



Comparison of Staple Line Reinforcement versus No Reinforcement to Minimize the Risk of Leakage and Bleeding after Laparoscopic Sleeve Gastrectomy; a Randomized Controlled Trials

Mohamed Mahmoud Eltaweel^{1*}, ABDULHAMED HIFNY MOHAMADAIN^{1,4}, Ahmed Abd El Aal Sultan¹, Yasser Hussain Hassan Metwally¹, Ayman Helmy Ibrahim¹, Saed Abdelmonem Elgohary¹, Walid Rafat Abdelaty Abdelfattah¹, Mohamed Ibrahim Shalamesh, Hamada Rashad Mohammed Abdelkader^{1,2,3}, Hamdy Abdel alim Mohamed Farag

¹General Surgery Department, Faculty of Medicine, Al Azhar University, Cairo, Egypt

²Consultant General Surgery, King Khaled Hospital, Hail, KSA

³Consultant General Surgery, Mustashark Hospital, Aseer, KSA

⁴Alrayan colleges, Al-Madinah Al-Munawarah, KSA

*Corresponding author: Mohamed Mahmoud Eltaweel,

E-mail: dr.mo1718@gmail.com, Mobile phone: +971 58 219 9059

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Abstract

Introduction: Staple line leakage and bleeding are major complications that occur after sleeve gastrectomy. There was no agreement on whether a reinforcement approach should be routinely performed. **Aim:** The goal of this randomized controlled experiment was to examine the performance of staple line reinforcement, using V-Lock suture for the prevention of surgical complications after LSG. **Patients and Methods:** 90 cases who qualified for laparoscopic sleeve gastrectomy participated in this prospective, randomized, double-blind, controlled clinical research. Cases were divided randomly into two equal groups receiving staple line oversewing using V-Lock suture, compared to no staple line reinforcement. The incidence of complications following surgery was measured and contrasted among the 2 groups. **Results:** Postoperative bleeding was significantly more prevalent in the non-reinforced group contrasted with the V-Lock suture group (11 vs. 2 %, $p=0.029$). Moderate to severe bleeding was reported in one case in the non-reinforced group, which required urgent exploration. This study reported a statistically significant higher prevalence in the non-reinforced versus the V-Lock reinforced group (4.4 Vs 0 %, $p= 0.001$). **Discussion and Conclusion:** The findings of our investigation revealed that staple line oversewing through a V-Lock suture can considerably minimize postoperative staple line leakage and bleeding. Total time spent in the hospital was more prolonged in the no reinforcement group. Additional high-quality, large-sample RCTs are required to validate the study's future findings.

Keywords: Laparoscopic Sleeve Gastrectomy, Reinforcement, Oversewing, V-Lock suture.

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Introduction

The health and economic burden associated with obesity are substantial in both developed and developing nations.¹ Changing one's lifestyle, adjusting one's food, taking medication, or undergoing bariatric surgery are all effective methods for managing obesity. In fact, bariatric surgery has been and always will be the only truly effective therapy for extreme obesity.² Bariatric surgery has important benefits beyond only weight loss, including the potential for type 2 DM to go into remission. The most recent improvements in bariatric surgery procedures have likely contributed to a rise in the popularity of this treatment during the previous ten years. The declining rates of complications after bariatric surgery in recent years also contribute to the procedure's rising popularity.³

Stapler tools play an important role in conducting laparoscopic sleeve gastrectomy (LSG). Despite continuous technological advancements in surgical staplers, the incidence of post-LSG staple line (SL) complications stays high. This is especially true when a long SL is combined with application of large staplers, which can not adequately seal the staple line.⁴ Increase in intragastric pressure is thought to be the primary cause of the 2 most concerning after surgery consequences after LSG: bleeding & leaks.⁵ The incidence of leaks after LSG has been shown to vary from zero to five point seven percent, However, the procedures taken to strengthen the staple line, hemorrhage from the staple line varies from zero to eight point seven percent. Six surgeons have argued that the SL should be fortified to decrease the hazard of these complications. Multiple reinforcement techniques have been proposed, including staple-line oversewing, V-Lock suture, fibrin glue, and buttressing. Indeed, no consensus was reached on whether reinforcement techniques should be routinely performed.⁷ This randomized, controlled clinical experiment sought to determine the effectiveness of staple line reinforcement, using V-Lock suture for the prevention of surgical problems following LSG.

Patients and Methods

Ethical Approval

Ninety cases were enrolled after receiving individual written informed consent and official ethical approval from the Al-Azhar University ethics board.

Sample Size Calculation

The sample size was calculated using the MedCalc program version 11.3.0.0. to establish the representative sample and assure the validity of the results. The effect size was estimated based on the data revealed by Shaban et al, who included 50 cases and reported that bleeding was more prevalent in the non-reinforced versus reinforced group (7 Vs 1, P 0.049), respectively.⁸ Adjusting the confidence interval to 95%; power to 80% & ratio amongst groups to 1:1; a sample of 80 cases was found reliable. Estimating a dropout ratio of 10%, we finally included 90 cases eligible for LSG between September 2021 to August 2022 at Al-Azhar University Hospital.

Eligibility Criteria

We enrolled patients, undergoing LSG, with age (eighteen-sixty-five) years, American Society of Anesthesiology (ASA) (I-III), and BMI more than thirty-five kg/m². The criteria of exclusion were patient refusal, coagulopathy, sepsis, hepatic/renal failure, ASA IV, and pre-existing severe psychological distress.

Randomization

To allocate individuals, a computer-generated randomization procedure was utilized. The researchers tested a telephone-mediated central allocation strategy for allocation concealment.

Procedure

Preoperative Evaluation

Each case underwent a comprehensive clinical evaluation consisting of a review of their medical and surgical background, a physical examination (including vital signs), height & weight measurements using a calibrated scale, investigation via routine blood tests, chest X-ray, ECG, assessment of thyroid and growth hormone levels, and upper gastrointestinal (GIT) endoscopy, pulmonary function investigations, Other possible imaging or cardiac referral and psychological assessment.

Surgical procedure

All individuals receiving forty IU of enoxaparin (Clexane) the night before surgery are placed supine on the surgical table, with the surgeon positioned among the case's legs. Using the table's whole incline in the anti-trendelenberg position was optimal. In spite of this, the case was positioned supine for port installation. The pneumoperitoneum is then created using a versus needle and CO₂ at a pressure of fifteen mmHg. Optical entry is the most common technique of entering the abdominal cavity with a twelve-mm trocar and a ten-mm zero-degree scope. This scope is modified to either a thirty-degree or forty-five-degree scope. Left of the midline, four trocars twelve-mm are placed obliquely through the abdomen wall, including right & left upper quadrant trocars, epigastric, and a supra-umbilical trocar, during the insertion of a fifth five-mm trocar in the anterior axillary line of the left lumbar area. Around ten cm from the pylorus, a window is created at the junction of the bigger curvature & the greater omentum. With the (ultraprecision Harmonic scalpel), the gastroepiploic, short gastric & posterior fundic arteries are divided from 4 cm proximal to the pyloric ring to the angle of His (Harmonic; Ethicon Endosurgery, Cincinnati, OH, USA). The anesthesiologist inserts a thirty-six Fr bougie orally down the esophagus & into the stomach after the dissection is complete. The physician then maneuvers the instrument along the smaller curvature and into the pyloric duct & duodenal bulb. About four-six cm proximal to the pylorus, gastric transection begins. The right mid epigastric port places and shoots a sixty mm green or gold cartilage across the antrum. In the direction of the gastroesophageal junction, the second stapler is positioned roughly one to two cm from the edge of the smaller curvature. To avoid stapling over a dislodged bougie, the bougie must be held in place during this phase of the operation until the stomach transaction is complete. At the left crus, the gastric transection is finished by firing staplers sequentially along the boundary of the bougie on the lesser curvature. When the transaction is complete, the entire

staple line is examined to confirm that the staples were made appropriately, especially in the antrum, where the stomach is thickest.

Method of Reinforcement

The staple line is strengthened by running seromuscular stitches using unidirectional absorbable v-lock 2/0 sutures (Covidien, Mansfield, MA, USA) commencing from angle of his down to the pylorus invaginating the staple line fully.

Checking for Leakage

When the stomach transaction is complete, the pylorus is crushed with a surgical grasper & Methylene blue is used to verify the strength of the staple line. Methylene blue is administered (through the bougie) into the stomach & the staple line is carefully scrutinized to rule out macroscopic suture line leakage. After that, the stomach dye is extracted, as does the bougie. A nelaton drain with an 18Fr diameter is placed along the incision. All trocar sites are closed with 0 Vicryl.

Outcome Assessment

The primary outcome was postoperative complications, including leak and bleeding. The secondary outcomes included the time of SLR, duration of LSG, and duration of hospital stay.

Statistical Analysis

SPSS version 23.0 is considered for analysis. The presentation was based on the type, normality, and distribution of the variables. Kolmogorov test was first applied. Normally distributed variables, explicated mean and standard deviation, whilst non-normal data explicated median and IQR. The Mann-Whitney U test and the student-t test were discussed in this study for inter-group analysis regarding the non-parametric and parametric numerical variables, respectively. In addition, categorical variables were analyzed using the Chi-square (χ^2) test. A point of 0.05 was set as the substantial level.

Results

Operative and Demographic Characteristics

After obtaining ethical approval, 90 patients were finally included for LSG in this randomized, double-blinded clinical study. **Figure 1** represents the flow of the study process. There were no significant distinctions amongst groups, with respect to age, gender, BMI, and the associated comorbidities (**Table 1**). Regarding the operative characteristics, all the surgical techniques were accomplished by the surgical team laparoscopically under general anesthesia. The duration of surgery was more extended in the reinforced group versus the non-reinforced group (112.4 vs. 84.9, $p=0.001$) respectively (**Table 2**). This can be explained by the time consumed in the reinforcement. The mean time of V-Lock suture reinforcement is 25.1 minutes. In addition, no significant distinction was reported between the two study arms in terms of the length of hospital stay ($p=0.217$) (**Table 2**).

Postoperative Complications

There were no intraoperative consequences noted in the two study groups. Postoperative bleeding was significantly more prevalent in the non-reinforced group compared to the V-Lock suture group (11 vs. 2 %, $p=0.029$) (**Table 3**). Moderate to severe was recorded in one case, which required surgical exploration and blood transfusion. Moreover, mild to moderate bleeding was reported in four cases in the non-reinforced group. Bleeding was controllable with conservative management and follow-up. Of the four cases managed conservatively, one patient required a blood transfusion without the need for surgical exploration. Regarding the V-Lock group, one patient reported mild to moderate bleeding, controlled conservatively without the need for blood transfusion (**Table 4**) (**Figure 2**). Regarding postoperative leakage, this study reported a significant higher prevalence in the non-reinforced versus the V-Lock reinforced group (4.4 Vs 0 %, $p= 0.001$). Postoperative effusion was seen in only 2 patients in the non-reinforced group. Conservative management & follow-up was suitable to one case, whilst the other case required endoscopy to control leakage by stenting the staple line (**Table 3**).

Table 1. Patients and demographic characteristics.

Demographic data	V-Lock (n=45)	No SLR (n=45)	p-value
Age (years)	36.4±7.5	37.1±8.6	0.461
Gender n (%)			
Male	13 (28.9)	15 (33.3)	0.538
Female	32 (71.1)	30 (66.7)	
BMI (kg/m ²)	46.1±5.7	45.2±5.2	0.609
Comorbidities n (%)			
Obstructive Sleep Apnea	2 (4.4)	1 (2.2)	0.915
Hypertension	8 (17.8)	9 (20)	1.000
Diabetes Mellitus	10 (22.3)	11 (24.4)	0.729

Table 2. Comparison between groups regarding length of the operation and hospital stay.

	V-Lock (n=45)	No SLR (n=45)	p-value
Time of surgery (minutes)	112.4±13.5	84.9±8.6	0.001
Time of SLR (minutes)	25.1±7.4	-	-
Duration of hospital stay (days)	3.7±1.5	4.2±1.4	0.217

Table 3. The incidence of consequences following surgery in the study groups.

	V-Lock (n=45)	No SLR (n=45)	p-value
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	N	%	n	%	
Leakage	0	0	2	4.4	0.001
Bleeding	1	2	5	11	0.001

Table 4. Comparison amongst the two study groups regarding the severity of postoperative bleeding.

	V-Lock (n=45)			No SLR (n=45)			p-value
	n	%	Management	n	%	Management	
Mild-Moderate	1	2	Conservative	4	9	Conservative (3) Blood Transfusion (1)	0.001
Moderate-Severe	0	0	-	1	2	Exploration	0.025

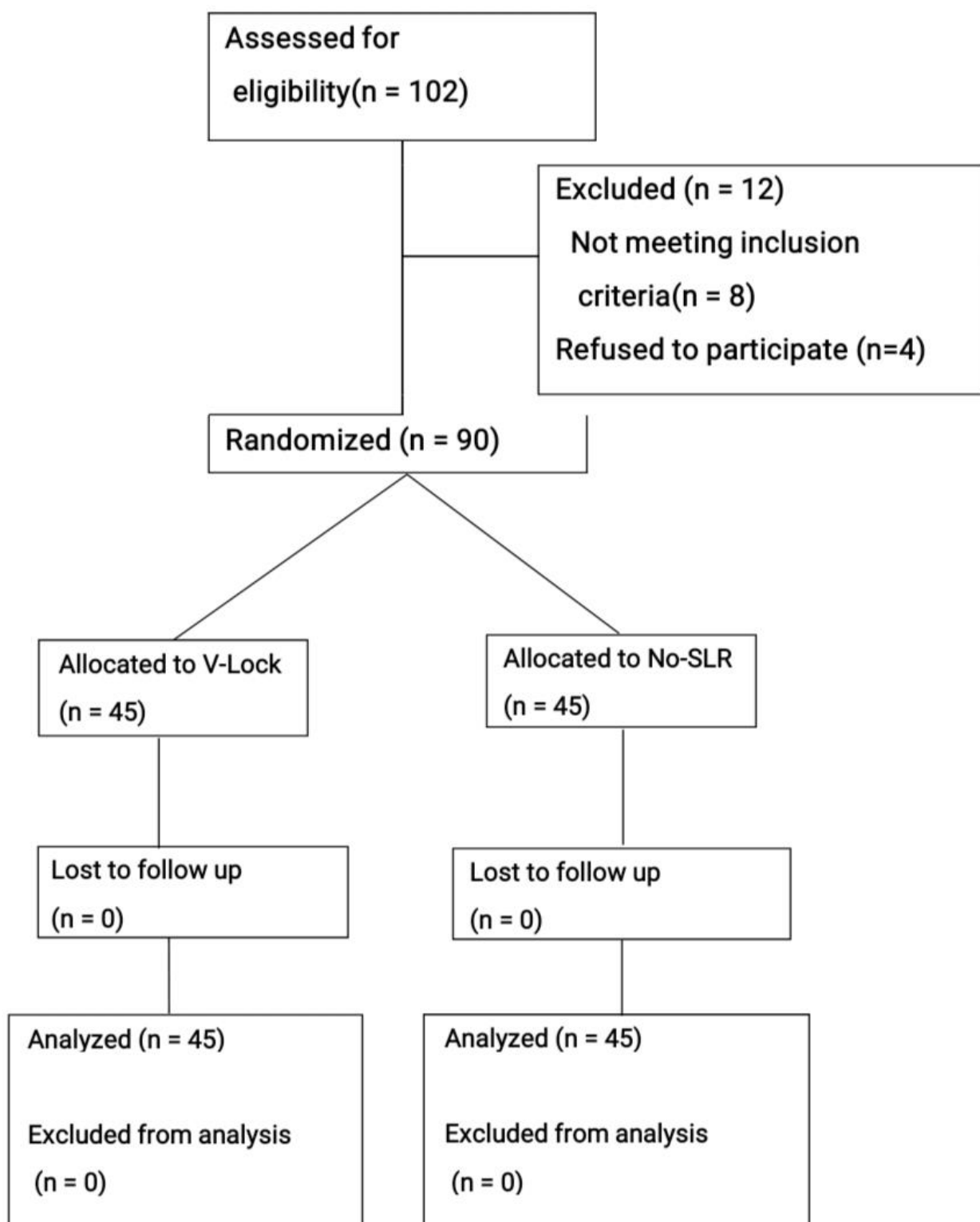


Figure (1). Consort flow diagram of the study process.

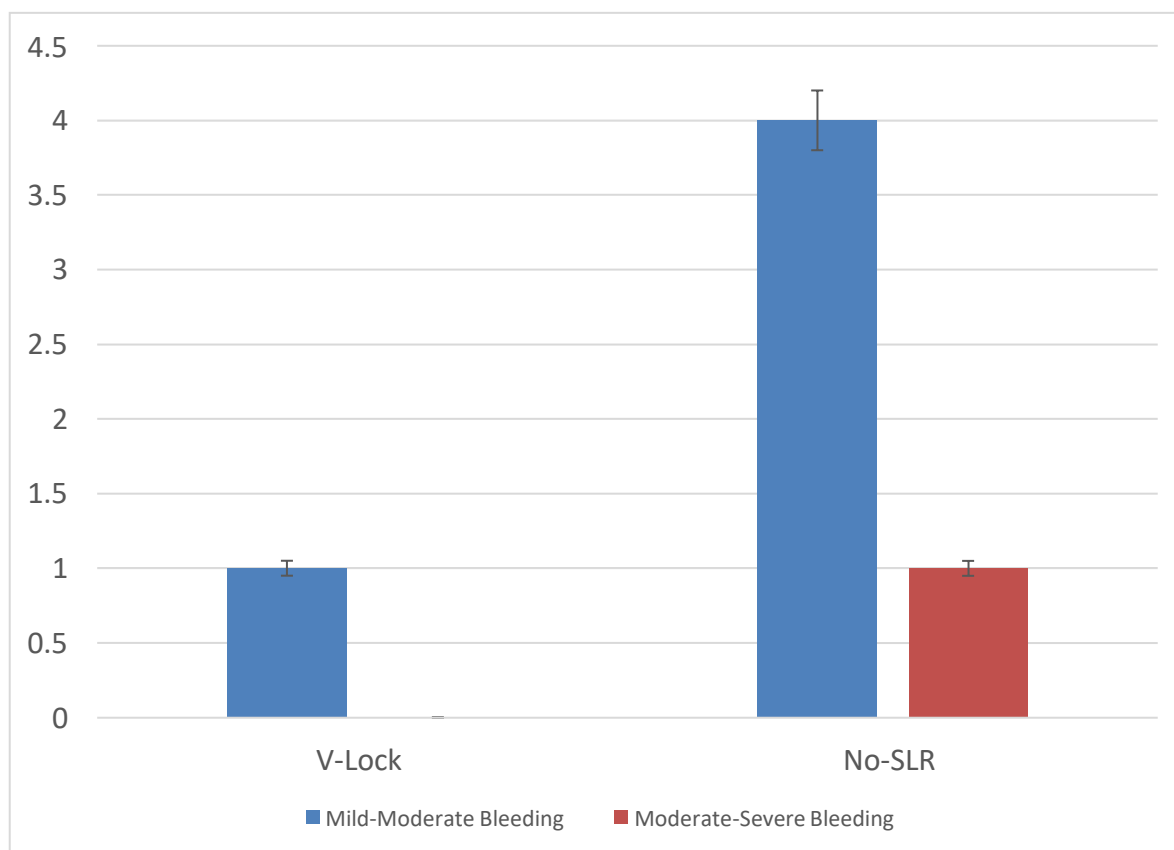


Figure 2. Distribution of the severity of bleeding in the two groups.

Discussion

Many publications have extensively accepted LSG as a stand-alone surgery for treating morbid obesity. It has several benefits, including the prevention of malabsorption, the preservation of gastrointestinal integrity, and the lack of implanted non-absorbable material.⁹ Nonetheless, LSG has several unpleasant complications that are closely related to staple line, such as postsurgical bleeding & leakage. If not detected early, postoperative leakage can proceed to abdominal sepsis, persistent gastric fistula and multi-organ failure. Furthermore, postoperative staple line leakage would greatly lengthen the hospital stay, contrasted with the average hospital stay after sleeve gastrectomy.¹⁰ Reinforcing the staple line was implemented to decrease the likelihood of after surgery consequences related to the staple line. This is accomplished through increasing strength of the staple line. Despite the lack of high-quality evidence, different methods of reinforcing the staple line during LSG, such as biologic glue, suture line suturing, absorbable buttressing material, staple line inversion & distal fixation, would be readily accepted & utilized by surgical clinicians to decrease the risk of after surgery consequences. Various methods of strengthening the staple line have already been suggested. Abdallah et al. performed a retrospective study of staple line inversion and distal fixation, claiming that it was an effective method of reducing staple line bleeding despite increasing the time of surgery duration of LSG.¹¹ Moreover, Chen et al. performed a comprehensive review & meta-analysis, which revealed that buttressing the staple line might minimize the frequency

of postsurgical bleeding; nonetheless, it was regarded a debatable treatment as standard precaution for postsurgical leakage.¹² In a comprehensive study conducted by Gagner and Buchwald, staple-line reinforcement using absorbable polymer membrane (APM) considerably reduced the occurrence of postsurgical leakage. Stitching above the staple line, which is the most popular method of reinforcement, serves a similar purpose.¹³ Our study utilized V-Lock suture as a suitable method for reinforcement.

Our study revealed that postoperative bleeding occurred in 2% (one case in the V-Lock group) and 11% (5 cases in the No-SLR group). The percentages of postsurgical leakage in the SLR and No-SLR groups were 0% and 4.4% respectively. Other recent papers have also supported our findings. In a systematic evaluate by Gagner and Shikora et al., they discussed several techniques of SLR during LSG. The results revealed that V-Lock suturing the staple line may greatly minimize leakages rates after surgery.¹⁴ D'Ugo et al. found that reinforcement the staple line by V-Lock suture reduced the potential for leakage and bleeding after surgery by (1.4% and 3.0%), respectively.

Musella et al., on the other hand, oversewing's efficacy was called into doubt through randomized controlled trials, with the final findings proving that oversowing contributed to a rise in postsurgical stenosis.¹⁵ In addition, Wang et al. conducted a recent meta-analysis of 7 RCTs involving 845 cases, which concluded that oversewing the staple line during LSG did not reduce postoperative bleeding or leakage incidence, but just increased the duration of operation.¹⁶ A recent meta-analysis of eight RCTs authored by Wang et al found that buttressing or roofing materials may decrease overall staple line consequences, however oversewing the staple line increased surgical time without reducing postsurgical leakage or bleeding.⁷

Many factors determine the length of hospital stays, such as hospital productivity, management, and output quality, the technical degree of medical care & departmental collaboration. Virtually all researches indicated that oversewing the staple line did not affect the length of hospital stays. In fact, according to Dapri et al., oversewing the staple line resulted in a much shorter hospital stay than the No-SLR group. Moreover, the author noted that cases in the No-SLR group who experienced surgical problems required a much longer hospital stay.¹⁷ In accordance with our findings, the No-SLR group had a longer mean length of hospital stay than the SLR group, compared to the SLR group, with non-significant comparison. Moreover, the surgical duration was then influenced by a variety of factors, includes the skill of the surgeon, competency & collaboration amongst surgeons and assistants or nurses. Our study indicated that oversewing the staple line using V-Lock suture during LSG significantly increased the operation time. Supportingly, the randomized controlled study conducted by Shaban et al., found that staple line oversewing using V-Lock suture significantly increased the duration of LSG. Furthermore, Carandina et al., in a randomized controlled experimental reported a similar finding, in terms of the duration of surgery.¹⁸ According to Albanopoulos et al., no statistically substantial variance was seen amongst the SLR and No-SLR groups, regarding the surgical duration, which is inconsistent with our results.¹⁹

Limitations

Our study had several limitations. Firstly, the prerequisites for cases included in the research differed, as did the physical state of the patients, such as age and BMI. Moreover, various research used different staplers and sutures during LSG. Consequently, large-scale to establish the superiority of one reinforcement approach over another, well-designed randomized controlled trials are required.

Conclusion

The findings of our research demonstrated that staple line oversewing through a V-Lock suture can considerably minimize postoperative staple line leakage and bleeding. The duration of hospital stay was more prolonged in the no-reinforcement group. Additional high-quality, large-sample RCTs are required to confirm the study's future results.

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