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Effect of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Roux-en-Y Gastric Bypass on Weight Loss in Patients With Morbid Obesity
The SM-BOSS Randomized Clinical Trial

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IMPORTANCE Sleeve gastrectomy is increasingly used in the treatment of morbid obesity, but its long-term outcome vs the standard Roux-en-Y gastric bypass procedure is unknown.

OBJECTIVE To determine whether there are differences between sleeve gastrectomy and Roux-en-Y gastric bypass in terms of weight loss, changes in comorbidities, increase in quality of life, and adverse events.

DESIGN, SETTING, AND PARTICIPANTS The Swiss Multicenter Bypass or Sleeve Study (SM-BOSS), a 2-group randomized trial, was conducted from January 2007 until November 2011 (last follow-up in March 2017). Of 3971 morbidly obese patients evaluated for bariatric surgery at 4 Swiss bariatric centers, 217 patients were enrolled and randomly assigned to sleeve gastrectomy or Roux-en-Y gastric bypass with a 5-year follow-up period.

INTERVENTIONS Patients were randomly assigned to undergo laparoscopic sleeve gastrectomy (n = 107) or laparoscopic Roux-en-Y gastric bypass (n = 110).

MAIN OUTCOMES AND MEASURES The primary end point was weight loss, expressed as percentage excess body mass index (BMI) loss. Exploratory end points were changes in comorbidities and adverse events.

RESULTS Among the 217 patients (mean age, 45.5 years; 72% women; mean BMI, 43.9) 205 (94.5%) completed the trial. Excess BMI loss was not significantly different at 5 years: for sleeve gastrectomy, 61.1%, vs Roux-en-Y gastric bypass, 68.3% (absolute difference, −7.18%; 95% CI, −14.30% to −0.06%; *P* = .22 after adjustment for multiple comparisons). Gastric reflux remission was observed more frequently after Roux-en-Y gastric bypass (60.4%) than after sleeve gastrectomy (25.0%). Gastric reflux worsened (more symptoms or increase in therapy) more often after sleeve gastrectomy (31.8%) than after Roux-en-Y gastric bypass (6.3%). The number of patients with reoperations or interventions was 16/101 (15.8%) after sleeve gastrectomy and 23/104 (22.1%) after Roux-en-Y gastric bypass.

CONCLUSIONS AND RELEVANCE Among patients with morbid obesity, there was no significant difference in excess BMI loss between laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass at 5 years of follow-up after surgery.

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Supplemental content

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Bariatric surgery is the most effective treatment for patients with morbid obesity. Until recently, Roux-en-Y gastric bypass was regarded as the standard bariatric procedure. However, sleeve gastrectomy is being performed with increasing frequency despite the lack of evidence regarding its long-term efficacy.[1] The sleeve gastrectomy procedure is technically easier, faster to perform, and potentially safer compared with Roux-en-Y gastric bypass. However, much more data on clinical and metabolic long-term outcomes are available on the Roux-en-Y gastric bypass procedure. Early and midterm results of sleeve gastrectomy showed potential benefit, but only a limited number of randomized studies have compared outcomes of sleeve gastrectomy and Roux-en-Y gastric bypass head to head, most of which were underpowered because of low patient numbers, short follow-up, or both.[2-6]

The purpose of this trial was to compare differences between sleeve gastrectomy and Roux-en-Y gastric bypass in the treatment of morbid obesity in terms of weight loss, changes in comorbidities, quality of life, and adverse events.

Key Points

Question Is there a difference in weight loss between laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass in patients with morbid obesity?

Findings In this randomized clinical trial that included 217 adults with morbid obesity, percentage excess body mass index loss in patients undergoing sleeve gastrectomy compared with gastric bypass was 61.1% vs 68.3% after 5 years, a difference that was not statistically significant after adjustment for multiple comparisons.

Meaning This study did not find a significant difference in weight loss between sleeve gastrectomy and gastric bypass.

Methods

The study was conducted in accordance with the principles of the Declaration of Helsinki,[7] approved by each local ethical committee, and registered at the clinical trials registry of the National Institutes of Health. All patients gave written informed consent.

Study Design

The trial protocol and statistical analysis plan are available in Supplement 1. In brief, the trial was a 2-group, randomized, multicenter study including 217 patients with morbid obesity at 4 bariatric centers in Switzerland and conducted from January 2007 until November 2011, with final follow-up in March 2017 (**Figure 1**). One of the 4 centers was added in 2008 to increase the size of the study population and decrease the enrollment time.

Participants

Following the general criteria for bariatric surgery in Switzerland, study inclusion criteria were a body mass index (BMI) greater than 40 or a BMI greater than 35 with the presence of at least 1 comorbidity (BMI calculated as weight in kilograms divided by height in meters squared), an age of 18 to 65 years, and failure of conservative treatment for 2 years. Exclusion criteria were contraindications for major abdominal surgery, previous bariatric surgery, severe symptomatic gastroesophageal reflux disease despite medication, large hiatal hernia, expected dense adhesions at the level of the small bowel, need for endoscopic follow-up of the duodenum, and history of inflammatory bowel disease.

Randomization

A central, computer-based block randomization (block size of 20) with sealed envelopes was carried out. There was no blinding with regard to the type of operation: patients as well as physicians and dietitians assessing follow-up data were informed about the procedure performed.

Interventions

In sleeve gastrectomy, the majority of the stomach is vertically resected and a tube-shaped remnant is left along the lesser curvature. In Roux-en-Y gastric bypass, a small gastric pouch is connected to the small intestine, bypassing the stomach, duodenum, and the proximal part of the jejunum. The 2 interventions were standardized across the centers and all procedures were performed laparoscopically. The surgical interventions, number of participating surgeons, and centers are described in more detail in **Table 1** and **Table 2** and in eAppendix 1 in Supplement 2.

Outcomes

All patients were assessed as part of a routine follow-up program in the outpatient clinic of each participating center according to Swiss guidelines and were seen on a regular schedule 6 weeks and 3, 6, 9, 12, 18, and 24 months postoperatively. Thereafter, patients were seen annually. The primary end point of the study was weight loss, defined as percentage excess BMI loss (100 × [baseline BMI − follow-up BMI]/[baseline BMI − 25]), over a 5-year period. Weight was measured at each visit. Exploratory clinical end points were (1) changes in comorbidities (arterial hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, gastroesophageal reflux, arthralgia, depression, and hyperuricemia; assessed by a physician at each visit); (2) quality of life assessed on the Gastrointestinal Quality of Life Index (36 items; scale range, 0-144 points; most desirable option: 4 points; least desirable option: 0 points; mean score among healthy individuals, 125.8 points)[8] and the Bariatric Analysis and Reporting Outcome System quality-of-life (BAROS QoL) score (5 items; scale range, −3 to 3 points; most desirable option: 1 point for 1 item, 0.5 point for the other 4 items; least desirable option: −1 point for 1 item, −0.5 point for the other 4 items)[9,10]; (3) the rate of perioperative and long-term morbidity necessitating reoperation or intervention; and (4) mortality. Metabolic effects and mechanisms were previously analyzed as exploratory end points in subgroups.[11-15] Definitions of comorbidities are described in eTable 1 in Supplement 2.

The following exploratory end points mentioned in the original study protocol (Supplement 1) are not reported herein: duration of the operation (previously published[16]), costs (analysis abandoned because of changes in reimbursement system in Switzerland), and quality of food intake (analysis abandoned because of inappropriate questionnaire). Other exploratory

outcomes included BMI changes, weight loss, percentage of original weight loss, and cut points of 25%, 50%, and 75% in excess BMI loss (scale of weight loss divided into quartiles following the classification of the BAROS score[10]).

Statistical Analysis

The power estimation for excess percentage BMI loss was based on the assumptions of equal variances in both treatment groups, a pooled standard deviation of 20%, a base effect of excess BMI loss at 5 years of 50% in the control group and a minimum detectable difference of an additional 10%, and an α=.05. A sample size of 100 patients per group was estimated to provide a power of 94% to reject the null hypothesis of equal means using a 2-sided, 2-sample equal-variance *t* test.[17,18] According to a meta-analysis, a difference of 10% in excess BMI loss resulted in a superior type 2 diabetes remission rate when comparing gastric banding, Roux-en-Y gastric bypass, and biliopancreatic diversion.[19] Therefore, a minimal difference of 10% excess BMI loss was considered clinically relevant.

All comparisons between treatment groups are reported as absolute differences with 95% confidence intervals and *P* values. Missing follow-up data were imputed by a multiple imputation technique using the fully conditional specification method based on Markov chain Monte Carlo simulation. From the imputed data set, the other weight-related parameters were calculated.

Longitudinal data were first analyzed for all of the follow-up time points jointly by a linear mixed-effects model analysis using type of intervention, center, sex, and visits (time) as fixed effects and age and initial BMI as random effects, in which visits represented the repeated measures of the longitudinal data. This approach was used instead of the originally planned repeated-measures analysis of variance to better capture the data structure of the repeated measures. Afterward, pairwise comparisons between treatment groups were performed for each time point separately, with multiple unpaired *t* tests with subsequent step-down Bonferroni-Holm correction for *P*-value adjustment for multiple comparisons.

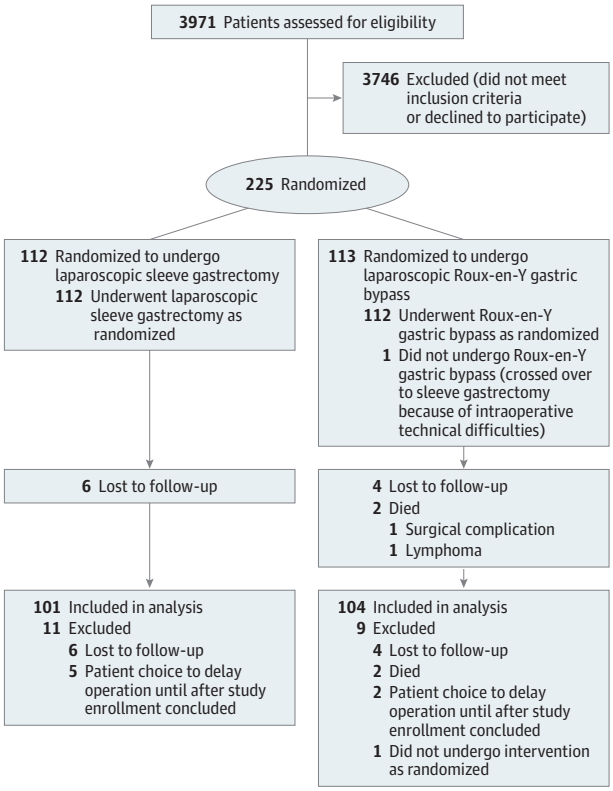
For the analysis of adverse events and comorbidities, proportions were compared by χ^2 and Fisher exact tests as appropriate. Exploratory outcomes were compared between baseline and 5-year follow-up and for the difference between both time points. All statistical tests were 2-sided and $P < .05$ was considered statistically significant.

SPSS for Windows, version 25 (IBM), and R, version 3.4.2 (R Project for Statistical Computing, R Foundation; http://www.r-project.org/; chisq.test, fisher.test, and prop.test) were used for data analysis (see original statistical plan in Supplement 1 and eAppendix 2 in Supplement 2).

Results

Of the 225 patients randomized, a total of 217 were included and randomly assigned to undergo either sleeve gastrectomy (n = 107) or Roux-en-Y gastric bypass (n= 110). Eight patients were excluded from the analysis: 7 patients chose to undergo later operation (when the enrollment phase had already been concluded) and 1 patient crossed over from the Roux-en-Y gastric bypass group to the sleeve gastrectomy group because of unexpected dense adhesions of the jejunum, which were detected intraoperatively. Baseline demographic characteristics are shown in Table 1. After 5 years, data from 205 patients (94.5%) were available for evaluation. Ten patients were lost to follow-up, 2 patients died (1 within 30 days of operation because of a surgical complication and 1 after 2.5 years because of lymphoma) (Figure 1). Missing data for weight was 0% at baseline, 0.46% at 1 year, 25.8% at 2 years, 3.2% at 3 years, 31.8% at 4 years, and 5.5% (including 12 dropouts) at 5 years. All reported *P* values are corrected for multiple comparisons unless indicated otherwise.

Figure 1. Participant Flow Through the Swiss Multicenter Bypass or Sleeve Study



Primary Outcome

Overall, both treatments significantly reduced percentage excess BMI loss over the observation period, with significant overall differences between the groups without adjustment for multiple comparisons (*P* = .03). However, in the primary analysis that adjusted for multiple comparisons, there were no statistically significant differences in percentage excess BMI loss for sleeve gastrectomy compared with Roux-en-Y gastric bypass, respectively, at 1 year (72.4% vs 76.7%; absolute difference, −4.22%; 95% CI, −9.96% to 1.51%; *P* = .30); at 2 years (71.9% vs 77.4%; absolute difference, −5.57%; 95% CI, −11.84% to 0.71%; *P* = .25); at 3 years (69.5% vs 73.9%; absolute difference, −4.32%; 95% CI, −10.59% to 1.59%; *P* = .30); at 4 years

Table 1. Baseline Demographic Characteristics[a]

Characteristics	Sleeve Gastrectomy (n = 107)	Roux-en-Y Gastric Bypass (n = 110)
Age, mean (SD), y	43.0 (11.1)	42.1 (11.2)
Female	77 (72.0)	79 (71.8)
Weight, mean (SD), kg	123.5 (19.4)	124.8 (19.8)
Body mass index, mean (SD)[b]	43.6 (5.2)	44.2 (5.3)
Type 2 diabetes	26 (24.3)	28 (25.5)
Dyslipidemia	72 (67.3)	56 (50.9)
Gastroesophageal reflux	47 (43.9)	51 (46.4)
Hypertension	67 (62.6)	65 (59.1)
Obstructive sleep apnea	51 (47.7)	46 (41.8)
Back or joint pain	65 (60.7)	75 (68.2)
Hyperuricemia	16 (15)	11 (10)
Depression	21 (19.6)	12 (10.9)

[a] Data are expressed as No. (%) of participants unless otherwise indicated.

[b] Calculated as weight in kilograms divided by height in meters squared

Table 2. Interventions per Surgeon

	No. (%)	
Surgeons	Sleeve Gastrectomy (n = 107)	Roux-en-Y Gastric Bypass (n = 110)
A	63 (58.9)	60 (54.5)
B	24 (22.4)	21 (19.1)
C	11 (10.3)	6 (5.5)
D	3 (2.8)	9 (8.2)
E	4 (3.7)	11 (10.0)
F	2 (1.9)	3 (2.7)

(64.1% vs 70.8%; absolute difference, −6.73%; 95% CI, −13.25% to −0.20%; P = .22); and at 5 years (61.1% vs 68.3%; absolute difference, −7.18%; 95% CI, −14.30% to −0.06%; P = .22) (**Figure 2**). Results without adjustment for multiple comparisons were not significantly affected by center (P = .19; for absolute differences among centers, see eTables 2 and 3 in Supplement 2), age (absolute difference, 0.25%; 95% CI, 0.004%-0.50%; P = .28), and sex (absolute difference, 5.45%; 95% CI, −0.72% to 11.61%; P = .08), but initial BMI (absolute difference, −1.44; 95% CI, −1.94 to −0.94; P < .001) significantly contributed to the percentage excess BMI loss.

There was a significant trend (P < .001) for a linear decrease in excess BMI loss over the follow-up period for both treatment groups (for sleeve gastrectomy, slope, −3.05% [95% CI, −4.53% to −1.58%] per year; P < .001; intercept, 77.0% [95% CI, 72.07%-81.85%]; P < .001 and for Roux-en-Y gastric bypass, slope, −2.34% [95% CI, −3.72% to −0.97%] per year; P = .001; intercept, 80.4% [95% CI, 75.9%-85.0%]; P < .001).

Exploratory Outcomes

At baseline, 26 (25.7%) of 101 in the sleeve gastrectomy group and 28 (26.9%) of 104 in the Roux-en-Y gastric bypass group had type 2 diabetes; 6 (23.1%) of 26 in the sleeve gastrectomy group and 6 (21.4%) of 28 in the Roux-en-Y gastric bypass group were receiving insulin treatment. At 5 years after surgery, complete remission was seen in 16 (61.5%) of 26 in the sleeve gastrectomy group vs 19 (67.9%) of 28 in the Roux-en-Y gastric bypass group (absolute difference, −0.04%; 95% CI, −0.37% to 0.28%; P > .99). Marked amelioration of glycemic control was seen after 5 years compared with baseline, with no significant differences between the treatment groups in fasting glucose (sleeve gastrectomy, 114.1 mg/dL, vs Roux-en-Y gastric bypass, 101.1 mg/dL; absolute difference, 13.0 mg/dL; 95% CI, −7.50 to 33.49 mg/dL; P = .21) or hemoglobin A_{1c} (sleeve gastrectomy, 6.2%, vs Roux-en-Y gastric bypass, 5.9%; absolute difference, 0.30%; 95% CI, −0.06% to 0.82%; P = .09), uncorrected for multiple comparisons (**Table 3** and **Table 4**).

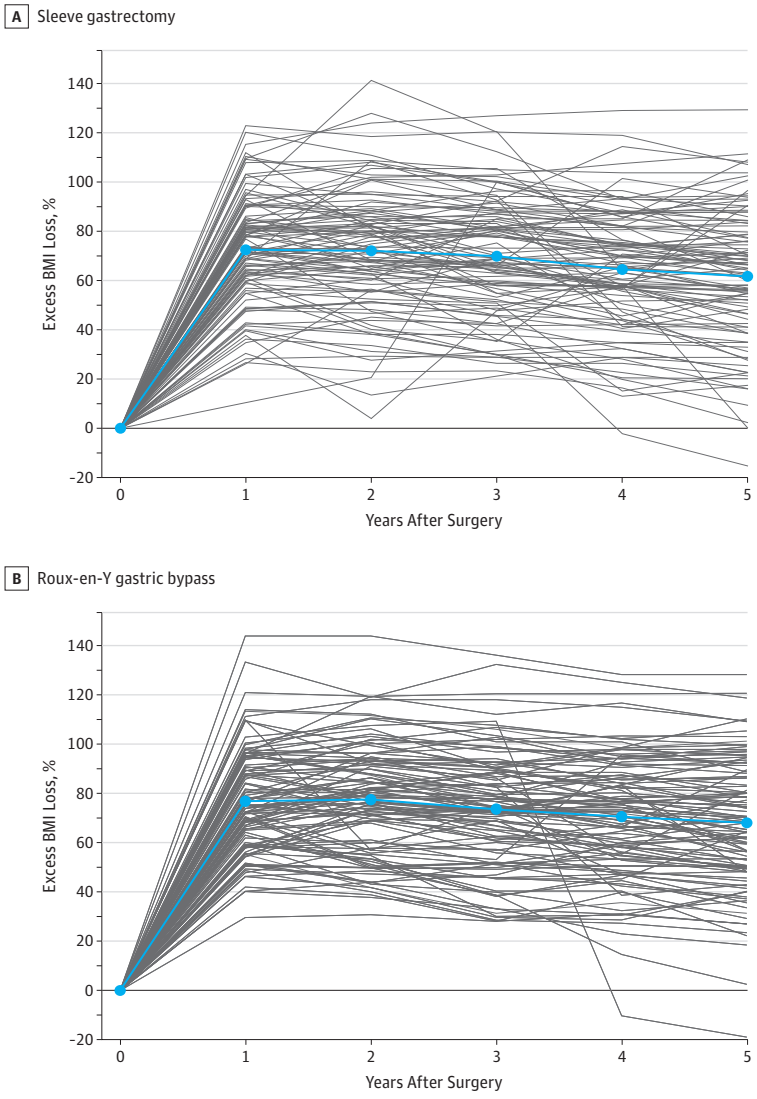
Before surgery, 68 (67.3%) of 101 in the sleeve gastrectomy group and 53 (51%) of 104 in the Roux-en-Y gastric bypass group had dyslipidemia. Complete remission was seen in 29 (42.6%) of 68 in the sleeve gastrectomy group vs 33 (62.3%) of 53 in the Roux-en-Y gastric bypass group 5 years after surgery (absolute difference, −0.19%; 95% CI, −0.38% to −0.003%) (Table 3).

Significant amelioration was seen after 5 years for total and high-density lipoprotein cholesterol, ratio of total cholesterol to high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides in both groups (Table 4). Although there was no significant difference in total and high-density lipoprotein cholesterol and triglycerides between the groups, the ratio of total cholesterol to high-density lipoprotein cholesterol (sleeve gastrectomy, 3.3, vs Roux-en-Y gastric bypass, 3.0; absolute difference, 0.38; 95% CI, 0.06-0.70; P = .02) and low-density lipoprotein cholesterol (sleeve gastrectomy, 116.1 mg/dL, vs Roux-en-Y gastric bypass, 101.1 mg/dL; absolute difference, 14.95 mg/dL; 95% CI, 3.91-25.99 mg/dL; P = .008) were both significantly better 5 years after Roux-en-Y gastric bypass (Table 4).

At the time of surgery, 44 (43.6%) of 101 in the sleeve gastrectomy group and 48 (46.2%) of 104 in the Roux-en-Y gastric bypass group experienced some degree of gastroesophageal reflux disease. After 5 years, remission of reflux symptoms was seen in 11 (25%) of 44 in the sleeve gastrectomy group and 29 (60.4%) of 48 in the Roux-en-Y gastric bypass group (absolute difference, −0.36%; 95% CI, −0.57% to −0.15%; P = .002) and worsening of symptoms was more often seen in the sleeve gastrectomy group (14/44 [31.8%] vs 3/48 [6.3%]; absolute difference, 0.36%; 95% CI, 0.13%-0.59%; P = .006). In addition, 18 (31.6%) of 57 patients who had no gastroesophageal reflux disease at baseline reported de novo reflux symptoms 5 years after sleeve gastrectomy, whereas this was the case only in 6 (10.7%) of 56 patients who underwent Roux-en-Y gastric bypass (absolute difference, 0.31%; 95% CI, 0.08%-0.54%; P = .01) (Table 3).

Quality of life increased significantly in both groups between baseline and 5 years. There were no statistically significant differences between the 2 groups on the Gastrointestinal Quality of Life Index (sleeve gastrectomy, 113.6 points, vs Roux-en-Y gastric bypass, 117.9 points; absolute difference, −4.33 points; 95% CI, −15.07 to 6.40 points; P = .42) and the BAROS QoL score (1.4 vs 1.7 points, respectively; absolute difference, −0.25 points; 95% CI, −0.64 to 0.14 points; P = .20), uncorrected for multiple comparisons (Table 4).

Figure 2. Percentage Excess BMI Loss After Sleeve Gastrectomy (n=101) or Roux-en-Y Gastric Bypass (n=104) Over 5 Years of Follow-up



Time course of superimposed cumulative individual values of percentage excess body mass index (BMI) loss over the 5-year period after surgery. Circles indicate mean values at 1, 2, 3, 4, and 5 years after surgery. Missing values were imputed for number of participants at each time point. Body mass index is calculated as weight in kilograms divided by height in meters squared.

Adverse Events

Early Complications (0-30 Days After Surgery)

One patient in the sleeve gastrectomy group and 5 patients in the Roux-en-Y gastric bypass group required additional surgical or endoscopic intervention in the perioperative period (1/107 [0.9%] vs 5/110 [4.5%]; absolute difference, −0.19%; 95% CI, −0.57% to 0.20%; P = .66, uncorrected for multiple comparisons). In the sleeve gastrectomy group, 1 obstruction of the gastric sleeve was treated by laparoscopic revision. In the Roux-en-Y gastric bypass group, 2 patients needed surgical evacuation of intraabdominal abscess formation and 1 for pleural empyema, and 1 patient had an obstruction of the biliopancreatic limb. One patient had a leakage at the gastrojejunostomy with a complicated course, which eventually led to multiorgan failure and death.

Late Complications

Fifteen (14.9%) of 101 patients in the sleeve gastrectomy group and 18 (17.3%) of 104 in the Roux-en-Y gastric bypass group required additional surgical or endoscopic interventions from postoperative day 30 through 5-year follow-up (absolute difference, −0.05%; 95% CI, −0.25% to 0.16%; P = .77, uncorrected for multiple comparisons). In the sleeve gastrectomy group, 9 patients underwent conversion to Roux-en-Y gastric bypass because of severe gastroesophageal reflux disease, 5 patients had insufficient weight loss (3 converted to biliopancreatic diversion duodenal switch and 2 to Roux-en-Y gastric bypass), and 1 patient had incisional hernia repair. Among the 9 patients who converted to Roux-en-Y gastric bypass during the 5 years of follow-up, 1 had developed de novo Barrett mucosa, 1 had hiatal herniation of the sleeve, and 7 experienced reflux esophagitis that was not responsive to proton pump inhibitor treatment.

In the Roux-en-Y gastric bypass group, 2 patients had small bowel obstruction, 9 patients were treated for internal hernia (of which 5 had primary closure of the defects and 4 did not at the time of primary operation), and 2 patients with insufficient weight loss underwent renewal of the gastrojejunostomy with

Table 3. Changes in Comorbidities at 5 Years

Comorbidities[a]	No. (%)		Absolute Difference, % (95% CI)[b]	*P* Value	
	Sleeve Gastrectomy (n = 101)	Roux-en-Y Gastric Bypass (n = 104)		Unadjusted	Adjusted[c]
Type 2 Diabetes					
Comorbidity present at baseline	26/101 (25.7)	28/104 (26.9)	−0.02 (−0.18 to 0.15)	.97[d]	
Remission	16 (61.5)	19 (67.9)	−0.04 (−0.37 to 0.28)	.77[d]	>.99
Improved	4 (15.4)	2 (7.1)	0.22 (−0.28 to 0.45)	.40[e]	>.99
Unchanged	3 (11.5)	3 (10.7)	0.03 (−0.42 to 0.49)	>.99[e]	>.99
Worsened	3 (11.5)	4 (14.3)	−0.05 (−0.49 to 0.48)	>.99[e]	>.99
De novo development of comorbidity	0	3/76 (3.9)	−0.50 (−1.00 to 0.08)	>.99[e]	
Dyslipidemia					
Comorbidity present at baseline	68/101 (67.3)	53/104 (51)	0.17 (0.02 to 0.39)	.03[d]	
Remission	29 (42.6)	33 (62.3)	−0.19 (−0.38 to −0.003)	.03[d]	.09
Improved	28 (41.2)	16 (30.2)	0.12 (−0.08 to 0.32)	.21[d]	.36
Unchanged	11 (16.2)	4 (7.5)	0.20 (−0.09 to 0.48)	.18[e]	.36
Worsened	0	0			
De novo development of comorbidity	3/33 (9.1)	6/51 (11.8)	−0.07 (−0.46 to 0.32)	>.99[e]	
Gastroesophageal Reflux					
Comorbidity present at baseline	44/101 (43.6)	48/104 (46.2)	−0.03 (−0.17 to 0.12)	.71[d]	
Remission	11 (25)	29 (60.4)	−0.36 (−0.57 to −0.15)	.0006[d]	.002
Improved	4 (9.1)	3 (6.3)	0.10 (−0.36 to 0.56)	.71[e]	.94
Unchanged	15 (34.1)	13 (27.1)	0.08 (−0.16 to 0.33)	.47[d]	.94
Worsened	14 (31.8)[a]	3 (6.3)	0.36 (0.13 to 0.59)	.002[e]	.006
De novo development of comorbidity	18/57 (31.6)	6/56 (10.7)	0.31 (0.08 to 0.54)	.01[d]	
Hypertension					
Comorbidity present at baseline	64/101 (63.4)	64/104 (61.5)	0.02 (−0.12 to 0.16)	0.90[d]	
Remission	40 (62.5)	45 (70.3)	−0.09 (−0.29 to 0.11)	0.34[d]	>.99
Improved	16 (25)	14 (21.9)	0.04 (−0.18 to 0.27)	.68[d]	>.99
Unchanged	4 (6.3)	2 (3.1)	0.17 (−0.30 to 0.65)	.67[e]	>.99
Worsened	4 (6.3)	3 (4.7)	0.08 (−0.38 to 0.53)	>.99[e]	>.99
De novo development of comorbidity	2/37 (5.4)	2/40 (5)	0.01 (−0.49 to 0.51)	>.99[e]	
Obstructive Sleep Apnea					
Comorbidity present at baseline	48/101 (47.5)	43/104 (41.3)	0.06 (−0.08 to 0.21)	.45[d]	
Remission	22 (45.8)	19 (44.2)	0.02 (−0.21 to 0.24)	.87[d]	>.99
Improved	24 (50)	22 (51.2)	−0.01 (−0.23 to 0.21)	.91[d]	>.99
Unchanged	0	1 (2.3)	−0.53 (−1.00 to 0.08)	.47[e]	>.99
Worsened	2 (4.2)	1 (2.3)	0.14 (−0.54 to 0.83)	>.99[e]	>.99
De novo development of comorbidity	5/53 (9.4)	1/61 (1.6)	0.39 (−0.01 to 0.79)	>.99[e]	
Back or Joint Pain					
Comorbidity present at baseline	60/101 (59.4)	72/104 (69.2)	−0.11 (−0.26 to 0.05)	.19[d]	
Remission	33 (55)	35 (48.6)	0.06 (−0.12 to 0.25)	.46[d]	>.99
Improved	23 (38.3)	22 (30.6)	0.09 (−0.11 to 0.28)	.35[d]	>.99
Unchanged	3 (5)	13 (18.1)	−0.30 (−0.55 to −0.06)	.03[e]	.12
Worsened	1 (1.7)	2 (2.8)	−0.12 (−0.79 to 0.54)	>.99[e]	>.99
De novo development of comorbidity	0	0			
Hyperuricemia					
Comorbidity present at baseline	15/101 (14.9)	10/104 (9.6)	0.12 (−0.11 to 0.35)	.35[d]	
Remission	15 (100)	10 (100)	0.12 (−0.11 to 0.35)	.35[d]	.35
Improved	0	0			
Unchanged	0	0			
Worsened	0	0			
De novo development of comorbidity	0	0			

(continued)

Table 3. Changes in Comorbidities at 5 Years (continued)

Comorbidities[a]	No. (%)		Absolute Difference, % (95% CI)[b]	P Value	
	Sleeve Gastrectomy (n = 101)	Roux-en-Y Gastric Bypass (n = 104)		Unadjusted	Adjusted[c]
Depression					
Comorbidity present at baseline	21/101 (20.8)	12/104 (11.5)	0.17 (−0.03 to 0.37)	.11[d]	
Remission	8 (38.1)	6 (50)	−0.11 (−0.51 to 0.28)	.51[d]	>.99
Improved	8 (38.1)	6 (50)	−0.11 (−0.51 to 0.28)	.51[d]	>.99
Unchanged	0	0			
Worsened	5 (23.8)	0	0.43 (0.13 to 0.73)	.13[e]	.39
De novo development of comorbidity	7/80 (8.8)	2/92 (2.2)	0.33 (−0.01 to 0.45)	>.99[e]	

[a] Remission: no symptoms and/or no medication; improvement: fewer symptoms and/or less medical treatment or medications; unchanged: same symptoms and equivalent therapy; worsened: more symptoms or increase in therapy. De novo comorbidity: comorbidity not present at baseline but newly developed within 5 years postoperatively. Remission of type 2 diabetes: hemoglobin A_{1c} <42 mmol/mol (6.0%), fasting glucose <100 mg/dL, and at least 1 year with no active pharmacologic therapy.

[b] Prop.test (R Project).

[c] Adjustment by step-down Bonferroni-Holm correction for multiple comparisons for the number of subitem tests.

[d] χ^2 Test.

[e] Fisher exact test.

pouch resizing. Furthermore, 3 patients experienced severe dumping and underwent reoperation, twice by pouch revision and once by bypass reversal. In addition, 1 patient needed incisional hernia repair, and in another patient laparoscopy was performed for endoscopic access to the gastric remnant. Weight loss to below a BMI of 18, hypoalbuminemia, and life-threatening complications or deaths associated with the interventions did not occur up to 5 years after surgery. In total (early and late complications), 16 patients in the sleeve gastrectomy group and 23 in the Roux-en-Y gastric bypass group required revisions (absolute difference, −0.10%; 95% CI, −0.29% to 0.09%; *P* = .33) (**Table 5**).

Post Hoc Outcomes

All *P* values reported under post hoc outcomes are uncorrected for multiple comparisons because comparisons were made only for baseline vs 5 years.

The percentage of patients with a percentage excess BMI loss greater than 50% at 5 years was 68.3% in the sleeve gastrectomy group and 76% in the Roux-en-Y gastric bypass group (absolute difference, −0.1%; 95% CI, −0.26% to 0.07%; *P* = .28). A percentage excess BMI loss greater than 75% was observed in 31.7% vs 40.4%, respectively (absolute difference, 0.09%; 95% CI, −0.06% to 0.25%; *P* = .21). A percentage excess BMI loss less than 25% was observed in 9.9% of sleeve gastrectomy patients and 3.8% of Roux-en-Y gastric bypass patients (absolute difference, −0.24%; 95% CI, −0.52% to 0.05%; *P* = .10).

Mean BMI decreased significantly from baseline to 5 years after operation (in the sleeve gastrectomy group, from 43.5 to 32.5, and in the Roux-en-Y gastric bypass group, from 44.3 to 31.6; *P* < .001 for both groups). There was no significant difference in BMI at 5 years between the interventions (absolute difference, 0.91; 95% CI, −0.77 to 2.6; *P* = .29). Mean weight reduction was not significantly different between the groups at 5 years (sleeve gastrectomy, 33.0 kg, vs Roux-en-Y gastric bypass, 36.6 kg; absolute difference, 3.6 kg; 95% CI, −1.8 kg to 9.0 kg; *P* = .19). In both groups, weight loss nadir was reached between 1 and 2 years after surgery (eFigure 1 in Supplement 2). Mean weight loss expressed as percentage of original weight loss was lower in the sleeve gastrectomy group vs the Roux-en-Y gastric bypass group at 5 years (sleeve gastrectomy, 25.0%, vs Roux-en-Y gastric bypass, 28.6%; absolute difference, −3.7%; 95% CI, −6.7% to −0.6%; *P* = .02) (eFigure 2 in Supplement 2).

Discussion

In this trial including 217 morbidly obese patients randomized to undergo either laparoscopic sleeve gastrectomy or Roux-en-Y gastric bypass, no significant difference in percentage excess BMI loss was found 5 years after surgery in analyses that adjusted for multiple comparisons. Furthermore, obesity-associated comorbidities, including type 2 diabetes and dyslipidemia, were reduced after both procedures, with the exception of gastroesophageal reflux disease, which was achieved more often after Roux-en-Y gastric bypass. Moreover, worsening of reflux symptoms was found more frequently in patients who underwent sleeve gastrectomy. There was no statistically significant difference between the 2 groups in the increase of quality of life or in the number of reoperations or interventions.

This trial did not detect a statistically significant difference in weight loss when measured as percentage excess BMI loss, which is in contrast to 2 recent meta-analyses comparing the 2 interventions, both of which found greater weight loss with Roux-en-Y gastric bypass.[20,21] However, both meta-analyses included mainly nonrandomized studies without appropriate controls, and in most studies, definitions for the resolution of comorbidities were not reported. Also, the few randomized studies that were included had either a shorter follow-up time or included fewer patients compared with the current trial. When this study was designed, it was common to report outcomes from bariatric surgery as percentage excess weight or BMI loss. In recent years, the preferred means of reporting weight loss following bariatric surgery is percentage weight loss relative to original body weight.[22] In this trial, post hoc analysis of percentage body weight loss compared with

Table 4. Laboratory and Quality-of-Life Measurements

Measures	Mean (95% CI)		Mean Difference (95% CI)[a]	*P* Value Between Groups[b]
	Sleeve Gastrectomy	Roux-en-Y Gastric Bypass		
Preexisting type 2 diabetes	n=26	n=28		
Fasting glucose, mg/dL				
Baseline	139.2 (111.5 to 166.8)	120.3 (103.7 to 136.9)	18.83 (−12.90 to 50.55)	.21
Year 5	114.1 (97.2 to 131.0)	101.1 (88.8 to 113.4)	13.00 (−7.50 to 33.49)	
Difference, baseline to 5 y	27.0 (5.0 to 48.9)	19.9 (2.3 to 37.5)	7.05 (−20.30 to 34.40)	.61
Hemoglobin A_{1c}				
%				
Baseline	7.6 (6.8 to 8.4)	7.2 (6.4 to 8.0)	0.41 (−0.64 to 1.46)	.09
Year 5	6.2 (5.9 to 6.6)	5.9 (5.7 to 6.1)	0.30 (−0.06 to 0.82)	
Difference, baseline to 5 y	1.4 (0.7 to 2.1)	1.8 (1.2 to 2.4)	−0.39 (−1.43 to 0.65)	.45
mmol/mol				
Baseline	59.7 (51.3 to 68.1)	55.7 (47.6 to 63.8)	4.04 (−7.60 to 15.68)	.09
Year 5	44.6 (40.8 to 48.4)	40.1 (37.6 to 42.6)	4.45 (−0.63 to 9.53)	
Difference, baseline to 5 y	15.2 (7.4 to 23.0)	19.5 (13.5 to 25.5)	−4.27 (−15.61 to 7.07)	.45
Preexisting dyslipidemia	n=68	n=53		
Total cholesterol, mg/dL				
Baseline	217.8 (206.5 to 229.0)	205.0 (192.3 to 217.7)	12.69 (−4.16 to 29.55)	.17
Year 5	195.8 (185.4 to 206.2)	186.4 (177.7 to 195.1)	9.43 (−4.13 to 22.98)	
Difference, baseline to 5 y	24.5 (9.0 to 40.0)	17.1 (5.7 to 28.5)	7.39 (−14.39 to 29.17)	.50
HDL-C, mg/dL				
Baseline	44.9 (41.5 to 48.3)	44.3 (41.2 to 47.4)	0.61 (−3.96 to 5.18)	.33
Year 5	62.5 (58.2 to 66.8)	65.5 (60.6 to 70.4)	−3.05 (−9.19 to 3.08)	
Difference, baseline to 5 y	17.2 (13.9 to 20.5)	21.3 (17.6 to 25.0)	4.13 (−1.41 to 9.68)	.14
Cholesterol/HDL-C ratio				
Baseline	5.3 (4.8 to 5.8)	4.7 (4.3 to 5.1)	0.48 (−0.11 to 1.07)	.02
Year 5	3.3 (3.0 to 3.6)	3.0 (2.8 to 3.2)	0.38 (0.06 to 0.70)	
Difference, baseline to 5 y	2.0 (1.6 to 2.4)	1.8 (1.5 to 2.1)	0.23 (−0.34 to 0.80)	.42
LDL-C, mg/dL				
Baseline	129.3 (121.0 to 137.7)	127.8 (117.4 to 138.2)	1.51 (−11.73 to 14.75)	.008
Year 5	116.1 (107.3 to 124.9)	101.1 (91.0 to 111.2)	14.95 (3.91 to 25.99)	
Difference, baseline to 5 y	10.1 (−0.7 to 20.9)	22.8 (13.9 to 31.7)	−12.75 (−31.06 to 5.57)	.17
Triglycerides, mg/dL				
Baseline	193.8 (167.8 to 219.8)	176.7 (150.5 to 202.9)	17.24 (−19.86 to 53.99)	.24
Year 5	172.3 (51.7 to 292.9)	97.8 (86.4 to 109.2)	74.52 (−50.38 to 199.42)	
Difference, baseline to 5 y	79.9 (60.0 to 99.8)	76.8 (51.1 to 102.5)	3.12 (−32.79 to 39.15)	.86
Quality of life	n=101	n=104		
GIQLI score[c]				
Baseline	99.7 (95.6 to 103.8)	99.3 (95.9 to 102.7)	0.44 (−5.74 to 6.62)	.42
Year 5	113.6 (108.9 to 118.3)	117.9 (114.8 to 121.0)	−4.33 (−15.07 to 6.40)	
Difference, baseline to 5 y	18.9 (13.7 to 24.1)	18.1 (14.7 to 21.5)	0.81 (−11.08 to 12.70)	.89
BAROS score[d]				
Baseline	0.1 (−0.1 to 0.3)	0.2 (−0.1 to 0.5)	−0.12 (−0.52 to 0.27)	.20
Year 5	1.4 (1.1 to 1.7)	1.7 (1.5 to 1.9)	−0.25 (−0.64 to 0.14)	
Difference, baseline to 5 y	1.3 (1.0 to 1.6)	1.4 (1.1 to 1.7)	−0.13 (−0.70 to 0.44)	.66

Abbreviations: HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

SI conversions: To convert total cholesterol, HDL-C, and LDL-C to mmol/L, multiply by 0.0259. To convert triglycerides to mmol/L, multiply by 0.0113. To convert glucose to mmol/L, multiply by 0.0555.

[a] Prop.test (R Project).

[b] Unpaired 2-sided *t* test; equal variances are not assumed. *P* values are not corrected for multiple comparisons.

[c] Gastrointestinal Quality of Life Index (GIQLI): 36 items; scale range: 0-144 points; most desirable option: 4 points; least desirable option: 0 points; mean score for healthy individuals, 125.8 points.[8]

[d] Bariatric Analysis and Reporting Outcome System (BAROS) quality-of-life score: 5 items; scale range: −3 to 3 points; most desirable option: 1 point for 1 item, 0.5 for the other 4 items; least desirable option: −1 point for 1 item, −0.5 point for the other 4 items.[9,10]

Table 5. Mortality and Adverse Events Requiring Reoperation or Endoscopic Intervention

Events	No. With Event/Total No. (%)		Absolute Difference (95% CI)[a]
	Sleeve Gastrectomy	Roux-en-Y Gastric Bypass	
Early morbidity (0-30 d)	1/107 (0.9)	5/110 (4.5)	−0.19 (−0.57 to 0.20)
Leak	0	1	
Infection	0	3	
Obstruction	1	1	
Death	0	1[b]	
Late morbidity (1 mo-5 y)	15/101 (14.9)	18/104 (17.3)	−0.05 (−0.25 to 0.16)
Operative			
Conversion to Roux-en-Y gastric bypass due to gastroesophageal reflux	9	NA	
Small bowel obstruction	0	2	
Internal hernia	0	9	
Incisional hernia	1	1	
Gastroscopy necessary: laparoscopy	NA	1	
Severe dumping	0	3[c]	
Insufficient weight loss	5[d]	2	
Death	0	1[e]	
Total reoperations or interventions	16/101 (15.8)	23/104 (22.1)	−0.10 (−0.29 to 0.09)
Total mortality	0	2/104 (1.9)	−0.50 (−0.82 to −0.18)

Abbreviation: NA, not applicable.

[a] Prop.test (R Project).

[b] Surgical complication (leakage).

[c] Two pouch revisions and 1 bypass reversal.

[d] Three laparoscopic biliopancreatic diversions (duodenal switch) and 2 conversions to laparoscopic Roux-en-Y gastric bypass.

[e] Lymphoma.

original body weight at 5 years revealed less weight loss with sleeve gastrectomy relative to that achieved by Roux-en-Y gastric bypass. Although statistically significant, these differences were small and not clinically important.

No statistically significant difference in remission rates of type 2 diabetes could be shown in this trial. While bariatric surgery is recognized as a potent treatment option in patients with obesity and type 2 diabetes, differences between the available interventions in the efficiency to improve glycemic control in patients with and without type 2 diabetes are still unclear, as a certain gradient of efficiency among the surgical interventions has been reported in several trials.[23] Overall, malabsorptive biliopancreatic diversion has been shown to be the most efficient operation in terms of type 2 diabetes remission rates (but the most radical in terms of potentially severe adverse effects), followed by Roux-en-Y gastric bypass, sleeve gastrectomy, and gastric banding.[24] However, when comparing sleeve gastrectomy with Roux-en-Y gastric bypass head to head, Roux-en-Y gastric bypass appears superior for diabetes remission rates, at least in the long term.[4,25-29] For example, the STAMPEDE trial compared best medical treatment vs sleeve gastrectomy and Roux-en-Y gastric bypass over a period of 5 years. Although no statistically significant difference between the 2 surgical groups was found for the primary end point of hemoglobin A_{1c} of less than 6.0%, other end points, such as the number of antidiabetic medications, showed superiority of Roux-en-Y gastric bypass vs sleeve gastrectomy.[4] A similar outcome in terms of glycemic control in patients with type 2 diabetes was also reported in 2 recent meta-analyses, including randomized trials comparing sleeve gastrectomy with Roux-en-Y gastric bypass only.[26,29]

Patients with severe, preexisting gastroesophageal reflux disease and large hiatal hernia were not included in the study, as Roux-en-Y gastric bypass is generally regarded as superior to sleeve gastrectomy in these cases. Nevertheless, many patients with morbid obesity experience intermittent gastroesophageal reflux, which can exacerbate after sleeve gastrectomy. In this trial, preexisting gastroesophageal reflux disease was found to be significantly better treated by Roux-en-Y gastric bypass compared with sleeve gastrectomy. Moreover, worsening of reflux symptoms was more often seen after sleeve gastrectomy, and patients with no gastroesophageal reflux disease at baseline more often reported de novo reflux symptoms 5 years after sleeve gastrectomy than after Roux-en-Y gastric bypass. In most cases, gastroesophageal reflux symptoms could be treated conservatively with proton pump inhibitors. However, in nearly 10% of patients, pharmaceutical treatment was insufficient and sleeve gastrectomy had to be converted to Roux-en-Y gastric bypass despite that during primary intervention, hiatal hernias had always been repaired.[16]

Bariatric surgery is associated with a higher risk of reinterventions than other types of surgeries. In addition, recently published reports indicate development of Barrett mucosa after sleeve gastrectomy in up to 17% of asymptomatic patients.[30,31] Depending on the grade of dysplasia and the length of the Barrett segment, the incidence of Barrett carcinoma ranges from 0.3% to 2.4% per year.[32] Longer follow-up is needed to address the issue of gastroesophageal reflux disease and Barrett esophagus, with endoscopic surveillance potentially needed in long-term follow-up. Thus, recommending sleeve gastrectomy to every patient because it seems safer, with less perioperative morbidity and no difference in morbidity up to 5 years, may be shortsighted.

Quality of life improved significantly after both procedures at each time point compared with baseline (Table 4), with no significant difference between the 2 groups, which is in contrast to current literature.[23]

There also was no significant difference in complications necessitating surgical or endoscopic revision within the first 5 years postoperatively. The most frequent reason for reoperation after sleeve gastrectomy was gastroesophageal reflux disease, followed by insufficient weight loss. After Roux-en-Y gastric bypass, the most frequent reinterventions were for internal hernia in almost 10% of patients, a potentially dangerous complication. In this trial, the rate of internal hernia was rather high, which may be due to the fact that closure of mesenteric defects was not mandatory in the study protocol. According to recent evidence, the incidence of internal hernias after Roux-en-Y gastric bypass can possibly be reduced by closure of all mesenteric defects.[33,34] Other causes for reoperation after Roux-en-Y gastric bypass were late dumping or small bowel obstruction, complications that rarely occur after sleeve gastrectomy. Thus, the types of complications are different, but the frequency is not statistically different.

This study has several limitations. First, the study is underpowered for the exploratory end point of type 2 diabetes remission. Although no significant differences were found between the 2 procedures regarding their antidiabetic effects, this trial does not allow for firm conclusions on the absence of differences. Second, because randomized trials are conducted under idealized and rigorously controlled conditions, their generalizability might be compromised. The willingness to participate in a randomized trial might per se also lead to patient selection bias. However, the study outcomes are in line with outcomes seen in unselected bariatric cohorts and can be considered to be generalizable.

In addition, the protocol did not include an upper limit for BMI, and there were a few patients with BMI above 60 in both groups. This trial cannot answer the question whether patients with extremely high BMI may have greater benefit from a staged concept with initial sleeve gastrectomy followed by Roux-en-Y gastric bypass or biliopancreatic diversion. Patients and staff were not blinded to the type of operation. Both operations have specific complications (eg, internal hernia, which is only possible after Roux-en-Y gastric bypass) and physicians in charge as well as patients must know what kind of operation was carried out. In our opinion, blinding would have been unethical.

Conclusions

Among patients with morbid obesity, there was no significant difference in excess BMI loss between laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass at 5 years of follow-up after surgery.

ARTICLE INFORMATION

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