgeon console utilizes a binocular vision system with an endoscopic camera containing two lenses directing each image to a different eye. This system creates a stable 3D immersion into the surgical field. The surgeon controls the robotic camera system, an advantage over laparoscopy where the camera is controlled by a bedside assistant (or medical student). The surgeon's hands operate two controls

with pincer grasp mechanisms and the ability to clutch into more ergonomic positions. The hand motions can be scaled from 1:1 to 5:1 disguising tremors and increasing precision of motion. Foot pedals control the camera, field of view, application of energy and stapling, and toggling between surgical instruments, if the third arm is utilized. The entire console interface is adjustable, bringing the head and elbows to rest comfortably in position. In 2009 a dual surgeon console model was introduced which allows two surgeons on different consoles to work in the same operating field. We find the dual console especially rewarding in the teaching of robotic techniques. There is a microphone on each console allowing the surgeon(s) to communicate with the ancillary staff in the room. Instrument exchange and control is conducted from the console interface. There is also a pointer function that allows one to "point" to areas on the surgical field while the other surgeon is operating to further facilitate teaching in the operating room [6].

The patient trolley is composed of the robotic arms on a moveable cart-like mechanism. Moving the patient cart to the bedside and attaching the arms to the trocars is called "docking." Many different docking methods have been described and are unique to surgeon preference, operating room layout, and type of surgery to be performed. Docking times decrease with experience [10]. For bariatric cases, the patient cart may approach the OR table directly over the patient's head, or the cart may approach the table over either shoulder, via a straight line or parallel to the bed. Docking position is an important consideration to avoid external collisions of robotic arms which may impede ease of intra-abdominal maneuvers.

The more recent models of the Da Vinci® system have four arms; one for the camera and up to three working arms for instruments. The fourth arm is another advantage of robotic surgery, allowing the surgeon control of a static retractor arm allowing for improved exposure and less dependence on the bedside assistant. With a robotic platform, surgeons control a stable camera and three instruments, doubling the number of instruments directly controlled versus laparoscopic cases. The articulating arms and the wristed instruments offer additional surgeon benefits compared to laparoscopy. Robotically there are seven degrees of motion built in to needle drivers, graspers, energy, and stapling devices [6, 7]. Currently the robot offers monopolar, bipolar, and ultrasonic energy devices. Staplers include articulating 45 mm green and blue loads with white loads also available on the most current model. Staple loads accommodate buttress material if desired.

The imaging system operates like typical laparoscopy visual towers, including CO2 insufflation, a light source, and a camera that is mounted in the tower below the monitor. There is also a draw option on the accessory monitors that allows the surgeon at the console to view educational instruction provided by faculty should it be needed.

The Da Vinci® robotic system also has an external simulator function which can be connected to the console for practice and familiarization with console features. The simulator has multiple activities which replicate all the functions of the robotic console controls, while assessing economy of motion, time, force on tissue, collision of instruments, and amount of time instruments are kept out of the field of view [6]. It is our experience that surgeons new to robotics and our residents enjoy working with the simulator and better prepare them for real-time surgical applications.

Robotic Index Bariatric Outcomes

Tieu and colleagues [11] published the largest series of robotic RYGB to date with 1100 patients over 8 years with no deaths. The authors report a major complication rate of 4% which included <1% life-threatening complications from infection, bleeding, and PE, including only 1 gastrojejunal anastomotic leak (0.09%) [11]. They report a mean operative time of 155 min and a substantial lowering of operative time over the course of the study period culminating with an average of 90 min for the last 100 robotic RYGB in the community practice [11].

In a systematic review, Cirocchi and colleagues [2] confirmed no mortality and low complication rate in bariatric robotic surgery, including a 0.29% gastrojejunal leak rate in 2225 robotic RYGB and no leaks in 83 robotic sleeve gastrectomy [2]. They concluded the analysis was limited by a lack of high-quality studies, and although robotic surgery strongly facilitates some of the complex surgical steps (such as a gastrojejunostomy) and substantially reduces the learning curve, the clinical outcome evidence does not prove superiority of robotic over traditional laparoscopy at this point [2].

A meta-analysis of 27 studies comparing outcomes of robotic to laparoscopic bariatric surgery in nearly 28,000 patients found similar overall complication rates, with the exception of lower leak rates in robotic RYGB gastrojejunal anastomosis [3]. They reported robotic cases had longer operating room times, length of stay, and generally higher cost [3].

Surgical Ergonomics

While minimally invasive surgery leads to less patient pain and disability, Park and colleagues [12] reported on the "impending epidemic" of surgeons' suffering as 87% of laparoscopic surgeons reported physical symptoms and discomfort due to poor ergonomics of traditional laparoscopy [12]. Traditional laparoscopy requires hours of standing at the OR table, often in awkward and static positions, with high force exertion that places stress on the neck and back, shoulders, elbows, and wrists. The physical stress is compounded when operating on the obese patient. There is also substantial mental workload and stress, especially in the obese patient, when performing complex technical tasks such as suturing. The cumulative effects can result in overuse injury, missed work, disability, lost productivity, and even shortened careers [13].

In robotic surgery, the surgeon operates from a comfortable console with adjustable ergonomic controls. In "the aching surgeon" report from Stanford University, Plerhoples and colleagues [14] found that surgeons reported less pain in the neck and back as well as all joints (but more eye and finger pain) with robotic surgery, regardless of case volume, than laparoscopic and open surgery [14]. Other studies have reported that, compared to laparoscopic surgery, robotic operators have less muscle activation on surface electromyography, lower heart rate, and lower mental tension [15–18].

Robotic surgeons still must remain mindful of ergonomics in the console. Neck, back, shoulder, and finger pain are possible, especially if the operator's arms are held in awkward, static positions for long periods of time (mimicking learned laparoscopic techniques from within the console). Arms should be maintained in the neutral position with elbows in toward the sides and forearms resting on the console pad with frequent clutching back to this neutral position after repositioning instruments. Fingers should not be pinched with excessive, unnecessary force. The forehead should rest gently on the pad without straining the neck. Eye pain and fatigue can be reduced by intentionally taking breaks outside the console to adjust focus onto a distant object to balance the exercise of ocular muscles.

Hallbeck and colleagues [13] demonstrated that intraoperative "microbreaks" of 60–90 s of stretching exercises at medically convenient 20–40 min intervals resulted in significantly less shoulder pain, a trend toward less neck and back pain, and generally improved physical performance without increasing OR case time or disrupting the flow of the case [13]. We have incorporated microbreaks into our routine during robotic bariatric cases to briefly leave the console to join the team for intentional neck, back, and extremity stretching, eye exercises, and a mental break without noticing a disruption of flow in the operation. We have noticed an apparent increase in morale of the entire surgical team during these intentional microbreaks.

Learning Curve

The initial learning curve for laparoscopic RYGB appears to be around 75–100 cases [19] and fewer cases for laparoscopic sleeve gastrectomy [20]. One argument suggested for a robotic approach to bariatric surgery is to reduce the substantial learning curve of traditional laparoscopic bariatric surgery given the difficulty of operating on the morbidly obese patient with large livers, small working spaces, and complex technical moves such as suturing.

A randomized trial was performed at Stanford with a single fellow without any bariatric experience involving 50 laparoscopic and robotic RYGB to evaluate the learning curve [21]. Sanchez and colleagues [21] reported no major postoperative complications in either group and that the mean operating time was significantly shorter for robotic versus laparoscopic RYGB (131 versus 149 min, $p = 0.02$), especially pronounced in larger BMI patients (robotic cases averaged nearly 30 min shorter case time), and proficiency to an average OR time of <2 h achieved by the fellow after only ten robotic cases [21]. A retrospective follow-up study in subsequent fellows reaffirmed the learning curve of 10–15 robotic RYGB cases with median operating time of 140 min and no leaks [22].

Ecker and colleagues [23] suggested sleeve gastrectomy is a model for robotic training as they reported on 13 consecutive third- and fifth-year general surgery residents operating at the console who had no prior robotic experience. Based on their

definitions, proficiency was achieved after 5 cases (as measured by operative time) with overall mean operating room time of 96 min in 411 consecutive robotic sleeve gastrectomy operations [23].

In our experience, surgical residents are able to successfully complete complex tasks (such as a hand-sewn bowel anastomosis) and perform more complex procedures, including bariatric procedures, at an earlier PGY level when operating at the robotic console than with laparoscopy. Our residents complete online courses, dry-run training, and simulator exercise training in the intern year. Bedside assisting and console exposure begin in the PGY-2 year. We have noticed translation of robotically obtained skills to faster acquisition of laparoscopy skills. This translation has been demonstrated in published studies [24].

Cost Considerations of Robotic Surgery

There are significant direct costs of robotic technology including the capital cost of the robotic system, the yearly service plan, additional technology upgrades, specialized drapes, and disposable (or limited use) robotic instruments as well as laparoscopic instruments for the bedside assistant. Additional costs potentially include course fees and travel for training, case observations, as well as simulation. Indirect costs accrued during the learning curve from relatively longer OR times before proficiency is achieved could also result in comparatively higher case costs.

Other factors affecting cost should also be considered when comparing robotics to traditional laparoscopic (or open) surgery such as complication rates, hospital length of stay, laparoscopy capital costs, instrumentation, and training costs. Furthermore, there may be possible long-term indirect economic benefits of robotics from improved surgeon ergonomics in the form of less pain and disability leading to less workplace injury, disability leave, and shorter operating career.

Published cost analyses vary considerably in design and variables making cost comparisons challenging. Previous literature reports comparing robotic to laparoscopic bariatric procedures have reported robotic cases to be generally more expensive than laparoscopic cases [4]. Contrary to this, an in-depth comparison of laparoscopic and robotic RYGB by Hagen and coworkers [5] suggested that by reducing leak rates and using less staplers, robotic RYGB was overall less expensive than a laparoscopic and an open approach [5].

There are also local variables that may affect overall profitability in a given hospital such as whether or not a robotic system is already in place, frequency of use (the capital cost per case is a function of total number of robotic cases performed), OR time costs, efficiency of the robotic team, turnover, the surgeon's learning curve, and disposable equipment choices by the surgeon. Finally, incremental changes in hospital volumes attributable to a robotic program (especially in fields with higher robotic penetrance such as urology and gynecology) may be a factor affecting the overall economic analysis for a given hospital.

In our hospital's retrospective economic analysis of a mature robotic bariatric practice, the overall hospital charges for robotic cases (combined RYGB and sleeve gastrectomy) were not statistically different from laparoscopic bariatric cases (unpublished data). Additionally, establishment of the robotic program in the hospital directly led to a substantial increase in prostatectomy and gynecological oncologic procedures being performed and less patient migration from the community. An accurate economic analysis of robotics is best considered locally by taking into account all of the relevant factors for a given hospital.

Conclusion and Considerations for Robotics in Index Bariatric Surgery

Compared to traditional laparoscopic bariatric surgery, robotic bariatric studies demonstrate generally equivalent clinical outcomes and complication rates (with the possibility of a lower gastrojejunal anastomotic leak rate in robotic RYGB), a shorter learning curve, and improved ergonomics, with longer operating room times at a generally higher per case cost. Robotic operating room times decrease with experience, and perhaps lower leak rates and surgeon ergonomic benefits will factor favorably into cost analysis; costs may be considered locally based on numerous direct and indirect factors.

Given the safety and excellent clinical outcomes of traditional laparoscopic index bariatric surgery, a surgeon considering a robotic approach needs to carefully consider their goals and system resources. A surgeon training residents and fellows will likely appreciate the lower learning curve and faster skill acquisition, and the newly minted bariatric surgeon may experience a lower gastrojejunal leak rate with a robotic approach. The hurting surgeon may welcome the ergonomic advantages of sitting in a comfortable console, being mindful of correct posture and taking microbreaks every 30–40 min. Having control of a stable, HD-3D camera platform with multiple, wristed instruments may benefit in complex operative maneuvers, extremes of anatomy or BMI, and difficult cases such as revisional surgery.

As with traditional laparoscopy, the entire team is essential to a successful robotic program, including a capable bedside assistant. Currently many robotic bariatric surgeons are using traditional laparoscopic staplers, deployed by the bedside assistant, instead of the robotic stapler. Ideally the robotic bariatric surgeon will have a dedicated team and a consistent assistant.

It is generally recommended that interested surgeons attend a case observation at an experienced robotic bariatric center early in the decision-making process. There are industry-provided, web-based learning modules to complete, dry labs, computer simulations, and wet training labs prior to first cases. Initial cases should be proctored (number determined by hospital credentials but typically a minimum of three cases) ideally by an experienced robotic bariatric surgeon. There are also advanced courses in bariatric surgery offering both didactic, hands-on training, and retrospective video reviewing of surgical technique is available commercially (C-STATS, Inc. Seattle, WA, USA).

Patient selection is important to early success, and initial cases should occur soon after training courses. Lower BMI, index cases, and more favorable expected intra-abdominal anatomy (such as gynecoid phenotype and lack of adhesions) are considerations. A graduated approach from less to more complex operations may be wise as a surgeon familiarizes himself or herself with the robotic functionality and becomes facile at docking and console operating. For instance, some surgeons have started with less complex general surgery cases or sleeve gastrectomy, while others starting with RYGB have predetermined an amount of time to operate robotically (before completing laparoscopically) or perform certain predetermined steps of an RYGB robotically (as a hybrid laparoscopic robotic case) instead of totally robotic in their first few cases. As with any other learning curve, early and repeated exposure to the robotic approach should result in greater proficiency, and proficiency should improve before increasing complexity. The focus should be on patient safety and good clinical outcomes.

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Chapter 28
Duodenal Switch: Technique and Outcomes

Cheguevara Afaneh and Alfons Pomp

Abbreviations

AGB	Adjustable gastric banding
BMI	Body mass index
BPD/DS	Biliopancreatic diversion with duodenal switch
EWL	Excess weight loss
RYGB	Roux-en-Y gastric bypass
SADI	Single-anastomosis duodeno-ileal bypass
SG	Sleeve gastrectomy
SIPS	Stomach intestinal pylorus-sparing surgery

Introduction

Bariatric surgery is the most effective treatment of morbid obesity and the related comorbidities [1, 2]. The most commonly performed bariatric procedures include the Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) followed by adjustable gastric banding (AGB); however, the most effective bariatric procedure for both weight loss and resolution of comorbidities is the biliopancreatic diversion with duodenal switch (BPD/DS) [1, 3–7]. Nevertheless, the BPD/DS is the least commonly performed bariatric procedure (Fig. 28.1).

A traditional BPD/DS procedure combines the weight loss properties of a restrictive procedure as well the metabolic effects of a malabsorptive procedure. Given the complexity of the procedure, it was initially performed via an open approach;

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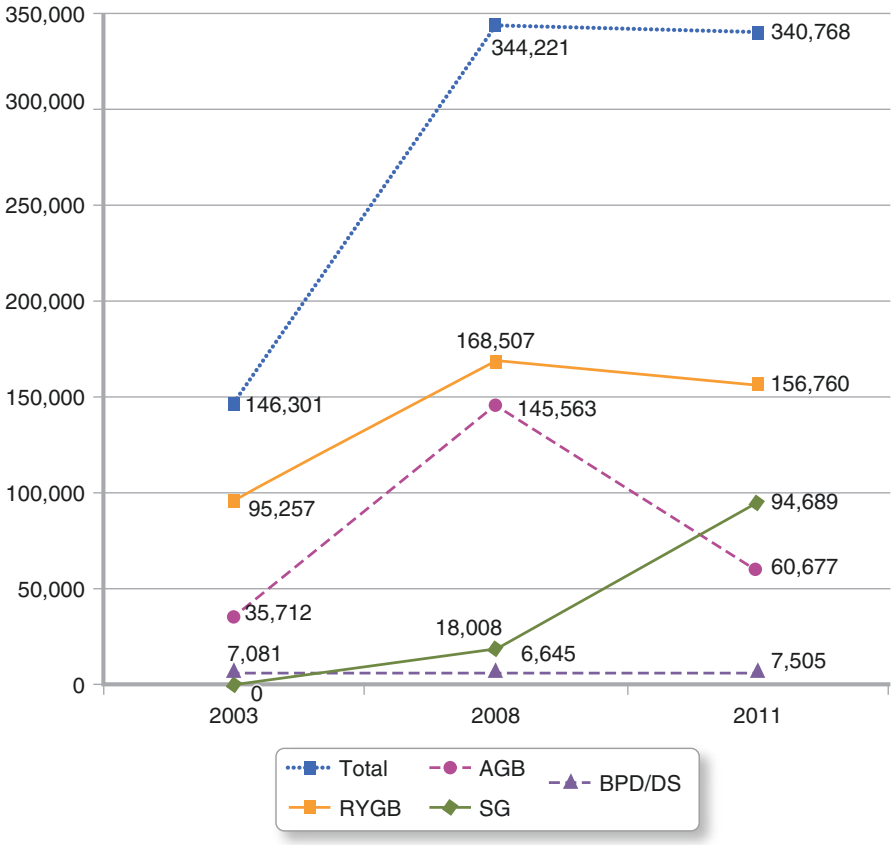

Fig. 28.1 Distribution of primary bariatric procedures worldwide (Used with permission of Springer Science from Buchwald and Oien [22])

however, modern techniques include both laparoscopy and robotic-assisted approaches. The laparoscopic approach described by Gagner consists of a SG (restrictive procedure) as well as an alimentary limb of 150–200 cm anastomosed to the proximal duodenum and a 50–125 cm common channel [3]. The combination of a restrictive procedure in combination with a malabsorptive procedure maximizes both weight loss and comorbidity resolution [5, 6]. The procedure is both technically complex, especially when performed via minimally invasive approaches, and requires astute patient selection, as the potential for malabsorptive complications is significantly higher than other bariatric procedures. Moreover, the morbidity of the procedure and risk of long-term nutritional complications further limit its role in the bariatric surgeon's armamentarium to combat morbid obesity [3–6].

Over the last few years, several variations of the traditional BPD/DS have emerged expanding the pool of suitable patients. The most commonly performed variations include the single-anastomosis duodeno-ileal bypass (SADI) and stomach

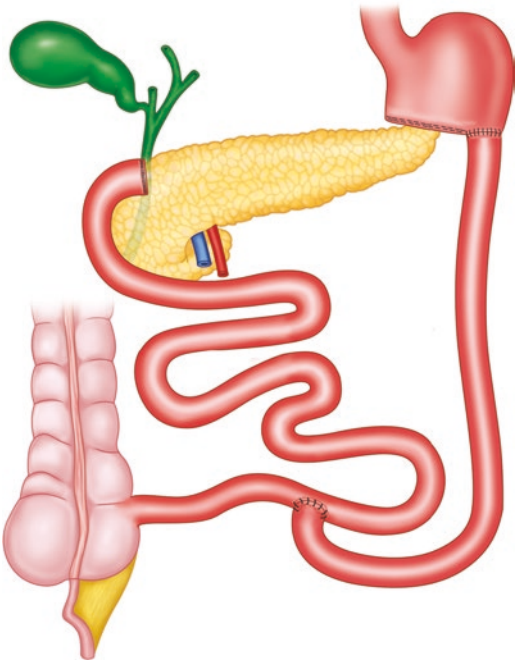

Fig. 28.2 Biliopancreatic diversion (Scopinaro procedure)

intestinal pylorus-sparing (SIPS) surgery [8]. These variations are technically less demanding with significantly less morbidity. Moreover, the incidence of long-term nutritional deficiencies is significantly less.

The scope of this chapter is to review the techniques of the traditional BPD/DS as well as some of the more modern variations. Moreover, a review of the perioperative outcomes, in comparison to more traditional procedures, will help delineate proper patient selection for these procedures.

Biliopancreatic Diversion with Duodenal Switch (BPD/DS) Technique

The original BPD (Fig. 28.2) was described by Scopinaro and coworkers [4]. This was later modified by Hess and colleagues (Fig. 28.3) to the more traditional BPD/DS [5]. The procedure begins by mobilizing the greater curvature of the stomach to allow for creation of a sleeve gastrectomy. The SG performed during a BPD/DS is traditionally wider, accommodating a bougie size of 60 fr, as opposed to modern SG which is performed over bougie sizes commonly ranging between 36fr and 40fr. Once the SG gastrectomy is complete, the transected portion of the stomach is removed.

Next, the first portion of the duodenum is circumferentially dissected free and then transected 2 cm distal to the pylorus. The ileocecal valve is then identified, and a small bowel loop approximately 250–325 cm proximal to the ileocecal valve is

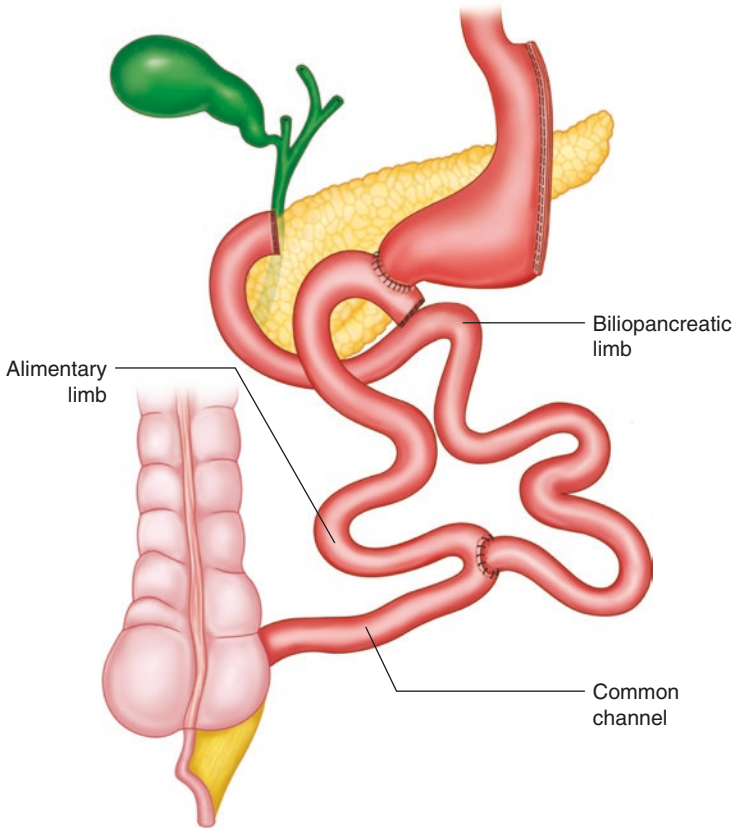

Fig. 28.3 Biliopancreatic diversion with duodenal switch

transected. The distal end is then anastomosed to the duodenum in an end-to-side fashion. The newly fashioned anastomosis effectively creates an alimentary limb. Approximately 150–200 cm distal to the new duodenal-enteric anastomosis, a second anastomosis is created in a side-to-side fashion between the biliopancreatic limb that was previously stapled off and the alimentary limb. Effectively, a common channel is now formed, ranging in length between 50 and 125 cm. All mesenteric defects are typically closed using nonabsorbable sutures.

BPD/DS and Weight Loss Outcomes

Early studies demonstrated the efficacy of the BPD/DS. In a meta-analysis by Buchwald and colleagues, 136 studies reported on over 22,000 patients undergoing various bariatric procedures, including AGB, RYGB, SG, and BPD/DS [1]. With respect to excess weight loss (EWL), the BPD/DS achieved the highest percentage

of EWL. Long-term studies of 10 years or more by both Scopinaro and colleagues [4] and Hess and colleagues [5] reported EWL of 75% or more.

The magnitude of EWL was further confirmed by various other groups. Marceau and coworkers reported EWL rates of 73% with up to 15-year follow-up on approximately 1500 patients [6]. Furthermore, more than 80% of patients achieved at least 50% EWL. Over 80% of patients in this cohort achieved a body mass index (BMI) < 40. A group from Britain reported on a series of 121 super morbidly obese patients who underwent BPD/DS with 90% EWL at 4 years [9]. A multicenter study by Pata and colleagues demonstrated a median BMI reduction by over 20 points sustained at over 10 years [10].

The magnitude of weight loss achieved with BPD/DS can be fully appreciated when compared to various other bariatric procedures, such as RYGB and SG. In 2007 we reported on a series of patients undergoing RYGB or BPD/DS [11]. Patients undergoing BPD/DS had both a significantly higher percent change in BMI (23% vs 16%; $P < 0.001$) and significantly higher change in body fat percentage (24% vs 17%; $P < 0.001$). Moreover, the BPD/DS patients achieved a normal body fat percentage (23%), which is in the normal range. A corollary study was performed comparing BPD/DS to AGB, SG, and RYGB [12]. The most effective procedure with respect to EWL was the BPD/DS (83%), compared to 70% for RYGB, 50% for SG, and 37% for AGB. Additionally, the BPD/DS had the most significant change in body at 22.9%, compared to 16% with RYGB, 11.5% for SG, and 6% with AGB.

A systematic review and meta-analysis by Hedberg and coworkers compared 874 morbidly obese patients undergoing BPD/DS to 1149 morbidly obese patients undergoing RYGB [13]. With a follow-up period of at least 2 years, patients undergoing BPD/DS yielded 6.24 additional BMI units compared to patients undergoing RYGB (95% CI, 5.0–7.5). Meta-regression analysis of the difference in BMI loss between the two procedures demonstrated larger differences in weight result with increasing baseline BMI ($P < 0.05$).

BPD/DS and Diabetes Treatment

The most effective treatment of diabetes mellitus is the BPD/DS procedure. Buchwald and coworkers described this in a meta-analysis in 2004 [1]. The BPD/DS was the most effective weight loss procedure but also demonstrated the highest rate of diabetes resolution at 98%, compared with 84% with RYGB and 48% with AGB. A more recent study by Mingrone and coworkers demonstrated the superiority of bariatric surgery over medical therapy for the treatment of type 2 diabetes in a single-center randomized, controlled trial of 60 patients [2]. Morbidly obese patients with type 2 diabetes for at least 5 years with a glycosylated hemoglobin of at least 7% were randomized to receive conventional medical therapy or bariatric surgery (BPD/DS or RYGB). At a 2-year follow-up, none of the patients in the conventional medical group had resolution of type 2 diabetes compared to 75% in the RYGB

group ($P < 0.001$) and 95% in the BPD/DS group ($P < 0.001$). Furthermore, mean glycosylated hemoglobin levels were lowest in the BPD/DS group (4.95%) compared to the 6.35% in the RYGB group and 7.69% in the conventional medical therapy.

Similar results were validated in super obese patients with type 2 diabetes. In a case-controlled study by Prachand and coworkers of 350 super obese patients with type 2 diabetes, all patients undergoing BPD/DS were medication-free at a mean follow-up of 36 months, compared to 60% of patients who underwent RYGB [14]. Morbidity rates were not significantly different between patients undergoing BPD/DS and RYGB.

BPD/DS and Nutritional Considerations

The evidence in the literature clearly supports BPD/DS as the most effective procedure for weight loss and metabolic syndrome resolutions; however, this procedure is not commonly utilized to treat the morbidly obese patient given the technical complexity and self-selection for higher-risk patients. Part of the hesitation in employing this technique is the result of the morbidity of the procedure. Buchwald and coworkers reported a mortality rate of 1.1% for patients undergoing BPD/DS, while patients undergoing RYGB had a 50% lower mortality rate [1]. A two-stage approach can somewhat mitigate the perioperative morbidity and mortality. Nevertheless, the deleterious nutritional effects of the traditional BPD/DS remain. Careful patient selection and proper nutritional screening and counseling mitigate the nutritional complications. A thorough understanding of the nutritional complications can prevent potential complications from deficiencies.

One of the most common malnutrition parameters in BPD/DS patients is hypoalbuminemia. Marceau and colleagues reported on a series of approximately 1500 patients who underwent BPD/DS over a 15-year period [6]. Over 90% of patients had normal albumin levels, with only 8% demonstrated hypoalbuminemia. The incidence of albumin deficiency was less than 1%. In most cases, hypoalbuminemia can be dealt with oral hyperalimentation with rare instances of temporary parenteral nutrition. Common channel limb lengthening for malnutrition is fairly rare, required in less than 1% in patients. Most patients had a common channel length of approximately 100 cm. Despite supplementation with folate, vitamin B12, and iron, anemia was present in approximately 14% of patients; however, less than 1% of patients had a hemoglobin <10 g/dL. Vitamin A levels were noted to be low in 21% of patients and deficient in nearly 2% of patients. Nonetheless, oral supplementation was adequate to correct this in most patients. Vitamin D levels were either normal or slightly elevated in most patients (due to hypersupplementation), yet 20% of patients had low levels of serum calcium with about 1% being deficient, and nearly half the patients had elevated levels of PTH.

Other studies demonstrated similar vitamin and mineral derangements. A study of 51 patients by Topart and coworkers demonstrated vitamin D deficiency in the 51 patients who underwent BPD/DS and followed for 5 years [15]. These patients were

noted to have increasing PTH levels over time as well. None of the patients developed hypoalbuminemia, and common channel limb lengthening was necessary in two patients for chronic diarrhea. Magee and colleagues reported on a series of 121 patients who underwent BPD/DS with 4-year follow-up [9]. Approximately 12% of patients were deficient in vitamin A, and 40% were deficient in vitamin D. Hypoalbuminemia occurred in six patients which was treated with temporary parenteral nutrition. Of note, night blindness developed in four patients with vitamin A deficiency years after surgery, further highlighting the need for adequate long-term follow-up. Quality of life assessments demonstrated an 85% satisfaction rate with the BPD/DS.

The most significant factor in developing malnutrition is the length of the common channel. Gracia and colleagues demonstrated a hypoalbuminemia rate of 11% in patients with a common channel of 50 cm but only 3% in patients with a common channel of 75 cm [16]. Of those patients with a 50 cm channel, 3.2% of patients required a limb-lengthening procedure. Iron deficiency was noted in 52% of BPD/DS patients. Patients with 50 cm common channels had a rate of 62%, compared to 40% in patients with a 75 cm common channel. In general, patients with shorter common channels appear to be at higher risk of additional nutritional deficiency compared to those with longer channels.

Single-Anastomosis Duodeno-Ileal Bypass (SADI) and Stomach Intestinal Pylorus Saving Surgery (SIPS) Techniques

The single-anastomosis duodeno-ileal bypass (SADI) with sleeve gastrectomy is a modification of the biliopancreatic diversion/duodenal switch (Fig. 28.4) [17]. The traditional BPD/DS was highly effective in curing metabolic disease; however, the morbidity, in relation to other bariatric procedures, carried a heavy toll on both surgeon and patient, except with meticulous patient selection. The rationale behind a modified duodenal switch ultimately stemmed from a combination of necessity, i.e., metabolic surgery that can cure diabetes, and safety, i.e., less short-term and long-term morbid procedure. The technique was first described in 2007 by Sanchez and coworkers and later modified in the United States by Cottam and coworkers [17, 18]. The modified procedure by Cottam and colleagues was coined stomach intestinal pylorus saving (SIPS) surgery (Fig. 28.5). The procedure is characterized by creating a SG first. The group from Spain (Sanchez) used a 54 fr bougie (SADI), while Cottam and colleagues used a bougie size of 40 fr (SIPS). The duodenum was transected at the level of the gastroduodenal artery. Then an ileal loop was brought up to the duodenal stump in an antecolic manner, and an end-to-side duodeno-ileal anastomosis was fashioned using either a hand-sewn or stapled technique, creating an effective anastomosis size of 30 mm. Sanchez typically created a common channel length of 200–250 cm, while Cottam routinely created a common channel length of 300 cm to mitigate the risk of malnutrition. Cottam's groups place two

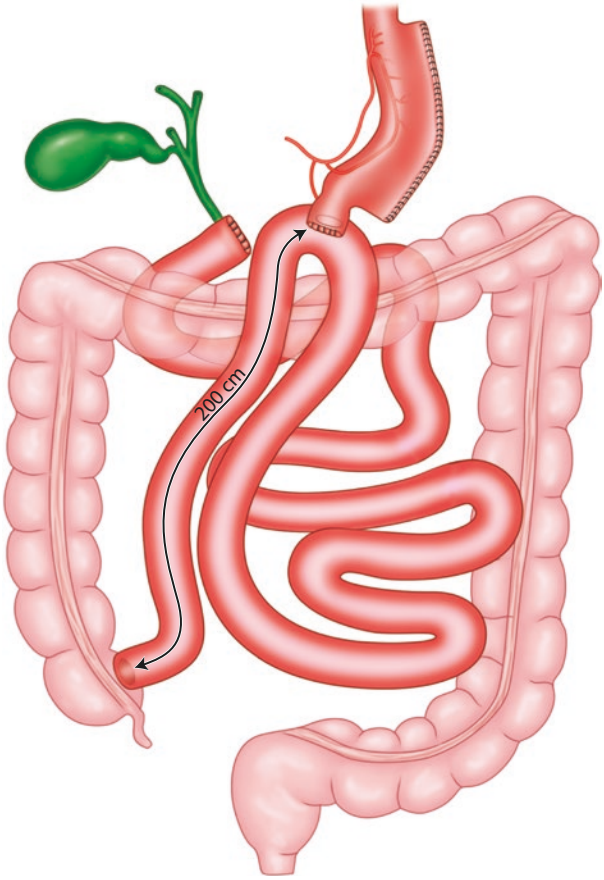

Fig. 28.4 Single-anastomosis duodeno-ileal bypass (SADI)

interrupted sutured between the afferent limb and the antrum as well as the afferent limb and omentum to prevent chronic nausea and volvulus. Surgical drains were routinely placed by Sanchez.

SADI and SIPS Outcomes

Early studies commenting on the SADI and SIPS procedure demonstrated safety and efficacy. Sanchez and coworkers reported on the initial series of 97 morbidly obese patients with type 2 diabetes mellitus undergoing SADI plus sleeve gastrectomy (SADI-S) or SADI after sleeve gastrectomy [17]. Total weight loss at 1, 2, and 5 years after surgery were 39%, 39%, and 38%, respectively. One anastomotic leak occurred as well as two reoperations: one for hemoperitoneum and the other for an

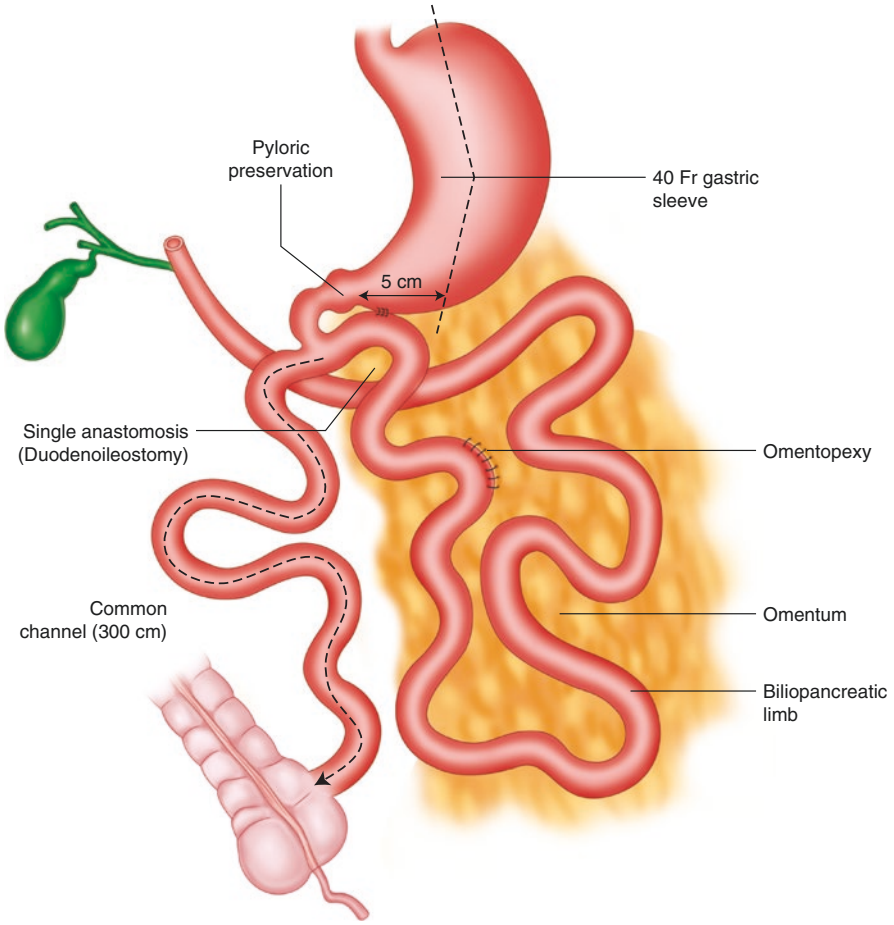

Fig. 28.5 Stomach intestinal pylorus saving (SIPS) surgery

incarcerated umbilical hernia. Only three patients developed hypoproteinemia requiring reoperation. At 1 year, 100% of patients reduced their HgA1c to <6%; these results were sustained at 5 years in 84% of patients. Even in patients using preoperative insulin therapy, all but 3/40 were completed off insulin therapy. Overall diabetes remission rates, as defined as HgA1c < 6% without antidiabetic medications, at 1, 2, and 5 years were 71.6%, 77%, and 52%, respectively. Moreover, lipid profiles and hypertension also significantly improved in most patients. The incidence of hypoalbuminemia at 3 years was less than traditional BPD/DS as only 12% of cases developed this nutritional deficiency. Low levels of vitamin A and parathormone were noted in 53% and 54% of patients, respectively, at 3 years.

The modified approach by Cottam and colleagues demonstrated similar perioperative outcome with improved nutritional profiles [17]. The authors compared 61 morbidly obese patients who underwent SIPS to 61 matched patients who underwent

traditional BPD/DS. Total weight loss was not significantly different between patients who underwent SIPS or BPD/DS at 1 year (36% vs. 38.4%, respectively) or 2 years (38.7% vs. 44.2%, respectively). One patient developed a stricture of the sleeve gastrectomy (history of Nissen fundoplication) and ultimately small bowel perforation requiring reoperation. One patient developed a postoperative gastrointestinal bleed. The HgA1c levels returned to normal in 86% of patients at 1 year in the SIPS group, which was not significantly different than the BPD/DS group (87%, $p = 0.701$). Only one patient in the SIPS group required common channel limb lengthening. None of the patients developed bile reflux, and there were no cases of volvulus. Albumin levels were abnormal in only 3% of patients at 1 year. Other vitamin and mineral deficiencies, such as Vitamin B12 and calcium, were similar or less than long-term deficiencies of RYGB as reported by Higa and colleagues [19].

Subsequent studies demonstrated similar outcomes. The Cottam group from Utah combined data with Roslin's group in New York to report on a series of 123 morbidly obese patients who underwent SIPS [20]. One stricture in the sleeve was noted requiring endoscopic therapy. One reoperation was needed. Total weight loss at 1 year was 38.6%. All but two patients had normal albumin levels. Moreover, other nutritional parameters, such as vitamin B1, vitamin B12, and vitamin A, were normal or close to normal in almost all patients.

The SADI procedure has been shown to be effective as a second-step procedure to optimize weight loss. Balibrea and colleagues reported on a series of 30 consecutive patients who underwent SADI as a second-step procedure following SG [21]. Two early postoperative leaks occurred. Total weight loss at 1 and 2 years were 41% and 46%, respectively. Severe hypoalbuminemia requiring total parenteral nutrition occurred in three patients which required surgical revision of the common channel length. Over the follow-up period, the diabetes remission rate was 71.4%. A $\geq$ 50% remittance or improvement rate was noted for dyslipidemia and hypertension. Over 20% of patients had hypoalbuminemia at 2 years. Two-thirds of patients had abnormal parathormone levels, while vitamin B12 was abnormal in one-third of patients. Of note, the authors noted that no nutritional deficiencies were noted in patients with common channel lengths of 300 cm.

Conclusion

The obesity epidemic in the United States and worldwide continues to grow. More effective tools in the bariatric surgeon's armamentarium are needed to optimize metabolic outcomes without compromising morbidity. Bariatric surgery remains the most effective treatment modality for weight loss and metabolic syndrome. The BPD/DS is the most effective bariatric surgical procedure both in terms of weight loss and combating metabolic syndrome. Multiple long-term studies have validated the safety and efficacy of this procedure. Surgical variations of this procedure, such as SADI and SIPS, have emerged as viable options in well-selected patients.

The surgical complexity and nutritional morbidity of the BPD/DS have hindered widespread use of this procedure to combat morbid obesity. Nevertheless, careful patient selection and education can essentially remove the barriers associated with this procedure. Often, this procedure is generally reserved for the most complex bariatric patients, such as the super obese and those who have already failed other weight loss procedures. Certainly, both these patient populations will continue to expand, making BPD/DS a more commonly utilized bariatric procedure.

Of all bariatric procedures, the BPD/DS is the most effective treatment of diabetes. Nonetheless, nutritional morbidity must be factored into this procedure to avoid poor patient outcomes. Proper patient selection, education, and surgical staging can mitigate much of this morbidity. The short- and long-term nutritional derangements should not be underestimated. Although most patients will not develop severe nutritional deficiencies, certain patients will, even in the most experienced BPD/DS bariatric centers. Patients and physicians should be aware of possible protein, iron, calcium, vitamin A, and vitamin D deficiencies. Lifelong nutritional supplementation and follow-up is necessary to optimize patient outcomes and minimize nutritional morbidity of this procedure.

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Chapter 29
Comparative Surgical Outcomes in Bariatric Surgery

Rafael Alvarez and Dana A. Telem

Introduction

The obesity epidemic affects hundreds of millions of children and adults worldwide. The prevalence of obesity has more than doubled since 1980, reaching 600 million or 13% of adults in 2014. Globally, 41 million children under the age of 5 were overweight or obese in 2014 [1]. In the United States, the prevalence of obesity from 2011 to 2014 was just over 36% in adults (age 20 years or older) and 17% in youth (age 2–19) [2].

Bariatric surgery is the most effective therapy for obesity and related comorbidities, and the number of bariatric operations performed every year continues to grow. Compared with intense medical management alone, bariatric surgery offers superior weight loss and glycemic control [3, 4]. In the United States, an estimated 196,000 bariatric procedures were performed in 2015 which represented a 24% increase from 2011 [5, 6].

This chapter reviews the short-, mid-, and long-term outcomes following three key bariatric operations: Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and biliopancreatic diversion/duodenal switch (BPD/DS). Given the dramatic reduction in the number of adjustable gastric banding (AGB) procedures performed over the past decade, discussion of outcomes following this operation will be limited to weight loss, mainly for historical purposes. We follow previously established criteria for standardized reporting of bariatric surgery outcomes and specifically define short-, mid-, and long-term outcomes as those occurring at 2, 3, and 5–10 years, respectively [7]. Outcomes discussed here include weight loss, resolution of medical comorbidities, and procedural complications. Given the established benefits associated with bariatric surgery as well as its increasing utilization,

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familiarization with the differential outcomes following these dominant bariatric operations is key to better tailor the surgical management of obesity.

Weight Loss

To effectively assess weight loss outcomes after surgery, familiarity with the different terminology is fundamental. Weight in excess to ideal body weight, determined by the Metropolitan Life tables or body mass index (BMI) <25 kg/m^2, defines excess body weight (EBW) [8, 9]. The percentage of EBW lost following bariatric surgery is referred as percent excess body weight loss (%EBWL). BMI is the ratio of weight in kilograms divided by height in m^2. Excess BMI (EBMI) is defined as that exceeding 25 kg/m^2. BMI reduction following bariatric surgery is given by percent EBMI loss (%EBMIL). Recently, to standardize weight loss reporting after bariatric surgery, percentage total body weight loss (%TBWL) has been frequently utilized. For this reason, we will use %TBWL whenever available throughout the chapter; however, weight loss ranges in %EBWL and %EBMIL will still be included in tabular format.

Preceding the bulk of our discussion focusing on our three dominant operations, we herein provide, for the sake of completeness, a brief overview of recent comparative reports including AGB. Sudan and colleagues investigated weight loss at 1 year for AGB, SG, RYGB, and BPD/DS. In this large study, unmatched mean %EBWL (± SD) at one year was 31.0% (± 18.3) for AGB, 51.7% (± 21.0) for SG, 60.5% (± 20.3) for RYGB, and 65.2% (± 22.2) for BPD/DS. Mean matched absolute BMI unit reduction (± SD) was 7.2 (± 4.3), 13.6 (± 5.2), 15.8 (± 5.0), and 19.9 (± 6.1) for AGB, SG, RYGB, and BPD/DS correspondingly. Compared with patients undergoing AGB, mean (± SE; p value) BMI unit reduction at 1 year was 5.7 (± 0.06; $p < 0.0001$) for SG, 9.3 (± 0.03; $p < 0.0001$) for RYGB, and 10.6 (± 0.15; $p < 0.0001$) for BPD/DS [10]. Dogan and collaborators reported on weight loss outcomes at 2, 3, and 5 years in their matched retrospective laparoscopic cohort of AGB ($n = 245$), SG ($n = 245$), and RYGB ($n = 245$). Mean %EBWL (± SD) at 2, 3, and 5 years were 44.2% (±19.8), 42.7% (±22.1), and 44.6% (±30.0) for AGB; 75.4% (±24.7), 69.7% (±25.1), and 62.5% (±23.8) for SG; and 72.3% (±23.6), 69.7% (±25.5), and 65.1% (±23.2) for RYGB, respectively. Percentage EWBL was significantly greater for all points in time for SG and RYGB when compared to AGB [11]. Maciejewski and coinvestigators reported on the weight loss outcomes of Veterans Affairs (VA) patient undergoing AGB ($n = 249$), SG ($n = 381$), and RYGB ($n = 1844$) in their retrospective cohort study. At 1 year, %TBWL was 13.0% for AGB, 23.4% for SG, and 30.9% for RYGB. At 4 years, %TBWL was 10.6%, 17.8%, and 27.5% for AGB, SG, and RYGB correspondingly, while mean %EBWL (±SD) was 28.6% (±30.5) for AGB, 43.0% (±28.1) for SG, and 60.0% (±26.1) for RYGB [12]. Angrisani and colleagues reported on mid- and long-term weight loss of their randomized controlled trial (RCT) where 51 patients were allocated to AGB ($n = 27$) or RYGB ($n = 24$). At 3, 5, and 10 years, %EBWL was 47.3%, 47.5%, and

45.9%, respectively, for AGB and 51.3%, 66.6%, and 69.0% correspondingly for RYGB. Although significance was not reported at earlier points in time, at 10 years the authors noted statistically superior %EBWL for RYGB when compared to AGB ($p = 0.003$) [13]. Although by no means comprehensive, this review underscores the inferior short- and long-term weight loss outcomes that occur after AGB when compared to those appreciated following SG, RYGB, and BPD/DS.

The pattern and extent of weight loss following bariatric surgery varies depending on the specific bariatric operation performed. For patients undergoing RYGB or SG, rapid weight loss occurs over the first few months, continuing at a slower rate over the next year to year and a half before reaching a plateau [3, 14]. Following BPD/DS, patients experience weight loss at a slightly higher rate when compared to RYGB and SG up to 1 year, then continuing at a slower rate before plateauing by 18 months to 2 years [15–17]. Regardless of the procedure performed, recent data from the Michigan Bariatric Surgery Collaborative (MBSC) by Varban and colleagues showed that operating earlier, at BMI < 40 kg/m^2, was associated with higher likelihood of achieving a BMI < 30 kg/m^2 [18].

Specific short-term weight loss outcomes at 2 years by operation are summarized in Table 29.1. Patients undergoing RYGB experience a %TBWL ranging from 21.0% to 37.4% [19–22]. Following SG, patients can be expected to achieve a %TBWL ranging from 23.4% to 34.1% [23, 24]. Lastly, 2-year %TBWL after BPD/DS ranges from 33.8% to 36.7% [21, 25].

Table 29.1 Short-term comparative outcomes at 2 years

	RYGB	SG	BPD/DS
Weight loss			
%EBWL	61.4–79.8 (21,22,32,34,115)	60.8–77.8 (32,34,115)	65.1–69.4 (21,25)
%EBMIL	74.7–84.8 (3,19–22,33)	72.1–74.7 (11,33)	76.1–85.0 (16,21,25)
%TBWL	21.0–37.4 (19–22)	23.4–34.1 (23,24)	33.8–36.7 (21,25)
Comorbidities			
Diabetes remission; %	66.7–75.0 (21,69,70)	35.0–41.0 (70,71)	95.0–100 (21,69)
Hypertension remission; %	53.0–65.4 (75)	54.0–72.0 (36,37)	49.3–76.0 (37,76)
Dyslipidemia remission; %	52.0–57.0 (75,77)	60.0–65.2 (36,82)	70.0–92.1 (76,77)
GERD remission; %	61.0 (77)	77.4 (36)	48.0 (77)
OSA remission; %	29.0–100.0 (19,28,33,35–39)	56.2–100.0 (19,28,33,35–39)	80.0–100.0 (19,28,33,35–39)

RYGB indicates Roux-en-Y gastric bypass, *SG* sleeve gastrectomy, *BPD/DS* biliopancreatic diversion with/without duodenal switch, *%EBWL* percent excess body weight loss, *%EBMIL* percent excess body mass index loss, *%TBWL* percent total body weight loss, *GERD* gastroesophageal reflux disease, *OSA* obstructive sleep apnea

Mid- and long-term weight loss outcomes from 3 to 10 years, when available, are depicted in Table 29.2. When considering these long-term data, it is important to keep in mind that these are mostly derived from retrospective and heterogeneous studies with limited follow-up. Nevertheless, following RYGB, %TBWL ranges at 3, 5, and 10 years are 29.4–35.3%, 25.6–34.4%, and 27.7–29.6% respectively [13, 17, 19, 22, 26]. Percent TBWL at 3, 5, and 10 years for SG is 28.2–34.6%, 23.6–25.1%, and 21.0–26.3% correspondingly [24, 27–29]. BPD/DS results in a %TBWL of 45.2% at 3 years, 31.1–40.7% at 5 years, and 33.4–39.0% at 10 years [15, 17, 25, 26, 30, 31].

Notable randomized clinical trials (RCTs) which exemplify the short- and long-term comparative weight loss variations between RYGB and SG are briefly discussed next. The single-center "Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently" (STAMPEDE) trial randomized 150 patients with uncontrolled type 2 diabetes and BMI 36 ± 3.5 kg/m^2 to receive either intensive medical therapy alone or intensive medical therapy plus RYGB or SG. For patients undergoing SG, BMI at 2 years was 27.9 kg/m^2 from 36.1 kg/m^2 at baseline, for a %EBMIL of 73.9. For patients undergoing RYGB, BMI at 2 years was 27.3 kg/m^2 from 37.1 kg/m^2 at baseline, for a %EBMIL of 81.0. At 3 years, BMI was 29.2 (%EBMIL=62.1) and 27.9 kg/m^2 (%EBMIL=76.0) for SG and RYGB, respectively. The reduction in body weight was statistically greater after RYGB compared to SG ($P = 0.02$). This significance was maintained at 5 years ($P = 0.01$), with %EBMIL of 60.9 for SG and 67.5 for RYGB [3, 4].

These data agree with another trial by Ignat and colleagues. In this study, 100 patients were randomized to undergo RYGB (BMI = 47.0 ± 5.6) or SG (BMI = 45.5 ± 4.8). Although no difference in %EBWL was appreciated at 2 years for SG (77.8%) vs. RYGB (79.8%), subsequent values showed statistically greater ($P = 0.024$) weight loss at 3 years for RYGB (83.0%) compared with SG (66.3%). The significance ($P = 0.045$) was maintained at 5 years with %EBWL values of 74.8 and 65.1 for RYGB and SG, respectively [32].

Another RCT comparing these differences in weight loss is the Swiss Multicenter Bypass or Sleeve Study (SM-BOSS). This multicenter study randomized 217 patients with an overall BMI of 44 ± 11 kg/m^2 to SG or RYGB. Percent EBMIL at 2 years was 74.7 and 77.7 for SG and RYGB correspondingly, while at 3 years %EBMIL was 70.9 for SG and 73.8 for RYGB. No statistical differences were noted between groups [33]. Interestingly, Kehagias and colleagues encountered slightly different results. This single-center RCT randomized 60 patients with BMI <50 kg/m^2 to RYGB or SG. In this study, %EBWL at 2 years was statistically greater ($P = 0.05$) for SG (73.2%) compared with RYGB (65.3%). However, no statistical difference was appreciated at 3 years between SG (%EBWL = 68.5%) and RYGB (%EBWL = 62.1%) [34].

A brief discussion of the available RCTs exploring the comparative weight loss differences between RYGB and BPD/DS follows. Mingrone and colleagues randomized 60 patients with at least a 5-year history of diabetes, glycated hemoglobin of ≥ 7.0%, and BMI ≥ 35 kg/m^2 to receive medical therapy, RYGB, or BPD/DS in a single-center RCT design. Weight loss at 2 years was not significantly different

Table 29.2 Mid- and long-term comparative outcomes at 3 to 10 years

	RYGB			SG			BPD/DS		
	Midterm	Long-term		Midterm	Long-term		Midterm	Long-term	
	3 years	5 years	10 years	3 years	5 years	10 years	3 years	5 years	10 years
Weight loss									
%EBWL	61.7–83.0 (13,22,32,34,115)	66.6–74.8 (13,22,32)	57.1–69.0 (13,22)	61.1–68.5 (32,34,115)	60.3–65.1 (32,121)	52.5 (29)	83.0 (15)	63.8–79.3 (25,122,123)	67.9–73.4 (25,31)
%EBMIL	64.1–78.2 (19,3,4,33,13,22)	46.1–79.8 (4,13,17,19,22,26)	52.5–71.3 (13,19,22)	70.9–82.4 (27,33)	59.0–74.8 (28,121)	62.5[a] (27)	—	71.1–74.9 (17,25,26)	66.2–78.9 (25,30,31)
%TBWL	29.4–35.3 (13,19,22)	25.6–34.4 (13,17,19,22,26)	27.7–29.6 (13,19,22)	28.2–34.6 (24,27)	23.6–25.1 (24,28)	21.0[a]–26.3 (27,29)	45.2 (15)	31.1–40.7 (17,25,26)	33.4–39.0 (25,30,31)
Comorbidities									
Diabetes remission; %	77.0–90.0 (33,34,69)	37.0–66.7 (69,70)	42.6–54.7 (19,73)	60.0–91.2 (33,34,72)	26.0–80.0 (28,70–72)	—	90.0–93.1 (37,69)	63.0–91.7 (69)	91.3 (74)
Hypertension remission; %	52.0–71.2 (33,34,68)	42.0–57.0 (75,79)	20.4 (19)	65.2–80.0 (33,34,36,72)	52.9–54.5 (28,72)	—	68.0–85.8 (77,78)	70.6–88.4 (78,80)	80.9–91.4 (78,81)
Dyslipidemia remission; %	26.3–90.0 (34,77)	51.4–53.0 (39,75)	—	57.4–75.0 (34,36,72)	25.0–52.2 (28,72)	—	72.0–79.1 (77,80)	61.9 (83)	50.9–95.0 (74, 81)
GERD remission; %	64.7–100 (33,34,77,86)	—	25.5 (19)	61.0–100 (33,34,36)	30.8–95.7 (38)	—	48.6 (77)	—	—
OSA remission%	74.0–85.0 (19,28,33,35–39)	50.0–93.5 (19,28,33,35–39)	54.7 (19,28,33,35–39)	23.0–100.0 (19,28,33,35–39)	33.0–88.9 (19,28,33,35–39)	—	74.0 (19,28,33,35–39)	—	—

RYGB indicates Roux-en-Y gastric bypass, *SG* sleeve gastrectomy, *BPD/DS* biliopancreatic diversion with/without duodenal switch, *%EBWL* percent excess body weight loss, *%EBMIL* percent excess body mass index loss, *%TBWL* percent total body weight loss, *GERD* gastroesophageal reflux disease, *OSA* obstructive sleep apnea

[a]Outcomes at 11+ years

between RYGB (%TBWL=33.3) and BPD/DS (%TBWL=33.8). Similar findings were reported at the 5-year follow-up study with no significant difference between RYGB (%TBWL=29.1) and BPD/DS (%TBWL=32.5) [21, 26]. Contrasting results were reported by Risstad and colleagues, albeit in patients with BMI 50–60 kg/m^2. In this single-center RCT, 60 patients were randomized to RYGB or BPD/DS. At 5 years, reported %TBWL was significantly greater ($P < 0.001$) for BPD/DS (40.7%) than for RYGB (25.6%) [17].

Based on the best evidence available from RCTs, weight loss at 2 years may be comparable between SG and RYGB, but superior weight loss outcomes may occur for RYGB at 3 and 5 years. Although 10-year data may depict a similar trend, it is important to keep in mind that these are mostly derived from retrospective and heterogeneous studies with limited follow-up. When comparing RYGB to BPD/DS, although 2-year weight loss outcomes may be comparable for both operations, data from several retrospective reports and at least one RCT in patients with BMI 50–60 kg/m^2 argue for superior weight loss for BPD/DS in the longer term and in patients with higher BMI.

Comorbidity Resolution

Bariatric surgery is the most effective treatment for obesity-related comorbidities. Reviewing the comparative surgical effectiveness on each comorbidity is outside the scope of this chapter. Instead, we will focus on those comorbidities well-detailed in the available RCT literature. These include diabetes, hypertension, and dyslipidemia. In addition, given the controversial and potentially differential impact of different bariatric procedures on gastroesophageal reflux (GERD), it will also be discussed in this section. Remission rates for obstructive sleep apnea are offered in Tables 29.1 and 29.2; however, given the lack of good quality evidence and standard reporting, these will not be addressed further in this chapter [19, 28, 33, 35–39]. In interpreting these data, it is important to note that most of the existent literature utilizes subjective criteria rather than postoperative polysomnography to define remission. Ultimately, obesity is also a risk factor for many other comorbidities including several cancers, joint pathology, polycystic ovarian syndrome, urinary incontinence, female infertility, nonalcoholic steatohepatitis, and psychological disorders [40–52]. Although comparative data on these are lacking, many of these conditions have been noted to improve following bariatric surgery [51–66].

Diabetes Mellitus

The superiority of bariatric surgery over medical management/lifestyle interventions in inducing remission and/or improvement of diabetes has been extensively documented, and a review of this topic is not pertinent to the focus of this chapter

[3, 4, 21, 26, 67, 68]. Based on a heterogeneous group of studies, the short-, mid-, and long-term remission rates for type II diabetes that can be expected following SG, RYGB, and BPD/DS are discussed next and presented in Tables 29.1 and 29.2. Ranges for diabetes remission at 2 years following SG, RYGB, and BPD/DS are 35.0–41.0%, 66.7–75.0%, and 95.0–100%, respectively [21, 69–71]. At 3 and 5 years, reported diabetes remission ranges are 60.0–91.2% and 26.0–80.0% for SG, 77.0–90.0% and 37.0–66.7% for RYGB, and 90.0–93.1% and 63.0–91.7% for BPD/DS [28, 33, 34, 37, 69–72]. At 10 years, available outcomes for diabetes remission are 42.6–54.7% for RYGB and 91.3% for BPD/DS [19, 73, 74]. We will next concentrate on briefly summarizing the highest evidence available from the two trials thus far specifically designed to explore the differences in diabetes remission and/or improvement that can be expected following our three operations.

The STAMPEDE trial showed that at 3 years, while achieving a similar reduction in glycated hemoglobin, patients in the RYGB group experienced a significantly greater reduction in the total number (0.48 ± 0.80 vs. 1.02 ± 1.01; $p < 0.05$) and discontinuation (69.0% vs. 43%.0; $p < 0.05$) of antidiabetic medications, including insulin, when compared to SG. These differences persisted at 5 years with a greater proportion of patients in the RYGB group discontinuing all antidiabetic medication (45.0% vs. 25.0%; $p < 0.05$) compared to patients in the SG group [3, 4]. In the trial by Mingrone, at 2 years, patients in the BPD/DS experienced a higher rate of partial remission (95.0% vs. 75.0%; $p < 0.0001$), greater reduction in percent glycated hemoglobin (−43.0 ± 9.64% vs. −25.2 ± 20.89%; $p = 0.01$), and shorter time to normalization of fasting glucose and glycated hemoglobin (4 ± 1 months vs. 10 ± 2 months; $p = 0.01$) when compared to RYGB. Differences in partial remission were maintained at 5 years (RYGB:63.0% vs. BPD/DS:37.0%; $p = 0.0007$) [21, 26].

Although additional RCTs exploring these differences are needed, it could be concluded that, based on these high-quality data, diabetes remission and/or improvement may be highest following BPD/DS, followed by RYGB, and comparably lower for SG.

Hypertension

Significant remission or improvement of hypertension is appreciated following bariatric surgery. Specific rates for hypertension remission at 2 years range between 54.0–72.0%, 53.0–65.4%, and 49.3–76.0% for SG, RYGB, and BPD/DS, respectively [36, 37, 75, 76]. Reported midterm rates for hypertension remission at 3 years are 65.2–80.0% for SG, 52.0–71.2% for RYGB, and 68.0–85.8% for BPD/DS [33, 34, 36, 68, 72, 77, 78]. At 5 years, hypertension remission rates have been reported to be 52.9–54.5% for SG, 42.0–57.0% for RYGB, and 70.6–88.4% for BPD/DS [28, 72, 75, 78–80]. Available rates of hypertension remission at 10 years are 20.4% for RYGB and 80.9–91.4% for BPD/DS [19, 78, 81]. These values are summarized in Tables 29.1 and 29.2.

Several RCTs compare the effectiveness of RYGB and SG in inducing remission and/or improvement of hypertension. At 3 years, the STAMPEDE trial showed similar systolic (SBP) and diastolic blood pressure (DBP) reductions following SG and RYGB in the setting of significant medication discontinuation when compared to medical management. Diuretics were the only class of medication that showed a significantly higher discontinuation rate for RYGB than for SG. In addition to these findings, at 5 years, beta-blockers also showed a significantly higher discontinuation rate for RYGB than for SG [3, 4]. The SM-BOSS trial reported no statically significant difference between remission and improvement of hypertension at 3 years between RYGB (71.2%/25.0%) and SG (65.2%/34.8%) [33]. Similar findings were reported by Kehagias [34].

Comparing RYGB to BPD/DS, Mingrone noted a similar reduction in SBP/DBP for both operations at 2 and 5 years. Although, at 5 years, both surgical groups used significantly fewer antihypertensive medications, no significant differences between the surgical groups were reported [21, 26]. Similar results were reported by Risstad [17].

Based on the available high-quality evidence from RCTs, we can conclude that significant remission and/or improvement in hypertension can be expected following each of the three bariatric operations. According to these data and although none of these trials were explicitly designed to detect potential differences in remission and/or improvement of hypertension, not one operation appears to be clearly superior over the others.

Dyslipidemia

Dyslipidemia notably improves following bariatric surgery. Ranges for reported remission rates for dyslipidemia are summarized in Tables 29.1 and 29.2. At 2 years, reported remission frequencies for dyslipidemia are 60.0–65.2% for SG, 52.0–57.0% for RYGB, and 70.0–92.1% for BPD/DS [36, 75–77, 82]. Midterm dyslipidemia remission at 3 years ranges between 57.4–75.0%, 26.3–90.0%, and 72.0–79.1% for SG, RYGB, and BPD/DS, respectively [34, 36, 72, 77, 80]. Long-term remission rates at 5 years are 25.0–52.2% for SG, 51.4–53.0% for RYGB, and 61.9% for BPD/DS [28, 39, 72, 75, 83].

Three RCTs provide comparative dyslipidemia outcomes between RYGB and SG. In the STAMPEDE trial, patients in both surgical arms experienced a similar reduction in low-density lipoprotein (LDL) and discontinuation of lipid-lowering agents at 3 years. These findings were also present at 5 years [3, 4]. Similar outcomes regarding normalization of high-density lipoprotein (HDL), LDL, and triglycerides between RYGB and SG were reported by Kehagias [34]. Contrastingly, the SM-BOSS trial reported significantly higher dyslipidemia remission rates, reflecting total and LDL cholesterol differences, for RYGB than for SG (71.7% vs. 43.8%; $p = 0.008$) at 3 years [33].

Two RCTs assessed dyslipidemia outcomes following RYGB and BPD/DS. Although without detailing lipid-lowering agent use, Mingrone reported lower LDL (64.63 ± 15.93% vs. 17.21 ± 36.21%; $p < 0.001$) and triglyceride (56.79 ± 16.70% vs. 21.17 ± 41.23%; $p = 0.001$) levels following BPD/DS than RYGB, while HDL (29.66 ± 18.21% vs. 12.98 ± 20.66%; $p = 0.001$) was higher after RYGB compared to BPD/DS at 2 years. Similar findings were noted at 5 years [21, 26]. Somewhat similar results at 5 years were reported by Risstad. In this trial, LDL levels decreased significantly only after BPD/DS, and while a significant reduction in triglyceride levels was appreciated after both interventions, a significantly greater reduction ($p = 0.01$) was noted after BPD/DS than following RYGB. On the other hand, HDL levels increased significantly after both interventions, with a significantly larger increase ($p = 0.002$) after RYGB. Again, lipid-lowering agent usage was not provided [17].

Based on the evidence previously presented, one could conclude there may be some variations with regard to dyslipidemia outcomes between these surgeries. In so doing, it is important to realize that these trials were not specifically powered to detect differences in dyslipidemia outcomes. Secondly, the potentially superior dyslipidemia outcomes for RYGB compared to SG noted in the SM-BOSS are at best controversial given the equivalent results between the two operations reported by two other RCTs. When comparing RYGB and BPD/DS, whereas the available evidence points toward superior outcomes for BPD/DS, interpreting these results in the absence of reporting of lipid-lowering agent usage is problematic. Further RCTs specifically designed to answer these questions are needed before the superiority of one procedure over the others, regarding dyslipidemia, can be concluded.

GERD

The role of obesity as a risk factor for GERD has been well-described [84, 85]. Improvement and/or remission of GERD following bariatric surgery may be dependent on the specific operation performed although this is a topic of evolving debate and controversy. Outcome reporting for GERD varies widely. We have chosen to provide short-, mid-, and long-term GERD remission rates, when available, in Tables 29.1 and 29.2 [19, 33, 34, 36, 38, 77, 86]. Caution must be used when interpreting these, as they are derived from heterogeneous studies with multiple methodologic limitations to consider when attempting to understand the evolution of GERD following each procedure. To better understand the comparative differences that may exist regarding GERD following these operations, a summary of notable studies is included next.

The recent retrospective study by Sudan and collaborators identified a total of 73,702 patients from the Bariatric Surgery Center of Excellence (BSCOE) data file undergoing primary RYGB ($n = 66{,}324$), SG ($n = 5942$), and BPD/DS ($n = 1436$). The matched odds (95%CI) for GERD remission at 1 year, with 57,094 patients undergoing AGB as the reference group, were 0.87 (0.79–0.95), 1.53 (1.48–1.58),

and 1.20 (0.95–1.52) for SG, RYGB, and BPD/DS, respectively, with only RYGB showing significant odds for resolution. Regarding RYGB and SG, these findings are paralleled by the American College of Surgeons Bariatric Surgery Center Network (ACS-BSCN) data, which showed that 70% of patients achieved symptom improvement or resolution at 1 year following RYGB, while only 50% saw the same benefit following SG [87]. Similar results were reported by DuPree and colleagues after reviewing the Bariatric Outcomes Longitudinal Database (BOLD) and looking at patients undergoing SG ($n = 4832$) and RYGB ($n = 33{,}867$). In this study, whereas 62.8% of patients experienced resolution of GERD at 6 months following RYGB, 84.0% of patients continued to have symptoms following SG. Additionally, they noted a de novo GERD rate of 8.6% following SG [88]. Data from the MBSC identified SG as a significant predictor of acid reduction therapy use at 1 year [89]. Others have also noted improvements in GERD following RYGB. In a study that looked at 53 patients (BMI 46 ± 7.7 kg/m^2) undergoing RYGB, Madalosso and colleagues reported a significant reduction in GERD prevalence at 6 months (40%) and 39 ± 7 months (23%) compared to preoperative values (64%). Significant improvement in esophagitis and total acid exposure were also reported [86].

The role of SG in the setting of GERD is controversial. A systematic review by Chiu and colleagues noted mixed results regarding GERD improvement or resolution following SG, with seven studies reporting a decrease in prevalence while four studies noted an increase [90]. The lack of agreement in terms of GERD outcomes that can be expected following SG is also evident in the 2014 Fifth International Summit for Laparoscopic Sleeve Gastrectomy Consensus Conference [91].

The RCTs providing data on the comparative GERD outcomes following these three bariatric procedures are scarce. The SM-BOSS trial showed significant worsening of preexisting GERD after SG compared to RYGB at 3 years [33]. Although starting out with a low prevalence of GERD, the trial by Kehagias noted no difference in GERD resolution between RYGB and SG at 3 years [34].

Outcomes for GERD may vary following different operations. Whereas the RCT literature on this topic is very limited and not equipped to answer this question, several retrospective studies provide some insight into the matter. In addition, there are but a few studies comparing GERD outcomes between different bariatric procedures which include data on BPD/DS. Nevertheless, based on the best available evidence, outcomes for GERD may be superior after RYGB when compared to SG and BPD/DS.

Complications

Bariatric procedures are among the safest of operations, yet these surgeries occasionally result in complications. There are several factors which may negatively affect morbidity and mortality following a bariatric operation. These include patient characteristics such as male gender, older age, total number and type of comorbidities, and poor functional status. Also relevant are surgeon and institution elements,

such as operative volumes, and surgical approach, with open intervention conferring higher risk compared to a laparoscopic or robotic method [92–112]. More pertinent to the theme of this chapter, the incidence of major complications following bariatric procedures varies with the type of operation performed. Complications are defined as early if they occur within 30 days of operative intervention and late if presenting after 30 days [7].

Ranges for selected complications based on a heterogeneous group of reports are offered in Table 29.3. Although there are several additional complications following bariatric surgery as well as unique complications to each operation, we will focus on summarizing the comparative literature between SG, RYGB, and BPD/DS regarding leaks, bleeding, venous thromboembolism (VTE) (including deep venous thrombosis (DVT) and pulmonary embolism (PE)), mortality, readmission, and reoperation within 30 days. We will mostly focus on 30-day complications because these are most consistently reported. We have chosen to concentrate on leaks, bleeding, and VTE because these account for most of the mortality observed following bariatric surgery and are common to the three operations, making comparison meaningful. Lastly, given the overall rarity of these complications regardless of the bariatric operation performed, the ensuing discussion mostly focuses on the largest available comparative series.

Mortality

Patients undergoing bariatric operation experience a reduction in long-term mortality when compared to patients suffering from obesity who do not undergo surgery [113]. Yet, surgery-derived mortality may be incurred differently by each of these three operations. Although not reporting on mortality individually, matched odds (95%CI) for serious adverse events (SAEs), mortality included, reported by Sudan were 3.60 (2.90–4.47), 5.43 (4.75–6.21), and 17.91 (14.71–22.64) for SG, RYGB, and BPD/DS, respectively, with AGB as the reference group. This finding persisted at one year with matched odds (95%CI) for SAEs at 3.22 (2.64–3.92), 4.92 (4.38–5.54), and 17.47 (14.19–21.52) for SG, RYGB, and BPD/DS correspondingly [10].

Melissas and collaborators queried the International Bariatric Registry (IBAR) and compared patients undergoing SG (n = 6413) and RYGB (n = 10,622). In this study, patients in the RYGB group tended to be older, have more comorbidities, and be more likely to undergo a laparoscopic approach, while patients in the SG group tended to have a higher BMI. Unadjusted mortality rates were 0.016% and 0.009% correspondingly for SG and RYGB, and mortality did not significantly differ between groups [114]. Similar findings were reported in a smaller two-institution trial by Rondelli and colleagues specifically looking at laparoscopic cases including 301 patients in the RYGB group and 280 patients in the SG group. Patients undergoing SG had slightly higher BMI. Unadjusted mortality rates at 30 days were no different between groups (RYGB=0.7% vs. SG=0.0%; p = 0.5) [115].

Table 29.3 Early and late comparative complications

	RYGB	SG	BPD/DS
Early < 30 days			
VTE; %	0.1–1.1 (10,11,79,117,118)	0.0–1.7 (10,11,37,117,118)	0.2–3.4 (10,15,37,117,124)
Leak; %	0.2–6.5 (10,11,16,19,79, 114–117, 125, 126)	0.1–2.8 (10,11,24,37,114,117,121,127,128)	0.0–8.4 (10,15,16,37,116,117,124,129)
Bleeding; %	0.8–2.0 (10,11,19,114,115,117)	0.5–5.7 (10,11,24,37,114,115,117,121,128)	0.4–3.4 (10,15,37,117,123,124)
SBO/Sleeve stenosis; %	0.1–5.3 (21,79,114,116,117)	0.1–3.5 (24,114,128,130)	0.5–7.7 (15,116,117,124,131)
Death; %	0.0–0.8 (16,114–116,132)	0.0–0.02 (24,114,115,121)	0.6–4.1 (16,74,116,129,133)
PNA; %	0.4 (11,16)	0.4–0.6 (11, 121)	0.4–0.9 (15,16,123)
SSI; %	0.0–5.2 (11,16,19,79,114,115,117)	0.0–2.0 (11,114,115,117,121)	0.6–5.1 (15,16,117,123,124)
Readmission; %	0.4–1.9 (11,114)	1.6–4.5 (11,114,128)	2.8–6.7 (74,124)
Reoperation; %	1.0–3.9 (11,16,114,117)	1.2–5.6 (11,24,114,117)	0.6–3.5 (15,16,74,117,124)
Late > 30 days			
Readmission; %	3.3–29.0 (114,120,126)	1.0–32.0 (114,120)	8.0–17.2 (74,126)
Reoperation; %	1.3–4.8 (11,16,19,114)	0.5–10.2 (11,114)	1.1–13.0 (16,74)

RYGB indicates Roux-en-Y gastric bypass, *SG* sleeve gastrectomy, *BPD/DS* biliopancreatic diversion with/without duodenal switch, *VTE* venous thromboembolism, *SBO* small bowel obstruction, *PNA* pneumonia, *SSI* surgical site infection

In a meta-analysis by Hedberg and others, ten small single-center studies, three of which were RCTs, were used to report on mortality for BPD/DS (n = 692) and RYGB (n = 837). Mortality rates for BPD/DS and RYGB were 0.6% and 0.2%, although this difference was not statistically significant (p = 0.33) [116]. Nelson and colleagues also reported on mortality for RYGB (n = 77,406) and BPD/DS (n = 1545) after querying the BOLD registry. Patients in the BPD/DS group were more likely to be male, have a higher BMI, and more comorbidities. In this report, the unadjusted mortality rate was significantly higher for BPD/DS when compared to RYGB (1.2% vs. 0.3%; $p < 0.001$). This finding persisted in subgroup analyses for patients with BMI > 50 kg/m^2 and those undergoing the laparoscopic or open approaches [16].

Biertho and colleagues retrospectively compared 378 patients following SG and 422 undergoing BPD/DS in a single-center study. The unadjusted mortality rates at 30 days did not significantly differ between SG (0.0%) and BPD/DS (0.4%). In this study, patients in the BPD/DS group were younger, more likely to be females, and have fewer comorbidities [37].

Based on the best available evidence and given the overall low mortality rate following bariatric surgery in general, it is impossible to conclude superiority of one procedure over another regarding mortality. Nonetheless, BPD/DS likely incurs in higher mortality than RYGB, with the relationships between RYGB and SG and BPD/DS and SG less clearly demonstrated. Further large studies comparatively reporting on adjusted or matched mortality rates for these operations are needed.

Bleeding

Several comparative studies report on the incidence of bleeding between SG, RYGB, and BPD/DS. Sudan noted the unmatched incidence of bleeding at 0.63, 1.38, and 0.99% for SG (n = 19,959), RYGB (n = 123,825), and BPD/DS (n = 2478). At 1 year, the incidence of bleeding remained stable at 0.67, 1.46, and 1.00% for SG, RYGB, and BPD/DS. Taking AGB as the reference group, the matched odds (95%CI) for bleeding at 30 days were 6.45 (4.87–8.54), 12.24 (9.86–15.21), and 9.41 (5.80–15.25) for SG, RYGB, and BPD/DS, respectively. These findings persisted at 1 year [10]. Contrasting results were noted in a small, single-institution report by Topart and others. In this study, SG (n = 88), RYGB (n = 360), and BPD/DS (n = 59), all performed laparoscopically, were compared. Patients in the SG group had the most comorbidities, followed by patients in the BPD/DS, while patients in the RYGB group had the fewest comorbid conditions. Patients in the SG group were also more likely to be males and older, while patients in the BPD/DS group had higher BMI. The incidence of bleeding was 5.7, 0.8, and 3.4% for SG, RYGB, and BPD/DS. Unadjusted analyses revealed a significantly higher rate (p = 0.0021) for SG than for RYGB only [117]. Alternatively, others, including the large study by Melissas, have noted no differences in bleeding incidence between SG and RYGB [11, 114, 115]. Similarly, Biertho noted similar incidence of bleeding for SG and BPD/DS [37].

Once again, discrepant results are evident even when appraising the largest reports available. Still, the recent study by Sudan stands out as the largest and perhaps most meaningful analysis by accounting for the significant differences in baseline characteristics through matching. In this report, bleeding was highest for RYGB, followed by BPD/DS, and lowest for SG. More studies reproducing these findings are needed before confidently concluding on this topic.

Leak

Selected reports on the leak rate for SG, RYGB, and BPD/DS are discussed next. The unmatched 30-day leak rate reported by Sudan was 0.14, 0.36, and 0.89% for SG, RYGB, and BPD/DS. Leak rate increased at 1 year for SG (0.24%), RYGB (0.43%), and BPD/DS (1.18%). The matched odds (95%CI) for leak at 30 days were 20.08 (8.21–49.09) and 46.67 (21.02–103.62) for SG and RYGB. Understandably, even with the relatively large initial sample size for BPD/DS, the low overall occurrence of this complication made matched analysis for this operation inadequate and therefore not reportable [10]. The small study by Topart reported unadjusted leak rates, including peritoneal abscesses without evidence of leakage, of 2.3 ($n = 2$), 1.1 ($n = 4$), and 3.4 ($n = 2$) percent for SG, RYGB, and BPD/DS correspondingly for their laparoscopy-only cohort. No statistically significant differences were noted [117].

The large comparative report between SG and RYGB by Melissas reported unadjusted leak rates (SG=0.15% vs. RYGB=0.38%; $p = 0.01$) comparable to those noted by Sudan [114]. Given the low event frequency of this complication, smaller studies differ slightly in their reported rates and lack statistical power to show differences [11, 115].

Nelson reported on the comparative leak rates for RYGB and BPD. They noted an unadjusted leak rate for BPD/DS at 1.6%, which was significantly higher ($p < 0.001$) than that of RYGB at 0.8%. This finding persisted in the subgroup analysis for patients with BMI > 50 kg/m^2. Subgroup analyses for laparoscopic and open approach still showed higher rates for BPD/DS although significance was lost likely due to a reduction in power [16]. The meta-analysis by Hedberg also reported a significantly higher leak rate for BPD/DS when compared to RYGB (5.0% vs. 2.2%; $p = 0.002$) [116].

Comparison between SG and BPD/DS by Biertho revealed a higher unadjusted overall leak rate for BPD/DS when compared to SG (2.7% vs. 1.0%). They did not report on statistical differences for overall leak rates between the two operations [37].

While leaks are a rare complication of contemporary bariatric surgery, the summation of these studies point to clear differences in the frequency of this problem for each of the three surgeries. Based on these reports and comparing these three bariatric operations, we can conclude that leaks appear to be most frequent after BPD/DS, of intermediate occurrence following RYGB, and least commonly a complication of SG.

VTE

Comparative differences in VTE rates for SG, RYGB, and BPD/DS are reported by the following studies. Sudan reported PE rates of 0.11, 0.13, and 0.54% corresponding to SG, RYGB, and BPD/DS. These rates remained stable at 1 year for SG (0.11%) and RYGB (0.14%) while slightly increasing for BPD/DS (0.74%). Matched odds (95%CI) for PE at 30 days, with AGB as the reference group, were 2.88 (1.65–5.05), 3.11 (2.16–4.48), and 13.96 (7.30–26.73) for SG, RYGB, and BPD/DS correspondingly [10]. The smaller study by Topart reported VTE rates of 0.0, 0.3, and 3.4% for SG, RYGB, and BPD/DS [117].

Others have reported on VTE rates for SG and RYGB. Jamal and colleagues evaluated 709 patients undergoing SG and 2945 patients following RYGB. They noted the unadjusted incidence of VTE at a median time of 24 days to be 1.7% for SG and 1.1% RYGB. No significance was reported for this difference between the two operations [118]. Similar results were noted by another small study [11]. Biertho reported VTE rates of 0.3 ($n = 1$) and 0.2 ($n = 1$) for SG and BPD/DS, where the episode in the former group was a DVT, while the patient in the latter group experienced a PE [37]. While this last group of small studies may offer some insight into the comparative differences regarding VTE incidence for the bariatric operations discussed herein, it should be noted that they lack the statistical power to yield solid conclusions in the setting of the extremely low frequency of this complication.

Frequency of VTE is likely influenced by the type of bariatric operation performed. Whereas most of the comparative literature exploring this question is based on reports with a relatively small number of patients, given the rarity of VTE events, larger studies with appropriate matching are better prepared to conclude on the matter. Moreover, the importance of adjusting for patient's characteristics or matching cannot be overstated, as reports like the one put forward by Finks and colleagues have shown that, in addition to the type of bariatric procedure and approach utilized, factors such as previous history of VTE, operative time, sex, and age may impact the incidence of VTE [119]. The largest study to date offering evidence on the topic, points to BPD/DS as the bariatric procedure with the highest VTE incidence, followed by RYGB and SG with lower rates of this complication [10].

Readmission and Reoperation

Readmission and reoperation rates may also differ for each operation although most of the studies reporting on these outcomes do not correct for patient and perioperative characteristics that may act as confounders. Some studies compared 30-day readmission rates between RYGB and SG. While not statistically different, Melissas noted 30-day readmission rates slightly lower for SG at 1.6% than for RYGB at 1.9%. However, late readmissions were significantly higher for RYGB than for SG

(3.3% vs. l.0%; <0.0001) [114]. By contrast, a smaller study by Dogan reported significantly higher readmission rates at 30 days for SG compared with RYGB (4.5% vs. 0.4%; $p = 0.003$) [11]. Similarly, a larger comparative series using the New York State Planning and Research Cooperative System (SPARCS) and including 12,439 and 601 patients undergoing RYGB and SG, respectively, reported significantly higher unadjusted readmission rates within 20 years for SG compared to RYGB (32% vs. 29%; $p < 0.001$) [120].

In the small study by Topart, reoperation rates within 30 days postoperatively were noted to be very similar for SG (3.4%), RYGB (3.9%), and BPD/DS (3.4%) [117]. Several studies compared the reoperation rates between SG and RYGB. While the frequency of reoperations was similar at 30 days for SG (1.2%) and RYGB (1.0%), Melissas noted late reoperations occurred more frequently for RYGB (2.1%) than for SG (0.5%) [114]. In their laparoscopy-only cohort, Rondelli and colleagues reported significantly higher 30-day re-intervention rates for RYGB than for SG (7.6% vs. 0.7%; $p < 0.001$) [115]. Somewhat conflictingly, Dogan noted statistically similar rates of reoperation within 30 postoperative days for SG (3.7%) and RYGB (2.9%), while the late reoperation rate was significantly higher for SG when compared to RYGB (10.2% vs. 4.1%; $p = 0.009$). This was due to revisions of SG to RYGB mostly for weight regain and insufficient weight loss [11]. Lastly, when comparing RYGB and BPD/DS, Nelson reported significantly higher frequency of early reoperation for BPD/DS than for RYGB (3.3% vs. 1.5%; $p < 0.001$), while noting no differences in late reoperations between the two operations (1.3% vs. 1.1%). Similar findings were noted in the subgroup analyses for BMI > 50 kg/m^2 and by surgical approach [16].

While most reports note comparative differences between these operations, the overall picture is not clear on the superiority of one procedure over the others regarding readmission and reoperation. Additional research is needed before this topic can be settled.

Conclusions

Obesity rates and associated comorbidities continue to rise nationally and worldwide. Bariatric surgery, as the key intervention within a multidisciplinary program, is currently our best hope for controlling this pandemic. Yet, differential effectiveness in weight loss, comorbidity resolution, and complication profiles may result from each bariatric procedure. Throughout this chapter, we have explored the comparative outcomes of three key contemporary bariatric operations, namely, SG, RYGB, and BPD/DS.

While some outcomes, particularly in the longer term, such as weight loss and improvements in diabetes and GERD, appear to favor one procedure over others, additional measures of effectiveness including improvement of hypertension and dyslipidemia are less clearly defined in the literature. Similarly, even selected complications are not uniformly allocated to each of these operations. Whereas there is an overall trend for higher complications, including mortality, bleeding, leaks, and

VTE after BPD/DS, with lower rates for RYGB, and lowest following SG, drawing conclusions on readmission and reoperation rates is problematic. Given the minuscule rate at which these complications occur, additional reports including large number of patients derived from national or statewide prospectively maintained databases with standardized data collection and risk-adjusted reporting are needed.

In the era of surgical collaboration for the sake of quality assessment and improvement in patient care, models such as the one put forward by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), BOLD, and MBSC, with a focus on bariatric-specific outcomes, can help close the comparative knowledge gaps between different bariatric operations. Consequently, these data will guide the tailoring of surgical therapy to the individual patient suffering from obesity and related comorbidities.

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Part IV
Complications

Chapter 30
Complications of Endolumenal Bariatric Therapies (EBTs)

Emanuel Eguia and Bipan Chand

Introduction

Worldwide, obesity has more than doubled since 1980 according to the World Health Organization (WHO). Today, more than one third (36.5%) of adults in the United States are obese, posing a serious health problem in this country. Laparoscopic bariatric surgery has been well-described as an effective treatment option in achieving substantial weight loss and improving obesity-related comorbidities. Surgery can carry a moderate risk, including death, for certain individuals. As a result, there is a growing demand for less invasive procedures that can assist in weight loss. Many of these procedures and techniques may offer an overall lower risk profile when compared to surgery. Endolumenal bariatric therapies (EBTs) can function as a primary treatment for obesity, bridge to surgical therapy, or revision of a prior surgical intervention. EBTs may offer a quicker recovery, lower morbidity and mortality, and possibly a more cost-effective means of achieving meaningful weight loss.

Endoscopic Gastric Procedures

Intragastric Balloons

One of the earliest endoscopic transoral restrictive devices was the intragastric balloon (IGB). Initially introduced in 1982, early generations of the intragastric balloons (i.e., Garren-Edwards, Ballobes, Taylor, Wilson-Cook balloons, De Castrol,

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etc.) were abandoned due to significant complications, including premature deflation, and failure to achieve meaningful weight loss. Intragastric balloons work by occupying space in the stomach in potentially affecting gastric emptying and satiety. In a randomized control study by Gomez and colleagues, 29 patients with obesity were randomized to IGB vs. control. Patients with IGB at 8 and 16 weeks had a higher percent total body weight loss (TBWL) [1] when compared to the controls. However, the early versions of these balloons were riddled with issues, such as low volume capacity and non-durable material. Furthermore, serious complications such as gastric erosion and gastric outlet obstruction resulted in less than desirable safety profiles. Since then, the intragastric balloons have gone through multiple device alterations to provide less risk of premature deflation and smoother surfaces that lead to less erosions. Most notably, the BioEnteric® Intragastric Balloon (BIB®, Inamed, Santa Barbara, CA, USA), developed in 1987, addressed previous major issues [2]. Today, there are currently several commercially available balloons in the United States and include the ReShape® Integrated Dual Balloon System (ReShape Medical, San Clemente, CA, USA), Orbera® Intragastric Balloon System (Apollo Endosurgery, Austin, TX, USA), and Obalon® Balloon System (Obalon Therapeutics, Inc., Carlsbad, CA, USA).

According to Genco and colleagues study in 2005 using the BIB, the overall complication rate was 2.8% (70/2515 patients) [3]. Five patients developed gastric perforation of which four (0.19%) had previously undergone gastric surgery, which is a relative contraindication to balloon therapy. Balloon intolerance requiring balloon removal was the most common issue within the first week of insertion with 19 reported cases (0.76%). Balloon rupturing occurred in nine cases (0.36%). Esophagitis and gastric ulcers were seen in 32 patients (1.27%) and 5 patients (0.2%), respectively, both treated with medical therapy. Furthermore, de Castro and colleagues reported that approximately half of their patients experienced nausea and vomiting [4]. Epigastric pain, nausea, and reflux symptoms were the next most common side effects which is why proton pump inhibitors are routinely prescribed. Also, de Castro's group had 13% early removal secondary to persistent nausea and vomiting. Two patients developed gastrointestinal bleeding requiring balloon removal [4].

The Orbera balloon is a small, flexible balloon introduced in the collapsed state and expands into a spherical shape, 11 cm in diameter, when filled with 500 mL of saline solution. Volume adjustments range between 400 and 700 mL. The Orbera balloon shell is made of an inert, nontoxic silicone elastomer that is resistant to gastric acid and has a radiopaque self-sealing valve. The complications associated with the Orbera Balloon System include nausea, vomiting, and abdominal cramps. Other complications include Mallory-Weiss laceration during removal or spontaneous balloon deflation (2%) [2]. In a prospective study of superobese patients, the mortality rate following intragastric balloon placement was less than 1% [5]. A pivotal study showed that 16 patients had a total of 17 device- or procedure-related serious adverse events (SAEs) resulting in SAE rate of 10% (16/160, 95% CI). Thirty of the 160 patients had their balloon removed prior to 6 months [6]. Eight of these were due to device intolerance which included adverse events such as gastroesophageal reflux

disease (GERD), nausea, vomiting, and abdominal pain. Other device-related SAEs included gastric outlet obstruction (0.63%), gastric perforation (0.63%), aspiration pneumonia (0.63%), and IGB fluid infection (0.63%) [7].

In another study by Kumar and colleagues, the Orbera intragastric balloon was associated with GERD, esophagitis (2.4–9.4%), balloon migration (0.5–2.6%), and ulcer formation [8]. This study showed that the balloon was tolerated regardless of the filling volume with no difference in the rate of early removal, GERD symptoms, or ulcer formation, although it was noted that esophagitis was more common in lower filling volumes, often managed with acid-reducing medications.

The ReShape Integrated Balloon is a dual balloon with two independently inflated, noncommunicating silicone balloons bonded to a central silicone shaft. Each balloon can be inflated to a volume of 450 cc of saline. The balloon can stay in the stomach for up to 6 months. A pivotal study found that 7.5% of patients had device- or procedure-related SAEs including emesis, abdominal pain, epigastric pain, and nausea. The remaining adverse events included ulcer-associated GI bleed, ulcer presenting with abdominal pain, contained esophageal perforation, esophageal tear, and post-procedural pneumonia [9].

The Obalon Balloon System is another temporary intragastric balloon system made of nylon and polyethylene. It is delivered by swallowing a capsule made of porcine gelatin containing a balloon attached to an inflation catheter. The balloon is then inflated with nitrogen gas instead of saline. A total of three balloons can be placed into the stomach. In a pivotal study, minimal SAEs were noted, 0.3% (1/336, 95% CI). A patient with peptic ulcer disease developed a GI bleed 6 weeks after receiving the third balloon. There was no other SAE recorded in the pivotal study [10].

The SatiSphere™ Device (EndoSphere Inc., Columbus, OH, USA) is made of 1-mm nitinol wire with pigtail ends and several mesh spheres mounted along its course. It is placed via endoscopy and released in the duodenum. The SatiSphere Device is thought to induce weight loss by delaying transit time of nutrients through the duodenum. A study by Sauer and coworkers revealed that 10/21 patients in the treatment group developed SAE including migration of the device, which led to spontaneous excretion or required some form of intervention to remove it. None of the patients complained of nausea, emesis, or flatulence [11]. This device is not currently available commercially.

Endoscopic Sutured Gastroplasty

The Bard® EndoCinch™ Suturing System (C.R. Bard, Murray Hill, NJ, USA) was the first endoscopic suturing device used in the treatment of obesity. It was initially created for treating gastroesophageal reflux disease, but due to lack of durability, its role in control of gastroesophageal reflux disease (GERD) was abandoned [12–14]. As a result, its focus was transitioned to creating endoluminal vertical gastroplasty (EVG) for the primary intervention of morbid obesity.

In a study using the EndoCinch device to create a vertical gastroplasty, the author placed one continuous polypropylene suture through 5–7 full-thickness plications in a cross-linked fashion from the proximal fundus to the distal body [15]. All 64 patients were discharged on the same day without any serious adverse events. Common symptoms consisted of nausea and reflux that resolved within 24 h. Brethauer and coworkers also conducted a pilot study called TRIM (transoral gastric volume reduction) which revealed no serious procedure-related complications. Patients experienced mild nausea, vomiting, and abdominal discomfort. However, all patients in this trial underwent an upper endoscopy at 12 months showing loss of plications in 72% (13 patients) [16]. This device is no longer available in the United States.

The OverStitch™ (Apollo Endosurgery, Austin, TX, USA) is a full-thickness endoscopic suturing device that can apply interrupted and running sutures with real-time suture reloading [17–19]. A retrospective study by Lopez and coworkers showed that patients who underwent endoscopic sutured gastroplasty (ESG) had mild adverse events such as abdominal pain, nausea, and vomiting. Five patients (2%) developed SAE which included a perigastric inflammatory fluid collection, extragastric hemorrhage, pulmonary embolism, pneumoperitoneum, and pneumothorax. All these patients recovered without requiring any further surgical intervention [20]. Abu Dayyeh and coworkers conducted a prospective study with 25 patients [21]. In this study, SAE also included a perigastric fluid collection, pulmonary embolism, and a small pneumothorax. The authors contribute these secondary to the initial technique and with further refinements have had no further serious adverse events. This device is currently commercially available in the United States.

The Primary Obesity Surgery Endolumenal (POSE™) procedure uses the Incisionless Operating Platform™ (IOP, USGI Medical, San Clemente, CA, USA) which is an endoscopic procedure that places transmural plications using specialized suture anchors [22]. This procedure works by potentially mediating changes in caloric intake capacity and increasing gastric emptying delay [21–23]. A prospective observation study of 45 patients by Espinos and coworkers revealed no mortalities associated with this procedure and minimal side effects including nausea and chest and abdominal pain [22]. A study by Sullivan and colleagues revealed that procedure-related adverse effects occurred in 77.8% of patients. The most common included pain (45.2%), nausea (21.3%), and vomiting (19.5%), often occurring within the first week of the procedure. Other complications included an extragastric bleed (0.5%) (which required surgery) and one patient who developed a hepatic abscess (0.5%) [24]. This device is not commercially available in the United States.

Endolumenal Stapling

The Transoral Gastroplasty System (TOGA®, Satiety, Palo Alto, CA, USA) was the first endoscopic stapling device used to create a gastric sleeve with full-thickness staples placed along the lesser curve of the stomach [25]. The entire procedure

mimics the surgical vertical gastroplasty commonly performed in the 1980s. Devière and colleagues conducted the first human prospective, multicenter, single-arm trial studying the safety and feasibility of the TOGA system in 21 patients (35–53 kg/m^2). No serious complications were noted besides postoperative nausea, vomiting, abdominal pain, and transient dysphagia [25].

A single-arm prospective follow-up study was also created by Devière and colleagues studying the safety and feasibility of a second-generation TOGA system. The trial consisted of 11 patients. No serious adverse events were noted besides procedure-related complications of transient epigastric pain, nausea, esophagitis, and mild dysphagia [26]. Familiari and colleagues published a subsequent European trial in 2011 which consisted of 67 patients. In this study two major complications occurred which were respiratory insufficiency and asymptomatic pneumoperitoneum [27].

All together, these studies showed that the TOGA system is feasible and safe and induces significant weight loss in the short-term follow-up. The multicenter, randomized FDA trial was terminated prematurely secondary to lack of efficacy. The company dissolved and the device was never approved in the US market.

Transoral Endoscopic Restrictive Implant System (TERIS)

The Transoral Endoscopic Restrictive Implant System (TERIS) (Barosense, Redwood City, CA, USA) is an endoscopic system that implants a prosthetic restricting device to create a gastric reservoir at the level of the cardia. Implantation entails creation of five gastric plications using five silicone anchors followed by deployment of a gastric restrictor [28].

A randomized, uncontrolled, open-label, single-group phase I human trial by Biertho and colleagues was used to describe the initial feasibility and safety of the TERIS system in 20 human subjects [28]. Their study showed no intra- or post-procedure complications. Patients were discharged home on post-procedural day 2 tolerating a soft diet. The TERIS system requires further investigation and has not been FDA approved.

TransPyloric Shuttle

The TransPyloric Shuttle (TPS®) (BAROnova, Goleta, CA, USA) is a novel non-surgical device that is delivered endoscopically into the stomach. According to Marinos and colleagues, the TransPyloric Shuttle has a functional shape consistent of a large spherical bulb attached to a smaller cylindrical bulb by a flexible tether which consists of medical grade silicone. This device results in intermittent gastric outlet obstruction.

A prospective, nonrandomized, single-center study was conducted in 20 patients to evaluate the safety and efficacy of the procedure and device. Marinos and coworkers reported all patients underwent successful deployment and retrieval of the device without immediate complications [29]. Complications included gastric ulceration requiring removal of the device with subsequent resolution in some patients; the exact number was not reported.

Initial studies of the TransPyloric Shuttle show it to be a safe and feasible nonsurgical method of weight loss. It is still, however, undergoing appropriate trials and has not been FDA approved in the United States. Further studies will be needed to evaluate efficacy and associated improvement in obesity-related comorbidities.

Endoscopic Barriers, Magnets, Ablation, and Aspiration Therapy

Enteric Barriers

The Duodenal-Jejunal Bypass Sleeve (DJBS) (EndoBarrier, GI Dynamics, Lexington, MA, USA) is an endoscopically placed barrier device made of using a 60-cm-long fluoropolymer liner anchored in the duodenum with a self-expanding nitinol ring with barbs. The barrier extends into the jejunum and prevents mixture of pancreatico-biliary secretions with food. The device is delivered under both fluoroscopy and endoscopy.

In 2008, a pilot study performed by Rodriguez-Grunert and colleagues reported on the first human experience. This study evaluated the delivery and retrieval of the DJBS in 12 patients with a 12-week endpoint [30]. Primary outcomes were to identify and describe the severity of adverse events. All 12 patients had successful deployment of the sleeve; however, only 10 of 12 patients completed the 12-week course. Two patients had intractable abdominal pain, nausea, and vomiting requiring early retrieval. Most complications occurred within 2 weeks of implantation which included abdominal pain, nausea, and vomiting. Of note, there was one partial pharyngeal tear and one esophageal tear during explantations. Furthermore, localized inflammation at the duodenal bulb anchoring site was seen in all patients. The device underwent modifications and was subsequently reintroduced.

Tarnoff and collaborators conducted a second open-label, multicenter, prospective randomized control trial comparing the effect of the DJBS with a low-fat diet versus a low-fat diet alone for 12 weeks [31]. The study consisted of 25 patients in the experiment arm versus 14 patients within the diet-alone control arm. Five of 25 patients required early device explantation due to three GI bleeds, one anchor migration, and one sleeve obstruction.

A recent multicenter randomized control trial was conducted by Schouten and collaborators in 41 preoperative bariatric surgery patients. Thirty patients were randomized to the treatment arm and 11 patients were randomized to the diet control

group. A total of 26 devices were successfully implanted for 12 weeks. There were four device failures; one had dislocation of the anchor, another had obstruction of the sleeve, another had migration of the sleeve, and the last patient had intractable epigastric pain. All complications required early removal of the device [32].

The published safety profile of the EndoBarrier showed complications such as barrier migration (4.9%), GI bleeding (3.86%), sleeve obstruction (3.4%), liver abscess (0.126%), cholangitis (0.126%), acute cholecystitis (0.126%), and esophageal perforation (0.126%) secondary to trauma from an uncovered barb at withdrawal [33]. The pivotal US trial was prematurely halted secondary to significant liver abscess formation. This was thought to be secondary to translocation of bacteria via the fixation barbs in the duodenum. Modifications to the fixation platform are currently underway and hope to revive the pivotal US trial [33].

Future studies are needed to elucidate the safety and feasibility of the DJBS. With the current device, major adverse events range from 10 to 20% and are mostly related to the fixation within the duodenum.

The ValenTx Endoluminal Bypass (ValenTx, Carpinteria, CA, USA) attempts to mimic the Roux-en-Y gastric bypass (RNYGB). The implantable 120-cm sleeve is placed endoscopically starting at the gastroesophageal junction and extends into the proximal mid-jejunum. The goal of the therapy includes bypassing the stomach and duodenum [34]. Currently the technique requires both endoscopic deployment and suturing under laparoscopic visualization [35]. Sandler and collaborators in 2011 conducted the first pilot study consisting of a single-center prospective human trial in 22 patients. Only 17 patients completed the 12-week trial period with 5 patients (23%) requiring device removal all due to odynophagia. No major complications occurred during the placement or retrieval of the device [36].

The ValenTx sleeve appears to be a very promising device in the treatment of metabolic derangements. The device and technique are still undergoing refinements prior to the pivotal US FDA trial.

Magnet Endoscopic Incisionless Anastomosis System

The self-assembling magnetic endoscopic incisionless anastomosis system known as either IAS (Incisionless Anastomosis System) or SAMSEN (Smart self-Assembling MagnetS for ENdoscopy) is a new device created by GI Windows (West Bridgewater, MA, USA). It consists of two self-assembling magnets which are placed by simultaneous enteroscopic and colonoscopic guidance into the distal ileum and mid-jejunum [17–37]. The compressive forces between the two rings create a large compression side-to-side anastomosis. Once the anastomosis is formed, the magnets automatically pass spontaneously through the GI tract [37]. The benefits from the side-to-side anastomosis may be secondary to early entry of food into the distal small bowel, therefore altering the hormonal effect of incretins and altering hunger and satiety response. Two porcine trials have been described one creating a large jejuno-colonic anastomosis and the other creating jejunoileal bypass

both of which showed promising results [38, 39]. As a result, the technology was piloted in a human trial consisting of ten patients. All ten subjects had successful device placement and creation of the compression anastomosis [40]. Reported complications were mainly transient nausea and diarrhea. The device is now undergoing evaluation for a pivotal US trial.

Revita™ Duodenal Mucosal Resurfacing Procedure

Duodenal mucosal resurfacing involves hydrothermal ablation of the duodenal mucosa using the Revita DMR (Fractyl Laboratories, Lexington, MA, USA). In this procedure a catheter is placed in the duodenum that injects saline into the mucosa distal to the ampulla of Vater. A balloon catheter is then inflated with heated water, which then causes circumferential ablation of duodenal mucosa [41]. This procedure is associated with minimal weight loss, but it is thought to improve glycemic control by causing duodenal mucosa to re-epithelialize with normal mucosa or alter the signaling mechanism in the duodenum. A study by Rajagopalan and colleagues, which include 40 patients, showed that patients developed post-procedure abdominal pain (8/40 patients). Three patients developed duodenal stenosis, which presented as epigastric pain and emesis 2–6 weeks after the procedure and was treated with endoscopic balloon dilation [8]. The device and technique are early in development and have not undergone FDA approval.

AspireAssist®

AspireAssist (Aspire Bariatrics, King of Prussia, PA, USA) is a device that eliminates food and liquid from the stomach. This procedure uses a 30-French percutaneous endoscopic gastrostomy (PEG) tube. The device consists of a valve port placed at the skin level to assist in aspirating gastric contents. The technique includes infusing water into the stomach 20 min after a meal and then manual gastric content drainage. The efficacy of aspiration therapy was demonstrated in three separate studies [17]. The device leads to weight loss by aspiration of calories and behavior changes which leads to decreased overall food intake [41].

In a study by Sullivan and colleagues, no major complications were noted. Minor complications were related to the gastrostomy tube and included three skin infections and one persistent fistula. The fistula eventually closed without intervention after removal of the system. Patients also noted abdominal pain from the initial version of the device and were successfully remedied by redesign [12]. Similar Forssell and colleagues also only noted abdominal pain and skin infection. In this study a patient developed an intra-abdominal fluid collection and skin breakdown around the stoma. Notably, 52% of patients experienced moderate abdominal pain during the first week with 12% experiencing severe pain [17, 42, 43]. Finally the multicenter

Table 30.1 EBTs with side effects and complications

Procedure	Orbera [7]	Obalon [10]	ReShape [9]	OverStitch [20]	POSE [24]	TERIS [28]	TransPyloric Shuttle [29]	EndoBarrier [33]	ValenTx [36]	Magnet endoscopic incisionless anastomosis system [40]	Duodenal mucosal resurfacing procedure [41]	AspireAssist [44]
Adverse events												
No intra- or postoperative complications						0%				0%		
Duodenal stenosis											7.5%	
Peristomal bleeding												1.8%
Migration								4.93%	0%			
Mucosal erosions							75%					
Extragastric bleed					0.5%							
GI bleed				0.4%				3.86%				
Liver abscess					0.5%			0.126%				
Sleeve obstruction								3.47%				
Cholangitis								0.126%				
Acute cholecystitis								0.126%				
Esophageal perforation								0.126%				
Perigastric fluid collection				0.8%								
Pulmonary embolism				0.4%								
Pneumothorax				0.4%								
Dehydration	1.3%		0.4%									
Pneumonia	0.63%		0.4%									

(continued)

Table 30.1 (continued)

Procedure	Orbera [7]	Obalon [10]	ReShape [9]	OverStitch [20]	POSE [24]	TERIS [28]	TransPyloric Shuttle [29]	EndoBarrier [33]	ValenTx [36]	Magnet endoscopic incisionless anastomosis system [40]	Duodenal mucosal resurfacing procedure [41]	AspireAssist [44]
Esophageal mucosal injury	1.3%	4.2%	0.4%									
Device intolerance	5%											
Gastric outlet obstruction with moderate diffuse gastritis	0.63%											
Abdominal cramping and infection	0.63%											
Peptic ulcer disease		0.3%	10.3%				80%					
Nausea	86.8%	56.0%	61.0%		21.3%		45%	58.7%				18.9%
Vomiting	75.6%	17.3%	86.7%		19.5%		15%	39.4%				18.9%
Abdominal pain (general)	75.6%	72.6%	54.5%		45.2%		30%				20%	37.8%
GERD	30.0	16.7%	6.8%		8.1%		20%					
Eructation	24.4%	9.2%	16.7%									
Dyspepsia/bloating	21.3%	14.6%	17.8%									
Abdominal distention	17.5%	9.2%	11.0%									
Dehydration	14.4%											
Diarrhea	13.1%	8.3%	3.0%				25%					
Flatulence	11.2%	2.4%										
Esophagitis	0.6%	1.8%	0.4%									
Gastric erosion					0.5%							

PATHWAY trial revealed that most common complications were abdominal pain, postoperative granulation tissue, and peristomal irritation [44]. When combining all reported studies, the most common adverse events included constipation, bloating, nausea, peristomal skin irritation, and peristomal bleeding [44, 45].

Currently the AspireAssist appears to have promising short- and mid-term data and currently has obtained FDA approved.

Conclusion

Given the growing prevalence of obesity in the United States and worldwide, there is a growing demand for less invasive treatment options. Endoluminal bariatric therapies (EBTs) will fit this need and can offer therapy as a primary intervention, bridge to bariatric surgery, and revision of a prior surgical procedure. This chapter focused on current primary endolumenal therapies with an emphasis on complications. It is important to remember that many of these devices will continue to evolve and that the current device-related complications may change in the future. Also as the techniques become more familiar and widely used and the learning curve is overcome, the overall complication rates will certainly decrease. The overall benefits of EBTs are to offer less morbidity and an alternative to surgical therapies with the ultimate goal of obesity treatment often seen with surgical procedures [46, 47]. Table 30.1 summarizes the therapies covered and the overall safety profile.

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Chapter 31
Complications of Adjustable Gastric Banding

Ann M. Defnet and Marina S. Kurian

Introduction

Proficiency and ultimate mastery of bariatric surgery require complete understanding of not only of the preoperative and procedural minutia of the field but also postoperative care. Adjustable gastric banding (AGB) was once the leading bariatric procedure in 2008–2010 given the ease of placement via the laparoscopic technique, minimal recovery time, reversibility, and lower cost [1]. Although early reports estimated minimal morbidity from complications, over time the frequency of complications that arose from the procedure appears to have increased significantly, up to 40% at 10 years [2], including slippage, erosion, and infection. The frequency and magnitude of these complications contributed to the decline in popularity of AGB. Despite the decrease in patients undergoing AGB, the postoperative complications discussed in this chapter remain critically important for the clinician caring for patients who have previously undergone AGB, as well as for counseling patients wishing to undergo AGB.

In this chapter, we will review the major late postoperative complications observed with AGB placement: band slippage, band erosion, infection, and other port issues, including diagnosis and management.

Band Slippage

Band slippage, or gastric prolapse, one of the most common complications associated with adjustable gastric banding, occurs when a portion of the gastric wall herniates cephalad under the band. The herniated stomach can then cause tilting of the

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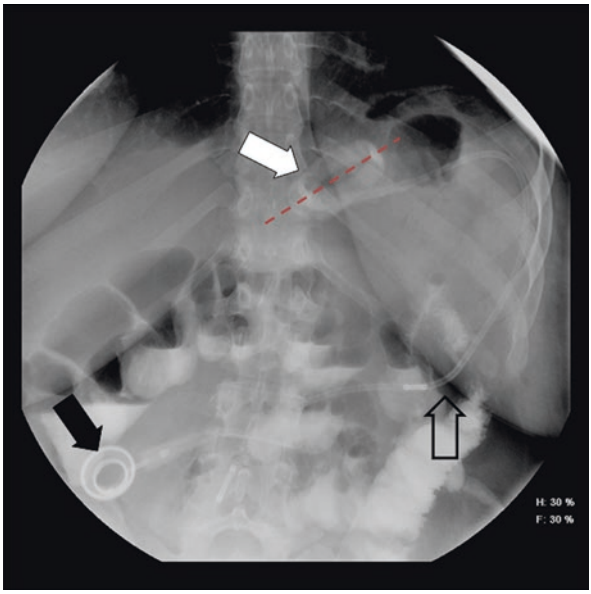

Fig. 31.1 Normal band positioning (white arrow) along an axis from 2 o'clock to 8 o'clock (dotted line). The port is indicated by the black arrow and the tubing by the open arrow

band, resulting in subsequent obstruction at the level of the band. Patients with band slippage present with epigastric pain, dysphagia, vomiting, food regurgitation, and food intolerance, not dissimilar to the symptoms of having too tight of a band. Diagnosis of gastric band slip is confirmed radiographically with esophagram or upper gastrointestinal (GI) series to evaluate for obstruction or prolapsed area of the stomach, as well as the angle of the band in situ. After insertion, the band is typically on an angle from the 1–3 o'clock position to the 7–9 o'clock position (Fig. 31.1) [3]. Esophagram in patients with band slippage will reveal abnormal angulation of the band, often associated with enlarged gastric pouch and failure of passage of contrast beyond the band (Fig. 31.2).

Once previously thought to occur in about 15% of patients with AGB, the incidence of slippage greatly decreased after adoption of the pars flaccida technique of AGB placement (reportedly 3–12%) [4, 5]. The main steps of the pars flaccida technique include division of the pars flaccida to expose the caudate lobe of the liver, identification of the right crus as it enters the retroperitoneal fat, and then dissection just medial to the right crus behind the gastroesophageal junction to the previously dissected angle of His. This dissection preserves retrogastric attachments, securing the band posteriorly versus the previously used gastrogastric technique that dissected all retrogastric attachments and created a larger gastric pouch [4, 5]. The transition to the pars flaccida technique of AGB greatly decreased the incidence of posterior gastric prolapse [4, 5]. Additionally, gastrogastric plication of the band has also decreased the rate of anterior band slippage [6].

Treatment for band slippage depends on the patient symptoms. The first step is to deflate the band. If the patient can tolerate liquids, the esophagram can be repeated in a week to see if the stomach has reduced below the band. If the patient has upper

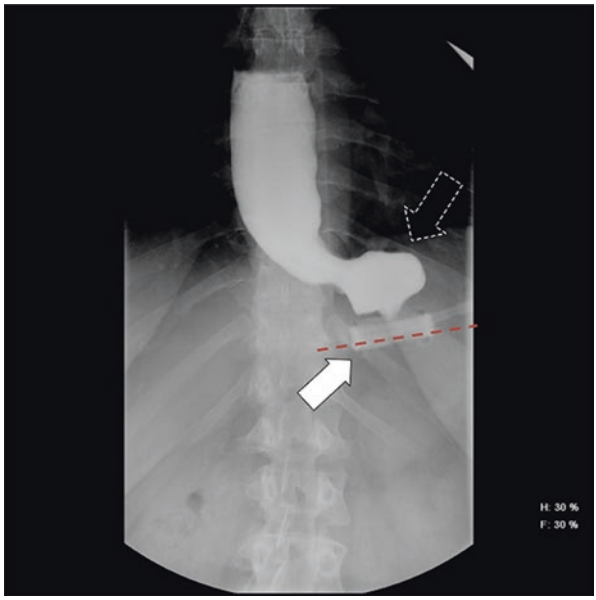

Fig. 31.2 Esophagram showing the band (white arrow) sitting in a nearly horizontal position (along the dotted line). Contrast passes into the stomach outlining the gastric prolapse (dotted arrow) but fails to pass distal to the band

abdominal or left chest pain or cannot tolerate liquids, inpatient hospitalization with intravenous hydration and monitoring is indicated. Occasionally, band deflation alone will allow for reduction of the prolapsed stomach and resolution of symptoms as seen with a challenge of oral intake while monitored. Most often, however, surgical management of band slippage is necessary. Although laparoscopic unbuckling, reduction of the prolapse, and rebuckling of the band, either at the primary procedure or at a second procedure, has been shown to be safe [7], there is also a high incidence of recurrence of slippage using this technique [8, 9]. Most centers now simply remove the band when slippage occurs, with placement of a subsequent band or transition to another bariatric procedure at a later date, if requested by the patient. In some cases, band slippage may cause ischemia or necrosis of the prolapsed stomach. In such cases, immediate surgical exploration with band explantation and possible gastric resection is necessary.

Concentric gastric pouch dilatation is another complication associated with AGB that is commonly grouped with band slippage, although the etiology and treatment are very different [10]. Although patients present with similar symptoms to band slippage, including food intolerance, dysphagia, and vomiting, upper GI series will reveal normal positioning of the gastric band with evidence of an enlarged pouch associated with decreased flow of contrast across the band. The etiology of concentric pouch dilatation involves overtightening of the band associated with a patient who overeats. Treatment involves a "band holiday" where all fluid is removed from the band and the dilatation is allowed to resolve as evidenced on repeat upper GI series. Patients with successful resolution of dilatation then may undergo band adjustments with lower volumes and closer follow-up. Chronic concentric pouch

dilatation despite band holiday may necessitate band repositioning, removal, or conversion to another bariatric procedure [6].

Band Erosion

A feared, although uncommon, complication of adjustable gastric banding is band erosion, or migration of the band itself into the lumen of the stomach. A recent review of the literature regarding erosion of adjustable gastric bands found an overall incidence of 1.46%, ranging from 0.23% to 32.65% based on the individual series [11]. The incidence of erosion was influenced by operative experience, with surgeons and centers with more volume and experience reporting lesser incidence. The proposed etiology of band erosion includes underlying gastric damage during initial placement, cautery injury, or tension placed on the stomach by gastrogastric sutures [11]. There also appears to be a decreased incidence of band erosion with the pars flaccida technique of band placement versus the perigastric technique, from 8% to 0.9% in one series [12] and from 6% to 1.1% in another series [13]. The proposed mechanism for this change in incidence of band erosion is both decreased trauma to the gastric wall with the pars flaccida technique and retention of some lesser curvature fat as a cushion for the band [13].

Despite appearing to be a catastrophic complication, the clinical course of band erosion is typically benign. The most common patient presentation includes abrupt loss of satiety, non-specific abdominal pain, and chronic port site infections [14]. Very rarely patients have been reported to present with acute and potentially life-threatening symptoms associated with band erosion, including hemorrhage [15–17], peritonitis [14], or obstruction [18–20]. Diagnosis of band erosion can only be made with upper endoscopy as both upper GI series and abdominal computed tomography are not specific enough to make the diagnosis [13]. Upon upper endoscopy, eroded portions of the band will be clearly visible intraluminally (Fig. 31.3). A retroflexed view of the gastroesophageal junction is critically necessary to fully assess for erosion [13].

The initial step in treatment of band erosion is removal of the gastric band. The primary route of removal in the literature is via laparoscopic surgery, although both open operations and endoscopic retrieval of eroded gastric bands have been described [11, 21–23]. In many cases, explanting the band is the only procedure without subsequent replacement or further bariatric operation, most commonly due to patient request [11]. Reinsertion of an adjustable gastric band after initial removal is also described in the literature, either during the initial retrieval procedure or delayed in a second procedure. Advocates of delayed reinsertion of the adjustable gastric band site a possible lower rate of re-erosion [24, 25]. Conversion to other bariatric procedures, including Roux-en-Y gastric bypass, sleeve gastrectomy, and biliopancreatic diversion, after band retrieval is more frequently described [11]. Perioperative complication rates for patients undergoing treatment for band erosion were low at 3.4% after delayed band reinsertion, 6.5% after immediate replacement,

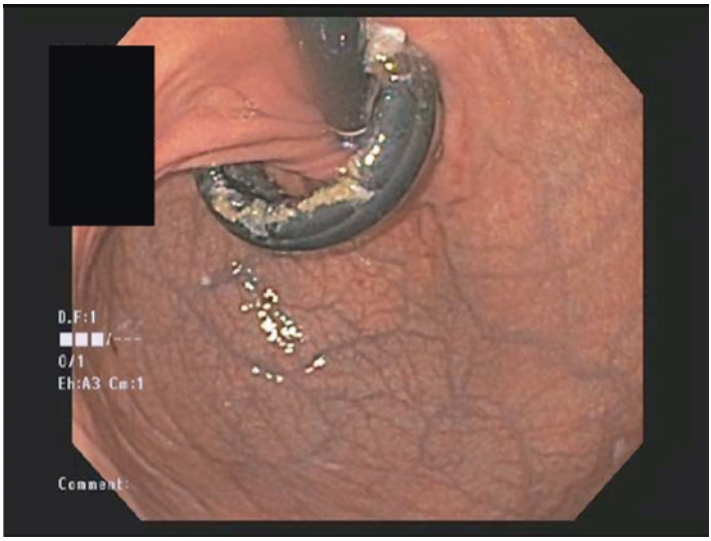

Fig. 31.3 Near-complete erosion of an adjustable gastric band as seen on a retroflexed view during upper endoscopy

and between 3% and 20% after conversion to another bariatric procedure [11]. These complications were typically reported to be minor, including wound infection, abdominal pain, and gastric fistula. As reported in a 2001 review of band erosion by Egberts and coworkers, continued weight loss was best for patients who underwent delayed replacement of the adjustable gastric band, followed by those who had immediate replacement, and worst in patients who did not have their bands replaced [11].

Port and Tubing Issues, Including Infection

Port and tubing issues associated with AGB are the most common complication, at an incidence of 4.3–24% in the literature, and, although not life-threatening, they remain a great source of patient morbidity [6, 26]. In fact, tubing and port issues commonly cause failure of the bariatric procedure itself. The LAP-BAND™ (Apollo Endosurgery, Austin, TX, USA) system of adjustable gastric band consists of silicone tubing that is connected to the port via a metal connector at the time of the initial placement. Over time, the silicone tubing becomes brittle and is more prone to breakage or disconnect from the port itself. Studies have suggested that tubing issues associated with AGB are related to the length of follow-up [26, 27]. The majority of tube disconnect or breakage issues can be uncovered clinically when the amount of fluid aspirated from the band is incongruent with what was noted to be instilled and is typically associated with failure of weight loss. The diagnosis can be

confirmed with X-ray or fluoroscopic investigation of the port and tubing. Typically, tubing disconnect or breakage requires laparoscopic intervention if the tubing terminates in the abdominal cavity [26].

Port site infection may be chronic in some patients, secondary to seeding during initial placement, during adjustments, or by another procedure (i.e., abdominoplasty), and thus can require multiple interventions and eventually port removal with replacement after the infection clears [26]. An important caveat in port site infection is the possibility of seeding from an eroded band; therefore endoscopic evaluation for erosion is indicated in all patients with a port site infection [6, 26, 27].

Problems accessing the port itself also occur frequently, whether due to body habitus, poor port positioning, or even port inversion secondary to poor port fixation. Studies in the literature propose radiographic assistance when accessing ports placed on the abdominal wall, as this appears to decrease attempts at accessing the port and anecdotally decrease port site infections [27]. Port inversion can be confirmed via abdominal X-ray and usually can be remediated utilizing local anesthesia without a hospital stay [26, 27]. Many different methods of port fixation have been entertained, including using mesh, but there is no clear consensus. Generally, it is recommended to fix the port to the fascia at minimum of three points with nonabsorbable suture [26]. Ideal anatomic placement of the port is also debated in the literature. Korenkov and colleagues report easier access with presternal placement of ports, although this placement is also associated with increased pain and complaints of port prominence [28]. As such, most centers routinely site the port on the abdominal wall.

Conclusion

Although once the most prominent bariatric procedure, adjustable gastric banding has fallen in prominence partly secondary to the frequency of postoperative complications, including band slippage, band erosion, and port or tubing issues, including infection. These complications, including diagnosis and treatment, are summarized in Table 31.1. Despite the frequency of complications, there is evidence that improvement in band design has decreased the incidence of postoperative complications, including band slippage and band erosion. Beitner and colleagues determined that rates of complications dropped nearly in half (19% vs 10%) from first-generation adjustable gastric bands (LAP-BAND™ 9.75, 10.0 and VG) versus second-generation adjustable gastric bands (LAP-BAND™ AP standard and large) [29]. With continued innovation, the incidence of complications associated with AGB could continue to fall, again placing this technique of bariatric surgery into prominence.

Table 31.1 Summary of the complications of adjustable gastric banding

Complication	Description	Diagnosis	Treatment
Band slippage	Herniation of the stomach caudally through the band, causing obstruction	Upper GI series–evaluate transit of contrast and positioning of band	First – deflation of band, likely laparoscopic removal of band necessary
Concentric gastric pouch dilatation	Global dilatation of the gastric pouch secondary to too tight of a band and patient overeating	Upper GI series–pouch dilatation without change in positioning of the band	"Band holiday" – deflation of band with gradual adjustments after resolution of dilatation
Band erosion	Migration of the band into the lumen of the stomach	Upper endoscopy with retroflexed view	Band retrieval, with possible replacement or transition to another bariatric procedure
Port/tubing issues	Tubing disconnect or breakage, port inversion	Abdominal X-ray, fluoroscopy	Local versus laparoscopic procedure to reconnect tubing or revise port fixation
Port infection	Abscess around port site, fistula, or drainage around port site	Abdominal X-ray, ultrasound. Upper endoscopy to rule out band erosion	Drainage, possible local port removal and replacement

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Chapter 32
Complications of Sleeve Gastrectomy

Fabio Garofalo and Radu Pescarus

Introduction

The concepts behind the sleeve gastrectomy are simple, but some components of the operation, if performed incorrectly, can result in serious complications. A recent expert panel consensus statement has been published with a resulting drive toward standardization, providing guidance for essential aspects of the procedure, indications and contraindications, surgical technique, management, and prevention of complications [1].

The increasing popularity of laparoscopic sleeve gastrectomy (LSG) is also partly due to major advantages that we do not find in other bariatric procedures, such as laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic adjustable gastric banding (LAGB). These advantages include technical efficiency, lack of an intestinal anastomosis, normal and intact intestinal absorption, absence of risk of internal hernias, no implantation of a foreign body, pylorus preservation thereby preventing dumping syndrome, and an appropriate first step in extremely obese patients [2].

Concerns remain, however, regarding potential complications associated with LSG including staple line leak, stenosis, and postoperative hemorrhage. A recent review of the literature, with a total of 940 patients, showed a LSG mortality rate of 0–3.3%, and major complications ranged from 0% to 29% (average 12.1%) [3]. Table 32.1 lists common surgical complications associated with LSG.

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Table 32.1 Complications of laparoscopic sleeve gastrectomy

Complication	Incidence (%)	Time period
Staple line leak	0.9–2.2 [4–6]	Early and late
Stenosis	0.1–3.9 [26–29]	Late more than early
Hemorrhage	< 2 [45]	Early more than late
GERD	0.5–31 [49, 52–54]	Late more than early
Incisional hernia	< 1 [65, 66]	Late more than early
Wound infection	Rare	Early

Early is defined as ≤ 7 days; late is defined as > 7 days

Staple Line Leak

Clinical Presentation and Diagnosis

Leak is the most concerning complication after LSG. The most common location of a leak is near the gastroesophageal junction (GEJ). Ischemia of the upper part of the staple line may be responsible for leaks in this area. Another important factor that can contribute to a proximal leak is a distal gastric outflow obstruction. This can occur secondary to a truly stenotic lumen or, more commonly, twisting or kinking of the sleeve at the incisura angularis resulting in a functional obstruction with resultant proximal overpressure [4]. The incidence of gastric leaks can increase from 0.9% to 2.2% [5–7] for primary LSG to up to 5.7% for revisional LSG [6, 8, 9]. Staple line reinforcement has not been proven to reduce gastric leaks [6].

A high index of suspicion and early identification of leaks after LSG are critical in order to achieve better outcomes after this complication. Unexplained tachycardia, fever, abdominal pain, or persistent hiccups after the procedure are some of the clinical clues that should prompt surgeons to investigate for a leak.

In cases of suspected leaks, a CT scan with oral and intravenous contrast material could provide more information, including the site of the gastric leak and identification of infected fluid collections, in addition to other potential postoperative complications such as hematomas, pulmonary embolisms, and pleural effusions [4] (Fig. 32.1a, b).

According to best practice guidelines from the International Sleeve Gastrectomy Expert Panel Consensus, leaks should be categorized according to their occurrence time from the operative procedure (acute, < 7 days; early, within 1–6 weeks; late, 6–12 weeks; and chronic, > 12 weeks) [1]. The current treatment algorithm includes abscess drainage, antibiotics, nutritional support, and endoluminal control.

General Principles of Treatment

The management of perigastric collections depends on the patient's clinical condition and available resources and expertise [4, 10, 11]. If the leak presents as a well-defined abscess and the patient is clinically stable, percutaneous image-guided

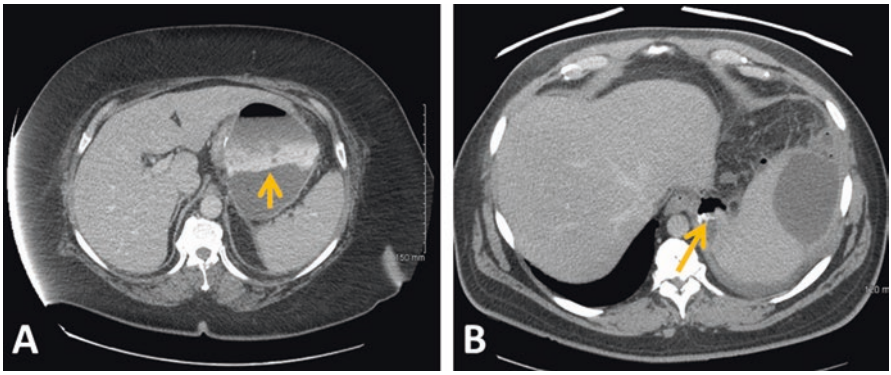

Fig. 32.1 (**a**, **b**). Two different patterns of presentation of a gastric leak. (**a**). A 68-year-old patient presented to the emergency department with fever and abdominal pain 23 days after LSG. Axial CT scan shows a large left upper quadrant abscess containing extravasated contrast material (arrow) and extraluminal air. (**b**). A 44-year-old woman presented with nausea, vomiting, and intermittent abdominal pain without fever 35 days after revisional LSG. Axial image of a CT scan shows a small amount of contrast extravasation and free air (arrow) indicating a micro-leak at the GEJ

drainage is appropriate. Recently, internal endoscopic drainage championed by Donatelli's group offers the advantage of avoiding the percutaneous route, therefore diminishing the risks of external fistula formation [12]. In case of an unstable patient, laparoscopic drainage in the operating room is the preferred choice [4]. Together with drainage, endoluminal control must be established to facilitate closure of the leak. As mentioned earlier, this can be accomplished through the use of stents or internal pigtails performed endoscopically. Concomitant treatment of the axial deviation that is often present in these cases is also essential. This will be discussed in more detail in the next section.

An essential part of the treatment is nutritional optimization. This can be achieved preferentially through the enteral route with the placement of a naso-jejunal tube or through a surgical feeding jejunostomy. Parenteral nutrition can also be used in cases in which the enteral route is not available or not tolerated by the patient.

Stenting, Endoscopic Internal Drainage, and OTSC

Various endoscopic modalities can be used in the treatment of LSG leaks. Among these, stents are the current gold standard modality in the early postoperative period. Complications include stent migration (11.1–83%, mean 45.3%) and difficulties in stent removal, which is a feared complication that has been described with the use of partially covered stents [13, 14]. Moreover, stents are often difficult for patients to tolerate for the required length of treatment, as they may have symptoms of retching, regurgitation, or epigastric or chest tightness.

Different types of stents are commercially available, and these include partially covered metallic stents (Wallstent™, Boston Scientific, Ireland) and long fully covered stents (Megastent™, Taewoong Medical Industries, South Korea; Hanarostent™,

MI Tech, Seoul, South Korea) [15–17]. Partially covered esophageal metallic stents have been until recently the best option in the treatment of sleeve leaks. They are, however, prone to migration given their shorter length (up to 155 mm), and they are harder to remove due to the ingrowth occurring at both ends of the stent. More recently, fully covered Megastents™ up to 230 mm in length and with a large diameter (up to 28 mm) appear to be more resistant to migration [18]. They are also easy to remove given the full silicone covering. One additional option includes the longer Megastents™, which allow for complete coverage of the gastric sleeve past the incisura angularis. This results in reduced proximal overpressure and potentially allows for a better healing of the fistula [18, 19] (Fig. 32.2a–d).

Recently, treatment with endoscopically inserted double-pigtail catheters has been proposed in the European literature [12, 20]. The pigtail is placed across the fistula between the lumen of the esophagus and the cavity of the abscess. The pigtail allows for internal drainage of the abscess. The pigtail is then endoscopically removed 3–6 weeks after placement. In a recent series of Donatelli and colleagues [12], endoscopic internal drainage (EID) via pigtail was used for the treatment of leaks post LSG. Fifty out of 67 patients (74.6%) were cured by EID after a mean time of 57.5 days and an average of 3.14 endoscopic sessions. Internal pigtail drainage is well tolerated by most patients with early re-alimentation and few complications described. Validation by multiple teams worldwide is necessary to gain more evidence, but at this point endoscopic pigtail placement appears to be a possible alternative to stents.

Over-the-Scope Clips (OTSC) (Ovesco™ Endoscopy, Germany) are also part of the endoscopic armamentarium for the treatment of gastric sleeve leaks [15–17]. Keren and colleagues [17] presented a series of 26 patients that underwent endoscopic OTSC treatment after SG leaks. Twenty-one (80.76%) leaks were successfully treated with a median time to complete oral nutrition of 32 days (range: 14–70 days). Similarly, Mercky and colleagues [21] reported 11 of 19 cases (57.8%) of post-LSG fistula were successfully treated with OTSC alone and 4 (21.1%) patients with combination of OTSC and self-expandable stent. In four (21.1%) cases, even combined treatments failed.

In our experience, placement of the OTSC is often difficult post-LSG leak. First, deployment of the OTSC is more challenging at the level of GEJ. Second, the edges of the fistula present as either an important inflammatory reaction in acute cases or a more fibrous reaction in chronic cases, both limiting the grasping of the fistula edges even with the help of proprietary endoscopic graspers.

Stricturotomy, E-Vac, and Surgical Treatment

Other endoluminal treatment modalities have also been described as part of the treatment options of gastric leaks. Galvao Neto and colleagues [22] recently proposed internal drainage and stricturotomy for treatment of LSG leaks. This treatment consists of a combination of stricturotomy of the septum between the

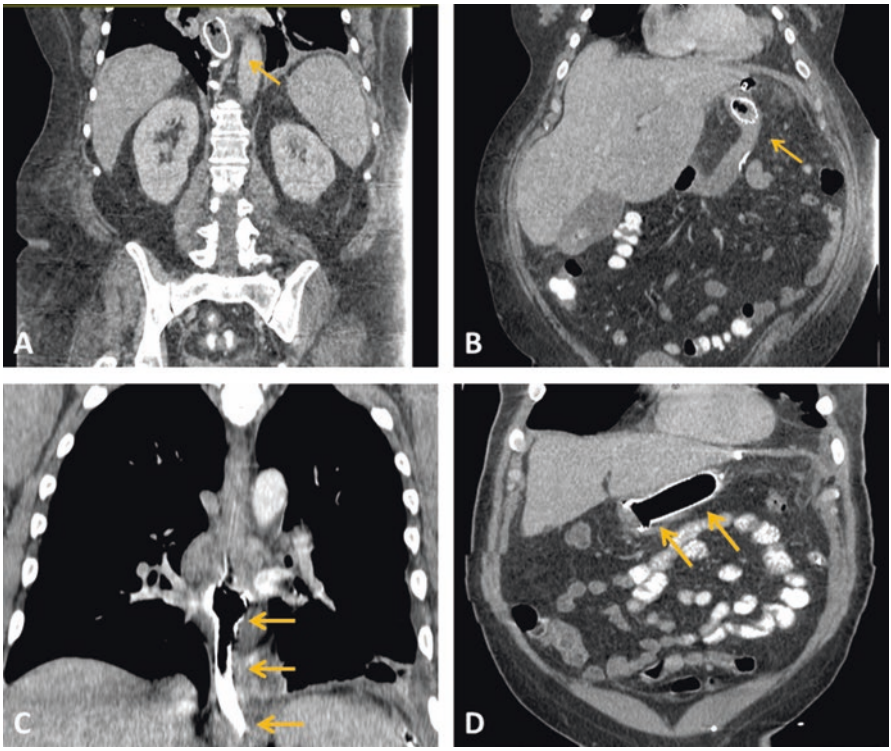

Fig. 32.2 (**a**–**d**). Different stent placements. All CT images belong to a 62-year-old woman that presented with a leak at the GEJ, 7 days after LSG. Endoluminal control was initially attempted via placement of a Wallstent™ projecting across the GEJ (**a**, **b**). While the proximal part of the stent covers the leak site, the distal end of the stent (arrow in B) is not able to project distal to the incisura angularis. Despite the presence of a Wallstent™ for 4 weeks, leakage persisted. Complete healing of the leak was achieved by placement of a long fully covered stent (Megastent™) for another 3 weeks. (**c**), (**d**): Megastent™ placement covering the leak site at the GEJ and also overcoming the incisura angularis (arrows), reducing proximal overpressure, hence promoting healing of the leak

perigastric cavity and the gastric sleeve, along with use of a 30 mm achalasia balloon dilatation in cases of axial deviation at the incisura angularis. Although further studies need to confirm these results, this modality treatment seems encouraging, especially for late or chronic leaks diagnosed more than 30 days after LSG.

The use of endoluminal vacuum (E-Vac) therapy has also been described as an alternative treatment in case of lower and upper gastrointestinal leaks [23–25]. In a recent study, Smallwood and colleagues [23] performed E-Vac therapy post-foregut leak or perforation. Healing was achieved in all patients ($n = 6$) after an average of 35.8 days (range, 7–69 days) and 7.2 different E-Vac changes (range, 2–12). Although the E-Vac therapy has shown interesting results, the endo-sponge changes have to be done every 3–5 days under general anesthesia. This makes this technique difficult to implement in an era of efficient utilization of resources.

Chronic fistula after LSG is a challenging problem. If a fistula persists for more than 3 months despite adequate drainage, endoluminal therapy, and nutritional support, reoperation may be the only solution. Several surgical options have been reported including the creation of a fistulo-jejunostomy, connecting a jejunal Roux limb to the fistula, and proximal gastrectomy with esophagojejunostomy [4, 11]. A chronic leak can also progress into a gastrocolic or gastro-pleural fistula. Laparoscopic resection of the fistula tract with interposition of healthy tissue can be a valid option in these rare cases [26].

Summary

Gastric leaks after LSG represent complex, difficult-to-treat problems. Often patients suffer from prolonged hospitalizations, and multimodal management is necessary. Transfer to a tertiary bariatric care setting should be considered, as patients need access to interventional radiology, therapeutic endoscopy, and possibly revisional bariatric surgery. On the basis of our experience and published literature, we propose a simplified algorithm that can guide the treatment of gastric leak post LSG (Fig. 32.3). Once the diagnosis has been established, one has to take into consideration the overall condition of the patient, the time since the initial surgery, associated conditions such as axial deviation of the gastric conduit, and previous attempts at closing the fistula. Stenting with a long, preferably fully covered stent that covers the GEJ and extends below the incisura angularis and/or internal pigtail

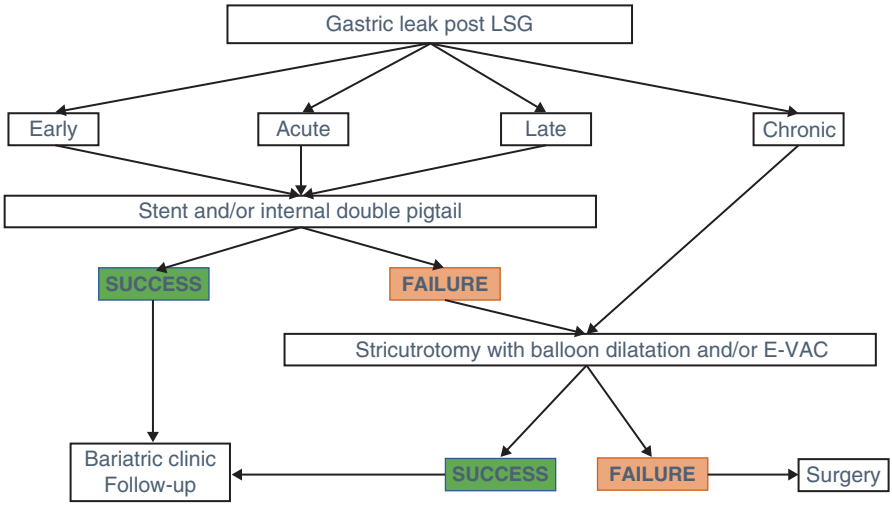

Fig. 32.3 Treatment algorithm following gastric leak post LSG

drainage should be the first option in case of acute, early, and late fistula. In case of an axial deviation of the sleeve, balloon dilatation should be performed concomitantly. In cases of failure, a stricturotomy with balloon dilatation should be attempted, with the goal of achieving internal drainage of the extra-gastric cavity. Similarly, E-Vac therapy is suggested as a rescue treatment or initial treatment in patients presenting in extremis with large perforations and large extraluminal abscess cavities. Chronic fistula may be first managed with stricturotomy and balloon dilatation and/or E-Vac placement. In case of failure of these endoscopic modalities, a surgical revision becomes mandatory. We believe that even in cases in which all endoscopic measures fail, initial endoscopic treatment may help reduce the septic burden of the patient and improve local conditions in order to decrease the overall surgical risk.

Gastric Stricture

Clinical Presentation and Diagnosis

Stenosis or obstruction of the gastric conduit due to abnormal angulation following sleeve gastrectomy has been increasingly recognized, with a reported incidence ranging between 0.1% and 3.9% [27–30]. Two types of stenoses are usually documented. The first and most frequently encountered is an axial deviation commonly located at the incisura angularis. It can be visualized endoscopically as a sharp angulation even though the scope passes into the antrum. Less frequently encountered is mechanical stenosis, presenting as an anatomical obstruction. It can be found anywhere along the proximal gastric conduit and is usually described on endoscopy as a mucosal narrowing (Figure 32.4a, b). Clinically, both types of stenoses can present with regurgitation, dyspepsia, retrosternal burning, early satiety, abdominal pain, nausea, vomiting, and rapid weight loss. In order to confirm the diagnosis of gastric sleeve stenosis, endoscopic and fluoroscopic investigations are essential.

Different mechanisms are thought to be responsible for the creation of sleeve stenosis during LSG [31, 32]. Reinforcement of the staple line with a running suture on a tight sleeve has been pinpointed as a potential culprit in mechanical stenosis [27, 33]. Most importantly, aggressive or unequal traction on the greater curvature during gastric stapling, or insufficient posterior dissection of the posterior stomach off the retroperitoneum, can contribute to axial deviations [34, 35]. In case of revisional LSG, complete posterior dissection is usually more challenging and, together with previous scar tissue, may contribute to a higher stenosis rate. The use of a smaller size bougie (< 40F) and intimate hugging of the bougie during stapling have been proposed as possible mechanisms as well.

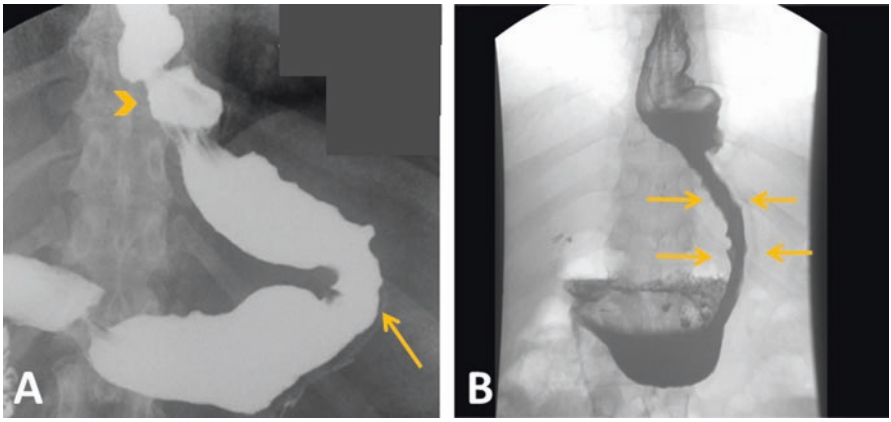

Fig. 32.4 (**a**). A 46-year-old patient presenting with dysphagia, 1 year after LSG. UGI study shows a sharp angulation at the level of the incisura angularis (arrow). Herniation of the cardia (arrowhead) through the esophageal hiatus is also visualized. (**b**). A 44-year-old man presenting with dysphagia following re-sleeve gastrectomy. Anteroposterior fluoroscopic image demonstrates a long gastric stenosis (arrows) leading to secondary dilatation and formation of a proximal neo-fundus

Principles of Treatment

The timing of clinical presentation following sleeve gastrectomy varies among patients, but may occur within days or in some cases months after the surgery. Once the diagnosis of sleeve stenosis or axial deviation has been established, various treatment options are available. Initial management includes symptomatic treatment with antiemetics, IV fluids, and endoscopic assessment [29, 30]. A complete nutritional workup is mandatory, and nutritional supplementation might be necessary, especially in those patients who were initially happy with their dramatic weight loss and were lost to follow-up.

Endoscopic techniques rely mainly on dilatation with achalasia over-the-wire balloons (30–40 mm) or stent placement for refractory cases. An endoscopic stricturoplasty together with balloon dilatation has been proposed by Galvao Neto in refractory cases [36]. When reviewing the literature on endoscopic treatment of post-LSG stenosis, results are rather heterogeneous [30, 33, 34, 37–41]. Success rates vary from 44% to 100%, with a total of 179 patients treated. In our experience with 27 cases, pneumatic dilatation with 30–40 mm achalasia over-the-wire balloons seems to be a safe and effective procedure in this patient population. Overall, at our institution, the success rate approaches 56% when axial deviation is treated endoscopically (unpublished data).

For patients with twisted sleeves, revisional laparoscopic surgery is often necessary when endoscopic measures fail. LRYGB is currently considered the best surgical option in case of refractory stenosis, with good short- and long-term outcomes

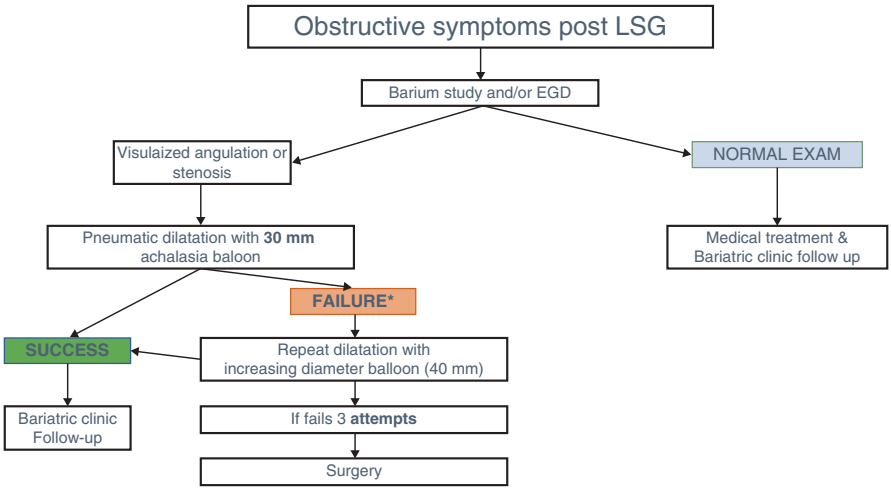

Fig. 32.5 Treatment algorithm following gastric sleeve stenosis post LSG

[27, 33, 37, 42]. Laparoscopic seromyotomy, in which a partial-thickness cut on the gastric wall is performed over the stenotic gastric segment, has been described in a few case series [43]. Others have described a gastric wedge resection, in which the stenotic segment is resected and a gastro-gastric anastomosis is performed [44]. Both options have been associated with relatively poor results in the literature.

Summary

Based on our experience and published literature [33, 34, 41], we propose the following treatment algorithm (Fig. 32.5). If the patient presents with obstructive symptoms post LSG, a barium study and diagnostic upper endoscopy should be performed, together with a thorough nutritional assessment. In case of abnormal angulation or stenosis of the sleeve, a dilatation using a 30 mm achalasia balloon should be attempted. If this fails, two more endoscopic dilatations should be attempted with increasing diameter of the balloon. If the three attempts fail, surgical revision to LRYGB is indicated, with consideration given to other surgical options. Upon revisional LRYGB, precise identification of the narrowed segment can be accomplished using intraoperative endoscopy, such that the gastrojejunal anastomosis is performed proximal to the stenotic area.

Intra- and Postoperative Bleeding

Significant bleeding requiring transfusions or reoperation occurs in less than 2% of LSG cases [45], and this tends to decrease drastically with the surgical learning curve. Common sites of bleeding include the gastric staple line, the short gastric vessels, or branches of the gastroepiploic arcade that have been divided during dissection of the greater curvature of the stomach.

There is some evidence suggesting that the use of bioabsorbable material as buttressing or placing a running suture on the gastric staple line can decrease intraoperative and postoperative bleeding [46, 47]. Routine use of a running suture on the gastric staple line should be approached with caution as this may cause staple line ischemia or further accentuate a pre-existing axial deviation.

When bleeding is suspected in the postoperative period based on a significant hemoglobin drop or changes in the vital signs, a CT scan can be considered to help establish the diagnosis. A CT scan without IV or oral contrast may be sufficient to establish the diagnosis, but administration of IV and/or oral iodinated contrast may be useful in the assessment of other potential complications such as leaks.

Postoperative bleeding usually occurs at the level of the gastric staple line. Conservative treatment is often effective [48]. Surgical exploration may be mandatory in case of ongoing bleeding necessitating transfusion, or active bleeding. Nevertheless, cataclysmic bleeding requiring multiple transfusions and emergency surgical intervention is rarely needed.

Gastroesophageal Reflux Disease (GERD)

GERD remains a significant problem after LSG, and the onset of severe refractory GERD after LSG may be an indication for surgical revision. New-onset GERD after LSG has been reported to be 0.5–31% [49–52]. GERD symptoms may be related to a neo-fundus [50], corresponding to a dilated pouch of the proximal sleeve which may also be responsible for weight regain. The presence of a sliding hiatal hernia or a patulous GEJ can also contribute to symptoms of reflux. Concomitant hiatal hernia repair (HHR) and LSG have been proposed in order to reduce postoperative GERD. However, in a recent study from Samkar and coworkers [53], authors reported that 15.6% of asymptomatic patients developed de novo GERD symptoms despite a HHR.

Revisional surgery after LSG is occasionally needed in the context of severe GERD resistant to medical treatment. The gold standard is conversion into a LRYGB, often times with a concomitant hiatal hernia repair [42, 54, 55]. Other treatment options have also been described, such as the Hill procedure, in which the anterior and posterior phrenoesophageal bundles are sutured to the preaortic fascia [56]. Lower esophageal sphincter (LES) augmentation using the LINX® device or the delivery of radiofrequency to the GEJ by the Stretta® technology represents two

other options. Limited data have been published in the medical literature to confirm the efficacy of these other procedures in the bariatric population [56, 57].

Prevention is also a key point to reduce the risk of postoperative GERD. According to the 2013 updated TOS/ASMBS/AACE Clinical Practice Guidelines (CPG) [58], systematic gastrointestinal evaluation pre-bariatric surgery is not indicated. Upper endoscopy is only recommended if clinically indicated [58]. Recently, Wolter and coworkers [59] found abnormal endoscopic findings in 65.7% of 817 patients undergoing systematic preoperative evaluation for bariatric surgery. The most common conditions were gastritis (32.1%) and gastroesophageal reflux (24.8%). Upper gastrointestinal malignancies were observed in 0.5% of all patients. Similarly, in a study that analyzed subjective and objective GERD outcomes in 100 candidates for bariatric surgery, Tutuian and coworkers demonstrated a 71% objective evidence of GERD, even though only 54% reported regurgitation or heartburn symptoms [60]. These papers highlight the potential yield of an upper gastrointestinal workup, even in an asymptomatic patient, before any bariatric procedure.

Ongoing debate surrounds the question of what is the right surgical bariatric procedure to perform for patients with preoperative GERD. The 2014 International Sleeve Gastrectomy Expert Panel Consensus attempted to reach an agreement [32]. Overall, 23.3% of bariatric surgery experts (defined as having performed more than 1000 cases) consider GERD to be a contraindication to LSG, while 52.5% of the general bariatric surgeons (defined as having performed less than 1000 cases) consider it to be a contraindication. Several papers report an increase in incidence of reflux after sleeve gastrectomy [50, 51, 53], whereas others such as Morino and coworkers [61] report only 5% GERD de novo after 2 years. This prospective clinical study concluded that GERD is actually improved after sleeve gastrectomy, and it should not be a contraindication [32].

While the role of LSG in causing or treating GERD remains controversial, there is significant evidence that LRYGB is an excellent procedure to treat reflux in obese patients [62–64]. In our opinion, LRYGB should be the preferred operation for the obese patient with GERD.

Other Complications

Other surgical complications have been described after sleeve gastrectomy. Infarction of the superior pole of the spleen is frequently seen after LSG. This can result from ligation of the short gastric vessels to mobilize the gastric fundus during LSG.

Incisional hernias have also been described. Their incidence rate is comparable to other bariatric procedures performed laparoscopically (<1%) [65, 66]. When they are present, they usually occur at the gastric extraction site, which is a 12–15 mm incision that sometimes has to be dilated to allow the passage of the gastric specimen.

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Chapter 33
Complications of Roux-en-Y Gastric Bypass

Erica D. Kane and John R. Romanelli

Introduction

The number of bariatric procedures being performed is increasing with the rising prevalence of morbid obesity [1]. By 2011, about 158,800 Roux-en-Y gastric bypasses (RYGB) were being performed worldwide, comprising 46.6% of all bariatric surgeries [2], with 23,750 RYGB performed in the United States alone in that year [3]. Given the rise in bariatric procedures, the absolute number of complications is also increasing. Complications after RYGB can be divided into perioperative (within 72 h), early postoperative (72 h to 8 weeks), and late acute and late chronic postoperative (over 8 weeks) events (Table 33.1). Perioperative complications include hemorrhage, early obstruction, leak at an anastomosis or staple line, surgical site infection, trocar site hernia, and venous thromboembolism [4]. Early postoperative complications comprise staple-line dehiscence, nutritional deficiencies, and sequela due to early postoperative nausea and vomiting (e.g., Wernicke's encephalopathy) and stricture. Late acute complications include internal hernia, incisional hernia, and other etiology of small bowel obstructions. Late chronic complications encompass marginal ulceration, gastrogastric fistula, chronic pancreatitis, cholelithiasis and choledocholithiasis, nutritional deficiencies (e.g., anemia), postprandial hypoglycemia, chronic pain, weight loss failure, and increased propensity toward substance dependence or abuse, depression, and suicidal ideology [5–7].

Complication rates differ by RYGB technique. A recent prospective database study comparing open and laparoscopic RYGB over a 10-year follow-up period found that open cases had a higher incidence of postoperative incisional hernia, anastomotic stenosis, and marginal ulceration and lower rates of dumping syndrome over the long-term compared to laparoscopic cases [3]. The authors found no

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Table 33.1 Complications after RYGB.

Perioperative complications (up to 72 h)
Bleeding[a]
Leak[a]
Surgical site infection
Trocar site hernia
Venous thromboembolism
Early postoperative complications (1–8 weeks)
Staple-line dehiscence
Acute nutritional deficiencies (e.g., Wernicke's encephalopathy)[a]
Early stricture
Late acute postoperative complications (over 8 weeks)
Internal hernia[a]
Incisional hernia
Other etiology of small bowel obstruction[a]
Late chronic postoperative complications (over 8 weeks)
Anastomotic stricture[a]
Marginal ulceration[a]
Gastrogastric fistula[a]
"Candy cane" syndrome[a]
Chronic pancreatitis
Cholelithiasis/choledocholithiasis[a]
Nutritional deficiencies and sequela[a]
Weight loss failure[a]
Post-gastric bypass hypoglycemia[a]
Chronic pain
Increased risk of alcohol and/or substance abuse[a]
Increased risk of depression and suicidal ideology[a]

[a]Complications addressed in this chapter

difference in patient survival on Kaplan-Meier analysis. Another large review found that 5.8% of patients who underwent laparoscopic RYGB experienced a major perioperative complication versus 4.6% of open cases [8]. Multiple comparative studies and reviews evaluating outcomes after laparoscopic versus robotic RYGB found that the robotic approach was associated with equivalent or possibly fewer postoperative complications [9–18]. A recent meta-analysis found a reduced occurrence of anastomotic stricture events, reoperations, and shorter length of hospital stay for patients who underwent robotic RYGB compared to a laparoscopic approach; however, the level of evidence used in the analysis was low [19].

Mortality after RYGB has been reported between 0.16% and 1.0% [1, 8, 20], most commonly due to pulmonary thromboembolism, followed by sepsis due to the delayed diagnosis of an anastomotic leak [1]. Risk factors for increased perioperative mortality include higher body mass index, male sex, older age, and a higher number of comorbidities [21]. Prophylactic medication for venous thromboembo-

lism, specifically low molecular weight heparin, is recommended for all patients undergoing bariatric procedures to attenuate the risk of a life-threatening thromboembolic event [22].

Perioperative and Early Postoperative Complications

Leak

Background

Incidence of staple-line or anastomotic leaks has been reported as 0–5.6% for laparoscopic RYGB and 1.6–2.6% after open RYGB [5, 23–27]. Potential leak sites include the gastrojejunostomy (42.2–67.8%), gastric pouch (10.2%), remnant stomach (3.4%), jejunojejunal anastomosis (5–7.8%), gastrojejunostomy and pouch (3.4%), pouch and excluded stomach (3.4%), or undetermined site (6.8%) [2, 23]. While this complication occurs infrequently, it accounts for the second most common cause of death, after pulmonary thromboembolism. Mortality can reach as high as 50% for jejunojejunostomy leaks [23, 24, 28], while mortality after gastrojejunostomy leaks tend to be much lower, under 3% [2].

The majority (95%) of postoperative leaks occur within 72 h of surgery and are usually secondary to technical failure, such as stapling error or excessive anastomotic tension. One example of stapling error is inadequate staple engagement or closure when the stapler is deployed, which results in improper seating of the staple limbs in the tissue and subsequent dislodgment; this can occur when an incorrectly sized staple cartridge is selected. A second cause of stapler malfunction is due to a retained loose staple at the apex of the previously fired staple line, damaging the staples being deployed across it [23].

Another risk factor for leak is anastomotic tension exceeding the staple or suture strength. As anastomotic leaks commonly occur at the gastrojejunostomy, surgeons often test the integrity intraoperatively via infiltration of methylene blue or air through an orogastric tube or endoscope, while the anastomosis is submerged under irrigation. Reinforcement of the suture line has been described to minimize suture line leakage, with mixed results. While biologic buttress materials like polyglycolic acid and trimethylene carbonate have shown limited efficacy, particularly over bovine pericardial strips [23, 29, 30], fibrin glue sealant has been shown to reduce suture line leaks in some studies [30, 31]. Series utilizing omental reinforcement of the anastomosis have shown some success in preventing leak [32, 33]. Newer experimental bioabsorbable staple reinforcement material is being developed as well [34, 35].Though there are reports of favorable results utilizing staple line reinforcement, safe outcomes without reinforcement are routine and widely reported, and thus use remains a subject of controversy.

While one study demonstrated a 4.9-fold increased risk of leak after open versus laparoscopic RYGB [36], other reports have described nearly a twofold increased

incidence after laparoscopic RYGB. Additionally, a large meta-analysis showed no difference between hand-sewn versus mechanical anastomosis [37]. It has been postulated that the increased anastomotic leak rate sometimes demonstrated in laparoscopic techniques is due to the adoption of stapled closure over the more technically demanding two-layer hand-sewn suture method, as is often performed in the open approach. Robotic RYGB may more easily facilitate a double-layered hand-sewn technique given the improved dexterity of the robotic instrumentation. Some comparative studies have shown a decreased anastomotic leak rate after robotically hand-sewn anastomoses versus laparoscopic stapled closures [13, 15].

Early postoperative leaks are often due to ischemia at the staple line or excessive intraluminal pressure from distal obstruction. This occurs most often at the gastrojejunostomy, followed by the gastric pouch staple line, and then jejunojejunal anastomosis [1]. Disruption at these areas generally occurs between 5 and 7 days after surgery and is independently associated with superobesity, age above 55 years, male sex, poor nutritional status, a history of diabetes mellitus, sleep apnea, hypertension, cirrhosis, renal failure, or smoking [23, 38].

Presentation and Diagnosis

Patient presentation is variable, ranging from asymptomatic to septic with multisystem organ failure depending on the time of diagnosis; hence early recognition of a leak is essential. The earliest symptom and most sensitive indicator is persistent tachycardia [1]. Other symptoms include abdominal pain, tachypnea or shortness of breath, fever, and oliguria. The surgeon must have a high degree of suspicion as minimizing the time to diagnosis is critical to prevent progression to sepsis and life-threatening sequela. Patients with chronic, subacute leaks are at risk of developing a fistula, which may present later with more indolent symptoms, like abdominal discomfort, acid reflux from the gastric remnant, or weight loss failure.

Acute leak may result in leukocytosis and/or acidosis, but these laboratory values are neither sensitive nor specific and should not alter patient management. The most common diagnostic test to identify the presence of a gastrointestinal leak or fistula is a radiograph with water-soluble oral contrast, which is generally the initial screening test performed in a stable patient. The sensitivity of this evaluation is reported to be widely variable, however (22–75% [38]). Alternatively, a computed tomography (CT) scan may be chosen, as it provides the advantage of being able to reveal an unconnected abscess or fluid collection and examining the extra-luminal environment. Other diagnostic modalities include endoscopic evaluation with a bubble test under surgical guidance or endoscopy with fluoroscopy and examination of the mucosa for disruption [1]. Oral administration of methylene blue dye with inspection of the adjacent abdominal drain contents has fallen out of favor as the flow of the dye, even in the setting of a leak, may not reach the drain. Choice of work-up may be influenced by the acuity of the presentation; furthermore, diagnostic imaging or laboratory values should not delay proceeding to the operating room for an unstable patient with suspicion of a leak.

Management

All patients should immediately be made nil per os (NPO) and appropriately resuscitated. Nonoperative management may be executed for contained leak in a stable patient, with an anticipated 75% resolution rate for asymptomatic, small leaks [39]. These patients require broad-spectrum intravenous antibiotics, percutaneous drain placement to control the site of the leak, and parenteral nutrition or distal enteric feeding. Vital signs, white blood cell count, and physical exam should be monitored closely in these patients, with plans to proceed to operative management if they exhibit worsening tachycardia, leukocytosis, or abdominal pain. Surgical treatment differs depending on the chronicity of the leak and the location, but the objectives are the same: removal of the enteric contents from the abdominal cavity and source control. Surgical treatment options for early acute leaks may include abdominal washout and closed suction drainage, T-tube placement to develop a controlled gastrocutaneous fistula, primary repair and drainage, or endolumenal stenting. Attempts at primary closure may be achievable for defects of the jejunojejunostomy or gastric remnant, though this may not be optimal due to poor integrity of inflamed tissue, particularly for leaks from the gastrojejunostomy. Revision of the anastomosis may be necessary although the ability to do so in an unstable patient makes this option often difficult. Placement of a gastrostomy tube in the remnant stomach or a feeding jejunostomy tube should be considered at the time of operation given the necessity to maintain adequate nutrition to promote healing and support nutrition in the postoperative period.

More recently, anastomotic leak has been managed endoscopically with either placement of a covered self-expanding metal stent to promote internal (intraluminal) drainage of the leaked contents or primary endoscopic closure for smaller wall defects. This approach avoids reoperation when abdominal washout is not required and any leaked collections can be managed by interventional radiologic drainage. Self-expandable endoscopic stents decrease intraluminal pressure and divert enteric drainage. They should be placed early after identification of the leak as a fibrous fistulous tract is more likely to form with a longer interval, reducing the probability of closure. They are generally left in place for 4–8 weeks to allow gastrointestinal tissues to heal but to avoid excessive mucosal hyperplasia. The stents are typically well tolerated by patients, with return to oral diet within 1–3 days and only occasional minor symptoms of nausea or abdominal discomfort; however, high rate of stent migration and associated morbidity of migration remains their most prominent issue. Although metal stents have a higher friction coefficient, they have been shown to migrate at similar rates as polyester stents [1, 40]. Endoscopic closure of small chronic leaks have been managed with over-the-scope clips, injection of sealant materials (e.g., fibrin glue, cyanoacrylate), acellular matrix biomaterial plugs, and endoscopic suturing systems with good outcomes in select patients, but prospective trials and consensus recommendations are still pending regarding these modalities [40].

Gastrointestinal Bleed

Background

Gastrointestinal hemorrhage after RYGB occurs as either an early complication, usually presenting immediately perioperatively, or as a late complication after 30 days. Overall incidence of postoperative hemorrhage has been reported in up to 9.4% of cases [41].

Perioperative and early postoperative bleeds occur in 1–5% of cases, most commonly as a result of inadequate hemostatic compression at an anastomotic staple or suture line at the gastrojejunostomy, jejunojejunostomy, or the excluded gastric remnant [1, 23]. There is a discrepancy surrounding the most common site of hemorrhage. Heneghan and coworkers reported 40% of bleeds occurred at the gastric remnant and 30% at each anastomosis, while Nguyen and coworkers demonstrated that perioperative hemorrhage was most frequently encountered at the gastrojejunostomy [42–44]. Medical factors predisposing a patient to an anastomotic bleed are chronic use of anticoagulation medications (e.g., warfarin, heparin, low molecular weight heparin) or antiplatelet medications (aspirin, nonsteroidal anti-inflammatory medications (NSAIDs), clopidogrel) and history of diabetes mellitus [2]. Technical risk factors are thicker tissue within the staple site, shorter staple length used, and intraoperative adhesiolysis. A systematic review also noted a higher rate of acute postoperative bleed for laparoscopic versus open RYGB (1.9% versus 0.6%, respectively), possibly due to overuse of VTE chemical prophylaxis and/or a lower frequency of oversewing the staple lines [23]. Less common etiologies of acute intra-abdominal bleed are due to insufficient hemostasis within dissected tissue prior to desufflation, bleeding from trocar sites, or existing undetected pathology such as peptic or duodenal ulcer in the excluded segment (prevalence 0.26% [45]), gastritis, or an undetected necrotic submucosal tumor [41].

Late bleeding is most frequently secondary to either stomal or marginal ulceration (to be discussed in more detail later in this chapter), though can also be due to gastrogastric fistula, gastritis, NSAID gastropathy, or less frequently neoplasm.

Presentation and Diagnosis

Presentation of an acute hemorrhage can mimic that of a leak or pulmonary embolism, with tachycardia, hypotension, oliguria, or most commonly a persistent decrease in hemoglobin levels. In this scenario, the patient may demonstrate cyclic tachycardia (corresponding with bleeding episodes), as opposed to sustained tachycardia noted with sepsis. Less commonly, the patient may experience hematemesis, hematochezia, or melena. Hematemesis is more often associated with hemorrhage at the gastrojejunostomy and bright red blood per rectum is more often seen with a jejunojejunostomy bleed, but these associations may not always present in this manner.

Significant bleeding should be investigated with endoscopic exploration with minimal carbon dioxide insufflation to prevent too much tension on the staple lines and overdistension of the small intestine. If the bleed is located within the gastric remnant or Roux limb, balloon-assisted enteroscopy may be necessary to identify the site, though this portends a risk of perforating the immature anastomoses. To identify intra-abdominal bleeds or sites that are not reachable by enteroscopy, a CT scan with IV contrast should be performed to identify collections or infrequently active extravasation. Of note, in a stable patient with a chronic lower GI bleed, colonoscopy should be considered in the absence of identification on upper endoscopy due to the increased incidence of the colorectal cancer in patients with obesity [41, 46].

Prevention

Ensuring that the bariatric patient has discontinued antiplatelet medication at least 1 week prior to the RYGB, that their INR has normalized, and that they have maintained glycemic control will reduce the risk of bleeding complications in the perioperative setting. Intraoperatively, techniques to aid with hemostasis include oversewing of staple lines, use of appropriately sized staple leg lengths, reinforcement of the staple lines (as described in the previous section), and intraoperative endoscopy to visualize the intraluminal side of the gastric pouch and gastrojejunal anastomosis.

Management

Many iatrogenic causes of perioperative bleed result in a small and self-limited vascular injury and can usually managed conservatively with fluid resuscitation or blood transfusion. Over 80% of acute postoperative bleeds will spontaneously self-resolve [44]. These patients should receive serial monitoring of vital signs, abdominal exam, hemoglobin levels, and urine output. In cases of severe bleeding or an unstable patient, intervention is required, whether that be via endoscopic or surgical exploration [1]. For both acute and delayed bleeds, if the site of hemorrhage is intraluminal and accessible via endoscopy at a staple line, anastomosis, or marginal ulcer, endoscopic clipping or epinephrine injection may be all that is necessary for hemostasis. Electrosurgery should be avoided due to possibility of thermal injury and delayed perforation. If the source is found to be due to gastritis or an ulcer, cessation of NSAID and tobacco use, work-up of *Helicobacter pylori*, and initiation of a proton pump inhibitor are indicated. Double-balloon enteroscopy can be attempted in cases of delayed bleed to access the biliopancreatic limb if ulcers within the gastric remnant or duodenum are suspected, but this procedure has a poor success rate without the adjunct of laparoscopic assistance. This procedure should be performed with caution in the acute setting given the fragility of the new anastomoses.

If the patient is hemodynamically unstable and has persistent bleeding from recurrent ulcers, there is ongoing hemorrhage within the abdominal cavity, the site is not accessible by enteroscopy, or there is no skilled endoscopist available, operative intervention via diagnostic laparoscopy or laparotomy is indicated to identify the site of the bleed, evacuate the hematoma, and obtain hemostasis. Generally oversewing the site of the bleed provides cessation. Many times no source will be able to be distinguished on re-exploration, but evacuation of hematoma will stabilize the patient due to reduction of fibrinolysis and promote more rapid recovery. Finally, angioembolization of the bleeding site has been described; however, embolization of the left gastric artery often results in gastric pouch ischemia and is only recommended as a last resort in poor surgical candidates [47].

Late Acute Postoperative Complications

Intestinal Obstruction

Background and Etiology

Intestinal obstruction after RYGB can result from a number of potential causes in both the early and late postoperative period, including internal herniation and intussusception, adhesive disease, Roux limb constriction as it passes through the mesocolic window, kinking or stricture at the gastrojejunostomy or jejunojejunostomy, incarceration at an incisional or ventral hernia, and volvulus. Reviews of the literature have noted that early obstruction tends to occur most often at jejunojejunostomy secondary to technical problems, and late obstruction is most frequently due to internal hernias or adhesive disease [48]. Overall incidence has been reported between 1.5% and 7% across series, with one large series reporting 2% occurrence after antecolic positioning and 7% after retrocolic [49–52].

Obstructive issues specific to RYGB patients are often technical and present in the early postoperative period. Obstruction at the jejunojejunostomy can occur by creating a too small window between the adjacent lumens of the anastomosis during staple closure. Mesocolic window stenosis occurs in 1–2% of retrocolic RYGB patients and is generally avoided with antecolic positioning of the alimentary limb [53]. It can be seen early, with edema of the window or narrow window creation, or in the late postoperative period due to ongoing narrowing of the window.

Presentation and Diagnosis

The most common presenting symptoms of small bowel obstruction after RYGB are abdominal pain, nausea, and vomiting, with up to one third of patients presenting with all three symptoms. Evidence of small bowel obstruction after RYGB is seen on 35% of plain abdominal films, 33–55% of upper gastrointestinal series, and

48–90% of CT scans [49]. Administration of water-soluble oral contrast is of particular importance in these imaging modalities to identify the site and possibly cause of the obstruction (e.g., the abdominal wall for an incisional hernia). When attempting to identify mesocolic window stenosis rather than transmesenteric herniation, radiographic findings are reported to aid in the diagnosis: a transition point at the jejunojejunostomy will be seen with dilation proximal to the mesocolic window with a decompressed afferent loop [53].

Management

Patients should immediately be made NPO and resuscitation initiated. Obstruction for any reason almost always requires prompt surgical intervention for resolution and to prevent potentially catastrophic small bowel ischemia. The use of a nasogastric tube (NGT) should be carefully considered in patients with small bowel obstruction after gastric bypass. On the one hand, the gastric pouch is small and there remains the potential for injury and perforation with blind NGT placement. On the other hand, a Roux limb that is dilated and fluid-filled presents with similar aspiration risk as other SBO patients. Rapid sequence induction of anesthesia should also be considered.

Causes of small bowel obstruction, like adhesive disease, incisional hernia, or volvulus, should be addressed and repaired surgically as they would in other postoperative circumstances. Obstructive issues specific to RYGB patients may require revision of the Roux construction. One note of caution is that earlier intervention is recommended in gastric bypass patients as a delay in diagnosis can result in catastrophic small bowel ischemia, and in particular, inability to decompress the biliopancreatic limb can lead to pancreatitis and remnant stomach ischemia and perforation.

Internal Hernia

Background and Etiology

Internal hernia is the most common cause of small bowel obstruction after RYGB and over time becomes the most common surgical complication of RYGB, with incidence of 0.5–11% of patients [54–57]. Herniation can occur any time postoperatively and can manifest at two anatomic sites after an antecolic approach or at three anatomic sites after a retrocolic approach. Both approaches create potential defects within the mesentery between the jejunojejunostomy and between the mesentery of Roux limb and transverse colon (Petersen's space). The retrocolic approach also creates an additional defect through the transverse mesocolon, which is the most common site of internal herniation after retrocolic bypasses. The likelihood of internal hernia is evenly distributed between the jejunojejunostomy defect and Petersen's

space when an antecolic technique is performed [58]. Herniation is more common in patients who have a retrocolic limb compared to an antecolic (3.7–9.3% versus 0.4–1.8%, respectively) [49, 59], as well as after laparoscopic RYGB compared to open techniques. Proposed reasons for the increased incidence after laparoscopic RYGB include more rapid excess weight loss after laparoscopic cases causing a widening of the mesenteric defects [60]. Also, reduced bowel manipulation during laparoscopic Roux construction drives less adhesions, causing less fixation of the Roux limb and scarring of the mesenteric defects compared to the open procedure [61, 62].

Prevention

Multiple studies have demonstrated reduced incidence of internal hernia with closure of the mesenteric defects compared to non-closure [55, 63]. Despite generalized consensus that all mesenteric defects should be closed, a meta-analysis of 30 studies (21,789 patients) cited rates of complications which occurred directly due to the closure technique, including small bowel obstruction from incomplete closure and internal herniation, kinking of the jejunum, and obstruction due to adhesions [64]. Nevertheless, the rates and morbidity associated with these complications were less than that of internal hernias, and closure with running suture is still the best means of preventing small bowel strangulation and/or perforation due to herniation. Other important technical considerations involve the avoidance of excessive narrowing of the Roux limb as it passes through the transverse mesocolon in a retrocolic approach, complete division of the mesentery to its base and lengthening of the Roux limb to avoid tension on the gastrojejunostomy in an antecolic approach, and performing a running sutured outer layer of the gastrojejunostomy to prevent kinking.

Presentation and Diagnosis

Symptoms of herniation are often intermittent and vague, ranging from recurrent colicky abdominal pain to nausea and vomiting, abdominal distention, peritonitis, and septic shock. At presentation, patients should undergo a small bowel series or CT scan with water-soluble oral contrast. Described radiologic signs that should alert the surgeon are mushroom sign, clustered loops, small bowel behind the superior mesenteric artery, and right-sided distal anastomosis [65]. One report described the following pathognomonic triad of findings on CT: ileum and cecum located in the right upper quadrant, whirling of the mesentery, and the majority of small bowel loops residing on one side of the abdomen [34]. Another small comparative study found the signs on CT with the highest sensitivity and specificity were mesenteric swirl (86–89% and 86–90%, respectively) and superior mesenteric vein beaking (80–88% and 94–95%) [65]. Nevertheless, definitive radiographic findings are often absent as the herniating bowel spontaneously reduces in a large proportion of patients.

Management

As both patient presentation and diagnostic evaluation often do not provide a clear diagnosis, surgeons must have a high index of suspicion for internal hernia and plan for a laparoscopic exploration with repair of all of the defects, even in stable patients, if no other etiology is identified. Closure of mesenteric defects should be performed with a running suture to prevent inadequate closure of the defects or other associated complications with interrupted suture or clips [64]. Patients presenting with an unstable picture should be taken emergently for bypass of the obstructed site, lysis of adhesions, reduction of the internal hernia, resection of any ischemic bowel, and/or revision of the gastric bypass.

Retrograde Intussusception

Retrograde intussusception (RI) at the jejunojejunostomy is a problem unique to Roux-en-Y reconstructions and should be considered in the differential diagnosis for patients who present with upper abdominal pain and obstructive symptoms after RYGB. While most intussusceptions are antegrade, in the post-RYGB patient, they are typically retrograde; that is, the common channel tends to intussuscept upward into the anastomosis, which can become patulous and dilated over time. Prevalence appears to be rare, considerably less than 1% in two series, occurring at 51 and 52 months [66, 67]. A review in 2011 demonstrated only 63 known cases in the literature, although it is likely that the problem is underreported [66]. Diagnosis is typically made with CT scan of the abdomen, with a "target sign" the most common diagnostic finding [67]. RI can present with an acute or chronic course; acute presentations can present with necrotic bowel necessitating resection. Of note, when resecting the jejunojejunostomy, two anastomoses are required to perform the reconstruction, one to reanastomose the Roux limb and common channel and one to reconnect the biliopancreatic limb to the common channel. Almost all patients end up with surgical correction via open or laparoscopic approaches, either by resection and reanastomosis or by enteropexy. It is not uncommon (43%) to find only a dilated jejunojejunostomy at the time of surgery but no evidence of RI at the time of surgical exploration [67]. One case series had only one recurrence in a patient who underwent resection and reanastomosis, although another showed a higher recurrence rate (22% versus 12.5%) in patients who underwent enteropexy [66]. For patients undergoing enteropexy, a technique that seems to be easy to perform and with minimal morbidity is to suture the proximal common channel to the biliopancreatic limb with interrupted sutures, with a gentle, non-obstructing loop made such that future RI is not technically possible.

Late Chronic Postoperative Complications

Marginal Ulcer

Background and Etiology

Ulceration at the gastrojejunal anastomosis is one of the most common complications after RYGB and occurs in 0.6–25% of patients at 1–6 months after undergoing RYGB [1, 24, 68, 69]. Types of ulceration can be divided into marginal ulcer, on the jejunal side of the anastomosis, and stomal ulcer, on the gastric side. Distinguishing the type is important because the etiology for each differs. Stomal ulcers are known to occur due to ischemia, whereas proposed causes of marginal ulcers are direct jejunal exposure to gastric acid, which does not secrete a bicarbonate buffer like the duodenum for acid protection, NSAID and/or alcohol use, or local ischemia, often due to tobacco use. The presence of a foreign body, which induces an ongoing inflammatory reaction, like permanent suture or staple, is thought to promote marginal ulcer formation as well, with absorbable suture having been shown to reduce the incidence of marginal ulceration in studies [70, 71]. Some publications have pointed to an association between *Helicobacter pylori* and increased development of postoperative marginal ulcer even after the organism had been eradicated due to pre-existing mucosal damage [24, 72]; however, multiple other studies found no effect of seropositivity on the development of marginal ulcers [73–75]. Other reports have postulated that a gastric pouch greater than 50 mL predisposes patients to the formation of marginal ulcers due to increased parietal cell mass and that limiting the pouch to just the cardia reduces the rate of ulceration to 0.6% at 3 years [76].

Presentation and Diagnosis

Over half of patients with early marginal ulcers present with burning epigastric pain, up to 58% present with nausea and vomiting, 36% with dysphagia, and 5% with gastrointestinal bleed [69]. While any of these symptoms has a low (40%) positive predictive value for early ulceration, localized nocturnal epigastric pain is highly predictive of a late marginal ulcer [69]. Patients with a marginal ulcer may also be asymptomatic and present emergently with perforation [45]. Overall, the incidence of perforation is 1.4% at a mean of 12 months [69]. Upper endoscopy should be performed for all patients with suspected ulceration.

Management

Medical

Ulcer management is primarily medical with most ulcers healing over the course of several weeks with antisecretory agents, like proton pump inhibitors or H_2-blockers, and mucosal coating agents, like sucralfate. Patients may also be prescribed orally ingested anesthetic solutions, such as viscous lidocaine, for symptomatic relief. Treatment should begin promptly, as protracted ulceration can lead to stricture development at the anastomosis and gastric pouch outlet obstruction. Moreover, duration of antisecretory therapy tends to be longer for marginal ulcers than peptic ulcers, requiring approximately 3–4 months to heal. Resolution should be confirmed by endoscopy prior to cessation of treatment. Given the high rate of marginal ulcers in cigarette smokers [77, 78], smoking cessation should be discussed with any patient that presents with an ulcer.

Surgical

Therapeutic endoscopy is useful in cases of foreign body removal (e.g., embedded permanent suture or staples), with reported improvement in 70% of cases. In this case, endoscopic reevaluation is indicated at 8 weeks to verify resolution [1].

Recurrent or refractory ulcers may require surgical revision of the gastrojejunal anastomosis, incorporating healthier nearby jejunum into the new anastomosis, although strategies to prevent future ulceration (smoking cessation, PPI use) should be an important part of the patient's postoperative care plan. In the case of a perforated ulcer, laparoscopic patch repair has been described as the optimal management, with a mortality rate of 10% [69].

Gastrogastric Fistula

Background and Etiology

Refractory marginal ulcers should prompt the surgeon to investigate the presence of a gastrogastric fistula due to persistent exposure to acidic secretions. Incidence of fistula is 1.5–6.0%, with reduced rates after the incorporation of proton pump inhibitor therapy into management strategy [76, 79]. Causes of fistula include incomplete gastric transection at the index case, tissue ischemia, drainage of a contained leak into the gastric remnant, and the presence of a foreign body, leading to ulceration and fistulization between the gastric pouch and remnant.

Presentation and Diagnosis

In the case of nonhealing ulcers, a gastrogastric fistula, if present, may be able to be identified on endoscopy, although smaller fistulas can easily be missed. Large fistulas present as either incidental findings on CT (e.g., contrast in the remnant stomach) or as weight loss failure, prompting further endoscopic evaluation for definitive diagnosis. Upper gastrointestinal contrast study is considered the most sensitive test for fistula, as published in a large series of 1292 patients [80].

Management

Smaller gastrogastric fistulas can also be treated successfully with proton pump inhibitors and those that do not respond may resolve with endoscopic therapy. They may become asymptomatic and fistula division may be unnecessary. Larger fistulas are less likely to respond to medical management and tend to require surgical intervention [81].

Multiple approaches may be taken for non-resolving gastrogastric fistulas with weight loss failure and/or persistent marginal ulceration. Smaller fistulas may be able to be isolated and transected with a laparoscopic stapler. Surgical takedown of a fistula could include remnant gastrectomy with either excision or exclusion of the fistulous tract, generally performed laparoscopically [82, 83].

Anastomotic Stricture

Background and Etiology

The incidence of anastomotic stricture of the gastrojejunostomy has been reported between 3% and 33% [1, 84, 85]. Stenosis of the gastrojejunostomy has been defined in the literature as having a diameter less than 10 mm or does not allow the passage of a diagnostic endoscope, though many patients with a 10-mm opening are asymptomatic. Causative factors are believed to be due to excessive scar formation, tension, and/or ischemia at the anastomosis. Medical factors predisposing patients to stenosis are the use of NSAIDs, tobacco, and alcohol [1]. Recurrent vomiting may also lead to the formation of stenosis. Anastomotic technique seems to have the greatest impact on stenosis formation, with the highest risk due to the utilization of a 21-mm circular stapler (incidence of 14–31%) [76, 86]. Using a 25-mm stapler reduces this risk by half; however, use of the larger stapler may result in weight loss failure due to a wide stoma and possibly rapid pouch emptying. Frequency of stomal stenosis after anastomosis creation with a linear stapler has been reported between 3.1% and 6.8%, and hand-sewn anastomoses have been shown to have the lowest incidence of stenosis, at 3–4.1% [76, 79, 85]. This divergence explains the higher incidence after laparoscopic compared to open RYGB, where stapled

anastomoses are preferred over hand-sewn. Some authors allege that robotic RYGB combines the advantages of a minimally invasive approach with the facility to perform hand-sewn anastomoses. A recent meta-analysis identified improved outcomes of stomal stenosis for the robotic approach over laparoscopic RYGB [18].

Presentation and Diagnosis

Patients with anastomotic stricture have milder presentations, generally with dysphagia, early satiety, and/or intolerance to solid foods, requiring them to cut foods into small pieces and eat very slowly [87]. Nevertheless, they too can present with postprandial nausea, vomiting, and less frequently with epigastric or substernal pain. Gastrojejunal stenosis usually occurs at 1–2 months postoperatively. If the patient presents after 4 months, the stenosis is likely secondary to ulceration or a foreign body at the anastomosis, such as retained suture.

While anastomotic stricture can be evaluated by upper gastrointestinal series with high specificity, it has poor sensitivity, making it a suboptimal screening test. Endoscopic assessment not only carries near 100% sensitivity and specificity, it allows for simultaneous therapeutic intervention at the stenotic area. Therefore, all eligible patients with symptoms suggesting anastomotic stenosis should undergo endoscopic examination as a primary option for the potential of dilation of strictures, if found.

Management

Over 90% of cases of anastomotic strictures can be managed definitively with endoscopic through-the-scope esophageal or anastomotic balloon or Savary-Gilliard bougie dilation [1]. For strictures that permit the passage of an endoscope or guide wire, serial dilations up to 15 mm may be safely performed over the course of about one to three sessions [1, 76]. Most authors will recommend fluoroscopic guidance when attempting to transverse a severely stenotic anastomosis to prevent entry into the jejunal blind limb, but smaller series have reported successful dilation without perforation without the use of fluoroscopy [88]. The patient should return approximately 2 weeks following the last dilation in each of these cases to ensure durable potency of the anastomosis. Patients with severe stenosis or complete obstruction of the stoma to guide wire penetration should not undergo initial attempts at dilation due to the 2.2–12% risk of perforation and require surgical revision of the anastomosis [89–92].

Alternative endoscopic techniques that have been described in cases of failed dilation are endoscopic incision of the stoma with a needle-knife papillotome, saline injection, or steroid administration prior to further balloon dilation [1, 89]. Trials of endoscopic stent placement in patients with failed dilations have not proven efficacious [2]. Of note, in cases where the stenosis is secondary to a marginal ulcer, medical management of the ulcer should be pursued first.

"Candy Cane" Syndrome

One postoperative problem that can ensue after RYGB is that of a redundant blind end of the Roux limb. Over time, this pouch can elongate up to 22 cm in size [93], although it is typically 3–7 cm long. One possible cause of this problem is an angulation of the takeoff of the Roux limb such that the orifice to the blind limb is vertically oriented below the gastrojejunostomy. Symptoms of this syndrome are primarily epigastric pain, bloating, and nausea/vomiting [93], although regurgitation, reflux, weight regain, and postprandial fullness have also been described [94]. Treatment of the syndrome is resection of the blind limb, stapling as close to the anastomosis as possible. This has been described in small case series [93–95]. One technical consideration is to place an endoscope to help visualize the Roux limb and to prevent stenosis of the gastrojejunostomy after resection of the redundant blind limb. This syndrome can typically be avoided by leaving the blind end as short as possible during creation of the blind limb at the index case.

Choledocholithiasis

Due to rapid weight loss from RYGB, patients experience increased cholesterol mobilization into bile, decreased biliary motility, and decreased secretion of cholecystokinin, predisposing them to the development of gallstones. Incidence of post-RYGB cholelithiasis has been reported as 32–42% (compared to 2–15% in the general population [96]) and choledocholithiasis as 0.22–0.44% [96, 97]. While there is no consensus on the optimal expectant management of biliary disease after RYGB, prophylactic cholecystectomy at the time of RYGB has decreased in favor, due to a potential increase in morbidity [98]. There is also divergent opinion on the prophylactic administration of ursodiol, which had been shown in a prospective, double-blinded, randomized controlled trial to reduce gallstone formation from 32% postoperatively to 2% [99]. Ursodiol is expensive and poorly tolerated, may cause nausea and diarrhea, and as such may be self-discontinued by patients. Given the altered anatomy of the RYGB, the standard management of common bile duct (CBD) stones with endoscopic retrograde cholangiopancreatography (ERCP) becomes more difficult and is often not feasible, even with retrograde access via the biliopancreatic limb with or without double-balloon enteroscopy. Alternative interventions include laparoscopic transcystic common bile duct exploration, percutaneous transhepatic cholangiography, laparoscopic choledochoduodenoscopy, endoscopic ultrasound-guided transhepatic ERCP, and laparoscopic-assisted transgastric (antegrade) ERCP, with varying efficacy and complication rates ranging from 0% to 17% [100]. A recent review of 26 articles examining laparoscopic-assisted transgastric ERCP demonstrated successful ductal cannulation in 98.5% of cases, which was increased to 100% with endoscopic ultrasound guidance. While they report a 14% adverse event rate, the majority of complications were minor and managed conservatively (e.g., wound infection and post-ERCP pancreatitis) [101].

Other Chronic Postoperative Complications which Require Consideration

Nutrient Deficiency

Micronutrient deficiencies typically associated with RYGB most commonly occur months to years after the index procedure. However, earlier presentations occur and can be severe. One early nutrient deficiency that can result in a devastating outcome if missed is that of thiamine deficiency. This can be observed in patients with early nausea/vomiting, such as in a gastrojejunal stricture. It can be seen as soon as 6–8 weeks after surgery. Patients who are admitted with dehydration are at highest risk for the development of Wernicke's encephalopathy and should be treated with glucose in intravenous fluids as well as supplemental intravenous thiamine [102]. Neurologic symptoms (Korsakoff's syndrome) include dizziness, confusion, short-term memory loss, and visual disturbances. Neurologic symptoms can progress to permanency, and as such, prompt recognition and treatment are critical [103].

Most other micronutrient deficiencies are chronic and present as laboratory abnormalities or with a slow, indolent course. The prevalence of micronutrient deficiency is increasing for all patients who have undergone RYGB and other bariatric procedures, yet nutrition monitoring and malnutrition screening at follow-up is diminishing [104, 105]. According to the 2016 American Society for Metabolic and Bariatric Surgery Integrated Health Nutritional Guidelines for the Surgical Weight Loss Patient, the prevalence of thiamine deficiency after weight loss surgery ranges between <1% and 49% based on the type of procedure and time since the surgery [1–5]. Iron deficiency remains one of the most common overall complications of RYGB, with a prevalence of over 50% despite routine supplementation [8, 104, 106]. Other known vitamin deficiencies following RYGB are vitamin B12 and folate, typically manifesting clinically as megaloblastic anemia, although peripheral neuropathy has also been reported. Less common deficiencies include calcium, zinc, copper, and vitamin A deficiency. While some reviews report that the majority of patients who undergo bariatric surgery experience low levels of vitamin D, prevalence of this deficiency is more influenced by geographic location [107, 108]. The clinical manifestations of these deficiencies, such as peripheral neuropathy and megaloblastic anemia and iron-deficiency anemia, typically worsen over time if not corrected [108], and some are nonreversible (e.g., blindness from reduced absorption of fat-soluble vitamins) [107]. Protein-calorie malnutrition, most often seen after distal RYGB with a Roux limb longer than 150 cm, can also cause significant health ramifications, such as edema, hypoalbuminemia, anemia, and hair loss [105]. Most of these deficiencies occur due to malabsorption from bypass of the duodenum and most of the jejunum, persistent vomiting, reduced production of intrinsic factor, delayed mixing of protein with bile and pancreatic enzymes, and achlorhydria [41].

Only 10–15% of patients continue to follow up with their surgeon or bariatric team up to 10 years after surgery, despite recommendations for lifelong surveillance for metabolic sequela [109, 110]. While patients tend to follow up more reliably

with their primary care practitioner, the level of nutritional monitoring is still low as evidenced by inadequate micronutrient supplementation [105]. Individual tailoring is necessary, as patients may still be deficient in some nutrients due to malabsorption (e.g., iron) and simultaneously have hypervitaminosis with multivitamin supplementation [41, 111, 112]. The authors recommend that a greater emphasis needs to be placed on multidisciplinary metabolic and nutritional care and guidelines following weight loss surgery [105].

Weight Loss Failure or Weight Gain

Ten percent of patients regain weight by 5 years postoperatively, and 20% regain weight after 10 years after a spectrum of bariatric surgical procedures [24]. While causes are generally multifactorial, they can be divided into anatomic/physiologic and nonanatomic/behavioral categories. Anatomic etiology may involve gastrogastric fistula, dilated gastrojejunostomy, or an enlarged pouch. Patients may also experience loss of satiety and dumping syndrome, contributing to an urge to overeat. Some authors advocate for narrowing of the gastrojejunostomy in cases of dilation, referring to the use of endoscopic over-the-scope clipping and/or endoscopic suturing devices feasible, safe, and successful options [40]. Behavioral factors associated with weight gain include decreased physical activity, low self-esteem, reduced engagement in self-monitoring, lack of control over food urges, concern for addiction to alcohol or other drugs, fewer clinic follow-up visits, and poorer overall postoperative well-being [109, 113]. These patients require multidisciplinary team counseling and follow-up to comprehensively address the various facets of this issue.

Post-Gastric Bypass Hypoglycemia (PGBH)

A particularly vexing problem for patients after RYGB is postprandial hypoglycemia. The inherent problem is that patients with normal gastrointestinal anatomy typically ingest sugar- or carbohydrate-rich foods or liquids to raise their serum glucose, but RYGB patients often cannot do so due to the risk of dumping syndrome. The risk was thought to be 0.1–0.36% [114, 115], although a more recent retrospective review demonstrated a rate of 2.6% [116]. Many more patients complain of symptoms, however, that may or may not be dumping syndrome, so the true prevalence is unknown. PGBH is defined as postprandial hypoglycemia due to hyperinsulinism that occurs despite adherence to an accepted bariatric diet [117]. Clinical hypoglycemia can be confirmed by Whipple's triad: Symptoms of low blood glucose, measured low blood glucose levels, and relief of symptoms when the low blood glucose is corrected. These symptoms can range from autonomic symptoms such as anxiety, diaphoresis, palpitations, and tremulousness to neuroglycopenic symptoms including confusion, falls, loss of consciousness, and seizures [118].

Nonhyperinsulinemic causes of hypoglycemia should be ruled out, such as adrenal insufficiency, hypothyroidism, liver disease, or medication use, as well as hyperinsulinemic etiologies, like early and late dumping syndromes, insulinoma, and abuse of exogenous medications like insulin or insulin secretagogues [117]. Although exact mechanisms are uncertain, excessive release of incretins such as glucagon-like peptide 1 (GLP-1) and gastric inhibitory peptide (GIP) are thought to have a role.

Treatment of PGBH, after confirming the diagnosis, begins with dietary changes. Avoidance of high-glycemic index foods, eating pure carbohydrates only with fat or protein, and limitation of total carbohydrates to only 15–30 g/meal with snacks devoid of carbohydrates should be the starting point [117]. Hypoglycemic episodes should be treated with a simple sugar combined with protein and fat, to avoid dumping symptoms (which can be remarkably similar) and also to avoid recurrent hypoglycemia. Alpha-glucosidase inhibitors can be a helpful adjunct but have a high rate of gastrointestinal side effects and thus may be poorly tolerated. Other medications such as calcium channel blockers, diazoxide, and octreotide have been described. Severe cases can result in the need for surgery as a last resort, typically RYGB reversal or even a partial pancreatectomy to resect the hypertrophied islet cells, although the incidence of this is extremely rare.

Dumping Syndrome

Dumping syndrome is seen in patients who undergo RYGB and other upper intestinal reconstructions. It typically occurs after ingestion of carbohydrate-rich foods, and the symptoms are thought to be caused by the rapid transit of larger sugars into the proximal jejunum. This can cause a fluid shift and a sympathetic response that presents with diarrhea, nausea and vomiting, palpitations, and tachycardia [117]. Early dumping syndrome is common in the first few months after surgery and typically occurs within 20 min of a meal and is not accompanied by hypoglycemia [117]. Late dumping syndrome (defined as occurring up to 4 h after the ingestion of carbohydrates), which can appear similar to PGBH, resolves with only dietary changes and does not tend to have neuroglycopenic symptoms [117]. Interestingly, a recent study has shown that dumping syndromes can also be triggered by fat although those patients did not have an increase in glucose and insulin levels [119]. Some authors believe that the threat of dumping syndrome acts as an aid in RYGB patients, avoiding carbohydrate-rich foods. This sequence may contribute to sustainable weight loss in the long-term [120]. A recent estimate of the prevalence of early dumping and/or hypoglycemia was 12.6% [121], although it remains unclear what anatomic factors contribute to this condition after RYGB. One proposed factor is a patulous gastrojejunostomy, causing rapid emptying into the Roux limb, and a new study looked at endoscopic sutured revision of the dilated gastrojejunostomy using an endoscopic suturing device [122]. Thirteen of fourteen patients with late dumping syndrome who underwent the procedure reported no dumping symptoms 1-month post-intervention.

Increased Risk of Substance Dependence and Psychological Illness

Investigations have confirmed the association between bariatric surgery and the increased prevalence of alcohol use disorder (AUD) and substance use disorder (SUD; encompassing marijuana, cocaine, hallucinogens, inhalants, phencyclidine, and amphetamines), as well as proclivity toward postoperative patient need for psychiatric care, diagnosis of psychiatric disorders, and suicidal ideation. Previous studies had not discerned whether there was a true difference before or after undergoing surgery, leaving the question of whether it was simply this patient demographic that was prone to these disorders, and not the effects of the procedure. The Longitudinal Assessment of Bariatric Surgery-2, a prospective cohort study, demonstrated an increased prevalence of AUD in RYGB patients from 7% before surgery to 16% at 7 years after surgery [123]. Compared to bariatric patients who underwent laparoscopic adjustable gastric banding, postoperative RYGB patients carried approximately twice the risk of incident AUD and 3.5 times the risk of SUD, with male sex and low income as other independent risk factors. Similar findings for increased alcohol use were confirmed in a large population-based cohort study [50]. Many theories exist explaining the rise in substance addiction after RYGB. "Addiction transfer" is frequently cited describing the substitution of one addiction (i.e., food) for an alternative addiction, like alcohol, to cope with negative emotions; however, this was not substantiated for SUD, as it was for AUD [124]. Other explanations look to multiple pharmacokinetic studies which have shown higher peak serum alcohol concentrations postoperatively compared to preoperatively and non-RYGB patients, as well as rodent models which have demonstrated altered expression of ghrelin and neurologic reward circuitry response independently of alcohol absorption [123, 125].

A similar trend is noted for post-RYGB patients with two to three times the risk of self-harm attempts increasing in this population [50, 125, 126]. Furthermore, authors from a large nationwide population-based study concluded that patients had a significantly higher psychiatric service use and increase in psychological diagnoses compared to before surgery [127]. While many of these disorders may have been underlying prior to surgery, they were identified or manifested postoperatively. Therefore, adequate screening and counseling for a potential addictive or psychological disorder by a multidisciplinary team prior to undergoing RYGB is essential, and if noted, the patient should be referred for timely evaluation and treatment by a specialist.

Conclusion

While RYGB persists as the durable standard for bariatric procedures, complications still exist. Bariatric surgeons should be knowledgeable regarding the signs and symptoms of both acute and chronic adverse events. While many patients present postoperatively with vague complaints such as abdominal pain, nausea, vomiting, or dysphagia, a high index of suspicion is necessary to investigate etiologies like

anastomotic leak, staple-line dehiscence, or bowel obstruction, which could result in significant morbidity. Patients presenting with a septic picture should direct the surgeon toward prompt surgical intervention. The same vague symptoms may lead the surgeon to the diagnosis of a more indolent issue requiring intervention as well. Therefore, developing a solid understanding of the timing of these postoperative events will provide the surgeon a framework to develop a differential diagnosis, initiate an appropriate management strategy, and address life-threatening complications in a timely manner.

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Chapter 34
Complications of Biliopancreatic Diversion and Duodenal Switch

Nabil Tariq and Jihad Kudsi

Introduction

Though the duodenal switch without any gastric resection has been described before for the treatment of bile gastritis and biliopancreatic diversion was described in 1979 by Scopinaro, this chapter will mostly talk about biliopancreatic diversion with duodenal switch [1, 2]. This version involves the preservation of the pylorus, a sleeve gastrectomy, a 250 cm alimentary limb, and a 100 cm common channel. We will also briefly refer to a newer version of this, the SADI (single-anastomosis duodeno-ileal bypass), where relevant.

Though the total number of BPD-DS surgeries being performed around the world has not decreased, the proportion it forms of total surgeries certainly has decreased. According to one survey of bariatric surgery national societies, the proportion of BPD-DS has decreased from 4.9% in 2008 to 1.5% in 2013 [3]. This is partly due to the sleeve gastrectomy becoming the dominant procedure, especially in the USA. However, increasingly the BPD-DS or its younger sibling—the SADI—is being touted as an option for weight regain after sleeve gastrectomy. This means that the total number of cases of BPD-DS/SADI will likely increase. It is very important and relevant to be aware of the potential short-term and long-term complications associated with these operations.

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Early Complications

Mortality

Though the BPD-DS may be the most effective in weight loss and resolution of comorbidities among the current bariatric procedures, it does come at a cost: mortality rates are higher than for other bariatric operations. Morality from BPD-DS varies significantly between published series, perhaps because of small numbers of patients. Kim and colleagues reported a rate of 5.6% in their series of 54 patients, with around half the patients having an open procedure. The mortality was 7.6% (2 of 26 patients) for the laparoscopic group [4]. In a systematic review and meta-analysis, Buchwald and colleagues found that the 30-day mortality was around 1.11% for laparoscopic DS and 0.7% for open DS [5]. Comparatively, the overall mortality for all bariatric procedures was only 0.28% [5].

Results such as these have caused widespread concern, resulting in decreased performance of these procedures. There are, however, several series now that have demonstrated lower mortality rates. Weiner and colleagues published a series with 63 patients without mortality [6]. Parikh and colleagues reported on no mortality in 43 patients, and Rabkin and coworkers also reported no deaths in 345 patients with a mean BMI of 50 kg/m^2 [7, 8]. Prachand and coworkers published their large series of 198 super obese patients, and only had one mortality, for a rate of 0.51% [9].

In one of the largest series published to date, Biertho and coinvestigators described perioperative complications in 1000 consecutive duodenal switch patients. There were 228 patients that were done laparoscopically and 772 that were done in an open fashion. They had one perioperative mortality, with the patient expiring from a pulmonary embolism, for a mortality rate of 0.1% [10]. In another series of 121 laparoscopic duodenal switch patients from the UK, Magee and coworkers reported a 0% 90-day mortality [11].

Whether these improved mortality rates are indicative of refinement of technique or more experience, especially with the laparoscopic approach, is unclear, but both likely play a role, as well as improved perioperative and multidisciplinary care over the years.

As BPD-DS is frequently performed in those with a BMI > 50 kg/m^2 or super obese, it has been suggested that the morbidity and mortality may be reduced by staging the operations and performing the sleeve gastrectomy portion first and then adding the malabsorption part of the procedure later [12].

Infectious Complications

Wound Infections

Superficial wound complications are reported but are relatively uncommon, especially in the laparoscopic DS procedures. In a series of 1000 patients by Biertho and coworkers, the wound infections occurred in 1.3% in the laparoscopic group and

3.5% in the open group [10]. Magee and coinvestigators reported a wound infection rate of 2.5% in their 121 patients [11]. In another more recent report from 2016 by Biertho and coworkers, their wound infection rate was only 0.4%, an impressively low rate in this series of 566 patients undergoing laparoscopic DS [13]. Overall the rates are similar to other bariatric procedures.

Anastomotic/Staple Line Leaks

Anastomotic leak rates are generally considered to be higher than for other procedures, such as the gastric bypass. The signs and symptoms are similar to other leaks as described elsewhere. These include tachycardia, tachypnea, hypoxia, and/or hypotension. Like in other obese patients, abdominal pain and tenderness may not be dominant symptoms. Delayed diagnosis can be associated with increased risk of mortality, and the clinician must always have a high index of suspicion.

In a systematic review and meta-analysis of a single institution, Hedberg and coworkers compared 599 patients who underwent DS to 929 patients who underwent gastric bypass. The leak rates reported were 5% for DS and 2.2% for gastric bypass [14]. In a series of 345 laparoscopic or hand-assisted DS, the total leak rate was 3.2%, with 2% at the gastric staple line and 1.2% at the duodenal anastomosis [8]. Biertho and collaborators reported a total rate of 3% in their 1000 patient series, with 1.5% each of gastric leak and duodenal leak. They also had one small bowel anastomosis leak [10]. In the recent series of 566 laparoscopic DS patients published from the same group, these rates were significantly reduced to 0.7% for duodenal leak and 0.2% for gastric leak. However, there was a 0.5% intra-abdominal abscess rate reported [13]. In the series by Magee and coinvestigators, they reported a 3.3% leak rate, with half the leaks occurring at the gastric staple line and the other half at the duodenal anastomosis or stump [11].

Though the rates of major leaks have improved overall, they are still higher than other bariatric procedures. This may be because of the number of areas in which the gastrointestinal tract is divided. This reason—and the fact that the DS is frequently done in the super obese (BMI$\geq$ 50 kg/m^2)—results in general acceptance of these increased risks.

As there are multiple potential points of leakage, the diagnosis is best achieved through a CT scan of the abdomen and pelvis with water-soluble oral contrast, though upper GI contrast studies are often useful and complementary. Intravenous contrast can be helpful but not always needed, especially if renal function is worsening. Duodenal stump leaks may need a nuclear biliary scan to diagnose them definitively.

The treatment of these leaks can be complex and may require multimodal staged therapy. The gastric staple line leaks are treated similar to sleeve gastrectomy leaks, which involves drainage, possible stent placement, distal feeding, and antibiotics. If the leak is small, and especially if presenting in a delayed fashion with an abscess, it can be treated with radiological drainage, antibiotics, and distal feeding or parenteral nutrition. Most of the duodenal area leaks reported in various series did require

surgical intervention with drainage and distal feeding access, such as a jejunostomy tube in the biliopancreatic limb. Gastric decompression with a nasogastric (NG) tube is useful if the leak is from the duodenoileostomy, but an NG tube is not needed if the leak is from the duodenal stump. With these measures, most leaks will resolve with time.

Venous Thromboembolism

Venous thromboembolism remains one of the main causes of mortality in the bariatric surgery patient. Deep vein thrombosis (DVT) has been reported in 0.3–3.5% of patients, and pulmonary embolism (PE) in up to 1.5% of patients [15–20]. These rates are predicted to be higher in patients undergoing the DS, as they tend to have higher BMI and more comorbidities.

In a series of 362 patients that underwent laparoscopic DS procedures, the DVT rate was 2.2% and PE rate was 1.1% [21]. In their protocol, patients received perioperative subcutaneous heparin, including a dose preoperatively. Those with a BMI> 50 got extended prophylaxis for 2 weeks. Prophylactic inferior vena cava (IVC) filters were also placed in 28.2% of patients. This did not increase DVT rates, but it did result in increased operative time and length of stay [21]. Rabkin and collaborators published a combined DVT and PE rate of 1.5% in 345 patients [8]. In the two large series by Biertho and collaborators, the PE rates were 0.2–0.8% [10, 13]. These rates are either similar to or slightly higher than those reported for other bariatric procedures like the gastric bypass [22]. Given their higher BMI and more frequent comorbidities, patients undergoing DS are at higher risk for thromboembolism, and aggressive perioperative chemical prophylaxis is likely warranted.

Bleeding

Given the more extensive nature of the DS procedure, bleeding rates were traditionally thought to be higher. In early series, especially the early laparoscopic experience, postoperative bleeding rates were as high as 6–10% [23–26]. The rates were reported to be lower in the open series, as shown in Table 34.1.

However, more recent series note a lower postoperative bleeding rate. In a series of 1000 DS procedures by Biertho and collaborators, the rates of bleeding were similar in the open and laparoscopic groups at around 0.5% [10]. Buchwald and collaborators reported a 1.6% rate of postoperative bleeding that required re-exploration in the operating room (3/190 patients) [32]. Biertho and coinvestigators reported a reoperation rate of 0.4% for bleeding (2/566 patients) [13]. Some of the variation in reported rates also may be related to whether they are reporting any bleeding, bleeding enough to require a transfusion or bleeding enough to require a procedure or an operation.

Table 34.1 Complications of open and laparoscopic biliopancreatic diversion and duodenal switch procedures

First author, year	PE %	Leak %	Bleeding %	Pancreatitis %	Delayed gastric emptying %	Wound infection/ dehiscence %	Marginal ulcer %	Stomal stenosis %	Incisional hernia %	Revisions for protein malnutrition %
Open BPD-DS										
Marceau, 1998 [27]	0.7	4.9	–	1.7	6.2	1	0	–	–	0.1% per year
Hess, 1998 [28]	0.5	4	1.4	–	–	–	0	–	–	2.3
Rabkin, 1998 [24]	5.4	54.	–	2.7	–	5.4	–	–	24	12.2
Baltasar, 2001 [25]	0.8	4	1.6	0	–	0.8	–	–	5.8	2.4
Anthone, 2003 [29]	0.6	0.7	0.7[a]	–	–	0.7	–	–	–	5.7
Dolan, 2003 [26]	0	6.5	0	0	0	−8	–	–	0	–
Laparoscopic BPD-DS										
Ren, 2000 [30]	0	2.5	10	0	0	0	–	–	–	–
Baltasar, 2002 [31]	0	0	6.3	–	6.3	18.8	–	–	–	–
Rabkin, 2003[a] [8]	0.9	4.3	–	–	–	–	–	1.7	–	–
Dolan, 2004 [26]	0	6.6	6.6	3.3	0	–	–	0	–	–

Used with permission of Springer Science from Ren [23]

[a]Includes three splenectomies

Bleeding can be intraluminal or intraperitoneal. As in other bariatric procedures, hematemesis and melena indicate a lumenal bleed. These can be managed expectantly with fluid resuscitation and transfusion as needed but may require upper endoscopy for evaluation and management if bleeding persists. In a DS, only the gastric staple line and the duodenoileostomy will be reachable with a regular endoscope in the early postoperative period. Appropriate therapy with clipping or injection may be used if a bleeding area is identified. Cautery is generally avoided early postoperatively.

For hemodynamic instability or persistent bleeding, laparoscopic or open exploration may be needed for diagnosing and treating an intraperitoneal bleed.

Early Bowel Obstruction

Early small bowel obstructions are more common after BPD-DS than other procedures. Hedberg and coinvestigators found early small bowel obstructions (SBO) in 2.9% (7/245) of BPD-DS patients and in 1.1% (3/271) of Roux-en-Y gastric bypass patients [14]. Rabkin and coinvestigators reported on rate of early SBO of 1.5% (5/345 patients), with 3 of the 5 requiring an operation. Biertho and coinvestigators reported a 0.5% rate of early SBO requiring surgery [8, 13]. Treatment depends on intraoperative findings and may involve revision of an anastomosis.

Miscellaneous Complications

There are several other rare complications that have been reported. These include myocardial infarction, pneumonia, pancreatitis or pancreatic leak, biliary leak, and acute renal failure. There are almost no reports of marginal ulcers after BPD-DS.

Gastric outlet obstruction from duodenoileostomy stenosis is possible but fortunately rare. In the early postoperative period, this can occur from technical error, as the duodenal diameter is small when making the anastomosis. Delayed stenosis can occur from ischemia, suture material, or a subclinical leak causing prolonged inflammation. Stricture may respond temporarily to dilation, but these stenoses frequently require surgical revision.

Long-Term Complications

Internal Hernias

The internal hernias that can follow DS are similar to those seen after gastric bypass. Hernias can occur at the mesenteric defect of the ileoileostomy or under the free, cut edge of the mesentery of the Roux limb (Petersen defect). If the reconstruction is

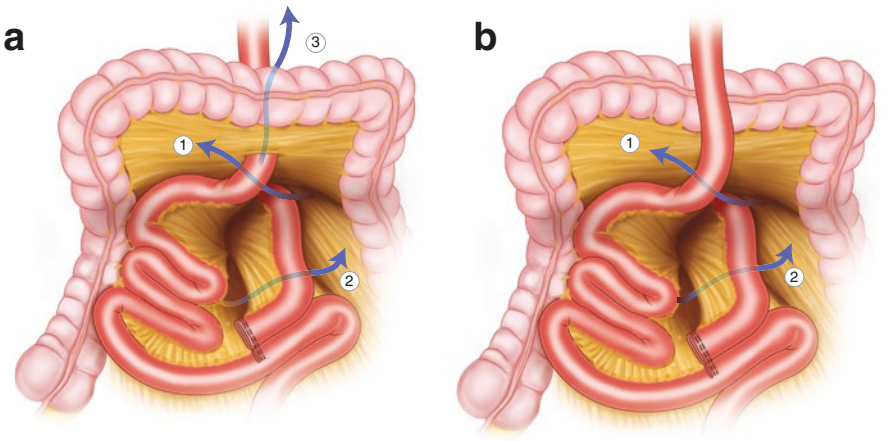

Fig. 34.1 (**a**, **b**) Sites of internal hernias: 1. Petersen's defect. 2. Ileoileostomy defect. 3. Retrocolic mesenteric defect

done retrocolic, a herniation between the Roux limb and the mesocolon is another potential site (Fig. 34.1a, b). While most surgeons close the ileoileostomy mesenteric defect, closing the Petersen defect is more controversial. Even when those potential hernia sites are closed, the defects can open again in a few months, as the mesentery becomes thinner with weight loss. There are minimal data regarding internal hernia after DS, but extrapolation can be made from large numbers of gastric bypass patients. The few studies that do report these findings don't always differentiate between internal hernias and postoperative small bowel obstructions, but the rates seem similar to or slightly higher than gastric bypass patients [13, 14, 23, 33, 34].

Internal hernias commonly present with abdominal pain without nausea or vomiting. An increase in liver enzymes or bilirubin might indicate an obstruction of the biliopancreatic limb, in which case the patient might still be passing gas and having bowel movements. Biliopancreatic limb obstruction can progress rapidly to small bowel ischemia as the limb cannot be decompressed with a nasogastric tube. Duodenojejunal dilation can be detected on CT, and urgent surgical intervention is warranted. A delay in diagnosis can result in catastrophic complications, such as ischemia of a majority of small bowel. The surgeon must have a low threshold for returning to the operating room for exploration. In addition to the classic findings of small bowel obstruction on CT, mesenteric swirl is considered one of the best predictors of an internal hernia [35].

Usually surgical repair of an internal hernia can be achieved laparoscopically by evaluating the small bowel starting at the ileocecal valve and running it proximally toward the ileoileostomy, where the surgeon should assess for any bowel loops herniating through a mesenteric defect. If this is normal, the remainder of the small bowel should be inspected proximally up to the duodenoileostomy as well as the biliopancreatic limb. The surgeon should inspect for any small bowel herniating

through the Petersen defect. Any identified mesenteric defects should be closed with a permanent suture. The authors use a 2–0 ethibond suture on an SH needle to repair mesenteric defects.

GI Symptoms: Diarrhea, Bloating, and Steatorrhea

DS is associated with substantial malabsorption of protein, fat, calcium, iron, and vitamins B12, A, D, E, and K, which can lead to foul-smelling stools and diarrhea. Intestinal bacterial overgrowth can occur despite the lack of a blind limb. Having malabsorption and undigested food can create an environment of bacterial overgrowth that can lead to symptoms such as abdominal bloating, diarrhea, and proctitis. A diet lower in protein and higher in carbohydrates can exacerbate this. Treatment with diet modification and antibiotics to treat bacterial overgrowth can be successful [23]. Persistent and refractory cases may have to be treated with a procedure to lengthen the common channel, which is described in the next section. Dumping syndrome is not common after duodenal switch, as the pylorus remains intact.

Nutritional Deficiencies

Duodenal switch is associated with substantial malabsorption of macronutrients, which results in significant weight loss. Twenty-five percent of protein and 72% of fat are not absorbed, which can lead to diarrhea, protein-calorie malnutrition, and micronutrient malabsorption, including fat-soluble vitamins [36]. Secondary malabsorption can occur as a consequence of the decrease in gastrointestinal transit time and limited contact of food with the brush border in the shortened common channel [36].

Protein Deficiencies

Giving the significant malabsorption that follows DS operations, protein-calorie malnutrition is possible. There are three components that can affect protein metabolism. These are the size of remaining stomach after gastrectomy, the length of the alimentary limb, and the length of the common channel [37]. Additional protein losses may occur from intestinal exposure to acid without buffering by bile and/or changes in intestinal and colonic flora, but these mechanisms are not well understood.

In the classic BPD, protein needs are thought to double over baseline. With the DS modification, including preservation of the pylorus and a larger residual stomach, protein requirements are less than for the traditional BPD. With preservation of pylorus, antropyloric titration of food passage, and lack of dumping syndrome,

ingested protein is better prepared for absorption in the small bowel [37]. A slightly longer common channel, from 50 cm to 75–100 cm, also helps this.

The incidence of severe protein malnutrition following DS operations is reported to be around 3–4% [3, 5]. However, temporary hypoproteinemia can be detected in 10–20% of patients in the first year and improves later on as protein intake improves [38]. Symptoms of hypoproteinemia include edema, weight loss, fatigue, and skin, nail, and hair problems. Low albumin and serum total protein levels can be detected on laboratory testing.

Increased oral protein intake might be enough to reverse a mild protein deficiency. The recommended amount is at least 90 grams per day [37, 39]. Parenteral nutrition is needed in an estimated 3% of this patient population [40, 41].

If parenteral nutrition is consistently required, a revisional surgery to lengthen the common channel may be indicated. Revisional surgery for excessive malabsorption has been reported in 0.5–4.9% of patients after BPD-DS, which is lower than what is reported for BPD alone (3–18.5%) [42]. Revisional surgery has been reported more commonly when the common channel length is 50 cm, compared to 100 cm. Half of revisional surgery performed after DS is attributed to protein malnutrition. The most common revisional option involves lengthening of the common channel by at least 100 cm for BPD-DS and 150 cm for BPD [42]. This is shown in Fig. 34.2a, b.

Reversal can also be done as shown in Fig. 34.3a–d. Creating a side-to-side jejunoileostomy can be a simple way to reduce malabsorption as shown in option B in Fig. 34.3a–d.

Micronutrient Deficiencies

Obese patients suffer from deficiencies in micronutrients even before any weight loss surgery. Special attention should be paid to detecting any deficiencies and correcting them preoperatively [43]. Significant numbers of vitamin and mineral deficiencies are found in DS patients, despite vitamin supplementation [26, 39].

Fat-Soluble Vitamins/Zinc

Normal absorption of fat-soluble vitamins occurs passively in the upper small intestine. Given that fat malabsorption is associated with the DS, vitamins and minerals relying on fat metabolism, including vitamins D, A, E, K, and zinc, are affected [24].

Vitamin A deficiency is common after DS, present in an estimated 30–69% of patients [39, 44]. Despite this, clinical consequences such as night blindness are very rare. Recommended vitamin A supplementation for DS patients is 10,000 IU/d [45].

Vitamin D deficiency is common. Studies have shown that up to 60% of patients have low vitamin D levels at 4 years postoperatively [39, 44]. Osteoporosis may

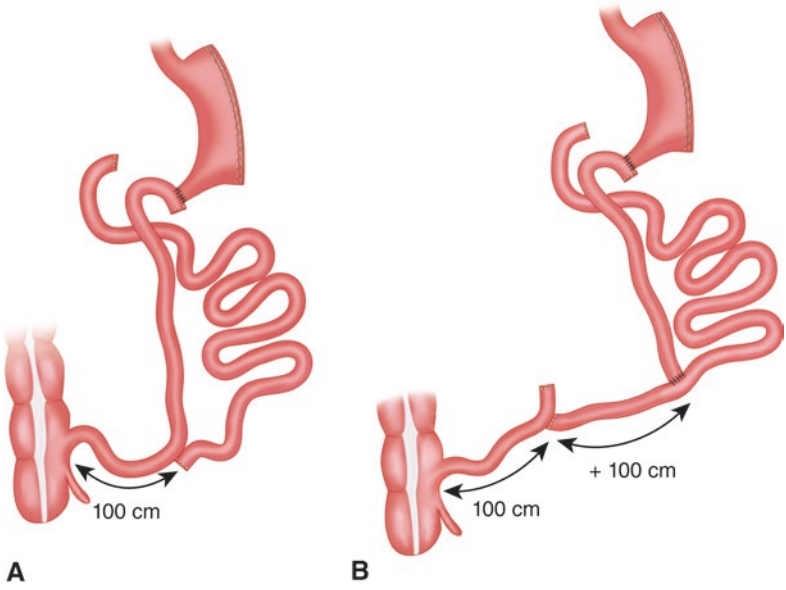

Fig. 34.2 (**a**, **b**) Common channel elongation after biliopancreatic diversion with duodenal switch. (**a**) Initial procedure. (**b**) Revisional procedure

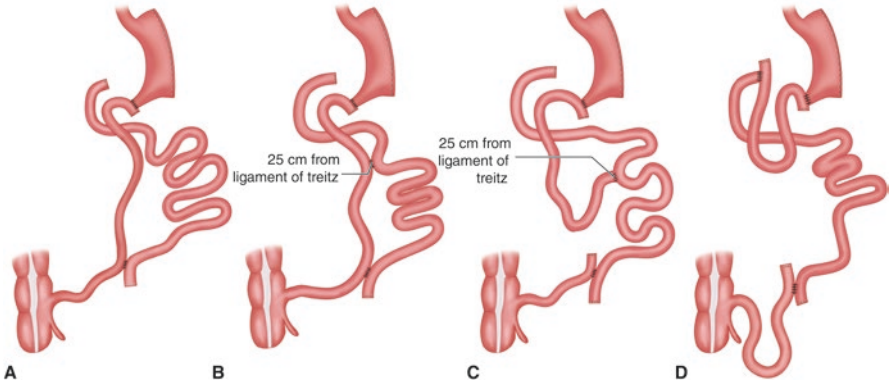

Fig. 34.3 (**a**–**d**) Restoration options after biliopancreatic diversion with duodenal switch. (**a**) Initial procedure. (**b**–**d**) Reversal options

result from chronic vitamin D deficiency, which is also exacerbated by poor calcium absorption. Recommended vitamin D supplementation for DS patients is at least 3000 IU/d to maintain D,25 (OH) levels 4–30 ng/mL [45].

Vitamin K deficiency can occur in approximately 60% of patients [39, 44]. While low levels are commonly detected, it is not usually associated with clinically significant decreases in coagulation factor activity or bleeding [46]. Recommended vitamin K supplementation for DS patients is 300 ug/d [45].

Vitamin E deficiency occurs in an estimated 5% or fewer patients [39]. Recommended vitamin E supplementation for DS patients is 15 mg/d [45].

Since *zinc* is a nutrient that depends on fat absorption, it is common to have zinc deficiency after DS, with deficiencies noted in as many as 90% of patients. Zinc has a major role in cell growth and differentiation, and its deficiency can have significant effects on tissues with a rapid cell turnover, such as cells of the skin, gastrointestinal tract mucosa, and immune system [47]. Recommended zinc supplementation for DS patients is 16–22 mg/d [45].

Repletion recommendations for micronutrient deficiency can be found in Table 34.2.

Calcium

Hypocalcemia is reported in up to 50% of patients following DS and is associated with increased serum parathyroid hormone values in almost 70% of patients. Hypocalcemia, in conjunction with vitamin D deficiency, can be severe enough to cause osteoporosis. Evidence of increased bone resorption is noted in 3% of patients [39]. Recommended calcium supplementation for DS patients is 1800–2400 mg/d [45].

Iron/Copper/Selenium/Magnesium/Potassium

Absorption of iron is most efficient in the duodenum and proximal jejunum. While iron deficiency after DS is multifactorial, bypassing the duodenum is a major contributing factor. Iron deficiency is present in 40% of DS patients [44]. Iron deficiency is usually asymptomatic unless it is significant enough to cause anemia, which would present with fatigue and a diminished capacity to exercise. Recommended iron supplementation for DS patients is 45–60 mg of elemental iron daily [45]. Taking vitamin C with iron increases absorption.

Copper, Selenium, and Magnesium

Copper is absorbed by the stomach and proximal small bowel. Copper deficiency is present in an estimated 90% of DS patients. Deficiencies in copper can cause anemia and myelopathy, with symptoms similar to those of vitamin B12 deficiency. Copper deficiency should be considered in any DS patient who presents with signs and symptoms of neuropathy but who has normal B12 levels [36]. Recommended copper supplementation for DS patients is 4 mg/d [45].

Multiple studies have found decreased selenium, magnesium, and potassium levels following bariatric surgery. All these studies highlight the importance of multivitamin supplements that are complete in minerals [26, 48, 49].

Table 34.2 Repletion recommendations for post-WLS micronutrient deficiency

Thiamine
Practitioners should treat post-WLS patients with suspected thiamine deficiency before or in the absence of laboratory confirmation of deficiency *and* monitor and evaluate resolution of signs and symptoms (grade C, BEL 3) √
Repletion dose for TD varies based on route of administration and severity of symptoms:
Oral therapy: 100 mg two to three times daily until symptoms resolve (grade D, BEL 4) √
IV therapy: 200 mg three times daily to 500 mg once or twice daily for 3–5 d, followed by 250 mg/d for 3–5 d or until symptoms resolve, then consider treatment with 100 mg/d orally, usually indefinitely or until risk factors have been resolved (grade D, BEL, 4) √
IM therapy: 250 mg once daily for 3–5 d or 100–250 mg monthly (grade C, BEL 3) √
Simultaneous administration of magnesium, potassium, and phosphorus should be given to patients at risk for refeeding syndrome (grade C, BEL 3) √
Vitamin B12 (cobalamin)
Post-WLS patients with B12 deficiency should take 1000 μg/d to achieve normal levels and then resume dosages recommended to maintain normal levels (grade B, BEL 2) √
Folate (folic acid)
All post-WLS patients with folate deficiency should take an oral dose of 1000 μg of folate daily to achieve normal levels and then resume recommended dosage to maintain normal levels (grade B, BEL 2) √
Folate supplementation above 1 mg/d is not recommended in post-WLS patients because of the potential masking of vitamin B12 deficiency (grade B, BEL 2)
Iron
In post-WLS patients with post-WLS iron deficiency, oral supplementation should be increased to provide 150–200 mg of elemental iron daily to amounts as high as 300 mg two to three times daily (grade C, BEL 3)
Oral supplementation should be taken in divided doses separately from calcium supplements, acid-reducing medications, and foods high in phytates or polyphenols (grade D, BEL 3). Recommendation is downgraded to D, since majority of evidence is from non-WLS patients
If iron deficiency does not respond to oral therapy, intravenous iron infusion should be administered (grade C, BEL 3)
Vitamin D and calcium
Vitamin D levels must be repleted if deficient or insufficient to normalize calcium (grade C, BEL 3) √
All post-WLS patients with vitamin D deficiency or insufficiency should be repleted with the following doses:
Vitamin D3 at least 3000 IU/d and as high as 6000 IU/d, or 50,000 IU, vitamin D2 one to three times weekly (grade A, bel 1) √
Vitamin D3 is recommended as a more potent treatment than vitamin D2 when comparing frequency and amount needed for repletion. However, both forms can be efficacious, depending on the dosing regimen (grade A, BEL 1) √
The recommendations for repletion of calcium deficiency varies by surgical procedure (grade C, BEL 3):
BPD/DS: 1800–2400 mg/d calcium
LAGB, SG, RYGB: 1200–1500 mg/d calcium √
Vitamin A

(continued)

Table 34.2 (continued)

In post-WLS patients with vitamin A deficiency without corneal changes, a dose of vitamin A 10,000–25,000 IU/d should be administered orally until clinical improvement is evident (1–2wk) (grade D, BEL 4)
In post-WLS patients with vitamin A deficiency with corneal changes, a dose of vitamin A 50,000–100,000 IU should be administered IM for 3 d, followed by 50,000 IU/d IM for 2 wk. (grade D, BEL 4)
Post-WLS patients with vitamin A deficiency should also be evaluated for concurrent iron and/or copper deficiencies because these can impair resolution of vitamin A deficiency (grade D, BEL 4)
Vitamin E
The optimal therapeutic dose of vitamin E in post-WLS patients has not been clearly defined. There is potential for antioxidant benefits of vitamin E to be achieved with supplements of 100–400 IU/d. This is higher than the amount typically found in a multivitamin; thus, additional vitamin E supplementation may be required for repletion (grade D, BEL 4)
Vitamin K
For post-WLS patients with acute malabsorption, a parenteral dose of 10 mg vitamin K is recommended (grade D, BEL 4)
For post-WLS patients with chronic malabsorption, the recommended dosage of vitamin K is either 1–2 mg/d orally or 1–2 mg/wk. parenterally (grade D, BEL 4)
Zinc
There is insufficient evidence to make a dose-related recommendation for repletion. The previous recommendation of 60 mg elemental zinc orally twice a day needs to be reevaluated in light of emerging research that this dose may be inappropriate
Repletion doses of zinc in post-WLS patients should be chosen carefully to avoid inducing a copper deficiency (grade D, BEL 3)√
Zinc status should be routinely monitored using consistent parameters throughout the course of treatment (grade C, BEL 3)√
Copper
In post-WLS patients with copper deficiency, the recommended regimen for repletion of copper will vary with the severity of the deficiency (grade C, BEL 3) √:
Mild to moderate deficiency (including low hematologic indices): Treat with 3–8 mg/d oral copper gluconate or sulfate until indices return to normal
Severe deficiency: 2–4 mg/d intravenous copper can be initiated for 6 d or until serum levels return to normal and neurologic symptoms resolve
Once copper levels are normal, monitor copper levels every 3 mo (grade C, BEL 3) √

Used with permission from Buchwald et al. [5] and Parrott et al. [45]
WLS weight loss surgery, *BEL* best evidence level, *TD* thiamine deficiency, *IV* intravenous, *IM* intramuscular, *BPD/DS* biliopancreatic diversion/duodenal switch, *LAGB* laparoscopic adjustable gastric band, *SG* sleeve gastrectomy, *RYGB* Roux-en-Y gastric bypass
√: New recommendation since Aills et al. [36] is noted by √; otherwise, there is no change in the current recommendation

Water-Soluble Vitamins: Vitamins B1, B6, and B12 and Folate

Thiamine (vitamin B1) is absorbed primarily in the duodenum and proximal jejunum [50], which puts DS patients at a particularly high risk, as their alimentary path bypasses these absorptive territories. The body's store of thiamine may be depleted in 18–20 days. Deficiency can be exacerbated by postoperative vomiting.

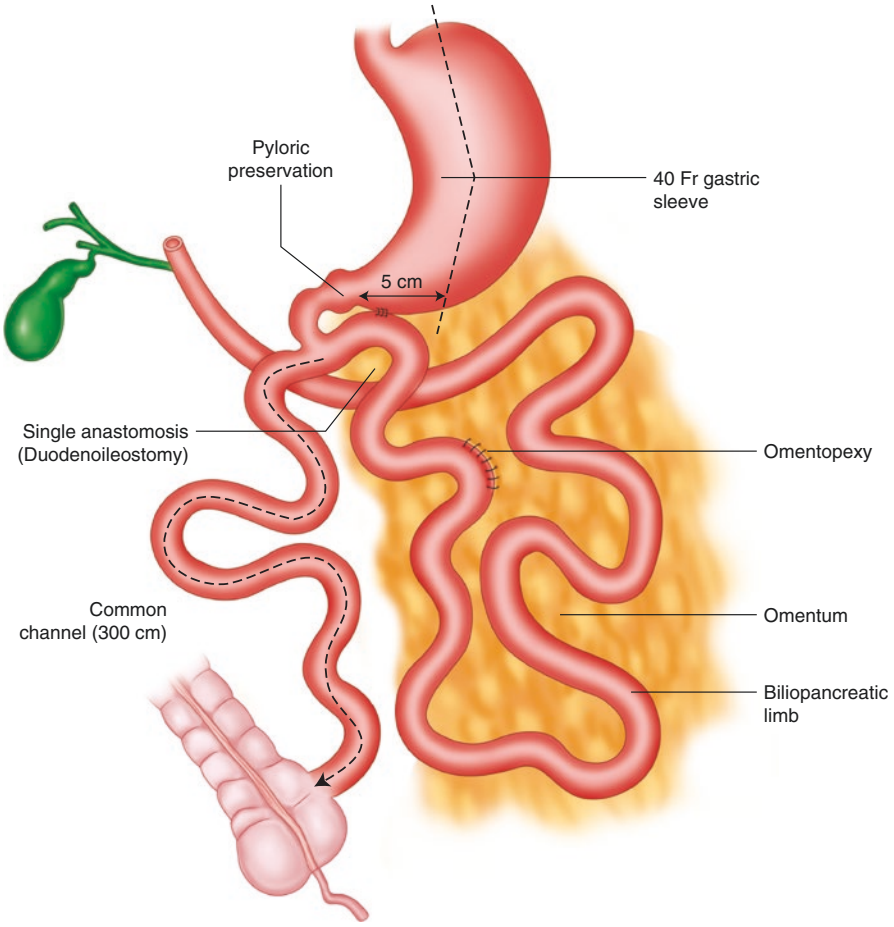

Fig. 34.4 Stomach intestinal pylorus sparing surgery (SIPS)

Thiamine deficiency often presents with symptoms of peripheral neuropathy or Wernicke's encephalopathy and Korsakoff's psychosis [51]. The incidence of this rare complication is largely unknown, but more than 30 cases of Wernicke's encephalopathy have been reported following different bariatric procedures [52]. Intravenous solutions containing glucose without thiamine or other vitamins might deplete the remaining available thiamine and precipitate Korsakoff's syndrome. Recommended thiamine supplementation for DS patients is at least 12 mg thiamine daily [45].

Vitamin B12 deficiency can lead to macrocytic anemia or may present with polyneuropathy, paresthesia, or permanent neural impairment. With a significant decrease in hydrochloric acid, pepsinogen is not converted into pepsin, which is necessary for the release of vitamin B12. While B12 stores are known to exist for long periods (3–5 years), some studies have predicted that B12 deficiency might

occur 8 months after DS [53]. Recommended B12 supplementation for DS patients is 350–500 micrograms daily orally by disintegrating tablet, sublingual, or liquid [45].

Folate absorption occurs preferentially in the proximal portion of the small intestine. Malabsorption and low oral intake caused by DS operations can result in folate deficiency. Folic acid stores can be depleted within a few months after surgery. Most patients who are folate deficient are asymptomatic, but chronic deficiency can lead to macrocytic anemia. Recommended folate supplementation for DS patients is 400–800 micrograms oral folate daily. A multivitamin is enough to correct this deficiency in most bariatric patients [45].

Vitamin B6 is not routinely measured so little information is available about its changes following DS operations. Vitamin B6 deficiency is rare but can be caused by malabsorption and low oral intake associated with DS operations. Symptoms of B6 deficiency include anemia, weakness, insomnia, cheilosis, and stomatitis. Normal range is 5–24 ng/mL. Treatment dose is 50 mg/d [36]

Repletion recommendations for post weight loss surgery micronutrient deficiency can be found in Table 34.2.

Single-Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)

The single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) includes the creation of a sleeve gastrectomy but replaces the Roux-en-Y reconstruction of the DS with a single anastomosis consisting of a duodenoileostomy. Common channel length is usually 200 cm in SADI, though the operation originally was described with a 250 cm common channel [54]. New modifications have been described that include creating a smaller sleeve gastrectomy and a longer 300 cm common channel to maximize gastric restriction and minimize malabsorption [55]. This has been called stomach intestinal pylorus sparing surgery (SIPS) [56]. There are limited data regarding long-term nutritional effects of SADI, but the combination of a tighter sleeve combined with malabsorption might put SADI patients at higher risk for the aforementioned nutritional complications. Special attention should be made to assure appropriate supplementation as previously described. See Fig. 34.4.

Short-term results are encouraging. Surve and coinvestigators compared their experience of 62 BPD-DS patients vs 120 SIPS patients. In the BPD-DS group, they reported rates of 3.2% for anastomotic leak, 3.2% for postoperative bleeding, 1.6% for duodenal stump leak, and 1.6% for postoperative SBO rate, while the SIPS group had a 0% rate for all these complications. They do admit, however, that the BPD-DS procedures were associated with a learning curve, and the SIPS procedures were performed following their experience with the BPD-DS [56]. With respect to long-term complications (up to 24 months), diarrhea was reported in 11.2% and malnutrition in 8% of BPD-DS patients. In SIPS patients, both were

reported as only 0.8% each. There were no significant differences in vitamin and mineral levels checked at 2 years [56].

Topart and coinvestigators recently published a review of the current literature on SADI or SIPS patients and found a total of 1041 patients from 9 institutions. Early data on excess weight loss appear similar to or slightly less than the BPD-DS, with the mean EWL (excess weight loss) of 78% at 1 year with SADI [57]. There were no deaths reported and a very low overall reoperation rate in most of the series [57]. There is a pending randomized trial comparing SADI and BPD-DS.

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Part V
Revision and Conversion

Chapter 35
Weight Recidivism After Bariatric Surgery: Evaluation and Implications

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Background

Bariatric surgery has been shown time and again to be the most effective and durable treatment for morbid obesity and related comorbidities [1–5]. Despite this, a minority of bariatric patients will experience weight regain in the postoperative period. Some series report a rate of up to 35% in long-term analyses [6–8]. This generally occurs within the first 2 years and is more common in the super-morbidly obese [9]. Weight regain or recidivism is generally defined as greater than 10 kg weight increase from the nadir weight, although this definition is inconsistent in the literature [10–12]. The amount of weight regain is also highly variable, even within the same surgical procedure type [13–15].

Weight recidivism after bariatric surgery is multifactorial in nature, including anatomic, physiologic, behavioral/environmental, and psychosocial factors. Depending on the surgery type, there may be different anatomic factors that contribute to weight regain, which will be discussed in detail later in the chapter.

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Physiology

Physiologic factors can play a significant role in the development of weight regain. Enteric hormone balance is a complex dynamic which is not fully understood, especially as it relates to bariatric surgical patients. There are, however, several hormones that have been identified as key contributors, including leptin, peptide YY (PYY), cholecystokinin (CCK), ghrelin, and glucagon-like peptide-1 (GLP-1) [16]. Orexigenic hormones (including ghrelin) have been shown to decrease post-bariatric surgery, while anorexigenic hormones (including GLP-1 and PYY) are increased [17, 18]. It is hypothesized that the surgical manipulation of the gastrointestinal tract leads to such alterations, but this effect may fade over time, resulting in weight regain.

Pregnancy status can also contribute to a certain extent. Patients are generally counseled to avoid pregnancy for at least 1 year after undergoing bariatric surgery in order to avoid nutritional complications and to maximize weight loss. Gestational weight gain above the recommended, expected range is a strong risk factor for long-term weight regain [19]. Patients should be instructed by both their bariatric surgeon and obstetrician to remain within the appropriate goal range during the pregnancy. Similarly, weight gain has been associated with menopause, likely due to change in body composition with increased visceral adiposity and decreased levels of estrogen [20]. Studies on the effects of menopause in the bariatric population are sparse, however.

Finally, it is important to perform a comprehensive history in order to identify any other contributing factors. This includes a thorough medical reconciliation, as some medications are associated with weight gain (including antipsychotics, antidepressants, and steroids). Recent smoking cessation may also contribute to weight gain. While uncommon, patients may develop a new medical condition that could contribute to weight regain or inadequate weight loss, including endocrinopathies like Cushing's syndrome and hypothyroidism.

Behavioral/Environmental

Behavior modification is essential to the success of the surgical patient, including dietary compliance and structured physical activity. Dietary adjustments are paramount to achieving sustained weight loss, as the surgery alone will not result in long-term success. Evidence suggests that caloric restriction can lessen over time, especially after the first few years [21]. Grazing and general non-compliance with bariatric diet (high-calorie, high-fat content foods or increased portions) are major contributors to weight recidivism in the postoperative period.

Physical activity is another cornerstone of successful weight loss after bariatric surgery. Patients who are several years post-bariatric surgery perform varying levels of physical activity, both in terms of time per week and intensity of activities. While many bariatric patients remain motivated following initial weight loss, one study

found that postoperative bariatric patients who participated in the National Weight Control Registry (NWCR) had a lower caloric expenditure from physical activity when compared to case-matched controls of nonsurgical NWCR patients [22]. In addition, another study found that those who performed moderate-to-vigorous physical activity for >150 min per week experienced greater weight loss and maintenance of weight [23]. Together, these findings reinforce the importance of physical activity in postoperative weight loss maintenance among bariatric surgery patients.

Psychosocial

It is critical to consider psychological factors when evaluating a post-bariatric surgical patient with weight regain. Depression is prevalent among obese and morbidly obese patients, and depression scores are consistently lower after bariatric surgery with resultant weight loss [24]. Stressful life changes must also be evaluated, which can result in maladaptive eating behaviors and weight regain [25]. Binge eating disorder (BED) and night eating syndrome (NES) are two psychiatric medical conditions that are seen in a subset of bariatric patients. While these diagnoses can be identified and addressed through the preoperative psychological evaluation, they may manifest again in the postsurgical patient.

Evaluation and Management

For the bariatric surgical patient who experiences postoperative weight regain, a comprehensive and thorough evaluation is necessary to detect and manage any contributing factors. This begins with a detailed history and physical examination. A review of the patient's symptoms, duration, and recent changes in any medical conditions should be performed, as well as a reconciliation of home medications. A focused assessment of eating behaviors and review of food diaries are important. It is also important to take the time to identify any social stressors or recent life changes and how these may be contributing in a temporal manner to the weight regain.

Depending on the etiology identified, the treatment of weight regain can vary drastically. For anatomic or mechanical causes specific to the primary bariatric surgical procedure, revisional surgery may be indicated and is discussed in greater detail below. It should be noted that obesity is a chronic, progressive disease, so multiple interventions may be required in a staged fashion over a varying period of time in order to effectively resolve the issue. For newfound endocrinopathies or other medical conditions thought to be contributing, the appropriate medical treatments should be applied with consideration for referral to a specialist. Weight-gaining medications should be discontinued and substituted with an alternative regimen, if available.

Referral to a bariatric dietitian is helpful for many bariatric patients who suffer from weight recidivism. A review of appropriate dietary choices, eating patterns, and vitamin/mineral supplementation will help redirect the patient toward weight stabilization or weight loss. The provider should place emphasis on the importance of food logging, both for calorie counts and patterns/timing of meals. Other options include meal replacement programs offered by many bariatric centers. Physical activity should also be assessed by a qualified bariatric provider. Important elements include type of activity, level of exertion (intensity and duration), and frequency of exercise. Many times, enrollment in a formal exercise program will provide the necessary structure and encouragement for patients to halt or reverse weight gain and to maintain healthy lifestyle habits.

Patients who, on evaluation for weight regain, exhibit symptoms concerning for depression or other mood disorders should be referred for psychological assessment and intervention. Counseling and support are essential, including providing coping strategies for life stressors, attendance at support groups, as well as cognitive behavioral therapy.

Pharmacotherapy may have a role as an adjunctive treatment for weight regain following bariatric surgery. New medications, including lorcaserin which has serotonergic properties and acts as an anorectic and phentermine/topiramate, have become increasingly popular. Phentermine is a sympathomimetic amine which serves as an appetite suppressant and stimulant. Topiramate is an anticonvulsant that also induces weight loss. Both medications elicit their effects through currently unknown mechanisms. Topiramate has shown significant efficacy in weight loss results after weight regain in the bariatric surgical patient, especially after Roux-en-Y gastric bypass (RYGB) [26].

Adjustable Gastric Banding

Weight loss after adjustable gastric banding (AGB) is generally slower than other procedures and stabilizes after the first 2–3 years [27]. Due to its mechanism of action as an implantable device, the patient will require frequent adjustments to titrate the level of restriction and early satiety in order to maximize weight loss potential. Success with the AGB is quite highly dependent on the frequency and compliance of postoperative adjustments, especially in the first few years. Therefore, avoidance of weight regain is intimately associated with regular, long-term follow-up [28]. A chronically underfilled band or infrequent visits for adjustments will directly contribute to inadequate weight loss or weight regain because of the lack of restriction. Simultaneously, the perigastric fat pad and visceral adiposity decreases with early weight loss, resulting in the need for increased inflation of the band in order to provide the external compression necessary to produce early satiety and caloric restriction. It is important to recognize that about one-third of AGB patients will not achieve at least 30% EWL within the first few postoperative years [29].

Long-term results, including those greater than 10 years of follow-up, with the AGB show percent excess weight loss (%EWL) to be in the range of 33–60% [30–34]. O'Brien and colleagues published one of the largest series of over 3000 patients with up to 15 years of follow-up having a 47% EWL [35]. In addition, it is now evident that AGB is associated with a significant revision rate of approximately 20–30% [36]. This may be for a host of reasons, including band intolerance, gastric prolapse, pouch dilation, hiatal hernia, inadequate weight loss, or weight regain. There is evidence that revision of the gastric band results in sustained weight loss when performed for pouch-related problems [37]. Otherwise, inadequate weight loss or weight regain after AGB is most commonly managed with conversion to another bariatric procedure, namely, sleeve gastrectomy (SG) or RYGB.

After a thorough history and physical examination, highlighting the items listed previously in this chapter, the diagnostic workup of a patient with an AGB and weight regain should begin with an upper gastrointestinal contrast study (UGIS) to evaluate for the band position, pouch dilation, band erosion, or other anatomic abnormality. An upper endoscopy can be helpful if there is clinical suspicion for erosion or ulceration or if the patient exhibits symptoms of intractable reflux to assess for esophagitis. If anatomic or mechanical factors have been identified or if the patient has been evaluated and cleared from a nutrition and psychological standpoint, conversion surgery is usually recommended.

The choice of conversion procedure should be based on multiple factors. The presence of certain comorbid medical conditions may make one procedure preferable to another. For instance, in a patient with significant gastroesophageal reflux disease, conversion to RYGB is likely to effectively resolve the reflux in addition to the weight regain. Secondly, technical factors may affect the choice of revision, including significant inflammation or previous band erosion. Weight loss outcomes after conversion from AGB are variable, ranging from 48 to 66% after conversion to RYGB and 47–65% after conversion to SG, which is superior to band revision alone [38–41].

Conversion to RYGB is a common approach and generally the author's preference, given the failure of a previously restrictive operation, the prevalence of reflux disease, and the favorable weight loss results compared to conversion to SG, as demonstrated by Marin-Perez and colleagues [42]. In addition, during conversion, the pouch creation can be positioned above or below the level of the previous band, so as to avoid stapling through inflamed, thickened tissue. This is in contrast to conversion to SG, where the previous band tract must be stapled to form the vertical sleeve. Conversion to sleeve gastrectomy has also been shown to have a higher leak rate in this setting [43, 44], although unpublished data from the authors' own group suggest that conversion from AGB to either RYGB or SG can be performed safely in one stage. Specific roles for band conversion to SG after weight recidivism include patients that have inflammatory bowel disease, malnutrition, or other contraindications to malabsorptive procedures, those that are at high perioperative risk, adolescents, or those requiring chronic anticoagulation, nonsteroidal anti-inflammatory drugs (NSAIDs), or aspirin use.

Sleeve Gastrectomy

Originally described as the first stage of biliopancreatic diversion (BPD), sleeve gastrectomy has gained popularity, as it is currently the most commonly performed procedure in the United States. Increased performance of laparoscopic SG as a primary weight loss operation is attributed, in part, to its technical ease and promising results. Studies demonstrate metabolic and weight loss outcomes superior to those of the adjustable gastric band and approaching those of the RYGB [13, 45]. As it is a relatively new procedure, data about long-term results and weight regain are still relatively scarce.

A recent systematic review regarding weight regain in patients at least 2 years postoperatively reports rates of regain from 5.7% at 2 years to 75.6% at 6 years [12]. Thus, it is important for the surgeon to understand the potential for weight regain, the reasons behind it, and the potential revisional surgeries to address this complication. In addition, revisional procedures can present a challenge due to tissue fibrosis and altered anatomy, which may lead to higher rates of complications [46–48].

Reasons for weight regain are multifactorial and include anatomic considerations such as initial sleeve size/technical reasons and sleeve dilation, inadequate follow-up support and education, increased ghrelin levels, and maladaptive lifestyle behaviors [12, 49, 50].

Major reasons for weight regain are inadequate support and follow-up. It is established the long-term dietary support and standard follow-up visit are beneficial for patients in order to prevent weight regain. Lombardo examined if frequent follow-up visits prevent weight regain in a study of 71 patients and reported that more follow-up visits may help reduce weight regain and improve comorbidities [51]. In our practice, we have a follow-up of every 3 months up to 1 year, every 6 months for the second year, and then every year following procedure in order to assess for any complications or weight regain.

Another reason for weight regain is lifestyle behaviors, such as maladaptive eating and poor exercise. Regardless of the surgery type, poor results will be expected if a patient continues to eat high-calorie foods. Complications from SG, such as reflux, dysphagia, or vomiting, can lead to improper eating decisions; thus, educating patients is critical. In a study of 115 patients who were receiving continuous postoperative support, the group developed a lifestyle modification score and discovered that majority of the patients with sufficient weight loss (81.25%) had a lifestyle modification score of >0.5, showing significant lifestyle modification, compared to none of the patients that did not lose sufficient weight [52].

Technical considerations when creating a sleeve, which may later result in weight regain, include adequate sleeve volume, bougie size >40 French (Fr), retained antrum or fundus, and sleeve dilation. Early sleeve gastrectomy was often created with large (>40 Fr) bougies, thus creating large pouches. Larger amounts of gastric antrum were left or fundus was not adequately excised. In a study of 120 patients, Weiner compared three groups: SG without a calibration tube and resulting in a high sleeve volume ($n = 25$), SG with a calibration tube of 44 Fr ($n = 32$), and SG with a calibration tube of 32 Fr ($n = 63$). Patients with large sleeve volume (removed gastric volume <500 cc) showed a slight weight regain during the 5 years postoperatively. Rate

of reoperation was 13.3%, as two patients underwent redo sleeves, seven underwent LBPD-DS, and three were converted to Roux-en-Y gastric bypass [53]. Four years later, the authors described their experience with >900 patients undergoing SG. Rate of subsequent procedures was 9.4% for weight regain and insufficient weight loss. The authors discussed that approximately 50% of primary treatment failure was due to technical issues, such as an incompletely resected fundus. In cases with successful weight loss complicated by weight regain, they speculated it was due to dilated antrum [54]. Other findings leading to poor weight loss or weight regain include the concept of "neofundus" described previously [13] and retained antrum [55, 56]. Sleeve dilation has also been demonstrated 2–3 years postoperatively; however, it is unclear if dilation correlates with patient outcomes [57, 58].

Initial evaluation should include a thorough history and physical exam, concentrating around evaluation of weight loss versus weight regain, resolution of comorbidities, and possible symptoms. Review of proper diet and exercise should be performed, as well as discussion of maladaptive behaviors. Non-compliance should be evaluated and addressed if present prior to proceeding with any further procedures.

Initial tests that can be performed to evaluate for anatomical abnormalities with the sleeve include an upper gastrointestinal series and/or an endoscopy. UGIS can evaluate for sleeve dilation, retained fundus, or antral dilation. An endoscopy can show inflammation, such as esophagitis, hiatal hernia, strictures, or pouch dilations.

As reoperation can be technically challenging and is associated with increased morbidity, initial treatment involves lifestyle modifications. Surgical options include re-sleeving and conversion to BPD-DS or RYGB. As revisional surgery is associated with higher rate of morbidity, first-line treatment is to evaluate for other reasons of either poor weight loss or weight regain, such as malabsorptive behavior. When all other reasons have been addressed, further procedures can be considered.

AlSabah and colleagues proposed an algorithm for conversional bariatric surgery. The authors proposed that in the case of dilation of the stomach >4 cm in diameter, the patient can undergo isolated redo sleeve gastrectomy. If sleeve has no abnormalities on UGI or endoscopy, a conversion to either RYGB or BPD-DS can be performed [57]. In addition, conversion to RYGB is considered if there is narrowing of the incisura, a hiatal hernia >3 cm, and no evidence of dilation or esophagitis [57].

As discussed previously, early SG were performed with larger size bougies, thus leaving a large pouch, an antrum, or a fundus. These anatomic abnormalities can be addressed with revision of the SG, and adequate weight loss can be achieved following revision, as described by AlSabah [57] and supported by others [58–60]. Dapri examined 7 patients who underwent revision of their SG compared to 19 patients who underwent conversion to BPD-DS. One patient had a leak at the angle of His following revision. The authors concluded that revision of SG is feasible and safe, while conversion to BPD-DS seemed to have more efficacy [58].

Since SG is the initial step to BPD-DS, when encountering weight regain or insufficient weight loss, it is natural that patients undergo the second portion of the procedure. However, as described by Dapri, the rates of complications following

BPD-DS were higher; thus, patients should be aware of the potential of more complications [58].

Conversion to RYGB is another option with good results reported in some series [61–64]. Yorke and colleagues reported 18 patients undergoing conversion to RYGB due to inadequate weight loss or severe reflux. Conversion to RYGB was safe and led to resolution of comorbidities [62]. Ianelli reported conversion of SG to RYGB of 29 cases for weight loss and 11 cases for refractory GERD. Mean percent weight loss and percent excess weight loss were 34.7% and 64%. Postoperative complication rate was 16.7% [64]. However, in other studies, there was no difference between revisional SG and conversion to RYGB in terms of weight loss at 24 months or greater follow-up time [65]. As conversion is associated with increased rate of leaks, patients should be appropriately canceled.

Moszkowicz described conversion of previously failed SG to a mini gastric bypass for failed weight loss. The technique involved an antecolic end-to-side stapled gastrojejunal anastomosis and connecting the long narrow gastric tube to the jejunum about 200 cm downstream from the ligament of Treitz. The procedure was performed in 23 patients, with 19 (81%) performed laparoscopic. The conversion resulted in additional weight loss, achieving a mean BMI of 36.5 and 26.8% excess BMI loss (EBL) at 12 months and mean BMI 35.7 with ELB of 51.6% at 24 months. There was no mortality and morbidity was <10% [66].

Roux-En-Y Gastric Bypass

Roux-en-Y gastric bypass remains the gold standard although there is a decrease in numbers. Although many reports prove the validity of weight loss and resolution of weight-related comorbidities, there is insufficient weight loss or weight regain in about 15–35% of patients [67–70]. A number of factors have been associated with weight regain or poor weight loss, including genetic, behavioral and psychological, and anatomic.

Reasons for weight regain or poor weight loss are multifactorial. Studies have reported several patient factors that have been associated with poor weight loss, including older age, black race, male sex, marital status, greater initial weight and BMI, the presence of comorbidities such as diabetes, larger pouch area, poor follow-up, and insurance status [71]. One of the most common causes is poor eating habits. Changing poor eating habits remains a challenge, and relapse is often seen. This highlights the importance of follow-up in order to provide adequate monitoring. Other factors include anatomic factors such as dilated gastric pouch or anastomosis and short alimentary or biliopancreatic limb.

Patient evaluation should involve a multidisciplinary team, including the surgeon, dietitian, and psychologist. If concerns for the pouch or gastrojejunostomy (GJ), an evaluation can be performed by a gastrografin esophagram.

Anatomic aspects can dictate the type of subsequent procedure. A dilated gastric pouch or gastrojejunostomy or both can be addressed by a revision of the pouch.

Dilation is defined as pouch >6 cm long or >5 cm wide [72]. Several options have been suggested, both surgical and endoscopic. Endoscopic therapy includes the use of sclerotherapy, plication, and endoscopic suturing or clipping. Surgical options include trimming of the GJ anastomosis or pouch, endoscopic suturing, placement of an adjustable band over the pouch, or revision of the anastomosis [73–77]. If there is a need to increase the malabsorptive aspect of the RYGB, more extensive procedures can be performed such as lengthening of the alimentary limb (AL) or biliopancreatic limb (BPL).

Endoscopic techniques are an attractive alternative, since it is believed to be associated with lower risk [78]. Sclerotherapy was first reported in 2003 by Spaulding [79]. In the study, sclerotherapy was achieved by injecting sodium morrhuate. It included 20 patients, with 15 patients losing 9% total weight at 6 months [79]. It is deemed as a straightforward procedure with few complications. Although it can be repeated, its effectiveness is limited, with relatively modest weight loss. In a study, while only 30% lost weight, 42% had no change, and 28% gained weight [80].

StomaphyX™ (Endogastric Solutions, Redwood City, CA, USA) uses H-fasteners in order to create full-thickness, serosa-to-serosa plication. StomaphyX can have relatively good weight loss [81]; however, the limitation of the device is that it can only access the pouch rather than the GJ. Endoscopic suturing is another option, which involves the ROSE (restoring obesity surgery endoscopic) procedure [82]. However, long-term outcomes and weight loss are not known for this procedure, as small studies of 5 and 20 patients were evaluated at 1 and 3 months with average weight loss of 8.8 kg at 3 months [81–83].

Revision of the gastric pouch and/or anastomosis appears to be a safe and effective modality to address insufficient weight loss. In a study of 44 patients who underwent trimming of the pouch, BMI loss was 7 kg/m^2 and mean %EWL was 38%. One patient developed a hematoma and no mortality was reported [84]. Another possibility is the addition of a nonadjustable silicone ring loosely fitted around the gastric pouch [85].

For frequent eating, additional malabsorption can be required by manipulating the limb components. Distalization of RYGB has an increased risk of protein-calorie malnutrition. There are two techniques: AL is divided close to the enteroenteric anastomosis and moved distally to crease a long BPL, or BPL is divided close to the enteroenteric anastomosis and moved distally, creating a long AL [86]. Conversion to BPD-DS is another option but can be a technically challenging procedure.

Conclusion

Although bariatric surgery remains the most effective treatment for obesity, weight recidivism has been observed. There is limited understanding of how to predict which patients are more likely to regain weight and how to treat them. The underlying reasons for weight recidivism are multifactorial, including anatomic, physiologic, nutritional, and behavioral pathology, and can be procedure-specific as well.

Management includes multidisciplinary counseling and may require one or more revision or conversion surgeries.

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Chapter 36
Revision Endolumenal Therapies for Weight Recidivism

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Introduction

Bariatric surgery has been growing throughout the world with gastric sleeve surgery being the most frequent surgery for obesity performed today. However, gastric bypass is also a common surgery, and a substantial portion of patients is submitted to this technique [1]. The most common late complication of gastric bypass is weight regain in which the main associated factors are inappropriate diet and sedentary life style; the most important coadjuvant factors are enlarged gastric pouch and dilatation of the anastomosis [1–4]. Anastomoses smaller than 10 mm influence patients to select liquid food due to intolerance or even vomiting and in most cases require dilatation using an endoscopic approach. However, large anastomoses have also been associated with weight regain and may be associated with a complaint of decreased satiety [5–8].

About 52.0% of the bariatric patients present some psychiatric disorder associated with eating habits [9]. Less restriction to food ingestion due to a dilated anastomosis or a large pouch may act as an additional factor in respect to these eating disorders and directly influence weight loss.

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The main endoscopic procedures that aim to reduce the diameter of the gastrojejunal anastomosis are OverStitch™ (Apollo Endosurgery, TX, USA) and argon plasma coagulation as described by Aly in 2009.

Literature Review

Abnormal anatomical findings are found in 71.2% of patients after weight regain; 58.9% have a dilated gastrojejunal anastomosis, 28.8% have an enlarged pouch, and 12.3% have both [7]. Thus, several methods have been proposed to reduce weight in patients who fail to maintain weight loss after gastric bypasses. These include endolumenal injections of a sclerosant (sodium morrhuate) in the anastomosis, endolumenal reduction of the gastrojejunal anastomosis (EndoCinch®, Bard®, Billerica, MA, USA), the ROSE procedure (restorative obesity surgery, endolumenal, USGI®, San Clemente, CA, USA), StomaphyX (EndoGastric Solutions®, Redmond, WA, USA), OTSC Clip (Ovesco AG®, Tubingen, Germany), OverStitch™ (Apollo Endosurgery® Inc. Austin, TX, USA), and coagulation of the gastrojejunal anastomosis with argon beam [1, 7, 8, 10–14]. The use of endoscopic sutures in association with argon plasma ablation is also an option within the arsenal of minimally invasive techniques; this technique has a 100% success rate in reducing the anastomosis diameter and results in statistically significant weight loss when compared to a control group [15, 16]. Surgical revision is the most common approach to weight regain; however, it is associated with higher incidences of complications, morbidity, and mortality when compared to the endoscopic treatments described in the literature [14] .

A summary of the findings related to the endolumenal treatment of weight regain and follow-up of the different techniques used are listed in Table 36.1.

Impact of the Pouch and Dilated Anastomosis

There are two trains of thought: one believes restriction due to the size of the gastroplasty and the diameter of the anastomosis are vital, and the other believes that these are less important factors for weight loss. Endoscopic methods to treat the anastomoses and pouch are not intended to influence postoperative weight loss but rather to affect the regained weight when it is significant after initial loss. Heneghan and colleagues concluded that patients with a “normal” postsurgical anatomy regained less weight than patients with the proximal surgical anatomy altered, in particular widening of the gastrojejunal anastomosis [17]. Abu Dayyeh and colleagues, after assessing 165 patients, concluded that the diameter of the anastomosis is a risk factor for weight regain after Roux-en-Y gastric bypass (RYGB) and that this variable should be included as a predictor of weight regain [5].

Table 36.1 Summary of literary findings: study parameters and comparisons of the techniques used to reduce weight regain, success rate, type of study, patient population, references, percentage of weight loss, and follow-up time

Reference	Country	Patients *n*	Study type	Technique	Complications	Success rate (%)	(%) Excess weight loss	Follow-up (month)th
Thompson et al. (2013)	USA	77	Randomized trial	Transoral outlet reduction (TORe)	None	96	15	6
Jirapinyo et al. (2011)	USA	9	Matched cohort study	OverStitch™	1 stenosis, 1 emesis	100	20	12
Kumar et al. (2013)	USA	118		Superficial-thickness TORe versus full-thickness TORe	None	90	18	12
Heylen et al. (2011)	USA	94	Prospective	Over the Scope Clip	None	70	16.5	6
Rodriguez et al. (2013)	Chile	31	Retrospective	OverStitch™	None	87	17	24
Zundel et al. (2013)	Colombia	3	Retrospective	OverStitch™	None	87	19	12
Al.varado et al. (2013)	Panamá	3	Retrospective	OverStitch™	None	87	15	12
Sahdal.a et al. (2013)	Dominican Republic	4	Retrospective	OverStitch™	None	87	18	6
Fernández-Esparrach et al. (2010)	USA	6	Prospective	EndoCinch®	None	65	65	19
Thompson et al. (2006)	USA	8	Prospective	EndoCinch®	None	80	23.4	4
Thompson et al. (2010)	USA	220	Randomized	EndoCinch®	None	89	60	6
Cambi et al. (2015)	Brazil	49	Prospective	Argon Plasma	None	90	41	12
Brethauer et al. (2012)	USA	18	Prospective	RESTORe endoscopic suturing device	None	80	27.7 ± 21.9	12

(continued)

Table 36.1 (continued)

Reference	Country	Patients *n*	Study type	Technique	Complications	Success rate (%)	(%) Excess weight loss	Follow-up (month)th
Abu Dayyeh et al. (2015)	USA	10	Multiple series	OverStitch™	None	90	30	6
Sharaiha et al. (2015)	USA	25	Prospective	OverStitch™	None	90	18.7 ± 10.7	12
Lopez-Nava et al. (2016)	Spain	10	Prospective	OverStitch™	None	90	54% ± 0%	12
Lopez-Nava et al. (2016)	Spain	8	Prospective	OverStitch™	None	85	45% ± 41%	20
Kumar et al. (2015)	USA	126	International multicenter series	OverStitch™	None	90	14.5	6
Kumar et al. (2015)	USA	126	International multicenter series	OverStitch™	None	90	19.5	12
Mullady et al. (2009)	USA	20	Prospective series	Surgery endolumenal	None	60	7.3	3
Ryou et al. (2009)	USA	5	Prospective series	Surgery endolumenal	None	60	6.5	3
Horgan et al. (2010)	USA	116	Prospective multicenter series	Surgery endolumenal	None	97	32	6
Thompson et al. (2012)	USA	66	Prospective multicenter	Surgery endolumenal	None	97	14.5	12
Thompson et al. (2012)	USA	60[a]	Prospective multicenter	Surgery endolumenal	None	92	24	12
Gal.lo et al. (2015)		27	Retrospective	Surgery endolumenal	None	50	18	72
Souza et al. (2016)	Brazil	10	Cases series	Argon Plasma	None	90	9.8	1
Mikami et al. (2010)	USA	39		StomaphyX	Sore throat, epigastric pain in most of the patients	87	9	
Leitman et al. (2010)	USA	64		StomaphyX	None	79	10	

Manouchehri et al. (2011)	Canada	14		StomaphyX	Headache, back pain	100	11	
Galvao Neto et al. (2011)	Brazil	8		OverStitch™	1 hematemesis	50	12	
Baretta et al. (2015)	Brazil	30		Argon Plasma	2 severe stenosis	90	23	Decrease in mean BMI and mean diameter ($P < 0.05$)
De Souza et al. (2015)	Brazil	37	Retrospective	Argon Plasma	None	50	24	16

Recently, Ramos and colleagues evaluated the size of the gastrojejunal anastomos is and its influence on weight loss. In their 2-year follow-up, they showed that an anastomosis of 15 mm presents statistically better results than a 45-mm anastomosis [18]. It is not a coincidence that the desired diameter after endoscopic treatment is between 10 mm and 15 mm.

Thompson and coworkers, in a prospective controlled study in 2013, demonstrated the effectiveness of anastomosis treatment with respect to weight regain after bypass surgery [16]. Several other studies by the chapter authors substantiate the efficacy in terms of weight loss after weight recidivism following the treatment of dilated anastomoses.

Selection and Indication of Endoscopic Treatment of the Pouch and/or Anastomosis

As mentioned above, about 20% of patients submitted to gastric bypass fail to maintain weight loss. The most relevant of the several factors involved is the interruption by the patient of the follow-up with the multidisciplinary team and, consequently, a break in dietary and behavioral monitoring. As with any other chronic disease such as hypertension and diabetes, obesity needs a foundation for management so that all subsequent treatments can be effective. In the case of diabetic patients, the control of sugar intake is essential and the control of sodium intake is paramount for pressure control in hypertensive patients. Obesity is no different, and a balance between diet-behavior-physical activity and control of anxiety is the foundation of treatment. That being said, it is clear that this is the first target of treatment especially for patients treated surgically to control obesity. Surgery is currently the best treatment for the morbidly obese, and it is not just a simple endoscopic procedure in isolation that will be able to control weight regain after the current gold standard surgical treatment. Thus, it is clear that the first criteria of patient selection for endolumenal therapy for weight regain is a careful follow-up with the multidisciplinary team. There must be a consent and understanding within the team that the patient in question is able to achieve this next step within the natural history of the illness.

After this first stage, other aspects are relevant such as the surgery time and endoscopic alterations of the pouch and anastomosis. The weight loss curve is attained within the first 2 years after gastric bypass, which is followed by a plateau and consequently weight stability with a variation of about 5% gain being considered normal. After surgery, weight regain is characterized as levels of 10% above the nadir, i.e., when the patient regains at least 10% of the weight lost.

Regarding the endoscopic alterations after gastric bypass, the most relevant aspects to indicate endoscopic treatment are large gastric pouch and gastrojejunal anastomosis. However, there is a need to discard other concomitant findings that may be leading the patient to an inappropriate diet [7]. The presence of a gastrogastric fistula can result in relapse of the disease by reconnecting the isolated stomach;

in these cases, the treatment of the fistula itself would be the initial approach. Another important condition is stenosis of the anastomosis or the presence of the containment ring. Currently containment rings are not being used, but they were widely used in the past, and many patients still have them, especially patients in the late postoperative period, which is the group that suffers from weight regain. Any type of chronic stenosis causes food intolerance for which patients will, over the years, select the food that most appeals to them. As they have difficulty in ingesting solids due to the obstruction, they tend to select what does not induce dysphagia, such as liquid carbohydrates. These are poor food choices from the nutritional and caloric perspective. Under these conditions, it is difficult to follow a correct diet, as it is not possible to ingest solid foods, especially red meat. It is obvious that the focus of treatment in this group of patients, regardless of pouch size, is the obstructive factor. Balloon dilation or stricturoplasty can be performed in cases of stenosis of the anastomosis, and the use of an achalasia balloon or a prosthesis may be the endoscopic treatment of choice in cases of food intolerance due to a containment ring.

Knowing the aforementioned factors, we will now discuss the most important anatomical factors considered in the indication of endolumenal therapy: gastric pouch size and diameter of the gastrojejunal anastomosis.

It is critical to know the normal patterns and the sizes that are considered ideal for the pouch size and gastrojejunal anastomosis. A postoperative pouch size between 4 and 7 cm in length is considered normal, and a wide pouch is one with a diameter > 4 cm. Short and wide pouches are more likely to cause satiety compared to a long and narrow pouch of the same capacity in theory. Thus, a pouch with a length of between 4 and 7 cm would be a condition for endoscopic treatment by endosuture. Large pouches can contain a greater amount of food even with a normal caliber anastomosis, so the target of treatment in these cases would be a reduction in pouch volume, which can be performed endoscopically with endosutures, excluding the use of argon plasma coagulation.

Regarding the gastrojejunal anastomosis, a desired anastomosis should have a maximum diameter from 10 to 14 mm. Anastomoses smaller than 10 mm lead to the patient choosing food that does not induce dysphagia, and anastomoses larger than 15 mm can lead to a decrease in satiety and the possibility of any type of food and volume being able to pass through the anastomosis. A wide variety of treatments have been and are being used to narrow the gastric passage; the most common are endosutures and argon plasma coagulation (techniques to be discussed later).

In summary, the main selection criteria for patients who are candidates for endoscopic therapy are:

- To be accompanied by a specialized multidisciplinary team.
- Have the consent of the entire team but especially the surgeon, nutritionist and psychologist.
- A postoperative period of more than 2 years.
- A weight regain of more than 10% above the nadir.

- Exclusion of endoscopic findings that cause food intolerance (stenosis or obstruction due to a ring).
- Absence of gastrogastric fistula.
- Pouch size between 4 and 7 cm in length.
- Pouch width <4 cm in diameter (if opted for the isolated use of argon).
- Present gastrojejunal anastomosis greater than or equal to 15 mm

Diagnostic Endoscopy

An endoscopic examination prior to any therapeutic endoscopic procedure is as important as the therapy itself. The endoscopy report should be complete and cite the relevant endoscopic aspects so that the team, together with the patient, can make a decision regarding the best therapy.

In the previous section, we cited the endoscopic aspects relevant to the diagnosis of a possible candidate for endolumenal therapy; however, plotting numerical knowledge to endoscopic practice can be a challenge. In this section, we focus on the main possibilities and tips for the endoscopic diagnosis of a large pouch and anastomosis. For this, we will divide it into two subitems: measurement of the pouch and measurement of the gastrojejunal anastomosis.

How to Measure the Pouch

In practice, we must find mechanisms that facilitate a precise and adequate measurement of the pouch so that we have data for the endoscopic report. The pouch length can be measured simply using the endoscope tip from the anastomosis to the esophagogastric transition. If there is a containment ring, the distance of the ring from the anastomosis should be measured (e.g., whether the ring is 2 cm from the anastomosis or close to it, etc.). The measurement of the width of a pouch is a more complicated task; in narrow pouches, it is difficult to perform the retroflexion maneuver easily. Thus, in a practical way, we can consider a wide pouch one in which we can perform the retroflexion maneuver easily.

Measuring the Anastomosis

The largest axis of the gastrojejunal anastomosis should be measured with adequate distension of the pouch. Several methods can be used, from direct vision (less reliable) to the use of endoscopic rulers (more reliable) and using clamps with previously known diameters. The different realities around the world in terms of accessibility to materials and the economic factors of each country and each service

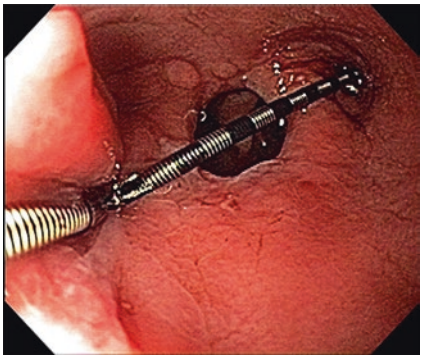

Fig. 36.1 Endoscopic image demonstrating the Olympus articulated ruler with 2-mm graduations

must be taken into account. As relevant cutoff points, it is extremely important to measure or describe in the report some points: to say that an anastomosis is 12 mm when it really is 13 mm will have little relevance. However, to estimate that an anastomosis is 12 mm when in fact it is 20 mm will adversely impact the selection of treatment. Thus, the following cutoff points should be used in the report: anastomosis < 10 mm, 10–15 mm, 15–20 mm, or > 20 mm. Purely visual methods are only reliable when the apparatus passes tightly through the anastomosis, where, knowing the diameter of the apparatus, it is possible to give an accurate size.

One widely used technique in the endoscopic practice is to use clamps of known sizes. For example, we can measure the diameter (or see in the specifications) of a specific foreign body clamp and then open it inside the anastomosis. Thus, if the clamp is 20 mm in diameter, we can tell if the anastomosis is less than, equal to, or greater than 20 mm.

The most accurate way is to use endoscopic rulers with different grades. The most commonly used ruler in the USA has 2-mm gray and black segments and is articulable (Fig. 36.1); however, this is no longer clinically available. A simple and inexpensive way to measure an anastomosis is to mark a cholangiography catheter using a pen or create a ruler using a cholangiography guide [6]. (Figure 36.6a–h shows a ruler made using a guide wire with graduations of 5 mm. In addition to its low cost, black and white are visually contrasting and thus facilitate measurements by endoscopy.)

Therapeutic Endoscopic Technique

After the selection of the patient and indication criteria, the type of therapy to be used must be chosen. Basically, we can use endoscopic suturing mechanisms or simply use argon plasma coagulation. The use of sutures allows the concomitant treatment of a dilated anastomosis and a large pouch, or the treatment of one or the other in isolation. The main disadvantages, which can be very important in some places, are that this technique has a high cost and needs a service of high

complexity. However, it can be performed in one session. Argon plasma coagulation can only be employed to narrow the anastomosis as it is not indicated in cases of enlarged pouches. If the cost is low, it is more accessible and does not need a service of high complexity, with sedation being the means of anesthesia. On average, it is necessary to perform three sessions every 2 months to have the desired result, which, at least, brings the patient to the doctor's office more often, improving the possibility of follow-up care.

We describe below the techniques most commonly used for the endoscopic treatment of enlarged pouches and dilated gastrojejunal anastomosis:

- *Narrowing the pouch using endosuturing devices*

  1. General anesthesia with orotracheal intubation.
  2. The decubitus position can be used. We prefer the left lateral decubitus position.
  3. Evaluate the gastric chamber.
  4. Introduction of the overtube and the endosuturing device.
  5. After treating the anastomosis (if indicated), start suturing using 2–0 Prolene thread in the distal to proximal direction.
  6. The sutures should be performed in such a way that the great curvature is stitched employing plicatures of the anterior and posterior walls; they may be running sutures in U or in X.
  7. The proximal pouch (2 cm below the esophagogastric transition) can be spared depending on the technical difficulty.
  8. The final format should be a narrow gastric tube with a narrow passage for the double-channel endoscope.

- *Narrowing of the anastomosis using OverStitch*™ (Figs. 36.2a–d, 36.3a–d, and 36.4a, b)

  1. General anesthesia with orotracheal intubation.
  2. The decubitus position can be used. We prefer the left lateral decubitus position.
  3. Evaluate the gastric chamber.
  4. Introduction of the overtube and the endosuturing device.
  5. Perform ablation with argon plasma (2 L/70 W) around the anastomosis.
  6. Perform suturing starting at the small curvature using 2–0 Prolene sutures.
  7. Sutures can be made in the following sequence starting from the right side and following to the left of the monitor: anterior wall, small curvature (great curvature when on the left), and posterior wall.
  8. Complement with separated sutures from one side to the other until there is a small central gap that allows the passage of a standard-sized endoscope.

- *Narrowing of the anastomosis using argon plasma* (Figs. 36.5 and 36.6a–h)

  1. Patient in left lateral decubitus position under sedation.
  2. Evaluation of gastric chamber and anastomosis.
  3. Adjust flow (2 L/90 W) and purge catheter.

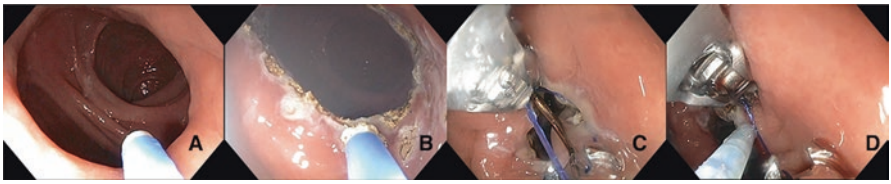

Fig. 36.2 Endoscopic image of anastomosis treatment using the Apollo device: (**a**). View of anastomosis size; (**b**). Circumferential ablation of anastomosis using argon plasma; (**c**). View of suturing device; (**d**). View of securing tissue using Helix forceps

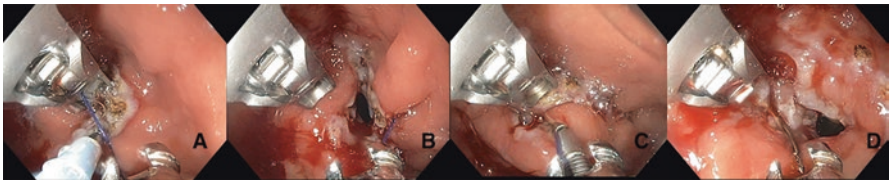

Fig. 36.3 Endoscopic image of securing tissue using Helix forceps: (**a**). Draw the tissue into the suture device; (**b**). Suture; (**c**). Traction of the tissue with needle holder; (**d**). Final view of anastomosis after suturing

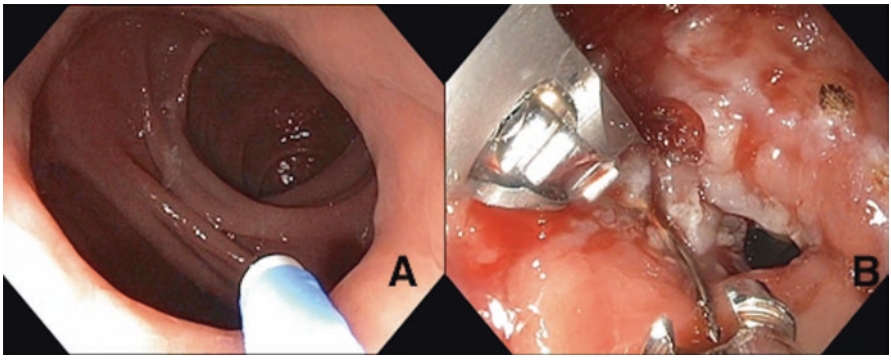

Fig. 36.4 Comparative endoscopic image: anastomosis before (**a**) and anastomosis after (**b**) application of argon plasma and suturing

4. Test plasma on gauze soaked with saline solution.
5. After evaluating the anastomosis, mark four cardinal points in transition anastomosis/jejunal loops with argon (small curvature, great curvature/middle of the anterior wall, and middle of the posterior wall).
6. Perform ablation (one quadrant at a time) without touching the mucosa and always evaluating the submucosal dissection by gas and distension of the jejunal loops, after each quadrant aspirate all gaseous contents from the efferent loop (Fig. 36.5).
7. Perform ablation of the entire circumference and up to 1–2 cm proximal (Fig. 36.6a–h).
8. Review burns and aspiration of gaseous contents of jejunal loops.

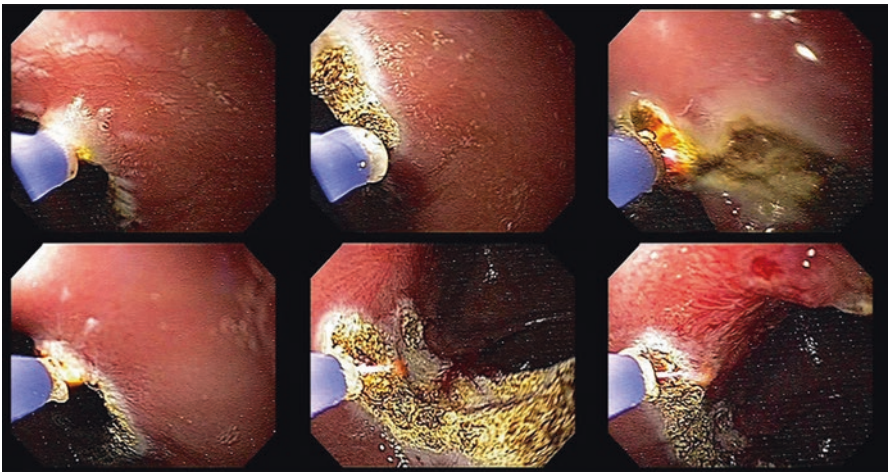

Fig. 36.5 Endoscopic sequence of the ablation using argon plasma performed in the quadrant without contact between the forceps and the gastric mucosa (sequence from left to right on the upper column and inferior column)

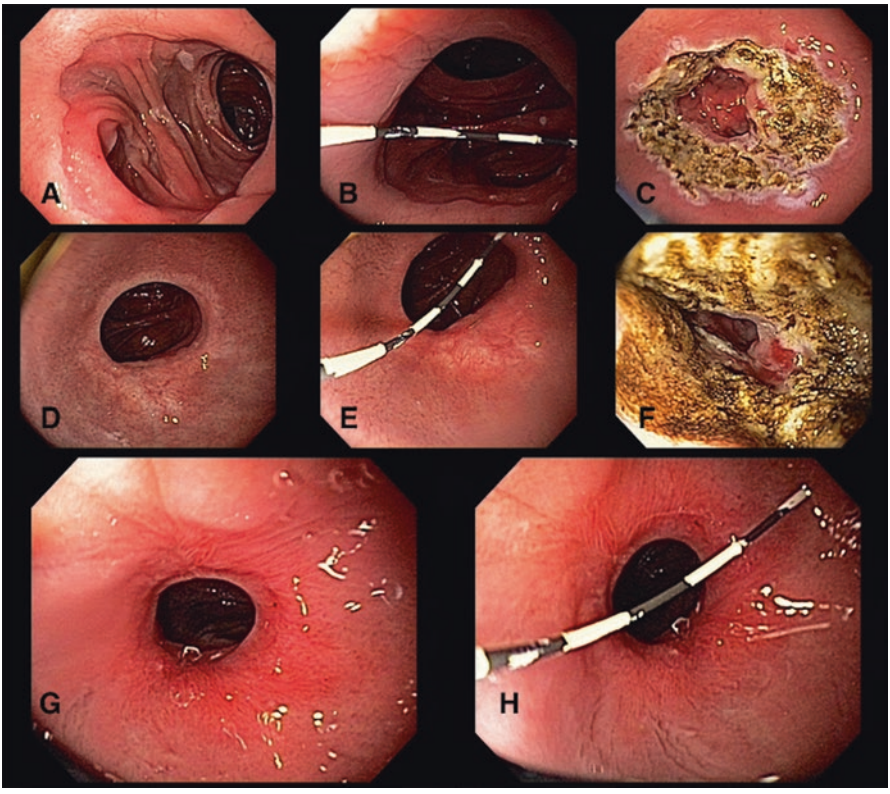

Fig. 36.6 Sequence of endoscopic images with application of argon plasma: (**a**). Size of the anastomosis before the first argon session; (**b**). Measurement of the anastomosis with graduated ruler; (**c**). Application of argon plasma; (**d**). View of anastomosis 2 months after application of argon plasma; (**e**). Measurement of the anastomosis; (**f**). Second application of argon plasma; (**g**, **h**). Final size of the anastomosis measuring 10 mm

Discussion

Weight regain is associated with decreased quality of life and recurrence of comorbidities [3, 19]. Thus, endoscopic techniques have been developed in an attempt to effectively reduce the anastomotic diameter and consequently reduce weight.

Abnormal anatomical findings were found in 71.2% of patients who fail to maintain weight loss; 58.9% had dilated gastrojejunal anastomosis, 28.8% had pouch enlargement, and 12.3% had alterations to both [20]. Several methods have been proposed for the endolumenal reduction of the gastrojejunal anastomosis in patients submitted to gastric bypass for weight reduction. These include endolumenal reduction of the gastrojejunal anastomosis (EndoCinch®, Bard®, Billerica, MA, USA), the ROSE procedure (restorative obesity surgery, endolumenal; USGI®, San Clemente, CA, USA), StomaphyX (EndoGastric Solutions®, Redmond, WA, USA), OTSC Clip (Ovesco AG®, Tubingen, Germany), OverStitch™ (Apollo Endosurgery®, Inc. Austin, TX, USA), and coagulation of the gastrojejunal anastomosis with argon. [1, 4, 6, 8, 10, 12, 13, 15, 16, 19–21].

Techniques of endosuturing of the gastrojejunal tract have been employed to manage complications over years of clinical practice. In 2006, Thompson and coworkers demonstrated the applicability of this method to treat weight regain in eight patients with dilated gastrojejunal anastomosis following gastric bypass. The mean diameter of the anastomosis was 25 mm, with the procedure reducing the diameter by 68% of the initial size (mean final diameter of 10 mm). The percentage excess weight loss was 23.4% [19].

The endoscopic system Over the Scope Clip (OTSC Clip, Ovesco AG) has also been used to reduce the diameter of the gastrojejunal anastomosis in patients with post-gastric bypass weight regain. In 2011, Heylen and coworkers performed this procedure in 94 patients who had an average dilated gastrojejunal anastomosis of 35 mm in diameter and a 10% weight regain. Generally, one to two clips were applied with the final mean anastomotic diameter being 8.0 mm achieving a mean excess weight reduction of 80%. The body mass index (BMI) at 1 year of follow-up reduced on average from 32.8 kg/m^2 to 27.4 kg/m^2 [22].

The use of argon plasma to reduce the size of the dilated anastomosis has been shown to be an effective and safe method in the treatment of weight regain. Argon coagulation reduces the diameter of the anastomosis and consequently delays gastric emptying and early satiety and improves weight reduction [8, 20]. Reducing the diameter of a dilated anastomosis may lead to a 23.0% reduction in excess weight. From the endoscopic point of view, information such as the diameter of the anastomosis, complications after bariatric surgery, follow-up with specialized staff, and physical activity contribute to a better indication in patients who regain weight after gastric bypass.

In this context, one study compared the relative efficacy of transoral outlet reduction (TORe) and the use of argon plasma coagulation at 3 and 6 months to treat weight regain after gastric bypass (RYGB). Ten consecutive patients were submitted to TORe using a plicature of interrupted tissue. The results were compared with 20 patients submitted to argon plasma coagulation. The mean age was 50.9 ± 1.7 years

with a pre-RYGB BMI of 46.7 ± 1.1 kg/m^2. The nadir of the BMI was 28.8 ± 0.8 kg/m^2. TORe was performed 10.5 ± 0.9 years after RYGB, with a pre-TORe BMI of 36.6 ± 1.0 kg/m^2. The mean gastrojejunal anastomosis aperture was 18.5 ± 0.7 mm. The mean number of treatments with argon plasma coagulation was 1.3 (range 1–4). There were no major adverse events. The results of weight loss were better for patients submitted to the application, both at 3 and at 6 months. Larger and longer-term studies are needed to assess differences in the durability of these results.

In one study by Baretta and coworkers (2015), 30 patients were submitted to 3 endoscopic sessions (on average) of argon plasma coagulation at 8-week intervals with an intensity of 70 W at 2.0 L/min. In their results, they reported a mean weight loss of 15.0 kg. The long-term results are still pending. The coagulation of the anastomosis with endoscopic argon plasma can be performed serially and as often as needed as described above. Endoscopic controls should be performed frequently, seeking to prevent this probable dilatation and, consequently, further weight regain [8].

In conclusion, when well indicated and accompanied by a specialized multidisciplinary team, endolumenal procedures are safe and effective to treat weight recidivism and provide good results.

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Chapter 37
Conversion and Revisional Surgery: Sleeve Gastrectomy

Andrew T. Strong and Javed Ahmed Raza

Introduction

The sleeve gastrectomy (SG) was developed as a component of the biliopancreatic diversion with duodenal switch. The origin of this procedure has been alternately attributed to both Hess [1] and Marceau [2], both reporting their initial experience with the duodenal switch in the late 1980s and early 1990s. It was not until the early 2000s that interest formed for the sleeve first as a staged procedure prior to biliopancreatic diversion and later as an isolated weight loss operation [3]. The first edition of this text included sleeve gastrectomy in the context of a staged operation, with no chapters specifically dedicated to sleeve gastrectomy as a stand-alone procedure [4]. Since that publication, the sleeve gastrectomy has become increasingly standardized [5] and has been the subject of several international conferences, including five international consensus statements regarding current best practices related [6–10]. The American Society of Metabolic and Bariatric Surgeons (ASMBS) made a position statement supporting SG as a stand-alone procedure in 2007, which was updated in 2012 [11, 12].

Other chapters in this text have reviewed details of operative techniques for SG, comparative outcomes, as well as complications of sleeve gastrectomy. Here we focus on surgical revision of the sleeve gastrectomy. The history of revisions from sleeve gastrectomy is unique within the field of re-operative bariatric surgery as the SG has been considered revisable from its inception as a stand-alone procedure [13]. This fact has been reflected in each of the international consensus statements,

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where consideration of preferred revisional operations, surgeon experience, and descriptions of techniques for conversion have been included [6–10].

A recent systematic review published by the ASMBS established a nomenclature for re-operative bariatric surgery, which will be used within this chapter. *Conversion* refers to surgical procedures that alter the anatomy of an index bariatric operation to a different type of procedure or anatomy. *Corrective* surgery, on the other hand, addresses complications or incomplete treatment effects of an index bariatric operation. The systematic review also defines *reversal*, but this generally does not apply when sleeve gastrectomy is the index operation, since the resected portion of the stomach cannot be restored [14].

Defining Failure of Bariatric Surgery for the Purpose of Revision

Numerous publications have reported definitions of failure of bariatric surgery, but no consensus definition exists. Publications cite the 1991 consensus guidelines for bariatric surgery published by the National Institutes of Health (United States of America) [15] and/or the Reinhold criteria [16], though both lack precise definitions of failure [17]. Most commonly, failure of bariatric surgery is defined in terms of weight loss outcomes, including failure to achieve a threshold percent excess weight loss (%EWL), or weight recidivism after initial weight loss. In some circumstances, failure to improve, recurrence, or development of de novo obesity-related comorbidities constitutes failure of bariatric operations in published literature. The general term, "weight loss failure or weight recidivism" will be used in this chapter.

Summary of Indications for Revising a Sleeve Gastrectomy

In our view, revisions following SG generally fall into two categories. In the early term, SG revisions or conversions address perioperative complications, while later revisions correct mechanical or functional abnormalities of the sleeve. Specific indications for early revision include acute and early leak from the staple line, and perforation [14]. Later revisions are typically for stenosis, stricture, a helical twist of the gastric pouch, or medically refractory gastroesophageal reflux disease [14]. Conversions may also occur for weight loss failure, weight recidivism, or a planned second-stage bariatric procedure. Revision in these settings is an attempt to produce additional weight loss rather than intervene upon a primary pathology of the sleeve.

The number of surgeries to correct SG complications or convert to another operation is not known. Overall, there is a trend toward an increasing number of revisional operations occurring annually. Estimates of the rate of conversion or corrective procedures from SG in reported literature are variable and are largely

dependent upon the inclusion of planned revisions, the length of follow-up, and whether the hospital is a referral center. One single-center series of 1118 patients undergoing primary SG reported 30 revisions (2.7% revision rate), though they point out only 9 had their index operation at their institution (0.8% same-institution revision rate) [18]. Another single-center series of 630 patients included 12 conversions (1.9% revision rate) [19]. One of the few multicenter studies followed 110 patients, for a mean of 11.7 years of follow-up period, and reported that 20 patients eventually underwent revision (31.7% conversion rate) [20]. As follow-up periods increase, it is likely that rates of SG revision will increase. Revisional bariatric surgery is associated with in increased risk of complication compared to equivalent primary bariatric operations [21, 22]. As a result current recommendations advise that revisional operations take place in centers with capabilities to provide multidisciplinary pre- and postoperative care and that operations be performed by experienced bariatric surgeons [14].

Key Technical Aspects of Surgical Revision of Sleeve Gastrectomy

While each corrective or conversion surgery has unique technical aspects, some key points emerge as a theme when revising SG. Approaching revisional bariatric surgery from a laparoscopic platform, even when prior operations were performed open, has been shown to be a reasonable option [23, 24]. The advantages of laparoscopy in terms of earlier ambulation, decreased hospital length of stay, and earlier return to work compared to laparotomy are particularly true in re-operative bariatric surgery. In preparation for SG revision, upper gastrointestinal series and upper endoscopy should be performed for patients undergoing corrective surgery. In the setting of weight loss failure or weight recidivism, either study may also reveal a dilated sleeve, which has implications for choice of operation, and should be evaluated preoperatively. We have found that having upper endoscopy performed by the same individual eventually performing SG revision is particularly useful, as it more easily facilitates intraoperative comparisons to the preoperative state. Esophageal manometry and pH probe studies may also be indicated in some patients, especially in the setting of gastroesophageal reflux disease and regurgitation.

In the operating room, patients are generally positioned supine. Preoperative prophylactic antibiotics are given. Gaining access to the peritoneum can be established with a Veress needle or optical entry trocar but should be performed away from any prior surgical incisions to minimize risk of inadvertent visceral injury. As the vast majority of SG operations have been performed laparoscopically, intra-abdominal adhesions are typically not severe; however, in the presence of a staple-line leak, there can be significant adhesive disease in the left upper quadrant. The surgeon should not hesitate to place additional 5 mm trocars to facilitate adhesiolysis and delineate anatomy. Adhesions between the gastric sleeve the left lobe of the liver are

common. Dissecting this plane early in the operation allows placement of a liver retractor, which greatly aids in visualization for the remainder of the case. The specific port configuration used will vary based on surgeon preference, preferred operating position, and the planned operation. Generally at least one trocar of 10–12 mm is needed to accommodate laparoscopic linear staplers or suturing instruments. A 30 or 45 degree laparoscope is typically used, with the patient positioned in reverse Trendelenburg for the majority of the operation. Prior to beginning the operation, consideration should be made for postoperative nutrition. In our practice, enteral access tubes placed in either the proximal jejunum or in the excluded distal stomach in the case of a conversion to Roux-en-Y anatomy are used liberally, especially when preoperative nutrition has been compromised by sleeve pathology. Closed-suction drains are used electively.

Revision/Conversion to Treat Leaks and Staple-Line Disruption

Staple-Line Leak After Sleeve Gastrectomy

Estimates of staple-line leak after SG vary from 0.7% to 7.0% in reported literature, most in the 1–2% range [25]. Most leaks occur near the angle of His, at the esophagogastric junction, and decrease with individual surgeon experience [26]. Proximal leaks behave differently from distal staple-line leaks [5]. A systematic review of more than 8000 cases reported a leak rate of 2.1% [27]. In the largest study of SG to date, a consensus panel of high-volume bariatric surgeons accrued results of more than12000 patients and reported a leak rate of 1.06% [5]. That same study established the convention for classifying staple-line leak based on time of presentation after surgery: acute leaks present within 7 days of operation, early leaks within 1–6 weeks, late leaks after 6 weeks, and chronic leak after 12 weeks [5].

Numerous reasons exist or more likely coexist to result in gastric leaks after sleeve gastrectomy. The preservation of the pylorus and narrow lumen, removal of the capacitive gastric fundus, and low compliance each contribute to increase intraluminal pressure of the sleeve [13, 28]. This may be in combination with relative stenosis at the mid-gastric body or the gastric outlet [13]. Narrower caliber sleeves, as measured by the size of the sizer, increase the risk of leak [5]. In addition to pressure dynamics, foreign material (suture, staples, and staple-line reinforcement materials) coexists within a milieu of impaired tissue healing, inadequate blood flow, systemic poor oxygenation, and infection. Lastly, energy devices used to divide the short gastric vessels during mobilization of the proximal stomach have been linked to thermal injury [13].

Surgical Therapy for Acute and Early Staple-Line Leaks

All acute staple-line leaks and some early leaks are best managed by reoperation, and laparoscopy is generally possible as adhesions are not yet robust or highly vascularized [25]. The goal of the operation should not be to close the defect, as high intragastric pressures, local inflammation, and the frequent presence of abscesses make this unlikely to be successful [13]. Rather, the goal of reoperation for acute leak should be evacuation and debridement of infected tissue with drain placement [25]. In the acute perioperative period, laparoscopy is typically successful, and the same trocar sites can be used. In a patient who is hemodynamically unstable, an omental flap should be sutured in the disrupted portion of the staple line if technically feasible [25]. Following operation, nutritional support is a key element of the treatment for these patients. A feeding jejunostomy should be considered at the time of laparoscopy as a means of provide durable enteral access for nutrition distal to the leak site.

For stable patients with early proximal gastric leaks, initial management with endoscopic stent placement alone or in combination with endoscopic clips or fibrin glue is a reasonable option, though success is variable. Specific details of these techniques are reviewed elsewhere in this text. Failure to close a staple-line leak fistula within 6–8 weeks with endoscopic therapy may warrant reoperation [13]. Endoscopic therapy is less successful when initiated for chronic leaks, though it may temporize an operation, allowing for nutritional augmentation prior to undertaking a revisional operation. Patients developing tachycardia or fever, or other signs consistent with sepsis or peritonitis at any point, warrant operative exploration.

Surgical Therapy for Late and Chronic Staple-Line Leaks

Late and chronic leaks after SG follow a separate management paradigm than acute and early leaks. In the setting of chronic leak, preoperative nutritional optimization is essential [18]. Enteral nutrition is preferable when possible. Upper gastrointestinal series are useful to delineate anatomy of chronic leaks and communication with potential abscess cavities or fistulas to other hollow organs.

Surgical intervention for late and chronic leaks almost invariably involves conversion to another anatomic configuration. In some cases proximal leaks can be completely resected while preserving a small cuff of stomach tissue; however, total gastrectomy with en bloc fistulectomy and Roux-en-Y esophagojejunostomy reconstruction is more likely necessary [18, 29]. One paper estimates that as many as 1/3 of patients with chronic leaks will eventually need total gastrectomy [30]. One center has published their experience with 12 patients requiring total gastrectomy as a definitive therapy for chronic proximal sleeve leak with no mortality and minimal morbidity [31]. This is similar to other smaller series [32, 33]. In some circumstance,

isolated proximal gastrectomy is possible, which, while still necessitating Roux-en-Y esophagojejunostomy, preserves the distal stomach as a conduit for enteral access. Two separate series from the same institution report favorable results of this approach [34, 35].

Operative management is more complicated when chronic leaks develop into fistulas to other cavities or organs. Surgical options for these often involve multidisciplinary care, and prolonged hospitalization is common. The general principles of treating these complex fistulas are to drain/control sepsis and optimize nutritional status and physical therapy and rehab prior to surgical intervention followed by appropriate surgical intervention. Interventional radiology and advanced endolumenal procedures play an increasingly significant role in preparing these patients for surgical intervention. When adequately prepared, the operative goals are to resect the entire fistulous tract and reconstruct as possible. For some fistulas into the thoracic cavity, eventual esophagectomy has been described as a final, definitive operation [36].

Published series cited in this section largely report technical feasibility and favorable short-term outcomes; however, the authors offer a caveat to these favorable results. Each is a result of single center, usually a single surgeon with extensive experience performing revisional bariatric surgery, and as such generalizability is likely limited. Thus we recommend that complex revisional surgery should be undertaken at centers that have experienced multidisciplinary bariatric teams and full support structure in terms of surgical critical care, interventional radiology, and nutritional support services.

Revision/Conversion to Treat Mechanical Complications: Stenosis, Stricture, Twist, and Gastroesophageal Reflux Disease

Purely Mechanical Complications of Sleeve Gastrectomy: Stricture, Stenosis, and Twist

A number of mechanical problems can occur with sleeve gastrectomy, including stenosis, twist, and altered motility contributing to gastroesophageal reflux disease (GERD). Fixed stenosis and functional stenosis resulting from a longitudinal helical twist of the gastric sleeve typically present with obstructive symptoms. The initial presentation may be as few as days after the index operation but more commonly appears weeks to months later as more solid food is introduced. Estimates of the incidence of sleeve stenosis range from 0.6% to 4% in reported series; however, not all series separate fixed mechanical stenosis and functional stenosis [37]. In a single-institution series including 230 patients, there were eight patients who had symptomatic sleeve stenosis (3.5%). Compared to patients without stenosis, patients with stenosis were younger and had staple-line reinforcement; four of the patients had

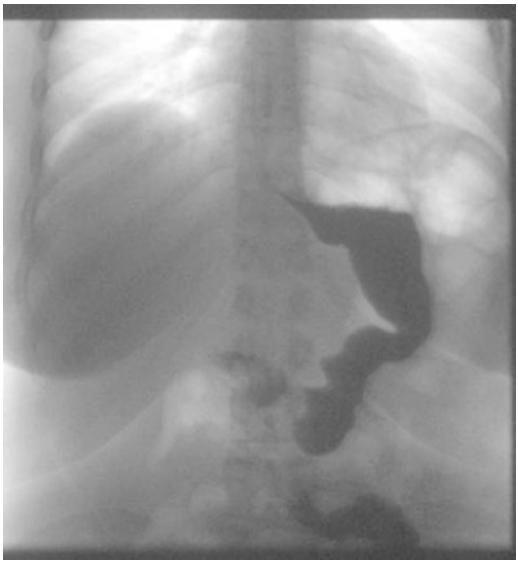

Fig. 37.1 Fluoroscopic image of the gastric phase of a contrast-enhanced upper gastrointestinal series depicting narrowing at the incisura of the stomach. Note the abrupt caliber change at the incisura and mild proximal dilation of a gastric sleeve

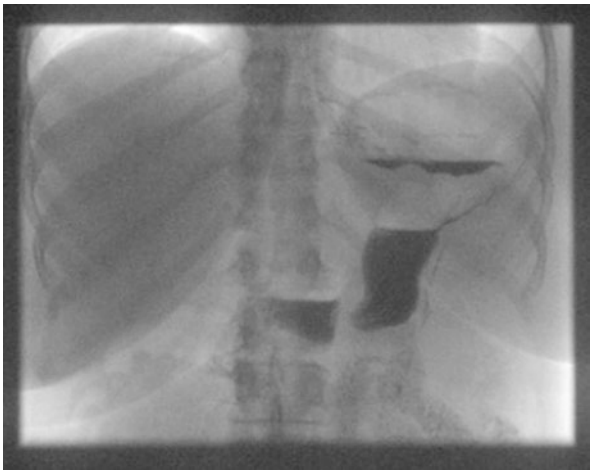

Fig. 37.2 Fluoroscopic image of the gastric phase of a contrast-enhanced upper gastrointestinal series depicting severe twist of a gastric sleeve with associated proximal gastric dilation

segmental imbrication of the staple line as well [37]. Fixed mechanical stenosis most commonly occurs at the incisura and does not depend on the dilator size (Fig. 37.1). Over-retraction of the greater curvature stretches the stomach before and during stapled division. Once the dilator is removed, the tissue recoils, creating a fixed narrowing [37]. A twisted or spiral sleeve is generated from a progressive rotation of the staple line traveling anterior to posterior and inferior to superior (Figs. 37.2 and 37.3).

Upper gastrointestinal series is a sensitive diagnostic test for stenosis, given that it is obtained at least a few days after the operation, as abnormal contrast appearance is common in the early postoperative period [37]. Following upper gastrointestinal

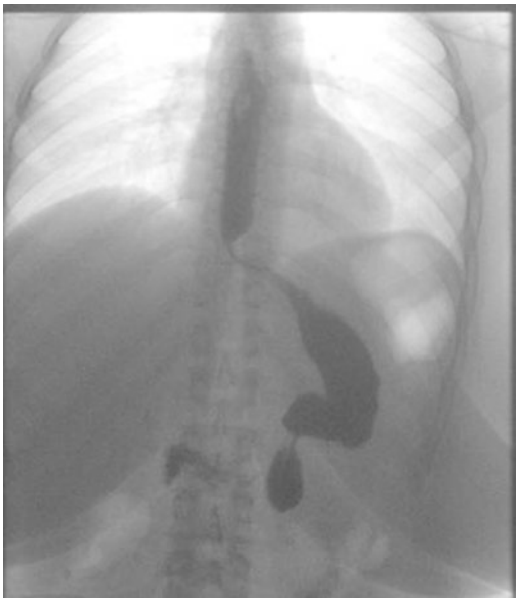

Fig. 37.3 Fluoroscopic image of the gastric phase of a contrast-enhanced upper gastrointestinal series depicting typical appearance of functional obstruction of a gastric sleeve. Note the "apple core"-like appearance in the mid-gastric body and delayed transition of contrast from the esophagus to the stomach

series, upper endoscopy allows visual inspection of the sleeve [37]. Differentiating fixed and functional obstructions during upper endoscopy is possible. In the case of a sleeve twist, twisting the endoscope with the curve of the staple line allows easy passage to the pylorus, compared to fixed mechanical narrowing that typically occurs at the incisura where such passage is difficult or impossible [37, 38]. We caution that a helical twist can be easily missed by the endoscopist unless specifically looking for this abnormality, as insufflation can straighten the twist and allow unimpeded scope passage. The upper gastrointestinal series should be carefully studied prior to endoscopy, especially if there is clinical suspicion for a twist. A dilated fundus may be found in association with a twisted sleeve.

Surgical Options to Correct Sleeve Stenosis

The first international consensus conference convened for sleeve gastrectomy proscribed a stepwise approach for sleeve strictures and stenosis: observation, endoscopic dilation, seromyotomy, and conversion to RYGB [5]. Endoscopic intervention, including pneumatic dilation, and endoscopic stent placement are first-line therapies for stenosis discovered after the immediate perioperative period. Success rates for endoscopic therapy for sleeve stenosis have been reported as high as 88–94% [38, 39].

Early strictures/stenosis benefit from reoperation, as they are typically due to either mural hematoma or a single imbricating stitch, which can be released [25]. This likely explains a strong correlation between early diagnoses of sleeve stenosis

and better outcomes [40]. Preoperative upper endoscopy is required prior to early reoperation so that intraoperative repeat endoscopy can confirm correction of the stenosis. The operative approach is typically laparoscopic, and the same port sites can be reused. Once intraoperative endoscopy has identified the location of stenosis, previously placed sutures can be simply cut with laparoscopic scissors.

For patients that fail endoscopic therapy for sleeve stenosis, corrective surgery with seromyotomy has been described [41, 42]. Longer stenotic segments are associated with failure of endoscopic therapy and have also been shown to be the most amenable to resolution with seromyotomy. Seromyotomy is typically performed laparoscopically. Following trocar placement and enterolysis, the stenotic segment is identified with intraoperative endoscopy. Under magnified laparoscopic vision, the serosa and muscle fibers of the anterior gastric wall are divided in the stenotic region and 1 cm proximal and distal using electrocautery, preserving the mucosa intact. This technique is analogous to a pyloromyotomy undertaken for pyloric stenosis. An omental buttress is then usually sutured in place over the exposed mucosa [41]. While this technique has been shown to be successful in some centers, the risk of delayed perforation due to thermal injury to the mucosa likely limits its generalizability, and we do not advocate this treatment as a routine.

Conversion to RYGB is considered a definitive therapy for stenosis of the midbody of the gastric sleeve and is likely the most common revisional operation performed in the setting of sleeve stenosis. Conversion to RYGB can be completed laparoscopically in most cases. Port placement should mirror port sites utilized for primary RYGB. Once the gastric sleeve has been freed from adhesions to the liver and the retroperitoneum, the sleeve is transected with a linear stapler proximal to the stenosis to create the gastric pouch [25]. The left gastric vascular pedicle should be identified and preserved with the pouch. Gastrojejunal anastomosis can be fashioned with end-to-end anastomotic staplers, linear staplers, or fully hand-sewn techniques. The distal stomach can be retained in situ, or resected, excising the stenotic segment.

Preservation of the distal stomach provides a location for enteral access to be placed, which is advisable if the patient has had an extended period of poor nutrition preoperatively. In some severe cases of stenosis, total gastrectomy may be necessary [25].

The Relationship Between Gastroesophageal Reflux Disease and Sleeve Gastrectomy

Gastroesophageal reflux disease, obesity, and SG exist within a complicated interplay. Numerous studies and reviews are dedicated to this topic alone [43–46]. GERD in the obese patient is non-controversial, as increased BMI, or more correctly, increased waist circumference, is strongly associated with an increased transgastric pressure and thus an increased gastroesophageal pressure gradient [44, 46].

Concomitant hiatal hernias are often also present in the obese population, which may only become symptomatic after SG. There is accumulating evidence that obesity is a risk factor for esophageal dysmotility as well and may contribute to GERD. In published series, the prevalence of esophageal dysmotility among obese individuals ranges from 20% to 61% [47]. When tracked within a prospective series, a significant proportion of obese patients undergoing bariatric surgery had preoperative esophageal motility disorders, including defective lower esophageal sphincter (16%), hypertensive lower esophageal sphincter (18%), diffuse esophageal spasm (3%), nutcracker esophagus (5%), ineffective esophageal motility (2%), and nonspecific motility disorder (23%) [48].

Following SG, the natural history of GERD and reflux symptoms becomes unclear. In some series, improvement in GERD symptoms has been documented following SG. Putatively, this is due to a number of factors, including reduction in intra-abdominal pressure from weight loss, reduced acid production from removing parietal cell mass, accelerated gastric emptying, and reduced gastric volume [46]. Altieri and Pryor reviewed several studies that support improvement in GERD after SG [43]. However, numerous studies show the converse relationship with GERD either worsening or developing de novo after SG. This may be due to a combination of factors, including lack of gastric compliance; increased intragastric pressure; removal of the capacitive gastric fundus; unrepaired, persistent, or recurrent hiatal hernia; and technical issues with sleeve construction including the aforementioned twist and stenosis or underlying esophageal dysmotility [46]. A recent series of 100 patients with a mean follow-up of 8.5 years after laparoscopic SG showed 47.8% of patients developed GERD and/or were continued on antisecretory medication in the form of proton pump inhibitors following SG. The relative risk of developing GERD was 2.59 after SG [49]. Other series have a much lower estimate of post sleeve GERD of 3% [50]. A multicenter retrospective review showed that patients with GERD prior to SG were not cured of their GERD during 11-year follow-up [20]. Other series have demonstrated that GERD tends to improve over the first 1–3 years after SG [51, 52]. Altieri and Pryor review as well studies that demonstrate worsening and development of de novo GERD after SG [43]. For patients who develop de novo GERD after SG, medical therapy should be attempted first [25, 43, 50].

Surgical Options for Gastroesophageal Reflux Disease After Sleeve Gastrectomy

Prior to pursuing an anti-reflux procedure or attempted surgical intervention for GERD post SG, the sleeve itself must be evaluated. Development of new GERD symptoms more than 6 months after SG is often related to either a twist in the sleeve or a stenosis. Often there is either an associated hiatal hernia or excess retained fundus. In these situations, cruroplasty alone is unlikely to improve the symptoms. Radiographic and endoscopic investigations should be completed prior to planning

any intervention with attention to the presence of esophagitis, Barrett's esophagus, or possibly malignant lesions. Esophageal manometry is a reasonable adjunct as well, since the presence of esophageal dysmotility may eliminate some treatment options. A pH probe study is generally indicated as well to establish symptom correlation with acid exposure.

Since the majority of the gastric fundus is excised during SG, fundoplication is not an option at anti-reflux operations. In our practice, when it is feasible and safe to perform, dissection of the hiatus is performed routinely for patients undergoing revision or conversion where GERD is the primary indication. We have found that small hiatal hernias are often present. In cases where hiatal hernia is the only abnormality discovered, then cruroplasty and/or gastropexy with no change to the gastric sleeve has been reported to relieve reflux symptoms [25]. However, in most centers, cases of GERD post SG that are refractory to medical therapy undergo conversion to RYGB [25, 49]. In this setting RYGB functions as a parietal cell-separating procedure, isolating the bulk of remaining parietal cell mass from direct luminal connection to the distal esophagus. The presence of Roux-en-Y anatomy also prevents bile reflux where that was contributory to reflux symptoms. In some centers, GERD is the most common reason for conversion from SG to RYGB [19, 53]. A recent single-center series of 22 patients found 100% GERD symptom relief after conversion of SG to RYGB [54]. Studies have also demonstrated reversal of Barrett's esophagus following RYGB; however, it is not clear if this is also true after conversion from SG [55, 56]. Conversion from SG to RYBG for GERD can typically be performed laparoscopically. Whether to retain an excluded portion of the stomach or resect to reduce parietal cell mass has not been well studied. As in the case of SG to RYGB conversion for stenosis, retaining the distal stomach provides an access point for enteral access should this be necessary at the time of revision or later.

There may be additional laparoscopically placed devices and/or endoscopic therapies that emerge as viable option to treat medically refractory GERD after SG in the future. Small trials have been performed using magnetic sphincter augmentation to treat GERD after SG with favorable results (LINX® Reflux Management System; Torax Medical, St. Paul, Minnesota) [57]. Also currently underway is a prospective multicenter trial to investigate efficacy of radio frequency ablation in the distal esophagus to treat GERD after SG (Stretta ®, Mederi Therapeutics, Inc., Norwalk, Connecticut) [43].

Revision/Conversion to Treat Failure of Weight Loss, Weight Recidivism, or Recurrence of Comorbidities

Despite overall excellent weight loss and metabolic improvement after SG, it is not universally effective. A significant number of patients fails either to lose adequate weight or regain weight after a period of initial weight loss. Conversions in this setting may provide additional weight loss or metabolic benefit. Prior to any further

surgical procedures, patients should be assessed by multidisciplinary bariatric team. Correctable patient-related factors should be taken into consideration and addressed where applicable. These may include psychiatric care, nutritional education or reeducation, medically supervised weight loss, exercise education, or correction of endocrinopathies. In some cases, pharmaceutical appetite suppressants may be used as an adjunct. Following maximal noninvasive therapies, a patient may be considered for operative intervention. As most cases of weight recidivism or failure of weight loss after SG correlate to an increase in gastric volume demonstrable on either endoscopy or radiographic studies, both are recommended as routine preoperative investigations [58]. There is some thought that patients, with weight regain after initial sleeve, may regain weight a second time after revision [59, 60]. However, revision or conversion from SG to another operation generally facilitates a favorable additional weight loss.

Re-sleeve for Weight Loss Failure or Weight Recidivism

Re-sleeve was introduced as an option by Iannelli and colleagues, wherein a new vertical staple line divides a dilated gastric sleeve, creating or restoring conventional sleeve anatomy over a standard-size dilator. Putatively, advantages of re-sleeve are reduction in gastric volume thus decreasing gastric output, less dumping syndrome due to preservation of the pylorus, decreased risk of vitamin deficiencies, and faster operative times [61]. However, increased risk of sleeve leak should be seriously considered and patient counseled appropriately. Re-sleeve should not be considered if GERD is present [51, 62].

Consideration of re-sleeve should typically be reserved from those patients where the initial sleeve was too wide or secondary dilation occurred [51]. Indications for re-sleeve are either weight recidivism or less than <50% EWL at 1 year post sleeve gastrectomy, in conjunction with radiographic evidence of persistent gastric fundus or dilation of gastric body on an upper gastrointestinal series [63]. For patients not meeting these radiographic criteria, later study included residual gastric volumetry as a differentiating test in the setting of weight recidivism [62]. A standard mass of sodium bicarbonate and tartaric acid were ingested followed by 30- and 60-second computed tomography scans to calculate gastric volume. A gastric volume over 250 cc was considered for re-sleeve, while gastric volume <250 cc was referred for additional evaluation to consider conversion to either RYGB or biliopancreatic diversion with duodenal switch [62]. Dilation of the gastric sleeve is classified into primary and secondary dilation. Primary dilation is defined as upper posterior gastric pouch that was incompletely dissected at the index operation, which is likely not true dilatation, but rather a technical failure of the primary procedure to resect the fundus. Determining whether proximal dilation is associated with either a twist or stricture of the mid-body of the stomach is vitally important, as re-sleeve in these situations can lead to higher risk of perforation due to high

intraluminal pressure. Secondary dilation is defined as a homogenously dilated gastric tube >250 cc by radiographic volumetry [61]. In published series the re-sleeve is performed laparoscopically with port placement similar to a primary SG operation. A 34 French dilator is used to size the pouch. In the limited available literature, only one perigastric hematoma and two gastric stenoses have been recorded as complications [61, 62].

Re-sleeve as a revisional operation is confined to only a few centers, and greater study is needed to better characterize operative complications and weight loss and metabolic outcomes. In one series %EWL at 20 months after re-sleeve was 58%, while 74.1%EWL at 12 months is reported from another center [61–63]. There is little comparative evidence of re-sleeve currently published. One nonrandomized retrospective case-control study comparing SG to RYGB conversion and re-sleeve among a population of patients with either weight loss failure or weight recidivism included 24 patients undergoing re-sleeve and 12 undergoing conversion to RYGB. Radiographic sleeve anatomy was used to determine treatment group, where the presence of a dilated gastric sleeve (secondary dilation) prompted re-sleeve, while an "ideal" sleeve anatomy prompted conversion to RYGB. At 12 months following revisional operation, the re-sleeve group had 57%EWL compared to 61% for the SG to RYGB conversion group [64]. Other series have reinforced additional weight loss following re-sleeve, but generally not the same degree as RYGB [60].

Conversion to Roux-en-Y Gastric Bypass for Weight Loss Failure or Weight Recidivism

Conversion from SG to RYGB is likely the most common operation performed for weight loss failure or weight recidivism after SG. The metabolic effects of RYGB performed as a conversion are similar to primary RYGB. Similar to conversion from SG to RYGB for other indications, laparoscopic operations are typically feasible. Careful attention should be paid to the left gastric vascular pedicle, which must be preserved with the gastric pouch. In our practice when weight loss failure or weight recidivism is the primary indication for SG revision, a 150 cm Roux limb and a 50 cm biliopancreatic limb are typically fashioned, identical to primary RYBG. Complications are more common for conversion compared to primary RYGB. A multicenter series including 34 patients undergoing conversion from SG to RYBG, with 31 being for weight regain reported a 11.7% 90-day complication rate [65].

Following conversion from SG to RYGB, almost all patients experience additional weight loss as well as resolution of weight-related comorbid condition. Predicting the extent of additional weight loss with any degree of certainty is difficult, partially due to heterogeneity in the manner in which weight loss is reported after revisional operations. One study of 30 patients showed that patients achieved an additional 30.9%EWL after conversion from SG to RYGB [18]. Another single

center reported an additional ~20% EWL after conversion from SG to RYGB, to a total of 64.6% EWL from baseline [66]. This is similar to the expected %EWL after a primary RYGB. Another series of 22 patients reported a modest weight loss of 2.0–2.5 BMI points for conversion from SG to RYGB, although nearly half of the patients in that series underwent conversion for GERD, not weight loss failure [54]. In recent retrospective case-control study comparing primary RYGB and revisional RYGB, with all patients having prior SG, resolution of co-comorbidities was similar, though primary RYGB resulted in a greater %EWL at 3 years (44 ± 23.3 vs 52.0 ± 26; $p = 0.007$) [67]. A systematic review that included 218 patients that were converted from SG to RYGB demonstrated a 60% EWL at 12 months after revision [60].

Conversion to Biliopancreatic Diversion with Duodenal Switch for Weight Loss Failure or Weight Recidivism

BPD-DS is a less commonly performed procedure both as a planned second-stage procedure and as an additional procedure after weight regain. It requires careful patient selection in terms of their ability to consume higher amounts of protein and compliance with nutritional supplementation and follow-up. Series that include discussion of conversion from SG to BPD-DS for weight recidivism are difficult to find, given the high proportion of patients who undergo BPD-DS as a planned second-stage operation. One of the few is an 11-year longitudinal study with 110 patients (65 available for full follow-up). In that series, 14 patients (21.5%) underwent conversions to BPD-DS for weight recidivism [20].

Conversion from SG to BPD-DS is associated with significant additional weight loss, but is not without risk. A retrospective single-institution study compared SG to RYGB and SG to BPD-DS conversion following 43 patients with 18 converted to RYGB and 25 converted to BPD-DS. Conversion to BPD-DS resulted in greater weight loss after revision (59%EWL vs 23% EWL; $p = 0.008$) at 34-month follow-up. However, BPD-DS was associated with longer operative times and a trend toward greater perioperative complications [68]. This study does include a proportion of patients with planned staged SG to BPD-DS, which likely explains the higher preoperative BMI in the BPD-DS group in that study [68]. Another single-institution retrospective study compared nine patients undergoing SG to BDP-DS conversion to ten undergoing SG to RYGB with weight loss failure or weight recidivism as the primary indication in each case. There were no perioperative complications in either group, though postoperative nutritional deficiencies developed in the three patients in the BPD-DS group [69]. The authors of that study described an algorithm wherein higher operative risk, history of small bowel resections, vitamin deficiencies, prior improvement of hypertension and diabetes after the SG, and a BM less than 50 kg/m^2 at the time of index SG all favored conversion RYGB over conversion to BPD-DS [69].

Revision/Conversion as a Planned Staged Procedure

Given the history of SG, we would be remiss to not at least mention the role SG plays in planned staged procedures for patients who are super-morbidly obese. As stated at the beginning of this chapter, from the outset, SG is considered a revisable and convertible operation [13]. Completing a malabsorptive operation in individuals with super-morbid obesity can be difficult. Patients often present a significant anesthetic risk, needing high airway pressures to maintain ventilation, and often carry a myriad of comorbid conditions that make both anesthetic induction and recovery potentially problematic. Fatty infiltration of the left lobe of the liver makes it larger and more floppy, restricting or obscuring working space around the stomach. The significant thickness of the abdominal wall requires higher pressures to maintain pneumoperitoneum and generates significant torque on the instruments. Lastly, central adiposity creates thickened and foreshortened mesentery, such that reaching intestinal limbs for bypass from the stomach is difficult or impossible. In this setting, a SG can be performed with relative speed and low rate of complications. This often allows a patient to achieve significant weight loss in the ensuing 6–12 months and may aid in resolution of comorbid diseases. Following this initial weight loss, reoperation to convert SG to a malabsorptive procedure is a safer endeavor.

A recent systematic review compared outcomes of SG in high-risk patients with a planned second operation to those undergoing primary SG. Aggregation studies of 1749 patients undergoing primary SG were compared to 821 patients undergoing SG as the first-stage operation. There was a trend toward lower mean BMI (46.6 vs 60.0), lower overall complication rate (6.2% vs 9.4%), and a greater mean %EWL (60.4% vs 46.9%) in the primary SG group, though none of these were statistically significant. Interestingly patients undergoing primary SG have a higher leak rate compared to the higher-risk patients undergoing planned staged procedures (2.7% vs 1.2%; $p = 0.02$) [70]. Inconsistent reporting of metabolic outcomes prevented comparison

It is also important to note that there are a significant proportion of patients who undergo first-stage SG who either achieve sufficient weight loss with the SG or opt out of a second operation. The earliest study to report on this followed 87 super-obese patients (BMI > 50 kg/m^2) undergoing SG with a planned later BPD-DS. The first-stage GS had a 16.04% complication rate, which is far higher than most series of SG. In the time between SG and planned BDP-DS, 15 patients elected to not undergo a second operation, and 8 developed additional medical comorbidities that prevented a second operation. Overall, only 27 out of 85 (31.7%) underwent the planned second-stage operation [71]. Another series showed a 11.4% complication rate for the first-stage SG, with only 41 out of 61 (67.2%) completing the second-stage conversion [72]. In that series there were five re-sleeve procedures and one conversion to RYGB as well [72]. Similar results have been reported in other studies as well [73].

Despite comparatively high complication rates at the initial stage, complications are overall lower compared to single-stage BPD-DS in this patient population. A

two-center case-control study followed 220 patients, 110 single-stage DS and 110 with a planned staged SG to BPD-DS conversion. Only 30 patients (27.2%) went on to second-stage BPD-DS. Among the groups there was no statistical difference in terms of leak, bleeding, hernia formation, bowel obstruction, venous thromboembolism, or hospital length of stay. However, there were 80 patients in the planned staged group that never needed a second operation [74].

Options for planned second-stage procedures for weight loss failure or weight recidivism after SG are not limited to BPD-DS, from which SG was initially developed and RYGB. There is literature precedent for conversion from SG to single anastomosis duodeno-ileostomy (SADI-S), one anastomosis gastric bypass (OAGB), single anastomosis gastroileostomy (SAGI), adjustable gastric band of the previous sleeve gastrectomy, gastric plication, and ileal interposition as well [75]. The paucity of existing literature prevents widespread utilization of these techniques outside of Institutional Review Board approved protocols.

Conclusion

As a stand-alone operation, SG can be an effective operation for many patients, with a favorable morbidity profile. However, numerous indications may prompt corrective operations for conversion after SG. In almost all series, conversions to another bariatric operation have been shown to be safe with either open or laparoscopic approaches. However, consideration of the underlying indication and the patient's anatomy should dictate the decision as to the specific conversion undertaken, revisional bariatric surgery has higher morbidity compared to primary surgery and should be undertaken by experienced bariatric surgeons backed by full multidisciplinary team and facilities to provide postoperative care. Patients being considered for conversion due to weight loss failure or weight recidivism after SG should undergo multidisciplinary team assessment and support prior to surgery; for carefully selective patients, conversion is safe generally associated with additional weight loss and possible resolution of weight-related comorbidities.

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Chapter 38
Conversion and Revisional Surgery: Roux-en-Y Gastric Bypass

Andrew T. Strong and John H. Rodriguez

Introduction

The Roux-en-Y gastric bypass (RYGB) was introduced by Mason in 1967 and was always intended to be a weight loss operation [1], though longitudinal follow-up of patients demonstrated it to be an effective therapy for diabetes as well [2]. Advances were further made, thereby adapting RYGB to a laparoscopic technique and later robotic technique [3, 4]. Those developments, specifics of the operative technique, and review of complications are detailed elsewhere in this text. Here reasons for revision of RYGB are reviewed. The first edition of this text included a related chapter regarding revision of RYGB, detailing the operative techniques of a staged RYGB operation for super-super obese patients [5].

A systematic review concerning re-operative bariatric surgery established the following nomenclature, which will be used throughout this chapter. Conversions are procedures that change an index procedure to a different type of procedure. Corrective procedures address complications or incomplete treatment effects of an index bariatric operation. Reversal restores normal or near-normal anatomy [6].

While numerous reasons exist for revising RYGB, in general they can be grouped into two general categories: to treat complications or to treat failure of RYGB. Complications may occur early as perioperative complications such as leak or later chronic complications such as fistulae, recalcitrant marginal ulcers, or malnutrition. Failure of RYGB is broadly defined as insufficient weight loss, weight recidivism, or recurrence of comorbid conditions. Conversions or revisions in this setting attempt to produce additional weight loss. Similarly some patients who are super

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obese at the time of RYGB undergo planned second-stage conversions to produce satisfactory weight loss.

The frequency of RYGB revisions or conversions is not known; however, the absolute number of bariatric operations that are re-operative continues to increase annually. One of the earliest series had a 4.5% revision rate [7]. However, recent data from the American Society for Metabolic and Bariatric Surgery (ASMBS) show that from 2011 to 2015, the proportion of bariatric surgeries performed in the United States that were revisional increased from 6% to 13.6%, at the same time the overall volume of surgeries increased by 24% as well [8]. Revisional surgery is associated with a higher risk of complications compared to primary procedures. Acute complications such as bleeding, leaks, and bowel obstruction are estimated at 8.5–18%, and chronic complications range from 8.9 to 20% [9–11]. ASMBS currently recommends that revision bariatric surgery be undertaken in centers with sufficient resources to manage these patients and be performed by experienced bariatric surgeons [6]. Multidisciplinary care, both prior to and after revisional bariatric operations, is key to success.

A detailed discussion of every operative technique is outside the scope of this chapter; however, some key points are discussed with the specific revisions and conversions from RYGB below. The authors generally approach revisional bariatric surgery using laparoscopic techniques, even when prior open surgeries have been performed, similar to other centers with high volumes of revisional bariatric surgery [12, 13]. The advantages of laparoscopy in the re-operative setting are earlier ambulation and shorter hospitalization, with the caveat that surgeons must have the requisite technical skills to accomplish similar outcomes. The patient is positioned supine on the operating room table, and we typically leave arms out on arm boards. Entry into the peritoneal cavity is generally achieved with an optical entry trocar, placed away from any prior surgical incisions. Depending upon the burden of adhesive disease, remaining trocars are placed right away. When significant adhesions exist, we liberally use additional 5 mm trocars to lyse adhesions and delineate existing anatomy. Almost invariably, the left lobe of the liver is adhered to the gastric pouch and/or the excluded stomach. A plane must be developed prior to inserting a liver retractor. The preferred retractor in our practice is a Nathanson liver retractor, which is inserted through a stab incision in the epigastrium, away from the working trocars. Once adhesions are freed, a 5 mm supraumbilical port is placed in a gentle "U" shape with the surgeon at the patient's right side. Typically the surgeon utilizes a 5 mm trocar for the left hand and a 12 mm trocar for the right. The 12 mm port accommodates both laparoscopic linear stapler and curved needles for free hand suturing. The camera port may be either a 5 or 12 mm trocar that accommodates a 45 degree angled laparoscope. The two trocars of the assistant vary based on the case. The assistant's left hand can be upsized to a 12 mm trocar when difficult stapling angles are not reachable from the surgeon's trocar. The assistant's right hand is upsized to a 15 mm trocar or extended to allow space for insertion of a circular end-to-end anastomosis stapler or for specimen extraction. At a minimum an upper endoscopy should be performed prior to pursuing a revisional bariatric operation [14, 15]. At our institution, upper endoscopy is routinely used intraoperatively during bariatric operations, especially during revisional procedures. The endoscope may be utilized to identify previous

staple lines, eroded foreign bodies, fistulous openings, and strictures. In addition, the endoscope allows visual inspection of new suture and staple lines, assessment of intraluminal bleeding, and leak testing once reconstruction is complete.

While it is not yet routine practice, a number of endoscopic devices and techniques are being developed for revision of bariatric operations. None have reached mainstream application, but increasingly revisional bariatric surgery may be possible without skin incisions [16]. Here we focus on principle indications for revision divided between treating complications and treating failure.

Preoperative Evaluation

Knowledge of postsurgical anatomy is key when planning revisional surgery. Obtaining and carefully reviewing operative reports from previous operations can help build a road map. Description of the original operation may help understand basic principles such as size and anatomy of the pouch, presence of foreign bodies (bands or rings), length and location of Roux limb (antecolic vs. retrocolic), presence of previous feeding tubes, and whether the pouch was constructed in a divided vs. undivided fashion.

Further preoperative investigation should always include upper endoscopy and upper gastrointestinal series. Endoscopy is key in further defining the anatomy, size, and appearance of the pouch. It may help identify gastrogastric fistulae, marginal ulcers, ongoing gastritis, long candy cane, or loop configuration of the gastrojejunostomy. Radiologic studies may help further define postsurgical anatomy. The authors routinely obtain upper gastrointestinal series when planning revisional surgeries. This study may help identify gastrogastric fistulae that were not seen on endoscopy, presence of a hiatal hernia, or thoracic migration of the pouch and may hint the presence of esophageal dysmotility.

Revisions and Conversions to Treat Complications

Overall RYGB has an excellent safety profile, with a low incidence of complications. Complications have been covered in other chapters in this text, and we refer the reader there for a more comprehensive review of incidence and nonoperative management. As mentioned previously, perioperative or acute complications typically occur within 2 weeks of RYGB [17]. Revision is uncommon in this setting, but not unheard of. Typical acute complications that necessitate operative exploration are staple line leaks; hemorrhage; early postoperative bowel obstruction, including hemobezoar; or acute internal herniation [18]. In the acute setting, correction of the Roux-en-O configuration is likely the only true revisional operation that is undertaken [19]. Roux-en-O describes the situation where the biliopancreatic limb is mistakenly anastomosed to the gastric pouch. Presentation is typically severe

dehydration, biliary emesis, esophagitis, and abdominal pain [18]. Diagnosis can be difficult, and hepatobiliary iminodiacetic acid scan (HIDA scan) may be the best imaging test for diagnosis [19]. Surgical correction is to take down the gastrojejunostomy and jejunojejunostomy, properly identify anatomy, and reconstruct with a neo-gastrojejunostomy and neo-jejunojejunostomy.

Chronic complications (>12 weeks) after RYGB are the more common indication for revision or conversion. As follow-up has increased to 10 and 20 years and beyond after RYGB, there has been increasing appreciation of late complications. This includes leaks and fistulae, marginal ulceration, anastomotic strictures, as well as excessive weight loss and malnutrition [20]. Each of these will be discussed.

Revisions for Marginal Ulceration and Stricture

Anastomotic or marginal ulcers occurring at the gastrojejunostomy are one of the more common chronic complications of RYGB. In one large single-center experience, there was a 2.3% marginal ulcer rate, despite routine use of proton pump inhibitor therapy for 90 days after RYBG. Of the 59 patients included in the series, 44.1% needed operative intervention [21]. The incidence of marginal ulcer may be as high as 50% looking at the subgroup of patients with GERD undergoing RYGB [22]. In an international survey of bariatric surgeons, the reported rate was nearer 16% [23]. The underlying pathology is not well understood, though alteration in blood flow, anastomotic tension, smoking, and *Helicobacter pylori* infection have all been posited to play a role. Medical therapies with proton pump inhibitor and/or sucralfate are mainstays to initial management [23, 24]. Patients with recalcitrant ulcers especially associated with chronic gastrodynia, nausea, or vomiting and subsequent malnutrition may be candidates for surgical revision of the gastrojejunostomy. Acute perforations of marginal ulcers are indications for urgent operation [6, 25]. Typically, acute perforations can be approached similar to peptic ulcers in a patient with native anatomy and can be oversewn and reinforced with a pedicled omental patch [25].

Chronic ulceration or recurrent ulceration can lead to stricture of the gastrojejunostomy. While varying definitions are used to define stricture of the gastrojejunostomy in the literature, most would agree that the inability to pass a 10 mm endoscope across the anastomosis is a defining characteristic [26]. The incidence of stricture is estimated from 2.9% to 23.0% [18, 26, 27]. The role the technique used to fashion the anastomosis plays in the development of later strictures is controversial, but may play a role as well [18, 26, 28, 29]. Typically endoscopic balloon dilation is trialed initially and is frequently successful [28, 30, 31]. Patients with severe strictures such that a guidewire cannot be placed to complete dilation or which have become non-responsive to repeated dilation are candidates for surgical revision of the gastrojejunostomy. Risk factors for failure of endoscopic dilation have been identified as ischemia segments and concomitant presence of fistula, longer time from index operation, and failure to resolve at the first dilation [32, 33].

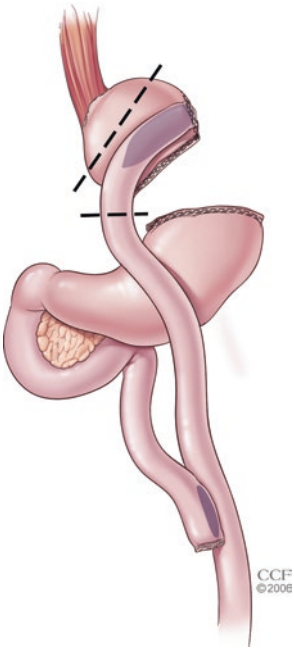

Fig. 38.1 Resection of gastrojejunostomy for revision after Roux-en-Y gastric bypass (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

Revision of the gastrojejunostomy can be curative in the small subset of patients that develop recalcitrant marginal ulcers or gastrojejunal strictures that fail to resolve with endoscopic dilation. In two separate series, 32% of patients with marginal ulcers eventually underwent revision, which is similar to results from an international survey [23, 34, 35]. In the absence of a concomitant gastrogastric fistula, revision can generally be accomplished by revision of the gastrojejunostomy alone. The goal of this operation is to isolate and resect the gastrojejunal complex, as well as identify adequately perfused tissue that can be used to refashion a tension-free anastomosis. The surgical approach begins as described above. In the presence of marginal ulceration, dense inflammatory tissue may be present both anterior and posterior to the gastric pouch. The posterior dissection of the pouch involves freeing pouch form the pancreas and retroperitoneal structures. The splenic artery can easily be injured in this dissection, and the surgeon should take care to identify it during the dissection. Once the gastric pouch and gastrojejunostomy is freed from the liver and surrounding strictures, the integrity of the left gastric pedicle must be ensured. Prior to division of the gastric pouch and Roux limb, ensuring there is an open plane between the excluded stomach and pouch is essential to (a) definitively rule out a previously undiagnosed gastric fistula and (b) avoid iatrogenic creation of a gastrogastric fistula. In the setting of ischemic strictures, the entire ischemic section must be resected. Division is typically accomplished by linear stapler. Compared to a primary operation, increased staple heights may need to be utilized to accommodate gastric tissue in the re-operative field (Fig. 38.1). After division, use of immunofluorescent intravenous dye such as indocyanine green may be a useful adjunct to ensure

adequate tissue perfusion prior to anastomosis. Measurement of the limbs of the Roux-en-Y is prudent, as short limbs allowing bile reflux is one etiology of chronic ulceration and stricture. Limb lengthening to at least 75 cm Roux should occur if necessary. Techniques of reanastomosis are identical to primary RYGB and include hand-sewn, linear stapled, and circular end-to-end stapled techniques. If foreign body reaction is suspected to have caused ulceration, or previously staples eroded intraluminal, a hand-sewn anastomosis is typically performed to minimize this effect. Surgical drains are used electively in our practice. Patients with malnutrition preoperatively also undergo placement of a gastrostomy tube in the excluded stomach for feeding in the early postoperative period and supplementation after discharge.

In some centers, truncal vagotomy is added as an adjunct to gastrojejunal revision for chronic marginal ulceration, though data on this technique are limited [36]. When there is no concomitant gastrogastric fistula, generally the entire excluded stomach can be preserved. There is some evidence that removal of the excluded stomach at the time of initial RYGB may be protective in terms of development of marginal ulcers, though the additional morbidity associated with that additional portion of the operation is not likely warranted by the marginal benefit [37]. We would not recommend resection of the remnant, unless there was concomitant bleeding of the excluded stomach, severe ulcer disease there, or a gastrogastric fistula.

Revision for Chronic Leaks and Fistulae

Published literature fails to definitively identify a difference between chronic postoperative leaks and chronic fistula following bariatric surgery [38]. Accordingly, accurate estimates of the incidence of postoperative fistula following RYGB are challenging. In most literature, the term fistula is used more commonly >12 weeks after the index operation, though this is inconsistently applied [39]. Traditionally the term fistula refers to an abnormal connection between two tubular epithelialized structures [40, 41]. A temporal element is implicit in this definition, as it is clearly differentiated from a gastrointestinal perforation [41]. Naming of fistulae are typically from the origin to the terminus, which in generally is the higher pressure organ to the lower pressure organ [40, 41]. A simple fistula generally refers to a single outlet, whereas a complex fistula contains multiple outlets [42].

Fistulae following RYGB are thankfully uncommon; however, few centers have sufficient volume to develop expertise. Following RYGB, a number of fistulae have been described in case reports, series, and trials. We briefly mention gastrobronchial, gastropericardial, gastropleural, gastrocutaneous, and gastrocolonic fistulae as a matter of interest. Management of these fistulae typically involves multiple surgical teams, with a combination of endoscopic and surgical interventions, generally customized to the patient based upon the anatomy of the fistula.

The most common fistula after RYGB is likely gastrogastric fistula (GGF), which arises from the gastric pouch and connects to the excluded portion of the stomach.

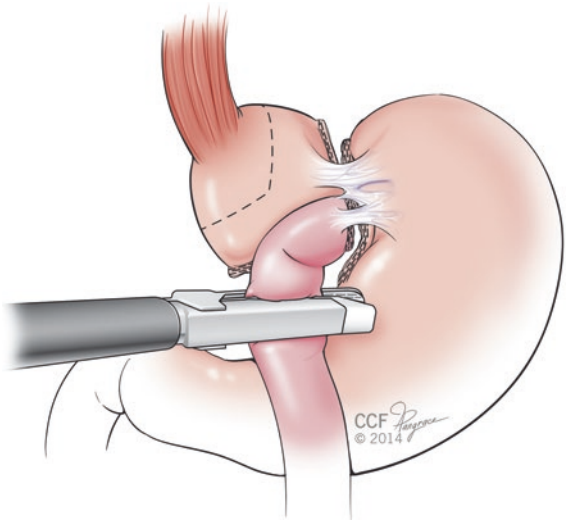

Fig. 38.2 Resection of gastrogastric fistula including pouch, Roux limb, and gastric remnant (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

Undivided gastric bypass is the strongest predictor of the development of a gastrogastric fistula, and formation approached 50% [43]. Routine division of the gastric pouch and excluded stomach reduced the GGF rate to 1–6% [44]. Risk factors for GGF include failure to completely divide the proximal stomach, foreign body erosions, ischemia usually related to perforations of marginal ulcers, and acute or chronic staple line leak [45]. Foreign body erosions may include sutures, staple material, and various adjustable and nonadjustable gastric bands. GGF has been subclassified in some publications as type 1 involving the proximal gastric pouch and type 2 when located near the gastrojejunostomy [46]. Upper endoscopy and upper gastrointestinal series should both be performed in all patients with a suspected GGF and complement each other in terms of identifying anatomy [47]. In some cases endoscopic therapies can be successful or at least temporize a patient to better physical conditioning and nutritional parameters prior to a corrective operation.

As opposed to corrective surgery at the gastrogastrostomy for marginal ulcers or gastrojejunal stricture, operations for GGF oblige at least a partial resection of the excluded stomach with or without revision of gastrojejunostomy, and the amount of resection is driven by fistula anatomy (Fig. 38.2). Important considerations are the location of the gastrojejunostomy related to the esophagus, presence of foreign bodies, fibrosis/inflammation, abnormality of the gastric tissue, and vascular supply. GGF that arise from marginal ulcers or leak at the gastrojejunostomy typically necessitate concomitant revision of the gastrojejunostomy as well as partial gastrectomy, while fistulae arising from the vertical staple line may be managed with resection of the pouch and partial gastrectomy, leaving the gastrojejunostomy intact.

Once access is gained to the peritoneal cavity and trocars are placed, entering the gastrocolic ligament early in the operation and operating in the retrogastric space can avoid inadvertent injury to the left gastric pedicle, the gastrojejunal complex, or

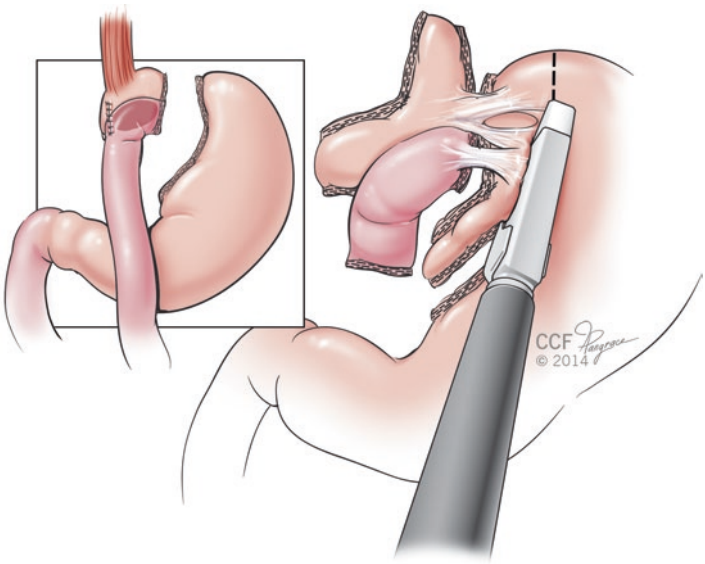

Fig. 38.3 Division of Roux limb and distal gastric remnant to access retrogastric space (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

the pouch (Fig. 38.3). The greater curve of the stomach should be mobilized and the short gastric vessels divided. Only after do we typically approach the gastrohepatic ligament. Distal division of the stomach is accomplished with sequential firing of linear staplers. Once this occurs, the origin of the fistula along the vertical staple line or gastrojejunal complex can be more easily identified. Occasionally extending the vertical staple line medially to create a neo-pouch will enable complete resection of the GGF while sparing the original gastrojejunostomy. If performing this maneuver, avoid narrowing the proximal pouch at the angle of His. In the more common case of involvement of the gastrojejunostomy, the gastrojejunal complex is divided similar to the steps described above. The objective is to remove the GGF en bloc and then reconstruct with uninflamed/nonfibrotic tissue without tension [44, 48]. Gastrostomy tubes are placed in the remaining excluded stomach on selected cases, typically based on preoperative nutritional indices. Surgical drains are generally placed along the neo-anastomoses.

While control of a GGF can typically be accomplished by resection of only a small portion of the excluded stomach, in some cases, a subtotal gastrectomy is necessary. When choosing the location for distal division in this case, attention should be made to ensure there is sufficient distal stomach to place a gastrostomy tube. Proximal division of the gastric pouch should again be guided by the location of the lesser curve vasculature, and every attempt should be made to preserve the integrity of these vessels. Injury in this case likely obligates performance of a completion gastrectomy with Roux-en-Y esophagojejunostomy, which is technically

more challenging to perform and has a higher risk of anastomotic complications. If at all possible, attempt should be made to keep at least some stomach, as even a small gastric pouch is generally better tolerated by patients compared to an esophagojejunostomy. This has only been published by a few centers for noncancer operations and should be performed by an experienced surgeon [49].

Revision for Excess Weight Loss or Malnutrition

The same alterations of gastrointestinal anatomy that produces the intended effects of early satiety, weight loss, and reversal of diabetes and other comorbid conditions also put patients at risk to develop malnutrition and certain vitamin deficiencies. A subset of patients will develop chronic malnutrition and failure to thrive. In the short term, this can be treated with dietary supplementation or occasional parenteral nutrition; it is a difficult process to correct with diet alone. Alternatively, some patients develop other chronic symptoms, such as intractable nausea and vomiting, postprandial hypoglycemia, or dumping syndrome, that may prompt a surgeon to consider reversal [50, 51]. In systematic review encompassing 100 patients in the reported literature from 1986 to 2015, malnutrition was the most common indication for reversal [51].

The key concept in reversal of RYGB is to reestablish a normal or near-normal stomach volume and passage of food from the stomach to the duodenum. To accomplish this, a gastrogastrostomy is formed, reconnecting the gastric pouch and the excluded stomach. After peritoneal access is gained, adhesiolysis is necessary to identify the biliopancreatic and Roux limbs, the excluded stomach, and the gastric pouch. The Roux limb is divided in the region of the gastrojejunostomy, typically distal. The excluded stomach is then mobilized and brought in proximity to the gastric pouch. The gastrogastrostomy is more typically formed in a hand-sewn fashion, though linear staplers can also be used [51, 52]. The Roux limb may either be divided just proximal to the jejunojejunostomy and removed as a specimen or placed back into continuity. In the latter case, the biliopancreatic limb is stapled off the jejunojejunostomy. A side-to-side functional end-to-end anastomosis can then be formed. One series mentions that pyloroplasty may be a useful adjunct, as vagal branches may be divided or injured during prior operations [52]. A sleeve gastrectomy has been described in conjunction with the reversal if patient still desire a restrictive procedure [53]. Reversal and/or reversal with conversion to sleeve gastrectomy are high-risk operations and have frequent complications.

Revisions for Weight Recidivism and Weight-Related Comorbid Disease

Successful weight loss and improvement of weight-related comorbid conditions are much more the rule than the exception following RYGB. Typically patients undergoing RYGB can expect to lose 60–80% of excess body weight with maximal weight loss typically occurring 18–24 months after the operation followed by a modest regain (8–10%) of weight [54, 55] . However, a subset of patients will either fail to achieve appropriate initial weight loss or regain an excessive amount of weight at some point after the operation [54, 55]. Associated with weight regain may also be redevelopment of previously improved weight-related comorbid conditions or de novo development of new weight-related comorbidities. While most surgeons would generally accept these as defining conditions for failure of RYGB, objective definitions are variable. In a systematic review of the definitions of failure after bariatric surgery, it has been noted that most manuscripts refer to the 1991 NIH consensus guidelines [56] and the Reinhold criteria [57], though neither in fact included a precise definition of failure [58]. While no consensus exists, failure to achieve greater than 50%EWL after RYGB is the most common definition of primary failure after RYGB. Defining weight regain is less exact. Other manuscripts state failure of RYGB is related to the failure to improve or redevelopment of weight-related comorbid conditions. However, preoperative comorbid disease severity is likely highly predictive of later failure [58].

Weight regain after RYGB especially after a period of adequate weight loss may herald a complication of the gastric pouch. Both pouch dilation and gastrogastric fistulae contribute to weight regain. Accordingly the majority of reoperations for weight regain are not conversion procedures, but rather are corrective and targeted at the gastrojejunal anastomosis, the gastric pouch, and the length of intestinal limbs.

Resection and Revision of Gastric Pouch and Gastrojejunostomy for Weight Regain

In the presence of weight regain, upper endoscopy and/or upper gastrointestinal series can confirm a diagnosis of pouch dilation, dilation of the gastrojejunal anastomosis, or both [59, 60]. Accepted literature definitions for pouch dilation are >6 cm in length, >5 cm wide, or the presence of fundus on retroflexed view during upper endoscopy or on upper gastrointestinal series [47]. Dilated gastrojejunal anastomoses are those >2 cm [47]. In general dilated gastrojejunal anastomoses are predictive of weight regain [60]. The gastric pouch size plays a role in satiety, but does not generally correlate with weight loss [61]. However, resection and revision of a large gastric pouch or dilated gastrojejunal anastomosis can slow food transit into the small intestine and improve feelings of satiety as a result of increased restriction producing greater weight loss.

Pouch resizing has been described with both open and laparoscopic approaches; however, laparoscopic approach is more common. A number of series have described techniques and short-term outcomes. One series describes a laparoscopic hand-sewn technique to plicate the vertical staple line of the pouch and 7 cm distal in the Roux limb. Suturing is performed over a 34 French Bougie in that series. Of note none of the patients in that series had abnormalities of gastrojejunal anastomosis [62]. This results in reduction in an average of 5 BMI points and additional 46.2%EWL at 6 months, with no complications [62]. Most series, however, describe the use of a laparoscopic linear stapler to divide the lateral aspect of gastric pouch and create a new vertical staple line. This technique is similar to the formation of the vertical staple line in a sleeve gastrectomy. Once adhesions are freed, a Bougie is placed of 36–40Fr, and multiple firings of the laparoscopic linear stapler are performed beginning along the jejunum, resecting the blind jejunal limb and proceeding through the gastric pouch toward the left crus of the diaphragm [63, 64]. This resulted in a mean additional %EWL of 12–21% [63, 64]. Oversewing of the neo-staple line can aid in hemostasis and may further reduce the size of the gastric pouch. This technique has the advantage of avoiding left gastric vascular supply along the lesser curve of the stomach, from which the gastric pouch derives the majority of its blood supply. Moreover, because there is little mobilization of the Roux limb, this can be performed quickly. However, the reduction in size of the gastrojejunal anastomosis is likely modest and may not produce necessary weight loss.

Dilated gastrojejunal anastomosis most often benefits from complete revision, which generally occurs with reduction in pouch size. This can be thought of as a revision of both the vertical and horizontal staple lines of the gastric pouch. One early series of five patients described a laparoscopic approach [65]. In this technique a neo-gastric pouch is fashioned by firing horizontal and vertical staplers across the pouch. The neo-gastrojejunal anastomosis is fashioned with a circular end-to-end anastomotic stapler (Fig. 38.4). The specimen is divided when the enterotomy is closed [65]. This is similar to the technique used at our institution, and we add the following technical suggestions. Identification of the Roux limb position early in the operation will guide further dissection, recalling that most often open RYGB were historically performed with a retrocolic alimentary limb, and laparoscopic RYGB are more commonly fashioned antecolic. Mobilization of a retrocolic alimentary limb must be approached from beneath the mesocolon. The most important step in the operation is identification of the left gastric blood supply. The left gastric artery defines the proximal limit along the lesser curvature of the gastric pouch. Staple heights frequently need to be thicker compared to a non-revisional case. Intraoperative endoscopy and leak test of the pouch are typically performed prior to reconstruction.

Peroral or endoscopic reduction of gastrojejunal anastomosis has well been described. Endoscopic suture devices can be used to plicate the anastomosis and reduce the aperture. Endoscopic plication to reduce pouch size has also been described. However, these technologies require great facility with the endoscope, have limited evidence especially in terms of weight loss produced, and have yet to reach mainstream adoption.

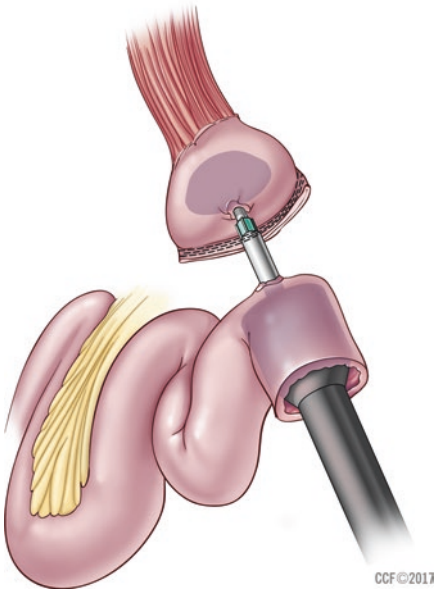

Fig. 38.4 Coupling of EEA stapler for gastrojejunostomy (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2006–2017. All Rights Reserved)

Placement of Fixed or Adjustable Band over Existing Pouch for Weight Regain

Correction of dilated gastrojejunal anastomosis and pouch dilation is based on the principle of neo-restriction to produce additional weight loss. In some cases, placement of adjustable or fixed bands has been described.

Initial experience with this technique was with placement of a laparoscopic adjustable gastric band across the proximal aspect of a dilated gastric pouch [66, 67]. This approach fell out of favor in parallel with the decrease in popularity of the laparoscopic adjustable gastric band as a primary procedure. A systemic review reported on 88 patients, in 6 studies, with a short-term complication rate of 19% and a reoperation rate of 18% (recalculated, excluding one study with a nonadjustable band placed) [68]. The typical complications of adjustable gastric band, including erosion, tubing disconnection, and port complications, occur at least the same rate as a primary adjustable gastric band procedure. The technical approach to adjustable gastric band placement is similar to primary adjustable gastric band. Again adhesiolysis frees the gastric pouch. The most extensive dissection in the retrogastric space that may be needed should be approached cautiously, and the splenic vasculature should be identified to avoid injury. Placement of the adjustable gastric band itself is similar, including the pars flaccida approach through the gastrohepatic ligament, development of a retrogastric tunnel, band insertion, and subsequent positioning just proximal to the gastrojejunostomy. The port and tubing are placed in an identical fashion to the primary operation. However, as adjustable gastric bands

have fallen out of favor as a primary weight loss operation, so also has their application as a RYGB revisional procedure.

Placement of nonadjustable silicone bands has also been described. One series reported 13% EWL [69]. Another series saw 23% EWL when silicone bands were placed around the gastrojejunostomy as a revisional procedure [70]. There were very few complications in either series [69, 70]. Current thought is to consider the nonadjustable band not as a mechanism for weight loss, but as insurance against later re-dilation of the gastrojejunal anastomosis and subsequent weight regain. This also reflects the role that silicone banding plays when placed during a primary procedure for super-obese patients [71, 72]. From a technical standpoint, placement of a silicone ring is similar to the adjustable gastric band, with the exception that they are typically placed at the gastrojejunal anastomosis, and are generally sutured in position.

Limb Lengthening: Resection and Revision of Jejunojejunostomy for Weight Regain

In the setting of a normal gastric pouch and normal gastrojejunal anastomosis, failure of RYGB can be revised with conversion to a procedure with a greater malabsorptive component. The typical length of an alimentary limb in a conventional RYGB is 150 cm. The length of the small intestine distal to the jejunojejunal anastomosis is defined as the common channel, where both biliopancreatic secretions and food comingle. There are two general approaches: to either lengthen the Roux limb (distance from gastrojejunostomy to common channel) or decrease the common channel length (distance from the ileocecal value to jejunojejunostomy. Several techniques have been described, which will be briefly detailed, but overall there is little evidence published outside of single-center case series with very little comparative data. Patients undergoing limb-lengthening procedures are at increased risk for both macro- and micronutrient deficiencies. As a result, these procedures are best performed in comprehensive bariatric surgery centers with a well-established multidisciplinary team, shared patient selection, and sufficiently high volume for surgeons to develop technical expertise.

Conversion to distal bypass has been reported from some centers. The initial description was published by Fobi and coworkers. In that series, 65 patients underwent revision to distal RYGB. Indications for revision were distributed among weight loss failure (<40%EWL, n = 14), persistent BMI >35 kg/m^2 despite >40%EWL (n = 15), weight regain for >14 kg (n = 14), and n = 16 who requested revision for maximal weight loss performed simultaneous with another operation. Revision resulted in a mean weight loss of an additional 20 kg, which corresponded to an average BMI decrease of 7 points [73]. Perioperative complications were acceptable, with wound complications being the most common at 9.2%; however, longer term at 23.1% developed malnutrition [73]. In another series, patients expe-

rienced an additional ~20%EWL after revision, with a similar 7-point reduction in BMI [74]. Two other series reported greater weight loss, but were otherwise similar [75, 76]. Long-term outcomes, however, drove this technique to largely be abandoned, as severe protein-calorie malnutrition had been reported in 30–100% of patients, often requiring parenteral nutrition or re-revisional surgery [74, 76]. Moreover, careful reading of the surgical techniques within these series reveals a heterogeneous array of operative techniques, with dissimilar strategies to measure the intestinal limb lengths.

Conversion of Failed RYGB to Duodenal Switch

Conversion from RYGB to a biliopancreatic diversion-duodenal switch (BPD-DS) has become increasingly popular, though still an uncommon operation. The BPD-DS combines restrictive and malabsorptive operations in the form of a sleeve gastrectomy and a lengthy intestinal bypass [77]. Preservation of the pylorus is key to maintain adequate postoperative blood glucose levels [78]. A variation with a single anastomosis is also possible [77]. The laparoscopic technique was originally described by Parikh, Pomp, and Gagner [79]. This involves four anastomosis: gastrogastrostomy (performed prior to sleeve gastrectomy), duodenoileostomy (neo BP limb to the first part of the duodenum), ileoileostomy (connecting the alimentary and biliopancreatic limbs), and a jejunojejunostomy, reconnecting the BP limb with the prior Roux limb, constructed in that order [79–81]. In the 12 patients included in the series, there was an additional 10.5-point reduction in BMI and an additional mean weight loss of 35.5 kg after conversion of BPD-DS. The mean total %EWL of 79.4% (range 48.3–98.1%) was similar to primary BPD-DS [79]. There were four patients with strictures at the gastrogastrostomy, three of which were successfully treated endoscopically [79].

A similar conversion is to the single-anastomosis duodenal switch (SADS). While this is a misnomer in the setting of a conversion, there are fewer anastomoses with this technique, relying on looped configuration with a 300 cm common channel measured from the ileocecal valve. Centers who have performed both describe less frequent steatorrhea and diarrhea with the SADS procedure [77]. The SADS procedure appeared to have few complications both perioperatively and long term [77]. However, the 17.3% perioperative complication rate that included peritonitis, abdominal abscess, gastric leak, and gastric outlet obstruction is not insignificant. In terms of weight loss outcomes, SADS was reported to provide 52.8%EWL at 12 months and 54.5%EWL at 24 months (note this calculated from peak weight prior to index RYGB operation). Technical descriptions of this operation are published elsewhere, and the authors will refer the reader there, as this procedure is not performed at our institution [77, 82].

Conclusion

As patients with prior RYGB age further from their index operations, more chronic complications will merit surgery for revision or conversion. Increasingly revisional bariatric surgery is a part of the bariatric surgeon's typical practice, and this will continue to increase. Revisions and conversions should be tailored to patient presentation, underlying pathology, and surgeon experience.

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Chapter 39
Conversion and Revisional Surgery: Duodenal Switch

Mitchell Roslin, Sarah Sabrudin, Sarah Pearlstein, and Billie Borden

Background

For those that have failed a previous bariatric operation, revising to a more aggressive operation is logical and reasonable. Duodenal switch (DS) has been shown to offer greater weight loss than Roux-en-Y gastric bypass (RYGB) or vertical sleeve gastrectomy (VSG). Therefore, in patients with inadequate weight loss, conversion to DS is an attractive option. Alternatively, bariatric providers must remain aware of the patient-specific reasons the initial procedure failed. Often those who do not perform well with previous procedures have a propensity for poor nutritional choices, such as selecting a diet with many empty calories that is low in protein and fiber. Following DS, it is mandatory for the patient to comply with the need for increased protein intake and vitamin supplementation. Failure to do so could make nutritional complications more likely.

Despite their noteworthy results, DS and its modifications represent a minority of bariatric procedures. Buchwald and coworkers reported that in 2008, biliopancreatic diversion (BPD) represented just 2% of the bariatric surgeries performed worldwide [1]. Many surgeons have had limited exposure to these procedures in practice or training and are concerned about the technical complexity and the need for postoperative nutritional monitoring. It is reasonable to question whether there should be more liberal application of DS for revision. Proponents would highlight the greater likelihood of sustained weight loss and cite that the risk is justified by the history of previous failure. Antagonists may question utilizing this type of procedure in a population whose initial outcomes may have been compromised by poor adherence to postoperative protocols.

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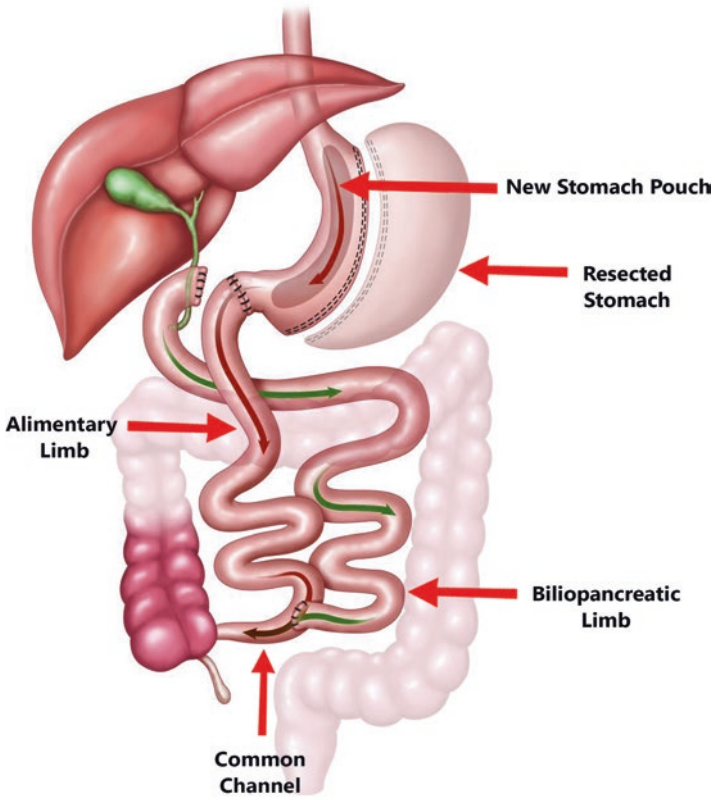


Fig. 39.1 Duodenal switch (DS) (Used with permission from Ethicon-Endosurgery Ltd., Somerville, NJ, and Cincinnati, OH, USA)

A fresh look and interest in these procedures is being driven by the increased prevalence of vertical sleeve gastrectomy (VSG). Originally, the VSG was described as the first part of a staged DS by Gagner [2]. Following these humble origins, it has grown to become the most popular bariatric procedure performed in the world. However, with time, failures are being noted. Thus it is logical to go back to its origin and offer the second stage or the intestinal bypass portion of the procedure to more patients.

The DS is a procedure that combines a sleeve gastrectomy with an aggressive intestinal bypass (Fig. 39.1) [3]. The theory behind the operation was to allow the stomach to have enough capacity to allow adequate protein intake, as it is estimated that approximately 20% of protein consumed is not absorbed following DS. Thus 100 grams of protein intake daily is recommended. Additionally, the short common channel ensures that fat is poorly absorbed. At the time that these operations were first performed, it was believed that fat was the leading cause of weight gain. Furthermore, there was limited insight into the hormonal alterations caused by bariatric procedures. As a result, the impact of the surgery was thought to be purely

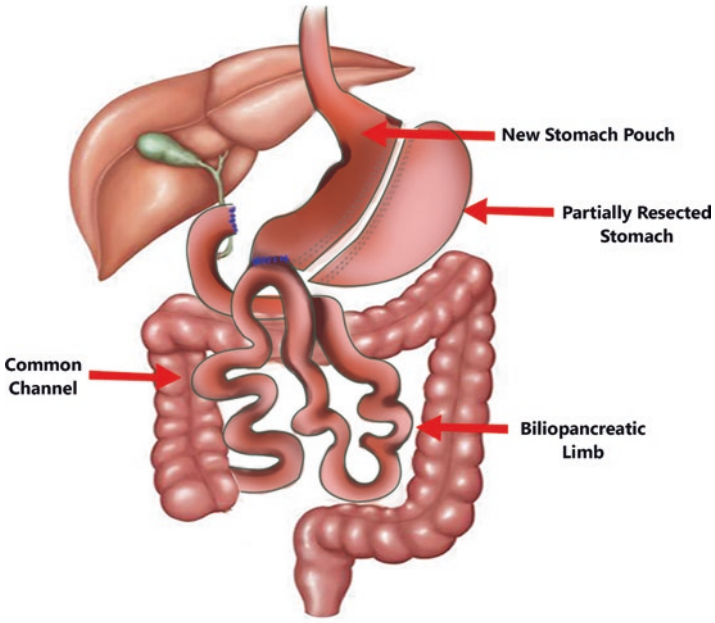


Fig. 39.2 Stomach intestinal pylorus-sparing surgery (SIPS)

mechanical. With increased knowledge, it allowed the surgical community to look at these procedures with a fresh perspective.

Lengthening the common channel and total intestinal length has been shown to allow for adequate weight loss and potentially reduce nutritional complications. Biron has shown similar weight loss with a tendency for lower vitamin deficiency in a cohort that had a 200 cm common channel [4]. For SADI procedures, the common channel or efferent limb is 250 cm [5]. In SIPS, the efferent limb is 300 cm [6] (Fig. 39.2). These procedures have shown impressive weight loss [6].

The data may ultimately show that gastric-only procedures such as the VSG have compromised long-term efficacy. For salvage, adding an intestinal bypass may be the preferential option. There remains considerable question as to the best method to construct such a bypass. Issues include how much bowel to bypass, whether the anastomosis should be gastric or post-pyloric, and whether a Roux construction or single anastomosis is preferred. To date, there are no objective data that definitively answers these questions. There are many case series cohorts that do offer insight.

Conversion to Duodenal Switch from Other Bariatric Procedures

Laparoscopic Adjustable Gastric Banding (LAGB)

Initially popularized and widely used in the 1990s and 2000s, laparoscopic adjustable gastric banding (LAGB) has since fallen out of favor due to inadequate weight loss and high propensity for adverse events. In their retrospective chart review of 120 patients undergoing LAGB as a primary bariatric procedure, Kindel and coworkers reported a 44% failure rate due to unmanageable symptoms or inadequate weight loss [7]. Aarts and coworkers retrospectively reviewed 38 patients who had their LAGB removed at least 1 year after placement without any further bariatric surgery. Among these patients, median excess weight loss (EWL) decreased from 41% at the time of band removal to 9% at 1 year, 0% at 2 years, and −11% at 5 years [8].

Because of this high failure rate and subsequent weight gain, there is a demand for conversion to another bariatric procedure. The optimal management of these patients is controversial. For example, whether single- versus double-stage reconstruction should be performed is debatable.

Options for reconstruction following LAGB include conversion to RYGB, VSG, or DS and its modifications. There are no randomized trials, but a retrospective review comparing results across 89 patients who underwent conversion of failed LAGB to LRYGB or LSG demonstrated no difference in complication rates, hospital stay, and early weight loss [9]. In their prospective study, Poyck and coworkers analyzed the conversion of 35 patients from failed LAGB to DS, finding EWL of 55% after LAGB conversion to DS and 48% for DS alone at 3 years, as well as a reduction in obesity-related comorbidities [10]. Conversion to DS is associated with the greatest amount of weight loss. In a matched cohort analysis, the presence of an adjustable band had a negative impact on weight loss in VSG, but no impact in modified DS (SIPS) [10]. Many surgeons think that conversion of LAGB to VSG has suboptimal outcomes as a result of converting one restrictive gastric operation to another [11].

Conversion from LAGB to DS allows for a larger sleeve which can potentially be better accommodated by the post-band patient while offering a malabsorptive component as well. It is important to highlight that a longitudinal gastrectomy is still part of the procedure, which causes high pressures in the gastric tube, requiring appropriate esophageal motility to overcome this increased resistance. As a result, it is with great caution that this procedure should be performed in patients that have dilatation of their esophagus or evidence of dysmotility. These findings are common in patients with slippage or very tight band. In these patients, staged reconstruction or gastric bypass is preferential. While there are data suggesting greater weight loss with conversion to DS than RYGB, there are no long-term data that compare the complication profiles [12].

In summation, conversion of LAGB to DS or modified DS offers the greatest weight loss and lowest probability of weight loss failure. However, there are no data to determine whether complications are increased, decreased, or similar to RYGB.

Vertical Sleeve Gastrectomy

VSG has become the most popular procedure for weight loss internationally, but there is risk for weight regain and recidivism. Subsequently, there is a large pool of patients considering revision [13, 14]. In a retrospective review of 500 patients who underwent laparoscopic sleeve gastrectomy, 6.4% (32/500) required revisional surgery. Revision was performed for poor weight loss in 8, weight regain in 18, and GERD symptoms in 6 [13]. In this subset of patients with GERD symptoms or dysphagia after VSG, conversion to RYGB is preferential.

Greater weight loss is achieved following conversion to DS or single anastomosis versions (SIPS or SADI) than RYGB. Collating the sum of various case series, the overall weight loss for two-stage DS is greater than 80%. In comparison, weight loss following two-stage RYGB is 65% [15]. There are several potential explanations for the difference. Gastric bypass is a low-resistance circuit and thus preferential for GERD. In a technically adequate VSG, any neurologic or hormonal mechanism of action has been utilized. As a result, for weight loss to occur, there needs to be elongation of the biliopancreatic (BP) limb. When the BP limb is lengthened, food comes into contact with less small bowel, therefore resulting in increased malabsorption. The majority of RYGB have long Roux (alimentary) limbs and relatively short BP limbs (traditionally 50–100 cm), which will result in less weight loss compared to the DS.

Recently, there has been improved understanding regarding what proportion of weight loss comes from the stomach or the intestine. The Quebec group analyzed patients that had either a sleeve gastrectomy or the intestinal aspect of the case. At 1 year, the VSG patients had greater weight loss. However, at 4 years the results were reversed. The intestine-only group had a 37% excess weight loss compared to 17% for the VSG-only group [16]. It is important to note that at the time of study, the VSG was usually created wider than is commonly accepted today. Cottam and Roslin have used matched cohort to compare VSG to SIPS. At 6 months and 14 months, the weight loss difference was 12% and 30%, favoring SIPS [17]. It is apparent that early weight loss is rapid following VSG. However, the intestinal bypass promotes late weight loss and inhibits recidivism.

In comparing the efficacy of bariatric procedures, weight loss varies directly with the length of the BP limb – the longer the BP limb, the higher the weight loss. However, there is an inverse correlation with protein and vitamin deficiency. With respect to weight loss, BPD, BPD-DS, SIPS, and SADI have the highest weight loss and longest BP limbs. Single-anastomosis gastric bypass has a longer BP limb and seems to have greater weight loss on average than the standard RYGB.

In conclusion, for conversions following VSG to have the highest probability for success, the BP limb must be elongated. Advantages of a post-pyloric construction include the ability of the pylorus to limit solid emptying, reduction in the risk of diarrhea, and buffering of gastric acid to mitigate the risk of marginal ulcer.

RYGB

Perhaps the most complex issue regarding revisional bariatric surgery is the management of the failed RYGB. There are numerous proposed treatments that range from endoscopic suturing, LAGB over the pouch, pouch reduction with new anastomosis, and shortening of the common channel. Converting to DS is considered, as it is an operation that offers greater weight loss.

Lengthening the BP limb will maximize weight loss. However, to leave the gastrojejunal anastomosis intact and to move the jejunojejunostomy distal place the patient at risk for severe diarrhea and protein malnutrition. Sugerman and Fobi published separate clinical series where the rate of protein malnutrition approached 25% with this type of approach [18, 19].

These complications may be mitigated by instead reattaching the stomach (reversing the gastrojejunal anastomosis) and converting to a DS or modified-type procedure, thereby utilizing the pylorus to mitigate food entry into the small intestine. However, this is a complex operation that can have complications. The stomach has been previously divided; therefore, the blood supply to the gastro-gastric reattachment can be questionable. To perform the VSG aspect of the case, division of epiploic branches and short gastric vessels is required. Leak and stricture rates greater than 20 percent have been reported. Weight loss in these cases has approached values similar to primary DS.

One recent suggestion to reduce complications is to preserve the distal epiploic blood supply. In our own technique, we suggest that a minimum of six epiploic branches be maintained. Since performing RYGB to DS in this manner, we have not had any leaks or strictures, but our case number is still small. In this approach, the pouch and the remnant are anastomosed, then a bougie is placed and the modified sleeve gastrectomy is performed. In this construction, food travels from the pouch to the remnant. From there, the food would pass through the pylorus and into the distal intestine.

Another approach suggests using the Roux limb as a conduit between the pouch and remnant. The Roux is attached to the remnant and then divided. Thus food would go from the gastric pouch to a very short Roux limb and then into the remnant. From there, food would pass through the pylorus and into the DS. Concern for marginal ulcer is present with this reconstruction. It is unclear whether these modifications will reduce the complication rate while also providing appropriate weight loss. See Fig. 39.3a–d.

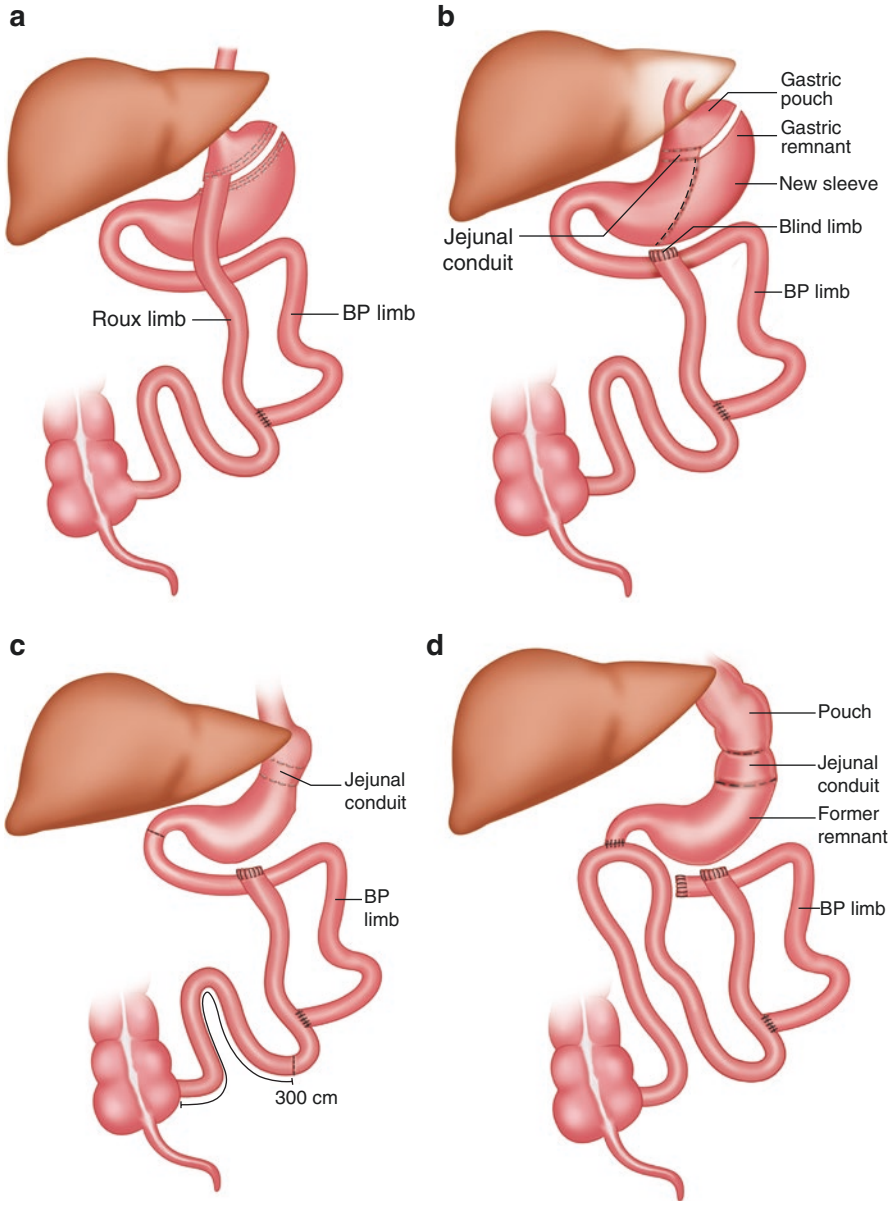


Fig. 39.3 Roux-en-Y conversion to SIPS. (**a**) Roux-en-Y. (**b**) The gastric pouch is connected to the remnant stomach carefully preserving the epiploic branches, via a jejunal conduit and the rest of the former Roux limb is left as a blind pouch. The re-anastomosed stomach is then sleeved. (**c**) Next, the ileum is measured 300 cm proximally from the ileocecal valve. The duodenum is divided 3 cm post-pyloric, and the post-pyloric proximal portion is anastomosed to the bowel 300 cm from the ileocecal valve. (**d**) Final configuration

Revisions for Complications of DS

In order for DS to achieve its robust weight loss, there must be substantial distortion of gastrointestinal anatomy. As the procedure includes both a longitudinal gastrectomy and a bypass of a significant portion of the bowel, side effects are possible. Long-term issues can include bloating, frequent bowel movements, small bowel bacterial overgrowth, and the consequences of short bowel syndrome, protein deficiency, and vitamin malnutrition. Secondary anorectal complaints, the risk of anemia, and bone loss are other complications that are not uncommon. Liver failure can potentially occur in patients that have preexisting fatty liver disease and consume a high-carbohydrate diet postoperatively. As a result, careful case selection, monitoring and nutritional evaluation, and adherence to supplement routines are mandatory. Blood work should be obtained at least twice in the first year postoperatively and then at least annually thereafter. Patients who present with poor quality of life due to malabsorption, especially with hematologic or metabolic abnormalities, should be considered for surgical revision by increasing their bowel length.

Technique

Revision for Traditional Duodenal Switch

For patients that have a standard DS, the distal anastomosis is located and the BP limb traced. A total of 150 cm of BP limb is counted and then anastomosed to the Roux limb. There is no need to divide the Roux limb. The purpose of the procedure is to lengthen the amount of bowel that comes into contact with food thus decreasing the BP limb. The operation has been called "kissing cousins," as food can go down two paths and there is no need to divide the bowel. Additionally, patients who have hypoalbuminemia should have a feeding jejunostomy inserted in the BP limb (Fig. 39.4). Alternatively, the same procedure can be performed and the original Roux limb divided just past the new anastomosis. This would effectively increase the common channel by 150 cm. It has been our experience that the division of the Roux limb is not necessary, and allowing food to go down either path is adequate.

Revision for SIPS: Version 1

For patients that have a single anastomosis, there are two potential options to lengthen the BP limb. The first is to divide the duodenal-enteral anastomosis. At this point there is a large enterotomy in the small bowel. Primary closure of this can lead to stricture. As a result, we place an endoscopic stapler through the open anastomosis and into the proximal and distal limbs of the small bowel to create a side-to-side

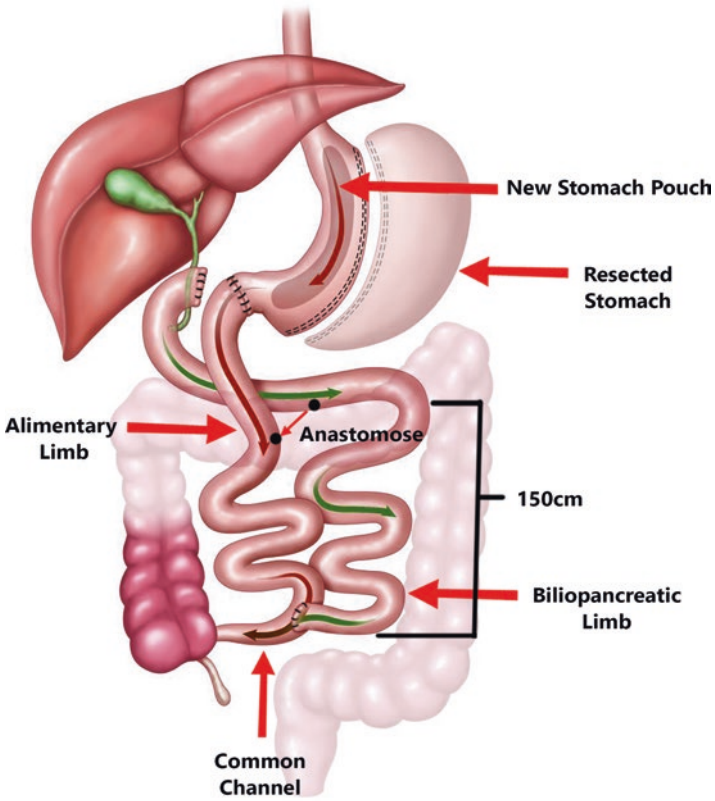


Fig. 39.4 Duodenal switch modification 1

staple line and then close the enterotomy with an additional stapling (Fig. 39.5). The surgeon then measures the bowel 150 cm distal to the duodenal stump. A new duodeno-enterostomy anastomosis is then created. This will increase the length of the common channel to 4–5 meters. It is not infrequent to find that the efferent limb was shorter than intended when the initial operation was performed, and we suggest that the efferent limb ultimately measure a minimum of 4 meters following revision (Fig. 39.6).

Revision for SIPS: Version 2

Alternatively, two small bowel anastomoses can be performed. The small bowel can be transected immediately proximal to the duodeno-enteric anastomosis and then attached approximately 50 cm downstream, converting to a Roux orientation. Then, similarly to revision of a standard DS from Fig. 39.1, 1.5 meters of the BP limb is

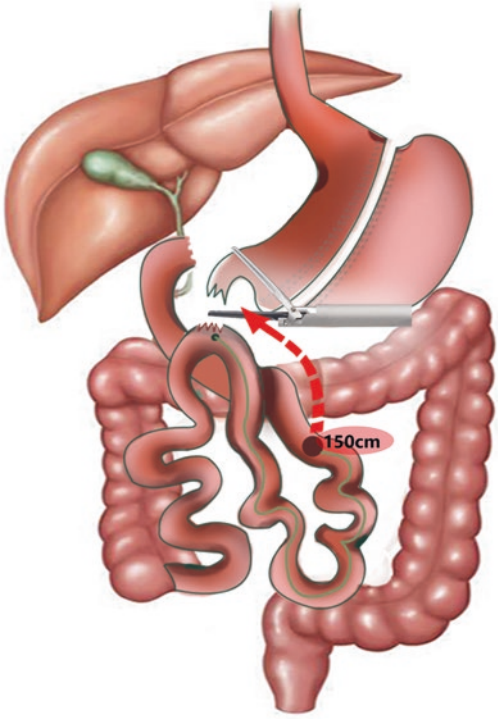


Fig. 39.5 SIPS modification for malnutrition: Version 1

counted, and this point is attached to the now proximal Roux limb, creating a second channel. A feeding jejunostomy should be placed. There is no need to transect the Roux limb, and food can go down either conduit. This is usually extremely effective for frequent bowel movements and malnutrition (Figs. 39.6 and 39.7).

Proper nutritional guidance and education are imperative, as patients that require these revisions usually have a diet that is rich in simple carbohydrates or very high-fat foods. They should be considered high risk and are encouraged to have frequent interaction with the dietary staff.

Other Complication of DS: Gastroesophageal Reflux Disease (GERD)

Another occasional issue that can require revision after DS is refractory GERD. Similar to VSG, the DS involves a longitudinal gastrectomy. It is suggested that the gastrectomy be larger than that of a primary VSG (i.e., 36 F for VSG and 42 F for DS). Patients that have GERD symptoms can usually be treated medically.

For those in whom GERD is refractory to medical treatment, there are numerous options for treatment. Stretta (Mederi Therapeutics Inc., Norwalk, CT, USA) is an endoscopic radiofrequency procedure used to increase thickening of the lower esoph-

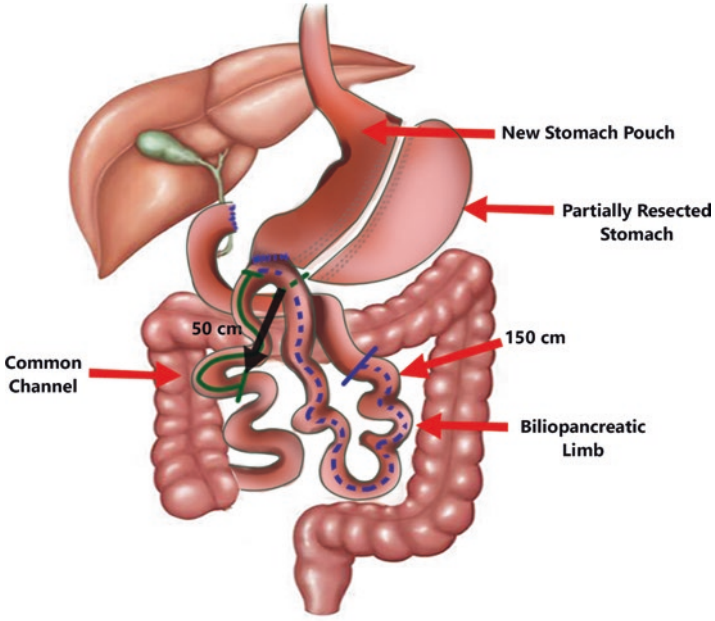
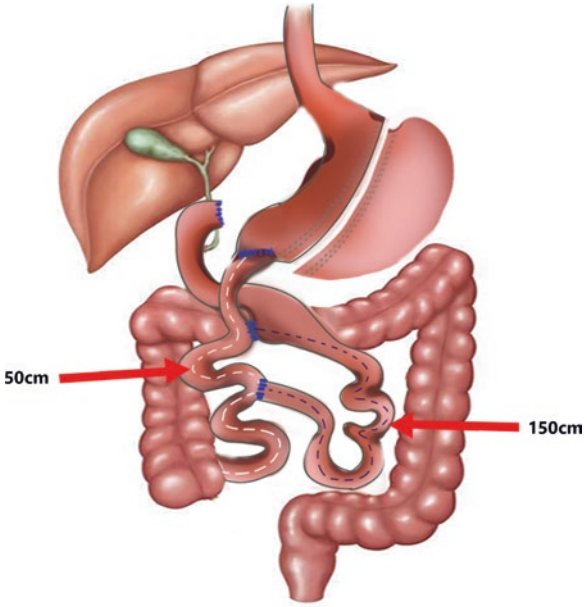


Fig. 39.6 SIPS modification for malnutrition: Step A

Fig. 39.7 SIPS modification for malnutrition: Step B



ageal sphincter, causing decreased transient lower esophageal sphincter relaxation and reducing esophageal acid exposure. A meta-analysis of controlled and cohort studies of patients with GERD showed a significant reduction in erosive esophagitis, reduction in esophageal acid exposure, increased LES pressure, subjective improvement in heartburn symptoms, and reduced proton pump inhibitor use [20].

Placement of the LINX® (Torax Medical Inc., Shoreview, MN, USA) device around the esophagus is an experimental technique. The LINX is a magnetic sphincter augmentation system intended to increase lower esophageal sphincter tone, thereby preventing reflux. A retrospective review of seven patients showed subjective improvement in GERD-related symptoms [21]. The use of these devices is not thoroughly studied in the bariatric population.

Hiatal hernia repair may also be needed to combat GERD symptoms. However, without fundoplication, the efficacy of surgical repair of the hiatus is unproven.

For patients with severe esophagitis after DS, refractory to medications, conversion to RYGB can be offered. To accomplish, the VSG is divided to create a pouch, and the Roux limb constructed from the previous BP limb. The duodenal attachment can be left in place. This is a procedure that is rarely required but remains an option for refractive patients.

Summary

It is our anticipation that the increasing issues with sleeve gastrectomy will generate interest in DS and its modifications, as the longitudinal gastrectomy created during DS lends itself to being a logical revisional solution. Knowledge of these procedures will become of greater importance. While there are substantial concerns about the long-term complications from DS, it is our belief that far fewer patients will require modification for inadequate nutrient parameters than will require conversion for poor weight loss or weight regain. Consequently, we predict DS and its modified versions will be among the fastest-growing bariatric procedures in the next 5–10 years.

Conversion to DS from other procedures, especially for failed weight loss, is an effective option. Surgeons must be aware that any revision carries higher risk. This is because of altered anatomy and patient-dependent factors that may have contributed to the need for revision following the initial procedure.

Bariatric operations that offer the greatest weight loss will also have the highest risk of nutrient deficiencies. As discussed in this review, RYGB can be converted to DS for inadequate weight loss or weight regain. However, DS can be converted to RYGB for GERD symptoms. Finally, even patients with DS can experience inadequate weight loss and weight regain. Bariatric surgeons need to understand all potential alternatives and attempt to find the best balance for each individual patient.

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Chapter 40
Robotic Conversion and Revisional Surgery

Melissa Felinski, Adam Purtell, Erik B. Wilson, and Shinil K. Shah

Introduction

As the number of primary bariatric procedures performed increases and our understanding of obesity continues to evolve, it is not surprising that the volume and complexity of re-operative bariatric surgery are also on the rise. Currently, the overall incidence of reoperations after any bariatric procedure is estimated to be between 5% and 54% [1]. The focus of this chapter is to review key points regarding the application of robotic surgery technology to the field of revisional bariatric surgery.

Re-operative Bariatric Surgery

While the majority of patients who undergo bariatric surgical procedures achieve successful results after their initial operation, there is a subset of patients who present with insufficient weight loss, weight recidivism, persistent comorbid medical conditions, or complications that require additional intervention. Although patients generally achieve a favorable treatment effect following reoperation, as with other surgical procedures, re-operative bariatric surgery is more challenging than the index operation and is associated with a higher rate of complications. It should also be stated that the degree of complexity and the reported outcomes of re-operative weight loss operations vary significantly among the types of procedures performed and the surgeon who performs the procedure [2]. This, in particular, highlights the

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need for thorough preoperative patient evaluation and selection, in addition to surgeon expertise in the area of re-operative bariatric surgery.

Types of Re-operative Procedures

The types of re-operative procedures are best categorized based on the anatomic modifications performed at the time of the reoperation.

- Revisions [1]
  - Basic anatomy of the primary surgery is maintained.
  - Most commonly performed for chronic complications of an initially effective primary procedure (i.e., adjustment of slipped gastric band, recreation of the gastrojejunostomy due to recurrent marginal ulcers, treatment of internal hernias).
- Conversions [1]
  - Basic anatomy of the primary surgery is changed to a different type of operation.
  - Most commonly performed for inadequate treatment.
- Reversal [1]
  - Restoration of original anatomy
  - Usually performed for severe malnutrition or other complications of massive weight loss

Indications for Re-operative Procedures

Re-operative weight loss surgery may be necessary for patients who experience the following:

- Failure [1]
  - Weight regain after hitting their lowest weight nadir
  - Insufficient weight loss
  - Recurrence of comorbid diseases
- Complications
  - Anatomical (complications will vary depending on the specific primary procedure: gastric band slip or erosion, hiatal hernia, symptomatic gastroesophageal reflux disease, gastric outlet obstruction, marginal ulcer, anastomotic stricture, anastomotic leak, gastrogastric fistula, gastric remnant complications,i.e., recurrent ulcers, bowel obstruction, and bleeding) [1]

– Nutritional or metabolic derangements (severe malnutrition, macronutrient/micronutrient deficiencies, refractory neuroglycopenia, and liver failure) [1]

Robotic Revisional Bariatric Surgery

Laparoscopic surgery has widely become the standard approach for both primary and revisional surgeries. However, in the case of revisional operations, the complexity of surgery continues to increase. Re-operative bariatric surgery has higher morbidity and mortality rates than primary procedures [2]. Operating on patients who failed or developed complications related to their index surgery presents specific challenges due to a variety of concerns. Anatomic features related to a high body mass index such as a thick abdominal wall, hepatomegaly, abundant visceral fat, adhesions, and disturbance of tissue planes in a re-operative abdomen can make exposure, dissection, and reconstruction difficult [3].

Robotic technology serves as a way to enable and enhance minimally invasive surgery by offering tools that may help extend surgical capabilities, including three-dimensional visualization, wristed instruments that increase degree of freedom of movement, elimination of surgeon tremor, and ease of laparoscopic suturing. Robotic surgery is a promising tool in complex re-operative bariatric surgical procedures.

Advantages and Limitations of Current Robotic Surgical Platforms

Advantages

Robotic platforms may help overcome many of the limitations of traditional laparoscopy. The robotic system offers the following visual and ergonomic advantages:

- Three-dimensional visualization with up to 10x magnification.
- Surgeon-controlled camera movement.
- Tremor elimination.
- Motion scaling up to 3:1.
- Wristed instruments with 7 degrees of freedom to mimic motion capabilities of its human operator.
- Ability to sit at a console during potentially lengthy surgeries may decrease surgeon fatigue and strain.

The value of robotic surgery may be magnified in the patient with morbid obesity undergoing re-operative surgery and may offer an advantage during particular portions of the operations, including exposure, dissection, and reconstruction.

Exposure

Abdominal wall thickness, body habitus, and visceral fat can make the ergonomics of revisional weight loss procedures particularly challenging. Movements of laparoscopic ports in a thick abdominal wall may cause local tissue trauma. Remote center technology may help reduce transmission of torque on ports and minimize port-site trauma. The surgeon has control of all robotic arms to assist in retraction and facilitate exposure, especially in smaller working spaces.

Dissection

Robotic platforms offer high definition three-dimensional imaging, which may assist with enhanced visualization. Improved dexterity may be afforded by the ability of the robotic platform to downscale surgeon's movements and enable fine tissue dissection. Integrated fluorescence-based imaging may help provide additional information regarding perfusion, which may be beneficial in re-operative cases.

Reconstruction

One of the widely accepted benefits of robotic platforms is the ability to perform extensive intracorporeal suturing with relative ease. The robotic approach offers needle drivers with increased degrees of freedom allowing for ambidextrous forehand and backhand suture placement, which makes intracorporeal suturing, particularly at odd angles when completing hand-sewn gastrointestinal anastomoses, less challenging. Robotic platforms may also help with creating more uniform pouch and gastrojejunal outlet sizes [4, 5].

Limitations

There are several limitations to the currently available robotic platforms (Intuitive Surgical, Inc., Mountain View, CA, USA). Some of these limitations are likely to be addressed with the planned introduction of new competing platforms over the next several years, including systems being developed by Verb Surgical (Mountain View,

CA, USA), Medtronic (Minneapolis, MN, USA), TransEnterix (Morrisville, NC, USA), and Auris Surgical (San Carlos, CA, USA).

Although the da Vinci® SI platform (Intuitive Surgical, Inc.) offers instrumentation to accommodate 5 and 8 mm trocars, the most recent XI platform offers all instrumentation to accommodate 8 mm trocars. Although the robotic platform minimizes the ergonomic impact on surgeons of a large or heavy abdominal wall, surgeons may not realize the torque on the abdominal wall placed by the robotic arms and the possible resultant effect on true fascial defect size. This is likely to be accentuated with larger trocar sizes, with a possibility of increased long-term incisional hernia rates.

Cost of robotic platforms and instrumentation represent another potential disadvantage. Almost all published reports of robotic-assisted laparoscopic weight loss surgery report increased costs, including a recent systematic review (nearly 3000 patients) that demonstrated an increase of approximately $3500 with no noted difference in complication rates [6]. This has been reported in nearly all published studies [7–9], with only one study reporting decreased costs with the robotic approach [10]. The issue of cost and robotics in revisional bariatric surgery may be more complicated. The increase in procedural- and platform-related costs may be offset if studies can demonstrate decreased rates of conversion to open procedures as well as reduced complication rates. Additionally, some of the increased costs may be negated with the use of hand-sewn as opposed to stapled anastomoses as well as with the introduction of competing robotic systems.

Other disadvantages, including lack of haptic feedback, difficulty with some robotic platforms in performing multi-quadrant surgery (alleviated to some degree with the XI platform), and lack of flexibility of certain energy devices, are being addressed as the technology continues to advance and as new competing platforms are being developed.

Technical Considerations

In general, the operative strategy is similar when considering revision of adjustable or fixed gastric bands and sleeve gastrectomy to Roux-en-Y gastric bypass (RYGB) or duodenal switch with biliopancreatic diversion, revision of adjustable gastric bands, or revision of adjustable gastric bands to sleeve gastrectomy.

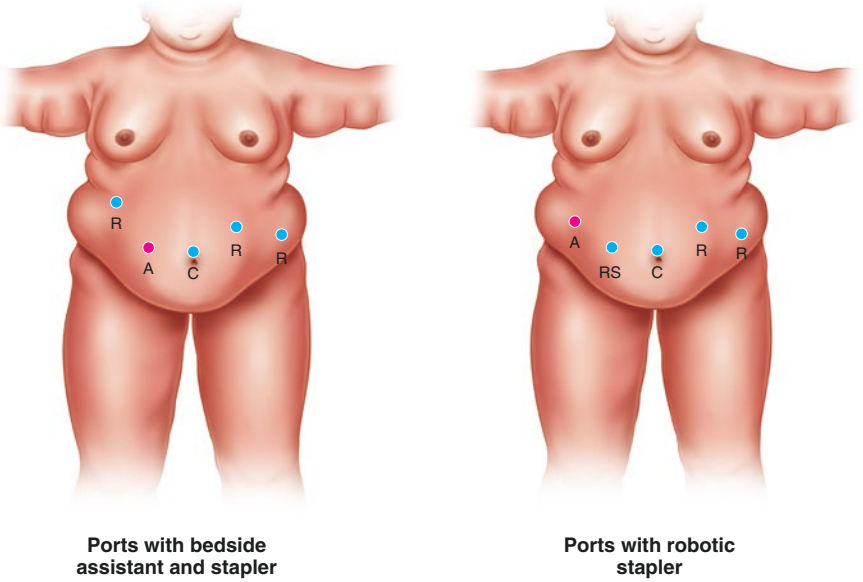

Fig. 40.1 Depicted below is the general port placement for revisional bariatric surgery. *R* robotic trocar, *A* accessory trocar, *C* camera trocar, *RS* robotic stapler. When utilizing a non-robotic stapling device (*left*), the assist port is generally placed on the patient's right side between the right upper quadrant robotic trocar. When utilizing the robotic stapling device (*right*), typically, the assist port is placed to the right of the first right mid-abdomen robotic trocar, which generally accommodates the robotic stapler

Operative Details

Setup

Initial entrance is generally obtained via optical entry techniques in either the right or left upper quadrant. Lysis of adhesions is usually done with a standard laparoscopic approach in order to place the robotic trocars. Evaluation of the small bowel for adhesions and mobility is also advisable if conversion to RYGB is planned. In the case of planned conversion to duodenal switch, and especially when using the SI platform, consider measuring and marking limb lengths laparoscopically prior to docking of the robotic patient side cart.

Port placement for the robotic approach must take into account the length of the robotic instruments and the need for external space between the functioning arms. After insufflation, the highest point of the dome of the upper abdomen is identified and the camera port is placed 5 cm below this point in the midline. In the case of a large falciform ligament, placing the camera to the left of midline may help with visualization. The remaining ports are placed as depicted in Fig. 40.1 with the camera port being the reference for level of placement of the remaining trocars. For the SI platform, we generally utilize a 12 mm port for the camera port with remaining

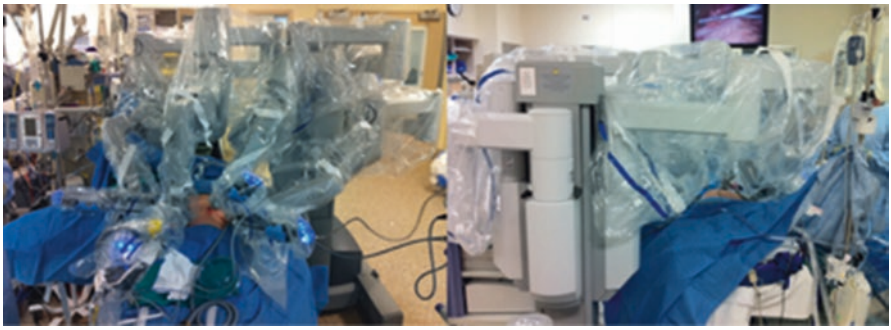

Fig. 40.2 The parallel side dock technique is useful for foregut operations using the SI platform. The patient side cart is brought parallel to the patient's bed along the left side of the bed, allowing for easy access to the head for anesthesia as well as for intraoperative endoscopy

robotic arms being 5 mm trocars. In the case of re-operative cases and especially when conversion to a RYGB is planned, we generally place an 8 mm (as opposed to a 5 mm) trocar in the left mid-abdomen to utilize the monopolar shears. In the case of a large hiatal or paraesophageal hernia, the left mid-abdomen port may need to be placed slightly higher to assist with the mediastinal dissection. The XI platform requires 8 mm ports for both the camera and robotic arms. The bedside assist port for bedside stapling is generally a 12–15 mm port depending on the type and loads of the stapling device being utilized. If the robotic stapler is being used, the bedside assist port, if required, can be a 5–12 mm port depending on the surgeon's preference.

Liver retraction in revisional surgery is often achieved with the adhesions naturally formed from the liver to the anterior abdominal wall from previous surgery. If possible, these adhesions are left in place during dissection. For required liver retraction, one can use a Nathanson liver retractor via an epigastric incision or an internal liver retractor.

Parallel side docking (Fig. 40.2) is a maneuver in which the robotic patient side cart is brought in on the left side of the bed parallel to the patient. The camera arm is positioned to the level of the camera port, and the remaining arms are then moved over the operating field. This allows for more room at the head of the bed for anesthesia and for intraoperative endoscopy when compared with docking directly over the head. Docking issues are generally minimized with the XI platform, with the patient side cart generally being positioned along the patients left (or right) side depending on the setup of the operating room.

Perioperative Care

Preoperative transverse abdominis plane/quadratus lumborum blocks prior to the operation may help with postoperative pain control [11]. Enhanced recovery after surgery (ERAS) type protocols utilizing multimodal pain medications and aggressive use of regional anesthesia may help to limit intra- and postoperative narcotic

utilization [11–14]. All patients should ambulate the day of surgery. For revisional or conversion surgery, we generally have patients undergo an upper gastrointestinal series with water-soluble contrast the morning following surgery prior to initiation of a liquid diet to evaluate for leak or obstruction.

Robotic Training and Learning Curve

With any new technology, it is important that the surgeon and operating teams are appropriately trained in the robotic surgical platform's function and capability while allowing for safe and efficient implementation during surgery. In addition to curriculums for robotic training, there is opportunity to facilitate the transition and adoption of robotics in the form of skills labs, surgical simulators, fellowships/minifellowships, case observation, or wet labs. It is recommended that the first cases performed by a novice robotic surgeon be proctored. Less complex operations such as sleeve gastrectomy or primary RYGB should be mastered prior to tackling more challenging revisional weight loss procedures.

One of the advantages of robotic surgery may be in decreasing the learning curve of RYGB. The operative efficiency for performing laparoscopic Roux-en-Y gastric bypass has been reported to be about 100 cases. In comparison, reports have demonstrated learning curves for robotic Roux-en-Y gastric bypass to be less than 20–25 cases [15, 16]. This is also true when considering other bariatric procedures. Proficiency of the robotic biliopancreatic diversion with duodenal switch requires about 50 cases, whereas robotic sleeve gastrectomy seems to be around 20 cases, with some studies showing that it may be as few as 10 cases [17–20].

Robotic Re-operative Bariatric Surgery Outcomes

Since the first robotic bariatric surgical procedure was performed in 1999 [21], the use of robotics in weight loss surgery has steadily increased. While the adoption of robotic technology in many gastrointestinal surgical procedures has outpaced the literature to support its use, there is some promising small series that suggest that robotic surgery may have a place in revisional bariatric surgery.

Particularly relevant to the field of revisional bariatric surgery is the opportunity to achieve relatively lower complication rates and improved outcomes with the assistance of the robot as compared to a traditional laparoscopic approach. As listed below, there are a number of studies that report decreased conversion, anastomotic strictures, and leak rates in both primary and re-operative bariatric cases. A recent study of 60 patients evaluating various approaches for revisional bariatric surgery (open, laparoscopic, and robotic) demonstrated that the robotic approach was associated with lower conversion rates (0% as compared to 14.3% for straight laparoscopy), decreased hospital length of stay, and less overall complications.

[22] Interestingly, in many of the series, major complication rates resemble outcomes following first-time weight loss surgery [23–25]. Previously, leaks – arguably one of the more devastating complications – with the standard laparoscopic approach have been reported to range in various series from 0 to 22% [2, 26]. Snyder and coworkers published a series of 99 robotic revisional bariatric operations showing a total complication rate of 17%, with no leaks or perioperative mortalities [23]. Ayloo and coworkers reported a series of 14 cases of revisional weight loss surgery, including revision of gastric bands to sleeve gastrectomy, RYGB, and anastomotic revisions with no postoperative leaks or other major complications [24]. Bindal and coworkers reported 32 patients (conversion of gastric band, sleeve gastrectomy or previous RYGB to RYGB) undergoing robotic revisional bariatric surgery; no leaks, strictures, or bleeding complications were reported in this small series [25]. Kim and colleagues recently compared 1234 primary robotic RYGB to 130 re-operative robotic RYGB. Re-operative robotic RYGB required longer operative time and length of hospitalization in comparison to primary robotic cases. However, using the robotic approach, rates of morbidity and mortality were relatively comparable (leak rate of 0.08% versus 0% for primary versus revisional RYGB) [27]. Given the technically complex nature of revisional operations, it is not a surprise that operative and hospitalization times are increased. More interesting though are the apparent equivalent outcomes of revisional as compared to primary RYGB. Kim and colleagues have also reported on a series of 156 robotic revisional bariatric procedures, including conversion to RYGB as well as gastrojejunal anastomotic revisions and RYGB reversal. In this series, they report a 0% leak and stricture rate [28]. These preliminary series highlight the promising role of robotic technology in revisional bariatric surgery and certainly highlight the need for further study.

Conclusion

Minimally invasive surgery provides patients with morbid obesity a viable and safe option for durable weight loss and control of medical comorbidities. With the increased utilization of bariatric surgery comes the challenge of re-operative procedures for those who fail to meet weight loss expectations or develop complications. The robotic surgical platform may be particularly valuable in re-operative cases. Robotic technology overcomes many of the difficulties with traditional laparoscopy and may provide ergonomic and technical advantages. Decreased learning curves and early reports of improved outcomes may be additional contributions afforded by robotic assistance and deserve further study. The role of robotics in revisional bariatric surgery will likely continue to evolve with further development of robotic surgical platforms and as more surgeons and institutions publish data regarding their experience.

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Part VI
Special Circumstances

Chapter 41
Bariatric Emergencies for the General Surgeon

Richard M. Peterson, Pedro Pablo Gomez, and Patrick Nguyen

Introduction

From 2011 to 2015, nearly 1 million bariatric surgeries were performed in the United States [1]. Patients in the United States may have their weight loss operation performed at one of over 750 Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) centers [2] in addition to non-accredited centers performing bariatric procedures. However, a general surgeon providing acute care coverage at one of 5564 registered hospitals in the United States [3] may be called upon to evaluate and provide treatment for a patient presenting with a complication of a bariatric surgery procedure. With the number of bariatric surgeries being performed in the United States totaling nearly 200,000 cases annually, the general surgeon faces a growing number of bariatric surgical emergencies. This chapter deals with the most common surgical emergencies following the three most common bariatric surgeries being done currently and the best way in which to deal with them. Algorithms are provided at the end of the chapter as Appendices for quick reference.

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Table 41.1 Roux-en-Y gastric bypass emergencies

Obstructive	Peritonitis
Internal hernia	Gastrojejunostomy leak
Jejunojejunostomy mesentery	Jejunojejunostomy leak
Retro-roux limb (Petersen's hernia)	Perforated marginal ulcer
Mesocolic	
Adhesions	
Intussusception	
Gastrojejunostomy stricture	

Gastric Bypass

The approach to managing the patient that presents following Roux-en-y gastric bypass (RYGB) is best characterized by symptoms. The clinical presentation will also dictate the need for emergent operative intervention versus further testing.

An unstable patient may be characterized by the presence of fever >101, hypotension, tachycardia of >120 beats per min (for more than 4 h), tachypnea, hypoxia, and/or decreased urine output. These findings are not specific to the RYGB procedure, but rather are markers of the patient's stability.

The common emergencies that the general surgeon may be faced with following RYGB can be separated into two broad categories: obstructive and peritoneal (Table 41.1).

Obstructive

Obstruction following RYGB must be managed expeditiously. While small bowel obstructions in the general surgery population can be managed conservatively in 40–78% of cases [4, 5], in the post-RYGB patient, nasogastric tube decompression and bowel rest are not sufficient. The altered anatomy of the RYGB patient limits the utility of these standard, conservative measures.

Internal Hernia

In the RYGB patient that presents with abdominal pain, nausea, and emesis, the surgeon should be concerned about an internal hernia. Internal hernias are much more likely to be present if the patient had a laparoscopic gastric bypass compared to the open procedure, as there are fewer adhesions to stabilize the small bowel intraperitoneally [6]. They most commonly present just after the first year of surgery [7, 8]. The rate of internal hernia after laparoscopic RYGB is about 2.5% (range 0.2–10%) [9, 10]. The rate of internal hernia after open RYGB is 0–0.7% [11].

The surgeon should be mindful that the cause of the obstruction may in fact be adhesive disease from prior surgeries. In series by Rogula and colleagues [8] and

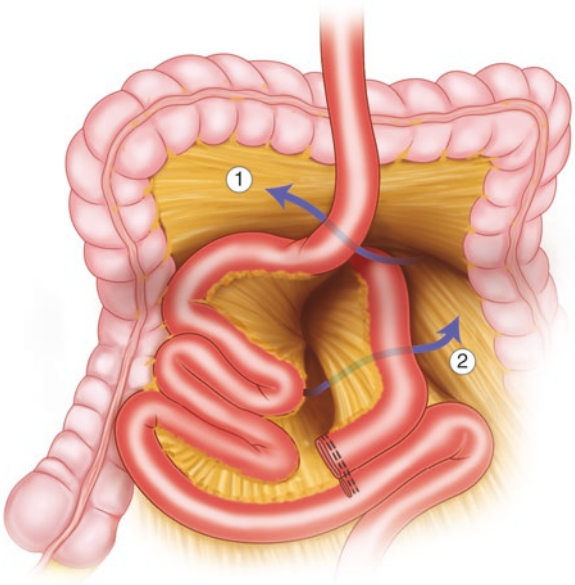

Fig. 41.1 Antecolic gastric bypass hernia defects: (1) retro-Roux limb hernia (Petersen's hernia), (2) mesomesenteric (JJ) hernia

Zak and colleagues [12], they found that internal hernia was as common a cause of bowel obstruction as adhesive disease. Rogula reported that the cause of bowel obstruction was internal hernia in 40.9% and adhesive disease in 34.1%. Zak reported the cause as internal hernia in 15.7% and adhesions in 17.6%.

When faced with an internal hernia, the surgeon should be aware of the potential areas of herniation and the likelihood of their occurrence. The most common site of internal herniation is at the jejunojejunostomy (JJ) mesenteric defect, occurring in 50–62% of all cases (Fig. 41.1). The Petersen's hernia occurs in 12–15% of internal hernia cases. In the retrocolic gastric bypass, another site of internal hernia is found at the transverse mesocolon [13, 14] (Fig. 41.2).

The patient with a history of gastric bypass who presents with abdominal pain, nausea, and emesis should undergo a computed tomography (CT) scan with oral and IV contrast. In the acute setting, there are some classic findings that can help the surgeon identify an internal hernia. Classically a swirl sign of the mesentery can be seen in an acute internal hernia (Fig. 41.3). This finding is the most specific and sensitive [15]. Gastric remnant distention with or without air is another sign (Fig. 41.4). The finding of the jejunojejunostomy on the patient's right side should also be an indicator that there is an internal hernia (Fig. 41.5). Additionally, a "beak sign" may occur at transition points from obstructed to non-obstructed bowel (Fig. 41.6).

Some laboratory indicators may be beneficial. Spector et al. [16] found that when the biliopancreatic limb was obstructed secondary to internal hernia, there was an increase in the amylase and lipase levels. These laboratory values were elevated in 48% of patients with any-cause small bowel obstruction, 94% of patients with

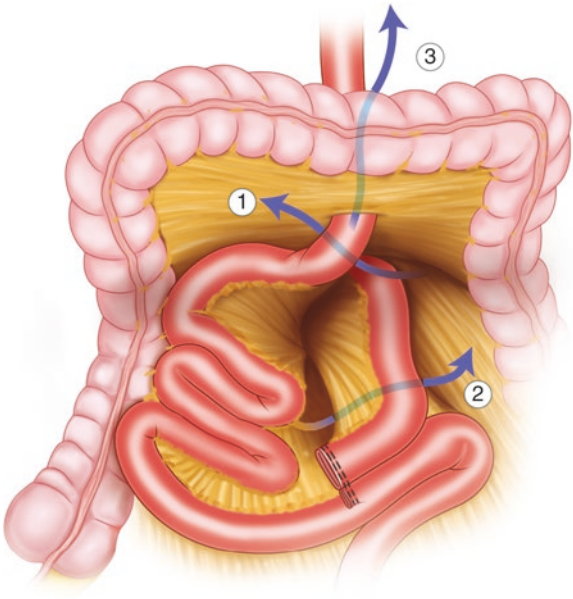

Fig. 41.2 Retrocolic gastric bypass hernia defects: (1) retro-Roux limb hernia (Petersen's hernia), (2) mesomesenteric (JJ) hernia, (3) mesocolic hernia

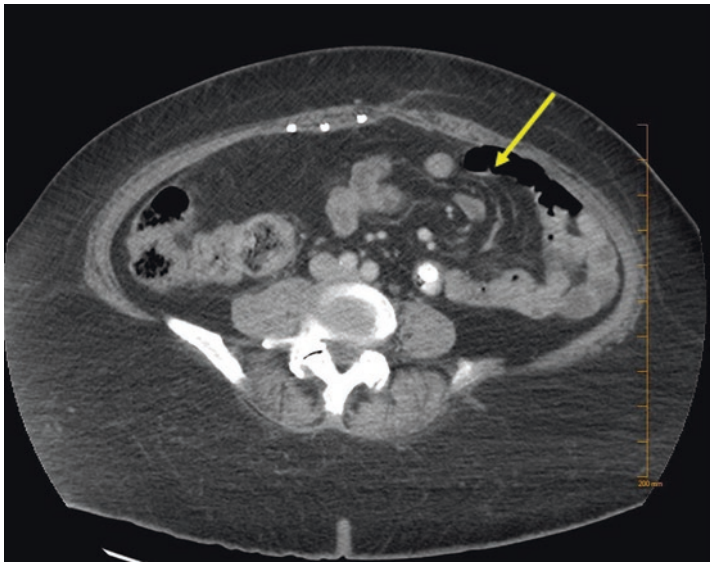

Fig. 41.3 Mesenteric swirl sign in internal hernia. Yellow arrow indicates the area of swirling mesentery

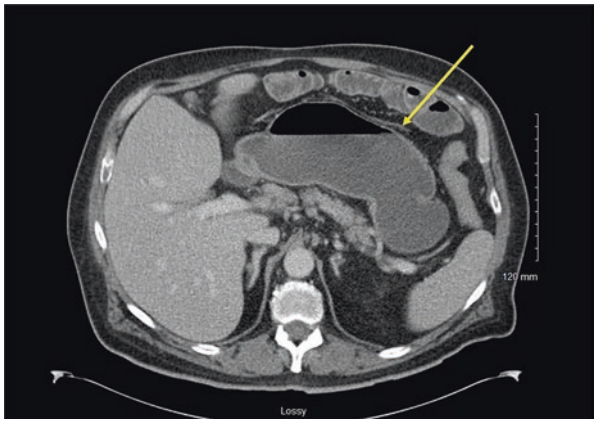

Fig. 41.4 Gastric remnant distention. Yellow arrow indicates dilated fluid filled remnant with air

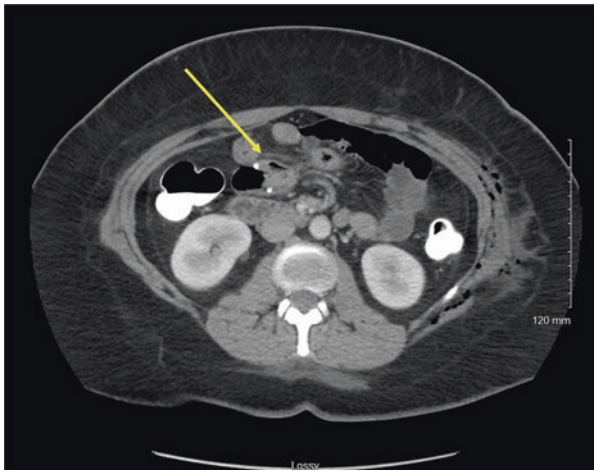

Fig. 41.5 Jejunojejunostomy (JJ) on patient right side. Yellow arrow indicates JJ

biliopancreatic limb obstruction, and only 27% of patients with obstruction not involving the biliopancreatic limb. This cheap and readily available laboratory test may help the surgeon narrow their search as they approach the patient surgically. The authors cautioned that amylase and lipase levels greater than 1000 would more likely suggest the diagnosis of acute pancreatitis.

Optimal treatment for patients suspected to have internal hernia is operative exploration. This can be approached laparoscopically or open, depending on the surgeon's comfort. The mainstay of treatment is to reduce the internal hernia before bowel ischemia is irreversible. (Fig. 41.7). Best technique involves identification of the cecum and tracing the small bowel proximally. When the internal hernia is approached from the actual site of herniation, the chance of reducing the bowel in the wrong direction exists. If the bowel is run proximally, the surgeon will reduce the hernia and reinstate the appropriate configuration. At this point the surgeon can evaluate the anatomy and the type of bypass performed. The common channel will already have been identified and run from the terminal ileum to the JJ. At the JJ, the

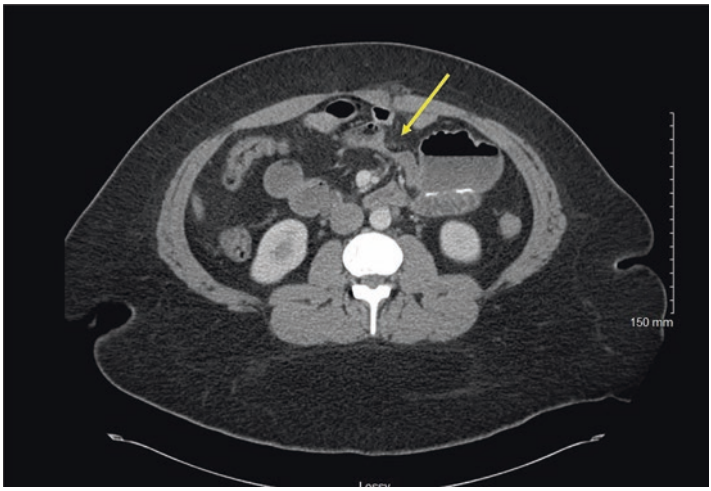

Fig. 41.6 "Beak sign" with bowel traversing midline through Petersen's hernia. Yellow arrow indicates transition point

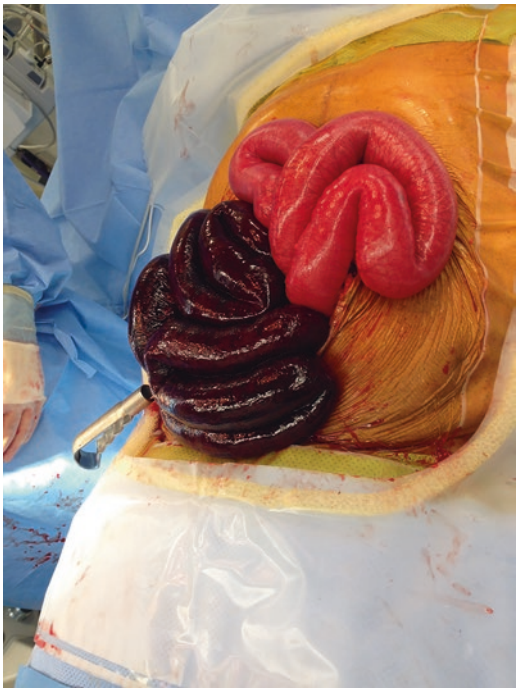

Fig. 41.7 An internal hernia with both ischemic and viable small bowel

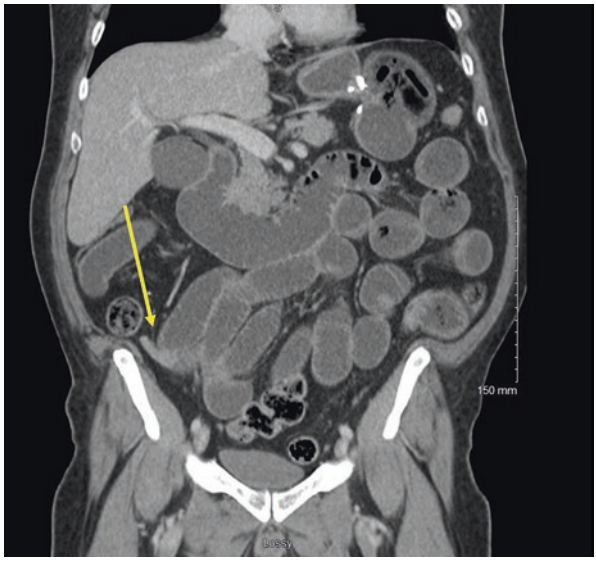

Fig. 41.8 Adhesive disease secondary to prior appendectomy in post-gastric bypass patient presenting as obstruction. Note the dilated remnant and diffuse dilated loops of bowel. Yellow arrow indicates point of adhesion and obstruction

assistant should maintain control of the common channel, and the surgeon then continues to run the bowel proximally. If the bowel goes in an antecolic fashion, this is the Roux limb and can be followed to the stomach pouch. If the bowel goes posterior, then the surgeon must evaluate whether it is the biliopancreatic limb or a retrocolic Roux limb. The retrocolic Roux limb will be lateral to the biliopancreatic limb as it leaves the ligament of Treitz.

Based on the type of bypass performed, the surgeon should then evaluate for possible hernia defects. All defects should be closed with permanent suture (Fig. 41.1). The Petersen's retro-Roux limb defect should be closed from the colon mesentery to the root of the Roux limb mesentery. The JJ mesenteric defect should be closed in running fashion. In the case of the retrocolic bypass (Fig. 41.2), the mesocolic window must be inspected as well.

In the setting of adhesive disease in a gastric bypass patient, standard approaches to adhesiolysis remain the mainstay of treatment. Examples of obstruction from adhesive disease can be from prior surgeries such as an appendectomy, as demonstrated in this image (Fig. 41.8).

In the setting of a dilated remnant stomach, the reduction of the internal hernia should be sufficient to allow the stomach to decompress. In rare cases if the stomach remnant is extremely distended, then it may require decompression with a gastrostomy tube, since there is no way to postoperatively access it with nasogastric tube decompression.

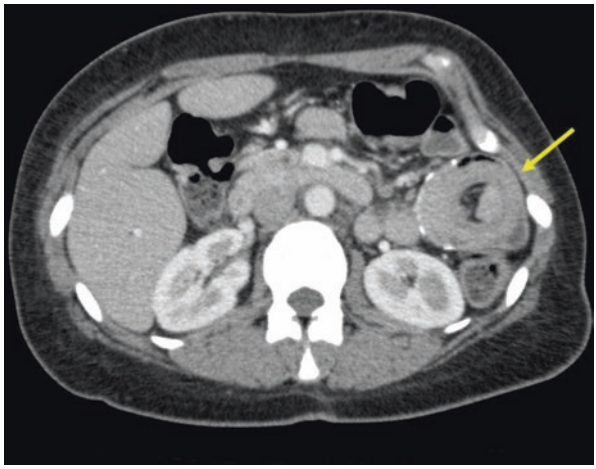

Fig. 41.9 Intussusception of jejunojejunostomy. Classic "target sign." Yellow arrow denotes area of intussusception

Intussusception

Intussusception is a less common cause of post-gastric bypass obstruction. If a CT scan is performed during the patient's active episode, imaging will reveal a "target sign" (Fig. 41.9). This is pathognomonic for intussusception. This most commonly occurs at the JJ, with the anastomosis acting as a lead point. Theoretical mechanisms include a patulous JJ, disruption of intestinal pacemakers, and orientation of the JJ (isoperistaltic vs antiperistaltic) [17]. These patients typically will require a surgical intervention with reduction of the intussuscepting segment. If the JJ is the lead point, this will likely require revision or resection.

Gastrojejunostomy (GJ) Stricture

Gastrojejunostomy strictures most commonly present in the sixth to eighth week after surgery and occur in 3–27% of gastric bypass patients [18, 19]. They typically do not present as an acute emergency but rather a progressive inability to tolerate solids and then liquids. Patients often present with dehydration and require fluid resuscitation. The diagnosis can be made with an upper GI radiology exam. Additionally, upper endoscopy will be both diagnostic and therapeutic.

The expected caliber of the anastomosis is 15 mm. If the GJ is narrower than this, pneumatic balloon dilation is warranted [20]. The earlier the intervention, the higher the success rate (98% of early vs 61% of late) [21].

Peritonitis

Gastrojejunostomy Leak

Anastomotic leaks after RYGB remain a major concern and source of morbidity. The most recent data suggest the leak rate ranges from 1% to 3% [22]. The typical time to presentation is 10 days following surgery (range 5–15 days) [23].

Patients with a leak will often present with tachycardia, fever, and abdominal pain. Other less specific signs can include nausea, vomiting, tachypnea, shortness of breath, and altered mental status. The clinician must also consider pulmonary embolism in the differential diagnosis of the bariatric patient with these non-specific signs and symptoms. The use of an upper GI study or CT scan with water-soluble contrast is indicated in stable patients. The CT scan remains a significantly more sensitive test to detect a GJ leak.

The mainstay of treatment for patients with GJ leak is controlling the source of sepsis [24, 25]. Lavage of the abdomen and wide drainage of the area of leak should be performed. Primary repair in some cases may be feasible, but if the inflammatory response is too great, then trying to close the leak may worsen the complication. Placement of a gastrostomy tube in the remnant stomach provides safe enteral decompression in this setting, where postoperative ileus is likely. It also provides enteral feeding access away from the area of leak. Broad-spectrum antibiotics are indicated.

Interventional radiology approaches may be considered to drain early leaks, but they are limited by their inability to adequately lavage the abdomen. Access to the remnant stomach is also limited.

Stenting across a GJ leak can be considered after initial source control is obtained. Studies report success rates of 87%. With the use of self-expanding covered stents, patients were able to begin a clear liquid or high-protein liquid diet within 24–48 h after stent placement [26].

Jejunojejunostomy Leak

The jejunojejunostomy (JJ) leak, which is less common, is often more difficult to diagnose and carries a 40% higher mortality than GJ leaks [27]. This is most likely due to delayed diagnosis. When patients present with signs of a peritonitis (tachycardia, fever, abdominal pain), studies such as UGI and CT scan are unlikely to detect the JJ leak. In the patient who has clinical signs of a leak, but a negative UGI or CT scan, further investigation with laparoscopy or laparotomy is warranted. Unlike the GJ leak, a leak at the JJ is more often amenable to primary repair and rarely is a revision of the anastomosis required. As in all operations, control of sepsis, lavage, and drainage are mainstays of care. In addition, broad-spectrum antibiotics should be initiated.

Table 41.2 Risk factors in the development of marginal ulcer

Smoking	Gastric acid hypersecretion
NSAIDs	Stress
Steroids	Recent surgery
Nonabsorbable suture material	Alcohol use
H. pylori infection	

Perforated Marginal Ulcer

Perforated marginal ulcer (MU) occurs at a rate of about 0.5–1% [28, 29]. There are several risk factors in the development of MU (Table 41.2). Felix and colleagues [30] published a series of patients with MU perforation which found that 51% were actively smoking, 29% were taking NSAIDs, and 6% were taking steroids.

Symptoms and signs of perforated MU are the same as any other perforated viscus. Patients will often exhibit tachycardia, fever, and severe abdominal pain with abdominal rigidity and peritoneal signs. Plain films or CT scan will likely exhibit free air (Fig. 41.10).

Once the diagnosis is made, treatment is based on the surgeon's comfort level and the patient's level of stability. Both laparoscopic and open repairs are advocated. Abdominal washout and primary repair of the ulcer with omental patch is successful in the majority of patients, thus mitigating the need for anastomotic revision [31] (Fig. 41.11). The success of this technique is highest when performed within the first 24–48 h. Some authors advocate for placement of a gastrostomy tube in the remnant stomach as a means for enteral access and as a decompressive tube in the setting of an expected ileus. This is best done selectively, as adding a gastrostomy can add morbidity to the operation. Postoperatively, it is imperative to counsel the patient regarding risk modification for MU formation.

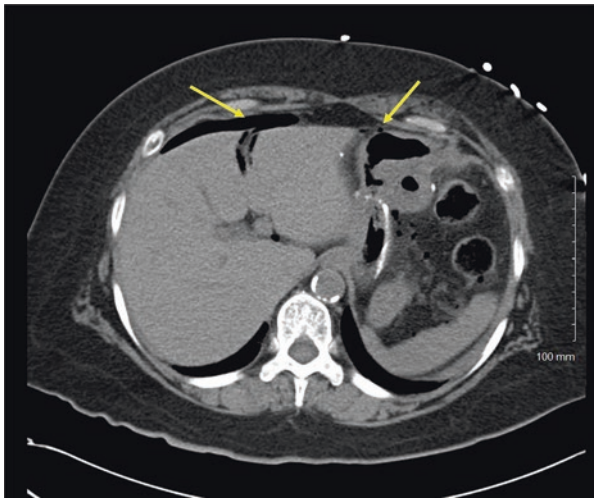

Fig. 41.10 CT scan demonstrating perforated marginal ulcer on the anterior surface of the antecolic roux limb and free air. Left arrow notes free air, right arrow notes perforation

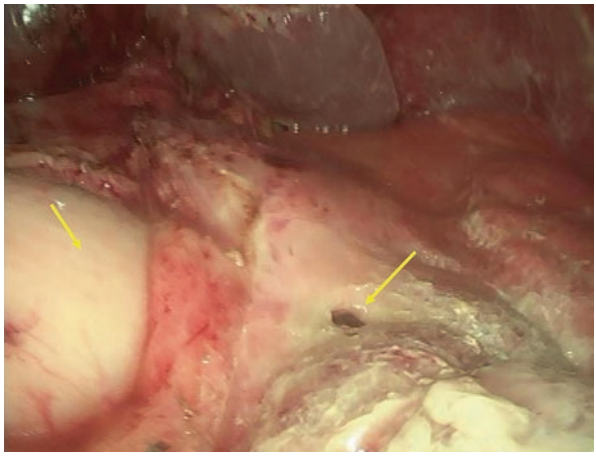

Fig. 41.11 Image demonstrating perforated marginal ulcer on the anterior surface of the antecolic roux limb. Left arrow notes remnant stomach, right arrow notes perforation

Sleeve Gastrectomy

Laparoscopic sleeve gastrectomy (LSG) has become the most commonly performed weight loss operation in the United States, accounting for 53.8% of weight loss operations in 2015, up from 17.8% in 2011 [32]. Complication rates of the LSG are positioned between LAGB and LRYGB, with a 30-day morbidity rate of 5.61% and an overall 30-day mortality rate of 0.12% [33]. The most common complications of LSG include leak, hemorrhage, and stenosis, with mean incidences reported as 1.1 ± 2.2%, 1.8 ± 3.1, and 0.9 ± 1.6%, respectively [34].

Leak

Leak after LSG results in significant increase in mortality rate (3.7% vs 0.2%) [35] and requires expeditious work-up and treatment. Most leaks occur after discharge home from the index operation, with over half occurring more than 10 days postoperatively [36]. Any patient presenting with tachycardia, fever, and abdominal pain after LSG should undergo prompt evaluation for a leak. Tachycardia is the most important and constant clinical finding [37]. CT of the abdomen with IV and PO water-soluble contrast has been shown to have the highest detection rate for gastric leaks [38]. CT findings of free fluid or a collection of fluid, extravasation of contrast into the abdominal cavity, or persistent pneumoperitoneum are diagnostic findings of a leak or fistula. Upper GI radiography with water-soluble contrast and endoscopy are other options for the diagnosis of a leak if CT is not available, as in the case where the patients exceed the weight limit for a CT scan or image quality is limited and the diagnosis cannot be reliably made.

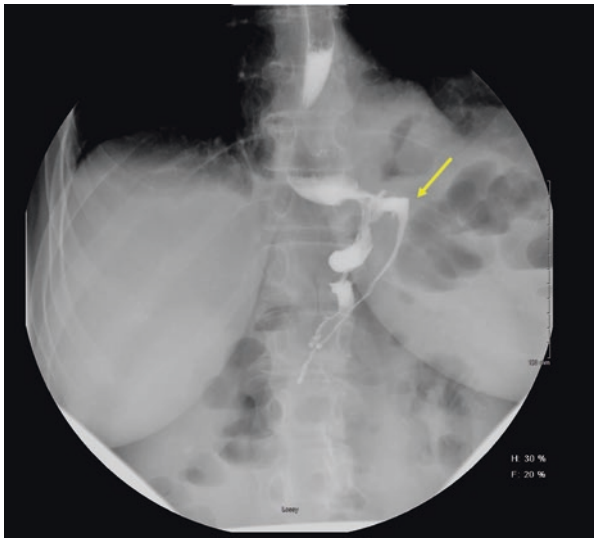

Fig. 41.12 Radiographic image demonstrating large leak at proximal sleeve. Yellow arrow indicates leak

The management of a leak after LSG depends on the patient's hemodynamic status. Patients who are unstable or septic upon presentation should under prompt laparoscopic or open washout and drainage. The most common location of a leak after LSG is proximal, in the region of the esophagogastric junction (Fig. 41.12) [36]. The decision to debride and suture the leak depends on the condition of the patient and the tissues, as well as the skills and experience of the surgeon. It is important to note that repair of the leak is not absolutely indicated and has been reported to fail postoperatively [36, 39]. Abdominal irrigation and drainage are necessary. Following surgery, the patient should remain *nil per os* (NPO), and nutrition is delivered either via total parenteral nutrition or nasojejunal feeds.

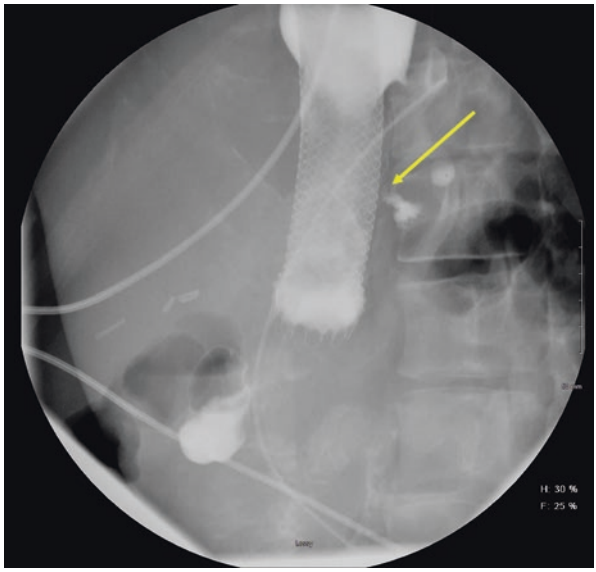

Fig. 41.13 Radiographic image demonstrating stent at location of proximal leak on sleeve. Yellow arrow indicates leak

Patients presenting with a leak after LSG who are clinically stable should be treated conservatively with adequate hydration, percutaneous drainage of any fluid collection, and broad-spectrum antibiotics. Once stabilized, they should be referred to a bariatric surgeon where follow-up imaging by upper gastrointestinal series is performed to ensure healing. Leaks that do not heal after 2 weeks can be considered for endoscopic management. Endoscopic management of a leak after SG has been reported using covered stents [40] (Fig. 41.13). However, the general surgeon's role in the management of a patient presenting with post-sleeve gastrectomy leak should include stabilization of the patient and drainage of the leak, either percutaneously or surgically.

Bleeding

Hemorrhage after LSG can be intra- or extraluminal. Patients with intraluminal hemorrhage will present with hematemesis or melena. Early upper endoscopy is indicated to diagnose and control the source of bleeding. Extraluminal sources include the gastric staple line, mesentery of the greater curvature of the stomach, trocar sites, spleen, or liver. The patient may present with declining hemoglobin levels as well as overt signs of bleeding, such as tachycardia, altered mentation, abdominal distension, or hypotension. If the patient is clinically unstable and demonstrates signs of bleeding, urgent operation to diagnose and control the source of hemorrhage is imperative. The operative goals are evacuation of blood and clot, identification of the source, and controlling the source. Bleeding from the gastric staple line can be controlled with clips or oversewing the staple line.

Patients with signs of bleeding who are clinically stable should undergo routine management of postoperative bleeding. This includes establishment of large bore intravenous access, close monitoring, serial blood counts, stopping anticoagulants, and blood transfusion if necessary. Most bleeding episodes will resolve spontaneously and not require surgical intervention. Patients with ongoing bleeding as evidenced by declining hemoglobin, increasing transfusion requirements, or clinical deterioration will require surgical exploration.

Stenosis

Stenosis after LSG may present acutely after surgery with dysphagia as result of postoperative edema but more commonly presents in a delayed manner with food intolerance, dysphagia, nausea, emesis, worsening reflux, or early satiety. Patients who are suspected to have a stenosis should undergo an upper gastrointestinal contrast study to assess the location and length of the stenosis (Fig. 41.14). Once a diagnosis has been made, endoscopic technique using pneumatic balloon dilation or bougie dilation has been used successfully to treat stenosis after sleeve gastrectomy [41, 42]. Some patients require more than one dilation to achieve resolution of their symptoms. If advanced endoscopy is not available, then the patient should be transferred to a center with a bariatric surgical specialist [43].

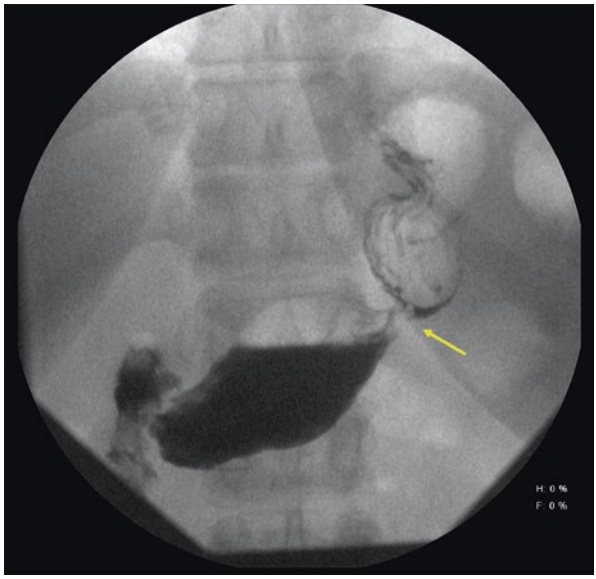

Fig. 41.14 Radiographic image demonstrating sleeve stricture on mid-body of sleeve. Yellow arrow indicates stenosis/stricture

Laparoscopic Adjustable Gastric Banding

The overall complication rate for LAGB is reported as 12–48% [44]. Although the 30-day morbidity and mortality related to the use of LAGB are lower than LSG or LRYGB, there are some unique and well-described complications specific to gastric banding that require surgical intervention and early recognition by the general surgeon. For more detailed information please refer to Chap. 31.

Erosion

Erosion of a LAGB is defined as the migration (partial or complete) of the implant into the gastric lumen. Literature reports an incidence rate between 0.2% and 4% for primary placement of the LAGB and higher for those undergoing revisional procedures [45]. Patients usually present approximately 2 years after LAGB implantation with complaints of weight regain, loss of satiety, and need to frequently refill the device. Some will present with hematemesis or spontaneous infection of the access port. All LAGB port site infections should be considered an erosion until proven otherwise. Although LAGB erosion is rarely a surgical emergency, clinical suspicion is paramount to identify this entity and direct patients to centers with experience managing this complication.

Upper endoscopy confirms the diagnosis with direct visualization of intragastric portions of the LAGB (Figs. 41.15 and 41.16). Occasionally, band erosion is diagnosed intraoperatively as part of exploration for other purposes or during revisional

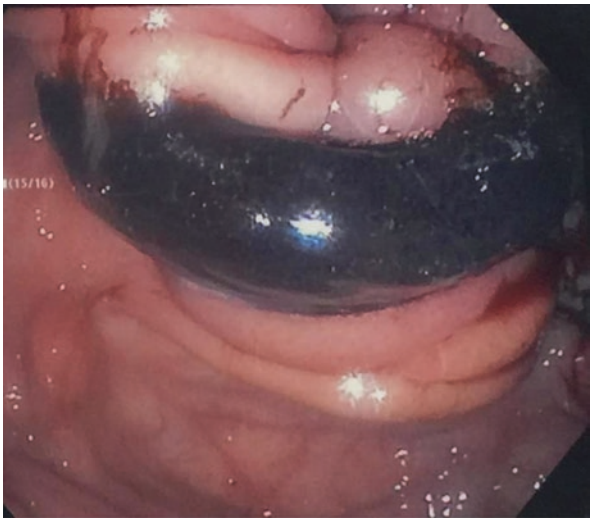

Fig. 41.15 LAGB erosion: intragastric band observed during upper gastrointestinal endoscopy

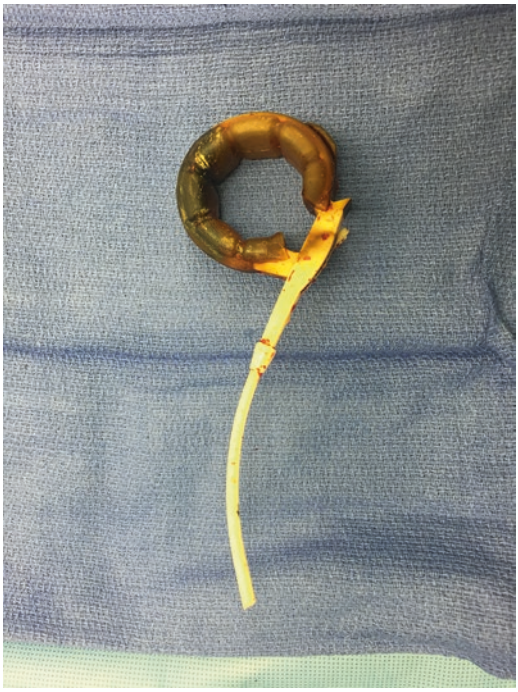

Fig. 41.16 LAGB erosion: excised eroded LAGB – note the stained band, indicative of erosion

bariatric surgery. Endoscopic versus laparoscopic or open surgical removal of the device has been successfully achieved. In situations of band erosion, a staged bariatric procedure is recommended to decrease morbidity [46]. Referral to tertiary centers familiar with revisional bariatric surgery procedures should be sought if erosion is encountered in a stable, non-acute patient.

Slippage

Band slippage has been defined as the cephalad prolapse of the body of the stomach or caudal movement of the band. Slippage can be classified as posterior or anterior based on which portion of the stomach herniates through the band (Fig. 41.17a–c).

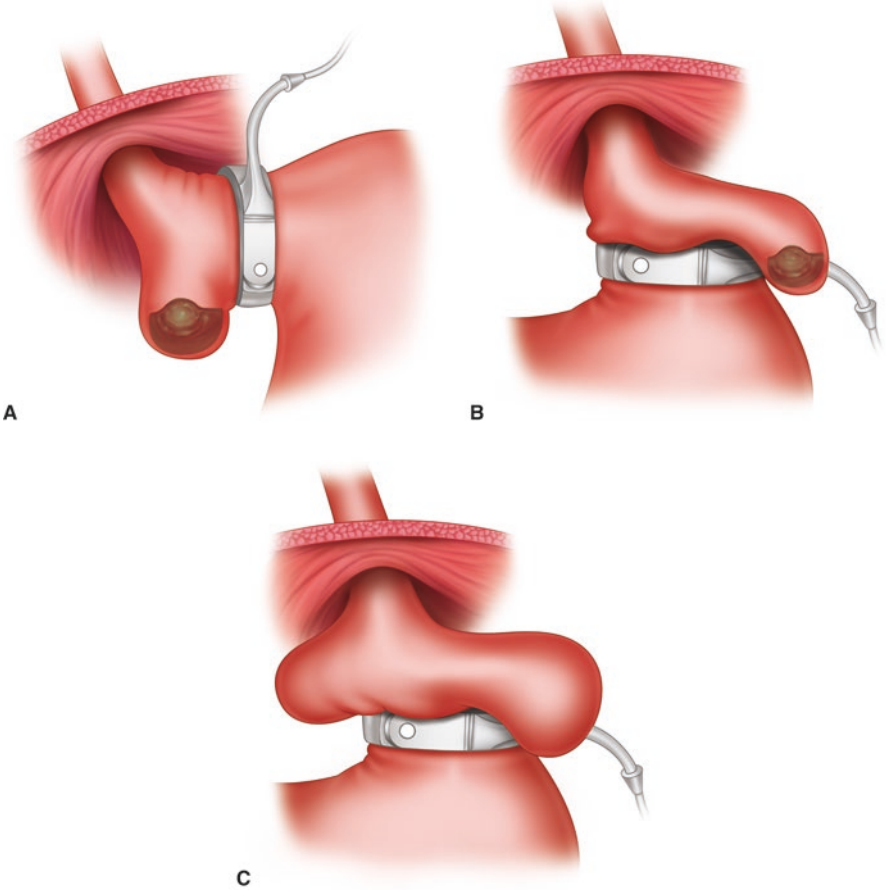

Fig. 41.17 A-C LAGB slippage. (**a**) Posterior band slippage with gastric prolapse. Anterior band slippage with gastric prolapsed (**b**). Concentric pouch dilation (**c**)

Additionally, concentric pouch dilation has been defined as dilation of the gastric pouch with or without change in the Phi angle in patients that present without signs of obstruction [47].

Immediate postoperative prolapse secondary to inappropriate band placement requires laparoscopic revision with adequate band repositioning. In the non-emergent symptomatic LAGB slip, it is recommended to deflate the band and observe for symptom resolution. When this strategy fails, a surgical approach is sought with most cases ultimately resulting in band removal.

The general surgeon should be aware of the unfortunate cases of anterior or posterior slippage that present acutely with gastric ischemia or necrosis. The most prudent strategy is to remove the band and resect the affected portion of the stomach via laparoscopic or open approach depending on the surgeon's level of comfort [48].

Port Site Infection

The incidence of port site infection varies widely in the literature, from 4.3% to 24% [49]. Clinical presentation varies from induration, abscess, and sinus formation to LAGB erosion. Although initial management with antibiotics and drainage should be attempted, the risks of development of systemic infection and potential intragastric band erosion need to be taken into consideration. In patients in whom medical therapy fails or those who present with recurrent port infections, the optimal approach includes port disconnection, removal of the port, and placement of the tubing in the abdominal cavity. Once infection control is achieved and local healing is adequate, a new access port can be placed with reconnection of the tubing via laparoscopic approach. Although not widely used, the implantation of antibiotic beads around the infected subcutaneous port has been proposed as a rapid and simple technique to allow retention of the original port [50].

Esophageal Dilation

Esophageal dilation has been described as a long-term complication following LAGB. The literature reports an incidence between 0.5% and 50%. This complication is a common reason for revisional surgery after band implantation. Symptomatic patients usually present with reflux esophagitis, dysphagia, heartburn, regurgitation, nausea, and emesis. Overinflation of the band is responsible for most cases. Others have postulated dietary deficiencies and preimplantation esophageal motility disorders as etiologies of esophageal dilation, ultimately causing outlet obstruction [51]. Initial investigation with a water-soluble contrast study and upper gastrointestinal endoscopy can aid in the diagnosis of esophageal dilation.

Upon recognition of this complication, the general surgeon should be familiar with the percutaneous approach for band deflation which can provide partial or complete symptom relief. For patients in whom deflation is not enough, referral to a bariatric center is recommended.

Trocar Site Hernia

Postulated risk factors contributing to the development of trocar site hernias include advanced age, diabetes, smoking, surgical site infections, COPD, diabetes, and obesity. Multiple studies recommend the routine closure of ports that are 10 mm or larger in non-bariatric laparoscopic operations to prevent the formation of hernias [52, 53].

Closure of port sites is considerably more difficult in obese patients, and thus many surgeons do not routinely perform fascial closure as part of their routine. Coblijn et al. recently reported a 0.5% trocar site hernia rate [54] among 1249 patients undergoing either laparoscopic RYGB, AGB, SG, or revisional procedures. Similarly, Pilone and colleagues [55] described a 1.6% incidence for trocar site hernias when ports equal or larger than 10 mm were used. Even when port site hernias are found, they are likely to be asymptomatic and carry low risk for significant complications.

Early trocar site hernias (less than 30 days) can present with bowel or omental strangulation. Early recognition is essential to prevent bowel ischemia or necrosis. Upon identification, a laparoscopic approach can be utilized to reduce the herniated contents and perform a thorough bowel inspection for viability. Late hernias (more than 30 days) manifest as bulging at the trocar site secondary to the development of a hernia sac. These latter types of hernias are usually observed after significant weight loss has been achieved. Elective repair for symptomatic patients is recommended. Clinical suspicion and the liberal use of CT scanning can help make the diagnosis and guide the general surgeon.

Pulmonary Embolism

Pulmonary embolism (PE) and deep venous thrombosis (DVT) following bariatric surgery are well-known risks, with the prevalence of PE and DVT reported to be 0.9–1.3%, respectively [56]. Obesity is a risk factor for the development of venous thromboembolism (VTE), and its contribution to the thromboembolic risks of surgery has led most bariatric surgeons to use chemoprophylaxis in the form of low-molecular-weight heparin or low-dose unfractionated heparin in combination with elastic stockings or intermittent pneumatic compression. Patients who develop a PE postoperatively have an in-hospital mortality of 2.88% [57].

PE is the second leading cause of death following bariatric surgery. The mean time from surgery to diagnosis of PE and DVT is 24 days [58]. Patients presenting with dyspnea, chest pain, tachypnea, and tachycardia should be considered to have a PE until proven otherwise. Patients may report leg swelling as well; however, not all patients with PE will be found to have a DVT. The work-up of a patient suspected to have a thromboembolic event should include a CT pulmonary angiogram, in addition to a duplex study of the lower extremities. It is important to obtain a CT angiogram if PE is suspected, as negative duplex studies of the lower extremities have been shown to occur in up to 38.5% of patients who are diagnosed with PE [59]. The addition of a CT of the abdomen with oral contrast during the evaluation of the chest is beneficial in evaluating the patient presenting with tachycardia, since a postoperative leak is in the differential diagnosis.

The recommended treatment of a patient who has developed a PE or DVT postoperatively is 3 months of anticoagulant therapy [59]. Current guidelines recommend treatment in patients without cancer using dabigatran, rivaroxaban, apixaban, or edoxaban over vitamin K antagonist (VKA) therapy. Initial parenteral anticoagulation (i.e., heparin given as a bolus dose with subsequent dose adjustments to keep the activated partial thromboplastin time at 60–100 s) is given before dabigatran and edoxaban, but not given before rivaroxaban and apixaban, and is overlapped with VKA therapy [60].

Nutritional Emergencies

In this chapter we will discuss the two nutritional deficiencies that constitute an emergency, whereas other (non-emergent) nutritional deficiencies are covered in a separate chapter.

Thiamine (B1)

Unrecognized thiamine (vitamin B1) deficiency can have disastrous consequences. The body has very limited stores of vitamin B1. Studies have reported preoperative deficiency of thiamine in 12–29% of patients [60, 61]. Since the primary location for thiamine absorption is in the first part of the small intestine, the altered anatomy of the gastric bypass or duodenal switch can exacerbate this deficiency. In addition to the early symptoms that are not uncommon in this group of patients, namely, limited oral intake and sometimes emesis, thiamine deficiency can be seen and exacerbated earlier than most other vitamin deficiencies. The body's thiamine stores can be depleted in as little as 2 weeks.

Thiamine deficiency can be divided into early signs and advanced signs, as outlined by the ASMBS nutritional guidelines [62] (Table 41.3).

Table 41.3 Thiamine deficiency signs

Early
Dry beriberi (without edema): characterized by brisk tendon reflexes, peripheral neuropathy and/or polyneuritis, muscle weakness and/or pain of the upper and lower extremities *Wet beriberi*: heart failure with high cardiac output, edema in lower extremities, tachycardia or bradycardia, lactic acidosis, dyspnea, heart hypertrophy and dilation, respiratory distress, systemic venous hypertension, bounding arterial pulsations *Other/gastroenterologic*: slow gastric emptying, nausea, vomiting, jejunal dilation or megacolon, constipation
Advanced
Wernicke's encephalopathy: polyneuropathy and ataxia, ocular changes (ophthalmoplegia and nystagmus), confabulation, short-term memory loss

If thiamine deficiency is suspected, rapid treatment is imperative. Avoid glucose in initial IV fluids, as this can exacerbate the symptoms and increase the risk of permanent neurologic impairment. The use of lactated Ringer's (LR) or normal saline (NS) with an ampule of multivitamin can be initiated in the emergency room. Many facilities with bariatric surgery programs have initiated protocols in their emergency departments to include administration of 1 L of normal saline (NS) with an ampule of multivitamins, thiamine, and folate (aka the "banana bag") to all bariatric patients presenting with symptoms of vomiting. In the advanced or severe form, treatment includes thiamine 500 mg IV three times per day for up to 5 days, followed by 250 mg IV daily until symptoms resolve. When switching to oral therapy, the dose is 100 mg 2–3 times per day.

Cobalamin (B12)

Preoperative B12 deficiency occurs in up to 18% of patients with obesity [63, 64]. Cobalamin is a multivitamin whose absorption requires coupling with intrinsic factor (IF) from the stomach to allow for absorption in the terminal ileum. This mechanism is disrupted in the case of the gastric bypass or duodenal switch. Manifestations of B12 deficiency are listed in Table 41.4.

Table 41.4 Manifestations of B12 deficiency

Early
Pernicious anemia, fatigue, anorexia, diarrhea Numbness and paresthesia in extremities, ataxia Light-headedness or vertigo Tinnitus Palpitations
Advanced
Angina or congestive heart failure Altered mental status

Treatment should consist of 1000 mcg IM or IV. For severe deficiencies, treatment includes B12 1000 mcg daily for 1 week and then weekly injections of 1000 mcg for 1 month [65]. Subsequent B12 supplementation should include 1000 mcg/d orally. This should be in the form of a sublingual route to ensure absorption of the multivitamin.

Appendix

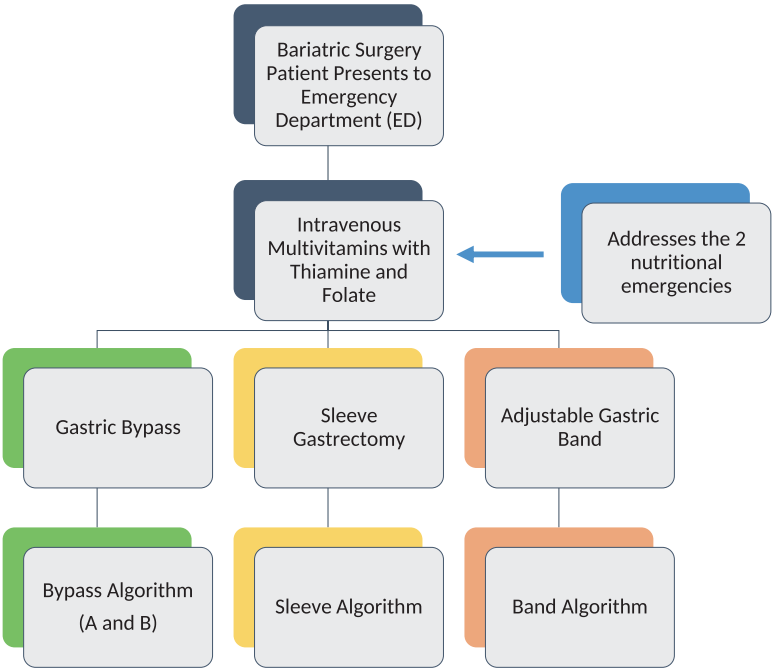

Fig. 41.18 General algorithm for bariatric surgery emergencies

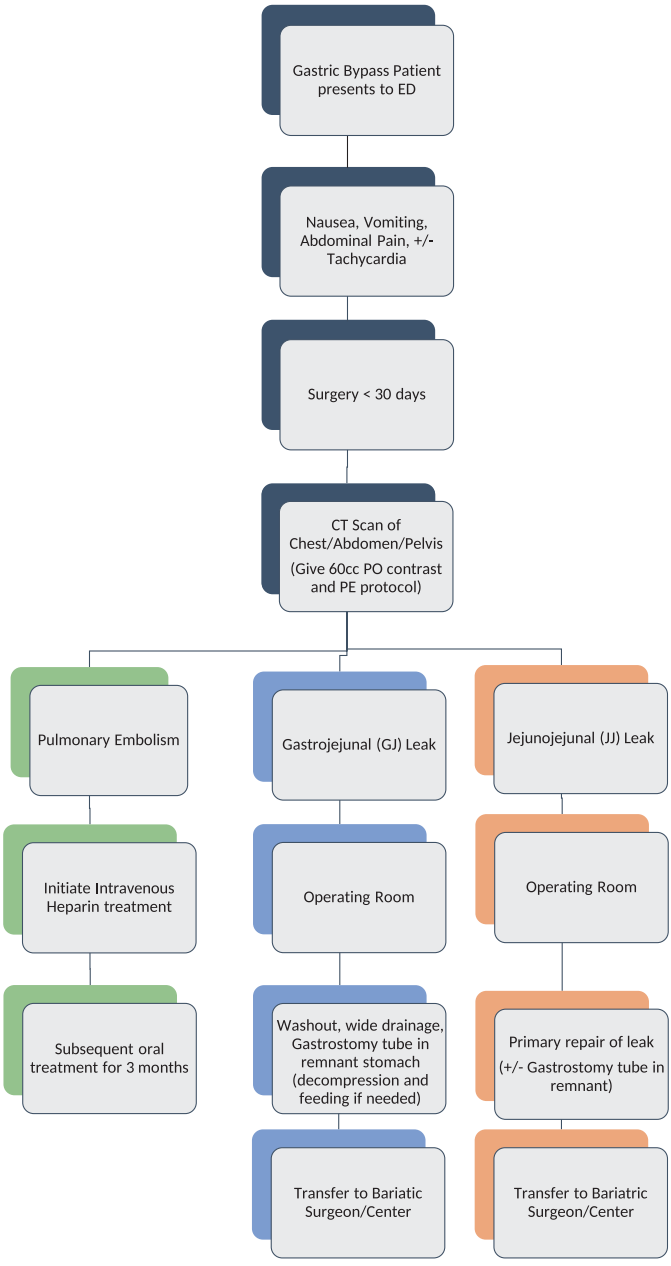

Fig. 41.19 Bypass algorithm A (<30 days from surgery) for bariatric surgery emergencies. Abbreviations: ED emergency department, CT computed tomography, PO per oral

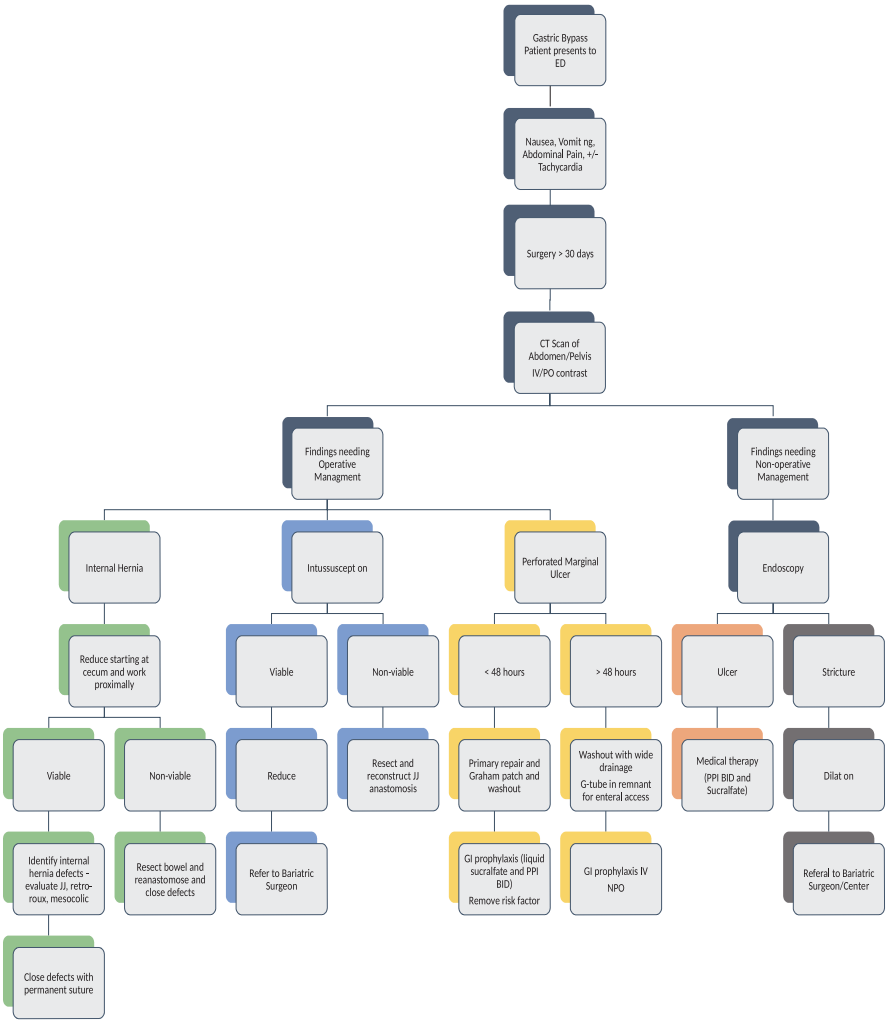

Fig. 41.20 Bypass algorithm B (>30 days from surgery) for bariatric surgery emergencies. Abbreviations: ED emergency department, CT computed tomography, PPI proton pump inhibitor, GI gastrointestinal, BID two times daily, NPO *nil per os*, JJ jejunojejunostomy, IV intravenous, PO per oral

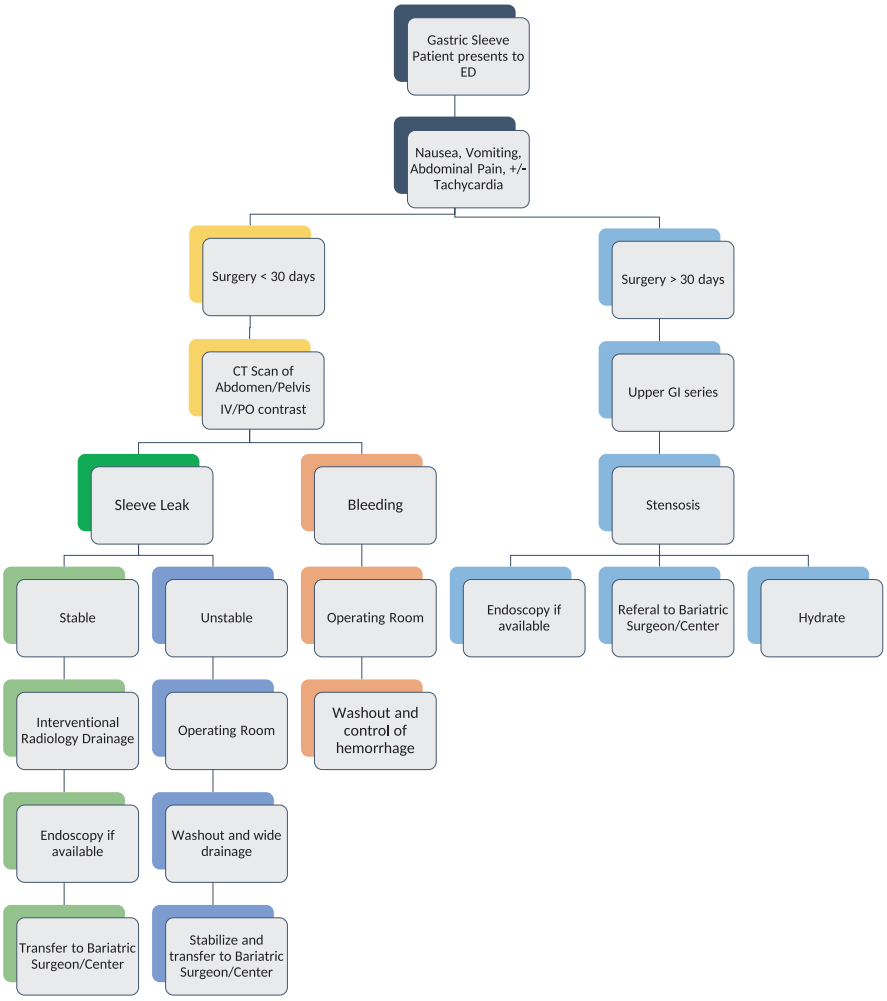

Fig. 41.21 Sleeve gastrectomy algorithm for bariatric surgery emergencies. Abbreviations: GI gastrointestinal, CT computed tomography, IV intravenous, PO per oral

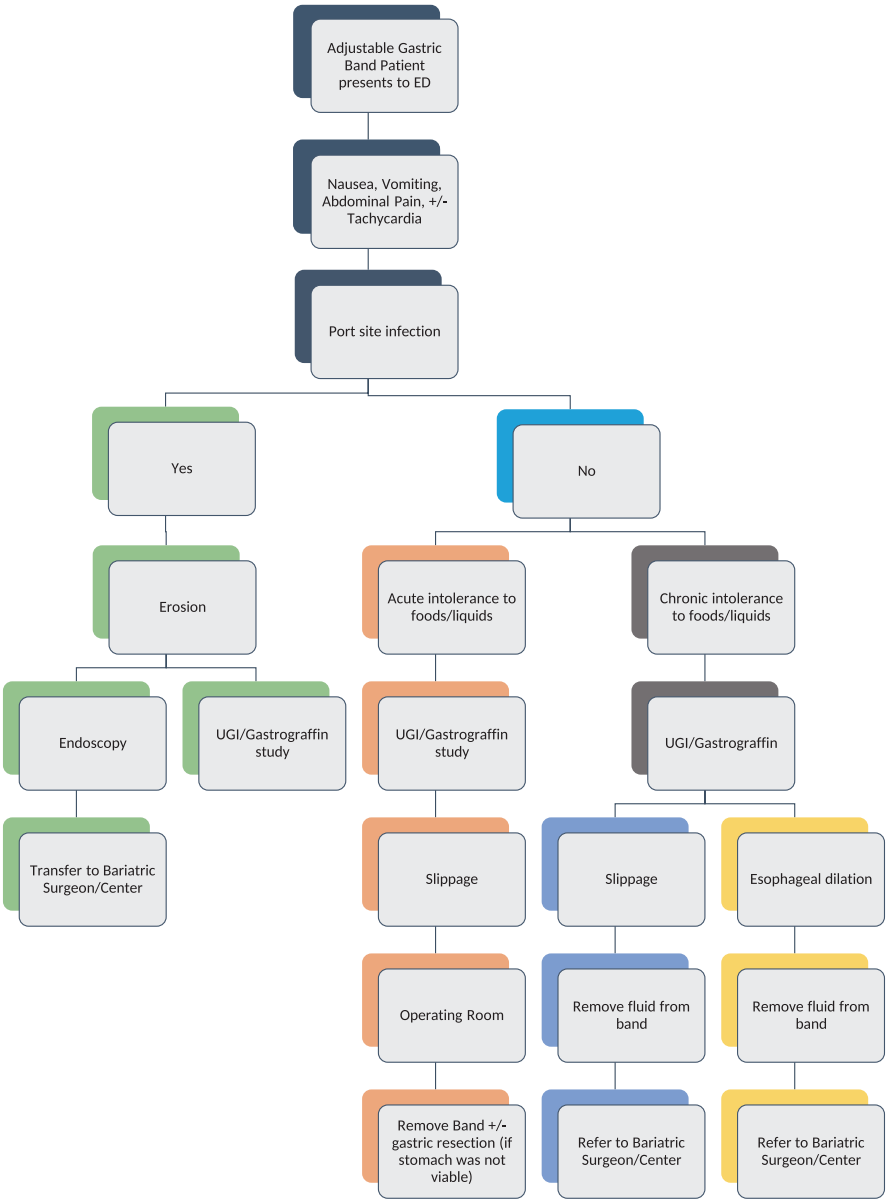

Fig. 41.22 Adjustable gastric band algorithm for bariatric surgery emergencies. Abbreviations: UGI upper gastrointestinal

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Chapter 42
Social Media and Bariatric Surgery

Philip E. George and Brian P. Jacob

Introduction and History

Social networking sites, or social media, are defined as web-based services that allow users to create a unique profile in the bounds of that site, create a network of other individuals, and then disseminate information using that platform [1, 2]. To date there are hundreds of social media platforms available with the most popular being Facebook ™, Twitter™, and YouTube™. There are roughly 2.3 billion worldwide users of social media, with roughly 87% of US citizens utilizing the services. These numbers are constantly increasing. The access to social media sites used to be restricted to desktop or portable computers, but with the increased use of mobile devices, the percentage of time users access these sites on mobile devices is increasing. Up to 68% of time spent on Facebook by users is on a mobile device [3]. This brings an already easily accessible platform with us wherever we go.

The increase in social media occurred after the rise of what is commonly referred to as "Web 2.0" in the late 1990s, which was a revolution in the way that websites are run, allowing them to be more interactive. This is in comparison to Web 1.0 which allowed for basic hyperlink based webpages, with minimal amounts of interaction [4]. This advance in programming allowed for a paradigm shift in the way we interact with the web, with users becoming producers of content instead of just consumers. This ease of creation and ease of content spread allowed blogs, personal websites, and eventually sites like Facebook, Myspace, and LinkedIn to rise.

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Physician and medical student use of social media has been increasing since its inception. The use among medical students is as high as 96% and in physicians as high as 65% [5]. In a survey of both US oncologists and primary care physicians, 61% of respondents admitted to using social media to try to incorporate information into their practice and 46% admitting to creating content for use in those channels [6]. In the same cohort, 57.9% of respondents thought that the use of social media for their practice helped them care for their patients more effectively. The use among surgeons may be even higher. A survey done by the American College of Surgeons in 2011 showed that roughly 55% of participating surgeons say they log onto Facebook, and up to 81.6% of surgeons use YouTube [7]. YouTube is a website where content creators (authors) can upload videos along with audio from variable sources and have other users able to comment on and share them. Not regarded as a classical social media platform, YouTube has increasingly become popular among surgeons who are able to share their surgeries from any number of perspectives (laparoscopy tower, head camera, live surgery, etc.).

The use of several of these platforms has evolved over the past decade from a primitive source for spreading basic patient information to collaborative groups between healthcare providers for different interests. Facebook is one of the most widely used of these popular social media platforms. Many surgeons use the site as a personal source, but only a small percentage use this platform as a professional collaboration tool. There are several methods of utilization of the website, but some of the more common uses are increasing awareness of certain diseases, aiding in distributing patient information and education, and publishing of recent studies or guidelines. More recently, it has been used as a channel for medical education, case discussion, and to alert organizations' members of upcoming events or courses.

A benefit of social media and its ease of use has been apparent with medical journals. Information gleaned by receiving a physical copy of a journal in the mail is rapidly diminishing and may be antiquated. Today, not only can we access most journals online or on any mobile device, but we can share relevant articles with colleagues and friends in seconds via many platforms. Some journals are even using social media to try to increase readership. A study done by the *Journal of the American College of Radiology* showed that by implanting a Twitter-based outreach intervention, they were able to increase both 7- and 30-day site visits to the specific article mentioned in the tweet [8].

There have been several strategies to try to improve the field of medical education using social media as well. Blogs are the most commonly implemented learning tools (71%) followed by Wikis, Twitter, and then Facebook [9]. Most interactions with these forms of education have had positive results, but in most studies there have been no comparative groups. In one study, however, students did prefer in-person problem-based learning to virtual collaboration for improvement of their critical thinking skills.

For bariatric surgery, the penetration of social media has yet to be fully explored, but great strides are being made to integrate most health systems. At the end of 2016, there were roughly 692 bariatric surgery organizations registered with ASMBS and MBSQIP [10]. Of these, 1294 social media accounts were found with

783 of them registered to private groups and 511 registered to academic groups. 44.8% of private groups utilized Facebook, while similarly 43.6% of academic groups were using Facebook. A smaller percentage was using Twitter, and even smaller was using YouTube.

Use by Residency Programs

There have been several fundamental changes in most general surgery residency programs, and subsequently general surgery fellowship programs, over the past decade. Generation Y, defined as the offspring of the baby boomers, born between the years 1970 and 2000, are the new wave of applicants to the field of general surgery [11]. Trying to attract a technologically advanced population is difficult without utilizing social media. When residents are viewing prospective programs, they once had to receive a handout from the institution or discuss matters with someone who was familiar with the institution. Now there are websites and social media profiles spanning Facebook, Twitter, LinkedIn, etc. This makes information about the program more visible and transparent. Additionally, the sites are interactive with inclusion of broadcasts, podcasts, or video discussion, which will enable persons from this Generation Y to be more interested than ever.

There have been little to no research on the effectiveness of social media on recruiting potential applicants to residency or fellowship positions, but many program directors admit to using these sources and are pleased with the results. The use is high among program directors (PDs) with 68% using Facebook and 40% using Twitter [12]. Professionalism is of utmost importance to program directors, and thus 11% of PDs admit to lowering a medical student on their rank list because of social media activity. Likewise, 10% of PDs also admit to instilling disciplinary action against a resident for activity on social media. Although the approach of the subject is difficult, since very few institutions have policies regarding conduct on social media, this is likely to change.

Medical Education

Since the inception of social media, there have been strides to incorporate these platforms in graduate and postgraduate programs to enhance medical education. Blogs and Twitter have been used to quickly share information about conferences, events, evidence-based medicine, journal club articles, or case presentations [13]. One of the more useful applications found in the literature was using an interactive blog as an adjunct to discuss case presentations as well as to present journal club articles in which members could hold a virtual journal club.

Another example of implementation of a social media-driven medical education strategy was a trial by Bergl and coworkers in which a chief resident of internal

medicine was given access to a Twitter account followed by the rest of the residents [14]. The account would post information ranging from morning report, relevant news in the world of medicine, subjects from grand rounds, and to up-to-date journal articles with an emphasis on practice change. At the end of the study, 69% of the residents expressed that this activity improved their education during residency.

There are several other groups that participate in interaction with medical students and junior residents, including the Eastern Association for the Surgery of Trauma Journal Club, the International General Surgery Journal Club, and the *Journal of the American Medical Association* (JAMA) network. Access to these groups is through Facebook and Twitter.

Interaction with Patients

As a specialty, the plastic surgery community has readily developed a social media presence and, as such, is a source of emerging trends when it comes to patient interaction [15]. Surgery has a unique place in the medical world, where many patients seek out physicians for their technique, skills, or services offered and where significant research and evaluation takes place on the Internet and on social media. Because of this, the benefits of having a pleasant and visible presence are more important than ever. When many bariatric surgeons offer similar services, an individual surgeon may distinguish one's individual practice with a social media, or at least an interactive web presence. Through the generation of online content, responses to patient queries, or other activities, the visibility of the surgeon and their practice improves. This may lead to increased consultations and surgeries. Patients may see this interaction with surgeons as more valuable than simply viewing their qualifications on their website. No prospective studies have been performed correlating the interactions on social media with patient throughput or economic implications, but as online metrics and analysis programs improve, this research is on the horizon.

One of the most useful ways a surgeon can utilize social media is to inform patients about the surgery they might undergo. Showing patients surgeries that they will be undergoing using social media sites such as YouTube or Vimeo was often previously avoided but is now more widely accepted. Another way of interaction is by sharing with patients the expectations for pre- and postoperative care. This not only allows patients to set expectations before even seeing the surgeon but also allows them to have some knowledge of what to expect. This may allow for the consultation to function as discussed in contrast to a one-way conversation.

Another use of social media by patients is support forums. There are numerous different support forums for patients with medical issues and of those who are undergoing and have undergone treatment for disease processes. For obesity and bariatric surgery, some of the popular forums currently available to patients include www.obesityhelp.com, www.bariatricpal.com, and www.realself.com (Fig. 42.1). These forums are platforms for users to have discussions with other individuals regarding specific subject matter, in this instance, obesity and bariatric surgery.

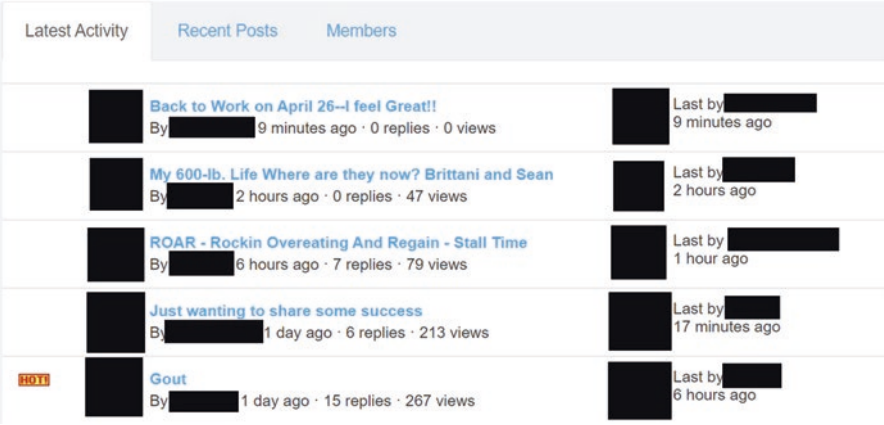


Fig. 42.1 Example of recent forum posts and replies on Obesityhelp.com (Used with permission of ObesityHelp.com, Irvine, CA, USA)

Users who have, as well as those who haven't, undergone medical or surgical therapy are able to interact with each other, obtain advice, or discuss other pressing matters in a monitored environment. Most of these groups are free to join for patients and are easily accessible on a mobile device. The feedback from physicians for patients using such a platform is overall positive, but some of the drawbacks are misinformation, lack of evidence, and issues of confidentiality [16]. As expert moderation and access become widespread, these shortcomings may disappear.

Impact on Surgeons

Facebook

A website started in 2004 first as a closed site to members of Harvard University is now seen and used by 1.86 billion monthly active users [17]. After opening to the public in 2006, adoption became widespread and for a spectrum of different purposes. Anyone over the age of 13 can create an account, can create a profile page with associated career and personal information, and can upload text, photos, or videos with an almost unlimited size potential. First used as a purely personal vehicle, Facebook has now evolved into a potential professional tool for physicians around the world.

One of the most basic uses of the platform is for a physician or physician practice aiming to promote themselves with sharing of practice updates, patient stories, or testimonials. This has evolved to take many different forms, from sharing of information by medical journals, posting of current guidelines, recruiting patients, to even having direct patient interaction. Since the medium is so new, there has been very little discussion on quality oversight of physicians using social media.

Fig. 42.2 Facebook™ welcome page for the International Bariatric Club (Used with permission of the International Bariatric Club; www.ibcclub.org)

Facebook groups have been one way in which physicians are able to utilize Facebook for professional use. These are groups of users that focus on discussion of a specific subject matter. They can be either open or closed, and each message that a user posts can be viewed by all members of the group. These features facilitate discussion between members and can include text, images, videos, polls, hyperlinks, and with the inclusion of hyperlink shortening programs like bit.ly (Bitly™, New York, NY, USA) an almost unlimited range of information.

The group can add members on an almost instantaneous basis after review. Once added to the group, users receive access to previous posts and group updates. These privatized groups allow for discussion in a safer space than by posting on a user's wall, in which all friends of the user can see. In this regard, a user can form a professional and personal divide in the posting of their content. The other benefit of sharing information using these groups is that the content can be viewed almost instantaneously without the need for waiting for a connection. There is even a way in which content can be shared "live" with a recording device sharing video or images with the viewer live.

One such instance of Facebook groups being used is with the International Bariatric Club (IBC) (Fig. 42.2). The IBC was started in 2008 by Dr. Tomasz Rogula, who at the time was an Assistant Professor of Surgery at the Cleveland Clinic in Ohio. The IBC has grown to be the third largest bariatric organization after the American Society of Metabolic and Bariatric Surgery (ASMBS) and the Brazilian Society for Bariatric Surgery [18]. In the beginning, the group's activities consisted of 1 hour talks on recently published articles in bariatric surgery that were broadcast over the Internet. After it was clear that the feedback from an online medium for sharing information was overwhelmingly positive, the IBC Facebook page was set up in November 2010. Since then the club has grown exponentially. In December 2011 there were 399 mem-

Table 42.1 Aims of the International Bariatric Club

Aims of the International Bariatric Club	
1	Promotion and exchange of knowledge, ideas, and experiences related to the preoperative, intraoperative, and postoperative care of the bariatric patient with bariatric professionals throughout the world
2	Sharing of bariatric surgery videos relevant to management of intraoperative and postoperative complications
3	Promotion of the monthly Webinar coordinated by the Cleveland Clinic in association with WebEx
4	Promotion and involvement in national and international meetings relevant to bariatric and metabolic surgery

bers, and now at the time of this writing, the group consists of 4109 members, with 79 added in the past week alone. This club is a free and nonprofit organization, open to any physician. The aims of the organization are listed in Table 42.1.

The most common ways of interacting on the Facebook group are sharing patient cases and petitioning other members for help with certain clinical scenarios. Patient case presentations usually make up most the posts, with assistance with pre-, post-, and sometimes intraoperative questions. Direct case advice is not the only material that gets posted. Commonly, broad clinical questions regarding decision-making and patient care, questions about coding, or surgical technique are also proposed. New research, up-to-date guidelines, and other medical literature are also shared with the group. The benefits of the platform of Facebook groups are that users can respond and comment on the submitted content immediately with visibility to all members of the group. This facilitates discussion and sharing of ideas and incorporating innovative ideas in an ongoing discussion.

A major concern regarding the ease of exchange is the protection of personal patient information. As a closed group, the IBC has the benefit of only sharing information with privileged physicians who are in the field and who are expected to respect patient rights. All posts should have identifying information removed such as wristbands, charts, or specific scars or body marks, unless the patient gives expressed permission. Additionally, the editors of the Facebook group can delete posts that either violate patient privacy or are unprofessional.

Other Facebook groups exist for different specialties. The International Hernia Collaboration has high impact on the field of hernia surgery, and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has several distinct groups present for interested candidates to be able to join in the field of colorectal, foregut, and bariatric surgery. Another major Facebook group is that of the SOARD Journal Club, which is an extension of the *Surgery for Obesity and Related Diseases*, the official journal of ASMBS. Started by Richard Peterson and now with 1073 members, the SOARD Journal Club Facebook group is an excellent source for bariatric and metabolic surgeons to discuss the most recent literature in one location. Polling among Facebook group members is another mechanism to stimulate discussion and engagement, as well as to gauge the overall group's views on a specific topic (Fig. 42.3). A benefit of using Facebook groups as a collaborative medium is

Fig. 42.3 SOARD Journal Club poll and response on Facebook™ (Used with permission of the American Society for Metabolic and Bariatric Surgery, Gainesville, FL, USA; www.asmbs.org)

to evaluate separate components of the discussion, including the participants of the discussion, along with types of posts or comments and subsequent responses. These data can help determine recurring themes and specific needs of the group to be addressed. For instance, if there is an overwhelming submission of patient cases, there could be a method in place to only show the highest impact cases.

Facebook can also be valuable for physicians who are already members of professional societies. ASMBS is the owner of a Facebook page that shares updates, announcements, and events, as well as opportunities for scholarly pursuits such as awards and ongoing projects within the society. The page at present has 4426 "likes" which are user-generated markers of support for the page (Fig. 42.4).

A significant advantage of Facebook as a medical and professional platform is its established presence for personal use. Many physicians are already familiar with the interface and facile with posting and sharing functions. Even with minimal integration of medical content, a user while scrolling for personal means can encounter a scientific article or participate in a discussion on a medical topic. In this way, knowledge dispersion can occur through the compulsions of taking out mobile phones when one is distracted or bored. Little is known about the penetration of these medical sources into the Facebook feed, but overall feedback is positive.

Twitter

Twitter is a media platform founded in 2006 which allows users to send text transmissions, referred to as "tweets." This method of communication occurs through 140 character text messages to everyone who is following the transmitter [19].

Fig. 42.4 ASMBS sharing an update on a reminder for abstract submission (Used with permission of the American Society for Metabolic and Bariatric Surgery, Gainesville, FL, USA; www.asmbs.org)

The name Twitter arises from the idea that these short messages represent chirps from a bird, representing the brevity of the message. Pictures can be sent as part of the text message, and the medium also allows for imbedding a foreshortened URL link to another website with more extensive information on the topic. As of 2016, Twitter had 319 million monthly active users. As a singular news media source, it was the largest single source of dissemination of 2016 presidential election result with 40 million tweets related to the election sent on that day.

For professional organizations, Twitter is a resource to improve viewership. For surgical societies in particular, interaction with members can drive them to view additional content and initiatives online or at sponsored meetings [20] (Fig. 42.5). Using Twitter, a short hyperlink, a title, and a picture can lead to substantial increases in redirected traffic. Of note, Twitter reports an interesting phenomenon of virality, where a follower can retweet a message which then is viewed by all their followers who, in turn, might retweet this message. This successive forwarding may result in the information "going viral." This effect can be further enhanced when there is a high percentage of influential followers or followers with their own large cohort of followers.

A distinct advantage of this type of social media is the ability to organize subjects by hashtags. This requires a user to place a hashtag (#) in front of a topic, and this allows other users to view this tweet as part of a collection of

Fig. 42.5 ASMBS' Twitter™ site with example tweet (Used with permission of the American Society for Metabolic and Bariatric Surgery, Gainesville, FL, USA; www.asmbs.org)

other tweets that contain this same identifier. An example is the recent hashtag #ilooklikeasurgeon, which is part of a larger campaign to increase diversity and equality in the surgical field.

YouTube

Not formally regarded as social media, YouTube has become the largest video-sharing site in the world with more than 1 billion hours of videos watched per day [21]. First used to share personal videos, the site is popular with surgeons looking to share their works to educate patients, residents, or other surgeons in their techniques or methods. Many professional journals use YouTube links to accompany manuscripts. One of the more cited uses for YouTube is its assistance in preparing junior and senior surgeons alike for surgery. A recent survey showed that 90% of responding medical students, surgical residents, and surgical faculty used YouTube as a preparation for surgery and 86% claimed that this was their primary source for preparatory information [22].

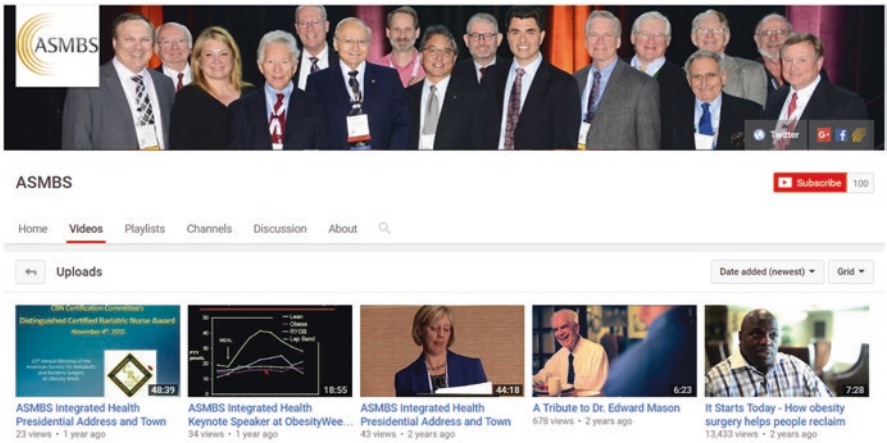


Fig. 42.6 YouTube™ website of ASMBS (Used with permission of the American Society for Metabolic and Bariatric Surgery, Gainesville, FL, USA; www.asmbs.org)

Like similar social media channels, users create profiles and can create or view content. Users can subscribe to another user's channel and get updates via a method of their choice for videos that they post. Apart from viewing surgeries, by entering a query into the search bar, one can search for any number of lectures, presentations, or other media from different surgical societies, physician groups, or physicians (Fig. 42.6). This platform can similarly be used for patient education as well, preparing them for surgery, and expectations for before and after the procedure.

Words of Caution

In this era of increasing ease of sharing critical medical information, it is absolutely necessary to respect patients' rights while discussing cases or sharing information. The Health Insurance Portability and Accountability Act (HIPAA) was enacted in 1996 to protects patients' privacy regarding divulging their healthcare information to certain entities [23]. Any practitioner who transmits health information is subject to HIPAA. Practitioners must take care to limit sharing of protected health information (PHI) as much as possible, which includes all identifying factors of patients. Failure to limit exposure of patient PHI can result in civil or monetary penalties. With relation to social media, the legal grounding of what violates dissemination of health information is called publication. Divulging information to one or two colleagues does not qualify as publication, but open sharing of information in an unprotected post on Facebook would qualify.

In taking care to post information on social media sites, it's important to understand the legal discoverability of the content. The idea of a "social media privilege" where there is assumed to be automatic privacy of information posted have been rejected by many court rulings [24]. All information that is shared in an open manner to all followers of one's social media account can be admissible in a court of law, since some of this information can be readily search for in an Internet or social media search engine. As such, it is important to ensure that information divulged is shared in a closed forum and with the informed consent of the patient.

Informed consent is obtained in a specific manner and with every patient whose information is shared using social media. The patient must be told that identifying information will be removed and that this information will be shared for the purposes of education. The patient should also understand that even if the information is deleted, there is a chance that remnants of the information might be permanent.

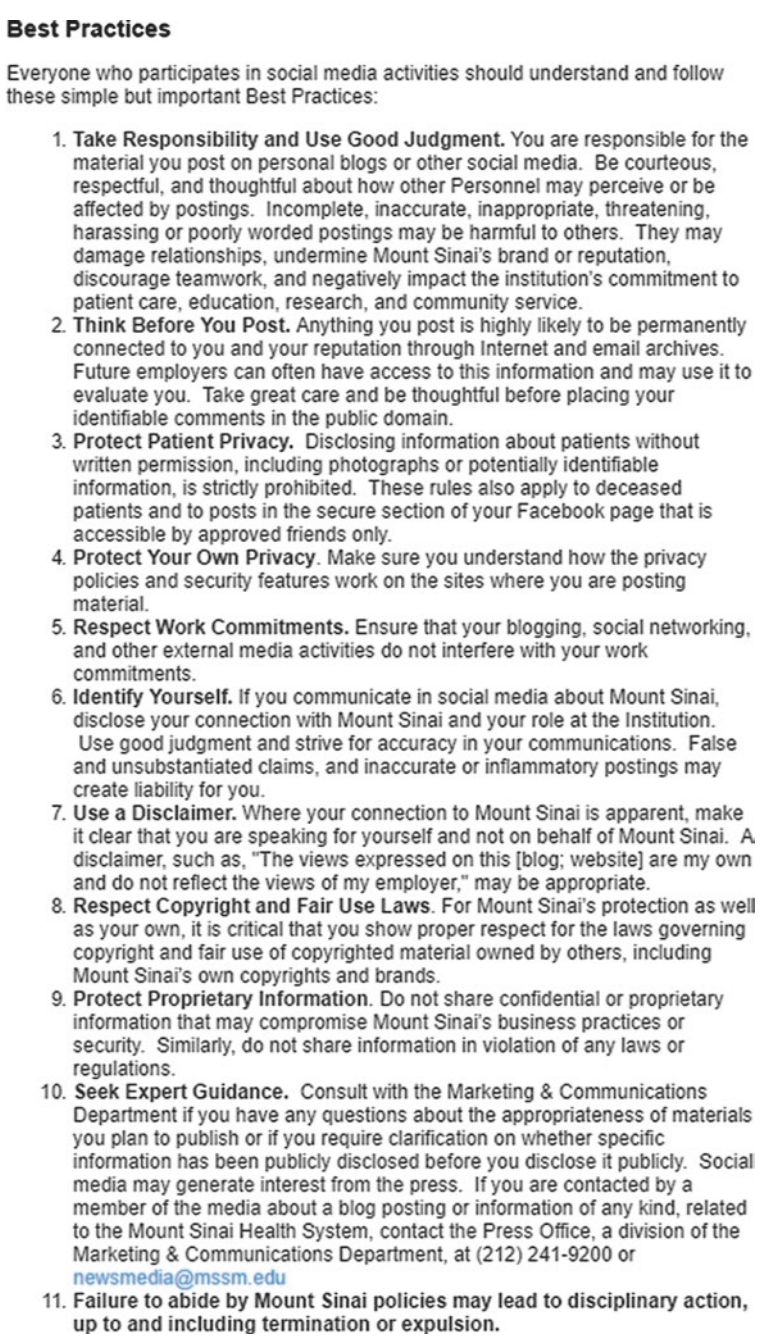
One of the dangers of social media is that since it is such a new medium to share information, there are ambiguous legal zones and that professional decorum is upheld. To use social media as a professional platform, the appearances of one's profile and conversation must be professional.

Due to the risk of emotional damage to the patient, as well as possible legal implications regarding confidentiality, social media policies should be implemented by medical institutions guiding behaviors. As an example, certain residency training programs have implemented social media policies, with the goal to engage medical personnel sooner in their training. Inability to limit professionalism and patient privacy has led to deleterious legal actions.

An example of an institution-wide social media policy is shown in Fig. 42.7 by the Mount Sinai Hospital in New York.

Conclusion

The field of social media is growing rapidly and is an excellent, yet still underutilized, source of communication and collaboration between medical professionals. These platforms allow dissemination of information, promotion of practices, and ultimately improvement in the medical care that patients receive. For residency and fellowship programs, it is not a question of whether social media should be adopted; the question is rather how best the program can utilize it. In this new age of social media, policies need to be put in place to guide how members interact with each other. With commitment and collaboration, the bariatric surgery community can lead the way in medical education, quality improvement, and evidence-based medical practices on a global level.



Best Practices

Everyone who participates in social media activities should understand and follow these simple but important Best Practices:

1. **Take Responsibility and Use Good Judgment.** You are responsible for the material you post on personal blogs or other social media. Be courteous, respectful, and thoughtful about how other Personnel may perceive or be affected by postings. Incomplete, inaccurate, inappropriate, threatening, harassing or poorly worded postings may be harmful to others. They may damage relationships, undermine Mount Sinai's brand or reputation, discourage teamwork, and negatively impact the institution's commitment to patient care, education, research, and community service.
2. **Think Before You Post.** Anything you post is highly likely to be permanently connected to you and your reputation through Internet and email archives. Future employers can often have access to this information and may use it to evaluate you. Take great care and be thoughtful before placing your identifiable comments in the public domain.
3. **Protect Patient Privacy.** Disclosing information about patients without written permission, including photographs or potentially identifiable information, is strictly prohibited. These rules also apply to deceased patients and to posts in the secure section of your Facebook page that is accessible by approved friends only.
4. **Protect Your Own Privacy**. Make sure you understand how the privacy policies and security features work on the sites where you are posting material.
5. **Respect Work Commitments.** Ensure that your blogging, social networking, and other external media activities do not interfere with your work commitments.
6. **Identify Yourself.** If you communicate in social media about Mount Sinai, disclose your connection with Mount Sinai and your role at the Institution. Use good judgment and strive for accuracy in your communications. False and unsubstantiated claims, and inaccurate or inflammatory postings may create liability for you.
7. **Use a Disclaimer.** Where your connection to Mount Sinai is apparent, make it clear that you are speaking for yourself and not on behalf of Mount Sinai. A disclaimer, such as, "The views expressed on this [blog; website] are my own and do not reflect the views of my employer," may be appropriate.
8. **Respect Copyright and Fair Use Laws**. For Mount Sinai's protection as well as your own, it is critical that you show proper respect for the laws governing copyright and fair use of copyrighted material owned by others, including Mount Sinai's own copyrights and brands.
9. **Protect Proprietary Information**. Do not share confidential or proprietary information that may compromise Mount Sinai's business practices or security. Similarly, do not share information in violation of any laws or regulations.
10. **Seek Expert Guidance.** Consult with the Marketing & Communications Department if you have any questions about the appropriateness of materials you plan to publish or if you require clarification on whether specific information has been publicly disclosed before you disclose it publicly. Social media may generate interest from the press. If you are contacted by a member of the media about a blog posting or information of any kind, related to the Mount Sinai Health System, contact the Press Office, a division of the Marketing & Communications Department, at (212) 241-9200 or newsmedia@mssm.edu
11. **Failure to abide by Mount Sinai policies may lead to disciplinary action, up to and including termination or expulsion.**

Fig. 42.7 Example of Icahn School of Medicine social media policy (Used with permission of Mount Sinai Health System, New York, NY, USA; www.mountsinai.org)

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Chapter 43
Bariatric Tourism: Bidirectional and in the United States

Abhishek D. Parmar and Farah A. Husain

Introduction

The American Society of Metabolic and Bariatric Surgery (ASMBS) defines medical tourism as "the practice of traveling across international borders to access healthcare systems or physician services that are not available or less attractive in a person's native country" [1]. Broadly, medical tourism can be classified as outbound (US patients seeking care outside the United States), inbound (international patients seeking care inside the United States), and intrabound (US patient traveling within the country for medical care). In a report for the Organization for Economic Cooperation and Development, Lunt and colleagues make it clear that while medical tourism is a burgeoning and expanding occurrence, much of the evidence and research to date has been based on empirical research or derives from indirect research; much is still not understood [2]. As an actively expanding industry, medical tourism will increasingly affect health outcomes for bariatric patients both worldwide and within the United States over time, with considerable interest domestically. A 2007 survey by International Communications Research of 1003 Americans found that 20–40% of families would seek care in another country if provided with financial incentives to do so [3]. In addition, internet searches for medical tourism also reveal the level of burgeoning interest and access; in May 2007 a search for "medical tourism" and "bariatric" would yield 24,600 results; in May 2011, that resulted in over 400,000 sites [4].

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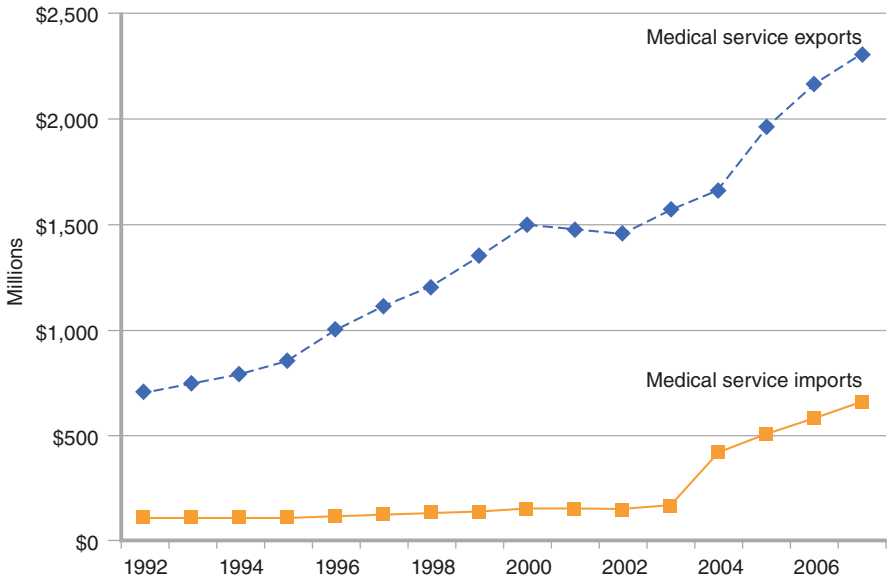

Fig. 43.1 Medical service imports and exports for the United States, 1992–2007 (Used with permission of Elsevier from Johnson and Garman [6])

While the published literature is sparse on the exact number of patients who pursue medical tourism and their attendant outcomes, an estimate by Deloitte Health Solutions suggested that roughly 750,000 Americans pursued medical care in another country (outbound) in 2007 [5]. A more conservative estimate was obtained by Johnson and colleagues, who queried information from the US Bureau of Economic Analysis and the US International Trade Administration to estimate that the outbound estimates for tourism were 50–121,000 for 2007, while inbound estimates were 43,000–103,000 [6]. Both estimates were an increase from prior years (Figs. 43.1 and 43.2). The graph does depict a sharp decrease in inbound medical tourism in 2001, hypothesized to occur as a result of the September 2001 terrorist attacks and reduced emigration; since that time a slow but steady trend toward increased inbound tourism has occurred. Based on hospital surveys, Johnson and colleagues estimated that the majority of inbound medical tourists traveled from the Middle East or Mexico (Fig. 43.3). While current estimates are unknown, in their 2009 report Deloitte estimated that 1.2 million Americans sought medical care outside the United States in 2012, while only 561,000 patients would travel to the United States for care by 2017. Internationally, broad estimates place medical tourism rates at anywhere from 60,000 to 50 million patients annually, with most conservative estimates around five million [7]. Given the inherent logistical limitations of recording and documenting medical tourism rates across hundreds of countries, it is unlikely that more precise estimates will exist.

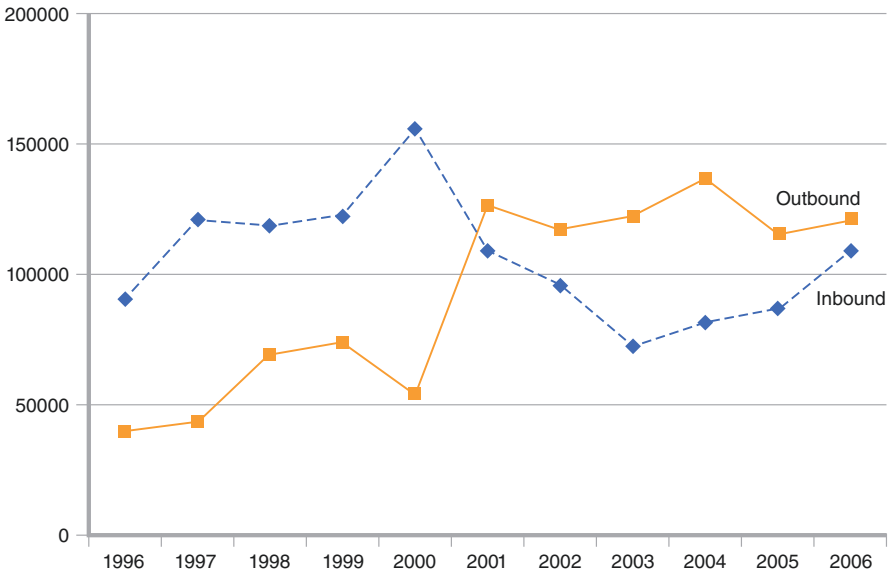

Fig. 43.2 International travelers reporting health treatment as the primary purpose for their trip, 1996–2006 (Used with permission of Elsevier from Johnson and Garman [6])

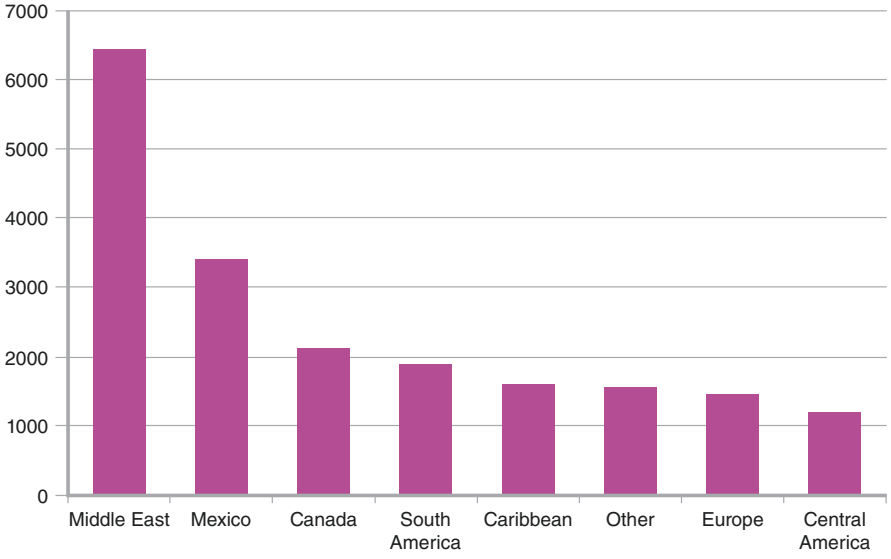

Fig. 43.3 Origin of inbound medical travelers to the United States, 2006 (Used with permission of Elsevier from Johnson and Garman [6])

Current Guidelines

The American College of Surgeons in 2009 published a position statement on medical tourism, outlining the need to preserve patient autonomy and choice while outlining the inherent risks of the practice. The organization's position statement also encourages patients to take measures to improve follow-up and continuity of care [8]. The American Medical Association has also been cautiously supportive of a patient's right to pursue medical tourism to potentially optimize value and choice [9]. In contrast, the ASMBS has taken a less conciliatory tone, focusing on the inherent risks of undergoing a complex operation (that innately requires long-term follow-up and care) in a foreign locale. In a 2011 position statement, the ASMBS reframed the concept of medical tourism as "global bariatric healthcare," defined as "travel to undergo bariatric surgery across any distance that precludes routine follow-up and continuity of care with the surgeon or program" [10]. This qualitative perspective, while generally supporting an obese patient's right to choose their care, outlines numerous complicating factors that are unique to the obese patient. First, bariatric surgery is complex and exposes patients to multiple perioperative complications that can be life-threatening if not identified early. Traveling to another country increases the potential for delay in diagnosis of a complication, given the inherent logistical vacuum of oversight and unified care in the immediate follow-up period. Next, the necessity for close follow-up and nutritional surveillance that is unique to metabolic surgery is many times lost or ignored when patients pursue care in another country. Finally, extensive travel to undergo an operation exposes an obese patient that is already at high risk for thromboembolism to unique complications and compounded risk by immobilization on a plane or during long-term travel.

Based on these and other unique considerations for the bariatric patient, the ASMBS' position statement makes multiple practical recommendations and safeguards for patients who might pursue medical tourism [10]:

1. *Because of the unique characteristics of the bariatric patient, the potential for major early and late complications after bariatric procedures, the specific follow-up requirements for different bariatric procedures, and the nature of treating the chronic disease of obesity, extensive travel to undergo bariatric surgery should be discouraged unless appropriate follow-up and continuity of care have been arranged and transfer of medical information is adequate.*
2. *The ASMBS opposes mandatory referral across international borders or long distances by insurance companies for patients requesting bariatric surgery if a high-quality bariatric program is available locally.*
3. *The ASMBS opposes the creation of financial incentives or disincentives by insurance companies or employers that limit patients' choices of bariatric surgery location or surgical options and, in effect, make medical tourism the only financially viable option for patients.*
4. *The ASMBS recognizes the right of individuals to pursue medical care at the facility of their choice. Should they choose to undergo bariatric surgery as a part*

of a medical tourism package or pursue bariatric surgery at a facility a long distance from their home, the following guidelines are recommended:

(a) *Patients should undergo procedures at an accredited JCI institution or, preferably, a bariatric center of excellence.*
(b) *Patients should investigate the surgeon's credentials to ensure that the surgeon is board eligible or board certified by a national board or credentialing body. Individual surgeon outcomes for the desired procedure should be made available as a part of the informed consent process whenever possible.*
(c) *Patients and their providers should ensure that follow-up care, including the management of short and long-term complications, are covered by the insurance payor or purchased as a supplemental program before traveling abroad.*
(d) *Surgical providers should ensure that all medical records and documentation are provided and returned with the patient to their local area. This includes the type of band placed and any adjustments performed in the case of laparoscopic adjustable gastric banding, as well as any postoperative imaging studies performed.*
(e) *Before undergoing surgery, the patient should establish a plan for postoperative follow-up with a qualified local bariatric surgery program to monitor for nutritional deficiencies and long-term complications and to provide ongoing medical, psychological, and dietary supervision.*
(f) *Patients should recognize that prolonged traveling after bariatric surgery could increase the risk of deep venous thrombosis, pulmonary embolism, and other perioperative complications.*
(g) *Patients should recognize that there are risks of contracting infectious diseases while traveling abroad that are unique to different endemic regions.*
(h) *Patients should recognize that travel over long distances within a short period before bariatric surgery could limit appropriate preoperative education and counseling regarding the risks, benefits, and alternatives for bariatric operations. This also significantly limits the bariatric surgery program's ability to medically optimize the patient before surgery.*
(i) *Patients should understand that compensation for complications could be difficult or impossible to obtain.*
(j) *Patients should understand that legal redress for medical errors for procedures performed across international boundaries is difficult.*

5. *When a patient who has undergone a bariatric procedure at a distant facility presents with an emergent life-threatening postoperative complication, the local bariatric surgeon on call should provide appropriate care to the patient consistent with the established standard of care and in keeping with previous published statements by the ASMBS. This care should be provided without risk of litigation for complications or long-term sequelae resulting from the initial procedure performed abroad. Routine or nonemergent care for patients who have undergone*

bariatric surgery elsewhere should be provided at the discretion of the local bariatric surgeon.[1]

Quality and Outcomes

While multiple case reports have been published outlining the perioperative complications and logistical issues with medical tourism, no large-scale quality reporting studies of medical tourism have been undertaken for patients undergoing bariatric surgery [11]. Case reports have identified the problems with lack of appropriate follow-up [4], delay in access to care [12], issues with continuity in care [13], increasing costs [14], and even documented cases of mortalities [15] that typify the concerns in the ASMBS position statement. However, without a grasp of the denominator and the number of patients who have undergone successful bariatric surgery in other countries, these published case reports (much like anecdotal clinical cases) serve little but to cloud our perception without informing our practice.

The Joint Commission International (JCI) has established standards for credentialing in international medicine that may improve outcomes for medical tourists [16, 17]. A branch of the Joint Commission that preserves standards in healthcare in the United States, JCI was established in 1994 as a nonprofit organization to provide a standard for safety in international healthcare organizations. In addition, the recredentialing process ensures that these organizations are up to date in medical care. While enrollment in JCI accreditation is voluntary, at present the JCI has accredited over 900 organizations in 100 nations across the world. While several studies have established improved outcomes for nursing [18], medication administration [19], and percutaneous cardiac interventions [20], the effects of the JCI on bariatric surgery outcomes have yet to be determined.

Motivations for Medical Tourism

A patient's motivation to seek bariatric medical tourism is complex and in many cases is related to specific health economic and structural factors unique to the individual and circumstance. While cost is many times the key motivating factor, other factors must be considered.

Glinos and coworkers [21] have provided a framework within which to consider patient mobility in bariatric tourism. They have defined the problem in terms of patient motivators (availability, affordability, familiarity, and perceived quality) and funding considerations (with or without funding). These factors result in a matrix of

[1] Excerpted with permission of Elsevier from American Society for Metabolic and Bariatric Surgery Position Statement on Global Bariatric Healthcare. Clinical Issues Committee. Surg Obes Relat Dis. 2011;7(6):669–71.

eight different possible patient-specific scenarios. In contrast, Laugesen and coworkers have established a different framework to understand why patients seek medical care elsewhere [22]. In their model, cost and quality are the driving forces and are influenced by gaps in care, access to coverage, and the presence or absence of government-funded medical care. These conceptual typologies are useful because they enable us to take the first steps toward understanding the mechanisms that underlie patient decision-making in medical tourism.

For patients undergoing bariatric tourism in the United Kingdom, Hanefeld and coworkers conducted a qualitative analysis to identify the motivating factors behind their decisions [17]. In interviews of 11 patients, the authors identified key overarching themes driving medical tourism in bariatric surgery. For British patients specifically, the decision was multifactorial and included lack of timely access to care within the National Health Service, mistrust in the system, expertise, and cost. While all respondents mentioned that cost played a role in their decision to seek care elsewhere, the most compelling factor in their decision was actually expertise (or perceived quality). For these patients, they felt that bariatric expertise and experience were actually superior outside of the United Kingdom, and that drove their decision to travel for their care.

As the Hanefeld study demonstrates, the major driving market force in medical tourism is cost. This has implications both at the patient level and from the standpoint of health populations. For the individual patient, bariatric surgery in the United States can be of prohibitive cost and is often not covered by a patient's insurer. One study suggested that costs for medical care can be 50–80% cheaper internationally than in the United States [23]. Multiple estimates of gastric bypass costs have been demonstrated to be significantly cheaper in foreign countries than the United States. While gastric bypass may cost $25,000 in the United States, the same operation can be offered in India ($6000) or Mexico ($8000) for much cheaper [24]. As a result, patients pursue medical tourism simply to identify a less expensive alternative. In other countries such as Canada, bariatric medical tourism is sought because of significant delays in access to care; in some cases patients may wait up to 5 years prior to undergoing a bariatric operation [14]. However, Canadian patients who pursue care elsewhere to return home for treatment of complications place significant strain on the single-payer government-funded insurance system, a problem that is clearly multifaceted on multiple levels of care [25].

On a population-based level, medical tourism may also represent cost savings for institutional healthcare payers, as was observed in the United Kingdom. In a review of medical tourists and calculated costs, Hanefeld and collaborators found that the United Kingdom's government-run National Health Service actually saved money when bariatric patients pursued their operations elsewhere, provided there were few complications [26]. Health economists have also hypothesized that medical tourism can be leveraged to be mutually beneficial to both the exporting country and the importing country [27]. The concept is that the increased competition with medical tourism can result in a decrease in costs, as sometimes occurs in free market economics [2].

These analyses, however, do not account for complications that are assumed by the host country. A recent cost analysis estimated that the Canadian public healthcare system absorbed over $550,000 over a one-year period in managing the complications of bariatric meditourists [14]. Another Canadian study expounded the benefits of expanding homeland bariatric surgery to avoid the expenditures of managing complications from returning medical tourists [28].

Ethical Issues

Ethics is the final consideration of the medical tourism phenomenon. Conventional medical ethics is based on the balance and interplay between patient autonomy, beneficence (do good), non-maleficence (do no harm), and justice. Within these tenets, bariatric tourism involves the potential lack of significant oversight (non-maleficence), the uncertainty in responsibility and who assumes those roles in the perioperative period when complications arise (beneficence), the interplay between cost containment and quality control (justice vs. autonomy and beneficence), and the allocation of resources (justice) [2, 29]. While JCI attempts to establish quality in participating institutions, there is no governing body or accepted standards for bariatric care internationally, and medical tourists potentially expose themselves to substandard care. Since there are no standards for informed consent, it is unclear if patients receive the requisite information necessary to make the decision to undergo bariatric surgery. Patients also may not receive the appropriate perioperative evaluation and intraoperative care. Without oversight patients lack the ability to address medicolegal issues should they arise. Finally, multiple US insurance companies have offered coverage for procedures in other countries [30]. In this manner, cost control plays a negative role in bariatric tourism, as American insurance companies may be incentivized to pursue cheaper alternatives for patients abroad instead of identifying the optimal value and quality [31].

At the population level, the expansion of medical tourism in underserved countries has the potential to shift the allocation of resources away from native populations and toward medical tourists willing to pay more [32, 33]. Lunt and collaborators have described this phenomenon as an exacerbation of the two-tier system [2]. In this scenario, an influx of medical tourists results in a change of the entire structure of the healthcare system to accommodate the visitors, potentially at the expense of the native peoples, who become the second, lesser tier. Future studies are needed to understand the influence of medical tourism on the ethics of health economics.

Conclusion

Bariatric tourism represents a complex interplay of personal, societal, and economic forces. Much is still not understood about the impact of bariatric tourism, both domestic and abroad. As such, additional research is needed to understand the extent

to which bariatric tourism is occurring, the effects of tourism on bariatric surgery patients, and overall clinical, ethical, and economic outcomes in all countries involved. Until these issues are better understood, the best approach remains one in which we place patient care and continuity of care at the forefront of our focus.

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Chapter 44
Pregnancy and Bariatric Surgery

John N. Afthinos and Allison M. Barrett

Introduction

Utilization of bariatric surgery has increased substantially over the past few decades, notably among women of childbearing age. The incidence of bariatric surgery increased 800% between 1998 and 2005, with 83% of patients between ages 18 and 45 being female [1]. It is well known that obesity is a risk factor for infertility, and many women seeking bariatric surgery do so with the goal that weight loss will result in future pregnancies. However, data on pregnancy outcomes following bariatric surgery are mostly from retrospective, observational studies.

Most surgeons advise patients to wait at least 12–24 months following bariatric surgery before pursuing a planned pregnancy. This is largely due to unstable nutritional needs immediately postoperatively, the risk for intrauterine growth retardation, and the decrease in total body weight lost from bariatric surgery [2, 3]. However, many pregnancies are unplanned, and there may be consequences in those patients who become pregnant soon after weight loss surgery.

Obesity, Pregnancy, and Infertility

Obesity during pregnancy is a risk factor for miscarriage, fetal anomalies, macrosomia, preeclampsia, gestational diabetes, venous thrombosis, need for cesarean section, and postpartum hemorrhage [4]. Obesity is also an independent risk factor for reduced fertility, with OR 0.92 for overweight women and OR 0.82 for obese women [5]. One study found that 40.4% of obese women have abnormal menstrual

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cycles, with infertility in 29.3% [6]. Polycystic ovarian syndrome (PCOS) is intricately linked to obesity and insulin resistance, which can result in anovulation. Even in obese women with normal menstrual cycles, fertility is reduced [5].

Weight loss can result in resolution of anovulation and subsequent pregnancy [7]. This has also been demonstrated with weight loss from bariatric surgery [8]. For these reasons, many women of childbearing age who are obese turn to bariatric surgery for assistance with obtaining and maintaining a healthy pregnancy.

Pregnancy Following Lap Band

Compared to obese women without an adjustable gastric band (AGB), women with AGB have a lower risk of gestational diabetes and hypertension, cesarean section rates, fetal macrosomia, and preeclampsia [9].

In some patients, presence of AGB can cause mechanical complications requiring intervention. Band slippage is a known complication of AGB that can occur at any time, though some speculate that the risk may be increased during the peripartum time period. Theories regarding peripartum band slippage include the vertical displacement of the AGB due to intra-abdominal pressure and girth [10], use of the Valsalva maneuver during vaginal labor, and hormonal changes that may result in laxity of ligamentous attachments [11]. Carelli found that 3 of 133 pregnancies were complicated by band slippage, with one requiring surgical removal of the AGB during pregnancy [11]. Band slippage during pregnancy can be diagnosed by plain abdominal radiograph, with observation for the "O" sign and presence of an enlarged gastric bubble superior to the AGB, indicating downward displacement of the AGB into a horizontal position. If needed, a gastrografin swallow study can be performed for confirmation, with careful shielding of the uterus [12].

Rare complications such as AGB erosion, gastric torsion, and gastric rupture have been reported during pregnancy [13, 14].

Management of AGB balloon volume during pregnancy is controversial. Some surgeons advocate for full AGB deflation to theoretically lessen the risk of band slippage, while others will only empty the AGB based on the patient's symptoms of nausea and vomiting [10, 15]. Carelli found that 71% of pregnant patients underwent AGB adjustment at some point during pregnancy, usually based on symptoms of nausea or vomiting. In patients whose AGB was fully or partially deflated, weight gain was higher during pregnancy, especially if the AGB was emptied during the first trimester [11]. Cornthwaite and colleagues found that women who had the AGB deflated during pregnancy gained more weight, had an increased risk of gestational hypertension, and had a higher risk of fetal macrosomia [16].

Pregnancy Following Sleeve Gastrectomy

Sleeve gastrectomy (SG) has now become the most common bariatric surgery being performed in the United States [17]. Outcomes regarding pregnancy and the perinatal period following SG are limited, given its recent development as a stand-alone operation. One theoretical concern is the potential for vitamin B12 deficiency, as the portion of stomach resected generates intrinsic factor necessary for its absorption. Protein deficiency can also be present from inadequate oral intake [18]. An additional concern is the incidence of newborns that are small for gestational age (SGA), which has been inconsistently reported for SG.

One study in France, employing a prospectively maintained database, evaluated 63 pregnancies in 54 women who had undergone SG. Women who conceived within 1 year of undergoing SG had a higher, but not significant, rate of transfer of their newborn to a neonatal intensive care unit [19]. There were no significant rates of low birth weight (LBW) or incidence of SGA. The authors also noted that patients who became pregnant within a year after SG gained less weight than their counterparts who became pregnant after 1 year. In Korea, 12 patients who became pregnant after SG were followed and evaluated. The authors observed no congenital abnormalities or deaths. There were no apparent complications identified in their small group of patients [20].

A comparative study performed in Greece focused on nutritional aspects with respect to pregnancy outcomes. The authors' study demonstrated significant declines in vitamin B12 when compared to before and during pregnancy [21]. Their patients received routine intramuscular injections of vitamin B12 to remove compliance as a confounding variable. With respect to newborn outcomes, there were no increased rates of SGA or LBW observed with SG. They did observe a statistically significant decline in serum albumin from the post-surgery state to pregnancy (4.33 ± 0.38 vs. 4.02 ± 0.39 g/dL; $p = 0.038$). Although the level is still acceptable, its decline is noteworthy. This study suggests that close monitoring of protein, vitamin, and mineral status before and during pregnancy is important, even in SG.

In summary, the perinatal outcomes after SG are largely unknown, and further study is warranted. Given the unknown, it is likely best to follow a conservative approach, recommending avoidance of pregnancy for 2 years, and prenatal evaluation by the bariatric surgery team before initiating pregnancy. In this manner, vitamin levels can be appropriately evaluated and optimized to avoid any deficiencies.

Pregnancy Following Gastric Bypass

The Roux-en-Y gastric bypass (RYGB) was the most common weight loss operation until recently [17], and it has shown clear benefits in improving fertility. There is also documented improvement in gestational diabetes, preeclampsia, stillbirths, Apgar scores, macrosomia, and caesarian section [22–24]. However, the

malabsorptive component of the operation can cause problems during pregnancy. Supplementation of protein, vitamins, and minerals are mandatory to prevent deficiencies which can be significant and sometimes life-threatening. These are well documented in the literature [25–28]. RYGB can have significant effects on both the mother and fetus, along with peripartum complications.

Several studies have shown a link between RYGB and SGA status of the newborn baby [29–32]. A multicenter study from Spain documented a 12.7% rate of SGA among RYGB patients [29]. The authors performed a logistic regression analysis, and only the RYGB and other malabsorptive procedures were risk factors. BMI, maternal age, and time from surgery to pregnancy were not significant factors. Similarly, Kjaer and colleagues identified a 7.7% rate of SGA newborns among RYGB patients [30]. Comparing with matched controls, there was an adjusted OR of 2.8 for SGA after RYGB. They showed no difference in APGAR score < 7, need for NICU admission, or perinatal death as a result of RYGB. Norgaard and colleagues found a higher rate of SGA at 18.8%. There was no statistical difference in SGA rate in patients who became pregnant before or after 18 months post-RYGB [31]. A Danish national cohort study evaluated outcomes in women after RYGB and compared them to matched obese controls. The authors found a higher rate of SGA, a higher need for neonatal intensive care units, and higher rate of illness in the neonatal period requiring hospitalization. They did not find a difference in congenital malformations [32]. The RYGB patients did, however, have a higher risk for acute abdominal pain during pregnancy (RR 6.4).

RYGB patients often have vitamin and mineral deficiencies. These are largely due to a combination of dietary habits, non-compliance with supplementation, and poor follow-up. Commonly encountered deficiencies include vitamin B12, which is seen in low levels in 30–70% of patients. Iron deficiency anemia (20–49%) and folate deficiency (9–18%) are also seen after RYGB [33]. Low levels of vitamin D can be seen in as many as 55–66% of post-RYGB patients [34]. These factors increase the risk for neural tube defects, maternal osteomalacia, neonatal hypocalcemia and rickets, low birth weight, preterm labor, and fetal mental retardation [35]. Vitamin A can also be deficient, although it is less studied. This can lead to developmental problems with eyes and vision. One group found an 11% incidence of vitamin A deficiency among a cohort of RYGB patients [36]. Infants with vitamin A deficiency may become immunocompromised.

A Brazilian study compared the presence of vitamin A deficiency among pregnant patients who had RYGB versus normal controls. They identified that 75% of the pregnant women with a history of RYGB reported night blindness, correlating with significantly lower rates of serum retinol and β-carotene [37]. The patients were counseled to take 5000 IU of retinol orally upon documentation of pregnancy. Despite this, their serum levels remained low. Vitamin A deficiency has been shown to cause microphthalmia or anophthalmia and hypoplasia of the optic nerve and tracts. There have been documented cases of these defects in infants born to patients after RYGB who were deficient in vitamin A [38].

Other groups have evaluated the incidence of iron deficiency anemia among RYGB patients who became pregnant. The authors observed a higher incidence of iron deficiency anemia among this group (29%) [39, 40].

The post-RYGB patient is prone to thiamine deficiency secondary to duodenal exclusion. Supplementation is critical to avoiding deficiencies and the associated complications. In the pregnant female with hyperemesis gravidarum, oral intake can be significantly reduced and precipitate thiamine deficiency in these patients. There have been case reports of Wernicke's encephalopathy in the setting of hyperemesis gravidarum and recent RYGB surgery [41]. Thiamine stores can be depleted in a matter of 4 weeks without any intake, but clinical manifestations are seen within 2–3 weeks of deficiency. The sequela can be serious and irreversible. Although Wernicke's encephalopathy is classically manifested by a triad of ophthalmoplegia, ataxia, and confusion, the presenting neurologic manifestations may not be classic. A high index of suspicion must exist, and the vomiting gastric bypass patient should be given intravenous thiamine immediately.

Vomiting after RYGB is not normal and may be a manifestation of an intestinal obstruction or internal hernia. RYGB patients carry a lifetime risk of internal hernia of up to 10%. The classic symptoms of left upper quadrant pain and vomiting may be obscured during pregnancy. Unrelated abdominal pain, increased intra-abdominal pressure, displacement of the small bowel, and the gravid uterus contribute to difficulty in a timely and accurate diagnosis. Thus, a high index of suspicion must be maintained, and a bariatric surgeon should be consulted in any pregnant woman with abdominal pain and a history of bariatric surgery. There are multiple reports of internal hernias arising during pregnancy; failure to identify them early can result in bowel necrosis and maternal and fetal death [42–46]. Retrospective reviews show delays of more than 48 h significantly increase the risk of bowel ischemia and resection. These reviews also report massive bowel necrosis and ultimate maternal demise [42]. These dramatic outcomes underscore the importance of a high index of suspicion and early operative evaluation to avoid the complication of missed bowel ischemia.

In conclusion, the pregnant patient with a history of RYGB should have her vitamin levels checked routinely throughout pregnancy and be encouraged to remain compliant with supplementation. If abdominal pain or vomiting develops during pregnancy, a high index of suspicion should be maintained for complications related to RYGB, including internal hernia.

Pregnancy Following Duodenal Switch

The biliopancreatic diversion-duodenal switch (BPD-DS) is an operation which has a significant malabsorptive component. There is a high risk of protein malabsorption, fat-soluble vitamin deficiency, and B12 and iron deficiency [21, 47]. Likewise, many atypical vitamin and mineral deficiencies have been described in patients who

did not have proper intake postoperatively. Some of these include selenium deficiency, which can result in serious, but potentially reversible cardiomyopathy [48].

In light of these postoperative effects, pregnancy after BPD-DS can theoretically confer a higher risk of fetal defects. This is not necessarily borne out by the literature. There are studies demonstrating good neonatal and maternal outcomes when proper perinatal care, counseling, and support are given in the context of having had bariatric surgery [49].

There are, however, reports of vitamin A deficiency in mothers leading to congenital birth defects of the eyes, microcephaly, hypotonia, growth restriction, and renal defects [50, 51]. These defects can have devastating effects and highlight the need for close lifelong follow-up and coordinated care in the prenatal period.

Other reports exist of vitamin K deficiency in a mother and her newborn. The mother experienced significant bleeding. Her infant was hypocoagulable but asymptomatic. Supplementation with vitamin K reversed the coagulopathy, and the infant suffered no complications as a result of this deficiency [52].

Patients seeking to undergo BPD-DS should be warned of the potential for serious birth defects without appropriate follow-up and close prenatal monitoring. Preoperative counseling for the female patient of childbearing age should include a detailed discussion of the need for close follow-up and strict adherence to vitamin supplementation after surgery for life.

Conclusion

In conclusion, pregnancy may be easier to attain following bariatric surgery, as fertility is improved with weight loss. However, the post-bariatric patient does face some risks during pregnancy, including mechanical problems from the LAGB and protein and vitamin deficiency from the malabsorptive operations. The patient should be followed closely during pregnancy by both a bariatric surgeon and a maternal-fetal medicine physician to ensure that these risks are mitigated by proper medical care.

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Chapter 45
Solid Organ Transplantation and Bariatric Surgery

Levan Tsamalaidze and Enrique F. Elli

History of Transplantation

The roots of modern transplantation date back to the third century BC. According to Roman legend, Saints Cosmas and Damian surgically removed a gangrenous leg of a patient and replaced it with the leg of recently deceased Moor [1]. However, the first realistic case of early transplantation was performed by an Indian surgeon Sushruta in the second century BC, when he relocated autografted skin from a patient's cheek to use for reconstruction of the nose after rhinoplasty [2]. More than twenty centuries later, the first solid organ (kidney) transplantation between identical twins was performed by Joseph Murray and J. Hartwell Harrison in 1954, and no rejection of the transplanted organ occurred [3].

In the 1950s, British biologist Peter Medawar revealed a causal relationship between changes in the immune system and graft rejection following transplantation. This finding helped him to propose that immunosuppressive medications could solve the problem of rejection. In 1960, at the age of 45, he was rewarded with the Nobel Prize for his work on acquired immunologic tolerance [4]. Discovery of the powerful immunosuppressive drug cyclosporine in 1970 led to a revolution in transplant surgery [5]. Consequently, the first successful orthotopic solid organ (heart) transplantation was performed in 1967, by Christiaan Barnard in South Africa [6].

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Bariatric Surgery in Transplant Patients

Obesity and the Pretransplant Patient

Obesity-related metabolic, cardiovascular, and pulmonary disorders can cause a variety of medical complications and have negative effects on postoperative outcomes following major surgical procedures [7]. Likewise, obese patients are at increased risk of developing graft failure and mortality after solid organ (kidney, liver, heart) transplantation [8–11]. As a result, the majority of transplant centers exclude patients with a BMI higher than 35 kg/m^2. Obese patients are required to lose weight to be included on a UNOS (United Network for Organ Sharing) waiting list [12–16]. However, many patients struggle to maintain weight reduction to qualify for a transplant [17, 18]. Unlike medical management, bariatric surgery results in long-lasting weight loss for morbidly obese patients and appears to be more cost-effective than nonsurgical management [18–20]. Furthermore, more than half of the patients with conditions such as diabetes, hypertension, hyperlipidemia, and obstructive sleep apnea experience resolution or improvement following weight loss surgery [21, 22]. Due to increasing popularity and the safety profile of obesity surgery, more patients with chronic liver, kidney, and cardiac disease are referred for evaluation [14]. Bariatric surgery has shown acceptable weight loss in patients awaiting transplantation and has been recommended as a safe alternative to medical management, providing a "gateway to transplant" for obese patients with end-stage organ failure [11, 13, 23].

Obesity in the Posttransplant Patient

Unfortunately, morbid obesity is a problem not only for pretransplant patients but also for those who have already had a transplant. There is a strong relationship between glucocorticoids and immunosuppressive medications and dramatic weight gain in patients following transplant. Other risk factors include reduced physical activity, fewer dietary limitations, and increased appetite from steroid use [24–26]. According to a prospective cohort study comprised of 1359 patients undergoing solid organ transplantation, almost 40% of the patients developed obesity at 3 years after transplantation [27].

There is some suggestion that posttransplant obesity, and its related metabolic syndrome, correlates with graft dysfunction, failure, and rejection. El-Agroudy and colleagues [26] found substantial differences in the frequency of hypertension, diabetes mellitus, and cardiac complications between obese and nonobese patients following kidney transplantation. Likewise, following orthotopic liver transplant (OLT), 20% of patients with obesity-related metabolic syndrome, hypertension, and diabetes mellitus experienced recurrence of nonalcoholic steatohepatitis (NASH) and cryptogenic cirrhosis (CC) [28].

Obesity and its related comorbidities have also affected the post-heart transplant population. New-onset diabetes mellitus, along with hypertension and hyperlipidemia, is considered to have a negative influence on the transplanted organ, causing cardiac allograft vasculopathy (CAV) (29)]. Consequently, the tendency of post-transplant patients to gain weight makes the graft vulnerable to decreased function [29].

Bariatric Surgery in the Posttransplant Patient

In non-transplant patients, bariatric surgery has demonstrated its significant predominance over medically managed weight loss, with a higher rate of remission of disorders such as diabetes mellitus (DM) and metabolic syndrome [30]. However, the effectiveness of bariatric surgery in posttransplant patients has not been evaluated comprehensively. Patients undergoing weight loss procedures after solid organ transplantation may experience inferior healing and higher rates of infections and leaks [31]. There is also concern regarding the absorption of immunosuppressive medications following malabsorptive procedures.

Usually, immunosuppressive therapy following solid organ transplantation consists of triple therapy: tacrolimus, mycophenolic mofetil, and prednisone. Several studies demonstrate that morbidly obese patients undergoing laparoscopic gastric bypass surgery would likely require higher doses of immunosuppressive medications in order to provide target concentration of antirejection therapy [32, 33]. However, other studies have reported that patients did not experience significant changes in medication absorption following kidney, liver, and heart transplantation [34–38].

The laparoscopic sleeve gastrectomy (LSG) is technically less challenging than Roux-en-Y gastric bypass (RYGB) and is considered purely restrictive in nature [39]. The LSG has proven to be important in morbidly obese patients with multiple comorbidities. Analysis of 1000 non-transplant patients undergoing LSG revealed that percent of excess body weight loss (%EBWL) was 86.6% at 12 months after surgery and 84.1% at 3 years [40]. In solid organ transplant patients, LSG resulted in %EBWL of 45.7% at 12 months and significant resolution of DM or reduction in insulin dosage (more than 50% of patients, $P = 0.02$). Also notable were significant increases in estimated GFR ($P = 0.03$) in kidney transplant patients, improved graft function in liver transplant patients, and improved left ventricular ejection fraction by 10% in heart transplant patients [41]. Elli and colleagues did not find any significant difference ($P = 0.45$) in %EBWL following LSG between patients with and without solid organ transplant [31]. In conclusion, multiple reports emphasize the role of LSG after solid organ transplantation, resulting in effective long-term weight loss and resolution of comorbidities, while reducing surgical trauma and lowering the incidence of wound infection [31, 35, 41–44].

Adjustable gastric banding (AGB) has also been considered for the posttransplant patient [45]. Despite the simplicity of the operation, it necessitates foreign

body implantation in immunocompromised patients and therefore can represent an increased risk of infection postoperatively. The AGB also has less weight loss than other bariatric operations [42]. Because of these reasons, as well as the need for frequent adjustments, the AGB is less useful in transplant patients [46].

There is obvious concern regarding the need for two surgical interventions—the transplant and the bariatric surgery—in the patient with end-stage disease. Therefore, some centers have performed sleeve gastrectomy simultaneous with transplantation and have achieved tolerable results [47–49].

In conclusion, due to relatively insufficient information regarding bariatric surgery in transplant patients, no consensus exists of the ideal bariatric procedure. Several factors must be taken in consideration when choosing the appropriate operation. RYGB is a malabsorptive procedure that can alter the absorption of immunosuppressive medications and creates a barrier for endoscopic interventions on the biliary tree in OLT patients. AGB results in less weight loss and requires foreign body implantation, which may increase a risk of infection in an immunocompromised patient. Sleeve gastrectomy is purely restrictive, less complex and less technically challenging than the RYGB, does not entail malabsorption of medications, and has shown competitive results regarding weight loss and resolution of comorbidities. However, there is a 1–3% incidence of staple-line leaks and postoperative bleeding following sleeve gastrectomy in transplant population [50].

Bariatric Surgery in Kidney Transplant Patients

Pretransplant

It is widely believed that obesity is a contributing factor in the development of hypertension and diabetes, which can lead to end-stage renal disease (ESRD) [51]. More than 100,000 new cases of ESRD are recorded annually in the US Renal Data Registry System. This number continues to rise by more than 3.5% yearly. Consequently, in 2014 the UNOS kidney transplant list increased by 3% from the prior year, reaching 88,231 candidates awaiting a donor organ [52].

Compared to patients with BMI < 30 kg/m^2, patients with BMI > 35 kg/m^2 undergoing kidney transplant were found to have significantly prolonged hospitalization ($P = 0.01$) and increased risk of acute rejection ($P = 0.01$). Furthermore, in patients with pretransplant severe obesity, there was significant decreased graft survival ($P = 0.01$) and decreased overall survival at 1 and 5 years posttransplant [8, 14, 16]. Morbidly obese kidney transplant patients had significantly greater ($P = 0.01$) readmission rates [53]. Eventually, because of these differences in posttransplant outcomes between obese and nonobese patients, most programs implemented a BMI threshold of 35 kg/m^2, above which the patient would be declined for transplant [13–15, 54]. For morbidly obese patients who fail medically managed diet programs, minimally invasive bariatric surgery can provide a “bridge to kidney

transplant" and offer substantial weight loss [13, 14, 16, 55]. However, limited information is available regarding obese patients with end-stage renal disease (ESRD) undergoing bariatric operations.

Laparoscopic Sleeve Gastrectomy

LSG is a reliable, restrictive bariatric procedure resulting in significant weight loss in obese patients, even with severe comorbidities. However, LSG in patients with ESRD carries a high risk of specific postoperative complications, such as infection and dehydration.

Four case series evaluated obese pre-kidney transplant patients [14, 15, 55, 56]. A total of 32 patients underwent LSG. Patients experienced %EBWL from 49.2% to 75.9% at 1 year after surgery and met criteria for transplantation. This was also confirmed that pretransplant LSG had positive influence on posttransplant outcomes, improving graft and patient survival as well as overall quality of life. Therefore, obese patients awaiting kidney transplantation benefitted from undergoing LSG.

Roux-en-Y Gastric Bypass

RYGB may play a role in the ESRD patient. We analyzed case series from two different studies [13, 34] involving 48 obese patients with ESRD undergoing RYGB (8 open and 40 laparoscopic). The results showed that %EBWL ranged from 47% to 70.5% at 1 year postoperatively, and the patient's odds of getting a donor organ increased. This surgery carries unique risks in the ESRD patient. First, the malabsorptive nature of the procedure can cause nephrolithiasis and renal oxalosis, resulting in further deterioration of renal disease [57, 58]. One analysis of 504 obese patients undergoing RYGB revealed that 8.5% developed significant kidney injury provoked by post bariatric rhabdomyolysis and nephrolithiasis [58]. Second, hypovitaminosis D resulted from 42% less absorption, which contributed in development of hypocalcaemia and subsequent hypoparathyroidism [59]. Third, patients are more likely to have nutrient deficiencies (vitamin B12, folate, iron, zinc, protein) than those following sleeve gastrectomy [60]. Finally, one must also consider the absorption of immunosuppressive medications following transplant [32, 33, 46].

Posttransplant

High-dose immunosuppressive medications, corticosteroids, improved appetite, and less dietary limitations, as well as less physical activity, can lead to weight gain following renal transplant. Patients who underwent kidney transplant experienced a mean increase in BMI of 0.458 kg/m^2 in the first postoperative month, which

appeared to be an important predisposing factor for reduced glomerular filtration rate (GFR) in the transplanted kidney [61]. According to several studies, patients gained 8.3–43% of their initial weight during the first year after transplantation. Significant adverse effects of obesity on functional status of the transplanted organ were observed, resulting in decreased graft survival, increased cardiovascular morbidity, and worsened overall 5-year survival [26, 61–63]. Additionally, surgical site infection (SSI) was frequently detected in posttransplant obese patients [64].

There are limited data on the utility of bariatric surgery following kidney transplantation.

Laparoscopic Sleeve Gastrectomy

There are limited data on the role of LSG in orthotopic kidney transplant (OKT) recipients. Three consecutive studies ($n = 11$) evaluated LSG in posttransplant obese patients [31, 35, 41]. One patient with diabetic nephropathy and previous kidney transplantation experienced reoperation for bleeding from short gastric vessels. No mortality was observed. Meaningful %EBWL ranging from 35.83% to 68.8% was reported 1 year after surgery. Patients postoperatively experienced significant resolution of comorbid conditions (hypertension, DM, OSA) and did not require changes in antirejection therapy. Moreover, marked improvement of patient and graft survival, as well as better quality of life, were observed in this population.

Laparoscopic Roux-en-Y Gastric Bypass

We analyzed data regarding LRYGB in kidney recipients. Outcomes of 14 consecutive patients were presented in two different studies [34, 35]. The authors reported effective long-lasting weight loss (excess BMI from 61.5% to 71%). There was one mortality in a 52-year-old female who suffered from cardiac complications at 6 months postoperatively. Nutrient deficiency, hypovitaminosis, and alterations in pharmacokinetics of immunosuppressive medications were commonly seen in patients following malabsorptive procedures.

Conclusion

Priority should be given to LSG when choosing an appropriate bariatric procedure for obese patients requiring kidney transplantation, with recognition of higher complication rates. It is important that patients be well educated about fluid intake in the postoperative period to avoid dehydration, hypotension, and cardiopulmonary complications. In an effort to avoid hypovolemia and its negative influence on the compromised renal system, timely evaluation of the postoperative patient is imperative. It is important to note that the line between dehydration and fluid overload is thin in

patients with chronic kidney failure. For this reason meticulous postoperative care is required.

Regarding the treatment of kidney recipients suffering from weight gain, LSG appears to be safe, effective, less technically demanding, and with comparable results in this specific population.

A single case study reported a combined robot-assisted kidney transplantation and sleeve gastrectomy. Authors appreciated the use of a single operation under one-time anesthesia, as well as the possibility of more precise oversewing of the staple line [65]. Such simultaneous approaches may become more widely accepted in the future.

Bariatric Surgery in Liver Transplantation

Pretransplant

Obesity-related conditions play a key role in evolution of nonalcoholic steatohepatitis (NASH). NASH causes hepatocyte injury, focal necrosis with infiltration, and fibrosis, resulting ultimately in liver failure. According to a UNOS database analysis, frequency of NASH as an indication for liver transplant has increased from 1.2% to 9.7% between 2001 and 2009, and NASH was reported to be the third most common reason for transplantation in the United States [66]. A study of 23,675 patients in the UNOS database undergoing liver transplantation from 1988 to 1996 revealed that 5% had severe obesity (BMI > 35 kg/m^2), and 2% were morbidly obese (BMI > 40 kg/m^2) [10]. Comparatively, an analysis from 2002 to 2006 involving 29,136 patients showed that 9% and 2% were severely and morbidly obese, respectively [67]. Patients with BMI exceeding 35 kg/m^2 had significantly higher posttransplant mortality, mostly related with primary graft dysfunction (*P* value <0.05). They also had significantly higher long-term mortality from cardiopulmonary complications (*P* value <0.05) [10]. Eventually, the American Association for the Study of Liver Diseases (AASLD) published guidelines in 2005 that cited morbid obesity (BMI > 40 kg/m^2) as a contraindication for liver transplantation [68]. Similarly, many transplant centers [13, 23, 27, 47] implemented BMI < 35 kg/m^2 as a target weight for transplantation.

Obesity surgery in patients with liver disease carries a higher risk of complications. Patients with cirrhosis and end-stage liver disease (ESLD) had 0.9% and 16.3% mortality rate, respectively, versus 0.3% of general population [69]. Limited data are available regarding bariatric surgery outcomes in patients with ESLD awaiting transplantation.

Laparoscopic Sleeve Gastrectomy

According to available data, LSG is associated with higher perioperative complications in pretransplant patients than in non-transplant population. Takata and colleagues [13] and Lin and colleagues [70] reported a total of 28 patients with cirrhosis, ESLD, and BMI˃35 kg/m^2 who underwent LSG. Three patients developed postoperative bleeding, and two of them required re-intervention. One patient developed a staple-line leak, resulting in a chronic fistula. The overall morbidity rate was 23%. No 30-day mortality was identified. Percent EBWL ranged from 24% to 61.3% at 1 year after surgery. Obesity-related comorbidities were improved in all transplant candidates, and 7 of 13 diabetic patients experienced complete resolution of the disease.

Laparoscopic Roux-en-Y Gastric Bypass

Surgeons performing RYGB in patients with ESLD and portal hypertension may face intraoperative technical challenges. Likewise, RYGB requires intestinal reconstruction, which would make future transplant surgery very difficult. Because of these reasons, this type of bariatric procedure is not recommended in patients awaiting liver transplantation.

During Transplant

Most likely, patients with ESLD, obesity, and obesity-associated comorbidities will require two separate surgical interventions: bariatric surgery and transplantation itself. As previously discussed, bariatric surgery is associated with higher perioperative morbidity and mortality in OLT patients than in non-transplant ones. Because of this, some centers have applied novel treatment strategies and performed simultaneous sleeve gastrectomy at the time of liver transplantation [47–49].

The risks of two different, major operations simultaneously may discourage some surgeons from pursuing a combined operative approach. Despite this, three groups [47–49] have performed simultaneous sleeve gastrectomy and liver transplantation with promising results. In 11 severely obese patients with ESLD, combined sleeve gastrectomy and OLT was performed between 2006 and 2017. One patient developed a leak from the staple line requiring reoperations and an extended hospital stay. The overall morbidity rate was 36%. No mortalities were reported. All patients received postoperative immunosuppressive therapy without alterations and had significant weight loss (mean BMI changed from 42.5 kg/m^2 to 29.3 kg/m^2 in the time period 6 months to 2 years after surgery). All experienced marked resolution of comorbid diseases.

Posttransplant

As in kidney transplant recipients, immunosuppressive therapy, lack of dietary restriction, and decreased physical activity can cause weight gain following OLT. This can result in adverse effects on graft and patient survival. Obesity provokes NASH and cryptogenic cirrhosis. Consequently, recurrence rate of NASH or cryptogenic cirrhosis is 5% to 10% at 10 years from transplantation [28, 71]. Perkins and coworkers reported a 3.4 times increased mortality in obese patients following liver transplantation [72].

Bariatric surgery is a relatively new treatment option for obesity in the OLT population, but it is gaining increased acceptance. The bariatric surgeon may encounter technical challenges associated with previous abdominal surgeries in the OLT patient. As a result, almost 50% of bariatric procedures were performed by open approach because of potential adhesions in this population. Partially because to this, metabolic surgery entails higher morbidity in this group than in general population [73].

Sleeve Gastrectomy

Four studies reported data on 24 obese OLT patients who underwent sleeve gastrectomy (LSG = 22, robotic SG = 1, and open = 1) [31, 41–43]. Four patients required reoperation postoperatively. One patient developed bleeding from the short gastric vessels. A second patient was found to have a bile leak from the surface of the liver. A third patient required conversion of gastric sleeve to Roux-en-Y esophagojejunostomy due to delayed esophageal emptying. A fourth patient who underwent open sleeve gastrectomy required an incisional hernia repair on postoperative day 2. There were no mortalities. Percent EWL varied considerably, with a range of 27.6–71.5% at 1 year after surgery. Significant improvement of obesity-related comorbidities was noted. There was no difference in pre- and post-sleeve gastrectomy antirejection therapy.

At our own institution, 303 patients underwent LSG from 2011 to 2016, with 12 (4%) having prior OLT [74]. In a case-control comparison, non-OLT patients had significantly shorter hospital stay (1.7 vs 3.1 days, $P = 0.01$) than the OLT group (Table 45.1). For patients with long-term follow-up, no differences existed for change in BMI after LSG for both groups (Fig. 45.1), but the non-OLT patients had significantly more excess body weight loss at 2 years (Fig. 45.2). Resolution of comorbidities was noted in both groups in the range of 6 to 50%. LSG caused no significant changes in dosage of immunosuppressive medications, and no liver-related complications occurred in these patients.

Robotic sleeve gastrectomy in a post-liver transplant patient was first reported by Elli and coworkers [42]. To our knowledge, this is the only case existing in the literature. This novel approach allowed safer separation of the stomach from the left lobe of the transplanted liver and provided more precise oversewing of the staple

Table 45.1 Patient characteristics and post-LSG outcomes in OLT vs non-OLT patients

Characteristic	Group[a]		*P* value
	OLT (*n* = 12)	Non-OLT (*n* = 36)	
Age, year	56.6 (8.9)	53.84 (4.68)	0.11
BMI, kg/m^2	45.31 (6.19)	43.16 (5.1)	0.24
Men	7 (58.3)	16 (44.4)	0.78
Hypertension	11 (91.6)	21 (58.3)	0.45
NASH Diabetes mellitus High cholesterol/triglycerides	0 9 (75) 7 (58.3)	3 (8.3) 11 (30.6) 17 (47.2)	0.44 0.09 0.46
Cardiac disease	4 (33.3)	11 (30.6)	0.57
Obstructive sleep apnea	7 (58.3)	20 (55.6)	0.57
Time after OLT, month	63.08 (33.18)	–	–
ASA class			
II	2 (16.65)	7 (19.4)	0.61
III	9 (75.0)	24 (66.7)	0.60
IV	1 (8.35)	5 (13.9)	0.55
Operative time, min	122 (54)	125 (6.77)	0.74
LOS, day	3.08 (1.24)	1.7 (0.12)	0.01
90-day morbidity			
Minor (cl grade I–II)	1 (8.3)	4 (11.1)	0.64
Major (cl grade III–V)	3 (25.0)	1 (2.7)	0.07
Death	0	0	–
Follow-up, month	25.3 (5.1)	23.6 (2.45)	0.13

Abbreviations: *ASA* American Society of Anesthesiologists, *BMI* body mass index, *Cl* Clavien-Dindo classification, *LOS* length of stay, *LSG* laparoscopic sleeve gastrectomy, *NASH* nonalcoholic steatohepatitis, *OLT* orthotopic liver transplant

[a]Values are mean (SD) or no. of patients (%).

line. Larger groups are needed to assess outcomes of robotic bariatric surgery in OLT population.

Laparoscopic Roux-en-Y Gastric Bypass

LRYGB is hard to perform in patients with previous liver transplantation, secondary to adhesions and the technical complexity the intestinal reconstruction. Three studies identified 10 OLT patients who underwent RYGB (open = 9, laparoscopic = 1) [38, 75, 76]. RYGB operation [75] appeared to be tremendously challenging for surgeons due to adhesions in the upper abdomen. Considerable weight loss and resolution of comorbidities were seen in patients postoperatively. Higher doses of immunosuppressive medications were needed for keeping target antirejection concentration following surgery. One patient with sepsis, secondary to Fournier's gangrene and metastatic esophageal squamous carcinoma, died eventually at 9 months after surgery.

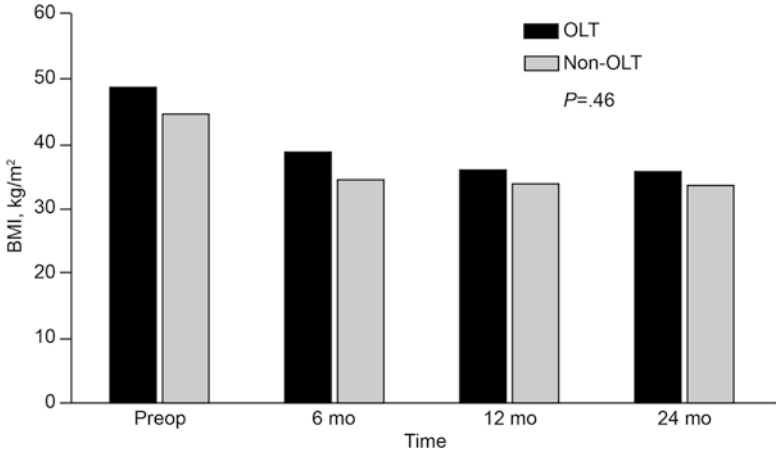

Fig. 45.1 Comparison of mean body mass index (BMI) for OLT (n = 6) and non-OLT (n = 18) patients after laparoscopic sleeve gastrectomy. OLT indicates orthotopic liver transplant (Used with permission of Springer Nature from Tsamalaidze et al. [74])

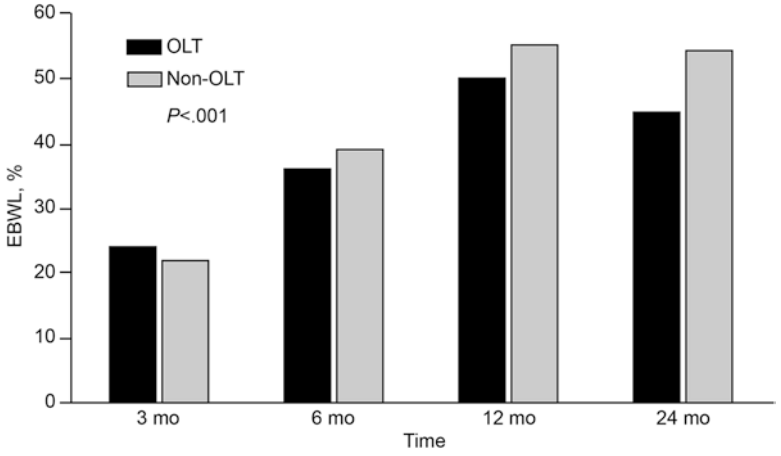

Fig. 45.2 Comparison of mean excess body weight loss (EBWL) for OLT (n = 6) and (n = 18) non-OLT patients after laparoscopic sleeve gastrectomy. OLT indicates orthotopic liver transplant (Used with permission of Springer Nature from Tsamalaidze et al. [74])

One limitation for the gastric bypass following OLT is the lack of endoscopic access to the biliary tree after surgery. This is important, as the overall postoperative biliary complication rate in OLT recipients is 17% [77].

Conclusion

LSG appears to be a safe, feasible, well-tolerated bariatric procedure, providing sustained weight loss and a "bridge to transplant" in patients with ESLD. Careful multidisciplinary management by well-qualified surgeons, experienced ICU physicians, and proficient nutritionists is needed to avoid undesirable complications in this high-risk population.

Single-staged liver transplant and sleeve gastrectomy is technically attainable but exposes the patient to higher risks. RYGB in liver transplant patients (pre and post) raises concerns about possible malabsorptive complications, restrictions for endoscopic approach to the biliary tree, greater technical challenges, and limitations for MIS operations. LSG surgery appears to be less challenging and has comparable early and long-term postoperative outcomes than RYGB in OLT patients. However, LSG in OLT patients resulted in higher risk of staple-line leak and postoperative bleeding than in non-OLT patients.

Bariatric Surgery in Heart Transplantation

Pretransplant

According to ACC/AHA (American College of Cardiology/American Heart Association) Guidelines, obesity-related hypertension, diabetes, dyslipidemia, and metabolic syndrome cause evolution of heart failure [78, 79]. "Obesity cardiomyopathy," which is very similar to dilated cardiomyopathy, is increasingly seen in obese populations without diabetes, coronary artery disease, or others provoking factors [80]. The registry of International Society for Heart and Lung Transplantation reported increased numbers of heart transplants over the past two decades, with a statistically significant increase in the BMI in recipients. It also reported more frequent obesity-related comorbidities, which can affect surgical treatment and postoperative therapy [81].

A study of the UNOS database from 1998 to 2007 including 27,002 consecutive orthotopic heart transplant (OHT) candidates revealed that obese patients waited longer for a heart and had less chance to receive a heart. Consequently, obese patients with end-stage heart disease (ESHD) had lower survival rate than nonobese ones [82, 83]. Moreover, pretransplant morbid obesity was correlated with the reduced posttransplant survival rate after heart transplantation [84].

A variety of complex weight loss programs are available to obese heart transplant candidates, but they do not always achieve sufficient weight loss [54]. Bariatric surgery may be a good alternative.

Laparoscopic Sleeve Gastrectomy

Obese patients with ESHD are being considered for surgical weight loss more frequently. We analyzed 5 publications [23, 85–88] with 11 pre-cardiac transplant patients with mean BMI of 45 kg/m^2 who underwent LSG. Overall perioperative morbidity was 36%, and no mortalities were reported. Complications included fluid overload, atrial fibrillation, and pneumonia. These were managed successfully with conservative treatment. One patient with sleeve gastrectomy and concomitant partial fundoplication required reoperation and resection of the fundus due to the ischemia. Nine patients experienced effective weight loss (mean BMI decreased to 29 kg/m^2 at 12-month follow-up) and became appropriate candidates for cardiac transplantation. Four patients had significant improvement of cardiac function at 2-year follow-up and were removed from UNOS list.

Laparoscopic Roux-en-Y Gastric Bypass

RYGB has shown comparable results in patients awaiting cardiac transplantation. A total of 14 RYGB (13 laparoscopic and 1 open) were performed, as reported in two studies [85, 87]. Patients had a mean BMI of 49.5 kg/m^2. Overall morbidity was 28%, and no mortalities were reported. Complications included postoperative gastrointestinal bleeding, pulmonary edema, transient hypotension, and transient renal insufficiency. These were managed conservatively. All patients had sufficient weight loss (mean BMI = 36.6 kg/m^2) and were included on the UNOS list.

Posttransplant

Obesity, hyperlipidemia, diabetes, and hypertension were found to have an adverse effect on cardiac allograft by causing vasculopathy and “chronic” rejection in late posttransplant patients. This results in decreased overall patient survival [11, 29, 54, 84, 89–92]. Few reports exist of bariatric surgery in the post-cardiac transplant patient.

Laparoscopic Sleeve Gastrectomy

LSG has been reported in the post-cardiac transplant patient. Two patients with BMI 34 kg/m^2 and 37.3 kg/m^2 underwent LSG. There was no morbidity or mortality. Patients experienced effective weight loss (%EBWL of 24.4% and 72% at 1 year) and significant resolution or improvement of obesity-associated comorbidities, without changes in immunosuppressive therapy [41, 44].

At our own institution, we operated on a 47-year-old male with a history of dilated cardiomyopathy, obesity, and steroid-induced diabetes mellitus. We performed a LSG 2 years following OHT. His BMI decreased from 36.2 kg/m^2 to 30 kg/m^2 during the year after surgery, and the patient experienced complete resolution of DM [93].

Laparoscopic Roux-en-Y Gastric Bypass

RYGB has demonstrated promising outcomes in OHT recipients. We identified two single case reports [36, 37] of patients undergoing RYGB (one laparoscopic and one open due to concomitant hernia repair) after cardiac transplantation. No complications were observed postoperatively. The first patient was a 58-year-old female who had 84% EBWL at 2 years after surgery. She experienced complete resolution of DM and significant improvement of obesity-related comorbidities. The second patient was a 55-year-old male whose BMI decreased from 31 kg/m^2 to 23 kg/m^2 at 4 years postoperatively, and the patient had remarkable improvement in his quality of life. No significant changes were needed in the dosage of immunosuppressive medications for either patient. Larger studies are needed to evaluating the influence of RYGB on posttransplant immunotherapy.

Current practice of our institution involves laparoscopic robotic-assisted RYGB. We performed this procedure on a 37-year-old woman with history of OHT for postpartum cardiomyopathy. Six years after OHT, she presented with volume overload, dyspnea on exertion, orthopnea, and lower extremity swelling bilaterally. Her body mass index (BMI) was 37.5 kg/m^2. After performing laparoscopic robotic-assisted RYGB, her BMI lowered to 27.5 kg/m^2 at 1 year postoperatively, with complete resolution of DM [93].

Conclusion

LSG has acceptable results in patients with ESHD. Experience showed that concomitant intervention in combination with LSG had an increased risk of postoperative complications and difficulties in perioperative management. However, with sufficient weight loss, some patients may improve enough to be removed from the transplant list. Comparable results are seen in RYGB patients awaiting cardiac transplantation.

LSG and LRYGB have shown promising results in the post-OHT population. Both operations seem to be safe if patients are carefully selected. RYGB results in more weight loss in this group than LSG, and it does not carry the burden of managing intraperitoneal adhesions as seen in the kidney and liver transplant patients. Further larger studies are necessary for drawing final conclusions.

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Chapter 46
Adolescents and Bariatric Surgery: Techniques and Outcomes

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Definition of Childhood Obesity

The Centers for Disease Control and Prevention (CDC) define *overweight* or *obese* as "weight that is higher than what is considered as a healthy weight for a given height" [1]. An adult is deemed normal, overweight, or obese if their BMI (body weight in kilograms divided by the height in meter squared) is between 18.5 and 25, greater than 25, or greater than 30, respectively. Obese individuals are further subdivided into three classes of obesity. In the pediatric population, BMI may be a less reliable surrogate for obesity than in the adult population, due to the frequent fluctuations in height and weight that a normal child undergoes [2]. Therefore, based on CDC and National Center for Health Statistics growth references, the American Academy of Pediatrics (AAP) classifies children and adolescents with a BMI between the 85th and 95th percentile as *overweight*, and a BMI greater than the 95th percentile as *obese* [3, 4].

Epidemiology

While the obesity epidemic among adults in the United States is well documented, childhood obesity is often overlooked and undertreated [5, 6]. Over the past 30 years, the percentage of obese children in the United States has more than tripled [7]. Currently, approximately one in five school-aged children are obese, and among children aged 2–19 years, 33.4% are considered obese or overweight [7, 8].

Although the epidemic of childhood obesity has crossed all racial, ethnic, and socioeconomic divisions, some groups are disproportionately affected. Compared

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to Caucasians and Asian Americans, the prevalence of childhood obesity is higher in Native Americans, African Americans, and Hispanics [9–11]. Children of lower socioeconomic status are also unequally affected by obesity, and some evidence suggests that poverty may be a more relevant risk factor than race and ethnicity [12, 13].

Etiology

Extensive research regarding the etiology of childhood obesity has identified both genetic and environmental factors that may be responsible for our current epidemic. Studies of monozygotic and dizygotic twins robustly illustrate the heritable nature of adiposity [14, 15]. While the 2011–2014 National Health and Nutrition Examination Survey found no difference in the prevalence of obesity between gender, there is evidence that compared to boys, girls are more susceptible to family and environmental factors that lead to obesity, are less sensitive to insulin, and may possess a higher frequency of genetic factors correlated to obesity [11, 16, 17].

Over the past several decades, changes in economic forces have resulted in an increase in the incidence of dual-earner households. As a result, families are increasingly relying on the availability of fast food or processed food for daily consumption [18]. These industrially prepared foods have become ubiquitous in our society and are often more affordable than other more nutritious home-prepared meals [19]. Additionally, school lunch programs are often associated with high caloric, low nutritional value meals [20]. Further compounding the problem with school lunch programs are the attractive contracts with beverage companies in exchange for much-needed financial support [21]. Schools have also been reducing structured physical education programs from their curriculums. Because of the lack of adequate supervision, many families do not allow prolonged outdoor activities, and therefore entertainment often is provided in the form of “electronic babysitters” or technology, such as television and video games, which have largely replaced after-school physical activity [22]. These behaviors of low weekly levels of physical activity, high levels of television viewing, and routine participation in school lunch programs are highly predictive of obesity [13].

Health Impact of Childhood Obesity

Childhood obesity is associated with a host of comorbidities, many of which were once considered “adult” diseases. As a high percentage of children with obesity carry their adiposity into adulthood, many of these comorbidities follow [23–25].

In the early 1990s, type two diabetes mellitus (T2DM) in the pediatric population was exceedingly rare, hence the alternative name for the disease “adult-onset diabetes.” Between the early 2000s and 2009, however, the prevalence of T2DM

among children under 20 in the United States increased by 30.5% with over 3700 new cases diagnosed per year [26, 27]. Compared to persons who develop T2DM later in life, adolescents with the disease appear to have more rapid deterioration of glycemic control and increased progression of diabetes-related complications such as retinopathy, renal disease, micro albuminuria, dyslipidemia, and hypertension [28–31].

Obesity not only predisposes but also potentiates one to obstructive sleep apnea (OSA) [32]. Unsurprisingly then, with the rise in childhood obesity, OSA in children has emerged as a relatively prevalent disease. Marcus and colleagues found that 46% of obese children undergoing polysomnography had OSA [33]. Similarly, Capdevilla and colleagues reported a 35% increase in obesity-associated OSA in children between the early 1990s and the early 2000s [34].

Childhood OSA has been linked to alterations in blood pressure regulation, systemic hypertension, and abnormal ventricular geometry [35, 36]. OSA in children generates sleep fragmentation and, thus, promotes impaired daytime functioning, which consequently adversely affects cognitive function [37, 38]. Furthermore, increasing evidence suggests that obesity-associated OSA in adolescence leads to irritability, depressed mood, and decreases in quality of life [39].

The rate of nonalcoholic fatty liver disease (NAFLD) has also been rising at an alarming rate in adolescents. The prevalence of NAFLD among obese children is 40–70% [40]. NAFLD is now the most common form of liver pathology in the pediatric population, and it is expected to become the leading indication for liver transplant in children and adolescents within the next 10 years [41].

Behavioral and Medical Therapy

Given the complex etiology of childhood obesity, which involves genetic, environmental, and socioeconomic factors, it follows that multimodal interventions are likely the most efficacious. Several recent meta-analyses suggest that a comprehensive approach to the treatment of pediatric obesity produces the best overall outcomes [42–45].

The first-line treatments for childhood and adolescent obesity are behaviorally based interventions [42]. These may include education, cognitive and behavioral management techniques, dietary modification, exercise programs, limiting sedentary activities and, when appropriate, family counseling on maladaptive or unhealthy rearing patterns [42, 44, 45]. Behavior-based therapies involve parents or entire families, often in conjunction with school-based support systems.

While current research suggests that high-intensity, multicomponent behavioral therapy can be effective, some children will continue to struggle with excess weight and associated comorbidities despite these interventions [43, 46]. For adolescents who have failed a formal trial of intensive lifestyle modification, obese children with comorbidities, or those with severe obesity (BMI > 99th percentile), the AAP, Pediatric Endocrine Society, US Preventive Services Task Force (USPSTF), and the

National Guideline Clearinghouse (NGC) endorse the consideration of pharmacotherapy to be used as an adjunct to behavioral interventions [42, 45, 47, 48].

While there are several drugs authorized to treat adult obesity, only orlistat is approved by the US Food and Drug Administration (FDA) for treatment of childhood obesity and only in children ≥12 years of age [45].That said, given the negative health consequences of pediatric obesity, several studies of "off-label" drugs have been performed with findings of varying degrees of safety and efficacy. These include, but are not limited to, metformin, phentermine, fluoxetine, octreotide, and bupropion [43, 47, 49]. A recent Cochrane Review assessing 21 trials of various medications concluded that pharmacologic interventions have small effects in reduction of BMI and bodyweight in obese children and adolescents [49]. Common adverse events reported were dyspepsia, nausea, and diarrhea for orlistat and metformin and dry mouth and loose stools for fluoxetine [49]. Although the side effects of these medications are generally well tolerated, the risk of pharmacotherapy must be weighed against seemingly moderate benefits.

Bariatric Surgery: Indications

Bariatric surgery results in superior weight reduction and resolution of comorbid disease relative to behavioral and pharmacologic interventions for the severely obese adolescent and has become an increasingly utilized treatment option in the obese pediatric population [50, 51]. However, there are significant concerns with offering elective surgery to adolescents. General concerns with adolescent bariatric surgery relate to the risk of complications of surgery such as anastomotic leaks and stricture, potential side effects such as nutritional deficiencies, potential for adverse psychosocial impact, uncertainty of long-term outcomes, ethical considerations regarding the process of informed consent in adolescents, and the irreversibility of many of the procedures offered [50, 52].

In an effort to provide guidelines for surgery in carefully selected, severely obese adolescents, the American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee in conjunction with the Betsy Lehman Center for Patient Safety and Medical Error Reduction recently published a "Best Practice Updates for Pediatric/Adolescent Weight Loss Surgery" [52]. Per the committee guidelines, selection criteria for bariatric surgery in adolescents should include a BMI of 35 kg/m^2 with major comorbidities (e.g., T2DM, moderate to severe OSA, severe NASH) or a BMI of 40 kg/m^2 with other comorbidities (e.g., hypertension, insulin resistance, glucose intolerance, impaired quality of life) [52]. The committee also recommends that risk-benefit analysis should take into consideration the potential long-term consequences of untreated or undertreated obesity in the adolescent candidate [52].

In addition to the above recommendations, the International Pediatric Endosurgery Group (IPEG) recommends that candidate patients should have attained or nearly attained 95% of their anticipated adult stature, have failed to

attain a healthy weight with prior organized attempts at conventional weight management, be willing to adhere to postoperative nutritional guidelines and complete a comprehensive pediatric psychological evaluation pre- and postoperatively, and agree to avoid pregnancy for *at least* 1 year postoperatively [53]. In addition to the following rigorous guidelines, the decision to perform bariatric surgery in the obese adolescent should be determined by an experienced multidisciplinary team, which includes the patient and their household, the bariatric surgeon, pediatrician/s with training in adolescent obesity, a pediatric psychologist, pediatric dieticians, and behavioral/family therapists [52].

Bariatric Surgery: Techniques

As a result of the improvement in technique and technology, bariatric surgery today is most commonly performed using minimally invasive techniques [54]. In general, the most frequently employed procedures for adolescent bariatric surgery are the Roux-en-Y gastric bypass (RYGB), the vertical sleeve gastrectomy (VSG), and the adjustable gastric band (AGB) [2]. Over time, however, there has been a shift in procedure use with a relative increase in VSG and decrease in AGB [55, 56].

The RYGB involves creation of a small proximal gastric pouch that is anastomosed to a Roux limb of small bowel. Caloric intake is restricted due to a 15–30 ml gastric pouch, and enteric contents are diverted away from biliopancreatic secretions by way of the Roux limb. In this sense, the RYGB is a considered a restrictive and hormonal procedure.

In contrast to the RYGB, the AGB is a purely a restrictive procedure whereby a prosthetic band is placed around the stomach, about the upper portion of the cardia, thus compartmentalizing the upper stomach and restricting rapid inflow of food. The AGB is not FDA approved in adolescents younger than 18 years, but it has been used in clinical trials in this population. Of note, in the adult population, long-term outcomes have shown a high weight loss failure, complication rate, and reoperative rate associated with AGB, resulting in a recent decline in the number of bariatric surgeons offering this procedure [57–59]. This trend may be anticipated to encompass the pediatric population as well over the next decade.

Once used as the first stage in a two-stage procedure, the VSG is now used as a primary bariatric surgical procedure. The procedure involves creating a “sleeve” of stomach by removing the majority of the fundus. The mechanism of weight loss was originally thought to be purely restrictive, similar to the AGB. However, more recent evidence suggests the procedure results in changes in expression of gut hormones such as ghrelin, peptide tyrosine-tyrosine (PYY), and incretins and thus may have restrictive and metabolic effects as well [60].

Adolescent Bariatric Surgery: Outcomes

In experienced centers, the short-term complication rates of adolescent bariatric surgery are low and comparable to those of the adult bariatric surgical patient population [54]. However, many primary care physicians remain reluctant to refer their obese adolescent patients for surgery due to concerns regarding perioperative and long-term outcomes [61, 62]. To help address the above concerns, several registries and prospective trials designed to study the perioperative and long-term outcomes of adolescent bariatric surgery have been created. These include the Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study from the United States, the Adolescent Morbid Obesity Surgery (AMOS) study in Sweden, and the German Obesity Registry.

The Teen-LABS is a prospective, multi-institutional, observational study assessing perioperative safety outcomes of adolescents undergoing bariatric surgery. Two hundred seventy-seven participants aged 19 years or younger undergoing bariatric surgery were enrolled from five academic referral centers in the United States. The analysis examined major and minor complications within 30 days of surgery. Procedure types included Roux-en-Y gastric bypass (RYGB), vertical sleeve gastrectomy (VSG), and adjustable gastric banding (AGB). Major complications (e.g., reoperation) were observed in 8% and minor complications (e.g., dehydration) in 15%. No deaths were reported [56].

The AMOS study enrolled 81 adolescents undergoing laparoscopic RYGB with a follow-up period of 5 years. Secondary outcomes included 30-day morbidity and mortality, and complications related to surgery thereafter. The authors reported three complications within 30 days of surgery, two self-limiting intra-abdominal bleeds requiring blood transfusions and one patient with evidence of an intra-abdominal infection requiring intravenous antibiotics. In all, the 30-day morbidity rate was found to be 3.7%. By 2 years, surgical complications (e.g., reoperation, cholecystectomy, etc.) were found to be 15%. No deaths were reported [63].

The "Study for Quality Assurance in Obesity Surgeries" is a prospective, longitudinal German registry of adolescents and young adults aged 21 years or younger undergoing bariatric surgery. The study enrolled 345 patients from 58 hospitals with a median follow-up period of 388 days. The authors reported a general short-term complication rate of 2.5%, 5.2%, and 9% for gastric banding, gastric bypass, and sleeve gastrectomy, respectively. Again, no deaths were observed in the cohort [64].

In addition to being safe with acceptable complication rates as demonstrated by the aforementioned studies, bariatric surgery in carefully selected obese adolescents has proven to be effective in resulting in long-term weight loss and treatment of obesity-associated comorbidities.

The Teen-LABS consortium recently reported on the health status and weight loss of a cohort of adolescent bariatric surgery patients 3 years following bariatric surgery. Two hundred and forty-two adolescents from five US centers undergoing bariatric surgery were prospectively enrolled. Patients undergoing RYGB (161 participants) and VSG [67] were included in the analysis. At 3 years postoperatively,

the mean weight had decreased by 27% in the total cohort, by 28% among participants who underwent RYGB, and by 26% among those who underwent VSG. Additionally, the authors reported remission of T2DM in 95% of participants who had had the condition at baseline, remission of abnormal kidney function in 86%, remission of prediabetes in 76%, remission of elevated blood pressure in 74%, and remission of dyslipidemia in 66% (95% CI, 57–74). Weight-related quality of life (WQOL) also improved significantly [65].

The Follow-up of Adolescent Bariatric Surgery at 5 Plus Years (FABS-5+) extension study aimed to characterize long-term outcomes (>5 years) in a cohort of severely obese adolescents aged 13–21 years undergoing RYGB. The FABS-5+ is a single institution, prospective follow-up analysis that included 58 participants. At mean follow-up of 8 years, the authors reported a mean decrease in BMI of 29.2% with significant declines in the prevalence of hypertension and T2DM [66].

At 5-year follow-up of the AMOS study, mean BMI reduction was 13.1 kg/m^2 with an associated 37% resolution of obesity. Additionally, the majority of adolescents undergoing RYGB experienced sustained improvement or resolution in obesity-associated comorbidities as well as enhancement of quality of life at 5 years after surgery [67].

As noted previously, the use of the AGB is decreasing relative to the VSG due to concerns about efficacy and long term complication rates. Still, there is literature reporting some efficacy for severely obese adolescents. Zitsman and coworkers reported on 3-year outcomes following laparoscopic AGB in a cohort of 137 morbidly obese adolescents aged 14–19 years. At 3-year follow-up, the mean BMI reduction was 18.9%. Patients experienced improvement or resolution of their obesity-related comorbidities 3 years following the procedure as well as improvement in emotional well-being, characterized by decreases in Beck depression indices and increases in Peds Quality of Life Inventory scores [68].

Benedix and coworkers reported on outcomes of 362 adolescents aged 12–21 years undergoing laparoscopic VSG. This German multicenter observational study prospectively acquired data in the German Bariatric Surgery Registry. At 12 and 24 months, follow-up information was available for 168 adolescents. The 12- and 24-month mean BMI reduction was 16.8 and 18.0 kg/m^2, respectively. At 12 months, 90.9% of adolescents had complete resolution or improvement of T2DM, and 78.7% had resolved or improved hypertension. Likewise, OSA resolved or improved 81.3%. Twenty-four months after the procedure, 100% of adolescents experienced resolution of T2DM, and 75% had resolution of hypertension [69].

Summary

The childhood obesity epidemic is rapidly emerging as one of the most serious public health issues today, the etiology of which is multifactorial, and involves genetic, environmental, behavioral, and socioeconomic components. Prevention should be the primary goal, as once obesity and obesity-related comorbidities develop in the

adolescent, the efficacy of lifestyle modifications with or without pharmaceutical adjuncts are modest. That said, treatment of childhood obesity should proceed in a stepwise manner. Multicomponent behavioral interventions are more effective than isolated strategies. For patients who have failed a formal trial of lifestyle modification, providers may consider pharmacotherapy in conjunction with behavioral therapy.

In spite of the above therapies, there are severely obese adolescents who prove to be refractory to nonsurgical management. For these carefully selected obese adolescents, bariatric surgery has been shown to be an effective strategy with an acceptable safety profile. Given the sensitive issue of offering bariatric surgery to adolescents, professional organizations such as the ASMBS, IPEG, and SAGES have outlined best practice guidelines for patient selection. Ideally, the decision to perform bariatric surgery for the severely obese adolescent should be made by an experienced multidisciplinary team with both the adolescent and their family involved in the surgical education, consent, and long-term follow-up process.

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Chapter 47
Esophageal Reflux Disease Before and After Bariatric Surgery

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Introduction

The aim of this chapter is to review esophageal reflux disease in the bariatric patient before and after weight loss surgery. It is well known that obesity is a risk factor for the development of esophageal reflux disease (GERD). The impact of bariatric surgery and GERD is an evolving topic of discussion, as incidence and improvement of GERD may be dependent upon the type of bariatric procedure performed. One of the main questions is, "What is the effect of different bariatric procedures on GERD?" There is a rationale for different pathways of reflux management based on surgery type. They can be creative depending on the procedure, including intragastric balloon (IGB), adjustable gastric banding (AGB), sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), as well as biliopancreatic diversion with duodenal switch (BPD-DS).

We will review the physiology and prevalence of reflux in the bariatric patient population. We will also discuss the evaluation and treatment options of esophageal reflux disease following bariatric surgery. In most patients, the treatment of GERD involves dietary and lifestyle intervention along with proton pump inhibitors (PPIs) which are effective in controlling reflux symptoms. However, for those bariatric patients with GERD refractory to PPIs, surgical options will need to be investigated and personalized. As understood, fundoplication for treatment of GERD has been associated with higher failure rates in the severely obese patients, although results are conflicting [1].

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When it comes to bariatric patients and GERD, much of the treatment effort is focused on weight loss. Bariatric surgical procedures (AGB, SG, RYGB, BPD-DS) can be used to treat not only obesity but also GERD. However, each surgery poses certain challenges in the obese patient with GERD. For this reason, a bariatric surgeon should be prepared to diagnose and treat new and worsening GERD before and after weight loss surgery. As more endoscopic and surgical options become available, as well as the possibility of combining two techniques for the same patient, it is important to keep abreast of the different possibilities in treating obese patients with GERD before and after weight loss surgery.

Prevalence of Reflux in Bariatric Patients

Gastroesophageal reflux disease is a common problem in the West. Approximately 10–20% of the general population suffers from reflux-related symptoms [2]. Another study quotes a prevalence of GERD in the general population as high as nearly 30% [3]. In obese patients, the prevalence of GERD is even higher. Hong and colleagues found that in morbidly obese patients being evaluated for bariatric surgery, with a mean BMI of 50.1, 38% of patients complained of reflux-related symptoms with a total of 54% of patients having abnormal manometric findings, consisting of LES dysfunction and other esophageal dysmotility issues [4]. The Houston VA Medical Center Study found that 39% of obese patients (BMI > 30 kg/m^2) demonstrated reflux-related symptoms of heartburn or regurgitation [5]. Another study quoted the prevalence of reflux symptoms in the morbidly obese to be over 50%, with greater than 70% of the morbidly obese demonstrating evidence of reflux disease on pH monitoring [6]. Additional smaller studies as well as larger, population-based studies have demonstrated similar findings, with one population-based study indicating an odds ratio for GERD to be 2.6 for obese individuals as compared to the nonobese [7]. Interestingly, the risk of reflux symptoms has also been linked to waist-to-hip ratio in a dose-responsive fashion [2], and the 2006 data from the Nurses' Health Study demonstrated that incremental weight gain among women with normal body mass indices is associated with a proportionate increase in reflux symptoms [8]. Other studies have demonstrated that overweight patients (BMI 25–29) and obese patients (BMI > 30) are at a higher risk for the development of GERD [2, 9].

The high prevalence of GERD in the obese patient is linked to many pathophysiologic mechanisms, most notably to the presence of hiatal hernia and to extrinsic gastric compression. As compared to the general population, obese patients have a threefold increase in the prevalence of hiatal hernia [2], and therefore it is not surprising that we see an increase in the prevalence of GERD in this population, given the known link between hiatal hernia and GERD symptoms.

The prevalence of GERD after bariatric surgical procedures is quite variable and is dependent on the type of bariatric procedure that the patient undergoes. A higher prevalence of new or worsened GERD symptoms after laparoscopic sleeve gastrectomy (SG) has been shown [2, 10, 11]. On the contrary, one prospective cohort

study on approximately 260 patients demonstrated at least a significant early benefit from SG on GERD symptoms, when hiatal hernias were repaired, if identified, at the time of the SG. Follow-up after surgery, however, was poor (7%) after 36 months, and so long-term benefit or symptom recurrence was not able to be assessed [12]. Adjustable gastric banding (AGB) has been shown to provide a short-term benefit in the reduction of GERD symptoms [13–16], with long-term worsening and loss of benefit due to the link between AGB and esophageal dysmotility [2, 13, 17]. Newly developed GERD symptoms after AGB are quoted as high as 50% and range from 6% to 50% [13]. The prevalence of GERD after RYGB is quite low, and overall RYGB is linked to a decreased incidence of GERD [2, 13, 18]. In fact, RYGB is offered with success to patients with de novo GERD symptoms after AGB or SG [13, 19] and is offered as a viable option for persistent GERD after failed fundoplication [13, 20].

Pathophysiology of GERD in Obese Patients before Bariatric Surgery

The pathophysiology of GERD in the bariatric patient is multifactorial and includes mechanical, anatomical, and biochemical considerations. Essentially, GERD arises when the normal gastroesophageal pressure gradient is altered and intragastric pressure becomes greater than that of the distal esophagus [21]. This can occur from the failure of endogenous anti-reflux mechanisms, namely, lower esophageal sphincter tone and spontaneous esophageal clearance. There are several proposed theoretical mechanisms linked to the failure of endogenous anti-reflux mechanisms in the general population: (1) hiatal hernia causing disruption of the gastroesophageal junction, (2) incompetence of the lower esophageal sphincter, and (3) transient lower esophageal sphincter relaxations (TLESRs) or spontaneous LES relaxations [2, 21]. Hiatal hernias decrease the efficacy of the LES, causing a hypotensive LES and promoting increased intragastric pressure, and thereby leading to the development of GERD symptoms. TLESRs are longer-duration relaxations than those observed during normal deglutition and are generated by vagovagal reflexes that are relatively poorly understood and have been shown to be present in those with GERD as well as in healthy individuals [3]. However, some evidence suggests that there is an increase number of TLESR and reflux during the postprandial period in obese patients [22–24].

Aside from the mechanical and anatomical impact of hiatal hernia on the development of GERD symptoms, the increased intra-abdominal adiposity often seen in obese patients contributes to extrinsic gastric compression and subsequently promotes a gradient favorable for reflux to occur [2]. Anatomic displacement of the esophagus into the chest in obese patients may also play a role in the failure of intrinsic anti-reflux mechanisms and the development of reflux symptoms. In this setting, there is a decreased impact of the diaphragm on the LES, decreasing the overall LES pressure, which promotes an increased gradient across the GE junction and production of GERD symptoms [2].

Several biochemical mechanisms linking GERD and obesity are also important to consider. Studies have demonstrated a link between fatty food intake and the development of GERD symptoms as well as the positive effect of endogenous and exogenous gastrin release on LES pressures [3, 5, 23, 25]. Increased fatty food intake reduces the effects of endogenous and exogenous gastrin release on the LES, thus leading to decreased LES pressures in the postprandial period and the development of reflux symptoms.

Evidence also suggests a link between high carbohydrate intake and the development of GERD symptoms [3, 26]. In the general population, approximately 2–20% of all carbohydrates consumed remain undigested and are metabolized by colonic microflora into short-chain fatty acids. In the setting of excessive carbohydrate intake, common among obese individuals, a humoral pathway, mediated by regulatory peptides, is described by which exposure of the ileum and proximal colon to increased short-chain fatty acids creates a dose-dependent relaxation of the proximal stomach, triggering TLESRs [26].

Altered regulatory pathways with respect to the hormones ghrelin and leptin may also be important biochemical, pathophysiologic mechanisms that contribute to the development of GERD in the bariatric patient, with ghrelin having an effect on gastric motility and leptin on LES tone. However, the exact mechanisms for this effect remain to be elucidated [2, 3].

Additionally, significant work is being conducted to evaluate the link between the autonomic nervous system, obesity, and GERD. Evidence exist demonstrating a link between autonomic dysregulation and obesity, particularly in relation to the parasympathetic nervous system, but the direct link to GERD has not been defined [3, 23, 24].

Pathophysiology of GERD in Post-bariatric Surgery Patients

As mentioned previously, with regard to AGB, a short-term benefit has been demonstrated, likely related to the alteration of the LES. The gastric band creates a longer, intra-abdominal pressure zone and prevents against hiatal hernia due to its physical presence. These mechanisms, as a result, create a reduction in GERD symptoms. However, in the long term, distal esophageal dilatation proximal to the band has been shown, due to narrowing of the esophageal outlet and as a result reduced flow across the banded area. In turn, this decreases esophageal clearance of food, leading to food stasis, reflux of ingested material, and dilatation of the distal esophagus [2, 13]. In addition to this, proximal gastric pouch formation has been shown to occur after AGB. Similar to hiatal hernia, a proximal pouch creates a reservoir for food, causing frequent regurgitation and thereby pathologic reflux and reflux esophagitis. Unlike esophageal dilatation due to AGB, proximal pouch formation is often permanent and can lead to infarction of the pouch with overdistention [2].

With regard to SG, pathophysiologic mechanisms both for the improvement and worsening of GERD symptoms have been shown. The finding of new or worsened GERD symptoms after SG is multifactorial but has been linked to the alteration created at the angle of His after SG. This angle is often blunted as a result of SG. There is also an increased prevalence of hiatal hernia (6–27%) after SG [2, 27–29]. Some studies [10, 11] have shown that this effect is transient and resolves after approximately 3 years. Additionally, the overall weight loss and decreased intra-abdominal adiposity as well as the increased gastric emptying and removal of the acid-producing parietal cells of the gastric fundus with SG have been shown to cause an improvement in GERD symptoms [13, 30].

Contrary to these findings, dysfunction of the LES after SG is seen, due to division of gastric fundal sling fibers, which causes decreased LES pressures. There is also an increased prevalence of hiatal hernia after SG as previously mentioned, and migration of the proximal sleeve above the diaphragmatic hiatus has also been described. In both cases, there is decreased influence of the diaphragm on the LES resulting in worsening GERD symptoms. Additionally, after SG, the stomach can become conical rather than cylindrical, with tapering near the pylorus. This can create a "neofundus" that serves as a reservoir for food storage leading to gastric stasis and increased acid production, both contributing to worsened GERD symptoms. Finally, the resection of the gastric fundus removes an important portion of the stomach responsible for ghrelin production, which can result in slowed gastric emptying and worsening of GERD symptoms [2]. There are many other proposed pathophysiologic mechanisms linking SG to GERD, many very clearly outlined and referenced by Altieri and colleagues [13].

Worsening of GERD symptoms after RYGB is highly uncommon. The majority of patients see a drastic improvement in GERD symptoms after RYGB. Decreased acid production after RYGB due to the proximal gastric division, the small gastric pouch created (20–30 mL) that minimizes any reservoir creation for food stasis, and regurgitation and rapid gastric emptying in addition to the rapid weight loss that is observed in these patients are the primary pathophysiologic means for the improvement in GERD symptoms after RYGB [2]. Additionally, an anti-reflux effect from diverting bile from the Roux limb contributes to decreased reflux symptoms [13]. RYGB is overall associated with decreased GERD incidence and is the procedure of choice for obese patients undergoing bariatric surgery who have a history of GERD [2, 13].

Rationale and Management of Reflux in Bariatric Patients

Morbidly obese patients who have symptoms of GERD and have chosen to undergo bariatric surgery should be counseled regarding the full range of options for bariatric procedures and their respective effects on GERD. As DuPree and colleagues discussed in their review of the Bariatric Outcomes Longitudinal Database (BOLD),

all bariatric patients need to be evaluated for the presence and severity of GERD and counseled regarding the relative efficacy of weight loss operations before surgery [27]. For the purpose of this section, we will consider fundoplication, the intragastric balloon (IGB), adjustable gastric banding (AGB), sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion with duodenal switch (BPD-DS).

Fundoplication

Laparoscopic Nissen fundoplication is a safe and effective treatment for GERD, but several studies have questioned the efficacy for patients with obesity and GERD. The purpose of the anti-reflux operation is to correct the competence of the lower esophageal sphincter and to repair the hiatal hernia. In a small study of 12 patients divided to 2 groups, namely, laparoscopic Nissen fundoplication and laparoscopic gastric bypass groups, both surgeries were effective in treating heartburn symptoms and objective acid reflux in morbidly obese patients [31]. At follow-up, they found no statistical difference between the outcomes of both groups. The study was unable to conclude if both procedures produced equal results, but it was able to conclude that they were both effective, particularly with regard to symptoms. Other studies have also demonstrated outcomes in obese patients that are comparable to those in non-obese patients [32–35].

However, it still remains controversial with regard to the long-term efficacy and durability of fundoplication in the setting of obesity. In a study of 224 patients with 3-year follow-up who underwent laparoscopic fundoplication, overall symptomatic recurrence was 31.3% in obese patients (22.9% Nissen, 53.8% Belsey Mark IV), compared to 4.5% in normal-weight patients [36]. Another study showed preoperative severe obesity was associated with a higher rate of fundoplication failure [37]. Preoperative morbid obesity (BMI > 35 kg/m^2) was associated with failure ($p = 0.036$), while obesity (BMI 30–34.9 kg/m^2) was not.

Intragastric Balloon

The intragastric balloon (IGB) typically is inserted endoscopically and left in place for 6 months. During that time, the patient is kept on proton pump inhibitor (PPI) therapy for ulcer prophylaxis. In spite of this, one study showed that more than 50% of patients required increased dosage of PPI to control worsening GERD symptoms [38]. Early during the period in which the balloon is indwelling, patients often have symptoms of nausea, vomiting, and GERD, up to 70% in some studies [39]. The incidence of GERD symptoms can be affected by balloon positioning, with the antral position associated with a higher risk of prolonged GERD than the fundal position, but the antral position was associated with slightly more weight loss [39].

While GERD, unless severe and intractable, is not a contraindication to placement of an intragastric balloon, patients should be counseled as to the risk of increased GERD during the time the balloon is indwelling. In addition, a greater than 5 cm hiatal hernia on endoscopy is a contraindication to balloon placement, regardless of preoperative GERD symptoms.

Adjustable Gastric Banding

The effect of AGB on GERD symptoms is not entirely clear. While multiple studies have shown an improvement in symptoms after surgery independent of percent excess weight loss (%EWL), several have shown marked increased symptoms and new symptoms [7, 13, 40, 41]. Authors who looked specifically at esophageal motility and esophageal dilation have found that AGB is associated with impaired motility and an increased risk of dilation in a significant percentage of patients [7, 13, 40–42]. These effects are not immediate, therefore, it seems that there is a short-term barrier effect of AGB that improves reflux symptoms, but a longer-term effect that negatively affects motility and can lead to worsening or new symptoms, even in the absence of band prolapse or overfilling. Patients with GERD who are seeking AGB should be counseled that their GERD may improve in the short term, but worsen in the future.

Sleeve Gastrectomy

SG was officially endorsed by the ASMBS in 2012 as a stand-alone procedure for the treatment of obesity [2]. SG has significantly increased in popularity over the past several years. This is due in part to the SG being a technically simple procedure to perform; however, one could describe this procedure as "easy to perform but easy to perform poorly." There is a wide variability in the procedure from surgeon to surgeon and patient to patient, in terms of size of bougie, distance of the staple line from the pylorus, shape of the sleeve, dissection of the hiatus, and repair of hiatal hernia.

There exists literature showing a significant proportion of patients with improved GERD symptoms and severity of esophagitis [43–45], but other studies show high percentages of patients with worsening or persistent GERD, or de novo GERD after surgery [29, 46–48], and worsening of objective tests of esophageal function and reflux, including decreased resting lower esophageal sphincter pressure and increasing DeMeester score [46]. In a nationwide analysis of the Bariatric Outcomes Longitudinal Database (BOLD), DuPree and colleagues noted 44.5% of patients undergoing SG had symptoms of GERD preoperatively. Only 15.9% of patients with preoperative GERD who underwent SG experienced resolution of symptoms, while 84.1% continued having symptoms, with 9% having symptom increase. In

addition, 8.6% of patients who did not have GERD symptoms preoperatively developed them after SG. Preoperative GERD was associated with a statistically significant increase in the risk of complications after SG (15.1% vs. 10.6%) as well as an increased risk of failure to achieve at least 50% excess weight loss (34% vs. 28%) [27].

A study of 110 patients by Genco and colleagues with specific attention to preoperative and postoperative upper endoscopy showed an increase in GERD symptoms from 33.6% preoperatively to 68.1% postoperatively, increased daily PPI use from 19.1% preoperatively to 57.2% postoperatively, and increased findings of esophagitis and increased severity of esophagitis on upper endoscopy. Perhaps most concerning in this study was the new diagnosis of Barrett's esophagus in 17.2% of patients, with 26.4% of those patients having no GERD symptoms. All 110 patients had undergone preoperative upper endoscopy with biopsies and none had been found to have Barrett's preoperatively [49].

The mechanisms for an increase in GERD symptoms following SG are thought to be related to multiple factors. These include impairment of the valve mechanism at the angle of His, decreased gastric compliance, missed hiatal hernia at surgery, development of new hiatal hernia after surgery, and formation of a "neofundus" [2, 13, 37].

As the above findings would suggest, some have found that GERD symptoms can be managed with proper operative technique. The study by Genco and colleagues showed lower rates of all classes of esophagitis and Barrett's in patients with concomitant hiatal hernia repair, though these numbers did not reach statistical significance [49]. Studies by Lyon and coworkers and Daes and coworkers suggest that aggressive investigation for hiatal hernias and repair of these when present could result in improved GERD symptoms after SG [12, 50].

Patients with severe GERD preoperatively were treated by SG with anterior fundoplication in an article by Moon and colleagues [51]. In a study of 31 patients, they found a statistically significant decrease in the GERD scores preoperatively to 3–4 months postoperatively. The technique involves preservation of extra stomach lateral to the angle of His which is used to wrap anteriorly and is sutured to the right crus, with the left side of the upper sleeve being sutured to the left crus (Fig. 47.1). Another study with variation on the standard sleeve technique to add a fundoplication was by Nocca and colleagues. This was a small study of 25 patients followed for 1 year who all had GERD preoperatively. A full 360-degree fundoplication was added along with the sleeve (Fig. 47.2). Only 3 of 25 had reflux symptoms at 1 year [52].

While it appears there are measures that can be taken to mitigate the effects of SG on patients who have GERD preoperatively, these are still investigational, and the studies on these techniques are small. Aside from these studies, there is a large body of evidence showing increased GERD symptoms and changes in the distal esophagus related to GERD in patients who have undergone SG. It would therefore be the safest course of action to offer RYGB to patients with preexisting GERD, as discussed below. However, if one does choose SG in a patient with GERD, it is of utmost importance to pay close attention to the hiatus with repair of any defects found.

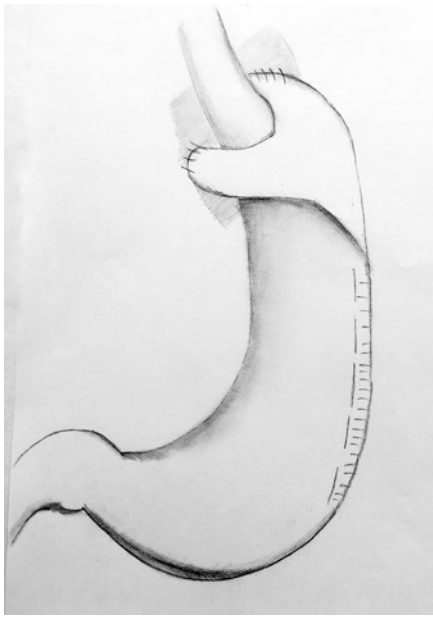

Fig. 47.1 Sleeve gastrectomy with anterior partial fundoplication (Illustrator: Jonathan S. Pincus, MFA)

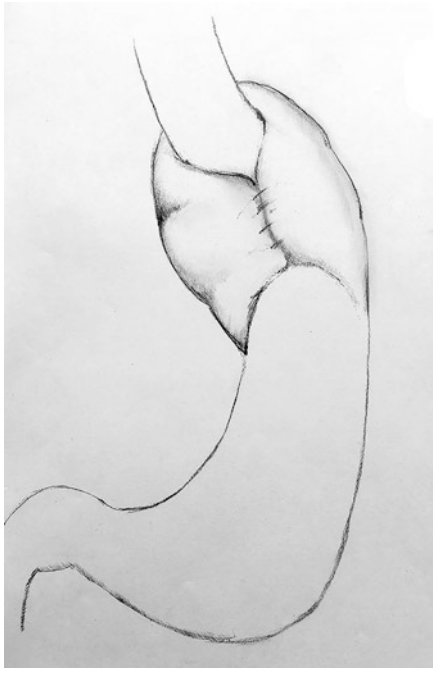

Fig. 47.2 Sleeve gastrectomy with a full 360-degree fundoplication (Illustrator: Jonathan S. Pincus, MFA)

Gastric Bypass

The Roux-en-Y gastric bypass has long been regarded as the gold standard not only for bariatric procedures but specifically for bariatric procedures in patients with preexisting GERD [31, 41]. In addition to weight loss, the mechanisms for GERD improvement after RYGB include decreasing abdominal pressure over the LES, diversion of bile from the roux limb, promoting weight loss, low or no gastric acid production in the pouch, and decreased reservoir capacity of the pouch for regurgitation [1, 2, 7, 13, 38, 41, 48, 53].

The overwhelming evidence supports the use of RYGB for treatment of GERD in obese patients, showing extreme reductions in typical and atypical GERD symptoms, antisecretory medication use, and DeMeester score [7, 41, 53–55]. Not only does the RYGB improve these measures when comparing preoperative and postoperative values, multiple studies have shown superiority of the RYGB in treating GERD when compared with SG [27, 40, 48, 56] and DS [1, 56]. In the DuPree study detailed above, preoperative GERD symptoms were associated with an increased risk of complications and inadequate weight loss after SG, but these risks were not present in the RYGB group.

RYGB has also been shown to positively affect Barrett's esophagus (BE). Because of the low incidence of Barrett's in terms of power for clinical studies, the published data are based on smaller case series. Gorodner and Csendes published series of 25 patients or less who underwent preoperative and periodic postoperative upper endoscopy with standard biopsies for BE. Both of these studies showed no progression of BE, regression in 20–57%, decrease in the length of the BE segment, and even resolution of low-grade dysplasia in some patients [57, 58].

The RYGB is a significantly effective procedure for both weight loss and GERD. The chance of improvement in symptoms and objective measures is high, and the chance of persistent, worsening, or new symptoms is low. In terms of GERD and BE, RYGB outperforms all other bariatric procedures currently performed [56]. Morbidly obese patients whose main or only co-morbid condition is GERD should therefore be counseled that the procedure most likely to improve their GERD and produce adequate weight loss is the RYGB.

There are several studies that have investigated the outcomes of RYGB used for revision of Nissen fundoplication. Hallowell and colleagues described their experience with 11 patients who underwent RYGB following previous foregut surgery. 81.1% patients presented with preoperative GERD, and 9.1% had persistent GERD after RYGB [22]. The study was small and not all 11 patients had previous Nissen fundoplication, but the study showed some patients with reduction in symptoms of GERD as well as weight loss. The possible risks of increased complications should be addressed with this subpopulation of patients.

Biliopancreatic Diversion with Duodenal Switch (BPD-DS)

The BPD-DS is an effective procedure for weight loss and comorbidity reduction but is performed less frequently than the other procedures discussed above [41]. Weight loss after BPD-DS has been shown to be superior to AGB, SG, and RYGB [56]. Its effects on diabetes mellitus and several other comorbidities are greater as well [1, 41]. However, the same studies showing superiority of BPD-DS in weight loss and most comorbidities still show less resolution of GERD when compared to the RYGB. Prachand and colleagues directly compared 198 BPD-DS and 152 RYGB performed at a single institution by 2 surgeons over 3 years. They showed that while resolution of diabetes mellitus, hypertension, and dyslipidemia was statistically significantly higher for BPD-DS than for RYGB, resolution of GERD was higher for RYGB (76.9% vs. 48.57%, $p < 0.05$) [1]. Sudan and colleagues queried a large database of AGB, SG, RYGB, and BPD-DS over 4 years and found BPD-DS to be superior to all other procedures in percent excess weight loss and resolution of type II diabetes mellitus and hypertension. BPD-DS also performed better than AGB and SG for resolution of GERD. Using AGB as the reference for odds of disease remission at 1 year, the authors found an odds ratio of 1.53 for RYGB and 1.20 for BPD-DS ($p < 0.0001$). Interestingly, SG performed more poorly than AGB, with an OR of 0.87.

The mechanism for resolution of GERD in BPD-DS has been hypothesized to involve not only weight loss but diversion of biliopancreatic secretions [41]. This would account for the greater effect of BPD-DS on GERD than SG alone. In super-obese patients with multiple comorbidities including diabetes mellitus as well as GERD, BPD-DS seems to be an acceptable option for surgeons who readily perform this procedure.

Evaluation for Reflux Following Bariatric Surgery

Initial treatment of GERD in the post-bariatric patient is medical therapy similar to that used in the general population. If symptoms continue or worsen despite pharmacologic therapy, further evaluation is needed. In case weight loss surgery is performed at another institution, information regarding previous studies can be helpful. Several tests aid the diagnosis of GERD after bariatric surgery, such as the 24-hour pH study, an upper endoscopy, and manometry. And of these studies, the 24-hour pH study is the gold standard for detection of GERD. Specifically, impedance studies can differentiate acid and nonacid reflux. Manometry evaluates esophageal motility dysfunction. Gastrointestinal radiographic images may also be helpful for detection of hiatal hernia and to help identify an outlet problem as well as gastro-gastric fistula. A real-time fluoroscopy can detect reflux events. A standard

fluoroscopic examination can include standing, prone oblique, and other provocative maneuvers for reflux. An endoscopy can evaluate for Barrett's esophagus, esophagitis, gastro-gastric fistula, patency of the anastomosis, or presence of a hiatal hernia. When performing an endoscopy, the gastroenterologist or surgeon should be aware of the weight loss surgery performed with attention to gastric pouch or sleeve size, anastomotic characteristics, and potential fistulae.

Mion and colleagues assessed the usefulness of high-resolution impedance manometry (HRIM) in patients with upper gastrointestinal (GI) symptoms after sleeve gastrectomy (SG). In their study, they were able to describe the HRIM patterns after SG, identifying impedance reflux episodes after SG [59]. The combination of high-resolution manometry (HRM) and intralumenal impedance monitoring (HRIM) allowed the assessment of pressure as well as bolus clearance and reflux episodes within the esophagus and proximal stomach. HRIM has potential usefulness for diagnostic workup of patients with GERD "de novo" after SG. It will be interesting if future studies could compare results of HRIM with prolonged esophageal pH-impedance monitoring on patients after SG.

Anti-reflux Treatment Options after Bariatric Surgery

In spite of some data sets showing lack of resolution of GERD symptoms following SG, there is a significant amount of data showing improvement in symptoms in all bariatric surgical procedures. Therefore all four bariatric surgical procedures (AGB, SG, RYGB, BPD-DS) can be used to treat not only obesity but also GERD. But the risk of new or worsening GERD is not zero for any of these procedures. GERD symptoms are common complaints for any bariatric surgeon to address, both preoperatively and postoperatively, and thus the bariatric surgeon should be prepared to diagnose and treat new or worsening GERD after surgery.

Evaluation of the postoperative bariatric surgical patient with symptoms of GERD should establish the etiology of the symptoms in order to tailor treatment appropriately. Postoperative complications from any of the above procedures can mimic GERD and thus require careful attention and a high index of suspicion. Ruling out band prolapse, anastomotic ulcer or stricture, sleeve stenosis, gastro-gastric fistula, and new or recurrent hiatal hernia can avoid further complications and narrow the diagnosis.

Control of GERD symptoms when possible should include acid reducing medications and anti-reflux behavior changes. Titrating dosage and frequency of proton pump inhibitors (some advocate opening the capsules), addition of H2 blockers, and avoidance of food and position triggers can all be undertaken to treat GERD symptoms. If the diagnosis of GERD is established with other complications ruled out and symptoms are refractory to medical therapy, then further surgery can be planned.

As new techniques continue to develop, such as the LINX device, the MUSE system, Stretta procedure, and EsophyX, among other endolumenal therapies,

new choices emerge. These procedures may be performed either postoperatively in patients with newly developed reflux or concurrently in patients desiring procedures such as a sleeve; however, only limited data are available currently for these approaches.

Treatment Options for GERD after AGB

AGB has been shown to have mixed to favorable results for GERD [13, 38, 41]. Overall, AGB carries with it a high risk for reoperation over the life of the device [60], for various indications, mostly for weight gain/regain and mechanical problems. Development of GERD with evidence of relative obstruction or dilated esophagus on contrast swallow should be first treated with removal of fluid from the band [61]. If there is evidence of slippage or no resolution of obstruction, surgical management is warranted. Unfortunately, completely emptying the band can lead to weight regain and patient dissatisfaction for other reasons. If the primary indication for revision surgery is to treat GERD, conversion to a gastric bypass would be the procedure of choice, as optimizing chances of GERD remission would be the highest priority [56]. When undertaking a revision from AGB to RYGB, dissection at the left lobe of the liver and hiatus can be impaired by adhesions, but restoration of normal anatomy must be achieved. All imbricating sutures should be identified and divided to ensure adequate pouch size and tissue thickness on the lateral aspect of the pouch.

Treatment Options for GERD after SG

GERD is a common problem after SG [27, 29, 46–48]. This can result in spite of normal anatomy in a well-performed sleeve but often occurs due to errors in technique and anatomical factors that develop after surgery [2, 13, 38]. If a patient develops GERD symptoms after SG, standard workup should include contrast swallow and upper endoscopy and should rule out technical factors such as a neofundus, narrowing at the incisura, twisting of the sleeve, and new or recurrent hiatal hernia. Manometry and pH probe can also be useful to evaluate esophageal function and determine acid versus bile reflux.

In the patient without anatomical abnormalities resulting from surgery who has severe GERD refractory to maximal medical management, further procedures can be offered. A new technology that has shown promise in treatment of GERD refractory to medical management is the LINX® magnetic sphincter augmentation device [62]. This has been studied in small case series with good results in patients status post SG [63]. As this would be currently (2017) off-label use, it should be undertaken by a surgeon experienced with the procedure after an extensive workup. A clinical trial is pending enrollment at this time.

The indications for revision surgery after SG most often involve weight regain or inadequate weight loss [19, 64–66]. GERD as primary or secondary indication for revision ranges from 2% to 27% [12, 19, 64–66]. While re-sleeve has been performed for weight regain [67, 68], this is less advisable in patients whose primary reason for revision is GERD.

Conversion of sleeve gastrectomy to RYGB has been well described as an option in controlling reflux symptoms. Several authors have reported revision of SG to RYGB for GERD [65]. In particular, Parmar and colleagues reported their outcomes of conversion of SG to RYGB in 22 patients. Five of their patients also underwent anterior crural approximation for a hiatal hernia. Their study demonstrated that conversion of SG to RYGB was effective for eight of their ten patients with GERD symptoms [19].

While conversion to BPD-DS is a good option for inadequate weight loss, converting SG to BPD-DS without addressing problems with the sleeve that led to GERD would leave the patient with continued symptoms. In the case of revision for GERD, revision to RYGB is the procedure of choice [65, 66, 68].

Treatment Options for GERD after RYGB

Although RYGB is the best of the currently available procedures in terms of resolution of GERD, there are still patients who have persistent symptoms or new symptoms after surgery. Post-RYGB patients should have a workup to evaluate for marginal ulceration, stricture, or gastro-gastric fistula, which often includes upper endoscopy. A contrast swallow study can also be used to evaluate the size of the pouch and patency of the anastomosis and can detect genuine reflux events when using real-time fluoroscopy. Manometry and pH probe can also evaluate for esophageal acidity and esophageal motility dysfunction.

One relatively new piece of technology available for treatment of GERD which has been used sparingly in post-RYGB patients is radiofrequency energy, or Stretta® (Mederi Therapeutics, Norwalk, CT, USA) [69]. Mattar and colleagues reported five of six patients with resolution of GERD symptoms and improvement in DeMeester scores after post-RYGB Stretta®. The LINX® (Torax Medical Inc., Shoreview, MN, USA) magnetic sphincter augmentation device has also been used in a few patients (Fig. 47.3) with good success after RYGB [70, 71].

Operative revisional strategies for post-RYGB GERD include pouch resizing, lengthening the alimentary limb if short enough to allow for bile reflux, and fundoplication with the remnant stomach. Case reports have shown favorable results, and there is unpublished experience that has been reported to be favorable as well [72, 73]. A case of conversion to a Belsey Mark IV fundoplication has been described in the literature, although that is not standard. Surgeons have applied Hill gastroplasty utilizing the gastric pouch and pre-aortic fascia [74]. Others have proposed fundoplication using the bypassed stomach. Kawahara and colleagues described their experience of performing a loose, short 3 cm wrap using the excluded stomach.

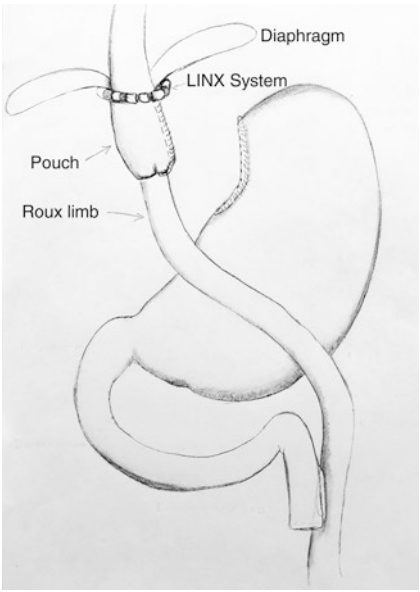

Fig. 47.3 LINX magnetic sphincter augmentation device after a Roux-en-Y gastric bypass (Illustrator: Jonathan S. Pincus, MFA)

Approximately 6 cm of the excluded stomach was passed behind the esophagus, and the anterior and posterior excluded stomach lips were sutured together with three interrupted 3-0 polypropylene sutures [73]. They were able to compare 24-hour pH testing and manometry pre- and postoperatively. Patient remained asymptomatic without reflux or dysphagia 6 months later. We are unaware of any prospective clinical trials regarding the long-term effects of Nissen fundoplication as a surgical option for treating persistent reflux after RYGB.

Treatment Options for GERD after BPD-DS

Assessment and management of GERD after BPD-DS is similar to the SG. Treatment in a patient with normal sleeve anatomy can involve LINX® or Stretta®. Re-sleeve and hiatal hernia repair has also been described in patients post BPD-DS [75].

Conclusion

GERD is a significant comorbidity in bariatric patients preoperatively and postoperatively. Several studies have shown that up to 70% of weight loss surgery patients have GERD [29, 76]. Surgeons should be aware of appropriate evaluation, procedure choices, and management options. Revision surgery for reflux symptoms is not uncommon, and appropriate anatomy and outcomes should be

considered when offering these interventions to our patients. Patient selection is important to avoid postoperative development or worsening of GERD. As more endoscopic and surgical options become readily available, this will allow surgeons to safely and efficiently address challenging situations when it comes to esophageal reflux disease and bariatric patients before and after weight loss surgery.

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