In the News

JUNE 22, 2018

Nissen Fundoplication Or LINX for Gastroesophageal Reflux Disease?

It’s that time again! You may ask, what time is that? It’s time for two experts to do battle over the surgical treatment of gastroesophageal reflux disease.

This month, we are bringing you a no-holds-barred debate between two distinguished foregut surgeons on the best way to surgically treat GERD. I think you’ll find this month’s debate not only informative and educational but fun to read. Although our debaters are known to be friends, they have held nothing back in trying to convince you that their position is the right one.

As we all know, the number of procedures being performed to surgically treat GERD peaked, and has been on the decline in recent years. Is this because our traditional operations are not as good as we claimed, that long-term complications are too great, or that we just haven’t been performing the procedures well enough? Maybe the answer lies with the LINX Reflux Management System (Torax Medical). Our two debaters discuss all of these questions and more.

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Nissen Fundoplication Is Preferred Approach for GERD

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GERD affects almost 20% of the population in the United States. Today, proton pump inhibitors are the most frequently prescribed drugs, with an estimated cost of $10 billion per year. Although these medications control heartburn in the majority of patients, other symptoms such as regurgitation and respiratory symptoms often are not controlled, particularly in patients with large hiatal hernias. In these patients, a properly performed laparoscopic fundoplication allows control of both esophageal and extraesophageal symptoms, and avoids lifelong medical therapy.

Three elements are important for the performance of a successful fundoplication: (1) a comprehensive preoperative workup, (2) correct indications for the operation, and (3) respect for the key technical elements.

**Preoperative Workup**

In 2013, a panel of expert gastroenterologists and surgeons published an evidence- and experienced-based consensus that recommended the following tests before proceeding with antireflux surgery:

- **Symptomatic evaluation:** This step identifies typical/esophageal symptoms (heartburn, regurgitation and dysphagia) and atypical/extraesophageal symptoms (cough, hoarseness and enamel erosion). A symptomatic evaluation alone should never be considered enough to plan an operation. Many studies have shown that the presence of symptoms alone, even for typical symptoms such as heartburn, has low accuracy and leads to a wrong diagnosis of GERD in 30% to 50% of patients.\(^2\)\(^-\)\(^4\) A good response to PPIs is considered an important prognostic factor for the success of a fundoplication,\(^5\) whereas lack of response—usually labeled as “refractory GERD”—should raise the suspicion that the symptoms are caused by a different disease.\(^2\)\(^,\)\(^4\)
- **Barium swallow:** This test defines the anatomy of the gastroesophageal junction and the presence, size and type of a hiatal hernia.
- **Upper endoscopy:** This test determines the presence and severity of esophageal mucosal damage.
Esophageal manometry: This test assesses quality of esophageal peristalsis, rules out achalasia, and determines the position of the lower esophageal sphincter (LES) for placement of the catheter for pH monitoring.

Ambulatory pH monitoring: This study is considered the gold standard for the diagnosis of GERD, as it establishes the presence of abnormal reflux and the temporal correlation between symptoms and episodes of reflux.

Gastric emptying studies and impedance pH should be considered in very few selected patients.

Overall, the presence of heartburn, a good response to PPIs and pathologic reflux as shown by pH monitoring are important predictors of a successful outcome of a fundoplication (see story, June issue, page 8).⁵

**Indications for the Operation**

The operation is indicated when patients experience complications of PPI therapy, do not want to take medications for the remainder of their lives, or do not have complete control of their symptoms, particularly when regurgitation persists and is associated with cough or episodes of aspiration pneumonia. Caution must be exerted when there is a complete lack of response to PPI therapy and patients are labeled as having “refractory GERD.” A complete workup is of paramount importance to ensure that the symptoms are not caused by other esophageal disorders, such as achalasia or eosinophilic esophagitis, or by other gastrointestinal diseases, such as irritable bowel syndrome or cholelithiasis.²⁻⁴

**Key Technical Elements**
Extent of mobilization: mediastinum and division of short gastric vessels to create a tension-free fundoplication.

Location of the gastroesophageal junction after dissection: about 3 to 4 cm below the hiatus.

Closure of hiatus: nonabsorbable sutures.

Size of the bougie (56-60 Fr) decreases the incidence of postoperative dysphagia.6

Type of wrap: The stomach is passed behind the esophagus, and a shoeshine maneuver is performed. A 360-degree fundoplication is created by placing three stitches of nonabsorbable material at 1-cm intervals to approximate the right and left side of the fundoplication. In patients with very severe abnormalities of peristalsis, a partial fundoplication is the procedure of choice, as it is associated with a lower incidence of postoperative dysphagia.7,8

Although transient dysphagia is common in the initial weeks after fundoplication surgery, long-term dysphagia is rare. As previously reported, the use of a bougie decreases the incidence of postoperative dysphagia. Patterson et al showed that the incidence of long-term severe postoperative dysphagia was 5% when a bougie was used, but was 14% when it was not used.6 In addition, transection of the short gastric vessels allows a tension-free fundoplication, with a lower incidence of postoperative dysphagia.9 The presence of dysphagia preoperatively is the best predictor of postoperative dysphagia.10

Dallemagne et al reported the 10-year follow-up of 100 consecutive patients after laparoscopic fundoplication.11 Ninety-three percent of patients did well after Nissen fundoplication. Excellent results were also reported among 2,655 patients who underwent laparoscopic fundoplication in Sweden between 2005 and 2014. At a median follow-up of 5.6 years, 82.3 were symptom-free and off medications.12 In the remaining patients, it was not clear whether symptoms and use of PPIs were due to recurrent reflux.13

In conclusion, laparoscopic fundoplication is an effective and long-lasting treatment for GERD. Its success is based on a careful evaluation and patient selection, and on an operation that respects the key technical elements that already have been identified. Considering the proven safety and effectiveness of laparoscopic antireflux surgery, new antireflux techniques should be studied rigorously and adopted cautiously.

References
Despite the increasing incidence of GERD, and wariness about the safety of medical treatment of GERD, Nissen fundoplication has sadly, but not unsurprisingly, failed to step up and fill the gap. In fact, the incidence of fundoplication continues to decrease in proportion to the number of GERD patients—data Dr. Patti just published.¹ No wonder: It’s a nonphysiologic operation even older than Dr. Patti! Most patients with an intact Nissen fundoplication can’t vomit, and have a hard time belching; 30% to 50% have more flatus; and 10% develop troublesome gas–bloat syndrome. That’s not just not physiologic, it’s not fun! It’s time to enter the 21st century, sir.
What’s so unphysiologic about a Nissen procedure is that it creates a one-way flap valve. A pig’s Nissen wrap sutures will dehisce before the valve gives way. Patients report they will retch and either disrupt their wrap/hernia repair and vomit, or just remain miserable. Nissen patients developing a small-bowel obstruction have developed gastric ischemia because, guess what, their stomachs can’t vent. No wonder patients don’t want this surgery!

The LINX device, on the other hand, creates a pressure-release valve, emulating the venting ability of a normal LES. The LINX is a bracelet of interconnected magnetic beads placed noncompressively around the LES. It takes a pressure of about 30 mm Hg to overcome the magnetic attractions between the beads, allowing the LES to open for bolus passage. Reflux occurs when the LES opens spontaneously, on the order of 10 to 14 mm Hg, a pressure insufficient to overcome the LINX-augmented LES. However, and unlike a fundoplication, the increased intragastric pressure of vomiting or belching can generate pressure to open the LINX-augmented LES. Ninety percent of LINX patients report they can belch and vomit. Data from the University of Southern California have shown that troublesome gas–bloat syndrome is reported by 10% of Nissen patients, compared with 0% after LINX implantation; this is confirmed by other studies. 3,4
LINX controls GERD: More than 85% of LINX patients experience long-term relief of reflux symptoms and are able to stop daily acid-suppressive medications, comparable to Nissen fundoplication. Recent, but unpublished, data demonstrate normalization of pH in 70% to 85% of patients. That's pretty darn good, and consistent across series! Now, I am sure that Dr. Patti's results with Nissen fundoplication are fantastic; he's a talented and experienced surgeon. But across the nation, and in other prospective studies, the success rate of Nissen fundoplication is embarrassing.

What about safety? Erosions? Isn't LINX just an Angelchik prosthesis in disguise? In a few years, won't we be looking down the esophagus at beads? LINX has 6% the volume of the Angelchik and responds dynamically to esophageal distention, both factors in decreasing erosion risk. The Angelchik erosion rate was greater than 3%, and the migration rate was 11%, with serious complications. Based on MAude/Torax data, the erosion risk per device is between 0.3% and 0.4%; the majority of erosions occur within one to four years. All devices have been removed uneventfully without serious complications. No migrations have been reported.

The reoperation rate after LINX has been consistent at 2% to 4%; Nissen fundoplication rates often are higher.

What about safety? Let's instead compare LINX with Dr. Patti's beloved laparoscopic Nissen fundoplication, which has an increasing complication rate, a perioperative leak rate of 1% to 2% (up to 6% in a recent report), and a reoperative complication rate of 20% to 30%! Without minimizing any complication, crying “erosion,” Dr. Patti, is invoking a bogeyman.

Regarding dysphagia, yes, it is higher with LINX in the short term, but equal to a Nissen fundoplication at one year.

The Nissen fundoplication is a big gun that was devised in the 1950s for end-stage reflux disease patients who would tolerate its inherent side effects. GERD is a spectrum; patient tolerance to side effects is decreasing, and new technologies such as LINX enable a more tailored approach. The Nissen fundoplication is still a good operation in certain circumstances: horrible, refractory reflux—a very small segment of patients who could benefit from a good antireflux procedure. LINX is not a good choice for patients with severely impaired esophageal peristalsis. Although it was initially studied in patients with no more than 3-cm hernias, short-term studies reveal that hernia size may not be a limiting factor for LINX.

With all due respect, Dr. Patti, the Nissen fundoplication has seen its day as the surgical treatment for GERD. Put out to pasture. An old saw. In the minds of many surgeons with experience in LINX, including mine, LINX has become the first choice based on success,
durability and a more physiologic mechanism.

References

Dr. Patti’s Rebuttal

Looking at Dr. Bell’s publication list, it is clear that he has been trying whatever is available to avoid a Nissen fundoplication, including the transoral incisionless fundoplication, and now LINX. While innovation is very important—when done with an open mind and objectivity—I wonder if his choices reflect his own results with the Nissen fundoplication!

I would like to discuss some of the statements made by Dr. Bell.

The Nissen fundoplication was first described many decades ago, but the procedure we perform today reflects only minimally the operation that bears the name of Rudolph Nissen. It is time to abandon the eponyms (Nissen, Toupet, Lind, Guarner, Hill, etc.) and rather focus on the key technical elements that allow the performance of a fundoplication associated with minimal side effects and long-lasting efficacy. Technique is very important, and I am positive that if Dr. Bell needed an esophagectomy, he would not choose a surgeon with limited technical skills due to poor training. In addition, the study he quoted to describe the complications of the Nissen fundoplication was published in 1997; so yes, Dr. Bell, it is time to enter the 21st century.

The LINX device adds between $1,500 and $3,000 to the cost of a procedure done laparoscopically and under general anesthesia. Many insurance companies are refusing payment for the LINX, as they are concerned that the follow-up in many studies is too short—months compared with years for the Nissen.
The device was first recommended for patients with no hiatal hernia or hernias less than 3 cm in size. Recently this recommendation was discarded, and patients with large hiatal hernias (>5 cm) have been treated. The outcome has been good, but the follow-up was only eight months. In addition, the authors of this study describe reduction of the stomach with approximation of the crura to narrow the hiatus, and even use of mesh to reinforce the closure. So, how can they distinguish between the effect of these maneuvers from the effect of LINX in the control of reflux? Reduction of the hernia as solo treatment was initially proposed by Allison in 1951, and today is recognized as a key element of antireflux surgery.

Quoting George Santayana, “Those who cannot remember the past are condemned to repeat it.” Being as old as the Nissen fundoplication, I have witnessed over and over that whatever you place around the esophagus sooner or later tends to find its way inside the lumen. It is the story of the Angelchik prosthesis; it is the story of the gastric band. There are now reports of erosion of the device and the need for its removal. All patients did well, but it is important to stress that these patients were treated by experienced esophageal surgeons in high-volume esophageal centers. The outcome might be different when the procedure is performed by a surgeon with limited experience with esophageal surgery.

Finally, some friendly advice to Dr. Bell: Following Ulysses’ example, tie yourself to the mast of your ship and resist the appeal of the sirens—in your case, the sirens of the industry.

References

Dr. Bell’s Rebuttal
Dr. Patti concisely covered key aspects of patient selection and evaluation for any type of antireflux surgery. Nice job!
He also covered the technical aspects of mediastinal dissection and hiatal hernia repair, which surgeons globally have neither delineated nor revered adequately. Surprise! Fundoplications fail far more often due to a recurrent hernia—up to 90% in many series—than to dehiscence of the wrap.\textsuperscript{1} Most studies of LINX involved patients with hiatal hernias no more than 3 cm. Hernia recurrences have been almost nonexistent in this LINX group at five-year follow-up, significantly lower than for fundoplications.\textsuperscript{2,3} We should revere the hiatus as a secondary, accessory sphincter.\textsuperscript{4} Once restored, augmenting the primary sphincter is probably independent of the hernia size.\textsuperscript{5} LINX may not be limited to patients with small hernias.\textsuperscript{6,7} Take that, Dr. Patti! Hehe, hoho!

I’d like to lord this over Dr. Patti, but I won’t. Why not? Because we need to do better at getting a great hiatal hernia repair, or LINX may get the same bad rap (pardon the pun) and go the way Nissen has—sailing off into the sunset.

Oh, and what else is good about the LINX? It’s far less destructive to normal anatomy than a Nissen. It’s not a flap valve. Oh wait, did I say that already? It can be removed, and its effects reversed; many consider a Nissen to be irreversible. And it’s a more physiologic valve. Oh, did I say that already? And patients don’t like being unable to vomit, etc., etc., that comes with a Nissen. Oh, did I say that already?

I’d like to find some common ground to (w)rap up. Dr. Patti appreciates a venerable if antediluvian solo procedure. We probably do agree that as the number of players on the field proliferates, we need specialization in foregut surgery.

Oh, and did I say that already?

References