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SHORT- AND MID-TERM OUTCOMES OF SLEEVE GASTRECTOMY FOR MORBID OBESITY: THE EXPERIENCE OF THE SPANISH NATIONAL REGISTRY

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ABSTRACT

Background Reports on laparoscopic sleeve gastrectomy (LSG) communicate very good short-term results on very high-risk morbid obese patients. However, mid- and long- term results are still unknown. A National Registry has been created in Spain to achieve information on the outcomes of this bariatric procedure.

Methods Data were obtained from 17 centers and collected in a database. Technical issues, preoperative comorbid conditions, hospital stay, early and late complications, and short- and mid-term weight loss were analyzed.

Results Five hundred forty patients were included; 76% were women. Mean BMI was 48.1 ± 10. Mean age was 44.1 ± 11.8. Morbidity rate was 5.2% and mortality rate 0.36%. Complications presented more frequently in superobese patients (OR, 2.8 (1.18–6.65)), male (OR, 2.98 (1.26–7.0)), and patients >55 years old (OR, 2.8 (1.14–6.8)). Staple-line reinforcement was related to a lower complication rate (3.7 vs 8.8%; $p = 0.039$). Mean hospital stay was 4.8 ± 8.2 days. Mean follow-up was 16.5 ± 10.6 months (1–73). Mean percent excess BMI loss (EBL) at 3 months was 38.8± 22, 55.6 ± 8 at 6 months, 68.1 ± 28 at 12 months, and 72.4± 31 at 24 months. %EBL was superior in patients with lower initial BMI and lower age. Bougie caliber was an inverse predictive factor of %EBL at 12 and 24 months (RR, 23.3 (11.4–35.2)). DM is remitted in 81% of the patients and HTA improved in 63.2% of them. A second-stage surgery was performed in 18 patients (3.2%). *Conclusions* LSG provides good short- and mid-term results with a low morbid-mortality rate. Better results are obtained in younger patients with lowest BMI. Staple-line reinforcement and a thinner bougie are recommended to improve outcome.

KEYWORDS

Sleeve gastrectomy

Mid-term results

Spanish National Registry

Obesity surgery

INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) was initially proposed as a first-stage procedure to perform in higher- risk patients to achieve a significant weight loss prior to complete more complex bariatric procedures in a second stage [1, 2]. Many surgeons reported an acceptable complication rate and a significant weight loss following LSG in higher-risk patients [3–6]. Soon, it was noted that patients frequently lost so much weight that they did not require a second stage. These positive results encouraged surgeons to perform LSG more frequently. Some surgeons commenced to perform LSG as a sole bariatric operation, going on to a second stage only in those selected patients in which weight loss was inadequate [7]. Moreover, LSG was proposed as a technique for patients whose weight was not severe enough to require a complex bariatric operation [8]. Eventually, LSG was performed in some patients with special conditions in which usual bariatric operations might be too aggressive [9–11].

Preliminary data shared in the Congress of Spanish Society of Obesity Surgery and Metabolic Diseases (SECO) in 2007 suggested that the number of LSG performed in Spain had grown exponentially in the last years; we proposed to perform a Multicenter Spanish National Registry to evaluate results following LSG in our country attending not only to morbidity and mortality but to know also mid- and long-term weight loss results.

PATIENTS AND METHODS

An electronic data sheet (50 items) was specifically created. It was e-mailed to all members of the SECO. Returning data were collected together in an electronic database (Microsoft Excel 2003 Microsoft Corporation, One Micro- soft Way, Redmond, Washington 98052-6399, USA) for statistical analysis.

Study endpoints included technical issues (distance from the staple-line to the pylorus, bougie caliber, staple- line reinforcement) preoperative comorbid conditions (hypertension, diabetes, osteoarthritis), length of hospital stay, early complications (gastrointestinal hemorrhage, abdominal hemorrhage, anastomosis leakage, obstruction, wound infection, urinary infection, pulmonary embolism, pneumonia, phlebitis, cardiopulmonary complication…), late complications (stenosis, obstruction, ventral hernia, etc.), and mid-term weight loss (total weight loss, final BMI, excess BMI loss, and percentage of patients with more than 50% of excess BMI loss). Follow-up was obtained at 3, 6, 12, 24, and 36 months.

Statistical analysis was performed with the Statistical Package for the Social Science (SPSS) 13.0 for Windows (SPSS Inc, Chicago, IL, USA). Descriptive data were expressed as mean value ± SD or percentage. The Chi- square test or the Fisher test, when necessary, was used to compare qualitative variables, and the ANOVA or Mann– Whitney tests were performed to compare quantitative ones. Multivariate logistic regression and multivariate lineal regression were performed to evaluate prognostic factors. A $p < 0.05$ was considered significant.

RESULTS

Data from 540 patients who underwent LSG from February 2002 to May 2008, treated at 17 centers (17 surgeons), were included into the Spanish National Registry. All procedures were performed laparoscopically; 76% of the patients were women and 24% were men with a mean BMI of 48.1 ± 10.0 kg/m^2 (range 28–82) and a mean age of 44.1± 11.8 years (range 10–72).

Technique Selection

Different reasons to choose LSG were reported. Only on 39.2% of the cases was LSG performed on patients with a BMI over 50 kg/m^2 and severe conditions associated. The rest of the patients were submitted to LSG for other different reasons: in 21% of the cases, a BMI under 40 kg/m^2 and two comorbid conditions indicated the operation; in two cases, the young age of the patient was the reason to perform LSG; in seven cases, it was the advanced age; in ten cases, hepatomegaly or cirrhosis; in seven cases, gastric pathology; in two cases, a giant ventral hernia; and in three cases, technical difficulty.

Technical Issues

Five trocars were used in most of the cases (two 12 mm, two to three 10 mm, one 5 mm). The staple- line started close to the pylorus in 58, 8% of reported cases, while in

41% of the patients, the first stapler was applied at a minimum distance of 5 cm from the pylorus. A bougie was used in 76.1% of patients. The caliber of the bougie was 32–34 French in 68.3% of the cases, 38 F in 25.5%, and 48, 54, or 60 F in just a few cases. Staple-line reinforcement was performed in 70.6% of the patients: In 82.2% a running monofilament absorbable suture was applied; in 12.6%, a running monofilament non-absorbable suture was used; and in 5.2%, Gore Seamguard® bioabsorbable membranes (WL Gore & Associates, Newark, DE, USA) were used.

Table 1 Staple-line reinforcement reduced staple-line complications

Postoperative Complications

The postoperative complication rate was 5.2%. Major complications were staple-line leakage that presented in 2% of the cases, abdominal bleeding in 0.7%, gastrointes- tinal bleeding in 0.4%, pulmonary embolism in 0.2%, and one case each of subphrenic abscess, liver failure, and stricture in relation to the running suture, which was removed in a second operation. Minor complications reported were one case of bradycardia, one urinary sepsis, one wound infection, and two cases of hematuria.

Gastric leakage was detected in 11 patients. In most of the cases, it was diagnosed after a upper gastrointestinal examination; in one case, it was diagnosed after methylene- blue oral administration. Only one leakage was reported in patients submitted to LSG as a second procedure after a lap-band failure (2.9%); this patient required reoperation for debridement,

and the leak healed in 21 days. In two cases, a coated self-expanded wallstent was employed; in two patients, a gastro-jejunostomy was performed; one patient required a re-sleeve of the upper stomach; two patients were reoperated for debridement; and the rest were maintained with nothing per os, intravenous antibiotics, and total parenteral nutrition.

Thromboembolic prophylaxis was performed with low- molecular weight heparin on the day before surgery, 8 h after surgery, and once daily to complete 30 days after the operation. Early deambulation was promoted by all groups, and in some centers, sequential compression devices were also used during the operation.

Complications presented more frequently among super- obese patients (BMI >50 kg/m^2; 8.1% vs 3.4%; p=0.015). The rate of complications increased parallel to the increase in BMI: In patients with BMI under 40 kg/m^2, the complication rate was 2.7%; in patients with BMI between 40 and 49 kg/m^2, it was 3.3%; for patients with BMI between 50 and 59 kg/m^2, it was 7.2%; and when the BMI was over 60 kg/m^2, the complication rate was 10% (p=0.009). Male patients suffered more complications than female ones (10.1% vs 3.5%, p=0.001). An increase in the complication rate was observed with the increase in the age of the patient (OR, 1.04 (1.01–1.07)); a higher risk was observed for patients over 55 years (OR, 2.8 (1.14–6.8) p=0.023).

Staple-line reinforcement reduced global complications (3.7% vs 8.8%; p = 0.039), especially the staple-line complications, as bleeding or leak, were both reduced (Table 1). There were no differences between the employ- ment of a running suture or Gore Seamguard® (WL

Gore). The distance of the first stapler to the pylorus or the caliber of the bougie was not related to postoperative complications.

Multivariate logistic regression analysis revealed male gender (OR, 2.98 (1.26–7.04), p=0.007), BMI over 50 kg/m^2 (OR, 2.8 (1.18–6.65), p=0.023), and age over 55 years (OR, 2.8 (1.14–7.04), p=0.023) as the three independent prognos- tic factors for an increased probability of postoperative complications.

Two patients died during the postoperative period (0.36% mortality rate). One of them was a male patient with 73 kg/m^2 BMI who suffered port-site postoperative bleeding and developed a multiple organ failure after reoperation. The other one was a male patient with sleep apnea who developed respiratory failure with pneumonia and died in the 14th postoperative day. Mean hospital stay was 4.8±8.2 days (range 1–108).

Regarding the late complications, there were four cases (0.7%) of biliary reflux reported: Three of them were reoperated and submitted to a laparoscopic gastric bypass, while the other was maintained on medical therapy.

Weight Loss

Mean follow-up was 16.5± 10.6 months (range 1–73). There were 281 patients with 12 months follow-up and 120 patients with 24 months follow-up, and only 33 patients reached 36 months follow-up.

Mean initial BMI was 46.97±9.8. During follow-up, a significant decrease of BMI was

observed in most patients. Mean BMI was 37.9±8.1 at 3 months, 34.03±7.3 at 6 months, 31.8±7.2 at 12 months, 30.38±7.8 at 24 months, and 31.3±6.2 at 36 months. Mean BMI at 6 months was 34.03±7.3, mean BMI at 12 months was 31.8±7.2, mean BMI at 24 months was 30.38±7.8, and mean BMI at 36 months was 31.3±6.2. Mean percentage of overweight loss (%EWL) at 3 months was 40.67±13.9, at 6 months was 55.13±14.9, at 12 months was 63.83±19.1, at 24 months was 68.5±35.2, and at 36 months was 67.12±23.6. Mean percentage of excess BMI loss (%EBL) at 3 months was 38.8±22, at 6 months was 55.6±8.0, at 12 months was 68.1±28.9, at 24 months was 72.4±31.1, and at 36 months was 72.1±21.8.

Patients (81.7%) lost more than 50% of EB at 12 months of follow-up; 86% lost more than 50% of EB at 24 months; and 85.7% of patients lost more than 50% of EB at 36 months. % EBL was higher in patients with lower initial BMI, especially in those with initial BMI under 40 kg/m^2 (Table 2). Patients (15%) were considered failures in weight loss if they had regained their weight in the first 3 years of follow-up.

Weight loss was not related to gender. However, a significant inverse correlation was observed between age and %EBL during follow-up. %EBL was significantly lower when patients were above 50 years old (Table 3).

Some technical features were found related to weight loss. A close application of the first stapler to the pylorus was related to a higher %EBL during the first and second years of follow-up, though statistical signification was only obtained in the first year (Table 4).

Calibration of the stomach with a thinner bougie was also related to a better weight loss (32–36 French bougie vs 38–60 French ones, Table 5). The multivariate analysis revealed bougie caliber as an inversely correlated independent prognostic factor of % EBL at 6 months (RR 28.8 (19.9–37.7), $p<0.005$), 12 months (RR 23.3 (11.4–35.2), $p < 0.005$), and 24 months (RR 37.3 (5.1–69.7), $p=0.024$).

Alimentary Comfort

Most of the patients reported a very good alimentary comfort with an adequate tolerance for most aliments; only beef meat was poorly tolerated in some cases, but protein intake was adequate.

Comorbid Condition Outcome

Diabetic patients (81%) reported remission of their diabetes (evaluated by local endocrinologist: Remission was considered when there were no needs of medical treatment and blood glucose was under 126 mg/ml). Remission or improvement of hypertension was reported in 63.2% of the cases. Patients (85%) reported significant improvement of joints pain. Collected data regarding sleep apnea evolution were inadequate to extract any conclusion due to a high number of missing values.

Second-Stage Surgery

Eighteen patients were submitted to the second-stage surgery (3.3%). In ten patients, a laparoscopic Roux-en-Y gastric bypass (LRYGB) was performed, and in eight patients, a duodenal switch (DS) was carried out. The indication of a second stage was insufficient weight loss in most cases but in three, in which the indication was a severe gastro-esophageal reflux. One patient died 2 months after the second operation because of heart failure. No other complications were reported.

DISCUSSION

The number of LSG performed all over the world has increased in the last years but long-term results are still unknown [1–8]. The "Position Statement on Sleeve Gastrectomy as a Bariatric Procedure" issued by the American Society for Metabolic and Bariatric Surgery responded to numerous inquiries made by patients, physi- cians, and surgeons about this "new" bariatric procedure [12, 13]. In Spain, we observed something similar, with an exponential increase in the number of LSG performed in the last 2 years. Nevertheless, there was a lack of information about preliminary results of this operation in our country. Thanks to the collaboration of the Spanish bariatric surgeons, we collected 540 cases of LSG performed in Spain. Regarding safety of the procedure, we observed a low mortality rate (0.36%), lower than the overall published mortality associated to laparoscopic gastric bypass (LRYGB; 0.5%) or bilio-pancreatic diversion (BPD; 1.1%) [14, 15]. Complications rate (5%) was also lower than the overall published complication rate follow- ing LRYGB or BPD (10–20%) but the complications related to the staple-line (leak 2%, bleeding 1.1%) are close to

those published after LRYGB [14]. We found some risk factors related to postoperative complications. Male gender, BMI>50 kg/m^2, and age over 55 years old have demonstrated to be independent prognostic factors of a higher rate of complications. The same prognostic factors were identified for other bariatric procedures [16–18]. Laparoscopic surgery for morbid obesity is still not a common procedure, and thus, careful evaluation of opera- tive complications is essential. Although LSG may be a safer alternative in the superobese, LSG is not technically straightforward in patients with a massively enlarged left liver lobe. Surgeons performing laparoscopic bariatric surgery need to acquire the necessary skills in laparoscopic surgery and bariatric procedures, and a learning curve may be a decisive factor also in LSG [5].

In relation to postoperative complications, staple-line hemorrhage and leaks were significantly reduced when staple-line reinforcement was used. A significant reduction in staple-line complications may result in a shorter hospital stay, possibly leading to a decreased cost after laparoscopic bariatric surgery [19, 20].

In relation to weight loss results, we observed %EBL in the range of published results following LRYGB in the mid-term [14, 15]. The overall weight loss results we registered are better than many of the published series (Table 6) [21]. Probably, this may be caused by the employment of a thinner bougie (32–34 F) that Spanish surgeons use most frequently compared to the 46–60 F bougies referred in other studies [2, 3, 13, 21, 22, 26]. Consensus about the volume of the gastric tube is still pending. When LSG is associated with intestinal bypass, the final gastric volume may not be so influent in the amount of weight

loss, as was described by Sánchez- Pernaute et al. [23], and the same happens when LSG is performed as the first step of a duodenal switch. But, if the LSG was made as a sole technique, the volume of the gastric tube might be more important in the follow-up [24, 25], and LSG should be more restrictive than in the full DS as was suggested by Baltasar et al. [8].

The group of patients with smaller gastric tube had similar postoperative complications than the others, and they did not present more frequent vomiting or difficulty in gastric emptying. Although gastric dilatation after LSG is not common in the mid-term studies [26], we believe that an initial narrow tube may decrease the incidence of gastric dilatation and the need of further reoperation [27, 28].

With regard to weight loss following LSG, this has been superior than expected as a purely restrictive technique [29]. The gastric fundus resection may be in relationship with this outcome. Frübeck et al. [30] have suggested that the reduction in circulating ghrelin concentrations after bariatric procedures depends on the degree of exclusion of the gastric fundus, the principal site for ghrelin production and release. In the LSG, most of the fundus is removed, and this may be related to a reduction in ghrelin concentrations and a higher weight loss than other restrictive procedures as Lap-Band or vertical gastrectomy [31, 32]

In 6.8%, a LSG was performed after gastric banding failure, but we do not have additional data about the different techniques performed after band failure in Spain. In our opinion, LSG may be a good option after a band failure, especially in patients with adequate weight loss but with late complications related to the band. In patients with inadequate weight loss after a band, we may obtain poor results with the LSG as well. Although LSG seems to get better weight loss results than the gastric band in some studies [31, 32], more than 5 years follow-

up studies are needed to recommend LSG after a band failure. Studies comparing LSG with gastric banding in patients with BMI <50 are also necessary.

Our data showed better results regarding weight loss when initial BMI was lower. Patients with BMI under 40 kg/m^2 registered excellent results (86% EBL at 2 years). Superobese patients got poorer weight loss results (67% EBL at 2 years). This suggests that patients with lower BMI are probably the best candidates to perform LSG as a sole bariatric technique but probably, there are a larger number of patients with BMI superior to 40 kg/m^2 that will not need the second stage. Less than 4% of second step was reported in the Spanish Registry, but probably, there will be more cases needing a second surgical procedure with a longer follow-up in the future.

Age above 55 years old was a predictor for worst weight loss results. We think that if one-step surgery is considered, probably a more complex bariatric technique should be considered in this group of patients, especially in those with BMI >50 kg/m^2.

Regarding resolution of comorbidities, we found very good results in diabetes clinical remission (81%). A local endocrinologist evaluated the outcome of diabetes, and they reported to the database only the item “complete remission” or “improvement”, but HbA1c and oral glucose curve were not included in our first protocol. Nevertheless, we think that this information is nowadays essential, and it will be registered in further reviews of this study.

We observed that only 39% of patients in our Spanish Registry received LSG because BMI was superior to 50 kg/m^2 and they were considered as “higher-risk patients”. More than 60%

of patients received LSG for other reasons (hepatomegaly, cirrhosis, gastric pathology, giant ventral hernia, BMI <40 kg/m^2, children, elderly, conversion after lap-band failure, etc.). As Baltasar et al. [8] suggested, the LSG has been considered as a multi-purpose bariatric operation by Spanish surgeons.

At present time, LSG seems to be a very good alternative in higher-risk patients as first-step surgical procedure and can be considered a feasible alternative in patients with special conditions or even in cases of technical difficulties to complete a more complex bariatric technique. In our opinion, this study has some important limitations. One relevant weaknesses of this study is the large number of centers and surgeons involved in the National Registry. We have identified some variations in the technique that can influence weight loss results and may be different follow-up methods. However, this heterogeneous information we have got in this study is going to be very useful for designing some prospective studies dealing with LSG in Spain.

Obviously, more homogeneous and long-term follow-up studies are needed to assess the precise role of LSG in bariatric surgery.

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TABLES

Table 1. Staple-line reinforcement reduced staple-line complications

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Percentage	Without reinforcement (*n*=159)	With reinforcement (*n*=381)	p
Postoperative morbidity	8.8	3.7	0.039
Leak	5.3	2.6	0.24
Peritoneal bleeding	1	0.8	0.81
Gastrointestinal bleeding	1	0.4	0.47

Table 2. Relationship between initial BMI and weight loss outcome

	BMI <40 (*n*=112)	BMI 40-49 (*n*=212)	BMI 50-59 (*n*=146)	BMI >60 (*n*=70)	*p*	Mean (*n*=540)	Samples
%EBL 3m	48.01±29.3	43.8±18.6	27.8±13.01	36.3±25.04	<0.001	38.8±22.1	430
%EBL 6m	62.32±39.8	63.8±18.3	42.4±12.3	48.2±23.26	<0.001	55.6±8.01	381

%EBL 12m	77.9±43.7	74.4±20.1	55.29±18.6	67.7±20.7	<0.001	68.16±28.9	281
%EBL 24m	85.9±45.8	69.1±30.2	72.1±27.9	67.5±20.7	Ns (0.416)	72.38±31.1	120
%EBL 36m	101.3±5.3	60.9±18.3	72.5±24.4	78.9±16.6	Ns (0.067)	72.07±21.85	33

510 Table 3. Percentage of excess of BMI loss in relationship with age(cut point, 50 years old)

	Age <50 (*n* =356)	Age >50 (*n* =184)	*p*
%EBL 3 m	41.5±21.0	33.9±23.4	0.004
%EBL 6 m	58.9±24.4	49.9±27.4	0.005
%EBL 12m	71.8±27.3	62.1±30.5	0.015
%EBL 24m	76.3±34.6	65.2±19.2	0.076
%EBL 36m	79.6±22.9	59.3±14.1	0.015

Correlation (r Spearman) between age and %EBL in every period: Spearman coefficient at 3 months r=−0.21(p<0.0005); at 6 months r=−0.23 (p=0.0005); at 12 months r=−0.21 (p=0.0005); at 24 months (ns); at 36 months r=−0.38 (p=0.043)

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Table 4. Percentage of excess of BMI loss in relationship with first staple-line distance from pylorus

%EBL 3 m	46.6±18.7,0	32.9±22.6	<0.0005
%EBL 6 m	64.0±20.9	48.7±27.4	<0.0005
%EBL 12m	74.7±26.4	62.4±29.8	0.001
%EBL 24m	75±36.2	70.1±24.7	0.48
%EBL 36m	70.8±24.9	73.2±19.5	0.78

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Table 5 Relationship between excess of BMI loss (%) with bougie caliber

	Without boggie (*n*=117)	Bougie 32–36F (*n*=300)	Bougie 38–60F (*n* =123)	*p*
%EBL 3 m	46.3±17.7	48.4±17.5	21.2±20.26	<0.0005
%EBL 6 m	60.1±17.3	67.1±20.1	36.7±26.6	<0.0005
%EBL 12 m	65.1±21.3	80.3±23.7	55.3±32.1	<0.0005
%EBL 24 m	79.8±28.3	77.5±39.1	65.3±19.1	0.122
%EBL 36		70.04±22.5	66.17±11.8	0.62

m				

Table 6. Comparison of weight loss results (percentage of overweight loss (%EWL)) between Spanish Registry and other published series

Author(n)	Patients (n)	Preoperative BMI	Follow-up	%EWL	Complication rate (%)	Bougie
Lee et al. [35]	216	49	2 years	59	7.4	32 F
Cottam et al. [2]	126	65.3	1 year	46	13	46-50
Moon Han et al. [33]	60	37.2	1 year	83	2.9	48
Himpens et al. [34]	40	39	3 years	66	5	34
Baltasar et al. [8]	7	61–74	2–27 months	56	6.7	32
	7	>40	4–16 months	33–90		
	16	35–43	3–27 months	62		

Roa et al. [21]	30	41	6	52	13.3	52
Langer et al. [26]	23	48	18	57	nr	48
Regan et al. [3]	7	63	11	33	3	60
Spanish Registry 2008	540	48	24	68	5.2	(68% 32–34 F)