International Journal of Nutritional Sciences

Open Access

Austin Publishing Group

Research Article

Impact of a Low-Calorie, Moderate-Carbohydrate Diet (MCD) on BMI and Body Composition in Patients Undergoing ELIPSE™ Intragastric Balloon Treatment: A Pre-Post Pilot Study

Nagham Alkaragholi, MD[1*]; Nour Amin Elsahoryi, PhD[2]; Ruba Mousa Musharbash, PhD[3]

[1]Consultant General Surgeon, Jordan University of Science and Technology, Farah Hospital, Jordan

[2]Department of Nutrition, Faculty of Pharmacy and Medical Sciences, University of Petra, Jordan

[3]Clinical dietitian, Ruba Musharbash Center for Nutrition Counseling, Amman, Jordan

***Corresponding author:** Nagham Alkaragholi**

Jordan University of Science and Technology, Farah Hospital, Consultant General Surgeon, Jordan.

Email: naghamkaragholi@gmail.com

Received: January 06, 2024

Accepted: February 10, 2024

Published: February 17, 2024

Abstract

Introduction: The study explores the impact of the Elipse™ Intragastric Balloon (EIGB) and a low-calorie, Moderate-Carbohydrate Diet (MCD) on weight management. EIGB, a non-endoscopic approach, is known for reducing appetite and food intake. This research aims to measure weight changes and assess body composition in participants undergoing EIGB treatment.

Aim: The primary goal is to evaluate the effectiveness of EIGB combined with a low-calorie, MCD over a four-month period. The study assesses weight loss, changes in body composition, and associated symptoms.

Method: Twenty participants with a Body Mass Index (BMI) of 27-45 kg/m² underwent EIGB treatment, followed by a low-calorie, MCD diet under dietitian guidance. Measurements included BMI, body composition, and dietary compliance assessments.

Result: Participants, predominantly female, exhibited an average age of 32±8.6 years and a mean BMI of 35.2±7.1 kg/m². Following the intervention, there was a significant mean weight loss of 6.9±4.7 kg, a decrease in BMI by 2.8±2.2 kg/m², and a reduction in body fat percentage by 2.5±2.4%. Mild gastrointestinal symptoms were reported, mostly resolved within one to two weeks.

Conclusion: EIGB, in conjunction with a low-calorie, MCD, proved effective in inducing weight loss and positive changes in body composition. The study suggests that this approach, accompanied by manageable symptoms, holds promise for weight management. Future research with larger sample sizes and controlled designs is recommended.

Keywords: Elipse intragastric balloon; Weight management; non-endoscopic approach; Low-calorie, moderate-carbohydrate diet; Body composition; Gastrointestinal symptoms

Abbreviations: BIA: Bioelectrical Impedance Assay; BMI: Body Mass Index; BW: Body Weight; CVD: Cardiovascular Disease; EIGB: The Elipse™ Intragastric Balloon; IGBs: Intragastric Balloons; FFM: Fat-Free Mass; FM: Fat Mass; GI: Gastrointestinal; GOT: Glutamic Oxaloacetic Transaminase; GPT: Glutamic Oxaloacetic Transaminase; LCD: Low-Calorie Diet; LCKD: Low-Carbohydrate Ketogenic Diet; MCD: Moderate-Carbohydrate Diet; MM: Muscle Mass; RMR: Resting Metabolic Rate; BMR: Basal Metabolic Rate; SMM: Skeletal Muscle Mass; TBW: Total Body Water; TBW: Total Body Water; VF: Visceral Fat Rate; WC: Waist Circumference; WL: Weight Loss; T2DM: Type 2 Diabetes Mellitus; VAS: Visual-Analog Scales; ESHA: Elizabeth Stewart Hands and Associates.

Citation: Alkaragholi N, Elsahoryi NA, Musharbash RM. Impact of a Low-Calorie, Moderate-Carbohydrate Diet (MCD) on BMI and Body Composition in Patients Undergoing ELIPSE™ Intragastric Balloon Treatment: A Pre-Post Pilot Study. Int J Nutr Sci. 2024; 9(1): 1081.

Introduction

Obesity constitutes a substantial global public health issue, given its association with increased morbidity, mortality, and consequential economic repercussions [1]. It is intricately connected to a heightened susceptibility to various chronic conditions, including diabetes, dyslipidemia, stroke, Cardiovascular Disease (CVD), and certain forms of cancer. Moreover, obesity is correlated with an elevated risk of both overall mortality and mortality specifically attributed to CVD [1,2]. Obesity rates in Jordan stand notably higher than those in neighboring countries. Based on the International Diabetes Federation Waist Circumference (WC) criteria, the adjusted prevalence of obesity is reported at 60.4% for men and 75.6% for women. Additionally, approximately three-quarters of both genders were identified as overweight or obese [3].

Recently, EIGB (Allurion Technologies, Wellesley, Massachusetts, USA) has been launched worldwide and has become highly popular because it is a self-emptying and excreted gastric balloon that doesn't need hospital recovery, upper Gastrointestinal (GI) endoscopy, or aesthesia as endoscopic gastric balloons. In addition, it is safe and effective in achieving weight loss and is also well-tolerated by patients [4-8].

The EIGB, or Expandable Intragastric Balloon, is ingested as a swallowable capsule and then transforms into a balloon upon being filled with a pH-titrated liquid administered through a stomach catheter. To ensure precise placement, the capsule is equipped with a small radiopaque ring, facilitating verification via an abdominal X-ray [4,7,9]. The capsule is easily swallowed with water, and the subsequent abdominal X-ray serves as a valuable tool for the physician to confirm the accurate positioning of the balloon within the stomach. This non-invasive procedure provides a reliable method for weight management and is accompanied by a straightforward and patient-friendly administration process [4,7,9]. Upon ingestion of the capsule, the balloon is filled with 550 mL of fluid (distilled water containing a potassium sorbate preservative) through a catheter. Subsequently, the catheter is removed, and a second X-ray is conducted to confirm the proper inflation of the balloon and its accurate placement within the stomach. Approximately four months later, a time-activated release valve opens, allowing the balloon to deflate naturally. This facilitates its passage through the digestive system for eventual excretion, ideally obviating the necessity for endoscopic surgery. This timed deflation feature adds to the convenience and minimally invasive nature of the EIGB procedure [4,7,9].

Following EIGB placement, a standard Low-Calorie Diet (LCD) is typically recommended, providing approximately 1000–1200 kcal/day [10]. The combination of EIGB and the prescribed diet has demonstrated a substantial reduction in both weight and Fat-Free Mass (FFM). Maintaining FFM within the normal range is crucial to prevent adverse effects on the overall body metabolism. Significantly decreasing FFM could impact the Resting Metabolic Rate (RMR), potentially impeding Weight Loss (WL) and increasing the likelihood of weight gain. Striking the right balance between caloric intake, weight management strategies, and preserving FFM is essential for optimizing the outcomes of EIGB interventions (7,10).

Numerous previous studies have explored the implantation of EIGBs in conjunction with diverse dietary interventions. One notable example is the trial conducted by Dogan *et al.* (2013), wherein patients were administered a 1,000-calorie diet consisting of 146 g of carbohydrates, 68 g of fats, and 1 g of protein per kilogram of ideal body weight. This study contributes valuable insights into the interplay between EIGB placement and specific dietary approaches, shedding light on the potential effects of such interventions on weight management on long-term weight maintenance. In another study, patients adhered to a standard 800-calorie diet, a recommendation made after consulting with a dietitian. However, the prescribed diet for each patient was a well-balanced hypocaloric one, comprising 50% carbohydrates, 30% lipids, and 20% proteins. This carefully crafted diet aimed to create a daily caloric deficit of 1,000 kcal, determined based on the basal energy expenditure measured using the Harris-Benedict method. This approach underscores the significance of individualized dietary planning in the context of EIGB implantation, tailoring caloric intake to specific needs and metabolic considerations [11]. However, in a study by Schiavo *et al.* (2021), two distinct diet regimens were implemented. The first involved a conventional low-calorie diet plan with an intake of approximately 1200 kcal/day, distributed as 40% carbohydrates, 43% proteins, and 15% fats. In contrast, the second regimen adopted a low-calorie ketogenic diet, also totaling around 1200 kcal per day but with a composition of 71% fats, 25% proteins, and 4% carbohydrates. This dual-diet approach highlights the variability in dietary strategies applied in conjunction with EIGB placement, showcasing the diversity in nutritional approaches explored in clinical settings.

To date, there has been a limited number of research studies investigating the use of a low-calorie, MCD alongside EIGB procedures. Therefore, the aim of our study was to assess the effectiveness of the EIGB in conjunction with a low-calorie, MCD for weight management. Specifically, we aimed to measure changes in weight, BMI, and body composition over a four-month period in participants with a BMI ranging from 27 to 45 kg/m². Additionally, our study aimed to investigate the occurrence and resolution of accommodative symptoms associated with EIGB placement and dietary intervention.

Methodology

Study Hypothesis

Based on the study's aim, the hypothesis is the combination of the EIGB with a low-calorie, MCD will lead to a significant and effective reduction in weight, BMI, and body fat percentage over a four-month period in participants with a BMI ranging from 27 to 45 kg/m². Additionally, we hypothesize that the occurrence of accommodative symptoms associated with EIGB placement will be mild and of limited duration, with a significant proportion of participants experiencing symptom resolution within the initial weeks of the intervention.

Study Design and Subjects

Between January and June, a pre-post interventional study was conducted on consecutive overweight and obese patients undergoing EIGB at Istishari Hospital, Amman, Jordan, and Ruba Musharbash Diet Centre, Amman, Jordan between February and December 2022. The inclusion criteria comprised individuals with a BMI ≥27 kg/m^2 but less than 45 kg/m^2, aged between 18 and 65 years, and those who could successfully swallow and excrete the EIGB. However, certain exclusion criteria were applied, such as patients with a history of previous bariatric or gastric surgery, bowel obstruction, hiatal hernia exceeding 5 cm, heart failure, blood coagulation disorders, multiple prior abdominal or gynecological operations, certified pregnancy, or eating disorders (bulimia, binge eating disorder, or night eating syndrome). Individuals with serum creatinine levels exceeding 1.8 mg/dL or liver enzyme (Glutamic Oxaloacetic Transaminase (GOT) or Glutamic Pyruvic Transaminase (GPT)) levels less than three times the upper limit of normal were also excluded. Inability to adhere to the planned diet for religious reasons, as well as a history of chewing or swallowing problems, were additional exclusion criteria.

Participants were monitored over a 4-month period, concluding on the anticipated day of balloon excretion. Follow-up appointments were scheduled at 2-, 4-, and 6-weeks post-treatment for abdominal imaging, aiming to evaluate balloon volume, positioning, and provide fundamental nutritional counseling. Before their participation, each individual provided informed written consent, having been thoroughly briefed on the study's purpose and nature.

Pre- and Post-EIGB Placement Medical Treatment

Patients were given proton pump inhibitors, anti-emetics, and antinausea and vomiting medicines before and after the EIGB placement, as well as before and after the EIGB installation, according to the standard protocol [7]. The EIGB, developed by Allurion Technologies in Natick, MA, USA, is encapsulated within a swallowable vegan capsule connected to a slender catheter. Once in the stomach, the balloon is filled with 550 mL of liquid, a process performed without the need for endoscopy or sedation during a brief 20-minute outpatient visit. Following the filling and confirmation of the balloon's correct position via abdominal X-ray, the thin catheter is removed. At approximately 4 months, a valve in the EIGB autonomously opens, leading to the balloon's emptying and subsequent excretion through the gastrointestinal tract. In cases where swallowing may be challenging, a thin guidewire, serving as a stylet, can be utilized [12].

Figure 1: Wireless Bluetooth®-enabled body composition scale, along with a smartphone application.

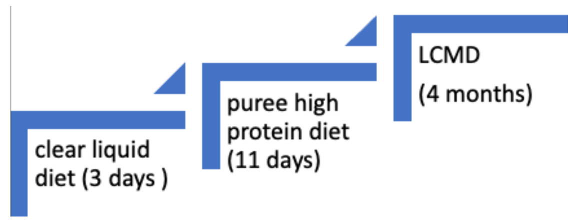

Figure 2: Transition of dietary intervention over 4 months of Elipse™ balloon procedure; LCMD: low-calorie, moderate-carbohydrate diet.

In addition to the EIGB, a smartphone application and a wireless body composition scale with Bluetooth® capability are offered. These devices enable the monitoring of weight loss and promote collaboration among the patient and their healthcare team (Figure 1).

Dietary and Physical Activity Recommendations

Patients were discharged within 2–4 hours following EIGB placement. To maintain uniformity, all participants were instructed to adhere to a consistent diet, with detailed discussions held with a nutritionist both before initiating the diet and after the 4-month EIGB treatment. The dietary intervention transition is illustrated in Figure 2.

In the initial three days following EIGB treatment, participants were instructed to consume a minimum of 2-3 liters of water and were advised to follow a clear liquid diet [7,13]. This diet comprises warm water, herbal teas, jelly, broth-based soups, and unsweetened fruit juices. Following this, participants progressed to a high-protein, low-calorie diet that included protein shakes, pureed vegetable and potato soup, boiled vegetables, yogurt, lactose-free milk, unsweetened fruit juices, fruits, eggs, and cheese. After the initial two weeks, participants were recommended to shift to a low-calorie, MCD consisting of 40–45% carbohydrates, 20–23% proteins, and 33–37% fats, totaling 1200–1500 kcal per day [14].

Patients were encouraged to engage in regular and moderate physical activity, aiming for at least 30 minutes per day. An illustrative diet plan is provided in Table 1.

Primary Outcomes

The primary outcomes of the study centered on evaluating changes in BMI and body composition, with a specific emphasis on parameters such as Total Body Water (TBW), FFM, and body fat.

BMI and Body Composition Measurements

The measurement of body weight (kg) and height (cm) in this study adhered to standardized conditions as outlined by Flegal *et al.* (2019). Height measurements were conducted using the

Table 1: Macronutrient amount in the diet plan prescribed for EIGB participants.

Macronutrient	Clear liquid diet (first 3 days)	A pure, high-protein diet (day 4–14)	low-calorie MCD 1200 Kcal (min-max)	low-calorie MCD 1500 Kcal (min-max)
Energy (Kcal)	847	1270	1200	1500
Carbohydrate (%)	97.2	50.9	40-45	40-45
Carbohydrate (g)	212	166	120-135	150-168.75
Protein (%)	1.7	32.4	22-23	22-23
Protein (g)	3.76	105.7	66-69	82.5-86.25
Fat (%)	1.1	16.8	33-37	33-37
Fat (g)	1	24	44-49	55-62
Saturated fat (%)	0.9	3.7	3.4-4.4	3.1-3.4
Polyunsaturated (%)	0	0.6	2.7-3.4	2.4-2.7
Monounsaturated (%)	0	0.8	10.8-15.9	9.6-12.3
Fiber (g)	8.28	18	18.75-19.13	18.68-18.92

BSM 170 Digital Stadiometer from InBody Co., Ltd., South Korea, with dimensions of 15.3 (W) x 19.7 (L) x 86.2 (H) inches. Body Weight (BW) and the participants' body composition were assessed through Bioelectrical Impedance Analysis (BIA) utilizing the InBody 770 body composition analyzer digital scale (capacity 270 kg, InBody Co., Ltd., South Korea). This state-of-the-art instrument, incorporating the latest multi-frequency technology, represents the most recent generation in body composition analysis.

Prior to BIA measurements, participants were required to adhere to specific guidelines, including fasting for at least four hours, consuming a minimum of two liters of water the day before, refraining from physical activity for at least eight hours, avoiding coffee or alcoholic beverages for at least 12 hours, and abstaining from diuretic use for at least 24 hours. These measures were implemented to ensure accurate and consistent body composition assessments.

Dietary Compliance Assessment Methods

Nutritional assessments and dietary counseling sessions were arranged at 1, 2, 3, and 4 months following the EIGB placement. Questionnaires, primarily employing 3-day estimated food records and 72-hour recalls [15], were utilized to gauge dietary habits. The determination of nutrients in the intervention diet plan was facilitated through the use of Elizabeth Stewart Hands and Associates (ESHA) software.

Visual-Analog Scales

Visual-Analog Scales (VAS) were utilized in this study, with 10-cm scales completed within the first two weeks of the ingestion of each assigned supplement [16]. The VAS scales were anchored with "Lowest Possible" and "Highest Possible" and were employed to assess various parameters including Belching, passing gas indigestion, Intestinal and stomach pain, Heartburn, Bloated feeling, Constipation, Diarrhea, and Nausea. Participants marked their responses on the scales, providing a quantitative measure of their experience with each of these digestive symptoms at different time points in relation to supplement ingestion.

Ethical Approval

This research received approval from Petra University's Scientific Committee in Amman, Jordan (Grant number: E/H/3/1/2022) and was conducted in accordance with the principles outlined in the CONSORT statement [17].

Statistical Analysis

As this was a pilot study, power calculations were not conducted. All volunteers successfully completed the entire study protocol, and their data were included in the final analysis. Statistical analysis was carried out using SPSS v21 for Windows (SPSS Inc., Chicago, IL). Descriptive statistics were generated for all variables, with mean Standard Deviation (SD) for normal variables and percentages for categorical variables, including clinical symptoms. The primary endpoint of the study was weight loss, and data were analyzed using an intention-to-treat approach, adhering to the treated principle. The Wilcoxon signed-rank test was employed to assess differences between paired variables within the group (pre- and post-intervention). The two-tailed P-value (<0.05) was considered statistically significant.

Table 2: Participant's characteristics, n=20.

Characteristics	Categories	N (%)
Gender	Male	2 (10%)
	Female	18 (90%)
Status	Single	8 (40%)
	Married	12 (60%)
Smoking	Current	5 (25%)
Job	Not working	10 (50%)
	Full time	10 (50%)

Table 3: Mean Body Mass Index (BMI) and mean body composition post (4 months) of EIGB.

Characteristics	Pre EIGB	Post-EIGB	Change (post-pre)	SE	*p-value
Age (year)	32±8.6	-	-	1.9	-
Height (cm)	162.8±8.2	-	-	1.8	-
Weight (kg)	91.6±16.4	84.7±15.8	- 6.9±4.7	3.7	<0.001
BMI (kg/m2)	35.2±7.1	32.4±6.3	- 2.8±2.2	1.6	<0.001
WC (cm)	105.2±10.3	98.3±11.4	- 6.8±3.2	2.3	<0.001
Hip circumference (cm)	120.7±10.7	113.9±10.5	- 6.7±3.6	2.4	<0.001
BMR	1650±242	1577±237.8	-73.4±51.5	54.1	<0.001
Body fat mass (kg)	39.1±11	34.1±10.6	- 4.96±3.7	2.4	<0.001
Body fat %	42.1±5.7	39.6±6.3	-2.5±2.4	1.3	<0.001
SMM (kg)	26.9±4.7	25.7±4.7	- 1.2±1.5	1	0.001
MM (kg)	49.9±7.4	48±7.3	-1.9±1.5	1.7	<0.001
VF	9.6±3.8	8.3±3.7	-1.4±1.1	0.8	0.001
FFM (kg)	52.4±7.6	50.5±7.8	-1.9±1.7	1.7	0.001
TBW (kg)	37.5±5.5	35.8±5.7	-1.6±1.1	1.2	<0.001

The values are expressed as Mean (SD). p-value <0.005. Body Mass Index (BMI), Waist Circumference (WC), Basal Metabolic Rate (BMR), Skeletal Muscle Mass (SMM), Muscle Mass (MM), Visceral Fat Rate (VF), Fat-Free Mass (FFM), Total Body Water (TBW) *Between-group comparisons analyzed by Mann-Whitney U test. p-value <0.05.

Table 4: Digestive tract symptoms after EIGB (within the first two weeks), n=17.

Symptoms	N (%)
Nausea	7(35%)
Diarrhea	3(15%)
Constipation	7(35%)
Bloated feeling	6(30%)
Heartburn	2(10%)
Intestinal and stomach pain	10(50 %)
indigestion	1(5%)
Belching, passing gas	4(20%)

Note: The data for three subjects was not obtainable, and their symptoms were not included.

Results

Participants Characteristics

Table 2 provides an overview of the key characteristics of the study sample. The cohort comprised twenty participants, with a distribution of two males and eighteen females. In terms of marital status, forty percent were identified as single, while the remaining fifty percent were married. Furthermore, a quarter of the participants reported being smokers, and half of the participants indicated having full-time employment.

Changes in Body Composition

Table 3 illustrates the BMI and average body composition following EIGB intervention. The study involved 20 participants with an average age of 32±8.6 years, an average weight of 91.6±16.4 kg, and an average height of 162.8±8.2 cm. Despite these figures, the participants, on average, fell into the obesity weight category with a BMI of 35.2±7.1 kg/m², with 90% being females and 10% males. The observation period lasted four months.

During this period, participants experienced significant weight loss, averaging 6.9±4.7 kg, accompanied by a notable decrease in BMI (-2.8±2.2 kg/m²; P<0.0001). The analysis further indicated statistically significant changes in waist and hip circumference after four months of EIGB.

Gastrointestinal Symptoms

Table 4 presents the digestive tract symptoms (VAS-Scale) observed after EIGB placement. Among the twenty individuals, seven reported experiencing nausea, while diarrhea was noted in fifty percent, and constipation in thirty-five percent. Only 2 out of 20 individuals reported heartburn, while 6 out of 20 experienced bloating. Indigestion was reported by only one participant, but stomach and intestinal pain were observed in 50% of the subjects. Belching was reported by four out of the twenty participants. Notably, a significant proportion of the participants saw resolution of these symptoms within one to two weeks following the intervention.

Discussion

Obesity represents a major global public health challenge, given the considerable economic burden, morbidity, and mortality associated with this condition [2]. In recent years, EIGB from Allurion Technologies in Wellesley, Massachusetts, USA, has garnered substantial global recognition and popularity. This is attributed to its unique characteristics as an excreted and self-emptying gastric balloon [9]. Unlike traditional endoscopic gastric balloons, Allurion Technologies' EIGB does not necessitate hospital recuperation, upper gastrointestinal endoscopy, or the administration of anesthetics. The conventional gastric balloon has demonstrated safety and efficacy as a short-term method to assist patients in managing their weight [12]. Previous research has shown that Intragastric Balloons (IGBs) therapy, when combined with changes in lifestyle, is a viable approach for achieving short-term weight reduction [12]. Furthermore, a study conducted by Machytka *et al.* (2016) illustrated the safety and efficacy of EIGB in facilitating weight loss. Another study by Ienca *et al.* (2020) reported a mean weight loss of 13.5±5.8kg and a mean decrease in BMI of 4.9±2.0 points after a 4-month period.

When comparing various IGBs, Orbera stands out as having the closest resemblance in terms of intragastric volume occupancy, consistency, and configuration to EIGB. Recent studies have indicated the efficacy of IGBs at two specific time points: 3- and 6-months post-insertion. Orbera, for instance, has demonstrated a mean weight loss of 12.9 kg at the 3-month mark, accounting for 80% of the total weight loss observed over a 6-month period (Raftopoulos and Giannakou, 2017; NHS, 2020; [19]. Interestingly, these findings align closely with results from EIGB at the 4-month interval, despite the shorter lifespan of the EIGB device. This suggests comparable effectiveness between Orbera and EIGB within a shorter timeframe for the latter [20]. Indeed, the design of the EIGB is tailored for a 4-month duration, aligning with the concept that maximum weight loss is typically attainable within this timeframe. The limited period of implantation aims to optimize the effectiveness of the device in promoting weight loss during the specified duration, reflecting a strategic approach to achieve the desired outcomes within a defined timeframe [20].

Following the insertion of EIGB, a predominant approach in dietary interventions involves the adoption of low-carbohydrate or ketogenic diets, along with high-protein diets for many individuals [21]. As far as our current knowledge extends, this study serves as the pioneering exploration into the utilization of a low-calorie, MCD, designed to offer patients a more extensive array of food choices. The principal advantage of a low-calorie, MCD lies in its facilitation of a more straightforward dietary plan, particularly over an extended timeframe. Recent evidence has demonstrated the effectiveness of LCD in weight reduction, leading to their growing popularity worldwide [22]. Additionally, a study conducted by Naude et al. in 2022 revealed that when overweight and obese adults, both with and without type 2 diabetes (T2DM), were randomly assigned to either low-carbohydrate or balanced-carbohydrate diets, the outcomes indicated comparable weight loss for a duration of up to two years.

In our study, a noteworthy reduction in weight by 6.9±4.7 kg and a decrease in BMI by 2.8±2.2 kg/m² were observed after a 4-month period compared to the baseline. A similar study conducted in Kuwait, where lifestyle patterns resemble those in Jordan, involved 51 participants. At the conclusion of the study, the average weight loss was 8.84 kg (ranging from -6 to +21.5), and the mean change in BMI was 3.42 kg/m². Additionally, the mean reduction in waist circumference was 8.62 cm (ranging from -10 to +31), with 47 females and four males participating in the study [5].

The combination of EIGB and dietary intervention resulted in a significant decrease of 2.5±2.4 in body fat percentage and a reduction of 4.96±3.7 kg in body fat mass. This was achieved by following a high-protein, low-calorie diet for the first week, followed by a low-calorie MCD in the subsequent two weeks. The MCD consisted of 40–45% carbohydrates, 20–23% proteins, and 33–37% fats, amounting to 1200–1500 kcal/day.

In accordance with our research, alterations were observed in FFM, Skeletal Muscle Mass (SMM), and Basal Metabolic Rate (BMR) after EIGB (-1.9±1.7, -1.2±1.5, and -73.4±51.5, respectively). Gaździńska et al. (2020) similarly reported a 5.4% decrease in FFM between one month before and three months after IGB implantation, correlating with weight and BMI loss. After four months, there was a lesser loss of FFM and RMR following a Low-Carbohydrate Ketogenic Diet (LCKD) compared to a LCD (3.55% vs. 14.3%, p<0.001; 9.79% vs. 11.4%, p<0.001, respectively) [7].

Hence, it appears that any diet plan following the EIGB protocol may lead to a decline in FFM, SSM, and BMR. Considering that diet and exercise are fundamental components of therapy for individuals dealing with overweight and obesity, it is crucial to recommend the inclusion of an exercise program alongside the use of a gastric balloon, as suggested by [23]. For instance, a regimen of walking for 45 minutes, five times a week, could be proposed [24]. Approximately 50% of the subjects had symptoms of intestinal and stomach pain, whereas over 70% of the participants did not report any additional symptoms. These findings bear a resemblance to a previous study conducted by [25].

Strength and Limitations

The study introduces an innovative dietary approach by investigating the impact of a low-calorie, MCD following the insertion of the EIGB. This provides valuable insights into a novel dietary strategy for weight management. Comprehensive monitoring of participants throughout the entire four-month study period enhances the reliability of the data. This close monitoring allows for a detailed understanding of the intervention's effects on various body composition parameters, including BMI, FFM, body fat percentage, and gastrointestinal symptoms. The inclusion of diverse measurements contributes to a comprehensive evaluation of the intervention's outcomes. Assessing multiple body composition parameters provides a holistic view of the participants' responses to the EIGB and dietary intervention. Real-world applicability is a strength of the study, considering the global prevalence of obesity and the increasing popularity of EIGB. The findings may have practical implications for weight management interventions, offering insights into the effectiveness of the studied approach.

A notable limitation is the small sample size, resulting from participant withdrawals and procedural challenges. This may impact the generalizability of the findings to a larger population, and caution should be exercised when interpreting the results. Incomplete follow-up due to participant attrition poses a challenge in assessing the long-term effects and adherence to the intervention. The inability to maintain a comprehensive follow-up throughout the entire four-month duration limits the study's ability to observe sustained outcomes. The study's single-arm design, lacking a control group, hinders the comparison of the low-calorie, MCD with other dietary interventions. Future research with randomized controlled trials could provide a more robust evaluation of the studied dietary approach. Reliance on self-reported data, particularly in collecting information on dietary habits through methods like food records and recalls, introduces the potential for reporting bias. The accuracy of these self-reported data may impact the overall validity of the study.

The study's focus on a specific population in Jordan may limit the generalizability of the findings to broader demographic groups. Consideration of cultural and regional factors is necessary when extrapolating the results to different populations.

Conclusion

In conclusion, our study demonstrates that the combination of the EIGB and a low-calorie, MCD yields significant and effective weight loss results over a four-month period. Participants experienced a notable reduction in body fat percentage and mass, with mild and transient accommodative symptoms. The study, while limited by a relatively small sample size, suggests the potential of this approach for short-term weight management. Future research should explore this intervention on a larger scale, compare it with alternative dietary strategies, and consider the long-term implications and diverse participant characteristics. Additionally, incorporating structured physical activity alongside the intervention and enhancing patient education on potential side effects could further optimize outcomes.

Study Implantation

The implementation of our study involved administering the EIGB to 20 participants with a BMI ranging from 27 to 45 kg/m². Over four months, participants followed a low-calorie, MCD, guided by a clinical dietitian. The study yielded a significant average weight loss of 6.9±4.7 kg, accompanied by reductions in BMI and body fat percentage. Accommodative symptoms were mild and of short duration, showcasing the feasibility and effectiveness of the EIGB approach with this dietary intervention.

Author Statements

Data Availability

The corresponding author can provide the data used to support the findings of this study upon request.

Financial Disclosure

The authors did not receive any funds for this study.

Conflict of Interest

The authors have reported no conflicts of interest.

Acknowledgment

The authors would like to acknowledge the University of Petra, Amman, Jordan, for the ethical approval of this study. As well as all of the volunteers that took part in this study.

References

1. Hruby A, Hu FB. The Epidemiology of Obesity: A Big Picture. Pharmacoeconomics. 2015; 33: 673–89.
2. Tremmel M, Gerdtham U-G, Nilsson P, Saha S. Economic Burden of Obesity: A Systematic Literature Review. Int J Environ Res Public Health. 2017; 14: 435.
3. Ajlouni K, Khader Y, Batieha A, Jaddou H, El-Khateeb M. An alarmingly high and increasing prevalence of obesity in Jordan. Epidemiol Health. 2020; e2020040.
4. Taha O, Abdelaal M, Asklany A, Alaa M, Belal S, El.Assal I, et al. Outcomes of a Swallowable Intragastric Balloon (ElipseTM) on 96 Overweight and Obese Patients. Obes Surg. 2021; 31: 965–9.
5. Ciprian G, Khoury J, Ramirez L, Miskovsky J. Endoscopy Management of Complete Gastric Outlet Obstruction Secondary to ElipseTM Intragastric Balloon. Cureus. 2021; 13: e17542.
6. Jamal MH, Elabd R, AlMutairi R, Albraheem A, Alhaj A, Alkhayat H, et al. The Safety and Efficacy of One Anastomosis Gastric Bypass as a Revision for Sleeve Gastrectomy. Obes Surg. 2020; 30: 2280–4.
7. Schiavo L, De Stefano G, Persico F, Gargiulo S, Di Spirito F, Griguolo G, et al. A Randomized, Controlled Trial Comparing the Impact of a Low-Calorie Ketogenic vs a Standard Low-Calorie Diet on Fat-Free Mass in Patients Receiving an ElipseTM Intragastric Balloon Treatment. Obes Surg. 2021; 31: 1514–23.
8. Jamal MH, Almutairi R, Elabd R, AlSabah SK, Alqattan H, Altaweel T. The Safety and Efficacy of Procedureless Gastric Balloon: a Study Examining the Effect of Elipse Intragastric Balloon Safety, Short and Medium Term Effects on Weight Loss with 1-Year Follow-Up Post-removal. Obes Surg. 2019; 29: 1236–41.
9. Machytka E, Gaur S, Chuttani R, Bojkova M, Kupka T, Buzga M, et al. Elipse, the first procedureless gastric balloon for weight loss: a prospective, observational, open-label, multicenter study. Endoscopy. 2016; 49: 154–60.
10. Genco A, Ernesti I, Ienca R, Casella G, Mariani S, Francomano D, et al. Safety and Efficacy of a New Swallowable Intragastric Balloon Not Needing Endoscopy: Early Italian Experience. Obes Surg. 2018; 28: 405–9.
11. ETotté E, Hendrickx L, Pauwels M, Van Hee R. Weight Reduction by Means of Intragastric Device: Experience with the Bioenterics Intragastric Balloon. Obes Surg. 2001; 11: 519–23.
12. Ienca R, Al Jarallah M, Caballero A, Giardiello C, Rosa M, Kolmer S, et al. The Procedureless Elipse Gastric Balloon Program: Multicenter Experience in 1770 Consecutive Patients. Obes Surg. 2020; 30: 3354–62.

13. NHS. Dietary advice for patients following a Gastric balloon insertion. National Heal Serv. 2020.

14. Saslow LR, Daubenmier JJ, Moskowitz JT, Kim S, Murphy EJ, Phinney SD, et al. Twelve-month outcomes of a randomized trial of a moderate-carbohydrate versus very low-carbohydrate diet in overweight adults with type 2 diabetes mellitus or prediabetes. Nutr Diabetes. 2017; 7: 304.

15. Shim J-S, Oh K, Kim HC. Dietary assessment methods in epidemiologic studies. Epidemiol Health. 2014; 36: e2014009.

16. Weigl K, Forstner T. Design of Paper-Based Visual Analogue Scale Items. Educ Psychol Meas. 2021; 81: 595–611.

17. Schulz KF. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials. Ann Intern Med. 2010; 152: 726.

18. Raftopoulos I, Giannakou A. The Elipse Balloon, a swallowable gastric balloon for weight loss not requiring sedation, anesthesia or endoscopy: a pilot study with 12-month outcomes. Surg Obes Relat Dis. 2017; 13: 1174–82.

19. Saber AA, Shoar S, Almadani MW, Zundel N, Alkuwari MJ, Bashah MM, et al. Efficacy of First-Time Intragastric Balloon in Weight Loss: a Systematic Review and Meta-analysis of Randomized Controlled Trials. Obes Surg. 2017; 27: 277–87.

20. Choi WJ, Park JG, Yoo SJ, Kim HO, Moon HR, Chun MW, et al. Syntheses of and Cyclopentenone Derivatives Using Ring-Closing Metathesis: Versatile Intermediates for the Synthesis of and Carbocyclic Nucleosides. J Org Chem. 2001; 66: 6490–4.

21. Maekawa S, Niizawa M, Harada M. A Comparison of the Weight Loss Effect between a Low-carbohydrate Diet and a Calorie-restricted Diet in Combination with Intragastric Balloon Therapy. Intern Med. 2020; 59: 1133–9.

22. Sackner-Bernstein J, Kanter D, Kaul S. Dietary Intervention for Overweight and Obese Adults: Comparison of Low-Carbohydrate and Low-Fat Diets. A Meta-Analysis. Siegel A, editor. PLoS One. 2015; 10: e0139817.

23. Farina MG, Baratta R, Nigro A, Vinciguerra F, Puglisi C, Schembri R, et al. Intragastric Balloon in Association with Lifestyle and/or Pharmacotherapy in the Long-Term Management of Obesity. Obes Surg. 2012; 22: 565–71.

24. Mohammed MA, Anwar R, Mansour AH, Elmasry E, Othman G. Effects of Intragastric Balloon Versus Conservative Therapy on Appetite Regulatory Hormones in Obese Subjects. Trends Med Res. 2014; 9: 58–80.

25. Mitura K, Garnysz K. Tolerance of intragastric balloon and patient's satisfaction in obesity treatment. Videosurgery Other Miniinvasive Tech. 2015; 3: 445–9.