

Laparoscopic sleeve gastrectomy at a new bariatric surgery centre in Canada: 30-day complication rates using the Clavien–Dindo classification

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Background: Newfoundland and Labrador (NL) has the highest rate of obesity in Canada, prompting the establishment of a bariatric surgery program at the Health Sciences Centre in NL. This retrospective study examined 30-day complication rates in more than 200 consecutive patients who underwent laparoscopic sleeve gastrectomy (LSG) between May 2011 and February 2014.

Methods: We performed a chart review and collected data on 30-day postoperative complications. Complications were graded and reported using the Clavien–Dindo classification. Grades I and II were defined as minor and grades III and higher were defined as major complications.

Results: We reviewed the charts of the first 209 patients to undergo LSG. The mean body mass index was 49.2, 81% were women and the average age was 43 years. Comorbidities included hypertension (55.0%), obstructive sleep apnea (46.4%), dyslipidemia (42.1%), diabetes (37.3%), osteoarthritis (36.4%) and cardiovascular disease with previous cardiac stents (5.3%). Furthermore, 38.3% of patients reported psychiatric diagnoses, such as depression and anxiety. The overall 30-day complication rate was 15.3%. The complication rate for minor complications was 13.4% and for major complications was 1.9% (2 leaks, 1 stricture and 1 fistula).

Conclusion: Our results support the feasibility of safely performing LSG surgery at bariatric centres completing fewer than 125 procedures annually.

Contexte : Comme la province de Terre-Neuve-et-Labrador (T.-N.-L.) a le taux d'obésité le plus élevé au Canada, un programme de chirurgie bariatrique a été mis en place au Centre des sciences de la santé de T.-N.-L. La présente étude rétrospective a étudié les taux de complications dans les 30 premiers jours chez plus de 200 patients consécutifs ayant subi une gastrectomie longitudinale laparoscopique (GLL) entre mai 2011 et février 2014.

Méthodes : Après avoir effectué une analyse des dossiers et recueilli des données sur les complications postopératoires survenues dans les 30 jours, nous avons évalué et consigné les complications à l'aide de la classification de Clavien–Dindo. Les grades I et II étaient des complications mineures et les grades III et plus, des complications majeures.

Résultats : Nous avons analysé les dossiers des 209 premiers patients à avoir subi une GLL. L'indice de masse corporelle moyen était de 49,2, 81 % des patients étaient des femmes et l'âge moyen était de 43 ans. Les comorbidités comprenaient l'hypertension (55,0 %), l'apnée obstructive du sommeil (46,4 %), la dyslipidémie (42,1 %), le diabète (37,3 %), l'arthrose (36,4 %) et les maladies cardiovasculaires avec des antécédents d'endoprothèses cardiaques (5,3 %). De plus, 38,3 % des patients ont mentionné un diagnostic psychiatrique, comme la dépression ou l'anxiété. Le taux global de complications dans les 30 jours était de 15,3 %. Le taux de complications mineures était de 13,4 % et celui de complications majeures, de 1,9 % (2 fuites, 1 striction et 1 fistule).

Conclusion : Nos résultats viennent confirmer qu'il est possible d'effectuer des GLL de façon sécuritaire dans les centres bariatriques qui pratiquent moins de 125 interventions par année.

Obesity, defined as a body mass index (BMI) of 30 or higher, has been associated with comorbidities, such as diabetes, obstructive sleep apnea, cardiovascular disease, hypertension and dyslipidemia, as well as an increased incidence of certain cancers.¹ Although numerous treatment options exist for obesity, bariatric surgery has proven to be the only effective treatment

resulting in substantial and sustainable weight loss, substantial improvement in comorbid conditions and quality of life, and reduction in the risk of death.^{2,3} According to Canadian guidelines, surgical treatment of adult obesity is indicated in medical refractory patients with a BMI of 40 or higher or with a BMI of 35 or higher combined with at least 1 comorbid condition.⁴

Newfoundland and Labrador (NL) has the highest rates of obesity in Canada, with estimated increases projected.⁵ In 2011, Eastern Health established a provincial bariatric surgery program in NL at the Health Science Centre. This multidisciplinary program consists of 3 surgeons, a nurse practitioner and a dietician, with referral to other allied health professionals if required. Laparoscopic sleeve gastrectomy (LSG) is the primary bariatric procedure (96%) performed at this centre.

Laparoscopic sleeve gastrectomy originated as an initial step of a 2-step procedure known as the biliopancreatic bypass. It has gained popularity and is currently the second most commonly performed bariatric surgery in Canada.⁶ Its relatively short duration of surgery, shorter learning curve and lower complication rates make it an increasingly popular alternative to the laparoscopic Roux-en-Y gastric bypass (LRYGB).⁷

Current literature provides evidence that supports lower complication rates with LSG than with LRYGB.^{8,9} A 2010 systematic review of 15 studies including 940 patients analyzed the clinical outcomes and operational impact of LSG. The authors reported a major complication rate (e.g., staple line leakage and internal bleeding) ranging from 0% to 29%. The range was 0%–5.5% for leakage and 0%–15.8% for bleeding. Mortality ranged from 0% to 3.3%. In the systematic review some studies reported all minor complications (e.g., vomiting, nausea and diarrhea), and others did not, confounding the analysis.¹⁰ In a more recent systematic review and meta-analysis on the effectiveness and risks of bariatric surgery, Chang and colleagues² reported complication rates associated with LSG from both randomized controlled trials (RCTs) and observational studies. The meta-analytic results from the 10 observational studies ($n = 3647$ patients) reported perioperative and postoperative mortality for LSG as 0.29% and 0.34%, respectively. The complication rate after LSG ranged from 8.9% (8 observational studies, $n = 4987$ patients) to 13% (2 RCTs, $n = 137$ patients).²

In response to a growing number of people living with obesity, specifically those with severe obesity (BMI ≥ 35), there has been an increase in the volume of bariatric surgeries performed in many Canadian provinces. In Canada, 28% of bariatric procedures performed between 2012 and 2013 were LSG.⁶ With the increasing number of LSG procedures being performed, outcome assessment is of utmost importance.

The Surgical Review Corporation (SRC), American Society of Bariatric Surgery (ASBS) and Bariatric Surgery Center of Excellence (BSCOE) established guidelines to ensure patient safety and operative quality.¹¹ While the NL program complies with some of the criteria (i.e., including a dedicated

bariatric team and long-term patient follow-up) for a BSCOE, operative volumes are less than the minimum annual 125 bariatric procedures required to be classified as a COE.¹² The purpose of this study was to assess 30-day complication rates and mortality in the first 209 consecutive patients undergoing LSG. We used the Clavien–Dindo classification system to grade and report surgical complications in a standard and comparable format to allow valid and reliable comparisons.¹³

METHODS

Study setting

The Provincial Bariatric Surgery Program was established in May 2011. This multidisciplinary team consists of 3 surgeons trained in bariatric surgery, a nurse practitioner and a dietician. The 3 surgeons (D.P., D.B., C.S.), who performed all procedures in this study, have advanced laparoscopic skills. Two of the surgeons (D.P. and C.S.) are fellowship-trained in minimally invasive and bariatric surgery.

Study design

We conducted a cross-sectional study of all patients who underwent LSG between May 2011 and February 2014 in the NL Bariatric Surgery Program. Newfoundland's Health Research Ethics Authority approved this study.

The eligible population consisted of all patients meeting the Canadian clinical practice guidelines⁴ criteria for the surgical treatment of obesity (BMI ≥ 35 with risk factors, or BMI ≥ 40) who were referred by their primary care provider to the bariatric team using a standardized referral form submitted to a central intake system and who underwent preliminary eligibility screening with the nurse practitioner. Following mandatory attendance at a presurgical bariatric surgery general orientation and an education session provided either face-to-face or via webinar, patients were required to undergo extensive preoperative work-up, including a 2-week diet trial (1 wk full-fluid diet and 1 wk healthy eating), and to complete a food journaling activity. All patients met with the nurse practitioner one-on-one or via Telehealth for further assessment, including a detailed review of their weight history and past weight loss attempts, bloodwork and a sleep study to identify and treat any sleep-disordered breathing, as necessary. If any other medical concerns were identified, patients were referred for consultation with the appropriate specialist (e.g., cardiologist, endocrinologist, respirologist) based on the comorbid condition. An appointment with 1 of the 3 bariatric surgeons in the bariatric surgery clinic was arranged to obtain formal surgical consent.

Participants

We included patients aged 19–70 years with a BMI ≥ 40 or ≥ 35 as well as severe obesity-related comorbidities who

had attempted nonsurgical weight loss in the past and who were deemed medically, psychologically, and emotionally stable to consent to surgery and partake in a diet and lifestyle modification regimen. We excluded patients who were pregnant or planning a pregnancy within 2 years of surgical treatment, who had a medical condition that would make surgery too risky (i.e., not fit for surgery), and who had a BMI > 60.

Operative procedure

Two surgeons were present for all LSG procedures. All cases involved a 5- or 6-port approach. The vascular supply of the stomach was divided along the greater curve, starting 5 cm proximal to the pylorus and carried to the angle of His. A gastric sleeve was created using 60 mm linear staplers along with a 42-Fr bougie, which was advanced via the oropharynx into the stomach by the anesthesiologist. The gastric specimen was removed via the left upper quadrant port site. The staple line was leak-tested with a gastroscope. On postoperative day 1, all patients underwent a gastrografin swallow to assess for a leak from the gastric staple line and to ensure patency on the sleeve. If no problem was identified, patients were started on a clear liquid diet and generally discharged home on postoperative day 2 with dietary instructions. Follow-up visits with the multidisciplinary team were scheduled at 1, 3, 6, 12, 18 and 24 months and annually thereafter. Patients followed up with their surgeon at 6 weeks and as needed from then on.

Data collection

We reviewed the charts of all patients included in our study. For each chart, a single data collector (V.F.) reviewed preoperative and postoperative clinic visit records, relevant laboratory investigations and hospital discharge summaries. We collected data on patient demographics, postoperative complications and mortality. We used the Clavien–Dindo (CD) Classification (Table 1) to grade the complications, and we then grouped the complications as minor and major.¹³ Minor complications were defined as CD grades I and II, and major complications were defined as CD grades III–V. All complications were independently reviewed by the data collector (V.F.) and 1 of the surgeons (D.P.); inter-rater agreement was 100%.

Statistical analysis

We conducted our analyses using SPSS for Windows version 21 (IBM). Categorical variables are described using frequencies and percentages. Continuous variables are described using means and standard deviations if they were normally distributed or medians and interquartile ranges if they were not normally distributed.

RESULTS

Between May 2011 and February 2014, 209 patients underwent LSG at our centre. The mean preoperative BMI was 49.2 (range 35.0–67.4), 81% of patients were women, and the average age was 43.4 (range 22–70) years. The 4 most common obesity-related comorbidities among the patients were hypertension (55.0%), obstructive sleep apnea (46.4%), dyslipidemia (42.1%) and diabetes (37.3%) (Table 2). All procedures were successfully completed laparoscopically. Data on the duration of surgery were available for 206 patients and ranged from 40 to 177 min (mean 78.63 ± 23.43 min). Mean hospital length of stay

Table 1. Clavien–Dindo classification of surgical complications¹³

Grade	Description
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiologic interventions. Acceptable therapeutic regimens are drugs, such as antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
II	Requires pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions, antibiotics and total parenteral nutrition are also included.
III	Requires surgical, endoscopic or radiological intervention.
IIIa	Intervention under regional/local anesthesia.
IIIb	Intervention under general anesthesia.
IV	Life-threatening complication requiring intensive care/intensive care unit management.
IVa	Single-organ dysfunction.
IVb	Multiorgan dysfunction.
V	Patient demise.

Table 2. Characteristics of first 209 patients undergoing LSG

Characteristic	Mean ± SD [range] or no. (%)
Age, yr	43.4 ± 9.55 [22–70]
Female sex	169 (80.9)
Preoperative weight, kg	134.3 ± 23.31
Preoperative BMI	49.2 ± 6.72
Duration of surgery, min	78.63 ± 23.43 [40–177]
LOS, d	2.2 ± 1.26 [1–16]
Comorbidity	
HTN	115 (55.0)
OSA	97 (46.4)
Diabetes	78 (37.3)
GERD	76 (36.4)
CVD	11 (5.3)
OA	76 (36.4)
DLD	88 (42.1)
Anxiety/depression	80 (38.3)

BMI = body mass index; CVD = cardiovascular disease; DLD = dyslipidemia; GERD = gastroesophageal reflux disease; HTN = hypertension; LOS = length of stay; LSG = laparoscopic sleeve gastrectomy; OA = osteoarthritis; OSA = obstructive sleep apnea; SD = standard deviation.

was 2.2 ± 1.26 (range 1–16) days. There was no 30-day postoperative mortality.

Eight (3.8%) patients experienced CD grade I complications: 4 required intravenous fluid rehydration, 2 had a rash requiring antihistamines, 1 had urinary retention, and 1 had a substantial drop in hemoglobin leading to prolonged LOS but not transfusion. Grade II complications occurred in 20 (9.6%) patients: 6 experienced a postoperative drop in hemoglobin requiring blood transfusion, 2 had a pulmonary embolism (PE) and were started on anticoagulation therapy, and 12 had minor infections requiring oral antibiotics. Two (1.0%) patients experienced a grade IIIa complication: 1 experienced a gastric fistula treated with percutaneous drainage and 1 had a stricture requiring endoscopic bougie dilation. Two (1.0%) leaks occurred, requiring intervention under general anesthesia (grade IIIB). One of these patients required percutaneous drainage as well as placement of an endoscopic stent under general anesthesia. The other patient experienced an almost immediate postoperative leak treated with reoperation on postoperative day 1 (Table 3). The overall minor complication rate was 13.4%, and the major complication rate was 1.9%.

DISCUSSION

Laparoscopic sleeve gastrectomy has been shown to be an effective stand-alone bariatric procedure.⁷ It generally has a shorter duration and easier learning curve than the current gold standard, LRYGB. With the increasing number of Canadians living with severe obesity and the increased volume of LSG surgeries being performed in Canada, the safety of LSG as a treatment for severe obesity must be examined.

Our institution is a newly established bariatric surgery centre comprising 3 bariatric surgeons who collectively

perform fewer than 125 procedures annually. Our study population demographics and comorbidity profile are similar to those of other bariatric surgery populations (e.g., average age 43 yr, > 80% women, average presurgery BMI 49).⁶ More than one-third of our patients had comorbid type 2 diabetes, gastroesophageal reflux disease and dyslipidemia, close to half had obstructive sleep apnea, and more than half had hypertension.

We compared our study results with those of other studies that used the CD classification (Table 3). In the study by Vidal and colleagues,¹⁴ minor complications were reported in 5 (4.4%) patients: urinary tract infection ($n = 2$), pseudomembranous colitis ($n = 1$), hypertensive crisis ($n = 1$) and subphrenic abscess ($n = 1$). Major complications were reported in 5 (4.4%) patients: gastric leak ($n = 2$), bleeding from the port site ($n = 2$) and acute myocardial infarction resulting in death ($n = 1$).

In the study by Peterli and colleagues,¹⁵ minor complications were reported in 7.5% of patients, 3 of which were nonsurgical, 1 was surgical and 3 were due to dysphagia. Obstruction ($n = 1$) and infection ($n = 1$) were identified as major complications, for a rate of 0.9%.

Lemanu and colleagues¹⁶ reported 38 minor complications and 29 major complications. The 28 major complications included 23 grade III, 5 grade IV and 1 grade V. The authors reported staple line leakage (2%), staple line bleeding (2.5%) and 1 death (0.3%).

Goiten and colleagues¹⁷ also used the CD classification and reported an overall complication rate of 4.1%. Sixty-two (2.3%) patients experienced minor complications and 48 (1.8%) experienced major complications. Absolute 30-day complication rates were reported as follows: bleeding 2.5% ($n = 66$), leakage 0.8% ($n = 22$), venous thromboembolism 0.2% ($n = 4$) and obstruction 0.1% ($n = 3$).

Table 3. Thirty-day complication rates associated with LSG using the Clavien–Dindo classification and categorized as major and minor complications¹³

Clavien–Dindo grade	Study; no. (%)				
	Present study ($n = 209$)	Lemanu et al. ¹⁶ ($n = 400$)	Vidal et al. ¹⁴ ($n = 114$)	Peterli et al. ¹⁵ ($n = 107$)	Goiten et al. ¹⁷ ($n = 2651$)
Minor					
I	8 (3.8)	20 (5)	—	5 (4.7)	19 (0.7)
II	20 (9.6)	18 (4.5)	5 (4.4)	3 (2.8)	43 (1.6)
Minor complication rate	28 (13.4)	38 (9.5)	5 (4.4)	8 (7.5)	62 (2.3)
Major					
III	—	23 (5.6)	—	1 (0.9)	—
IIIa	2 (1.0)	—	—	—	18 (0.7)
IIIb	2 (1.0)	—	4 (3.5)	—	22 (0.8)
IV	—	5 (1.3)	—	—	—
IVa	—	—	—	—	5 (0.2)
IVb	—	—	—	—	2 (0.07)
V	—	1 (0.3)	1 (0.9)	—	1 (0.04)
Major complication rate	4 (1.9)	29 (7.3)	5 (4.4)	1 (0.9)	48 (1.8)
Overall complication rate	32 (15.3)	67 (16.8)	10 (8.8)	9 (8.4)	110 (4.1)

LSG = laparoscopic sleeve gastrectomy.

In our study, the major complication rate was 1.9%. This finding falls in the range reported by the other comparable studies that used the CD classification (range 0.9%–7.3%; Table 3). The minor complication rate of 13.4% found in our study is higher than those of the other studies that reported minor complication rates (range 2.3%–9.5%; Table 3). Our overall complication rate of 15.3% falls within the range of 4.1%–16.8% reported by the other comparable studies. In the present study there was no 30-day mortality. Mortality was also low in the comparable studies and ranged from 0%–0.9%.

Strengths and limitations

This study has a number of strengths. First, we used a reliable and valid classification system to grade and report surgical complications following LSG. Second, we had complete follow-up data on our first 209 patients. Third, all procedures were performed by surgeons at the same academic-affiliated health care institution using a 2 surgeons per case approach. Finally, we conducted a comprehensive chart review, which is more likely to capture all minor complications (e.g., rash, dehydration), thus describing the morbidity associated with LSG more accurately.

Our study also has some limitations: its retrospective, observational design and its focus on 30-day complication rates only; we did not capture potential complications known to occur long after LSG, such as gastroesophageal reflux disease, hernia and gastric fistula.

This study suggests that an annual bariatric surgery procedure volume of 125 cases is not required. Although the rationale for this guideline is clear, our results suggest that a lower number is acceptable. This may be explained by the fact that all cases in this study were performed with 2 surgeons present, with at least 1 of the surgeons involved being fellowship-trained in bariatric surgery. Also, before starting the program, the first 2 cases were proctored by an experienced visiting surgeon who had performed several hundred LSGs.

In order to standardize grading and reporting of complications following bariatric surgery, future studies should use the CD classification. In addition, future research should include an examination of long-term complications, such as nutritional deficiencies after LSG. Finally, identifying predictors of complications after LSG and the potential contribution complications make to unsuccessful weight loss after surgery may help to inform clinical decision-making.

CONCLUSION

A new, low-volume bariatric centre can safely perform LSG if steps are taken to ensure that the surgeons are appropriately trained and patients have access to a dedicated bariatric health team. The CD classification system appears to be a useful, standardized method for comparing 30-day complication rates following LSG.

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Competing interests: None declared.

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