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Elipse, the first procedureless gastric balloon for weight loss: a prospective, observational, open-label, multicenter study

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ABSTRACT

Background and study aims Conventional gastric balloons for weight loss require endoscopy for placement and removal. The Elipse device is swallowed, resides in the stomach for 4 months, and is then expelled. The objectives of this study were to assess the safety of Elipse and to measure its effects on weight loss, metabolic parameters, and quality of life.

Methods Each participant swallowed one Elipse device, which was filled with 550 mL of filling fluid through a thin delivery catheter that was then removed. Weight was measured every 2 weeks, and metabolic parameters and quality of life were assessed at baseline and at trial exit.

Results 34 patients, with a mean body mass index of 34.8 kg/m^2, were enrolled. All 34 patients successfully swallowed the Elipse device. All adverse events were either self-limiting or resolved with medication. All balloons were safely excreted. At 4 months, the mean percent total body weight loss was 10 %. Mean waist circumference was reduced by 8.4 cm. Improvements were also seen in hemoglobin A1c, triglycerides, low density lipoprotein, and blood pressure. At trial exit, quality of life measures had improved across all domains.

Conclusion These results demonstrate clinically significant weight loss with the Elipse, the first procedureless gastric balloon. The weight loss was similar to that seen in previous studies of endoscopically placed balloons. In addition, Elipse therapy led to improvements in waist circumference, several metabolic parameters, and overall quality of life.

ClinicalTrials.gov identifier: NCT 02802007.

Introduction

Worldwide more than 2 billion individuals are either overweight or obese [1]. Bariatric surgery has had a limited impact in treating this epidemic, as bariatric surgery is not indicated for overweight, class I obese, and class II obese individuals without medical co-morbidities, and most severely obese individuals either have no access to surgery or find surgery unacceptable because of fear of complications [2]. Endoscopic gastric balloons have emerged as a nonsurgical option for overweight and obese individuals in whom diet, behavior modification, and/or medical treatment have failed, and who either do not qualify for or do not want surgery. Gastric balloons have been in use for decades as temporary weight loss devices and have been shown to be safe and effective in both large multicenter studies and randomized controlled studies [3–6]. Multiple systematic reviews of the literature have concluded that gastric balloons are effective tools for obesity management [7–9].

Despite their effectiveness, recent studies have highlighted several limitations of endoscopic gastric balloons. First, endoscopic removal of balloons can be unsafe. In one large multicenter study of an endoscopic balloon, several serious adverse events occurred related to balloon removal including esophageal mucosal tear, esophageal perforation, and aspiration pneumonitis [6]. Second, all endoscopic balloons require either sedation or anesthesia, both of which can lead to adverse events in an overweight or obese individual. Third, several case reports have been published describing how endoscopic balloons that have not been removed from individuals who were lost to follow-up have eventually migrated into the intestines

▶ **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). A US quarter is shown for size comparison purposes.

and caused a bowel obstruction [10–14]. Finally, both the endoscopy and anesthesia used for placement and removal significantly add to the cost.

The Elipse device (Allurion Technologies, Wellesley, Massachusetts, USA) is a procedureless gastric balloon for weight loss that can be deployed in an outpatient setting without the use of endoscopy or anesthesia (▶ **Fig. 1**). The balloon is folded inside a vegetarian capsule and attached to a thin catheter via a patented, 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. If an individual 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. 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. The resorbable material must completely degrade before a patented release valve opens and allows the balloon to empty within minutes. Importantly, the release valve remains closed until the resorbable material is fully degraded. The empty balloon passes through the gastrointestinal tract and is excreted.

A proof-of-concept pilot study, conducted previously and using a smaller and shorter-duration prototype version of the device in eight participants, reported no serious adverse events. All eight participants were able to swallow and expel the device [15]. The current investigation evaluates the efficacy and safety of the Elipse gastric balloon in a multicenter study.

Patients and methods

Study design and participants

The study had a prospective, observational, and open-label design (ClinicalTrials.gov registration: NCT02802007). Eligible participants had a body mass index (BMI) of 27.0–40.0 kg/m^2. A previous proof-of-concept pilot study, conducted between October and December 2013, evaluated a smaller, shorter-duration version of the Elipse in participants with a BMI between 27.0 and 35.0 kg/m^2 [15].

Informed consent was obtained from all participants included in the study. Participants were treated between November 2014 and December 2015 at two sites: the University Hospital Ostrava (Ostrava, Czech Republic) and Iatriko Medical Center (Athens, Greece). The protocol was approved by the hospital and national ethics committees at both sites. The primary outcome measure was the frequency of adverse events and device effects, and the secondary outcome measures included changes in weight, metabolic parameters, and quality of life.

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. 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 a single cesarean section, laparoscopic cholecystectomy or appendectomy, or an exploratory laparoscopy more than 12 months prior to the Elipse deployment date were allowed to enrol. Individuals with a history of smoking in the past 12 months were excluded. A complete listing of inclusion and exclusion criteria can be found on clinicaltrials.gov (NCT02802007).

Individuals were not permitted to take nonsteroidal anti-inflammatory drugs (NSAIDs) starting 14 days prior to 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 3 days prior to deployment and continuing through the end of therapy. For antiemesis, oral ondansetron (8 mg, three times per day, for 5 days) and/or oral aprepitant (125 mg on deployment day, 80 mg daily for 2 days) were prescribed. No endoscopy was performed prior to deployment day. Participants were asked to record the number of vomiting and retching episodes they experienced over the first 14 days.

Participants were seen every 2 weeks for weight and waist circumference measurements, when they received nutritional counseling and were encouraged to follow a high protein, 1000–1200 Calories/day diet. Waist circumference was measured with a nonstretchable measuring tape in a horizontal plane around the abdomen at the level of the iliac crest.

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 with comparable ethical standards.

Statistical analysis

Results are reported using descriptive statistics and expressed as means with standard deviation (SD). Changes in weight and metabolic parameters from baseline were tested for significance with a two-sided, one-sample *t* test. *P* values less than 0.05 were considered statistically significant.

Results

Baseline characteristics

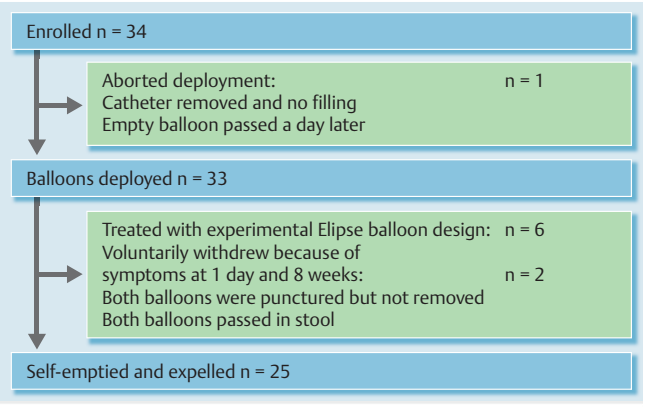
A total of 34 individuals (23 women, 11 men) were included in this study. The first 28 participants were treated with Elipse devices containing a radiopaque marker and made of nonradiopaque film. The last 6 participants were treated with Elipse devices with an experimental design made from radiopaque film. In addition, these devices were packed into a slightly smaller capsule to ease swallowing. As this design was experimental, only qualitative observations are reported from these 6 participants (▶ **Fig. 2**).

On the day of deployment, the mean age of participants was 42 years (range 18 – 59), mean BMI was 34.8 kg/m^2 (range 27 – 40 kg/m^2), and mean weight was 101.8 kg (range 73 – 134 kg) (▶ **Table 1**).

Performance

All of the first 28 participants swallowed the device, either with use of the stylet (n = 13, 46 %) or without (n = 15, 54 %). All 6 participants (100 %) treated with the Elipse in a smaller capsule swallowed the device without use of the stylet. No endoscopy or anesthesia was required. All devices were visualized on X-ray prior to filling (▶ **Fig. 3**). Of the 28 balloons, 27 (96 %) were successfully filled with 550 mL filling fluid (▶ **Fig. 4**). The mean (SD) deployment time, including swallowing, X-ray, filling, and catheter removal, was 22 (8) min. One capsule did not enter the stomach immediately and remained at the lower esophageal sphincter despite the participant's drinking more water. Upon the participant's request, the catheter was removed by pulling back, allowing the capsule to detach. The capsule then spontaneously entered the stomach, and an endoscopy performed within 30 minutes revealed the capsule in the stomach. There were no anatomical abnormalities or injuries at the esophagus, gastroesophageal junction, or stomach. The capsule was left inside the stomach and an empty balloon passed in the stool the following day.

Two participants requested that the balloon be decompressed, after 1 day and 8 weeks, respectively, because of intolerance. Of note, neither of these participants received the combination antiemetic medication regimen for symptom management. In both cases, the participants underwent an endoscopy with conscious sedation. The esophagus and stomach appeared normal. The balloon was punctured in multiple locations using either a biopsy forceps or a 23-gauge needle. The empty balloon was left in the stomach and in both cases passed in the stool uneventfully. There were no adverse events related to either the endoscopy or the passage.

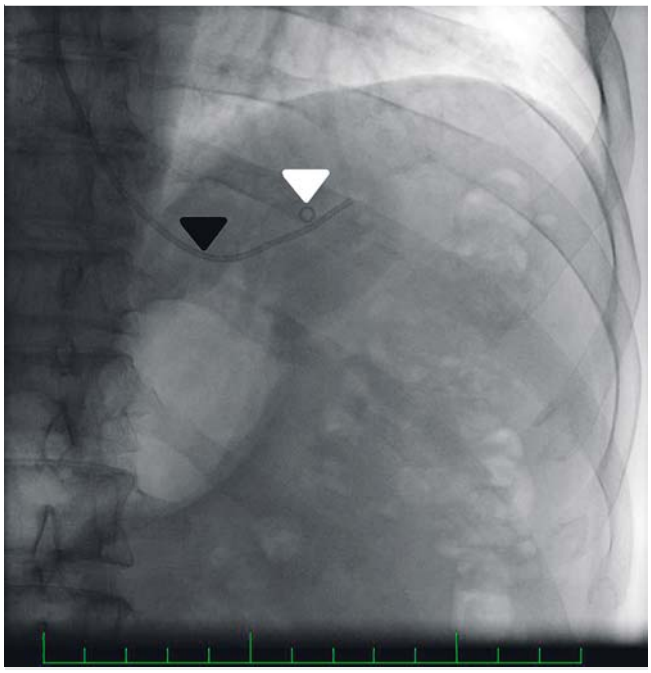


▶ **Fig. 2** Elipse gastric balloon: multicenter trial participants and progression through the study.

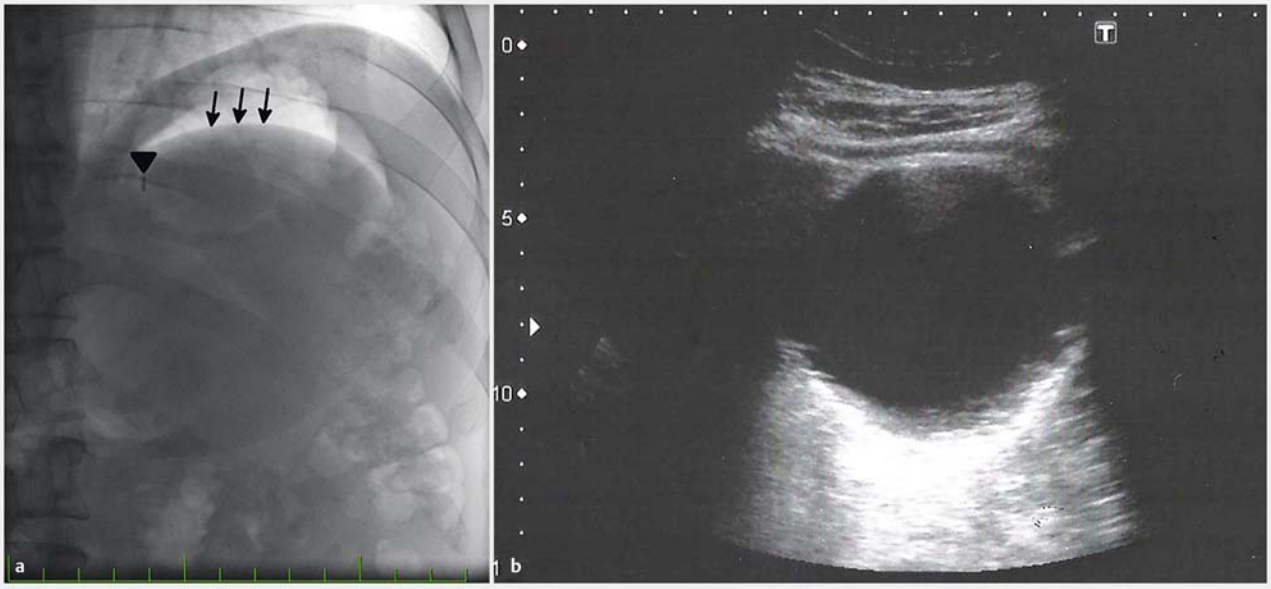
▶ **Table 1** Participants treated with the Elipse procedureless gastric balloon: data are shown for the first 28 participants, who were treated with the Elipse balloon containing a radiopaque marker and made with nonradiopaque film.

	Mean (SD)	Range
Age, years	42 (11)	18 – 59
Weight, kg	101.8 (17.1)	73 – 134
Body mass index (BMI), kg/m^2	34.8 (3.7)	27 – 40

SD, standard deviation.



▶ **Fig. 3** Elipse gastric balloon: X-ray after swallowing but before filling. The radiopaque catheter (black arrowhead) is seen entering the stomach. The radiopaque marker inside the balloon (white arrowhead) is also visible.



▶ **Fig. 4** Elipse gastric balloon after filling. **a** The outline of the balloon (arrows) and the radiopaque marker inside the balloon (arrowhead) can be seen on X-ray. **b** The outline of the balloon can be seen on ultrasound.

In the 6 participants treated with Elipse devices made from the experimental radiopaque film, the residence time in the stomach was found to be highly variable (range 30 – 141 days). All these balloons were passed safely in the stool. The use of this experimental film was abandoned because its effect on the valve led to a highly variable residence time.

For the remaining participants (n = 25; ▶ **Fig. 2**), the mean (SD) residence time of the Elipse in the stomach was 117 (14) days.

All balloons were excreted safely. A total of 30 (88 %) were passed in the stool and 4 (12 %) were expelled in emesis uneventfully. In all cases where the balloon was expelled in emesis, the expulsion occurred after approximately 16 weeks, and the participant experienced nausea immediately prior to vomiting the balloon. According to the participants, all vomited balloons were nonbloody and appeared empty. The nausea and vomiting resolved immediately after the balloons were expelled. No adverse events were experienced after excretion.

Weight and waist circumference

The mean (SD) percent total body weight loss, BMI point reduction, and waist circumference reduction were 10.0 % (6.6 %), 3.9 kg/m^2 (3.1 kg/m^2), and 8.4 cm (6.5 cm), respectively, at 16-week follow-up (▶ **Table 2**). All reductions were statistically significant.

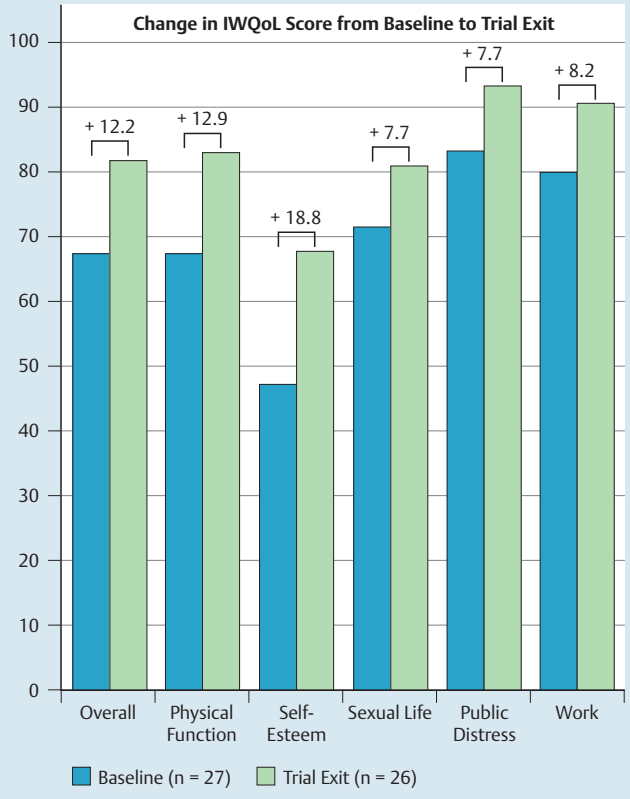
Metabolic parameters

Mean reductions were hemoglobin A1c (HbA1c), 0.16 %; low density lipoprotein (LDL), 9.7 mg/dL; and triglycerides, 16.4 mg/dL. Mean reductions in systolic blood pressure (SBP), and diastolic blood pressure (DBP) were 9.6 mmHg, and 5.8 mmHg, respectively. Reductions in HbA1c, SBP, and DBP were statistically significant (▶ **Table 2**).

▶ **Table 2** Elipse procedureless gastric balloon treatment: weight loss and metabolic parameter improvement at 16-week follow-up. For participants who exited the study just prior to the 16-week follow-up visit (e. g. at 14 weeks), the last observation is carried forward.

	Reduction Mean (SD) 95 %CL	**n**	***P* value**
Percent total body weight loss (%TBL)	10.0 % (6.6 %) (7.28, 12.72)	25	<0.001
BMI, kg/m^2	– 3.9 (3.1) (– 5.18, – 2.62)	25	<0.001
Waist circumference, cm	– 8.4 (6.5) (– 11.08, – 5.72)	25	<0.001
Hemoglobin A1c, mg/dL	– 0.16 % (0.16 %) (– 0.231, – 0.089)	22	<0.001
LDL	– 9.7 (27.6) (– 21.35, 1.95)	24	0.099
Triglycerides	– 16.4 (50.9) (– 37.9, 5.1)	24	0.128
Systolic blood pressure	– 9.6 (16.1) (– 16.25, – 2.95)	25	0.006
Diastolic blood pressure	– 5.8 (7.9) (– 9.06, – 2.54)	25	0.001

SD, standard deviation, 95 %CL, 95 % confidence limits; BMI, body mass index; LDL, low density lipoprotein.



▶ **Fig. 5** Quality of life in participants treated with the Elipse gastric balloon: change in Impact of Weight on Quality of Life (IWQoL) scores, from baseline to trial exit.

Quality of life

All aspects of quality of life measured by the Impact of Weight on Quality of Life (IWQoL) questionnaire demonstrated statistically significant improvements. Specifically, overall quality of life, physical function, self-esteem, sexual life, public distress, and work-related quality of life improved by 12.2, 12.9, 18.8, 7.7, 7.7, and 8.2, respectively (▶ **Fig. 5**). Improvements greater than or equal to 7.7 are considered statistically significant [16].

Safety

There were no serious adverse events or serious adverse device effects. All adverse events were anticipated. Among gastrointestinal adverse events, 18 participants (64 %) had vomiting, 15 participants (54 %) experienced nausea, and seven participants (25 %) had abdominal pain (▶ **Table 3**).

Of note, three different antiemetic regimens were used sequentially during the study. Participants were treated with ondansetron alone (n = 8), aprepitant alone (n = 8), or a combination of ondansetron and aprepitant (n = 17). The proportion of participants who experienced no vomiting in each group was 0/8 (0 %), 1/8 (12.5 %), and 10/17 (59 %) (▶ **Fig. 6**). There were no early decompression requests due to intolerance in participants treated with a combination of ondansetron and aprepitant.

▶ **Table 3** Gastrointestinal adverse events related to Elipse procedureless gastric balloon treatment, in 28 participants.

	Adverse events, n	Participants experiencing adverse event(s)	
		n	%
Abdominal distension	1	1	3.6
Abdominal pain	7	7	25.0
Constipation	5	5	17.9
Diarrhea	4	4	14.3
Gastroesophageal reflux disease	3	3	10.7
Nausea	19	15	53.6
Vomiting	21	18	64.3
Total	60	24	85.7

Discussion

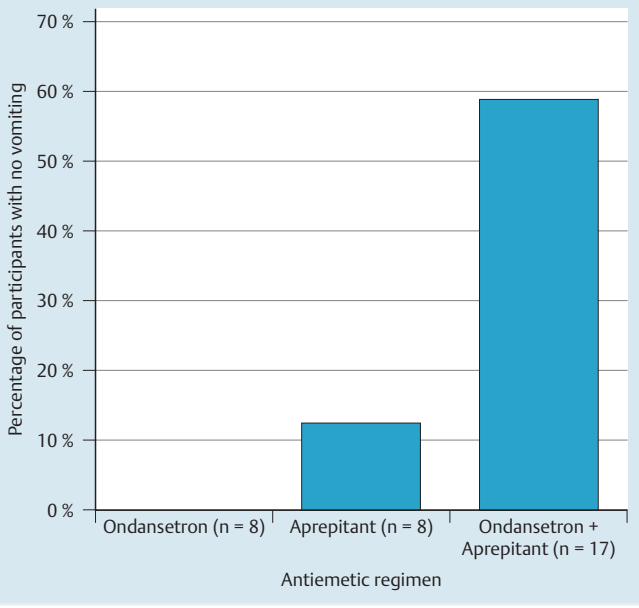
This study describes the first observational, multicenter experience with Elipse, a procedureless gastric balloon for weight loss. There were no serious adverse events and all adverse events were expected and typical of intragastric balloon therapy.

All participants were able to swallow Elipse and pass it safely. We have previously reported on a smaller, shorter-duration Elipse prototype with a 100 % swallow and passage rate [15]. In contrast to the prototype device used in that version, the Elipse device used in this study was filled to 550 mL and intended to last in the stomach for 4 months. These results demonstrate an average residence time of approximately 4 months with a standard deviation of 2 weeks.

Use of the Elipse eliminates the need for endoscopy and anesthesia and as a result, avoids the serious complications that can occur with endoscopic balloons. In particular, endoscopic removal of balloons has previously been associated with aspiration pneumonitis, esophageal perforation, esophageal mucosal tear, and esophageal bleeding [6]. Elipse is designed to pass naturally, thereby eliminating the need for endoscopic removal. Moreover, eliminating endoscopy and anesthesia improves turnover time and the overall physician and participant experience. The average visit time for device placement was only 22 minutes. Finally, without endoscopy and anesthesia, Elipse may be offered at a lower cost than other weight loss devices.

In this study, there were no serious adverse events, such as gastric/esophageal perforation, bleeding, ulcers, and obstructions that have been reported with other gastric balloons.

Importantly, individuals with a history of open abdominal surgery or multiple laparoscopic surgeries were excluded in this study. However, individuals with a single laparoscopic appendectomy or cholecystectomy, exploratory laparoscopy, or a cesarean section at least 12 months prior to Elipse deployment were included. Previous studies have demonstrated that the risk for small-bowel obstruction in individuals with a history



▶ **Fig. 6** Performance of three antiemetic regimens in participants receiving the Elipse gastric balloon. Participants were treated with either ondansetron alone, aprepitant alone, or a combination of ondansetron and aprepitant. The percentage of participants who experienced no vomiting in each group is shown.

of a single laparoscopic cholecystectomy or appendectomy or a cesarean section is less than 1 % [17, 18]. In this study, 10 individuals (36 %) had a history of abdominal surgery. No obstructions were observed.

Four individuals did expel the Elipse through emesis, after it had emptied. In all cases, this occurred uneventfully within a relatively short period of time from the onset of nausea, without requiring any intervention, and without development of gastric obstruction. In all cases, device emesis occurred at the end of Elipse therapy, following the opening of the valve and emptying of the balloon. We hypothesize that after balloon deflation, transient obstruction at the pyloric outlet may occur resulting in emesis. In contrast, gastric obstruction is a known complication of other gastric balloons that may require early balloon removal [3, 19]. Although this study represents a very early experience, given the safe expulsion of the Elipse device through emesis in approximately 10 % of our total experience with the device, it appears that vomiting may also be a safe mode for Elipse excretion. Previous studies with much bulkier endoscopic balloons have demonstrated that expulsion through emesis can occur safely. Roman et al. [20] report that of 176 individuals treated with the BioEnterics Intragastric Balloon, 49 excreted the balloon spontaneously with 45 balloons (92 %) passed in the stool and 4 (8 %) expelled through emesis.

Similar to previous gastric balloon studies, because of intolerance some participants requested decompression of the Elipse balloon. Previous studies on gastric balloons have reported early removal rates of 4.2 % to 9.1 % and severe nausea and vomiting that can last for up to 1 week after balloon deployment [6, 8]. In this study, participants were treated with either ondansetron alone, aprepitant alone, or a combination of the two. Aprepitant has been shown previously to control nausea and vomiting in individuals after surgery and those undergoing chemotherapy, and has been studied extensively in multiple randomized, controlled trials [21 – 23]. In addition, its use with ondansetron has been reported to significantly decrease vomiting in individuals treated with another intragastric balloon [24]. In this study, intolerance was dramatically reduced with a combination of ondansetron and aprepitant. Whereas nearly all participants experienced vomiting with a single antiemetic regimen, nearly 60 % were symptom-free on the combination therapy. No participant receiving combination antiemetic therapy requested that the balloon be decompressed early.

While this study was not powered to detect a specific change in weight, metabolic parameters, or quality of life, improvements were observed in all three areas. The weight loss observed in this study is similar to the weight loss reported in previous studies on gastric balloons [8]. Furthermore, despite the shorter gastric residence time of 4 months, the observed weight loss is comparable with that found in previous studies on gastric balloons with longer gastric residence time, confirming earlier reports that around 80 % – 90 % of the weight lost during gastric balloon therapy occurs in the first 3 – 4 months [25]. The improvements in metabolic parameters are modest in comparison to those with other balloons studied previously and it is unclear how long these improvements may be sustained. However, the participants enrolled in this study were relatively healthy at baseline with an average hemoglobin A1c and LDL within normal limits compared to previous studies where intragastric balloons were tested in participants with confirmed metabolic syndrome [26].

An experimental Elipse design made from radiopaque film and containing a smaller capsule was tested in 6 participants. None of these participants required the stylet for swallowing, indicating that the smaller capsule is likely easier to swallow. While these balloons were all expelled safely, the residence time in the stomach was highly variable. Further development is needed on this design to ensure a more reproducible residence time.

The limitations of this study include its small size and nonrandomized design. Future work will focus on assessing Elipse in larger cohorts and in a randomized, controlled setting, with the intention of also evaluating weight maintenance after Elipse expulsion and the potential synergistic effects of other antiemetics.

Conclusion

This study demonstrates the efficacy, performance, and safety of Elipse, the first procedureless gastric balloon for weight loss. The results reported here indicate that weight loss after Elipse placement compares favorably with that for other balloons, and that the device offers additional benefits of improved safety profile and participant experience without requiring endoscopy or anesthesia at either insertion or removal. In addition, these results indicate that the Elipse balloon used with a combination of ondansetron and aprepitant can dramatically decrease the side effects associated with balloon therapy. While future work will evaluate this device in larger studies with a randomized,

controlled design, this initial experience indicates that the Elipse device may be uniquely positioned to be offered in a wide variety of outpatient settings, without sacrificing efficacy, safety, or the participant experience.

Competing interests

E. M. and I. R. received consulting fees from Allurion Technologies. E. M.-V. is a consultant to Allurion Technologies. R. C., S. L., and S. G. are shareholders in Allurion Technologies.

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