

The Role of Gastric Balloon as an Adjunct to Lifestyle Modification in Weight Loss and Management of Type 2 Diabetes: A Prospective Study on Metabolic Outcomes and Patient Adherence

Fauwaz Fahad Alrashid^{1*}, Saeed Ali Alsareii², Alfatih Mohamed Ahmed Alnajib³, Abeer Hassan Elhaj⁴, Ahmed MS Hegazy⁵, Khalil Alshammari⁶, Mohammed Khalid Hussein Khalid⁷, Rana Aboras⁸, Muhammad Ahmad Khan⁹, Omnia Abdalla Mahmoud Higazy¹⁰, Gamal Eldin Mohammed Osman Elhussein¹¹, Hamad Turki Alreshidi¹², Samiyah Menwer Alrashdi¹³ and Mwaib Mohamed Ahmed¹⁴

¹Department, Institution and University of Ha'il, Saudi Arabia

²Department of Surgery, College of Medicine, Najran University, Saudi Arabia

³Department of Surgery College of Medicine, University of Hail, Saudi Arabia

⁴Department of Community Medicine, College of Medicine, University of Hail, Saudi Arabia

⁵Anatomy department, faculty of medicine, northern border university, Saudi Arabia

⁶Department of Internal Medicine, Al Imam Mohammad Ibn Saud Islamic University (IMSIU), Riyadh, Saudi Arabia

⁷Department of Nursing, College of Nursing and health Science, Jazan University, Saudi Arabia

⁸Department of Family and Community Medicine, College of Medicine, University of Ha'il, Saudi Arabia

⁹King Khalid Hospital, Hail, Saudi Arabia

¹⁰Department of Nursing, College of Nursing and Health Sciences, Jazan University, Saudi Arabia

¹¹Department of Pediatric College of Medicine, University of Ha'il, Saudi Arabia

¹²Ministry of Health, Hail health cluster, Saudi Arabia

¹³Health Informatics, University Clinics, University of Hail, Hail, Saudi Arabia

¹⁴Department of Anatomy, College of Medicine, University of Ha'il, Saudi Arabia

Author Designation: ^{1,3}Associate Professor, ^{4,5,7,10,11,13}Assistant Professor, ⁹Anesthesia Consultant, ¹⁴Lecturer

*Corresponding author: Fauwaz Fahad Alrashid (e-mail: Fa.Alrashid@uoh.edu.sa).

©2026 the Author(s). This is an open access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>)

Abstract Background: Obesity is a major contributor to the development and progression of type 2 diabetes mellitus (T2DM). Although lifestyle modification remains the cornerstone of management, sustained weight loss is often difficult to achieve. The intragastric balloon has emerged as a minimally invasive adjunctive therapy to enhance weight reduction and improve metabolic outcomes. **Objective:** To evaluate the effectiveness of intragastric balloon therapy as an adjunct to lifestyle modification in achieving weight loss and improving glycemic control in patients with obesity and T2DM. **Methods:** This prospective interventional study included 255 adult patients with obesity (BMI ≥ 30 kg/m²) and established T2DM. All patients underwent endoscopic intragastric balloon placement combined with structured dietary, physical activity, and behavioral counseling. The balloon was removed after six months. Patients were followed for 12 months. Primary outcomes were percentage total body weight loss (%TBWL) and change in HbA1c at six months. Secondary outcomes included fasting blood glucose, BMI reduction, medication adjustments, and safety outcomes. **Results:** The mean baseline BMI was 34.8 ± 3.9 kg/m² and mean HbA1c was $8.4 \pm 1.2\%$. At six months, mean %TBWL was $14.5 \pm 3.6\%$, and BMI decreased to 29.7 ± 3.2 kg/m². HbA1c improved significantly to $7.1 \pm 0.9\%$. At 12 months, sustained %TBWL of $11.9 \pm 3.4\%$ was observed, with HbA1c maintained at $7.3 \pm 1.0\%$. A total of 89.8% achieved $\geq 5\%$ weight loss, and 65.9% required reduction in antidiabetic medications. Early intolerance symptoms occurred in 24.3%, while 4.3% required premature balloon removal. No major complications were reported. **Conclusion:** Intragastric balloon therapy combined with lifestyle modification resulted in significant weight loss, improved glycemic control, and reduced medication requirements with an acceptable safety profile. It represents an effective intermediate option between conservative therapy and bariatric surgery for patients with obesity-related T2DM.

Key Words Intragastric Balloon, Obesity, Type 2 Diabetes Mellitus, Weight Loss, Glycemic Control, Lifestyle Modification

INTRODUCTION

Obesity has emerged as one of the most pressing global public health concerns, with its prevalence increasing steadily across both developed and developing countries. It is a well-established risk factor for numerous chronic conditions, most notably type 2 diabetes mellitus (T2DM) [1]. The pathophysiological link between obesity and T2DM is primarily mediated through insulin resistance, chronic low-grade inflammation, altered adipokine secretion, and ectopic fat deposition [2]. Excess visceral adiposity plays a particularly critical role in metabolic dysregulation, contributing to impaired glucose tolerance, beta-cell dysfunction, and progressive hyperglycemia. As a result, obesity not only increases the risk of developing T2DM but also complicates its management and accelerates the onset of cardiovascular and microvascular complications [3].

Lifestyle modification, including calorie-restricted diets, structured physical activity programs, and behavioral interventions, remains the first-line therapy for both obesity and T2DM. Clinical trials have consistently demonstrated that a 5–10% reduction in total body weight can significantly improve glycemic control, reduce HbA1c levels, enhance insulin sensitivity, lower triglycerides, and improve overall cardiovascular risk profiles [4]. However, despite strong evidence supporting lifestyle interventions, long-term adherence remains challenging. Many patients experience initial weight loss followed by gradual weight regain due to metabolic adaptation, hormonal changes affecting appetite regulation, and behavioral relapse. Pharmacological therapies for weight loss and glycemic control have expanded in recent years, including agents that target appetite suppression, glucose excretion, or incretin pathways. While these medications provide meaningful metabolic benefits, they may be associated with adverse effects, high costs, or contraindications in certain patient populations [5]. Bariatric surgery, including procedures such as sleeve gastrectomy and Roux-en-Y gastric bypass, has demonstrated profound and sustained weight loss with high rates of diabetes remission. However, surgical interventions carry inherent perioperative risks, require lifelong nutritional monitoring, and may not be suitable or accessible for all individuals with obesity and T2DM [6]. In this therapeutic landscape, endoscopic bariatric interventions have emerged as a minimally invasive alternative positioned between lifestyle therapy and surgery. Among these, the intragastric balloon (IGB), also known as the gastric balloon, has gained widespread clinical acceptance [7]. The device is inserted endoscopically and filled with saline or gas, occupying gastric volume and inducing early satiety. The presence of the balloon delays gastric emptying and promotes portion control, thereby facilitating caloric restriction. Typically placed for six months, the balloon provides a temporary mechanical aid to support structured weight management programs [8].

Clinical studies have reported total body weight loss ranging from 10–15% during the balloon placement period, with corresponding improvements in metabolic parameters. In patients with T2DM, reductions in fasting plasma glucose

and HbA1c have been documented, often accompanied by decreased requirements for antidiabetic medications [9]. These metabolic improvements are believed to result not only from weight reduction but also from enhanced insulin sensitivity and potential alterations in gut hormone signaling. Furthermore, weight loss achieved through gastric balloon therapy may reduce hepatic steatosis and improve lipid profiles, offering additional cardiometabolic benefits [10]. Nevertheless, the long-term sustainability of weight loss following balloon removal remains a key consideration. Without continued adherence to lifestyle modification, weight regain is common. Therefore, the gastric balloon should not be viewed as a standalone solution but rather as a catalyst that enhances patient engagement in dietary and behavioral change [11]. The structured support provided during the balloon period often including nutritional counseling, physical activity guidance, and psychological support plays a crucial role in optimizing outcomes. Identifying patients who are most likely to benefit from this adjunctive therapy is essential for maximizing effectiveness [12]. Safety and tolerability are also important aspects of gastric balloon therapy. Common adverse effects include nausea, vomiting, abdominal discomfort, and early intolerance, particularly during the initial adaptation period. Serious complications are rare but may include balloon deflation, migration, or gastric ulceration. Careful patient selection and close follow-up are therefore essential to minimize risks and ensure therapeutic success [13].

Objective

Methodology: This was a prospective interventional study conducted at Hail city tertiary care from January, 2025 February, 2026, to evaluate the effectiveness of intragastric balloon therapy as an adjunct to structured lifestyle modification in weight loss and management of type 2 diabetes mellitus. A total of 255 adult patients diagnosed with obesity and type 2 diabetes were enrolled during the study period. Patients aged 18–65 years with a body mass index (BMI) ≥ 30 kg/m² and established type 2 diabetes mellitus were included. Eligible participants had inadequate weight reduction or suboptimal glycemic control despite at least six months of supervised lifestyle modification. Patients with previous bariatric surgery, severe gastroesophageal reflux disease, active peptic ulcer disease, large hiatal hernia, uncontrolled psychiatric illness, pregnancy, or contraindications to endoscopy were excluded.

Intervention

All participants underwent endoscopic placement of a saline-filled intragastric balloon under conscious sedation. The balloon was filled according to manufacturer recommendations and left in situ for six months. During the balloon placement period, patients were enrolled in a structured lifestyle modification program consisting of individualized dietary counseling, caloric restriction plans, supervised physical activity recommendations, and behavioral therapy sessions. The balloon was removed endoscopically after six months.

Data Collection

Baseline data were recorded prior to balloon placement, including age, gender, BMI, weight, waist circumference, fasting blood glucose, HbA1c, lipid profile, blood pressure, and duration of diabetes. Follow-up assessments were conducted at 3 months, 6 months (at balloon removal), and 12 months' post-placement. Parameters recorded at each visit included body weight, BMI, percentage of total body weight loss (%TBWL), HbA1c levels, fasting blood glucose, changes in antidiabetic medication requirements, and adverse events. The primary outcomes were percentage total body weight loss (%TBWL) and change in HbA1c levels at six months. Secondary outcomes included changes in fasting blood glucose, BMI reduction, proportion of patients achieving $\geq 5\%$ and $\geq 10\%$ weight loss, reduction in antidiabetic medication usage, and maintenance of weight loss at 12 months. Safety outcomes included incidence of procedure-related complications and balloon intolerance.

Statistical Analysis

Data were analyzed using SPSS version 26. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Paired t-tests were used to compare baseline and follow-up continuous variables. Repeated measures analysis of variance (ANOVA)

was applied to evaluate changes over time. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the institutional review board. Written informed consent was obtained from all participants prior to enrollment. Patient confidentiality was maintained throughout the study, and all procedures were conducted in accordance with ethical standards for human research.

RESULTS

The study included 255 patients with a mean age of 44.6 ± 9.8 years. Males comprised 54.1% of the cohort. The mean baseline weight was 98.6 ± 12.4 kg, with a mean BMI of 34.8 ± 3.9 kg/m², indicating class I–II obesity. The average duration of diabetes was 6.3 ± 3.1 years. Baseline glycemic control was suboptimal, with a mean HbA1c of $8.4\pm 1.2\%$ and fasting blood glucose of 176.5 ± 32.7 mg/dL (Table 1).

Significant progressive weight reduction was observed. Mean weight decreased from 98.6 ± 12.4 kg at baseline to 84.3 ± 10.8 kg at 6 months, corresponding to $14.5\pm 3.6\%$ total body weight loss. At 12 months, mild weight regain was noted (86.9 ± 11.2 kg), but weight remained substantially

Table 1: Baseline Demographic and Clinical Characteristics (N = 255)

Variable	Category	N (%) / Mean $\pm$ SD
Age (years)	Overall	44.6 $\pm$ 9.8
Gender	Male	138 (54.1%)
Gender	Female	117 (45.9%)
Weight (kg)	Baseline	98.6 $\pm$ 12.4
BMI (kg/m ²)	Baseline	34.8 $\pm$ 3.9
Duration of diabetes (years)	Overall	6.3 $\pm$ 3.1
HbA1c (%)	Baseline	8.4 $\pm$ 1.2
Fasting blood glucose (mg/dL)	Baseline	176.5 $\pm$ 32.7

Table 2: Weight and BMI Changes Over Time (N = 255)

Parameter	Baseline	3 Months	6 Months	12 Months
Weight (kg)	98.6 $\pm$ 12.4	90.8 $\pm$ 11.6	84.3 $\pm$ 10.8	86.9 $\pm$ 11.2
BMI (kg/m ²)	34.8 $\pm$ 3.9	32.0 $\pm$ 3.5	29.7 $\pm$ 3.2	30.6 $\pm$ 3.3
% Total Body Weight Loss	—	7.9 $\pm$ 2.4	14.5 $\pm$ 3.6	11.9 $\pm$ 3.4

Table 3: Glycemic Outcomes Over Time (N = 255)

Parameter	Baseline	3 Months	6 Months	12 Months
HbA1c (%)	8.4 $\pm$ 1.2	7.6 $\pm$ 1.0	7.1 $\pm$ 0.9	7.3 $\pm$ 1.0
Fasting Blood Glucose (mg/dL)	176.5 $\pm$ 32.7	152.3 $\pm$ 28.5	138.6 $\pm$ 24.9	144.8 $\pm$ 26.2

Table 4: Weight Loss Achievement and Medication Reduction (N = 255)

Outcome	n (%)
$\geq 5\%$ weight loss at 6 months	229 (89.8)
$\geq 10\%$ weight loss at 6 months	198 (77.6)
Reduction in antidiabetic medication	168 (65.9)
Discontinuation of at least one oral agent	41 (16.1)
Insulin dose reduction	52 (20.4)

Table 5: Safety and Tolerability Outcomes (N = 255)

Adverse Event	N (%)
Early intolerance symptoms	62 (24.3)
Balloon removal due to intolerance	11 (4.3)
Major complications (perforation/migration)	0 (0)

lower than baseline. BMI reduced from 34.8 ± 3.9 kg/m² to 29.7 ± 3.2 kg/m² at 6 months, with partial maintenance at 12 months (Table 2, Figure 1).

Mean HbA1c improved from $8.4 \pm 1.2\%$ at baseline to $7.1 \pm 0.9\%$ at 6 months, demonstrating significant glycemic improvement. At 12 months, HbA1c remained improved at $7.3 \pm 1.0\%$. Fasting blood glucose declined from 176.5 ± 32.7

mg/dL to 138.6 ± 24.9 mg/dL at 6 months, with sustained improvement at 12 months (Table 3, Figure 2).

At 6 months, 89.8% of patients achieved $\geq 5\%$ weight loss and 77.6% achieved $\geq 10\%$ weight loss. Medication requirements improved substantially, with 65.9% requiring dose reduction, 16.1% discontinuing at least one oral agent, and 20.4% achieving insulin dose reduction (Table 4, Figure 3).

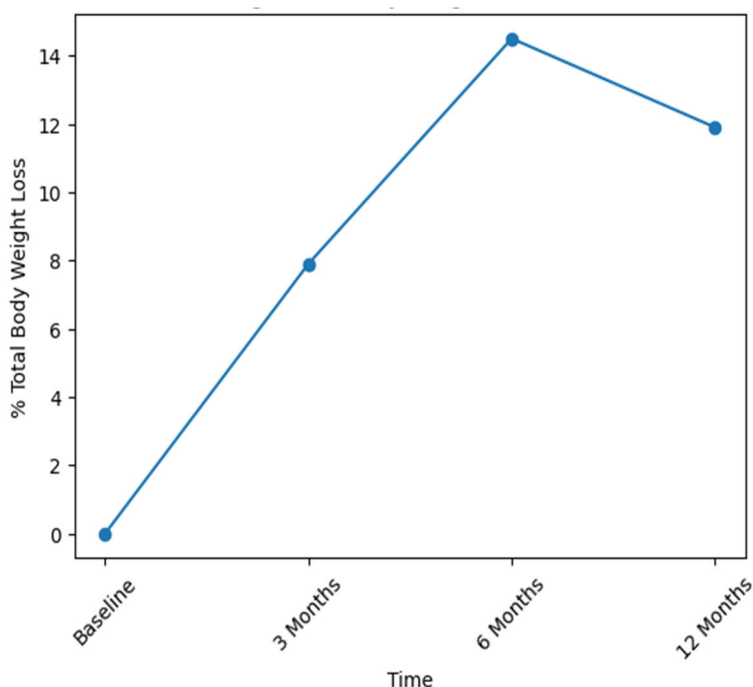


Figure 1: Percentage Total Body Weight Loss over Time

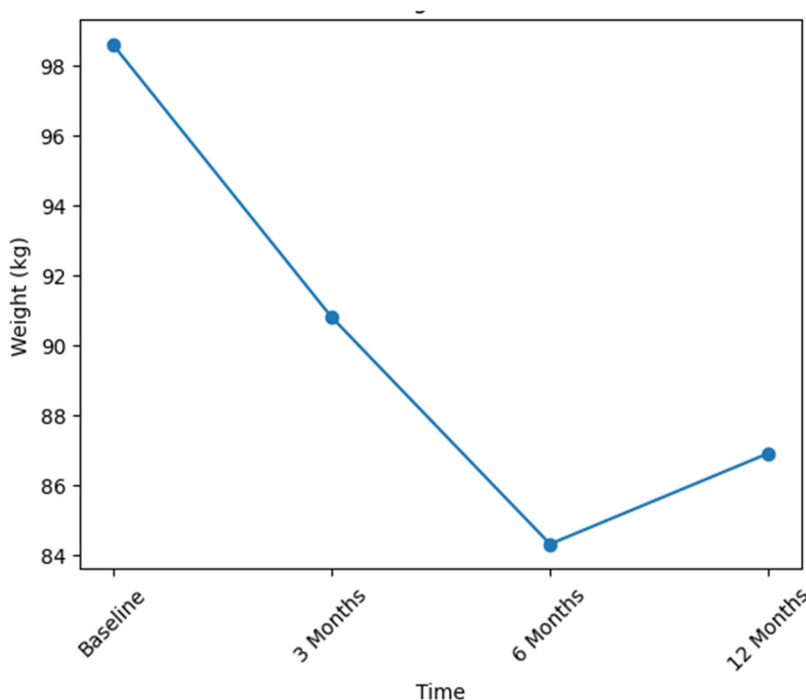


Figure 2: Mean Weight over Time

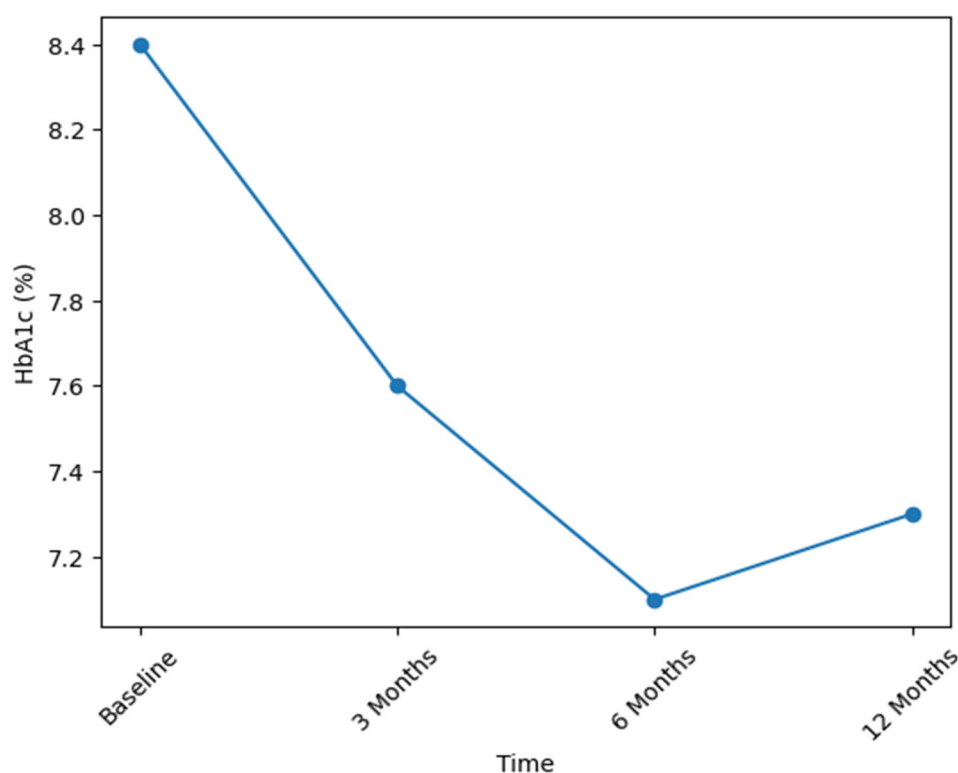


Figure 3: Mean HbA1c over Time

Early intolerance symptoms were reported in 24.3% of patients, primarily during the first week. Balloon removal due to intolerance was required in 4.3% of cases. No major complications such as perforation or migration were observed, indicating an acceptable safety profile (Table 5).

DISCUSSION

This study evaluated the effectiveness of intragastric balloon therapy as an adjunct to structured lifestyle modification in 255 patients with obesity and type 2 diabetes mellitus. The findings demonstrate significant short-term weight reduction and meaningful improvement in glycemic control, with acceptable safety and moderate weight maintenance at 12 months. The mean total body weight loss of $14.5 \pm 3.6\%$ at six months is clinically significant and exceeds the 5–10% threshold known to confer substantial metabolic benefit. Nearly 90% of patients achieved $\geq 5\%$ weight loss, and over three-quarters achieved $\geq 10\%$ weight loss, highlighting the intervention's strong efficacy during the balloon placement period. These results are consistent with previous research reporting 10–15% weight reduction with intragastric balloon therapy when combined with structured dietary and behavioral support [14]. The mild weight regains observed at 12 months, with maintained $11.9 \pm 3.4\%$ total body weight loss, reflects a common trend seen after balloon removal but still represents sustained improvement compared to baseline. Importantly, weight loss was accompanied by significant improvement in glycemic parameters. Mean HbA1c decreased from $8.4 \pm 1.2\%$ at baseline to $7.1 \pm 0.9\%$ at six

months, with maintenance at $7.3 \pm 1.0\%$ at one year. This degree of HbA1c reduction is clinically meaningful and comparable to the glycemic improvement achieved with several pharmacologic therapies [15]. Fasting blood glucose demonstrated a parallel reduction, reinforcing the metabolic benefit of weight reduction in patients with T2DM. Previous research has similarly demonstrated that intragastric balloon-induced weight loss improves insulin sensitivity and reduces glycemic burden, particularly when combined with structured lifestyle programs [16].

The reduction in antidiabetic medication requirements further underscores the therapeutic value of this approach. Nearly two-thirds of patients required dose reductions, and a notable proportion discontinued at least one oral hypoglycemic agent. Insulin dose reduction in over 20% of patients reflects improved endogenous metabolic control. Such medication de-escalation not only reduces treatment costs but also minimizes the risk of hypoglycemia and medication-related adverse effects [17]. Comparable reductions in pharmacotherapy burden have been reported in previous clinical cohorts undergoing endoscopic bariatric therapy. The safety profile observed in this study aligns with established data on intragastric balloon therapy. Early intolerance symptoms were relatively common but generally self-limiting. Only 4.3% required premature removal, and no major complications were reported. This supports the role of gastric balloon therapy as a minimally invasive and relatively safe alternative for patients who are not candidates for bariatric surgery or prefer less invasive interventions

[18]. However, careful patient selection and close follow-up remain essential to minimize adverse events. A key finding of this study is the importance of adjunctive lifestyle modification. The sustained improvement at 12 months, despite balloon removal at six months, suggests that structured dietary counseling and behavioral reinforcement contributed significantly to maintenance of outcomes. Previous research has emphasized that without ongoing lifestyle support, weight regain is common after balloon removal [19]. Therefore, the gastric balloon should be viewed as a facilitator of behavioral change rather than a standalone solution. While bariatric surgery remains the most effective intervention for long-term weight loss and diabetes remission, not all patients qualify for or accept surgical procedures. In this context, the gastric balloon provides an intermediate option with meaningful metabolic impact and lower procedural risk. For patients with moderate obesity and poorly controlled T2DM, this approach may serve as a valuable bridge therapy [20-21].

Limitations

This study has several limitations that should be considered when interpreting the findings. First, although the sample size was relatively large ($n = 255$), the study was conducted at a single center, which may limit the generalizability of the results to other populations or healthcare settings. Differences in patient selection, lifestyle counseling intensity, and follow-up protocols across institutions could influence outcomes. Second, the study did not include a control group receiving lifestyle modification alone. Therefore, while significant improvements were observed, it is not possible to quantify the independent contribution of the intragastric balloon beyond structured lifestyle intervention. A randomized controlled design would provide stronger evidence regarding comparative effectiveness. Third, the follow-up duration was limited to 12 months. Although weight loss and glycemic improvements were largely maintained at one year, longer-term follow-up is necessary to determine durability of results and long-term impact on diabetes remission, cardiovascular risk, and weight maintenance.

CONCLUSION

It is concluded that intragastric balloon therapy, when used as an adjunct to structured lifestyle modification, is an effective and minimally invasive strategy for achieving significant weight loss and improving glycemic control in patients with obesity and type 2 diabetes mellitus. The intervention resulted in meaningful reductions in body weight, BMI, HbA1c, and fasting blood glucose, along with decreased antidiabetic medication requirements. Although mild weight regain was observed after balloon removal, substantial metabolic benefits were maintained at 12 months. With an acceptable safety profile, the gastric balloon represents a valuable intermediate option between conservative management and bariatric surgery. Long-term

follow-up and controlled studies are warranted to further assess durability and optimize patient selection.

REFERENCES

- [1] Jense M.T.F. *et al.* "The swallowable intragastric balloon combined with lifestyle coaching: Short-term results of a safe and effective weight loss treatment for people living with overweight and obesity." *Obesity Surgery*, vol. 33, no. 6, 2023, pp. 1668–1675. <https://doi.org/10.1007/s11695-023-06573-8>.
- [2] Barakat K. *et al.* "Adjunctive semaglutide in patients undergoing intragastric balloon for weight loss: 12-month prospective comparative study." *Obesity Surgery*, vol. 35, 2025, pp. 5398–5409. <https://doi.org/10.1007/s11695-025-08368-5>.
- [3] Eisenberg D. *et al.* "2022 American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) indications for metabolic and bariatric surgery." *Obesity Surgery*, vol. 33, no. 1, 2023, pp. 3–14. <https://doi.org/10.1007/s11695-022-06332-1>.
- [4] Zorginstituut Nederland. "Medicijn Saxenda in basispakket voor kleine groep met ernstig overgewicht." 2022. <https://www.zorginstituutnederland.nl/actueel/nieuws/2022/02/28/medicijn-saxenda-in-basispakket-voor-kleine-groep-met-ernstig-overgewicht>.
- [5] Zorginstituut Nederland. "GVS-advies naltrexon in combinatie met bupropion (Mysimba®) voor de behandeling van obesitas." 2022. <https://www.zorginstituutnederland.nl/publicaties/adviezen/2022/05/17/gvs-advies-naltrexon-in-combinatie-met-bupropion-mysimba>.
- [6] Apovian C.M. *et al.* "Pharmacological management of obesity: An Endocrine Society clinical practice guideline." *Journal of Clinical Endocrinology & Metabolism*, vol. 100, no. 2, 2015, pp. 342–362. <https://doi.org/10.1210/jc.2014-3415>.
- [7] May M. *et al.* "Modern pharmacological treatment of obese patients." *Therapeutic Advances in Endocrinology and Metabolism*, vol. 11, 2020, p. 2042018819897527. <https://doi.org/10.1177/2042018819897527>.
- [8] Sudlow A.C. *et al.* "Review of advances in anti-obesity pharmacotherapy: Implications for a multimodal treatment approach with metabolic surgery." *Obesity Surgery*, vol. 29, no. 12, 2019, pp. 4095–4104. <https://doi.org/10.1007/s11695-019-04206-7>.
- [9] Kotinda A. *et al.* "Efficacy of intragastric balloons for weight loss in overweight and obese adults: A systematic review and meta-analysis of randomized controlled trials." *Obesity Surgery*, vol. 30, no. 7, 2020, pp. 2743–2753. <https://doi.org/10.1007/s11695-020-04558-5>.
- [10] Silva L.B. and Neto M.G. "Intragastric balloon." *Minimally Invasive Therapy & Allied Technologies*, vol. 30, no. 1, 2021, pp. 1–10. <https://doi.org/10.1080/13645706.2020.1765325>.
- [11] Ramai D. *et al.* "Influence of the Elipse intragastric balloon on obesity and metabolic profile: A systematic review and meta-analysis." *Journal of Clinical Gastroenterology*, vol. 55, no. 10, 2021, pp. 836–841. <https://doi.org/10.1097/MCG.0000000000001484>.
- [12] Ienca R. *et al.* "The procedureless Elipse gastric balloon program: Multicenter experience in 1770 consecutive patients." *Obesity Surgery*, vol. 30, no. 9, 2020, pp. 3354–3362. <https://doi.org/10.1007/s11695-020-04539-8>.

- [13] Brethauer S.A. *et al.* "Standardized outcomes reporting in metabolic and bariatric surgery." *Surgery for Obesity and Related Diseases*, vol. 11, no. 3, 2015, pp. 489–506. <https://doi.org/10.1016/j.soard.2015.02.003>.
- [14] Jamal M.H. *et al.* "The safety and efficacy of procedureless gastric balloon: Short- and medium-term effects on weight loss with 1-year follow-up post-removal." *Obesity Surgery*, vol. 29, no. 4, 2019, pp. 1236–1241. <https://doi.org/10.1007/s11695-018-03671-w>.
- [15] Raftopoulos I. and 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." *Surgery for Obesity and Related Diseases*, vol. 13, no. 7, 2017, pp. 1174–1182. <https://doi.org/10.1016/j.soard.2017.02.016>.
- [16] Genco A. *et al.* "Safety and efficacy of a new swallowable intragastric balloon not needing endoscopy: Early Italian experience." *Obesity Surgery*, vol. 28, no. 2, 2018, pp. 405–409. <https://doi.org/10.1007/s11695-017-2877-1>.
- [17] Vargas E.J. *et al.* "Single fluid-filled intragastric balloon safe and effective for inducing weight loss in a real-world population." *Clinical Gastroenterology and Hepatology*, vol. 16, no. 7, 2018, pp. 1073–1080.e1. <https://doi.org/10.1016/j.cgh.2018.01.046>.
- [18] Khatoon F. *et al.* "Correlation of vitamin D levels with TNF- α and IL-6 expression in insulin-resistant type 2 diabetes mellitus patients." *Scientific Reports*, vol. 16, 2026, pp. 28142. <https://doi.org/10.1038/s41598-026-57757-y>.
- [19] Gaur S. *et al.* "Balancing risk and reward: A critical review of the intragastric balloon for weight loss." *Gastrointestinal Endoscopy*, vol. 81, no. 6, 2015, pp. 1330–1336. <https://doi.org/10.1016/j.gie.2015.01.054>.
- [20] Zheng Y. *et al.* "Short-term effects of intragastric balloon in association with conservative therapy on weight loss: A meta-analysis." *Journal of Translational Medicine*, vol. 13, 2015, pp. 246. <https://doi.org/10.1186/s12967-015-0607-9>.
- [21] Ciprian G. *et al.* "Endoscopy management of complete gastric outlet obstruction secondary to Elipse intragastric balloon." *Cureus*, vol. 13, no. 8, 2021, pp. e17542. <https://doi.org/10.7759/cureus.17542>.