

Laparoscopic Adjustable Gastric Bandings

A Prospective Randomized Study of 400 Operations Performed With 2 Different Devices

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Objective: To evaluate potential differences between 2 devices used to perform laparoscopic adjustable gastric bandings (the Swedish adjustable gastric band and the Lap-Band).

Design: The following groups were considered eligible: (1) patients with a body mass index (calculated as weight in kilograms divided by height in meters squared) of greater than 40; (2) patients with a body mass index between 35 and 40, with associated comorbidities; and (3) patients with a body mass index of greater than 60 who could not undergo derivative procedures.

Results: We recruited 400 patients. The mean \pm SD body mass index decreased to 40.6 ± 3.0 after the first year and to 35.2 ± 7.0 after 2 years. The average excess weight loss reduction was 48.2% after 1 year and 56.0% after 2 years. The excess weight loss reduction was inversely related to the initial weight: patients with an estimated weight excess of 50 kg or less (108 patients [27.0%]) had an excess

weight loss reduction of 55% after 2 years; those with a weight excess of greater than 50 kg (292 patients [73.0%]) had an excess weight loss reduction of 44% ($P = .004$). We recorded 1 death (0.2%). Transient gastric occlusions (24 patients [6.0%]) and slippages (12 patients [3.0%]) were the most common complications. The devices used (Swedish adjustable gastric band and Lap-Band) were similar in terms of correction of obesity and morbidity.

Conclusions: Laparoscopic adjustable gastric banding is a safe and feasible technique with specific indications in moderately obese patients and, secondarily, in highly obese patients who are unfit for more invasive techniques. No differences were found among the devices examined.

Trial Registration: isrctn.org Identifier: ISRCTN22839090

Arch Surg. 2007;142(10):958-961

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MORBID OBESITY HAS been spreading among industrialized countries; its incidence has increased in the United States and worldwide.¹⁻⁴ Gastric restrictive procedures have been valid treatment options for many decades. The least invasive operation—laparoscopic adjustable gastric banding (LAGB)—has been used since 1993 as a minimally invasive alternative to various procedures.⁵ Laparoscopic adjustable gastric banding proved safe, did not require interruption of bowel continuity, and provided satisfactory long-term results in terms of weight loss and correction of associated comorbidities.⁶

There are several types of adjustable gastric bands on the market, with 2 leading systems—the Swedish adjustable gastric band (SAGB) (Obtech, Ethicon Endo-Surgery, Cincinnati, Ohio) and the Lap-Band (Inamed Health, Santa Barbara, California). The Lap-Band is a

13-mm-wide band that, when fastened, forms a circular ring with an inside circumference of 9.75 or 10.00 cm and transitions to a 50-cm-long silicone tube. The band is made of silicone elastomer, chosen for its biocompatibility. The inner surface of the band is inflatable, and the radiopaque kink-resistant tube is used to connect the inflatable section to the access port. An end plug is provided to seal the system while the band is being passed around the stomach. The access port is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the access port needle. The SAGB adheres to the same functional principles as the Lap-Band. It was used for the first time in 1984 in Sweden and was implanted by vertical gastropasty. The band is wider and has a larger fill volume; however, the additional volume should not be filled with more than 8.5 mL of liquid. The stoma diameter ranges from 0 to 30 mm, a wider range than that of a Lap-Band. At

larger fill volumes, it works as a “vacuum system,” thus making the precise adjustment of the stoma diameter somewhat easier.

The aim of this study was to analyze, in a prospective randomized trial of 400 patients, eventual differences with these devices.

METHODS

The following groups were considered eligible for bariatric surgery: (1) patients with a body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) of greater than 40; (2) patients with a BMI between 35 and 40, with associated comorbidities; and (3) patients with a BMI of greater than 60 who could not undergo derivative procedures. Exclusion criteria consisted of a BMI of greater than 60 (fit for derivative procedures), previous surgery on the upper abdomen, and psychic illnesses that could endanger a close postoperative follow-up. Excluded patients were operated on with a Roux-en-Y gastric bypass. All operations were performed by the same team (3 different surgeons [A.A., F.A., and V.C.] experienced with the technique) at Dolan Park Hospital.

PREOPERATIVE DATA

An accurate evaluation of patients was done during preoperative visits, including the attainment of a general history, a physical examination, specific examination of body fat and skin elasticity-redundancy, BMI measurements, and assessment of associated pathological features. Oral anticoagulants were discontinued 7 days before surgery. National Institute for Clinical Excellence guidelines were adopted for preoperative testing.⁷

An extensive pulmonary evaluation was done on patients who had symptoms of sleep apnea syndrome. Those with a positive history for cardiac disease were evaluated with echocardiography. For the greater safety of surgery, a preoperative weight loss of 4 kg was achieved with a diet (10 kg for those with a BMI of >60).

All patients received low-molecular-weight heparin, 4000 U/d, 1 hour before surgery and in the first postoperative day until mobilization was achieved. Furthermore, during surgery, elastic stockings and mechanical calf compression were also used for the prevention of deep venous thrombosis. One dose of cephazoline, 2 g intravenously, or ciprofloxacin, 400 mg, was administered 10 to 30 minutes before the operation for infection prophylaxis. All patients underwent general anesthesia and nasogastric suction.

SURGICAL TECHNIQUE

Patients underwent LAGB. We used the “pars flaccida technique” modification of the old perigastric technique first described by Forsell^{8,9} and Kuzmak^{10,11} and coworkers. Two different types of gastric bandings were used: the Lap-Band and the SAGB.

POSTOPERATIVE CARE

Nasogastric suction was removed after surgery, and patients could drink fluids 2 hours later. Early mobilization occurred 3 hours after the operation, for deep venous thrombosis prevention. A second dose of antibiotic was administered in the early postoperative period. The day after surgery, a barium swallow was performed before discharge. Patients with normal conditions were discharged during the first postoperative day. Elastic bands or garments were maintained for 2 weeks.

Outpatient follow-up visits were planned on the 7th, 14th, 30th, 60th, and 90th postoperative days. After that, visits were planned every 6 months during the first 2 years. The postoperative diet consisted of liquids during the first 2 weeks, with a gradual passage to a regular diet. Patients have their first follow-up visits on the 7th and 14th postoperative days. During these visits, the dietitian recorded clinical data and the nurse helped the patient undress. Gastric banding adjustments began 6 weeks after surgery. Adjustments are usually 2 to 8 per year, when the body weight stabilizes or patients begin to change their nutrition habits. Control of the gastric banding with barium swallow is routinely scheduled 12 weeks after surgery if the patient is asymptomatic; otherwise, it is scheduled when clinically required. The excess weight loss (EWL) was calculated every 6 months after surgery.

Participants were recruited during preoperative outpatient visits after assessment of eligibility. During the visits, 2 surgeons (G.G. and A.A.) explained the experimental nature of the trial, obtained the signed informed consent, and randomly allocated patients to treatments. Randomization was performed using closed envelopes (2 similar closed envelopes were presented to the patient, containing 2 different papers: “Lap-Band” and “SAGB”). Patients were blinded to treatment and to the researcher assessing outcomes (D.D.). After data analysis, group allocation was revealed.

STATISTICAL ANALYSIS

All data analysis was performed using a commercially available software program (SPSS for Windows, version 13.0; SPSS Inc, Chicago, Illinois). Descriptive statistics were mean \pm SD for parametric continuous variables (after confirmation of normal distribution with histograms, Q-Q plots, and the skewness-kurtosis test), median (minimum-maximum) for nonparametric continuous variables (postoperative stay), and frequencies for categorical variables. The *t* test (1-tailed) was used to compare EWL reduction after 1 and 2 postoperative years. The χ^2 test was used to analyze differences among categorical variables (ie, complications). *P* < .05 was considered significant.

RESULTS

We followed Consolidated Standards of Reporting Trials criteria for the development and description of this trial.¹² The study began November 3, 2002, and ended November 27, 2004, with the enrollment of the last patient. Follow-up terminated November 14, 2006. We analyzed 400 patients. Eight patients (2.0%) had a BMI of less than 35 but were operated on to improve associated medical comorbidities, such as severe diabetes mellitus (*n* = 2), hypertension (*n* = 3), asthma (*n* = 1), depression (*n* = 1), and sleep apnea syndrome (*n* = 2) (1 patient had hypertension and sleep apnea syndrome). Furthermore, 6 patients (1.5%) with a BMI of greater than 60 were operated on with the LAGB and not with the gastric bypass or the biliopancreatic diversion for the elevated surgical risk.

There were 354 women (88.5%) and 46 men (11.5%); their mean \pm SD age was 43.6 \pm 10.2 years. Their mean \pm SD weight was 128.7 \pm 25.7 kg, and their mean \pm SD BMI was 46.2 \pm 6.6. The mean \pm SD operative time was 62.7 \pm 27.0 minutes. The Lap-Band and the SAGB were each used on 200 patients. Seven patients (1.8%) had concomitant gallbladder lithiasis and were treated with concomitant laparoscopic cholecystectomy. Thirty-two patients (8.0%)

Table. Demographics, Clinical Characteristics, and Postoperative Complications^a

Variable	All Patients (N=400)	Type of Laparoscopic Gastric Band	
		Lap-Band (n=200)	SAGB (n=200)
Male sex	46 (11.5)	19 (9.5)	27 (13.5)
Age, y ^b	43.6±10.2	41.4±8.1	46.1±12.3
Weight, kg ^b	128.7±5.1	126.4±4.6	135.4±6.4
BMI ^b	46.2±6.6	44.7±5.1	47.7±8.0
<35	8 (2.0)	5 (2.5)	3 (1.5)
35-40	74 (18.5)	41 (20.5)	33 (16.5)
41-50	229 (57.2)	110 (55.0)	119 (59.5)
51-60	83 (20.8)	42 (21.0)	41 (20.5)
>60	6 (1.5)	2 (1.0)	4 (2.0)
Operating time, min ^b	62.7±27.0	58.7±18.0	63.5±32.0
Concomitant colecystectomy	7 (1.8)	2 (1.0)	5 (2.5)
Concomitant Nissen fundoplication	32 (8.0)	19 (9.5)	13 (6.5)
Transient gastric occlusion	24 (6.0)	14 (7.0)	10 (5.0)
Ring slippage	12 (3.0)	8 (4.0)	4 (2.0)
Port defect	6 (1.5)	2 (1.0)	4 (2.0)
Colonic perforation	2 (0.5)	1 (0.5)	1 (0.5)
Pneumonia	1 (0.2)	0	1 (0.5)
Pulmonary embolism	1 (0.2)	0	1 (0.5)
Death	1 (0.2)	1 (0.5)	0
Total	47 (11.8)	25 (12.5)	19 (9.5)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); SAGB, Swedish adjustable gastric band.

^aData are given as number (percentage) of each group unless otherwise indicated. All comparisons were not significant.

^bData are given as mean±SD.

had a hiatal hernia and asymptomatic acid reflux. They underwent a concomitant Nissen fundoplication at LAGB and, of these, 19 (4.8%) were treated with the Lap-Band and 13 (3.2%) with SAGB ($P > .05$).

The median postoperative stay was 1 day (minimum, 1 day; and maximum, 3 days), excluding 2 patients who had complications with colonic perforations (12 and 14 days of recovery) and 1 patient who died on the 15th postoperative day. Complications are listed in the **Table**. There were no gastric erosions, infections, conversions to open surgery, or cases of esophageal achalasia. All ring slippages were anterior and treated laparoscopically by removing and replacing the old band. Transient gastric occlusions resolved spontaneously. Among the 24 patients with a transient gastric occlusion, 4 underwent Lap-Band surgery and fundoplication and 3 underwent SAGB and fundoplication. The incidence of transient gastric occlusion in patients operated on with the Lap-Band and fundoplication was higher than the incidence in those operated on with the Lap-Band alone (4 of 19 patients [21.1%] vs 10 of 181 patients [5.5%]), and the difference was significant ($P = .01$). The incidence of transient gastric occlusion in patients operated on with SAGB and fundoplication was higher than the incidence in those operated on with SAGB alone (3 of 13 patients [23.1%] vs 7 of 187 patients [3.7%]), and the difference was significant ($P = .002$). Among the 12 patients with a ring slippage, 2 underwent Lap-Band surgery and fundoplica-

tion and 1 underwent SAGB and fundoplication. The incidence of ring slippages in patients operated on with the Lap-Band and fundoplication was higher than the incidence in those operated on with the Lap-Band alone (2 of 19 patients [10.5%] vs 6 of 181 patients [3.3%]), but the difference was not significant ($P > .05$). Even the incidence of ring slippages in patients operated on with SAGB and fundoplication was higher than the incidence in those operated on with SAGB alone (1 of 13 patients [7.7%] vs 3 of 184 patients [1.6%]), but the difference was not significant ($P > .05$).

Both intestinal perforations involved the colon and received laparoscopic treatment with bandage removal (because of the increased risk of infections). The first patient had a left colonic perforation, probably because of the trocar insertion. In this case, we formed a temporary stoma in the transverse colon. The second patient experienced a transverse colonic perforation during adhesion removal and was treated with an ileal stoma. Both patients underwent recanalization surgery 3 months later. One patient died of pneumonia that occurred on the 15th postoperative day.

We observed 392 patients (98.0%) for 1 year (192 who underwent Lap-Band surgery and 200 who underwent SAGB) and 355 patients (88.8%) for 2 years (174 who underwent Lap-Band surgery and 181 who underwent SAGB). Follow-up data show that the mean ± SD BMI decreased to 40.6 ± 3.0 after the first year and to 35.2 ± 7.0 after 2 years. The average EWL reduction is 48.2% after 1 year and 56.0% after 2 years. The EWL reduction was inversely related to the initial weight. Patients with an estimated weight excess of 50 kg or less (108 patients [27.0%]) had an EWL reduction of 55% after 2 years; those with a weight excess of greater than 50 kg (292 patients [73.0%]) had an EWL reduction of 44% (t test, $P = .004$).

COMMENT

Gastric banding is a favorable treatment for morbid obesity. It is the least invasive of available surgical options and has given good long-term results.¹³ In recent years, the laparoscopic insertion has been adopted in clinical practice, with consistent further improvements in hospital stay, postoperative pain, and return to normal activities, with similar results to the classic "open" technique for correction of obesity and comorbidities.¹³⁻¹⁶ Laparoscopic gastric banding also recorded minor complication rates and, in cases of failure, did not prevent the use of more invasive and radical procedures.¹⁷⁻¹⁹

Different devices for laparoscopic gastric banding exist. The most used are the SAGBs^{13,15,16} and the Lap-Bands.^{13,15} These devices differ conceptually: the SAGB is a low-pressure and high-volume system, whereas the Lap-Band is a high-pressure and low-volume system. Excellent results were published for both, and no significant differences in terms of complication rates were registered, as shown by a recent meta-analysis.¹³ However, the meta-analysis also indicated that it was difficult to compare single-institution articles because of the heterogeneity of data and because no specific study compared the SAGB with the Lap-Band.

In our experience, LAGB has been an effective operation for the treatment of clinically moderate and severe

obesity. The short duration of surgery, the indication even in patients unfit for derivative procedures, the low morbidity and mortality rates, and the postoperative weight loss indicated that this technique was a safe and effective procedure. We found no significant differences in terms of weight loss or complication rates between the Lap-Band and the SAGB groups.

In our series, we recorded 12 anterior slippages. We used the pars flaccida technique, which involves minimal dissection around the stomach with placement of the band circumferentially behind the right diaphragmatic crus and the angle of His. We also put stitches on the anterior stomach serosa to better fix the band. The anterior gastric wall prolapse is thought to be the result of an insufficient fixation to the anterior stomach wall. Three patients were asymptomatic, and complications were detected by radiographic assessment during follow-up, while 6 patients were symptomatic (epigastric pain, vomiting, and reflux). We had 24 transient gastric occlusions (6.0%) that spontaneously resolved. In these cases, the perigastric inflammation created an indirect tightening of the band.

Derivative procedures are more radical than LAGB. In highly obese patients, the EWL obtained with these techniques is greater than the EWL obtained with LAGB.²⁰ The final result is that LAGB is often not enough for this subset of patients and derivations are necessary, except in specific risky cases. In moderate obesity, the EWL obtained with derivative procedures is approximately similar to that obtained with LAGB, but the former have greater rates of complications.²¹ Our results recorded after 2 years of follow-up outline that the EWL of those undergoing laparoscopic banding was greater in the moderately obese patients (reaching approximately a normal weight) than in the highly obese patients. For these reasons, we believe that the primary correct indication of LAGB is moderate obesity and our experience also suggests that it can find a role in highly obese patients unfit for more radical procedures. Furthermore, although not directly investigated, we confirm that LAGB procedures have shorter operative times and lower complication rates when compared with published results for the Roux-en-Y gastric bypass.²²⁻²⁴

In conclusion, LAGB is a safe and feasible technique with specific indications in moderately obese patients and, secondarily, in highly obese patients who are unfit for more invasive techniques. Transient gastric occlusions and slippages were the most common postoperative complications. The devices used (SAGB and Lap-Band) were similar in terms of correction of obesity and morbidity.

Accepted for Publication: February 5, 2007.

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