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Outcomes of magnetic sphincter augmentation - A community hospital perspective

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ABSTRACT

Background: Magnetic sphincter augmentation (MSA) is FDA approved for the surgical treatment of GERD. While multiple reports from academic settings exist, we report the early experience from two community-based health systems.

Methods: The first 102 post-trial cases of MSA were reviewed. Outcomes were compared to those in the initial clinical trial.

Results: Mean follow-up duration was 7.6 months. GERD medication use decreased from 98% preoperative to 8% postoperative ($P<0.001$). Median GERD health-related quality of life (HRQL) improved from 27 preoperative to 5 postoperative ($P<0.001$). Patient satisfaction increased from 8% preoperative to 84% postoperative ($P<0.001$). Results were similar to the trial data.

Conclusions: MSA is a safe and effective treatment for GERD, with significant improvement in quality of life. GERD-HRQL, medication reduction, operative times, and dysphagia rates were similar to other reports, demonstrating the reproducibility of MSA. Lower dilation rates may be due to refinements in technique and postoperative dietary management.

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1. Introduction

Gastroesophageal reflux disease (GERD) is a pathologic process surrounding the loss of mechanical lower esophageal sphincter (LES) function. Current recommendations for the treatment of GERD begin with an initial attempt at medical management of the disease with acid suppression medication. However, if patients continue to have symptoms while on medication, have side effects from proton pump inhibitors (PPIs), or if they are concerned about the long-term effects of these medications, surgical intervention is the recommended next step in the treatment algorithm.[1] Historically, acid suppression has been achieved with the use of PPIs; however, these medications have been shown to provide only partial control of symptoms in up to 40% of patients, and do not address the underlying physiological mechanism of an incompetent lower esophageal sphincter.[2]

The long-term effects of PPI use continue to be investigated, but potential safety concerns have been raised. Increased risk of *clostridium difficile* infection, pneumonia, absorptive nutritional deficiencies (B12 and Iron), osteoporotic fractures, and more recently, renal failure, myocardial infarction, and dementia have been associated with long-term PPI use.[3–5] Therefore, the potential to reduce these complications with a safe, definitive surgical treatment is appealing.

The surgical treatment that has been traditionally performed to treat GERD is some form of gastric fundoplication, most commonly, the Nissen fundoplication. The Nissen fundoplication was first performed in 1956 and has been shown to provide relief of symptoms in up to 90% of patients.[6] This success rate has been questioned and smaller studies outside of large academic centers have not been able to achieve the same level of success.[7] Currently, laparoscopic Nissen fundoplication (LNF) is the most common surgical treatment of GERD. The Nissen fundoplication does pose

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postoperative risk to patients in the form of side effects including gas bloat syndrome, the reduced ability to vomit or belch, dysphagia, and increased flatulence, all of which are due to the supra-physiologic sphincter pressure created by a Nissen fundoplication. In some patients, the wrap can come apart, or herniate into the chest, requiring another operation to repair. These side effects are known to limit the utilization of the procedure amongst both surgeons and patients.[8]

Magnetic sphincter augmentation (MSA) with the LINX® Reflux Management System (Torax Medical, Maple Grove, MN) is currently available for the treatment of GERD following U.S. Food and Drug administration (FDA) approval in 2012.[9–11] The MSA device is a ring of connected titanium cased magnetic cores linked by titanium arms (Fig. 1). It is designed to be placed at the gastro-esophageal junction and functions to augment the resting LES pressure. Augmentation supports the LES, prevents effacement, and reduces reflux, though still allowing for physiologic transport of food boluses, belching and vomiting. Magnetic sphincter augmentation has been shown to decrease esophageal exposure to acid, improve reflux symptoms, and results in decreased PPI use.[9–11] This evidence has been born out through the initial feasibility study in 2008 and the prospective clinical trial published in 2013.[9–11] These initial studies have also been supported by long-term follow-up studies confirming the safety and efficacy of this device, out to five years at both community and academic centers.[10,12–14]

In comparison, the Nissen fundoplication works by supporting a failed LES by recreating the angle of His and endoluminal flap valve. Surgically, it requires division of the short gastric vessels, creation of a 360-degree wrap of the fundus around the lower esophagus. It is well known that there is considerable variability in results that are largely operator dependent. Surgical volume and training are known factors in this variability. One theoretical advantage of MSA is that it can be performed without altering the stomach anatomy and relies on objective sizing measurement for placement; and is therefore less surgeon dependent in terms of outcomes.

The objective of this study was to report the early experience of LINX® Reflux Management System in two community-based hospitals and compared outcomes to those reported in the FDA clinical trial.[9]

2. Material and methods

2.1. Study design

A retrospective review of prospectively collected data of the initial post-trial MSA procedures performed at two independent community hospitals, Gundersen Health System in La Crosse, WI and The Heartburn & Acid Reflux Center at Baylor Scott & White Healthcare in Round Rock, TX was completed. The magnetic device was placed by one of two foregut surgeons (SNK, FPB) using standard laparoscopic equipment and techniques as previously described.[9] Repair of a concurrent hiatal hernia was performed at the discretion of the operating surgeon. Gundersen Health System is an integrated multi-specialty group practice with a 325-bed hospital serving 19 counties over a 3-state region with an accredited general surgery residency program, graduating three chief residents per year, as well as an accredited fellowship in minimally invasive bariatric surgery and advanced laparoscopy, graduating one fellow per year. Baylor Scott & White Healthcare is a 46 hospital healthcare system in Texas. The Round Rock campus is a 110-bed community hospital with multi-specialty Heartburn & Acid Reflux Center. It serves as a teaching facility for Texas A&M medical students.

Both objective and subjective outcomes data were collected and reviewed. Descriptive and statistical analyses were conducted comparing the outcomes with the results of the initial FDA trial results, including demographic data, operative times, dilation rate, device removal rates, and satisfaction with outcomes using Fisher's Exact Test. Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) scores were compared before and after surgery using McNemar's test and Wilcoxon Signed Rank test. A P value less than 0.05 was considered significant.

2.2. Study population

Inclusion and exclusion criteria were identical to the initial FDA trial. Patients were included if they were between 18 and 75 years of age, had at least a 6 month history of reflux disease, had a partial

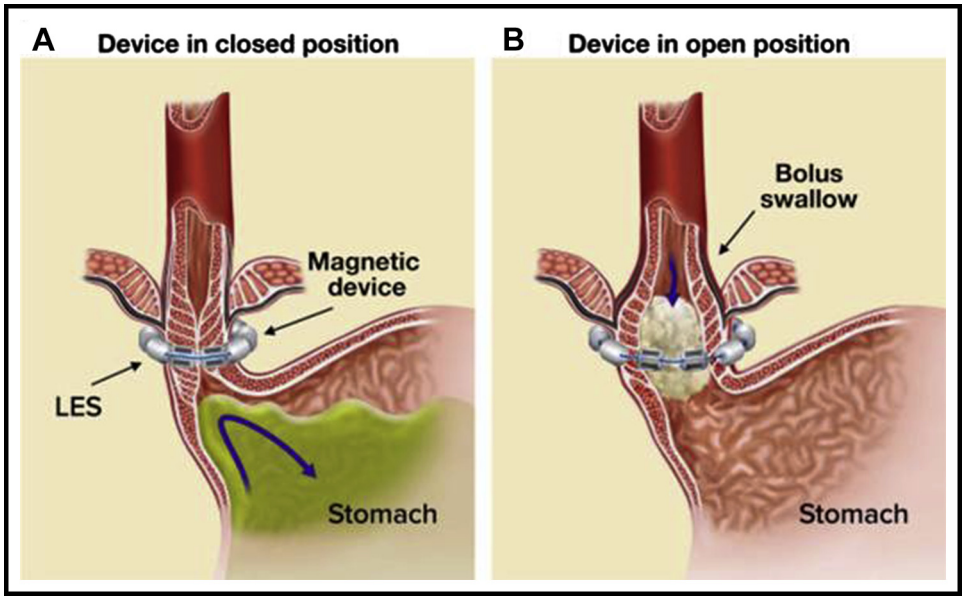

Fig. 1. Magnetic sphincter augmentation of the lower esophageal sphincter in the closed position (A), in which the magnetic attraction of the beads augments the lower esophageal sphincter to prevent its opening and subsequent reflux of gastric content into the esophagus, and in the open position (B), which allows transport of food, belching, and vomiting. *Reprinted with permission from Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux. Clin Gastroenterol Hepatol, 2016;14(5):671–7.10.* (Color version of figure available online.)

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