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Novel endoscopic bariatric therapies: A glimpse into the future

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ABSTRACT

The management of obesity generally consists of lifestyle interventions, which are often inadequate, or invasive surgery, that carries a high cost and strict eligibility requirements. The recent rise of endoscopic bariatric interventions has the potential to provide a minimally invasive, cost-effective, and reversible option for patients. Although a few of these therapies have already gained Food and Drug Administration (FDA) approval, many more are in various stages of development and clinical trials. These methods use a wide array of techniques, including reducing gastric capacity, limiting absorption, duodenal mucosal resurfacing, and creating intestinal diversion. This review focuses on these newer, nonFood and Drug Administration approved approaches, which have the potential to drastically change the landscape of bariatric interventional options in the near-term future.

1. Introduction

In the United States, nearly 35% of the population are obese (body mass index [BMI] $\geq$ 30), and nearly 17% are categorized as morbidly obese (BMI $\geq$ 40) [1]. Obesity is a significant risk factor for other comorbid health problems, including coronary artery disease, stroke, type 2 diabetes mellitus, obstructive sleep apnea, and certain types of cancer, among other conditions. Unsurprisingly, obesity, therefore, has a sizeable effect on health care expenditures, costing more than $147 billion annually [2].

Managing obesity is notoriously difficult, with lifestyle alterations being an important, but often inadequate intervention. Surgical interventions (laparoscopic sleeve gastrectomy, Roux-en-Y gastric bypass, and laparoscopic adjustable gastric banding) can be effective for weight management in patients with severe obesity, but typically carry strict eligibility requirements. Furthermore, surgical interventions carry substantial risks, including a complication rate of 11%-23% [3], as well as postsurgical adverse events, such as marginal ulcerations, anastomotic leaks, food intolerance, and malabsorption or dumping syndromes. As a result, bariatric endoscopic approaches, which are minimally invasive, less costly, and often reversible, are becoming increasingly attractive. Although a few endoscopic bariatric procedures have gained Food and Drug Administration (FDA) approval, many are currently under various stages of clinical trials and development. As these interventions fully mature, they have the potential to vastly reshape the management of obesity in the coming years.

The following article discusses novel endoscopic therapies for patients undergoing bariatric surgery. According to the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric Surgery (ASMBS) Task Force on Endoscopic Bariatric Therapy, all endoscopic approaches for primary obesity intervention should evoke a 25% excess weight loss at 12 months [4]. To accomplish this goal, endoscopic therapies have employed various strategies, which are highlighted in this review. Some techniques focus on limiting gastric capacity by using space-occupying devices, directly reducing available gastric volume, or impairing gastric emptying. Overall, these therapies limit oral intake and stimulate early satiety by limiting stomach capacity. Other methods evoke malabsorption by partially inhibiting either the breakdown or absorption of nutrients. Alternatively, some newer, emerging therapies focus on other mechanisms, such as gastric stimulation or fecal transplant. Finally, the discovery of improved glycemic control with bariatric surgery has led to the emergence of endoscopic therapies for the treatment of diabetes.

2. Techniques that impair gastric capacity

2.1. Intragastric balloons

Intragastric balloons are some of the most rigorously studied devices for endoscopic bariatric interventions, with some having

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already gained approval by the US FDA for the endoscopic treatment of obesity. These devices consist of a fluid or air-filled balloon, which is endoscopically placed in the stomach to promote weight loss by physically impeding intake, decreasing intragastric volume, and increasing gastric emptying time. They may trigger satiety centrally by activating gastric stretch receptions that serves as a feedback to the hypothalamus [5].

Historically, intragastric balloons have been in use for more than 30 years. Although the air-filled Garren-Edwards gastric bubble was the first to gain FDA approval in 1985, it, along with many of the other first generation balloons, was eventually withdrawn from the market because of a failure to demonstrate efficacy, significant complications, and new consensus on ideal balloon designs [6,7]. Recent consensus guidelines suggest intragastric balloons be (1) constructed from a smooth, durable material with low ulcerogenic and obstructive potential, (2) incorporate a radiopaque marker to allow appropriate follow-up in case of deflation, and (3) possibility to adjust to a variety of sizes [8].

2.1.1. FDA-approved devices: the Orbera and ReShape dual balloons

Two iterations of intragastric balloons, the Orbera balloon and ReShape Dual balloons, have earned FDA approval. The Orbera Intragastric Balloon (Apollo Endosurgery, TX; originally from Bioenterics Intragastric Balloon, Allergan, CA) is approved for use in patients with BMI of 30-40, and is composed of a balloon filled with 450-700 mL of saline and methylene blue, which changes urine color with leakage or rupture. After 6 months of implantation, 83% of patients achieve an average excess weight loss of 55%-61% [9,10]. However, the average excess weight loss was notably lower at 3 and 5 years, with only 23% of patients able to maintain an excess weight loss more than 20% after 5 years [9,10]. Furthermore, the balloon has been shown to foster the improvement or resolution of diabetes, hypertension, and obstructive sleep apnea [11]. Although the Orbera balloon is typically implanted for 6 months, repeated balloon placement is possible and has been shown to help maintain or resume weight loss. Although Orbera balloon has also been studied as a presurgical adjuvant therapy to improve surgical outcomes by maximizing presurgical weight-loss, its use in this setting is unclear. Although some studies have shown shorter hospitalization and fewer adverse intraoperative events, others have found no additional benefit [12,13].

The other intragastric balloon to earn FDA approval is the ReShape Dual balloon system (ReShape Medical, CA). The ReShape system consists of 2 connected balloons filled with 450 cc of saline and methylene blue and remains in the stomach for 6 months. The dual balloon design provides additional gastric filling whereas potentially decreasing balloon migration. In the REDUCE trial, a prospective, multicenter, randomized, controlled trial of 330 patients, those treated with the ReShape balloon for 6 months achieved an excess weight loss of 25.1%. In comparison, those who only underwent dietary modification managed an excess weight loss of 11.3% [14]. Complications included balloon deflation without migration (6%) and removal for nonulcer intolerance (9%). Gastric ulcers were noted in 35% of patients who had a balloon implanted, however, all were minor and asymptomatic except for 1 case. Ulcers were attributed to pressure from the distal device tip, which underwent intratrial modification that resulted in a significant, 74% reduction in ulcer frequency.

2.1.2. Non-FDA-approved intragastric balloons

There are a number of criticisms of the currently available intragastric balloon options, including a 6-month limit to balloon implantation, a reduction in efficacy after 2-3 months, significant nausea postimplantation, and difficulty adjusting volume after implantation [15]. A number of balloons currently in development have been designed to address these limitations.

2.1.3. Spatz balloon system

The Spatz Balloon System (Spatz Medical, NY) consists of a spherical silicone balloon, an anchor to prevent balloon migration, and a filling tube volume to facilitate adjustment after implantation (Figure 1A). Further more, the balloon has designed for a longer (up to 1 year) implantation time. Early studies found a 45.7% excess weight loss [15] with the device. When coupled with adjustments to balloon volume, the longer implantation time appears to result in greater weight loss (on average, an additional 7-9 kg [15,16]), however, the benefit of the longer implantation time has been difficult to assess independently, and this additional weight loss was less than 10% of the preadjustment weight loss [15]. Furthermore, complication rates requiring removal are

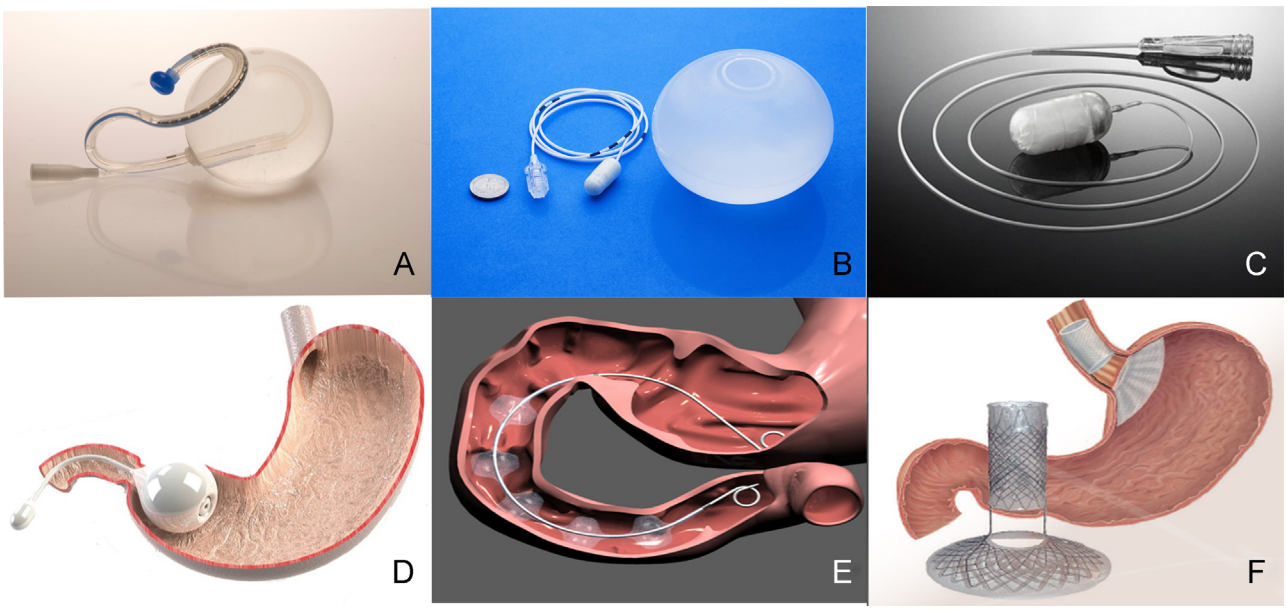

Fig. 1. Images of the (A) Spatz intragastric balloon, (B) Obalon intragastric balloon, (C) Allurion elipse intragastric balloon, (D) BAROnova TransPyloric Shuttle, (E) Endosphere SatiSphere System, and (F) Sentinel full sense device. Images taken from the respective manufacturer's website. (Color version of figure is available online.)