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Original Article

Assessment of Staple line Reinforcement versus Conventional Laparoscopic Sleeve Gastrectomy

Ahmed M. Sallam; Abdelrahman Sarhan; Tamer Wasefy; Omar Mahmoud Agwa; Walid A. Mawla.

General Surgery Department, Faculty of Medicine, Zagazig University, Egypt.

Corresponding author:

Omar Mahmoud Agwa.

Email:

omaragwa19@gmail.com

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ABSTRACT

Background: Obesity causes around 4.7 million preventable deaths worldwide each year. It is more challenging to calculate the burden of obesity since it is a consequence of its comorbidities rather than a direct effect. This research aims to assess the effectiveness of staple line reinforcement vs traditional sleeve gastrectomy. **Patients and methods:** This randomized controlled trial was conducted at General Surgery Department, Zagazig University Hospitals during the period from February 2023 to November 2023. This study was conducted on 30 patients with morbid obesity. All patients were divided into 2 equal groups, staple line reinforcement by over sewing group and No reinforcement group each group contain 15 patients. **Results:** There is statistically insignificant difference between both groups regarding their Pre-operative associated comorbidity and pre-operative anthropometric measures. There is statistically significant difference between both groups regarding operation duration where group A longer than group B. There is statistically insignificant difference between both groups regarding their postoperative complications. There was statistically insignificant difference of patients Weight, BMI, percent of Weight loss 6months post-operative of both groups ($p>0.05$). **Conclusion:** A promising method for lowering morbidity and the rate of gastric leakage is laparoscopic sleeve gastrectomy with staple line reinforcement.

Keywords: Staple line Reinforcement; Laparoscopic Sleeve Gastrectomy; Obesity

INTRODUCTION

Being obese is a complicated illness with many facets. Since 1980, the prevalence of overweight and obesity has increased twofold globally, to the point where about one-third of the global population is currently considered overweight or obese. Regardless of geographic location, ethnicity, or financial position, obesity rates have risen in all ages and sexes; nevertheless, older people and women are more likely to be obese than other groups. Despite significant

variations in the absolute prevalence rates of overweight and obesity, this trend was consistent across nations and regions. The prevalence of obesity appears to have plateaued in a few wealthy nations during the last many years [1].

The most successful method for lowering body weight and obesity-related illnesses in obese patients is weight loss surgery (WLS), which is now a commonly used therapeutic strategy [2].

Restrictive or malabsorptive qualities are associated with bariatric procedures. Restrictive surgeries lower the amount of food that can be eaten at once, which lowers the amount of calories consumed overall. Reduced absorption of eaten goods results from malabsorptive operations, which divert large parts of the digestive tract [3].

A surgical weight-loss technique known as a sleeve gastrectomy, or vertical sleeve gastrectomy, is performed. Usually carried out laparoscopically, this technique entails making several tiny incisions in the upper belly through which tiny devices are inserted. About 80% of the stomach is removed during a sleeve gastrectomy, leaving a tube-shaped stomach that resembles a banana in size and form. Hormonal changes brought on by the surgery also aid in weight loss. These same hormonal shifts also aid in the relief of overweight-related illnesses like heart disease and high blood pressure [4].

The performance of surgeons with different levels of knowledge and expertise may influence patient outcomes and may be a major cause of prejudice. It has been demonstrated that these operator-related variables are crucial in influencing the length of the procedure, the amount of blood lost, and the overall complications. [5].

Staple line complications (SLC) can have severe clinical consequences for the patient as well as financial consequences for the facility due to extended hospital stays and resource usage. Staple line reinforcement (SLR) methods that aim to lower the frequency of early SLC have been observed [6]. It has been reported on suture oversewing (SR), glue reinforcement (GR), clipping (CR), and bioabsorbable staple line reinforcement (Gore Seamguard) (GoR). In contrast, a lot of surgeons decide against reinforcing staple lines (NR) due to financial concerns or a lack of evidence of benefit [7]. So, This study aimed to assess the effectiveness of staple line reinforcement vs traditional sleeve gastrectomy.

PATIENTS AND METHODS

Study design:

(1) Location: this study was carried out in the General Surgery Department, Zagazig University Hospitals, after local ethics committee and Institutional Research Board approval.

(2) Sample size: Assuming the mean operation duration is 78.2 ± 9.5 vs 64.1 ± 16.5 in oversewing vs clipping. At 80% power and 95% CI, the estimated sample will be 30 cases, 15 cases in each group.

Inclusion criteria

Patients who are over the age of 18. Index of body mass (BMI) was $35\text{--}50 \text{ kg/m}^2$. They attempt with alternative methods of losing weight.

Exclusion criteria

Patient who has had bariatric surgery in the past. Restricted pulmonary function is one reason why laparoscopic sleeves are contraindicated. Also, Refusal of the patient, and $\text{BMI} < 50 \text{ kg/m}^2$ were excluded.

Operational Design

This study involved thirty individuals with severe obesity, all of whom had laparoscopic sleeve gastrectomy.

Pre-operative Evaluation

Demographic data and careful history taking of the condition were performed regarding onset, course, duration, previous methods of weight loss and degree of success, as well as comorbidities. History of previous surgeries, including laparotomies and other bariatric procedures, as well as any difficulties or anesthesia-related issues following the procedure. Clinical examination that includes a general check of vital signs and other systems to determine suitability for anaesthesia and surgery, hernia diagnosis, and BMI calculation.

Complete blood profile (CBC), serum iron ($60\text{--}170 \text{ mcg/dL}$), transferrin saturation ($25\text{--}35\%$), total iron binding capacity (TIBC): $240\text{--}450 \text{ mcg/dL}$, vitamin B12 ($<74 \text{ pmol/L}$), vitamin D ($20\text{--}40 \text{ ng/ml}$), folate ($2.7\text{--}17 \text{ ng/ml}$), serum calcium ($9\text{--}10.5 \text{ mg/dL}$), thyroid function (TSH, T3, T4), and cortisol (AM, PM) are examples of laboratory

examinations. Both a UGI endoscopy and an abdominal ultrasonography were done to rule out gallbladder stones and hiatus hernias.

Patients were divided into two groups:

- Group (A) 15 cases operated with reinforcement of staple line with over sewing technique.
- Group (B) 15 cases operated with the conventional technique with no reinforcement.

To lower the size of the liver, the patient is given a low-calorie protein diet for two weeks before to surgery. The patient is told not to smoke for a month before surgery and not to start again for at least three months following the procedure.

Prophylactic treatment for deep vein thrombosis involves the administration of enoxaparin, a low molecular weight heparin, 12 hours before to surgery. Additionally, lower limbs are covered with elastic stockings or wrapped with creep bandages.

Ethical consideration:

Informed consent was obtained from all participants after being informed about the aims and process of the study as well as applicable objectives. The principal investigators have kept individual data as private information safely. An approval of the study was obtained from Zagazig University Academic and Ethical Committee. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Surgical Procedure

Group A:

The patient was put in the reverse Trendelenburg position, with the assistant on the left, the cameraman on the right, and the operator sandwiched between the patient's legs. Using a Veress needle with pressure set to 14–16 mmHg, pneumoperitoneum is generated. First, the anesthesiologist uses a nasogastric tube to decompress the stomach. After that, the greater omentum is separated from the greater stomach curvature and coagulated, with the procedure known as endoscopic ethicon endo-surgery continuing

4–6 cm proximal to the pylorus and proximally into the esophagus. Beginning tangentially from the right lateral port and 4–6 cm proximal to the pylorus, the antrum was resected using a green load of a Covidien Endo GIA Ultra 60-mm stapler (Covidien Inc.). The tissue was squeezed for 15 to 20 seconds prior to the device being fired. In order to prevent stenosis and permit imbrication of the staple line, the residual distance between the stapler device and the bougie was measured using the grasper tip, and it was between 2 and 3 mm. Using blue loads, the remaining stapling was done through the 12-mm port at the left midclavicular line. Following the transected stomach's removal, the 12-mm left midclavicular port is used. From the angle of His to close to the pylorus, the staple line was imbricated using a running suture (Lembert technique) using a 2/0 monofilament suture (poliglecaprone 25, Monocryl®; Ethicon Inc.). In order to avoid putting too much pressure on the tissue, the stitches were spaced 3 to 5 mm on either side of the staple line and 5 mm distant. The methylene blue test is used to check the stomach's water tightness when a tube drain is inserted (Figure 1).

Group B:

Conventional laparoscopic sleeve gastrectomy was done without reinforcement of staple line.

Post-operative Treatment

On the operative day, ambulation and clear drinks begin that evening. Intraoperative and intraweekly thrombosis prophylaxis (enoxaparin 40 once daily) was used. Close observation is kept on the patients' vital signs and for any concerning symptoms, such as fever, peritonism, or an elevated leukocytic count. If stable, patients were released on the third post-operative day. It was advised for patients to start exercising during the first week following surgery.

After surgery, proton pump inhibitors were administered for four months. For the first two weeks, a low-calorie, high-protein liquid diet was followed by a soft diet for one week, and finally, solid food. There was strict

dietician supervision available. For a further six months, multivitamins were systematically approved.

Follow up

A week following surgery, the patients were evaluated as outpatients. They were then examined again after two weeks. If a patient's symptoms worsened in between follow-up appointments, they were also seen at the outpatient clinic.

STATISTICAL ANALYSIS

Data analyzed using Microsoft Excel software then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean \pm SD. Differences between quantitative independent multiple by ANOVA or Kruskal Wallis. P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

The mean age of group A was 32.4 ± 8.4 years and ranged from (22-50) and mean age of Group B was 33.2 ± 7.8 years and ranged from (23-49), the difference statistically non-significant. Females dominant in both groups were 66.7% with Group A and 60.0% Group B the difference statistically non-significant. There is statistically insignificant difference between both groups regarding their Pre-operative associated comorbidity $p>0.05$. There was statistically non-significant difference between both groups regarding their pre-operative anthropometric measures $p>0.05$ (Table 1).

There is statistically significant difference between both groups regarding operation duration where group A longer than group B $p<0.05$. There is statistically insignificant difference between both groups regarding their postoperative complications $p>0.05$ (Table 2).

Patients Weight, BMI, 3months post-operative of Group A lesser than patients Weight, BMI, 6months post-operative of Group B but the difference statistically insignificant $p>0.05$ (Table 3).

There was decrease mean of Weight and BMI at six-month post-operative compared to pre-operative group A; difference highly statistically significant $p<0.001$. Moreover, decrease mean of Weight and BMI six months post-operative compared to three month post-operative difference highly statistically significant $p<0.001$ (Table 4).

There was decrease mean of Weight and BMI at six-month post-operative compared to pre-operative group B; difference highly statistically significant $p<0.001$. Moreover, decrease mean of Weight and BMI six months' post-operative compared to three months' post-operative difference highly statistically significant $p<0.001$ (Figure 2).

There was statistically insignificant difference between associated comorbidity GERD pre and post-operative of both groups $p>0.05$ (Figure 3).

Table (1): Demographic data of the studied patients.

Variables	Laparoscopic sleeve gastrectomy				t-test	P-value
	Group A , n=15		Group B, n=15			
Age per years • Mean ± SD • Range	32.4 ± 8.4 (22-50)		33.2 ± 7.8 (23-49)		0.27	0.79
Sex • Females • Males	N	%	N	%	0.14	0.71
	10	66.7	9	60.0		
	5	34.3	6	40.0		
Pre-operative associated comorbidity	GERD	N	2	3	0.99 (NS)	
		%	13.33%	20.0%		
	No	N	13	12		
		%	86.777%	80.0%		
Weight (kg) Mean ± SD range	142.47±7.05 132-158		142±5.15 134-151		0.207	0.84 (NS)
Height (cm) Mean ± SD range	165±6.24 154-181		162±3.51 158-170		1.622	0.116 (NS)
BMI Mean ± SD range	52.433±3.17 43.34-56.98		54.131±1.95 49.82-58.15		1.76	0.088 (NS)

t= t test of sig , χ^2 Chi square test, (NS) non-significant, f=Fisher exact test

Table (2): Operation duration and Postoperative complications of the studied patients.

Operation duration (minute) Mean ± SD Range	Laparoscopic sleeve gastrectomy				P-value
	Group A		Group B		
		101.4±11.2 85-120	91.86±6.37 80-100	2.87	
Postoperative complications 1- Bleeding	yes	n	1	1	-
		%	6.66%	6.66%	
	No	N	14	14	
		%	93.34%	93.34%	
2- Leakage	yes	N	0	1	0.99 (NS)
		%	0.0	6.66%	
	No	N	15	14	
		%	100.0%	93.34%	
3- Twisting	yes	N	0	1	0.99 (NS)
		%	0.0	6.66%	
	No	N	15	14	
		%	100.0%	93.34%	

t= t test of sig, (S) p<0.05 significant

Table (3): Anthropometric measures three month’s post-operative of the studied patients.

	Group		f	Post hoc
	Group A	Group B		
Weight 3 months post-operative				
Mean ± SD	84.733±6.3	85.6±5.43	0.403	0.690
Range	76-95	76-94		
BMI 3 months post-operative				
Mean ± SD	31.14±1.926	32.646±2.32	1.937	0.063
Range	27.78-34.16	27.58-36.79		
% of Weight loss 3 months post-operative				
Mean ± SD	40.513±3.52	39.677±3.86	0.62	0.54
Range	35.81-47.47	31.88-48.99		

t= t test of sig, (HS) p<0.001 significant.

Table (4): Anthropometric Measures of Laparoscopic sleeve gastrectomy with staple line reinforcement of the studied patients throughout study phase. Group A

Anthropometric Measures	Laparoscopic sleeve gastrectomy with staple line reinforcement			f	Post hoc
	pre-operative	Three months Post-operative	Six months Post-operative		
Weight (kg)					
Mean ± SD	142.47±7.05	84.733±6.3	64 ±4.88	1936	(0.0001)*
range	132-158	76-95	56-72	P=0.000	(0.0001)**
BMI					
Mean ± SD	52.433±3.17	31.14±1.926	23.52±1.5	1413	(0.0001)*
range	43.34-56.98	27.78-34.16	20.15-26.13	P=0.000	(0.0001)**

F=Repeated measure anova, (HS) p<0.001 significant, post hoc (Pre-operative & Six months Post-operative)*, post hoc (three months & six months Post-operative)**

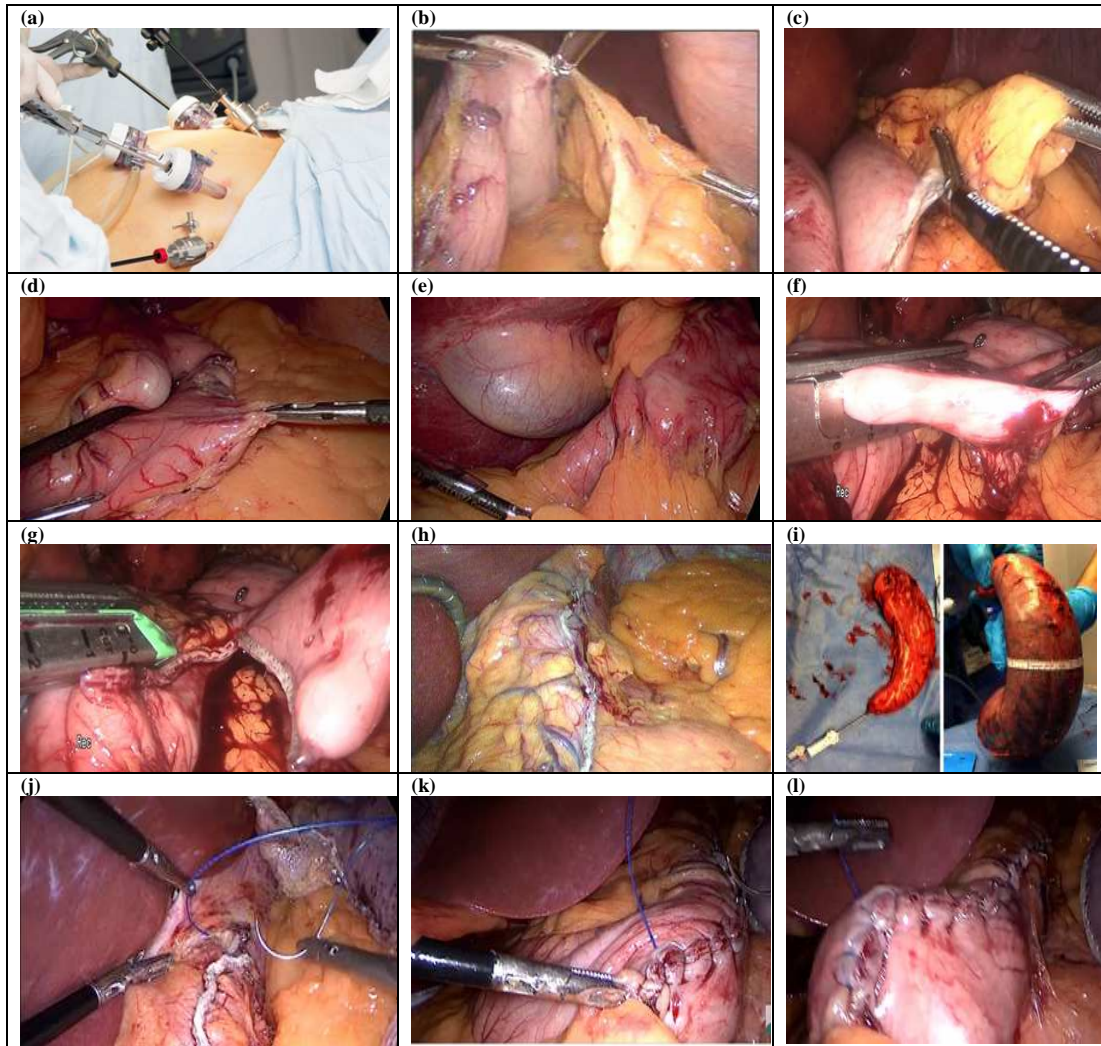


Figure (1): Surgical technique procedures: (a) Laparoscopic Trocars' Placemen; (b) release of omentum; (c) coagulation and separation of omentum using energy based device (Enseal Ethicon endo-surgery); (d) atraumatic graspers guiding the placement of bougie, (e) Bougie has been pushed through the pylorus to the first part of duodenum; (f) insertion of first stapler cranially; (g) after firing first stapler; (h) final situation after removal of the 36F gastric tube; (i) the excised specimen from the stomach ; (j) starting reinforcement of staple line by absorbable suture; (k) reinforced staple line without any increase in tension; and (l) final view of staple line after reinforcement.

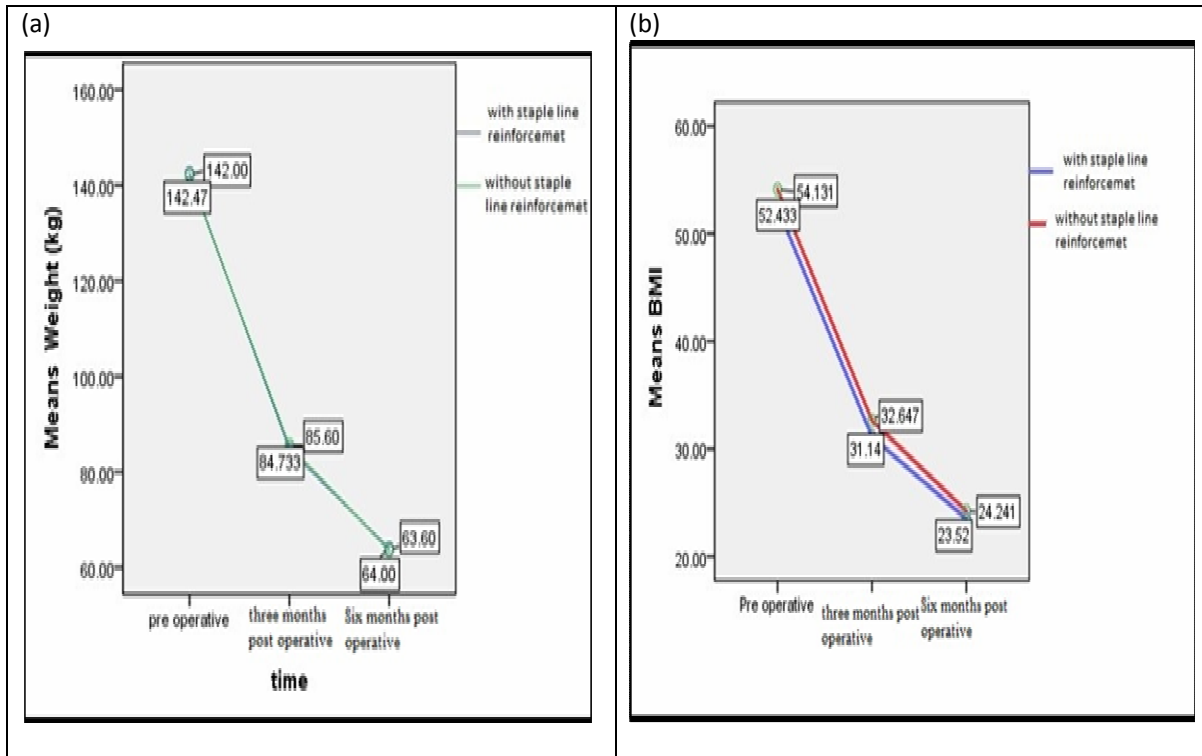


Figure (2): (a) Weight; (b) BMI of the studied patients throughout study phase.

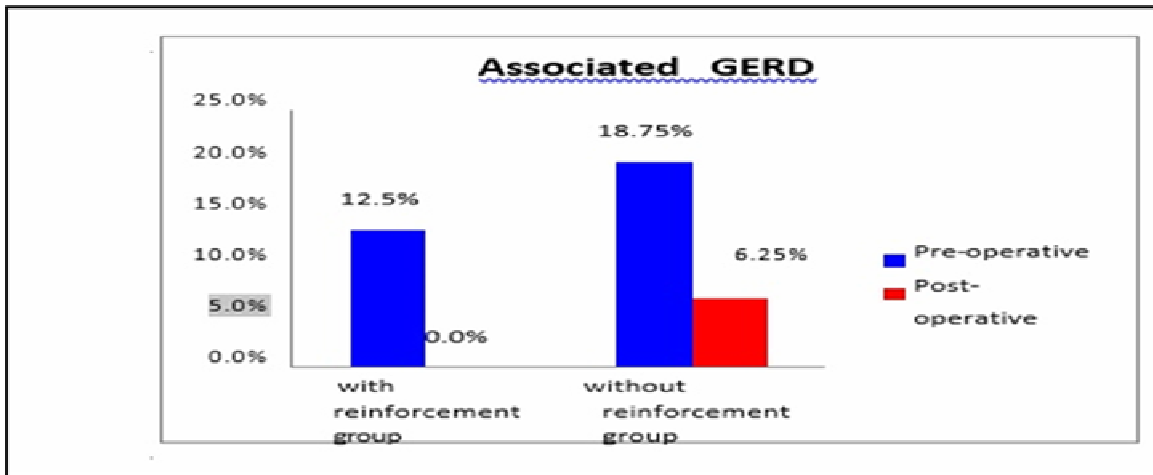


Figure (3): Percentage of associated comorbidity of the studied patient's Pre- operative and post-operative.

DISCUSSION

Morbid obesity is a global health concern that has significant effects on the social, psychological, medical, and economic spheres. In the Arab world, obesity is considered a pandemic issue. BMI, a simple weight-for-height index, is frequently used to classify people as underweight, overweight, or obese. It is calculated as kg/m², which is

the weight in kilograms divided by the height in meters (kg/m²) [8]. The World Health Organization defines obesity as having a BMI of 30 and overweight as having a BMI of 25 [9].

The popularity of laparoscopic sleeve gastrectomy (LSG) has increased due to the procedure's perceived ease of use, ability to resolve co-morbidities, and outstanding

results for weight loss. LSG is now generally regarded as the principal restrictive bariatric procedure; in 2014, it accounted for 45.9% of all bariatric procedures performed. In line with the 2014 IFSO global survey [10].

The incidence of early staple line complications (SLC), such as bleeding and leakage, can range from 1 to 6% [11]. Results can be clinically devastating for the patient and expensive for the facility with prolonged hospitalization and resources utilization. In an attempt to reduce the incidence of early SLC, different techniques for staple line reinforcement (SLR) have been described [12]. There have been reports of clipping (CR), bioabsorbable staple line reinforcement (Gore® Seamguard®) (GoR), reinforcement with glue (GR), and suture oversewn (SR). On the other hand, because to financial concerns or a lack of evidence of efficacy, a considerable number of surgeons have opted not to reinforce staple lines (NR). To evaluate the effect of different reinforcement strategies on the prevention of early SLC, numerous research have been published [13].

The current study conducted 11 males (36.6%) and 19 females (63.33%), yielding a total of 30 patients. The finding of our study was compared with studies [5, 13-18].

Aiolfi et al. [12] reported 3994 patients (17 RCTs) were included. Among them, 1641 (41.1%) had NR, 1507 (37.7%) SR, 689 (17.2%) GR, 107 (2.7%) GoR, and 50 (1.3%) CR procedures. When compared to NR, SR was linked to a considerably lower risk of bleeding, staple line leaks, and general health; however, no differences were observed when compared to GR, GoR, and CR. SR's operational time was noticeably longer than NR's. Sleeve stenosis, reoperation, 30-day mortality, hospital duration of stay, and surgical site infection (SSI) did not significantly differ among treatments.

Cunningham et al. [14] revealed that 127,521 (67.4%) of the 173 SG cases that were detected had SLR use. According to the unpaired analysis, the cohort that did not use SLR had considerably greater rates of bleeding and reoperation. Bleeding and reoperation rates in the cohort lacking SLR

utilization remained considerably higher in both propensity score and case-control matched analysis. The cohorts did not differ in terms of mortality or staple line leak rates, concluding that SLR had no negative effects on staple line leak rate and greatly lowers bleeding and reoperation rates after SG.

Schwartz et al. [15] reported that for the 6,286 patients for whom SLR data is available after single-stage bands were converted to sleeves, 56.9% of surgeons used SLR exclusively, 21.3% used no reinforcing technique (no SLR), 13.4% used SLR plus over-sewing of the staple line (SLR+OSL), and 8.4% used OSL alone. The rates of death, reoperation, readmission, re-intervention, number of bleeding events, and staple line leaks were not statistically different across the groups. Therefore, the frequency of bleeding events or the staple line leak rate are unaffected by the choice of SLR.

Lin et al. [16] included 914 patients in their study, whereas 530 had a running suture of SLR, 384 had a hybrid one. Following stomach transection, the rate of staple line hemorrhage and disruption was 4.9% and 39.2%, respectively. Compared to running suture, hybrid suture had a somewhat shorter SLR suture time and required less additional suture to stop suture site bleeding after staple line strengthening. Following hybrid suture, the incidence of postoperative bleeding was much lower than following running suture (0 vs 1.3%, $P = 0.02$). In the running suture group, two patients experienced serious postoperative leaks. None of the patients had any postoperative blockage. The two groups' 1-year excessive weight loss was comparable. They observed that despite surgical complexity, hybrid suture appears to be able to lower the incidence of postoperative bleeding compared to running suture. However, its influence on leak and obstruction requires more clinical validation.

Di Capua et al. [17] reported that two hundred LSG-eligible patients were randomly assigned to one of five groups according to the reinforcement technique used in the operation: no reinforcement, oversewing with 3-0 polydioxanone (PDS) suture, oversewing

with 4-0 barbed absorbable closure device (V-Lock), fibrin sealant glue, and buttress material. Complications that occurred during and after surgery were noted and examined. Only 2.5% of the patients in the no-reinforcement group needed reintervention, despite the group having greater bleeding rates (20%). The bleeding rates were improved in all groups utilizing staple-line reinforcement ($P < .05$). Regarding the intraoperative complications, reintervention rate, leakage rate, and surgical timeframes, no statistically significant differences were found between the groups.

Wang et al. [18] reported that a total of 791 patients (453 cases and 338 controls) from eight randomized controlled trials were examined. Staple line reinforcing was linked to a decreased risk of overall problems and staple line hemorrhage when compared to doing no reinforcement. Regarding postoperative leaking, no discernible variation was seen. It required more time to operate when the staple line was oversewn.

Kwiatkowski et al. [19] reported that the oversewing group had a mean operative length of 78.2 ± 20.5 min, which was longer than the clipping group's 64.1 ± 16.5 min, $p < 0.001$). In both groups, the average length of hospital stay was similar. Following surgery, there was no statistically significant difference between the groups in terms of stenosis and leakage (both outcomes: oversewing, $n = 0$, vs. clipping, $n = 1$ (2.3%); $p = 0.46$) or bleeding (oversewing, $n = 0$ vs. clipping, $n = 2$ (4.6%); $p = 0.21$).

Taha et al. [20] revealed the average BMI was 42.4 ± 4.3 kg/m² and the average operative age was 33.7 ± 9.4 years. Age, gender, weight, BMI, and other baseline patient characteristics and comorbidities did not significantly differ across the treatment groups in most cases. Patients in the no-reinforcement group had shorter surgical times ($44.3 \pm$ vs. 51.3 ± 4.3 min; $p < 0.01$) and lower EWL percentages (73 ± 13.8 vs. $80.7 \pm 13.6\%$, $p < 0.01$). In the non-reinforced group, a patient experienced a complicated stomach leak. Patients who had oversewing of

the staple line during LSG had a significantly decreased staple-line bleeding rate ($p 0.05$).

CONCLUSION

Staple line reinforcement may not change the outcome of laparoscopic sleeve gastrectomy in terms of post-operative bleeding although it is associated with longer operative time. However, the lower frequency of these issues with that technique suggests that it might act as an additional precaution against leaking. To reduce morbidity and the rate of stomach leaks, laparoscopic sleeve gastrectomy with staple line reinforcement may be a viable surgery.

RECOMMENDATION

The importance of staple line reinforcement is still debatable, hence further extensive multicentric comprehensive investigations are required to validate our findings and support the role of staple line reinforcement. There is evidence to suggest that one of the primary variables reducing morbidity and gastric leak rate is surgical technique.

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