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CLINICAL RESEARCH

Laparoscopic Gastric Banding Is Safe in Outpatient Surgical Centers

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Abstract
Background Due to constraints on resources and capacity, as well as advances in surgical technique and care, there has been progressive change toward converting surgical procedures to the outpatient setting when feasible. This study was designed to investigate the safety of laparoscopic adjustable gastric banding (LAGB) as an outpatient procedure for morbid obesity in Canada.
Methods This retrospective analysis included consecutive patients who underwent outpatient LAGB at the Surgical Weight Loss Centre in Ontario, Canada, beginning with our initial experience in February 2005 and continuing to July 2009. Eligible patients were morbidly obese adults whose outpatient clinic surgery had been performed by one of two experienced surgeons.
Results A total of 1,641 patients were included in this analysis. The average presurgical body mass index was 46.7 kg/m^2 (range 35.0 to 79 kg/m^2). Fifteen patients (0.91%) experienced minor complications during surgery or within 30 days of surgery (dysphagia, $n=5$; wound infection, $n=3$; port infection, $n=2$; all other complications occurred in one patient each). Four patients required transfer to hospital from the clinic on the day of surgery, and three were admitted. None of the complications were serious and all were resolved. The device was explanted in two patients. The average time from sedation to discharge was <4 hours (h).
Conclusions The ability to treat patients within 4 h and the extremely low complication rates reported here contribute to a growing literature supporting the safe performance of LAGB in an outpatient setting for the treatment of morbid obesity.

Keywords Laparoscopic gastric banding (LAGB) · Obesity · Lap-Band · Ambulatory · Outpatient · Freestanding clinic · Ambulatory clinic

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Introduction

Bariatric surgery is an established treatment option for morbidly obese patients, producing a significant and sustained decrease in percent excess weight loss (% EWL) and subsequent proven reduction in obesity-related comorbidities [1, 2]. Laparoscopic adjustable gastric banding (LAGB) is becoming an increasingly common bariatric surgical procedure for the management of morbid obesity in the USA, and remains the most commonly performed weight loss procedure in Australia, Canada, and most of Europe. The procedure is adjustable and reversible and is not associated with nutritional deficits that may accompany other techniques [3]. The increasing popularity of LAGB is due to its reduced complication rates, lower rate of perioperative adverse outcomes, shorter hospital stay, and lower readmission rates compared with other bariatric procedures [4–6].

Several features of LAGB make it suitable for the outpatient setting, including its low complication rate, the use of laparoscopy, and the predictable speed with which

the operation can be completed [7]. Outpatient procedures are desirable because they are more cost effective and are generally preferred by patients [7]. Investigators have reported success with the outpatient Roux-en-Y gastric bypass surgery [8–10], but the more invasive nature of this procedure will likely limit its applicability. Previous reports have shown that LAGB can be performed safely and effectively as an outpatient procedure [10, 11]. Other comparably invasive procedures such as laparoscopic cholecystectomy have long been successfully performed in the outpatient setting [12, 13].

In Canada, there are significant pressures on publicly funded hospital facilities. One method of addressing this problem is to move surgical procedures to the outpatient non-hospital facilities when possible. In order to further evaluate the safety of LAGB performed in an outpatient setting, we conducted a retrospective analysis of 1,641 patients treated by our center in Ontario, Canada.

Methods

Study Design and Patients

This study was a retrospective chart review of patients referred to the Surgical Weight Loss Centre (SWLC) in Mississauga, Ontario, Canada for the surgical treatment of morbid obesity. Eligible patients were those ≥18 years of age who had undergone outpatient LAGB between February 2005 and July 2009.

All procedures were carried out in a freestanding surgical facility that is located less than 2 km from a tertiary care facility (Trillium Health Centre, Mississauga, Ontario, Canada). The facility has two fully equipped operating rooms and all the specialized bariatric equipment necessary for gastric band procedures. Procedures are in place for transfer to the hospital if necessary. The recovery area has full monitoring capabilities and can accommodate up to six patients. Surgeons and anesthetists stay in the facility until the patient has met discharge criteria.

The procedures were performed by one of two experienced surgeons at the Centre (C.C. or D.M.) in the outpatient surgery clinic. Patients must have met the National Institutes of Health (NIH) definition for morbid obesity: a body mass index (BMI) ≥40 kg/m^2 or a BMI≥35 and <40 kg/m^2 with at least one associated comorbidity. This study excluded patients who were not morbidly obese, who had previous bariatric surgery, and those whose surgery was performed at the local hospital either as an admitted patient or outpatient (Table 1).

Each patient was individually assessed by the surgeon, in consultation with the anesthetist, as to the whether LAGB should be performed in the outpatient facility or at the hospital. The only absolute contraindications to outpatient surgery were untreated severe obstructive sleep apnea (OSA) and cardiac or respiratory comorbidities that would make general anesthesia unsafe.

Table 1 Patients excluded from the analysis

Reason for exclusion	Number of patients
BMI 35–39.9 kg/m^2 without comorbidities	283
BMI<35 kg/m^2	148
Planned surgery in hospital	72
Previous bariatric surgery	23
Total	526

Patient comorbidities were assessed by questionnaire and by the surgeon at the time of the consultation. Only patients who were receiving active pharmacotherapy for diabetes, hypertension, hypercholesterolemia or asthma, or continuous positive airway pressure treatment for OSA were listed as having the associated comorbidity for the purpose of this study.

As part of the pre-operative protocol of SWLC, all patients were directed to use a very low calorie diet (VLCD) product (Optifast®). This was done to reduce fatty infiltration of the liver as previously reported [14, 15]. The duration of VLCD therapy was at least 2 weeks for all patients and varied with their weight at the time of the surgical consultation.

Surgical Technique

All LAGB procedures were performed using the LAP-BAND® Adjustable Gastric Band (Allergan, Inc., Irvine, CA, USA) and the standardized pars flaccida technique. Repair of the diaphragmatic crura was performed in 47% of patients in this study and is now a standard part of the procedure at our center for patients who present with such upon initiation of LAGB surgery. Our standard technique utilizes three or four anterior gastro-gastric sutures of 2-0 Ethibond™ to anchor the band as well as a single suture to plicate the anterior surface of the stomach below the band. The access port is anchored to the fascia of the abdominal wall using four 0 silk sutures. The access port incision is closed with suture to close the subcutaneous space and monofilament absorbable suture in the skin. Local anesthesia is infiltrated in the skin.

Standard anesthesia techniques are used. Anesthesia is induced with patients in a semi-upright position. Propofol, inhalational agents, and short-acting neuromuscular blockade are used. All neuromuscular blockade is reversed before patients leave the operating theater. Patients are nursed in the semi-upright or upright position in the recovery room. The use of narcotic analgesics and sedation is minimized. Discharge criteria include satisfactory oxygenation on room air, absence of bleeding, control of pain and nausea, ability to drink water,

and ability to ambulate. When these criteria are met, patients are discharged into the care of a responsible adult who must be with them for at least 24 h. All patients receive a follow-up call on the morning after surgery.

Medical Records Review

All files are maintained electronically at the clinic, and the data pull used the entire population of patients treated with LAGB at SWLC to identify all consecutive patients who met the inclusion criteria.

For each eligible patient, the following variables were entered into an electronic spreadsheet: patient age, sex, weight, and BMI prior to surgery; anesthesia time (from initiation to completion of anesthesia); recovery time (from the time the patient enters the recovery room to time of discharge); and complications. Events were classified as complications if they resulted in hospitalization or additional unplanned medical or surgical intervention. Only complications that occurred prior to discharge on the day of surgery, or within 30 days of surgery, were evaluated for the present analysis.

Complications

Complications were graded on the I–V scale described by Parikh and colleagues (Table 2) [4], which is based on the widely used scale for surgical complications developed by Clavien et al. [16]. This scheme was used to maintain objectivity in the grading of complications by assessing the consequence of the complication rather than the event itself [17]. Hospitalizations, surgical interventions, and other consequences were also classified according to this scheme. The timing of each complication was recorded.

For internal record-keeping and to ensure patient safety, all known complications, both short and long term, are recorded in our medical records. For the purpose of this study, all recorded complications that occurred the day of surgery and anytime within the first 30 days of surgery were analyzed and included in this analysis. Any complications that occurred after this time frame were not considered to be associated with whether the procedure was performed on an outpatient basis or not and therefore were excluded from this analysis.

Outcome Variables and Statistics

Outcome variables included (1) rate and grade [4] of complications overall, (2) comparison of complications between the current LAP-BAND AP™ System (standard and large size; Allergan, Inc.) and previous models, LAP-BAND™ System 10 (Allergan, Inc.), and LAP-BAND™ System VG (Allergan, Inc.), and (3) comparison of complications for the first 100 patients (putative learning curve effect) versus subsequent patients. We also evaluated anesthesia time (time from initiation to completion of anesthesia) and recovery time (time from patient entry into the recovery room to departure from the clinic).

Descriptive statistics and frequency tables were used to summarize patient demographics, clinical characteristics, and complications, as well as anesthesia and recovery times. Statistical analyses of physician experience (first 100 patients versus subsequent patients) and LAGB model were conducted using Fisher's exact tests. P values <0.05 were considered statistically significant.

Results

Patients

A total of 2,167 patients underwent LAGB for the treatment of morbid obesity at the SWLC between February 2005 and

Table 2 Parikh's classification of complications from bariatric operations [4]

Grade	Definition
I	Events carrying "minor risks"
	1. Not life threatening
	2. Not requiring use of drugs other than analgesics, antireflux agents, antipyretics, antiemetics, antidiarrheals, or drugs required for urinary retention or low urinary tract infections
	3. Requiring only interventions that can be performed at the bedside
	4. Never associated with hospital stay greater than twice the median stay for the procedure
IIa	Events requiring use of drug therapy, TPN, or blood transfusions or events requiring hospital stay greater than twice the median stay
IIb	Events requiring therapeutic imaging procedures, therapeutic endoscopy, or reoperation (not requiring organ resection or anastomotic revision)
III	Events with residual and lasting disability and/or requiring organ resection
IV	Death as a result of any complication

Adapted from [4], with permission from Elsevier

July 2009. Of these patients, 526 did not meet the inclusion/exclusion criteria (Table 1), leaving a total of 1,641 included in the present analysis.

Patient demographics and clinical characteristics are shown in Table 3. Most patients were female, and the average age was 44 years (range 18 to 73 years, median 44 years). The average overall BMI was 46.7 kg/m^2 (range 35.0 to 79 kg/m^2, median 45.4 kg/m^2). Of the 1,641 patients in the study, 1,592 (97.0%) used a very low calorie diet (VLCD) product (Optifast®) prior to surgery as part of the pre-operative protocol of SWLC.

Over half of the patients reported at least one comorbidity (59.6%), with 28.5% reporting two or more comorbidities (Table 3). The most frequently reported comorbidity was hypertension, followed by high cholesterol, sleep apnea, diabetes, and asthma (Table 3).

The American Society for Anesthesiologists (ASA) status of patients is shown in Fig. 1. More than 95% of patients had an ASA status of 2 or 3. Procedural durations are presented in Table 4. As can be seen from the table, anesthesia time was, on average, 82 min, and recovery time was just over 2 h. Thus, the average total duration of the anesthesia and recovery times together was less than 4 h.

A total of 1,081 surgeries were performed by C.C., and 560 surgeries were performed by D.M. The majority of patients were implanted with the LAP-BAND AP™ System standard device (n=1,065; 64.9%), followed by LAP-BAND AP™ System Large device (n=338, 20.6%), LAP-BAND™ System 10 (n=145; 8.8%), and LAP-BAND™ System VG (n=93; 5.7%).

Overall Complications

There were no mortalities or serious complications in this series.

A total of 15 of 1,641 patients (0.91%) experienced complications on the day of surgery or within 30 days of surgery (Table 5), with each of these patients experiencing no more than one complication. The complication occurred on the day of surgery for five of the patients and within 30 days post-surgery for 10 of the patients (Table 5). The severity levels of the complications were grade I in three patients, grade IIA in eight patients, and grade IIB in four patients, according to the classification of Parikh and colleagues [4]. Complications were resolved for all 15 patients.

All five complications that occurred on the day of surgery were resolved without conversion to laparotomy, and in all of these cases, the device remained implanted. Four patients were transferred to the hospital, and one was discharged from hospital the same day. Six of the 10 patients with a post-surgical complication required reoperation and were admitted for hospitalization for at least one night. The device was explanted in two patients. The mean duration for nine of the 10 patients admitted for overnight stay was 2.0 days (range 1–7 days); one patient had a stay of 60 days. This patient returned to her home, which was distant from our facility. The diagnosis and management of a subsequent port infection were delayed and eventually required removal of the entire LAGB device.

An analysis of complication rates among the various band models revealed no statistical significance in compli-

Table 3 Patient demographics and baseline characteristics

Characteristic	N=1,641
Age (years), mean (SD, range)	44 (10.9, 18–73)
Gender—female, *n* (%)	1,324 (80.7%)
Weight upon admission for surgery (kg), mean (SD, range)	131 (24.3, 81–264)
BMI upon admission for surgery (kg/m^2), mean (SD, range)	46.7 (7.0, 35–79)
VLCD, *n* (%)	1,592 (97.4)
Comorbidities, *n* (%)	
Hypertension	602 (36.7)
High cholesterol	333 (20.3)
Sleep apnea	288 (17.6)
Diabetes	258 (15.7)
Asthma	240 (14.6)
Number of patients with 0–5 comorbidities, *n* (%)	
0	663 (40.4)
1	510 (31.1)
2	250 (15.2)
3	159 (9.7)
4	55 (3.4)
5	4 (0.2)

VLCD very low calorie diet

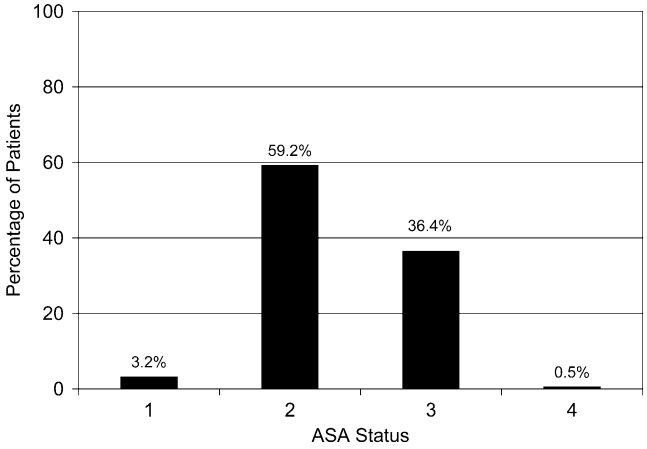

Fig. 1 Percentage of patients at each ASA status level. Data were missing for seven patients (0.4%)

cation rates when comparing the current model, LAP-BAND AP™ System AP (standard and large sizes were combined; 11 complications out of 1,403 implanted) versus the older generation models, LAP-BAND™ System 10 and VG combined (total of four complications out of 238 implanted) (p=0.2557). If complication rates between the current AP models and each of the two older models used are compared separately, still no difference in complication rates is found (p=0.1739). It is notable here that the older models (10 and VG) were used early on in the surgeons' experience. It is therefore difficult to decipher whether any difference in complication rates (which are not significant) between band models are due to the band models themselves or perhaps because the older models were used earlier in the surgeons' learning curve.

Complications by Surgeon Experience

Although the percentage of complications observed among the first 100 patients for each surgeon was more than twice as high as that among subsequent patients, the difference was not statistically significant. Of the first 100 patients for each physician, four experienced complications (four of 200; 2.0%), in contrast to 11 of the subsequent 1,441 patients (0.8%) (P=0.0993).

Complications in Excluded Patients

Although various cohorts of patients were excluded from formal statistical analysis for the purpose of this paper (as outlined in the exclusion criteria above), there was one complication in a patient who did not meet the NIH criteria for morbid obesity. This patient had minor bleeding that did not require transfusion, but this patient did require overnight hospitalization for observation. There were no other short-term complications reported in the excluded cohorts of patients.

Discussion

The present results add to a growing literature documenting the safety of performing LAGB in the outpatient setting [7, 11, 18, 19]. In this report, 15 of 1,641 (0.91%) experienced complications during surgery or within 30 days of surgery, and none of these were life threatening. This low rate of intra- and perioperative complications of LAGB surgery in the outpatient setting is in line with those reported by several other groups, as shown in Table 6. In an early feasibility study conducted at a clinic in Belgium, De Waele and colleagues did not note any complications in their group of 10 patients during surgery or in the first 30 days post-surgery [18]. A subsequent study in the USA reported that 2.8% of 343 patients experienced complications [19], and a further study reported that 1.2% of 320 superobese patients (mean BMI 55.4 kg/m^2) experienced intra- or perioperative complications [7]. In the single study to follow outpatients for 1 year post-surgery, 10% of 2,411 patients experienced complications, the majority of which were longer-term complications such as band slippage and erosion [11].

The purpose of this report is to document complications related to the performance of LAGB as an outpatient procedure. It is reasonable to assume that any complications related to the procedure itself will be detected within 30 days of the surgery. As previously noted, the rate of complications in other studies with short-term follow-up of outpatient LAGB procedures has ranged from 0% to 2.8% (Table 6). The rate of long-term complications tends to be somewhat higher—4.3% and 10% in the two published studies [7, 11], but long-term complications are unlikely to be related to whether or not the patient was discharged the same day.

Our results showed that the complication rate tended to decrease with physician experience, although the results were not statistically significant—probably because of the low overall rate of complications. Of the first 100 patients for each surgeon, four (2%) experienced complications, whereas the complication rate for the subsequent 1,441 patients was less than half that—only 0.8%. Other investigators have also reported the beneficial effects of physician experience on complication rates [20], as well as the successful performance of the surgical procedures overall [19]. Some have argued, and we agree, that the

Table 4 Procedural durations/outcomes

Procedural outcome	N=1,641
Anesthesia time (min), mean (SD)	82.4 (20.5)
Recovery time (min), mean (SD)	125.5 (29.0)
Diaphragmatic crural repair, n (%)	778 (47.4%)

Table 5 Complications during or within 30 days of surgery

	All patients (N=1,641)	Complication grade[a]	Resolution
Total patients with complications	15		
Complications day of surgery	5		
Needle left in patient	1	IIB	Diagnostic (exploratory) laparoscopy, retrieval of lost needle 2 days post-op
Subcutaneous emphysema	1	IIA	Hospitalization, observation overnight
Back pain	1	IIA	Hospitalization, observation overnight
Shortness of breath	1	IIA	Transfer to hospital, discharged same day
Dysphagia	1	IIA	Hospitalization, observation overnight
Post-surgical complications	10		
Dysphagia	4	IIA	Hospitalization, band emptied (n=3)
			Hospitalization, observation (n=1)
Port infection	2	IIB	Hospitalization, entire device removed after delay (n=1)
			Hospitalization, port removed (n=1)
Wound infection	3	I	Wound debrided
Peritonitis	1	IIB	Hospitalization, laparoscopic removal of gastric band

[a] Complications graded according to Parikh's scheme [4] (see Table 1)

experience of anesthesiologists with bariatric surgery is equally critical to successful outcomes, as is the ability of surgeons to perform the procedure quickly (approximately 1 h, on average) [7]. Combined with the present trend toward reduced complication rates over time, these observations strongly suggest that physician (surgeon and anesthetist) experience and practice effects are essential to maximizing the benefit-risk ratio of LAGB and bariatric surgery in general.

Other authors [11, 19] have developed inclusion and exclusion criteria for ambulatory LAGB surgery. We have used these criteria and others for guidance, but our approach has been that the decision to perform surgery at the hospital as opposed to the clinic, or as an inpatient, should not be rigid, but is more appropriately based on the comorbidities and health status of the individual patient, as well as the experience of the surgical team. The decision as to the location is made after consultation between the surgeon and the anesthetist. There were no absolute contraindications to outpatient surgery. Comorbidities such as sleep apnea, hypertension, and cardiac and pulmonary disease, as well as diabetes, were not considered contraindications unless they were untreated and not controlled.

When we began our program, we were cautious and performed surgery on high BMI and higher risk patients at the hospital. The first six patients had LAGB surgery at the hospital to ensure the safest environment possible. For the next 18 months, patients over 350 lb (159 kg) routinely had surgery at the hospital. This was due to limitations of equipment available at the clinic and due to the recognized limitations of our experience with super obese patients. We were able to discharge these super obese patients safely from the hospital the same day and therefore began to expand the criteria for patients who would be candidates for LAGB surgery in our freestanding surgical clinic. We have now changed the weight limit to 475 lb (215 kg) for outpatient LAGB surgery at our clinic. We continue to review the medical history of each patient carefully before assigning him or her to surgery at either the clinic or at the hospital.

We have not experienced complications specifically associated with higher BMI patients, nor specifically associated with obstructive sleep apnea (OSA) of any severity. Specific protocols and care maps have been established to identify and treat these risk factors. There was only one respiratory-related complication in this series: one case of mild respiratory distress (shortness of breath likely related to chest discomfort), for which the patient was admitted and released from the hospital the same day. The discussion of the management of OSA in ambulatory bariatric surgery was not a specific goal of this study.

We did not analyze information on weight loss for our population of patients as part of this study. However, % EWL at 1 year after LAGB implantation has ranged from approximately 40% to 50% in several previous studies [1, 11, 21, 22]. Many studies have shown that although initial weight loss with LAGB may be slightly lower than Roux-en-Y gastric bypass procedures, medium-term weight loss (3–10 years) is comparable between these two procedures [1].

LAGB is associated with significantly fewer overall complications and significantly fewer severe complications

Table 6 Summary of complications in adults with outpatient LAGB in the published literature

Study	Number of patients	Mean BMI (kg/m^2)	Follow-up duration (months)	Patients with intraoperative or post-operative complications
Present study	1,641	46.7	1	15 (0.91%)
				5 dysphagia
				3 wound infections
				2 port infections
				1 each: shortness of breath, subcutaneous emphysema, back pain, needle left in patient, peritonitis
De Waele [18]	10	38.4	1	0
Watkins [22]	343	44.5	Not listed	9 (2.8%)
				5 stoma occlusions
				3 port problems
				1 superficial wound infection
				1 colon perforation
Montgomery [7]	320 (superobese)	55.4	Intra- or perioperative[a]	4 (1.2%)
				3 stoma occlusion or gastric edema
				1 colon perforation
			Late[a]	10 (3.1%)
				7 port problems
				2 eroded bands
				1 slipped band
Watkins [11]	2,411 (2,027 outpatient; results not reported separately)	45.7	12	241[b] (10%)
				1 death
				1 conversion to open procedure
				6 superficial wound infections
				1 pulmonary embolus
				40 gastric edemas
				56 port problems
				124 slip/pouch dilations
				13 band explanations

[a] Duration not defined

[b] Although the individual events add to 242, the number 241 was used as per the published article by Watkins and colleagues [11]. This does not alter the percentage of patients with adverse events.

than Roux-en-Y gastric bypass surgery [4, 6]. In an American study that compared inpatient LAGB with laparoscopic gastric bypass procedures in 31,333 patients, LAGB was associated with significantly shorter hospitalization, lower morbidity, lower 30-day readmission rate, lower in-hospital mortality, and lower hospital costs [5]. Outpatient LAGB may be expected to result in even greater cost savings. Cost analysis of outpatient LAGB surgery was not a part of this study but it will be important to address this issue in future studies.

Results of the present study, combined with those in the published literature [7, 11, 18, 19], suggest that the low complication rate associated with outpatient LAGB—particularly in the hands of experienced surgeons—provides an important treatment option for obese patients. LAGB is a reproducible operation that allows comparison between centers in both efficacy and safety. From the present results, we conclude the following:

1. Low complication rates support the argument that morbidly obese patients can be treated safely and effectively outside of traditional hospital settings with LAGB surgery.
2. Effective patient selection for outpatient procedures can be individualized to each patient's medical history and risk factors, as opposed to rigid criteria.
3. Complication rates tend to decrease as physician experience increases.

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Conflict of interest statement Dr. Cobourn was the recipient of an unrestricted educational grant from Allergan Inc. LAP-BAND is a registered trademark of Allergan, Inc. L. Wells is an employee of and owns stock in Allergan, Inc. M.A. Chapman has received compensation from and owns stock in Allergan, Inc.

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