Curr Treat Options Gastro (2023) 21:172–184
DOI 10.1007/s11938-023-00420-6

Endobariatrics: a Still Underutilized Weight Loss Tool

Niel Dave, MD[1*,]
Enad Dawod, MD[2]
Okeefe L. Simmons, MD[3,4]

Address
[*,1]Division of Gastroenterology at HCA Florida Aventura Hospital, 20900 Biscayne Blvd, Aventura, FL 33180, USA
Email: nield91@gmail.com
[2]Division of Gastroenterology, Weill Cornell Medicine, New York Presbyterian Hospital, 1305 York Avenue, 4th Floor, New York, NY 10021, USA
[3]Simmons MD Advanced Weight Loss Solutions, 2820 NE 214th Street, Suite 1002, Miami, FL 33180, USA
[4]Division of Gastroenterology, Miami Veterans Affairs Healthcare System, 1201 NW 16th Street, Miami, FL 33125, USA

Published online: 6 May 2023

Keywords Bariatric · Obesity · Endoscopy · Intragastric balloons (IGB) · Transpyloric shuttle (TPS) · Aspiration therapy (AT) · Primary obesity surgery endoluminal (POSE) · Duodenal mucosal resurfacing · Endoscopic sleeve gastroplasty

Abstract

Purpose of review Bariatric and metabolic endoscopic therapies provide an option for patients seeking clinically significant weight loss with fewer adverse events than conventional bariatric surgery. Our aims are to provide an overview of the current state of primary endoscopic treatment options for weight loss and to emphasize the importance of including these therapies when presenting weight loss options to qualified patients.
Recent findings Bariatric endoscopy procedures are associated with a lower adverse event rate when compared to bariatric surgery and result in more weight loss than most existing pharmacotherapies approved by the Food and Drug Administration.
Summary Sufficient evidence exists to implement bariatric endoscopic therapies—namely, the intragastric balloon and endoscopic sleeve gastroplasty—as safe and effective treatment options for weight loss when used in combination with lifestyle changes. However, bariatric endoscopy remains an underutilized option by weight management providers. Future studies are needed to identify patient and provider-level barriers to adopting endoscopic bariatric therapies as an option for the treatment of obesity.

Introduction

Over 40% of the USA population has obesity, which has resulted in an estimated 173 billion dollars annually spent on obesity-related healthcare expenses [1]. Diet and lifestyle modifications, in combination with pharmacotherapy or bariatric surgery, have been the mainstay of obesity treatment. Despite advancements in surgical technique and anti-obesity pharmacotherapy, many patients continue to have difficulty achieving significant weight loss while avoiding potential surgery-related adverse events. Although bariatric surgery results in the most weight loss among current obesity treatment options, there are a number of patient and provider-related factors, including surgical cost and adverse event rate, that have limited the uptake of bariatric surgery relative to the population in the USA who qualify for surgery. With the exception of semaglutide, most approved anti-obesity medications result in 5–10% total body weight loss (TBWL) [2•]. For the subset of patients who successfully achieve at least 10% TBWL, many struggle to maintain this weight loss [2•, 3].

The development and growth in the field of bariatric endoscopy offers providers another option in the treatment algorithm for weight management (Table 1). Endoscopic bariatric therapies, such as the intragastric balloon (IGB) and endoscopic sleeve gastroplasty (ESG), describe a group of minimally invasive procedures associated with significant weight loss and an improvement in obesity-related comorbidities. When compared to bariatric surgery and anti-obesity pharmacotherapy, the field of bariatric endoscopy has evolved recently with multiple changes in areas including Food and Drug Administration (FDA) procedure and device approval (Table 2), FDA authorization, and more available outcome data. We aim to provide an overview of the current state of primary bariatric and metabolic endoscopic therapies and to address the underutilization of these effective anti-obesity treatment options.

Intragastric balloons (IGB)

Intragastric balloons are among the most widely utilized endobariatric interventions. IGB are devices that are endoscopically placed or swallowed and are either gas filled or fluid filled. The balloon occupies

Table 1. Weight loss interventions and the indications which warrant their use

Intervention	Indication for use
Medications	• BMI ≥ 27 kg/m^2 with comorbidities* • BMI ≥ 30 kg/m^2 with failure of lifestyle modifications at 6 months
Endobariatrics	• BMI ≥ 30 kg/m^2 • BMI ≥ 35 kg/m^2 without comorbidities* • BMI ≥ 35 kg/m^2 with comorbidities* but are not surgical candidates
Bariatric surgery	• BMI ≥ 35 kg/m^2 with comorbidities* • BMI ≥ 40 kg/m^2

*Comorbidities include heart disease, hypertension, diabetes, sleep apnea, fatty liver, polycystic ovarian syndrome, dyslipidemia, congestive heart failure, and osteoarthritis

Table 2. FDA approved/authorized/evolving endoscopic devices/procedures

Device/procedure	FDA approval or authorization	Company
Intragastric balloon	*2015 (Orbera) *2016 (Obalon)	Apollo Endosurgery, Inc. (Austin, TX) Obalon Therapeutics (Carlsbad, CA)
Transpyloric shuttle	*2019 (Transpyloric Shuttle)	BAROnova (San Carlos, CA)
Aspiration therapy	*2016 (AspireAssist) Stopped commercial sales in 2019	Aspire Bariatrics, Inc. (King of Prussia, PA)
Endoscopic sleeve gastroplasty (^Overstitch)	#2022 (Apollo ESG)	Apollo Endosurgery, Inc. (Austin, TX)
Duodenal mucosal resurfacing (+Revita DMR)		Fractyl Health, Inc. (Lexington, MA)
Primary surgery obesity endoluminal (+POSE)		USGI Medical (San Clemente, CA)
Endoluminal duodenal-jejunal bypass liner (+EndoBarrier)		GI Dynamics, Inc. (Boston, MA)

^Overstitch device is FDA approved for tissue approximation. *FDA approved. #FDA authorized. +Evolving technologies not yet FDA approved.

approximately one third of the stomach leading to physiologic changes including delayed gastric emptying, increased satiety, and the alteration of key hormones (such as cholecystokinin and possibly ghrelin) [4, 5]. Candidates for IGB placement have a body mass index (BMI) of at least 30 kg/m^2 and failed lifestyle modifications with diet and exercise. Absolute contraindications to IGB placement include history of gastrointestinal surgery, hiatal hernia larger than 5 cm, upper gastrointestinal lesions high risk for bleeding, pregnancy, breastfeeding, coagulopathy, or cirrhosis [6–9]. The device remains in the stomach for a 6-month duration, after which it must be endoscopically removed. In 1991, Orbera was the first available IGB. Among IGBs, Orbera is the most commonly used and is the primary source of available data on IGB [10–14]. The procedure-less balloons (Obalon and Elipse) are compressed and fitted into capsules allowing the patient to easily swallow them. The Obalon has a small catheter connected to it which allows for automated balloon inflation and the Elipse spontaneously inflates within the stomach. The endoscopically placed IGBs tend to have saline or air and range from 300 to 1000 ml in volume whereas the swallowable forms contain nitrogen gas or liquid and range from 550 to 750 ml in volume [15].

In an American Gastroenterological Association (AGA) review of data from 12 RCTs, significant weight loss was shown in patients who had an IGB compared to standard of care (i.e., lifestyle modification) [7, 14, 16–22]. Significant excess weight loss (EWL) was seen in the IGB group compared to standard of care (SOC): 21–50% vs. 4–18% at 6 months (CI: 14–23%) and 27–39% vs. 5–19% at 9 months (CI: 16–25%). Among patients with an IGB placed for 6–8 months, 71–85% of patients experienced 5% total body weight loss (TBWL) and 41–61% achieved 10% TBWL [7, 14, 16–22]. IGBs have also been associated with significant improvements in markers of obesity-associated metabolic changes including insulin resistance, hepatic steatosis, and hypertriglyceridemia [16, 19, 22–24, 25•, 26]. Finally, one may question the effectiveness of the procedure-less balloons compared to those endoscopically placed; however, a systematic review and meta-analysis on the Elipse suggested these balloons were just as effective; the pooled %TBWL at 4–6 months was 12.8% (CI: 11.6–13.9%) and 10.9% at 12 months (CI: 5–16.9%) [27•].

IGBs have proven safety data. A meta-analysis showed a premature removal rate of IGB of approximately 4% and the most common adverse events were mild [25•]. Pooled data from 10 RCTs demonstrated that 9% of patients with IGBs required premature removal with the most common indication being gastrointestinal-related symptoms (e.g., nausea, vomiting, abdominal pain) [7, 12, 14, 16–22, 28]. In April 2020, the FDA issued a letter explaining potential risks associated with IGBs including the possibility of acute pancreatitis, balloon hyperinflation, or death. These complications were rare (0–1.3% rate) and reported prior to FDA approval [29].

Endoscopic sleeve gastroplasty

Endoscopic sleeve gastroplasty has emerged as an effective therapeutic option for the treatment of obesity. The safety and efficacy of ESG have been proven in several retrospective studies and recently in a multicenter randomized clinical trial [30, 31••, 32–35]. Although the greatest weight loss is seen with bariatric surgery, only 1% of qualified patients undergo bariatric surgery due to factors including issues with insurance coverage, limited patient/provider knowledge, and concerns of the safety and efficacy [36, 37]. Generally, patients must have a BMI of at least 30 kg/m^2 to be considered for an ESG. During the ESG, an FDA-approved full-thickness endoscopic suturing device (Overstitch; Apollo Endosurgery, Austin, TX, USA) is used to approximate the anterior and posterior gastric walls to reduce the luminal volume (Fig. 1) [33, 38–40]. This gastric luminal reduction leads to decreased caloric intake, delayed gastric emptying, and favorable changes in gastrointestinal and metabolic hormones [41–44, 45•].

In a 2019 meta-analysis by Hedjoudje et al., TBWL persisted for up to 18–24 months following ESG [43]. A mean TBWL of 15.1% was achieved in 6 months and at 17.2% TBWL was seen at 18–24 months. In addition, subjects had a 6.5 kg/m^2 decrease in their BMI and a relative excess weight loss (EWL) of 66.9% at 24 months. Long-term results up to 5 years after the procedure were shown by Sharaiha et al. in a prospective cohort study of 216 patients who underwent ESG [46••]. At 5 years, mean TBWL was 15.9% ($p < 0.001$); 90% of patients maintained 5% TBWL and 61% of patients maintained 10% TBWL.

Studies have compared the efficacy and safety of LSG and ESG. Participants in a 2:1 (83 LSG:54 ESG) matched control (age, sex, and body mass index) study by Fayad et al. had 17.1% TBWL at 6 months in the ESG group

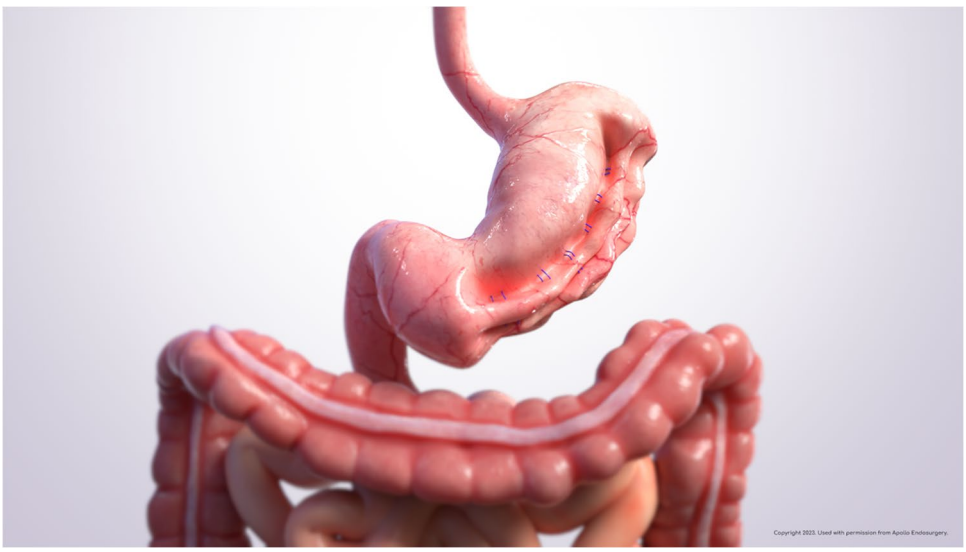

Fig. 1 Stomach appearance after ESG. Copyright with the permission of Apollo Endosurgery

compared to 23.6% TBWL in the LSG group ($p < 0.01$) [47]. Adverse events were reported in 5.2% of patients in the ESG group compared to 16.9% in the LSG group ($p < 0.05$). Notably, a lower proportion of patients who underwent ESG had new-onset GERD (1.9% vs. 14.5%, $p = 0.05$) [46••]. A recent comparative meta-analysis of 6775 patients with obesity demonstrated that, although ESG is associated with clinically significant weight loss, the % TBWL is less compared to LSG with a pooled mean difference of − 7.63% in favor of LSG [37]. There were fewer adverse events, including GERD symptoms, in the ESG group. In 2018, Novikov et al. published a study comparing 12-month outcomes of 278 patients who underwent ESG or bariatric surgery [48]. Patients were divided into 3 groups: ESG ($n = 91$), LSG ($n = 120$), or laparoscopic adjustable gastric banding LAGB ($n = 67$). The LSG cohort had the highest %TBWL (29.28%) when compared to ESG (17.57%) and LAGB (13.3%) ($p < 0.001$). The ESG group had significantly less morbidity ($p = 0.01$) than both surgical groups and a decreased length of stay (ESG: 0.34 vs. LSG: 3.09 vs. LAGB: 1.66 ± days) ($p < 0.01$) [48].

A study published in 2020 by Hajifathalian et al. assessed the impact of ESG on insulin resistance, estimated hepatic steatosis, and fibrosis [45•]. One-hundred and eighteen patients with nonalcoholic fatty liver disease (NAFLD) who underwent ESG were included in the study. HOMA-IR (Homeostatic Model Assessment for Insulin Resistance), a marker of insulin resistance, decreased by 6.1 at 1 week following the procedure. The improvement in HOMA-IR was sustained at a 2-year follow-up [45•].

Recently, the first prospective, multicenter, randomized trial of endoscopic sleeve gastroplasty for treatment of class 1 and class 2 obesity—the MERIT trial—was published [31••]. At 52 weeks, the mean % EWL in the ESG group ($n = 85$) was 49.2%, compared to 3.2% for the control group ($n = 124$) ($p < 0.0001$). The % TBWL was 13.6% in the ESG group and 0.8% in the control group ($p < 0.0001$). Favorable changes in metabolic comorbidities were seen in 80% of the ESG subjects.

EndoBarrier

EndoBarrier is an endoluminal duodenal-jejunal bypass liner (DJBL). The device consists of a polymer sleeve anchored in the first part of the duodenum by a nitinol stent [49]. The anchored device works as a barrier to prevent ingested food from interfacing with the mucosa of the proximal upper intestine. Much like the duodenal-jejunal exclusion portion of gastric bypass surgery, EndoBarrier results in beneficial metabolic effects on glucose metabolism. However, this is achieved without having to undergo invasive surgery, thus avoiding the possible long-term complications of surgically altered gastrointestinal anatomy. The few randomized controlled trials evaluating the efficacy of the EndoBarrier have highlighted its efficacy and safety [50–52]. Recently, a study by Ruban et al. demonstrated that 24% of patients who underwent DJBL with intensive medical care achieved ≥ 15% weight loss, compared to 4% in the control group. The DJBL

group also had significantly greater improvement in systolic blood pressures, liver enzymes, and cholesterol at 12 months [51].

DMR

Duodenal mucosal resurfacing (DMR) is an emerging endoscopic procedure shown to improve glycemic control in patients with type 2 diabetes mellitus (T2D) independent of weight loss. During the procedure, a catheter is used to achieve circumferential duodenal mucosal lifting, followed by hydrothermal ablation of the lifted mucosa [53]. One international multicenter, open-label study assessed the safety and feasibility of DMR, as well as its effect on glucose levels at 24 weeks and 12 months [53]. In this study of patients with diabetes mellitus on oral glucose-lowering medications, DMR was found to be an effective and safe procedure that resulted in a sustained improvement in glycemic control (hemoglobin A1c at 24 weeks: -10 ± 2 mmol/mol, $p < 0.001$). Statistically significant weight loss (-2.5 kg, $p < 0.001$) at 24 weeks was shown, and the improvement in glycemic control was independent of weight loss [53–55].

Gastric aspiration therapy (AT)

In 2016, the FDA approved aspiration therapy (AT) as a treatment for obesity. AT involves placing a specialized gastrostomy tube to allow patients to drain gastric contents 20 min after each meal. This enables patients to remove one third of ingested calories. A multicenter RCT that followed patients undergoing AT over 4 years showed a significant and sustained %TWL across all time periods: 14.2% at 1 year, 15.3% at 2 years, 16.6% at 3 years, and 18.7% at 4 years. Nearly 70% of subjects attained 10% or more %TWL at the termination of the study [56]. Another 52-week clinical trial found that 58.6% of patients who underwent AT lost at least 25% of their excess body weight compared to 15.3% of those in the SOC group [57]. However, as of April 2022, the AspireAssist device is no longer on the market. Aspire Bariatrics Inc. terminated production due to the financial impact of the coronavirus-19 pandemic.

Transpyloric shuttle (TPS)

The transpyloric shuttle (TPS) is a device placed endoscopically containing 2 silicon bulbs (1 small and 1 large) fastened by a tether. The larger bulb is inflated by its internal coil and the device remains in the stomach for 12 months. As the patient eats, peristalsis propels the device toward the pylorus causing temporary obstruction, delayed gastric emptying, and decreased caloric consumption. The device was FDA approved in April 2019 after results from the ENDObesity II trial were published. In this trial, patients

with a TPS experienced 9.3% TBWL (vs. 2.8% in controls), and 40% achieved 10% or more %TBWL (vs. 14% in controls) at 1 year [58]. Another smaller study showed 14.5% TBWL at 6 months (59). The most common side effect was mild gastrointestinal distress. Overall, 2.82% of the TPS population suffered a serious adverse event (SAE) with the most common being device impaction (1.97%) [58].

Primary surgery obesity endoluminal (POSE)

Primary surgery obesity endoluminal (POSE) is an endoscopic procedure which involves creating plications (folds) from the gastric fundus to the distal body. The procedure results in reduced stomach volume, delayed gastric emptying, and a favorable hormonal response (reduced ghrelin, increased neuropeptide YY, and improved glucose/insulin ratio) [59]. The current data available suggests that POSE induces 5–19% TBWL at 6–15 months [59–61, 62•, 63]. A meta-analysis reported an average of 13% TBWL at 12–15 months [63]. The most common adverse events were nausea, vomiting, and pain within 1–2 weeks of the procedure. Furthermore, nearly all of these symptoms resolved within 30 days (9). Although POSE is not currently FDA approved, the FDA did approve the expansion of a study involving a novel technique known as POSE II. During POSE II, plications are placed from the incisura to the proximal body of the stomach creating a smaller and shorter gastric reservoir then that seen with POSE.

Utilization of bariatric endoscopy procedures

The availability and uptake of primary bariatric endoscopy procedures as a tool for weight loss by physicians has remained suboptimal. Despite the advances in procedural technique, FDA approval/authorization of select devices (Table 2), and additional outcome data proving safety and efficacy, there remain barriers to adopting these procedures in the weight loss algorithm. Familiarity with the data supporting these procedures as effective options for weight loss and improvement in markers of metabolic health, concern about the relative novelty of the field when compared to bariatric surgery and anti-obesity pharmacotherapy, and costs likely represent a few of the patient and provider-level barriers impacting the growth of bariatric endoscopy procedures as a primary option for weight loss.

A 5-year analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) registry showed a decline in use of IGBs from 2016 (953 cases) to 2019 (418 cases) [64]. Of note, data in the MBSAQIP registry is primarily provided by surgeons, while bariatric endoscopy procedures are performed by both gastroenterologists and surgeons. IGBs result in clinically significant weight loss effective weight loss; however, there is widespread concern regarding the trend toward weight

regain after the balloon is removed (Fig. 2). Studies examining the benefit of combination therapy—the IGB and anti-obesity pharmacotherapy—have attempted to address the concern about weight regain. Anti-obesity medication, such a liraglutide, used in combination with the IGB resulted in additional weight loss and more durable weight loss [25•, 65•]. As more effective anti-obesity medications, such as semaglutide, become more available, a combination approach with bariatric endoscopy procedures may represent the best non-surgical approach for weight loss for select patients. Weight loss resulting from the IGB remaining in the stomach for less than a year has also been used to benefit patients as a "bridge" to bariatric surgery. In one study, patients who had an IGB prior to laparoscopic gastric bypass had fewer intraoperative complications, postoperative complications, and hospitalization days than those who underwent surgery without IGB placement [26, 66, 67]. An additional barrier with IGB utilization is the cost and poor insurance coverage for this procedure at this time. The average cost of IGB placement is $8000 (6).

ESG is a durable, effective weight loss option that fills a widely recognized gap in the management of obesity, as it results in clinically significant weight loss with fewer adverse events than bariatric surgery. Barriers to more widespread use, such as physician and provider awareness of the benefits associated with the procedure and high cost, are similar to those seen with the IGB. The cost of ESG is variable, and accessibility to patients is limited due to the restrictive insurance coverage. Although ESG has proven durability with weight loss, similar to IGB it is likely that additional weight loss and metabolic benefits are seen when ESG is combined with anti-obesity pharmacotherapy. Unlike IGB placement and removal, performing an ESG is more technically challenging. The technical difficulty and few opportunities for formal training at academic medical centers in the USA have resulted in few qualified providers offering this procedure.

Investigational gastric and small bowel therapies are limited by the few physicians who have the expertise and specialized clinical training to perform

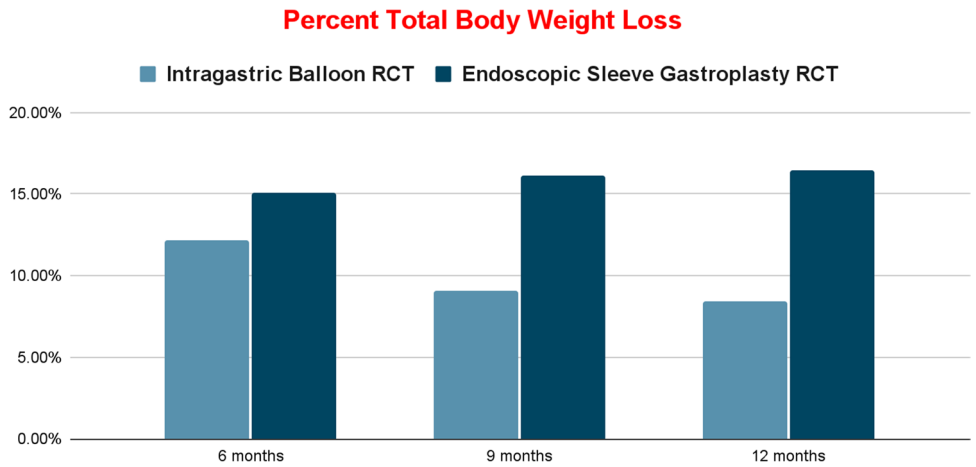

Fig. 2 Pooled weighted-mean %TBWL from two different RCTs at 6, 9, and 12 months in patients who received IGB or ESG (12, 13)

these procedures and the lack of FDA approval. POSE and POSE II offer promising results with clinically significant weight loss. Available data suggests that endoscopic small bowel therapies offer promising alternatives for patients with metabolic comorbidities that are not adequately managed with pharmacotherapy or those who do not undergo bariatric surgery.

Conclusion

There have been significant advancements made in the field—including FDA approval of three intragastric balloons, the transpyloric shuttle, and FDA authorization of the endoscopic sleeve gastroplasty during the last 5 years. However, despite proven weight loss efficacy and safety data, there remains widespread underutilization of these procedures to address the worsening obesity pandemic. The IGB and ESG have the most available data, yet patient and provider barriers continue to hinder physicians from adopting these valuable options into their weight loss algorithm. Suspected barriers include awareness, availability of qualified providers, cost, and lack of insurance coverage. The first step is to conduct formal studies to identify these barriers. Only then can we implement strategies to mitigate these obstacles and make strides toward the ultimate goal of advancing obesity care.

Declarations

Conflict of Interest
Niel Dave declares that he has no conflict of interest. Enad Dawod declares that he has no conflict of interest. Okeefe L. Simmons declares that he has no conflict of interest.

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This study demonstrates the favorable effect of ESG on the metabolic profile in patients with obesity.

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