Article

Five-year Outcomes of Sleeve Gastrectomy: A Prospective Multicenter study

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Abstract

Background: Sleeve gastrectomy (SG) is the most frequently performed bariatric procedure in the world. Our purpose was to evaluate the percentage of excess weight loss (%EWL), resolution of obesity-related comorbidities after SG, and identify predictive factors of weight loss failure.

Methods: A prospective cohort study of adults who underwent SG during 2014 in 7 Belgian-French centers. Their demographic, preoperative, and postoperative data were prospectively collected and analyzed statistically.

Results: Overall, 529 patients underwent SG, with a mean preoperative weight and body mass index (BMI) of 118.9 ± 19.9 kg and 42.9 ± 5.5 kg/m^2, respectively. Body mass index significantly decreased to 32.2 kg/m^2 at 5 years ($P <$ .001). The mean %EWL was 63.6% at 5 years. A significant reduction in dyslipidemia (28.0%-18.2%), obstructive sleep apnea (OSAS) (34.6%-25.1%), and arterial hypertension (HTN) (30.4%-21.5%) was observed after 5 years, but not for diabetes and gastroesophageal reflux disease (GERD). At multivariate analysis, age >50 years old, BMI >50 kg/m^2, and previous laparoscopic adjustable gastric banding (LAGB) remained independent predictors of weight loss failure.

Conclusions: Five years after SG, weight loss was satisfactory; the reduction of comorbidities was significant for dyslipidemia, OSAS, and HTN, but not diabetes and GERD. Age >50 years old, BMI >50 kg/m^2, 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

After being introduced in the nineties as a new type of gastrectomy for biliopancreatic diversion[1] and as the initial step of a 2-stage laparoscopic Roux-en-Y gastric bypass for high-risk patients,[2] sleeve gastrectomy (SG) is now proposed as the only and definitive treatment for morbid obesity by several authors.[3] According to the latest International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) survey, SG represents 37% of all bariatric procedures performed in Western countries and is currently the most frequently performed bariatric procedure in the world.[4] The great success of SG can be attributed to its potential "surgical" benefits,

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including the apparent technical simplicity and the short operative time, associated with promising results in terms of weight loss and resolution of comorbidities.[4] In addition to the restrictive effect, SG 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.[5-7]

The present Belgian-French prospective multicenter study aimed to analyze the percentage of excess weight loss (%EWL) 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 5 years.

Methods

We conducted a prospective multicenter study on all consecutive patients who underwent SG between January 1st, 2014 and December 31st, 2014 in 7 Belgian or French bariatric surgery centers. Inclusion criteria were a body mass index (BMI) >40 kg/m^2, or a BMI >35 kg/m^2 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 workup was performed for each patient including cardiovascular, pulmonary, gastrointestinal, endocrine, psychological, and nutritional assessment to identify any potential problems and correct as appropriate to ensure safety and success during and after the operation. This assessment including nutritional evaluation and supervised weight management program with low calorie diet is required of all our patients preoperatively, to determine the patients' awareness and understanding of the planned operation, potential operational risks, postoperative adverse effects and benefits, and lifestyle changes required to achieve the most favorable outcomes.

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* were 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, and operating time. Compression stockings and subcutaneous low molecular weight heparin from the first 24 hours-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 up during 5 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 %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/m^2. 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's 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 $P \leq .2$ in univariate analysis. A P value $\leq .05$ was considered to be statistically significant.

Results

Over the study period, 529 patients underwent SG in 7 bariatric centers: 4 Belgian hospitals and 3 French hospitals. Follow-up rates were 74%, 62%, and 54% at 1 year, 2 years, and 5 years, respectively.

Patients' Characteristics

The mean age was 41.4 ± 11.8 years, and 75.4% of patients were women (Table 1). The mean preoperative weight and BMI were 118.9 ± 19.9 kg and 42.9 ± 5.5 kg/m^2, 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 SG in 73 patients

Table 1. Baseline Patient's Characteristics.

	SG 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/m^2 (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 (.6)
LAGB	59 (11.2)
Intragastric balloon	11 (2.1)
Eating profile, n (%)	
Volume eaters	275 (52.0)
Sweet eaters	49 (9.3)
Other eating profiles	205 (38.8)

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

(13.8%), including 3 SG, 59 laparoscopic adjustable gastric banding (LAGB), and 11 intragastric 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 2 procedures converted to open approach because of dense intra-abdominal adhesions (.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 < 6 cm in 294 patients (55.6%) and ≥6 cm 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%.

Follow-Up

During the 5 years of follow-up, the mean BMI constantly decreased from 42.9 kg/m^2 preoperatively to 31.1 ± 8.6 kg/m^2 and 33.2 ± 5.6 kg/m^2 at 1 year and 5 years, respectively ($P < .001$). The %EWL was 77.2% at 1 year and 63.6% at 5 years (Figure 1).

Regarding obesity-related comorbidities, we observed a significant reduction in dyslipidemia (28%-18.2%, $P = .002$), OSAS (34.6%-25.1%, $P = .005$), and HTN (30.4%-21.5%, $P = .006$) rates at 5 years. Gastroesophageal reflux disease tends to appear after SG (25%-31.4%) but not significantly ($P = .051$). Interestingly, resolution of T2DM in both groups: T2DM treated with oral hypoglycemics only and T2DM treated with insulin treatment (insulin with or without additional hypoglycemic medications) were not statistically significant (Table 3).

Table 2. Intraoperative Data.

Surgical characteristic	SG in 2014 n = 529
Surgical approach, n (%)	
Laparoscopy	527 (99.6)
Laparoscopy converted to laparotomy	2 (.4)
Laparotomy	0 (0)
Stapling distance from pylorus, n (%)	
< 6 cm	294 (55.6)
≥6 cm	235 (44.4)
Gastric calibration tube diameter, n (%)	
< 35F	80 (15.1)
≥35F	449 (84.9)
Operating time, min (mean ± SD)	63.6 ± 24.4

Abbreviations: BMI, body mass index, %EWL, percentage of excess weight loss.

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 fifth year: age >50 years old, BMI >50 kg/m^2, 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 ≥6 cm were not associated with weight loss failure.

In multivariate analysis, only age >50 years old (OR 2.72; 95% CI: 1.42-5.73, $P = .003$), BMI >50 kg/m^2 (OR 4.57; 95% CI: 2.55-8.20, $P < .001$), and previous LAGB (OR 4.86; 95% CI: 2.24-10.49, $P < .001$) remained independent predictors of weight loss failure (Table 4).

Discussion

This present prospective multicenter study of a large series of SG showed satisfactory long-term outcomes, especially a significant and stable weight loss. The mean %EWL was 77.2% and 63.6% at the first and the fifth postoperative years. Our results are comparable to other published studies. Diamantis et al[8] reported a mean %EWL of 62.3% 5 years after the operation. In addition to weight loss, our

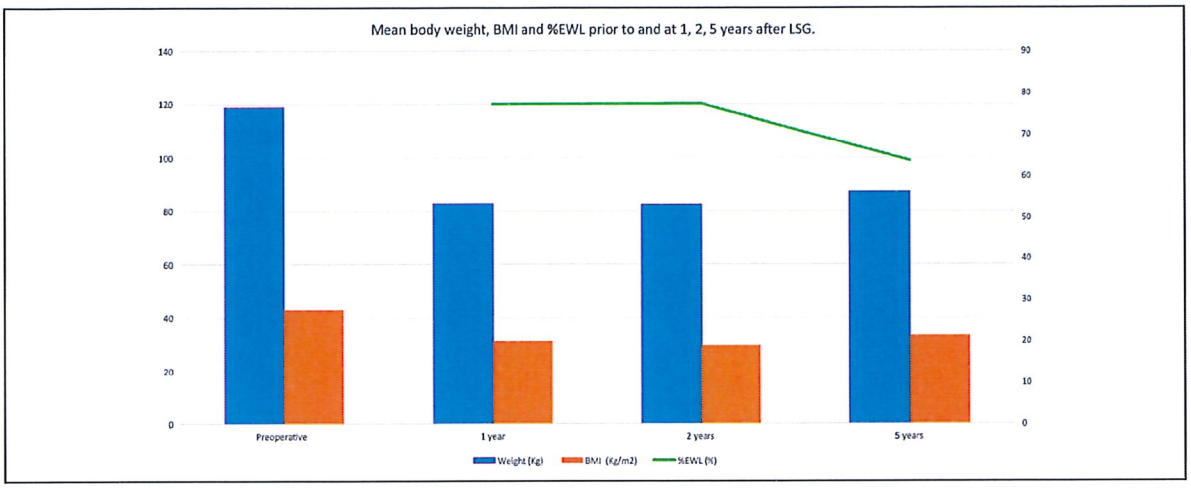

Figure 1. Mean body weight, body mass index and percentage of excess weight loss prior to and at 1, 2, and 5 years after sleeve gastrectomy.

Table 3. Proportion of Patients (%) With Obesity-Related Diseases Prior to and at 5 Years After SG.

	Preoperative n = 529	5 year n = 285	*P* value
Dyslipidemia (%)	28.0	18.2	.002
OSAS (%)	34.6	25.1	.005
HTN (%)	30.4	21.5	.006
GERD (%)	25.0	31.4	.051
T2DM (%)	15.7	14.3	.596
Treated with oral hypoglycemics	4.5	3.7	.588
Treated with insulin treatment	11.2	10.6	.794

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

data showed that SG 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.[9,10] 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),[11] improvement in autonomic nervous activity, and ectopic fat mobilization.[12] 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.[13]

Resolution of T2DM occurred in only 1.4% and was not statistically significant in both groups: T2DM treated with oral hypoglycemics only and T2DM treated with insulin treatment (insulin with or without additional hypoglycemic medications); unfortunately, the data concerning the hemoglobin A1c (HbA1c) monitoring were not completed during this study. The impact of SG on diabetes is variable in the literature; Gill et al[14] found in their systematic review of studies of diabetic patients who underwent SG 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.[15] In the present study, there is no significant decrease in prevalence of this comorbidity during the first 5 years after SG.

The rate of GERD tended to increase after SG, and these results are consistent with recent studies. Fløl o et al[16] reported an increase in prevalence of GERD from 12% to 35% at 5 years after SG. The anatomy modifications after SG 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.[17] Yehoshua et al[18] demonstrated decreased gastric compliance and increased gastric pressures after SG responsible for the increase in GERD. These observations justify a preoperative endoscopic

Table 4. Univariate and Multivariate Analysis of Weight Loss Failure at 5 Years (%EWL <50%) After SG.

	Univariate analysis			Multivariate analysis		
	OR	CI	P	OR	CI	P
Age >50 years	3.51	1.93-6.47	<.001	2.72	1.42-5.37	.003
Sex F	1.37	.71-2.62	.423			
BMI >50 kg/m^2	4.59	2.59-7.83	<.001	4.57	2.55-8.20	<.001
Smoking	1.22	.62-2.41	.632			
Dyslipidemia	1.13	.56-2.14	.773			
GERD	1.51	.70-3.46	.363			
HTN	1.89	1.08-3.20	.034	1.54	.88-2.93	.218
OSAS	2.13	1.23-3.70	.006	1.88	.98-3.41	.074
T2DM	1.29	.68-2.32	.563			
Past surgical history of LAGB	3.58	1.81-6.90	<.001	4.86	2.24-10.49	<.001
Eating profile of volume eaters	.27	.40-1.31	.324			
Calibration tube diameter ≥35F	1.05	.46-2.21	.726			
Stapling distance from pylorus ≥6 cm	1.32	.75-2.86	.687			

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

GERD screening for all patients who want to undergo bariatric surgery, and if significant reflux is found, a SG should be contraindicated and another surgical technique such as Roux-en-Y gastric bypass should be preferred. More precise monitoring of GERD is also recommended during the postoperative phase.

Although the SG 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 independent predictors of weight loss failure at 5 years; these results are consistent with those of previous studies.[19,20] 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 redo surgery in patients with prior LAGB, make 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 SG was significant, but less than after conversion to Roux-en-Y gastric bypass.[21]

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 (<6 cm) 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.[22] The high leak rates observed when using narrow bougie could be attributed to increased intragastric pressure, wall tension, and ischemia in the staple line.[22] Another controversial point is the stapling distance from the pylorus; in the most recent randomized study,[23] authors found an accelerated gastric emptying and higher antral volume in the antral preservation group (antrum resection 5 cm from the pylorus) than antrum resection group (antrum resection 2 cm from the pylorus); the 2 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 and 6 cm distances from the pylorus; however, weight loss was greater in the 2 cm group at 6 months.[24]

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; there is a lack of precise data on diabetes such as the hemoglobin A1c (HbA1c) monitoring. The patient follow-up rate is low after 5 years; 1 possible reason is that some centers accept patients seeking bariatric surgery from all over Belgium and France; this far-off physical proximity probably discourages 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 SG in bariatric surgery.

Conclusion

Five years after performance of SG, satisfactory outcome can be achieved regarding the weight loss and some obesity-related comorbidities, including dyslipidemia, OSAS, and HTN, but not T2DM and GERD. Age >50 years old, BMI >50 kg/m^2, and previous LAGB were independent predictors of weight loss failure.

Declarations Conflict Interests

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