Is the Use of a Bougie Necessary for Laparoscopic Nissen Fundoplication?

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Hypothesis: Esophageal intubation with a bougie during laparoscopic Nissen fundoplication (LNF) is commonly used to prevent an excessively tight wrap. However, a bougie may cause intraoperative gastric and esophageal perforations. We hypothesized that LNF is safe and effective when performed without a bougie.

Design: Retrospective review of 102 consecutive patients who underwent LNF without a bougie.

Setting: Tertiary care university hospital.

Patients: All patients presented with symptoms of reflux disease. Mean (± SD) percentage of time with pH of less than 4 was 12.6%±9.4%. Mean DeMeester score was 47.8. Mean (± SD) resting lower esophageal sphincter pressure was 15.0±9.4 mm Hg. Mean (± SD) distal esophageal amplitude was 69.4±39.2 mm Hg.

Intervention: During LNF, we obtained 2 to 3 cm of intra-abdominal esophagus, divided all short gastric vessels, reapproximated the crura, and performed a loose 360° fundoplication without a bougie.

Main Outcome Measures: Postoperative rates of dysphagia, gas bloat, and recurrent reflux.

Results: In the early postoperative period, 50 patients (49.0%) complained of mild, 11 (10.8%) of moderate, and 7 (6.9%) of severe dysphagia. Average (± SD) duration of early dysphagia was 4.6±2.1 weeks. Dysphagia resolved in 61 (89.7%) of 68 patients within 6 weeks. Late resolution of dysphagia was noted in 4 (5.8%) patients. Three patients were successfully treated with esophageal dilatations. Persistent dysphagia was found in 1 patient. Thirty patients (29.4%) had transient gas bloat. Mild persistent reflux, requiring daily medication, was noted in 5 (4.9%) patients.

Conclusions: Performance of LNF without a bougie offers a safe and effective therapy for gastroesophageal reflux disease. While avoiding the potential risks for gastric and esophageal injury, it may provide low rates of long-term postoperative dysphagia and reflux recurrence.

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ASTROESOPHAGEAL reflux disease (GERD) is a common condition troubling nearly 40% of the population. Dietary modifications, combined with occasional or daily medications, usually eliminate most reflux symptoms. Unfortunately, many patients do not respond to or are unable to tolerate maximum medical therapy, and life-threatening sequelae of reflux may develop. Since 1955, when Nissen performed the first fundoplication for GERD, antireflux surgery has gained in popularity and has been shown to be very effective in treating complicated GERD. During the past 10 years, laparoscopic Nissen fundoplication (LNF) has become the preferred surgical approach. A success rate of greater than 90% and very low morbidity and mortality figures have resulted in a lower threshold for surgical referral. Many patients decide to undergo an operative intervention to avoid the lifelong need for daily medications or to improve minimal reflux symptoms.

Despite being minimally invasive, laparoscopic antireflux surgery carries many complications and adverse effects associated with the traditional operative approach. Although intraoperative complications are minimal in experienced hands, postoperative sequelae such as recurrent GERD, gas bloat, and delayed gastric emptying still occur with the same frequency. Moreover, troublesome persistent dysphagia remains a major nemesis for patients and surgeons. Although relatively rare, severe dysphagia adversely affects patients’ quality of life and satisfaction, and may result in dangerous food impactions and aspirations.
PATIENTS AND METHODS

One hundred forty-one consecutive patients who underwent LNF at the University of Massachusetts Medical Center, Worcester, from August 1, 1998, through October 31, 2000, were reviewed retrospectively. We excluded patients with a history of antireflux surgery. Inpatient, outpatient, and clinical medical charts were reviewed, and all data were stored using Excel (Microsoft Corp, Redmond, Wash). Unless otherwise indicated, the data are expressed as mean ± SD.

PREOPERATIVE EVALUATION

All patients referred for antireflux surgery underwent a thorough history and physical examination. We performed 24-hour pH monitoring, flexible upper endoscopy (esophagogastroduodenoscopy), and esophageal manometry in each patient to confirm the diagnosis of GERD, to rule out additional pathologic changes, and to evaluate esophageal motility. Pathologic reflux was defined by esophageal acid exposure for more than 5% of total monitoring time and/or a DeMeester score of at least 15 while 15 patients were not receiving antisecretory medications. Mean distal esophageal amplitudes of at least 30 mm Hg and failed peristalsis in less than 30% of esophageal contractions were considered normal.

OPERATIVE TECHNIQUE

We performed LNF in standard fashion using 5 upper abdominal ports. The right and left diaphragmatic crus were dissected away from the distal esophagus. Complete mobilization of the gastroesophageal junction and distal esophagus was performed to allow at least 2 to 3 cm of distal esophagus to rest comfortably within the abdomen. The vagus nerves were identified and protected. All short gastric vessels were divided with an ultrasonic dissector along the upper one third of the stomach. Posterior attachments of the gastric fundus to the left crus were divided. A generous retroesophageal window was created under direct visualization. The right and left crus were reaproximated posteriorly using interrupted nonabsorbable sutures. Crural closure was calibrated visually and with a blunt grasper, leaving enough space (5-10 mm) to introduce easily an instrument through the hiatal closure.

A short (2-cm), loose, 360° fundoplication was performed after delivering the fundus through the retroesophageal window. Appropriate orientation of the fundus was confirmed, and a “shoe-shine” maneuver was performed to ensure a tension-free wrap. The fundoplication was extended 1 to 2 cm above the gastroesophageal junction and was secured with 2 or 3 interrupted nonabsorbable sutures. Each suture incorporated wide, seromuscular bites of the stomach and partial-thickness bites of the anterior esophagus. Bites on the stomach were taken well lateral to the esophagus to maintain a bulky but floppy wrap. Appropriate calibration of the wrap was confirmed by passing a blunt grasper between the wrap and the distal esophagus on either side. No esophageal bougie was used in any patient. Nasogastric tubes or other drains were also not used.

POSTOPERATIVE CARE AND FOLLOW-UP

Patients were discharged to home on the first or second postoperative day. Patients were seen by an operating surgeon (J.J.K., M.P.C., and D.E.M.L.) at 3 and 6 weeks postoperatively and then as needed. Clear liquid diets were maintained for all patients for the first 24 hours. The diets were advanced to soft mechanical for the next 3 to 4 days. The patients were allowed to resume solid food intake at 1 week. They were instructed to avoid meat, bread, and carbonated beverages for the first 2 to 3 weeks after surgery. Diets were subsequently liberalized. Patients with early dysphagia were encouraged to continue a soft mechanical diet until symptoms resolved.

POSTOPERATIVE DYSPHAGIA ASSESSMENT

Postoperative dysphagia was interpreted to be mild, moderate, or severe on the basis of the type and/or consistency of food swallowed and on the frequency of the dysphagia episodes. (Table 1.) Symptoms caused by solid foods known to cause dysphagia (eg, meat, and bread products) were distinguished from those caused by other solid foods in our analysis. All liquids were considered together. Dysphagia was considered to be frequent if it occurred at least once a week. It was considered to be early if it occurred or resolved within 8 weeks postoperatively. Dysphagia that resolved or persisted beyond 8 weeks was considered to be late.

Table 1. Dysphagia Assessment Scale

<table>
<thead>
<tr>
<th>Degree of Dysphagia</th>
<th>Symptoms</th>
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<tbody>
<tr>
<td>Mild</td>
<td>Occasional dysphagia of some solids</td>
</tr>
<tr>
<td>Moderate</td>
<td>Frequent dysphagia of some solids or</td>
</tr>
<tr>
<td></td>
<td>Occasional dysphagia of most solids and/or</td>
</tr>
<tr>
<td></td>
<td>Occasional dysphagia of liquids</td>
</tr>
<tr>
<td>Severe</td>
<td>Frequent dysphagia of most solids and/or</td>
</tr>
<tr>
<td></td>
<td>Frequent dysphagia of liquids</td>
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</table>

Over time, several modifications of Nissen’s original operation have been implemented to improve outcomes after fundoplication.4,12 Most investigators advocate the use of an esophageal bougie to help prevent an excessively tight wrap and to reduce the occurrence of long-term dysphagia.1,4,13,14 However, esophageal intubation with a bougie may prolong the operation and, more important, may result in esophageal or gastric perforations.1,3,15-17 The standard approach at our institution is to avoid placement of a bougie during LNF. In this retrospective review, we analyzed the efficacy and safety profile of LNF performed without routine use of a bougie.

RESULTS

From August 1, 1998, through October 31, 2000, 62 women and 40 men with an average age of 54 years un-
underwent a first-time LNF. All patients presented with primarily typical GERD symptoms, as seen in the following tabulation:

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Percentage of Patients</th>
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<tbody>
<tr>
<td>Heartburn</td>
<td>88.2</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>50.9</td>
</tr>
<tr>
<td>Epigastric/ chest pain</td>
<td>45.1</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>28.4</td>
</tr>
<tr>
<td>Respiratory</td>
<td>12.7</td>
</tr>
<tr>
<td>Other</td>
<td>11.8</td>
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Maximal medical therapy failed in 73.5% of patients. The results of preoperative evaluation are summarized in Table 2. Two of 5 patients with a benign stricture underwent an esophageal dilatation preoperatively. Twenty-eight patients (27.5%) were found to have mild to moderate esophageal motility abnormalities that did not preclude an LNF.

We performed an LNF in all patients. Eighteen (17.6%) underwent additional procedures, including laparoscopic cholecystectomy (n=8), umbilical/ventral hernia repair (n=4), laparoscopic liver biopsy (n=3), laparoscopic gastrojejunostomy (n=2), and laparoscopic pyloroplasty (n=2). There were no conversions to an open procedure. No major perioperative complications or mortality occurred. The average length of stay was 1.5±0.3 days (range, 1-4 days). The average length of the available follow-up was 6.25 months.

Initially, 68 patients (66.7%) complained of dysphagia (Figure). This early dysphagia resolved spontaneously by 6 weeks in 89.7% of patients. The average duration of dysphagia was 4.6±2.1 weeks. Late resolution of dysphagia was noted in 4 (5.8%) of the 68 patients with postoperative dysphagia at 11.4±2.8 weeks (range, 8-17 weeks). Persistent dysphagia was noted in 1 patient. This patient had preexisting severe dysphagia that improved after surgery.

Three patients (2.9%) underwent uneventful esophageal dilatations with a 36F bougie. One patient required a dilatation at 2 weeks postoperatively for severe dysphagia resulting in an episode of food impaction. Two additional patients underwent esophageal dilatations at 8 and 12 weeks with resolution of symptoms.

Gas bloat was seen transiently in 30 patients (29.4%). The average duration of transient gas bloat was 6.5±2.2 weeks. One patient complained of persistent gas bloat.

Persistent or recurrent reflux symptoms were noted in 8 patients (7.8%). Five patients (4.9%) required daily medications to control their reflux disease. One of these 5 patients underwent a second LNF.

Laparoscopic Nissen fundoplication has become the operation of choice for most patients in whom medical management fails or who are unwilling or unable to tolerate lifelong medical therapy. The minimal invasiveness of the laparoscopic approach fuels patient expectations of a speedy and complication-free recovery.1,2 However, for a small subset of patients, LNF may be associated with major postoperative morbidity, the most troubling of which is long-term dysphagia.

Initial dysphagia is very common,11,13,19 and may even be desirable.16 Although early dysphagia may be of concern to patients, it is likely to be transient.20,21 This dysphagia is probably due to intraoperative esophageal stretching and postoperative local edema that usually resolves.12,19,21 Approximately 90% of our patients with early dysphagia had uneventful resolution of symptoms. However, even early dysphagia can be severe enough to predispose to food impactions and to require a dilatation, especially in patients who are not compliant with postoperative dietary instructions.21 One patient in our study presented with an early esophageal obstruction after a large steak meal. In cases of severe early dysphagia, we routinely evaluate the wrap by obtaining barium esophagram initially, followed by upper endoscopy as needed.

Patients with late dysphagia may be better served with expectant management. In fact, dysphagia resolved spontaneously in 4 (57.1%) of our 7 patients who complained of difficulty swallowing beyond 8 weeks after the LNF. Gas bloat, a symptom often attributed to an overly tight wrap, was seen only transiently in less than a third of our patients.

Recurrent or persistent reflux symptoms may signify a failed fundoplication wrap. The efforts to avoid an

*LES indicates lower esophageal sphincter.
been widely accepted.\textsuperscript{1,4,14} Many authors believe that a bougie closure\textsuperscript{10} to most commonly, sizing and creation of short, floppy Nissen fundoplication.

With the advancement of surgical technique, the rates of postoperative dysphagia have decreased. The modifications introduced by DeMeester et al\textsuperscript{12} have revolutionized the way that fundoplication is performed. Shortening the length of the fundoplication to 1 cm, routine division of short gastric vessels, and increasing bougie size from 36F to 60F decreased the incidence of persistent postoperative dysphagia from 21% to 3%.\textsuperscript{12,22} Hunter and colleagues\textsuperscript{13} achieved a 2% dysphagia rate with creation of a short, floppy Nissen fundoplication.

The use of a large esophageal stent during fundoplication, first introduced by DeMeester and colleagues,\textsuperscript{22} has been widely accepted.\textsuperscript{1,4,14} Many authors believe that a bougie decreases long-term dysphagia by preventing an excessively tight wrap.\textsuperscript{14,17} However, this potential benefit comes with risk. Because of their high morbidity and mortality rates, gastric or esophageal perforations are among the most recognized and feared complications of antireflux procedures.\textsuperscript{10,13,16} In fact, esophageal perforations during laparoscopic fundoplications are more common than one might expect, occurring in about 1% of patients.\textsuperscript{10,13,16}

Several mechanisms of esophageogastric perforations associated with bougie use have been described. The presence of the bougie in the esophageal lumen during the retroesophageal dissection may contribute to perforation due to distention and fixation of the esophageal wall.\textsuperscript{15} However, such perforations are relatively infrequent because the bougie is rarely used at this stage of the operation in modern fundoplication surgery. Perforations may also occur during intraoperative passage of the bougie through the distal esophagus. Forceful advancement of the bougie and incorrect gastric retraction, resulting in significant angulation of the gastroesophageal junction, predispose to mucosal lacerations and transmural perforations.\textsuperscript{15,16} In addition, anesthesiology personnel, who may be unfamiliar with proper techniques, usually perform passage of the bougie, further increasing the risk for perforations.\textsuperscript{15,16}

The caliber of the bougie that is used during LNF varies among surgeons. DeMeester et al\textsuperscript{12} compared the use of a 60F bougie with a much smaller 36F stent. The subsequently observed reduction in dysphagia rates may have been due to the increased diameter (floppiness) of the wrap, rather than the presence of the bougie itself. Many authors today routinely use smaller (<50F, \textsuperscript{5,12}52F, \textsuperscript{5,12}54F, \textsuperscript{10}and 56F\textsuperscript{1,2,5}) stents with an equal success rate.

The reported timing and duration of the bougie insertion vary from esophageal dissection\textsuperscript{15} to sizing of the hiatal closure\textsuperscript{10} to, most commonly, sizing and creation of a fundoplication wrap.\textsuperscript{3,4,13} Such technical variability may indicate that the routine use of a bougie is more a matter of habit than of necessity.

At our institution, we do not insert an esophageal bougie during LNF. However, we have not seen higher rates of postoperative dysphagia. We believe that this finding relates to the complete mobilization of gastric fundus and to the creation of a loose, floppy wrap. With experience, visual inspection of the wrap for proper construction becomes reliable, while the potential risk for esophageogastric perforation is avoided. Our observed low rate of persistent dysphagia is comparable with that of other investigators using the esophageal stent.\textsuperscript{3,4,14,17,24}

The benefits of bougie use have not been studied objectively until recently. Based on a randomized prospective study, Patterson and colleagues\textsuperscript{1} concluded that the intraoperative use of a bougie significantly reduced the rate of postoperative dysphagia. Although well designed, their study has been criticized for using an overly sensitive dysphagia scale. As a result, the observed long-term dysphagia rates of 31% and 17% in the no-bougie and bougie groups, respectively, appear to be rather high for an experienced group of surgeons, reflecting the sensitivity of the scale. Moreover, although the dysphagia severity scores differed significantly between the groups, the incidence of severe long-term dysphagia was not statistically different. Furthermore, the need for postoperative esophageal dilatations in patients with severe dysphagia was equal in the bougie and no-bougie groups (9.9% and 7.8%, respectively).\textsuperscript{3} In other words, the difference in dysphagia scores may not have reflected a clinical difference between the 2 groups.

Our dysphagia assessment also has several potential sources of bias. First, it is limited by the retrospective nature of the study. Second, the operating surgeon, who may have been partial in the outcome, conducted the follow-up assessment.\textsuperscript{7} However, the low rate of required postoperative bougie dilatations supports the observed overall low rate of significant severe dysphagia. The development and implementation of a dysphagia scale that accurately reflects the true rate of clinically significant symptoms and their adverse effects on patients' quality of life would be instrumental in evaluating and comparing different surgical techniques.

The etiology of postoperative dysphagia is not completely understood. Fundoplications involving a failed crural closure, an overly tight wrap, a gastric fundus that is under significant tension, or one that is incorrectly positioned are known to contribute to postoperative dysphagia.\textsuperscript{3,10} However, dysphagia may persist even after a technically sound operation. No esophageal manometric differences were found in postfundoplication patients with or without dysphagia.\textsuperscript{25,26} Furthermore, as proposed by Patterson et al,\textsuperscript{1} the actual role of the bougie in the minimization of dysphagia is unknown and may not necessarily be due to prevention of a tight wrap. We believe that patients may be better served by the avoidance of a risky and possibly unnecessary step during LNF, and the bougie dilator may be needed in only those few patients in whom severe symptoms develop postoperatively.

CONCLUSIONS

Laparoscopic Nissen fundoplication is the procedure of choice in surgical treatment of GERD. Several modifications of the original technique have significantly reduced the occurrence of postoperative complications. In experienced hands, LNF performed without esophageal bou-
gie intubation offers a safe and effective therapy for GERD. While avoiding potential risks for gastric and esophageal perforations, LNF provides low rates of reflux recurrence with minimal postoperative long-term dysphagia.

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REFERENCES


Joseph F. Amaral, MD, Providence, RI: I find particular beauty in this study in that it challenges an established surgical dogma, something we should continuously do. Although it is retrospective and has historical controls, it confirms in my mind what many surgeons are doing today. The objective data they produce in their study clearly document that, at least in their skilled and experienced hands, a bougie is not necessary during this procedure. I agree with those conclusions from my own practice in that I have not done it for 3 years.

The important message in this study is in the technical points that are discussed for the procedure itself. I do not think that they can be overstated, since it would be my opinion that if one does not pay attention to the fine points of the operation that Dr Novitsky has gone over, dysphagia will result more frequently with or without a bougie.

We have focused a lot of attention on the wrap itself and using a bougie; however, there are certainly other causes that he addresses, which I will emphasize. One is not to have too tight a crural closure. The esophagus should dilate to at least twice its size when a bolus of food passes. Dr Novitsky has addressed that by calibrating the crural closure with an instrument, size unspecified but presumed to be 10 mm. He has addressed another cause of dysphagia in the operative report section, which is to avoid a twist in the stomach by using the shoe-shine maneuver, and he has addressed avoiding tension, which can occur even over a bougie, by division of the short gastric vessels. Those 3 steps are key in avoiding dysphagia. It is not just using or not using a bougie, but careful attention to detail of the operation.

There are 2 other considerations in postoperative dysphagia that are not discussed or addressed. One is overanulation of the esophagus at the hiatus, particularly in large hernias, which can lead to postoperative dysphagia, and another is the situation of the patient who has a pre-existing stricture that is treated intraoperatively with the bougie. Therefore, I would ask them how those 2 situations are handled and what considerations they give to them.

Dr Novitsky: Regarding the angulation of the esophagus, it goes along without saying that the technical steps of the operation are paramount to achieve good results. Obviously, we pay attention during the crural closure and try to avoid this pitfall. Once again, thank you for emphasizing the importance of all the steps of the operation.

Regarding the second question of preoperative esophageal dilatation, in the manuscript we mentioned that 2 out of 5 patients who had subclinical strictures were dilated by our GI colleagues. So often this is done before the surgical referral. We do not routinely perform those dilatations and, in fact, it is still debatable whether the bougie dilatation during the surgery addresses the subclinical strictures. It may be, and a lot of surgeons who use bougies feel that bougie intubation prophylactically dilates everybody during the operation. We do not do that, even if we know that there is a subclinical small stricture, reserving the use of a bougie for those few patients postoperatively who develop dysphagia and require intervention. By doing that, we essentially avoid the esophageal bougie intubation in more than 95% of our patients, leaving this procedure for those few who do develop problems and require an intervention postoperatively.