Case Report

Gastric Ulcer Hemorrhage – a Potential Life-Threatening Complication of Intragastric Balloon Treatment of Obesity

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Key Words

Intragastric balloon · Complication · Obesity · Gastric hemorrhage · Gastric ulcer · Gastric bleeding

Abstract

Background: Some morbidly obese patients do not qualify for bariatric surgery due to general health contraindications. Intragastric balloon treatment might be a therapeutic option in the above-mentioned cases. It can prime super-obese patients with end-stage disease for bariatric surgery. As a neoadjuvant therapy before surgery, it leads to a downstage of the disease by preliminary weight reduction, to an improvement in general health and, in summary, to a reduction of the perioperative risk. It is generally considered to be a safe method. However, due to the wide range of possible complications and unusual symptoms after intragastric balloon treatment, an interdisciplinary, instead of only a surgical or endoscopic, treatment and follow-up might be recommended in these patients. **Case Report:** We here describe a potential life-threatening complication in the form of gastric bleeding as a consequence of intragastric balloon treatment and simultaneous aspirin taking and *Helicobacter pylori* infection. **Conclusion:** There have been reports of some complications of intragastric balloon treatment. However, to the best of our knowledge there were no reports concerning life-threatening hemorrhage from gastric ulcer.

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Introduction

Obesity has become a global pandemic. It is a chronic disease leading to complications such as type 2 diabetes, hyperlipidemia, hypertension, fatty liver, sleep apnea syndrome, osteoarthritis, gastro-esophageal reflux, gout, polycystic ovary syndrome, cancers, and many

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others. It leads to considerable morbidity, substantial mortality, and impaired quality of life. In 2014, the World Health Organization estimated that 39% of adults (i.e., more than 1.8 billion people) were overweight ($\text{BMI} \geq 25 \text{ kg/m}^2$), and 13% were obese ($\text{BMI} \geq 30 \text{ kg/m}^2$) [1].

Options for obesity treatment include behavioral modification (by physical exercise programs, dietary modification, caloric restriction, and psychosocial interventions), pharmacotherapy, and bariatric surgery. As previous studies have demonstrated, bariatric surgery is the most effective way to achieve sustained weight reduction and amelioration of its complications [2, 3]. However, some morbidly obese patients do not qualify for bariatric surgery due to general health contraindications. Intra-gastric balloon treatment might be a therapeutic option in the above-mentioned cases. It can prepare super-obese patients with end-stage disease for bariatric surgery. As a neoadjuvant therapy prior to definitive treatment, i.e., bariatric surgery, it leads to a downstage of the disease by preliminary weight reduction and improvement in general health [4, 5].

Intra-gastric balloon placement is an endoscopic method. It is a minimal invasive procedure that induces weight loss by reducing the gastric reservoir capacity leading to premature satiation and prolonged satiety, and by regulating hormone-mediated signal transduction [6]. The balloon is a smooth, spherical, saline or air-filled, silicone elastomer. The procedure was first performed in the early 1980s as one of the earliest devices used for endoscopic bariatric intervention and became popular in recent years in Europe [7]. In 2015, in the US, the FDA (Food and Drug Administration) approved two types of intra-gastric balloons for obesity treatment [8, 9].

Intra-gastric balloon placement appears to be a safe, tolerable, and potentially effective procedure for the initial treatment of morbid obesity [10, 11]. The general opinion is that it is an easy procedure, which can be performed by every specialist. However, due to wide range of possible complications and unusual symptoms after intra-gastric balloon treatment, an interdisciplinary, instead of only a surgical or endoscopic, treatment and follow-up might be recommended in these patients. Therefore, we have doubts whether this method is really as safe as it appears to be.

There have been several reports of serious complications, including death, after intra-gastric balloon application. However, only one publication mentioned gastric ulcer bleeding as a possible complication, unfortunately without providing any details on the bleeding cause [12]. Thus, to the best of our knowledge, there have been no reports concerning life-threatening bleeding from gastric ulcer in patients with intra-gastric balloon insertion.

The aim of our report is to advise surgeons and endoscopists of the possibility of potential life-threatening bleeding from gastric ulcer in the course of intra-gastric balloon treatment.

Case Report

We report the case of a 42-year-old Caucasian man, with a history of type 2 diabetes mellitus, hypertension, dyslipidemia, sleep apnea syndrome, fatty liver, and umbilical hernia who underwent an uneventful intra-gastric balloon insertion (initial BMI 57.8 kg/m^2). He did not have a past history of surgery or any specific family history of disease. He had no history of alcohol intake or tobacco use. His maximum body mass was 200 kg, his height was 1.86 m. Weight gain occurred at the age of 30 when he changed work and decreased physical activity. The patient was disqualified from surgical treatment under general anesthesia by the anesthesiologist due to comorbidities and the high risk of postoperative complications. Therefore, we decided to treat this patient by a saline-filled intra-gastric balloon placement. This procedure was planned as a neoadjuvant therapy prior to surgery. There was no pathology in the preoperative gastroscopy, and for this reason we did not perform gastric biopsy. The *Helicobacter pylori* test was negative, and there were no signs of reflux disease, gastric erosions or ulcerations. In June 2015, the saline-filled balloon (MedSil®; Varimed, Wrocław, Poland) was inserted endoscopically into the stomach. The localization of the collapsed balloon was controlled by re-inserting the gastroscopy, and under direct observation the balloon was filled, near the antral region,

Fig. 1. Endoscopic views showing multiple gastric erosions and an ulcer with signs of recent hemorrhage (Forrest IIa) treated with argon plasma coagulation.

Fig. 2. Endoscopic views showing multiple gastric erosions and an ulcer with signs of recent hemorrhage (Forrest IIa) treated with argon plasma coagulation.

with 650 ml of saline (stained with 10 ml of methylene blue). The procedure was performed without any complications. The patient was discharged in a stable condition. In accordance to the guidelines [13] for similarly saline-filled intra-gastric balloons, the patient received 40 mg/day of an oral proton pump inhibitor for the whole treatment period with intra-gastric balloon. His post-treatment course was unremarkable for the first 20 weeks. In November 2015, 20 weeks after intra-gastric balloon insertion, the patient was urgently admitted to hospital after losing consciousness. Anamnesis revealed, among other symptoms, weakness, easy fatigue, and melena in the previous few days. For the last 7 days, he took doxycycline ordered by a general practitioner because of pharyngitis. The patient also used aspirin, without prescription, without any medical consultation, and against explicit instructions not to use nonsteroidal anti-inflammatory drugs (NSAIDs) during intra-gastric balloon treatment. During the first 20 weeks of treatment, the patient had lost 30 kg of his weight, reaching a BMI of 49.1 kg/m². On admission he was pale, sweaty, with a fever (37.8 °C), normotensive (blood pressure was 121/65 mm Hg), normocardiac (heart rate was 89/min). Melena was detected on digital rectal examination. Laboratory results revealed hemoglobin –5.8 g/dl and hematocrit –18.4%. Stabilization was achieved by transfusion of five units of packed red blood cells and crystalloid infusion. Immediate medication with double standard dose of proton pump inhibitor (esomeprazole 80 mg) intravenously, followed by constant infusion (esomeprazole 8 mg/h) was started. 4 h after admission, an

Fig. 3. Endoscopic views showing multiple gastric erosions and an ulcer with signs of recent hemorrhage (Forrest IIa) treated with argon plasma coagulation.

Fig. 4. Endoscopic views showing multiple gastric erosions and an ulcer with signs of recent hemorrhage (Forrest IIa) treated with argon plasma coagulation.

emergency gastroscopy was performed. The balloon was removed. Coffee-ground color gastric contents were aspirated. Multiple gastric erosions and an ulcer with signs of recent hemorrhage were found. It was classified as Forrest IIa classification of upper gastrointestinal hemorrhage due to visible vessel (fig. 1–4). It was treated with argon plasma coagulation. *H. pylori* test was positive.

The patient was discharged from hospital on the 4th day after the above-mentioned gastroscopy in good condition, with a hemoglobin level of 8.7 g/dl and without any symptoms of recurrent bleeding. He received *H. pylori* eradicating treatment with amoxicillin, metronidazole and esomeprazole. The patient has remained in follow-up.

Conclusions

In the case presented here, we observed a possible life-threatening complication in the form of gastric bleeding as a consequence of intragastric balloon treatment and simultaneous aspirin taking and *H. pylori* infection.

Intra-gastric balloon insertion is a popular, minimally invasive procedure for the treatment of morbid obesity. Safety analysis [6] showed that side effects occurred at a high rate. Fortunately, most of them were self-healing. The most common side effects were nausea (72%), abdominal pain (39%), vomiting (3%), gastric erosion (32%), flatulence (24%), gastric ulcer (5%), premature balloon deflation (8%), and esophagitis (1.5 %) [14]. There were reports of rare and serious complications such as gastric perforation [15], small intestinal obstruction [16, 17], small bowel necrosis [18], and acute pancreatitis [19, 20]. There were also descriptions of fatal complications in the course of intra-gastric balloon treatment [21–23].

Gastric ulcers are not caused by one single factor. They are usually caused by an infection with *H. pylori* and use of NSAIDs or aspirin [24]. There are also gastric ulcers related to the use of ulcerogenic medications like steroids, potassium chloride, nitrogen-containing bisphosphonates, and some immunosuppressive medications. Other rare etiologies for gastric ulcers may include unusual systemic diseases and unusual infectious pathogens.

- Uncommon systemic diseases: Crohn's disease, mastocytosis, amyloidosis, sarcoidosis, vasculitis, eosinophilic gastroenteritis, and Zollinger-Ellison syndrome.
- Unusual infections: *Helicobacter heilmannii*, cytomegalovirus, herpes simplex virus, tuberculosis, syphilis, and fungal infection [25].

Furthermore, gastric ulcer may be the result of stress (hypoxic ischemic mucosa), may occur in the course of sepsis [26], severe burn (Curling's ulcer) [27], or after brain injuries (Cushing's ulcer) [28]. Some factors and behaviors may increase the risk of developing gastric ulcers, e.g., smoking, excessive consumption of alcohol, age over 60 years, and Caucasian race [25, 29]. We should be aware that an ulcer may be a sign of gastric cancer. Gastric ulcer can lead to complications such as bleeding, perforation, pyloric stenosis, etc. Gastric hemorrhage could be a life-threatening event, especially in patients with comorbidities. The treatment used in our patient was urgent gastroscopic intervention with effective hemostasis, proton pump inhibitor administration, and blood transfusion. Symptoms of a gastric ulcer can include abdominal pain, abdominal fullness, nausea, vomiting, and loss of appetite. Loss of appetite and abdominal fullness in this patient might have been related not only with the ulcer but also with the presence of the intra-gastric balloon. Symptoms characteristic for bleeding are hematemesis and melena. In the present case, there was no hematemesis.

Which procedure should be considered to minimize the risk of gastric ulceration and hemorrhage from gastric ulcer? We need to identify and reduce the risk factors of gastric ulcer in patients with intra-gastric balloon. It is particularly important to inform the patient not to apply any medications without consulting a doctor. In many countries, including Poland, NSAIDs such as aspirin are available without a prescription. Patients who have undergone balloon insertion should be informed of the risk to suffer from complications when using these drugs.

The case presented here unambiguously proves that the use of NSAIDs during intra-gastric balloon treatment could lead to potential life-threatening complications such as gastric ulcer hemorrhage. We should be aware that obese patients, especially those in whom surgery is associated with a higher risk, can have additional risk factors for gastric ulcer. The probability of bleeding events increases with every adverse risk factor. We need to identify and reduce such risk factors or, if there is a necessity, apply preventive measures. It is particularly important to inform patients not to apply any medications without consulting a doctor. If there is bleeding from the upper gastrointestinal tract, urgent gastroscopy with the removal of the balloon and hemostasis control appears to be an effective procedure. In gastric ulcer disease, testing for *H. pylori* is mandatory, and eradication reduces the re-bleeding risk [30]. When any new and alarming symptoms appear in a patient with a balloon, especially after a long time since its application, we should consider the possibility of gastric ulcer bleeding.

Acknowledgments

We acknowledge Polish National Science Center (NCN) for support under grant #2013/09/B/NZ7/03763.

Disclosure Statement

None of the authors declared any conflict of interest.

References

- 1 World Health Organization: Obesity and Overweight. Fact Sheet. Updated June 2016. www.who.int/media-centre/factsheets/fs311/en/ (last accessed April 3, 2017).
- 2 Colquitt JL, Pickett K, Loveman E, Frampton GK: Surgery for weight loss in adults. *Cochrane Database Syst Rev* 2014;8:CD003641.
- 3 Ribaric G, Buchwald JN, McGlennon TW: Diabetes and weight in comparative studies of bariatric surgery vs conventional medical therapy: a systematic review and meta-analysis. *Obes Surg* 2014;24:437–455.
- 4 Zerrweck C, Maunoury V, Caiazzo R, Branche J, Dezfoulian G, Bulois P, Verkindt H, Pigeyre M, Arnalsteen L, Pattou F: Preoperative weight loss with intra-gastric balloon decreases the risk of significant adverse outcomes of laparoscopic gastric bypass in super-super obese patients. *Obes Surg* 2012;22:777–782.
- 5 Mitura K, Garnysz K: In search of the ideal patient for the intra-gastric balloon – short- and long-term results in 70 obese patients. *Wideochir Inne Tech Maloinwazyjne*. 2016;10:541–547.
- 6 Zheng Y, Wang M, He S, Ji G: Short-term effects of intra-gastric balloon in association with conservative therapy on weight loss: a meta-analysis. *J Transl Med* 2015;13:246.
- 7 Gleysteen JJ: A history of intra-gastric balloons. *Surg Obes Relat Dis* 2016;12:430–435.
- 8 U.S. Food and Drug Administration: ReShape Integrated Dual Balloon System - P140012. www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm456293.htm (last accessed April 3, 2017).
- 9 U.S. Food and Drug Administration: ORBERA™ Intra-gastric Balloon System - P140008. www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm457416.htm (last accessed April 3, 2017).
- 10 Göttig S, Daskalakis M, Weiner S, Weiner RA: Analysis of safety and efficacy of intra-gastric balloon in extremely obese patients. *Obes Surg* 2009;19:677–683.
- 11 Mitura K, Garnysz K: Tolerance of intra-gastric balloon and patient's satisfaction in obesity treatment. *Wideochir Inne Tech Maloinwazyjne* 2015;10:445–449.
- 12 Tai CM, Lin HY, Yen YC, Huang CK, Hsu WL, Huang YW, Chang CY, Wang HP, Mo LR: Effectiveness of intra-gastric balloon treatment for obese patients: one-year follow-up after balloon removal. *Obes Surg* 2013;23:2068–2074.
- 13 Apollo Endosurgery: ORBERA™ Intra-gastric Balloon System (ORBERA™) Directions for Use (DFU). http://apolloendo.com/wp-content/uploads/2016/10/GRF-00346-00_R01.pdf (last accessed April 3, 2017).
- 14 Mathus-Vliegen EM, Alders PR, Chuttani R, Scherpenisse J: Outcomes of intra-gastric balloon placements in a private practice setting. *Endoscopy* 2015;47:302–307.
- 15 Smigielski J, Szewczyk T, Modzelewski B, Mandryka Y, Klimczak J, Brocki M: Gastric perforation as a complication after BioEnterics intra-gastric balloon bariatric treatment in obese patients-synergy of endoscopy and videosurgery. *Obes Surg* 2010;20:1597–1599.
- 16 Ozturk A, Akinci OF, Kurt M: Small intestinal obstruction due to self-deflated free intra-gastric balloon. *Surg Obes Relat Dis* 2010;6:569–571.
- 17 Moszkowicz D, Lefevre JH: Deflated intra-gastric balloon-induced small bowel obstruction. *Clin Res Hepatol Gastroenterol* 2012;36:17–19.
- 18 Drozdowski R, Wyleżół M, Frączek M, Hevelke P, Giaro M, Sobański P: Small bowel necrosis as a consequence of spontaneous deflation and migration of an air-filled intra-gastric balloon – a potentially life-threatening complication. *Wideochir Inne Tech Maloinwazyjne* 2014;9:292–296.
- 19 Mohammed AE, Benmoussa A: Acute pancreatitis complicating intra-gastric balloon insertion. *Case Rep Gastroenterol* 2008;2:291–295.
- 20 Issa I, Taha A, Azar C: Acute pancreatitis caused by intra-gastric balloon: a case report. *Obes Res Clin Pract* 2016;10:340–343.
- 21 Genco A, Bruni T, Doldi SB, Forestieri P, Marino M, Busetto L, Giardiello C, Angrisani L, Pecchioli L, Stornelli P, Puglisi F, Alkilani M, Nigri A, Di Lorenzo N, Furbetta F, Cascardo A, Cipriano M, Lorenzo M, Basso N: BioEnterics intra-gastric balloon: the Italian experience with 2,515 patients. *Obes Surg* 2005;15:1161–1164.
- 22 Spyropoulos C, Katsakoulis E, Mead N, Vagenas K, Kalfarentzos F: Intra-gastric balloon for high-risk super-obese patients: a prospective analysis of efficacy. *Surg Obes Relat Dis* 2007;3:78–83.

- 23 Koutelidakis I, Dragoumis D, Papaziogas B, Patsas A, Katsougianopoulos A, Atmatzidis S, Atmatzidis K: Gastric perforation and death after the insertion of an intra-gastric balloon. *Obes Surg* 2009;19:393–396.
- 24 Berkelhammer C: *Helicobacter pylori* and ulcer in patients taking NSAIDs. *JAMA* 1995;1:376.
- 25 Chung CS, Chiang TH, Lee YH: A systematic approach for the diagnosis and treatment of idiopathic peptic ulcers. *Korean J Intern Med* 2015;30:559–570.
- 26 Liu B, Liu S, Yin A, Siddiqi J: Risks and benefits of stress ulcer prophylaxis in adult neurocritical care patients: a systematic review and meta-analysis of randomized controlled trials. *Crit Care* 2015;19:409.
- 27 Kanchan T, Geriani D, Savithry KS: Curling's ulcer – have these stress ulcers gone extinct? *Burns* 2015;41:198–199.
- 28 Kemp WJ, Bashir A, Dababneh H, Cohen-Gadol AA: Cushing's ulcer: further reflections. *Asian J Neurosurg* 2015;10:87–94.
- 29 Lau JY, Sung J, Hill C, Henderson C, Howden CW, Metz DC: Systematic review of the epidemiology of complicated peptic ulcer disease: incidence, recurrence, risk factors and mortality. *Digestion* 2011;84:102–113.
- 30 Biecker E: Diagnosis and therapy of non-variceal upper gastrointestinal bleeding. *World J Gastrointest Pharmacol Ther* 2015;6:172–182.