



Sleeve Gastrectomy: University Hospital Experience

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Abstract: Introduction: Nowadays laparoscopic sleeve gastrectomy (LSG) is considered to be a stand-alone bariatric procedure with increasing indication and major advantages. The authors present the experience with this technique analyzing baseline demographics, comorbidities (hypertension, dyslipidemia and insulin-resistance), operative outcomes, complications and weight loss. **Methods:** The authors retrospectively analyzed the records of the first consecutive 119 patients, submitted to LSG between May 2010 and June 2013. Follow-up data was available on 112 and 110 patients at three and six months, respectively. **Results:** A total of 93 female and 26 male patients underwent LSG over the study period. Overall complications rate occurred in 4,2% of the patients. There was no mortality. Mean body mass index (BMI) declined considerably from the initial 44.8kg/m2 to 37.8kg/m2, and 34.6kg/m2, at three and six months. Mean percentage of excess weight loss (%EWL) gradually increased from 36.3% at three months to 51.3% at six months. At six months follow-up, studied comorbidities as well as the number of prescribed medications were all significantly reduced. **Conclusion:** Results from our study indicate LSG to be safe and efficient as a stand-alone bariatric procedure. Whether these good results will be maintained will require prolonged follow-up with special attention to unwanted regained weight.

Keywords: Obesity; Bariatric Surgery; Gastroplasty; Gastrectomy; Weight Loss.

Introduction

Obesity is a condition of abnormal or excessive fat accumulation in adipose tissue that may affect health adversely. The prevalence of obesity (BMI≥30) is rapidly increasing worldwide and is now considered a global epidemic disorder 1. Portugal is no exception with 14,2% of obese adults and 39,4% being overweight (BMI≥25) 2. Bariatric surgery is becoming an increasingly popular treatment in obese patients producing considerable and long-term changes in body weight 3. There are several bariatric procedures. Laparoscopic gastric bypass (LGB) and laparoscopic adjustable gastric banding (LAGB) are two of the most tested surgical methods with proven results 4. In Laparoscopic sleeve gastrectomy (LSG) the fundus and the greater curvature of the stomach are excised, fashioning the lesser curvature into a tube. This is more than a restrictive technique because it removes the majority of ghrelin-producing cells, thereby reducing the levels of hunger-regulating hormone ghrelin and, hence, appetite 5. Stomach size is reduced by about 80% 6 but the pylorus is preserved and therefore dumping is prevented 3,7. Initially, this technique was attempted as a first-step procedure for high-risk patients aiming for drastic weight loss in order to optimize subsequent surgical interventions ⁸. When used as a first-step procedure it was followed by both, biliopancreatic diversion with duodenal switch or Roux-en-Y gastric bypass, in grossly obese patients ⁷. Nowadays LSG is considered a stand-alone bariatric procedure with increasing indications ⁹ and some major advantages: efficiency, no risk of diaphragmatic hernia, absence of an intestinal anastomosis, normal intestinal absorption, no implantation of a foreign body, in addition, to being the preferred option in extremely obese patients ⁸.

In this paper the authors present their experience with the first 119 consecutive patients undergoing LSG from May 2010 till June 2013. The main objective was to evaluate whether the team succeeded in reducing excessive body weight whilst reversing obesity related comorbidities in patients such as insulin resistance, hypertension and dyslipidemia. Secondly, the authors also aimed to assess whether or not the complications rate was as low as those described in the literature ^{8,10}.





Material and Methods

Patient Selection

Patients with, either a BMI>40kg/m² or >35kg/m² and associated comorbidity, were accepted for the University Hospital Bariatric Surgery Program. Suitable candidates were enrolled and evaluated by a dedicated multidisciplinary bariatric team. Following detailed discussion and counseling regarding the available suitable techniques a final decision was reached and informed consent was obtained. Exclusion criteria included patients with hiatal hernia, or with functional impairments of the lower esophageal sphincter, psychiatric disorders or with any known addiction to either drugs or alcohol.

This study, upon institutional review board approval in December 2013, was conducted to review the files of the first 119 consecutive patients undergoing LSG as a single-stage procedure for the treatment of morbid obesity, between May 2010 and June 2013. Patient's follow-up, according to clinical protocol, was scheduled at one, three and six months post operation, with laboratory evaluation every 6 months. Complications and reoperations were recorded for all patients. Follow-up data after 8 of January 2014 has not been included in this study.

Surgical technique

All of the procedures were performed by surgeons of the bariatric unit with a high experience in bariatric and laparoscopic surgery. A 44-Fr Bougie tube was used to avoid stenosis and dysphagia. The green staple load (4.1/60mm) was used for the first staple firing, followed by gold staple loads (3.8/60mm) to complete the sleeve.

Data analysis

Pre-operative data was available in all 119 patients; however, follow-up data was only available on 112 and 110 patients at three and six months, respectively, either due to defaulting or because the six months post operation had not yet elapsed. Collected data included age and gender, weight, BMI, comorbidities (hypertension, dyslipidemia, insulin-resistance and obstructive sleep apnea - OSA) and number of prescribed medications previous to surgery. Intra-operative data included surgery duration, mortality, complications and reversal to laparotomy. Post operation length of stay, mortality and immediate complications were collected. At three and six months, weight and BMI were determined and, in addition, at

six months, the pre-defined comorbidities, excluding OSA, as well as medications prescribed, were also recorded.

Definitions

Ideal body weight was assumed up to the highest limit of normal, considering 24kg/m2 BMI to be the upper limit, for any given height. Excess weight loss (EWL) is calculated with the following formula:

Initial Excess Weight (IEW) = Initial Weight — Ideal Weight

Total Weight Loss (TWL) = Initial Weight - Actual Weight

Percentage of Excess Weight Lost (%EWL) = TWL/IEW x 100

For ease of calculations all values entered or calculated have been rounded off to, either the next or the same figure, depending whether the digit after the decimal was ≥ 0.5 or < 0.5.

Statistical analysis

Results are expressed as mean. Statistical analysis were preformed using IBM® SPSS® Statistics 21.0 software program. Student t-test was used to compare quantitative variables. The McNemar test and the Wilcoxon signed-rank test were used for nonparametric variables as appropriate. The Spearman test and Kendall test were used to correlate ordinal nonparametric variables. A P value of .05 or less was considered statistically significant.

Results

Preoperative results

A total of 119 patients (93 female, 26 male) underwent LSG over the study period. One patient due to technical difficulties required conversion to laparotomy (0.8%).

As it can be appreciated from results presented in table 1, with the exception of significant differences in weight (p=0,026) and in OSA (p=0,01) there were no other differences between men and women, regarding other comorbidities, as well as number of prescribed medications before surgery.

More detailed analysis of the considered morbidities revealed that although twenty six (21,8%) of the





patients had none of the comorbidities, 29 (24,4%) patients had one, 34 (28,6%) had two, 19 (16%) had three and 11 patients (9,2%) had the all four comorbidities included in this study and a strong correlation (p=0.01) was found between the pre-existing morbid status and the number of medications being taken (graphic 1).

Intraoperative results

Mean operating time was 85 minutes (range, 25-220 minutes). There was no mortality. There was one spleen injury during laparoscopy treated conservatively (0,8%). None of the patients required blood transfusions.

Postoperative results

Mean hospital stay was 6 days (range, 4-24 days) with only one readmission in the first 30 days after surgery (0.8%). No mortality was registered. Complications were kept to a minimum: two patients had persistent fever needing antibiotics (1,7%) and two patients presented with persisting vomiting (1,7%). Pancreatitis, as a more serious complication, only observed in one single patient (0,8%). In our series, no fistula or leak was observed.

Evaluation at three and six months follow-up

Throughout both periods, none of the patients put on weight. The overall weight loss, for the whole population, 6 months post surgery was 27.1kgs (range 9 – 55.4 kg), although men remained significantly heavier during the study period (110.4kg versus 86.6kg, p=0.02). Mean % EWL gradually increased from 36.3% at three months to 51.3% at six months (p<0.001). (table 2) Neither, TWL nor %EWL showed any significant differences between men or women (p=0.696 versus p=0.623 respectively), at 6 months follow-up.

Mean BMI declined considerably from the initial 44.8 kg/m2 (range 32,9-74,2 kg/m2) to 37.8 kg/m2, p <0.001 (range 29,2-60,5 kg/m2) and 34.6 kg/m2, p<0.001 (range 25,6 to 54,5 kg/m2) at three and six months, respectively and, similarly to %EWL the reduction in BMI was equally achieved in both men and women, without any significant differences (p=0.129). (Graphic 2)

From data shown in table 3 it can be seen that at six months follow-up comorbidities, from hypertension to dyslipidemia to insulin resistance as well as the prescribed medications were all significantly reduced.

Hair loss was found in 13 (11.9%) of all patients, 12 (92,3%) being women (p=0.005) at six months follow-up.

Discussion

Bariatric surgery has been shown to be more effective than medical treatment for morbid obesity, with consistent weight loss and resolution of obesity-related comorbidities 11. Minimally invasive approaches have been shown to drastically reduce postoperative morbidity with shorter hospital stay, reduced blood loss and fewer complications 12. LSG is gaining popularity worldwide as a bariatric procedure 13. LSG compared to Laparoscopic Roux-en-Y gastric bypass (LRYGBP) appears to have several advantages, namely: inducing a greater excess weight loss at six months and to be followed by a marked reduction in fasting ghrelin levels with a significant release suppression in response to a meal in comparison with LRYGBP. Appetite decreases with both techniques but to a greater extent after LSG 14.

Results from this series indicate LSG to be safe and efficient as a stand-alone bariatric procedure. There was just one intra-operative complication - one case of spleen injury (0,8%). Complications, during hospital stay, were reduced to a minimal with only one patient developing an acute pancreatitis (0,8%) and a couple of incidental events: two patients with persistent fever (1,7%) and two patients with repeated vomiting (1,7%). There were no cases of significant bleeding requiring any blood transfusions in contrast to other serie 6 or the need to be re-operated 15.

In an updated statement the American Society for Metabolic and Bariatric Surgery (ASMBS) Clinical Issues Committee quotes, for large single-center series (n>100)), an overall complication rate of <15% and a mortality rate of 0.19%. 10 This study, with no mortality and 2.5% of intra-operative complications, is well within this expected goal.

The efficacy of LSG as a stand-alone weight loss operation was expressed across all BMI ranges (32,82-74,22kg/m2) equally, for both, males and female patients. The percentage of excess weight loss of 36,2% at three months increasing to 51,3% six months after surgery, besides being within the expected range 13, is also another feature of success.

We found that LSG also resulted in statistically significant improvement in obesity-related comorbidities in as little as six months following







surgery. A relevant number of patients with hypertension, insulin resistance and dyslipidemia saw improvements in their conditions and in a significantly statistical number of cases, a full remission was observed. Some studies have shown that these remissions and improvements are still more expressive at two years and further more at 5 years post surgery 16,17. Contradictory, other studies noted a post-LSG renewed weight gain after two years 17 one at three years 18 and another after five years from surgery 16. These later observations have been similarly reported in other purely restrictive bariatric surgical procedures. In these particular procedures there are some plausible explanations for the regained weight. It has been suggested that the sleeved stomach might distend over time leading the patient to eat more without satiety and some patients might even present "neo-fundus" formation" 18. Another study postulates the complex neurohormonal changes following SG as a possible reason for the weight regain 19. Whatever the case, there is a need to reinforce the importance of environmental changes, from regular physical activity to the implementation of a healthier nutritional lifestyle starting straight from the beginning of the process. This will improve the results and avoid weight regain years after 16.

On another important issue, the authors found that the overall number of medications being prescribed before surgery was significantly reduced at the six months follow up, reflecting a major impact on individual as well as public health budgets, although we excluded vitamin supplements from this analysis.

Similar to other studies 20,21 we found that 11,9% of patients, almost all of them women (12 out of 13, p=0,005) developed hair loss at follow-up. It has been reported as a consequence of all different types of bariatric procedures, LSG being no exception 20,21. Several mechanisms have been postulated as possible explanations, from excessive telogen effluviun to all sorts of nutrient deficits, including zinc, selenium, biotin, iron, etc, either directly or indirectly as intermediate mediators 22,23. Whatever the complexity of the underlying causes and the controversial response to treatment, hair loss remains an obscure and troublesome side effect.

In this series the mean operating time was 85 minutes (range, 25-220 minutes). It is similar or lesser than that of others centers with overlapping experiences 15,24 although a center with considerable more cases report a mean operation time of 47 minutes after some 400 surgeries 25. Mean hospital stay was 6 days (range 4-24 days) similar to another center 15 but other series claim a in-patient stay of 4 days or less 24-26. This experience should prompt to reevaluate the protocol in order to minimize hospital related risks and costs.

After six months following surgery there was no need to reoperate but it is, of course, too early to evaluate this need. Literature mentions that 6,8% of all patients with LSG will eventually need reoperations. According to other published results reoperating can increase up to 25%, either due to insufficient weight loss or regained weight 4. It can be argued that these discrepant results might be due to patients selection and excluding criteria, to individual series, to surgical techniques and surgical skills, to patient compliance and so forth, and that might well be. However, it must be emphasized that the overall commitment of all of those concerned, from the bariatric team to patients and their relatives, are of paramount importance and the road to success.

This study has several limitations. It is retrospective and non-randomized. Quality of life, vitamin and iron deficiencies were not assessed. Long-term follow up is needed to better assess the risk-benefit ratio and the real impact in the life of the patients. Continuous follow-up is mandatory in the future to detect early weight regain, and sustained improvement of the comorbidities (including OSA), to monitor patient's compliance to diet and to evaluate whether nutritional program is being well managed.

Conclusion

Laparoscopic Sleeve Gastrectomy is an innovative procedure for the management of obesity as a standalone bariatric technique. This study confirmed LSG to be an efficient procedure without mortality and with minor complications. At six months follow-up, sustained weight loss and reduction in the associated comorbidities were observed. Whether these good results will be maintained will require prolonged follow-up with special attention to unwanted regained weight and relapse of the comorbidities. Over and above, particular care needs to be observed, regarding the possibility of nutritional deficits that may or may not be induced by the procedure. Nevertheless, besides the bariatric team itself, the personal motivation of each individual patient is of paramount importance to the success of the bariatric surgery, an involvement that cannot be ignored and that must be strongly emphasized.





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	Male (n=26)	Female (n=93)	Between Genders*	Total
Avg. Age-years	43,8y (22-65y)	44,7y (22-65y)	p=0.931	44,5y (22-65y)
Avg. Weight	139,3kg (104-198kg)	112,6kg (80-190kg)	p=0.026	118,5kg (80- 198kg)
BMI-Kg/m ²	45,9kg/m2 (35,12- 67,22)	44,59kg/m2 (32,9- 74,2)	p=0.201	44,8 9kg/m2 (32,87-74,22)
Hypertension-n (%)	14 (53,8%)	48 (51,6%)	p=0.635	62 (52,1%)
Dyslipidemia-n (%)	14 (53,8%)	54 (58%)	p=0.537	68 (57,1%)
Insulin resistance-n (%)	10 (38,4%)	33 (35,4%)	p=0.736	43 (36,1%)
OSA-n (%)	9 (34,6%)	16 (17,2%)	p=0.01	25 (21%)
Mean Prescribed-Med	3,23 (0-12)	3,45 (0-13)	p=0.609	3,4 (0-13)

Table 1 - Pre-operative data and demographics.





	Male	Female	Total	Relation to previous follow-up*
% Excess Weight Loss 3M	36,5% (σ =13,9)	36,2%(o =12,3)	36,3% (σ =12,8)	Not applicable
Total Weight Loss 3M	23,2 kg (σ =7,8)	18 kg (σ =7,5)	19,1 kg (σ =7,8)	Not applicable
% Excess Weight Loss 6M	47,8% (σ =14,3)	52,3% (σ =15,2)	51,3% (σ =15,2)	p<0.001
Total Weight Loss 6M	31,1 kg (σ =9,6)	26,1 kg (σ =9,5)	27,1 kg (σ =9,5)	p<0.001

Table 2: % Excess Weight Loss and Total Weight Loss at 3 months and 6 months after the surgery.

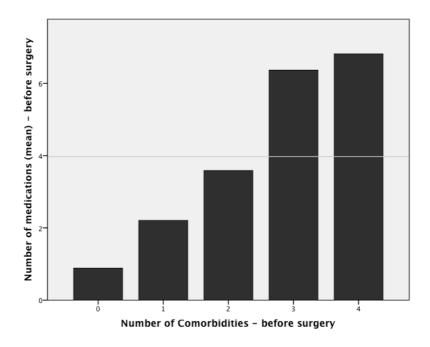
*Differences between 6 and 3 months

	Before Surgery	6 months after Surgery	Number of patients with comorbidity solved
Insulin resistance	43 (36,1%)	20 (18,3%) p<0.001	23 patients
Hypertension	62 (52,1%)	41 (37,6%) p<0.001	21 patients
Dyslipidemia	68 (57,1%)	51 (46,8%) p<0.007	17 patients
Number of medication	3,4 (σ =3,1)	2,75 (σ= 2,99) p<0.001	Not applicable

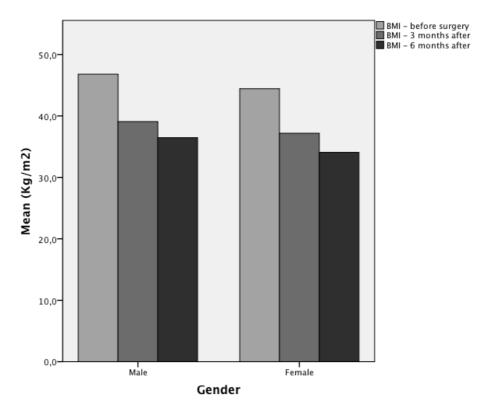
Table 3 - Comorbidities and prescribed medications before and six months after surgery

BMI





Graphic 1 - Number of comorbidities before surgery (Insulin resistance, dyslipidemia, hypertension and OSA) versus the number of medications.



Graphic 2 – BMI before surgery, 3 months and 6 months after surgery by gender.