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TECHNICAL INNOVATION

Laparoscopic Reinforced Sleeve Gastrectomy: Early Results and Complications

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Abstract
Background Sleeve gastrectomy (SG) was pioneered as a two-stage intervention for super and super-super obesity to minimize morbidity and mortality; it is employed increasingly as a primary procedure. Early outcomes and integrity of laparoscopic SG (LSG) against leak using a technique incorporating gastric transection-line reinforcement were studied.
Methods Between 2003 and 2009, 121 patients underwent LSG (16, two-stage; 105, primary). Of the patients, 66% were women, mean age 38.8±10.9 (15.0–64.0), and body mass index (BMI, kg/m^2) 48.7±9.3 (33.7–74.8). Bovine pericardium (Peri-Strips Dry [PSD]) was used to reinforce the staple line. Parametric and nonparametric tests were used, as appropriate. The paired *t* test was used to assess change from baseline; bivariate analyses and logistic regression were used to identify preoperative patient characteristics predictive of suboptimal weight loss.
Results Mean operative time was 105 min (95–180), and mean hospitalization was 5.6 days (1–14). There was no mortality. There were 6 (5.0%) complications: 1 intraoperative leak, 1 stricture, 1 trocar-site bleed, 1 renal failure, and 2 wound infections. There were no postoperative staple-line leaks. Following 15 concomitant hiatal hernia operations, 3 (20%) recurred: 1 revised to RYGB and 2 in standby. Two post-LSG hiatal hernias of the two-stage series required revisions because of symptoms. BMI decreased 24.7% at 6 months (n=55) to 37.5±9.3 (22.2–58.1); %EWL was 48.1 ±19.3 (15.5–98.9). Twelve-month BMI (n=41) was 38.4± 10.5 (19.3–62.3); %EWL was 51.7±25.0 (8.9–123.3). Forty-eight-month BMI (n=13) was 35.6±6.8 (24.9–47.5); %EWL was 61.1±12.2 (43.9–82.1) (p<0.001). Preoperative BMI was predictive of >70% of patients who experienced <50% EWL at 6 months. At 2 weeks, 100% of type 2 diabetes patients (n=23) were off medication (mean HbA_{1C}, 5.9± 0.5%; glycemia, 90.0±19.9 mg/dL (p<0.01) at 3 months).
Conclusions Laparoscopic PSD-reinforced LSG as a staged or definitive procedure is safe and effective in the short term and provides rapid type 2 diabetes mellitus reduction with a very low rate of complications.

Keywords Bariatric surgery · Laparoscopic · Sleeve gastrectomy · Morbid obesity · Staple-line reinforcement · Buttress material · Gastric leak

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Introduction

Sleeve gastrectomy (SG) was approved as a primary bariatric procedure in 2009 by the American Society for

Metabolic and Bariatric Surgery. The operation, performed open or laparoscopically (LSG), constitutes the gastric portion of the biliopancreatic diversion with duodenal switch (BPD/DS) [1]. SG was pioneered during the past decade as the first operation of a two-stage intervention for super and super-super obesity (body mass index [BMI, kg/m^2] >50 and >60 [2]) and/or high operative risk as a strategy to minimize morbidity and mortality [3–7]. SG has been employed increasingly, since 2006, as a stand-alone, primary procedure [8–12], sometimes requiring "completion" with a second operation due to inadequate weight loss [13, 14].

A systematic review of the literature by Brethauer et al. reported short- and intermediate-term outcomes in 2,570 SG patients with mean overall excess weight loss (EWL) of 55.4% (range 33.0–85.0; summarized in 1,662 patients,); 46.9% (33.0–61.4; n=821) for SG performed within a staged approach; and 60.4% (36.0–85.0; n=1,749) when intended as a definitive procedure [15]. In the same review, the majority of patients with comorbid illness (n=754) experienced comorbidity improvement or resolution; >70% of patients experienced improved or resolved type 2 diabetes mellitus (T2DM). The efficacy of SG appears to extend to morbidly obese patients (BMI≥40, or ≥35 with two or more comorbidities [2]) with average operative risk [16, 17] and to certain lower-BMI populations with severe adiposity and/or high risk [18]. SG effectiveness as a primary procedure is comparable to other approved bariatric procedures through the intermediate term [19–22], although long-term follow-up data with which to evaluate it are still needed [1, 23].

Use of SG is on the rise; in a recent survey of metabolic/bariatric surgery worldwide, no SGs/LSGs were reported performed in 2003, whereas they represented 5.4% (0.3% SG, 5.1% LSG) of bariatric procedures reported in 2008 [24]. LSG has been described as one of the most rapid and least difficult of bariatric procedures to perform [25]. The complication rate for SG is reasonably low, mean 9.4% (0–23.8) in high-risk or staged patients, and 6.2% (0–21.7) in primary procedures; leak is the most frequently reported complication, 2.2%, followed by bleeding, 1.2%, and stricture, 0.6%, with low mortality, 0.19% [15]. Leak may be related to too small a calibration of the sleeve segment, or to imperfect closure of the gastric transection line. Although the overall leak rate is not high, due to the extensive resection that characterizes SG, in the context of a proximal stricture, a persistent leak may result in total gastrectomy as the sole surgical option [1]. At our institution, we applied our experience in a prior randomized trial of staple-line reinforcement in Roux-en-Y gastric bypass (RYGB) for bleeding reduction [26] toward the goal of minimizing leak in SG. In a consecutive series of morbidly obese patients, we performed LSG between 2003 and 2006 as part of a planned, two-stage approach for super-obese patients, and from 2007 to 2009, as a primary procedure, independent of BMI, to be revised and completed if necessary. Early efficacy outcomes and the integrity of LSG against leak using a technique incorporating gastric transection-line reinforcement were studied.

Methods

Institutional Review and Study Design

The study was reviewed and approved by the institutional review board of San Giovanni Bosco Hospital, Naples, Italy. Adherence to the ethical conduct standards of the Declaration of Helsinki ensured patients' welfare [27]. The study was retrospective, using prospectively collected data.

Patient Eligibility, Informed Consent, and Preparation

Patients seen at the hospital for treatment of their morbid obesity underwent a multidisciplinary evaluation to consider the option of bariatric surgery [28]. Eligible patients met the International Federation for the Surgery of Obesity (IFSO), the European Association for the Study of Obesity (EASO), and the National Institutes of Health (NIH) indications for bariatric procedure eligibility [29, 30]. Patients in the super obese and super-super obese categories who qualified for LSG as a primary procedure were informed that they were at greater risk of requiring a second procedure if adequate weight loss was not attained through LSG alone. Informed consent was obtained from all patients. Each patient underwent comprehensive medical evaluation. Prior to surgery, antibiotic prophylaxis and venous stasis prophylaxis were instituted.

Surgical Technique

Venous stasis prophylaxis was performed by external pneumatic compression (SCD™ Compression Sleeves; Covidien, Mansfield, MA) at time of surgery, with administration of low molecular heparin for a period of 20 days postoperatively and early patient mobilization the day after surgery. Under general anesthesia, the patient was placed in reverse Trendelenburg lithotomic position, arms and legs abducted, with the surgeon positioned between the patient's legs, the first assistant on the patient's left, and the camera operator, on the right. Closed CO_2 pneumoperitoneum was induced by subcostal Veress needle insertion in the left upper quadrant. Five trocars (T) were positioned: (T1) a 10-mm trocar approximately 20 cm below the xyphoid process in the midline for a 30° camera system, (T2) a 10-mm trocar in the subcostal region on the left

anterior axillary line, (T3) a 5-mm trocar 2 cm below the xyphoid process for liver retraction, (T4) a 5-mm trocar on the left mid-clavicular line and transverse umbilical line, and (T5) a 10–12-mm trocar (for Ethicon Endo-Surgery [EES] staplers) or a 10–15-mm trocar (for Covidien staplers) on the right mid-clavicular line and transverse umbilical line.

The gastrocolic ligament attached to the stomach was opened, beginning 10–12 cm from the pylorus toward the lower pole of the spleen. The gastric greater curvature was freed up to the cardioesophageal junction close to the stomach with the use of a vessel-sealing device (Ultracision Harmonic Scalpel®, EES, Cincinnati, OH; LigaSure®, Covidien, Mansfield, MA) sparing the gastroepiploic vessels. Meticulous dissection was performed at the angle of His with full mobilization of the gastric fundus. Large fat pads of Belsey were resected to provide a clean field for stomach resection. The esophageal hiatus was carefully inspected for a hiatal hernia (HH). In the instance of a hernia, the esophagus was encircled, and the diaphragmatic crura were completely dissected to the mediastinal space. The gastric herniation was reduced into the abdomen. Reconstruction was performed using nonabsorbable (0 Ethibond) interrupted sutures reinforced with a 1″×1″ pledget of bovine pericardium with collagen matrix (Peri-Strips Dry® [PSD] with Veritas® Collagen Matrix Staple Line Reinforcement, Synovis Surgical Innovations, St. Paul, MN), calibrated on a 40 French orogastric bougie. Mobilization of the stomach continued with inferior dissection of the greater curvature toward the antrum up to 3–5 cm from the pylorus. Serosal attachments of the posterior gastric wall to the pancreatic capsule were divided until visualization of the caudate lobe of the liver was obtained. The final surgical preparation was a mobilized stomach tethered at the celiac axis.

The anesthesiologist inserted a 40 French orogastric calibrating bougie directed toward the pylorus along the gastric lesser curvature. The stomach was resected with the linear stapler parallel to the orogastric tube along the lesser curve, starting 3–5 cm from the pylorus. The antrum was partially resected by firing 3–5 green endoscopic linear stapler cartridges (ETS Flex® 4.1, EES; Echelon 60®, EES; Endo GIA 60® 4.8, Covidien) from the right-sided trocar (T5). As the muscular layer of the stomach is thicker, the staple line at the level of the antrum is reinforced with seroserosal running sutures rather than staples. After passing by the level of the angular incisure, the gastric corpus and fundus were transected with 4–5 cartridges of the 45-mm linear stapler or 3–4 cartridges of the 60-mm stapler, depending on their availability in the operating room (Endo GIA Universal®, Autosuture, Norwalk, CT; Endopath ETS®, EES; Echelon 60®, EES), and using multiple blue cartridges loaded with PSD to reinforce the staple line and facilitate tissue remodeling. The buttressed transection line was reinforced with titanium clips to obtain perfect hemostasis; the nonbuttressed transection line was reinforced with a manual, running, absorbable, polydioxanone seroserosal suture.

The calibrating bougie was replaced by a nasogastric tube positioned in the distal stomach to perform the methylene blue dye test for determination of staple-line integrity. A clean sponge was placed along the transection line, the bowel clamp was placed distal to the suture line, and the reduced stomach was inflated with 60–80 cc of methylene fluid; the swab and the transection line were inspected for the presence of methylene blue dye. Following a negative test, the resected stomach was removed through the T5 trocar in a specimen bag, usually without elongating the incision, and a left subcostal drain was placed. The 10-mm trocar access sites were closed with a suture passer (Endoclose®, Covidien, Norwalk, CT) with 2–0 absorbable vicryl suture. The 5-mm trocars were only inspected for bleeding.

Outcomes and Data Collection

Data collection was facilitated using Microsoft Excel® 2008 (version 12.2.5, Redmond, WA). Operative time and duration of hospital stay were recorded. Effectiveness end points included mean BMI change from baseline at 6 months; mean %EWL at 6 months and trends in BMI and %EWL (noted to 48 months); %EWL is calculated as the difference in baseline and postsurgery weight divided by the difference in baseline and ideal body weight (i.e., upper limit value of the medium-frame range on the Metropolitan Life Insurance Tables [31]) multiplied by 100; and metabolic outcomes in diabetic patients at 2 weeks and 3 months. Safety end points were perioperative and long-term complications. Data were scheduled to be collected preoperatively, on the day of surgery, and at postoperative visits at 2 weeks, every 3 months for the first postoperative year, at 1 year, and at a minimum, yearly thereafter.

Statistical Analysis

The SPSS® software package (version 17, SPSS [IBM], Chicago, IL) was used to perform all statistical analyses. Continuous demographic variables were reported as mean, standard deviation (SD), and range; categorical variables were reported as number and percentage. Concomitant surgical procedures and complications were also reported as number and percentage. Continuous outcome variables were generally reported as mean, SD, range, mean change, and percentage change. Ninety-five percent confidence intervals (CIs) were calculated for weight-loss outcome

data. Fisher's exact test was used to investigate relationships between categorical variables. Between-group comparisons along continuous measures were carried out by means of parametric and nonparametric tests, as appropriate (i.e., independent samples *t* test or analysis of variance [ANOVA]; Mann–Whitney *U* test or Kruskal–Wallis test). Measures of change from baseline were analyzed using either the paired samples *t* test or the Wilcoxon signed-rank test. In addition, bivariate unadjusted analyses were performed to identify preoperative characteristics associated with suboptimal weight loss; logistic regression was applied in the development of the predictive model. Statistical significance was set at $p<0.05$.

Results

One hundred twenty-one patients qualified to receive LSG. Sixteen patients (from January 2003 to December 2006) underwent LSG as part of a staged bariatric procedure. From 2007 to 2009, 105 patients were operated on with the intent of performing LSG as a primary procedure. One patient who had undergone laparotomic intragastric balloon (IB) positioning with antral rupture, bleeding, and perforation in 2005 was explored laparoscopically with the intent of performing LSG in 2009; however, due to the poor quality of the tissue noted during gastric preparation, the operation performed was RYGB with gastrectomy of the remnant stomach. A second patient, intended for staged LSG 8 months after gastric band removal, presented with scar tissue and a difficult gastric preparation resulting in multiple positive intraoperative methylene blue tests at the level of the incisura angularis corresponding to the first buttressed transection line. After several failed attempts at staple-line repair with gastrogastric seroserosal sutures, this patient was converted to RYGB with distal gastrectomy.

Patient Characteristics

Baseline characteristics of intent-to-treat patients are shown in Table 1. Sixty-six percent of patients were women. The mean age was 38.8±10.9 (15.0–64.0). Mean absolute weight was 134.6±29.0 kg (80.0–200.0), mean BMI 48.7±9.3 (33.7–74.8), and mean excess body weight 74.1±26.8 kg (26.3–130.5). In operative risk assessment, American Society of Anesthesiologists (ASA) physical status score [32] was mean 3.6±0.6 (2.0–4.0). Hypertension was the most prominent comorbid illness (43, 36.1%), followed by obstructive sleep apnea (OSA; 30, 25.2%), T2DM (23, 19.3%), and hyperlipidemia (17, 14.3%).

Prior to LSG, as a first-step in weight reduction, 32 patients (mean weight, 167.37±31.94 kg; mean BMI, 60.91±11.83 kg/m^2; mean EW, 125.69%±49.17) were submitted to IB positioning. After removal of the IB at 6 months, mean weight was 146.66±29.12 kg; mean BMI was 53.28±10.03 kg/m^2. The LSG procedure was performed after IB removal at 49±75 weeks. Only 18/32 IB patients were admitted to surgery within 16 weeks after BIB removal, as most of their weight loss was regained before the time of LSG surgery.

Table 1 Preoperative patient characteristics

Characteristic	Value, mean±SD (range), *N*=121
Age (years)	38.8±10.9 (15.0–64.0)
Height (m)	1.7±0.1 (1.5–2.0)
Absolute weight (kg)	134.6±29.0 (80.0–200.0)
Excess body weight (kg)	74.1±26.8 (26.3–130.5)
Ideal body weight (kg)	60.6±5.4 (50.5–77.6)
BMI (kg/m^2)	48.7±9.3 (33.7–74.8)
ASA score	3.6±0.6 (2.0–4.0)
Number of comorbidities	1.0±1.2 (0.0–4.0)
Gender (*N*, %)	
Male	41 (34.5)
Female	78 (65.5)
Comorbidities (*N*, %)	
Hypertension	43 (36.1)
OSA	30 (25.2)
T2DM	23 (19.3)
Hyperlipidemia	17 (14.3)
Arthroses	5 (4.2)
Celiac disease	1 (0.8)
GERD	1 (0.8)

BMI body mass index, *ASA* American Society of Anesthesiologists (physical status classification score), *OSA* obstructive sleep apnea, *T2DM* type 2 diabetes mellitus, *GERD* gastrointestinal esophageal reflux disease

Percentage ideal body weight and excess body weight determined by the Metropolitan Weight Tables for Life Insurance, 1983

Operative Time, Concomitant Procedures, and Hospital Stay

Mean operative time was 105 min (95–180). Among 32 concomitant procedures, 8 (25%) were cholecystectomies, 1 (3.1%) omentectomy, 1 (3.1%) biliointestinal bypass restoration, 7 (22%) umbilical hernia repairs, and 15 (47%) HH reductions with cruroplasty (Table 2). One patient underwent both the omentectomy and biliointestinal bypass restoration. The biliointestinal bypass restoration consisted of closure of the biliointestinal anastomosis with a linear stapler (60-mm ENDO GIA), cholecystectomy, closure of ileo-ileal anastomosis (T-L), and a restoration of intestinal continuity with a new ileo-ileal anastomosis, followed by

Table 2 Concomitant procedures and complications in 121 patients

Concomitant procedure	*N* (%)
Cholecystectomy	8 (6.7)
Omentectomy	1 (0.8)
Biliointestinal bypass restoration	1 (0.8)
Umbilical hernia repair	7 (5.8)
Hiatal hernia reduction and cruroplasty	15 (12.6)
Complication	*N* (%)
Intraoperative leak	1 (0.8)
Stricture	1 (0.8)
Extraluminal bleeding (trocar site)	1 (0.8)
Acute renal failure	1 (0.8)
Wound infection	2 (1.7)
Postoperative leak	0 (0.0)

sleeve gastrectomy. The omentectomy in this patient resulted in the complete excision of the omentum close to its emergence from the transverse colon. Mean postoperative time in hospital was 5.6 days (1–14).

Mortality, Leak Rate, and Complications

There was no perioperative or postoperative mortality in the series. In one case of intraoperative leak (0.8%) at the level of the incisura angularis corresponding to the first buttressed transection line, suture repair was not successful; after repeating the methylene dye test with two positive results, the procedure was converted to an RYGB. There were no postoperative leaks in the series. Overall complications (6, 5.0%) included one stricture, treated with endoscopic dilation; one extraluminal bleed at the trocar site, treated with a blood transfusion; one acute renal failure 1 week after surgery, treated in the intensive care unit (patient discharged after 10 days); and two wound infections, managed with drainage and antibiotics (Table 2).

The patient who developed stricture postoperatively had a gastric band removed 8 months prior to the planned LSG; the stricture developed before the gastric angle at the level of the last unbuttressed staple line. The patient with postoperative bleeding experienced a decrease of hemoglobin concentration from 14.5 to 11.0 mg/dL within the first 24 postoperative hours; there was no blood drainage through the drainage tube positioned close to the excision line. A CT contrast study in POD1 showed a large properitoneal blood collection near the left side trocar site. This acute bleeding was treated with blood cell unit transfusion and resolved within 48 h.

Of the 15 patients operated concomitantly for HH, three (20%) recurred; one of these, who had also previously received crural repair by interrupted nonabsorbable sutures that was reinforced with a pledget of bovine pericardium with collagen matrix (PSD), was revised to an RYGB. Two patients of the two-stage series developed HH following LSG; one was revised 14 months postsurgery to RYGB, and the other, who received to a BPD/DS 5 months after the sleeve, underwent cruroplasty and fundectomy 38 months after the second stage because of untreatable symptoms. In this case, in a 50-year-old woman with a preoperative BMI of 78 kg/m^2, HH was not clearly recognized during her LSG procedure, and a complete fundectomy was difficult to achieve at that time; thus, during the revisional cruroplasty (at which time the patient had a BMI of 27 kg/m^2), a re-resection of the fundus was performed to control her reflux symptoms (Fig. 1). The fundectomy was performed with the use of reinforced 45-mm blue cartridges close to a 40 Fr gastric bougie. The assistant surgeon exposed the fundus using posterolateral traction while the surgeon applied traction on the sleeved stomach with the left hand, and transected the stomach with the linear stapler in the right hand, as close to the 40 Fr gastric bougie as possible.

Weight Loss

In the follow-up of 55 patients at the postoperative 6-month point, BMI decreased 24.7% to 37.5±9.3 (range 22.2–58.1) representing a significant change of −12.3 from baseline ($p<0.001$). Total group %EWL at 6 months was 48.1±19.3 (15.5–98.9) (Table 3). In the subgroup analysis of %EWL at 6 months, there were no significant differences between males and females, age groups (<33, ≥33–<43, ≥43 years), or comorbidity group (comorbidity presence vs. not present); however, a significant difference was found between BMI subgroups (<40, ≥40–<50, ≥50; $p<0.001$). Nonparametric ANOVA followed by independent Mann–Whitney *U* tests

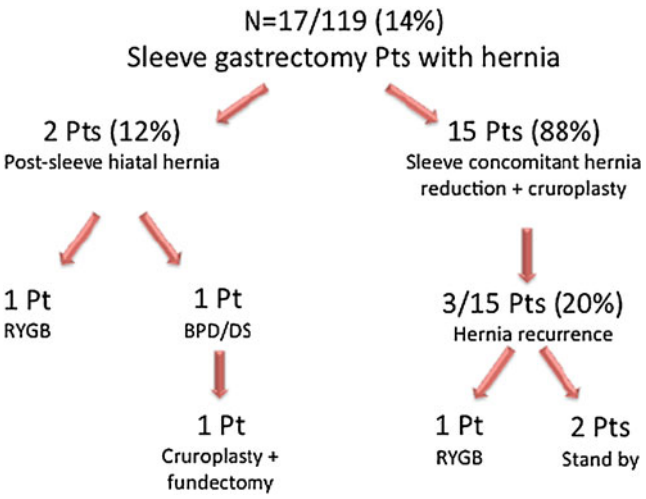

Fig. 1 Laparoscopic sleeve gastrectomy and hiatal hernia. *Pts* patients, *BPD/DS* biliopancreatic diversion/duodenal switch, *RYGB* Roux-en-Y gastric bypass

Table 3 Total and subgroup weight loss at 6 months

Total group	Value N=55			
	Mean ± SD (range)	Mean change (% change)	95% CI	p value[a]
Absolute weight (kg)	103.0±26.8 (59.6–165.9)	−33.9 (24.8)	−37.7–−30.2[b]	<0.001
BMI (kg/m^2)	37.5±9.3 (22.2–58.1)	−12.3 (24.7)	−13.6–−11.0[b]	<0.001
EWL (%)	48.1±19.3 (15.5–98.9)	–	42.9–53.3[c]	–
Subgroups	N	Mean ± SD (range)	95% CI[c]	p value
EWL (%), by gender				
Females	37	48.1±20.2 (15.5–98.9)	41.4–54.8	NS[d]
Males	18	48.1±17.8 (17.4–82.6)	39.2–57.0	
EWL (%), by age (years)				
<33	18	53.3±21.8 (15.5–87.6)	42.5–64.1	NS[e]
≥33–<43	16	45.2±19.6 (20.8–98.9)	34.8–55.6	
≥43	21	45.9±16.7 (17.4–71.6)	38.3–53.5	
EWL (%), by BMI				
<40	12	63.3±20.5 (29.4–98.9)	50.3–76.3	<0.001[e]
≥40–<50	15	54.7±11.7 (29.4–70.3)	48.2–61.2	
≥50	28	38.0±16.5 (15.5–86.9)	31.6–44.4	
EWL (%), by comorbidity				
Present	29	46.2±19.9 (15.5–98.9)	38.6–53.8	NS[d]
Not present	26	50.2±18.7 (20.8–87.6)	42.7–57.8	

BMI body mass index, *EWL* excess weight loss, *CI* confidence interval

[a] Paired samples t test assessing change from baseline

[b] 95% CI of mean difference

[c] 95% CI of the mean

[d] Independent samples Mann–Whitney U test

[e] Kruskal–Wallis one-way ANOVA

revealed significant differences between the lowest and highest BMI groups, and also between the mid-range BMI and highest BMI groups, but no statistically significant difference between the lowest and the mid-range BMI groups (Table 3). Figure 2 presents mean BMI and %EWL following LSG with respect to time from 1 to 48 months. At 12 months (n=41), BMI was 38.4±10.5 (19.3–62.3) with 51.7±25.0 (8.9–123.3) %EWL; at 24 months (n=23), BMI was 37.5±7.5 (24.7–49.7) with 53.1±16.6 (25.3–84.5) % EWL; at 36 months (n=11), BMI was 35.5±8.8 (25.9–51.9) with 63.9±14.0 (35.2–81.0) %EWL; and at 48 months (n=13), BMI was 35.6±6.8 (24.9–47.5) with 61.1±12.2 (43.9–82.1) %EWL.

Table 4 presents the bivariate analysis results investigating preoperative clinical variables and their potential value in predicting suboptimal weight loss at 6 months. Pre-sleeve BMI was the only significant predictor in the bivariate analysis; however, patient ASA score and presence of T2DM trended toward significance and were, therefore, incorporated into the multivariate model. Figure 3a depicts the results of bivariate correlation analysis of %EWL and BMI at 6 months (Pearson r=−0.58; p< 0.001). Preoperative BMI accounted for 33.6% of the variance in %EWL and, as a lone predictor, was found to correctly classify >70% of patients who experienced <50% EWL at 6 months. (At 3 years, preoperative BMI accounted for 72.3% of the variance in %EWL, n=11.) Figure 3b presents results of logistic regression analysis in the form of a probability curve. As BMI remained the only significant predictor (odds ratio=1.13, 95% CI 1.05–1.21, p<0.001) in the multivariate model, its beta coefficient and associated constant were used to develop the equation characterizing the likelihood of suboptimal weight loss (%EWL <50 at 6 months) as a function of preoperative BMI.

Diabetes Subgroup Analysis

Two weeks following LSG, 100% of preoperative T2DM patients (n=23, mean preoperative T2DM duration 3.7 years [range 1–10]) were in remission and off all medical therapy. Mean glycosylated hemoglobin (HbA_{1C}, %) in the diabetic subgroup was 6.5±0.8, reduced from a baseline HbA_{1C} of 7.6±1.6 (p<0.01); mean glycemic level (mg/dL) was 90.6± 22.4, reduced from 133.9±29.6 (p<0.01). Three-month data (Table 5) confirmed and reinforced 2-week results: 100% of patients remained off diabetic medication; HbA_{1C}

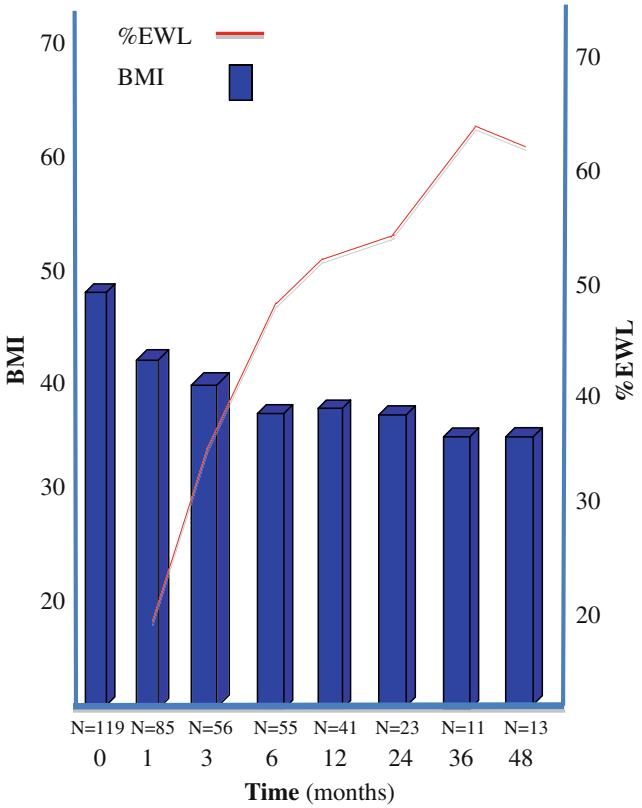

Fig. 2 Body mass index (BMI) and percentage excess weight loss (% EWL) with respect to time following laparoscopic sleeve gastrectomy

was 5.9±0.5, a decrease of 22.4% from baseline ($p<0.001$); and mean glycemic level, 90.0±19.9, a decrease of 32.8% from baseline ($p<0.01$). Cholesterol and triglyceride reduction in the T2DM subgroup trended toward significance. In addition, at 3 months, diabetic subgroup BMI decreased 18.7% from baseline ($p<0.01$) with a mean %EWL of 37.2±11.7 (18.8–53.1), which was not significantly different from %EWL of the nondiabetic subgroup (34.1±13.0 [16.0–66.5]).

Discussion

San Giovanni Bosco Hospital, Naples, has steadily increased its annual use of the LSG procedure since 2002; this is consonant with increased performance of SG in Italy, and globally [24, 33]. We began performing LSG as the first step of a two-stage procedure (BPD-DS) in super-obese patients (1/62 cases in 2002, 4/74 [2003], 6/100 [2004], 3/100 [2005], 3/97 [2006]). Considering the minimal morbidity and complications experienced by our patients, combined with satisfactory weight loss, in 2007, we began offering LSG as a definitive procedure for the treatment of mild obesity as well, extending this procedure to a larger number of patients (15/102 [2007], 19/96 [2008], 67/110 [2009], 148/169 [2010]).

In the current study, our early findings of 48.1% and 51.7% EWL at 6 and 12 months, respectively, are in the range of the mean EWL, 55.4%, reported in the systematic review of 2,570 SG patients (36 studies, 3–60 month follow-up) by Brethauer et al. [15], and 60.7% in a large international questionnaire-based consensus review (representing 14,776 SG patients, 12-month follow-up) by Gagner et al. [34]. Other approved bariatric procedures realize a weight-loss zenith at 2–4 years with some weight regain at 3–5 years. In the only >5-year SG series with

Table 4 Bivariate analysis of preoperative clinical variables with respect to weight loss following sleeve gastrectomy at 6 months

Variable	<50% EWL (*N*=29)	≥50% EWL (*N*=26)	*p* value
Age	39.5±10.5	38.1±11.3	NS[a]
Male sex	9 (31.0%)	9 (34.6%)	NS[b]
BMI	54.2±8.8	45.0±8.2	<0.001[a]
ASA score	3.6±0.6	3.4±0.7	NS[a] (0.16)
Number of comorbidities	1.2±1.4	0.9±1.2	NS[a]
Comorbidity			
Hypertension	12 (41.4%)	12 (46.2%)	NS[b]
OSA	9 (31.0%)	6 (23.1%)	NS[b]
T2DM	8 (27.6%)	3 (11.5%)	NS[b] (0.13)
Hyperlipidemia	5 (17.2%)	2 (7.7%)	NS[b]

EWL excess weight loss, *BMI* body mass index, *ASA* American Society of Anesthesiologists (physical status classification score), *OSA* obstructive sleep apnea, *T2DM* type 2 diabetes mellitus

Data are expressed as mean ± SD for continuous variables, and *N* (%) for categorical variables

[a] Mann–Whitney *U* test

[b] Fisher's exact test

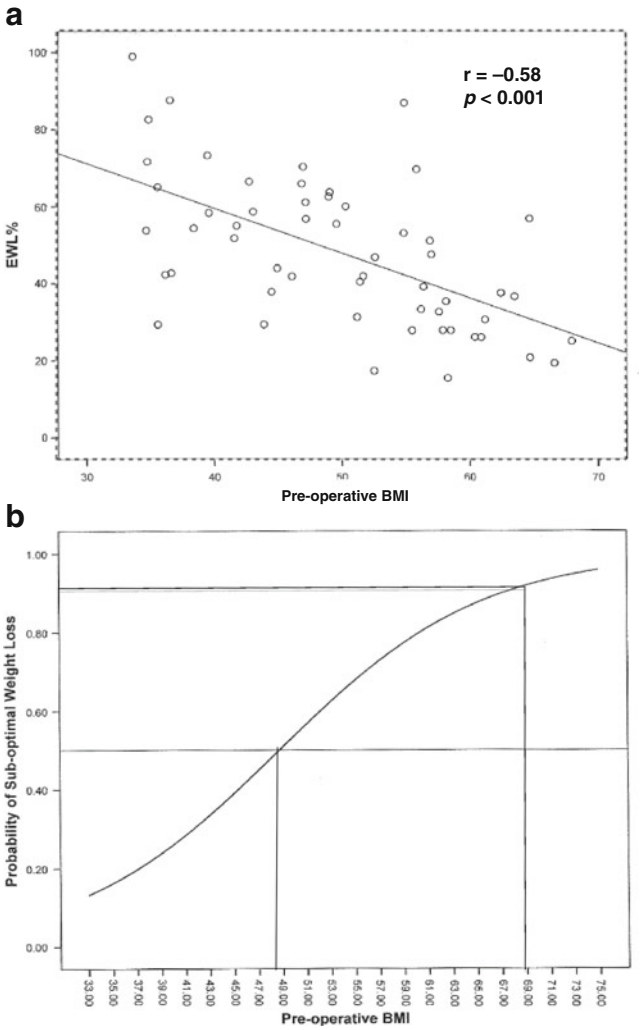

Fig. 3 **a** Scatter plot and regression line depicting inverse relationship between preoperative body mass index (BMI) and percentage excess weight loss (%EWL) following laparoscopic sleeve gastrectomy at 6 months. **b** Probability curve characterizing likelihood of patient with a given preoperative BMI experiencing %EWL <50 6 months following laparoscopic sleeve gastrectomy. For example, a patient with a pre-sleeve BMI of 48.5 is predicted to have a 50% chance of experiencing a 6-month weight-loss outcome of <50% EWL, whereas a patient with a pre-sleeve BMI of 69 is predicted to have a 90% chance of experiencing a 6-month weight-loss outcome of <50% EWL

complete follow-up (n=26), a 2010 study by Bohdjalian et al., 3-year EWL was 60%, and 55% at 5 years [35]. Although only a small number of LSG patients in our study had reached 3-year (63.9% EWL) and 4-year (61.1% EWL) follow-up, their weight loss suggests a similar trend.

In our series, the lowest BMI group (<40) experienced the greatest %EWL, significantly more than the highest BMI group (≥50). When treated as a continuous variable, correlation and logistic regression analyses demonstrated that preoperative BMI was predictive of suboptimal weight loss. This analysis, and resultant probability curve, may be useful in aiding patients to visualize their likelihood of requiring a second operation, and may promote realistic weight-loss expectations. For example, a patient with a pre-LSG BMI of 48.5 would have a 50% chance of experiencing a 6-month outcome of <50% EWL, whereas a pre-LSG BMI of 69 would predict a 90% chance of <50% EWL at 6 months. This finding may be due to the fact that the patients with a higher preoperative BMI were initially subjected to temporary IB treatment which resulted in substantial weight loss prior to undergoing LSG.

Rapid improvement of T2DM following the primarily restrictive SG typically occurs within weeks of surgery, similar to that following primarily malabsorptive procedures. In the current study, mean HbA_{1C}, glycemia, and triglyceride levels were reduced to within normative reference ranges at 3 months after surgery, and 100% of the T2DM subgroup no longer required T2DM medication. The percentage of those in whom T2DM resolved was superior to resolution observed in the majority of SG reports, which ranges from 14% to 100% [5–7, 36–45].

There was no mortality in our series. In two recent reviews of LSG (n=3,510), mortality ranged from 0.17% to 0.24% [15, 46]. The overall complication rate ranges from 0% to 24% (mean 9.4% high-risk/staged, 6.2% primary [15]) in the SG literature; complications in the current study were low, 5.0%. Hiatal hernia, sometimes with gastroesophageal reflux disease (GERD), is a frequent occurrence in the obese (15% incidence symptomatic HH in BMI >35 [47]), and in most instances, bariatric surgery successfully treats the hernia (restoring cardioesophageal competence [48, 49]), obesity, and GERD [50]. In our series of 15 patients with HH operated concomitantly with LSG, three (20%) recurred, one was revised to RYGB, and two await reoperation. Of patients who developed HH postoperatively (patients of the two-stage series), one was revised 14 months postsurgery to RYGB, and the other, who received a BPD/DS 5 months after the sleeve, underwent cruroplasty and fundectomy 38 months after the second stage because of untreatable symptoms.

In the super-super obese patients undergoing LSG, it may be very difficult to recognize a crural defect, and especially considering the aim of this "salvage operation," it might not be indicated to perform complex and risky esophageal dissection. In the case of a 50-year-old woman with a preoperative BMI of 78 kg/m^2, during her LSG procedure, HH was not clearly recognized, and a complete fundectomy was not attempted at that time. SG can improve or ameliorate symptoms of preoperative GERD in 40% to 85% of patients if there is successful crural repair [51]. In the authors' experience, "trans-hiatal sleeve migration" with crural dehiscence carries severe GERD symptom recurrence. When HH cannot be satisfactorily repaired at time of LSG, conversion to RYGB should be considered. In

Table 5 Metabolic outcomes for diabetic patients at 3 months

Outcome	Value			
	Mean ± SD (range) N=23			
	Preop	Postop	Mean change (% change)	p value[a]
Absolute weight (kg)	137.6±31.3 (80.0–196.2)	111.6±26.2 (72.0–149.0)	−26.0 (18.9)	<0.01
BMI (kg/m^2)	50.8±8.9 (34.0–62.4)	41.3±7.9 (32.3–54.9)	−9.5 (18.7)	<0.01
Systolic BP (mmHg)	123.3±5.8 (110.0–140.0)	120.0±10.0 (110.0–130.0)	−3.3 (2.7)	NS
Diastolic BP (mmHg)	82.0±2.0 (60.0–90.0)	72.0±10.6 (60.0–80.0)	−10.0 (12.2)	NS
Glycemia (mg/dL)	133.9±29.6 (93.0–234.0)	90.0±19.9 (62.0–116.0)	−43.9 (32.8)	<0.01
OGTT (mg/dL)	138.1±46.4 (92.0–232.0)	87.3±20.3 (62.0–122.0)	−50.8 (36.8)	<0.05
HbA_{1C} (%)	7.6±1.6 (6.2–13.5)	5.9±0.5 (5.3–7.2)	−1.7 (22.4)	<0.001
Cholesterol (mg/dL)	217.4±47.6 (138.0–289.0)	198.9±35.4 (133.0–297.0)	−18.5 (8.5)	NS (0.07)
HDL (mg/dL)	46.4±9.8 (29.0–56.0)	43.6±5.7 (36.0–60.0)	−2.8 (6.0)	NS
LDL (mg/dL)	122.8±35.5 (69.0–184.0)	122.5±33.6 (72.0–172.0)	−0.3 (0.2)	NS
Triglycerides (mg/dL)	239.6±157.6 (83.0–567.0)	132.6±45.2 (86.0–215.0)	−107.0 (45.0)	NS (0.09)

Preop preoperative, *Postop* postoperative, *BMI* body mass index, *BP* blood pressure, *OGTT* oral glucose tolerance test, HbA_{1C} glycosylated hemoglobin, *HDL* high-density lipoprotein, *LDL* low-density lipoprotein

[a] Paired samples t test assessing change from baseline

reference to this problem, Himpens et al. [52], in their long-term study, had preoperatively excluded patients with significant GERD and reported 23% to 26% of patients suffering from frequent episodes of GERD. They also claim that the "neo-fundus" formation was responsible for both weight regain and GERD. With these indications, two patients in their series were re-sleeved. In this classic paper, no mention is made of crural dissection and repair.

Although incidence of anastomotic leak is relatively low in SG, 2.2% (0% to 20%) [53], its potential to increase morbidity, length of hospital stay, and mortality is great, and there is no agreed standard procedure for leak prevention. Kasalicky et al. report no leak at 18-month SG follow-up without a reinforced staple line; their technique incorporates waiting 30–60 s after stapler closure before firing, use of 1–2 interrupted stitches to control bleeding, and covering the staple line with 100% oxygenous cellulose to prevent residual bleeding [42]. However, the 2009 international summit on SG reported that staple-line reinforcement was employed by 65.1% of surgeon responders; 42.1% used buttressing material, 50.9% oversewed, and 7.0% used both methods [34]. Surgeons have employed running or interrupted absorbable or nonabsorbable sutures to oversew the transection line, as well as segments of dehydrated bovine pericardium (Per-Strips Dry® [PSD], Synovis), absorbable polymer (Seamguard®, Gore), and fibrin sealants. A randomized trial of buttressing material used in SG by Dapri et al. found no significant difference in postoperative leak between no reinforcement, Seamguard, and suturing (PSD was not a comparator) [54]. Other studies have evaluated PSD efficacy in their procedures and demonstrated minimization of leak [26, 55–58]. In a prior randomized trial at our institution, RYGB staple-line reinforcement with PSD mounted on the linear stapler was shown to significantly reduce extraluminal bleeding, obtain a dry operating field, abbreviate operating time, and also, reduce leak [26]. This evidence combined with that of prior SG studies with good results using PSD buttressing influenced our use of the same material to reinforce the transection line in SG. The incidence of leak in the current study was 0. Although there was no controlled comparison, we speculate that the use of PSD reinforcement was a central factor in this outcome. Since summarizing the current data, we have continued our series of reinforced LSGs, now totaling 250 patients, 42 with cruroplasty, maintaining 0 gastric leaks and no mortality.

A limitation of the study is that it was retrospective and lacked a controlled comparison group. Also, early staged procedures in high-risk patients were combined with primary operations, and comorbidity data other than for T2DM were not studied in detail.

In conclusion, improved strategies for diagnosis and management of hiatal hernia preoperatively and intraoperatively in SG are needed; crural repair pledgets and/or mesh, and the associated procedure for their implementation, require standardization. The combination of meticulous surgical technique, PSD reinforcement of the gastric staple line, and a low threshold of conversion to RYGB or

BPD/DS make SG a safe and effective operation in the short term. Weight loss and T2DM outcomes for SG require confirmation over the long term.

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

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