

Balancing risk and reward: a critical review of the intragastric balloon for weight loss

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Worldwide, more than 1.4 billion adults are overweight or obese and either have or are at increased risk of numerous, potentially disabling conditions. In the United States, 68% of adults are overweight or obese, and the epidemic is spreading to children.^{1,2} Obesity is associated with a number of comorbidities including type 2 diabetes mellitus, coronary heart disease, sleep apnea, stroke, gallbladder and liver disease, musculoskeletal disease, and an increase in the prevalence of certain cancers.³ Decreasing body weight by only 5% to 10% has been shown to slow and even prevent the onset of obesity-related comorbidities such as type 2 diabetes⁴ and has historically been recommended as the initial goal for weight loss therapy.⁵⁻⁷

However, the availability of safe and effective weight loss therapies is limited. Although bariatric surgery has proven to be an effective weight loss intervention for the morbidly obese, its invasiveness, cost, and sometimes life-long side effects have limited its use in the moderately obese population.⁸ Prescription drug therapies are less invasive and costly, but they produce limited weight loss and have significant side effects.⁹

Endoscopically placed intragastric balloons (IGBs) are an option for overweight and obese patients with a body mass index (BMI) greater than 27 kg/m².⁸ The Garren-Edwards Gastric Bubble (GEB; American Edwards Company, Santa Ana, Calif) was the first IGB made available in the United States in 1985. The GEB was an endoscopically placed

and removed IGB filled with 220 mL of air, which was left in the stomach for 3 months. Adverse events related to the GEB reported in the medical literature include small-bowel obstruction secondary to unplanned deflation, gastric ulcers with GI hemorrhage, and gastric perforation.¹⁰⁻¹³ Of the first 20,000 GEB implantations, 79 required surgical removal after the balloon had migrated into the intestines.¹² Multiple randomized, sham-controlled studies failed to demonstrate a significant difference in weight loss between sham and GEB patients enrolled in a diet and exercise program.^{11,14-16} For these reasons, the GEB was removed from the market.

In 1987, a multidisciplinary conference in Tarpon Springs, Florida convened 75 international experts in gastroenterology, surgery, obesity, nutrition, and behavioral medicine to offer recommendations to improve the safety and efficacy of future IGBs. The conference recommended that future IGBs should (1) be effective at promoting weight loss, (2) be filled with liquid (not air), (3) be capable of adjustment to various sizes, (4) have a smooth surface with low ulcerogenic and obstructive potential, (5) contain a radiopaque marker, and (6) be constructed of durable materials.¹²

Several safer and more effective IGBs were subsequently developed over the next 2 decades in accordance with several of these recommendations. To date, the most commonly used IGB worldwide is the Orbera Intragastric Balloon (formerly the Bioenterics Intragastric Balloon) (Apollo Endosurgery, Austin, Texas) (Fig. 1). The Orbera balloon is placed in the stomach endoscopically, filled with saline solution, remains in the stomach for 6 months, and is then removed endoscopically. In nonrandomized studies, the weight loss achieved in obese patients during 6 months of Orbera balloon therapy with diet and exercise counseling averaged 17.8 kg with few severe adverse events.¹⁷ In a recent randomized study in obese patients with metabolic syndrome, the weight loss achieved after 6 months of Orbera balloon therapy combined with diet and exercise counseling was 14.4 kg compared with 5.1 kg with diet and exercise counseling alone. In addition, Orbera balloon therapy has been shown to lead to a reduction in several obesity-related comorbidities including metabolic syndrome, type 2 diabetes, hypertension, hypercholesterolemia, and liver steatosis.¹⁸⁻²⁰

Abbreviations: BMI, body mass index; EWL, excess weight loss; GEB, Garren-Edwards Gastric Bubble; IGB, intragastric balloon.

DISCLOSURE: Dr Gaur is a shareholder in Allurion Technologies. Dr Chuttani is a shareholder in Allurion Technologies. Dr Levy is a consultant for and shareholder in Allurion Technologies. Dr Mathus-Vliegen disclosed no financial relationships relevant to this article.



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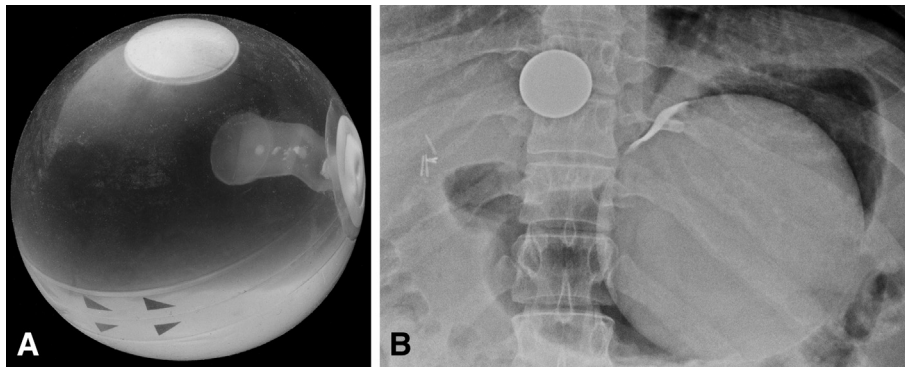


Figure 1. The Orbera Intragastric Balloon (formerly the Bioenterics Intragastric Balloon) **(A)** and abdominal radiograph of an Orbera balloon in situ **(B)**. The balloon is made of a silicone elastomer and filled with 500 to 700 mL of saline solution. The valve is radiopaque, allowing the balloon to be visualized on radiography. In this radiograph, a coin is taped on the lower sternum to permit follow-up comparisons of balloon size.

TABLE 1. Search terms used in MEDLINE database review

Search	Search Term
1	intra-gastric[Title/Abstract]
2	intragastric [Title/Abstract]
3	gastric [Title/Abstract]
4	#1 AND #2 AND #3
5	balloon [Title/Abstract]
6	#4 OR #5
7	obes*[Title/Abstract]
8	weight [Title/Abstract]
9	#7 OR #8
10	#6 AND #9
11	bioenterics [Title/Abstract]
12	#10 OR #11
13	Filter: Abstract available

The Orbera balloon is an attractive intermediate option between prescription drugs and bariatric surgery for overweight and obese patients hoping to lose a significant amount of weight without the invasiveness of surgery or the systemic side effects of prescription drugs. As a result, the Orbera balloon has become the most widely used and studied IGB around the world but has been known to induce time-limited weight loss and cause time-dependent device malfunction that may lead to serious adverse events. The goal of this review was to assess the kinetics of weight loss during and after Orbera balloon therapy and the timing of serious adverse events reported in the literature.

METHODS

The MEDLINE database was searched for publications with the search terms listed in Table 1. A total of 436 studies with abstracts available were found. A total of 281 studies were review articles, case studies, editorials, or not relevant to the effectiveness of the Orbera balloon and were

excluded. The remaining 155 studies were assessed for weight loss data reported in the first and second halves of Orbera balloon therapy, data on device malfunction leading to adverse events, and weight measurements reported after removal of the Orbera balloon (Fig. 2).

RESULTS

Weight loss kinetics

Seven studies (409 patients) reported weight loss data after 3 and 6 months of Orbera balloon therapy (Table 2). The average starting BMI of patients in these studies ranged from 36 to 43.3 kg/m². The average weight loss after 3 and 6 months of Orbera balloon therapy was 12.9 ± 0.8 kg and 16.0 ± 0.9 kg, respectively, indicating that 80% of the weight loss achieved in 6 months of Orbera balloon therapy occurs within the first 3 months.

Two studies (157 patients) reported weight loss data monthly during 6 months of Orbera balloon therapy (Fig. 3). Peker et al³⁹ included 31 patients with an average starting BMI of 41.8 kg/m². Totte et al⁴¹ included 126 patients with an average starting BMI of 37.7 kg/m². The most dramatic weight loss occurs in the first 3 months, after which the weight loss begins to plateau.

Sustained weight loss after Orbera balloon removal

Nine studies (547 patients) reported weight at baseline, at the time of Orbera balloon removal, and at 6 or 12 months after Orbera balloon removal (Table 3). In 6 studies, the patients were seen regularly after Orbera balloon removal. At baseline, the average weight was 116.2 kg compared with 99.5 kg at the time of Orbera balloon removal (average loss of 16.7 kg). Average weight at 6 and 12 months after Orbera balloon removal was 113.1 kg (average loss of 15.9 kg) and 96.8 kg (average loss of 8.7 kg), respectively. The data indicate that, on average, 52% of the weight lost during Orbera balloon therapy is sustained 12 months after Orbera balloon removal.

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