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ORIGINAL CONTRIBUTIONS

Elipse™, a Procedureless Gastric Balloon for Weight Loss: a Proof-of-Concept Pilot Study

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Abstract
Background Endoscopic gastric balloons have been used effectively as weight loss devices for decades, but the requirement for endoscopy and sedation poses several limitations. The goal of this pilot study was to evaluate the safety and performance of a prototype version of Elipse™, a procedureless gastric balloon.
Methods Eight patients (mean BMI=31.0 kg/m^2) participated in this study. Each patient swallowed one Elipse™ balloon intended to remain in the stomach for 6 weeks, self-empty, and then pass. Each balloon was filled with 450 mL of filling fluid. Patients returned every 2 weeks for abdominal ultrasound. No specific diet or exercise plan was prescribed.
Results All eight patients successfully swallowed the device. The most common adverse events were nausea and vomiting. There were no serious adverse events, and all balloons were excreted safely. Despite not being prescribed a diet or exercise plan, all eight patients lost weight. In 6/8 patients, the balloon remained full through 6 weeks, self-emptied, and passed. In one patient, the balloon appeared partially collapsed on ultrasound after 11 days and was endoscopically punctured. One asymptomatic patient elected to have the balloon endoscopically punctured after 19 days. Both balloons passed in the stool after 4 days. In both cases, endoscopic examination of the upper GI tract showed no abnormalities.
Conclusions This pilot study demonstrates the safety and performance of Elipse™, a procedureless gastric balloon for weight loss. Future studies will test a commercial design filled to 550 mL intended to last in the stomach for at least 12 weeks.

Keywords Gastric balloon · Intragastric balloon · Weight loss · Overweight · Obesity

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Introduction

Over 1.4 billion adults worldwide are either overweight or obese. Bariatric surgery is currently not offered to overweight individuals, and when it is indicated in obese individuals, only 1–2 % of patients go on to have surgery [1]. Most patients cite fear of complications as the reason for not opting for surgery [1]. Several endoscopic weight loss devices are either commercially available or under development to serve as alternatives to surgery in obese patients or to augment diet and exercise interventions in overweight patients [2]. Endoscopic

gastric balloons in particular have been studied extensively in the overweight and obese populations. Balloons have led to superior weight loss in randomized, controlled studies with few complications, and several variations on balloon size, residence time in the stomach, and filling (gas vs. liquid) have been tested [3–6].

However, endoscopic gastric balloons have several limitations. First, all require an invasive and sometimes technically complex endoscopic procedure for either balloon placement or removal. These procedures require endoscopic training and increase the cost and overall risk to the patient. Second, all require some type of anesthesia or sedation [7]. Third, patients who fail to return and have the balloon removed risk spontaneous balloon deflation, migration into the intestines, and small bowel obstruction [8–10].

Elipse™ (Allurion Technologies, Wellesley, MA, USA) is a swallowed, self-emptying, and excreted gastric balloon for weight loss (Fig. 1). The balloon is folded inside a vegetarian capsule and attached to a thin catheter via a self-sealing valve. Once the capsule is swallowed, its position in the stomach is confirmed through visualization of the balloon's radiopaque marker on an abdominal x-ray. The radiopaque marker was constructed specifically from materials known to be radiopaque in the bowel with surrounding debris and to have a size and shape known to be easily visualized in the gastrointestinal tract. The balloon is then filled through the catheter with the supplied filling fluid. After filling is complete, the catheter is removed by simply pulling back. The balloon is designed to remain inside the stomach and then empty at a pre-determined time. During gastric residence, a resorbable material inside the balloon degrades. The resorbable material must completely degrade before a release valve opens and allows the balloon to empty instantaneously. The deflated balloon is designed to pass through the gastrointestinal tract and be excreted. Neither endoscopy nor sedation is required for Elipse™ therapy.

Elipse™ is designed to be filled with 550 mL of filling fluid and remain in the stomach for 4 months. This pilot study was conducted with a prototype version of the device filled to 450 mL and designed to last for 6 weeks to more quickly assess the feasibility and safety of Elipse™ therapy. The objectives of the study were to (1) determine if Elipse™ can be swallowed, (2) assess durability of Elipse™ in the stomach, and (3) demonstrate safe passage and excretion of Elipse™ through the gastrointestinal tract.

Methods

Study Design and Subjects

The study had a prospective, non-randomized design. Eligible subjects had a BMI of 27–35 kg/m^2. Informed consent was obtained from all individual participants included in the study. Exclusion criteria included a history of previous abdominal surgery, small bowel obstruction, or any signs or symptoms of esophageal, gastric, or intestinal disease, known intestinal strictures, inflammatory bowel disease, or cancer. Subjects were not permitted to take non-steroidal anti-inflammatory drugs (NSAIDs) starting 14 days prior to treatment and continuing 14 days post-treatment. They were also prohibited from taking weight loss medications during the study. Patients were treated with omeprazole starting 3 days prior to treatment and continuing through the end of treatment. Anti-emetics were prescribed to be taken as needed. No endoscopy was performed prior to treatment day. Patients were seen 2, 4, and 6 weeks after treatment day for abdominal imaging to assess balloon volume and positioning and basic nutritional counseling. No specific diet or exercise plan was prescribed as part of this study.

Performance and Safety Measures

Performance measures included the ability to swallow the Elipse™ capsule, residence in the stomach for 6 weeks, and passage and excretion of the balloon through the gastrointestinal tract. While this pilot study was designed to assess only safety and performance, patients were weighed at all follow-up visits. No specific diet or exercise plan was prescribed as part of this study.

Fig. 1 The Elipse™ gastric balloon is folded into a vegetarian capsule and attached to a thin catheter (*left*). After it is swallowed, the balloon is filled with liquid (*right*)

Safety measures included the frequency of adverse events (AEs), adverse device effects (ADEs), serious adverse events (SAEs), and unanticipated device effects (UADEs).

Results

Baseline Characteristics

Eight patients (seven female/one male) were included in this study. The mean age was 40 years (range 24–60), mean BMI was 31.0 kg/m^2 (range 27.6–35.0 kg/m^2), and mean weight was 88.0 kg (range 74.8–112.8 kg).

Performance

All devices were swallowed, and no endoscopy was required for device placement. All devices were visualized successfully on x-ray prior to filling (Fig. 2). All balloons were filled successfully (mean fill time=15 min) with 450 mL filling fluid and visualized successfully on either x-ray or ultrasound (Fig. 3). The mean visit time was 26 min. Six balloons were visualized on ultrasound at the 2-, 4-, and 6-week follow-up visits and confirmed to be full. They then self-emptied and were excreted. An abdominal x-ray was taken at trial exit to confirm that the balloon had passed. One balloon deflated after 11 days due to a manufacturing defect. The collapsed balloon was found in the stomach on ultrasound. An endoscopy was performed, and the esophagus and stomach were normal. The balloon film was punctured with a needle, torn with forceps, and left in the stomach. It passed in the stool 4 days later. One asymptomatic patient requested the balloon be decompressed after 19 days as she "no longer enjoyed eating." On endoscopy, the balloon appeared full, and the esophagus and stomach were normal. The balloon was punctured and torn in a similar fashion, left in the stomach, and passed in the stool 4 days later.

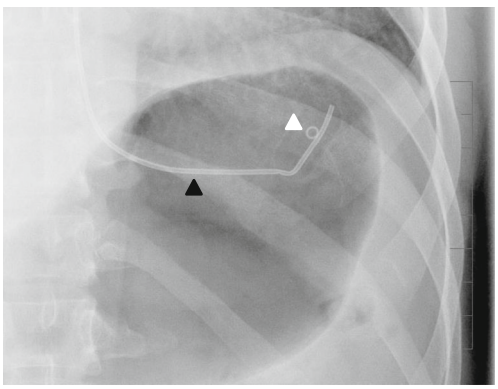

Fig. 2 X-ray of Elipse™ after it is swallowed but before it is filled. The radiopaque catheter (*black arrowhead*) is seen entering the stomach. The radiopaque marker inside Elipse™ (*white arrowhead*) is also visible

Safety

There were no SAEs or SADEs. All AEs were anticipated. Six out of eight patients (75 %) reported nausea beginning after Elipse™ treatment, five out of eight (62.5 %) patients reported vomiting after Elipse™ treatment, and three out of eight (37.5 %) patients reported abdominal cramping. All nausea, vomiting, and cramping were either self-limiting or resolved with medications. All AEs were rated by the investigator as mild (94.4 %) or moderate (5.6 %).

Weight Loss

Despite not being prescribed a diet or exercise plan, all eight patients lost weight in the course of the study. After 6 weeks of Elipse™ therapy, the mean weight loss was 2.4 kg and mean percent excess weight loss (%EWL) was 12.4 %.

Discussion

This pilot study demonstrated the safety and performance of a prototype version of the Elipse™ gastric balloon. All devices were swallowed and did not require endoscopy or sedation for placement, and all balloons safely transited the gastrointestinal tract and were excreted. All balloons were visualized on either x-ray or ultrasound both prior to and after filling. Moreover, all patients lost weight during the study, even though a specific diet and exercise regimen was not prescribed.

No serious adverse events occurred in this study, and all but one adverse event was rated as mild. In particular, there were no aspiration events during swallowing, small bowel obstructions during balloon passage, or evidence of ulcers. The nausea, vomiting, and abdominal cramps reported here was similar to previous studies on liquid-filled gastric balloons even though no prophylactic anti-emetic medications were administered [3, 11].

Unlike endoscopic gastric balloons, Elipse™ is entirely designed from a thin film without rigid parts with the sole purpose of allowing safe passage through the gastrointestinal tract. Elipse™ is designed to be administered in an office setting without endoscopy or sedation. While the Obalon® balloon was designed to be swallowed, it still requires endoscopy and sedation for removal [12]. By eliminating endoscopy and anesthesia, Elipse™ could be offered at a lower price than endoscopic gastric balloons and pose fewer safety concerns to the patient, especially obese patients who incur risk from sedation and anesthesia [7]. In addition, Elipse™ is intended to be convenient for the patient: even though this was the first trial of Elipse™ in the clinic, the average patient visit time was only 26 min.

Complications can occur with endoscopic gastric balloons when patients are lost to follow-up. Previous

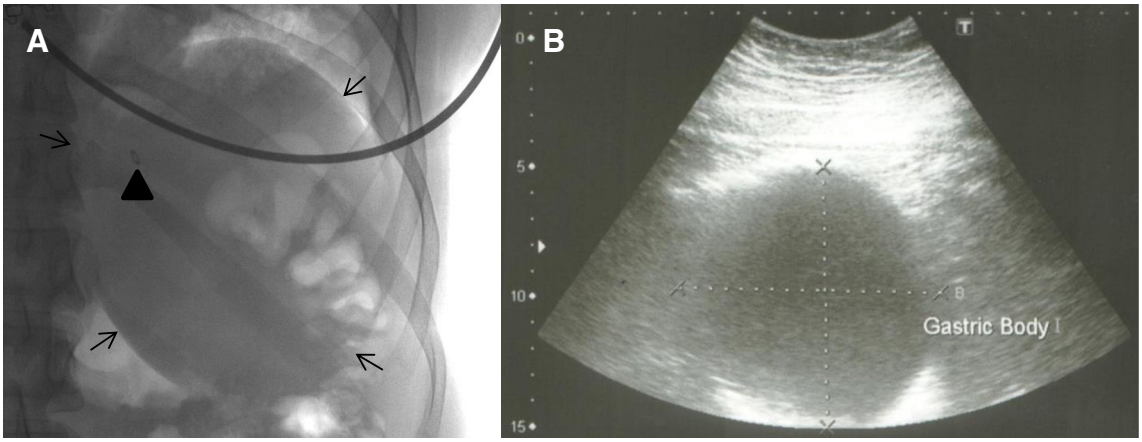

Fig. 3 X-ray (**a**) and ultrasound (**b**) of Elipse™ after it is filled. The outline of the Elipse™ balloon (*arrows*) and the radiopaque marker inside the balloon (*arrowhead*) can be seen on x-ray (**a**) and the outline of the balloon can be seen on ultrasound (**b**)

reports demonstrate that balloons are more likely to spontaneously empty, migrate into the intestines, and occasionally cause an obstruction when patients do not return to have the balloon removed [8–10]. While filling balloons with methylene blue-stained liquid is intended to alert the patient that the balloon has opened, it is not a fail-safe technique [13]. However, since Elipse™ is specifically designed to self-empty and pass, methylene blue is not required as patients lost to follow-up during Elipse™ therapy should not incur any additional risks.

One potential concern regarding a swallowed balloon is the absence of a screening endoscopy prior to balloon placement. However, the diagnostic yield of endoscopy in asymptomatic patients is quite poor, and the endoscopy itself is not without risk. Previous balloon investigators have argued that a screening endoscopy is not required in patients without digestive symptoms at baseline [12]. In this pilot study, all patients were asymptomatic at baseline, did not receive a screening endoscopy, and did not experience any serious adverse events.

The Elipse™ prototype used in this study was filled to 450 mL and designed to last for 6 weeks inside the stomach. The commercial version of Elipse™ will be filled to 550 mL and designed to last for at least 4 months inside the stomach. While a 4-month dwell time is less than the 6-month dwell times of other liquid-filled gastric balloons, previous work has demonstrated that 80 % of the weight lost in gastric balloon therapy occurs in the first 3 months of therapy [13]. Moreover, previous studies have demonstrated that balloons can be repeated in patients who require additional weight loss [14–16].

The limitations of this study include its small size and non-randomized design. Moreover, the device used in this study was an Elipse™ prototype and not the commercial model. Future studies will use the commercial model of the Elipse™ filled to 550 mL and designed to remain in the stomach for 4 months, offer patients prophylactic anti-emetics, and expand the inclusion criteria to BMI 27.0–40.0 kg/m^2.

Conclusion

This pilot study demonstrated the safety and feasibility of the Elipse™ gastric balloon. In particular, Elipse™ was successfully swallowed, filled, imaged, and passed in all eight patients without the use of endoscopy or sedation. In addition, all eight patients lost weight. Future studies will assess a commercial version of Elipse™ that is larger and has a longer dwell time inside the stomach. Since it does not require endoscopy or sedation, Elipse™ can potentially be used by physicians in an office setting and poses less invasiveness, risk, and cost to the patient.

Conflict of Interest MB, TK, and MB declare that they have no competing interests. EM received consulting fees from Allurion Technologies. KS is a consultant to Allurion Technologies. RC, SL, and SG are shareholders of Allurion Technologies.

Ethical Standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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