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Laparoscopic Sleeve Gastrectomy for Morbid Obesity in a Belgian-French Prospective Multicenter study: Outcomes and Predictors Weight Loss Failure.

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Introduction: Laparoscopic sleeve gastrectomy (LSG) became the most frequently performed bariatric procedure worldwide, gaining rapidly popularity thanks to its technical simplicity and the relatively good results. The aim of this Belgian-French study was to evaluate postoperative complications, weight loss, and resolution of obesity-related comorbidities after LSG, and identify predictive factors of weight loss failure.

Patients and methods: A prospective multicenter study was conducted on all LSG performed during 2014 in 7 centers. Their demographic, preoperative, and postoperative data were prospectively collected and analyzed statistically.

Results: Overall 529 patients underwent LSG, with a mean preoperative weight and body mass index (BMI) of 118.9±19.9kg and 42.9±5.5kg/m², respectively. Postoperative mortality was null and early postoperative morbidity was 6%, including 2.5% of gastric leakage. BMI significantly decreased to 31.1kg/m² and 30.0kg/m² at 1 and 3 years, respectively ($p<0.001$). The mean %EWL was 77.2% and 74.6% at 1 and 3 years. A significant reduction in dyslipidemia (28.0% to 16.8%), obstructive sleep apnea (OSAS) (34.6% to 23.3%) and arterial hypertension (HTN) (30.4% to 20.2%) was observed after 3 years, but it does not concern diabetes and gastroesophageal reflux disease (GERD). At multivariate analysis, age>50 years old, BMI>50kg/m² and previous laparoscopic adjustable gastric banding (LAGB) remained independent predictors of weight loss failure.

Conclusions: LSG for morbid obesity is safe and effective. Satisfactory outcome after 3 years can be achieved regarding %EWL and some comorbidities such as dyslipidemia, OSAS, and HTN, but not diabetes and GERD. Age>50 years old, BMI>50kg/m² and previous LAGB were independent predictors of weight loss failure.

Keywords: Sleeve gastrectomy; Obesity-related comorbidities; Postoperative outcome; Excess weight loss; Weight loss failure

Introduction

Obesity has become a major public health concern worldwide, including in Europe. Currently, morbid obesity and its related comorbidities including diabetes, arterial hypertension (HTN) and even several cancers have posed a medical and financial burden to all countries [1]. According to the World Health Organization report, 50% of both men and women in Europe are overweight, and roughly 23% of women and 20% of men are obese [2]. Consequently, in order to face this alarming 21st century disease, the demand for the surgical treatment of severe obesity constantly increases, especially for laparoscopic sleeve gastrectomy (LSG) [3].

After being introduced in the nineties as a new type of gastrectomy for bilio-pancreatic diversion [4] and as the initial step of a 2-stage laparoscopic Roux-en-Y gastric bypass for high-risk patients [5], LSG is now proposed as the only and definitive treatment for morbid obesity by several authors [6-7]. According to the latest International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) survey, LSG represents 37% of all bariatric procedures performed in Western countries, and is currently the most frequently performed bariatric procedure in the world [3]. The great success of LSG can be attributed to its potential "surgical" benefits, including the apparent technical simplicity and the short operative time, associated with promising results in terms of weight loss and resolution of comorbidities [3]. In addition to the restrictive effect, LSG has an important metabolic effect possibly due to accelerated gastric emptying of solid food and reduction of ghrelin levels after resection of the gastric fundus responsible for human ghrelin production [8-10].

The present Belgian-French prospective multicenter study aimed to analyze the early postoperative complications after LSG, as well as weight loss and resolution of obesity-related comorbidities including type 2 diabetes mellitus (T2DM), HTN, gastroesophageal reflux disease (GERD), obstructive sleep apnea (OSAS) and dyslipidemia, and to identify

predictive factors of weight loss failure after 3 years.

Material and methods

We conducted a prospective multicenter study on all consecutive patients who underwent LSG between January 1st, 2014 and December 31th, 2014 in seven Belgian or French bariatric surgery centers. Inclusion criteria were a body mass index (BMI) >40 kg/m², or a BMI >35 kg/m² associated with significant obesity-related comorbidities, such as T2DM, HTN, GERD and OSAS. All patients consented for participation and the study was approved by the Institutional Review Board. A standardized detailed preoperative work-up was performed for each patient including cardiovascular, pulmonary, gastrointestinal, endocrine, psychological, and nutritional assessment. Volume eaters were defined as patients who reported consuming large quantities of food and sweet eaters used to eat sweet foods containing refined sugars on a daily basis. Helicobacter Pylori was eradicated before surgery when present.

The following technical variations among surgeons were recorded: type of surgical approach, distance from the pylorus to the first line of gastric transection, gastric calibration tube diameter, use of surgical drains and operating time. Compression stockings and subcutaneous low molecular weight heparin from the first 24 hours to 2 weeks were administrated for antithrombotic prophylaxis postoperatively. Proton pump inhibitors were administrated for at least 6 weeks after surgery, daily multivitamin supplements were prescribed and physical exercise was recommended.

Patients were followed during 3 years, by physical examination and routine laboratory tests every 3 months in the first year, every 6 months in the second year and once a year thereafter.

Additional examinations, such as esophagogastroduodenoscopy and/or upper gastrointestinal contrast study, were performed when indicated.

The primary endpoint was the % of excess weight loss (%EWL) defined as 100*[weight loss/baseline excess weight], with the calculation of ideal body weight as that equivalent to a BMI of 25 kg/m2 [11]. The secondary endpoints include early postoperative complications within the first 30 days, postoperative mortality and resolution of obesity-related comorbidities. Resolution of comorbidities was determined by cessation of medications and resolution of signs and symptoms. This included resolution of symptoms for GERD, normal blood pressure for HTN, normal fasting blood sugar for T2DN, and normal lipid panel for dyslipidemia, and resolution of OSAS was affirmed by discontinuation of C-PAP or, for patients not using C-PAP, by the bed partner's observation that apnea did not occur during sleep anymore, and/or by good quality restorative sleep combined with absence of daytime somnolence. Weight loss failure was defined as %EWL <50%.

Statistical analysis

Values were expressed as means (with standard deviation, SD) or as the number of patients with percentages. Analysis of data was performed using SPSS 11.0 statistical analysis software. We used the Chi square test or Fisher test to compare qualitative variables, and ANOVA or the Mann–Whitney test to compare quantitative variables. Multivariate analysis was performed by using binomial logistic regression, and included all factors associated with a $p \leq 0.2$ in univariate analysis. A p value ≤ 0.05 was considered to be statistically significant.

Results

Over the study period, 529 patients underwent LSG in seven bariatric centers: four Belgian hospitals and three French hospitals. Follow-up rates were 74%, 62% and 57% at 1-year, 2-year and 4-year, respectively.

Patients' characteristics

The mean age was 41.4 ± 11.8 years, and 75.4% of patients were female (Table 1). The mean preoperative weight and BMI were 118.9 ± 19.9 kg and 42.9 ± 5.5 kg/m², respectively. Preoperative assessment highlighted dyslipidemia in 148 patients (28%), GERD in 132 patients (25%), OSAS in 183 patients (34.6%), T2DM in 83 patients (15.7%), and HTN in 161 patients (30.4%). Smoking addiction was present in 91 patients (17.2%). A previous bariatric procedure was performed before LSG in 73 patients (13.8%), including 3 LSG, 59 laparoscopic adjustable gastric banding (LAGB) and 11 intra-gastric balloon. The eating behavior of patients was characterized as volume eaters in 52%, sweet eaters in 9.3% and other eating profiles in 38.8%.

Surgical procedure

All procedures were performed by laparoscopy, with two procedures converted to open approach because of dense intraabdominal adhesions (0.4%). The mean operating time was 63.6 ± 24.4 minutes (Table 2). The first gastric transection line was performed at a distance from the pylorus < 6cm in 294 patients (55.6%), and ⩾ 6cm in 235 patients (44.4%). Gastric calibration tube was used in all patients, with a tube diameter ⩾ 35F in 84.9% and < 35F in 15.1%. A surgical abdominal drainage tube was left in all patients except in 7.

Postoperative outcome

There was no postoperative death. Early postoperative morbidity rate was 6% (Table 3). Leakage on the gastric staple line was the most common complication (2.5%), all located in the upper part, and was treated by endoscopic stenting (n = 6), re-operation for intra-abdominal irrigation and drainage (n = 2), endoscopic stenting + reoperation (n = 2) or clinical observation with fasting, parenteral nutrition and antibiotics (n = 3). Intra-abdominal bleeding was observed in 9 patients (1.7%), including 3 requiring laparoscopic surgical hemostasis; the other 6 patients were observed, including 2 requiring blood transfusions. Five patients (0.9%) were readmitted at hospital within the first month after surgery for nausea, vomiting and inability to tolerate fluid intake. They had a narrowing of the gastric sleeve at fluoroscopic imaging, and were treated either by endoscopic dilatation (n = 2) or conservatory treatment with fasting, administration of non-steroidal anti-inflammatory drugs, rehydration with intravenous fluids, parenteral nutrition and closed observation (n = 3). Respiratory complications were observed in 3 patients (pulmonary atelectasis, respiratory distress, or pleural effusion) and portal vein thrombosis in 2 treated with anticoagulation therapy. The mean length of hospital stay was 4.2 ± 3.9 days.

Follow-up

During the 3 years of follow-up, the mean BMI constantly decreased from 42.9 kg/m² preoperatively to 31.1 kg/m² and 30 kg/m² at 1 year and 3 years, respectively ($p<0.001$). The %EWL was 77.2% at 1 year, and 74.6% at 3 years (Table 4).

Regarding obesity-related comorbidities, we observed a significant reduction in dyslipidemia (28% to 16.8%, $p<0.001$), OSAS (34.6% to 23.3%, $p<0.001$), and HTN (30.4% to 20.2%, $p<0.001$) rates at 3 years. GERD tends to appear after LSG (25% to 30.1%) but not significantly ($p= 0.111$). Interestingly, resolution of T2DM occurred in only 4.4% and was not statistically significant (Table 5).

Predictive factors of weight loss failure

In the univariate analysis of predictive factors for weight loss failure, the following variables were associated with a significantly greater percentage of weight loss failure in the third year: age >50 years old, BMI >50 kg/m², HTN, OSAS, and previous laparoscopic adjustable gastric banding (LAGB). Female gender, smoking, dyslipidemia, GERD, T2DM, eating profile of volume eaters, use of calibration tube diameter ⩾ 35F and a stapling distance from pylorus ⩾ 6cm were not associated with weight loss failure.

In multivariate analysis, only age > 50 years old (OR 2.76; 95% CI: 1.42–5.73, p = 0.003), BMI >50 kg/m² (OR 4.57; 95% CI: 2.55–8.20, p < 0.001), and previous LAGB (OR 4.85; 95% CI: 2.24–10.49, p < 0.001) remained independent predictors of weight loss failure (Table 6).

Discussion

In the present prospective multicenter study of a large series of LSG, we observed a relatively low early postoperative morbidity of 6% comparable to reported rates ranging from 5.8% to 6.3% in other studies [12-13]. The most feared complication for the bariatric surgeon is the gastric staple line leakage, reported around 2.2%–2.4% in two large systematic reviews [14-15]. In the present study, the rate of leakage on the gastric staple line was 2.5%, most leakage were treated conservatively without invasive procedure, but sometimes required endoprosthesis placement or surgical re-exploration for peritoneal lavage and drainage. The high-risk site for gastric fistulas is located at the His angle, especially when a previous LAGB was performed, because of the fragility and thickness of the gastric wall due to fibrosis contact with a silicone band. In the latter situation, placement of abdominal drainage at the end of the procedure could be indicated. The use of abdominal drain after LSG remains

controversial in the bariatric surgeons' community. Leaving a drain may have some theoretical advantages for the early detection of hemorrhage and digestive leaks. However, there has never been any evidence of a significant benefit of a routine drainage. Albanopoulos et al. [16] observed that placement of drains does not facilitate detection of leak, abscess or bleeding, and do not seem to decrease the reoperation rate for these complications.

LSG showed satisfactory long-term outcomes, especially a significant and stable weight loss. The mean %EWL was 77.2% and 74.6% at the first and the fourth postoperative years. Our results are comparable to other published studies. Diamantis et al. [16] reported a mean %EWL of 56.3% (range: 49.5-71.3%) five years after the operation. In addition to weight loss, our data showed that LSG is effective for resolution of comorbidities related to obesity, such as of dyslipidemia, OSAS and HTN. Most authors reported similar results in resolution and improvement of these comorbidities [17-19]. Reduction of blood pressure after bariatric surgery could be attributable to beneficial hemodynamic changes associated with weight loss (decrease blood volume, stroke volume, and cardiac output) [20], improvement in autonomic nervous activity [21] and ectopic fat mobilization [22]. Resolution of OSAS is explained by improvements in the respiratory system thanks to reduction of subcutaneous contributing to decrease the physical pressure on the upper airway [20]. A reduction in central adiposity allows the reduction in the production of adipokines, which activates the central nervous system to improve the neuromuscular control of pharyngeal caliber [23].

The impact of LSG on diabetes is variable in the literature. Gill et al. [24] found in their systematic review of studies of diabetic patients who underwent LSG that the mean improvement rate ranged from 14% to 100%. The differences in preoperative diabetic status and varied definitions for diabetes remission may limit the validity of comparisons with these studies. Compared to Roux-en-Y gastric bypass, a recent meta-analysis of randomized

controlled trials found that both procedures are effective for diabetes remission [25]. In the present study, there is no significant decrease in prevalence of this comorbidity during the first 3 years after LSG.

The rate of GERD tended to increase after LSG, and these results are consistent with recent studies. Fløl o et al. [26] reported an increase in prevalence of GERD from 12% to 35% at 5 years after LSG. The anatomy modifications after LSG can predispose to GERD with the disruption of the anatomical anti-reflux mechanisms, including the His angle and resection of the sling fibers of the lower sphincter [27]. Yehoshua et al. [28] demonstrated decreased gastric compliance and increased gastric pressures after LSG responsible for the increase in GERD. These observations can justify a more accurate screening by pH and/or endoscopy studies in the postoperative course, as well as preoperatively.

Although the LSG is a well-established procedure within the specialty of bariatric surgery, we note that some patients did not lose weight after surgery. Identifying predictive factors for weight loss failure can help us to practice a more focused approach of these patients. Age > 50 years old and BMI >50 kg/m are an independent predictor of weight loss failure at 3 years; these results are consistent with those of previous studies [29-30]. The history of LAGB is also an independent predictor of weight loss failure in our study. Strong adhesions between the inferior face of the liver and the anterior gastric wall in the fundal region, and the increased thickness of the gastric around the fibrous capsule founded during re-do surgery in patients with prior LAGB, makes difficult a complete resection of the gastric fundus, which is known to be the main localization of ghrelin-producing cells. This could impede the decrease of plasma ghrelin levels postoperatively. A recent multicenter study found that weight loss achieved after conversion of a failed LAGB to LSG was significant, but less than after conversion to Roux-en-Y gastric bypass [31].

Regarding comorbidities, only HTN and OSAS were associated with a significantly greater percentage of weight loss failure at 3 years in univariate analysis, but in the multivariate analysis, these two factors were not independently predictors of weight loss failure. Pekkarinen et al. found that the preexistence of co-morbidities does not predict postoperative weight loss success at 2-year and long-term control after bariatric surgery [32].

We did not find any relationship between some technical surgical points and the weight loss results. Application of a thinner bougie (<35F) during the calibration of the stomach tube and closed distance of the staple line to the pylorus (<6cm) were not significantly correlated with weight loss success. In the literature there is still no consensus on the size of bougie. Yuval et al. reviewed 32 publications consisting of 4999 patients, they found that in groups where a larger bougie (≥40F) was used, the rate of leak was lower, but there was no difference in weight loss [33]. The high leak rates observed when using narrow bougie could be attributed to increased intragastric pressure, wall tension and ischemia in the staple line [14,33]. Another controversial point is the stapling distance from the pylorus, in the most recent randomized study [34], authors found an accelerated gastric emptying and higher antral volume in the antral preservation group (antrum resection 5 cm from the pylorus) compared to antrum resection group (antrum resection 2 cm from the pylorus), the two groups were similar in terms of %EWL at 1 year. In another recent prospective randomized study, no difference was found in terms of %EWL at 1 year, quality of life and improvements in comorbidities between 2 cm vs 6 cm distances from the pylorus, however, weight loss was greater in the 2 cm group at 6 months [35].

This study has several limitations. As a multicenter study, it is associated with the inherent heterogeneity due to the participation of multiple surgeons and several hospitals. Secondly, the patient follow-up rate is low after 3 years. One possible reason is that some centers accept

patients seeking bariatric surgery from all over Belgium and France, this far-off physical proximity probably discourage some patients from going to the centers for follow-up. More homogeneous and long-term follow-up studies are needed to assess the precise role of LSG in bariatric surgery.

Conclusion

LSG for morbidly obese patients is a safe and effective procedure with low morbidity and no mortality in the present study. Satisfactory outcome can be achieved regarding the weight loss and some obesity-related comorbidities, including dyslipidemia, OSAS and HTN, but not T2DM and GERD. The absence of HTN, no previous history of LAGB, and volume eating behavior were the independent predictors of a good weight loss success at three years after surgery.

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Table 1. Baseline patient's characteristics.

	LSG in 2014 n = 529
Age, y (mean ± SD)	41.4 ± 11.8
Female gender, n (%)	399 (75.4)
Preoperative weight, kg (mean ± SD)	118.9 ± 19.9
Preoperative BMI, kg/m² (mean ± SD)	42.9 ± 5.5
Smoking, n (%)	91 (17.2)
Obesity-related comorbidities, n (%)	
- **Dyslipidemia**	148 (28.0)
- **GERD**	132 (25.0)
- **OSAS**	183 (34.6)
- **T2DM**	83 (15.7)
- **HTN**	161 (30.4)
Bariatric procedure history, n (%)	
- LSG	3 (0.6)
- LAGB	59 (11.2)
- **Intra-gastric balloon**	11 (2.1)
Eating profile, n (%)	
- Volume eaters	275 (52.0)
- Sweet eaters	49 (9.3)

- **other eating profiles**	205 (38.8)

LSG, laparoscopic sleeve gastrectomy; BMI, body mass index; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnea; T2DM, type 2 diabetes mellitus; HTN, hypertension; LAGB, laparoscopic adjustable gastric banding.

Table 2. Intraoperative data.

Surgical characteristics	***LSG in 2014 n = 529***
Surgical approach, n (%)	
- Laparoscopy	527 (99.6)
- Laparoscopy converted to laparotomy	2 (0.4)
- Laparotomy	0 (0)
Stapling distance from pylorus, n (%)	
- < 6cm	294 (55.6)
- ⩾ 6cm	235 (44.4)
Gastric calibration tube diameter, n (%)	
- < 35F	80 (15.1)
- ⩾ 35F	449 (84.9)
Use of surgical drains, n (%)	
- Yes	522 (98.7)
- No	7 (1.3)
Operating time, min (mean ± SD)	63.6 ± 24.4

Table 3. Postoperative course.

	LSG in 2014 **n = 529**
Leakage, n (%)	
- Treated by endoscopic stenting	6 (1.1)
- Treated by surgery	2 (0.4)
- Treated by endoscopic stenting + surgery	2 (0.4)
- Treated **conservatively**	3 (0.6)
Bleeding, n (%)	
- Treated by endoscopy	3 (0.6)
- Treated **conservatively**	6 (1.1)
Gastric stenosis, n (%)	
- Treated by endoscopy	2 (0.4)
- Treated **conservatively**	3 (0.6)
Respiratory complications, n (%)	3 (0.6)
Thromboembolic complications, n (%)	2 (0.4)
Early postoperative mortality, n (%)	0 (0)
Length of stay, d (mean ± SD)	4.2 ± 3.9

Table 4. Mean body weight, BMI and **%**EWL prior to and at 1, 2, 3 years after LSG.

	Preoperative **n = 529**	**1 year** **n = 391**	**2 years** **n = 328**	**3 years** **n = 301**	**P value**		
					1 year vs. 0 months	**2 years vs. 0 months**	**3 years vs. 0 months**

Weight (Kg)	118.9 ± 19.9	82.8 ± 17.8	82.4 ± 18.3	83.9 ± 18.0	<0.001	<0.001	<0.001
BMI (Kg/m2)	42.9 ± 5.5	31.1 ± 8.6	29.6 ± 5.6	30.0 ± 5.5	<0.001	<0.001	<0.001
%EWL (%)	-	77.2 ± 27.2	77.3 ± 27.2	74.6 ± 27.3			

Data are presented as mean ± standard deviation, BMI body mass index, **%**EWL excess weight loss

Table 5 Proportion of patients (%) with obesity-related diseases prior to and at 1, 2, 3 years after LSG.

	Preoperative n = 529	**1 year n = 391**	**2 years n = 328**	**3 years n = 301**	**P value**		
					1 year vs.0 months	**2 years vs. 0 months**	**3 years vs. 0 months**
Dyslipidemia (%)	28.0	14.0	14.3	16.8	<0.001	<0.001	<0.001
OSAS (%)	34.6	22.9	24.5	23.3	<0.001	0.002	<0.001
HTN (%)	30.4	23.2	19.8	20.2	0.016	<0.001	<0.001
GERD (%)	25.0	25.1	27.1	30.1	0.972	0.495	0.111
T2DM (%)	15.7	12.1	13.4	11.3	0.122	0.357	0.080

Data are presented as percentage; OSAS, obstructive sleep apnea; HTN, arterial hypertension; GERD, gastroesophageal reflux disease; T2DM, type 2 diabetes mellitus.

Table 6 Univariate and multivariate analysis of weight loss failure at 3 years (**%**EWL < 50%) after LSG.

	Univariate analysis			Multivariate analysis		
	OR	**CI**	**P**	**OR**	**CI**	**p**
Age > 50 years	3.54	1.93 – 6.47	<0.001	2.76	1.42 – 5.37	0.003
sex F	1.36	0.71 – 2.62	0.360			
BMI >50 kg/m²	4.51	2.59 – 7.83	<0.001			
Smoking	1.23	0.62 – 2.41	0.552			
Dyslipidemia	1.10	0.56 – 2.14	0.789			
GERD	1.56	0.70 – 3.46	0.276			
HTN	1.86	1.08 – 3.20	0.024	1.51	0.81 – 2.82	0.191
OSAS	2.14	1.23 – 3.70	0.007	1.83	0.98 – 3.41	0.058
T2DM	1.26	0.68 – 2.32	0.462			
Past surgical history of LAGB	3.53	1.81 – 6.90	<0.001	4.85	2.24 – 10.49	<0.00
Eating profile of volume eaters	0.24	0.40 – 1.31	0.288			
Calibration tube diameter ≥35F	1.13	0.53 – 2.40	0.741			
Stapling distance from pylorus ≥6cm	1.21	0.57 - 2.60	0.616			

OR , odds ratio; CI, confidence interval, **%**EWL, excess weight loss; BMI, body mass index; OSAS, obstructive sleep apnea; HTN, arterial hypertension; GERD, gastroesophageal reflux disease; T2DM, type 2 diabetes mellitus; LAGB, laparoscopic adjustable gastric banding