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SURGICAL ENDOSCOPY
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Laparoscopic adjustable silicone gastric banding for morbid obesity

Results and complications in 715 patients

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Abstract
Background: Laparoscopic adjustable silicone gastric banding (LASGB) was used as the initial bariatric procedure for more than 36 months. The efficacy and safety of LASGB were studied.
Methods: Patients were followed up prospectively in a multidisciplinary center for the perioperative and long-term courses, and for complications.
Results: Between November 1996 and May 1999, 715 patients underwent surgery. The mean age was 34.6 years (range, 16–72) years, and the mean body mass index (BMI) was 43.1 kg/m^2 (range, 35–66 kg/m^2). The mean operative time was 78 min (range, 36–165 min), and the postoperative hospitalization time was 1.2 days (range, 1–8 days). There were six intraoperative complications (0.8%), eight early postoperative complications (1.1%), and no deaths. For follow-up evaluation, 614 patients (86%) were available. Late complications included band slippage or pouch dilation in 53 patients (7.4%), band erosion in 3 patients, and port complications in 18 patients. In 57(7.9%) patients, 69 major reoperations were performed. In patients with a follow-up period longer than 24 months, the average BMI dropped from 43.3 kg/m^2 (range, 35–66 kg/m^2) to 32.1 kg/m^2 (range, 21–45 kg/m^2).
Conclusion: Laparoscopic adjustable silicone gastric banding is safe, with a lower complication rate than any other bariatric procedure. Most reoperations can be performed laparoscopically with low morbidity and short hospitalizations. On the basis of intermediate-term follow-up evaluation, it is an effective procedure for weight-reducing purposes.

Key words: Laparoscopy — Morbid obesity — Gastric banding

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Surgical procedures for the treatment of morbid obesity fall into one of two categories: bypass and restrictive procedures (or a combination of both). The restrictive procedures usually are simple, short operations with a low complication rate [8] These procedures have been performed in large patient groups with good results [3, 8]. The criticism of these procedures is based on several facts. First, the procedures, whether based on a foreign body such as a silastic ring, an adjustable silicone band or a staple line, require some patient cooperation for the creation of a functional partition of the stomach. Unrestricted diet, forced feeding, and frequent vomiting tend to enlarge the proximal stomach or damage the restrictive device, rendering the procedure nonfunctional. Second, restrictive procedures only are effective in reducing the volume of solid food consumed by the patient. Liquid and semisolid, high-calorie foods enable some patients to maintain the excessive weight, making these procedures ineffective for the treatment of sweet-eaters who are morbidly obese.

Bypass procedures are aimed essentially at creating a controlled malabsorption. Several procedures technically produce some degree of malabsorption by reducing the contact of digested food with the small bowel, pancreatic and billiary secretions, or both [5]. These procedures, theoretically, enable the patient to continue eating an unrestricted diet and still lose weight. However, these procedures have several drawbacks. They are extensive, and were shown in some studies to have a substantial rate of morbidity and even mortality [9]. The formation of fundamental changes in the structure of the gastrointestinal tract is required. Some of these changes are difficult or impossible to reverse. In addition, the degree of malabsorption is difficult to predict, and in some patients, the result is an undesirable degree of malabsorption necessitating reoperations and modifications to the original procedure.

The first readily available laparoscopic bariatric procedure was introduced in 1993 [2]. After the introduction of laparoscopic adjustable silicone gastric banding (LASGB) and a short pilot study, we decided to implement it as the procedure of choice for weight-reducing purposes in our

practice. We found it very appealing that the procedure is relatively simple, may be performed laparoscopically, and is completely reversible. We also thought the possibility of modifying the stoma size during the follow-up period and tailoring it to meet the changing needs of the patient is a theoretical advantage.

Since November 1996, we have performed LASGB as the initial procedure for all patients undergoing surgery for morbid obesity, and for reoperative surgery in failed open restrictive procedures. The operative technique is standardized [1]. It is a modification of the original technique described by Belachew [2] using the LapBand system (Bio-Enterics, Carpenteria, California, USA). The data for all the patients who undergo surgery, including preoperative evaluation, operative and immediate postoperative course, and long-term ambulatory follow-up evaluation, all are registered in a central database in a multidisciplinary ambulatory service, the Obesity Center.

Patients and methods

Between November 1996 and May 1999, surgery was performed on 715 patients. All referred patients were scheduled for LASGB, without exclusion. There were 545 women (76.2%) and 170 men (23.8%). The mean age was 38.1 years (range, 15–72 years), and the mean body mass index (BMI) was 43.7 kg/m^2 (range, 35–66 kg/m^2). All the patients underwent extensive evaluation before referral to surgery according to the National Institutes of Health (NIH) consensus and guidelines [6]. Patients underwent surgery on the day of admission. The operative technique has been standardized [1]. It is a modification of the original technique described by Belachew [2]. Patients are allowed to drink 6 to 12 h after surgery. They are discharged when they can tolerate fluids by mouth and their pain is well controlled. An attempt is made to follow all patients actively in the outpatient clinic (Obesity Center). In addition, information is obtained using telephone interviews.

Results

The laparoscopic procedure was completed in all but six patients (99.2%). Conversions were necessitated by a posterior gastric injury, a splenic injury, and a very large left liver lobe in one patient each, and by inadequate instruments that did not allow good exposure in three patients.

There were six (0.8%) intraoperative complications: bleeding in four patients, a pneumothorax in one patient, and a stomach injury in one patient. Additional procedures were performed in 33 patients (4.7%): cholecystectomy in 21 patients, hiatal hernia repair in 10 patients, and umbilical hernia repair in 2 patients. The mean operative time was 78 min (range, 36–165 min).

Six patients (0.84%) underwent reoperation during the first 3 postoperative days: one for a bleeding trocar site, and five, all during the first 50 operations, for band repositioning because of band malposition and outlet obstruction. All early repositioning procedures were performed through a laparotomy. The average hospital stay was 1.2 days (range, 0–8 days). There were no early or late postoperative deaths.

Of the patients who underwent surgery, 614 (86%) were available for follow-up assessment. Over a mean follow-up period of 17 months (range, 1–36 months), there were seven (1%) major and 12 (1.6%) minor complications (Table 1).

Band dislodgment or pouch dilation occurred in 53 patients (7.4%). All these patients had radiographic studies to prove band dislodgment, and all underwent laparoscopic surgery for band repositioning or band removal. The reasons for band removal were patient request or patient refusal of regular follow-up evaluation in 20 patients, band erosion in 3 patients, and previous band repositioning in 9 patients. Altogether, 69 major procedures were performed in 57 patients (Table 2). In addition, 18 procedures were performed on the ports, most with the patient under local anesthesia. The data for 181 patients with a follow-up period longer than 2 years were studied to obtain long-term follow-up information. A total of 121 patients (66.8%) were available for a mean follow-up period of 30 months (range, 24–36 months). The BMI for these patients dropped from 43.3 to 32.1. The BMI pattern of these patients is presented in Fig. 1.

Table 1. Postoperative complications after laparoscopic adjustable silicone gastric banding in 715 patients

Complication	*n*
Major	
Subphrenic abscess	2
Infected splenic hematoma	1
Trocar-site hernia	1
Band erosion	3
Total	**7 (1%)**
Minor	
Wound infection	3
Painful port site	9
Total	12 (1.7%)

Discussion

Our results, as previously reported [1], demonstrate that LASGB is a safe and effective procedure. The early and late complication rates are lower than those reported for other bariatric procedures [3, 4], and on an intermediate-term follow-up assessment, there is a sustained, acceptable weight loss.

It is true that the weight loss data is somewhat inferior to the results published after bypass procedures. However, the number of patients followed is relatively large, and according to our ambulatory service data, it seems that many of the patients who dropped out of the follow-up evaluation have good results and simply decline what seems to them an unnecessary follow-up visit. Also, the proportion of patients with an intact device (95.5%), as compared with a disruption rate of nearly 30% in other restrictive procedures [8], still shows LASGB to be a good surgical option.

Because LASGB is a relatively new operation, data considering the safety of the device for long-term use are not available. As follow-up periods get longer, new technical problems are encountered. For example, 17 ports had to be replaced because detachment of the tubing resulted from the design of the port. In two patients, we observed a fluid leak from the band, which occurred for the first time more than 2 years after surgery, eliminating the possibility of this phenomenon resulting from injury to the device during the initial operation.

After encountering several cases of band dislodgment and pouch dilation, we modified the initial position of the

Table 2. Reoperations after laparoscopic adjustable silicone gastric banding in 715 patients

	n	Procedure
Early band repositioning	5	Laparotomy
Late band repositioning	31	Laparoscopy
Band extraction	32	Laparoscopy
Bleeding trocar site	1	Laparoscopy
Trocar-site hernia	1	
Major re-operations	**69**	
Port	18	
Total re-operations	**87**	**(12%)**

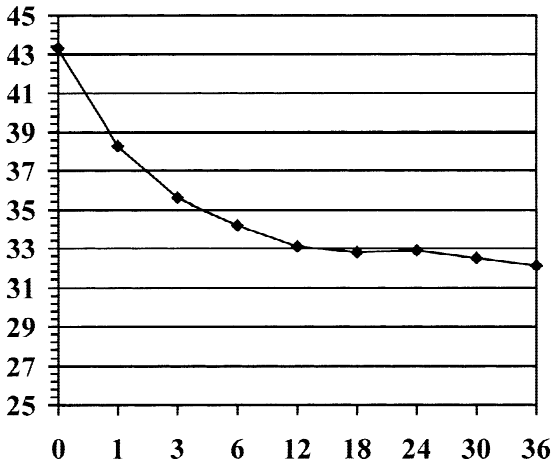

Fig. 1. BMI pattern in 121 patients following LASGB, with a follow up period of over two years. There is a sustained reduction of BMI on follow up of up to 36 months.

band to leave a very small pouch proximal to the band. We believe that leaving no pouch at all (i.e., placing the band virtually on the esophagus), as suggested by some authors [7], serves only as a restrictive device without giving the patient a feeling of satiety produced by the stretching of the stomach wall. In a patient who is morbidly obese, the gastroesophageal junction (GEJ) often is covered by a large fat pad. Considering the anatomic relations between the esophagus and the stomach at the GEJ, a difference of 1 to 2 cm in location is very hard to judge. It seems to us that as long as the principle of keeping a very small pouch is observed, the precise location is of lesser importance.

As demonstrated in our data, the most troublesome complication over a long follow-up period is band dislodgment and pouch dilation. We found that there is a good correlation between the patient's compliance with regular follow-up evaluation and this type of complication. Patients who drop out from follow-up assessment may return to their old eating habits. With the band in place, this results in frequent vomiting, with pressure increases in the upper stomach pouch and continuous pushing of the band. On the basis of this observation, we have established the Obesity Center. This multidisciplinary ambulatory service follows up patients actively. With the involvement of nutritionists, psychologists, endocrinologists, the surgical team, and the coordinating nurse, our service helps patients tailor their diet and medical care to their changing needs.

We found that band repositioning may be performed

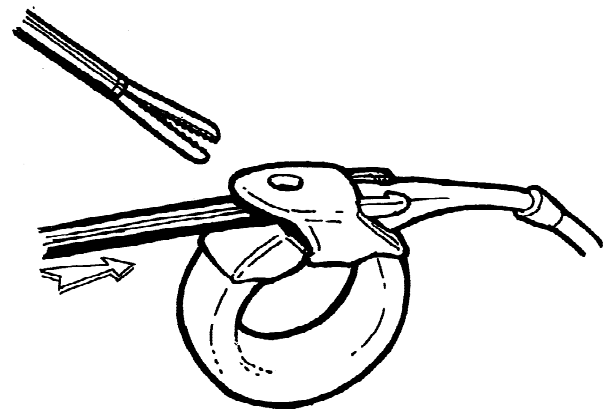

Fig. 2. Laparoscopic technique for opening a LapBand device. A blunt instrument is introduced into the locking mechanism of the band.

laparoscopically in most cases. The procedure is technically demanding, but feasible. We believe are several technical options exist in these operations. The first option recognizes it is not always necessary to open the band. Sometimes it is possible to dissect the band free, dissect the area of the GEJ, and pull the stomach down through the closed band, securing it with multiple sutures. A second option involves opening the band, relocating it after a thorough dissection of the upper stomach, and securing it. The band may be opened by inserting a blunt instrument into the locking mechanism and releasing it (Fig. 2 and 3). However, this maneuver is not recommended by the manufacturer, who claims that the device might be damaged during the maneuver. The third option, used when there are extensive adhesions around the band, is to cut the band, remove it, and place a new band after a new dissection close to the GEJ.

In 32 patients we have elected to remove the band. In three patients, the band was removed after the diagnosis of band erosion. In 29 patients, the band was removed because it seemed that this type of restrictive procedure was inappropriate. When diagnosed with band slippage or pouch dilation, 20 of the patients requested that the band be removed, or were persuaded because of inadequate follow-up evaluation or noncompliance with the diet restrictions that such removal was necessary. In nine patients, the band was removed after a previous relocation operation and repeated band slippage.

Performed correctly, LASGB probably is the safest bariatric procedure. It is, however, far from being the panacea for morbid obesity. The keys to a high success rate and low complications are several. First, patient selection should be carefully performed. In a program with a high rejection rate, it has been shown that the complication and failure rates are lower (personal communication). Conversely, an attempt to admit as many good candidates as possible and a lack of good objective criteria to exclude potential failures makes the selection process very problematic.

Second, both the patient and the treating personnel must understand that the procedure is only a part of the treatment. The nature of LASGB is such that it requires a degree of patient cooperation, including major modifications in lifestyle and eating habits. For a patient who is morbidly obese, this may prove to be a very difficult task requiring professional support.

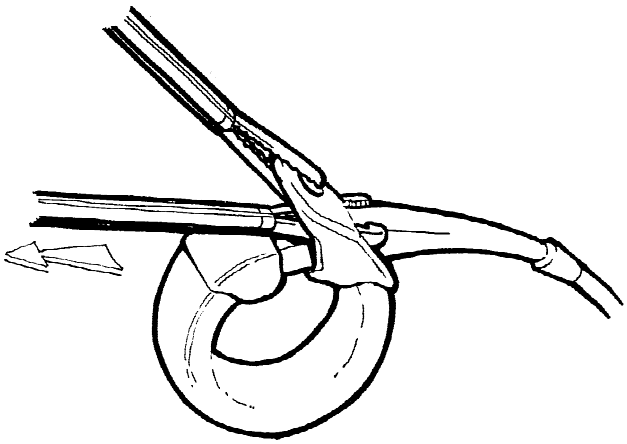

Fig. 3. The locking "shoulders" are grasped and pulled open.

To treat the patients via a more holistic approach, a multidisciplinary center is very useful. It enables the selection and preparation of patients for surgery, provides support shortly after surgery, and deals with problems that arise during the follow-up period. These may involve frequent modifications or cessation of medications for the control of hypertension and diabetes, dietary supplements of essential minerals and vitamins, and psychological and social support for patients with rapid changes in body image. The pathophysiology of obesity and the mechanisms of body–weight homeostasis are only beginning to be elucidated. Because LASGB is a completely reversible procedure, with no structural changes in the anatomy of the gastrointestinal tract, it will be an appealing option when a more physiologic solution is anticipated in the near future.

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