JAMA Insights | CLINICAL UPDATE

Gastric Balloons for Weight Loss in 2020

Dana A. Telem, MD, MPH; Amir A. Ghaferi, MD, MS

Effective interventions for weight management that are low risk, reversible, and applicable to the population who are not candidates for bariatric surgery are appealing. In recent years, the US Food and Drug Administration (FDA) has approved several such devices, with gastric balloon systems being the most widely adopted. As of 2018, it is estimated that gastric balloons comprised 2% of all bariatric procedures.[1] At present, gastric balloon systems are FDA-approved for persons with a body mass index (BMI) of 30 to 40 who have been unable to lose weight through diet and exercise and who participate in a multidisciplinary weight loss program.[2] Understanding the evidence and areas where further investigation are needed for these devices may help ensure optimal patient care, access, and safety.

Gastric Balloons: A Nonsurgical Approach to Weight Loss

Gastric balloon systems are intended as restrictive devices that take up space in the stomach and delay gastric emptying. There are currently 2 FDA-approved gastric balloon devices (**Figure**). Orbera is a spherical fluid-filled balloon placed endoscopically while the patient is under mild sedation. This system is temporary and requires endoscopic removal within 6 months of initial placement. Obalon is an air-filled balloon delivered to the stomach inside of a swallowable capsule that is attached to a thin inflation catheter. Up to 3 balloons can be placed within a 6-month period, and endoscopic retrieval of the device is required at 6 months. Of note, the ReShape balloon is no longer FDA-approved. This device was removed from the market in 2018 following the acquisition of ReShape by Orbera.

Clinical Practice: Efficacy

Several randomized clinical trials (RCTs) have evaluated the effectiveness of gastric balloons for weight loss against sham procedures and diet and exercise alone. The fluid-filled balloon is the most studied of the currently available gastric balloon systems. One of the first and more rigorously designed RCTs evaluating this balloon system assigned 66 patients with a BMI of 30 to 40 and metabolic syndrome to undergo 12 months of behavioral modification with placement of the gastric balloon system for the initial 6 months (n = 31) or without placement of the gastric balloon system (n = 35). Patients who received the gastric balloon system achieved greater percentage of total body weight loss than those who underwent lifestyle modification alone at 6 months (14.2% vs 4.8%) and at 12 months (9.2% vs 5.2%). No deaths occurred in the study, but the gastric balloon was removed prematurely in 3 patients due to gastrointestinal intolerance.[3] Although these findings support the efficacy of the balloon, this study had numerous limitations that limit the strength of the conclusion. The small sample size may not capture serious adverse events. Additionally, the authors noted that the control group had a much larger weight loss than would be expected for a typical weight loss study, perhaps suggesting that the results of this trial are better than one would expect in usual clinical practice. This was a single-center trial, which limits the generalizability across patients.

A 2017 sponsor-initiated multicenter RCT randomized 255 adults with a body mass index of 30 to 40 to undergo endoscopic placement of a gastric balloon plus lifestyle intervention or lifestyle intervention alone.[4] Balloons were removed at 6 months and lifestyle intervention continued for both groups through 12 months. At 9 months, the primary study end point, mean percentage of excess weight loss, was 26.5% for persons who underwent gastric balloon placement and 9.7% for those who underwent only the lifestyle intervention. At least 1 device-related adverse event occurred in 98% of persons who had a gastric balloon device, of which 59.4% were classified as mild, 35.6% as moderate, and 3.1% as severe. Additionally, 18.8% of persons required device removal prior 6 to months. No deaths were reported.[4] A key limitation of this study included the early termination of patient enrollment prior to reaching initial study targets, which limited the study power and conclusions. Additionally, the open-label study design permitted both clinicians and patients to know what treatment was given, which possibly influenced reporting or measurement of the outcome and introduced bias. Also, the study duration of 9 months was inadequate to detect longer-term adverse events and weight loss durability.

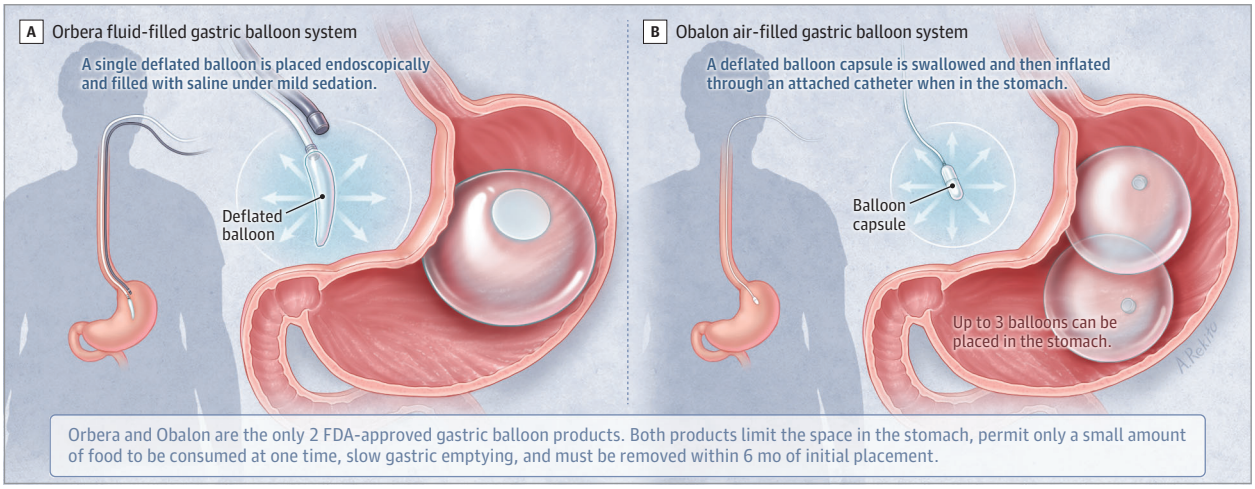
The air-filled gastric balloon system has been evaluated in 1 RCT.[5] This double-blind, randomized, sham control study included 419 patients, of whom 387 were able to successfully swallow the device. A total of 198 patients received the air-filled gastric balloon device and 189 received a sham capsule that did not contain the balloon. A modified intent-to-treat analysis was performed on persons who completed the study. Patients who received the air-filled balloon system lost 14.4 lb (6.48 kg; 6.6% total body weight loss) vs 7.4 lb (3.33 kg; 3.4% total body weight loss) among those who received the sham device.[5] Important limitations of this RCT center on the modified intent-to-treat analysis for patients who swallowed 1 balloon. Patients who could not tolerate the device were excluded after randomization, potentially biasing results in favor of the balloon. Limited data on adverse events were provided, and there was incomplete reporting of control group outcomes.

Clinical Practice: Safety

Mild to moderate adverse events are frequent with either gastric balloon system and can occur in up to 91% of persons undergoing gastric balloon placement.[3-6] Most patient concerns are related to gastrointestinal symptoms, such as nausea, vomiting, dyspepsia, and pain. The majority of patients are treated with proton pump inhibitors and antiemetic or antispasmodic medications. Less than 3% of events require unplanned endoscopic intervention or early removal of the gastric balloon system.[3-6]

In 2017, the FDA issued an alert to clinicians about potential risks associated with liquid-filled balloons. Reports of spontaneous overinflation of the fluid-filled gastric balloon system and acute pancreatitis have been received by the FDA. Prompt removal is often required if this occurs.[7] In June 2018, the FDA amended the device alert to include reports of deaths associated with the gastric balloon. Since 2016, the FDA has received reports of 12 deaths that have occurred

Figure. US Food and Drug Administration (FDA)–Approved Gastric Balloon Products for Weight Loss



worldwide following placement of liquid-filled gastric balloon systems. At this time, neither the root cause or incidence rate of patient death can be definitively attributed to the devices or the insertion procedures for these devices. However, these deaths have resulted in additional manufacturer labeling about possible death associated with these devices.[7]

A study assessing the safety profile of gastric balloon systems compared with laparoscopic bariatric surgery demonstrated higher rates of adverse events with the gastric balloon system. Using the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database, investigators found that gastric balloon placement was independently predictive of 30-day adverse outcomes (odds ratio, 1.97 [95% CI, 1.10-3.52]; $P = .02$). This was due to a significantly higher nonoperative reintervention rate in the gastric balloon cohort (4.2% vs 1.0%; $P < .001$) and early balloon removal (2.8%).[8]

Role in the Multidisciplinary Management of Obesity

The possible advantages of balloon therapy include use in patients with a lower BMI who do not qualify for or are not interested in bariatric surgery. Studies are needed to evaluate this therapy in higher-risk patients for whom surgery is contraindicated or as a bridge therapy to another procedure.

Bottom Line

Use of FDA-approved gastric balloon systems under manufacturer guidelines and in the context of a multidisciplinary weight loss program in select patients may have benefit and fit into a comprehensive weight loss strategy. However, given uncertainty of the sustainability and overall long-term safety of these devices, wide adoption should be cautioned. They should not be used in lieu of bariatric surgery when it is appropriate and feasible.

ARTICLE INFORMATION

Author Affiliations: Department of Surgery, University of Michigan, Ann Arbor (Telem, Ghaferi); Center for Healthcare Outcomes and Policy, University of Michigan, Ann Arbor (Telem, Ghaferi).

Corresponding Author: Dana A. Telem, MD, MPH, Department of Surgery, University of Michigan, 1500 E Medical Center Dr, Ann Arbor, MI 48109 (dtelem@med.umich.edu).

Conflict of Interest Disclosures: Dr Telem reported receiving grants from Medtronic, the Agency for Healthcare Research and Quality, and the National Institutes of Health outside the submitted work. Dr Ghaferi reported receiving grants from the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes Research Institute, and the National Institutes of Health and salary support from Blue Cross Blue Shield of Michigan.

REFERENCES:

1. Estimates of bariatric surgery numbers, 2011-2018. American Society for Metabolic and Bariatric Surgery. Accessed April 2, 2020. https://asmbs.org/resources/estimate-of-bariatric-surgery-numbers

2. Weight-loss and weight-management devices. US Food and Drug Administration. Published September 5, 2019. Accessed October 1, 2019. https://www.fda.gov/medical-devices/products-and-medical-procedures/weight-loss-and-weight-management-devices

3. Fuller NR, Pearson S, Lau NS, et al. An intragastric balloon in the treatment of obese individuals with metabolic syndrome: a randomized controlled study. *Obesity (Silver Spring)*. 2013;21(8):1561-1570. doi:10.1002/oby.20414

4. Courcoulas A, Abu Dayyeh BK, Eaton L, et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. *Int J Obes (Lond)*. 2017;41(3):427-433. doi:10.1038/ijo.2016.229

5. Sullivan S, Swain J, Woodman G, et al. Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss. *Surg Obes Relat Dis*. 2018;14(12):1876-1889. doi:10.1016/j.soard.2018.09.486

6. Kumar N, Bazerbachi F, Rustagi T, et al. The influence of the Orbera intragastric balloon filling volumes on weight loss, tolerability, and adverse events: a systematic review and meta-analysis. *Obes Surg*. 2017;27(9):2272-2278. doi:10.1007/s11695-017-2636-3

7. The FDA alerts health care providers about potential risks with liquid-filled balloons. Published February 9, 2017. Accessed April 2, 2020. https://www.fda.gov/medical-devices/letters-health-care-providers/fda-alerts-health-care-providers-about-potential-risks-liquid-filled-intragastric-balloons

8. Dang JT, Switzer NJ, Sun WYL, Raghavji F, Birch DW, Karmali S. Evaluating the safety of intragastric balloon: an analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program. *Surg Obes Relat Dis*. 2018;14(9):1340-1347. doi:10.1016/j.soard.2018.05.003