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Effect of A New Swallowable Intragastric Balloon (Elipse™) on Weight Loss and Metabolic Syndrome

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Abstract

Purpose: The aim of this study was to investigate the effect of 16 weeks of treatment with a new intragastric balloon (Elipse™ Balloon, Allurion Technologies, Natick, MA USA) on weight loss and Metabolic Syndrome (MS) in obese patients.

Materials and Methods: Forty-two obese patients with MS (F/M: 29/13, mean age: 47.2 ± 10.3 years, mean weight: 110.5 ± 21.9 kg, and mean Body Mass index - BMI: 39.2 ± 6.7 kg/m^2). were selected for treatment with Elipse™ Balloon. This device does not need upper endoscopy for placement and removal, it was swallowed and after 4 months is excreted through the digestive tract.

Results: At the end of treatment with Elipse™ Balloon the mean weight loss was 12.9 kg, mean percent excess weight loss was 27%, and mean BMI reduction was 4.5 kg/m^2. Total body weight loss was 11.6%. There was a significant reduction in major co-morbidities related to MS: blood pressure ($p<0.02$), waist circumference ($p<0.002$), triglycerides ($p<0.0001$), blood glucose ($p<0.001$) and HOMA-IR index ($p<0.001$). One balloon was endoscopically removed, 41 balloons were naturally excreted in the stool.

Conclusions: Statistically significant and clinically relevant improvements in weight loss and in co-morbidities related to MS were observed after treatment with Elipse™ Balloon.

Keywords: Elipse™; Intragastric Balloon; Metabolic Syndrome; Obesity

Introduction

The obesity is a metabolic disease with epidemic proportions and its incidence is increasing worldwide. In 2016, more than 1.9 billion adults were overweight and of these over 650 million were obese [1,2]. Overweight and obesity lead to adverse metabolic effects on blood pressure, cholesterol, triglycerides and insulin resistance [3]. Management of obesity can include lifestyle changes, dietary modification, increased physical activity, the use of medications, and in some cases the recommendation for bariatric surgery [4].

Intragastric balloons (IGB) have been used for several years to reduce weight in obese patients before bariatric surgery [5,6]. IGB can also be used in obese patients that are not ready or candid able for surgical intervention as an alternative to lifestyle modification alone. The procedure associated with the IGB treatment is substantially less invasive than bariatric surgery, though the placement and removal usually require conscious or unconscious sedation and an Upper Endoscopy (UE) [7]. A new liquid-filled, swallowable intragrastic balloon became an attractive treatment for patients who are looking for an obesity therapy without procedures. The device is placed under fluoroscopy without anesthesia or UE and it is conceived to open spontaneously in the stomach and be excreted through the digestive tract after 16 weeks [8,9]. The purpose of this study was to evaluate whether this intragastric-balloon without sedation and UE is associated with significant body weight loss and might have an impact on the metabolic syndrome and its parameters, such as hyperglycemia, blood hypertension, and dyslipidemia.

Material and Methods

Study Design and Subjects

This was a prospective study conducted in obese patients during the period between June 2016 and June 2017. Inclusion criteria were age between 18 and 65 years and Body Mass Index (BMI) greater than or equal to 27 kg/m^2 and less than 45 kg/m^2. Exclusion criteria included any following condition: previous bariatric or gastric surgery or more than one other abdominal/gynecological operation, history of bowel obstructions, hiatal hernia (>5 cm), heart failure, eating disorders (bulimia, night eating syndrome or binge eating disorder), blood coagulation disorders and certified pregnancy. All patients underwent clinical and anthropometric evaluation (height, weight, waist circumference, and blood pressure). Moreover, blood tests including complete blood count, fasting insulin and glucose, and lipid panel were conducted. Following approval by the ethics committee, informed consent was obtained from all participants.

Elipse Balloon Deployment

The Elipse™ Balloon (Allurion Technologies, Natick, MA USA) is a gastric balloon that does not need upper endoscopy for placement and removal. It is enclosed in a small capsule that is easily swollen with a glass of water. A volume of 550 mL of liquid consisting of distilled water with potassium sorbate preservative was inserted into each balloon. A small radiopaque ring containing into the balloon is used to confirm the correct position of balloon inside the stomach through an abdominal x-ray. This device is designed to spontaneously empty after approximately 16 weeks of treatment and be naturally excreted. Patients fasted for at least 8 hours prior to the procedure and 4 hours before the deployment of the balloon. Anti-emetics and antispasmodic drugs were prescribed for few days during the post-insertion period, with a proton pump inhibitor taken daily from 2 weeks prior to placement and continued until the end of treatment.

Behavioral Modification Program and Follow-Up

Patients followed a fluid diet for the first 24 hours. During the first week, a gradual progression to a semi-liquid diet (yogurt, mashed potatoes, thin soup, puréed vegetables) was recommended. Generally, at the beginning of the second week, the patient proceeded with caution to a regular diet about 1000-1200 kcal, including at least 1 gr of protein/kg of ideal weight. Regular physical activity was suggested to all patients. All patients were closely followed for 16 weeks. The follow-up visits, including clinical and nutritional evaluation, were performed at weeks 0 (baseline), 2, 4, 8, 12 and 16 (end of the treatment). During each visit, BMI reduction, waist circumference, total body weight loss and excess of body weight loss percentage were recorded. The blood tests (fasting insulin and glucose, triglycerides and HDL cholesterol) were evaluated for each patient at baseline and at the end of treatment.

Statistical Analysis

All results are reported as mean ± Standard Error (SE). Statistical differences for single comparisons were studied using t-tests for non-paired data. Multiple regression analysis was performed to assess values for the VAS scale, BMI, weight, and waist circumference between the time points. A p-value of 0.05 ± SD was considered statistically significant. Statistical analysis was carried out using SPSS/19.0 (SPSS, Chicago, IL, USA) and GraphPad Prism Version 5 (GraphPad Software Inc., San Diego, CA).

Results

Baseline Characteristics

A total of 42 patients were enrolled. At baseline, there were 29 females (69%) and 13 males (31%). The mean age was 47.2 ± 10.3 years, mean weight was 110.5 ± 21.9 kg and mean BMI was 39.2 ± 6.7 kg/m^2. Forty subjects (91%) met the criteria for MS as defined by the Third Report of the National Cholesterol Education Program's Adult Treatment Panel (ATP III) Criteria (Table 1) [10]. All patients demonstrated good compliance on nutritional recommendations and underwent all follow-up visits.

	Female (n: 29)	Male (n: 3)
Age (yrs)	46.5 ± 1.5	48.5 ± 11.5
Weight	129.3 ± 24.0	102.1 ± 4.7
BMI kg/m^2	42.0 ± 8.4	38.3 ± 5.1
Waist (cm)	134.3 ± 16.7	118.2 ± 5.4
Caucasian (%)	100	100
MS	28	12

Table 1: Demographics, mean ± SD.

Safety

All patients were able to swallow the capsule with a glass of water. No complications as a results of balloon deployment were recorded. No serious adverse events were observed. In particular, there were no gastric perforations, symptoms of ulceration, intestinal obstructions and gastrointestinal hemorrhage during the treatment.

All intolerance symptoms - including nausea, vomiting, cramping, abdominal pain, regurgitation, difficulty in swallowing liquid and solid foods - we're self-limiting or resolved with anti-emetics and antispasmodic drugs within the first week. One patient after 10 weeks of treatment presented nausea and vomiting which resolved with IV fluid hydration, anti-spasmodic and anti-emetics and continued the treatment without any further complications. No patients requested early removal of the balloon. At approximately 16 weeks, all balloons emptied through the release valve and were naturally and uneventfully excreted.

Weight Loss

All patients lost weight during treatment. We had a statistically significant difference in weight loss after 16 weeks:

the mean weight loss was 12.9 kg, mean BMI reduction was 4.5 points kg/m^2, mean percent excess weight loss was 27%, and mean total body weight loss was 11.9%.

Health Outcomes

Consistent with significant weight loss achieved with Elipse balloon, the remission rate of metabolic syndrome was 72.5%. At the end of the study, only 11 participants (27.5 %) met the diagnostic criteria of MS. The treatment produced a significant reduction in the factors related to metabolic syndrome: blood pressure ($p<0.02$), waist circumference ($p<0.002$), triglycerides ($p<0.0001$), blood glucose ($p<0.001$) and HOMA-IR index ($p<0.001$) (Table 2).

	T0	T1	p-value
Systolic BP (mmHg)	132.5 ± 12.1	125.5 ± 12.3	0.045
Diastolic BP (mmHg)	85.5 ± 8.5	80.5 ± 9.5	0.037
Waist (cm)	123.5 ± 16.9	111 ± 16.2	0.0031
Tryglicerides (mg/dl)	152 ± 22	118 ± 29	<0.0001
Blood glucose (mmol/L)	108 ± 11.5	98 ± 13.5	<0.001
HDL (mmol/L)	38 ± 6.5	41 ± 7.5	NS
HOMA-IR	3.55 ± 1.2	2.65 ± 1.6	<0.001
BMI (Kg/m^2)	39.2 ± 6.7	34.7 ± 5.3	<0.001
MS	40	13	<0.001
T0: day of deployment; T1: end of treatment; NS: not significant.			

Table 2: Changes in BMI, blood pressure and metabolic factors before and after treatment with Elipse Balloon; mean ± SD.

Discussion

The results of our study indicate that Elipse™ Balloon induces a significant and clinically relevant improvements in weight loss and in factors related to MS. In addition, the Elipse balloon appears to be a safe device that can be swallowed and excreted without serious adverse events. This device is the first balloon not needing UE or sedation for placement and removal, and represent a valid alternative treatment for obese patients who don't tolerate these procedures.

The main finding of the present study was a significant BMI reduction and MS remission rate within 4 months of treatment instead of 6 months, as happen with other balloons. Our results are in line with the results of previous studies on weight loss with IGB and confirm reports that 80-90% of the weight that is lost during balloon therapy happens during the first 4 month [11]. Our study presents some limitations. First, the sample of study was small and non-randomized. Second, it lacked a control group that did not receive IGB or receive another type IGB. Finally, these results reflect the experience of a single center. First,

Conclusion

The results of this study on 42 consecutive patients show that the Elipse balloon is safe and could be well-accepted by patients due to the lack of endoscopy and sedation for placement and removal, improving the compliance to treatment. This device also shows clinically relevant improvements in weight loss and in co-morbidities related to MS. We are evaluating the efficacy of Elipse balloon on 1 year of follow-up, the results will be published soon as possible. To date, one study reports the 12-month efficacy and performance outcomes of the Elipse Balloon. These results are encouraging, but the sample size is too small [12]. However, further studies involving a larger number of patients are needed to confirm these preliminary results and to investigate the role of this device on mid or long-term.

Conflict of Interest Statement

No authors have any conflicts of interest.

Ethical Approval

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.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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