

Outcomes of the adjustable gastric band in a publicly funded obesity program

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Background: Laparoscopic adjustable gastric banding (LAGB) is considered a safe and effective treatment for severe obesity and obesity-related comorbidities. We sought to examine the outcome of LAGB delivered through a Canadian publicly funded obesity program.

Methods: We retrospectively analysed the cases of patients who underwent LAGB within a comprehensive, multidisciplinary, publicly funded obesity program.

Results: A total of 178 patients underwent LAGB. Mean percentage total body weight loss at 1, 2 and 3 years was 15.8%, 20.7% and 20.3%, respectively. The most common short-term complication was postoperative nausea (19%). The medium-term complications included band migration (5.6%) and port site complications, band leakage and incisional hernia at 1% each. The reoperation rate was 4.5%. The mean surgery duration was 56 minutes and the mean length of stay was 1.4 days. The average numbers of clinic visits and band adjustments were highest in the first year. The most common investigation for postoperative symptoms was fluoroscopy (86%). An outcome comparison between the 2 generations of the REALIZE gastric band was inconclusive, requiring further data collection.

Conclusion: Publicly funded LAGB results in effective weight loss and acceptable safety over the short term. Our patients may represent a distinct population that differs from that in the private system. Long-term data are necessary to determine the cost-effectiveness of this important surgical option for severe obesity.

Contexte : L'anneau gastrique ajustable posé par laparoscopie (AGAL) est considéré comme un traitement sécuritaire et efficace contre l'obésité sévère et les comorbidités connexes. Nous avons cherché à analyser le résultat de la pose d'un AGAL réalisée dans le cadre d'un programme public de lutte contre l'obésité au Canada.

Méthodes : Nous avons analysé de façon rétrospective les cas de patients qui ont reçu un AGAL dans le contexte d'un programme intégré et multidisciplinaire de lutte contre l'obésité financé par le secteur public.

Résultats : Au total, 178 patients ont reçu un AGAL. La perte procentuelle moyenne totale de masse corporelle à 1, 2 et 3 ans s'est établie à 15,8 %, 20,7 % et 20,3 % respectivement. Les nausées postopératoires ont constitué la complication à court terme la plus fréquente (19 %). Les complications à moyen terme ont inclus le déplacement de l'anneau (5,6 %) et des complications du côté porte, la fuite au niveau de l'anneau et une hernie à celui de l'incision : elles ont atteint 1 % dans chaque cas. Le taux de répétition de l'intervention a atteint 4,5 %. L'intervention chirurgicale a duré en moyenne 56 minutes et le séjour moyen 1,4 jours. Le nombre moyen de visites à la clinique et celui des rajustements de l'anneau étaient les plus élevés au cours de la première année. Les symptômes postopératoires sont examinés le plus souvent par fluoroscopie (86 %). Une comparaison des résultats entre les 2 générations de l'anneau gastrique REALIZE n'a pas été concluante, ce qui oblige à réunir d'autres données.

Conclusion : La pose d'un AGAL financée par le secteur public entraîne une perte de poids efficace et offre une sécurité acceptable à court terme. Nos patients peuvent représenter une population distincte qui diffère de celle du secteur privé. Il faut des données à long terme pour déterminer la rentabilité de cette option chirurgicale importante en cas d'obésité sévère.

Laparoscopic adjustable gastric banding (LAGB) was first demonstrated successfully by Belachew and colleagues in 1995.¹ Despite the early enthusiasm and an explosive growth of interest in this technique for obesity surgery, there are reports of high complication and failure rates.^{2,3} Over

the years, with improvement of LAGB technique (transition from a perigastric to pars flaccida approach), the complication rate for LAGB has dropped to an acceptable standard.^{4,5} However, the current literature reports a mixture of results from the private and public systems, with no uniform long-term data. In addition, there is no consensus currently on patient selection criteria for LAGB.^{6,7} These controversies are reflected in that not all Canadian provinces fund LAGB as a treatment for obesity.

The publicly funded obesity treatment program at our institution is a referral-based, multidisciplinary clinic providing tertiary medical, psychological and surgical interventions. Our program recognizes obesity as a chronic disease and provides extensive preoperative multidisciplinary assessment and long-term follow-up after selecting the most appropriate patients for LAGB.

It is not known whether the current literature is representative of the outcomes that may be achieved in a Canadian, publicly funded system. We sought to examine and compare the short-term weight loss results achieved through LAGB in the publicly funded obesity program to those reported in the literature. The 2 generations of the REALIZE adjustable gastric band manufactured by Ethicon Endo-Surgery were used in this group of patients undergoing LAGB, and the difference in performance between the 2 products was also part of our investigation.

METHODS

Selection criteria and study design

The study was performed in accordance with the principles in the Declaration of Helsinki, and the Human Research Ethics board approved our study protocol. Patients who attended the Weight Wise Clinic (WWC) and underwent an LAGB procedure were identified from clinic records. The patients were initially referred to the WWC if they met the eligibility criteria.⁸ After completion of a multidisciplinary team evaluation and the medical management component of the program, the patients were educated on all of the available surgical obesity management options, including LAGB, gastric bypass and sleeve gastrectomy. Patients at this stage had a good understanding of obesity as a disease and had undergone lifestyle, behavioural and medical treatment modifications to address this condition. The type of surgery offered was based on patient choice after individual surgical consultation unless there was absolute contraindication owing to medical or surgical history. Currently, there is no strict patient selection criteria for LAGB in our publicly funded program other than those mentioned previously⁸ and successful completion of the multidisciplinary preoperative program.

We performed a retrospective study involving patients who underwent LAGB during a 6-year period from 2005 to 2010. Short-term weight loss results at 1-, 2- and 3-year

follow-up were analyzed. We excluded patients who underwent LAGB but had not reached at least a 1-year follow up postoperatively at our clinic from our analysis.

Outcome measurements

We calculated the weight loss results as both percentage total body weight loss (%TBWL) and percentage excessive body weight loss (%EBWL) based on an ideal body weight generated using a normal body mass index (BMI) of 24.9. The results were further categorized into initial and preoperative weight. Initial weight referred to follow-up weight compared to the weight recorded when the patient first arrived at the WWC. Preoperative weight referred to follow-up weight compared to the weight before surgery, typically after 12 months of lifestyle modifications and medical treatment. Comparison between the 2 data points helped to establish the effectiveness of conservative non-surgical weight management achieved at the WWC.

We separated our analysis of complications into 2 categories: short and medium term. Short term referred to the postoperative period before discharge from hospital, and medium term was the period from discharge up to 3-year follow-up. To determine the operational costs for ongoing LAGB care, we assessed the duration of surgery, length of stay (LOS), frequency of clinic visits and band fillings, and methods of investigation used during the follow-up period.

REALIZE gastric band comparison

We compared the first and second generations of the REALIZE adjustable gastric band manufactured by Ethicon Endo-Surgery (Real 1 and 2). The band type was identified by specific serial number from the manufacturer, and we examined the weight loss, complication rate, operative time and LOS between the 2 groups.

Statistical analysis

Statistical analysis was performed using Stata 10 software. Results are expressed as means and standard deviations (SD) with 95% confidence intervals. We considered results to be significant at $p < 0.05$.

RESULTS

Weight loss

We identified 178 patients who underwent LAGB during the study period: 153 women (86%) and 25 men (14%). The average age was 42.8 years, and the average preoperative BMI was 44.2 (SD 7). The weight loss results at 1, 2 and 3 years are presented in Table 1. The trends of weight loss over the 3 years are illustrated in Figure 1. Three patients' weight data were not included in the weight loss

analysis owing to early removal of band ($n = 1$) and complication or pregnancy affecting weight ($n = 2$) before 1-year follow-up. The preoperative conservative weight management achieved a %TBWL average of 4.4%.

Safety profile

The most common short-term complications were postoperative nausea (19%) and non-surgical site infections, such as pneumonia and urinary tract infections (1%). The medium-term complication rates are presented in Table 2. The reoperation rate was 4.5%.

Operational costs

In an analysis of operational costs, the average duration of surgery was 56 minutes, and the average LOS was 1.4 days. Clinic visits occurred most frequently in the first year, with an average of 7 visits, and dropped to 4 visits in the next 2 years. The average number of band fillings required was 3 fills in year 1, and 1 fill only in the other 2 years. We found that 36% of our patients required at least 1 investigation postoperatively. Fluoroscopy was the most common method (86%), followed by computed

tomography (9%) and upper endoscopy (4%).

REALIZE gastric band comparison

The comparison between Real 1 and 2 gastric bands is presented in Table 3. We found significant differences in preoperative BMI, weight loss and duration of surgery. The weight loss analysis was based on 1-year follow-up data because not enough patients who received the newer Real 2 band had complete 2-year follow-up data.

DISCUSSION

With an increasingly obese population in developed countries, bariatric surgery has been shown to be a successful treatment for obesity and its associated comorbidities.^{9,10} Our study demonstrates that LAGB is a safe and effective method of bariatric surgery in a Canadian system.

The weight loss achieved through LAGB in the short-term plateaued between the second and third year reaching a %TBWL of 20% and %EBWL of 44%. The %TBWL is the preferred method of discussing weight loss in our clinic, as it offers several advantages, including simplicity for patient understanding, and avoids discussion and calculations based on ideal body weight, which introduces unrealistic goals and discrepancy in reporting weight loss.¹¹ The %TBWL achieved through our program over the 3 years was greater than the reported average of 17%.¹⁰ Looking at the 3-year %EBWL reported in the literature, which averages around 50%, our results appear to be slightly

Table 1. Postoperative compared with initial and preoperative weight loss in patients who underwent laparoscopic adjustable gastric band surgery

Characteristic	Follow-up period; mean (SD)*		
	Year 1	Year 2	Year 3
No. of patients	175	79	38
Initial weight loss, kg	21.5 (12.2)	28.2 (16.4)	27.1 (14.4)
Average BMI	40.2 (6.5)	38.5 (7.9)	37.7 (7.7)
Total body weight loss, %			
Initial	15.8 (7.6)	20.7 (11)	20.3 (10)
Preoperative	9.9 (7.6)	15.1 (12)	16.8 (11)
Excess body weight loss, %			
Initial	34.1 (16)	44.0 (23)	43.4 (21)
Preoperative	20.9 (18)	34.7 (29)	37.5 (25)

BMI = body mass index; SD = standard deviation.
*Unless otherwise indicated.

Table 2. Medium-term complication rate from laparoscopic adjustable gastric band surgery during 3-year follow-up

Medium-term complication	%
Band migration	5.6
Port site complication	1.0
Band leakage	1.0
Incisional hernia	1.0

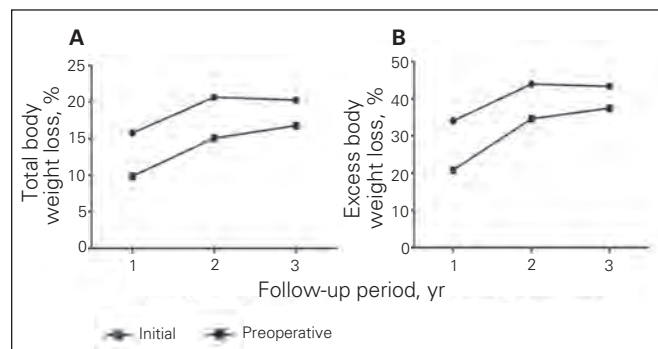


Fig. 1. Percentage total body weight loss and percentage excess body weight loss among patients who underwent laparoscopic adjustable gastric band surgery.

Table 3. Comparison between the first (Real 1) and second generation (Real 2) of the REALIZE adjustable gastric band at 1-year follow-up

Characteristic	Gastric band; mean (SD)*		p value
	Real 1	Real 2	
No. of patients	90	57	
Age, yr	44.2 (10)	41.1 (9.8)	0.09
Preoperative BMI	45.7 (7.9)	41.2 (5.4)	< 0.001
Operative time, min	52.1 (14)	55.1 (10)	0.013
LOS, d	1.40 (1.4)	1.20 (0.045)	0.73
Excess body weight loss, %	22.7 (20)	12.1 (14)	0.002
Complication, %	5.5	0	0.15

BMI = body mass index; LOS = length of stay; SD = standard deviation.
*Unless otherwise indicated.

inferior.¹² It is difficult to explain the apparent difference, especially when the literature data are pooled from both public and private centres with different patient selection criteria, preoperative management and follow-up processes. Calculation using %EBWL could also introduce inconsistency based on the method chosen to determine ideal weight.

One of the criticisms of LAGB is the lengthy and cumbersome follow-up, which can be difficult to maintain in a public system. The cost-effectiveness of obesity surgery has been demonstrated in moderately to severely obese patients.¹³ The high front-end costs can be seen in our data secondary to operation, LOS, investigations, clinic visits and band fillings. However, it is clear that the frequency of clinic visits and band fillings dropped significantly in the second and third years. The duration of surgery and LOS are among the shortest compared to other types of bariatric surgery. Many of our patients transitioned back to their family physicians for ongoing care, with stable weight established by the third year.

The high rate of postoperative nausea in our series may have resulted from multiple factors, such as anesthetic agents and tissue reaction from trauma of surgery and band placements. All of these were resolved with antiemetic agents before discharge. In severe cases, an upper gastrointestinal swallow study was conducted to rule out obstruction. With respect to safety, our complication rates were all within acceptable standards.¹⁴ The reoperation cases could mostly be attributed to band migration. The short duration of surgery, LOS, reversibility of the surgery and excellent complication profile make LAGB the least complex obesity surgery that a public system can offer.

Regarding the comparison between the first and second generations of the REALIZE gastric band, the data suggest significant differences in the duration of surgery and weight loss at 1-year follow-up. The surgery was 3 minutes longer in the newer Real 2 band group, which likely represents a small learning curve using the new product. The %EBWL was higher in the Real 1 group; however, the preoperative BMI between the 2 groups was also significantly different, with the Real 1 group having a higher BMI. Since the 2 groups' baseline characteristics were not identical, especially with respect to preoperative weight, it is difficult to determine whether the observed difference in %EBWL is truly significant. More data collection with longer follow-up will be needed to further investigate the difference in weight loss observed between patients who received the different bands.

CONCLUSION

Adapting bariatric surgery in the Canadian public health care system has the potential to alleviate ongoing health care burden from obesity-related disease. Our data suggest that the weight loss achieved with LAGB in a sustainable public program is substantial and successful. The safety of the procedure has also been demonstrated clearly. Long-

term data are still required to ultimately decide the true cost-effectiveness of LAGB in our system. The present study of the short-term results of LAGB in a Canadian, publicly funded program represents a realistic view of achievable weight loss through this safe and least complex obesity surgery option.

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Contributors: C.J. Chiu, D.W. Birch and S. Karmali designed the study. C.J. Chiu and S. Karmali wrote the article. All authors analyzed the data, reviewed the article and approved its publication.

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