




# Surgical Management of Intra-gastric Balloon Complications, Single-Center Experience, and Literature Review

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## Abstract

**Introduction** In Saudi Arabia, the prevalence of obesity has multiplied in the last decades leading to a surge in bariatric surgery and other endoscopic modalities. The intra-gastric balloon (IGB) is the most used endoscopic modality. Surgical management for IGB complications is required for gastrointestinal perforation and/or obstruction. However, the literature seems to underestimate these complications.

**Materials and Methods** A retrospective descriptive study was conducted in King Fahd University Hospital, Saudi Arabia, from Jan 2017 to Dec 2021, including all patients with complicated IGB who necessitated any surgical procedure. Exclusion criteria were patients with complicated IGBs that were only managed conservatively or endoscopically.

**Results** A total of 326 patients were admitted with different complications after bariatric procedures. Of them, six patients were referred due to IGB complications that necessitated operative intervention. All patients were young females. Three patients had gastric wall perforation, and were managed by endoscopic removal of the IGBs followed by exploratory laparotomy. One patient had an intestinal obstruction on top of a migrated IGB that was surgically removed. One patient had failed endoscopic retrieval of IGB and required a laparoscopic gastrotomy. Another patient had an esophageal rupture that required left thoracotomy, pleural flap, and insertion of an esophageal stent. All cases were discharged and followed up with no related complications.

**Conclusion** IGB is an endoscopic alternative, within specific indications, for the management of obesity. However, surgical management may be necessary to manage its complications, including gastrointestinal perforation, IGB migration, and failure of endoscopic removal.

**Keywords** Intra-gastric balloon · Complications · Gastric perforation · Esophageal perforation · Intestinal obstruction · Intra-gastric balloon migration

## Key Points

- This study discusses the different clinical presentations of IGB complications.
- Six patients had IGB complications that necessitated operative intervention.
- Three patients had gastric wall perforation, one patient had an esophageal rupture, one patient had intestinal obstruction on top of a migrated IGB, and one patient had failed endoscopic retrieval.

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## Introduction

In Saudi Arabia, the prevalence of obesity has multiplied in the last decades, reaching 35.1% and 58.7% in males and females, respectively [1, 2]. This continual increase in obese patients has led to a growing surge in bariatric surgery and other endoscopic and pharmaceutical modalities to combat this epidemic.

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The intra-gastric balloon (IGB) is the most used endoscopic modality for managing obesity with considerable effectiveness, as compared to medical therapy, for class I obesity. The average reported percentage of excess weight loss 6 months after removal ranges from 14 to 27.2% [3, 4]. After the introduction of the Garren-Edwards Gastric Bubble in 1984, different types and generations have been introduced to the markets [5]. However, all of them depend on the restrictive mechanism to achieve weight loss by limiting gastric capacity, decreasing oral intake, increasing satiety, and delaying gastric emptying as well as alteration of the neuroendocrinal functions of the stomach [3, 6]. In general, IGBs are silicone balloons, classically introduced using the esophago-gastro-duodenoscopy (EGD), inflated with approximately 450–900 ml of saline and/or gas and then removed after 3–6 months using EGD [3]. The new generations of IGBs allow complete insertion and expelling without EGD [7].

Although IGB is a less invasive procedure, complications after the insertion do occur and can be classified into gastrointestinal symptoms, balloon migration, gastric ulceration or perforation, gastrointestinal bleeding, intestinal obstruction, spontaneous deflation or overinflation, acute pancreatitis, and esophageal perforation [8, 9]. The overall estimated rate of morbidity and mortality is 2.5% and 0.05%, respectively [9–11]. Early unplanned balloon removal may be needed in 3% of patients [8, 11].

Surgical management for IGB complications has been described in only few reported cases of gastrointestinal perforation or obstruction [12]. We aim to report our experience as a tertiary university hospital in the Eastern Province of Saudi Arabia in dealing with different complications of IGBs that necessitated any type of surgical intervention.

## Methods

After being approved by the local Institutional Review Board, a retrospective descriptive study was conducted in King Fahd University Hospital, Imam Abdulrahman Bin Faisal University, the tertiary university hospital in the Eastern Province of Saudi Arabia, for 5 years, from Jan 2017 to Dec 2021, including all patients with complicated IGBs who necessitated any surgical procedure. Exclusion criteria were patients with complicated IGBs that were only managed conservatively or endoscopically. Their electronic medical files were reviewed to collect their demographic data, past medical and surgical history, weight, BMI, postoperative symptoms, postoperative medications, findings of contrast studies and endoscopy, second operations details, postoperative course, and improvement of symptoms.

## Results

Between Jan 2017 and Dec 2021, 326 patients were admitted to our hospital with different complications after different bariatric procedures, either performed in our hospital or referred from other hospitals. Of them, six patients met our inclusion criteria and were referred due to IGB complications that necessitated operative intervention in the form of laparoscopy, laparotomy, or thoracotomy. All these patients had their IGBs inserted outside our hospital; therefore, limited data were available regarding their primary insertion of IGBs.

All patients were young females. In five of the cases, IGBs were inserted for the first time. The duration between insertion and complications ranged from 10 days to 18 months. Their body mass index (BMI) upon presentation ranged from 27 to 36.8 kg/m<sup>2</sup>. All patients had no previous gastric surgeries. Three patients had gastric wall perforation, one patient had an esophageal rupture, one patient had intestinal obstruction on top of a migrated IGB, and one patient had failed endoscopic retrieval of IGB and required a laparoscopic gastrostomy to retrieve the IGB (Table 1).

Three cases had generalized peritonitis on top of gastric perforation. All of them underwent contrast-enhanced computed tomography of the abdomen (CT) that confirmed perforation of the gastric wall and pneumoperitoneum with/without free intraperitoneal fluid. One of them, who had an IGB inserted for the third time one month prior to the presentation, was on regular long-term steroid therapy for rheumatoid arthritis. These three cases were managed by endoscopic removal of the IGBs that confirmed the gastric perforation, followed by exploratory laparotomy and omental patch repair. One case had a posterior gastric perforation, while the other two cases had anterior perforations (Fig. 1).

One of the cases refused to remove her IGB despite being inserted for 18 months. Her body mass index (BMI) decreased from 50.6 to 36.8 kg/m<sup>2</sup>, and she endeavored more weight loss. She presented with repeated vomiting. However, multiple trials of endoscopic removal failed, even under general anesthesia, owing to a distorted balloon and the patient's short neck. Therefore, it was laparoscopically removed (Fig. 2).

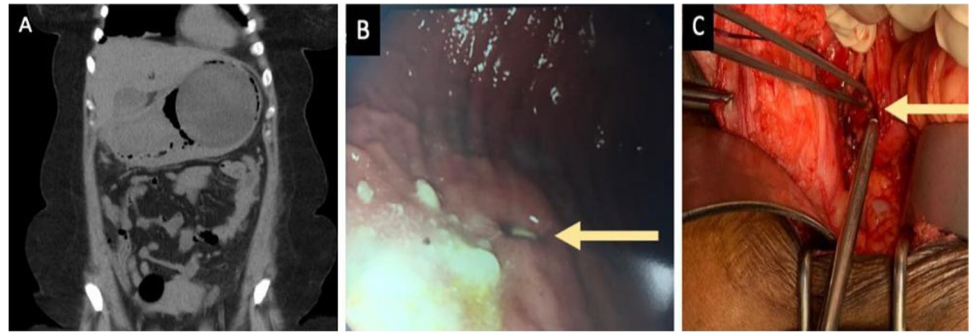
Another case had an intestinal obstruction on top of a migrated IGB, which was inserted 9 months prior to this presentation. She presented with abdominal distension, abdominal pain, and vomiting for 3 days without peritoneal irritation signs. An abdominal CT revealed a migrated IGB inside the ileum, 40 cm proximal to the terminal ileum, that was subsequently surgically removed (Fig. 3).

The last case had an esophageal rupture after a difficult IGB insertion. She had immediate severe chest pain after insertion; therefore, IGB was deflated and left to pass during defecation. Another balloon was inserted during the same

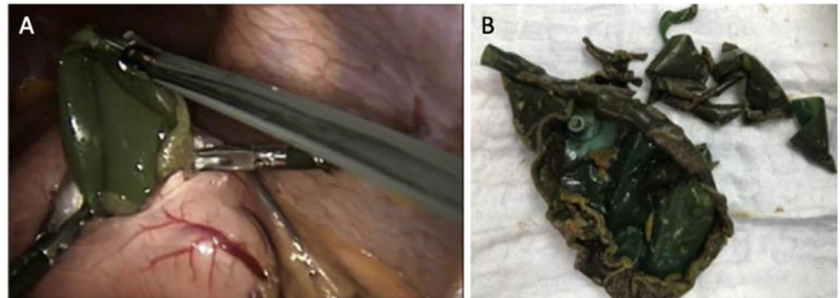
**Table 1** Details of included patients, ordered according to the duration of inserted IGB. IGB intra-gastric balloon, Duration from IGB to presentation, ICU admission in intensive care unit, N/A not available. \*Three IGBs were inserted, the last IGB was one month prior to presentation

No	Age/gender	BMI before IGB	Duration	Cause of presentation	Comorbidities/predisposing factors	BMI at presentation	Endoscopic findings	Imaging findings	Approach	Intervention	ICU
1	41/f	NA	10 days	Septic shock, dyspnea, chest pain	Irrelevant	34	Esophageal rupture Failure of endoscopic removal	- IGB inside left hemithorax - Lung abscess - Pleural effusion	Thoracotomy	IGB removal Pleural flap Decortication Endoscopic esophageal stent	Yes
2	35/f	NA	1 month*	Severe abdominal pain for 5 days	Rheumatoid arthritis on steroids	33	IGB removal Perforated big gastric ulcer	Pneumoperitoneum	Laparotomy	Repair with omental patch	Yes
3	38/f	NA	4 months	Severe abdominal pain for 2 days	Excessive use of NSAIDs for 3 weeks	31.2	IGB removal Perforated gastric ulcer	Pneumoperitoneum	Laparotomy	Repair with omental patch	No
4	32/f	NA	7 months	Severe abdominal pain for 1 day	Irrelevant	34.2	IGB removal Perforated gastric ulcer	Pneumoperitoneum	Laparotomy	Repair with omental patch	No
5	25/f	NA	9 months	Intestinal obstruction	Irrelevant	27	Not done	- IGB inside ileum	Laparotomy	Extraction via enterotomy	No
6	44/f	50.6	18 months	Vomiting	Irrelevant	36.8	Deformed thickened IGB Failure of removal	Not done	Laparoscopy	Laparoscopic extraction via gastrostomy	No

**Fig. 1** One of the patients with perforated gastric ulcers. **A** Abdominal CT scan, coronal view, showing the intra-gastric balloon and pneumoperitoneum. **B** Endoscopic view showing the perforated gastric ulcer (yellow arrow). **C** Intraoperative image showing the perforated gastric ulcer (yellow arrow)



**Fig. 2** The patient who underwent laparoscopic removal of IGB. **A** Laparoscopic view during removal of IGB through a gastrostomy. **B** Thickened deformed IGB after laparoscopic removal



**Fig. 3** The patient with intestinal obstruction on top of a migrated IGB. **A** Abdominal CT scan, axial view, showing dilated small bowel loops with a migrated IGB. **B** Intraoperative image during IGB removal through an enterotomy. **C** The migrated IGB after removal

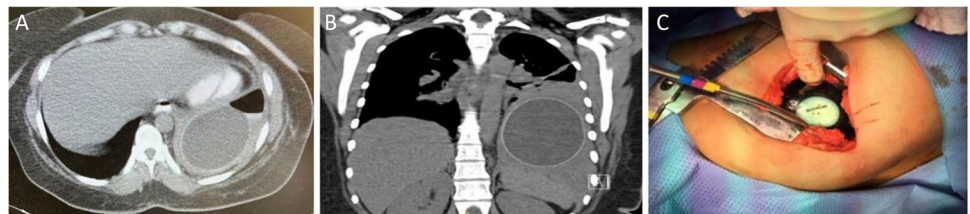


session. Ten days later, she presented with dyspnea, fever, and chest pain. She was referred to us for the management of her chest condition after the endoscopic removal of the second IGB at the same hospital. A chest CT confirmed esophageal rupture with the presence of the first IGB in the left hemithorax (Fig. 4). We assumed that the first balloon was erroneously inflated, by an inexperienced endoscopist, inside the lower end of the esophagus, rather than the stomach, leading to the esophageal rupture as there was no endoscopic evidence of pre-existing esophageal diseases or esophageal diverticulum. After that, another IGB was inserted inside the stomach. She underwent left thoracotomy, removal of the IGB, pleural

decortication, and pleural flap for the esophageal rupture. Moreover, an esophageal stent was inserted for 8 weeks.

Eventually, all cases were discharged in good condition. They were followed up from 6 months to 2 years with no related complications. It is worth to mention that all these cases had their IGBs inserted outside our hospital with unclear follow-up regimens and instructions. All cases reported being on proton pump inhibitors (PPIs) after IGB insertion, but their compliance was questionable. In our hospital, IGB is usually inserted and followed by the expert bariatric endoscopists in the gastroenterology department after a thorough multidisciplinary assessment of the patients.

**Fig. 4** The patient with esophageal rupture. **A, B** Chest CT scan (axial and coronal view) showing IGB inside the left hemithorax. **C** Intraoperative image during IGB removal through lateral thoracotomy



## Discussion

A recent literature review for the visceral complications of different types of IGBs reported a total of 22 cases of gastric perforation, 10 cases of intestinal obstruction, and two cases of esophageal perforation [12]. Neto et al. [9] reported 20 cases of perforation during dwelling or extraction (0.3% and 0.1%, respectively) but not during placement of IGB. About 40% of gastric perforation occurred within 3 days [12]. Barichello et al. [13] reported a mortality rate of 14.2% after gastric perforation. However, we still believe that many cases were not reported or included, as the ones reported were based on case reports.

In Saudi Arabia, IGB is one of the most popular endoscopic modalities for severe obesity. However, there is no precise data regarding the number of inserted IGBs. We conducted a literature review of the English literature using the terms “intra-gastric balloon,” “intra-gastric balloon,” “gastric balloon,” and/or “balloon” along with “Saudi Arabia,” “KSA,” “Middle East,” and/or “Gulf region” in the title,

keywords, and/or abstract of the indexed articles in Medline, Scopus, and Google Scholar databases. Only 20 articles discussed the intra-gastric balloon in Saudi Arabia, and most of them were case reports (Table 2) [14–33]. Surgical management for IGB complications was required in ten cases. Five cases of intestinal obstruction were reported, and two of them were laparoscopically managed [23, 31]. Two cases of perforation were reported (gastric and jejunal) [15, 21].

Our center is the regional tertiary referral center that receives most complications after any bariatric procedures. All cases in this study were referred after the insertion of their IGBs in other facilities. In general, all referred cases to our centers are managed by a multidisciplinary approach of our bariatric surgeons, endoscopists, radiologists, endocrinologists, nutritionists, and clinical pharmacists, as well as psychiatrists. All involved physicians are experts in dealing with complicated procedures, and the management plan is tailored accordingly. In this study, we focused only on those cases that required any surgical procedures to manage their complicated IGB.

**Table 2** Summary of literature review of Saudi publications of intra-gastric balloon including seven retrospective studies, two case series, and ten case reports. Surgical management was required in ten cases;

five of them were intestinal obstruction. \*Two published case reports included in the current study

No	Author/year	Type of study	No of included patients	Complications required surgical management	Surgical management
1	Subei et al. (14)	Retrospective study	41	No	Not required
2	Al-Momen et al. (15)	Retrospective study	44	Gastric perforation	Laparoscopic repair of gastric perforation
3	Helmy et al. (16)	Case report	1	No	Not required
4	Mohammed et al. (17)	Case report	1	No	Not required
5	Matar et al. (18)	Case report	1	Intestinal obstruction	Laparotomy
6	Al Kahtani et al. (19)	Retrospective study	173	No	Not required
7	Yasawy et al. (20)	Retrospective study	100	No	Not required
8	Al-Zubaidi et al. (21)	Case report	1	Intestinal perforation	Laparotomy
9	Aljiffry et al. (22)	Case series	4	No	Not required
10	Almoghaseeb et al. (23)	Retrospective study	301	Intestinal obstruction	Laparotomy
				Intestinal obstruction	Laparoscopic removal
11	Mosli et al. (24)	Retrospective study	108	Intestinal obstruction	Laparotomy
12	Aljahdli et al. (25)	Case report	1	No	Not required
13	Aljehani et al. (26)*	Case report	1	Esophageal rupture	Thoracotomy
14	Alsohaibani et al. (27)	Case series	10	No	Not required
15	Sharroufna et al. (28)*	Case report	1	Failure of endoscopic retrieval	Laparoscopic removal
16	Almadi et al. (29)	Letter to editor	0	No	Not required
17	Al Ghadeer et al. (30)	Case report	2	No	Not required
18	Ntyl et al. (31)	Case report	1	Intestinal obstruction	Laparoscopic removal
19	Al-Kadi et al. (32)	Case report	1	Incidental finding of old IGB during LSG	Laparoscopic removal during LSG
20	Bawahab et al. (33)	Retrospective study	126	No	Not required

The main reason for gastric perforation after IGB is its lodgment with continuous pressure on the gastric mucosa, which causes ischemia of the gastric mucosa and alterations of prostaglandins production resulting in ulcerations and, eventually, gastric wall perforation. Multiple risk factors have been postulated, including longer duration of insertion, previous gastric surgeries, non-compliance to PPIs, use of non-steroidal anti-inflammatory drugs, and other comorbidities such as diabetes [12, 13]. Alfredo et al. [34] reported that 44% of patients who delayed the removal of their IGBs were seeking more weight loss, while 1.3% of IGBs were removed after 15 months. Genco et al. [10] reported previous gastric procedures in four out of five cases with gastric perforation.

The classical presentation of gastric perforation is sudden severe abdominal pain with/without gastrointestinal bleeding. The most common site of perforation is anterior gastric wall [13]. The gold standard imaging modality is contrast-enhanced computed tomography. After resuscitation, laparoscopy, endoscopy, combined endoscopy/laparoscopy, and laparotomy are valid options for management according to the clinical presentation and experience. A conservative approach has also been reported infrequently [13, 35].

In our study, three patients had severe abdominal pain, and none of them had a previous gastric surgery; however, one of them was on regular long-term steroid therapy for rheumatoid arthritis and had an IGB inserted for the third time. The gastric wall perforation was anterior in two patients and posterior in one patient. The posterior gastric wall perforation can be easily missed; therefore, it necessitates meticulous exploration.

Esophageal perforation is rare and typically happens at the gastro-esophageal junction or the upper esophageal sphincter during forceful insertion or emergency removal. Its reported incidence is 0.02%, and it carries a significant mortality rate reaching 40% [36–39]. Its clinical presentation and management differ according to the site of perforation and time of diagnosis. If diagnosed during the procedure, endoscopic management can be sufficient [35].

This study exclusively discusses IGB complications that need further surgical intervention in a single tertiary institute; thus, we believe that these complications are underreported. The limitations of this study are few. Its retrospective single-center descriptive design is the main limitation. Second, the incidence of IGB complications cannot be estimated as all these cases were referred to our hospital, and the real number of IGB insertions in the region is not accurately reported. Third, limited data were available regarding IGBs' type, brand, volume, and follow-up regimens. Therefore, larger long-term prospective studies are required to accurately investigate the IGB complications.

## Conclusion

IGB is a good endoscopic alternative, within certain indications, for the management of obesity. However, surgical intervention may be necessary to manage its complications, including gastric wall perforation, esophageal perforation, intestinal obstruction, IGB migration, and failure of endoscopic removal. Multiple IGBs insertions and long-duration of IGBs insertion, as well as steroid therapy, may increase the risk for IGBs complications. Further long-term prospective studies are required to assess the risk factors for IGB complications.

## Declarations

**Ethics Approval and Consent to Participate** The study was approved by the local Institutional Review Board. Informed consent was obtained from all individual participants included in the study.

**Conflict of Interest** The authors declare no competing interest.

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