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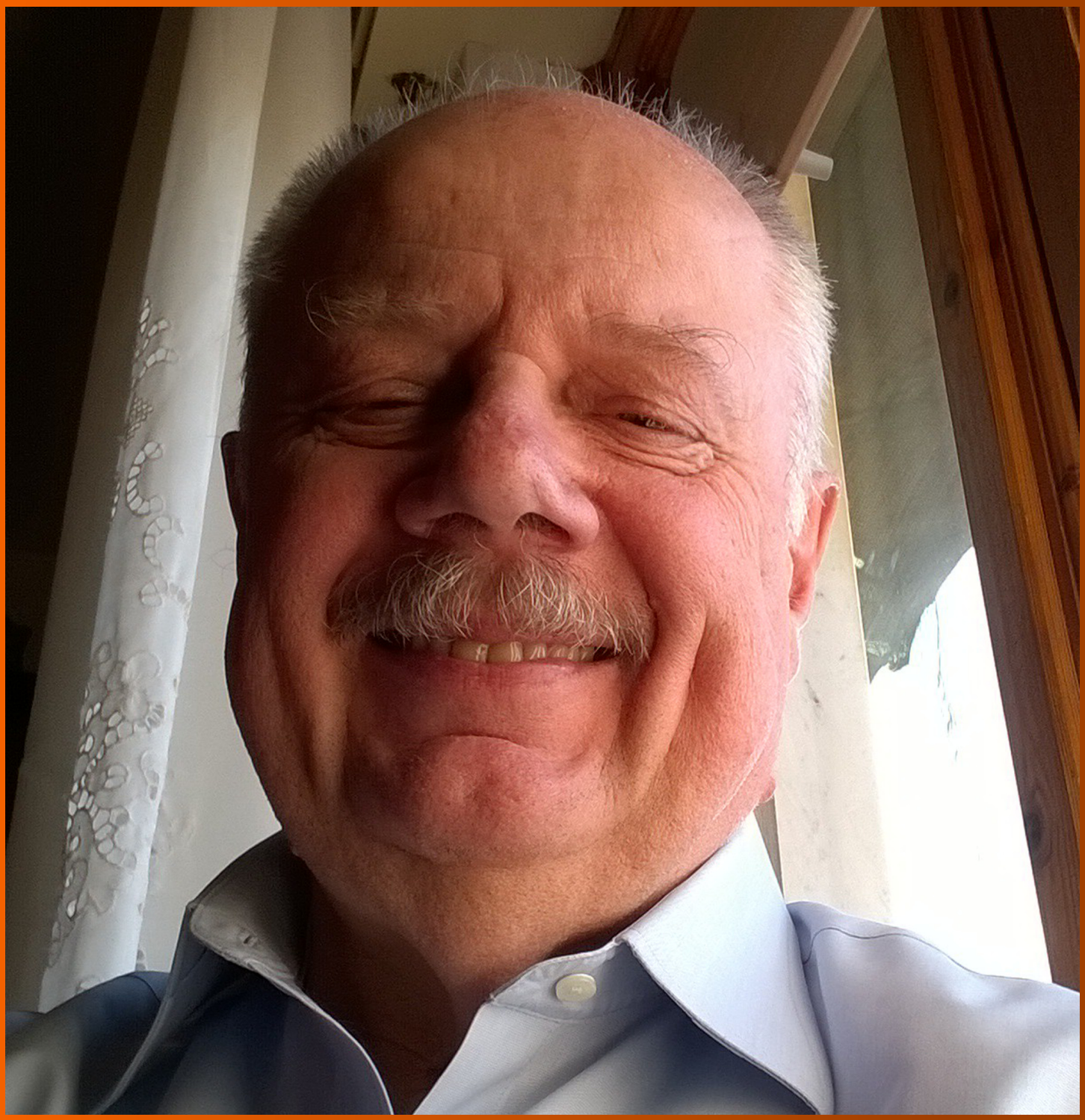

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EDITORIAL

Gastroesophageal reflux disease and morbid obesity: To sleeve or not to sleeve?

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Abstract

Laparoscopic sleeve gastrectomy (LSG) has reached wide popularity during the last 15 years, due to the limited morbidity and mortality rates, and the very good weight loss results and effects on comorbid conditions. However, there are concerns regarding the effects of LSG on gastroesophageal reflux disease (GERD). The interpretation of the current evidence is challenged by the fact that the LSG technique is not standardized, and most studies investigate the presence of GERD by assessing symptoms and the use of acid reducing medications only. A few studies objectively investigated gastroesophageal function and the reflux profile by esophageal manometry and 24-h pH monitoring, reporting postoperative normalization of esophageal acid exposure in up to 85% of patients with preoperative GERD, and occurrence of de novo GERD in about 5% of cases. There is increasing evidence showing the key role of the surgical technique on the incidence of postoperative GERD. Main technical issues are a relative narrowing of the mid portion of the gastric sleeve, a redundant upper part of the sleeve (both depending on the angle under which the sleeve is stapled), and the presence of a hiatal hernia. Concomitant hiatal hernia repair is recommended. To date, either medical therapy with proton pump inhibitors or conversion of LSG to laparoscopic Roux-en-Y gastric bypass are the available options for the management of GERD after LSG. Recently, new minimally invasive approaches have been proposed in patients with GERD and hypotensive LES: the LINX® Reflux Management System procedure and the Stretta® procedure. Large studies are needed to assess the safety and long-term efficacy of these new approaches. In conclusion, the recent publication of pH monitoring data and the new insights in the association between sleeve morphology and GERD control have led to a wider acceptance of LSG as bariatric procedure also in obese patients with GERD, as recently stated in

the 5th International Consensus Conference on sleeve gastrectomy.

Key words: Sleeve gastrectomy; Gastroesophageal reflux; Morbid obesity; Ambulatory pH monitoring; Esophageal manometry

Core tip: The current evidence about reflux control and the occurrence of de novo gastroesophageal reflux disease (GERD) after laparoscopic sleeve gastrectomy (LSG) is controversial. Recent studies that have objectively evaluated GERD after LSG have shown no significant increase in postoperative GERD. The absence of mid-stomach narrowing and retained fundus, and the repair of a concomitant hiatal hernia seem to be key in reducing the risk of postoperative GERD. We discuss the currently available evidence on the impact of LSG on GERD, focusing on surgical technical aspects and new minimally invasive approaches for the management of postoperative GERD.

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INTRODUCTION

Gastroesophageal reflux disease (GERD) is a highly prevalent condition in morbid obese patients[1]. The pathophysiology by which the increase in body mass index leads to increase in esophageal acid exposure is multifactorial, with the increased intraabdominal pressure playing a major role[2]. Laparoscopic Roux-en-Y gastric bypass (LRYGB) is considered by most experts the procedure of choice for the management of GERD in obese patients, with excellent results in terms of reflux control and long lasting weight loss[3,4].

During the last 15 years, laparoscopic sleeve gastrectomy (LSG) has rapidly become a very popular bariatric procedure, since it is less technically demanding than LRYGB, it is burdened by low rates of postoperative complications, and it is associated with significant weight loss and improvement or resolution of several comorbidities[5]. However, the effect of LSG on GERD is still unclear, with conflicting evidence about pre-existing reflux control and the occurrence of de novo GERD after surgery[6].

The aim of this paper is to critically analyze the impact of LSG on GERD, in terms of symptom control and changes in gastro-esophageal function. Surgical technical aspects, including the shape of the sleeve and the repair of a concomitant hiatal hernia, and new minimally invasive approaches to manage postoperative GERD are also discussed.

GERD AND LSG: THE EVIDENCE

Several studies have evaluated the effects of LSG on pre-existing GERD and on the new onset of GERD, showing controversial results: some reported amelioration of GERD, while others showed the postoperative occurrence of de novo GERD or worsening of preoperative GERD[7-44] (Table 1). The analysis of the literature is challenged by the heterogeneity of the studies in regard to the definition of GERD the timing of patients' evaluation. Most studies defined GERD based on proton pump inhibitors (PPIs) use, symptoms evaluation, and presence of esophagitis. Only few studies objectively analyzed patients by esophageal manometry and 24-pH monitoring[15,20,29,33,34,38,40,43,44].

Discordant data are available regarding the change in the use of PPIs. While Catheline *et al*[25] observed an increase in the use of PPI from 11.1% to 33.3% at 5 years after LSG, a large population-based study involving 1567 obese patients treated with LSG found that 37.3% of patients who used acid reducing medications preoperatively discontinued the treatment at 1 year[39]. This discordance is secondary to the fact that the use of acid reducing medications has a poor correlation with the presence of real GERD[19].

The studies that used validated questionnaires to assess the prevalence of GERD after LSG report conflicting results. For instance, Carter *et al*[16] found that among 176 obese patients treated by LSG, the incidence of GERD symptoms increased from 34.6% to 47.2%. Conversely, DuPree *et al*[36] found a decrease in GERD symptoms prevalence after LSG. They conducted a retrospective review of the Bariatric Outcomes Longitudinal Database over a 4-year period, including a total of 4832 patients who had LSG for morbid obesity, reporting resolution of symptoms in 15.9%. We recently published the results of a prospective study aiming to evaluate the physiopathologic changes after LSG[38]. A total of 28 patients with preoperative 24-h pH monitoring positive for pathological reflux completed the Gastroesophageal reflux disease Symptom Assessment Scale (GSAS) questionnaire preoperatively and at 2 year-follow-up: the decrease in the GSAS score demonstrated a significant improvement of symptoms.

New-onset GERD has been investigated based on symptom evaluation by several studies, reporting a wide range of incidence, from 0% to 34.9%. For instance, Himpens *et al*[12] invited 30 obese patients at 6 years or more after LSG to complete a questionnaire on GERD symptoms. They reported new-onset GERD symptoms in 23% of patients. However, the absence of 24-h pH monitoring data challenges the interpretation of these findings. In a recently published prospective series, we observed that GERD symptoms were present

Table 1 Laparoscopic sleeve gastrectomy and gastroesophageal reflux disease: Evidence from studies with more than 45 patients followed up for at least 12 mo after surgery

Ref.	No. of patients	Follow-up (mo)	GERD symptoms	Use of acid reducing medications	LES pressure	Peristalsis amplitude	DMS	New onset GERD symptoms (%)	New onset pathologic esophageal acid exposure (%)
Moon Han *et al*[7]	60	12	↓	NR	NR	NR	NR	0	NR
Weiner *et al*[9]	120	24	↓	↓	NR	NR	NR	NR	NR
Arias *et al*[11]	130	24	↑	NR	NR	NR	NR	2.1	NR
Lakdawala *et al*[14]	50	12	↑	NR	NR	NR	NR	4	NR
Carter *et al*[16]	176	12	↑	↑	NR	NR	NR	12.6	NR
Mohos *et al*[18]	47	38	↔	↔	NR	NR	NR	NR	NR
Chopra *et al*[21]	185	16	↓	NR	NR	NR	NR	3.7	NR
Abrahim *et al*[23]	83	12	↑	NR	NR	NR	NR	11.4	NR
Tai *et al*[24]	66	12	↑	NR	NR	NR	NR	44.8	NR
Catheline *et al*[25]	45	60	↑	↑	NR	NR	NR	22.2	NR
Rawlins *et al*[26]	49	60	↓	NR	NR	NR	NR	11	NR
Zhang *et al*[28]	200	12	↔	↔	NR	NR	NR	0.2	NR
Carabotti *et al*[30]	74	13	↔	NR	NR	NR	NR	22	NR
Sharma *et al*[32]	32	12	↓	NR	NR	NR	NR	NR	NR
Kular *et al*[35]	76	60	↑	NR	NR	NR	NR	15.7	NR
Våge *et al*[37]	117	24	↑	NR	NR	NR	NR	14.6	NR
Rebecchi *et al*[38]	65	24	↓	↓	↔	↔	↓	5.4	5.4
Sheppard *et al*[42]	205	12	↑	↑	NR	NR	NR	NR	NR

GERD: Gastroesophageal reflux disease; LES: Lower esophageal sphincter; DMS: DeMeester score; ↑: Increase; ↔: No differences; ↓: Decrease; NR: Not reported.

in all obese patients with positive 24-h pH monitoring at 2 years after surgery. However, the evaluation of the correlation of symptoms with the pH monitoring trace showed that only 5.4% (2/37) patients had real "de novo" GERD. Outlet obstruction in the upper portion of the gastric sleeve producing symptoms simulating "de novo" GERD caused the pH decrease below 4 in 13.5% (5/37) patients[38]. These controversial findings highlight the fact that GERD cannot be diagnosed on the basis of symptoms evaluation only, since the sensitivity and specificity of typical symptoms is low and leads to a wrong diagnosis of GERD occurs in about one third of cases[45].

To date, only a few studies have specifically looked at changes in esophageal function after LSG by using esophageal manometry, 24-h pH monitoring or 24-h MII pH monitoring. Regarding manometric changes, very controversial data have been published[15,20,29,33,34,38,40]. Some small studies have found a significant decrease in lower esophageal sphincter (LES) pressure, while others showed a significant increase in LES pressure postoperatively. For instance, Braghetto *et al*[15] prospectively evaluated 20 patients undergoing LSG for morbid obesity. They showed that LES pressure significantly decreased in 85% of patients at 6 mo after surgery. Total length and abdominal length of the high pressure zone were also reduced. The authors proposed the partial section of the sling fibers of the cardias as cause of these findings. On the contrary, Petersen *et al*[20] reported an increase in LES pressure regardless of the weight loss, suggesting that this manometric change is related to the position of the stapler in relation to the angle of His. Specifically, the closer the staple line to the gastroesophageal junction, the higher the LES pressure. In our prospective study of 65 patients, we observed no significant manometric changes in LES pressure and esophageal peristalsis amplitude[38]. Only Del Genio *et al*[33] showed in a series of 25 obese patients an increase in ineffective peristalsis with no changes in LES function at a median follow-up of 13 mo.

Only 4 studies[33,38,40,43] have objectively evaluated the presence of pathologic reflux by 24-h MII pH monitoring or 24-h pH monitoring at 12 mo or more after LSG, reporting conflicting results. Del Genio *et al*[33] reported the results in a series of 25 obese patients with no preoperative GERD, who were evaluated with 24-h MII pH monitoring preoperatively and 13 mo postoperatively. They detected a significant increase in the median DeMeester's score (DMS), in the median percentage with esophageal pH < 4 in supine position, the total number of reflux episodes non-acid reflux episodes in both upright and recumbent position. Gorodner *et al*[40] prospectively assessed the esophageal function in 14 obese patients preoperatively and at 1 year after LSG. The DMS increased from 12.6 to 28.4 ($P < 0.05$): in particular, the number of episodes longer than 5 min, duration of longest episode, % of time the pH < 4 (total) increased. Overall, "de novo" GERD developed in 5 (36%) patients, while pre-existing GERD got worse in 3 (21%) patients. Very recently, Georgia *et al*[43] prospectively studied 12 obese patients without preoperative reflux symptoms by using 24-h multichannel intraluminal impedance-pHmetry (MIIpH) before and one year after LSG. Mean preoperative DMS was 18.15. DMS was abnormal in 5 (42.7%) patients. Postoperatively, abnormal DMS was detected in 10 (83.3%) patients. At one year after surgery, DMS was

almost 2.5 times higher than the preoperative DMS.

In our study[38], 24-h pH monitoring performed at 2 years after surgery in 28 patients with preoperative GERD showed significantly decreased DMS and total %pH < 4. Four (14.3%) patients still had pathologic, even though reduced, esophageal acid exposure. We observed a significant postoperative decrease in both mean symptom index (SI) score and percentage of patients with SI greater than 50% (from 89.3% preoperatively to 14.3% postoperatively). Among patients with negative preoperative 24-h pH monitoring, 7 (18.9%) patients had pathologic DMS and total %pH < 4. No significant changes in the mean SI score were reported at 2 years after LSG compared with the baseline value. Overall, we observed a slightly increase in the percentage of patients with SI of more than 50%, from 8.1% before LSG to 18.9% at 2 years after LSG (P = 0.308). However, as mentioned before, real "de novo" GERD was detected in 5.4% (2/37) patients according to the correlation between symptoms and the 24-h pH monitoring data.

PROPOSED MECHANISMS FAVORING THE OCCURRENCE OF GERD AFTER LSG

Several anatomic and pathophysiologic changes of the LES function secondary to the creation of the gastric sleeve that might cause GERD after LSG have been hypothesized. While data regarding LES function are scarce and controversial, there is increasing evidence supporting the key role of the surgical technique on the incidence of postoperative GERD. Main surgical technical issues are: a relative narrowing of the mid portion of the sleeve, a redundant upper part of the sleeve and the presence of a concomitant hiatal hernia[46].

The shape of the gastric sleeve plays a major role in leading to GERD. For instance, Himpens *et al*[47] noted that GERD symptoms were reported by 21.8% of patients at 1 year after LSG, by 3.1% of patients at 3 years and again by 23% of patients at 6-year follow-up[12]. While the decrease of the incidence of GERD symptoms may be secondary to the increase in gastric compliance, the late reappearance of symptoms might be explained by weight regain with associated increased intra-abdominal pressure, and dilatation of the proximal sleeve leading to the formation of a "neofundus"[12]. Keidar *et al*[48] reviewed the UGI Gastrografin series obtained on postoperative day 1 in 8 patients who developed postoperative GERD. They found that a combination of dilated upper portion of the sleeve and a relative narrowing of the mid-stomach was present in all patients. This anatomical situation may be secondary to a too narrow construction of the sleeve in association with retention of part of the gastric fundus by stapling far away from the left pillar of the crus, in order to minimize the risk of postoperative upper gastric fistulas. It has been speculated that the relative mid-gastric narrowing impairs the emptying of the upper part of the sleeve, causes food stasis and fermentation, while the retained fundus keeps producing acid, thus favouring the onset of reflux of acid gastric contents into the esophagus. Similar findings were recently reported by Toro *et al*[49]. They reviewed 76 patients who had routine upper gastrointestinal series with Gastrografin on postoperative day 1 or 2 after LSG and completed the GERD-HRQL score. Sleeve shape was classified as upper pouch, lower pouch, tubular or dumbbell. At 12 mo, 59.2% of patients did not report any GERD-related symptom, while only 7.8% complained moderate to severe reflux symptoms. Patients with the upper pouch shape had the highest severity of symptoms according to the GERD-HRQL score. The lower pouch shape was on the contrary associated with fewer GERD symptoms, suggesting an effective gastric emptying when the antrum is preserved.

The impact of the size of the bougie on the prevention of sleeve narrowing and GERD is unclear, since there is no standardization of the surgical technique (the diameter of the bougies used ranges between 26.4 Fr to 50 Fr). While there is increasing consensus that smaller bougies are associated with leaks secondary to gastric strictures[50], the limited data available do not allow to draw any association between the size of the bougie and GERD. The use of a smaller bougie might lead to the creation of a narrower sleeve with a higher intra-sleeve pressure, thus exposing the patient to a higher risk of postoperative GERD. However, the use of a larger bougie might also favour the occurrence of GERD because the creation of a larger sleeve is associated with reduced weight loss and increased number of residual parietal cells.

Finally, the presence of a hiatal hernia is not considered by many bariatric surgeons a contraindication to LSG[50]. However, the current evidence on this topic is limited by several factors: (1) there are very few studies including more than 100 patients; (2) mean follow-up is short; and (3) those studies that describe the hiatal hernia repair report different ways to close the hiatus: suture posterior cruroplasty (most common), suture anterior cruroplasty. and hiatal herniorrhaphy with mesh (biological or polypropylene mesh). In addition, all studies based their results on symptom evaluation without assessing postoperative GERD by 24-h pH monitoring or 24-h pH MII monitoring. A recent review of the literature[51] investigated the results and the technical aspects of simultaneous LSG and hiatal hernia repair. A total of 17 studies (737 patients) were included. Mean follow-up was 13.9 mo. Most studies reported satisfactory postoperative results in terms of reduction of symptoms and use of acid reducing medications[52]. However, less satisfactory results have been recently reported[53,54]. For instance, Santonicola *et al*[53] compared 78 patients undergoing LSG and HH repair with 102 patients without HH who underwent LSG alone. With a mean follow-up of 14.6 mo in the

LSG with HH repair group and 17.1 mo in the LSG only group, a significant reduction in the prevalence of GERD symptoms was reported only in patients treated with LSG alone, while no improvement was observed among patients undergoing LSG and HH repair. In the absence of recommendations about the use of mesh to close large hiatal hernia defects, Ruscio *et al*[55] recently reported no mortality and no mesh-related complications in 48 patients undergoing LSG with on-lay synthetic absorbable mesh-reinforced cruroplasty for a large HH (hiatal area defect > 4 and < 8 cm^2). With a mean follow-up of 19 mo, GERD symptoms resolved in 95% of patients, while de novo GERD symptoms developed in 3.6% of patients:

We feel that large prospective (randomized) studies with long follow-up and objective evaluation of GERD are needed before drawing any definitive conclusion on the real effect of LSG in patients with concomitant hiatal hernia.

TREATMENT OPTIONS OF GERD IN PATIENTS AFTER LSG: THE PRESENT AND FUTURE PERSPECTIVES

Medical therapy with PPIs represents the initial treatment option in patients with GERD after LSG. However, data reported in the literature regarding the efficacy of this approach are heterogeneous, mainly due to the lack of consistency in defining GERD. For instance, Hendricks *et al*[56] recently analyzed 919 obese patients undergoing LSG. GERD was defined based on pH manometric findings. They found de novo GERD in 3% of patients: most patients were successfully managed with low or high doses of PPIs and conversion to LRYGB was necessary in only 4% of them. Sheppard *et al*[42] found similar results. On the contrary, other authors reported high rates of failure of PPI therapy, suggesting revisional surgery in patients with refractory GERD after LSG[57,58].

To date, conversion of LSG to LRYGB is the procedure of choice in patients with objectively documented postoperative GERD. Several studies have reported excellent results in terms of improvement or resolution of reflux symptoms[57-61]. Revisional minimally invasive gastric gastric bypass is highly effective in controlling GERD related symptoms and is currently the standard option in these patients[62]. Very recently, new minimally invasive approaches have been proposed in patients with GERD and hypotensive LES: the LINX® Reflux Management System procedure and the Stretta® procedure. Desart *et al*[63] retrospectively revised retrospective reviewed 7 consecutive patients treated with the laparoscopic placement of the LINX® magnetic sphincter device (Torax Medical Inc, Shoreview, MN, United States) for refractory GERD after LSG. All patients reported a significant improvement in GERS symptoms at 2 to 4 wk after surgery. While these results are promising, the few patients evaluated and the lack of long-term follow-up do not let draw any conclusion and further large prospective studies are awaited.

The Stretta® (Mederi Therapeutics Inc, Norwalk, CT, United States) procedure has been studied in non-obese patients only, and has been shown to lead to durable improvement of symptoms and decrease in acid reducing medications use in selected patients[64,65]. The first study that will give some information about the outcomes in patients treated with Stretta after LSG is the ongoing observational prospective study Management of Reflux after Sleeve using Stretta (MaRSS), ClinicalTrials.gov Identifier: NCT02637713.

CONCLUSION

There is a multifactorial relationship between LSG and GERD. Most recent studies have shown satisfactory postoperative reflux control in the majority of patients and low rates of de novo GERD. The shape of the gastric sleeve appears to be one of the main factors predicting the risk of postoperative GERD. These data are leading to a wider acceptance of LSG as bariatric procedure also in obese patients with GERD, provided that a tubular sleeve is created, as recently stated in the 5th International Consensus Conference on sleeve gastrectomy[50].

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