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ORIGINAL CONTRIBUTIONS

Sleeve Gastrectomy and Development of "De Novo" Gastroesophageal Reflux

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Abstract
Background Sleeve gastrectomy (SG) is currently gaining popularity due to an excellent efficacy combined to minimal anatomic changes. However, some concerns have been raised on increased risk of postoperative gastroesophageal reflux disease (GERD) due to gastric fundus removal, section of the sling muscular fibers of gastroesophageal junction, reduced antral pump function, and gastric volume. We undertook the current study to evaluate by means of high-resolution impedance manometry (HRiM) and combined 24-h pH and multichannel intraluminal impedance (MII-pH) the impact of SG on esophageal physiology.
Methods In this study, 25 consecutive patients had HRiM and MII-pH before and after laparoscopic SG. The following parameters were calculated at HRiM: lower esophageal sphincter (LES) pressure and relaxation, peristalsis, number of complete esophageal bolus transit, and mean total bolus transit time. The acid and non-acid GER episodes were assessed by MII-pH with the patient in both upright and recumbent positions.
Results At a median follow-up of 13 months, HRiM showed an unchanged LES function, increased ineffective peristalsis, and incomplete bolus transit. MII-pH showed an increase of both acid exposure of the esophagus and number of non-acid reflux events in postprandial periods.
Conclusions Laparoscopic SG is an effective restrictive procedure that creates delayed esophageal emptying without impairing LES function. A correctly fashioned sleeve does not induce de novo GERD. Retrograde movements and increased acid exposure are probably due to stasis and postprandial regurgitation.

Keywords Sleeve · GERD · HRiM · MII-pH · Hiatal hernia

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Introduction

Sleeve gastrectomy (SG) is currently gaining popularity due to an excellent efficacy combined to minimal anatomic changes related to a combination of restrictive and hormonal effects [1]. However, some concerns have been raised on potential increased risk of "de novo" postoperative gastroesophageal reflux disease (GERD) due to gastric fundus removal, section of the sling muscular fibers of gastroesophageal junction, reduced antral pump function, and gastric volume. To date, combined multichannel intraluminal impedance and pH (MII-pH) is the most sophisticated instrument for studying GERD. Over 24 h of monitoring, it enables detection of every antegrade or retrograde movement into the esophagus [2, 3].

High-resolution manometry with impedance (HRiM) using 36 manometric and 9 impedance sensors located into the catheter is a new device able to accurately evaluate the esophageal and gastric pressures and the bolus transit [4]. To the best of our knowledge, there is a lack of specific data on objective measurement able to define the impact SG which is likely to have on esophagogastric function. We undertook the current study to evaluate by means of MII-pH and HRiM the effect of SG on the esophagogastric physiology.

Materials and Methods

From a prospectively maintained database of 350 patients referred for bariatric procedure to the center of Esophagogastric and Obesity Surgery (EGO) at the Second University of Naples, a consecutive series of 18 women and 7 men (median age, 42 years (22–62 years)) underwent between May 2009 and July 2010 HRiM and MII-pH before and after SG. Each patient was informed about the investigational nature of the study and received detailed information about the study protocol. Before subjects entered the study, specific informed consent was obtained from each.

Patient inclusion criteria were as follows: age 18 years or older and younger than 60 years. Patients who for at least 5 years had morbid obesity (BMI >40 or >35 with comorbidities) with transient or insufficient response to nutritional treatment were offered the alternative of continuing with diet, psychiatric support, and physical activity and not surgical treatments (e.g., cycles of enteral protein-based diet with nasogastric tube, endoscopic intragastric balloon). The surgical treatment options were offered after discussion at multidisciplinary meeting and definitively chosen with the patient.

Patients exclusion criteria were as follows: symptoms of GERD, previous upper gastrointestinal surgery, paraesophageal (type 2), mixed (type 3), or sliding hiatal hernias of 3 cm or more, presence of esophagitis, and Barrett's metaplasia at upper endoscopy. These patients were candidates to antireflux surgery (i.e., laparoscopic Nissen–Rossetti fundoplication [5]) or different bariatric procedure (e.g., laparoscopic gastric bypass [6], or Scopinaro's biliopancreatic diversion [7]). Symptoms were assessed by giving patients, pre- and postoperatively, a standardized questionnaire dealing with the frequency and intensity of esophageal symptoms (such as heartburn, regurgitation, epigastric pain, and bloating) [8].

High-Resolution Impedance Manometry A solid-state combined manometry and impedance recording assembly incorporating 36 circular and unidirectional strain gauge pressure sensors spaced at 1-cm intervals and nine impedance-recording rings (five impedance segments) spaced at 2-cm intervals spanning was used (Sandhill Scientific Inc., Highlands Ranch, CO, USA). Subjects fasted for at least 6 h before transnasal placement of the HRiM. Studies were conducted with the subjects in supine position; catheter was positioned with a station technique to locate and to measure the length of lower esophageal sphincter (LES). The catheter was placed with manometric and impedance sensor able to record the entire esophageal length and at least 3–4 cm of proximal stomach. The HRiM was fixed in place by taping it to the nose. The protocol included 30 s without swallows to assess basal esophageal gastric junction (EGJ) pressure and morphology followed by ten 5-ml swallows of 0.3 % saline solution (Sandhill Scientific Inc.) [9].

MII Definitions Data were analyzed using BioView analysis software (Sandhill Scientific Inc.), and each tracing was personally reviewed by one investigator (S.T.). For each swallow, complete (effective) bolus transit occurred when the bolus entered the first pair of sensors and exited all the distal pair of sensors [10]. The study was considered abnormal if complete bolus transit occurred less than 80 % of the time for liquid swallows. Bolus transit time was expressed as time in seconds from entrance of the bolus in the proximal channel (channel 1) to the exit in the most distal channel (channel 5). These definitions are based on a multi-institutional trial of normal subjects [11].

Manometry definitions HRiM motility patterns were graded as the recently developed Chicago classification by means of esophageal pressure topography. Weak peristalsis was defined as breaks of 2–5 cm in length in >30 % of liquid swallows (small defect) or breaks >5 cm in length in >20 % of liquid swallows (large defect) in the 20 mmHg isobaric contour plot [12] (Fig. 1).

Combined 24-H pH-Multichannel Intraluminal Impedance Twenty-four-hour ambulatory combined pH-multichannel intraluminal impedance studies were performed to document the presence of GERD. A dedicated catheter (Sandhill Scientific Inc., Highlands Ranch, CO, USA) with a pH sensor 5 cm above the LES and six pairs of impedance sensors positioned in the esophagus 3, 5, 7, 9, 15, and 17 cm above the upper limit of the high-pressure zone were placed transnasally. Abnormal total acid and non-acid exposure was defined as described elsewhere [13].

Surgical Technique Dissection of greater omentum started perpendicularly under the incisura angularis alongside greater gastric curvature (IAGGC) respecting the integrity of gastroepiploic veins. Posterior gastric wall was completely made free from pancreatic body and tail, taking care not to injure the splenic artery or vein. Dissection was accomplished once the left crus got separated from retrogastric fat of the bursa omentalis, and a portion of the esophageal longitudinal muscular fibers were visible into the abdomen. Intraoperative

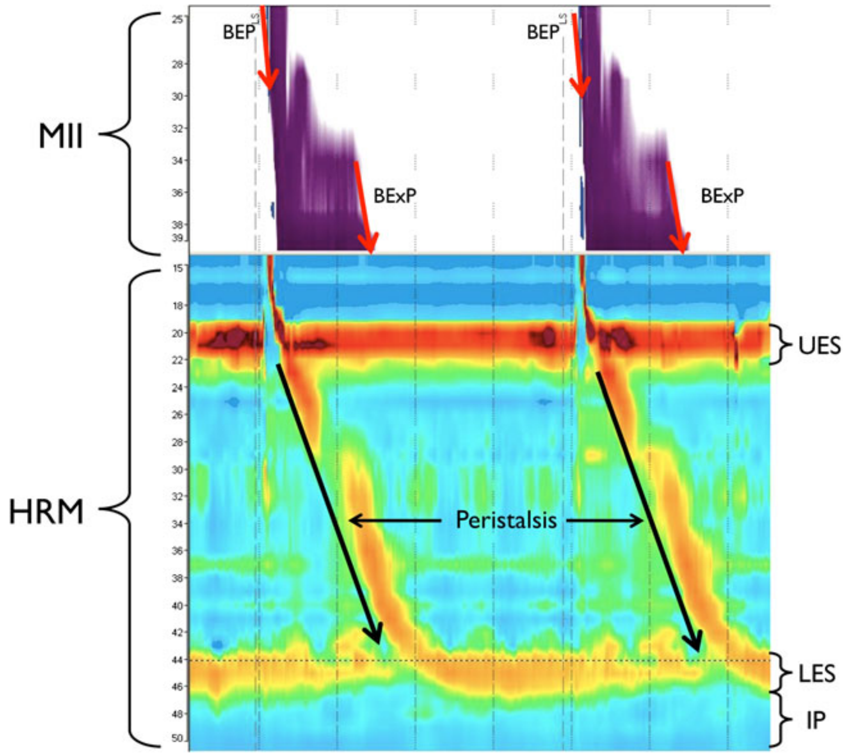

Fig. 1 Example of two normal swallows at high-resolution impedance manometry (*HRiM*) with effective peristalsis, normal sphincters relaxation, and a bolus that fully clears. *MII* multichannel intraluminal impedance, *HRM* high-resolution manometry, *BEP* bolus entrance point, *BExP* bolus exit point, *UES* upper esophageal sphincter, *LES* lower esophageal sphincter, *IP* intragastric pressure

endoscopy was performed to exclude unexpected hiatal hernia. Section was started alongside a 40 Fr tube up to the EGJ preserving majority of the antrum and the integrity of the sling fibers of Helvetius. Attention was paid to have a regular shape of the sleeve and in particular not to create an excessive narrowing of the sleeve at the incisura angularis or an incomplete removal of the posterior wall at fundus ("hourglass type"). Too large proximal gastric lumen size, absence of intraluminal bleeding, or defective stapler line were excluded by intraoperative endoscopy. On demand, partial, running oversewn, or single knots were used to reinforce the stapler line.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows (version 17; SPSS Inc., Chicago, IL, USA). Continuous data are expressed as median and interquartile (25–75th) range, unless otherwise indicated. Differences between preoperative and postoperative parameters were compared by Wilcoxon paired rank test. For all tests, a two-sided $p<0.05$ was considered statistically significant.

Results

No patient was found to have unexpected intraoperative hiatal hernia either at laparoscopic view or intraoperative endoscopy. The evaluations were performed at a median interval of 10 days (2–14) before the sleeve and 13 months (11–17) afterward. The preoperative (130.8 kg (119–156), BMI=46.1 (38–58)) and postoperative (98 kg (72–110), BMI=34.7 (28–46)) anthropology was statistically different with 56 % excess weight loss. After surgery, the incidence of symptoms related to reflux was not modified; in particular, no increase in perception of heartburn, regurgitation, and epigastric pain was observed.

Table 1 shows a detailed pre- and postoperative assessment at HRiM. The total esophageal length did not change after surgery (22.3 vs. 22.4 cm, respectively; $p=0.114$); median

Table 1 Pre-and postoperative assessment at high-resolution impedance manometry (HRiM)

	Pre-surgery* ($n=25$)	Post-surgery* ($n=25$)	$P^{\dagger}$
Esophageal length‡	22.3 (20.6–22.8)	22.4 (20.6–22.7)	0.114
LES length‡	4.1 (3.3–4.5)	3.8 (3.3–4.3)	0.741
LES resting pressure§	21.3 (18.5–33)	22 (19–33)	0.920
LES complete relaxation¶	91.2 (90–96)	90.6 (90–96)	0.849
Ineffective motility¶	10 (0–20)	46 (30–50)	<0.0001
Complete bolus transit	90 (80–100)	50 (30–70)	<0.0001
BTT∞	8.0 (7.8–9)	8.4 (7.8–9)	0.5093

*Values are median (IQR 25th–75th), ‡centimeters, § mmHg, percentage, ∞seconds. *LES* lower esophageal sphincter, *BTT* bolus transit time. † Wilcoxon rank sum test for paired data

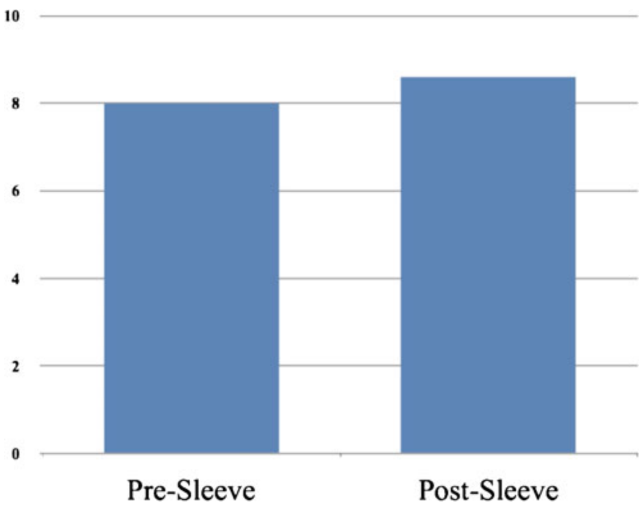

Fig. 2 Pre- and postoperative total bolus transit time expressed as a mean in seconds for liquid and viscous swallows at high-resolution impedance manometry (*HRiM*)

LES length was not statistically reduced postoperatively (4.1 vs. 3.6 cm, respectively; $p=0.741$). Median LES resting pressure was not statistically increased postoperatively (from 21.3 to 21.4 mmHg; $p=0.920$). The percentage of LES complete relaxation did not change after surgery (91.2 vs. 90.6, respectively; $p=0.849$). Median percentage of ineffective peristaltic waves at high-resolution manometry increased from 10 to 46 % ($p<0.0001$). The median percentage of impedance complete bolus transit decreased from 90 to 50 % ($p<0.0001$) after sleeve. Median bolus transit time was not affected postoperatively by the presence of vertical gastrectomy (8.0 vs. 8.6 s; $p=0.509$) (Fig. 2).

Median MII-pH time of monitoring was not different between the preoperative (1,250 min) and postoperative (1,220 min) groups. The median registration for the recumbent position was similar in the preoperative (430 min) and postoperative (480 min) evaluation. The preoperative median percentage with esophageal pH<4 was 1.47 for total time, 1.1 and 1 in the upright and recumbent positions, respectively. Postoperatively, DeMeester's score ($p=0.041$) and the median percentage with esophageal pH<4 in recumbent position ($p=0.04$) significantly increased (Table 2).

Table 2 Standard pH values detected at multichannel intraluminal impedance and pH-metry (MII-pH) before and after sleeve gastrectomy

	Pre-surgery* (*n*=25)	Post-surgery* (*n*=25)	$P^{\dagger}$
Total‡	1.47 (1–2)	3.25 (2–5)	0.818
Upright‡	1.1 (0.1–1.2)	1.97 (0.2–2.6)	0.384
Recumbent‡	1 (0–1.2)	3.1 (0–4.2)	0.04
DeMeester's Score	9 (4.1–12.5)	18.2 (8.0–30.5)	0.041

*Values are median (IQR 25th–75th). ‡ Percentage of time with esophageal pH<4, † Wilcoxon rank sum test for paired data

Table 3 Detailed findings at multichannel intraluminal impedance and pH-metry (MII-pH) before and after sleeve gastrectomy

Pattern of reflux	Pre-surgery* (*n*=25)	Post-surgery* (*n*=25)	$P^{\dagger}$
Total	33 (19–39)	53 (30–57)	<0.0001
Upright	26 (15–30)	38 (20–40)	<0.0001
Recumbent	7 (4–9)	15 (10–17)	<0.0001
Total acid	12 (9–14)	16 (9–18)	0.342
Upright	9 (8–10)	13 (7–15)	0.207
Recumbent	3 (2–4)	3 (0–6)	0.936
Total non acid	17 (10–21)	36 (16–44)	<0.0001
Upright	13 (8–16)	28 (10–32)	<0.0001
Recumbent	4 (2–5)	8 (6–12)	<0.0001
Postprandial	12 (6–19)	28 (17–40)	<0.0001
Acid	6 (3–10)	8 (6–13)	<0.0001
Non-acid	6 (3–9)	20 (11–27)	<0.0001
BCT Total‡	13 (10–15)	34 (26–40)	<0.0001
Upright‡	13 (10–15)	31 (30–38)	<0.0001
Recumbent‡	13 (11–16)	36 (19–50)	0.0002

*Values are median (IQR 25th–75th). ‡ Seconds, *BCT* bolus clearance time, † Wilcoxon rank sum test for paired data

Table 3 shows detailed findings regarding the effects of SG at MII-pH. The SG produced an increase of total reflux

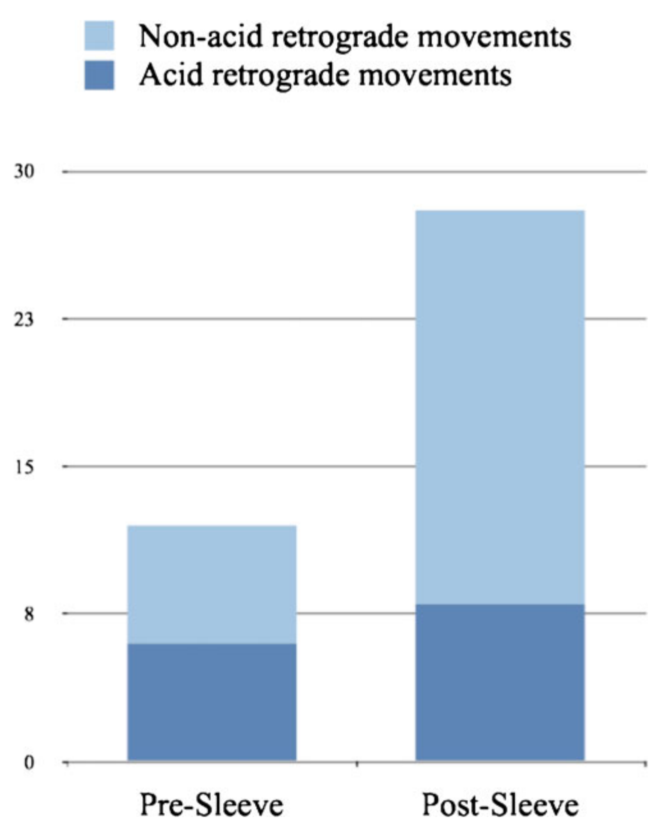

Fig. 3 Postprandial vs. fasting retrograde movements at combined 24-h ph-impedance (*pH-MII*) before and after sleeve gastrectomy. GERD does not increase postoperatively during fasting recording

episodes (33 vs. 53; $p<0.0001$) detected at MII. Specifically, a significant increase of postoperative non-acid reflux episodes in both upright (17 vs. 28; $p<0.0001$) and recumbent (4 vs. 8; $p<0.0001$) position was detected. Postprandial retrograde movements increased significantly after SG (12 vs. 28; $p<0.0001$). Either the acid (6 vs. 8; $p<0.0001$) or non-acid (6 vs. 20; $p<0.0001$) types of postprandial retrograde movements increased after surgery, as showed in Fig. 3. Esophageal bolus clearance time increased after SG (13 to 34 s; $p<0.0001$).

Discussion

Some authors recently focused attention on an increased risk of new onset postoperative GERD after SG [14, 15]. As suggested by Melissas et al. [16], surgical division of the ligaments around the abdominal esophagus and destruction of EGJ might account for worsening of GERD symptoms. Using traditional manometry, Braghetto et al. [17] reported that LES pressure was reduced after SG due to section of the sling muscular fibers at EGJ when stapling in proximity to His angle. Himpens et al. [18] hypothesized the lack of gastric compliance due to gastric fundus removal, and elimination of His angle was responsible for an increase of GERD symptoms at 1 year after SG. At contrast, Petersen et al. [19] recently reported that SG significantly increased lower esophageal pressure at manometry, independent of weight loss, and may protect obese patients from gastroesophageal reflux. However, no specific studies have been published in literature on "de novo" GERD following SG assessed by standard pre- and postoperative HRiM and MII-pH [20].

To our knowledge, this study provides for the first time objective data to demonstrate how a correctly fashioned SG acts as an effective procedure able to not impair the LES. There was no impact on LES pressure and relaxation, probably because the integrity of the sling fibers of Helvetius at EGJ was always preserved. For this purpose, it is advisable to drive the last stapler to the left, aiming to keep it at least 1 cm away from the EGJ.

Progression of the bolus was tested by impedance that directly detects and measures all its physical movements inside the esophagus. A decrease in esophageal transit after surgery was demonstrated by raise of ineffective peristaltic

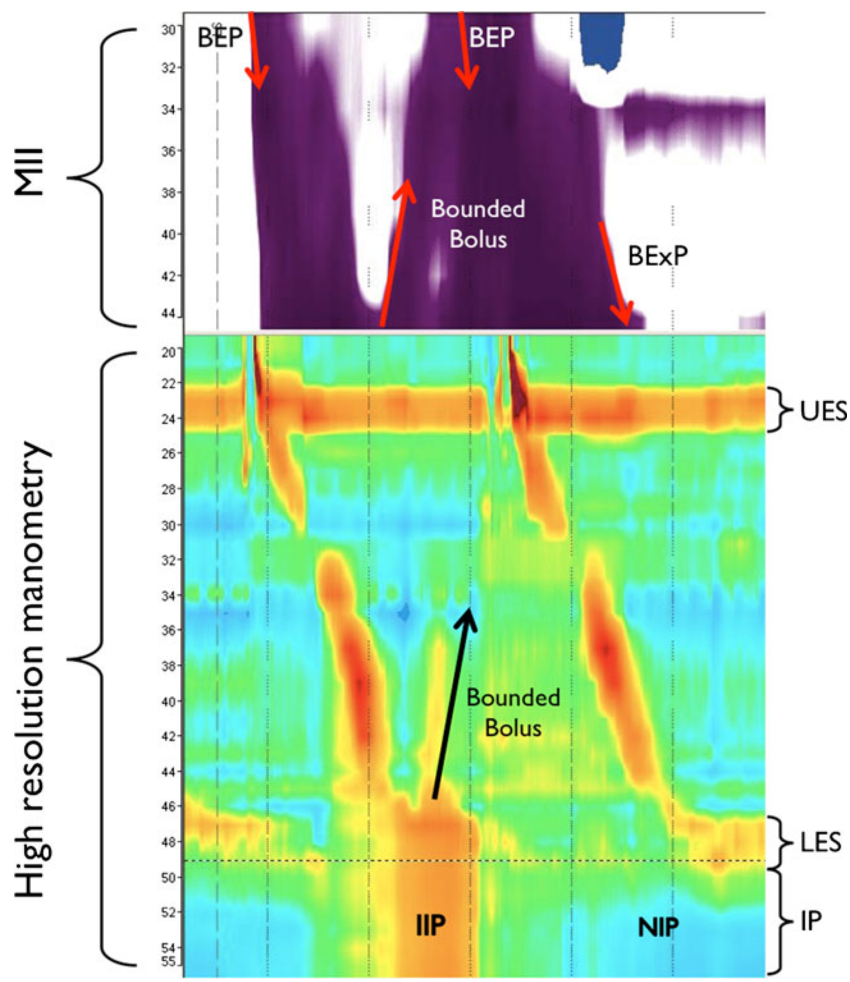

Fig. 4 Bounded bolus at high-resolution impedance manometry (*HRiM*) due to an increased intraluminal pressure after sleeve gastrectomy. At second swallow, the normal intragastric pressure allows a complete bolus exit. *MII* multichannel intraluminal impedance, *HRM* high-resolution manometry, *BEP* bolus entrance point, *BExP* bolus exit point, *UES* upper esophageal sphincter, *LES* lower esophageal sphincter, *IP* intragastric pressure, *IIP* increased intragastric pressure, *NIP* normal intragastric pressure

waves and reduction of complete bolus transit swallow after SG. Meanwhile, bolus transit time did not change after SG. This was not surprising, as SG is an effective restrictive procedure but does not impact esophageal mechanism of peristaltic progression itself.

It is crucial to achieve a straight lumen, applying each stapler line on the same row that goes parallel to the lesser curve, from IAGGC point to the left side of EGJ in order to obtain a functional SG emptying. It is also important not to leave an excessive posterior gastric fundus that has to be placed out from the remaining tube before closing the stapler. A smaller bougie size (<40 Fr) or an excessive strength of tension applied to the gastric tissue before stapling may reduce the final lumen volume and potentially may increase the risk of GERD.

The manual review of MII-pH traces showed several reflux episodes. After a careful analysis, it was clear these episodes were due to retrograde movements into the esophagus during postprandial periods. This can be explained by the postoperative lack of gastric fundus in the normal stomach, as bolus reaching the gastric lumen causes distention of the fundic wall that maintains a stable intragastric pressure, up to a certain range of volume (e.g., 1–2 l). Therefore, a normal subject is able to complete a meal without regurgitation, vomiting, or reflux, whereas after SG, the narrow vertical gastrectomy causes a relevant reduction of the gastric compliance. Once the stomach gets full (e.g., 100–200 cc), the intraluminal pressure increases according to Laplace's law. In this condition, part of the bolus impacts against the elevated gastric pressure and "bounces back" into the esophagus. This phenomenon due to an intraluminal stasis and not to de novo GERD produces an esophageal acidification, wrongly interpreted at standard ph monitoring as GERD. This is consistent with Klaus and Yehoshua [21, 22] that recently reported that the remaining sleeve was associated with a greater intraluminal pressure and smaller volume compared to the whole stomach. Braghetto [23] also found an abnormal increase of esophageal acid exposure after SG. Lastly, the physiological gastric digestion includes a continuous mechanism of timed contractions in the muscular wall of the stomach, necessary to shuffle the gastric contents from antrum up to fundus before emptying. In a normal stomach, the compliance of the fundus receives the alimentary contents pushed up from the antrum. On the contrary, after SG, if the antral pump is intact because of anatomic preservation and integrity of the vagal innervation, the non-distensible wall creates a subsequent increase in intraluminal pressure that may overcome LES resting pressure (Fig. 4). This mechanism may lead to temporary postprandial regurgitation and eventually heartburn, but it can be assumed that an increase in gastric volume and compliance could account for the improvement of GERD-related symptoms at a long follow-up. If this mechanism or the reduced intraabdominal pressure due to weight loss or a more controlled diet or other reason may or not influence GERD needs a longer-term follow-up. Moreover, this study did not investigate the patients with preoperative GERD and/or large hiatal hernia. In particular, Soricelli et al. [24] have recently shown that these patients may potentially benefit from simultaneous SG and hiatoplasty. In this respect, a controlled randomized trial comparing different techniques may draw definitive conclusion regarding a correct indication for obese patients with preoperative GERD and/or hiatal hernia. Whether SG should be indicated or not in case of preoperative symptomatic GERD was not an endpoint of this study. An established flowchart to treat patient with GERD and/or hiatal hernia by SG need additional evidence. Lastly, this study is limited by a restricted number population and a short follow-up.

At present, it seems reasonable to assert that a SG with a regular tube, preserving antral function, and sling fibers integrity does not impact the LES function. On the other hand, the results demonstrate change in the esophageal motility and a raise of intragastric pressure that may lead to an increase in postprandial regurgitation episodes that may simulate "de novo" GERD in patients without preoperative symptoms. The retrograde movements and the increase of acid exposure are probably due to stasis and postprandial regurgitation. HRiM and MII-pH can be either useful decision making tests for determining whether or not to offer SG or to be employed in the postoperative follow-up.

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Conflict of Interest None

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