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Original article

Banded Roux-en-Y gastric bypass for the treatment of morbid obesity

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Abstract

Background: Laparoscopic Roux-en-Y gastric bypass (LRYGB) is the most effective treatment for morbid obesity. The additional benefit of placing a nonadjustable band around the pouch remains to be determined. The objective of this study was to compare outcomes between banded and non-banded LRYGB patients in a single bariatric center.

Methods: A matched cohort analysis was performed between patients who had undergone banded and nonbanded (standard) LRYGB. In the banded bypass cohort, an 8 F, 6.5 cm silastic ring was placed around the proximal gastric pouch. Both cohorts were matched for age, body mass index (BMI), and anastomotic technique. Endpoints included percentage excess weight loss (%EWL), postoperative morbidity, and band-related complications.

Results: Between January 2007 and July 2010, 134 banded LRYGB were performed (55% female, mean age 45 years). They were compared with a matched cohort of 134 concurrent nonbanded LRYGB patients (67% female, mean age 45.4 years). Mean preoperative BMI was 54.6 and 52.8 kg/m², respectively ($P = .084$). At 24 months postoperatively, the average %EWL was 58.6% in banded bypass patients and 51.4% in the nonbanded group ($P = .015$). The difference in EWL was more pronounced in super-obese patients than in those with BMI < 50 (among super-obese, 57.5% versus 47.6%, $P = .003$; among those with BMI < 50, 62.9% versus 57.9%, $P = .406$). There was no difference in early (19.4% versus 19.4%) or late complications (10.4% versus 13.4%, $P = .451$) between banded and nonbanded LRYGB patients.

Conclusion: Banding the pouch during LRYGB can be performed safely and may provide better weight loss, particularly in super-obese patients. Further prospective and long-term comparative studies of this technique are warranted. (*Surg Obes Relat Dis* 2013;■:00–00.) © 2013 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Bariatric surgery; Roux-en-Y gastric bypass (RYGB); Banded gastric bypass; Silicone ring; Weight loss; Morbid obesity

Bariatric surgery is well established as the most effective treatment for morbid obesity, resulting in sustained weight loss, remission or improvement in obesity-related comorbidities, and reduced mortality [1–3]. As the obesity epidemic soars globally, the phenomena of super (body mass index (BMI) > 50 kg/m²) and super-super (BMI > 60 kg/m²) obesity present formidable therapeutic challenges given the high-risk characteristics and technical difficulties

of operating on these severely obese patients [4,5]. The Roux-en-Y gastric bypass (RYGB) procedure has had extremely high success rates in the treatment of morbidly obese individuals. However, evidence suggests that patients with BMI > 50 kg/m² do not compare as favorably after gastric bypass as the less obese population, with lower percentage of excess weight loss (%EWL) and greater weight recidivism over time [6,7]. Capella and Capella [8] and Halverson and Koehler [9,10] proposed that failed gastric bypass procedures are in part attributable to pouch dilation and loss of restriction at the gastrojejunal anastomosis over time. Data from the authors' institution also

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supports an association between weight regain after gastric bypass and increased pouch and stoma sizes [11].

In an effort to address this problem, bariatric surgeons have attempted to revise failed RYGB procedures with placement of a nonadjustable or adjustable band around the gastric pouch [12,13], with reasonable success and rescue rates. An alternative approach is to consider placement of a nonadjustable gastric band around a newly fashioned gastric pouch at the time of primary RYGB. Despite some evidence suggesting superior and durable weight loss after a banded gastric bypass, it has not become widely practiced, mainly because of a lack of comparative data between it and the current RYGB. With the emerging problem of super-morbid obesity in recent years, renewed interest has arisen in the banded gastric bypass as a favorable modification of the RYGB in the super-obese population (Table 1). The aim of this study was to compare clinical outcomes between banded and nonbanded RYGB patients in a single tertiary referral bariatric center.

Methods

In January 2007, several of the surgeons at the authors' institution began to modify the standard laparoscopic RYGB for patients with super-morbid obesity. The only modification to the procedure was the placement of a nonadjustable silicone ring around the gastric pouch. Participating patients were consented specifically for this modification, and the institutional review board approved the present review of the database.

Study cohort

A matched cohort analysis was performed between patients who had undergone the modified banded LRYGB and nonbanded (standard) LRYGB. Both groups' procedures were contemporaneously performed between January 2007 and July 2010. The matching process was based on the following variables: patient's preoperative BMI (± 2 kg/m²), age, and gender. The control group was randomly selected from a total cohort of 1017 patients who underwent nonbanded laparoscopic gastric bypass during the study period. Selection was performed by an individual who was otherwise not involved in this study. All participants met the National Institutes of Health criteria for bariatric surgery [14]. Patients' medical records were reviewed and data obtained on their demographic characteristics and clinical history, operative details, and their postoperative course.

Surgical technique

A standard technique was used for RYGB in all patients [15], including creating a 150-cm antecolic antegastric Roux limb and using a linear-stapler technique to create a <2-cm gastrojejunostomy (GJ) and an approximately 15–20-mL gastric pouch. After the GJ anastomosis was formed,

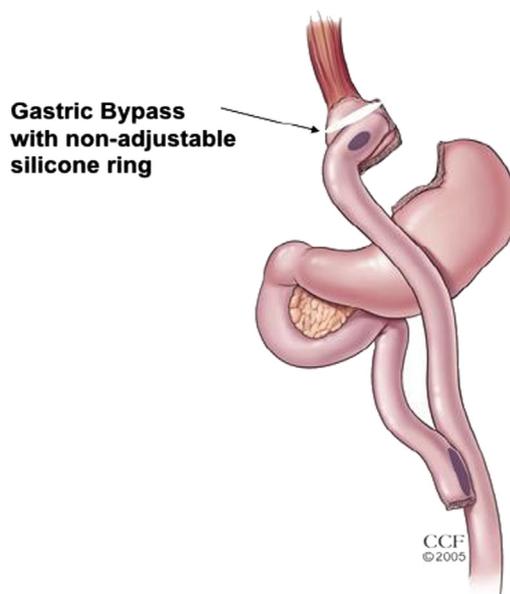


Fig. 1. Schematic drawing of the banded gastric bypass anatomy.

a 10 cm long 8 F silicone ring was placed around the pouch, at a distance 1–2 cm below the esophagogastric junction through an opening in the lesser omentum. A 2-0 silk suture was used to secure both ends and close the ring to create a 6.5-cm circumference ring. Interrupted plication sutures were inserted to fix the silicone ring to the gastric pouch (Fig. 1).

Study endpoints

Primary endpoints included %EWL and the absolute decrease in weight and BMI at 24 months postoperatively. Secondary endpoints included mortality, morbidity, and band-related complications in the banded-bypass group. The details of any upper endoscopies performed postoperatively in the entire study cohort also was recorded.

Data analysis

Data were analyzed using the Predictive Analytics SoftWare package, version 18.0, for Windows. Descriptive statistics were computed for all variables; data regarding patient characteristics, management, and outcomes are outlined in numbers and percentages. Parametric data are presented as mean (\pm standard deviation) and analyzed using Student's two-sample *t* test for any 2 sample comparisons and ANOVA, followed by Tukey HSD (honestly significant difference) post hoc test, where appropriate. Differences between proportions and categorical variables were determined using the χ^2 test. Subgroup analyses were performed of the super-obese population and those with >12 month follow-up. All tests were two-tailed, and results with a *P* value of <.05 were considered statistically significant.

Table 1
Summary of studies reporting clinical outcomes of banded-RYGB procedures to date

Author	Year	Follow-up (months)	Banded RYGB, %EWL (n)*	Non-banded RYGB, %EWL (n)	Morbidity	Band-related morbidity	Mortality
Fobi et al. [31]	1994	24	77.3% (n = 84)	n/a	20%	0%	1.2%
Crampton et al. [20]	1997	43	69% (n = 64)	n/a	25%	14%	0%
Capella et al. [8]	2002	60	77% (n = 652)	n/a	12.5%	46%	3%
Fobi et al. [30]	2005	12	74.98% (n = 50)	n/a	14%	2%	0%
White et al. [32]	2005	49	87.1% (n = 342) [†]	n/a	41.2% [‡]	7%	0%
Bessler et al. [22]	2007	36	73.4% (n = 46)	57.7% (n = 44)	26%	0%	0%
Mali et al. [33]	2007	60	69.7% (n = 183) [†]	n/a	n/a	n/a	n/a
Pajecki et al. [34]	2007	87	71.8% (n = 75)	n/a	n/a	n/a	3.1%
Arceo-Olaiz et al. [35]	2008	24	69.1% (n = 30)	71.4% (n = 30)	13.3%	6.7%	0%
Salinas et al. [36] [§]	2009	60	83% (n = 160)	n/a	50.6%	1.25%	6%
Awad et al. [27]	2012	120	82% (n = 260)	63% (n = 218)	n/a	1.15%	n/a

EWL = excess weight loss; n/a = not available; RYGB = Roux-en-Y gastric bypass.

*Most banded RYGBs were performed open. Salinas et al [36] performed 3 cases laparoscopically. Fobi et al. [30] performed 82% of cases laparoscopically in their 2005 series. Awad et al. [27] performed 20% of cases laparoscopically.

[†]EWL at 5 years postoperatively.

[‡]Perioperative morbidity was 24.2% and late morbidity was 17%.

[§]Salinas et al. [36] performed a Silastic ring vertical gastric bypass with jejunal interposition.

^{||}Awad et al. [27] did not report overall morbidity; however, the rate of band erosion was 1.15% (3 of 260 cases).

Results

Patient characteristics

Over a 42-month period, a total of 134 patients underwent the banded bypass procedure, as described above. This group was case-matched to 134 patients who underwent standard RYGB using identical surgical technique except for placement of a 6.5-cm circumference, 8 F silicone ring around the gastric pouch. All procedures were completed laparoscopically. The demographic characteristics and baseline characteristics of both groups were comparable except for higher proportions of super-obese and dyslipidemic patients in the banded-bypass group (Table 2). The proportion of patients lost to follow-up at 2 years postoperatively was 39.6%. Overall, the mean follow-up among the study cohorts was 20.6 (12.0) months for the banded bypass group and 22.8 (15.7) months for the nonbanded bypass group.

Weight loss outcomes

The banded bypass group attained significantly greater %EWL at 24 months postoperatively compared with the nonbanded bypass group (58.6% versus 51.4%, $P = .015$, Fig. 2). The absolute decreases in weight (lb) and BMI points (kg/m^2) were also higher for the banded bypass group (Table 3). Subgroup analysis was performed of the super-obese population in the banded and nonbanded RYGB groups. The preoperative mean (standard deviation) BMI was very similar in these 2 groups at 57.1 (7.8) kg/m^2 and 57.6 (6.9) kg/m^2 , respectively ($P = .620$). The absolute decrease in weight, BMI, and the %EWL were all significantly greater in the super-obese banded RYGB group compared with matched nonbanded RYGB patients

(Table 4, Fig. 3). In contrast, there was no significant difference in postoperative weight loss outcomes between the less obese groups (those with BMI < 50, Table 4).

Utilization of upper gastrointestinal investigations postoperatively

All patients in our unit routinely undergo an upper gastrointestinal barium study (UGI) on the first postoperative day to assess the integrity of the GJ anastomosis. The proportion of patients reported to have an abnormal UGI study was 14.9% in the banded bypass group and 6.0% in the nonbanded bypass group ($P = .015$). The specific anomalies detected on UGI were reported to be abnormalities at the GJ junction and gastroesophageal (GE) junction predominantly. Over the duration of the follow-up period,

Table 2
Baseline patient characteristics

Characteristics	Banded RYGB	Non-banded RYGB	<i>P</i> value
Number	134	134	
Gender (% F/M)	67/33	73/27	.282
Age, years	45.4 (11.6)	46.8 (11.9)	.320
Preoperative BMI, kg/m^2	54.6 (8.6)	52.8 (8.7)	.084
Super-obese, %	78%	63%	.005
Comorbidities			
Diabetes	43%	37%	.319
Hypertension	74%	72%	.681
Dyslipidemia	63%	46%	.003
Follow-up, months	20.6 (12)	22.8 (15.7)	.200
Range, months	1–34	1–34	

BMI = body mass index; F = female; M = male; RYGB = Roux-en-Y gastric bypass.

Data presented as mean (standard deviation).

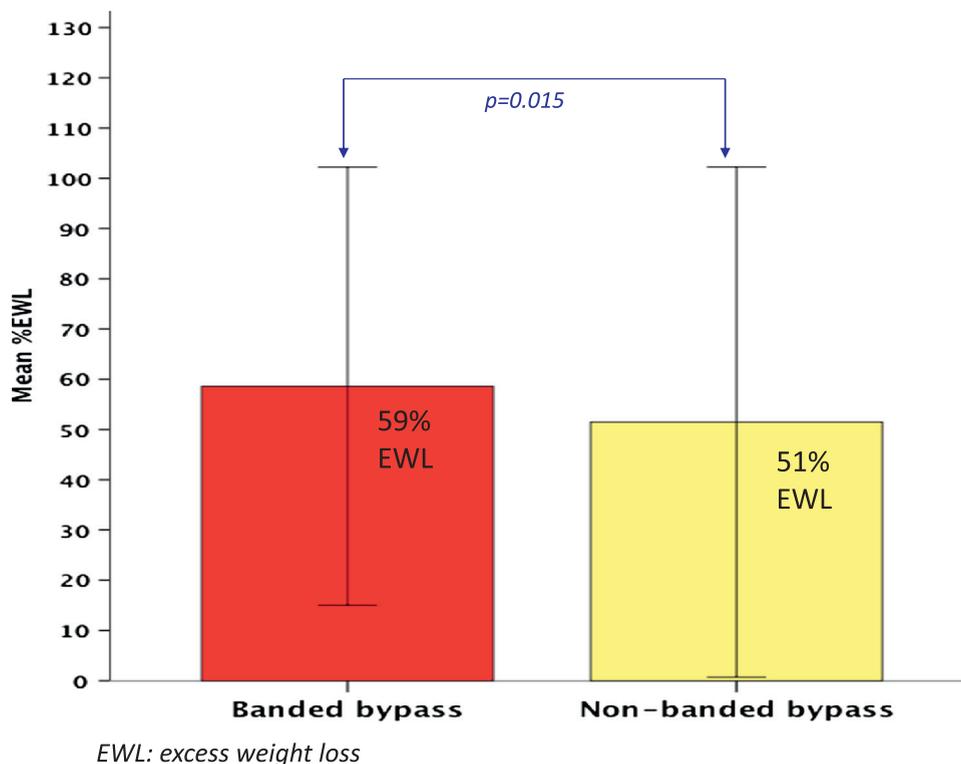


Fig. 2. Mean % excess weight loss was significantly higher in the total banded bypass group compared with the nonbanded bypass group (59% versus 51%, $P = .015$), at 24 months postoperatively.

upper endoscopy (UE) was performed in 23.1% of the banded bypass group and 23.9% of the nonbanded bypass group for investigation of functional symptoms such as dysphagia, nausea, and vomiting. There was no significant difference in the need for UE between the 2 groups ($P = .912$). Abnormalities such as marginal ulceration, erosion, and anastomotic stricture were identified at UE in a greater proportion of the nonbanded bypass group, although the difference was not statistically significant (7.5% versus 5.2%, $P = .452$).

Morbidity and mortality

There was no early (30-day) mortality in the entire study cohort. Late mortality occurred in 1 patient in the banded

Table 3
Postoperative outcomes at 24 months postoperatively

	Banded RYGB	Non-banded RYGB	<i>P</i> value
Number	134	134	
Decrease in weight postoperatively, pounds	110.9 (50.5)	91 (48.5)	.001
Decrease in BMI postoperatively, kg/m ²	16.9 (6.8)	13.8 (7.1)	<.001
Early morbidity	19.4%	19.4%	1
Late morbidity	10.4%	13.4%	.451

BMI = body mass index; RYGB = Roux-en-Y gastric bypass.
Data presented as mean (standard deviation).

bypass group and 1 patient in the nonbanded bypass group, at 20 and 26 months postoperatively, respectively. The cause of death was not related to bariatric surgery in either patient. The mortality in the banded bypass group was secondary to a pulmonary embolus > 30 days after surgery, and the mortality in the nonbanded bypass group was secondary to a cardiac event > 5 months postoperatively.

Table 4
Weight loss outcomes in the super-obese and non-super-obese cohorts at 24 months postoperatively

	Banded RYGB	Non-banded RYGB	<i>P</i> value
<i>Super-obese (BMI > 50)</i>			
Number	105	84	
Decrease in weight postoperatively, pounds	119 (52)	102 (50)	.025
Decrease in BMI postoperatively, kg/m ²	18.0 (6.9)	15.2 (7.3)	.008
%EWL	57.5 (21.9)	47.6 (22.6)	.003
<i>Morbidly obese (BMI < 50)</i>			
Number	29	50	
Decrease in weight postoperatively, pounds	81 (32)	72 (40)	.271
Decrease in BMI postoperatively, kg/m ²	12.6 (4.5)	11.3 (5.9)	.278
%EWL	62.9 (21.3)	57.9 (28.5)	.406

BMI = body mass index; %EWL = percentage excess weight loss; RYGB = Roux-en-Y gastric bypass.

Data presented as mean (standard deviation).

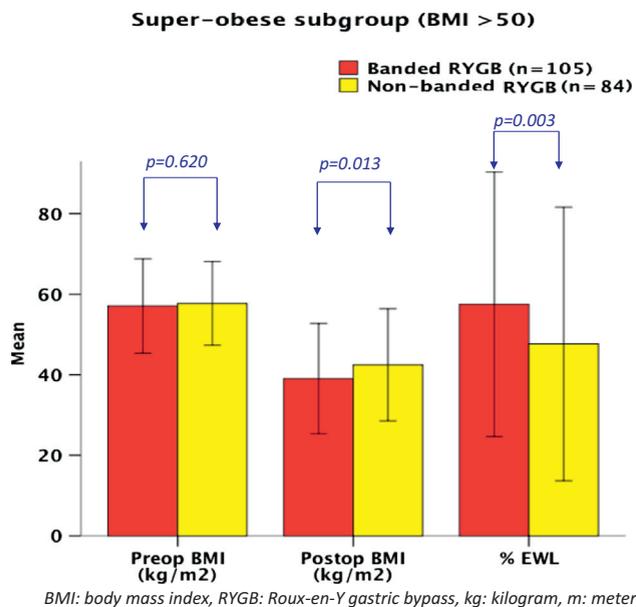


Fig. 3. Among the super-obese population in this study (78% of the banded bypass group and 63% of the nonbanded bypass group), the mean preoperative body mass index (BMI) was similar in both the banded and nonbanded bypass groups. Postoperatively, at a mean follow-up of almost 2 years, the decrease in BMI and %EWL were significantly greater in the banded-bypass group.

Early morbidity was comparable in both groups: 26 patients (19.4%) in each group developed a postoperative complication within 30 days of surgery, most of which were minor complications). The incidence of late morbidity was also similar among banded-bypass and standard RYGB patients (10.4% versus 13.4%, $P = .451$). Band-related complications occurred in 3 patients (2.2%). Two of these 3 patients presented with epigastric pain and dysphagia; upper endoscopy found band erosion in both cases, and it was possible to remove the band endoscopically and without sequelae. Both patients made an uncomplicated recovery, although they have experienced weight regain since removal of the silicone ring and resolution of their upper GI symptoms. A third patient who underwent a banded RYGB experienced dysphagia in the early postoperative period and underwent endoscopic investigations that found a stricture at the GJ anastomosis, distal to the level of the silicone ring. The patient responded well to balloon dilation of this stricture and did not require removal of the band.

Discussion

Obesity surgery has evolved over the past decade, with novel techniques and modifications to original procedures emerging in an attempt to improve outcomes. It is well accepted that the ideal weight loss procedure, in terms of efficacy and durability, is one that combines gastric restriction with some degree of malabsorption [16]. The gastric bypass is the prototype procedure in this regard and, consequently, has become the most commonly performed

weight loss operation in the United States [17]. It has been shown that enlargement of the gastric pouch and GJ over time are associated with weight regain [11]. Furthermore, reoperation to reduce the size of a dilated gastric pouch or GJ stoma has been shown to reinitiate weight loss [18,19]. Another modification of the standard RYGB procedure, used occasionally over the past 25 years, is the placement of a nonadjustable band or ring around a newly fashioned gastric pouch. This banded bypass procedure was pioneered by Fobi [20–22] and Capella and Capella [8,23] and Capella et al. [24] in the late 1980s. Their early case series of open banded bypass operations resulted in improved and sustained weight loss with this procedure, particularly in the super-obese subgroup. However, the potential for complications from a banded bypass was higher than the typical morbidity rate expected from either technique alone. The incidence of band erosion in Fobi's large series of more than 3000 procedures over 10 years was 2.8% [25]. In addition to band erosion, some groups found a high rate of functional problems thought to be related to the band, such as dysphagia and intolerance for solids [26]. Awad et al. performed a retrospective non-randomized comparison of patients who underwent banded and nonbanded gastric bypass procedures with 10 years of follow-up. The authors reported a weight loss benefit among the banded bypass group, but this only became significant after 3 years [27]. Furthermore, although there was some increased intolerance to food intake in the banded bypass patients, this did not reduce patients' quality of life. Several other small case series evaluating the outcomes of open banded gastric bypass procedures have reported durable weight loss [28–31].

Few trials have directly compared the banded-RYGB to the standard nonbanded RYGB procedure. Bessler et al. performed the first randomized double-blinded trial of banded versus nonbanded gastric bypass for 90 super-obese patients in 2007. After 36 months, the banded bypass patients appeared to have greater weight loss (73.4% versus 57.7%; $P < .05$), although the authors did not observe a significant difference in the %EWL at 6, 12, and 24 months postoperatively (43.1% versus 24.7%, 64.0% versus 57.4%, and 64.2% versus 57.2%, respectively). However, banded patients did report greater functional gastrointestinal symptoms postoperatively, such as vomiting and food intolerance (79% versus 33%) [28]. To the authors' knowledge, this prospective trial included only open bariatric procedures. There has not been any comparison of laparoscopic banded and nonbanded gastric bypasses. The present study compared the outcomes of a consecutive cohort of laparoscopic banded-RYGB patients with case-matched contemporaneous nonbanded laparoscopic RYGB cases. The data suggests that after almost 2 years follow-up, on average, the banded RYGB yields superior weight loss. Interestingly, the benefit in terms of %EWL applied only to super-obese patients (BMI > 50 kg/m²), who achieved an additional

10% EWL after banded RYGB when compared with nonbanded RYGB (57.5% versus 47.6%, $P = .003$).

Critics of the banded RYGB cite the potential for band-related complications as one of the main deterrents to performing this procedure. Erosion of the nonadjustable band through the gastric wall is reported to occur in 1%–6% of cases and may be related to the specific position of the band [25,28,31]. In his earliest cases, Fobi noted that almost all bands placed around the gastroenterostomy eroded through the stomach. Applying the band in a more proximal position, at least 2 cm above the gastroenterostomy, greatly reduced the incidence of erosion [25]. In our experience, applying the nonadjustable silicone ring 1–2 cm distal to the gastroesophageal junction and at least 2 cm above the gastroenterostomy resulted in a very low rate of band erosion (1.5%, $n = 2$). Furthermore, when this complication occurs it usually presents subtly, and it is often possible to manage the situation by endoscopically retrieving the band [25].

Another criticism of the banded bypass is the potential for functional upper GI symptoms postoperatively, secondary to the placement of a nonadjustable ring around the pouch. Our study does not support this assumption; almost equal numbers of patients in the banded and nonbanded bypass groups required upper endoscopy for investigation of functional symptoms such as dysphagia, nausea, and vomiting (23.1% and 23.9%, respectively). Although a higher proportion of patients in this study were reported to have abnormal upper GI contrast studies after the banded bypass (14.9% versus 6.0%), this was not clinically significant. The constriction of the pouch at the level of the silicone ring was often reported by radiologists to be abnormal, when in fact the restriction to flow of contrast correlated with the appropriate position of the silicone ring and the patients was usually asymptomatic.

Many questions remain to be answered in relation to the use of a nonadjustable band around the gastric pouch. Technical considerations include the size of ring to apply (6.0–7.0 cm) and whether this should vary on an individual patient basis, where best to position the ring and how to secure it, and what material is most suitable to use (e.g., silicone, marlex mesh, porcine or bovine graft). If the banded bypass procedure was to become widely performed, these issues should be standardized.

The mechanisms of action of the banded bypass appear obvious; it is thought that applying a nonadjustable band around the gastric pouch should prevent dilation of the pouch and gastrojejunostomy. There is evidence to suggest that weight loss postgastric bypass is superior among patients with normal postoperative anatomy, which has been defined as a pouch no ≤ 5 cm \times 6 cm and a GJ < 2 cm in diameter [11]. A further theory, based on observational data of weight loss outcomes > 3 years after a banded gastric bypass, is that the effects of enforced pouch restriction become more important over time, as the dumping phenomena and other postoperative functional

symptoms resolve. In the absence of pouch reinforcement, it is assumed that the natural history of postoperative gastric bypass anatomy involves a degree of pouch and/or stoma dilation. Consequently, restriction at the anastomosis is lost, and patients are able to ingest larger amounts of food to the detriment of their weight loss goals. Although this is the first case-matched cohort study evaluating banded and nonbanded laparoscopic gastric bypasses, a number of limitations are inherent to the study. Allocation to the 2 study groups was not randomized or controlled. The subgroup analysis of patients with BMI < 50 kg/m² is susceptible to a type II statistical error, because the number of patients in this subgroup was small ($n = 79$); a larger sample size will be required to determine the benefit of the banded RYGB in this subgroup. Follow-up is still relatively short, although these patients continue to be followed prospectively.

Conclusion

Applying a nonadjustable band around the gastric pouch during a gastric bypass is associated with greater weight loss compared with that achieved after a standard nonbanded RYGB, in the first 2 years postoperatively at least. The benefit appears to be specific to the super-obese bariatric population and also seems to be durable in the short-to-medium term. The banded bypass can be performed safely, and the incidence of band-related morbidity is low. However, further prospective and long-term comparative studies of this technique are warranted to confirm its safety and temporal superiority over the standard nonbanded gastric bypass.

Disclosures

Dr. Brethauer is a speaker, consultant, and scientific advisory board member for Ethicon Endo-Surgery, has served as a speaker for Covidien, and receives research support from Bard/Davol. Dr. Schauer discloses the following relationships: consultant and scientific advisory board member for Ethicon Endo-Surgery, from which he also receives research support; Remedy MD board of directors; Stryker Endoscopy: scientific advisory board, educational grant; Bard/Davol: scientific advisory board, consultant; Gore: consultant, educational grant; Baxter: educational grant; Barosense, Surgique, Cardinal/Snowden Pencer: scientific advisory board; Covidien: educational grant; Allergan: educational grant; and Surgical Excellence LLC: board of directors. Drs. Heneghan, Annaberdyev, Eldar, and Rogula have no conflicts of interest or financial ties to disclose.

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