

Review Article

Bariatric Surgery: Is It a Safe Treatment Modality?

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ABSTRACT

Introduction: Bariatric surgery is currently the most effective treatment for morbid obesity with proven benefits in terms of improvement of the quality of life, obesity related morbidity and obesity related mortality. Safety of bariatric surgery is widely documented in the literature. In this review, we discuss types of bariatric surgeries and their safety and

complications.

Methods: A review of the current literature concerning bariatric surgery and its complications and safety was undertaken.

Conclusion: Bariatric surgery is very safe with safety profile comparable to commonly performed abdominal surgeries.

KEY WORDS: bariatric surgery, metabolic Surgery, obesity, weight loss, safety, gastric bypass, complication, morbidity, mortality

INTRODUCTION

Bariatric surgeries performance is increasing worldwide for several factors^[1]. Bariatric surgery is the most and probably the only effective durable treatment for the severe obesity and does have positive effect on long term survival and quality of life of the obese individuals. The adoption of minimally invasive techniques in the field of bariatric surgery made it even more widely used^[1-5]. Based on data of 2008, an estimated 350,000 bariatric procedures per year were performed worldwide, which correspond to the absolute growth rate of 135% since 2003^[6]. Although these are impressive numbers, we are in fact treating only less than 2% of eligible patients surgically annually^[6-8].

Obesity and diabetes are major underlying causes of death and disabilities in Kuwait. While recent high quality evidences including randomized controlled trials and long-term studies have shown the remarkable effects of bariatric surgery on type 2 diabetes with respect to glycemic control and cardiovascular risk factor modification, the safety profile of bariatric/metabolic surgery has been a matter of concern among patients and physicians. Kuwait was the only country in the world with a ban on bariatric surgery in 2013, that lasted for 3 months^[9]. It was a result of public and political pressure due to concerns over safety of bariatric surgery. In this review we will focus on the morbidity and mortality associated with different bariatric procedures in order to show its safety

WHO IS A SURGICAL CANDIDATE?

Surgical candidates are those with a body mass index (BMI) ≥ 40 kg/m², or those with a BMI ≥ 35 kg/m² with significant obesity-related co-morbidities^[10]. An additional criteria should be met by surgical candidates including failed previous weight loss attempts, the patient's commitment to long-term follow-up and aftercare, and absence of ongoing substance abuse, or unstable psychiatric illness, and severe medical conditions making anesthesia or surgery very risky (Table 1)^[1,8]. Overall, medical, social, and psychological aspects of an individual patient should be considered to determine the eligibility for weight loss surgery. Table 2 summarizes potential contraindications of bariatric surgery^[1,8].

CLASSIFICATION OF BARIATRIC SURGERY

Traditionally, bariatric surgery has been classified as either restrictive, malabsorptive, or both (Table 3). Restrictive component reduces the volume of the gastric reservoir, and malabsorptive component reduces the absorptive surface of GI tract by changing nutrient flow. Commonly performed bariatric operations include laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG), Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion (BPD), and the duodenal switch variant (BPD-DS) (Fig. 1)^[1-6,11,12]. Laparoscopic gastric

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Table 1: Characteristics of candidates for bariatric surgery^[1, 8]

Body mass index (BMI) > 40 kg/m²; or BMI = 35 - 40 with significant obesity-related co-morbidities
 Acceptable operative risk
 Documented failed attempt on nonsurgical methods of weight-loss
 Psychologically stable with realistic expectations

Table 2: Potential contraindications for bariatric surgery^[1, 8]

1. Severe medical disease that makes anesthesia or surgery prohibitively risky (American Society of Anesthesiologists class IV)
2. Mental incompetence that prevents the patient from understanding the procedure
3. Inability or unwillingness of the patient to change lifestyle postoperatively
4. Drug, alcohol, or other substance addiction^b
5. Uncontrolled bulimia or other eating disorder
6. Psychologic instability
7. Nonambulatory status
8. Patient view of surgery as a “magic bullet”
9. Antagonistic family, unsupportive home environment
10. Noncompliant behavior

^a These relative contraindications should be weighed against the potential benefits of surgery which may be the only treatment likely to yield significant weight loss and clinical improvement in the high-risk patient.

^b Requirement of cessation of smoking varies among surgeons.

Table 3: Classification of Bariatric/Metabolic Procedures

Classification	Procedures
Restrictive	Adjustable gastric banding (AGB) Sleeve gastrectomy (SG) Gastric plication (GP) Vertical banded gastroplasty (VBG) ^a
Malabsorptive	Biliopancreatic diversion (BPD) Jejunioleal bypass (JIB) ^a
Combined restrictive and malabsorptive	Roux-en-Y gastric bypass (RYGB) BPD with duodenal switch (BPD-DS) Mini-gastric bypass (MGB) Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)
Experimental metabolic operations ^b	Duodenal-jejunal bypass (DJB) Ileal interposition (IT)

^a Now offered infrequently and of historic interest only.

^b For use in experimental setting now.

plication (LGP), mini-gastric bypass (MGB), and single anastomosis duodeno-ileal bypass (SADI) have emerged as new procedures in the recent years and their long-term results have yet to be verified^[13-15]. The significant long-term complications and suboptimal long-term results of the Jejunioleal bypass (JIB) and vertical banded gastroplasty (VBG) made them fall out of favor^[8].

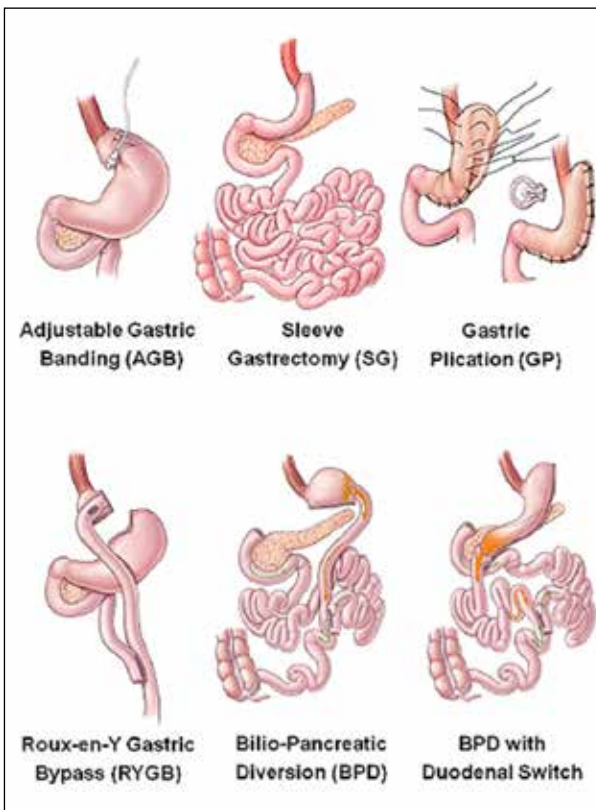


Fig. 1: Bariatric Operations Performed in Clinical Practice^[1]

Open approach was utilized in the past for all bariatric surgeries, but now it’s only reserved for some revisional cases and complex bariatric procedures.

Minimally invasive approach is utilized in the majority of bariatric procedures, as it has been shown to be associated with fewer postoperative complications than the open approach, most notably the risk of wound infection and incisional hernia^[7, 16]. Robotic and single incision laparoscopic approaches are considered emerging platforms in the field of bariatric surgery with more studies required to ascertain their risks and potential benefits.

Not all bariatric procedures focus on weight loss as the single aim of surgery. The terms “metabolic surgery” or “diabetes surgery”, are favored over “bariatric surgery” when the primary intention of surgical approach is to improve metabolic syndrome and diabetes. Several experimental procedures (e.g., duodenal-jejunal bypass (DJB) and ileal interposition (IT)) aim to treat diabetes and not to reduce weight (Fig. 2). The clinical utility of these procedures need to be determined, but it is shown by limited clinical studies some promising anti-diabetic results^[1-5, 17].

PREOPERATIVE ISSUES^[1]

All patients are encouraged to attempt conservative approaches of weight loss with diet and exercise prior

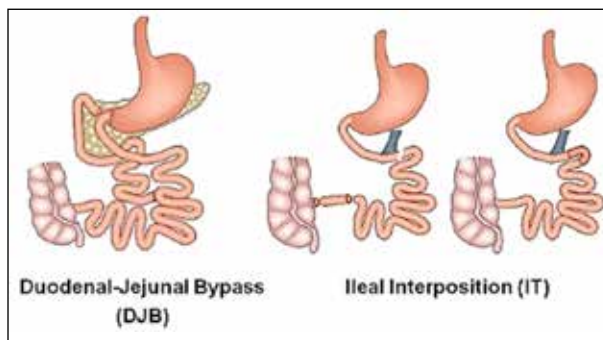


Fig. 2: Novel Experimental Metabolic Procedures^[17]

to choosing bariatric surgery. In this way, the severely obese patients practice the life-style changes which are the key to long-term success after any bariatric operation. In order to reduce the size of the liver to expand the operative field, some surgeons instruct patients to follow a low calorie diet in the immediate preoperative period (*e.g.* 800 - 1200 calorie per day for 2 weeks prior to surgery). Moreover, this preoperative weight loss approach is shown by some studies to be associated with better outcomes^[1-8].

Preoperative evaluation and optimization of bariatric surgical candidates requires multidisciplinary team approach. Before operation, careful nutritional, medical, and psychological assessments are essential steps in preparation of patients for surgery. Cardiac evaluation for patients over age 50 or those with known cardiovascular disease is necessary. Pulmonary evaluation is indicated for patients with asthma, hypoventilation syndrome, and pulmonary hypertension. In patients with symptoms suggestive of obstructive sleep apnea (OSA) including history of loud snoring, tiredness, and falling asleep easily during the day, a diagnostic sleep study is indicated. Once diagnosis of sleep apnea is confirmed, patients should use continuous positive airway pressure (CPAP) appliance. Use of CPAP in the immediate postoperative period is especially important to prevent episodes of hypoxia and cardiac arrhythmias. Prophylactic ursodiol in a daily dose of 600 mg for the first six months after the surgery has been shown to decrease the incidence of gallstone formation^[18]. A preoperative screening Upper GI (UGI) endoscopy is indicated in patients with history of UGI diseases including gastroesophageal reflux disease (GERD) to rule out internal pathologies such as Barrett's esophagus. This evaluation is especially important for patients planning RYGB, where the distal stomach and duodenum will not be easily accessible after operation. Baseline routine blood tests, renal, liver, and thyroid function tests are indicated. Before surgery, a preoperative anesthesiology visit for assessment of air-way issues and co-morbid medical problems is

also necessary for all patients undergoing bariatric surgery^[8,19].

SURGICAL PROCEDURES^[1]

a) Laparoscopic adjustable gastric banding

Considered a restrictive procedure, the LAGB is achieved by the placement of an inflatable silicone band just below the gastroesophageal junction, thus creating a small gastric pouch and a narrow stoma. The band is attached to a subcutaneous port that allows adjustment of tightness of the band. Saline is injected in to the port usually beginning one month after surgery. Frequent follow-up is essential after the LAGB to achieve the optimal band tightness for each patient. Overall, the LAGB is the most reversible and one of the safest and least invasive bariatric procedures. Most of postoperative complications are non-life-threatening events and overall mortality is about 0.1%^[1,11,19-22].

b) Laparoscopic sleeve gastrectomy

The LSG is a restrictive procedure initially described as the first procedure in very high-risk super-obese patients who ultimately underwent BPD-DS or RYGB. After excellent weight loss results of LSG were reported, it rapidly gained popularity as a stand-alone bariatric operation. In this procedure, a linear cutting stapler is utilized to make a narrow gastric tube along the lesser curvature. The remaining 75% to 80% of the gastric body and fundus are removed. The LSG is a safe and relatively simple procedure and is associated with a reasonably low complication rate even in very high-risk patients^[12,20-22].

c) Laparoscopic gastric plication

Laparoscopic gastric plication is performed by suturing the greater curvature of the stomach and invaginating it creating a tubular stomach replicating potentially the shape of the stomach after sleeve gastrectomy. Therefore, it is a low cost restrictive procedure that is potentially reversible on the short term, since it does not involve resection or anastomosis. The weight loss associated with LGP is less than that of LSG, but it is theoretically associated with lesser complications rate given that there is no gastric resection involved. A recent systematic review of the published literature on LGP found that the percentage of excess weight loss (%EWL) varied from 31.8% to 74.4% with follow-up from 6 months to 24 months and rate of major complications requiring reoperation ranged from 0% to 15.4% (average 3.7%)^[23]. We still need to clarify the durability of weight loss resulting from LGP, as no sufficient data exists.

d) Roux-en-Y gastric bypass

In laparoscopic RYGB, which is the most common approach, the jejunum is divided approximately 50 cm from the ligament of Treitz and the proximal end of jejunum is anastomosed to the distal part of jejunum at 150-cm below the site of transection (jejunojejunostomy). The resultant 150-cm Roux limb of proximal jejunum is brought up and anastomosed to the proximal gastric pouch of small size (15 - 30 ml). The effect of RYGB is more pronounced in terms of beneficial effects on weight and co-morbidities, especially type 2 diabetes and GERD^[20-22, 24].

e) Billiopancreatic diversion and duodenal switch

In BPD, a horizontal partial gastrectomy (resection of the distal ½ to 2/3 of stomach) is performed. Then the terminal ileum is divided 250 cm proximal to the ileocecal valve. The distal end of that divided ileum (alimentary Roux limb) is anastomosed to the stomach (gastroileostomy). The proximal end of the ileum (biliopancreatic limb) is then anastomosed to the terminal ileum approximately 50 to 100 cm proximal to the ileocecal valve to create a small common channel. Prophylactic cholecystectomy is performed due to the high incidence of gallstone formation following the malabsorption of bile salts. High incidence of marginal ulcers at gastroileal anastomosis after BPD led to a modification in original technique. The modified procedure, BPD-DS, differs from the BPD only in the gastric portion of the operation. In the BPD-DS variant, instead of horizontal gastrectomy, a narrow sleeve gastrectomy is performed and pylorus is preserved. After division of duodenum, the Roux alimentary limb is anastomosed to the first portion of the duodenum after pylorus (duodenoileostomy) and distal duodenal end is closed. Again, a short common channel is created by connecting the biliopancreatic limb to the alimentary limb 50 to 100 cm from the ileocecal valve. Preservation of the pylorus significantly

reduces the incidence of marginal ulcer and dumping syndrome^[20-22, 24].

Both procedures provide excellent and durable weight loss (70 - 75% EWL, >15 years). In addition to weight loss, they are generally superior to other bariatric procedures for resolution of most of co-morbidities, but in the expense of technical difficulty, higher perioperative and late complications and nutritional deficiencies. Lifetime follow-up and nutritional supplements are essential to maintain good health^[8,20,24].

COMPLICATIONS

Bariatric surgery is safe, with morbidity and mortality comparable to other common abdominal operations such as cholecystectomy, appendectomy, and hysterectomy. Post bariatric surgery complications can be divided to procedure-independent (table 4), which can occur after any type of weight loss surgery, or procedure-specific complications (Table 5)^[12,21].

SAFETY ANALYSIS

The Longitudinal Assessment for Bariatric Surgery consortium performed a prospective multicenter observational study to evaluate the 30 day outcome in consecutive patients who underwent bariatric surgery in 10 centers in the US. Out of 4,610 patients undergoing RYGB or LAGB, the overall 30-day mortality was 0.3% with no mortality in any of the patients undergoing LAGB. Mortality rate following open and laparoscopic RYGB was 2.1% and 0.2%, respectively^[25].

In a meta-analysis of mortality data, 85,048 patients were subjected to analysis in 3,061 studies and 478 treatment arms. Meta-analysis of 30-day total mortality was 0.28% and total mortality at >30 days to 2 years was 0.35%. Thirty day mortality rate of restrictive procedures (AGB and VBG) was 0.30%, RYGB 0.41%, and BPD and BPD-DS 0.76%. With the exception of BPD and BPD-DS, the meta-analysis

Table 4: Procedure-independent Complications of Bariatric Surgery^[1]

Early Complications	Late Complications
Surgical site infection (superficial, deep)	Intractable nausea and vomiting, food intolerance, dehydration
Bleeding (GI, intraperitoneal)	Intestinal obstruction (due to adhesion, abdominal wall hernia)
Pulmonary complications (airway obstruction, atelectasis, pneumonia, pneumothorax, respiratory failure)	Incisional hernia
Deep vein thrombosis and pulmonary embolism	Weight loss failure
Nausea and vomiting, food intolerance, dehydration	Weight regain
Prolonged post-operative ileus	Nutritional deficiencies
Intestinal obstruction (due to intraluminal clot, adhesion, abdominal wall hernia)	Hypoglycemia
Cardiac arrhythmia (induced by hypoxia)	
Myocardial infarction	
Dehiscence and evisceration	
Rhabdomyolysis (due to pressure necrosis of the gluteal muscles), acute tubular necrosis	
Pancreatitis	
Sepsis and multiple organ failure	

Table 5: Procedure-specific Complications of Bariatric Surgery^[1]

Procedure	Early Complications	Late Complications
LAGB	Gastroesophageal reflux Band misplacement Band slippage	Gastroesophageal reflux Pouch enlargement, esophageal dilation Gastric prolapsed Band slippage Mechanical port and tubing complications Band erosion into the stomach Necessity for multiple adjustments
LSG, LGCP	GI leak (generalized peritonitis, abscess, fistula formation) Gastric obstruction Gastroesophageal reflux	Gastroesophageal reflux Gastric dilation
RYGB	GI leak (generalized peritonitis, abscess, fistula formation) Acute distal gastric dilatation and rupture Roux limb obstruction	Stomal stenosis (at gastrojejunostomy) Marginal ulcer (at gastrojejunostomy) Dumping syndrome Internal hernia Staple line disruption and gastro-gastric fistula Stomal dilation Gallstone Nutritional deficiencies (Calcium, Iron, Vitamin D & B12)
BPD, BPD-DS	GI leak (generalized peritonitis, abscess, fistula formation) Roux limb obstruction	Diarrhea and flatulence Marginal ulcer (after BPD) Dumping syndrome (after BPD) Internal hernia Electrolyte abnormalities Liver failure Gallstone Renal stone High risk of nutritional deficiencies: Anemia Protein-calorie malnutrition Vitamin B12 deficiency Hypocalcemia, Osteoporosis Night blindness

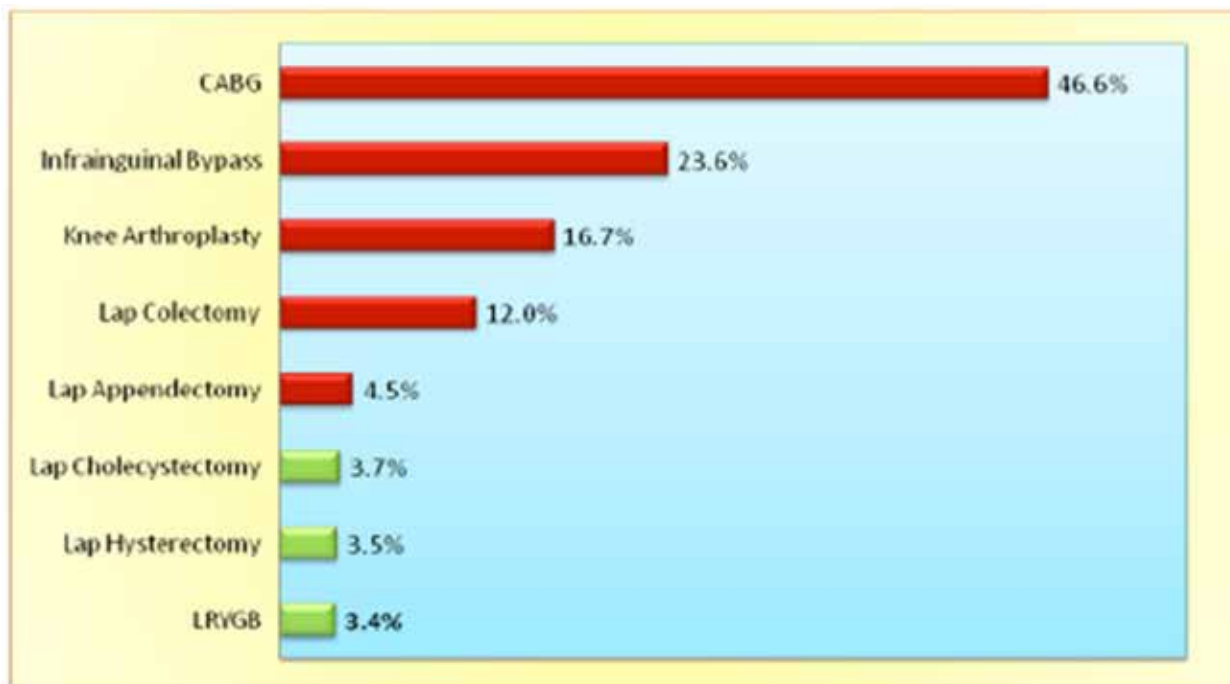
showed a higher mortality for open than laparoscopic approach. Mortality rates had a downward trend over the years^[26].

The total sixty day mortality of bariatric procedures was reported to be 0.25% based on an analysis of a national database containing details on 13,871 bariatric procedures. The type of surgical procedure significantly influenced mortality risk: 0.1% AGB, 0.15% VBG, 0.54% RYGB, 0.8% BPD. Pulmonary embolism represented the most common cause of death (38.2%), followed by cardiac failure 17.6%, and intestinal leak 17.6%. Open surgery and case load per center were among the major risk factors of mortality^[27].

The US national average in-hospital mortality rates after aortic aneurysms (3.9%), coronary artery bypass grafting (3.5%), craniotomy (10.7%), esophageal resections (9.9%), hip replacement (0.3%), pancreatectomy (8.3%), and pediatric heart surgery (5.4%) all, with the exception of hip replacement, are >1%, exceeding that of the generally reported experience with bariatric surgery (<0.5%)^[28].

Short-term safety analysis of bariatric/metabolic surgery in a cohort of diabetic patients using the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) dataset

was recently reported. Of the 66,678 diabetic patients included, 16,509 underwent laparoscopic RYGB. The mean operative time of laparoscopic RYGB and length of hospital stay were 138 min and 2.5 days, respectively. Serious events within 30-days after LRYGB included need for transfusion (1.22%), sepsis (0.81%), pneumonia (0.66%), deep vein thrombosis (0.36%), septic shock (0.30%), acute renal failure (0.22%), pulmonary embolism (0.22%), myocardial infarction (0.16%), and stroke (0.05%), which led to a mortality rate of 0.30%. The composite complication rate after laparoscopic RYGB was comparable to laparoscopic cholecystectomy and hysterectomy (Fig. 3). Mortality rate of LRYGB (0.30%) was comparable to total knee arthroplasty (Fig. 4). Gastric bypass patients had significantly better short-term outcomes in all examined variables compared to coronary artery bypass graft, infra-inguinal revascularization, and laparoscopic colectomy (Fig. 3 and 4). The study concluded that RYGB can be considered a safe procedure in diabetics with comparable short-term morbidity to common procedures such as cholecystectomy and appendectomy and mortality similar to knee arthroplasty. The mortality risk of RYGB is one-tenth that of cardiovascular surgery

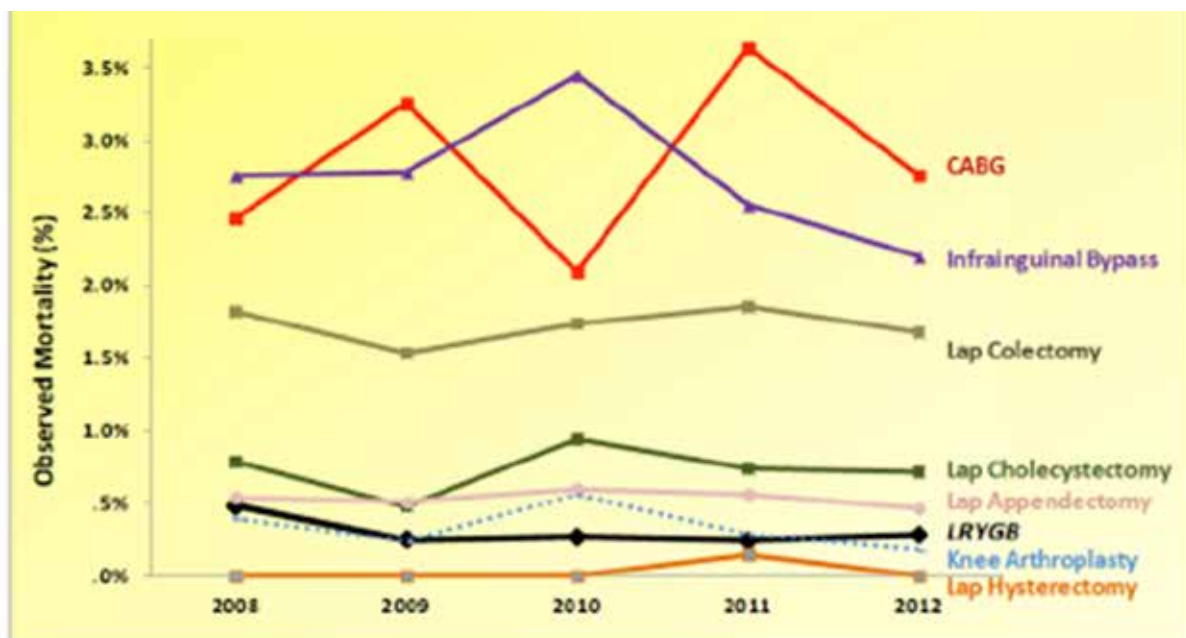


Of the 66,678 diabetic patients included, 16,509 underwent LRYGB.

Fig. 3: US national data of postoperative composite complication rate (%) of 8 procedures in patients with Type 2 Diabetes^[29]

and earlier intervention with bariatric/metabolic surgery to treat diabetes may eliminate the need for some later higher-risk procedures to treat diabetes complications^[29].

In a study performed by our group, we looked at the highest risks patients undergoing bariatric surgery by using the Obesity Surgery Mortality Risk Score (OS-MRS). We strictly defined an extremely high-



Mortality Rate of LRYGB = 3 in 1000

Fig. 4: Mortality rates (%) of 8 procedures in diabetics in the United States, 2008-2012^[29]

risk group of patients by age at the time of surgery ≥ 65 years, BMI ≥ 50 kg/m², and presence of at least 2 of 6 cardiopulmonary or vascular comorbidities. We identified 44 extremely high-risk patients who underwent laparoscopic Roux-en-Y gastric bypass (N = 23), adjustable gastric banding (N = 11), and sleeve gastrectomy (N = 10). Only thirteen (29.5%) 30-day postoperative complications occurred; with only six were major complications. Thirty-day postoperative re-admission, re-operation, and mortality rates were 15.9%, 2.3%, and zero, respectively. In a mean follow-up time of 24 months, late morbidity and mortality rates were 18.2% and 2.3%, respectively. Therefore, laparoscopic bariatric surgery in the extremely high-risk patients can be done safely with acceptable early and late morbidity and mortality rates. Advanced age, high BMI, and severe cardiopulmonary comorbidities should not exclude patients from consideration for bariatric surgery^[30].

Summary

Safety and efficacy are two fundamental factors when a treatment modality is being evaluated in clinical practice. Currently, bariatric surgery is the most effective weight loss method and is associated with favorable metabolic outcomes and survival benefit among morbidly obese individuals^[31-33].

Improvement in surgical techniques and perioperative management protocols has led to continuous improvement of the safety profile. Mortality of bariatric surgery has decreased substantially from 1.5 - 2% two decades ago to 0.1 - 0.3%. The reported complication rate of surgery based on several available large databases is about 2 - 4%^[25,29,34]. Despite high quality data on safety and efficacy of bariatric and metabolic surgery that has led to incorporation of surgery in management guidelines for obesity and diabetes^[35], many physicians and patients do not consider the option of surgery. One reason may be an incorrect perception of the risk-to-benefit ratio of medical and surgical approaches in obesity and diabetes management, *i.e.*, overestimation of benefit of medical approach and risk of surgical approach^[29,36]. Nonetheless, the obesity epidemic we currently face caused a dramatic rise in the numbers of bariatric surgeries performed.

CONCLUSION

Safety of bariatric surgery can be enhanced, if performed in high volume centers, if high risks patients are identified properly preoperatively, and if the appropriate procedure is tailored to the right patient. A review and audit of national results should be undertaken periodically, to improve results and encourage research in the field.

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