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Endoscopic bariatric procedures: Assessment of postintervention safety and success

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ABSTRACT

Morbid obesity has become one of the largest health care crises facing modern medicine. Medical intervention alone has proven inadequate in addressing this issue. Although bariatric surgery has been proven to be the most effective treatment for the medical comorbidities associated with morbid obesity, only a fraction of obese patients will undergo bariatric surgery owing to fear, financial restraint, and limited access to surgical expertise. There exists a void for which endoscopic therapies can provide substantial improvements in the care of the morbidly obese patient. Compared to traditional surgical therapies, endoscopic approaches may potentially speed recovery with decreased pain, incisional hernia development, and surgical site infections. Primary endoscopic bariatric procedures can be classified as space-occupying, restrictive, or bypass. These procedures, as well as foresight into endoscopic bridges to surgery and revisional approaches, are discussed herein.

1. Introduction

The obesity epidemic has continued to expand despite the availability of diet and lifestyle counseling, pharmacologic therapy, and bariatric surgery. Although lifestyle modification is effective in achieving initial weight loss, follow-up studies demonstrate weight regain within 1 year [1-3]. Pharmacotherapy has been similarly disappointing, often revealing marginal weight loss with bothersome side effect profiles [4-6]. Bariatric surgery is the most effective treatment for the medical comorbidities associated with morbid obesity. Despite these clearly documented benefits, only a fraction of obese patients will undergo surgical intervention. It is estimated that approximately 1% of eligible patients consider surgical methods of weight loss, in part owing to its invasiveness and availability [7]. At present, Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy constitute most weight loss procedures performed in the United States. Such operations remain highly invasive and carry a significant postoperative mortality rate of 0.31%, adverse event rate of 10%-17%, and failure rate of 10%-20% with weight regain reported in 20%-30% of the patient population [8].

There remains a sizeable unmet need for minimally invasive, safe, and effective long-term therapies for obesity. Recent advancements in endoscopic technology and techniques have opened a new field of minimally invasive endoscopic treatment options for combatting obesity both as a first line and adjunctive therapy. Endoscopic treatments have the opportunity to provide a more cost-effective, accessible, and, at times, reversible intervention when compared to traditional surgical intervention. The use of endoscopy in treatment of obesity may prove advantageous in potentially reducing postoperative convalescence with decreased pain, incisional hernia development, and surgical site infections compared to standard surgical techniques. Current primary endoscopic bariatric procedures can be classified as space-occupying, restrictive, or bypass. Revisional endoscopic therapies also play a role in decreasing morbidity in patients who are in need of reconstruction following earlier surgical interventions. Index procedures, as well as an introduction of endoscopic bridges to surgery and endoscopic approaches to the patient in need of surgical revision, are discussed.

2. Space-occupying devices

Space-occupying devices displace volume and induce gastric distention, but may also alter gastrointestinal motility, nutrient

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transit, and hormone levels. Balloons have established roles in Europe as a bridge to bariatric surgery in patients with high risk for anesthesia, temporary use in patients eligible for bariatric surgery but unwilling to undergo it, and temporary use in patients not eligible for bariatric surgery, as part of an integrated medical weight loss program.

2.1 Orbera intragastric balloon

The Orbera (formerly BioEnterics) balloon (Apollo Endosurgery, Austin, TX) is an endoscopically implanted spherical silicone elastomer that is attached to a preloaded catheter and advanced blindly into the stomach. Then, under direct visualization with endoscopy, the balloon is inflated with 450-700 mL of saline. The balloon is resistant to gastric acid and remains in situ for 6 months. The balloon is designed to act as a bezoar and moves freely within the stomach while inducing weight loss via gastric distension, reduced gastric emptying, and increased baroreceptor stimulation thereby inducing satiety [9].

The device was studied in a 2008 meta-analysis of 3608 patients in 15 studies; early device removal was required in 4.2% of patients. Reported adverse events included nausea, vomiting, bowel obstruction (0.8%), and gastric perforation (0.1%). Average weight loss after 6 months was 14.7 kg or 32.1% excess weight loss (EWL), with a drop in body mass index (BMI) of 5.7 kg/m^2 [10]. The largest included study was an Italian cohort of 2515 patients who demonstrated a 9 kg/m^2 BMI reduction at 6 months, with a percentage EWL of 25.6% [11]. Statistically significant improvements in blood pressure, fasting glucose, and lipid profiles were seen. A significant decrease in, or normalization of, HbA1c was reported in 87.2% of the 488 diabetic patients. There was an associated 2.8% complication rate and 0.19% gastric perforation rate.

The benefit of repeat or serial Orbera balloon placement for maintaining weight loss remains unclear. In 2010, 19 patients requesting repeat Orbera placement were nonrandomized: 8 patients underwent direct repeat balloon placement at 6 months, whereas 11 patients had a balloon-free interval [12]. Those patients undergoing a second balloon placement with a balloon-free interval regained 13.6 kg on average during that interval. The second balloon did result in weight loss, although its magnitude was smaller than that of the initial therapy (9 kg vs 14.6 kg, or 18.2% EWL vs 49.3% EWL). The effect of second balloon placement dissipated by the third year of follow-up.

The long-term weight loss trend after the removal of the Orbera balloon was studied in 500 patients with an average BMI of 43.7 [13]. At the 1, 2, and 5-year follow-up, 53%, 27%, and 23% of study patients, respectively, achieved greater than 20% EWL. The strongest predictor of EWL greater than 20% at the 5-year follow-up was achieving greater than 80% EWL in the first 3 months of balloon implantation.

The use of Orbera as a bridge to gastric bypass was studied in 60 consecutive super-obese subjects (average BMI 66.5 kg/m^2), comparing patients who received Orbera within 3 months before LGB to patients who solely underwent surgery [14]. The preop balloon placement group demonstrated a BMI reduction of 5.5 kg/m^2 with an EBL of 11.2% at the time of surgery. The mean operative time (146 vs 201 minutes, $P < 0.01$) and the composite adverse event endpoint (intensive care unit admission, open laparotomy conversion, and death) were significantly lower in the preoperative balloon group. Weight loss was similar among groups 1 year after gastric bypass. This study suggests a role for balloon therapy as a preoperative method to optimize success of bariatric surgery. Orbera balloon therapy has also been reported to improve several metabolic parameters. An Italian prospective study involving 130 obese patients showed significant improvement in glycemia, insulin resistance, triglyceridemia, and liver steatosis in addition to significant weight loss in 91 responders to the intragastric balloon [15].

The Orbera balloon gained Food and Drug Administration (FDA) approval in 2015 for insertion for up to 6 months in obese patients with BMI between 30 and 40 after a multicenter US pivotal trial involving 215 patients. An average of 10% total body weight loss was seen at the time of balloon removal, as compared with 4% in the control group at 6 months. The reported EWL was approximately 40% vs 13%, respectively. Three months after device removal, the mean EWL was 26.5% in the balloon group [16].

2.2 ReShape Duo Balloon System

The ReShape Duo Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, CA) is a dual-balloon implant that is endoscopically placed and retrieved following 6 months of treatment. The 2 silicone spheres are filled with 450 mL of saline each for a total 900 mL volume. The dual balloon design is thought to provide increased flexibility, enhanced gastric space filling, and reduced balloon migration [17]. However, as compared to the Orbera balloon, the ReShape Duo is a relatively new device with significantly less-published clinical data regarding safety and efficacy. A 60 patient, prospective observational trial was performed in 2015 and demonstrated a 6-month weight loss, with reported EWL of 47.9% [18]. In a prospective sham-controlled US pivotal trial (REDUCE), the Reshape balloon resulted in significantly greater %EWL (25.1% intent-to-treat, 27.9% completed cases) as compared with patients managed with diet and exercise alone at 24 weeks. There were no deaths, intestinal obstructions, gastric perforations, or device migrations. Balloon deflation occurred in 6% and early retrieval for nonulcer intolerance was required in 9.1%. Gastric ulceration at the incisura was observed in 39% but was significantly reduced to 10% after an intrastudy switch to a softer device tip [17]. The Reshape Duo balloon gained FDA approval in 2015 for patients with a BMI of 30-40 in a structured weight loss program with unsuccessful attempts at weight loss.

2.3 Heliosphere Bag

The Heliosphere Bag (Helioscope, France) is another temporary intragastric balloon system; however, it differs in that it is filled with 950 mL of air rather than fluid. It has been postulated that the lightness (< 30 g) of the air-filled bag may limit nausea and vomiting. The heliosphere bag was compared with the Orbera balloon in a study of 60 patients (average BMI 46.3). The heliosphere group achieved a BMI decrease of 4.2 vs 5.7 in the Orbera group. The heliosphere group had significantly longer extraction procedure time and significantly more discomfort during extraction [19]. Another prospective study of 91 patients compared Orbera (72 patients) to Heliosphere (18 patients). Balloons were implanted for 6 months, with 13.2% removed early because of intolerance. Average weight reduction at 6 months was 13.3 kg, and BMI reduction was 5 kg/m^2. Overall 88% of weight reduction occurred in the first 3 months. Weight loss was similar between balloon types; however, the Heliosphere bag was significantly more likely to result in retrieval complications [20].

2.4 Obalon intragastric balloon

The Obalon intragastric balloon (Obalon Therapeutics, Carlsbad, CA) is a 250-mL gas-filled balloon that is swallowed under fluoroscopic visualization rather than inserted endoscopically. Elimination of an endoscopic procedure to implant the balloon removes a risk associated with sedation and procedural costs. The balloon is enclosed in a capsule and a catheter that extends