Intragastric Balloons in Clinical Practice

Marianna Papademetriou, MD[a], Violeta Popov, MD, PhD[b,*]

KEYWORDS

• Intragastric balloons • Obesity • Weight loss • Review • Efficacy

KEY POINTS

- Intragastric balloons (IGBs) are a minimally invasive endoscopic weight loss method available for use in the United States.
- IGBs consistently lead to 10% to 15% total body weight loss and improvement in metabolic risk factors, with a low rate of serious adverse events.
- The most common adverse events are postimplantation nausea and vomiting, and early removal of the device owing to intolerance.
- Effective early management of symptoms can prevent or reduce these complications.
- Successful use in practice requires a multidisciplinary approach and long-term follow-up plan.

The current standard of care for weight loss is caloric restriction with dietary changes and increased calorie expenditure through exercise. Should this strategy prove insufficient or lack durability, medical therapy can be added. Many patients continue to struggle with weight loss and may then consider more invasive approaches. Bariatric surgery provides the most effective and durable method of weight loss. However, bariatric surgery is associated with mortality in 0.2% to 1.0% of cases, a reoperation rate of 4.3% to 8.3%, and serious adverse events in 26%.[1] Furthermore, many patients in various parts of the United States do not have access to comprehensive bariatric surgery centers.[2] Owing to concern over potential complications as well as lack of availability, only a small percentage of obese patients require and qualify for bariatric surgery to treat obesity and associated metabolic conditions.[3] Thus, novel treatment strategies that are more effective than diet and pharmacotherapy and safer than surgery are being developed.

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[a] Gastroenterology, New York University School of Medicine, 220 First Avenue, New York, NY 10016, USA; [b] Division of Gastroenterology, NY VA Harbor Healthcare (Manhattan), New York University School of Medicine, 423 East 23rd Street, 15 North, New York, NY 10010, USA
* Corresponding author.
E-mail address: Violeta.popov@nyumc.org

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INTRAGASTRIC BALLOONS

Intragastric balloon (IGB) devices are the most popular minimally invasive option for treatment of obesity. Early devices released in the 1980s, however, were ineffective and potentially hazardous. The first such device was the Garren-Edwards Gastric Bubble,[4] an air-filled balloon. About 20,000 such devices were implanted. In practice, spontaneous deflation occurred in 31% of cases and gastric ulcers were seen in 26%.[5] Adverse events including gastric perforations and intestinal obstructions requiring surgical extraction eventually led to the withdrawal of the device. Nevertheless, this encouraged the development of safer and more effective IGBs.

The second-generation IGBs have been used outside of the United States for more than 25 years. These balloons are made of more durable silicone-based material and filled with saline or air. The most commonly used IGB worldwide is the Bioenterics Intragastric Balloon, a fluid-filled single balloon, marketed in the United States as the Orbera Intragastric Balloon System (Apollo Endosurgery, Austin, TX). More than 250,000 Orbera balloons have been placed since its introduction in 1996. It was approved for use in the United States in 2015.

ReShape (ReShape Medical Inc., San Clemente, CA), a dual balloon system, was approved at the same time. In September 2016, the US Food and Drug Administration (FDA) approved a gastric balloon that is swallowed, the Obalon (Obalon Therapeutics, San Diego, CA). The Obalon Balloon is unique in that it allows for placement through the swallowing of a deflated balloon in the form of a capsule. Owing to the smaller overall capacity of 250 mL, up to 3 balloons can be placed in the stomach over a 3-month period. The Obalon balloons are filled with nitrogen mixed gas rather than saline through a catheter that remains attached until the balloon is fully inflated within the stomach.[6] All 3 IGBs are approved for patients with a body mass index (BMI) of 30 to 40 kg/m^2 who have failed nutritional counseling and lifestyle therapy. Until recently, there was no other effective weight loss procedure available for this group, because a BMI of 40 kg/m^2 is usually required for consideration of bariatric surgery.

MECHANISM OF ACTION

The mechanism of action by which IGBs lead to weight loss is multifactorial and incompletely understood. It is hypothesized that these devices facilitate weight loss by reducing the stomach's potential volume and inducing early satiety (**Fig. 1**). In this manner, total caloric intake for the day may be reduced with adherence to nutritional counseling. Additional proposed mechanisms include changes in gastric emptying and hormonal changes. One study found that gastric emptying rates are reduced at 1 and 4 months after balloon insertion, and return to normal 1 month after balloon removal. Recent experiments added additional evidence to the role of delayed gastric emptying in promoting weight loss after IGB placement.[7] A subset of patients with normal or increased gastric emptying times before balloon placement experienced greater weight loss with IGB therapy compared with patients with baseline delayed emptying. The group with baseline delayed emptying may benefit from different mechanistic approaches to achieve weight loss other than IGBs.

Other proposed mechanisms include changes in appetite-regulating hormones. Fasting plasma ghrelin and leptin were decreased significantly when the balloon was in the stomach, leading to decreased hunger.[8] However, there are conflicting reports of observed hormonal changes in other studies. It is likely that many of these factors together contribute to the overall weight loss achieved.