Gastroesophageal Reflux Management with the LINX® System for Gastroesophageal Reflux Disease Following Laparoscopic Sleeve Gastrectomy

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Abstract

Background Laparoscopic sleeve gastrectomy (LSG) has gained significant popularity in the USA, and consequently resulted in patients experiencing new-onset gastroesophageal reflux disease (GERD) following this bariatric procedure. Patients with GERD refractory to medical therapy present a more challenging situation limiting the surgical options to further treat the de novo GERD symptoms since the gastric fundus to perform a fundoplication is no longer an option.

Objectives The aim of this study is to determine if the LINX® magnetic sphincter augmentation system is a safe and effective option for patients with new gastroesophageal reflux disease following laparoscopic sleeve gastrectomy.

Settings This study was conducted at the University Medical Center.

Methods This is a retrospective review of seven consecutive patients who had a laparoscopic LINX® magnetic sphincter device placement for patients with refractory gastroesophageal reflux disease after laparoscopic sleeve gastrectomy between July 2014 and April 2015.

Results All patients were noted to have self-reported greatly improved gastroesophageal reflux symptoms 2–4 weeks after their procedure. They were all noted to have statistically significant improved severity and frequency of their reflux, regurgitation, epigastric pain, sensation of fullness, dysphagia, and cough symptoms in their postoperative GERD symptoms compared with their preoperative evaluation.

Conclusion This is the first reported pilot case series, illustrating that the LINX® device is a safe and effective option in patients with de novo refractory gastroesophageal reflux disease after a laparoscopic sleeve gastrectomy despite appropriate weight loss.

Keywords Gastroesophageal reflux disease · Sleeve gastrectomy · LINX® system

Introduction

Laparoscopic sleeve gastrectomy (LSG) has gained significant popularity in the USA, and in some reports has recently surpassed Roux-en-Y gastric bypass (RYGB) as the most commonly performed weight loss surgery.1–3 Both procedures are highly effective weight loss tools and dramatically improve important obesity-related conditions including type II diabetes, hypertension, and obstructive sleep apnea.4 Gastroesophageal reflux disease (GERD) is another condition highly prevalent among the morbidly obese population. While RYGB is well documented to both improve GERD and limit new-onset GERD, there is no consensus regarding the relationship between LSG and GERD.4–9 It is clear, however, that 18–22% patients will experience new-onset GERD following LSG.8–10 In the majority of these patients, proton pump inhibitors (PPIs) are effective in controlling reflux symptoms.4 Those patients with GERD refractory to PPIs present a more challenging situation limiting the surgical options to further treat the de novo GERD symptoms. The traditional surgical method of
using the patient’s gastric fundus to perform a fundoplication is no longer an option for these patients and the treatment alternatives for patients experiencing GERD symptoms after LSG are few.

Most commonly, conversion of a sleeve gastrectomy to RYGB is undertaken and is highly effective in controlling reflux symptoms. Although this is a well-described option in the literature, the inherent risks associated with a repeat bariatric operation, and those factors influencing the initial choice of LSG over RYGB still remain. We sought to identify an alternative approach to the management of refractory GERD after LSG and recognized an opportunity with the LINX® magnetic sphincter device. The LINX® Reflux Management System (Torax Medical, Inc., Shoreview, MN, USA) was approved for the treatment of GERD in March of 2012. The existing literature supports this device as a safe and effective option for the treatment of medically refractory GERD. Therefore, we present the first seven known cases of LINX® device implantation for the management of refractory GERD following LSG.

Methods

We performed a retrospective review of seven consecutive patients who had a laparoscopic LINX® magnetic sphincter device placement for patients with refractory gastroesophageal reflux disease after laparoscopic sleeve gastrectomy between July 2014 and April 2015. The division’s database was interrogated after institutional review board approval, and the patient demographic characteristics, operative details, and postoperative outcomes were collected and analyzed. The operative procedure was completed by the same surgeon for all seven patients to avoid technical variability. We dissected the posterior vagus nerve from the esophagus and implanted the device in a similar fashion as previously described in the literature (Figs. 1 and 2).

All patients had a preoperative and postoperative upper gastrointestinal (UGI) study. All the radiographic swallow studies were performed at the same facility using similar dynamic techniques while performing maneuvers to elicit reflux. Similarly, the 24-h pH probe and esophageal manometry were performed as part of their GERD evaluation. They were all interviewed regarding their reflux symptoms using the GERD score questionnaire as we have previously reported. Allen et al. have previously validated this questionnaire. The patients were specifically asked to score the severity and frequency of their reflux, regurgitation, epigastric pain, sensation of fullness, dysphagia, and cough symptoms. In addition, they were also asked whether they were satisfied with their GERD symptoms following the laparoscopic LINX® procedure.

Results

We identified seven patients from this time period who had a laparoscopic LINX® magnetic sphincter device placement for refractory gastroesophageal reflux disease following their laparoscopic sleeve gastrectomy. Table 1 shows the patient demographic and surgical characteristics. Mean age was 53 years, five were females, five were Caucasians, one Hispanic, and one African-American. Refractory gastroesophageal reflux was the dominating presenting symptom which was not present prior to their LSG. Mean body mass index (BMI) for the study cohorts was 50.7 kg/m² (range 40–68.5 kg/m²) prior to their laparoscopic sleeve gastrectomy. The mean weight loss and change in BMI prior to their laparoscopic LINX® magnetic sphincter device placement was 42.7 kg (range 25–69.6 kg) and 15.3 kg/m² (range 9.4–25.5 kg/m²), respectively. The mean and median period of time between the patients’ LSG and implantation of the LINX® device was 18.1 and 10.1 months, respectively (range 9–36 months). All
patients had a 24-h pH probe and esophageal manometry study indicating a mean DeMeester score of 56.6 and a hypotensive LES. One patient did not tolerate the placement of esophageal probes; hence, both studies were aborted. An upper Gastrograffin esophagogram study was performed preoperatively and postoperatively illustrating gastroesophageal reflux in the supine and upright position which completely resolved following the placement of the LINX® magnetic sphincter device. None of the patients had a hiatal hernia present on the preoperative esophagogram or intraoperatively while placing the LINX® magnetic sphincter device. None of the patients had a hiatal hernia present on the preoperative esophagogram or intraoperatively while placing the LINX® magnetic sphincter device.

We evaluated all the patients’ reflux symptoms using the GERD score questionnaire 2–4 weeks after their surgical procedure. All patients were noted to have self-reported greatly improved gastroesophageal reflux symptoms 2–4 weeks after their procedure. They were all noted to have statistically significant improved severity and frequency of their reflux, regurgitation, epigastric pain, sensation of fullness, dysphagia, and cough symptoms in their postoperative GERD symptoms compared with their preoperative evaluation ($P<0.05$). All participants were extremely happy with their surgery.

**Discussion**

Obesity is a significant risk factor for GERD,\textsuperscript{26} with prevalence rates as high as 30% in the morbidly obese.\textsuperscript{25} In patients with preexisting GERD, LSG improves symptoms of GERD in 2.8–20%.\textsuperscript{10} RYGB, on the other hand, is a highly effective antireflux surgery and resolves GERD symptoms in 70–80%.\textsuperscript{28,29} More troubling is development of new-onset GERD following LSG, observed in as many as 8.6–22% of patients.\textsuperscript{8,30}

In patients with reflux refractory to medical therapy, limited surgical options exist since the LSG procedure involves removal of the fundus. As a result, fundoplication is extremely difficult to perform with the limited amount of fundus tissue present in patients with prior LSG. Consequently, the Roux-en-Y gastric bypass has been recommended as a conversion procedure for those who develop or continue to have reflux after LSG. Alternatively, the LINX® procedure can be considered as another viable option that may potentially have fewer surgical complications compared to RYGB. Furthermore, the LINX® device is implanted in the area of the gastroesophageal junction which is largely undisturbed with LSG. This study is the first to evaluate the LINX® device for GERD in post-LSG patients.

The LINX® gained FDA approval in 2012. The initial Investigational Device Exemption (IDE) feasibility trial enrolled 44 patients between 2007 and 2008 and follow-up data exists out to 4 years.\textsuperscript{12,16} Esophageal pH normalization was demonstrated in 16 of 20 patients at 3 years. Based on the GERD-HRQL questionnaire, 87% of patients (20/23) reported satisfaction with their current condition at 4 years (measured off PPIs). Dysphagia was the most common adverse event, reported in 43% (20/44) of patients. This symptom was noted immediately postoperatively but decreased to <5% at 1 year. Three patients have undergone device explantation. The first required device removal at 226 days after implantation secondary to persistent dysphagia, with symptom resolution after the explant. A second elected for device removal at 3.5 years secondary to persistent GERD symptoms and underwent Nissen fundoplication. The third patient to undergo device explantation did so electively to have an MRI. No reports of device erosion or migration have been reported in these 44 patients.

The second IDE pivotal study was a prospective, nonrandomized clinical trial enrolling 100 patients for which 3-year follow-up data has been reported.\textsuperscript{24} At 12 months, only 64% of patients met the primary efficacy endpoint of normalization of or at least a 50% reduction in esophageal acid exposure. At 3 years, 94% of patients reported satisfaction with their reflux, and 87% reported complete cessation of PPIs. Similar to

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GERD score\textsuperscript{25}: severity and frequency of their reflux, regurgitation, epigastric pain, sensation of fullness, dysphagia, and cough symptoms
the feasibility trial, dysphagia was the Most common adverse event and occurred in 68% of patients. Six patients required device removal; three for persistent dysphagia that resolved after explantation, one for intermittent vomiting that did not resolve, one for persistent reflux, and another for persistent chest pain. At 2 years, there were no reports of device erosion or migration. Traditionally, conversion to RYGB has been the procedure of choice in these patients. Although highly effective in controlling reflux symptoms, conversion to RYGB is a major operation with many known risks. Furthermore, some patients are not candidates for this conversion due to unfavorable gastrointestinal anatomy or issues with malabsorption. In the current pilot case series, we demonstrate that LINX® implantation is a safe and effective option in patients with de novo refractory GERD after LSG despite appropriate weight loss. These patients did not have or developed a hiatal hernia as a result of their LSG. Hence, we only included patients that had de novo refractory gastroesophageal reflux without hiatal hernia to minimize an additional variable in our pilot study.

All patients were very satisfied with their weight loss since the mean weight loss and BMI reduction was 42.7 kg and 15.3 kg/m², respectively at 18 months. All patients reported improvement in GERD symptoms and objective radiographic measurements demonstrated decreased esophageal acid exposure. Lastly, none of the patients were noted to have gastric pouch dilatation as compared to their initial UGI study immediately following their bariatric sleeve gastrectomy procedure, and they did not have a hiatal hernia as a cause of their GERD.

We appreciate that this is a small series of patients to conclude long-term results considering we did not perform a repeat esophageal pH probe or manometry for our patients to determine if the DeMeester score has changed. However, we could not justify doing so based on the patients’ symptoms improvement, cost and potential adverse event.

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Furthermore, with the second IDE pivotal trial indicating no reports of device erosion or migration at 2 years, we felt that this would be a low-risk surgical treatment as compared to the alternative more complex bariatric revision. In fact, the LINX® device can be easily explanted and does not preclude conversion to RYGB should this need arise. With the increasing incidence of new-onset GERD following LSG and limited surgical options, we firmly believe that a multicenter study is needed to ensure the long-term safety and efficacy of the LINX® device in LSG population.

References


