Original Article

Comparative study of two different techniques for leak and bleeding prevention during laparoscopic sleeve gastrectomy

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Abstract:

Background: Laparoscopic sleeve gastrectomy has gained more popularity as an independent bariatric procedure because laparoscopic sleeve gastrectomy was reported to be an effective, safe, and time-saving procedure, leading to adequate weight loss for morbidly obese patients and becoming one of the most common procedures performed for the treatment of morbidly obese patients in the last few years until now.

Objectives: The aim of this study is to compare two different techniques of the reinforcement of staple line during LSG in the reduction of major complications (bleeding and leak).

Patients and methods: prospective randomized study of a consecutive series of 126 patients that underwent LSG between April 2014 till August 2015. Patients were randomly enrolled in two different techniques of reinforcing the staple line during LSG, Group A consisted of 63 patients that underwent sleeve gastrectomy using Ethicon Endo GIA stapleTM with staple line oversewn using 2.0 prolene continuous suture, group B also 63 patients who had the staple-line oversewn with a continuous suture using V-locTM and Covidien Endo GIA tristapleTM.

Results: 126 patients who underwent LSG, 82(65%) were women and 44(35%) were men. Median age was 36 years (range, 19–58 years) and median preoperative BMI was 45.4 kg/m2 (range, 37–62 kg/m2), Three patients (4.76%) from group (A) and 2 patients (3.17%) from group (B) developed primary hemorrhage (within the first 24 hours post operatively), overall bleeding rate in both groups was (3.96%), no leak in both groups and no mortality.

Conclusion: laparoscopic sleeve gastrectomy is a safe procedure as a sole weight reduction operation. The combination of meticulous surgical technique, reinforcement of the gastric staple line, lead to decrease the incidence of staple line leak whatever the suture material or stapler type used, but there is no significant decrease in the incidence of bleeding with staple line reinforcement.

Keywords: sleeve gastrectomy, staple line reinforcement, leak, bleeding.

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Introduction:

According to WHO, obesity is a chronic disease that has a global impact. As of 2008, over 500 million adults globally are obese(1). The impact of obesity spans all demographic types, and has been increasing in prevalence among youth. Obesity significantly affects the entire body, and is associated with millions of premature deaths. Comorbidities of obesity include cardiovascular, adrenal, orthopedic, gastrointestinal, and an increased risk of cancer(1,2).

Laparoscopic sleeve gastrectomy (LSG) was originally performed as a bridge procedure to laparoscopic Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch(2,3). Recently, LSG has gained more popularity as an independent bariatric procedure because LSG was reported to be an effective, safe, and time-saving procedure, leading to adequate weight loss for morbidly obese patients(2,3,4).

In 2009 LSG was recognized by the American Society for Metabolic and Bariatric Surgery as a primary procedure for the surgical management of morbid obesity(5,6). This technique is also associated with several important benefits, including maintenance of gastrointestinal continuity without an anastomosis, avoidance of malabsorption, absence of implantable nonabsorbable material, and potential convertibility to other operations(5,6).

Sleeve gastrectomy involves the creation of small gastric reservoir based on lesser curvature of the stomach, which is fashioned by a longitudinal gastrectomy that preserves the antrum and pylorus together with its vagal innervation(7). Recently, laparoscopic sleeve gastrectomy (LSG) is viewed as a multipurpose bariatric procedure that restricts the stomachs size to induce satiety and resects fundal ghrelin-producing cells to decrease appetite(7,8).

Nevertheless LSG is not without complications(8). The least severe of these are gastroesophageal reflux disease, insufficient weight loss, and stricture or dilation of the gastric tube(6,8). The most serious and feared complications are bleeding and leakage from the gastric staple line. These events can lead to significant morbidity, ranging from a prolonged hospital stay for conservative treatment, stenting, the need for a total gastrectomy, or death(6,8).

The incidence of significant hemorrhage from the staple line, requiring blood transfusion or reoperation, is reported to be

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1.1%–8.7%(6,9,10). The most dangerous and life-threatening complication is the staple-line leak; the mean incidence is 2.7%(6,10,11). Leaks usually occur just below the gastroesophageal junction, perhaps because of the high internal pressure subsequently to the tubularization of the stomach(6,11).
Management of the leak, however, is usually difficult and may include conservative treatment with the placement of endoscopic stents or may require reoperation that includes peritoneal draining and placement of drainage tubes or even total gastrectomy(12). Therefore, any technique that can reduce the likelihood of these complications would be of tremendous benefit to the field of bariatric surgery. As a result, a continuous effort to improve the performance of stapling devices by reinforcing the staple line is underway(12,13,14).
The aim of this study was to compare two different techniques of the enhancement of staple line during LSG: using Covidien Endo-GIATM with Tri-staple technology with suturing of the staple line using a V-loc 2.0 suture vs Ethicon Endo-GIATM staple with suturing of the staple line using prolene suture 2.0 in the reduction of major complications (bleeding and leak).

Patients and Methods:

This prospective randomized study of a consecutive series of 126 patients that underwent LSG by the same surgeon at Saint Raphael hospital between April 2014 till August 2015. Patients were randomly enrolled in two different techniques of reinforcing the staple line during LSG. Group A consisted of 63 patients that underwent sleeve gastrectomy using Ethicon Endo GIA stapleTM with staple line oversewn using 2.0 prolene continuous suture, group B also 63 patients who had the staple-line oversewn with a continuous suture using V-locTM and Covidien Endo GIA tristapleTM. 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.
Informed consent was signed preoperatively by all patients. Inclusion criteria were a body mass index (BMI) greater than 40 kg/m2 or greater than 35 kg/m2 accompanied with relevant co-morbidities. There were no exclusion criteria.
The preoperative investigations included: blood tests (random blood sugar, renal and liver function tests and a complete blood count), chest x-ray, ECG, abdominal ultrasound, and endocrinological nutritional evaluation. All patients were kept on a low carbohydrate diet for 4 weeks prior to surgery in order to decrease steatosis. All patients received a one-dose prophylactic intravenous antibiotic (cefitriaxone 1g), deep vein thrombosis prophylaxis consisted of pneumatic compression stockings and a low molecular weight heparin SC (Innohep 3500 IU) at induction of anesthesia.
A laparoscopic sleeve gastrectomy was performed on all patients by the same surgeon, as mentioned previously, and it consisted of the following steps:
In group A patients the greater curvature was deranged from its vascular supply by dividing it starting 6-7 cm from the pylorus and continuing towards the angle of the His by the use of a Harmonic Scalpel (Ethicon Endo Surgery U.S.A). On reaching the spleen, the short gastric vessels were carefully detached ascending in the cephalad direction until the left crus of the diaphragm was reached.
The sleeve gastrectomy started at the antrum with the use of Ethicon Endo GIA staplerTM with a 4.1mm thickness (green) followed by successive 5-6 firings of 3.8mm loads (gold), including the body and the fundus up to the angle of the His. This was done while a calibrating 36 Fr calibrating tube was closely applied to the lesser curvature of the stomach to achieve a good sleeved stomach without any possible stenosis.
The staple line was then reinforced by burying it using continuous non-absorbable 2.0 prolene seromuscular suturing starting at the angle of the His and ending at least at the mid-part of the stomach. Then the calibrating tube was withdrawn and a bubble test was performed to check for any possible leaks.
In group B patients, the same steps done except for the using of Covidien Endo GIATM Medium/thick tissue purple tri-staple and the staple line was reinforced by V-LocTM suture.
In all patients, a corrugate drain was fixed near the staple line and brought out through left upper quadrate port incision, to check for any signs of bleeding or leak.
The patients were kept in the hospital for 3 to 4 days. On the first day they were kept on IV fluids and nil by mouth.On 3rd post operative day corrugate drain was removed in all patients . From day 2-14 they were on clear fluids, followed by a soft diet for up to six weeks post-operation, after which the patients were kept on a protein-enriched, low-calorie solid diet with long-term oral multivitamin supplements.

Statistical analysis:

Quantitative data were expressed as mean, median, or range. Statistical analysis was performed using the chi-square test (Pearson, Mantel–Haenzel test for linear association) with the Yate's correction or the Fisher's exact test and Mann–Whitney U test whenever needed. The cut-off for statistical significance was defined as $P<0.05$. The statistical package used was SPSS 16.0.

Results:

From the 126 patients who underwent LSG, 82(65%) were women and 44(35%) were men. Median age was 36 years (range, 19–58 years) and median preoperative BMI was 45.4 kg/m2 (range, 37–62 kg/m2). Patient characteristics were similar between the two groups **(Table 1).**

	Group (A)	Group (B)
Number	**63**	**63**
Age		
Median	**37**	**35**
Mean	**37.6**	**37.9**
Sex		
Male	**18(28.5%)**	**26(41.2%)**
Female	**45(71.5%)**	**37(58.8%)**
***BMI**		
Median	**46.08**	**45.55**
Mean	**45.15**	**47.4**

*Body Mass Index

Total operative time ranged from 45 to 60 min for group A and 40 to 55 min in group B. Number of stapler cartridges and mean hospitalization was similar between the two groups. Main outcome measures are depicted in **Table 2.**

Main outcome	Group (A)	Group (B)
Total operative time (mins)		
Mean	**52.5**	**47.5**
Range	**45-60**	**40-55**
Stapler cartridges number		
Mean	**6**	**6**
Range	**5-7**	**5-7**
Hospital stay (days)		
Mean	**3.5**	**3.5**
Range	**3-4**	**3-4**

Conversions to open procedures did not happen. Three patients (4.76%)from group (A) and 2 patients (3.17%)from group (B) developed primary hemorrhage (within the first 24 hours post operatively), overall bleeding rate in both groups was (3.96%), the patients with bleeding had tachycardia and drop of hemoglobin level of more than 3 units and required transfusion with 1 unit of RBCs, all of them were re-operated via a laparoscopic route, a bleeding point from stapler line was identified in all patients and treated by hemostatic clip, no anastomotic leakage, and no mortality in both groups.

Table (3): surgical complications in both groups

Surgical complications	Group (A)	Group (B)	P.value
Overall	**3(4.76%)**	**2(3.17%)**	**>0.05**
Leak	**0**	**0**	
Bleeding	**3(4.76%)**	**2(3.17%)**	**>0.05**
Reoperation	**3(4.76%)**	**2(3.17%)**	**>0.05**
Mortality	**0**	**0**	

Discussion:

The seduction of surgeons by sleeve gastrectomy is due to its multiple advantages: less complex laparoscopic procedure, no enteric anastomosis and no risk of internal hernia, dumping syndrome, or marginal ulcer(2,15). In addition, sleeve gastrectomy decreases the level of ghrelin hormone, has a less malnutritive effect, allows continued endoscopic access to the pancreaticobiliary system, and provides comparative weight loss and subsequent resolution of comorbidities that parallels gastric bypass surgery(2,6,15). Several studies now have demonstrated that the laparoscopic sleeve gastrectomy is safe and provides similar weight loss and resolution of comorbidities to that of duodenal switch or Roux-en-Y gastric bypass(5,7,15). Bleeding and staple-line leak, although rare, are the most common postoperative complications of LSG (11,12,16). Bleeding usually occurs along the staple line or the greater omentum which has been freed from the greater curvature during the procedure (12,16). A leak occurs when intra-luminal pressure exceeds the strength of the tissue and the staple line. Postoperative leak after LSG typically appears just below the gastroesophageal junction and it is related with the high pressure that is created after the vertical tubulization of the stomach, with tissue ischemia and mechanical deficiencies at the site of stapling, resulting in significant morbidity, sepsis, organ failure, and maybe death(9,15,16). Because ischemic leaks are known to occur 5– 7 days postoperatively, when wound healing is between the inflammatory and fibrotic phases, the most common causes of the vast majority of leaks, which occur within 48 h, are mechanical(12,15,16). Although the impor-

tance of staple-line reinforcement in bariatric operations has been described in the literature (9,12,17), it remains controversial in LSG (12,18). The options for reinforcement include oversewing the staple line, application of fibrin glue sealants and incorporation of buttressing materials (18). In our study the leak rate was zero in both groups, this result is the same in many authors that used staple line reinforcement, Ser et al(18) had a zero leak rate after reinforcement of the staple line using 3.0 vicryl suture, Yehoshua et al(19) also reinforced the staple line with running absorbable suture with zero leak, Bellanger et al(20) had zero leak used glue for reinforcement of staple line , Chowbey et al(3) also had zero leak also used Ethicon Endo GIA staple with Seamguard reinforcement, Albanopoulos et al(16) using PDS 0 suture with zero leak rate, Sheppard et al(21) used tristaple technology without reinforce the staple line, also without a leak, Bülbüller et al(22) used V-locTM suture with a 2 cases out of 16 had leak but this result is not statistically significant, cause of a small study size. So the result of this study suggesting that staple line reinforcement is very important to decrease leak rate but it will not eliminate the risk, regardless the type of staple used or the reinforcement method, also it is apparent that an assessment of the various elements involved in the surgical procedure would be warranted and skilled surgical maneuvers are very important in decreasing and preventing staple line leak(15,22). In our study bleeding rate is 4.76% in group A and 3.17% in group B, no statistical significance between 2 groups, p.value >0.05 , overall bleeding rate is 3.96% , this result is the same comparing to other studies who oversewn the staple line, Yazbek et al(23) had a bleeding rate of 4.4%, a meta analysis by Choi et al showed a bleeding rate ranged from 0-8.7%, may be this is due to oversewing the staple line may increase the risk of tearing at the sutured point (17,23), which could cause hemorrhage, also the risk of bleeding may be depending on the dose of innohep that given at the time of induction of anesthesia(24).

Conclusion:

laparoscopic sleeve gastrectomy is a safe procedure as a sole weight reduction operation. The combination of meticulous surgical technique, reinforcement of the gastric staple line, lead to decrease the incidence of staple line leak whatever the suture material or stapler type used, but there is no significant decrease in the incidence of bleeding with staple line reinforcement.

References:

Kasalicky M, Michlasky D, Housova J, et al. Laparoscopic sleeve gastrectomy without an over-sewing of staple line. Obes Surg 2008; 18:1257-62.

Gluck B, Movitz B, Jansma S, et al. Laparoscopic sleeve gastrectomy is a safe and effective bariatric procedure for the lower BMI (35.0-43.0 kg/m2) population. Obes Surg 2011; 21:1168-1171.

Chowbey P, Dhawan K, Khullar R, et al. Laparoscopic sleeve gastrectomy: an Indian experience- surgical technique and early results. Obes Surg 2010; 20:1340-47.

Marquez M, Ayza M, Lozano R, et al. Gastric leak after laparoscopic sleeve gastrectomy. Obes Surg 2010; 20:1306-11

Ugo S, Gentileschi P, Benavoli D, et al. Comparative use of different techniques for leak and bleeding prevention during laparoscopic sleeve gastrectomy: a multicenter study. Surgery for obesity and related diseases 2013;article in press:1-5.

Frezza E, Reddy S, Laura L, et al. Complications after sleeve gastrectomy for morbid obesity. Obes Surg 2009; 19:684-687.

Durmush E, Ermerak G and Durmush D. Short term outcomes of sleeve gastrectomy for morbid obesity: does staple line reinforcement matter. Obes Surg 2014; 24:1109-16.

Baker R, Foote J, Kemmeter P, et al. The science of stapling and leaks. Obesity surgery 2004; 14:1290-98.

Gill R, Switzer N, Driedger M, et al. Laparoscopic sleeve gastrectomy with staple line buttress reinforcement in 116 consecutive morbidly obese patient. Obes Surg 2012; 22:560-564.

Casella G, Soricelli E, Rizzello M, et al. Non surgical treatment of staple line leaks after laparoscopic sleeve gastrectomy. Obes Surg 2009; 19:821-826.

Dapri G, Bernard G and Himpens J. Reinforcing the staple line during laparoscopic sleeve gastrectomy: prospective randomized clinical study comparing three different techniques. Obes Surg 2010; 20:462-467.

Albanopoulos K, Alevizos L, Flessas J, et al. Reinforcing the staple line during laparoscopic sleeve gastrectomy: Prospective randomized clinical study comparing two different techniques, preliminary results. Obes Surg 2012; 22:42-46.

Angrisani L, Cutolo P, Buchwald J, et al. Laparoscopic reinforced sleeve gastrectomy: early results and complications. Obes Surg 2011;21:783-793.

Szewczyk T, Janczak A, Janiak A, et al. Laparoscopic sleeve gastrectomy- 7 years of own experience.Videosurgery 2014;9:427-435.

Aurora A, Khaitan L, Saber A. Sleeve gastrectomy and the risk of leak: a systemic analysis of 4888 patients. Surg Endosc 2012;26:1509-15.

Albanopoulos K, Tsamis D, Arapaki A, et al. Staple line reinforcement with stitch in laparoscopic sleeve gastrectomies. Is it useful or harmful. Journal of laparoendoscopic and advanced surgical techniques 2015;25(7):561-565.

Choi Y, Bae J, Hur K, et al. Reinforcing the staple line during laparoscopic sleeve gastrectomy: does it have advantages? A meta analysis. Obes Surg 2012;22:1206-13.

Ser K, Lee W, Lee Y, et al. Experience in laparoscopic sleeve gastrectomy for morbidly obese Taiwanese: staple line reinforcement is important for preventing leakage. Surg Endosc

2010;24:2253-59.
Yehoshua R, Eidelman L, Stein M, et al. Laparoscopic sleeve gastrectomy volume and pressure assessment. Obes Surg 2008;18:1083-88.
Bellanger D and Greenway F. Laparoscopic sleeve gastrectomy 529 cases without a leak: short term results and technical consideration. Obes Surg 2010; 1-5.
Sheppard C, Whitlook K, Biroh D, et al. Laparoscopic sleeve gastrectomy with tri-stapleTM reinforcement for severe obesity. Surgery Curr Res 2013;3(4):1-4.
Bülbüller N, Aslaner A, Oner O, et al. Comparison of four different methods in staple line reinforcement during laparoscopic sleeve gastrectomy. Int J clin Exp Med 2013;6(10): 985-990.
Yazbek T, Safa N, Denis R, et al. Laparoscopic sleeve gastrectomy a good bariatric option for failed laparoscopic adjustable gastric banding (LAGB): a review of 90 patients. Obes Surg 2013;23:300-305.
Kakoulidis T, Karringer A, Gloaguen T, et al. Initial results with sleeve gastrectomy for patients with class I obesity (BMI 30-35 kg/m2). Surgery for obesity and related diseases 2009;5:425-428.