



Case Report: An Off-label Use of the Air-filled Gastric Balloon System as an Adjunct to Bariatric Surgery

Mai Gandhi*, Brian Welch, Stephanie Luster and Noman Khan

Department of Surgery, Flushing Hospital Medical Center, USA

Abstract

Despite lifestyle modification and weight-loss programs, the obesity epidemic is on the rise. A variety of new laparoscopic and endoscopic techniques exist to aid in the weight loss process, with some of the newest advances in intra gastric balloons. In this case report, we aim to answer the question of whether the Air-filled Gastric Balloon System can act as a bridge to definitive bariatric surgery, as an off-label use, in patients with a BMI greater than 65 kg/m².

Introduction

The prevalence of obesity is increasing worldwide, and The Center of Disease Control (CDC) data indicates that 39.8% of adults and 18.5% of youth in the United States are obese [1]. Obesity is associated with several comorbidities, including heart disease, stroke, diabetes, and various types of cancer. Additionally, obesity and related co morbid conditions impart an increasing economic burden on health care systems. For example, in 2008, it was estimated that the United States spent \$142 billion USD on obesity-related medical costs [2].

Although lifestyle modifications are first-line treatments for obesity, these approaches are generally ineffective due to several factors, particularly lack of patient compliance. Thus, various surgical interventions have emerged over the last five decades to facilitate obesity management. Since the first jejunoileal bypass was performed in 1954 by Dr. Kremen, bariatric surgical procedures have continued to evolve [3]. With relatively recent advancements in endoscopic and laparoscopic techniques, there are now several procedures with varying degrees of complexity used for obesity management. An emerging treatment option for obesity is the intra gastric balloon.

Intra gastric balloons are currently used as an adjunctive therapy for weight loss in obese individuals. The principle mechanism of action of these balloons is to target the mechanoreceptors of the gastric wall. Once delivered into the stomach, they occupy the gastric cavity, induce an early sensation of satiety, and thereby reduce caloric intake.

Currently there are two types of intra gastric balloons: fluid-filled and air-filled. The Obalon Balloon System was approved for use in 2016 and is the first FDA approved swallow able balloon system designed for weight loss. Currently, the Obalon Balloon System is indicated for temporary use to facilitate weight loss in adults with a BMI of 30 kg/m² to 40 kg/m² who have failed to lose weight through diet and exercise. The system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program.

The Obalon Balloon System comes in a set of three balloons that the patient swallows. Occasionally, endoscopy is used to assist in intra gastric placement of the balloon. All balloons must be removed 6 months after the first balloon is placed [4]. Of the air-filled intra gastric balloon options, the Obalon Balloon System has been shown to be the most likely to achieve weight loss [5]. Aside from a rare potential association between fluid-filled intra gastric balloons and acute pancreatitis [6], the side effect profile of the Obalon Balloon System is relatively benign. The most common adverse effects reported are nausea and emesis [7]. Small bowel obstruction has also been reported from a migrating Obalon balloon, which was managed endoscopically [8]. Additionally, there is one reported case in Korea of gastric perforation in a patient with noncompliance of PPI therapy after intra gastric balloon insertion, however, it should be noted that the Obalon Balloon System was not used in this case [9].

Here, we report the first use of air-filled gastric balloon system (Obalon) as a successful adjunctive modality for bariatric surgery in a patient with morbid obesity in extremely high BMI (>65 kg/m²). To our knowledge, there has not been any other documented off-label use of an intra

OPEN ACCESS

*Correspondence:

Mai Gandhi, Department of Surgery,
Flushing Hospital Medical Center, New
York, USA,

E-mail: mdang86@gmail.com

Received Date: 12 Sep 2019

Accepted Date: 25 Sep 2019

Published Date: 30 Sep 2019

Citation:

Gandhi M, Welch B, Luster S, Khan N.
Case Report: An Off-label Use of the
Air-filled Gastric Balloon System as an
Adjunct to Bariatric Surgery. *Clin Case
Rep Int.* 2019; 3: 1121.

Copyright © 2019 Mai Gandhi. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

gastric balloon system.

Case Presentation

A 52-year-old male with a history of arthritis, hypertension, hypothyroidism and morbid obesity presented in July 2018, for evaluation for bariatric surgery. His weight was 243 kg (BMI 70.7 kg/m²) and previous attempts to lose weight with nutritional modification were unsuccessful. In addition, due to a history of arthritis, the patient was bed-bound and unable to carry out activities of daily living. Immobility and morbid obesity resulted in the development of an acute lower extremity deep vein thrombosis and shortness of breath, likely due to a pulmonary embolism, which was never confirmed because of the weight limit of the CT scanner. Due to his high BMI, and associated co morbid conditions, the patient was considered to be an extremely high risk bariatric surgical candidate. The decision was made, after comprehensive discussion with the patient, to utilize the Air-filled Gastric Balloon System to attempt weight loss and optimize the patient for bariatric surgery. He underwent insertion of a total of three intra gastric balloons from July to September 2018. He presented to Flushing Hospital Medical Center on February 5th, 2019 for removal of the balloons.

Our patient lost a total of 73 kg and weighed 170 kg (BMI 49.5 kg/m²) at the time of the intra gastric balloon removal. He is currently scheduled to undergo sleeve gastrectomy sometime in the next 3 to 4 months.

Risk Profile

Based on the ACS NSQIP Surgical Risk Calculator [10], we calculated that with our patient's initial weight (243 kg, BMI 70.7 kg/m²) and severe co morbid conditions, his risk of serious postoperative complications would have been 5.5%, which is double that of the average population at 2.4%. His calculated overall postoperative complication risk would have been 6.9%, compared to 3% in the average risk patient. By lowering his weight, his calculated risk of serious postoperative complication would decrease to 2.7% (which is similar to those at average risk at 2.4%).

Discussion

Intra gastric balloons have emerged as a safe and practical adjunct for weight loss in obese individuals. Among the air-filled balloon options, the Obalon Balloon System has been demonstrated to be most likely to result in weight loss [5]. Moreover, while the other methods involve at least an endoscopic suite for placement, the Obalon Balloon System is available in pill form and can be administered in an ambulatory setting. Since there is no requirement for anesthesia, the risk of complications is lower.

The safety profile of the Obalon Balloon System is based off of a double blinded, randomized controlled, clinical trial that included 387 patients with a BMI between 30 kg/m² and 40 kg/m². These patients were randomized to receive either the Obalon Balloon System or a sham device and were assessed for weight loss and safety outcomes after an initial 24-week period [11]. Since this study, the Food and Drug Administration has approved the Obalon Balloon System for a targeted patient BMI between 30 kg/m² to 40 kg/m².

An important consideration in applying the Obalon Balloon

System is the cost. The Obalon Balloon System is not currently covered by insurance, thereby imparting a patient-provided cost of \$6,000 to \$8,500 USD. Thus, there is a potential socioeconomic burden that may affect endpoints in the future.

Our patient chose to undergo a pioneering procedure for a patient of his BMI. Had this not been offered, alternative options to this off-label use include intensive inpatient dietary modification and exercise programs, or direct to surgery. For patients with a BMI greater than 65 kg/m², these alternate options, if failed, pose a greater risk and cost.

Prospective studies should be conducted to investigate the feasibility of using intra gastric balloons as a bridge to bariatric surgery in extremely obese individuals, that otherwise have a prohibitive risk for surgical intervention.

Conclusion

Effective and safe weight loss in patients with morbid obesity is essential. In our patient, the air-filled gastric balloon system (specifically Obalon) offered a minimally invasive and compelling method in achieving adequate weight loss prior to bariatric surgery. We demonstrated the successful off-label use of the air-filled gastric balloon system as an adjunctive therapy to facilitate weight loss and serve as a bridge to bariatric surgery in a patient with an initial BMI greater than 65 kg/m².

References

- Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of Obesity Among Adults and Youth: United States, 2015-2016. *NCHS Data Brief*. 2017;(288):1-8.
- Overweight & Obesity. Centers for Disease Control and Prevention.
- Faria GR. A Brief History of Bariatric Surgery. *Porto Biomed J*. 2017;2(3):90-2.
- PMA P160001: FDA Summary of Safety and Effectiveness Data.
- Bazerbachi F, Haffar S, Sawas T, Vargas EJ, Kaur RJ, Wang Z, et al. Fluid-Filled Versus Gas-Filled Intra-gastric Balloons as Obesity Interventions: a Network Meta-analysis of Randomized Trials. *Obes Surg*. 2018;28(9):2617-25.
- Gore N, Ravindran P, Chan DL, Das K, Cosman PH. Pancreatitis from intra-gastric balloon insertion: Case report and literature review. *Int J Surg Case Rep*. 2018;45:79-82.
- Trang J, Lee SS, Miller A, Cruz Pico CX, Postoev A, Ibikunle I, et al. Incidence of Nausea and Vomiting After Intra-gastric Balloon Placement in Bariatric Patients- A Systematic Review and Meta-analysis. *Int J Surg*. 2018;57:22-9.
- Vlachou E, Direkz S, Murino A, Wylie P, Hamilton MI, Murray CD, et al. Small Bowel Obstruction Caused by a Migrated Obalon Gastric Bariatric Balloon: Nonsurgical Management by Antegrade Double-balloon Panenteroscopy. *Endoscopy*. 2016;48(S 01):E403-4.
- Yoo IK, Chun HJ, Jeon YT. Gastric Perforation Caused by an Intra-gastric Balloon: Endoscopic Findings. *Clin Endosc*. 2017;50(6):602-4.
- ACS NSQIP Surgical Risk Calculator.
- Sullivan S, Swain J, Woodman G, Edmundowicz S, Hassanein T, Shayani V, et al. Randomized sham-controlled trial of the 6-month swallowable gas-filled intra-gastric balloon system for weight loss. *Surg Obes Relat Dis*. 2018;14(12):1876-89.