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Emerging Outcomes for Treatment of Obesity with Type 2 Diabetes Mellitus: Novel Swallowable Balloon Process

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Abstract

Background: Swallowable balloon process is a new way for the treatment of obesity and type 2 diabetes (T2DM). The aim of this study was to assess the outcomes of the novel swallowable balloon on T2DM remission, weight loss, and adverse events in individuals with T2DM and obesity.

Methodology: We treated forty-two T2DM patients with obesity at our center with a swallowable balloon. During the 6-month follow-up diabetes remission was defined as HbA1c<6.5% without T2DM medication and diabetic improvement was HbA1c<7.0% with decreased usage of oral diabetes medications.

Results: At 6 months of follow-up, 87.8% of the cohort treated by swallowable balloon experienced diabetes remission. The highest diabetes remission was 66.7% (HbA1c 6.43%; 95%CI 6.2-6.5 and FPG 120.3; 95% CI 111.6-124.9) occurred between 3-and 4-months post balloon insertion, and 12.5% recrudescence of diabetes during the end of follow-up. Improvement of diabetes without full remission was observed in 27.8% and 36.1% of patients at 4 and 6 months (HbA1c, 6.8% 95% CI 6.5-7.0). These patients achieved diabetes control (HbA1c, 6.8% 95%CI 6.5-7.0) with decreased usage of oral diabetes medications and withdrawal of insulin when previously used. Significant ($p<0.001$) improvements in %TWL were 6.5 %,10.1 %, 12.7%, 15.14%,14.7%, and 14.4% at 1-2-3-4-5-6 months, respectively were noted after the insertion of the balloon. There was a significant ($p<0.001$) resolution in diabetes-related comorbidities (75% HTN and 73.3% DLP).

Conclusion: New emerging swallowable balloon process is an effective tool to reduce HbA1c and put T2DM into remission and weight loss.

Keywords: Type 2 diabetes; Obesity; Swallowable balloon; Weight loss

Introduction

Type 2 diabetes mellitus (T2DM) is associated with obesity and multiple metabolic derangements, leading to increased morbidity, mortality, and financial burden. Although population based efforts through lifestyle interventions are essential to prevent and deal with the parallel epidemics of obesity and T2DM. Only a few patients who have already developed T2DM and obesity are able to comply and accomplish long-term weight loss and glycemic control [1]. Therapeutic management for both obesity and T2DM are dieting, exercise, and medications. Long-term success rates of lifestyle modifications can be disappointing [2]. However, despite an ever-increasing armamentarium of pharmacotherapeutics, adequate glycemic control often remains elusive [3]. Moreover, most diabetes medications promote weight gain, and using them to achieve tight glycemic control increases the risks of hypoglycemia [4]. In cases where lifestyle interventions and medications fail to promote adequate weight loss and/or glycemic control, a new emerging novel swallow balloon process currently introduced is a non-surgical approach that offers a powerful alternative [5]. Given its role in metabolic regulation, the gastrointestinal tract constitutes a biologically and clinically meaningful target to treat T2DM with obesity.

The Elipse Swallow (ES) balloon (Allurion Technologies, Natick, MA, USA) is the first swallowable balloon for weight loss that requires no surgery, endoscopy, or anesthesia allowing the patient to remain conscious throughout the procedure. At approximately 16 weeks after placement, the swallowable balloon self-empties and passes naturally. A proof-of-concept pilot study previously conducted on a prototype version of the swallowable balloon in eight patients reported no serious adverse events. All patients were able to swallow and excrete the balloon [5-7]. The new swallowable balloon process showed early promising outcomes for the treatment of diabetes and weight loss. There are limited data on the real-world performance of the swallowable gastric balloon approach in patients with obesity and T2DM receiving standard follow-up based on current guidelines [5,8,9]. Accordingly, we evaluated the effect of swallowable balloon on patients with T2DM and obesity. We examined whether swallowable balloon in these obese patients could safely improve glycemic control, leading to remission or improvement of diabetes and related comorbidities. Over a 6-months follow-up period, we measured postoperative changes in body weight, fasting plasma glucose (FPG), hemoglobin A1c (HbA1c), and diabetes medication requirements, as well as adverse events (AE) as outcome measures.

Materials and Methods

Study design

We retrospectively studied and observed 42 consecutively selected patients who had T2DM and a BMI of 30-40 kg/m^2, who elected to undergo swallowable balloon process between 10th January 2021 to

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13th August 2022. RT-PCR for Covid-19 infection was done in all the patients.

All patients were informed about any possible adverse events of the procedure. Written informed consent was obtained from all patients, and the ethics committee of our hospital approved this study. All patients diabetes was inadequately controlled preoperatively, despite appropriate lifestyle modifications and use of oral antidiabetes medications and/or insulin for ≥1 year.

The diagnosis of diabetes was based on the following American Diabetes Association criteria FPG ≥126 mg/dL or HbA1c ≥6.5% [10]. Patients were excluded if they had diabetes secondary to a specific disease (maturity-onset diabetes of the young, pancreatitis (or) pancreatectomy) drug or alcohol addiction, recent vascular event (myocardial infarction, coronary angioplasty (or) stroke within 6 months) internal malignancy, inability to cooperate in short-term follow-up, poor understanding of the approach.

Swallowable balloon procedure

A fluid diet was started one day before the insertion, followed by 10 h of fasting. A plain abdomen x-ray was obtained initially and confirmed normally. 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 style guide wire was used to insert the capsule orally. The placement of the capsule in the stomach was confirmed. Subsequently, inflation will establish. 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.

Data collection

During the study period, we performed >600 swallowable balloon procedures out of which 42 were treated with T2DM and obesity. All procedures were performed as outpatient procedures of the comfort unit by a single surgeon with one assistant. All patients received an extensive preoperative evaluation, including history and physical examination, nutritional and psychiatric evaluations, and specialty consultations as indicated. Primary data including demographic (age, sex, weight loss requirement), clinical (co-morbidities), and anthropometric (weight, height) were collected from all patients and screened for diabetes using FPG, HbA1c, and duration of diabetic medications (oral or insulin) were recorded. Post-operative outcome (weight loss, T2DM remission, early complications, post-op swallowable balloon concerns) data were documented (electronic healthcare records).

Follow-up

Weight-loss outcome

Subjects were asked to attend outpatient guidance sessions and were also reviewed by their physicians every month. The percentage of total weight loss [%TWL; (initial weight-current weight/initial weight) ×100] and percentage of excess weight loss [%EWL; (weight loss/(initial weight-weight at BMI 25)×100] were calculated at 1-2-3-4-5-6 month.

Diabetes outcomes classification

Diabetes remission was defined as HbA1c <6.5% without the use of any diabetes medications. Diabetes was considered improved if patients still required oral medication at lower dosages than at baseline (but no insulin) and had HbA1c <7.0%.

Criteria for reduction or withdrawal of diabetes medications

Diabetes medications were titrated, with dosage decreased if fasting and postprandial glucose levels were <120 and <160 mg/dL, respectively. Diabetes medications were discontinued if HbA1c levels remained <6.4%.

Changes in diabetes-related conditions

We also assessed other metabolic syndrome components (hypertension and dyslipidemia) as defined by The Endocrine Society guidelines [11]. Hypertension was considered resolved if a patient was normotensive (<130/80 mmHg) without blood pressure medication. Dyslipidemia was considered resolved if serum levels of these lipids normalized without lipid-lowering medication (e.g., triglycerides <150 mg/dL; LDL <130 mg/dL in patients with resolved diabetes or <100 mg/dL in patients with persistent diabetes).

Adverse events (AE)

Safety measures included the incidence of accommodative symptoms and any other side-effects or adverse events (AE) such as nausea, vomiting, nausea & vomiting extending beyond one week, abdominal pain, constipation, and GERD after the placement of swallowable balloon.

Statistical analyses

Results are expressed as the mean (standard deviation). Differences between baseline values and those at each follow-up month after swallowable balloon placement were evaluated by continuous variables. Changes from baseline in metabolic parameters were evaluated with Bonferroni-adjusted repeated-measures ANOVA. Statistical analyses were conducted using SPSS (Version 21.0. Armonk, NY: IBM Corp) software. All tests were two-sided, and P values <0.05 were considered significant.

Results

Demographic and Baseline characteristics

Table 1 shows preoperative patient characteristics pertaining to diabetic and comorbidity profiles. Balloon insertion was successfully accomplished in all patients. All patients were able to swallow the balloon capsule. No sedation or invasive procedures were needed for the successful placement of the balloon. Balloon filling was uncomplicated and X-ray control was technically easy and uneventful. Out of 42 patients, 01 patient withdraws due to adverse effects after enrolment. There were no major complications and the balloon was safely removed and was excluded from analyses. Participants underwent the swallowable balloon procedure and were serially followed postoperatively for up to 6 months only. Five patients did not attend the follow-up month visits despite reminders and did not provide data for analyses at the time point (Table 1).

Weight loss outcome

We have calculated the mean %TWL and %EWL after the insertion of swallowable balloon at regular follow-up intervals. Significant (p<0.001) improvements in EWL and TWL were noted after insertion. It was seen that their mean %TWL were 6.5 %,10.1 %, 12.7%, 15.14%,14.7%, and 14.4% at 1-2-3-4-5-6 months, respectively. The mean %EWL was 14.9%, 23.0%, 28.2%, 34.2%, 33.2%, and 32.68% at each follow-up visit post-operatively. (Table 2). Patients with %TWL and % EWL at their nadir weight after swallowable balloon process had a mean of 15.14% (95%CI 14.5-15.8) and 34.2% (95%CI 31.4-37.1) at 4

Table 1: Preoperative patient characteristics.

Patients Characteristics (n= 42)	
Male: n (%)	15 (35.7%)
Female: n (%)	27 (64.3%)
Age (years): Mean (range)	39.6 (17-61)
Height: (cm): Mean (SD)	167.9(12.9)
Weight (kg): Mean (SD)	112.5 (28.0)
BMI (kg/m^2) Mean (SD)	39.7 (13.3)
Diabetics profile	
HbA1C (%): Mean (SD)	8.6 (0.9)
FPG (mg/dL): Mean (SD)	157.8 (21.2)
Oral Diabetics Drug: n (%)	34 (81)
Insulin usage: n (%)	5 (11.9)
Oral + Insulin: n (%)	3 (7.1)
Duration of Diabetics (Years): Mean (range)	3.31 (1-11)
Comorbidity profile	
HTN: n (%)	12 (28.6)
DLP: n (%)	15 (35.7)
BMI: Body mass index; **HbA1C**: Haemoglobin A1c; **FPG**: Fasting Plasma Glucose ; **HTN**: Hypertension; **DLP**: Dyslipidemia; **Kg**: kilogram; **N**: Number; **SD**: Standard Deviation	

Table 2: Weight loss outcome post balloon insertion.

	Follow-up (n=41) (%)	**Weight (kg) Mean (SD)**	**%TWL Mean (SD)**	**%EWL Mean (SD)**	**Paired Differences**	**95 % CI (Kgs)**	**p- value**
1 Month	40 (97.5%)	106.5 (26.9)	6.5(1.3)	14.9 (5.3)	**Pre-1M**	7.5-8.3	0.001
2 Months	39 (95.1%)	102.4 (26.3)	10.1 (1.8)	23.0 (7.8)	**1M-2M**	3.9-4.8	0.001
3 Months	38 (92.6%)	99.6 (23.8)	12.7 (2.3)	28.2 (7.7)	**2M-3M**	2.4-5.1	0.001
4 Months	36 (87.8%)	96.2 (18.5)	15.1 (2.0)	34.2 (8.3)	**3M-4M**	2.4-3.9	0.001
5 Months	36 (87.8%)	98.9 (19.0)	14.7 (2.1)	33.3 (8.4)	**4M-5M**	1.1-0.4	0.001
6 Months	36 (87.8%)	100.1 (18.9)	14.4 (2.1)	32.7 (8.2)	**5M-6M**	0.3-0.04	0.012
Nadir Mean (95%CI)	**-**	96.2 (93.9-101.4)	15.1 (14.5-15.8)	34.2 (31.4-37.1)	**Regain**	2.9 kgs	
%TWL: Total Body Weight Loss; **%EWL**: Excess Weight Loss; **Kg**: Kilogram; **SD**: Standard Deviation; **CI**: Confidence Interval							

months. Patients' mean weight gain after nadir was 2.9 kgs until the end of the follow-up period (95% CI 1.1-0.04 kgs) (Table 2).

Diabetes remission outcome

The mean HbA1c for the entire cohort fell progressively throughout the study from 8.6 ±0.9 to 6.8±1.7%, and FPG fell from 157.8±21.2 to 120.1±6.5 mg/dL (P, 0.001 for both) (Figure 1A and 1B). Most of these changes, especially for HbA1c, occurred within the first 2 months.

Remission of diabetes (i.e., HbA1c,6.5% without diabetes medications) was achieved highest that is 66.7% of patients (24 of 36) at 4 months (Figure 1C), whose diabetes medications were discontinued first 2-3 months after swallowable balloon procedure. In this group, the mean duration of known diabetes was 2.4±1.8 years (range1-7). Three subjects took insulin preoperatively, and the rest used oral diabetes medications. After the 4 months, 3 patients who experienced diabetes remission based on a diabetes drug–free HbA1c, 6.5% subsequently exhibited an HbA1c greater than that level or resumed diabetes medications in later evaluations. In other words 12.5% recurrence remission during our 6-month follow-up.

Improvement of diabetes without full remission was observed in 27.8% of patients (10/36) and 36.1% of patients (13 of 36) at 4 and 6 months (Fig. 1C). This group achieved diabetes control (HbA1c,7.0%) with decreased usage of oral diabetes medications and withdrawal of insulin when previously used (at 2 months after swallowable balloon procedure). The mean duration of known diabetes in this group was 4.5±2.1 years (range 2–11). Preoperatively, three of the improved patients used insulin; the remaining used oral agents. Only two patients, with 4 months of known diabetes, showed no clear postoperative disease improvement (Figure 1).

Effects on diabetes-related conditions

Among patients with other metabolic syndrome features, hypertension resolved in 75% (9 of 12) and dyslipidemia resolved in 73.3% (11 of 15). Mean blood pressure for the entire cohort decreased progressively over 6 months (p= 0.001 for diastolic and systolic) (Figure 2), with reductions in diastolic pressure reaching statistical significance by 6 months and thereafter reductions in systolic pressure becoming significant by 1 month and thereafter. Mean lipid parameters for the group also improved steadily for 6 months. There were clear, progressive reductions in total cholesterol (p=0.001), LDL cholesterol (p=0.001), and triglycerides (P=0.003) as well as an increase in HDL cholesterol (p =0.001) (Figure 2).

Adverse events

Adverse events occurred in one patient (2.7%) or the balloon was punctured and removed during the endoscopic procedure, with immediate symptom relief. Four patients (11.1%) who developed nausea and vomiting extending beyond one week were admitted to the hospital 2 days after balloon insertion with vomiting and dehydration. Nausea and vomiting developed in 17 (47.2%) patients and there were no major complications. (Table 3) Abdominal X-ray was unremarkable, with the balloon in the expected position with no sign of gastric or small bowel dilation. The patient was admitted overnight for intravenous fluids and antiemetics with symptom relief and an uneventful course during the rest of the study period.

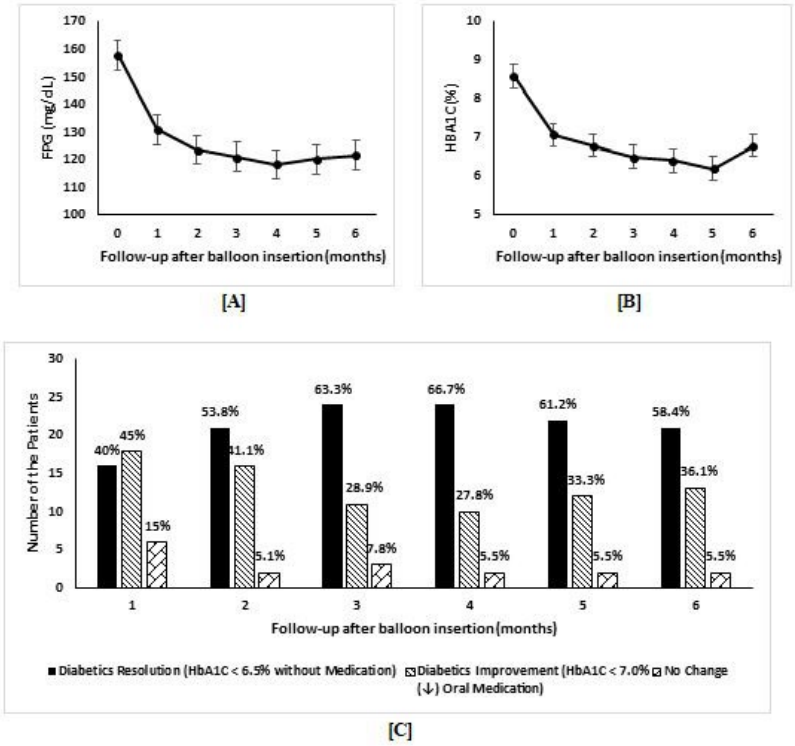

Figure 1: Improvement in diabetes during 6 months post balloon insertion. Mean (±SE) FPG (**A**) and HbA1c (**B**) for the entire cohort decreased from values representing poorly controlled diabetes, despite all patients being on diabetes medications at baseline, to the non-diabetic or normal range from 1 month through 4 months after balloon insertion, with 66.7% of patients discontinuing all diabetes medications. n= 16/40 at 1, 21/39 at 2, 24/38 at 3 24/36 at 4 22/36 and 21/36 at 6 months. (**C**) At the time of the follow-up, 58.4% of patients experienced remission of diabetes (i.e., HbA1c, 6.5% off all diabetes medications), 36.1% had improved diabetes, and only 2 individuals did not display a clear change in diabetic control. The highest remission occurred between 3- and 4 months post balloon insertion, and the 12.5% diabetes remission group subsequently experienced a recrudescence of diabetes during follow-up. Classification as diabetes improved was based on participants' status at the time of the follow-up. All patients who used insulin at baseline discontinued insulin usage between 2 and 3 months after balloon insertion. A significant difference between equivalent preoperative and postoperative measurements (P=0.001 in all cases).

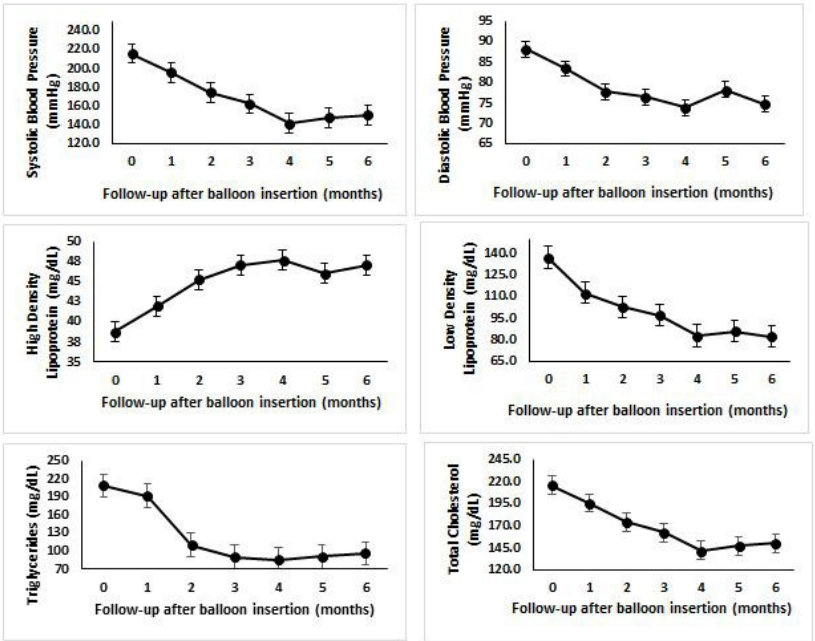

Figure 2: Improvements in blood pressure and lipid levels during 6 months post balloon insertion. Data represent means Mean(±SE) for all patients. There were significant, progressive decreases in average systolic and diastolic blood pressure (P=0.001 for both) in the entire cohort over the course of the study. There also were significant, progressive decreases over the course of the study in total cholesterol (P=0.001), LDL cholesterol (P=0.001), and triglycerides (P=0.003), as well as an increase in HDL cholesterol (P=0.001).

Discussion

Obesity is a modifiable risk factor in the development of T2DM, with the prevalence of both increasing worldwide [12] Bariatric surgery is the most fruitful, sustainable long-term therapeutic option for obesity. Among these included Roux-en-Y gastric bypass (RYGB), One-anastomosis (mini) gastric bypass (OAGB-MGB), or Sleeve gastrectomy (SG) [13,14]. Although it has efficacy in achieving weight loss and resolution of associated comorbidities, only a minority of those obese patients are eligible for surgery [15]. Difficult accessibility, cost, patient refusal or non-preference, fear of surgery, morbidity, and mortality are the major drawbacks of surgery [14]. Thus, there is a continuous search for novel, safe, and effective methods for weight loss, like endoscopic approaches, including swallowable gastric balloon [16].

Elipse swallowable balloon is a new and advanced technique under which a balloon helps to lose weight without any invasive surgery. The procedure involves a special balloon that needs to be swallowed then the balloon is filled with water while it is in the stomach. This reduces the volume of food in the stomach and is highly effective in losing weight. Unlike gastric surgery, this balloon is a temporary measure and bursts in the stomach after 16 weeks of placement, the filled water is released and the balloon itself is excreted.

Several studies in recent years have shown that data on both the efficacy and safety of the swallowable gastric balloon compare very favorably with other, longer-duration balloons [6-8,17,18]. The Orbera balloon, the most widely used endoscopically inserted intragastric balloon, is the closest in size, shape, and function to the Elipse balloon. The largest analysis by Orbera [19] shows that Orbera's early balloon removal rate is 7.5%.

In this study, swallowable balloon placement for six months resulted in a statistically significant weight loss. The mean %EWL was 14.9%, 23.0%, 28.2%, 34.2%, 33.2%, and 32.68% at 1-2-3-4-5-6 months, respectively which is similar to Buzga M, et al. [20], who obtained mean weight loss and BMI of 18.4 kg and 5.5 kg/m2, respectively, as they have the same type of swallowable balloon, like us. Moreover, this agrees with the results of Kim SH, et al. [21]. A slight weight regain was noticed 6 months after swallowable gastric balloon removal, with a decrease in %EWL from 31.4±11.8 to 22.1±14.9%, which is similar to other studies [20,21]. Results include ease of insertion, balloon safety and performance, and complications, as well as the effect of the gastric balloon on weight and metabolic parameters. Overall efficacy results are in line with those reported in previous, smaller swallowable gastric balloon studies [6-8] Moreover, our finding showed diabetes remission was 66.7% occurred between 3-and 4-months post balloon insertion, and 12.5% recrudescence of diabetes during the end of follow-up. Remission of diabetes is typically defined as lowering HbA1c to below 6.5%, indicating that the average patient in the diabetes group achieved remission after just 4 months. In patients with prediabetes, mean HbA1c decreased from 6.0% to 4.9% with a mean 15.1% percentage of TWL. Improvement of diabetes without full remission was observed in 27.8% and 36.1% of patients at 4 and 6 months. These patients achieved diabetes control with decreased usage of oral diabetes medications and withdrawal of insulin when previously used. This suggests that this may be associated with persistent and strong physiological changes during treatment, maintenance of lifestyle changes induced by continued use of the scale and applicator, or a combination of both.

In the current literature, serious complications due to gastric balloon placement are rare. Among these complications, mortality is reported at a rate of 0.05%, gastric ulcer at 0.3%, gastric perforation at 0.1%, and balloon migration at 0.09% [22]. None of our patients had any serious complications related to the balloon procedure. Only four patients developed nausea and vomiting extending beyond one week, which responded to medical management. Frequent follow-up of cases and ensuring their easy access to the physician would be an appropriate approach to minimize the risk of complications. Genco A, et al. removed the balloon within 24 h of placement in 11 of 2515 cases (0.44%) due to treatment intolerance [23]. In our study, only one patient balloon removal was done within 24 h due to intolerance. Although balloon was effective in achieving an acceptable loss of weight and diabetic management, many studies have reported that the results lasted for a brief period, and most of the patients regained weight after balloon removal like our findings [6-7,21-24]. Furthermore, advances in balloon properties and procedural techniques are required to improve its safety and efficacy. Limitations of this study included the lack of long-term data regarding the durability of the procedure in terms of weight loss and control of associated comorbidities.

Conclusion

The new emerging swallowable balloon process is excellent and limits the size of the stomach for food and helps change the eating habits of people. Our finding shows after four months of treatment, there was a reduction in HbA1c level among T2DM patients. It indicates that there are other mechanisms at work as well as, hormonal mechanisms related to the balloon when it comes to the improvement of diabetes. The results of this procedure lead to a significant amount of weight loss and diabetes control. Safety, efficacy, and short-term durability will determine the role that such a process will serve in the treatment of obesity and metabolic diseases**.** However, the balloon stays for a temporary period in the stomach. It is important to maintain a healthier lifestyle for the treatment of obesity and T2DM.

Conflict of Interest

The authors declare that they have no competing interest

Financial Disclosure

All authors declare no financial support.

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