Intragastric Balloon Hyperinsufflation as a Cause of Acute Obstructive Abdomen

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ABSTRACT
Recently, the Food and Drug Administration approved the use of the Orbera balloon for obesity treatment. However, the Food and Drug Administration later issued a warning about the possibility of 2 complications not previously reported: acute pancreatitis and balloon hyperinsufflation. This case report is intended to alert all clinicians that, although rare, cases of hyperinsufflation should be considered in patients with an intragastric balloon (IGB) and acute abdomen. IGB removal will resolve the complaints, provided there is no irreversible ischemia of the stomach walls. Care should be taken with respect to an increased risk of pulmonary aspiration at the time of balloon removal, and endotracheal intubation is highly recommended.

INTRODUCTION
Obesity, given its high prevalence and associated comorbidities, is a chronic, progressive, and incurable disease that has become a major public health concern worldwide. Obesity negatively affects the quality of life of sufferers and results in a high financial burden. In the United States, approximately 70% of the adult population is overweight (body mass index (BMI) 25–30 kg/m²) or obese (BMI >30 kg/m²). Weight loss may improve or completely resolve the comorbidities associated with obesity. Although bariatric surgery is the most effective and longest-lasting therapy used to treat this pathology, it is only indicated for advanced cases of the disease. For less severe cases (e.g., overweight, Class I obesity, Class II obesity), bariatric endoscopy is rapidly emerging as an effective and less invasive alternative, with intragastric balloon (IGB) placement being one of the most common procedures performed for these cases.

CASE REPORT
A 46-year-old woman presented with an initial BMI 31.6 kg/m². She had no other comorbidities or previous history of abdominal surgery. She opted for IGB placement (Orbera, Apollo Endosurgery, Austin, TX) to treat mild obesity. Three months after the procedure, she had lost a total of 16 kg with a reduction in BMI to 25.4 kg/m².

At 3 months after IGB placement, the patient consulted the bariatric endoscopy service due to progressively worsening epigastric pain over 48 hours, nausea, vomiting, and abdominal distension. On physical examination, the...
Patient had bulging of the upper abdominal wall and presented diffuse pain on palpation, but she showed no other signs of peritoneal irritation or hemodynamic instability (Figure 1).

Abdominal radiography showed an increase in the diameter of the IGB (Figure 2). The patient was admitted to the emergency department and was treated with intravenous scopolamine, dipyrene, and bromopride, which provided symptomatic relief. Due to the improvement of symptoms including the pain on palpation, the patient fasted for 12 hours to reduce the gastric contents and diminish the risk of pulmonary aspiration during intubation. After upper digestive endoscopy of the gastric cavity and aspiration of a large quantity of gastric residues, IGB hyperinsufflation was confirmed with evident high levels of gas (approximately 50% of the total volume of the balloon was filled, whereas the normal fill volume is restricted to a very small quantity) (Figure 3). The balloon was emptied using a needle according to the conventional technique to remove the balloon. However, the IGB ruptured after puncturing it with the needle (Figure 4). The liquid contents of the IGB were aspirated, and the balloon was removed without further complications (Figure 5).
The patient exhibited clinical improvement, and she was discharged on the same day as the procedure.

**DISCUSSION**

Surgical procedures are approved for patients with $\text{BMI} \geq 40 \text{ kg/m}^2$ or $\text{BMI} \geq 35 \text{ kg/m}^2$ when the patient has associated comorbidities. The Food and Drug Administration (FDA) has approved the use of 3 IGBs: ReShape Integrated Dual Balloon System (ReShape Medical Inc., California), Obalon Balloon System (Obalon Therapeutics, Carlsbad, California), and Orbera for use in patients with $\text{BMI} \geq 30 - 40 \text{ kg/m}^2$. IGBs are placed endoscopically and promote weight loss, not only because they take up space in the patient’s stomach but also by delaying gastric emptying.\(^4\)

Orbera is the most widely used IGB in the world, and it has been approved for use in Europe since 1997.\(^5\) An assessment of 154,955 procedures performed between 2006 and 2013 found that 3,316 (2.1%) unspecified events/complaints had occurred.\(^5\) A recent review of 68 studies reported the need to remove the IGB early in 7% of patients.\(^6\) The most commonly reported adverse events (33% of cases) were mild gastrointestinal symptoms (pain and nausea); the rate of severe adverse events is low, with IGB migration occurring in 1.4% of cases and gastric perforation in 0.1% of cases (4 out of 8 perforations reported were in patients with a history of gastric surgery). Other possible complications are erosions and gastric ulcers.\(^7\)

The FDA recently issued a warning about the possibility of 2 previously unreported complications involving these balloons that may require early IGB removal and, in some cases, hospitalization: acute pancreatitis and balloon hyperinsufflation.\(^7\) Symptoms of IGB hyperinsufflation include severe abdominal pain, abdominal distension (with or without associated pain), dyspnea, and vomiting.\(^7\) The cause of hyperinsufflation is unknown. Some investigators have conjectured that it may be due to permeability of the IGB, which results in the entry of fluids and gases by osmosis (given that the balloon is filled with saline solution), or due to the presence of an anaerobic bacteria that produce gas, as previously reported in cases of hyperinsufflation of silicone breast implants filled with saline solution.\(^3,8-10\)

This case report describes a rare event of acute IGB hyperinsufflation. This complication should be considered in cases of persistent food intolerance, pain, and abdominal distension after the adaptation period of the balloon (i.e., the first 3 days). The fragility of the IGB structural components caused by hyperinsufflation may increase the risk of rupture when it is punctured, and it is therefore suggested that upper digestive tract endoscopy is performed with endotracheal intubation to prevent pulmonary aspiration of the balloon contents and to reduce the risk of morbidities. In our case, the main hypothesis of hyperinsufflation was contamination by bacteria inside the balloon. Whenever possible, the aspirated liquid should be collected and sent for analysis to identify possible microorganisms responsible for this complication, although in cases of balloon rupture this is impracticable due to contamination with gastric fluid.

In conclusion, although rare, cases of hyperinsufflation should be suspected in patients with an IGB and acute abdomen. Removal of the IGB will resolve the complaints provided there is no irreversible ischemia of the stomach walls. Care should be taken in respect to an increased risk of pulmonary aspiration at the time of balloon removal due to the high pressure in the proximal portion of the balloon; thus, endotracheal intubation, with immediate anesthesia if necessary, is highly recommended.

**DISCLOSURES**

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Informed consent was obtained for this case report.

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**REFERENCES**

1. Berthoud HR, Klein S. Advances in obesity: Causes, consequences, and therapy. Gastroenterology. 2017;152:1635-37.
2. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. JAMA. 2010;303:235–41.
3. Tate CM, Geliebter A. Intragastric balloon treatment for obesity: Review of recent studies. Adv Ther. 2017;34(8):1859–75.
4. Sullivan S, Edmundowicz SA, Thompson CC. Endoscopic bariatric and metabolic therapies: New and emerging technologies. Gastroenterology. 2017;152(7):1791–801.
5. ORBERA intragastric balloon system. San Diego: Apollo Endosurgery; 2015. 1–30.
6. Abu Dayyeh BK, Edmundowicz SA, Jonnalagadda S. Endoscopic bariatric therapies. Gastrointest Endosc. 2015;81:1073–86.
7. Kumbhari V, Hill C, Sullivan S. Bariatric endoscopy: State-of-the-art. Curr Opin Gastroenterol. 2017;33:358–65.
8. Robinson OG, Benos DJ, Mazzochi C. Spontaneous autoinflation of saline mammary implants: Further studies. Aesthetic Surg J. 2005;25:582–6.
9. Seng P, Bayle S, Alliez A, Romain F, Casanova D, Stein A. The microbial epidemiology of breast implant infections in a regional referral centre for plastic and reconstructive surgery in the south of France. Int J Infect Dis. 2015;35:62–6.
10. Misiakos EP, Bagias G, Patapis P, Sotiropoulos D, Kanavidis P, Machairas A. Current concepts in the management of necrotizing fasciitis. Front Surg. 2014;1:36.