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Robotic or laparoscopic SLEEVE-DOR (sleeve gastrectomy with anterior Dor 180° fundoplication) for obesity: preliminary results of a series of 80 patients

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Abstract

Aims: Sleeve gastrectomy (SG) is currently the most performed bariatric surgery worldwide. For patients with obesity and symptomatic gastroesophageal reflux disease (GERD), the indication of SG is a matter of concern due to the possibility of worsening or de novo reflux in the postoperative follow-up. A new method, the combination of a 180-degree anterior fundoplication (SLEEVE-DOR) using only one barbed nonabsorbable suture, is proposed to allow the use of SG for this set of patients aiming to minimize the occurrence of de novo GERD. The study aims to evaluate the safety, feasibility and efficacy of SG with SLEEVE-DOR for the therapy of patients with obesity.

Methods: The study describes the largest series of SG combined with anterior hemifundoplication. Since June 2018, all patients with indications for bariatric surgery and having proton pump inhibitor (PPI) therapy for symptomatic reflux at least 6 months before surgery were prospectively documented. All operations were performed laparoscopically (45) or with a robotic DaVinci platform (35). Clinical data were collected from our bariatric center database. The primary outcomes included technical success, perioperative complications and mortality, and the resolution of symptomatic gastroesophageal reflux after the SLEEVE-DOR procedure.

Results: The procedure was successfully performed for all patients ($n = 80$). Mean operative time was 60.1 min. All patients started oral fluids one hour after the surgery and were discharged between 1st and 3rd postoperative day.



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Postoperative complications occurred in three patients, with one leak, one peritonitis due to colonic thermic lesion from adhesions, and one postoperative death due to massive pulmonary embolism. Four patients claimed intractable reflux between 3 and 6 months and were later converted to a Roux-en-Y gastric bypass (RYGB). The remaining patients experienced complete resolution of reflux symptoms in the 6-month follow-up. The percentage of excess weight loss (%EWL) was 58.5% on postoperative 12 months.

Conclusions: SLEEVE-DOR with one nonabsorbable barbed suture is a safe, effective, and technically simple alternative procedure to allow the performance of SG for morbidly obese patients with preoperative mild symptomatic gastroesophageal reflux, especially for patients with severe obesity as the first step operation.

Keywords: Sleeve gastrectomy, anterior fundoplication, D-SLEEVE, SLEEVE-DOR, barbed suture, gastroesophageal reflux disease, Barrett esophagus, GERD

INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) has rapidly become one of the most common bariatric surgeries worldwide^[1,2]. Several factors have contributed to its increasing popularity, including minimal alterations in gastrointestinal anatomy, short operative time, and efficacy in weight reduction and resolution of comorbidities. Despite these advantages, some studies have recently demonstrated that sleeve gastrectomy (SG) may exacerbate gastroesophageal reflux disease (GERD) symptoms or even increase the risk of “*de novo*” postoperative GERD^[3,4].

For the above-mentioned clinical conditions, many novel methods and solutions have been described and evaluated in recent years. Initial series using Nissen-Sleeve (N-Sleeve) showed good results for treating and avoiding gastroesophageal reflux associated with SG^[5-7]. Olmi *et al.* demonstrated that SG combined with the modified Rossetti antireflux fundoplication procedure could achieve satisfactory weight loss and significant improvement of GERD^[8]. The percentage of patients with GERD respectively fell to 6.3% and 1.0% at 6 and 24 months postoperatively. Nevertheless, the techniques involving larger wraps have the disadvantage of a considerable amount of remaining gastric fundus and inadequate weight loss, and were also associated with a higher incidence of complications in the literature, including leaks and wrap necrosis up to 5.6%^[9-13].

A simpler alternative technique, anterior fundoplication SG (SLEEVE-DOR procedure or D-Sleeve), was first described by Nelson *et al.* in 2016^[14-16]. With this technique, after the resection of the gastric greater curvature, the small upper gastric fundus was rotated anteriorly and was sutured to the left- and right-crus and the arcuate ligament, and 93% cases showed significant improvement of GERD symptoms. Furthermore, del Genio *et al.* performed a similar D-SLEEVE procedure in 32 cases and could control and prevent GERD after surgery^[17]. However, although different types of fundoplication have been combined with LSG to control and/or prevent the GERD after SG, the role for these technical refinements is still controversial.

In the present study, our research group describes a larger series of SG combined with 180-degree anterior fundoplication (SLEEVE-DOR) using a simplified technique with only one barbed suture, and evaluated its safety, feasibility and efficacy for the therapy of morbidly obese patients accompanied with symptomatic GERD.

METHODS

Study design

This is a prospective, non-randomized study. Between June 2018 and July 2023, patients with obesity accompanied by mild symptomatic gastroesophageal reflux candidates to LSG with SLEEVE-DOR were consecutively included in this study. All eligible patients had well-controlled GERD [permanent proton pump inhibitor (PPI) therapy; 1-2 times, 40 mg/day; at least for the last 6 months], which was preoperatively confirmed via esophagogastroduodenoscopy. Exclusion criteria were patients with preoperative Barrett esophagus, large hiatal hernia more than 3 cm in diameter, severe esophagitis Grade C of Los Angeles and higher and GERD with conservative criteria of need for chronic medication. The informed consent was preoperatively signed and attained from all patients, and the present protocol was approved by the local ethics committee (EA1/193/16) and performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

All clinical data of eligible patients were collected from our Bariatric and Metabolic Center database in Potsdam-Germany. The follow-up information was obtained via regular visits in the outpatient clinic at intervals of every 3 months. PPIs were prescribed for 60 days postoperative and then interrupted.

The primary outcomes of the study were technical success, perioperative complications and mortality, and the resolution of the symptomatic gastroesophageal reflux after SLEEVE-DOR. The second outcome was the percentage of excess weight loss (%EWL). Weight loss is expressed as %EWL and percentage of total weight loss with the calculation of ideal weight as that equivalent to a body mass index (BMI) of 25 kg/m² and percentage of excess BMI loss with excess BMI > 25 kg/m².

Surgical technique

Laparoscopic SLEEVE-DOR procedure [Figures 1 and 2]

Under general anesthesia, patients were placed in the supine position with intubation. Prophylactic antibiotics [single shot of antibiotic (1 g sulbactam + 2 g Ampicillin)] were given at the induction of the anesthesia, and a sequential compressive system (Medtronic) was applied to both legs. The surgeon stood on the right side of the patient, while the first assistant (camera assistant) was on the left side. The legs of the patients were not spread. Five trocars were inserted after intraabdominal CO₂ insufflation [Figure 3A]. SG was performed in the usual technique using the Thunderbeat device (Olympus, Hamburg, Germany) by separating the greater omentum from the greater curvature of the stomach 3 cm from the pylorus all the way up to the angle of His, to expose the left and right crus. Hiatal hernia was checked and only dissected and repaired when present using 2/0 barbed nonabsorbable V-Loc running suture (Covidien, Mansfield, MA) with a 36 French calibration bougie. The greater curvature was stapled beginning from 3 cm oral to the pylorus until 4 cm from the gastroesophageal junction [Figure 3B]. At this point, the stapling line was directed to a 45-degree deviation to the left of the patient (no longer following the bougie), resulting in a flap of gastric fundus of around 3 cm distance from the gastroesophageal junction. A methylene blue test was performed before fundoplication. Subsequently, an anterior 180-degree fundoplication was conducted by suturing the resulting gastric fundus to the right crura. Typically, one barbed running suture (V-LOC 2-0, nonabsorbable) was placed from the remaining fundus to the right crus. Subsequent stitches using the same suture secured the crura at first 1 cm and, in aboral progression, also fixed it to the anterior wall of the sleeve [Figure 3C]. The fundic wrap was not sutured to the esophagus, and the fundoplication was performed over the 36Fr bougie. Finally, the resected stomach was removed through a 12 mm trocar site [Supplementary Film 1]. In cases where a gastroscopy was performed, usually 3 months later, the results showed an adequate anterior fundoplication [Figure 3D].

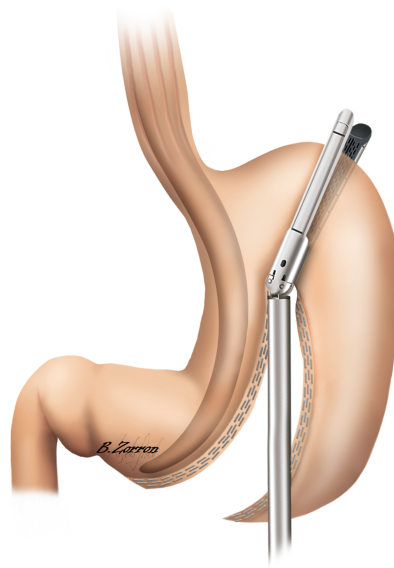


Figure 1. Schematic illustration of steps of sleeve gastrectomy with SLEEVE-DOR anterior 180° Fundoplication. Stapling pattern leaving 3 cm of gastric fundus for anterior fundoplication. SLEEVE-DOR: 180-degree anterior fundoplication.

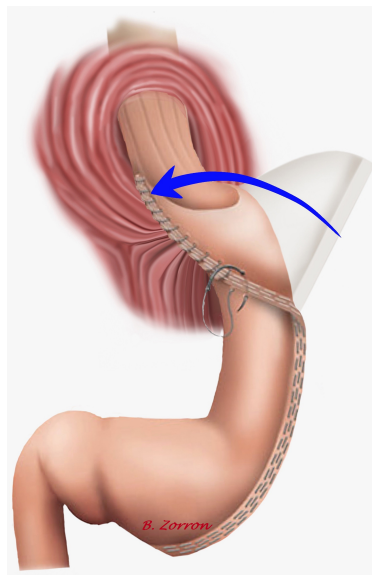


Figure 2. Schematic illustration, fixation of the 180° wrap to the right crus and anterior gastric wall with one nonabsorbable 2-0 V-Loc suture.

Robotic SLEEVE-DOR procedure with DaVinci Xi

The position and anesthetic procedure were the same for the robotic technique. The DaVinci robotic arms were docked after placing two 8 mm and one 12 mm DaVinci trocars under direct vision. The left 12 mm site was used to perform the stapling with DaVinci stapler (Sureform) using green and blue cartridges. A flap of 4 cm of gastric fundus was left to perform the anterior fundoplication, which was performed with the same technique described. In cases of hiatal hernia, these were repaired using a nonabsorbable V-Loc 2-0 suture.

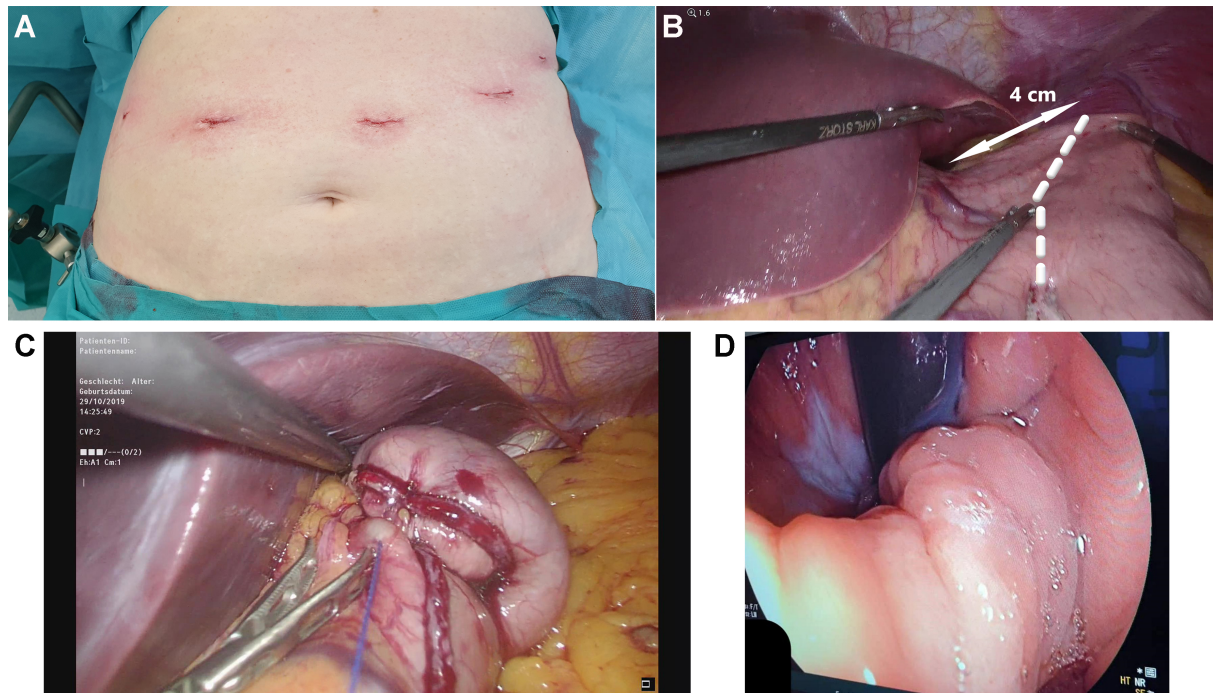


Figure 3. Intraoperative aspect of sleeve gastrectomy with SLEEVE-DOR anterior 180° Fundoplication. (A) Position of the trocars for SLEEVE-DOR procedure. The two trocars on the right are used for the left and right hand of the surgeon, and the two left for the assistant. A fifth 5 mm Trocar can be added on the right side for liver retraction if needed; (B) Stapling pattern leaving 3 cm of gastric fundus for anterior fundoplication; (C) Fixation of the 180° wrap to the right crus and lower esophagus with one nonabsorbable 2-0 V-Loc suture; (D) Endoscopic view showing adequate anterior Dor fundoplication at 3 months postoperatively. SLEEVE-DOR: 180-degree anterior fundoplication.

Statistical analysis

The continuous variable and the classified variable were expressed as the mean and the percentage, respectively. All clinical data were statistically analyzed by using the (IBM SPSS 27) system.

RESULTS

SLEEVE-DOR procedures were successfully performed laparoscopically ($N = 45$) or robotically assisted with DaVinci Xi ($N = 35$) for all patients, with no conversions. The average preoperative weight and BMI were 139.8 kg and 47.1 kg/m², respectively. The mean age was 47.6 years, ranging from 31 to 61 years. The mean operation time for laparoscopic technique was 77.3 minutes, without intraoperative complications or conversion. The operative time was significantly shorter for patients submitted to robotic SLEEVE-DOR with DaVinci Xi (mean 38 min). Here, we identified some bias, as heavier patients were performed by less experienced surgeons by laparoscopy, as a first-step procedure in a 2-step approach, and lower weight patients were operated mostly by expert surgeons by robotic techniques. The average length of postoperative hospitalization was 2.4 days [Table 1]. The evaluations for all patients were regularly performed two weeks before SLEEVE-DOR and 3, 6 and 12 months after the procedure.

Postoperative complications occurred in three patients, with a leak rate of 1.3% (one case). One patient had a leak due to perforation of the staple line of the wrap with local abscess on the 9th postoperative day. The patient underwent laparoscopic drainage, and after 21 days of endoscopic vacuum-assisted closure (VAC) therapy, the defect was successfully closed using the endoscopic Apollo Overstitch technique. A second patient was diagnosed with a perigastric abscess without a leak at endoscopy on the 14th postoperative day

Table 1. Results of a series of patients submitted to SLEEVE-DOR technique in the study

Patients (80, Female 56)		
Technique	Laparoscopic	Robotic DaVinci
GERD medication [*]	45	35
Postoperative free of proton-pump inhibitors at 12 months	43 (93.3 %)	34 (97.1%)
Preop BMI	52	38
Operative time	77.3	38
Hiatal hernia repair	3	8
Complications	4	0
Postoperative stay (days)	2.3	1.4
%EWL (12 months)	52.8	61
Postoperative conversion to RYGB due to GERD	3	1

^{*}With exclusion of 4 patients submitted for RYGB for postoperative GERD. SLEEVE-DOR: 180-degree anterior fundoplication; GERD: gastroesophageal reflux disease; BMI: body mass index; %EWL: the percentage of excess weight loss; RYGB: Roux-en-Y Gastric Bypass.

and underwent laparoscopic drainage. Before the planned discharge from the hospital without sepsis, the patient experienced a massive lung embolism and did not survive despite attempted cardiac resuscitation. One patient was reoperated on the 9th postoperative day with peritonitis in the lower abdomen. At laparoscopy, the inspected SLEEVE-DOR was intact and without leak, and the reason for the peritonitis was a thermic lesion of the transverse colon due to previous adhesiolysis. The lesion was successfully sutured laparoscopically and the patient was discharged. The remaining patients did not present any complications.

In 12-month follow-up time after the SLEEVE-DOR procedure, the symptomatic gastroesophageal reflux had complete resolution and the PPI therapy was stopped in 95% of the cases. However, four patients (5%), although persistently receiving the therapy with pantoprazol 80 mg/day, still had continuously experienced severe heartburn and regurgitation symptoms for 3 months after surgery. Meanwhile, the control gastroscopy at 3 months postoperatively showed an adequate fundoplication but with grade II esophagitis in these cases. Therefore, the four patients were subsequently converted to Roux-en-Y gastric bypass (RYGB), with one using a DaVinci platform and the others undergoing laparoscopy. For these revisions to RYGB, the Dor Fundoplication was not dismantled. One patient developed a chronic anastomotic ulcer after RYGB; the segment was successfully resected, and a new anastomosis was constructed. In view of this, weight, BMI and %EWL at 6 months postoperatively of these patients submitted to revisions were not included in the calculations of weight loss in the study. At 12 months postoperatively, the average weight and BMI were 101.6 kg and 32.3 kg/m², respectively, and the mean %EWL was 58.5% [Table 1].

DISCUSSION

As the indication for SG has grown worldwide, the incidence of GERD symptoms after SG has gradually risen, ranging from 2% to 37.9%^[18-20], resulting in the relative contraindication of this procedure for morbidly obese patients with preoperative symptomatic GERD. High risk factors for worsening the GERD symptoms or leading to de novo GERD after SG include gastric fundus removal, destruction of the anatomy of the gastroesophageal junction, reduced gastric pump function, and decrease of the volume of the resulting gastric sleeve^[21-23]. The conservative therapies for symptomatic GERD after SG included dietary changes, antacid medications and a combination of both treatments. In some cases, a more radical solution is needed, such as a conversion of SG to a RYGB. Gardiot *et al.* and Hendricks *et al.* have detailed that 2%-4% of their patients who underwent LSG had to be converted to RYGB due to reflux symptoms, which was consistent with our experience^[24,25]. In the present study, four patients had to be converted to RYGB at 6

months after SG, because of the remaining severe GERD symptoms. In general, it is estimated that 10% to 20% of patients suffer from symptomatic reflux after the SG, regardless of whether they have preoperatively symptomatic GERD^[26]. A nationwide, cohort study conducted in the United States has reported that among 4,832 patients underwent SG, and 44.5% patients had GERD preoperatively^[1]. After SG, only 15.9% cases had complete resolution of GERD, while the rest patients (84.1%) still continued to have symptomatic GERD; among them, 9% cases even worsened subsequently. Meaningfully, the results of the study demonstrated that the overall incidence of reflux after SG was nearly 45%.

A recently published multicentric study evaluating systematic endoscopy up to 6 years after SG by Sebastianelli *et al.* showed scary results^[20]. The prevalence of Barrett esophagus after SG was 18.8%. The prevalence for GERD symptoms, esophagitis and use of PPIs heightened statistically relevant from 22%, 10% and 22% before SG to as high as 76%, 41% and 52% at follow-up, respectively.

However, these findings may be overstated, as a recent study from Johari *et al.* showed that possible misinterpretation from endoscopic findings may contribute to this high rate, finding that many cases interpreted as Barrett esophagus are in fact a tubularized gastric mucosa, demanding further studies to evaluate the real incidence of de novo reflux and Barrett alterations^[27]. Hawasli *et al.* have demonstrated the effectiveness of laparoscopic anterior fundoplication with posterior crura approximation for patients who presented with GERD after LSG^[28]. They reported that the mean excess BMI loss was $75.5\% \pm 22.9\%$, and reflux was resolved in all patients after surgery. One patient re-experienced GERD symptoms and one required re-sleeving.

Nowadays, different kinds of gastric fundoplication such as Nissen, modified Rossetti, and Dor fundoplication have been gradually and successfully combined with SG and been performed for morbidly obese patients with or without preoperative symptomatic GERD, to control and/or prevent symptoms of reflux after surgery. The above-mentioned procedures have all achieved satisfactory outcomes, but with differences in complexity and procedure-related complications.

Several studies have demonstrated an increased incidence of leaks and septic complications in patients who underwent N-Sleeve^[9-13]. In a recent and largest series, Nocca *et al.* reported a series of 356 patients submitted to N-Sleeve beyond their learning curve, with a reduced leak and perforation rate (2.24%, eight patients) in addition to two late wrap perforations at 8 and 9 months postoperatively^[29]. Olmi *et al.* have reported SG and modified Nissen-Rossetti fundoplication for 220 patients with obesity^[8]. The incidence of patients without symptomatic GERD was 93.7% and 99% at 6 and 24 months postoperatively, respectively. Meanwhile, this study reported 5.5% cases with postoperative wrap perforation and leak. In a further prospective randomized study by the same group comparing 140 SG with 139 patients with SG and Rossetti fundoplication, there was no difference in weight loss but still a significantly higher occurrence of wrap perforation and leaks in the fundoplication group (4.4% vs. 0.7%)^[30], contrasting with the few moderate or major complications in our study.

In 2016, Nelson *et al.* in Orlando^[14-16] described and evaluated the anterior fundoplication SG procedure (SLEEVE-DOR) in 31 cases, where the fundus was rotated anteriorly and sutured to the left and right crus and the arcuate ligament. In 4 months after surgery, 93% patients (30/31) were free from GERD symptoms, which was comparable to the results of our study. The weight loss results had a mean %EWL of 47% at 4 months postoperatively. Moreover, del Genio *et al.* have performed LSG with anterior fundoplication (D-SLEEVE) for 32 cases^[17]. At 14 months after surgery, all of them were free from GERD symptoms, and the postoperative BMI and %EWL were 32.1 kg/m² and 59%, respectively. However, both studies and our

present study had limited follow-up time to evaluate the real benefit on reflux avoidance and long-term weight loss. In the current literature for the SLEEVE-DOR technique, one case of a leak, treated conservatively, was reported^[15]. This innovative surgical method using only one barbed suture to construct the fundoplication seems advantageous to other techniques and possibly with a shorter learning curve. For sure, this new technique may not be broadly applied to all patient candidates for SG. In our study, three patients presented with serious adverse events (SAEs). One patient succumbed to a pulmonary embolism following subhepatic abscess drainage, another developed peritonitis due to adhesiolysis, and the third had a leak that was successfully treated.

SLEEVE-DOR is a proposal of a technical change to standard SG, to attempt to attain the lower risk of leak and better control of GERD symptoms over time. In our study, reflux control was obtained among our patients on early postoperative time; 95% of the patients attained complete resolution of the symptomatic GERD at 12 months postoperatively. The technique, by avoiding extensive dissection of the anatomy of lower gastroesophageal sphincter, represents a simple and effective technique, typically with a low learning curve. Our study showed few perioperative surgical complications, which were also limited by our sample size. In our study, the occurrence of leak was 1.3%, lower than in other series using Nissen or Nissen-Rossetti techniques that required more extensive dissection and larger gastric wraps possibly due to ischemia. As the mean time before patients developed symptoms of reflux after SG requiring the surgical intervention was found to be 33.2 ± 12.5 months^[27], it is possible that longer follow-up time studies may show lower effectiveness of this technique in avoiding de novo reflux. Nevertheless, the conversion of only four cases to a gastric bypass is lower than the higher rate found in reoperations for the current sleeve technique in the literature.

Regarding the techniques used in this study, the indication of whether a laparoscopic or robotic approach was based on availability of the professional and robotic slots for the operation room. Besides that, patients with severe obesity were scheduled mostly for a 2-stage laparoscopic procedure. These criteria produced some bias regarding the comparative results. Robotic surgery was mainly performed by experts and senior surgeons (authors AT and RZ), and laparoscopic SLEEVE-DOR was mainly performed by younger surgeons and residents, and the mean BMI was higher for the laparoscopic patients. Possibly for these reasons, operative times and mean hospital stays were significantly shorter for the robotic approach.

Our study has some limitations; firstly, this study is a prospective documented series with a small sample size; therefore, comparative randomized studies including more eligible patients and cooperative medical centers will be needed in the next step. Secondly, the follow-up time of the present study was only 12 months; thus, the information of longer follow-up time is required subsequently, and a routine control gastroscopy, pH-impedance and esophageal manometry will be performed in 1-year intervals to be reported in a further study. Subsequently, prospective and randomized control trials are needed to evaluate different types of fundoplication and try to find adequate responses for this new upcoming issue.

In conclusion, SLEEVE-DOR is emerging as a safe and effective alternative technique to allow the performance of SG for patients with obesity with preoperative symptomatic gastroesophageal reflux, especially for patients with severe obesity as the first step operation. Further studies with longer follow-up time and controlled series compared to current techniques are needed to understand its role, especially regarding long-term results for GERD.

DECLARATIONS

Authors' contributions

Conception and design of the study: Zorron R, Teixeira A

Involved in data acquisition, or analysis and interpretation: Specht M, Zorron R, Li R

Drafted the article or critically revised it for important intellectual content: Li R, Eskander W

Gave final approval of the version to be submitted: Zorron R

Availability of data and materials

The raw data supporting the conclusions of this article will be made available by the authors.

Financial support and sponsorship

None.

Conflicts of interest

Li R acknowledges the financial support from China Scholarship Council outside the submitted work, while the other authors have declared that they have no conflicts of interest.

Ethical approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the local ethics committee (EA1/193/16). Informed consent was obtained from all patients.

Consent for publication

Not applicable.

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