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Bariatric Surgery Complications

The Medical Practitioner's Essential Guide

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Foreword

Bariatric surgery for the treatment of severe obesity and metabolic disease has gone through transformational changes over the past two decades. First, the operation has changed from an invasive, open procedure to primarily a minimally invasive, laparoscopic procedure. Second, more emphases were placed on a multidisciplinary team approach in preoperative and postoperative management of the bariatric patients. Lastly, the safety of bariatric surgery has improved significantly with the development of the Center of Excellence programs with mortality now exceedingly low and comparable to that of common general surgical procedure such as that of laparoscopic cholecystectomy.

A large part of reducing the morbidity and mortality associated with bariatric surgery is education of all practitioners caring for the bariatric patient. Particularly during the perioperative period, hospitalists, intensivists, gastroenterologists, resident, and nursing staff must be able to recognize bariatric surgery-related complications in its early stage and intervene expeditiously with appropriate measures. Failure to provide early, effective interventions can lead to catastrophic consequence for the patient. At long-term follow-up, primary care physicians, emergency room physicians, and general surgeons will also likely encounter bariatric patients and will need to be able to recognize and manage the various nutritional and procedural-related bariatric complications.

During her tenure as President of the American Society for Metabolic and Bariatric Surgery (ASMBS), Dr. Robin P. Blackstone promoted many initiatives to improve the care and safety for bariatric patients. This book is part of her ongoing effort in this quest. This concise and easy to read book contains the most current, collective knowledge of optimal care for the bariatric patient from 25 premier practitioners. The book succinctly emphasizes best practices and highlights the potential pitfalls in caring for the bariatric patient. Whether the bariatric patient presents with unexplained abdominal pain, weight regain, general surgery considerations, or bariatric-related complications that arise immediately after the bariatric operation or years later, this book provides essential information and advice for caring for this complex and unique patient group. I encourage every provider that care for the bariatric patient should be familiar with the critical knowledge contained in this book.

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Ninh T. Nguyen

Preface

For the last 16 years, I have operated on and cared for patients affected by obesity and been humbled by their resilience and determination to overcome their disease. They continually inspire me to seek answers to improve their health. Patients with obesity are uniquely complex. When they arrive for their bariatric surgical procedure, their general health in most cases is already severely compromised by a plethora of pre-existing obesity-related diseases. This sets the stage for a perfect storm of complications to occur. The expert management of these complications, both short and long term, is essential to achieving good care and good results. Having personally performed over 5000 metabolic and bariatric surgeries, I have had the privilege of managing the complications of bariatric surgeries in concert with many dedicated colleagues. Together we have learned how to anticipate complications, what to watch for, and how best to react. Sharing what we have learned allows us to help improve care for all patients with obesity.

Obesity and overweight affects over 60 % of the population. People with obesity and obesity-related disease make up a large number of the patients managed by the primary care community. After unsuccessfully pursuing various remedies to reduce their weight, some of these patients eventually opt for surgical intervention. Over 180,000 people a year will undergo bariatric surgery and be cared for not only by bariatric surgeons but also by many other members of the health care community at different points along the way. Complications, if and when they occur, must be optimally handled in order to avoid poor patient outcomes. Doctors in the emergency department, gastroenterologists, general surgeons, primary care doctors, and integrated health staff will have primary responsibility for the evaluation and management of these complications.

The purpose of this book is to provide guidance to those frontline providers who will manage acute emergencies and chronic long-term problems in this population of patients. Each chapter is written by experts in that field and based on current peer-reviewed literature. The book provides a focused approach to the identification and treatment of bariatric surgery complications.

Phoenix, AZ, USA — Robin P. Blackstone

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1 The Surgical Management of Obesity

Shanu N. Kothari and Julie J. Kim

1.1 Epidemiology of Obesity

The obesity epidemic among adults in the USA is well established. Body mass index (BMI) data from the National Health Examinations Survey (NHANES) reveals significant growth of clinically severe obesity (BMI greater than 40 kg/m^2) over the past several decades. Among US adults, 33.0 % are overweight, 35.7 % are obese, and 6.3 % are extremely obese. It is estimated that by 2030, the obesity rates will be over 40 % and clinically severe obesity will reach 11 % of the US population [1, 2].

An encouraging report from the most recent NHANES data shows that there have been no significant changes in obesity prevalence in youth or adults between 2003–2004 and 2011–2012 [3]. However, obesity prevalence remains high in the USA.

Obesity results in a variety of obesity-related conditions, including but not limited to diabetes, cardiovascular disease, obstructive sleep apnea, nonalcoholic steatohepatitis, hypertension, dyslipidemia, osteoarthritis, and cholelithiasis. Obesity increases the risk of many of these conditions [4]. In addition to several obesity-related comorbid conditions, obesity is an independent risk factor for a variety of cancers including breast, prostate, colon, and uterine cancer [5, 6].

The economic impact that obesity has on the workforce is significant. Finkelstein et al. showed that overweight men and women miss more days of work per year than their leaner counterparts. In addition, the more severely obese, the more number of days were missed [7]. Although only 3 % of the employees studied had grade 3 obesity, they accounted for 21 % of the healthcare costs associated with obesity. It has been estimated that absenteeism secondary to obesity costs approximately $4.3 billion annually in the USA [8].

Another concept that has been put forth is underperformance while at work. This term has been coined "presenteeism." Studies have been done evaluating the impact of BMI and work loss productivity [8, 9]. Gates et al. estimated the loss in productivity while present on the job is 4.2 % for employees with a BMI greater than 35 kg/m^2 [10]. This translated to approximately $500 annually in losses per worker. This productivity loss was present despite no difference in absenteeism in the two groups in the cohort. The multitude of obesity-related conditions results in significant economic impact on healthcare expenditures (Table 1.1) [11–14]. In addition, several studies have shown the beneficial economic impact of bariatric surgery on healthcare

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Table 1.1 Economic impact of obesity on healthcare expenditures

First author	Year	Article type	N	Data source	Outcome/conclusions
Daviglus	2004	Retrospective	17,601	Medicare data (1984–2002); Chicago Heart Association Detection Project in Industry (1967–1973)	In multivariate analyses, average annual and cumulative Medicare charges (CVD related, diabetes related, and total) were significantly higher by higher baseline BMI for both men and women
Cai	2010	Retrospective	5043	NHANES; Medicare claim data	Obese 45-year-olds had a smaller chance of surviving to age 65 and, if they did, incurred significantly higher average lifetime Medicare costs than normal-weight 45-year-olds ($163,000 compared with $117,000)
Wilkins	2012	Retrospective	10,300	Medicare Current Beneficiary Survey (MCBS) 2000–2005	Adjusted models revealed that those who stayed obese had increased total and multiple expenditure types that were significantly higher than those whose BMI stayed normal including total (11 %), outpatient (25 %), prescription (9 %), and medical provider (4 %). Compared to those whose BMI stayed normal, total expenditures were both 26 % higher for obese-overweight and overweight-obese
Mason	2013	Retrospective, case matched	4,398,129	Healthcare Cost and Utilization Project Nationwide Inpatient sample database (2005–2009)	Adjusted total hospital costs incurred by obese patients were 3.7 % higher with a significantly ($P<0.0001$) higher per capita cost of $648 (95 % confidence interval [CI]: $556–$736) compared with nonobese patients. LOS was significantly increased in obese patients (mean difference = 0.0253 days, 95 % CI: 0.0225–0.0282) and resource utilization determined by costs per day was greater in obese patients due to an increased number of diagnostic and therapeutic procedures needed postoperatively (odds ratio [OR] = 0.94, 95 % CI: 0.93–0.96). Postoperative complications were equivalent in both groups (OR = 0.97, 95 % CI: 0.93–1.02)

expenditures demonstrating that the initial cost of the surgery can be recouped over the first few years (Table 1.2) [15–18]. Treatment options for obesity include lifestyle intervention, medical management, and bariatric surgery. Currently, bariatric surgery is the only long-term, sustainable treatment for obesity, and several standard procedures have been established.

1.2 Standard Bariatric Procedures

Early bariatric procedures were first described in the 1950s and were primarily designed to minimize nutrient absorption in the small intestine. Although these early procedures were successful in achieving weight loss they were associated with prohibitive morbidity including protein malnutrition, liver failure, and high rates of reoperation and mortality. The lack of a standardized scientific approach to both the understanding of the mechanism of action of these procedures and the process to evaluate the introduction of new procedures marred the field of bariatric surgery for many years. Similarly, the lack of a standardized approach to patient selection, perioperative care, and long-term follow-up had a negative impact on patient outcomes.

The ongoing efforts to improve patient safety and quality included efforts by both the American Society for Metabolic and Bariatric Surgery (ASMBS) and the American College of Surgeons (ACS) culminating in the establishment of the Metabolic Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), a singular program of accreditation and quality improvement which involves the hospital, surgeon, and allied health team with the ability to collect ongoing long-term data, on both an individual program and national level.

Bariatric procedures today are safer than many commonly performed general surgery procedures, with mortality rates and a risk profile comparable or better than laparoscopic cholecystectomy [19]. The current bariatric and metabolic procedures have been standardized and are performed primarily via a laparoscopic approach. Regardless of the procedure choice, standardized criteria for patient selection and presurgical preparation have been in place since the 1991 National Institutes of Health (NIH) guidelines were published [20]. Bariatric surgery can be offered to patients with a BMI of at least 40 kg/m^2 or 35 kg/m^2 with associated serious comorbid conditions (e.g., diabetes, hypertension, and sleep apnea). Given the complexity of obesity as a disease, a multidisciplinary team evaluation to include dietary, behavioral, medical, and surgical components is considered mandatory, as is the long-term postoperative follow-up and evaluation of the patient to ensure safety and provide ongoing support. The current bariatric procedures include the adjustable gastric band (AGB), Roux-en-Y gastric bypass (GB), sleeve gastrectomy (SG), and duodenal switch (DS) (Fig. 1.1) [21].

1.2.1 Adjustable Gastric Band

The AGB is a purely restrictive procedure. A soft silicone band is positioned around the upper part of the stomach, creating a small gastric pouch. The inner balloon is inflatable allowing for modifiable mechanical restriction of the pouch outlet or stoma, which minimizes the amount of food that can be consumed during a meal, as well as increases the time for emptying of the gastric pouch. Mechanical restriction is thought to be the main mechanism of satiety and weight loss. The AGB procedure gained popularity as an alternative to the GB with its superior safety profile and simpler technique. Once the most commonly performed weight loss procedure in the USA, it has seen a steady decline in recent years [22].

Current devices evolved from non-AGB placed via an open technique to AGB that are placed laparoscopically. These modifications were developed during a time when bariatric surgeons had become comfortable with the technique of open vertical banded gastroplasty (VBG), yet desired to offer treatments for morbid obesity utilizing a minimally invasive approach with the flexibility and advantage of an adjustable outlet. There are two FDA-approved devices in the USA. The REALIZE® band (manufactured

Table 1.2 Cost recoupment of bariatric surgery

First author	Year	Article type	N	Outcome/conclusions
Cremieux	2008	Retrospective, case matched	7302	The mean bariatric surgery investment ranged from approximately $17,000 to $26,000. After controlling for observable patient characteristics, the authors estimated that all costs are recouped within 2 years for laparoscopic surgery patients and within 4 years for open surgery patients
Hodo	2008	Retrospective	605	Mean number of prescription claims/person decreased after surgery, from 6.93 ± 7.16 before to 4.88 ± 5.84 after surgery ($P < 0.001$). Mean number of claims for office visits decreased from 5.52 before to 3.94 after surgery ($P < 0.0028$), and mean number of claims for outpatient visits
Klein	2011	Retrospective, case matched	1616	Surgery costs were fully recovered after 26 months for laparoscopic surgery. At month 6, 28 % of surgery patients had a diabetes diagnosis, compared to 74 % of control patients ($P < 0.001$). Among pre-index insulin users, insulin use dropped to 43 % by month 3 for surgery patients, vs. 84 % for controls ($P < 0.001$). By month 1, medication and supply costs were significantly lower for surgery patients ($P < 0.001$)
Keating	2012	Retrospective, case matched	11,769 gastric band patients, 140,000 general population	Severely obese subjects utilized significantly more medical services annually compared to the general population (mean: 22.8 vs. 12.1/person), standardized incidence ratio (SIR): 1.89 (95 % CI 1.88–1.89), translating to a twofold higher mean annual costs (Australian $1140 vs. $567/person). The greatest excess costs in the obese related to consultations with general practitioners, psychiatrists/psychologists, and other specialists, investigations for obstructive sleep apnea, and in vitro fertilization. Severely obese subjects also utilized significantly more pharmaceutical prescriptions annually (mean: 11.4 vs. 5.3/person, SIR 2.18 (95 % CI: 2.17–2.19)), translating to 2.2-fold higher mean annual costs ($595/person vs. $270/person)

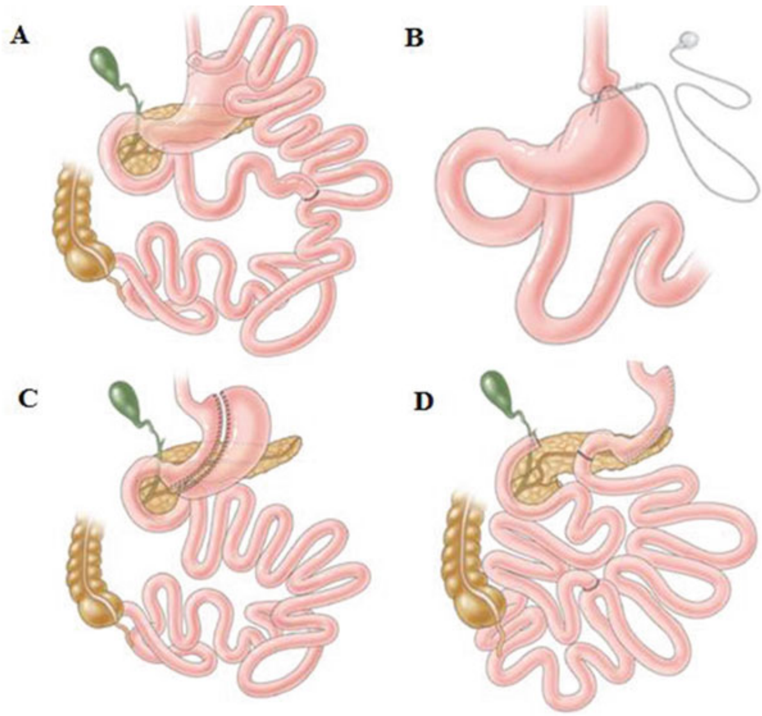

Fig. 1.1 Common bariatric procedures include (**a**) gastric bypass, (**b**) adjustable gastric band, (**c**) sleeve gastrectomy, and (**d**) biliopancreatic diversion with duodenal switch (from Bradley D, Magkos F, Klein S. Effects of Bariatric Surgery on Glucose Homeostasis and Type 2 Diabetes. Gastroenterology. 2012;143(4): 897–912, with permission)

by Ethicon) is a high-volume, low-pressure device modeled after the Swedish adjustable gastric band (SAGB). The LAP-BAND™ (manufactured by Allergan, Santa Barbara, CA), in contrast, is a high-pressure, low-volume band, similar to that of the Kuzmak band, which was placed in an open fashion in 1984 [23]. Belachew is credited with describing the first laparoscopic placement of an AGB in 1993 [24].

The AGB procedure begins after initial trocar placement and retraction of the liver. The placement of the band was originally described via a perigastric approach, similar to that utilized in open placement of non-AGB, with an opening in the lesser curve of the stomach medial to the gastric vessels [23]. This has largely been replaced by the pars flaccida technique, developed to decrease the incidence of prolapse and pouch dilation seen with the perigastric technique. In the pars flaccida approach, the lesser sac is not entered, and instead a smaller footprint retroesophageal window is created by dissecting the peritoneum at the edge of the right crus. The phrenogastric ligament at the angle of His is also dissected. A blunt articulating dissector is then passed from the vicinity of the right crus to the dissected area of the angle of His, through which the tubing of the band can be pulled and the band buckled into place. A calibrating balloon can be used to size the gastric pouch at 10–20 mL. Although not utilized by all surgeons, three to four gastrogastric plication sutures can be placed to stabilize the gastric pouch anteriorly. Less weight loss and increased risk of prolapse have been associated with findings of unrepaired hiatal hernias after AGB. It is therefore felt to be important to look for the presence of hiatal hernias, frequently missed on preoperative imaging studies. Concomitant hiatal hernia repair when identified during AGB has been found to be safe and is associated with decreased subsequent band-related complications [25]. The band tubing is then externalized and connected to a subcutaneous access port, which is positioned and secured on the anterior rectus sheath. Port placement should also consider the ease of superficial palpation of the port, as well as avoiding the oblique muscles, which may promote more movement or flipping of the port. Some surgeons may choose to reinforce the access port placement with a small piece of fitted mesh to create additional natural adhesion formation for added security.

Patients are seen for interval visits for band adjustments usually beginning at 4–6 weeks after surgery. Incremental amounts of saline can be added or removed from the access port. Band adjustments are an integral part of maximizing the efficacy of the device and are generally performed in the office by palpating the access port and inserting a long Huber-type needle. Adjustments can also be performed with the aid of ultrasound or fluoroscopy when the port is difficult to identify. Fluoroscopy with contrast can also be useful to calibrate the outlet visually. Given variable stomach thicknesses and individual tolerance to restriction, there is no standard amount of fluid or number of adjustments appropriate for all patients. Most patients, however, will require anywhere from 5 to 7 adjustments per year in the first 1–2 years, with varying number of adjustments thereafter. Partial or complete deflation of the band can be performed for any negative symptoms resulting from over-restriction (nausea, vomiting, dysphagia, gastroesophageal reflux disease (GERD)). Fluoroscopy is the diagnostic study of choice to evaluate for changes in the position of the band, and evaluate for obstruction of flow, prolapse (anterior or posterior protrusion of the stomach), or slip. Chronic over-restriction and vomiting can result in erosion of the gastric band, where a part of the band or its entirety becomes internalized within the lumen of the stomach. The diagnostic study of choice for evaluation of a suspected erosion is upper endoscopy. Port complications, such as infection, flipping (limiting the ability to access the port), local pain, and separation of the port from the band tubing (resulting in band leakage and inadequate restriction), are a rare cause of major morbidity, and can generally be repaired with a brief outpatient procedure; but they occur frequently, as reported in a recent systematic review with 15-year follow-up, by O'Brien et al., at 21 % [26].

The primary benefit of the AGB over other bariatric procedures is its safety profile, as well as the ability to restore original anatomy if necessary. Given that the stomach is not divided or stapled, it is not surprising that the AGB has the lowest mortality rate of any bariatric procedure, ranging from 0 to <0.1 % in most published series [26]. There is also no alteration in the pathway of nutrient flow; therefore, it has the lowest risk of micronutrient deficiency and medication malabsorption. Several meta-analyses and systematic reviews with long-term follow-up show durable weight loss of over 40–50 % excess weight loss (%EWL) beyond 10 years [26]. The limitations of the AGB are related to higher variability of weight loss between individuals as well as the high rate of reoperations ranging in published studies from 8 to 60 % at 10 or more years of follow-up [27].

1.2.2 Sleeve Gastrectomy (SG)

The sleeve gastrectomy (SG) is both the newest and now most commonly performed bariatric procedure in the USA, surpassing rates of GB in 2013 [28]. The SG is technically less challenging than the GB and biliopancreatic diversion with duodenal switch (DS), as no anastomosis is created, but, unlike the AGB, results in changes in gut hormones and gastric emptying, among others. The SG involves removal of the majority of the greater curvature of the stomach resulting in a significantly narrowed and tubularized stomach. The reduced capacity restricts the amount of food consumed and the removal of the fundus reduces both fasting and postprandial levels of ghrelin (a gut hormone involved in stimulating appetite) [29]. The SG provides an alternative option for patients where the GB may be contraindicated, such as patients with inflammatory bowel disease (where manipulation of the small intestine is generally not advised), and who require chronic steroid or NSAID use (promotes marginal ulceration). The SG may also be preferable for those patients who have a history of extensive prior abdominal surgery, large concomitant ventral hernias, chronic renal disease, and early cirrhosis.

Creation of a sleeve gastrectomy is the first part or stage of the DS. The DS procedure is a technically complex procedure with two separate anastomoses and has been associated with a high morbidity and mortality rate when performed in super-super obese patients (BMI >65 kg/m^2) [30]. In an effort to help reduce the operative morbidity and mortality, the DS was sometimes aborted after the SG component or offered as a planned two-stage procedure, in which only the sleeve gastrectomy was performed. Patients would then be followed for interval weight loss and would be brought back for the malabsorptive portion (second stage) or completion DS once there had been improvement in visceral adiposity, generally 6–12 months later. The utilization of the SG as a staged procedure for DS was first performed in 2000 by Gagner, who also described the utilization of the SG as a staged procedure with completion GB for super obese patients [31]. Over time, it was recognized that some patients were able to achieve and maintain adequate weight loss and did not need to undergo the second stage to a DS or GB. In 2007, there were several studies published looking at the merits of standardization and utilization of the sleeve gastrectomy as a new stand-alone primary treatment for morbid obesity [32, 33]. In 2009, the ASMBS recognized the SG as a standard primary treatment for morbid obesity as well as an option for staging, based on reasonable mid- to long-term data on the safety, efficacy, and durability of outcomes [34]. Ongoing efforts for standardization of SG (technique, management) have led to several international consensus summits and international expert panels, beginning in 2007, which have helped provide collective input on many clinical aspects of the SG, in the form of best practice guidelines and statements [35, 36].

The modern SG begins after trocar placement (generally 5–6), retraction of the liver, and identification of the pylorus. A distance of 2–4 cm on the antrum is marked to begin dissection of the greater curve vessels and ultimate division of the stomach. A bougie or calibrating tube is used to help standardize the size of the gastric conduit, as well as to prevent overnarrowing of the sleeve, and is considered a mandatory component of the modern SG with reported sizes ranging from 32 to 46 Fr. Sequential firings of the linear stapler are continued toward the angle of His. It is important to identify the left crus to ensure adequate dissection as it is also generally recommended to repair any concomitant hiatal hernias to prevent worsening of GERD [34, 35].

Early complications include bleeding, stricture, and leak. Late complications include chronic fistula, stricture, pouch dilatation, unrecognized hiatal hernias, and worsening of GERD. Leaks have been identified and described more than 30 days after SG. Most late leaks occur secondary to findings of distal stricture or kinking of the sleeve. The most common location for leaks after SG is the upper portion of the sleeve near the angle of His. Vascular changes as well as pressure changes from a tubularized, less distensible stomach against a closed pylorus are thought to be contributing factors in the etiology of leaks after SG [37, 38]. A recent meta-analysis found a slightly higher incidence of leak after SG, ranging from 2.3 % compared to 1.9 % after GB. The mortality, however, is comparable or less than that of GB, at 0.2 % for SG vs. 0.4 % for GB [39]. This is comparable to findings in a systematic review by the Clinical Issues Committee of the ASMBS, which reported a leak rate of 2.2 % and mortality rate of 0.19 % for SG. Percent EWL with at least 3-year follow-up was reported at 55 % [40].

Like GB and DS, weight-independent improvement of glycemic control and resolution of diabetes have been shown after SG. As with GB and DS, the mechanisms of diabetes resolution and weight loss are not completely understood. Although the SG does not involve alteration in the pathway of nutrient flow, findings of both increased gastric emptying and intestinal transit have been shown in animal models [41]. It is thought that this may be a mechanism to help explain findings of increased incretin production of hormones such as peptide YY (PYY) and glucagon-like-peptide-1 (GLP-1), not observed after AGB, which are both promoters of an anorectic state as well as implicated in glucose homeostasis [42]. Both SG and GB have been shown in a recent randomized controlled trial (RCT) reported by Schauer et al. to have significantly greater glycemic control for obese diabetics compared to best medical management with mid-term results at 3 years [43]. Ongoing research is required to fully understand the durability of these effects.

1.2.3 Gastric Bypass (GB)

Once the most commonly performed bariatric procedure in the USA, the GB has been positioned as the "gold standard" bariatric procedure since the early 1990s, but was surpassed in volume of cases per year by the SG in 2013 [28]. The GB procedure was first described in 1967 by Mason and Ito, and involved a horizontally based gastric pouch and "loop" gastroenterostomy [44]. Complications of bile alkaline reflux and marginal ulcers led to many modifications of the procedure over the subsequent years, with changes in both the size and configuration of the gastric pouch (lesser curve or vertically based) as well as replacing the "loop" anastomosis with a Roux-type anastomosis. The procedure was performed in an open fashion though an upper midline incision. Not surprisingly, abdominal wound infections and incisional hernias were fairly common complications seen after open gastric bypass surgery [45]. Advances in laparoscopic technology and minimally invasive surgery techniques as well as improved perioperative outcomes from fewer wound and cardiopulmonary complications, reduced length of stay, and shorter recovery witnessed for cholecystectomy, hernia, and anti-reflux procedures in the early 1990s helped provide the rationale for utilizing such techniques in bariatric surgery. In 1994, Wittgrove and Clark detailed the first laparoscopic gastric bypass procedure. Using six trocars, they created a small 15–30 cm^3 proximal pouch, a 21 mm circular stapled end-to-end (EEA) gastrojejunal anastomosis, and a 75 cm retrogastric, retrocolic Roux limb [46].

In 2000, Wittgrove and Clark published the results of 500 consecutive laparoscopic GB procedures with up to 60-month follow-up to show 0 % mortality, leak rate of 2.2 %, overall complication rate of less than 10 %, and mean excess body weight loss of 73 % at 54 months [47]. The modern GB is performed using 4–6 abdominal trocars and consists of a small proximal 15–30 cm^3 gastric pouch, with a Roux limb (alimentary limb) length of 75–150 cm to prevent bile reflux, which is then anastomosed to the biliopancreatic limb. Since 1994, there have been many different laparoscopic GB techniques described, with minor variations in how the gastrojejunal anastomosis is created (hand–sewn vs. linear vs. circular stapled) and positioned (retrogastric, retrocolic, antegastric, antecolic, or combination). The use of robotic assistance has also been described [48]. These different GB techniques are generally felt to be comparable in safety, efficacy, and outcomes with surgeon preference being the predominant factor in determining which approach is chosen [49–51].

The primary mechanisms of weight loss include caloric restriction, and reduction of ghrelin. Ghrelin is a peptide hormone secreted primarily in the stomach and foregut that stimulates the early phase of meal consumption and is significantly reduced after GB [52]. Increased incretin production of hormones such as PYY and GLP-1 seen after GB may also contribute to an anorectic state and are also thought to contribute to the weight-independent metabolic changes resulting in improved glycemic control, reduced insulin resistance, and euglycemia which can be seen within days of GB, long before significant weight loss has occurred [53, 54]. Although the metabolic changes relative to improved glycemic control after GB were first published by Pories in 1995, the mechanisms of diabetes improvement after GB remain an area of ongoing research [54, 55]. Additional mechanisms of weight loss are related to the creation of a gastrojejunostomy and loss of the pylorus which can allow symptoms of dumping syndrome to occur such as nausea, abdominal discomfort, diarrhea, and diaphoresis after ingestion of foods high in sugar or fat. The negative response to sugar-rich foods after GB has long been thought as a potential benefit to inhibit the patient from consuming carbohydrates over purely restrictive procedures [56].

The GB procedure has an excellent safety profile. Recent published data from the American College of Surgeons National Surgical Quality Improvement Program database shows 30-day mortality rates of 0.15 % [57]. This is similar to findings in a large systematic review and meta-analysis published by Buchwald in 2007, with mortality rates of 0.16 % [58]. Early complications include leak, deep venous thrombosis/pulmonary embolus, bleeding, and strictures with major morbidity of 5.8 % [58]. Late complications include internal hernias, marginal ulcers, gastro-gastric fistulas, biliary tract disease, as well as nutritional deficiencies [59].

There is a variable range of long-term weight loss outcomes after GB. A recent systematic review of RCTs and observational studies that included at least 50 patients, with 2 or more years of follow-up and at least 80 % of patients at follow-up, reported the sample size-weighted mean percentage of EWL for gastric bypass at 65.7 %. This study also found sample size-weighted remission rates of diabetes, hypertension, and hyperlipidemia resolution rates at 66.7 % ($n = 428$ patients), 38.2 % ($n = 808$ patients), and 60.4 % ($n = 477$ patients), respectively [60]. It is understood that some weight regain can occur, as well as the development of new-onset diabetes or recurrence of diabetes. Adams et al. showed a reduction of diabetes remission rates after GB from 75 to 62 % at 2–6 years after surgery [61]. Adams and others have documented a reduction in overall mortality after GB [61, 62].

1.2.4 Duodenal Switch (DS)

The DS is a modern variant of the biliopancreatic diversion (BPD), a malabsorptive procedure developed by Scopinaro in 1979 [63]. The BPD, itself, was a modification of an older now abandoned procedure, the jejunoileal bypass (JIB) from the 1950s, which provided excellent weight loss from malabsorption of nutrients, but had a very long blind intestinal limb-promoting stasis, bacterial overgrowth, and even liver failure [64]. Scopinaro omitted the stasis in the intestinal bypass by separating the intestine into a long alimentary and biliopancreatic limb. A subtotal gastrectomy was performed, which provided additional restriction of food and removed the antrum to reduce the risk of peptic ulcer disease. Malabsorption resulted from a short common channel (where the biliopancreatic limb is connected to the alimentary limb) positioned at a variable distance of 50–125 cm from the ileocecal valve. This procedure provided excellent weight loss but had a high rate of postgastrectomy complications from removal of the pylorus such as dumping, and marginal ulcer. The BPD was modified to preserve the pylorus, switching from a subtotal gastrectomy to a lesser curve-based tubular sleeve gastrectomy, with transection of the duodenum and addition of a duodenoileostomy, described by both Hess and Hess and Marceau in 1998 [65, 66]. These modifications resulted in significant reduction of postgastrectomy symptoms and incidence of marginal ulcer. In long-term studies reported by Marceau et al. and Hess et al., with 15-year and 10-year follow-up, marginal ulceration was reduced to 0.1 % and 0.3 %, respectively [67, 68].

The DS is the most technically difficult bariatric procedure, with operative times routinely 60–120 min longer than other bariatric procedures, which has traditionally been performed as an open procedure and was the last of the contemporary bariatric procedures to be adapted to a laparoscopic approach [30]. The modern DS begins with trocar placement of six or more abdominal trocars and creation of a sleeve gastrectomy, beginning 4–6 cm from the pylorus, generally larger in capacity than the standard SG (performed as a primary procedure), with bougie sizes of 36–60 Fr described. Duodenal transection ensues, with creation of a retroduodenal tunnel at the level of the gastroduodenal artery. Duodenal transection is generally considered the most technically challenging part of the DS procedure given the risks of bleeding, pancreatic injury, and ischemia of the duodenum. The common, alimentary (Roux limb), and biliopancreatic limbs are then created by first identifying the ileocecal valve and measuring proximally a distance of 75–100 cm which marks the position of the common channel. This location is usually marked with a stitch. The bowel is run proximally an additional distance of 150–175 cm and transected. The alimentary limb (portion of the transected bowel that is in continuity with the colon) is then brought up and connected to the duodenum through an opening in the omentum or mesocolon. Hand-sewn, linear, and circular stapled duodenoileostomy techniques have been described. The distal end of the transected jejunum or ileum (depending on where the intestine is transected) that is in continuity with the ligament of Treitz is the biliopancreatic limb, which is then anastomosed to the ileum at the common channel where a stitch marks a total distance of 75–100 cm. Enteroenterostomy defects are generally closed to prevent internal hernias. The closure of the Petersen defect (cut edge of Roux limb mesentery) is controversial with some surgeons advocating closure and others who feel that closure risks leaving the potential for a small defect with greater risk of bowel strangulation [69, 70]. The ileoileostomy or jejunoileostomy has been described using hand-sewn, partial, or total linear stapled techniques. As with GB, minor differences in the technical approach to DS are generally felt to have similar outcomes with the chosen technique based primarily on surgeon preference. A decision to stage the DS remains an option intraoperatively and should be determined before committing to the malabsorptive components of the procedure. Reasons for staging include anatomic issues affecting feasibility to complete the malabsorptive component laparoscopically as well as physiologic concerns related to intraoperative stability or intolerance to pneumoperitoneum.

Common early complications after DS include venothrombotic events (VTE), bleeding, and leaks. Although leaks can occur at any of several staple lines; similar to that seen with SG, most leaks after DS occur in the proximal gastric staple line near the angle of His. Series of open and laparoscopic DS (with n ranging from 26 to 465 patients) have reported leak rates of 2.5–8 % with mortality rates of 0–7.6 % [30, 68, 71, 72]; however, Hess and Hess have reported leak rates of 0.7 % and mortality of 0.57 % with the largest series of 1150 patients with up to 12-year follow-up, suggesting a greater variability of morbidity and mortality outcomes than other bariatric procedures [67]. Late complications include internal hernia, nutrient deficiencies, and strictures. Given the anatomical changes a bowel obstruction regardless of the etiology (adhesion, internal hernia) has a higher possibility of developing a closed loop-type obstruction, which carries a higher risk of ischemia or perforation. A low threshold for surgical exploration for abdominal pain is accepted as a diagnostic tool [70].

Like GB, the underlying mechanisms of weight loss after DS are not fully understood, but are thought to be multifactorial involving a combination of restriction from the sleeve gastrectomy, malabsorption of macronutrients, and subsequent changes in gut hormones. Similarly to the SG and GB, reduced levels of ghrelin are seen which promote satiety. Similarly to the GB, increased levels of GLP-1 and PYY are found after DS which is likely related to the rapid transit of nutrients into the distal bowel which promote an anorectic state as well as participate in improved glucose homeostasis. Unique to DS is ongoing fat malabsorption, which is thought to play a role in long-term weight loss and maintenance.

The DS is generally accepted as the most effective of the bariatric procedures as far as improvement or resolution of obesity-related disease and the magnitude of %EWL. Hess et al. published reports of EWL of 75 % at 12 years with 75 % follow-up [67]. The DS has also been shown to have better weight loss outcomes than GB in super obese patients or those individuals with a BMI of 50 kg/m^2 [70, 73, 74]. The DS has also been shown to have better durability of resolution of diabetes and weight loss compared to GB [74]. The only clinical outcome that has been shown to be better after GB compared to DS is resolution of GERD [70].

Given the degree of malabsorption of micronutrients including fat-soluble vitamins and macronutrients, in particular, fats, the DS also has the highest risk of perioperative morbidity and risk of protein malnutrition and excessive weight loss, resulting in a higher reversal rate than seen for GB [75]. As of 2013, the DS was reported by the ASMBS to comprise only 1 % of all bariatric procedures performed in the USA [28]. Careful patient selection and efforts to ensure compliance to follow-up are essential to ensuring long-term safety. Clinical expertise and experience of the surgeon and interdisciplinary team with DS are equally crucial.

1.3 Novel Procedures Performed Outside the USA

1.3.1 Duodenal-Jejunal Bypass Liner

The duodenal-jejunal bypass liner, also known as the EndoBarrier (GI Dynamics, Inc., Lexington, MA), is a 60 cm long impermeable sleeve-like device that is endoscopically placed in the proximal small intestine under general anesthesia (Fig. 1.2) [76]. Small barbs anchor the device to the wall of the duodenum. Ingested nutrients pass through the barrier while bile and pancreatic juice flow between the barrier and small bowel mucosa, mixing together distal to the sleeve. It was designed for use up to 12 months. The primary use of the device is for improvement in diabetes, independent of weight loss, as is seen in duodenal-jejunal bypass experiments which support the foregut hypothesis [77].

A small prospective randomized trial has been performed [78]. The typical BMI of the patients studied ranged from 39 to 49 kg/m^2. Short-term (3-month) percent EWL has been observed up to 19 %. Improvements in blood glucose and hemoglobin A1C have also been noted [79, 80]. Side effects include nausea, upper abdominal pain, vomiting, implant site inflammation, pseudopolyp formation, and bleeding. Long-term trials are necessary to solidify this technique's role in the care of the obese diabetic patient. The device does not have FDA approval.

1.3.2 Single-Anastomosis Duodenal-Ileal Bypass

Single-anastomosis duodenal-ileal bypass (SADI) is an operation pioneered by Pernaute in Madrid, Spain [81–84]. The goal was to develop an operation that had the benefits of a duodenal switch, but had less technical complexity. The Roux-en-Y is eliminated, and following a sleeve gastrectomy, a single ileal anastomosis is constructed 250 cm proximal to the cecum in an antecolic loop fashion to the duodenum (Fig. 1.3). Preliminary reports show a significant and substantial weight loss similar to biliopancreatic diversion with duodenal switch (BPD/DS) and significant improvement in diabetes. Protein malnutrition can be seen with SADI but is reduced

Fig. 1.2 The EndoBarrier gastrointestinal liner (*left*) and in situ (*right*) (from Rohde U, Hedbäck N, Gluud LL, Vilsbøll T, Knop FK. Effect of the EndoBarrier Gastrointestinal Liner on obesity and type 2 diabetes: protocol for systematic review and meta-analysis of clinical studies. BMJ Open. 2013;3(9):e003417, with permission)

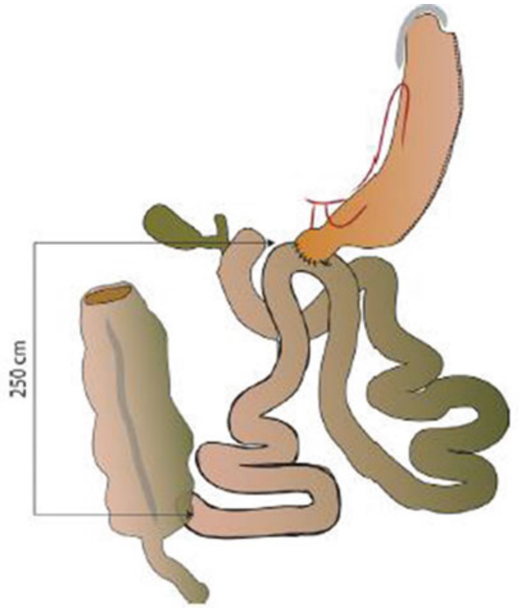

Fig. 1.3 SADI-S schematic representation: Sleeve gastrectomy followed by one-loop duodenoileostomy, with 250 cm between anastomosis and ileocecal valve. The anastomosis is performed in antecolic and isoperistaltic manner (from Sánchez-Pernaute A, Rubio MÁ, Pérez Aguirre E, Barabash A, Cabrerizo L, Torres A. Single-anastomosis duodenoileal bypass with sleeve gastrectomy: metabolic improvement and weight loss in first 100 patients. Surg Obes Relat Dis. 2013;9(5):731–5, with permission)

Fig. 1.4 Gastric plication (from Campanile FC, Boru CE, Rizzello M, Puzziello A, Copaescu C, Cavallaro G, Silecchia G. Acute complications after laparoscopic bariatric procedures: update for the general surgeon. Langenbecks Arch Surg. 2013;398(5):669–86, with permission)

when the common channel is 250 cm in length. Average frequency of bowel movements is 2–3 per day. Complications include those inherent to a sleeve gastrectomy (leaks, bleeding, strictures) as well as the risk of anastomotic leak from the duodenoileostomy. Advantages include one less anastomosis than traditional DS and no mesenteric division, which could result in less internal hernias. Longer term data is needed to determine the role that SADI will have in bariatric surgeons' repertoire.

1.3.3 Gastric Plication

Gastric plication is a restrictive procedure designed to reduce the gastric volume of the stomach without the need for resection. Radiographically, it mimics a vertical sleeve gastrectomy. Gastric plication is performed by imbricating the greater curve on itself using a non-absorbable running suture in two layers over a bougie (Fig. 1.4) [85]. The mechanism of action has yet to be fully elucidated. It is doubtful that ghrelin levels will decrease as the fundus and greater curve remain intact. In theory, since there is no resection, there is no potential for staple-line leakage. However, there are reports of leaks occurring following gastric plication. In addition, bleeding has also occurred. Other complications unique to this procedure include gastric prolapse (early or late) often requiring reoperation with fundectomy or definitive sleeve gastrectomy as treatment [86]. In general, weight loss and reduction in the feeling of hunger are less after gastric plication than sleeve gastrectomy [87]. Minor

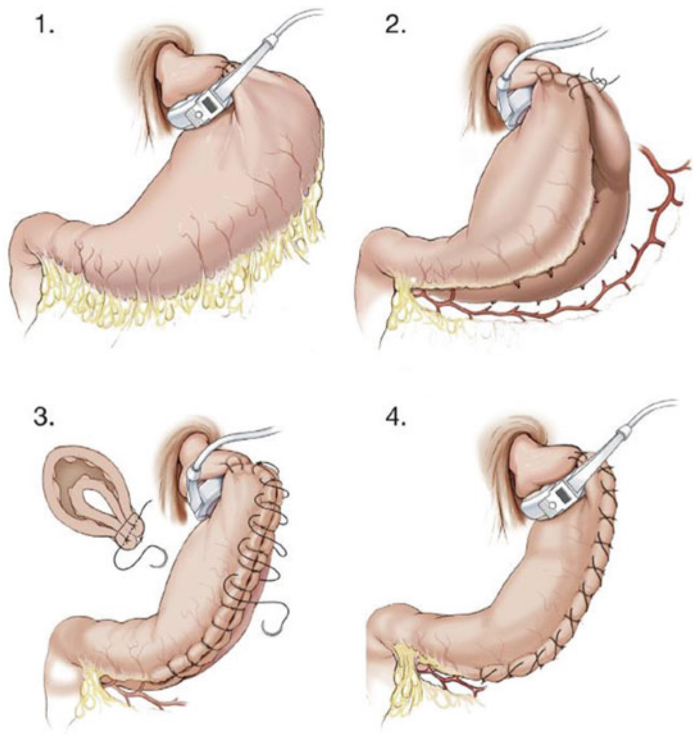

Fig. 1.5 Key operative steps of laparoscopic adjustable gastric banded plication (LAGBP) (from Chaudhry UI, Osayi SN, Suzo AJ, Noria SF, Mikami DJ, Needleman BJ. Laparoscopic adjustable gastric banded plication: case-matched study from a single U.S. center. Surg Obes Relat Dis. 2015;11(1):119–24, with permission)

complications include nausea, vomiting, and sialorrhea, which are treated conservatively. Advantages of the plication over the sleeve gastrectomy include no use of staplers with the inherent cost savings and no need to enlarge a trocar site for specimen extraction that may lessen the risk of trocar-site pain and herniation. Larger studies in a prospective fashion with longer term follow-up are necessary before definitive conclusions can be drawn.

1.3.4 Laparoscopic Adjustable Gastric Banded Plication

Laparoscopic adjustable gastric banded plication (LAGBP) is a modification to the traditional lap band technique in which greater curve plication is added in addition to the band placement (Fig. 1.5). The theory is that the weight loss with the band can be augmented by the added restrictive component of the plication. In small series, the %EWL appears to be improved over the band itself, although no prospective randomized trials have been performed to confirm this [88, 89]. In addition, it has been shown in one single-center study to decrease the number of band adjustments in the early postoperative period. Complications that can occur are those inherent to both the band and plication as noted previously. It has been suggested that this technique could also be used as a salvage procedure after suboptimal results with a lap band [88].

1.3.5 Sleeve Gastrectomy with Ileal Interposition

Bariatric surgeries often involve alteration of the foregut or hindgut or a combination. Bypass of the duodenum as in gastric bypass supports the foregut hypothesis of weight loss and diabetes remission via a yet-unknown hormonal mechanism. The “ileal brake” or hindgut theory suggests that the hormone peptide YY (PYY) produced in the terminal ileum can cause satiety, reduction in food intake, and weight loss. In addition, glucagon-like peptide-1 (GLP-1) has been

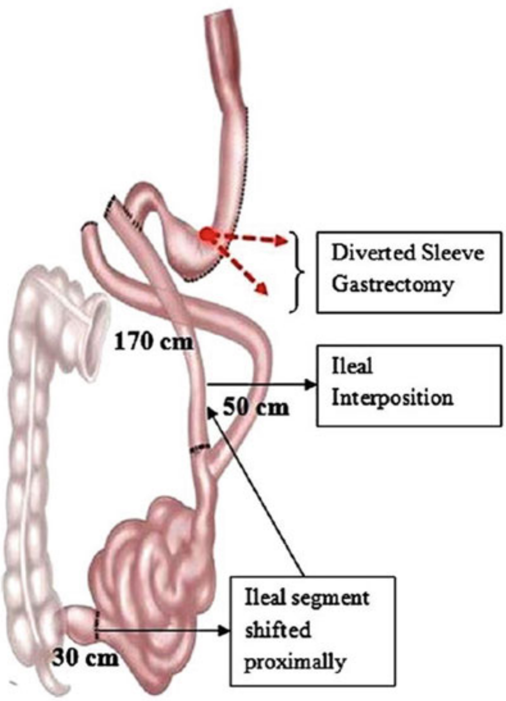

Fig. 1.6 Diagrammatic representation of ileal interposition with diverted sleeve gastrectomy (from Kota SK, Ugale S, Gupta N, Modi KD. Laparoscopic ileal interposition with diverted sleeve gastrectomy for treatment of type 2 diabetes. Diabetes Metab Syndr. 2012;6(3):125–31, with permission)

known to be elevated following gastric bypass and sleeve gastrectomy presumably due to shortened transit time for food to trigger these hormones in the distal ileum. Sleeve gastrectomy with ileal interposition is an operation designed to take advantage of even quicker exposure of nutrients to the terminal ileum by transplanting a segment of it more proximal in the gastrointestinal tract (Fig. 1.6).

Early animal studies with ileal interposition added to a sleeve gastrectomy have shown that there is enhanced secretion of GLP1 and PYY [90–92]. To perform the procedure initially, a traditional sleeve gastrectomy is performed. Then the duodenum is transected 2–3 cm distal to the pylorus. A mesocolic window is then created to allow the sleeve to be visible in the infracolic region. The ileocecal valve is identified and the last 30 cm of ileum is preserved while the next 170 cm is transected with its blood supply and mesentery intact. An ileoileostomy is then reconstructed followed by duodenoileostomy and finally the ileojejunostomy is completed (Fig. 1.6) [93].

Complications and outcomes have been reported by Celik et al. in humans and have shown a 6 % major complication rate which includes leaks, bleeding, and strictures. The biggest complaint patients had was change in bowel habits. Regarding remission of diabetes, they observed an 88 % remission rate, but it must be noted that this was in diabetic patients with only grade 2 and 3 obesity [94, 95]. Further research is necessary to determine the long-term effects of this unique procedure.

1.4 Heterogeneity of Response to Surgical Management

Approximately 150,000–180,000 bariatric procedures are performed in the USA each year and over 460,000 are estimated to be performed annually worldwide [96, 97]. Choice of procedure is based on a multitude of factors including patient and surgeon comfort, risks, benefits, and insurance restrictions. Buchwald et al. published a systematic review and medical analysis of over 136 studies comprising over 22,000 patients [98]. As one progresses from purely restrictive operations (laparoscopic gastric banding and gastroplasty) to more metabolically active procedures (gastric bypass and biliopancreatic diversion/duodenal switch), one can see progressive improvements in %EWL, improvements in obesity-related comorbidities, but also increased operative mortality (Table 1.3).

In recent years, laparoscopic sleeve gastrectomy has gained popularity over the laparoscopic gastric bypass. As a result, Hutter et al. analyzed data from the American College of Surgeons Bariatric Surgery Center Network Accreditation Program to see where the sleeve gastrectomy fit with regard to perioperative risk compared to laparoscopic gastric band and gastric bypass [99]. This is a prospectively collected data collection system, which included over 109 hospitals and over 28,000 patients. They noted

Table 1.3 Outcomes by bariatric procedure

	Excess weight loss	Diabetes remission	Mortality
Procedure	%		
Gastric banding	48	48	0.1
Gastric bypass	62	84	0.5
Biliopancreatic diversion/duodenal switch	70	98	1.1

Data from Buchwald H, Avidor Y, Braunwald E, Jensen MD, Pories W, Fahrbach K, Schoelles K. Bariatric surgery: a systematic review and meta-analysis. JAMA. 2004;292(14):1724–37

Table 1.4 Risk-adjusted outcomes from American College of Surgeons–Bariatric Surgery Center Network-accredited centers

Variable	Laparoscopic sleeve gastrectomy	Laparoscopic adjustable gastric band	Laparoscopic RYGB	Open RYGB
N	944	12,193	14,491	988
Mortality, %				
30 days	0.11	0.05	0.14	0.71
1 year	0.21	0.08	0.34	1.11
30-day outcomes, %				
Morbidity	5.61	1.44	5.91	14.98
Readmission	5.4	1.71	6.47	9.41
Reoperation/intervention	2.97	0.92	5.02	5.06

Data from Hutter MM, Schirmer BD, Jones DB, Ko CY, Cohen ME, Merkow RP, Nguyen NT. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the band and the bypass. Ann Surg. 2011;254(3):410–20

that sleeve gastrectomy had a higher risk-adjusted morbidity, readmission, and reoperation rate compared to laparoscopic adjustable gastric banding, but lower reoperation rates compared to laparoscopic or open gastric bypass. There were no differences in mortality. Reductions in BMI and obesity-related comorbidities following sleeve gastrectomy also appeared to lie between those of laparoscopic gastric band and laparoscopic/open gastric bypass (Table 1.4).

1.5 Conclusion

There are several standard and well-studied metabolic surgery procedures currently performed in the USA. There are also several novel procedures that are early in their development in other countries. Future research will determine which will become standard techniques in years to come. The remainder of this book will focus on outcomes, complications, and management of traditional metabolic/bariatric procedures commonly encountered in practice.

1.6 Self-Assessment Questions

1. All of the following are standard operations performed in the USA except:
   (a) Gastric bypass
   (b) Sleeve gastrectomy
   (c) Laparoscopic adjustable gastric band
   (d) Sleeve gastrectomy with ileal interposition

   Correct response: (d) Sleeve gastrectomy with ileal interposition

2. Which of the following bariatric procedures is irreversible?
   (a) Sleeve gastrectomy
   (b) Laparoscopic adjustable gastric band
   (c) Gastric bypass
   (d) None of the above

   Correct response: (a) Sleeve gastrectomy

3. Which of the following procedures' mechanism of action works predominantly through restriction?
   (a) Gastric bypass
   (b) Laparoscopic adjustable gastric band
   (c) Sleeve gastrectomy
   (d) Duodenal switch

   Correct response: (b) Laparoscopic adjustable gastric band

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Thirty-Day (Early) Complications of Bariatric Surgical Procedures

2

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A total of 179,000 bariatric surgeries were performed in the USA in 2013, with Roux-en-Y gastric bypass (RYGB) comprising 34 % and laparoscopic sleeve gastrectomy (SG) 42 % of the procedures [1]. This chapter focuses on the complications from RYGB, SG, laparoscopic adjustable gastric band (LAGB), and biliopancreatic diversion with duodenal switch (DS) that occur within the first 30 days. Given that surgical intervention may be required, patients presenting with complications in the early postoperative period may benefit from transfer to their bariatric surgeon or a bariatric surgery center. In the event of peritonitis or hemodynamic instability, prompt transfer and treatment may not be feasible. Therefore, it is important for general surgeons to be able to recognize and manage acute bariatric surgical complications. Initial evaluation should proceed with special attention to the type of bariatric procedure, giving intravenous fluid resuscitation and correction of electrolytes, obtaining a complete blood count with coagulation markers, and possibly obtaining appropriate imaging.

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2.1 Gastric Bypass Complications

Results from a patient database including over 26,000 patients who had undergone RYGB demonstrated a 30-day complication rate of 8.7 % [2]. The early complications most commonly encountered included bleeding (2.1 %), leak (1.8 %), port-site-related complications (0.6 %), and small bowel obstruction (1.0 %).

2.1.1 Bleeding

Bleeding may not always require surgical intervention, but it should be high on the differential for patients who present with tachycardia or hypotension unresponsive to fluid resuscitation early in the postoperative period. Patients may also present with abdominal wall distention or ecchymosis. Other symptoms suggesting hemorrhage include hematemesis, melena, and hematochezia [3]. Patients routinely ambulate early and may experience positional lightheadedness or dizziness when they get up to ambulate. Laboratory evaluation may reveal a reduction in hemoglobin and hematocrit levels. Prompt volume resuscitation, cardiac monitoring, and serial hemoglobins should experience instituted. If the patient remains hemodynamically stable and the hemoglobin plateaus, volume resuscitation and discontinuation of chemical thromboprophylaxis

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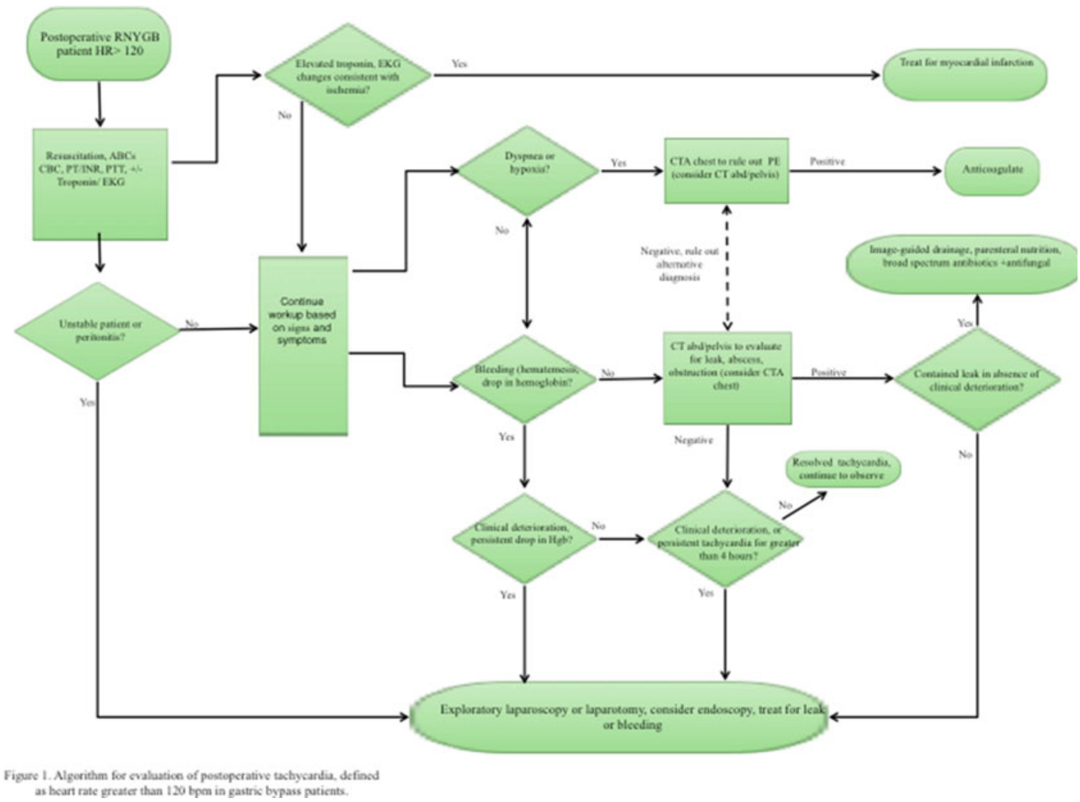

Fig. 2.1 Algorithm for management of sustained tachycardia in the post-bariatric surgical patient

may suffice. Nevertheless, reoperation should not be delayed if tachycardia or hypotension persists and active bleeding is suspected (Fig. 2.1). In a retrospective review of 450 patients undergoing RYGB, 20 (4.4 %) developed a postoperative hemorrhage; 12 (60 %) of these had evidence of intraluminal bleeding and melena, 15 (75 %) required blood transfusions, and 3 (15 %) required surgery [4].

Potential intra-luminal sites of bleeding include the staple lines of the pouch, excluded stomach, gastrojejunostomy, or jejunojejunostomy [3]. Bleeding from the staple lines into the excluded stomach is particularly hard to detect. Extraluminal sources of bleeding include the staple lines along the pouch or excluded stomach, mesentery, and port sites. Laparoscopic exploration may reveal an extraluminal source of bleeding, but frequently, the site of bleeding has already clotted off. When active extraluminal staple-line bleeding is found, the application of clips or sutures to achieve hemostasis usually suffices.

If the patient presents with hematemesis, bloody bowel movements, or melena, an intraluminal source should be suspected [3]. There are a few case reports of bleeding causing obstruction [5, 6]. Intraluminal clot from gastrointestinal bleeding may cause an intestinal obstruction, which is associated with nausea, vomiting, tachycardia, and abdominal pain [5]. Bleeding into the distal remnant, with clotting of the duodenum, may result in acute gastric distension and will present as sustained retching from irritation of the diaphragm. A bleed from the gastrojejunal anastomosis usually presents with hematemesis and results in a dilated, clot-filled Roux limb, but this may also result from a jejunojejunostomy bleed with retrograde extension of intraluminal clot.

Fig. 2.2 Upper gastrointestinal study demonstrating contrast extravasation consistent with a gastrojejunostomy leak after RYGB

The combination of laparoscopy and intraoperative endoscopy plays an important role in the evaluation of persistent GI bleeding. Intraoperative upper endoscopy may be performed at the time of diagnostic laparoscopy to rule out an intraluminal bleed from the gastrojejunostomy. The bleeding anastomosis may need to be opened to achieve hemostasis or to evacuate intraluminal clot. Peeters et al. reported one intraluminal bleed out of 796 RYGB in which a laparotomy was performed. An enterotomy was made distal to the jejunojejunostomy for clot removal [5]. Gastrostomy tube placement for decompression of the excluded stomach may also be necessary [4].

2.1.2 Anastomotic Leak

An anastomotic leak is a serious complication of RYGB and can result in life-threatening sequelae (Fig. 2.2). The incidence of leak after laparoscopic RYGB ranges from 0.3 to 4.3 % [7, 8]. A recent multicenter study of 4444 patients who underwent RYGB reported an anastomotic leak rate of 1.0 % [9]. No specific technique for the gastrojejunostomy was associated with an increased rate of leak. However, this study revealed a statistically significant increase in the rate of anastomotic leak among patients who had open surgery, revisional surgery, and placement of an abdominal drain.

A high suspicion for an anastomotic leak must be maintained in a patient with persistent unexplained sustained tachycardia exceeding 120 beats per minute, even in the absence of radiologic findings of a leak [10]. In addition to tachycardia, a sensitive sign of leak is an increase in oxygen requirement of the patient. Other symptoms include abdominal pain, nausea, vomiting, and a feeling of impending doom. It cannot be overemphasized that persistent tachycardia should not be dismissed because a patient is afebrile with a benign abdominal exam, normal white blood cell count, or negative upper gastrointestinal imaging. Negative contrast studies may be falsely negative and should not delay treatment. The sensitivity of swallow studies conducted on postoperative day 1 after RYGB has been reported as 25 %, with a positive predictive value of 31 % [11]. In contrast, sustained tachycardia has been shown to be a reliable indicator of anastomotic leak [10, 12].

Initial management consists of volume resuscitation and coverage with broad-spectrum antibiotics and antifungal therapy. While nonoperative management of anastomotic leak has been described [13, 14], early surgical treatment of leaks is associated with a shorter hospital stay [15]. Standard of care for patients with anastomotic leaks consists of prompt reoperation for abdominal washout, repair of the leak, and drainage. Enteral access should be strongly considered; a gastrostomy tube may be placed in the gastric remnant. Nonoperative management may be appropriate in select cases depending upon the patient's clinical status and availability of local expertise with the use of nonoperative techniques. If the patient had surgery or is being treated for the complication in a community hospital setting, transfer to a tertiary bariatric center which has the ability to rescue the patient is optimal soon after the patient is initially stabilized.

2.1.3 Obstruction

Early small bowel obstructions after RYGB are most commonly caused by technical problems such as narrowing or angulation at the jejunojejunostomy [16] or bleeding [5, 17]. Other possible etiologies include Roux-en-O configuration [18], a twist of the Roux limb, or obstruction at the transverse mesocolon [16, 19]. Bilious vomiting suggests a Roux-en-O configuration [18, 20], gastrogastric fistula, or obstruction distal to the jejunojejunostomy [20]. Therefore, prompt exploration should be undertaken for early bowel obstructions to rule out technical complications. Nausea, vomiting, and dysphagia may be presenting symptoms of a gastrojejunostomy stricture, which is diagnosed by upper endoscopy. The presentation occurs 1–3 months postoperatively, with 90 % presenting between 30 and 60 days and 10 % between 60 and 90 days [21]. Endoscopic dilation is generally successful after 1–3 dilations [21].

Shimizu et al. reported that 0.5 % of laparoscopic RYGB patients underwent surgical management for small bowel obstruction within 30 days after surgery [17]. In this study, all of the patients had undergone antecolic-antegastric RYGB. The 11 patients with early small bowel obstruction were diagnosed by CT with oral contrast and underwent laparoscopic exploration. Causes included a kink at the jejunojejunostomy, intraluminal blood clot, intra-abdominal hematoma, and pelvic adhesions. Bowel resection was only required in one patient and four patients were converted to laparotomy. Endoscopy was a valuable adjunct for assessing hemostasis, decompressing the Roux limb, and confirming patency at the jejunojejunostomy.

An additional cause of early small bowel obstruction is incarceration of small bowel in an unrepaired ventral hernia. Ventral hernias may be left open to be more optimally repaired after the patient has lost a substantial amount of weight, as the hernia may reoccur if a repair is attempted when the patient still carries a substantial amount of weight. When a ventral hernia is identified prior to surgery, patients should be consented for simultaneous hernia repair with possible mesh placement. The use of synthetic mesh raises a concern for mesh infection because of the GI anastomoses. If a ventral hernia is detected at the time of surgery, a postoperative conversation should ensue with the patient to explain the intraoperative decision making, signs and symptoms of small bowel obstruction, and specific instructions regarding postoperative activity restrictions. In all cases, if a ventral hernia is left unrepaired, a specific note should be made in the operative record, in case the small bowel obstruction presents to another surgeon/team.

2.2 Sleeve Gastrectomy Complications

The sleeve gastrectomy (SG) was initially described as a component of the duodenal switch [22, 23]. It was subsequently proposed as the initial procedure in a two-stage approach for high-risk patients [24]. Over the past decade, it has gained tremendous popularity as a primary bariatric surgical procedure [25] and has now surpassed the RYGB in volume at academic medical centers [26].

In a recent literature review, there were no significant differences in overall complication rates between RYGB and SG; the reported leak rate for SG was 2.3 % versus 1.9 % in RYGB [27]. The rates of bleeding and stenosis were slightly but significantly higher for SG but there was no significant difference in leak rates between RYGB and SF. In a single-institution study comparing outcomes among SG, RYGB, and DS, the rate of leakage for RYGB and SG was similar but hemorrhage was more frequent after SG [28].

2.2.1 Sleeve Leak

Management of leaks after SG remains a challenging clinical problem that can lead to devastating sequelae if not recognized and treated promptly [29]. Leaks most commonly occur in the proximal stomach at the gastroesophageal junction [29, 30] (Fig. 2.3). Unrecognized leaks may lead to abscess formation and sepsis [31] and persistent leaks may lead to fistula formation [32]. A literature review of 4888 primary SG patients in 29 studies documented a leak rate of 2.4 % [30]. Leaks were more frequent in patients with a body mass index (BMI) of greater than 50 kg/m² (2.9 %) [30].

There is no consensus regarding the optimal bougie size for SG. According to the International Sleeve Gastrectomy Expert Panel Consensus Statement, the use of a bougie size less than 32 French has been associated with an increased risk of leaks and strictures [33]. In the meta-analysis by Aurora et al., the leak rate for using a bougie size of 40 French or greater was 0.6 % versus 2.8 % when using a bougie smaller than 40 French [30]. This is concordant with the data from Parikh et al. whose meta-analysis demonstrated a lower leak rate for a bougie size of greater than or equal to 40 French [34]. There is no consensus regarding whether buttressing reduces the leak rate [33, 34].

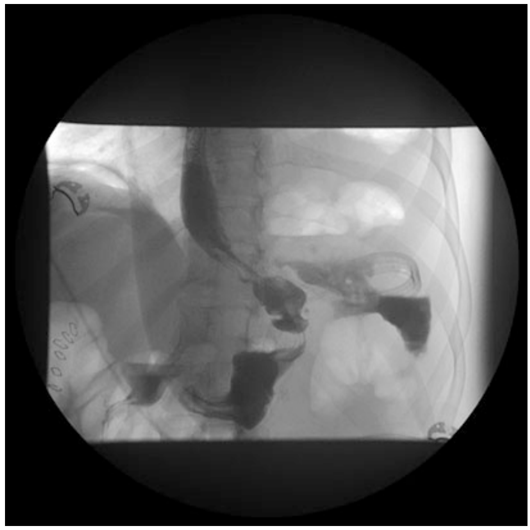

Fig. 2.3 Upper gastrointestinal study demonstrating a leak 20 days after SG

Signs and symptoms of an SG leak include fever, chills, left shoulder pain, nausea, vomiting, abdominal pain, tachycardia, and tachypnea [31]. Chest radiographs may demonstrate a left pleural effusion. A UGI study may be useful in establishing the diagnosis, but CT scan with oral water-soluble contrast will not only diagnose the leak but also guide percutaneous treatment of an associated abscess. Initial management consists of bowel rest, fluid resuscitation, antibiotics, and parenteral nutrition.

Leaks may be classified as acute (within 7 days), early (1–6 weeks), late (greater than 6 weeks from procedure), and chronic (greater than 12 weeks) [33]. Leaks after SG are more frequently seen as a late complication; 79 % of leaks present more than 10 days postoperatively [30]. The endoscopic and surgical options for sleeve leaks depend upon the timing and presentation. Endoscopic options include endoscopic stenting [35] or clip placement [36]. The 2011 Expert Panel Consensus guidelines recommend that stents are a valid treatment for acute proximal leaks, and advise that stenting after 30 days is less likely to be effective [33]. Moon et al. recommended that late leaks should be treated with endoscopic clips or fibrin glue if small (less than 1 cm) or with stent placement if larger or unresolved [31]. Keren et al.

reported a success rate of 81 % for treating SG leaks with an endoscopic clip [36].

Similar to bypass patients, SG patients with fever and sustained tachycardia should undergo immediate reoperation for lavage, omental patch repair, and drainage [33]. Given that healing of a SG leak may be prolonged because the sleeve is a high-pressure system, providing enteral nutritional access should be considered in patients who warrant surgical exploration. Persistent leaks may need to be converted to RYGB as a last resort [31]. A period of at least 12 weeks of nonoperative therapy should elapse prior to undertaking revision to RYGB if these measures fail [33].

Moon et al. published a retrospective study of 539 sleeve gastrectomy patients with a 2.8 % leak rate after a mean follow-up of 12 months [31]. The diagnosis was established at a mean of 27.2 ± 29.9 postoperative days. Two out of the fifteen patients with a leak were diagnosed prior to discharge and underwent successful laparoscopic repair with omental patching. Five patients underwent endoscopic intervention such as fibrin glue and hemoclip placement to close the leak, which was successful in four out of the five patients (80 %). Eight of the fifteen were managed nonoperatively with antibiotics, total parenteral nutrition, and CT-guided drainage and among these eight, only one leak (12.5 %) resolved and six (75 %) required stent placement, which was successful in 50 %. One patient with persistent fevers required laparoscopic repair and drainage. The authors concluded that acute sleeve leaks presenting prior to discharge may be optimally repaired laparoscopically; however, conservative therapy alone without stenting had a high failure rate. If the hospital where the patient presents is unable to offer stenting, it may be best to transfer the patient for revisional surgery.

2.2.2 Stenosis and Bleeding

Stenosis after sleeve gastrectomy occurs in less than 1 %. The rate of stricture is not significantly different between surgeons who oversew the staple line versus those who do not [30]. Stenosis may be caused by angulation of the stapler, kinking or twisting of the stomach, hematoma, or edema. Patients typically present with regurgitation, vomiting, or dysphagia. The incisura angularis is the most common site of strictures [33]. Symptomatic strictures should be treated with observation, followed by endoscopic dilation, and then possibly seromyotomy or revision to RYGB if endoscopic dilations fail [33].

In their systematic analysis, Aurora et al. reported that the incidence of bleeding after SG requiring surgical intervention was 0.7 % [30]. The use of staple-line oversewing or reinforcement was not associated with lower bleeding rates in their study. Bleeding complications following SG should be managed similar to RYGB patients; however, the division of the short gastric vessels makes the possibility of major hemorrhage immediately postop substantial. A patient who drops their blood pressure in the immediate postoperative period should be evaluated for bleeding without delay.

2.3 Complications of Laparoscopic Adjustable Gastric Banding

LAGB patients presenting with abdominal pain, nausea, intractable reflux, or intolerance of oral intake should have the fluid from the band withdrawn. This is accomplished by accessing the subcutaneous port with a non-coring needle. A plain abdominal X-ray should also be done to evaluate for band slippage. In addition, one should assess the tubing from band to port on plain films to rule out port disconnection. If emptying the fluid does not resolve symptoms or plain films suggest band slippage, a UGI study may be done for further evaluation (Fig. 2.4).

Complications requiring reoperation from LAGB within the first 30 days are rare. In a study of over 6,000 LAGB patients, 14 (0.2 %) patients required emergency surgery for a complication related to the band [37]. The median time of presentation was 19 months and ranged from 1 to 61 months. The most common complication was band slippage with or without gastric necrosis. Other complications included small bowel obstruction, perforated gastric ulcer, bowel penetration, and port disconnection.

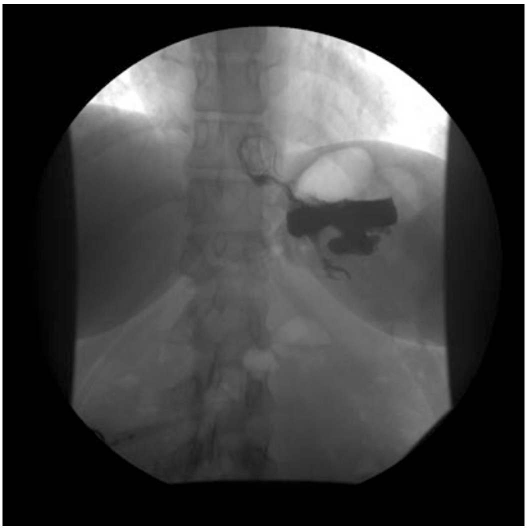

Fig. 2.4 Band slippage and gastric prolapse

Symptoms of acute band slippage include epigastric pain, dysphagia, gastroesophageal reflux, and vomiting [38]. A contrast study may reveal anterior or posterior prolapse in which the anterior or posterior wall of the stomach herniates above the band. The prolapsed stomach may become ischemic or necrotic [39]. Therefore, emergent surgical intervention is indicated. If gastric ischemia or necrosis is present, urgent explantation would be required. The band may be removed laparoscopically by cutting the tubing first distally which traverses the abdominal wall and then mobilizing the soft tissue where it connects to the band, incising the capsule anterior to the band, and then mobilizing and releasing the band from the stomach. The band is then removed from a 15 mm trocar site and the subcutaneous port is then dissected free and removed. If the stomach is viable, repositioning of the band at the gastroesophageal junction may be feasible [40] only if the patient has had satisfactory weight loss with the band. If the patient is a partial or nonresponder, consideration for removal only should be given, with plans to convert to a metabolic procedure after the acute situation is resolved.

Port-site infections in the early postoperative period may be treated with antibiotics if infection is limited. Band erosion should be suspected if the access port is erythematous or tender [41]; this is best evaluated with upper endoscopy and would require band removal. However, band erosion is rarely seen in the early postoperative period. In the absence of band erosion, if there is an abscess at the port site or if there is no response to antibiotics, the port should be disconnected and removed and the band tubing should be left inside the peritoneal cavity for future reconnection to a new access port [42]. Damage to the port may be diagnosed by loss of volume of the injected fluid and failure of satiety despite band fills. Port leakage or leakage along the band tubing may be diagnosed by injecting contrast into the port under fluoroscopy. Port removal or band replacement may be necessary and this may be done electively.

2.3.1 Complications of Duodenal Switch

The biliopancreatic diversion/duodenal switch (DS) constitutes 2.2 % of all bariatric procedures [43]. While it has the highest weight loss compared to the other bariatric surgical procedures [44], it has been shown to have the highest short-term complication rate of all of the bariatric procedures [45]. Thirty-day morbidity ranges from 7 to 8.6 % for one-stage procedures [46, 47]. Buchwald et al. reported on their early postoperative outcomes in 190 patients ≤30 days after open or laparoscopic/robotic DS [48]. The total complication rate was 19.5 % and no mortalities. There were 14 patients who had 18 serious complications (9.5 %), including 2 leaks (1 %).

Until recently, the DS was most often performed through open access. Wound complications are the most common complication after DS, occurring in 7.7–10 % of patients [47, 48]. Leaks after DS occur in 1–2.3 % of patients, and most often arise from the gastric sleeve staple line [43, 46, 47]. Leaks are managed as per the SG recommendations above, with endoscopic stenting or clips versus surgical exploration and drainage if endoscopic measures fail [43, 47]. A meta-analysis of 16 single-center studies comparing a total of 874 DS and 1149 RYGB procedures demonstrated a higher leak rate for DS (5 % vs. 2.2 % RYGP, $p = 0.002$) and no significant difference in mortality (0.6 % DS vs. 0.2 % RYGP, $p = 0.33$) [49]. In a study of 27 patients who underwent two-stage DS, 3 patients had bleeding complications that presented within 3 days postoperatively [50]. Four patients presented with stenosis of the duodeno-ileal anastomosis between 1 and 3 months after surgery and were generally treated with endoscopic dilation [50].

A single-institution study of 1000 patients undergoing DS demonstrated no difference in the 30-day complication rates between laparoscopic and open DS (7 % vs. 7.4 %, $p = 0.1$) [46]. The open group was more likely to have gastric leaks (2 % vs. 0 % laparoscopic, $p = 0.02$) and wound complications. There was one mortality in the laparoscopic group (0.1 %) from massive pulmonary embolism.

An analysis of data from the American College of Surgeons NSQIP database demonstrates that the overall morbidity for laparoscopic DS is higher than for laparoscopic RYGB (8.8 % vs. 4.6 %, $p = 0.33$) and a laparoscopic DS patient is nine times more likely to have a complication than a laparoscopic RYGB patient [47]. In a single-center study of 178 DS patients who were matched to 139 RYGB patients, there were more frequent visits to the emergency department in the DS patients (40 % vs. 25 % in RYGB, $p < 0.01$) but no significant difference in overall morbidity rates between DS and RYGB. There were no 30-day mortalities for either procedure [51].

The DS requires surgical expertise and a highly trained interdisciplinary team. This is not an optimal procedure for many surgeons/centers that have little experience with the RYGB or who do not practice in a setting with resources for the rescue of a medically complex patient. The patients who often require a DS are heavier and may have a higher burden of obesity-related disease.

2.3.2 Venous Thromboembolism

Venous thromboembolism (VTE), which includes deep venous thrombosis (DVT) and pulmonary embolism (PE), is a preventable cause of mortality after bariatric surgery [52]. Given the widespread use of thromboprophylaxis, the rate of VTE after bariatric surgery is low, ranging between 0.21 and 0.42 % within 90 days of surgery [45, 53, 54]. After laparoscopic DS, the rate of VTE is 2.2–3.3 % [47, 55].

Most bariatric surgery patients are at high risk for VTE [52]. Obesity itself is an independent risk factor for VTE [56]. Obesity, especially class 3, may be accompanied by poor mobility. In addition, obesity hypoventilation/sleep apnea syndrome, truncal obesity, venous stasis disease, and a body mass index (BMI) ≥60 kg/m^2 increase the risk of VTE [57]. Due to the high risk, many patients are given chemical VTE prophylaxis an hour or two prior to surgery and that is continued after the procedure during their hospital stay. The other two components of prevention are mechanical prophylaxis with sequential compression stockings and early ambulation.

Classic signs and symptoms of DVT are lower extremity edema, pain, warmth, and erythema. If DVT is suspected, a lower extremity venous duplex should be obtained. Patients who present with tachycardia and respiratory distress should be suspected having a PE. After initial resuscitation and initiation of cardiac and pulmonary monitoring, diagnosis should be established by spiral computerized tomography (CT) with PE protocol. Some patients cannot be accommodated in the scanner because of their weight or abdominal girth and other imaging modalities such as ventilation/perfusion scanning or pulmonary angiography may need to be considered. Knowledge of the weight limits and girth limits of hospital diagnostic imaging is required for surgeons/programs doing these procedures.

Options for initial treatment of VTE include LMWH, intravenous unfractionated heparin (UFH), or fondaparinux as a bridge to vitamin K antagonists. The risk of bleeding in the postoperative patient must be balanced against the risk of PE. Use of a weight-based protocol for UFH or LMWH dosing in this population may lead to coagulopathy and hemorrhage [58]; therefore, close monitoring is necessary and dose capping should be considered [59]. When bariatric surgical patients are transitioned to Coumadin, they may be prone to having a supratherapeutic INR [60], which is not surprising given that their dietary intake of vitamin K tends to be low in the early postoperative period. Close follow-up by the surgeon and team is essential. In addition, thorough education of the patient and personal contact with the primary care physician to discuss the follow-up plan and risk for supratherapeutic INR is optimal.

2.3.3 Mesenteric Thrombosis

Mesenteric thrombosis is a rare but potentially lethal complication that has been described in patients who have had laparoscopic bariatric surgery. The incidence has been reported as 0.3 % for all bariatric patients [61] and 1 % after SG [62, 63]. Most patients initially present with new-onset epigastric pain after an average of 10 postoperative days [61]. They may also endorse pain radiating to the back or left scapula, nausea, and vomiting [61]. CT scan with intravenous contrast is the diagnostic modality of choice [61, 62, 64] (Fig. 2.5). Treatment consists of intravenous hydration, bowel rest, and anticoagulation with low-molecular-weight heparin or intravenous unfractionated heparin followed by the initiation of oral anticoagulation [61]. Workup for thrombophilia is warranted and anticoagulation is usually recommended for 6–12 months. If patients may present with peritonitis or CT findings concerning for bowel ischemia, emergent exploration with bowel resection and planned second-look surgery should be undertaken. Thrombolysis via direct catheterization of the portal vein has been reported in cases of complete thrombosis [61].

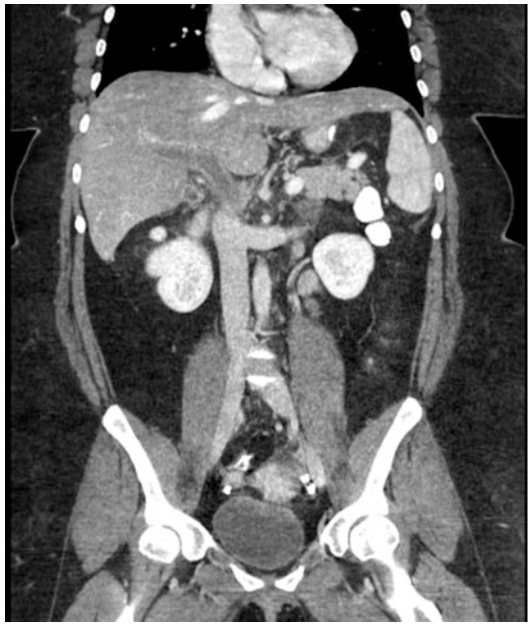

Fig. 2.5 CT scan of the abdomen with IV contrast demonstrating massive portal vein thrombosis. The patient presented with severe epigastric and back pain

2.4 Conclusion

Outcomes after complications in the early postoperative period after bariatric surgery depend upon early recognition and treatment. Bleeding after RYGB may present as an intestinal obstruction. The combination of laparoscopy and intraoperative endoscopy is useful in managing anastomotic bleeds. Early obstruction after RYGB should be considered a technical complication warranting surgical intervention. RYGB and SG patients with sustained tachycardia should be considered to have a leak until proven otherwise by surgical exploration. Leaks after SG are usually a late complication and their management options vary widely. Bariatric surgical patients are at higher risk for VTE than the routine general surgical patient. Dosing of anticoagulation in obese patients requires close monitoring.

2.5 Self-Assessment Questions

1. A 56-year-old female with a BMI of 52 kg/m^2 is postoperative day 2 from a laparoscopic Roux-en-Y gastric bypass. The upper GI study from postoperative day 1 was negative for leak. She has a sustained tachycardia of 130 bpm which does not respond to fluid bolus. EKG and troponins are negative. After resuscitation and initiation of cardiac monitoring, what is the most appropriate next step in management?
   (a) Repeat upper GI study

(b) CT scan of the chest, abdomen, and pelvis
(c) Surgical exploration
(d) IV lorazepam

2. Which is *not* likely to be a source of hemorrhage on postoperative day 1 after a gastric bypass?
(a) Stomach staple lines
(b) Gastrojejunostomy
(c) Jejunojejunostomy
(d) Port sites
(e) Marginal ulcer

3. Leaks after sleeve gastrectomy are most commonly:
(a) At the proximal gastric staple line
(b) At the distal staple line
(c) From esophageal injuries from bougie placement
(d) From small bowel injury

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3 Late Complications of Bariatric Procedures

Marina Kurian and Collin Creange

Late-term complications in bariatric surgery are classified as those that occur 30 days or more after the initial procedure. The four most common bariatric surgeries performed today are the laparoscopic adjustable gastric band (LAGB), the Roux-en-Y gastric bypass (RYGB), the sleeve gastrectomy (SG), and the biliopancreatic diversion with duodenal switch (BPD/DS). Some complications are common to all bariatric procedures, but for brevity's sake will only be covered once.

3.1 Laparoscopic Adjustable Gastric Band

While 30-day morbidity and mortality are extremely low for the LAGB, late complications are not infrequent. Complication rates range in various studies from 10 to 25 % [1]. The predominant complications from LAGB are band slippage and port-site issues (infection, malfunctioning port). Other less common but concerning complications include band erosion and megaesophagus.

3.1.1 Band Slippage

3.1.1.1 Presentation

Band slippage is a general term that indicates either a cephalad migration of the stomach above the lap band or caudal migration of the band. As migration of the band occurs the stomach can become completely obstructed. Stomach herniation through the band can occur in a variety of ways (Fig. 3.1). The patient will present with signs and symptoms of obstruction, including abdominal pain, nausea, vomiting, and dysphagia. Reflux symptoms will also typically be present. Figure 3.2 contains a treatment algorithm for suspected band slippage.

3.1.1.2 Diagnosis

A plain abdominal X-ray will exhibit migration of the band or abnormal orientation, but will not be able to demonstrate stomach herniation. If the abdominal XR is not diagnostic, an esophagram is an effective and rapid way to diagnose slippage. The contrast study should show a dilated gastric pouch proximal to the band, with little to no contrast passing distally (Fig. 3.3). A dilated proximal pouch with normal passage of contrast is suggestive of pouch dilation, an important but

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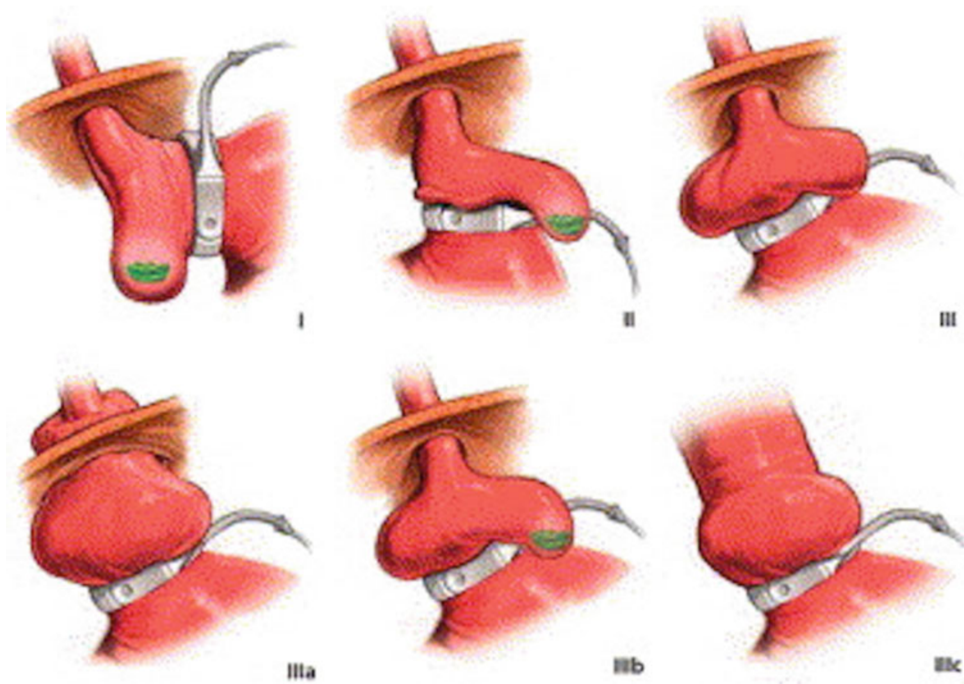

Fig. 3.1 Types of gastric pouch enlargement: *type 1*, posterior gastric pouch prolapse; *type 2*, anterior gastric pouch prolapse; *type 3*, concentric gastric pouch dilation; *type 3a*, pouch dilation with hiatal hernia; *type 3b*, pouch dilation with prolapse; and *type 3c*, gastroesophageal dilation (from Ponce J, Fromm R, Paynter S, Outcomes after laparoscopic adjustable gastric band repositioning for slippage or pouch dilation. Surg Obes Rel Dis 2006;2(6):627–631, with permission)

less urgent problem related to overeating that can be addressed by unfilling the band.

3.1.1.3 Treatment

Initial management of band slippage is prompt deflation of the band. The lap band port is accessed using a Huber needle, and the band is deflated completely. If bedside band deflation cannot be accomplished, ultrasound or fluoroscopy must be utilized. This is usually successful in achieving symptomatic relief, and once the patient is able to tolerate clear liquids, he/she is safe to be discharged from the ER to follow up as an outpatient. Band revision can be safely accomplished laparoscopically in the vast majority of cases, which involves dividing the adhesions around the band and reducing the gastric prolapse [2, 3]. At the time of revision, a gastric plication may also be performed inferiorly to the band to increase stomach bulk and decrease the change of future band slippage [4].

Despite deflation of the band, some patients will continue to have intolerance to liquids and abdominal pain. At this point, urgent surgical intervention is indicated to rule out gastric band erosion or gastric necrosis. Persistent left upper quadrant or left chest pain despite deflation of the band should also be considered as an urgent indication (Table 3.1).

3.1.2 Band Erosion

3.1.2.1 Presentation

Gastric erosion of the LAGB is a rare but serious complication of lap band placement. Rates of erosion vary according to case study, but most series report a rate between 0.5 and 1 % [5]. Erosion can present either early or late, depending on the cause. Early erosions, covered in another chapter, generally occur secondary to undetected intraoperative gastric trauma/injury.

Table 3.1 Causes of abdominal pain after gastric bypass

Behavioral, dietary disorders	Functional disorders	Biliary disorders	Pouch, remnant stomach disorders	Small intestine disorders	Other
Overeating, rapid eating	Constipation, diarrhea, flatus	Cholelithiasis: colic, cholecystitis	Ulcer disease	Abdominal wall hernias: ventral, trocar	Omental infarction
Food intolerance	Irritable bowel syndrome	Choledocholithiasis: cholangitis, pancreatitis	Gastrogastric fistula	Adhesions	SMA syndrome
Micronutrient deficiencies	Esophageal motility disorders	Sphincter of Oddi	GERD	Internal hernia	Bezoar
Micronutrient supplementation	Dumping syndrome		Hiatus hernia, gastrojejunostomy stenosis	Intussusception, jejunojejunostomy stenosis	

From Greenstein AJ, O'Rourke RW. Abdominal pain after gastric bypass: suspects and solutions. Am J Surg 2016:819–827, with permission

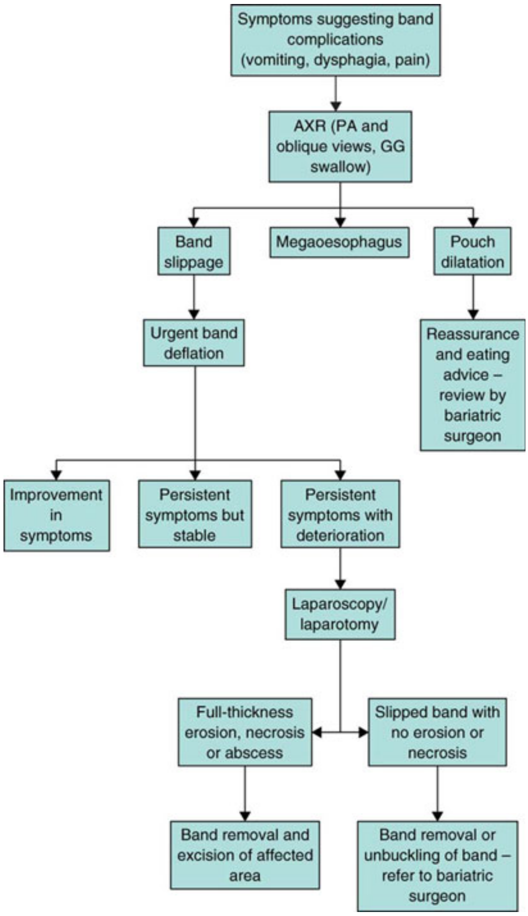

Fig. 3.2 Flowchart for diagnosis and management of band slippage (from Hamdan K, Somers S, Chand M. Management of late postoperative complications of bariatric surgery. Br J Surg. 2011 Oct;98(10):1345–5, with permission)

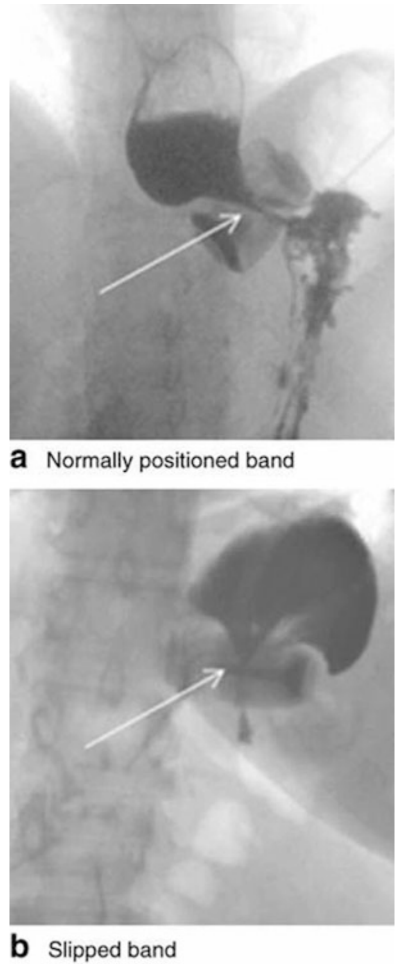

Fig. 3.3 (**a**) Contrast study showing a normally positioned band (*arrow*) lying at approximately 45° to the spine. (**b**) Slipped band (*arrow*) lying horizontally with a dilated pouch proximally and little or no contrast passing through it (from Hamdan K, Somers S, Chand M. Management of late postoperative complications of bariatric surgery. Br J Surg. 2011 Oct;98(10):1345–5, with permission)

Late erosions occur slowly and chronically. The band penetrates the gastric lumen slowly enough that there is adequate time for a protective peritoneal layer to form over the band and attached tubing. Micro-erosions eventually give way to larger erosions, and the leaking gastric contents will track along the gastric band tubing to the port site. Finally, a clinically obvious port-site infection will emerge that will not respond to drainage and antibiotics. At this point, gastric erosion must be suspected.

Erosions must also be a consideration in patients with abdominal pain and chronic NSAID use, as gastric ulcers can be a predisposing factor to erosion formation. Loss of weight restriction despite band adjustments is also a common presentation of band erosion. Lastly, patients who have undergone prior band revision or who have had bands placed secondary to other bariatric procedures are more prone to erosion, and as such one should have a higher index of suspicion in this group.

3.1.2.2 Diagnosis

As mentioned above, the presentation of gastric erosion is variable. The most common presenting symptom is port-site abscess, followed in descending order by port-site sinus, subphrenic abscess, unexplained weight gain, left pyelonephritis, band deflation, peritonitis, and mucus collection at the port site [6]. Definitive diagnosis is provided by upper GI endoscopy. As erosion is normally secondary to pressure ischemia from the band, most erosions occur anteriorly where the gastric fundus has been plicated over the band. Endoscopy should be visualized by sutures or band material, though small erosions can be difficult to detect.

3.1.2.3 Treatment

Once the diagnosis of band erosion is established, treatment is removal of the offending band. This can usually be managed laparoscopically, though it may require lysis of dense adhesions between the omentum and abdominal wall, as well as adhesions to the left lobe of the liver. Dissection and identification of band tubing are essential in this process. The tubing can be followed to the buckle of the band, which can then be transected and easily removed. The gastric plication should not be taken down during the procedure. Once the gastric perforation is identified, it should be closed in two layers, if possible, and a drain may be left at the closure site. Furthermore, methylene blue testing through an orogastric tube may be performed to assess for any further leakage or missed gastrotomies. OR EGD may also be used to distend the stomach and check for a leak. Patients will then typically have an upper GI series performed on postoperative day 1, and can usually be discharged with oral antibiotics and a clear liquid diet. If there is a >50 % erosion of the band into the lumen, it can be removed endoscopically with a cutting wire. The particular wire that cuts the band is not FDA approved for use in the USA for this purpose. However outside the USA, the use of this technique for band removal has been described in the literature. The technique of using the wire is to remove the port surgically and divide the band tubing distal to the port. The cutting wire is placed endoscopically and cut the band and the band is extricated through the mouth. The patient gets an esophagram the following day [7].

3.1.3 Megaesophagus

3.1.3.1 Presentation

Megaesophagus is a rare complication of gastric band placement. The gastric band can impair esophageal peristalsis and cause impaired relaxation of the lower esophageal sphincter. Over time, this can lead to esophageal dilation, termed megaesophagus. Symptoms include dysphagia, regurgitation of salivary contents, and severe acid reflux. Upper GI series demonstrates a dilated esophagus, and esophageal manometry shows either aperistalsis or secondary/tertiary peristaltic contractions. Arias et al. found the incidence of megaesophagus in gastric band patients to be approximately 2 % [8].

3.1.3.2 Treatment

Initial treatment includes prompt deflation of the lap band. If symptoms and esophageal dilation do not improve after deflation, removal of the lap band system is the ultimate therapy [9].

3.1.4 Port Problems

Port problems are a common issue amongst lap band patients. These can range from port malpositioning to port leakage/breakage and port-site infections.

3.1.4.1 Port Malfunctions

Port-related complications are reported to occur in 5–10 % of patients with lap bands. Some of the more simple issues involved tube breakage or leakage from the port site. These leaks can be caused by needle perforations during failed adjustment settings, or tubing fatigue from long-standing ports [10]. Medical staff who are not well versed in lap band management may also attempt to drain the band using a regular needle instead of a Huber needle, which could shorten the life span of the device.

Ports have also been known to dislodge from their sutures after placement. Ideally, the port will be affixed to abdominal fascia, preferably the anterior rectus sheath. In certain patients it may be very difficult to identify a fascial layer, and the port may inadvertently be sutured to subcutaneous fat. If that happens, it can subsequently rotate in a way that makes it inaccessible to the surgeon. A simple abdominal X-ray can confirm positioning, and if the port cannot be accessed it may need surgical revision.

3.1.4.2 Port-Site Infection

As mentioned earlier in the chapter, port-site infections that occur late in the patient's operative course are evidence of gastric erosion until proven otherwise. Port-site infections should be treated with systemic antibiotic therapy for 2–3 weeks. If the infection does not subside with this treatment, further studies must be performed to rule out gastric erosion. Even if erosion is not the precipitating cause, recurrent infections may require port removal and replacement after the infection is adequately treated.

3.2 Roux-en-Y Gastric Bypass

3.2.1 Intestinal Obstruction

3.2.1.1 Presentation

Intestinal obstruction after gastric bypass is a rare but well-known complication of the procedure. Rates have ranged from 1.5 to 5 % in various series [11]. The nature of the bypass lends itself towards obstructive complications; internal hernias can occur through the mesocolic defect of a retrocolic Roux limb, the jejunal mesenteric defect at the jejunojejunostomy, or through Petersen's space, the space between the Roux limb and the transverse mesocolon (Fig. 3.4). Adhesions, stricturing, limb kinking, and port-site hernias are also common causes of obstruction. Gastrojejunostomy strictures typically occur 3–12 weeks after the initial surgery [12]. As in all surgical obstruction, the presenting symptoms include abdominal pain, nausea, and vomiting.

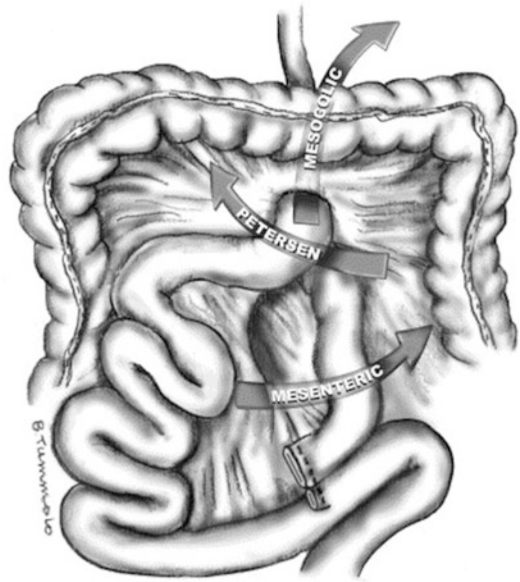

Fig. 3.4 Potential sites for internal hernia formation after gastric bypass (from Capella RF, Iannace VA, Capella F, bowel obstruction after open and laparoscopic gastric bypass surgery for morbid obesity. J Am Coll Surg 203(3):328–335, with permission)

The bypass patient, however, may only vomit small amounts due to the reduced gastric pouch. If the obstruction is in the biliopancreatic limb, the patient may have abdominal pain as the only presenting symptom (Table 3.1). The high morbidity from a delayed diagnosis of intestinal obstruction requires a high suspicion for this complication. Any obstruction in a patient with a history of RYGB requires urgent exploration.

3.2.1.2 Diagnosis

Diagnosis of intestinal obstruction is usually confirmed through a radiologic study. Plain abdominal films may demonstrate dilated loops of bowel, though an upper GI series is more sensitive, and a CT scan with oral and IV contrast is the best current study. A mesenteric swirl sign appears to be the most reliable indicator of an internal hernia after the RYGB [13]. However, the gold standard for diagnosis is still exploratory laparoscopy/laparotomy, as CT scan sensitivities appear to be highly variable from study to study, and a missed internal hernia has devastating consequences.

3.2.1.3 Treatment

Laparoscopy is often diagnostic and therapeutic for this complication. Areas of stenosis or kinking may require takedown and revision of the prior anastomosis. Internal hernias should be reduced, and any mesenteric defects detected should be closed.

Strictures of the gastrojejunostomy can be dilated instead of surgically revised. This can usually be done up to three times before dilations are deemed a failure and surgery is necessary. In some studies, this has been shown to be almost 100 % successful in fixing the problem, avoiding surgery altogether [12].

3.2.2 Marginal Ulceration

3.2.2.1 Presentation

Marginal ulcerations are ulcers that occur at the gastrojejunal anastomosis. They commonly occur on the jejunal side, and are suspected to partly be the result of jejunal exposure to acid. Studies have proven them to be multifactorial in nature, however. Patients with the following conditions have all been shown to have increased marginal ulceration rates [14]:

- Gastric acid
- Foreign body
- NSAID use
- *H. pylori* infection
- Cigarette smoking
- Alcohol use
- Local ischemia
- Anastomotic tension

Marginal ulcers may present at any time after Roux-en-Y gastric bypass. Common signs and symptoms include epigastric pain, dysphagia, and nausea. Patients also report pain after eating, in contrast to patients with peptic ulcer disease. Occasionally, patients will present with acute GI bleeding, perforation, or obstruction, but most will report a more chronic problem.

Diagnosis is often made with clinical presentation and confirmed with radiological studies. Upper endoscopy is the most effective mode of diagnosis, providing direct visualization and the ability to characterize the ulcers (Fig. 3.5). UGIS can identify ulcers and may also identify other gastric abnormalities caused by the ulceration [15].

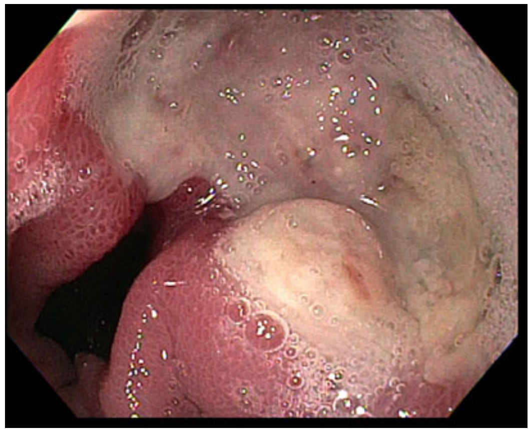

Fig. 3.5 Endoscopic view of marginal ulcer (courtesy of Grigoriy Gurvits, MD, NYU)

3.2.2.2 Treatment

Once the diagnosis of marginal ulceration is made, treatment is directed at acid suppression and resolution of the underlying cause. Patients may need to be treated for *H. pylori* infection, counseled to reduce NSAID use, smoking, or consumption of alcoholic beverages. They are routinely placed on a PPI for 6–12 months. Treatment will oftentimes continue until repeat endoscopy confirms resolution of ulcers.

Surgical intervention is reserved for patients who have acute issues or are refractory to maximal medical management. Some causative agents of marginal ulceration require curative surgery, e.g., foreign material in the ulcer, gastrogastric fistula, or excessive pouch size. Determining the ultimate cause of the disease process is essential in tailoring one's surgical approach to the problem.

3.3 Sleeve Gastrectomy

Late complications for sleeve gastrectomy are rare. Within 30 days of surgery, staple line leak is the major feared complication. After 30 days, nutritional deficiencies and port-site hernias (an issue common to all bariatric procedures) are the main issues facing patient and surgeon.

3.3.1 Nutritional Deficiencies

3.3.1.1 Presentation

Sleeve gastrectomy and gastric bypass patients are at high risk for nutrient deficiencies due to the loss of parietal cells that reside within the gastric fundus. Parietal cells secrete both hydrochloric acid and intrinsic factor, essential for absorption of micronutrients and B12, respectively. Loss of the gastric fundus or disconnection from the gastric fundus also results in decreased ghrelin production, a hormonal appetite stimulant. These combined issues, along with the micronutrient deficiencies inherent to obese patients, make it essential for SG and RYGB patients to have close nutritional follow-up after surgery [16].

Vitamin deficiencies usually do not manifest as clinical syndromes, and are ideally detected and treated during regular follow up appointments with the patient's surgeon, primary care physician, or dietician. Common recommended supplementation after sleeve gastrectomy includes B-12, iron, and a multivitamin, but the majority of patients were not found to be compliant with recommendations at follow-up. In year 1, only 28.9 % of patients reported taking supplements, compared to 42.9 % in year 3 and 63.3 % in year 5 [17]. As was mentioned before, most vitamin deficiencies have minimal to no clinical presentation; an exception is a deficiency in vitamin B1, resulting in Wernicke's encephalopathy.

3.3.2 Wernicke's Encephalopathy

3.3.2.1 Presentation

Wernicke's encephalopathy is caused by a deficiency in thiamine (vitamin B1). The classic triad of symptoms is ocular impairment, cerebellar dysfunction, and confusion. SG patients with persistent vomiting and confusion after surgery should raise one's clinical suspicion for the disease. The process of developing Wernicke's is often anatomical in origin: any complication of either SG or RYGB causing persistent vomiting and general food intolerance exacerbates vitamin depletion. Clinical symptoms of B1 deficiency can occur as soon as 3 weeks after surgery, and almost all present within 6 months of surgery [18].

3.3.2.2 Diagnosis

Diagnosis is clinical, as assays for thiamine levels may take a prolonged period of time to process. Upper endoscopy or upper GI series may diagnose obstruction or stenosis leading to hyperemesis. Treatment should be initiated immediately with any clinical suspicion of Wernicke's, as delay in treatment may have severe and permanent neurologic consequences [18].

3.3.2.3 Treatment

The best treatment is prophylaxis. Patients are educated prior to surgery about the importance of proper eating patterns, vitamin supplementation, and early communication with their surgeon of symptoms of stenosis or stricture with food intolerance. When B1 deficiency is suspected, treatment involves 500 mg of intravenous thiamine, three times per day, for 3 days [19]. Oral supplementation is then indicated if the patient responds to the initial treatment. It is important to note that in any patient who has suspected Wernicke's, intravenous fluid needs to be supplemented with thiamine. IV administrations with glucose but no thiamine can precipitate lactic acidosis in the medial thalamus, contributing to neuronal damage. Ultimately, treatment of the underlying disorder causing the patient's food intolerance is necessary to prevent future recurrences.

3.3.3 Port-Site Hernia

3.3.3.1 Presentation

Port-site hernias are a problem endemic to all laparoscopic intra-abdominal surgeries. The vast majority of current bariatric surgeries are performed laparoscopically with multiple ports placed in any given procedure. A systematic review of port-site hernias in all laparoscopic procedures showed an incidence of 0.74 %, though bariatric procedures actually had the lowest incidence reported of the group, at 0.57% [20]. They typically present with signs and symptoms of small bowel obstruction, though they may also present years after surgery with a notable bulge at the port site.

3.3.3.2 Diagnosis

Diagnosis of port-site hernias is usually made clinically and confirmed radiologically. Patients present with abdominal pain, nausea, and vomiting. They may report pain at a specific port site, and a palpable bulge may be noted. Reduction can be attempted outside the operating room, but if unable to reduce, or if the patient demonstrates signs of intestinal obstruction or ischemia, prompt operative exploration is required. On CT scan, a knuckle of bowel can be seen herniating into a port site. Upright abdominal X-ray may also demonstrate distended loops of small bowel, consistent with an obstructive picture.

3.3.3.3 Treatment

Management of port-site hernias invariably involves operative exploration and repair. Even if the hernia is able to be reduced, surgery is still recommended at a later date due to high risk of recurrence and intestinal strangulation. Exploratory laparoscopy, reduction, and closure of hernia defect are normally sufficient for treatment, though bowel may require resection if it appears ischemic. Studies of port-site hernias show that the vast majority of hernias occur through port sites that are 10 mm and larger. A higher incidence is also reported with entry obtained via bladed trocars vs. blunt trocars, and through port sites in the midline of the abdomen [20].

3.4 Biliopancreatic Diversion with Duodenal Switch

Some of the delayed postoperative complications from the BPD/DS have been mentioned earlier in the chapter. These include marginal ulcers, intestinal obstruction, and port-site hernias. Two late-term complications specific to the biliopancreatic diversion are gastric outlet obstruction and nutritional deficiencies relating to the malabsorptive nature of the procedure.

3.4.1 Gastric Outlet Obstruction

3.4.1.1 Presentation

Gastric outlet obstruction can present after BPD/DS as both an early and a late complication. In the early phase, obstruction is usually secondary to edema and resolves within several days. Prolonged early obstruction may also be from a technical error resulting in stomal narrowing; if unresponsive to dilation, it may require reoperation and revision of the anastomosis.

Delayed stomal stenosis normally arises 4–6 weeks after surgery, and has several predisposing factors. Ischemia caused by anastomotic tension or compromise of vascular supply may also lead to the same issue. Suture material may cause an inflammatory reaction, leading to fibrosis and stomal narrowing. Lastly, a contained leak at the gastroenterostomy will result in inflammation, fibrosis, and obstruction of the viscera.

3.4.1.2 Diagnosis

Upper endoscopy can confirm patency or stricture of the anastomosis. An upper GI series will also demonstrate obstruction and failure of contrast passage [21].

3.4.1.3 Treatment

Treatment of gastric outlet obstruction, ultimately, involves surgical revision of the anastomosis. Temporizing measures can include dietary changes and ballooning of a stenosed gastroenterostomy, but definitive treatment will be surgical.

3.4.2 Nutritional Deficiencies

3.4.2.1 Protein Malnutrition

Protein absorption after BPD/DS is dependent on multiple factors, primarily the length of the common channel, nutritional transit time, and the number of villi in the alimentary and common channel. Any event that adversely affects these three factors, such as gastroenteritis, bacterial overgrowth, fistula formation, or inflammatory bowel disease, can result in severe protein malnutrition. Treatment includes correcting the offending agent and proper hydration of the patient. Some patients may require pancreatic enzyme supplementation or even TPN to treat their hypoalbuminemia. If all medical management fails, surgical revision of the alimentary limb and common channel is necessary to definitively treat this issue.

3.4.2.2 Vitamin Deficiency

The long-term weight loss seen with BPD/DS patients is attributed to the many changes in hormonal signaling, changes in the microbiome, increase in thermogenesis, epigenetic reset, and malabsorptive effects of the procedure. Pancreatic enzymes and bile only mix with food in the "common channel," the portion of ileum distal to the anastomosis of the biliopancreatic limb and the Roux limb. The end result is that only 28 % of ingested fat is absorbed. Fat-soluble vitamins (vitamins A, D, E, and K), therefore, are also absorbed in decreased amounts. A study by Slater et al. showed that 4 years after the procedure, vitamins A, D, E, and K were deficient in 70 %, 63 %, 42 %, and 4 %, respectively [22]. Zinc was also found to be low in 50 % of patients over the same time frame.

Calcium and vitamin D deficiency is also common after malabsorptive bariatric procedures. Calcium is preferentially absorbed in the duodenum and jejunum, and vitamin D is absorbed in the jejunum and ileum. These sites are bypassed during a BPD/DS, leading to the lowered serum levels. The decreased vitamin D further exacerbates the calcium deficit, causing a concomitant elevation in PTH and calcium depletion from bones [23]. The previously mentioned study by Slater found that 85 % of their patients were hypocalcemic 1 year after surgery, and 52 % remained hypocalcemic at 4 years.

3.4.2.3 Anemia

Microcytic anemia is an expected complication of the BPD/DS due to the fact that iron is primarily absorbed in the duodenum. The addition of several centimeters of duodenum in the BPD/DS compared to the BPD has not been shown to decrease the percentage of patients with postoperative anemia [24]. Rarely do patients have symptomatic anemia requiring transfusions; the exceptions are patients with active blood loss, such as menstruating women or patients with stomal ulceration. Gastric bypass patients can experience similar issues with anemia, as their reconstructed anatomy also bypasses the duodenum.

3.5 Self-Assessment Questions

1. A 40-year-old woman undergoes laparoscopic Roux-en-Y gastric bypass. At her 3-month postoperative visit she complains of increased fatigue. What is the next step in her diagnostic workup for this issue?
   A. Upper endoscopy
   B. No further workup necessary
   C. Complete blood count
   D. Referral for sleep study
   E. Return to clinic in 1 month if symptoms do not improve

   Answer: C. Iron-deficiency anemia is especially pronounced in gastric bypass patients because the duodenum and proximal jejunum are being bypassed, which are the primary locations of iron absorption in the intestine. The patient is also premenopausal, which increases the likelihood of anemia. Iron-deficiency anemia will often manifest clinically as fatigue, and a complete blood count is the initial diagnostic step in testing for anemia.
2. A gastric bypass patient comes to the emergency department 6 months after his surgery, complaining of 2 days of abdominal pain and emesis with no relief of symptoms. Vital signs are stable with the exception of mild tachycardia to 105 beats/min. His abdominal exam shows mild distention, normal bowel sounds, and minor abdominal tenderness to palpation. CT of the abdomen reveals normal passage of contrast to the colon, but dilation of the entire biliopancreatic limb and excluded stomach. The BP limb appears to be in its normal location. The patient will most likely require which of the following?
   A. Revision of the gastrojejunostomy
   B. Excision of a marginal ulcer
   C. Reversal of gastric bypass

D. Lysis of adhesions
E. Revision of jejunojejunostomy

Answer: E. This patient is presenting to the ED with obstruction of the biliopancreatic limb, most likely secondary to stenosis of the jejunojejunostomy. The normal location of the BP limb suggests that an internal hernia is not the cause of obstruction, and normal passage of contrast to the colon means that the obstruction is not more distal. He will most likely require revision of the jejunojejunostomy to definitively treat this problem.

3. A 35-year-old male with a BMI of 55 is following up in the office 1 year after placement of a gastric band. His preoperative BMI was 65, and he has not lost weight for the past 2 months. He also reports some redness and pain around the port site for the gastric band. Upon exam, a small amount of purulent fluid is noted to be draining from around the port site. What is the most likely diagnosis?

A. Primary port-site infection
B. Gastric erosion of the lap band
C. Necrotizing fasciitis
D. Leaking port
E. Normal irritation after port manipulation

Answer: B. A port-site infection must be considered evidence of band erosion until proven otherwise. This patient has clear clinical evidence of a port infection, as well as no weight loss over the past 2 months—both of which are suggestive of band erosion. Diagnosis can be confirmed by upper GI series or upper endoscopy, and treatment involves removal of the band.

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4 Failure to Rescue the Patient with a Complication

D. Brandon Williams and Matthew D. Spann

4.1 Definition of Failure to Rescue and Use as a Quality Metric

In the late 1990s, the Institute of Medicine (IOM) estimated that as many as 98,000 people die each year as a result of medical errors. To address this staggering number, a new era emerged focusing on patient safety and quality of healthcare in the USA. Patient safety was defined as freedom from accidental injury due to medical care or medical errors [1]. The Agency for Healthcare Research and Quality (AHRQ) received the task of reducing medical errors via creation of the Center for Patient Safety. The Affordable Care Act (ACA) added further weight to the initiatives brought forth by the IOM, authorizing the Center for Medicare and Medicaid Services (CMS) to link reimbursement with outcomes. The ACA allowed CMS to penalize hospitals for potentially avoidable events and substandard delivery of care. Thus began an era of value-based healthcare with two main goals: diminishing gaps in healthcare quality and minimizing preventable adverse events.

The initial challenge faced by the AHRQ was identifying metrics of harm and, therefore, areas for improvement. An AHRQ expert panel used existing literature to identify diagnoses linked directly to patient harm as well as those that signaled a possible deviation in the expected course of treatment and recovery. An exhaustive review of ICD-9 and Diagnostic-Related Group (DRG) codes associated with in-hospital morbidity and mortality in over two million hospital records from the state of New York yielded nearly 200 diagnoses that may be linked to patient harm. The diagnoses were organized into groups, termed Patient Safety Indicators (PSI), that are used to identify potential harm and assess quality improvement in medical, surgical, and obstetric cases [2]. Validation of the algorithms revealed that patients with one of the given diagnoses at discharge had a significantly higher morbidity, mortality, and increased length of stay. The PSI groups are listed in Table 4.1 [3].

Prior to the 1990s, healthcare quality was often linked to hospital volume, complication rates, and mortality rates. While no perfect metric exists, many experts agreed that these factors do not truly reflect the quality of care at an institution. The concept of failure to rescue (FTR) was defined by Silber and colleagues in the 1990s as

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Table 4.1 Current patient safety indicators

Complications of anesthesia	Postoperative respiratory failure
Death in low-mortality DRGs	Postoperative pulmonary embolism or deep vein thrombosis
Decubitus ulcer	Postoperative sepsis
Failure to rescue	Postoperative wound dehiscence
Foreign body left during procedure	Accidental puncture or laceration
Iatrogenic pneumothorax	Transfusion reaction
Selected infections due to medical care	Birth trauma—injury to neonate
Postoperative hip fracture	Obstetric trauma—vaginal delivery with instrument
Postoperative hemorrhage or hematoma	Obstetric trauma—vaginal delivery without instrument
Postoperative physiologic or metabolic derangement	Obstetric trauma—cesarean delivery

death following an adverse occurrence [4]. This concept provided some explanation as to why hospitals with the most complications do not always have the highest mortality rates. To assess FTR as a quality metric, Silber and colleagues initially compared FTR rate with mortality rate and complication rate following cholecystectomy and transurethral prostatectomy. The findings revealed that FTR was associated with multiple variances in hospital factors, not patient factors, thus validating its use as a quality metric. FTR rates have subsequently been used to assess the quality of care delivered in multiple specialties including general surgery, cardiac surgery, and critical care. Throughout the disciplines, FTR remains a superior quality indicator when compared to mortality rate alone [5–8].

Over the last decade, the definition of FTR has been modified to assess certain nursing, administrative, and patient-specific factors. The AHRQ included FTR as a PSI and defined it specifically as death that occurred following six key complications of care as listed in Table 4.2 [3]. FTR assesses a hospital system's ability to recognize and adequately treat an unexpected or adverse event. FTR has been shown to reflect multiple gaps in healthcare delivery within a hospital system and is, therefore, a useful metric to monitor performance and improvement [7].

Table 4.2 Complications included in the failure to rescue metric

Acute renal failure	Pneumonia
Sepsis	Pulmonary embolism or deep vein thrombosis
Shock or cardiac arrest	Gastrointestinal hemorrhage or acute ulcer

4.2 Failure to Rescue Due to Delayed Escalation of Care

Certainly a key component of FTR is delayed escalation of care. Johnston and colleagues identified key steps in the postoperative care escalation process in an academic medical center and potential reasons for failure at each step [9]. In the nursing level, some of the steps where escalation could potentially fail included the following: the patient failing to inform the nursing assistant of feeling unwell, failure of the nurse to attend to the patient or notice deterioration, failure to measure or document vital signs correctly, and failure to inform the junior resident about the deterioration. Clinical understaffing was determined to be the principal root cause of all these failures. At the junior resident level, potential points of care escalation failure included failure to perform an adequate history and physical, failure to initiate treatment, and failure to inform a senior resident of the deterioration. Root causes of these failures included hierarchical barriers to communicating to the senior resident, senior resident unavailability, and poor chart design or legibility. Lastly, at the senior resident level, failure to arrange definitive management was recognized as a potential point of escalation failure, with root causes of hierarchical barriers to communicating with the attending surgeon and lack of hospital resources. Proposals to address all the above root causes included increasing nurse-to-patient ratios, adding more permanent nursing staff, investment in electronic vital sign recording and medical records, removal of hierarchical barriers, increased use of smartphone technology, educating junior residents about the importance of prompt care escalation, development of a clear escalation protocol, development of guidelines defining appropriate levels of care according to diagnosis and physiological parameters, and ensuring adequate access to resources, such as operating rooms and surgical intensive care unit beds.

Further illustrating the importance of hospital systems and communication in the quality of postoperative care, Symons and colleagues analyzed postoperative care of 50 patients undergoing elective major general surgery and found that process failures accounted for 57 % of all preventable adverse events, and more than half of those failures were due to communication errors and delays in patient care [10].

4.3 Relationship Between Failure to Rescue and Mortality

To determine the relative importance of FTR as a reason why some hospitals have higher surgical mortality rates, Hyder and colleagues compared hospitals on the basis of mortality rates using data from the Nationwide Inpatient Sample [11]. They established five subpopulations as potential targets for mortality improvement: patients with one of the six AHQR FTR-qualifying complications, patients with high estimated preoperative risk, emergency surgery patients, elderly patients, and patients with diabetes. Comparing hospitals with high mortality rates to those with low mortality rates, mortality risk differences were greatest in the high-risk and FTR subpopulations. They found in simulations that optimizing outcomes in the FTR population could potentially reduce the mortality gap between the highest and lowest mortality hospitals by as much as 75 %.

Also making the connection between FTR and mortality, Wakeam and colleagues used rates of secondary complications after common index complications (a failure to arrest progression of complications) as a surrogate for FTR [12]. Using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) data, they found a wide variation in the rate of complications among hospitals. Hospitals in the highest quintile of secondary complications after pneumonia, myocardial infarction, and surgical site infection had significantly greater mortality rates.

Also using ACS-NSQIP data, Ferraris and colleagues stratified patients according to their propensity for developing serious postoperative complications based on more than 50 demographic and preoperative clinical variables [13]. They then defined FTR as death after a serious postoperative complication and found that 88 % of patients with FTR were in the highest risk quintile, and 95 % were in the two highest risk quintiles. A single postoperative complication often preceded the development of multiple complications. As the number of complications increased, so did the FTR rate, as shown in Fig. 4.1 [13]. More than two-thirds of the FTR patients had multiple postoperative complications, and the mortality rate increased exponentially with the number of complications. Interestingly, patients with surgical residents involved in their care had lower FTR rates.

In a recent review article, Johnston and colleagues found that the reported incidence of FTR in surgery patients varied between 8.0 and 16.9 % [14]. Several studies found that an increased incidence of FTR was associated with high mortality rates and low hospital volume. Illustrating the importance of patient factors in FTR, lower FTR rates were associated with patient age <70 years, absence of malignancy, and white ethnicity. The nature of the initial complication also affects FTR. Greater FTR rates were found in patients with medical (as opposed to surgical) complications, surgical site infections, DVT, pneumonia, sepsis, and gastrointestinal complications. Just as reported in other studies, hospital system issues affect the FTR rate. Multiple studies showed increased mortality rates when escalation of care was delayed. The reasons for such a delay included incorrect diagnosis, clinical inexperience, poor communication due to hierarchical barriers, fear of criticism, high workload, overconfidence, frequent interruptions, and clinician unavailability.

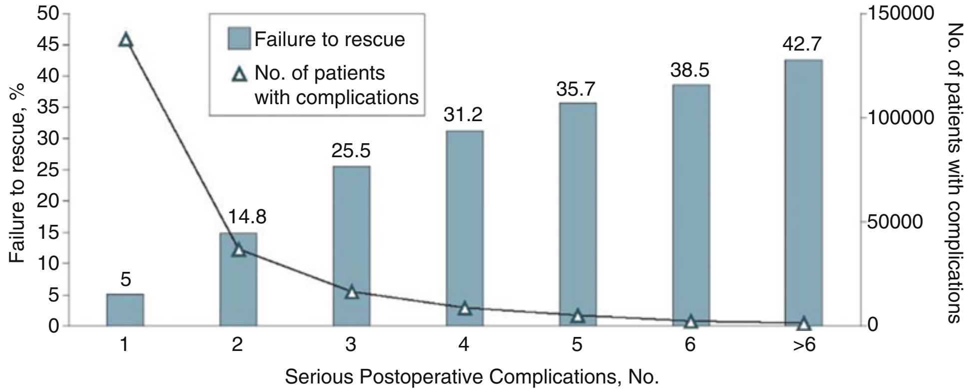

Fig. 4.1 Failure to rescue increases with serious postoperative complications (from Ferraris VA, Bolanos M, Martin JT, et al. Identification of patients with postoperative complications who are at risk for failure to rescue. *JAMA Surg* 2014; 149(11):1103–8, with permission)

Using FTR as a safety and quality metric is not without flaw. FTR rates are calculated from administrative data sets and, thus, rely on accurate coding. Certain diagnoses, such as trauma and immunocompromised status, are often excluded from analysis [3]. Education, patient selection, and communication are only a few variables that result in failing to rescue a patient from a complication. Therefore, it is often very difficult to determine the exact cause of differences in FTR rates. FTR should be used as one of many quality metrics when assessing a program, hospital, or system. It is clear that FTR is an important indicator to provoke and assess change, but the exact impact on patient safety in the US healthcare system will be difficult to determine. While not currently part of the selected PSIs used by CMS to impact reimbursement, FTR in the coming years may be linked to financial consequences.

4.4 Patterns of In-Hospital Mortality

The Institute of Medicine reports *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the twenty-first Century* increased attention to identifying and preventing medical errors and resulted in the implementation of many quality measures. Assessing the effectiveness of these interventions remains difficult. Ultimately, reporting overall mortality for surgical procedures is challenging since most reports are from single institutions, small groups of hospitals, or a single state. Gawande and colleagues looked at 30-day outcomes reported in the Nationwide Inpatient Sample and found that inpatient deaths were lower in 2006 than 1996 [15]. Similar improvements have been reported in the National Hospital Discharge Survey database, the National Surgical Quality Improvement Project, and other national health data registries [16–18]. The observed decrease in mortality, however, does not correlate directly with a decrease in adverse or potentially preventable events. Since the implementation and tracking of PSIs, there has been an overall decrease in FTR rates [19]. In contrast, the rates of some important PSIs have increased, namely postoperative thrombotic events, sepsis, respiratory failure, hospital-acquired infections, decubitus ulcer, and accidental puncture or laceration [15, 19].

While most PSI events are increasing, postoperative mortality rates are decreasing. The reason for this discordance is unknown, but several other observations offer plausible explanations. The decrease in FTR rates over this interval suggests improvement in education and communication, thus leading to earlier recognition of complications before progression to mortality [18]. Patients are living longer and have increasing comorbidities, and operating on higher risk patients leads to more postoperative complications [20]. Moreover, with increased attention to patient safety, more resources have been devoted to proper coding, leading to more reported complications.

4.4.1 Rapid Response Teams

Practically, most preventable in-hospital deaths are preceded by changes in a patient's clinical status. Narcosis, pneumonia, sleep apnea, sepsis, acute heart failure, and pulmonary embolism will be preceded by changes in heart rate, respiratory rate, and oxygen saturation. These measurable changes are the basis for creation and evolution of the rapid response team (RRT). However, when considering the pathophysiology of the complication, the typical vital sign derangements that activate an emergency response may only become apparent late in the development of a complication. Lynn and Curry categorized the patterns of unexpected death into three types: Type I is respiratory distress from compensation due to underlying metabolic acidosis, type II is hypoventilation from narcosis, and type III is airway obstruction, often due to sleep apnea [21]. For each type of death, the alarm threshold took place in advanced stages of the complication, making rescue from the pathophysiology more difficult. As shown in Fig. 4.2, notification of a RRT for a patient in need of rescue from obstructive physiology as seen in sleep apnea will occur when the complication is in advanced stages making rescue more difficult [21].

Studies have reported inconclusive evidence that RRTs improve hospital mortality and reduce cardiac arrest rates [22]. In general, benefits are observed in single-center studies but not large multicenter randomized trials. However, there are multiple plausible explanations as to why the implementation of RRTs might fail to improve outcomes. Unfortunately, there are many situations where culture trumps strategy. Calling the RRT may be seen as a sign of weakness or inadequacy of care, or bypassing the typical chain of command, and that culture can limit the benefits of RRT utilization. Additionally, there must be sufficient utilization of the RRT for a change in outcomes to be statistically significant. Lastly,

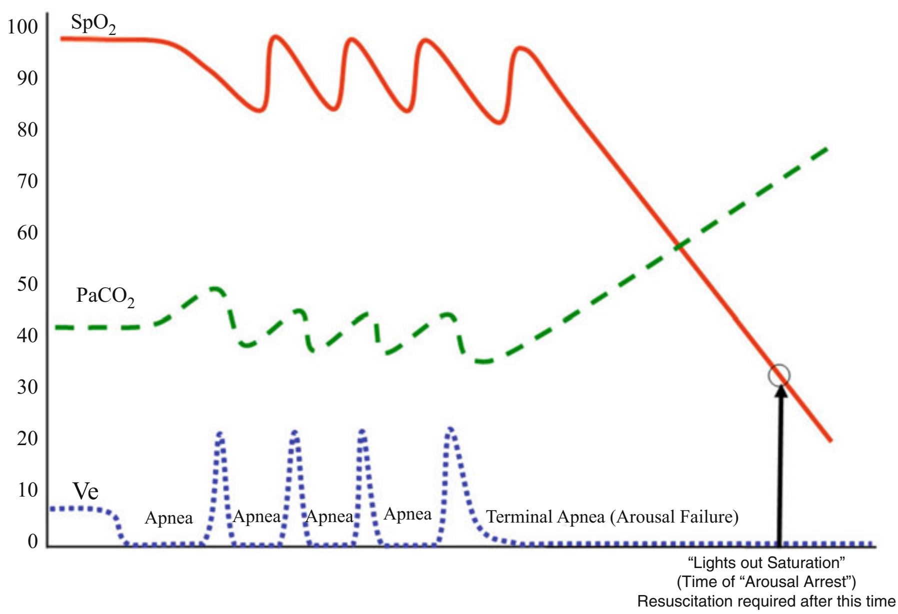

Fig. 4.2 Notification of a RRT for a patient in need of rescue from obstructive physiology as seen in sleep apnea (from Lynn LA, Curry JP. Patterns of unexpected in-hospital deaths: a root cause analysis. *Patient Saf Surg* 2011;5(1):3, with permission)

any given system must go through a learning curve in which effective implementation matures.

Recently in a study from the Mayo Clinic, investigators examined the benefit of RRT implementation, specifically using the original AHRQ definition of FTR [23]. Overall hospital mortality did not significantly change, but they found a significant drop in the FTR rate. Illustrating the point that the benefits of RRTs will not be immediately appreciated after implementation. The FTR drop occurred approximately 12 months after full RRT implementation, going from 17.8 to 13.8 %. Interestingly, FTR rates improved for specific complications and not for others. In particular, FTR rates decreased for shock and/or cardiac arrest and renal failure, with no statistically significant change for pneumonia, DVT/PE, sepsis, or gastrointestinal bleeding. Of note, the improvement in the FTR rate coincided with an increase in RRT utilization, which went from 6 up to 12 activations per 1000 discharges, supporting the concept of a dose–response relationship between the rate of RRT activation and incidence of fatal events. Also during that time, the unplanned ICU transfer rate increased, going from 13.7 transfers to 15.2 per 1000 floor days.

Another potential limitation to RRT benefits, as mentioned above, is that they may be activated only after severe derangements of vital signs appear. One study assessed the impact of RRTs when clinical judgment was promoted as a primary criterion for activation [24]. To foster a culture of RRT acceptance, staff members were explicitly instructed to activate the RRT without hesitation for any degree of clinical concern, without threat of reprisal, regardless of whether specific vital sign abnormalities were present. They found that 43 % of RRT calls were activated for reasons other than altered vital signs, namely mental status change or simply because "the patient did not look right." Mortality decreased significantly from 15.50 to 13.74 deaths per 1000 discharges, as did cardiopulmonary arrests outside the ICU. Of note, the RRT was widely utilized in this study, with 10.8 activations per 1000 discharges, in contrast to RRT utilization rates of 2.5 and 8.7 per 1000 admissions in previous negative studies [25, 26].

4.4.2 Protocols and Checklists

In addition to implementation of RRTs, utilization of protocols or checklists is another way to prevent FTR. Checklists can be particularly helpful in crisis situations, when complications have already progressed. Pucher and colleagues identified the most common complications after complex gastrointestinal operations and developed corresponding treatment checklists [27]. They then retrospectively analyzed 37 postoperative complications to evaluate adherence to the newly proposed checklists. They found that management of the complication was fully compliant only 16 % of the time, with outright errors in 65 %, and a median treatment delay of 6 h. Data analysis revealed poor checklist compliance to be the only significant factor for developing further morbidity.

Although some factors of unexpected hospital death will be related to hospital systems, crucial factors lie within the surgeon, highlighting the importance of proper training, morbidity and mortality review, continuing education, and quality improvement initiatives [28]. The desire for surgeons to help with the treatment of disease must be carefully balanced, as the first opportunity to improve postoperative mortality may be to avoid an operation altogether. The surgeon must carefully weigh the patient's diagnosis with the goals of an operation and how operative and nonoperative approaches will affect the patient's life expectancy and quality of life. Many procedure-specific risk calculators are available to help quantify the risk/benefit ratio [29]. Palliative care specialists can also help providers and patients identify goals of care, decreasing futile procedures [30]. A surgeon must also assess the resources available to manage a complication should one occur prior to any operative intervention.

4.4.3 Morbid Obesity and Bariatric Surgery

Morbidly obese patients pose significant challenges due to increased risk of pulmonary, thrombotic, and cardiac complications following surgery. Particular attention must be paid to tachycardia and changes in respiratory status, arguably the most sensitive indicators of a postoperative complication [31–33]. Attention to detail throughout the perioperative process is necessary to avoid major complications and an FTR event.

With respect to bariatric surgery, mortality rates have improved over the current era [34]. Evidence suggests that this improvement may be related to the laparoscopic technique, high-volume centers, and center accreditation. In a comprehensive systematic review, Zevin and colleagues found that both surgeon and hospital annual volumes correlated positively with outcomes [35]. In another pooled analysis, Markar and colleagues found reduced morbidity and mortality at high-volume institutions with high-volume surgeons [36].

Morton and colleagues showed that accredited bariatric surgery centers have a lower incidence of FTR, likely due to better patient and staff education, resources, and personnel available to recognize and treat complications earlier in their development [37]. They also found that high-volume centers had decreased complication rates, but accreditation status still independently predicted complication rates after controlling for hospital volume in multivariate logistic regression analysis. In New York state, bariatric hospital Center of Excellence accreditation was associated with significantly lower rates of perioperative morbidity and mortality as well as all-cause long-term mortality [38]. Within academic medical centers, accreditation status was associated with lower in-hospital mortality (0.06 % vs. 0.21 %). Moreover, bariatric operations performed at those centers were also associated with shorter lengths of stay and lower cost [39].

In contrast, two studies have shown no statistically significant differences in morbidity or mortality for operations performed at accredited versus non-accredited bariatric centers. However, in one of these studies the data was obtained from the 2005 National Inpatient Survey, when the accreditation process had just begun and was not fully refined and implemented [40]. The other study was from Michigan, where the Michigan Area Bariatric Surgery Collaborative was already in place to provide a quality improvement program similar to that of the American College of Surgeons accreditation system [41].

4.5 Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), a collaboration between the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery, has established guidelines for the care of bariatric surgery patients. The standards address the full range of care, from surgeon volume to facility preparedness [42]. Perhaps the biggest change is a requirement of continuous quality improvement initiatives and proper training and education to decrease FTR. MBSAQIP provides national benchmarks for bariatric surgical outcomes, further advocating better patient care. Specific required standards aimed at decreasing FTR and mortality rates include the following:

- The center must have a metabolic and bariatric surgery committee that provides a venue for sharing best practices, maintaining ethical and quality standards, reviewing all adverse events in a timely fashion, and fostering a culture to improve patient care. This committee must convene at least three times per year. This standard provides an opportunity to analyze FTRs, consider root causes, and initiate quality improvement initiatives to improve the center's structure and process, and thereby help prevent future FTR events. Here again, note the emphasis on systems and processes, promoting a culture of safety.
- The center must have a process of formally educating all of the center's staff (nurses, physicians, and surgeons) interacting with metabolic and bariatric surgery patients, with a

focus on patient safety and early complication recognition.

- Written protocols for both nurses and surgeons must detail the rapid communication and response to initial vital sign alterations that are suggestive of a complication in order to minimize treatment delays. Notice the emphasis on educating all team members throughout the center, fostering communication, and minimizing intervention delay.
- The program must develop inclusion and exclusion criteria for patient selection, including types of procedures performed and patient operative risk. Notice the consideration of available resources and judgement as to situations where operation intervention is too risky.
- A trained clinical reviewer must be dedicated to entering short-term and long-term data in the national data registry. The collected data allows the center to compare its outcomes with national averages and identify targets for improvement.
- Surgeon credentialing requires a minimum annual volume, critical self-assessment of outcomes as determined by metrics from an acceptable data registry, participation in at least two quality meetings annually, and completion of yearly metabolic and bariatric surgery-specific continuing education.
- An Advanced Cardiovascular Life Support (ACLS) qualified healthcare provider must be on site at all times when patients are present, and the critical care unit must be staffed by a physician credentialed to manage critically ill patients and must be equipped for patients with morbid obesity. Note the emphasis on having available resources for rapid escalation of care.
- Patient education protocols must emphasize postoperative lifestyle changes which will help prevent complications and help in early recognition of signs and symptoms of complications. Notice the emphasis on education, involving patients in an early recognition of complications.
- Perioperative care protocols with standardized postoperative order sets must emphasize complication prevention and processes for the early recognition and treatment of warning signs of complications.
- The center must participate in at least one quality improvement initiative per year. Notice again the emphasis on developing a culture of safety and improved quality of care.

4.6 Tertiary Care and Transfer to a Higher Level of Care

Escalation of care may require transferring a patient to another facility capable of providing a higher level of care. The MBSAQIP Standards require centers to have a plan for safe transfer of a patient to a higher level of care if the center is unable to manage the full range of potential complications. Again notice the provision for escalation of care and attempt to minimize delays by having transfer agreements already in place. The plan must include a signed written transfer agreement with a tertiary center if the primary center lacks the following resources: a critical care unit, endoscopy capability, interventional radiology capability, and specialized consultant services including pulmonology and/or critical care, cardiology, and nephrology.

Generally speaking, a transfer agreement is a legal document between two centers that describes the necessary patient criteria for transfer to be deemed appropriate, the logistics of transfer initiation and execution, and handling of follow-up care. The agreement primarily serves to facilitate escalation of care in a crisis situation with minimal delay. The agreement may also address miscellaneous medicolegal and billing issues.

In order to help prevent the need for transfer, the MBSAQIP Standards require initiation of operative care for higher risk patients at a tertiary center. Toward this end, the MBSAQIP program designates centers as Low Acuity Centers, Comprehensive Centers, or Comprehensive Centers with Adolescent Qualifications. Low Acuity Centers are defined as those performing 25–49 stapling procedures annually, and are only approved to perform procedures on low-acuity patients.

The MBSAQIP program defines low-acuity patients as greater than or equal to 18 years old and less than 65 years old, male patients with a body mass index (BMI) less than 55 kg/m^2 and female patients with a BMI less than 60 kg/m^2, patients without organ failure or need for organ transplant (e.g., severe congestive heart failure, end-stage renal disease, severe liver disease) or history of organ transplant, patients who are ambulatory, and patients who are not seeking revisional intra-abdominal bariatric procedures.

Other risk stratification systems may help to identify patients for whom initiation of care should commence at a tertiary center. DeMaria and colleagues developed an obesity surgery mortality risk score, which incorporates the following criteria: BMI greater than or equal to 50 kg/m^2, male gender, diagnosis of hypertension, risk factors for pulmonary embolism (previous venous thromboembolism, indwelling IVC filter, obesity hypoventilation, and pulmonary hypertension), and age greater than or equal to 45 years old [43]. Using this scoring system, Thomas and colleagues found that in patients with one or less of these risk factors, the mortality rate was 0.26 %, but in patients with 2–3 risk factors the mortality rate increased to 1.33 %, and in patients with 4–5 risk factors the mortality rate increased to 4.34 % [44]. In general, patients are probably also at significantly higher risk of perioperative complications when they have a history of extensive prior open abdominal operations, prior large ventral hernia repair with mesh, or a long history of poorly controlled comorbidities.

4.7 Conclusion

The paradigm shift from paternalistic and anecdotal care to evidence-based standard of care is evolving [21]. While great progress has been made in overall patient survival, the challenge of uncomplicated surgery followed by uncomplicated recovery will remain the goal of a health care system ultimately controlled by fallible humans humbly working together to achieve perfection.

4.8 Self-Assessment Questions

Please choose the statement that best completes the sentence

1. Failure to rescue
   (a) Was created by the Institute of Medicine as a quality measure to help compare high- and low-volume centers.
   (b) Is defined as death following an adverse occurrence.
   (c) Is a key factor in current Center for Medicare and Medicaid hospital reimbursement.
   (d) Should replace mortality rate as a quality measure.
2. Early warning systems and rapid response teams
   (a) Have essentially eliminated unexpected in-hospital death after surgery.
   (b) Have activation parameters that often do not notify advanced providers until a complication is in its final stages.
   (c) Should be activated based on strictly defined objective measures, such as vital signs.
   (d) Decrease the number of ICU transfers shortly after implementation.
3. The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)
   (a) Restricts metabolic and bariatric operations to only high-volume centers.
   (b) Would require a 60-year-old female patient with a body mass index (BMI) of 55 kg/m^2, diabetes, hypertension, obstructive sleep apnea, and wanting Roux-en-Y gastric bypass to have her operation at a comprehensive metabolic and bariatric surgery center.
   (c) Requires centers to have a metabolic and bariatric surgery committee that meets at least quarterly.
   (d) Requires surgeons to perform a certain minimum number of metabolic and bariatric operations per year.

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5 Management of the Patient with a History of Bariatric Surgery and Abdominal Pain in the Emergency Department

Aurora D. Pryor and Dana A. Telem

The proper evaluation and management of bariatric emergencies depend on resource availability. In the emergency department, proper management includes a baseline level of practitioner awareness of bariatric complications and anatomic considerations. Postoperative bariatric patients may have undergone one of many procedures, each with different anatomy and risks. The workup of the patient's abdominal pain may also require the availability of plain radiography, CT scanning, and a trained radiologist who can perform and read upper GI series. In order to properly treat these patients, the clinician should be aware of the relevant anatomy, physiology, and procedure-specific complications. If the treating physician is unsure regarding possible bariatric issues, they should consult a trained bariatric surgeon. The lack of any of the above elements would represent a critical void in the complete care of bariatric patients, and patients with non-life-threatening issues should be transferred to a high-volume bariatric center when safe and feasible. The majority of bariatric surgery in the USA is performed at high-volume centers that are usually located in populated, urban areas, which poses a challenge if these patients present to a smaller institution in a more rural environment and reinforces the need for more physicians to understand the spectrum of abdominal complaints relevant to previous bariatric surgery [1, 2]. It is critical that all general surgeons in the community are aware of potential life-threatening complications that can occur in this patient subset and possess skills to acutely manage. In certain cases, a delay while waiting on transfer to another institution may result in severe morbidity or death. Stabilization of the patient remains the first priority before any transfer or definitive treatment. The patient should be thoroughly evaluated by the covering general surgeon and a surgeon-to-surgeon discussion should occur prior to interinstitutional transfer.

Timely management is particularly true when there is small bowel obstruction with suspicion of internal hernia following Roux-en-Y gastric bypass. Increasing the amount of time to intervention poses incrementally higher risk of small bowel necrosis, ischemia, and death that is often preventable. While not all general surgeons perform bariatric surgery, most should be able to successfully reduce an internal hernia and relieve the imminent danger to the bowel. While the availability of bariatric surgeons may facilitate the treatment of these patients, most institutions currently possess the capability to treat these

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patients in the emergent setting. Further, the safe and expeditious management of these patients does not require laparoscopic intervention, although a laparoscopic technique is preferable if the surgeon is proficient.

Abdominal pain in the postoperative bariatric patient must always be taken seriously, as it may represent a life-threatening pathology. When evaluating a patient in the acute setting, an accurate history is essential. In addition to the history and timing of the patient's current symptoms, more information regarding the specific type of bariatric procedure, timing of presentation in relation to the procedure, social history (e.g., alcohol, drugs, tobacco), and previous medical history should be obtained. The three most common types of bariatric surgery performed today include the Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and adjustable gastric band (AGB). Although other procedures have been or are still performed in a smaller subset of patients (duodenal switch, jejunal-ileal bypass), we will limit our discussion to these three given their prevalence in the current patient population.

5.1 Laparoscopic Adjustable Gastric Band

Each procedure carries its own particular set of postoperative risks and anatomic considerations. The laparoscopic adjustable gastric band (Lap Band) is a silicone cuff, placed around the fundus of the stomach, which can be tightened or loosened by injecting saline through a subcutaneous port. First devised in 1986, the inflatable device received FDA approval in 2001 and was immediately popular due to its ease of insertion and same-day discharge from the hospital [3]. The effect of the band is the creation of a restrictive gastric pouch that limits the amount of food that can be ingested. While these patients can expect an average of 50 % of their excess body weight (EBW) lost, long-term data has shown a higher incidence of weight regain and this technique has become less popular in recent years [4]. Nevertheless, many patients currently have gastric bands in place, and the device does carry a certain degree of risk.

The most common complications of the band itself include band slippage/migration, overtightening (proximal gastric obstruction), and erosion into the stomach [4]. Additionally, an infectious process involving the cuff, as may be secondary to erosion, may migrate up the tubing to the subcutaneous port, thereby producing a secondary cellulitis or abscess requiring removal the port and cuff system [4–6]. Many of these complications are similar to other implantable foreign bodies.

A gastric band patient presenting to the emergency department with abdominal pain should be immediately evaluated and a thorough physical examination performed. The practitioner's exam should rule out any signs of generalized peritonitis, which warrants prompt surgical exploration. While a benign exam is reassuring, it should not preclude additional workup.

The patient's clinical history should be gathered with particular emphasis on the maintenance of the gastric band, including a history of band placement, inflation, deflation, and any previous revisions. If the patient reports dysphagia or food intolerance, the time period and relation to device manipulation should be elucidated. If the patient is acutely obstructed, the band port should be accessed with a non-coring needle and all fluid removed prior to any other extensive workup. If the primary complaint is abdominal pain, the nature and onset of the pain can point toward an acute pathology or a progression one.

In addition to a primary evaluation and basic laboratory studies, radiographic studies may be obtained emergently. The first study to be gathered should be an upright chest X-ray, preferably as part of an obstructive abdominal series. This modality is fast and easy to obtain, and enables the practitioner to triage the patient should any ominous findings be seen. These findings include pneumoperitoneum or band slippage/migration. Easily seen radiographic findings that may indicate the presence of a slipped band include the presence of an "O" sign (the circular ring of the band easily visible), an air-fluid level in the proximal stomach,

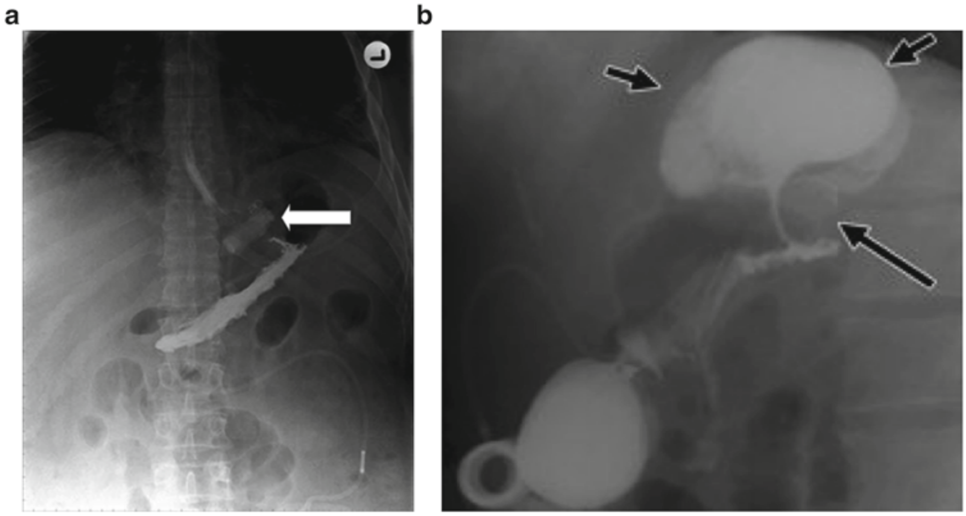

Fig. 5.1 (**a**, **b**) Easily seen radiographic findings that may indicate the presence of a slipped band include the presence of an "O" sign (the circular ring of the band easily visible), an air-fluid level in the proximal stomach, or the location of the band greater than 3 cm below from the diaphragm

or the location of the band greater than 3 cm below from the diaphragm (Fig. 5.1a, b).

While the basic abdominal radiograph is a good initial study, an upper GI series will give the same information plus the real-time movement of material through the stomach. This modality can help diagnose a stricture/overtightening, gastric perforation, as well as issues related to delayed gastric emptying. However, due to the "real-time" nature of the study, an upper GI series is dependent on the skill of the radiologist performing and interpreting the study.

Computed tomography is rapidly gaining favor in most institutions as a quick and reliable diagnostic modality. With the addition of oral contrast, a CT scan may obtain much of the same information as an upper GI series, as well as three-dimensional visualization of the abdominal viscera and any fluid collections or signs of inflammation. It does, however, miss the motility issues demonstrated on upper GI. CT should also be reserved for patients who are hemodynamically and clinically stable.

Using the described diagnostic modalities, a definitive diagnosis should be obtained. Should the source of the patient's symptoms be due to obstruction at the band, the treatment is simply deflation of the gastric cuff via the subcutaneous port, as mentioned above. Evaluation of the patient post-intervention can then be pursued by clinical resolution or radiographic means. If the patient's pain resolves there is no need to emergently remove the band; the patient can be safely discharged with referral to their original bariatric surgeon or a local bariatric specialist. If there is concern for ischemia, foreign body, or device erosion, however, an upper endoscopy should be obtained to definitively diagnose and possibly treat the pathology. Emergent surgery is rarely required for a band erosion; the erosive process is typically progressive over weeks or months, giving ample time to contain any perforation. In an unstable patient, however, band removal with extensive drainage should stabilize a patient for transfer to a bariatric center. Urgent surgical intervention on gastric bands should be reserved for persistent symptoms/obstruction, as well as adequate clinical suspicion for bowel ischemia or necrosis. It is also appropriate if band removal for complications is desired. Further, a surgical consultation and evaluation should always be obtained, even if the patient does not require emergent surgical intervention.

5.2 Laparoscopic Sleeve Gastrectomy

The laparoscopic sleeve gastrectomy has increased in popularity in recent years owing to its efficacy (average 60 % EBW loss), relative ease, and rapid postoperative recovery [7]. The procedure was first described by Marceau in 1993 as the first stage of a biliopancreatic diversion [8]. In super-obese individuals, the diversion was performed as a two-stage procedure, with the sleeve gastrectomy portion first. Patients experienced such significant weight loss prior to the second stage that many surgeons began performing the sleeve gastrectomy as a stand-alone procedure. Since 2010, laparoscopic sleeve gastrectomy has become the bariatric procedure of choice in many high-volume centers [2].

The effectiveness of sleeve gastrectomy is attributed to both a restrictive effect from removal of significant gastric reservoir and decreasing the hunger stimulus by reducing the secretion of ghrelin [9]. Normally, ghrelin levels rise prior to a meal and subsequently fall; this cycle does not occur after sleeve gastrectomy, thereby inhibiting a key stimulus of hunger. This can help explain how the procedure produces outcomes superior to the Lap Band [9]. However, despite greater efficacy, the procedure does carry its own set of complications. These patients may present postoperatively with intraabdominal or intragastric bleeding, gastric stricture, gastric volvulus, or leak from the gastric staple line.

Upon presentation to the emergency department, postoperative sleeve gastrectomy patients should be evaluated in a manner similar to gastric band patients, the key difference being the absence of an implanted foreign body and its potential complications. As always, a thorough history and physical should be performed, taking great care to elucidate the nature and timing of the abdominal pain, as well as the patient's ability to tolerate liquids or solids [10]. The progression of radiographic studies mirrors the workup of the gastric band patient, with any ominous findings indicating free perforation or bowel ischemia prompting urgent surgical exploration.

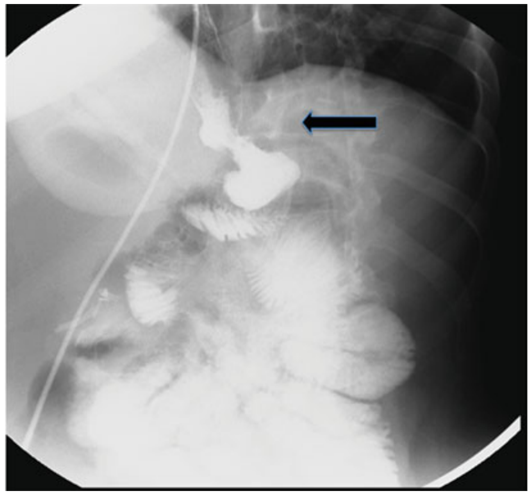

Fig. 5.2 Leak may present early or late after sleeve gastrectomy

The treatment of many post-sleeve complications is a rapidly changing algorithm, the cause of which is the rapid advancement of endoscopic and "interventionalist" techniques and the skill of those who perform them. Endoscopic intervention can successfully treat many post-sleeve complications. Paradoxically, leak may present early or late after sleeve gastrectomy (Fig. 5.2). A number of endoscopic devices, including over-the-scope clips, fibrin sealant, and endoscopic suturing, have been moderately successful in promoting closure of the perforation [11, 12]. Additionally, the placement of covered stents over the site of perforation can help to decrease the extravasation of gastric contents through the perforation, thereby promoting healing. Should these efforts remain unsuccessful, the patient may be placed on prolonged oral restriction with parenteral nutritional support [13]. For these patients, surgical management may be necessary. Endoscopy is also the first-line therapy for endoluminal bleeding, which can be controlled by electrocautery or endoscopic clips in a similar fashion as the treatment of bleeding peptic ulcers.

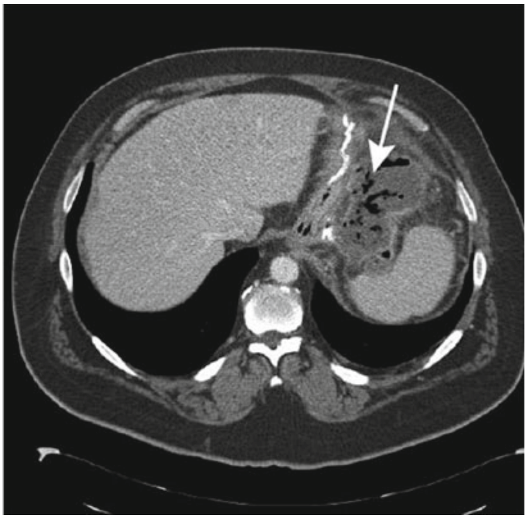

Fig. 5.3 Signs of sepsis and fluid collection observed on imaging may necessitate a drainage procedure and antibiotic therapy

If a patient presents with signs of sepsis and a fluid collection observed on imaging (Fig. 5.3), a drainage procedure is required in addition to antibiotic therapy. If the collection is accessible via the skin, a percutaneous drainage procedure may be performed. However, in the event a drainage window cannot be obtained, operative drainage is required. Patients should be widely drained. Fistulas from the leak may be controlled with a t-tube or urinary catheter to facilitate transfer to a bariatric center. Similarly, a patient who presents with an intraperitoneal hematoma from the gastric staple line may require operative exploration if they are hemodynamically unstable or show continuing signs of bleeding.

5.3 Laparoscopic Roux-en-Y Gastric Bypass

The "gold standard" bariatric operation remains the Roux-en-Y gastric bypass, which is typically performed laparoscopically [14]. The first laparoscopic bypass was performed in 1993. The first open gastric bypasses were performed in the 1960s, with many of these patients still alive today [15]. The surgery redirects the alimentary stream, and creates a smaller gastric reservoir. The gastric pouch, usually 15–30 cm^3 in volume, is created using staplers. The small bowel is then divided at the proximal jejunum. The distal limb is then anastomosed to the gastric pouch (creating the "Roux limb"), while the proximal (or biliopancreatic) limb is anastomosed 100–150 cm downstream. The benefit of this diversion is that the enteric contents travel between the gastric pouch and the distal anastomosis without any contact with bile or pancreatic enzymes, thus limiting its nutritional absorption [14].

By rerouting the bowel, several problems can arise. In addition to the numerous nutritional deficiencies that can present postoperatively, several acute anatomic pathologies may develop [16]. The new anatomy of the small bowel creates 2 or 3 new sites of potential internal herniation, all of which may lead to small bowel obstruction or strangulation [17, 18]. The most significant of these is Petersen's defect, which is the space created between the mesentery of the Roux limb and the transverse mesocolon, transverse colon, and retroperitoneum. The advancement of laparoscopic surgery initially leads to an increase in internal hernias through this and other sites, owing to decreased intraabdominal adhesions to hold the bowel in place, thus leading most laparoscopic surgeons to suture these defects closed [14]. Despite closure, it is still possible to develop internal herniation. Bowel trapped in these locations may lead to closed loop obstruction or obstruction of only the biliopancreatic limb as well as alimentary tract obstruction.

Both of the new anastomoses (gastrojejunostomy and jejunojejunostomy) created in the gastric bypass may also be complicated by stricture formation. If this develops at the gastrojejunostomy, the patient may present with progressive dysphagia and oral intolerance. However, if it develops in the jejunojejunostomy, it creates an obstruction of the biliopancreatic limb and gastric remnant, which can progress to necrosis and perforation if severe and/or untreated [16]. These patients may only complain of "vague" epigastric or mid-abdominal pain, but a dilated gastric remnant and biliopancreatic limb should be seen easily on imaging.

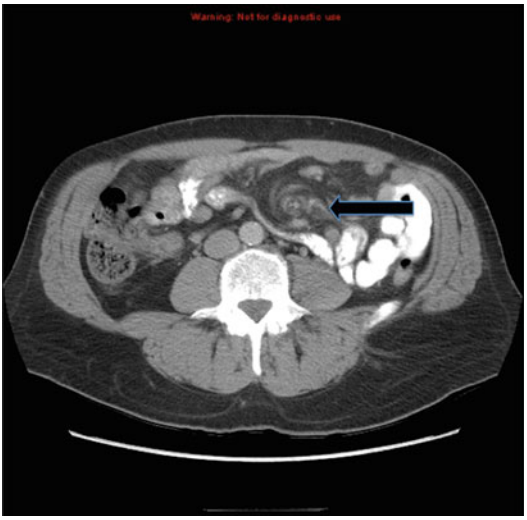

Fig. 5.4 In the post-bypass patient, abnormal findings may need to be investigated via diagnostic laparoscopy

A gastric bypass patient presenting acutely with abdominal pain is a surgical emergency until proven otherwise. Since many of the complications after gastric bypass can rapidly progress to bowel perforation or ischemia, the amount of time until intervention can be critical [16, 18]. Surgical practitioners should always maintain a low threshold for performing a diagnostic laparoscopy in these cases.

As a diagnostic algorithm, the post-bypass patient should be urgently evaluated and examined by the emergency department staff and the surgical team. If the patient presents with signs of peritonitis, the patient should be taken to the operating room for exploration. If the exam is benign, the next step is to proceed with plain abdominal radiographs. Abnormal findings warrant urgent surgery unless recent exploration was without evidence of internal hernia. However, negative findings still warrant further workup with CT scan; abnormal findings should be investigated via diagnostic laparoscopy (Fig. 5.4). In the case of normal CT findings, however, the patient could be closely observed with serial abdominal exams or taken to the OR for exploration, depending on the patient's complaints and symptoms. It is important to note that while a negative laparoscopy subjects the patient to the risks of any laparoscopic procedure, it is superior to possible necrotic bowel and short-gut syndrome. A negative CT scan should not preclude surgical exploration in a symptomatic patient [19].

Much like the emergent surgical management of sleeve gastrectomy leaks, the management of gastric bypass leaks in the septic patient should be centered on adequate drainage and control of the enteric contents. Leaks may occur at any of the staple lines in the gastric pouch, gastric remnant, gastrojejunostomy, or jejunojejunostomy. In the acute setting, control of the leak may include the placement of adequate intraperitoneal drains and the evacuation of any fluid collections [20]. Marginal ulcers at the gastrojejunostomy anastomosis may present months or years postoperatively and, while surgical revision may be required, the use of drainage in the emergent setting is acceptable. While this does not constitute definitive treatment, it can stabilize the patient for subsequent transfer to a high-volume bariatric center.

5.4 Conclusion

The increasing numbers of patients who are presenting after bariatric surgery underscores the need for practitioners of all fields to educate themselves in the various procedures and complications. This is especially true for practitioners in the fields of emergency medicine and general surgery. For post-bariatric patients presenting with acute-onset abdominal pain, timing to intervention is a critical variable that may be the difference between recovery and mortality. If the situation requires emergent intervention, most institutions have the capability within general surgery to address the emergent situation and stabilize the patient. Transfer of the stabilized patient to a center with key diagnostic and therapeutic resources, such as advanced endoscopy, critical care services, and a trained bariatric surgeon, provides the optimal treatment paradigm.

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6 Postoperative Management of Obesity-Related Diseases

Toms Augustin and Ann M. Rogers

A host of medical conditions and diseases are related to and tend to coexist with obesity. The long-term follow-up and management of the more common of these conditions after weight loss surgery (WLS) are discussed here, with emphasis on the more complicated aspects of treatment that may arise.

6.1 Obesity-Related Diseases

A host of medical conditions and diseases are related to and tend to coexist with obesity. The long-term follow-up and management of the more common of these conditions after weight loss surgery (WLS) are discussed here, with emphasis on the more complicated aspects of treatment that may arise.

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6.1.1 Diabetes Mellitus

The effect of WLS on remission and resolution of type 2 diabetes (T2DM) is in large part the reason for the increased acceptance and advancement of the field. The short-term and medium-term effects of WLS on T2DM remission are well established, and an ever-increasing body of literature is exploring the long-term (beyond 5 years) durability of diabetes improvement after WLS. High-quality randomized controlled trials have shown remission, defined as HbA1c < 6.5 % without medications, to be about 67–75 % after Roux-en-Y gastric bypass (RYGB) [1]. A detailed review of the mechanisms contributing to this improvement is beyond the scope of this chapter but involves both weight-loss-dependent- and -independent enhancement of insulin secretion and hepatic sensitivity as well as changes in gut hormones and bile acids [2].

Immediate Postoperative Management: The steep decrease in blood sugar after RYGB and biliopancreatic diversion (BPD) in the immediate postoperative period require a decrease in dosage or cessation of diabetes medications to prevent symptomatic hypoglycemia. Moderate glycemic control (140–180 mg/dL) in inpatients with diabetes may be safer than hypoglycemia from aggressive treatment. Patients on insulin almost always require dose adjustments with decreases, often by 75 % or more, preferably using a sliding scale of short-acting insulin [3, 4]. Oral hypoglycemics

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Table 6.1 Diabetes definitions on WLS follow-up

Definitions of glycemic outcomes after bariatric surgery	
Outcome	Definition
Remission (complete)	Normal measures of glucose metabolism (A1C <6 %, FBG <100 mg/dL) in the absence of antidiabetic medications
Remission (partial)	Sub-diabetic hyperglycemia (A1C 6–6.4 %, FBG100–125 mg/dL) in the absence antidiabetic medications
Improvement	Significant reduction in A1C (by >1 %) or FBG (by >25 mg/dL) OR reduction in A1C and FBG accompanied by decrease in antidiabetic medications requirement (by discontinuing insulin or one oral agent, or 1/2 reduction in dose)
Unchanged	The absence of remission or improvement as described above
Recurrence	FBG or A1C in the diabetic range (≥126 mg/dL and ≥6.5 %, respectively) OR need for antidiabetic medication after initial complete or partial remission

A1C, glycated hemoglobin, *FBG* fasting blood glucose
Data from [9, 10]

can often be stopped altogether in the immediate postoperative period. Among these medications, metformin appears to be the safest in the postoperative period. Sulfonylureas and meglitinide should preferably be avoided due to significant risk of hypoglycemia. At the time of discharge, up to 30 % of patients with diabetes who undergo RYGB or BPD will no longer require insulin and will be appropriately controlled on diet alone [5].

Long-Term Management: Patients with T2DM who have undergone WLS need lifelong lifestyle support and medical monitoring [6]. Management should start with appropriate classification of disease state postoperatively (Table 6.1). On average, the remission rate of T2DM after WLS is 72 % at 2 years, 61 % at 5 years, 38 % at 10 years, and 30 % after 15 years [7, 8]. This indicates resolution and remission may not be durable, particularly in the face of recidivism or weight regain. There are no consensus guidelines for diabetes management specifically oriented to the post-bariatric patient. ADA recommendations can, however, be extrapolated to this patient population. Patients in both complete and partial remission need routine follow-up with an endocrinologist or primary care physician (PCP). Lifestyle interventions, including regular physical activity and good food choices, are standard recommendations after WLS; these are also key to maintaining long-term glycemic control. Support groups may additionally enhance compliance [9, 10].

Relapse and its Management: The reemergence of hyperglycemia is seen more commonly with pure gastric restrictive procedures such as adjustable gastric band (AGB) and vertical sleeve gastrectomy (VSG) than with RYGB or BPD. Additionally, relapse is associated with initial duration and severity of diabetes as well as weight regain or inadequate weight loss [7]. Detailed management of relapse is beyond the scope of this section, but initial enquiry into modifiable factors such as compliance with diet and lifestyle recommendations, psychological factors such as resurgence of depression, presence of eating disorders, and adherence to scheduled visits is an excellent starting point. In patients without weight regain but who experience diabetes reemergence, β-cell exhaustion may be the reason and in these patients early use of sulfonylurea and insulin in addition to diet and exercise can be considered (Fig. 6.1).

Laboratory Studies: Laboratory evaluation is based on standards established for patients with diabetes overall, there being no separate standards for the post-WLS patient. Due to the risk of relapse, regular and lifetime follow-up is important. Patients using insulin should monitor blood glucose three or more times daily. HbA1C testing should be done at least two times a year in patients with stable glycemic control, including patients in partial or complete remission. HbA1C should be considered quarterly in patients whose treatment has changed or who are not meeting glycemic goals [6].

Medications: Metformin remains the first line of treatment, as it has been shown to improve insulin sensitivity beyond what is attained by RYGB [11]. In contrast, thiazolidinediones may hamper weight loss. Sulfonylurea, while sometimes causing hypoglycemia and aggravating

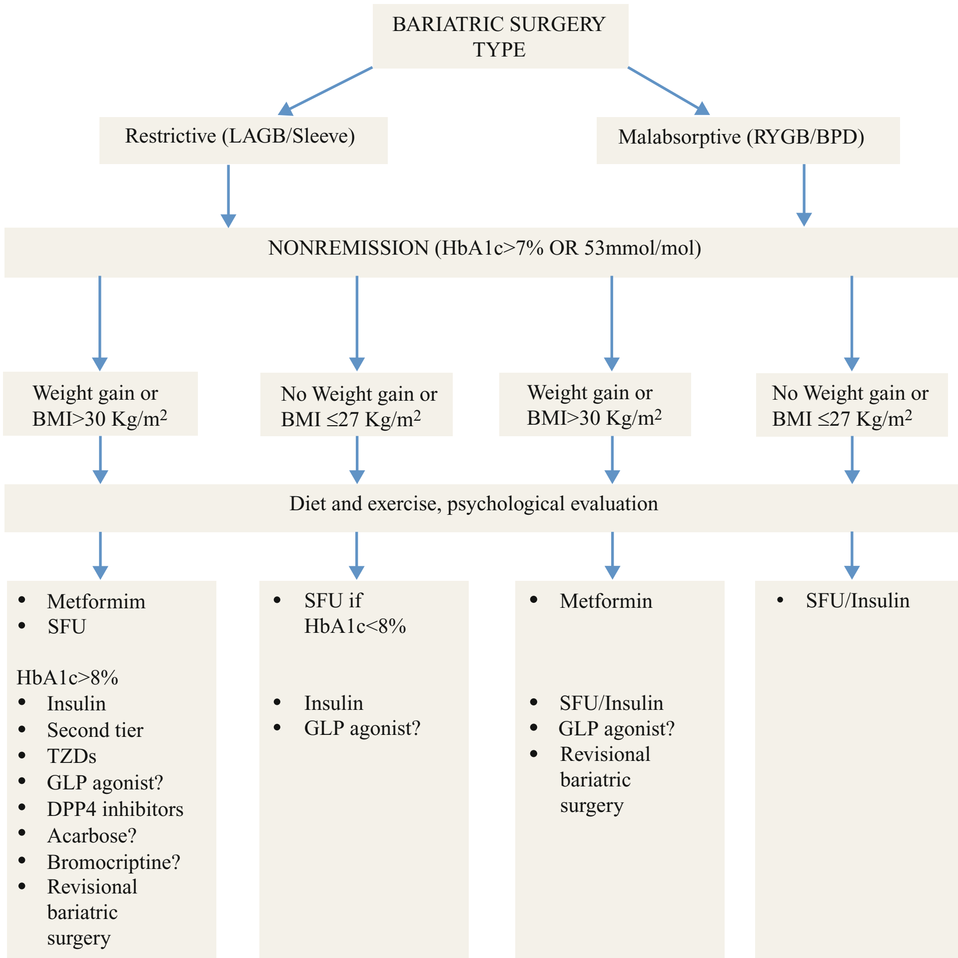

Fig. 6.1 Algorithm for management of residual diabetes following bariatric surgery. *LAGB* laparoscopic adjustable gastric banding, *RYGB* Roux-en-Y gastric bypass, *BPD* biliopancreatic diversion, *SFU* sulfonylurea, *TZD* thiazolidinedione, *GLP* glucagon-like peptide-1, *DPP4* dipeptidyl peptidase-4 inhibitor. Assessment of preoperative diabetes: *Type 1* vs. *type 2* DM, autoimmune status; diabetes duration and glycemic control; presence of microvascular complications; insulin use vs. oral agents vs. diet controlled (adapted from Kashyap SR, Schauer P. Clinical considerations for the management of residual diabetes following bariatric surgery. Diabetes, obesity and metabolism 2012;14:773–79, with permission)

dumping syndrome in the early postoperative period, improves and supplements the effect of metformin in patients with relapse, particularly in those with weight regain. Insulin therapy should be considered in patients who have inadequate control despite aggressive oral therapy [12].

Follow-Up for Diabetes-Related Complications: WLS leads to a decrease in both micro- and macrovascular complications related to diabetes [8]. While the improvement of diabetes-related nephropathy has been demonstrated in both retrospective [7] and prospective studies [13] the effect on diabetic retinopathy is less clear [14]. There is also a dearth of literature exploring the effect of WLS on peripheral neuropathy. Follow-up and management of microvascular complications of diabetes following bariatric surgery should follow ADA guidelines [15].

6.1.2 Hypertension

The study of the effects of WLS on improvement and remission of hypertension (HTN) is challenging for many reasons, including the variable indications for starting antihypertensive medications such as for migraines, atrial fibrillation, and after myocardial infarction. Further, there are innumerable medications in the market and a wide range of definitions used to quantify HTN, pre-HTN, and hypertensive crisis. Additionally, "normal" values of high blood pressure may vary with age. Currently there is no standard for HTN or stage of HTN consistently used in studies of WLS. Further, there is no published randomized controlled trial (RCT) of WLS studying HTN as the primary outcome. Available research has shown varied and conflicting results: one high-quality RCT with diabetes as the primary outcome showed a significant reduction in antihypertensive medication use at 1 year without a significant change in blood pressure values [16] and a second RCT showed no benefit at 2 years [17]. Thus it is possible that the effects of WLS are more pronounced in the short term than in the long term. This differential effect of WLS on HTN with early improvement and subsequent relapse has additionally been suggested in the Swedish Obesity Subjects (SOS) study group [18]. However, this effect may vary with different surgery types, with suggestion of a high long-term rate of cure after BPD [19]. Additionally, in the absence of long-term benefit through nonsurgical means, WLS continues to be the best option with at least significant effects on medication reduction usually achieved and sustained in the short and long term [20].

Immediate Postoperative Management: Antihypertensive medications are commonly discontinued in the immediate postoperative period in many patients for various reasons including limited oral intake and increased risk of dehydration. Diuretics are thus preferably stopped. For the same reason, angiotensin-converting enzyme inhibitors are not preferred. Intravenous betablockers may be used based on serial monitoring of blood pressure in the immediate postoperative period. After discharge and upon resuming adequate oral intake, blood pressure should be measured weekly and medications resumed, often at lower doses.

Long-Term Management: Due to current evidence suggesting a possible relapse of HTN in the long term after WLS, patients need to be routinely followed especially in the first 2–5 years after surgery. Medication management of HTN should be tailored based on age, race, and other coexisting comorbidities including diabetes and coronary artery disease, and should be consistent with current guidelines. There are no published guidelines on the specific management of HTN in the post-WLS population. Management is based on established guidelines in adults [21].

6.1.3 Obstructive Sleep Apnea

There is a high prevalence of obstructive sleep apnea (OSA) in the severely obese patient population, ranging from 38 to 88 % [22–25]. Self-reported remission of OSA after WLS is about 60 % at 1 year but varies with age, gender, and type of surgery undergone [26]. A recent meta-analysis also found that the reduction in OSA after WLS is superior to that from nonsurgical weight loss [27]. However, data regarding resolution of OSA is plagued by underdiagnosis, lack of direct correlation between weight loss and resolution of OSA, poor compliance with recommended treatment, use of subjective and self-reported improvement as resolution, unclear guidelines on repeat testing after surgery, sparse postoperative testing data available, and a lack of RCTs [25, 28, 29]. While multiple screening tools are available, such as the Epworth sleepiness score and the Berlin questionnaire [30], none have been validated in the severely obese population. Polysomnography is the only currently valid test to determine severity of OSA. Diagnosis rests on at least five apneic or hypopneic episodes per hour. Severity is classified based on the apnea hypoxia index (AHI) or respiratory disturbance index; <5 events is normal, 5–14 is mild, 15–29 events is moderate, and ≥ 30 events is severe.

Preoperative Management: The management of OSA starts with appropriate testing and treatment before surgery. Patients should be seen by a pulmonologist or sleep specialist, and undergo a polysomnogram to enable the diagnosis and provide recommendations for management with continuous positive airway pressure (CPAP). While no recommendations exist about the duration of time a patient should be on CPAP prior to surgery, optimal preparation should allow time for the patient to become accustomed to and consistently use the device.

Immediate Postoperative Management: There is no risk of increased anastomotic complications in the immediate postoperative period after gastric bypass related to use of CPAP [31]. American Society of Anesthesiology (ASA) guidelines for the general surgical population with OSA recommend continuous pulse oximetry as well as availability of an emergency airway cart in postoperative patients for at least 3 h beyond standard observation time of non-OSA patients, or for as long as obese patients are considered to be at risk [32]. In reality, postoperative monitoring of WLS patients depends on multiple factors including details of the operation, open versus laparoscopic surgery, severity of OSA, age, presence of other pulmonary disease, presence of other comorbidities, as well as capabilities at the institution. Most patients can be monitored on a general surgical floor. It may be good practice to request a respiratory therapy consultation based on institutional guidelines to optimize CPAP use, and to educate in the use of an incentive spirometer and respiratory maneuvers to decrease the risk of pulmonary events [33]. Higher risk patients may be better monitored in the critical care setting. This may include patients with a BMI greater than 60, age greater than 50, or severe OSA documented preoperatively [34, 35]. Additionally, male gender may confer a higher risk of complications requiring ICU monitoring [34, 35]. Patients using CPAP at home should continue to do so after surgery, with their own home device brought in for postoperative use in order to allow for appropriate fit and individualized settings.

Long-Term Postoperative Management: As discussed above, results regarding improvement of OSA vary based on the methods used to characterize the disease with self-reports showing greater improvement than objective testing based on polysomnogram. Based on a 2009 meta-analysis, resolution of AHI after surgery may be as high as 71 % [36]. However, the same study still showed significant residual disease with an AHI greater than 15 in 62 % of patients after surgery [36]. While short-term resolution of OSA may be as high as 83 % based on definition and follow-up methods used [37], some studies are now showing that these improvements may also be sustained long term [38]. Unfortunately, weight regain has been shown to be associated with a relapse of OSA symptoms [29, 39]. Thus it is important to consider retesting patients with weight regain after surgery, especially if they have recurrence of previously improved or resolved comorbidities. This is particularly important in the context of consideration for reoperative surgery. Again, it is important to be aware that subjective improvements in OSA may not correlate with objective improvement on polysomnographic testing, nor be predicted by significant weight loss. Thus diagnostic sleep testing should be obtained whenever possible after attaining stable weight loss or goal weight. This allows not only objective quantification of disordered sleep breathing but may also allow for retitration of CPAP, potentially increasing compliance [40].

6.1.4 Dyslipidemia

"Dyslipidemia" and "hyperlipidemia," which are used interchangeably in the literature, signify abnormalities in one or more lipid subfractions in the blood. Traditionally, it is quoted that hyperlipidemia affects up to 50 % of patients with obesity, although this number has been variable in studies of patients undergoing WLS [41–43]. Multiple factors make the study of hyperlipidemia in patients undergoing surgery challenging. This includes incomplete diagnostic data, lack of unifying definitions in studies, variable number of patients on pharmacologic treatment, and significant overlap of statin use for other medical conditions including patients with diabetes mellitus, Alzheimer's dementia, and stroke, to name a few [44]. The relationship of obesity to elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and triglycerides, (TG) and decreased high-density lipoprotein cholesterol (HDL-C), has been demonstrated in epidemiological studies [45, 46]. However, while the relationship of obesity to TG and HDL-C has been affirmed in more recent studies, the relationship to LDL-C has been questioned [47]. Meanwhile studies of weight loss surgery have continued to report improvement in all lipid fractions after bariatric surgery. Of the effects noted, the increase in HDL-C has been demonstrated more consistently compared to the decrease in LDL-C [41, 48]. This is clinically significant since bariatric surgery is one of the very few interventions that can lead to an increase in HDL-C. Thus the effect of obesity and weight loss on subfractions of lipoproteins is still being studied, and reliable and replicable data on the effect of WLS is lacking. The most recent American College of Cardiology guideline (2013) for management of dyslipidemia additionally deemphasizes laboratory measurement of lipid profile to guide treatment, which might lead to incomplete data further on [49].

Perioperative Management: The American Society for Metabolic and Bariatric Surgery (ASMBS) released standard reporting guidelines for various medical conditions around the time of bariatric surgery [9]. The guideline recommended complete fasting lipoprotein profile in all patients being considered for WLS. Screening in low-risk patients with non-fasting TC and HDL was noted as a secondary option with full fasting panel if TC is greater than or equal to 200 mg/dL or if the HDL is less than 40 mg/dL. The guideline additionally recommended complete fasting lipid profile after WLS. However, it is not established when the labs should be drawn and how often should they be drawn. The improvement in lipid profile after WLS happens in the first 6 months after surgery and study has shown a sustained effect at the 2-year mark [42]. It would thus make clinical sense to draw such profiles every 6 months for the first 2 years after surgery and annually thereafter, based on the common weight loss pattern after surgery. So while patients will commonly continue their medications immediately postoperatively further adjustments should be based on laboratory follow-up. A detailed review of medication management after WLS is beyond the scope of this chapter.

6.1.5 Stress Urinary Incontinence

Stress urinary incontinence (SUI) is commonly seen in the setting of obesity, with evidence that each five unit increase in BMI increases the risk for SUI by 20–70 % [50]. In addition, SUI disproportionately affects middle-aged and older women [51] and is therefore present to a significant degree in bariatric patients. For unclear reasons, some ethnicities are more significantly affected than others, with SUI seen more frequently in Hispanic and white women, compared to black and Asian women [51]. As with many obesity-related conditions, even modest weight loss through diet and exercise can significantly improve SUI, but by far the most dramatic effects are seen with WLS. Observational studies show a presurgical prevalence of SUI between 61 and 67 %, with a decrease to 12–37 % between 1 and 5 years postoperatively after a variety of operations [50]. Based on this, it seems unlikely that long-term management of SUI after WLS will be a significant issue for surgeons or PCPs. If it does not resolve entirely, it is likely to improve to a considerable extent and only requires ongoing lifestyle modification by the patient, as would be necessary in the lean population.

6.1.6 Other Respiratory Diseases

Obesity is associated with a variety of respiratory issues. Excess weight can limit chest wall compliance and decrease lung volumes, causing a restrictive ventilatory pattern and associated dyspnea on exertion [52]. This is more common with central obesity. Along with OSA and obesity hypoventilation syndrome as previously discussed, chronic obstructive pulmonary disease (COPD) is also associated with obesity and along with lower respiratory infections is currently tied as the third leading cause of death in the world [53]. In addition, asthma is more common and sometimes harder to treat in obese patients. One study showed that the prevalence of asthma was increased by 92 % in obese patients [54]. A prospective study of WLS patients showed significant improvements in asthma control and asthma-related quality of life in asthmatic patients after surgery [55]. Changes in inflammatory markers associated with asthma may be involved in such improvement, but have not yet been shown, in the small studies available, to be significantly altered after WLS. As with other obesity-related diseases, it is likely that COPD and asthma will improve or resolve after WLS, depending on the severity and associated causes of the disease process. Long-term management, therefore, is likely to be less problematic for patients undergoing WLS. Short-term management includes appropriate pulmonary toilette and use of inhalers on an as-needed basis.

6.1.7 Liver Disease

Nonalcoholic fatty liver disease (NAFLD) is now the most common cause of liver disease and cirrhosis in the USA [56]. NAFLD, unfortunately, is generally asymptomatic and patients may be unaware of its presence until it is incidentally diagnosed. In addition, there is no other proven effective treatment for NAFLD beyond weight loss [57]. However, there is significant evidence of improvement of obesity-related liver disease after WLS. A systematic review and meta-analysis of 15 studies with over 700 paired liver biopsies showed that after a variety of WLSs and at different time points (2–111 months), the proportion of patients with histopathologic improvement or resolution of steatosis was 91.6 %, in steatohepatitis was 81.3 %, and in fibrosis was 65.5 % [58]. Even in patients with preoperatively diagnosed severe liver disease including cirrhosis, there are multiple studies confirming that WLS can still be safely performed [59–61]. There is every reason to expect that, like other components of the metabolic syndrome, NAFLD and its spectrum of progression are likely to improve to a great extent in patients who are able to lose significant weight through WLS. There should be no need for long-term follow-up in most patients unless they have progressed to cirrhosis. Such patients should be followed in conjunction with a liver specialist.

6.1.8 Thyroid Disease

Thyroid hormone alterations have been noted in obese patients, but whether such changes lead to or are caused by obesity is unclear. Studies have shown a fairly linear correlation between increasing BMI and increasing thyrotropin (TSH) concentrations [62, 63]. In one study of a cohort of WLS patients, over 10 % were found preoperatively by laboratory evidence to have subclinical or previously undiagnosed hypothyroidism, which resolved with significant weight loss in all patients [64]. In a study of RYGN patients with preoperatively clinically diagnosed and treated hypothyroidism, 43.5 % of these patients were significantly improved after excess weight loss of 57 % [65]. Thyroid disease, which in the majority of obese patients is manifested as hypothyroidism, is potentially another weight-related comorbid condition that may improve or resolve after WLS. Thyroid function, in particular TSH and T4 levels, in such patients should be followed as long as necessary to assure clinical stability, and medications may be reduced depending on the effect of weight loss on laboratory studies.

6.1.9 Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is commonly seen in the obese population, and may be due to multiple factors including genetics, abnormal relaxation of the lower esophageal sphincter (LES), presence of a hiatal hernia, or increased intra-abdominal pressure from weight [66].

GERD can lead to a constellation of symptoms as well as asymptomatic findings, including Barrett esophagus, a precancerous condition. In addition, correlating symptoms with pathologic findings can be difficult [67], so reporting on the presence or resolution of GERD is sometimes problematic. Weight loss and lifestyle modification have been shown to improve symptomatic GERD in a significant percentage of patients. However, because of the subjective nature of the reporting of GERD symptoms and the lack of strict guidelines on the preoperative documentation of actual reflux in bariatric patients, improvement or resolution of GERD after WLS is difficult to quantify. The current literature consists of systematic reviews and subjective questionnaire studies in WLS patients, and the results differ depending on the type of surgery done.

A small retrospective review of VSG patients undergoing pre- and postoperative upper gastrointestinal swallow studies showed that 18 % more patients showed reflux after the procedure than had shown it preoperatively [68]. However, in a review of 15 studies on patients undergoing VSG, Chiu and colleagues reported that four studies showed an increased prevalence of GERD symptoms and seven showed a decreased prevalence after surgery [69].

A review of thousands of patients from the Bariatric Outcomes Longitudinal Database (BOLD) comparing VSG and RYGB patients showed that 84.1 % of VSG patients with GERD continued to have symptoms, with 15.9 % demonstrating resolution after surgery. In contrast, among the RYGB patients with GERD, 62.8 % showed resolution of symptoms within 6 months [70]. Several other studies have shown similar improvement of GERD symptoms after RYGB, which may be attributable not only to the decreased acid production in a proximal pouch but also to the fact that unlike VSG, RYGB in general does not alter the anatomy of the LES [66].

In AGB patients there are conflicting studies, with some showing improvement of GERD symptoms and a decrease in medication use after band placement, even in the absence of significant weight loss, perhaps due to augmentation of the LES by the implanted device [66]. Other studies have shown that while some symptomatic patients with GERD see improvement after AGB, a significant percentage of patients develop new-onset GERD symptoms afterwards [71]. Some symptoms are more difficult to quantify as representing actual GERD in band patients, but may in fact be related to esophageal dysmotility and dilation from maladaptive eating with the band.

In summary, GERD is a prevalent weight-related condition that may or may not improve or resolve after WLS. Because few WLS programs routinely require pH probe or manometric testing before or after surgery, the actual incidence and rate of improvement or worsening of GERD will be difficult to quantify. Therefore, the long-term management of GERD in WLS patients will require individual approaches for each patient, and the involvement both of the bariatric surgeon and the PCP.

6.1.10 Cardiovascular Disease

Autopsy studies in obese individuals have shown an excess of epicardial fat as well as ventricular fatty infiltration [72]. This leads to thickening and stiffness of the ventricle that results in dysfunction [73]. There is a linear relationship between BMI and systemic HTN, with ensuing left ventricular hypertrophy and dilatation, ultimately followed by cardiac failure [74]. The National Health and Nutrition Examination Survey (NHANES) showed that obese patients are 30 % more likely to develop heart failure than lean individuals [75], an entity referred to as obesity-related cardiomyopathy. OSA and obesity-hypoventilation syndrome, when present, are associated with systemic HTN, right ventricular dysfunction, pulmonary HTN, and atrial fibrillation [76, 77]. Changes in the heart's electrical conduction system related to excess weight, and cardiac effects of gut hormones related to obesity, are also under current study. In addition, obesity is a well-recognized risk factor for all aspects of the metabolic syndrome and therefore increases the risk for atherosclerosis and cardiovascular disease in general [78]. With the significant weight loss commonly associated with WLS, hypertension, diabetes, and dyslipidemia tend to improve in the majority of cases, and thereby cardiovascular risk is mitigated [79]. This was shown in the SOS study [80], with an improvement in various cardiovascular parameters at 10 years after surgery, and Christou's group [81] showed a 72 % decreased risk of cardiovascular disease at 5 years after surgery.

Improvement of cardiac parameters must be weighed against the increased operative risk of patients with underlying heart disease. Patients with concurrent cardiovascular disease should be managed postoperatively in conjunction with an appropriate cardiology team, and issues related to anticoagulation or aspirin use in patients with stents or atrial fibrillation must be individualized. The caution against use of nonsteroidal anti-inflammatory (NSAID) medications after operations such as RYGB should be counterbalanced by the additional heart protection conferred by low-dose aspirin, particular of the enteric-coated variety, in patients who have already been taking it prior to surgery.

6.1.11 Degenerative Joint Disease

The effects of increasing BMI on the weight-bearing joints have been examined extensively, in both clinical and radiologic studies. This includes back pain as well as pain in the hips, knees, and feet. There is good-quality evidence that WLS allows for reasonable reduction in back pain [82] in patients who suffered from this preoperatively. Similarly, there is evidence that significant weight loss through surgery leads to decreased pain and improved physical functioning in patients suffering from knee osteoarthritis [83]. Improvement in symptoms from degenerative joint disease (DJD) will likely allow patients to postpone or possibly avoid total joint replacement, and may actually make them candidates for joint replacement when it would not have been offered to them at a higher BMI. The need for long-term NSAID use is problematic for some bariatric patients, such as those who have undergone RYGB. This must be discussed prior to surgery in patients with severe symptoms, and alternatives should be offered in patients who will not be able to discontinue NSAID use.

6.1.12 Other Weight-Related Conditions

Multiple other medical comorbidities may be associated with severe obesity and may see improvement after WLS. This includes polycystic ovarian syndrome, infertility, abnormal sexual function, chronic kidney disease, acanthosis nigricans, pseudotumor cerebri, fibromyalgia, and a host of different entities. In addition, several cancers are associated with obesity; whether WLS prevents their occurrence or recurrence is under significant study. The long-term management of such conditions is beyond the scope of this chapter.

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7 International Perspective on the Endoscopic Treatment of Bariatric Surgery Complications

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The increasing prevalence of obesity has resulted in a rise in the number of complications unique to bariatric surgical procedures. Given the fact that almost all current techniques revolve around the esophagus and stomach, there is a need to attempt to resolve these complications endoscopically, decreasing morbidity. Thus, technically advanced endoscopic procedures have come into practice to help treat complications related to bariatric surgery, creating a specialty named bariatric endoscopy [1].

This chapter aims to present an overview of the role of bariatric endoscopy and the technical details of endoscopic surgery in the treatment of complications that may arise after the most commonly performed techniques of bariatric surgery: Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and laparoscopic adjustable gastric band (LAGB).

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7.1 Complications After Roux-en-Y Gastric Bypass

7.1.1 Anastomotic Stricture

A stricture is diagnosed when the lumen of the anastomosis is less than 10 mm in diameter, making it difficult for a standard endoscope (9.8 mm in diameter) to pass through (Fig. 7.1). The main presenting symptom is dysphagia, most commonly occurring after the introduction of solid foods [2]. The suggested causes of anastomotic strictures are ischemia, gastric hyper secretion, foreign body reaction to staples, or anastomotic surgical technique [2].

Upper gastrointestinal endoscopy is the diagnostic and therapeutic method of choice. In cases of early stenosis, occurring within the first week after surgery, initial administration of corticosteroids can reduce anastomotic edema; when this fails to improve symptoms, endoscopic therapy is indicated. Balloon dilation can be used in such cases with caution, using low inflation pressure to decrease the risk of perforation [3].

Initial treatment with through-the-scope (TTS) balloon dilation is done up to a maximum diameter of 15 mm when inflated. Subsequent balloon dilation sessions up to 20 mm may be used as needed. Studies indicate that a small number of sessions, between one and two, are often enough to resolve the stricture. Persistent stenosis after two dilations, or presence of gastrojejunostomy

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Fig. 7.1 Endoscopic view of gastrojejunal anastomotic stricture, due to marginal ulcer

fibrosis, is managed by division of the fibrous stenosis (stenotomy), which may be performed using a needle-knife. Complication rates of the dilation procedure can be as high as 2.5 %. The most common is perforation, occurring in up to 1.86 % of patients, with conservative treatment in most cases [2].

7.1.2 Food Impaction

Food impaction may occur after RYGB; it may be associated with the use of surgically implanted restrictive ring due to ring slippage or erosion, dietary noncompliance, gastric pouch, or gastrojejunostomy stenosis. Clinical presentation is consistent with upper gastrointestinal obstruction, involving nausea, retrosternal pain, epigastric discomfort, and postprandial vomiting. Endoscopy can be used for diagnosis and immediate treatment.

An endoscopic retrieval basket is the most commonly used accessory for foreign body removal. When it is difficult to remove all of the fragments orally, retained fragments can be gently pushed into the distal jejunal loop, passing the restriction point. It is advised to use minimal sedation during the procedure, due to a potentially increased risk of aspiration of gastric contents. This risk can be prevented by undertaking the procedure under general anesthesia after endotracheal intubation with or without the use of an overtube. The overtube is a device through which the endoscope is passed, protecting the cardia, esophagus, and airways during foreign body removal [4, 5]. It is also strongly advised that after resolution of symptoms, the etiology of the narrowing is investigated and resolved.

7.1.3 Marginal Ulcer

Marginal ulcers may occur either early or late in the postoperative period of RYGB. This complication's etiology is still not completely understood, and there is no established treatment protocol [6, 7]. It can be found in 27–36 % of symptomatic patients; interestingly, it is also incidentally detected in up to 6 % of asymptomatic patients after surgery [8].

When appearing as an early postoperative complication, it is thought to be associated with the surgery itself. In the late phase it may be secondary to the existence of a large or long gastric pouch (greater number of parietal cells) or presence of nonabsorbable sutures or staples [9]. The development of a marginal or anastomotic ulcer after RYGB may be explained by the preservation of the antrum and the vagus nerve, causing hypergastrinemia and increased gastric acid production. They are often located in the jejunal mucosa just below the gastrojejunal anastomosis and may involve the entire circumference of the small bowel [6] (Fig. 7.2).

Presentation includes epigastric pain and obstructive symptoms caused by edema. Upper GI endoscopy is the investigation of choice; findings include injury to the gastrojejunal anastomosis, varying in size and depth, commonly on the lesser gastric curvature side of the pouch and with a fibrin-covered ulcer base.

Prophylaxis with acid suppression after surgery is increasingly being used with the aim to prevent marginal ulcer formation. However, no consensus exists about the duration of the prophylaxis, usually varying from 30 days to 2 years, with some recommending lifelong usage [10]. Treatment of marginal ulcers should include

Fig. 7.2 Endoscopic view of RYGB pouch, showing deep, terebrating marginal ulcer, with hematin on base

high-dose PPI therapy (for at least 2 months) and sucralfate (10 days). Upper GI endoscopy should be repeated to ensure healing.

7.1.4 Choledocolithiasis

The incidence of gallstone disease is increased after RYGB. Management of choledocolithiasis in these patients can be challenging due to difficulty in access of the common bile duct (CBD), as a result of surgically altered anatomy of the stomach and duodenum [11]. A combination of laparoscopy and endoscopy can be used to perform a transgastric endoscopic retrograde cholangiopancreatography (ERCP), along with laparoscopic cholecystectomy. Access can be done by a 1 cm incision in the anterior wall of the remnant stomach through which a duodenoscope (introduced laparoscopically) is passed. The procedure is then performed as a conventional ERCP [12].

In the cases where this is technically difficult, an alternate technique reaches access to CBD via jejunum, facilitated by a double-balloon enteroscope. This approach has a successful biliary cannulation rate of up to 60 % [13].

7.1.5 Ring Erosion

With evolution and modifications of standard bariatric procedures, the use of a band or silastic ring implanted around the gastric pouch at the time of RYGB was widely accepted. This technique presents a new array of complications, the most significant among them is gastric erosion. The incidence of intragastric ring erosion varies from 0.9 to 7 %, occurring slowly with an inflammatory capsule formation. This inflammation prevents the leakage of gastric contents into the abdomen, leading to a nonspecific clinical presentation, with up to 15 % of the patients asymptomatic. When symptoms do occur, they include weight regain, epigastric pain, and obstructive symptoms, and sometimes even upper gastrointestinal bleeding [14].

At diagnostic endoscopy, the eroding prosthesis is often seen directly in the lumen of the gastric pouch. An early endoscopic finding may be an ulcer at the site of ring erosion; these patients should be started on high-dose PPIs, with evidence suggesting that migration of the ring is found in more than 50 % of such patients [15].

The eroded ring can be removed with a standard one-channel endoscope, utilizing endoscopic scissors [16]. In cases of failure due to the rigidity of the ring, an endoscopic lithotripter (or gastric band cutter) can be used.

In cases of early migration, if the ring has only a small area of intragastric erosion and is adherent to the gastric pouch wall, a dual-channel device can also be used. This allows the introduction of a foreign body-grasping forceps for traction, for better ring exposure. The other channel can then be utilized to pass an argon ablation catheter to divide the ring, or even scissors.

7.1.6 Ring Slippage, Intolerance, and Stenosis

Postprandial vomiting, dysphagia, and other obstructive symptoms should always be investigated in bariatric patients, specially when a ring was used. Ring slippage corresponds to distal displacement of the prosthesis, subsequently causing obstructive symptoms. In cases of complete slippage, there can be signs of esophagitis from excessive vomiting, gastric pouch dilatation, or formation of a gastric “neofundus” [17]. Food residues can also be seen in the gastric pouch and a site of stenosis is seen in the jejunal folds distal to the anastomosis.

Some patients may have frequent episodes of vomiting with no evidence of stenosis, a condition quoted by the authors as "food intolerance secondary to the presence of the ring" [18].

Dilation with a 30 mm balloon (Rigiflex®—Boston Scientific, Natick, MA) promotes stretching or rupture of the ring and the fibrotic bands caused by its presence, which can relieve symptoms, even in the patients diagnosed with food intolerance and no stenosis. If symptoms persist, a self-expanding plastic stent can be used, promoting intragastric ring erosion and allowing a completely endoscopic removal with minimal complications [17, 19].

7.1.7 Weight Regain After RYGB

Some patients who undergo RYGB may regain lost excess weight; around 20–30 % regain a large proportion of their lost weight, leading to a negative impact on quality of life [20]. Several factors may be related to regain, such as poor nutrition, fistula, surgical technique, and ring complications, among others. It is important to evaluate dietary and behavioral habits in cases of inadequate weight loss, such as volume quality of the meal and anxiety disorders.

Dilation of the gastrojejunal anastomosis and gastric pouch enlargement are possible causes of RYGB failure. In the presence of a dilated stoma, the most traditional approach is surgical. Even if reoperation is done laparoscopically, it is still complex and associated with significant morbidity and questionable efficacy. Development of endoluminal therapies for pouch and stoma revision can be a less invasive approach for failure or weight regain after bariatric surgery.

A multidisciplinary team evaluation, as well as endoscopic or radiologic imaging of the surgical anatomy, should be done in cases of weight regain in the late postoperative period. An increase of 10 mm on the stoma diameter was associated with an 8 % increase in the percent of maximal weight lost after RYGB that was regained [21]. The ideal anastomosis should have an approximate diameter of 10 mm, not exceeding 14 mm.

Application of argon plasma has been reported as a way to induce the formation of a fibrotic scar and consequent anastomotic diameter reduction [22, 23]. To produce the desired effect, the anastomosis should be coagulated in a circumferential way. There is an initial edema and inflammatory response, causing immediate restriction. This effect decreases over time, and the edema is substituted by fibrosis. More than one session is necessary in order to achieve long-lasting effects [24]. This leads to a delayed gastric emptying, early satiety, and weight loss.

Endoscopic suturing devices, such as the Apollo OverStitch® (Apollo EndoSurgery, Austin, Texas), have been presented as minimally invasive alternatives, and may be used alone or in association with argon plasma coagulation. The procedure involves suturing the internal mucosa, thereby restricting the gastric lumen. The sutures are performed under direct vision, with the aid of a curved needle [25].

7.2 Gastric Fistula After RYGB and Sleeve Gastrectomy

This is one of the most feared complications after bariatric surgery and may present with variable symptoms according to the site of the fistula [26, 27].

The incidence has decreased in recent years (currently, it is approximately 1 %), due to the recognition of its etiology and improved surgical technique. Leaks are more common in the first few weeks after surgery, and this complication is still associated with high morbidity [1]. The pathogenesis can be explained in some cases by ischemia of the angle of His, increased intraluminal pressure after surgery, and staple line or suture failure [28].

The leak may be difficult to control and, in some cases, conventional treatment is not enough to achieve healing (reoperation, intraabdominal drainage, and feeding distal to the leakage). When external drainage is not adequate, a chronic internal fistula (gastrocutaneous, gastrogastric, gastrojejunal, gastrocolic, and gastrobronchial) may develop [29, 30].

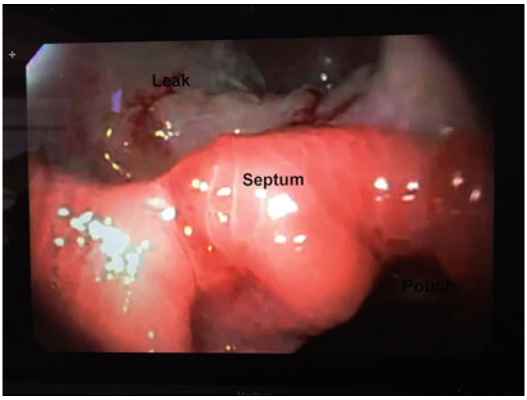

Fig. 7.3 Endoscopic view of sleeve gastrectomy His angle leak, showing leak orifice, septum, and gastric pouch lumen

When direct surgical closure is attempted, fistula healing might be difficult due to increased pressure in the gastric pouch, secondary to distal stricture. Surgery is recommended in selected cases for abscess drainage and should always be performed in case of peritonitis [31].

Upper GI endoscopy facilitates diagnosis and simultaneous minimally invasive therapy. In RYGB leaks, a stenosis can usually be identified distal to the fistula and should be treated. Stricturoplasty and balloon dilation can treat this stricture, facilitating gastric pouch emptying, reducing intragastric pressure, and decreasing fistula output [31]. Also, occlusion of the internal opening of the fistula is possible with implantation of a removable self-expandable stent (Figs. 7.3, 7.4, and 7.5).

Acute (less than 7 days) and early (7–45 days) leaks are treated with stents, achieving good results [26]. In the late (1.5–3 months) and chronic (more than 3 months) stages, balloon dilation and septotomy with electrocautery or argon plasma coagulation are better options. Stenotomy (incision of the fibrotic bands followed by balloon dilation) is used in cases of gastric pouch stricture. These procedures are repeated on a weekly basis in an outpatient setting, until the digestive secretion flow and pouch axis are corrected, encouraging permanent fistula healing [11, 32].

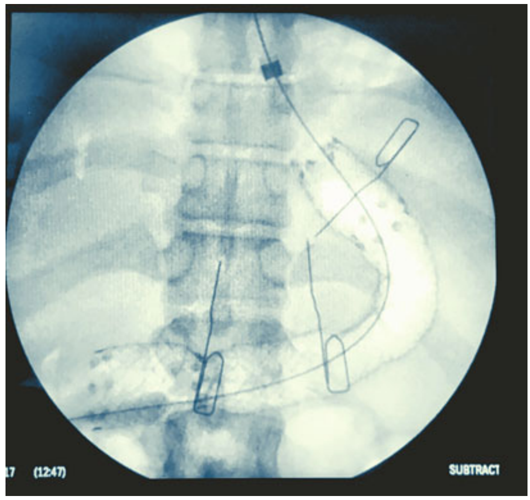

Fig. 7.4 X-ray image of sleeve leak showing fully covered metallic stent, positioned from distal esophagus to duodenum first portion

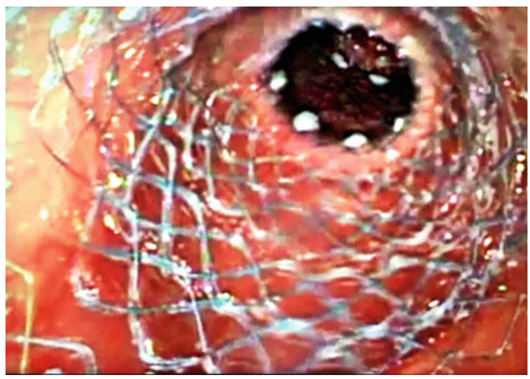

Fig. 7.5 Endoscopic view of fully covered metallic stent, occluding leak orifice and treating distal gastric stricture

Other procedures such as clip placement and endoscopic application of sealants have also been described in small case series, although they might not be effective when the distal stricture is not treated.

Leaks after sleeve gastrectomy tend to be more difficult to heal, due to the increased pressure of the gastric pouch. The endoscopic treatment follows the same principles described for RYGB leaks. Options available to treat a chronic fistula after sleeve gastrectomy are open/laparoscopic reoperations or endoscopic procedures. There is still no standard of care for these conditions.

Often, the surgical approach tends to be complex [30]. Therapeutic endoscopy has good results with low complication rates, through stent placement, stenotomy, septotomy, and dilation with 30 mm balloons [33].

7.3 Sleeve Gastrectomy Complications

7.3.1 Twisted Gastric Tube After Sleeve Gastrectomy

The gastric pouch may remain twisted after sleeve gastrectomy, a complication rarely described in the international literature, leading to food intolerance, nausea/vomiting, and leaks. The diagnosis can be made through plain or contrast X-ray, computerized tomography (CT) scanning, and endoscopy. X-ray images may be difficult to interpret, as there is radiological evidence of a stenosis in the absence of stricture on endoscopic examination.

At endoscopy, twisted gastric folds with an axis deviation are pathognomonic of twisted gastric tube. Endoscopic treatment can be attempted by balloon dilation with a 30 mm balloon. If it persists, open incision of the great curvature including the first muscle layer, followed by balloon dilatation, is indicated. This procedure can be performed with argon plasma or electrocautery (Needle knife®, Cook), being comparable to the gastric seromyotomy reported by Himpens [34], and is relatively less invasive.

7.4 Laparoscopic Adjustable Gastric Band Complications

7.4.1 Band Erosion

Intragastric band erosion can occur in about 1.5 % of patients (0.23–32.65 %) most commonly 12 months after device placement [35] (Fig. 7.6).

Clinical presentation may be characterized by epigastric pain radiating to the shoulder, retrosternal pain, subcutaneous port infection, or weight regain. Diagnostic endoscopy is the exam of choice, with the advantage of being able to facilitate treatment in most cases. On retroflexion, the eroding band can be directly seen in the gastric lumen, at the level of cardia.

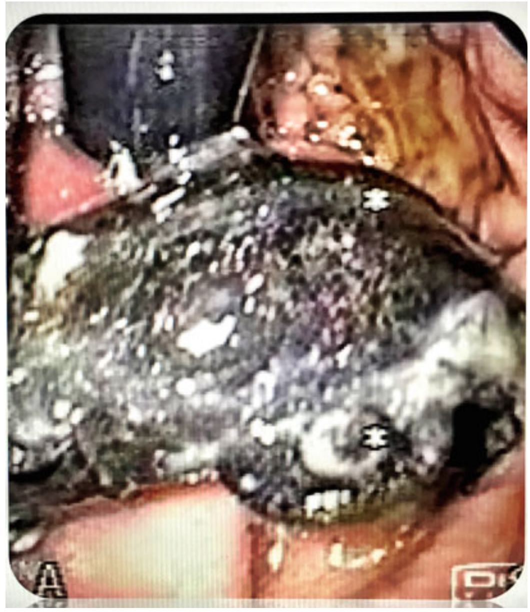

Fig. 7.6 Endoscopic U-turn view of an eroded adjustable gastric band

In asymptomatic patients with minimal erosion, close supervision needs to be maintained, due to the risk of gastrointestinal bleeding or intraabdominal infection [36, 37]. PPIs should be prescribed, to minimize further gastric acid damage until the band is removed.

Endoscopic removal of LAGB is less invasive and is therefore increasingly preferred to surgical removal [38]. Division of the LAGB can be performed with a gastric band cutter (GBC; Agency for Medical Innovations, A.M.I. GmbH, Götzis, Switzerland), facilitating endoscopic removal of the band, followed by surgical removal of the subcutaneous port [38].

7.4.2 LAGB Slippage

With distal displacement of the band, there is subsequent dilation of the proximal gastric pouch. The common presentation is vomiting, dysphagia, heartburn, or halitosis. Endoscopy and or contrast swallow imaging is required to confirm the diagnosis.

The band should be immediately deflated in all patients with a suspected slippage. This allows the stomach to return to its normal anatomical position decreasing the need for emergency surgery in most patients.

Should this fail to resolve symptoms, an upper GI endoscopy can be performed to evaluate if the band is still displaced. In these cases, hyperinflation of the stomach helps force proximal displacement of the band, thus repositioning the band to its usual site, with temporary relief of obstructive symptoms. This procedure is performed with the patient in lateral decubitus position under conscious sedation.

It is important to note that this is a temporary measure that allows definitive management by surgical removal of the band in an elective setting in the future. In cases where this fails, the band needs to be surgically removed [11]. An increased risk of aspiration at the time of endotracheal intubation needs to be anticipated.

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8 Role of Endoscopy, Stenting, and Other Nonoperative Interventions in the Management of Bariatric Complications: A US Perspective

Amber L. Shada, Kristin W. Beard, and Kevin M. Reavis

Obesity is a national and global epidemic, with over 2/3 of US adults classified as overweight and obese and 1/3 classified as morbidly obese [1]. Surgical treatment of obesity is the most sustainable method to induce substantial durable weight loss in this population [2]. Bariatric surgery is now an established surgical discipline in the USA, and the opportunity for partnering health care providers including non-bariatric general surgeons, emergency physicians, nurse practitioners, and primary care physicians to care for patients who have had bariatric surgery is increasingly common. Sleeve gastrectomy and Roux-en-Y gastric bypass are the more common bariatric surgical procedures performed in the USA with adjustable gastric banding and duodenal switch comprising the remaining small percentage of operations (Fig. 8.1a–d). These procedures are highly effective for weight loss and are enjoying an increasingly safe track record, but still carry a morbidity rate of 3–20 % and a mortality rate of 0.1–0.5 % [3, 4]. Historically, complications of bariatric surgery required operative therapy. However, the role of endoscopy is emerging as a more common approach to managing many of these complications nonoperatively.

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8.1 Forensic Endoscopy

For many patients who have undergone bariatric surgery in the distant past, determining the baseline-altered anatomy before venturing into the realm of diagnosing the acute concern is paramount. Due to economic, familial, and professional circumstances, many well-intended patients are unable to maintain close connection with their bariatric providers. Some patients develop surgically related complications long after their index procedure has been completed. Most hospitals purge their systems of operative reports and other pertinent medical information 10 years after care has concluded. This places increased importance on the reliability of the

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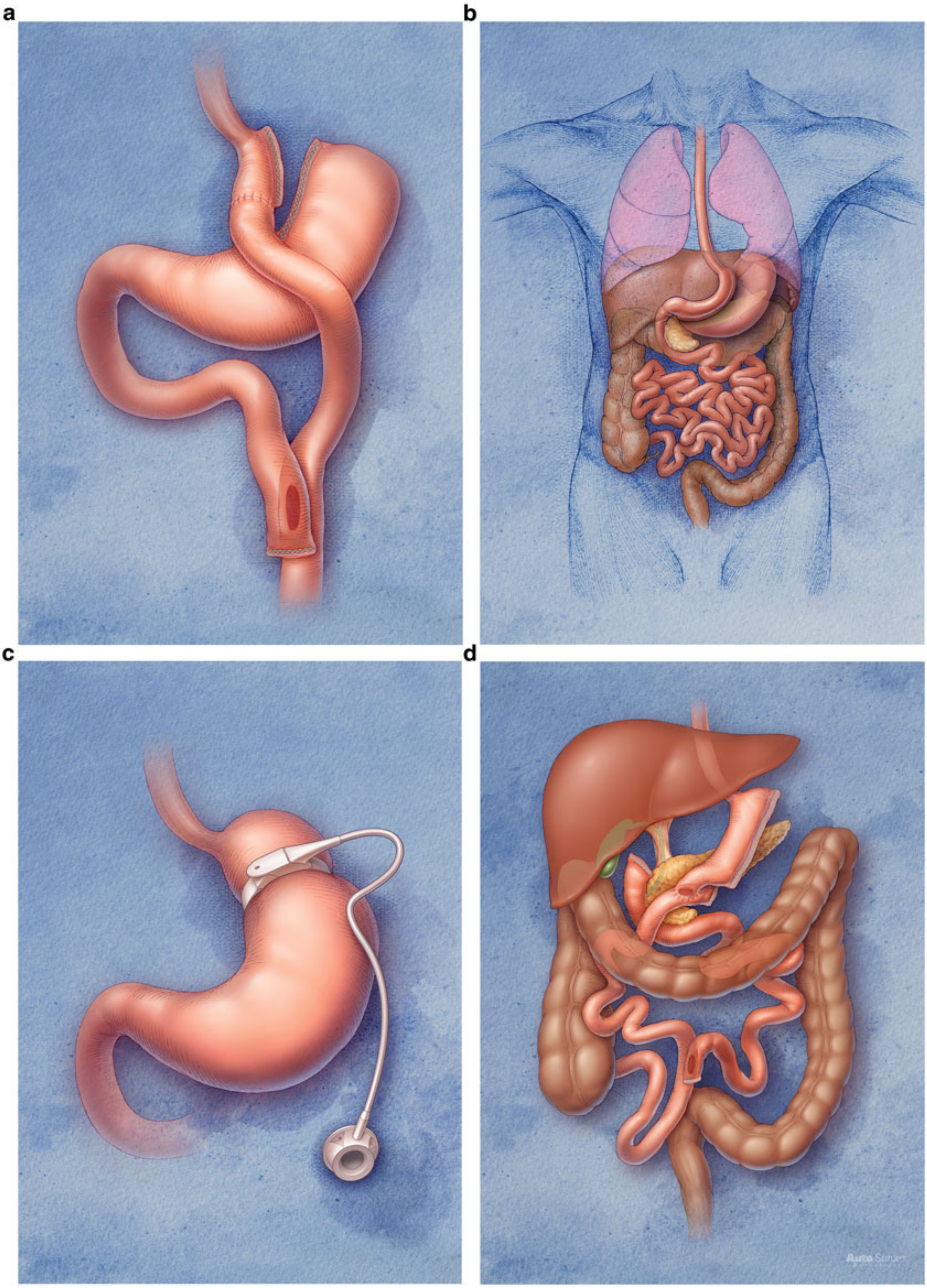

Fig. 8.1 Bariatric surgical anatomy: (**a**) Roux-en-Y gastric bypass, (**b**) sleeve gastrectomy, (**c**) adjustable gastric band, (**d**) duodenal switch (All rights reserved. Used with the permission of Medtronic)

patient's personal account of his or her surgical history. Although well intended, many are not able to muster more detail than the fact that he or she had gastric surgery. In these circumstances a diagnostic or forensic endoscopy by the physician and radiographic studies, most commonly upper gastrointestinal swallow studies and computerized tomography, are used to determine the likely index operation, what has recently changed resulting in the specific presenting complaint, and what can be done to reinstitute functional gastrointestinal anatomy in order to resolve the patient's concern.

For individuals who have a known recent surgical history and for those for which forensic endoscopy and radiography have provided a blueprint of the concern at hand an endoscopic approach to definitive management is often a reasonable nonoperative option.

8.1.1 Leaks

Anastomotic (and long staple line) leak is one of the most feared complications of any gastrointestinal surgery. Gastric bypass and duodenal switch procedures incorporate two anastomoses at risk for postoperative leak (Fig. 8.1a, d). The gastrojejunostomy and duodenojejunostomy in particular can be under tension and have subsequent ischemia, leading to leak. Leak rates of these proximal anastomoses are typically higher than the distal enteroenterostomies and are less likely to be under tension. From an endoscopic perspective, this is fortunate since the distal anastomoses are more difficult to access. Sleeve gastrectomy entails removal of the greater curvature of the stomach, leaving behind a tubularized stomach with intact pylorus. This leaves a high-pressure system with a long staple line when compared to the other stapled procedures. Leaks along the sleeve staple line can become chronic and very slow to heal. Two areas particularly prone to being troublesome include the very proximal stomach at the angle of His which is at risk for leakage, and the distal stomach alongside the incisura which is at risk for functional obstruction due to folding resulting in upstream pressurization. Leaks typically manifest with tachycardia, fatigue, malaise, shortness of breath, and hypotension. An upper GI fluoroscopy study can help elucidate the site of the leak. However, a negative upper GI study does not completely rule out a leak, and if there is clinical concern for a leak it is appropriate to investigate further endoscopically or operatively.

Endoscopically placed stents (either tubular or pigtail) can be helpful in the immediate postoperative period. When used in an acute setting, stents can be highly effective as a solo treatment of leak [5]. Even in cases where another therapy is required, use of a tubular exclusion stent can allow patients to continue to take oral nutrition. In some settings, percutaneous drainage of intra-abdominal abscess or laparoscopic drainage of extralumenal fluid may speed the rate of healing a leak [6, 7]. The use of pigtail stents facilitates internal drainage of a leak-related abscess in the same fashion as the management scheme used for pancreatic pseudocysts with formation of a cyst-gastrostomy. Use of pigtail stents is rarely associated with migration or erosion; however distal enteral access is usually needed for nutritional support to avoid ongoing outflow through the leak from proximal enteral intake.

Stents are not risk free. Tubular stents used to treat leaks and nonmalignant strictures in the USA are for the most part being used in an off-label (although often effective) manner. They are not perfectly designed to complete the task for which they are often being used. Tubular stent migration is a common nuisance, seen in nearly 50 % of stent placements [7]. Inserting a second "nested" stent into the first creating a longer effective stent with distal abutment in the antrum can decrease the migration rate, and increase coverage of a sleeve staple line to ensure coverage of an entire staple line if necessary. Stents can also be sutured into place to decrease migration, either using an endoscopic suturing device or with laparoscopic assistance [8].

Other morbidities related to tubular stents include erosion and fistula formation due to the radial pressure applied by the stent. Radial pressure is crucial to maintain stent position and exclude the leak. These rates increase as stent duration increases, and it is advised to leave stents in no longer than 28 days before removal or exchange [9]. Use of tubular stents for short durations can be very useful, but the total duration of stent use should be limited to 2–3 months due to the potential concerns of erosion, stenosis, and fistula formation noted earlier [10].

When a leak persists over the course of weeks and becomes chronic, tubular stents are less likely to facilitate a nonoperative durable solution. In a study of stents placed for chronic leak, only 19 % had a successful closure with stent alone [7]. Thus, in this population, stents are likely most effective as a bridge therapy to definitive surgical closure. In this setting, they can help with control of sepsis and allow patients to resume enteral nutrition. Use of downstream jejunal feeding access, which can be placed percutaneously with endoscopic guidance, can also avoid parenteral nutrition in many circumstances.

Endoscopic clips are also useful to manage small leaks. Typically these work best if the leak is discovered in the early postoperative period. Clips are available in several types. Through-the-scope clips are available from multiple manufacturers. They are small, and can close mucosal defects; however they do not ordinarily provide full-thickness approximation of tissue. Over-the-scope clips, although more cumbersome and bulky, can provide full-thickness approximation of gastric tissue, and thus are the most helpful type of clip for treatment of leak.

Leak algorithm: Assess stability of patient and acute/chronic nature of leak. If acute and small, endoscopic closure with through-the-scope or over-the-scope clip can be performed. If acute and large, tubular stent with external drainage and distal enteral access should be performed. If chronic and small, pigtail stent ± distal enteral access can be performed. An over-the-scope clip can be attempted if tissue is pliable. If chronic and large either type of stent can be used for local control (alternate is using endoscopic/surgically placed endolumenal/external drain to create a controlled fistula). Distal enteral access is advised and plans should be made for surgical revision if the leak fails to close (Videos 8.1, 8.2, and 8.3).

8.1.2 Hemorrhage

Hemorrhage from staple lines and anastomotic sites is often intralumenal and well suited to endoscopic hemostasis. Acute bleeding manifests in the first 72 h after surgery with tachycardia, palor, fatigue, malaise, and/or a drop in hemoglobin. Many of the staple lines are easily accessible endoscopically. Epinephrine injection, argon plasma coagulation, heater probe cautery, endoscopic suturing, and endoscopic clipping are all potentially useful adjuncts to treat staple line bleeding. Through-the-scope clip application is particularly useful for fresh anastomoses, as it avoids thermal damage that may further compromise staple line healing.

Through-the-scope clips are effective for both gastrojejunostomy and sleeve gastrectomy bleeding. Over-the-scope clips are capable of compressing larger areas of tissue and thus larger vessels. Bleeding from the enteroenterostomy of a Roux-en-Y gastric bypass or duodenal switch is far enough downstream that it is unlikely to be managed endoscopically. Luckily, bleeding at that site is fairly rare and can often be managed expectantly or in severe cases with laparoscopic oversewing of the staple line.

Intraperitoneal bleeding can occur from staple lines, as well as from the short gastric vessels and mesentery and solid organs which can be inadvertently damaged during surgery (particularly the spleen and liver). These areas are less amenable to endoscopic hemostasis and require formal surgical treatment.

Bleeding algorithm: Assess stability of patient and acute/chronic nature of hemorrhage. If patient is vomiting blood the site is endolumenal and proximal for which endoscopy is ideal. Therapeutic endoscope with large suction channel is helpful for removing clot enabling precise placement of endoscopic clip or suture to achieve hemostasis. If patient is passing blood per rectum with no proximal symptoms the site is likely distal requiring laparoscopic assessment and potentially oversewing the staple line. If patient has no gastrointestinal symptoms but has decreasing hemoglobin/hematocrit and symptoms of shock, the site is likely extralumenal and requires surgical treatment.

Table 8.1 Risk factors for marginal ulceration after gastric bypass

Ischemia (technical, smoking, diabetes)
Acid production in pouch
Foreign body
Gastro-gastric fistula
Helicobacter pylori
Nonsteroidal anti-inflammatory drugs

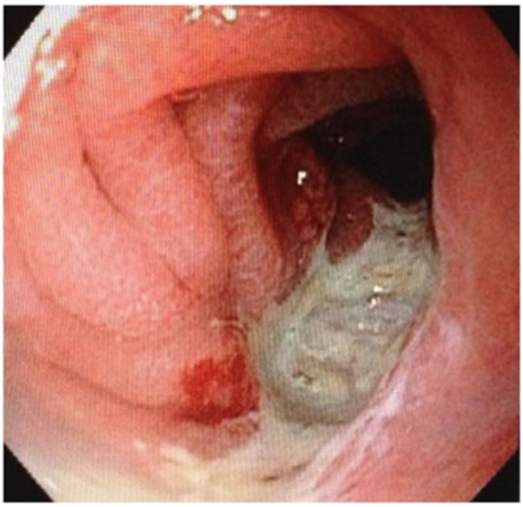

Fig. 8.2 Marginal ulcer

8.1.3 Marginal Ulceration

The anatomy of a Roux-en-Y gastric bypass can lead to a marginal ulceration. Marginal ulceration can occur in up to 16 % of patients [11]. This ulcer, often seen in the jejunum just distal to the gastrojejunal anastomosis, can be multifactorial, Table 8.1 (Fig. 8.2). Ischemia is one common cause. Operative ischemia and microvascular ischemia are both culprits. Smoking in particular has been shown to cause microvascular ischemia that can lead to marginal ulceration, and patients who have had a gastric bypass are discouraged from smoking. The cardia cells in the gastric pouch are capable of acid production, and if an ulcer develops a trial of antisecretory therapy is appropriate to eliminate acid production that might cause the ulceration to develop or propagate. Foreign material can be a nidus for marginal ulceration, and the use of absorbable suture is helpful in avoiding this complication. If there is permanent suture present at the anastomosis, it can be removed endoscopically as long as there has been adequate time for anastomotic healing (typically 6 weeks, but can vary depending on each individual situation). *Helicobacter pylori* infection is another cause for ulceration, and all patients should be screened and treated for *Helicobacter pylori* preoperatively to avoid this. Nonsteroidal anti-inflammatory drugs can also exacerbate marginal ulcers, and patients should avoid their use if they have other risk factors for marginal ulceration.

Marginal ulcers can be difficult to manage. Medical therapy is an appropriate first line, but is not always effective. Smoking cessation, proton pump inhibitor therapy, and a coating agent such as sucralfate should be considered early in the treatment of marginal ulcers. Recurrence is also fairly common, particularly when risk factors are not adequately addressed [12]. Endoscopic therapies, such as oversewing or clipping, are useful strategies for treating marginal ulcers [13].

In rare cases, ulcers can perforate. This may require surgical therapy, but if detected early with minimal enteric spillage, this situation may also be palliated effectively with either a tubular stent placement or over-the-scope clip or suturing device for source control and broad-spectrum antibiotics. If not endoscopically amenable, then addressing the issue in the operating room may be required to obtain adequate control and closure. Ulcers can also present with GI bleeding, and can be managed endoscopically via the bleeding algorithm.

In some cases, endoscopic therapy can be used as a bridge to definitive therapy. Some cases of marginal ulceration clearly require surgical revision of the proximal anastomosis. This is more difficult in a setting of acute bleeding or perforation. Temporarily managing these issues endoscopically to allow resolution of acute inflammation can often turn a difficult laparoscopic operation into a relatively manageable one, or turn a scenario requiring open surgery into one where a laparoscopic approach can be used.

8.1.4 Strictures

Anastomotic stricture is a rare but troubling complication of bariatric surgery. Strictures after gastrojejunostomy can cause dysphagia, vomiting, and unwanted, accelerated weight loss. This is typically a chronic problem. Ischemia, from surgical technique or microvascular causes (smoking, diabetes), and chronic ulceration are common culprits. Once the root cause has been resolved these strictures can often be treated endoscopically with dilation. Dilation over a wire and using a through-the-scope balloon are effective. Steroid injection of the anastomosis can also help soften the stricture and increase success of dilation. Occasionally, serial dilation every couple of weeks for a period of time is necessary. When endoscopic management of strictures fails, operative revision of the anastomosis or stricturoplasty is appropriate.

The enteroenterostomy, when strictured, is more difficult to manage endoscopically due to its location. A stricture in this location often requires surgical revision.

8.1.5 Erosion

First with the vertical banded gastroplasty, and more recently with the adjustable gastric band, erosion of foreign material into the proximal stomach can create problems after bariatric surgery (Fig. 8.3). Common presenting symptoms include dysphagia, epigastric pain, and cellulitis of the port due to enteral bacteria traveling along the band's tubing. Endoscopy and upper GI contrast study can demonstrate erosion, and occasionally the eroded object is visible in the lumen during endoscopy. When that is the case, it is feasible to attempt removal endoscopically, understanding that laparoscopic assistance might become necessary. These patients ultimately may require conversion to another bariatric operation (often a Roux-en-Y gastric bypass), but removal of the offending foreign body endoscopically can spare the patient one or more operations.

Erosion of the staple line through to the gastric remnant after gastric bypass is another potential morbidity of bariatric surgery. When carried full thickness and into the remnant stomach, this can create a gastro-gastric fistula. These can create morbidity including dysphagia, additional acid secretion into the pouch and subsequent marginal ulcerations, and postprandial epigastric pain as well as weight regain due to reestablishment of the native flow of enteral contents through the bypassed portion of the GI tract. Endoscopic treatment with suture closure and fibrin injection of these has been attempted with some success [14].

Fig. 8.3 Eroded band

8.1.6 Fistulas

Fistulization between the gastric pouch and gastric remnant can occur after gastric bypass. This was more common due to staple line failure when the pouch was created with a nondividing stapler, which has fallen out of favor. Other causes include incomplete division of fundus during gastric bypass, pouch staple line leak with abscess formation and decompression into the remnant, and marginal ulcer that erodes into the gastric remnant [15]. Fistulas can present with symptoms similar to marginal ulcer, or with weight regain and lack of satiety. Endoscopy

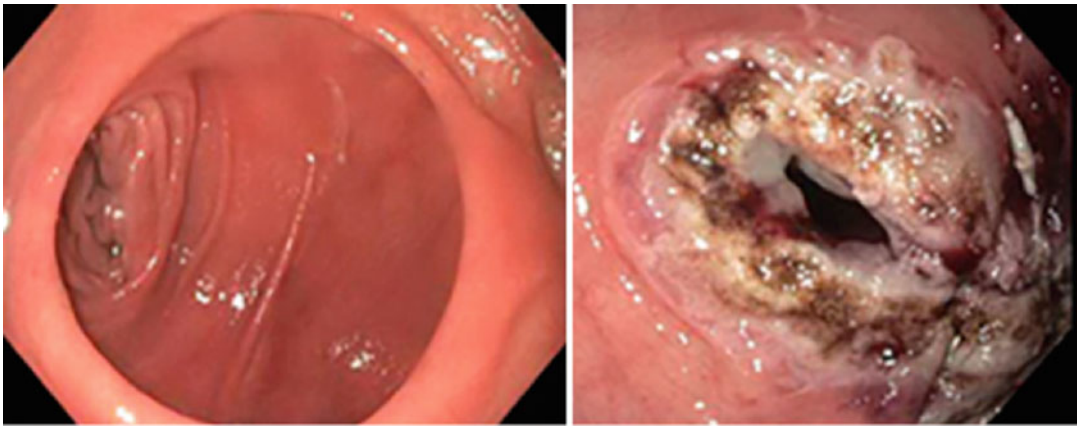

Fig. 8.4 Stoma dilation: pre- and post-endoscopic plication

is the best initial diagnostic test to evaluate for fistula along with an upper GI fluoroscopy study. If a fistula is present, there are multiple options for repair. Surgical repair is most definitive, but carries higher morbidity rates. For small fistulas of a less than 5 mm in size, endoscopic closure with over-the-scope clip or suturing is a useful technique to achieve closure [14]. While this does have some rate of recurrence, in some patients it can improve symptoms sufficiently as an outpatient procedure to avoid a more complex surgical approach with a prolonged convalescence (Video 8.4).

8.1.7 Weight Regain/Stoma Dilation

Bariatric surgery is the most effective long-term form of weight loss, but there is still a subset of patients who regain weight after surgery. One of the etiologies of this is pouch and stoma accommodation/dilation. Surgical revision is one option, but can be difficult, can recur, and carries a significant amount of revision-based morbidity [16]. Endoscopic pouch plication and stoma reduction are alternative options that are less morbid in a subset of patients (Fig. 8.4) [14, 17]. Durability of the associated new weight loss has not been adequately substantiated and compliance with lifestyle modification and the support programs associated with nationally accredited bariatric centers likely play a large role in long-term success.

8.2 Conclusion

Bariatric surgical patients have become a mainstay in the general population. Historically their care was delegated only to the surgeons dedicated to the practice of bariatric surgery. As patients travel and find themselves in areas without formal bariatric coverage it has become common for non-bariatric general surgeons, emergency physicians, nurse practitioners, and primary care physicians to care for these patients and their sometimes unique postsurgical issues. Historically, complications of bariatric surgery required operative therapy. However, the role of endoscopy is emerging as a more common approach to managing many of these complications nonoperatively. It is strongly encouraged that physicians who will be caring for these patients develop an endoscopic acumen in order to facilitate the diagnosis and initial if not definitive management regimens for endoscopically approachable complications following bariatric surgery.

8.3 Self-Assessment Questions

Correct answer in bold.

1. The most appropriate device for obtaining full-thickness tissue in order to close an small acutely detected leak is:
   (a) Argon plasma coagulation

(b) Through-the-scope clip
(c) **Over-the-scope clip**
(d) Pigtail stent

2. Patients suffering from anastomotic leak often present first with:
   (a) Early satiety
   (b) Pruritus
   (c) Low abdominal pain
   (d) **Tachycardia**
3. Gastro-gastric fistula commonly presents with :
   (a) Hematemesis
   (b) **Epigastric pain/heartburn**
   (c) Accelerated weight loss
   (d) Diarrhea

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Postoperative Bariatric Complications Not Related to the Bariatric Surgical Procedure

9

David A. Provost

Metabolic and bariatric surgery has proven to be the most effective treatment for obesity and the metabolic syndrome, conferring benefits in survival, quality of life, and improvements of obesity-associated comorbid conditions. Although perioperative mortality is now less than 0.1 %, complications can and do occur, both perioperatively and late. While anastomotic and staple line leaks, strictures, marginal ulcer, band prolapse or erosion, and internal hernia bare complications that can be directly related to the mechanics or anatomy of a bariatric operation, other complications may occur that are not directly related to the procedure. This chapter covers these indirect complications that have not been addressed in previous chapters. Perioperative complications including perioperative cardiac morbidity, venous thromboembolism, and rhabdomyolysis, as well as late complications such as biliary tract disease, nutritional disorders, postprandial hyperinsulinemic hypoglycemia, and alcohol-use disorders, are covered.

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9.1 Perioperative Cardiac Morbidity

Diabetes, hypertension, hyperlipidemia, congestive heart failure, as well as obesity itself are risk factors for perioperative cardiac morbidity often present in candidates for bariatric surgery. Despite multiple risk factors for coronary vascular disease (CVD), cardiac events are infrequent in modern bariatric surgery. In an evaluation of risk factors for perioperative events following 25,469 bariatric procedures in the Michigan Bariatric Surgery Collaborative (MBSC) database, only 22 patients suffered a myocardial infarction or cardiac arrest (0.1 %) [1]. Major cardiac events remain a major cause of perioperative mortality. Among 6114 patients with available 30-day follow-up in the Longitudinal Assessment of Bariatric Surgery (LABS), cardiac events were the second most common cause of perioperative mortality, accounting for 28 % of deaths (0.08 % of the total cohort) [2].

An appropriate, evidence-based preoperative cardiac evaluation can reduce the incidence of major adverse cardiac events. The 2014 ACC/AHA guideline on perioperative cardiovascular evaluation recommend starting with a clinical risk assessment and evaluation of functional status [3]. Patients with moderate or better functional capacity (climbing a flight of stairs or walking on level ground at 4 mph) may usually proceed to surgery without stress testing.

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Stress testing is indicated in patients with poor or unknown functional capacity. Surgery should be delayed 14 days after balloon angioplasty, 30 days after implantation of bare metal stents, and 365 days after drug-eluting stent implantation. The risk/benefit of discontinuation of antiplatelet agents should be discussed with the treating cardiologist. Beta-blockers should be continued in patients who have been on them chronically, but should not be started on the day of surgery in beta-blocker-naïve patients. The ACC/AHA guideline should be reviewed for more detailed perioperative treatment recommendations in patients at higher risk for perioperative cardiac events.

9.2 Venous Thromboembolism

The published incidence of deep venous thrombosis (DVT) and pulmonary embolism (PE) in bariatric surgery ranges from 0 to 6 %. With the implementation of venous thromboembolism (VTE) prophylaxis pathways in the vast majority of metabolic and bariatric surgery programs, the incidence of VTE in most large series is less than 1 % [4]. VTE was the third leading cause of perioperative mortality in LABS, accounting for 17 % of the deaths following bariatric surgery [2]. The MBSC identified risk factors for VTE following bariatric surgery including prior VTE (OR 4.15), male gender (OR 2.08), operative time over 3 h (OR 1.86), increasing age, increasing BMI, and procedure type (BPD/DS > open RYGB > laparoscopic RYGB > sleeve gastrectomy > LAGB) [5]. Additional risk factors may include immobility, venous stasis disease, and use of hormone therapy.

There is no class I evidence to guide the choice of VTE prophylaxis, although guidelines from the ASMBS [4], American College of Chest Physicians [6], and the MBSC recommend combination therapy with mechanical and chemoprophylaxis. A review of the MBSC database demonstrated superiority of low-molecular-weight heparin (LMWH) over unfractionated heparin for VTE prophylaxis [7]. Extended, post-discharge prophylaxis with LMWH should be considered in the highest risk patients including those with a prior history of VTE, those with venous insufficiency, and those with a BMI ≥60.

CT angiography of the chest is the diagnostic study of choice in the postoperative patient with suspected pulmonary embolism. As the symptom complex of tachycardia and shortness of breath are also present in anastomotic leakage, combining the CTA with an abdominal CT adds little time, and may help in determining the etiology of the patient's symptoms. Compression ultrasonography is the preferred test for suspected DVT. LMWH or fondaparinux is preferred in the initial treatment of VTE. The latest guideline update from the ACCP [8] recommends factor Xa or direct thrombin inhibitors over warfarin for the extended treatment of VTE. The standard duration of anticoagulation is 3 months.

9.3 Rhabdomyolysis

Rhabdomyolysis is a syndrome caused by injury to skeletal muscle which results in the release of potentially toxic intracellular contents into the bloodstream, including creatinine kinase (CK), myoglobin, potassium, and phosphate. Myalgias, generalized muscle weakness, and dark urine are presenting symptoms. A CK level 5 times the reference range suggests rhabdomyolysis, though levels 100 times the reference range may occur. The precipitation of myoglobin in the glomeruli may lead to acute kidney injury. Rhabdomyolysis has been reported following bariatric surgery in numerous case series and reviews. A systemic review identified 145 patients with rhabdomyolysis following bariatric surgery with 14 % developing acute renal failure. Male sex, higher BMI, and longer operative times were risk factors [9]. A multicenter prospective study or rhabdomyolysis in bariatric surgery identified rhabdomyolysis in 62 of 480 patients (12.9 %), defining rhabdomyolysis as a postoperative CK >1000 U/L [10]. Duration of surgery was the only independent risk factor, with an operative time greater than 230 min as the best cutoff predictor. Although the incidence of clinically relevant rhabdomyolysis is much lower, the diagnosis must be considered in patients with dark or decreased urine output, particularly following longer procedures in high-BMI patients.

Preventative measures include padding of all pressure points, changes in patient position, and minimizing operative time. Following the diagnosis of rhabdomyolysis, aggressive hydration titrated to maintain a urine output of 200 mL/h should be continued until myoglobinuria is no longer present. Alkalization of the urine by the administration of intravenous sodium bicarbonate, as well as diuretic therapy with mannitol or furosemide, has been recommended to prevent acute kidney injury. Serum CK measurements should be obtained every 6–12 h. Patients should be monitored for the development of disseminated intravascular coagulation (DIC). Electrolyte disturbances, particularly hyperkalemia, should be corrected.

9.4 Biliary Tract Disease Following Bariatric Surgery

Gallstone formation is an acknowledged complication of rapid weight loss, with the reported incidence as high as 40 % following bariatric surgery. Ursodiol, 600 mg/day, reduced the incidence of postoperative cholelithiasis from 32 to 2 % in a multicenter, randomized, placebo-controlled trial [11]. The incidence of symptomatic cholelithiasis and subsequent cholecystectomy were not reported. Prophylactic cholecystectomy at the time of bariatric surgery was a common practice in the era of open surgery; however in the current era of laparoscopy, a more selective approach to cholecystectomy is advocated by most authors. A review of 15 studies reporting various gallbladder management protocols at the time of gastric bypass surgery suggests that the incidence of subsequent cholecystectomy for symptomatic cholelithiasis is generally less than 10 % irrespective of postoperative ursodiol treatment or cholecystectomy for asymptomatic gallstones at the time of gastric bypass surgery [12]. A conventional approach, advocating post-bypass cholecystectomy only in symptomatic patients without ursodiol or preoperative screening for gallstones, was recommended.

Choledocholithiasis following gastric bypass and duodenal switch procedures presents an additional challenge due to the relative inaccessibility of the major duodenal papilla. In patients with a gallbladder, laparoscopic common bile duct exploration concurrent with laparoscopic cholecystectomy is advocated. Various approaches in patients with choledocholithiasis and prior cholecystectomy have been reported. Transoral ERCP through the Roux and biliopancreatic limb, utilizing an enteroscope, has reported success rates between 60 and 80 %. Increased success has been reported utilizing double- or single-balloon enteroscopes. Transoral ERCP through Roux-en-Y anatomy is extremely operator dependent, with most series coming from specialized centers. Laparoscopic-assisted trans-gastric ERCP [13, 14] has reported success rates >95 %, and is more widely utilized. Percutaneous transhepatic cholangiography with balloon dilation of the sphincter under local anesthetic and surgical common bile duct exploration are less commonly used approaches to common bile duct stones with the surgical absence of the gallbladder. Prophylactic cholecystectomy when performing a duodenal switch is often recommended as the absence of a gastric remnant and the very long biliopancreatic limb make ERCP much more difficult, although laparoscopic assisted access through the biliopancreatic limb has been reported.

9.5 Nutritional Complications Following Bariatric Surgery

Nutritional deficiencies represent a frequently observed complication of bariatric surgery. Malabsorption of iron, calcium, and vitamin B12 is commonly reported following Roux-en-Y gastric bypass and to a lesser extent following sleeve gastrectomy. The reduction in nutrient intake may produce deficiencies in vitamins, minerals, and proteins in both malabsorptive and restrictive bariatric procedures. Reduced absorption of protein, fat-soluble vitamins, and other micronutrients is greater following malabsorptive operations, such as the biliopancreatic diversion (BPD) and biliopancreatic diversion with duodenal switch (BPD/DS). Appropriate supplementation and **monitoring** of **vitamins** and minerals reduce the incidence of nutritional deficiencies following bariatric surgery [15]. Rapid weight loss in the early postoperative period and protracted vomiting may result in an increased risk of protein and micronutrient deficiencies, as will noncompliance with dietary and supplement recommendations.

Varied neurological complications including neuropathies, myopathies, and encephalopathy may occur, often in the setting of protracted vomiting. These include Wernicke's syndrome, Korsakoff's psychosis, beriberi, Guillain-Barre syndrome, and nutritional polyneuropathy [16]. Thiamine and vitamin B12 deficiencies are often associated with polyneuropathies; however it is not always possible to identify the specific micronutrient deficiency producing the neurological complication in post-bariatric surgery patients. Vitamin A, B1, B2, B6, folate, B12, D, and E and copper and zinc levels should be tested and aggressive inpatient vitamin and mineral supplementation should be initiated in an attempt to reverse the neurological symptoms, although residual deficits may persist in up to 50 % of patients.

Decreased intake of calcium and vitamin D, combined with malabsorption of calcium in gastric bypass, and calcium, vitamin D, and protein following BPD/DS raises concerns regarding bone loss and the development of osteoporosis following bariatric surgery. Obesity alone has been associated with vitamin D deficiency and secondary hyperparathyroidism, and nonsurgical weight loss has been associated with a decrease in bone density and an increase in hip fracture risk in middle- and older aged women and older men. Despite these findings, a position statement by the ASMBS clinical issues committee notes that current evidence does not conclusively report an increased risk of osteoporosis or fracture following bariatric surgery [17]. Recommendations include the preoperative assessment of 25-hydroxy vitamin D and intact parathyroid hormone levels in bariatric surgery candidates with implementation of preoperative supplementation as indicated. Procedure-specific recommendations for postoperative supplementation and monitoring are consistent with recent guidelines [18].

9.6 Postprandial Hyperinsulinemic Hypoglycemia

Postprandial hyperinsulinemic hypoglycemia is an uncommon complication of bariatric surgery. Most often associated with gastric bypass, symptoms include confusion, altered level of consciousness, fatigue, slurred speech, weakness, and impaired cognition with documented low blood glucose. Traditionally called "late dumping syndrome" symptoms may develop months to years following gastric bypass. The incidence is less than 0.5 %, although upon questioning, up to one-third of gastric bypass patients may report occasional hypoglycemic symptoms, particularly following dietary indiscretion. The cause is believed to result from altered glucose kinetics and homeostasis from the altered gastric bypass anatomy, not an increase in pancreatic beta-islet cell mass as initially proposed [19]. Diagnosis requires normal fasting glucose and insulin levels, postprandial hypoglycemia (plasma glucose <50 mg/dL), and hyperinsulinemia (serum insulin >50 μU/L). C-peptide levels should be increased. Low C-peptide levels suggest factitious hypoglycemia. Insulinoma should be excluded.

Dietary modifications successfully manage symptoms in the majority of patients. Patients should eat several small meals per day while avoiding sugars and simple carbohydrates. Protein and high-fiber foods are encouraged. Patients should avoid skipping meals. Pharmacologic therapies are reserved for patients who remain symptomatic despite dietary modification. Calcium channel blockers including nifedipine and verapamil, acarbose, diazoxide, and octreotide have been utilized with varying degrees of success [20]. Placement of a gastrostomy in the gastric remnant is the recommended initial surgical treatment in patients not responding to medical management. Intragastric feeds should reverse the metabolic disturbances of postprandial hyperinsulinemic hypoglycemia, in addition to predicting the success of gastric bypass reversal, if necessary. Bypass reversal is the treatment of last resort, while partial pancreatectomy is not recommended.

9.7 Alcohol-Use Disorders

There is evidence that alcohol-use disorders (AUD) are more frequent following bariatric surgery, particularly gastric bypass. Analysis of the LABS data demonstrated a significant increase in AUD at 2 years post-surgery compared to the year prior to surgery (9.6 % vs. 7.6 %). Male sex, younger age, and preoperative AUD, smoking, and illicit drug use were risk factors for the development of AUD after gastric bypass. An increase in AUD was not observed following LAGB [21]. AUD was increased following gastric bypass in the Swedish Obese Subjects study compared with controls, with a hazard ratio of 4.97 [22]. Breath alcohol content (BAC) was measured following ingestion of a 5 oz glass of wine in gastric bypass patients preoperatively and at 3 and 6 months postoperatively. Peak BAC was higher and BAC took longer to return to normal following gastric bypass [23]. Data is lacking regarding the risk of AUD following sleeve gastrectomy. Patients considering bariatric surgery, particularly gastric bypass, should receive preoperative counseling regarding the adverse effects of alcohol, and the possible increased incidence of alcohol-use disorders.

9.8 Conclusion

Complications of bariatric surgery not directly related to the procedures may occur in both the perioperative and late time frames. Cardiac complications and VTE are the second and third leading causes of perioperative mortality following bariatric surgery. Biliary and nutritional complications, hyperinsulinemic hypoglycemia, and alcohol-use disorders may present long after the perioperative period. Preventive measures may reduce the incidence of these events, while prompt diagnosis and treatment can limit their consequences.

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Weight Regain After Bariatric Surgery

10

Robin P. Blackstone

10.1 Physiology of Obesity

Understanding weight regain in the bariatric patient first requires an understanding of the physiology of obesity. Why do people get big? The current science of obesity demonstrates that obesity is a result of a genetic predisposition to be big, coupled with a series of epigenetic changes that occur as people gain weight through their interaction with the environment. At some point of body fat and weight, these epigenetic changes hard wire the obese physiology into place. As a person becomes bigger there are a myriad of changes in the health of the fat, causing systemic inflammation that results in obesity-related disease. Moreover, the larger a person becomes the more resistance his/her body exerts in an effort to maintain the obese physiology. The body defends that point of "fatness." Any attempt to lose weight by exercise or dieting is ultimately sabotaged by actions of the brain to realign intake and metabolism and return to the status quo. The only therapy that breaks through this set point is bariatric surgery.

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Metabolic procedures like the sleeve gastrectomy, gastric bypass, and duodenal switch have profound and sustainable affects on not only weight loss but also the improvement or remission of metabolic disease. They work primarily through changes in physiology. Devices, like the adjustable gastric band, tend not to have the same intrinsic effects as procedures. The mechanism of action of devices tends to be mechanical. Devices generally result in greater initial resulting weight loss than behavioral treatments and pharmaceuticals, but far less than metabolic procedures. Every single procedure or intervention has variability in the response of the patient in terms of weight and remission of obesity-related disease. The response to adjustable gastric band and gastric bypass in careful, well-designed studies shows five broad groups of responders [1] (Fig. 10.1), with about 7 % weight regain between the second and sixth years [2] (Fig. 10.2).

10.2 Understanding the Mechanism of Action of Metabolic Procedures

Understanding how to maximize weight loss and obesity-related disease remission and understanding weight regain requires a broad understanding of how the procedures work. In the early history of bariatric procedures surgeons primarily

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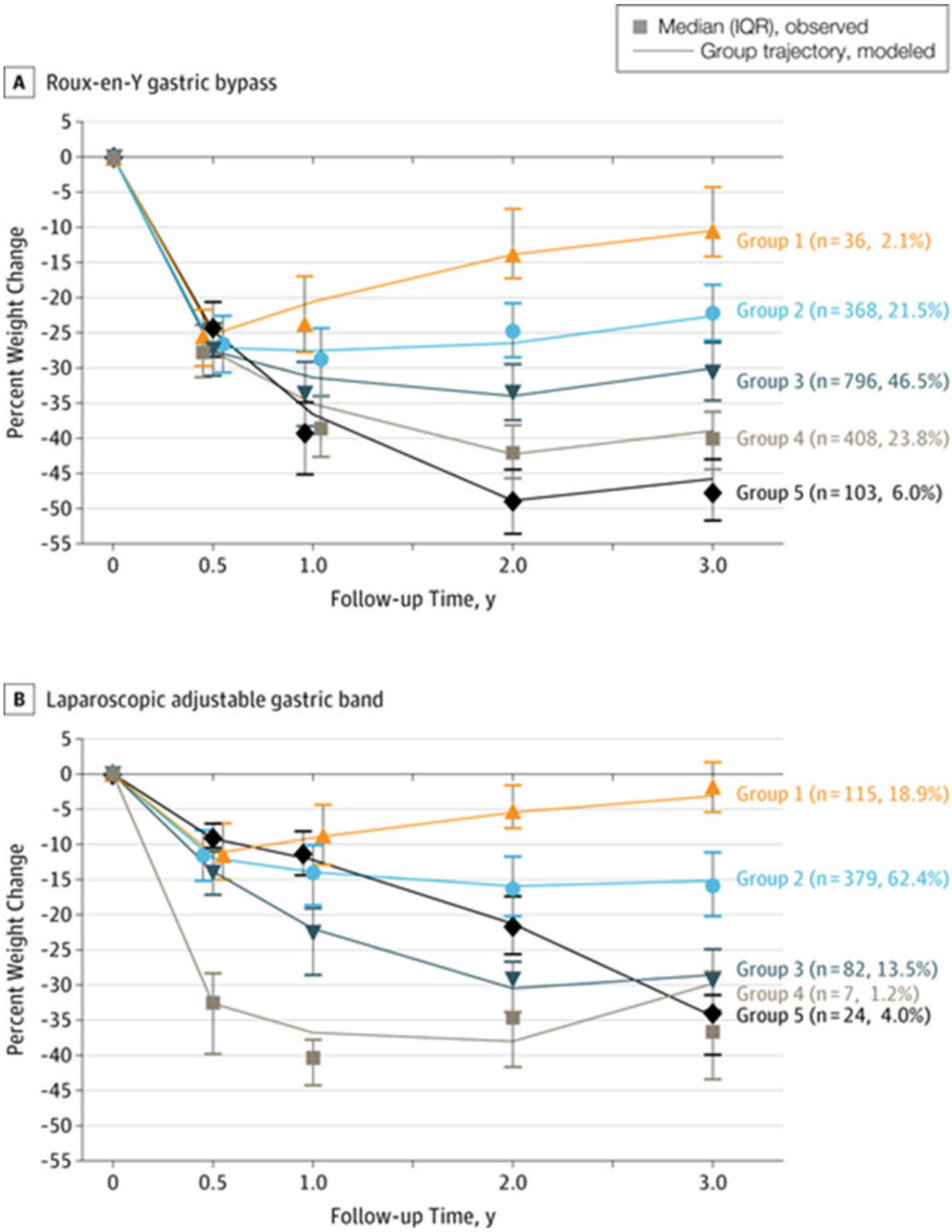

Fig. 10.1 Percent weight change trajectories for Roux-en-Y gastric bypass and laparoscopic adjustable gastric band (from Courcoulas AP, Christian NJ, et al. Weight change and health outcomes at 3 years after bariatric surgery among individuals with severe obesity. JAMA. 2013;310(22), with permission)

constructed alterations in the stomach that were designed to restrict the amount of food people could eat (stapling of the stomach) or created malabsorption (bypassing a portion of the bowel). At the time, our understanding of the primary mechanism of surgery was limited to these two theories. The observation of remission of obesity-related disease, in particular diabetes, spurred the development of animal models to study how it was occurring.

We learned that procedures that cause restriction, like the adjustable gastric band, result in

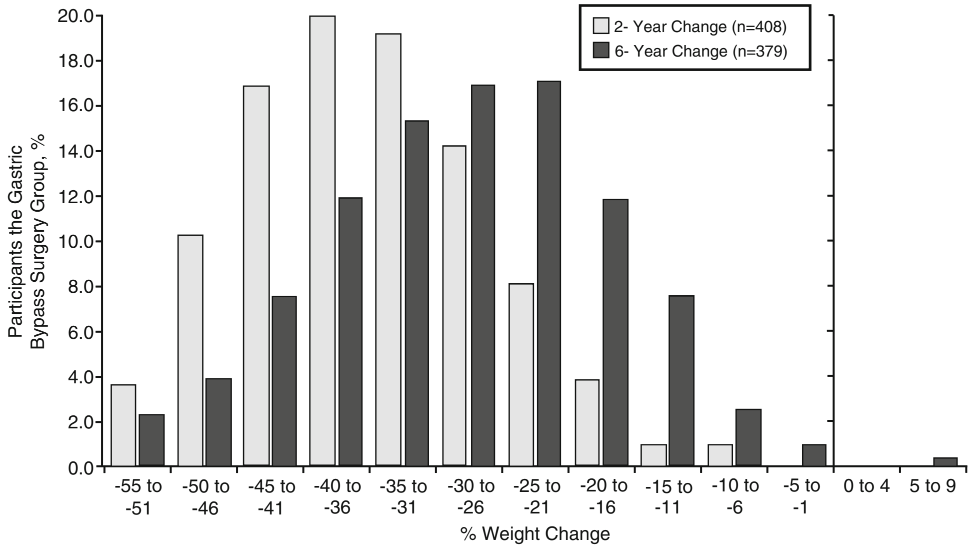

Fig. 10.2 Gastric bypass surgery weight regain between the second and sixth years postoperatively (from Adams TD, Davidson LE, Litwin SE, Kolotkin RI, LaMonte MJ, Pendleton RC, et al. Health benefits of gastric bypass surgery after 6 years. JAMA. 2012;308(11):1122–31, with permission)

changes in intestinal hormones that are very similar to what would happen to a patient on a voluntary diet. For example, the hormone that causes hunger, ghrelin, increases after the adjustable gastric band is inserted, thereby making the patient hungry. The hormone that triggers satiety, GLP1, decreases. Devices that are based on restriction are similar to a voluntary diet and over time many patients are unable to maintain the initial weight loss. In a large and well-conducted trial, the 3-year weight loss after adjustable gastric band was only 19 % on average [1]. Metabolic procedures, like the sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB), operate primarily through different mechanisms. Currently, it appears that sleeve or gastric bypass restriction of food and malabsorption of calories account for only 5–7 % of the weight loss effect.

The changes that occur after a metabolic bariatric procedure are the following(3):

1. A change occurs in the hormone signaling from the gut to the brain.
2. Changes in the microbiome occur due to the different ways in which food is processed: these changes favor bacteria that are not as efficient at wringing calories out of food.
3. Changes occur in the thermodynamics of the patient which causes an increase in energy expenditure in part through hormonal signaling and activation of receptors that cause an increase in thermogenesis.
4. Changes occur in the food-reward part of the brain which cause postsurgical patients to crave different and healthier foods that are lower in fat and sugar.
5. Leptin levels decline as the fat percentage decreases, resulting in less leptin resistance.
6. The level of inflammation decreases as fat cells shrink in size, there by affecting the level of inflammation of the blood vessels that, in turn, affect every body system.

10.3 Why Weight Gain Occurs After a Bariatric Procedure

Once the patient experiences the Genetic Reset™ afforded by a metabolic bariatric surgery procedure, the patient then has an opportunity to make a permanent change in his/her weight and improve his/her health. Nationally accredited bariatric surgery programs have specific preoperative and postoperative education and support programs designed to allow the patient to maximize their Genetic Reset™ and health. Some patients may have such an overwhelming burden of genetic predisposition to obesity that any given procedure may not force enough change on the system. These patients may gain weight after the procedure regardless of the environmental changes they make. However, it seems likely that the failure of a patient to maximize his/her environmental change opportunities will make weight loss less robust or long lived. Interviews with patients who have regained a substantial amount of weight often show a long-standing history of familial obesity and an inability or failure to make substantial changes in their culture around food and exercise.

10.4 Ongoing Monitoring of Bariatric Surgical Patients

10.4.1 Measurement and Communication of Weight Status

All patients undergoing bariatric surgery procedures should be subsequently coded in the electronic health record as having a history of bariatric surgery (ICD10 Z98.84). Every patient seen in the practice for any reason should have a measured height, weight, and waist circumference taken with calculation of BMI and body fat percentage. Taking these measurements as a standard part of every physical exam for all patients will minimize any feeling of being singled out. These important vital signs of health should be given in writing to the patient. The patient will have a nadir of weight loss after bariatric surgery ranging in time from 6 months to 2 years after the procedure. After that, some weight regain may occur and it is crucial that the patient knows to immediately seek care and not delay until they have gained a substantial amount—**defined as more than 10 %**. Weight regain is accompanied by all the previous metabolic and epigenetic changes back into the patient's system, making it harder to get that weight back off. Often patients who have been big are extremely sensitive to weight regain and want to have help and guidance if they start to regain weight.

10.4.2 Ongoing Evaluation of Obesity-Related Disease

Patients who have been obese will have a history of obesity-related disease. In the medical record, the obesity-related disease should be documented, i.e., history of type 2 diabetes and obstructive sleep apnea, so that providers are aware of these previous diagnoses. Once the patient loses weight they often go into temporary or permanent remission of obesity-related disease. The amount of weight loss and remission depends on the type of device or procedure utilized. For example, type 2 diabetes has a remission rate of 68.7 % after RYGB and 30.2 % of LAGB at 3 years [4] (Fig. 10.3). For this reason annual testing of HbA1C and fasting blood sugar is a required component of a patient's annual lab work. Treatment of obstructive sleep apnea should not be discontinued without proof that the apnea has indeed resolved. Hypertension does not respond as well as other obesity-related diseases and often the bariatric patient will continue to need treatment even after massive weight loss and almost certainly during weight regain.

If weight gain reoccurs, obesity-related disease may also reemerge. Knowing the patient’s history, measuring the patient for weight gain, and testing for previous obesity-related disease constitute excellent long-term follow-up care.

10.4.3 Surveillance of Medications That Cause Weight Gain

One critical component of care is to look at the medications the patient is on to treat obesity-related disease. Many may directly cause or contribute to weight gain, especially medications used to treat depression, anxiety, and hyperglycemia. *Making choices about utilizing medications*

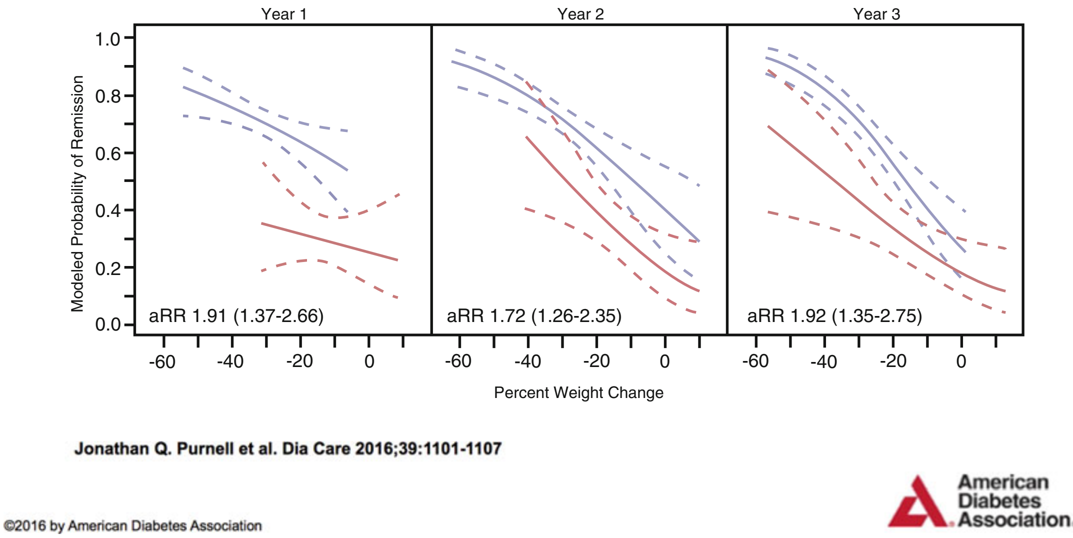

Fig. 10.3 Modeled probabilities and 95 % CIs for diabetes remission for each postoperative year of follow-up as a function of percent weight loss in participants undergoing LAGB (*red lines*) and RYGBP (*blue lines*). aRR estimates and 95 % CIs for the association between surgical type (RYGBP vs. LAGB) and diabetes remission are adjusted for percent weight change from baseline and a propensity score consisting of baseline demographic and clinical characteristics associated with the type of bariatric surgical procedure. aRR is greater for RYGBP than LAGB at each postoperative year; $P \leq 0.001$ for each time point (from Purnell JQ, Selzer F, Wahed AS, Pender J, Pories W, Pomp A, et al. Type 2 diabetes remission rates after laparoscopic gastric bypass and gastric banding: results of the longitudinal assessment of bariatric surgery study. Diabetes Care. 2016;39(7):1101–7, with permission. Copyright 2016 by American Diabetes Association)

that do not encourage weight gain is essential. If the medication prescribed does have the tendency to promote weight gain, that should be disclosed to the patient and the patient should be placed in a weight-monitoring program to detect any early change in weight.

10.4.4 Common Strategies That Apply to All Patients with Weight Gain After MBS

A stable and calm approach is advised when a patient first begins to gain weight after a bariatric procedure. The provider wants to create a safe and blame-free environment to treat the patient so that the patient will stay engaged. Frequent follow-up is essential and accountability and caring are the keys to reversing the trend. Weight gain patterns are specific for different procedures and are explained below. Once a threshold of 7–10 % weight regain has been crossed, the patient should be referred back to the bariatric surgery team for a comprehensive evaluation by the bariatric surgeon. The patient should be reconnected with support groups, the dietician, and psychological support. This may shortcut many years of frustration and unnecessary cost in testing that is not particularly relevant to weight regain.

10.4.5 Food and Exercise

Patients who establish strong postoperative exercise habits are not as likely to gain weight again. Patients with body fat percentage lower than 32 % for women and 25 % for men are less likely to regain weight and this goal is primarily achieved through exercise. Our team recommends daily exercise of 1 h that produces an increase in thermogenesis typified by sweating.

All patients can engage in some form of exercise. An evaluation by a progressive physical therapy team prior to and monitoring after the MBS procedure can help facilitate this transition. Becoming active is an important postsurgery goal and one that often is sacrificed when one is facing difficult life events. Exercise in the post-bariatric surgery patient is particularly important because of the epigenetic "echo" of increased metabolism that is triggered by exercise and lasts about 48 h. This increase in metabolism from exercise adds to the increase in thermogenesis that is a primary effect of the procedures.

In some ways the postoperative period is characterized by experimentation of the patient in regard to food choices. Since the procedures primarily work through the signaling changes between the gut and the brain, choices of food become a critical component in the paradigm of weight stabilization and long-term weight maintenance. The food reward centers also get "rewired" meaning that patients may be apt to choose healthier foods (less fat and sugar) than before surgery. These choices can be enhanced by working closely with the registered dietician in the program. There is much confusion around food choices so it is important to align the strategy about maximizing the gut brain interaction to promote burning of food sources for energy rather than storing those food sources as fat.

Often the patient will have experienced some negative life event that may have tipped them into weight regain. In the experience of our team these life events can be job loss, divorce, loss or chronic illness of a family member or close friend, or personal injury. Patients may give up their exercise habits and engage in unhealthy eating or drinking behaviors during this time. Prior to the initial MBS procedure the patient would have been interviewed and tested by a psychologist and evaluated for potential barriers to long-term success of weight loss. In addition, the patient may have done some form of counseling or therapy during the preoperative period. The written consultation of that psychological testing becomes an important document to study for hints as to what may be happening to patients when they regain weight.

10.4.6 Psychosocial Functioning, Alcohol-Use Disorder, and Suicide

Patients with obesity who undergo MBS have a high incidence of psychiatric illness and psychological disorder, including 33.7 % with at least one current Axis I disorder and 69.8 % with at least one lifetime Axis I disorder [5]. Axis I disorders include all clinical mental disorders such as substance-related disorders, schizophrenia and other psychotic disorders, mental disorders due to a general medical condition, delirium, dementia, amnesia and other cognitive disorders, and disorders diagnosed in infancy, childhood, or adolescence like learning disorders and attention-deficit/hyperactivity disorder.

Most of these are related to depressive disorder, alcohol abuse or dependence, and binge eating disorder. The lifetime rates of Axis 1 disorder are confirmed in two additional studies [6, 7].

Psychiatric and psychological disorders impact outcomes. Patients with preoperative depression often develop postoperative depression and have less weight loss than predicted. Although psychopathology can improve after surgery, it sometimes reemerges within 2–3 years afterwards. Alcohol dependence occurs in about 33.2 % of patients after bariatric surgery [6]. The risk of self-harm is 3.6 per 1000 patients per year vs. 1.2 per 1000 patients per year in a baseline obese population, with self-harm being much more prevalent in disadvantaged populations.

Patients who are identified as high-risk individuals should have ongoing screening during long-term follow-up that includes risk assessment for alcohol and medication misuse and depressive disorders. Emergency department visits for self-harm may prompt screening opportunities for mental health issues.

10.4.7 Diagnostic Evaluation of Weight Regain

The assessment of weight regain relies largely on an undertanding of the patient's particular bariatric procedure. Patients that underwent an adjustable gastric band and are experiencing weight regain have often developed a complication that requires unfilling the band. One of the most common complications in these patients are development of gastroesophageal reflux (GERD), presbyesophagus or megaesophagus, and esophageal dysmotility. These are usually diagnosed with a gastrografin swallow or upper gastrointestinal series. These two studies also may make the diagnosis of a prolapse or erosion of the band. In these cases the band is unfilled by accessing the port with a non-coring Huber needle using sterile technique and taking all the fluid out of the band. The patient's symptoms will likely resolve but the side effect is weight gain. Once the symptoms have resolved the band, depending upon its condition, may be refilled. Since many of the problems that occur with the band require unfilling, it is recommended that these patients be followed and managed by a bariatric surgery team.

For bariataric procedures like sleeve and gastric bypass, the diagnostic workup will, often include a CT scan of the abdomen and pelvis with oral and IV contrast. The last 100 cc of oral contrast is given just as the patient is going through the scanner in order to capture the upper part of the gastrointestinal tract. An esophagogastrojejunostomy may also be helpful to define and describe the anatomy and help determine if there is a fistula (connection between the stomach pouch and the distal remnant of the stomach in a gastric bypass patient). It is important to ensure that the GI specialist is completely comfortable with the MBS patient and familiar with the anatomy in order to maximize the testing done.

10.5 Conversions and Revisions of Previous Bariatric Surgery Procedures

Conversions from a device-based strategy to a bariatric surgical procedure-based strategy for weight loss are common at this time. These types of conversions are much different than conversions of a previous bariatric surgical procedure to another bariatric surgical procedure or a revision of the first procedure. Devices do not work in a similar fashion to procedures. In general they are less effective long term and act more like behavioral and dietary manipulations. When patients experience weight gain after the band, it is usually because they cannot tolerate the band fill or because they have a complication of the band that requires its removal. If the band has eroded, then band and port removal is done. If the band has slipped or the patient has GERD, esophageal motility, or presbyesophagus, then often the adjustable gastric band is converted laparoscopically to the sleeve gastrectomy or gastric bypass during the same procedure as the explant of the adjustable gastric band and port. Data suggests that these conversions offer patients the same weight loss and remission of obesity-related disease as if they had undergone a metabolic procedure as their index procedure.

The sleeve gastrectomy can be converted to either a gastric bypass or a duodenal switch. Conversions to a gastric bypass are most often driven by GERD, development of a Barrett's esophagus, or development or worsening of type 2 diabetes not weight regain. The weight loss from sleeve and gastric bypass is similar in randomized prospective 3-year data [8].

Conversions of the sleeve gastrectomy for weight regain are sometimes a planned event. For instance, the sleeve may be offered to people in a very high weight class, when the long-term strategy is to do a duodenal switch (DS). The DS is a procedure which creates the most profound set of alterations in the epigenetic makeup of the patient and it essentially combines the effects of the sleeve and the bypass together to achieve a very high remission rate (85–90 %) of type 2 diabetes and weight loss [9]. In this strategy the sleeve is used to decrease the risk of the more complex procedure and patients will typically lose 125–150 or more pounds with the sleeve. These patients are closely followed and when their weight loss reaches a plateau or they start to regain weight then the second stage of the procedure, the duodenal switch, is performed. The bariatric surgery team usually follows these patients.

In the past, when metabolic procedures were presumed to work by restriction and malabsorption, surgeons would offer patients a revision of the gastrojejunostomy or would propose the use of other devices or techniques to reestablish restriction at the gastrojejunostomy or within the sleeve gastrectomy. Currently, there are still some surgeons who perform those types of procedures, but rarely as a stand-alone procedure and more often within the context of a comprehensive approach that seeks to maximize a procedure already performed. There is controversy about the indications for this set of procedures.

10.6 National Accreditation in Metabolic and Bariatric Surgery

The setting in which a patient undergoes metabolic and bariatric surgery is important to the patient's outcome. In 2005, the American Society for Metabolic and Bariatric Surgery and American College of Surgeons established the requirements of infrastructure, process, and data reporting that is now required to qualify for designation as an MBSAQIP-certified center. Nationally, over 800 MBSAQIP centers collaborate on national quality improvement projects such as Decreasing Readmissions through Opportunities Provided (DROP). Each center is able to use the reported data to improve care locally. Primary care physicians are urged to form an alliance with a local bariatric center that ideally provides both medical and surgical care for patients and is responsive and collaborative when patients either from anywhere need help. Working with a team from a nationally accredited program assures that the surgeon and the team have the expertise, infrastructure, and process to be able to offer maximum and best practices support to the patient with a complication.

10.7 Conclusion

Some weight regain after bariatric surgery is natural as the patient ages and adjusts to the procedure. Expectations regarding reweight gain should be set realistically with patients. Weight regain after gastric bypass has been characterized as approximately 7 % of total weight from year 2 to year 6, and then stable up to 20 years. Weight regain can be manipulated through regular exercise and healthy food choices, which in turn maximizes the epigenetic and metabolic changes that bariatric surgery proceduresafford. Patients who participate in comprehensive programs like those provided within a nationally accredited bariatric program may have an advantage in achieving long-term weight loss. Much of the opportunity in long-term follow-up, however, will occur in the primary care setting. The optimal approach to maximize health in a patient with a history of bariatric surgery is to be followed annually as part of their routine primary care. Indeed, any time that a patient is seen for any reason by his/her provider, the opportunity should be taken to take objective measurements in order to detect weight regain.

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11 Pregnancy in the Woman with a History of Bariatric Surgery

Melissa M. Davis and Robin L. Parry

Obesity is rapidly becoming the nation's number one health risk and bariatric surgery has become the most effective approach for sustainable weight loss and reduction of morbidities associated with obesity [1]. Obesity is defined as having a body mass index (BMI—calculated as weight in kilograms divided by height in meters squared) of 30 or greater [2]. It can be further subdivided into class I obesity defined as a BMI of 30–34.9, class II obesity with a BMI of 35–39.9, class III obesity with a BMI of 40 or greater [3, 4]. Currently, all 50 of the US states have an obesity rate of more than 20 %. In 2013, 18 states had an obesity prevalence of 30 to <35 %, and 2 states had an obesity prevalence of 35 % or greater [5].

Approximately 36 % of adult women in the USA are obese [5]. More than 80 % of all bariatric procedures done in the USA are performed on women; and approximately 50 % of these women are of reproductive age [6, 7]. Given these statistics, health care providers need to be prepared to care for obese women and women with a history of bariatric surgery.

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11.1 Background

Adipose tissue is an active endocrine organ. In women who are obese, leptin is increased and adiponectin is decreased, which can lead to increased insulin resistance. Excess body fat causes the production of high levels of the hormone leptin. Leptin decreases the production of the gonadotropin-releasing hormone (GnRH), changing the release of the luteinizing hormone (LH) and follicle-stimulating hormone (FSH) which are essential to ovulation. Androgen levels may also be increased, which, in combination with other hormonal changes, can lead to anovulation [8–10].

Adverse pregnancy outcomes in obese women are often attributed to the increased prevalence of insulin resistance and diabetes, but recently have been associated with increased adipose tissue and the deregulation of metabolic, vascular, and inflammatory pathways [11]. Women with obesity have increased rates of preeclampsia, gestational hypertension, gestational diabetes, cesarean delivery, stillbirths, first trimester and recurrent stillbirth, and large-for-gestational-age birth [12–16].

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11.2 Obesity and Infertility

Hormones are chemical mediators that regulate bodily functions such as cardiovascular activity, digestion, appetite, immunity, metabolic growth, and sleep. In women they also regulate menstrual cycles and reproductive health [17]. Reproductive function in women is governed by the ovaries, hypothalamus, and pituitary gland and their relationship is known as the hypothalamus-pituitary-ovarian (HPO) axis. Normal menstrual cycles begin with the release of gonadotropin-releasing hormone (GnRH) from the hypothalamus. The presence of GnRH causes the pituitary gland to produce luteinizing hormone (LH) and follicle-stimulation hormone (FSH). The result is stimulation of the growth of multiple estrogen-secreting follicles in the ovaries—one of which will eventually mature and, following a surge of LH, release an egg. After ovulation, the remainder of the follicle, or corpus luteum, begins to produce progesterone, along with smaller quantities of estrogen. Both progesterone and estrogen are necessary for maintenance and further development of the endometrial lining for conception [17–19]. Any disruption to the HPO axis can cause anovulation, prevent implantation, or inhibit normal embryonic development, resulting in infertility [20].

Infertility is often experienced by obese women, and may be the primary reason obese women seek bariatric surgery [20]. In obese women it is most commonly the result of oligo-ovulation and anovulation [21]. There is an increased risk for complications in obese women who conceive including gestational diabetes, hypertension, preeclampsia, cesarean section delivery, stillbirth, and postpartum weight retention [12, 22–26]. After bariatric surgery, and subsequent weight loss, fertility improves. In fact, as little as 5 % weight loss can improve ovulation rates, resulting in spontaneous pregnancy. Factors associated with improved fertility include the reduction in insulin resistance, decrease in androgen levels, and stabilization of sex hormones. Psychological influences may also be a factor with women feeling more attractive [27].

A study of 3029 couples having problems conceiving for more than 1 year, where all of the women were classified according to their BMI, strongly supports that obesity influences the ability to conceive. This study's results showed that those women with a BMI ≥ 30 had the most trouble conceiving. More specifically, those with a BMI > 35 were 26 % less likely to achieve a spontaneous pregnancy than women who were normal weight or overweight, but not obese, and those with a BMI > 40 or more were 43 % less likely to get pregnant at all [9]. In addition, an analysis of data based on 56,857 children showed an increased incidence of major congenital malformations of 35 % when mothers were overweight (BMI of 25–29.9 kg/m^2), and 37.5 % when they were obese (BMI of 30–39.9 kg/m^2) [28].

11.3 Bariatric Surgical Procedures

There are many different bariatric surgical procedures and devices. The weight loss mechanism of devices is largely understood to be associated with some form of restriction but has the disadvantage of causing hormonal changes that promote weight regain. For all procedures, weight loss is now known to be achieved through multiple mechanisms, including anatomical changes, neural hormonal responses, and genetics [29]. For post-bariatric surgery pregnancies, the specific surgical procedure, and its resulting anatomical and metabolic changes, will determine clinician considerations, recommendations, and guidelines. Ideally, the clinician will be able to optimize their patient's surgical procedure in order to help prevent excess weight gain during pregnancy, or to effectively lose any excess weight gained during the pregnancy.

Once pregnancy has occurred in a post-bariatric surgery patient, the health care provider will need to confirm what type of bariatric surgical procedure their patient has had, as the anatomical and physiological changes can affect daily caloric intake, food tolerances, absorption of medications, and the woman's ability to adhere to pregnancy weight gain recommendations [30].

Nutritional considerations may also vary based on the type of surgery [31].

11.3.1 Adjustable Gastric Band

The adjustable gastric band (AGB) is a device placed around the upper part of the stomach with a goal of limiting the amount of food the patient can tolerate. This device was approved for use in the USA by the Federal Drug Administration (FDA) in 2001 [32].

Weight loss is achieved by management of the volume of fluid within the band, as it can be adjusted by the patient's health care provider. The band is tightened by adding fluid to a reservoir, or port, attached to the band, which creates increased pressure and tightens the band around the stomach. The band is loosened by removing fluid from the reservoir, which reduces pressure in the band and loosens it.

11.3.1.1 Pregnancy Post-adjustable Gastric Band

Patients who have an adjustable gastric band are at risk for dysphagia and vomiting, but, if persistent, become at risk for nutritional deficiencies as well. Persistent dysphagia and vomiting may be due to the band itself, the amount of fluid placed in the band that narrows the opening of the stomach, or resulting postoperative adhesions [33, 34]. According to the American Society for Metabolic and Bariatric Surgery [33], intolerance to foods after adjustable gastric band surgery is common, and often results after eating foods that are denser, such as meats, vegetables, and grains—common sources of dietary iron and multiple vitamins.

Women in the first trimester of pregnancy are known to frequently experience persistent vomiting due to high levels of B-hcG or decreased levels of progesterone. As a result, morning sickness, or the more severe hyperemesis gravidarum, may prevent adequate intake of fluids. Pregnant women who have an adjustable gastric band may need to have their band emptied or partially loosened to facilitate adequate intake of food, liquids, and calories with or without hyperemesis. Adjusting, decreasing, or removing the fluid present in the band may completely alleviate symptoms, but prescribing antiemetic class B medication may also be necessary [35]. Pregnancy can also increase a patient's risk for gastric prolapse or gastric slip, and the clinician will need to anticipate a complete unfilling of the patient's band if this is suspected or confirmed [36, 37]. In addition, early consultation with a bariatric surgeon is advised.

Current recommendations support regular monitoring of patients weight, caloric intake, and nutritional parameters, and that some patients with an adjustable gastric band may never need an adjustment during pregnancy [37–40].

11.3.2 Sleeve Gastrectomy

The sleeve gastrectomy (SG) is performed by removing approximately 75–80 % of the stomach. The shape of the resulting stomach facilitates rapid passage of food through the stomach "tube" and into the distal small intestine. The intestines are not bypassed or changed, and the remaining stomach is tubular in shape.

The sleeve gastrectomy has an effect on the gut hormones influencing hunger, satiety, and blood sugar control. Because of the decrease in stomach surface area, patients are potentially at risk for malnutrition; however, this is rare [41].

The sleeve gastrectomy can be performed as a primary bariatric procedure in patients with lower BMIs, but is also used as part 1 of the staged approach to the biliopancreatic diversion/duodenal switch (BPD/DS) in other patients [33, 42].

11.3.3 Gastric Bypass Roux-en-Y

Gastric bypass Roux-en-Y (GBP) has been performed since the 1950s, regularly since the 1980s, and laparoscopically since the 1990s. In this procedure, a small pouch is created by dividing the upper part of the stomach creating a stomach pouch of about 30 cc and completely separating it from the rest of the stomach. Next, the jejunum is divided and one end is brought up and attached to the stomach pouch to allow food to bypass the lower stomach and the entire duodenum. This change in anatomy results in minimal malabsorption or restriction but does produce significant changes in hunger and satiety hormones.

Fifty percent of post-surgery patients will experience “dumping” syndrome, or rapid gastric emptying. Dumping syndrome is caused by the postprandial release of gut hormones and occurs when food, especially sugar, moves from the stomach into the small bowel too quickly. “Early” dumping occurs approximately 30–60 min after eating, while “late” dumping occurs after approximately 1–3 h [43, 44].

Symptoms of dumping syndrome include palpitations, nausea, abdominal pain and cramping, diarrhea, bloating, sweating, weakness, dizziness, and flushing. These symptoms can be quite unpleasant and potentially affect nutritional status [33, 42, 43].

11.3.4 Biliopancreatic Diversion with Duodenal Switch

The biliopancreatic diversion with duodenal switch (BPD/DS) is a rarely performed procedure with two components. The first stage of the procedure is to create a sleeve gastrectomy. The second stage of the procedure may be performed at the same time or later when weight loss from the sleeve gastrectomy has plateaued. Next, a large portion—roughly three-fourths—of the small intestine is bypassed. Postoperatively, the food empties from the new stomach directly into the ileum of the small intestine. Because the food does not mix with the bile and pancreatic enzymes until very far down the small intestine, there is a significant decrease in the absorption of calories and nutrients (protein and fat) as well as vitamins dependent on fat for absorption (A, D, E, and K). Like other procedures, hunger and satiety gut hormones are affected as well as blood sugar control [42, 45].

11.3.4.1 Pregnancy Post-sleeve Gastrectomy, -Gastric Bypass Roux-en-Y, or -Duodenal Switch with Biliopancreatic Diversion

Pregnant patients post-sleeve gastrectomy, -gastric bypass Roux-en-Y, or -duodenal switch/ biliopancreatic diversion, and who experience hyperemesis gravidarum, are at risk for ulcerations of their gastric pouch with symptoms including nausea, vomiting, heartburn, intolerance to foods, and gastroesophageal reflux. Because these symptoms can be common during pregnancy, especially in the second and third trimesters, it is important to rule out the patient’s bariatric surgery as the primary source in order to avoid delaying treatment [46]. Pregnant patients post-gastric bypass Roux-en-Y or -biliopancreatic diversion/duodenal switch, with complaints of abdominal pain must also be worked up for potential internal hernia, kidney stones, cholecystitis, or other complications. Clinicians should consult with or refer to the patient’s bariatric surgeon as soon as possible, to avoid an emergent situation [47, 48].

If it is necessary to place patients on any new medications, the immediate release form is always preferable to extended-release (ER), sustained-release (SR), or long-acting (LA) formulas [49].

11.4 Contraception

The greatest amount of weight loss occurs 12–18 months postoperatively. Delaying pregnancy until after this time will optimize the patient’s ability to achieve a healthy weight prior to conception. Additionally, this eliminates the confusion between postsurgical complications and early pregnancy symptoms [50].

Contraceptive use should be used for 12–18 months after WLS. However, oral contraceptive’s absorption can be decreased as a result of WLS. Therefore, alternatives to oral contraception should be encouraged. Vaginal contraceptives or intrauterine devices (IUD) are preferred examples to consider [51].

11.5 Antepartum

Post-bariatric surgery patients can expect a normal, uncomplicated pregnancy as nutritional balance will decrease morbidity and mortality in these women [52, 53]. Weight loss surgery (WLS) can reduce risks for intrapartum complications associated with obesity including preeclampsia, cesarean section, large-for-gestational-age infants, and wound infections [54] and prevent the genetic and epigenetic transfer of genes that predispose offspring to obesity and diabetes.

Gestational diabetes screening can present problems for the post-bariatric surgery patient. As dumping syndrome occurs in approximately 50 % of post-bariatric patients [55] alternative methods for evaluating the presence of gestational diabetes should be considered. Home glucose monitoring or A1C testing is widely preferred to the more traditional glucose tolerance test used in pregnancy, as this may cause severe dumping symptoms [52].

Women often experience nausea and vomiting after bariatric surgery due to either eating too fast or not thoroughly chewing their food. They may also experience nausea and vomiting in the first trimester of pregnancy due to either elevated human chorionic gonadotropin (HCG) or decreased progesterone levels. Consequently, the combination of bariatric surgery and pregnancy for the post-bariatric surgery obstetrical patient may increase the difficulty of this period of pregnancy [40, 53].

11.5.1 Risks

Gallstones, gastrointestinal hemorrhage, abdominal hernias, and internal bowel herniations are rare, but potential risks for the post-bariatric surgery patient as a result of nutrient absorption, enlarging uterus, and metabolism changes [40, 53]. Three periods in which the risk of obstruction is greatest are when the uterus becomes an abdominal organ, labor, and involution of the uterus postpartum [56]. Symptoms include nausea, vomiting, flu-like symptoms, and severe abdominal pain [53]. While these risks are rare, educating the patient on the signs and symptoms of potential risks or complications is recommended.

It is also recommended that identification and communication with the patient's bariatric surgeon occur early in the pregnancy. If the patient's bariatric surgeon is not available, establishing a bariatric surgeon and practice willing to work with and care for the patient is recommended. Establishing a relationship early in the pregnancy, between the obstetrician and bariatric surgeon is also critical, and may prevent or allow rapid diagnosis of conditions potentially affecting maternal or fetal health.

11.5.2 Vitamin/Mineral Recommendations

Non-pregnant, post-bariatric patients are routinely advised to take nutritional supplements, and may includea multivitamin, calcium citrate, vitamin D, folic acid, elemental iron, and vitamin B12. In addition, post-bariatric patients are advised to have annual laboratory studies that confirm compliance and repletion of vitamins. Despite these recommendations, some patients may fail to comply and every opportunity should be taken to reinforce recommendations. Once pregnant, the post-bariatric patient may have nutritional deficiencies that are unique to the healthy obstetric patient [52]. Symptoms that may suggest a nutritional deficiency include easy bruising, muscle cramps, and skin and mucosal changes [55].

The American College of Obstetrics and Gynecology (ACOG) guidelines recommend evaluating serum B12 and folate during pregnancy as well as CBC, iron, ferritin, calcium, and vitamin D each trimester [27].

11.5.3 Supplements

11.5.3.1 Calcium

Recommendations may include 1000 mg from calcium citrate with 10 μg of vitamin D to 2000 mg calcium citrate with 50–150 μg of vitamin D. Inadequate calcium intake can result in maternal bone loss, insufficient bone mineralization in the fetus, and decreased calcium in breast milk. In addition, serial ultrasounds should be performed in the pregnancy [54].

11.5.3.2 Iron and B12 Deficiency

Iron deficiencies may result due to multiple reasons:

There is a decrease in absorption of iron due to failure of the bypassed stomach to make intrinsic factor and of bypassing the area of iron absorption in the duodenum. Replacement should be in the form of ferrous at 40–65 mg daily [40, 57].

Vitamin B12 deficiency may be due to decreased acid from inadequate secretion of intrinsic factor, or decreased absorption in the terminal ileum [37]. Decreased cobalamin (B12) can result in increased homocysteinemia which can contribute to early pregnancy loss. Signs and symptoms of low B12 are neurobehavioral disorders in the infant, depression, confusion, memory impairment, and inability to concentrate [58]. Supplemental sublingual cobalamin of 10 μg daily is recommended [54]. However if this delivery source is not providing adequate results, 1000 μg IM monthly would be the alternative [37].

11.5.3.3 Folic Acid

Folic acid is an important supplement in all pregnancies to prevent neural tube deficiencies such as anencephaly and spinal bifida [40]. However, foods that are rich in folate bypass the duodenum, or may not be well absorbed in the post-bariatric patient.

Inadequate maternal stores of folate increase the risk for preterm death and birth defects in subsequent pregnancies. Folic acid dosing of 4 mg daily may decrease these risks, however, there is limited evidence to support this claim [27, 59].

11.5.4 Vitamin A Deficiency

Approximately 10 % of gastric bypass patients suffer a deficiency in vitamin A. By passing the duodenum, causes a delay in the mixing of dietary fat, bile salts, and pancreatic enzymes which may result in decreased absorption [37].

Vitamin A is essential in the second and third trimesters for normal fetal lung development and maturation. Inadequate vitamin A can result in bronchopulmonary dysplasia (BPD) in premature infants [57]. Additionally, vitamin A deficiency decreases iron levels increasing the susceptibility for respiratory infections and diarrhea, resulting in increased morbidity and mortality. Vitamin A deficiency may also have an influence of iron stores in the liver of the fetus [60].

Care must be given to avoid these complications by periodically evaluating plasma retinol levels. If oral supplements are needed, they cannot exceed 5000 IU/day [27]. Excessive amounts of retinol can have severe consequences to the infant and are well known to be teratogenic [40]. Beta-carotene, however is non-teratogenic and may be an alternative supplement [57, 61].

11.5.5 Vitamin K Deficiency

Placental transfer of vitamin K is limited. Excessive vomiting and malabsorption of fat that may occur in women after bariatric surgery can result in a vitamin K deficiency in the neonate. There are documented cases of intracranial bleeding as well as malformation of the fetal skeleton as a result of vitamin K deficiencies post-bariatric surgery. Close observation is recommended as currently there are no recommendations for replacement [61].

11.5.6 Zinc

Zinc levels can be decreased by approximately 30 % in the normal pregnancy. Risks associated with low zinc levels include preterm delivery, low birth weight, abnormal fetal development, and spina bifida. Additionally, deficiencies in zinc while breastfeeding can cause dermatitis reactions, and failure to thrive in the infant [61].

11.5.7 Magnesium

Magnesium needs during pregnancy are double that of the nonpregnant female. Supplemental magnesium in pregnancy may reduce incidences of low birth weight, fetal growth restriction, and preeclampsia [57, 62]. Magnesium 200–1000 mg daily is recommended if a deficiency is present [63].

11.5.8 Iodide

Iodide requirements double in pregnancy and approximately 50 % of pregnant women have an iodide deficiency. Iodide levels need to be assessed and repleted early, particularly in the first trimester of pregnancy. WHO recommendations include 250 μg/day for the pregnant and lactating woman [64].

11.6 Pregnancy and Weight Gain

The measurement of BMI at conception guides maternal weight gain (Table 11.1) [65] and maternal weight gain needs to be closely monitored in the post bariatric surgical patient. Most bariatric patients have an understandable fear about any weight gain, even if recommended by their health care provider. Sensitivity and early discussion about the expectation and amount of weight gain are critical. Patients need reassurance that some weight gain may be healthy and necessary, depending on their weight at conception.

It is important, however, for the clinician caring for the pregnant post-bariatric patient to understand that using the patient's procedure to minimize weight gain, while achieving a healthy pregnancy and delivery, is ideal. Postpartum return to healthy weight should be an expectation established early in the pregnancy. Frequent post-delivery follow up with a supportive bariatric provider will often facilitate this, and should be emphasized and encouraged.

Table 11.1 Pregnancy weight gain recommendations

Prepregnancy BMI	BMI (kg/m^2) (WHO)	Total weight gain range (lbs)	Rates of weight gain in second and third trimesters (mean range in lbs/week)
Underweight	<18.5	28–40	1 (1.0–1.3)
Normal weight	18.5–24.9	25–35	1 (0.8–1.0)
Overweight	25.0–29.9	15–25	0.6 (0.5–0.7)
Obese (includes all classes)	≥30.0	11–20	0.5 (0.4–0.6)

From IOM and National Research Council. Weight gain during pregnancy: reexamining the guidelines, 2009

11.7 Breastfeeding

Breastfeeding is encouraged. However, close monitoring of the mother's nutritional status is needed to insure the neonate is getting adequate micronutrients. Signs and symptoms of failure to thrive, anemia, and developmental delays can occur as a result of mother's micronutrient deficiencies (Table 11.2) [40, 53].

11.8 Conclusion

Loss of excess body weight following bariatric surgery improves fertility as hormones normalize. Pregnancy in the post-bariatric

Table 11.2 Micronutrient recommendations: post-bariatric surgery pregnancy

One prenatal vitamin daily that includes or should be supplemented by:	
Calcium citrate	1000–2000 mg daily
Vitamin D	50–150 μg daily
Ferrous iron	40–65 mg daily
Cobalamin SL	350 μg daily or 1000 μg IM monthly
Folic acid	4 mg daily
Zinc	15 mg daily

surgery patient is shown to be as safe as the non-bariatric patient, when nutritional status and weight are closely monitored by the patient's obstetrician, primary care provider, and bariatric surgeon.

Successful management of a pregnant post-bariatric surgery patient is dependent on their clinician's knowledge of their previous bariatric surgery procedure and associated potential health risks. Nutritional status will be dependent on the procedure, and management should include identification and treatment of nutritional deficiencies early in and throughout the pregnancy.

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12 General Surgery Procedures in the Obese Patient with and Without a History of Bariatric Surgery

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Physicians of all specialties will have the opportunity to treat the patient with obesity. One could make an argument that patients with both a surgical disease and obesity may be given the best care if delivered by a bariatric surgeon in the context of a metabolic and bariatric surgery team approach. When metabolic and bariatric surgery embraced laparoscopy, complications declined rapidly. In an analysis of risk factors for conversion from laparoscopic to open surgery in 176,014 appendectomy, cholecystectomy, and bariatric surgery cases, Papandria et al. noted that although obesity increased laparoscopic to open conversion rates overall, bariatric surgeries were least likely to convert [1]. All bariatric surgeons are specialized general surgeons, and thus the cholecystectomy, ventral hernia, appendectomy, or colectomy in a patient with obesity is well within their training. In addition, the ability to complete complex cases laparoscopically may offer the general surgery patient with obesity reduced length of stay, complications, and cost. Leveraging the bariatric unit and staff to provide expert care of patients with obesity having general surgery procedures allows familiarity with the pathophysiology of obesity and will improve surgical outcomes.

Adipocytes increase in number until adolescence and become hyperplastic in a patient with obesity. They produce hormones that cause inflammation, and a resultant constellation of symptoms. Metabolic syndrome is not clearly defined, but generally includes obesity, hyper- or dyslipidemia, insulin resistance, and hypertension. Patients with metabolic syndrome have higher risk for type 2 diabetes and all-cause mortality than the general population [2].

When approaching the bedside of a patient with congestive heart failure, renal disease, or diabetes, a surgeon has been taught to have a list of special concerns and cautions. Obesity is a serious chronic disease that, like the aforementioned conditions, requires particular therapies. In some cases, obesity makes common practices more important: proper positioning on the operating table, anticoagulation, and adequate pain control are examples. Other issues, like the proper dosing of medications and anesthetic agents, and the challenge of sleep apnea are more unique parts of the obesity picture.

This chapter shares techniques for care of the obese patient undergoing a general surgery procedure. It is roughly divided into preoperative, intraoperative, and postoperative sections, but obviously some therapies will cross over as patients progress through their hospitalization.

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12.1 Equipment

The equipment and physical plant of the hospital should be assessed prior to the treatment of the overweight patient. Confirm that the entrances to patient rooms and the operating room itself are adequately sized and that the tables in the operating room, CT scanner, and interventional radiology accommodate large patients.

For open surgery, think through which instruments will aid exposure and reach into a deep abdominal cavity. Check to be certain that large retractors, Bovie extenders, long needle drivers, and other long instruments are available. Platforms for both surgeon and assistant to stand on may also be useful.

If the planned procedure is laparoscopic, a long Veress needle may be desired. Sometimes long trocars are needed but not often. A patient can have a tremendous amount of intra-abdominal adipose tissue and yet the subcutaneous fat deposition may not be too thick. Long staplers, a long tip for the suction-irrigator, and long ultrasonic shears may be needed, in addition to needle drivers, graspers, and scissors.

12.2 Preoperative Preparation

As with any other patient, begin with a thorough history and physical exam. Special attention to a complete past surgical history will prevent surprises in the operating room, and an accurate current medication list sometimes unveils medical history that the patient failed to disclose.

Chest X-ray, EKG, and laboratory values including CBC, chemistry panel, liver function tests, cholesterol, thyroid function, hemoglobin A1C, and brain natriuretic peptide help identify possible undiagnosed conditions or underlying pathology.

If you have luxury of time afforded by an elective case, recruit consultants to get the patient into their best possible physical condition prior to surgery. Cardiac risk assessment and the indicated further testing have heightened importance in this patient population because of obesity's association with hypercholesterolemia and subsequent coronary artery disease. Hypertension and diabetes control is important, as is medical treatment into euthyroid state.

Smoking cessation is preferable in all patients, but 8 weeks of abstinence has been shown to be the best time to operate on a patient who cannot/will not quit permanently [3]. Furthermore, all patients should receive incentive spirometry training and careful instructions about what medications to continue and discontinue.

Obstructive sleep apnea is of special concern in the patient population with obesity. A sleep study and an arterial blood gas would be ideal, but the STOP-BANG questionnaire can be a useful screening tool. The acronym stands for Snoring loudly, Tiredness in daytime, Observed apnea during sleep, high blood Pressure, Body mass index > 35, Age > 50 years, Neck circumference > 40 cm, and male Gender. A point is given for each criteria met, and a score greater than three means that the patient is at high risk for sleep apnea [4]. One would expect sleep apnea be associated with pulmonary and cardiac complications, but interestingly high STOP-BANG scores have been associated with an increased risk of many different intraoperative and postoperative adverse events (Table 12.1) [5].

In patients with proven sleep apnea who have time for preoperative preparation, a recent meta-analysis suggests that 3 months of continuous positive airway treatment is long enough to make an impactful improvement in the patient's condition [6].

12.3 Antibiotics

Any discussion of obesity and wound infection must lead with the advantage of laparoscopy over open surgery. Whenever possible, staying laparoscopic is best. Nguyen et al. demonstrated this in a randomized trial on bariatric patents [7]. It is common sense that wound infection and hernia rates are lower with laparoscopy when compared to open procedures. Furthermore, when the patient has obesity, laparoscopy will often provide better visualization for the surgeon.

Pessaux et al., in a multivariate analysis of prospective multicenter data from 4718 patients, found obesity to be a risk factor for infection [8].

Table 12.1 STOP-BANG questionnaire

Height _____ inches/cm	Weight _____ lb/kg	Age _____ Male/Female	BMI _____ Collar size of shirt: S, M, L, XL, or _____ inches/cm	Neck circumference[a] _____ cm
1	Snoring	Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?	Yes	No
2	Tired	Do you often feel tired, fatigued, or sleepy during daytime?	Yes	No
3	Observed	Has anyone observed you stop breathing during your sleep?	Yes	No
4	Blood pressure	Do you have or are you being treated for high blood pressure?	Yes	No
5	BMI	BMI more than 35 kg/m^2?	Yes	No
6	Age	Age over 50 years?	Yes	No
7	Neck circumference	Neck circumference greater than 40 cm?	Yes	No
8	Gender	Gender male?	Yes	No

[a]Neck circumference is measured by staff
High risk of OSA: answering yes to three or more items
Low risk of OSA: answering yes to less than three items
Adapted from Chung F, et al. STOP questionnaire: a tool to screen patients for obstructive sleep apnea. Anesthesiology. 2008;108:812–21, with permission

The recommended preoperative antimicrobial prophylaxis for most general surgical procedures is cefazolin (Ancef). The American Society of Health-System Pharmacists recommends increasing the dosage of cefazolin from 2 to 3 g for patients weighing more than 120 kg, and redosing 4 h later [9]. It is tempting to use broader spectrum antimicrobial agents, but evidence for this is lacking. Administer the first dose 30 min before skin incision to ensure adequate tissue penetration.

Glycemic control in diabetic patients will also aid in healing and diminish surgical site infection.

12.4 Anticoagulation

Kornblith and colleagues showed that obese patients were hypercoagulable and have 85 % increased odds of developing a thromboembolic complication after trauma for each 5 kg/m^2 increase in body mass index [10].

In a very large analysis of 30,000 patients for in-hospital venous thromboembolism events, major risk factors were alcohol use, open surgery instead of laparoscopic, and chronic renal disease. Other associated factors were congestive heart failure, male sex, and chronic lung disease [11]. Venous stasis disease has also been identified as a risk factor.

Consensus among obesity treatment experts exists regarding the need for deep venous thrombosis prophylaxis, but regimens vary. Sequential compression devices beginning prior to anesthesia intraoperatively and continuing through postoperative period are recommended. Heparin 5000 IU either q8 or q12 or enoxaparin 40 mg daily or twice a day [12] is used. Administer the first dose before surgery begins.

Before an elective case in a patient with a history of venous stasis disease, deep venous thrombosis, pulmonary embolism, BMI greater than 55, or known hypercoagulable disorder, an inferior vena cava filter could be considered [13, 14]. This is controversial and should be assessed on a case-by-case basis.

12.5 Positioning

A recurring theme of this chapter is that the actions we take with all surgical patients need to be implemented even more carefully and urgently in patients with obesity. Any discussion of positioning must first begin with ensuring that appropriate equipment is present in the room. A table that can hold the weight of the patient, while still possessing its tilt functions, is fundamental. Some have side extenders for use when needed, or options for using arm boards to increase table width. Follow the manufacturer's recommendations. Safety straps are always important, but even more so if the table angle will be altered during the case.

If reverse Trendelenburg position is planned, a footboard is an important part of the setup. Foley catheter insertion, pneumatic compression device or sequential stocking placement prior to the footboard will keep the team from positioning the lower extremities twice.

The weight of the patient places increased pressure on every point of contact, from the table itself to the positioning devices. The Association of Perioperative Registered Nurses recommends that padding and positioning devices maintain a normal capillary interface pressure of 32 mmHg or less [15]. Patients with obesity are more likely to sustain nerve injuries or pressure sores; even rhabdomyolysis has been described [16]. Foam pads have been proven ineffective because they compress excessively. Many different kinds of elasto-polymer gel pads exist, and they should be used liberally to protect the patient from pressure. For some surgical cases, a beanbag would be utilized, and careful assessment for pressure points must be performed after the beanbag is put to suction.

Transfers are so challenging for this patient population that it is good practice to move from operating room table onto an appropriately sized hospital bed where they can remain through the post-anesthesia care unit and then to the hospital room. Careful attention to both patient and personnel safety is needed to prevent injuries [17]. Some centers use specialized air mattress transfer devices to assist.

There is data that suggests repositioning patients every 2 h in the post-anesthesia care unit and beyond results in a significant reduction in pressure ulcers [18]. Devices such as nasogastric tubes, endotracheal tubes, and Foley catheters need evaluation for tissue pressure in the postoperative setting, too.

12.6 Electrocautery

All operating room personnel are familiar with the electrosurgical unit technology that is used to cut and coagulate blood vessels. Brief knowledge of the principles of electricity is needed to keep patients safe during its use. The return electrode is designed to be placed over a large muscle. Any tissue with impedance greater than muscle can diminish dispersal of the current to the pad. Adipose tissue has a greater impedance than muscle. Impedance of the current causes tissue to heat and possible arcing of current to the electrode could result in a burn [19]. A larger dispersive pad surface area is needed to disperse the current density and complete the circuit to the generator [20]. Some machine manufacturers recommend the use of two grounding pads in patients who weigh more than 300 lb. It is important that the pads are positioned side by side, not on different body parts, to achieve desired effect of increased dispersive pad surface area to draw the current. If the pads were placed on different legs, for example, the current would choose the pathway of least resistance and go to one side preferentially. Some electrosurgical units have an adapter that can be used to connect two dispersive pads to the same generator. Other companies address this issue by manufacturing a larger size dispersive pad to use in patients with obesity. Follow the manufacturer's guidelines on all electrocautery equipment.

12.7 Anesthesia

Perioperative care of a patient with obesity is best accomplished by a team of experts, and the anesthesiologist and CRNA could be the most important members. They perform critical life support and monitoring functions when the patient is most vulnerable. The anesthesia team is often first to recognize an adverse perioperative event and their expertise can make the difference between a recognized and corrected problem and a tragedy.

Vascular access is understandably more difficult to achieve in the patient with obesity. Patience, a warm extremity, and good knowledge of the anatomy will improve success with peripheral venous access. Thick tissue unfortunately also diminishes visibility via ultrasound guidance. Careful central venous catheter insertion must be considered if peripheral access can't be found. Under no circumstances should the surgical case proceed with tenuous vascular access.

Hypertension is a known weight-related comorbidity and management of blood pressure intraoperatively begins with its accurate measurement. An arterial line is ideal and should be utilized in patients with worrisome cardiopulmonary status, or when repeated arterial blood gases may be needed. Poorly fitting upper arm blood pressure cuffs give a falsely elevated reading. The length of the cuff bladder should be equal to at least 80 % of the measured circumference and width should be equal to at least 40 % of the measured arm circumference at the midpoint of the upper arm [21]. Appropriately sized cuffs should be standard hospital equipment, but LeBlanc et al. demonstrated that forearm blood pressure correlated well with invasive intra-arterial blood pressure measurement if cuff size or anatomic issues prevent utilizing the upper arm [22].

Heightened concern about aspiration is prudent in the presence of a disease state that increases the likelihood of gastroesophageal reflux disease. Pretreatment with prokinetic, H2 receptor antagonists, or proton pump inhibitors would hopefully reduce volume and acidity of gastric contents. Rapid sequence intubation, cricoid pressure, ramped position, or even awake fiber-optic intubation may help minimize aspiration [2].

Assessment and management of difficult airways is a voluminous topic and beyond the scope of this chapter. In general, adequate preoxygenation followed by head-elevated laryngoscopy position for intubation and extubation is suggested [23]. Video laryngoscopes and other techniques are options. General anesthesia with a secure airway is preferable to deep sedation without a secure airway [24]. Head of bed elevation or other non-supine position is good practice whenever possible.

Regional techniques (central neuraxial block) or peripheral nerve blocks are preferable to general anesthesia in patients with obesity. It is expected, however, that difficult anatomy makes this technically challenging and more likely to fail.

Drug pharmacokinetics are altered by the body composition of patients with obesity (Table 12.2). Drug dosing on the basis of total body weight metric may result in overdose [25]. Lipid-soluble drugs are dosed based on total body weight, whereas non-lipid-soluble drugs should be dosed on ideal body weight [26].

12.8 Postoperative Pain

It is fortunate that in the twenty-first century we perform more and more cases laparoscopically instead of open, and the resultant diminished pain and decreased hospital stay is widely documented. There are also complications that will be less likely if adequate pain control is achieved. We need the patient to be feeling well enough to get up to walk and use the incentive spirometer. These principles apply to all patients, but the presence of obesity increases deep venous thrombosis, pressure ulcers, and pulmonary complications like atelectasis or pneumonia.

Table 12.2 Common medications and suggested dosages based on weight

Medication	Dosing weight
Propofol	Lean body weight (induction)
	Total body weight (maintenance)
Etomidate	Lean body weight
Succinylcholine	Total body weight
Vecuronium	IBW
Rocuronium	IBW
Cisatracurium	Lean body weight
Sufentanil	Total body weight
Remifentanil	IBW
	Lean body weight
Morphine (PCA)	Lean body weight
Neostigmine	Total body weight
Sugammadex	IBW + 40 % or total body weight
Lidocaine (local)	Total body weight

From Leonard K, et al. Perioperative management of obese patients. Surg Clin N Am. 2015;95:379–90, with permission

In 1984 Rand et al. studied open cholecystectomy patients and open bariatric surgery patients with two hypotheses:

1. That morbidly obese patients would experience less postsurgical pain than normal-weight adults because of increased endogenous opiates
2. That preoperative measures of psychiatric distress and past use of psychoactive medications would be positively related to their postoperative narcotic use

Both of these hypotheses proved correct and the authors noted that previous surgeries correlated with decreased analgesic use, perhaps by lowering anxiety [27].

Thus, although it is possible that patients with obesity may need less analgesia than others, there are individual factors that will induce variability.

Opioid analgesics are the mainstay of postsurgical pain control, but obesity increases risks. Morbid obesity is associated with a high rate of obstructive sleep apnea and the combination of airway obstruction and possible respiratory depression makes the side effect profile of opioids particularly unappealing. Taylor et al. said that 77 % of morbidity due to opioids occurs in the first postoperative day and patients with sleep apnea were at particularly high risk [28].

Multiple sources recommend multimodal analgesia with combinations of agents to reduce opioid requirements. Preemptive analgesia and regional anesthesia, whenever feasible, are recommended [29, 30].

NSAIDS are an option for nonsedative analgesia. Ketorolac and acetaminophen are both excellent choices and some evidence shows that using both may be best [31]. Ketamine as a bolus, followed by infusion, has also been shown to be useful.

Blaudsen et al. performed a meta-analysis of randomized controlled trials and determined that perioperative systemic alpha-2 agonists clonidine and dexmedetomidine decreased postoperative opioid consumption, pain intensity, and nausea. Unsurprisingly, hypotension and bradycardia can also occur [32].

Regional anesthetic techniques beginning in the operating room and continuing into the postoperative period have been shown to reduce opioid-related complications. The patient's body habitus can make placement more challenging, but positioning techniques and guidance systems like ultrasound can assist.

A lidocaine infusion device may be placed directly on top of the fascial closure [33]. This has more utility in long open incisions than in laparoscopy.

If the aforementioned techniques do not provide enough pain control, then opioids should be administered. Provide oxygen, continuous pulse oximetry, and close monitoring by personnel to ensure patient safety. In patient-controlled analgesia (PCA), demand-only and no basal rate can safeguard against overdosage.

12.9 Other Postoperative Considerations

After surgery the patient with obesity must be transferred to the appropriate level of care, into the hands of an educated and sensitive multidisciplinary team. Each time, consider whether higher acuity setting is dictated by the patient's chronic disease states. Various aforementioned principles carry through into the postoperative setting, including head of bed elevation, careful monitoring of the level of sedation, positioning, adequate pain control, assisting with early and frequent ambulation, and incentive spirometry use. Apply supplemental oxygen until maintaining sat >90 % even while sleeping and utilize continuous pulse oximetry, not intermittent. Continuing noninvasive positive pressure ventilation (NIPPV) or continuous positive airway pressure (CPAP) in patients who used it before surgery is also important. Blood glucose monitoring and control in patients with diabetes are essential during surgical recovery.

12.10 Discharge

Just as the hospital equipment needs to be assessed prior to providing care for a patient with obesity, the facilities of the discharge disposition also need to be checked. Appropriately sized walkers, wheelchairs, commodes, or electronic beds may be necessary. The patient's physical condition may be altered secondary to injury or postoperative pain. A previously independent person might need nursing services at home.

Clear instructions, both verbal and written, must be given to continue excellent care of the patient with obesity after hospital discharge. The need for good nutrition, mobility, use of incentive spirometer, hygiene, and pressure reduction [34] persist during convalescence.

12.11 Conclusion

Much has been written about the so-called obesity paradox. When first described, cardiac failure patients with a higher body mass index were noted to have lower mortality and longer survival than normal- or low-body-mass-index patients. Since those early publications, the "paradox" has been demonstrated in other serious chronic diseases like cancer, rheumatoid arthritis [35], chronic obstructive pulmonary disease [36], and renal failure [37].

Initial studies used body mass index alone to draw their surprising conclusion that obesity could be helpful. When the patients with obesity were evaluated more thoroughly with assessments of muscle mass and function, nutritional status, and measurements of inflammation, however, the survival benefit appears to be because the high BMI patients were younger and had better nutritional status [38]. The "obesity paradox" is really a reflection of the fact that obesity accelerates development of dangerous chronic diseases in younger, healthier people. Although they survive better, it is actually quite tragic rather than being a positive thing.

The limitations of body mass index also may play a role in the "obesity paradox" phenomenon, and waist-to-hip ratios or waist-to-hip-to-height ratios may be more reliable predictors of mortality and morbidity in patients with obesity.

It is important that the techniques in this chapter are utilized to protect patients through needed surgeries. After the patient recovers from the general surgery procedure, however, the author's final suggestion for the care of a patient with obesity is to encourage, and assist, them with obtaining obesity treatment.

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13 Metabolic and Bariatric Surgery Accreditation: Why It Matters to Your Patient

Wayne J. English

Essential elements for surgical quality improvement include institutional commitment with readiness to embrace the culture of quality improvement, a surgeon champion with effective leadership skills, and solid infrastructure. The willingness to collect high-quality data, critically look at outcomes, develop and implement process and quality improvement initiatives, and reassess outcomes are important steps in recognizing and correcting gaps in treatment being delivered to patients.

Surgical quality improvement has developed from a culmination of experiences over the past century. Throughout history, surgeons have been providing care to patients with what they believed to be of high quality, but they have not been required to monitor outcomes and make necessary changes to improve. Surgeons often graduate from residency and fellowship training programs to find themselves in a position in which they never participate in a formal critical review of their outcomes. It has not been until recently that a high priority has been placed on systems to monitor, benchmark, and report surgical outcomes.

This chapter reviews the history of quality measurement and improvement, and discusses the development and current efforts of accreditation and QI programs being utilized by metabolic and bariatric surgeons today.

13.1 Sentinel Quality Improvement Efforts in History

The cornerstone of quality improvement involves the standardization of care, which has been shown repeatedly in history, and is a subject taken very seriously in an effort to protect the welfare of patients.

Quality improvement efforts can be followed back to the mid-1800s, when Ignaz Semmelweis in Vienna, Austria, established hand hygiene protocols after realizing that hospital-acquired diseases were transmitted via the hands of healthcare workers [1]. During the Crimean War in 1850, Florence Nightingale was credited with recognizing the association between high mortality rate among soldiers treated at army hospitals and poor ventilation, sanitation, and hygiene standards [2].

Ernest Amory Codman, considered the pioneer of outcome-based quality improvement, developed a system in which he would follow up with his patients for years after treatment and record the end result to determine the effectiveness of care. Dr. Codman's concept influenced

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the founding of the American College of Surgeons (ACS) in 1917, and would eventually transform into the Hospital Standardization movement, a precursor to what we readily recognize today as The Joint Commission [3].

Avedis Donabedian, in 1966, described a conceptual framework for defining and assessing quality of healthcare services [4]. He identified three basic components essential to quality of care: *structure, process*, *and outcome*, emphasizing that properly integrating these components is critical in improving the quality of care.

13.2 History of Bariatric Surgery and Evolution of Quality Improvement

Procedures for weight loss began in the 1950s with the introduction of the jejunoileal bypass (JIB). However, the procedure was abandoned in the 1970s when a significant number of patients subsequently developed severe nutritional deficiencies, hepatic cirrhosis, and death. Reversal or conversion to another bariatric procedure was recommended in all patients who underwent a JIB procedure in order to prevent development or progression of these severe complications [5].

In 1966, Edward Mason performed the first gastric bypass connecting a loop of jejunum to the gastric pouch [6]. This technique was later modified in 1977, introducing the Roux-en-Y configuration to replace the loop gastrojejunostomy [7].

In 1971, Dr. Mason introduced the vertical-banded gastroplasty (VBG) in an attempt to avoid the complications associated with JIB [8]. Unfortunately, less than half of the patients maintained satisfactory weight loss after 5 years and many patients went on to require reoperations due to staple-line dehiscence, pouch dilation, band erosions, and weight loss failure [9].

In 1985, the inflatable gastric band was introduced and, in the 1990s, the sleeve gastrectomy was described as a component of the biliopancreatic diversion with duodenal switch procedure [10, 11].

Bariatric surgery became more widely accepted in 1990s as mounting evidence demonstrated durable weight loss and comorbidity remission. Case series using laparoscopic technique were published and there was a surging interest in learning this technique, sparking a major evolution in the field of bariatric surgery.

In 2001, the IOM report on complications among hospitalized patients focused concern around patient safety. The IOM published "Crossing the Quality Chasm: A New Health System for the Twenty-first Century," a disheartening report revealing the flaws of our healthcare system. The report stated, "The quality of healthcare received by people of the United States fall short of what it should be [12]."

In 2005, a report by Flum et al. focused attention on the overall mortality in Medicare patients undergoing bariatric surgery, citing that the risk of early death after bariatric surgery is considerably higher than previously suggested [13].

After the introduction of laparoscopic bariatric surgery in 1994, there was a steady, practically exponential, increase in the number of surgeons performing laparoscopic bariatric surgery. Evaluation of the Nationwide Inpatient Sample between two time periods (1998 and 2002; 2003 and 2008) demonstrated that the rate of bariatric surgery increased from 6.3 to 32.7 to 54.2 procedures per 100,000 adults in 1998, 2002, and 2008, respectively. In 1998, only 2.1 % of all bariatric surgery procedures were completed laparoscopically. This proportion increased to 17.9 % in 2002, and greater than 90 % in 2008. The number of bariatric operations performed in 1998 was 12,775, which increased to 70,256 in 2002, peaked in 2004 at 135,985 cases, and plateaued at 124,838 cases in 2008. The number of bariatric surgeons with membership in the ASMBS increased from 131 in 1998 to 1819 in 2008 [14, 15].

Many surgeons would attend a 2- or 3-day course and start performing bariatric surgery without the appropriate infrastructure necessary to provide safe care for the patient. The numbers of complications realized were significant during this period, thus starting a frenzy of activity as prominent national newscasters were delivering negative news about bariatric surgery outcomes on a regular basis. Subsequently, the public and many payors were questioning the relevance and role of bariatric surgery as a means of treating morbid obesity. Many payors eventually stopped providing insurance coverage, deeming the procedures cost prohibitive due to high morbidity and mortality rates. Furthermore, surgeons would be subjected to skyrocketing malpractice insurance premiums if they elected to perform bariatric surgery. The future of bariatric surgery was in grave jeopardy, which necessitated critical scrutiny and improvement of the services being provided by bariatric surgeons if the specialty's integrity and reputation were to remain intact.

In response, the ASMBS BSCOE and ACS BSCN programs decided to establish separate, but similar, accreditation programs to improve the quality of bariatric surgery care, in an effort to resolve the conflicts.

13.3 American Society for Metabolic and Bariatric Surgery Centers of Excellence (ASMBS BSCOE) Program and the American College of Surgeons Bariatric Surgery Center Network (ACS BSCN)

The ASMBS BSCOE was developed in 2004 to provide means to identify bariatric surgery programs providing high quality of care by administering comprehensive standardized surgical care, long-term follow-up, and management of the morbidly obese patient. Data was entered into the Bariatric Longitudinal Outcomes Database (BOLD).

In a parallel effort, the ACS, in 2005, gave highest priority for developing the Bariatric Surgery Center Networks (BSCN) to improve quality and facilitate access to care for morbidly obese patients. The ACS would recognize certain hospitals as Level 1a and 1b Bariatric Centers with high-volume practices that would manage the most challenging and complex patients with optimal opportunity for safe and effective outcome. Recognizing the need for access to bariatric surgery and recognizing that high-quality surgical care occurs in other than high-volume tertiary centers, they designated certain facilities as Level 2a and 2b Bariatric Surgery Centers that could provide high-quality care to a lower volume of risk-stratified patients with lower body mass index and less comorbidities. Outpatient Bariatric Surgery Centers would be designated to those centers that provided the application and adjustment of laparoscopic gastric bands with discharge from the unit in less than 24 h [16].

Both programs consisted of standards that provided an opportunity for bariatric surgery centers to develop the necessary infrastructure, process, and outcomes to improve their standards, education, and training to meet specific guidelines. Uniform data elements would be collected and outcomes compiled to provide programs with an opportunity to assess and verify risks and benefits of bariatric surgery. The majority of centers offering bariatric surgery in the USA participated in at least one of these accreditation programs. The data registries for both programs in 2011 had greater than 100,000 patients per year being entered into one of the two registries.

13.4 Evolution of New Standards for Bariatric Surgery Accreditation

These programs likely contributed to improvements in bariatric surgery across the board as data from the Nationwide Inpatient Sample program revealed that bariatric surgery in-patient mortality dramatically improved from 0.8 % in 1998 to 0.21 % in 2003, and would decrease further to 0.1 % in 2008 [14, 15].

However, the existence of two accreditation programs created confusion and, in some cases, centers required duplicated effort in data collection. The accreditation programs proved to be biased and unintentionally restricted access to care. Programs were accredited based on structural and process elements only, not on outcomes, and the accreditation process could not truly differentiate between those programs that were "excellent" and those that were not.

The Center for Medicare and Medicaid Services (CMS) and some insurance payors would require one of these designations in order for bariatric surgery centers to provide care to beneficiaries within their network. As a result of this selective referral environment, many facilities offering high-quality bariatric surgery care would be excluded from participating due to difficulty meeting annual facility volume requirements. It was difficult for new programs to develop due to high-volume requirements, and more than one-third of programs were unable to meet the requirements to maintain accreditation.

In many cases, patients would be forced to leave their local communities to undergo surgery at centers hours away, just to return home and be treated by general surgeons with minimal or no bariatric surgery experience when complications developed. Studies looking at CMS's policy limiting bariatric surgery coverage only to hospitals designated as "Centers of Excellence" ("COE") found no difference in adjusted rates of complications and reoperations, as well as cost savings, in the time before and after the national coverage decision [17, 18]. This would eventually lead to a policy change in which patients are no longer required to undergo surgery only at programs participating in the ASMBS BSCOE or ACS BSCN [19]. This generated a debate regarding the importance of COE programs, as there was also data suggesting that COE centers were indeed the cornerstone of improving quality in bariatric surgery [20].

Additional shortcomings of these accreditation programs included the inefficiency and readability of the reports that were provided to the participating centers. The BOLD registry captured a large amount of rich data. However, the reports were not meaningful and readily understood in order for centers to assess their own performance compared to other centers. It was difficult to initiate quality improvement efforts as the reports lacked risk adjustment and benchmarking on outcomes, and definitions of data elements were vague. In addition, there were unacceptably low 30-day and long-term follow-up rates.

Regarding the volume requirement of 125 cases seen in the previous programs, evidence supported reducing the annual volume criteria to 50 stapling cases, thus keeping a balance of maintaining quality while not restricting access to care for morbidly obese patients [21].

13.5 American College of Surgeons National Surgical Quality Improvement Program

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) was established as a result of a government mandate to improve the quality of surgical care within the 133 Veterans Administration (VA) hospitals.

In 1985, there was a report citing disappointingly high mortality and complication rates in the VA hospital system. In 1986, Congress mandated that all VA hospitals report their outcomes annually and compare them with the national average. This effort was hampered due to the lack of national average data and risk-adjusted data models for various surgical specialties. The legislative act allowed for the development of a risk-adjustment model that would take into account the patient's severity of illness in order to level the playing field for comparison. Between 1991 and 1993, VA surgeons developed the risk-adjustment models for 30-day mortality and morbidity in nine surgical specialties. In 1994, the VA NSQIP was created allowing for all VA hospitals to work in a collaborative manner and comply with the legislative mandate to monitor and improve surgical outcomes. Mortality and morbidity rates were reduced by 27 % and 45 %, respectively [22].

The VA NSQIP program proved to be so successful that, in 1999, the ACS initiated a pilot program involving 14 academic centers and 7 private community hospitals. The pilot study results validated the VA NSQIP results, and thus the ACS NSQIP was officially established in 2004 with support from AHRQ [23].

Currently, there are 640 hospitals participating worldwide, collecting data elements on preoperative risk factors, operative factors, and 30-day outcomes for morbidity and mortality. Risk-adjusted outcomes are presented to each hospital biannually, measuring observed versus expected (O/E) outcomes. Best practices are identified and shared with the participating hospitals. Participating hospitals have access to a wide variety of evidence-based service tools including best practice guidelines and case studies, risk calculator tool, and collaborative support.

ACS NSQIP has 13 regional collaboratives, 14 system-wide collaboratives, and 8 virtual/pilot collaboratives. One study showed that each year a hospital participates in the ACS NSQIP; it has the opportunity to reduce the number of complications by 250–500, and saves 12–36 lives. If every US hospital used ACS NSQIP, possibly more than 100,000 lives could be saved annually, and more than 2.5 million complications could be prevented, thereby potentially reducing costs by more than $25 billion [24].

13.6 Collaborative Quality Improvement

In 2005, a regional model of collaborative quality improvement (CQI) gained traction in Michigan and led to successful QI in bariatric surgery and other areas as well.

13.6.1 Michigan Health and Hospital Association Keystone Center ICU Project

The Michigan Health and Hospital Association (MHA) Keystone ICU Project was formed in an effort to reduce catheter-related bloodstream infections (CRBSI) in ICUs across Michigan. The primary goal was to increase patient safety, which was accomplished by shifting the existing culture, developing the mindset of working as a team, and strengthening communication skills.

Daily goal sheets and evidence-based interventions were developed, implemented, and monitored. A critical component of the success was the surgeon and nurse champions who were trained to lead the ICU team and work with infection-control teams to obtain standardized data. As a result of the positive change in safety culture, development of strong clinical leadership, and standardized outcome data, a significant decline in CRBSI was readily realized and sustained [25]. The following list includes the lesson learned during the project [26]:

1. Understand the differences between leadership and authority: cultivate leaders.
2. Get both the technical and adaptive work right.
3. Strive to find the "sweet spot" between scientifically sound, yet feasible, measures and interventions.
4. Match project goals, objectives, and database design at the outset.
5. Stay focused on original aims.
6. Link culture improvement and clinical outcomes.
7. Reduce bias in data collection.
8. Reduce the quantity, not the quality, of collected data.
9. Keep a "laser-sharp" focus on patients.
10. Expect the project to occasionally stall.
11. Improve upon quality improvement models.

13.6.2 Northern New England Cardiovascular Disease Study Group

In the wake of federally mandated outcomes reporting for coronary artery bypass graft procedures, the Northern New England Cardiovascular Disease Study Group (NNECDSG) was formed in 1987. Cardiac surgeons in New England invariably felt that the reports were false and that their outcomes were better than what was being publicly reported, but soon realized the validity of the reports when they first started looking more closely at their own data.

Participation in the group was voluntary as clinicians and administrators developed methods to improve quality of care, patient safety, and efficiency in utilizing hospital and financial resources. With significantly different mortality rates noted throughout the group, their first project was to reduce mortality associated with CABG throughout New England.

Continuous performance feedback with ongoing self-assessment and benchmarking, training on how to perform CQI, and site visits allowed participating centers to share best practices in a scholastic manner. The effort of all participating centers achieved an improvement in post-CABG in-hospital mortality by 24 % [27].

13.6.3 Surgical Care and Outcomes Assessment Program

In 2006, Surgical Care and Outcomes Assessment Program (SCOAP) was formed in Washington state in an effort to improve outcomes in general surgery. The group has since expanded its involvement to include vascular and spine surgery. SCOAP's core mission is to improve quality through tracking of risk-adjusted outcomes to assist in constructing interventions that will allow underperforming facilities to improve.

With standardized data collection, significant variation in utilization and outcomes was noted, which ultimately resulted in the development of numerous protocols for quality and process improvement. Some of the protocols developed include beta-blocker use after surgery, discharge VTE prophylaxis in cancer patients, reducing NGT use after surgery, reducing blood transfusion utilization, obtaining glycemic control during surgery, improving nutritional parameters prior to surgery, reducing the rate of perforated appendix, reducing leaks by routinely performing intraoperative leak testing in colorectal surgery, and reducing the number of patients who are not voiding spontaneously after receiving epidurals for surgery.

The overall cost reduction per case for appendectomy, colorectal, and bariatric procedures in Washington state hospitals participating in SCOAP from 2006 to 2009 was approximately $2000. When taking into account the costs noted at non-SCOAP hospitals during this same time period, the overall cost savings associated with these differences amounted to $67.3 million [28].

13.6.4 CQI in Michigan

States with a dominant insurance payor present themselves with a great opportunity to reduce overall costs by developing CQI. Michigan hospitals and Blue Cross and Blue Shield (BCBS) of Michigan/Blue Care Network work in conjunction with the many specialty-specific CQI programs to achieve their best possible patient outcomes at the lowest reasonable cost. Currently, there are 20 CQIs that cover multiple areas of care (see list below).

- Michigan Cardiovascular Consortium—Percutaneous Coronary Intervention
- Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative
- Michigan Bariatric Surgery Consortium
- Michigan Surgical Quality Collaborative
- Michigan Breast Oncology Quality Initiative
- Michigan Cardiovascular Consortium—Vascular Interventions Collaborative
- Lean for Clinical Redesign Collaborative Quality Initiative
- Michigan Anticoagulation Quality Improvement Initiative
- Michigan Oncology Quality Consortium
- Hospital Medicine Safety Consortium
- Michigan Trauma Quality Improvement Project
- Michigan Urological Surgery Improvement Collaborative
- Michigan Radiation Oncology Quality Consortium
- Michigan Arthroplasty Registry Collaborative for Quality Improvement
- Michigan Spine Surgery Improvement Collaborative
- Michigan Value Collaborative
- Anesthesiology Performance Improvement and Reporting Exchange
- Michigan Pharmacists Transforming Care and Quality Consortium
- Michigan Emergency Department Improvement Collaborative
- Integrated Michigan Patient-Centered Alliance on Care Transitions

13.6.5 Michigan Bariatric Surgery Collaborative

The Michigan Bariatric Surgery Collaborative (MBSC) was developed in 2006 as part of the overall CQI effort throughout Michigan. Funding from the Blues enables hospitals to work in a collaborative environment. BCBS provides resources for data collection and analysis along with administrative oversight. A separate coordinating center serves as a data warehouse, conducts data audits, performs data analyses, and generates comparative performance reports. Participating hospitals work together by sharing data and best practices to improve patient care throughout the state of Michigan.

When data was first collected, it was noted that approximately 10 % of patients had preoperative inferior vena cava (IVC) filters inserted to prevent venous thromboembolism (VTE). There was wide variation in the use of IVC per hospital, ranging from 0 to 35 %, with most IVC filter insertions being concentrated within only 5 of the 20 participating centers.

The data demonstrated that more complications were associated with the IVC filter, being responsible for over 50 % of the mortality and permanent disability. Complications seen included fatal pulmonary embolism despite having an IVC filter in place, filter migration, and complete IVC occlusion [29].

As a result, the members of the MBSC agreed to develop and implement statewide guidelines for a standardized approach to administering VTE prophylaxis to minimize the risks of postoperative VTE as well as reducing complications associated with IVC filters and bleeding. Using a risk-prediction model, VTE risk can be stratified into low, medium, or high risk. Low-risk patients would receive in-hospital prophylaxis only; medium-risk patients would receive in-hospital prophylaxis and post-discharge prophylaxis; high-risk patients would be treated with therapeutic anticoagulation [30]. This effort significantly reduced the number of IVC filters being placed for bariatric surgery patients throughout Michigan and resulted in an overall cost savings of $4 million.

13.7 Challenges to Regional Collaborative Quality Improvement

There are a number of potential obstacles that come with developing and maintaining a collaborative. Funding is typically a problem, as most collaboratives will generally have little or no resources available. In some cases when incentives for quality and safety also result in cost savings a dominant payor, like BCBS MI, offers to fund the operational costs. If the data is shared with payors the payor may also provide nominal financial incentives to participate in meetings, and pay-for-performance incentives for the top-performing centers in the state.

Dedicating time and effort into collaborative activities is often voluntary, and may be a burden to some who consider that a day off from work is money not being earned, especially when there is usually no, or little, financial reward to the physician or practice for participating in a collaborative.

The competitive nature of business may exert tension on relationships with other surgeons in the community. Geographic challenges may exist for those living many hours away from a designated meeting place. Virtual meetings can be considered to ease the burden for these situations. Developing trust and a sense of community is essential to the success of a collaborative, and takes strong leadership.

Data collection can be costly, and hospital administrators may have limited funds, finding it difficult to justify hiring extra personnel dedicated to entering data. It is important that data is entered accurately, and leaders within the collaborative should audit sites regularly to determine that data is indeed being entered accurately. This aspect of data collection is crucial, as surgeons and teams must believe and trust the data in order to act on it. Administrators must believe and trust the data in order to fund quality improvement. In addition, electronic medical records may not be aligned among participating centers and may provide a disadvantage for some centers [28].

13.8 A New Era in Bariatric Surgery Quality Improvement: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

Much was learned from the previous bariatric surgery accreditation programs, but NSQIP and the Michigan model helped provide further insight allowing collaborative quality improvement to emerge as an important concept for the future development of the new accreditation program: most importantly, understanding how to standardize patient care with accurate data collection, providing meaningful data feedback with critical analysis of data (locally, regionally, and nationally), and sharing best practices by collaborating with other centers.

In 2012, the ACS and ASMBS announced that it would combine their respective national bariatric surgery accreditation programs into a single unified national accreditation program for bariatric surgery centers, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). A bariatric surgery center achieves accreditation following a rigorous review process during which it proves that it can maintain certain structural requirements, and standards of practice. MBSAQIP provides a platform for continuous monitoring of mortality and morbidity, emphasizing continuous quality improvement. There are currently over 700 MBSAQIP-accredited programs in the USA [31].

In this time of cost consciousness and containment, it is critical to develop quality improvement initiatives that improve value in the services we provide. If quality improves and costs can be minimized, everyone wins. Value analysis should be regularly incorporated in the operational aspects of maintaining a high-quality bariatric surgery center. Understanding the value equation in healthcare (value = quality of care + quality of service/cost) is essential to a surgeon's effort to maintain institutional support for continuous quality improvement.

A study of insurance claims from bariatric procedures during 2001–2002 found that the most costly aspect of bariatric surgery was readmissions. The study suggested that a saving of approximately $38,000 could be realized per avoided readmission. The total risk-adjusted healthcare payments were $65,031 for readmitted patients with complications within 6 months after surgery, compared to $27,125 for non-admitted patients with complications [32]. In another study looking at costs in patients undergoing major noncardiac surgery, the average difference between patients with and without complications was shown to be $29,876 [33].

Within a short period of time since the start of MBSAQIP, a collaborative effort was undertaken to improve the value of care bariatric surgeons provide to their patients by decreasing readmissions. The "Decreasing Readmissions with Opportunities Provided" (DROP) project is a nationwide effort to standardize patient care pathways and identify patients at risk for readmission. Programs participating in the study have a goal of reducing readmissions by 20 %. Several studies have demonstrated a 30-day readmission rate of between 5.1 and 7.3 % for laparoscopic gastric bypass and approximately 5.5 % for laparoscopic sleeve gastrectomy [34–36]. With approximately 190,000 new bariatric surgery procedures being performed annually, approximately 9500 patients are readmitted within 30 days of their index procedure. A 20 % reduction would decrease the 30-day readmission rate to 7600 patients and could possibly result in costs savings of over 57–70 million dollars annually based on the data presented earlier.

Once the DROP project is completed, additional national collaborative projects will be undertaken on a regular basis to improve the value bariatric surgery can offer for patients, hospitals, payors, and ultimately society. The next national project being considered is Enhanced Recovery After Surgery (ERAS). Considerable economic benefit could be gained from ERAS as it is associated with significant reduction in length of stay and complication rates. A meta-analysis demonstrated that ERAS shortened length of stay by approximately 2.3 days in patients undergoing major abdominal surgery, and reduced complications by approximately 40 % [37].

13.9 Developing Quality Improvement at the Local Level: What Can You Do at Your Own Health System?

It is important to develop a formal structure and process that allows you to objectively assess and monitor the quality and value of the services your center provides for patients. Embracing and fostering a culture of quality are essential as you educate hospital staff in an effort to enhance your program. Developing and implementing quality improvement plans requires a systematic approach with dedicated leaders, properly trained staff, truthful and precise data collection and feedback, and willingness to continuously review data, identify strengths and weaknesses, and create plans to adapt according to findings. The quality improvement plans will serve to guide clinical and operational management of a center.

The IOM report, *Crossing the Quality Chasm*, recommended that a fundamental change be made within the healthcare system based on six key dimensions: safety, timeliness, effectiveness, efficiency, equitability, and patient centeredness [12]. When developing a quality improvement plan, strong consideration must be given to avoiding injury, decreasing harmful delays, providing evidence-based care, avoiding waste, sensitivity to fair and equal care, and treating patients with respect and responding to patient's needs.

The following key elements must be taken into consideration when developing a high-quality bariatric surgery program that will provide patients with safe and effective care:

1. Leadership and governance (physician and executive)
2. Infrastructure
3. Data collection and analyzing evidence
4. Identifying best practice
5. Process to implement best practice
6. Data collection to reanalyze data
7. Developing a collegial environment to learn from others (collaborative development)

13.9.1 Leadership: Surgeon and Hospital Administrative Champions

One of the most important elements of developing quality in a bariatric surgery program is leadership, at both the surgeon and administrative levels. A committed surgeon and administrator will be the backbone of the program. The surgeon would not be expected to fully understand the business aspect of running a practice or organizing staff, nor should an administrator be expected to fully understand the clinical and technical aspects of bariatric surgery. It is the cohesiveness of the team at the local level that is critical to the success of your program. Once dedicated parties are involved, the center should reference the MBSAQIP standards as a guide to achieve their goals of developing and maintaining a high-quality bariatric surgery center.

13.9.2 Metabolic and Bariatric Surgery Committee

The control of the program resides in the Metabolic and Bariatric Surgery (MBS) Committee and should consist of, at a minimum, a surgeon director, all surgeons performing metabolic and bariatric surgery at the center, coordinator, clinical reviewer, and institutional administration representatives involved in the care of metabolic and bariatric surgical patients. Where it is necessary to have a surgeon champion and administrator lead the charge in the bariatric surgery quality movement, it is just as critical to have all surgeons practicing bariatric surgery at the center participate on the committee. All participants of the committee should provide input towards the final decisions in developing structure, process, and improvement plans for the bariatric surgery program.

Other members of the MBS Committee can include, but are not limited to, charge nurses for dedicated patient areas, and personnel that can provide information on services provided with patient transportation, central supply, radiology, and equipment purchasing.

The MBS Committee is where the mission, vision, goals, and objectives of the program are discussed and agreed upon, with an understanding that these may change as the program matures. It provides a setting for sharing best practices, reducing practice variation, and responding to adverse events. After identifying opportunities for improvement, committee team members must be willing to enact changes in an effort to decrease complication rates, as well as improve the patient's overall experience at the center [38].

13.9.3 Surgeon Credentialing

Surgeons who are proficient to perform bariatric surgery are essential in delivering high-quality care to bariatric surgery patients consistently. Uniform credentialing guidelines, endorsed by

ASMBS, ACS, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), and Society for Surgery of the Alimentary Tract (SSAT), are available to assist centers in preparing their local credentialing criteria for bariatric surgeons. These guidelines also include recommendations for surgeons with little or no experience. Credentialing criteria for bariatric surgeons should be thoroughly discussed among the MBS Committee members and approved before being submitted to the hospital's credentialing committee for official use by the hospital [39].

13.9.4 Qualified Call Coverage

All surgeons performing metabolic and bariatric surgery at a center must have qualified coverage at all times by a colleague who is responsible for the emergency care of a metabolic and bariatric surgery patient. Consideration must also be given for providing care for patients who did not have surgery at your institution. Protocols should be discussed and agreed upon at the level of the MBS Committee [40].

13.9.5 Metabolic and Bariatric Coordinator

A designated coordinator who reports to and assists the MBS Director assists in center development, managing the accreditation process and ensuring continuous compliance with accreditation bodies, maintaining relevant policies and procedures, patient education, outcome data collection, quality improvement efforts, and education of relevant institution staff in the various aspects of the metabolic and bariatric surgery patient with a focus on patient safety. The coordinator supports the development of written care pathways and education of nurses detailing the rapid communication and basic response to critical vital signs that are specifically required to minimize delays in the diagnosis and treatment of serious adverse events. The coordinator serves as the liaison between the hospital and all surgeons performing metabolic and bariatric surgery at the center [41].

13.9.6 Data Collection and the Clinical Reviewer

Managing data is a critical component of performance improvement. The center must designate a person or department that is accountable for gathering the data and making it available when necessary. In an effort to maintain integrity of the data and eliminate bias, the designated clinical reviewer should not be contributing to patient care and should work closely with the institution and clinicians to ensure that appropriate short-term and long-term data points are properly entered and available in the medical records and the database [42].

13.9.7 Data Review

Accurate data collection, feedback, and data review are necessary in developing a high-quality bariatric surgery program. Participating MBSAQIP centers have the capability of comparing their individual center data to all centers nationally; thus they can determine where they rank among their cohorts. This data can be critically analyzed between all surgeons at the center, which would be known as the institutional collaborative, and can take place during the MBS Committee meetings. Collectively, decisions can be made based on the data to assist in developing and implementing quality improvement measures at the center. In addition, your institution can elect to develop a local, statewide, or regional (involving multiple states) collaborative to establish a forum in which you can share data with one or more institutions in order to share best practices.

Critical analysis and interpretation of data will help identify opportunities for improvement. Once deficiencies are recognized, the center can apply interventions for quality improvement. The list below includes, but is not limited to, some of the methods employed for quality and process improvement [43–45].

1. *Plan-Do-Study-Act (PDSA)*: This method will look at a plan for change, carry out the plan, look at the results, and decide what action is necessary to improve. The theoretical framework of PDSA is to run through multiple computational process cycles. Depending on the knowledge gained from a PDSA cycle, the following cycle may seek to modify, expand, adopt, or abandon a change that was tested. The center should undergo small-scale beta testing, use data over time, and document steps throughout the process.
   (a) **Plan**: Change or test aimed at improvement
   Identify objective
   Identify questions and predictions
   Formation of a hypothesis for improvement
   Plan to carry out the cycle (who, when, where, when)
   (b) **Do**: Carry out the change or test (preferably on a small scale)
   Conduct study protocol with collection of data
   Execute the plan
   Document problems and unexpected observations
   Begin data analysis
   (c) **Study**: Examine the results. What did we learn? What went wrong?
   Complete the data analysis
   Compare data to predictions
   Summarize what was learned
   Analysis and interpretation of the results
   (d) **Act**: Adopt the change, abandon it, or run through cycle again
   What changes are to be made?
   What will the next cycle entail?
   Iteration for what to do next
2. *Focus-Analyze-Develop-Execute-Evaluate (FADE)*: This is a cyclic process which defines the process needing change (**Focus**), data is analyzed and root cause is determined (**Analyze**), solutions are proposed (**Develop**), action plans are implemented and monitored (**Execute**), and further assessment takes place to determine if the desired change occurred (**Evaluate**).
3. *Six Sigma*: Six Sigma is a measurement-based strategy for process improvement looking at existing processes (DMAIC), and new processer products (DMADV). One critical aspect of Six Sigma is the emphasis on carefully selecting, prioritizing, and scoping improvement opportunities. Not all issues are suitable for a Six Sigma project. The process is to define a clear opportunity that is attentive to organizational objectives, and focuses on quality improvement that will yield measurable results (return on investment, both clinically and financially). This is a powerful approach to quality improvement that can be used in healthcare organizations to meet needs and expectations of patients as well as to improve profitability and cash flow [46].
   (a) Define-Measure-Analyze-Improve-Control (DMAIC)
   (b) Define-Measure-Analyze-Design-Verify (DMADV)
   Define the goal and scope of the project. For example, improve patient satisfaction, and reduce average patient waiting time.
   Measure performance baseline and compare data evidence errors. Develop a quantifiable upper and lower control limits for the average level of performance indicator.
   Analyze collected data and performance continuously. If the level of performance goes below the lower limit of expected performance level, then analyze root causes of the problem; solve, not just fix, the problem by removing the root cause.
   Improve performance level. **Design** and implement procedures to remove the root cause of the problem.
   Verify improvement by evaluating performance before and after implementation of the procedures. **Control** the environment.

13.9.8 Patient Selection and Procedure Choice

Risk assessment should not only apply to patient factors (BMI, comorbidities, etc.) as surgeons are deciding which procedure to perform. Resource availability, infrastructure, and the expertise of the surgeon and staff need to be taken into strong consideration as well when selecting patients for surgery. Surgeons must consider the learning curves of the personnel within the institution and should only consider operating on lower risk patients until the center is mature enough to handle higher risk patients appropriately.

All patients should undergo extensive evaluation prior to surgery. There are a number of risk prediction models established to assess the patient's overall risk associated with metabolic and bariatric surgery [30, 47–52]. Risk factors demonstrated in several studies are listed below:

- Increasing age
- Male gender
- Increasing body mass index
- Mobility limitations
- Hypertension
- Prior history of a venous thromboembolism
- Coronary artery disease
- Myocardial infarction within the previous 6 months
- Angina
- Prior history of coronary intervention
- Congestive heart failure
- History of stroke
- Bleeding disorder
- Smoking history
- Procedure type
- Procedure time greater than 3 h
- Obstructive sleep apnea
- Dyspnea
- Corticosteroid use
- Peripheral vascular disease
- Liver disease
- Diabetes
- Increased total bilirubin
- Low hematocrit

Centers should take the necessary precautions and additional supportive measures to further assess known and undiagnosed conditions with the ultimate goal of optimizing surgical outcomes.

13.9.9 Patient Safety

All relevant staff must be educated on patient safety and complication recognition. An important goal in reducing complications would be to prevent "failure-to-rescue" situations, in which differences in mortality are proposed to result from the failure to timely recognize, and effectively manage, a postoperative complication. Additional training for the surgical teams and the integrated health personnel in postoperative complication recognition and management may improve outcomes.

Local, regional, or statewide bariatric surgeons can choose to meet face to face, or arrange conference calls, with other local or regional surgeons on a regularly scheduled basis to discuss clinical outcomes and complications based on data being entered into a uniform database (MBSAQIP). Many bariatric surgeons are ASMBS members participating in a state, or regional, chapter. Chapter meetings can be used as a backdrop to hold these discussions.

There are distinct advantages with social networking opportunities to interact with your peers and learn from each other during these meetings. Surgeons may adapt better to collectively supporting to change a process in each of their practices, or change a surgical technique, rather than being mandated to implement a change. The camaraderie that develops from these discussions can be extremely helpful in reducing practice variation, and ultimately resource utilization due to complications.

Increased statistical power is another advantage of working collaboratively as there is an opportunity to pool data to create larger sample sizes. This improves the group's ability to perform clinical outcome studies that will eventually develop best clinical practices.

13.10 Conclusion

Standardization is the cornerstone of quality improvement. However, quality improvement cannot be accomplished unless strong surgeon and executive leadership work together to recruit the critical core of individuals to ensure that the highest quality care is delivered to your patients. Collaboration with other bariatric surgeons and centers can prove to be of great value to patients with improved quality of care, and to physicians and hospitals with greater efficiency, less resource utilization, and ultimately significant cost savings. Successful collaborative development requires a rich data registry, change in attitude and culture, effective leadership, but most of all a commitment to provide the best care possible for your patients.

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