Evaluating the Effect of Staple Line Reinforcement on Reducing the Complications of Laparoscopic Sleeve Gastrectomy: A Randomized Clinical Trial

Nasser Malekpour Alamdari[1], Mohammadreza Abdolhoseini[1], Hamed Askarpour[1], Mahmood Bakhtiyari[2,3]

[1] Department of General Surgery, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

[2] Department of Community Medicine, School of Medicine, Alborz University of Medical Sciences, Karaj, Iran

[3] Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

Received: 28 Jul. 2017; Accepted: 11 Dec. 2017

Abstract- Laparoscopic sleeve gastrectomy (LSG) is the most common bariatric surgery technique. In this technique, bleeding and staple line the leakage is considered as the most important complications. The current study aimed at evaluating the effect of reinforced the taple line on the level of bleeding and leakage after the surgery. Overall, 199 patients meeting the eligible criteria with morbid obesity (BMI>40 kg/m^2) were enrolled in the study after signing the written informed consent. Patients were randomly allocated to intervention group (with reinforced staple line) and control group (Standard treatment) using simple randomization technique. Out of 199 cases, 120 (60%) were female, and 80 (40%) male; their mean BMI was 44.79± kg/m^2, ranging from 40 to 58 kg/m^2. Staple site bleeding was observed; therefore, no significant relationship was observed between the groups regarding bleeding decrease. Staple line leakage was observed in 2 cases of the control (without reinforcement) group and none of the cases in the intervention (with reinforcement) group. According to the results of the current study, no statistically significant relationship was observed between the groups regarding the level of leakage (P=0.249). Also, there was no significant relationship between age, gender, and BMI of cases, and the level of bleeding and leakage from the staple site. The average duration of surgery was 52.03 and 69.64 minutes for the control and intervention groups, respectively, which indicated prolonged surgery in the intervention group (P<0.001). The current study results indicated no significant relationship between the groups regarding the level of bleeding and leakage from the staple site.

Acta Med Iran 2018;56(5):334-340.

Keywords: Bariatric surgery; Sleeve gastrectomy; Staple line; Leakage; Bleeding

Introduction

Sleeve gastrectomy (SG) is a procedure in which the size of the stomach is limited to produce satiety and to limit the ghrelin-producing cells in fundus to lower the appetite. This procedure is validated as the first step for high-risk morbid obese patients by ASMBS (the American Society for Metabolic and Bariatric Surgery) in 2012 (1,2). Medicare officialized the SG as a one-step effective procedure for morbidly obese patients who meet the National Institute of Health criteria in Jun 2012 (1, 3-5). Addition to simplicity, low rate of late complication, and acceptable outcome in weight loss, SG have other benefits such as lack of using foreign devices (gastric band), loss of appetite just after the surgery, lower operation time, and the ability of conversion to other surgical techniques. However, post-operative bleeding, leakage from surgery site, stenosis in the gastric pouch, gastric dilatation, gastroesophageal reflux and insufficient weight loss are the main disadvantage of this procedure. The most common cause of post-operative bleeding is hemorrhage from stapling line. The leak which is more dangerous than bleeding could contribute to morbidity, mortality, and necessity of multiple interventions. According to data from 12,799, leak ratio is 1.06 reported in laparoscopic SG (LSG) that can be variable from 1-3% in primary procedures to 10% in reoperations (1,6,7). Other

Corresponding Author: N. Malekpour Alamdari
Department of General Surgery, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran
Tel: +98 912 8246152, Fax: +98 21 22074101, E-mail address: nassermalekpour@gmail.com

methods include suturing by absorbable or non-absorbable materials, stapler site coverage with omentum or jejunum (8-10), using Gelatin-fibrin matrix (11), and flusil or absorbable gore tapes (12). The most common method is suturing among all method of staple line reinforcements. However, the purpose of suturing is not only for reinforcement to prevent leaks, but also for a better hemostasis (13). Leak could occur in any part of staple line although it often occurs in proximal segment of gastric sleeve, just below the gastroesophageal junction (GEJ), because of high internal pressure (14). Leakage etiology included ischemic and mechanical (technical faults, improper instruments). Ischemic leaks occur mostly in 5-7 days after surgery, but the most common time for mechanical leaks is the first 48 h after surgery (15). Different methods have been advocated to prevent post-LGS leakage which staple line reinforcement is one of them. Due to disadvantages of this method; ischemic events, leakage from tearing caused by sutures, and increasing surgery duration, there is no consensus among surgeons about suturing (16-18).

The aim of this study was to evaluate the suturing pros and cons in 199 patients who underwent LSG.

Materials and Methods

The current randomized control trial (RCT) was conducted on patients with obesity and body mass index (BMI) >40 kg/m^2). Homeless, derelict, and addict patients with the systemic diseases affecting surgery complications, such as collagen vascular and immunodeficiency diseases, cardiovascular, and liver failures were excluded from the study.

Simple random sampling method using random numbers table was employed to select the study cases out of the patients with obesity (BMI >40 kg/m^2) referred to the Surgery Clinic of Shahid Modarres Hospital, Tehran, Iran, from June 2015 to October 2016. A total of 199 patients were enrolled into the study, after signing the informed consent, out of which 100 cases were randomly assigned to the control group (without staple line reinforcement) and the rest to the intervention group (with staple line reinforcement) using simple random allocation technique (as below flowchart) (Figure 1).

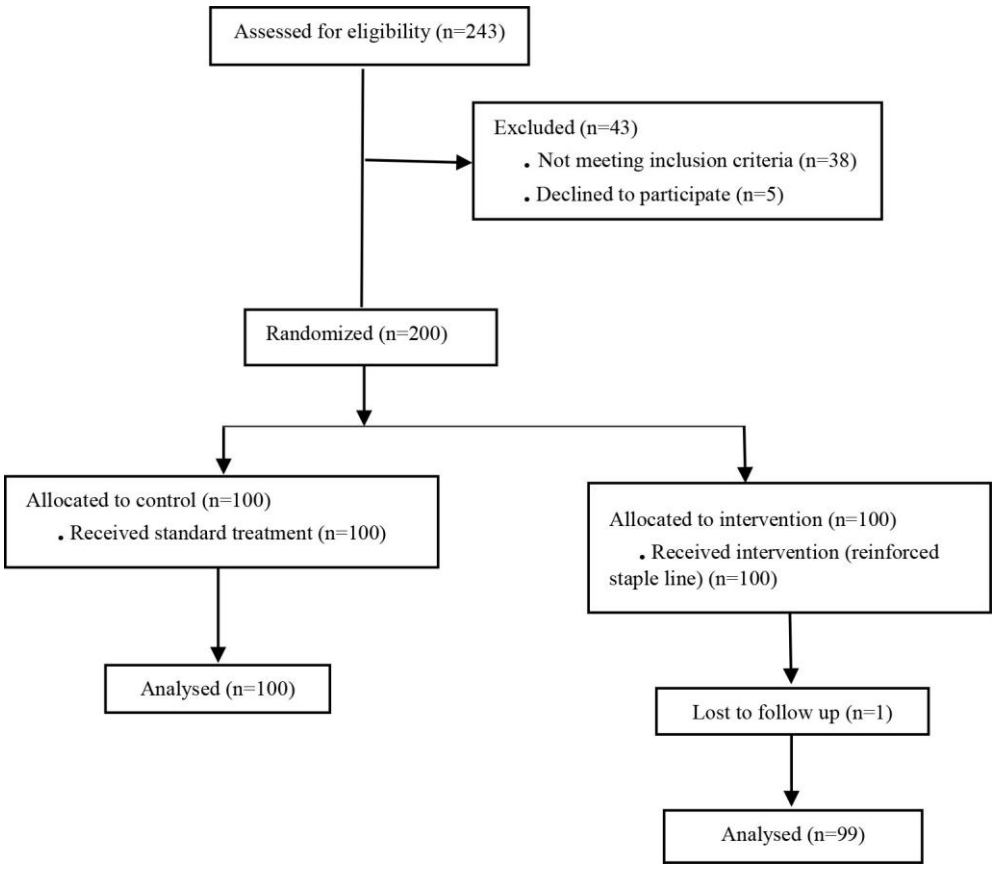

Figure 1. This Diagram showed method of sampling

The primary measured outcome in this study was the level of bleeding and leakage after the surgery. Demographic data of the cases including age, gender, BMI, and the duration of surgery were recorded in separate datasheets.

In the control group, after gastrolysis 5 cm from the pylorus up to the angle of His and stapling of the stomach, using bougie 38, the drain (Hemovac) was placed and, then, the surgery was finished, without reinforcing the staple line.

In the intervention group, the staple lines were reinforced using PDS 00 suture strings and omental patch at the staple site.

Then, the cases in both groups were followed-up for 3 months to evaluate of leakage and bleeding from staple site, based on their clinical symptoms, paraclinical parameters, and imaging results.

The patients were admitted to the surgery ward under closed monitoring or the intensive care unit (ICU) for the first night after the surgery. The cases were evaluated for fever, leukocytosis, type and volume of Hemovac secretions, possible hemoglobin decline, abdominal pain, nausea, vomiting, etc. on the day after the surgery, the patients were investigated by Gastrografin, and in the case of normal results, and they were discharged by starting water and soft drinks consumption and removing the drain. But, if the results of Gastrografin investigation were abnormal, the computed tomography (CT) scan with negative oral contrast was used to confirm the leakage.

However, if the imaging results were normal, patients were discharged after being informed about warning signs and the way to follow the postoperative diet.

The following schedule was used for the further visits to the surgery clinic:

A) First visit: 2 weeks after surgery
B) Second visit: at the end of the 3rd month after surgery

The patients were evaluated for the symptoms such as abdominal pain, abdominal tenderness, and complete blood count (CBC). Also, the cases were recommended to refer to the emergency department of hospitals immediately after the incidence of warning symptoms. The proposal of this trial was approved and registered in the ethics committee of Shahid Beheshti University of Medical Sciences.

The sample size was calculated based on the observed difference between the proportions of Staple-line bleeding in intervention group and control group (45.1% vs 79.6%) with 95% power and α error probability equal to 5% (19).

Demographic and clinical data with continuous scale were presented as mean and standard deviation, and categorical variables were shown as frequencies and percentages. To assess the independence of two categorical variables Chi-square test or Fisher's exact test was used. All of the statistical analyses were performed using Stata version 12 (Stata Corporation, College Station, Texas).

Table 1. Demographic and basic data of studied participants

Variables		Control group (n=100) Mean (SD)	Intervention group (n=99) Mean (SD)	*P*
Age (Year)		32.8±4.2	31.6±3.7	0.503
Gender	**Female**	62 (62%)	58 (58.5%)	0.333
	Male	38 (38%)	42 (42.5%)	0.31
BMI (Kg/m^2)		44.61±5.8	44.97±6.6	0.293
Staple-line leaks (n)		2 (2%)	0 (100%)	0.249
Staple-line bleeds (n)		0 (100%)	0 (100%)	--
Surgery duration (Min)		52.03±8.1	69.64±9.6	<0.001

BMI: Body mass index

Results

In the current study, 199 patients who underwent laparoscopic sleeve gastrectomy (LSG) were enrolled into the study after applying the inclusion and exclusion criteria.

The mean age of the patients was 32.26±3.9 years; ranging from 18 to 54 years. The mean age of the subjects in the control and intervention groups was 32.8±4.2 and 31.6±3.7 years, respectively.

Totally, 120 (60%) cases were female and 80 (40%) male; 62% female and 38% male in the control group, and 58% female and 42% male in the intervention group.

The mean BMI of the cases was 44.8±6.4 kg/m^2;

ranging from 40 to 58 kg/m^2. BMI values were 44.6±5.8 and 45±6.6 kg/m^2 in the control and intervention groups, respectively.

The duration of the surgery among the cases ranged from 42 to 82 minutes, with the mean time of 60.84 minutes.

By evaluating the surgery complications, no bleeding was reported in the cases; while, leakage from staple line was reported in 2 cases of the control group.

No significant difference was observed between the control and intervention groups regarding bleeding; in other words, staple site bleeding was not observed in any of the 199 studied cases.

There were only 2 cases with the staple line leakage; both from the control group. No staple line leakage was observed in the intervention group (staple line was reinforced with PDS 00 string and omental patch); therefore, no significant difference was observed between the groups in this regard (*P*=0.249).

The mean BMI of the cases with staple line leakage was 41.95 kg/m^2; while it was 44.82 in the cases with no evidence of leakage and the difference between the cases in this regard was insignificant (*P*=0.287).

The mean ages of the cases with and without staple line leakage were 36.50 and 32.22 years, respectively; accordingly, no significant relationship was observed between the cases in this regard (*P*=0.640).

One of the cases with staple line leakage was female, and the other one was male; therefore, no significant relationship was observed between the gender and staple line leakage (*P*=0.641).

Duration of surgery in the control and intervention groups were 52.03 and 69.64 minutes, respectively; hence, duration of surgery in the intervention group was significantly longer than that of the control group (*P*<0.001).

Discussion

Laparoscopic sleeve gastrectomy (LSG) is a bariatric surgical procedure. The employment of LSG, as an initial, staging, or corrective surgery, is increasing (14). This procedure restricts stomach capacity to induce satiety and removes ghrelin-producing cells of the fundus to reduce appetite. LSG was approved by ASMBS (the American Society for Metabolic and Bariatric Surgery) in 2012 as an initial surgical procedure for the patients at high risk (2,14). LSG was introduced as the first stage of the bariatric procedure, which prevents the common complications of patients with obesity (20,21). Medicare (2012) recognized LSG as the effective and appropriate procedure for weight-loss in patients who meet the criteria of National Institute of Health (1,3).

Technical simplicity of LSG, compared with Roux-en-y gastric bypass (RYGB), biliopancreatic diversion, or duodenal switch (other bariatric surgeries), and its positive effects in addition to superior weight loss and lack of long-term complications of adjustable gastric banding (AGB) increases its popularity. Comparing bariatric surgeries showed that LSG almost replaced AGB, and more than half of bariatric procedures in some areas of Europe and America were allocated to LSG; however, it was the most common bariatric surgery in the recent decade (22).

In addition to relative simplicity, low long-term complications, and superior weight loss, LSG has other advantages such as no need to use external objects such as gastric band, lower influence on the physiology of gastrointestinal tract and maintaining its continuity, prevention from dyspepsia, reducing appetite immediately after the surgery, lower duration of surgery, and the ability to convert other surgical procedures (23,24).

In spite of all aforementioned advantages of LSG, the procedure also has some disadvantages; for example, bleeding after the surgery, staple line leakage, stricture and dilation of the stomach, gastroesophageal reflux, and inadequate weight loss are the most important disadvantages of LSG (25-28). Bleeding and leakage are the short-term and most common causes of postoperative death in bariatric procedures, which are even more dangerous than those of other surgical procedures (17).

In LSG procedure, the stomach is removed from antrum to gastroesophageal junction (GEJ) by forming a tube by the repetitive stapling called sleeve. Long staple line as a result of high intraluminal pressure increases the risk of bleeding and mechanical leakage from the staple suture line (29-31); the complication is reported in 2.9% of the patients (32).

Staple site bleeding is the most common cause of post-LSG gastrointestinal bleeding. But, intraabdominal bleeding, result from removal of omentum, causes more severe complications as it reduces the quality of laparoscopy and surgical precision; it usually needs suction, and washing and cleaning of the camera, which result in prolonged surgery and hospitalization, and blood transfusion (33,34).

Staple line leakage is even more dangerous than staple site bleeding; the complication can lead to morbidity (septic shock and peritonitis) and mortality; it

may become chronic, recur, or even need different interventions (32). According to the data of 12799 cases that underwent LSG, the rate of leakage was 1.06%, ranging from 1%-3% in the initial procedures to 10% in the corrective procedures. However, the rate was reduced by 1.09 %, using new technologies (1,22,35).

Staple line leakage can occur throughout the staple suture line; but, it mostly occurs at the proximal end of GEJ, due to high pressure (16). The etiology of leakage is divided into mechanical and ischemic reasons, including extension, ischemia, poor wound healing, technical problems, improper equipment, iatrogenic damages, and distal occlusion. Ischemic leakages occur 5 to 7 days after the surgery when the wound healing is in inflammatory fibrotic processes; but staple line leakage mostly occurs in the first 48 postoperative hours, which roots in mechanical reasons (15).

Different methods are developed to control LSG postoperative leakage, its outcomes, and complications; besides, lack of proper guidelines and approaches attract more attentions to prevent the leakage (36). Surgeons used different methods to reinforce staple line; for example, using absorbable and non-absorbable sutures, covering the staple site with omentum or jejunum, using gelatin-fibrin matrix (Floseal) or absorbable patches (Gore® Seamguard® polyglycolic acid: trimethylene carbonate) (9-12). The ideal staple line reinforcement material should be user-friendly, eco-friendly, strong, flexible, and cost-effective (15,37).

Among the staple line reinforcement methods, stitching is the most cost-effective one. The staple line reinforcement strengthens the suture line to prevent leakage and provides better hemostasis (13). However, there are some disadvantages in this method; for example ischemic events, leakage from tears by stitches, excessive rotation of mucosal end, staple deformation, and prolonged surgery (16-18).

Staple line reinforcement has multitude supporters and opponents; the risk of leakage in LSG procedure is so low that 10 000 procedures are needed to reduce the current rate by 50%; the studies designed and conducted in this regard are inadequate, and there is no consensus. Although staple line reinforcement can reduce the risk of bleeding and leakage, some studies indicated that this method prolonged the surgery and increased the cost, with no positive influence. Based on the mentioned disagreements, the current study aimed at clarifying the effect of staple line reinforcement by stitching.

The current RCT selected 199 eligible patients with BMI >40 kg/m^2, after applying the inclusion and exclusion criteria; the cases were randomly divided into 2 groups of control (without reinforcement) and intervention (with reinforcement). Statistical analyses by SPSS showed that reinforcement of staple line by omentum via PDS00 sutures had no effect on the reduction of bleeding or staple site leakage, and reinforcement of staple line only prolonged the surgery.

On the other hand, detailed statistical evaluations showed no significant relationship between the age, gender, and BMI of patients and the level of postoperative bleeding and leakage in LSG procedure.

The current RCT indicated no significant relationship between the reinforcement of staple line in LSG procedure via omental patch stitching and reduction of staple site bleeding and leakage, and that reinforcement of staple line only prolonged LSG procedure.

Also, there was no significant relationship between age, gender and staple site leakage. In addition, no significant relationship was observed between BMI of patients and staple line leakage.

References

1. Rosenthal RJ, International Sleeve Gastrectomy Expert Panel, Diaz AA, Arvidsson D, Baker RS, Basso N, et al. International Sleeve Gastrectomy Expert Panel Consensus Statement: best practice guidelines based on experience of> 12,000 cases. Surg Obes Relat Dis 2012;8:8-19.
2. Updated position statement on sleeve gastrectomy as a bariatric procedure. Surg Obes Relat Dis 2012;8:e21-6.
3. Bohdjalian A, Langer FB, Shakeri-Leidenmühler S, Gfrerer L, Ludvik B, Zacherl J, et al. Sleeve gastrectomy as sole and definitive bariatric procedure: 5-year results for weight loss and ghrelin. Obes Surg 2010;20:535-40.
4. Baltasar A, Serra C, Pérez N, Bou R, Bengochea M, Ferri L, et al. Laparoscopic sleeve gastrectomy: a multi-purpose bariatric operation. Obes Surg 2005;15:1124-8.
5. Fischer L, Hildebrandt C, Bruckner T, Kenngott H, Linke GR, Gehrig T, et al. Excessive weight loss after sleeve gastrectomy: a systematic review. Obes Surg 2012;22:721-31.
6. Foletto M, Prevedello L, Bernante P, Luca B, Vettor R, Francini-Pesenti F, et al. Sleeve gastrectomy as revisional procedure for failed gastric banding or gastroplasty. Surg Obes Relat Dis 2010;6:146-51.
7. Lacy A, Ibarzabal A, Pando E, Adelsdorfer C, Delitala A, Corcelles R, et al., Revisional surgery after sleeve gastrectomy. Surg Laparosc Endosc Percutan Tech 2010;20:351-6.
8. Givon-Madhala O, Spector R, Wasserberg N, Beglaibter N, Lustigman H, Stein M, et al. Technical aspects of

laparoscopic sleeve gastrectomy in 25 morbidly obese patients. Obes Surg 2007;17:722-7.
9. Nguyen N, Longoria M, Chalifoux S, Wilson SE. Bioabsorbable staple line reinforcement for laparoscopic gastrointestinal surgery. Surg Technol Int 2004;14:107-11.
10. Franklin ME Jr, Ramila GP, Treviño JM, González JJ, Russek K, Glass JL, et al. The use of bioabsorbable staple line reinforcement for circular stapler (BSG "Seamguard") in colorectal surgery: initial experience. Surg Laparosc Endosc Percutan Tech 2006;16:411-5.
11. Consten EC, Gagner M, Pomp A, Inabnet WB. Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane. Obes Surg 2004;14:1360-6.
12. Albanopoulos K, Alevizos L, Flessas J, Menenakos E, Stamou KM, Papailiou J, et al. Reinforcing the staple line during laparoscopic sleeve gastrectomy: prospective randomized clinical study comparing two different techniques. Preliminary results. Obes Surg 2012;22:42-6.
13. Rogula T, Khorgami Z, Bazan M, Mamolea C, Acquafresca P, El-Shazly O, et al. Comparison of reinforcement techniques using suture on staple-line in sleeve gastrectomy. Obes Surg 2015;25:2219-24.
14. Knapps J, Ghanem M, Clements J, Merchant AM. A systematic review of staple-line reinforcement in laparoscopic sleeve gastrectomy. JSLS 2013;17:390-9.
15. Baker RS, Foote J, Kemmeter P, Brady R, Vroegop T, Serveld M. The science of stapling and leaks. Obes Surg 2004;14:1290-8.
16. Burgos AM, Braghetto I, Csendes A, Maluenda F, Korn O, Yarmuch J, et al. Gastric leak after laparoscopic-sleeve gastrectomy for obesity. Obes Surg 2009;19:1672-7.
17. Márquez MF, Ayza MF, Lozano RB, Morales Mdel M, Díez JM, Poujoulet RB. Gastric leak after laparoscopic sleeve gastrectomy. Obes Surg 2010;20:1306-11.
18. Deitel M, Gagner M, Erickson AL, Crosby RD. Third International Summit: current status of sleeve gastrectomy. Surg Obes Relat Dis 2011;7:749-59.
19. Shah SS, Todkar JS, Shah PS. Buttressing the staple line: a randomized comparison between staple-line reinforcement versus no reinforcement during sleeve gastrectomy. Obes Surg 2014;24:2014-20.
20. Ren CJ, Patterson E, Gagner M. Early results of laparoscopic biliopancreatic diversion with duodenal switch: a case series of 40 consecutive patients. Obes Surg 2000;10:514-23.
21. Silecchia G, Boru C, Pecchia A, Rizzello M, Casella G, Leonetti F, et al. Effectiveness of laparoscopic sleeve gastrectomy (first stage of biliopancreatic diversion with duodenal switch) on co-morbidities in super-obese high-risk patients. Obes Surg 2006;16:1138-44.
22. Gagner M, Buchwald JN. Comparison of laparoscopic sleeve gastrectomy leak rates in four staple-line reinforcement options: a systematic review. Surg Obes Relat Dis 2014;10:713-23.
23. Godoy EPd, Coelho D. Gastric sleeve fixation strategy in laparoscopic vertical sleeve gastrectomy. Arq Bras Cir Dig 2013;26:79-82.
24. Chen B, Kiriakopoulos A, Tsakayannis D, Wachtel MS, Linos D, Frezza EE. Reinforcement does not necessarily reduce the rate of staple line leaks after sleeve gastrectomy. A review of the literature and clinical experiences. Obes Surg 2009;19:166-72.
25. Frezza EE. Laparoscopic vertical sleeve gastrectomy for morbid obesity. The future procedure of choice? Surg Today 2007;37:275-81.
26. Brethauer SA, Hammel JP, Schauer PR. Systematic review of sleeve gastrectomy as staging and primary bariatric procedure. Surg Obes Relat Dis 2009;5:469-75.
27. Serra C, Baltasar A, Andreo L, Pérez N, Bou R, Bengochea M, Chisbert JJ. Treatment of gastric leaks with coated self-expanding stents after sleeve gastrectomy. Obes Surg 2007;17:866-72.
28. Hawasli A, Bush A, Hare B, Meguid A, Thatimatla N, Szpunar S. Laparoscopic management of severe reflux after sleeve gastrectomy, in selected patients, without conversion to roux-en-Y gastric bypass. J Laparoendosc Adv Surg Tech A 2015;25:631-5.
29. Moszkowicz D, Arienzo R, Khettab I, Rahmi G, Zinzindohoué F, Berger A, et al. Sleeve gastrectomy severe complications: is it always a reasonable surgical option? Obes Surg 2013;23:676-86.
30. Benedix F, Benedix DD, Knoll C, Weiner R, Bruns C, Manger T, et al. Are there risk factors that increase the rate of staple line leakage in patients undergoing primary sleeve gastrectomy for morbid obesity? Obes Surg 2014;24:1610-6.
31. Consten EC, Dakin GF, Gagner M. Intraluminal migration of bovine pericardial strips used to reinforce the gastric staple-line in laparoscopic bariatric surgery. Obes Surg 2004;14:549-54.
32. Lalor PF, Tucker ON, Szomstein S, Rosenthal RJ. Complications after laparoscopic sleeve gastrectomy. Surg Obes Relat Dis 2008;4:33-8.
33. Dapri G, Cadière GB, Himpens J. Reinforcing the staple line during laparoscopic sleeve gastrectomy: prospective randomized clinical study comparing three different techniques. Obes Surg 2010;20:462-7.
34. Angrisani L, Lorenzo M, Borrelli V, Ciannella M, Bassi UA, Scarano P. The use of bovine pericardial strips on

linear stapler to reduce extraluminal bleeding during laparoscopic gastric bypass: prospective randomized clinical trial. Obes Surg 2004;14:1198-202.

35. Puig CA, Waked TM, Baron TH Sr, Wong Kee Song LM, Gutierrez J, Sarr MG. The role of endoscopic stents in the management of chronic anastomotic and staple line leaks and chronic strictures after bariatric surgery. Surg Obes Relat Dis 2014;10:613-7.
36. Rached AA, Basile M, Masri HE. Gastric leaks post sleeve gastrectomy: review of its prevention and management. World J Gastroenterol 2014;20:13904-10.
37. Rayburn, G.L., et al., Device and method for reinforcing surgical staples. 1997, Google Patents. (Accessed May 2018, 22, at www.tandfonline.com/doi/abs/10.1080 /13571510600784706).