Should Sleeve Gastrectomy Be Considered Only as a First Step in Super Obese Patients? 5-Year Results From a Single Center

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Purpose: Sleeve gastrectomy (SG) has been originally conceived as a first step procedure for super obese (SO) patients, but it is currently considered a stand-alone intervention. Medium-term to long-term studies have shown weight regain and risk of de novo gastroesophageal reflux (GERD). The aim of this study was to evaluate outcomes of SG in SO subjects.

Materials and Methods: A retrospective analysis of a prospectively maintained database was carried out to find all SO patients who had undergone SG with a minimum follow-up of 5 years. Inclusion criteria were preoperative endoscopy negative for esophagitis and/or hiatal hernia, and no GERD or acid reduction medication before SG. Reflux symptoms were evaluated using a validated questionnaire and endoscopy. Remission rates from comorbidities and percentage of excess body mass index (BMI) loss were recorded.

Results: A total of 66 (45 male/21 female) patients were included in our study. Mean preoperative BMI and age were 57.4±5.8 kg/m² and 32.7±11.2 years, respectively. After 5 years, mean percentage of excess BMI loss was 56.42±27.8, and remission rates from hypertension, diabetes, and dyslipidemia were 33.3%, 5.3%, and 20%, respectively. After 5 years, new-onset GERD occurred in 66.7% of patients and 33.3% were taking acid reduction medication. Endoscopy revealed 12 (18.2%) cases of esophagitis ➤ grade A

Conclusions: After 5 years, weight loss in SO patients is satisfactory, but the vast majority of patients is still in class II obesity, and resolution of comorbidities is disappointing. High rates of de novo GERD and esophagitis may occur.

Key Words: sleeve gastrectomy, super obese, GERD, bariatric surgery

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Because of its laparoscopic feasibility, short learning curve, and satisfactory outcomes, sleeve gastrectomy (SG) has gained increasing popularity in the field of bariatric surgery. Originally SG was described as a first step procedure for super obese (SO) patients, but, as many

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Informed consent was obtained from all the individual participants included in the study.

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The author declares no conflicts of interest.

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patients lost enough weight with the sleeve, the secondary procedure was no longer necessary. According to the IFSO (International Federation of Surgery for Obesity) survey, SG overcame Roux-en-Y gastric bypass (RYGB) as the most commonly performed procedure worldwide in 2016. Furthermore, the fourth IFSO global registry report showed that SG accounted for 46% of all bariatric interventions in 2018. Despite this success, short (staple-line leak, bleeding) and long-term (gastroesophageal reflux disease, GERD) complications have been associated with SG. Indeed, SG's popularity has been seriously undermined by several studies, whose results showed that postoperative GERD can be a worrisome problem after this procedure. Some articles have also described intestinal metaplasia (Barrett cophagus, BE) after SG due to chronic acid exposure of the lower esophagus. Rate of GERD in the general population is 10% to 20%, but morbidly obese patients have a significantly higher prevalence (37% to 72%). Thereby, GERD represents a serious problem for morbidly obese patients with a significant impact on their quality of life. The aim of our study was to evaluate weight loss, obesity-related diseases' remission, and de novo GERD at 5 years after SG in SO patients.

MATERIALS AND METHODS

The prospectively maintained database of our university bariatric center was searched to find all consecutive SO patients who had undergone SG at our department with a minimum follow-up of 5 years. Inclusion criteria were age between 18 and 60 years, body mass index (BMI) > 50 kg/m², and no GERD symptoms before surgery. Exclusion criteria were *Helicobacter pylori* infection, use of acid reduction medication (ARM) at baseline, preoperative endoscopy positive for esophagitis and/or hiatal hernia, and history of previous bariatric or abdominal surgery. Collected data were age, BMI, de novo GERD, obesity-related diseases' remission, and weight loss.

Surgical Technique

Closed CO₂ pneumoperitoneum was achieved through Veress needle. Five trocars (3×10 mm and 2×5 mm) were placed in the upper quadrants. Gastrocolic ligament was opened near the greater curvature of the stomach starting 4 cm from the pylorus up to the angle of His. Thus, preservation of antrum and complete visualization of the left crus were routinely performed. A 38 Fr bougie was used to calibrate the sleeve. The stomach was divided using a laparoscopic linear stapler with a complete excision of the fundus. ¹⁰⁻¹²

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Weight Loss

Weight loss was calculated as percentage excess body mass index loss (%EBMIL): (initial BMI-final BMI)/(initial BMI-25)×100. Our database was searched to find data on %EBMIL at 1, 3, and 5 years. Success at 5 years was defined as %EBMIL \geq 50, nonresponse was set as %EBMIL < 50 at 5 years for a patient who had previously achieved %EBMIL > 50. In addition, weight loss outcomes were also classified according to the criteria of Reinhold¹⁴ modified by Christou et al¹⁵: insufficient when BMI > 35 kg/m², good when BMI = 30 to 35 kg/m², and excellent when BMI < 30 kg/m².

Remission From Obesity-related Disease

Remission of diabetes was considered as fasting blood glucose <126 mg/dL on 2 different occasions and as a value of glycated hemoglobin A1c <6.5% off antidiabetic medications. Hypertension remission was defined as blood pressure <140/90 with no requirement for antihypertensive medication. Hypercholesterolemia, hypertriglyceridemia, and low high-density lipoprotein cholesterolemia were diagnosed when values were 200 in men and 150 mg/dL in women and 40 mg/dL in men and 50 mg/dL in women. Cutoffs points were chosen according to the American Heart Association criteria to identify metabolic syndrome. Is

GERD and Severity of Symptoms

At our center, GERD symptoms and ARM use are routinely investigated during clinical appointments, and all patients are asked to undergo preoperative endoscopy. All patients included in this study who had not undergone postoperative endoscopy were contacted to have the procedure. According to the Lyon Consensus Conference oriteria, GERD was clinically diagnosed in case of heartburn and/or regurgitation, ¹⁹ while endoscopic diagnosis was established in case of esophagitis ≥ grade A. Severity of symptoms was evaluated with the GERD HRQL (Gastroesophageal Reflux Disease Health-Related Quality of Life) questionnaire, which is validated to assess the impact of GERD on quality of life. Items are scored from 0 to 5 (0 = no symptoms, 5 = symptoms are incapacitating, unable)to do daily activities). The summation of all scores represents overall quality of life, as it relates to GERD symptoms (0 = best score, 50 = worst score). ^{20,21} GERD-HRQL questionnaire was administered to all patients to calculate preoperative and 5-year scores.

Statistical Analysis

Means were compared using an unpaired 2-tailed t test. Significance was set at a P-value <0.05.

RESULTS

A total number of 87 SO patients were found in our database with a minimum follow-up of 5 years. Ten patients were excluded due to preoperative endoscopic or clinical diagnosis of GERD; 8 subjects refused to undergo post-operative endoscopy and could not be included in the study. Three patients had previously undergone intragastric balloon positioning and were also excluded. Thus, 66 subjects (45 male/21 female) were eventually included in the present study. Initial age and BMI were 32.7 ± 11.2 years and 57.4 ± 5.8 kg/m², respectively.

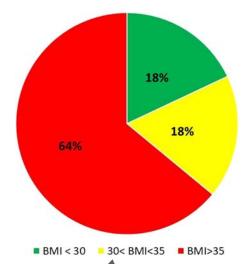


FIGURE 1. Classification of patients at 5 years according to Christou/Reinholds criteria BMI indicates body mass index.

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Weight Loss

At 5 years, mean BMI was $39.8 \pm 10.5 \text{ kg/m}^2$; 12 patients (18.2%) reached a BMI <30 kg/m², other 12 (18.2%) had a BMI between 30 and 35 kg/m^2 , while 42 (63.6%) still had a value > 35 kg/m^2 . Classification according to Christou and Reinhold is shown in Figure 1. After 5 years, mean % EBMIL was 56.42 ± 27.8 ; 6 patients (9.1%) were non-responders (% EBMIL <25%), 38 (57.6%) achieved a success (% EBMIL >50%), and 20 (30.3%) had a weight tegain. %EBMIL during follow-up is presented in Figure 2.

De Novo GERD

At 5 years, 44 (66.7%) subjects were complaining of heartburn and regurgitation and were diagnosed with new-onset GERD. Among these patients, 22 (33.3%) were taking ARM. Endoscopy revealed 12 (18.2%) cases of esophagitis at 5 years: 11 (91.7%) were grade B, and 1 (8.3%) was grade C.

Overall GERD-HRQL score at baseline and after 5 years was 0.64 ± 0.55 and 7.12 ± 6 (P<0.01), respectively; postoperative score was significantly higher in patients with GERD when compared with asymptomatic patients (3.1 ± 2.5 and 8.8 ± 6.3; P<0.01). GERD score also resulted significantly higher in ARM- than in ARM+ patients (8.9 ± 6.6 and 4.2 ± 3.1; P<0.05).

Obesity-related Diseases' Remission

At baseline, 24 (36.4%) patients were diagnosed of hypertension, 19 (28.8%) were diabetic, and 15 (22.7%) had dyslipidemia. After 5 years, remission rate from hypertension, type 2 diabetes mellitus, and dyslipidemia were 33.3% (n = 8), 5.3% (n = 1), and 20% (n = 3), respectively.

DISCUSSION

The number of SO patients seeking bariatric surgery is rapidly growing, ²¹ and the best treatment for these subjects is a matter of an ongoing debate. ²² SG has been conceived as a first step for obese individuals with BMI > 50 kg/m², ²³ but it is now considered as a stand-alone procedure. However, several studies have demonstrated that RYGB²⁴ or mini gastric bypass-one anastomosis gastric bypass²⁵ achieve better results for this category of patients in terms of weight loss and remission from obesity-related diseases.

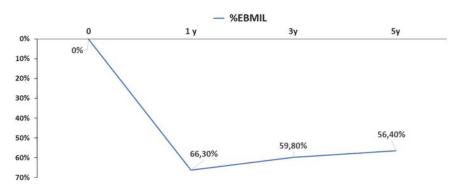


FIGURE 2. Percentage of excess body mass index loss (%EBMIL) during follow-up. full color

Nevertheless, bariatric procedures on SO patients represent a technical challenge, and they may require an experienced surgeon, as postoperative mortality increases with BMI during the learning curve. 26,27 Moreover, several studies have reported satisfactory outcomes after SG in SO patients, comparable to those achievable in morbidly obese individuals.^{28,29} In other studies, the comparison of the most common obesity-related diseases—diabetes, obstructive sleep apnea, hypertension, dyslipidemia—between patients with a BMI between 30 and 50 kg/m² and those with BMI \geq 50 kg/m² did not show a lower resolution after SG.30,31 For these reasons, SG is still offered to SO individuals undergoing bariatric surgery.³² Our outcomes demonstrated that, even if an acceptable mean %EBMIL was obtained at 5 years, the vast majority of subjects still had a BMI > 35 kg/m²; resolution from comorbidities disappointing, and weight regain occurs in 30% of cases. It is predictable that most of these patients will need a second procedure in the future.³³ Moreover, morbid and super obesity are also associated with higher incidence of gastro-esophageal reflux. Excess of visceral fat causes a chronic increase in the intra-abdominal pressure, which reduces the efficacy of the lower esophageal sphincter, and induces the development of hiatal hernia.³⁴ Despite some studies that reported improvement of symptoms after SG,^{35,36} published evidence shows a worsening of preexisting GERD and newonset disease. 37,38 Undoubtedly, the main cause of postoperative GERD is that a sleeved stomach has an increased intragastric pressure with decreased compliance. Technical mistakes could also lead to a stenotic or twisted sleeve, which causes regurgitation of acid content into the esophagus.4 Chronic reflux can lead to esophagitis and subsequent BE, which is a precancerous lesion for the development of esophageal carcinoma.³⁹ Braghetto and Csendes⁴⁰ first reported an incidence of 1.2% of BE at 1 year after SG; lately, other authors reported a rate of 15% to 17% after a longer follow-up (5 to 10 y).^{6,7} Surprisingly, Soricelli et al41 have shown that, in 21% of cases, BE arises in asymptomatic patients. However, in a recent multicenter study, 42 all but one patient with BE were suffering with GERD; the authors also stressed that they found only short BE, and no case of dysplasia was recorded. Indeed, the rate of malignant transformation of BE has been evaluated between 0.6% and 0.7% per year, 43,44 and the annual incidence of malignant transformation was 1.4% and 6% only in the presence of low-grade and high-grade dysplasia, respectively. 6,45 Remarkably, there are no reports in the literature of esophageal adenocarcinoma after duodenal switch, where the stomach is sleeved, after > 25 years of this

surgery, and rare cases were published after SG. ^{46,47} Besides endoscopic and histopathologic changes of gastroesophageal mucosa after SG, clinical symptoms negatively impact patients' quality of life and forces them to permanently depend upon antireflux medication. For these reasons, our study focused not only on weight loss and remission from obesity-felated disease in SO, but we decided to assess clinically and endoscopically de novo GERD as well in SO patients. A recent systematic review showed a rate of de no to GERD of 20%, ⁴⁸ while a meta-analysis found that the increase of postoperative GERD after sleeve was 19%, and de novo reflux was 23%. ⁴⁹ Our data showed a high rate of clinical de novo GERD, as almost 70% of patients had new-onset symptoms, and one third are taking antacid medications. GERD-HRQL questionnaire scores demonstrated an overall increase compared with baseline and a relief of symptoms in patients taking ARM. Moreover, endoscopic findings showed a worrisome rate of esophagitis at only 5 years.

Strengths and Limitations

The retrospective nature of the study and collection of data from a single center are the limitations of the present study. However, the strengths of our paper are a deep analysis of weight loss and a proper evaluation of GERD through endoscopy and a validated clinical questionnaire. Moreover, the evaluation of the new-onset symptoms in patients with no clinical or endoscopic preoperative signs of GERD is more objective and less subject to bias.

CONCLUSIONS

After 5 years, mean weight loss in SO patients is satisfactory, but the vast majority of patients is still in class II obesity, and resolution of obesity-related diseases is disappointing. High rates of de novo GERD and esophagitis may occur. SG patients should be adequately informed that postoperative GERD or not successful weight loss may require conversion to other bariatric procedures, such as RYGB^{50,51} or one anastomosis gastric bypass.^{52,53}

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