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CASE REPORT

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Hidden dangers and updated labels on gastric balloons

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Abstract

In recent years, intragastric balloons (IGBs) have emerged as an efficacious, nonsurgical modality to treat obesity. We present a case in which an IGB caused a gastric ulcer, only unearthed after the novel technique of deflation and early retrieval.

KEYWORDS

early retrieval, gastric ulcer, intragastric balloons

1 | INTRODUCTION

IGBs were first introduced in 1982 by Nieben—who described them as an artificial space-occupying device that leads to gastric distension, increased satiety, and decreased food intake.[1] The IGB promotes early satiety by activating gastric stretch receptors to ultimately decrease the amount of food eaten.[2]

Proposed as an alternative to bariatric surgery, IGBs are indicated in: (a) patients with a body mass index (BMI) >35, (b) patients with a BMI >30 with comorbidities that negatively affect cardiovascular health, (c) preemptively in those with a BMI <30, who have failed lifestyle alterations and pharmacotherapy interventions, (d) bridging morbidly obese patients with a BMI >40 to decrease the complications of bariatric surgery, and (e) patients who are not surgical candidates or those who decline surgical routes.[2] The IGB is left in for approximately six months, during which time mean total body weight loss (TBWL%) ranges from 9.7% to 11.8%. After 6 months of therapy, efficacy is diminished and the risk of complications increases.[3]

As of June 2018, the Food and Drug Administration (FDA) advised intragastric balloon (IGB) manufacturers to address the possibility of death with these devices. This came after the worldwide death toll from gastric balloons increased from 7 to 12 persons since 2016—secondary to

gastric perforation and/or intestinal obstruction. Herein, we review the literature on FDA-approved intragastric balloons and describe a case of a gastric ulcer caused by an intragastric balloon only unearthed after deflation and early retrieval.

2 | CASE PRESENTATION

A 44-year-old Egyptian female six-month post-IGB insertion presented with nausea, nonbloody nonbilious vomiting, extreme weight loss of 40 pounds, and mid epigastric dull nonradiating abdominal pain (Figure 1). She had been told her IGB could stay in place for one year as per her physician in Egypt, so she was resistant to having it removed. After persistent symptomatology including per oral intolerance, she agreed to deflation and retrieval of her IGB via esophagoduodenoscopy (EGD). Endoscopic inspection of gastric mucosa after deflation of the balloon revealed a 1-centimeter (cm) gastric ulcer in the body of the stomach, along with erosive reflux-induced esophagitis in the distal one third of the esophagus (Figures 2, 3). Symptoms improved significantly once IGB was removed. The patient was eventually discharged once she regained per oral capabilities with proton pump inhibitors (PPIs) and a follow-up EGD on outpatient.

3 | DISCUSSION

3.1 | History and indications

The first IGB was invented in 1982. Two years later, the FDA approved the first IGB as an adjunctive therapy to treat obesity.[2] Due to the multiple significant complications and disappointing weight regain postremoval led to discontinuation of the device and revocation of FDA approval for the device in 1992.[4,5] The evolving design of IGBs continued in order to develop more effective and safer balloons. In 1999, methylene blue was mixed in the saline injected into IGBs. If the balloon perforated, the methylene blue would be absorbed systemically resulting in blue or green urine signaling immediate intervention. The device has never been approved in the United States by the FDA, but the colored urine indicator has persisted in current IGBs.[5] Current FDA-approved IGB systems include the Orbera, the ReShape Duo, and the Obalon.[6] Their indications, duration of treatment, TBWL%, and adverse events are reported in Table 1.

3.2 | Adverse effects

As summarized in Table 1, the characteristics, safety and efficacy of the Obera, ReShape, and Obalon IGBs are the

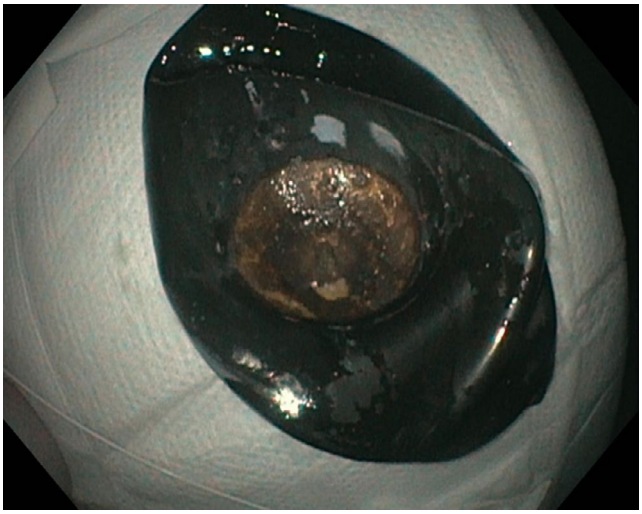

FIGURE 2 Deflated intragastric balloon (IGB)

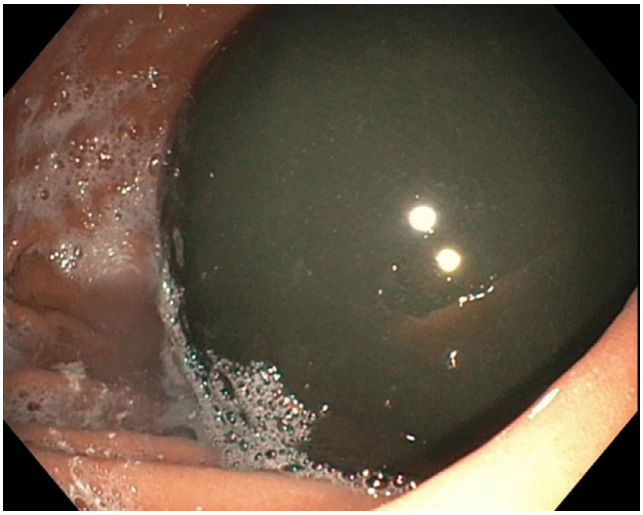

FIGURE 1 Inflated intragastric balloon (IGB)

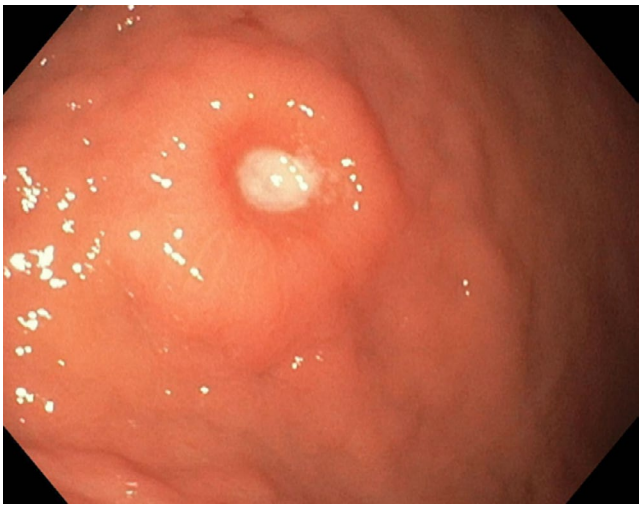

FIGURE 3 Gastric ulcer uncovered after balloon deflation

	Orbera	ReShape	Obalon
FDA indication	Class I and II obesity	Class I and II obesity	Class I and II obesity
Duration of placement	6 mo	6 mo	6 mo
Most common adverse events	Nausea, emesis, abdominal pain	Gastric ulcers	Abdominal pain and cramping, nausea
Most common *significant* adverse events	Device intolerance	Gastric ulcers, balloon deflation, device intolerance	Bleeding gastric ulcers
TBWL at 6 mo	10.2% ± 6.6%	7.6% ± 5.5%	6.6% ± 5.1%
Control-subtracted TBWL at 6 mo	6.9% ± 8.4%	4.0% ± 8.4%	3.2%

TABLE 1 Characteristics, safety, and efficacy of various intragastric balloons[1,2,5,9-11,13,22,23]

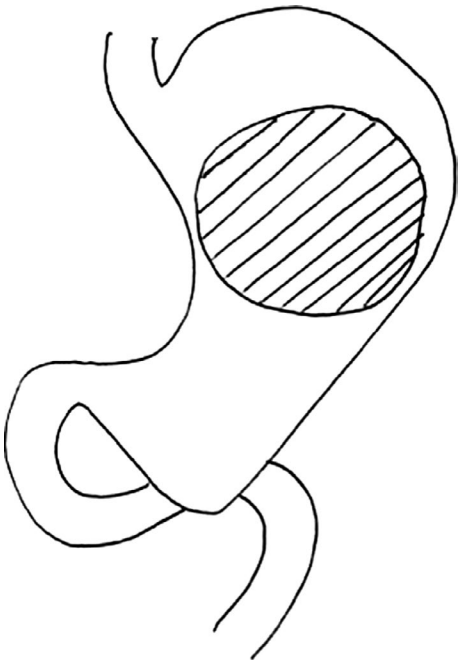

FIGURE 4 Sketch representation of an Orbera balloon within the fundus of the stomach

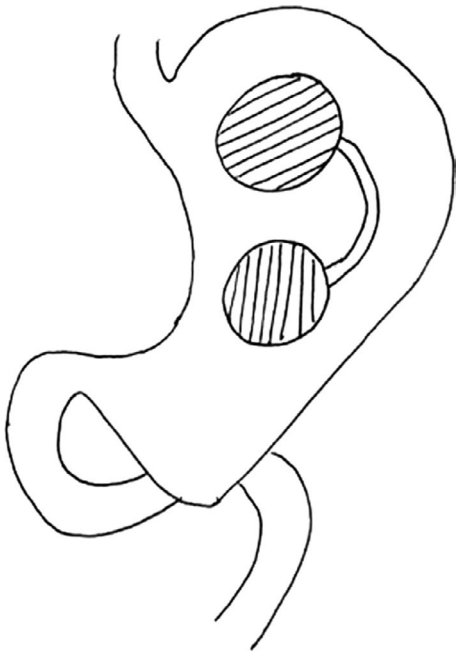

FIGURE 5 Sketch representation of a bilobed Reshape balloon within the stomach

precipitating factors for their respective use (Table 1). In general, IGBs come with a spectrum of adverse effects (AEs). The probability of an IGB-related AE increases with increased duration of the IGB in place. Historically, the complication rate of IGBs is approximately 5.5% and 8% of patients required early retrieval.[12] A recent meta-analysis indicated the majority of IGB-related complications were mild, and the early retrieval rate was 4.2%.[13]

The Food and Drug Administration (FDA) advised intragastric balloon (IGB) manufacturers to address fatal complications as a result of gastric perforation or intestinal obstruction. This issue arose after the death toll from gastric balloons increased from 7 to 12 persons since 2016. IGB-related AEs commonly include abdominal pain or discomfort usually epigastric, nausea, vomiting, halitosis, belching, flatulence, and psychological discomfort toward the presence of a foreign body.[14] In one study, the most common side effects reported were nausea, abdominal pain, gastric erosion, and flatulence occurring 72%, 39%, 32%, and 24% of the time, respectively.[15] Early retrieval of the IGB under conscious sedation or general anesthesia has resulted in aspiration pneumonia, perforation or mucosal tears within the esophagus, ulcers within the gastroesophageal junction, and pneumonitis.[7,16,17] Pancreatitis is an increasingly recognized complication of IGB insertion and generally occurs within 1-year post-IGB insertion.[18] It is unknown whether continuous pressure on the pancreas occurs from the outset or only once the balloon settles into

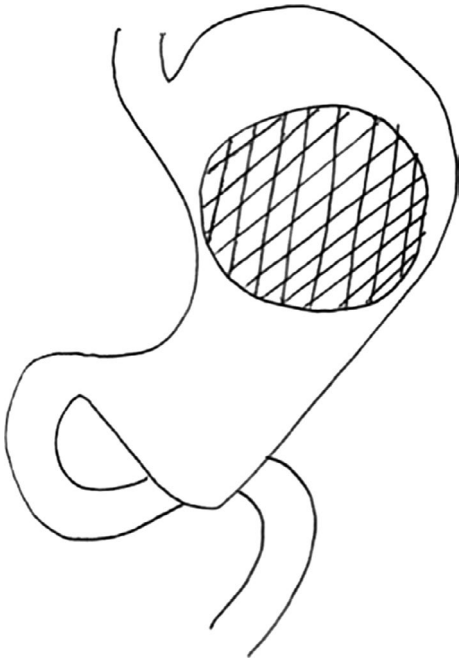

FIGURE 6 Sketch representation of an initially inflated Obalon balloon within the fundus

the fundus. Notably, visceral complications remain a real concern in patients undergoing IGB insertion.[19] A dozen cases have revealed bowel obstruction as a possible AE of IGB.[19] Serious AEs such as esophageal, gastric, and intestinal perforation have also been reported, although less frequently.[19]

Early AEs with the Orbera system include abdominal pain, nausea, early explantation, migration, and gastrointestinal perforation.[14] Notably, IGBs have been identified as an important cause of gastric outlet obstruction with resultant perforation if early retrieval is not implemented affecting up to 0.8% of patients in certain populations.[13,14] Removal of the IGB can be done through conscious sedation later; however, with reports of deaths from aspiration pneumonia and difficulty in IGB removal, some endoscopists prefer endotracheal intubation and general anesthesia. The balloon is punctured with an endoscopic needle, and a grasper is used to retrieve the deflated balloon.[16] Of note, studies using the Orbera system showed an absence of any spontaneous deflation, which was a far more common complication of other IGB systems.[20].

Patients with ReShape balloon insertion were reported to have frequent gastric ulcers with IGB placement.[7,17] A large study found gastric ulcers and erosions to be frequent adverse events of ReShape IGBs, initially observed in almost 40% of study participants.[21] However, a subsequent modification in the device design led to a decrease in both ulcer frequency and size.[21] Notably, one ulcer-related upper GI hemorrhage required blood transfusion.[21] During retrieval, common adverse effects include contained perforations of the cervical esophagus, mucosal tears of the esophagus, ulcers at the gastroesophageal junction, and pneumonitis.[7,16,17,21]

Common AEs reported following Obalon placement include epigastric pain, vomiting, and nausea. Despite this, the balloon seems to be generally well tolerated with a significantly lower incidence of accommodative symptoms compared to those observed with other fluid-filled balloons. The three balloon types are drawn as a sketch below to highlight their location and structural appearance (Figures 4-6).

3.3 | Efficacy

During its six months, IGBs have shown to decrease insulin resistance and fasting glucose levels in accordance with weight lost. Its effect on ghrelin, appetite-stimulating hormone, was paradoxically increased as patients lost weight and then returned to baseline within 1 month after the IGB was removed. However, most studies study total ghrelin which includes both active and inactive forms, so it is unlikely they are representative of the active form's levels and its effects. Leptin, the appetite-suppressing hormone, was reduced and returned to normal upon removal of the IGB, leaving no lasting effects on appetite behaviors. IGBs have shown little to no effect on adiponectin, which influences weight loss, as well as formation of obesity-related comorbidities such as coronary artery disease.[8,22,23] Analysis of these trends demonstrates that IGBs have no long-term effect on hormones regulating weight loss and thus make it difficult to have sustained weight loss following removal. While patients can expect to lose 5.6%-15.4% of their TBWL at the end of 6 months when the IGB is removed, examining weight loss at the end of one year shows a 4% regain with most averaging only 2.8 kg loss at the end of 1 year. At a growing cost of approximately $8150 for implantation and retrieval, its side effects and outcomes should be adequately explained to patients to align with their expectations.[8]

4 | CONCLUSION

In conclusion, IGB remains an important non-operative treatment strategy in bariatric patients. The potential complications are cumbersome and require clinician knowledge to prevent mortality. As early retrieval and deflation can be key to diagnosis, clinicians should now be aware of this important procedural technique to prevent serious sequelae.

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None.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

Sindhura Kolli and Simcha Weissman: drafted the manuscript, critically revised the manuscript, and finally approved the manuscript; Andrew Ofosu, Harini Gurram, Paul Khoi Dang-Ho, Tej I Mehta, and Hailie Gill: drafted the manuscript; Krishna Gurram: provided images and supervised the study.

INFORMED CONSENT

Informed consent was obtained for this case.

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