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Safety and Efficacy of Bariatric and Metabolic Surgery

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Abstract

Purpose of Review Bariatric surgery is the most effective and durable method for treating obesity. This review highlights the results and safety of bariatric surgery.

Recent Findings The global prevalence of obesity and its related comorbidities including cancer are on the rise. Bariatric surgery has demonstrated more robust and durable weight loss than current medical treatment. Bariatric surgery also reduces significantly the risk of complications associated with obesity comorbidities, such as diabetes and cardiovascular disease, and the risk of mortality in comparison with medical management. Due to accreditation efforts, the safety profile of bariatric surgery is equivalent or superior to many common operations.

Summary Obesity is associated with increased all cause morbidity and mortality. The current bariatric procedures produce significant and durable weight loss and reduce the morbidity and mortality associated with obesity-related diseases substantially. The risk/benefit ratio for bariatric surgery is decidedly in favor for the benefit for bariatric surgery.

Keywords Obesity · Bariatric surgery · Metabolic surgery · Safety · Outcome · Type 2 diabetes mellitus · Cardiovascular disease

Introduction

According the World Health Organization, global obesity has nearly tripled since 1975. More than 1.9 billion adults were overweight, of which 650 million were obese in 2016 [1]. The prevalence of obesity was 39.8% in US adults in 2016 [2]. Obesity is associated with a number of serious comorbidities, including type 2 diabetes mellitus (T2DM), cardiovascular disease, dyslipidemia, obstructive sleep apnea, nonalcoholic fatty liver disease, joint disease [3], and many common cancers such as esophageal, colorectal, endometrial, kidney, pancreas, and postmenopausal breast cancers [4]. The risk of obesity-related cancer is increasing in younger cohorts in the USA [5].

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Bariatric surgery has demonstrated the most effective and durable treatment for severe obesity, and results in marked improvement or resolution of obesity-related comorbidities [6–9]. Bariatric surgery is safe, and complications rates are comparable with such common operations as cholecystectomy and appendectomy [10•]. According to The American Society of Metabolic and Bariatric Surgery (ASMBS), nearly 252,000 individuals underwent bariatric surgery in the USA in 2018 [11]. Sleeve gastrectomy (SG) is the common procedure followed by Roux-en-Y gastric bypass (RYGB), while adjustable gastric band (AGB) has plummeted to less than 3% of all procedures because of inconsistent weight loss and device-related complications, and more invasive biliopancreatic diversion with duodenal switch (BPD/DS) make up less than 1% of surgeries. The number of global bariatric procedures approached 635,000 cases in 2016 [12].

The impact of bariatric surgery on many obesity-related illnesses, such as obstructive sleep apnea, nonalcoholic fatty liver disease, gastroesophageal reflux disease, joint disease, and polycystic ovarian syndrome, is well documented. This review focuses mainly on weight loss, T2DM and cardiovascular disease outcomes, and safety of surgery.

Weight Loss Outcomes

Bariatric surgery has shown superiority in magnitude and duration of weight loss over medical weight loss in multiple studies, including randomized control trials [8, 9, 13–15, 16•]. The Swedish Obese Subjects (SOS) trial, a prospective controlled intervention study of bariatric surgery versus controls, showed that mean changes in body weight after 2, 10, 15, and 20 years were − 23%, − 17%, − 16%, and − 18% in the surgery group and 0%, 1%, − 1%, and − 1% in the control group, respectively [13].

Comparison of bariatric surgery outcomes in a matched national sample of Bariatric Surgery Centers of Excellence in the USA, including 130,796 patients revealed the following reduction in excess weight (kg) at 1 year: AGB 20.1 ± 11.9, SG 38.2 ± 15.5, RYGB 44.2 ± 14.8, and BPD/DS 56.9 ± 19.4 [17]. A MEDLINE and Cochrane databases review of 7371 clinical studies on outcomes bariatric surgery, found 29 studies (7971 patients) that had more than 2 years of outcome information, and had follow-up measures for at least 80% of the initial cohort. The mean weighted percentage of excess weight loss (%EWL) for RYGB was 65.7% ($n = 3544$) vs 45.0% ($n = 4109$) for AGB [7].

Weight loss outcome at 1, 3, and 5 year after bariatric surgery were compared with a retrospective observational cohort study of 65,093 patients aged 20 to 79 years in 41 health systems in the National Patient-Centered Clinical Research Network. Estimated mean percent total weight loss (TWL) at 1 year was 31.2% (95% CI, 31.1–31.3%) for RYGB, 25.2% (CI, 25.1–25.4%) for SG, and 13.7% (CI, 13.3–14.0%) for AGB. Five-year mean TWL were 25.5% (CI, 25.1–25.9%) for RYGB, 18.8% (CI, 18.0–19.6%) for SG, and 11.7% (CI, 10.2–13.1%) for AGB [18].

A meta-analysis to assess the long-term (≥ 5–10 years) and very long-term (≥ 10 years) effects of bariatric surgery in adults included 80 articles with 87 arms. The %EWL was 47.94% and 47.43% after LAGB at ≥ 5 and ≥ 10 years, respectively. RYGB resulted in %EWL of 62.58% at ≥ 5 years and 63.52% at ≥ 10 years, and SG resulted in %EWL of 53.25% at ≥ 5 years [19]. Another systematic review and meta-analysis of all studies that provided outcomes at 10 or more years after bariatric surgery included 33 reports. Weighted means of the %EWL were calculated. Seventeen reports of LAGB showed 45.9% EWL, 2 reports of SG showed 58.3% EWL, 18 reports of RYGB showed 56.7% EWL, and 9 reports of BPD/DS showed 74.1% EWL [20].

Overall, these results show that bariatric surgery produces significant and long-lasting weight loss beyond 10 years. The more complex operations such as RYGB and BPD/DS, which are typically performed on patient with higher BMI and comorbid disease burden, offer greater weight loss but carry higher risk, while SG produces long-term weight loss approaching RYGB with less risk [21, 22]. However, very long-term (> 10 year) outcome data for SG are emerging.

Type 2 Diabetes Mellitus (T2DM) Outcomes

Bariatric/metabolic surgery results in drastic improvement or resolution of T2DM. The evidence of the impact of bariatric surgery on T2DM is so consistent that the Second Diabetes Surgery Summit (DSS-II), an international consensus conference of clinicians and scholars (75% non-surgeons) held in 2015, issued a joint statement endorsed by 45 international organizations that for the first time incorporates metabolic surgery in the treatment algorithm for T2DM [23••]. Metabolic surgery should be recommended to treat T2DM in class III obesity (BMI ≥ 40 kg/m^2), and class II obesity (BMI 35–39.9 kg/m^2) when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy. Surgery should also be considered for class II obesity with adequate glycemic control, and class I obesity (BMI 30–34.9 kg/m^2) when hyperglycemia is inadequately controlled by optimal medical therapy. For Asian patients, these BMI thresholds should be lowered by 2.5 kg/m^2 [23••].

The 1-, 3-, and 5-year results from a nonblinded randomized controlled trial has shown that bariatric surgery with intensive medical therapy is more effective than intensive medical therapy alone in decreasing or resolving hyperglycemia in those with T2DM and BMI 27–43 kg/m^2 [14, 15, 16•]. The study uses strict primary endpoint of glycated hemoglobin (A1C) of 6% or less with or without medications. At 5 years, the primary end point was achieved by 2/38 (5%) with medical therapy, 14/49 (29%) with RYGB, and 11/47 (23%) with SG ($p \leq 0.3$ for surgery versus medicine). The mean reduction in A1C was significantly higher with surgery than with medicine (2.1% versus 0.3%, $p = 0.003$). All patients in RYGB group and 98% in SG group required at least one diabetes medication before surgery. At follow-up 45% of RYGB group and 25% of SG did not require any medication for diabetes. Insulin use was decreased from 47 to 12% after RYGB and from 45 to 11% after SG [14, 15, 16•].

In another nonblinded randomized controlled trial, 60 adults with BMI ≥ 35 kg/m^2 and at least 5 years of diabetes with A1C level of 7.0% or more were randomly assigned to conventional medical therapy or RYGB or biliopancreatic diversion (BPD). The primary end point was T2DM remission at 2 years defined as a fasting glucose level of < 100 mg/dL and A1C level < 6.5% without pharmacologic therapy. None in the medical therapy group achieved the end point versus 75% with RYGB and 95% with BPD ($p < 0.001$ for both comparisons). At 2 years, the average baseline A1C (8.65 ± 1.45%) had improved the most in the surgery group; A1C 6.35 ± 1.42% in RYGB and 4.95 ± 0.49% in BPD versus 7.69 ± 0.57% in medical therapy [24].

In the matched national sample of Bariatric Surgery Centers of Excellence in the USA (130,796 patients), T2DM resolution at 1 year were better after BPD/DS (OR 5.62, 95% CI 4.60–6.88), RYGB (OR 3.5, CI 3.39–3.64) and SG (OR 2.11, CI 4.60–6.88) in comparison to AGB [17]. In a systematic review (29 studies, 7971 patients with more than 2 years of outcome information), weighted remission rates for T2DM (A1C $< 6.5\%$ without medication) were 66.7% for RYGB ($n = 428$) and 28.6% for AGB ($n = 96$) [7].

Bariatric surgery has also shown to prevent T2DM. A prospective controlled study examined the long-term effects of bariatric surgery on the prevention of T2DM [25]. The study included 1658 patients who underwent bariatric surgery and 1771 obese matched controls. Despite matching, the baseline body weight was higher, and risk factors were more prominent in the bariatric-surgery group. During the follow-up period of 15 years, the incidence rates of T2DM was 28.4 cases per 1000 person-years in the control group and 6.8 cases per 1000 person-years in the surgery group (bariatric surgery hazard ratio 0.17; 95% CI 0.13–0.21; $p < 0.001$). Of note, the difference was significant despite the fact that the majority of surgery patients (69%) underwent vertical banded gastroplasty, a legacy operation that is not performed any more, and AGB (19%) as opposed the more effective RYGB (12%) [25].

Cardiovascular Disease Outcomes

The reduction in cardiovascular disease risk after bariatric/metabolic surgery is documented by a number of studies, including the Swedish Obese Subjects (SOS) trial showing reduced number of cardiovascular deaths after surgery (28 in 2010 patients) versus the control group (49 in 2037 patients), (adjusted hazard ratio [HR] 0.47, $p = 0.002$). The number of first-time myocardial infarction or stroke was also lower in the surgery group (adjusted HR 0.67; $p < 0.001$) [26].

The GATEWAY randomized trial is a nonblinded randomized trial of 100 patients with obesity and hypertension (using ≥ 2 medications), who underwent RYGB versus medical therapy [27]. At 1 year, a significantly greater number of RYGB with medical therapy achieved the primary end point (reduction of $\geq 30\%$ of the total number of antihypertensive medications) than the medical group (83.7% versus 12.8%). RYGB also resulted in 46–50% remission of hypertension versus none in the medical therapy group. Waist circumference, BMI, fasting plasma glucose, A1C, low-density lipoprotein cholesterol, triglycerides, high-sensitivity C-reactive protein, and 10-year Framingham risk score were lower in RYGB than in the control group [27]. In a follow-up study, the authors showed that RYGB also improved BP variability and decreased the burden of resistant hypertension [28].

In a retrospective cohort study of 13,722 patients with type 2 diabetes and obesity, of whom 2287 underwent metabolic surgery and 11,435 matched controls, metabolic surgery was associated with a significantly lower risk of major adverse cardiovascular events (all-cause mortality, coronary artery events, cerebrovascular events, heart failure, nephropathy, and atrial fibrillation) [29••]. The cumulative incidence of these events at 8 years was 30.8% in the surgical group versus 47.7% in the nonsurgical group ($p < .001$). The cumulative incidence of all-cause mortality at 8 years was 10.0% in the surgical group versus 17.8% in the nonsurgical group [29••].

A comparison of the effect of bariatric/metabolic surgery on 10-year and lifetime atherosclerotic cardiovascular disease (ASCVD) risk, as defined by the American College of Cardiology/American Heart Association, included 536 patients of whom 438 underwent RYGB and 98 underwent SG [30]. In comparison to the baseline, the 10-year and lifetime ASCVD risks were significantly lower at 1 year after surgery, ($4.2 \pm 6.0\%$ vs. $2.2 \pm 3.5\%$, $p < 0.001$; and $50 \pm 11\%$ vs. $39 \pm 12\%$, $p < 0.001$). RYGB resulted in greater reductions in ASCVD risks than SG (10 year, $1.7 \pm 3.5\%$ vs. $0.8 \pm 2.4\%$, $p < 0.001$; Lifetime, $11 \pm 23\%$ vs. $0 \pm 12\%$, $p < 0.001$, respectively) [30].

In a systematic review (29 studies, 7971 patients with more than 2 years of outcome information), remission rates of hypertension (blood pressure < 140/90 mm Hg without medication) were 38.2% for gastric bypass and 17.4% for gastric band [7]. For hyperlipidemia (cholesterol < 200 mg/dL, high-density lipoprotein > 40 mg/dL, low-density lipoprotein < 160 mg/dL, and triglycerides < 200 mg/dL), remission rates were 60.4% for gastric bypass and 22.7% for gastric band [7]. In the matched national sample of Bariatric Surgery Centers of Excellence in the USA (130,796 patients), hypertension resolution were better after the BPD/DS (OR 3.82, 95% CI 3.21–4.55) or after RYGB (OR 3.08, 95% CI 2.98–3.18) in comparison to AGB [17]. The nonblinded randomized trial of surgery (RYGB and SG) versus intensive medical therapy for obesity and diabetes showed significant improvement in triglyceride and high-density lipoprotein cholesterol levels in the surgery group versus medical therapy [16•].

According to practice guidelines developed by the American College of Cardiology and American Heart Association for the management of overweight and obesity, the benefit-to-risk ratio for bariatric surgery is favorable in appropriately selected patients at high risk for obesity-related morbidity and mortality. Bariatric surgery leads to improvements in both weight-related outcomes and many obesity-related diseases; therefore, it is an appropriate option for a dults with BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 with obesity-related diseases who have not responded to behavioral treatment with sufficient weight loss to achieve targeted health outcome goals [31].

Bariatric Surgery Safety

Several factors have made bariatric surgery safe, including the widespread adoption of minimally invasive/laparoscopic techniques, near universal fellowship training of bariatric surgeons, institutional investment in bariatric surgery programs, and national quality improvement projects. The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), created by the American college of Surgeons and the American Society for Metabolic and Bariatric Surgery (ASMBS), is a keystone of bariatric surgery quality and safety [32]. This national program was created to advance safe and high-quality care via the accreditation of bariatric surgical centers in the USA and Canada. Centers are accredited through a voluntary and independent rigorous review process to ensure standard practice protocols, and presence of certain human and physical resources. All accredited centers report their outcomes to the MBSAQIP database and participate in regular reviews to evaluate their bariatric surgical programs against national benchmarks for continuous quality improvement. Also, the MBSAQIP participant use file is a set of unidentified data that is available for research [32]. Multiple studies have demonstrated the advantage of accredited vs. non-accredited hospitals including showing reduction of mortality, cost, and complications at accredited centers [33].

The MBSAQIP 2015 participant use file data were used to review 30-day morbidity for 135,413 patients undergoing sleeve gastrectomy (67%), Roux-en-Y gastric bypass (29%), adjustable gastric banding (3%), and duodenal switch (1%). The most common complications were bleeding (0.7%), wound infection (0.5%), urinary tract infection (0.3%), VTE (0.3%), and leak (0.2%) [34]. Using AGB as benchmark for comparison of bariatric surgery outcomes, a sample of 130,796 patients from Bariatric Surgery Centers of Excellence in the USA revealed odds of serious adverse events at 1 year for SG, OR 3.22; RYGB, OR 4.92; and BPD/DS, OR 17.47 [17]. While the 30-day rates of major adverse events in a retrospective observational cohort study of 65,093 patients in 41 health systems in the National Patient-Centered Clinical Research Network were 5.0% for RYGB, 2.6% for SG, and 2.9% for AGB [18].

Despite the challenging anatomic, physiologic, and comorbidity characteristics of patients with obesity, there has been a substantial reduction in bariatric surgery mortality rate over the past 20 years from 1.5–2% to 0.3%, while complication rates are in the range of 2–4% [10•, 35, 36]. The overall 30-day postoperative mortality rate is 0.2–0.6% in many studies [35–37]. Aminian and colleague used 6 years of data from the American College of Surgeons National Surgical Quality Improvement Program database to compare the morbidity and mortality of LRYGB to seven other procedures (16,509 of 66,678 patients underwent RYGB) [10•]. The RYGB complication rate of 3.4% was similar to those of laparoscopic cholecystectomy and hysterectomy, and the RYGB mortality rate of 0.3% was similar to that of knee arthroplasty. The RYGB group had significantly better short-term outcomes than coronary bypass, infrainguinal revascularization and laparoscopic colectomy groups [10•].

Conclusion

The tripling of global obesity burden in just over three decades is associated with dramatic increase in obesity-related disease and increased mortality. Preventative efforts are difficult due to multifactorial nature of obesity, and treatment can be challenging. Bariatric surgery has proven the most effective treatment for obesity both in terms of magnitude of weight loss and durability. Surgery leads to remission or improvement of obesity-related comorbidities such as T2DM, cardiovascular disease, obstructive sleep apnea, nonalcoholic fatty liver disease, gastroesophageal reflux, joint disease, and polycystic ovarian syndrome. In fact, the most recent practice guidelines from major medical societies, such as the American Diabetes Association, the Endocrine Society, and the American Heart Association, include bariatric surgery in the treatment algorithm of individuals with obesity and T2DM and/or cardiovascular disease. Surgery also improves patient reported quality of life outcomes [38, 39], and it is associated with decreased mortality. Various studies have shown significant reduction in all cause of mortality, including cardiovascular deaths, T2DM-related deaths, and cancer-related deaths after surgery in comparison with matched controls [13, 40, 41]. Despite surgery's efficacy and benefits, incorrect perception of risk may be a source of concern for some physicians. Recent studies show that the risk of complications for bariatric surgery is on par with common procedures such as appendectomy and hysterectomy and mortality risk on par with knee arthoplasty. Accreditation of bariatric programs through the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) has created national benchmarks for quality and safety with continuing review of all participating programs. The field of bariatric surgery is evolving as developing endoluminal and endoscopic techniques are providing adjunct procedures, and weight loss medications are used to augment surgery [42]. The use of large electronic health data will eventually create algorithms to help tailor the procedure type and therapy for optimal outcomes in individuals for treatment of a very complex chronic disease.

Compliance with Ethical Standards

Conflict of Interest The authors declare no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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