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ORIGINAL CONTRIBUTIONS

Gastroesophageal Reflux After Sleeve Gastrectomy: New Onset and Effect on Symptoms on a Prospective Evaluation

Vincenzo Pilone[1,2] · Salvatore Tramontano[2] · Michele Renzulli[2] · Claudio Zulli[3] · Luigi Schiavo[4,5]

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Abstract

Background Gastroesophageal reflux disease (GERD) is present in half of the obese candidates for bariatric surgery. Variability of symptoms and new onset of GERD are often debated. Prior studies have demonstrated that sleeve gastrectomy (SG) is associated with significant weight loss.

Objectives We prospectively evaluated the effect of a standardized SG technique on GERD symptoms in 104 patients.

Methods All patients were surveyed on the presence of heartburn and/or regurgitation with a specific questionnaire (GERD-HRQL). Esophagogastroduodenoscopy (EGDS) was performed in the preoperative phase and after 12 months.

Results All patients completed a 12-month follow-up. In the preoperative phase, 27.9% presented GERD symptoms (29 cases), while endoscopic findings were observed in 19.2% (20 cases). Preoperative GERD was ameliorated/solved in 65.5% of cases. The mean value of the GERD-HRQL score was significantly lower in postoperative evaluation (33.8 vs 19.4; $p < 0.05$). At 12-month EGDS, esophagitis was present in 13.5%, and GERD-HRQL symptoms were recorded in 10.6%. Considering patients treated until December 2015 (group 1, 44 patients) and those treated after December 2015 (group 2, 60 patients), all new clinical and endoscopic GERD diagnoses were observed in group 1; the majority of unsolved GERD cases was present in Ggoup 1 (8 vs 2; $p < 0.05$).

Conclusion Significant amelioration on preoperative GERD was confirmed after SG. New characteristics of reflux are emerging in SG patients, often asymptomatic. Standardization is necessary to define the real effect of SG on GERD.

Keywords Sleeve gastrectomy · Gastroesophageal reflux · GERD-HRQL · Obesity · Esophagitis

Introduction

A strong association exists between obesity and gastroesophageal reflux disease (GERD) [1]. GERD is reported to be present in half of the obese candidates for bariatric surgery [2]. Variability of symptoms, personalization of bariatric procedure, and new onset of GERD are in fact debated [2, 3]. In addition, the effect of new anatomy induced by sleeve gastrectomy (SG) is a problematic issue in relation to gastric emptying time and pH-evaluation after surgery [4]. Prior studies have demonstrated that SG is associated with significant weight loss and the improvement of most comorbidities [2, 4]. However, the effect of SG on GERD is unknown, and a number of studies have suggested that anatomical changes

✉ Salvatore Tramontano
salvytra@libero.it

Vincenzo Pilone
vpilone@unisa.it

Michele Renzulli
miky.renz86@gmail.com

Claudio Zulli
zulli.caludio@gmail.com

Luigi Schiavo
luigi.schiavo@unicampania.it

[1] Department of Medicine, Surgery, and Dentistry, University of Salerno, Salerno, Italy

[2] General, Bariatric and Emergency Surgical Unit of Fucito Hospital, University Hospital of Salerno, Salerno, Italy

[3] Endoscopic Unit of Fucito Hospital, University Hospital of Salerno, Salerno, Italy

[4] Department of Cardio-Thoracic and Respiratory Science, University of Campania "Luigi Vanvitelli", Naples, Italy

[5] IX Division of General Surgery, Vascular Surgery, and Applied Biotechnology, Naples University Polyclinic, Naples, Italy

associated with SG can exacerbate GERD symptoms or induce GERD in previously asymptomatic patients [5]. The definition and evaluation of GERD have been standardized and updated over recent years, in order to define symptoms and indication for diagnostic examinations [6]. Moreover, for bariatric patients and mostly for patients who have undergone SG, GERD has been variously evaluated, for instance, in de novo diagnosis or for improvement or worsening after surgery [2, 4, 5]. Although Roux-en-Y gastric bypass (RYGB) is considered the best procedure for severe symptomatic GERD, many authors have recently reported favorable results on reflux after SG, mostly in relation with the incidence of new cases of GERD [7]. Many studies have reported an increase in the incidence of reflux symptoms during the first year following SG and then a gradual decrease up to the third postoperative year [5]. Asymptomatic cases remain the most difficult group to study because they are not treated or can evolve into Barrett's esophagus (BE), as recently demonstrated [8]. The present study prospectively evaluated the effect of SG, performed with standard technique and after a technical variation, on the incidence of GERD symptoms in 104 patients followed until to 30 months, and the technical evolution of the new onset of GERD after 2016 was also evaluated.

Methods

This is a prospective study involving the collection of data. All patients who underwent SG from January 2015 to December 2016 were all evaluated. Patients without a giant hiatal hernia (defect greater than 5 cm) and GERD were also enrolled in the study. The scoring of GERD was in accordance with the Los Angeles endoscopic classification [9]; BE was diagnosed according to the Praga endoscopic classification [9]. Exclusion criteria were the following: patients with grade D esophagitis (according to the Los Angeles classification) and/or BE and redo patients (with previous bariatric procedure) that may have predictable altered esophageal motility. All patients underwent a multidisciplinary preoperative evaluation and met the criteria of the Italian Society for Obesity Surgery (SICOB) for SG [10]. All patients were surveyed about the presence of heartburn and/or regurgitation with a specific questionnaire (GERD-Health Related Quality of Life (HRQL) questionnaire [11]), presented in Fig. 1. Atypical symptoms were also recorded. The patients received a detailed explanation on the definition of each symptom. GERD was generally diagnosed by the presence of heartburn and/or regurgitation symptoms two or more times a week [6]. In order to apply a reproducible and comparable evaluation, we compared the GERD-HRQL score, an objective method, with endoscopic findings: a value of >25 was used for identifying severity of GERD [11]. The mean value of the entire cohort, before and after SG, and for patients with preexisting GERD, was used for analysis. Similarly, we considered this score for groups of patients with preoperative GERD, to evaluate the effect of surgery at 12-month follow-up. The presence of esophagitis in some degree, BE, or other endoscopic findings were evaluated with esophagogastroduodenoscopy (EGDS) in the preoperative phase and at 12-month follow-up in all patients. Esophagitis was classified with the endoscopic Los Angeles classification [9]. Diagnosis of hiatal hernia was made when measuring at least 2 cm, while cardial incontinence without gastric hernia was not considered for study. The patient was reevaluated at 1, 3, 6, and 12 months postoperatively, with the GERD-HRQL administered at 12-month follow-up, and the adaptation to a restricted gastric size was considered during the first postoperative months. Early EGDS or GERD-HRQL evaluations were indicated if a patient had difficulty tolerating solid food or if new symptoms occurred. Administration of proton-pump inhibitors (PPI) was recorded in preoperative and postoperative phase, to confirm good resolution of symptoms. Preoperative GERD cases were specifically evaluated, in order to consider any variation in symptoms. Asymptomatic esophagitis in the preoperative and postoperative phases was recorded. All patients with unresponsive symptoms or who were symptomatic with negative EGDS finding were recruited for 24-h pH and multichannel intraluminal impedance studies, to confirm a diagnosis of GERD.

To evaluate if technical standardization reduced the incidence of GERD or modified GERD onset, we considered two groups of patients, those who underwent surgery up until December 2015 (group 1) and those who underwent surgery after December 2015 (group 2). All patients were also evaluated with a GERD-HRQL questionnaire at the last follow-up (20–44 months). Follow-up was completed on September 2018, for data analysis.

Surgical Procedure

We performed SG according to our standardized procedure [12]. Currently, we use five ports as follows: a 12-mm port at the umbilicus for the camera; a 12-mm port at the right flank, also used for the stapler during section; a 15-mm port at the left flank for gastric manipulation and transection; and two additional 5-mm ports, one at the epigastric area for liver retraction and one at the left lateral subcostal area for the assistant. The greater curvature was devascularized using an ultrasonic device starting at about 4 cm proximal to the pylorus and continuing until the fundus was dissected free of the left crus of the diaphragm. We did not close hiatal defects because giant hernia cases were excluded from the study to avoid a possible selection bias. A 32-French bougie was introduced up the distal antrum. Division of the stomach was started 4 cm proximal to the pylorus, keeping the bougie adjacent to the lesser curvature. We generally fire a 60–4.8-mm

GERD-Health Related Quality of Life Questionnaire (GERD-HRQL)

Institution:_____ Patient ID:_____ Date___/___/___

□ On PPIs □ Off PPIs If off, for how long? _____ days / months

Scale:
0 = No symptom
1 = Symptoms noticeable but not bothersome
2 = Symptoms noticeable and bothersome but not every day
3 = Symptoms bothersome every day
4 = Symptoms affect daily activity
5 = Symptoms are incapacitating to do daily activities

Please check the box to the right of each question which best describes your experience over the past 2 weeks

1.	How bad is the heartburn?	□0 □1 □2 □3 □4 □5
2.	Heartburn when lying down?	□0 □1 □2 □3 □4 □5
3.	Heartburn when standing up?	□0 □1 □2 □3 □4 □5
4.	Heartburn after meals?	□0 □1 □2 □3 □4 □5
5.	Does heartburn change your diet?	□0 □1 □2 □3 □4 □5
6.	Does heartburn wake you from sleep?	□0 □1 □2 □3 □4 □5
7.	Do you have difficulty swallowing?	□0 □1 □2 □3 □4 □5
8.	Do you have pain with swallowing?	□0 □1 □2 □3 □4 □5
9.	If you take medication, does this affect your daily life?	□0 □1 □2 □3 □4 □5
10.	How bad is the regurgitation?	□0 □1 □2 □3 □4 □5
11.	Regurgitation when lying down?	□0 □1 □2 □3 □4 □5
12.	Regurgitation when standing up?	□0 □1 □2 □3 □4 □5
13.	Regurgitation after meals?	□0 □1 □2 □3 □4 □5
14.	Does regurgitation change your diet?	□0 □1 □2 □3 □4 □5
15.	Does regurgitation wake you from sleep?	□0 □1 □2 □3 □4 □5
16.	How satisfied are you with your present condition? □ Satisfied □ Neutral □ Dissatisfied	

_____ _____
Administered by Monitored by

_____ _____
Date (mm/dd/yy) Date (mm/dd/yy)

Fig. 1 Gastroesophageal reflux disease-HRQL questionnaire

staple cartridge initially, followed by four to six 60–3.5-mm cartridges, carefully avoiding a relative narrowing at the junction between the vertical and horizontal parts of the stomach, and we also avoid leaving an antrum that is too small. A wide angle at the junction between the horizontal antrum and the vertical body of the stomach was preferred. An accurate preparation of posterior wall is necessary, to keep the sleeve from rolling or spiraling, which may result in food intolerance or GERD. Metallic clips, coagulation, or suturing are employed in case of bleeding. Stapler reinforcing is not routinely used; only those at high risk of bleeding are selected, mostly at the first two fires (within the thickest wall). We then retract the bougie proximally, test the sleeve with a solution of about 200 ml with 25–35 mL of methylene blue, and, after incising the aponeurosis, we extract the stomach through the left flank port without a bag. A perigastric drain is located at the end of the procedure, that can be removed after radiographic control with hydrosoluble contrast, on the third postoperative day. The patient is discharged the following day after tolerating a liquid diet, generally on postoperative days 5 or 6, and receiving a complete set of postoperative instructions from the nurse coordinator.

The learning curve was completed in 2014 (first 100 cases). Starting from 2016, we adjusted the technical approach, essentially by three steps: the tightness of the sleeve was increased by sectioning near to the orogastric tube; a more accurate preparation of the His angle was made in order to reduce the risk of residual fundus on the sleeve; and antrum preservation was improved to avoid a lesion of the gastric pump that enhanced faster gastric emptying after SG. These three tips, based on international experience and analysis of follow-up cases, were specifically considered in comparison of the two groups.

Statistical Analysis

We used an Office 2000 database (Microsoft, Redmond, WA) for data collection and Epi info 7.0 software (Centers for

Disease Control, Atlanta, GA) for statistical analysis. For all comparative analysis, a two-sided p value of < 0.05 was considered significant. For bivariate analysis, we employed the $\chi 2$ test or Fisher's exact test for categorical data and the independent paired t test for continuous data. All data analyzed had normal distribution.

Results

A total of 120 patients, candidates to SG after multidisciplinary evaluation, was recruited for study. Sixteen patients refused EGDS 12 months after surgery and were excluded. A total of 104 patients completed GERD-HRQL. All patients accessed follow-up until 12 months. Anthropometric data and results on weight loss are explained in Table 1. Regarding complications, only three cases of bleeding were treated with medical therapy, while no leaks occurred in the present cohort. No reintervention or mortality was recorded. Mean follow-up was 26.4 months (range 20–44). All patients referred to indicated follow-up.

In the preoperative phase, 27.9% presented GERD symptoms (29 cases), while endoscopic finding (esophagitis with or without hiatal hernia) was observed in 19.2% (20 cases): 16.3% presented hiatal hernia (17 cases), 12.5% esophagitis (13 cases). All patients were treated with PPI and responded well, except for four patients (13.8% of preoperative GERD patients), for which 24-h pH and multichannel intraluminal impedance study was indicated. All these patients presented pathologic results, confirming a diagnosis of GERD (mean DeMeester score: 32.8, range 17.2–41.0).

Table 1 Anthropometric data of cohort

Patients' data	
Sex (male/female)	43/61
Mean age (± SD)	37.5 years (± 9.3)
Mean weight (± SD)	130.0 kg (± 18.3)
Mean BMI (± SD)	44.2 kg/m^2 (± 4.2)
EWL% at 3 months (± SD)	17.2% (± 4.4)
BMI loss at 3 months (±SD)	2.2 kg/m^2 (± 1.0)
EWL% at 6 months (±SD)	29.5 (± 9.8)
BMI loss at 6 months (± SD)	3.5 kg/m^2 (± 3.3)
EWL% at 12 months (± SD)	44.9 (± 14.9)
BMI loss at 12 months (± SD)	8.8 kg/m^2 (± 6.7)
Preoperative GERD (incidence; pts. number)	27.9% (29 pts)
Postoperative GERD (incidence; pts. number)	10.6% (11 pts)*
Preoperative esophagitis (incidence; pts. number)	19.2% (20 pts)
Postoperative esophagitis (incidence; pts. number)	13.6% (14 pts)
Early complications	
Major complications (incidence; pts. number)	2.9% (3 pts)[a]
Minor complications (incidence; pts. number)	3.8% (4 pts)[b]
Mean hospital stay (range)	5.2 (4–14)

SD standard deviation, *BMI* body mass index, *%EWL* % excess weight loss, *GERD* gastroesophageal reflux disease

*$p < 0.05$

[a] 3 bleeding, all treated with conservative therapy

[b] 2 surgical site infection, 1 pneumonia, all treated with conservative therapy

In 18 cases, EGDS was anticipated because of specific transitory symptoms (vomiting in seven cases, persistent pain in three cases, and severe heartburn at 3–6 months in eight cases): nine of these (50%) presented preoperative both clinical and endoscopic GERD, while postoperative GERD was endoscopically confirmed in seven cases of this subgroup (38.8%). In postoperative evaluation of all cohort, a significant reduction of both GERD results (questionnaire and EGDS findings) was observed, with statistical significance only for GERD-HRQL, as evidenced in Table 1. A total of 14 cases of esophagitis was observed at 12-month EGDS (13.5%), while positive GERD-HRQL was recorded in 10.6% (11 cases) of the cohort. All postoperative GERD responded well to PPI; for this, 24-h pH and multichannel intraluminal impedance study were not indicated. Moreover, with regard to grade, a comprehensive reduction (not significant) was found. No cases of BE were observed on postoperative EGDS. Comparative data of endoscopic and GERD-HRQL results are explained in Fig. 2. Asymptomatic esophagitis was found in two cases of the entire cohort (15.3% of esophagitis cases); both patients had not preoperative GERD.

In detail, preoperative GERD was ameliorated/solved in 65.5% of cases (19 cases), stable in 10 cases, and worsened in none. Positive GERD-HRQL well related with the endoscopic findings on postoperative analysis. On postoperative evaluation, 11 patients (10.6%) used currently PPI, and, at last follow-up, 8 patients (7.7%) continued to request this drug. Both this data were statistically significant, in comparison with preoperative one (p, 0.04 and p, 0.03). As explained in Table 2, four cases of new esophagitis were observed (5.3%), and all were confirmed by GERD-HRQL. The GERD-HRQL results of the last follow-up are also indicated in Table 2. The mean value of the GERD-HRQL score was significantly lower in postoperative evaluation (33.8 vs 19.4; $p < 0.05$). When only the patients with preoperative GERD were considered, the score was significantly lower in the postoperative analysis (48.2 vs 29.5; $p < 0.05$). Atypical symptoms were not recorded in neither the preoperative nor the postoperative phases.

In addition to the comprehensive evaluation, we compared two groups of patients, SG performed until December 2015 (group 1) or after (group 2). A total of 44 patients was included in group 1 and 60 in group 2. The mean value of the GERD-HRQL score was comparable among groups before (23.2 vs 21.6) and after surgery (22.3 vs 20.0). As evidenced in Fig. 3, all new GERD diagnoses and all positive questionnaires were observed in group 1; similarly, the majority of

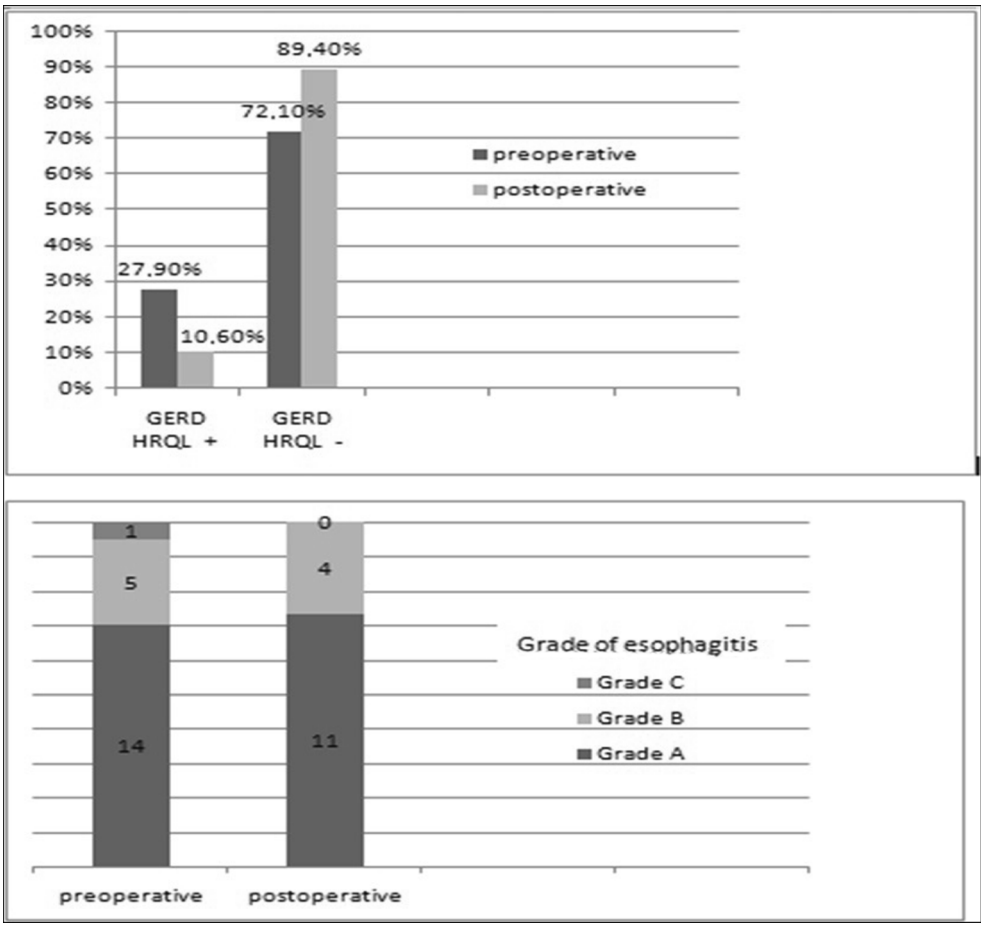

Fig. 2 Incidence of gastroesophageal reflux disease, before and after sleeve gastrectomy (12-month follow-up); grade of esophagitis, according to Los Angeles classification

unsolved GERD cases are present in group 1 (8 vs 2; $p < 0.05$). On this line, postoperative pathological score of GERD-HRQL was more frequent in group 1 (9 vs 2; $p < 0.05$).

Discussion

Our results showed a very low incidence of GERD symptoms up until 42 months after SG, which was markedly evident in group 2. Preoperative GERD cases improved/solved symptoms in over 60% of cases. The inclusion criteria with only the exclusion of giant hiatal hernia, severe esophagitis, and BE add value to our results. The incidence of preoperative GERD diagnosis in our series was near to 28%, which is similar to in other reports [1, 7]. We chose an objective method for diagnosis and comparison, with a GERD-HRQL score > 25, that related well with endoscopic findings and with symptomatic GERD, as confirmed in other studies [5, 11]. Although majority of application is for comparative analysis and for therapeutic response, in our analysis, GERD-HRQL was used to confirm clinical suspicion, with an adequate cutoff of security (more than 25). This analysis is more sensitive and reproducible than general anamnesis and the quantification of symptoms [6, 8]. In group 2, the improvement in GERD results was significantly more evident: standardization of SG, with special regard to tight tubule, and antrum preservation are determinants of GERD onset. This was confirmed by many studies, in which the upper pouch was associated with new GERD [4, 13].

Table 2 Results of GERD-HRQL questionnaire and endoscopic findings

	Positive preoperative GERD history (29 pts)	Negative preoperative GERD history (75 pts)
Pathologic preoperative GERD-HRQL/EGDS	29/20	0/0
Pathologic 12-month GERD-HRQL/EGDS	7/10	4/4
Pathologic GERD/HRQL at last follow-up (mean months)	6 (32.2 months)	3 (29 months)

GERD–HRQL gastroesophageal reflux disease–health-related quality of life questionnaire,*EGDS* esophagogastroduodenoscopy

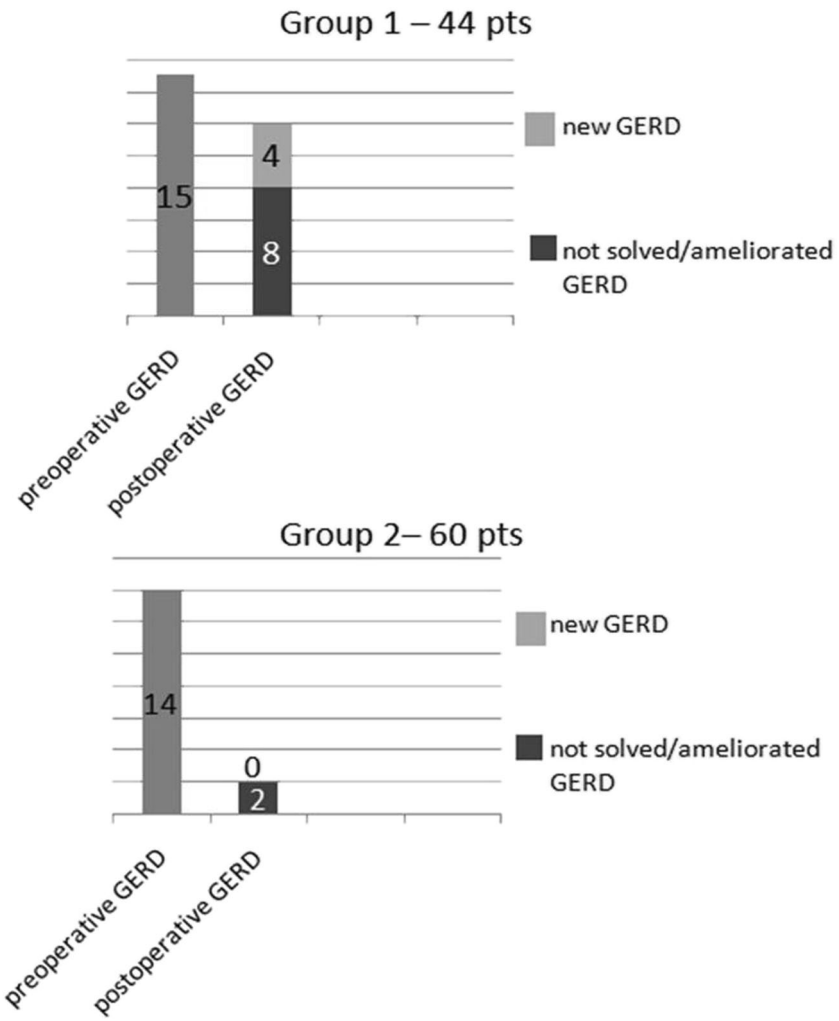

Fig. 3 Comparison of groups according to operation data (before and after December 2015; see text), before and after sleeve gastrectomy (12-month follow-up)

When considering all bariatric surgery, it is undeniable that RYGB, a technique that is effective for GERD in the majority of patients, is preferred by most surgeons [7]. Nonetheless, published data on GERD after RYGB showed a varying percentage of patients remaining symptomatic [14]. In parallel, consistent data on GERD and SG are defining real reflux in SG patients [15]. SG was originally performed as the initial restrictive stage in a two-step malabsorptive operation, but has established popularity as a single definitive procedure for weight loss based on its success, relative feasibility of operation, and low complication profile [12]. In the Fourth International Consensus Summit on SG in 2012, GERD was the most frequently reported postoperative complication, with a referred incidence near to 8% [16]. The availability of new case series and standardization of the procedure have led to a better evaluation of symptoms and real incidence of GERD. Heterogeneity of population, type of sleeve, and to diagnostic approach, have led to a variation in sensitivity and, consequently, a different incidence of GERD [5, 17].

Standardization of the procedure and an objective definition of GERD are mandatory to a correct approach [12]. We prospectively evaluated patients treated with SG, using a standardized diagnostic and surgical approach, in order to identify new cases of GERD and asymptomatic cases. The patients were evaluated from 1 year after SG, to define the effects of this procedure. In this way, the comparative analysis of two surgical periods confirmed our hypothesis. Different types of sleeve, in terms of calibration, conservation of fundus and antrum, and involvement of the fibers of the lower esophageal sphincter (LES), are probably the principal causes of different results on GERD [18]. Similarly, preexisting GERD is rarely correctly evaluated, and is undetermined or underestimated in many cases [19]. Recent trials have focused on technical standardization and an accurate preoperative evaluation [12, 20]. This may determine better results on GERD after SG, as in our report. In addition, there may be a possibility that a *new onset* is not pathologic reflux because it is not acidic, owing to a decrease in total acid production post-surgery [20]. Major observations of post-SG GERD in patients with an upper pouch (major fundus conservation) are in accordance with possible new onset of GERD. The complete resection of the fundus in our cohort, which is performed in the majority of SG, is the

best approach to obtaining this result [13]. The data of Lazoura [21] confirmed the relation between symptoms and the type of sleeve. In their series, an overall tendency toward the relief of heartburn and an increase in regurgitation and vomiting is frequent during the first year following SG, and these findings especially characterize the tubular pattern. The new situation explains the increased regurgitation and vomiting without heartburn. This trend seems to be confirmed by the data of Rebecchi [22] and validated in a report by Gagner [23], which evidenced the protective effect of SG on GERD in terms of symptoms.

Such anatomical factors are involved in the manipulation of the LES region, gastric sling fibers, the phrenic-esophageal ligament, and the cardiac-phrenic ligament and are related with the alteration of the antireflux barrier [22, 24]. Moreover, this possible new onset requires a different endoscopic surveillance, such as indicated by Genco [9], who found a high incidence of severe erosive esophagitis after SG in patients without symptoms (up to 40% of cases). An emerging problem in new post-SG and post-RYGB anatomy seems to be also severe esophagitis related to biliary reflux, which is actually underestimated and physiopathologically not defined [9, 10]. Moreover, biliary reflux is difficult to detect, and routine endoscopy remains a topic, mostly for asymptomatic patients [9].

In literature, recent manometric studies and reflux analysis did not confirm an increase of GERD after SG. Although the number of both acidic and non-acidic reflux episodes seems to be increased after SG, 24-h pH, and multichannel intraluminal impedance profile did not resulted in a difference between preoperative and postoperative analysis [25, 26]. It is hypothesized that reflux episodes are related with retrograde movements induced by intraluminal stasis that produce high intragastric pressure. Technical evaluation is now under examination: Klaus and Weiss [27] suggested that preoperative manometry should be routinely performed and that patients with LES pressure should not undergo SG, because this is a common and typical observation after SG. Del Genio [28], analyzing a small case series, reported delayed esophageal emptying, without impairing LES function, and confirmed that the new standardized fashioned sleeve does not induce de novo GERD, but only retrograde esophageal movements, with stasis and postprandial regurgitation. De novo GERD, defined by symptoms and/or endoscopy, could be introduced if it will be confirmed by other analysis of non-acidic reflux [8]. Scintigraphic confirmation of this new onset of GERD was supposed by Sharma, who evaluated the symptoms as not pathologic for GERD [29]. On this line, a recent prospective analysis, which underlined de novo cases, evidenced the enhancement of symptoms, more than reflux episodes, in half of preoperative GERD patients.

Analysis with 24-h pH monitoring should be effective in demonstrating the real effect of the procedure. Rebecchi [21] reported a long-term amelioration of acid exposure (2 years after SG), while new cases of GERD were observed in 18.4% and symptomatic only in 5.4% of cases. Synthesis of all data is very difficult: Stenard [2] reported 13 studies that included 5953 patients in which a negative influence of SG is suggested, although only one study was prospective and randomized. Disappointing results, such as in the report by Dupree [30], where preoperative GERD was associated with increased postoperative complications, 9% worsening of the symptoms, and the lack of resolution in 84% of cases, seem to be conditioned by the timing of SG. A possible positive effect on GERD induced by SG is early gastric emptying, confirmed by most studies [2, 5]: this may be necessarily linked to the maintenance of structural LES, with standardized SG. Moreover, variability of results is related to severity of reflux and to possible worsening of hiatal hernia.

The limits of our analysis remain follow-up too short, for which a good validation of results is necessary over time. In addition, there may be a bias on the observed results because the cohort presented a high rate of preoperative A-grade GERD.

Conclusion

The incidence of GERD after SG is acceptable, with significant amelioration on preoperative GERD. An accurate and objective preoperative evaluation and endoscopic monitoring are mandatory to avoid complications in patients after SG, which were frequently not related with GERD symptoms. Our study compared procedures from 2015 to 2016, confirming that technical issues may contribute to resolution of reflux symptoms. New onset of none-acid reflux is now emerging in SG patients, which seems to be often asymptomatic. Technical standardization and collecting data are mandatory to define the real effect of SG on GERD.

Compliance with Ethical Standards

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

Statement of Human Rights All procedures 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.

Informed Consent Specific informed consent was obtained by each patient, and the local Institutional Ethical Committee approved the study.

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