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Original Research

A prospective pilot study of the efficacy and safety of Elipse intragastric balloon: A single-center, single-surgeon experience

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ABSTRACT

Background: Elipse™ is the least invasive IGB for weight loss that needs no sedation or endoscopy. It is a swallowable capsule filled with 550 mL of fluid, which stays in the stomach for 16 weeks and is excreted from the gastrointestinal tract. Kuwait is one of the first countries to start using Elipse™ as a weight loss device. This study aims to evaluate the efficacy and safety of Elipse™ intragastric balloon (IGB).

Materials and methods: This is a single-center prospective pilot study of 51 Elipse™ insertions at our clinic. The patients were followed for 4 months to monitor their weight and body mass index (BMI) at 1, 2, and 4 months. Total weight loss, % excess weight loss (%EWL), % total body weight loss (%TBWL), and change in BMI and waist circumference (WC) were recorded at the end of the study. A short survey was administered to evaluate symptoms, complications, and overall satisfaction.

Results: Fifty-one patients participated, of which five had Elipse™ removed because of intolerance. One case vomited the balloon; one had early deflation. The total weight loss was 8.84 kg, %TBWL 10.44%, %EWL 40.84%, change in BMI 3.42 kg/m^2, and the total WC reduction 8.62 cm. Symptoms after insertion were severe, whereas those during excretion were mild and self-limiting. No serious complications were recorded, and the overall satisfaction was above average.

Conclusion: Our data proves that Elipse™ is a safe and effective device for weight loss. Nevertheless, some limitations were observed that need to be overcome for better outcomes. Larger studies are needed to support our findings.

1. Introduction

Obesity prevalence is increasing worldwide, and Kuwait is currently considered to be the country with the most obese population [1]. Weight loss procedures have been standardized based on the body mass index (BMI), and the more advanced surgeries were for class II obesity (i.e., BMI = 35–39.9 kg/m^2) and above [2]. In patients who are overweight (i.e., BMI = 25–29.9 kg/m^2) and are classified under class I obesity (i.e., BMI = 30–34.9 kg/m^2), weight loss options are limited after failed diet attempts [2]. Thus, in 1985, the Garren-Edwards gastric bubble, considered as the first intragastric balloon (IGB), was approved for weight loss and was introduced in the United States [3]. However, it was withdrawn because of its serious adverse effects; nevertheless, advances to its design led to the development of new, more effective, and safer IGBs [3]. Conventional endoscopic IGBs have been proven to be safe and effective, with excess weight loss (%EWL) of 25–50% [4].

A new swallowable IGB, Elipse™ (Allurion Technologies, Wellesley, Massachusetts, USA), has been launched recently in Kuwait and became highly popular because of the unique concept of being procedureless [5]. Elipse™ is a weight loss device that requires no sedation, endoscopy in its "way in or out" [6]. It is designed as a swallowable capsule that is converted to a balloon in the stomach after filling it with a pH-titrated fluid through a catheter [6]. It works by reducing the intragastric volume and, consequently, weight loss is achieved by decreasing the overall food quantity intake [7]. After 4 months, a self-releasing valve opens and the fluid is gradually expelled into the stomach [7]. Thereafter, the thin paper-like wall of the balloon passes through the gastrointestinal (GI) tract and excreted [7].

This prospective study aims to evaluate the efficacy and safety of the Elipse™ IGB as a weight loss device. Due to relative paucity of published data on outcomes for this procedure, we share our experience with this new type of balloon in Kuwait, one of the first countries to start officially using this new device.

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2. Material and methods

2.1. Study design

This is a prospective single-center pilot study of all Elipse™ IGB insertions by the same surgeon at Faisal Polyclinic in Kuwait City from July 2016 to January 2017. After insertion, the patients were followed for 4 months until the expected day of excretion. Weight (Wt.), BMI, and waist circumference (WC; two fingerbreadths above the anterior superior iliac spine), were evaluated once at pre-insertion on the first outpatient visit and at 1, 2, and 4 months post-insertion in the clinic. Patients were also encouraged to send their body composition data through e-mail using similar electronic scales (Allurion Technologies, Inc, version 2.2) at home in a weekly basis provided by the clinic. Although we had high noncompliance rate with electronic scales, the results retrieved were helpful in recording the primary outcomes with cases missed the clinic visits scheduled post-insertion. The staff recorded all data regarding any difficulties or adverse events during the procedure. At the last visit, a short questionnaire was administered to the patients to evaluate their commitment to pre- and post-procedural instructions, symptoms, problems encountered after insertion and during excretion, and overall satisfaction. Ethical approval was obtained from the Kuwait Ministry of Health and National Ethics Committee.

2.2. Patient preparation

At the initial visit, full body composition (body weight, height, BMI, basal metabolic rate, body fat rate, body water, bone mass, muscle mass, and visceral fat) was measured using a body composition analyzer, and thorough history taking and physical examination were performed to ensure eligibility to the procedure according to our patient selection criteria (Fig. 1). All patients were informed about any possible adverse events of the procedure. A written informed consent was obtained from all patients.

2.3. Insertion technique

Fluid diet was started 1 day before the insertion, followed by 10 h of fasting. In the fluoroscopy room, a plain abdomen x-ray was obtained initially and confirmed normal. The quality and safety of the system were assessed (Fig. 2). The capsule was swallowed with a sip of water until the third mark (50 cm) of the catheter is just at the level of the mouth. After three failed swallowing attempts, a stylet guide wire was used to insert the capsule orally. Placement of the capsule in the stomach was confirmed by fluoroscopy. Subsequently, inflation was established. Using a bag insufflator, we administered 550 mL of fluid. Resistance due to catheter kink was overcome by force injection using 30 mL syringe. Complete fluid delivery was ensured in all cases. The catheter was then detached from the balloon by gently pulling it out. Another fluoroscopy was performed to confirm balloon position (Fig. 3).

2.4. Drug regimen

Patients who met the inclusion criteria were scheduled to undergo the procedure after 7 days of proton pump-inhibitor therapy (Esomeprazole, 40 mg PO, OD), which was extended to 2 weeks for those with gastroesophageal reflux disease (GERD) or previously treated gastritis. All patients received aprepitant (Emend™, 125 mg PO, OD) the night prior to the procedure, which was continued with a dose of 80 mg for 2 more days. Ondansetron (Onda™) 8 mg PO and hyoscine butylbromide (Buscopan™) 10 mg PO were administered as necessary. This regimen was used because it was proven to be highly effective in preventing vomiting [8]. If uncontrolled severe symptoms occur after insertion, the patients were advised to visit the clinic for intravenous (IV) drip and medications on an outpatient basis.

2.5. Patient follow-up

Patients were instructed to have a liquid fluid diet and to refrain from taking ulcerogenic products. They were followed on a regular basis and seen by a dietitian once a month. At the end of the follow-up, primary outcomes were evaluated, including total weight loss (kg), % total body weight loss (%TBWL), %EWL, and change in WC (cm). All data were also recorded throughout the study for secondary outcomes. A short questionnaire was administered during the last visit, which included adverse events during the procedure, period and severity (0–10 scale) of symptoms after insertion including cause of removal if any, adverse events while the balloon is in the stomach, pre-excretion events, overall cost, and overall satisfaction.

2.6. Inclusion and exclusion criteria

All patients who underwent Elipse™ IGB insertion (aged 18–65 years with BMI of 27–40 kg/m^2) were included. All patients lost to follow-up anytime during the study period were excluded. All patients who had endoscopic balloon removal or vomited the balloon were excluded from the primary outcome, but included in the secondary outcome, evaluation.

2.7. Statistical analysis and data interpretation

Statistical analysis was performed using IBM SPSS Statistics v. 20. In this study, data analysis was performed by calculating the frequency distribution, measures of central value, and measure of variability; descriptive statistics was used to determine the distribution and to calculate the number of respondents with correct results (n) by gender, the arithmetic mean, standard deviation, coefficient of variability, minimum score, maximum score, and the range of results for each variable. To test the normality of distribution, asymmetry (skewness) and curvature flatness (kurtosis) were measured, in addition to Kolmogorov-Smirnov test. This test was used over the other powerful tests because it is known to be capable in testing small samples with many identical values. To determine any statistically significant differences in several indicators between balloon insertion time and after 1, 2, and 4 months, a paired sample *t*-test was performed. Results of the paired sample *t*-test indicate whether a statistically significant difference in the mean values of Wt., BMI, WC, and change in BMI categories (i.e., overweight, class I obesity, and class II obesity) with time exists. P values < 0.05 were considered statistically significant.

3. Results

Fifty-one patients were enrolled in the study, of which 47 (92.2%) were females and four (7.8%) were males. The mean age was 33.6 years (18–65 years). Elipse™ IGB was removed by gastroscopy in five (9.8%) female patients because of intolerance (four after the first 3 days and one after 4 weeks from insertion). All removals were uneventful. One female patient (2.0%) vomited the balloon at week 10, and another female (2.0%) had early deflation at week 6. Before insertion, 48 cases (94%) were healthy, two (4%) had mild GERD, and one (2%) had history of treated gastritis. Uneventful insertions were recorded in 47 cases (91.2%), the remaining four cases (8.7%) used a stylet device. The symptoms noted after insertion were weakness (38.4%), abdominal pain (35.1%), vomiting (16.5%), and nausea (10.0%). Symptom severity was 9.51 during the first 72 h, which was calculated using the average subjective indicator (0–10 scale). Symptoms were resolved by prescribed medications in 71.1% of cases, spontaneously in 15.6%, and by IV drip in 13.3%. Most of the cases (64.4%) followed the low-calorie diet program of our clinic, and the rest (35.6%) had no diet commitment. Majority of the patients were not exercising during the treatment