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A five year Canadian laparoscopic adjustable gastric band experience

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Obesity;
Laparoscopic adjustable band;
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Abstract

BACKGROUND: The aim of this study was to review 5 years of laparoscopic adjustable gastric band (LAGB) procedures in which low-pressure bands were used.

METHODS: All LAGB cases at the authors' center were retrospectively analyzed. A survey of these patients was conducted in 2008 and 2009.

RESULTS: Of 90 LAGB patients, 86 were surveyed. Follow-up averaged 17.5 months. Weight loss averaged 24.8 ± 19.4 kg. Weight loss averaged 2.7 kg/mo and did not significantly drop over the last 10.7 months (2.7 vs 1.5 kg/mo, $P = .16$). Excess body weight loss was 27.5%, 39.1%, and 67.2% in the first, second, and following years, respectively. Patients averaged 4.14 adjustments of their bands and vomited 2.13 times per week. The mortality rate was 0%. No band slippages or band erosion occurred. Resolution or improvement occurred in most obesity-related illness. Gastroesophageal reflux disease symptoms worsened in 25% of patients.

CONCLUSIONS: These results replicate world LAGB literature. Low complication rates result either from the authors' band or their techniques.

Over the past 20 years, our surgical group in Victoria, British Columbia, has performed bariatric surgery. Laparoscopic adjustable gastric band (LAGB) procedures have been performed at our center from the spring of 2004 to the present. The introduction of LAGB was driven by lower complication rates (11% vs 25%) and mortality rates (1/2,000 vs 1/200) compared with laparoscopic gastric bypass, with equivalent weight loss in a large systematic review.[1] Recognizing LAGB complications, including band erosions, band slippage, pouch dilation, band migration, and infection (.5%, 2.6%, 2.1%, and 1.1%, respectively),[2] we began our LAGB practice using MIDBAND (Médical Innovation Développement, Limonest, France). Of the approved Canadian LAGBs, we expected this low-pressure product to have very low complication rates in terms of slippages, migration, and erosions. This presumption was based on the product's diffuse pressure dispersion, as is common for many of the newer generation low-pressure adjustable band products. With our center's adoption of this product exclusively since initiating LAGB, our experience would allow an analysis of a low-pressure adjustable band in a Canadian series.

Method

A retrospective chart review of all LAGB cases at our practice between March 2004 and March 2009 was per-

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formed. Variables of interest included documented office weights (on a specialized bariatric weighing scale), band adjustments, hospital operative times, and hospital length of stay. Weight loss was analyzed as percentage weight change over the first year, second year, and beyond. Weight loss per month was analyzed for the first follow-up period, up until the February 2008 survey, and then the subsequent months until the next survey in March 2009. This was used to determine any weight-loss changes that were occurring in our band practice. Percentage excess body weight loss was calculated in the standard fashion.[3] By convention, percentages of patients losing 40% and 50% excess body weight were calculated for graphical representation.

In addition to the chart review, a telephone survey of all our LAGB patients was conducted. Variables of interest in the survey included overall satisfaction with the LAGB, compliance with dietary and exercise instruction, and improvement of obesity-related illnesses, including diabetes, hypertension, dyslipidemia, obstructive sleep apnea, hypertension, arthritic joint pain, polycystic ovarian disease, gastroesophageal reflux disease (GERD), depression, and anxiety symptoms. LAGB side effects, including the number of regurgitation and vomiting episodes per week, were also surveyed. Surveys were conducted after obtaining patient consent to participate in our study and were conducted in February 2008 and March 2009. The survey used a 5-point scale for variables of interest, with responses being either resolved, improved, unchanged, worse, or not applicable for each obesity-related illness. For satisfaction and compliance with recommended healthy diet and exercise, answers were given as either poor, fair, good, or excellent.

Statistical analysis was performed by a qualified statistician using SPSS version 16.0 (SPSS, Inc, Chicago, IL) and included Student's t test for continuous variables and χ^2 analysis for categorical variables.

Surgical technique and patient management

At our center, 3 surgeons perform bariatric surgery, and all follow the standard National Institutes of Health guidelines (1991) for bariatric surgery patient selection. We incorporate a multidisciplinary approach, including dietician assessment and enrollment in regular physical activities with regular journal documentation of lifestyle changes. We also require patient participation in a regular bariatric support group. These support groups can be attended throughout British Columbia or in an online forum. Because of demand, patients will often wait up to 2 years for their bariatric procedures, and close follow-up is continued during the preoperative period to monitor lifestyle changes. Over our study period, we have offered LAGB, laparoscopic gastric bypass, and recently laparoscopic sleeve gastrectomy.

Our LAGB technique involves the pars flaccida technique. We place our port subcutaneously rather than on the fascia to facilitate ambulatory clinic filling. Our highest volume surgeon (>75% of cases) abandoned the use of gastrogastric tunnel (fundic) sutures in the latter half of the study period. Postoperatively, patients must be tolerating fluids before discharge, which is now arranged the day of surgery if no complications are encountered. Patients are instructed to consume a low-calorie semisolid diet for the first 6 weeks after banding and are then reassessed for dietary restriction and weight loss. If restriction is not felt to be adequate, adjustments are made to the band so that small amounts of consumption elicit satiety. Follow-up visits after 6 weeks are made when weight loss is not adequate or at 3-month intervals until weight loss is either steady or weight-loss goals have been achieved. Assessment of lifestyle changes, as well as oral restriction and current weight, are made at each visit. Band adjustments are performed in the office. Fluoroscopically guided band adjustments are only performed when patients are having difficulty losing weight. If patients become dysphagic, they are seen urgently, and the band reservoir is emptied until oral intake is possible. If there is ongoing protracted dysphagia and vomiting after complete reservoir emptying, a barium contrast study is done to investigate potential band slippage or erosion.

Results

Ninety patients underwent LAGB surgery at our center, and all were followed. Eighty-six answered the survey. Mean follow-up was 17.5 months. The demographics of our patients are illustrated in Table 1. Total weight loss in our patients averaged 24.8 ± 19.4 kg. Overall, weight loss was an average of 2.68 kg/mo for the entire length of follow-up and was 1.50 kg/mo over the last 10.7 months (range, 1–13 months; n = 41) of follow-up (nonsignificant drop, P = .16). Excess body weight loss was 27.5 ± 6.34%, 39.1 ± 18.0%, and 67.2 ± 31.3% at 0 to 1, 1 to 2, and ≥2 years, respectively. The numbers of patients in each of the 0 to 1, 1 to 2, and ≥2-year groups were 34, 33, and 23, respectively. Patient weight loss was significantly higher 1 to 2 years following LAGB surgery than <1 year afterward (P = .03) and significantly higher ≥2 years than 1 to 2 years following LAGB surgery (P = .00016). This illustrates a

Table 1 Demographics

Variable	Value
Number	90
Age (y), mean ± SD	48.2 ± 6.2
Age (y), mean (range)	48.2 (22–73)
Women (%)	80
BMI (kg/m^2), mean ± SD	46.7 ± 7.5
BMI (kg/m^2), range	32–78
Follow-up (mo), mean	17.5
Follow-up (mo), range	1–67

BMI = body mass index.

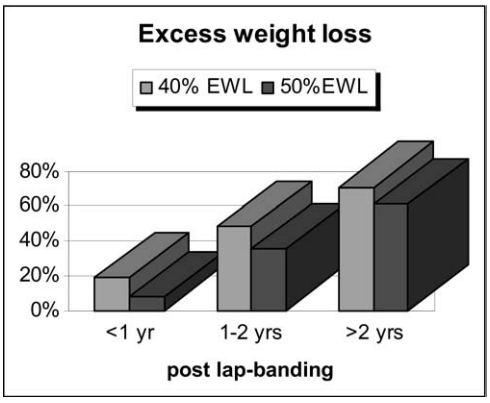

Figure 1 Average weight loss. EWL = excess weight loss.

lack of weight-loss plateau. Rates of 40% and 50% excess body weight loss are illustrated in Figure 1 for the <1, 1 to 2, and >2-year time intervals. Weight loss was not significantly associated with a good or excellent self-reported increase in activity ($P = .18$) or compliance with a healthy diet ($P = .14$).

On average, patients had a total of 4.14 adjustments of their bands and vomited 2.13 times per week. The mortality rate was 0%. No patient experienced unremitting dysphagia or vomiting, and there were no band slippages, no band erosions, and no mechanical failures. Two reservoir ports were repositioned under local anesthetic, and 1 patient underwent early laparoscopic exploration for reservoir tube–associated diaphragm irritation.

Overall, satisfaction was excellent or good in 87.5% of patients. Resolution or improvement in obesity-related illness is illustrated in Figure 2. GERD was worse in 25% patients. Operative times and hospital stays from our first and last 45 LAGB patients are illustrated in Figures 3 and 4, respectively, and there was a significant drop in these times in our later experience ($P = .006$ and $P = .005$, respectively).

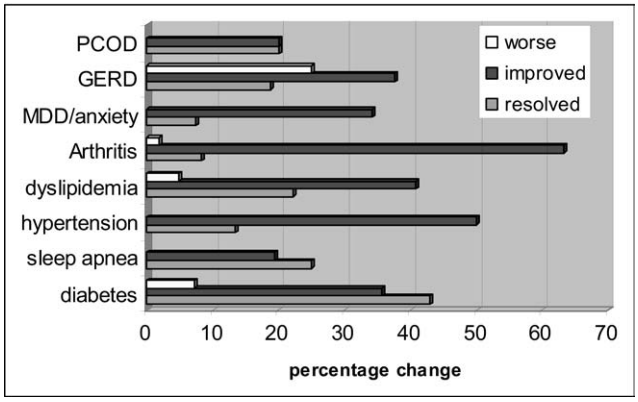

Figure 2 Obesity-related comorbidity improvement. MDD = major depression disorder; PCOD = polycystic ovarian disease.

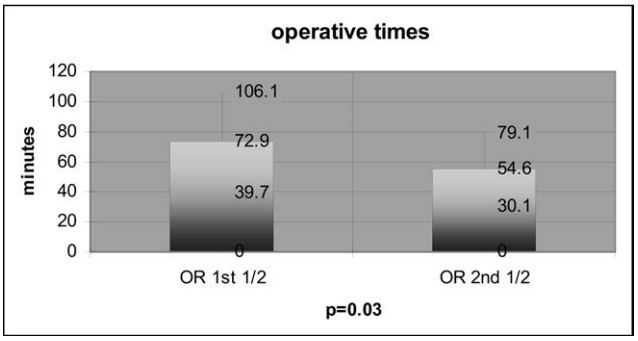

Figure 3 Operative times comparing first and second half of study (with standard deviations). OR = operating room.

Comments

Our weight loss and comorbidity results are comparable with the world LAGB literature.[1] We confirm that the bariatric LAGB surgery can be a safe and effective means for improving health-related complications in the western Canadian obese population. In our study and others, LAGB surgery demonstrates ongoing effective weight loss to 2 years and beyond.[4] Our excess body weight loss of 67% at >2 years is higher than or equivalent to that in most studies.[5,6] We did not compare our results with those of our gastric bypass patients, but these results have been published previously.[7] LAGB surgery has been reported to be more successful in patients with lower preoperative body mass indexes (<45 kg/m^2).[8,9] The average body mass index of the patients in this study was 46.7 kg/m^2, and this may explain the excellent weight loss results that were achieved.

In our experience, the improvement and resolution of medical comorbidities was similar to that of several other large LAGB series, particularly with respect to diabetes, hypertension, and dyslipidemia.[10–12] GERD symptoms significantly increased in our LAGB patients. The increased incidence of GERD symptoms is very important, because it may well lead to pouch dilatation and food intolerance.[13] It is also relevant given GERD's association with esophageal cancer. As a result, we have initiated closer GERD surveillance of our patients. To date, we have not documented any pouch dilatation or decreased weight loss in the GERD

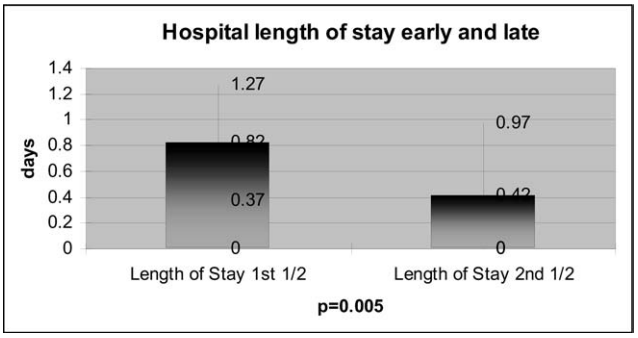

Figure 4 Hospital stays comparing first and second half of study (with standard deviations).

group of patients. However, our results are not long term, with 74% of the patients having ≤2 years of follow-up. Pouch dilatation and poor weight loss may occur at a later date, and close surveillance of this group is required. This association with GERD requires further evaluation in LAGB patients. It is important to recognize the limitations of our comorbidity data by the inherent bias in a self-report survey. The strength of this survey was its 96% response rate.

Our operative times are slightly longer than a series of 2,800 patients[14] (54.6 vs 32 minutes). This may represent an ongoing learning curve present in LAGB practice. Length of hospital stay in both our early and later patients was shorter than the 23 hours reported in this larger series.[14] This shorter length of stay resulted from our increased comfort with same-day discharges, a practice that has been shown to be safe.[15]

Our use of a low-pressure silicone gastric band has resulted in a low complication rate (0% for slippages, occlusion, and erosions) and is similar to other reported complication rates with these products (<2% slippage).[16] These complication rates are lower than those seen in more rigid gastric bands (11% and 7% occlusion and slippage rates for LAP-BAND [Allergan, Inc, Irvine, CA] and Swedish Adjustable Gastric Band [Obtech Medical, Baar, Switzerland]).[17] A further meta-analysis has substantiated the same concerns in these more rigid products.[18] Our excellent midterm results support the use of low-pressure gastric bands as surgical therapy for morbid obesity. We recognize that there are other factors involved in minimizing the LAGB-specific complications of band erosion and slippage. Some of these are surgical technique, surgeon experience, patient selection, postoperative patient care, and follow-up, as well as the physical characteristics of the band itself.

Further product comparison studies, including larger evaluation of low-pressure silicone-based bands with direct comparison with other bands, is required. This will ensure band development and refinements that improve outcomes and decrease complications of LAGB surgery. In the United States between 2004 and 2007, a total of 31,333 bariatric surgery procedures were performed in the University HealthSystem Consortium alone. This consortium represents 90% of the US nonprofit academic medical centers. During this time period, LAGB procedures increased from 7% to 23% of all bariatric procedures.[19] LAGB is now the most common bariatric procedure performed outside the United States.[20] Clearly, with the increasing prevalence of obesity and the use of LAGB for treatment, ongoing study of all gastric band products is required.

Although decreased slippage rates have been described with the pars flaccida technique compared with the original perigastric technique,[21] our results also question the necessity of the anterior gastric tunnel or fundic fixation suture(s). Because of the low slippage rate (0%) with either technique, our study was not statistically powered to analyze any differences in complications on the basis of these surgical technique changes. Longer follow-up and a greater number of patients are required to analyze the necessity of the anterior gastric fundic fixation suture(s) to prevent gastric slippage and band obstruction.

In summary, our first 5 years of LAGB experience has been promising with regard to low complication rates, sustained weight loss, and comorbidity improvement, particularly diabetes. The increased incidence of GERD in our study and its effect on the longer term success and complications of LAGB surgery has yet to be determined. This series reinforces the growing evidence that the low-pressure LAGB is an excellent modality for treatment of morbid obesity and its attendant medical comorbidities.

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Discussion

Dr. Emma Patterson (Portland, OR): Although this is a small series with a short term follow-up, the weight loss results are certainly excellent with patients receiving 66% of excess weight loss after more than 2 years. As the authors point out, these excellent results may in part be attributed to patient selection; these are relatively small patients (mean BMI of 46.7 kg/m^2) for North American population. Further, these patients are required to document extensively lifestyle changes for an extended 2-year waiting period before surgery. These factors likely contributed to the excellent clinical outcomes, yet make the results somewhat less generalizable.

Along with excellent weight loss, the authors have demonstrated excellent improvement in co-morbidities, such as diabetes, joint pain and hypertension. However, I would caution the use of a self-reported patient survey to determine the severity of obstructive sleep apnea. This serious co-morbidity is more reliably re-evaluated with overnight polysomnography or auto-titrating CPAP. Interestingly, while 56% of the patients in this study had improvement in GERD, another 25% experienced worsened symptoms. It would be interesting to know whether these patients were evaluated with UGI series to look for pouch dilatations or slips. The practice described in the manuscript of obtaining an UGI only after complete band deflation and ongoing protracted dysphasia or vomiting seems rather conservative. In my experience, the more aggressively you look for slips, the more you will find. A more standard approach to vomiting in a band patient would be to remove some fluid until they can eat, and then get an UGI.

The average presentation time for a slip is about 18 months, which corresponds with the average follow-up of this study. In the same time period of this study I performed 616 LAGBs and repaired 24 slips for a rate of 3.8%, which is consistent with the current literature. Statistically, there will likely be two or three slips in these 90 patients in this paper after two years.

Since 2004, there have been several improvements in banding technology and surgical technique which have led to reduced slip rates: the introduction of lower pressure bands (Allergan Lap-Band AP and Ethicon Realize band became available in the US in 2007), and also the more aggressive dissection of the diaphragmatic crura and repair of hiatal hernias. In the 382 bands I have performed in the last two years, I have fixed 7 slips so far (1.8%). Although this slip rate is decreased from our earlier series, I do expect it to increase with longer follow-up of these patients. For this reason, I think that long-term follow-up is important with band patients, as with all other bariatric patients. The authors see patients every three months, "until their weight loss is steady or weight loss goals are achieved." I'm curious what their long-term follow-up protocol is after three years.

Concomitant procedures, such as hiatal hernia repair are not mentioned in this series, and I wonder what the rate of such repair is in this series, how aggressively the authors sought out crural defects, and whether this rate increased over the five year study period. This paper also discusses the question of gastro-gastric suturing. Personally I have been a proponent of suturing and am one of several who have described the addition of an "anti-slip" gastro-gastric suture inferior to the band. I am aware of large series of low pressure LAGB without suturing reporting very low slip rates, but to my knowledge there are no controlled trials comparing suturing versus not.