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Original article

Maximal weight loss after banded and unbanded laparoscopic Roux-en-Y gastric bypass: a randomized controlled trial

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Abstract

Background: Laparoscopic Roux-en-Y gastric bypass (LRYGB) leads to significant weight loss and correction of co-morbidities in most patients. Banded LRYGB was designed to enhance weight loss and avoid weight regain.

Methods: A randomized controlled pilot trial was designed to comparatively analyze the results and complications of banded (6.5 cm) and unbanded LRYGB. The present study was an interim analysis focused on morbidity, mortality, and maximal weight loss.

Results: The 60 patients were divided into 2 groups. Group 1 underwent unbanded LRYGB (n = 30) and group 2 underwent banded LRYGB (n = 30). No differences were found between the 2 groups in terms of age, gender, body mass index, or operative time. No significant differences were found in the percentage of excess weight loss and body mass index at 6, 12, and 24 months between the 2 groups. The frequency of complications was similar in both groups; 1 patient required band removal because of stenosis at the level of the mesh.

Conclusion: The weight loss pattern in both groups was similar at 1 and 2 years postoperatively. Proper assessment of weight maintenance and late weight regain will require longer follow-up. (Surg Obes Relat Dis 2008;4:507–511.)

Keywords: Morbid obesity; Obesity surgery; Gastric bypass; Banded gastric bypass

Obesity is a public health problem that has grown exponentially worldwide [1]. Morbid obesity, defined as a body mass index of ≥40 kg/m^2 has become a particular challenge [2]. It usually involves co-morbidities with a direct effect on patients' health, quality of life, and life expectancy [1].

Bariatric surgery has been recognized as the most effective treatment for morbid obesity. However, the debate about the best surgical procedure is still considerable. Among a wide range of operations that have been used for morbid obesity, Roux-en-Y gastric bypass (RYGB) has shown an appropriate risk/benefit balance and has achieved a high degree of acceptance in America, particularly after the advent of the laparoscopic approach [3–5].

RYGB induces weight loss through some well-described mechanisms, including gastric restriction, prolonged satiation, intolerance to carbohydrates, bowel malabsorption, and lack of appetite [6,7]. The weight loss pattern in RYGB is characteristic and includes significant weight loss during the first 2 years after surgery, followed by some weight regain after the second or third postoperative year [6,8–11].

In 1985, Linner [12] introduced the concept of anastomosis reinforcement, with the aim of enhancing the amount of weight loss and preventing excessive postoperative weight regain. Subsequently, Fobi et al. [7] and Capella [10], among others, described alternative methods to avoid rapid gastric emptying due to enlargement of the gastroje-

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Table 1
Demographic characteristics

Characteristic	LRYGB	BLRYGB
Gender (n)		
Male	4	3
Female	26	27
Mean age (yr)	36.5 ± 9.7	37.8 ± 9.6
Mean preoperative body weight (kg)	125 ± 17	126.8 ± 17
Mean preoperative excess weight (%)	113 ± 21	110 ± 21
Mean preoperative BMI (kg/m^2)	47 ± 5	48 ± 5
Mean operative time (min)	180 ± 44	180 ± 34
Mean hospital stay (d)	7 ± 6	6 ± 6

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

junostomy over time. These methods included the placement of a premeasured band or ring around the gastric reservoir, adjacent to the gastroenterostomy. This procedure has been called banded RYGB [10–12]. Some investigators have reported sustained excellent weight loss in their patients with this technique [13–15].

With the aim of comparatively analyze the advantages and disadvantages of banded versus unbanded RYGB, a pilot study was conducted using the method of a controlled randomized trial. The outcome variables of the general study included morbidity, maximal weight loss, and late weight regain. The aim of the present pilot study was to perform an interim analysis of the surgical morbidity and mortality and maximal weight loss in patients undergoing these 2 procedures.

Methods

A cohort of 60 patients with morbid obesity (body mass index of 40–55 kg/m^2), who agreed to participate in this study and provided written informed consent, were randomized into 2 groups. Sealed envelopes were used for randomization. They were opened immediately before each operation. Our institutional review board approved the study. The number of patients was arbitrarily determined. The first group consisted of 30 patients who underwent unbanded laparoscopic RYGB (LRYGB). The second group included 30 patients who underwent banded LRYGB (BLRYGB). Our standard technique for gastric bypass consisted of a hand-sewn gastrojejunostomy in 2 layers using 3-0 Polyglactin for the internal and 3-0 silk for the external layer. To ensure a diameter of 1–1.5 cm, a 32F boogie was used to calibrate the anastomosis. The length of alimentary and biliopancreatic limbs was approximately 150 cm and 50 cm, respectively. In all patients, the alimentary limb was brought up in an antecolic and antegastric manner. A close drain adjacent to the gastrojejunostomy and the gastric partition was routinely left in place. For patients undergoing BLRYGB, the size of the gastrojejunostomy was 2–2.5 cm. A 6.5-cm polypropylene Marlex mesh was placed immediately cephalad to the gastrojejunostomy, as previously described by Cruz-Vigo et al. [15]. Using the formula $C = (pi) \cdot d$ for calculating any circumference and considering a gastric wall thickness of 3 mm, the diameter of the gastric outlet using a 6.5-cm mesh should be close to 1.8 cm.

The patients were followed up in our outpatient clinic, with weight lost, food tolerance, and complications specifically considered. All patients had undergone standard nutritional and psychological counseling before and after surgery.

Results

The demographics, operative time, and hospital stay were very similar in the 2 groups (Table 1). One patient in each group developed a gastric leak that was controlled by the drains left at surgery, and neither required surgical reintervention. One patient in the BLRYGB group developed gastric outlet obstruction. The obstruction persisted after 4 endoscopic balloon dilations and was resolved by surgical transection of the band. Bowel obstruction from an internal hernia was diagnosed in 2 patients, 1 in each group. Both were treated laparoscopically. A trocar port hernia was also seen in 1 of these patients.

The presence of vomiting at 3, 6, 9, and 12 months after surgery is shown in Table 2. At 3 months postoperatively, 2 patients in the LRYGB group had vomited twice a week, 1 patient 3 times a week, and 1 patient once a week. From the 5 patients who presented with vomiting at 3 months after BLRYGB, 1 experienced vomiting 6 times a week, 2 patients 4 times a week, 1 patient twice a week, and 1 once a week. Most patients experiencing vomiting reported a combination of saliva and small food particles in their vomit. From the 2 patients for whom the vomiting persisted at 6 months after surgery, 1 presented with an average of 18 vomiting episodes a week. Stenosis at the level of band placement was identified by endoscopy. After 4 unsuccessful balloon dilations, the patient underwent laparoscopic band removal.

Table 2
Comparative frequency of vomiting after surgery

Postoperative interval (mo)	LRYGB	BLRYGB
3	4/30	5/30
6	0/30	2/30
9	0/30	1/29
12	0/30	0/29

Abbreviations as in Table 1.

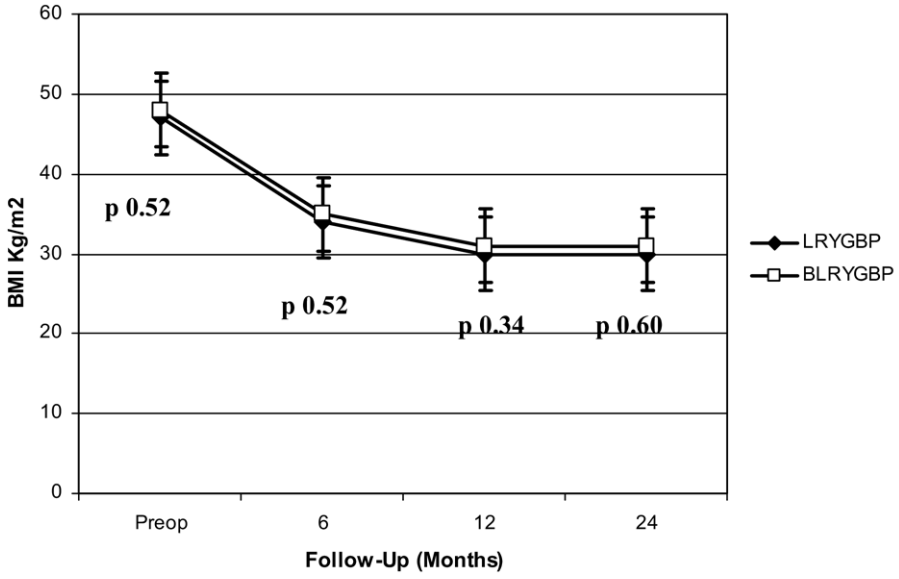

Fig. 1. Comparative changes in body mass index (BMI) after surgery in patients undergoing LRYGB and BLRYGB.

No statistically significant differences were found in the maximal excess weight lost and the body mass index between the 2 groups (Figs. 1 and 2).

Discussion

Weight loss after RYGB has had wide variations in different series. Analyzing some of the most representative meta-analysis and systematic reviews published in recent years, the percentage of excess body weight loss at 2 years has been close to 70% [16,17]. However, the range has been 33–77% [16]. Many potential causes exist for this variation. The inclusion of a multidisciplinary team approach in the bariatric surgery programs has improved weight loss and patient adherence. Also, the ethnic and cultural characteristics of the patients might have played a role, and the technical details of the operation would also have affected the results.

At least 5 physiologic mechanisms are involved in weight loss after RYGB. The exclusion of most of a part of the stomach has been associated with low levels of ghrelin, leading to a significant reduction in appetite [18,19]. Direct communication of the small gastric pouch to the jejunum induces the dumping syndrome, which limits the intake of

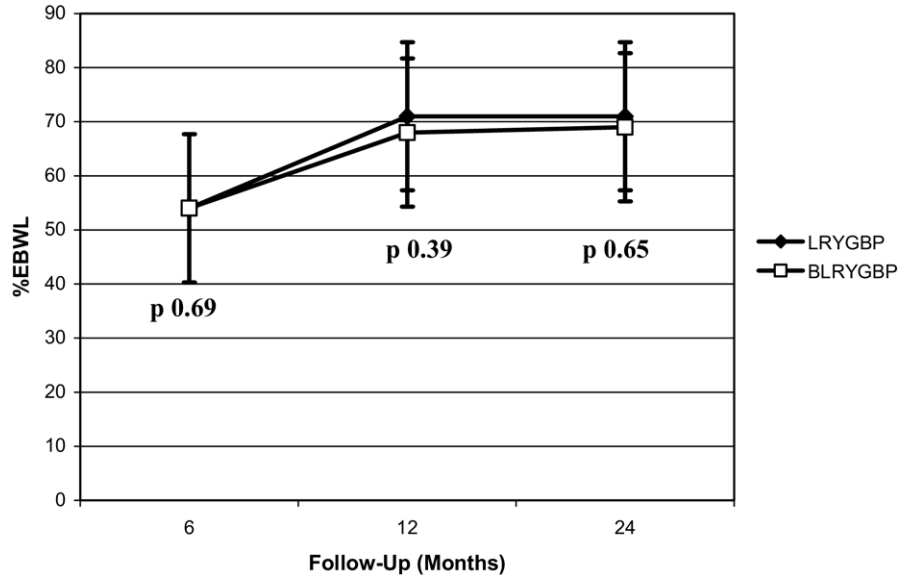

Fig. 2. Comparative percentage of excess body weight loss (%EBWL) after surgery in patients undergoing LRYGB and BLRYGB.

carbohydrates [7]. A small gastric pouch produces early satiation, and the small opening between the gastric reservoir and the jejunum prolongs satiety [20]. In the absence of absorption in most of the biliopancreatic and alimentary limbs, the total absorptive capacity of the small bowel is reduced [21]. The net effect of each mechanism on weight loss has not been determined, and the affect of technical variations on the physiology of the operation is still unclear. Small changes in limb length for instance have not shown significant differences in weight loss [22]. Considering the pattern of ghrelin secretion in the stomach, the ghrelin response after surgery might be related to the size and shape of the gastric reservoir.

Weight regain years after surgery has clearly been associated with increased food intake over time. Flanagan [23] performed a study in which cottage cheese was given to patients at 1 month and 1 and 2 years after RYGB. They found a significant increase in cottage cheese tolerance with the increased time postoperatively, from 2.5 oz to 9 oz, on average [23]. A tolerance to larger amounts of food can be explained by 3 different anatomic changes. One is gastric pouch enlargement. Changes in pouch size have been evaluated by some investigators. A study measuring pouch size after bariatric surgery showed a statistically significant negative correlation between pouch size and the percentage of excess body weight loss at 6 and 12 months after surgery [24]. They also found that the initial gastric pouch size was a significant factor for successful weight loss, because the weight loss was significantly greater for patients with smaller pouches. A second potential mechanism is enlargement of the anastomosis. It has been suggested that the size of the anastomosis controls the rate of pouch emptying [7]. The absorptive capability of the small bowel also increases with time. This has been observed in patients with the short bowel syndrome in which the intestine adapts, modifying morphologically and functionally the brush border membrane to increase nutrient absorption [25].

With the aim of enhancing weight loss and preventing more rapid emptying of the gastric pouch as a consequence of anastomosis enlargement, Fobi et al. [7] and Capella and Capella [26], among others, have recommended placement of a silastic ring or mesh around the lower aspect of the pouch. In addition to preventing rapid transit of food through an enlarged anastomosis, it has the potential advantage of allowing the construction of a wider anastomosis that might be easier to perform and could have an important effect in reducing the number of anastomotic leaks. Using this technique, Fobi et al. [7] and Capella and Capella [26] reported a 62% and 84% excess body weight loss, respectively, at 4 years. The use of BLRYGB has gained acceptance in some countries of South America and in Spain. However, studies assessing this technique are scarce. The reasons some surgeons refuse to add a band to the procedure include the fear of placing foreign material in contact with the stomach because it could produce erosion [27].

For our pilot study, we decided to use a 6.5-cm Marlex mesh, as previously reported by Cruz-Vigo et al. [15]. The rational for this size was to achieve some gastric restriction and avoid erosion and solid food intolerance. In the analysis of our results, we found a similar number of complications in both groups. One patient developed gastric stenosis at the level of the Marlex mesh (3%). In the study of 944 patients reported by Fobi et al. [7], anastomotic obstruction due to band migration or a stenosed outlet was documented in 32 patients. Of these, 59% required band removal in a revision procedure. The high rate of leaks in our study was probably just a coincidence, because our leak rate was close to 1%, as we have previously reported [28].

Although vomiting can develop after RYGB, its occurrence is rather uncommon. Most cases of persistent vomiting are caused by stenosis of the pouch outlet [6]. Dilation is usually successful, except in patients with prosthetic stomal reinforcement, which will require surgical removal. The incidence of vomiting in our study was slightly greater in the BLRYGB group, and it resolved spontaneously in all but 1 patient in whom it was directly related to stenosis. Behavior modification and training have an important role in preventing/controlling emesis in most patients.

In our study, the weight loss pattern in both groups was similar at 6, 12, and 24 months after surgery. The proper assessment of weight maintenance and late weight regain will necessarily require longer follow-up.

We realize that different lengths of the rings or band and perhaps different sizes of the gastrojejunostomy in the banded procedures could give different results. Standardization of the procedures will then be important.

Disclosures

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

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