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Original article

Sleeve gastrectomy with concomitant hiatal hernia repair in obese patients: long-term results on gastroesophageal reflux disease Luigi Angrisani, M.D.^a, Antonella Santonicola, M.D.^{b,*}, Vincenzo Borrelli, M.D.^c, Paola Iovino, M.D.^b

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Abstract

Background: Hiatal hernia repair (HHR) during Sleeve Gastrectomy (SG) is recommended when the defect is intraoperatively found; however, the long term effect on gastro-esophageal reflux disease (GERD) remains controversial.

Objectives: This study aimed to report long-term follow-up data, at least after 7 years, of SG with concomitant HHR and the outcome on GERD symptoms.

Setting: Tertiary-care referral hospital.

Methods: This study retrospectively analyzed 91 obese patients submitted to SG + HHR with a minimum of 7-years follow-up. The preoperative evaluation included GERD symptoms assessment by a standardized questionnaire, proton pump inhibitor usage evaluation, an upper gastrointestinal endoscopy, and a barium-swallow esophagogram to detect the presence of HH. At long-term follow-up visit, GERD assessment was performed to evaluate remission, persistence, or new onset of typical GERD symptoms; proton pump inhibitor usage was also investigated. Patients underwent barium-swallow esophagogram and/or upper gastrointestinal endoscopy.

Results: At long-term evaluation, 2 of 91 patients (2.2%) were lost and 1 patient underwent Rouxen-Y gastric bypass. Of patients with preoperative GERD, 60% had GERD resolution; however, 27 of 88 (30.6%) patients reported postoperative GERD symptoms. Among these patients 15 (55.5%) showed the HH recurrence detected by barium-swallow esophagogram. All patients with HH recurrence had esophagitis and 1 case had a Barrett's esophagus. In the remaining 12 patients (44.4%) with postoperative GERD without HH recurrence, the barium-swallow esophagogram showed signs of reflux in reverse Trendelenburg.

Conclusions: At long-term follow-up HH recurrence was consistently related to the presence of GERD symptoms and to a high rate of esophagitis and Barrett's esophagus. In all patients with GERD symptoms after SG + HHR, a HH recurrence should be suspected and an upper gastrointestinal endoscopy strongly recommended to rule out esophagitis, and especially Barrett's esophagus. (Surg Obes Relat Dis 2020;16:1171–1177.) © 2020 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

Key words: Hiatal hernia repair; Sleeve gastrectomy; Gastroesophageal reflux disease; Hiatal Hernia recurrence

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Hiatal hernia (HH) is common in obese patients [1,2] ranging from 23% up to 52.6% [3–5], depending on the different diagnostic techniques [6,7] and is also considered an independent risk factor for the development of gastroesophageal reflux disease (GERD) [8,9].

Bariatric surgery is growing worldwide [10] and sleeve gastrectomy (SG) is the most frequently performed procedure. The indication of SG has been questioned in obese patients with HH and GERD. Current guidelines recommend concomitant HH repair (HHR) during bariatric surgery when the defect is intraoperatively found [11], although the strength of recommendation is weak. In a large bariatric population, in facts, the preoperative prevalence of GERD was higher in Roux-en-Y gastric bypass than SG patients although the SG patients were twice more likely to undergo concurrent HHR [12]. The effect of SG with concomitant HHR on GERD remains controversial [13], and long-term data are lacking. GERD symptoms may severely decrease the quality of life of SG patients and an alarming rate of Barrett's esophagus (BE) has been reported [14]. The only systematic review examining the effect of SG + HHR on GERD [15] demonstrated the majority of the studies reported GERD resolution postoperatively although the number of patients was little, the surgical techniques heterogeneous, the follow-up period short or not clearly reported, and GERD symptom assessment not standardized [16–19].

Some authors reported the occurrence of HH after SG, defined as intrathoracic sleeve migration [20,21]; others demonstrated the recurrence of HH after SG + HHR in 12% of patients at 21 months [22] and 10.7 at 5 years [23] after surgery.

The aim of this study was to report long-term follow-up data, at least after 7 years, of SG with concomitant HHR and the outcome on GERD symptoms.

Methods

Based on a single surgeon (L.A.) with experience of >1100 cases of SG, data were retrospectively retrieved by a prospective database collection. All patients that received primary SG and HHR were selected and those with a minimum of 7-years follow-up were identified.

Adherence to the ethical conduct standards of the Declaration of Helsinki ensured patients' welfare [24]. The study was approved by the Ethical Committee of the ASL Napoli Centro. Informed consent was obtained from all patients. Exclusion criteria were pregnancy, preoperative evidence of BE, and previous esophageal or gastric surgery.

Preoperative evaluation

All patients routinely underwent a GERD symptoms assessment by a standardized questionnaire, proton pump inhibitor (PPI) usage evaluation, an upper gastrointestinal endoscopy (UGIE) to disclose the presence of erosive reflux disease, an evaluation for *Helicobacter pylori* infection, and a barium-swallow esophagogram to detect the presence of HH. An abdominal ultrasonography was also performed to rule out cholelithiasis.

Surgical technique

All the surgical procedures were performed laparoscopically by a single surgeon (L.A.). The presence of a sliding HH was defined according to the following protocol [25]: the esophagogastric junction (EGJ) and its relationship to the hiatus were carefully inspected without an orogastric tube in the stomach to disclose the presence of sliding HH. If a clear diaphragmatic defect was observed and/or the EGJ was above the diaphragm, the diagnosis of a HH was obtained. When the diagnosis of a HH was not clear, a standard greater curvature dissection would be performed with dissection of the left crus, complete mobilization of the gastric fundus and meticulous dissection of the fat pad to clearly identify the EGJ at the level of the angle of His.

If the EGJ was in the chest above the level of the diaphragm, the HH diagnosis was carried out. The intraoperative diagnosis of a HH was considered to be the gold standard. Whenever intraoperative HH was found it was always posteriorly repaired on the basis of the following technique: the esophagus was encircled, and the diaphragmatic crura were completely dissected to the mediastinal space. The gastric herniation was reduced into the abdomen [25].

Reconstruction was performed using nonabsorbable (0 Ethibond) interrupted sutures; in some cases, the sutures were reinforced with a 1×1 pledget of Marlex (Bard; Murray Hill, NJ, USA). The gastric greater curvature was freed up to the cardioesophageal junction close to the stomach with the use of a vessel-sealing device (Ultracision Harmonic Scalpel; EES, Cincinnati, OH, USA; LigaSure; Covidien, Mansfield, MA, USA) sparing the gastroepiploic vessels. The final surgical preparation was a mobilized stomach tethered at the celiac axis. The stomach was resected with the linear stapler parallel to a 40-Fr orogastric tube along the lesser curve. The calibrating bougie was replaced by a nasogastric tube positioned in the distal stomach to perform the methylene blue dye test for determination of staple-line integrity then, the resected stomach was removed [25].

According to Society of American Gastrointestinal and Endoscopic Surgeons guidelines, at the completion of the hiatal repair, the intraabdominal esophagus measured at least 3 cm [11].

Postoperative evaluation

At the long-term follow-up visit (at least 7 yr), the following data were collected: weight, improvement/remission of co-morbidities, complications, and revisional surgery. Weight loss outcomes are reported as percentage total weight loss and percentage excess weight loss (% EWL). The criteria of surgical success were EWL >50% [26].

The assessment of GERD was performed evaluating the remission, persistence or new onset of typical GERD symptoms, such as heartburn and/or regurgitation. PPI usage was also investigated. All patients had routine abdominal ultrasonography to rule out cholelithiasis. Patients with GERD symptoms had barium-swallow esophagogram and UGIE. Patients without GERD symptoms had barium-swallow esophagogram.

Statistics

Data are expressed as mean \pm standard deviation unless otherwise indicated. χ^2 test, Mann-Whitney U and Wilcoxon tests were used to compare nonparametric data. Analysis of variance and linear regression analyses were used as appropriate. An additional analysis was performed to compare patients with body mass index (BMI) \geq 50 and <50 kg/m².

The significance level was set <.05. The statistical program used was the Statistical Package for Social Sciences (SPSS) for Windows, version 12.0 (IBM Corp, Armonk, NY, USA).

Results

From 2007 to 2012 the HH was intraoperatively diagnosed and repaired in 91 patients.

Preoperative evaluation

Table 1 reported the demographic characteristics and the prevalence of the obesity-related co-morbidities (hypertension, hyperlipidemia, type 2 diabetes) in the 91 participants. Data were also separately shown in patients with BMI \geq 50 kg/m² (n = 16) and BMI <50 kg/m² (n = 75).

Of patients, 36 of 91 (39.6%) referred typical GERD symptoms; half of them assumed PPI (Omeprazole 20 mg/ die) "on demand" and/or antacids.

The preoperative barium-swallow esophagogram and/or UGIE revealed a HH in approximately 37 patients, among them approximately 34% complained typical GERD symptoms. There was not any significant difference for age, weight, BMI, and smoking habits (P = .8, P = .9, P = .6, P = .3 respectively). The prevalence of esophagitis at UGIE in patients with preoperative diagnosis of HH with GERD symptoms was 24% versus 14.3% of those without GERD symptoms.

The prevalence of typical GERD symptoms and HH at UGIE and/or barium-swallow esophagogram in patients with BMI \geq 50 kg/m² and BMI <50 kg/m² was not significantly different (*P* = .8 and *P* = .3, respectively).

In 18 of 91 patients (19.8%) a pledget of Marlex was used during HHR.

Postoperative evaluation

At long-term evaluation, 2 of 91 patients (2.2%) were lost at follow-up and were excluded from analysis. Mean follow up was 94 \pm 10 months. One patient underwent Roux-en-Y gastric bypass 11 months after SG + HHR for severe GERD (Fig. 1).

All patients who completed the 7-years follow-up (n = 88) underwent a reassessment of anthropometric characteristics and prevalence of co-morbidities. Mean weight was 85.1 \pm 17.1 kg and mean BMI 34.9 \pm 4.9 kg/m². Both weight and BMI were significantly lower than before SG + HHR (P < .001 and P = .002, respectively). Mean %EWL was 58.4 \pm 15.6%. Of patients, 53 of 88 (60.2%) showed an EWL >50%, achieving the surgical success. The percentage of surgical success was similar in patients with BMI <50 and \geq 50 kg/m² (63% versus 46.3%, P = .2). There were not any significant differences of %EWL at 1, 3, 5, and 7 years of

Table 1

Preoperative demographic characteristics, prevalence of the obesity-related co-morbidities (hypertension, hyperlipidemia, T2D), and prevalence of GERD symptoms and HH in all the study's population, and in patients with BMI $<50 \text{ or } \ge 50 \text{ kg/m}^2$

	Total population $n = 91$ pts	BMI $<$ 50 kg/m ² n = 75	BMI \geq 50 kg/m ² n = 16
Weight, kg	118.4 ± 18.2	113.5 ± 15.2	141.4 ± 12.5
BMI, kg/m ²	44.8 ± 6.1	42.7 ± 4.5	54.3 ± 2.7
Age, yr	38.8 ± 11.8	39.3 ± 11.3	36.5 ± 14.2
Women, n (%)	75 (82.4)	62 (82.7)	13 (81.3)
Hypertension	18 (23.1)	14 (21.5)	4 (30.8)
Hyperlipidemia	14 (17.9)	13 (20)	1 (7.7)
T2D	8 (10.3)	7 (10.8)	1 (7.7)
GERD symptoms	36 (39.6)	30 (40)	6 (37.5)
HH at preoperative UGIE and/or barium- swallow esophagogram	37 (40.6)	30 (40)	7 (43.7)

T2D = type 2 diabetes; GERD = gastroesophageal reflux disease; HH = hiatal hernia; BMI = body mass index; UGIE = upper gastrointestinal endoscopy.

Data are expressed as percentage (%) or mean \pm standard deviation, when appropriate

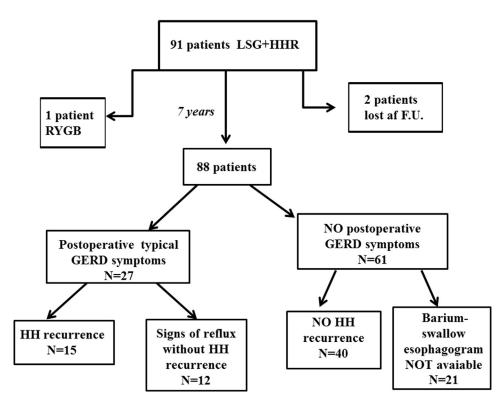


Fig. 1. Flowchart and postoperative findings after SG + HHR. HHR = hiatal hernia repair; SG = sleeve gastrectomy; RYGB = Roux-en-Y-gastric bypass; GERD = gastroesophageal reflux disease.

follow-up in super-obese compared with patients with a preoperative BMI $<50 \text{ kg/m}^2$ (Fig. 2). Percentage total weight loss also was similar in the 2 groups (P > .05).

The prevalence of hypertension, hyperlipidemia, and type 2 diabetes was significantly lower than before surgery (P = .006; P < .001, P = .02, respectively).

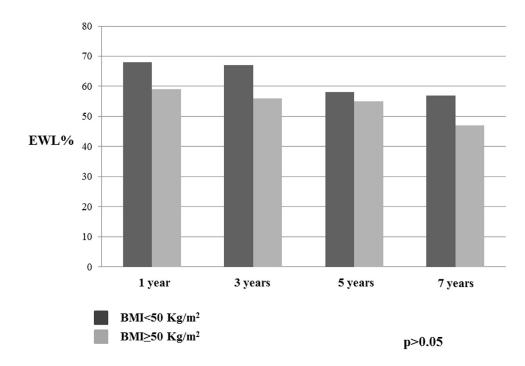


Fig. 2. Percent EWL after 1, 3, 5, and 7 years after SG + HHR in patients with preoperative BMI <50 or \ge 50 kg/m². HHR = hiatal hernia repair; SG = sleeve gastrectomy; EWL = excess weight loss; BMI = body mass index.

Among patients with preoperative GERD (n = 35), 21 (60%) had GERD resolution postoperatively.

However, among patients who completed the 7-years follow-up, 27 of 88 (30.6%) complained of postoperative GERD symptoms; 14 patients had GERD persistence and 13 GERD new-onset. All patients assumed PPI (Omeprazole, 20 mg/die) "on demand" and/or antacids. The prevalence of GERD symptoms was not significantly different in patients who achieved or not the surgical success (EWL >50%) (P = .11). Furthermore, there were not any significant differences in patients who had undergone HHR with and without a pledget of Marlex (P = .4) and in smokers (P = .8).

All patients with postoperative GERD underwent both a barium-swallow esophagogram and UGIE. The barium-swallow esophagogram showed the migration of the sleeved stomach in the chest (HH recurrence) in 15 of 27 (55.5%) of patients (Fig. 1). All patients with HH recurrence had esophagitis and 1 case had a BE. In the 12 patients with postoperative GERD without HH recurrence, the barium-swallow esophagogram showed signs of reflux in reverse Trendelenburg (Fig. 1) and 33.3% had a grade A/B esophagitis; no cases of BE were found.

Mean BMI and %EWL were similar in patients with and without HH recurrence (P = .6 and .3, respectively). HH recurrence rate was not significantly different in patients who had undergone HHR with and without a pledget of Marlex (P = .17).

Of patients, 61 of 88 (69.3%) did not report any GERD symptoms postoperatively. Among them 40 (65.6%) accepted to undergo a barium-swallow esophagogram that revealed neither any of signs of reflux in reverse Trendelenburg or HH recurrence; the remaining patients refused.

Discussion

The vertical resection of the stomach was originally described in bariatric surgery by Marceau [27] and Hess [28] as part of biliopancreatic diversion to reduce the acid gastric secretion in prevention of perianastomotic ulceration of duodenoileostomy, while the intervention of hiatoplasty was developed to avoid the chest migration of the gastric wrap after a Nissen fundoplication in lean patients. Both techniques, originally described in open surgery, have been reproduced laparoscopically and, in recent years, performed simultaneously in obese patients. Although the intraoperative diagnosis of HH is considered the gold standard, the identification of HH in an obese population can be difficult, especially in the case of small HH [29] and can sometimes create new HH because of iatrogenic rupture of the phrenoesophageal ligament [30]. Furthermore, concomitant HHR during bariatric surgery might be challenging for either technical aspects of the repair or patient features. Nevertheless, "The International Sleeve Gastrectomy Expert Panel Consensus Statement: best practice guidelines based on experience of 12,000 cases" by Rosenthal et al. [31] concluded that surgeons should always dissect the phrenoesophageal membrane and inspect the greater curvature side of the stomach for the presence of a HH. Eighty-three percent of the surgeons agreed the aggressive identification of HH intraoperatively is appropriate, and when identified, dissection should be carried out posteriorly to achieve appropriate closure of the crura lowering the possibility of early sleeve migration. Furthermore, the complexity of this procedure necessitates an experienced surgeon [32]. This is an outcome report of a single surgeon, who performed from 2008 to 2012, 91 HHR and gradually improved his surgical technique in bariatric patients, based on a solid experience on digestive laparoscopic surgery in lean patients.

The interesting findings of this study were as follows:

- 1. The majority of patients (60.4%) who underwent HHR repair at time of SG for the presence of intraoperative HH, did not complain of any GERD symptoms preoperatively;
- Preoperative diagnostic accuracy of HH based on standard investigations (barium-swallow esophagogram and UGIE) was low even in a high-volume center;
- 3. Of patients, 60% with preoperative GERD who underwent SG + HHR achieved GERD symptoms resolution at a minimum follow-up of 7 years;
- 4. Of patients, 24% without preoperative GERD developed de novo GERD; and
- 5. All patients with HH recurrence had both GERD symptoms and mucosal injuries even a BE.

In study's population the surgeon (L.A.) did not use any mesh and adopted pledgets in Marlex in 20% of patients; however, the prevalence of HH recurrence was not significantly different in these patients.

The revision of literature on the outcome of SG + HHR showed discordant results at short follow-up while at long follow-up data are scanty. We have previously demonstrated that patients who underwent SG with concomitant HHR had a significantly higher heartburn intensity-frequency score than patients who underwent LSG alone at short-term follow-up (16 \pm 8 mo) [25]. Samakar et al. [33] confirmed our results, demonstrating at a mean 2-year follow-up period, two thirds of patients with preoperative GERD remained symptomatic after SG with concomitant HHR and 15.6% of previously asymptomatic patients developed de novo reflux symptoms. Conversely, other authors found an improvement of GERD symptoms at short-term intervals after SG with HHR [18,22], describing GERD remission in 73.3% [18] and 89% [22] of patients. Boru et al. [23] reported outcome's data at 60 months of follow-up after SG + simple HHR (group A) and SG + HHR reinforced with bioabsorbable mesh (group B) showing GERD resolution in 89% of patients and GERD recurrence in 15.7% of group

A and in 19.5% of group B. They also reported a higher rate of HH recurrence in patients who underwent simple HHR (group A, 18.4%) compared with those who underwent reinforced HHR (group B, 4.3%) with an overall rate of HH recurrence of 10.7%. Furthermore, they did not reveal neither any Barrett's lesions nor de novo GERD [23]. A longer follow-up period and differences in the surgical technique might explain the higher percentage of postoperative GERD in our patients.

The pathophysiology of GERD, de novo or persistence, in patients who underwent SG plus HHR is not completely understood. In the last years, the number of studies reporting a high incidence of esophagitis and BE at long-term follow-up are increasing [14,34] and probably these aspects might gain a growing importance in the near future, with an increasing number of patients needing of a revisional procedure for GERD with or without HH recurrence.

However, the presence of HH recurrence seems to play a pivotal role. In fact, in this study all patients with HH recurrence had more severe GERD with at least mucosal injuries, such as esophagitis and, even a BE; however, other mechanisms, such as the alteration of the angle of His or the lower esophageal sphincter dysfunction, should be taken into account in developing GERD and its complications postoperatively. To date, studies performing esophageal function tests before and/or after SG (high-resolution manometry and 24-h pH/impedance) are scarce and the outcome of HHR not specifically addressed [29,35,36].

This study has several limitations. First, it is a retrospective evaluation of a single-surgeon (L.A.) experience. Moreover, at the long-term follow-up after SG + HHR, only patients who referred GERD symptoms underwent UGIE; in fact, the majority of patients without GERD symptoms refused to receive an endoscopic evaluation and, even 21 of 61 refused to undergo a radiologic evaluation. Thus, the prevalence of erosive esophagitis and BE is possibly underestimated. Another limitation is the absence of esophageal motility tests, such as high-resolution manometry that has been suggested as new gold standard for the diagnosis of HH [29,37].

Conclusion

At long-term follow-up, HH recurrence was consistently related to the presence of GERD symptoms and to a high rate of esophagitis and BE. In all patients with GERD symptoms after SG + HHR, a HH recurrence should be suspected and an UGIE strongly recommended to rule out esophagitis, and especially BE. Furthermore, a preoperative HRM might suggest risk factors for developing HH recurrence, for example a hypotensive lower esophageal sphincter or motility impairment as well as postoperatively it might add very important information to better manage these patients.

Disclosures

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

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Luigi Angrisani and Antonella Santonicola equally contributed to this work.

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Editorial comment

Comment on: Sleeve gastrectomy with concomitant hiatal hernia repair in obese patients: long-term results on gastroesophageal reflux disease

In the paper by Angrisani et al. [1], the authors tackle an important question, namely, what are the long-term outcomes regarding gastroesophageal reflux disease (GERD) in patients undergoing sleeve gastrectomy (SG)? Many surgeons consider GERD to be the Achilles' heel of the SG, and it is one of the main reasons for conversion of the SG to other procedures, such as the gastric bypass [2]. The last International Consensus Conference on SG demonstrated >50% of surgeons considered GERD to be a relative contraindication to the SG, and also hiatal hernias (HH) should be repaired when encountered [3]. The authors of the paper under discussion followed 91 patients who had a SG with a concomitant hiatal hernia repair (SG+HHR) for an average of 7 years and specifically evaluated outcomes in regard to GERD. They found that of patients who had GERD

preoperatively, 60% resolved their symptoms after SG+HHR. At 7-year follow-up, 30.6% of patients complained of postoperative GERD symptoms; 14 patients had GERD persistence and 13 GERD new onset. Of those patients, 15 of 27 (55.5%) had recurrent HH with migration of the sleeve into the chest. There were 12 patients with GERD without a HH, with demonstrated reflux during barium swallow in reverse Trendelberg. One patient was found to have Barrett's esophagus (BE). The authors conclude that HH recurrence is closely associated with GERD and esophagitis.

The authors are to be commended for their long-term follow-up. Their average follow-up of 97.8% at 7 years is actually incredible. Bariatric surgeons know the difficulty of getting patients to follow-up long term. The average follow-up for bariatric patients is quite low after the first 1