

Figure 1. Large-capacity intragastric balloon after deployment. Balloon is filled with a mixture of saline solution and methylene blue.

provement in hepatic steatosis²⁰ and obstructive sleep apnea,²¹ and a significant reduction in hemoglobin A1c levels in those who lost weight.^{18,22} Finally, a small uncontrolled study found that weight loss caused by preoperative BIB therapy may reduce the rate of conversion of laparoscopic gastric banding to open surgery and decreased intraoperative complications.²³

There are 2 published randomized, clinical trials of the BIB, and they are limited by small sample size and short follow-up. One study randomized 23 patients to sham treatment and 20 patients to a balloon treatment group for 3 months. There was no difference in weight loss between the groups.²⁴ No major complications were noted in this study. A subsequent double-blind, randomized, sham-controlled study allocated 32 patients to a BIB or sham procedure followed by crossover after 3 months.²⁵ Patients receiving active treatment during the first 3 months had greater decrease in mean BMI (5.8 kg/m² vs 4 kg/m², $P < .001$). After crossover, the balloon group again had a greater decrease in mean BMI (5.1 kg/m² vs 1.1 kg/m², $P < .001$). No complications were reported. A meta-analysis including 30 studies (18 prospective and 12 retrospective) and a total of 4877 patients found that the

overall short-term (after 6 months) weight loss was 17.8 kg (mean 4.9–28.5 kg) after BIB placement.²⁶

There are 2 case series that include follow-up beyond 1 year. In 1 series, 100 consecutive patients were followed for a mean of 4.8 years; the BIB was removed at 1 year. Weight loss that was 10% or greater that baseline and sustained at 2.5 years was achieved in 24% of individuals.²⁷ A prospective, nonrandomized study of 118 patients reported 5-year follow-up after single versus repeated BIB placement. The single treatment group had balloon in place for 6 months, and the repeat treatment group had the balloon placed immediately after the first balloon removal ($n = 8$) or after IGB-free interval ($n = 11$, median IGB-free interval of 16.3 months). Compared with subjects with a single treatment ($n = 99$), those with repeat treatment ($n = 19$) had greater weight loss in kilograms at 1 year (12.0 kg vs 6.0 kg) and excess weight loss (percentage of EWL calculated by dividing actual weight loss by ideal weight loss) (40.9% vs 20.8% EWL; $P = .008$), but the difference became less than 2 kg starting at 3 years.²⁸

Taken together, these studies suggest that BIB placement can result in short-term weight loss in the range of 14 to 18 kg in 6 months, but the weight loss does not appear to last, and 20% to 40% of patients fail to achieve significant weight loss.

OTHER IGBs

Other available IGBs include the Heliosphere (IHB) (Helioscopie, Vienne, France), Silimed (Silimed, Rio de Janeiro, Brazil), and Semstationary Antral Balloon (JP Industria Farmaceutica, Ribeirao Preto, Brazil). The placement of the IHB is similar to that of the BIB except that the balloon is inflated with air. Data regarding the efficacy and safety of IHB are limited.^{29–31} In the largest published study, which included 82 consecutive patients and a median follow-up of 182 days, 70% achieved more than 10% body weight loss. There are very few data on the other 2 IGBs to date.³²

Comparison of IGBs

There is a single study comparing the BIB and IHB. In this prospective, double-blind study, 18 patients were randomized to IHB and 15 to BIB. Weight loss was similar in both groups at 6 months.³³

Complications of IGBs

Complications of IGBs reported in a large case series and a meta-analysis include esophagitis (1.27%), gastric perforation ($\leq 0.21\%$), gastric outlet obstruction (0.76%), gastric ulcer (0.2%), balloon rupture (0.36%), and death (0.07%).^{10,26}

Other reported complications of the BIB include esophageal perforation,³⁴ small-bowel obstruction requiring surgery,^{35–37} and 1 case report of cardiac arrest after BIB

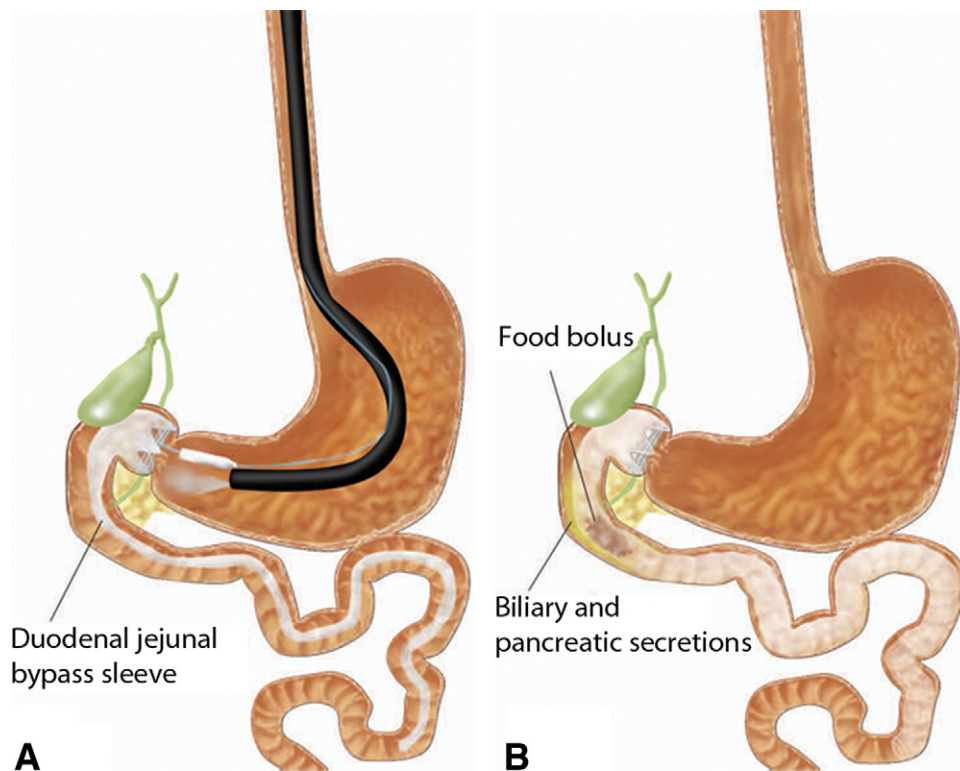


Figure 2. A, Duodenojejunal bypass sleeve is deployed over a guidewire and anchored in the duodenum under direct visualization. **B,** The sleeve creates a barrier to absorption and also delays mixing of food with biliary and pancreatic secretions.

placement, which was thought to be secondary to vagal nerve activation caused by stretching of the gastric wall.³⁸ Among 82 patients who underwent IHB placement, nausea and vomiting during the first week of insertion occurred in 7.4% of patients. Two (3%) spontaneous deflations without migration were noted, but only 1 early surgical removal (1.2%) was required.³²

DUODENOJEJUNAL BYPASS SLEEVE

The first strictly endoluminal implant that effectively bypasses the proximal small intestine is the duodenojejunal bypass sleeve (DJBS), also known as Endobarrier Gastrointestinal Liner (GI Dynamics Inc, Lexington, Mass). The device is a 60-cm long, impermeable plastic sleeve that is anchored in the duodenal bulb and extends into the proximal jejunum. Because the sleeve covers the duodenum and a portion of the jejunum, it creates a barrier to absorption and delays the mixing of food with pancreaticobiliary secretions (Fig. 2). The sleeve system is passed over a guidewire, and then, under direct visualization, it is fully deployed in the duodenal bulb to anchor the device. It may be removed by grasping the polypropylene drawstring with a custom device. It is withdrawn with the aid of a foreign-body retrieval hood to avoid trauma to the stomach or esophagus.

A multicenter study randomized 30 patients to DJBS and 11 to low-calorie diet alone. In a per-protocol analysis,

the mean percentage of EWL after 3 months was 19.0% for device patients compared with 6.9% for control patients ($P < .002$).³⁹ In a prospective, sham-controlled, single-blind trial randomizing 13 patients to DJBS and 24 to a sham procedure, weight loss at 12 weeks was significantly greater in the treatment group (8.2 kg vs 2.1 kg, $P < .05$).⁴⁰ Eight of 13 DJBS subjects were terminated early because of side effects including GI bleeding, abdominal pain, nausea, and vomiting.

In a small study of 10 patients who underwent placement of DJBS modified with a proximal flow restrictor of a 4-mm diameter, the percentage of EWL was 40% at 24 weeks. Episodes of nausea, vomiting, and abdominal pain required endoscopic dilation of the restrictor orifice in 8 patients, with no clinically significant adverse events.⁴¹

These small studies suggest that DJBS may be effective in achieving weight loss but appears to be poorly tolerated in its current design. Larger trials with longer follow-up are needed.

ENDOLUMINAL RESTRICTIVE PROCEDURES

Gastroplasty decreases gastric volume to induce weight loss. The available devices for endoluminal gastroplasty are the EndoCinch Suturing System (C.R. Bard, Murray Hill, NJ) and the Transoral Gastroplasty System (TOGA) (Satiety, Inc, Palo Alto, Calif). The Trans-oral Endoscopic Restrictive Implant System (TERIS; BaroSense,

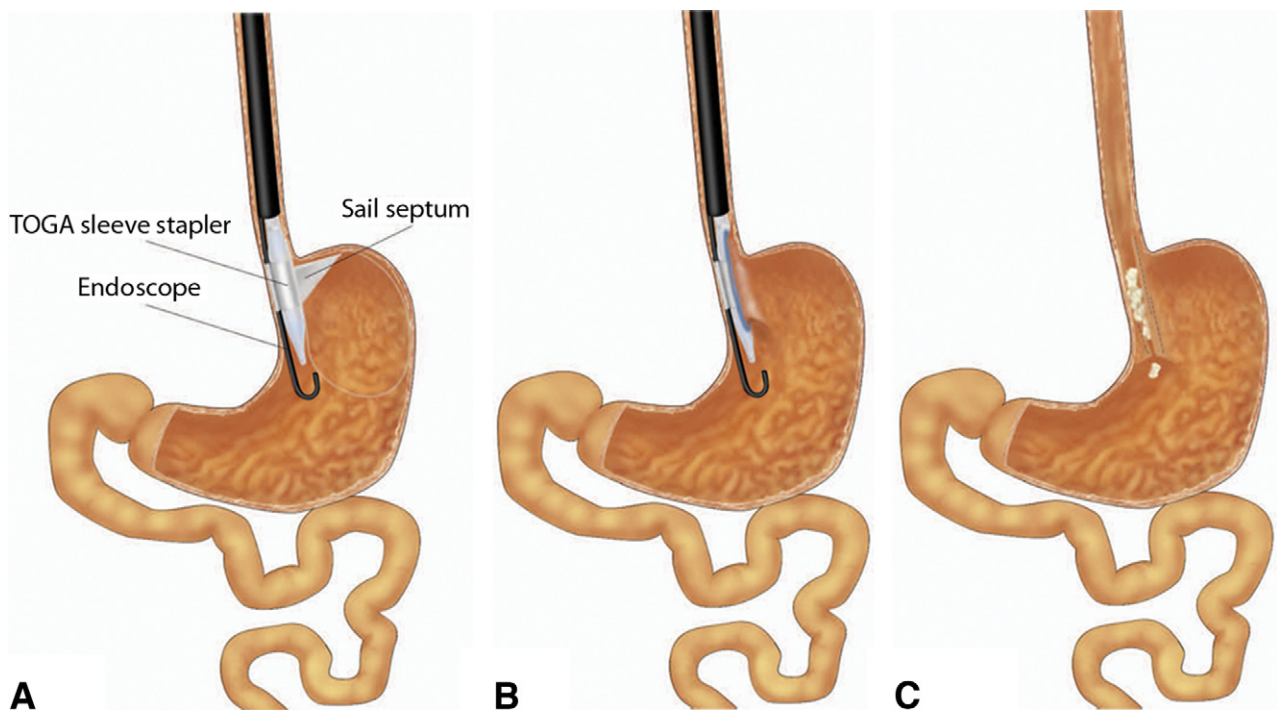


Figure 3. **A**, The TOGA device. A “sail septum” is used to keep the stomach in the desired position for the procedure. **B**, Gastric mucosa being suctioned into the TOGA device to create restrictive pouch. **C**, restrictive pouch.

Redwood City, CA) restricts oral intake via an implantable diaphragm.

EndoCinch, originally developed as an endoscopic treatment for GERD, is a suturing device that is mounted on the tip of the endoscope. This overtube-based device uses a suction chamber to capture the gastric wall and creates pleats using tagged sutures to reduce gastric volume. A mean EWL of 21% at 1 month and 58% at 12 months was achieved in 64 patients who underwent the procedure.⁴² Eleven of 14 patients who underwent follow-up endoscopy had intact plication sutures.

The TOGA system is an endoscopic full-thickness stapling device that allows exclusion of much of the stomach by creating a narrow gastric sleeve (Fig. 3). It is composed of a flexible 18-mm shaft device that is introduced into the proximal stomach over a guidewire. The endoscope is passed through a special channel within the shaft. Once its position is confirmed endoscopically, a “sail septum” is deployed to stabilize the anterior and posterior walls of the body and greater curvature and prevent their incorporation into the sleeve. Suction pods located within the stapling device are activated, bringing lesser curvature tissue within the jaws of the device. The stapler is then fired, creating the narrow sleeve, and the maneuvers are repeated to create an 80- to 90-mm sleeve, approximately 19 mm in diameter extending from the esophagus along the lesser curvature. The sleeve is then narrowed at the outlet using the TOGA restrictor.

In a series of 21 patients who underwent gastroplasty with the TOGA system, the mean EWL was 24.4% at 6

months. The most commonly reported adverse events were vomiting, pain, nausea, and transient dysphagia.⁴³ Because gaps in the staple line were evident in 13 patients, the technique was subsequently improved by the development of an adjustable septum, allowing closer apposition of the 2 staple lines. Eleven patients who underwent the modified technique had a mean of 46.0% EWL at 6 months.⁴⁴ Laparoscopic Roux-en-Y gastric bypass was technically feasible in all 4 patients who previously underwent the TOGA procedure and did not interfere with the short-term results of the laparoscopic RYGB.⁴⁵

The Trans-oral Endoscopic Restrictive Implant System creates a restriction analogous to gastric banding. The technique involves stapling plications into the gastric cardia with anchor placement and subsequent attachment of a restrictor diaphragm. This results in a restrictive pouch with a 10-mm orifice (Fig. 4). It is designed to be a permanent implant, which may be removed or modified as needed. In a preliminary study of 12 patients, the EWL was 12.3% and 22.2% at 1 and 3 months, respectively.⁴⁶ In 1 patient, gastric perforation developed that required surgery, and in 2 patients, pneumoperitoneum developed that was treated conservatively. Weight loss was reported to be comparable to that with laparoscopic gastric band placement.

OTHER TECHNIQUES

The use of botulinum toxin (Botox; Allergan Inc) in obesity is based on animal studies that showed weight loss

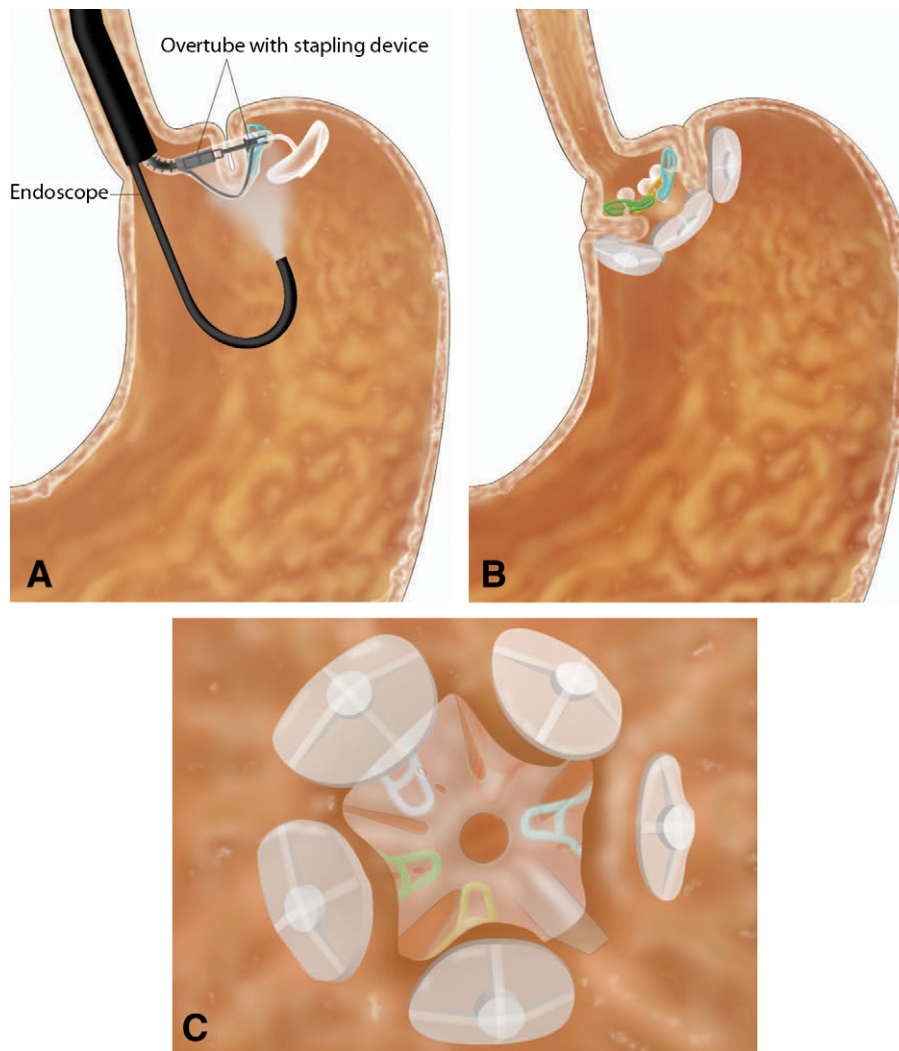


Figure 4. **A**, The Trans-oral Endoscopic Restrictive Implant System (TERIS) device creates a small gastric pouch by means of multiple gastric plications using a specialized stapling device. **B**, Completed TERIS procedure with small restrictive gastric pouch. **C**, Inner view of the TERIS procedure showing restrictive diaphragm with 10-mm orifice.

by decreasing gastric emptying as a result of cholinergic denervation.⁴⁷ Injection in the prepyloric antral gastric wall in 12 patients failed to induce weight loss.⁴⁸ However, injection of Botox into the fundus as well as the antrum resulted in significantly higher BMI reduction (4.0 ± 0.36 kg/m² vs 2 ± 0.58 kg/m², $P < .001$) at 8 weeks in a randomized, sham-controlled study of 24 obese patients. No significant side effects were reported.

There are several other endoluminal bariatric devices at various stages of development, including an endoscopically placed removable sleeve (ValenTx bypass sleeve; ValenTx, Inc, Carpinteria, Calif) and a device for radiofrequency antralplasty (Silhouette Medical, Mountain View, Calif). Intra-gastric balloon placement using an ingestible capsule has been reported. The volume of the capsule can be adjusted wirelessly after being swallowed by the patient.⁴⁹

AREAS FOR FUTURE RESEARCH

Long-term data on the safety, efficacy, and durability of endoluminal bariatric techniques are needed. Further studies comparing different endoluminal techniques and their proper role in treating obesity are required.

SUMMARY

Less-invasive weight loss methods are needed to address the growing obesity epidemic. Endoluminal bariatric techniques are a promising area of research with the potential to have an impact on this growing health issue. Further study on their role is required before incorporation into clinical practice.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: BIB, BioEnterics intragastric balloon; BMI, body mass index; IGB, intragastric balloon; IHB, intragastric heliosphere balloon; DJBS, duodenojejunal bypass sleeve; EWL, excess weight loss; TOGA, Transoral Gastroplasty System.

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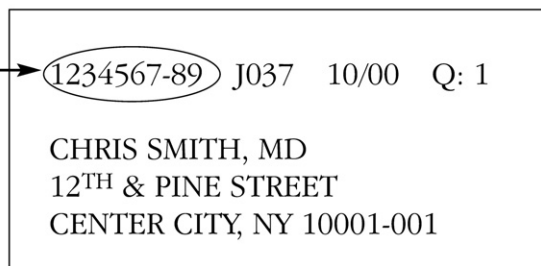
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