The American Journal of Surgery 217 (2019) 496–499

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Laparoscopic placement of the LINX® system in management of severe reflux after sleeve gastrectomy

Abdelkader Hawasli*, Moutamn Sadoun, Ahmed Meguid, Mosab Dean, Mohamad Sahly, Bianca Hawasli

St. John Hospital and Medical Center, Detroit, MI, USA

ARTICLE INFO

Article history:
Received 24 July 2018
Received in revised form
21 October 2018
Accepted 24 October 2018

ABSTRACT

Background: Management of severe reflux after sleeve gastrectomy (SG) is often done by conversion to Roux-en-Y gastric bypass (RYGB). The LINX® system could be an alternative treatment.
Method: Between 2015 and 2017, 13 patients had LINX® system placed to manage their reflux after SG. Pre-operative evaluation included a barium swallow, endoscopy with pH monitor and esophageal motility.
Results: Ten females and three males with mean age of 49 ± 13 years were evaluated. Their mean weight before placing the LINX® system was 193 ± 45 lbs. and mean BMI of 33 ± 6 kg/m^2. The mean time between SG and placing the LINX® system was 43 ± 19 months. The mean Bravo score was 46 ± 26 (normal 14.7). One patient developed severe dysphagia post-operatively requiring removal of the LINX® after 18 days and one patient was lost to follow up. The mean follow-up in the remaining 11 patients was 26 ± 12 months. The mean GERD-HRQL score dropped significantly from 47/75 ± 17/75 to 12/75 ± 14/75 ($p = .0003$).
Conclusion: The LINX® system may be used as an alternative to RYGB conversion in managing refractory post-SG reflux.

Introduction

Sleeve gastrectomy (SG) is gaining wide acceptance as a procedure of choice to treat morbid obesity. A review of over a decade of data of 73,361 primary bariatric procedures documented in the registry of the Michigan Bariatric Surgery Collaborative (MBSC) showed an increase in the percentage of SG from 2.52% (118 cases of 4686) in 2007 to 82.05% (6734 cases of 8207) in 2017 (Fig. 1).

The relationship between SG and postoperative gastroesophageal reflux disease (GERD) has been described and investigated in a number of reports.[1,2] Medical management is usually the initial treatment of this problem using proton pump inhibitors (PPI). Conversion to Roux-en-Y gastric bypass (RYGB) is usually the recommended surgical option for severe and refractory conditions.[2]

The LINX® system (Torax Medical, Inc., Shoreview, MN, USA) was approved by the Food and Drug Administration (FDA) in 2012 for the treatment of refractory esophageal reflux by using magnetic beads to augment the lower esophageal sphincter (LES).[3] The existing literature supports the use of this device as a safe and effective treatment option in the general population, however, its use for the treatment of reflux after sleeve gastrectomy has not been widely reported.[4,5]

Our objective from this study was to evaluate the safety and effectiveness of treating severe refractory reflux, after SG, using the LINX® system in patients who refused the RYGB option.

Material and method

A retrospective chart review was conducted on all patients who had placement of the LINX® system to manage their reflux after SG between January 2015 and December 2017 in one practice by one surgeon. All patients refused the conversion of their SG to RYGB, understanding that the conversion is the usual recommended option to treat this condition.

Pre-operative work up included, barium swallow (UGI), upper gastro-intestinal endoscopy (EGD) with Bravo capsule pH monitor and esophageal motility. All barium swallows were performed at the same facility and all EGD with Bravo capsule pH monitor

* Corresponding author.
E-mail address: eastsidesurgical@aol.com (A. Hawasli).

https://doi.org/10.1016/j.amjsurg.2018.10.040
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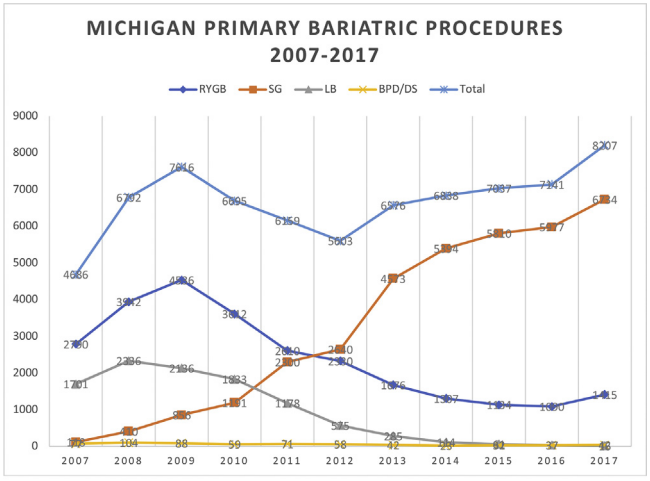

RYGB: Roux-en-Y Gastric Bypass, SG: Sleeve Gastrectomy, LB: Lap-Band, BPD/DS: Bilio-Pancreatic-Diversion/Duodenal Switch.

Fig. 1. RYGB: Roux-en-Y Gastric Bypass, SG: Sleeve Gastrectomy, LB: Lap-Band, BPD/DS: Bilio-Pancreatic-Diversion/Duodenal Switch.

placements were performed by the same surgeon. Patient's demographics, BMI, weight loss, presence of esophagitis, hiatal hernia, and Bravo pH score were recorded.

During the operative procedure, all patients had lysis of adhesions along with opening the phreno-esophageal ligament with mobilization of the mediastinal esophagus into an abdominal position. All patients had a posterior cruraplasty leaving a hiatus opening which accepted a 48 fr. bougie without difficulties. The placement of the LINX® system was performed after removing the bougie with an empty and relaxed esophagus.[4] Gastric plication, to decrease the size of the dilated gastric pouch, was performed when necessary. A post-operative UGI barium swallow was performed on post-operative day one to assess for any injuries, obstruction or reflux. Standardized patient questionnaire, the Health-Related Quality of Life (HRQL), was administered pre-operatively and at the post-operative clinic visits or by phone updates. Post-operative long term follow-up testing, such as UGI barium swallow, EGD with Bravo or motility, were requested based on patients' recurrence of symptoms and limited by insurance approval.

Our hospital IRB deemed this study "exempt" since all patients are part of the MBSC and the national MBSAQIP of the American College of Surgery Bariatric Registries. The statistical analysis was done using paired samples *t*-test.

Results

During the two-year study period, 13 patients had placement of the LINX® system to manage their severe acid reflux after SG after failed medical management. Ten (76.9%) patients were females and three (23.1%) were males. The mean age was 49 ± 13 years. Reflux was present in 11 (84.6%) patients before the SG and de novo reflux developed in two (15.4%) patients after SG.

The initial mean weight before the SG was 269 ± 50 lbs. and mean BMI was 46 ± 8 kg/m2. All patients had lost weight. Their lowest mean weight after the SG was 182 ± 43 lbs. Nine (69.2%) of the thirteen patients gained weight before placement of the LINX® system, ranging from 5 to 34 lbs., with a mean weight gain of 17 ± 10 lbs. The mean weight before placement of the LINX® system was 193 ± 45 lbs. with a mean BMI of 33 ± 6 kg/m2 showing a mean weight loss after the SG of 82 ± 34 lbs.

The mean time between the SG and the placement of the LINX® system was 43 ± 19 months. Nine patients had 2 cm hiatal hernia, one patient had 3 cm hiatal hernia, and three patients had less than 2 cm hiatal hernia. Eight (61.5%) patients had dilated proximal gastric pouch. The mean Bravo pH score was 46 ± 26 (normal = 14.7). Esophagitis was present in 5 (38.4%) patients.

The mean operative time was 79 ± 23 min. All patients had posterior cruraplasty. All eight patients with dilated gastric pouch had gastric plication. The post-operative mean hospital length of stay was 1.1 ± 0.3 day. There were no intra-operative complications. All 13 patients had a postoperative UGI on the first post-operative day showing the LINX® to be in good position with no evidence of reflux (Fig. 2: A&B).

Post-operatively one patient had severe dysphagia and demanded removal of the LINX® system after 18 days of its placement. This patient was removed from the follow up.

One patient was lost to follow up. The remaining eleven patients (91.7% of the total 12 who still have the LINX®) completed either an office or phone follow up with a mean of 26 ± 12 months. Five (45.5%) patients stopped their PPI completely. The remaining six (54.5%) patients had complete resolution of their reflux initially and developed recurrence of reflux after a mean period of 7 ± 6 months. In three of these patients the recurrent reflux was mild and occasional depending on what they ate. They took PPI occasionally. In the other three patients their recurrence required daily intake of PPI but to a lesser degree than their original PPI intake before the placement of the LINX®.

The mean GERD-HRQL score in these eleven[11] patients showed a statistically significant drop from 47/75 ± 17/75 to 12/75 ± 14/75 ($p = .0003$).

Discussion

The relationship between obesity and GERD is well established, with up to 50% of patients with BMI >30 kg/m^2 having GERD.[6,7] Data from the MBSC registry of 73,361 patients who had a primary bariatric procedure performed from 2007 to 2017 showed GERD to be present in 50.3% of these patients. The popularity of SG worldwide is increasing rapidly in the last decade, and this observation is also reflected in the MBSC data registry where in the last decade SG increased from 2.5% to 82.05% while RYGB declined from 59.54% to 17.24% of cases.

On the other hand, as the number of SG is on the rise, the relationship between GERD and sleeve gastrectomy is still in dispute. Following the procedure, patient's GERD may improve or worsen while in those patient who do not have reflux, the SG in itself, can cause a "de novo" reflux. Chiu et al. did a systemic review of the effect of SG on GERD and found 15 studies. Four studies showed an increase in GERD after SG, while seven studies found a postoperative reduction in GERD prevalence. From the studies in which an overall reduced prevalence was reported, the investigators noted that patients with pre-existing GERD had shown resolution in 75% following SG and improvement in 8%, but that new cases of GERD had developed as de novo after SG in 21.8%.[8]

Many reasons have been blamed for the increase in GERD after SG, including the higher intragastric pressure, dilatation in the proximal gastric pouch, phrenoesophageal ligament disruption, sling fiber resection, the weakening of contraction amplitude in the lower esophagus, and decreased gastric compliance.[2] Although we did not study these factors we noticed that weight gain accompanied the presence of GERD in 69.2% of our patients. In addition, the higher intragastric pressure may explain the continued use of PPI in 54.5% of our patients by overcoming the magnetic strength of the LINX® beads.

The recommended conversion of SG to RYGB to treat refractory

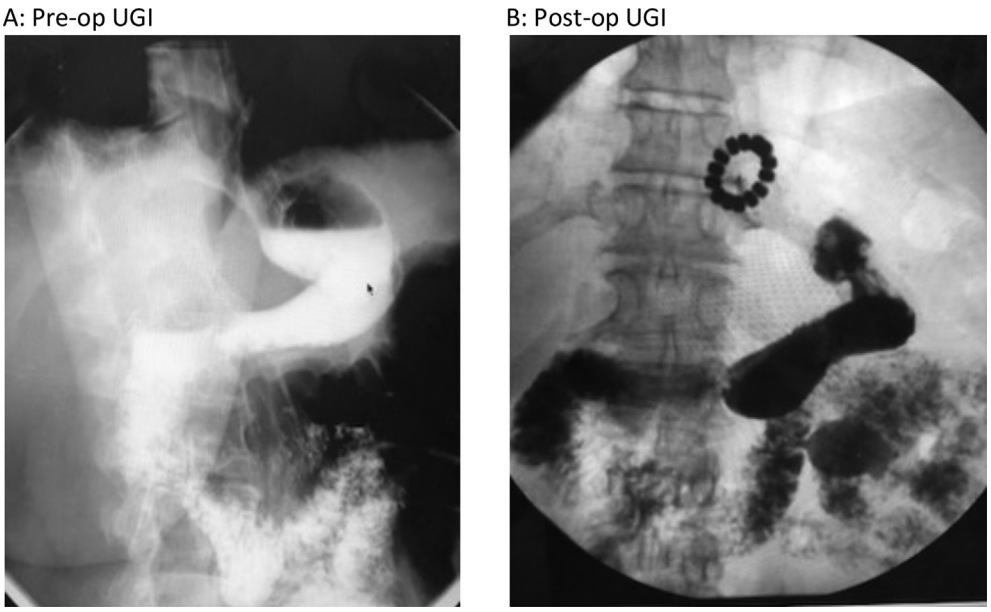

Fig. 2. Pre and post operative UGI.

post-SG reflux carries a high risk of complications such as significant blood loss, greater risk for intensive care unit (ICU) stay, intraoperative liver and spleen injuries, and more enterotomies even in experienced hands.[9] Unfortunately, RYGB only diverts the acid from the esophagus and does not address the original problem of the reflux, which is the weakness in the LES and its transient relaxation. Not to mention that even patients with RYGB have issues with reflux as well. Verban et al. reported on 10,766 patients who completed one year survey on the use of anti-reflux medication (ARM) and found that 43.8% of those who underwent RYGB continued to use ARM in addition to 19.2% new users.[10] This observation was documented as well by Pallati et al. who found improvement in reflux score in only 56.5% (7955 out of 14,078 patients) of those who underwent a RYGB with hiatal hernia repair.[11]

Our group had reported on an alternative surgical approach in the presence of dilation of the proximal gastric pouch by performing a laparoscopic anterior fundoplication with posterior crura approximation.[12] Nevertheless, for patients with severe GERD who refuse the conversion to RYGB, who have contraindication for such conversion (such as a pre-existing malabsorption condition), or who have an unfavorable anatomy (such as no dilatation of the proximal gastric pouch), there is no other surgical option for them to treat their reflux.

With the introduction of the LINX® system, and approval by FDA as an alternative to Nissen fundoplication to treat reflux disease in the general population, we saw a possibility for using this device in treating these patients.

The LINX® system works in controlling reflux by augmenting the LES pressure with its magnetic beads without using the gastric fundus.[3] This feature works well in patients post SG since the option of creating a wrap is very limited. It should be mentioned, however, that the FDA had a precaution on using the LINX® system in patients who had previous gastric or esophageal surgery merely because the safety and effectiveness of the LINX® system has not been studied in this population. All our patients were informed about this precaution by the FDA and signed off on it.

There are two published studies using the LINX® system to treat reflux after SG. A case report with one year follow up showing good control of the reflux without medication.[4] The other study was by Desart et al. where the group enrolled seven patients and reported similar results in regard to the control of the reflux symptoms, with very good patient satisfaction and no intraoperative complication.[5] Their follow-up time, however, was only 2–4 weeks and they excluded patients with hiatal hernia.

Our study has limitations related to sample size. First, as a retrospective, single center study, it is not possible to draw conclusions about the efficacy of the LINX® system in comparison with other potential treatments. Second, because of the small sample size and relatively short follow up time, it is not possible to determine the extent to which the resolution of reflux is sustainable using the LINX® system. Further research with longer follow up is needed to fully evaluate the efficacy of this treatment approach, which remains relatively novel.

Our current approach to managing patients with reflux after SG is medical treatment for one year. If this failed then the patient is offered the RYGB. If the patient refuses, then we offer the LINX® system as an alternative, provided that the patient's BMI is ≤ 35 kg/m^2. For patients with BMI >35 kg/m^2 and a dilated gastric pouch, or those whose insurance does not cover the LINX® system, an anterior fundoplication with repair of the hiatal hernia, if present, is offered.

Conclusion

The laparoscopic placement of the LINX® system for management of severe refractory reflux after SG is safe and may be offered as an alternative to the conversion to RYGB. Patients should be informed about the FDA precaution and should sign off on it. A prospective randomized control study is needed to ensure the reproducibility of our results, as well as, the long-term effectiveness of this approach in treating refractory reflux after SG.

Conflicts of interest

None.

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