

Original Article

Effect of Fibrin Glue or Suture on Leakage in Patients Undergoing Laparoscopic Sleeve Gastrectomy

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ABSTRACT

Introduction: Sleeve gastrectomy represents one of the most common surgical procedures used in bariatric surgery. The most feared complication following laparoscopic sleeve gastrectomy (LSG) is the leak that occurs at the staple line. One method to reduce the risk of leak is the use of reinforcement material at the suture line. In this study, the efficacy of sutures and fibrin glue in the prevention of staple leak has been compared retrospectively. **Methods:** A total of 250 patients undergoing LSG between October 2011 and August 2015 at the Medical Faculty of Firat University were retrospectively assessed using the hospital database system records. **Results:** There were 77 males (31%) and 173 (69%) females, with a mean age of 34 years (range: 16–65 years) and mean body mass index of 45 kg/m². Staple line was sutured in 54 patients (22%). Neither suture nor fibrin glue was used for reinforcement of the staple line in 61 (24%) patients. Only fibrin glue was used for the reinforcement of the staple line in 135 (54%) patients. Postoperative leak occurred in eight patients (3.2%). Neither suture nor fibrin glue was used for reinforcement in 6 (9.8%) of these patients. One of them was in sutured staple line group and the other was in fibrin glue group (0.7%). One patient died due to leak and the consequent development of sepsis (0.4%). **Conclusion:** Despite some controversies, strong evidence exists on the effectiveness of fibrin glue in the prevention of leaks in patients undergoing LSG from this study.

KEYWORDS: Fibrin glue, leak, sleeve gastrectomy

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INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) is a surgical method that is commonly used for the treatment of morbid obesity. Over time, this procedure has been increasingly more frequently preferred by the surgeons.^[1-3] The most common complications due to increased postoperative intragastric pressure and long staple line include leak and bleeding.^[4,5] The reported incidence of leak after LSG varies between 0% and 5.5%,^[3-5] and patients with leaks are prone to local or systemic severe complications.^[6-8] Prevention of leaks in patients undergoing LSG is of significant importance with regard to reducing mortality and morbidity as well as reducing the costs associated with the treatment of leaks.

Materials and methods that can be exploited in reducing the risk of leaks are a matter of debate, with literature

discussions on the caliber of the tube to be used, the distance between the transection line and pylorus, and the type of staple to be utilized. Another issue surrounded by controversy is the use of reinforcement materials on the staple line.^[9] A recent review suggested a reduced leak rate when a tube of 40 Fr or higher is used. In the same review, no effect of the distance between the transection line and the pylorus on leak rate has been found.^[10] Materials that have been previously used for the reinforcement of the staple line include bioprosthetic materials such as fibrin glue

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or bovine pericardium strips or absorbable polymer membranes.^[3,9,11] However, there is a scarcity of studies examining the relative efficacy of these methods in reducing the leak risk.^[11]

In our study, we retrospectively compared the efficacy of sutures and fibrin glue in preventing the staple line leak.

METHODS

A total of 250 patients undergoing LSG between October 2011 and August 2015 at the Medical Faculty of Firat University were retrospectively assessed using the hospital database system records. Patients were divided into three groups due to the chronological change occurring in the technique used by the surgery team. The staple line was sutured in the first group but not sutured in the second group. Upon observing a high leak rate in the latter group, fibrin glue was sprayed onto the staple line in the third group of patients. These three groups were retrospectively compared with regard to leak and formation of intra-abdominal abscesses. Demographic and clinical data of the patients are summarized in Table 1. All patients underwent a comprehensive examination preoperatively by surgery, endocrinology, and anesthesiology teams. If required, consultation from other medical departments was also requested.

Surgical procedures were performed by the same surgery team. Except for the support on the staple line, a standard technical procedure was used. The greater curvature was released at a 2-cm distance from the pylorus using the energy device and this procedure was continued until the angle of His. A 40 Fr tube was placed via the oral route extending from the stomach to the duodenum. Using two green followed by blue cartridge staples depending on the tissue thickness, sleeve gastrectomy was performed 4 cm away from the pylorus. In Group 1, the staple line was sutured in a continuous manner using 2/0 PDS[®]. In Group 2, neither suture nor fibrin glue was used for reinforcement of the staple line. In Group 3, 10 ml of fibrin glue (Fibrin sealant 2 ml, Tissel Baxter Healthcare Corporation) was sprayed onto the staple line using a laparoscopic applicator. A drainage tube was placed in all patients.

A passage radiography was obtained in all patients at postoperative day 2 using water-soluble contrast medium. In patients with suspicious leak image in contrast radiography as well as in patients with gastric content aspiration from the drain tube, abdominal pain, or in those with suspicious findings of leak in the physical examination, an abdominal tomography with intravenous contrast enhancement was performed. Oral 150–200 cc contrast was given if there is no certain finding suggesting leakage. For management of these

cases, oral food intake was stopped and intravenous fluid support and wide-spectrum antibiotics were given. A number of methods such as the placement of a percutaneous drain tube, endoscopic placement of a covered stent, and antibiotics for intra-abdominal abscess were used.

Statistical analyses

Jump 12.0 software (SAS, NC, USA) package was used for statistical analyses. Data were presented as mean and standard deviation. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 250 patients (77 males [31%] and 173 females [69%]) with a mean age of 34 years (range: 15–65 years) and mean body mass index of 45 kg/m² were included in this study. The number of patients without reinforcement material at the staple line was 61 (24%), while supportive sutures or fibrin glue was used in 54 (22%) and 135 (54%) patients, respectively [Table 1].

Eight patients (3.2%) had postoperative leak; of these, 6 (9.8%) were in the group with no use of reinforcement material at the suture line and two patients (one each) were in the supportive suture group (1.9%) and the fibrin glue group (0.7%) [Table 2].

In two of the eight patients (25%) with a leak, oral intake was stopped and conservative management with proton pump inhibitors, antibiotics, and total parenteral nutrition was given. In three patients (37.5%), the treatment involved the use of percutaneous drainage and stenting in two (25%) and laparoscopic drainage and stenting in one (12.5%). While seven patients underwent treatment for fistula formation, one patient who had reinforcement suture at the staple line died

Table 1: Demographic and clinical parameters

Gender	
Female	173 (69%)
Male	77 (31%)
Age	
Median (range)	34 (16-65)
BMI (kg/m ²)	
Median (range)	45 (37-66)
Operation time (min)	
Median (range)	105 (44-219)
Mean±SD	110.7±2.6
Reinforcement method	
Nonreinforcement	61 (24%)
Suture	54 (22%)
Fibrin glue	135 (54%)
Leakage	8 (3.2%)

Table 2: Comparison of demographic and clinical parameters between groups

	I. Group (Suture) (n=54)	II. Group (None reinforcement) (n=61)	III. Group (Fibrin glue) (n=135)	P I vs. II	P I vs. III	P II vs. III
Gender						
Female	16 (30%)	16 (26%)	45 (33%)	0.685	0.621	0.316
Male	38 (70%)	45 (74%)	90 (67%)			
Age						
Mean±SEM	38.3±1.6	36.6±1.4	34.1±0.9	0.450	0.023*	0.089
BMI (kg/m ²)						
Mean±SEM	46.8±0.7	45.8±0.8	46.2±0.5	0.102	0.253	0.643
Leakage	1 (1.9%)	6 (9.8%)	1 (0.7%)	0.058**	0.522	0.002*
Operation time (min)	146.9±5.5	103.9±4.8	99.7±3.1	<0.0001*	<0.0001*	0.584

Table 3: Multivariate analysis

Parameter	P	Hazard ratio	95% CI
Modality			
Suture vs. none reinforcement	0.118	0.2	0.01-1.4
Suture vs. fibrin glue	0.436	3.2	0.1-83.5
None reinforcement vs. fibrin glue	0.002*	14.6	2.4-281.1
BMI (kg/m ²)			
<48 vs. ≥48	0.139	4.2	0.7-81.3
Age			
<48 vs. ≥48	0.887	1.2	0.2-23.5
Gender			
Female vs. Male	0.420	0.5	0.1-2.8

due to sepsis (0.4%). The mortality reported by Knapps *et al.* was 0.8%,^[5] as compared to 0.4% in the current study.

Multivariate and univariate analyses on leak frequency showed a statistically significant effect of fibrin glue on the prevention of postoperative leak. However, as a weakness of our study, it should also be noted that the study period in which fibrin glue was used coincided with the completion of our learning curve. Accordingly, when patients were divided into two groups based on the order of surgery, i.e., those 125 patients operated in the first half of the study duration and those 125 operated in the second half, although a difference was noted in the univariate analysis, no significant differences could be detected in the multivariate analysis.

The duration of surgery in no reinforcement, suture reinforcement, and fibrin glue groups was 103.9, 146.9, and 99.7 min, respectively. The duration of surgery in the suture group was significantly higher.

Two patients in this study had intra-abdominal abscess formation despite the absence of a leak and both of these patients were in “the no support group.”

Univariate analysis suggested a marginal significance for the use of reinforcement sutures for reducing the leak rate. The multivariate analysis showed that

parameters (reinforcement suture, age, gender, body mass index, etc.) other than the use of fibrin glue had no effect on the leak frequency [Table 3].

DISCUSSION

Although LSG is being more frequently used as a bariatric surgical procedure, an increase in complication rates is also observed. The authors were unanimous on the effect of the reinforcement of the staple line on leak frequency.^[4,10] In this series, a significantly higher rate of leak was observed among patients who had no use of additional material in the staple line. LSG is associated with an increased intragastric pressure postoperatively, and we assume that sutures or fibrin glue material may have a role in reducing the leak rate through increased resistance to this increased pressure. In addition, fibrin glue may help prevent microleaks that cannot be visualized by leak test.

In a systemic review by Knapps *et al.*, the reported leak rate was 3.9%,^[5] consistent with our observations. Although use of sutures at the staple line was not associated with a positive effect on leak rate in the multivariate analyses, it had a favorable effect in the univariate analysis. As compared to the use of fibrin glue, although the use of reinforcement sutures may appear to offer certain cost benefits, it should be remembered that it is also associated with longer surgery as well as prolonged occupation of the surgery room and the team. In a study by Bransen *et al.*, the average cost of leak per patient has been estimated to be in the order of €9283 including the costs associated with intensive care, prolonged hospital stay, and use of medications and medical consumables.^[9] Although high acquisition costs of fibrin glue seem to be increasing the overall cost of surgery, the advantages of the prevention of the leak should also be borne in mind.

In the systematic review by Gagner and Buchwald^[3] where studies implementing nonabsorbable porcine pericardial strips, absorbable polymer membranes, suture

reinforcement, or none reinforcement were compared, absorbable polymers were associated with the lowest leak rate of 1.01%. Similarly, in this study, fibrin glue group exhibited a leak rate of 0.7%.

While surgery with use of fibrin glue or no use of reinforcement material was comparable in terms of the overall duration of the procedure, surgery was significantly longer in the suture support group, which may be considered as a limiting factor for the use of this less costly option. This longer operation time for the suture group also may be due to the learning curve because those patients were in the first period of our LSG series.

Increased leak rate has been previously reported when the staple line is left without reinforcement,^[11] in line with our observations. In a recent systematic review including 88 studies and 8920 patients, the reported leak rate in patients who had suture support at the staple line was 2.0%, comparable to our figures of 1.9%. Does staple line reinforcement or buttressing prevent or decrease the leak rate is a question that was addressed in several studies, some of them concluded that reinforcement with oversewing decreases the leakage rate, some of these authors were based on retrospective, noncontrolled studies.^[12] Fibrin sealants were also addressed in some studies with good impact in terms of decreasing leakage rate.^[12] For all that, staple line reinforcement is not well standardized.^[13]

Two patients without reinforcement had intra-abdominal abscess formation, despite the absence of a leak. Probably, use of sutures or fibrin glue could also be related with lower risk of intra-abdominal abscess formation due to the prevention of microleaks. However, to reach a more definitive conclusion, further and more comprehensive studies are warranted.

While seven patients underwent treatment for leaks, one patient who had reinforcement suture at the staple line died due to sepsis. The mortality reported by Knapps *et al.* was 0.8%,^[5] as compared to 0.4% in the current study.

The retrospective nature is a limitation of this study. Due to the chronological order of the groups, outcome is expected to be in favor in the last group because of the learning curve.

CONCLUSION

Despite certain limitations of our study, it provides strong evidence for the efficacy of the use of fibrin glue

material in LSG in the prevention of leaks. This approach appears to be effective in increasing the resistance of the staple line against leaks in patients undergoing LSG.

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Conflicts of interest

There are no conflicts of interest.

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