

Prospective randomized clinical trial of laparoscopic sleeve gastrectomy versus open Roux-en-Y gastric bypass for the management of patients with morbid obesity

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Abstract

Introduction: Roux-en-Y gastric bypass (RYGB) is considered the gold standard bariatric procedure with documented safety and effectiveness. Laparoscopic sleeve gastrectomy (LSG) is a newer procedure being done with increasing frequency. Randomized comparisons of LSG and other bariatric procedures are limited. We present the results of the first prospective randomized trial comparing LSG and RYGB in the Polish population.

Aim: To assess the efficacy and safety of LSG versus RYGB in the treatment of morbid obesity and obesity-related comorbidities.

Material and methods: Seventy-two morbidly obese patients were randomized to RYGB (36 patients) or LSG (36 patients). Both groups were comparable regarding age, gender, body mass index (BMI) and comorbidities. The follow-up period was at least 12 months. Baseline and 6 and 12 month outcomes were analyzed including assessment of percent excess weight lost (%EWL), reduction in BMI, morbidity (minor, major, early and late complications), mortality, reoperations, comorbidities and nutritional deficiencies.

Results: There was no 30-day mortality and no significant difference in major complication rate (0% after RYGB and 8.3% after LSG, $p > 0.05$) or minor complication rate (16.6% after RYGB and 10.1% after LSG, $p > 0.05$). There were no early reoperations after RYGB and 2 after LSG (5.5%) ($p > 0.05$). Weight loss was significant after RYGB and LSG but there was no difference between both groups at 6 and 12 months of follow-up. At 12 months %EWL in RYGB and LSG groups reached 64.2% and 67.6% respectively ($p > 0.05$). There was no significant difference in the overall prevalence of comorbidities and nutritional deficiencies.

Conclusions: Both LSG and RYGB produce significant weight loss at 6 and 12 months after surgery. The procedures are equally effective with regard to %EWL, reduction in BMI and amelioration of comorbidities at 6 and 12 months of follow-up. Laparoscopic sleeve gastrectomy and RYGB are comparably safe techniques with no significant differences in minor and major complication rates at 6 and 12 months.

Key words: bariatric surgery, morbid obesity, gastric bypass, sleeve gastrectomy, randomized trial.

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Introduction

Obesity is a major epidemic of the twenty first century. Bariatric surgery is the only effective treatment for morbid obesity, leading to sustained weight loss and amelioration of comorbidities [1]. Laparoscopic sleeve gastrectomy (LSG) is one of the newer restrictive operations being performed with increasing frequency for the treatment of morbid obesity. The procedure was originally described as a part of biliopancreatic diversion with duodenal switch by Hess in 1988 [2]. Sleeve gastrectomy is now most commonly performed as a stand-alone laparoscopic operation [3]. Since its first implementation in 2004 as a laparoscopic stand-alone procedure, LSG has proved to be effective in weight loss and in improvement of comorbidities [4]. Roux-en Y gastric bypass (RYGB) is the most frequently performed bariatric procedure, providing significant and sustained weight loss at long-term follow-up [5]. It is considered the gold standard in bariatric surgery and other bariatric operations should be compared to RYGB. Buchwald *et al.* [6] in an evaluation of the state of bariatric surgery worldwide reported that RYGB was the most commonly performed bariatric procedure (49.3% of all bariatric operations) and 13% of all RYGB procedures were done as open surgery. Most RYGBs are nowadays performed laparoscopically, but in the first report published in 2011 of 28 616 patients undergoing bariatric surgery from the American College of Surgeons Bariatric Surgery Center Network 14 491 had laparoscopic RYGB and 988 open RYGB [7].

Aim

The aim of this prospective randomized study was to compare 6-month and 1-year outcomes in patients undergoing LSG and open RYGB in a single teaching hospital in Poland.

Material and methods

Between November 2008 and March 2011 seventy-two patients who matched the inclusion criteria were randomized to either RYGB or LSG treatment groups. The study was approved by the Research and Ethics Committee of the Medical University of Warsaw and was conducted according to the principles of the Declaration of Helsinki. Written informed consent was obtained from all eligible patients before

enrolment. All the operations were performed by the same surgical team.

The inclusion criteria for the study were: (1) body mass index (BMI) ≥ 40 kg/m² or BMI ≥ 35 kg/m² with at least one comorbidity associated with obesity (type 2 diabetes, hypertension, dyslipidemia, obstructive sleep apnea), (2) age = 18-60 years.

Exclusion criteria included: (1) BMI > 60 kg/m², (2) poorly controlled significant medical or psychiatric disorders, (3) active alcohol or substance abuse, (4) active duodenal/gastric ulcer disease, (5) difficult to treat gastro-esophageal reflux disease (GERD) with a large hiatal hernia, (6) previous major gastrointestinal surgery, (7) diagnosed or suspected malignancy.

All the patients had a thorough preoperative evaluation by an internal disease specialist, a dietician and a surgeon. A psychiatric evaluation was obtained if considered necessary. Upper gastrointestinal endoscopy, abdominal ultrasound examination, Doppler ultrasound of the veins of the lower extremities and spirometry were performed in all the subjects. Peptic ulcer disease and *Helicobacter pylori* infection were treated before surgery if diagnosed during the initial assessment. Cholecystectomy was performed at the time of bariatric surgery only if gallstones were symptomatic.

The open RYGB technique included creation of a small (15-20 cc) gastric pouch and an antecolic-antegastric Roux-en-Y reconstruction with routine transection of the greater omentum. The biliopancreatic and alimentary limbs were 100 cm long each. Side-to-side gastrojejunostomy and end-to-side jejunojejunostomy were performed using hand-sewn technique. The resulting mesenteric defects were routinely closed at the time of surgery. No drains were left in the peritoneal cavity.

In LSG a Veress needle is used to establish CO₂ pneumoperitoneum of 15 mm Hg and five ports are routinely inserted (Figure 1). At the beginning the branches of the gastroepiploic artery are divided close to the gastric wall, then the short gastric vessels of the greater curvature and retrogastric attachments are divided with a sealer/divider or ultrasonic shears (LigaSure Atlas™, Covidien or SonoSurg™, Olympus). The dissection extended proximally to the esophagogastric junction and distally toward a point located 5-6 cm from the pylorus. The majority of the antrum was preserved as the resection was initiated 5-6 cm proximal to the pylorus and extended up to the angle of His. Calibration of the gastric

sleeve was done with a 36-French gastric bougie inserted into the stomach along the lesser curvature. Continuously applied linear staplers (60 mm and 45 mm long, Endo GIA™ Ultra Universal Stapler with Articulating Medium/Thick Reload, Covidien) were used to transect the stomach. The stapler line was reinforced with a running absorbable braided 2-0 suture using a suturing device (Endo Stitch™ 10 mm, Covidien). The resected stomach was removed through the left flank trocar site. One drain was left in the peritoneal cavity. The use of a 36-Fr bougie corresponds to 50-100 ml volume of a stomach.

Amoxicillin with clavulanic acid (1.0 g) and metronidazole (0.5 g) at a single preoperative dose were used as an antibiotic prophylaxis. Compression stockings and low molecular weight heparin (40-60 mg *s.c. b.i.d.*) administered until fully ambulatory were given as an antithrombotic prophylaxis. The upper gastrointestinal (UGI) series were performed during the first or second postoperative day, before commencing oral intake. The patients received a clear liquid diet after correct UGI for 3-6 days. They continued with a pureed diet for the next 2-3 weeks. Roux-en Y gastric bypass patients were usually discharged on day 5-7, and LSG patients on day 4-6 after the procedure. The length of hospitalization after the operation, the minor, major, early (≤ 30 days) and late (> 30 days) complications and mortality were recorded during hospital stay and outpatient visits. A major complication was defined as a complication resulting in death or reoperation, a hospital stay of more than 7 days after the procedure, or a need for blood transfusions of four or more units. All other postoperative complications were considered minor complications.

Vitamin and mineral supplementation was prescribed to both RYGB and LSG patients in a uniform manner to avoid confounding factors related to differences in nutrient supplementation. Postoperatively, one tablet of multivitamin and mineral supplements and sublingual iron at a dose of 0.1 g daily were prescribed. Vitamin B₁₂ supplementation was given sublingually every month at a dose of 1000 μ g.

All patients attended the outpatient clinic immediately after discharge to control for early complications and then at 1, 3, 6, 9 and 12 months after the operation. Beginning at the 1 month follow-up visit complete subject evaluation was performed, including anthropometric and clinical parameters, nutritional deficiencies and blood sampling for labo-

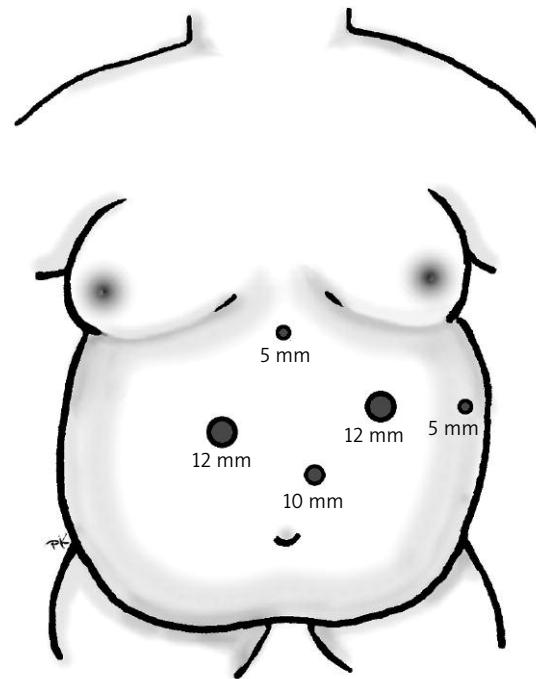


Figure 1. Trocar placement for the laparoscopic sleeve gastrectomy

ratory tests. Weight loss was assessed using BMI and percent of excess weight loss (%EWL). Excess weight was calculated as the amount of initial body weight in excess of the upper limit of the normal weight range estimated at the BMI of 25 kg/m² for a given patient height.

Hypertension (HTN) was diagnosed when SBP ≥ 140 mm Hg and/or DBP ≥ 90 mm Hg or on anti-hypertensive therapy; diabetes mellitus (T2DM) when fasting plasma glucose ≥ 126 mg/dl or 2-h plasma glucose ≥ 200 mg/dl or on antidiabetic drug \pm insulin therapy; impaired glucose tolerance (IGT) when 2-h plasma glucose ≥ 140 mg/dl and ≤ 200 mg/dl; dyslipidemia (DL): fasting lipid profile, HDL < 40 mg/dl for men, HDL < 50 mg/dl for women and/or triglycerides (TG) > 150 mg/dl and/or LDL > 100 mg/dl or use of lipid-lowering agents. Remission or improvement of comorbidities was assessed according to the clinical, biochemical, hormonal and radiological documentation. The improvement of comorbidity was defined as a reduction of medication taken and improvement of the symptoms or blood investigation specific to the comorbidity. Remission of hypertension was defined as normal systolic and diastolic arterial pressure without active antihypertensive treatment. Remission of type 2 diabetes was defined

as normal fasting glucose levels (< 100 mg/dl) and HbA_{1c} < 6.0% in the absence of active antidiabetic treatment. Remission of dyslipidemia was defined as normal levels of total cholesterol (TC), TG, HDL-C and LDL-C in the absence of active lipid-lowering treatment. The other comorbidities were not specifically addressed in the present report.

Statistical analysis

Simple randomization was used to assign patients to the treatment groups. Categorical variables were presented using absolute values and percentages. Comparisons of categorical variables between groups were done using the χ^2 test and for small frequencies Fisher's exact test. Continuous variables were reported as mean \pm standard deviation (SD) or median (range) where applicable. Differences between groups in normally distributed continuous variables were tested using the independent samples *t* test, and for non-normally distributed variables the Mann-Whitney *U* test was used. Continuous variables were compared within groups with analysis of variance (ANOVA) with *post-hoc* Tukey HSD test for specific comparisons. In all the tests used *p* values of less than 0.05 were considered significant. Statistical analyses were performed using Statistica 8.0 (StatSoft Inc., 2008).

Results

Eighty-six patients were admitted to hospital for surgery during the study period and evaluated for eligibility for the study. Fourteen patients were not

enrolled in the study, including 6 patients not eligible for the study (5 patients were older than 60 years, one was suspected of malignancy) and 8 patients who refused to participate in the study. A total of 72 patients were randomized; 36 patients were assigned to the RYGB group, 36 to the LSG group, and all of them underwent the intended procedure. The follow-up rate for the 6-month visit was 100% and 94% for RYGB and LSG respectively and for the 12-month visit it was 97% and 94% for RYGB and LSG groups respectively. At the end of the study period 1 patient from the RYGB group and 2 patients from the LSG group were lost to follow-up.

Mean age at the time of surgery was 43.9 \pm 10.8 years (RYGB) and 44.9 \pm 10.6 years (LSG), male to female ratio 23/36 (RYGB) and 26/36 (LSG), mean weight 137.7 \pm 17.7 kg (RYGB) and 130.7 \pm 15.5 kg (LSG), BMI 48.6 \pm 5.4 kg/m² (RYGB) and 46.1 \pm 5.9 kg/m² (LSG) (Table I). Preoperatively, the prevalence of obesity-related comorbidities was: 14 (38.9%) (RYGB) and 10 (27.8%) (LSG) for type 2 diabetes, 30 (83.3%) (RYGB) and 25 (69.4%) (LSG) for arterial hypertension, 31 (86.1%) (RYGB) and 31 (86.1%) (LSG) for dyslipidemia (Table I). There were no statistical differences between the study groups regarding patient demographics and comorbidities. There was no mortality in either surgical group at the 1-year follow-up. Most of the comorbidities in both groups improved or resolved 1 year after surgery.

There was no statistical difference in remission or improvement of comorbidities 1 year after surgery between RYGB and LSG except for a greater decrease in dyslipidemia after RYGB (Table II).

Table I. Baseline patients' characteristics

Characteristic	Gastric bypass	Sleeve gastrectomy	Value of <i>p</i>
Body weight [kg]	137.7 \pm 17.7	130.7 \pm 15.5	NS
BMI [kg/m ²]	48.6 \pm 5.4	46.1 \pm 5.9	NS
Excess weight [kg]	66.4 \pm 15.0	60.6 \pm 14.4	NS
Age [years]	43.9 \pm 10.8	44.9 \pm 10.6	NS
Female sex, <i>n</i> (%)	23 (63.9%)	26 (72.2%)	NS
Hypertension, <i>n</i> (%)	30 (83.3%)	25 (69.4%)	NS
Type 2 diabetes, <i>n</i> (%)	14 (38.9%)	10 (27.8%)	NS
Dyslipidemia, <i>n</i> (%)	31 (86.1%)	31 (86.1%)	NS

BMI – body mass index, NS – not significant

The median length of hospitalization after the operation was 6.0 (4-9) days in the RYGB group and 6.0 (range 4-77) days in the LSG group ($p > 0.05$). Early (< 30 days) morbidity was 16.6% ($n = 6$) in the RYGB group and 19.4% ($n = 7$) in the LSG group ($p > 0.05$). All the early minor and major complication are presented in Table III. The minor complication rate for the LSG group (10.1%; $n = 4$) was lower than the rate for the RYGB group (16.6%; $n = 6$) but the difference did not reach significance. On the other hand, the major complication rate was higher in the LSG group (8.3%; $n = 3$) vs. the RYGB group (0%) but still not statistically significant ($p > 0.05$). No patients in the RYGB group and 2 patients in the LSG group required a reoperation. One patient had a leak from the upper part of the gastric suture line that required drainage and one patient had bleeding from the gastric suture line that required hemostasis and drainage of the abdominal cavity. There was no statistical difference in the reoperation rate between the study groups ($p > 0.05$). There were no 30-day readmissions because all the major complications were diagnosed during the initial hospitalization. Minor complications were treated on an ambulatory basis.

Weight and BMI reduction were significant 6 months and 1 year after either operation (Table II). At 1 year BMI was reduced to 33.8 ± 5.4 kg/m² and 32.8 ± 5.6 kg/m² after RYGB and LSG respectively

($p > 0.05$). Similarly, no statistical significance was recorded in %EWL at 6 months and 1 year between RYGB and LSG groups (54.4% vs. 58.1% and 64.2% vs. 67.6% respectively, $p > 0.05$). The proportion of patients who achieved an EWL greater than 50% at 1 year postoperatively was 78% after RYGB and 75% after LSG (Table II).

Discussion

Bariatric surgery has been shown to be more effective than the medical treatment of morbid obesity [8]. During the last years LSG has been established as a new approach to the surgical management of morbid obesity. The increasing volume of literature on this procedure gives a very clear indication of its popularity. There have been encouraging reports suggesting that LSG, initially described as a part of BPD-DS, is also effective as a stand-alone procedure [9]. Laparoscopic sleeve gastrectomy is considered easier, faster and less traumatic compared to RYGB. Its advantages include preservation of endoscopic access to the upper gastrointestinal tract, normal intestinal absorption, the lack of an intestinal anastomosis and prevention of the dumping syndrome by pylorus preservation.

In this initial report from a randomized study, we present the results from comparison of LSG and open RYGB, the gold standard in bariatric surgery. We show that LSG seems to be a safe and effective procedure

Table II. Results of RYGB vs. LSG during follow-up

Variables	RYGB 6 m	LSG 6 m	Value of <i>p</i>	RYGB 12 m	LSG 12 m	Value of <i>p</i>
BMI [kg/m ²]	36.0 ±4.8	34.7 ±5.2	NS	33.8 ±5.4	32.8 ±5.6	NS
Weight [kg]	103.0 ±2.6	97.1 ±2.6	NS	96.8 ±2.9	91.7 ±2.9	NS
%EWL [%]	54.4%	58.1%	NS	64.2%	67.6%	NS
%EWL > 50%, <i>n</i> (%)	20 (55.6%)	24 (66.7%)	NS	28 (77.8%)	27 (75%)	NS
Hypertension, <i>n</i> (%)	24 (66.7%)	17 (47.2%)	NS	19 (52.7%)	17 (47.2%)	NS
Δ Hypertension, <i>n</i> (%)*	6/30 (20%)	8/25 (32%)	NS	11/30 (36.7%)	8/25 (32%)	NS
Type 2 diabetes, <i>n</i> (%)	6 (16.7%)	6 (16.7%)	NS	5 (13.9%)	6 (16.7%)	NS
Δ Type 2 diabetes, <i>n</i> (%)	8/14 (57.1%)	4/10 (40%)	NS	9/14 (64.3%)	4/10 (40%)	NS
Dyslipidemia, <i>n</i> (%)	27 (75%)	27 (75%)	NS	18 (50%)	26 (72.2%)	NS
Δ Dyslipidemia, <i>n</i> (%)	4/31 (12.9%)	4/31 (12.9%)	NS	13/31 (41.9%)	5/31 (16.1%)	< 0.05

BMI – body mass index, %EWL – % excess weight loss, NS – not significant ($p > 0.05$), *Δ denotes a reduction in number (%) of patients with the diagnosis of comorbidity in relation to the baseline prevalence

Table III. Complications during follow-up period

Characteristic	Gastric bypass	Sleeve gastrectomy	Value of <i>p</i>
Early < 30 days			
Death	0	0	
Leak	0 (0%)	1 (2.7%)	NS
Bleeding	0 (0%)	2 (5.5%)	NS
Venous thrombosis	0 (0%)	1 (2.7%)	NS
Wound healing problems:			
Infection	2 (5.5%)	1 (2.7%)	NS
Fluid collection	4 (10.1%)	2 (5.5%)	NS
Late > 30 days			
Death	0	0	
Incisional hernia	1 (2.7%)	0 (0%)	NS
Cholelithiasis	1 (2.7%)	5 (13.8%)	NS
Nutritional deficiencies			
Serum iron	9 (25%)	12 (33.3%)	NS
Vitamin B ₁₂	11 (30.6%)	5 (13.8%)	NS

NS – not significant (*p* > 0.05)

in the treatment of morbid obesity and obesity-related comorbidities. We demonstrated comparable efficacy of LSG and RYGB in this field. Our 1-year results are similar to other series [10, 11]. Weight loss in terms of %EWL and BMI is similar following LSG and RYGB at 1 year of follow-up [12]. There are some technical aspects in the configuration of the gastric sleeve which determine the sleeve remnant volume and probably affect the outcomes. The main ones are the diameter of the gastric sleeve and the distance from the pylorus where the gastric resection starts. The diameter of the sleeve created depends on the size of the bougie used. We routinely used a 36-Fr bougie and started gastrectomy around 5-6 cm from the pylorus. Our good results regarding %EWL and BMI after LSG can be attributed to the small volume of the gastric sleeve, reduced capacity of the antrum, which may promote rapid gastric emptying and the early arrival of a meal to the small intestine, and the complete removal of the gastric fundus, which has been linked by many authors to the resection of the site of production of the orexigenic hormone ghrelin [13].

In our randomized trial both procedures, LSG and RYGB, were performed with acceptable safety and no mortality. The first report from the American College of Surgeons Bariatric Surgery Center Network shows that the mortality rate of LSG is 0.11% at 30 days and 0.21% at 1 year. These data position LSG between laparoscopic adjustable gastric banding (LAGB) (0.05% and 0.08%) and laparoscopic RYGB (0.14% and 0.34%); however, the results are not statistically significant [14]. The most common major complications of LSG according to several studies include staple line leakage, stricture of the created tube, dilatation of the created tube, hemorrhage from the short gastric vessels or staple line, and iatrogenic splenic injury [15, 16]. During the Second International Consensus Summit for Sleeve Gastrectomy held in Miami in 2009, mortality of the procedure was reported as 0.2 ± 0.9%, and prevalence of the major complications was for high leak 1.5%, hemorrhage 1.1%, splenic injury 0.1%, and late stenosis 0.9% of 14 776 patients recruited by completing questionnaires regarding cases of LSG [17].

Major complications in our series were rarely observed after LSG and RYGB, as mentioned above. One leak occurred in the upper part of the sleeve and was managed with relaparoscopy, drainage and total parenteral nutrition. Although the differences in complication rate were not statistically significant, they seemed clinically significant because of the serious consequences. Minor complication rates, especially related to wound healing, favor LSG over RYGB but these results depend on the type of abdominal access, not the procedure itself. It was shown in previous studies [18] that the laparoscopic approach in bariatric surgery improves recovery and wound healing in morbidly obese patients and further reduction of port number (such as the single incision approach) may be even more beneficial. The open approach still comprises a significant percentage of gastric bypasses performed worldwide, as was shown in the meta-analysis of Buchwald *et al.* [6], mainly because it may be a priori safer in some difficult patients [19] or is a result of conversion.

The impact of RYGB on metabolic profile has been proved to be satisfactory for the resolution of many comorbidities [20] but studies reporting efficacy of LSG in this field are quite limited [21]. Recent publications have revealed that LSG is similarly effective as RYGB in the treatment of comorbidities [22]. In our study with more than 1-year follow-up after LSG and RYGB, we found comparable rates of arterial hypertension remission, slightly better rates of type 2 diabetes remission after RYGB but without statistical significance, and a better remission rate for dyslipidemia after RYGB ($p < 0.05$). Other authors have reported similar results [23]. The early restoration of euglycemia and high rate of diabetes resolution 1 year after LSG and RYGB is probably due to changes in GI hormones [24-26]. It has been suggested that RYGB leads to more nutritional deficiencies in comparison to LSG [27]. In the present study, at 1-year follow-up we did not observe any significant differences in this field among the two groups (Table III).

In conclusion, according to this randomized clinical study LSG and RYGB are equally effective and safe bariatric procedures at 1-year follow-up with regard to weight reduction and amelioration of comorbidities.

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