

Original article

Modified laparoscopic sleeve gastrectomy with Rossetti antireflux fundoplication: results after 220 procedures with 24-month follow-up

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Abstract

Background: Gastroesophageal reflux disease (GERD), including erosive esophagitis, is highly prevalent in the obese population. Laparoscopic sleeve gastrectomy (LSG) is one of the most frequently performed bariatric procedures. The relationship between LSG and GERD has gained increasing attention. This retrospective study aimed to assess the effectiveness of combined LSG and modified Rossetti antireflux fundoplication for the treatment of GERD on morbidly obese patients after bariatric surgery.

Objectives: To assess the effectiveness, on morbid obese patients, of combined SG and Rossetti fundoplication for the treatment of GERD in obese patients.

Setting: Public Hospital, Italy.

Methods: From January 2015 to May 2018, 220 obese patients (167 female; 53 male) underwent LSG and modified Rossetti antireflux fundoplication procedure, performed by 4 different expert bariatric surgeons. Data have been collected in an Excel file and processed by XLStat to perform statistical analyses. We analyzed short-term complications and medium-term results with 24-month follow-up in terms of weight loss, remission of co-morbidities, and resolution of GERD.

Results: Mean BMI was 42.58 ± 5.93 kg/m² (range, 31.70–63.16). Patients suffering from GERD before surgery were 137 of 220 (62.3%). No intraoperative complications or conversion were reported. Regular postoperative course was recorded in 90% of patients (198 of 220 patients). Gastric perforation has always occurred on the fundoplicated portion of the stomach. This perforation, which is different from the well-known post-LSG gastric fistula, may be because of incorrect gastric fundus manipulation. Rate of reoperation was 14 of 220 (6.4%). A good sense of repletion without episodes of vomiting, nausea, or dysphagia was reported in 95% of the analyzed patients. Of patients, 98.5% did not suffer from reflux symptoms and did not take proton pump inhibitors. A decrease in BMI and percent of total weight loss at follow-up were comparable with LSG. Endoscopic follow-up is still ongoing. Improvement in esophagitis was observed in 63 of 65 (96.92%) patients and all 4 patients shows improvement in Barrett's esophagus.

Conclusions: LSG and modified Rossetti antireflux fundoplication procedure is a tolerated and feasible procedure in obese patients, with good postoperative weight loss results and improvement

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Key words: Sleeve gastrectomy; GERD; Gastroesophageal reflux disease; Fundoplication

Bariatric surgery is now widely accepted as the only long-standing, effective therapy for morbid obesity. Laparoscopic sleeve gastrectomy (LSG) is one of the most performed surgical procedures [1–5]. An increasing number of large monocentric studies and reviews are reporting good overall outcomes concerning the safety of the procedure, its medium-term results, and the positive impact on bariatric-related morbidities [6–10]. Gastroesophageal reflux disease (GERD) can be considered an obesity-related illness with a very high overall incidence and obese patients with GERD are poor candidates for antireflux surgery alone [11,12]. It is difficult to have a precise estimate of the worsening of GERD after bariatric surgery and in particular after LSG, as the literature data are contradictory [13–15]. Often GERD in the obese undergoes a contextual improvement in weight loss, with variable results depending on the technique [13]. In the past years, many authors have debated this topic not only regarding bariatric surgery, but also as a collateral effect of the procedure. In particular, LSG is burdened by a 10% to 30% rate of postoperative de novo GERD [4,13–16]. Therefore, laparoscopic Roux-en-Y gastric bypass is considered the criterion standard [11,13,14], although the debate is still open. Above all, some authoritative authors indicate LSG can be performed even in patients suffering from gastric reflux or esophagitis [17]. In the past 10 years, several studies have emphasized the association between cruroplasty and/or fundoplication with LSG guarantees a reduction of postoperative GERD [18–21]. This retrospective study aimed to assess the effectiveness, safety and results at 24 months, on morbidly obese patients who underwent LSG combined with modified Rossetti antireflux fundoplication for the treatment of obesity-associated GERD after bariatric surgery.

Methods

This retrospective study analyzed data from patients who underwent LSG and modified Rossetti antireflux fundoplication procedure from January 2015 to May 2018. All the procedures were performed in the same bariatric surgery center. Of 3300 bariatric surgical procedures performed, we performed 220 modified procedures with antireflux fundoplication (167 females; 53 males). Over 100 patients were enrolled in a preliminary pilot study, and other patients were enrolled in 2 prospective studies, which are still in progress. In particular (1) 103 obese patients (46.8%) from preliminary study about modified LSG; (2) 47 obese patients (21.4%) from observational study about GERD and

modified LSG (to study the modified LSG as a cure for bariatric patients affected from GERD, started from June 2017 and still ongoing); and (3) 70 obese patients (31.8%) from a randomized controlled trial about LSG versus modified LSG on non-GERD obese patients (to study the modified LSG to prevent GERD onset in bariatric patients, started from June 2017 and is ongoing).

The total population of this retrospective analysis was 220 modified LSG procedure from January 2015 to May 2018. All the patients suffered from morbid obesity and were suitable for surgery following the recommendations of the Italian Society for Bariatric and Metabolic Surgery. All patients underwent clinical and endoscopic evaluation, according to the internal protocol and national and international guidelines. In the randomized clinical trial, enrolled patients did not suffer from GERD. However, the observational clinical study and the preliminary study involved patients with a diagnosis of GERD based on the endoscopic findings of esophagitis according to the Los Angeles classification and Montreal definition [22]. All patients were studied for GERD by means of GERD questionnaire tests [23] and endoscopy to detect reflux disease signs, esophagitis (classified according to the Los Angeles classification [24]) and Barrett's esophagus. Preoperative characteristics of the population are summarized on Table 1. All surgical procedures were performed by 4 different surgeons with large experience on laparoscopic bariatric surgery. One surgeon (S.O.), in particular, had previously had extensive experience in GERD surgery. All patients underwent a multidisciplinary evaluation by psychologist, dietician, and anesthesiologist; instrumental evaluation included polysomnography, abdominal ultrasound, and upper endoscopy with biopsies. Informed consent was obtained from each patient before surgery.

Surgical technique

Pneumoperitoneum is induced with the Veress needle technique in the left subcostal space (Palmer's point). The procedure requires 4 trocars, a 10- or 12-mm trocar is inserted in left subcostal space lateral to the midclavicular line (this trocar is used for the insertion of a 30° angled optic); a 5-mm trocar is inserted in the epigastric region; a 5-mm trocar in the right flank/hypochondrium; and a fourth 15-mm trocar in the supraumbilical area. The surgeon is positioned between the patient's legs, who is in a semiseated position. The first surgical step is the mobilization of the greater gastric curve with a 5-mm radiofrequency dissector (Ligasure Maryland; Medtronic, Minneapolis, MN, USA),

Table 1
Patient characteristics and preoperative assessment

Demographic characteristics (number of patients = 220)	
M/F, n (%)	53 (24.1)/167 (75.9)
Age, yr, mean \pm SD (range)	42.7 \pm 10.4 (18–67)
Weight, kg, mean \pm SD (range)	114.0 \pm 19.5 (82–183)
BMI, kg/m ² , mean \pm SD (range)	42.58 \pm 5.93 (31.70–63.16)
Ideal weight, kg, mean \pm SD (range)	60.42 \pm 10.23 (36–91)
Excess weight, kg, mean \pm SD (range)	53.54 \pm 15.48 (26.50–111.00)
Excess weight, %, mean \pm SD (range)	90.77 \pm 30.03 (34.62–236.11)
Endoscopic findings	
No GERD, n (%)	83 (37.7)
No GERD without endoscopic lesions, no GERD, %	84.3
No GERD with endoscopic lesions, no GERD, %	15.7
GERD, n (%)	137 (62.3)
GERD without endoscopic lesions, GERD, %	62.8
GERD with endoscopic lesions, GERD, %	17.2
LA classification: grade A, n (%)	36 (16.4)
LA classification: grade B, n (%)	8 (3.6)
LA classification: grade C, n (%)	3 (1.4)
LA classification: grade D, n (%)	0 (0)
Barrett's esophagus, n (%)	4 (1.8)
Hiatal hernia, n (%)	62 (28.2)
Co-morbidities	
Diabetes, n (%)	26 (11.8)
Hypertension, n (%)	87 (39.5)
Sleep apnea syndrome, n (%)	99 (45.0)

M = male; F = female; SD = standard deviation; BMI = body mass index; GERD = gastroesophageal reflux disease; LA = Los Angeles.

starting 4 to 5 cm from the pylorus and ending with the mobilization of the fundus through the section of the phrenofundic ligament. The left diaphragmatic pillar is isolated (Fig. 1). If a hiatal hernia is present, its reduction is performed by opening the space between the left pillar and the esophagus. If not, dissection of the diaphragmatic hiatus and the right pillar is minimal (Fig. 1), just enough to allow for the creation of a retroesophageal window for the passage of the gastric fundus (Fig. 2). In comparison to the Nissen technique, we do not dissect the hepatogastric ligament and the diaphragmatic crus is not completely isolated. Only in the case of a large hiatal defect, a cruroplasty is performed by 2 or 3 braided nonabsorbable suture (Ethibond Excel; Ethicon Endo-Surgery, Cincinnati, OH, USA). The esophagus is intubated with a 38-Fr bougie. The fundoplication is performed with the Rossetti variation as follows: only the fundus is used to create the valve and no esophageal sutures are performed. The surgeon grasps the lateral and medial part of the fundus to create a wrap with as little gastric fundus as possible (Fig. 3). This maneuver is important to allow the almost complete resection of the gastric fundus during the LSG. Fundoplication is performed with 2 single extracorporeal knottings (Roeder knots) (Fig. 4), with 0 braided nonabsorbable suture (Ethibond Excel; Ethicon Endo-Surgery), without sutures between the anterior wall of the esophagus and the gastric wrap. The correct

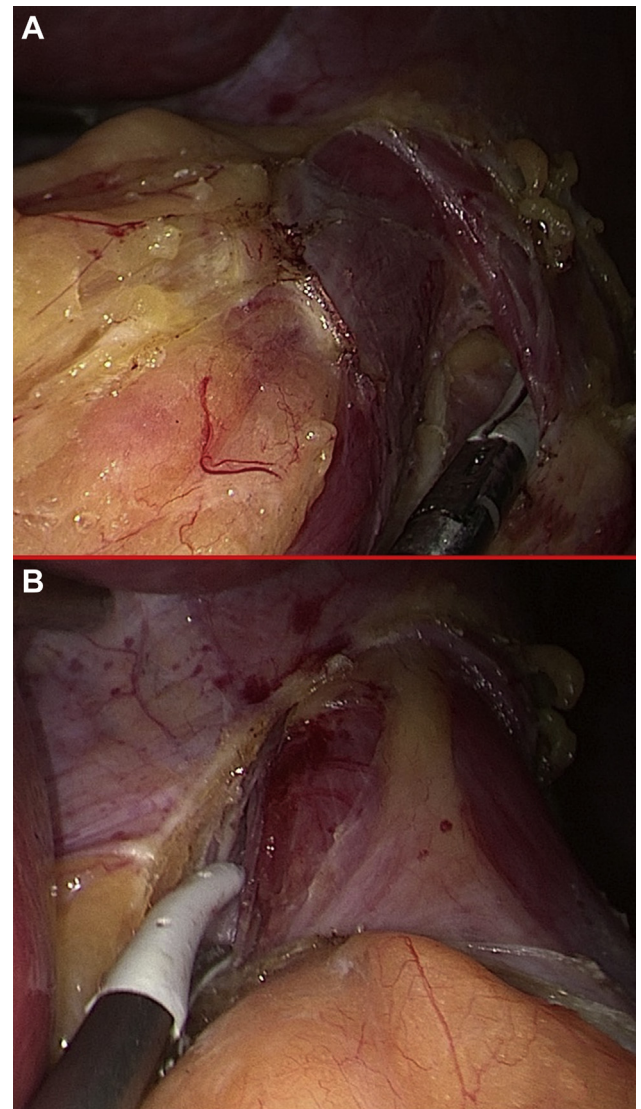


Fig. 1. Dissection of left (A) and right (B) diaphragmatic pillar. Note the anterior vagus nerve, carefully respected during hiatal dissection.

tightness of the plication is checked with a 10-mm blunt laparoscopic bougie, introduced between the esophagus (which is intubated with 38-Fr bougie inside) and the wrap. LSG is then performed starting 4 to 5 cm from the pylorus and ending a few centimeters medially from the lateral edge of the left gastric flap (Fig. 5). The section has to involve as much fundus as possible. Stapling is usually performed with 3 black and 3 purple cartridges (Signia with Tri-Staple™ technology; Medtronic). At the beginning of our experience, we also performed a volumetric test that showed a total capacity of 150 mL and vascularization of fundoplication with a green indocyanine test was evaluated (Fig. 5C). The surgical result is a very short fundoplication with a gastric fundus resection as complete as possible (Fig. 6A).

On the first postoperative day, the patient is mobilized and the urinary catheter is removed. On the second postoperative

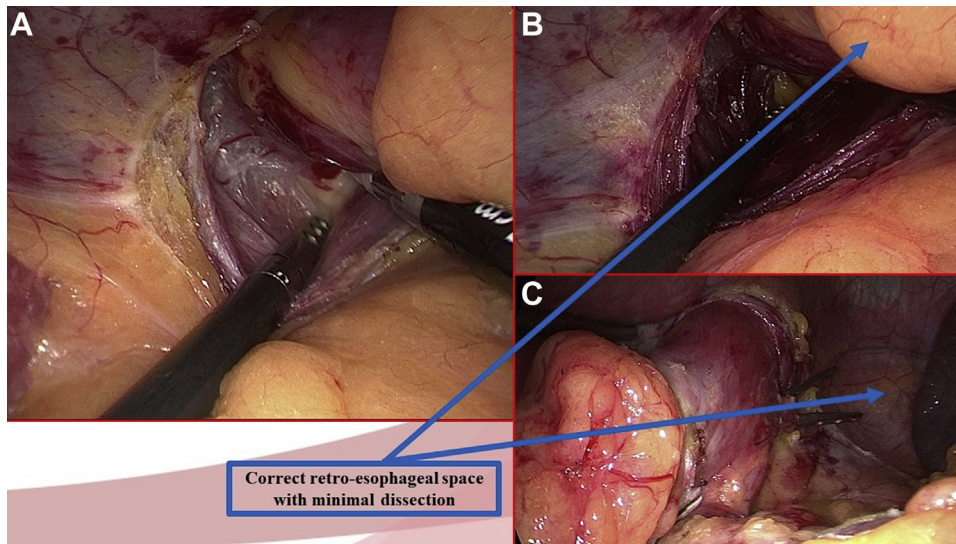


Fig. 2. Dissection of the diaphragmatic hiatus and the right pillar is minimal (A), just enough to allow for the creation of a retroesophageal space for the passage of the gastric fundus without leaving a wide space (B, C).

day, the patient undergoes a gastroesophageal X-ray with water-soluble oral contrast medium administration (Fig. 6B). If the transit is regular, the patient starts a liquid diet on the same day. If there is any sign of perforation on the X-ray, or if clinical signs of complication, such as fever, are present, a computed tomography scan with water-soluble oral contrast medium administration is performed. Blood tests, including C-reactive protein, were performed on the first and third postoperative days. If the postoperative course is regular, discharge is scheduled on the third postoperative day. We did not apply enhanced recovery after surgery protocols in this experimental phase. The patient must continue with low molecular weight heparin for 24 days and proton pump inhibitors

(PPI) up to 60 days after surgery. Patients are regularly followed up at 1, 3, 6, 12, 18, and 24 months after discharge. We analyzed the demographic characteristics of the population, including sex, age, weight, body mass index (BMI), and co-morbidity. Weight loss is expressed as percentage of excess weight loss and percentage of total weight loss with the calculation of ideal weight as that equivalent to a BMI of 25 kg/m^2 and percentage of excess BMI lost with excess BMI $>25 \text{ kg/m}^2$. We also collected information about operative time, number and type of cartridges used, deviation of normal postoperative course, complications, and reoperation. Data have been collected in an Excel file and processed by XLStat (Microsoft, Redmond, WA, USA) to perform statistical analyses.

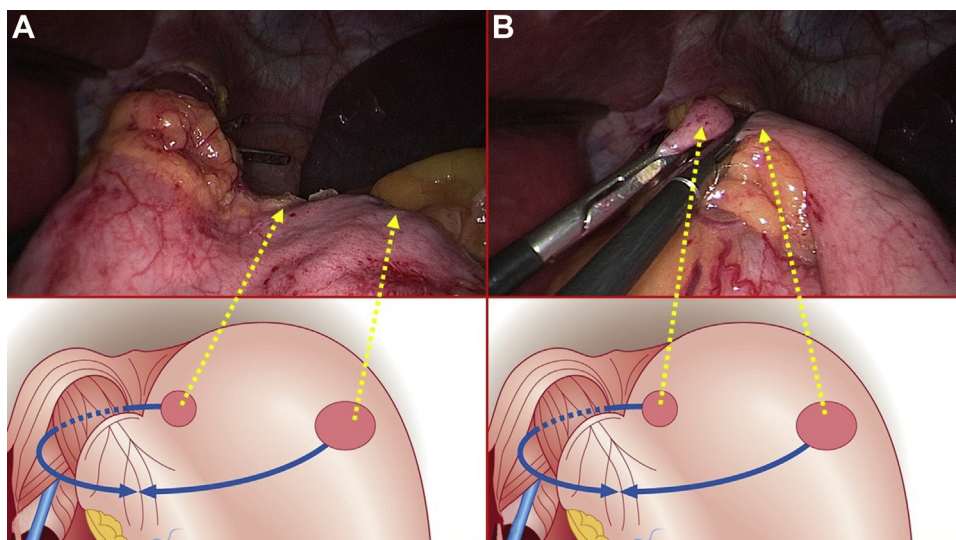


Fig. 3. Rossetti technique. Only the fundus is used to create the valve. The surgeon grasps the lateral and medial part of the fundus (A) to create a wrap with as little gastric fundus as possible (B).

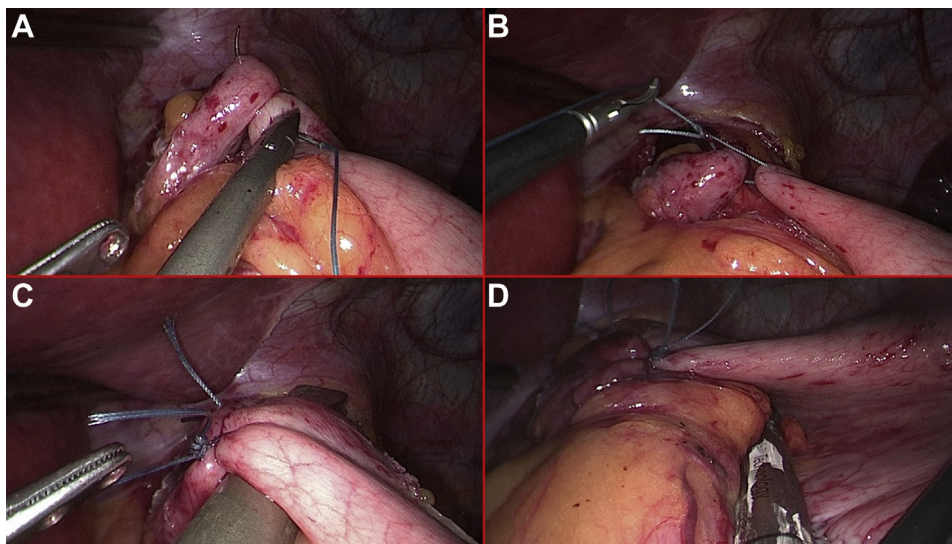


Fig. 4. Fundoplication is performed with 2 single extracorporeal knotting (Roeder knots) (A, B), without sutures between the anterior wall of the esophagus and the gastric wrap. The correct tightness of the plication is checked with a 10-mm blunt laparoscopic bougie (C). Stapling is usually performed with 3 black and 3 purple cartridges (Signia with Tri-Staple™ Technology) (D).

Results

Preoperative data

Two hundred twenty patients underwent LSG combined with modified Rossetti fundoplication. Patient characteristics and preoperative assessment are summarized in [Table 1](#). Patients suffering from GERD before surgery were 137 of 220 (62.3%). In >80% of cases, the patient had taken PPI at least once in the 3 months before surgery. Over 60% of patients need a chronic daily intake of PPI. The preoperative endoscopic study of patients with clinical GERD symptoms detected the presence of endoscopic GERD lesions in 37.2% of the cases. Conversely, no endoscopic signs of GERD were found in 62.8% of patients affected from clinical GERD symptoms. The subpopulation of 83 patients without clinical GERD was characterized by the presence of endoscopic lesions attributable to GERD in 15.6% of cases. The endoscopic lesions found in the preoperative analysis are reported in [Table 1](#). In particular, there were 4 cases of Barrett's esophagus (1.8%). These data are comparable with the normal distribution of comorbidities in the general obese population [25,26].

Surgery and postoperative course

In [Table 2](#), we have summarized the main data relating to surgical and postoperative results. No intraoperative complications or conversion were reported. Laparoscopic cruroplasty has been performed in 4 of 220 cases (1.8%). We performed <2% of cruroplasty despite having a preoperative diagnosis of almost 30% of hiatal hernias because the hiatal hernia was not confirmed at surgery. We recorded a regular postoperative course in 90% of patients (198 of

220 patients). [Table 2](#) reports the postoperative course and the main occurring complications. According to the Clavien-Dindo classification ([Table 2](#)), the following complications are reported:

1. Grade 1: 5 of 220 (2.3%)—4 Anemia without need for blood transfusions; 1 mild dysphagia, self-withdrawal without therapy;
2. Grade 2: 7 of 220 (3.2%)—2 anemia with need for blood transfusion; 5 pneumonia treated with antibiotic therapy;
3. Grade 3 b: 14 of 220 (6.4%)—12 of 220 (5.5%) for gastric fundus perforation; 2 of 220 (.9%) for perigastric abscess without obvious perforation of fundoplication; and
4. Grade 4 b: 1 of 220 (.5%)—for fistula after reintervention (conversion to LSG) and resection of the gastric fundoplication, with need of intensive care unit admission and positioning of gastric endoprosthesis (gastric stent).

The most common surgical complication was gastric fundus perforation (12 of 220; 5.5%). In addition to the standard X-ray on the second postoperative day, which allowed for the detection of leaks in 2.7% of the population, computed tomography was performed with oral contrast ingestion to recognize perforation or the presence of a perigastric abscess. Computed tomography scan was performed only in cases of suspected perforation on standard radiography or in cases of postoperative hyperpyrexia. Standard postoperative investigation in patient with a regular postoperative course without clinical suspicion or complication was standard X-ray with oral contrast on the second postoperative day. Gastric perforation always led to reoperation, and we have always found a gastric lesion at the site of 1

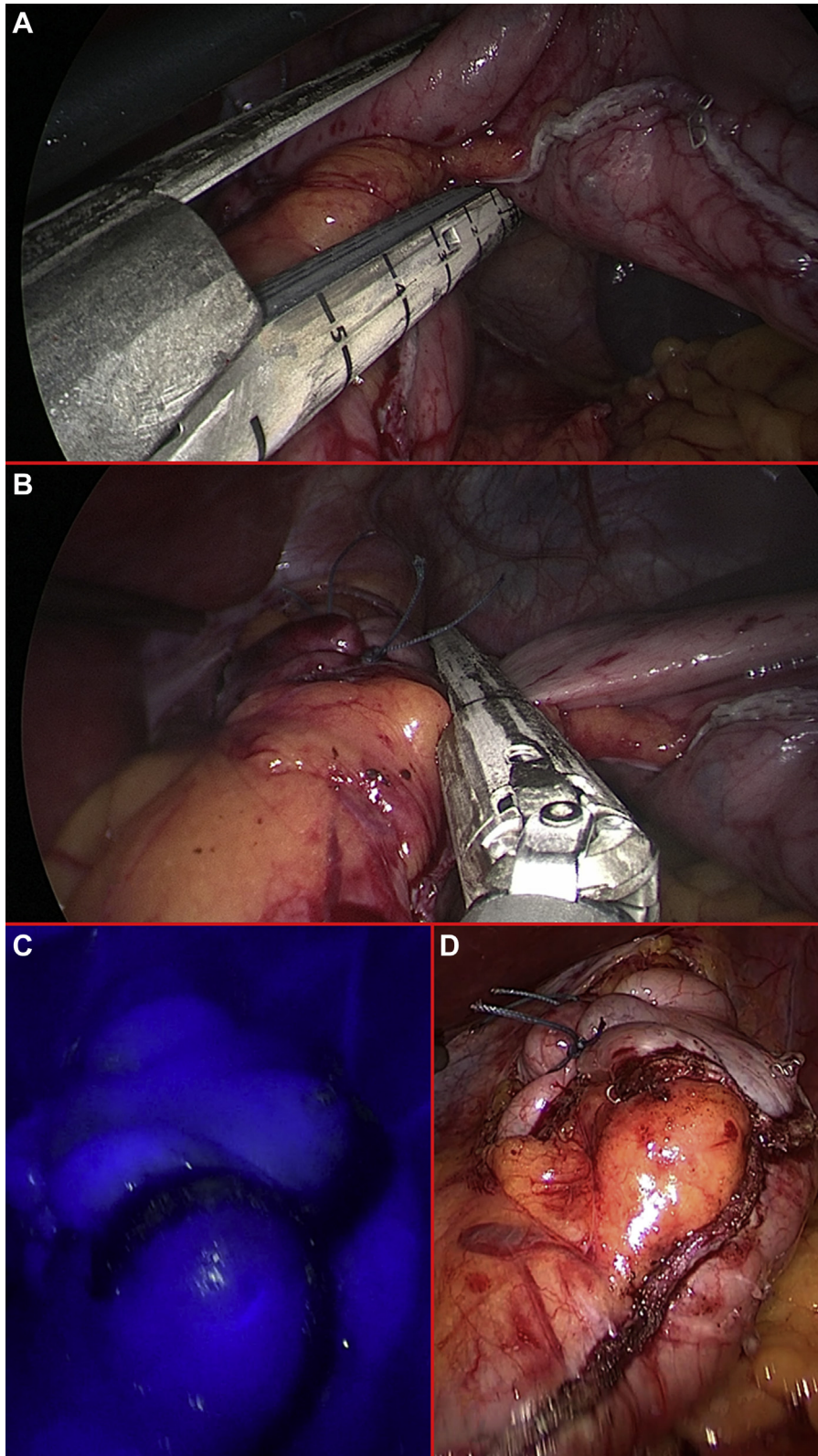


Fig. 5. Sleeve gastrectomy is performed ending a few centimeters medially from the lateral edge of the left gastric flap (A). The section needs to involve as much fundus as possible (B). We also evaluated vascularization of fundoplication with Indocyanine test (C, D).

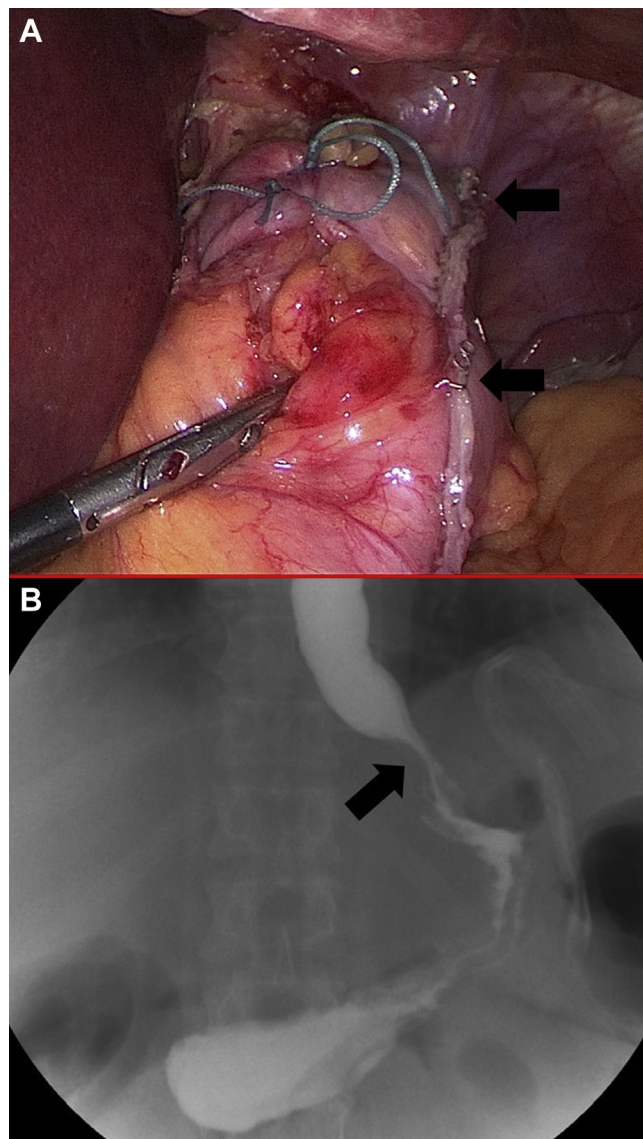


Fig. 6. This is a surgical result. A very short fundoplication, in the right position, with a gastric fundus resection as complete as possible (A). Gastroesophageal X-ray with water-soluble contrast by mouth on second postoperative day (B).

of 2 wraps of the fundoplication. This perforation never originated from the staple line, which indicates the origin of this lesion is probably because of an incongruous manipulation of the stomach during surgery. The other most common surgical complication, in conjunction with leakage, was bleeding (6 of 220; 2.7%), in most cases without need for transfusion. The global rate of reoperation was 14 of 220 (6.4%). In all 14 cases, laparoscopic reoperation consisted in perigastric abscess drainage (if present) and resection of the gastric fundoplication, with conversion into standard LSG. All revised patients had a subsequent regular course, without further therapies needed or invasive maneuvers, except for 1 case (1 of 220; .5%) in which

Table 2
Perioperative and postoperative data

Surgical procedure	
Operative time, min, mean \pm SD (range)	48 \pm 18 (20–120)
Staplers fire, n, mean \pm SD (range)	5 \pm 1 (4–6)
Trocars, n, mean \pm SD (range)	4 \pm 0 (4)
Reinforcement suture, n (%)	27 (12.3)
Hiatoplasty, n (%)	4 (1.8)
Conversion, n (%)	0 (0)
Postoperative course	
Length of hospital stay, d, mean \pm SD (range)	4.2 \pm 3.7 (3–46)
Regular course, n (%)	194 (88.2)
Clavien-Dindo Grade 1	5 (2.3%)
Clavien-Dindo Grade 2	7 (3.2%)
Clavien-Dindo Grade 3	14 (6.4%)
Clavien-Dindo Grade 3 a	0 (0%)
Clavien-Dindo Grade 3 b	14 (6.4%)
Clavien-Dindo Grade 4	1 (.5%)
Clavien-Dindo Grade 4 a	1 (.5%)
Clavien-Dindo Grade 4 b	0 (0%)
Clavien-Dindo Grade 5	0 (0%)
Gastric leak (X-rays), n (%)	6 (2.7%)
Gastric leak (computed tomography scan), n (%)	12 (5.5%)
Reoperation, n (%)	14 (6.4)
30-d readmission, n (%)	0 (0)
Deaths, n (%)	0 (0)

SD = standard deviation.

endoprosthesis was placed postoperatively and then removed at week 4. In these 14 cases, refeeding began after further radiologic control on the second postoperative day, with discharge in all cases not later than the tenth postoperative day in >95% of cases.

Follow-up

The follow-up data are summarized in Fig. 7. We have noted an improvement in all the parameters analyzed since the first follow-up at 1 month (in this period—as specified—PPI is administered until the end of the second month). A good sense of satiety without episodes of vomiting, nausea, or dysphagia was reported in 95% of the analyzed patients. Concerning dysphagia after fundoplication, we evaluated all patients during follow-up with clinical evaluation. In the few cases of disorders due to dysphagia, we first corrected the incorrect eating habits, also thanks to the support of the multidisciplinary team. We therefore performed further clinical monitoring at 15 to 20 days, with resolution, without persistent cases of dysphagia. In particular, starting from a preoperative incidence of GERD of 62.3%, this percentage falls to 6.3% from the sixth postoperative month. At 18 months after surgery with a follow-up of >80% of patients, the percentage of clinical GERD is .5%, and the PPI intake is 1.5%. These data are confirmed even after 2 years and reported in Fig. 7. The results for co-morbidities (hypertension, diabetes, and obstructive sleep apnea) are

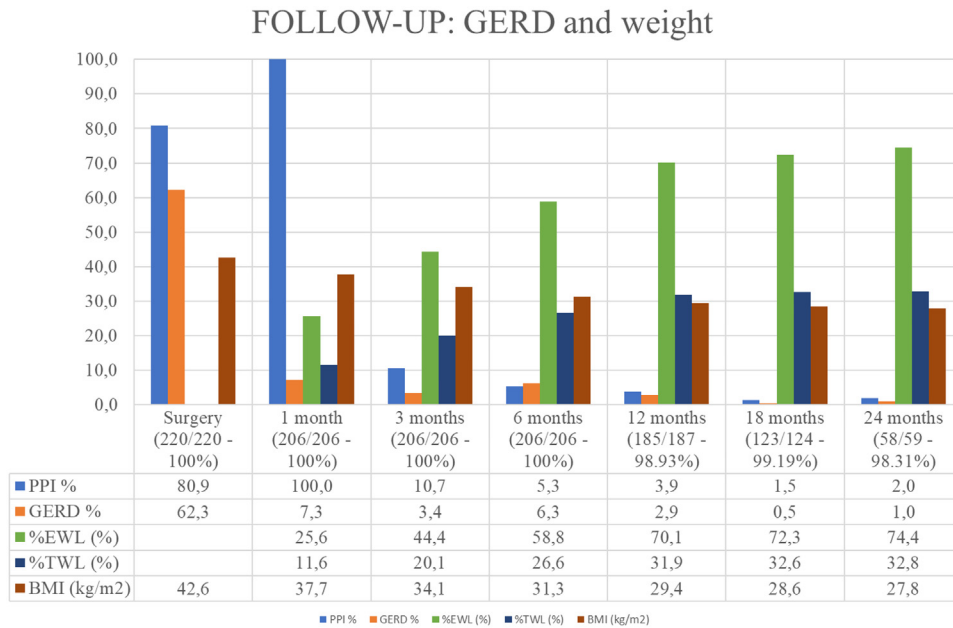


Fig. 7. Follow-up. PPI = proton pump inhibitor; GERD = gastroesophageal reflux disease; EWL = excess weight loss; TWL = total weight loss; BMI = body mass index.

comparable to the normal 2-year course of bariatric surgery, with complete remission in >95% of cases at 1 year. These findings are confirmed at 24 months, with a follow-up in progress, as shown in Fig. 7. Also, with regard to weight loss, results confirm the comparability with the standard LSG (as reported in Fig. 7). Endoscopic follow-up is still in progress (65 of 220; 29.54%). Improvement in esophagitis was observed in 63 of 65 (96.92%) patients.

Discussion

The experience of the last decade has confirmed LSG is a safe and reliable intervention [27,28]. If the benefits of LSG were to be associated with the reduction of postoperative reflux and the nonset of post-LSG de novo reflux, a further step would be taken in the treatment of obesity and associated co-morbidities. Since 2016, Nocca et al. [19] simultaneously and independently of our group, have a similar experience of performing LSG with an antireflux fundoplication, with promising results in preliminary experiences [21]. The techniques of our group and those of Nocca et al. [19] are different for what concerns fundamental technical and methodologic differences. The decision to use an antireflux fundoplication according to the Rossetti technique [29] among the various possible fundoplication techniques derives from the experience in esophago-gastric surgery and the surgical treatment of GERD that our group has matured in >25 years. For technical reasons, it is mandatory to section the short gastric vessels to perform the LSG with fundoplication. Surgical landmarks are also different in Rossetti fundoplication. The gastric fundus is

grasped on its medial and lateral edges, while in Nissen procedure, both the gastric fundus and the body are grasped. The diaphragmatic hiatus is isolated enough to create a retroesophageal window for the retroassage of the gastric fundus. In Rossetti technique, the left diaphragmatic pillar is isolated, but the dissection is minimal. The dissection of the diaphragmatic hiatus and the right diaphragmatic pillar is also minimal, just sufficient to allow the creation of a retroesophageal space for the passage of the gastric fundus, without leaving a wide space. In comparison to the Nissen technique, the hepatogastric ligament is not dissected, and the diaphragmatic crus is not completely isolated. The technical advantages deriving from performing an antireflux fundoplication are (1) covering the angle of His to avoid the development of proximal staple line leak; (2) raising the pressure of the lower esophageal sphincter to reduce postoperative de novo GERD; (3) reduce gastroesophageal reflux symptoms in symptomatic obese patients before surgery; (4) treating esophagitis in patients with preoperative diagnosis; and (5) induced patient to eat and chew slowly to avoid gastric fistula because of the LES pressure increase.

Rossetti's variation without esophageal suture reduces the risk of vagal and esophageal injuries and prevents gastric emptying disorders. Fundoplication sec. Rossetti ensures a better seal of the fundoplication with lower risk of migration and better results in terms of GERD improvement. The Rossetti technique allows us to obtain vertical gastric resection as narrow as possible, with almost complete removal of the gastric fundus. In our experience, in fact, the filling test at the end of the procedure has not shown any differences with respect to traditional LSG. This technique makes it

possible to easily manage many therapeutic failures. A patient who has undergone this surgery can be reoperated exactly like a patient who underwent standard LSG, allowing eventual redo bariatric surgeries, such as re-LSG or conversion to Roux-en-Y gastric bypass or 1-anastomosis gastric bypass. Our surgical results show the combination of LSG and modified Rossetti fundoplication is feasible and safe. No intraoperative complications were reported. The most common surgical complication was represented by gastric fundus perforation (12 of 220; 5.5%), but as we have already pointed out, in our experience, this event is not comparable to the classic post-LSG fistula. This gastric fundus perforation, in fact, has always occurred at the level of 1 of 2 wraps of the fundoplication and it is caused by an incongruous manipulation of the gastric fundus during surgery, with a consequent metatraumatic injury. Other authors, as well, have hypothesized that this complication was probably a consequence of inadequate grasper handling or thermal injury; thus, it must be considered a perforation rather than a leakage [19]. Moreover, similar rates of reoperation, although over the long term, are reported in case studies related to funder interventions for GERD, with 5-year reintervention rates of 9.5% [30]. Therefore, comparing the complication rate of this new procedure only with the LSG complication rate can be limiting, especially for a procedure still in the final standardization phase. Other associated interventions of gastric bariatric surgery and fundoplication [31] report comparable complication rates if not higher than our series, with reoperations in 8% of cases. Authors affirm, and we agree, that standardization of the technique has improved the postoperative outcomes. In our technique, suture at the level of the fundoplication has never caused problems. We do not believe that gastric perforations are because of inadequate gastric vasculature (as confirmed by the green Indocyanine test). Finally, although large series [32–34] can retrospectively affirm a 1% reintervention rate after LSG, this comparison is not completely correct, as it compares a completely standardized, reproducible intervention, performed for many years with an experimental intervention in standardization phase. Moreover, the same author states, "...surgeons develop greater experience performing LSG, which resulted in a decrease in the rate of complications, readmissions, and reoperation following LSG..." [32]. All patients reoperated had a subsequent regular course, without further need of therapy or invasive maneuvers, except for 1 case (1 of 220; .5%) in which endoprosthesis was placed with removal programmed at 4 weeks. Thus, the rate of gastric leakage after this procedure was 1 of 220, equal to .5%. The rationale is to cover the angle of His with the anti-reflux valve and to move the staple line to a better-vascularized area [19]. A good sense of satiety without episodes of vomiting, nausea, or dysphagia from the first follow-up visit to 24 months of follow-up were recorded. Compared with the standard GERD medical treatment, the

results of this study can be considered positive. Starting from a preoperative incidence of GERD of 62.3%, at 18 months after surgery with a follow-up of >80%, the percentage of clinical GERD is .5%, and the PPI intake is 1.5%. These data are confirmed even at 2-year follow-up. We recorded normalization of BMI within 30 kg/m² starting from 12 months (mean BMI 29.4 ± 4.5 kg/m²), and these data were confirmed at 24-month follow-up (mean BMI 27.8 ± 4.5 kg/m²). Finally, the remission of comorbidities showed no differences with the standard LSG. Unfortunately, we cannot present definitive data concerning the endoscopic follow-up because of patients delays in the performance of this examination or to the nonavailability by all patients to carry out control gastroscopies after surgery. However, partial endoscopic follow-up showed an improvement in the esophagitis lesions found in the preoperative period and in particular a notable improvement in Barrett's esophagus. In particular, in the 4 cases of patients with Barrett's esophagus we recorded regression of lesions, to esophagitis A within 18 months in 2 cases and complete regression in the remaining 2 cases. This last result is an initial but very important benefit of the effective anti-GERD effect of LSG associated with modified Rossetti fundoplication, maintain good results for what concerns weight loss and remission of other co-morbidities. Main limitations of this study are represented by being a single-center retrospective study without control group. A further limitation is the not complete achievement of the endoscopic follow-up, which prevents a statistical analysis of these particular results. We believe that the ongoing prospective studies will overcome these limitations.

Conclusion

Although we recognize that it has limits and we are still in an experimental and investigative phase, this work is a further confirmation with adequate follow-up and a series of >200 patients that the combination between LSG and modified Rossetti fundoplication is a tolerated and feasible procedure in morbidly obese patients with a documented GERD. In this experimental phase, we recorded a discrete complication rate, but the standardization of the technique allowed it to be reduced. Moreover, even in the case of a surgical complication, the postoperative course was, after reoperation, comparable if not better than the postoperative LSG course complicated by gastric fistula. Finally, although with incomplete endoscopic follow-up, we have seen an improvement in esophagitis, with complete remission of Barrett's esophagus. These results after 24-month follow-up confirm the preliminary efficacy and safety of the technique. Data from prospective studies in progress are needed.

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

Study has been approved by San Marco Hospital GSD Ethical Committee

Study does not contain data deriving from experiments involving humans or animals

Disclosures

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

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