

Laparoscopic Adjustable Gastric Banding Results after 2 Years with Two Different Band Types

D. Collet; A. Rault; A. Sa Cunha; D. Larroude; B. Masson

Service de chirurgie, Maison du Haut Lévêque, Centre Hospitalier et Universitaire de Bordeaux, Pessac, France

Background: Laparoscopic gastric banding is the most common operation in Europe for morbid obesity. Many devices from different companies are now available. The aim of this study was to compare the results over a 2-year period of 2 types of band: the Lap-Band® and the Minimizer® band.

Methods: In a non-randomized study, 2 consecutive groups were prospectively analyzed. Group A consisted of 120 patients who received the Lap-Band®, and group B consisted of 68 patients who received the Minimizer band which contains eyelets. All the bands were placed above the lesser sac by the perigastric approach.

Results: 4 early complications were observed in group A (1 phlebitis, 1 pneumopathy and 2 early displacements of the band); and 1 in group B (1 retention of urine). After a follow-up of 2 years, the displacement rate of the band was 10.8% in group A and 0% in group B. One gastric erosion was observed in group B, but not in group A. After 2 years, the average loss of excess weight was 50% in both groups.

Conclusion: With the Minimizer band, we did not observe any slipping, and the efficacy with respect to weight loss was equivalent to the Lap-Band®.

Key words: Morbid obesity, laparoscopy, gastric banding, short-term results

Introduction

In recent years, the adjustable gastric band has become the most common bariatric operation in France. This has led to the marketing of different types of bands. All these bands are based on the principle of a gastric restriction that can be adjusted by

inflation/deflation of the band with saline via an access port and tubing. However, there are differences between the brands with respect to material, inflation pressure of the inner tube, the way in which the band is fixed to the gastric wall, the implantable chamber, and the system by which it is connected to the band.

Since 1998, we used two different types of band: the Lap-Band® (Inamed Health, Santa Barbara, CA, USA) and the Minimizer® (HospiMedical GmbH, Meerbusch, Germany). We evaluated the 2-year results obtained with these two bands.

Methods

Between May 1998 and May 2004, 240 patients underwent surgery for morbid obesity in our clinic. Laparoscopic gastric banding was intended for patients with a BMI >40 kg/m², or those with a BMI between 35 and 40 kg/m² with obesity-related morbidities. The decision for intervention was confirmed following nutritional and psychological assessment, after a cooling-off period of at least 3 months. Postoperatively, the patients were reviewed in a systematic surgical check-up at 1, 3, 6 and 12 months and again after a further year. Also, patients were instructed to consult us at any time in the event of a complication or if the procedure was ineffective. In parallel, a nutritional and psychological follow-up was carried out, but with a different timetable. All individual data were prospectively collected and entered into a database (Microsoft Access, Microsoft, Seattle, WA, USA). All patients who had not been seen within 6 months previously were contacted by telephone in order to update the database so that this research project could be conducted.

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Reprint requests to: Prof. Denis Collet, Service de chirurgie digestive, Maison du Haut Lévêque, CHU de Bordeaux, 33604 Pessac, France. Fax (33) 05 57 65 60 19; e-mail: denis.collet@chu-bordeaux.fr

The patients were divided into two groups for this non-randomized consecutive study. Patients operated during the first period from June 1999 to June 2001 (group A) received the Lap-Band[®], while those operated during the second period from February 2002 to April 2004 (group B) received the Minimizer[®] band. In order to overcome a learning curve, which is associated with increased morbidity,¹ the first 20 patients in each group were not included in the study groups. However, we have a personal experience of 437 funduplications for reflux, 40 cases of para-esophageal hernias, and 27 myotomies for achalasia – all performed laparoscopically. Group A consisted of 120 patients and Group B of 68. Only the first 700 days of follow-up in each group were taken into account, in order to compare equivalent periods. Finally, this study does not take into account the 12 patients in whom placement of the band was deemed impossible during surgery, because of difficulty in exposure or because of the occurrence of a gastric perforation. The characteristics of both groups are presented in Table 1. The co-morbidities associated with obesity and the preoperative ASA scores are reported in Table 2.

The operation was carried out laparoscopically with 4 trocars: sub-xiphoid (5 mm), left hypochondrium (15 mm), epigastric (10 mm) and right hypochondrium (10 mm). The band was placed after inflation to 15 ml and pulling back of an intragastric balloon in order to calibrate the proximal gastric pouch. All bands in both groups were introduced via the perigastric approach and were in contact with the gastric wall according to the technique described by Belachew,² above the lesser

Table 2. Co-morbidities and ASA score (percentages are in brackets)

	Group A		Group B	
	Preop	At 2 yrs	Preop	At 2 yrs
Arterial hypertension	29 (24)	26 (21)	29 (42)	24 (35)
Diabetes	12 (10)	8 (7)	17 (26)	13 (19)
Osteoarticular pathology	31 (26)	21 (17)	18 (26)	12 (18)
Sleep apnea	4 (3)	4 (3)	4 (6)	3 (4)
ASA 1	39 (32)		16 (23)	
ASA 2	73 (61)		48 (70)	
ASA 3	8 (7)		4 (6)	

sac, after creation of the retrogastric tunnel. The way in which the bands were fixed constituted the main difference between the two types of band: the Lap-Band[®] was covered by imbricating serosa-to-serosa with non-absorbable suture, on the anterior gastric wall; the Minimizer[®] was fastened to the gastric wall, using eyelets designed for that purpose, by means of 6 non-absorbable sutures. The reservoir was placed just below the xyphoid. As soon as weight loss no longer progressed or when the sensation of fullness showed a tendency to decrease, the band was inflated with saline under radiological control.

Comparison of qualitative criteria was by Chi-squared analysis and of quantitative criteria by Student's *t*-test. $P < 0.05$ was considered significant.

Results

Perioperative Results

The average duration of pneumoperitoneum was 65 minutes (range 20-240) in group A and 51 min (range 30-125) in group B (NS). One conversion was required in group A due to difficulties in exposure. Postoperative complications were observed 4 times in group A (1 phlebitis, 1 pneumopathy and 2 early displacements of the band). In group B, one postoperative complication was observed (one urinary retention in a female with a history of surgery for urinary incontinence). No deaths occurred in this study. The two patients with early displacement of the band underwent repeat surgery during the first postoperative week so that the band could be returned to a cor-

Table 1. Operated patients

	Group A	Group B	P
No. of patients	120	68	NS
Females/males	110/10	52/16	NS
Average age (years)	41.6	40.0	NS
Average excess weight	60 kg	62 kg	NS
Minimum excess weight	33 kg	32 kg	NS
Maximum excess weight	128 kg	122 kg	NS
BMI >35 and <40	25 (20.8 %)	9 (13.2 %)	NS
BMI >40 and <45	47 (39 %)	28 (41 %)	NS
BMI >45 and <50	25 (15 %)	16 (23.5 %)	NS
BMI >50 and <55	18 (15 %)	11 (16 %)	NS
BMI >55 and <60	1 (1 %)	3 (4 %)	NS
BMI >60	4 (3.3 %)	1 (1.4 %)	NS

rect position; the subsequent courses were uncomplicated in each case. The length of hospitalization was 3.4 days (range 2-10 days) in group A and 2.7 (range 2-7 days) in group B.

Adjustment of the Band

The band was adjusted 2.3 times (range 0-3) in group A and 1.8 times (range 0-2) in group B (NS).

Secondary Interventions

A repeat intervention under local or general anesthetic was performed in 27 patients in group A (22.5%) and 7 in group B (10.3%) (Table 3). There were 13 secondary slippages of the band in group A and none in group B. An attempt to replace the band was always made in the case of repeat intervention for displacement; thus, 6 bands were able to be repositioned in group A, while 7 had to be removed because of technical difficulties encountered (Table 4). On the other hand, one erosion of the gastric wall was observed in Group B, which required removal of the Minimizer[®] band in the 4th postoperative month. The band was removed at the request of 3 patients in group A, because they no longer felt the need for gastric restriction, and 2 of them were satisfied with the results already obtained. All patients who had band removal regained weight.

Table 3. Indications for reoperation

	Group A	Group B	P
Displacement	13 (10.8%)	0	<0.05
Port disconnection	8 (6.7%)	6 (8.8%)	NS
Removal demanded			
by patient	3 (2.5%)	0	NS
Port Infection	3 (2.5%)	0	NS
Erosion of the gastric wall	0	1 (1.5%)	NS

Table 4. Type of reoperations

	Group A	Group B
Removal of band	11 (9.2%)	1 (1.5%)
Repositioning of band	6 (5.0%)	0
Reconnection of port	8 (6.7%)	6
Removal of port	2 (1.7%)	0

Results on Weight

Weight loss is illustrated in Figure 1. On average, the weight loss over 2 years in each group was equivalent to 50% of the initial excess weight.

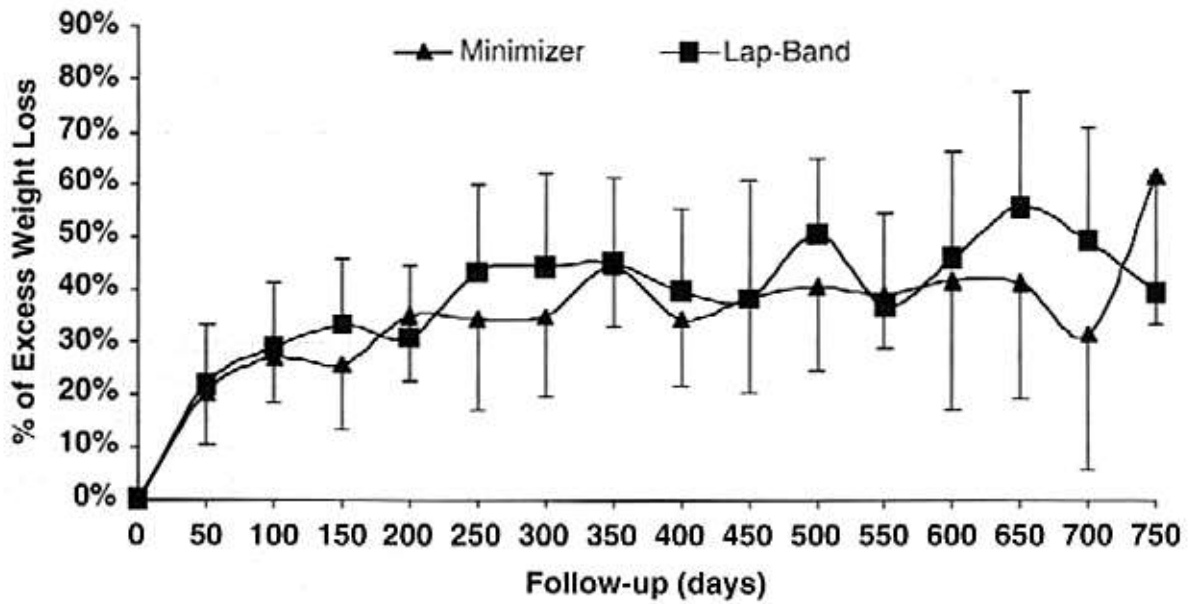
Discussion

The methodology of this prospective non-randomized study permits some conclusions to be drawn. However, it must be noted that we inserted the Lap-Band[®] by the perigastric approach, whereas slippage has been uncommon with the subsequent pars flaccida approach.^{3,4}

The increase in morbid obesity in Western society has become a significant public health problem.⁵ Among the possible surgical treatments, gastric banding using an adjustable band has in recent years become the most frequently performed operation. While it is perhaps slightly less effective than a gastric bypass,⁶ the associated morbidity and mortality are less. Moreover, the intervention is easily reversible and does not preclude gastric and duodenal endoscopy. It was to be expected that the success of this operation would stimulate manufacturers to attempt to manufacture ever-more effective bands.

One of the specific complications of this intervention is the backwards displacement of the band downwards, under the effect of the pressure in the proximal gastric pouch. This complication has had a frequency of 2-8%.^{4,7-10} The consequences can be serious, involving complete aphagia, sometimes complicated by dehydration and sometimes by proximal gastric necrosis requiring emergency gastrectomy.¹¹ A repeat operation is required, most frequently as an emergency, in order to replace the band or, if that proves impossible, to remove it.^{12,13} The frequency of this complication has now been reduced by two technical strategies: firstly, by placing the band within the phrenogastric ligament above the posterior cavity of the lesser sac,⁵ and secondly, by positioning the band so it is in contact with the crura of the diaphragm by the pars flaccida approach.⁴ Nevertheless, slippage is still reported in recent studies, with a rate of <1% in the best series.³ The Lap-Band[®] is fixed by tunnelizing it on the anterior gastric wall.

One of the Minimizer's specific features is its



No. of patients at each follow-up period

Days	0	50	100	150	200	250	300	350	400	450	500	550	600	650	700	750
Minimizer®	68	68	57	58	48	52	50	61	57	52	58	49	51	53	54	59
Lap-Band®	120	120	114	110	112	105	100	108	98	96	101	98	95	94	102	116

Figure 1. Percentages of excess weight loss calculated in both groups. Bars on one side of each time-point (Minimizer® or Lap-Band®) indicate the standard deviation.

direct attachment to the gastric wall by means of eyelets, which enable suturing the band to the gastric wall. In our experience, this system has been effective, because we have never observed Minimizer band displacement. One could fear that this method of attachment could lead to damage of the gastric wall and increase the frequency of fistulas or gastric erosions. The only erosion that we observed so far occurred near the angle of His, some distance from the attaching sutures, and appeared therefore to be independent of the attachment system. Another potential advantage of this type of material is the ease of ablation; it is simpler to cut the anchoring sutures instead of dismantling the covering gastric tissue.

Apart from complications related to band displacement, repeat interventions were required in 21 patients (14 from group A and 7 from group B). Most of these were not serious and were able to be performed under local anesthesia. This underlines the necessity for regular follow-up of any patient who has a gastric band, about which the patient

must be clearly informed before surgery. In the event of refusal by the patient or the impossibility of this follow-up with a particular patient, another type of bariatric operation should be proposed, such as a vertical banded gastroplasty or a gastric bypass.

The efficacy with respect to weight loss at 2 years was the same for both types of band. At 2 years, the loss of excess weight averaged 50%, which agrees with other studies with the adjustable band.^{6,14-17} Although this weight loss may appear to be modest, it is sufficient to improve significantly the co-morbidities associated with obesity^{16,18} as well as the quality of life.¹⁹ Furthermore, no medical therapy can reach such a sustained result.

In conclusion, in our experience, gastric banding using the Minimizer® adjustable band has not been associated with band displacement, and has been effective with respect to weight loss over the 2-year period. We are continuing our prospective study to validate these early results over the long term.

References

1. Shapiro K, Patel S, Abdo Z et al. Laparoscopic adjustable gastric banding: is there a learning curve? *Surg Endosc* 2004; 18: 48-50.
2. Belachew M, Legrand M, Vincent V et al. Laparoscopic placement of adjustable silicone gastric band in the treatment of morbid obesity: how to do it. *Obes Surg* 1995; 5: 66-70.
3. Dargent J. Pouch dilatation and slippage after adjustable gastric banding: is it still an issue? *Obes Surg* 2003; 13: 111-5.
4. Chevallier JM, Zinzindohoué F, Douard R et al. Complications after laparoscopic adjustable gastric banding for morbid obesity: experience with 1,000 patients over 7 years. *Obes Surg* 2004; 14: 407-14.
5. Mouiel J. L'obésité morbide, problème de santé publique: traitement chirurgical sous laparoscopie *Bull Acad Natle Méd* 2001; 185: 1475-93.
6. Buchwald H, Williams SE. Bariatric surgery worldwide 2003. *Obes Surg* 2004; 14: 1157-64.
7. Allen JW, Coleman MG, Fielding GA. Lessons learned from laparoscopic gastric banding for morbid obesity. *Am J Surg* 2001; 182: 10-4.
8. Forsell P, Hallerbäck B, Glise H et al. Complications following Swedish adjustable gastric banding: a long-term follow-up. *Obes Surg* 1999; 9: 11-6.
9. Sarker S, Herold K, Creech S et al. Early and late complications following laparoscopic adjustable gastric banding. *Am Surg* 2004; 70: 146-50.
10. Weiner R, Blanco-Engert R, Weiner S et al. Outcome after laparoscopic adjustable gastric banding – 8 years experience. *Obes Surg* 2003; 13: 427-34.
11. Kirchmayer W, Ammann K, Aigner F et al. Pouch dilatation after gastric banding causing gastric necrosis. *Obes Surg* 2001; 11: 770-2.
12. Vertruyen M. Repositioning the Lap-Band® for proximal pouch dilatation. *Obes Surg* 2003; 13: 285-8.
13. Peterli R, Donadini A, Peters T et al. Re-operations following laparoscopic adjustable gastric banding *Obes Surg* 2002; 12: 851-6.
14. Evans JD, Scott MH, Brown AS et al. Laparoscopic adjustable gastric banding for the treatment of morbid obesity. *Am J Surg* 2002; 184: 97-102.
15. Ren CJ, Horgan S, Ponce J. US experience with Lap-Band system. *Am J Surg* 2002; 184: 46S-50S.
16. Vella M, Galloway DJ. Laparoscopic adjustable gastric banding for severe obesity. *Obes Surg* 2003; 13: 642-8.
17. Steffen R, Biertho R, Ricklin T et al. Laparoscopic Swedish adjustable gastric banding: a five-year prospective study *Obes Surg* 2003; 13: 404-11.
18. Frigg A, Peterli R, Peters T et al. Reduction of comorbidities 4 years after laparoscopic adjustable gastric banding. *Obes Surg* 2004; 14: 216-23.
19. Mathus-Vliegen EM, de Weerd S, de Wit LT. Health-related quality of life in patients with morbid obesity after gastric banding for surgically induced weight loss. *Surgery* 2004; 13: 489-97.

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