



Original Research

Randomized controlled trial of monopolar cautery versus clips for staple line bleeding control in Roux-en-Y gastric bypass

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ABSTRACT

Background: Bleeding from the staple line is a rare but serious problem following bariatric surgery. Staple line bleeding control (SLBC) can be achieved in different ways such as the application of sutures, clips, glue or buttressing materials over the staple line. Cauterization alone is generally not preferred due to concerns about debilitating the staple line.

Objectives: The aim of this study was to compare the clip and monopolar cauterization methods for SLBC in laparoscopic Roux-en-Y gastric bypass.

Setting: University hospital.

Methods: A total of 70 morbidly obese patients were randomized into two groups. Patients with previous upper gastrointestinal surgery, re-do procedures and open surgeries were excluded. Their demographic characteristics, intraoperative and postoperative outcomes were examined.

Results: A total of 489 SLBC interventions (274 clips and 215 cauterizations) were performed after 280 stapling applications. SLBC intervention number and location, additional trocar requirement, blood loss and operation time were not different between the groups. In the clip group, two patients required monopolar cauterization when clipping failed. No intraabdominal bleeding or gastrointestinal leakage was seen in any group. Postoperative gastrointestinal hemorrhage was seen in three patients, two in the clip group and one in the cautery group. There was no difference between the groups in terms of postoperative pain score, abdominal drainage amount, hemoglobin level alteration, morbidity or length of stay.

Conclusions: In laparoscopic Roux-en-Y gastric bypass, monopolar cauterization for SLBC can be used instead of clipping. It appears that monopolar cautery is a safe and effective approach for SLBC in laparoscopic Roux-en-Y gastric bypass.

1. Introduction

Obesity is a growing health problem in developed and developing countries. According to the recent National Health and Nutrition Examination Survey, fewer than one-third of the adult population in the United States is not overweight [1]. In response to the obesity endemic, bariatric surgery has gained an intense interest and sleeve gastrectomy has become the most popular bariatric procedure in the world [2]. Roux-en-Y gastric bypass (RYGB) is the second most preferred bariatric procedure worldwide even though it has restrictive and malabsorptive features [2].

Both sleeve gastrectomy and RYGB require the use of stapling

devices and bleeding from the staple line is one of their major complications [3]. In the literature, staple line bleeding control (SLBC) studies were mostly examined in patients with sleeve gastrectomy and they included studies that used synthetic/biological materials, clips and sutures [4–7]. Using cautery for SLBC is not a new issue and possibly it is a more frequent application in surgical practice than being a title in an article. As far as we know, there was limited numbers of articles that mentioned only in the “methods of the articles” about the cauterization of staple lines with a bipolar cautery device during sleeve gastrectomy [8,9] and to the best of our knowledge there has been no study comparing SLBC methods in laparoscopic RYGB or using monopolar cautery for SLBC during any bariatric surgical procedure. Our aim was to

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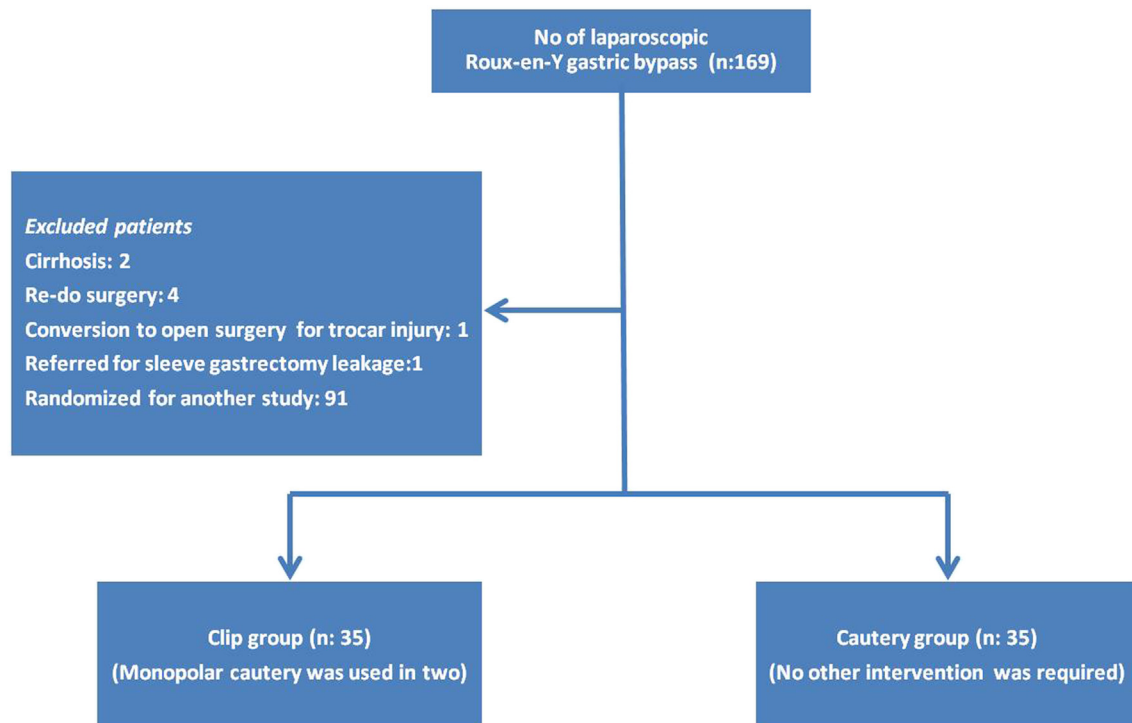


Fig. 1. Flow chart of the study.

investigate the efficacy of the clip and monopolar cauterization practices in laparoscopic RYGB in terms of SLBC.

2. Materials and methods

This study was approved by University Ethical Committee (2016/180) and registered by www.clinicaltrials.gov (NCT03240367). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. In a power analysis, when $\alpha:0.05$, $1-\beta(\text{power}):0.80$ was calculated, the bleeding difference between the cautery and the clip groups needed at least 23 cases per group. However, we decided to increase the number of patients in each group to 35 because of the potential loss of data and the inability to reach statistical significance. The inclusion criteria were patients with a body mass index (BMI) $> 40 \text{ kg/m}^2$ or $35\text{--}40 \text{ kg/m}^2$ with accompanying obesity related comorbidities. Patients who had previous gastric surgery, open RYBP cases, converted cases to open surgery during trocar placements, patients with cirrhosis and patients included in another randomized study were excluded. Groups were randomized using a two by toss-up method. The surgical technique was previously described in detail [10]. In summary, a gastric pouch and gastrojejunostomy were created with linear staples (Ethicon Echelon Flex Endopath or Medtronic Endo-Gia Universal - 60 mm-blue load). Alimentary and biliopancreatic limbs were 150–50 cm in length and the anastomotic openings were closed intracorporeally by 3/0 polypropylene sutures. After stapling, we meticulously examined the staple line and counted the number of all active bleeding points by one by and then we did hemostatic application immediately by clip or cautery. SLBC was performed with a 10 mm disposable clip applicator (Covidien-ML-10 mm) in the clip group, and in the other group monopolar cauterization was performed in coagulation mode (level of 40 W), connected to endoscopic scissors. No additional hemostatic material or suturing was used. A drain was routinely placed in the left upper quadrant trocar site.

Patients' age, gender, body mass index, comorbid diseases, anticoagulant history, preoperative INR level, prior abdominal surgery, SLBC numbers and locations, additional intervention requirements, additional trocar requirement, duration of surgery, blood loss and blood replacement requirement, hemoglobin level decline, amount of abdominal drainage, visual analog scales (VAS) scores, intraoperative and postoperative morbidities were noted.

Postoperative hemoglobin decrease was considered as the difference between the admission and discharge levels. Prior abdominal surgeries were categorized as upper and lower abdominal operation. The location of SLBC was as follows: the first transverse staple to the stomach was recorded as number 1, while the other two vertical gastric staples were recorded as number 2–3 and transecting the small bowel was recorded as number 4 (Fig. 1). To assess the postoperative pain, a visual analog scale (VAS) was used that ranged between zero (no-pain) and 10 (worst-pain) [11]. VAS scores were asked in the morning before any analgesic requirements. Postoperative complications were categorized according to the Dindo-Clavien classification [12].

The work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

3. Statistical analysis

Statistical analysis was performed according to the intention to treat protocol. Descriptive statistics including mean values and percentages are provided for all data. The continuous and categorical variables were compared using unpaired t-tests. The categorical variables were compared with each other by the Chi-square test or Fisher's exact test. Statistical significance was accepted as $p < 0.05$. The data were analyzed using SPSS version 16.0 and Microsoft Excel 2013.

4. Results

Between November 2016 and November 2017, a total of 169 morbidly obese patients were treated with laparoscopic RYGB. Seventy eligible patients (59 female, mean age 37.7 years and mean BMI 47.2 kg/m^2) were included (Fig. 1). Forty-nine percent had previous

Table 1
Demographic, perioperative and postoperative data.

Parameters	Clipping (n:35)	Cautery (n:35)	p
Gender (Female/Male)	30/5	29/6	1.00
Age	37.6 ± 11.3	37.9 ± 10.3	0.90
Body mass index	46.9 ± 7.4 kg/m ²	47.6 ± 7.3 kg/m ²	0.69
Co-morbidity	12 (34%)	15 (42%)	0.62
Diabetes mellitus	7 (20%)	7 (20%)	
Hypertension	7 (20%)	4 (11%)	
Chronic obstructive pulmonary disease	3 (8%)	1 (2%)	
Cardiac disease	1 (2%)	1 (2%)	
Goiter	2 (5%)	3 (8%)	
Periferic vascular disease	1 (2%)	2 (5%)	
Allergy	0	1 (2%)	
Prior abdominal surgery	18 (51%)	16 (45%)	0.81
Upper quadrant			
Cholecystectomy	2	4	
Splenectomy	1	0	
Epigastric hernia	0	1	
Lower quadrant			
Gynecological operation	12	11	
Appendectomy	3	0	
INR	0.99 ± 0.05	0.98 ± 0.09	0.56
Additional trocar requirement	1 (2%)	1 (2%)	1.00
Intraoperative complications	1 (2%)	3 (8%)	0.61
Nasogastric tube trapping into staple line	0	2	
Submucosal tunneling during anastomosis	0	1	
Bleeding from trocar site	1	0	
Duration of surgery	167 ± 55 min	170 ± 55 min	0.81
Intraoperative bleeding	56 ± 42 ml	50 ± 59 ml	0.61
Postoperative complications	2 (5%)	1 (2%)	1.00
Gastrointestinal bleeding	2	1	
Intraabdominal hemorrhage	0	0	
Anastomotic leakage	0	0	
Infection	0	0	
Mortality	0	0	
Postoperative hemoglobin decrease	1.6 ± 0.8	1.8 ± 0.9	0.32
VAS score on postoperative day 1	4.1 ± 2.4	4.6 ± 1.8	0.32
VAS score on postoperative day 2	3.8 ± 2.1	3.1 ± 1.8	0.13
VAS score on postoperative day 3	2.6 ± 2.5	1.9 ± 1.4	0.15
Total VAS score for three days	10.6 ± 6.3	9.6 ± 3.9	0.42
Abdominal drainage on postoperative day 1	61.2 ± 59.5	98.5 ± 124.5	0.11
Abdominal drainage on postoperative day 2	40.5 ± 40.1	50.5 ± 54.8	0.38
Abdominal drainage on postoperative day 3	43.6 ± 52.8	28.0 ± 33.2	0.14
Total abdominal drainage amount for three days	116.0 ± 92.6	161.0 ± 163.5	0.16
Length of hospital stay	3.6 ± 2.1 days	3.1 ± 0.5 days	0.17

VAS: visual analog scale. Upper quadrant surgery does not involve gastric surgery, which is included in the exclusion criteria of the study.

abdominal surgeries and 39% had co-morbidities (Table 1). Patients were divided into two groups by block randomization each including 35 patients. There was no difference between the two groups in terms of demographic features (Table 1). An additional trocar was required for one patient in each group (for retraction of a large left liver lobe in the clip group and to facilitate a troublesome gastroenterostomy anastomosis in the cautery group).

After 280 (70 × 4) stapler applications, intervention for SLBC was necessary to treat 489 active bleeding points (274 clips and 215 cauterizations). Overall mean SLBC interventions for the first, second, third and the fourth staple lines were 2.1, 3.5, 1.8 and 6.1, respectively (Fig. 2). In two patients in the clip group, the hemostasis method was switched to monopolar cautery when SLBC failed with clips. According to the intention-to-treat analysis, these patients and their results were

evaluated in the clip group. Intraoperative complications occurred in four patients. A trocar site bleeding was controlled with Ligasure in the clip group. Two nasogastric entrapments into the staple lines and one submucosal gastrojejunostomy were all in the cautery group and all of these complications were managed without the need for conversion to open surgery. There was no difference between the groups in terms of operating time and blood loss (Table 1).

There were three postoperative complications and all of them were gastrointestinal bleedings diagnosed with melena and a decrease in hemoglobin level, two in the clip and one in the cautery group (Dindo-Clavien 2). Two patients were treated successfully by conservative methods but a patient in the clip group required laparotomy for a hematoma in the remnant stomach and a perforation at the proximal common limb. After bleeding control, the perforation was repaired primarily and the patient was discharged on the 14th postoperative day (Dindo-Clavien 3B). There was no difference between the groups in terms of hemoglobin decrease. The amount of daily abdominal drainage decreased progressively by day (80 ml, 46 ml, and 36 ml) and there was no difference between groups in terms of abdominal drainage. Overall postoperative VAS scores diminished progressively within days (4.4, 3.5, and 2.4) and the VAS scores of both groups were similar (Table 1). There was no mortality and patients were discharged with a median on day three (range 3–14 days).

5. Discussion

Increasing the number of staple applications as expected leads to an increase in the number of staple line complications. Sleeve gastrectomy seems to have one of the longest staple lines in gastrointestinal surgery and the majority of serious complications following sleeve gastrectomy are associated with this long staple line. Therefore, most studies in the literature on staple line related complications, their prevention and management, are about sleeve gastrectomy. However, RYGB has a longer total length of staple lines than sleeve gastrectomy (on both sides as the gastric pouch and the remnant stomach and on the two transected small bowel sides). As far as we know, there is no study on SLBC methods following RYGB. Here, in a randomized study comparing clip application and monopolar cauterization for SLBC during laparoscopic RYGB, we demonstrated that there was no difference among the groups in terms of complications and other outcomes. Based on these results, we concluded that monopolar cautery for SLBC during laparoscopic RYGB as safe and effective. Moreover, it is practical and cheap and it is our preferred technique for SLBC.

There are several methods such as applications of sutures, clips, fibrin glue or buttressing materials for SLBC. Most of these methods have been studied on patients who underwent sleeve gastrectomy and there is no consensus on the best procedure [13–22]. In our daily practice, we are not using these materials for SLBC and we have preferred only monopolar cautery for years. We transferred this practice to our laparoscopic routine from our open surgical experience of 20 years. From the beginning of our bariatric surgery program (March 2006), we have performed more than 1000 bariatric procedures so far, mainly RYGB (85%), with this hemostasis technique and have found no adverse effects of monopolar cauterization for SLBC. Interestingly, we could not find any previous study on monopolar cauterization for SLBC during laparoscopic bariatric surgeries. In a limited number of papers, it has been reported that bipolar cauterization is rarely performed for SLBC in laparoscopic sleeve gastrectomies and their suture line leak rate was reported as 1% [8,9]. Since the staple line leak rates have been specified as between 0.5 and 5% following sleeve gastrectomy [13–22], the monopolar cauterization method should not be considered to increase the rate of staple line leaks.

We predicted that an intervention with monopolar cautery for SLBC would increase the likelihood of intraluminal hemorrhage because the cautery has no mechanical effect like the clips. However, there were two clinically significant events of intraluminal bleeding in the clip

No of staple line hemostasis	Clipping (n:35)	Cautery (n:35)	P
Total	8.0±6.1	6.1±5.0	0.15
1. Staple line	1.2±1.6	0.9±1.2	0.49
2. Staple line	2.1±2.4	1.4±2.0	0.18
3. Staple line	1.2±2.2	0.6±1.2	0.16
4. Staple line	3.0±3.1	3.1±2.5	0.88

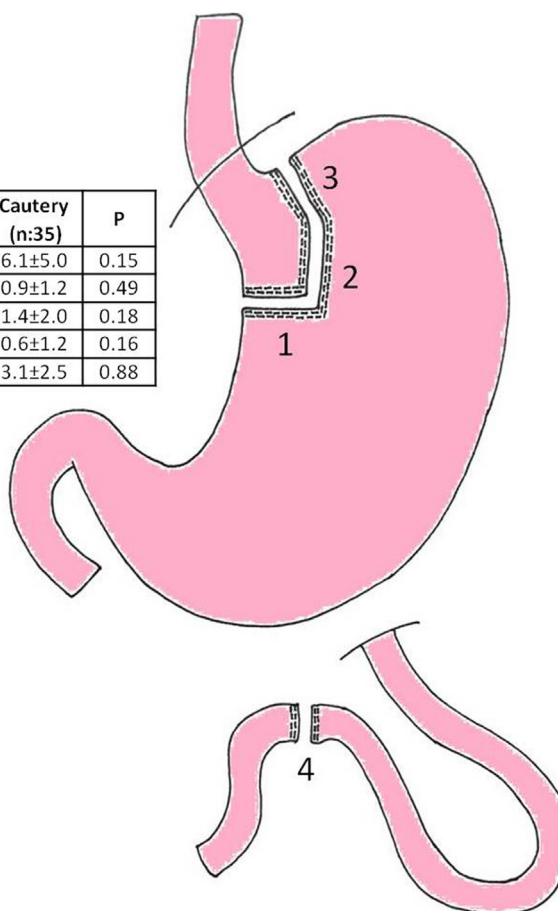


Fig. 2. Staple line orders and their hemostatic intervention numbers in both groups.

group (5.7%) but only one in the cautery group (2.8%). Alasfar and co-workers [23] checked for intraluminal bleeding by routine intraoperative endoscopy during RYGB and found its rate was 3.4%, and our 2.8% rate with the monopolar cautery was not significantly different than this reported rate. The number of hemostasis interventions for SLBC was slightly higher in the clip group but it was not significant. When cautery was applied, it affected a wider contact surface on the staple line than the clip. In other words, the clip is a vertical application to the staple line but the cautery is a horizontal one. For this reason, the number of interventions in the cautery group were lower. At the beginning of the study, we expected that bleeding control with cautery would take less time than clipping. However, there was no difference in operation time. Using a disposable clip applicator might have been time-consuming. To ensure the hemostasis by monopolar cauterization, cautery had to have contact with the staple line for a few seconds but clipping had a shorter application time. Lastly, cauterization caused some smoke that clouded the view and required some waiting or desufflation that resulted in extra operative time.

We found the bleeding points were more after small bowel division than the stomach divisions. This was because our preference of blue-cartridge in all divisions. Using a stapler with a white-loaded cartridge on small intestine may decrease the number of those bleeding points. Another issue is using bipolar cautery that may cause less thermal injury than monopolar cautery. Here we compared the monopolar cautery, it was our choice for SLBC for years, with the one of the most popular hemostatic method. Future studies are necessary to analyze the efficiency and safety of bipolar cautery for SLBL as well.

RYGB is a commonly used bariatric surgical procedure that results in successful weight loss for a long time. Despite the increased experience and improvements in equipment in bariatric surgical procedures,

staple line leaking and the bleeding are still major problems and both are main research topics at the present time. The increased number of bariatric surgeries is also a burden on general health expenditures. The economic burden brought about by the surgical equipment is becoming increasingly important. In a study investigating the effectiveness of products to support the staple line, the materials increased the cost per patient of \$1600 without the advantage of a shortened hospitalization time [24]. Although a limitation of our study was the lack of analysis of cost, we believe that SLBC with a monopolar cautery was a less expensive method than the others.

6. Conclusions

We believe that the use of monopolar cautery for SLBC during laparoscopic RYGB has similar results to clip application. It appears that monopolar cautery is a safe and effective approach for SLBC in laparoscopic Roux-en-Y gastric bypass. We continue to prefer monopolar cauterization, because besides its safety and efficiency, it is also cheaper.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Ethical approval

This study was approved by Inonu University Ethical Committee (2016/180) and registered by www.clinicaltrials.gov (NCT03240367).

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This study was approved by Inonu University Ethical Committee (2016/180).

Sources of funding

There were no sources of funding for our research.

Conflicts of interest

There were no conflicts of interest.

Author contribution

FS and CK conceived the present idea. EG and AA designed the study model and the framework. EG, CK, FS, AA, MS, and KS did the procedures and collected the data. EC and CG performed the analysis. EG, CK and UU wrote the manuscript. All authors provided critical feedback and helped shape the research and all authors discussed the results and contributed the final manuscript.

Research registration number

This study was registered by www.clinicaltrials.gov (NCT03240367).

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References

- [1] W.T. Garvey, J.I. Mechanick, E.M. Brett, et al., American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity: executive summary, *Endocr. Pract.* 22 (7) (2016) 842–884.
- [2] L. Angrisani, A. Santonicola, P. Iovino, et al., Bariatric surgery and endoluminal procedures: IFSO worldwide survey 2014, *Obes. Surg.* 27 (9) (2017) 2279–2289.
- [3] N.T. Nguyen, M. Longoria, S. Chalifoux, S.E. Wilson, Gastrointestinal hemorrhage after laparoscopic gastric bypass, *Obes. Surg.* 14 (10) (2004) 1308–1312.
- [4] A. Csendes, I. Braghetto, P. Leon, A.M. Burgos, Management of leaks after laparoscopic sleeve gastrectomy in patients with obesity, *J. Gastrointest. Surg.* 14 (9) (2010) 1343–1348.
- [5] L. Angrisani, P.P. Cutolo, J.N. Buchwald, et al., Laparoscopic reinforced sleeve gastrectomy: early results and complications, *Obes. Surg.* 21 (6) (2011) 783–793.
- [6] J. Armstrong, S.P. O'Malley, Outcomes of sleeve gastrectomy for morbid obesity: a safe and effective procedure? *Int. J. Surg.* 8 (1) (2010) 69–71.
- [7] M.E. Abd Ellatif, E. Abdallah, W. Askar, et al., Long term predictors of success after laparoscopic sleeve gastrectomy, *Int. J. Surg.* 12 (5) (2014) 504–508.
- [8] D. Michalsky, P. Dvorak, J. Belacek, M. Kasalicky, Radical resection of the pyloric antrum and its effect on gastric emptying after sleeve gastrectomy, *Obes. Surg.* 23 (4) (2013) 567–573.
- [9] P. Noel, M. Nedelcu, M. Gagner, Impact of the surgical experience on leak rate after laparoscopic sleeve gastrectomy, *Obes. Surg.* 26 (8) (2016) 1782–1787.
- [10] C. Kayaalp, F. Sumer, A. Abdullayev, Laparoscopic Roux-en-Y gastric bypass, *Laparosc. Endosc. Surg. Sci. (LESS)* 23 (2016) 110–118.
- [11] O. Bilge, Y. Tekant, A. Yavru, K. Acarli, G. Gulbaba, The effect of post-incisional injection of bupivacaine on post-operative pain in laparoscopic cholecystectomy: a prospective randomized study, *Turk. J. Surg.* 13 (5) (1997) 349–353.
- [12] D. Dindo, N. Demartines, P.A. Clavien, Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey, *Ann. Surg.* 240 (2) (2004) 205–213.
- [13] A. Yavuz, H. Bulus, The Effect of reinforcement methods with knotted and knotless sutures: comparison of burst pressures, *J. Laparoendosc. Adv. Surg. Tech.* 27 (6) (2017) 629–632.
- [14] H. Coskun, E. Yardimci, Effects and results of fibrin sealant use in 1000 laparoscopic sleeve gastrectomy cases, *Surg. Endosc.* 31 (5) (2017) 2174–2179.
- [15] S.K. Ghosh, S. Roy, E. Chekan, E.J. Fegelman, A Narrative of intraoperative staple line leaks and bleeds during bariatric surgery, *Obes. Surg.* 26 (7) (2016) 1601–1606.
- [16] S.A. Shikora, C.B. Mahoney, Clinical benefit of gastric staple line reinforcement (SLR) in gastrointestinal surgery: a meta-analysis, *Obes. Surg.* 25 (7) (2015) 1133–1141.
- [17] M. Gagner, J.N. Buchwald, Comparison of laparoscopic sleeve gastrectomy leak rates in four staple-line reinforcement options: a systematic review, *Surg. Obes. Relat. Dis.* 10 (4) (2014) 713–723.
- [18] M. Timucin Aydin, O. Aras, B. Karip, K. Memisoglu, Staple line reinforcement methods in laparoscopic sleeve gastrectomy: comparison of burst pressures and leaks, *J. Soc. Laparoendosc. Surg.* 19 (3) (2015) e2015 00040.
- [19] R. Karakoyun, U. Gunduz, N. Bulbuller, et al., The effects of reinforcement methods on burst pressure in resected sleeve gastrectomy specimens, *J. Laparoendosc. Adv. Surg. Tech.* 25 (1) (2015) 64–68.
- [20] J. Knapps, M. Ghanem, J. Clements, A.M. Merchant, A systematic review of staple-line reinforcement in laparoscopic sleeve gastrectomy, *J. Soc. Laparoendosc. Surg.* 17 (3) (2013) 390–399.
- [21] N. Bulbuller, A. Aslaner, O.Z. Oner, et al., Comparison of four different methods in staple line reinforcement during laparoscopic sleeve gastrectomy, *Int. J. Clin. Exp. Med.* 6 (10) (2013) 985–990.
- [22] S. Cetinkunar, H. Erdem, R. Aktimur, et al., The effect of laparoscopic sleeve gastrectomy on morbid obesity and obesity-related comorbidities: a cohort study, *Ulus Cerrahi Derg* 31 (4) (2015) 202–206.
- [23] F. Alasfar, B. Chand, Intraoperative endoscopy for laparoscopic Roux-en-Y gastric bypass: leak test and beyond, *Surg. Laparosc. Endosc. Percutaneous Tech.* 20 (6) (2010) 424–427.
- [24] N.T. Nguyen, M. Longoria, S. Welbourne, A. Sabio, S.E. Wilson, Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass: a prospective randomized trial, *Arch. Surg.* 140 (8) (2005) 773–778.