Endoscopic sleeve gastroplasty safety profile – retrospective, single-center analysis of 222 consecutive patients including the learning curve period

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Abstract

Introduction: *The global obesity epidemic affects over 1.9 billion adults, with an additional 650 million classified as obese. Endoscopic sleeve gastroplasty (ESG) is a type of minimally invasive endobariatric procedure. It is a less invasive alternative to laparoscopic sleeve gastrectomy (LSG). Although the effectiveness of ESG is lower, it might have a better safety profile.*
Aim: *To assess the safety profile of ESG and describe complications classified as grade II or higher, using the Clavien-Dindo classification, with an overview of the learning curve.*
Material and methods: *We included 222 patients who underwent ESG at the Endoscopic and Bariatric Surgery Center of the hospital in Brzeziny from January 2021 to October 2023. The severity of complications was evaluated based on the Clavien-Dindo classification, considering complications of grade II or higher.*
Results: *Among the studied group of patients, a total of 4 (1.8%) cases of perioperative bleeding into the gastrointestinal tract were recorded. One (0.5%) patient had the most severe grade IVb complication that required treatment in the Intensive Care Unit. All patients with serious adverse events (SAE) fully recovered. We did not observe an association between the learning curve, procedure duration, and the frequency or severity of postoperative complications.*
Conclusions: *The presented results confirm the high safety of ESG in the treatment of obesity.*

Key words: *obesity, complications, bariatric surgery, sleeve gastrectomy, endoscopic sleeve gastroplasty.*

Introduction

Obesity is a worldwide epidemic with more than 1.9 billion adults being overweight and over 650 million adults being obese [1]. The multifaceted nature of obesity, influenced by genetic, environmental, and lifestyle factors, necessitates comprehensive management approaches [2]. Traditional non-surgical methods, such as reduced-calorie diet and optimal physical exercise with pharmacotherapy, remain crucial treatment and prevention components [3]. Glucagon-like peptide-1 (GLP-1) receptor agonists and the combination of GLP-1 with glucose-dependent insulinotropic polypeptide (GIP), recently introduced in clinical practice, represent the most effective pharmacotherapy currently available [4, 5]. However, the limitations of non-surgical methods in achieving sustained weight loss, especially in severe obesity (body mass index – BMI > 40 kg/m^2), underscore the need for more aggressive treatment strategies [6].

Surgical interventions have emerged as highly effective tools in obesity therapy, providing long-

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term solutions for individuals resistant to conventional approaches. Laparoscopic sleeve gastrectomy (LSG) is considered the gold standard for its proven efficacy and safety. It involves the removal of about 80% of the stomach volume along its greater curvature, leading to reduced food intake and metabolic alterations [7]. Its less invasive alternative is endoscopic sleeve gastroplasty (ESG), which involves the application of endoscopic suturing techniques to create a sleeve-like structure within the stomach, mimicking the effects of LSG without the need for abdominal incisions. Notably, both ESG and LSG yield satisfactory weight loss outcomes, with modest superiority of LSG [8, 9]. However, in direct comparison, LSG has been associated with a higher incidence of adverse events and new-onset gastroesophageal reflux disease (GERD) in comparison to ESG [10]. This suggests that while LSG is more effective in terms of weight loss, the safety considerations could make ESG a preferred method for some patients.

Aim

This study aimed to assess the safety profile of ESG in a retrospective, single-center cohort, with all procedures performed by the same surgeon. We describe complications classified as grade II or higher, using the Clavien-Dindo classification, focusing on those categorized as grade IV. We also describe the learning curve of ESG, providing information on how the procedure safety changed over time.

Material and methods

This was a single-center, retrospective analysis of 222 patients (139 women and 83 men) who underwent ESG at the Endoscopic and Bariatric Surgery Center of the Brzeziny Hospital between January 2021 and October 2023 (33 months). All procedures were conducted by a single, experienced operator (M. Spychalski) and were performed with the endoscopic suturing system Apollo OverStitch (Endosurgery, Austin, Texas, USA) under general anesthesia with endotracheal intubation. Participants were included in the study with a BMI of 30–40 kg/m^2 if they had been unsuccessful in achieving weight loss through diet and exercise and were interested in an ESG for weight loss. Patients with a BMI of 27–29.9 kg/m^2 were eligible providing that they had associated comorbidities such as hypertension or diabetes. Patients with a BMI $\geq$ 40 kg/m^2 were included only if they disagreed with invasive surgical procedures including LSG or gastric bypass. Patients were excluded if they had comorbidities that precluded the administration of general anesthesia or if they had psychiatric conditions that were not pharmacologically controlled. Each patient underwent gastroscopy at least 4 weeks before the procedure. One day before the surgery laboratory tests were performed (morphology, electrolyte panel, coagulation profile, fasting glucose and insulin, lipid profile, liver function tests, urea, uric acid, HBsAg, TSH, creatinine, and blood group). Consultations with obesity specialists, dieticians, psychotherapists, physiotherapists, and, if necessary, diabetologists were conducted. The perioperative pharmacological prophylaxis included thromboprophylaxis (enoxaparin) and antibiotic prophylaxis (cefazolin or amoxicillin with clavulanic acid). Moreover, omeprazole, ondansetron, drotaverine, fluid therapy, and if needed, adjunctive analgesics were administered. In the case of uncomplicated hospitalization, an oral diet was introduced on the first day after the surgery. Complications were evaluated using the Clavien-Dindo classification, emphasizing clinically significant issues of grade II or higher. Complications classified as grade I, such as abdominal pain, nausea, and vomiting requiring only symptomatic treatment, were excluded from the analysis. Continuous variables are presented as means with ranges or standard deviations (SD) and nominal variables are presented as numbers with percentages.

Results

The mean age of the patient group was 43 years (range: 22–66 years) and the mean BMI was 40 kg/m^2 (range: 28–59). The average procedure duration was 55 min (SD = 19), and the average duration of the first 50 procedures was 72 min (SD = 29.2). Most patients were discharged from the hospital within 2 to 3 days after surgery (Table I).

Safety

Of 222 patients, 4 cases of perioperative complications were recorded, corresponding to 1.8% of all ESG procedures. Each of the 4 cases involved bleeding into the gastrointestinal tract, including 1 (0.5%) case of grade II, 2 (0.9%) cases of grade IIIb, and 1 (0.5%) case of grade IVb (Table II). All patients with serious adverse events (SAE) fully recovered and the primary safety objective of 5% or less observed

device-related or procedure-related serious adverse events was met. We did not observe an association between the learning curve, procedure duration, and the frequency or severity of postoperative complications.

Efficacy

The follow-up of the study group at 6 weeks and 12 months after surgery was 28.8% (62 patients out of 215) and 9.9% (14 patients out of 141), respectively. Total body weight loss (TBWL) after 6 weeks was 10.23%, and after 12 months was 22.17%. The low percentage of patients returning for follow-up visits restricts full assessment of the long-term effectiveness of ESG.

Case report of complications

Grade II complication

A 40-year-old woman with a BMI of 33.43 kg/m². The surgery proceeded without complications. On postoperative day 0, the patient experienced vomiting with bloody content. Laboratory follow-up revealed a decrease in hemoglobin levels by 1.8 g/dl. Antihemorrhagic pharmacotherapy was initiated with a favorable effect. There was no need for blood transfusions or endoscopic/surgical interventions. The patient was discharged home on the 4th day after the surgery.

Grade IIIb complications

1) A 40-year-old man with a BMI 41.55 kg/m². There were no chronic diseases or long-term pharmacotherapies in the past medical history. The procedure duration was 60 min. It was the 46th ESG performed. Immediately after the operation, the patient experienced vomiting with bloody content and severe, resistant hypertension (upon discharge, the patient admitted to being addicted to narcotics). On postoperative day 0, he underwent endoscopic treatment using hemostatic techniques (clips, injection of adrenaline solution, and hemostatic powder). The patient was discharged home on the 3rd postoperative day.
2) A 50-year-old woman with a BMI 34.25 kg/m². It was the 16th ESG procedure performed. A potential technical error (incomplete suture) was the cause of bleeding along the suture line. The patient underwent endoscopic treatment twice on postoperative day 0 (endoclips and injection of adrenaline solution). Due to a decrease in hemoglobin levels to 8.1 g/dl (initially 13.4 g/dl), 2 units of packed red blood cells and 2 units of fresh frozen plasma (FFP) were transfused. The

Table I. Patients' characteristics (n = 222)

Variable	Value
Age [years], mean ± SD	42.9 ±8.85
Sex, *n* (%):	
Male	83 (37.4)
Female	139 (62.6)
BMI [kg/m²], mean ± SD	40.0 ±6.4
Procedure duration [min], mean ± SD	54.6 ±18.9
Hospitalization time [days], median (IQR)	3 (3–4)

SD – standard deviation, IQR – interquartile range.

Table II. Demographic and clinical characteristics of each case of severe adverse effect (SAE)

SAE grade (Clavien-Dindo)	Age [years]	Sex	BMI [kg/m²]	Comorbidities	Procedure number	Procedure time [min]	SAE	Treatment
II	40	Female	33.43	Depression	104	40	Bleeding	Conservative
III b	40	Male	41.55	Arterial hypertension, drug addiction	46	60	Bleeding	Endoscopic procedure
III b	50	Female	34.25	Hypothyroidism	16	120	Bleeding	Endoscopic procedure
IV b	65	Male	44.1	Arterial hypertension, gout	110	45	Bleeding, type II myocardial infarction, cardiopulmonary failure, *C. difficile* infection	Endoscopic procedure, laparotomy

patient was discharged on the 4th day after the surgery.

Grade IVb complication

A 65-year-old man with well-controlled pharmacological arterial hypertension and a history of gout. BMI 44.10 kg/m². Duration of the procedure: 45 min. It was the 110th endoscopic sleeve gastroplasty (ESG) performed. The procedure proceeded without complications. The patient was discharged home in good condition on the 2nd postoperative day. He reported postprandial fullness after consuming a small amount of food (approximately 30–50 ml of liquid food) on the day of discharge.

Later that evening, he experienced profuse vomiting of a large amount of hemolyzed blood and was admitted urgently to the hospital. Due to anemia, red blood cell concentrate and plasma were transfused and hemostatic drugs were administered. During emergency gastroscopy, blood and clots were suctioned from the stomach, adrenaline solution was injected into the proximal line of ESG sutures, and endoclips were placed on the detected mucosal defect in the subcardiac area. Post-procedurally the patient was stable, and additional units of blood products were transfused due to persistently low hemoglobin values around 7 g/dl. One day after the procedure the patient reported chest pain. Blood tests and electrocardiogram (ECG) revealed a type II myocardial infarction due to anemia.

On day 6 after the re-admission hematemesis recurred, prompting another attempt to manage the bleeding endoscopically. Due to a large number of clots in the stomach and the inability to suction and locate the bleeding site, the patient underwent emergency laparotomy and gastrotomy. A potential bleeding site near the proximal line of ESG sutures was sutured. Due to massive blood transfusions and the patient's critical condition, he was transferred to the Intensive Care Unit for further treatment and monitoring, where the patient initially required intravenous analgosedation, respiratory therapy, catecholamine circulatory support, and correction of hematologic and coagulation deficiencies.

Later throughout hospitalization no signs of gastrointestinal bleeding were observed. The patient was discharged from the department in good general condition on day 18 after readmission. After a week at home, the patient was readmitted due to symptoms of high gastrointestinal obstruction. Gastroscopy revealed two visible sutures in the middle part of the gastric body, which were cut. Oral nutrition was initiated on the following days with good tolerance. Additionally, the patient experienced *C. difficile* infection, which was pharmacologically treated within the hospital. Ultimately, the patient recovered without permanent damage.

Discussion

In this study, we evaluated the safety profile of ESG procedures in a single-center retrospective cohort. We provided detailed characteristics of all complications graded at II or higher according to the Clavien-Dindo classification, including their therapeutic management.

Since ESG is minimally invasive, serious adverse events are extremely rare. Importantly, the management of these events is typically non-operative [11–13]. In our patient cohort, ESG-related adverse events occurred in four (1.8%) of 233 patients, with no deaths, consistent with the safety profile reported in meta-analyses performed by Hedjoudje *et al*. [13] and Singh *et al*. [12] that showed complication rates of 2.2 % (95% CI: 1.6–3.1%) and 2.26% (95% CI: 1.25–4.03), respectively. Gastrointestinal bleeding and perigastric fluid collection are the most commonly reported serious adverse events (SAE) [12]. In our cohort, all 4 described SAE were cases of gastrointestinal bleeding. In 3 of those, bleeding was managed conservatively with or without blood transfusions, while 1 patient with grade IV SAE required surgical treatment. We did not observe any other types of SAE and no common features predisposing patients to gastrointestinal bleeding were noted.

The benefit of ESG when compared with LSG is its minimal invasiveness, safety, and potential for reversibility. ESG is characterized by a shorter length of hospitalization [14], and procedure duration that allows for reduced anesthesia time [8, 10], which is particularly significant in obese patients with comorbid conditions [15]. ESG achieves lower complication rates when compared with LSG [14, 16]. Gastrointestinal bleeding, although it is the most common complication in both ESG and LSG, occurs less frequently in ESG (Yoon, 1.1% vs. 2.6%, $p < 0.05$) [17].

The incidence of postoperative bleeding following LSG varies in the range 0–10% [18–20]. Bleeding can primarily occur from the dissection of the

greater curve of the stomach or the staple line [21]. Its occurrence may be associated with factors such as the technique used to reinforce the staple line or the patient's blood pressure in the last 10 minutes of the surgery [22, 23]. Other complications associated with LSG are staple line leaks, fistulas [21, 24], acute pancreatitis [25], development of an abscess, nutritional deficiencies, and gastroesophageal reflux disease (GERD). While both ESG and LSG may lead to new-onset GERD, the risk is lower in the case of ESG compared to LSG (Fayad L, 1.9% vs. 14.5%, $p < 0.05$) [9]. An expert consensus indicated that preoperative GERD is a contraindication to LSG [26]. Although our retrospective analysis confirms its higher safety profile, it should be noted that the treatment's effectiveness is significantly lower. LSG demonstrated a higher percentage of excess weight loss (%EWL) at 12 months than ESG, with an absolute difference of 18.12% (±0.89; 95% CI; $p < 0.05$) [8].

According to the 2020 Brazilian consensus, the ideal candidate for ESG as a primary therapy is a patient with a BMI of 30–40 kg/m², with or without medical comorbidities, in whom conservative interventions were ineffective [27]. Delaying intervention to favor a lifestyle change does not seem to confer any advantages [28]. The U.S. Food and Drug Administration (FDA) authorizes the use of ESG in patients with obesity with a BMI of 30–50 kg/m², expanding its applicability to a larger cohort of individuals. In our study of 103 patients with BMI ≥ 40 kg/m², the 1.9% rate of SAE was consistent with the expert recommendation of maintaining a SAE rate below 5% in endoscopic bariatric and metabolic therapy [29]. The described safety profile is also consistent with a recent study by Maselli *et al*. [30], where an excellent SAE rate of 0.2% was reported in a cohort of patients with BMI ≥ 40 kg/m².

The data collected so far only allow for a limited analysis of the effectiveness of the procedure. In our cohort, the total body weight loss percentage (TBWL%) at 12 months was 22.2%. In comparison, the TBWL% at 12 months in the prospective, multicenter trial (MERIT) was 13.6% [28]. The difference in favor of our study may be attributed to superior overall compliance among patients from our cohort who attended follow-up appointments.

The strengths of our study include a relatively large patient cohort and the fact that all procedures were performed by a single operator, eliminating differences in technique. This is one of the largest studies on the safety of ESG conducted in the Polish population. The multidisciplinary character of the center (including endoscopic, surgical, internal, and intensive therapy wards) enabled adequate and effective treatment of complications.

The study was limited by its retrospective and single-centered design. Additionally, ESG is not a reimbursed procedure in Poland and imposes a considerable financial burden on patients. Consequently, the described patient population predominantly comprises individuals with a higher socioeconomic status that might confer better overall health and a reduced prevalence of uncontrolled chronic diseases. The high cost of the procedure may have also contributed to the low percentage of patients attending follow-up appointments, thus restricting a precise assessment of the procedure's effectiveness. This may limit the extrapolation of our findings to broader populations.

Conclusions

Although ESG is a procedure with an excellent safety profile, complications cannot be eliminated. Most of them can be treated conservatively. Special attention should be addressed to a history of drug addiction and proper hypertension treatment before the procedure. In the rare case of severe bleeding, emergency surgery with subsequent ICU treatment may be necessary.

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Ethics approval

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Conflict of interest

The authors declare no conflict of interest.

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