



Effect of Banded Roux-en-Y Gastric Bypass Versus Sleeve Gastrectomy on Diabetes Remission at 5 Years Among Patients With Obesity and Type 2 Diabetes: A Blinded Randomized Clinical Trial

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OBJECTIVE

To determine whether silastic ring laparoscopic Roux-en-Y gastric bypass (SR-LRYGB) or laparoscopic sleeve gastrectomy (LSG) produces superior diabetes remission at 5 years.

RESEARCH DESIGN AND METHODS

In a single-center, double-blind trial, 114 adults with type 2 diabetes and BMI 35–65 kg/m² were randomly assigned to SR-LRYGB or LSG (1:1; stratified by age-group, BMI group, ethnicity, diabetes duration, and insulin therapy) using a web-based service. Diabetes and other metabolic medications were adjusted according to a prespecified protocol. The primary outcome was diabetes remission assessed at 5 years, defined by HbA_{1c} <6% (42 mmol/mol) without glucose-lowering medications. Secondary outcomes included changes in weight, cardiometabolic risk factors, quality of life, and adverse events.

RESULTS

Diabetes remission after SR-LRYGB versus LSG occurred in 25 (47%) of 53 vs. 18 (33%) of 55 patients (adjusted odds ratios 4.5 [95% CI 1.6, 15.5; *P* = 0.009] and 4.2 [1.3, 13.4; *P* = 0.015] in the intention-to-treat analysis). Percent body weight loss was greater after SR-LRYGB than after LSG (absolute difference 10.7%; 95% CI 7.3, 14.0; *P* < 0.001). Improvements in cardiometabolic risk factors were similar, but HDL cholesterol increased more after SR-LRYGB. Early and late complications were similar in both groups. General health and physical functioning improved after both types of surgery, with greater improvement in physical functioning after SR-LRYGB. People of Māori or Pacific ethnicity (26%) had lower incidence of diabetes remission than those of New Zealand European or other ethnicities (2 of 25 vs. 41 of 83; *P* < 0.001).

CONCLUSIONS

SR-LRYGB provided superior diabetes remission and weight loss compared with LSG at 5 years, with similar low risks of complications.

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See accompanying article, p. 1495.

It is well established that bariatric surgery is an effective treatment for people with obesity and type 2 diabetes. Diabetes remission is associated with reduction in long-term vascular complications (1) and mortality (2) and represents a key driver of bariatric surgery cost effectiveness (3). Randomized trials comparing the two most common bariatric procedures, Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG), have shown mixed results for diabetes remission and weight loss (4–6), with a paucity of long-term results (6–8).

Both RYGB and SG procedures reduce stomach size, but only RYGB includes bypass of the duodenum. Duodenal bypass is thought to enhance diabetes remission through stimulating incretin hormone production (9) and inducing greater improvements in bile acids (10) and gut microbiota (11). Furthermore, the banded modification of the RYGB involves placing a silastic ring (SR) around the gastric pouch to limit stomal dilation and is designed to limit weight regain over time (12). Given the beneficial impact of weight loss on diabetes remission (13), the additional weight regain-limiting effects of SR-RYGB may provide metabolic superiority over SG in the longer term.

This assessor and patient-blinded randomized trial compared SR-laparoscopic RYGB (SR-LRYGB) with laparoscopic SG (LSG) among people with obesity and type 2 diabetes to test the hypothesis that SR-LRYGB would produce superior diabetes remission at 5 years. Comparative changes in weight loss, blood pressure, lipid levels, renal function, adverse events, and quality of life were also evaluated.

RESEARCH DESIGN AND METHODS

Study Design

This single-center, prospective, parallel, two-arm, randomized, double-blind superiority trial compared SR-LRYGB with LSG conducted at a single hospital center in Auckland, New Zealand. All participants provided written informed consent. The study was approved by the Northern A Health and Disability Ethics Committee, Ministry of Health, New Zealand. The detailed trial design protocol has been published (14).

Participants

Eligibility criteria included age 20–55 years, type 2 diabetes of at least 6 months duration, a BMI of 35–65 kg/m² for at least 5 years, being suitable for either of the two surgical procedures, able to provide written informed consent, and committed to follow-up. Exclusion criteria included C-peptide < 350 pmol/L, pregnancy, type 1 diabetes or secondary diabetes, chronic pancreatitis, oral steroid therapy, current smoking, and not suitable for general anesthesia.

Randomization and Blinding

Computer-generated random number codes (Minim, London, U.K.) were used to randomly assign participants 1:1 to either SR-LRYGB or LSG, with stratification according to age category (20–39 years, 40–55 years), BMI category (35–44.9 kg/m², 45–54.9 kg/m², 55–65 kg/m²), ethnicity (Māori, Pacific, New Zealand European, other), duration of diabetes diagnosis (<5 years, 5–10 years, >10 years), and the presence of insulin therapy. The operating surgeon entered the participant's baseline data into a secure web-based randomization system on the day of surgery, following induction of general anesthesia, to determine whether the allocation was to SR-LRYGB or LSG. To maintain allocation concealment and blinding of the patients and all other research and clinical team members, both operations were performed using identical incisions with a four-port laparoscopic technique. An emergency unblinding system was available and designed so that anyone involved in outcome assessments remained masked to treatment allocation.

Procedures

Participants were prescribed a very-low-calorie diet with three servings of OPTIFAST (Nestlé, Vevey, Switzerland) containing ~150 calories plus vegetables for 2 weeks before surgery. All operations were performed under the direct supervision of an experienced bariatric surgeon (M.W.C.B.) by bariatric surgical fellows. For LSG, a sleeve was fashioned starting 2 cm proximal to the pylorus using serial applications of an Echelon Flex 45 stapler (Ethicon) over a 36-Fr orogastric bougie. Staple heights ranged from 1.8 to 2 mm, with generally two cartridges of 2-mm staple firings across the antrum followed by four to five cartridges of 1.8-mm staple firings

to the body and fundus of the stomach. Staple line buttressing was not used. For SR-LRYGB, a lesser curve-based gastric pouch was fashioned over a 32-Fr orogastric tube, with a 50 cm biliopancreatic limb, 100-cm antecolic Roux limb with hand-sewn single-layer gastrojejunostomy over a 32-Fr orogastric tube. A 6.5-cm open-ended SR tube was passed posteriorly to the pouch and then the ends secured together around the gastric pouch with a prolene luminal suture. The ring was then secured to the gastric pouch 2–3 cm above the gastrojejunostomy anastomosis using serosal sutures. Postoperatively, all patients were prescribed a twice-daily multivitamin (Centrum Plus; Pfizer; New Zealand) containing 200 mg elemental calcium and 600 IU vitamin D3.

Trial Outcomes

The primary outcome was a glycated hemoglobin A_{1c} (HbA_{1c}) level of <6% (42 mmol/mol) without any glucose-lowering medications at 5 years as defined by American Diabetes Association criteria for complete remission of type 2 diabetes (15). Prespecified secondary outcomes included proportions achieving alternative glycemic thresholds of HbA_{1c} levels of <7% (53 mmol/mol), <6.5% (48 mmol/mol), or ≤5.6% (38 mmol/mol), each without the need for any glucose-lowering medication.

The secondary outcome of weight loss at 5 years was calculated from both the baseline weight at the initial bariatric surgery evaluation visit and weight immediately presurgery. Percent absolute weight loss was calculated as $([\text{baseline weight} - \text{follow-up weight}] / [\text{baseline weight}]) \times 100$, and percent excess weight loss was calculated as $([\text{baseline weight} - \text{follow-up weight}] / [\text{baseline weight} - \text{ideal weight for BMI } 25 \text{ kg/m}^2]) \times 100$.

Other secondary outcomes assessed at 5 years included blood pressure, lipid levels, renal function, quality of life (as evaluated using the RAND 36-Item Health Survey [16], and the Hospital Anxiety and Depression Scale [HADS] [17]). Mortality, revisional surgery, and postoperative complications were also assessed up to 5 years and classified as major or minor and occurring early (<30 days) or later (>30 days) after the surgery. Any complications that resulted in a prolonged hospital stay (>7 days) or required

reoperation, reintervention, or administration of an anticoagulant were classified as major, in accordance with standard outcome reporting guidelines (18).

Follow-up

Postoperative care and follow-up were identical for both groups. All pharmacological agents for diabetes were stopped at the time of surgery. Glucose-lowering therapy was restarted if mean postoperative capillary glucose was >12 mmol/L. All patients were reviewed by an endocrinologist (D.D.W.K., R.C.) for adjustment of metabolic medications according to a prespecified adjustment protocol (14). They were blinded as to the procedure performed.

Power Calculation and Statistical Analysis

The trial was designed to provide 80% power to detect 29% greater diabetes remission in the SR-LRYGB group than in the LSG group at a two-sided α of 0.05 after 5 years follow-up (assuming 88% diabetes remission after SR-LRYGB and 59% after LSG on the basis of previous studies and data derived from an audit of our institution's outcomes) (14). An expected loss to follow-up rate of 20% required at least 53 patients per group.

Normally distributed continuous variables are reported as means and SDs and not normally distributed variables as medians and interquartile ranges. For the primary analysis, the difference in proportion of participants achieving diabetes remission was compared between SR-LRYGB and LSG at 5 years, adjusting for stratification variables using logistic regression. Based on a multiple imputation procedure, this included all patients randomly assigned according to the treatment assignment at randomization (intention-to-treat population). Within-group changes and between-group differences are reported with point estimates and 95% CIs. For HbA_{1c} and BMI assessed at baseline and on multiple occasions over 5 years, a repeated-measures mixed-effects model with adjustment for stratification variables was used to compare changes from baseline in the two groups. Least squares means with SEs were plotted graphically. Use of anxiety or depression medications was examined using generalized mixed-effects model analysis. Two-sided $P < 0.05$ was considered to indicate statistical

significance. Analysis was performed using SAS 9.4 statistical software (SAS Institute, Cary, NC).

RESULTS

Patients

From 20 September 2011 to 20 August 2015, 114 patients (52% women) were recruited and randomly assigned to undergo SR-LRYGB ($n = 56$) or LSG ($n = 58$) (14,19). Baseline characteristics are summarized by treatment allocation in Table 1. Overall, mean age was 46.0 (SD 6.6) years, mean BMI was 42.8 (SD 6.5) kg/m², and mean HbA_{1c} was 7.9% (SD 1.4%) (63.4 [SD 15.6] mmol/mol). Twenty-eight percent of participants had diabetes for >10 years, and 30% were treated with insulin. There were two deaths over the 5-year follow-up period (one as a result of malignancy and one as a result of a car accident), and four patients were not contactable (Fig. 1). At 5 years, diabetes status and dispensed medications were available for 108 (95%) of the 114 participants; however, only 99 (87%) of the 114 participants attended other scheduled clinical assessments.

Primary Outcome

An intention-to-treat analysis was performed for all 114 patients randomly assigned, including the 6 patients (3 after SR-LRYGB, 3 after LSG) with missing HbA_{1c} values at 5 years. The multiple

imputation approach yielded remission rates of 48% after SR-LRYGB and 31% after LSG, with an adjusted odds ratio (OR) of 4.2 (95% CI 1.3, 13.4; $P = 0.015$) as defined by a measured HbA_{1c} of $<6\%$ (42 mmol/mol) at 5 years without any glucose-lowering medications (Table 2). As shown in Table 2, for the available data analysis, diabetes remission at 5 years, using the same criteria, was more likely after SR-LRYGB at 47% (25 of 53 participants) compared with 33% (18 of 55 participants) after LSG (adjusted OR 4.5; 95% CI 1.6, 15.5; $P = 0.009$). There was no difference by sex. People of Māori or Pacific ethnicity had a lower incidence of diabetes remission at 5 years than those of New Zealand European or other ethnicity (2 [8%] of 25 vs. 41 [49%] of 83; $P < 0.001$).

Nadir HbA_{1c} was reached by 24 months after both SR-LRYGB and LSG and maintained through to 5 years (Supplementary Fig. 1A) on fewer diabetes medications (Supplementary Table 1). Diabetes remission was related to the magnitude of weight loss: for every 1 kg of total body weight loss, the adjusted odds of diabetes remission increased by 8% ($P = 0.001$).

Weight Loss

Participants who received the SR-LRYGB had a greater percent body weight loss from baseline than those who received LSG (26.9% vs. 16.3%; absolute difference

Table 1—Baseline characteristics of patients

Characteristic	SR-LRYGB ($n = 56$)	LSG ($n = 58$)
Age (years), mean (SD)	46.6 (6.7)	45.5 (6.4)
Female, n (%)	33 (59)	26 (45)
Ethnicity, n (%)		
New Zealand European	34 (61)	38 (66)
Māori	11 (20)	9 (16)
Pacific	6 (11)	4 (7)
Other	5 (9)	7 (12)
Duration of diabetes (years), n (%)		
<5	26 (46)	24 (41)
5–10	13 (23)	19 (33)
>10	17 (30)	15 (26)
Use of insulin, n (%)	17 (30)	16 (28)
HbA _{1c} , mean (SD)		
mmol/mol	64.5 (18.1)	61.9 (12.8)
%	8.1 (1.7)	7.8 (1.2)
Body weight (kg), mean (SD)	123.4 (21.3)	126.7 (24.5)
BMI (kg/m ²), n (%)		
35–44.9	43 (77)	41 (71)
45–54.9	9 (16)	15 (26)
55–65	4 (7)	2 (3)

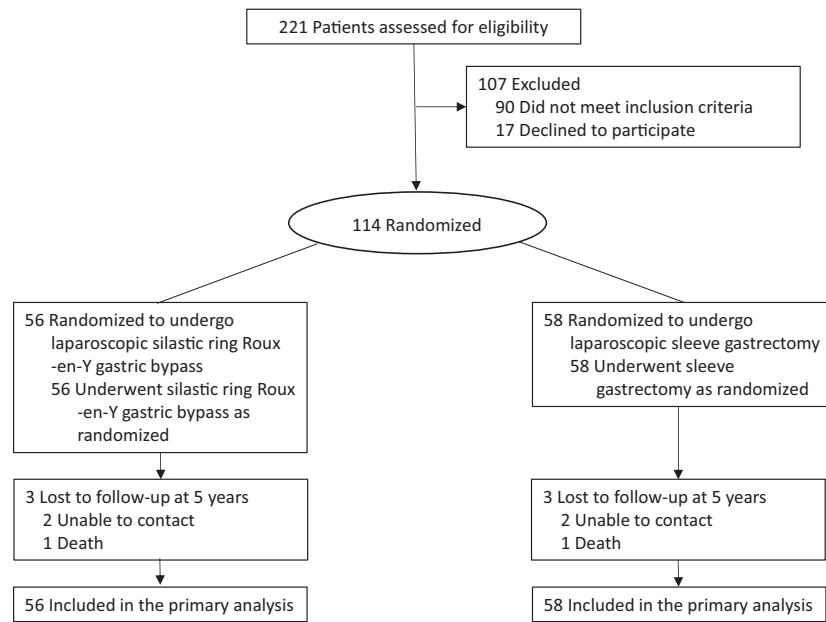


Figure 1—Patient flow through the SR-LRYGB versus LSG trial.

10.7%; 95% CI 7.3%, 14.0%; $P < 0.001$) (Table 2). The difference in the absolute weight change from baseline between those who received LRYGB versus LSG was 12.2 kg (95% CI 6.9, 17.5 kg; $P < 0.001$). Similar patterns of superior percent excess weight loss or weight loss from presurgery were observed after SR-LRYGB (Table 2). Nadir body weight was reached at 12 months after SR-LRYGB and at 9 months after LSG, after which there was steady mean weight regain to 5 years. The weight difference widened over time (time-surgery interaction $P < 0.001$) (Supplementary Fig. 1B).

Cardiovascular Events, Risk Factors, and Medication Use

In the SR-LRYGB group, there was one nonfatal myocardial infarction that occurred 1 year after surgery. In the LSG group there was one admission for angina, and one transient ischemic event. SR-LRYGB resulted in a greater increase in HDL cholesterol than after LSG ($P = 0.03$), although both procedures resulted in similar changes in total cholesterol, triglycerides, and LDL cholesterol (Table 2) in the presence of less lipid-lowering therapy (Supplementary Table 1). Changes in systolic and diastolic blood pressure were not significantly different at 5 years (Table 2), although there was lower antihypertensive medication use 5 years after both SR-LRYGB and LSG (Supplementary Table 1). Most

antihypertensives were from the ACE inhibitor class for the indication of persistent microalbuminuria.

Renal Function

At 5 years, there were no significant changes from baseline in urinary albumin-to-creatinine ratio after either SR-LRYGB or LSG. While there were statistically significant increases in serum creatinine and decreases in estimated glomerular filtration rate after 5 years in both groups (using the MDRD equation), these were clinically insignificant in magnitude (Supplementary Table 2).

Quality of Life

There were significant improvements from baseline in physical functioning and general health domains after both types of surgery (Table 2). Physical role limitations improved only among those who received SR-LRYGB, and overall physical functioning improved more after SR-LRYGB. HADS anxiety scores were unchanged after both types of surgery, while depression symptoms declined in the LSG group (Table 2). Changes in the proportion of people taking anxiety and/or depression medications (18–23% [10 of 56 to 12 of 52] after SR-LRYGB and 14–21% [8 of 58 to 11 of 53] after LSG) did not differ between the groups ($P = 0.54$) and were not significant overall ($P = 0.11$).

Surgical Adverse Events

Detailed early complications (<30 days) and late complications (>30 days until the 5-year follow-up) are reported in Table 3. The early minor morbidity rate was 12.5% ($n = 7$) for SR-LRYGB and 5.2% ($n = 3$) for LSG ($P = 0.20$), while early major morbidity rate was 3.6% ($n = 2$) for SR-LRYGB and 8.6% ($n = 5$) for LSG ($P = 0.44$). There was no surgery-related mortality. Late minor and major complications were 19.6% ($n = 11$) and 12.5% ($n = 7$) after SR-LRYGB vs. 12.1% ($n = 7$) and 3.4% ($n = 2$) after LSG ($P = 0.31$ and $P = 0.09$, respectively). SRs were replaced for significant food intolerance in three participants (5.4%) between 3 and 12 months after the index procedure. A standard 6.5-cm SR was replaced for a larger size tailored to sit loosely around the gastric pouch in the original position. There was no involvement of the SR in the three participants with anastomotic perforation. These perforated ulcers were related to resumption of smoking and taking contraindicated medications (nonsteroidal anti-inflammatory drugs). There was one participant in whom the LSG was converted to RYGB because of severe reflux symptoms at 16 months after LSG.

CONCLUSIONS

In this double-blind (patient and assessor) randomized trial of adults with obesity and type 2 diabetes, SR-LRYGB produced significantly greater diabetes remission compared with LSG after 5 years, using the threshold HbA_{1c} of <6% in the absence of glucose-lowering therapy. Alternative thresholds of achieving an HbA_{1c} of <6.5%, according to the more recent expert consensus definition (20), produced similar results. The SR-LRYGB resulted in greater weight loss, greater improvement in HDL cholesterol, and better physical functioning than LSG, with a similar low prevalence of complications after both procedures. Similar HbA_{1c}, blood pressure, renal function, and non-HDL cholesterol measurements achieved after both types of surgery, in the presence of lower medication use after SR-LRYGB, is likely due to equally aggressive protocol-driven adjustments to metabolic medications made by the blinded endocrinologist investigators.

We previously reported no difference in type 2 diabetes remission after SR-LRYGB compared with LSG at 1 year yet

Table 2—Primary and secondary end points at 5 years

	SR-LRYGB	LSG	OR or absolute difference (95% CI)*
Primary end point			
HbA _{1c} (without diabetes medication)	<i>n</i> = 56	<i>n</i> = 58	
<6.0% (42 mmol/mol)	27 (48)	18 (31)	4.23 (1.33, 13.42)†
Secondary end points			
HbA _{1c} (without diabetes medication)	<i>n</i> = 53	<i>n</i> = 55	
<6.0% (42 mmol/L)	25 (47)	18 (33)	4.50 (1.55, 15.52)†
≤5.6% (38 mmol/mol)	17 (32)	13 (24)	2.90 (1.01, 9.42)†
<6.5% (48 mmol/mol)	33 (62)	28 (51)	4.69 (1.52, 16.62)†
<7.0% (52 mmol/mol)	37 (70)	32 (58)	3.43 (1.20, 10.83)†
Body weight	<i>n</i> = 50	<i>n</i> = 49	
Baseline (kg), mean (SD)	123.1 (22.1)	124.4 (23.5)	
Presurgery (kg), mean (SD)	113.8 (19.5)	116.9 (21.9)	
Year 5 (kg), mean (SD)	89.8 (18.1)	103.3 (16.8)	
Difference (kg), mean (95% CI)			
Baseline to 5 years	−33.3 (−37.0, −29.6)	−21.1 (−25.0, −17.2)	−12.2 (−17.5, −6.9)‡
Presurgery to 5 years	−24.0 (−26.9, −21.0)	−13.6 (−16.8, −10.3)	−10.4 (−14.8, −6.0)‡
Difference, mean % (95% CI)			
Baseline to 5 years	−26.9 (−29.3, −24.5)	−16.3 (−18.6, −13.9)	−10.7 (−14.0, −7.3)‡
Presurgery to 5 years	−21.1 (−23.5, −18.6)	−10.9 (−13.1, −8.7)	−10.1 (−13.4, −6.9)‡
BMI (kg/m ²), mean (SD)	<i>n</i> = 50	<i>n</i> = 49	
Baseline	42.2 (6.0)	42.6 (6.2)	
Year 5	30.7(5.3)	35.4 (4.7)	
Difference (baseline to 5 years), mean (95% CI)	−11.4 (−12.7, −10.2)	−7.2 (−8.4, −5.9)	−4.3 (−6.0, −2.6)‡
Excess weight loss, mean % (95% CI)	69.7 (63.0, 76.4)	40.3 (35.0, 45.7)	29.4 (20.9, 37.9)‡
Total cholesterol (mmol/L), mean (SD)	<i>n</i> = 50	<i>n</i> = 53	
Baseline	4.6 (1.2)	4.4 (1.0)	
Year 5	5.1 (1.0)	5.1 (1.0)	
Difference (baseline to 5 years), mean % (95% CI)	14.7 (6.2, 23.3)	20.2 (11.1, 29.4)	−5.5 (−17.9, 6.9)‡
HDL cholesterol (mmol/L), mean (SD)	<i>n</i> = 50	<i>n</i> = 53	
Baseline	1.1 (0.3)	1.1 (0.3)	
Year 5	1.6 (0.4)	1.4 (0.4)	
Difference (baseline to 5 years), mean % (95% CI)	42.3 (33.3, 51.3)	29.8 (23.2, 36.4)	12.5 (1.6, 23.4)‡
LDL cholesterol (mmol/L), mean (SD)	<i>n</i> = 50	<i>n</i> = 53	
Baseline	2.6 (1.0)	2.4 (0.9)	
Year 5	2.9 (0.9)	2.9 (0.9)	
Difference (baseline to 5 years) mean % (95% CI)	25.1 (8.7, 41.6)	40.6 (18.9, 62.2)	−15.4 (−42.4, 11.6)‡
Triglycerides (mmol/L), mean (SD)	<i>n</i> = 50	<i>n</i> = 53	
Baseline	1.9 (1.2)	2.1 (1.3)	
Year 5	1.2 (0.5)	1.6 (0.7)	
Difference (baseline to 5 years), mean % (95% CI)	−22.9 (−34.3, −11.5)	−10.5 (−23.3, 2.3)	−12.4 (−29.4, 4.6)‡
Systolic blood pressure (mmHg), mean (SD)	<i>n</i> = 42	<i>n</i> = 44	
Baseline	135.6 (15.2)	136.5 (13.9)	
Year 5	132.8 (14.7)	135.5 (15.4)	
Difference (baseline to 5 years), mean % (95% CI)	−1.2 (−5.4, 3.1)	−0.0 (−4.1, 4.0)	−1.1 (−6.9, 4.7)‡
Diastolic blood pressure (mmHg), mean (SD)	<i>n</i> = 42	<i>n</i> = 44	
Baseline	85.9 (10.3)	85.2 (12.1)	
Year 5	83.3 (11.1)	84.8 (10.6)	
Difference (baseline to 5 years), mean % (95% CI)	−2.1 (−6.8, 2.7)	0.9 (−3.8, 5.7)	−3.0 (−9.6, 3.6)‡
HADS (difference, baseline to 5 years), mean (95% CI)	<i>n</i> = 49	<i>n</i> = 48	
Anxiety	−0.21 (−1.42, 1.00)	−0.85 (−2.25, 0.55)	0.64 (−1.18, 2.46)‡
Depression	−1.10 (−2.22, 0.02)	−1.07 (−2.12, −0.02)	−0.03 (−1.54, 1.49)‡
RAND 36-Item Health Survey domains	<i>n</i> = 49	<i>n</i> = 48	
(difference, baseline to 5 years), mean (95% CI)			
Physical functioning	21.2 (14.1, 28.3)	10.9 (3.7, 18.0)	10.4 (0.4, 20.3)‡
Physical role limitations	12.8 (0.7, 24.9)	5.3 (−8.8, 19.4)	7.4 (−10.9, 25.7)‡
Bodily pain	8.4 (−0.5, 17.3)	6.8 (−2.5, 16.1)	1.6 (−11.2, 14.3)‡
General health	22.8 (16.4, 29.1)	19.7 (12.4, 27.1)	3.0 (−6.5, 12.6)‡
Energy/fatigue	6.4 (−0.2, 13.0)	5.0 (−1.8, 11.8)	1.4 (−8.0, 10.7)‡
Social functioning	−5.1 (−14.7, 4.5)	−1.6 (−9.6, 6.5)	−3.5 (−15.9, 8.8)‡

Continued on p. 1508

Table 2—Continued

	SR-LRYGB	LSG	OR or absolute difference (95% CI)*
Emotional role limitations	−4.8 (−14.7, 5.2)	−0.7 (−12.2, 10.7)	−4.1 (−19.0, 10.9)‡
Emotional well-being	−4.7 (−10.1, 0.6)	−1.4 (−7.7, 4.8)	−3.3 (−11.4, 4.8)‡

Data are *n* (%) unless otherwise indicated. The ORs were obtained using logistic regression adjusting for the randomization stratification variables (age category: 20–29, 30–39, or 40–55 years; BMI category: 35–44.9, 45–54.9, and 55–65 kg/m²; ethnicity: Māori, Pacific, New Zealand European, and other; duration of diabetes diagnosis: <5, 5–10, and >10 years; presence of insulin therapy). *The 95% CIs were not adjusted for multiple comparisons. †OR. ‡Mean absolute difference between groups.

significantly greater weight loss after SR-LRYGB (19). Here, we report the proportions of people with type 2 diabetes remission who remained stable between 1 and 5 years after SR-LRYGB (52% and 47%, respectively) and those who declined between 1 and 5 years after LSG (49% and 33%, respectively), concurrent with mean weight increasing after LSG yet remaining stable after SR-LRYGB over

time. After correcting for weight change at 5 years, there was no significant difference in diabetes remission after SR-LRYGB relative to LSG ($P = 0.14$), suggesting that the greater diabetes remission after SR-LRYGB was mostly accounted for by the greater weight loss maintenance after this type of surgery (21–23).

None of the three other randomized studies comparing standard RYGB and

SG has detected a significant difference in type 2 diabetes remission at 5 years, and only one of these demonstrated greater weight loss after RYGB. In the single-institution, nonblinded Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) study, 22% (11 of 49 participants) after LRYGB vs. 15% (7 of 47 participants) after LSG achieved a diabetes remission

Table 3—Complications for SR-LRYGB and LSG

Event	SR-LRYGB (<i>n</i> = 56)	LSG (<i>n</i> = 58)	Absolute difference, % (95% CI)
Early minor: total	7 (12.5)	3 (5.2)	7.3 (−3.0, 17.7)
Anastomotic leak*	1 (1.8)	0	
Neuropraxia	2 (3.6)	0	
Colonic serosal injury†	1 (1.8)	0	
Pulmonary atelectasis	2 (3.6)	0	
Constipation and urinary retention	0	1 (1.7)	
Stricture/stenosis requiring dilation	1 (1.8)	0	
Vomiting	0	1 (1.7)	
Nonspecific abdominal pain	0	1 (1.7)	
Early major: total	2 (3.6)	5 (8.6)	−5.1 (−13.8, 3.7)
Pneumonia‡	1 (1.8)	0	
Hemorrhage§	1 (1.8)	1 (1.7)	
Prolonged hospitalization (>7 days)	0	1 (1.7)	
Wound infection requiring debridement	0	1 (1.7)	
Incisional hernia requiring return to theater	0	1 (1.7)	
Stenosis requiring prolonged hospitalization	0	1 (1.7)	
Late minor: total	11 (19.6)	7 (12.1)	7.6 (−5.8, 20.9)
Food bolus obstruction	1 (1.8)	0	
Symptomatic cholelithiasis	1 (1.8)	4 (6.9)	
Stricture/stenosis requiring dilation	6 (10.7)	3 (5.2)	
Marginal ulcer	2 (3.6)	0	
Negative re-exploration¶	1 (1.8)	0	
Late major: total	7 (12.5)	2 (3.4)	9.1 (−0.8, 18.9)
Anastomotic ulcer perforation#	3 (5.4)	0	
Dysphagia requiring change of SR**	3 (5.4)	0	
Stricture requiring conversion to RYGB	0	1 (1.7)	
Death††	1 (1.8)	1 (1.7)	

Data are *n* (%) unless otherwise indicated. *Radiologic leak, managed conservatively with intravenous antibiotics. †Colonic serosal injury recognized intraoperatively, converted to open because of adhesions. ‡Required admission to intensive care and a prolonged hospital stay. §Participant with SR-LRYGB required return to theater for mesenteric bleed; participant with LSG required blood transfusion and endoscopy for staple line bleed. ||Poor oral intake, cause not identified. ¶Diagnostic laparoscopy for pain, cause not identified. #One patient had two perforations, 3 years apart. **One patient also had resection of afferent part of Roux limb. ††One death was a result of malignancy and one as a result of a car accident.

threshold of $HbA_{1c} \leq 6\%$ at 5 years without the use of diabetes medications ($P = 0.34$). This was despite greater reduction in body weight after LRYGB compared with LSG (mean weight loss 23% vs. 19%, respectively; $P = 0.01$) (34). In the nonblinded Swiss Multicentre Bypass or Sleeve Study (SM-BOSS), no significant difference in diabetes remission was seen between LRYGB (68%, 19 of 28 participants) and SG (62%, 16 of 26 participants), while percent excess BMI loss was also similar (68% vs. 61%) (35). In the multicenter, nonblinded Sleeve vs. Bypass (SLEEVEPASS) study of 240 obese patients, of whom 101 (42%) had type 2 diabetes at baseline, diabetes remission at 5 years (defined by $HbA_{1c} < 6\%$ and fasting glucose < 5.6 mmol/L in the absence of medications) was seen in 25% (10 of 40 patients) after LRYGB compared with 12% (5 of 41 patients) after LSG ($P > 0.05$), while mean percent excess weight loss at 5 years was 57% after LRYGB and 49% after LSG (36). The marked differences in the proportions of diabetes remission seen across these studies (12–68%) most likely reflect clinical heterogeneity in the characteristics of patients with type 2 diabetes included in each study. Our study used stratified randomization to prevent imbalance between treatment groups for known factors that influence the likelihood of type 2 diabetes remission, such as age, BMI, duration of diabetes, insulin treatment, and ethnicity. Most of these variables are used in clinical scoring tools to predict the likelihood of diabetes remission after surgery (37).

Both weight-dependent and weight-independent glucose-lowering effects of RYGB compared with SG have been proposed. More favorable changes in gut peptides, bile acids, gut microbiota, and small intestine glucose utilization may contribute to maintaining a longer-term reduction of weight and/or type 2 diabetes to a greater extent after RYGB than SG procedures (24). However, the more durable mechanical restriction of caloric intake afforded by the banded version of the RYGB over SG is the most likely driver of greater weight reduction and associated diabetes remission. The importance of the band in providing superior long-term weight loss has been demonstrated in several studies comparing primary banded versus unbanded RYGB or SG. Of the three randomized studies

that have compared outcomes from primary banded RYGB versus RYGB (21–23), there was similar weight loss at 1 and 2 years postoperatively, but increased weight loss maintenance at 3 years after banded RYGB (21) and 5 years after banded RYGB in a nonrandomized prospective study (25). No difference in diabetes remission was noted in a systematic review and meta-analysis of banded versus nonbanded RYGB, although numbers were low beyond 2 years follow-up (26). Primary banded SG provided better weight loss at 3 years compared with unbanded SG in a randomized trial but was underpowered to detect differences in diabetes remission (27).

Supporting the importance of gut restriction to achieving and maintaining weight loss is the observation of gastric pouch dilation after SG or dilation of both the gastric pouch and gastrojejunostomy after RYGB among people with insufficient weight loss or weight regain (28–31). Hence, surgical interventions that improve gut restriction (such as revision of SG to RYGB), endoluminal interventions for gastrojejunostomy reduction (32), or salvage banding (33) as treatment for weight regain after RYGB have been shown to be effective.

People of Māori or Pacific ethnicity, who represented 26% of the trial population, had significantly lower diabetes remission at 5 years than those of New Zealand European or other ethnicities. It remains to be investigated whether ethnicity is a significant independent predictor of diabetes remission in the presence of other factors, such as socioeconomic determinants of health, that assist with maintaining weight loss after surgery. There have been conflicting reports on differences in diabetes remission in the few studies that have examined interethnic differences in bariatric surgery outcomes (39,40). Even fewer studies have evaluated the comparative efficacy and safety outcomes from bariatric surgery among indigenous and nonindigenous people (38).

Several studies indicated significantly reduced levels of anxiety and depression symptoms after surgery, with potential for reappearance or worsening of symptoms later (41,42). In this study, anxiety scores were unchanged 5 years after both types of surgery. The proportion of people prescribed psychotropic medications from

baseline to 5 years did not change significantly after either type of surgery in this study.

Most bariatric surgeons do not perform SR-RYGB, perhaps because of cost and time spent to insert the band or fear of complications. We have previously reported a significant increase in theater time (~ 80 min) for performing SR-LRYGB compared with LSG (43), which is an important cost consideration in addition to the cost of the band. The need for postoperative endoscopic intervention was similar between the two groups, but diagnostic endoscopies were more prevalent after SR-LRYGB. Complications of SR placement involving erosion and migration have been reported to require band removal in $\sim 2\%$ patients (26,44) but were not seen in our study. Rather, band replacement occurred in three participants (5.4%) for food intolerance, which has been reported to occur more frequently with banded RYGB (45). Despite the potential for a learning curve effect from several surgical fellows performing the SR-LRYGB, the early and late major surgical complications were comparable to what has been reported in other studies comparing nonbanded RYGB and SG (34–36).

This study has several key strengths. It was a double-blind (assessor and patient), randomized study powered for detecting a clinically important difference in the primary outcome of diabetes remission at 5 years. Double-blinding is essential to prevent bias in reporting and assessment of outcomes, especially in adjustment of glucose-lowering medications, which underpins the definition of diabetes remission. Randomization should ensure balance of recognized and unrecognized participant characteristics that may be correlated with the outcome of diabetes remission in a large clinical trial. However, stratified randomization by recognized baseline participant characteristics associated with long-term diabetes remission, such as age, diabetes duration, and insulin treatment (46–48), is a way of achieving this in relatively small trials such as this one. This trial was embedded in our center's health care delivery system and thus reflects usual care for the multiethnic patients referred for bariatric surgery and enhances the external validity and generalizability of the findings.

Our study also had some limitations. First, the single-center design, while reducing variation in operative and perioperative procedures, may make the study results potentially less generalizable. However, given that the procedures were performed by several bariatric surgical training fellows, these results are likely to be more generalizable to routine surgical practice. Second, in the absence of a non-banded RYGB comparative group in this study, we do not know whether the superior diabetes remission after SR-LRYGB compared with LSG also applies to non-banded RYGB. On balance, given that diabetes remission is related to weight loss and that there is less weight regain seen after banded RYGB, it is likely that banding contributes to the long-term superiority of RYGB over LSG in both diabetes remission and weight loss. Finally, 5% of the participants were lost to follow-up at 5 years, which is similar to most other studies.

Among patients with type 2 diabetes and obesity, SR-LRYGB produced significantly greater long-term remission of type 2 diabetes, weight loss, and improvements in physical functioning with minimal additional complications or surgical morbidity compared with LSG. These results suggest an important role for this type of metabolic surgery.

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