

Original Article

Comparison of four different methods in staple line reinforcement during laparoscopic sleeve gastrectomy

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Abstract: The main early complications of Laparoscopic Sleeve Gastrectomy are bleeding and gastric leakage. Many reinforcement methods are performed in order to reduce these complications. In this prospective, randomized study, we compared four different techniques to evaluate staple line reinforcement in Laparoscopic Sleeve Gastrectomy. Between January 2012 and May 2013, 65 patients were prospectively randomized into four groups in which different techniques were used in handling the staple line during Laparoscopic Sleeve Gastrectomy. Of the four groups, there wasn't any reinforcement used on 15 patients during LSG (group 1), continuous serosal 3-0 prolene sutures were used on 16 patients for staple line reinforcement (group 2), staple line was supported with v-loc suture in 16 patients (group 3), and 18 patients had Tisseel fibrin sealant applied throughout the staple line (group 4). 40 of 65 patients were females, the mean age was 36.8 years (20-58 years), and the mean BMI was 49.2 (41-60 kg/m²). Characteristics of patients among groups were similar. There wasn't any significant difference found between groups for BMI. Gastric leakage was detected from the staple line in 2 patients of the v-loc group. According to our results, we demonstrated that good results can be obtained without any reinforcement. Reinforcement with propylene suture only prolongs the operation time, and tissue fibrin sealant increases the cost. In conclusion, we should be more careful using v-loc sutures, and further series with larger numbers are needed to test v-loc.

Keywords: Laparoscopic Sleeve Gastrectomy (LSG), reinforcement, v-loc, tisseel, suture

Introduction

Laparoscopic Sleeve Gastrectomy (LSG) was first applied in 2000 [1]. Since then it has become popular among surgeons interested in obesity because of its positive results on weight loss and lower comorbidities.

Postoperative bleeding [2], gastric leakage [3], stricture [4], gastric dilatation [5], gastroesophageal reflux disease development [6] and insufficient weight loss [7] are the main complications. Bleeding and gastric leakage are among the early complications. Bleeding can be either from the staple line on the gastric surface or from the detached omentum surface. Although this condition can be managed conservatively [8], usually reoperation is needed [9]. Leakage can be from any place throughout the vertical stomach as a result of residue from the stapler surface [10]. Management of gastric leakage is

a difficult practice and would include a long hospital stay or stent [11].

Several reinforcement methods are used to support the staple line during LSG. Suturing with seroserosal absorbable and nonabsorbable materials [12], gelatine fibrin matrix application (Flo Seal) [13], and bioabsorbable staple line reinforcement (Gore Seamguard-Polyglycolic acid: Trimethylene carbonate) are some of these methods [14, 15].

In this randomized, prospective study, we aimed to compare the early stage complications of 4 methods-leaving the stapler line without intervention during Laparoscopic Sleeve Gastrectomy, strengthening by continuous suturing with 3-0 prolene (Ethicon USA), strengthening by continuous suturing with v-loc 180 (Covidien, USA) suture, and application of tissue fibrin sealant.

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Table 1. Characteristics of patients among groups

	Group 1	Group 2	Group 3	Group 4
n	15	16	16	18
Age	35.2	35.6	39.6	36.2
Gender M/F	6/9	6/10	6/10	7/11
Mean BMI	49.2	50.2	48.3	48.7

Materials and methods

65 patients between 18-60 years of age that underwent Classical Laparoscopic Sleeve Gastrectomy (LSG) in the General Surgery Department of Antalya Training and Research Hospital between January 2012 and May 2013 were included in the study. Body Mass Index of all the patients was over 40. After obtaining Antalya Training and Research Hospital Ethics Committee approval and informed consent from the patients, they were operated on after randomizing into four groups. During LSG, support to stapler line was not reinforced in 15 patients (group 1), individual sutures with 3-0 propylene were used to reinforce stapler line in 16 patients (group 2), stapler line was strengthened by v-loc suture in 16 patients (group 3), and Tisseel 4 ml fibrin sealant (Two component Fibrin Sealant; 2 ml fibrinogen and 2 ml thrombin - Eczacıbaşı Baxter Drugs) was applied in 18 patients throughout stapler line (group 4).

Age, gender and BMI of the LSG patients with the diagnosis of morbid obesity were recorded (Table 1).

Patients were followed-up on for postoperative complications such as, duration of hospital stay, bleeding, anastomosis leakage, wound site infection, and abscess formation.

Statistical analysis

Statistical package SPSS 17.0 (SPSS Inc, Chicago, IL) was used for statistical analysis. Quantitative data were expressed as mean. Statistical analysis was performed using the chi-square test (Pearson, Mantel-Haenzel test for linear association), Yate's correction or Fisher's exact test, and Mann-Whitney U test, whenever needed. A p -value <0.05 was considered statistically significant.

Surgical method

The patient was carefully placed and secured to the operation table in supine position, and

the legs were separated. A nasogastric drainage tube was inserted and removed after aspiration of gastric content. A foley catheter was inserted. The patients were dressed with anti-embolic socks. The surgeon stood between the legs of patient, cameraman stood at the right side of the patient, and the first assistant stood at the left side of the patient. A total of 5 trocars were placed: 10 mm trocar from the middle line 25-30 cm below the xyphoid and above the umbilicus, 5 mm trocar from the left anterior axillary line, 12 mm trocar from the left mid clavicular line, 10 mm trocar from the left mid clavicular line, and 5 mm trocar below the xyphoid process. A window to the omentum was opened by laparoscopic Ligasure (Covidien, USA) approximately 4 cm proximal of pylorus from the greater curvature of the stomach. From this window, the surgeon proceeded by detaching omentum towards proximal of stomach. The spleen was liberalized by cutting short gastric vessels. Diaphragmatic left crus was revealed. 32 Fr orogastric tube was connected to the stomach up to pylorus by advancing through smaller curvature. Stomach transection was initiated beginning from antrum about 3 cm proximal to the pylorus and was continued to the Hiss angle. Echelon 60 stapler (Ethicon-Mexico) was used for closing. First ignition was started with green cartridge then proceeded with blue cartridge. At proximal, the stomach was detached from the gastroesophageal junction in order to be about 1 cm away without tension. The whole stapler line was checked for any bleeding and gastric leakage. Leakage control was performed with intraoperative methylene blue or air fluid test. The orogastric tube was removed and the nasogastric tube was inserted. For stapler line reinforcement, none was added in Group 1, in Group 2, continuous 3-0 prolene serosal sutures were added from the last ignited stapler line to the first stapler line, in Group 3, serosal sutures were added by v-loc suture, and in Group 4, the whole stapler line was covered with 2 (8 ml) Tisseel fibrin sealant to distal stomach.

Resected stomach was removed from the 12 mm trocar hole. Finally the whole stapler line was washed out with saline and residual fluid was aspirated. A drainage tube was placed throughout the stapler line. To prevent fascial port side hernias, fascia was closed by 2-0 vicryl. Skin was sutured using 3-0 prolene.

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Table 2. BMI, postoperative complications and operation time among the groups

	Without suture	Suture	v-loc	Tisseel	P value
n=65	15	16	16	18	p>0.05
BMI	49.2	50.2	48.3	48.7	p>0.05
Anastomosis leakage	0	0	2	0	p>0.05
Postoperative bleeding	0	0	0	0	p>0.05
Re-operation	0	0	0	0	P=1
Mortality	0	0	1	0	p>0.05
Operation time (min)	138.1	196.0	166.4	138.2	p>0.05

BMI: Body Mass Index.

Patients were mobilized on the first postoperative day. The nasogastric drainage tube was removed on the third postoperative day. On the third postoperative day, gastric passage graphy was performed by giving the patients a radiopaque substance. The abdominal drainage tube was removed on the third postoperative day as long as there were no complications. Patients without complaints were discharged on the morning of the fifth postoperative day in order to apply polyclinic control.

Results

65 patients who had LSG were included in the study. 40 patients were female and 25 were male. Mean age was 36.8 years (20-58 years), and mean BMI was 49.2 (41-60 kg/m²). Of the patients randomized into four groups, no reinforcement was applied in 15 patients during LSG (group 1), continuous serosal sutures with 3-0 prolene were used in 16 patients for stapler line reinforcement (group 2), the stapler line was supported with v-lock suture in 16 patients (group 3), and 18 patients had Tisseel fibrin sealant applied to the stapler line (group 4). Characteristics of patients among groups were similar. There wasn't any significant difference found between groups for BMI (**Table 2**).

Except for cholecystectomy in one patient, umbilical hernia in another patient in group 1, appendectomy in one patient in group 3, and abdominal hysterectomy in one patient in group 4, there were no previous operations in the history of all other patients.

No complications developed intra-operatively. Patients were followed-up on for postoperative bleeding, anastomosis leakage, and formation of abscess.

In post-operative follow-ups, gastric leakage was detected from the stapler line in 2 patients of the v-loc group. In the first patient, leakage was detected by radiographic evaluation performed on the third postoperative day. She was treated by placing additional abdominal drainage tubes. She was checked for the presence of loculated fluid or abscess. Total parenteral nutrition was given. After 43 days,

no drainage was detected, and the well patient was discharged. Leakage in the other patient was detected because of the content in the drainage tube. Considering that the closure would take a long time, endoscopic stent (Megastent, 23 cm x 24 mm x 32 mm, Taewoong, Korea) was inserted into the patient on the 13th postoperative day. In the follow-up, since the stent was replaced and occluded the passage, the patient was exitus after aspiration. None of the patients were operated on again, and there wasn't any other complications observed.

Discussion

Many surgeons have used several, different methods for staple line reinforcement in laparoscopic sleeve gastrectomy operations; however, a definitive, joint decision has not been reached. Although the importance of staple line reinforcement is described in literature, it is still controversial. Supportive reinforcement to the staple line has benefits such as increasing staple line tension force, decreasing bleeding, and reducing the risk of leakage. Currently, many products can be applied for reinforcement.

In this study, we have compared three different types of staple line reinforcement and a group without reinforcement. We found similar results in the group without reinforcement, the group reinforced by continuous sutures of propylene suture material, and the group reinforced with tisseel tissue fibrin sealant. Since gastric leakage developed in two of the patients in the v-loc suture group, and one of the patients died, we are worried about the use of these sutures for serosal reinforcement.

Several studies compare reinforcing the staple line by differing methods and not reinforcing it

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at all. Although it is reported the results in many studies are similar, it has been reported in some studies that reinforcement reduces the risk of gastric leakage.

Choi et al reported in a meta-analysis that staple line reinforcement has advantages for preventing postoperative leakages and general complications, but further studies are needed [16]. Shikora reported that the usage of reinforcement materials in laparoscopic gastric bypass reduces bleeding and gastric leakage [17]. Consten reported that absorbable polymer membranes reduce bleeding and leakage from staple line [13]. In a study in which PSD-Peri-Strips Dry bovine pericardium was used for staple line reinforcement, it was reported as safe and effective in the short term [18].

However, in a retrospective study conducted by Simon et al, they reported that there isn't certain evidence that the usage of Seamguard decreases staple line leakage and bleeding [19]. Again, in a study in which Seamguard (Gore) and PDS 2.0 sutures were used, there wasn't a difference found between the two techniques [14]. Similar findings have been reported in another study in which staple line reinforcement wasn't performed in one group and was compared to the two other groups, and, again, there wasn't any significant difference found [20]. In another study, according to literature screening and their experiences, Bo Chen has demonstrated that staple line reinforcement does not lead to a significant decrease in staple line leakage rates [21].

We have not discovered any problems in the group in which we reinforced with continuous suture technique with prolene. However, the duration of operation was longer than the group without suture. Also, concerns like curling inside of the closed staplers by applied suture support, more diverge of mucosal endings, and losing the formation of the staplers come to mind.

Lee et al reported that the usage of tissue fibrin adhesives were effective on reducing the risk of anastomosis leakage [22]. In a retrospective study with 74 patients, it was suggested that Thrombine matrix is safe and can be an alternative to other techniques for LSG [23]. We also have not met with any problems in patients whom we applied tissue fibrin sealant. However,

Salgado et al concluded in their study that two techniques were compared for staple line reinforcement during open Roux-en-Y gastric bypass and that the fibrin sealant group was excluded from the study because of two leakages. They also concluded that seamguard is easier than suture but more expensive [24].

Not reinforcing the staple line in LSG has also been reported as safe. Kasalicky et al did not use reinforcement for the staple line in their experiences and presented a reliable and effective LSG result with low complication and mortality incidence [25]. We also did not find any problems in the group of 15 patients in whom reinforcement was not applied. Although our number of cases was few, we were convinced that a method not using reinforcement can be reliable, and these results encouraged us in performing operations without support on the staple line.

From the point of leakage following staple line reinforcement, we had two leakages in the v-loc group, and one of the patients died.

V-Loc™ is an absorbable wound closing device that closes wounds safely without the need for knotting, disperses tension throughout the wound, and closes the wounds 50% faster with similar holding power to conventional sutures. We have not found any study in pubmed, medline or embase about the usage of V-Loc™ 180 (Covidien, USA) for obesity. There are studies suggesting that V-loc is not only ideal for skin closure but ideal for laparoscopic peritoneum closure as well. There are studies that demonstrated v-loc is effectively used for laparoscopic gastrointestinal anastomosis and closures, significantly shortened the duration of surgery, and recommended its use [26]. Although two leakage cases were not significant, it made us think the usage of this hard suture for serosal support can be inconvenient. The reason for the leakage could be due to serosal defects created during the traction of stomach by small hard processes that prevent the escaping back of suture. Further studies are necessary to investigate this.

Consequently, in this study we compared four different techniques to evaluate staple line reinforcement in LSG. Our findings demonstrated to us that good results can be obtained without reinforcement and encouraged us. The

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same results were obtained in the group without reinforcement. Strengthening with propylene suture only prolongs the duration of operation, and tissue fibrin sealant increases the cost. However, one should be more careful using v-loc, and it is thought that further, larger serials are needed to test V-loc.

Disclosure of conflict of interest

The Authors have nothing to disclose.

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