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Mini-invasive Surgery

Review

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Primary endoscopic interventions in bariatric surgery

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Abstract

The global prevalence of obesity [body mass index (BMI) ≥ 30 kg/m^2] was estimated to affect nearly 890 million adults in 2022, with increasing rates in both adults and children. While comprehensive lifestyle management (diet, exercise, behavioral modification) and pharmacotherapy are central to obesity treatment, metabolic bariatric surgery (MBS), such as sleeve gastrectomy and Roux-en-Y gastric bypass (RYGB), remains the most effective and durable approach for obesity and obesity-related comorbidities, including hypertension, type 2 diabetes, and cardiovascular disease. Despite its effectiveness, MBS is significantly underutilized due to multiple barriers such as the risk of surgery, access limitations, prohibitive social factors, the perceived need for surgery, and fear and beliefs about surgery. Endoscopic bariatric and metabolic therapies (EBMTs) have emerged as an alternative approach to address this gap. While EBMTs are less invasive and have fewer complications than MBS, they are also less effective, though more effective than lifestyle modifications and pharmacotherapy alone. EBMTs, including procedures that involve gastric volume reduction through gastric remodeling or space-occupying devices, malabsorption, or caloric intake reduction, are recommended by the American Society for Gastrointestinal Endoscopy (ASGE) and American Society of Metabolic and Bariatric Surgery (ASMBS) for patients who have not succeeded with lifestyle changes or medications, and as bridge therapies for patients who require weight loss for additional medical treatments. Although EBMTs do not replace bariatric surgery, they complement the existing treatment options, offering patients a less invasive pathway to weight loss and improved metabolic health. Reimbursement models for physicians and the associated financial cost of EBMTs may present inherent complexities. Nevertheless, the prospect of enhanced patient outcomes, substantial reductions in long-term healthcare costs, and expansion of insurance coverage to include these procedures collectively foster optimism for the wider integration of these innovative therapies into clinical practice.

Keywords: Endoscopic bariatric and metabolic therapies, endoscopic sleeve gastroplasty, primary obesity surgery endoluminal, intragastric balloons, incisionless magnetic anastomosis system, magnetic system

INTRODUCTION

The global prevalence of obesity [body mass index (BMI) ≥ 30 kg/m^2 in most countries] was estimated to affect nearly 890 million adults in 2022, with incidence rates continuing to rise in both adults and children[1]. Comprehensive lifestyle management (diet, exercise, behavioral modification) is a cornerstone of obesity management, and pharmacotherapy has gained attention in recent years. However, metabolic bariatric surgery (MBS), such as Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG), has been shown to be the most effective and durable therapy for obesity and obesity-related comorbidities (e.g., hypertension, type-2 diabetes, dyslipidemia, cardiovascular disease, obstructive sleep apnea)[2,3].

Despite a low risk of perioperative and postoperative mortality (0.08%-0.31%), MBS continues to be underutilized. Among individuals with severe obesity (Class III) in the United States, only about 1 in 400 undergo bariatric surgery[4]. Barriers to MBS may include the risk of major (4.3%) and overall adverse outcomes (up to 17.3%)[5,6], limited access to bariatric surgeons, low referral rates, inadequate social support systems, irreversibility of some surgeries, and the cost of surgery/lack of insurance, the perceived need for surgery, as well as fear and beliefs about surgery[7,8]. This creates a treatment gap in the obesity management. Furthermore, there are patients who do not meet the BMI threshold for MBS and for whom lifestyle modifications and pharmacotherapy have not been effective and, therefore, need a different treatment modality.

Endoscopic interventions for bariatric surgery, also referred to as endoscopic bariatric and metabolic therapies (EBMTs), offer an opportunity to fill this treatment gap created by non-interventional and surgical alternatives. As adjunctive therapy, EBMTs have been shown to be more effective than lifestyle modification and medications, but less effective than MBS. They also represent less invasive options with lower incidence of complications, which may benefit patients who are not ideal candidates for MBS based on their comorbidity burden.

The American Society for Gastrointestinal Endoscopy (ASGE) and American Society of Metabolic and Bariatric Surgery (ASMBS) recommend EBMT for patients for whom lifestyle modification alone has not resulted in weight loss or weight maintenance, those who meet the BMI criteria for EBMT (criteria may vary for each therapy), and as bridge therapy for patients with medical conditions that require weight loss in order to receive additional therapy. EBMT can be used in the primary and secondary management of obesity. While most of these interventions involve the stomach, others involve the small intestine.

The mechanisms employed by EBMTs result in restriction (reduction of gastric volume by remodeling/plication or implantation of space-occupying devices), malabsorption (intestinal bypass creation, mucosal resurfacing, slowing of gastric emptying), or caloric intake reduction via aspiration[9,10]. EBMTs are not meant to replace bariatric surgery but rather to complement the spectrum of available treatment options.

We categorize the primary endoscopic interventions discussed herein [Table 1] as:

1. Gastric remodeling/endoscopic suturing devices
2. Space-occupying devices
3. Absorption-limiting interventions
4. Others

Table 1. Overview of EBMT by category: mechanisms, indications, and efficacy

EBMT	Mechanism	Indication	Efficacy (at 12 months, unless otherwise specified)
Gastric remodeling/endoscopic suturing devices			
ESG	Gastric volume reduction via full-thickness endoscopic suturing	BMI ≥ 30 kg/m^2, failed lifestyle/medical therapy, bridge to surgery	%TBWL: 15.6-19.2 %EWL: 47.9-71.0
POSE	Endoscopic gastric plication using suture-anchor devices	Class I-II obesity, failed lifestyle/medical therapy	%TBWL: 7.0-15.7 %EWL: 45.0
TOGA	Stapled pouch creation along the lesser curvature	Morbid obesity, early satiety induction	%TBWL: Not consistently reported %EWL: 44.8
Space-occupying devices			
IGBs • Fluid-filled IGBs: Orbera balloon system, Orbera 365 balloon, ReShape balloon system, the Spatz3 adjustable balloon system • Gas-filled balloons: Obalon balloon system, the Heliosphere® BAG, the Elipse™ balloon	Saline-filled balloons placed endoscopically; Spatz3 is adjustable Gas-filled or air-filled balloons; some are capsule-based and excreted naturally	BMI 30-40 kg/m^2; adolescents/adults; bridge therapy BMI 30-40 kg/m^2, failed lifestyle modifications	%TBWL: 3.1-14.7; %EWL: 25.4-29.0 %TBWL: 7.1-14.2[‡]; %EWL: Not clearly reported
TPS	Intragastric-duodenal device delaying gastric emptying	Class I-II obesity	%TBWL: 9.5% %EWL: Not clearly reported
SatiSphere	Self-expanding duodenal device that slows food transit	Obesity, delayed gastric emptying desired	%TBWL: Not specified %EWL: 18.4[*]
Absorption limiting interventions			
DJBL	60-cm impermeable fluoropolymer sleeve anchored in the duodenal bulb to prevent mixing of chyme with bile and pancreatic secretions	Morbid obesity with comorbidities	%TBWL: 15.0 %EWL: 44.5
GJBS	120-cm impermeable sleeve anchored at the gastroesophageal junction, bypassing the stomach, duodenum, and proximal jejunum	Obesity + diabetes	%TBWL: Not reported %EWL: 35.9
IMAS	Endoscopic placement of self-assembling magnets to create a side-to-side jejunoileal bypass without incisions	Severe obesity +/- T2DM	%TBWL: 14.6 %EWL: 40.2
MS	Duodenoileostomy using self-assembling magnets	T2DM with mild obesity (BMI 24-40)	%TBWL: 28.1[†] %EWL: 66.2[†]
Others			
DMR	Hydrothermal ablation of duodenal mucosa to reset intestinal hormone signaling and improve insulin sensitivity	Experimental, abandoned; occasional use with high-dose multi-injection	%TBWL: ~1.9-3.1 kg (modest)[†] %EWL: Not significant[†]
Aspiration therapy	Percutaneous gastrostomy tube used to aspirate ~30% of ingested food	BMI 35-55 kg/m^2, failed non-surgical therapy	%TBWL: 16.5-17.8 %EWL: 46.2
Intragastric BTA injection	Inhibits acetylcholine, delays gastric emptying, suppresses appetite	Investigational use only; largely abandoned due to limited efficacy	%TBWL: 2.0-4.4 kg (BMI: 1.25 kg/m^2)[§] %EWL: Not significantly different from control in most studies

[*]After 3 months; [‡]after 4 months; [†]after 6 months; [§]weight loss after multiple injections. EBMT: Endoscopic bariatric and metabolic therapy; ESG: endoscopic sleeve gastroplasty; BMI: body mass index; TBWL: total body weight loss; EWL: excess weight loss; POSE: primary obesity surgery endoluminal; TOGA: transoral gastroplasty; IGBs: intragastric balloons; TPS: TransPyloric Shuttle; DJBL: duodenojejunal bypass liner; GJBS: gastroduodenojejunal bypass sleeve; IMAS: incisionless magnetic anastomotic system; T2DM: type 2 diabetes mellitus; MS: magnetic anastomosis system; DMR: duodenal mucosa resurfacing; BTA: botulinum toxin A.

GASTRIC REMODELING/ENDOSCOPIC SUTURING DEVICES

Endoscopic sleeve gastroplasty

Endoscopic sleeve gastroplasty (ESG) was first reported by Abu Dayyeh *et al.* in 2013 and has gained more popularity in recent years[11]. It is performed using an endoscopic suturing device, such as the Overstitch Endoscopic Suturing System (Boston Scientific, Marlborough, MA). The procedure involves incisionless transoral endoscopic full-thickness suturing of the wall of the stomach along its greater curvature, typically beginning at the angular notch and progressing toward the gastric body while keeping the fundus and antrum intact [Figure 1A][12]. The goal of this gastric plication and remodeling is to mimic the effects of a surgical SG by restricting the gastric volume and slowing gastric emptying[13], leading to a prolonged feeling of fullness along with reduced caloric intake. Although the original greater curvature ESG was performed in 2008, the current full-thickness device was first used in 2012 to perform ESG as an innovative, organ-preserving bariatric procedure[14,15]. Since then, it has gained momentum as a less invasive and safer alternative to traditional bariatric surgery. ESG is the most common EBMT today.

Studies have demonstrated significant weight loss and metabolic improvements with mean total body weight loss (%TBWL) of 14.86%-16.9%, 16%-16.43%, and 12.8%-20.01% at 6, 12, and 24 months, respectively. Excess weight loss (%EWL) has been reported to be as high as 49.9%-61.84% within the first year and 39.3%-60.4% at 24 months. %EWL within the first month after ESG has been reported to be an early predictor of success at 24 months. Studies have reported sustained weight loss and metabolic benefits up to five years after ESG, rivaling some surgical bariatric procedures. ESG has also been associated with remission of diabetes (55.4% of patients), hypertension (62.8%), dyslipidemia (56.3%), and OSA (51.7%)[16].

A systematic review and meta-analysis of studies that compared ESG and laparoscopic sleeve gastrectomy (LSG) demonstrated that ESG is significantly less effective than LSG. Pooled %TBWL at 6, 12, and 24 months was 15.2, 19.1, and 16.4, respectively, for ESG compared to 18.8, 28.9, and 22.3 for LSG[16,17]. %EWL for ESG at 6 and 12 months were 66.7 and 71.04, respectively, and 76.6 and 94.9 for LSG. Although ESG had a lower incidence of adverse events than LSG, which was not statistically significant[16], the incidence of gastroesophageal reflux disorder (GERD) was significantly lower after ESG (1.3%) than LSG (17.9%)[16]. Another study (216 patients, average baseline BMI 39 ± 6 kg/m^2) reported 5-year outcomes after ESG at 1-, 3-, and 5-year follow-up[18]. Average EWL was 47.9%, 45.1%, and 45.3%, respectively ($P < 0.001$), whereas average TBWL was 15.6%, 14.9%, and 15.9%, respectively. At 5 years, 74% of patients maintained 25% EWL, whereas 90% and 61% of patients maintained 5% and 10% TBWL, respectively. The rate of moderate adverse events was 1.3%, but there were no severe or fatal adverse events.

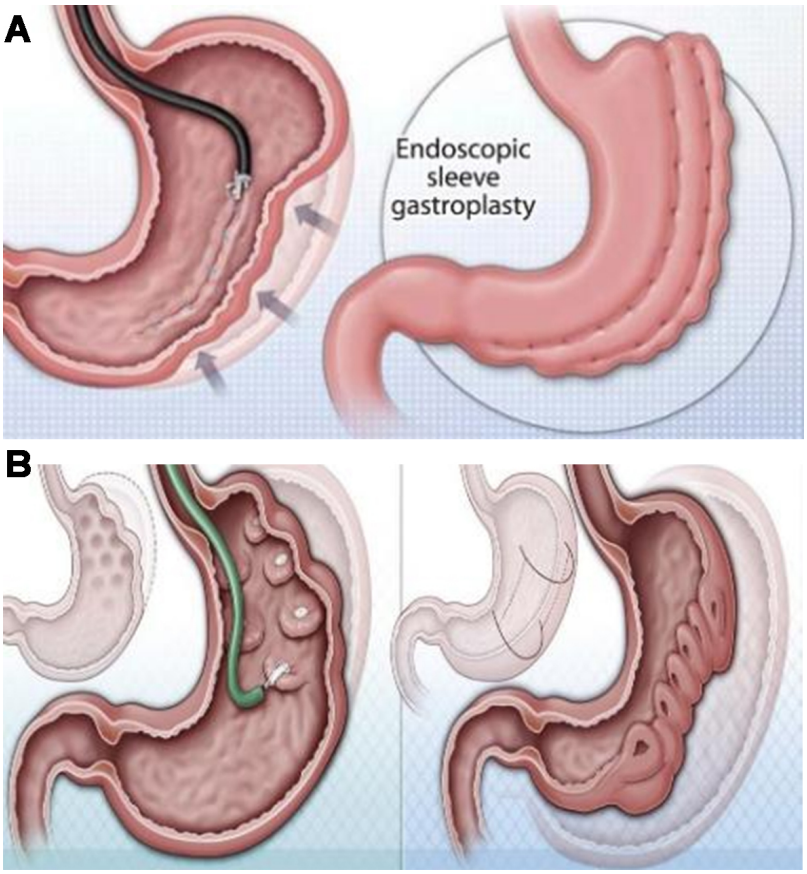

Figure 1. Gastric remodeling/endoscopic suturing devices. (A) ESG[12]; (B) Traditional POSE (left) and modified POSE (POSE 2.0; right)[21]. ESG: Endoscopic sleeve gastroplasty; POSE: primary obesity surgery endoluminal.

ESG is widely considered a safe procedure with a low incidence of serious adverse events (2.26%). Complications such as gastrointestinal (GI) bleeding and perigastric fluid collections are rare (< 1%). A 2019 multicenter collated report of serious adverse events occurring after ESG demonstrated low rates of intraabdominal collection (0.4%), hemorrhage that required endoscopic intervention or transfusion (0.4%), refractory symptoms leading to a reversal of ESG (0.2%), pulmonary embolism (0.1%), pneumothorax and pneumoperitoneum (0.1%)[19]. There was no report of perforation or death in this report. Other rare complications include persistent nausea or vomiting in the short term and the need for revision or reversal due to inadequate weight loss or intolerance. ESG, however, avoids surgical incisions, reducing risks associated with open or laparoscopic bariatric surgery, and is performed on an outpatient or short-stay basis.

Contraindications to ESG include prior gastric, esophageal, or duodenal surgery, active GI disorders such as ulcers or severe gastritis, pregnancy, breastfeeding, active eating disorders, severe psychiatric disorders, or substance abuse.

Studies have reported sustained weight loss (mean TBWL 15.9%)[18] up to five years after ESG. ESG bridges the gap between non-invasive methods (diet, lifestyle, and medications) and surgical treatments, offering a cost-effective, less invasive alternative for weight loss. In 2024, Medicare & Medicaid Services (CMS) established new Healthcare Common Procedure Coding System codes for ESG, which may improve reimbursement for this procedure[20].

Primary obesity surgery endoluminal

Similar to ESG, primary obesity surgery endoluminal (POSE) is an endoscopic gastric plication and suturing procedure with the goal of inducing weight loss by reducing the capacity for caloric intake through gastric remodeling. Performed with the Incisionless Operating Platform™ (USGI Medical, San Clemente, CA, USA) under general anesthesia, full-thickness suture-anchor plications are placed along the fundus and distal body of the stomach to create endoluminal folds, invaginating the fundus and lowering the gastroesophageal junction [Figure 1B][21-26]. The resultant decrease in gastric compliance reduces its capacity for food intake, induces earlier and prolonged satiety, and improves glucose homeostasis[24,27]. Furthermore, it produces delayed gastric emptying and changes in GI neuroendocrine physiology (decreased ghrelin and increased peptide YY).

The MILEPOST multicenter randomized controlled trial (RCT) compared weight loss and satiety outcomes after 12 months of conventional diet and exercise counseling therapy with (treatment group) and without (control group) the POSE procedure in individuals with classes I and II obesity. TBWL at 6 and 12 months were 12.5% and 13.0%, respectively (EWL, 45.5% and 45.0%, respectively) after POSE and 4.7% and 5.3% (14.5% and 18.1%, respectively) with diet and exercise only. At 12 months, individuals who underwent POSE showed significant reduction ($P < 0.001$) in the three satiety parameters evaluated (satiety volume, satiety calories, and time to satiety). The control group, however, only had mild to marginal reductions in satiety volume ($P = 0.041$) and satiety calories ($P = 0.036$) but no reduction in time to satiety[23]. No major intraoperative complications or serious adverse events related to the procedure were reported. Two patients experienced minor postoperative bleeding that resolved within 24 h without sequelae, and some patients reported postprocedural abdominal and throat pain, which resolved prior to discharge home[23]. Another multicenter (ESSENTIAL) trial that evaluated the safety and efficacy of the POSE procedure randomized 332 patients with classes I and II obesity into active and sham groups, and 34 patients to an unblinded lead-in cohort[28]. At 12 months, the TBWL was 7.0% ± 7.4% in the lead-in, 4.95% ± 7.04% in the active, and 1.38% ± 5.58% in the sham cohorts. The responder rates (percent of individuals with ≥ 5% TBWL) were 41.55% in the active group and 22.11% in the sham group ($P < 0.0001$). However, this did not meet the predefined responder rate goal of 50% in the active group. Pain, nausea, and vomiting were the most common adverse events and often presented immediately post-procedure or within 1 week and quickly self-resolved or with supportive therapy (pain medication, antiemetics, and intravenous fluids). Procedure-related serious adverse event rates were 5.0% (active) and 0.9% (sham) ($P = 0.068$). No unanticipated or serious adverse events were reported[28].

A modified POSE procedure (POSE 2.0, Figure 1B[21]) aimed at narrowing and shortening the stomach by decreasing its anteroposterior diameter and decreasing its vertical length was reported by Lopez-Nava *et al.* in 2020[29]. The POSE 2.0 was performed on 73 obese patients, resulting in a TBWL of 15.7% at 6 months. There were no reported adverse events at 6 months. However, further studies that include a control group are needed to assess the efficacy of POSE-2[29]. A recent prospective multicenter study of 44 patients (mean BMI 37 ± 2.1 kg/m^2) with POSE 2.0 showed a mean TBWL of 16.3% ± 6.4% and 15.7% ± 6.8% at 6 and 12 months, respectively[30]. Additionally, 98%, 86%, and 58% of patients achieved a TBWL of > 5%, > 10%, and > 15%, respectively, at 12 months. Extended follow-up of outcomes on 26 patients demonstrated TBWL 14% ± 7.3% and 12.2% ± 9.6% at 18 and 24 months, respectively. At 24 months, 77%, 61.5%, and 27% of patients in this group maintained > 5%, > 10%, and > 15% TBWL, respectively[30]. A retrospective cohort study of 49 patients who underwent POSE 2.0 (mean BMI 34.6 kg/m^2) demonstrated a TBWL of 11.5%, 13.2%, and 14.8% at 3, 6, and 12 months, respectively.

Common postprocedural adverse events included pain (54.2%), nausea and vomiting (36.7%) with no serious adverse events[31]. Contraindications to the POSE procedure are similar to those for ESG[31].

Weight loss outcomes in ESG *vs.* POSE

A 2019 meta-analysis of twenty-two studies including 2,475 patients with a mean baseline BMI of 37.8 ± 4.1 kg/m^2 demonstrated an average 6- (P = 0.02) and 12-month (P = 0.04) EWL of 57.9% ± 3.8% and 44.4% ± 2.1% after ESG, compared to 68.3% ± 3.8% and 44.9% ± 2.1%, respectively, after the POSE[32]. Another meta-analysis of 12 studies showed mean 6- and 12-month EWL of 49.67% and 52.75%, respectively, following ESG, compared to 43.79% and 44.91% EWL, respectively, after POSE. With a mean %EWL difference of 6.17% (P = 0.01) and 7.84% (P = 0.06) in favor of ESG, the authors concluded that ESG was superior to the POSE in terms of weight loss[33]. Given the development of POSE 2.0[29], studies comparing ESG and POSE 2.0 are needed to elucidate long-term outcomes.

Transoral gastroplasty

Transoral gastroplasty (TOGA) involves using two stapling devices to create a small, restrictive gastric pouch along the lesser curvature. This pouch was designed to induce early and prolonged satiety after small meals. An early pilot trial reported EWL of 19.2%, 33.7%, and 46.0% at 1, 3, and 6 months, respectively, with no serious adverse events[34]. A study involving individuals with an average BMI of 42.16 ± 3.80 kg/m^2 demonstrated improved glucose metabolism, with half of the participants experiencing a reversal of diabetes to either normal glucose tolerance (NGT) or impaired glucose tolerance (IGT), as well as a reversion of IGT and impaired fasting glucose (IFG) to NGT after 1 year[35]. One prospective, multicenter RCT (67 patients) showed EWL of 33.9%, 42.6%, and 44.8% at 3, 6, and 12 months, respectively. After 12 months, hemoglobin A1c levels dropped to 5.7% from a baseline of 7.0% (P = 0.01). Triglyceride levels decreased to 98 from 142.9 mg/dL (P < 0.0001), while high-density lipoprotein (HDL) levels rose to 57.5 from 47.0 mg/dL (P < 0.0001). Two complications were reported: respiratory insufficiency and a case of asymptomatic pneumoperitoneum, which were managed conservatively[36]. This device did not meet the FDA trial endpoints and it is not commercially available.

SPACE-OCCUPYING TECHNIQUES/GASTRIC VOLUME REDUCTION

Intragastric balloons

Intragastric balloons (IGBs) are anatomy-preserving, space-occupying devices that are temporarily placed in the stomach [Figure 2][37]. It is thought that by filling a significant portion of the stomach, decreasing its potential capacity and delaying gastric emptying, IGBs also activate GI neurohormonal pathways that induce early satiety and, consequently, reduce food intake[38-42]. They are designed for patients with a BMI of 30-34.9 kg/m^2 who also have one or more obesity-related comorbidity or BMI of 30-40 kg/m^2, for whom medical or lifestyle interventions have not been successful[41]. US FDA-approved IGBs include Orbera, ReShape, Obalon, TransPyloric Shuttle (TPS), and Spatz3, while the Allurion (formerly Elipse) Balloon remains under study. IGBs are often placed endoscopically, but in some cases, they are swallowed as capsules[38-41]. They are most commonly left in place for 6 months (4-12 months, depending on the type) and are either removed endoscopically or spontaneously excreted from the body. Advances in IGB technology have improved safety and efficacy, with modern designs addressing early challenges such as complications (e.g., gastric erosions and ulcers) and limited weight-loss success[38-41,43,44]. While other methods may be favored in adults due to weight recidivism, IGBs may serve as a good alternative to less reversible procedures in adolescents who are more amenable to lifestyle modification[45]. There are several available IGBs worldwide, but fewer have regulatory approval for use. While most systems have one balloon, the Obalon system uses up to three balloons[44]. Most balloons are made of silicone or polyurethane and may be classified as either fluid-filled or gas/air-filled[44].

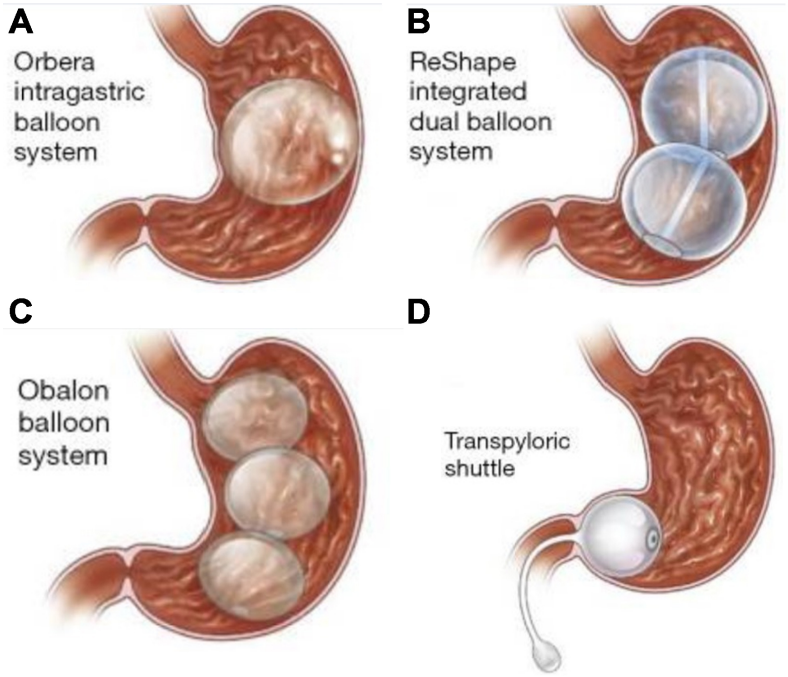

Figure 2. Space-occupying devices[37]. (A) Orbera balloon; (B) ReShape balloon; (C) Obalon balloon; (D) TPS. TPS: TransPyloric Shuttle.

Fluid-filled IGBs

Among the most common fluid-filled IGBs are the ORBERA™ Intragastric Balloon System (Apollo Endosurgery, Inc., Austin, TX, USA), the ReShape® Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA, USA), and the Spatz3™ balloon (Spatz Medical, Fort Lauderdale, FL, USA).

Orbera balloon system

The Orbera system consists of a single silicone elastomer balloon that is implanted endoscopically [Figure 2A][37,46]. It is inflated into a spherical shape by filling it with saline (400-700 cc). However, the volume is not adjustable once it has been filled. A self-sealing valve allows the balloon to detach from the external catheter used during placement.

A multicenter, prospective, randomized, non-blinded comparative trial (IB-005) demonstrated that 6, 9, and 12 months after Orbera balloon placement, EWL were 38.4%, 34.6%, and 29.0%, respectively, and TBWL were 3.3%, 3.4%, and 3.1%, respectively. Some weight recidivism was noted by month 12 (6 months after device removal) as the responder rates at 5%, 7%, and 10% TBWL decreased from 99%, 87%, and 58% to 75%, 54%, and 40%, respectively. However, throughout the study, the treatment group maintained a higher %TBWL than the control group[46]. The Orbera has been shown to meet the ASGE Performance Goals for Interventional Weight Loss (PIVI) threshold[47]. A meta-analysis of 17 studies involving 1,683 patients found that the Orbera IGB achieved an EWL of 25.44% at 12 months. In three RCTs, the mean difference in EWL over controls was 26.9% ($P \leq 0.01$). Additionally, the pooled TBWL after Orbera implantation was 12.3% at 3 months, 13.16% at 6 months, and 11.27% at 12 months, all exceeding the 5% TBWL ASGE PIVI threshold for bridge obesity therapies. In comparison, the duodenojejunal bypass sleeve (DJBS) met the ASGE PIVI EWL threshold at 12 months with a 35% EWL but failed to meet the requirement of 15% EWL above controls[47].

Orbera 365 balloon

A more recently available type of the Orbera balloon system, Orbera 365 (Boston Scientific, Marlborough, MA), is designed to remain *in situ* for 12 months[48]. One study showed no significant difference in %TBWL in patients who underwent IGB placement for 6 months with Orbera or 12 months with Orbera 365 (15.3% *vs.* 14.7%, $P = 0.7$)[48].

ReShape balloon system

The ReShape system features two balloons that are filled with saline (450 mL) and methylene blue dye (450 mL) connected by a central tube with an implant duration of 6 months [Figure 2B][37]. The use of methylene blue enabled early detection of balloon deflation or rupture[42]. A retrospective study of 34 patients (mean baseline BMI of 37.1 ± 5.5 kg/m^2) who underwent ReShape balloon placement reported an average TBWL of 6.8% ($P < 0.001$) and a significant decrease in diastolic blood pressure. While nausea was the most common complication (22.9%), one patient had a small bowel obstruction due to balloon migration, and another experienced a bleeding gastric ulcer[49]. This device is no longer available for unclear reasons.

The Spatz3 adjustable balloon system

The Spatz3 is a volume-adjustable silicone balloon filled with saline and 1% methylene blue designed to remain *in situ* for 8 months[44]. Its unique feature is an extractable filling catheter that enables *in situ* bidirectional volume adjustments based on patient tolerability and desired weight outcomes. The volume may be increased to enhance weight loss, or decreased to alleviate intolerance and maximize treatment duration[44,50]. A multicenter RCT of 288 patients found that the addition of Spatz3 therapy to lifestyle intervention led to a significantly higher mean TBWL after 8 months compared to lifestyle intervention alone (15% *vs.* 3.3%, $P < 0.0001$) with a 92% response rate. 80% of patients underwent volume adjustments for weight loss or intolerance, leading to a 3.1% greater mean TBWL in patients who were adjusted[50]. Upward adjustment alone led to an additional 5.2% TBWL compared to no adjustment. Early removal occurred in 17% of patients, and the most common serious adverse events included nausea (3%), vomiting (3%), dehydration (2%), nutritional or metabolic disorders (2%), diarrhea (1%), and abdominal pain (1%) without any mortality[50].

Gas-filled balloons

Obalon balloon system

The Obalon balloon system (Obalon Therapeutics, Carlsbad, CA, USA) involves a series of three thin-walled nylon polyethylene blend balloons, each filled with 250 mL of nitrogen gas[28,42]. These three balloons [Figure 2C][37] are swallowed as capsules (prior to inflation with an attached thin catheter) in sequence over time but require endoscopic removal after six months[28,44]. A multicenter, double-blind RCT of 387 patients found a significantly greater TBWL in patients who underwent Obalon balloon therapy compared to those managed with lifestyle interventions alone (7.1% *vs.* 2.6%, $P = 0.0085$) at 6 months. The responder rate was 66.7% ($P < 0.0001$) and the treatment group maintained 88.5% of their weight loss at 48 weeks. Patients in the treatment group experienced improvements in multiple cardiometabolic risk factors such as blood pressure, glucose, fasting plasma total cholesterol and triglycerides. There was a 0.4% rate of severe adverse events (one balloon deflation and a bleeding ulcer)[51]. This system is no longer commercially available following the company's merger with ReShape Lifesciences.

Other existing IGBs include:

The Heliosphere® BAG: a lightweight, air-filled polymer balloon encased in a silicone shell. It was developed to reduce the nausea and vomiting commonly caused by liquid-filled balloons, which result from their

heavier weight. It is placed endoscopically and remains *in situ* for up to 6 months[44].

The Elipse™ balloon: a non-endoscopic, procedure-free IGB that eliminates the need for endoscopic placement or removal. It is compacted into an ingestible vegan capsule attached to a slender catheter, allowing it to be filled with 550 mL of liquid once it reaches the stomach, typically during an outpatient visit. Placement is confirmed via abdominal X-ray, after which the catheter is removed. After about 4 months, the balloon self-empties through a built-in valve and is naturally excreted via the GI tract[52]. This device is currently being evaluated by the FDA.

Overall safety and efficacy of IGBs

One meta-analysis of RCTs comparing IGB with sham or lifestyle interventions in patients who are overweight or who have obesity found a significantly higher EWL (17.98%) and TBWL (4.4%) in the IGB group[53]. Sub-group analysis demonstrated no significant difference in EWL between balloon types, but the Spatz balloon was found to have the greatest effect on the observed higher TBWL than other balloon types (Obalon, Orbera, and ReShape Duo).

Another meta-analysis of 5,668 patients showed that IGBs are more effective than lifestyle changes alone in improving obesity-related metabolic parameters such as triglyceride (-19 mg/dL), waist circumference (-4.1 cm), diastolic blood pressure (-2.9 mmHg), and fasting plasma glucose) levels (FPG, -12.7 mg/dL) with a 1.4% odds of diabetes resolution and a low adverse event rate (1.3%)[54].

Serious adverse events reported in studies include perforation (0.3%), esophageal mucosal injury (0.8%), gastric ulcer or bleeding (0.76%), severe dehydration (0.7%), aspiration pneumonia (0.4%), and gastric outlet/bowel obstruction (0.12%)[55]. No mortality was reported in a review of studies including 741 patients[55]. Complications reported by the US FDA in post-approval studies include balloon hyperinflation (2.3%), mostly from the Orbera balloon, and acute pancreatitis (1.3% from ReShape). Additional reports include more episodes of pancreatitis from Orbera than from Reshape[55,56]. These complications often led to early balloon removal. Hyperinflation or acute pancreatitis were not reported with the gas-filled Obalon system.

Fluid-filled *vs.* air-filled IGB

A meta-analysis of 22 RCTs evaluating 6-month %TBWL outcomes found that fluid-filled IGBs resulted in 2.8% more weight loss compared to gas-filled balloons[55]. Contraindications to IGB include but are not limited to prior bariatric surgery, any inflammatory disease of the GI tract (e.g., esophagitis, gastric ulceration, duodenal ulceration, cancer, or specific inflammation such as Crohn's disease), presence of a gastric mass, hiatal hernia, and severe coagulopathy[46,49].

TPS

The TPS (BARONova Inc, San Carlos, CA, USA) is a removable intragastric device made up of a large proximal bulb connected by a silicone tether to a smaller distal bulb. Delivered and assembled endoscopically, the smaller bulb rests in the duodenum while the larger bulb remains in the stomach [Figure 2D][37]. The device creates intermittent gastric outlet obstruction during peristalsis, delaying gastric emptying and reducing food intake. TPS is designed to be used for 12 months, after which it is removed endoscopically using the BARONova Retrieval Kit[57]. A recent double-blind RCT found that patients with classes I and II obesity who received TPS therapy had a significantly higher TBWL than the control group (9.5% *vs.* 2.8%) after 12 months. Sixty-seven percent of the treatment group achieved ≥ 5% TBWL, compared to 29.3% in the control group. The treatment group also experienced significantly lower blood pressure, total cholesterol, and low-density lipoprotein. Serious adverse events related to the device or procedure occurred in 6 patients (2.8%), with no reported deaths[58]. Of 213 patients, there was one

occurrence each of esophageal rupture (associated with unsuccessful TPS deployment), upper abdominal pain, vomiting and device impaction, device intolerance and device impaction, gastric ulcer and device impaction, and device impaction[58]. Although this device achieved FDA approval, it was never commercially marketed.

SatiSphere

The SatiSphere (Endosphere, Columbus, OH) is 20-25 cm long and is composed of mesh spheres that are mounted on a preformed memory wire with curled ends that adapt to the shape of the duodenum. It self-anchors in the distal stomach and proximal duodenum, where it slows food transit through the duodenum. This delayed transit may impact GI satiety hormone regulation and glucose metabolism[59,60]. EWL was 18.4% among patients who completed the treatment compared to 4.4% in the control group (P = 0.02). However, 10 out of 21 patients in the treatment group experienced spontaneous device migration, with management varying based on the device's location. Three devices were excreted naturally without causing intestinal damage, one was removed via upper GI endoscopy, four through colonoscopy, and two required laparoscopic surgery[60]. This led to the premature termination of the trial.

ABSORPTION-LIMITING DEVICES

Duodenojejunal bypass liner

EndoBarrier (GI Dynamics, Lexington, MA), also referred to as the duodenojejunal bypass liner (DJBL), is a single-use endoscopic device consisting of a 60-cm impermeable fluoropolymer liner that is anchored in the duodenal bulb to prevent the mixing of chyme with bile and pancreatic secretions [Figure 3A][37,61,62]. It is placed and removed endoscopically with fluoroscopic assistance, and removal is recommended within 12 months due to increased risks without added benefits for prolonged use. DJBL mimics the metabolic effects of RYGB by excluding the duodenum and proximal jejunum, which enhances insulin sensitivity and glucose regulation. It works by reducing the anti-incretin effect, increasing glucagon-like peptide-1 (GLP-1) and peptide YY (PYY) levels, and decreasing glucose-dependent insulinotropic polypeptide (GIP), leading to improved glycemic control and enhanced satiety. Unlike RYGB, which reduces ghrelin levels, the DJBL tends to increase fasting ghrelin. Both interventions expose the distal small intestine to undigested food, which triggers hormonal changes that support weight loss and metabolic improvements[61,62]. DJBL has been shown to have a lower mean TBWL (15.04% *vs.* 27.93%, $P < 0.05$) and mean EWL (44.48% *vs.* 67.26%) than RYGB but similar improvement in glycemic control after 12 months[61]. Severe adverse event rate has been reported to be 19.7%. The most concerning adverse events are liver abscesses, GI bleeding (often due to ulcerations and perforations with prolonged use), device migration, and obstruction[63]. FDA approval is still pending.

Gastroduodenojejunal bypass sleeve

The gastroduodenojejunal bypass sleeve (GJBS; ValenTx, Inc., Maple Grove, MN) is a 120-cm fluoropolymer with a polyester cuff at its proximal end, which is attached to the gastroesophageal junction with transmural anchors. The sleeve extends into the proximal jejunum [Figure 3B][37]. Its placement requires a combined endoscopic and laparoscopic procedure with fluoroscopic assistance, but its retrieval, which is done after 12 months, is accomplished endoscopically[64]. It is designed to replicate the effects of RYGB by restricting food intake, bypassing the stomach and a portion of the small intestine, and delivering undigested food directly to the jejunum[22]. In a small prospective study of 12 patients, 2 of the 12 patients who underwent device implantation did not tolerate the device and required early explantation within the first 4 weeks. The remaining 10 patients who completed the study had a mean EWL of 35.9% with improvement in comorbidities (diabetes mellitus and blood glucose control, hypertension, hyperlipidemia) during the 12-month study period. However, 4 patients were found to have partial cuff detachment. The mean EWL in those with intact cuffs was 54% at 12 months and 30% at 14 months post-explantation. No

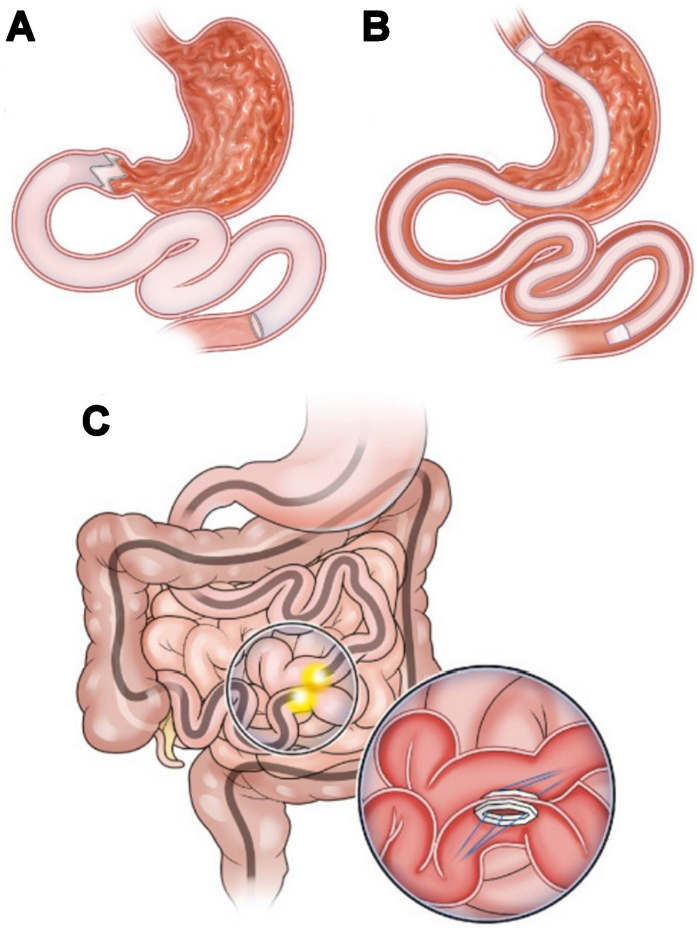

Figure 3. Absorption-limiting interventions[37]. (A) DJBL (EndoBarrier); (B) GJBS; (C) IMAS. DJBL: Duodenojejunal bypass liner; GJBS: gastroduodenojejunal bypass sleeve; IMAS: incisionless magnetic anastomotic system.

esophageal leak or death was noted during the study[64]. This device has not received FDA approval.

Incisionless magnetic anastomotic system

The incisionless magnetic anastomotic system (IMAS; GI Windows, West Bridgewater, MA) uses self-assembling magnets to create a side-to-side anastomosis between the proximal jejunum and the terminal ileum. Delivered endoscopically via colonoscopy and upper endoscopy in a linear configuration (sometimes, with laparoscopic supervision), the magnets reconfigure into a large-caliber octagon, forming a bypass larger than traditional endoscopic methods allow [Figure 3C][37]. After several days (8-28 days), the magnets are expelled naturally through the stool. This creates a partial jejunoileal bypass that reroutes bile acids and nutrients to the ileum, reducing nutrient absorption[65]. A small pilot study demonstrated an average TBWL of 14.6% (40.2% EWL) at 12 months post-procedure and a significant decrease in hemoglobin A1c (HbA1c) in both diabetic (1.9%) and prediabetic (1.0%) patients with decreased use or discontinuation of antihyperglycemic medications. There was a 23% reduction in alanine aminotransferase values from the baseline[65]. FDA approval is pending.

Magnetic anastomosis system

The magnetic anastomosis system (MS; GT Metabolic Solutions, San Jose, CA, Figure 4[66]) is intended for use in the creation of a side-to-side duodeno-ileal (DI) anastomosis[66] in patients with prior SG (MagDI-

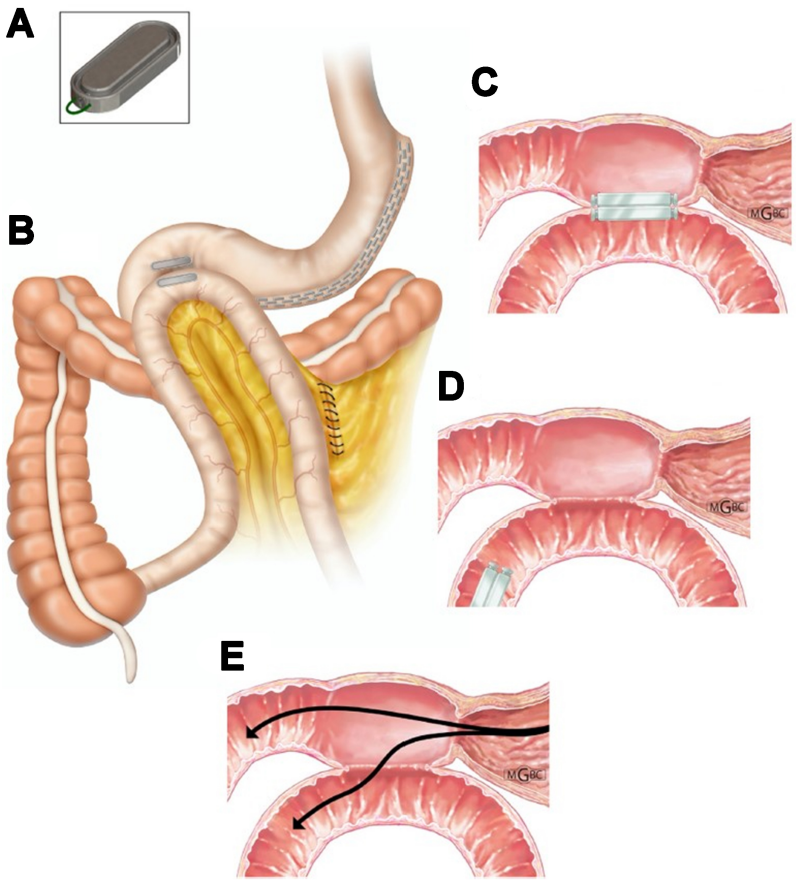

Figure 4. The MS[66]. (A) MS linear magnets; (B and C) The magnets are endoscopically placed and laparoscopically guided to the duodenum and ileum to initiate magnet fusion and gradual side-to-side duodeno-ileal anastomosis. The mesenteric space is closed; (D and E) The magnets fuse and are expelled after a few weeks, leaving a duodeno-ileal anastomosis that permits the passage of gastrointestinal contents from the duodenum into the ileum. MS: Magnetic anastomosis system.

after-SG) or patients who will undergo concurrent SG at the time of magnet implantation (MagDI + SG)[66]. Two linear MS magnets are endoscopically placed [Figure 4A] in the duodenum and ileum with laparoscopic guidance [Figure 4B]. They are aligned to initiate magnet fusion and gradual DI anastomosis formation [Figure 4C]. Then, SG is performed in patients without prior SG. The magnets are naturally expelled after a few weeks [Figure 4D and E]. It is designed to be technically simpler than other single-anastomosis procedures such as the single-anastomosis duodeno-ileal bypass with SG and single-anastomosis sleeve ileal bypass[66]. Early results from a multicenter study showed an average EWL of 17.4% ± 5.9% and TBWL of 7.0% ± 2.1% at 6 months in the MagDI-*after*-SG cohort. The MagDI + SG cohort experienced significantly greater weight loss with an average EWL and TBWL of 66.2% ± 3.4% and 28.1% ± 1.0%, respectively. There were significantly fewer overall adverse events in the MagDI-*after*-SG group (10.9%) than in the MagDI + SG cohort (89.1%). 43.8% were associated with the surgical operation itself. No serious adverse events or device-related adverse events (anastomotic leakage, bleeding, infection, obstruction, or mortality) were reported[66]. This device received US FDA clearance in 2024.

Longer-term results and comparison of outcomes with established single-anastomosis surgeries are needed for adequate evaluation of the safety and efficacy of these magnetic techniques.

OTHERS

Duodenal mucosa resurfacing

Duodenal mucosa resurfacing (DMR), Revita DM (Fractyl Laboratories, Inc., Lexington, MA), uses a specialized catheter to perform circumferential hydrothermal ablation of the duodenal mucosa to improve glycemic control [Figure 5A][22,37,67]. To protect the outer layers of the duodenum, saline is injected to lift the mucosa before ablation. Given that duodenal mucosal hyperplasia has been implicated in insulin resistance, the goal of ablation with subsequent mucosal regeneration is to improve glycemic control[68]. A prospective, multicenter study of patients with type 2 diabetes mellitus (BMI 24-40) on stable oral glucose-lowering medication reported a decrease in HbA1c (-10 ± 2 mmol/mol, i.e., 0.9%, $P < 0.001$), FPG (-1.7 ± 0.5 mmol/L, $P < 0.001$), hepatic transaminase levels, and improved Homeostatic Model Assessment for Insulin Resistance (-2.9 ± 1.1, $P < 0.001$) 6 months post-DMR. Weight was modestly reduced (-2.5 ± 0.6 kg, $P < 0.001$) but did not correlate with a change in HbA1c. There was one serious adverse event ($P = 0.002$)[67]. Among patients with baseline liver MRI proton density fat fraction (MRI-PDFF) > 5% and FPG ≥ 10 mmol/L, the DMR group showed a significantly greater median reduction in liver MRI-PDFF compared to the sham group ($P = 0.001$). One patient experienced a jejunal perforation due to endoscope manipulation during an upper endoscopy, which required surgical repair[69]. This technology is awaiting FDA approval.

Aspiration therapy

The AspireAssist (Aspire Bariatrics, King of Prussia, Pa, USA) was a device approved for individuals aged 22 and older with a BMI of 35-55 kg/m^2 who have not achieved sustained weight loss through non-surgical methods[70]. Designed like a modified percutaneous gastrostomy tube [Figure 5B][71] that can remove approximately 30% of ingested food, it promoted weight loss through calorie removal and reduced food intake, with calorie removal being the primary mechanism. It was designed for long-term use alongside lifestyle modification and continuous medical supervision[22,70].

A meta-analysis by the ASGE found a 16.5%-17.8%, 18.3%, 19.1%, and 18.6% (all $P < 0.0001$) TBWL after 1, 2, 3, and 4 years, respectively, of aspiration therapy. EWL at the same time points were 46.3%, 46.2%, 48.0%, and 48.7%, respectively (all $P < 0.0001$). Additionally, aspiration therapy resulted in improvement in systolic and diastolic blood pressure, triglyceride level, HDL, HbA1c, aspartate aminotransferase level, and alanine aminotransferase levels[72]. The pooled serious adverse event rate was 3.8% and included buried bumper (2.2%), peritonitis treated with intravenous antibiotics (0.5%), severe abdominal pain treated with pain medication (0.5%), abdominal pain due to a prepyloric ulcer (0.3%), and product malfunction requiring catheter replacement (0.3%). There were also reports of fistula formation, especially in devices that were removed over 2 years after placement[73]. There were no reports of new development of eating disorders or mortality[72]. Contraindications to its use include history of abdominal surgery due to increased risk of gastrostomy tube placement, esophageal or gastric diseases, such as esophageal stricture, gastric varices, and refractory gastric ulcers, severe coagulopathy, chronic abdominal pain, and eating disorders such as binge eating syndrome and bulimia nervosa[70,72]. These findings indicate that aspiration therapy fulfilled the PIVI criteria established by the ASGE[47]. However, in 2022, the manufacturer withdrew the device from the market, citing financial challenges[73].

Intragastric botulinum toxin A injection

Injection of botulinum toxin A (BTA) into the stomach wall [Figure 5C] inhibits the release of acetylcholine, which causes paralysis of the injected muscle and slows down gastric emptying. It also inhibits ghrelin secretion, potentially causing appetite suppression[74]. A meta-analysis including 192 subjects only showed a significant difference in weight loss from the control group after a BTA dose ≥ 200 U (mean difference, -2.04 kg) with multiple intragastric injection sites combined with diet control. A significant mean BMI decrease (-1.25 kg/m^2) and an increase in gastric half-emptying time (mean difference, 11.37 min) were

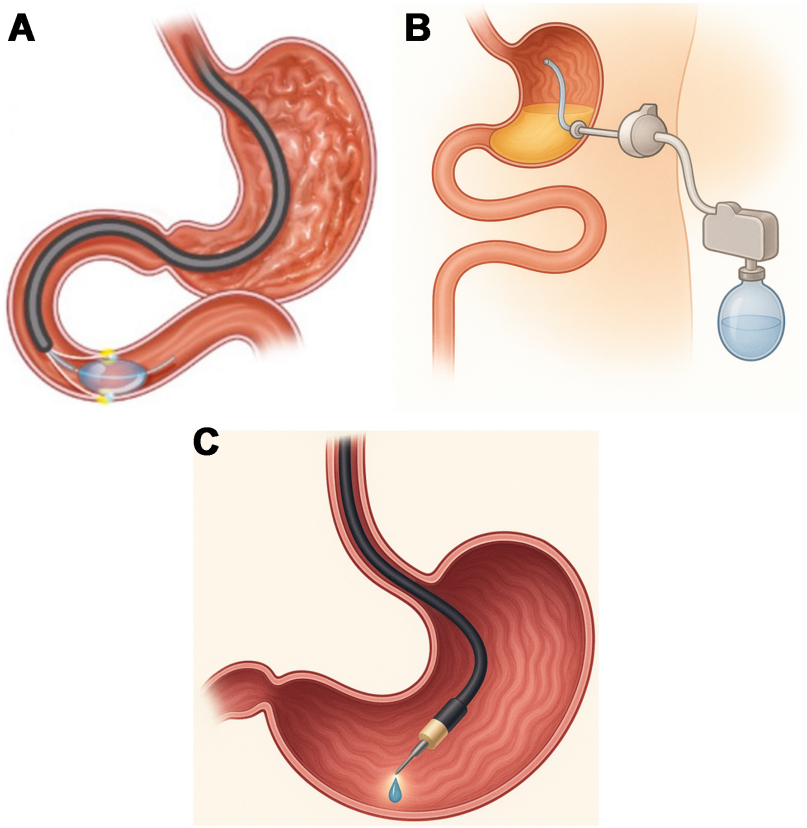

Figure 5. Other endoscopic interventions. (A) Duodenal mucosal resurfacing[37]; (B) AspireAssist (Aspiration Therapy)[71]; (C) Intragastric BTA injection. BTA: Botulinum toxin A.

reported after BTA injection. However, the method of endoscopic ultrasound-guided injection or the follow-up duration was not associated with a difference in weight loss outcomes[75], and this practice has largely been abandoned.

SAFETY AND EFFICACY EBMT

Threshold for safety and efficacy

A joint task force formed by the ASGE and the ASMBS established safety and efficacy criteria for endoscopic procedures in a Preservation and Incorporation of Valuable Endoscopic Innovations document[76]. The task force recommended that an EBMT intended to be used as a primary intervention for obesity in individuals with Class II/III obesity should achieve a mean minimum threshold of 25% EWL measured at 12 months. In addition, it should achieve a minimum mean difference of 15% EWL between a primary EBMT group and a control group, and the difference should be statistically significant. However, when used as a non-primary intervention (e.g., early intervention, bridging, or metabolic therapy), the EBMT should achieve an average minimum threshold of 5% total weight loss. The risk of the incidence of serious adverse events associated with EBMT should be at a rate of ≤ 5%. If an EBMT with a low/negligible risk profile proves to have a significant impact on one or more obesity-related comorbidities, the threshold for intervention may extend to individuals with Class I obesity (BMI 30-35 kg/m^2)[76].

A meta-analysis of 22 studies (2,141 patients) evaluating the efficacy of bariatric EBMTs found that most EBMTs demonstrated superior efficacy with TBWL mean difference of 4.9% (POSE), 4.5% (DJBL), 5.3%

(fluid-filled balloon), and 10.4% (aspiration therapy), respectively, relative to lifestyle modification (control). Furthermore, the EWL after POSE (15.3%), DJBL (13.0%), fluid-filled balloon (22.4%), and aspiration therapy (27.3%) were superior to the control group. However, gas-filled balloons and botulinum toxin injection did not show a significant difference in TBWL and EWL relative to the control group[10].

EBMT IN THE GLOBAL CONTEXT OF PATIENT CARE

Weight loss interventions have been shown to yield better results when integrated into a comprehensive, multidisciplinary treatment plan. Similarly, EBMTs should be utilized within this framework to maximize their effectiveness. Key components of these programs include nutritional support, skilled nursing care, behavioral medicine specialists, and physicians with expertise in managing obesity. Additionally, it is recommended that physicians and surgeons who can handle potential complications in obese patients be available and accessible[76].

FINANCIAL ASPECTS OF EBMTS

As EBMTs become more widely utilized, understanding the financial aspects of these interventions, including physician reimbursement, becomes crucial, both for healthcare providers and patients.

Physician reimbursement for endoscopic bariatric therapies

Physician reimbursement for EBMTs varies depending on the healthcare system and the payer. In the United States, reimbursements from government programs like Medicare or Medicaid are often lower than those from private insurance companies[77]. Despite ESG being a minimally invasive procedure with promising clinical outcomes, reimbursement remains a challenge. The cost of the procedure itself, which includes equipment and facility fees, can be substantial, but physicians may face pressure from payers who have yet to establish standardized reimbursement rates for such newer interventions.

Currently, many insurers classify ESG as an experimental or investigational procedure, meaning that reimbursement is often denied or provided at a lower rate compared to traditional bariatric surgery. This is due to the lack of long-term data and FDA approval, although ESG is FDA-cleared for diagnostic use. As more clinical data become available, particularly demonstrating ESG's effectiveness and safety in the long term, insurers may update their policies and reimbursement schedules, potentially improving financial sustainability for physicians performing these procedures. A new level 1 CPT code will become available for use on January 1, 2026, which may dramatically change the possibility of offering the procedure to patients[78].

Financial costs of endoscopic bariatric procedures

The financial burden of ESG, both for healthcare systems and individual practices, is multifaceted. The initial procedure cost typically includes the use of specialized endoscopic equipment (such as a balloon or suturing device), the physician's time, and operating room expenses. While ESG offers lower direct costs than traditional surgery by eliminating hospital stays, the overall price can still be significant. Hospitals and outpatient clinics must factor in staff salaries, facility overhead, and any additional follow-up care that may be required.

Patients, in turn, may experience out-of-pocket costs depending on their insurance coverage. For those without adequate insurance, the procedure can be prohibitively expensive, which may limit access to ESG and other EBMTs. This financial barrier underscores the importance of considering the cost-effectiveness of ESG compared to traditional operations such as RYGB or SG, which involve higher upfront costs but may be more likely to be reimbursed.

Cost analysis and future directions

A growing body of research suggests that ESG, despite its relatively lower cost per procedure, can be a cost-effective option for treating obesity, especially when factoring in the long-term healthcare savings related to weight loss and improved comorbidities, such as diabetes and hypertension. In this context, ESG offers an alternative for cost-conscious healthcare systems that are looking to reduce the financial burden of obesity-related complications.

However, financial analysis must also consider the potential for increased demand as patients become more aware of minimally invasive alternatives. The scalability of ESG, given its reduced need for postoperative care and shorter recovery times, may position it as a key player in the evolving landscape of obesity management.

While physician reimbursement and financial costs associated with EBMTs remain complex, the potential for improved patient outcomes, reduced long-term healthcare costs, and increased availability of coverage through insurers offer optimism for broader adoption. Ongoing research into the efficacy and cost-effectiveness of EBMTs, along with changes in reimbursement policies, will be essential for maximizing the financial sustainability of these innovative treatments.

FUTURE OF EBMT

With the magnitude of the global obesity problem, significant resources have been deployed to develop endoscopic therapies to treat obesity and related diseases. While many of these technologies have proven ineffective, others - despite demonstrating clinical efficacy - have failed in the marketplace and are no longer available. Despite these limitations, there remains significant interest in EBMTs. ESG and magnetic anastomoses for intestinal bypass seem to be the most promising of the currently available therapies. We anticipate seeing increased utilization of these technologies in the coming years. As with other surgical decisions, selecting the most appropriate EBMT for a given patient requires a more comprehensive, multifactorial assessment of factors such as the patient's clinical profile and treatment goals, the available EBMT options, the surgeon's skill set, and the relative risks and benefits of the considered EBMT compared with other alternatives.

DECLARATIONS

Authors' contributions

Made substantial contributions to the conception and design of the study: Pryor AD, Nwaiwu CA, Giorgi M
Performed writing and critical review of the manuscript: Pryor AD, Nwaiwu CA, Giorgi M, Hunte EM

Availability of data and materials

Not applicable.

Financial support and sponsorship

None.

Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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