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Effects and results of fibrin sealant use in 1000 laparoscopic sleeve gastrectomy cases

Halil Coskun[1] · **Erkan Yardimci**[1,2]

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Abstract
Background Staple-line leakage and bleeding are worrisome and feared postoperative complications after laparoscopic sleeve gastrectomy (LSG) in morbidly obese patients. The purpose of this study was to review clinical evidence following the use of fibrin sealant in standard LSG.
Methods Morbidly obese patients who underwent standard technique of LSG with using fibrin sealant were included in the study. Demographics variables [age, gender, body mass index (kg/m^2), and comorbid conditions], the re-admission rate, and postoperative early complications, such as bleeding, staple-line leak, twist and stricture, were evaluated at the follow-up during the postoperative first month.
Results In total, 1000 patients [586 female (58.6 %)] with a mean age of 42.6 ± 13.6 years underwent LSG. Fibrin sealant was used in all operations. In total, 186 patients (18.6 %) had previous abdominal surgery. The mean operative time was 72 ± 19 min, and the mean hospital stay was 3.2 ± 1.1 days. Only 3 patients (.3 %) experienced bleeding. Staple-line leakage, twist and stricture were not observed. The re-admission rate was .5 %, and no mortalities were noted.
Conclusion This retrospective study indicates that bariatric surgeons should consider implementing standardized surgical operative technique for reduced postoperative complications in LSG. Fibrin sealant is a reliable and useful tool to reinforce the staple line and may prevent potential twists of the sleeved stomach.

Keywords Sleeve gastrectomy · Staple line · Fibrin sealant · Reinforcement

Bariatric and metabolic surgeries are increasingly used for weight loss and improved obesity-related comorbidities. The criteria for bariatric surgery include patients with a body mass index (BMI) of 40 kg/m^2 or a BMI of 35 kg/m^2 associated with at least one comorbidity, such as arterial hypertension, diabetes mellitus, obstructive sleep apnea and dyslipidemia [1, 2]. Laparoscopic sleeve gastrectomy (LSG) is a straightforward technique and has a shorter learning curve compared with other procedures used to treat obesity, such as laparoscopic Roux-en-Y gastric bypass (LRYGB) and biliopancreatic diversion with duodenal switch (BPD-DS), and its results regarding the % total weight loss (%TWL) and resolution of comorbidities are very satisfactory [2–5]. The advantages of LSG include a low complication rate, but the main complications after LSG include bleeding and staple-line leakage [5, 6]. Therefore, some surgeons use various materials, such as Peri-Strips Dry with Veritas, Seamguard, fibrin sealant and/or gelatin matrix agents, sutures and clips, to achieve better hemostasis and decrease the incidence of early complications, such as staple-line leaks [7–10]. Fibrin sealant has been approved by the Food and Drug Administration (FDA), and it is the only agent that provides hemostasis, sealing and adhesion [11]. Fibrin sealant has been safely

✉ Erkan Yardimci
drerkanyardimci@yahoo.com

Halil Coskun
halilcoskun@hotmail.com

[1] Department of General Surgery, Bezmialem Vakif University, Istanbul, Turkey

[2] Present Address: Department of General Surgery, Arnavutkoy State Hospital, Eski Edirne Str, Arvanutkoy, 34275 Istanbul, Turkey

used in a wide variety of surgical procedures, such as cardiovascular surgery, spleen and liver trauma, the closure of colostomies, and repair of bronchial fistulas and dural tear [12–15]. Fibrin sealant consists of two components: One is thrombin, and the other is fibrinogen. Fibrin sealant is a biological tissue adhesive that initiates the last step of the coagulation when a solution of human fibrinogen is broken down to fibrin monomer by thrombin. The fibrin monomer polymerizes in the presence of small amounts of factor XIII and calcium to form a fibrin polymer, which is precipitated as fibrin fibrils in the tissue and is expected to be completely resorbed in 10–14 days [16]. We used fibrin sealant in all patients who underwent LSG given its safety and reported use in many laparoscopic surgeries [17, 18].

Materials and methods

The present study was approved by the Institutional Review Board for Bezmialem Vakif University Faculty of Medicine. Informed consent was obtained from all individual participants included in the study. This is a retrospective review of prospectively collected data related to all cases of LSG performed between November 2010 and January 2016 in two centers. Data concerning patient demographic variables [age, gender, body mass index (BMI, kg/m^2), and comorbid conditions], previous surgeries, postoperative complications and postoperative readmissions were collected. None of the obese patients were excluded from this study. All patients were administered 1–2 mg/kg of subcutaneous low molecular weight heparin before surgery until the end of the second postoperative week to prevent thromboembolism. Standard LSG was performed by one surgeon, and two 4 ml boxes of human fibrin sealant (Tisseel^{TM}, Baxter$^{@}$ Deerfield, IL, USA) were sprayed along the suture line in all patients. A swallow Gastrographin X-ray control was routinely performed on the postoperative second day. Complications were determined in the first follow-up month. Early hospital readmission is defined as at least one readmission for any reason within 30 days postoperatively. Continuous variables were expressed as the mean ± standard deviation. Categorical variables were expressed as frequencies.

Surgical procedure

First-generation cephalosporins (cefazolin sodium, 2 g, intravenous) are applied at the induction of anesthesia as an antibiotic prophylaxis. The operation is performed in the French position in which the surgeon is positioned between the legs of the patient. Elastic stockings and intermittent pneumatic compressing device are used for prophylaxis of thromboembolism. The first trocar with a diameter of 10 mm is placed 1–2 cm above the umbilicus by Visiport^{TM} Plus optical trocar (Covidien, Mansfield, MA, USA). After creation of a 15-mmHg pneumoperitoneum, a five-trocar approach is used for optimal visibility (Fig. 1). A 5-mm trocar is positioned at the subxyphoid area for insertion of the Nathanson liver retractor (Cook Medical Inc., Bloomington, IN) to lift the left lobe of the liver and to obtain the optimal view of the stomach. Initially, the stomach is decompressed with a nasogastric tube by the anesthesiologist. While using a Harmonic scalpel (UltraCision, Ethicon Endo-Surgery), the omentum is released from the greater curvature, starting opposite to the Crow's foot (approximately 6 cm proximal to the pylorus) because it is easier to enter the lesser sac at this area. Next, the greater curvature is dissected up to 1 cm lateral to the angle of His and 2 cm proximal to the pylorus. Staple-line leakage is generally observed at the proximal of the gastric tube [10]; therefore, dissection should be performed carefully to provide the blood supply of the gastroesophageal junction (Fig. 2A). Complete mobilization of the fundus, including removal of the fat pad located at the gastroesophageal junction, before the transection is regarded as the critical point for the success of the technique. While holding the stomach with the 5 mm grasper, the surgeon carefully dissects the gastropancreatic area preserving the left gastric artery and its branches (Fig. 2B). A calibrating 39F bougie is inserted by the anesthesiologist into the stomach to create a tube. The stomach is divided using linear Roticulator stapler with a 60 mm cartridge (Echelon, Ethicon Endo-Surgery Cincinnati, OH) inserted into the abdomen via the right-sided 12-mm trocar. To create a straight staple line, good lateral traction of the stomach should be performed via the grasper inserted at the left upper quadrant trocar. The first stapler is fired at a point 2 cm proximal to the pylorus for antral resection of the stomach, and the remaining staplers are then fired in cranial direction along the greater curvature of the stomach

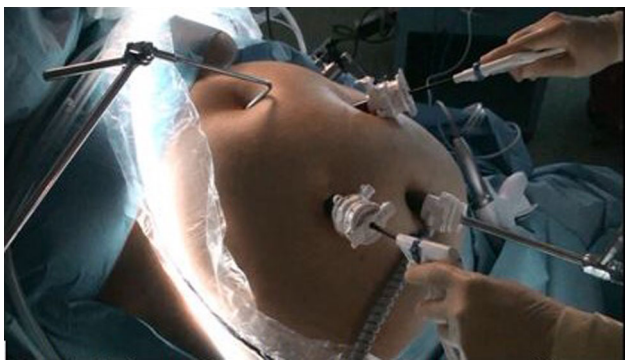

Fig. 1 Patient position, the location of the trocars and liver retractor

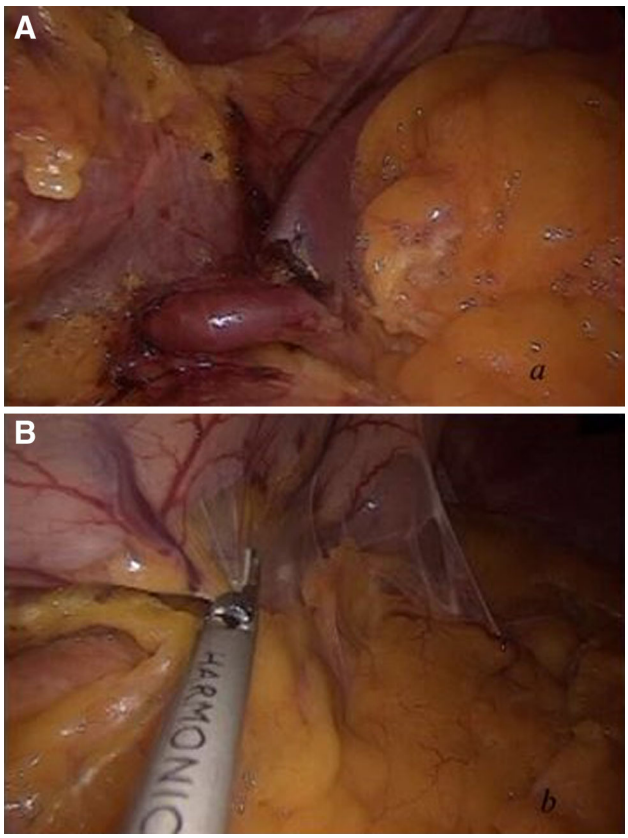

Fig. 2 Greater curvature dissection up to 1 cm lateral to the angle of His (**A**). Dissection of the adhesions in the gastropancreatic area (**B**)

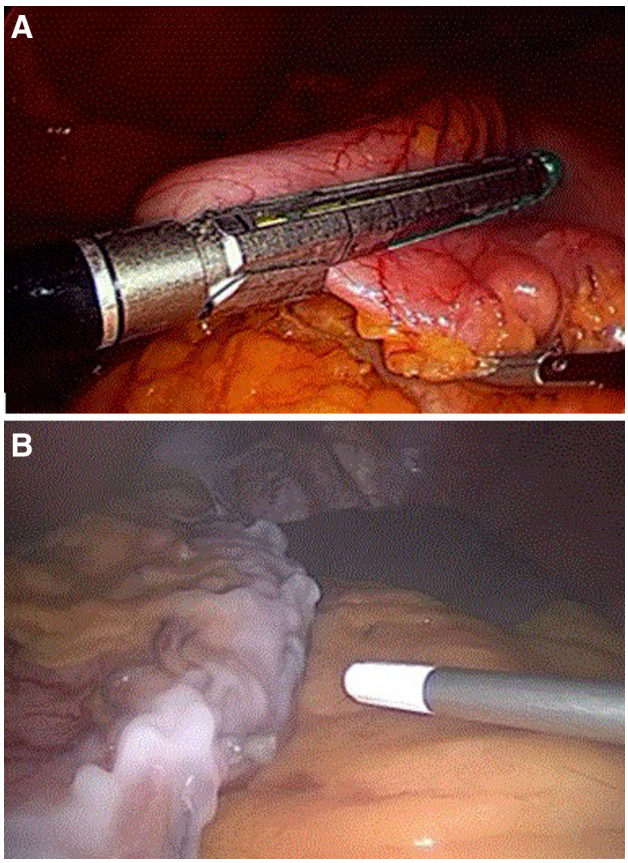

Fig. 3 First stapler firing at a point 2 cm proximal to the pylorus for antral resection of the stomach (**A**). The human fibrin sealant spraying along the suture line (**B**)

(Fig. 3A). The closed height of the stapler should be greater than 2 mm because the thickest part of the stomach is in the antrum. Therefore, green cartridges (4.1 mm staple height) are used for the first two firings. Blue cartridges (3.5 mm staple height) are used for the resection of the upper stomach. We waited 45 s between stapler closure and firing. Approximately, 5–6 cartridges are necessary to complete the transection in all operations. Any staple-line bleeding is strengthened with clips. The calibrating bougie is removed and changed to a nasogastric tube. All the sleeved stomachs are tested by methylene-blue injection through the nasogastric tube. Two boxes (8 ml) of human fibrin sealant were sprayed along the suture line and posterior to the sleeved stomach through a dedicated laparoscopic set (Easyspray^{TM}—Baxter$^{@}$ Deerfield, IL, USA) to provide hemostasis, sealing and adhesion (Fig. 3B). The patient was brought from a normal position to the reverse Trendelenburg position to access the omental tissue to the staple line and proximal of the sleeved stomach. The omentum, left lobe of the liver and pancreas pasted the sleeved stomach and provided a strong barrier to prevent bleeding, leakage and twist. A closed-suction drain is placed near the staple line.

Results

Of the 1000 patients who underwent LSG, 516 (51.6 %) of the patients had obesity-related comorbid conditions with a BMI > 35 kg/m^2. The mean age of the patients was 42.6 ± 13.6 years. Demographic and anthropometric variables and types of comorbid conditions are provided in Table 1. In addition, 186 of the 1000 patients (18.6 %) previously underwent abdominal surgery, and 61 of 186 patients failed previous bariatric surgery, such as laparoscopic adjustable gastric band (LAGB) (56 patients) and laparoscopic gastric plication (5 patients), for %TWL. Laparoscopic cholecystectomy was performed during LSG for symptomatic gallbladder stones in 67 patients (6.7 %). All operations were completed laparoscopically, and the mean operative time was 72 ± 19 min. No intraoperative leak was identified during methylene-blue test. The mean hospital stay was 3.2 ± 1.1 days. Postoperative complications are presented in Table 2. No leakage and early stricture were identified in the upper gastrointestinal contrast studies. Five patients (.5 %) were readmitted to the hospital for postoperative abdominal pain. Two of 5

Table 1 Characteristics and preoperative comorbidities of patients undergoing LSG

Demographics	Value
Age[a]	42.6 ± .6
Gender	
Female[b]	586 (58.6)
Male[b]	414 (41.4)
Previous abdominal surgery[b]	186 (18.6)
Body mass index (kg/m^2)[a]	43.7 ± 12.2
Comorbid conditions	
Diabetes mellitus[b]	276 (27.6)
Arterial hypertension[b]	312 (31.2)
Obstructive sleep apnea[b]	134 (13.4)
Hyperlipidemia[b]	101 (10.1)
Anticoagulant use[b]	22 (2.2)

[a] Mean ± standard deviation, or percentage

[b] n (%)

Table 2 Postoperative outcomes

	Value
Operative time (min)[a]	72 ± 19
Hospital stay (day)[a]	3.2 ± 1.1
Complications	
Bleeding[b]	3 (.3)
Leakage and/or fistulas[b]	–
Stricture[b]	–
Twist[b]	–
Pulmonary emboli[b]	–
Re-operation[b]	1 (.1)
Re-admission[b]	5 (.5)
Mortality[b]	–

[a] Mean ± standard deviation

[b] n (%)

patients experienced superior mesenteric vein thrombosis, and the abdominal pain in the other patients was non-specific. All patients who were re-admitted to the hospital were treated by medical therapy. No re-intervention was performed in these patients, and no mortality occurred. The rate of bleeding was .3 %, and 1 of 3 patients with hemodynamic instability underwent re-laparoscopy on the second postoperative day. Surgery was converted from laparoscopic to open, and the abdominal hematoma was removed. However, we did not identify any bleeding. We thought that the bleeding stopped spontaneously. The other 2 patients with hemodynamic stability were treated conservatively. The patients were discharged from the hospital on the 6th postoperative day. Patients did not experience other complications during the first follow-up month.

Discussion

Bariatric surgery has provided %TWL and better survival in addition to reduced potentiality mortality for obesity and related diseases [19, 20]. Laparoscopic sleeve gastrectomy has been increasingly used, whereas other bariatric procedures, such as LAGB, LRYGB and DS, have experienced a concurrent reduction [6, 21]. Laparoscopic sleeve gastrectomy does not include gastrointestinal anastomosis, creation of mesenteric defects or risk of internal herniation [2]. Currently, LSG has become comparable with the other procedures based on its advantages and efficient results; however, many worrisome complications can be noted depending on the surgical technique. All surgeons aim to decrease the risk of complications; therefore, many of them use various materials to provide hemostasis and reinforce the staple line. Nevertheless, no materials were routinely used for prevent rotation of the gastric tube and/or stricture. According to our experience, the most important strategy to avoid the twist and stricture include the use of a bougie. In addition, when the stomach started to divide .5 cm lateral to the bougie, the other staplers should be fired on the same staple line. In our standard technique, if the stomach divided straight and human fibrin sealant was sprayed on the staple line, left crus of the diaphragm and posterior of the stomach, then the surrounding tissues adhered to the gastric tube. Therefore, this technique provided a normal position for the stomach and hemostasis of the staple line. Consequently, our results revealed that fibrin sealant helps to prevent twist and stricture of the sleeved stomach by ensuring adherence and preventing postoperative staple-line leakage. In the literature, the rate of staple-line leak and stricture following LSG ranged from 0 to 4.2 % [8, 22, 23] and 0 to 2.1 %, respectively [10, 24, 25], and these complications can lead to major morbidity and mortality. Bleeding is the other feared complication of LSG, and the rate of bleeding ranged from 1.7 to 13.7 % [10, 28, 29]. Numerous options are available to avoid bleeding. According to our findings, abdominal hemorrhage after LSG should be followed carefully with proper hydration, including erythrocyte suspensions. Patients should not rush to undergo surgery if the hemodynamic parameters remain stable. Nevertheless, hemodynamically instable patients despite adequate liquid and electrolyte therapy should immediately undergo surgery. These worrisome complications are more difficult to treat and take a long time to heal. In a review by Gagner and Buchwald [26] involving 8920 patients, four reinforcement options were studied: no reinforcement, oversewing (suture), bovine pericardial strip reinforcement (BPS, Peri-Strips Dry), and absorbable polymer membrane reinforcement (APM, Seamguard). The study indicated that the overall

complication rates ranged from 5.5 (APM) to 8.9 % (no reinforcement) and the leak rates ranged from 1.09 (APM) to 3.3 % (BPS). According to the 5th International Consensus report, 81.4 % of Expert Surgeons accepted the usage buttress materials. Most of them (55.5 %) agreed with the using non-absorbable sutures to oversew staple lines might cause granulomas and fistulae [30]. Buttressing materials that are passed on the stapler are used to prevent leaks from the staple line. However, these materials have some main challenges and restrictions. Materials are expensive, and difficulties are occasionally experienced. When staple is placed, the fitted covering increases the staple thickness and causes discoloration of the cartridge, which is used indirectly. Given that standardization is always difficult, none of these covers can completely prevent leakage. Another technique used to prevent staple-line leaks involves suturing. The important disadvantage of the use of sutures to reinforce the staple line at the incisura angularis involves stenosis. A study by Nimeri et al. [27] that included 310 patients assessed the routine use of oversewing sutures to reinforce the staple line during LSG. Stenosis was detected on intraoperative endoscopy in 10 patients (3.2 %), and all cases were treated after removing the over-sewing sutures. Other major disadvantages of this method is that it is time-consuming and it occasionally causes bleeding and ischemia. The stomach must remain larger for the sero-serosal sutures, and there is no standardization. Recent studies make no recommendations about the use of suture [31]. Some authors suggest that the omentum should be stitched up to the staple line to prevent leakage. However, it is doubtful that the durability obtained with the fibrosis will be able to achieve full adherence on the staple line.

We use Tisseel because of the following advantages. Tisseel ensures resolution after a certain time and partially inhibits the effect on bleeding given its content. We have never used this agent before to prevent a possible significant leak directly. However, the tissue adhesive effect of Tisseel allows the omentum to be in the area of the staple line and causes rapid staple line-omental adhesion. This adhesion is particularly intense at the level of the left crus. A real-time tissue durability enhancing effect was noted clinically for the staple line-omental adhesion, and we believe that the potential twist can be prevented given that the staple line fixes lateral sticking.

Limitations

The limitations of our study were that this was a retrospective study, it lacked the comparative control groups and the number of patients was thought to be inadequate to achieve statistically significant results.

Conclusion

Multiple approaches to reduce the rate of complications have been achieved by synthetic or biological reinforcement materials, but no consensus is available regarding the best method for staple-line reinforcement or its necessity. Fibrin sealant is a reliable and useful tool to reinforce the staple line and may prevent twists in the sleeved stomach.

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Compliance with ethical standards

Disclosures Drs. Halil Coskun and Erkan Yardimci have no conflicts of interest or financial ties to disclose.

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