ORIGINAL ARTICLE

Nonsurgical Approaches to Weight Loss and Diabetes Remission: A Comprehensive Study of the Swallowable Balloon Intervention

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Abstract

Introduction: Obesity and type 2 diabetes mellitus (T2DM) pose significant health challenges, necessitating innovative interventions. This study aims to explore the efficacy of a novel swallowable balloon process in addressing these dual burdens.

Methodology: To evaluate weight loss, diabetes remission, and adverse events (AEs) in 150 patients with a body mass index of 30–40 kg/m^2. The swallow balloon was inserted, and outcomes were assessed over a 6-month follow-up period.

Results: The swallowable balloon process demonstrated consistent and significant ($p < 0.001$) weight loss, with mean percentage total weight loss (%TWL) ranging from 6.8 to 14.6% and mean percentage excess weight loss (% EWL) ranging from 15.5 to 32.8% over the 6-month follow-up period. Remarkably, diabetes remission rates were notable at 30% in 3 months and an impressive 67% in 6 months post-balloon insertion. However, AEs, particularly nausea and vomiting extending beyond one week, occurred in 12% of participants, leading to hospital admission, highlighting the importance of careful monitoring and management. Additionally, nausea and vomiting occurred in 46.6% and 40.6% of participants, respectively, without major complications.

Conclusion: The swallowable balloon process demonstrates promising outcomes in weight loss and diabetes remission over the end of period. AEs require careful consideration, emphasizing the need for ongoing research to optimize safety and efficacy. This intervention offers a nonsurgical approach for individuals with obesity and T2DM, marking a significant step toward addressing these interconnected health challenges.

Keywords: Obesity, Nonsurgical process, Swallow balloon, Type 2 diabetes mellitus, Weight-loss.

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Introduction

Obesity stands as a critical global health concern, intricately linked to the rising prevalence of type 2 diabetes mellitus (T2DM) and various metabolic disorders.[1] This complex interplay contributes not only to increased morbidity and mortality but also places a substantial financial burden on healthcare systems worldwide.[2,3] While population-based interventions targeting lifestyle modifications are paramount in preventing and addressing the dual epidemics of obesity and T2DM, a considerable challenge persists in achieving long-term weight loss and glycemic control for those who have already developed these conditions.[4] Current therapeutic approaches encompass a combination of diet, exercise, and medications, aiming to manage both obesity and T2DM. However, the long-term success rates of lifestyle modifications can be disheartening, and achieving optimal glycemic control remains elusive despite the growing pharmacotherapeutic arsenal. Furthermore, many diabetes medications inadvertently contribute to weight gain, and aggressive glycemic control with these medications heightens the risk of hypoglycemia.[5–7]

In cases where conventional interventions prove insufficient in promoting substantial weight loss and glycemic control, an innovative and nonsurgical method has recently emerged: The swallowable balloon process. This novel approach presents a potential breakthrough in the management of obesity and T2DM by leveraging the gastrointestinal tract's role in metabolic regulation. The elipse swallow (ES) balloon, developed by Allurion Technologies in Natick, MA, USA, represents a pioneering advancement in weight loss interventions that requires no surgery, endoscopy, or anesthesia. Remarkably, patients can undergo the procedure while remaining conscious throughout. The swallow balloon self-empties and passes naturally approximately 16 weeks after placement, adding to its appeal as a minimally invasive intervention.[8,9] Previous proof-of-concept studies conducted on a prototype version of the swallowable balloon in a small cohort of patients reported encouraging results with no serious adverse events (AEs). All participants successfully swallowed and excreted the balloon, providing initial evidence of its safety and

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feasibility.[8] The introduction of this swallowable balloon process holds promise in addressing the intertwined challenges of obesity and T2DM. Despite these initial positive findings, real-world data on the performance of the swallowable gastric balloon approach in a larger cohort, adhering to standard follow-up protocols outlined in current guidelines, are limited.[8–11] Hence, there is a critical need to investigate the effectiveness and safety of the swallowable balloon process in a more extensive and diverse patient population. In response to this gap in knowledge, our study aims to evaluate the impact of the swallowable balloon on patients with both obesity and T2DM. Our study assesses the postoperative changes in key parameters, including body weight loss, fasting plasma glucose (FPG), hemoglobin A1c (HbA1c), and diabetes medication requirements. Additionally, we meticulously document any AE associated with the swallowable balloon process. The objective is to determine whether the swallowable balloon can safely and effectively improve glycemic control, potentially leading to the remission or improvement of diabetes and its associated comorbidities in obese individuals. This study contributes to the growing body of evidence on the swallowable balloon process, offering insights into its real-world performance and its role in managing the intricate relationship between obesity and T2DM. The outcomes of this research hold the potential to inform clinical practice, guide treatment strategies, and contribute to the ongoing dialogue surrounding innovative interventions in the field of metabolic health.

Materials and Methods

Study Design

The study design and data collection methods were implemented with ethical considerations and adherence to relevant guidelines. Institutional review board approval was obtained prior to the commencement of the study. This prospective observational study aimed to assess the impact of the swallowable balloon process on 150 patients with a body mass index (BMI) ranging from 30 to 40 kg/m^2. The study spanned from April 2023 to November 2023, encompassing a comprehensive evaluation of primary data, including demographic information and various postoperative outcomes.

Participant Selection

A total of 150 patients meeting the BMI criteria were recruited for the study. All participants underwent the swallowable balloon process as part of their weight-loss intervention. Informed consent was obtained from each participant prior to inclusion in the study.

Data Collection

Data were collected through electronic healthcare records, capturing a range of parameters to comprehensively evaluate the outcomes of the swallowable balloon process. Primary data, including demographic information age, gender, and baseline comorbidities, were recorded. Postoperative outcome measures—changes in body weight, T2DM remission, early patient-reported concerns, or complications related to the swallowable balloon—were recorded.

Follow-up Assessments

The study incorporated a structured follow-up schedule to track the trajectory of weight loss and diabetes outcomes.

Table 1: Demographic and baseline characteristics

Characteristics	*Mean/Percentage*
Age (years)	42 ± 2.12
Height (cm)	166.23 ± 21.32
Weight (kg)	112.23 ± 18.34
BMI (kg/m^2)	39.23 ± 11.23
Gender (Male/Female)	45 (30%)/105 (70%)
T2DM	72 (48%)
HTN	108 (72%)
OSA	99 (66%)

HTN, hypertension; OSA, obstructive sleep apnea

Weight-loss Outcome

Follow-up assessments were conducted at 1, 2, 3, 4, 5, and 6 months postoperatively to monitor changes in both percentage total weight loss (%TWL) and percentage excess weight loss (%EWL).

T2DM Remission

Diabetes-related parameters, including glycemic control and potential remission, were specifically assessed at the 3- and 6-month follow-up. The American Diabetes Association's FPG ≥ 126 mg/dL or HbA1c ≥6.5% criteria were used to diagnose T2DM.[12]

AE Monitoring

The occurrence of adverse events was closely monitored throughout the study period. AEs of interest included nausea, vomiting, prolonged nausea and vomiting beyond one week, abdominal pain, constipation, and Gastroesophageal Reflux Disease. These events were documented and analyzed to evaluate the safety profile of the swallowable balloon process.

Statistical Analyses

Statistical analyses were performed to assess the significance of the observed outcomes. Descriptive statistics, including means, standard deviations, and percentages, were calculated for demographic variables and primary outcome measures. Inferential statistical methods, such as *t*-tests and Chi-square tests, were employed to determine the significance of changes in weight, diabetes outcomes, and the occurrence of AEs over the study period.

Results

Demographic and Baseline Characteristics

Table 1 summarizes the demographic and baseline characteristics of the study population. The study included a diverse cohort of participants (n = 150) with a mean age of 42 years (±2.12) and a balanced gender distribution of 30% males and 70% females. Anthropometric measurements revealed an average height of 166.23 cm (± 21.32), a mean weight of 112.23 kg (±18.34), and a mean BMI of 39.23 kg/m^2 (±11.23). The baseline characteristics highlighted a significant prevalence of comorbidities among the participants, with 48% diagnosed with T2DM, 72% with hypertension (HTN) and 66% with obstructive sleep apnea (OSA), respectively. These findings underscore the complexity of the study population, reflective of the multifaceted health challenges associated with obesity.

Weight Loss Outcome

We have calculated the mean %TWL and %EWL at regular follow-up intervals post-insertion of the swallowable balloon. It was seen that their mean %TWL were 6.8, 10.5, 12.9, 15.7, 15.1, and 14.6% at 1, 2, 3, 4, 5, and 6 months, respectively. The mean %EWL was 15.5, 24.3, 29.1, 34.6, 33.9, and 32.8% at each follow-up visit postoperatively (Table 2 and Fig. 1). Statistical significance ($p < 0.001$) was observed for both %TWL and %EWL at each follow-up interval, indicating substantial improvements in weight loss post-balloon insertion.

Diabetes Remission Outcome

Table 3 outlines the diabetes remission outcomes at different follow-up intervals. Notably, 30% of patients experienced diabetes remission at 3-month post-balloon insertion, with a substantial increase to 67% at the 6-month mark. Statistically significant improvements in diabetes remission rates were observed at both 3 and 6 months post-balloon insertion.

Adverse Events

Adverse events were carefully documented, revealing nuanced insights into the safety profile of the swallowable balloon process. Notably, 12% of participants experienced nausea and vomiting extending beyond one week, leading to hospital admission in 2% of cases. Additionally, nausea and vomiting occurred in 46.6 and 40.6% of participants, respectively, without major complications (Table 4). These findings underscore the importance of vigilant monitoring and management of AEs, particularly those leading to hospitalization, and highlight areas for potential optimization in patient care.

Discussion

In this study, we investigated the impact of a swallowable balloon process on weight loss, diabetes remission, and associated outcomes in a cohort of patients with obesity and T2DM. Our results demonstrate significant and sustained improvements in weight loss, both in terms of %TWL and %EWL, at various follow-up intervals. The progressive increase in mean %TWL and %EWL from months 1 to 6 suggests the effectiveness of the swallowable balloon process over an extended period. These findings align with existing literature on the benefits of bariatric interventions in achieving substantial weight reduction and improving metabolic health.[8–11] The mean %TWL values ranging from 6.8 at month 1 to 14.6% at month 6 indicate a gradual and consistent weight loss trajectory. Similarly, the mean %EWL values, ranging from 15.5 at month 1 to 32.8% at month 6, reflect the substantial reduction in excess weight over the study duration. The significance of these improvements ($p < 0.001$) underscores the clinical relevance of the swallowable balloon process in the context of managing obesity. These findings resonate with studies that have explored the efficacy of various bariatric interventions. The observed weight loss not only contributes to improvements in body composition but may also alleviate obesity-related comorbidities, including T2DM. The sustained %EWL at 6 months suggests the potential for long-term metabolic benefits, although continued follow-up is essential to ascertain the durability of these outcomes.

A noteworthy outcome of our study is the substantial rate of diabetes remission observed at 3 months (30%) and 6 months (67%) post-balloon insertion. These findings suggest a rapid and sustained positive impact on glycemic control, reinforcing the notion that interventions addressing obesity can play a pivotal role in the management of T2DM. The observed remission rates align with studies investigating the metabolic effects of weight-loss interventions. Weight loss, particularly through bariatric procedures, has been associated with improvements in insulin sensitivity and glucose metabolism. The mechanisms behind the observed diabetes remission may involve changes in hormonal signaling, inflammatory modulation, and improvements in beta-cell function. The rapid onset of remission at 3 months suggests that the swallowable balloon process may exert prompt effects on metabolic parameters. Moreover, the comprehensive evaluation of diabetes-related conditions is crucial for understanding the holistic impact of the intervention. While specific details on these effects were not provided in the current study, further investigations into changes in insulin resistance, HbA1c levels, and other relevant markers would enhance our understanding of the metabolic benefits associated with the swallowable balloon process.

Table 2: Weight loss outcome

Follow-up (months)	*Mean %TWL*	*Mean %EWL*	*p-value (vs Baseline)*
1	6.8%	15.5%	<0.001
2	10.5%	24.3%	<0.001
3	12.9%	29.1%	<0.001
4	15.7%	34.6%	<0.001
5	15.1%	33.9%	<0.001
6	14.6%	32.8%	<0.001

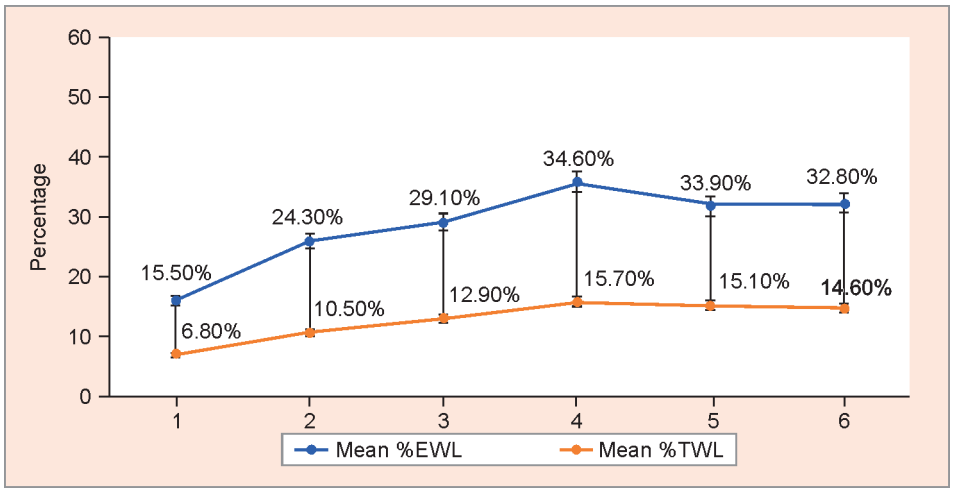

Fig. 1: Weight loss outcome

Table 3: Diabetes remission outcome

Follow-up (months)	*Remission (%)*	*p-value (vs Baseline)*
3	30%	<0.001
6	67%	<0.001

Table 4: Adverse events

Adverse events	*Incidence (%)*	*Outcome*
Nausea and vomiting extending beyond 1 week	18 (12%)	2% hospital admission, 2 days post-balloon insertion, due to vomiting and dehydration
Nausea	70 (46.6%)	No major complications observed
Vomiting	61 (40.6%)	No major complications observed
Abdominal pain	–	–
Constipation	–	–
Gastroesophageal reflux disease	–	–

Despite the promising metabolic outcomes, the study highlights the importance of monitoring AEs associated with the swallowable balloon process. Notably, 12% of patients developed nausea and vomiting extending beyond one week, leading to hospital admission in a subset of cases. These AEs, while not uncommon in bariatric interventions, underscore the need for vigilant patient monitoring and appropriate management strategies. The incidence of AEs, particularly gastrointestinal symptoms, raises questions about the tolerability and acceptance of the swallowable balloon process. Nausea and vomiting, common side effects associated with intragastric devices, can significantly impact patient experience and adherence. Identifying strategies to mitigate these AEs, such as optimized patient selection, tailored dietary counseling, and proactive symptom management, could enhance the overall safety and acceptability of the intervention. While the study reports no major complications, the focus on AEs reinforces the importance of balancing the potential benefits of the swallowable balloon process with its safety profile. Understanding the factors contributing to AEs can inform future modifications in the intervention protocol to optimize patient outcomes.

Despite the valuable insights provided by this study, certain limitations should be acknowledged. The relatively short follow-up period of 6 months limits our understanding of the long-term sustainability of weight loss and metabolic improvements. Future studies with extended follow-up durations are warranted to assess the durability of outcomes and potential late complications. Additionally, the absence of a control group in this study limits our ability to attribute the observed changes solely to the swallowable balloon process. Comparative studies, preferably randomized controlled trials, would strengthen the evidence base and provide a clearer understanding of the intervention's efficacy.

Conclusion

Our study contributes to the evolving landscape of nonsurgical interventions for obesity and T2DM. The swallowable balloon process demonstrates significant and sustained weight loss, rapid diabetes remission, and an acceptable safety profile. These findings, while promising, necessitate further exploration in larger, controlled trials with longer follow-up periods. The potential of the swallowable balloon process as a viable and minimally invasive option in the management of obesity and T2DM warrants continued investigation and optimization. As the field of metabolic interventions advances, ongoing research efforts will refine our understanding of these interventions, providing meaningful options for individuals struggling with the dual burden of obesity and metabolic disorders.

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