Obesity Surgery (2019) 29:3629–3637
https://doi.org/10.1007/s11695-019-04044-7

ORIGINAL CONTRIBUTIONS

Laparoscopic Sleeve Gastrectomy for High-Risk Patients in a Monocentric Series: Long-Term Outcomes and Predictors of Success

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Published online: 1 July 2019
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Abstract

Background Laparoscopic sleeve gastrectomy (LSG) has gained popularity as a stand-alone bariatric procedure, but only a few reports provide data of long-term outcomes on high-risk patients.

Objective To evaluate long-term efficacy of LSG as a definitive management on high-risk obese patients and to study factors that predict its success.

Setting University hospital in Spain.

Methods A retrospective analysis of prospectively collected data from 134 high-risk patients undergoing LSG from January 2007 through December 2016. Long-term weight loss, resolution of comorbidities, morbidity, and mortality were analyzed.

Results One hundred thirty-four high-risk patients underwent LSG. The mean overall follow-up time was 70.9 ± 4.5 months. The mean age was 47 ± 11.0 years. The mean preoperative body mass index (BMI) was 55.9 ± 6.7 kg/m^2 (83.5% were super-obese and 24.6% had BMI ≥ 60). The incidence of postoperative complications was 15%. Mean percentage of total weight loss (%TWL) at 5, 6, 7, and 8 years was 30.7 ± 12.8%, 28.7 ± 14.0%, 29.7 ± 12.3%, and 27.9 ± 11.1%, respectively. Differences were found in age, preoperative BMI, time to reach nadir weight and percentage of excess weight loss (%EWL) at 1 year between patients considered a failure compared to those considered a success. Using multivariate regression analysis, only age ($p = 0.009$) and time to reach nadir weight after surgery ($p = 0.008$) correlated with %EWL at 4 years. Resolution of type 2 diabetes (T2DM) was achieved in 62.2% of patients.

Conclusion This study supports effectiveness and durability of LSG as a definitive bariatric procedure in high-risk patients.

Keywords Laparoscopic sleeve gastrectomy · Long-term results · Weight loss · Comorbidities · Factors predict success

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Introduction

Obesity is frequently associated with severe comorbidities, which are often progressive and potentially life threatening. Bariatric surgery has proven to be an exceptionally effective and durable solution for morbidly obese adults [1]. Laparoscopic sleeve gastrectomy (LSG) was first described by Hess and Marceau as the restrictive component of the biliopancreatic diversion-duodenal switch operation [2]. LSG was later popularized by Gagner et al. as a first-step procedure to minimize surgical risk in high-risk and super-morbidly obese patients followed later by either a gastric bypass or duodenal switch [3]. In 2009, LSG was approved as a primary bariatric procedure by the American Society for Metabolic and Bariatric Surgery (ASMBS) [4]. LSG is now commonly performed as a definitive bariatric operation for lower BMI (body mass index) patients due to its relative technical ease and good results [5]. Short- and mid-term results are extensively reported in the literature [6, 7]. Recently, a growing number of series with follow-up of up to 5 years have been published [8–11]. In these studies, a constant decrease of the mean percent excessive weight loss (%EWL) was observed over the years with some weight regain.

In our hospital, LSG was selected as a one-stage procedure for high-risk patients. We conducted this retrospective study in order to review our experience with the application of LSG as a definitive procedure for high-risk obese patients and to examine long-term outcomes on weight loss, evolution of obesity-related comorbidities, weight regain, de novo gastroesophageal reflux disease (GERD), and predictors of weight loss success.

Materials and Methods

The study population consisted of 134 patients who had LSG performed at the CR University General Hospital from January 2007 to December 2016. All patients met the National Institutes of Health (NIH) criteria for bariatric surgery and, in the surgeon's opinion, had a high risk. The decision was based on extreme BMI (> 60), advanced age (> 60 years), BMI > 50 with several comorbidities (hypertension, type 2 diabetes mellitus, severe obstructive sleep apnea syndrome, dyslipidemia, etc.) mainly in males, or an organ dysfunction (cirrhosis, severe heart or pulmonary disease, or renal dysfunction).

Patients with symptoms of reflux or esophagitis in the preoperative endoscopy were precluded of the study. At the time of the study, selected patients were eligible for at least a 2-year follow-up. Data was retrospectively reviewed using a prospectively collected database. The study was approved by the Hospital Ethics Committee. All participants gave informed consent prior to participation in the study. The study complies with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments on human beings [12], and the data were computerized in accordance with the guidelines established by Organic Law 15/1999 on Data Protection [13]. All protocols used were approved by the hospital's Clinical Research Ethics Committee.

Surgical Technique

The pneumoperitoneum was established with Veress needle insufflation (pressure of 14–16 mmHg) and five trocars were placed in the upper abdomen. The greater curvature of the stomach was devascularized; short gastric vessels, gastrocolic vessels, and gastrosplenic ligaments were divided using a Ligasure® device. A longitudinal resection of the fundus, body, and antrum was performed leaving a tubularized stomach conduit. The resection was extended from 5 cm from the pylorus to the angle of His. The stomach was excised with EndoGia 60 mm reload with Tri-stapler over a 36-Fr bougie. Suture reinforcement was performed with an absorbable suture (V-lock®) in 83.5% of patients. Intraoperative methylene blue stressed leak test was routinely performed. The excised stomach was removed. A drain was routinely inserted in all patients. All patients were operated on by the same four surgeons.

On the second postoperative day, leakage was checked again by oral methylene blue. The patients were encouraged to start oral fluid for 15 days and progress to semi-solid for a further 2 weeks and then solid foods after the fourth week. Patients received anticoagulant and proton pump inhibitor for 1 month after discharge.

Weight Loss and Comorbidity Outcome

All patients are reviewed at 4 weeks, every 3 months in the first year, every 6 months in the second year, and yearly thereafter. The patients' data were entered into a data sheet for statistical purposes, including clinical, radiologic, laboratory, operative and postoperative findings, hospital stay, morbidity, mortality, weight loss, and evolution of comorbidities.

Follow-up was mostly carried out by means of clinic visits and medical record reviews. After the fifth year, in order to check weight and comorbidities, we obtained data from endocrine reports.

Weight loss was expressed in terms of percentage of total weight loss (%TWL) and percentage of excess weight loss (%EWL), with ideal body weight being calculated as equivalent to a BMI of 25 kg/m^2. Inadequate weight loss was defined as %EWL < 50% according to the Reinhold Criteria modified by Christou [8, 9].

Remission of comorbidities was defined as clinical resolution without medical treatment. Diabetes remission was defined as fasting plasma glucose and HbA1c below the diagnostic thresholds (< 126 mg/dL and < 6.5%, respectively) for at least 1 year in the absence of antidiabetic medication. Criteria for HTN diagnosis were current treatment with

Table 1 Demographic data and comorbid conditions

Patient characteristics	
Total number of patients	$N = 134$
Female sex	
N (%)	82 (61.2%)
Age (years)	
Mean (± SD), range	47 ± 11.0 (18–69)
Initial weight (kg)	
Mean (± SD), range	147.0 ± 23.8 (91–219)
Initial BMI (kg/m^2)	
Mean (± SD), range	55.9 ± 6.7 (37.4–71.1)
Excess weight (kg)	
Mean (± SD), range	88.7 ± 20.2 (37–133.4)
Super-obese (BMI > 50)	
N (%)	112 (83.5%)
Follow-up (months)	
(mean ± SD)	70.9 ± 4.5
Comorbidities *N* (%)	
Hypertension	77 (57.4%)
Type 2 diabetes mellitus	52 (38.8%)
Dyslipidemia	40 (29.8%)
Sleep apnea	65 (48.5%)
Heart disease	13 (9.7%)
Chronic obstructive pulmonary disease	14 (10.4%)
Asthma	7 (5.2%)
Renal disease	5 (3.7%)
Cirrhosis	2 (1.5%)

antihypertensive agents and/or systolic blood pressure (BP) > 140 mmHg and/or diastolic BP > 90 mmHg and HTN remission was defined as normalization of blood pressure maintained after discontinuation of medical treatment. OSA remission was defined as discontinuation of continuous positive airway pressure or bi-level positive airway pressure (CPAP/BiPAP) at 1 year. Dyslipidemia remission was defined as normalization of lipid parameters and stopping statins for at least 1 year.

Statistical Analysis

Statistical analyses were performed using the SPSS software (version 19.0 for Windows; IBM). A 95% CI was considered and significance was established at $p < 0.05$. Normality of quantitative variables was checked by the Kolmogorov–Smirnov and Shapiro–Wilk tests. Depending on the result, Student's *t* test for paired samples or the Wilcoxon test was performed for comparison. Student's *t* test for independent samples (with Levene's test to assess the equality of variances) or the Mann–Whitney *U* test was used for unpaired variable comparisons.

Multivariable analysis was performed to determine factors associated with success (%EWL ≥ 50). We estimated regression coefficients (β) and 95% confidence intervals using a multivariable adjusted logistic regression model. The model was controlled for potential confounders based on published factors and those variables with $p < 0.2$ in the bivariate analysis. In addition, a survival analysis was performed to represent the cumulative success in weight loss (%EWL ≥ 50) using a Kaplan–Meier test.

Results

Patient Characteristics

From January 2007 to December 2016, 134 patients underwent a laparoscopic sleeve gastrectomy at the CR University General Hospital (25.6% of total bariatric procedures). All patients complied with the 1991 National Institutes of Health

Table 2 Weight loss outcomes

Year after surgery	Actual/potential follow-up	%EWL mean ± SD	%TWL mean ± SD	Success (%EWL ≥ 50)		Failure (%EWL < 50)	
				N (%)	Mean ± SD	*N* (%)	Mean ± SD
1 year	108/120	61.3 ± 18.0	39.1 ± 21.3	78 (72.2%)	70.1 ± 18.0	30 (27.8%)	38.5 ± 17.9
2 years	95/120	62.6 ± 22.7	34.3 ± 13.2	64 (67.3%)	75.5 ± 22.7	31 (32.6%)	35.8 ± 22.1
3 years	78/108	55.5 ± 25.2	30.5 ± 14.6	45 (57.7%)	73.7 ± 25.0	33 (42.3%)	30.7 ± 25.2
4 years	52/88	55.2 ± 27.6	30.4 ± 15.2	33 (63.5%)	71.9 ± 27.4	19 (36.5%)	26.3 ± 27.9
5 years	36/68	55.2 ± 23.2	30.7 ± 12.9	23 (63.9%)	69.8 ± 23.4	13 (36.1%)	29.4 ± 23.5
6 years	28/60	52.3 ± 24.9	28.7 ± 14.1	16 (57.1%)	71.2 ± 25.5	12 (42.8%)	27.1 ± 25.5
7 years	17/50	52.2 ± 20.5	29.8 ± 12.4	11 (64.7%)	64.4 ± 20.5	6 (35.3%)	29.9 ± 21.0
8 years	13/41	49.8 ± 17.3	27.9 ± 11.2	7 (53.8%)	64.1 ± 16.1	6 (46.1%)	33.3 ± 17.3
9 years	13/32	51.7 ± 21.5	29.4 ± 12.9	5 (38.5%)	75.7 ± 22.3	8 (61.5%)	36.6 ± 20.8
10 years	10/18	54.4 ± 17.0	31.2 ± 10.0	6(60%)	67.4 ± 16.9	4(40%)	35.0 ± 18.8
11 years	5/5	60.3 ± 15.1	34.8 ± 8.8	3(60%)	72.2 ± 15.1	2(40%)	42.5 ± 18.3

(NIH) standards for obesity surgery [14]. Patients' mean age was 47 ± 11.0 (range 18–69 years) and mean preoperative BMI 55.9 ± 6.7. Eighty-two of the patients (61%) were women. One hundred and twelve (83.5%) were super-obese (BMI ≥ 50 kg/m^2) and 33 of them (24.6%) had BMI ≥ 60. Thirty-four patients (25.3%) had an organic dysfunction. Fourteen patients (10.4%) were ≥ 60 years old. Most patients (79.8%) had some major comorbidity (diabetes, hypertension, sleep apnea, or dyslipidemia) and 57.5% had two or more of such comorbidities. Demographic data and comorbid conditions identified in our patient population are summarized in Table 1.

Postoperative Course

Early complications within 30 days of surgery occurred in 21 patients (15.7%). Ten patients developed staple line leaks (7.5%), 2 gastrointestinal bleeding (1.5%), 3 intraabdominal abscesses (2.2%), 1 pulmonary embolisms and 1 deep venous thrombosis (1.5%), 2 splenic infarction (1.5%), and 1 esophagus perforation with the calibration tube. The mean length of stay was 6.6 ± 2.0 days.

There were five 30-day perioperative deaths (3.7%): One unknown cause in another center, three deaths due to leak with sepsis and multi-organic failure (one of these patients returned to the hospital too late with established septic shock), and the fifth death was due to massive pulmonary embolism. The five patients belonged to category C (mortality risk 2.4–7.6%) of the Obesity Surgery Mortality Risk Score (OSMRS). Two patients died late into the follow-up from non-procedure-related causes (due to amyotrophic lateral sclerosis and lymphoma).

Late complications included 10 patients (7.4%) who developed new onset gastroesophageal reflux disease (GERD) after sleeve gastrectomy—they needed proton pump inhibitor for a long period to treat their reflux symptoms—and one patient who developed stricture treated by endoscopy dilatation.

Weight Loss and Remission of Comorbidities

The mean follow-up time was 70.9 ± 34.0 months (range 24–132 m). Available follow-up data per year, %EWL, and %TWL are summarized in Table 2. Mean %TWL at 5, 6, 7, and 8 years was 30.7 ± 12.8%, 28.7 ± 14.0%, 29.7 ± 12.3%, and 27.9 ± 11.1%, respectively. The %EWL at 5, 6, 7, and 8 years was 55.2 ± 23.2% (36 patients followed), 52.3 ± 24.9% (28 patients followed), 52.2 ± 20.5% (17 patients followed), and 49.8 ± 17.3% (13 patients followed), respectively. The percentage of patients with inadequate weight loss, defined as %EWL < 50, was 36.1% at 5 years. Success and failure rates per year are summarized in Fig. 1 and %EWL (means and SD per year) in success and failure groups are shown in Fig. 2.

Only seven patients (5.2%) underwent revision to laparoscopic Roux-en-Y gastric bypass at various time points after initial LSG and were included in the analysis up to the point of the revision surgery.

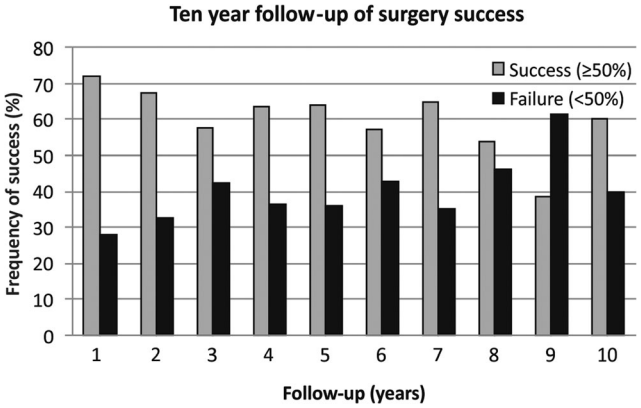

Fig. 1 Success and failure rates per year

Obesity-related comorbidities decreased after surgery. The best remission rate was for diabetes mellitus (T2DM). The remission rate was 62.2% for T2DM, 30.4% for hypertension (HTN), 48.6% for dyslipidemia (DLP), and 66.1% for obstructive sleep apnea syndrome (OSAS).

Predictors of Long-Term Weight Loss After LSG

Age, gender, preoperative BMI, number of preoperative major comorbidities, presence of postoperative complications (first 30 days), time after surgery when the nadir weight is reached, and %EWL at 1 year were studied in order to find differences between successful and failed patients (at 4 years). Differences were found in age, preoperative BMI, number of comorbidities, time to reach nadir weight, and %EWL at 1 year as shown in Table 3. Gender and complications did not influence %EWL. Using multivariate regression analysis, only age ($p = 0.009$; OR = 0.837; 95% CI 0.732–0.956) and time point when the nadir weight is reached ($p = 0.008$; OR = 5.476; 95% CI 1.565–19.158) were independent factors that predict success (Table 4).

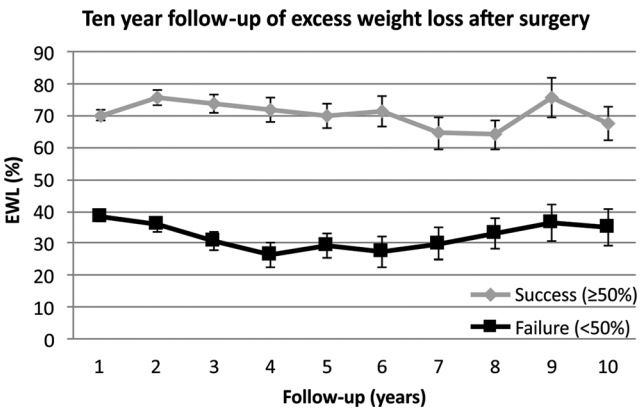

Fig. 2 The %EWL (means and SD per year) in success and failure groups

Table 3 Weight outcomes at 4 years after LSG according to different variables. Univariate analysis

Variables	Success (%EWL ≥ 50) mean ± SD	Failure (%EWL < 50) mean ± SD	*p*
Age	42.0 ± 9.6	55.3 ± 7.9	< 0.001
Preoperative BMI	57.6 ± 6.6	51.7 ± 6.8	0.003
Number major comorbidities	1.6 ± 1.6	2.6 ± 1.5	0.021
Time nadir weight reached (years)	2.3 ± 0.9	1.2 ± 0.6	< 0.001
%EWL 1 year	72.1 ± 12.4	48.8 ± 13.3	< 0.001

%EWL percentage of excess weight loss

Using the Kaplan–Meier survival analysis, the probability of remaining failure free was 62.8% (95% CI 53.6–72.1) at 5 years and 50.5% (95% CI 39.5–61.4) at 7 years (Fig. 3).

Discussion

Sleeve gastrectomy is a technically simple procedure to perform with a short operating time in patients with advanced age, extreme obesity, and high comorbidity. The efficacy of a bariatric procedure depends on durability of weight loss and improvement in comorbidities. The long-term results of LSG are defined as the effects over 5 years or more without the addition of any other bariatric procedure.

The mortality rate in this series is higher than that published by other authors in which it does not exceed 1%. Perhaps this is because they are high-risk patients with comorbidities, a high proportion of super-obese and super-super-obese and that 25.3% have an organ dysfunction. We started performing this technique in 2007 and most of the leaks were during the learning curve. In two cases of death due to a leak, patients came back to the hospital too late with clear signs of septic shock. A substantial proportion of our patients come from geographically distant areas, which also explains our long length of stay after LSG.

A median %EWL at 5 years of 55.2 ± 23.2% was achieved with LSG in our institution, and 63.9% of patients have %EWL ≥ 50 at 5 years. Hamoui et al. reported a median of 51% EWL at 18 months with similar high-risk patients (same median of age and same median of preoperative BMI as this study). Hamoi et al. reported a smaller mortality rate and 15% of morbidity compared to this study [15]. Another report of long-term outcomes after LSG in high-risk patients was published by Eid et al. with %EWL at 7 years of 57% [10].

The success rate after LSG in high-risk patients decreased throughout the follow-up. At 3–5 years, follow-up weight loss seems stable (mean %EWL of 55%) but the results worsened at 8 years (49.8 ± 17.3%). Our short- and mid-term results are worse than others published [11, 16, 17] but long-term results are comparable to the results recently published by Gadiot and Garg et al. [18, 19], although higher weight loss has also been reported [17, 20]. Table 5 summarizes the published literature in relation to long-term weight loss, improvement in comorbidities, and morbi-mortality after LSG [6, 10, 11, 16–26].

In our study, inadequate weight loss after surgery (defined by %EWL < 50%) is 36.1% (*N* = 13) at 5 years, similar to the results obtained by Golomb et al. (38.5%) and Garg et al. (28.8%) [19, 27]. Although 46.1% (*N* = 6) of patients in this study were considered a failure after 8 years of follow-up, most of these patients were still satisfied and did not consider revision surgery. Only seven patients (5.2%) underwent a

Table 4 Independent factors associated with success in weight loss (%EWL ≥ 50)

	β	HR	95% CI	*p* value
Age	− 0.178	0.837	0.732–0.956	0.009
Number of major comorbidities	0.184	1.202	0.639–2.261	0.568
Time nadir weight reached (years)	1.70	5.476	1.565–19.158	0.008

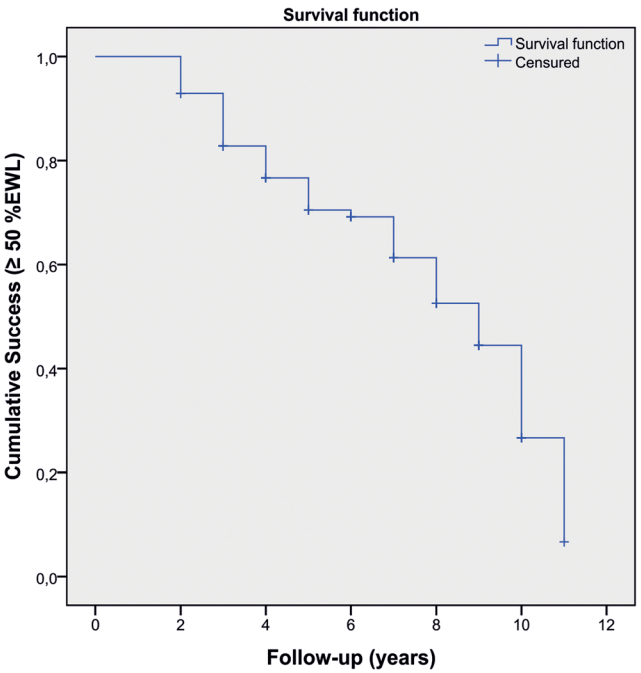

Fig. 3 The probability of remaining failure free

Table 5 Studies on long-term outcome of LSG

Author year country	Patients actually followed/ expected followed	Preoperative median BMI % with BMI > 50	Median % excess weight loss % success	Mortality morbidity	Resolution comorbidities	Weight regain novo GERD revisional surgery	Factors predicting success
Sarela 2012 UK	*N* = 13/20 2000–2001	Median BMI: 45.8 BMI > 50: 45%	8–9 years: 68% EWL EWL > 50%: 55% at 8–9 years			Revision surgery: 20%	Successful patients (at 8–9 years) had significantly greater %EWL at 1 year
Eid 2012 USA	*N* = 69/74 2002–2004	Median BMI: 66	5–6 years: 52% 6–7: 43% 7–8: 46%	Mortality: 0% Morbidity: 15% Leak: 1.3%	T2DM: 37.1% HTN: 9.3% OSAS: 8.6%	Novo GERD: 12% Revision surgery: 40%	
Catheline 2013 France	*N* = 53/65 2005–2007	Median BMI: 49.9	2 years: 57.1% 5 years: 50.7% EWL > 50%: 43.1% at 5 years	Mortality: 0% Morbidity: 5.7% Leak: 3.8%			Age: predictor of surgical success (37.5 years success vs 47.5 years failure)
Ellatif 2014 Egypt	*N* = 1395/1419 2005–2013	BMI:46	5 years: 61% 6 years: 59% 7 years: 57%	Mortality: 0% Morbidity: 5.1% Leak: 0.8%	T2DM: 69% HTN: 54% HLP:43%	Novo GERD: 11.4% Revision surgery: 4%	Smaller bougie size and leaving smaller antrum were associated with higher %EWL
Hirth 2015 USA	*N* = 14/16	Median BMI: 43.5	7 years: 59.6% EWL > 50%: 78.5% at 8–9 years	Mortality: 0% Morbidity: 12.5%		Novo GERD: 35.7%	
Alexandrou 2015 Greece	*N* = 25/30	Median BMI: 55.5 BMI > 50: 60%	5 years: 56.4% EWL EWL > 50%: 68% at 5 years	Mortality: 0% Morbidity: 0%	T2DM: 66% HTN: 63% OSAS: 80%	Novo GERD: 16%	Preoperative BMI did not influence WL success at 5 years follow-up
Casella 2016 Italy	*N* = 148/182 2006–2008	BMI: 45.9	% EWL: 5 years: 70.2% 6 years: 67.3% 7 years: 65.7% EWL > 50%: 83.1% at 6 years	Mortality: 0% Morbidity: 5.4% Leak: 2.7%	T2DM: 83.8% HTN: 59.7% OSAS: 75.6%	Novo GERD: 16.9% Weight regain: 26.3%	Preoperative BMI greater or less than 50 did not significantly influence % EWL at 6 years
Felsenreich 2016 Austria	*N* = 53 2003–2005	BMI: 48.9 BMI > 50: 36%	10 years: 53.5%		BAROS: 2.4 at 10 years	Weight regain: 59% Revision surgery: 36%	No correlation between bougie size and weight regain
Arman 2016 Belgium	*N* = 47 2001–2003	BMI: 38.8	%EBMI 6 years: 75.9% > 11 years: 62.5%		HTN: 28.6% OSAS: 60% HLP:40%	Novo-GERD: 21.4%	
Gang 2017 New Delhi	*N* = 424 2008–2015	BMI:46.7 BMI > 50: 29.2%	5 years: 61.7% 6 years: 59.4% 7 years: 57.2%	Mortality: 0% Morbidity: 5.8% Leak: 1.2%	T2DM: 83.4% HTN: 38.5% OSAS: 100%	Novo-GERD: 2.8% Revision surgery: 1.8%	
Gadiot 2017 Netherlands	*N* = 277 2007–2010	BMI: 44.8 BMI > 50: 20.6%	5 years: 59% 6 years: 58.7% 7 years: 58.7% 8 years: 53.9%	Mortality: 0.7%	T2DM: 68% HTN: 53% OSAS: 88% HLP: 25%	Novo GERD: 7% Revision surgery: 15.9%	Failure rate was significantly higher in patients with preoperative BMI > 50 at 5- and 6-year follow-up
ECE	*N* = 163/186	Median BMI: 52.6	%EWL at 41 m	Mortality: 0%	MO/SO/SSO		

Table 5 (continued)

Author year country	Patients actually followed/ expected followed	Preoperative median BMI % with BMI > 50	Median % excess weight loss % success	Mortality morbidity	Resolution comorbidities	Weight regain novo GERD revisional surgery	Factors predicting success
2017 Turkey		MO: BMI ≤ 50: 50.9% SO: BMI > 50: 31.9% SSO: BMI > 60: 17.2%	MO: 65.6% SO: 59.8% SSO: 48.6%	Morbidity: 12.8% Leak: 2.4%	T2DM: 81/79.1/73.3 HTN: 78.1/80/7.6 HLP: 87/83.3/81.8		%EWL significantly lower for SSO group (BMI > 60)
Chang 2018 Taiwan	*N* = 1759 2005–2017	BMI: 37.9	5 years: 80.1% 10 years: 70.5%	Mortality: 0% Morbidity: 6.5%	T2DM: 83.4% HTN: 38.5% HLP:25% at 5 years	Novo GERD: 50% Revision surgery: 21.5%	
Csendes 2018 Chile	*N* = 102/109 2006–2010	4 BMI groups (mean): I: 33 II: 37 III: 43 IV: 62	% EBMIL at 6 years I: 84.8% II: 66.7% III: 52.7% IV: 28%			Weight regain: I: 3.6% II: 38% III: 85% IV: 100%	The higher the preoperative BMI, the higher the percentage of failure and weight regain

BMI body mass index, *%EWL* percentage of excess weight loss, *%EBMIL* percentage excess body mass index loss, *T2DM* type 2 diabetes mellitus, *HTN* hypertension, *OSAS* obstructive sleep apnea syndrome, *HLP* hyperlipidemia, *GERD* gastroesophageal reflux disease, *MO* morbidly obese, *SO* super-obese, *SSO* super-super-obese

second-step surgery, a LRYGB with relatively poor results. All conversions were due to weight regain.

Patients experienced progressive weight regain; at 5 years, 44.6% of patients had weight regain (> 10 kg from nadir weight). Felsenreich et al. reported weight regain in 59% of patients [22] and Casella et al. only in 26.3% [17]. Weight regain is multifactorial; dilation of the stomach remnant not only may be a cause but also the patient's failure to adopt lifestyle and dietary changes. Strict follow-up with psychiatric and nutritional counseling is crucial in order to maintain weight loss.

The incidence of GERD post-LSG is a problem. We found 7.4% of patients developing novo GERD after LSG, the same as Gadiot et al. [18], less than Ellatif, Hirthr, or Arman et al. [16, 20, 23]. Apart from the symptoms, no other tests were done in our institution to identify patients with GERD; esophago-gastro-duodenoscopy (OGD) was used only in four of these patients.

Rates of resolved obesity comorbidities after LSG in our study are consistent with data reported by other authors [16, 18, 21]. The best remission rate was for diabetes (62, 2%); a similar rate was published by Ellatif et al. [16] (with high proportion of super-obese patients) and Alexandrou et al. [21]. A recent meta-analysis showed similar long-term results in type 2 diabetes mellitus resolution after LSG and LRYGB [28, 29]. There are patients in our study with inadequate weight loss that still benefited from significant improvement of this comorbidity.

Several anthropometric and surgical technique factors have been advocated as predictors of long-term outcome after LSG. Concerning the role of preoperative BMI, data in literature at 5-year follow-up indicate that the %EWL in super-obese patients (BMI > 50 kg/m^2) tends to decrease compared with the %EWL in morbidly obese patients (BMI < 50 kg/m^2) [30, 31]. In this study, we found the opposite; preoperative BMI was significantly higher in the success group than in the failure one (57.6 vs 51.7; $p = 0.003$). In the case of other authors, preoperative BMI does not influence weight loss at 5-year follow-up [17, 21]. Age was significantly lower in the group with adequate weight loss than in the failure group at 4 years (42.0 vs 55.3 years, $p < 0.001$). In relation to Catheline et al., younger age was also a predictor of weight loss success after LSG [6].

Patients in this study achieved their nadir weight at 1.5 ± 0.8 years, as in other published studies [32]. Time point to reach nadir weight was an independent factor that predicts long-term success in our series (2.3 vs 1.2 years). According to this study, those patients who reached the nadir weight later and lost weight for a longer time in the postoperative period achieved the best long-term results. This makes us think that those patients who stop losing weight from the first year after surgery are those who are going to fail in the long term, which should lead us to encourage and advise them to intensify

exercise and prolong weight loss. Further research is needed to help us anticipate which patients would benefit from this procedure and to shed light on the role of food intake and physical exercise in long-term failure and weight regain.

This study is limited due to the retrospective nature of the analysis and the small number of patients with long-term follow-up. The definition and selection of "high-risk patient" was based on the surgeons' choice, taking into account the patient's age, BMI, comorbidities, and organ dysfunction, not optimally standardized. The number of patients included in this study might be too small in order to draw final conclusions about long-term success.

Conclusions

Patients in this study lost substantial weight and their overall health improved, but mortality after LSG in high-risk patients was higher than in other series. The percentage of successful patients at 6 years remains high in our series (57.1%) and despite weight regain, long-term resolution of T2DM was achieved in 62.2% of patients. Failure rate increases with long-term follow-up. The independent factors associated with adequate weight loss in the medium term were young age and nadir weight reached later after surgery.

Compliance with Ethical Standards

The study was approved by the Hospital Ethics Committee. All participants gave informed consent prior to participation in the study. The study complies with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments on human beings [12], and the data were computerized in accordance with the guidelines established by Organic Law 15/1999 on Data Protection [13]. All protocols used were approved by the hospital's Clinical Research Ethics Committee.

Conflict of Interest The authors declare that they have no conflict of interest.

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