

ORIGINAL ARTICLE

BUTTRESSING MATERIAL REINFORCEMENT FOR STAPLE-LINE USE AND FINANCIAL IMPLICATIONS IN A DEVELOPING COUNTRY

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ABSTRACT

BACKGROUND: Staple-line reinforcement is traditionally used in laparoscopic weight loss surgery in order to reduce bleeding and leakage. The purpose of this study was to find out the role of buttressing material Seam Guard (GORE)® for staple-line reinforcement and its financial implications in our setup.

METHODS: A prospective comparative study was done of morbidly obese patients who underwent weight loss surgery (Laparoscopic Sleeve Gastrectomy) over an 8-year period. Patients were enrolled in three groups; Group A received staple-line reinforcement throughout Group B only had partial reinforcement (at the fundus and pyloric end) and Group C were the ones on whom no reinforcement was used. The staple line was reinforced with Seam Guard (GORE)® strips.

RESULTS: A total of 364 patients, with a mean preoperative BMI of 53.3 kg/m² (range = 37.8–68.9), underwent LSG. 146 patients were in Group A, 105 in Group B and 113 in Group C. None of the patients in all three groups had leak.

CONCLUSION: Staple line reinforcement reduced surgical complications compared to standard stapling of the stomach for a Gastric Sleeve. No statistical significance was observed in the rates of bleeding or leaks between any of the groups. Thus the additional cost of the buttressing material such as Seam Guard (GORE) poses a financial burden on the patient considering the economic realities of our setup.

KEYWORDS: Bariatric surgery, cost effectiveness, gastric resection.

ABBREVIATIONS: LSG (Laparoscopic sleeve gastrectomy), ASA (American Society of Anesthesiology), BMI (Body mass index), DVT (Deep vein thrombosis), LMWH (low molecular weight heparin)

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INTRODUCTION

It has been observed over years that surgery is the most effective treatment for obesity with long term benefits. With the ever present laparoscope in the surgeon's domain, the surgery has been proven to be a safe and feasible way to address the epidemic of obesity. The minimally invasive procedure has been seen to benefit these patients who are at high risk due to their associated co morbidities. Amongst

the various obesity surgeries, Laparoscopic Sleeve Gastrectomy (LSG) has been shown to carry lesser surgical risks in specialized departments/centers.

Nowadays, LSG for many is considered a first-stage procedure to help the morbidly obese patient to lose weight initially before more complex procedures like biliopancreatic diversion with duodenal switch or Roux-en-Y gastric bypass are done, hence further decreasing the morbidity and mortality.¹ Stapling devices have a major impact in Laparo-

scopic sleeve gastrectomy. Worldwide approved staplers are considered safe provided they have been loaded properly and appropriately used according to tissue thickness. However, there are potential complications that may result including bleeding, leak and sometimes fistula formation. Reinforcement of Staple-line with buttressing material has shown promising results in reducing bleeding and leakage rates in some studies.²

The objective of this study was to arbitrate the effectiveness of using reinforcement with Seam Guard (GORE)® strips in reducing surgical complications than using none or even that of the more conventional methods and also to see its feasibility in a tertiary care set up of a developing country.

Staple line reinforcement reduces surgical complications compared to standard stapling or conventional reinforcement with suture for a Gastric Sleeve. However, there is no significant difference in the outcomes regarding rates of bleeding or leaks in particular in our study. Thus the additional cost of the buttressing material such as Seam Guard (GORE) poses a financial burden on the patient considering the economic realities of our setup.

METHODS

This is a comparative study carried out prospectively, including patients who underwent laparoscopic sleeve gastrectomy (LSG) by a single surgical team over an 8-year period in private sector hospitals; Ziauddin Hospital, Clifton Campus and National Medical Centre. Patients were randomized blindly in three groups. Group A were the ones who received reinforcement throughout the staple-line, Group B were the patients with partial reinforcement (only at the Fundus and Pyloric end) and those who did not receive any reinforcement along the staple line were included in Group C.

Inclusion criteria

- Body mass index (BMI) greater than 40 kg/m²
- BMI Greater than 35 kg/m² with co morbidities or/and metabolic syndromes were included.

Exclusion criteria

- Children under 16 years were excluded.
- ASA four and above patients were excluded.
- Patients with bleeding from sources other than the staple line were excluded from the study.

Every patient underwent fitness analysis to undergo General Anesthesia; cardiopulmonary function assessment, BMI calculation and upper gastrointestinal endoscopy were done as per protocol. Patients underwent a thorough review by a dietician and clinical psychologist as well. Written

informed consent was taken. Prophylactic antibiotic (2gms Ceftriaxone) was administered on induction of anesthesia. DVT prophylaxis was given to all patients; low-molecular-weight heparin, pneumatic pumps and TED stockings out of which LMWH was continued for one week post operatively.

Standard operative protocols were applied. Pylorus identified and greater omentum dissected from 5–7 cm in the direction of fundus. Lesser sac entered and all the branches of the gastroepiploic vessels along the greater curvature were tied and separated. Dissection performed with the LigaSure™ Maryland Jaw 44 cm laparoscopic sealer and divider (LF1744)² until the gastric fundus was completely mobilized. Mobilization was considered complete when the entire angle of His was visualized. Nasogastric tube would be replaced with a 40-Fr bougie; inserted into the stomach and advanced to the pylorus. Stomach divided over the bougie along the lesser curvature 5cm proximal to the pylorus, with the use of Covidien ENDO GIA™ ULTRA UNIVERSAL STAPLERS AND RELOAD cartridges. Black (4.5 mm) cartridges were used in the first 2-3 fires, then purple (4.0 mm) with the next fires and finally grey cartridge (2.0 mm) at the fundus. In group A, the whole Staple line was reinforced with Seam Guard (GORE)® strips. In group B, partial reinforcement was done only at the fundus and pyloric end and Group C in which no reinforcement was done.

- Postoperatively each patient was followed up with complete blood count and a gastrograftin upper GI series.
- Major bleeding was defined as hemoglobin drop of more than 1 gm.
- Staple-line leak was defined as a leak of contrast dye when an upper gastro-intestinal contrast studies are done.
- At the end of the procedure the whole staple line was reassessed for any points of bleeding and Methylene Blue dye test was also done to check for leakages as a standard in all procedures.
- According to protocol laid by the team of surgeons for every minimally invasive surgery, all procedures were recorded and were then reviewed post operatively for any complications; leak or bleed from the staple line.

A database was entered on SPSS 20. Mean and SD were calculated for staple line bleeding and leak, BMI, Age. Frequency and percentages were calculated for gender, and outcome variable i.e. staple line reinforcement. The three groups were compared for staple line reinforcement by applying student T test. Effect modifier controlled through stratification of age, gender, BMI to see effect of these on outcome variable by applying student t test. P value < 0.05 was taken as significant.

RESULTS

We had a total of 364 patients who underwent LSG [234 women, 130 men, 1.8/1 ratio; mean age = 42 years (range = 22–60)]. Mean preoperative BMI of 53.3 kg/m² (range = 37.8–68.9), (table-1).

Mean age of the students was 20.66 years (SD ±1.71) with 60.4% (n=290) females and 39.6% (n=190) males. Mean age of preclinical students was 19.09 years (SD ±1.08), with 55.9% (n=105) females and 44.1% (n=83) males. Mean age of clinical students was 21.67 years (SD ±1.20), with 63.4% (n=185) females and 36.6% (n=107) males.

Table-1: Number of women operated for LSG was more than men. BMI (body mass index)

Total number of patients	364	Mean age (years) 42 (range = 22–60)	Mean BMI (kg/m²) 53.3 (range: 37.8–68.9)
Females	234		
Males	130		
F:M Ratio	1.8:1		

The mean operating time was 58 minutes (range = 42–185). We found the mean hospital stay 3 days (range = 2–6) for all three groups as shown in (table – 2) None of the procedures needed to be converted to open surgery in all three groups. The procedure in all the groups was performed by the same team of surgeons, scrubbing nurse and anesthesia crew.

Table-2: The operative time and hospital stay remained similar for both men and women

Mean operative time (minutes)	Mean hospital stay (days)
58 (range = 42–185)	3 (range = 2–5)

There was no leak observed in Group A, where the reinforcement was throughout the staple line, however, 3 patients were observed with intra operative bleeding, they were due to malfunctioning of

the stapling device. There were 3 patients in Group C who had intra operative bleeding from the staple line, they were managed conservatively and settled. No bleeding incidences were observed in Group B. **Figure 1**

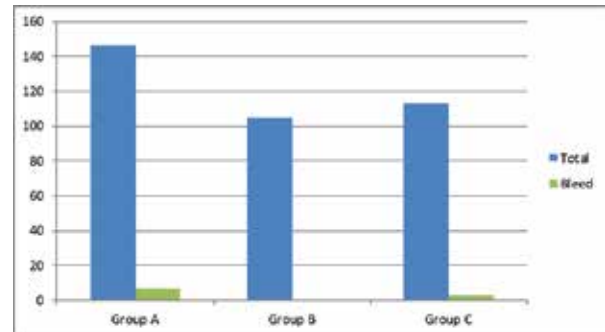


Figure-1: Comparison of leaks in the three randomized groups

Cost analysis

We have found the cost of one seam guard reinforcement in Pakistan to be Rs 25000. The number of reloads is 5 on an average (range 4-7) in each LSG. This calculates to an overall increase in the cost of operation to a median of (range = Rs.125000) for each procedure. Because the median in-hospital stay was similar in all three groups (median of 3 days, P = 0.139), we did not find that to be the cause of increase cost in this study. The procedure without the Seam Guard reinforcement was found to be 40% less expensive as compared with those in whom the buttressing material was used.

DISCUSSION

Over the years it has been observed that surgery is a very effective and proven treatment option for patients with severe obesity (body mass index of ≥35 kg/m²) and/or metabolic syndromes. Especially those patients, found to be resistant to conventional therapy or life style modifications. Bariatric surgeries have proven to significantly improve survival and to resolve co morbid medical conditions such as Diabetes Mellitus, hypertension, Polycystic ovarian disease and more that are known to be associated with severe obesity.²

Bariatric surgery is also considered metabolic surgery, treating the varied metabolic consequences of the co morbid diseases arising from severe obesity. Some operations are particularly effective treatments for such metabolic consequences. The term 'obesity surgery' has now been replaced by the term 'metabolic surgery' due to its significant effects on body hormones especially in increased insulin sensitivity.^{2,3}

During the years 1999 to 2003, here called the

bariatric revolution, the availability of a laparoscopic approach for bariatric operations caused major changes in the field, including a major increase in the number of procedures performed as well as an increased public and professional awareness and understanding of the field.²

Surgical management for obesity has been available for a long time now. The rapid emergence in minimally invasive surgery has caused a major paradigm shift in bariatric surgery. Moreover, the global obesity epidemic and the proportionate escalation in the number of surgeries for obesity over the period, helped in better understanding of the procedures and thus led to the development of much more professional approach with the establishment of multidisciplinary teams (MDT)³

With the growing trend of obesity surgeries in both developed and developing countries; laparoscopic sleeve gastrectomy is under continuous per lustration in the medical field. Since this procedure is being performed in increasing numbers world over with various levels of expertise, hence certain facets and peculiarities concerning its safety model continuously need to be analyzed.^{4,5}

The invention of endoscopic stapling devices has been proven to be revolutionary in laparoscopic bariatric surgery. On the other hand, complications associated with their use are not inconceivable; these may range from technical failure of the stapling device, bleeding from cut margins of the stomach, leakage at the site of resection, and even fistulas are known to be formed.^{6,7}

Frequently it is difficult to figure out the main cause of the complication; which may be either the device malfunction, the operator (surgeon), or use of inappropriate staples according to tissue thickness. Consequently, there is continuous research and development to improve the functionality of stapling devices. The rationale behind staple line reinforcement is quite impressive and entreating.⁸ The buttressing material should be malleable, thin, and should be effortlessly cut by the stapler's blade. It should also help and augment the healing process as well as complementing the mechanical properties of the resection. Ideally, it should increase the strength of the resection margins, curtailing the risk of complications from staple-line failure.

In our study we used SEAMGUARD (GORE) ® as a reinforcing tool for the staple line to compare whether the risk of bleed and leak decreases or not from those who do not get reinforcement. SEAMGUARD (GORE) ® is made from a synthetic copolymer—polyglycolic acid:trimethylene carbonate (PGA:TMC)—featuring an open, highly interconnected pore structure that facilitates cell infiltration and ingrowths. SEAMGUARD (GORE) ® Treatment with

buttressing material provides extra strength to the staple line; it then progressively is absorbed within six to seven months. According to the producers of stapling devices, their product is designed to decrease the chance of leak from the staple line and strengthen it by four times as compared to non-buttressed staple lines.⁶ This inherently would also provide security from leaks, specifically those that can occur in high intra-luminal pressure at the high pressure zones.^{7,9}

Our study showed that, buttressing of the staple line did give some form of protection from staple line bleeding. There was statistically no difference in reinforcing the whole staple line versus stapling the high pressure zone (at the fundus and pylorus) only. However, there is a statistical difference in cost effectiveness in both the groups in comparison to number of buttressing material used. The reason of intra operative bleeding from the staple line was inappropriate thickness of the tissue as compared to the staple depth being used. Whenever the blade is required to cut through more tissue than its specifications allow, it is recognized that there is an increased risk of complications as expected. Any of these factors may cause disastrous results for the patient as well as the surgeon. It is advisable that the buttressing material is loaded according to the recommended staple height so that the stapler cuts through adequately incorporating the buttressing material as well as the tissue.¹⁰ The fundamental logic of the buttressing material in decreasing the risks of complications like leak and bleeding seems to be the unique way it works; a row of clips hold the buttressing in place, this ensures that pressure is distributed evenly on the compressed cut tissue, thus achieving maximum control of bleeding along the staple line. In comparison, an economical alternative would be to over sew the staple line with suture. Though, this has been known to sometime run the risk of stricture of the gastric tube and may increase the risk of perforation at the point where suture is applied.^{11,12}

In our rumination there was no need for transfusion in group A and B as their blood levels remained stable after the surgery. In Group C there were only three cases of bleeding that required transfusions post operatively although we found no other obvious source of hemorrhage except the staple line. As our cost analysis shows, the expense of the surgery substantially increases with the use of buttressing of the staple line with SEAMGUARD (GORE) ®. However there was no statistically significant difference in securing the whole staple line versus only two staples. Although no significant difference was noted between the groups, patients who did not receive buttressing of the stapling line required transfusions but that did not alter the length of hospital stay. We found the application of staple-line reinforcement to be easy and safe with no increase in the operative time, our emphasis in

this study has been whether the results would defer when not using or partially reinforcing the staples in prevention of complications and to compare the hospital stay and cost effectiveness.

CONCLUSION

Since there was no significant difference in all the three groups in regards to the incidence of bleeding and leak from staple line, it can be safely said that staple line re-enforcement with a buttressing material poses just an added financial burden on the patient.

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