

Laparoscopic Sleeve Gastrectomy Performed with Intent to Treat Morbid Obesity: A Prospective Single-Center Study of 261 Patients with a Median Follow-up of 1 Year

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Abstract

Background The aim of the study is to look at laparoscopic sleeve gastrectomy as a procedure with intent to cure morbid obesity. Secondary endpoints are related to the safety profile of the procedure.

Methods This is a prospective clinical study conducted in a single university surgical clinic.

Results Two hundred sixty-one patients (2.5:1 female to male ratio, median age of 37 years) underwent sleeve gastrectomy. Median preoperative body mass index (BMI) was 45.2 kg/m². Mortality and morbidity rates were 0.7% and 8.4%, respectively. Risk factors for postoperative complications were history of diabetes mellitus under medical treatment (OR, 4.0; $p=0.014$) and prior bariatric operation on the same patient (OR, 5.7, $p=0.034$). Median follow-up was 12 months (range 1–29 months). A BMI > 50 kg/m² is connected with greater weight loss. Analysis of the percentage of excess weight loss (%EWL) during follow-up at specific time intervals showed a rapid increase for the first 12 months followed by a more gradual rise thereafter. The median %EWL for the first year of follow-up was 65.7 (range 33.8–102.3). The median BMI for the patients that had completed at least 1 year of follow-up was

30.5 kg/m² (range 21.2–42.7). The overall success rate after the first year was 74.3% when accounted for %EWL > 50 and 81.7% for BMI < 35 kg/m².

Conclusions The actual long-term efficacy of the procedure remains to be confirmed. Morbidity rates may prove higher than expected especially during the learning curve.

Keywords Laparoscopic sleeve gastrectomy · Morbid obesity

Introduction

Morbid obesity is deemed responsible for or associated with 2.5 million deaths per year worldwide [1]. Despite possible overestimation, the burden on public health and the relative cost is significant. It goes without saying that the vast majority of affected people reside in the Americas and Europe. As a consequence of the failure of conservative treatments, surgery appears as the only reliable treatment today.

The laparoscopic adjustable gastric banding (LAGB) is still popular among surgeons (and therefore patients) despite certain concerns related to the long-term efficacy and subsequent complications. Laparoscopic Roux-Y gastric by-pass (LRYGBP) remains the mainstay of surgical treatment of morbid obesity in the USA. Laparoscopic sleeve gastrectomy (LSG) emerged as a “bridge procedure” for super-obese patients. The initial promising results in terms of weight loss render LSG an attractive alternative; it may be appropriate as the final treatment for morbid obesity.

The aim of the study is to look at LSG as a procedure with intent to cure morbid obesity. Secondary endpoints are related to the safety profile of the procedure.

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Patients and Methods

This is a prospective clinical study of all patients operated by a single surgical team.

Patients' Selection

Patients were offered LSG in a standard interview where all known aspects of the procedure were analyzed. In the absence of standard international guidelines, patients gave written informed consent acknowledging all possible complications and the possibility to undergo a subsequent bariatric procedure in the future. Inclusion criteria were a body mass index (BMI) greater than 40 kg/m² or greater than 35 kg/m² accompanied with relevant co-morbidities. Exclusion criteria were age over 60 years and the inability to undergo general anesthesia. Patients with Barrett's esophagus or severe gastroesophageal reflux with esophagitis were also excluded from the study.

Data were prospectively recorded in a standard electronic database.

Preoperative Evaluation

Preoperative evaluation included tests for the evaluation of cardiopulmonary function and weight and height measurement on a standard electronic scale and upper gastrointestinal endoscopy. Patients under therapy by a clinical psychologist or psychiatrist were asked to provide written approval by their therapist. All patients gave written informed consent following at least two interviews with one of the researchers involved. Chemoprophylaxis was administered with 1.5 g of cefuroxime on induction of anesthesia. Thromboprophylaxis included preoperative administration of low molecular weight heparin and the use of elastic stockings.

Operative Technique

Operative technique was standardized as follows:

- The patient is positioned in a modified lithotomy position.
- Five trocars are inserted in the upper abdomen. The camera port is introduced with the use of OptiView visualizing trocar (Ethicon Endo-Surgery, Inc). The left liver lobe is retracted with the use of endoscopic liver retractor.
- The lesser sac is entered, and all the branches of the gastroepiploic vessels are ligated at their point of entrance to the greater curvature. Dissection is performed with the use of the LCSC5 Coagulating Shear (Ethicon Endo-Surgery, Inc) until the complete mobilization of the gastric fundus. Care is taken to divide all

the short gastric vessels and to free the stomach of any posterior attachments to the left crus. The mobilization of the fundus is considered complete when the entire angle of His is visualized along with the left crura. The pylorus is identified, and dissection of the greater omentum continues to 5–7 cm from it.

- A 38 Fr bougie is inserted in the stomach and advanced to the pylorus. The nasogastric tube is removed.
- The stomach is divided along the lesser curvature with the use of the Echelon Compact Linear Cutter, 60 mm loaded with the ECR60D cartridges (Ethicon Endo-Surgery, Inc). Gold (3.8 mm) cartridges were used in most cases. Alternatively, a combination of Green reloads (4.1 mm) for the first firings and Blue reloads (3.5 mm) for the upper stomach were used. In a number of patients, Peri-Strips Dry[®] (PSD; Synovis LT, Inc. MN, USA) Staple Line Reinforcement made of bovine pericardium were used.
- A silicon drain is left along the stapling line for 48 hrs.

Postoperative In-Hospital Evaluation

All the patients underwent upper gastrointestinal series with water-soluble contrast medium on the second postoperative day. Stapling line leak was defined as leak of contrast material, on upper UGIS or computed tomography (CT) scan. Intraabdominal abscess was defined as imaging of collection on CT scan in patients with septic signs. Only grade III/IV complications were included in the statistical analysis, i.e., complications that required intervention or led to extended hospital stay. Patients were discharged when able to resume liquid diet adequate for their daily requirements.

Follow-up Study

Follow-up included physical examination, weighting, and assessment of related co-morbidities. Patients were followed up on the first month and thereafter every three months or on ending of the study. An operation was defined as “successful” when the percentage of excess weight loss (%EWL) exceeded 50% or when BMI dropped below 35 kg/m² after a minimum of 12 months of follow-up.

Statistical Analysis

All statistical analyses were performed using the statistical package Stata/SE 10.0 for Windows (Stata Corp, College Station, TX, USA, 2007). The Chi-square test of equality of medians was used to determine whether there were any significant differences with regard to pre- and postoperative variables of interest between individuals with and without major complications. The Chi-square test of independence

was performed to test the differences in the prevalence of complications between categories of variables of interest. In case of 2×2 cross-tabulations with cells, including less than or equal to five cases, the Fisher's exact test was performed.

The odds of the occurrence of complications after surgery in comparison to the odds of not occurrence of complications were estimated through both uni- and multivariate logistic regression analyses using the following as possible determinants: sex of the patient, age either continuously or categorically (less than 40 years, between 40 and 50 years, and over 50 years), preoperative BMI continuously or in two categories using 50 kg/m^2 as a cut-off, PSD categorically (no or yes), previous operation categorically (no or yes), and diabetes mellitus categorically (no or yes). Significance was tested at the 5% level of statistical significance ($p < 0.05$).

Results

All operations were performed by the same group of attending surgeons. In total, 261 consecutive patients underwent LSG (188 women and 73 men, 2.5/1 ratio) of a median age of 37 years (range 16–60) in a period of 36 months. LSG represented 40% of the bariatric operations performed by the same team in the relevant period. Median preoperative BMI was 45.2 kg/m^2 (range 32.1–72.7). Median operative time was 58 min (range 42–185), and median hospital stay was 3 days (range 2–45). There was one conversion to open surgery (0.3%) due to bleeding from a short gastric vessel. In 12 patients, concomitant procedures were performed (cholecystectomies, postoperative hernias). Ten patients had previous failed bariatric operations (nine LAGB, one Mason's vertical gastropasty).

Postoperative Morbidity

In total, morbidity rate representing grade III/IV complications reached 8.4% (Table 1). Other complications that did not require major intervention were left pleural collection (eight patients), round ligament hematoma (one patient), splenic infarct (one patient), minor arrhythmias (four patients), and urinary tract infection (two patients). The most threatening complication was leaking from the gastric stapling line. The course of the 10 patients that developed leakage is shown in Table 2. Left upper quadrant abscesses were almost invariably observed in patients that had experienced postoperative bleeding. Five out of seven patients were subjected to CT-guided drainage that proved effective in controlling sepsis in four (one was drained laparoscopically). Of the remaining two patients, one was drained laparoscopically, while the other was managed conservatively.

Table 1 List of postoperative complications of laparoscopic sleeve gastrectomy in 261 consecutive patients

Complication	Patients, <i>n</i> (%)
Grade III–IV complications	22 (8.4)
Leak	10 (3.8)
Intraabdominal collection	7 (2.6)
Bleeding	5 (1.9)
Re-Admissions	22 (8.4)
Re-Operations	8 (3.0)

Most of the patients that required transfusion for intraperitoneal bleeding eventually developed intraabdominal abscess

Concerning the identification of predictors for the occurrence of surgical complications, in univariate model, reinforcement of the stapling line with PSD is a negative predictor for subsequent complications, while a high preoperative BMI, previous bariatric operation, and diabetes are positive predictors (Table 3). In both multivariate models, BMI turns out to be not significant (columns 2 and 3) but still, the positive association with major complications remains. The use of PSD reduced complications mainly related to bleeding from the stapling line and intraabdominal collections.

Regarding long-term complications, eight patients (3.0%) required laparoscopic cholecystectomy for symptomatic disease during the follow-up period. Forty patients complained of severe constipation, and eight (3%) developed acute anal fissure. Symptoms were relieved by adding fibers in the diet. A concerning 9.5% (25 patients) developed anemia with low levels of folic acid and ferritine that required medical treatment. During the follow-up period, two patients were operated for incarcerated umbilical hernia not related to trocar site. Approximately 25% of patients developed or suffered worsening of gastroesophageal reflux disease (GERD) symptoms, all responsive to proton pump inhibitors (PPI) treatment (65 out of 261 patients). Heartburn was significantly relieved after the first postoperative trimester. One patient attempted suicide in the follow-up period.

Postoperative Mortality

There was one postoperative death following sepsis from stapling line leakage. The patient never received adequate treatment as he was declared dead on arrival to the emergency department on the 13th postoperative day. One more patient died on the second postoperative month of pneumonia. The same patient had been previously treated for intraabdominal abscess. Overall mortality rate reached 0.7%. A late death was reported 6 months after surgery in a patient that had total gastrectomy following stapling line

Table 2 Treatment strategy and clinical outcome of patients with stapling line leak

Patients	Treatment strategy and outcome
1	DCS—fistula, healed
2	DCS—stenting, healed
3	DCS—stenting, healed
4	Dead on arrival
5	Stenting—total gastrectomy
6	Stenting—healed
7	DCS—stenting, chronic fistula
8	DCS—stenting, healed
9	Stenting—total gastrectomy
10	Stenting—healed

DCS damage control surgery consisting of washout–stitching–drainage

leak. Her death was attributed to severe electrolyte disorders while being under mental health care. This incidence raises long-term mortality to 1.1%.

Effect on Weight Loss

Patients were followed up for a median of 12 months (range 1–29 months). For the patients that had concluded at least 6 months of follow-up, a separate analysis was attempted to identify characteristics that affect the magnitude of the BMI loss using single and multiple linear regression models (Table 4). This showed that a BMI > 50 kg/m² is connected with greater weight loss.

Table 3 Predictors of major complications after surgery using uni- and multivariate logistic regression models

PSD Peri-Strips Dry[®]
^a Age was used as a categorical (three categories of Table 2) or ordered variable in alternative models. In all cases, no significance was found
^b BMI was used as a categorical (two categories of Table 2) in alternative models. In most cases, marginal nonsignificance was found
^c Variable indicating previous operation was dropped off when diabetes was entered into the model due to missing values
^d When diabetes was entered into the models, the sample size for the analysis reduced due to missing values

Determinants (n)	Univariate analysis			Multivariate analysis		
	Odds Ratio	95% CI	<i>p</i>	Odds Ratio	95% C I	<i>p</i>
Sex				Not used		
Men (73)	Ref					
Women (188)	1.00	0.40–2.54	0.998			
Age ^a				Not used		
<50 (221)	1.02	0.98–1.07	0.345			
>50 (40)						
Preoperative BMI ^b	1.06	1.00–1.11	0.035	1.04	0.99–1.10	0.136
<50 (202)						
>50 (59)						
PSD						
No (166)	Ref			Ref		
Yes (95)	0.15	0.03–0.67	0.012	0.17	0.04–0.78	0.022
Previous operation ^c						
No (251)	Ref			Ref		
Yes (10)	4.83	1.13–20.75	0.034	5.74	1.14–28.84	0.034
Diabetes mellitus ^d						
No (225)	Ref			Ref		
Yes (36)	4.62	1.60–13.37	0.005	4.02	1.33–12.12	0.014

Analysis of the %EWL during follow-up at specific time intervals showed a rapid increase for the first 12 months followed by a more gradual rise thereafter (Fig. 1). The median %EWL for the first year of follow-up was 65.7 (range 33.8–102.3). At the end of the study, the median BMI for the patients that had completed at least 1 year of follow-up was 30.5 kg/m² (range 21.2–42.7). The overall success rate after the first year was 74.3% when accounted for %EWL > 50 and 81.7% for BMI < 35 kg/m².

Effect on Co-morbidities

After the first postoperative year, 90% of patients with confirmed sleep apnea withdrew from CPAP mask (nine out of 10 patients). Anti-diabetic medication was reduced or discontinued in 84% of diabetic patients previously on medication (30 out of 36 patients). Hypertension requiring medication was resolved in 88.8% (72 out of 88 patients). Three female patients became pregnant and gave birth within the follow-up period.

Discussion

Morbid obesity has become endemic in Greece. According to data collected for the European Project of Medical and Social Co-Operation, in the year 2000 in a sample of 28,000, 30% of Greek men and women were found overweight or obese (first and second place in Europe, respectively), 26% of boys and 19% of girls aged 6–17

Table 4 Characteristics that affect the magnitude of the BMI loss after half year using single (univariate) and multiple linear regression models

Determinants	N=136	Univariate analysis			Multivariate analysis ^a		
		Coeff.	95% CI	<i>p</i>	Coeff.	95% CI	<i>p</i>
Sex	Men	Ref			Ref		
	Women	-2.4	-4.6 to -0.1	0.041	-0.8	-2.7 to 1.2	0.459
Age group ^b	<40 years	Ref			Not used		
	40–49 years	-1.8	-4.4 to 0.7	0.159			
	≥50 years	-0.4	-3.5 to 2.7	0.790			
Preoperative BMI ^c (kg/m ²)	Obesity (<40)	Ref			Ref		
	Morbid obesity (40–<50)	3.2	0.7 to 5.7	0.011	3.1	0.6 to 5.6	0.017
	Severe obesity (≥50)	9.6	6.8 to 12.3	<10 ⁻³	9.3	6.5 to 12.1	<10 ⁻³
Previous operation	No	Ref			Not used		
	Yes	0.5	-5.0 to 6.1	0.855			

^a All determinants (except those not used) are adjusted for each other (mutually adjusted in one model)

^b Age was also introduced as a continuous variable in alternative models. In all cases, no significance was found

^c BMI was used as a categorical in two categories (cut-off 50 kg/m²) or as continuous variable in several alternative models

were overweight. Greece has the highest prevalence of adolescent obesity in the European Union [2]. The magnitude of the problem but more importantly a trend of surgeons to train in bariatric surgery has increased significantly the number of bariatric operations performed in both the public and private sector.

In our department, LSG is offered as an operation with intent to treat morbid obesity since 2006. Patients' comprehension of the nature of the procedure was satisfactory in the preoperative interviews as was their determination to undergo surgery and consent to the possibility of complications. The operation is not especially demanding for experienced laparoscopic surgeons but certain technical aspects need to be standardized. The first step of the operation is the entrance to the lesser sac. This is easier and safer when attempted at the middle of the greater curvature of the stomach. At this level the layers of peritoneum that form the greater omentum are thinner and there is less fat to be dissected in order to enter the lesser sac. From this point on the surgeon is able to continue both

cephalad and distally so that the greater curvature is completely mobilized. Distal dissection should stop approximately 5–7 cm from the pylorus. Further dissection may facilitate the first firing of the stapler when this is inserted from the right lateral trocar, but then a greater part of the antrum will be resected. This may result in more cases of anemia in the future.

The critical and most technically demanding part of the operation is the complete mobilization of the gastric fundus. We believe that the degree of difficulty of the procedure is primarily determined by the relation of the fundus to the spleen. In certain cases, the short gastric vessels are short indeed, and peritoneal reflections from the fundus are densely connected with the upper pole of the spleen. In order to make certain that the entire fundus will be removed, the left crus has to be exposed in sufficient length. Peritoneal reflections that will not be cleared at this point will make the final stapling firings difficult and potentially dangerous. The gastroesophageal junction's fat pad should also be cleared to expose the entire angle of His. The best possible width of the bougie is not yet determined. The gastric tube should be thin enough to ensure food restriction but also adequate for a possible revision in the future [3, 4]. In our experience, a 38 Fr bougie is a fair choice. Care must be taken to secure all firings of the linear stapler in the best possible angle along the lesser curvature and also to have constant control of the bougie. This may require a few changes of port entries for the linear cutter.

In-hospital stay may be very short, but since most surgical complications will occur later, the patient should be very well informed and the clinic should apply a low threshold for readmission. Morbidity rates following sleeve gastrectomy range from to 7.4% to 15.3% for the open

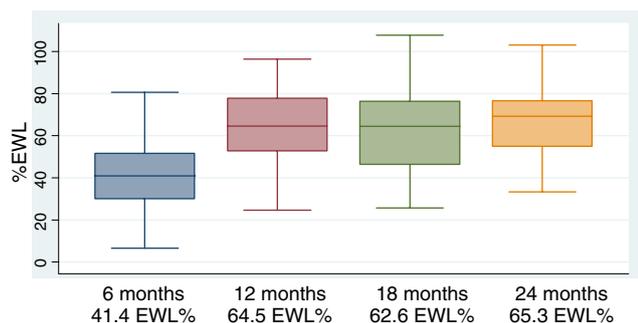


Fig. 1 Change in excess weight loss (percent) at specific time intervals during the first 2.5 years after surgery

technique in series with more than 100 cases [5, 6]. The incidence varies in accordance with the method of presenting complications with most papers emphasizing surgical complications. Overall in our series, we experienced 8.4% of major complications. Major intraoperative bleeding may occur from the stapling line or the short gastric vessels and the spleen. In the former case, bleeding can be controlled with stitches or clips, whereas in the latter, more needs to be done. In the immediate postoperative period, a possible source of bleeding is the gastric stapling line. While not life threatening, such hematomas may present within a week as intraabdominal septic collections. Blood clots exposed to the gastric mucosa of the stapling line are the ideal environment for abscess formation. In our series, all cases of intraabdominal collections were associated with postoperative drop of hemoglobin.

Leaks were almost invariably situated in the upper part of the gastric tube. Initial treatment consisted of stabilization and expectant management. When urgent operation was necessary, the point of leaking was sutured and covered with omental patch and the area was drained. In all cases, damage control surgery proved essentially ineffective as the patients developed gastrocutaneous fistulas. Endoluminal stenting of the gastric tube is a minimally invasive procedure that may prove valuable in order to avoid total gastrectomy [7]. Care should be taken to delay endoscopic stent placement if possible. In two cases, attempts to place an endoluminal stent did more harm than good. The stent (that is not manufactured for this purpose) may enlarge the leaking point, and the continuous pressure on the gastric walls may impair healing. In these cases, total gastrectomy may be the final solution. The procedure is difficult but safe if the lower esophagus is reached and dissected in between the hiatus. Total gastrectomy with esophago-jejunal Roux-Y anastomosis may seem like the last resort but is inevitable when the patient suffers successive septic episodes. The actual timing for this operation is not easy to determine. Management of each patient should be tailored as treating algorithms are not available. Leaks after LSG may be more difficult to treat compared to leaks from LRYGB as more bile refluxes and more dissection around the stomach has taken place. The latter creates a large open space to the left of the gastric tube, under the omentum and posteriorly toward the spleen. In this space and in the exposed lesser sac, it may be more difficult to contain inflammation and sepsis.

Predictors of surgical complications are not easy to identify. A high BMI was associated with the occurrence of major complications although in the multivariate statistical model its significance dropped. This possibly happens because diabetes is an independent risk factor while obviously associated with a high BMI. What also proved a significant risk factor was prior bariatric surgery. In cases

of failed previous LAGB, the fundus is thickened and unreliable to support the stapling clips. This was not proved in a small report of eight patients but confirmed in a larger multicenter trial [8, 9]. Inverting the stapling line by placing a sero-serosal continuous suture over the bougie has been suggested for minimizing leaks [10]. This requires a much larger bougie so that the inversion can be performed without resulting in stenosis of the stump. Reinforcement of the stapling line is a negative predictor for subsequent surgical complications. Beyond the association of PSD with major overall complications, it is difficult to specify the association with the separate complications due to low incidence. Still, there seems to be an association with abscess mainly and bleeding.

Postoperative mortality was high for a cohort of patients with a median age of 37. Each of the three fatalities had completely different characteristics with one patient transferred to the hospital with a 4-day delay despite over-the-phone suggestions to be readmitted. One patient died following a sequel of events that resulted to uncontrolled sepsis despite adequate treatment of his initial complication (a small abdominal abscess). Despite his young age, the patient was diabetic, hypertensive with coronary heart disease, and has an ASA III score. This emphasizes the fact that bariatric surgery is about treating very sick patients that do not easily withstand complications. All efforts should focus on the elimination of possible surgical complications.

Regarding long-term complications, nausea or vomiting after eating is either absent or infrequent, and constipation is easily treated with dietary adjustment. We observed that symptomatic cholelithiasis or cholecystitis may occur early in the postoperative course. This is not well documented in the literature, and the inclusion of cholecystectomy in the standard procedure is controversial. Symptoms of GERD are common especially in the first few months. This may be the result of an anatomic disruption of the lower esophageal sphincter. Other possible explanations include the disruption of the angle of His, alterations in the rate of gastric emptying, and entrapment of food in the small pouch that sometimes remains in the place of the gastric fundus. Practically all cases are responsive to PPI and the symptoms are subtle. Mild anemia may appear within the first year. It is not clear whether it should be attributed to excessive weight loss or low blood folate levels. Further studies are needed to address this point.

The mechanism that induces weight loss after sleeve gastrectomy is not absolutely defined. So far, restriction and the rapid emptying of the stomach is the proposed mechanism of action of the procedure [11]. In terms of weight loss, initial results are promising. Patients lose weight rapidly within the first postoperative year. In our series, patients dropped an average of 15 BMI units and lost

almost 70% of their excess weight. Similar results have been reported in the literature [12, 13]. Compared to LAGB, sleeve gastrectomy is more effective in terms of weight loss and maybe safer concerning long-term complications [14]. Resolution of obesity-related co-morbidities was comparable to what is expected following LRYGBP [15]. Bariatric operations are effective in resolving diabetes, and for reasons that remain unclear, this happens early in the course of weight loss [16]. Hypertension appears to be controlled much easier and sleep apnea is markedly improved.

Advantages of LSG include the maintenance of normal gastrointestinal continuity, the absence of malabsorption, and the facility to convert to multiple other operations [17]. The long-term efficiency of the procedure on weight loss remains to be demonstrated.

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