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Original article

Sleeve gastrectomy with tailored 360° fundoplication according to Rossetti in patients affected by obesity and gastroesophageal reflux: a prospective observational study

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Abstract

Background: Laparoscopic sleeve gastrectomy (LSG) is the most frequently performed bariatric procedure. Recent studies demonstrated the correlation between LSG and gastroesophageal reflux disease (GERD).

Objectives: To evaluate the effectiveness of LSG + Rossetti antireflux fundoplication in patients affected by morbid obesity and GERD.

Setting: High-volume bariatric center, Italy.

Methods: This is a prospective, observational cohort study that enrolled 58 patients affected by obesity and GERD who underwent surgery. All the patients had a 12-month follow-up. Gastroscopies were performed preoperatively and at month 12 for 35 patients.

Results: At 1 year after surgery, patients had a consistent decrease in body mass index, from 41.9 ± 4.6 kg/m^2 to 28.2 ± 3.7 kg/m^2. GERD improved in 97.1% of patients. Comorbidities, such as hypertension, type 2 diabetes, respiratory dysfunction, and arthropathies improved as well. The visual analogue scale score regarding the global state of health increased significantly, from 58.1 ± 17.1% before surgery to 98.8 ± 4.1% at 1 year after surgery. Two patients had a fundoplication perforation and needed reparative surgery (3.5%). One patient had anemia that needed a blood transfusion (1.7%). Complications were reduced with a learning curve.

Conclusion: LSG + Rossetti fundoplication was shown to be a safe and effective intervention. It could be considered an option in obese patients affected by GERD. A longer follow-up is needed to establish the long-term outcomes. (Surg Obes Relat Dis 2021;17:1057–1065.)

Keywords: Nissen fundoplication; Rossetti fundoplication; GERD; Obesity; Sleeve Gastrectomy; Quality of life

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Gastroesophageal reflux disease (GERD) and obesity are both highly prevalent diseases, and their worldwide occurrences are rapidly increasing [1]. The GERD prevalence is 3- to 6-fold higher among people with a body mass index (BMI) $\geq$ 35 kg/m^2 [2]. Reflux disease and obesity are strong and independent risk factors for esophageal adenocarcinoma, a cancer whose incidence rate has increased significantly during recent years [3,4]. For these reasons, treatment for obesity and GERD is becoming a trend topic within the scientific community.

Laparoscopic sleeve gastrectomy (LSG) is the most popular bariatric procedure, due to its high efficacy and low complication rate. Two randomized, multicentric clinical trials (SM-BOSS [5] and SLEEVEPASS [6]) showed that there is no significant difference between LSG and Roux-en-Y gastric bypass (RYGB) in terms of weight loss and co-morbidity improvements. However, both trials demonstrated a correlation between LSG and postoperative GERD. Furthermore, a recent systematic review and a meta-analysis of long-term follow-up studies revealed a prevalence of de novo and nondysplastic Barrett's esophagus after LSG of 11.4% [7].

RYGB is considered the procedure of choice for GERD and obesity, but a recent Swedish nationwide and population-based cohort study including 4258 patients showed that reflux symptoms remained or recurred in 55.8% (95% CI, 53.9%–57.8%) of the participants during the first year following RYGB and in 48.8% (95% CI, 46.8%–51.0%) during the second year. Thereafter, the prevalence of reflux remained stable, at around 50%, for up to 10 years after surgery [2].

The gold standard of surgical procedures for GERD in nonobese patient is 360° laparoscopic fundoplication [8,9], with as many as 90% of patients free of symptoms at 10 years of follow-up and 60% without proton pump inhibitors (PPIs) at 17 years of follow-up [10].

Numerous techniques have been proposed in obese patients to mitigate the severity of reflux after LSG: antireflux sleeve gastroplasty [11], laparoscopic partial sleeve gastrectomy with fundoplication [12], sleeve gastrectomy and crural repair [13], Nissen-sleeve gastrectomy [14], and sleeve gastrectomy associated with the LINX system [15].

The rationale of the combined sleeve gastrectomy and Rossetti fundoplication is to associate the most efficient bariatric procedure with the gold standard for the treatment of GERD. Our department started to perform this operation in January 2015, and the first retrospective study to assess its feasibility was published in 2017 [16].

The aim of this study was to evaluate the effectiveness of LSG + Rossetti antireflux fundoplication in patients affected by morbid obesity and GERD, in terms of GERD improvement, weight loss, co-morbidity improvements, increasing quality of life, safety, and postoperative complications.

Methods

Study design

This is a prospective, observational cohort, monocentric study. All the surgical procedures were performed at a high-volume bariatric surgery center (>1000 procedures per year since 2017), from June 2017 to September 2018 by the same team of expert surgeons. Data were collected in a prospectively held database and analyzed by another autonomous research center. The study was approved by the ethics committee and was conducted according to the Declaration of Helsinki.

The inclusion criterion was the concomitance of morbid obesity and GERD.

Morbid obesity and suitability for surgery were set according to S.I.C.OB. (Italian Society of Bariatric Surgery) recommendations [17]: patients need to be between 18 and 65 years old, with either a BMI >40 kg/m^2 or a BMI between 35 and 40 kg/m^2 with obesity-related morbidities that could improve or be resolved with the massive and long-standing weight loss achieved after surgery (metabolic disorders, cardio-respiratory diseases, advanced joint disease).

The diagnosis of GERD was based on the Montreal definition: "GERD is a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications" [18] and on the endoscopic findings of esophagitis according to the Los Angeles classification system [19]. All the patients enrolled in the study had both symptoms of GERD that required PPIs and esophagitis, demonstrated by an esophagogastroduodenoscopy (EGDS) performed no more than 3 months before enrollment. We did not routinely perform a 24-hour pH-metry or a manometry before surgery. The role of these diagnostic procedures in obese patients affected by GERD is still debated. The 2 procedures did not receive consensus as being mandatory even in symptomatic patients, regardless of the degree of esophagitis, or even in those with Barret esophagus [20].

The exclusion criteria were being <18 years old or >65 years old; the presence of esophageal motility disorders; having a previous surgery for obesity or procedures on the gastroesophageal (g-e) junction; any contraindications to laparoscopic surgery; performance status 3–4; or the presence of dietetic, psychological, or metabolic contraindications for surgery. The presence of esophageal motility disorders was assessed by the clinical presentation of dysphagia. No patient with dysphagia was enrolled in the study.

All patients underwent a multidisciplinary evaluation by a team that included a specifically trained psychologist, dietician, and anesthesiologist; along with an instrumental evaluation that included a polysomnography, an abdominal ultrasound, and an EGDS with biopsies.

Assuming that the prevalence of GERD (main outcome) was 3% at 1 year after antireflux surgery [21], accepting a 5% margin of error and a 95% confidence level, the recommended sample size for the observational study was 45 patients.

Surgical technique

A video of the LSG + Rossetti fundoplication and a description of the technique were recently published [22]. A first 10-mm trocar was placed in the left subcostal space for the optic camera, allowing a better view of the g-e junction. Three other trocars were placed under optic vision: a 5-mm trocar in the epigastrium for liver retraction, a 5-mm trocar in the right hypochondrium for the left hand of the surgeon, and a 15-mm trocar a few centimeters above the navel, along the left parasternal line, for the right hand of the surgeon.

The first part of the intervention was the same as the classic LSG and consisted of the complete mobilization of the greater gastric curvature by dissection of the gastrocolic ligament and short gastric vessels. During the manipulation of the gastric fundus, it was crucial to avoid damaging the gastric serosa, since this could lead to late perforation of the wrap. The most common causes of serosal injuries may be burns from electrocautery and tissue traction by graspers.

The second part of the intervention consisted of creating a fundoplication according to Rossetti's modification of Nissen's technique [23]: there is minimal dissection of the crura and hepato-gastric ligament, there is no complete isolation of the diaphragmatic crus, only the fundus is used to create the valve (medial and lateral part of the anterior surface of gastric fundus), and no sutures on the esophagus are performed (Fig. 1). A 1.5–2-cm long, floppy, 360° fundoplication was created with 2 interrupted, nonabsorbable, extracorporeal Roeder knots (Ethibond 0, Ethicon, Somerville, NJ). If a hiatal hernia was present, a hiatoplasty was performed.

The valve was built over a 38 Fr boogie. The same boogie was used for the sleeve resection (third part of the intervention).

A linear articulable stapler was used (Tristaple Signia stapling system, Medtronic, Dublin, Ireland) with 2 black cartridges, 2/3 purple cartridges for the gastric section, and 1 black and 1 purple cartridge for the valve. In contrast to the classic sleeve, the fundus cannot be completely resected, because a little part of it is used to create the wrap. The smallest part of the gastric fundus as possible is used to build the wrap. An indocyanine green (ICG) fluorescence imaging (SPIES™, Storz) test performed at the end of the operation demonstrated the proper vascularization of the staple line. A drain was positioned along the staple line.

Postoperative management and follow-up

On the second postoperative day, an upper gastrointestinal (UGI) series was performed with oral, water-soluble contrast (Gastrografin, Bracco Diagnostics, Italy). If negative, the patient started a liquid diet on the same day. If there were any signs of leakage after the UGI series, a computed tomography (CT) scan was performed with oral, water-soluble contrast. Blood analyses, including measurements of C-reactive protein (CRP), were performed on the first and third postoperative days. If the postoperative course was regular, the patient went home on the third postoperative day. The patient continued with low molecular weight heparin for 24 days and PPIs for 60 days after surgery, at 40 mg per day.

The patients had clinical follow-ups and assessments of quality of life at 1, 3, 6, and 12 months after surgery; they had EGDS preoperatively and 12 months after surgery.

The quality of life was assessed by the 5-Level EuroQol 5-Dimension Questionnaire (EQ-5 D-5 L). The EQ-5 D-5 L consists of 2 sections: the descriptive system and the visual analog scale (EQ-VAS). The EQ-5 D-5 L descriptive system consists of 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension in the EQ-5 D-5 L has 5 response levels, ranging from no problems to extreme problems. The EQ-VAS provides a single global rating of self-perceived health and is scored on a 0-mm to 100-mm scale representing the worst and the best state of health, respectively. The use of the EQ-5 D-5 L was authorized by the EuroQol Group.

Statistical analysis

Descriptive statistics were used to summarize patient baseline characteristics and clinical data. Continuous variables were compared using the Student *t*-test or Wilcoxon signed-rank test for matched samples. The XL-Stat software (Addinsoft Company, Paris, France) was used to perform statistical analyses. Statistical tests were considered significant at the level of .05.

Results

Demographic characteristics

The study included 58 patients who met the inclusion criteria and signed informed consent. All patients presented to us for morbid obesity and associated GERD. The mean BMI was 41.9 ± 4.6 kg/m^2. Three patients had a BMI > 50 kg/m^2 (5.2%). All patients had typical symptoms of GERD before the intervention. They were using PPIs, and the preoperative EGDS revealed esophagitis. In 7 patients (12.1%), the typical GERD symptoms were associated with atypical ones, such as cough, dysphonia, and sore throat. The preoperative characteristics of the patients are summarized in Table 1. All the patients underwent LSG +

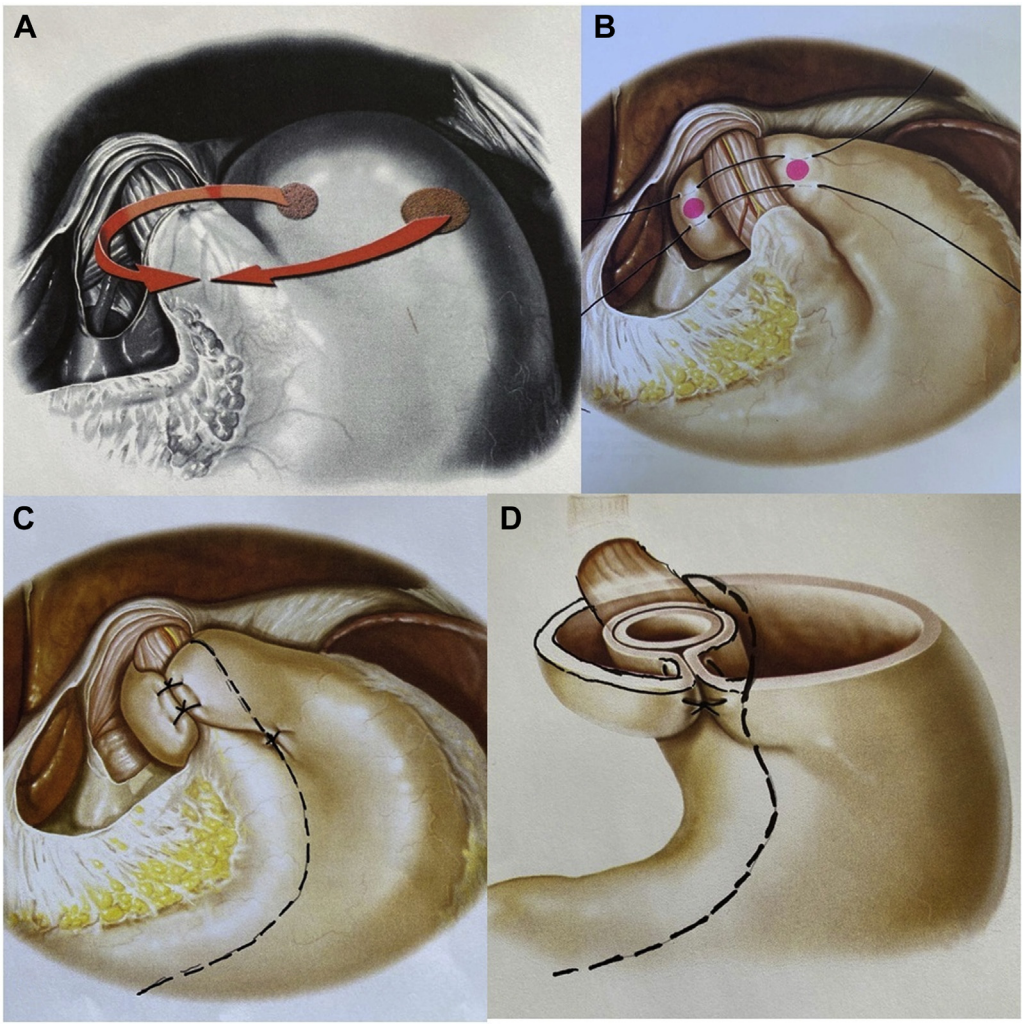

Fig. 1. Technical aspects of laparoscopic sleeve gastrectomy + Rossetti fundoplication. (A and B) A standard Nissen-Rossetti. (B and C) The sleeve over the stomach and the wrap. (A) The fundoplication is made only with the anterior wall of the fundus and a minimal dissection of the retro-esophageal space is required. (B) The esophageal wall is not included in the wraps' sutures. (C) The sleeve is performed along the oro-gastric boogie over the distal part of the stomach and the wrap, (D) leaving a completely functioning 360° fundoplication.

Rossetti fundoplication and had a UGI study on day 2 after surgery (Fig. 2).

Surgical outcome and complications

The mean operative time was 51.8 ± 19.5 minutes. No hiatal hernia susceptible to surgical reparation was found. Even though 30 patients (51.7%) had a small (<2 cm) sliding hiatal hernia according to the preoperative EGDS, none of the hernias were deemed susceptible to repair after having dissected the crura and built the fundoplication, because of the small dimensions of the hernias.

Of 58 patients, 7 (12.1%) were hospitalized for longer than the standard 4 days. The mean hospitalization for these 7 patients was 8.9 ± 3.4 days (range, 5–14 days). Prolonged hospitalizations were due to fundoplication perforations (n =2; 3.5%), anemia (n = 2; 3.5%), leukocytosis and a CRP increase (n = 1), radiological doubt of gastric perforation (n = 1), and hypokalemia (n = 1; Table 2).

One patient had a perforation of the fundoplication on day 2 after surgery and 1 patient had a perforation on day 7. Neither perforation was considered as due to typical leakage after a sleeve procedure, because neither appeared along the staple line. The 2 perforations occurred on the gastric fundus used to build the fundoplication, and they were likely related to minimal serosal lesions due to inappropriate traction during the fundoplication maneuvers. The perforations happened 21 days and 238 days after the beginning of the trial, in the first half of the patient group (until patient number 29). We did not observe perforations in the second 29 patients of the trial (Fig. 3). The patients with perforations developed sudden abdominal pain, associated with leukocytosis; an increase of CRP; and a high fever. They underwent a CT scan with oral, water-soluble contrast that revealed the

Table 1
Baseline characteristics of 58 patients

Characteristic	mean ± SD or n (%)
Patient	58 (100)
Sex, male	16 (27.6)
Age, yr	43.0 ± 8.4
Weight, kg	112.9 ± 16.7
BMI, kg/m^2	41.9 ± 4.6
Hypertension	18 (31.0)
Type 2 diabetes	7 (12.1)
Arthropathies	11 (19.0)
OSAS	27 (46.6)
CPAP	27 (46.6)
NASH	2 (3.5)
Dyslipidemia	6 (10.3)
Psychological distress induced by obesity	42 (72.4)
Typical GERD symptoms, %	58 (100)
Atypical GERD symptoms, %	7 (12.1)
Esophagitis	58 (100)
A	40 (69.0)
B	12 (20.7)
C	6 (10.3)
PPIs	58 (100)

BMI = body mass index; OSAS = obstructive sleep apnea syndrome; CPAP = continuous positive airway pressure; NASH = nonalcoholic steato-hepatitis; GERD = gastroesophageal reflux disease; PPIs = proton pump inhibitors.

The table shows preoperative characteristics of patients. Data are reported as percentages of the total (58 patients) or means ± standard deviations.

leakage of the contrast from the gastric fundoplication and a perigastric collection of fluid and air. Both patients with perforation underwent a laparoscopic revision. A minimal perforation of the gastric fundoplication was observed far from the staple line. The perigastric collection was aspirated. The fundoplication was opened through the section

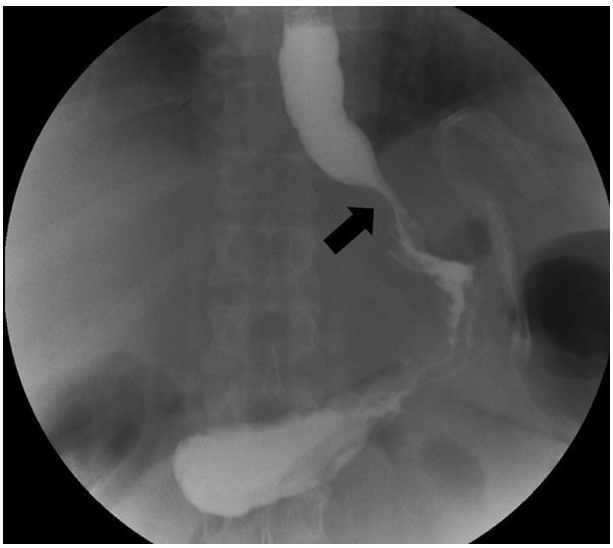

Fig. 2. Image of an upper gastrointestinal x-ray study with oral water-soluble contrast on day 2 after surgery. The arrow indicates the site of the fundoplication.

Table 2
Early and late surgical complications after laparoscopic sleeve gastrectomy + Rossetti fundoplication

Complication	n (%)	Reintervention required
Early complication, n = 4 (6.9%)		
Fundoplication's perforation	2 (3.5)	Yes
Anemia and perigastric hematoma	2 (3.5)	No
Anemia that required transfusion	1 (1.7)	
Mild anemia	1 (1.7)	
Late complication, n = 1 (1.7%)		
Fundoplication's disruption	1 (1.7)	Yes

Data are reported as percentage of the total (58 patients).

of the Roeder stitches. The fundus was pulled back under the esophagus and completely exposed. An orogastric boogie (38 Fr) was inserted carefully into the stomach, and the fundus was cut out by a Tristaple Signia 60 black cartridge × 2. The complete hospitalization times for these patients were 13 and 14 days.

Two patients had postoperative anemia. One needed a blood transfusion (Hb 7.6 g/dL, starting from a value of 12.1 g/dL). The other patient had mild anemia (Hb 12.1 g/dL, starting from 15.2 g/dL). Neither of the 2 needed surgical revision. CT scans revealed perigastric hematomas, which were 48.1 cm^3 for the patient who needed a transfusion and 101.3 cm^3 for the patient with mild anemia (formula = 4/3 π multiplied by the measure of the 3 semi-axis). Both patients went home 7 days after surgery. The frequency of bleeding and anemia was the same as that of normal LSG [24].

One patient had a doubtful image of air bubbles at the CT scan on day 2 after surgery. He did not develop fever, abdominal pain, or leukocytosis. He repeated imaging on day 4, which was negative for leakage or perigastric collection of fluid or air. He started a liquid diet and went home on day 6.

One patient had leukocytosis and a CRP increase on day 2 after surgery, without imaging of leakage. He started a liquid diet without problems and went home on day 8 (the seventh day after surgery).

One patient went home on day 5 (the fourth after surgery) after restoring the correct blood value of potassium.

One patient had a disruption of the fundoplication 5 months after surgery and needed a surgical revision and rebuilding of the wrap. No other long-term complications were noted after a complete follow-up of 1 year.

Weight loss, co-morbidities, and quality of life improvement

After 12 months of follow-up, the mean BMI decreased from 41.9 ± 4.6 kg/m^2 to 28.2 ± 3.7 kg/m^2 ($P < .05$). Co-morbidities improved after surgery. After 12 months, 8 out of 18 patients suspended therapy for hypertension (44.4%) and 2 out of 18 reduced it (11.1%). Seven patients

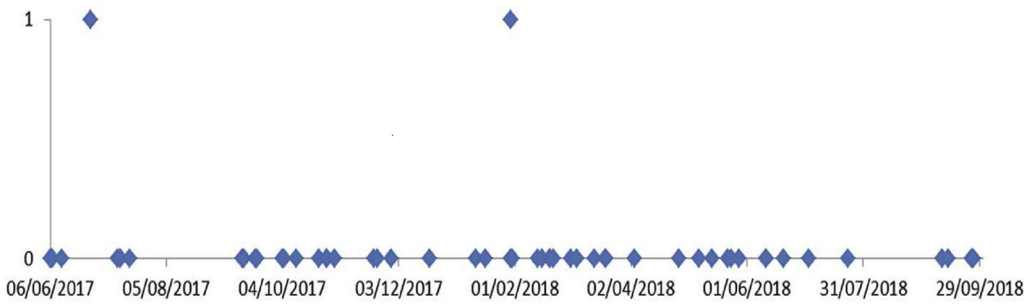

Fig. 3. Fundoplication's perforation considering the trial's time frame. Each point in the graph corresponds to an intervention. On the x-axis: date of intervention. On the y-axis: 0 = no perforation; 1 = perforation.

were diabetics in therapy with oral hypoglycemic agents, 3 (42.9%) of whom suspended therapy within 12 months after surgery, with normal values of glycated hemoglobin (<6%). None of the 27 patients with severe obstructive sleep apnea syndrome needed to continue continuous positive airway pressure at 12 months after surgery. All arthropathies improved with weight loss.

The quality of life improved after LSG + Rossetti fundoplication in terms of mobility, self-care, daily activities, pain/discomfort, and anxiety/depression (Fig. 4). After 12 months, the VAS score improved significantly, from 58.1 ± 17.1 to 98.8 ± 4.1 ($P < .05$).

GERD improvement

All the patients (58/58) were referred with GERD symptoms preoperatively and were on PPIs of 40 mg/d. Out of 58 patients, 35 (60.3%) had an EGDS after 1 year postoperatively (mean time 15.5 ± 4.8 mo). Of the remaining 23 patients, 21 did not have an EGDS for personal issues and 2 patients had to undergo surgical resection of the fundoplication following perforation, so that an EGDS would not have been significant from the perspective of this study. Thus, we considered pre- and postoperative esophagitis in 35 patients (Table 3).

GERD symptoms improved after surgery. The patients continued PPIs until the second month after surgery. After 1 month, only 3 patients reported typical symptoms (5.2%). After suspending PPIs, 5 patients referred typical symptoms in month 3 (8.6%), while 3 patients (5.2%) and 2 patients (3.5%) reported occasional regurgitation of sour liquid in months 6 and 12, respectively, which did not required therapy with PPIs.

Table 3 reports on the modification of esophagitis after sleeve + Rossetti fundoplication. Only 1 patient with esophagitis B did not improve. This patient did not report GERD symptoms and did not use a PPI. Both the patients with esophagitis were advised to begin using a PPI.

Considering the Montreal definition of GERD, all patients who underwent LSG + Rossetti fundoplication did not have "troublesome symptoms" 1 year after surgery. Only 1 patient did not have improvement of esophagitis at 1 year after surgery.

Discussion

LSG and Rossetti fundoplication are 2 well-known procedures. We started to combine them when a patient affected by obesity and GERD could not undergo gastric bypass or other malabsorptive procedures. We were encouraged in our attempt by the discovery in the literature that other surgeons were trying to combine LSG and antireflux procedures. In 2007, Fedenko et al. [11] called the combination "Antireflux Sleeve Gastroplasty"; in 2015, Le Page

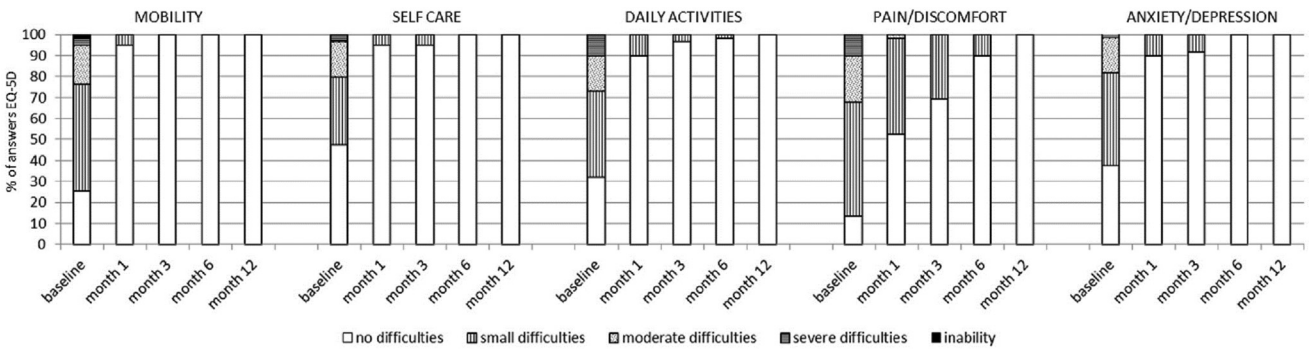

Fig. 4. Improving in quality of life after sleeve + Rossetti fundoplication according to the 5-level EuroQol 5-Dimension Questionnaire.

Table 3
Pre- and postoperative endoscopic findings of esophagitis according to the Los Angeles classification system

	Preoperatively, n	Postoperatively, n
Esophagitis A	24	1
Esophagitis B	7	1
Esophagitis C	4	0
Total	35	2

EGDS = esophagogastroduodenoscopy.

Data are according to the Los Angeles classification system [19]. Pre- and postoperative EGDS was compared in 35 of 58 (60.3%) patients with a mean follow-up of 15.5 ± 4.8 months after surgery.

et al. [12] called it "Laparoscopic Partial Sleeve Gastrectomy with Fundoplication"; and in 2016, Nocca et al. [14] called it a "Nissen Sleeve." Then, we found out that even the gold standard procedure for obesity and GERD, RYGB, may fail. A Swedish nationwide and population-based cohort study showed the prevalence of reflux remained stable, at around 50%, for up to 10 years after RYGB [2]. In contrast, we had good results from the first LSG + Rossetti fundoplication procedures in terms of weight loss and GERD improvement.

One of the requirements in performing the 360° wrap is to have normal esophageal motility. In this study, esophageal motility was assessed only clinically, by evaluation of dysphagia. From a clinical point of view, no dysphagia was assessed before and after sleeve + Rossetti fundoplication.

We chose Rossetti's variation on Nissen's technique as the antireflux procedure to be associated with LSG because of its characteristics and effectiveness. Rossetti's is the most frequently performed antireflux procedure in Italy, with esophagitis resolved in >90% of patients [25]. In Rossetti's variation, the fundoplication is made only with the anterior wall of the fundus (Fig. 1A), instead of using portions of anterior and posterior walls as in the original Nissen procedure [23]. This leads to a short fundoplication (max 2 cm) that is loose and without tension. The lower esophageal sphincter (LES) is about 2–3 cm long, and a 2-cm fundoplication is enough to replace adequate pressure at the LES level. Fundoplications longer than 4 cm have approximately a 70% chance of causing incomplete postswallowing relaxation and dysphagia [26]. Moreover, a 2-cm fundoplication made only by the anterior surface of the gastric fundus allows for the excision of all the excess posterior fundus, leading to an effective sleeve. Rossetti's technique involves minimal dissection of the retro-esophageal space [23], without the section of the hepato-gastric ligament. This allows the fundoplication to stay in the abdomen without tension, avoiding slippage into the mediastinum. Interference with various branches of the vagal nerve is avoided, and the gastric physiology is preserved. The esophageal wall is not included in the wraps' sutures [23]. This fact prevents the formation of granulomas, vagal nerve lesions, or esophageal lesions (tractions during postoperative vomiting). Moreover, if it becomes necessary to disassemble the fundoplication—for example, after a perforation—the absence of esophageal stitches makes the procedure much easier. The section of the stomach that was performed during LSG did not change the effectiveness of the antireflux wrap, which remained a complete 360° fundoplication (Fig. 1D). The excess of fundus of the left wrap was removed, leaving the internal wall of the fundoplication intact, close to the esophagus. This fact was demonstrated by preoperative and postoperative manometries that we performed in a selected patient. The preoperative and postoperative comparison was performed in a totally arbitrary way in a single patient to test whether there was a difference in terms of LES and esophageal pressure before and after surgery. The preoperative LES pressure was 9.7 mm Hg (normal range = 13–43 mm Hg). On the third postoperative day, the LES pressure was 27.9 mm Hg, with complete postswallowing relaxation and coordinate peristalsis. The esophageal manometry also revealed a correlation between the absence of clinical dysphagia and the absence of manometric esophageal motility disorders. A study that will include pre- and postsurgery manometric assessments in both sleeve and sleeve + fundoplication patients will follow in the next months.

We build the fundoplication over a 38-Fr boogie. In non-obese patients with GERD, we normally use a 60-Fr boogie to perform Nissen-Rossetti fundoplication, without postoperative dysphagia problems. In obese patients with GERD, we decided to use the same boogie that we use for sleeves to obtain minimal dysphagia, which could oblige patients to eat slower, with small and well-chewed bites. However, after sleeve + fundoplication, patients did not have dysphagia which required dilation or wrap disruption. Moreover, neither manometry nor gastroscopy showed esophageal decompensation.

For all these reasons, we chose Rossetti fundoplication as the antireflux procedure to be combined with LSG. The aim of this study was to assess the feasibility of this procedure and its effectiveness in weight loss and GERD improvement. The patients call this the "sleeve with tie" or "Tie-Sleeve" procedure. To verify the impact of the Tie-Sleeve on GERD, we only selected patients with obesity who simultaneously reported reflux of stomach contents, causing troublesome symptoms and/or complications, as it is specified in Montreal definition of GERD [18]; were in therapy with PPIs; and had esophagitis at the preoperative EGDS. At the 1-year follow-up visit, no patient reported GERD symptoms, no patient took PPIs, 34/35 patients had esophagitis improvement (97.1%), and 33/35 patients had complete resolution of esophagitis (94.3%) according to the EGDS administered 15.5 ± 4.8 months after surgery. These data show that LSG + Rossetti fundoplication is effective in improving GERD. The mean BMI was reduced

significantly, too, reaching the goal of falling below the obesity threshold at 1 year after surgery. Out of 58 patients, 4 had a complicated postoperative course with a longer hospitalization than the regular 4 days. The major complications after surgery were 2 fundoplication perforations (3.5%). In our LSG series, we have leakage in 1.6% of the cases [27]. The leakage rate in the literature varies from 1.1 to 5.3% [28]. Nocca et al. [14], in a pilot study on the Nissen sleeve, revealed 1 valve perforation without recognized ischemia out of 25 interventions (4%) [14]. The perforation in our study were not the same as those seen in classic LSG leakage in terms of etiology and therapy. They did not happen along the staple line, unlike in case of classic leakage. Instead, they were related to lesions of the gastric serosa due to inappropriate tissue traction during the maneuvers of fundoplication. The ICG test performed at the end of the intervention demonstrated the good vascular perfusion of the wrap. For this reason, we concur with Nocca [14] that the perforations were not related to the ischemia of the valve, but to a traumatic issue. The therapy consisted of disassembling the fundoplication and cutting off the perforated part of the fundus, crafting a classic sleeve. The resolution time was shorter than that seen with LSG classic leakage (12 ± 2.7 days versus at least 23 days in our series of LSG leakages [27]). The literature also reports 2 cases of valve necrosis related to perforations [29,30], 1 of which was treated by total gastrectomy. Necrosis could be the consequence of valve perforation and, if promptly recognized and treated in a specialized center, can be managed as a perforation without necrosis: that is, by disruption and resection of the valve. Perforation was related to a learning curve. All the perforations occurred within the first half of the patient group. We had 2 perforations in the first 29 patients, then we had no perforations in the last 29 patients. In terms of time, in the last 7 months of the study we did not have any perforations (Fig. 2). All the interventions were performed by expert bariatric surgeons (>200 procedure/yr). Among the bariatric surgeons, only 1 had considerable experience in antireflux surgery. A learning curve in building the fundoplication is needed for expert bariatric surgeons who do not have wide experience in antireflux surgery.

We did not have leakage from the staple line in LSG + Rossetti fundoplication. This finding could indicate that fundoplication reduces leakage incidences in the upper part of the staple line by reinforcing this critical area, which has the highest rate of leakages [31]. LSG + Rossetti fundoplication does not include sutures at the g-e junction. Moreover, we did not have any case of esophageal perforation, which is a well-known complication in antireflux surgery, especially related to the dissection of the posterior wall of the esophagus (0.9%) [32].

Another complication to consider is postoperative anemia: our 2 cases (3.5%) did not require surgical revision, although 1 out of the 2 patients needed blood transfusion. Finally, we had 1 patient with late disruption of the fundoplication that occurred 5 months after surgery (1.7%), which required a surgical revision and the rebuilding of the wrap.

The relatively short follow-up period could be a limitation of the study. Future studies will be conducted to assess the long-term efficacy of the procedure. Manometric studies before and after surgery will be run to evaluate the presence of preoperative esophageal motility disorders. These studies will also examine LES pressure before and after intervention, and may allow us to select those patients who can benefit the most from sleeve + Rossetti fundoplication, taking into account the fact that patients with normal LES pressure, even those with low esophagitis (e.g., esophagitis A), may undergo LSG with benefits to both weight loss and GERD symptoms

Conclusion

LSG + Rossetti fundoplication (Tie-Sleeve) seems to be a safe and effective option for obese patients affected by GERD. Results at 12 months of follow-up are encouraging. A learning curve is needed even for expert bariatric surgeons to avoid complications, mostly related to Rossetti fundoplication wrapping.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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Editorial comment

Sleeve gastrectomy with tailored 360° fundoplication according to Rossetti in patients affected by obesity and gastroesophageal reflux

We commend the authors for a remarkably interesting study [1] that makes efforts to answer an important clinical question regarding gastroesophageal reflux disease (GERD) and bariatric surgery. Reflux disease, whether identified in the preoperative workup or as a complication of bariatric surgery, represents a matter of debate that will continue in the upcoming years, and your manuscript brings forth some important information despite the relatively low number of cases. In the present study [1], the authors included 53 patients who underwent laparoscopic sleeve gastrectomy (LSG) with tailored 360° fundoplication according to Rossetti technique.

The topic of GERD and LSG has been largely discussed in the literature during the last decade, and new investigational procedures were described [2–4]. Which surgical strategy to adopt in case of GERD for a patient with morbid obesity disease is a controversy in the literature and is still a matter of debate. Although the Roux-en-Y gastric bypass (RYGB) was considered the gold standard procedure for patients with morbid obesity disease and GERD, the authors have very well summarized the risk of persistent reflux even after bypass. Moreover, more than 35% of patients who underwent RYGB had at least 1 complication within the 10-year follow-up period [5]. In another study, Weiss et al. [6] reported on 129,432 RYGB patients with overall mortality rates of 2.2%, 4.4%, and 8.1% at 1, 5, and 10 years, respectively. The number of patients hesitating or refusing to choose an RYGB because of long-term complications cannot be neglected. In this context, the current manuscript [1] reported the possibility of associating an anti-reflux procedure (Rossetti procedure) with an LSG, leading us to think that there is a possible place for this mixed