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BRIEF COMMUNICATION

# Major Gastric Haemorrhage After Intragastric Balloon Insertion: Case Report

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**Abstract** Intragastric balloons are a minimally invasive option for weight loss. They are generally well tolerated and rarely associated with serious adverse events. We report a case of major upper gastrointestinal haemorrhage after insertion of an Orbera® intragastric balloon.

**Keywords** Intragastric balloon · Morbid obesity · Endoscopy · Complications · Haemorrhage

## Introduction

The prevalence of obesity has more than doubled in Australia over the past two decades [1]. Even modest weight loss can substantially reduce premature morbidity and mortality from obesity-related diseases [2]. First-line therapy involves behavioural and dietary modification; however, these seldom lead to sustainable weight loss. In contrast, bariatric surgery has proven long-term efficacy but its universal appeal is limited by invasiveness, cost and potential surgical morbidity [3]. The intragastric balloon is a minimally invasive alternative, which may have a role in-between existing therapies. This temporary device is inserted endoscopically to restrict the reservoir capacity of the stomach, delay gastric emptying and promote satiety [4]. Intragastric balloon insertion is generally well tolerated, and potential side effects, such as nausea, abdominal pain and reflux, can usually be managed conservatively. Although serious complications are rare, there has been documentation of visceral perforation, postoperative bowel obstruction and acute pancreatitis leading to major morbidity and mortality [5, 6]. We report an unusual and life-threatening complication of severe gastric haemorrhage following intragastric balloon insertion, which has not been previously reported.

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## Case Report

A 49-year-old female with a body mass index of 35.2 kg/m$^2$ underwent insertion of an Orbera® intragastric balloon (Apollo Endosurgery, Austin, Texas) for weight control. She had a history of quiescent ulcerative colitis and infrequent gastro-oesophageal reflux symptoms. She consumed approximately two standard drinks of alcohol per week. Her medications were mesalazine 1.2 g twice daily, an oral contraceptive pill and Quick-Eze antacid tablets as required for reflux.

Upper endoscopy was performed prior to device placement. No macroscopic abnormality was detected. Biopsies of the stomach and duodenum were reported as normal and were negative for *Helicobacter pylori*. The intragastric balloon was inserted and filled with 700 mL of methylene blue-stained saline. The patient remained well overnight and was discharged home the following day on pantoprazole 40 mg daily, along with an anti-emetic regime and anti-spasmodic.

The patient presented to the emergency department on postoperative day nine after she experienced several episodes of melaena and syncope. On examination, she was pale but

with observations within normal limits. Laboratory results revealed haemoglobin 52 g/L, normal platelet count and normal coagulation profile. The patient received intravenous resuscitation, five units of packed red blood cells and intravenous pantoprazole 40 mg twice daily. Urgent upper gastrointestinal endoscopy revealed generalised gastritis and remnants of coffee brown staining on the gastric wall (Fig. 1). Views were obtained distally to the fourth part of the duodenum but showed no other evidence of bleeding, ulceration or mucosal injury. The intragastric balloon appeared intact and was left in situ. A biopsy of the gastric body demonstrated mild non-specific chronic gastritis.

The patient remained clinically stable with no further clinical nor haematologic evidence of bleeding for 24 h. Consequently, she was discharged home on both oral pantoprazole 40 mg and ranitidine 150 mg twice daily. Despite this, the patient continued to pass small amounts of melaena and over the subsequent week, repeat haemoglobin measurements declined to 63 g/L. She was readmitted to the hospital, required further transfusion and underwent repeat endoscopy. This revealed persistent gastritis and a small volume of intraluminal blood. No other source of active bleeding was identified. Repeat gastric biopsies again showed mild non-specific chronic gastritis. The intragastric balloon was removed, and the patient was discharged home with no further recurrence of her symptoms. The intragastric balloon was returned to the manufacturer for testing, but no cause was identified for this major adverse event.

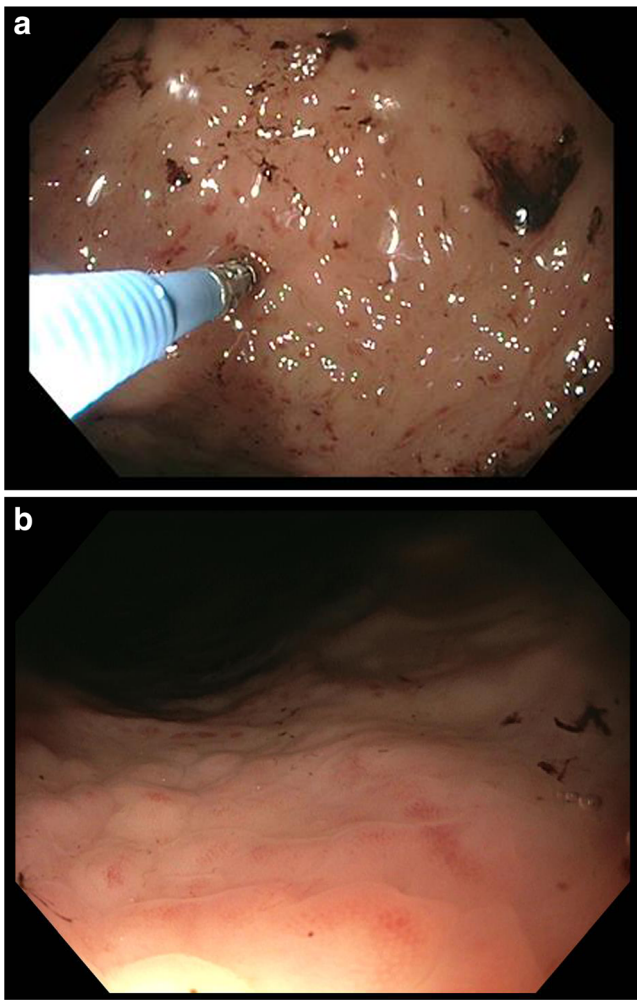


**Fig. 1** Upper endoscopy images showing mild generalised gastritis and brown staining within the stomach lumen

## Discussion

The Orbera® intragastric balloon is a non-toxic silicone elastomer which is filled with 400–700 mL of saline [7]. It can remain in vivo for up to six months due to the material's stability and acid-resistant properties [8]. Major post insertion morbidity is uncommon; however, typical side effects include abdominal pain (33.7% of patients), nausea (29%) and reflux (18.3%) [9]. These symptoms likely relate to gastric accommodation to the balloon and usually resolve with proton pump inhibitor, anti-emetic and anticholinergic medications [10].

Intragastric balloons have been associated with rare but serious adverse events, linked to insertion technique, delayed removal and device failure causing slippage and bowel obstruction [11, 12]. A recent meta-analysis by the American Society for Gastrointestinal Endoscopy reported Orbera® balloon migration in 1.4%, gastric perforation in 0.1% and death in 0.08% [9]. This is the first documented case of severe haemorrhage associated with an intragastric balloon without concurrent visceral tear, ulceration or perforation. There are also no previous documented reports of severe gastritis following intragastric balloon insertion necessitating multiple blood transfusions or early device removal.

In this case, recommendations were met in terms of balloon insertion lifespan and filling volume. Moreover, the patient was taking high doses of acid suppression therapy and lacked other risk factors for gastritis such as heavy alcohol intake, non-steroidal anti-inflammatory use and *Helicobacter pylori* infection. Gastritis is not a recognised side effect of oral mesalazine (5-aminosalicylic acid) although this medication may rarely cause blood dyscrasias in < 0.1% of patients [13]. Through unclear mechanisms, mesalazine is thought to exert local anti-inflammatory effects on the bowel wall. It may also be useful for gastritis associated with inflammatory bowel disease, as described in several case reports [14]. However, this potential benefit has not been formally tested in randomised controlled trials. Although ulcerative colitis classically spares the proximal alimentary tract, histological evidence of *Helicobacter*-negative chronic active gastritis has been reported in 15–30% of patients [15]. The rate of gastroduodenal involvement in quiescent disease is unclear. There is insufficient data to comment on whether ulcerative colitis

should be a relative contraindication to endoluminal bariatric devices; however, any adverse relationship seems to be extremely infrequent.

Previous reports of serious complications following intragastric balloon insertion have often occurred in patients with relative or absolute contraindications to the procedure. For example, five of nine reported cases of gastric perforation occurred in patients with a history of previous gastric surgery [10]. Other absolute contraindications to balloon placement include coagulation disorders, large hiatal hernia (> 5 cm), potentially bleeding lesion of the upper gastrointestinal tract, pregnancy, alcohol or drug abuse and severe liver disease. None of these conditions were met in our patient's case.

A search of the literature revealed one previous case report of gastritis associated with intragastric balloon therapy. Charalambous et al. report the case of a 63-year-old woman who developed gastric perforation two months following balloon insertion [16]. During endoscopic balloon deflation, severe generalised gastritis was noted in addition to the large anterior gastric wall defect. This patient experienced early epigastric pain, nausea and dyspepsia until eventually presenting with peritonitis two months postoperatively, but had no evidence of bleeding or transfusion requirements. It is unclear whether proton pump inhibitor therapy was instituted following balloon placement.

Direct contact between the intragastric balloon and gastric mucosa may help explain the development of postoperative gastritis. Intragastric balloons have been postulated to cause gastric wall irritation and lead to alterations in prostaglandin production, an important cryoprotective agent [17]. A retrospective study by Gottig et al. of intragastric balloon therapy in 109 patients with extreme obesity (BMI > 50 kg/m$^2$) found 3.7% had new or worsened gastritis at balloon extraction [18]. They tested for *Helicobacter pylori* preoperatively and placed all patients on regular proton pump inhibitor medication after balloon insertion. The mean treatment period was 177.6 ± 56.8 days although no correlation was observed between balloon duration and gastrointestinal complications.

Although prolonged contact between the balloon and stomach wall is less pertinent to our case, gastric balloon distention may be an important contributing factor. Devices need to be filled to an appropriate percentage of gastric capacity to promote weight loss while avoiding side effects. Studies have shown a filling volume of at least 400 mL can induce satiety and slow gastric emptying via gastric wall stretch [6, 19]. Over-filled balloons may cause abdominal pain, reflux and compress adjacent structures. A meta-analysis by Kumar et al. found variations in Orbera® balloon filling volume within the recommended range of 400–700 mL did not affect balloon tolerance, reflux symptoms or ulcer formation [19]. Furthermore, larger filling volumes above 600 mL were associated with significantly lower rates of balloon migration (although failed to correlate with increased weight loss at six months). The mechanical effects of mucosal stretch for a prolonged time period may contribute to gastric inflammation, erosion and perforation; although with so few reports of these complications, it is difficult to draw any definitive assertions.

## Conclusion

Intragastric balloon placement is becoming more commonplace. Intragastric balloons are generally considered a simple and safe, albeit temporary, measure of inducing weight loss. However, they have been linked with a number of serious and life-threatening adverse events. This case report highlights another major complication of the intragastric balloon: widespread gastritis and severe gastric haemorrhage. It is essential to be familiar with all potential side effects of intragastric balloons as increasingly more devices are inserted for weight loss. It is similarly important to recognise the development of complications early to prevent unnecessary and detrimental outcomes.

**Author Contributions**

1. Romy Granek—lead author
2. Michael Hii—editor
3. Salena Ward—consultant surgeon overseeing patient care, editor

**Conflict of Interest** The authors declare that they have no conflict of interest.

**Ethical Approval** This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** Does not apply.

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