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RESEARCH

Safety and Effectiveness of Two Different Fluid-Filled Intragastric Balloons: A Single Center Experience

Mohsen Alhashemi[1,2] · Ahmed Alkhamis[1,2] · Mohammad Jamal[1,2] · Husain Almahmeed[2] · Fatima Hamshari[2] · Carol Dsouza[1] · Sara Al-Hassani[1] · Ahmed Almousawi[2] · Wafaa Qasem[2]

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Abstract

Objective The aim of the study is to compare weight loss and safety outcomes of two different commonly available fluid-filled intragastric balloons (IGBs) used for weight loss.

Method A retrospective cohort study of a prospectively maintained database of adult patients who underwent IGB insertion between July 2020 and November 2021 in a single private clinic in Kuwait. The patient either received the Elipse™ or Orbera365™ balloon and was followed until the end of treatment.

Result A total of 358 patients were included, of which 265 and 93 each received the Elipse and Orbera365 balloons, respectively. The mean age of patients was 32.8 (SD 9), the mean body mass index (BMI) was 35 kg/m^2 (SD 4.8), and 72.1% of patients were female. In the Elipse group, 254 patients completed treatment, and 84 patients completed the treatment with Orbera365. Weight loss outcomes were measured at the end of treatment: 4 months after Elipse insertion, and 12 months after Orbera365 insertion. Interim 4 months weight loss outcomes were also measured for the Orbera365 balloon. Patients in the Orbera365 group had significantly better total body weight loss (%TBWL, 14.7 kg [SD 8.9]) compared to the Elipse group (%TBWL 10 kg, [SD 5.6], $p \leq 0.0001$) at the end of treatment, while there was no difference in weight loss outcomes between the two balloons at 4 months. There were more complications requiring premature balloon removal in the Orbera365 group (9.7%) compared to the Elipse group (3.4%).

Conclusion IGBs provide significant weight loss with an acceptable safety profile. The Orbera365 ballon shows better weight loss outcomes compared to the Elipse, likely due to longer duration of treatment. However, there was a higher rate of complications requiring premature balloon removal in the Orbera365 group. Studies with larger patient cohort is needed to verify the findings of this study.

Keywords Intragastric balloon · Elipse · Orbera · Obesity · Endoscopic bariatric therapy

Key Points

- IGB is a short-term, completely reversible, non-pharmacological, non-surgical obesity therapy that can be repeated several times and is considered to be generally safe with very low incidence of serious adverse events.
- IGBs can bridge the treatment gap of patients who are overweight (with or without co-morbidities), or those with class I obesity without metabolic co-morbidities who may benefit from weight loss, and who do not meet the current criteria for metabolic surgery.
- The Orbera365 balloon shows better weight loss outcomes compared to the Elipse, likely due to the longer duration of treatment. However, a higher rate of complications requiring premature balloon removal was observed.
- IGBs provide significant weight loss with an acceptable safety profile.

Extended author information available on the last page of the article

Introduction

Obesity is a complex chronic disease with wide variety of metabolic and mechanical detrimental health effects and decreases life expectancy in affected patients [1]. According to the Kuwait Nutrition Surveillance system, the prevalence of obesity in adults is at an alarming level of 38.1%, while a further 38.5% were classified as overweight [2]. Although metabolic and bariatric surgery (MBS) is the most effective treatment for obesity and obesity-related diseases compared to non-surgical treatment modalities, not all patients are candidates for MBS [3]. MBS is recommended for individuals with a body mass index (BMI) ≥ 35 kg/m^2, regardless of presence, absence, or severity of obesity-related diseases. Individuals with metabolic disease and BMI of 30–34.9 kg/

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m^2 can also be considered for MBS [4]. Patients who do not fit criteria for MBS, those who have contraindications to surgery, or do not wish to undergo a surgical intervention may benefit from other modalities of treatment. For those patients, intragastric balloons (IGB) may be an option for short-term weight management [5, 6].

IGB insertion is a minimally invasive treatment that causes satiety by partially filling the stomach, slowing down gastric emptying, thus inducing weight loss [7, 8]. They are considered safe and effective in short-term weight loss [9]. Most adverse events related to IGBs are considered mild and transient (including abdominal pain, nausea, vomiting), with low risk (< 3%) of persistent symptoms requiring balloon removal [10, 11]. Serious adverse events of IGB are rare, and include spontaneous rupture, gastrointestinal ulcers and bleeding, spontaneous hyperinflation, balloon migration and bowel obstruction, and acute pancreatitis [12, 13].

Multiple IGBs are currently available. Two common fluid-filled IGBs are the Elipse® Balloon system and the Orbera365 Balloon. The Elipse is a fluid-filled balloon that has been shown to be a safe and effective intervention with good weight loss results reaching total body weight loss of 7–14%, and has the advantage of not requiring endoscopic guidance for insertion, and is excreted naturally after around 16 weeks [6, 14–17]. The Orbera365 is also a fluid-filled balloon that requires endoscopic insertion and removal after 12 months, and has also shown to be safe and effective, achieving reported total body loss of around 15–16% [5, 18, 19].

To our knowledge, the current study is the only study that provides a direct comparison of two fluid-filled IGBs: Elipse and Orbera365, in terms of weight loss, tolerance, and safety at their respective end-term period. The aim of the study is to provide guidance to physicians in choosing the most appropriate IGB for their patients.

Materials and Methods

Study Design and Population

The study is reported according to The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [20]. This is a retrospective analysis of a prospectively maintained electronic health record of individuals who sought treatment for obesity with IGB in a single private clinic in Kuwait between July 2020 and November 2021. After consultation with the surgeon, patients were evaluated for eligibility for IGB, and the patients were offered either Elipse or Orbera365. The choice of the balloon was left to the preference and discretion of the patient and the surgeon after a detailed discussion of these options. Patients included in the study are adult patients (≥ 18 years) with a minimum BMI of 27 kg/m^2. Patients were excluded if they were < 18 years old, or have any contraindication to IGBs including eating disorders, history of Crohn's disease, severe gastroesophageal reflux disease (GERD), large hiatal hernia, bleeding disorders or patients on anticoagulation, history of varices, history of acute pancreatitis, pregnancy, and previous gastric surgery. Patients were offered MBS if they were found eligible but were still offered IGB if they chose not to undergo surgery. All patients had anthropometric measurements taken at first consultation including weight, height, and BMI, and at every 3–4 months until the balloon was excreted or removed. All patients were assigned to receive a follow-up session with a clinical nutritionist and were encouraged to do at least 10,000 steps per day and to follow a high protein diet with a maximum of 1500 kcal/day. Informed consent was obtained from the patients to participate in the study and to access their electronic medical data for research purposes. Each participant was assigned a unique study identification number, and the research dataset was anonymized and stored securely in a password-protected device accessible only to the research team. The study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the ethical committee for coordination of health and medical research of the Kuwait Ministry of Health (2017/261).

Description of Procedures

The Elipse™ Balloon

The Elipse™ balloon (Allurion Technologies, Natick, MA, USA) is a gastric balloon that does not require endoscopy nor sedation for placement and removal. The balloon is enclosed in a small vegetarian capsule attached to a thin catheter. The capsule is easily swollen with water, and the balloon contains a small radiopaque ring that can be used to confirm its correct position within the stomach with x-rays. Once the ring is verified to be within the stomach, the balloon is filled with 550 ml of liquid consisting of distilled water with potassium sorbate preservative. A repeat x-ray is then done to ensure the complete filling of the balloon prior to catheter removal. This device is designed to spontaneously empty through a release valve after around 16 weeks of treatment and be excreted through the gastrointestinal system.

Elipse Balloon Deployment

Patients were kept fasting for at least 8 h prior to the procedure and received a single oral dose of the antiemetic Aprepitant (Emend®, 125 mg) 4 h before balloon deployment.

The patients were asked to swallow the capsule with water, and in case of difficulty swallowing, a stylet is used through the catheter to stiffen it and the surgeon can help with the insertion during swallowing. The proper position of the capsule within the stomach was confirmed with x-rays, and the balloon was filled to a volume of 550 ml. X-rays were obtained after the procedure to ensure proper position and filling of the balloon. The patients were discharged home after the procedure.

Orbera365™ Balloon

The Orbera365™ intragastric balloon (Apollo Endosurgery, Austin, TX, USA) is a gastric balloon that is inserted under endoscopic guidance and is done under sedation or general anesthesia. Once in the stomach, the balloon filled with saline to obtain a spherical shape. The filling volume of the balloon depends on the fundus size, and it can be filled from 400 to 700 ml. The balloon contains a self-sealing valve that allows the detachment of the external delivery device. The external delivery device basically consists of a 6.5-mm external diameter polyurethane catheter, with the end connected to a sheath where the collapsed balloon resides. Balloon removal is also performed endoscopically under general anesthesia; an endoscopic needle is used to puncture the balloon and a catheter is introduced into the balloon to suction the fluid until the balloon is completely collapsed, prior to removing it with an endoscopic grasper.

Orbera365 Balloon Deployment

Patients were kept fasting for at least 8 h prior to the procedure and received a single oral dose of the anti-emetic Aprepitant (Emend®, 125 mg) 4 h before balloon deployment. They received a single dose of intravenous proton pump inhibitor, dexamethasone 8 mg, ondansetron 8 mg, and hyoscine butylbromide (Buscopan) 20 mg prior to the procedure. All balloons were inserted under general anesthesia and endotracheal intubation with the patient in a supine position. A gastroscopy is performed initially and then is removed to introduce the balloon. Gastroscopy is then repeated, and the balloon is filled under direct vision until the detachment of the external delivery tube to ensure no leakage of the balloon. Post-insertion, patients were kept under observation for 6 h to receive intravenous hydration. The balloon was removed 12 months after insertion.

Post-procedure Protocol

Patients were prescribed oral ondansetron 8 mg every 8 h, metoclopramide 10 mg every 6 h, and paracetamol 1 g every 6 h for the first 48 h. A phone follow-up was instituted for all patients in the first 3-day post-insertion and if the patient was thought to be dehydrated or could not tolerate oral intake, then they were offered intravenous hydration and antiemetics on outpatient bases. Patients were prescribed proton-pump inhibitors (omeprazole 40 mg) daily starting at 1 week prior to placement and was continued until the end of treatment. Fluid hydration was permitted for the first 24 h. During the first week, a gradual progression to a semi-liquid diet (yogurt, mashed potatoes, clear soup, puréed vegetables, and eggs) was recommended. At the beginning of the second week, the diet was progressed to a hypocaloric, textured diet plan. Patients were encouraged to exercise regularly.

Statistical Analysis

Continuous variables were summarized as means and standard deviations (SDs) and categorical variables were summarized as relative frequencies and percentages. Intergroup differences in weight changes were compared using paired *t*-test for normally distributed data and the Wilcoxon signed-rank test for non-normally distributed data. A one-way ANOVA, paired *t*-test, or Welch's *t*-test was used to compare weight changes across variable categories. p values < 0.05 were considered statistically significant. Analysis was conducted using GraphPad Prism 10.0.

Results

Study Population

The medical records of 358 patients were retrieved, of which 265 patients underwent Elipse balloon insertion and 93 patients underwent Orbera365 balloon insertion. The mean age of the patients was 32.8 years (SD ± 9.0) years, initial weight of 93.5 k g (SD ± 18.7), BMI of 35.0 kg/m^2 (SD ± 4.8), and comprised of 72.1% females. In the Elipse group, 254 (95.8%) patients completed treatment, and 84 (90.3%) patients completed the treatment with Orbera365. Patients who could not complete the treatment were excluded from the weight loss outcomes analysis (Table 1).

Weight Loss Outcomes

There was no difference in the baseline mean weight and BMI between the two groups (Table 1). In Elipse group, baseline mean weight and BMI were 93.7 kg (SD ± 18.5) and 34.9 kg/m^2 (SD ± 5.1), respectively, and showed significant weight and BMI reduction to 84.2 kg (SD ± 17.0) and 31.4 kg/m^2 (SD ± 4.6), respectively, at 4 months ($p < 0.0001$) (Fig. 1). In Orbera365 group, mean baseline weight and BMI were 94.6 kg (SD ± 19.2) and 35.2 kg/m^2 (SD ± 3.9), respectively, with significant weight and BMI reduction to mean 85.3 kg (SD ± 15.2) and 32.1 kg/m^2

Table 1 Baseline characteristic of patients, weight loss outcomes, and complications*

Variable	All patients ($n=358$) Mean (SD)	Elipse ($n=265$) Mean (SD)	Orbera365 ($n=93$) Mean (SD)	*p-value*
Age (years)	32.8 (9.0)	32.8 (9.1)	32.7 (9.1)	N/A
Sex (male/female)	100/268	78/187	22/81	N/A
Pre-intervention weight (kg)	93.5 (18.7)	93.7 (18.5)	94.6 (19.2)	N.S
Pre-intervention BMI (kg/m^2)	35.0 (4.8)	34.9 (5.1)	35.2 (3.9)	N.S
Post-intervention weight at 4 months (kg)	84.4 (16.6)	84.1 (17.0)	85.3 (15.2)	N.S
Post-intervention BMI at 4 months (kg/m^2)	31.5 (4.5)	31.4 (4.6)	32.1 (4.3)	N.S
Total body weight loss % at 4 months	− 9.9 (6.0)	− 10.0 (5.6)	− 9.5 (7.2)	N.S
Post-intervention weight at 12 months (kg)	-	-	79.2 (15.4)	N/A
Post-intervention BMI at 12 months (kg/m^2)	-	-	29.1 (6.3)	N/A
Total body weight loss % at 12 months	-	-	− 14.7 (8.9)	N/A
End term post-intervention weight (kg) (4-month Elipse v/s 12-month Orbera365)	82.9 (16.8)	84.1 (17.0)	79.2 (15.4)	*0.02*
End term post-intervention BMI (kg/m^2) (4-month Elipse v/s 12-month Orbera365)	30.8 (5.1)	31.4 (4.6)	29.1 (6.3)	*0.004*
End term total body weight loss % (4-month Elipse v/s 12-month Orbera365)	− 11.3 (6.8)	− 10.0 (5.6)	− 14.7 (8.9)	*< 0.0001*
Complications, *N* (%)*	18 (5.0)	9 (3.4)	9 (9.7)	N/A

SD, standard deviation; *BMI*, body mass index; *N.S*, non-significant

*Complications requiring premature removal of the balloon (< 4 months in Elipse, < 12 months in Orbera)

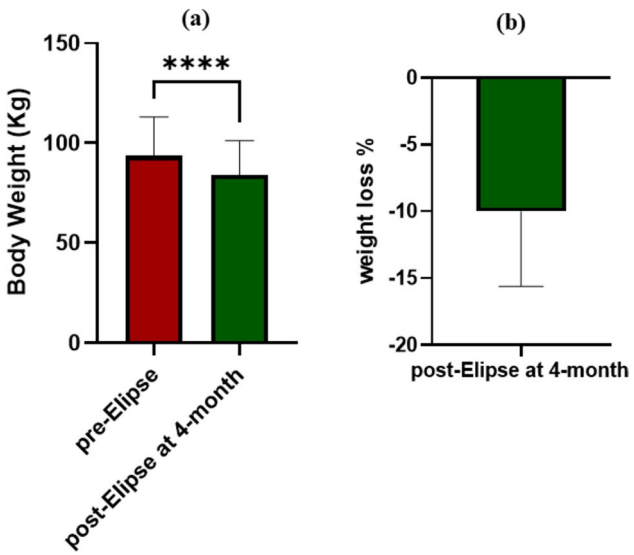

Fig. 1 **a** Mean change in weight (kg) from pre- to post-insertion of the Elipse balloon, and **b** percentage of total body weight loss (%TBWL) after Elipse balloon insertion

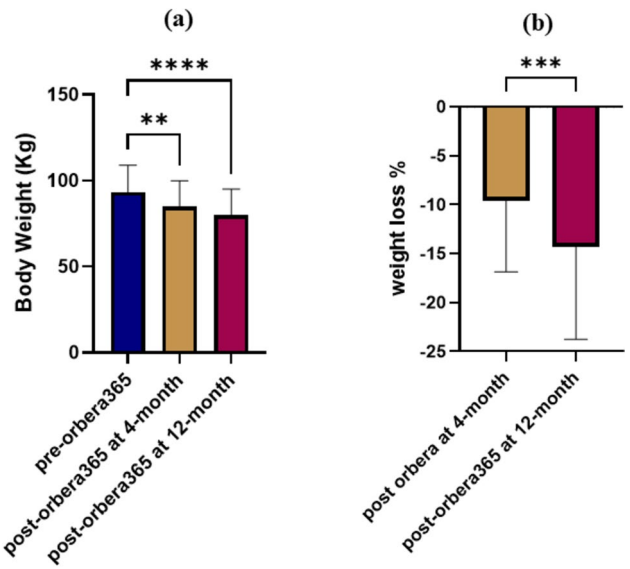

Fig. 2 **a** Mean change in weight (kg) from pre- to post-insertion of the Orbera365 balloon at 4 and 12 months, and **b** Percentage of total body weight loss (%TBWL) after Orbera365 balloon insertion at 4 and 12 months

(SD ± 4.3), respectively, at 4 months ($p < 0.001$), and weight and BMI reduction to mean 79.2 kg (SD ± 15.3) and 29.1 kg/m^2 (SD ± 6.3), respectively, at 12 months ($p < 0.0001$) (Fig. 2). At the end of term of each group, patients in the Orbera365 groups had significantly greater total body weight loss percentage (%TBWL) of 14.7% (SD ± 8.9) at 12 months, compared to the Elipse group, which had a mean %TBWL of 10.0% (SD ± 5.6) ($p \leq 0.0001$) (Fig. 3). However, there was no difference in weight and BMI reduction, and %TBWL between the Elipse and Orbera365 groups at 4 months (Fig. 4) (Table 1).

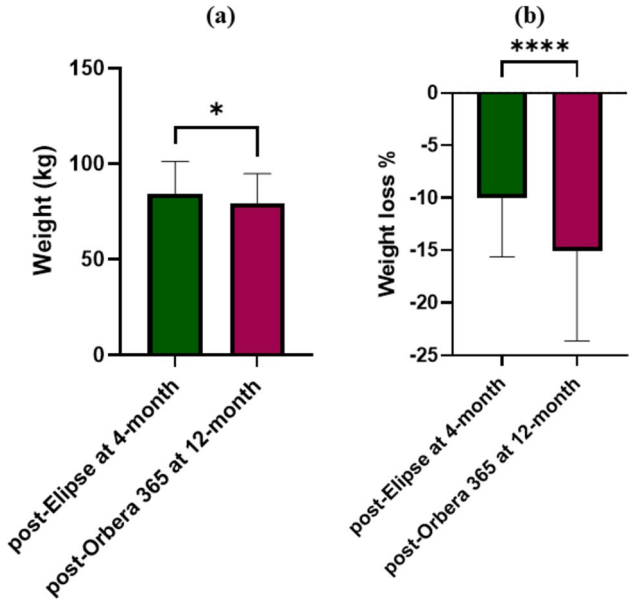

Fig. 3 **a** Comparison of the mean change in weight (kg) from pre- to post-insertion of the Orbera365 and Elipse balloons at end term (4 months Elipse, and 12 months Orbera365), and **b** comparison of the percentage of total body weight loss (%TBWL) after Orbera365 and Elipse balloons insertion at end term

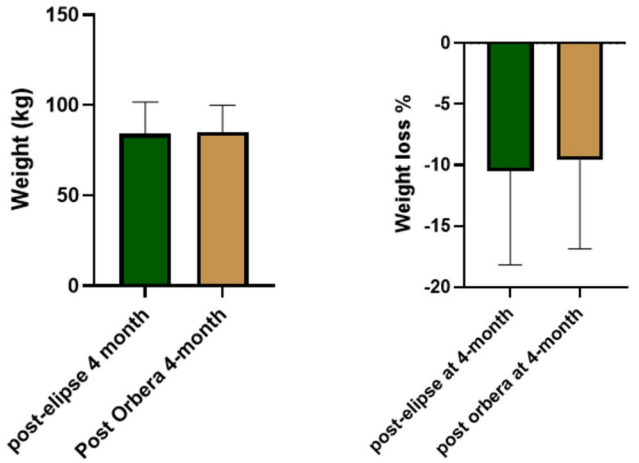

Fig. 4 **a** Comparison of the mean change in weight (kg) from pre- to post-insertion of the Orbera365 and Elipse balloons 4 months, and **b** comparison of the percentage of total body weight loss (%TBWL) after Orbera365 and Elipse balloons insertion 4 months

Complications and Intolerance

The total number of complications requiring premature balloon removal was 18, 9 in each the Elipse and Orbera365 groups, with an overall rate of 3.4% and 9.7%, respectively. In the Elipse group, 7 patients could not tolerate the balloon and had to be endoscopically removed within the first month, 1 patient had premature balloon deflation, and 1 patient suffered from pancreatitis at 3 weeks post-insertion requiring balloon removal. In the Orbera365 group, 4 patients could not tolerate the balloon; two were removed in the first 2 months and the other two had their balloons removed within 7 months post-insertion. Two patients in the Orbera365 had balloon deflation at 3 and 10 months requiring early removal. Finally, 3 patients suffered from pancreatitis in the Orbera365 group at 6 days, 3 weeks, and 6 months post-insertion, and the balloons were removed (Table 2).

Discussion

A 5% reduction in body weight is considered a clinically significant threshold for weight loss success, and is associated with improved quality of life and glycemic control, while weight loss greater than 10–15% is more clinically effective in the control of other obesity-related diseases [21–23]. IGB is a short-term, completely reversible, non-pharmacological, non-surgical obesity therapy that can be repeated several times [24], and is considered to be generally safe with very low incidence of serious adverse events [25]. In the current study, we compared the effectiveness of two commonly used IGBs, the Elipse and the Orbera365. These two balloons are the closest to each other in terms of size, shape, and function [26]. Our results indicated significant short-term weight loss with both systems, with better weight loss outcomes in the Orbera365 group (%TWL 14.7%) compared to the Elipse (%TWL 10.0%) at the end of the treatment. These results are in line with previously published literature [5, 6, 14–19, 25, 27, 28]. Interestingly, there was no difference in weight loss outcomes between the Elipse and Orbera365 groups at 4 months, which shows that the superior outcomes seen in the Orbera365 group are likely secondary to the longer duration of treatment. Nonetheless, the filling volume of the Ellipse is standardized at 550 ml, while the filling volume for the Orbera365 is left to the discretion of the physician, which may provide more restriction at higher volumes, a confounder that is not accounted for in our study. Moreover, this potentially higher filling volume may explain the higher incidence of complications requiring early balloon removal associated with the Orbera365 balloon compared to the Elipse, which is mainly due to intolerance. In our study, we reported 4 cases of pancreatitis, 3 in the Orbera365 and one patient in the Elipse group. Acute pancreatitis is a rare, but known complication of fluid-filled IGBs, particularly the Orbera and ReShape balloons, and the Food and Drug Administration (FDA) has previously issued warning to health providers with this regard [29]; however, we report a single case of acute pancreatitis in the Elipse group, which required the early removal of the balloon. The mechanism of acute pancreatitis following IGB insertion is not fully

Table 2 Type of complications requiring premature removal of the balloon

No	Elipse	Orbera365
1	Balloon spontaneously deflated at 2 months	Balloon spontaneously deflated at 3 months
2	Intolerance; balloon removed at 2 days	Pancreatitis at 3 weeks; balloon removed
3	Intolerance; balloon removed at 7 days	Intolerance; balloon removed at 7 months
4	Intolerance; balloon removed at 3 days	Intolerance; balloon removed at 6 months
5	Intolerance; balloon removed at 1 month	Intolerance; balloon removed at 5 days
6	Pancreatitis at 3 weeks; balloon removed	Balloon spontaneously deflated at 10 months
7	Intolerance; balloon removed at 6 days	Intolerance; balloon removed at 6 weeks
8	Intolerance; balloon removed at 14 days	Pancreatitis at 6 months; balloon removed
9	Intolerance; balloon removed at 7 days	Pancreatitis at 6 days; balloon removed

understood, but it is thought to be secondary to compression of the pancreatic head or tail, with multiple case reports in the literature reporting the development of acute pancreatitis after IGB insertion at variable severities and timing after IGB insertion [13, 30–36].

The current study has several strengths and limitations. First, although this study provides real-world data comparing the effectiveness and safety of two commonly available IGBs, its retrospective nature makes it vulnerable to biases not accounted for in the results. Second, the relatively small sample size, particularly in the Orbera365 group, may limit the generalization of the study results, and may not accurately reflect the true rate of low-incidence outcomes or complications. Although the weight loss outcomes at the end of treatment were significant for both the Elipse and Orbera365 balloons, the lack of long-term follow-up will not accurately capture the incidence of weight gain recurrence after each of these balloons, although this will unlikely differ significantly.

Nevertheless, despite these limitations, to our knowledge, this is the first study which provides real-world comparison of two commonly available IGBs for the management of obesity, and shows that the Orbera365 provides superior weight loss outcomes compared to the Elipse, likely due the longer duration of treatment, but comes at the cost of slightly increased risk of complications requiring early balloon removal, and requires endoscopic placement and removal, compared to the "procedureless" placement of the Elipse. Shared decision-making between the physician and the patient should consider these factors when choosing the most appropriate IGB.

Author Contribution Conceptualisation: MA and MJ. Protocol development: MA, AK and MJ. Data curation: MJ, AM and CD. Data analysis and interpretation: MA,AK, MJ and CD. Preparation of the first draft of the manuscript: MA,AK and MJ. Provision of critical insights and refinement of the manuscript: HM, WQ, FH, CD, AM and SA. All authors have read and approved the final version of the manuscript.

Data Availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

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Authors and Affiliations

Mohsen Alhashemi[1,2] · Ahmed Alkhamis[1,2] · Mohammad Jamal[1,2] · Husain Almahmeed[2] · Fatima Hamshari[2] · Carol Dsouza[1] · Sara Al-Hassani[1] · Ahmed Almousawi[2] · Wafaa Qasem[2]

✉ Mohsen Alhashemi
mohsen.alhashemi@ku.edu.kw

Ahmed Alkhamis
ahmed.alkhamis@ku.edu.kw

Mohammad Jamal
mohammad.jamal@ku.edu.kw

Husain Almahmeed
h.mahmeed@gmail.com

Fatima Hamshari
fhamshari@hotmail.com

Carol Dsouza
carol.dsouza@ku.edu.kw

Sara Al-Hassani
sara.alhassani@ku.edu.kw

Ahmed Almousawi
almousawiahmed98@gmail.com

Wafaa Qasem
drwafaashaban7@gmail.com

[1] Kuwait University, Kuwait City, Kuwait

[2] The Clinic, Kuwait, Kuwait