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Original article

Incidence of gastroenterostomy stenosis in laparoscopic Roux-en-Y gastric bypass using 21- or 25-mm circular stapler: a randomized prospective blinded study

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Abstract

Background: Laparoscopic Roux-en-Y gastric bypass is the most common bariatric procedure performed in the United States today. The most common early complication after laparoscopic Roux-en-Y is stenosis. No randomized studies have compared the effect of the different staplers on the incidence of stenosis or on long-term weight loss. We compared the anastomoses performed with the two sizes of circular stapler in common use.

Methods: A total of 200 patients were randomized to undergo 21-mm ($n = 100$) or 25-mm ($n = 100$) circular stapled gastroenterostomy after induction of anesthesia. No other differences were allowed in the operative technique. Stenosis was defined as patient complaints of dysphagia leading to endoscopy within 10 weeks of surgery, in which a 9-mm diameter endoscope would not pass through the gastroenterostomy without dilation.

Results: Of the 200 patients, 19 patients in the 21-mm group and 8 in the 25-mm group underwent endoscopy for symptoms ($P = 0.027$). Of the 19 and 8 patients, 17 and 7, respectively, had measurable stenosis at endoscopy ($p = 0.035$). Patients with a 21-mm anastomosis developed symptoms an average of 4.8 ± 1.2 weeks after surgery, and those with a 25-mm anastomosis developed symptoms an average of 8.9 ± 3.8 weeks postoperatively ($P < 0.001$).

Conclusions: We found a significant difference in the stenosis rate between the 21-mm and 25-mm circular stapled anastomoses in laparoscopic Roux-en-Y gastric bypass. The 21-mm staplers led to significantly more endoscopies than did the 25-mm staplers. Symptoms leading to endoscopy occurred significantly later with use of a 25-mm stapler than after a 21-mm stapler. (*Surg Obes Relat Dis* 2007;3:176–179.) © 2007 American Society for Bariatric Surgery. All rights reserved.

Keywords:

Laparoscopic Roux-en-Y gastric bypass; Stapled anastomosis; Stenosis; Endoscopic dilation

Worldwide, laparoscopic gastric bypass procedures are being performed in increasing numbers every year. Gastroenterostomy (GJ) can be formed by hand suturing, as advocated by Higa et al. [1], using circular staplers as recommended by Wittgrove and Clark [2], or using a linear cutter and sutures as advocated by Williams and Champion [3].

These techniques result in a variety of initial sizes of anastomosis and have also been implicated in a variable incidence of postoperative anastomotic stricture requiring endoscopic dilation, or rarely even requiring operative revision. In our practice, we had adopted the transabdominal circular stapled anastomosis but were troubled because stricture formation after surgery proved to be our most frequent complication [4]. We, therefore, decided to compare the incidence of stricture formation using a 21-mm versus a 25-mm circular stapler in a randomized, blinded, prospective trial.

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Methods

The Western Institutional Review Board approved this study. All patients gave written informed consent 2 weeks before the proposed procedure. Demographic data were collected, as was the incidence of comorbidities, to determine whether the groups had similar characteristics. All operations were performed at two American Society for Bariatric Surgeons-designated Centers of Excellence community hospitals.

Between January and September 2005, 200 patients were randomized to 2 groups of 100 each who were unaware of which stapler was used for their operation. Randomization was accomplished by drawing a numbered card after anesthesia had been induced. One group had their gastrojejunal anastomosis (GJ) formed using a 21-mm circular stapler. The GJ in the other group was formed using a 25-mm circular stapler (ILS Staplers, Ethicon Endosurgery). Patients have remained unaware of which stapler was used in their operation to date. All patients (100%) were followed up for 6–18 months to capture most stenoses related to postoperative healing. The volume of surgery performed during this study period prevented the surgeons from knowing the size of the stapler used without checking the chart; thus, they likewise remained unaware of the type of stapler used when deciding whether to perform endoscopy. Endoscopy was performed by the 3 surgeons who performed the gastric bypass procedures. The decision for endoscopy was made by the surgeon on call who evaluated the complaint of food intolerance made by the patient.

Using a preoperative power analysis with an 95% probability and assuming a 3% and 15% stenosis rate between the 2 groups, we needed 75 patients to show a 80% difference. We then rounded up the number up to 100 in each group to obtain a stronger study. This number was chosen on the basis of the study results of Cottam et al. [4], in which we showed a 7% rate of stenosis using the 21-mm stapler in our patient population, and Nguyen et al. [5,6].

All surgery was performed using an identical technique. The pouch was fashioned by first selecting a site along the lesser curvature 5 cm distal to the angle of His and placing a staple line using the 45-mm Ethicon 6-row stapler positioned perpendicular to the lesser curve. The anvil was placed using a transabdominal approach by way of a gastrotomy in the fundus lateral to the eventual location of the pouch. This was made using a harmonic scalpel after dilating the abdominal fascia with cervical dilators to allow passage of the anvil through the abdominal wall without difficulty. Using a string tied to the anvil as a guide, the anvil was then brought out through the lesser curve of the stomach using a band-passing device above this previously placed staple line. The pouch was then completed by 2–4 sequential firings of 45-mm staplers placed parallel to the lesser curve, with the division ending at the Angle of His. When check endoscopically, the length of the pouch from

esophagogastric junction to the anastomosis was documented and was consistently 4.5 ± 0.5 cm. To reduce tension on the staple lines, the 21-mm anastomoses were supported by 3 triangulated inverting horizontal mattress sutures (Vicryl, Ethicon Suture Division) equally spaced around the circumference of the anastomosis. The 25-mm anastomosis was supported by only 1 suture at the antimesenteric border of the small bowel. This difference was dictated by the observation that the 21-mm stapler often resulted in thin, sometimes incomplete, tissue donuts. In contrast, the 25-mm-stapler tissue donuts were always observed to be robust and full thickness. All anastomoses were pressure tested for leaks with air. Both the 21-mm and 25-mm staplers had a staple height set at 50% compression. The patients were discharged from the hospital on a puree diet for 5 weeks after surgery, after which they were to advance their diet to solid foods.

Stenosis was defined as a patient complaining of repetitive intolerance of ingested solid or pureed food leading to endoscopy in which the 9-mm diameter endoscope would not pass through the GJ anastomosis without balloon dilation.

The differences in the rates of esophagogastrroduodenoscopy and stenosis were analyzed by logical regression with the assistance of Secic Statistical Consulting. The difference in the interval to dilation was evaluated using the z test.

Results

No significant differences were found in the sex, weight, age, body mass index, or comorbidities (Table 1). Of the 200 patients, 19 in the 21-mm group and 8 in the 25-mm group required endoscopy ($P = 0.027$). Of these 19 and 8 patients, 17 and 7 had measurable stenosis ($P = 0.035$; Table 2). Patients with a 21-mm anastomosis developed symptoms an average of 4.8 ± 1.2 weeks after surgery, and those with a 25-mm anastomosis developed symptoms an average of 8.9 ± 3.8 weeks postoperatively ($P < 0.001$; Table 3). These differences were all statistically significant. No leaks, deaths, or pulmonary emboli occurred in either

Table 1
Patient characteristics

| Characteristic | 21-mm Stapler | 25-mm Stapler |
|--------------------------------------|---------------|---------------|
| Age (yr) | 43 | 45 |
| Men (%) | 20 | 19 |
| Average weight (lb) | 295 | 314 |
| Body mass index (kg/m ²) | 49.1 | 47.7 |
| Comorbidities (%) | 8.6 | 8.6 |
| Hypertension | 41 | 43 |
| Sleep apnea | 27 | 38 |
| Type 2 diabetes mellitus | 25 | 18 |
| High cholesterol* | 29 | 44 |
| High triglycerides | 34 | 34 |
| Insulin resistance | 20 | 19 |

* Significant at $p = 0.04$; all other differences were NS.

Table 2
Endoscopic results

| Outcome | 21-mm Stapler (n = 100) | 25-mm Stapler (n = 100) | Logistic regression analysis results | | | |
|----------|----------------------------|----------------------------|--------------------------------------|---------|------------|-----------|
| | | | Wald chi-square test statistic | P value | Odds ratio | 95% CI |
| EGD | 19 (19) | 8 (8) | 4.90 | 0.027 | 2.70 | 1.12–6.49 |
| Dilation | 17 (17) | 7 (7) | 4.46 | 0.035 | 2.72 | 1.08–6.89 |

CI = confidence interval; EGD = esophagogastroduodenoscopy.

Patients with 21-mm anastomosis had >2.5 times greater incidence of ≥ 1 EGD compared with patients with 25-mm anastomosis (i.e., 19% vs. 8%); they also had >2.5 times greater incidence of ≥ 1 dilation compared with patients with 25-mm anastomosis (i.e., 17% vs. 7%).

group. No complications resulted from endoscopy or dilation. No sutures were observed at, or near, the anastomoses during endoscopy, with or without dilation. The follow-up in both groups was 100%.

Discussion

Gastric bypass procedures have been performed since 1962 when first conceived as a treatment for morbid obesity by Mason and Ito [7,8]. Mason and Ito [7,8] stressed the importance of a small gastric pouch and small, restrictive outlet in forming the banded gastroplasty, and this concept was carried over to the Roux-en-Y gastric bypass. At present, surgeons fashion the GJ by sutures, circular staplers, or using a combination of the linear cutter/stapler and sutures [1–3,5,6,9,10]. Of these techniques, only the circular stapler offers the surgeon an exactly reproducible anastomosis from case to case. This eliminates interoperator variability that might make it difficult to scientifically assess the effect of anastomotic size on incidence of stenosis and on the eventual weight loss resulting from gastric bypass surgery. Furthermore, our technique of creating the pouch provided for uniformity of pouch size, independent of the anvil being used. The pouch was a cylindrical extension of the esophagus, beginning at the distal cut end of the first 45-mm stapler firing perpendicular to the lesser curve of the stomach and ending at the angle of His.

In 2001, Nguyen et al. [5] reported a significant reduction in the incidence of GJ stenosis by replacing the 21-mm circular stapler with the 25-mm stapler. They used staplers manufactured by the U.S. Surgical Corporation that created anastomoses with a smaller lumen than those created by the similarly labeled Ethicon Endosurgery staplers. In addition, their study had design limitations, as did so many others,

because the 2 patient groups were consecutive and not randomized. Therefore, operator experience and unobserved or temporal changes in patient instructions might have introduced variables that affected the reported outcomes. The present study was designed to eliminate these potentially confounding variables.

A 21-mm Ethicon ILS stapler creates a lumen of 0.7 cm² in area, and the 25-mm stapler enlarges the luminal opening to 0.995 cm². Our belief in this study was that this 29.6% increase in area would result in fewer endoscopies and fewer dilations. This increase did result in a concomitant reduction in perceived restriction by our patients; therefore, we had significantly fewer complaints leading to esophagogastroduodenoscopy in the 25-mm versus 21-mm group. It also lowered our overall stenosis rate to that reported by others using a linear cutter and hand-sewn anastomosis [1,2,9–11]. Although a recent report has suggested that multiple dilations were needed, we did not find that to be true in our patients, with a single dilation providing satisfactory relief in almost all cases [12]. The placement of 3 sutures with the 21-mm staplers and 1 with the 25-mm staplers may have further compromised the 21-mm anastomotic area in favor of the 25-mm anastomosis. However, we believe these sutures were far enough apart that any alteration was not significant compared with the 29.6% difference. The difference in stricture rates was so significant that a slight change would still have clinical implications. Additional study is needed to answer this question.

Several theories have been advocated regarding the cause of stenosis, ranging from tension on the suture (staple) line, ischemia at the anastomosis, the lack of mucosa-to-mucosa apposition with stapled anastomoses, and, more recently, the number of rows of staples in the cartridge [13]. We controlled for these possibilities by ensuring sufficient mesenteric length to avoid tension, avoiding interrupting the mesenteric blood supply to the anastomosis. Anastomotic ischemia inherent in the stapling itself was controlled by setting the same staple height before firing the stapler. All anastomoses suffered equally from the lack of direct mucosal apposition, eliminating this as a variable.

Potential criticisms of the study would include that the larger diameter of the 25-mm stapler also makes the size of

Table 3
Comparison of stapler size and interval to dilation

| Stapler size (mm) | Interval to first dilation (wk) |
|-------------------|---------------------------------|
| 21 | 4.8 \pm 1.2 |
| 25 | 8.9 \pm 3.8 |
| P value | <0.001 |

the peritoneal opening through which it is introduced more susceptible to herniation. Although true, we advocate closing all peritoneal defects larger than 1 cm, as advocated by the makers of all trocar products. Another criticism of the study would be the lack of comparative short- and long-term weight loss data. That portion of this study was not addressed in this report but will be reported separately when suitable follow-up data are available. Also concerning to some would be the differences in pain experienced by the patients between the 21- and 25-mm stapler at the introduction site. Although true that larger incisions are generally more painful, most of that pain is caused by suture closure of the fascia. This was controlled for, because both groups were treated exactly the same by placing one suture through the fascia using a Grice needle (Karl Storz) after dilation using the same set of cervical dilators. This avoided cutting the fascia, and we believe created smaller defects than would result from cutting. The 25-mm stapler does require additional dilation beyond that used for the 21-mm stapler. The last significant criticism of our report would be that our dilation rate differed from what we had previously reported. Our current 6% dilation rate with the 25-mm stapler is similar to our 7% dilation rate reported with the 21-mm stapler in our previous report [4]. We stand behind both sets of data, because we have noticed instances in which the dilation rates have fluctuated throughout the year with no identifiable trend. This has been part of our motivation for this randomized trial. Without prospective randomization, it would be difficult to adjust for variations such as allergies and postnasal drip on the tightness of the anastomosis. We believe many of these seasonal variations could be responsible for the large differences in stenosis rates.

Conclusion

This is the first, and only, randomized, double-blind trial comparing the effect of 2 circular stapler sizes on the incidence of postoperative stenosis. We found that the 29.6% increase in luminal area significantly decreased complaints leading to endoscopic intervention and reduced the stenosis rates by one half, as well as significantly delaying the onset of symptoms. The elimination of the 21-mm stapler could save bariatric surgeons time and potentially save insurers millions of dollars annually. It also results in stenosis rates similar to those of the hand-sewn and linear cutter anasto-

moses. However, the effect that stapler size has on weight loss remains to be determined.

Disclosures

Dr. Fisher is a consultant for Allergan, Inc. and Ethicon Endosurgery, Inc. (Johnson & Johnson, Inc.), and Medical Director for Bariatric Surgery for IASIS Health Insurance Company.

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