ELSEVIER

Surgery for Obesity and Related Diseases ▮ (2017) 00–00

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

The safety and efficacy of the procedureless intragastric balloon

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Received May 22, 2017; accepted December 1, 2017

Abstract

Background: Obesity is on a continuous rise worldwide, and with it, novel bariatric procedures have emerged. The introduction of gastric balloons has opened up a nonsurgical option for patients opting for it. However, they still require some form of sedation and endoscopy for insertion and/or removal.

Objectives: The Elipse balloon is a novel creation that has managed to bypass both these procedures; therefore, the investigation into its effectiveness is of importance.

Setting: Royale Hayat, Sabah, and Amiri Hospitals, Kuwait.

Methods: This is a multicenter, prospective analysis of all patients who underwent the Elipse balloon insertion. For the duration of 4 months, weight, body mass index, and the occurrence of adverse events was documented.

Results: A total of 135 patients were included, with a mean age of 33.5 years. At the 4-month mark, the mean weight of the patients showed a drop of 13.0 kg ($P = .000$), and the mean body mass index showed a drop of 4.9 units ($P = .000$). The mean percent total weight loss was 15.1%. All patients reported nausea in the first day of insertion; however, 69.6% reported complete resolution by the third day. Two patients (1.5%) vomited the balloon early, 3 patients (2.2%) had to have the balloon removed early due to intolerance, 3 patients (2.2%) experienced early deflation, 18 (13.3%) patients reported episodes of diarrhea around the time of deflation, and 29 (21.5%) patients experienced colicky abdominal pain in the week of balloon deflation. One patient experienced small bowel obstruction after which the balloon was removed via laparoscopic enterotomy.

Conclusion: This study aimed to evaluate the safety and effectiveness of the Elipse balloon in the largest population studied as of date. It was also able to demonstrate that it can be safely and successfully swallowed, filled, imaged, and passed. In addition, it effectively aided in weight loss, showing promising results. (Surg Obes Relat Dis 2017;▮:00–00.)

Keywords: Bariatric; Balloon; Elipse; precedureless; Kuwait

Obesity is on a continuous rise worldwide, with more than 1.9 billion adults being categorized as overweight by the year 2014, and 600 million of those being obese [1]. While bariatric surgery has proven to be an effective and safe method of treatment for a certain population of patients, according to the most current guidelines, it can only be performed on patients with a body mass index (BMI) of >40 or >35 with serious co-morbidities related to obesity [2]. Patients who do not fit into these categories or those who would rather opt out of surgery and have failed conventional weight loss therapies are left with minimal options for weight management.

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https://doi.org/10.1016/j.soard.2017.12.001
1550-7289/

However, the recent introduction of intragastric balloons has opened up a new door for the nonsurgical management of these patients. Being either air or liquid filled, these balloons are usually endoscopically inserted under sedation or general anesthesia while in the deflated state; when it is confirmed that they are situated in the stomach, they are then inflated [3]. Moreover, multiple systemic reviews have shown that gastric balloons are safe and effective temporary weight loss devices and are successful for obesity management [4–10]. Nonetheless, endoscopic balloons have proven to have limitations of their own, which include the invasive procedure needed to insert and remove them, the need for sedation or anesthesia, and complications such as nausea and intestinal obstruction [11–15].

The Elipse device (Allurion Technologies, Wellesley, MA) is a newly developed, procedureless gastric balloon that can be installed in an outpatient setting without the use of endoscopy or anesthesia. The balloon eventually self-deflates and passes through the gastrointestinal system and is excreted.

The aim of this study was to evaluate the safety and effectiveness of the Elipse balloon in our population of patients in Kuwait. To our knowledge, only 2 studies have been conducted on this balloon, 1 of which had 12 patients, and the other recruited 34.

Methods

Patient recruitment

Patients who were recruited for the study were those who presented to bariatric surgeons with the aim of losing weight and were either (1) not wanting to undergo a bariatric surgical procedure, or (2) not wanting a bariatric procedure that requires general anesthesia. This novel balloon was then proposed to these patients, and the procedure, as well as the risks and benefits, were explained to each patient on an individual basis according to their recruitment criteria.

Study design

This is a multicenter, prospective analysis of all patients that underwent the Elipse balloon insertion at Royale Hayat, Sabah, and Amiri Hospitals, Kuwait. Eligible participants had a BMI of 25 to 45 kg/m^2. The hospital and national ethics committees approved the protocol. The primary outcome measures were changes in weight, BMI, and percent total weight loss (%TBWL), and the secondary outcome measures included the frequency of adverse events and device effects.

Inclusion criteria

Patients included were either (1) obese but for whom bariatric surgery was not indicated, or (2) morbidly obese but had refused bariatric surgery and consulted for an alternative method of weight reduction.

Exclusion criteria

Key exclusion criteria included a history of small-bowel obstruction or any signs or symptoms of esophageal, gastric, or intestinal disease, inflammatory bowel disease, or cancer. Screening was done by taking a detailed history from the patients particularly referring to these symptoms and was according to what the patients reported. Patients were asked about previous existence of symptoms pertaining to these diseases and imaging modalities previously done. Individuals with a known large hiatal hernia were excluded. Individuals with a history of previous open abdominal surgery or more than one laparoscopic abdominal surgery were excluded. Individuals with a history of smoking in the past 12 months were excluded. Patients who have conditions that require the use of chronic nonsteriodal anti-inflammatory drug medications were also excluded.

The Elipse balloon placement protocol

Once the capsule is swallowed, its position in the stomach is confirmed using an abdominal x-ray, which visualizes the radiopaque marker on it. The balloon is then filled through the catheter with 550 mL of the supplied filling fluid. After filling is complete, the catheter is removed by simply pulling it back. The balloon remains inside the stomach for 4 months, during which a resorbable material inside the balloon degrades completely, which then allows a patented release valve to open and empty the balloon within minutes. The empty balloon then passes through the gastrointestinal tract and is excreted. If a patient has difficulty swallowing the capsule, a stylet can be fed through the catheter to stiffen it. The physician can then gently assist by pushing the stiffened catheter during swallowing. After the capsule reaches the stomach, the stylet is removed. No sedation is required for stylet-assisted swallowing.

Treatment protocol

Individuals were not permitted to take nonsteriodal anti-inflammatory drug starting 14 days before balloon deployment and continuing 14 days after the end of therapy. They were also prohibited from taking weight loss medications during the study. Participants were treated with oral omeprazole (20 mg, twice per day) starting 1 week before deployment and continuing for 16 weeks after. For antiemesis, oral ondansetron (8 mg, 3 times per day, started on the day of deployment, and continued for 1 wk after) and oral aprepitant (1 d before deployment, day of, and the day after deployment) were prescribed. No endoscopy was performed before deployment day. Participants were asked to record the number of vomiting and retching episodes