Journal of Visceral Surgery (2019) 156, 497—506

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ORIGINAL ARTICLE

Prospective, multicentric, comparative study between sleeve gastrectomy and Roux-en-Y gastric bypass, 277 patients, 3 years follow-up☆

J.-M. Catheline[a], M. Fysekidis[b], Y. Bendacha[a], J.-J. Portal[c], N. Huten[d], E. Chouillard[e], J. Gugenheim[f], G. Fourtanier[g], K. Arapis[h], S. Msika[i], J.M. Fabre[j], M. Sodji[k], E. Vicaut[c], R. Dbouk[a], J. Roussel[a], R. Cohen[a,*]

[a] *Department of digestive surgery, centre hospitalier de Saint-Denis, 2, rue du Docteur-Delafontaine, 93205 Saint-Denis, France*
[b] *Department of endocrinology, hôpital Avicenne, AP—HP, 125, rue de Stalingrad, 93000 Bobigny, France*
[c] *Clinical research unit, hôpital Fernand-Widal, AP—HP, 200, rue du Faubourg-Saint-Denis, 75475 Paris, France*
[d] *Department of digestive surgery, CHU de Tours, 2, boulevard Tonnellé, 37000 Tours, France*
[e] *Department of digestive surgery, CHI de Poissy, 10, rue du Champ-Gaillard, 78303 Poissy, France*
[f] *Department of digestive surgery, CHU de Nice, 151, route Saint-Antoine-de-Ginestière, 06202 Nice, France*
[g] *Department of digestive surgery, CHU de Toulouse, 1, avenue du Professeur-Jean-Poulhès, 31400 Toulouse, France*
[h] *Department of digestive surgery, hôpital Bichat, AP—HP, 46, rue Henri-Huchard, 75877 Paris, France*
[i] *Department of digestive surgery, hôpital Louis-Mourier, AP—HP, 178, rue des Renouillers, 92700 Colombes, France*
[j] *Department of digestive surgery, CHU de Montpellier, 80, avenue Augustin-Fiche, 34000 Montpellier, France*
[k] *Department of digestive surgery, clinique des Émailleurs, 1, rue Victor-Schoelcher, 87000 Limoges, France*

Available online 15 May 2019

☆ Presented as Oral communication: (1) 22nd World Congress of International Federation For the Surgery of Obesity and Metabolic Disorders (IFSO-2017) in London, United Kingdom, 29 August—2 September 2017. (2) 26th International EAES Congress in London, United Kingdom, 30 May—1 June 2018.

* Corresponding author. Department of digestive surgery, centre hospitalier de Saint-Denis, 2, rue du Docteur-Delafontaine, 93200 Saint-Denis, France.

E-mail addresses: jmcatheline@orange.fr (J.-M. Catheline), fisekidis_marinos@hotmail.com (M. Fysekidis), yasmina.bendacha@ch-stdenis.fr (Y. Bendacha), jean-jacques.portal@aphp.fr (J.-J. Portal), huten@med.univ-tours.fr (N. Huten), chouillard@yahoo.com (E. Chouillard), gugenheim.j@chu-nice.fr (J. Gugenheim), gilles@fourtanier.com (G. Fourtanier), konstantinos.arapis@bch.aphp.fr (K. Arapis), simon.msika@aphp.fr (S. Msika), jm-fabre@chu-montpellier.fr (J.M. Fabre), maximesodji87@gmail.com (M. Sodji), eric.vicaut@aphp.fr (E. Vicaut), rami.dbouk@ch-stdenis.fr (R. Dbouk), jyroussel@gmail.com (J. Roussel), regis.cohen@ch-stdenis.fr (R. Cohen).

https://doi.org/10.1016/j.jviscsurg.2019.04.013
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HIGHLIGHTS

- This study simultaneously compared the efficacy and safety of LSG and LYRGB. LSG was found non-inferior to LRYGB with respect to weight loss and was associated with lower risk of major complications during a 3-year follow-up but GERD increased in LSG group and decreased in LRYGB group.

KEYWORDS
Roux-en-Y gastric bypass;
Sleeve gastrectomy;
Prospective comparative study;
Clinical trial;
Morbid obesity

Summary
Background: Laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en Y gastric bypass (LRYGB) are commonly performed, but few studies have shown superiority of one strategy over the other.
Objective: Simultaneously compare LSG and LRYGB in terms of weight loss and morbimortality over a 36-month follow-up period.
Setting: University hospital and bariatric surgery centers, France.
Methods: Prospective, comparative study between LSG and RYGBP. The primary endpoint of this study was a joint hypothesis during the 36-month follow-up: the first primary outcome pertained to the frequency of patients with an excess weight loss (EWL) greater than 50% (% EWL > 50%) after LSG or RYGB; the second primary outcome was defined as a composite endpoint of at least one major complication. Secondary objectives were regression of comorbidities and improvement in quality of life.
Results: Two hundred and seventy-seven patients were included (91 RYGBP, 186 LSG). The mean age was 41.1 ± 11.1 years, and average preoperative body mass index of $45.3 \pm 5.5\,kg/m^2$. After 36 months, the %EWL > 50% was not inferior in the case of LSG (82.2%) relative to LRYGB (82.1%); while major complications rates were significantly higher in LRYGB (15.4%) vs. LSG (5.4%, $P = 0.005$). After 36 months, all secondary objectives were comparable between groups while only gastroesophageal reflux disease (GERD) increased in LSG group and decreased in LRYGB group.
Conclusions: LSG was found non-inferior to LRYGB with respect to weight loss and was associated with lower risk of major complications during a 3-year follow-up. But GERD increased in LSG group and decreased in LRYGB group.
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Introduction

The treatment of severe obesity has considerably evolved over the years. Bariatric surgery has produced excellent results not only with respect to weight loss, but also to long-term survival, quality of life, and alleviation of comorbid conditions such as type 2 diabetes mellitus (T2DM), hypertension, and obstructive sleep apnea syndrome (OSAS) [1—3]. Over the last 30 years, laparoscopic Roux-en-Y gastric bypass (LRYGB) demonstrated good results in terms of weight loss [4]. However, this procedure is associated with relatively frequent complications, such as digestive fistulae, intra-abdominal bleeding, occlusion, vitamin deficiencies [4]. Some authors even report an increased risk of self-harm emergencies compared to the general population [5]. Practice improvement in various aspects of laparoscopic sleeve gastrectomy (LSG) [6] have made it the preferred surgical procedure for treatment of severe obesity in France [7] and the United States of America [8,9].

Several cohort studies and prospective randomized studies have compared LSG with LRYGB. In a recent systematic review [10], LRYGB was considered more efficient than LSG in terms of weight loss, but was associated with a higher risk of complications. A different systematic review [11] and a randomized study challenged this conclusion, in that both procedures were found equally efficient regarding weight loss up to 3 years after surgery [12]. To the best of our knowledge, no clinical trial has been designed to study the risk—benefit ratio by simultaneously comparing both efficacy in terms of weight loss and morbimortality over 36 months between these procedures. The main objective of this study was to test a joint hypothesis that LSG is non-inferior to LRYGB in terms of weight loss and is associated with reduced morbimortality throughout the 3-year follow-up.

Patients and methods

Study design

This study was a registered clinical trial (NCT00722995). Its rationale, design, methods, and complete protocol were approved by the ethics committee (CCP Île-de-France IV: 2007/48sc). The institutional review board of Fernand-Widal also granted its approval in 2007, and the study was coordinated by the clinical research unit of Fernand-Widal Hospital in Paris, France (PHRC SLEEVE K060213/IDRCB2007-A00373-50). The trial was initially designed as a two-group (LSG vs. LRYGB), prospective randomized, multicenter study.

The first 40 patients included were randomized (25 LSG, 15 LRYGB). Hindered patient recruitment due to randomization refusal led to a methodological change into a nonrandomized prospective approach. The eligibility criteria were the age limit of 18—60 years and body mass index (BMI) $\geq 40\,kg/m^2$ or $\geq 35\,kg/m^2$ with one or more comorbid

conditions such as T2DM, OSAS, dyslipidemia, hypertension, and back pain/joint pain with arthritis [13,14]. Written informed consent was obtained from all patients before their enrollment. The exclusion criteria were poor life expectancy, contraindications to use of general anaesthesia, lack of affiliation to the French social health care system, major psychiatric or cognitive disorders, uncontrolled eating disorders, patent vitamin deficiencies, and pregnancy, either at the time of the study or planned during the year following the operation.

Patients and study measurements

Patients were recruited from 11 expert centers for bariatric surgery where surgeons had experience in both LRYGB and LSG (> 200 bariatric procedures per year). Baseline patient demographics (age, sex), relevant medical history including presence of weight-related or other comorbid conditions such as lung disease, cardiovascular disease, hypertension, hyperlipidemia, gastroesophageal reflux disease (GERD), urinary incontinence, T2DM, liver disease, history of venous thromboembolism (VTE), OSAS and musculoskeletal disorders, were recorded. Preoperative diagnosis of OSAS was established with polygraphy or polysomnography for all patients. Patients were assessed by either a psychiatrist or psychologist for mental disorders. All patients were under the care of a dietician or nutritionist six months prior to surgery. Diagnosis of arthritis was based on clinical manifestations (presence of joint or back pain) or on the history of treatment with nonsteroidal anti-inflammatory drugs. The status of comorbid conditions (including T2DM, hypertension, and dyslipidemia) was assessed preoperatively and at 18 and 36 months post-surgery. Resolution of OSAS was established by the withdrawal of C-PAP ventilation. The onset persistence, appearance, or resolution of GERD was appraised through the use of proton pump inhibitors (PPI) therapy, or through symptoms associated with GERD (heartburn and nocturnal cough) combined with upper endoscopy whenever needed. The following data points were also recorded at 18 and 36 months: weight loss; blood pressure; medication use; adverse events; disease-related complications; quality of life assessed by means of a 36-item short-form health survey (SF-36) [15]; and socioeconomic deprivation score (EPICES) [16] (Supplementary Table 1).

Operation technique

The technique used by the surgical teams was described in the medical records. For LSG, a 32- to 36-Fr bougie was recommended for calibration of the gastric tube; longitudinal resection of the stomach was performed 3—6 cm proximal from the pylorus and proceeding along the lesser curvature to the angle of His. LRYGB was performed with a 40- to 60-cm-long biliopancreatic limb and a 100- to 150-cm alimentary antecolic or retrocolic limb.

Joint criteria for primary outcomes

The primary endpoint of this study was to test a joint hypothesis comparing LSG and LRYGB. The first primary outcome was a non-inferiority criterion on the frequency of patients with excess weight loss greater than 50% (% EWL > 50%), defined by Reinhold as the threshold of successful weight loss [17]. The second primary outcome was defined as a composite endpoint of at least one major complication during 36 months postoperative period. Morbimortality refers both to mortality and morbidity that is the frequency of patients who had death or at least one major complication during a follow-up of 36 months. The following events related to the surgical procedure were registered: death; peritonitis; intra-abdominal abscess; gastrointestinal fistulae; intra-abdominal bleeding; gastric or anastomotic stenosis with or without anastomotic ulcer; trocar site hernia; internal bowel obstruction, either from internal hernia or due to adhesions; pulmonary infection; deep venous thrombosis; pulmonary embolism; rhabdomyolysis; and severe vitamin deficiency (disabling dysesthesia, beriberi, and encephalopathy).

Secondary outcomes and study end points

The secondary endpoints were early (< 30 days) and late (30 days to 36 months follow-up) postoperative complications namely, the operative time and the length of hospital stay. At 18 and 36 months after surgery, weight loss from the baseline, BMI reduction, percentage of excess weight loss (% EWL) and percentage of total weight loss (%TWL) were evaluated. In addition, the evolution of comorbid conditions (T2DM, hypertension, dyslipidemia, OSAS and GERD), the quality of life (SF-36) [15], and the economic deprivation score (EPICES) [16] were evaluated.

Sample size

The sample size was calculated to ensure sufficient power for the two tested hypotheses (i.e., non-inferiority for weight loss and fewer complications) [18]. A unilateral confidence interval with $\alpha \leq 0.05/2$ and 80% statistical power for a prespecified non-inferiority difference (δ) of 15% [19] was used to demonstrate the non-inferiority with respect to % EWL > 50% [18]. Demonstration of successful reduction in % EWL > 50% in 85% of the participants would have required a total sample size of 280 patients; the same sample was adequate to detect a 10% difference in the frequency of complications with Chi^2 test (statistical power: 90%; bilateral threshold of $\alpha = 5\%$). A 15% incidence of major complications after gastric LRYGB was factored in the study design [20].

Statistical analysis

Analyses were performed using SAS software, version 9.2 (SAS Institute; Cary USA). Non-inferiority for weight loss would be demonstrated if the upper value of the one-sided confidence interval was less than the threshold of non-inferiority δ previously set at 15%. The study would be in favour of LSG if both criteria were met, i.e., non-inferiority with respect to weight loss and fewer major postsurgical complications.

The frequencies of major postsurgical complications were analysed by the Mantel—Haenszel test (stratified by center) and the heterogeneity of the odds ratios between the centers was tested by Breslow—Day test (The Breslow—Day test is a test of differences of the odds ratios for major postsurgical complications from each center). Since the two tested hypotheses should be conducted simultaneously, it was not considered necessary to adjust for the risk of type 1 error for each test.

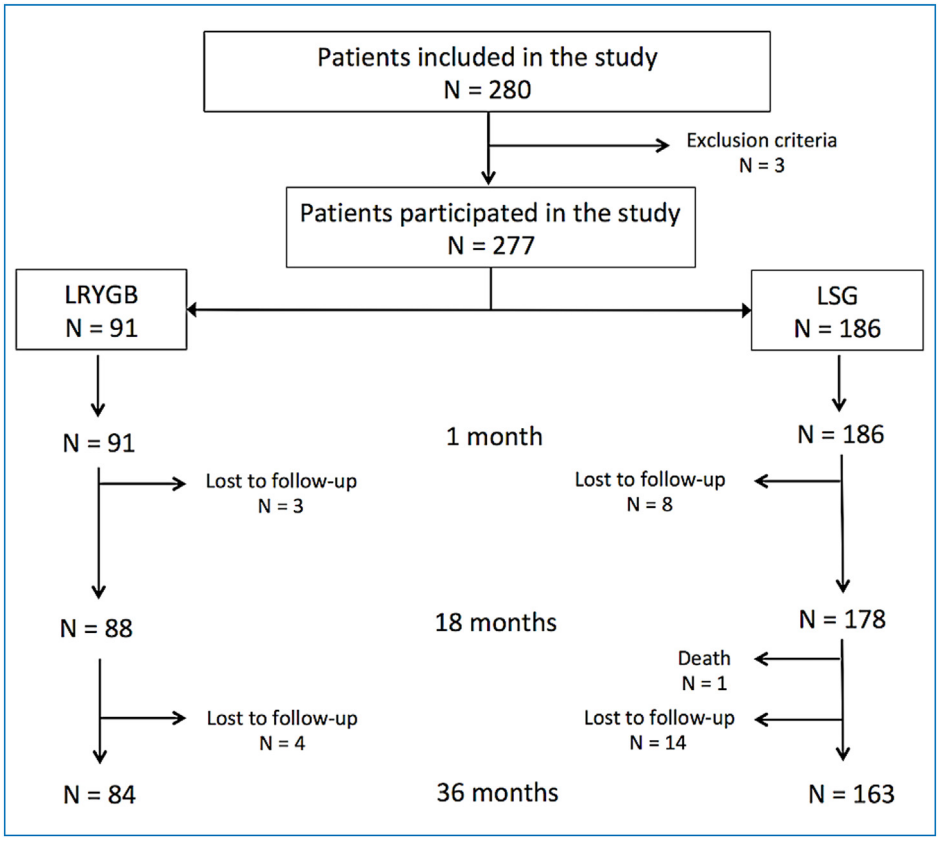

Figure 1. Flow chart ''population as treated''. LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy.

Results

Patients

A total of 280 patients were included in the study (Fig. 1). Three patients over 60 years old were erroneously included in the study and later excluded from the analysis. A total of 277 patients participated in the study from January 2008 to April 2015, end of the follow-up for the last patient included in March 2012. Among those, 91 were in the LRYGB group and 186 were in the LSG group. Seven and 22 patients were lost to follow-up at 36 months in the LRYGB and LSG groups, respectively. One patient died in the LSG group between the 18th and 36th month of follow-up. A total of 266 patients were evaluated at 18 months and 247 patients were evaluated at 36 months for the assessment of the safety and efficacy of both bariatric procedures (Fig. 1).

The baseline characteristics of the 277 patients are summarized in Table 1. The mean age was 41.1 ± 11.1 years; 85.9% were women; and the average BMI at baseline was 45.3 ± 5.5 kg/m^2. GERD was more frequent in the LRYGB group (24.2 vs. 14.5%, $P = 0.048$). There were no other significant differences between groups at baseline (Table 1).

Technical considerations

A calibration tube was used for 98.9% of the LSG group patients ($n = 184$) and for 64.8% of the LRYGB group patients ($n = 59$). A 33-, 34-, and 36-French bougie was used in 11.4%, 58.7%, and 29.3% of the LSG group patients and in 29.1%, 27.3%, and 29.1% of the LRYGB group patients, respectively. Seamguard®-type suture reinforcement was used in 20 LSG group patients (10.8%) and 23 (25.3%) LRYGB group. Reinforcement by running suture was used for 78 LSG group patients (41.9%) and for 6 (6.6%) LRYGB group. A drain was placed next to the staple line in 136 (73.1%) LSG group and 67 (73.6%) LRYGB group. In the LRYGB group, the alimentary limb was antecolic in 86 patients (94.5%) and retrocolic in five (5.5%). Gastrojejunal anastomosis was performed mechanically in 67 patients (73.6%) and manually in 24 patients (26.4%). It is noteworthy that 48 patients (17.3%) had a previous history of laparoscopic gastric banding with a tendency for lap band removal during surgery for LRYGB 9.9% ($n = 9$) vs. 2.7% ($n = 5$) for LSG ($P = 0.066$). Both groups had comparable rates for lap band removal prior to bariatric surgery [13.2% ($n = 12$) for LRYGB vs. 11.8% ($n = 22$) for LSG ($P = 0.11$)]. Conversion to laparotomy happened in 14 cases (5.1%). The conversion rate in the LRYGB group (13.2%) ($n = 12$) was significantly higher than that in the LSG group 1.1% ($n = 2$) ($P < 0.001$). Fourteen cases of conversions to laparotomy occurred (14/277; 5.1%); eight of them occurred from gastric banding to LRYGB (8/91; 8.8%) and one from gastric banding to LSG (1/186; 0.5%). Four cases of conversion to laparotomy occurred postoperatively after LRYGB (4/91; 4.4%) and one after LSG (1/186; 0.5%).

There were no significant between-group differences with respect to transfusion rate (2.2% vs. 1.1%, respectively; $P = 0.60$) and the leak incidence rates during the intraoperative methylene blue test (2.2% vs. 0.5%, respectively; $P = 0.25$) were similar. The mean operative duration and hospital stay in the LRYGB group were longer than those in LSG group: 2.9 ± 1.3 hours for the LRYGB group versus 1.8 ± 0.9 hours for the LSG group ($P < 0.001$); 6.5 ± 3.8 days for the LRYGBP group versus 5.1 ± 4.2 days for the LSG group ($P = 0.01$).

Table 1 Baseline characteristics of the study population.

	LRYGB ($n = 91$)	LSG ($n = 186$)	P^a
Mean age ± SD (years)	41.9 ± 10.6	40.7 ± 11.1	0.38
Sex (F, %)	82 (90.1)	156 (83.4)	0.16
Mean weight ± SD (kg)	121.6 ± 15.1	124.3 ± 21.6	0.28
Mean BMI ± SD (kg/m^2)	45.5 ± 5.3	45.1 ± 5.8	0.92
Hypertension (%)	33.0	37.1	0.50
T2DM (%)	24.2	21.0	0.55
Dyslipidemia (%)	34.1	32.8	0.83
OSAS (%)	38.5	47.3	0.16
Back pain/joint pain with arthritis (%)	41.8	43.0	0.84
GERD (%)	24.2	14.5	0.048
Urinary incontinence (%)	2.2	1.1	0.60
Sterility (%)	3.3	4.8	0.76
Asthma (%)	5.6	7.2	0.83
Smoking (%)	22.0	20.4	0.86
Previous gastric band (%)	23.1	14.5	0.085

LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy; SD: standard deviation; BMI: body mass index; T2DM: type 2 diabetes mellitus; OSAS: obstructive sleep apnea syndrome; GERD: gastroesophageal reflux disease.
[a] Fisher's exact test.

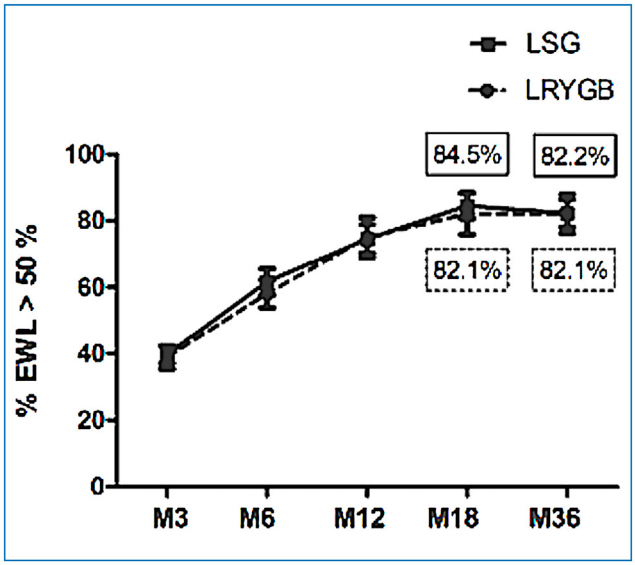

Figure 2. Evolution of percentage of patients with %EWL > 50% after 18- and 36-month follow-up. LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy; %EWL: % excess weight loss.

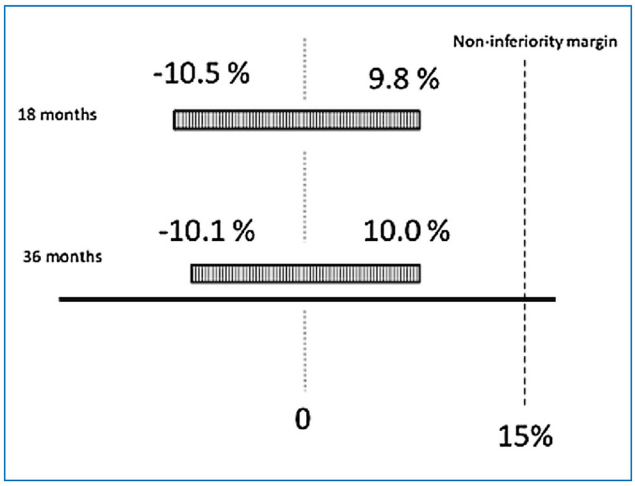

Figure 3. Non-inferiority confidence interval for weight loss for patients in the LSG group versus LRYGB group at the 18- and 36-month follow-up. Both intervals do not cross the predefined non-inferiority margin of 15%. LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy.

Composite primary endpoint

Patients with % EWL > 50%

Between the two groups, the difference of patients who achieved % EWL > 50% was −2.47% 95% CI (−10.5%; 9.8%), and −0.07% 95% CI (−10.1%; 10.0%) at 18 and 36 months respectively (Figs. 2 and 3). The upper limit of confidence interval was less than the non-inferiority threshold δ of 15%, which demonstrates the non-inferiority of LSG compared with LRYGP with respect to weight loss ratio at 18 and 36 months (Fig. 3, Supplementary Table 2). No LSG was converted to LRYGB for insufficient weight loss during 36 months follow-up.

Morbidity and mortality

No deaths occurred in the LRYGB group. One patient in the LSG group died 20 months after initial surgery due to surgery-related significant cachexia, septic shock, and multivisceral failure. At 36 months, morbimortality in the LSG group was significantly lower than that in the LRYGB group (5.4 vs. 15.4%, respectively) [Chi^2 test: $P = 0.005$, odds ratio (OR): 3.2; 95% CI: 1.40–7.5]. The events are listed in Table 2. Seven cases of digestive fistulae occurred (7/277; 2.5%), three of them occurred after gastric banding to LRYGB (3/91; 3.3%), two from gastric banding to LSG (2/186; 1.1%). One digestive fistulae occurred postoperatively after LRYGB (1/91; 1.1%), and one in LSG (1/186; 0.5%).

The risk for major complications was comparable between centers (Breslow–Day test, $P = 0.08$, Table 3). We

Table 2 Primary end point: major complications at 36 months follow-up.

Occurrence of major complications	LRYGB ($n=91$)	LSG ($n=186$)	Total ($n=277$)
Yes[a]	14 (15.4%)	10 (5.4%)	24 (8.7%)
No	77 (84.6%)	176 (94.6%)	253 (91.3%)
Death	0	1 (0.5%)	1 (0.36%)
Peritonitis	0	0	0
Intra-abdominal abscess	1 (1.1%)	1 (0.5%)	2 (0.7%)
Digestive fistulae	4 (4.4%)	3 (1.6%)	7 (2.5%)
Intra-abdominal bleeding	2 (2.2%)	2 (1.1%)	4 (1.4%)
Gastric or anastomotic stenosis with or not anastomotic ulcer	1 (1.1%)	0	1 (0.4%)
Trocar site occlusion	0	2 (1.1%)	2 (0.7%)
Internal hernia occlusion	2 (2.2%)	0	2 (0.7%)
Occlusion due to adhesion	0	1 (0.5%)	1 (0.4%)
Pulmonary infection	1 (1.1%)	0	1 (0.4%)
Deep venous thrombosis	1 (1.1%)	0	1 (0.4%)
Pulmonary embolism	0	0	0
Rhabdomyolysis	0	0	0
Severe vitamin deficiencies (disabling dysesthesia, Beriberi, encephalopathy)	2 (2.2%)	0	2 (0.7%)

LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy.
[a] Chi^2 test: $P=0.005$.

Table 3 The risk of major complications was similar among centers, Breslow—Day test: $P=0.08$.

Centers	Major complications at 36 months follow-up	
	Yes	No
Center 1	7 (5.6%)	118 (94.4%)
Center 3	3 (5.8%)	49 (94.2%)
Center 9	5 (16.1%)	26 (83.9%)
Center 10	1 (4.3%)	22 (95.7%)
Center 8	4 (20.0%)	16 (80.0%)
Other centers[a]	4 (15.4%)	22 (84.6%)

[a] Centers with less than 10 inclusions were grouped as other centers.

concluded that the risk for major complications across centers was similar.

Secondary endpoints

Early (< 30 days) and late (30 days to 36 months follow-up) major complications

Our study was underpowered for studying separately early and late postsurgical major complications. However, the LRYGB group exhibited a tendency for early complications: 8 cases (8.8%) for the LRYGBP group and 7 cases (3.8%) for the LSG group (Chi^2 test: $P=0.08$; OR: 2.5; and 95% CI: 0.9—7.0; Supplementary Table 3). Furthermore, late complications between 30 days to 36 months follow-up were also found more frequently in the LRYGB group: 6 cases (6.6%) versus 3 cases (1.6%) for the LSG group (Chi^2 test: $P=0.03$; OR: 4.3; 95% CI: 1.0—17.6).

Weight loss evolution

The parameters used to assess weight loss (change in BMI, % TWL, % EWL) were comparable between the two groups (Table 4).

Evolution of comorbid conditions

Occurrence of GERD increased after LSG and decreased after LRYGB (Table 5). Occurrence of GERD in the LRYGB group was significantly lower than that in the LSG group at both 18-month ($P=0.036$) and 36-month ($P=0.015$) follow-up. At 36-month follow-up, no significant between-group differences were observed regarding the resolution of comorbid conditions including hypertension, T2DM, OSAS, and dyslipidemia (Table 5).

Deprivation status and quality of life

The results of 36-items short-form health survey (SF-36) [15] including physical component score (PCS), mental component score (MCS), total score, and the socioeconomic deprivation score (EPICES) [16], in the LSG and LRYGP groups, were comparable at all three time-points (baseline, 18 months, and 36 months; Table 6).

Discussion

This prospective multicentric study has demonstrated that LSG was non-inferior to LRYGB with respect to weight reduction and is associated with lower postsurgical major complication rates over a follow-up period of 3 years. Late

Table 4 Secondary endpoints: weight loss evolution.

	LRYGB	LSG	P^a
BMI (kg/m^2) at inclusion (mean ± SD) *n* (missing)	45.2 ± 5.8 91 (0)	45.3 ± 5.3 186 (0)	0.92
BMI (kg/m^2) at M18 (mean ± SD) *n* (missing)	29.5 ± 5.9 88 (3)	29.9 ± 5.5 178 (8)	0.95
BMI (kg/m^2) at M36 (mean ± SD) *n* (missing)	29.8 ± 5.9 84 (7)	30.8 ± 5.5 163 (23)	0.46
BMI loss (kg/m^2) at M18 (mean ± SD) *n* (missing)	16.0 ± 5.0 88 (3)	15.2 ± 5.2 178 (8)	0.61
BMI loss (kg/m^2) at M36 (mean ± SD) *n* (missing)	15.7 ± 5.3 84 (7)	14.4 ± 5.3 163 (23)	0.57
%TWL at M18 (mean ± SD) *n* (missing)	35.2 ± 10.288 (3)	33.4 ± 9.9 178 (8)	0.66
%TWL at M36 (mean ± SD) *n* (missing)	34.3 ± 10.684 (7)	31.6 ± 10.3163 (23)	0.55
%EWL at M18 (mean ± SD) *n* (missing)	80.5 ± 24.488 (3)	77.4 ± 23.5 178 (8)	0.69
%EWL at M36 (mean ± SD) *n* (missing)	78.3 ± 6.1484 (7)	73.2 ± 24.6163 (23)	0.67

LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy; M18: 18 months; M36: 36 months; BMI: body mass index; %EWL: % excess weight loss; %TWL: %total weight loss; SD: standard deviation.
[a] Student *t*-test.

Table 5 Secondary endpoints: evolution of comorbidities and gastroesophageal reflux disease (GERD) at 18 and 36 months.

	LRYGB	LSG	*P*
Hypertension			
Inclusion, *n* (%)	30 (33.0%)	69 (37.1%)	0.500[a]
M18, *n* (%)	22 (25.0%)	35 (19.7%)	0.534[a]
M36, *n* (%)	16 (19.0%)	34 (20.9%)	0.730[a]
T2DM			
Inclusion, *n* (%)	22 (24.2%)	41 (22.0%)	0.620[a]
M18, *n* (%)	11 (12.5%)	23 (12.9%)	0.749[a]
M36, *n* (%)	8 (9.5%)	18 (11.0%)	0.950[a]
OSAS			
Inclusion, *n* (%)	35 (38.5%)	88 (47.3%)	0.160[a]
M18, *n* (%)	8 (9.1%)	18 (10.1%)	0.240[a]
M36, *n* (%)	4 (4.8%)	12 (7.3%)	0.740[a]
Dyslipidemia			
Inclusion, *n* (%)	31 (34.1%)	61 (32.8%)	0.846[a]
M18, *n* (%)	5 (5.7%)	21 (11.8%)	0.230[a]
M36, *n* (%)	5 (5.9%)	14 (8.6%)	0.845[a]
GERD			
Inclusion, *n* (%)	22 (24.2%)	27 (14.5%)	0.048[b]
M18, *n* (%)	8 (9.1%)	33 (18.5%)	0.036[b]
M36, *n* (%)	7 (8.3%)	33 (20.2%)	0.015[b]

LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy; M18: 18 months; M36: 36 months; T2DM: type 2 diabetes mellitus; OSAS: obstructive sleep apnea syndrome; GERD: gastroesophageal reflux disease.
[a] Fisher's exact test.
[b] Chi^2 test.

major complications between 30 days to 36 months follow-up were found more frequently in the LRYGB group and it was statistically significant. Hence the importance of monitoring after LRYGB for detection of major complications. The current study reported weight loss as % EWL > 50% (primary endpoint for weight loss) as well as % EWL and %TWL (secondary end point); the incidence of both endpoints was comparable between the two groups. These results challenge the findings of a recent systematic review in which LRYGB was found to achieve better weight loss as compared to LSG [10]. However, the latter systematic review included retrospective studies with limited sample sizes and relatively short duration of follow-up; moreover, there was considerable heterogeneity among the included studies. The

Table 6 Secondary endpoints: evolution of quality of life by 36-items short-form health survey (SF-36) [15] with physical component score, mental component score, and quality of life index; plus socioeconomic deprivation score (EPICES) [16] at 18 and 36 months.

	LRYGB ($n = 84$)	LSG ($n = 163$)	P^a
SF-36: Physical Component Score (PCS)			
Inclusion (mean ± SD)	39.5 ± 10.1	40.3 ± 10.1	0.536
M 18 (mean ± SD)	51.9 ± 7.0	49.8 ± 9.6	0.454
M 36 (mean ± SD)	49.6 ± 10.3	50.1 ± 9.9	0.922
SF-36: Mental Component Score (MCS)			
Inclusion (mean ± SD)	45.0 ± 11.7	43.8 ± 12.0	0.413
M 18 (mean ± SD)	48.8 ± 9.9	49.3 ± 7.8	0.9743
M 36 (mean ± SD)	46.4 ± 12.1	47.9 ± 9.4	0.849
SF-36: Total score			
Inclusion (mean ± SD)	84.6 ± 16.4	84.1 ± 16.5	0.812
M 18 (mean ± SD)	100.7 ± 13.1	99.1 ± 14.1	0.562
M 36 (mean ± SD)	96.0 ± 17.3	98.0 ± 15.8	0.608
Socioeconomic Deprivation Score (EPICES)			
Inclusion (mean ± SD)	27.8 ± 19.3	30.3 ± 17.5	0.281
M 18 (mean ± SD)	23.3 ± 19.6	25.2 ± 16.4	0.345
M 36 (mean ± SD)	30.0 ± 23.4	26.1 ± 21.3	0.404

LRYGB: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve.
[a] Mann—Whitney test.

recent results of SM-Swedish Obese Subjects (SOS) randomized study (3-year follow-up) have challenged the notion that LRYGB is a more efficient method to achieve weight loss [12] and the extent of weight loss achieved is consistent with that observed in the present study. Although the technical aspects of bariatric surgery are important for weight loss, obesity is a chronic disease and adequate postoperative follow-up is probably equally important for achieving weight loss [21]. The close follow-up during the study period (four consultations with the surgeon, the nutritionist, and the dietician) may also partially account for the discrepancy between studies and suggest a study effect.

The second main result of this study was the lower incidence of major complications after LSG, while the risk for major complications across centers was homogeneous. Patients with LRYGB were significantly more likely to experience major complications with an increased probability for conversion to laparotomy and longer operative time. To our knowledge, this is the first prospective study in the field of bariatric surgery designed which primary objective is to compare the rate of major complications between LSG and LRYGB during a 3 years follow-up. A major problem with the current literature is that major complications are often reviewed separately as early (< 30 days) or late (> 30 days) complications. Although such an analysis is relevant for clinical practice [22], sufficient number of events is required to obtain adequate statistical power for event analysis [23]. Patients with LRYGB had a tendency for both early and late complications. However, in our study, late complications were more common in the LRYGB group. We have to emphasize that the risk—benefit ratio of this surgery has improved considerably over the recent years. Creation of multidisciplinary teams, able to select patients and manage surgical complications has reduced post-surgery risks. Surgical techniques aimed at reducing the risk of fistula [24], endoscopic treatment of fistulae [25], and publication of guidelines [6] have all contributed to better results. Kizy et al. [26] reported that readmission was less likely for patients with LSG and that LSG was more cost effective than LRYGB. The shorter hospital stay after LSG, which reflects the lower incidence of complications, strongly suggests that sleeve gastrectomy may also be cost efficient.

This study and the SM-SOS studies reported equivalent weight loss and similar improvement in all comorbid conditions except GERD [12]. Occurrence of GERD decreased after LRYGB and increased after LSG [27]. However, it is likely that surgeons prefer LRYGB for patients with preexisting GERD, which may have introduced an element of bias [27]. The frequency of endoscopic surveillance, even in the absence of GERD, should be taken into account since recent studies have reported increased rates of non-dysplastic Barrett's esophagus after LSG [28]. Both operations showed similar results with respect to quality of life (SF-36) [15] and socioeconomic deprivation score (EPICES) [16]. Studies with longer follow-up will determine if regression of comorbidities remains similar between both procedures. Analysis of long-term data from observational studies like the SOS showed that the mean change in body weight after 20 years was about 20% [29]; however, these results are currently available for a limited number of patients only. Long-term mortality data after LSG is also scarce; patients with LRYGB have better survival rates compared to non-operated patients mostly due to regression of comorbidities [30,31].

Relevant limitations of our study include the follow-up limited at 36 months, the lack of randomization, and the absence of standardization in surgical techniques since each team tends to have its own preferences; however, the risk of complications was homogenous across centers. The strong points of our study were the design, prospective nature, adequate number of patients, and the completion of a long-term follow-up for a sufficient number of patients.

Conclusion

LSG was not inferior to LRYGB in terms of weight loss at 3 years. But LSG was safer than LRYGB with fewer serious

complications at 3 years follow-up. Serious complications between the 30th day postoperative and the 36th month were more frequent after LRYGB, calling for improvement in follow-up procedures. Concerning the evolution of the comorbidities and the quality of life, there was no difference between the results of both techniques. Occurrence of GERD decreased after LRYGB and increased after LSG. GERD was more common after LSG and this finding underlines the importance of long-term follow-up with endoscopic monitoring after LSG that needs to be determined by further studies. Prospective comparative studies with long-term follow-up over 3 and 5 years are needed.

Funding

This work was supported by a grant from the French Ministry of Health, Projet Hospitalier de Recherche Clinique (PHRC) 2007; SLEEVE K060213/IDRCB2007-A00373-50.

Clinical trial registration

The study was approved by Ethical Committee (Comité de Protection des Personne ''CPP'' Île-de-France IV: 2007/48sc) and registered as a clinical trial in a public database (Clinicaltrials.gov Identifier: NCT00722995).

Ethical statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The data file was declared to the French national commission for computerized files and liberty (declaration No. 1996605).

Consent statement

Informed consent was obtained from all individual participants included in the study.

Acknowledgements

We thank Dr. Naji Bdeoui, and Mrs. Vidhya Raghavan, Sophie Gérard for their patient information collection work. We thank Hugo Roussel for the correction of the manuscript.

Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.jviscsurg.2019.04.013.

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