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NOTE: This policy is not effective until June 1, 2025.

Medical Policy Manual Surgery, Policy No. 58

Bariatric Surgery

Effective: June 1, 2025

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IMPORTANT REMINDER

DESCRIPTION

Bariatric surgery is a major surgical intervention which aims to reduce weight, eliminate or improve comorbid conditions, and maintain weight loss in obese patients who have failed to achieve weight loss through lifestyle modifications.

MEDICAL POLICY CRITERIA

Note: Member contracts for covered services vary. Member contract language takes precedence over medical policy.

I. Bariatric surgery may be considered **medically necessary** in the treatment of obesity when all of the following criteria (A. and B.) are met**:**

   A. All of the general Criteria (1.- 4.) must be met:

      1. At the start of the medically-supervised, nonsurgical weight reduction program, one of the following must be met:

         a. BMI greater than or equal to 40 kg/(meter squared); or

         b. BMI greater than or equal to 35 kg/(meter squared) with at least one of the following comorbid conditions:

i. Type II diabetes mellitus; or
ii. Poorly controlled hypertension despite optimal medical management; or
iii. Coronary artery disease; or
iv. Obstructive sleep apnea as defined by an AHI equal to or greater than 15 per hour; and

2. The patient meets one of the following age requirements:
    a. Greater than or equal to 18 years; or
    b. Less than 18 years of age and has attained Tanner 4 or 5 pubertal development and one of the following must be met:
        i. BMI greater than or equal to 140 percent of the 95th percentile for age and sex; or
        ii. BMI greater than or equal to 120 percent of the 95th percentile for age and sex with at least one of the comorbid conditions listed in Criterion I.A.1.b.
3. Documentation of active participation for a total of at least 3 consecutive months in a structured, medically supervised pre-operative training program. The program must be provided by or approved and monitored under the supervision of the bariatric program.

    Documentation from the clinical medical records must indicate that the structured medical supervision meets all of the following Criteria:

    a. Program participation occurs during a total of at least 3 consecutive months within the 12 months prior to the request for surgery; and
    b. Include at least 2 visits for medical supervision, during the 3 consecutive months of program participation. One visit must occur at the initiation, and another at least 3 months later (90 days); and
    c. Be provided by an MD, DO, NP, PA, or RD in conjunction with the bariatric program; and
    d. Include assessment and counseling concerning weight, nutrition and diet that should be related to the type of planned bariatric surgery, exercise, and behavior modification; and
4. Preoperative evaluation to include both of the following:
    a. A licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters-level counselor, or NP in a behavioral health practice, documents the absence of significant psychopathology that can limit an individual's understanding of the procedure or ability to comply with medical/surgical recommendations (e.g., active substance abuse, eating disorders, schizophrenia, borderline personality disorder, uncontrolled depression); and
    b. Clinical documentation that the patient is an appropriate candidate for the surgery and is committed to the treatment plan; and

B. The request is for one of the following procedures:

1. Sleeve gastrectomy as a stand-alone procedure; or
2. Gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less
3. Biliopancreatic bypass with duodenal switch in patients ages greater than or equal to 18 years with BMI greater than or equal to 50 kg/(meter squared)

II. Reoperation may be considered **medically necessary** when one or more of the following criteria (A. or B.) are met:

A. Reoperation with revision of a bariatric procedure (i.e. sleeve gastrectomy, biliopancreatic bypass with duodenal switch, or gastric bypass), conversion of a sleeve gastrectomy to a gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less, or adjustable gastric band removal when one or more of the following documented significant complications is present:

1. Leak or bowel perforation, including band erosion; or
2. Documentation of band migration (slippage), that cannot be corrected with fluid adjustment.; or
3. Band infection; or
4. Obstruction exceeding the inherent obstruction of the original bariatric procedure, documented by imaging or endoscopic findings; or
5. Staple-line failure (such as, Gastro-gastric fistula); or
6. Weight loss to 90% or less of ideal body weight; or
7. One or more of the following severe, clinically-objective conditions that have been unresponsive to proton pump inhibitors (PPIs) for at least 4 months:
   a. Severe esophagitis documented as LA Grade C or D on endoscopy; or
   b. Barrett's esophagus confirmed by biopsy; or
   c. Cameron lesion(s); or
   d. Gastro-jejunal anastomotic ulcer(s).
8. For medication resistant gastroesophageal reflux disease, a conversion bariatric procedure may be considered **medically necessary** when there is documentation of all the following (a. - d.):
   a. The request is for conversion from sleeve gastrectomy to a gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150cm; and
   b. There is documentation that the sleeve gastrectomy was completed at least 18 months prior to the planned conversion surgery; and
   c. There is objective diagnostic confirmation of severe gastroesophageal reflux disease by ambulatory pH monitoring documented as a DeMeester score of 50 or greater; and
   d. Medication therapy that meets one or more of the following:
      i. A 4-month total trial of proton pump inhibitors (PPIs) is ineffective,

contraindicated, or not tolerated; or

ii. PPIs are used for 12 or more consecutive months within the past 18 months, and surgery is considered an alternative to long-term medication use.

B. Removal of adjustable gastric band with conversion to a gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less when Criterion I. A. is met. Note: Criterion I. A. must be met during the period after placement of the adjustable gastric band.

III. Sleeve gastrectomy, biliopancreatic bypass with duodenal switch, or gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less is considered **not medically necessary** when Criterion I. above is not met including but not limited to biliopancreatic bypass with duodenal switch in patients younger than 18 years of age or in patients with BMI less than or equal to 50kg/(meter squared).

IV. The vertical banded gastroplasty and adjustable gastric banding are no longer a standard of care and are therefore considered **not medically necessary**.

V. Reoperation or conversion of a prior bariatric procedure is considered **not medically necessary** when Criterion II. is not met, including but not limited to reoperation for early satiety, nausea, patient dissatisfaction, or inadequate weight loss or weight regain (see policy guidelines).

VI. Repair of sliding or paraesophageal hiatal hernia when performed at the time of any bariatric surgery would be considered **a component of and incidental** to the primary bariatric surgery.

VII. The following procedures are considered **investigational** for the treatment of:

A. Obesity including distal or partial gastrectomy (other than standard sleeve gastrectomy) performed with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction; and gastric restrictive procedure without gastric bypass for obesity (other than sleeve gastrectomy)

B. Obesity using only hiatal hernia repair including repair of sliding or paraesophageal hernia

C. Initial surgery for any condition *other than obesity* (e.g. gastroesophageal reflux disease or gastroparesis) including sleeve gastrectomy, biliopancreatic bypass with duodenal switch or gastric bypass using a Roux-en-Y anastomosis.

D. Any condition including but not limited to obesity and gastroesophageal reflux disease:

1. Mini-gastric bypass (gastric bypass using a Billroth II type of anastomosis)
2. Distal gastric bypass (long limb gastric bypass, i.e., >150 cm)
3. Biliopancreatic bypass (i.e., the Scopinaro procedure)
4. Duodenal switch with single anastomosis, D-Loop surgery, or stomach intestinal pylorus sparing surgery (SIPS)
5. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy followed by gastric bypass, sleeve gastrectomy followed by biliopancreatic diversion, removal of gastric band followed by sleeve gastrectomy or gastric bypass)

6. Any combination of adjustable gastric banding (e.g., Fobi pouch with silastic band) or adjustable gastric banding with Roux-en-Y gastric bypass, or sleeve gastrectomy, or other bariatric surgical procedure.
7. Parietal cell separating gastrojejunostomy
8. Gastric plication

VIII. Endoscopic procedures are considered **investigational** for the following:

A. As the primary bariatric procedure

B. Secondary bariatric procedures (See Policy Guidelines) to treat complications of primary bariatric surgery including but not limited to weight gain due to a large gastric stoma or large gastric pouch and dumping syndrome.

C. Balloon dilatation of strictures when Criterion II.A.4 is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Examples of endoscopic devices/procedures include but are not limited to the following:

1. StomaphyX (EndoGastric Solutions, Inc)
2. ROSE procedure (Restorative Obesity Surgery, Endoscopic)
3. EndoCinch (Bard)
4. EndoSurgical Operating System (EOS) (USGI Medical, Inc.)
5. Sclerotherapy of stoma
6. Endoscopic gastroplasty
7. Endoscopically placed duodenal-jejunal sleeve
8. Endoscopic stoma revision
9. Gastric balloon systems
10. AspireAssist
11. OverStitch Endoscopic Suturing System (Apollo Endosurgery, Inc.)

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could our impact review and decision outcome:

1. If patient is less than 18 years of age, documentation is provided of Tanner 4 or 5 pubertal development. For patients under 18 years of age, greater consideration should be given to psychosocial and informed consent issues.

2. Clinical documentation of a medically supervised nonsurgical pre-operative training program approved and monitored under the supervision of the healthcare practitioner providing medical oversight, that includes:
   A. BMI at the start of the program
   B. Comorbid conditions
   C. The program occurred during at least 3 consecutive months within the 12 months prior to request for surgery
   D. At least 2 visits for medical supervision during the 3 consecutive months of program participation. One visit must occur at the initiation, and another at least 3 months later.
   E. Assessment and counseling concerning weight, diet, exercise and behavior modification
   F. Documentation the program was provided by an MD, DO, NP, PA, or RD under the supervision of the bariatric program.
3. Preoperative evaluation by a licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters-level counselor, or NP in behavioral health that includes:
   A. Documentation of the absence of significant psychopathology that can limit an individual's understanding of the procedure or ability to comply with medical/surgical recommendations (e.g., active substance abuse, eating disorders, schizophrenia, borderline personality disorder, uncontrolled depression)
4. Clinical documentation that the patient is an appropriate candidate for the surgery and is committed to the treatment plan.
5. History and Physical including current medications.
6. Specific procedure being requested.
7. For Reoperation, Revision or Removal requests:
   A. Complication present
   B. Interventions attempted. NOTE: For band migration (slippage), that cannot be corrected with manipulation or adjustment. Records must demonstrate that manipulation or adjustment to correct band slippage has been attempted.
   C. Imaging, endoscopic findings documenting LA grade C or D and/or pH monitoring results (DeMeester score > 50). NOTE: For obstruction, records must demonstrate endoscopic findings or imaging has been performed.
   D. For severe esophagitis, Barret’s esophagus, Cameron lesions, gastro-jejunal anastomotic ulcers, or GERD, documentation must demonstrate medical management has been tried for at least 4 months.

CROSS REFERENCES

1. Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD), Surgery, Policy No. 110
2. Gastric Electrical Stimulation, Surgery, Policy No. 111
3. Gastroesophageal Reflux Surgery, Surgery, Policy No. 186
4. Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease, Surgery, Policy No. 190

BACKGROUND

Levels of overweight and obesity are currently determined by Body Mass Index (BMI) – which is calculated as weight (kg) / height (meters) squared. A normal BMI range is 18.5 to < 25.0 kg/m^2) – overweight and obesity is classified as follows:

Overweight:	25 to < 30.0 kg/m^2
Obesity:	Class I: 30 to < 35.0 kg/m^2
	Class II: 35 to < 40 kg/m^2
	Class III: ≥ 40.0 kg/m^2 (also referred to as severe obesity)

Note: BMI may be calculated by using the BMI calculator.

Individuals with class III obesity are at high risk for developing weight-related complications such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (colon, prostate, breast, uterus, and ovaries). In addition, class III obesity is associated with a shortened life span.[1]

The first-line treatment of severe obesity involves dietary and lifestyle changes. Although this strategy may be effective in some patients, a majority of patients with severe obesity do not achieve significant weight loss through lifestyle modifications. In addition, the weight loss may not be durable, as only a small number of patients are able to comply with the changes on a long-term basis. When conservative measures fail, some patients may consider surgery for severe obesity (bariatric surgery).

Several bariatric procedures have been developed, but based on the underlying mechanism of weight loss, all fall into one or both of the following categories:

Restrictive procedures

- Decrease the size of the stomach and limit food intake

Malabsorptive procedures

- Limit the absorption of calories and nutrients by altering the way food moves through the intestinal track

Multiple variants exist, differing in the reconfiguration of the small intestines and consequently the extent of malabsorption.

The following table briefly summarizes different bariatric procedures:

Procedure	CPT Code	Description
Gastric Bypass with Roux-en-Y Anastomosis (RYGBP) AKA: Proximal or Short Limb Gastric Bypass	43846 43644	• Involves both restrictive and malabsorptive components: o A small gastric pouch is created from the upper part of the stomach by segmentation or resection to restrict the amount of food that can be ingested o The mid portion of the jejunum is divided and the cut end of the distal limb (≤ 150 cm) is attached to the gastric pouch outlet (Roux limb). The cut end of the proximal limb (the limb consisting of the duodenum and proximal jejunum) is attached to the side of the Roux limb (the limb connected to the pouch). This creates the Y configuration of the small intestine, allowing food to bypass the duodenum and proximal jejunum, resulting in malabsorption.
Distal (Long Limb) Gastric Bypass	43847	• The procedure involves both restrictive and malabsorptive components and is a variant of the standard gastric bypass with the longer (>150 cm) Roux limb. The longer the Roux limb, the greater the bypass of the small intestine and consequently the degree of malabsorption.
Biliopancreatic Diversion (Bypass) Procedure AKA Scopinaro procedure	43847	• Involves both restrictive and malabsorptive components: o Subtotal (distal) gastrectomy creates small gastric pouch at the top of the stomach to limit food intake o A long limb Roux-en-Y anastomosis (>150 cm) results in the biliopancreatic juices being diverted into the distal ileum, significantly increasing malabsorption • Designed to preferentially inhibit the absorption of fat • Only partially reversible
Biliopancreatic Diversion (Bypass) with Duodenal Switch (BPD-DS)	43845	• This procedure is an adaptation of the standard biliopancreatic bypass: o The restrictive component involves subtotal gastrectomy resulting in a tube or sleeve-like stomach remnant that leaves the pyloric valve and the initial segment of duodenum intact. o The long limb Roux-en-Y anastomosis (>150 cm) provides malabsorption in this variant as well, but the distal ileum is connected to the duodenal segment leading from the stomach sleeve, instead of the stomach pouch itself.
Laparoscopic duodenal switch with single anastomosis AKA Single loop duodenal switch	No specific CPT code	• Restrictive and malabsorptive procedure • Simplified version of the BPD-DS procedure • Surgery consists of: o Creation of a small gastric pouch by section the curvature of the stomach o Duodenum is transected while keeping the pylorus intact o A 1-loop duodenal switch is performed with creation of a 200-250 cm anastomosis
Mini-Gastric Bypass	no specific code	• The procedure is a variant of the gastric bypass and involves both restrictive and malabsorptive components: o The stomach is segmented to create a small gastric pouch similar to traditional gastric bypass o Instead of creating a Roux-en-Y anastomosis, the loop of jejunum is anastomosed directly to the stomach pouch (similar to a Billroth II procedure) o Also referred to as The One Anastomosis Gastric Bypass (OAGB) or Omega Loop Gastric Bypass.
Sleeve Gastrectomy	43775	• Greater curvature of the stomach is resected resulting in a gastric remnant shaped like a tube or sleeve. • The pyloric sphincter is preserved leaving stomach function unaltered. • Not reversible • Can be performed as: o A stand-alone procedure (restrictive)

Procedure	CPT Code	Description
		o The first part of a two-stage surgical procedure for the very high-risk patients (BMI ≥50 kg/m^2) who need to lose some weight before they can proceed with a malabsorptive procedure (most commonly BPD-DS or RYGBP)
Adjustable Gastric Banding	43770-43774 43886-43888	• Restrictive procedure • An adjustable, external, constrictive band is wrapped around the upper portion of the stomach to create a small stomach pouch • The band can be adjusted through a subcutaneous access port, foregoing the need to enter the gastric cavity when adjusting the band • The least invasive and least technically complex bariatric procedure • Lap-Band® (original applicant, Allergan, Inc.; sold to Apollo Endosurgery, Inc.) and the REALIZE™ (Ethicon Endo-Surgery, Inc.) have received approval from the U.S. Food and Drug Administration (FDA).
Vertical Banded Gastroplasty AKA Vertically banded gastric partition or Gastric stapling	43842	• The vertical banded gastroplasty is no longer a standard of care. • Restrictive procedure • Surgical stapling is used to create a small, vertical gastric pouch at the top of the stomach • The pouch outlet (stoma) is reinforced with an external mesh collar
Endoscopic (Endoluminal) Bariatric Procedures	43290, 43291	• The access to the stomach is gained through the mouth, so no incisions are necessary. • Endoluminal procedures being developed: o Primary bariatric procedure o Revision (e.g. for treatment of enlarged gastric stoma and/or enlarged gastric pouches that may be associated with weight gain after bariatric surgery) • Examples of the endoscopic revision bariatric procedures include: o Gastroplasty using an endoscopically guided stapler (reduces the size of the gastric pouch) o Placement of gastric balloon (soft, silicone balloon inserted into the stomach and filled with sterile saline to induce feeling of satiety) o Placement of duodenal-jejunal sleeve (sleeve placed inside duodenum and upper jejunum to prevent contact between food and the intestine). • StomaphyX®, an endoscopically guided system intended for tissue plication and ligation, has received 510(k) FDA approval. The device is also being investigated for endoscopic treatment of gastroesophageal reflux. • OverStitch™ Endoscopic Suturing System is intended for endoscopic placement of sutures and approximation of soft tissue, and has received FDA approval. The system may be used as an incisionless revision surgery, with the intent to reduce the size of a stomach pouch that has stretched out following a previous bariatric procedure.
Laparoscopic Gastric Plication	No specific CPT code	• Sutures are laparoscopically placed over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. • The procedure involves 2 main steps: o Mobilization of the greater curvature of the stomach, and o Suture plication of the stomach to achieve gastric restriction

EVIDENCE SUMMARY

- Roux-en-Y Gastric Bypass (RYGBP)

  The Roux-en-Y gastric bypass is a commonly performed procedure with the most accumulated evidence in the published literature.[2] Consequently, in order to determine the safety and efficacy of other bariatric surgical procedures, they need to be compared to RYGBP in well-designed, well-executed randomized controlled trials (RCTs).

- Laparoscopic Adjustable Gastric Banding (LAGB)

  RCT data comparing LAGB and RYGBP are limited, however:

  - LAGB is reversible and the least invasive of all bariatric procedures.
  - Weight loss following LAGB is less than what is usually seen following RYGBP.
  - LAGB has low perioperative complications; however inadequate weight loss or long term complications of band erosion, slippage, or malfunction may require additional surgery.

- Sleeve Gastrectomy (SG)

  - SG has gained acceptance in clinical practice and is a commonly performed procedure.
  - SG offers an alternative to adjustable gastric banding with potentially greater weight loss but without the complications associated with malabsorptive procedures, such as RYGBP.

- Other Bariatric Surgical Procedures

  Randomized Controlled Trials

  Very few randomized controlled trials compared other bariatric procedures with RYGBP. Overall, the trials were of poor quality and the findings unreliable due to at least one of the following design flaws:

  - The trials had very small study populations, limiting the ability to rule out the role of chance as an explanation of findings.
  - The randomization scheme was either inadequate or not explained. Inadequate randomization of study participants may result in unequal distribution of potential confounders, such as clinical characteristics, which in turn may affect the outcome.
  - The studies have short follow-up times so there is no long-term (5-10 years or longer) evidence regarding:
    - durability of weight loss
    - complications (e.g. metabolic side effects, nutritional deficiencies, anastomotic ulcers, esophagitis, procedure-specific complications such as band erosion)
    - resolution of comorbidities (e.g. diabetes, hypertension, obstructive sleep apnea, increased cholesterol)
    - need for reoperations

- Short-term complications, adverse events, morbidity, resolution of comorbidities, and reoperation rates are inconsistently reported, limiting conclusions and comparisons across studies.
- There is limited understanding of appropriate patient selection criteria for each of the non-RYGBP bariatric procedures (e.g. superobese patients vs. morbidly obese patients).

Nonrandomized Studies

Although the published, peer-reviewed literature on non-RYGBP bariatric procedures is voluminous, it consists mostly of case series and retrospective, nonrandomized comparisons. Evidence from these studies is unreliable due to design flaws, such as non-random allocation of treatment, lack of adequate comparison groups, and short-term follow-up. In addition, the inconsistent reporting of weight loss, resolution of comorbidities, adverse events, morbidity, and reoperation rates further limit meaningful comparisons across these studies.

- Bariatric Surgery in the Pediatric Population

  Overall, there is enough evidence on the role of bariatric surgery in treating pediatric patients with severe obesity. Moreover, the evidence mostly comes from small, nonrandomized and therefore unreliable studies. Specifically:

  - There is enough evidence that bariatric surgery leads to clinically significant, long-term sustained weight loss and resolution of obesity-related comorbidities in the pediatric population.
  - There is still a lack of evidence regarding the long-term potential impact of bariatric procedures on growth and development in the pediatric population.

- Bariatric Surgery as a Treatment for Gastroesophageal Reflux Disease (GERD)

  In order to determine the safety and efficacy of bariatric surgical procedures as treatments for GERD, they need to be compared to standard medical or surgical treatments of this condition in well-designed, well-executed randomized controlled trials.

- Endoscopic Bariatric Procedures

  There is insufficient evidence to determine the safety and efficacy of any endoluminal procedure as either a primary bariatric procedure or a revision procedure. The published evidence is limited and consists of only a few case series and randomized trials with a high risk of bias.

- Multidisciplinary Approach to the Clinical Management of Bariatric Surgery Patients

  The National Institutes of Health/National Heart, Lung, and Blood Institute (NIH/NHLBI) clinical practice guidelines state the importance of a multidisciplinary approach to the clinical management of bariatric surgery patients. Comprehensive programs should address nursing, nutrition, exercise, behavior modification, and psychological support, and they should provide lifelong follow-up for treated patients.[1]

- Bariatric Surgery Centers of Excellence

The published evidence indicates that high volume bariatric centers are more likely to be successful in achieving optimal outcomes and lower complication and mortality rates than low volume bariatric centers.[3-5] These data have led to national efforts to establish bariatric surgery centers of excellence by the American Society for Metabolic and Bariatric Surgery, the American College of Surgeons, and the BlueCross BlueShield Association.

The following literature appraisal is based on randomized controlled trials (RCT), Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessments, Cochrane reviews, Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness reviews, Washington State Health Technology Assessment and evidence-based guidelines.

DISTAL (LONG LIMB) GASTRIC BYPASS

SYSTEMATIC REVIEWS

The 2005 Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessment identified six comparative trials of long limb gastric bypass with Roux-en-Y anastomosis (LL-RYGBP) vs. standard RYGBP.[2] However, only two were randomized controlled trials (RCT). The assessment determined that there was not sufficient evidence to reach conclusions on the efficacy and safety of LL-RYGBP compared to standard RYGBP:

- In both RCTs, there was no significant difference in weight loss between the two groups at 1 year.
- The evidence for the super obese (BMI ≥50 kg/m^2) population was weak and did not allow conclusions concerning whether LL-RGYBP is superior in this subgroup of patients
- The adverse events were poorly reported in all comparative studies. Some of the reports contradicted one another.
- There was no definite cut-off for “long” vs. “standard” limb, making comparisons even more challenging.

RANDOMIZED CONTROLLED TRIALS

Salman (2023) published a single site RCT comparing outcomes of one-anastomosis gastric bypass (OAGB) and long BPL RYGB regarding weight loss and comorbidity resolution.[6] This study included 62 patients equally allocated to OAGB or long BPL RYGB, with no dropouts during follow-up. At 6 months, there was no statistically significant difference between the two groups regarding postoperative BMI ($p = 0.313$) and the EBWL ($p = 0.238$). There was comparable remission of diabetes, hypertension, OSA, joint pain, and low back pain. Seven patients in the OAGB group experienced reflux symptoms ($p = 0.011$), which were managed by proton pump inhibitors. The authors noted that long BPL RYGB should be preserved for cases whom are more risky for bile reflux.

One RCT evaluated the effectiveness of the distal gastric bypass for weight loss and control of comorbidities.[7] The study included only severely obese patients (BMI ≥50 kg/m^2). There was no significant difference in the control or improvement of hypertension, sleep apnea, or gastroesophageal reflux disorder between the patients who underwent long-limb (Roux limb = 250 cm) and short-limb gastric bypass (Roux limb = 150 cm). In addition, there was no difference in excess weight loss between the groups. Although the study reports better control of lipid disorders and diabetes in patients who underwent the long-limb gastric bypass, several design flaws undermine the reliability of the study findings:

- The small study population (n=105) limits the ability to rule out the role of chance as an explanation of findings.
- The randomization scheme was not explained. Inadequate randomization of study participants may result in unequal distribution of potential confounders, such as clinical characteristics.
- The short-term follow-up limits conclusions regarding the long-term complications and the effectiveness of the distal gastric bypass in controlling weight loss and comorbidities.
- The study included only super obese patients limiting the generalizability of the study findings to other patient populations (i.e. morbidly obese).
- The need for nutritional supplementation after the surgery was reported for the two treatment groups, but there was a failure to include statistical testing for this outcome.

NONRANDOMIZED STUDIES

A number of nonrandomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing distal gastric bypass.[2, 8-10] As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable.

SECTION SUMMARY

Evidence regarding long limb gastric bypass with Roux-en-Y anastomosis (LL-RYGBP) vs. standard RYGBP is limited to three RCTs which showed either no benefit to the LL approach compared to the RYGBP and/or had numerous methodological limitations. In addition, without a standardized cut-off for long vs. standard limb length, comprehensive assessment of the long limb procedure is unlikely. Therefore, current evidence is insufficient to recommend LL-RYGBP over standard RYGBP, including in individuals with class III obesity.

BILIOPANCREATIC BYPASS AND BILIOPANCREATIC BYPASS WITH DUODENAL SWITCH

SYSTEMATIC REVIEWS

Nakanishi (2024) published a meta-analysis to investigate long-term nutrition outcomes after primary biliopancreatic diversion with duodenal switch (BPD-DS) in the management of obesity.[11] The study included eight studies with a total of 3443 patients who underwent primary BPD-DS. At long-term follow-up (≥ 5 years), a significant proportion of patients experienced nutrition deficiencies, including: vitamin A deficiency (25.4%, 95% CI: -.012, .520, I2 = 94%), vitamin D deficiency (57.3%, 95% CI: .059, 1.086, I2 = 86%), calcium deficiency (22.2%, 95% CI: .061, .383, I2 = 97%), and abnormal parathyroid hormone levels (69.7%, 95% CI: .548, .847, I2 = 78%). Additionally, 29.0% of patients had abnormal ferritin levels (95% CI: .099, .481, I2 = 79%). The authors concluded that BPD-DS can result in a high level of long-term nutrition deficiency.

In 2013, Colquitt updated a 2009 Cochrane review[12] which compared outcomes for a variety of surgical weight loss procedures.[13] Two RCTs were identified which assessed outcomes of biliopancreatic diversion with duodenal switch (BPD-DS) compared to RYGBP. At a mean three year follow-up, data from the two trials were pooled (n= 107) and the following conclusions were reached:

- BPD-DS resulted in significantly greater weight loss than RYGBP.

- Quality of life measures were similar between the two groups.
- Reoperation rates were higher in the BPD-DS group (16.1%-27.6%) compared to the RYGBP group (4.3%-8.3%), with one death reported in the BPD-DS group.

The 2005 BCBSA TEC Assessment identified only one comparative trial that compared RYGBP with BPD-DS.[2] Although the trial included 237 RYGBP and 113 BPD-DS patients, it was not a randomized clinical study (the choice of the surgery was determined by surgeon and/or patient) and it followed participants for only one year. The TEC Assessment did not find this data sufficient to determine the risk/benefit ratio for this procedure or that it results in greater weight loss than RYGBP:

- The % estimated weight loss (EWL) at one year was the same for both the RYGBP and BPD-DS groups.
- Data on short-term adverse events was limited, except for the mortality and wound infection rates which were equivalent in both groups.
- More anastomotic leaks were reported in BPD-DS group.
- Long-term complications were not reported.
- Nutritional concerns were not adequately addressed. This is of concern because BPD-DS further reduces fat absorption, affecting the absorption of fat soluble vitamins.

RANDOMIZED CONTROLLED TRIALS

Axer (2024) published a randomized clinical trial comparing single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI) and biliopancreatic diversion with duodenal switch (BPD/DS).[14] The study included 56 patients with a body mass index (BMI) ranging from 42 to 72 kg/m2 who were randomly assigned to either the SADI or BPD/DS procedure. The results showed that SADI had a significantly shorter mean operating time (109 min vs 139 min, p<0.001) compared to BPD/DS. Early complications occurred in 5 patients in the SADI group and 4 patients in the BPD/DS group, with no mortality. The median length of hospital stay was two days for both groups, and re-admission rates were similar. After one year, the percentage of excess weight loss (%EWL) and percentage of total weight loss (%TWL) were similar between the two groups with SADI (81.8% ± 13.6% and 40.1% ± 5.9%) and BPD/DS (84.2% ± 14.0% and 41.6% ± 6.4%).

Salte (2024) published a randomized clinical trial comparing the long-term outcomes of Roux-en-Y-gastric bypass (RYGB) and biliopancreatic diversion with duodenal switch (DS) surgery in patients with severe obesity (BMI 50-60 kg/m2).[15] The study included 60 patients who were followed up for a median of 12 years. The results showed that DS resulted in a greater reduction in BMI (20.3 vs 11.0, p<0.001) and total weight loss (33.9% vs 20.0%, p=0.001) compared to RYGB. The mean BMI reductions were 11.0 (95% CI, 8.3-13.7) for RYGB and 20.3 (95% CI, 17.6-23.0) for DS, with a mean between-group difference of 9.3 (95% CI, 5.4-13.1; P < .001). Additionally, DS resulted in greater improvements in serum lipid levels, except for high-density lipoprotein cholesterol and hemoglobin A1c. However, DS was also associated with a higher risk of adverse events, including vitamin deficiencies (21 vs 11, p=0.008) and severe protein-caloric malnutrition (14% vs 0%, p<0.001). Specifically, 25-hydroxyvitamin D deficiency was more common in the DS group (19 vs 9, p=0.005). Four of 29 patients in the DS group (14%) developed severe protein-caloric malnutrition, of whom 3 (10%) underwent revisional surgery. The total number of adverse events was higher after DS (135 vs 97 for RYGB; P = .02). Quality-of-life scores (Obesity-Related Problem Scale and the 36-Item Short Form Health Survey) were comparable across groups at 10 years. The authors concluded that while DS resulted in greater weight loss, RYGB had a better risk profile over 10 years, and DS may not be a better surgical strategy than RYGB for patients with a BMI of 50-60 kg/m2. .

Moller (2023) published a RCT comparing long-term outcome of BPD/DS and RYGB in patients with super obesity (BMI > 50 kg/m2).[16] This is a 13- to 17-year follow-up study of a single-center, single-blinded randomized trial in which 47 patients (BMI > 48 and eligible for bariatric surgery) were randomized 1:1 to BPD/DS and RYGB (25 men, 24 BPD/DS, 39.1 ± 9.9 years, BMI 54.5 ± 6.1 kg/m2). The primary outcome was weight loss. Thirty-four (18 BPD/DS) of the living 42 patients (81.0%) participated. BPD/DS resulted in higher BMI loss (20.4 ± 7.9 vs. 12.4 ± 8.6, p = .008) and higher percent of total body weight loss (37.5% ± 12.2 vs. 22.8% ± 14.8, p = 0.004). BPD/DS was associated with lower fasting glucose, glycated hemoglobin (HbA1c), and low-density lipoprotein (LDL) as well as lower hemoglobin. Adverse events were more common after BPD/DS (2.7 vs. 0.9 per patient, p = 0.004). The global assessment tool BAROS (Bariatric Analysis and Reporting Outcome System) demonstrated superior scores for BPD/DS (p = 0.047).

Two prospective randomized trials compared the experiences of obese patients undergoing RYGBP vs. BPD. The first trial compared weight loss, metabolic deficiencies, and resolution of comorbidities in morbidly obese patients undergoing RYGBP vs. a variant of BPD (BPD with RYGBP).[17] The study reports comparable nutritional deficiencies between the two procedures. Although better weight loss and resolution of diabetes and hypercholesterolemia was reported in the BPD group, several design flaws undermine the reliability of the study findings:

- The study employed an inadequate randomization scheme: the report states that patients were chosen to undergo RYGBP or BPD, but fails to provide any further explanation of how the treatment was assigned. Inadequate randomization of study participants may result in unequal distribution of potential confounders, such as clinical characteristics.
- The RYGBP group had a significantly higher level of preexisting comorbidities (p = 0.01), suggesting a difference between the treatment groups that may have affected the outcome.
- The small study population (65 patients/surgery group) limits the ability to rule out the role of chance as an explanation of findings.
- The short-term follow-up (2 years) limits conclusions regarding the long-term metabolic complications and the long-term effectiveness of the BPD in controlling weight loss and comorbidities.

Another small randomized trial (n=60) compared laparoscopic RYGBP and BPD-DS for superobese patients (BMI 50-60 kg/m^2).[18] The study found comparable 30-day perioperative safety and greater weight loss following BPD-DS in the first year.

In 2015, long-term 5-year follow-up results were published on data from 55 patients (92%).[19] Results indicated a mean reduction of body mass index was greater with duodenal switch compared to bypass (mean between-group difference was 8.5 [95% CI, 4.9-12.2; P < .001]); however, duodenal switch was associated with more surgical, nutritional and gastrointestinal adverse effects.

NONRANDOMIZED STUDIES

A number of non-randomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing biliopancreatic diversion with or without duodenal switch.[20-38] Many of these studies show successful weight loss after BPD compared to other bariatric procedures.

SLEEVE GASTRECTOMY

There are various types of gastrectomy, which include distal, partial (including sleeve gastrectomy) or complete gastrectomy which may be performed with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction. There is insufficient evidence regarding the use of gastrectomy, other than sleeve gastrectomy, as a treatment of obesity. Numerous studies were identified which evaluated outcomes of these alternative gastrectomy methods as a treatment of other conditions, including gastric cancer; however, no studies or clinical practice guidelines were identified which evaluated the efficacy of these alternative types of gastrectomy as a treatment of obesity. Therefore, the following evidence review will focus on the use of sleeve gastrectomy as a treatment of obesity, in the context of systematic reviews and well-designed randomized controlled trials:

SYSTEMATIC REVIEWS

Numerous recent systematic reviews have compared SG and RYGB with regard to effects on weight, comorbidities, and complications. Apaer (2024) published a meta-analysis comparing the clinical efficacy and safety of laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) in terms of short- and mid-term outcomes of weight loss, obesity-related comorbidities, and post-operative complications.[39] The study included 20 studies with 1270 patients and found that LRYGB had superior efficacy to LSG in BMI loss at 6 months (mean difference (MD) -1.35 kg/m2, 95% CI: -2.07 to -0.62, p=0.0003), 12 months (MD -1.09 kg/m2, 95% CI: -1.86 to -0.33, p=0.005), and 36 months (MD -1.47 kg/m2, 95% CI: -2.77 to -0.16, p=0.03). LRYGB also resulted in significantly higher remission rates of type 2 diabetes mellitus (T2DM) and dyslipidemia at 12 months. Additionally, LRYGB showed better improvements in T2DM-related and lipid biochemical parameters. However, LSG had a lower post-operative complication rate and shorter operating time.

Oliveira (2024) published a systematic review and meta-analysis to assess the safety, weight loss, improvement in associated comorbidities, and complications of the Single Anastomosis Sleeve Ileal (SASI) bypass.[40] The study included 18 studies in the qualitative analysis and 4 in the quantitative analysis, comparing SASI bypass with sleeve gastrectomy (SG) and One-Anastomosis Gastric Bypass (OAGB). The results showed that SASI bypass was associated with improved weight loss (mean difference (MD) = 11.32; 95% confidence interval (95%CI) [7.89;14.76]; p < 0.0001) and improvement or remission in type 2 diabetes mellitus (T2DM) (risk ratio (RR) = 1.35; 95%CI [1.07;1.69]; p = 0.011), dyslipidemia (DL) (RR = 1.41; 95%CI [1.00;1.99]; p = 0.048), and obstructive sleep apnea (OSA) (RR = 1.50; 95%CI [1.01;2.22]; p = 0.042) compared to SG. No statistically significant differences in any of the assessed outcomes were observed when compared with OAGB. The complication rate of SASI was similar to both SG and OAGB.

Lei (2024) published a meta-analysis comparing the outcomes of Laparoscopic Sleeve Gastrectomy (LSG) and Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) for the treatment of obesity.[41] The study included 18 eligible studies and found that LRYGB resulted in greater weight loss compared to LSG at five years, with a weighted mean difference (WMD) of -7.65 kg/m² (95% CI: -11.54 to -3.76, P=0.0001). However, there was high heterogeneity between the studies. LRYGB also achieved a higher resolution rate of type 2 diabetes mellitus (T2D) and dyslipidemia compared to LSG, with odds ratios (OR) of 0.60 (95% CI: 0.41-0.87, p=0.007) and 0.44 (95% CI: 0.23-0.84, p=0.01), respectively. There was no difference between the two procedures in terms of remission of hypertension and obstructive sleep apnea. Additionally, there was no difference in quality of life (QoL) after LRYGB or LSG. However, LSG had a lower morbidity rate compared to LRYGB, with a WMD of -0.07 (95% CI: -0.13, -0.02, P=0.01). There was no statistically significant difference in mortality between the two procedures.

Osland (2023) systematic review and meta-analysis of RCTs to investigate the comparative 5-year outcomes of both procedures in adults.[42] Three RCTs (LVSG=254, LRYGB=255) met inclusion criteria and reported on chronic disease outcomes. Improvement and/or resolution of hypertension favored LRYGB (odds ratio 0.49, 95% CI 0.29, 0.84; p = 0.03). Trends favoring LRYGB were seen for type 2 diabetes and dysplidemia, and LVSG for sleep apnea and back/joint conditions (p >0.05). The certainty of evidence associated with each assessed outcome ranged from low to very low, in the setting of 'some' to 'high' bias assessed as being present. The authors conclude that the limited certainty of the evidence does not allow for strong clinical conclusions to be made at this time regarding benefit of one procedure over the other.

Kermansaravi (2023) published an umbrella review with meta-analyis comparing the safety and efficacy of sleeve gastrectomy versus Roux-en-Y gastric bypass in elderly (>60 years) with severe obesity.[43] The umbrella review included six meta-analyses. The risk of early-emerging and late-emerging complications decreased by 55% and 41% in the patients underwent SG than in those receiving RYGB, respectively. The chance of the remission of hypertension and obstructive sleep apnea, respectively increased by 43% and 6%, but type-2 diabetes mellitus decreased by 4% in the patients underwent RYGB than in those receiving SG. RYGB also increased excess weight loss by 15.23% in the patients underwent RYGB than in those receiving SG. The authors conclude that lower levels of mortality and early-emerging and late-emerging complications were observed in the older adults undergoing SG than in those receiving RYGB, which was, however, more efficient in term of weight loss outcomes and recurrence of obesity-related diseases.

Vanetta (2023) published a SR and meta-analysis evaluate the safety and success of same day discharge following SG and RYGB.[44] A total of 14 studies with 33,403 patients who underwent SDD SG (32,165) or RYGB (1238) were included in the qualitative synthesis. Seven studies with 5000 patients who underwent SDD SG were included in the quantitative analysis, and pooled proportions (PPs) were calculated for the outcomes of interest. The SDD success rate was 63%-100% (PP: 99%) after SG and 88%-98.1% after RYGB. The readmission rate ranged from 0.6% to 20.8% (PP: 4.0%) after SDD SG and 2.4%- 4.0% after SDD RYGB. Overall morbidity, reoperation, and mortality were 1.1%-10% (PP:4.0%), 0.3%-2.1% (PP: 1.0%), and 0%- 0.1% (PP: 0%), respectively, for SDD SG, and 2.5%-4.0%,1.9%-2.5%, and 0%- 0.9%, respectively, for SDD RYGB. SDD after SG seems feasible and safe. The outcomes of SDD RYGB seem promising, but the evidence is limited to draw definitive conclusions. Selection criteria and perioperative protocols must be standardized to adequately introduce this practice.

Gu (2020) completed a meta-analysis of the medium- and long-term effects of laparoscopic SG and RYGB.[45] The evaluation included 9038 patients from 28 studies. Overall, 5 year follow-up results revealed that laparoscopic RYGB was associated with an improvement in percentage of EWL and remission of T2D, hypertension, and dyslipidemia as compared to laparoscopic SG.

Han (2020) also published a systematic review and meta-analysis involving 18 studies (N=2917) that compared weight loss and comorbidity resolution between laparoscopic SG and RYGB.[46] Results from this analysis revealed no significant difference in EWL or T2D resolution between the 2 procedures. Laparoscopic RYGB was found to be superior to SG with regard to dyslipidemia, hypertension, and GERD management; however, patients who underwent laparoscopic SG experienced fewer postoperative complications and reoperation rates.

Sharples (2020) performed a systematic review and meta-analysis evaluating long-term (5 years) outcomes of RYGB and SG.[47] Overall, both RYGB and SG resulted in sustained weight loss and comorbidity control with RYGB associated with a greater percent EWL, improved dyslipidemia outcomes, and a reduced incidence of GERD..

Shenoy (2020) published a systematic review and meta-analysis of nine studies that compared laparoscopic SG and RYGB in 2240 elderly (>55 years) patients.[48] Results revealed no significant differences between the two bariatric procedures with regard to the rate of early complications (3.6% LSG versus 5.8% LRYGB; p=0.15) and mortality (0.1% versus 0.8%; p=0.27). Additionally, there was no difference in EWL between the procedures at 1 year; however, the authors recommended SG for high-risk elderly patients due to the reduced mortality and complication rates with this procedure.

Another systematic review and meta-analysis by Xu (2020) involving 19 studies also concluded that SG was the preferable option for elder obese patients 60 years and older as it was found to be non-inferior to RYGB with regard to efficacy, but overall had an improved safety profile.[49]

Osland (2017) published a systematic review and meta-analysis of RCTs comparing laparoscopic vertical SG with RYGB.[50] The literature search, conducted from 2000 to November 2015, identified 9 RCTs for inclusion (N=865 patients). Four trials were included in meta-analyses comparing percent EWL between the 2 groups. Results at both 6- and 12-month follow-ups showed that the procedures are comparable. Osland (2020) recently published a continuation of their work that focused exclusively on long-term (5 year) weight outcomes of laparoscopic vertical SG versus RYGB.[51]https://www.evidencepositioningsystem.com/mpp_meeting/mpp_pub_final/_blank This systematic review and meta-analysis included 5 studies (SG=520; RYGB=508) and results revealed that a statistically significant BMI loss was seen with both SG: -11.37 kg/m^2 (range: -6.3 to -15.7 kg/m^2) and RYGB: -12.6 kg/m^2 (range: -9.5 to -15.4 kg/m^2) at 5 years. However, differences in reporting parameters limit the ability to reliably compare outcomes using statistical methods and the results may have been impacted by large dropout rates and per protocol analyses of the two largest included studies.

In 2017, Juodeikis evaluated five-year results following sleeve gastrectomy in a systematic review of the literature through May 2016.[52] The review was conducted according to PRISMA guidelines. Twenty studies were included for evaluation, however, only one study was a randomized controlled trial. Of the 2,713 patients included amongst all the studies combined, 1,626 reached at least five years follow-up (duration ranged from 5-11 years follow-up). Although mean percentage excess weight loss of greater than 56% was achieved at each time point from 5 to 11 years' time, the review was substantially limited by the lack of RCT data.

In 2016, Osland compared the efficacy of Roux-En-Y gastric bypass versus vertical sleeve gastrectomy in randomized controlled trials.[50] Six RCTs performed between 2005 and 2015 were included (N = 695; 347 for SG and 348 for RYGB). The authors summarized recent publications, without pooled analysis. Although the results stated comparable efficacy and improvement or resolution in comorbidities, the authors also noted the significant limitation of short follow-up time (one year, with significant loss of follow-up), and lack of blinding in five of the six studies included. In 2017, Osland published an additional meta-analysis, again comparing vertical sleeve gastrectomy in RCT's to LRYGB (N=865 patients; 437 for SG and 428 for LRYGB).[53] The authors concluded once again that a significant gap exists in the literature with respect to well-designed studies using intent-to-treat analysis.

In 2015, Zhang published a separate review comparing LSG to laparoscopic RYGBP (LRYGBP) which included 21 studies involving 18,766 morbidly obese patients.[54] Data regarding percentage of excess weight loss (%EWL), resolution or improvement of comorbidities, and adverse events were pooled. Although no difference in %EWL was observed between the two groups in the first 6 months-1.5 year follow-up, LRYGBP achieved higher %EWL compared to LSG ($p<0.05$). Except for improvements in type 2 diabetes, comorbidities did not differ significantly between the two groups. Adverse events were more frequent following Roux-en-Y bypass (OR for major complication: 1.29; 95% CI 1.22 to 3.22; $P<0.01$). Results of this review must be interpreted with caution as 13 of the 21 included studies were nonrandomized, limiting the ability to control for confounding factors.

A 2014 review by Zellmer compared complication rates of laparoscopic RYGBP to LSG in 61 publications which included 10,906 laparoscopic RYGBP patients and 4,816 LSG patients.[55] Authors reported similar leak and mortality rates in both groups; laparoscopic RYGBP (leak: 1.9%, mortality: 0.4%) vs. LSB (leak: 2.3%, mortality: 0.2%).

The 2013 Cochrane review of bariatric surgery identified only one randomized controlled trial that compared sleeve gastrectomy to gastric bypass with Roux-en-Y anastomosis (RYGBP).[12, 13, 56] This very small (n=32) and short trial that followed participants for only 1 year reported that:

- Weight loss and BMI were similar between the two procedures, but % excess weight loss was greater with sleeve gastrectomy.
- Two patients had diabetes at baseline, both in the RYGBP group. The condition was resolved at 1 year in both patients. The outcome of other comorbidities reported at baseline was not reported for the RYGBP or SG groups.
- Although the study reported no conversions to open surgery and no intraoperative and postoperative complications, the other complications and additional operative procedures were not reported.
- The study did not assess a two-stage approach using sleeve gastrectomy prior to another bariatric procedure and consequently no conclusions about the two-stage approach could be made.
- The short duration of the follow-up results in underestimation of the impact of late complications and the need for revision surgery.

In 2013, Trastulli published a systematic review of randomized trials that compared sleeve gastrectomy to other bariatric procedures.[57] A total of 15 RCTs with 1191 patients were included. In six trials laparoscopic sleeve gastrectomy (LSG) was compared to laparoscopic RYGBP. The authors reported mean complication rates with sleeve gastrectomy of 12.1% (range 10%-13.2) compared with 20.9% with laparoscopic gastric bypass (range 10%-26.4%). Percentage of excess weight loss ranged from 49%-81% with sleeve gastrectomy compared with 62.1%-94.4% with laparoscopic gastric bypass. Included studies which compared LSG to laparoscopic RYGBP were small[58-60] (n<60) and several contained a risk for bias which included unclear blinding, randomization methods and outcome data.

A 2013 meta-analysis by Li pooled data from five trials, four of which were included in the Trastulli review, to compare the impact of these procedures on type 2 diabetes rates.[61] Laparoscopic Roux-en-Y gastric bypass was associated with higher rates of type 2 diabetes remission and greater estimated weight loss, but higher rates of complications.

RANDOMIZED CONTROLLED TRIALS

Pajecki (2023) published three year outcomes of a RCT comparing SG and RYGBP in obese patients older than 65 years.[42] Of the 36 patients who underwent randomization, none were lost to follow-up through the 36 months of data collection. The baseline mean BMI was 45 ± 5.2 kg/m2. Weight loss was significantly better after LRYGB compared to LSG in the third year of follow-up, both on %TWL (30.3 ± 2.2% vs. 17.2 ± 2.2%, p = 0.001) and %EWL (63.1 ± 4.3 vs. 43.5 ± 6.7%, p = 0.018). After LRYGB, HbA1c (p < 0.001), HDL (p < 0.001), LDL (p = 0.007), and triglyceride (p < 0.001) levels improved significantly. After LSG, a significant difference was only seen in HDL levels (p = 0.004). Adherence to micronutrient supplementation was significantly more frequent in the LSG group (72.2% vs. 22.2%, p = 0.003). Hemoglobin and albumin levels remained stable for both procedures. The data in this study is limited to methodology concerns as all follow-up was via telephone contact only due to COVID-19.

Hofsø (2019) published the results of a single-center, triple-blind RCT comparing the efficacy of Roux-en-Y gastric bypass (RYGB) (n=54) vs sleeve gastrectomy (SG)(n=55) on diabetes remission and ß-cell function in patients with obesity and T2D. Inclusion criteria included previously verified BMI ≥35 kg/m2 and current BMI ≥33.0 kg/m2, hemoglobin A1c (HbA1c) ≥6.5% or use of antidiabetic medications with HbA1c ≥6.1%, and age ≥18 years. One-year follow-up was completed by 107 (98%) of 109 patients, with 1 patient in each group withdrawing after surgery. In the intention-to-treat population, diabetes remission rates were superior in the gastric bypass group than in the sleeve gastrectomy group (risk difference 27%; relative risk [RR] 1.57). Results were similar in the per-protocol population (risk difference 27%; RR 1.57). The two procedures had a similar beneficial effect on ß-cell function.

Peterli (2018) published a randomized study of adults with morbid obesity treated with either laparoscopic sleeve gastrectomy (SG) or Roux-en-Y gastric bypass (RYGB).[62] Two hundred five patients treated at four bariatric centers were randomly assigned to receive SG (n=101) or RYGB (n=104) with 5-year follow-up. Excess BMI loss was 61.6% for SG and 68.3% for RYGB. Gastric reflux remission was seen in 25.0% of SG and 60.4% of RYGB patients. Reoperations or interventions were necessary for 15.8% in the SG group and 22.1% of the RYGB group. The study was limited by the lack of analysis of diabetes remission information and the results may not be generalizable.

Salminen (2018) published a randomized trial (SLEEVEPASS) comparing 5-year outcomes of morbidly obese patients who underwent either laparoscopic sleeve gastrectomy (SG; n=121) or Roux-en-Y gastric bypass (RYGB; n=119).[38] Five-year estimated mean percentage excess weight loss was 49% for sleeve gastrectomy and 57% for gastric bypass. For SG and RYGB, respectively, rates of remission of type 2 diabetes were 37% and 45%. Medication for hypertension was discontinued in 20/68 (29%) SG patients and 37/73 (51%) RYGB patients. Overall 5-yr morbidity rate was 19% for SG and 26% for RYGB, and there was no significant difference in QOL between groups. The study was limited by the following: the study having a higher reoperation rate for sleeve gastrectomy than other trials reported, approximately 20% of patients were lost to follow-up, and there was a lack of reliable information for diabetes duration at baseline.

CLINICAL PRACTICE GUIDELINES

In 2012, the American Society for Metabolic & Bariatric Surgery (ASMBS) updated their position statement on *Sleeve Gastrectomy as a Bariatric Procedure.*[63] The ASMBS recognizes sleeve gastrectomy as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach. In addition, the group noted that substantial comparative and long-term data have now been published which demonstrate durable weight loss, improved medical comorbidities, long-term patient satisfaction, and improved quality of life after SG. However, the ASMBS Statement does not include a critical appraisal of the reviewed evidence.

SECTION SUMMARY

Recent systematic reviews of existing trials indicate sleeve gastrectomy (SG) is a comparable procedure to RYGBP. Although the evidence regarding SG with RYGBP compared to standard RYGBP is limited by short-term follow-up, SG has become a recognized surgical option in clinical practice for the treatment of morbid obesity.

ADJUSTABLE GASTRIC BANDING

SYSTEMATIC REVIEWS

Park (2019) conducted a systematic review with a network meta-analysis evaluating the comparative efficacy of various bariatric surgery techniques against standard-of-care in the treatment of morbid obesity and diabetes.[64] The literature search was conducted through February 2018, identifying 45 RCTs for inclusion on Roux-en-Y gastric bypass (RYGB; 2 studies), sleeve gastrectomy (SG; 3 studies), laparoscopic adjustable gastric band (LAGB; 5 studies), and biliopancreatic diversion with duodenal switch (BPD-DS; 3 studies vs RYGB). Based on 33 trials, superior efficacy for % excess weight loss compared to standard-of-care was seen for BPD-DS (mean difference [MD] 38.2%), RYGB (MD 32.1%), and SG (MD 32.5%) at 6 months post procedure. LAGB was not superior to standard-of-care (MD -0.2%). At 3 years post-procedure, superior efficacy for %EWL compared to standard-of-care was seen for RYGB (MD 45%) and SG (MD 39.2%). BPD-DS (RR 7.51), RYGB (RR 7.51), and SG (RR 6.69) were all superior to standard-of-care with respect to remission rates at 3-5 years post-procedure and remission rates were not significantly different among procedures. SG was found to have a relatively lower risk of adverse events compared to RYGB.

A 2017 systematic review by Kang reported results from a network meta-analysis of RCTs evaluating the three most commonly performed bariatric procedures – Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and laparoscopic adjustable gastric band (LAGB).[65] The review was conducted with literature through July 2016, and in accordance with PRISMA guidelines. Evidence was synthesized from 11 trials (8 RYGB vs SG; 2 RYGB vs LAGB; 1 SG vs LAGB) in order to evaluate the primary outcome of changes in weight loss, expressed as the mean difference in BMI reduction and in percentage excess weight loss (%EWL) following 1 year after the surgery. The smallest treatment effect was observed in LAGB (8 trials, totalling 656 patients). The mean %EWL for RYGB, SG, and LAGB were 67.3% (n=294), 71.2% (n=209), and 40.6% (n=153), respectively. Heterogeneity between studies was low (as evaluated by calculating the I^2 statistic), and the studies were consistent between direct and indirect comparisons – both demonstrated strengths of the analysis. The study was limited by fewer trials evaluating LAGB, and inclusions of RCTs with a lack of blinding.

The 2013 Cochrane review of bariatric surgery identified three randomized controlled trial that compared laparoscopic adjustable gastric banding (LAGB) to laparoscopic gastric bypass with Roux-en-Y anastomosis (RYGBP).[12, 13, 66] At five-year follow-up, the review reported the following conclusions:

- RYGBP was superior to LAGB on more than one measure of weight loss (% excess weight loss, mean BMI).
- Quality of life measures and comorbidities were not assessed due to the low quality of the evidence.
- RYGBP resulted in a greater duration of hospitalization and a greater number of late major complications.
- One study reported high rates of reoperation for removal of LAGB (9 patients, 40.9%).

In 2012, TEC conducted an updated Assessment, focusing on LAGB in patients with BMIs less than 35 kg/m^2.[67] TEC made the following observations and conclusions:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There was only one small randomized, controlled trial, which had methodologic limitations, one nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence was sufficient to determine that weight loss following LAGB was greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss was large enough that improvements in weight-related comorbidities could be assumed.
- There was very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB was uncertain, thus it was not possible to determine whether the benefit of LAGB outweighed the risk for this population. TEC concluded that while the short-term safety of LAGB was well-established, the long-term adverse effects occur at a higher rate and are less well-defined.

RANDOMIZED CONTROLLED TRIALS

An updated literature search failed to identify any additional randomized controlled trials that compare LAGB with RYGBP.

NONRANDOMIZED STUDIES

A number of non-randomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing LAGB.[37, 68-75] As noted at the beginning of the evidence section, conclusions cannot be reached as the evidence from these studies is considered unreliable.

SECTION SUMMARY

The evidence regarding the laparoscopic adjustable gastric banding (LAGB) compared to standard RYGBP is limited. Additionally, LAGB may have higher rates of reoperation and revisions. LAGB is no longer considered a standard of care.

LAPAROSCOPIC DUODENAL SWITCH WITH SINGLE ANASTOMOSIS

Several nonrandomized studies were identified which describe the experiences of patients undergoing laparoscopic duodenal switch with single anastomosis (LSDSA).[76-80] As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable. Well-designed RCTs which compare LSDSA with RYGBP are needed in order to evaluate the safety and efficacy of this procedure compared to accepted surgical treatments of morbid obesity.

SYSTEMATIC REVIEWS

Balamurugan (2023) published a systematic review comparing the safety and efficacy between Roux-en-Y gastric bypass (RYGB), one anastomosis gastric bypass (OAGB) and single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S). Eighteen eligible studies were included. Weight loss outcomes were greater with SADI-S (5 years) and OAGB (10 years). SADI-S offered better resolution of diabetes whereas hypertension and dyslipidaemia resolution were better with OAGB. Although early complications and mortality were higher with SADI-S, late complications were more frequent with RYGB. Both SADI-S and OAGB are as effective as RYGB for weight loss, but OAGB offers lesser complications. The authors conclude that more data is imperative to determine the next gold standard procedure.

Nakanishi (2022) published a systematic review of six studies including 1,846 patients with obesity who underwent either single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S) or a biliopancreatic diversion with duodenal switch (BPD-DS).[81] The BPD-DS group had a greater % excess body mass index loss (MD=-10.16%, 95% confidence interval: -11.80, -8.51) at two years compared with the SADI-S group. There was no difference observed in preoperative comorbidities and remission, including diabetes, hypertension, and dyslipidemia between SADI-S and BPD-DS cohorts. The SADI-S group had shorter hospital stays and fewer long-term complications. The authors concluded that additional randomized trials with extended follow-up periods are necessary to establish the safety and efficacy of the procedure.

Spinos (2021) conducted a systematic review to evaluate the effectiveness of patients who have undergone single-anastomosis duodenal bypass with sleeve gastrectomy/one anastomosis duodenal switch (SADI-S/OADS).[82] There were 14 studies included in the review including five retrospective cohort and nine case series. A total of 1086 patients were included in the analysis with preoperative BMI of 51.3 ± 9.5 kg/m2. The average body mass index (BMI) following SADI-S was 32.1 ± 6.7 kg/m2. Mean total body weight (TBW) loss ranged from 11.3% to 17.3% at three months, 21.5% to 41.2% at 12 months, and 25.8% to 46.3% at 24 months. Mean excess body weight (EBW) loss ranged from 21.8% to 40.2% at three months, 60.9% to 91.0% at 12 months, and 44.3% to 86.0% at 24 months. Mean excess BMI (EBMI) ranged from 9.4% to 31.1% at three months, 17.9% to 86.6% at 12 months, and 19.5% to 80.8% at 24 months. The comorbidity resolution rates were 72.6% for diabetes mellitus, 77.2% for dyslipidemia, 59% for hypertension, 54.8% for obstructive sleep apnea, and 25% for gastroesophageal reflux disease. The most common early postoperative complications after SADI-S included the need for reoperation (3.1%), bleeding (1.1%), wound infection (1.0%), anastomotic leak (0.9%), and intrabdominal collection/abscess (0.6%). Late postoperative complications were the need for reoperation (5.3%) and dumping syndrome (1.3%). The major limitation of this review is that studies were either retrospective cohort studies or case series with short-term follow ups.

CLINICAL PRACTICE GUIDELINES

In 2020, ASMBS published an updated statement on single-anastomosis duodenal switch (SADI-S) "in response to numerous inquiries made...by patients, physicians, society members, hospitals, and others regarding [this procedure] as a treatment for obesity and metabolic diseases."[83] The following recommendations were endorsed regarding SADI-S for the primary treatment of obesity or metabolic disease:

> "SADI-S, a modification of classic Roux-en-Y duodenal switch, is an appropriate metabolic bariatric surgical procedure."
>
> "Publication of long-term safety and efficacy outcomes is still needed and is strongly encouraged, particularly with published details on sleeve gastrectomy size and common channel length."
>
> "There remain concerns about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure. As such, ASMBS recommends a cautious approach to the adoption of this procedure, with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients, in particular for duodenal switch patients."

MINI-GASTRIC BYPASS/ONE ANASTOMOSIS GASTRIC BYPASS (OAGB)

SYSTEMATIC REVIEWS

Onzi (2024) published a systematic review and meta-analysis to compare the efficacy and safety of One Anastomosis Gastric Bypass (OAGB; or mini-gastric bypass) with Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) in the treatment of obesity.[84] The study included 11 randomized controlled trials with a total of 854 patients, of which 422 (49.4%) underwent OAGB. The results showed that OAGB was associated with a significantly higher percentage of excess weight loss at 1-year follow-up. No significant differences were observed between groups in BMI at 6-month and 1-year follow-up, but at 5-year follow-up, OAGB was associated with a significant decrease in BMI, with a weighted mean difference of -1.78 kg/m2. However, there were no significant differences in type-2 diabetes mellitus remission, complications, and gastroesophageal reflux disease rates between the groups. The overall quality of evidence was considered very low, five studies were deemed at some concerns risk of bias and six studies at high risk of bias.

In 2014, Georgiadou published a systematic review regarding the safety and efficacy of laparoscopic mini gastric bypass.[85] The review included a search of the literature through July 2013, and was conducted according to PRISMA guidelines. Ten articles with a total of 4,899 patients were included for review, of which three were comparative studies (two versus LRYGB and one versus LAGB). Excess weight loss at two years ranged from 64.4% ± 8.8% to 80%. Minor postoperative complication rates ranged from 3.6%-7.5%, and major early postoperative complication rates ranged from 0-7%. Authors noted a major concern for postoperative esophagitis and gastritis caused by bile reflux, and the risk for gastric cancer.

Overall, the study was limited by the limitations of the included studies (e.g., short term follow-up and noncomparative design).

RANDOMIZED CONTROLLED TRIALS

Robert (2024) published a multicenter prospective, open-label, non-inferiority randomized extension trial (YOMEGA) comparing the one anastomosis gastric bypass (OAGB) with the Roux-en-Y gastric bypass (RYGB) in patients with obesity.[86] The study included 253 patients who were randomly assigned to undergo either OAGB (one gastro-jejunal anastomosis with a 200 cm biliopancreatic limb) or RYGB. The primary endpoint was percentage excess BMI loss at five years. The authors concluded that OAGB was not inferior to RYGB, with a mean percentage excess BMI loss of -75.6% in the OAGB group versus -71.4% in the RYGB group (mean difference -4.1% [90% CI -12.0 to 3.7], p=0.0099). Remission of type 2 diabetes was similar in both groups, and nutritional status did not differ. However, the rate of clinical gastro-esophageal reflux disease was higher in the OAGB group (41% vs 18%, p=0.0030). Serious adverse events included conversion from OAGB to RYGB in 10 patients (8%). The authors concluded that OAGB was not inferior to RYGB regarding percentage excess BMI loss at five years, however, the long-term consequences of the high rate of clinical gastro-esophageal reflux disease after OAGB requires further investigation. This study was funded by Medtronics.

Delko (2024) published a non-inferiority randomized controlled trial to compare the effectiveness and safety of One Anastomosis Gastric Bypass (OAGB) and Roux-en-Y gastric bypass (RYGB) in patients with obesity.[87] The study included 80 patients who were randomized 1:1 to undergo either OAGB or RYGB. The primary endpoint was the percent excess weight loss (%EWL) at 12 months after surgery. The results showed that OAGB was associated with a higher %EWL at 12 months (104.1% vs 87.9%, p=0.006) and improved glucose control compared to RYGB. Additionally, OAGB showed a higher increase in glucagon-like peptide-1 (GLP-1) levels at 6 weeks (p=0.041) and 1 year after surgery (p=0.029). However, the rate of marginal ulcers was higher in patients with OAGB compared to those with RYGB (p=0.011). There were no significant differences in the remission of comorbidities, except for gastroesophageal reflux disease (GERD), which was higher in the RYGB group. Quality of life improved after both surgeries, without differences between the groups.

Karagul (2024) published a randomized prospective study comparing the 3-year results of one anastomosis gastric bypass (OAGB) and Roux-en-Y gastric bypass (RYGB) surgeries.[88] The study included 38 patients aged 18 - 65, who were randomly assigned to either OAGB (n = 20) or RYGB (n = 18) groups. Patients were evaluated at 6, 12, 24, and 36 months postoperatively. At the end of 3-year follow-up, BMI in the OAGB and RYGB groups was 28.80 ± 4.53 kg/m2 and 29.17 ± 5.36 kg/m2, respectively (p = 0.822). Percentage total weight loss (TWL%) was similar. No significant differences were found between the groups regarding percentage excess weight loss (EWL%). Remission of comorbidities was similar. De novo refluxes developed in four OAGB patients; there were no occurrences of these in RYGB patients (p = 0.066). The study's limitations include a small sample size and high loss to follow-up.

One small RCT compared the safety and effectiveness of laparoscopic RYGBP and mini-gastric bypass (MGBP).[89] The study found a comparable rate of late complications (>30 days post-op), weight loss, and comorbidity resolution. MGBP was associated with fewer early complications (<30 days post-op). However, the following design flaws undermine reliability of the study findings:

- The small study population (n=80) limits the ability to rule out the role of chance as an explanation of findings.
- Short-term follow-up (2 years) limits comparisons regarding the longer-term complications rates and the effectiveness of the two procedures in controlling weight loss and comorbidities

NONRANDOMIZED STUDIES

In 2017, Plamper reported a comparison of mini gastric bypass and sleeve gastrectomy in super-obese patients (i.e., BMI > 50 kg/m^2) at a single institution.[90] At one-year follow-up, 90.8% (99 of 109) and 78.7% (74 of 94) of the MGB and SG patients were available for follow-up, respectively. Reasons for loss of follow-up were not discussed. One patient in the SG group died within 30 days of the operation due to multi-organ failure after staple line leakage. Percent excess weight loss was statistically significantly greater in the MGB group at 12 months. The authors cited limitations of their review to include the retrospective design, and short-term results.

Several other nonrandomized studies (retrospective comparisons, case series), describe experiences of patients undergoing MGBP.[91-95] As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

SECTION SUMMARY

Data regarding the mini-gastric bypass (MGBP) or One Anastomosis Gastric Bypass (OAGB) is limited to small sample sizes, short duration follow-up and heterogeneity of methodology prohibiting conclusions regarding the efficacy of this procedure compared to RYGBP. Additionally, further research is needed to evaluate the potential of increased incidence of GERD after OAGB.

VERTICAL BANDED GASTROPLASTY (VBG)

VBG has largely been abandoned in the United States due to insufficient weight loss and high reoperation rates (approximately 30%).[12, 96]

HIATAL HERNIA REPAIR

Numerous studies[97-101] were identified which evaluated outcomes of hiatal hernia repair performed in conjunction with other bariatric surgical procedures; however, no studies or clinical practice guidelines were identified which evaluated the efficacy of hiatal hernia repair as an independent treatment of obesity.

CLINICAL PRACTICE GUIDELINES

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery.[102] The guideline contained the following conclusions and summary recommendations:

- "There is a significant link between obesity and hernia formation both after abdominal surgery and de novo. There is also evidence that abdominal wall hernia can more commonly present with obstruction or strangulation in patients with obesity."
- "There is a higher risk for complications and recurrence after hernia repair in patients with obesity."
- "In patients with severe obesity and ventral hernia, and both being amenable to laparoscopic repair, combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection. There is a relative lack of evidence, however, about the use of synthetic mesh in this setting."
- "In patients with severe obesity and abdominal wall hernia that is not amenable to laparoscopic repair, a staged approach is recommended. Weight loss prior to hernia repair is likely to improve hernia repair outcomes. Metabolic/bariatric surgery appears to provide far more significant and rapid weight loss than other modalities and would be a good option for selected patients with severe obesity and large, symptomatic abdominal wall hernia."

The 2022 ASMBS guidelines include the following recommendations: MBS is an effective treatment of clinically severe obesity in patients who need other specialty surgery, such as joint arthroplasty, abdominal wall hernia repair, or organ transplantation.[103]

In a 2024 position statement on concurrent hernia repair with bariatric surgery, the ASMBS indicates the decision and manner in which to repair a paraesophageal hernia concurrently with a bariatric procedure should be considered based on patient symptoms, anatomic factors including body mass index, size of the hernia, and the procedure being performed. [104] There are a few retrospective studies demonstrating that paraesophageal and bariatric procedures can be done safely, with similar rates of complications when performed concurrently. They do not address other hernia types in this position statement.

TWO-STAGE BARIATRIC SURGERY PROCEDURES

Bariatric surgeries that are performed in two stages have been proposed as a treatment option, particularly for patients with “super-obesity” defined as a BMI greater than 50. The rationale for a two-stage procedure is that the risk of an extensive surgery is prohibitive in patients with extreme levels of obesity. Therefore, an initial procedure with low risk, usually a sleeve gastrectomy, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a biliopancreatic diversion (BD), is performed.

RANDOMIZED CONTROLLED TRIALS

Coffin (2017) published results on the use of intragastric balloon (IGB) prior to a laparoscopic gastric bypass in patients with super-obesity.[62] Patients with BMI greater than 45 kg/m^2 were randomized to an IGB (n=55) or standard medical care (n=60) during the 6 months prior to a planned laparoscopic gastric bypass procedure. Five patients had the IGB removed earlier than 6 months due to complications (n=3) or patient request (n=2). Patients receiving IGBs during the first 6 months of the study experienced significantly more BMI reduction (2.8 kg/m^2; range 1.7-6.2 kg/m^2) than patients receiving standard care (0.4 kg/m^2; range 0.3-2.2 kg/m^2). Weight loss during months 6 through 12, after the laparoscopic gastric bypass procedure, was greater in the patients who received standard of care before the procedure. Duration of hospitalization after laparoscopic gastric bypass and quality of life did not differ between groups.

NONRANDOMIZED STUDIES

Case series on two-stage procedures for patients undergoing sleeve gastrectomy (SG) as the initial procedure generally did not report on the second-stage operation, and in those that did, only a minority of patients undergoing the first stage actually proceeded to the second-stage surgery. For example, Cottam[105] reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first portion of a planned two-stage procedure. A total of 36 patients (29%) proceeded to the second-stage procedure, which was laparoscopic gastric bypass. In a similar study, Alexandrou.[106] reported on 41 patients who underwent SG as the first stage of a planned 2-stage procedure. After 1-year follow-up, 12 patients (29%) achieved a BMI less than 35 and were not eligible for the second-stage procedure. Of the remaining 28 patients, 10 (24% of total) underwent the second-stage procedure. The remaining 18 patients (44% of total) were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo two-stage procedures are at risk for complications from both procedures. Silecchia.[107] described the complication rates in 87 patients undergoing a stage I SG followed by a BPD in 27 patients. For the first stage of the operation, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, major complications occurred in 29.6% including bleeding, duodenoileal stenosis, and rhabdomyolysis.

SECTION SUMMARY

The current evidence does not indicate that a two-stage bariatric surgery procedure improves outcomes for patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. A majority of patients who received SG as the initial procedure lost sufficient weight during the first year such that a second procedure was no longer indicated. In addition, patients undergoing a two-stage procedure are at risk for complications from both procedures; therefore, it is possible that overall complications are increased by this approach.

ENDOSCOPIC (ENDOLUMINAL) BARIATRIC PROCEDURES

SYSTEMATIC REVIEWS

Several systematic reviews of RCTs evaluating intragastric balloon (IGB) devices for the treatment of obesity have been published; none was limited to FDA-approved devices.[108-110]

Chen (2024) published a comprehensive systematic review aimed to evaluate the efficacy and safety of duodenal-jejunal bypass liner (DJBL) for obesity and type 2 diabetes mellitus.Thirty studies involving 1751 patients were included.[111] They reported that at 12 months post-implantation, DJBL resulted in a significant reduction in body mass index (BMI) of 4.8 kg/m2 (95% CI 4.1, 5.5), with an excess weight loss of 41.3% (95% CI 33.4%, 49.2%) and a total weight loss of 13.1% (95% CI 10.1%, 16.0%). Additionally, DJBL significantly decreased HbA1c and fasting glucose levels, with a standardized mean difference of -0.72 (95% CI -0.95, -0.48) and -0.62 (95% CI -0.82, -0.42), respectively. While these improvements were partially sustained after explantation, DJBL also significantly improved blood pressure and lipid levels while in situ. The review noted a pooled early removal rate of 19% and an incidence of severe adverse events of 17%, including device migration, gastrointestinal hemorrhage, device obstruction, and hepatic abscess. Further studies are needed to understand the long-term efficacy and safety.

Weitzner (2023) published a SR comparing the efficacy of endoscopic bariatric procedures as compared to other existing treatments.[112] Thirty-seven studies (15,639 patients) were included. Intragastric balloons achieved greater %TBWL with a range of 7.6-14.1% compared to 3.3-6.7% with lifestyle modification at 6 months, and 7.5-14.0% compared to 3.1-7.9%, respectively, at 12 months. When endoscopic sleeve gastroplasty (ESG) was compared to laparoscopic sleeve gastrectomy (LSG), ESG had less %TBWL at 4.7-14.4% compared to 18.8-26.5% after LSG at 6 months, and 4.5-18.6% as compared to 28.4-29.3%, respectively, at 12 months. For the AspireAssist, there was greater %TBWL with aspiration therapy compared to lifestyle modification at 12 months, 12.1-18.3% TBWL versus 3.5-5.9% TBWL, respectively. All endoscopic interventions had higher adverse events rates compared to lifestyle modification. The authors conclude that endoscopic therapies result in greater weight loss compared to lifestyle modification, but not as much as bariatric surgery.

Loo (2022) published a systematic review evaluating the utility of intragastric balloon as a bridge therapy to bariatric surgery in patients with severe obesity.[113] A total of 13 studies were included and the IGB resulted in a BMI reduction of 6.60 kg/m2 and post-operative complication rate of 8.13%. There was no evaluation of the risk reduction for subsequent bariatric surgeries or an assessment of long-term weight loss outcomes after the use of the bridge therapy. Additional follow-up and long-term studies are needed to assess the utility of IGB as a bridge therapy to bariatric surgeries.

Kotinda (2020) published a systematic review and meta-analysis that evaluated the efficacy of IGB devices in comparison to sham or lifestyle interventions in overweight and obese adults.[114] Thirteen RCTs with 1,523 patients were included. Results revealed that the mean percent EWL difference between the IGB and control groups was 17.98% (95% CI, 8.37 to 27.58; p<0.001), significantly favoring IGB. IGB was also significantly favored when evaluating the mean percent TWL difference between the groups: 4.40% (95% CI, 1.37 to 7.43; p<0.001). Similarly, the difference in actual weight loss and BMI loss was 6.12 kg and 2.13 kg/m2, respectively. Overall, IGB was found to be more effective than lifestyle intervention alone for weight loss. The majority of included RCTs used one fluid-filled IGB and there was significant heterogeneity between the included studies.

The systematic review by Tate (2017) focused on recent RCTs, published between 2006 and 2016.[115] Additional inclusion criteria were: sham, lifestyle modification, or pharmacologic agent as a comparator; at least 1 outcome of body weight change; and study duration of 3 or more months. Eight RCTs were included in the review, with four contributing to the meta-analysis. The meta-analysis included 777 patients and showed a significant improvement in percent TBWL with IGB compared with control (5.5%; 95% CI, 4.3% to 6.8%). However, there was significant heterogeneity among the trials (I^2=62%), so interpretation of results is limited. The percent TBWL with IGB is lower than expected with RYGB (reported 27%) or with the most efficacious pharmacologic agent (reported 9%).

Saber (2017) identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention.[110] IGB was compared with sham in 15 trials, behavioral modification in 4 trials, and pharmacotherapy in 1 trial. In 17 trials, patients received lifestyle therapy in addition to other interventions. Studies were published between 1987 and 2015 and sample sizes varied from 21 to 326 participants. Outcomes were reported between 3 and 6 months. In a meta-analysis of 7 RCTs reporting BMI loss as an outcome, there was a significantly greater BMI loss in the IGB group than in the control group (mean effect size [ES], 1.59 kg/m^2; 95% CI, -0.84 to 4.03 kg/m^2; p<0.001). Findings on other outcomes were similar. A meta-analysis of 4 studies reporting percent EWL favored the IGB group (ES=14.25%; 95% CI, 2.09% to 26.4%; p=0.02). Also, a meta-analysis of 6 studies reporting absolute weight loss favored the IGB group (ES=4.6 kg; 95% CI, 1.6 to 7.6 kg; p=0.003).

Although the review was not limited to FDA-approved devices, older devices were air-filled and newer devices, including the two approved by FDA in 2015, are fluid-filled. Sufficient data were available to conduct a sensitivity analysis of 3-month efficacy data. A meta-analysis of 4 studies did not find a significant difference in weight loss with air-filled IGB devices or a control intervention at 3 months (ES= 0.26; 95% CI, -0.12 to 0.64; p=0.19). In contrast, a meta-analysis of 8 studies of fluid-filled devices found significantly better outcomes with the IGB than with control (ES=0.25; 95% CI, 0.05 to 045; p=0.02).

In 2017, Vargas performed a systematic review of two observational studies with no comparator group combined with results from a multi-center study of 130 consecutive patients.[116] Between the three studies, 330 endoscopic transoral outlet reduction (TORe) cases were performed with the Apollo OverStitch system. TORe was performed in patients experiencing weight regain following RYGB. Study quality was evaluated using the Newcastle-Ottawa Quality Assessment Scale for cohort studies; all were rated to be of moderate overall quality. Using a random effects model, the pooled absolute weight loss at 6, 12, and 18–24 months was 9.5 kg (95% CI 7.9–11.1), 8.4 kg (95% CI 6.5–10.3), 8.4 kg (95% CI 5.9–10.9), respectively. Given the fluctuation of absolute weight loss reported between timelines by each of the three studies, longer term follow-up would aid in evaluating the overall efficacy of TORe.

A systematic review of the effect of EndoBarrier® on weight loss and diabetic outcomes was published in 2015.[117] There were five small RCTs included with a total of 235 individuals (range, 18-77) and follow-up ranging from 12 to 24 weeks. The comparators were diet and/or other lifestyle modifications, and 2 studies had sham controls. All studies were judged to be at high risk of bias using the Cochrane risk of bias tool. Combined results demonstrated that the EndoBarrier® group had 12.6% greater EWL (95% CI, 9.0 to 16.2) compared to medical therapy. For diabetic outcomes, there were trends toward greater improvement in the EndoBarrier® group that did not reach statistical significance. The mean difference in HgA1c was -0.8% (95% CI, -1.8 to 0.3) and the relative risk of reducing or discontinuing diabetic medications was 3.28 (95% CI, 0.54 to 10.73).

RANDOMIZED CONTROLLED TRIALS

In June 2016 the AspireAssist (Aspire Bariatrics, King of Prussia, PA) weight loss therapy system was approved by the FDA to assist in weight reduction in adults aged 22 and older with a BMI of 35.0-55.0 kg/m^2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. Feasibility data for the AspireAssist was reported by Sullivan and colleagues in 2013.[118] Preliminary results from the ongoing PATHWAY Pivotal Trial (sponsored by Aspire Bariatrics) are included in the FDA Summary of Safety and Effectiveness Data, though results have not been published in peer-reviewed literature at this point in time.[119]

In 2014, Eid reported results from a single-center RCT of the StomaphX device compared with a sham procedure for revision procedures in patients with prior weight loss after Roux-en-Y gastric bypass at least two years earlier.[120] Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group after preliminary analysis failed to achieve the primary efficacy endpoint in at least 50% of StomaphyX patients. The primary efficacy end point (reduction in pre-Roux-en-Y gastric bypass excess weight by 15% or more, excess BMI loss, and BMI less than 35, at 12 months post-procedure) was achieved by 10/45 (22.2%) of the StomaphyX group and 1/29 (3.4%) of the sham control group (P<0.01). Conclusions regarding the use of the StomaphX device as a primary procedure for the treatment of obesity may not be drawn due to the discontinuation of the trial and the limited use of the device as a revision procedure in patients who had failed a prior bariatric surgery.

In 2014, Koehestanie published results from an RCT of duodenal-jejunal bypass liner (DJBL) treatment in comparison with dietary intervention for obesity and type 2 diabetes mellitus (T2DM).[121] A total of 77 patients were included in the trial with 38 patients randomized to 6 months DJBL in combination with dietary intervention and 39 patients were randomized to dietary interventions only. The total study duration for both groups was 12 months, including 6 months of post-DJBL removal follow-up. At 6 months follow-up, prior to DJBL removal, the DJBL group lost a higher percentage of excess weight compared to the dietary only group, 32% (22%-46.7%) vs. 16.4% (4.1%-34.6%) respectively. However, better HbAIc levels improvement was observed in the dietary only group compared to the DJBL at both 6 and 12 month follow-ups. Conclusions are limited in this study as both groups underwent dietary interventions limiting the isolation of the effects of DJBL upon obesity and type 2 diabetes.

In 2013, Sullivan reported results from a small feasibility pilot RCT (n=18) comparing the AspireAssist siphon assembly (Aspire Bariatrics, King of Prussia, PA) combined with lifestyle therapy (AT) versus lifestyle therapy (LT) alone.[118] Only fourteen subjects completed the 12-month trial (10 in the AT group and four in the LT group). Although weight loss in the AT group was greater at 52 weeks than the LT group (18.6% ± 2.3% of body weight vs 5.9% ± 5.0%) the study was limited by the very small sample size, and unblinded design. The study was partially funded by the manufacturer. The authors all disclosed having previously performed contracted research for the manufacturer of the device and one author also disclosed having consulted on a pivotal trial for the company.

In 2013, Fuller published a small RCT (n=66) which evaluated intragastric balloons (IGB) compared to behavioral modification as a treatment of obesity.[122] Subjects were either randomized to IGB and 12 months behavior modification (BH) and or 12 months BH alone. At six months the IGB treatment group demonstrated superior weight loss compared to the BH group (-14.2 vs. -4.8; P < 0.0001). However, at 12 months the difference in weight loss between groups, although still statistically significant, diminished (-9.2 vs. -5.2; P = 0.007). There were numerous adverse events related to IGB placement which typically resolved in two weeks. Limitations of this study include a relatively small population size and short-term follow-up with which to evaluate the lasting effects of weight reduction with IGB. In addition, RCTs which evaluate IGB to other standard surgical treatments of obesity are needed.

Additional, small RCTs assessing IGB were identified[123-125]; however, large, long-term data remain lacking with which to evaluate the safety and sustained benefit of IGB in weight reduction compared to conservative measures and accepted bariatric procedures.

NONRANDOMIZED STUDIES

A small number of non-randomized studies, primarily case series, describe experiences of patients undergoing different endoluminal procedures, such as endoscopic gastroplasty and endoscopically placed sleeves, gastric balloons or tissue anchors.[116, 126-143] As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

CLINICAL PRACTICE GUIDELINES

The American Society for Gastrointestinal Endoscopy along with the European Society of Gastrointestinal Endoscopy (ASGE-ESGE) published a guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity (2024). [144] They include the following:

- In adults with overweight or obesity, the ASGE–ESGE suggests the use of endoscopic bariatric and metabolic therapies (EBMT) plus Lifestyle modification (LM) over LM alone for patients with a body mass index (BMI) of ≥30 kg/m^2 or BMI of 27.0 to 29.9 kg/m^2 with at least 1 obesity-related comorbidity. *(Conditional recommendation, very low certainty).*

Note: this guideline includes an extensive conflict of interest list.

SECTION SUMMARY

The evidence regarding endoscopic (endoluminal) bariatric procedures, including IGB, compared to standard RYGBP or SG is limited. Large, long-term data remain lacking with which to evaluate the safety and sustained benefit of endoscopic (endoluminal) bariatric procedures, including IGB, in weight reduction compared to conservative measures and accepted bariatric procedures.

LAPAROSCOPIC GASTRIC PLICATION

Similar to the data for endoscopic bariatric procedures, the data for laparoscopic gastric plication (also known as laparoscopic gastric imbrication) is limited to case series and case reports and few, small RCT's.

RANDOMIZED CONTROLLED TRIALS

Sullivan (2017) published results from the ESSENTIAL trial, a randomized sham-controlled trial evaluating the efficacy and safety of endoscopic gastric plication.[145] Patients (N=332) were randomized 2:1 to the active or sham procedure. All patients were provided low-intensity lifestyle therapy. The primary end point was total body weight loss (TBWL) at 12-month follow-up. The mean difference in TBWL for patients receiving the procedure compared with patients receiving the sham procedure was 3.6% (95% CI, 2.1% to 5.1%). Significant differences between the active and sham groups were also reported in a change in weight from baseline, percent excess weight loss, BMI, and improvement in diabetes. No significant differences were detected in improvements in hyperlipidemia or hypertension between the treatment groups.

Talebpour (2017) randomized patients to laparoscopic gastric plication (n=35) or laparoscopic SG (n=35).[146] Patients were followed for 2 years. Both procedures were equally effective based on weight reduction outcomes. Adverse events (eg, nausea, hair loss, vitamin D deficiency, iron deficiency) were similar between groups. One death due to pulmonary thromboembolism occurred in the gastric plication group.

NONRANDOMIZED STUDIES

Additional studies describe patient outcomes after different laparoscopic plication procedures.[147-151] As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

REVISION BARIATRIC SURGICAL PROCEDURES

There are a number of reasons why patients who are treated with accepted forms of bariatric surgery may not lose weight or may regain weight that is initially lost. These reasons include issues of adherence (compliance), as well as technical (structural) issues. A number of studies[152-156] have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of co-morbidities with somewhat higher complication rates than for primary surgery. However, criteria for classifying what constitutes a failed, primary bariatric procedure, has not been clearly established.[157]

Thomopoulos (2024) published a SR that included seven studies (one comparative study between RYGB and SADI, three including only SADI and three only RYGB) aiming to compare the long-term (5-year) safety and efficacy of Roux-en-Y gastric bypass (RYGB) and single anastomosis duodeno-ileal bypass (SADI) as revisional bariatric surgeries (RBS) after 'failed' sleeve gastrectomy (SG).[158] Indications for RBS included insufficient weight loss (EWL < 50% or residual BMI ≥ 35 kg/m2) for all included studies, but also intractable GERD and dysphagia, the latter especially when RYGB was chosen as a revisional procedure. The results showed that SADI had comparable outcomes to RYGB in terms of weight loss, nutritional deficiencies, and resolution of comorbidities. However, RYGB proved superior in terms of remission of reflux disease and resolution of other functional problems after SG. Overall, the study found that SADI is a promising method for suboptimal weight loss after SG, with comparable or even better results to RYGB after 5-year follow-up. Limitations include lack of RCTs and direct comparison studies, small sample sizes, heterogeneity of methods, lack of a standard definition of “failed” SG, differences in the initial BMI and limited long term follow-up.

Sargsyan (2024) published a SR to determine the safety and efficacy of converting one-anastomosis gastric bypass (OAGB) to Roux-en-Y gastric bypass (RYGB).[159] A total of six studies were included (all studies were retrospective analyses of prospectively kept databases) with 134 patients who underwent OAGB-RYGB conversion. The most common indications for conversion were reflux (47.8%), malnutrition (31.3%), and inadequate weight loss (8.2%). A total of 52.7% of cases had resolution of malnutrition symptoms (95% CI 0.148–0.907%, I2=100%) and 9.4% (95% CI 6.4–12.5, p<0.005) experienced post operation complications. Conversion to RYGB led to 100% resolution of bile reflux symptoms. There was a medium-term weight regain after conversion with a weighted mean BMI difference 0.61 (95% CI −3.81 to 2.59 p < 0.005) with high study heterogeneity (I2 = 89.4%).

Vitiello (2023) published a SR with meta-analysis comparing weight loss and gastroesophageal reflux disease (GERD) remission after one-anastomosis gastric bypass (OAGB) versus Roux-en-Y gastric bypass (RYGB) as revisional procedures after laparoscopic sleeve gastrectomy (LSG).[160] Six retrospective comparative articles were included. Weight loss analysis showed a mean difference = 5.70 (95% CI 4.84-6.57) in favor of the OAGB procedure (p = 0.00001) with no significant heterogeneity (I2 = 0.00%). There was no significant risk difference (RD) for leak, bleeding, or marginal ulcer after the two revisional procedures. After conversion to OAGB, remission from GERD was 68.6% (81/118), and it was 80.6% (150/186) after conversion to RYGB with a RD = 0.10 (95% CI -0.04, 0.24; p = 0.19), with high heterogeneity (I2 = 96%). De novo GERD was 6.3% (16/255) after conversional

OAGB, and it was 0.5% (1/180) after conversion to RYGB with a RD = -0.23 (95% CI -0.57, 0.11; p = 0.16), with high heterogeneity (I2 = 92%).

Franken (2023) published a SR with meta-analysis evaluating revisional techniques for addressing weight regain and insufficient weight loss after Roux-en-Y gastric bypass through a systematic review and meta-analysis.[161] Thirty-nine studies were included: four studies reported on argon plasma coagulation, four studies on transoral outlet reduction, nine studies on transoral outlet reduction + argon plasma coagulation, four studies on pouch/gastrojejunal anastomosis revision, five on laparoscopic gastric banding, two studies on laparoscopic gastric banding + pouch resizing, 10 on distalization-RYGB, and one on duodenal switch. All techniques resulted in short-term clinically relevant weight loss. Endoscopic procedures had a short follow-up and resulted in modest and temporary weight loss. Surgical revision techniques were successful for weight loss in longer term follow-up, at the expense of high complication rates.

Kermansaravi (2021) published a systematic review of 1,771 patients from 26 studies evaluating the efficacy of one anastomosis/mini gastric bypass (OAGB-MGB) as a revisional procedure.[162] Mean initial BMI was 45.7 which decreased to 30.5 at five year follow up with remission of type 2 diabetes reaching 78.1%. Leakage was the most common complication in the included patients and 7.4% of patients developed de novo GERD following OABG-MGB. Although the authors concluded that OAGB-MGB is a safe and effective choice for revisional bariatric surgery, RCTs on this topic are needed as currently only retrospective cohort studies with heterogenous data are available.

Parmar (2020) published a systematic review of 1,075 patients (n=17 studies) who underwent one anastomosis/mini gastric bypass as a revisional bariatric procedure after failure of a primary LAGB and SG.[163] No RCTs were available on this topic and no meta-analyses were performed as part of this systematic review. The most commonly reported reason for revisional surgery was poor response (81%) followed by gastric band failure (35.9%), GERD (13.9%), intolerance (12.8%), staple line disruption (16.5%), pouch dilatation (17.9%), and stomal stenosis (10.3%). Results revealed that after the revisional OAGB-MGB, the mean percent EWL was 50.8% at 6 months, 65.2% at one year, 68.5% at two years, and 71.6% at five years. Resolution of comorbidities after OAGB-MGB was significant with 80.5% of patients with T2D, 63.7% of patients with hypertension, and 79.4% of patients with GERD reporting resolution. The overall readmission rate following OAGB-MGB was 4.73%, the mortality rate was 0.3%, and the leak rate was 1.54%. Although the authors concluded that OAGB-MGB is a safe and effective choice for revisional bariatric surgery, RCTs on this topic are needed as currently only retrospective cohort studies with heterogenous data are available.

In 2016, Dang reported results from a systematic review and meta-analysis comparing revisional single-step versus two-step bariatric surgery from laparoscopic adjustable gastric banding (LAGB) to Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG).[164] Single-step procedures involved revisional surgery wherein the LAGB was removed and replaced by RYGB or SG in the same operation; two-step procedures allowed a delay before the second bariatric procedure was performed. Although the authors found comparable rates of complications, morbidity and mortality between the one- and two-step procedures, the study was not designed to evaluate differences in patient outcomes between the second bariatric procedure (i.e., RYGB vs SG).

NONRANDOMIZED STUDIES

A retrospective analysis of the MBSAQIP data registry was published by Dang (2023) to analyze serious complications and mortality in patients who underwent revision surgery (conversion of SG to RYGB, n = 13,432) or primary RYGB (n = 84,543) in 2020 and 2021.[165] This study included laparoscopic and robotic-assisted Primary RYGB and revisional SG-RYGB procedures. GERD was the most common indication for revision (55.3%), followed by weight regain (24.4%) and inadequate weight loss (12.7%). Revisional RYGB after SG was associated with a higher rate of serious complications than primary RYGB (7.2% vs. 5.0%, P < 0.001). There was no significant difference in 30-day mortality.

In 2018, Almalki published a retrospective analysis of patients diagnosed with failed restrictive procedure who underwent revision bariatric surgery.[53] One hundred sixteen patients between 2001 and 2015 had revision RY gastric bypass (R-RYGB) or revision single-anastomosis (mini-) gastric bypass (R-RSAGB); the primary indications for revisional procedures were weight regain (50.9%), inadequate weight loss (31%), and intolerance (18.1%). Major complications occurred in 12 patients without significant difference between groups. At one year after revision surgery, the R-SAGB group (76.8% EWL) showed better weight loss than R-RYGB (32.9% EWL). In the 37.1% of patients available for follow-up at five years, R-SAGB had significantly lower hemoglobin levels than R-RYGB (8.2 ± 3.2 g/dl vs 12.8 ± 0.5 g/dl). The study was limited by its retrospective nature, relatively short follow-up time, and lack of consideration of data related to patient compliance.

In 2014, Sudan reported safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database.[166] The Bariatric Outcomes Longitudinal Database is a large multi-institutional bariatric surgery-specific database to which data was submitted from June 2007 through March 2012 by 1,029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric surgery. Reoperations were further divided into corrective operations (when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy.) There were a total of 449,473 bariatric operations in the database of which 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3 %) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective operations and 8,750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N=204,705, 49.1 %), adjustable gastric banding (N=153,142, 36.5 %), sleeve gastrectomy (N=42,178, 10 %), and BPD±DS (N=4,260, 1 %), with the rest classified as miscellaneous. Adjustable gastric banding was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to Roux-en-Y gastric bypass). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 vs 1.8±4.9, P<0.001) and for conversions (2.86±4.58 vs 1.8±4.9, P<0.001). The mean % excess weight loss at one year was 43.5 % after primary operation, 39.3 % after conversions, and 35.9 % after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions compared with primary operations (0.31% vs 0.17%, P<0.001), but not for corrections compared with primary operations (0.24% vs0.17%, P=NS). One-year serious adverse event rates were higher for conversions compared with primary operations (3.61% vs 1.87%, P<0.001), but not for corrections compared with primary operations (1.9% vs 1.87%, P=NS). The authors conclude that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

CLINICAL PRACTICE GUIDELINES

As part of the 2014 American Society for Metabolic and Bariatric Surgery (ASMBS) Revision Task Force, Brethauer conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews.[167] The review was primarily descriptive, but the authors made the following conclusions:

> "The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise."

The 2024 Washington State Health Care Authority Health Technology Assessment (HTA) for Metabolic and Bariatric Surgery: New Populations and Procedures include the following evidence from professional guidelines for revisional surgeries[168]:

- The four guidelines included agreed on the following indications for revisional MBS:
  - Weight recurrence or nonresponse (i.e., inadequate weight loss)
  - Treatment of certain MBS-related complications (e.g., leaks, strictures)
  - Insufficient improvement or emergence of serious comorbidities (e.g., T2DM, GERD)
- In the 2024 HTA, they include specific recommendations from individual clinical practice guidelines :
  - Patient response should be evaluated no sooner than 18 to 24 months following the primary bariatric procedure to allow for weight stabilization
  - Primary nonresponse defined as:
    - 1) weight loss less than 10% of total baseline body weight;
    - 2) weight loss insufficient to not qualify for bariatric surgery based on BMI; or 3) inadequate control of baseline comorbidities with medical therapy
  - Secondary nonresponse defined as:
    - 1) ongoing progressive weight gain;
    - 2) weight recurrence sufficient to re-qualify for bariatric surgery based on BMI; 3) weight recurrence and inadequate control of baseline comorbidities with medical therapy
  - Conversion to RYGB may be considered for patients with a primary SG who develop medical treatment-resistant GERD with severe symptoms
  - Conversion to SG or RYGB may be considered in cases of persistent vomiting, regurgitation, and upper-gastrointestinal obstruction due to AGB-related complications (e.g., band slippage)

SECTION SUMMARY:

Systematic reviews, including mostly retrospective studies have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss and reduced comorbidities including GERD. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. A large retrospective analysis found a serious complication rate of 7.2% for conversion from SG to RYGB in 13,432 individuals and no difference in 30-day mortality compared to primary RYGB. GERD was the most common indication for revision. Professional guidelines recommend revisional MBS for indications such as weight recurrence or nonresponse, treatment of MBS-related complications, and insufficient improvement or emergence of serious comorbidities such as type 2 diabetes and GERD. The guidelines also emphasize the increased mortality and perioperative complication risks associated with revisional MBS. They recommend evaluating patient response at least 18-24 months post-primary MBS and considering procedure-specific revisions, such as converting to RYGB for medical treatment-resistant GERD.

REVISION OR REMOVAL OF ADJUSTABLE GASTRIC BAND

Evidence regarding the indications for band removal or revision procedure is primarily limited to small cohort[169] and case series studies; however, reoperation or removal rates are estimated to range from 4.1%- 53%, depending on the time of reported follow-up.[170-173] Several of the largest cohort studies have reported the following complications which resulted in reoperation or band removal:

> Arapis reported the following complications in 87 patients who underwent reoperation:[174] chronic dilatation of the proximal gastric pouch (27 patients - 14.5%), acute dilatation (21 patients - 11.3%), intragastric migration of the prosthesis (6 patients - 3.2%), reflux esophagitis (6 patients - 3.2%), infection of the gastric band (1 patient - 0.5%), and Barrett's esophagus (1 patient - 0.5%).
>
> Perathoner reported on 108 patients who underwent laparoscopic conversion of gastric banding to gastric bypass due to the following complications: band migration, inadequate weight loss, pouch dilation, band leakage, band intolerance, band infection and esophageal dilation.[175]
>
> Other reported complications included: band erosion,[172, 176, 177] gastric obstruction,[13] and gastric slippage.[172, 177]
>
> Avriel reported major respiratory complications and chronic disease development in 30 patients who underwent LAGB.[178] Reported complications included aspiration pneumonia (19 patients) including pulmonary abscess (4 patients) and empyema (2 patients), exacerbation of asthma (3 patients), hemoptysis (1 patient), interstitial lung disease (5 patients) and bronchiectasis (3 patients). However, the impact of LAGB upon the development of these conditions is unclear given that 83% of the patients smoked or had a smoking history (mean pack years 34).

Studies which evaluated band conversion to a second bariatric surgery primarily indicated that bypass was the preferred revision surgery due to better long-term outcomes compared to sleeve gastrectomy.[179-182] In one large retrospective study published in 2014, bypass was compared to sleeve gastrectomy after band removal and conversion.[183] National Surgical Quality Improvement Project data from 2005-2011 were analyzed and included 495 patients who converted from LAGB to bypass and 130 patients who converted to sleeve gastrectomy. Conversion to bypass was not associated with higher morbidity or mortality compared to primary RYGB; however, conversion to sleeve gastrectomy was independently associated with a higher rate of major complications and mortality compared to primary sleeve gastrectomy (OR 8.02, 95 % CI 1.08-59.34, p = 0.04).

SECTION SUMMARY

For surgical revision of bariatric surgery after failed treatment, evidence from nonrandomized studies suggests that revisions are associated with improvements in weight similar to those seen in primary surgery. However, evidence from large long-term studies is required to determine the appropriate clinical indications for band removal or reoperation.

BARIATRIC SURGERY IN PATIENTS WITH DIABETES WITH BMI < 35KG/M²

SYSTEMATIC REVIEWS

Zhou (2023) published a SR comparing the effect of surgical and nonsurgical treatment on patients with a BMI < 35 kg/m2 to reach diabetes remission.[184] Seven studies were included (544 participants) of which five reported number of patients reaching diabetes remission. Bariatric surgery is more effective than non-surgical treatment to reach diabetes remission [OR 25.06, 95%CL 9.58-65.54]. Bariatric surgery was more likely to result in reductions in HbA1c [MD -1.44, 95%CL (-1.84) - (-1.04)] and FPG [MD -2.61, 95%CL (-3.20) - (-2.20)]. Bariatric surgery resulted in reductions in BMI [MD -3.14, 95%CL (-4.41) - (-1.88)], which was more significant in individuals of Asian race. Limitations include time frame for data collection (different years) resulting in criteria difference defining T2DM remission, inconsistent follow-up time and small sample sizes.

In 2015 Muller-Stich published a systematic review comparing surgical versus medical treatment of type II diabetes in patients with a BMI less than 35 kg/m².[185] The analysis included data from five RCTs and six observational studies for a total of 702 patients. The follow-up of included studies ranged from 12-36 months. Authors concluded that surgery was associated with higher diabetes remission rate (OR: 14.1, 95% CI: 6.7–29.9, P < 0.001), higher rate of glycemic control (OR: 8.0, 95% CI: 4.2–15.2, P < 0.001) and lower HbA1c level (MD: −1.4%, 95% CI −1.9% to −0.9%, P < 0.001) compared to medical treatment. However, results are limited by inclusion of studies in which the BMI of some patients was greater than 35 kg/m² and short-term follow-up, limiting conclusion regarding the long-term benefits of bariatric surgery upon glycemic control.

In 2013, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review of bariatric surgery and nonsurgical therapy in adults with metabolic conditions, including diabetes, and a BMI of 30.0-34.9 kg/m².[186] The report evaluated key issues which included the effectiveness of bariatric surgery compared to nonsurgical therapies, short and long-term effects in symptom control and racial and demographic disparities regarding benefits and harms of surgery in patients with metabolic conditions and a BMI of 30.0-34.9 kg/m². Evidence was gathered from global literature searches, reference mining and titles identified from external sources. A total of 24 studies reported bariatric surgery results, with a majority of studies evaluating RYGBP or LAGB procedures in diabetic patients with a BMI of 30-35 kg/m². The AHRQ report concluded that there was moderate strength evidence of efficacy for certain bariatric procedures as a treatment for diabetes in the short term. However, the report noted that the evidence contained many limitations, "(m)ost importantly, very few studies of this target population have long-term follow-up. Only two studies followed patients for more than 2 years; one has a followup rate of only 13.8 percent and the other includes only seven patients. Thus, we have almost no data on long-term efficacy and safety." In addition, the AHRQ report noted the lack of evidence on major clinical outcomes such as all-cause mortality, cardiovascular risks, or peripheral arterial disease. Although short-term studies suggest an improvement in glucose control, the AHRQ report pointed out that, "…the available evidence from the diabetes literature indicates it may be premature to assume that controlling glucose to normal or near normal levels completely mitigates the risk of microvascular and macrovascular events. Thus, claims of a “cure” for diabetes based on glucose control within 1 or 2 years require longer term data before they can be substantiated.”

RANDOMIZED CONTROLLED TRIALS

Since the publication of the AHRQ report, two RCTs have been reported on bariatric surgery compared to medical therapy in diabetic patients with a BMI between 30-40 kg/m².

Ikramuddin performed an unblinded RCT of gastric bypass versus intensive medical therapy on 120 patients with type II diabetes for at least 6 months and an HgbA1C of at least 8.0%.[187] Patients were followed for 12 months with the primary endpoint being a composite of HgA1C less than 7.0%, low-density lipoprotein (LDL) cholesterol less than 100 mg/dl and systolic blood pressure less than 130 mm Hg. A total of 28 patients in the surgery group achieved the primary outcome compared to 11 patients in the medical therapy group (odds ratio [OR]: 4.8, 95% CI: 1.9-11.7). The percent of patients achieving HgbA1C of less than 7.0% was 75% in the surgery group compared to 32% of patients in the medical therapy group (OR: 6.0, 95% CI: 2.6-13.9). There were 22 serious complications in the surgery group, including 4 perioperative complications, compared to 15 serious complications in the medical group. A limitation of this study was that results were not provided separately for patients who were above and below a BMI of 35 kg/m², thus restricting conclusions regarding the benefits of bariatric surgery compared to medical management in diabetic patients with a BMI < 35 kg/m².

In 2014, Prikh published a small (n=57), short-term (6-month follow-up) RCT which compared intensive medical weight management to bariatric surgery in patients with a BMI of 30-35 kg/m² and type 2 diabetes.[188] Significant improvements in primary outcome measures of homeostatic model of insulin resistance and higher diabetes remission rates were observed in the surgical group compared to the MWM group. Additional small RCTs have been identified;[189] however, larger, long-term RCTs are needed to confirm these findings.

In 2015, Mingrone published results of a small (n=60) RCT comparing long-term outcomes of either medical treatment or surgery by Roux-en-Y gastric bypass or biliopancreatic diversion in patients with type II diabetes.[190] A total of 53 patients were included in the 5-year follow-up assessment. Primary outcome measures included the rate of diabetes remission at 2 years which was defined as glycated HbA1c concentration of 6.5% or less (≤47.5 mmol/mol) and a fasting glucose concentration of 5.6 mmol/L or less without active pharmacological treatment for 1 year. At 5-year follow-up 19 (50%) of the 38 surgical patients (7 of 19 [37%] in the gastric bypass group and 12 of 19 in the [63%] bilipancreatic diversion group) maintained diabetes remission at 5 years, compared with none of the 15 medically treated patients (p=0.0007). Fifteen incidents of hyperglycemic relapse occurred in 34 surgical of the patients who achieved 2-year remission, suggesting continued monitoring of glycemic control may be necessary. Authors also reported that both surgical procedures were associated with significantly lower plasma lipids, cardiovascular risk, and medication use and no late complications or deaths.

CLINICAL PRACTICE GUIDELINES

American College of Cardiology, American Heart Association, and the Obesity Society

In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published guidelines on the management of obesity and overweight in adults.[191] The guidelines were based upon a high-quality systematic review of the evidence which included transparent methods for grading the strength of the evidence and subsequent recommendations. The guidelines make the following recommendations related to bariatric surgery:

> "For adults with a BMI >40kg/m2 or BMI >35 kg/m2 with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment (with or without pharmacotherapy) with sufficient weight loss to achieve targeted health outcome goals, advise that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation." (Grade A: Indicating a strong recommendation, indicating there is a high certainty based on the evidence that the net benefit is substantial).

> "For individuals with a BMI <35 kg/m2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures." (No recommendation given, indicating there is insufficient evidence or evidence is unclear or conflicting).

American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery

In 2022 the American Association of Clinical Endocrinology published an updated Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan.[192] They include the following recommendations:

- Persons with a BMI 35 kg/m2 and one or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, NAFLD/NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure.
- Persons with BMI 30 to 34.9 kg/m2 and T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure.

In 2019, an update to the 2013 joint guidelines were published by the American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (AACE/ASM/Obesity Society) regarding the perioperative nutritional, metabolic and nonsurgical support of the bariatric surgery patient.[193, 194] Recommendations regarding which patients should be offered bariatric surgery indicated the following:

- "Patients with a BMI≥40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedures."
- "Patients with a BMI≥35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
- "Patients with the following comorbidities and BMI≥35 kg/m^2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of

operative risk; idiopathic intracranial hypertension; GERD; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."

- “Patients with BMI of 30 to 34.9 kg/m^2 with T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity." or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.”

- "The BMI criterion for bariatric procedures should be adjusted for ethnicity (eg, 18.5 to 22.9 kg/m^2 is normal range, 23 to 24.9 kg/m^2 overweight, and ≥25 kg/m^2 obesity for Asians)." “There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.”

- "Bariatric procedures should be considered to achieve optimal outcomes regarding health and quality of life when the amount of weight loss needed to prevent or treat clinically significant obesity-related complications cannot be obtained using only structured lifestyle change with medical therapy."

American Society for Metabolic & Bariatric Surgery[103]

The American Society for Metabolic and Bariatric Surgery (ASMBS), in combination with International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), updated their guideline on indications for metabolic and bariatric surgery. They recommend the following:

- Metabolic and bariatric surgery (MBS) is recommended for individuals with a BMI greater than or equal to 35 kg/m^2 regardless of presence, absence, or severity of co-morbidities.
- MBS should be considered for individuals with metabolic disease and BMI of 30-34.9 kg/m^2
- BMI thresholds should be adjusted in the Asian population such that a BMI greater than or equal to 25 kg/m^2 suggests clinical obesity and individuals with a BMI greater than or equal to 27.5 kg/m^2 should be offered MBS.

SECTION SUMMARY

Evidence regarding the efficacy of bariatric surgery as a treatment for diabetes in patients with a BMI< 35 kg/m^2 primarily consists of small cases series with short-term follow-up as noted in the AHRQ report. Since the publication of these reports a single RCT was identified which was limited by the inclusion of obese (BMI 35-40 kg/m^2) and non-obese (BMI 30-34.9 kg/m^2) patients, precluding conclusions regarding the clinically non-obese population. Clinical practice guidelines have recommended bariatric surgery in diabetic patients who do not meet the clinical definition of obesity; however, a lack of long-term data was noted. There are clinical concerns about durability and long-term outcomes at 5 to 10 years as well as potential variation in observed outcomes in community practice versus clinical trials. Overall, the current evidence does not demonstrate the safety and efficacy of bariatric surgery as a treatment for diabetes in patients with a BMI< 35 kg/m^2.

ADOLESCENT AND PEDIATRIC BARIATRIC SURGERY

SYSTEMATIC REVIEWS

Wu (2023) published a SR with meta-analysis aimed to evaluate the long-term outcomes of bariatric surgery in adolescents with obesity.[195] They included 29 cohort studies (4970 patients with age ranges from 12- 21 years). Body mass index ranged from 38.9 to 58.5 kg/m2. Females were the predominant gender (60.3%). After at least 5-year of follow-up, the pooled BMI decline was 13.09 kg/m2 (95%CI 11.75-14.43), with sleeve gastrectomy (SG) was 15.27 kg/m2, Roux-en-Y gastric bypass (RYGB) was 12.86 kg/m2, and adjustable gastric banding (AGB) was 7.64 kg/m2. The combined remission rates of type 2 diabetes mellitus (T2DM), dyslipidemia, hypertension (HTN), obstructive sleep apnea (OSA), and asthma were 90.0%, 76.6%, 80.7%, 80.8%, and 92.5%, (95%CI 83.2-95.6, 62.0-88.9, 71.5-88.8, 36.4-100, and 48.5-100), respectively. Postoperative complications were underreported. Combined with the current study, we found a low level of postoperative complications. Iron and vitamin B12 deficiencies were the main nutritional deficiency complications identified so far.The authors conclude that for adolescents with severe obesity, bariatric surgery (especially RYGB and SG) is an effective treatment option. After at least five years of follow-up, bariatric surgery in adolescents showed a desirable reduction in BMI and significant remission of T2DM, dyslipidemia, and HTN. Surgical and nutrition-related complications still need to be further explored by more long-term studies.

Qi (2017) published a SR and meta-analysis on the use of bariatric surgery for the treatment of adolescents with obesity. 49 studies were identified for inclusion and study quality was assessed using the Newcastle-Ottawa Scale. Age of patients ranged from 14 to 20 years. BMI ranged from 34 to 63 kg/m2. Overall results showed significant improvements in BMI as well as glycemic and lipid control with various bariatric surgery techniques. RYGB showed the largest improvements compared with other procedures, with LAGB and sleeve gastrectomy also showing improvements in this population.

The 2007 Washington State Health Technology Assessment evaluated the published, peer reviewed scientific literature describing bariatric surgery in the pediatric population.[196] Data from 17 studies that enrolled a total of 553 pediatric patients were included. Only one study was clearly prospective. Eight studies reported outcomes after LAGB, six after RYGBP, two after VBG, and one after banded bypass. The report concluded that:

- The evidence that LAGB for morbidly obese pediatric patients leads to sustained and clinically significant weight loss compared to non-operative approaches was weak at the longest follow-up after surgery (1.7 to 3.3 years).
- The evidence that RYGBP for morbidly obese pediatric patients leads to sustained and clinically significant weight loss compared to non-operative approaches was weak at the longest follow-up after surgery (1 to 6.3 years).
- The evidence was insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
- The evidence was insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.
- The evidence was insufficient to permit any conclusions about weight loss in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

- The evidence that LAGB for morbidly obese pediatric patients does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches was weak.
- The evidence that RYGBP for morbidly obese pediatric patients does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches was weak.
- The evidence was insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life improvement, or survival after any bariatric surgical procedure for pediatric patients.
- The evidence was insufficient to permit any conclusions about comorbidity resolution in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.
- The LAGB studies reported no in-hospital or postoperative death. However, the most commonly reported complication was band slippage. Reoperations were performed on 7.9% of the LAGB patients to correct various complications (band slippage, intragastric migration, port/tubing problems).
- The RYGBP studies reported one postoperative death. The most frequently reported complication was related to malnutrition and micronutrient deficiency. In addition, potentially life-threatening complications (shock, pulmonary embolism, severe malnutrition, bleeding, gastrointestinal obstructions) were reported.
- The evidence was insufficient to permit any conclusions on potential impacts of bariatric surgery on growth and development of pediatric patients.
- The evidence was insufficient to permit any conclusions on potential harms in specific age groups (18-21, 13-17, 12 or less).

In summary, the assessment found that longer term, prospective collection of data on physical growth, quality of life, weight loss, persistence or resolution of comorbid conditions, and long-term survival are needed in order to fully understand the role of bariatric surgical procedures in treating morbidly obese pediatric patients.

In 2013, Black published a systematic review and meta-analysis of 23 studies (22 nonrandomized) that included 637 young patients (age 6-18 years) who underwent bariatric surgery.[197] Although significant weight loss was reported at the 1-year follow-up, limitations of the evidence were similar to those reported in the Washington State Health Technology Assessment. Included studies were limited by small sample size with a median number of 24 patients per study (range: 10-108) and short-term follow-up (range: 6-12 months). Authors reported that complications were inconsistently reported and indicated that, “long-term, prospectively designed studies, with clear reporting of complications and comorbidity resolution, alongside measures of [health-related quality of life], are needed to firmly establish the harms and benefits of bariatric surgery in children and adolescents.”

In 2015, the Washington State Health Technology Assessment compared various bariatric procedures and also re-examined the role of bariatric surgery in children and adolescents upon obesity related comorbidities.[198] The group concluded that there was, “a lack of both short- and long-term data demonstrating effectiveness for any bariatric surgery procedure in both children and adolescents.” Only two studies were identified which were deemed to be of sufficient quality and only one of those was a RCT. In addition, no comparative studies were identified which evaluated any bariatric procedure exclusively in children (under 13 years).

Additional reviews were identified; however, conclusions were limited due to a lack of long-term follow-up.[199-204]

RANDOMIZED CONTROLLED TRIALS

Roebroek (2024) published a two-group randomized controlled trial investigating the efficacy and safety of bariatric surgery in adolescents with severe obesity who did not achieve sufficient weight loss after multidisciplinary lifestyle intervention (MLI).[205] The study included 59 adolescents aged 14-16 years with severe obesity, who were randomly assigned to either MLI combined with laparoscopic adjustable gastric banding (n = 29) or only MLI (n = 30). A total of 53 patients completed the 12-months follow-up (89.8%). The surgery group showed a mean weight loss of 11.2 ± 7.8%, compared to a weight gain of 1.7 ± 8.1% in the control group. Additionally, the surgery group demonstrated significant improvements in glucose metabolism, insulin resistance, and lipid profile. The study's limitations include a relatively small sample size and a short follow-up period of 12 months.

Jarvholm (2023) published a small randomized, open-label, multicentre trial (The adolescent morbid obesity surgery 2; AMOS2).[206] Adolescents aged 13-16 years with a BMI of at least 35 kg/m2, who had attended treatment for obesity for at least 1 year, passed assessments from a pediatric psychologist and a pediatrician, and had a Tanner pubertal stage of at least three, were randomly assigned (1:1) to MBS or intensive non-surgical treatment. 25 (19 females and six males) were randomly assigned to receive MBS and 25 (18 females and seven males) were assigned to intensive non-surgical treatment. Three participants (6%; one in the MBS group and two in the intensive non-surgical treatment group) did not participate in the 2-year follow-up, and in total 47 (94%) participants were assessed for the primary endpoint. Mean age of participants was 15·8 years (SD 0·9) and mean BMI at baseline was 42·6 kg/m2 (SD 5·2). After two years, BMI change was -12·6 kg/m2 (-35·9 kg; n=24) among adolescents undergoing MBS (Roux-en-Y gastric bypass [n = 23], sleeve gastrectomy [n = 2]) and -0·2 kg/m2 (0·4 kg; [n = 23]) among participants in the intensive non-surgical treatment group (mean difference -12·4 kg/m2 [95% CI -15·5 to -9·3]; p < 0·0001). Five (20%) patients in the intensive non-surgical group crossed over to MBS during the second year. Adverse events (n=4) after MBS were mild but included one cholecystectomy. Regarding safety outcomes, surgical patients had a reduction in bone mineral density, while controls were unchanged after 2 years (z-score change mean difference -0·9 [95% CI -1·2 to -0·6]). There were no differences between the groups in vitamin and mineral levels, gastrointestinal symptoms (except less reflux in the surgical group), or in mental health at the 2-year follow-up.

A small randomized trial compared the outcomes of gastric banding with an optimal lifestyle program in adolescents 14-18 years of age with a BMI >35.[207] Although the study reports that gastric banding resulted in greater percentage achieving a loss of 50% of excess weight, several flaws undermine the reliability of the study findings:

- The small study population (n=50) limits the ability to rule out the role of chance as an explanation of findings.
- The study had significant loss to follow-up suggesting a difference that may affect the outcome.
- Short-term follow-up (2 years) limits comparisons regarding the longer-term complications rates and the effectiveness of the procedure in controlling weight loss and comorbidities.

NONRANDOMIZED STUDIES

Studies with short follow-up time

A small number of nonrandomized comparative studies reported significant weight loss and resolution of some of the comorbidities in pediatric patients undergoing bariatric surgery.[208-210] However, the studies were small and had a very short follow up time. In 2014, Inge reported results from Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study, a prospective, multicenter observational study of bariatric surgery in patients aged 19 or under.[211] The study enrolled 242 participants, with mean age 17.1 and median BMI 50.5 (IQR 45.2-58.2) at the time of operation. All patients had at least 1 obesity-related comorbidity, most commonly dyslipidemia (74%), followed by sleep apnea (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%). Roux-en-Y gastric bypass, adjustable gastric banding, and vertical sleeve gastrectomy were performed in 66.5%, 5.8%, and 27.7%, respectively. Within 30 days of surgery, 20 major complications occurred in 19 patients (7.9%), most of which were perioperative complications. The cohort will be followed to assess longer-term outcomes.

Studies with mid-term follow-up time

Alqahtani (2021) conducted a prospective, noncomparative, cohort study analyzing durability of weight loss and comorbidity resolution, growth velocity, and adverse events associated with LSG in children and adolescents with severe obesity over 10 years.[212] Children and adolescents with class II or III obesity underwent LSG between 2008 and 2021. Overall, 2504 children and adolescents were included, with a mean age ± standard deviation (SD) 15.7 ± 3.7 years (range, 5 to 21 years) at the time of operation. In the 15- to 18-year age group specifically, there were 1517 children enrolled (61%). Mean ± SD baseline BMI was 44.8 ± 12.6 kg/m2, with a BMI z-score of 3.0 ± 0.5, representing 165% above the 95th percentile for age and sex, on average. In the overall cohort in the short- (1 to 3 years, n = 2051), medium- (4 to 6 years, n=1268), and long-term (7 to 10 years, n = 632) follow-up, mean %EWL was 82.3% ± 20.5%, 76.3% ± 29.1%, and 71.1% ± 26.9%, respectively. At baseline, 263 patients (10.5%) were diagnosed with T2D, 227 (9.1%) were diagnosed with dyslipidemia, and 377 (15.1%) had hypertension. At long-term follow-up, complete comorbidity remission was observed in 74% of T2D cases, 59% of dyslipidemia cases, and 64% of hypertension cases. Mean height z-score change at short-, medium-, and long-term follow-up was 0.1 ± 0.5, 0.1 ± 1.2, and 0.0 ± 0.8, respectively, representing no significant change in growth velocity at each follow-up stage (p= 0.95, p= 0.21, and p= 0.40, respectively). There were 27 (1%) reported adverse events within the first 90 days after operation, including 2 patients with a staple line leak, 22 patients with nausea and vomiting, and three patients with signs of metabolic neuropathy, with no procedure-related mortality. None of those patients with adverse events had long-standing sequelae or disability.

Dumont (2018) published a retrospective study of obese adolescents who underwent LAGB. Between 2006 and 2015, 97 consecutive teenagers (average age at surgery 17.2 ± 0.7 years; mean BMI of 44.9 ± 6.1 kg/m^2) who had achieved full growth and sexual maturity and had previously failed a medical nutritional and dietary management program for at least 1 year were enrolled in the study. After a mean follow-up time of 56.0 ± 22.0 months, mean total weight loss was 20.0 ± 16.6% and mean excess weight loss was 46.6 ± 39.5%. Nineteen patients underwent band removal (mean 43.0 ± 28.0 months). No limitations to the study were reported.

Two observational studies with mid-term follow-up times (≤10 and ≤8 years) reported experiences of pediatric patients undergoing LAGB (sample size 41 and 107 respectively).[213, 214] The first study found that weight loss was initially successful and resulted in resolution of some comorbidities, but it slowly increased over the time and ultimately was unsatisfactory in many patients. The second study reported 65.5% excess weight loss at eight years. Both studies reported high complication and reoperation rates (Lanthaler: 46% patients had complications that required reoperation; Mittermaier: 46% patients had complications and 29% required reoperation).

CLINICAL PRACTICE GUIDELINES FOR PEDIATRIC BARIATRIC SURGERY

American College of Physicians

The 2005 American College of Physicians (ACP) evidence-based guideline on use of bariatric surgery in adolescents and children states that the current evidence on surgical treatment of pediatric populations is limited to a few case series which do not permit quantitative analysis.[215] Further, the guideline states that it is unclear whether extrapolation of adult data for bariatric surgery to the pediatric population is appropriate and that RCTs are needed (and feasible) to establish the role of bariatric surgery in this population.

American Academy of Pediatrics

In 2023, the American Academy of Pediatrics (AAP) published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages two to 18 years) with obesity.[206] The recommendations put forth in the guideline are based on evidence from RCTs and comparative effectiveness trials, along with high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is below:

"Pediatricians and other PHCPs [pediatric health care providers] should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers (Grade C Evidence Quality)."

They list indications for adolescent metabolic and bariatric surgery that align with the 2019 indications.

American Heart Association

In 2013, the American Heart Association (AHA) published a statement regarding severe obesity in children and adolescents which concluded:[216]

> “Current treatment approaches using lifestyle modification and medications to reduce BMI and improve chronic disease risk factors are insufficient for most patients and significant residual risk (unacceptably high BMI and risk factor levels) remains. Although experts recommend stepped intensification of interventions, the “step” after behavior-based and pharmaceutical interventions to the next established alternative, bariatric surgery, is unacceptably large because of its limited applicability and availability.”

The AHA indicated that the following evidence was needed before bariatric surgery could be widely recommended in children and adolescents:

> “Generation of additional safety and efficacy data (especially long-term) on bariatric surgery, including studies describing improvements in vascular structure and function, insulin resistance, and β-cell function.”

Society of American Gastrointestinal and Endoscopic Surgeons

The 2008 the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) evidence-based guidelines state:[217]

> "RGB is well tolerated and produces excellent weight loss in patients younger than 18 years with 10-year follow-up… Well-designed prospective studies are just emerging to better define the place for adolescent bariatric surgery."

This statement is based on eight publications of which six are retrospective studies, each with less than 35 participants and most with limited follow-up. Two of the supporting articles are opinion papers.

Endocrine Society

In 2017, the Endocrine Society published an updated clinical practice regarding the assessment, treatment, and prevention of pediatric obesity.[218] The guideline was developed according to the GRADE system. The following statements were given a rating of "we suggest", i.e., weak recommendations, and were based on "very low quality" to "low quality" evidence. Given the evidence quality, and the suggestion as opposed to a *recommendation*, the following statements are ultimately, expert opinion.

For pre-adolescent children, pregnant or breast-feeding adolescents (and those planning on becoming pregnant within two years of surgery), and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has unresolved substance abuse, eating disorder or untreated psychiatric disorder, the Society suggests against bariatric surgery.

The Endocrine Society suggests that bariatric surgery be considered for adolescents only under the following conditions:

- The patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height, the patient has a BMI of >40 kg/m2 or has a BMI of >35 kg/m2 and significant, extreme comorbidities
- extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy
- psychological evaluation confirms the stability and competence of the family unit [psychological distress due to impaired quality of live (QOL) from obesity may be present, but the patient does not have an underlying untreated psychiatric illness]
- the patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits
- there is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.

Institute for Clinical Systems Improvement

In 2013, ICSI published updated guidelines regarding the prevention and management of obesity for children and adolescents.[219] The group noted that, "there is limited information on the long-term efficacy and safety of bariatric surgery in children and adolescents." However, ICSI concluded that bariatric surgery may be considered at centers of excellence when specific criteria where met and should not be considered in preadolescent children.

National Heart, Lung and Blood Institute

In 2011, National Heart, Lung and Blood Institute (NHLBI) published guidelines regarding cardiovascular health and risk reduction in overweight and obese children and adolescents which indicated bariatric surgery may be considered:[220]

> "For adolescents with BMI far above 35 kg/m2 and associated comorbidities, bariatric surgery on a research protocol, in conjunction with a comprehensive lifestyle weight loss program, improved weight loss, BMI, and other outcomes—such as IR, glucose tolerance, and cardiovascular (CV) measures—in a small case series."

This guideline is based on a Grade D recommendation which is defined as, "Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)."

American Society of Bariatric and Metabolic Surgery

In 2022, the ASMBS updated their guideline on indications for metabolic and bariatric surgery.[103] They noted that prospective data demonstrated durable weight loss and maintained co-morbidity remission in patients as young as five years of age. Additionally, the ASMBS stated that metabolic and bariatric surgery do not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery. Other statements supported 2018 recommendations, including that syndromic obesity, developmental delay, autism spectrum, or a history of trauma would not be considered a contraindication to bariatric surgery in children or adolescents.

In 2018, ASBMS published an update to the 2012 guideline.[221] Summary of major changes in the guideline included:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of GERD after vertical sleeve gastrectomy are still not well understood."
- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: (1) BMI cut offs of 35 kg/m^2 or 120% of the 95th percentile with a comorbidity, or (2) BMI >40 kg/m^2 or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI >40 to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI <45 kg/m^2) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from comorbidities."
- "Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes of medical therapies for T2D in children,

these comorbidities may be considered an indication for metabolic/bariatric surgery in younger adolescents or those with lower obesity percentiles."

- "Vitamin B deficiencies, especially B1 appear to be more common in adolescents both preoperatively and postoperatively; they should be screened for and treated. Prophylactic B1 for the first 6 months postoperatively is recommended as is education of patients and primary care providers on the signs and symptoms of common deficiencies."
- "Developmental delay, autism spectrum, or syndromic obesity should not be a contraindication to metabolic/bariatric surgery. Each patient and caregiver team will need to be assessed for the ability to make dietary and lifestyle changes required for surgery. Multidisciplinary teams should agree on the specific needs and abilities of the given patient and caregiver and these should be considered on a case-by-case basis with the assistance of the hospital ethics committee where appropriate."
- "Because metabolic/bariatric surgery results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity disease (BMI >120% of the 95th percentile or BMI of 35). Prior weight loss attempts, Tanner stage, and bone age should not be considered when referring patients to a metabolic/bariatric surgery program."
- "Unstable family environments, eating disorders, mental illness, or prior trauma should not be considered contraindications for metabolic/bariatric surgery in adolescents; however, these should be optimized and treated where possible before and surrounding any surgical intervention for obesity."
- "Routine screening of alcohol use is imperative across all procedures. Conservative clinical care guidelines, which strongly advocate abstinence, while appropriate, must also include information for this age group on harm reduction (i.e., lower consumption levels, how to avoid or manage situations related to alcohol-related harm) to mitigate clinical and safety risks. Risks of nicotine should be discussed and smoking or vaping nicotine should be discouraged."
- "The recognition of obesity as a chronic disease that requires multimodal therapies justifies the treatment of such a disease in a multidisciplinary team that can provide surgical, pharmacologic, behavioral, nutritional, and activity interventions. Pharmacologic therapies as adjuncts to surgical therapies may provide improved outcomes long term in the pediatric population; more studies are needed.

SECTION SUMMARY

There is evidence to suggest bariatric surgery may provide the benefits of weight reduction and improved comorbidities compared to non-surgical treatments in the obese children and adolescents.

GASTROESOPHAGEAL REFLUX DISEASE

This section focuses on evidence related to gastroesophageal reflux disease (GERD) as it relates to bariatric procedures as a treatment for obesity. See Cross References section, above, for policies focused on treatment of GERD.

SYSTEMATIC REVIEWS

Trujillo (2024) published a SR and meta-analysis to assess the incidence of reflux disease following laparoscopic sleeve gastrectomy (LSG) procedures.[222] A literature search was conducted to identify observational studies and clinical trials reporting patients developed GERD disease after LSG. Twenty-two studies included in the analysis, involve 20,495 participants, indicated that the estimated proportion of patients who developed post-surgery GERD was 0.35 (95% CI 0.30-0.41). Subgroup analysis revealed a proportion of 0.33 (95% CI 0.27-0.38) in observational studies and 0.58 (95% CI 0.39-0.75) in clinical trials. High heterogeneity was noted across studies (I2 = 98%). The findings suggest a moderate to high risk of developing GERD following LSG surgery.

Memon (2024) published a systematic review and meta-analysis to compare 5-year gastroesophageal reflux outcomes following Laparoscopic Vertical Sleeve Gastrectomy (LVSG) and Laparoscopic Roux-en-Y gastric bypass (LRYGB) based on high-quality randomized controlled trials (RCTs).[223] The study included four RCTs with a total of 525 participants (LVSG n = 266, LRYGB n = 259). Overall worsened GERD, including the development de novo GERD, occurred more commonly following LVSG compared to LRYGB (OR 5.34, 95% CI 1.67 to 17.05; p = 0.02; I2 = 0%; (Moderate level of certainty); Reoperations

to treat severe GERD (OR 7.22, 95% CI 0.82 to 63.63; p = 0.06; I2 = 0%; High level of certainty) and non-surgical management for worsened GERD (OR 3.42, 95%

CI 1.16 to 10.05; p = 0.04; I2 = 0%; Low level of certainty) was more common in LVSG patients. The authors concluded that LVSG was associated with the development and worsening of GERD symptoms compared to LRYGB at five years postoperatively, leading to either introduction/increased pharmacological requirement or further surgical treatment.

Valentini (2024) published a systematic review and meta-analysis to investigate the effects of sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) on gastroesophageal reflux disease.[224] The study analyzed changes in esophageal acid exposure, motility, and endoscopic findings before and after SG and RYGB, summarizing data from pH tests, manometry, and esophagogastroduodenoscopy (EGD) parameters. The study included 38 studies on SG with 2539 participants and 17 studies on RYGB with 651 participants. The average follow-up times were 30.2 months for SG and 20.1 months for RYGB. The mean ages of the patients were 41.0 years for SG and 39.5 years for RYGB, with mean BMIs ranging from 42.6 to 31.0 kg/m2 after SG and from 44.4 to 31.2 kg/m2 after RYGB. Acid exposure time (AET) and DeMeester score (DMS) significantly increased after SG (mean difference [MD]: 2.1 [95% CI, 0.3-3.9] and 8.6 [95% CI, 2.0-15.2], respectively). After RYGB, both AET and DMS significantly decreased (MD: -4.2 [95% CI, -6.1 to -2.3] and -16.6 [95% CI, -25.4 to -7.8], respectively). Lower esophageal sphincter resting pressure and length significantly decreased after SG (MD: -2.8 [95% CI, -4.6 to -1.1] and -0.1 [95% CI, -0.2 to -0.02], respectively). There were no significant changes in esophageal manometry after RYGB. The relative risks of erosive esophagitis were 2.3 (95% CI, 1.5-3.5) after SG and 0.4 (95% CI, 0.2-0.8) after RYGB. The prevalence rates of Barrett esophagus changed from 0% to 3.6% after SG and from 2.7% to 1.4% after RYGB. Limitations of the studies include a relatively small absolute report of each measured outcome, high heterogeneity in some parameters, and potential confounding factors such as differences in follow-up time, surgical technique, and evaluation methods.

Chiappetta (2022) published a SR with meta-analysis evaluating the indications and results of revisional bariatric surgery (RBS) in gastroesophageal reflux disease (GERD).[225] A total of 48 studies were included (n = 915 patients). RBS for GERD was mostly reported after sleeve gastrectomy (n = 796, 87%) and one anastomosis gastric bypass (n = 62, 6.8%) and was performed due to intractable GERD (71.6%), GERD and weight issues (16%), and biliary reflux (6.2%). Mean follow-up of the studies was 31.5 (3–84) months. Pooled estimation of a meta-analysis of studies reported 7% of GERD following primary surgery needing RBS, in which 99% of the patients experienced remission. Although current literature report seven different surgical treatment options, conversion in RYGB was the most performed RBS in this systematic review (n = 390 of 533 patients, 73.2%). Limitations to the studies include heterogeneity of methods and lack of standardized GERD diagnostic tools.

In 2016, Osland compared the efficacy of Roux-En-Y gastric bypass versus vertical sleeve gastrectomy in randomized controlled trials.[50] Six RCTs performed between 2005 and 2015 were included (N = 695; 347 for SG and 348 for RYGB). The authors summarized recent publications, citing worsened GERD symptoms following sleeve gastrectomy in patients with preoperative symptoms, and new symptoms in 9% of patients with no previous symptoms. Preexisting GERD in those who undergo sleeve gastrectomy is noted as being the cause of frequent revisional surgeries, and high rates of surgical complications. In addition those with preexisting GERD were found to have failure to achieve weight loss, and failure to resolve weight related comorbidities such as diabetes, obstructive sleep apnea, and hypertension.

In 2016, Oor reported results from a systematic review and meta-analysis of studies reporting prevalence of GERD symptoms, the use of anti-reflux medication, and/or outcome of esophageal function tests before and after laparoscopic sleeve gastrectomy (LSG) in patients with a BMI of more than 35.[226] Pooled data from seven studies using validated symptom questionnaires for new-onset of GERD symptoms resulted in a 20% incidence following LSG (follow-up time ranging from one- to 60-months). There was heterogeneity amongst these studies (I^2=68%). For difference in prevalence of GERD before and after LSG, the pooled risk difference was found to be 4.3%; with heterogeneity present (I^2=89%). Of the 24 studies reviewed, the authors found new-onset GERD symptom incidence to range from zero to 34.9%. The authors therefore concluded that LSG could induce serious GERD symptoms in patients with no preoperative GERD complaints. The heterogeneity found in analyses may be due to a lack of a standardized approach to LSG, as well has the variability in follow-up length. The authors also noted that range in prevalence of GERD symptoms may be in part due to the variability in reported preoperative BMI, as the LSG will be a more technically challenging procedure in those with a BMI of 60 kg/m^2 versus those with a BMI of 40 kg/m^2.

Li and colleagues (2016) conducted a systematic review and meta-analysis comparing Roux-en-Y gastric bypass (LRYGB) with LSG for treating morbid obesity.[227] Randomized controlled trials and nonrandomized studies were included. Amongst five studies that reported GERD resolution post-operation (147 in the LRYGB group and 93 in the LSG group), symptoms resolved significantly more after LRYGB as compared to LSG (OR = 8.99, 95% CI 4.77-16.95). Heterogeneity was not detected between these groups (I^2 = 48% P=0.12).

NONRANDOMIZED STUDIES

Several nonrandomized studies have retrospectively reviewed weight reduction and GERD symptoms following Roux-en-Y gastric bypass surgery for treatment of morbid obesity.[228-233] Authors have reported reduction in self-reported GERD symptoms, prescribed medications, and weight loss. As demonstrated in small case series, in combination with takedown of fundoplication, Roux-en-Y gastric bypass for morbid obesity has been effective in weight reduction as well as self-reported GERD symptom improvement.[231, 232] Evidence regarding high incidence of GERD following laparoscopic adjustable gastric banding and laparoscopic sleeve gastrectomy makes Roux-en-Y gastric bypass the ideal procedure in the presence of already existing reflux symptoms.[52, 234-238]

CLINICAL PRACTICE GUIDELINES

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

The SAGES clinical practice guidelines for the surgical treatment of GERD (2010) state the following:[239]

> Due to concerns for higher failure rates after fundoplication in the morbidly obese patient (BMI >35 kg/m2) and the inability of fundoplication to address the underlying problem (obesity) and its associated comorbidities, gastric bypass should be the procedure of choice when treating GERD in this patient group (Grade B). The benefits in patients with BMI > 30 is less clear and needs further study.

SECTION SUMMARY

Severe gastroesophageal reflux (GERD) is one of the most common indications for revision surgery. Several studies report that sleeve gastrectomy is associated with a moderate to high risk of developing or worsening GERD symptoms, with an estimated 20-35% of patients experiencing new-onset or worsened GERD after surgery. In comparing laparoscopic sleeve gastrectomy (LSG) with Roux-en-Y gastric bypass (RYGB) directly, GERD symptoms resolve significantly more post-RYGB as compared to LSG. Conversion to RYGB was the most reported performed revision bariatric surgery to address persistent or denovo GERD after SG. Systematic reviews, including retrospective studies, case series and a few prospective studies have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss and reduced comorbidities including GERD. . In the presence of GERD, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) clinical practice guidelines state that gastric bypass is the procedure of choice in patients who are morbidly obese. In those who are not morbidly obese, evidence does not indicate that bariatric surgery is an appropriate treatment for GERD. They do not address revisional surgeries due to persistent or denovo GERD. Studies included in the systematic reviews have limitations such as low quality study methodology, heterogeneity in the technical approach to the procedure and lack of standardization for diagnosing GERD. Currently, there is not enough evidence to support a primary bariatric surgery for the treatment of GERD. However, there is evidence and guidelines to support that conversion of SG to RYGB in patients with persistent or deNovo intractable GERD improves net health outcomes.

SAFETY OF BARIATRIC SURGERY

GENERAL SURGICAL RISKS

Bariatric procedures are associated with all the potential risks of any major abdominal surgical procedure including but not limited to:

- Bleeding
- Death
- Infection
- Injury to internal organs or gastrointestinal tract

- Thromboembolic complications

PROCEDURE-SPECIFIC SURGICAL RISKS

The following table summarizes the most common procedure-specific risks. However, other adverse events are also possible.

RYGBP[2, 240-242]	LL-RYGBP[2]	BPD/BPD-DS[2, 12, 240]	SG[12, 240, 243-246]	LAGB[69, 240]	MGB[89]	Endoluminal Procedures
• Cholecystitis • Depression • Dilated stomach pouch • Dumping syndrome† • Gastritis • Leaks or obstructions at the anastomotic site • Marginal ulcer • Reoperations††† • Staple line failure • Vitamin/mineral deficiencies (iron, folate, B_{12}) • Kidney stones	• All RYGBP risks • Additional unknown risks associated with the greater bypass of the small intestine and consequent increase in malabsorption††	• Dilated stomach pouch • Gastric obstruction • GERD • Leaks or stenoses at anastomotic sites • Malnutrition and/or vitamin deficiencies • Nausea/vomiting • Wound dehiscence	• Abscesses • Frequent vomiting • Gastric fistulas • GERD • Leaking from the stomach pouch • Reoperations†††	• Band slippage • Dilated stomach pouch • Erosion of the device through gastric wall • GERD • Malnutrition and vitamin deficiencies • Nausea and vomiting	• Bile reflux • Gastrojejunostomy leak • Marginal ulcer • Reoperations††† • Vitamin/mineral deficiency	The safety concerns are specific to the endoluminal procedure performed: Transoral circular stapler (SurgASSIST®):[247] • Bowel obstruction • Intra-abdominal adhesions Dduodenal-jejunal bypass sleeve (DJBS):[129] • Abdominal pain • Implant site inflammation • Nausea and vomiting TOGa system endoscopic stapling:[130] • Nausea • Vomiting • Pain • Transient dysphagia

† Abdominal pain, diarrhea, and/or vomiting shortly after eating due to reduced transit time in the intestine;
††The evidence, especially from the studies with long-term follow-up, is limited and not much is known about the long-term complications of LL-RYGBP;
†††Due to insufficient weight loss or technical issues;

SUMMARY

ROUX-EN-Y GASTRIC BYPASS, BILIOPANCREATIC BYPASS WITH DUODENAL SWITCH, AND SLEEVE GASTRECTOMY

Roux-en-Y gastric bypass is well established in clinical practice as a safe and effective bariatric procedure Sleeve gastrectomy as a stand-alone procedure gained acceptance in clinical practice. Sleeve gastrectomy offers an alternative to adjustable gastric banding with potentially greater weight loss and fewer complications. Therefore, Roux-en-Y gastric bypass, biliopancreatic bypass with duodenal switch, and sleeve gastrectomy may be considered medically necessary in the treatment of class III obesity (BMI ≥ 40 kg/m2) or class II obesity (BMI ≥ 35 kg/m2) when policy Criteria are met.

There is not enough research to show that Roux-en-Y gastric bypass, biliopancreatic bypass with duodenal switch, or sleeve gastrectomy improves health outcomes for any condition other thanclass III obesity (BMI ≥ 40 kg/m2) or class II obesity (BMI ≥ 35 kg/m2) with one comorbidity as defined in the policy Criteria. Therefore, primary bariatric surgery with Roux-en-Y gastric bypass, biliopancreatic bypass with duodenal switch, and sleeve gastrectomy are considered investigational for the treatment of any condition other than class II or III obesity, including, but not limited to gastroesophageal reflux disease.

There is not enough research to show that any other bariatric procedures improves health outcomes. Therefore, the use of distal, partial (not including sleeve gastrectomy) or complete gastrectomy with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction, are considered investigational as a treatment of obesity.

MINI-GASTRIC BYPASS, DISTAL GASTRIC BYPASS, BILIOPANCREATIC BYPASS, AND LAPAROSCOPIC DUODENAL SWITCH WITH SINGLE ANASTOMOSIS

There is not enough research for these procedures on health outcomes. Therefore, mini-gastric bypass, distal gastric bypass, biliopancreatic bypass, and laparoscopic duodenal switch with single anastomosis are considered investigational for the treatment of any condition including obesity orgastroesophageal reflux disease.

HIATAL HERNIA REPAIR

There is not enough research regarding the use of hiatal hernia repair as an independent treatment of obesity. In addition, no evidence-based clinical practice guidelines were identified which addressed the use of hiatal hernia repair as a treatment of obesity. Therefore, hiatal hernia repair is considered investigational as an independent treatment of obesity.

VERTICAL BANDED GASTROPLASTY AND ADJUSTABLE GASTRIC BANDING

Due to higher complications, insufficient weight loss, and high reoperation rates, vertical banded gastroplasty and adjustable gastric banding are no longer considered a standard of care and are therefore considered not medically necessary.

ENDOSCOPIC BARIATRIC PROCEDURES

There is not enough evidence to establish the safety and efficacy of any endoscopic bariatric procedure. Therefore, endoscopic bariatric procedures are considered investigational for all indications.

LAPAROSCOPIC GASTRIC PLICATION

There is not enough evidence to establish the safety and efficacy of any laparoscopic gastric plication bariatric procedure. Therefore, laparoscopic gastric plication procedures are considered investigational for all indications.

REVISION BARIATRIC SURGICAL PROCEDURES

Research regarding reoperation of a primary bariatric surgery is limited to noncomparative studies without long-term outcome data. In addition, current research shows that the complication and mortality rate is slightly higher in cases of reoperation. However, reoperation appears to be beneficial for patients with serious complications related to the primary bariatric surgery and may be considered medically necessary when Criteria are met.

Research regarding the revision or removal of an adjustable gastric band is limited to noncomparative studies with short-term follow-up. These studies suggest band removal or revision is associated with improvement in band related complications. In addition, studies indicate gastric bypass is the preferred secondary procedure in cases of adjustable band conversion as bypass is associated with fewer complications and lower mortality rates compared to sleeve gastrectomy. Therefore, adjustable gastric band removal and/or conversion to gastric bypass may be considered medically necessary when Criteria are met. The research is insufficient to determine the safety or efficacy of all other bariatric surgery reoperations or revisions; therefore, reoperations or revisions are considered not medically necessary when Criteria are not met.

TWO-STAGED BARIATRIC PROCEDURES

There is not enough research to establish the safety and efficacy of any two-stage bariatric procedure. Therefore, two-stage bariatric procedures are considered investigational for all indications.

ADOLESCENT AND PEDIATRIC BARIATRIC SURGERY

There is evidence to suggest bariatric surgery may provide the benefits of weight reduction and improved comorbidities compared to non-surgical treatments in children and adolescents under the age of 18 with obesity. Clinical practice guidelines suggest that bariatric surgery may be beneficial for patients under the age of 18 when they have achieved Tanner pubertal development of 4 or 5 and additional consideration is given to the psychosocial and informed consent issues. Therefore, bariatric procedures in patients younger than 18 years of age may be considered medically necessary when Criteria are met.

BARIATRIC SURGERY IN PATIENTS WITH DIABETES WITH BMI < 35KG/M^2

Research for the safety and effectiveness of bariatric procedures as a treatment for diabetes in patients with a BMI < 35 kg/m^2 is limited by small study sizes and short-term follow-up. High-quality studies that include long-term follow-up are needed in order to evaluate the impact of bariatric surgery on health outcomes in this population. In addition, the majority of evidence-based clinical practice guidelines do not recommend bariatric surgery in patients with diabetes with a BMI < 35 kg/m². Therefore, bariatric procedures in patients with diabetes with a BMI < 35 kg/m² are considered not medically necessary.

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CODES

NOTE: Code 43843 should not be reported if there is a more specific bariatric surgery code within code range listed below.

Codes	Number	Description
CPT	0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon
	43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
	43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
	43631	Gastrectomy, partial, distal; with gastroduodenostomy
	43632	;with gastrojejunostomy
	43633	;with roux-en-Y reconstruction
	43634	;with formation of intestinal pouch
	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	43659	Unlisted laparoscopy procedure, stomach
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (gastric band and subcutaneous port components)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
	43820	Gastrojejunostomy; without vagotomy
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical banded gastroplasty

Codes	Number	Description
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
	43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
	43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
	43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
	43865	;with vagotomy
	43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
	43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
	43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
HCPCS	C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
	C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
	S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Date of Origin: *January 1996*