Prevention of Pouch Dilatation after Laparoscopic Adjustable Gastric Banding

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Background: The major long-term complication of laparoscopic adjustable gastric banding (LAGB) is dilatation of the gastric pouch, that is reported with a frequency ranging from 1 to 25%, and often requires removal of the band. In addition to the usual recommendations of bariatric surgery centers and dietetic advice to prevent this complication, over the last 4 years we introduced a technical modification of the procedure.

Methods: From Nov 1993 to Dec 2004, 684 morbidly obese patients underwent adjustable gastric banding, 83 patients by open surgery and 601 patients by laparoscopy. The first 323 patients (group A) were operated by the perigastric approach, and 57 patients (group B) were operated by the pars flaccida approach. Since Dec 2000, 304 patients (group C) were operated with a modified pars flaccida technique, which consisted in suturing the gastric lesser curvature below the band with one or two stitches to the right phrenic crus to secure the band in place.

Results: In group A, the most important late complication was irreversible dilatation of the gastric pouch, which occurred in 35 patients (10.8%), and required removal of the band in 30 cases and replacement in 5. In group B, there were 3 pouch dilatations (5.2%). In group C, only 4 dilatations occurred (1.31%), which required 3 band removals and 1 band replacement.

Conclusion: Dilatation of the gastric pouch appears to be dramatically reduced by our minor technical modification of band placement.

Key words: Morbid obesity, bariatric surgery, laparoscopic adjustable gastric banding, gastric pouch dilatation

Introduction

In our experience,¹ as in the literature,²⁻⁶ the most significant and important late postoperative complication of adjustable gastric banding is dilatation of the gastric pouch. We observed a high rate of dilatations in spite of following the classic recommendations of bariatric surgery centers^{7,8} (Table 1), i.e. "virtual" pouch, retro-gastric tunnel above the lesser sac, band fixation with gastro-gastric sutures, not inflating the band for the first postoperative months, and educating the patient about the new eating behavior. If the dilatation is recognized early, it is usually reversible with deflation of the band, liquid diet, prokinetic agents, antacid therapy with a proton-pump inhibitor, psychological and dietetic support. However, if it is diagnosed too late, it is often irreversible and requires surgery. In order to prevent gastric pouch dilatation,

Table 1. Recommendations of bariatric surgery centers to prevent pouch dilatation

- Very small gastric pouch (≤15 ml), the "virtual" pouch
- Retro-gastric tunnel above the lesser sac
- Anterior fixation with gastro-gastric sutures
- Adequate patient training about the new eating behavior
- · Band left deflated in the first postoperative months
- Gentle band adjustments based on patient appetite
 and weight loss

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in December 2000 we introduced in a technical modification of the usual procedure of laparoscopic adjustable gastric banding (LAGB).

Materials and Methods

From November 1993 to December 2004, 684 morbidly obese patients (139 males and 545 females) underwent adjustable gastric banding (AGB). The indications followed by our center for the selection of patients for bariatric surgery are those recommended by the 1991 NIH Consensus Conference.⁹ The procedure was open in 83 cases and laparoscopic in 601 cases.

From November 1993 to January 2000, 323 patients (group A) underwent AGB by the classical procedure described by Belachew:¹⁰ dissection of the angle of His, perigastric (PG) approach on the gastric lesser curvature, retro-gastric tunnel above the lesser sac, and suture-fixation of the anterior wall, embedding the band completely. The gastric pouch was calibrated to 25 cc in the first 58 patients; in those following, the pouch was calibrated to 15 cc.¹ Mean age was 38 years (range 18-67), mean body weight was 118 kg (8-218), mean BMI was 44.1 kg/m² (35-70), and mean follow-up was 82 months (65-150).

In a subsequent group (group B) of 57 patients (mean age 38.5 years, mean body weight 115.5 kg, mean BMI 43.6 kg/m², mean follow-up 60 months), we abandoned the PG approach and adopted the pars flaccida (PF) pathway to place the band.¹¹ This procedure appeared to be easier and safer. In fact, in these patients no more gastric perforations occurred, but we still observed a high frequency of pouch dilatations (3 out of 57 patients, 5.2%).

Since December 2000, we have used a technical modification¹² with the PF approach, which consisted of suturing the lesser curvature just below the band to the right crus with one or two non-absorbable sutures (Figure 1), to stabilize the position of the band and avoid its slippage. To the present, 304 patients (group C) have been operated with this technique: mean age 39 years (range 24-62), mean weight 112.8 kg (95-204), mean BMI 43.2 kg/m² (36-68); mean follow-up 28 months (6-54).

Among the groups (Table 2), there was no significant difference in gender, age and BMI. The bands used

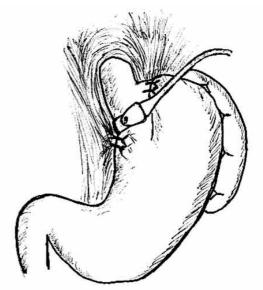


Figure 1. Scheme of our technical modification: the lesser curvature, just below the band, is sutured to the right crus, with one or two stitches.

were of different type and manufacturers: 409 Lap-Band[®] (Inamed, Santa Barbara, USA), 255 Heliogast[®] (Hélioscopie, France), 20 Swedish band SAGB[®] (Obtech, associated with Ethicon Endo-Surgery).

A Gastrografin[®] swallow was performed on the first postoperative day to confirm band position and to exclude leaks. All the bands were left completely empty for nearly 3 months postoperatively. Patients were reviewed at approximately 4-week intervals during the first year, then every 2-3 months. Band adjustments were performed in relation to the patient's weight loss and clinical symptoms. All the patients at the time of adjustment underwent barium swallow to assess the transit through the band, the position of the band and the gastric pouch: the more suitable were AP and lateral projections.¹³ Pouch dilatations were considered anterior or posterior in relation to the radiological appearance.¹⁴

Table 2. Patient demographics

	Group A	Group B	Group C
Number	323	57	304
M/F	66/257	10/47	63/241
Age (yrs)	38(18-67)	38.5(21-59)	39(24-60)
Weight (kg)	118(82-218)	115.5(90-189)	112.8(95-204)
BMI (kg/m ²)	44.1(35-72)	43.6(36-70)	43.2(36-68)
Follow-up (mos)	82(65-150)	60(55-65)	28(6-54)

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Statistical Analysis

All qualitative data were analyzed with the χ^2 test or Fisher's exact test when appropriate. All quantitative data were analyzed using Student's *t*-test. Level of significance was set at *P*<0.05.

Results

Table 3 shows the incidence of pouch dilatations observed in the three groups of patients. In group A, we observed a rate of 35 irreversible dilatations (10.8%). All patients underwent surgical treatment: in 30, we removed the band, and in five, we replaced it. We observed six anterior and 29 posterior dilatations.

In group B, there were three dilatations (5.2%), one anterior and two posterior, which were treated with band replacement. In the last series of 304 patients (group C), operated with the pars flaccida approach and our technical modification, only four gastric pouch dilatations occurred (1.31%), all anterior with clockwise rotation of the band. One was treated with band replacement, and the others with band removal.

The statistical analysis of our data showed a highly significant difference between group A and C (P<0.001), and significant between B and C (P=0.03). No statistically significant difference was observed between groups A and B. Among the three series of patients, there was no significant difference in weight loss. We observed six intragastric migrations, all in group A. No intragastric migrations were observed in group B and group C.

Figure 2 shows the pouch dilatations observed in our experience since 1994: most of them occurred within 24 months after the operation, even if the range was 6-51 months, and were not related to the type of the band.

	Patients	Pouch dilatations	%
Group A	323	35	10.8
Group B	57	3	5.2
Group C	304	4	1.31*

Group A = PG approach; Group B = PF approach; Group C = PF + lesser curvature to right crus fixation.

* = significant compared to group A (P<0.001) and to group B (P=0.03).

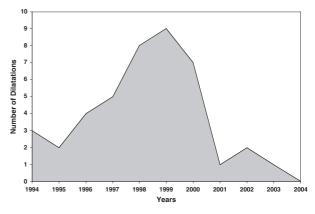


Figure 2. Rate per year of pouch dilatations in our experience (1994-2004).

Discussion

The incidence of obesity, and in particular morbid obesity, has been steadily increasing in Europe and in the United States during the last 20 years. Medical and dietetic approaches to morbid obesity have proved to be ineffective in maintaining weight loss, and bariatric surgery has been the only successful treatment.¹⁵

In approaching restrictive surgery, a reasonable risk/benefit ratio should be considered.¹⁶ A safe and feasible operation should be chosen on the basis of: rate and severity of early and late complications; percentage of failure of the surgical treatment; weight loss results; reversibility of the surgical technique.

In comparison with other procedures, LAGB is attractive because it is minimally invasive, reversible and can be adjusted to suit the patient's needs. It is widely used in Europe and Australia, and its use in the United States is growing,¹⁷ because the weight loss is similar to other more invasive gastric restrictive procedures, with a lower incidence of severe complications and death.^{18,19} Both in the literature²⁻⁶ and in our experience,^{1,13} the most important late complications of LAGB are pouch dilatation and intragastric migration. In our experience, pouch dilatation represents the most frequent late complication, because erosion occurred only in 6 out of 684 patients (0.8%), all in group A (perigastric technique): probably the main reason for this complication is related to the perigastric procedure, because intragastric migration did not occur with the pars flaccida approach.

In the first series of our patients (group A), we observed the classical recommendations of Belachew et al,¹⁰ which consisted of retro-gastric tunnel above the lesser sac, band fixation with anterior gastro-gastric stitches, and band deflation for 3 months after surgery. However, we observed gastric pouch dilatations in 10.8% of cases (35/323 patients). Gastric peristalsis, which is more active on the gastric lesser curvature, could be the cause of a progressive prolapse of the stomach and slippage of the band, which is displaced in an abnormal vertical position (counter-clockwise rotation of the band), becoming an obstacle to alimentary transit and causing posterior pouch dilatation.¹⁹ The change of procedure to the PF approach reduced the frequency of dilatations, but not completely, as reported by other Authors:^{5,20,21} we still observed three cases in 57 patients (5.2%). These dilatations were one anterior and two posterior. Therefore, we commenced fixing the band also on the lesser curvature, suturing the lesser curvature below the band to the right crus. In the patients in group C, the rate of dilatations dramatically dropped to 1.31%. The four dilatations observed were all anterior, with clockwise rotation (horizontal position) of the band. They were probably caused in part by technical failure, but above all by poor alimentary compliance of the patients, who did not follow dietetic advice after surgery. Mean follow-up of group C (28 months) was enough to detect pouch dilatation, since in our experience¹³ the mean time for onset of this complication had been <20 months.

Statistical analysis showed a significance only between group B vs C (odds ratio, OR=4.41), and group A vs C (OR=9.11). Group A had about a double rate of dilatations in comparison with group B; the difference, however, was not statistically significant due to the low number of patients in group B. The comparison between group A (perigastric technique) and group C (pars flaccida + right crus fixation) was highly significant (P<0.001); moreover, the OR showed a nine times higher risk of dilatations in patients in group A.

In spite of the low number of patients in group B (PF technique), the statistical analysis was significant comparing group B and group C, due to the very low number of dilatations in both groups. OR showed in this case a four times risk of dilatations in group B.

The causes of pouch dilatation are related to the technique of band placement and the eating behavior of the patients.^{5,22} The assessment of postoperative patient compliance is difficult, but eating too large a meal or too fast can produce prolapse of the stomach over the band.

Some studies have shown the decreasing rate of pouch dilatation with increasing experience of the surgeon (the "learning curve");^{1,19,21,23,24} good technique and correct postoperative care of the patients are important factors in the occurrence of late complications after LAGB.^{1,21,25,26}

The adoption of the pars flaccida technique has led to a lower incidence of pouch dilatation than the perigastric approach: PF technique has been able to prevent posterior dilatation.^{20-22,27} The PF approach minimizes exposure of the band to gastric peristalsis posteriorly, reducing prolapse of the stomach through the band.²⁰ Dargent found a rate of slippage of 6.2% with the PG approach and 0.6% adopting the PF technique.⁵ Chevallier and colleagues³ reported a 24% pouch dilatation rate with the PG approach compared to 2% for the PF pathway. Weiner et al²⁶ showed similar results: the pouch dilatation rate was 17% in the first 100 PG bands and dropped to 0% in the last 300 LAGBs performed with the two-step technique, which combines PF and PG band placement. Recently, Fielding and Duncombe²⁰ reported a rate of slippage of 9.5% in 123 patients operated with LAGB by the PG technique, compared to 4.3% in 162 operated by the PF approach (P<0.01). O'Brien and colleagues²¹ in a randomized controlled clinical trial evaluated the relative effectiveness and safety of the PG and PF techniques; they found 15 pouch dilatations (12 posterior and three anterior) in the PG group and only four (all anterior) in the PF group. This trial therefore showed that the PF pathway was significantly less likely to be associated with posterior prolapse.

In our group of LAGBs performed with PF technique, we still observed a high frequency of pouch dilatations. Therefore, we introduced a technical modification to stabilize the position of the band and to avoid its slippage. Our simple and not timeconsuming technical modification seems to show a still lower incidence of dilatations with similar results in weight loss and patient satisfaction.

In conclusion, gastric pouch dilatation still remains an issue, necessitating re-operation in some cases to remove or replace the band. For this reason,

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many bariatric surgeons seek different procedures and gastric banding has been not universally adopted. The PF approach, which seems to be associated with prevention of posterior prolapse, should be an important step in improving the safety of LAGB.²¹ Since Dec 2000, we have been using our technical modification, and the clinical follow-up of 304 patients showed a dramatic reduction in the frequency of dilatations, from 10.8% with the PG approach to 1.31%. We think that our technical modification can improve the efficacy and safety of LAGB and enhance the adherence of morbidly obese patients to gastric restrictive surgery.

References

- 1. Doldi SB, Micheletto G, Lattuada E et al. Adjustable gastric banding: 5-year experience. Obes Surg 2000; 10: 171-3.
- 2. Belachew M, Belva PH, Desaive C. Long-term results of laparoscopic adjustable gastric banding for the treatment of morbid obesity. Obes Surg 2002; 12: 564-8.
- 3. 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.
- 4. Favretti F, Cadière GB, Segato G et al. Laparoscopic banding: selection and technique in 830 patients. Obes Surg 2002; 12: 385-90.
- 5. Dargent J. Pouch dilatation and slippage after adjustable gastric banding: is it still an issue? Obes Surg 2003; 13: 111-15.
- O'Brien PE, Dixon JB. Weight loss and early and late complications – the international experience. Am J Surg 2002; 184: 42S-45S.
- Belachew M, Legrand M, Vincent V. History of Lap-Band[®]: from dream to reality. <u>Obes Surg 2001; 11:</u> 297-302.
- 8. Favretti F, Cadière GB, Segato G et al. Laparoscopic adjustable silicone gastric banding (Lap-Band[®]): how to avoid complications. Obes Surg 1997; 7: 352-8.
- 9. Gastrointestinal surgery for severe obesity: National Institutes of Health Consensus Development Conference Draft Statement. Obes Surg 1991; 1: 257-65.
- Belachew M, Legrand M, Vincent V et al. Laparoscopic adjustable silicone gastric banding. World J Surg 1998; 22: 955-63.
- 11. Fielding GA, Allen JW. A step-by-step guide to placement of the Lap-Band adjustable gastric banding system. Am J Surg 2002; 184: 26S-30S.

- 12.Zappa MA, Lattuada E, Mozzi E et al. A modified surgical technique to prevent pouch dilatations after laparoscopic adjustable gastric banding. Chir Gastroenterol 2005; 21 (Suppl 1): 7-10.
- 13. Lattuada E, Zappa MA, Micheletto G et al. Complications and results of adjustable gastric banding to treat morbid obesity. Osp Ital Chir 2003; 9: 53-9.
- Dargent J. Les complications de la gastroplastie avec anneau modulable par coelioscopie. J Coeliochir 1999; 29: 53-6.
- 15. Deitel M. Bariatric surgery is a cost-saving for the Healthcare System. Obes Surg 2005; 15: 301-3.
- Buchwald H, Avidor Y, Braunwald E et al. Bariatric surgery: a systematic review and meta-analysis. JAMA 2004; 292: 1724-37.
- 17. Ren CJ, Weiner M, Allen JW. Favorable early results of gastric banding for morbid obesity. The American experience. Surg Endosc 2004; 18: 543-6.
- 18. Fernandez AZ, DeMaria EJ, Tichansky DS et al. Experience with over 3000 open and laparoscopic bariatric procedures: multivariate analysis of factors related to mortality and leak. Surg Endosc 2004; 18: 193-7.
- 19. Chapman AE, Kiroff G, Game P et al. Laparoscopic adjustable gastric banding in the treatment of obesity: a systematic literature review. Surgery 2004; 135: 326-51.
- 20. Fielding GA, Duncombe JE. Clinical and radiological follow-up of laparoscopic adjustable gastric bands, 1998 and 2000: a comparison of two techniques. Obes Surg 2005; 15: 634-40.
- 21. O'Brien PE, Dixon JB, Laurie C et al. A prospective randomized trial of placement of the laparoscopic adjustable gastric band: comparison of the perigastric and pars flaccida pathways. Obes Surg 2005; 15: 820-6.
- 22. Lunca S, Vix M, Rikkers A et al. Late gastric prolapse with pouch necrosis after laparoscopic adjustable gastric banding. Obes Surg 2005; 15: 571-5.
- 23. Angrisani L, Furbetta F, Doldi SB et al. Lap Band[®] adjustable gastric banding system: the Italian experience with 1863 patients operated on 6 years. Surg Endosc 2003; 17: 409-12.
- 24. Rubenstein RB. Laparoscopic adjustable gastric banding at a U.S. Center with up to 3-year follow-up. Obes Surg 2002; 12: 380-4.
- 25. Vertruyen M. Experience with Lap-Band System[®] up to 7 years. Obes Surg 2002; 12: 569-72.
- 26. Weiner R, Blanco-Engert R, Weiner S et al. Outcome after laparoscopic adjustable gastric banding 8 years experience. Obes Surg 2003; 13: 427-34.
- 27. Wölnerhanssen B, Kern B, Peters T et al. Reduction in slippage with 11-cm Lap-Band[®] and change of gastric banding technique. Obes Surg 2005; 15: 1050-4.

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