Long-term effect of sleeve gastrectomy vs Roux-en-Y gastric bypass in people living with severe obesity: a phase III multicentre randomised controlled trial (SleeveBypass)

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Summary

Background Sleeve gastrectomy is the most performed metabolic surgical procedure worldwide. However, conflicting results offer no clear evidence about its long-term clinical comparability to Roux-en-Y gastric bypass. This study aims to determine their equivalent long-term weight loss effects.

Methods This randomised open-label controlled trial was conducted from 2012 until 2017 in two Dutch bariatric hospitals with a 5-year follow-up (last follow-up July 29th, 2022). Out of 4045 patients, 628 were eligible for metabolic surgery and were randomly assigned to sleeve gastrectomy or Roux-en-Y gastric bypass (intention-to-treat). The primary endpoint was weight loss, expressed by percentage excess body mass index (BMI) loss. The predefined clinically relevant equivalence margin was –13% to 13%. Secondary endpoints included percentage total kilograms weight loss, obesity-related comorbidities, quality of life, morbidity, and mortality. This trial is registered with Dutch Trial Register NTR4741: https://onderzoekmetmensen.nl/nl/trial/25900.

Findings 628 patients were randomised between sleeve gastrectomy (n = 312) and Roux-en-Y gastric bypass (n = 316) (mean age 43 [standard deviation (SD), 11] years; mean BMI 43.5 [SD, 4.7]; 81.8% women). Excess BMI loss at 5 years was 58.8% [95% CI, 55%–63%] after sleeve gastrectomy and 67.1% [95% CI, 63%–71%] after Roux-en-Y gastric bypass (difference 8.3% [95% CI, –12.5% to –4.0%]). This was within the predefined margin ($P < 0.001$). Total weight loss at 5 years was 22.5% [95% CI, 20.7%–24.3%] after sleeve gastrectomy and 26.0% [95% CI, 24.3%–27.8%] after Roux-en-Y gastric bypass (difference 3.5% [95% CI, –5.2% to –1.7%]). In both groups, obesity-related comorbidities significantly improved after 5 years. Dyslipidaemia improved more frequently after Roux-en-Y gastric bypass (83%, 54/65) compared to sleeve gastrectomy (62%, 44/71) ($P = 0.006$). De novo gastro-oesophageal reflux disease occurred more frequently after sleeve gastrectomy (16%, 46/288) vs Roux-en-Y gastric bypass (4%, 10/280) ($P < 0.001$). Minor complications were more frequent after Roux-en-Y gastric bypass (5%, 15/316) compared to sleeve gastrectomy (2%, 5/312). No statistically significant differences in major complications and health-related quality of life were encountered.

Interpretation In people living with obesity grades 2 and 3, sleeve gastrectomy and Roux-en-Y gastric bypass had clinically comparable excess BMI loss according to the predefined definition for equivalence. However, Roux-en-Y gastric bypass showed significantly higher total weight loss and significant advantages in secondary outcomes, including dyslipidaemia and GERD, yet at a higher rate of minor complications. Major complications, other comorbidities, and overall HRQoL did not significantly differ between the groups.

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Keywords: Roux-en-Y gastric bypass; Sleeve gastrectomy; Weight loss; GERD; Complications; Long-term follow-up

Research in context

Evidence before this study

We conducted a literature search on PubMed for randomised controlled trials comparing sleeve gastrectomy vs Roux-en-Y gastric bypass, with a minimum one-year follow-up period, published between January 1, 1995, and July 31, 2011, in English. The search terms included "randomised controlled trial," "sleeve gastrectomy," "Roux-en-Y gastric bypass," "weight loss," and "long-term follow-up." Additionally, we searched for meeting abstracts from the International Federation for the Surgery of Obesity and Metabolic Disorders, World, and European Conferences, focusing on both treatments and long-term follow-up. Two randomised controlled trials were identified. The trial by Kehagias et al. showed an excess BMI loss of 61% after Roux-en-Y gastric bypass and 68% after sleeve gastrectomy at 3 years (P = 0.12). The SM-BOSS trial by Peterli et al. presented preliminary results after 3 months, indicating an excess BMI loss of 43% after Roux-en-Y gastric bypass and 39% after sleeve gastrectomy (P = 0.36). A meta-analysis by Buchwald et al. had combined data due to a limited number of randomised trials and reported an excess BMI loss of 62% for Roux-en-Y gastric bypass and 68% for gastroplasty. These studies varied in follow-up and weight results. Moreover, there existed uncertainty regarding the clinically relevant equivalence.

Added value of this study

The study offers greater clarity on the long-term clinical comparability of sleeve gastrectomy and Roux-en-Y gastric bypass as treatments for obesity, with a 5-year follow-up of a large population. The results revealed an 8.3 percentage unit advantage in favour of Roux-en-Y gastric bypass, which, however, fell within the clinically relevant equivalence margin. No significant differences were observed in the improvement of Type 2 Diabetes and quality of life. De novo gastro-oesophageal reflux disease was more common after sleeve gastrectomy, while minor complications occurred more frequently after Roux-en-Y gastric bypass.

Implications of all the available evidence

Our results provide additional support for metabolic surgery with more clarification of the advantages and disadvantages of both types of surgeries. The study's results are expected to contribute valuable evidence for informed decision-making by clinicians and policymakers in obesity management through metabolic surgery.

Introduction

Obesity is a global problem, inducing health risks, diminishing health-related quality of life (HRQoL), and increasing costs.[1] Over the last 18 years, the prevalence of obesity (body mass index (BMI) above 30) has increased from 30.5% to 42.4% in the US and from 7.1–9.1% to 14.2–17.0% in Europe.[2,3]

Although medication such as glucagon-like peptide 1 agonists has shown promising results, metabolic surgery is regarded the most effective treatment.[4–6] Metabolic surgery leads to substantial long-term weight loss and has proven effectiveness for obesity-related comorbidities.[6]

Roux-en-Y gastric bypass and sleeve gastrectomy are the most common metabolic surgical procedures. Most relevant disadvantages of sleeve gastrectomy are its irreversibility and risk of gastro-oesophageal reflux disease (GERD), which can induce Barrett's oesophagus. Sleeve gastrectomy is the most performed procedure worldwide, presumably because it is technically less challenging than Roux-en-Y gastric bypass. This is attributed to the absence of an anastomosis, resulting in a shorter surgical duration and preservation of the small bowel anatomy, thereby leading to less dumping syndrome.[7] These factors might have beneficial effects on HRQoL, compared to Roux-en-Y gastric bypass.

The use of sleeve gastrectomy is supported by two recent randomised trials and systematic reviews comparing both procedures. The SM-BOSS trial was designed to show a difference of 10% excess weight loss between both procedures, whereas the SLEEVEPASS trial aimed to show equivalence in excess weight loss. These trials suggested a benefit in favour of Roux-en-Y gastric bypass, but no definitive conclusions could be drawn after long-term follow up. The Oseberg trial, which compared remission of Type 2 Diabetes between both procedures, demonstrated greater improvement of Type 2 Diabetes at 3-years follow-up in favour of Roux-en-Y gastric bypass.[8] Given the uncertain and varying long-term results, there are concerns that sleeve gastrectomy is inferior in terms of long-term weight loss and remission of Type 2 Diabetes.[5,8–10] HRQoL appears to be similar or better after sleeve gastrectomy, supposedly due to the earlier mentioned advantages.[5,9] Although weight loss is essential, deviations within an acceptable margin between the procedures do not necessarily exclude their clinical comparability, as other factors such as comorbidity and HRQoL may demonstrate alignment. Results of the present study will contribute to the evidence comparing sleeve gastrectomy with Roux-en-Y gastric bypass.

Methods

Study design

The SleeveBypass trial was a multicentre open-label randomised controlled trial in two Dutch high-volume hospitals. The protocol has been published before.[11] This study was conducted according to the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study protocol was approved by the Medical Research Ethics Committee, the Netherlands (protocol number 2011-48). Written informed consent was obtained from all participants.

Participants

All patients suitable for metabolic surgery according to the international guidelines were invited to participate.[12] Exclusion criteria were: daily symptomatic, severe GERD, that could not be managed without proton pump inhibitor (PPI) use, known hiatal hernia with symptoms, prior metabolic or major abdominal surgery, and inability of providing informed consent, or understanding the questionnaires.

Randomisation and masking

Patients were randomised 1:1 to sleeve gastrectomy or Roux-en-Y gastric bypass, using computerized variable block randomisation (block sizes: 6, 8, 12). Patients were stratified for sex, Type 2 Diabetes, and body mass index (BMI) > 50 kg/m2. No masking of investigators (including primary outcome assessor) or patients to treatment allocation was performed.

Procedures

The protocolised surgical techniques have been described previously.[11] In summary, sleeve gastrectomy was performed along a bougie size 36 Fr starting 6 cm prepyloric, no reinforcement was used. In Roux-en-Y gastric bypass, a 36 Fr bougie calibrated 5 cm long gastric pouch was connected to the jejunum creating a 3 cm long linear gastrojejunostomy, with a biliopancreatic limb of 60 cm and an alimentary limb of 150 cm. Both mesenteric defects were closed standardly, unless technically not feasible.

All patients followed the Enhanced Recovery After Bariatric Surgery protocol (ERABS), which was introduced in 2011 in the participating hospitals.[13] All data were collected at baseline and up to 5 years postoperatively. Annually, measurements of weight, blood tests, morbidity, and mortality, along with various questionnaires, were carried out. No protocol deviations occurred during the study, and no amendments affecting trial recruitment or conduct were implemented.

Outcomes

The primary outcome was weight loss by percentage excess BMI loss ([baseline BMI – follow-up BMI]/[baseline BMI – 25] x 100) after five years follow-up.

Secondary outcomes were percentage total weight loss (TWL), improvement/resolution of obesity related comorbidities (hypertension, Type 2 Diabetes, dyslipidaemia, OSAS, joint pain, and GERD), duration of surgery (from first incision to closing), length of hospital stay, additional outpatient and emergency room visits, morbidity and mortality within 30 days postoperative, revision metabolic surgery, and HRQoL. Definitions for improvement and remission of comorbidities were following the national guidelines and are described in detail in Supplementary File S3. Improvement in hypertension was defined as reduced medication or dose with a normal blood pressure. Remission of hypertension was defined as no longer needed drug therapy and normalization of blood pressure. Improvement of type 2 Diabetes was defined as less medicines or lower dose of medication with a glycosylated haemoglobin of <6.0%. Remission of Type 2 Diabetes was defined as a normal fasting glucose without medication and a glycosylated haemoglobin of <6.0%. Remission for dyslipidaemia was defined as total cholesterol <5 mmol/L and triglycerides <5.5 mmol/L without use of medication. Mild GERD symptoms were defined as symptoms that were not present daily and could be managed without the use of PPI. Remission of OSAS was defined as no Continuous Positive Airway Pressure (CPAP) or Mandibular advancement devices and Apnoea-Hypopnea Index (AHI) < 5). Remission of joint pain and GERD was defined as no symptoms and no use of equipment and/or medication. Improvement of comorbidities was defined as reduction in use of equipment and/or medication. Clavien-Dindo (CD) classification was used, with major complications defined as ≥ CD3a.[14] Generic HRQoL in this manuscript was measured using the short-form 36 (SF-36) (36-item, scale range 0–100 points; most desirable option: 100 points; least desirable option: 0 points), and disease specific HRQoL was measured by the Moorehead-Ardelt score (5 items; scale range,–3 to 3 points; most desirable option: 1 point for item 1 and 0.5 point for items 2 until 5; least desirable option: –1 point for item 1 and –0.5 point for items 2 until 5).[15,16] The other HRQoL endpoints mentioned in the study protocol will be described in a separate publication.

Statistical analysis

At least 620 patients had to be included (Equivalence margin (delta): ± 13%; type I error: 0.05 (two sided), type II error = 0.10, drop-out: 5%, standard deviation (SD) = 25.88 for both groups)[17,18] to accept or reject the null hypothesis that the mean percentage excess BMI loss after sleeve gastrectomy was not equal to the loss after Roux-en-Y gastric bypass.

All statistical analyses were performed according to the intention to treat principle. Absolute numbers with percentages were presented for categorical variables, and mean with standard deviation (SD) or median with

interquartile range (IQR) for continuous parameters. Differences between treatment groups were expressed as absolute difference with 95% confidence interval (CI). The primary outcome was analysed by a linear mixed model with dependent variable percentage excess BMI loss, using allocated treatment, and time as main effects (first follow-up moment coded as reference), centre, sex, Type 2 Diabetes status, BMI > 50 at baseline, and baseline BMI as adjusted covariables, and time multiplied by allocated treatment as interaction effect (covariance type unstructured). Based on the null hypothesis of no equivalence, the CI of the difference should be within the predefined margin, supported by an independent t-test to analyse comparability.

Other longitudinal data (difference in TWL, BMI, HbA1c and HRQoL and subgroups (Supplementary File S2)) were analysed using the linear mixed model, changing the covariable to initial weight when appropriate and changing the depended variable according to outcome. For comorbidities, complications, surgical reoperations, and revision surgery Chi squared-test or Fisher exact test (if one group had fewer than 5 participants) was used. Multivariable logistic regression was performed to compare comorbidity improvement between both groups at 1, 3, and 5 years, with dependent variable improvement of comorbidities (yes/no), and covariables allocated treatment, centre, sex, Type 2 Diabetes and baseline BMI > 50. Duration of surgery and hospitalization were analysed using an unpaired Student's t-test or a non-parametric Mann–Whitney U Test when appropriate. Bonferroni-Holm was used for multi comparison of weight, BMI, and comorbidities difference at each time point between groups. In secondary analyses other than repeated measurement multiple imputation, FSC method (with 5 imputations) was used for patients lost to follow-up, separately for groups with and without comorbidities at baseline. Statistical analyses were performed using IBM SPSS version 28 (IBM Corporation, Armonk, New York, USA). Significance threshold was $P < 0.05$ (two-sided). This trial is registered with the Dutch Trial Register NTR4741.

Role of the funding source
There was no funding source for this study.

Results

From Nov 24, 2012, to July 29, 2017, 641 patients were randomised (last follow-up 29 July 2022). Thirteen patients were excluded (twelve patients withdrew informed consent and one patient died before surgery). Data were analysed in 628 patients (mean age 43 [SD, 11] years; mean baseline BMI 43.5 [SD, 4.7]; 81.8% women) randomised between sleeve gastrectomy (n = 312, 49.7%) or Roux-en-Y gastric bypass (n = 316, 50.3%). During the course of the study, thirteen patients in the sleeve gastrectomy group underwent Roux-en-Y gastric bypass, whereas sixteen patients in the Roux-en-Y gastric bypass group underwent sleeve gastrectomy (cross-over).

At baseline, 214 (34.1%) had hypertension, 116 (18.5%) Type 2 Diabetes, 136 (21.7%) dyslipidaemia, 97 (15.4%) OSAS, and 145 (23.1%) severe joint pain (Table 1). 486 patients (77.4%) completed 5-year follow-up (Fig. 1).

The mean percentage excess BMI loss at 5 years was 58.8% (95% CI, 54.5% to 63.2%) after sleeve gastrectomy and 67.1% (95% CI, 62.8% to 71.4%) after Roux-en-Y gastric bypass (difference 8.3 percentage units [95% CI, –12.5% to –4.0%]). The CI of the difference was within the equivalence margin ($P < 0.001$) (Table 2 and Fig. 2).

	Sleeve gastrectomy (n = 312)	Roux-en-Y gastric bypass (n = 316)
Female	254 (81.4)	260 (82.3)
Age (years), mean ± sd	43 ± 10	43 ± 11
BMI (kg/m^2), mean ± sd	43.7 ± 4.8	43.3 ± 4.7
BMI > 50	33 (10.6)	34 (10.8)
Hypertension	111 (35.6)	103 (32.6)
Type 2 Diabetes	54 (17.3)	62 (19.6)
Dyslipidaemia	71 (22.8)	65 (20.6)
OSAS	39 (12.5)	58 (18.4)
Joint pain	67 (21.5)	78 (24.7)
Mild GERD	24 (7.7)	36 (11.4)
Hospitals participating in the study		
Rotterdam	253 (81.1)	252 (79.7)
Eindhoven	59 (18.9)	64 (20.3)

sd = standard deviation; BMI = body mass index; kg/m^2 = kilogram per squared meters; OSAS = obstructive sleep apnoea syndrome; Mild GERD = non-daily symptoms and no medical therapy for gastro-oesophageal reflux disease. [a]Data are expressed as Number. (%) of participants unless otherwise indicated.

Table 1: **Baseline characteristics.**[a]

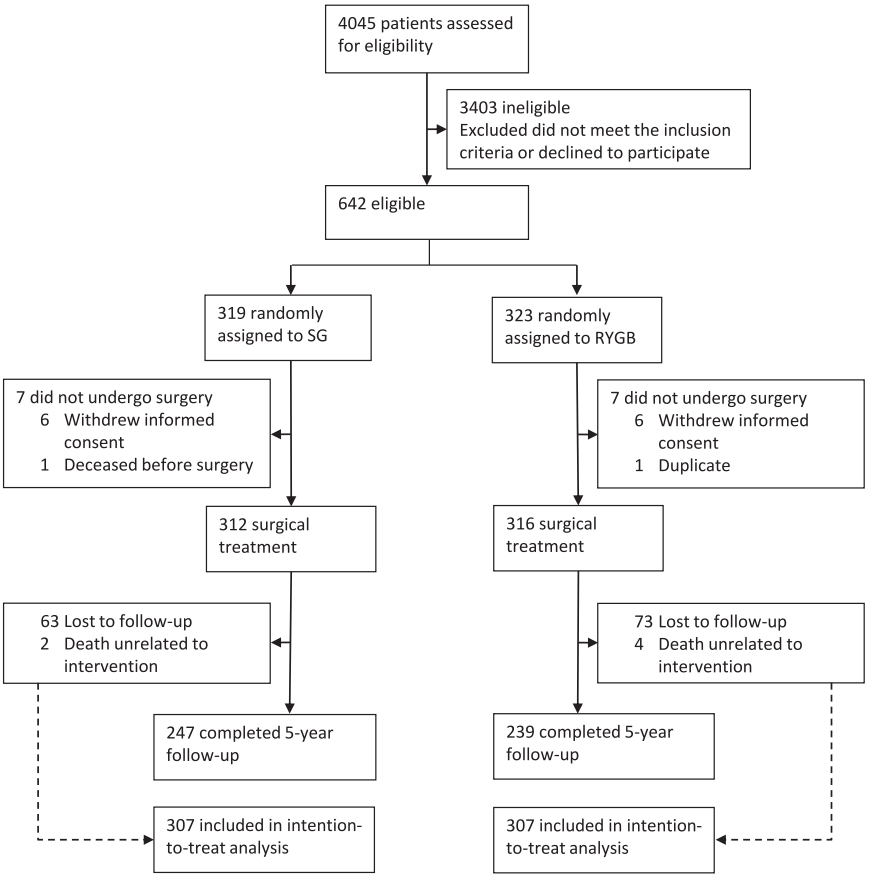

Fig. 1: Flow-chart. Abbreviations: SG = sleeve gastrectomy; RYGB = Roux-en-Y gastric bypass; y = year.

Percentage TWL was 22.5% (95% CI, 20.7% to 24.3%) after sleeve gastrectomy and 26.0% (95% CI, 24.3% to 27.8%) after Roux-en-Y gastric bypass (difference 3.5% [95% CI, –5.2% to –1.7%]). The mean BMI at 5 years was 33.6 kg/m2 (95% CI, 32.8 to 34.3) and 32.1 kg/m2 (95% CI, 31.3 to 32.9), respectively (difference: 1.5 kg/m2 [95% CI, 0.7 to 2.2], Table 2 and Fig. 2).

At baseline, 214 (34.1%) patients had hypertension (111 in the sleeve group and 103 in the bypass group). After 5 years, there was (partial) resolution of hypertension in 73/111 (66.8%) in the sleeve group vs 76/103 (73.8%) in the bypass group (difference 7.0% [95% CI, –13.9 to –0.3], $P = 0.20$).

At baseline, 116 (18.5%) patients had Type 2 Diabetes (54 in the sleeve group, 62 in the bypass group). At 5 years, improvement of Type 2 Diabetes was seen in 41/54 (75.9%) patients who had sleeve gastrectomy vs 44/62 (71.0%) patients who had Roux-en-Y gastric bypass (difference 4.9%, [95% CI, –11.2 to 21.0], $P = 0.55$). In the sleeve group, 30/54 (55.6%) patients had complete remission of diabetes, compared to 35/62 (56.5%) patients in the bypass group.

At baseline, 136 (21.7%) patients had dyslipidaemia (71 in the sleeve group, 65 in the bypass group). At 5 years, there was a statistically significant difference in improvement of dyslipidaemia in 44/71 (62.0%) after sleeve gastrectomy vs 54/65 (83.1%) after Roux-en-Y gastric bypass (difference 21.1% [95% CI, –35.6 to –6.6], $P = 0.006$).

At baseline, 60 (9.6%) patients reported mild and non-daily GERD symptoms without the need for medication or further analysis (Table 1). These symptoms had improved in 11/24 (45.8%) after sleeve gastrectomy vs 21/36 (69.4%) after Roux-en-Y gastric bypass (difference 23.6% [95% CI, –48.5 to 1.3], $P = 0.07$) after 5 years. GERD de novo (GERD symptoms with medical therapy) was observed in 46 patients (16%) and 10 (3.6%) patients, respectively (difference 12.4% [95% CI, 7.6 to 17.6], $P < 0.001$).

At baseline, 82 (13.1%) patients had OSAS (39 in the sleeve group, 58 in the bypass group). After 5 years, OSAS had improved in 32/39 (82%) in the sleeve group, compared to 48/58 (82.3%) in the bypass group (difference 0.3% [95% CI, –0.4 to 15.4], $P = 0.93$).

At baseline, 145 (23.1%) patients had joint pain (67 in the sleeve group, 78 in the bypass group), which improved after 5 years in 34/67 (50.7%) after sleeve gastrectomy compared to 41/78 (52.6%) after Roux-en-Y

	Sleeve gastrectomy (n = 307)	Roux-en-Y gastric bypass (n = 307)	Difference	P value
EBMIL%, mean (95% CI)				
1 year FU	73.2 (69.4–77.0)	76.5 (72.8–80.2)	−3.3 (−6.3 to −0.3)	0.03
5 year FU	58.8 (54.5–63.2)	67.1 (62.8–71.4)	−8.3 (−12.5 to −4.0)	<0.001
Difference 1 vs 5 year	14.4 (10.5–18.3)	9.4 (5.7–13.1)	−5.0 (−8.7 to 1.3)	<0.001
TWL%, mean (95% CI)				
1 year FU	28.4 (26.8–29.6)	29.9 (28.4–31.4)	−1.5 (−2.7 to −0.3)	0.02
5 year FU	22.5 (20.7–24.3)	26.0 (24.3–27.8)	−3.5 (−5.2 to −1.7)	<0.001
Difference 1 vs 5 year	5.8 (4.2–7.4)	3.8 (2.7–4.9)	−2.0 (−3.5 to −0.5)	<0.001
Weight (kg), mean (95% CI)				
1 year FU	88.2 (86.2–90.2)	86.2 (84.3–88.1)	2.0 (0.4–3.5)	0.01
5 year FU	95.4 (93.1–97.7)	90.9 (88.7–93.1)	4.5 (2.3–6.7)	<0.001
Difference 1 vs 5 year	7.2 (5.8–8.6)	4.7 (3.4–6.0)	2.5 (0.6–4.4)	<0.001
BMI (kg/m^2), mean (95% CI)				
1 year FU	31.0 (30.4–31.7)	30.4 (29.8–31.1)	0.6 (0.1–1.1)	0.03
5 year FU	33.6 (32.8–34.3)	32.1 (31.3–32.9)	1.5 (0.7–2.2)	<0.001
Difference 1 vs 5 year	2.6 (2.1–3.1)	1.7 (1.2–2.1)	0.9 (0.2–1.6)	<0.001

Data are expressed as mean (95% CI) and between-group difference (95% CI). All outcomes were analysed according to randomisation group. CI = confidence interval; EBMIL% = percentage excess body mass index loss; TWL% = percentage total weight loss; kg = kilogram; BMI = body mass index; kg/m2 = kilogram per square meters. [a]Repeated measurement using linear mixed model.

Table 2: **Weight loss at follow-up between groups.**[a]

gastric bypass (difference 1.9% [95% CI, −18.2 to 14.4], $P = 0.53$).

Table 3 and Fig. 3 display comorbidities at 1, 3, and 5 years.

The mean duration of surgery was 56.9 min (SD 14.2) in the sleeve group compared to 73.2 min (SD 20.2) in the bypass group (difference −16.3 min [95% CI, −19.0 to −13.5], $P < 0.001$). The median length of stay was 48 (IQR 27.8–48) hours after sleeve gastrectomy and 32.9 (IQR 27.1–48) hours after Roux-en-Y gastric bypass ($P = 0.34$).

In the first 30 days postoperative, additional visits to the emergency room or outpatient clinic occurred 24 (7.7%) times after sleeve gastrectomy and 24 (7.6%)

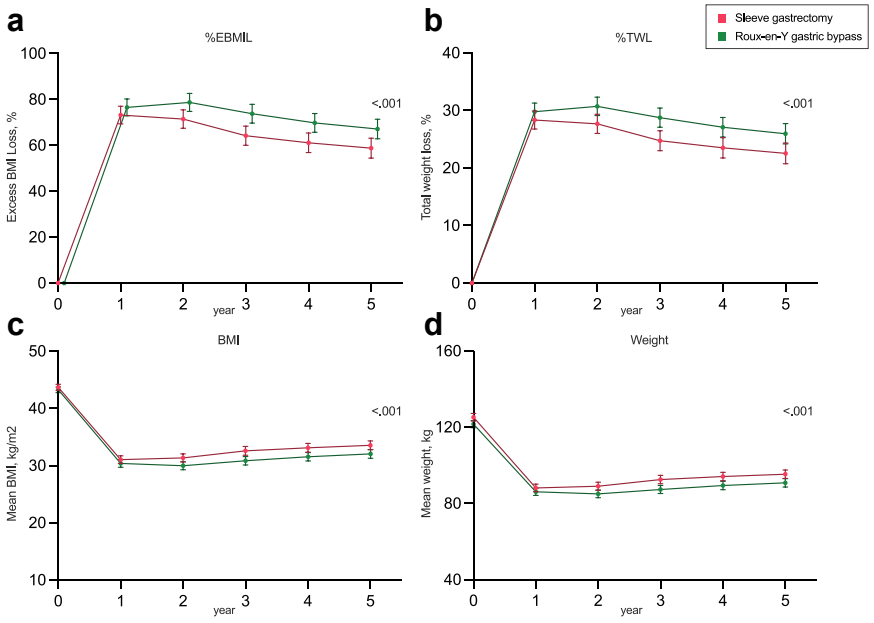

Fig. 2: **a–d** Weight loss at follow-up between groups[a]. All values are mean, whiskers show with a 95% CI. a, Repeated measurement using Linear mixed model. Abbreviations: %EBMIL = percentage excess body mass index loss; %TWL = percentage total weight loss; BMI = body mass index; kg/m2 = kilogram per square meters.

	Sleeve gastrectomy (n = 312)	Roux-en-Y gastric bypass (n = 316)	*P* value
Hypertension			
Comorbidity present at baseline	111/312 (35.6)	103/316 (26.9)	0.28[a]
Resolution	46 (41.4)	52 (51.8)	
Partly resolution	27 (24.3)	24 (24.7)	
No difference	32 (28.8)	19 (20)	
Worse	6 (5.4)	8 (3.5)	
De novo	5/201 (2.5)	0 (0)	UTD
Type 2 Diabetes			
Comorbidity present at baseline	54/312 (17.3)	62/316 (19.6)	0.76[a]
Resolution	30 (55.6)	35 (56.5)	
Partly resolution	11 (20.4)	9 (14.5)	
No difference	8 (14.8)	12 (19.4)	
Worse	6 (11.1)	6 (9.7)	
De novo	0 (0)	2/254 (0.8)	UTD
Dyslipidaemia			
Comorbidity present at baseline	71/312 (22.8)	65/316 (20.6)	0.04[a]
Resolution	30 (42.3)	37 (56.9)	
Partly resolution	14 (19.7)	17 (26.2)	
No difference	18 (25.4)	9 (13.8)	
Worse	9 (12.7)	2 (3.1)	
De novo	5/241 (2.1)	7/251 (2.8)	0.77[b]
OSAS			
Comorbidity present at baseline	39/312 (12.5)	58/316 (18.4)	0.77[a]
Resolution	19 (48.7)	25 (43.1)	
Partly resolution	13 (33.3)	20 (34.5)	
No difference	7 (17.9)	10 (17.2)	
Worse	0 (0)	0 (0)	
De novo	2/273 (0.7)	3/258 (1.2)	0.68[b]
Joint pain			
Comorbidity present at baseline	67/312 (21.5)	78/316 (24.7)	0.82[a]
Resolution	17 (25.4)	21 (26.9)	
Partly resolution	17 (25.4)	20 (25.6)	
No difference	13 (19.4)	15 (19.2)	
Worse	20 (29.9)	22 (28.2)	
De novo	5/245 (2.0)	8/238 (3.4)	0.41[b]
GERD			
Comorbidity present at baseline	24/312 (7.7)	36/316 (11.4)	<0.001[a]
Resolution	6 (25.0)	16 (44.4)	
Partly resolution	5 (20.8)	5 (13.9)	
No difference	5 (20.8)	7 (19.4)	
Worse	8 (33.3)	8 (22.2)	
De novo	46/288 (16.0)	10/280 (3.6)	<0.001[a]

Data are expressed as Number (%) of participants. All outcomes were analysed according to randomisation group (i.e. intention to treat). OSAS = obstructive sleep apnoea syndrome; GERD = gastro-oesophageal reflux disease. [a]Chi-Squared between groups. [b]Fisher exact.

Table 3: **Changes in comorbidities at follow-up of 5 year between groups.**

times after Roux-en-Y gastric bypass (difference 0.1% [95% CI –0.1 to 0.3], $P = 0.96$). Thirteen patients (4.2%) were readmitted after sleeve gastrectomy compared to 16 (5.1%) patients after Roux-en-Y gastric bypass (difference 0.9% [95% CI –1.1 to –0.7], $P = 0.59$).

Minor short-term complications were seen in 5 (1.6%) patients after sleeve gastrectomy and in 15 (4.7%) patients after Roux-en-Y gastric bypass (difference 3.1 [95% CI, –3.8 to –2.4], $P = 0.04$). Most minor complications consisted of vomiting, pain, or dysphagia.

Major complications <30 days after surgery occurred in 16 (5.1%) patients in the sleeve group and in 14 (4.4%) patients in the bypass group (difference 0.7% [95% Cl, –2.6 to 4.1], $P = 0.68$). Surgical reoperation for major complications <30 days was necessary in 14 (4.5%) patients after sleeve gastrectomy (n = 6 leakage of

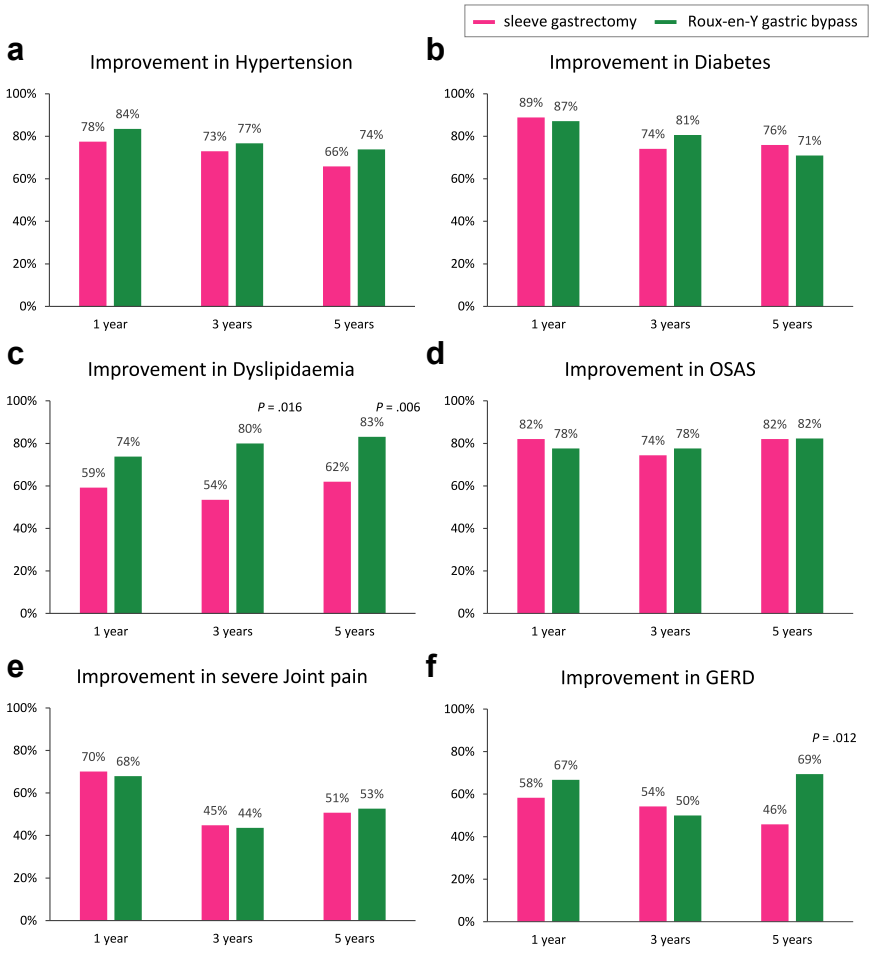

Fig. 3: **a–f** Changes in comorbidities and GERD at 1, 3 and 5 years[a]. All values are mean percentage. a, Multivariable logistic regression analysis for improvement (resolution + party resolution) of comorbidity between sleeve gastrectomy and Roux-en-Y gastric bypass. Corrected for multiple testing with step-down Bonferroni-Holm. Abbreviations: OSAS = obstructive sleep apnoea syndrome; GERD = gastro-oesophageal reflux disease.

the sleeve, n = 8 haemorrhage). In the bypass group, 12 (3.8%) patients underwent surgery (n = 5 haemorrhage, n = 3 anastomotic leakage, n = 3 obstructed anastomosis and 1 acute incisional hernia (difference 0.7% [95% CI, –2.4 to 3.8], $P = 0.65$).

Surgery >30 days was performed in 39 (12.5%) patients after sleeve gastrectomy and in 32 (10.1%) patients after Roux-en-Y gastric bypass (difference 2.4% [95% CI, –2.5 to 7.3], $P = 0.35$). Revision of sleeve gastrectomy to Roux-en-Y gastric bypass was conducted in 13 (33.3%) patients due to weight regain, in 12 (30.8%) patients due to GERD, in 11 (28.2%) due to both reasons, and in 2 (5.1%) due to symptomatic stenosis. In the bypass group, 7 (21.2) patients had an acute and 13 (65.6%) patients had an internal herniation found during planned laparoscopy which was possibly asymptomatic, 14 (43.8%) needed revision of one of the anastomoses, and 1 (3.1%) had a late abscess. There was no treatment related mortality during the follow-up (Table 4).

Regarding HRQoL, the baseline physical domain score of the SF-36 was 59.4 (SD 20.0) in the sleeve group and 58.5 (SD 20.4) in the bypass group at baseline. Mean HRQoL score improved to 73.2 (SD 23.1) and 75.9 (SD 22.5) respectively (13.8 vs 17.4, difference 3.6, [95% CI –9.1 to 2.0], $P = 0.27$). The baseline mental domain score was 67.5 (SD 18.7) in the sleeve group and 70.0 (SD 17.6) in the bypass group. At 5 years, there was no significant difference between the groups in mean HRQoL score 72.0 (SD 21.6) after sleeve gastrectomy vs 75.0 (SD 19.1) after Roux-en-Y gastric bypass (4.5 vs 5.0, difference 1.5, [95% CI –5.2 to 4.2], $P = 0.17$). Both groups scored 0.3 (SD 1.0) for the Moorhead-Ardelt pre-operatively. At 5 years, the Moorhead-Ardelt score was 0.8 (SD 1.1) in the sleeve group vs 1.0 (SD 1.2) in the bypass group

	Sleeve gastrectomy (n = 312)	Roux-en-Y gastric bypass (n = 316)	*P* value
Minor (≤30 days) complications			
Vomiting	4 (1.3)	4 (1.3)	
Stricture anastomoses	0	1 (0.3)	
Swallowing disorder	1 (0.3)	1 (0.3)	
UTI	0	1 (0.3)	
Pain	0	7 (2.2)	
Allergic reaction	0	1 (0.3)	
Total	5 (1.6)	15 (4.7)	0.04[a]
Major (≤ 30 days) complications			
Haemorrhage	6 (1.9)	5 (1.6)	
Leakage	6 (1.9)	2 (0.6)	
Infected hematoma	4 (1.3)	1 (0.3)	
Incisional hernia	0	1 (0.3)	
Torsion of the Enteroanastomosis	0	4 (1.2)	
Bowl perforation	0	1 (0.3)	
Total	16 (5.1)	14 (4.4)	0.68[b]
Reoperations (<30 days)			
Haemorrhage	4 (1.3)	5 (1.6)	
Leakage	6 (1.9)	3 (0.9)	
Infected hematoma	4 (1.3)	0	
Incisional hernia	0	1 (0.3)	
Strictured anastomosis	0	3 (0.9)	
Total	14 (4.5)	12 (3.8)	0.65[b]
Unplanned outpatient or ER visits <30 days	24 (7.7)	24 (7.6)	0.96[b]
Readmission < 30 days	13 (4.2)	16 (5.1)	0.59[b]
Surgical reoperations (>30 days)			
Acute internal herniation	1 (0.3)[c]	7 (2.2)	
Other internal herniation	0 (0)	13 (4.1%)	
Incisional hernia	2 (0.6)	3 (0.9)	
Infection	0	1 (0.3)	
Revisional surgery (>30 days)			
Revision to LRYGB after LSG	34 (10.9)	5 (1.6)[c]	
Revision to SADI-S	1 (0.3)	0	
Revision anastomosis after LRYGB	5 (1.6)[c]	8 (2.5)	
Undo LRYGB	0	1 (0.3)	
Total[d]	39 (12.5)[d]	32 (10.1)[d]	0.35[b]
Laparoscopic cholecystectomy	29 (9.3)	25 (7.9)	0.64[b]
Procedure related mortality	0	0	UTD

Data are expressed as Number (%) of participants. All outcomes were analysed according to randomisation group (i.e. intention to treat). UWI = urinary tract infection; ER = emergency room; LRYGB = laparoscopic Roux-en-Y gastric bypass; SADI-S = Single Anastomosis Duodenal-Ileal bypass with sleeve gastrectomy; LSG = laparoscopic sleeve gastrectomy. [a]Fischer's exact test. [b]Chi–Square test. [c]This patient went cross-over. [d]Number of patients needing surgery, some patients had more of the above described procedures.

Table 4: **Complications between groups.**

(difference 0.2, [95% CI −0.43 to 0.04], P = 0.11) (Table 5 and Fig. 4).

Sensitivity analyses showed consistent excess weight loss across subgroups (sex, Type 2 Diabetes, BMI > 50 kg/m2) at 5 years after sleeve gastrectomy vs Roux-en-Y gastric bypass (Supplementary File S3).

Discussion

The primary outcome, weight loss after sleeve gastrectomy and Roux-en-Y gastric bypass was within the defined equivalence margin at follow-up of 5 years. This implies that both surgical techniques are clinically comparable in terms of long term weight loss. However, in terms of some secondary outcomes, including total weight loss, dyslipidaemia and de novo GERD, Roux-en-Y gastric bypass demonstrated statistically significant advantages. No statistically significant differences were found in major complications, hypertension, Type 2 Diabetes, OSAS, joint pain, and HRQoL. Minor complications were seen more frequently after Roux-en-Y gastric bypass.

Health related quality of life	Sleeve gastrectomy (n = 312)	Roux-en-Y gastric bypass (n = 316)	*P* value[b]
SF-36 physical health[c]			
Baseline	59.4 (±20.0)	58.5 (±20.4)	
5 year FU	73.2 (±23.1)	75.9 (±22.5)	
Difference baseline to 5 years	13.8 (±28.5)	17.4 (±29.7)	0.28
SF-36 Mental Health[c]			
Baseline	67.5 (±18.7)	70.0 (±17.6)	
5 year FU	72.0 (±21.6)	75.0 (±19.1)	
Difference baseline to 5 years	4.5 (±29.1)	5.0 (±25.5)	0.15
BAROS[c]			
Baseline	0.3 (±1.0)	0.3 (±1.0)	
5 year FU	0.8 (±1.1)	1.0 (±1.2)	
Difference baseline to 5 years	0.5 (±1.5)	0.7 (±1.6)	0.12

BAROS = Bariatric Analysis and Reporting Outcome System; SF-36 = 36-item Short Form; sd = standard deviation; % = percentage. [a]Data are expressed as mean (±sd) unless otherwise indicated. [b]Repeated measurement using Linear mixed model. [c]A higher score means an improvement in quality of life.

Table 5: **Difference in health related quality of life over time between groups.**[a]

To the best of our knowledge, this trial included the largest number of randomised patients comparing sleeve gastrectomy with Roux-en-Y gastric bypass. Results regarding weight loss are in line with the SM-BOSS trial and a recent meta-analysis.[9,10] Unlike the SLEEVEPASS and Oseberg trial, the present trial demonstrates equivalence in terms of weight loss. This could be explained by the larger sample size and a slightly larger equivalence margin in the present trial. Furthermore, in both groups, the excess BMI loss at 5 years was higher compared to the SLEEVEPASS trial (60% and 49% after sleeve gastrectomy vs 68% and 57% after Roux-en-Y gastric bypass, respectively). This difference may be attributed to procedural or patient-related factors, considering the higher proportion of patients with Type 2 Diabetes in the SLEEVEPASS and Oseberg trial.[5,8] Additionally, the ongoing ByBandSleeve trial, is anticipated to be an important study in this field and may also shed further light on the long-term outcomes of both procedures.[19]

In today's context, percentage TWL is less influenced by preoperative BMI and would have been more suitable as primary endpoint.[20] However, when designing the current trial, excess BMI loss was most commonly used and widely accepted as standard outcome measure assessing weight loss. Several studies have suggested >20% total weight loss should be considered a good result after metabolic surgery.[21,22] Interestingly, the percentage total weight loss at 5 years follow-up was significantly lower after sleeve gastrectomy. As this is a relatively small difference (3.3%) and both procedures resulted in >20% total weight loss at 5 years, this is considered a good outcome. The clinical relevance of the difference in absolute weight loss can be seen as rather limited.

All obesity related comorbidities significantly improved after 5 years in both groups, with between group differences (in favour of the bypass group) for dyslipidaemia and GERD. After Roux-en-Y gastric bypass, hypertension remission rates exceeded 50%,

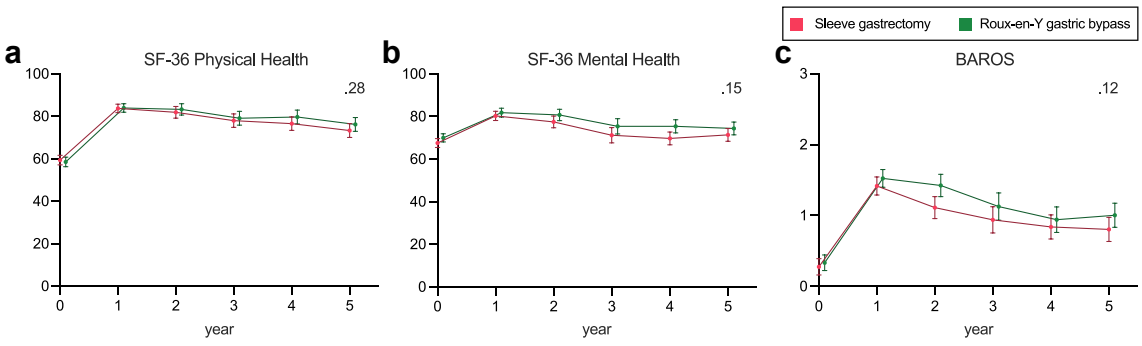

Fig. 4: **a–c** Improvement in quality of life over time between groups[a]. All values are mean, whiskers show with 95% CI. a, Repeated measurement using Linear mixed model. Abbreviations: SF-36 = 36-item Short Form; BAROS = Bariatric Analysis and Reporting Outcome System.

comparable to the Gateway trial. Similar to the SM-BOSS and STAMPEDE trial, no between-groups difference in hypertension improvement were seen. Yet, at the 10-year follow-up, Roux-en-Y gastric bypass might have a slight advantage.[23] Similar to the present trial, the SLEEVEPASS and SM-BOSS trials, although not powered to detect differences in remission of Type 2 Diabetes, demonstrated no difference between both groups.[5,9] In contrast, the Oseberg trial, which was designed to compare the effect of both procedures on Type 2 Diabetes suggests that Roux-en-Y gastric bypass is more effective for diabetes remission.[8,24] This may be due to differences in population, patient selection or the used definition for improvement. Moreover, the number of patients with Type 2 Diabetes in this trial is relatively low compared to other studies making comparison more difficult. Therefore, further long-term follow-up and research is needed.

OSAS improved in both groups after surgery without a significant difference between the two techniques. In a study by Dixon et al., weight loss seemed to be the most important factor for improvement of OSAS and no significant AHI score differences were found between surgery and conventional weight loss therapy. This could be due to the use of a stricter OSAS diagnosis (AHI > 20 compared to our mild OSAS > 5 AHI) and a different surgical procedure with less metabolic effects (laparoscopic adjustable gastric banding compared to sleeve gastrectomy and Roux-en-Y gastric bypass), possibly resulting in less OSAS remission[25] in the study by Dixen et al.

In the present study, patients with mild GERD at baseline had low symptom expression and did not use PPI. GERD patients who underwent sleeve gastrectomy demonstrated a lower rate of symptom resolution compared to the bypass group. Moreover, a significant proportion of patients who underwent sleeve gastrectomy required medical therapy or revisional surgery due to the development of de novo GERD. The pathophysiological mechanism for GERD after sleeve gastrectomy is uncertain, but a well-accepted explanation is the stomach's restrictive capacity with an intact pylorus and increased intra-luminal pressure.[26] Next to this mechanism, hiatal hernia and partial torsion of the elongated gastric tube might contribute to this condition. Roux-en-Y gastric bypass has been shown to be effective in reducing GERD by bypassing the pylorus, reducing acid reflux, and minimalizing biliary reflux with the Roux limb.[27] GERD may progress to Barrett's oesophagus, but despite a higher incidence of GERD after sleeve gastrectomy, the incidence of Barrett's oesophagus after sleeve gastrectomy appears to be similar to Roux-en-Y gastric bypass. However, quality of life related to GERD seems significantly lower in sleeve gastrectomy patients.[23] As a result, there is a reluctance to perform sleeve gastrectomy in patients with GERD.

A complication rate of 3.8% was observed in the bypass group, consistent with the SM-BOSS study (4.5%). The SLEEVEPASS study reported a higher complication rate (9.4%), which the authors explained by the surgeon's learning curve.[5,9] No venous thromboembolisms were reported, most likely due to extended prophylactic measures and the perioperative ERABS protocol.[13] In the sleeve gastrectomy group, an incidence of 1.9% for leakage was observed, which is in line with other literature that reports a range between 1.1% and 3.9%.[28,29] The use of staple line reinforcement, which was not used in this study, and the potential impact of the bougie size have been suggested to influence leakage rate.[28] However, a meta-analysis could not confirm this theory and concluded that leak risk is multifactorial.[30] Patients after Roux-en-Y gastric bypass had more minor complications, which was also found in the SLEEVEPASS trial. The present study revealed that these minor complications are mainly attributed to an increase in abdominal pain. This could be explained by the major change in digestive anatomy, requiring more adjusting of diet and lifestyle. Pain and diet problems are the most frequent reasons for patients to seek emergency medical care.[31] This emphasizes the importance of patient counselling about adequate hydration, diet and lifestyle choices. Revision surgery occurred more frequently in the sleeve gastrectomy group. This is partly because this group has a good surgical alternative for patients with serious complaints or poor results in terms of weight loss. For the bypass group on the other hand, there are only limited and more invasive surgical options, such as an undo of the bypass. This can be a reason for the difference in revisional surgery rate and does not necessarily mean that Roux-en-Y gastric bypass patients have less complaints or better QOL, complicating the comparison of revision rate between the groups.

Interestingly, despite observed variations in weight loss, comorbidities, and (minor) complications, the present study showed no significant differences in HRQoL between both groups. This suggests that there is no difference between the groups or that the questionnaires are not sensitive enough to observe certain quality of life disparities.

This study has several limitations, including the influence of baseline BMI on excess BMI loss as described above. Furthermore, at 5 years, loss to follow-up was 26%, which is similar to previous trials. Combined with the fact that some eligible patients declined to participate, this might introduce selection bias. However, repeated measurement analyses and multiple imputation allowed analysis of 614 patients. Secondly, the study was not powered to detect differences in secondary outcomes, such as comorbidities. Different outcomes were observed for Type 2 Diabetes improvement compared to Oseberg trial and for hypertension compared to SLEEVEPASS. Consequently,

no definitive conclusions can be drawn regarding these outcomes. However, OSAS, joint pain, and GERD outcomes aligned with prior randomised trials. Thirdly, the equivalence margin was slightly larger than the SLEEVEPASS trial. When determining the sample size using the available data at that time, a margin of 13% was chosen, based on the favourable clinical outcome being 50% long term excess BMI loss and the mean excess BMI loss of 63% after the golden standard procedure (Roux-en-Y gastric bypass).[17] Besides weight loss results, sleeve gastrectomy has other advantages compared to Roux-en-Y gastric bypass, such as preserving bowel anatomy, less minor complications, no lifelong risk of internal herniation, more nutritional options, good HRQoL, and less vitamin deficiencies. These advantages could merit a slight difference in weight loss compared with a Roux-en-Y gastric bypass.

At 5-year follow-up, sleeve gastrectomy and Roux-en-Y gastric bypass had clinically comparable excess BMI loss for people living with obesity grades 2 and 3 according to the predefined definition for equivalence. However, Roux-en-Y gastric bypass exhibited significantly higher total weight loss. Additionally, Roux-en-Y gastric bypass showed statistically significant advantages in secondary outcomes, including BMI, dyslipidaemia and GERD, yet at a higher rate of minor complications. Major complications, other comorbidities, and overall HRQoL did not significantly differ between the groups. These results can be helpful in shared decision-making for these procedures.

Contributors

UB and GM designed the trial. FS, SN, MD, HZ, IF, and JA recruited patients. JH and BN collected and analysed the data. The first draft of the manuscript was prepared by JH, BN, EB and UB based on the authors' comments on the manuscript outline. Subsequently, the first draft was critically reviewed and revised by all authors. All authors had full access to the data, interpreted the data and provided review, revision, and approval of the report.

Data sharing statement

Qualified researchers can request access to study documents (including the clinical study report, the study protocol with any amendments, and the statistical analysis plan) that support the methods and findings reported in this article. Requests for specific analyses or data can be submitted by email to j.hart@franciscus.nl.

Declaration of interests

All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr. SN reported receiving a Medtronic Educational Grant to the Catharina Obesity centre. No other authors reported disclosures.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lanepe.2024.100836.

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