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ORIGINAL CONTRIBUTIONS

One-Year Outcomes in a Supervised Program of Swallowable Intragastric Balloon—Analysis of 486 Patients in a High-Volume Bariatric Centre in Malaysia

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Abstract

Introduction The swallowable intragastric balloon (IGB) has recently emerged as a popular alternative for weight loss in Malaysia. It can reduce total body weight loss (TBWL) by 6–15%. We aim to observe positive weight loss up to a year after the swallowable IGB is implanted.

Methods A total of 486 consecutive patients with overweight or obesity who underwent swallowable IGB insertion were included in this prospective data collection.

Results Out of 486 patients, 404 patients (83%) had complete data at the end of 4 and 12 months. Patients included in the study had a starting mean body mass index of 35.3 ± 7.2 kg/m^2 which decreased to 31.5 ± 5.7 kg/m^2 ($p < 0.0001$) at the end of 4 months and further reduced to 30.3 ± 5.4 kg/m^2 ($p < 0.0001$) at the end of 12 months. At 4 months, the overall average weight loss was 9.8 kg, meanwhile, at 12 months, the average weight loss increased to 12.9 kg. At 4 months, the average TBWL was 10.5%, while at the end of 1 year, the combined %TBWL increased to 13.7%.

Conclusion Most weight loss is typically observed within the first 4 months following the procedure. However, it is important to note that patients can continue to experience ongoing weight loss for up to 1 year. The swallowable IGB is a safe

Key Points1. Allurion IGB is a revolutionary balloon in its field since it does not require sedation or endoscopy for either insertion or removal.

2. Single-centre large-scale study shows that it is safe and effective in achieving 10–15% weight loss with minimal side effects or complications.

3. One-year follow-up shows that weight loss is sustainable with the addition of adequate guidance and lifestyle modification and counselling along with IGB.

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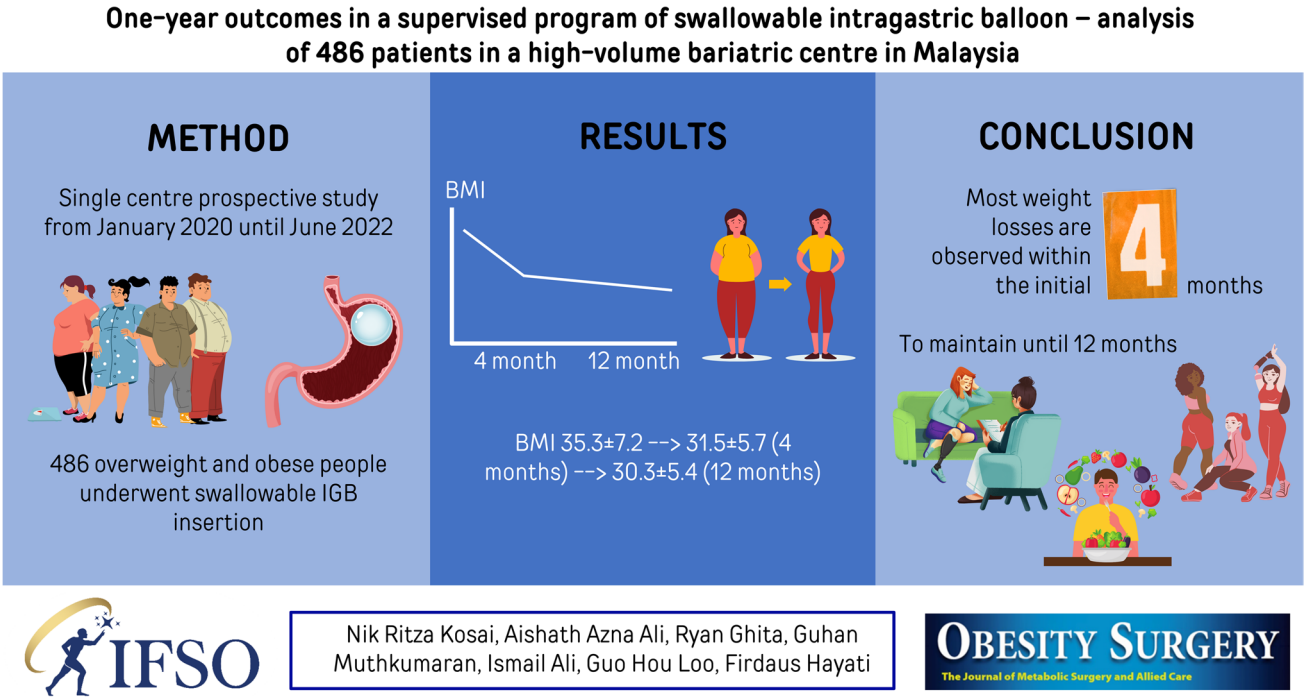
and effective option for patients seeking weight loss solutions. It offers numerous advantages, especially its non-invasive procedureless nature, which makes it more appealing to individuals considering this treatment.

Graphical Abstract



Keywords Bariatric surgery · Gastric balloon · Obesity · Weight reduction

Introduction

The ongoing struggle against the obesity pandemic has been a persistent endeavour. Based on the most recent report released by the World Health Organisation (WHO), it has been determined that in 2016, a total of over 1.9 billion individuals aged 18 years and older were found to be suffering from being overweight. Among this population, approximately 650 million adults were identified as being affected by obesity [1]. The global prevalence of obesity has experienced a significant increase over four decades. Among the Southeast Asian nations, Malaysia has emerged with the highest prevalence, reaching 19.7% in 2019 compared to 15.1% in 2011 [2, 3]. The escalating prevalence of obesity in Malaysia is a matter of significant concern due to the higher body fat percentage observed in the Asian population across all body mass index (BMI) categories. This, in turn, contributes to the development of comorbidities that elevate both mortality and morbidity rates [2, 4, 5].

Bariatric surgery has been demonstrated to yield substantial and enduring weight reduction [6, 7]. Nevertheless, the decision to undergo surgery may not be a bold undertaking that is embraced by all individuals. Non-surgical alternatives, such as intragastric balloons (IGB), are being utilised more frequently as a viable option for individuals who are affected by being overweight or obese and have experienced limited success in their weight loss endeavours through various strategies [8]. These individuals may not meet the necessary criteria for surgical intervention or may simply choose to forgo it. Research has demonstrated the efficacy of IGB in the management of weight. Since its authorisation and commercial availability in 1985, the intragastric balloon for obesity has undergone multiple revisions and modifications to enhance its acceptability, appeal, and consumer-friendliness [9].

Although multiple intragastric balloons (IGBs) are available in the market, the Allurion balloon stands out as the pioneering device that can be inserted and removed without the need for an endoscope or anaesthesia. This approach enhances practicality, ease of use, and overall safety, particularly for individuals living with obesity. The object in question has been intentionally designed to be ingested and subsequently expelled through the gastrointestinal tract within 4 months. Additionally, to confirm the placement, the presence of the balloon can be identified through fluoroscopy or an abdominal x-ray due to the inclusion of a radiopaque

catheter and ring within the device [10]. The Allurion balloon integrates a scale with Bluetooth capabilities and a corresponding application, enabling users to observe, track, and share their progress. Furthermore, the service offers a comprehensive dietary plan, which is accompanied by the availability of dieticians who actively monitor progress, maintain communication, and conduct regular follow-ups.

Method

This study is a retrospective analysis conducted on prospectively collected data from a consecutive cohort of patients who underwent Allurion (Allurion Inc., Natick, MA) balloon insertion at one of the teaching hospitals in Kuala Lumpur, Malaysia. The study design is prospective and conducted at a single centre between January 2020 to June 2022. Informed consent was obtained from all participants. The focus of our study was to evaluate the impact of the intervention on weight, BMI, and %TBWL, which are crucial indicators in assessing the effectiveness of bariatric procedures.

The inclusion criteria consisted of patients who had a BMI greater than 27 kg/m^2 and were either affected by being overweight or obese but did not meet the specific criteria for bariatric surgery. The age range is between 18 and 65 years. The existence of metabolic syndrome or disorders associated with obesity was also considered. Furthermore, it included those who rejected the surgical alternative or pursued it as a temporary solution before the definitive surgery. The main exclusion criteria consisted of patients with a documented medical history of small bowel obstruction, previous bariatric or metabolic surgery, or any indications of esophageal, gastric, or intestinal diseases, such as inflammatory bowel disease or cancer. Moreover, patients with a history of gastrointestinal bleeding, coagulopathy, patients on anticoagulant therapy, patients with eating disorders, severe psychological disorders, swallowing disorders, or pregnancy were also excluded.

The study adhered to a standardised protocol, which required all eligible patients to observe a 10-h fasting period before the insertion of the IGB. An antiemetic medication (Emend™, 125 mg, orally, once daily) was administered 1 h before the procedure. The medication was subsequently continued at a dose of 80 mg once daily for an additional 2 days. All patients were prescribed Hyoscine butylbromide (Buscopan™) 20 mg orally three times a day and Granisetron hydrochloride (Kytril™) 1 mg orally twice a day for 3 days. The administration of a 30 mg oral dose of Lansoprazole (Prevacid™), a proton pump inhibitor, was maintained for 2 weeks. A post-insertion nutrition regimen was recommended, consisting of three stages, each lasting for 1 week. The first step involved the consumption of liquids, the second stage involved a soft diet, and the third stage involved a normal diet.

The Allurion IGB is compressed into a swallowable vegan capsule connected to a thin catheter through which the balloon is filled with 550 mL of liquid once it reaches the stomach. A thin guidewire acting as a stylet was used at times when swallowing difficulty was encountered. The placement procedure was conducted as an outpatient procedure lasting approximately 15–20 min, without the use of endoscopy or sedation. After filling and once the correct position of the balloon is confirmed via an abdominal radiograph, the catheter is removed by gentle traction. At approximately 4 months, a valve within the Allurion balloon undergoes spontaneous opening, resulting in the subsequent deflation of the balloon. The deflated balloon is subsequently eliminated through the gastrointestinal tract.

Initial height and weight were recorded for all patients and BMI was calculated. The surgeon conducted follow-up assessments of the patients at intervals of 2 weeks, 2 months, and 4 months. The participants' weight was assessed monthly. Over 1 year, participants were given unrestricted access to and support from a team of registered dieticians primarily through text messages and phone conversations. A weekly check-up was conducted for the first month, followed by biweekly check-ups for the subsequent 3 months, and monthly check-ups for the remaining 8 months. This was necessary due to the COVID-19 pandemic, which required us to minimise in-person encounters.

All data analysis was performed using ANOVA. Values are expressed as mean with standard deviation (SD). Changes over time are based on one-way repeated ANOVA. Comparison of baseline weight and BMI to differences in weight and BMI status between each time point (4 or 12 months) were analysed using a paired two-sided *t*-test. Statistics were considered significant with a p value < 0.05.

Results

In this study, a total of 486 patients received the swallowable intragastric balloon. Out of these, 404 patients (83%) had complete data and a monthly weight recorded for 12 months. In 362 patients (90%), a stylet was utilised for the insertion of the balloon to prevent any additional discomfort following an unsuccessful attempt at swallowing the IGB without assistance. One patient (0.25%) could not tolerate the balloon due to hyperinflation, and it was removed a few days after insertion via endoscopy. Five patients (1.24%) were admitted within the first week for hydration purposes. Among them, 83% of the patients were female, and 61% had a starting BMI in the range of 30 to 39 kg/m^2, while 20% had a BMI of 40 kg/m^2 or higher. The combined mean weight loss at 4 and

12 months was 9.6 kg and 12.8 kg, respectively (Fig. 1). Consequently, the combined mean weight decreased from 93.2 to 83.6 kg after 4 months and further to 80.4 kg after 12 months (Table 1). Males had a higher mean weight loss at both 4 (15.8 kg) and 12 (20.2 kg) months. However, the starting weight for males was higher at 116.7 kg compared to 88.2 kg in females. Female weight loss was 8.8 kg and 11.7 kg at 4 and 12 months, respectively. As the starting BMI categories increased, the mean weight loss also increased, with those with a BMI of 40 kg/m^2 or higher achieving the greatest weight loss at 4 and 12 months (Table 1). Nonetheless, even patients with a BMI < 29.9 kg/m^2 achieved significant weight loss (Table 1).

Participants included in the study had a starting mean BMI of 35.3 ± 7.2 kg/m^2, which decreased to 31.5 ± 5.7 kg/m^2 ($p < 0.0001$) at the end of 4 months and further decreased to 30.3 ± 5.4 kg/m^2 ($p < 0.0001$) at the end of 12 months (Table 1). The combined mean %TBWL was 10.5% at 4 months and 13.7% at 12 months (Fig. 1). For males, the %TBWL was 15.6%, while for females, it was 13.3% at 12 months. The significantly higher mean weight loss in males corresponds to a similarly significant difference in %TBWL between males and females at both 4 and 12 months. Additionally, patients with a higher starting BMI demonstrated a significantly higher %TBWL compared to the lowest BMI category of < 29.9 kg/m^2 at both 4 and 12 months (Table 1).

Discussion

The mechanism by which IGBs contribute to weight loss involves a decrease in intragastric volume, an increase in gastric distension, and a delay in gastric emptying. These factors collectively result in reduced feelings of hunger and enhanced feelings of satiety [11–13]. According to a review article authored by Bazerbarchi et al. (2019), the use of intragastric balloons (IGB) has been found to result in a total body weight loss (TWBL) ranging from 6 to 15%, whereas lifestyle modification alone typically leads to a TWBL of only 1 to 5% [13]. The findings of our study revealed comparable outcomes, indicating a combined mean total body weight loss (TBWL) of 10.5% at the 4-month mark, which increased to 13.7% at the 12-month mark. In contrast to the findings of Perker et al.'s (2010) study, which indicated a cessation of weight loss between the 4- and 6-month mark, it is noteworthy that our patients exhibited ongoing weight reduction. Specifically, the collective average weight loss observed was 9.8 kg at 4 months, increasing to 12.9 kg at 12 months [14]. A study conducted in the Netherlands by Jense et al. (2023) yielded similar findings. It involved the combination of IGB and a 12-month coaching program, resulting in an average total weight loss of 11 kg after 12 months. These results further support our contention that a combined approach is more efficient in achieving and maintaining successful weight loss [15].

Based on our observations, we found that a significant proportion of initial weight loss occurred within the first

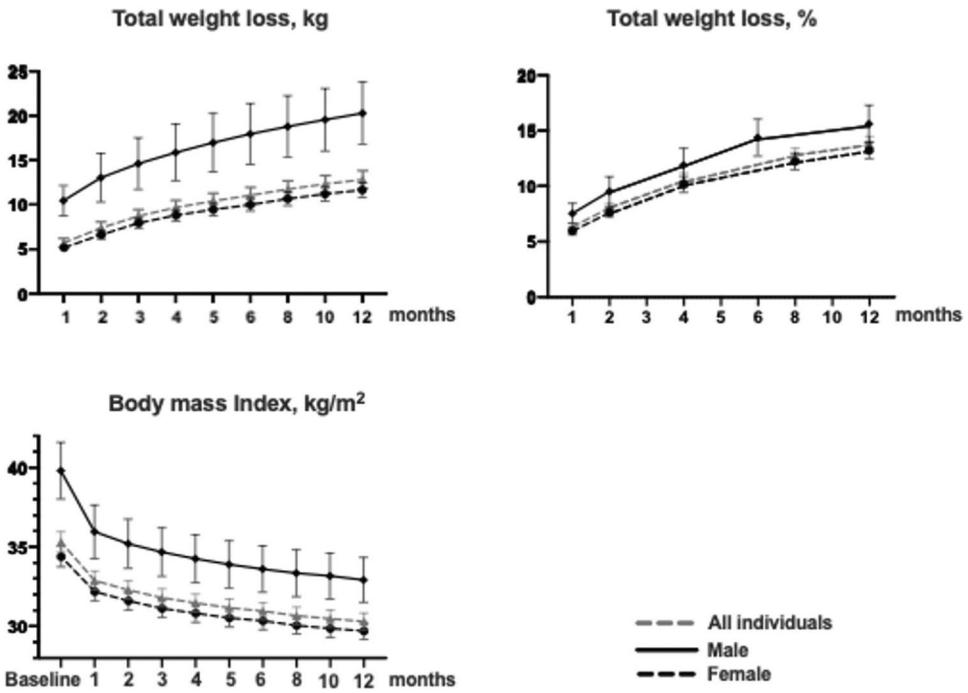


Fig. 1 Total weight loss, percentage total weight loss, and BMI from baseline to 12 months post-swallowable intragastric balloon. Males (solid black line), females (dashed black line), and all individuals (dashed grey line). Error bars represent a 95% confidence interval of the mean

Table 1 Changes in weight and body mass index (BMI) throughout the study. Patients were categorised into sex and BMI status before the procedure. Values are expressed as mean ± SD. * for significant difference ($p < 0.05$)

Parameter	*n*	Baseline weight recorded	Completed 12-month weight follow-up	Baseline	4 months	12 months	*p* value (over time comparison)	Baseline	4 months	12 months	*p* value (over time comparison)
				Weight (kg)				BMI (kg/m^2)			
All patients	486	486	404	93.2 ± 20.7	83.6 ± 18.2*	80.4 ± 17.1*	< 0.0001	35.3 ± 7.2	31.5 ± 5.7*	30.3 ± 5.4*	< 0.0001
Male	85	85	78	116.7 ± 24.9	100.9 ± 21.3*	96.46 ± 20*	< 0.0001	39.9 ± 8.3	34.2 ± 6.7*	32.9 ± 6.3*	< 0.0001
Female	401	401	326	88.3 ± 15.7	79.4 ± 14.6*	76.6 ± 13.75*	< 0.0001	34.4 ± 6.6	30.8 ± 5.3*	26.7 ± 5*	< 0.0001
BMI < 29.9	94	94	77	70.8 ± 6.5	64.3 ± 6.5*	62.7 ± 5.8*	< 0.0001	27.6 ± 1.6	25.1 ± 2.1*	24.4 ± 1.8*	< 0.0001
BMI 30–39.9	295	295	246	91.2 ± 11.8	81.5 ± 10.1*	78.3 ± 9.7*	< 0.0001	34.4 ± 2.7	30.6 ± 2.6*	29.5 ± 2.6*	< 0.0001
BMI 40 +	97	97	81	121.7 ± 20.8	108 ± 17.9*	103 ± 16.68	< 0.0001	45.3 ± 5.6	40.1 ± 4.9*	38.4 ± 4.6*	< 0.0001

month following insertion. Remarkably, all our patients exhibited weight maintenance or continued weight loss throughout the 1-year follow-up period. As previously mentioned, the Allurion team provides ongoing support, and typically, follow-up care concludes after the intragastric balloon (IGB) is naturally expelled within 4 months. However, our patients received comprehensive supervision for up to 1 year primarily through text messages and phone conversations. The ongoing support, combined with lifestyle coaching and modifications, could potentially contribute to facilitating their sustained weight loss journey. Once the balloon deflates after 4 months, its physical impact ceases, and the possibility of inevitable weight gain is there. However, an integrated 1-year program has shown the potential to sustain or enhance the outcomes achieved from the balloon intervention, as demonstrated by the findings of this study. Determining the duration of the impact is challenging.

Conclusion

The current study is the most extensive prospective investigation undertaken in Southeast Asia following the introduction of the Allurion balloon in the region. Including several ethnic groups within the Malaysian population enhances the demographic diversity of the study cohort. The results of our study offer empirical support for the notion that there are favourable and promising effects associated with the reduction of body weight and BMI. The utilisation of a combined therapeutic approach involving both balloon intervention and 1 year of supervision undoubtedly contributed significantly to the favourable outcomes observed throughout the trial. Consecutive and prolonged periods of monitoring and evaluation can yield useful data on the long-term sustainability of weight loss maintenance.

Limitation

A potential limitation of our study would be that patients lost to follow-up might have experienced complications or had the balloons removed at another institution.

Data Availability All data underlying the results are available as part of the article and no additional source data are required.

Declarations

Ethical Approval and Consent to Participate All procedures performed in studies involving human participants were following 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 was obtained from all individual participants included in the study.

Conflict of Interest The author declares no competing interests.

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