

Comparative effectiveness and safety of gastric bypass, sleeve gastrectomy and adjustable gastric banding in a population-based bariatric program: prospective cohort study

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Background: Bariatric surgery in Canada is primarily delivered within publicly funded specialty clinics. Previous studies have demonstrated that bariatric surgery is superior to intensive medical management for reduction of weight and obesity-related comorbidities. Our objective was to compare the effectiveness and safety of laparoscopic Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (LSG) and adjustable gastric banding (LAGB) in a publicly funded, population-based bariatric treatment program.

Methods: We followed consecutive bariatric surgery patients for 2 years. The primary outcome was weight change (in kilograms). Between-group changes were analyzed using multivariable regression. Last-observation-carried-forward imputation was used for missing data.

Results: We included 150 consecutive patients (51 RYGB; 51 LSG; 48 LAGB) in our study. At baseline, mean age was 43.5 ± 9.5 years, 87.3% of patients were women, and preoperative body mass index (BMI) was 46.2 ± 7.4 . Absolute and relative (% of baseline) weight loss at 2 years were 36.6 ± 19.5 kg ($26.1 \pm 12.2\%$) for RYGB, 21.4 ± 16.0 kg ($16.4 \pm 11.6\%$) for LSG and 7.0 ± 9.7 kg ($5.8 \pm 7.9\%$) for LAGB ($p < 0.001$). Change in BMI was greater for the RYGB (-13.0 ± 6.6) than both the LSG (-7.6 ± 5.7) and the LAGB (-2.6 ± 3.5) groups ($p < 0.001$). The reduction in diabetes, hypertension and dyslipidemia was greater after RYGB than after LAGB (all $p < 0.05$). There were no deaths. The anastomotic and staple leakage rate was 1.3%.

Conclusion: In a publicly funded, population-based bariatric surgery program, RYGB and LSG demonstrated greater weight loss than the LAGB procedure. Bypass resulted in the greatest reduction in obesity-related comorbidities. All procedures were safe.

Contexte : Au Canada, la chirurgie bariatrique est effectuée principalement dans des cliniques spécialisées financées par le secteur public. Des études ont démontré que les interventions de cette nature sont supérieures à la prise en charge médicale intensive pour la perte de poids et la réduction des affections comorbides liées à l'obésité. L'objectif de notre étude était de comparer l'efficacité et l'innocuité de la dérivation gastrique Roux-en-Y par laparoscopie (DGRY), de la gastrectomie longitudinale (GL) et de la gastroplastie par anneau gastrique modulable (GAGM) dans le cadre d'un programme de traitement bariatrique basé sur la population financé par les deniers publics.

Méthodes : Nous avons suivi pendant 2 ans des patients ayant subi une chirurgie bariatrique. Le résultat primaire à l'étude était la variation pondérale (en kilogrammes). Nous avons analysé la variation intergroupe au moyen d'une régression multivariable et utilisé la méthode d'imputation des données manquantes par report de la dernière observation.

Résultats : Nous avons retenu 150 patients consécutifs (51 DGRY; 51 GL; 48 GAGM). Au début de l'étude, l'âge moyen était de $43,5 \pm 9,5$ ans, 87,3 % des patients étaient des femmes, et leur indice de masse corporelle (IMC) avant l'opération était de $46,2 \pm 7,4$. Après 2 ans, la perte de poids moyenne (pourcentage du poids de départ) était de $36,6 \pm 19,5$ kg ($26,1 \pm 12,2$ %) pour la DGRY, de $21,4 \pm 16,0$ kg ($16,4 \pm 11,6$ %) pour la GL, et de $7,0 \pm 9,7$ kg ($5,8 \pm 7,9$ %) pour la GAGM ($p < 0,001$). La variation de l'IMC était plus grande pour le groupe DGRY ($13,0 \pm 6,6$) que pour les 2 autres groupes ($7,6 \pm 5,7$ pour la GL et $2,6 \pm 3,5$ pour la GAGM; $p < 0,001$). L'incidence sur le diabète, l'hypertension et la dyslipidémie était également plus grande après la DGRY qu'après la GAGM ($p < 0,05$ pour tous). Il n'y a eu aucun décès. Le taux de fuites anastomotiques et liées aux sutures était de 1,3 %.

Conclusion : Dans le cadre d'un programme de chirurgie bariatrique basé sur une population et financé par le secteur public, la DGRY et la GL ont entraîné une plus grande perte de poids que la GAGM. La dérivation a donné lieu à la plus forte réduction des affections comorbides liées à l'obésité. Toutes les interventions se sont avérées sécuritaires.

The prevalence of obesity in Canada has increased 225% since 1985.¹ In absolute terms, approximately 60% of Canadians are overweight and 24% are defined as clinically obese (body mass index [BMI] > 30).² The majority of this increased prevalence is accounted for by increases in class II (BMI > 35) and class III (BMI > 40) obesity.¹ Individuals with obesity demonstrate a 2- to 5-fold greater prevalence of type 2 diabetes, a 2- to 4-fold increased prevalence of cardiovascular risk factors (coronary artery disease, hypertension), and a reduction in life expectancy by 8 to 13 years^{3,4} compared with individuals with a healthy weight. Substantial increases in obesity-related morbidity and associated health care expenditures have been recognized.⁵⁻⁷

The weight loss effectiveness of bariatric surgery compared with medical management of obesity is well documented.⁸⁻¹⁰ In a recent randomized controlled study in a private U.S. health care setting, Schauer and colleagues¹¹ demonstrated increased weight loss and improvement in type 2 diabetes 36 months following bariatric surgery compared with intensive medical management. Similarly, a recent meta-analysis by Padwal and colleagues¹² reported substantial weight loss following bariatric surgery with low overall complication rates.

Parallel to the growing evidence supporting surgery over medical management, the number of people undergoing bariatric surgery has doubled worldwide (up to 350 000 procedures/yr) since 2000.¹³ Accordingly, funding for bariatric surgical care in Canada has greatly increased. For instance, in 2009 the province of Ontario contributed \$75 million in public funding toward a Bariatric Care Network, and the province of Quebec has doubled the number of bariatric procedures from 1000 to 2000 per year since 2005.^{14,15}

Bariatric surgical care in Canada is largely delivered within specialized multidisciplinary programs with central referral and triage.^{15,16} Compared with bariatric centres in the United States that are generally privately funded, the typical patient encountered in a public setting is likely to be of lower socioeconomic status, less highly selected and possibly more treatment-refractory. Therefore, outcomes in Canadian patients may differ from those of patients enrolled in studies from other countries.^{3,17,18} In Alberta, the Edmonton Adult Bariatric Specialty program is a publicly funded venture offering a tiered approach for centrally referred patients, who progress from a wait list to intensive medical management and ultimately to bariatric surgery (if indicated). In this clinic, there is no systematic process for choosing a specific type of bariatric surgery. Instead, a combination of empirical evidence, patient preference, institutional practice and surgeon advice is used.

At present, there is a lack of longitudinal studies that compare the effectiveness and safety of the common bariatric procedures on patients with obesity enrolled in a population-based, publicly funded system. Consequently,

the objective of this prospective cohort analysis was to compare weight loss, safety and obesity-related outcomes of laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic sleeve gastrectomy (LSG) and laparoscopic adjustable gastric banding (LAGB).

METHODS

A detailed study protocol, approved by the University of Alberta Health Research Ethics Board, has been previously published.³ All participants provided written informed consent.

Setting

The Edmonton Adult Bariatric Specialty program serves nearly 1.6 million residents within the Edmonton zone of the Alberta Health Services (AHS) network and constitutes one of the largest health care delivery systems in Canada. The program itself is a centralized, single point of access referral system for patients with a BMI of 40 or higher, or with a BMI of 35 or higher as well as obesity-related comorbidities (e.g., type 2 diabetes, sleep apnea, hypertension, osteoarthritis). All patients are placed on a wait list (first come first serve), and upon enrolment patients undergo intensive multidisciplinary evaluation and care, including health behaviour management, psychological support for mental illness and prior abuse and, if indicated, bariatric surgery.⁶ Between November 2008 and November 2011, this program received 2598 new patient referrals who were wait listed for enrolment (average wait time of 2 yr); of those who continued in the program, 2116 were enrolled in medical management and 498 bariatric surgeries were performed. All procedures were performed by 1 of 3 bariatric surgeons at a large tertiary teaching hospital in Edmonton, Alta. The surgical procedures are described in Appendix 1, available at canjsurg.ca.

Participants and study groups

Between November 2008 and November 2011, consecutive, consenting surgical patients aged 18–60 years from the Adult Bariatric Specialty program were enrolled into the Alberta Population-based Prospective Evaluation of the Quality of Life Outcomes and Economic Impact of Bariatric Surgery (APPLES) study. The overall results of this cohort, including 2-year weight changes in wait-listed, medically treated and surgically treated patients has been previously detailed.³ The present study focuses on detailing the results and adverse effects of surgical subgroups. Inclusion criteria and BMI thresholds for surgery were the same as the inclusion criteria for the APPLES study. Absolute contraindications to surgery included pregnancy or nursing, uncontrolled psychiatric illness,

active smoking or substance abuse, active eating disorders, or a high-risk medicosurgical comorbidity (e.g., severe coronary artery disease) precluding an operation. All surgical patients underwent approximately 24–36 weeks of intensive, multidisciplinary management of obesity, obesity-related comorbidities and mental health screening before the decision to undergo surgery was made. Approval for surgery was a joint decision between the patient and a multidisciplinary team, taking into account the perceived likelihood of adherence to postoperative instructions and diet. Patients accepted for surgery continued on close medical monitoring while waiting for the procedure to be performed (10–14 mo).

For approved patients, the choice of RYGB versus LSG versus LAGB was made based on surgeon advice, patient preference and local patterns of practice.

Measurements and data collection

Detailed case report forms have been previously published.⁶ Baseline data were collected within 2 weeks before surgery and included age, sex, race, marital status, employment status, household income, general medical history and obesity-related comorbidities, smoking status (current, past, never), medications, weight, BMI, waist circumference, blood pressure, fasting lipid levels, fasting glucose level, hemoglobin A1c (HbA1c) insulin and C-reactive protein (CRP). Body weight was recorded to the nearest 0.1 kg using a validated, calibrated bariatric scale (Scale Tronix, serial numbers 6702–4440 and 6702–6229). Participants wore light indoor clothing with empty pockets, no shoes and had an empty bladder. Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer. A single reading taken using an automated blood pressure monitor and appropriately sized blood pressure cuff was recorded after 5 min of seated rest.

Outcomes

The primary study outcome was weight change (in kilograms), measured every 6 months over the 2-year period. Both absolute and relative changes from baseline were analyzed. Ten percent weight reduction thresholds were also examined.¹⁹ Secondary outcomes included hypertension, dyslipidemia and glycemic control. Hypertension was considered present if self-reported, if blood pressure levels were 140/90 mm Hg or more (≥ 130 mm Hg in patients with type 2 diabetes), or if patients were currently taking antihypertensive medications. Type 2 diabetes was considered present if self-reported, if HbA_{1c} was 6.5% or greater, if fasting glucose level was 7.0 mmol/L or greater, or if patients were currently taking antidiabetic medications. Insulin resistance was assessed using the homeostatic model (HOMA-IR), as

previously reported.²⁰ Dyslipidemia was considered present if self-reported, if the patient was currently taking lipid lowering therapy or if any of the following biochemical parameters were present: total cholesterol of 6.2 mmol/L or greater, low-density lipoprotein (LDL) of 4.1 mmol/L or greater, high-density lipoprotein (HDL) less than 1.0 mmol/L, or triglycerides of 2.3 mmol/L or greater. Obesity-related comorbidities were considered present if any of the above-mentioned specific criteria were present. Comorbidity resolution was defined as the absence of all of the comorbidity-specific criteria listed above at any point during follow-up.

Adverse events

Adverse events were documented prospectively throughout follow-up appointments and classified according to a modified Clavien–Dindo surgical complications system, focusing on grades III or higher.^{21,22} Grade V complications were defined as death. Grade IV and grade III events included those requiring surgical, radiologic or endoscopic intervention. Major surgical adverse events, such as gastrointestinal/staple line leakage or bleeding, were confirmed intraoperatively. Anastomotic ulcers and strictures were confirmed endoscopically. Abscess or band slippage and hernia were confirmed with computed tomography if clinically suspected.

Statistical analysis

We performed descriptive analyses, including calculation of proportions, means, standard deviations, medians and interquartile ranges as appropriate. Within-group change scores were calculated and normality assumptions verified. Baseline variables were compared among study groups using 1-way analysis of variance (ANOVA) for continuous outcomes and χ^2 tests for dichotomous ones. Between-group change scores were compared using 2-way ANOVA plus Bonferroni post hoc or multivariable linear regression, adjusting for age, sex and baseline BMI with adjusted prediction and average marginal effects.²³ We considered results to be significant at $p < 0.05$. Patients were censored if they became pregnant ($n = 2$) or underwent a second (different) bariatric surgical procedure within the program ($n = 1$). We used a last-observation-carried-forward (LOCF) analysis to account for censoring or missing data in the primary analysis. We then repeated this analysis using a more conservative baseline-observation-carried-forward (BOCF) analysis as well as a more liberal (completers) analysis, including only patients who reached the 2 years of follow-up. We did not perform multiple imputations because the data were not missing completely at random. All analyses were performed using SAS software version 9.3 and STATA software version 14.1.

RESULTS

Participants

We enrolled 150 consecutive, consenting surgical patients in our study: 51 underwent RYGB, 51 underwent LSG and 48 underwent LAGB.

Baseline characteristics

Baseline characteristics of the study group are presented in Table 1. The mean age was 43.5 ± 9.5 years, and 87.3% of patients were women. On average, patients were in the severe obesity category with a mean BMI of 46.2 ± 7.4. There were statistically significant differences in the baseline BMI among participants undergoing different bariatric procedures, with BMI being lower in the LAGB group and larger in the RYGB group (Table 1). In terms of obesity-related comorbidities, there were no statistically significant differences among groups in blood pressure, lipid profile, HbA1c, fasting glucose, HOMA-IR index or plasma levels of CRP. Additionally, patients tended to come from varied socioeconomic backgrounds, including all levels of education, income ranges and family status. The percentage of patients who successfully completed the 2-year follow-up was 86.2% in the RYGB group, 84.6% in the LSG group and 87.5% in the LAGB group (Fig. 1).

Overall weight changes

In the primary LOCF analysis, absolute and relative (% of baseline) mean weight losses were 36.6 ± 19.5 kg (26.1 ± 12.2%) in the RYGB group, 21.4 ± 16.0 kg (16.4 ± 11.6%) in the LSG group, and 7.0 ± 9.7 kg (5.8 ± 7.9%) in the LAGB group (*p* < 0.001, ANOVA). Results of the BOCF and completers analyses were consistent with the primary analysis (Table 2). There was a significantly greater total weight loss and BMI reduction when comparing the RYGB group to the LSG and LAGB groups (both *p* < 0.05), as well as when comparing the LSG group to the RYGB group (all *p* < 0.05) at all time points (Fig. 2A and B). The proportion of 5% and 10% responders was significantly reduced in the RYGB group compared with other surgical groups at any time point (Fig. 2C and D).

Obesity-related comorbidities

At 2 years, the prevalence of type 2 diabetes, hypertension and dyslipidemia was reduced in all 3 surgical groups. For type 2 diabetes, the reduction in absolute prevalence was 33.3% for RYGB, 21.6% for LSG and 12.5% for LAGB. For hypertension, the reduction in absolute prevalence was 31.4% for RYGB, 11.8% for

Table 1. Baseline characteristics of study participants

Characteristic	Group; mean ± SD or %			<i>p</i> value*
	RYGB <i>n</i> = 51	LSG <i>n</i> = 51	LAGB <i>n</i> = 48	
Age, yr	41.9 ± 8.4	45.4 ± 9.6	43.1 ± 10.3	0.17
Weight, kg	137.6 ± 24.5	129.1 ± 25.2	116.2 ± 21.6	< 0.001
Body mass index	48.8 ± 6.9	46.5 ± 7.4	43.2 ± 6.8	< 0.001
Female sex	80.4	88.2	93.8	0.13
White race	100	90.2	91.7	0.08
Married/ common-law	52.9	68.6	64.6	0.22
Household annual income, \$CAD				
< 15 000	5.9	3.9	6.3	
15 000–30 000	7.8	0	8.3	
30 000–50 000	21.6	3.9	14.6	
50 000–80 000	21.6	27.5	29.2	
> 80 000	37.3	52.9	35.4	0.10
Education				
Some high school	7.8	5.8	4.2	
High school diploma	19.6	0	22.9	
Some postsecondary	17.7	27.5	16.7	
Completed postsecondary	54.9	66.7	56.3	0.05
Smoking status				
Current smoker	45.1	45.1	56.3	
Former smoker	51	54.9	43.8	
Never smoked	3.9	0	0	0.25
Cardiovascular risk factors				
Diabetes	45.1	39.2	50.0	0.55
Hypertension	64.7	67.8	56.3	0.66
Dyslipidemia	62.8	58.8	58.3	0.88
Clinical parameters				
Systolic BP, mm Hg	122 ± 10	125 ± 15	122 ± 10	0.24
Diastolic BP, mm Hg	74 ± 8	76 ± 11	72 ± 10	0.18
Total cholesterol, mmol/L	4.2 ± 0.9	4.4 ± 0.9	4.6 ± 0.9	0.14
HDL cholesterol, mmol/L	1.2 ± 0.6	1.2 ± 0.3	1.2 ± 0.3	0.87
LDL cholesterol, mmol/L	2.4 ± 0.7	2.5 ± 0.7	2.7 ± 0.7	0.23
Triglycerides, mmol/L	1.5 ± 0.6	1.5 ± 0.6	1.6 ± 0.8	0.69
HbA1c, %	5.8 ± 0.5	5.8 ± 0.7	6.1 ± 1.0	0.2
Fasting glucose, mmol/L	5.5 ± 0.9	5.7 ± 1.6	6.0 ± 1.6	0.3
HOMA-IR	4.8 ± 3.4	4.7 ± 4.2	5.4 ± 5.1	0.7
CRP, mg/L	8.7 ± 6.7	10.2 ± 6.9	9.9 ± 7.9	0.6

BP = blood pressure; CRP = C-reactive protein; HbA1c = glycated hemoglobin A1c; HDL = high-density lipoprotein; HOMA-IR = (fasting glucose mmol/L × fasting insulin mU/L)/22.5; LAGB = laparoscopic adjustable gastric banding; LDL = low-density lipoprotein; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric by-pass; SD = standard deviation.

*Using 1-way analysis of variance.

LSG and 8.3% for LAGB. For dyslipidemia, the reduction in absolute prevalence was 45.1% for RYGB, 31.3% for LSG and 18.8% for LAGB. While the change in absolute prevalence of type 2 diabetes, hypertension and dyslipidemia did not reach statistical significance between LSG and RYGB or between LSG and LAGB, there was a significantly greater change in prevalence after RYGB compared with LAGB at 2 years. Absolute and relative change in prevalence of comorbidities are presented in Figure 3. The 2-year changes in cardiovascular risk factors are shown in Table 3.

Adverse events

Adverse events were classified according to a modified Clavien–Dindo surgical complications system, focusing on grade III or higher.^{21,22} All reported adverse events required intervention, admission, or reoperation (Table 4). Total adverse event rates were 19.6% for RYGB, 9.8% for LSG and 14.6% for LAGB. There were no deaths in any group at 2-year follow-up. Surgical adverse events included 2 anastomotic/staple line leaks and 2 intraabdominal abscesses requiring radiologic drainage in the RYGB group.

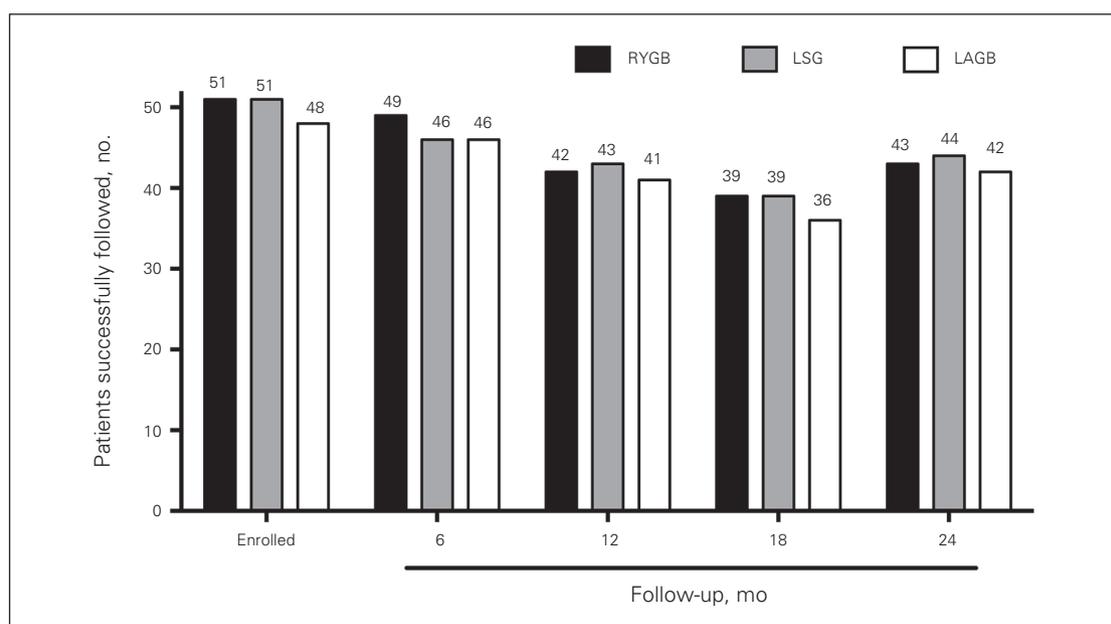


Fig. 1: Patient enrolment and 2-year follow-up completion among surgical groups. LAGB = laparoscopic adjustable gastric banding; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass.

Table 2. Two-year changes in weight and body mass index

Analysis; outcome	Group; mean \pm SD			<i>p</i> value*	RYGB – LSG Δ (95% CI)†	LSG – LAGB Δ (95% CI)†	RYGB – LAGB Δ (95% CI)†
	RYGB <i>n</i> = 51	LSG <i>n</i> = 51	LAGB <i>n</i> = 48				
LOCF							
Δ Weight, kg	-36.6 \pm 19.5	-21.4 \pm 16.0	-7.0 \pm 9.7	< 0.001	-11.8 (-17.5 to -6.2)	-12.4 (-18.2 to -6.6)	-24.2 (-30.2 to -18.3)
Δ Weight, %	-26.1 \pm 12.2	-16.4 \pm 11.6	-5.8 \pm 7.9	< 0.001	-8.4 (-12.6 to -4.2)	-10.4 (-14.7 to -6.2)	-18.8 (-23.2 to -14.4)
Δ BMI	-13.0 \pm 6.6	-7.6 \pm 5.7	-2.6 \pm 3.5	< 0.001	-4.3 (-6.3 to -2.3)	-4.5 (-6.5 to -2.4)	-8.8 (-10.9 to -6.6)
BOCF							
Δ Weight, kg	-31.0 \pm 22.6	-17.9 \pm 16.6	-6.4 \pm 9.8	< 0.001	-10.4 (-17 to -3.8)	10.0 (-16.7 to -3.3)	-20.5 (-27.4 to -13.6)
Δ Weight, %	-22.3 \pm 14.7	-14.0 \pm 12.3	-5.2 \pm 7.9	< 0.001	-7.4 (-12.2 to -2.6)	-8.8 (-13.7 to -3.9)	-16.2 (-21.2 to -11.2)
Δ BMI	-11.0 \pm 7.8	-6.5 \pm 6.0	-2.3 \pm 3.5	< 0.001	-3.8 (-6.1 to -1.4)	-3.7 (-6.1 to -1.3)	-7.4 (-9.9 to -5.0)
Completers							
Δ Weight, kg	-36.8 \pm 19.8	-20.8 \pm 16.1	-7.3 \pm 10.1	< 0.001	-11.8 (-17.9 to -5.6)	-11.6 (-17.7 to -5.5)	-23.4 (-29.7 to -17.0)
Δ Weight, %	-26.4 \pm 12.2	-16.2 \pm 11.8	-6.0 \pm 8.2	< 0.001	-8.6 (-13.1 to -4.0)	-9.9 (-14.5 to -5.4)	-18.5 (-23.3 to -13.7)
Δ BMI	-13.0 \pm 6.7	-7.5 \pm 5.8	-2.7 \pm 3.6	< 0.001	-4.3 (-6.5 to -2.1)	-4.2 (-6.4 to -2.0)	-8.5 (-10.8 to -6.2)

BMI = body mass index; BOCF = baseline observation carried forward; CI = confidence interval; LAGB = laparoscopic adjustable gastric banding; LOCF = last observation carried forward; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass; SD = standard deviation.

*Using analysis of variance.

†*p* < 0.05 using a Wald test of simple and composite linear hypotheses, adjusted for age, sex and BMI at baseline using multiple linear regression plus adjusted prediction with marginal effects at representative values.

There were 4 internal hernias after 1 year in the RYGB group, all of which required reoperation, and 3 anastomotic ulcers that were treated medically. There was 1 anastomotic/staple line bleed in the LSG group that required urgent reoperation and 1 intra-abdominal abscess that required radiologic drainage. There were 6 reoperations for band removal in the LAGB group. Other serious adverse events included 1 non-ST elevation myocardial infarction and 1 cardiac arrhythmia that required chemical cardioversion and 1 pulmonary embolus that required anticoagulation in the LSG group. In total, there were 21 grade IIIa or IIIb complications, and 1 grade IV complication.

DISCUSSION

To our knowledge, this is the first study to compare the effectiveness and safety of 3 common bariatric surgical approaches in a population-based, publicly funded, centrally triaged bariatric program. In this cohort with class III (BMI > 40) obesity, RYGB and LSG were effective in producing clinically important weight loss over a 2-year follow-up period. The RYGB procedure tended to produce the largest reduction in weight loss, followed by LSG, with the LAGB demonstrating modest weight loss at best. Additionally, RYGB demonstrated superiority in

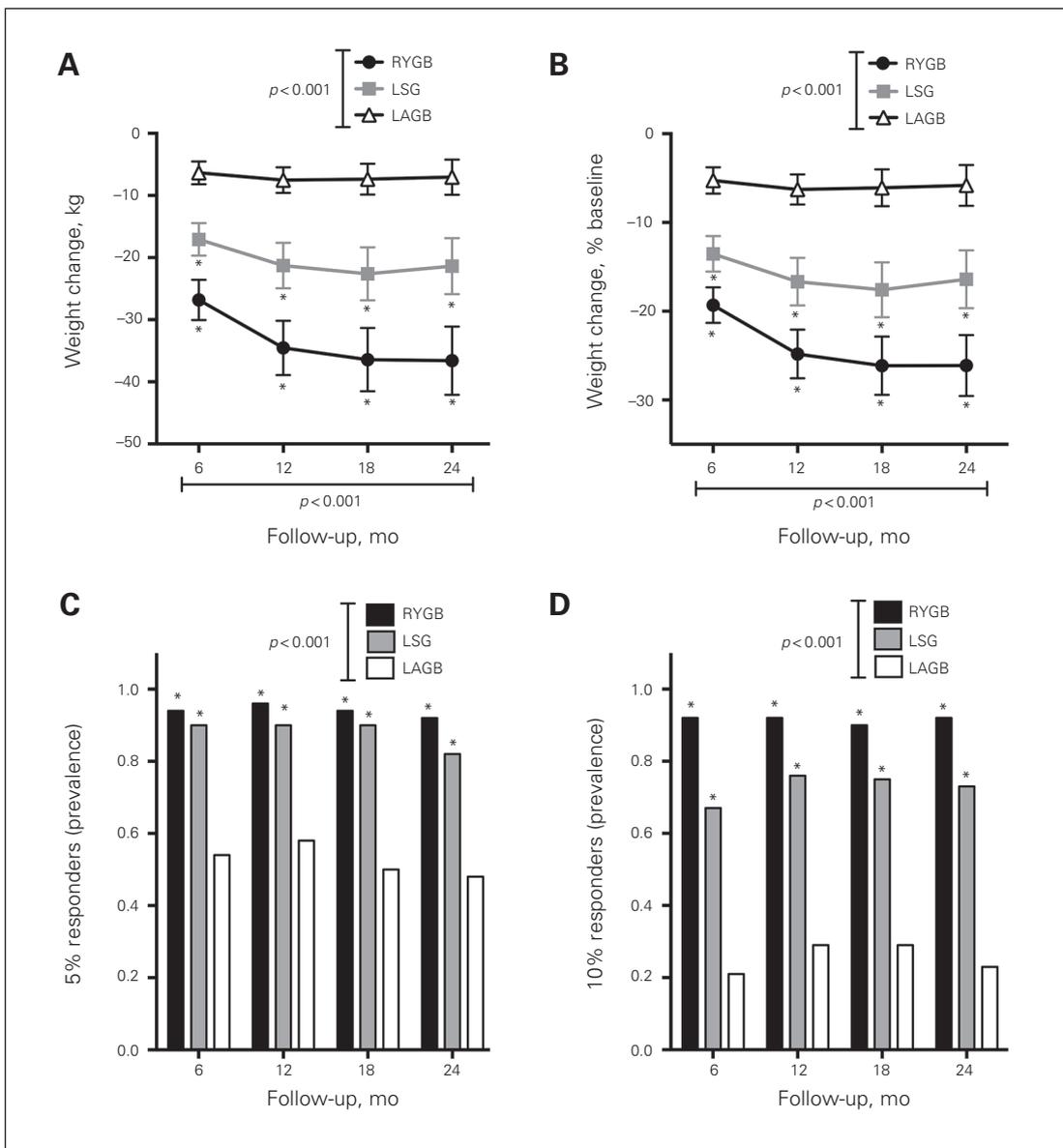


Fig. 2: Weight change among surgical subgroups. Data presented as (A) absolute weight change, (B) relative weight change and proportion of participants achieving weight loss greater than (C) 5% and (D) 10% of baseline. The *p* values represent significance in overall differences among surgical subgroups using 2-way analysis of variance (ANOVA). **p* < 0.05 compared to LAGB using a Bonferroni post hoc correction after 2-way ANOVA. LAGB = laparoscopic adjustable gastric banding; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass.

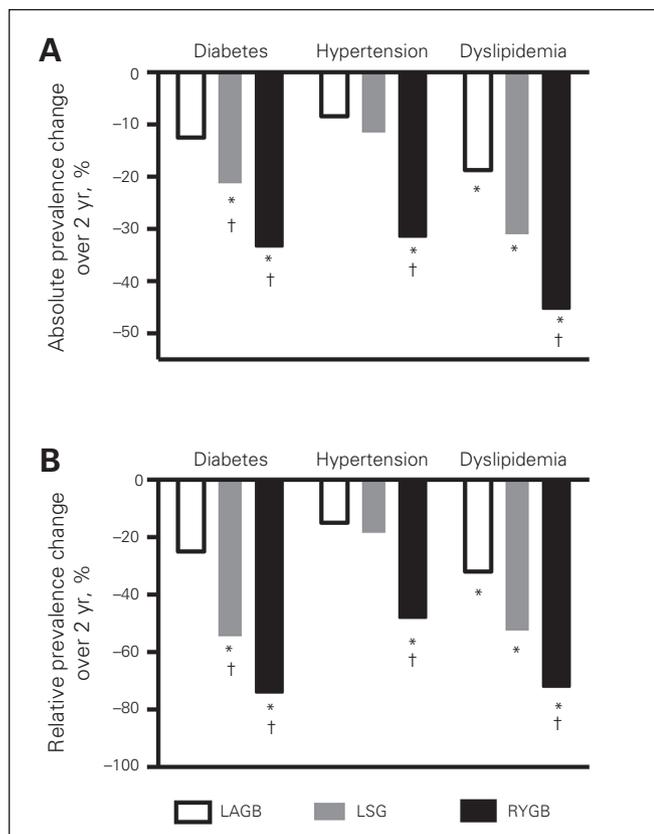


Fig. 3: Absolute and relative change in prevalence of comorbidities 2 years after surgery. Data presented as (A) absolute and (B) relative reduction in the proportion of participants with diabetes, hypertension and dyslipidemia 2 years after bariatric surgery. *Represents a significant change in prevalence ($p < 0.05$) relative to baseline in the same surgical subgroup. †Represents a significant difference in the prevalence of each risk factor compared to the effect observed in the those receiving laparoscopic adjustable gastric banding (LAGB). LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass.

reducing type 2 diabetes, hypertension and dyslipidemia as compared with LAGB. In terms of safety, there were no deaths in any group and low rates of major adverse effects. Both the RYGB and LSG groups had low rates of major early postoperative adverse effects, most importantly anastomotic/staple line leakage and gastrointestinal/staple line bleeding. The RYGB had the second highest rate of postoperative surgical intervention, with LAGB being the highest related to issues requiring removal of the band.

Comparison

Previous clinical trials have demonstrated the superiority of bariatric surgery combined with intensive medical treatment compared with medical treatment alone in obese individuals.¹¹ A randomized controlled trial by O'Brien and colleagues²⁴ reported significantly greater short-term and long-term (10-yr) weight reduction following LAGB compared with intensive medical weight loss in patients with a BMI of 30–35.^{2,24} Schauer and colleagues¹¹ compared intensive medical treatment and RYGB or LSG versus intensive medical treatment alone and also demonstrated greater weight loss and type 2 diabetes remission in both surgical groups with class II obesity (BMI > 35). Comparatively, both the trials by O'Brien and colleagues²⁴ and Schauer and colleagues¹¹ included patients with lower average BMIs than our population-based cohort (BMI 30–37 v. BMI > 40).

Additionally, comparative trials for bariatric surgical procedures are sparse in the literature. A prospective trial comparing RYGB versus LAGB by Angrisani and colleagues²⁵ randomized 51 patients with a mean BMI of 43.^{2,25} At 5-year follow up, the RYGB group had significantly greater weight reduction than the LAGB group

Table 3. Two-year changes in cardiovascular risk factors*

Outcome	Group; mean \pm SD			p value†	RYGB – LSG Δ (95% CI)‡	LSG – LAGB Δ (95% CI)‡	RYGB – LAGB Δ (95% CI)‡
	RYGB $n = 51$	LSG $n = 51$	LAGB $n = 48$				
Δ Systolic BP, mm Hg	1 \pm 16	1 \pm 16	0 \pm 16	0.90	0 (–6 to 6)	0 (–7 to 6)	0 (–7 to 6)
Δ Diastolic BP, mm Hg	0 \pm 13	1 \pm 12	3 \pm 12	0.50	–1 (–6 to 3)	–3 (–8 to 2)	–4 (–9 to 1)
Δ Total cholesterol, mmol/L	0 \pm 0.8	0.2 \pm 0.8	0.2 \pm 0.6	0.50	–0.2 (–0.5 to 0.1)	0 (–0.3 to 0.3)	–0.1 (–0.5 to 0.2)
Δ HDL cholesterol, mmol/L	0.3 \pm 0.7	0.4 \pm 0.3	0.2 \pm 0.2	0.08	–0.1 (–0.3 to 0.1)	0.2 (0.03 to 0.4)	0.1 (–0.1 to 0.3)
Δ LDL cholesterol, mmol/L	–0.2 \pm 0.6	–0.1 \pm 0.7	0.1 \pm 0.5	0.10	–0.1 (–0.4 to 0.1)	–0.2 (–0.4 to 0.1)	–0.3 (–0.6 to 0)
Δ Triglycerides, mmol/L	–0.4 \pm 0.5	–0.2 \pm 0.7	–0.2 \pm 0.5	0.30	–0.2 (–0.4 to 0.1)	0 (–0.3 to 0.2)	–0.2 (–0.4 to 0.1)
Δ HbA1c, %	–0.3 \pm 0.5	–0.1 \pm 0.5	–0.1 \pm 0.4	0.040	–0.2 (–0.4 to –0.01)	0 (–0.2 to 0.2)	–0.2 (–0.4 to 0)
Δ Fasting glucose, mmol/L	–0.5 \pm 0.9	–0.5 \pm 0.8	–0.5 \pm 1.0	0.90	0 (–0.4 to 0.4)	0 (–0.3 to 0.4)	0 (–0.3 to 0.4)
Δ HOMA-IR	–3.0 \pm 4.3	–1.8 \pm 4.2	–2.0 \pm 4.5	0.30	–0.9 (–2.6 to 0.7)	0.7 (–1.0 to 2.5)	–0.2 (–2.0 to 1.6)
Δ CRP, mg/dL	–3.7 \pm 17	–4.1 \pm 5.2	–1.3 \pm 14	0.50	1.6 (–3.8 to 7.1)	–2.7 (–8.2 to 2.9)	–1 (–6.8 to 4.7)

BP = blood pressure; CI = confidence interval; CRP = C-reactive protein; HDL = high-density lipoprotein; HOMA-IR = (fasting glucose mmol/L \times fasting insulin mU/L)/22.5; LAGB = laparoscopic adjustable gastric banding; LDL = low-density lipoprotein; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass; SD = standard deviation.

*Last observation carried forward imputation.

†Using 1-way analysis of variance.

‡ $p < 0.05$ using a Wald tests of simple and composite linear hypotheses adjusted for age, sex and BMI at baseline using multiple linear regression plus adjusted prediction with marginal effects at representative values.

(BMI 29.8 v. 34.9). The patients undergoing LAGB in their study had a change in BMI from 43.4 to 34.9, which was relatively greater than the modest -2.6 change in BMI seen in our cohort at 2-year follow-up. Interestingly, Christou and colleagues²⁶ retrospectively reviewed outcomes of RYGB versus LAGB in Canada with 5-year outcomes. Similar to our findings, they also reported significantly greater weight loss with RYGB than with LAGB. Sjöström and colleagues²⁷ reported 15-year follow-up data comparing RYGB, LAGB and vertical-banded gastroplasty. Their study did not include LSG, as it is the newest of the 3 procedures. At 2-year follow-up, the weight loss was 32% for RYGB and 20% for LAGB compared with baseline. Interestingly, in our study weight loss after RYGB was comparable; however, weight loss after LAGB was considerably less. It remains difficult to define the factors responsible for the variability in weight loss seen with LAGB among studies. Differences may relate to variations in patient selection (inclusion and exclusion criteria), local patterns of practice, or study design. This variability is unlikely related to different gastric banding devices or techniques, as previous trials have demonstrated.^{28,29}

Our data not only demonstrate marginal absolute weight loss with LAGB, but also superior comparative weight loss with LSG and RYGB, and greater reduction in obesity-related comorbidities with RYGB. Accordingly, in a shared decision-making model, our study will inform patients and referring physicians of the relative

lack of effectiveness of the band for weight loss and comorbidity resolution. Also, our findings will inform bariatric surgeons that LAGB should not be routinely offered to patients with severe obesity who are interested in substantial weight loss and improvement in type 2 diabetes, hypertension and dyslipidemia. Instead, the primary bariatric surgical approach for these patients should consist of RYGB or LSG.

Our data also suggest that all 3 bariatric surgical procedures are safe. This is similar to the systematic review by Chang and colleagues³⁰ in which mortality was 0.08% in a population of 161 756 patients. Both RYGB and LSG had greater and more serious adverse event rates than LAGB, related to the anastomotic and staple line challenges. However, the complication rates were similar to those reported in previous studies.^{11,25} We acknowledge that given the relative infrequency of these adverse effects, this study is likely underpowered to detect true differences in adverse effects.

Limitations

The APPLES surgical cohort analysis is unique in that it provides prospective data with a relatively large study population to compare 3 common types of bariatric surgery with relatively modest loss to follow-up. The major limitation is the nonrandomized nature of the study. This resulted in baseline imbalances in weight, which we addressed using

Table 4. Adverse events at 24 months of follow-up*

Adverse event	Group; no. (%)			
	RYGB n = 51	LSG n = 51	LAGB n = 48	Total n = 150
Death	0	0	0	0
Requiring hospitalization†	10 (19.6)	5 (9.8)	7 (14.6)	22 (14.7)
Requiring surgical intervention	5 (9.8)	1 (1.9)	6 (12.5)	12 (8.0)
Requiring radiological/endoscopic intervention	2 (3.9)	2 (3.9)	0	3 (2.0)
Surgical adverse events				
Gastrointestinal/staple line leak	2 (3.9)	0	0	2 (1.3)
Gastrointestinal/staple line bleed	0	1 (1.9)	0	1 (0.7)
Anastomotic ulcer	3 (5.9)	0	0	3 (2.0)
Stricture	1 (1.9)	0	0	1 (0.7)
Band slippage or removal	N/A	N/A	6 (12.5)	6 (4.0)
Intraabdominal abscess	2 (3.9)	1 (1.9)	0	3 (2.0)
Hernia	4 (7.8)	0	1 (2.1)	5 (3.33)
Other serious adverse events				
Intravenous hydration for hypovolemia	9 (17.6)	2 (3.9)	1 (2.1)	12 (8.0)
Transfusion	1 (1.9)	1 (1.9)	0	2 (1.3)
Transient renal insufficiency	1 (1.9)	1 (1.9)	0	2 (1.3)
NSTEMI/STEMI/arrhythmia	0	2 (3.9)	0	2 (1.3)
Pulmonary embolus	0	1 (1.9)	0	1 (0.7)
Total adverse events	10 (19.6)	5 (9.8)	7 (14.6)	22 (14.7)

LAGB = laparoscopic adjustable gastric banding; LSG = laparoscopic sleeve gastrectomy; N/A = not applicable; NSTEMI = non-ST-segment elevation myocardial infarction; RYGB = laparoscopic Roux-en-Y gastric bypass; STEMI = ST-segment elevation myocardial infarction.
 *Clavien-Dindo grade III or higher. Many patients had more than one event, or one complication leading to multiple adverse events. These events were not counted separately in the totals.
 †Either prolonged hospitalization (length of stay > 5 d) or rehospitalization.

regression techniques. In terms of generalizability, this study should be generalizable to publicly funded bariatric programs in Canada; however, generalizability beyond Canada should be made with caution. Additionally, with obesity being a chronic disease, our data provide only short-term follow up.

CONCLUSION

The RYGB and LSG procedures were substantially more effective for weight loss and resolution of obesity-related comorbid disease than LAGB in our population-based cohort. Although RYGB and LSG were associated with greater perioperative risk, these adverse effects were uncommon, and the weight loss efficacy of LAGB was relatively poor. Our findings will inform patients, primary physicians, multidisciplinary teams and surgeons in Canada regarding the effectiveness and safety of the 3 most common bariatric surgical procedures. Furthermore, our findings support the preferential use of RYGB and LSG in publicly funded bariatric surgical programs in Canada.

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