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CLINICAL RESEARCH

Reinforcing the Staple Line During Laparoscopic Sleeve Gastrectomy: Prospective Randomized Clinical Study Comparing Three Different Techniques

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Abstract
Background Gastric leak and hemorrhage are the most important challenges after laparoscopic sleeve gastrectomy (LSG). In order to reduce these complications, the staple line can be reinforced by absorbable sutures or by the use of glycolide trimethylene carbonate copolymer onto the linear stapler (Gore Seamguard®; W.L. Gore & Associates, Inc, Flagstaff, AZ). To our knowledge, there are no randomized studies showing the utility of staple line reinforcement during LSG. The purpose of this study was to randomly compare three techniques in LSG: no staple line reinforcement (group 1), buttressing of the staple line with Gore Seamguard® (group 2), and staple line suturing (group 3).
Methods Between January 2008 and February 2009, 75 patients were prospectively and randomly enrolled in the three different techniques of handling the staple line during LSG. The patient groups were similar (NS).
Results Mean operative time to perform the stomach sectioning was 15.9±5.9 min (group 1), 20.8±8.1 min (group 2), and 30.8±10.1 min (group 3) ($p<0.001$). Mean total operative time was 47.4±10.7 min (group 1), 48.9±18.4 min (group 2), and 59.9±19.6 min (group 3) ($p=0.02$). Mean blood loss during stomach sectioning was 19.5±21.3 mL (group 1), 3.6±4.7 mL (group 2), and 16.7±23.5 mL (group 3) ($p<0.001$). Mean total blood loss was 48.9±67.1 mL (group 1), 32.5±46.5 mL (group 2), and 61.9±69.4 mL (group 3) ($p=0.03$). Mean number of stapler cartridges used was 5.6±0.7 (group 1), 5.7±0.7 (group 2), and 5.8±0.6 (group 3) (NS). Postoperative leak affected one patient (group 1), two patients (group 2), and one patient (group 3) (NS). Mean hospital stay was 3.6±1.4 days (group 1), 3.9±1.5 days (group 2), and 2.8±0.8 days (group 3) ($p=0.01$).
Conclusions In LSG, buttressing the staple line with Gore Seamguard® statistically reduces blood loss during stomach sectioning as well as overall blood loss. No staple line reinforcement statistically decreases the time to perform stomach sectioning and the total operative time. No significant difference is evidenced in terms of postoperative leak between the three techniques of LSG.

Keywords Sleeve gastrectomy · No staple line reinforcement · Buttressing staple line · Staple line suturing · Leak · Bleeding

Introduction

Laparoscopic sleeve gastrectomy (LSG) is becoming a popular restrictive procedure for morbid obesity [1, 2]. Complications varies betweeen postoperative bleeding [3], appearance of gastric leak [4], development of gastroesophageal reflux disease (GERD) [5], appearance of stricture [6], dilation of the gastric tube [7], and insufficient weight loss [8].

The main complications in the early postoperative course are postoperative bleeding and the appearance of a gastric leak. Bleeding can occur along the staple line as well as along the greater omentum which has been freed from the greater curvature, allowing the resection of the fundus and body of the stomach. Sometimes, this complication cannot be treated conservatively [9], and the patient has to go back to the operative theatre for revision [10]. The appearance of

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a leak after LSG is related to the tubulization of the stomach with a long vertical staple line going from the antrum to the gastroesophageal junction. Typically, after LSG, leaks appear just below the gastroesophageal junction because of the high internal pressure created with the vertical tubulization of the stomach [11]. Management of the leak is difficult, with longer hospital stay, and quite often demanding placement of endoscopic stents [12].

Management of the staple line is actually not well standardized. Three options are available: no staple line reinforcement, buttressing the staple line with specific bioabsorbable material, and oversewing the staple line. Buttressing the staple line can be performed using glycolide trimethylene carbonate copolymer (Gore Seamguard®; W.L. Gore & Associates, Inc, Flagstaff, AZ) [13, 14], or bovine pericardium strips (Peristrips Dry and PSD Veritas; Synovis Surgical Innovations, St Paul, MN) [15, 16], or porcine small intestinal submucosa (Surgisis Biodesign, Cook Medical, Inc, Bloomington, IN) [17, 18]. The aim of this study was to prospectively and randomly compare in LSG the technique of no staple line reinforcement (group 1), buttressing the staple line with Gore Seamguard® (group 2), and staple line suturing (group 3). So far, to our knowledge, no randomized study has been published comparing these three different techniques during this procedure.

Patients and Methods

Between January 2008 and February 2009, 75 patients were prospectively and randomly enrolled in the study which compared three different techniques of staple line reinforcement during LSG. Twenty-five patients were allocated to the arm with no staple line reinforcement (group 1), 25 patients to the buttressing the staple line with Gore Seamguard® (group 2), and 25 patients to the staple line suturing (group 3). Patient characteristics were similar between the groups (NS) (Table 1). Obesity-related comorbidities affected 22 patients (group 1), 14 patients (group 2), and 17 patients (group 3), respectively (Table 2). This study was designed as a pilot study. Therefore, we did not specifically choose one primary endpoint and did not estimate a priori the required sample size. Main outcome measures were defined as the operative time to perform the stomach sectioning, the total operative time, blood loss during stomach sectioning, total blood loss, and the number of stapler cartridges used. Time to perform the stomach sectioning was calculated as the time between the introduction in the abdomen of the first linear stapler and the end of the last firing of stapler for group 1 and group 2, and the time between the introduction of the first linear stapler and the end of the oversewing the staple line for group 3. Total operative time was calculated in all groups as the time between the introduction of the trocars in the abdomen and the placement of the drain along the staple line. Blood loss was calculated by measuring the volume of blood in suction pump at the end of sectioning and at the end of the procedure. Secondary outcome measures were peroperative complications, hospital stay, early complications, and late complications. Since leak is a seldom event, our study had no possibility to detect between the groups a statistically significant difference in terms of this event. Hence, this complication has not been considered as a main outcome of this study.

Table 1 Patient characteristics

Characteristics	Group 1 No reinforcement	Group 2 Seamguard®	Group 3 Suturing	*p*
Gender (*n*)				
Female	15	14	8	0.19
Male	10	11	17	
Age (years)				
Mean ± SD	44.3±12.6	39.4±9.1	41.3±12.4	0.43
Range	21–65	22–58	21–61	
Weight (kg)				
Mean ± SD	124.3±18.1	138.8±25.1	143.5±35.7	0.09
Range	97–168	98–196	80–225	
BMI (kg/m^2)				
Mean ± SD	44.2±6.3	49.7±7	47.7±10.5	0.06
Range	36–60	38–65	35–70	
ASA score				
Mean ± SD	2.5±0.5	2.4±0.5	2.5±0.5	0.69
Range	2–3	2–3	2–3	

BMI body mass index, *ASA* American Society of Anesthesiologists

Table 2 Obesity-related comorbidities

Comorbidities	Group 1 No reinforcement	Group 2 Seamguard®	Group 3 Suturing
Arterial hypertension	13	8	13
Type II diabetes	6	5	6
Sleep apnea	4	5	4
Degenerative joint disease	13	4	2

Statistical Methods

Randomization was performed using randomly permuted blocks of sizes 6 and 9. The analysis included descriptive statistical methods: calculation of mean and standard deviation for continuous variables and contingency tables for categorical variables. The characteristics of patients between arms were compared using chi-square tests for categorical variables and analysis of variance for continuous outcomes. All the outcomes of the study were continuous variables. We compared therefore the arms using one-way analyses of variance and Fisher Snededore tests for assessing the statistical significance between the means of the outcome variables. A p value <0.05 was considered as statistically significant, and all reported p values were two-tailed.

Surgical Technique

The patient is positioned in supine position, with the legs apart and in reverse Trendelenburg position with a 10° tilt, carefully strapped to the operation table, and with the arms placed in abduction. Extreme care is taken to pad the pressure points and joints with foam cushions. The surgeon stands between the patient's legs, the assistant to the patient's left, and the cameraperson to the patient's right.

Abdominal insufflation is set at 15 mmHg. Trocars are placed as follows: a 10-mm trocar (T1) 20 cm below the xyphoid process for the 30° optical system, a 5-mm trocar (T2) on the left anterior axillary line, a 12-mm trocar (T3) on the left mid-clavicular line just between the first and the second trocars, a 15-mm trocar (T4) on the right mid-clavicular line, and a 5-mm trocar (T5) below the xyphoid process.

After identification of the Crow's foot, a straight line is marked with the coagulating hook from the Crow's foot up to the greater curve, delimiting the spared antrum. The lesser sac is accessed through a window made in the greater omentum 3 cm laterally from the marking, close to the greater curve and within the gastroepiploeic vessels. This window is opened, close to the greater curve, from left to right until the marked stomach is reached. It is made just sufficiently large enough so as to permit the performance of the first two firings of linear stapler 4.80/60-mm green load (EndoGIA, Covidien, New Haven, CT) through T4. In group 2, the linear stapler is supported by the application of the Gore Seamguard® before the introduction of the device in the abdomen. The first and the second linear staplers are oriented aiming in contact toward the endings of the small gastric vessels on the lesser curve and are fired. Further firings (3.5/60-mm blue cartridges), inserted through T3, are performed parallel to the lesser curve, and posterior gastric adhesions are sectioned before when present. Before the third firing of stapler, the anesthesiologist pushes down a 34-French orogastric bougie in order to guide the gastric section in the direction of the angle of His. Before the last firing of stapler (3.5/60-mm blue cartridge), the angle of His is freed and the stomach is transected without tension, staying at a distance from the gastroesophageal junction. In group 3, the staple line is reinforced by transfixing non sero-serosal running sutures using absorbable material (polydiaxone, 1 PDS), starting from the last firing of staple going caudad until the level of the antrum marked. The greater omentum is now dissected off the stomach along the greater curve using the Ligasure device (Covidien) until the left diaphragmatic crus is reached. The resected stomach is extracted from the abdomen by enlargement of the left upper quadrant 12-mm trocar, which subsequently is closed in layers, as well as the 15-mm trocar at the end of the procedure. A leak test is performed by insufflating air under pressure while keeping the stomach under water. A drain is left along the staple line before the removal of the trocars under visual control. The orogastric bougie is removed at the end of the procedure. No nasogastric tube is left in the following postoperative course.

Results

Main outcome measures are shown in Table 3. Mean operative time to perform the stomach sectioning was statistically significantly different between the three groups ($p<0.001$), lower for group 1, 15.9±5.9 min versus 20.8±8.1 min (group 2) and 30.8±10.1 min (group 3). Mean total operative time was statistically significantly different too ($p=0.02$), smaller for group 1, 47.4±10.7 min versus 48.9±18.4 min (group 2) and 59.9±19.6 min (group 3). Mean blood loss during stomach sectioning was statistically significantly different between the three groups ($p<0.001$), lesser for group 2, 3.6±4.7 mL versus 19.5±21.3 mL (group 1) and 16.7±23.5 mL (group 3). Mean total blood loss was statistically significantly different too ($p=0.03$),

Table 3 Main outcome measures

Main outcome measures	Group 1 No reinforcement	Group 2 Seamguard®	Group 3 Suturing	p
Stomach sectioning time (min)				
Mean ± SD	15.9±5.9	20.8±8.1	30.8±10.1	<0.001
Range	8–26	10–44	13–55	
Total operative time (min)				
Mean ± SD	47.4±10.7	48.9±18.4	59.9±19.6	0.02
Range	27–65	27–95	22–105	
Stomach sectioning blood loss (mL)				
Mean ± SD	19.5±21.3	3.6±4.7	16.7±23.5	<0.001
Range	5–80	0–20	0–100	
Total blood loss (mL)				
Mean ± SD	48.9±67.1	32.5±46.5	61.9±69.4	0.03
Range	5–280	0–200	10–280	
Stapler cartridges (n)				
Mean ± SD	5.6±0.7	5.7±0.7	5.8±0.6	0.65
Range	4–7	5–7	5–7	

smaller for group 2, 32.5±46.5 mL versus 48.9±67.1 mL (group 1) and 61.9±69.4 mL (group 3). Mean number of stapler loads used during the stomach sectioning was not statistically different between the groups ($p=0.65$), 5.6±0.7 (group 1), 5.7±0.7 (group 2), and 5.8±0.6 (group 3).

Peroperative complications are summarized in Table 4. Mean hospital stay was 3.6±1.4 days (group 1, range 2–9), 3.9±1.5 days (group 2, range 1–6), and 2.8±0.8 days (group 3, range 2–5) ($p=0.01$).

Postoperative leaks appeared in one patient (group 1), two patients (group 2), and one patient (group 3) (NS). Level of the leak was different between group 2 and others. Group 2 is the only one where the appearance of the leak was at the level of the antrum. Patients in groups 1 and 3 evidenced a leak under the gastroesophageal junction. A patient in group 1 presented a clinical leak on postoperative day 35, and after placement of covered metallic endoscopic stents, a complete fistula healing was reached on postoperative day 87. A patient in group 3 was discharged on postoperative day 3, and a clinical leak appeared on postoperative day 25. Thanks to the placement of endoscopic stents, the fistula healing was completed after 57 days of the procedure. Two patients in group 2 were readmitted to the hospital, respectively, on postoperative days 30 and 11 for sepsis due to abscesses around the area of the gastric antrum. The first patient was treated by percutaneous drain, transforming the leak into a gastrocutaneous fistula with a complete healing after 15 days. The second patient was taken to the operative theatre for laparoscopic lavage and drainage and subsequently underwent the placement of endoscopic stents, with a complete fistula healing after 74 days.

Other early complications were recorded in groups 1 and 3. One patient of group 1 presented a subphrenic hematoma 10 days after the procedure which was successfully treated by percutaneous drain. A patient in group 3 developed a subcutaneous abscess at the site of extraction of the specimen from the abdomen, 17 days after the procedure, which was resolved by medical treatment.

A late complication was noted in one patient in group 3 who developed a de novo GERD after 5 months of LSG and was treated by proton pump inihibitor (PPI) therapy.

Table 4 Peroperative complications

Peroperative complications	Group 1 No reinforcement	Group 2 Seamguard®	Group 3 Suturing
Short splenic vessels bleeding	1	–	–
Left hiatal crura bleeding	1	–	–
Splenic bleeding	1	–	–
Hepatic bleeding	–	4	–

Discussion

This study showed statistically significant differences in terms of operative time and operative blood loss between no staple line reinforcement (group 1), buttressing the staple line with Gore Seamguard® (group 2), and staple line suturing (group 3) in LSG.

Operative time to perform stomach sectioning appeared lower in the group without staple line reinforcement compared with the group using Gore Seamguard® or suture oversewing. Application of Gore Seamguard® on each firing of linear stapler required additional time, even with well-trained operating room personnel. The time to perform stomach sectioning is higher in group 3, obviously because of oversewing of the staple line. Suturing the entire staple line appeared time-consuming in this study and is dependent on the surgeon's learning curve. Considering total operative time, the difference between the groups reflected the difference of time needed for stomach sectioning since the time spent to finish the procedure after the section of the stomach was not different between the groups.

In terms of blood loss, this study showed that buttressing the staple line with absorbable material as Gore Seamguard® is superior to no staple line reinforcement or oversewing the staple line. These data have already been evidenced in a previous consecutive not randomized study enrolling 20 patients with LSG [13]. The authors reported a significant difference in mean blood loss of 120 mL in the group with Gore Seamguard® versus 210 mL in the group without Gore Seamguard® ($p<0.05$). Mechanism of blood loss reduction using Gore Seamguard® can be related to the compressive effect of the reinforcement material on the transected tissue [14]. The bioabsorbable material was specifically engineered so as to measure maximum 0.5 mm thickness, aiming at perfectioning the balance between the buttressing strength and the amount of material implanted. This effect is maintained for the following 4–5 weeks, and the bioabsorbable material is completely absorbed within 6 months [13]. Total blood loss differences between the three groups reflected the main difference of blood loss during stomach sectioning. However, in our study, this result appeared less significant than the partial one because peroperative bleeding can obviously occur during the dissection of the resected stomach from the greater omentum, with an increase of the value.

No statistically significant difference was evidenced between the groups in this study regarding the number of linear stapler loads used during stomach sectioning. This result is in accordance with earlier findings that between five and seven firings of linear stapler are usually required during the procedure of LSG [9]. Hence, the additional cost of the Gore Seamguard® par procedure (in Belgium) ranged between 640 euro (128 euro × 5) and 896 euro (128 euro × 7).

The additional cost of Gore Seamguard® and increased operative time must be weighed against the potential benefit of its use in bleeding reduction and consequently associated management of staple line hemorrhages.

Staple line leak after LSG may still occur despite the use of buttressing material or oversewing the staple line by resorbable suture. Leak after LSG usually appears just distal to the gastroesophageal junction, with an incidence between 0% and 5.7% [2, 19, 20]. Reason of the leak in this area could be related to the development of high intra-luminal pressure related to the long vertical tubulization of the stomach [11]. Moreover, this pressure is amplified by the fact that the compliance of the sleeve is ten times less than the complete stomach or the resected fundus [11, 21]. This physical situation could be the culprit for the leaks because in humans, the thickness of the gastric tissue is different between the antrum, the body, and the fundus, with a mean value reported to be of 3.1 mm, 2.4 mm, and 1.7 mm, respectively [22]. For these reasons, the gastric tissue at the angle of His appears more prone to developing leak. These theories might explain the nature of the leaks after LSG which appear much later than could be accounted for by technical flaws. Our patients in groups 1 and 3 were, respectively, readmitted to the hospital on postoperative days 35 and 25. Similar to our experience, other authors [23] evidenced the appearance of a leak at the gastroesophageal junction rather late in the postoperative course. This complication can occur in patients without reinforcement of the staple line as well as in whom it had been oversewn [23], as our study confirmed. This result contrasts with the theory of increased risk of tearing at the point of suture penetration in the distended gastric pouch [24]. The development of gastric leak at the level of the antrum, as was seen in two of our patients in group 2, is conceptually different. The thickness of the stomach increases approaching the pyloric antrum with significant patient to patient variability [22]. Therefore this increased tissue thickness could have compromised the complete closure of even the longest available staple height (green). Gore Seamguard® will increase the thickness of the area to be stapled by up to 0.5 mm, which should be considered especially in regions of thick tissue. Leaks at the antrum of the stomach can occur with the use of other buttressing material as well. Chen et al. [20] reported two leaks on 35 procedures (5.7%) with the use of bovine pericardium strips. Due to the potential for leaks in this region, additional care should be taken to inspect the staple line for proper staple formation.

In this study, we achieved a significantly shorter hospital stay in group 3 compared to groups 1 and 2. This was due to prolonged discomfort postoperatively in one patient in each group. Later, both patients developed the presence of the leak.

Regarding the early complications, one patient in group 1 developed a subphrenic hematoma. This complication has been reported after LSG [13] and probably occurred in our patient at the left hiatal crus because bleeding had been noted peroperatively. One patient in group 3 showed a subcutaneous abscess at the level of extraction of the specimen, probably due to local contamination of the muscular aponeurosis at this step, as reported in two out of 61 patients of Kasalicky's series [19].

A late complication was the development of de novo GERD in one patient (1.3%) in group 3. Appearance of de novo GERD during the first year is one of the possible complications occurring after LSG [1, 2]. This can be explained by the fact that the gastroesophageal antireflux barriers, such as the phrenogastric ligament and the angle of His, are altered during this procedure. This complication can initially be treated with PPI. In case of persistence of the GERD symptoms after several years, conversion of LSG to a RYGBP could abolish GERD, as reported in patients submitted to primary RYGBP and affected with GERD symptoms [25, 26]. Crookes [5] reported a complete resolution of GERD in 11 patients converted from LSG to RYGBP more effectively and with less morbidity than the seven patients converted to DS.

In conclusion, during LSG, staple line buttressing with Gore Seamguard® statistically reduces blood loss during stomach sectioning as well as overall blood loss. Absence of staple line reinforcement statistically decreases the time required for stomach sectioning as well as total operative time. No significant difference is evidenced in terms of postoperative leak between the three techniques of staple line reinforcement.

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