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Feasibility, results and endoscopic requirements of the Elipse® swallowable intragastric balloon: initial experience

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ABSTRACT

Background: the Elipse® intragastric balloon (EIGB) is a swallowable capsule that is filled under x-ray control. After 16 weeks, its self-releasing valve is degraded and the balloon is deflated and excreted naturally, without endoscopy. The aim of this study was to assess the feasibility of EIGB and its efficacy, duration, safety and endoscopic requirements.

Methods: this is a prospective, descriptive, non-randomized study of the first patients enrolled for EIGB. An x-ray was systematically performed after placement to ensure the correct filling of the balloon. The balloon duration was determined according to its excreted visualization or by x-ray/ultrasound. The efficacy, tolerance, adverse events

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

and their resolution outcome (endoscopic requirements), as well as the final satisfaction degree at 16 weeks, were analyzed.

Results: the study included 30 patients with a basal mean weight and body mass index (BMI) of 83.3 ± 10.7 kg and 30.6 ± 2.7 kg/m². All subjects swallowed the capsule with correct x-ray control. The mean weight loss was 11.2 ± 5.5 kg (12.1 ± 5.8% of total weight loss [TWL], 64.7 ± 25% of excess weight loss [EWL]), with a weight loss > 10% in 80% of patients ($p < 0.05$) after four months. Early elimination of the balloon with an insufficient duration (< 12 weeks) was observed in 2/24 patients (8.3%). There was an acceptable tolerance in 80%. With regard to adverse effects, one balloon was vomited up, there was one intolerance and the balloon was removed by gastroscopy and one small bowel ileal obstruction, which was removed by ileoscopy. The final satisfaction degree was good in 60% of cases.

Conclusions: EIGB placement by x-ray seems feasible and safe. Although some devices have a shorter duration than expected, such as < 16 weeks in 29% patients and < 12 weeks in 8.3% of patients, an acceptable weight loss at four months was obtained. There were some adverse effects that required endoscopy, thus we advise that the procedure be supervised by a bariatric endoscopist.

Key words: Intragastric balloon. Swallowable balloon. Elipse®. Obesity.

INTRODUCTION

Weight loss options are limited if diet attempts fail for those patients who are grade II overweight or have non-morbid obesity (BMI 27.0-39.9 kg/m²). Endoscopic treatment has proven to be an effective complementary alternative in these cases (1). Among the endoluminal methods, the placement of an intragastric balloon (IB) has become the most demanded procedure, which has been shown to be safe and effective for weight loss (2). Traditionally, all commercialized balloons required endoscopy for implantation and/or extraction (2-4).

The Elipse® (Allurion Technologies, Wellesley, Massachusetts, USA) is a new IB, which consists of a swallowable capsule that is filled with 550 ml of pH-titrated fluid through a thin catheter, under x-ray control (Fig. 1). After 16 weeks, a self-releasing valve is

degraded, the balloon is emptied and its polyurethane wall is gradually deflated until it is excreted naturally through the gastrointestinal tract (5,6). Therefore, it is the first intragastric balloon which in theory does not require endoscopy or sedation for insertion or removal (7). EIGB functioning is similar to that of previous intragastric balloons, although its release and elimination model are technically different. They induce weight loss by increasing satiety, delaying gastric emptying and reducing stomach volume to limit its food capacity (8).

In this study, we evaluate the feasibility of EIGB placement with x-ray control. Furthermore, the efficacy, duration, safety and degree of patient satisfaction during four-months of follow-up, or until the balloon deflated or was eliminated, was also assessed. Finally, endoscopy requirements to resolve potential complications were also assessed.

METHODS

A prospective, descriptive, non-randomized study was designed. The first patients referred to our center (Dexeus University Hospital, Barcelona) for insertion of an Ellipse® balloon between November 2017 and June 2018 were included. The inclusion and exclusion criteria were used as defined in the Spanish Consensus Document in Bariatric Endoscopy (3,4). Patients who were grade II overweight or had grade I-II obesity (BMI 27.0-39.9 kg/m^2) and between 18 and 70 years of age (2-4) were accepted for the study. In addition, a directed anamnesis was performed with a specific focus on gastric symptoms, gastroesophageal reflux disease (GERD) and the intake of NSAIDs, as well as history of hiatal hernia, Crohn's disease or enteral pathology, intestinal stenosis/occlusion or major previous abdominal-pelvic surgeries, which contraindicated the procedure.

A dietitian and a bariatric endoscopist with extensive experience in other IB models assessed all patients. Prior to the procedure, patients were treated with proton pump inhibitors (PPIs) for ten days, a liquid diet for 24 hours and fasted for at least eight hours. After placement, the same dietary and pharmacological guidelines were followed as those used with other endoscopic intragastric balloons. There was a face-to-face visit or phone contact at weeks 2, 4, 8, 12 and 16 and PPIs were maintained

(omeprazole 20 mg/24 h) for four months or until balloon excretion occurred.

All implantations were performed by the same endoscopist physician and with the help of the same nurse, in a single-hospital and out-patient. The balloon was folded inside a vegetal capsule and attached to a thin catheter (Fig. 1A). A stylet was fed through the catheter in order to stiffen it. The capsule was swallowed and pushed by the physician until its location in the stomach was confirmed by x-ray and no sedation was required. All the balloons were filled with 550 ml of distilled water containing citric acid and potassium sorbate preservative, without adding dye. Finally, an x-ray was systematically performed to ensure its correct location, complete filling and the absence of leakage and/or complications. The duration of the implant maneuver was estimated, from ingestion to the final x-ray after completion of the filling (Fig. 1A).

The duration of the implanted balloon was also determined, from its intake to the visualization of its elimination by the rectal route. If the balloon had not been eliminated at 16 weeks, an abdominal x-ray was performed. When there was a doubt, it was completed with ultrasound. Normal elimination was defined as its expulsion at least 16 weeks after implantation, early elimination was defined when it was eliminated between 12-15 weeks and early pathological elimination with an insufficient duration when expelled before 12 weeks.

Efficacy data included weight loss at 16 weeks that was expressed in weight (kg), BMI (kg/m^2), percentage of total weight loss (%TWL) and percentage of excess weight loss (%EWL). The degree of tolerance defined as good/bad according to subjective criteria of the patient was discriminated by retrospective questioning at 16 weeks. The major adverse events during follow-up, as well as their resolution, either medical, endoscopic or surgical, were also collected. The accommodative symptoms of the first week were not taken into account. Finally, a survey was performed of the final degree of satisfaction, using a subjective scale differentiating between good, regular or bad, with an added explanation.

The mean and standard deviation (mean ± SD) were calculated for the descriptive analysis of continuous quantitative variables and qualitative variables were expressed as the mean and percentages. The Student's test was used for the comparison over time (beginning *vs* final). The safety and efficacy results were expressed by intent to

treat and statistical significance was set at $p < 0.05$. Data analysis was performed using the RStudio Team program (RStudio 2016; Integrated Development for R. RStudio, Inc., Boston, MA; URL: http://www.rstudio.com/).

The placement of the balloon and this study was approved by the Ethics Committee of our hospital. A specific informed consent was obtained for the placement of the balloon and for the study.

RESULTS

The first 30 consecutive patients referred to our Bariatric Endoscopy Unit for Elipse® Intragastric Balloon (EIGB) were included in the study. Twenty-eight (93.3%) subjects were female and the mean age was 43.1 ± 8.2 years (range 29-62). Before EIGB insertion, the mean weight was 83.3 ± 10.7 kg (range 61.9-104.8), with a mean BMI of 30.6 ± 2.7 kg/m² (range 27-38) (Table 1). No patients in the study had symptoms of epigastralgy or GERD and none were under treatment with NSAIDs. Those patients with gastro-enteral pathology or major abdominal-pelvic surgeries were removed.

The first three patients swallowed the capsule with the catheter but without the internal stylet, albeit with some difficulty. Thereafter, all swallows were performed with the stylet through the catheter, facilitated by the manual thrust of the physician, without difficulty (Table 2). All balloons (100%) were filled with the entire expected liquid volume (550 ml) and the after-filling x-ray control was normal in all cases, with no migrations, leaks or incomplete fillings (Fig. 1B). The mean procedure time was 16 minutes (oscillating between 10-25 minutes). Therefore, there were no implantation-related incidents and all patients were able to complete the study.

All patients were successfully followed up for a period of four months and no patients were lost to follow-up. It was not possible to know the duration of the balloon in six patients (20%). This was due to the undetected elimination as they did not undergo the 16-week radiological control in five patients and the sixth patient had an intolerance that required early endoscopic removal. All the other 24 patients were able to document the moment of IB expulsion. The duration was normal (16 weeks or more) in 17 cases (70.8%), five cases (20.8%) presented an early elimination (12-15 weeks) and an early pathological elimination with insufficient duration (< 12 weeks)

occurred in two cases (8.3%) (Fig. 2).

The mean weight loss at 16 weeks was 11.2 ± 5.5 kg (range 3-19 kg), with a mean % total weight loss (%TWL) of 12.1 ± 5.8% (range 3.3-20%) and a mean excess weight loss (%EWL) of 64.7 ± 25% (8.5-95%), with an average decrease of BMI of 4.1 ± 2.1 kg/m² (range 1.2-7.2 kg/m²) ($p < 0.05$). Weight loss > 10% was obtained in 24/30 (80%) patients. When only the seven cases with early elimination of the balloon (< 16 weeks) were analyzed, they obtained a mean weight loss of 5.1 ± 1.7 kg (range 3-6.9 kg), with a %TWL of 5.8 ± 1.3% (range 3.3-7.2%). These results are lower than those obtained in the overall efficacy analysis in all patients, with a statistically significant difference between them ($p < 0.05$).

The overall tolerance of the balloon was good in 24/30 patients (80%). Six patients (20%) had a poor tolerance, one was exclusively clinical intolerance, one was migration with intestinal occlusion, there were two cases of persistent abdominal pain and two patients with recurrent nausea/heartburn. There were three major adverse events (10%): one case vomited the deflated balloon at 16 weeks and there was one clinical intolerance at three weeks and one ileal occlusion at 12 weeks. Of these, two therapeutic endoscopies were required. The first endoscopy was for the extraction of the IB due to clinical intolerance, which was performed as usual without observing gastric mucosal lesions or complications. The second case was an occlusion of the balloon in the middle ileum. The patient debuted with abdominal pain and vomiting at 12 weeks and an abdominal x-ray and computed tomography revealed a middle ileum obstruction due to the balloon. Furthermore, there were distended small bowel loops (jejunum and proximal ileum), with mild intestinal suffering and free fluid. A colonoscopy with ileoscopy was performed, which showed the balloon partially filled, conditioning stenotic ulcers by decubitus (Fig. 3). It was endoscopically removed, forcing the rupture of the balloon by tweezing foreign bodies and emptying its contents. No surgery was required in any case and there was no mortality.

The final degree of patient satisfaction was good in 18 cases (60%), regular in three cases (10%) and bad in nine cases (30%). Among the 12 cases that did not report a good satisfaction, it must be highlighted that six cases had a poor tolerance and six other cases expressed dissatisfaction due to an estimated insufficient weight loss and a

weight loss that was less than initially expected (Table 2).

DISCUSSION

The first intragastric balloon (IB) approved for weight loss was the Garren-Edwards Gastric Bubble in 1985, although it was withdrawn due to serious adverse effects and complications (9). Subsequently, different IB devices were made with similar results. The Bioenterics® (Orbera®) balloon appeared at the end of the 1990s and has since then remained the reference balloon, with numerous published studies on its safety and efficacy (10,11). Over the last ten years, new concepts, designs and models of IB have appeared, all of which require the use of endoscopy for placement and removal (2-4). The new O'balon device (Obalon Therapeutics Inc, Carlsbad, CA) (12) and a study with classic IB (13) have supported the possibility of inserting the IB without a strict requirement for endoscopy. However, it was essential to perform an endoscopy for removal in all cases.

The initial experience in the first series with Elipse® (5,6) documented the possibility of a correct swallowing of the capsule. In our experience, we would recommend doing it with the stylet through the catheter. Thus, we had no problem of oropharyngeal dysphagia, esophageal choking or catheter winding. Up to 8.3% of cases have been described of properly swallowed balloons but with a technical inability to fill it (5). All the balloons in our study were able to be filled with the total expected volume (550 ml). When filling is difficult, it can be resolved with two maneuvers. Firstly, by pulling slightly from the thin catheter and correcting its angulation and secondly, by manually filling the balloon with a syringe. Thus increasing the pressure on the valve exerted by the manometer that accompanies the device.

It is estimated that with diet and lifestyle changes a weight loss of 7-10% can be achieved and that endoscopic treatment should offer a weight loss of > 10% in > 75% of patients (3). In this sense, our results met this goal in 80% of patients. At 16 weeks, we obtained a weight loss similar to that described in the literature with this same balloon as follows: 11.2 kg, 12.1% TWL and a decrease of 4.1 kg/m² compared to 8.8-13 kg (14,15), 10-15.1% TWL (5,6,15,16) and a decrease of 3.2-4.9 kg/m² (14,15), as described in other series. Our results reveal a high %EWL of 64.7%, which is higher

than the 40.8% and 50.2% described by Al-Subbaie and Raftopoulos (14,5), probably due to the lowest basal BMI of our patients. Although the efficacy data of our study are limited due to a follow-up of four months, there are two publications that describe results at 12 months, showing a %TWL of 7.9% and 5.9%, with a %EWL of 17.6% (16,5). These results are a little better in patients with BMI < 34.9 kg/m² (16).

Compared to other IB models, the Ellipse® balloon seems to offer a slightly lower efficacy. The Brazilian consensus document, with > 40,000 IB (2), offers a weight loss of 18.3 kg, with 18.4% TWL and a decrease in BMI of 7.2. Three other systematic reviews and meta-analysis with six-month IB (11,17,18) reported a mean weight loss of 14.7-17.8 kg and a BMI decrease of 4-9 kg/m². The initial BMI and the duration of the device should probably be assessed as a responsible cause.

The estimated duration of the Elipse® balloon is 16 weeks. The literature includes short series with durations longer than 16 weeks in 100% of cases (5,6) and other longer series where early deflation is seen in between 1.9%-5.3% of cases (14-16). In our series, the duration of the balloon could not be determined in six patients (20%). This was due to intolerance and early extraction by gastroscopy in one case and because rectal elimination was not visualized in the remaining five cases. Dye was not added to the balloon filler in any case as we wanted to avoid any potential interference with the inner preservative fluid. This may have helped to identify these eliminations. We consider that these evacuations could probably have been normal, as those patients with an early evacuation contacted us specifically to comment about it. In this sense, other studies show up to 53.8% of expelled but not viewed balloons (16). Of the 24 patients where we observed the evacuation of the balloon, it was eliminated early (< 16 weeks) in seven cases (29.2%). Most published studies consider an abnormally early evacuation with an insufficient duration when the balloon is expelled before 12 weeks. This occurred in only two of the 24 cases (8.3%) of our series.

There are short series with Elipse® which have not reported any incidents (5,6). However, a potential disadvantage is that it must be filled with a universal volume of liquid (550 ml), without an adjustment based on the size of the gastric fundus endoscopically. This could cause a greater balloon intolerance of 2.2-9.8%, according to different series (14-16). The balloon was endoscopically removed with a standard

technique in our only case of intolerance, without incidents or evidence of gastric injuries to justify it. Another adverse effect described was the vomiting of the balloon in 1.5-25% of cases (5,4-16). Although not usually problematic, it can cause psychological distress and this possibility should be an important counseling point prior to insertion. Abdominal pain occurs in up to 21.5% of patients (15), mainly during the week of migration and elimination of the balloon (5,16,19).

The most serious complication reported in our series was the migration of one balloon with medium ileum obstruction at 12 weeks. Conservative treatment was initially attempted with nasogastric decompression, intravenous hydration and analgesia. Despite this, the radiological image worsened, so it was extracted endoscopically. Different causes of possible contributors to early migration of Elipse® and GI obstruction have been described such as intra-abdominal adhesions due to previous abdominal-pelvic surgeries, incomplete balloon filling during insertion, early catheter detachment during balloon filling, false release of the balloon valve during excretion and balloon leakage. More extensive studies are required to clarify this area. When intestinal occlusion occurs, various management options have been described such as percutaneous fine needle aspiration under ultrasound or CT guidance (20,21) or the use of double-balloon enteroscopy (22,23). Finally, if these methods fail, surgical removal of the balloon by enterotomy and extraction may also be required, via laparoscopic (15,16,19,24) or open (25) approaches. An enteroscope was not available at the time in our unit, so we decided to perform colonoscopy with ileoscopy. They were laborious procedures, although we were able to access the balloon, break, empty and evacuate it, thus avoiding surgery. Therefore, in order to ensure the maximum safety, our experience supports a balloon insertion that must be supervised by a bariatric endoscopist and the availability of an Endoscopic Emergency Service that could effectively resolve potentials complications as required (26,27).

In our series, the final degree of satisfaction and quality of life was somewhat lower than that of other published studies with the Elipse® balloon (5,6,14). This could be explained by the described cases of intolerance, the case of vomiting and the case of migration with IB impact. Furthermore, a possible partial lack of prior information due to our inexperience with this model may also have been a factor due to both the

possibility of abdominal pain during the evacuation of the IB and possible abnormal early eliminations. In addition, an inescapable comparison is created between the Elipse® and the classic IB. The shorter duration of Elipse® limited to four months could justify its reduced effectiveness for weight loss.

With regard to the cost-economic evaluation, although the price of the Elipse® device is higher than that of all other balloons marketed in Spain (about 2,100 euros Elipse® in comparison to 800-1,200 euros the other balloons), the absence of two endoscopy and sedation interventions compensates for the high price. Thus, it can be offered to the population for a lower final cost, as in our case.

Some of the limitations of the study are the low number of patients, being confined to a single physician and a single hospital, the absence of a randomized control arm, a limited follow-up to four months and the lack of evaluation of the comorbidities associated to obesity.

In conclusion, the technique of EIGB placement by x-ray seems a feasible and safe method, with a better tolerance when performance is facilitated by the stylet fed through the catheter. Although some devices have a shorter duration than expected (< 16 weeks in 29% patients, including < 12 weeks in 8.3% patients), an acceptable weight loss was achieved after four months. As in all IB, there is a percentage of intolerance and adverse effects that may require endoscopy. Thus, we advise that the procedure be controlled or supervised by a bariatric endoscopist, in experienced centers with an Endoscopic Emergency Room that allows any complications to be resolved, effectively and early.

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ENFERMEDADES DIGESTIVAS
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Table 1. Clinical and anthropometric data

	Basal features	*16 weeks*
Age	43.1 ± 8.2 years (r = 29-62)	
Gender Males Females	 28 (93.3%) 2 (6.7%)	
Weight	83.3 ± 10.7 kg (r = 61.9-104.8)	72.1 ± 5.5 kg (r = 3-19)*
BMI	30.6 ± 2.7 kg/m² (r = 27-38)	26.5 ± 2.1 kg/m² (r = 25.3-33.7)*
Total weight loss (%TWL)		12.1 ± 5.8% (r = 3.3-20)*
Excess weight loss (%EWL)		64.7 ± 25% (r = 8.5-95)*

Quantitative variables: results expressed as mean ± SD. Qualitative variables: results expressed as mean ± percentage. r: range. *$p < 0.05$.

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ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

Table 2. Main clinical and technical results of the device

Correct swallow	Correct x-ray control after swallow	Efficacy	Tolerance	Adverse effects	Endoscopy requirements	Satisfactio
30 (100%)	30 (100%)	11.2kg 12.1%TWL 64.7%EWL 4.1 IMC WL>10% in 80% pts	Good: 24 (80%) Bad: 6 (20%) 2 abdominal pain 2 nausea/heartburn 1 intolerance 1 intestinal occlusion	3 (10%) 1 IB vomited 1 intolerance 1 ileal impaction	2 (6.7%) 1 intolerance: gastroscopy 1 ileal impaction: colonoscopy + ileoscopy	Good: 18 Regular: 3 Bad: 9 (3 *3 insufficient **3 insufficient w bad tole

TWL: total weight loss; EWL: excess weight loss; WL: weight loss; IB: intragastric balloon.

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ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

Fig. 1. Morphological characteristics of the Elipse® balloon. A. External real image B. Radiological image with the balloon filled after implantation in the correct location and evidence of the radio-opaque marker.

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The Spanish Journal of Gastroenterology

Fig. 2. Duration of the balloon in our series.

Fig. 3 a-b-c

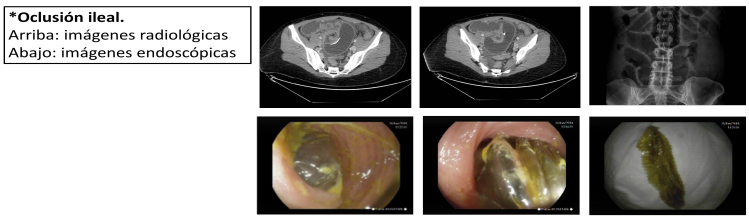

Fig. 3 d-e-f

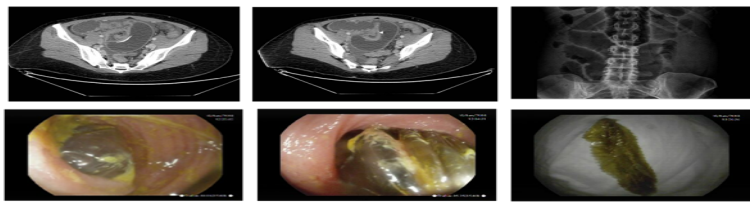

Fig. 3. Balloon occluded in the medium ileum. Radiological and endoscopic images. A and B. CT image of the migrated and impacted balloon (with radio-opaque marker) in the middle ileum, causing ileal occlusion. C. Simple abdominal Rx with significant intestinal handle bloating. D. Endoscopic image of a partial intestinal stenosis, conditioning impact of the balloon with ileal handle occlusion. E. Partially emptied balloon after endoscopic tearing of its polyurethane coating and in the ileal extraction pathways. F. Final result of the eliminated balloon.