Original Research Article

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Staple line reinforcement during laparoscopic sleeve gastrectomy: pros and cons

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ABSTRACT

Background: Nowadays, laparoscopic sleeve gastrectomy (LSG) is the most common performed bariatric procedure. Staple line reinforcement (SLR) advised for reducing gastric leaks and bleeding after LSG. The aim of this study is to evaluate the efficacy of SLR in reducing the postoperative complications compared to non-SLR during LSG.

Method: Sixty morbid obese patients were scheduled for LSG in this prospective randomized study at Sohag University Hospital in the period between March 2016 to February 2018. Patients were divided randomly into two groups: Group I included 30 patients underwent LSG with over sewing of the staple line with running suture using VLocTM V 3/0 suture. Group II underwent LSG without SLR (n=30).

Results: No cases with leaks or stenosis were detected in our series. The operative time was significantly longer in the SLR group compared to the non-SLR group (125 (110-160) vs 100 (90-125) minutes respectively, p<0.01). Staple line bleeding was detected postoperatively only in one case in group II (3.3%) which was treated conservatively. The length of hospital stay was longer in the non-reinforcement group but not significantly different (p=0.25).

Conclusions: Staple line reinforcement during LSG has no superiority on the outcome of this operation, used by surgeons as a personal preference and as a security shield rather than for its advantages.

Keywords: Gastrectomy, Laparoscopic, Reinforcement, Sleeve, Staple line

INTRODUCTION

Obesity nowadays is becoming a pandemic problem that might increase the risk of many related disorders including cerebrovascular accidents, sleep apnea, cardiovascular diseases, sexual disorder, diabetes and negative affection of the quality of life. 1

A promising long-term treatment modalities for morbid obesity have been achieved by bariatric surgery. Among different bariatric procedures, laparoscopic sleeve gastrectomy (LSG) has been widely accepted. In LSG, the stomach size is reduced to about 15% of its normal size by removing a large part of the greater curvature

leaving a tube-like structure. LSG is considered the simplest procedure that does not require a foreign material like gastric band to be inserted in the patient, with no effect on gastrointestinal continuity and does not require gastrointestinal anastomosis. For these reasons, LSG has become the most popular and the most frequently performed operation nowadays.

Because of the long staple line, bleeding and gastric leakage are the major postoperative complications after LSG.⁶ So staple line was reinforced by many surgeon to decrease complications. However, it has many disadvantages as leakage stitches, ischemic effect, staple deformation, and prolonged time of surgery.⁷

Due to the controversial data published in previous studies, we have conducted this trial to evaluate the early postoperative complications; bleeding, operative time, leak and length of hospital stay comparing between SLR versus non-SLR after LSG in morbid obese patients.

METHODS

In the period between March 2016 to February 2018. This study was carried out at general surgery department, Sohag University hospital, Egypt. Ethical committee approval for the study protocol was obtained. Informed consent was signed by all patients after full explanation of the surgical procedure and possible benefits and side effects.

Well-informed, motivated patients who met the following criteria were included in this study; body mass index (BMI) more than 40, patients with BMI more than 35 with associated comorbidities as diabetes or cardiovascular diseases and failed trials for body weight reduction for more than 2 years by conservative measures. The exclusion criteria include those who had previous bariatric procedure, contraindication to general anesthesia, and extreme of age (less than 18 and more than 65).

All patients selected for LSG were subjected to detailed history taking and clinical examination, pre-operative routine laboratory investigations, complete lipid profile, nutrient screening (iron studies, serum calcium level, folic acid, vitamin B12), endocrine evaluation (HbA1c - TSH – 24-hour serum cortisone level), plain X ray chest, echocardiography, abdominal ultrasound, lower limbs doppler ultrasound, upper endoscopy if clinically indicated. Randomization was done using computer generated random number sequences in concealed envelops with block randomization design.

Patients were enrolled prospectively into two groups, each group included 30 patients. First group (Group I) underwent LSG with over sewing of the staple line with running suture. The other group underwent LSG without SLR, but over clipping of the staple line, only when necessary.

The supine position of the patients with reverse Trendelenburg position and the shoulders abducted 90° was the preferred position for the surgical team. French position was the preferable position in our work. All patients were operated under general anesthesia by the same surgical team. Standard approach entailing the use of five ports technique was applied in all patients. We devascularise the greater curvature of the stomach by using an advanced vessel-sealing device starting 2 to 6 cm from the pylorus and continued proximally and we stopped devasculrization when the left crus of the diaphragm is reached (Figure 1).

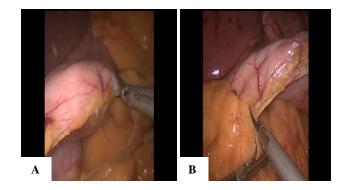


Figure 1 (A and B): Devasularization of the greater curvature of the stomach.

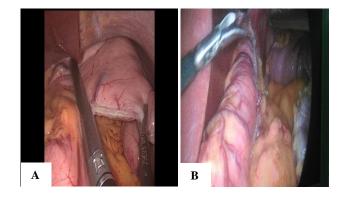


Figure 2 (A and B): Transection of the stomach.

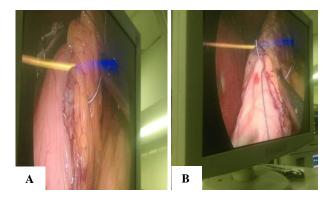


Figure 3 (A and B): Staple line reinforcement by oversewing suture.

A 36 F bougie is then inserted trans-orally by the anesthesiologist. Transection of the stomach is then started by using laparoscopic stapler beginning 2 to 6 cm from the pylorus. In our series, the stapler was Endo GIA (Covidien/Medtronic, USA), (Figure 1 and 2). After transection of the stomach the staple line was reinforced by monofilament absorbable suture VLocTM V 3/0 suture (Covidien/Medtronic), Figure 3, only in group I.

The resected stomach specimen was then extracted through 12-mm port. After testing of the transected stomach by methylene blue dye for leaks, a drain was placed. Water was allowed on the evening of the

operative day and patients have informed about the importance of early ambulation.

The patients were discharged on the 2nd postoperative day on a clear liquid diet for 10 days and advised to continue semisolid diet for 2 weeks then the usual diet. All patients were instructed to take prophylactic antireflux drugs (PPI), multivitamins and supplemental minerals for at least half a year. In our series, the patients were followed up according to the following protocol; weekly for the first month, monthly for the next 3 months, every 3 months for the rest of the 1st year and then annually.

Statistical analysis

Continuous variables were presented as median (interquartile range), while categorical variables were expressed as percentages. Quantitative variables were compared with t-test. For qualitative variables, Pearson Chi-square tests were used after assumptions have been verified. A 95% confidence interval (CI) was reported for both measures. A p<0.05 was considered statistically significant. All statistical tests were performed using IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp, Version 20.

RESULTS

Sixty patients (22 males/38 females), fulfilling the inclusion criteria of the study were randomly subdivided into 2 groups each involved 30 patients. The base line data of both groups were reported in (Table 1). Diabetes mellitus, hypertension, hyperlipidemia were the main associated co-morbidities in both group (Table 2).

Table 1: Patients' demographic data and BMI.

Patients characteristics	Group I (n=30)	Group II (n=30)	P value
Age (years)	36 (25-48)	33 (22-45)	0.22
Sex ratio, (male/female)	12/18	10/20	0.35
BMI (kg/m ²)	45 (38- 49)	42 (37-46)	0.12

Laparoscopic approach was completed in all patients, with no conversion to open technique. Duration of the procedure in the group I was significantly longer compared with group II (125(110-160) vs 100 (90-125) min., respectively, p<0.001). No significant difference was observed between both groups in the study as regard the length of hospital stay, which was somewhat longer in the group (II).

No intra-operative complications or mortality occurred. No detected cases with leaks or stenosis in both groups. In group II, the additional clipping for bleeding points from the staple line were only required in 16 cases. Staple line bleeding was detected postoperatively only in one

case in group II (3.3%) which was treated conservatively (Table 3).

Table 2: Patients' co-morbidities.

Co-morbidity	Group I	Group II	P value
Diabetes mellitus	5/30	6/30	1.0
Hypertension	4/30	5/30	1.0
Hyperlipidemia	22/30	24/30	0.12

Table 3: Perioperative outcomes.

	Group I	Group II	P value
Operative	125	100	< 0.01
duration	(110-160)	(90-125)	<0.01
Length of	2	3	0.25
hospital stay	(1-3) day	(1-4) day	0.23
Bleeding	0/30	1/30	0.72
leak	0/30	0/30	0
Stenosis	0/30	0/30	0

DISCUSSION

In the last decade, LSG had become the most popular and frequently performed bariatric operation all over the world. As it does not require any foreign material like gastric band to be inserted in the patients, also it does not require gastrointestinal anastomosis, with no effect on gut continuity. Despite the continuous advances in technology of the used stapling devices, staple line leaks and bleeding still the most serious complication of LSG.

SLR is still extensively debated between surgeons about its use in attempt to avoid these complications. There's no clear data in the literature to support its need during LSG. ¹⁰

There is no data in the literature about the best method of SLR which includes the following techniques; hemostatic sealants, over sewing and using of buttressing materials. Outre over-sewing of the staple line among the different reinforcement techniques is actually having the lower cost.

However many disadvantages were observed in this technique; such as ischemic effect, leakage from tears by stitches, staple deformation, excessive rotation of mucosal end and prolonged surgery. For this there is much debate over the efficacy of SLR in many literatures. 12,13

For this debate different series were done to assess the safety and efficacy of reinforcing the staple line. In meta-analysis done by Choi et al, over swing suture found to be more effective in reducing staple line leakage and bleeding rates. However, in a series reported by Simon et al, which showed that there is no evidence that the usage over swing suture decreases staple line leakage and bleeding. Bo Chen had stated that staple line

reinforcement does not lead to a significant reduction in staple line leakage rates. ¹⁶

In our series, there was 0% bleeding rate in group I. However, we have one patient (3%) complicated with bleeding in group II. These results were reported in multiple randomized controlled trials which demonstrated that the staple-line reinforcement in LSG had benefits over the postoperative staple-line hemorrhage and leakage. Aggrwal et al and Sroka et al suggested that the diminished bleeding rate after oversewed LSG may be attributed to the learning curve effect and not only the efficacy of oversewing. ^{18,20} Miller et al and Kasalicky et al stated that the low hemorrhage rate with the buttressing material usage could be related to the more compression during tissue excision. ^{22,23} Examples of materials used in staple-line reinforcement; fibrin sealants, bovine pericardial strips (BPS), or absorbable polymer membranes (APM) which are expensive. In our hospital, using these materials is too expensive; so, suturing is the best option in terms of costs and benefits.

Staple-line reinforcement by hand-sewing require additional operative time; in the current study, duration of the procedure in the group I and group II were ranged from (110-160) min. median: 125 min and (90-125) min. median: 100 min, respectively; hence, duration of the procedure in the reinforcement group was significantly longer than that of the other group (p<0.001). As regard the length of hospital stay in this study, it was relatively longer in group II compared to group I but it is not statistically significant.

As regard postoperative leaks, the leaks due to ischemia usually occur around postoperative days 5 to 7, when the healing is between the inflammatory and fibrotic phases. Most leaks which occur in the first 48 h may be attributed to mechanical cause. ²⁴ Till now, there are no sufficient data about the causative factors of leaks to support the rationale for the use of reinforcements. In this study there was 0% leak in both groups.

Limitations of our study are the small number patients and short term follow up. We were concerned to the 1st 30 days only after the procedure and do not include the complications that may occur in the first year such as stenosis or twist.

CONCLUSION

Inspite of being an inexpensive and easy technique, over sewing of staple line during LSG is an unrewarding surgical technique with the sole effect of prolonging the operative time without significant effect on postoperative leakage or bleeding.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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