Is Laparoscopic Sleeve Gastrectomy Without Staple Reinforcement Safer? Analysis of 426 Consecutive Cases

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AIM: Laparoscopic Sleeve Gastrectomy (LSG) is an accepted safe procedure and the most common surgical method used in the treatment of morbid obesity. Leakage and staple line bleeding are significant postoperative complications that can cause concern due to the long staple line. The purpose of this study to examine the risk of complications that may arise due to the lack of staple line reinforcement during the surgery.

METHODS: Between March 2021 and May 2023, 426 consecutive patients who underwent LSG in Avrupa Safak Hospital were identified through a retrospective database. The patients included in the study were divided into two groups according to the staple line reinforcement. Group A (n = 210) received staple line reinforcement (SLR) and Group B (n = 204) received non-staple line reinforcement (NSLR). Twelve patients who did not meet the inclusion criteria were excluded from the study. Patient demographics, operative time, postoperative and perioperative complications such as staple line leak, bleeding, conversion to open surgery, length of hospital stay, abdominal pain, morbidity and mortality-related data were analyzed.

RESULTS: The mean age, body mass index (BMI), and ASA scores were similar in both groups. Operative time was longer in SLR group ($p < 0.001$). Postoperative complications occurred in 6 (2.9%) and 9 (4.4%) patients in Groups A and B respectively ($p = 0.397$). There was no staple line leak in either group. There were two strictures in Group A. Mean length of postoperative hospital stay was 2.17 and 2.16 days in Groups A and B respectively ($p = 0.830$). There was no in patient death.

CONCLUSIONS: Reinforcing the staple line after LSG is not necessary to reduce the risk of staple line leaks and bleeding.

Keywords: sleeve gastrectomy; staple line bleeding; leakage; standardization; none-reinforcement

Introduction

The prevalence of obesity is continuing to increase worldwide, and the effectiveness of bariatric surgery in treating these patients is widely accepted [1,2]. Sleeve gastrectomy (SG) is the most commonly performed bariatric procedure in the World [3]. Among several bariatric procedures, Laparoscopic Sleeve Gastrectomy (LSG) is a technical simplicity, effectiveness, and safety procedure [4]. Despite the acceptance of LSG as a safe procedure, leakage and staple line bleeding are significant postoperative complications that can cause concern due to the long staple line. It has been suggested in the literature that staple line reinforcement (SLR) is a method to reduce the risk of leakage and staple line bleeding [5,6]. However, while many experienced surgeons in the field of bariatric surgery feel the need to reinforce the staple line during LSG, others skip this step and complete the operation. Nevertheless, there is very little information in the literature about the effect of the standard procedure on reducing complications and improving outcomes after LSG [7]. In this study, we aimed to examine the risk of complications that may arise due to the lack of staple line reinforcement (NSLR) during LSG and the standardization of the postoperative protocol and to contribute to the literature with our own experiences.

Materials and Methods

This retrospective study was conducted between March 2021 and May 2023. During the study period, a total of 426 consecutive patients who underwent Laparoscopic Sleeve Gastrectomy (LSG) at Avrupa Safak Hospital were assessed in this study. The surgical procedure was performed by two surgeons. This study was approved by the Istanbul Yeniyuzyıl University, Clinical Research Ethics Committee with the Approval No: 2024/03-1232. İnformed consent was obtained from the patients. The patients were included to the study according to international bariatric surgery societies criterias: the International Federation for the Surgery

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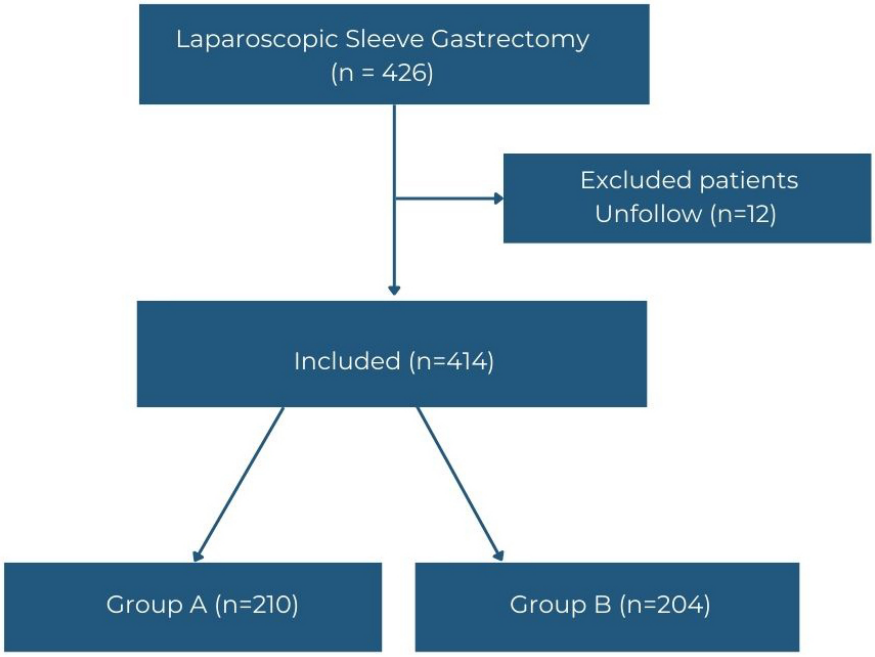

Fig. 1. Study Flowchart.

of Obesity (IFSO), the American Society for Metabolic and Bariatric Surgery (ASMBS), and the European Association for the Study of Obesity (EASO) [8–10]. Twelve patients with uncontrolled diabetes were excluded from the study. The patients included in the study were divided into two groups according to the staple line reinforcement. Group A received staple line reinforcement (SLR) and Group B received non-staple line reinforcement (NSLR). The study flowchart is shown in Fig. 1. Patient privacy was protected throughout the analysis. We examined patient demographics, operative time, staple line bleeding, conversion to open surgery, as well as postoperative and perioperative complications, length of hospital stay, morbidity and mortality-related data. Postoperative complications were defined as any adverse events occurring within 30 days after the surgery and were evaluated using the Clavien-Dindo classification [11]. Minor bleeding was defined as bleeding without clinical deterioration (sudden rapid heartbeat (tachycardia), weak pulse, low blood pressure (hypotension), sweating, cold hands or feet, urinating less than normal or not at all) and major bleeding as bleeding with clinical deterioration.

All patients underwent the standard LSG procedure, and the postoperative protocol was followed uniformly. Prior to the surgery, all patients received a comprehensive preoperative evaluation, which included complete blood count and biochemistry blood tests, abdominal ultrasound, respiratory function tests, electrocardiogram, plain chest X-ray, gastroscopy, and consultations with specialists in cardiology, chest diseases, and dietetics. Additionally, patients were placed on a liver-reducing diet two weeks before the surgery.

All procedures involving human participants adhered to ethical standards and were conducted in accordance with institutional ethical guidelines and the principles outlined in the Declaration of Helsinki.

Surgical Technique

Operations were performed under general anesthesia. Preoperative antibiotic therapy with ampicillin-sulbactam (2 grams) was administered to all patients. After positioning the patients in the reverse Trendelenburg position, the main surgeon stood between the legs of the patient, the camera man to the left of the surgeon, and the assistant to the right. After a closed pneumoperitoneum with the verrus needle, we inserted a 12 mm camera port, two working ports (15 mm on the right and 12 mm on the left), and a Nathanson liver retractor into the abdomen. Initially, using an energy device (Covidien Ligasure Maryland Jaw Laparoscopic Sealer/Divider), we dissected the greater curvature of the stomach from the omentum, starting 4 cm proximal to the gastric antrum and extending to the left diaphragmatic crus.

Next, we advanced a 38-French bougie towards the stomach and left it at the level of the antrum. We aspirated air and fluid from the stomach and stapled the pylorus using a black articulating reload with tri-staple (60 mm Covidien Endo GIA Black Articulating Reload with Tri-Staple - leg lengths 4.4/4.6/4.8), starting 2–4 cm proximal to the pylorus. We followed it with a second staple of a different color (60 mm Covidien Endo GIA Purple Articulating Reload with Tri-Staple - leg lengths 3.4/3.6/4.0). However, to prevent stricture and stenosis after surgery, we did not apply angulation in the incisura angularis during the firing of the first sta-

Table 1. Standardized postoperative protocol for Laparosopic Sleeve Gastrectomy.

Day of surgery	IV fluid 24 hours, PPI, antibiotics, antiemetics, analgesia (tramadol + NSAID + paracetamol), deep breathing exercises, out off-bed to walking (after 4 hours), chest physiotherapy, mobilize on ward
Day 1	IV fluid 12 hours, sips of methylene blue water (leaked test) after that sips of water, PPI, analgezia (paracetamol + NSAID), antibiotics, chest physiotherapy, mobilize on ward
Day 2	Sips only liquid diet,remove drain if haemoserous only, if there is no problemly discharge out of hospital

PPI, pronton pump inhibitors; NSAID, anti-inflammatory drug; IV, intravenous.

Table 2. Patient clinico-demographic details.

Variables	Group A	Group B	χ^2/t	p
	n = 210	n = 204		
Age (year)				
Mean ± SD	36.84 ± 12.32	34.75 ± 12.34	1.723***	0.086
Gender (F:M)	130/80 (61.9/38.1)	125/79 (61.3/38.7)	0.017****	0.895
BMI (kg/m^2)				
Mean ± SD	45.11 ± 5.15	44.97 ± 5.59	0.272***	0.786
Weight kg				
Mean ± SD	136.17 ± 18.72	133.64 ± 20.17	1.323***	0.187
ASA(ASA2/ASA3)	188 (89.5)/22(10.5)	179 (87.7)/25 (12.3)	0.325****	0.568
Co-morbidity	145 (69.0)	136 (66.7)	0.269****	0.604
Hypertension	130 (61.9)	115 (56.4)	1.311****	0.252
Diabaetes	95 (45.2)	101 (49.5)	0.757****	0.384
COPD	110 (52.4)	105 (51.5)	0.034****	0.853
Coronary artery disease	58 (27.6)	45 (22.1)	1.712****	0.191
Current steroid use	12 (5.7)	8 (3.9)	0.723****	0.395
Current anticoagulant use	35 (16.7)	30 (14.7)	0.301****	0.584
History of smoking	195 (92.9)	185 (90.7)	0.647****	0.421
Length of stay				
Mean ± SD	2.17 ± 0.49	2.16 ± 0.46	0.214***	0.830

BMI, body mass index; COPD, chronic obstructive pulmonary disease; SD, standard deviation; F, female; M, male. ***t, t test, ****χ^2, Chi-Square.

ple. The last staple was placed 1 cm lateral to the gastroesophageal junction (GEJ). Before each stapling, the bougie was moved back and forth by the anesthesia team to check for any narrowing. After removing the gastric specimen from the abdomen, we pulled the bougie back towards the GEJ and closed the pylorus using a hand-held instrument. We performed the methylene blue test, injecting 60 mL of fluid via bougie into the remaining stomach under pressure to check for any leakage along the staple line. Suture reinforcement was performed using polyglactin 910 3/0 sutures starting at the upper end of the staple line in a through-and-through continuous manner with invagination of the last 5–6 cm of the staple line for the hemosthasis in SLR group. Bleeding control was achieved by applying positive pressure using a laparoscopic clip in NSLR group. In all patients, we placed a 10 mm Jackson-Pratt drain near the gastric staple line at the end of the operation. All patients in the study followed a standardized postoperative protocol.

Twenty-four hours after the operation, we administered methylene blue and repeated the leak test. Patients without leakage were allowed to drink only water on the same day. Standardized Postoperative Protocol for LSG is shown in Table 1. From 48 hours after the operation, we started a clear fluid diet and discharged patients on the same day. First, we started with liquid diet an adequate intake of protein, calcium, and other nutrients, the liquid diet must be based on milk. After two weeks, we gradually started introducing foods with a soft moist texture. After four weeks we gradually started switching over to a diet of healthy protein rich, low-calorie solid foods.

Statistical Analysis

Statistical analysis was performed using the SPSS version 21.0 software (IBM Corp., Armonk, NY, USA). The conformity of continuous variables to normal distribution was investigated using visual (histogram and probability graphs) and analytical methods (Kolmogorov-

Table 3. Postoperative complications after the Laparosopic Sleeve Gastrectomy (LSG).

LSG	Group A	Group B	χ^2/t	p
	n = 210	n =204		
Operative time				
Mean ± SD	46.98 ± 5.2	43.36 ± 4.3	7.632*	< 0.001
Clavien-dindo classification				
I–II	7 (3.3)	5 (2.5)	0.286**	0.593
III–IV	4 (1.9)	4 (2.0)	0.100**	0.752
Chest infection	3 (1.4)	2 (1.0)	0.001**	0.974
Complications	6 (2.9)	9 (4.4)	0.716**	0.397
In-patient mortality	0	0		-
Stricture	2 (1.0)	0 (0.0)		0.499

*t, t test; **χ^2, Chi-Square; stricture, Fisher's test.

Smirnov/Shapiro-Wilk tests). Descriptive data were expressed in mean ± standard deviation (SD), or number and frequency, where applicable. The Fisher's test was used to determine whether there was a difference between the variables. The Chi-Square test was used to analyze whether there was a difference between categorical variables in the study. The Student's t test was used to compare continuous variables in independent groups. A p value of <0.05 was considered statistically significant.

Results

A total of 414 consecutive patients who underwent LSG were included in this study. Most patients were female in both groups. The mean age (p = 0.086) body mass index (BMI) (p = 0.786) and ASA (ASA2/ASA3) (p = 0.568) scores were similar in both groups. There is no statistical difference in clinico-demographic characteristics between groups. The clinico-demographic characteristics of the patients are presented in Table 2.

Perioperative Outcomes

Operative time was longer in SLR group ($p < 0.001$). Conversion to open surgery was required in two patients in Group A. One patient experienced technical difficulties due to intra-abdominal adhesions, while the other patient underwent open surgery due to uncontrollable bleeding from the short gastric arteries during the operation.

Minor bleeding occurred in three patients in Group A and four patients in Group B, but appropriate interventions were performed by replacing blood and blood products without any deterioration in their clinical condition. There were 3 (1.4%) patients with major bleeding with clinical deterioration in Group A and 5 (2.5%) patients in Group B. In this way, postoperative complications occurred in 6 (2.9%) and 9 (4.4%) patients in Groups A and B, respectively. We had a diagnostic laparoscopy for these patients. It has been identified as the staple line bleeding in these patients during diagnostic laparoscopy. We placed clips for the staple line bleeding. One patient underwent diagnostic laparoscopy due to abdominal pain, but no significant findings were detected in Group B. There were no cases of staple line leakage, dysphagia, early stricture, or mortality among the patients.

The mean length of hospital stay was 2.17 and 2.16 days in Groups A and B respectively (p = 0.830). Perioperative outcomes are summarized in Table 3. Also, postoperative vomiting occurred in 5 (2.4%) patients in Group A and 4 (2.0%) patients in Group B after 6 months. We performed contrast X-ray for the possible strictures. There were two strictures for these patients in Group A. We performed Roux-en-Y gastric bypass on these patients due to a twisted stomach.

Discussion

There is still ongoing debate among surgeons regarding the technique used in Laparoscopic Sleeve Gastrectomy (LSG). Efforts are being made to standardize the procedure and establish a consensus due to the existing data deficiencies [6,12]. In the literature, there have been various studies on this topic. Chang PC *et al.* [13] for example, did not encounter an increase in gastric stenosis episodes, particularly in the last 489 cases where a standardized procedure was implemented to prevent excessive narrowing of the incisura angularis. In our own experience, we have found that the main reason for not encountering gastric stenosis is the avoidance of angulation in the incisura angularis during the firing of the first staple.

The use of staple line reinforcement (SLR) in Sleeve Gastrectomyhas been advocated in various studies [14–16]. However, discussions regarding the necessity and effectiveness of SLR continue. There is a higher cost associated with the use of materials containing biodegradable polyglycolic acid and trimethylene carbonate in the SLR method. When examining the literature, various meta-analyses provide conflicting findings regarding the impact of SLR. Shikora and Mahoney [5] conducted a large cohort meta-analysis demonstrating the positive effects of SLR. Gagner and Kemmeter [6] reported a statistically significant

decrease in leak rates with the application of SLR. However, Niaz O *et al*. [17] in a series of 14,231 patients, found no effect of SLR on reducing the risk of leakage, while Knapps J *et al*. [18] in a review analyzing 4881 patients, concluded that SLR had no impact on reducing the risk of leakage. A study by El Masry MAMA and Attia MS [19] in 2023 who underwnt SLR did not show statistical significance in the difference in leakage rates. Additionally, Lynn W *et al*. [7] reported no leaks in 303 patients who did not undergo SLR. In our own series of 204 LSG cases without SLR, we achieved successful outcomes due to the standardized LSG technique and careful postoperative follow-up protocol, with no stapler leaks.

In this study, we specifically examined the risk of bleeding and reported a staple line bleeding rate of 2.85% and 4.41% in Group A and B respectively. There was no statistical significant between groups. When comparing with the literature, bleeding rates after LSG range from 0.7% [20] to 5.6% [21]. It is known that SLR reduces both intraoperative and significant postoperative bleeding rates [22]. Shikora and Mahoney's meta-analysis [5] which included 41,864 cases, reported a bleeding risk of 3.5% without SLR, which decreased to 1.2% in patients who underwent SLR. Postoperative bleeding is linked to longer hospitalization, complications (such as sepsis and organ failure), reoperation and mortality [23,24]. The reoperation rate for bleeding in bariatric surgery ranges from 0.5 to 3% [25,26]. It is close to our reoperation rate. However, Simon TE *et al*. [27] did not find any advantage in bleeding rate despite the use of SLR. It should be noted that there is a lack of data on the extent to which SLR affects bleeding rates, similar to the lack of data on its effect on leak risk.

SLR is performed by several technique, but whatever the method used, SLR increases the operation time [28]. A study by Albanopoulos K *et al*. [29] didn't show significant difference between the two groups in operative times. In our study the SLR increases the operative time.

We think that there are concerns about SLR, either because of uncertainty about its benefits and/or its financial costs. Also, it has been argued that oversewing itself could carry additional risks. The risks for leakage and bleeding could increase due to tearing at the suture penetration point, and the running suture may lead to sleeve stricture and tissue ischemia. In our study there is no statistical significance betwen groups. Moreover, we think the complication rates are linked with a surgeon's experience in SLR and non-SLR groups.

Our study has several limitations. First, the retrospective design potentially leads to analytic bias, second, there was no comparison with other staple line reinforcement methods, and non-randomized allocation. These limitations should be acknowledged when interpreting the results and considering their generalizability.

Conclusions

This study provides evidence suggesting that staple line reinforcement may not be necessary to reduce the risk of staple line leaks and bleeding in Laparoscopic Sleeve Gastrectomy (LSG).

We could not prove any benefit of reinforcement over stapling with no reinforcement. Leaving the staple line untouched appears to be safe, although the logic of reinforcement is understandable. Furthermore, the study also points out the lack of data regarding the effect of staple line reinforcement in other bariatric surgical procedures. This indicates the need for further research and studies to explore the role and efficacy of staple line reinforcement in different types of bariatric surgeries.

Availability of Data and Materials

The datasets used or analyzed during the current study are available from the corresponding author upon reasonable request.

Author Contributions

Conceptualization: NO and EH; methodology: NO and EH; formal analysis and investigation: NO, EH, MH, GC; writing- original draft preparation: NO, EH; writing-review and editing: NO, EH, MH, GC; supervision: NO, EH, MH, GC. All authors have been involved in revising it critically for important intellectual content. All authors gave final approval of the version to be published. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study was approved by the Istanbul Yeniyuzyıl Univesity, Clinical Research Ethics Committee with the Approval No: 2024/03-1232. Informed consent was obtained from the patients. All procedures involving human participants adhered to ethical standards and were conducted in accordance with institutional ethical guidelines and the principles outlined in the Declaration of Helsinki.

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Conflict of Interest

The authors declare no conflict of interest.

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