Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial

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Abstract

Background: Staple line failure, although uncommon, can result in significant morbidity and, even, mortality. Staple line buttressing has been developed to improve staple line strength, decrease bleeding, and minimize the risk of leak. Many different products are currently available. However, most have not been proved in clinical trials for their clinical relevance.

Methods: From April 2004 to March 2005, 48 morbidly obese patients who had undergone laparoscopic Roux-en-Y gastric bypass were enrolled in this study. The patients were randomly allocated to 2 groups according to whether polyglycolide acid and trimethylene carbonate (Seamguard) was (group 1, n = 24) or was not (group 2, n = 24) used in an investigator-initiated study. All patients underwent barium radiography at 3 and 12 months postoperatively.

Results: Peri- and postoperative mortality were absent. The intraoperative methylene blue test was positive in 1 patient in group 2. No conversion to laparotomy was needed. No patient required reoperation or transfusion for extraluminal bleeding, and no anastomotic leaks were detected in either group postoperatively. The mean number of clip instruments used was significantly lower in group 1 patients (2 versus 22, P < .0001, odds ratio 121.0, 95% confidence interval 12.5–1491). The operative time was significantly less in group 1 (115 ± 30.0 min, range 85–210) compared with that in group 2 (150 ± 51.7 min, range 90–240; P < .05). The postoperative hemoglobin level was significantly greater in group 1 (12.47 ± 1.7 mg/dL, range 9.2–14.8) compared with that in group 2 (11.1 ± 1.9 mg/dL, range 8.1–14.6; P < .05). Gastrogastric fistula formation was detected in 3 patients (12.5%) in group 2, with no statistically significant difference (P = .2).

Conclusion: The results of our study have shown that synthetic reinforcement material minimizes staple line bleeding and reduces the operative time, with no animal source contamination. No adverse events related to the resorbable buttressing material were observed. (Surg Obes Relat Dis 2007;3:417–422.) © 2007 American Society for Bariatric Surgery. All rights reserved.

Keywords: Morbid obesity; Laparoscopic gastric bypass; Anastomosis; Complication prevention; Leak; Hemorrhage; Surgical technique; Staple reinforcement

Gastric bypass procedures are currently the most common bariatric operations worldwide, and divided linear staple lines are a mainstay of gastrointestinal surgery [1]. Staple line failure has been reported to occur in 5–6% of laparoscopic gastric bypass procedures [2–5]. These failures lead to acute gastrointestinal leak, which results in significant morbidity and high mortality. Gastrogastric fistula between the gastric pouch and excluded fundus can also occur, with an incidence of 3–6% reported [6,7]. Staple line bleeding is another complication of the currently available stapling devices. Staple line bleeding can slow the time and momentum of the case, causing the surgeon to interrupt the operative flow to sew or cauterize the bleeding. Postoperatively, it can occasionally lead to the need for transfusion.

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and even repeat surgery [5]. Very little published data are available on the use of staple line reinforcement materials on human gastric staple lines. Chae et al. [8] first reported the use of bovine pericardial strips in 17 patients undergoing Roux-en-Y gastric bypass (RYGB) and noted no staple line failures and a minimal increase in operative time. Bovine pericardial staple line reinforcement reduces the likelihood of gastric leak and extraluminal bleeding [9,10]. Concern has been expressed concerning the use of dehydrated bovine pericardial material because it is quite thick and from an animal source [11,12]. The present prospective randomized study was designed to assess the effectiveness of staple line reinforcement on stomach transection using bioabsorbable material in gastric bypass surgery for morbid obesity.

Methods

Patients selected to undergo gastric bypass surgery for the treatment of morbid obesity were enrolled in this study. Eligible patients were >18 years of age and had a body mass index of ≥40 kg/m². Those patients with a body mass index of ≥35 kg/m² and co-morbidities according to the guidelines of the National Institutes of Health Consensus Development Conference Statement of March 25–27, 1991 were also enrolled in this study [13]. The exclusion criteria for the study were the presence of coagulopathy, patient refusal, and patient inability to provide written informed consent.

Study protocol

The ethical committee of the “Landesregierung Salzburg, Austria,” a government institution, approved the study. Each patient provided informed consent before the procedure and before initiation of the study. The randomization list was generated prospectively on a personal computer using the software programs from IDV-Versuchsplanung und Datenanalyse (Gauting, Munich, F.R.G.). Randomization was done in the operating room so that the reinforcement could be prepared by the scrub nurse.

This study was a single-center, randomized prospective trial to evaluate a polyglycolide acid and trimethylene carbonate staple reinforcement material (polyglycolide acid 67%, trimethylene carbonate 33%) called Seamguard (W.L. Gore & Associates, Flagstaff, AZ). No financial support, grant, or donation was provided by W. L. Gore & Associates.

The intraoperative and postoperative early and late complications, operative time, number of hemostatic clip applicators used, need for blood transfusion, and any specific event directly related to the prosthetic material were prospectively evaluated. Intraoperative blood loss was not recorded by blood suction, because it was never possible to remove all the blood from the abdomen during surgery. The hemoglobin level was measured 1 day before surgery and the lowest postoperative level was recorded within 1 week to evaluate the blood loss. Perioperative thrombosis prophylaxis consisting of Fraxiparin (nadroparin-calcium) at a medium-risk dosage of .3 mL and the use of pneumatic compression stockings was started 1 day before surgery and continued for 5 days postoperatively. All patients underwent a Gastrogafin swallow test on the first postoperative day and barium radiography at 3 and 12 months postoperatively.

Surgical technique

All procedures were performed using a laparoscopic technique with 5 trocars. We performed a proximal, antecolic, antegastric, 100-cm Roux-en-Y gastric bypass.

Fig. 1. Proximal, antecolic, antegastric, laparoscopic, 100-cm Roux-en-Y gastric bypass.
released after firing, leaving the bioabsorbable reinforcement material along the staple line on both sides. We used the blue stapler loads (3.5-mm staple height) during creation of the gastric pouch and the white stapler loads (2.5-mm staple height) during creation of the jejunojejunostomy. For patients randomized to the control group, no staple line reinforcement sleeves were used. Bleeding from the staple line was controlled with suction, irrigation, and clips until no signs of bleeding were observed.

Statistical analysis

With 24 patients in each treatment group, a difference in proportions of \(-0.2\) (20%) was required to achieve a beta of 0.2 and sigma of 0.52 based on a 2-sided test with a significance level of 0.05. Differences <0.2 were judged to be of doubtful clinical importance and considered clinically relevant (minimal difference of 20% in each group). All data were further analyzed on a personal computer using the software programs from IDV-Versuchsplanung und Datenanalyse. In each group, the median, standard deviation, standard error, range, upper and lower quartile, and total mean values were calculated. Univariate analyses were performed using the Wilcoxon-Mann-Whitney U test for continuous variables and a chi-square test on 2 \(\times\) 2 tables for binary variables (Fisher’s exact test). The \(P\) values presented are those computed for each comparison, and statistically significant variables were those at the 0.05 level (2-tailed). Odds ratios for categorical variables were computed, with the 95% confidence intervals. The odds ratios are significant at \(P < 0.05\) if the 95% confidence intervals do not include the value of 1. The number of intention (patients) to treat was calculated with the computer program from IDV-Versuchsplanung und Datenanalyse.

Results

A total of 48 patients undergoing laparoscopic RYGB were randomly allocated to 2 groups according to the use of polyglycolide acid and trimethylene carbonate (Seamguard) in an investigator-initiated study. Both groups consisted of 24 patients. The 2 groups were fairly well matched with respect to body mass index, age, and gender ratio (Table 1). The minimal follow-up was 12 months.

For gastric pouch construction, 4.0 ± 0.59 and 4.3 ± 0.56 staple magazines were used in groups 1 and 2, respectively \((P = 0.986)\). Peri- and postoperative mortality were absent. The intraoperative methylene blue test was positive in 1 patient in group 2 and the leak was repaired with a laparoscopic suture technique. Also, 1 patient in group 2 underwent postoperative gastroscopy and clipping because of intraluminal gastrojejunal bleeding at the circular stapled

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1 (Seamguard)</th>
<th>Group 2 (control)</th>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>Mean 34.1 ± 11.5</td>
<td>35.8 ± 10.8</td>
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<tr>
<td></td>
<td>Range 19–62</td>
<td>20–59</td>
</tr>
<tr>
<td>Gender (n)</td>
<td>Male 8</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Female 16</td>
<td>18</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>Mean 49.6 ± 5.2</td>
<td>51.0 ± 3.7</td>
</tr>
<tr>
<td></td>
<td>Range 39–65</td>
<td>42–78</td>
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<tr>
<td>Excess weight (%)</td>
<td>Mean 98.6 ± 14.5</td>
<td>99.1 ± 15.7</td>
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<td></td>
<td>Range 46.1–153</td>
<td>44.9–163</td>
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BMI = body mass index.

Data presented as mean ± standard deviation, unless otherwise noted.
anastomotic site. No other perioperative complications, such as mesenteric tear or hepatic or splenic injury, occurred. No conversion to laparotomy was required. No patient required repeat operation or transfusion because of extraluminal or intraluminal bleeding, and no anastomotic leak was detected in either group postoperatively.

The mean number of clip instruments used was significantly lower in group 1 than in group 2 (2 versus 22, P < .0001, odds ratio 121.0, 95% confidence interval 12.5–1491). The operative time was significantly less in group 1 (115 ± 30.0 min, range 85–210) compared with that in group 2 (150 ± 51.7 min, range 90–240; P < .05). The postoperative hemoglobin level was significantly greater in group 1 (12.47 ± 1.7 mg/dL, range 9.2–14.8) than in group 2 (11.1 ± 1.9 mg/dL, range 8.1–14.6; P < .05; Table 2). Gastrogastric fistula formation was detected in 3 patients (12.5%) in group 2, with no statistically significant difference (P = .2). One fistula was detected at 3 months and two at 1 year after the procedure. No postoperative anastomotic leakage or staple line failure was observed.

Discussion

The complications associated with the use of surgical stapling devices include bleeding, technical failure of the instruments, inadequate approximation of the tissues, stricture, enteric leakage, and fistula [15]. Randomized prospective clinical trials have demonstrated the safety and effectiveness of staple line reinforcement using bovine pericardial strips [9,10]. However, reinforcement with bovine pericardial strips has drawbacks. This material is nonresorbable [16] and can persist as a foreign body, which can have an adverse clinical impact. Several case reports have been published in thoracic studies describing expectoration of the staple line reinforcement and sequestration pneumonia [17,18], as well as 1 case of emesis of the pericardial reinforcement after gastric bypass [25]. An advantage of the polyglycolide co-polymer sleeves is that they are bioabsorbable; the sleeves should be completely absorbed within 6 months [11].

Baker et al. [25] described mechanical deficiencies in the anastomosis and tissue ischemia as the 2 major sources of leaks at the staple lines in gastrointestinal operations. Ischemic leaks usually present 5–7 days postoperatively and mechanical-type leaks are more immediate. Baker et al. [25] reported that the vast majority of leaks were noted within the first 2 days, suggesting a mechanical basis for the leak and highlighting the importance of ensuring a structurally sound staple line to avoid serious complications.

Intraoperative staple line bleeding and postoperative gastrointestinal hemorrhage are well-known complications of laparoscopic RYGB [19–23]. Podnos et al. [23] found that the incidence of gastrointestinal hemorrhage was greater after laparoscopic RYGB than after open gastric bypass (1.9% versus .6%, respectively). Oversewing of the staple lines during laparoscopic RYGB can be time-consuming. Staple line reinforcement sleeves have been used as a buttress material in an effort to eliminate the need for oversewing of the staple lines during laparoscopic RYGB [9,10,25,26].

Intraoperative staple line bleeding was significantly reduced in our study group, as demonstrated by the significantly lower use of clip instruments in group 1 versus 2 (2 versus 22; P < .05). We also found a significantly lower postoperative hemoglobin level in the control group (11.1 versus 12.47 mg/dL; P < .05). We hypothesized that the reduction in staple line hemorrhage resulted in a higher postoperative hemoglobin level. It is difficult to determine a cause-and-effect relationship between buttress material use and higher hemoglobin levels postoperatively. However, with all other treatment factors being the equal for all patients, one could suspect that the difference in postoperative hemoglobin might represent decreased staple line bleeding. More studies with objective criteria for intraoperative staple line bleeding are necessary to conclude that buttressing causes decreased staple line bleeding.

The mechanism for the reduction in staple line hemorrhage is the compressive effect of the staple line reinforcement material on the transected tissue. Oversewing of staple lines is very common but should be avoided because of the risk of leakage. Full-thickness oversewing past a fixed staple line can increase the risk of tearing at the point of suture penetration in the distended gastric pouch [25]. We did not oversew the staple lines on the gastric pouch but used clip instruments in 22 of 24 patients in the control group (group 2) and in 2 patients in the treatment group (group 1; P < .0001). No leakage was observed in either group.

Gastrogastric fistula between the gastric pouch and excluded fundus can also occur. Although less severe than acute leak, gastrogastric fistula can result in marginal ulceration and even weight loss failure. MacLean et al. [6] reported that the gastrogastric fistula incidence was approximately 3% after open gastric bypass with divided staple lines. Cucchi et al. [7] reported it to be 6%. In our study, gastrogastric fistula formation was detected in 3 patients.

Table 2

<table>
<thead>
<tr>
<th>Operating time, intravenous fluid, and lowest postoperative hemoglobin</th>
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<tbody>
<tr>
<td>Variable</td>
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<tr>
<td>Operating time (min)</td>
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<tr>
<td>Mean</td>
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<tr>
<td>Range</td>
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<tr>
<td>Hemoglobin</td>
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<tr>
<td>Preoperative (g/dL)</td>
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<tr>
<td>Range</td>
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<tr>
<td>Postoperative</td>
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<tr>
<td>Mean</td>
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<tr>
<td>Range</td>
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<tr>
<td>Total infusion (mL)</td>
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(12.5%) in group 2 at 3 months postoperatively. All our procedures were video documented. The video documentation of the patients who developed long-term complications such as stenosis or fistula were reviewed by us without any technical explanation found.

Although the application of Seamguard to the staple gun does require a few additional steps, it is easily and quickly mastered by the operating room personnel and does not affect the operative time. Moreover, any possible increase in operating room time is more than compensated for by the elimination of the time spent chasing staple line bleeding. The operative time was significantly reduced in our group of patients with staple line reinforcement because of the reduced number of surgical maneuvers needed to identify and control the bleeding source. More time will be consumed by the dissection of the gastric pouch in patients with hematoma and blood in the small space behind the stomach and on the way to the angle of His. Our findings demonstrated a significant reduction in the operative time when staple line reinforcement was used. A clear anatomic view saves time.

Laparoscopic surgery, and in particular, laparoscopic bariatric surgery, is incredibly resource dependent, because a multitude of instruments are required. Staple line reinforcement is not inexpensive, and its use can add significantly to the cost of the procedure, approximately 312 Euro ($399 USD) per case. It is important to weigh the benefits of its use against the cost to discern whether to adopt it into one’s practice. The avoidance of a single severe complication would make its use worth it.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

References