

Original article

Long-term results of a randomized trial comparing banded versus standard laparoscopic Roux-en-Y gastric bypass

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Abstract

Background: Banded Roux-en-Y gastric bypass was designed to avoid or diminish weight regain in the long term. In 2008, we published the initial results of a pilot study design to comparatively evaluate surgical morbidity, mortality, and maximum weight loss in patients undergoing banded and unbanded laparoscopic Roux-en-Y gastric bypass (LRYGB). The present study analyzes the 5-year results.

Methods: A randomized, controlled trial was carried out in 60 morbidly obese patients who underwent LRYGB. Patients were divided in 2 groups. Half of the patients underwent the banded version of the LRYGB, and half underwent the unbanded version. The 5-year excess weight loss (EWL) and loss of body mass index (BMI) were comparatively analyzed.

Results: There were 58 females and 2 males with a mean preoperative BMI of $47 \pm 4.9 \text{ kg/m}^2$. A total of 21 patients with banded LRYGB and 22 with unbanded LRYGB completed 5-year follow-up. One patient died 3 years after surgery from metastatic melanoma. EWL at 5 years was $61.6\% \pm 19.6\%$ versus $59.8\% \pm 15.9\%$ ($P = \text{ns}$), and loss of BMI was $32.9\% \pm 5.2\%$ versus $32.8\% \pm 4.3\%$ ($P = \text{ns}$), respectively, for the banded and unbanded group.

Conclusions: In this small study, there were no statistical differences in the EWL and the BMI lost at 5 years between the group of patients who underwent banded and unbanded LRYGB. (Surg Obes Relat Dis 2013;9:395–397.) © 2013 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Roux en Y gastric bypass; Banded

Morbid obesity has been on the rise worldwide, and surgery is currently the only effective treatment. The laparoscopic Roux-en-Y gastric bypass (LRYGB) has been reported to promote significant weight loss through a variety of mechanisms, including gastric restriction, intestinal malabsorption, and changes in the secretion of gastrointestinal hormones that induce rapid satiation, and lack of appetite [1].

Performance of weight after a LRYGB shows the following pattern. There is a significant weight loss in the

first 2 years, followed by a period of stabilization and some weight regain 3–5 years after surgery. Among the hypotheses to explain weight regain, one is that it may occur as a consequence of pouch enlargement or dilation of the gastrojejunostomy. Linner, Fobi, and Capella, among others, have suggested reinforcement of either the pouch or the anastomosis with a prosthetic material to avoid the risk of dilation and to maintain the weight loss [2–4].

In 2003, a randomized trial to comparatively analyze surgical morbidity, mortality, and weight loss in patients undergoing banded and unbanded LRYGB was initiated. Surgical outcomes and maximum weight loss were previously published [5]. The present study analyzes the 5-year results.

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Methods

This is a prospective, randomized, controlled trial that included 60 patients with morbid obesity. Patients signed an informed consent and were randomly assigned to the surgical procedure using sealed envelopes. Half of the patients underwent banded LRYGB, and half underwent unbanded LRYGB. All procedures were performed laparoscopically under general anesthesia. A small gastric pouch using the lesser curvature of the stomach was constructed with staplers. Approximate length of the limbs was 50 cm for the biliopancreatic and 150 cm for the alimentary. An antecolic and antegastric gastrojejunostomy was handsewn in 2 layers using 3-0 Polyglactin and 3-0 Silk. A 32F boogie was used to calibrate the anastomosis. In the group of patients with the banded LRYGB, a 6.5-cm polypropylene mesh was placed immediately cephalad to the gastrojejunostomy.

Patients were followed in the outpatient clinic with particular emphasis in weight loss, gastric tolerance, and the presence of complications. A comparative analysis between the 2 groups 5 years after surgery was performed using the χ^2 test. $P < .05$ was considered statistically significant.

Results

The initial cohort was formed by 60 patients, 53 females and 7 males, with a mean age of 36.5 ± 9.7 years. Preoperative weight and body mass index (BMI) were $48.1 \pm 4.8 \text{ kg/m}^2$ and $47.4 \pm 5.1 \text{ kg/m}^2$, respectively. Table 1 shows demographic characteristics of the initial cohort and the cohort of 43 patients followed at 5 years.

In the long-term follow-up, 1 patient died 3 years after surgery because of metastatic melanoma. There were 17 patients for whom we were unable to get 5-year follow-up, despite numerous attempts.

Excess weight loss (EWL) in the 43 patients with long-term follow-up was $61.3\% \pm 17.6\%$ and loss of the BMI was $33.6\% \pm 4.7\%$. Figs. 1 and 2 show the EWL and BMI throughout the study period. A total of 59.1% of patients with the unbanded and 61.9% of patients with the banded LRYGB reached a BMI $< 35 \text{ kg/m}^2$ at 5-year follow-up.

In the long term, there were no additional complications to those reported previously. Regarding food intake, 5 patients from the banded and 1 patient in the unbanded group reported poor tolerance to meat. One patient in each

Table 1
Preoperative demographic characteristics

	LRYGB	Banded LRYGB
Male/female	4/26	3/27
Mean age	36.5 ± 9.7	37.8 ± 9.6
Mean excess weight %	113 ± 21	110 ± 21
Mean BMI, kg/m^2	47 ± 5	48 ± 5

LRYGB = laparoscopic Roux-en-Y gastric bypass; BMI = body mass index.

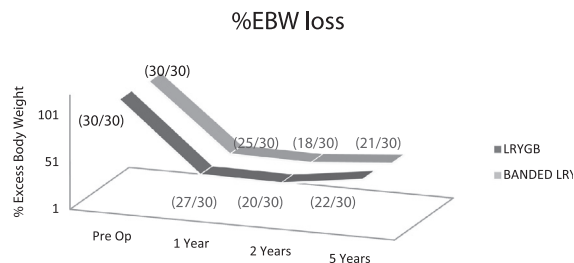


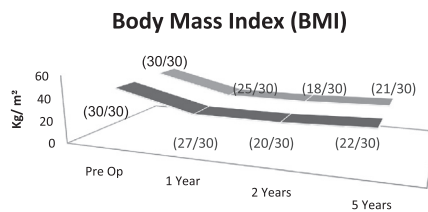
Fig. 1. Percentage excess weight loss. Laparoscopic Roux-en-Y Gastric Bypass (LRYGB).

group had occasional dysphagia, and 1 patient in each group experienced occasional nausea. It is worth mentioning that, during the first postoperative year, there were more patients with food intolerance in the banded group and that 1 patient with persistent vomiting required band removal.

Discussion

The goal of bariatric surgery is to promote durable weight loss to morbidly obese patients with minimum side effects. The LRYGB has been found to have a highly favorable risk-benefit balance. The surgical procedure has very small variations worldwide. The number of surgical complications has been significantly reduced. Surgical mortality is comparable to that of a laparoscopic cholecystectomy [6]. Mean EWL at 2 years is 61.23% (58–64%) [7], and net weight loss at 15 years, according to a Swedish study, is $27\% \pm 12\%$ [8]. However, as in all bariatric procedures, rapid weight loss observed in the first 2 postoperative years is followed by some weight regain that may be up to 50% of the weight lost after subsequent years [8,9].

The etiology of weight regain after RYGB appears to be multifactorial. For example, 1 study suggested that many patients with weight regain have some intolerance to red meat ingestion. This has been related to inadequate mastication and a decrease in gastric secretion. Low protein intake leads to low satiety and predisposes to weight gain as a consequence of the increased desire to eat [10].



	Pre Op	1 Year	2 Years	5 Years
■ LRYGB	47.4	30.2	30.1	32.8
■ BANDED LRYGB	48.1	31.1	30.9	32.9

Fig. 2. Body mass index. Laparoscopic Roux-en-Y Gastric Bypass (LRYGB).

Some authors have suggested that size of the gastric pouch and ultimate diameter of the gastrojejunostomy are closely related to weight loss and weight regain [11]. On the basis of this theory, a big gastric outlet could be a good reason for insufficient weight loss or weight regain [12]. Knowing the importance of the restrictive component of the procedure, a standard practice has been to construct small gastric pouches in the part of the stomach with less likelihood to dilate and to make small anastomosis between the stomach and the small bowel. However, both the gastric pouch and the gastrojejunostomy have the potential to dilate. To prevent that dilation of the anastomosis, which may be responsible for weight regain, some authors have suggested placing a band or a ring around the outlet of the gastric pouch [3,4,12–14].

Fobi et al., using a 5.5-cm silastic ring, reported a 100% success rate defined as $\geq 25\%$ of EWL over 2 years, a 98.7% success rate defined as $\geq 40\%$ EWL, and a 90.9% success rate defined as $\geq 60\%$ EWL. Only 2 patients required reoperation to remove the silastic ring band [14].

Capella and Capella reported that a small banded pouch along the lesser curvature of the stomach using a 5.5-cm band resulted in substantial and permanent weight loss with an early reoperation rate of 0.6% for problems related to the restrictive band. In their series, 63% of the 652 patients completed 5 years of follow-up. Mean BMI 5 years after surgery was 29 kg/m² (range 20–43), and mean EWL was 77% (range 32–108), with 93% of the patients with more than 50% EWL [15].

With the use of fascial reinforcement of the gastrojejunostomy, Drew et al. reported that 80% of patients undergoing primary RYGB and 79% undergoing a revised RYGB were within 50% of the ideal weight at a mean of 4.3 years after surgery postoperatively [16].

One comparative study of super obese patients by Bessler et al. [17] reported more weight loss at 36 months in the banded group, with no difference in the first postoperative year. In our study, there were no differences in final BMI or %EWL in the 5 years of the study [17].

The presence of a foreign material around the stomach may induce some complications. Stenosis, erosion, and infection have been reported with a frequency up to 2.8% [18]. Despite the fact that the size of our band may be slightly longer than others reported, we experienced food intolerance in a good number of patients, and in one patient the band had to be removed.

Conclusions

With our results, we do not support the use of the banded LRYGB to improve either maximum weight loss or weight regain.

Disclosures

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

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