MAGNETIC SPHINCTER AUGMENTATION IMPLANTATION PRIOR TO PRIMARY SLEEVE GASTRECTOMY AND DUODENAL SWITCH IN PATIENTS WITH CLINICALLY SEVERE GERD

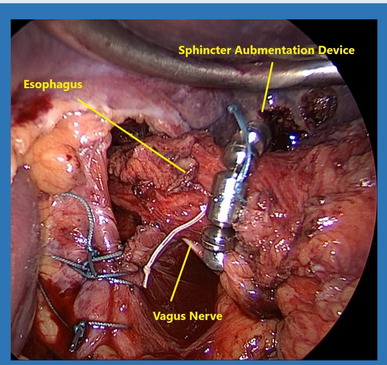
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INTRODUCTION

Gastroesophageal reflux disease (GERD) after sleeve gastrectomy is a controversial subject. GERD following sleeve gastrectomy is associated with esophagitis and progression to Barrett's esophagus. Treatment options for GERD after sleeve gastrectomy or duodenal switch are limited and conversion to Roux Y Gastric Bypass has become the most common operation currently performed. Magnetic Sphincter Augmentation (MSA) is approved by the FDA as an effective anti reflux operation. The utilization of MSA after bariatric surgery is unfortunately an "off label" use of the device. We propose utilizing MSA as an initial operation to eradicate GERD prior to any bariatric surgery. In order to utilize MSA as an approved operation to alleviate reflux in patients undergoing sleeve gastrectomy and duodenal switch, we proposed implanting the device in patients with clinically severe GERD as a separate operation before performing primary bariatric surgery. Using a two operation approach the implantation of MSA complies with the FDA instructions for use (IFU). In utilizing two operations the MSA device would be implanted first followed by bariatric surgery at a later date.

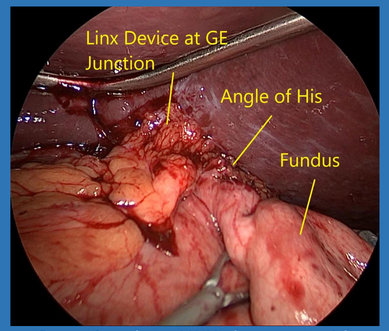
STUDY DESIGN

Four patients with significant, symptomatic, GERD were evaluated for possible MSA implantation prior to bariatric surgery. Each potential MSA candidate underwent preoperative motility studies, upper GI swallow and EGD. At the time of MSA implantation any associated hiatal hernia was repaired. The MSA device was sized and placed according to manufacturer's recommendations. Primary bariatric operations were performed 3-6 months after implantation.





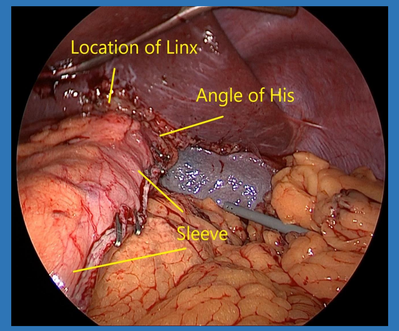
Operative Photo Hiatal Hernia Repair and LINX Pre-Bariatric Surgery and Post Operative Upper GI Swallow Study



Operative photo LINX placement with Sleeve Gastrectomy



Post Operative Upper GI Swallow Study



Operative Photo Completed LINX after Sleeve Gastrectomy

RESULTS

Four patients selected as appropriate candidates for MSA implantation. Reflux was confirmed on EGD and upper GI swallow. Four patients had a concomitant hiatal hernia. Esophageal motility studies were normal in all. All candidates were discharged without complication, within 24 hours of implantation. Post operative UGI demonstrated no evidence of reflux in all patients. Patients were followed for 3-6 months prior to bariatric surgery. One patient presented to the ER for evaluation of dysphagia. There were no readmissions to the hospital. There were no explanations. Three patients underwent sleeve gastrectomy. One patient underwent duodenal switch. All patients remained asymptomatic. There have been no reported episodes of reflux 90 days following bariatric surgery

DISCUSSION

MSA implantation prior to bariatric surgery in symptomatic patients may be an option to eliminate reflux related complications following bariatric surgery. Tolerance to the device can be demonstrated in the months prior to bariatric surgery. Patients who cannot tolerate MSA might not be appropriate patients to undergo reflux producing operations like the vertical sleeve gastrectomy. All of the patients that we have evaluated for preoperative implantation of a MSA device have tolerated the device and have undergone successful, reflux free, vertical sleeve gastrectomy or duodenal switch procedures. The utilization of Magnetic Sphincter Augmentation prior to bariatric surgery might reduce the incidence of clinically significant GERD postoperatively thereby reducing the incidence of postoperative esophagitis and Barrett's changes.

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