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Long-term Outcomes of Laparoscopic Adjustable Gastric Banding

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Objective: To determine the long-term efficacy and safety of laparoscopic adjustable gastric banding (LAGB) for morbid obesity.

Design: Clinical assessment in the surgeon's office in 2009 (≥12 years after LAGB).

Setting: University obesity center in Brussels, Belgium.

Patients: A total of 151 consecutive patients who had benefited from LAGB between January 1, 1994, and December 31, 1997, were contacted for evaluation.

Intervention: Laparoscopic adjustable gastric banding.

Main Outcome Measures: Mortality rate, number of major and minor complications, number of corrective operations, number of patients who experienced weight loss, evolution of comorbidities, patient satisfaction, and quality of life were evaluated.

Results: The median age of patients was 50 years (range, 28-73 years). The operative mortality rate was zero. Overall, the rate of follow-up was 54.3% (82 of 151 patients). The long-term mortality rate from unrelated causes was 3.7%. Twenty-two percent of patients experienced minor complications, and 39% experienced major complications (28% experienced band erosion). Seventeen percent of patients had their procedure switched to laparoscopic Roux-en-Y gastric bypass. Overall, the (intention-to-treat) mean (SD) excess weight loss was 42.8% (33.92%) (range, 24%-143%). Thirty-six patients (51.4%) still had their band, and their mean excess weight loss was 48% (range, 38%-58%). Overall, the satisfaction index was good for 60.3% of patients. The quality-of-life score (using the Bariatric Analysis and Reporting Outcome System) was neutral.

Conclusion: Based on a follow-up of 54.3% of patients, LAGB appears to result in a mean excess weight loss of 42.8% after 12 years or longer. Of 78 patients, 47 (60.3%) were satisfied, and the quality-of-life index was neutral. However, because nearly 1 out of 3 patients experienced band erosion, and nearly 50% of the patients required removal of their bands (contributing to a reoperation rate of 60%), LAGB appears to result in relatively poor long-term outcomes.

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THERE IS SUBSTANTIAL EVIDENCE that surgery is the only valid treatment for morbid obesity.[1,2] In recent years, several techniques, many of them laparoscopic, have emerged. Presently, the most commonly performed techniques are laparoscopic adjustable gastric banding (LAGB) and Roux-en-Y gastric bypass, which is also typically performed laparoscopically.[3-6]

See Invited Critique at end of article

Our team performed the first laparoscopic adjustable band gastroplasty in October 1992.[7] Use of this technique has since grown exponentially, first in Europe and Australia,[8-10] and subsequently in other parts of the world, including the United States. In Europe, since 2004, we have observed an important shift in treatment away from LAGB and in favor of the gastric bypass.[11]

In contrast, in the United States, an opposite trend has been noted, and in 2009, a greater number of adjustable band procedures were reported compared with gastric bypass procedures. Opponents of the adjustable band claim that this technique can result in a mediocre quality of life and a significant number of complications, and that there is a tendency for patients to regain weight after some years.[12,13] The purpose of our study is to analyze the long-

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term (≥12 years) effects of LAGB on patients in terms of weight loss, complications, reoperations, satisfaction, quality of life, as well as evolution of comorbidities and receipt of additional related treatments.

METHODS

STUDY DESIGN AND PATIENTS

Between January 1, 1994, and December 31, 1997, our team treated 151 consecutive patients for morbid obesity by laparoscopic placement of a 9.75-cm adjustable band (Lap-Band; BioEnterics Corp, Carpinteria, California). The decision to engage in bariatric surgery was made in accordance with the National Institutes of Health guidelines.[14] Part of this patient cohort was included in the LAGB prelaunch study by the US Food and Drug Administration.[15] Data were gathered from hospital medical records, postoperative office visit findings, responses to a questionnaire that had been sent to every patient, telephone interviews, and in-office evaluations performed by the authors a few weeks before writing this study.

PROCEDURES AND MEASUREMENTS

The laparoscopic adjustable band procedure was performed with the so-called perigastric technique. This technique has been extensively described by us and by others.[16,17] In brief, the patient was explored laparoscopically by means of 5 trocars. Using hook coagulation, we entered the plane between the first vessel and the gastric wall at the lesser curvature of the stomach's upper pole. With smooth dissection, a tunnel was developed posterior to the stomach by advancing a pair of blunt grasping forceps until the tip of the grasper emerged at the angle of His. Care was taken not to enter the lesser sac. Once the grasper tip had been freed at the angle of His, an adjustable band was introduced intraperitoneally after enlarging the left upper quadrant trocar opening. The band tubing was snapped by the grasper tip at the angle of His, and the band was looped around the upper part of the stomach, tightened, and locked. The band was stabilized by 4 seroserosal stitches of nonresorbable suture material on each part of the band, which was placed to the left of the locking system. The tubing was exteriorized and fixed to the port, which was sutured in place on the anterior abdominal fascia at the level of the enlarged trocar opening in the left upper quadrant. The band was left deflated for 4 weeks and subsequently gradually inflated under radioscopic control in the radiology suite, over the course of about 4 sessions. Restriction was judged to be sufficient when the patient experienced early satiety while there was still sufficient passage of dye, as evidenced upon barium swallow. After optimal filling, the patients were seen in the surgeon's office every 3 to 6 months the first year and every 6 months thereafter. Variable outcome measurements included weight loss, the type and number of possible complications, treatment mode, number of reoperations, a satisfaction index (very dissatisfied, somewhat dissatisfied, neutral, pleased, or very pleased), and a quality-of-life score (based on the Bariatric Analysis and Reporting Outcome System).[18] With the latter evaluation system, a score of up to 5 is given in 5 distinct categories: self-esteem, physical well-being, social life, capacity to work, and sexual health. Points were subtracted for complications and reoperations.

Among the long-term complications reported, incisional hernia, port infection, and tubing disconnection were considered minor complications, whereas pouch dilatation, band slippage, band erosion, band intolerance, and infection of the band leading to removal were considered major complications. Band intolerance was defined as complete food intolerance, possibly with esophageal dilation but without objective dilation (from radiography) of the stomach proximal to the band during upper gastrointestinal transit. Pouch dilatation and band slippage were defined similarly, but with radiograph-documented dilation of the stomach proximal to the band.

The data on weight loss included the values documented in the patients' medical records, the values obtained by analysis of the questionnaire, and the values recorded at the final physical examination. In addition, at that time, patients were asked to give an estimate of their yearly weight loss values. The change in weight between 2 recorded values was considered to be linear.

A diagnosis of band erosion was determined by the intraluminal appearance of at least part of the band at gastroscopy. Gastroscopy was systematically performed for all patients experiencing discomfort or pain and/or weight gain, or if the fluid inside the band appeared turbid when the band was adjusted. The evolution of comorbidities was evaluated by changes in treatment modalities, including antidiabetic oral agents, antihypertensive drugs, and continuous positive airway pressure.

STATISTICAL ANALYSIS

The McNemar test for paired variables was used for the statistical analysis of treatment evolution. The *t* test for paired variables was used for analysis of the evolution of weight, body mass index (BMI; calculated as weight in kilograms divided by height in meters squared), and excess weight loss (EWL). Results are represented as mean values, standard deviation, and range or as median values with ranges. Statistical significance was reached at $P < .05$.

RESULTS

Of the 151 patients who had benefited from LAGB between January 1, 1994, and December 31, 1997, 82 (54.3%) were available for full evaluation as a result of a written or telephone reply to the questionnaire and/or an examination in the office by one of the surgeons at the end of 2009. There were 8 men and 74 women, with a mean (SD) age of 50 (0.95) years (range, 28-73 years). The mean (SD) preoperative weight was 113.57 (18.17) kg (range, 86-180 kg), and the mean (SD) BMI was 41.57 (2.9) (range, 35-57). The operative mortality rate was zero. The median postoperative follow-up period was 13 years.[11-14] Three patients (3.7%) died of causes unrelated to the LAGB: one died of melanoma, one died of lung cancer, and one committed suicide for financial reasons. Forty-eight patients (58.5%) had minor and/or major complications.

MINOR COMPLICATIONS

Of the 82 patients, 18 (22.0%) had a total of 29 minor complications: 4 (4.9%) presented with an incisional hernia, 16 (19.5%) experienced 23 port-tubing disconnections, and 2 (2.4%) developed isolated port infection.

MAJOR COMPLICATIONS

Of the 82 patients, 32 (39.0%) had a total of 33 major complications: 9 (11.0%) had pouch dilatation, 6 of whom had their bands removed and 3 of whom had their bands

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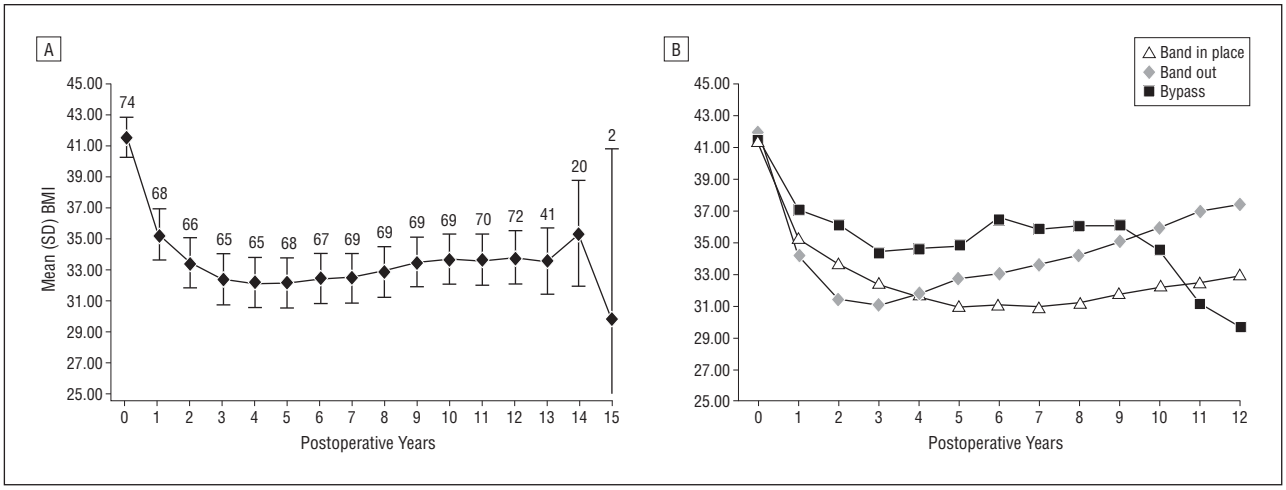

Figure 1. A, Evolution of the mean (SD) body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) for the entire (intention-to-treat) patient population per year after laparoscopic adjustable gastric banding. The number above each error bar represents the number of patients. B, Evolution of the mean (SD) BMI per year after laparoscopic adjustable gastric banding for patients who still have their band (band in place), for patients who lost their band without any further measures (band out), and for patients whose band was removed and for whom a gastric bypass was performed (bypass).

repositioned. Twenty-three patients (28.0%) presented with band erosion, which was diagnosed after a mean (SD) time of 4 (2.9) years (range, 1-11 years). Of these 23 patients, 17 had their bands removed, 2 had their bands repositioned, 2 were switched to laparoscopic Roux-en-y gastric bypass (LRYGB), and 2 declined treatment. One patient (1.2%) developed a band infection.

REOPERATIONS

Of the 82 patients, 49 (59.8%) underwent at least 1 reoperation, either for 1 or more complications or for weight issues (ie, a lack of weight loss or a regaining of weight). One patient (1.2%) was treated surgically for incisional hernia, 10 patients (12.2%) needed a total of 13 port-tubing reconnections, 2 patients (2.4%) required port removal, and 1 patient (1.2%) had her port replaced. Twelve patients (14.6%) required band repositioning; the mean (SD) elapsed time between placement and repositioning of the band was 3.6 (3.18) years (range, 2 months to 6 years). Forty-one patients (50.0%) needed band ablation for varying reasons: 17 (20.7%) for band erosion, 5 (6.1%) for pouch dilatation, 2 (2.4%) for erosion together with pouch dilatation, 1 (1.2%) for perforated bulbar ulcer, and 1 (1.2%) for band infection early in the postoperative course; for 5 patients (6.1%), the reason for band removal was unclear, and for 10 patients, the reason was weight gain. Fourteen of the 82 patients (17.1%) were switched to LRYGB: 10 for weight issues and 4 for band erosion. Band removal and the switch to LRYGB were performed in 1 stage for 11 patients and in 2 stages for 3 patients. The median elapsed time between placement and removal of the band was 9 years.[6-12,19] Of the 14 patients who switched to LRYGB, all were available for follow-up, and the median duration of follow-up was 5 years (range, 1-7 years). One (7.1%) of these 14 patients needed yet another laparoscopic reoperation with reconstruction of the gastrojejunal anastomosis for stenosis, which had persisted despite 2 balloon dilatations.

WEIGHT LOSS

The evolution of the BMI of patients and the evolution of the EWL of patients are represented in **Figure 1**A and B and **Figure 2**A and B, respectively. Complete weight loss data after 12 years (as recorded in the surgeon's office) are available for 70 of 151 patients (46.4%). Mean (SD) weight decreased from 113.57 (18.17) kg (range, 86-180 kg) to 92.82 (23.20) kg (range, 37-165 kg); mean (SD) BMI decreased from 41.57 (5.67) (range, 35-57) to 33.79 (7.52) (range, 16-53) (Figure 1). The mean (SD) percentage of EWL in this group of 70 patients was 42.8% (33.92%) (range, 24%-143%) (Figure 2). These latter numbers represent 22 patients who had their band removed without further surgical measures and who experienced EWL of 23%, 12 patients who had an LRYGB after band removal and experienced EWL of 64%, and 36 patients who still had their band in place and who experienced EWL of 48%.

SATISFACTION INDEX AND QUALITY OF LIFE AFTER 12 YEARS

Of 78 patients, 47 (60.3%) were either pleased or very pleased with their LAGB, 11 (14.1%) were neutral, and 20 (25.6%) were either dissatisfied or very dissatisfied.

EVOLUTION OF COMORBIDITIES

Of 78 patients, 20 (25.6%) were treated for arterial hypertension before band insertion, and 23 (29.5%) were treated for arterial hypertension 12 years after their LAGB ($P=.72$). Of 78 patients, 5 (6.4%) had type 2 diabetes mellitus before band insertion, and 11 had type 2 diabetes 12 years after their LAGB. Of 78 patients, 2 (2.6%) needed continuous positive airway pressure for sleep apnea before gastroplasty, and 6 (7.7%) needed continuous positive airway pressure for sleep apnea 12 years after gastroplasty.

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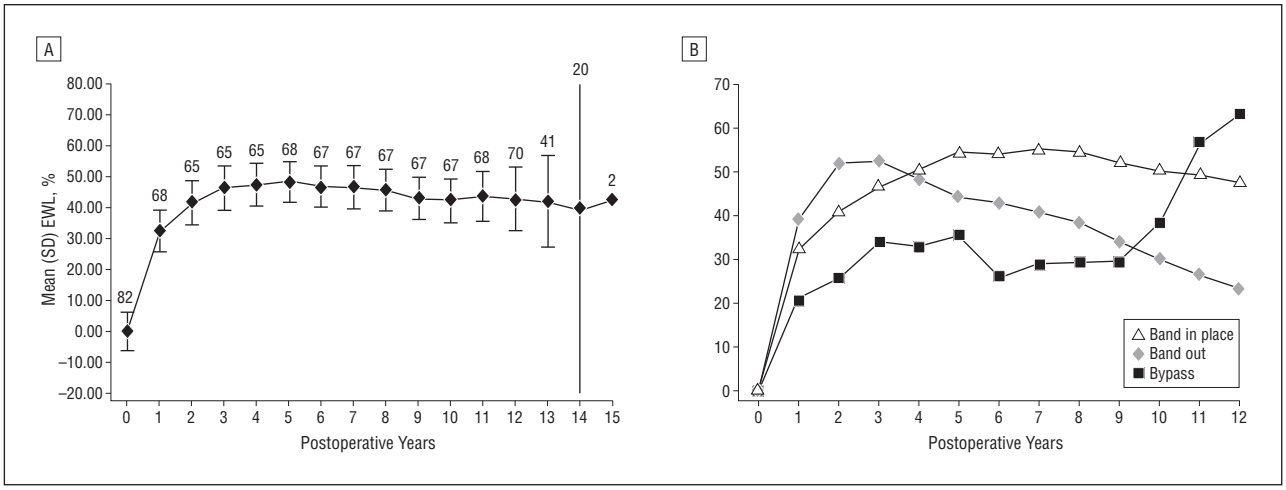

Figure 2. A, Evolution of the mean (SD) percentage of excess weight loss (EWL) for the entire patient population per year after laparoscopic adjustable gastric banding. Note that, for 2 patients, some confusion exists as to their correct initial weight. Therefore, these patients were omitted in the EWL graph, but they were included in the BMI graphs because their present weight is obviously known. The number above each error bar represents the number of patients. B, Evolution of the mean (SD) percentage of EWL per year after laparoscopic adjustable gastric banding for patients who still have their band (band in place), for patients who lost their band without any further measures (band out), and for patients whose band was removed and for whom a gastric bypass was performed (bypass).

COMMENT

All 151 patients from the cohort were contacted by certified letter and by telephone. Only 82 responded. This low response rate after 12 years is rather deceiving and could be attributed to a general lack of compliance among this particular patient population. However, it could just as easily be caused by the suboptimal administrative organization in our department, in particular, and in the Belgian health care system, both of which appear to be less effective than the Australian system, for instance, for which extremely high follow-up rates are reported.[20] Follow-up assiduity is a critical factor for success in bariatric procedures, in general, and in LAGB, in particular.[21] In addition, LAGB patients lost to follow-up are likely to experience very little weight loss.[22] Our results must be viewed from this perspective.

Another limitation of our study concerns the surgical technique. Indeed, there is some evidence to suggest that the more recent "pars flaccida" technique and the use of wider, softer bands provide better overall results than the "perigastric" technique that we used at the time, especially concerning the erosion rate and the incidences of band slippage and pouch dilatation.[23]

Last but not least, one could object that our results reflect a learning curve among surgeons. However, as mentioned earlier, our department started performing LAGB more than 14 months before the time of the onset of this study and had performed some 50 LAGB procedures at that time. It is generally accepted that the learning curve for an advanced laparoscopic procedure affects some 35 cases.[24]

Despite the aforementioned criticizable aspects of our study, we still think that our results elucidate the long-term outcomes of LAGB. To our knowledge, this is the first study on the outcomes of this procedure after more than 10 years. Our response rate and results actually match those of earlier studies available in the literature.[25-27] Moreover, because the perigastric technique has been used by a great number of surgical teams in a substantial number of patients everywhere in the world, the outcome concerns several thousands of patients. Furthermore, other prolific authors[28] were not able to detect a significant difference in the (excellent) results between the perigastric and pars flaccida techniques and are therefore still performing the former.

In our study, 48 patients had complications; however, only 14 of these patients experienced port-tubing disconnection, a minor complication that has become much less frequent with use of the newer band systems.[29]

Of 82 patients available for follow-up, 9 (10.9%) experienced pouch dilatation. In the literature, long-term results range from 4.5% to 21% of patients experiencing pouch dilatation.[25-27,30,31] Although the perigastric technique might again be a contributing factor, it is noteworthy that many dilatations appeared quite late (mean time, 3.6 years; median time, 2 years) after insertion, which seems to imply other factors. Other possible causes are overinflation of the band[32] or lack of compliance on the patient's part,[33] but the natural evolution of a hollow viscus proximal to a stenotic factor cannot be ruled out either.[34]

Twenty-three patients (28.0%) experienced band erosion, which was diagnosed after a median of 4 years. Theoretically, it is not surprising that a rigid structure placed around a hollow organ would erode in the lumen of the latter, as experienced earlier with the Angelchik prosthesis.[35] Nevertheless, our numbers are significantly higher than those in the literature.[25-27,30,31] The culprit here again could be the perigastric technique, with which substantially less tissue is left between the prosthesis and the stomach wall than is left when the pars flaccida technique is used. In contrast, the higher incidence that we found might at least partly be explained by our policy of performing gastroscopy systematically in all patients presenting with weight regain at some point after gastroplasty, even in the absence of other symptoms. This policy

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Table. Data on Excess Weight Loss, Dilatation, and Erosion in Patients Who Underwent Laparoscopic Adjustable Gastric Banding

Study	Patients, No.	Follow-up Period, Median, y	Patients, %		
			Erosion	Dilatation	EWL
Tolonen et al,[25] 2008	123	7	3.3	6.5	44
Martikainen et al,[26] 2004	123	5	9	21	21-36
Weiner et al,[30] 2003	100	8	0.3	4.5	54
Suter et al,[27] 2006	317	6	9.5	6.3	59 (at 5 y)
Belachew et al,[31] 2002	763	4	0.9	8	50-60
Our study	82	13	29.3	10.9	42

Abbreviation: EWL, excess weight loss.

might differ from others with a higher threshold for performing endoscopy and consequently a lower detection rate for silent erosion (**Table**).

Close to 50% of the patients lost their band within about 9 years. A substantial number of these patients benefited from LRYGB later on. The morbidity rate due to this switch to LRYGB was relatively low (7%), and the percentage of EWL was 64%, which compares favorably with the 48% observed when the band was still in place. This demonstrates the efficiency of the gastric bypass in patients who failed to achieve weight loss after receiving the gastric band.

Global excess weight loss was less than 50%. This relatively low figure might explain the lack of efficacy of the procedure in curing comorbidities among our patients. However, the evolution of these comorbidities must be weighed against their natural evolution during a similar time frame in a nonsurgical population.

Of 78 patients, 47 (60.3%) were pleased or very pleased (ie, the satisfaction index) with their LAGB, which is somewhat surprising considering the high number of reoperations and the relatively modest weight loss. The objective final quality-of-life score was 3, which corresponds to that observed in a normal, nonsurgical population. This can be considered a good result because points had been subtracted for complications and reoperations, which were frequent. Both these indices confirm and explain the fact that the public has not rejected the "lap-band" procedure, unlike many of the surgeons in Europe.

To conclude, based on an intention-to-treat evaluation, but with a follow-up of only approximately half of the patients, laparoscopic placement of a 9.75-cm adjustable band (ie, LAGB) appears to induce an excess weight loss of 42.8% after 12 years. Still, 60.3% of the patients were satisfied, and the quality-of-life index was comparable to the nonsurgical average. However, almost 1 out of 3 patients experienced band erosion, and close to 50% of the patients required removal of their band. The reoperation rate was 59.8%, and there was no beneficial influence on comorbidities. Fourteen of 82 patients (17.1%) were switched to laparoscopic gastric bypass, with good results. The high failure rate of LAGB, at least in our hands, could be detrimental to its future continued widespread use as a restrictive weight loss operation.

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To Band or to Bypass, That Is the Question

Himpens et al present a series of 151 patients who underwent laparoscopic adjustable gastric banding (LAGB). Of these 151 patients, 82 (54.3%) were followed up for 12 years or longer. Of these 82 patients, 23 (28.0%) experienced band erosion, which was diagnosed at a mean time of 4 years, and 41 (50.0%) had their band removed. Those who still had the band in place lost 48% of their excess weight, whereas those who had their band removed (because they did not lose weight) lost only 22% of their excess weight. The number and type of comorbidities (eg, diabetes, hypertension, and sleep apnea) in this group of patients increased over time.

These data do not shed a favorable light on the use of LAGB. Some of the data regarding band erosion and slippage or pouch dilatation may be related to the technique of band insertion (perigastric vs pars flaccida); the incidence of band erosion and slippage is significantly less with the pars flaccida technique than with the perigastric technique.[1] Although many authors report good results in terms of weight loss and subsequent complications, there are others who report excessive long-term complication rates or inadequate weight loss.[2-4] Therefore, the results of LAGB are somewhat inconsistent. Presently, LAGB and laparoscopic Roux-en-Y gastric bypass (LRYGB) are the most frequently used bariatric procedures in the United States. A meta-analysis of studies comparing LAGB with LRYGB demonstrated that LAGB is an easier operation that is associated with a shorter length of hospital stay and a lower operative morbidity. However, the number of subsequent operations for complications is greater in patients who underwent LAGB than in patients who underwent LRYGB, and the incidences of weight loss and resolution of obesity-related comorbidities are fewer in patients who underwent LAGB than in patients who underwent LRYGB.[5,6]

The data in this study, as well as the experience in our own institutions, should influence our choice of procedure (LAGB vs LRYGB) and the manner in which we inform our patients of the advantages and disadvantages of each procedure.

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