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Endoluminal bariatric and metabolic interventions

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ABSTRACT

Obesity has become a global pandemic reaching epic proportions. Despite advances in pharmacotherapy, surgery, and lifestyle interventions obesity's health burden continues to rise. Endoscopic bariatric techniques have arisen over the years, which are efficacious, reversible, safe, and cost effective; thus, potentially applicable to the larger cohort of patients with mild-to-moderate obesity. These therapies make gastrointestinal endoscopy a viable contender in the treatment of obesity. This review summarizes the current endoscopic bariatric techniques that are available in the US market or in advanced stages of development and regulatory approval.

1. Introduction

Obesity has become a major health concern worldwide. Greater than 68% of adults in the US are considered to be overweight or obese [1]. Increasing alongside are obesity's comorbid conditions such as type 2 diabetes, dyslipidemia, hypertension, metabolic syndrome, sleep apnea, and fatty liver disease [2]. Excess weight has been shown to be associated with a decreased life expectancy and increased risk of all-cause and cardiovascular mortality [3,4]. It accounts for up to 2.5 million preventable deaths annually and economic analyses revealed that greater than 150 billion dollars are spent to treat obesity-related medical problems. This latter figure represents about 21% of health care expenditures, threatening the integrity of our health care system [5].

Nonsurgical methods for the treatment of obesity such as lifestyle interventions (LI) and pharmacologic therapies have had modest success. However, most of this success is short lived [6]. Although an average of 5% total body weight (TBWL) is lost through LI, an additional 3%-9% weight loss can be achieved with pharmacologic therapy; though medication side effects and costs have limited their widespread use [7]. Overall, nonsurgical treatment of obesity is challenging given the redundant physiological pathways regulating body weight and the obesogenic environment we live in.

Bariatric surgery has been the most effective obesity treatment providing long-term benefit [8]. Currently, available surgeries include Roux-en-Y gastric bypass (RYGB), laparoscopic sleeve gastrectomy, laparoscopic adjustable gastric band, vertical banded gastroplasty, duodenal switch, and biliopancreatic diversion. Laparoscopic RYGB and sleeve gastrectomy are the 2 most popular bariatric surgical procedures associated with percentage excess weight loss (%EWL) ranging between 60% and 80% at 1 year with high rates for resolution of diabetes, hypertension, and obstructive sleep apnea [9,10]. Over a 20-year period after RYGB, approximately 11% (TBWL) appears to be maintained compared with that in nonsurgical therapies.

Despite its proven efficacy, less than 2% of eligible patients with obesity undergo any type of bariatric surgery [11,12]. This discrepancy is multifactorial, ranging from economic, psychological, to safety concerns. Thus, widespread application has been limited. Early postbariatric surgery complications include anastomotic leaks, bleeding, internal hernias, bowel obstructions, and venous thromboembolisms. Late complications include gallstones formation, marginal ulcers, anastomotic stenosis, fistulas, dumping syndrome, kidney stones, micronutrients deficiencies, and weight regain [13,14].

Understanding the physiological consequences of bariatric surgery and the anatomical manipulation of the gastrointestinal (GI) tract has propelled the development of less invasive treatment modalities that are able to reach a broader population without some of the short-term and long-term complications and cost of surgery [15-18]. This has resulted in a variety of cutting edge and innovative strategies that would change the way we treat obesity in the 21st century, allowing gastroenterologists to take a pivotal

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role in the management of this disease. This review focuses on endoscopic approaches for the treatment of obesity, which are available or in advanced stages of regulatory approval, organized by location and type.

2. Gastric interventions

Gastric volume reduction through creation of restrictive sleeves or gastric pouches is an important component of bariatric surgical procedures. In addition to decreasing the amount of space available for food intake, both sleeve gastrectomy and RYGB surgery have associated changes in the GI neuroendocrine environment that promote weight loss [19-23]. As a result, multiple endoscopic bariatric techniques (EBTs) target the stomach by reducing its volume, restricting its accommodation, or through removal of excess calories from the gastric reservoir.

2.1. Space-occupying devices

2.1.1. ORBERA (formerly bioenterics) intragastric balloon

The ORBERA balloon is a spherical-shaped elastic silicone balloon that is filled with 450-700 cc of normal saline (Figure 1A). Methylene blue can be added to help detect early spontaneous balloon deflation [24]. The balloon comes preloaded in a catheter where it is placed transorally without the use of an endoscope. After it has been inserted, an endoscope is used to visualize and confirm location in the stomach before inflation. It is generally placed for 6 months, and then requires removal. The ORBERA balloon has been in wide circulation outside the United States for many years with more than 220,000 balloons inserted. The safety profile of the ORBERA balloon is favorable. Although accommodative symptoms, such as nausea and vomiting for few days after insertion occur in most patients, serious side effects are rare with incidence of migration and gastric perforation of 1.4% and 0.1%, respectively [25]. Most of the reported perforations with the ORBERA balloon were in patients with previous gastric surgery, which is now considered a contraindication for its use in the United States. Medications such as proton pump inhibitors, antispasmodic drugs including anticholinergics, and antiemetics are usually prescribed prophylactically before, during, and after balloon placement to prevent or minimize expected common side effects. Early removal rate of the ORBERA balloon for intolerance is 7.5% [25]. In a recent meta-analysis, the pooled %TBWL after the ORBERA balloon implantation was 12.3% (95% CI: 7.91-16.73), 13.16% (95% CI: 12.37-13.95), and 11.27% (95% CI: 8.17-14.36) at 3, 6, and 12 months, respectively [25]. Sequential ORBERA balloons use in patients with higher body mass index (BMI) has been shown to be effective in prospective outside the US studies [26-28].

The ORBERA balloon pivotal US trial was a multicenter, prospective, randomized comparative study of 273 patients with obesity randomized to treatment with ORBERA balloon for 6 months in conjunction with a behavioral and lifestyle intervention program for 12 months ($n = 137$) vs behavioral and lifestyle intervention program alone for 12 months ($n = 136$). The ORBERA balloon resulted in significantly higher %EWL compared with that in behavioral and lifestyle control group (39.78 vs 17.34) and (29.28 vs 14.12) at 6 months (time of balloon removal) and 12 months (6 months after balloon removal), respectively [29]. The ORBERA balloon was recently approved by the Food and Drug Administration (FDA) for the treatment of obesity.

2.1.2. ReShape Duo intragastric balloon

The ReShape Duo balloon was developed by ReShape Medical (San Clemente, CA). It is an endoscopically placed and retrieved dual balloon system. The 2 balloons are interconnected by a flexible tube, and are independently filled with 450 mL of normal saline

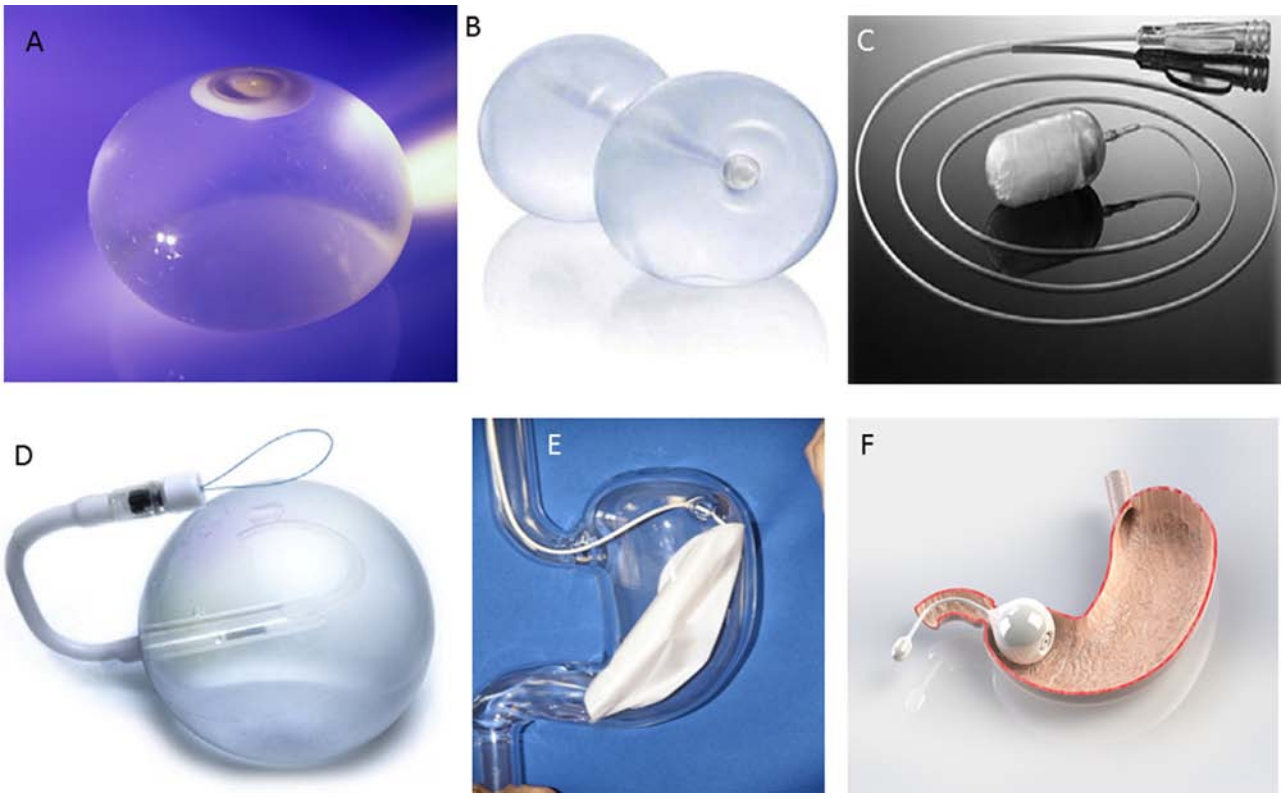

Fig. 1. Space-occupying devices endoscopic bariatric therapies: (A) ORBERA intragastric balloon, (B) ReShape Duo intragastric balloon, (C) obalon intragastric balloon, (D) Spatz adjustable intragastric balloon, (E) easy life adjustable intragastric balloon, and (F) transpyloric shuttle. (Color version of figure is available online.)