



Short-term outcomes of endoscopic sleeve gastroplasty

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Abstract

Background Obesity is a chronic disease with significant health implications and its prevalence has risen sharply worldwide. While metabolic and bariatric surgery (MBS) is the most effective intervention for obesity, not all patients qualify or wish to undergo surgery. Endoscopic sleeve gastroplasty (ESG) has emerged as an effective and safe minimally invasive alternative. However, mid-term outcome data remain limited, particularly in the Kuwaiti population. This study aims to evaluate the short-term efficacy and safety of ESG in this demographic.

Methods A prospective cohort study was conducted at a public hospital in Kuwait, enrolling 61 patients between January 2023 and August 2024. Inclusion criteria included adults (≥ 18 years) with a BMI > 30 kg/m² or > 27.5 kg/m² with comorbidities who underwent ESG, with a follow-up period of 12 months. Weight loss and safety outcomes were assessed.

Results Of the 61 patients, 49 completed 12 months of follow-up. Mean %TBWL was 6.7% at 2 weeks, 10.6% at 3 months, 13.4% at 6 months, 15.1% at 9 months, and 16.1% at 12 months ($p < 0.0001$). At 12 months, 57% of patients achieved $> 15\%$ %TBWL and 20% attained a normal BMI (< 25 kg/m²). ESG demonstrated a favorable safety profile, with a low number of mild complications and none of the patients required an invasive intervention.

Conclusion ESG is an effective and safe intervention for weight loss in the Kuwaiti population, yielding significant weight reduction and a low complication rate over 12 months. These findings support its role as a viable alternative for individuals who do not qualify for or prefer to avoid MBS. Future research should focus on long-term outcomes and larger multicenter studies to further validate these results.

Keywords Endoscopic sleeve gastroplasty · Obesity · Minimally invasive · Weight management

Introduction

Obesity is a complex chronic disease with a wide variety of metabolic and mechanical detrimental health effects and decreases life expectancy in affected patients. It is considered a global health crisis, with its prevalence nearly tripling since 1975, affecting over 650 million adults worldwide [1, 2]. According to the Kuwait Nutrition Surveillance system, the prevalence of obesity in adults is at an alarming level of 38.1%, while a further 38.5% were classified as overweight [3]. Although metabolic and bariatric surgery (MBS) is the most effective treatment for obesity and obesity-related diseases compared to non-surgical treatment modalities, not all patients are candidates for MBS [4]. MBS is recommended for individuals with a body mass index (BMI) ≥ 35 kg/m², regardless of the presence, absence, or severity of obesity-related diseases. Individuals with metabolic disease and a

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BMI of 30–34.9 kg/m² can also be considered for MBS [5]. Patients who do not fit the criteria for MBS, those who have contraindications to surgery, or do not wish to undergo a surgical intervention may benefit from other modalities of treatment.

Minimally invasive endoscopic bariatric and metabolic therapies (EBMTs) have emerged as viable alternatives for patients seeking effective weight loss with reduced risks and shorter recovery times. Among these, endoscopic sleeve gastroplasty (ESG) has gained traction for its ability to reduce gastric volume and alter gastric motility, mimicking some of the mechanisms of surgical sleeve gastrectomy [6]. ESG involves the placement of full-thickness sutures along the greater curvature of the stomach, creating a sleeve-like configuration. Compared to bariatric surgery, ESG is less invasive and has a lower-risk profile [7].

Recent studies have also explored the role of ESG in early intervention for obesity. A multicenter international study by Burlandi et al. demonstrated the efficacy of ESG in an overweight population of 189 patients with an average body mass index (BMI) of 27 kg/m², with an average %TBWL of 15% at 12 months, suggesting its potential as an early tool to prevent the progression to severe obesity [8]. ESG was also found to be effective across all obesity classes in a multicenter retrospective study, with the biggest benefit found to be in patients with class III obesity [9].

Finally, the landmark MERIT trial, a prospective, multicenter, randomized study by Abu Dayyeh et al., demonstrated that ESG achieved an average %TBWL of 13.6% at 12 months in patients with class 1 and 2 obesity, compared to 0.8% in a control group treated with lifestyle modifications alone, further supporting its efficacy in this population [10].

Recently, the International Federation of the Surgery of Obesity and Metabolic Disorders (IFSO) published an evidence-based review and position statement on ESG for obesity management. In this systematic review and meta-analysis that included a total of more than 15,000 patients, the authors analyzed the outcomes of ESG with a follow-up period reaching 60 months and showed that ESG resulted in significant total body weight loss (%TBWL) of 15–17% with sustained weight loss at 5 years. Based on these results, the IFSO Bariatric Endoscopy Committee endorsed endoscopic sleeve gastroplasty (ESG) as an effective treatment for obesity, particularly for patients with class I and II obesity and for those with class III obesity who are not candidates for metabolic bariatric surgery [11].

Despite the growing adoption of ESG, data on its outcomes, including weight loss durability and safety profile, remain limited, especially among different populations. To our knowledge, this is the only study from Kuwait assessing the weight loss outcomes and safety profile of ESG among our population.

Materials and methods

Study design and population

The study is reported according to The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [12]. This is a prospective cohort study conducted in a public hospital in the state of Kuwait and was registered and granted ethical approval by the standing ethical committee of the Ministry of Health, Kuwait (2022/2100).

After consultation with the participating surgeons, eligible patients were recruited between January 2023 and August 2024. Patients included in the study were adults aged ≥ 18 years with BMI > 30 kg/m² and BMI > 27.5 kg/m² with existing obesity-related comorbidities, such as hypertension, type 2 diabetes mellitus, or cardiovascular disease. Patients were excluded if they were < 18 years old or had any contraindication to ESG, including eating disorders, history of Crohn's disease, severe gastroesophageal reflux disease (GERD), large hiatal hernia, bleeding disorders, or patients on anticoagulation, history of varices, pregnancy, and previous gastric surgery. Severe GERD was defined as patients who had significant symptoms of reflux or those who were dependent on anti-acid medications. Patients were offered MBS if they were found eligible but were still offered ESG if they chose not to undergo surgery. Patients who received concomitant medical weight loss therapy were still included in the study.

Anthropometric measurements, including weight, height, and BMI, were taken for each patient at the initial consultation, along with percentage of total body weight loss (%TBWL) and post-procedural complications at 2-week, 3-month, 6-month, 9-month, and 12-month post-procedure. Additional follow-up was scheduled as needed. Patients were assigned to receive a consultation with a clinical nutritionist before and after the procedure and were encouraged to walk at least 10,000 steps per day and to follow a high-protein diet with a maximum of 1500 kcal/ day.

Written informed consent was obtained from all the patients to participate in the study and to access their electronic medical data for research purposes. Each participant was assigned a unique study identification number, and the research dataset was anonymized and stored securely in a password-protected device accessible only to the research team.

Description of the procedure and post-procedure protocol

The OverStitch system (Apollo Endosurgery, Austin, Texas, USA) device was used to create the narrowed stomach. On average 4–6 U-shaped stitches using non-absorbable sutures were applied starting at the antrum on the greater curvature side in a retrograde fashion, while sparing the fundus. A diagnostic endoscopy was performed before and after the procedure, and an esophageal overtube was used throughout the procedure to protect the esophagus. All procedures were performed under general anesthesia using CO₂ insufflation.

Post-procedure, the patients were prescribed intravenous Ondansetron 8 mg every 8 h, Omeprazole 40 mg, and paracetamol 1 g every 6 h for the first 48 h. Clexane was started 24 h after the procedure and continued for 10 days. Patients were discharged 48 h after the procedure. A phone follow-up was instituted for all patients in the first 3 days post-procedure, and if the patient was thought to be dehydrated or could not tolerate oral intake, then they were offered intravenous hydration and antiemetics on an outpatient basis. Patients were prescribed proton-pump inhibitors (Omeprazole 40 mg) daily for 3 months, along with multivitamins. Fluid hydration was permitted for the first 24 h. During the first week, a gradual progression to a semi-liquid diet (yogurt, mashed potatoes, clear soup, pureed vegetables, and eggs) was recommended. At the beginning of the second week, the diet was progressed to a hypocaloric, textured diet plan. Patients were encouraged to exercise regularly. Patients were followed up 2 weeks postoperatively and every 3 months for the first year and then twice yearly with the surgeon and the dietitian.

Statistical analysis

Descriptive statistics were reported as means (standard deviation, SD) or counts and percentages (%). Mixed-effect analysis, with Geisser-Greenhouse correction, was performed between baseline, 2 weeks, 3 months, 6 months, 9 months, and 12 months to measure weight, BMI change, and %TBWL over time. Tukey's multiple comparison test with individual variances was computed for each comparison. *P* values ≤ 0.05 were considered statistically significant. Analysis was conducted using GraphPad Prism 10.4.1.

Results

Baseline characteristics of the study population

61 patients underwent ESG and were included in the study; 53 were female (86.8%), with a mean age of 40.6 years

(SD $\pm$ 8.6). The mean initial weight and BMI were 83.7 kg (SD $\pm$ 11.3) and 32.5 kg/m² (SD $\pm$ 3.2), respectively. Of 61 patients, 49 patients completed 12 months of follow-up. Three patients had type 2 diabetes, 1 had pre-diabetes, 7 had hypertension, and 4 patients had dyslipidemia. Other comorbidities, including anemia, polycystic ovarian syndrome, irritable bowel syndrome, hyperthyroidism, eczema, G6PD deficiency, and obstructive sleep apnea, were noted in 21 patients (Table 1).

Weight loss

The %TBWL was 6.7% (SD: 3.1%; *p* < 0.0001) at 2-week, 10.6% (SD: 4.0%; *p* < 0.0001) at 3-month, 13.4% (SD: 4.9%; *p* < 0.0001) at 6-month, 15.1% (SD: 5.8%; *p* < 0.0001) at 9-month, and 16.1% (SD: 7.4%; *p* < 0.001) at 12-month post-procedure (Table 2, Fig. 1).

The mean BMI was 30.4 (SD: 3.1; *p* = 0.004) at 2 weeks, 29.0 (SD: 2.9; *p* < 0.0001) at 3 months, 28.1 (SD: 2.9; *p* < 0.0001) at 6 months, 27.6 (SD: 3.1; *p* < 0.0001) at 9 months, and 27.2 (SD: 3.3; *p* < 0.0001) at 12 months (Table 2, Fig. 1). At 12 months, of the 49 patients, 10 patients achieved normal BMI (< 25 kg/m²) (Table 2). Moreover, 28 patients (57%) achieved > 15% of %TBWL, while 9 patients (18.3%) achieved > 20% of %TBWL (Table 3, Fig. 2). Among the cohort, there were 11 patients on concomitant medical therapy (4 patients on Semaglutide and 7 on Tirzepatide) and achieved %TBWL of 16.2%. Only 7 patients on medical therapy had follow-up at 12 months, with %TBWL of 18.4%. In subgroup analysis, there was no difference in weight loss outcomes between the patients on concomitant medical therapy and the rest of the cohort.

Table 1 Baseline characteristic of the patients

Variable	All patients (<i>n</i> = 61) Mean (SD)/ <i>n</i> (%)
Age (years)	40.6 (8.6)
Sex (female/male)	53/8
Pre-procedure weight (kg)	83.7 (11.3)
Pre-procedure BMI (kg/m ²)	32.5 (3.2)
Comorbidities	
Pre-diabetes	1 (1.6%)
Diabetes	3 (4.9%)
Hypertension	7 (11.5%)
Dyslipidemia	4 (6.6%)
Others*	21 (34.4%)

SD, Standard deviation; BMI, Body mass index

*Other comorbidities include anemia, polycystic ovarian syndrome, irritable bowel syndrome, hyperthyroidism, eczema, G6PD deficiency, and obstructive sleep apnea

Table 2 Weight loss outcomes

Patients	Baseline	2-week post-ESG (n=61)	3-month post-ESG (n=56)	6-month post-ESG (n=55)	9-month post-ESG (n=53)	12-month post-ESG (n=49)	p value
Weight (kg) (SD)	83.7 ± 11.3	78.1 ± 10.7	75.2 ± 10.4	72.8 ± 10.4	71. ± 10.2	70.9 ± 10.5	$p < 0.05$
BMI (kg/m ²) (SD)	32.5 ± 3.2	30.4 ± 3.1	29.0 ± 2.9	28.1 ± 2.9	27.6 ± 3.1	27.2 ± 3.3	$p < 0.05$
%TBWL (SD)	N/A	6.7 ± 3.1	10.6 ± 4.0	13.4 ± 4.9	15.1 ± 5.8	16.1 ± 7.4	$p < 0.05$
BMI ≥ 34 (n)	11	9	4	2	2	1	N/A
BMI ≤ 25 (n)	N/A	0	2	5	8	10	N/A

SD, standard deviation; BMI, body mass index; %TBWL, percentage of total body weight loss; N/A, not applicable; n, number of patients
 p value < 0.05 is considered statistically significant

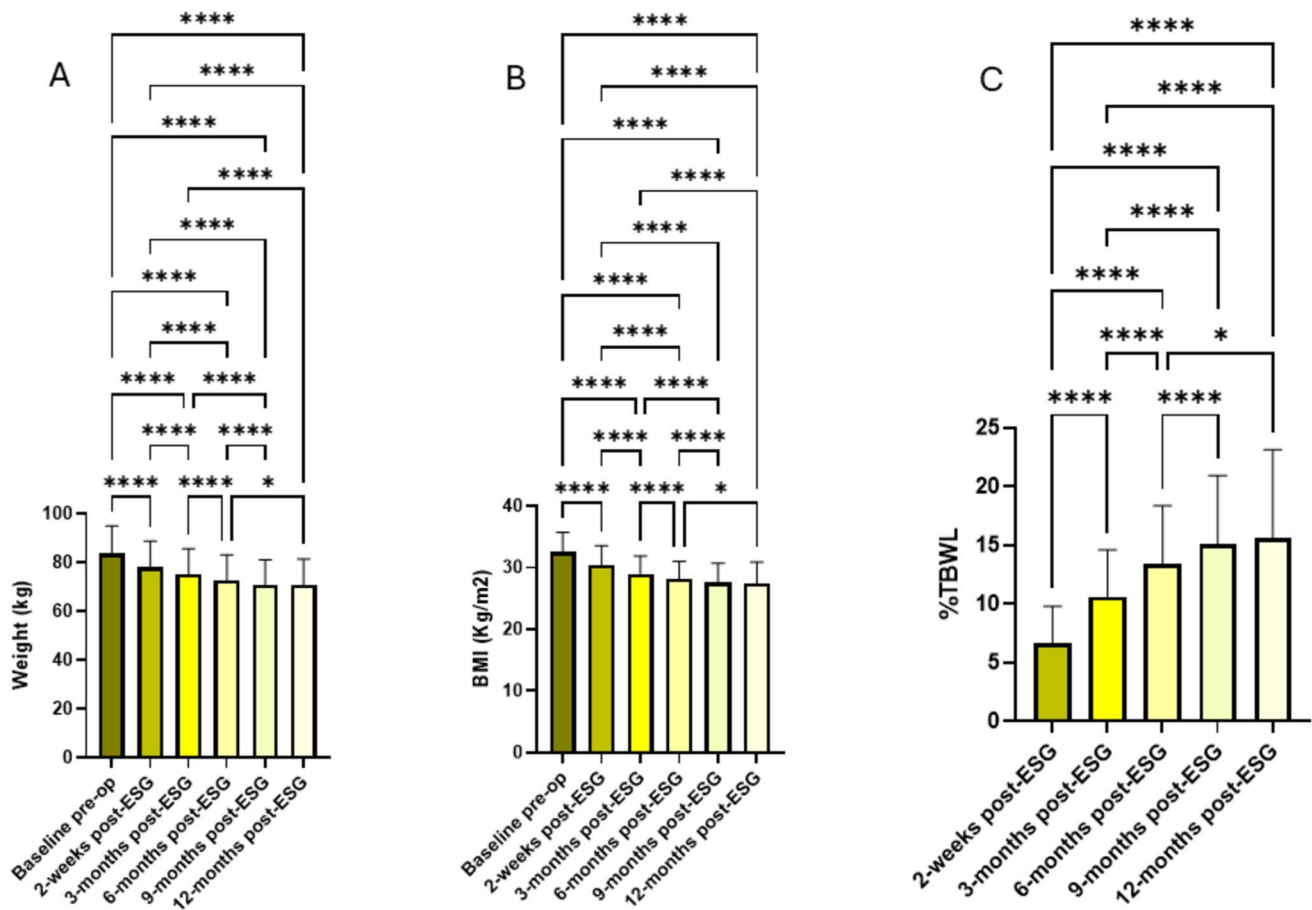


Fig. 1 **A** Mean change in weight (kg) from baseline to post-ESG at 2 weeks, 3 months, 6 months, 9 months, and 12 months, **B** mean BMI (kg/m²) change from baseline to post-ESG at 2 weeks, 3 months, 6 months, 9 months, and 12 months, and **C** percentage of total body

weight loss (%TBWL) post-ESG at 2 weeks, 3 months, 6 months, 9 months, and 12 months. Statistical assessment was done using mixed-effect analysis and considered statistically significant at * $P < 0.05$; **** $P < 0.0001$

Post-procedure complications

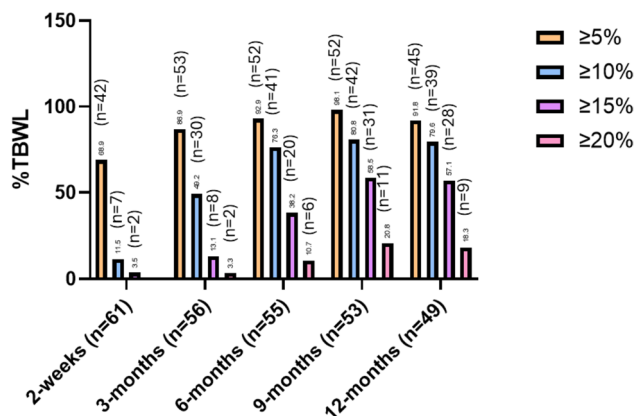
One patient was admitted with recurrent abdominal pain associated with diarrhea with a negative work-up except for positive *Helicobacter pylori* on endoscopy and received appropriate antibiotic therapy. One patient was readmitted with symptomatic anemia and melena, and gastroscopy

showed clean-based ulcer in the antrum without evidence of active bleeding and was managed conservatively. Two patients reported recurrent constipation, and 2 patients reported persistent nausea for more than 2 weeks and required outpatient oral anti-emetic therapy but did not require hydration therapy. None of the patients required surgical intervention.

Table 3 Change in percentage of total body weight loss over time

Time interval	> 5%TBWL	> 10%TBWL	> 15%TBWL	> 20%TBWL
2 weeks (<i>n</i> = 61)	68.9% (<i>n</i> = 42)	11.5% (<i>n</i> = 7)	3.5% (<i>n</i> = 2)	0
3 months (<i>n</i> = 56)	86.9% (<i>n</i> = 53)	49.2% (<i>n</i> = 30)	13.1% (<i>n</i> = 8)	3.3% (<i>n</i> = 2)
6 months (<i>n</i> = 55)	92.9% (<i>n</i> = 52)	76.3% (<i>n</i> = 42)	38.2% (<i>n</i> = 21)	10.7% (<i>n</i> = 6)
9 months (<i>n</i> = 53)	98.1% (<i>n</i> = 52)	80.8% (<i>n</i> = 42)	58.5% (<i>n</i> = 31)	20.8% (<i>n</i> = 11)
12 months (<i>n</i> = 49)	91.8% (<i>n</i> = 45)	79.6% (<i>n</i> = 39)	57.1% (<i>n</i> = 28)	18.3% (<i>n</i> = 9)

%TBWL, Percentage of total body weight loss; *n*, Number of patients

**Fig. 2** Percentage of patients who achieved percentage of total body weight loss (%TBWL) $\geq 5\%$, $\geq 10\%$, $\geq 15\%$, and $\geq 20\%$ at 2-week, 3-month, 6-month, 9-month, and 12-month post-ESG

Discussion

Obesity is a major global health issue, with its rates rising sharply in recent decades. Although metabolic and bariatric surgery (MBS) is acknowledged as the most effective solution for obesity and its associated health issues, not all patients are willing to undergo surgery, and it is not suitable for everyone. Consequently, the introduction of minimally invasive endoscopic bariatric and metabolic therapies (EBMTs), such as endoscopic sleeve gastropasty (ESG), offers a viable alternative for individuals who do not qualify for surgical options. Our study aimed to evaluate the short-term outcomes of ESG among the Kuwaiti population, focusing on weight loss, safety, and the durability of these outcomes. The results demonstrated significant weight loss over the 12-month follow-up period, with an average total body weight loss (%TBWL) of 16.1%. This aligns with previous studies, including the landmark MERIT trial [10], which emphasized ESG's efficacy in promoting weight loss, particularly among patients with class I and II obesity. Notably, our findings also indicated that 20% of patients achieved a normal BMI ($< 25 \text{ kg/m}^2$) at 12 months and 57% achieved over 15% of %TBWL, underscoring ESG's potential as a viable intervention for weight management.

The safety profile of ESG was also a critical aspect of our study. The complications observed were relatively mild and manageable, with one patient experiencing recurrent abdominal pain related to *Helicobacter pylori* infection, and another requiring readmission for symptomatic anemia due to a clean-based ulcer. Importantly, no invasive interventions were necessary for any of the patients. In the MERIT trial, the overall complication rate was reported to be relatively low, with major complications occurring in less than 5% of patients [10]. The most common adverse events included nausea, abdominal pain, and transient dysphagia, all of which were manageable without the need for invasive interventions.

Furthermore, a systematic review and meta-analysis by Hedjoudje et al. [14] analyzed data from 8 original studies spanning 2016 to 2019 and included 1772 patients, reported mean %TBWL at 15.1% with a low complications rate of 2.2% which included pain or nausea requiring hospitalization, upper gastrointestinal bleeding, and peri-gastric leak or fluid collection. A prospective study by Sharaiha et al. [15] included a total of 216 patients who underwent ESG from 2013 to 2019. Five-year follow-up was obtained on 68 patients which constituted 82% of the patients eligible for 5-year follow-up. The mean TBWL at 5 years was 15.9% (95% CI 11.7–20.5, $p < 0.001$). Most of the adverse events were mild including nausea, vomiting, epigastric pain, and short duration of heartburn. No bleeding was observed and only two patients had peri-gastric leak. One patient was managed with antibiotics only and the other required percutaneous drainage with antibiotics, but none required surgery. One patient in that cohort required endoscopic reversal due to pain occurring 18-month post-procedure. No severe complications rate nor mortality were observed. These studies highlight the long-term safety and efficacy of ESG. In the current study, we reported initial experience which, theoretically, should carry a relatively higher complications rate; however, despite that, we were able to achieve low rates consistent with the literature.

The study's design and methodology adhered to rigorous standards, including ethical approval and comprehensive follow-up protocols. Patients received continuous support post-procedure, including nutritional counseling and exercise recommendations, which are crucial for

sustaining weight loss and promoting healthy lifestyle changes. The structured follow-up regimen allowed for the timely identification of complications and reinforced the importance of patient adherence to dietary and lifestyle modifications.

Despite the promising outcomes, our study has several limitations. The relatively small sample size of 61 patients and the single-center design may limit the generalizability of the findings, and the true incidence of rare complications may not be captured. Additionally, the study's follow-up duration of 12 months limits the assessment of the long-term sustainability of weight loss and the potential for weight regain. Future research should aim to include larger, multicenter cohorts with extended follow-up periods to better understand the long-term effects of ESG. Finally, some of the patients included in the study were concurrently on GLP-1 or GLP-1/GIP agonists, and although subgroup analysis showed no difference in the weight loss outcomes of those patients compared to the rest of the cohort, this may be due to the small number of patients on these medications. Further studies with larger cohorts should address the effect of concurrent medical therapy on the weight loss outcomes of ESG.

The findings from this study contribute to the growing body of literature supporting ESG as an effective intervention for obesity management, particularly in populations with limited access to metabolic and bariatric surgery. The endorsement of ESG by the International Federation of the Surgery of Obesity and Metabolic Disorders (IFSO) reinforces its potential role in clinical practice, especially for patients with class I and II obesity or those with class III obesity who are not surgical candidates. However, we anticipate multiple potential hurdles in the wide adoption of ESG among our population, mainly that only a fraction of the cost of ESG is covered by the national health plan, which constitutes a significant financial burden on patients and may limit access to this promising procedure, and secondly, only a small number of specialists in Kuwait are trained in performing ESG, further limiting this access.

In conclusion, ESG represents a promising alternative for effective weight loss in individuals struggling with obesity. Our study highlights the procedure's efficacy and safety profile in the Kuwaiti population, providing valuable insights into its application as a treatment modality. As the prevalence of obesity continues to rise, it is imperative to explore and implement diverse treatment options that cater to the varying needs of patients. Continued research and clinical trials will be essential to further validate these findings and to refine the protocols surrounding ESG, ensuring that it remains a viable and effective option for those seeking to improve their health and quality of life through weight management.

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Declarations

Conflict of interest Drs. Mohammad Jamal, Mohsen Alhashemi, Saad Althuwaini, Khaled Alsharaf, Meshari Almuanna, Yousef Alshamali, Ahmed Almousawi, Ismael AlJazzaf, Suleiman Alsayegh, Muneerah Almuahini, Sara Al-Hassani, and Carol Dsouza have no conflicts of interest or financial ties to disclose.

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