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# Comparative Study Between Non-reinforced Staple Line and Reinforced Staple Line During Laparoscopic Sleeve Gastrectomy

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## Abstract

**Background:** Laparoscopic sleeve gastrectomy (LSG) is increasing in recognition rapidly and is becoming the preferred method for many obese individuals as well as their doctors throughout the world. Reinforcing the staple line has been suggested as a way to lessen the likelihood of bleeding besides leakage at the gastric staple line. Reinforcement, oversewing, and buttressing inside the stapler load are all possible choices for reinforcing the staple line.

**Objectives:** Throughout LSG, the staple line can either be left unreinforced or reinforced with sutures.

**Patients and methods:** Fifty individuals from the surgical departments at Al-Azhar university hospitals participated in this prospective randomized controlled two-arm blind interventional trial.

**Results:** An examination of multivariable linear regression with regard to the prediction of surgical time revealed significant variances between our examined groups with respect to Time of operation, Frequency of bleeding, and Frequency of leakage, Body mass index (BMI) as well as Reinforced staple line. When comparing the demographic along with weight data from our two groups, we found a statistically significant disparity.

**Conclusion:** There is a high statistically significant decrease in the BMI of both groups from preoperative values during 6 months of follow-up after having LSG for the treatment of obesity.

**Keywords:** Laparoscopic sleeve gastrectomy, Non-reinforced staple, Reinforced staple line

## 1. Introduction

As a worldwide epidemic, obesity calls for a comprehensive approach to care that integrates the fields of medicine and psychology, in addition to operations. The result is an alarming rise in mortality as well as illness, along with a decline in overall quality of life. Obesity is evaluated using BMI and is considered to exist when the BMI of an adult is 30 or more.<sup>1</sup>

Obesity is on the rise at a frightening rate around the whole world. The incidence of obesity and overweight now exceeds the number of people who were malnourished for the first time in 2009.<sup>2</sup>

Laparoscopic sleeve gastrectomy (LSG) is quickly rising in popularity and is becoming the operation

of choice for many obese patients and their doctors throughout the world. Technical viability, maintaining the typical structure as well as absorptive capacity of the intestine, not implanting foreign entities and reduced concerns of nutritional shortages all contribute to LSG's widespread acceptance.<sup>3</sup>

There are three key technical aspects to the procedure of bariatric surgery. As time goes by, these aspects get better and less intrusive, speeding up the recovery time for individuals. Weight loss procedures can be categorized as either restrictive (which limits how much food one can eat), disabsorptive (which blocks nutrients from being absorbed by the intestine), or as a combination of the two.<sup>4</sup>

Surgeons have looked into reinforcing staple lines as a way to lessen gastric leakage following

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LSG. Staple line over stitching; these include attempts to conceal the staple line with omentum or jejunum, use fibrin glue, or buttress the staple line with material already loaded onto the staple gun.<sup>5</sup>

It has been suggested that reinforcing the staple line can help prevent stomach staple line leakage and bleeding. There is conflicting evidence about the effectiveness of staple line strengthening, which involves either buttressing the tissue using bovine pericardium or synthetic polymers or the staple line oversewn with continuous suture are some of the techniques that can be used.<sup>6</sup>

Several surgeons advocate for staple line reinforcement, although it has not been rigorously investigated using either prospective or retrospective methods. In addition, there is a wide range of surgical practices when it comes to reinforcing staple lines. Non-reinforcement, oversewing, and buttressing inside the stapler load are all viable options for reinforcing the staple line.<sup>7</sup>

## 2. Patients and methods

Within the surgery departments of hospitals connected with Al-Azhar University, a total of 50 people participated in this prospective trial that was prospective randomized controlled two-arm blind research.

Participants were assigned randomly using a straightforward random allocation method in which 50 cards were organized by the principal investigator and placed in sealed envelopes before being mixed. Every participant selected an envelope after approving participation. The double-blind method was utilized, where both individuals and their caregivers were unaware of which group they belonged to.

Persons selected LSG after being thoroughly informed about the treatment and its positive and negative aspects, which was preceded by approval from the local ethics committee of Al-Azhar university hospitals.

Cases that have BMI  $>35$  kg/m<sup>2</sup> and also have at least one comorbidity, or more than 40 kg/m<sup>2</sup> and no comorbidities, were participating in the operation departments of Al-Azhar university hospitals over the course of a year (August 2022–November 2022) with a subsequent 6-month period of monitoring of patients.

Twenty-five patients were assigned to group A, which performed LSG with reinforcement of the stapler line by v-lock suture, as another 25 individuals were assigned to group B, which completed LSG with no reinforcement of the stapler line.

### 2.1. Inclusion criteria

Participants who are morbidly obese and meet the following criteria: BMI of at least 35 kg/m<sup>2</sup> with one or more comorbidities or BMI of at least 40 kg/m<sup>2</sup> with no comorbidities; age between 18 and 55 years old; either sex; prior attempts at supervised nonsurgical weight loss trials.

### 2.2. Exclusion criteria

Those with ASA4 or higher, patients at any stage of cancer; Substance misuse at the present time; Untreated serious mental disease; Obesity-related disorders with a BMI more than 55; Laparoscopy contraindications include coagulopathy, redo cases, refusal to participate along with additional conditions.

### 2.3. Preoperative

Guidelines developed by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) were utilized to narrow down the pool of candidates for surgery to those who stand to gain the most from it. Statistics on age, gender and BMI in addition to obesity-related comorbidities were collected beforehand.

### 2.4. Operative intervention

Laparoscopic procedures were performed while patients were under general anesthesia. The procedure followed the norm for such operations. The time of surgery was recorded by assessment of both the time of reinforcement and the time of procedure in group A and the time of the procedure in group B. During the operation, the operative time was noted, and any operative events, complications like leaks, bleeding, or conversions were documented (Figs. 1–6).

### 2.5. Statistical methods

SPSS v.25 (IBM, Armonk, New York, USA) was used for all of the data handling and statistical analysis. Standard deviations and means were used to summarize the numerical data. Numbers and % were used to summarize the categorical information. In order to do a comparison among the two groups, we used the independent *t*-test for the numerical data. When comparing categorical data, either the Chi-square (*c*<sup>2</sup>) test or Fisher's exact test was utilized. The influence that using a reinforced staple line has on the total amount of time needed

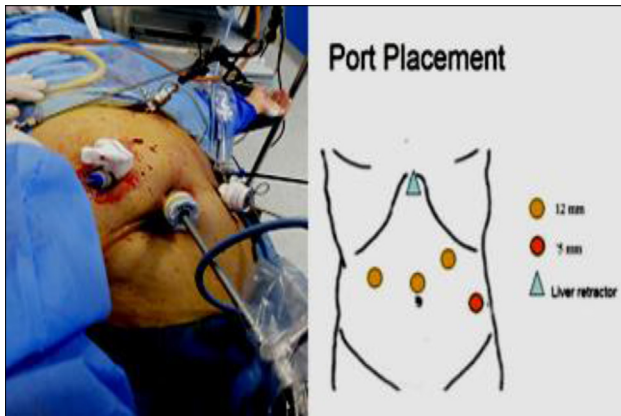


Fig. 1. Ports site in laparoscopic sleeve gastrectomy.



Fig. 4. Gastric transection and stapling.



Fig. 2. Freeing of the greater curve from the greater omentum.



Fig. 3. Introduction of the bougie.

for the procedure was examined with multivariate linear regression analysis, taking into account confounding variables.

### 3. Results

Table 1 showed that participants in both groups (A and B) were almost the same age (~34 years old; mean  $\pm$  SD;  $33 \pm 8$ ), with 9 males (36 %) as well as 16

females (64 %). When comparing the two groups by age and gender, there were no significant variations. Both  $P$  values were 0.887 and 0.765, respectively.

Table 2 showed that reviewing the data, it was found that both groups' mean weights were ~115 kg (mean  $\pm$  SD:  $121 \pm 18.3$  in group A and  $117.2 \pm 20.1$ ), with no statistically significant variation amongst them.  $P$  value was 0.484 (Fig. 7).

Statistical analysis revealed a significant disparity between the two groups (mean  $\pm$  SD:  $75 \pm 9$  for group A and mean  $\pm$  SD:  $45 \pm 4$  for group B;  $P < 0.001$ ) when it came to the length of time required to complete the surgeries (Table 3).

Table 4 showed that three individuals in group B (12 %), compared to zero people in group A (0 %), presented a statistically significant rise in the frequency of bleeding. There was a  $P$  value of 0.049 % chance of that happening. Additionally, in group B, one case required reexploration using laparoscopy) and the remaining two individuals were accomplished conservatively.

Table 5 showed that there was no leakage in group A or group B and demonstrated no significant alteration between the two groups.

Table 6 showed that over the course of 6 months after sleeve gastrectomy, the BMI of both groups decreased significantly from preoperative values [range=(34.7–44.7) to (range=(16.98–21.91))].

### 4. Discussion

The health risks and economic costs associated with obesity are enormous. Despite major attempts to raise awareness, the prevalence of obesity continues to rise alarmingly. Over 1.4 billion adults are overweight, while approximately half a billion are obese, according to reports from the World Health Organization.<sup>8</sup>

Bariatric operation has been proven to significantly alleviate the health problems linked with

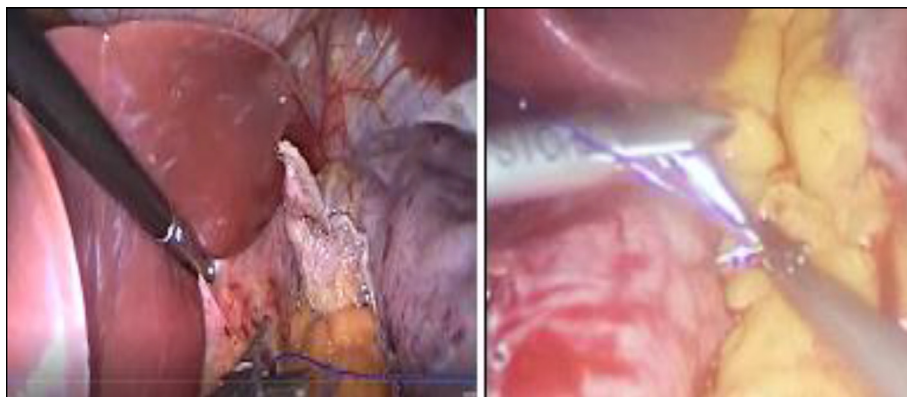


Fig. 5. Reinforcement of staple lines by v-lock 2/0 sutures.



Fig. 6. The specimen after extraction.

obesity and the metabolic disorders, such as type 2 diabetes as well as dyslipidemia.<sup>9</sup>

The current research consists of 50 cases; 9 men (36 %) along with 16 ladies (64 %) in group A, in addition to 8 men (32 %) as well as 17 women (68 %) in group B, with an average age of ~34 years; mean ± SD = 33 ± 8. No significant variations in age or sex among the two groups.

The respective *P* values were 0.88 and 0.76. These outcomes were comparable to a trial conducted by Shaban et al.,<sup>10</sup> who conveyed that 187 individuals had gastric sleeve surgery performed laparoscopically: 134 women (71.7 %), 53 men (28.3 %), a ratio of 2.5/1; and a median age of 36 years (range = 16–60).

Table 1. Demographic characteristics amongst the two groups.

	Group A (n = 25)	Group B (n = 25)	<i>P</i>
Age (years)			
Mean ± SD	33 ± 8	33 ± 8	0.887
Gender			
Males, n (%)	9 (36.0)	8 (32.0)	0.765
Females, n (%)	16 (64.0)	17 (68.0)	

Age was tested with independent *t*-test. Sexes assessments using Chi-square ( $\chi^2$ ).

Table 2. Weight measurement in each group.

	Group A (n = 25)	Group B (n = 25)	<i>P</i>
Weight (kg)			
Mean ± SD	121 ± 18.3	117.2 ± 20.1	0.484

Table 3. Procedure duration among each group.

	Group A (n = 25)	Group B (n = 25)	<i>P</i>
Time of surgery (min)			
Mean ± SD	75 ± 9	45 ± 4	<0.001

The percentage of individuals who are morbidly obese in our study was higher in females than males, as observed by Taha et al.<sup>11</sup> in total, 200 cases in each group performed LSG; gender (female/male) 113/87 in group A and 117/83 in group B. Besides the total mean age of the research persons was 33.7 ± 9.5 years.

Reviewing the duration of the operations, we observed that group A completed their tasks in more time with a mean ± along with a standard deviation of 75 ± 9, whereas group B completed their tasks in a shorter time mean± and standard

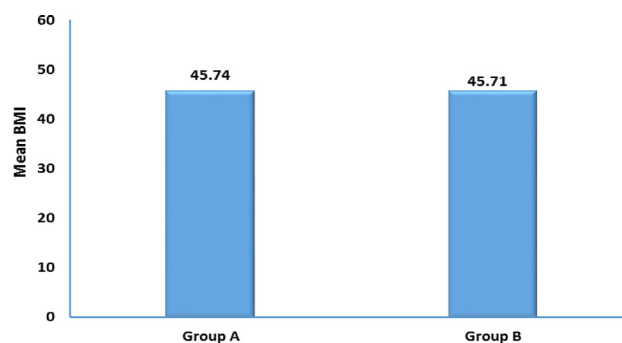


Fig. 7. BMI measurement in the two groups.

Table 4. Frequency of bleeding in all groups.

	Group A (n = 25)	Group B (n = 25)	P
Bleeding n (%)	0 (0)	3 (12)	0.049

Fisher's exact test was used.

Table 5. Frequency of leakage in each group.

	Group A (n = 25)	Group B (n = 25)	P
Leakage n (%)	0 (0.0)	0 (0.0)	0.63

deviation of  $45 \pm 4$ . There was statistical significance among the two groups. Our operative times were much longer than those stated by 'Hany and Ibrahim' (the mean operating time in group A was 69 min compared to group B's 50.8 min;  $P = 0.001$ ).<sup>12</sup>

Also, our duration in operation was far longer than what was indicated by 'Taha et al.'; however, participants who received LSG without oversewing of the staple line had a statistically significant shorter average surgical time ( $44.3 \pm 5.5$  min in group 1 vs.  $51.3 \pm 4.3$  min in group 2,  $P < 0.01$ ). We may have taken longer because we were at the beginning of the learning curve.<sup>11</sup>

Leakage from a broken staple line, excessive blood loss necessitating a second surgery or transfusion, and postoperative strictures necessitating endoscopic or operating intervention are only a few of the risks linked to LSG.<sup>13,14</sup>

One of the risks of LSG is bleeding near the staple line.<sup>15</sup> The lengthy staple line has been linked to gastric leak rates between 0 and 20 % as well as bleeding rates from 1 to 6 %.<sup>16,17</sup>

There was a statistically significant distinction between the two groups, with more bleeding occurring in group B, involving three individuals (12 %), than in group A, with no bleeding recorded (0 %). The significance level was found to be 0.049. In addition, two cases in group B required reexploration (by laparoscopy for staple line bleeding). Bleeding in the remaining one individual in group B resolved after conservative management, and

computed tomography scans were repeated weekly for 1 month. This rate of bleeding compared to that found in research by 'Hany and Ibrahim,' who found that 0.4 % of the people in group A, in addition to 1.5 % of individuals in group B, experienced bleeding, with a corresponding  $P$  value of 0.178.<sup>12</sup>

Our study's bleeding rate was less than that of a trial by 'Taha et al.' that found: The staple line flow of blood rate was considerably decreased in participants who performed reinforced LSG in contrast with participants who performed non-reinforced LSG (2 % in group A vs. 9 % in group B,  $P < 0.05$ ).<sup>11</sup>

Another major risk is a staple line leak, which can occur anywhere greater than 2–5 % of the time.<sup>15</sup>

Postoperative gastrointestinal leakage after bariatric operation has been associated with an enlarged risk of death.<sup>18</sup>

Among the numerous potential causes of such a leak is the amplified separation necessary for reoperative surgery, which increases the risk of tissue damage and ischemia. The esophagogastric connection has been identified as the common leak location following LSG.<sup>19,20</sup>

In the present research, the usage of V-Loc 3/0 decreased the hemorrhage also leakage to a great extent. Also these outcomes were appropriate by Nemecek et al.,<sup>21</sup> who stated that the V-Loc 3/0 (Covidien, Mansfield, Massachusetts, USA) is a barbed suture that permits knotless tissue approximation and involves less effort and time associated with the usual non-barbed sutures with no requirement to retention the suture repeatedly while stitching. Having a higher shattering pressure than non-barbed monofilaments, it is possible that it is more secure than monofilaments that do not have barbs.

The benefits of staple line reinforcement in LSG above postoperative staple line bleeding and leakage have been revealed in many randomized controlled trials, which corroborate these findings.<sup>22–24</sup>

Lastly, over the course of 6 months after sleeve gastrectomy, the BMI of both groups decreased significantly from preoperative values [range=(34.7–44.7) to Range=(16.98–21.91)]. Moreover Musella et al.<sup>25</sup> discovered no statistically significant

Table 6. BMI changes after surgery in both groups.

Time	BMI (kg/m <sup>2</sup> )		Range	Repeated measure ANOVA	P value
	Group A (n = 25)	Group B (n = 25)			
Preoperative	38.46 ± 3.46	42.52 ± 2.32	34.7–44.7		
1 m	34.94 ± 3.22	38.99 ± 4.63	31.25–40.59	2187.63	<0.001 (HS)
3 m	32.21 ± 0.28	28.79 ± 1.92	26.21–34.82		
6 m	20.71 ± 2.53	24.94 ± 1.73	21.99–27.93		

ANOVA (analysis of variances) test was used.

changes in BMI among the two groups, which decreased from  $48.3 \pm 9.2$  to  $33.1 \pm 6.6$ ,  $P$  less than 0.001.

Several randomized controlled trials demonstrate that LSG is, in the short term, a medication that actually works for extreme obesity.<sup>26</sup>

#### 4.1. Conclusions

The decrease in BMI is statistically significant in two groups from preoperative values over a 6-month period of monitoring after sleeve gastrectomy by laparoscopy for the management of obesity. Although the procedure took longer in group A due to the reinforcing of the staple line, the outcomes were promising in these individuals in terms of much less postoperative bleeding and leaking.

#### Conflicts of interest

There are no conflicts of interest.

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