

Endoscopic Weight Loss Options



Danse Bi, MD^a, Pichamol Jirapinyo, MD, MPH^{a,b,*}

KEYWORDS

- Endoscopic bariatric and metabolic therapy • EBMT
- Endoscopic gastric remodeling • EGR • Endoscopic sleeve gastroplasty • ESG
- Intra gastric balloon • Bariatric endoscopy

KEY POINTS

- Endoscopic bariatric and metabolic therapies (EBMTs) can be divided into gastric and small bowel interventions.
- Gastric EBMTs primarily aim to induce weight loss, with secondary benefits on metabolic outcomes, while small bowel EBMTs focus on improving metabolic diseases, with or without associated weight loss.
- Currently, EBMTs authorized or cleared by the Food and Drug Administration (FDA) in the U.S. are intra gastric balloons and endoscopic gastric remodeling, both of which are gastric interventions. Small bowel interventions are currently available only through clinical trials in the U.S.
- IGBs can be considered for patients with a body mass index (BMI) of at least 30 kg/m² or 27 to 29.9 kg/m² and with at least 1 obesity-related comorbidity. The average weight loss following IGB placement is approximately 11.3% of total weight loss after 12 months.
- EGR can be considered for patients with a BMI of at least 30 kg/m² or 27 to 29.9 kg/m² and with at least 1 obesity-related comorbidity. The average weight loss following IGB placement is approximately 17.3% of total weight loss after 12 months.

INTRODUCTION

Obesity is a chronic, relapsing disease that is pandemic. Currently, 1 in 8 adults worldwide is affected, and its prevalence continues to increase.¹ In the United States, it is estimated that 50% of adults will have obesity by 2030.¹ Obesity and its associated comorbidities place a significant burden on the health care system, with an estimated annual cost of \$260 billion in the United States.² Globally, the economic impact of obesity and overweight is projected to reach \$3 trillion by 2030 and \$18 trillion by 2060.³

^a Division of Gastroenterology, Hepatology, and Endoscopy, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, USA; ^b Harvard Medical School, Boston, MA 02115, USA

* Corresponding author. Division of Gastroenterology, Hepatology, and Endoscopy, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, USA

E-mail address: pjirapinyo@bwh.harvard.edu

Until recently, obesity treatments primarily included lifestyle modification, pharmacotherapy, and bariatric surgery. Lifestyle modifications with diet and exercise are often the initial approach but are typically insufficient for achieving clinically significant weight loss.^{4,5} Pharmacotherapy yields variable weight loss outcomes, with glucagon-like peptide 1 receptor agonists being associated with the highest total weight loss (TWL), ranging from 8% to 21%.^{6–9} However, long-term use of the medication is necessary to prevent recurrent weight gain, which can be costly and carry the risk of unknown adverse events. Although bariatric surgery is the most effective treatment of obesity, it remains the most invasive and is associated with risks of both short-term and long-term complications.¹⁰ Furthermore, although the recent statement from the American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders recommends bariatric surgery for individuals with a body mass index (BMI) of greater than or equal to 35 kg/m² or greater than 30 kg/m² with at least one obesity-related comorbidity, insurance coverage remains limited for those with class I obesity (BMI 30–34.9 kg/m²).¹⁰ Furthermore, less than 2% of eligible patients elect to undergo bariatric surgery, likely due to patient preference, perceived risks, and costs.¹¹

Over the past decades, bariatric endoscopy has emerged as an alternative treatment for obesity to bridge the gap between lifestyle modification or pharmacotherapy and bariatric surgery. Bariatric endoscopy is categorized into primary endoscopic bariatric and metabolic therapies (EBMTs), which are offered to patients without prior bariatric surgery and endoscopic management of bariatric surgical complications, such as recurrent weight gain. Primary EBMTs can be further categorized into gastric and small bowel interventions.^{12,13} Gastric EBMTs primarily aim to induce weight loss, with secondary benefits on metabolic outcomes, whereas small bowel EBMTs target improvements in metabolic diseases, with or without associated weight loss.^{12,13} Given the currently available safety and efficacy data on EBMTs, the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society for Gastrointestinal Endoscopy (ESGE) recently endorsed the use of primary EBMT in conjunction with lifestyle modification in patients with BMI greater than or equal to 30 kg/m² or BMI of 27 to 29.9 kg/m² with at least one obesity-related comorbidity.¹⁴

This article will focus on primary EBMTs, including devices and procedures that have been approved or cleared by the US Food and Drug Administration (FDA) or received a Conformité Européenne (CE) mark within the past 5 years. We will discuss the devices, procedural techniques, and their safety and efficacy data.

GASTRIC ENDOSCOPIC BARIATRIC AND METABOLIC THERAPIES

Intragastric Balloons

Intragastric balloons (IGBs) are space-occupying devices that have been used for weight management since the 1980s. The first FDA-approved IGB was introduced in 1985 but was withdrawn from the market in 1992 because of adverse events and limited efficacy.¹⁵ Since then, newer generations of IGBs have been developed, with the first of these receiving FDA approvals in 2015.¹⁶ IGBs are indicated for adults with a BMI of 30 to 40 kg/m² or 27 to 29.9 kg/m² and with at least one obesity-related comorbidity.^{14,17} Contraindications to IGB placement include a large hiatal hernia (>5 cm), severe gastroesophageal reflux disease, presence of gastric mass, severe coagulopathy, cirrhosis, especially with portal hypertension, and history of prior gastrointestinal surgery or bariatric endoscopy.

IGB functions by limiting space in the stomach, leading to early satiety and reduced food intake. Evidence suggests that IGB placement may delay gastric emptying

because of antral distention and fundic relaxation.¹⁸ Additionally, small studies have reported neurohormonal changes following IGB placement, which may contribute to weight loss, although further research is needed to confirm these findings.¹⁹ Multiple studies evaluating IGB have demonstrated improvement in metabolic parameters including fasting glucose, triglycerides, and blood pressure.^{20–23} In addition, IGB placement has been associated with improvements in liver-related outcomes.^{24–26}

Orbera balloon

The Orbera IGB System (Boston Scientific, Marlborough, MA, USA), previously known as the BioEnterics IGB, is an FDA-approved single fluid-filled silicone balloon that is endoscopically placed in the stomach and removed at 6 months (in the United States.) or 12 months (outside the USA.) (Fig. 1). The deflated balloon catheter is introduced into the stomach under direct endoscopic guidance, after which the balloon is filled with 400 to 700 mL of saline. Methylene blue may be added to the saline to detect potential balloon leakage. In a United States. multicenter, randomized controlled study, the amount of weight loss at 6 months was 10.2% TWL in the IGB group versus 3.3% TWL in the control group.²⁷ A metaanalysis of 17 studies showed TWL of 13.16% at 6 months and 11.27% at 12 months with Orbera.²⁸ Early device removal can occur in up to 18.4% of patients.²⁸ The most common adverse events include abdominal pain and nausea, while rare but serious adverse events include balloon migration and gastric perforation, which occur at rates of 1.4% and 0.1%, respectively.²⁸

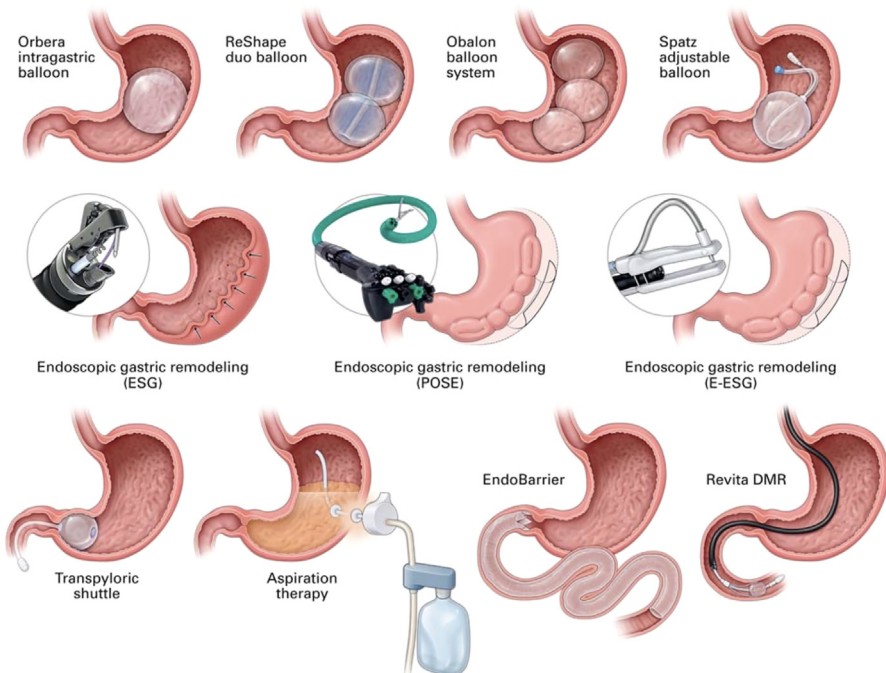


Fig. 1. Gastric and small bowel endoscopic bariatric and metabolic therapies. (Source Jirapi-nyo P, Hadeifi A, Thompson CC, et al. American Society for Gastrointestinal Endoscopy-European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity. *Endoscopy*. 2024;56(6):437-456. <https://doi.org/10.1055/a-2292-2494>.)

Reshape duo balloon

The ReShape Integrated Dual Balloon Systems (Boston Scientific, Marlborough, MA, USA) is an FDA-approved, fluid-filled 2 silicone balloon system connected by a shaft (see [Fig. 1](#)). Each balloon is filled with 450 mL of saline, resulting in a total volume of 900 mL. The dwell time for the system is 6 months. In the REDUCE trial, a randomized, double-blind, sham-controlled, multicenter study, patients with the balloon achieved 7.6% TWL compared to 3.6% TWL in the sham group.²⁹ A retrospective study of 202 patients reported TWL following balloon placement of 11.4%, 13.3%, and 14.7% at 6, 9, and 12 months, respectively.³⁰ Accommodative symptoms, such as abdominal pain and nausea were the most common adverse events, which could be managed medically.²⁹ Other serious adverse events include esophageal tear, cervical esophageal perforation, and postretrieval aspiration pneumonitis, occurring in 1% of patients. Reshape Medical was acquired by Apollo Endosurgery, the former manufacturer of Orbera, and most recently, Apollo Endosurgery was acquired by Boston Scientific.

Obalon balloon

The Obalon Balloon System (ReShape Lifesciences, Irvine, CA, USA) is an FDA-approved, gas-filled balloon that is swallowed. The balloon is packaged within a gelatin capsule attached to a catheter. After swallowing, the proximal end of the catheter is used to inflate the balloon with 250 mL of a nitrogen gas mixture (see [Fig. 1](#)). Additional balloons can be placed every 2 to 3 weeks, with a maximum of 3 balloons, resulting in a total volume of 750 mL. The balloons are endoscopically removed at 6 months. In the SMART trial, a randomized, sham-controlled, multicenter study, 198 patients received the Obalon balloon, while 189 patients received a sham capsule for 6 months. At the end of the study, TWL was 6.6% in the Obalon group compared to 3.4% in the sham group.³¹

Spatz balloon

The Spatz3 balloon (Spatz Medical, Fort Lauderdale, FL, USA) is an FDA-approved, adjustable, single fluid-filled balloon that is placed endoscopically. The balloon has a catheter attachment, allowing for volume adjustment (see [Fig. 1](#)). The balloon can be filled with 400 to 800 mL of fluid. Outside the United States., the dwell time is up to 12 months, while in the United States., the dwell time is 8 months. In a multicenter, randomized, open-label, controlled trial, TWL with the Spatz balloon was 15%, compared to 3.3% in the control group at 32 weeks.³² Serious adverse events related to the device occurred in 4% of patients.

Elipse balloon

The Elipse balloon (Allurion Technologies, Natick, MA, USA) is a fluid-filled balloon that is swallowed and then filled to 550 mL (see [Fig. 1](#)). After approximately 4 months, the balloon spontaneously empties and is naturally expelled. The first study of the Elipse balloon was conducted in 2017 on a small cohort of patients,³³ with results showing a TWL of 11.6% at 4 months. A subsequent prospective study involving 135 patients demonstrated a TWL of 15.1% at 4 months.³⁴ One patient required laparoscopic balloon removal because of small bowel obstruction. In an additional study evaluating TWL following balloon excretion in 112 patients, TWL at 6 and 12 months was reported as 10.9% and 7.9%, respectively.³⁵ The most recent multicenter study of 1,770 patients reported a 14.2% TWL at 4 months along with improvements in metabolic parameters.³⁶ Early removal due to patient intolerance occurred in 2.9% of cases, and the rate of serious adverse events was 0.06%. The Elipse balloon has received CE

mark and is commercially available in Europe. A United States. pivotal study on the Elipse balloon was recently completed, and the FDA review is currently pending.

Transpyloric Shuttle

The transpyloric shuttle (BAROnova, Inc., San Carlos, CA, USA) is an endoscopically placed gastric device that received FDA approval in 2019 for use in patients with a BMI of 30 to 40 kg/m². The approved dwell time for the device is 12 months. It consists of a large bulb attached to a flexible silicone catheter with a smaller bulb. After endoscopic placement, the small bulb migrates into the small bowel during peristalsis, while the larger bulb oscillates between the pylorus and antrum, creating intermittent gastric obstruction (see Fig. 1). An early pilot study involving 20 patients demonstrated 31.3% and 50.0% excess weight loss at 3 and 6 months, respectively.³⁷ Early device removal occurred in 2 patients due to persistent gastric ulceration. In the Endobesity II study, a randomized double-blind trial, 302 patients were included, with 270 patients in the device group and 32 patients in the sham group.³⁸ At 12 months, TWL was 9.8% in the device group compared to 2.8% in the sham group. The serious adverse rate was 2.8%. While the device has received FDA approval, it is currently not commercially available.

Aspiration Therapy

AspireAssist Systems (Aspire Bariatrics, King of Prussia, PA, USA) was approved by the FDA in 2016 for patients with a BMI of 35 to 55 kg/m² in conjunction with lifestyle modification. The device is a modified 26 Fr percutaneous endoscopic gastrostomy tube with a 15 cm fenestrated intragastric portion and an external port for draining gastric contents. After meals, patients can drain approximately 30% of the calories consumed (see Fig. 1). In the randomized controlled PATHWAY trial, TWL was 12.1% in the AspireAssist group compared to 3.5% in the lifestyle modification alone group at 1 year. At 4 years, 69% of patients maintained at least a 10% TWL.³⁹ A recent metaanalysis of 5 studies involving 590 patients showed TWL of 17.8% and 18.6% at 1 and 4 years, respectively. The study also demonstrated improvements in blood pressure, triglycerides, high-density lipoprotein, hemoglobin A1c, aspartate aminotransferase (AST), and alanine aminotransferase (ALT).⁴⁰ The pooled incidence of serious adverse event was 4.1%. Common adverse events included peristomal granulation tissue, postoperative abdominal pain, and peristomal irritation. Device removal within the first year occurred in 26.1% of patients. Placement of the device was not shown to be associated with the development of eating disorders.³⁹ While the device still has FDA approval, it is currently not available commercially.

Endoscopic Gastric Remodeling

Endoscopic gastric remodeling (EGR) is a procedure in which an endoscopic suturing or plication device is used to reduce the stomach's volume by approximately 50% to 70%. According to the most recent ASGE-ESGE guidelines, patients with a BMI greater than or equal to 30 kg/m², or those with a BMI of 27 to 29.9 kg/m² with 1 or more obesity-related comorbidities, may be considered for EGR.¹⁴ The procedure can be performed using either full-thickness plication or suturing techniques. Currently, there are 3 suturing or plication systems that are FDA-cleared or approved, which have been used to perform EGR.

Endoscopic sleeve gastropasty

Endoscopic sleeve gastropasty (ESG) is a procedure in which sutures are placed along the gastric body to reduce the gastric volume, resulting in a tubular stomach

appearance similar to laparoscopic sleeve gastrectomy (LSG). The first ESG using the newer generation of full-thickness suturing device was performed in 2012 by Christopher Thompson and Robert Hawes.^{41,42} Currently, the ESG procedure is performed using the Overstitch endoscopic suturing system (Boston Scientific, Marlborough, MA, USA), which recently received de novo authorization from the FDA for the treatment of obesity. The system can be attached to either a double-channel or single-channel scope, and uses a needle driver and tissue helix to place full-thickness stitches in the gastric tissue (see [Fig. 1](#)).

The proposed mechanism by which ESG induces weight loss involves a combination of gastric volume reduction and altered gastric motility.⁴³ Specifically, during the procedure, approximately 6 to 10 sutures are placed in a pattern designed to reduce both the length and width of the stomach. Although currently, there is no standard suture pattern for performing the procedure,^{44,45} the most common technique involves placing running stitches in a U-shaped pattern along the anterior, greater curvature, and posterior gastric walls to both narrow and shorten the stomach. Reinforcement sutures are sometimes placed between the running sutures to further reduce gastric volume and decrease suture tension, potentially enhancing suture retention and durability. Suturing the fundus is generally avoided because of the thinness of the tissue, which increases the risk of leaks. Small studies have shown that ESG is associated with delayed gastric emptying and increased satiety. Neurohormonal changes may also play a role in weight loss following ESG; however, larger studies are needed to further clarify the impact of ESG on gut hormones.

In an earlier international multicenter study of 248 patients, the TWL at 6 and 24 months was 15.2% and 18.6%, respectively.⁴⁶ Weight loss at 6 months was also found to be a predictor of weight maintenance at 24 months. The rate of severe adverse events was 2%. Subsequent studies have shown similar efficacy of ESG. In a series of 1,000 patients, TWL was 13.7%, 15%, and 14.8% at 6, 12, and 18 months, respectively.⁴⁷ At 5 years, TWL following ESG was 15.9%.⁴⁸ A recent systematic review and metaanalysis of 8 studies involving 1,859 patients reported TWL of 14.86%, 16.43%, and 20.01% at 6, 12, and 24 months, respectively. The pool incidence of serious adverse events was 2.26%, with gastrointestinal bleeding and perigastric fluid collections occurring in less than 1% of patients.⁴⁹

The MERIT trial, a multicenter randomized controlled trial involving 209 patients, found that 80% of patients undergoing ESG had improvement in 1 or more obesity-related comorbidities at 52 weeks.⁵⁰ Additional studies have demonstrated improvements in liver steatosis and fibrosis within the first 1 to 2 years following ESG.^{51,52} A small proportion of patients (1.2%) undergoing ESG may eventually require revisional LSG.⁵³ Conversion to LSG is feasible and is not associated with increased mortality, adverse events, or prolonged hospital stay. Similarly, conversion to Roux-en-Y gastric bypass is also feasible following ESG.⁵⁴

Primary obesity surgery endoluminal

Primary Obesity Surgery Endoluminal (POSE) reduces stomach volume similar to ESG but uses full-thickness tissue plications. The procedure is performed using the Incisionless Operating Platform (USGI Medical, San Clemente, CA, USA) plication system, which is cleared by the FDA for tissue apposition. The platform includes the Transport, a 54 Fr flexible overtube with a control knob and 4 working channels for the insertion of an ultraslim endoscope, a tissue approximator, and a tissue helix to create full-thickness plications (see [Fig. 1](#)).

The initial POSE procedure was designed to reduce gastric fundal accommodation by placing the plications in the gastric fundus.⁵⁵ In the pivotal sham-controlled

ESSENTIAL trial, POSE resulted in 4.95% TWL compared to 1.38% in the sham group.⁵⁶ A subsequent iteration, known as distal POSE, was more recently developed, which involves placing plications in the gastric body sparing the fundus.⁵⁷ Plications are placed along the length and width of the gastric body in a belt-and-suspenders pattern to reduce gastric volume, with an average TWL of 15.2% at 1 year using this technique. Additional studies comparing the single helix technique to double helix technique demonstrated that the double helix technique achieved greater weight loss and a higher proportion of patients with TWL greater than or equal to 10% at 12 months.⁵⁸ Improvements in obesity-related comorbidities, including blood pressure, insulin resistance, and fatty liver, were also noted. The incidence of serious adverse events was 0.9%, with 1 case of gastric perforation.⁵⁹ Delays in gastric emptying time and the degree of postprandial peptide YY (PYY) increase have been shown to be independent predictors of weight loss after POSE.⁶⁰

Endomina endoscopic gastric remodeling

Endoscopic gastric remodeling can also be preformed using the Endomina plication system (Endo Tools Therapeutics, Gosselies, Belgium), which has FDA clearance for tissue approximation. The device consists of an over-the-scope triangulation platform with 2 channels through which a preloaded needle and suture can be placed (see Fig. 1). A randomized control trial involving 71 patients reported an 11.8% TWL at 12 months.⁶¹ Various suture patterns have been evaluated for performing EGR with the Endomina system. A recent study evaluated 3 suture patterns aiming to decrease gastric volume showed no significant difference in weight loss between the 3 suture patterns.⁶² Overall, the average TWL was 10.11% at 12 months, with no serious events reported.

SMALL BOWEL ENDOSCOPIC BARIATRIC AND METABOLIC THERAPIES

Duodenal Mucosal Resurfacing

Duodenal mucosal resurfacing (DMR) is a small bowel EMBT designed to treat type 2 diabetes. The procedure is performed using the Revita DMR system (Fractyl, Lexington, MA, USA), which employs hydrothermal ablation to remodel the duodenal surface.^{63,64} Mucosal remodeling of the diseased duodenal tissue is thought to reset metabolic pathways involved in insulin resistance. Endoscopically, a catheter with a 20 -cm-long balloon is advanced over a guidewire into the duodenum. Saline is injected into the submucosal layer to lift the duodenal mucosa distal to the ampulla of Vater, and the balloon is inflated with heated water to achieve circumferential duodenal ablation. The process is then repeated until the desired length of mucosal ablation is achieved, typically extending to the ligament of Treitz (see Fig. 1).

In the first pilot study of DMR, 39 patients with type 2 diabetes on oral hypoglycemic agents were included.⁶⁵ The length of treated duodenal mucosa ranged from 3 to 15 cm. At 6 months, the overall reduction in HbA1c was 1.2%, while TWL was minimal at around 3%. Duodenal stenosis occurred in 3 patients but resolved with balloon dilation. Subsequent studies have also demonstrated improvements in glycemic indices.^{66,67} A small study involving 36 patients showed sustained improvement in HbA1c at 12 months.⁶⁸ A recent multicenter, randomized, sham-controlled trial conducted in Brazil and Europe demonstrated an improvement in HbA1c of 10.4 mmol/mol at 24 weeks and a reduction in liver fat density of 5.4% at 12 weeks.⁶⁹ The majority of adverse events were mild. Currently, a multicenter pivotal trial is underway in the United States.

Duodenal-Jejunal Bypass Liner

Endobarrier (Morphic Medical, Boston, MA, USA.) is a duodenal-jejunal bypass liner (DJBL) designed to inhibit nutrient absorption in the proximal small bowel to induce

weight loss and improve type 2 diabetes.⁷⁰ The fluoropolymer liner is 60 cm long and is endoscopically anchored proximally at the duodenal bulb (see [Fig. 1](#)). The device mimics the roux limb in Roux-en-Y gastric bypass (RYGB), bypassing a portion of the small bowel. A metaanalysis of 4 studies with 301 patients with type 2 diabetes who underwent DJBL placement showed a TWL of 18.9% at 12 months.⁷¹ Additionally, there was a reduction in HbA1c of 1.3% and a decrease in HOMA-IR of 4.6. Other studies have also demonstrated improvements in HbA1c, fasting glucose, and insulin resistance.^{72–76} Furthermore, there appears to be an improvement in markers of liver steatosis at 48 weeks.⁷⁷ The original US pivotal trial (the ENDO trial) met its efficacy endpoints, with 60% of patients achieving greater than or equal to 5% TWL and 34.8% reaching a HbA1c of lesser than or equal to 7%, compared to 20% and 9.8% in the sham arm, respectively. However, the study was discontinued early by the company because of a 3.5% rate of hepatic abscess formation.⁷³ Currently, a new US pivotal multicenter trial for the DJBL is underway, incorporating several mitigation strategies to reduce the risk of hepatic abscesses.

DISCUSSION

Obesity is a complex, chronic, and relapsing disease. There has been impetus to prevent and treat obesity and related comorbidities given the significant effects it has on an individual and health care systems level. Central to the treatment of obesity, remains diet, exercise, and behavioral modification. Weight loss results however can be variable, modest, and often difficult to maintain over time. The most effective treatment for weight loss is bariatric surgery, but only a small fraction of patients choose surgery. EBMT has emerged as a minimally-invasive intervention for obesity and has greatly expanded the treatment options for patients with obesity.

The development of EBMT has largely predicated on what is known about the restrictive and malabsorption mechanism from bariatric surgery. This ranges from endoscopic gastric devices to create restriction by decreasing space in the stomach to small bowel devices that aim to decrease length of absorption. Several studies of EBMT have also suggested that endoscopic manipulations can result in modification of gastric motility and gut neuroendocrine signaling. These changes may underscore the weight loss durability of EBMT and improvement in metabolic parameters although further studies are warranted.

Several EBMT now have FDA approval and more have pending approval. Current bariatric devices and procedures in clinical use meets ASGE/ASMBS standards of EWL greater than 25% and serious adverse events less than 5%. Many of the EBMT in current use are able to achieve weight loss of 5% to 10% and has been associated with improvement in obesity-related comorbidities. The 2 most commonly used primary EBMT are IGBs and EGR. Both are outpatient procedures, which can be completed within 1 hour, require short recovery times, and have limited serious adverse events. Compared to bariatric surgery, endoscopic therapies are less invasive, reversible, repeatable, and cost-effective. Similarly, endoscopic revision using argon plasma coagulation (APC), suturing, and plications of RYGB and sleeve gastrectomy is a minimally-invasive approach that can result in similar weight loss as revisional bariatric surgery with potentially less risk for complications.

More studies are showing that combination therapy with endoscopic bariatric procedures and anti-obesity medications may lead to greater weight loss and be comparable even to primary bariatric procedures, while other studies have looked at endoscopic bariatric procedure serving as a bridge to bariatric surgery. In deciding which therapies to use for patients with obesity, a multidisciplinary team including

bariatric surgery, endocrinology, obesity medicine, nutritionist, behavioral psychologist, and bariatric endoscopist, should be considered in order to offer patients the best outcomes. In the future of obesity, treatment should be tailored to the individual and be personalized.

SUMMARY

Treating obesity can be challenging; however, significant strides have been made in obesity management over the past decades. EBMTs, a newer and evolving field, have expanded the range of treatment options. For patients seeking minimally-invasive solutions, EBMT offers an effective and durable option that should be considered. Patient preferences, goals, and comorbidities should be taken into account when selecting the most appropriate EBMT. Additionally, combining EBMT with other treatment modalities has been shown to improve weight loss outcomes. As obesity management continues to evolve, a multimodality and multidisciplinary approach remains essential to effectively address obesity and its complexities in the long term.

CLINICS CARE POINTS

- Endoscopic bariatric and metabolic therapies (EBMTs) should be considered in patients with a body mass index of greater than or equal to 30 kg/m² or 27 to 29.9 kg/m² with at least 1 obesity-related comorbidity.
- Currently available EBMTs are gastric interventions, including intragastric balloons (IGBs) and endoscopic gastric remodeling (EGR). At 1 year, IGBs achieve an average of approximately 10% total weight loss (TWL), while EGR results in approximately 20% TWL, with durability reported for EGR up to at least 5 years.
- Small bowel interventions, primarily aimed at improving metabolic outcomes, are currently under investigation in the United States.

DISCLOSURES

D. Bi: No disclosures. P. Jirapinyo has received research support from Boston Scientific, United States, Fractyl, GI Dynamics and USGI Medical, has served as a consultant to Boston Scientific, Cook Medical, ERBE, Fractyl, GI Dynamics, Madrigal and Spatz Medical, has served as a co-founder for Bariendo, and has received royalty from Endosim.

REFERENCES

1. Obesity and Overweight. World Health Organization; 2024. Available at: <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>.
2. Cawley J, Biener A, Meyerhoefer C, et al. Direct medical costs of obesity in the United States and the most populous states. *J Manag Care Spec Pharm* 2021; 27(3):354–66.
3. Okunogbe A, Nugent R, Spencer G, et al. Economic impacts of overweight and obesity: current and future estimates for 161 countries. *BMJ Glob Health* 2022; 7(9):e009773.
4. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2015; 100(2):342–62.

5. American College of Cardiology/American Heart Association Task Force on Practice Guidelines, Obesity Expert Panel, 2013. Executive summary: guidelines (2013) for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society published by the Obesity Society and American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Based on a systematic review from the The Obesity Expert Panel, 2013. *Obesity* (Silver Spring) 2014;22(Suppl 2):S5–39.
6. Wilding JPH, Batterham RL, Calanna S, et al. Once-weekly semaglutide in adults with overweight or obesity. *N Engl J Med* 2021;384(11):989–1002.
7. Husain M, Birkenfeld AL, Donsmark M, et al. Oral semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med* 2019;381(9):841–51.
8. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. *Gastroenterology* 2022;163(5):1198–225.
9. Jastreboff AM, Aronne LJ, Ahmad NN, et al. Tirzepatide once weekly for the treatment of obesity. *N Engl J Med* 2022;387(3):205–16.
10. Eisenberg D, Shikora SA, Aarts E, et al. Publisher correction: 2022 American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Indications for Metabolic and Bariatric Surgery [published correction appears in *Obes Surg* 2023;33(1):3–14]. *Obes Surg* 2023;33(1):15–6.
11. Campos GM, Khoraki J, Browning MG, et al. Changes in utilization of bariatric surgery in the United States from 1993 to 2016. *Ann Surg* 2020;271(2):201–9.
12. Sullivan S, Edmundowicz SA, Thompson CC. Endoscopic bariatric and metabolic therapies: new and emerging technologies. *Gastroenterology* 2017;152(7):1791–801.
13. Jirapinyo P, Thompson CC. Endoscopic bariatric and metabolic therapies: surgical analogues and mechanisms of action. *Clin Gastroenterol Hepatol* 2017;15(5):619–30.
14. Jirapinyo P, Hadeifi A, Thompson CC, et al. American Society for Gastrointestinal Endoscopy-European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity. *Endoscopy* 2024;56(6):437–56.
15. Hogan RB, Johnston JH, Long BW, et al. A double-blind, randomized, sham-controlled trial of the gastric bubble for obesity. *Gastrointest Endosc* 1989;35(5):381–5.
16. Gleysteen JJ. A history of intragastric balloons. *Surg Obes Relat Dis* 2016;12(2):430–5.
17. Muniraj T, Day LW, Teigen LM, et al. AGA clinical practice guidelines on intragastric balloons in the management of obesity. *Gastroenterology* 2021;160(5):1799–808.
18. Bazerbach F, Vargas EJ, Abu Dayyeh BK. Endoscopic bariatric therapy: a guide to the intragastric balloon. *Am J Gastroenterol* 2019;114(9):1421–31.
19. Mion F, Napoléon B, Roman S, et al. Effects of intragastric balloon on gastric emptying and plasma ghrelin levels in non-morbid obese patients. *Obes Surg* 2005;15(4):510–6.
20. Guedes MR, Fittipaldi-Fernandez RJ, Diestel CF, et al. Impact of intragastric balloon treatment on adipokines, cytokines, and metabolic profile in obese individuals. *Obes Surg* 2019;29(8):2600–8.
21. Shah RH, Vedantam S, Kumar S, et al. Intragastric balloon significantly improves metabolic parameters at 6 months: a meta-analysis. *Obes Surg* 2023;33(3):725–32.

22. Popov VB, Ou A, Schulman AR, et al. The impact of intragastric balloons on obesity-related co-morbidities: a systematic review and meta-analysis. *Am J Gastroenterol* 2017;112(3):429–39.
23. Ramai D, Singh J, Mohan BP, et al. Influence of the elipse intragastric balloon on obesity and metabolic profile: a systematic review and meta-analysis. *J Clin Gastroenterol* 2021;55(10):836–41.
24. Chandan S, Mohan BP, Khan SR, et al. Efficacy and safety of intragastric balloon (IGB) in NON-ALCOHOLIC FATTY LIVER DISEase (NAFLD): a comprehensive review and meta-analysis. *Obes Surg* 2021;31(3):1271–9.
25. Bazerbachi F, Vargas EJ, Rizk M, et al. Intragastric balloon placement induces significant metabolic and histologic improvement in patients with nonalcoholic steatohepatitis. *Clin Gastroenterol Hepatol* 2021;19(1):146–54.e4.
26. de Freitas J JR, Ribeiro IB, de Moura DTH, et al. Effects of intragastric balloon placement in metabolic dysfunction-associated fatty liver disease: A systematic review and meta-analysis. *World J Hepatol* 2021;13(7):815–29.
27. Courcoulas A, Abu Dayyeh BK, Eaton L, et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. *Int J Obes (Lond)* 2017;41(3):427–33.
28. Abu Dayyeh BK, Kumar N, Edmundowicz SA, et al. ASGE Bariatric Endoscopy Task Force and ASGE Technology Committee. ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. *Gastrointest Endosc* 2015;82(3):425–38.e5.
29. Ponce J, Woodman G, Swain J, et al. The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. *Surg Obes Relat Dis* 2015;11(4):874–81.
30. Agnihotri A, Xie A, Bartalos C, et al. Real-world safety and efficacy of fluid-filled dual intragastric balloon for weight loss [published correction appears in *Clin Gastroenterol Hepatol* 2018;16(9):1538]. *Clin Gastroenterol Hepatol* 2018;16(7):1081–8.e1.
31. Sullivan S, Swain J, Woodman G, et al. Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss. *Surg Obes Relat Dis* 2018;14(12):1876–89.
32. Abu Dayyeh BK, Maselli DB, Rapaka B, et al. Adjustable intragastric balloon for treatment of obesity: a multicentre, open-label, randomised clinical trial. *Lancet* 2021;398(10315):1965–73.
33. Genco A, Ernesti I, Ienca R, et al. Safety and efficacy of a new swallowable intragastric balloon not needing endoscopy: early Italian experience. *Obes Surg* 2018;28(2):405–9.
34. Alsabah S, Al Haddad E, Ekrouf S, et al. The safety and efficacy of the procedure-less intragastric balloon. *Surg Obes Relat Dis* 2018;14(3):311–7.
35. Jamal MH, Almutairi R, Elabd R, et al. The safety and efficacy of procedureless gastric balloon: a study examining the effect of elipse intragastric balloon safety, short and medium term effects on weight loss with 1-year follow-up post-removal. *Obes Surg* 2019;29(4):1236–41.
36. Ienca R, Al Jarallah M, Caballero A, et al. The procedureless elipse gastric balloon program: multicenter experience in 1770 consecutive patients. *Obes Surg* 2020;30(9):3354–62.
37. Marinos G, Eliades C, Raman Muthusamy V, et al. Weight loss and improved quality of life with a nonsurgical endoscopic treatment for obesity: clinical results from a 3- and 6-month study. *Surg Obes Relat Dis* 2014;10(5):929–34.

38. Transpyloric shuttle/ transpyloric shuttle delivery device instructions for use. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180024D.pdf.
39. Thompson CC, Dayyeh BKA, Kushner R, et al. 381 The AspireAssist is an effective tool in the treatment of class II and class III obesity: results of a one-year clinical trial. *Gastroenterology* 2016;150(4):S86.
40. Jirapinyo P, de Moura DTH, Horton LC, et al. Effect of aspiration therapy on obesity-related comorbidities: systematic review and meta-analysis. *Clin Endosc* 2020;53(6):686–97.
41. Brethauer SA, Chand B, Schauer PR, et al. Transoral gastric volume reduction for weight management: technique and feasibility in 18 patients. *Surg Obes Relat Dis* 2010;6(6):689–94.
42. Kumar N, Abu Dayyeh BK, Lopez-Nava BG, et al. Endoscopic sutured gastroplasty: procedure evolution from first-in-man cases through current technique. *Surg Endosc* 2018;32(4):2159–64.
43. Abu DBK, Acosta A, Camilleri M, et al. Endoscopic sleeve gastroplasty alters gastric physiology and induces loss of body weight in obese individuals. *Clin Gastroenterol Hepatol* 2017;15(1):37–43.e1.
44. Espinet-Coll E, Nebreda-Durán J, Galvao-Neto M, et al. Suture pattern does not influence outcomes of endoscopic sleeve gastroplasty in obese patients. *Endosc Int Open* 2020;8(10):E1349–58.
45. Abu Dayyeh BK, Rajan E, Gostout CJ. Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity. *Gastrointest Endosc* 2013;78(3):530–5.
46. Lopez-Nava G, Sharaiha RZ, Vargas EJ, et al. Endoscopic sleeve gastroplasty for obesity: a multicenter study of 248 patients with 24 months follow-up. *Obes Surg* 2017;27(10):2649–55.
47. Alqahtani A, Al-Darwish A, Mahmoud AE, et al. Short-term outcomes of endoscopic sleeve gastroplasty in 1000 consecutive patients. *Gastrointest Endosc* 2019;89(6):1132–8.
48. Sharaiha RZ, Hajifathalian K, Kumar R, et al. Five-year outcomes of endoscopic sleeve gastroplasty for the treatment of obesity. *Clin Gastroenterol Hepatol* 2021;19(5):1051–7.e2.
49. Singh S, Hounaux de Moura DT, Khan A, et al. Safety and efficacy of endoscopic sleeve gastroplasty worldwide for treatment of obesity: a systematic review and meta-analysis. *Surg Obes Relat Dis* 2020;16(2):340–51.
50. Abu Dayyeh BK, Bazerbach F, Vargas EJ, et al. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. *Lancet* 2022;400(10350):441–51.
51. Hajifathalian K, Mehta A, Ang B, et al. Improvement in insulin resistance and estimated hepatic steatosis and fibrosis after endoscopic sleeve gastroplasty. *Gastrointest Endosc* 2021;93(5):1110–8.
52. Nunes BCM, de Moura DTH, Kum AST, et al. Impact of endoscopic sleeve gastroplasty in non-alcoholic fatty liver disease: a systematic review and meta-analysis. *Obes Surg* 2023;33(9):2917–26.
53. Alqahtani AR, Elahmedi M, Alqahtani YA, et al. Laparoscopic sleeve gastrectomy after endoscopic sleeve gastroplasty: technical aspects and short-term outcomes. *Obes Surg* 2019;29(11):3547–52.
54. Beitner M, Hopkins G. Conversion of endoscopic sleeve gastroplasty to laparoscopic Roux-en-Y gastric bypass. *Surg Obes Relat Dis* 2020;16(4):590–1.

55. Espinós JC, Turró R, Mata A, et al. Early experience with the Incisionless Operating Platform™ (IOP) for the treatment of obesity: the Primary Obesity Surgery Endolumenal (POSE) procedure. *Obes Surg* 2013;23(9):1375–83.
56. Sullivan S, Swain JM, Woodman G, et al. Randomized sham-controlled trial evaluating efficacy and safety of endoscopic gastric plication for primary obesity: the ESSENTIAL trial. *Obesity (Silver Spring)* 2017;25(2):294–301.
57. Jirapinyo P, Thompson CC. Gastric plications for weight loss: distal primary obesity surgery endoluminal through a belt-and-suspenders approach. *VideoGIE* 2018;3(10):296–300.
58. Jirapinyo P, Thompson CC. Comparison of distal primary obesity surgery endolumenal techniques for the treatment of obesity (with videos). *Gastrointest Endosc* 2022;96(3):479–86.
59. Singh S, Bazarbashi AN, Khan A, et al. Primary obesity surgery endolumenal (POSE) for the treatment of obesity: a systematic review and meta-analysis. *Surg Endosc* 2022;36(1):252–66.
60. Espinós JC, Turró R, Moragas G, et al. Gastrointestinal physiological changes and their relationship to weight loss following the POSE procedure. *Obes Surg* 2016;26(5):1081–9.
61. Huberty V, Boskoski I, Bove V, et al. Endoscopic sutured gastropasty in addition to lifestyle modification: short-term efficacy in a controlled randomised trial. *Gut* 2020;gutjnl(2020):322026.
62. Gkolfakis P, Van Ouytsel P, Mourabit Y, et al. Weight loss after endoscopic sleeve gastropasty is independent of suture pattern: results from a randomized controlled trial. *Endosc Int Open* 2022;10(9):E1245–53.
63. Fractyl: Changing the Treatment Paradigm in Metabolic Disease. Available at: <https://www.fractyl.com>.
64. Fractyl Revita System. Available at: <https://www.discoverrevita.co.uk/wp-content/uploads/2019/10/Fractyl-Instructions-for-use-leaflet.pdf>.
65. Rajagopalan H, Cherrington AD, Thompson CC, et al. Endoscopic duodenal mucosal resurfacing for the treatment of type 2 diabetes: 6-month interim analysis from the first-in-human proof-of-concept study. *Diabetes Care* 2016;39(12):2254–61.
66. Galvao Neto M, Rodriguez L, Becerra P, et al. Hydrothermal duodenal mucosal resurfacing: a novel procedural therapy for metabolic disease. *VideoGIE* 2016;1(1):10–1.
67. de Moura EGH, Ponte-Neto AM, Tsakmaki A, et al. Histologic assessment of the intestinal wall following duodenal mucosal resurfacing (DMR): a new procedure for the treatment of insulin-resistant metabolic disease. *Endosc Int Open* 2019;7(5):E685–90.
68. van Baar ACG, Holleman F, Crenier L, et al. Endoscopic duodenal mucosal resurfacing for the treatment of type 2 diabetes mellitus: one year results from the first international, open-label, prospective, multicentre study. *Gut* 2020;69(2):295–303.
69. Mingrone G, van Baar AC, Devière J, et al. Safety and efficacy of hydrothermal duodenal mucosal resurfacing in patients with type 2 diabetes: the randomised, double-blind, sham-controlled, multicentre REVITA-2 feasibility trial. *Gut* 2022;71(2):254–64.
70. GI Dynamics: EndoBarrier. Available at: <https://gidynamics.com>.
71. Jirapinyo P, Haas AV, Thompson CC. Effect of the duodenal-jejunal bypass liner on glycemic control in patients with type 2 diabetes with obesity: a meta-analysis

- with secondary analysis on weight loss and hormonal changes. *Diabetes Care* 2018;41(5):1106–15.
72. Rodriguez L, Reyes E, Fagalde P, et al. Pilot clinical study of an endoscopic, removable duodenal-jejunal bypass liner for the treatment of type 2 diabetes. *Diabetes Technol Ther* 2009;11(11):725–32.
 73. Gersin KS, Rothstein RI, Rosenthal RJ, et al. Open-label, sham-controlled trial of an endoscopic duodenojejunal bypass liner for preoperative weight loss in bariatric surgery candidates. *Gastrointest Endosc* 2010;71(6):976–82.
 74. Koehestanie P, de Jonge C, Berends FJ, et al. The effect of the endoscopic duodenal-jejunal bypass liner on obesity and type 2 diabetes mellitus, a multicenter randomized controlled trial. *Ann Surg* 2014;260(6):984–92.
 75. Schouten R, Rijs CS, Bouvy ND, et al. A multicenter, randomized efficacy study of the EndoBarrier Gastrointestinal Liner for presurgical weight loss prior to bariatric surgery. *Ann Surg* 2010;251(2):236–43.
 76. Tarnoff M, Rodriguez L, Escalona A, et al. Open label, prospective, randomized controlled trial of an endoscopic duodenal-jejunal bypass sleeve versus low calorie diet for pre-operative weight loss in bariatric surgery. *Surg Endosc* 2009;23(3):650–6.
 77. Karlas T, Petroff D, Feisthammel J, et al. Endoscopic bariatric treatment with duodenal-jejunal bypass liner improves non-invasive markers of non-alcoholic steatohepatitis. *Obes Surg* 2022;32(8):2495–503.