

Research Article

Does gastric resection volume influence sleeve gastrectomy results? a prospective study

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ABSTRACT

Background: Laparoscopic Sleeve Gastrectomy (LSG) is one of the most widespread procedures for the treatment of obesity. The results of LSG could be related to the gastric residual volume. Our aim is to evaluate the outcomes after LSG according to the resected gastric volume (RGV).

Methods: 105 patients were divided into three groups according to the RGV: 600-1200 mL (Group A: 34 patients), 1200-1800 mL (Group B: 38 patients), and >1800 mL (Group C: 33 patients). We evaluated the effects of LSG on weight loss (%EWL), gastroesophageal reflux (GERD), hypertension (HTA) and diabetes (DM2) at 3, 6, 12 and 36 months. Data were analyzed for normality of distribution with Shapiro-Wilk test.

Results: The overall %EWL at follow up was 34.8%, 42.6%, 53% and 57.7%. Statistically significant difference between group C and group A-B at 6 months was detected, as well as between group B-C and group A at 12 and 36 months. Overall prevalence of GERD was 63.8%, 62.9%, 61% e 43.8%, at 3, 6, 12 and 36 months respectively. An overall increase of GERD (40%) was observed at 12 months; this value decreased at 2.3% after 36 months. The HTA prevalence was 53.3%, 28.6%, 21% and 17.1%, with an overall reduction of 40% and 43.9% at 12 and 36 months. The DM2 prevalence was 28.6%, 18.1%, 12.4% and 9.5% at 3, 6, 12 and 36 months respectively, with an overall reduction of 31.5% at 36 months.

Conclusions: RGV influences outcomes of LSG on short-term and mid-term follow up and it predicts the results in terms of %EWL and improvement of DM2 and HTA.

Keywords: Obesity, Sleeve gastrectomy, Volume resected, Bariatric surgery

INTRODUCTION

Laparoscopic Sleeve Gastrectomy (LSG) represents nowadays one of the most popular operation for the treatment of morbid obesity.¹⁻³ During the consensus conference held in Coral Gable in 2011, Rosenthal et al

updated the best practice guidelines for the performing of LSG.³

However several authors describe different techniques.^{2,4} The mid- and long-term results after LSG in term of excess weight loss (%EWL) and reduction of comorbidities are not univocal.¹⁻³ This is due to the

different surgical techniques performed and protocols applied in the pre-, intra- and post-operative period.⁵⁻⁷ Some studies analyze the %EWL according to the surgical protocol,^{6,7} the reinforcement of the suture line^{5,8} and the calibre of the gastric tube used,^{1,2} aiming to demonstrate the relationship between the % EWL and the reduction of comorbidities on one side and the residual gastric volume on the other, without convincing results.

The aim of this study is to evaluate the improvement in weight loss and comorbidities after LSG, and their relationship with the resected gastric volume (RGV).

METHODS

This is a prospective observational study including morbidly obese patients who underwent LSG between April 2010 and September 2012 at our University Hospital.

According to the National Institute of Health, all patients with a body mass index (BMI) 40 Kg/m² or 35 Kg/m² with at least 1-coexisting obesity-related comorbidity, were eligible for the study. Before surgery, each patient was evaluated and followed for at least 6 months by a multidisciplinary team including the psychologist, the internist, the gastroenterologist and the nutritionist. All surgical operations were performed at the surgical unit of San Salvatore Hospital in L'Aquila (Italy), by a single surgeon with an experience of more than 500 LSG. The patients were divided into three different groups, according to the resected gastric volume (RGV), measured at the end of surgery. In the Group A were enrolled patients with a RGV inferior to 1200 ml, in Group B patients with a RGV between 1200 and 1800 ml, and in the Group C patients with a RGV greater than 1800 ml.

During the period considered, 147 patients met the inclusion criteria. Twenty patients were excluded due to complications that could affect the postoperative period and lead to possible bias. Twenty-two of the remaining patients were lost during the follow up (Figure 1). Finally 105 patients completed the three-year follow-up and were assessed.

The ethical committee of the Surgical Department of the University of L'Aquila approved the study's protocol. All patients signed a consent form.

Surgical technique and postoperative management

With the patient placed in the modified lithotomy position and in reverse Trendelenburg position with a 10° tilt a four trocars technique was used. The greater curvature of the stomach was dissected free by dividing the short gastric vessels with an ultrasonic scalpel (Ace® Ethicon Endo-Surgery), starting opposite to the Crow's foot (approximately 6 cm proximal to the pylorus) and reaching the angle of His. Sleeve calibration was

obtained by passing a 36-Fr gastric bougie, pushed toward and along the lesser curvature, and the stomach was transected with sequential firings of linear green and blue GIA reloads (Echelon® 60 mm Ethicon Endo-Surgery). The suture line was tested with methylene blue dye and reinforced with an absorbable running suture in case of positive test. A silicon drain was placed along the suture line. The resected stomach was extracted intact from the abdomen in a plastic bag, by enlarging the right subcostal incision. In order to measure the RGV and pressure leak, a 16-Fr Foley catheter was inserted in the gastric antrum and saline solution was manually injected using a 50-ml syringe until leakage was detected on the staple line. A suture was used to close the hole around the catheter. A simple manometric glass tube was used to evaluate the leak pressure in each specimen.



Figure 1: Study design.

All patients were double checked with a methylene blue test and upper gastrointestinal transit on the 2nd postoperative day and, if no leakage was detected, a liquid diet was started. The patients were discharged on the 5th postoperative day after eating mashed foods.

Follow up

The postoperative follow up was conducted by a bariatric surgeon of our team at 1, 3, 6, 12, 18 and 24 months after the operation and yearly thereafter. We evaluated the effects of LSG on % excess weight loss (%EWL), hypertension (HTA), type 2 diabetes (DM2) and

gastroesophageal reflux disease (GERD). %EWL was calculated according to the Metropolitan Life Insurance Tables for medium frame.⁹ Blood pressure was measured by the patient himself weekly during the rapid weight-loss phase, usually during the first 6 postoperative months, and re-checked at the outpatient clinic. We considered a blood pressure lower than 140/90 mmHg without antihypertensive drugs a resolution of the HTA.¹⁰ The diabetologists of our team monitored the patients every 3 weeks. A Plasma glucose level <100 mg/dL and HbA1c level <6.5% without hypoglycemic drugs were considered as resolution of diabetes.¹¹ Preoperatively we considered patients suffering from GERD in case of an antacid treatment was used for more than 2 weeks or the endoscopy showed esophagitis. According to Litterature,^{12,13} we use a medication score to assess the change in GERD conditions preoperatively, at 1, 3, 6 and 12 months postoperatively and twice a year thereafter. We assigned a number for each level as follows: 0 = no disease, 1 = borderline or controlled by diet and/or oral antacids, and 2 = proton pump inhibitors.

Statistical analysis

The study was designed as a prospective, parallel group trial to compare three different clinical entities. The data

were analyzed for normality of distribution with Shapiro-Wilk test. Because the data were distributed not normally, mean values of overall differences were compared among the groups, by a non-parametric analysis of variance, Kruskal-Wallis test, and post-hoc analysis for comparisons of pairs of mean values with Mann-Whitney test with Bonferroni adjustment for multiple comparisons, and thus significance for the univariate analyses was assessed at $p < 0.0167$. Categorical variables, expressed as percentage, were compared by χ^2 test and post-hoc analysis with Bonferroni adjustment for multiple comparisons. Comparisons between groups were analyzed on an intention-to-treat basis. For all other analysis to the exclusion therefore of post-hoc analysis a 5% significance level was adopted and the data analyzed using the Stata/IC 12.1 statistical package.

RESULTS

Patient's demographic characteristics are showed in Table 1. No statistical difference was found between the three groups in term of age, preoperative BMI, pressure leak and sex: RGV was not correlated to preoperative BMI or sex (Table 1).

Table 1: Characteristic of the patients studied, divided in group A, B and C (mean SD; N=105).

	Groups			Total N=105	p value
	Group A (VRS 600-1.200) n:34	Group B (VRS 1.200-1.800) n:38	Group C (VRS>1.800) n:33		
Age, mean±SD	39.8±11.8	40.8±13.7	41.1±12.5	40.37±13.7	p*=0.91
BMI, mean±SD	43.2±5.1	44.3±5.8	44.9±6.1	44.13±5.7	p*=0.89
Leak pressure (cmH ₂ O) mean±SD	27.1 ±9.2	26.5 ±13.8	23.8 ±11.6	26.1±11.2	p*=0.85
Sex, n (%) Female	22(64.7)	26 (68.4)	22 (66.6)	70 (66.7)	p°=0.78

BMI: body mass index; VRS: volume resected stomach; SD: standard deviation; $p^* > 0.05$ no statistically significant difference between each group using Kruskal Wallis test; $p^° > 0.05$ no statistically significant difference between each group using χ^2 test

Table 2: Relationships between volume resected stomach and percentage excess weight loss, %EWL, (mean SD; N=105).

Follow-up	Group A (VRS 600-1.200) n:34	Group B (VRS 1.200-1.800) n:38	Group C (VRS>1.800) n:33	Total N=105	P A vs B	P B vs C	P A vs C
3 po month, mean±SD	30.3±10.4	31.8±12.6	42.3±13.7	34.8±12.2	P=0.8	P=0.09	P=0.07
6 po month, mean±SD	38.6±9.2	40.5±14.3	48.6±15.4	42.6±12.9	P=0.8	P=0.04	P=0.02
12 po month, mean±SD	44.7±18.3	56.8±17.1	60.5±10.8	53±15.4	P=0.03	P=0.6	P=0.04
36 po month, mean±SD	51.4±21.6	60.1±21.2	65.6±18.4	57.7±20.4	P=0.03	P=0.8	P=0.03

Using Kruskal-Wallis test; $p < 0.05$ (statistically significant difference between each treatment); %EWL, percentage excess weight loss Group A vs Group B vs Group C

Overall %EWL at 3,6,12 and 36 months was 34.8%, 42.6%, 53%, 57.7%, respectively. A statistically significant difference between group C and group A-B at 6 months and between group B-C and group A at 12 and 36 months was found (Table 2 and Figure 2). Preoperative prevalence of GERD was 38.2%, 39.5%, 45.6%, respectively in group A, B, and C. The overall prevalence of GERD at 3, 6, 12 and 36 months showed a statistically significant difference in group C, with values of 72.8%, 69.7%, 69.7% e 54.5% respectively. An overall increase of GERD (20.1%) was observed after 12 months, but this value decreased at 2.9% after 36 months (Figure 3).

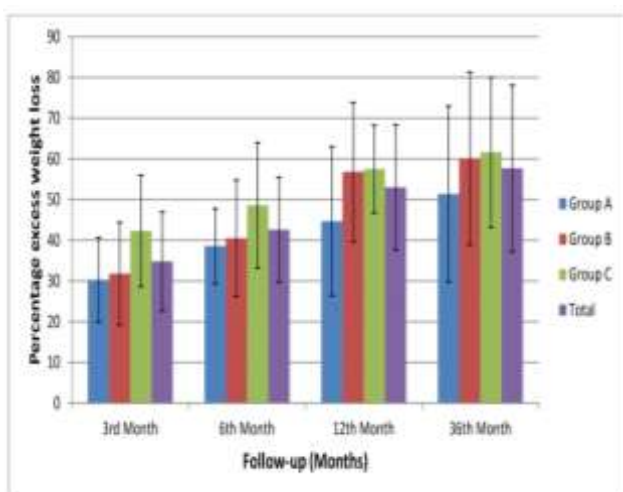


Figure 2: Evaluation of % EWL at 3, 6, 12 and 36 months in the three groups.

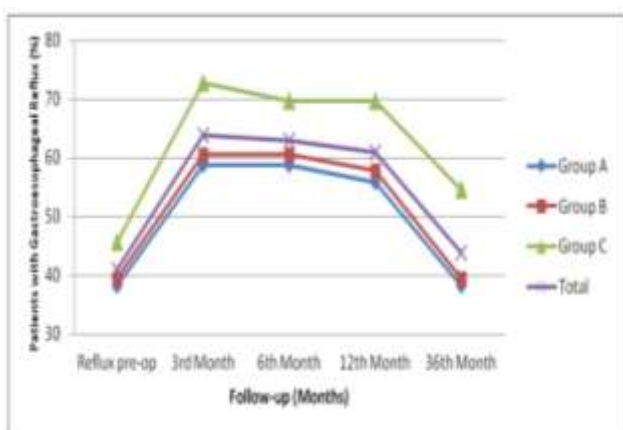


Figure 3: Evaluation of GERD at 3, 6, 12 and 36 months in the three groups.

Before undergoing LSG 64 patients (61%) were affected by HTA. The prevalence at 3, 6, 12 and 36 months was 53.3%, 28.6%, 21%, 17.1% respectively, with an overall reduction of 40% and 43.9% at 12 and 36 months. Comparison between the three groups showed a statistically significant difference at 3 and 6 months in favor of group C (Figure 4). This difference was no

longer present at subsequent follow-up. A similar trend was demonstrated for diabetes. Preoperative prevalence of DM2 was 41% (43 patients) while the overall prevalence at 3,6,12 and 36 months was 35.6%, 21.1%, 14.4%, 8.5%, respectively, with a reduction of 32.5% at 36 months. A statistically significant difference was observed only at 3 and 6 months in favor of group C. The results obtained in group C at 6 months of follow up were similar to those obtained in group B and C at 12 months (Figure 5).

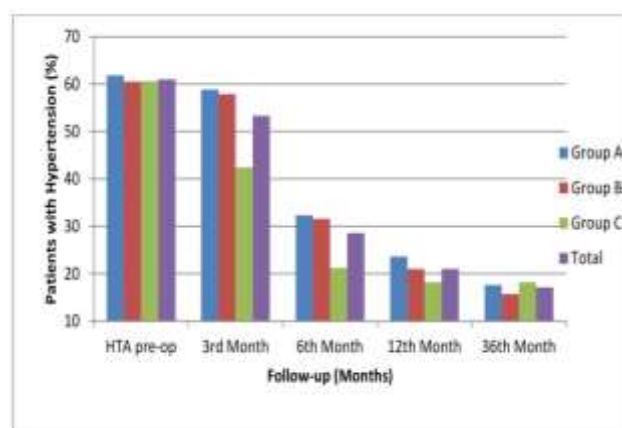


Figure 4: Evaluation of HTA at 3, 6, 12 and 36 months in the three groups.

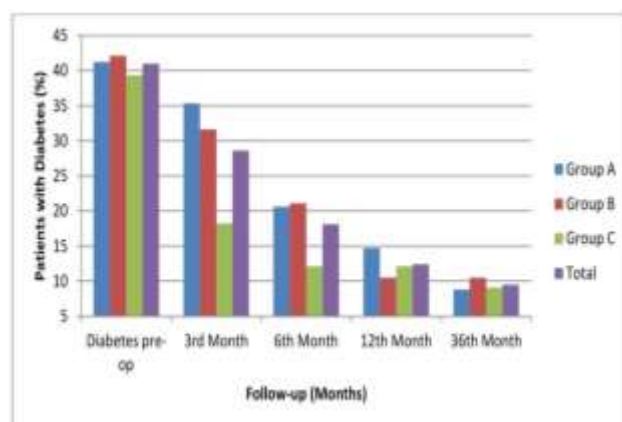


Figure 5: Evaluation of DM2 at 3, 6, 12 and 36 months in the three groups.

DISCUSSION

As for all bariatric restrictive procedures, the results of LSG are directly related to the volume of the remaining stomach. Several authors have documented less satisfactory results using larger probes to calibrate the sleeve.^{1,8} In our study we tried to find a direct correlation between the volume of the resected stomach and the results in term of weight loss and improvement of the comorbidities. In order to measure RGV, we manually injected saline solution in a 16-Fr Foley catheter inserted in the gastric antrum, until the leakage of the staple line, as found in Literature.^{14,15} We had no difference between

the leak pressure in three group and the Gastric fundus was the most frequent site of leakage. Causey MW et al.¹⁶ reported similar results about the leak pressure generated by the saline solution injection, suggesting the accuracy of this method of measurement. However, they showed no significant prevalence in the location of the leak.

According to the literature,^{2,17-19} we found no correlation between the preoperative BMI and the volume of the resected stomach. As a matter of fact being obesity a multifactorial disease, a large stomach is not a sufficient condition to determine a high BMI. Furthermore, some Authors²⁰ showed that gastric volumes in obese patients undergoing bariatric surgery were similar to those of control subjects, suggesting that the size and volume of the stomach in obese patients are similar to non-obese ones. At the same time we found a significant correlation between %EWL and RGV during the follow up. In particular, this association is established more rapidly for larger volumes of the resected stomach. In fact, during the first 6 months, the RGV exceeding 1800 mL resulted in a significantly higher % EWL. Furthermore, during the following 30 months, we observed a gradual improvement of %EWL for resections greater than 1200 mL. On the contrary RGV inferior to 1200 mL showed disappointing results during the whole follow-up. These poor results may depend on the elevated residual gastric volume that nullifies the two most important effects of LSG.²¹ In the LSG the reduction of gastric volume induces an early sense of satiety that is related to weight loss.^{7,17} In presence of a larger residual gastric volume this sense of satiety could be reached belatedly and so permitting a higher caloric intake. Moreover the gastric fundus resection determines a lowering in the ghrelin's plasma levels. This hormone produced by the oxyntic cells of the fundus has a pivotal role in the satiety's regulation as shown by its high circulating levels in obese patients.^{22,23} In case of a reduced gastric resection, a greater amount of oxyntic cells could remain with a consequential reduction in the hormone-induced satiety.

According to the literature, the resolution of HTA one year after LGS is between 64.2% and 84.6%^{19,22-24} and we observed as well an overall reduction of 40% at 12 months of follow up. Only one study¹⁸ compares the RGV and the prevalence of HTA during the follow up. This study shows no difference between the three groups examined. On the contrary in our study for resections greater than 1800 mL we obtained a substantial control of HTA at 6 months of follow up. This result is similar to those obtained 12 months after surgery in patients who underwent inferior resections. We suppose that the rapid stabilization of HTA for RGV greater than 1800 mL can be related to the ghrelin regulatory system, as already proposed by other authors.^{23,25} They also correlate this hormonal mechanism to the improvement of DM2.

The remission rate of DM2 after LGS is 37% and 78-85% at 12 and 24 postoperative months, respectively.²⁶⁻²⁸ Sing et al¹⁸ showed a diabetes' resolution's rate of 63.8%,

79.6% and 82.9% at 6, 12 and 24 months after LGS respectively, without difference among the three groups. Our results are similar except that we recorded a significant reduction in the prevalence of DM2 at 6 months after LGS for RGV greater than 1800 mL. These results may depend on a different hormonal response induced by resection.^{29,30} In fact, in these cases, we observed a rapid control of glucose levels: at 6 months of follow up we observed similar results to those obtained at 12 postoperative months for resection inferior to 1800 mL. In our opinion, the rapid stabilization of glucose levels and blood pressure indicate a major hormonal depletion induced by a major gastric resection. Some animal studies show an overexpression of ghrelin secreting duodenal cells several months after gastric resection, and a subsequent increase in hormonal blood levels.³⁰ Once confirmed in humans, these data could justify the different metabolic reaction in patients with an RGV>1800 mL. Further studies on hormonal signaling, especially ghrelin, are actually in progress in our Department to support this hypothesis.

One of the major concerns regarding the LSG is the possibility of causing or increasing GERD.^{31,32} Correlation between weight excess and GERD, and between bariatric surgery and GERD are demonstrated by several authors.^{3,31,33} Chiu et al showed in a recent review of 11 series conflicting results. Seven series demonstrated a reduction in the prevalence of GERD, while the other 4 a GERD increase.³² They postulated that reduction may be attributed to a quicker gastric emptying, while its increase to the altered physiology of His angle induced by LGS.³² Howard et al.³³ demonstrated, with a 32-week follow up, an increase of 18% in GERD's prevalence after LGS. Sheppard CE et al.³⁴ showed an increase of 29% six months after surgery. However, several Authors reported an overall rise between 10% and 35% 12 months after surgery.³⁴⁻³⁶ Our data show similar results with an average increase of prevalence of 24% and 22%, six and twelve months after surgery respectively. Currently there are no studies correlating GERD's prevalence and RGV after LGS. Our study shows a significant increase of GERD in all groups at 12 months of follow up. In our opinion, the significant increase of GERD recorded for resections exceeding 1800 mL could be in agreement with the hypothesis that a larger destruction of gastric fundus determines a greater alteration of His angle. On the other hand the subsequent improvement in GERD prevalence at 24 months could be attributed to the restoration of His angle that it happens three years after surgery.^{31,32}

This study presents several limitations including the impossibility to measure the residual volume in sleeve resection. There are no conclusive evidences in literature to determine exactly the size of gastric sleeve.^{3,37,38} In our study we assume that the standardization of the technique performed by only one surgeon can give similar results about the sleeve size.

Moreover the lack of randomisation and the small sample of patients are other limitations of this study: the small number of patients, whose results obtained a statistical significance, deprives the conclusions of a strong power. On the contrary, the standardization of the surgical procedure performed always by the same experienced surgeon permitted to remove any operative bias.^{3,4}

CONCLUSION

In conclusion, the results of our study show that RGV influences outcomes after LGS on short- and mid-term follow up. We can summarize our results as follows:

1. Gastric resections <1200 mL determine poor weight loss results.
2. Gastric resections >1800 mL determine rapid weight loss, that is, however, similar to those of gastric resections >1200 mL at mid-term follow up.
3. The prevalence of GERD in the first year after LGS can be attributed to the destruction of the His angle. The prevalence increases for gastric resections >1800 mL.
4. Gastric resections >1800 mL determine rapid control of DM2 and HTA, that are, however, similar to those of inferior gastric resections at mid-term follow up.

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Ethical approval: The study was approved by the institutional ethics committee

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