Endoscopic Management

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KEYWORDS

• Obesity • Endoscopic bariatric therapy • Intragastric balloon • Transpyloric shuttle
• Endoscopic sleeve gastroplasty • Primary obesity surgery endoluminal
• Aspiration therapy • Duodenal-jejunal bypass liner

KEY POINTS

- Multiple devices and procedures for primary treatment of obesity and treatment of weight regain after Roux-en-Y gastric bypass (RYGB) are now available.
- In many cases, efficacy of these procedures and devices has been demonstrated with randomized sham-controlled or nonsham-controlled trials.
- Multiple gastric and small bowel devices for weight loss are currently being evaluated or have US pivotal trials planned for US Food and Drug Administration approval.
- Endoscopic revision of the gastrojejunostomy for weight regain after RYGB is an effective treatment for weight regain as shown in a randomized sham-controlled trial for patients with dilation of the gastrojejunostomy.

INTRODUCTION

Endoscopic bariatric therapy (EBT) has the potential to play a significant part in both the primary and secondary therapy of obesity. EBT may have more effectiveness than lifestyle therapy alone or medications,[1] and while EBT generally is less effective than bariatric surgery, it has fewer complications and is less expensive. In 2015, the US Food and Drug Administration (FDA) approved 2 new endoscopic bariatric devices for primary obesity treatment: the ReShape Integrated Dual Balloon System (ReShape Dual Balloon, ReShape Medical, San Clemente, California) and the Orbera Intragastric Balloon System (Apollo Endosurgery, Austin, Texas). Several therapies are available for gastrojejunostomy revision for weight regain after Roux-en-Y gastric bypass (RYGB).

This article will discuss devices or techniques with FDA approval (including devices that have general FDA approval for nonspecific uses in the gastrointestinal [GI] tract),

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as well as those with currently running or planned US pivotal trials for FDA approval. EBT methods, their results and risks, are outlined.

PRIMARY THERAPY

The American Society for Gastrointestinal Endoscopy (ASGE) recently released a position statement supporting the use of EBT in conjunction with a multidisciplinary weight loss program for long-term obesity treatment.[2] EBT can be considered in those who have failed weight loss or maintenance with lifestyle intervention alone and meet BMI criteria for particular treatment modalities, or Have medical conditions that require weight loss for additional therapy (eg, bridge therapy to weight loss surgery). Current approved and investigational devices for primary EBT include space-occupying devices, tissue apposition devices, and nutrient-diverting devices.

Intragastric Balloons

The use of intragastric balloon (IGB) therapy for obesity was first described in 1982,[3] and the Garren-Edwards gastric bubble (GEGB), an endoscopically-placed air-filled balloon, was approved for use by the FDA in 1985. However, multiple adverse events were reported with this device, including gastric mucosal injury, small bowel obstruction following spontaneous balloon deflation and migration, and poor efficacy compared with lifestyle modification alone in several trials.[4–11] The GEGB was withdrawn from the US market in 1992. Several design flaws likely contributed to its ultimate failure. It was made from polyurethane, which deflated too easily, and had a cylindrical shape with edges, which led to mucosal injury.[12] Additionally, it filled only to a volume of 220 mL, whereas a volume of 400 mL has been shown to be the minimum necessary to reduce food intake.[13] Subsequent efforts to design IGBs have drawn from the experience with the GEGB to create safer and more effective devices.[14,15] This article focuses on the IGBs that are available in the United States or for which pivotal trials are either ongoing or planned in the United States. Devices are summarized in **Table 1**.

Fluid-filled single balloon: Orbera

The most-studied and widely used IGB is the Orbera IGB, which was introduced in 1991 and originally known as the BioEnterics Intragastric Balloon (BIB, Allergan, Irvine,

Table 1
Intragastric balloons approved for use or being studied in the United States for Food and Drug Administration approval

Device Name	Structure/Materials	Fill Type and Volume	Method for Placing and Removing	Dwell Time
Orbera (Apollo Endosurgery)	Single silicone balloon	400–700 mL saline	Endoscopic	6 mo
ReShape Duo (ReShape Medical)	Two tethered silicone balloons	750 or 900 mL saline	Endoscopic	6 mo
Spatz (Spatz Medical)	Single silicone balloon, attached catheter	400–1000 mL saline, adjustable	Endoscopic	12 mo
Obalon (Obalon Therapeutics)	Lightweight balloon enclosed in capsule	250 mL gas, can swallow up to 3 balloons	Swallowed, removed endoscopically	6 mo
Elipse (Allurion Technologies)	Lightweight balloon enclosed in capsule	550 mL saline	Swallowed, degrades, passes in stool	4 mo