Effect of an Esophageal Bougie on the Incidence of Dysphagia Following Nissen Fundoplication

A Prospective, Blinded, Randomized Clinical Trial

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Hypothesis: Based on retrospective, uncontrolled studies, it has been claimed that Nissen fundoplication should be performed over an esophageal bougie to minimize postoperative dysphagia. We hypothesized that a surgeon experienced in laparoscopic fundoplication will have similar rates of postoperative dysphagia whether or not an esophageal bougie is used.

Design: A patient and observer blinded, randomized, prospective clinical trial to assess the effect of intraoperative bougie use.

Setting: A tertiary care teaching hospital that is a regional referral source for complex laparoscopic foregut surgical procedures.

Patients: Three hundred thirty-six consecutive patients referred for laparoscopic fundoplication between March 1, 1996, and July 31, 1998, were evaluated for eligibility based on inclusion criteria and, if applicable, were offered randomization for fundoplication with or without a 56F bougie. One hundred seventy-one patients were enrolled in this study.

Interventions: All patients underwent laparoscopic Nissen fundoplication, 81 with a bougie (hereafter referred to as the bougie group) and 90 without a bougie (hereafter referred to as the no bougie group).

Main Outcome Measures: Dysphagia severity and frequency were assessed by a blinded observer using a standardized scoring system. Incidence of complications related to the use or absence of a bougie, operative times, and postsurgical recovery was also assessed.

Results: The mean operating time was 148 minutes (range, 65-295 minutes). The overall operative morbidity was 9% (7.4% in the bougie group and 11% in the no bougie group, P=.41). One esophageal injury (1.2%) occurred in the bougie group. The 30-day mortality was 0. Long-term dysphagia assessment was completed in 90% of patients, with a mean follow-up of 11 months. Overall, long-term postoperative dysphagia was present in 17 patients (17%) in the bougie group and 24 patients (31%) in the no bougie group (P=.047). Severe dysphagia occurred in 5% of patients in the bougie group and 14% in the no bougie group.

Conclusion: This study confirms the dogma that use of a large-caliber stent during the creation of a fundoplication decreases the long-term incidence of dysphagia; albeit at the risk of injury from the introduction of a bougie.


Gastroesophageal reflux disease is an increasingly common condition that has been reported to affect up to 40% of the population occasionally, and as many as 7% daily. The advent of minimally invasive antireflux techniques over the past decade has created a renewed interest in the surgical treatment of gastroesophageal reflux disease. A variety of laparoscopic and thoracoscopic antireflux procedures have been described, but the laparoscopic Nissen fundoplication is increasingly recognized as the preferred surgical procedure.

The long-term efficacy of open Nissen fundoplication has been well established, with an almost 90% symptom control rate at 10 years and less than 20% morbidity. Until recently, however, antireflux surgery was infrequently performed as most patients were directed toward medical treatments. Often considered a “last resort,” surgery was traditionally offered only to patients with severe disease resistant to medical therapy, or to those with serious reflux-related complications. The expectation of less pain, faster recovery, and better cosmesis has made laparoscopic Nissen fundoplication an attractive option to patients, gastroenterologists, and surgeons. Prospective studies have confirmed that the laparoscopic approach reduces the early morbidity of antireflux surgery and controls reflux symptoms in more than 90% of patients followed up for as long as 2 years.
PATIENTS AND METHODS

From March 1, 1996, to July 31, 1998, 336 consecutive patients with documented gastroesophageal reflux disease, referred for consideration of antireflux surgery, were evaluated for inclusion in this prospective study. Patients were excluded if their preoperative workup revealed an esophageal motility disorder that precluded a complete 360° wrap (27 patients), a shortened esophagus that was strongly expected to require a concurrent Collis gastroplasty (16 patients), a type 3 paraesophageal hernia (51 patients), or previous antireflux surgery (57 patients). Patients were not excluded if they had hypomotility confined to the distal esophageal segment alone which we believe does not preclude a complete fundoplication. Study consent was obtained from all patients. One hundred eighty-five patients met inclusion criteria; 9 refused participation and 5 were not randomized for other reasons. The 171 study patients were randomized while in the operating department under general anesthesia, just prior to fundoplication.

PREOPERATIVE EVALUATION

Patients referred for antireflux surgery completed a standardized gastrointestinal history and underwent esophagogastroscopy, 24-hour ambulatory pH testing, and esophageal manometry. Gastroesophageal reflux disease was documented by the presence of erosive esophagitis on endoscopic examination or severe acid reflux demonstrated on 24-hour pH testing while taking no peptic medications (total acid exposure >5% and/or a DeMeester score above the 95th percentile of norm [≥15]). Preoperative esophageal motility was assessed using water perfusion manometry (Arndorfer Medical, Greendale, Wis) and interpreted with standard motility software packages (Medtronic/Synechics, Shoreview, Minn, and Sandhill Scientific, Highland Ranch, Colo). Normal motility was defined as intact primary peristalsis with contraction amplitudes of 30 mm Hg or greater. Abnormal peristalsis was defined as more than 50% failed peristalsis (simultaneous or dropped contractions). All operative candidates had ongoing gastroesophageal reflux disease symptoms despite optimal medical management or expressed a desire to avoid lifelong medication. All data were collected prospectively and maintained on an Access (Microsoft, Seattle, Wash) database.

OPERATIVE TECHNIQUE

A laparoscopic Nissen fundoplication was performed as has been described previously.12,15-21 Critical elements of the procedure include complete dissection of the right and left diaphragmatic crura and mobilization of the gastroesophageal junction to achieve 2 to 3 cm of intra-abdominal esophagus. The short gastric vessels of the upper third of the greater curvature and retrogastric attachments are divided with ultrasonic coagulating shears (LCS; Ethicon Endo-Surgery, Blue Ash, Ohio). The crura are closed posterior to the esophagus using interrupted, intracorporeally tied, non-absorbable sutures.

Several maneuvers are performed for both groups to ensure a tension-free, floppy wrap. The fully mobilized cardia

Unfortunately, many of the postoperative side effects and complications seen with open Nissen fundoplication afflict the laparoscopic patients as well. In particular, postoperative dysphagia represents a common complaint. Transient dysphagia is very common in the initial weeks or months following fundoplication.11-13 Troublesome long-term dysphagia is fortunately rare, occurring in as many as 5% of patients after open surgery. Similar incidences have been reported in laparoscopic case series, albeit with shorter follow-up.12 From the patient’s viewpoint, dysphagia is annoying at best and can be a devastating complication leading to food impaction, aspiration, or other problems.2,14,15

Several modifications to Nissen’s original operation designed to minimize the incidence of postoperative dysphagia have been advocated, for the most part, without supporting scientific evidence from controlled clinical trials. Calibration of the fundoplication around a large-caliber bougie is anecdotally claimed to ensure an adequate esophageal lumen (creating the “floppy Nissen”) and to thereby reduce postoperative dysphagia.18,39 Esophageal perforations related to bougie use, however, have been reported to complicate approximately 1% of laparoscopic Nissen fundoplications.20

Any surgical procedure involves a balance of risks and benefits. This prospective study was designed to establish the relative risks vs benefits of bougie use during laparoscopic fundoplication.

RESULTS

Between March 1, 1996, and July 31, 1998, 171 patients undergoing laparoscopic Nissen fundoplication were enrolled in the clinical trial. Eighty-one patients were randomized to undergo fundoplication with a bougie and 90 patients to undergo fundoplication without a bougie. Long-term follow-up was complete for 154 (76 patients in the bougie group and 78 patients in the no bougie group) of the 171 patients (90%) enrolled. Seventeen patients were lost to long-term follow-up. One patient with cirrhosis died of unrelated causes within 6 months of undergoing surgery. One patient with a psychiatric disorder refused the interview; and 15 patients had moved or could not be contacted by telephone or by their referring physician. There were no deaths within 30 days of undergoing surgery.

PREOPERATIVE ASSESSMENT

Presenting symptoms are summarized in Table 2. Heartburn was the most common complaint, followed by regurgitation. While only 11 patients presented with dysphagia as their primary complaint, 57 patients (33%) admitted to some degree of preoperative dysphagia during standardized preoperative interview. A significantly greater number of patients with preoperative dysphagia were randomized to the bougie group than to the no bougie group (46% vs 28%, P<.05).
is carefully “walked” around the esophagus to prevent twisting. The wrap is inspected for tension or ischemia due to a small retroesophageal window. A “shoe-shine maneuver” is performed by pulling the left and right aspects of the wrap back and forth behind the esophagus to confirm that the gastric cardia is, in fact, being used for the wrap. At this time, the bougie group had a 360° fundoplication created using 3 interrupted intracorporeally tied sutures. Each suture incorporates the right side of the wrap, the anterior esophagus, and the left side of the wrap. The wrap is anchored to the hiatal closure posteriorly. At the completion of the operation, the looseness of the wrap is confirmed by passing a blunt laparoscopic instrument between the wrap and the distal aspect of the esophagus.

POSTOPERATIVE CARE

Nasogastric tubes are not routinely used. Patients receive a liquid diet 6 hours after surgery and full liquids soon afterward. Most patients are discharged from the hospital on the first or second postoperative day and are instructed to maintain a mechanical soft diet until seen in clinic 2 weeks postoperatively. At that time, if the patients are not having dysphagia, they are advanced to a regular diet but are instructed to take small bites, to chew their food carefully, and to avoid items that cause dysphagia or odynophagia (eg, bread, meat, and others).

No differences were noted between the 2 groups of patients for age, sex, height, or weight (Table 3). No significant difference was noted between the results of the 24-hour pH testing (including DeMeester score and percentage of time pH < 4). A large number of patients had endoscopic evidence of esophagitis, with an overall incidence of 80%. Benign stricture and esophageal body dysmotility were uncommon preoperative findings in both groups (Table 3).

OPERATIVE RESULTS

Thirty-four patients (20%) underwent additional concurrent laparoscopic procedures, including cholecystectomy, highly selective vagotomy, excision of a gastric stromal tumor, pyloroplasty, liver biopsy, umbilical hernia repair, vasectomy, and a posterior colporrhaphy. There were no conversions to laparotomy during the Nissen fundoplication. Following successful completion of the laparoscopic fundoplication, one patient was converted from laparoscopic to open cholecystectomy owing to inadequate visualization of a bleeding cystic artery. Another patient underwent open posterior colporrhaphy by a gynecologist following the Nissen fundoplication. Mean operating time, including the additional procedures, was 149 minutes (range, 80-290 minutes) in the bougie group and 147 minutes (range, 65-295 minutes) in the no bougie group (P = .79).

FOLLOW-UP ASSESSMENT

For the duration of the study, patients were not informed whether a bougie was used at their operation. Because the operating surgeons (L.L.S., B.A.S.) were aware of the patients’ randomization group, all postoperative dysphagia surveys were completed by a blinded research assistant (E.J.P., D.M.H., P.D.H., N.R.). Frequency and severity of dysphagia were assessed by a blinded investigator (E.J.P., D.M.H., P.D.H., N.R.) in the early (< 4 weeks) and late (  3 months) postoperative periods, using a structured survey (Table 1). Patients who failed to return for scheduled follow-up visits at 6 months or who were longer than 12 months postoperative were interviewed by telephone. All patients also underwent a standard follow-up algorithm for antireflux surgery that included a gastrointestinal tract symptoms assessment form at 2 weeks, 6 weeks, 6 months, 3 years, and 6 years as well as postoperative 24-hour pH test and esophageal motility assessment at 6 months and 3 years.

STATISTICAL ANALYSIS

One of us (D.M.H.) performed the statistical review. All statistical analyses were performed using a commercially available statistical software package (SPSS version 6.1.3; SPSS Inc, Chicago, Ill). \( \chi^2 \) (Pearson product moment correlation) or 2-tailed Fisher exact tests were used to analyze nonparametric data, as appropriate. Wilcoxon matched-pairs signed rank test was used for analysis of paired data. The \( t \)-tests with independent samples were used for comparison of means, with Levene test for equality of variances. Statistical significance was accepted at \( P < .05 \).

| Table 1. Scoring System for Dysphagia* |
|-----------------|-----------------|
| Frequency Score | Severity Score  |
| 0 = None        | 0 = None        |
| 1 = <1/mo       | 1 = Some solids, no liquids |
| 2 = <1/wk       | 2 = Many solids, no liquids |
| 3 = <1/d        | 3 = Most solids, no liquids |
| 4 = <1/meal     | 4 = All solids, some liquids |
| 5 = Every meal  | 5 = All solids, all liquids |

*Severity of dysphagia is determined by asking about difficulty swallowing certain food types: bread or meat, cooked vegetables, pudding, creamed soup, and water. Frequency of dysphagia is determined according to the frequencies in the table.

There were 6 operative complications (7.4%) in the bougie group, and 10 operative complications (11%) in the no bougie group (\( P = .41 \)), for a total operative morbidity of 9.4%. Operative complications were all minor and were handled laparoscopically (Table 4). There were no esophageal perforations in this series. The single bougie-related complication was a 2-cm distal esophageal mucosal laceration noted incidentally on intraoperative endoscopy. Upper gastrointestinal tract series obtained on the first postoperative day showed no extravasation of contrast medium, and no intervention was required for this patient, but discharge from the hospital was delayed until postoperative day 3. The patient recovered uneventfully and had no sequelae from the injury.
Two patients underwent reoperative laparoscopy on the first postoperative day for suspected intra-abdominal bleeding due to increased abdominal pain and hemodynamic changes. One patient was bleeding from a left upper quadrant trocar site, which was controlled with a suture. The second patient had a lesser sac hematoma and a bleeding peripancreatic vessel, which was controlled with a suture. The second patient had a lesser sac hematoma and a bleeding peripancreatic vessel, which was controlled with a suture.

Three patients underwent delayed reoperation following Nissen fundoplication; however, no patients required operative revision owing to dysphagia. One patient underwent a percutaneous endoscopic gastrojejunal tube 1 month after surgery, owing to delayed gastric emptying and gas bloat.

Esophageal dilation for severe or progressive dysphagia was performed in 15 patients (8.8%), 8 (9.9%) in the bougie group and 7 (7.8%) in the no bougie group, at an average of 10 weeks after surgery (range, 1-51 weeks). In most cases minimal or no resistance to passage of a 56F bougie was reported. There were no complications related to these dilations and all patients reported improvement in dysphagia with 12 patients (80%) having no residual dysphagia and 3 patients (20%) describing episodic swallowing difficulty to breads and meats. One patient with an initial complete response developed recurrent dysphagia at 14 months postoperatively and had a second dilation with good results. Of the 3 patients who had a partial response, 2 requested no further intervention and 1 had 2 more dilations with minimal change in the dysphagia score.

**POSTOPERATIVE ASSESSMENT**

The incidence of dysphagia, as determined by blinded clinical assessment in the preoperative, early postoperative, and late postoperative periods is shown in the Figure. Treatment groups were compared for incidence of any dysphagia, or severe dysphagia, defined as a total score of 5 or greater (sum of frequency score plus severity score). Dysphagia was equally common in both groups at 1 month after surgery: 68% in the bougie group and 71% in the no bougie group (Figure, left [P = .68]). There was also no difference in incidence of severe dysphagia (Figure, right) or dysphagia scores for frequency or severity (Table 5).

Long-term dysphagia assessment occurred at a mean 11.0 months after surgery and was found to be more common in patients whose operation was performed without a bougie (31%) compared with those whose surgery was done with a bougie (17%) (P = .047) (Figure, left). There was a 10% overall incidence of severe long-term dysphagia, with a trend toward a higher incidence in the no bougie group (14%) vs the bougie group (5%) (Figure, right) (P = .06). Comparing the dysphagia scores between the 2 groups at long-term follow-up, there was a significant difference in dysphagia frequency and a trend toward a difference in dysphagia severity (Table 5).

The presence of preoperative dysphagia did not predict late postoperative dysphagia that occurred in 26% of the patients who had preoperative dysphagia and 23% of the patients who did not have preoperative dysphagia. In fact, preoperative dysphagia frequency and severity scores were improved significantly more often than they were made worse by fundoplication (Table 6). Sex, esophagitis, esophageal body dysmotility, or stricture did not affect the incidence of postoperative dysphagia (P > .05).

Persistent postoperative dysphagia was a problem with the early classic Nissen procedure and has proven to be a con-

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**Table 2. Presenting Chief Complaint**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Bougie Group</th>
<th>No Bougie Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heartburn</td>
<td>52 (64.2)</td>
<td>48 (53.3)</td>
<td>100 (58.5)</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>6 (7.4)</td>
<td>9 (10.0)</td>
<td>15 (8.8)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>56 (6.2)</td>
<td>6 (6.7)</td>
<td>11 (6.4)</td>
</tr>
<tr>
<td>Water brash</td>
<td>4 (11)</td>
<td>7 (11)</td>
<td>11 (6.4)</td>
</tr>
<tr>
<td>Epigastric pain</td>
<td>2 (2.5)</td>
<td>8 (8.9)</td>
<td>10 (5.8)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>2 (2.5)</td>
<td>7 (7.8)</td>
<td>9 (5.3)</td>
</tr>
<tr>
<td>Hoarseness</td>
<td>5 (6.2)</td>
<td>0</td>
<td>5 (2.9)</td>
</tr>
<tr>
<td>Asthma</td>
<td>1 (1.2)</td>
<td>3 (3.3)</td>
<td>4 (2.3)</td>
</tr>
<tr>
<td>Aspiration</td>
<td>2 (2.5)</td>
<td>0</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0</td>
<td>1 (1.1)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Nausea</td>
<td>1 (1.2)</td>
<td>0</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Upper gastrointestinal tract bleeding</td>
<td>1 (1.2)</td>
<td>0</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Cough</td>
<td>0</td>
<td>1 (1.1)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Total No. of Patients</td>
<td>81</td>
<td>90</td>
<td>171</td>
</tr>
</tbody>
</table>

*All values are expressed as number (percentage) of patients.

**Table 3. Preoperative Patient Characteristics**

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Bougie Group</th>
<th>No Bougie Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>46.1 (12.8)</td>
<td>47.9 (13.8)</td>
<td></td>
</tr>
<tr>
<td>Sex, F/M</td>
<td>31/50</td>
<td>37/53</td>
<td></td>
</tr>
<tr>
<td>Height, cm</td>
<td>178 (36)</td>
<td>173 (8.4)</td>
<td></td>
</tr>
<tr>
<td>Weight, kg</td>
<td>88.2 (15.8)</td>
<td>86.5 (15.4)</td>
<td></td>
</tr>
<tr>
<td>DeMeester score</td>
<td>69 (55)</td>
<td>75 (48)</td>
<td></td>
</tr>
<tr>
<td>% of Time pH&lt;4</td>
<td>18.1 (16.1)</td>
<td>19.1 (12.9)</td>
<td></td>
</tr>
<tr>
<td>Esophagitis</td>
<td>85</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td>Stricture, %</td>
<td>22</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Dysmotility, %</td>
<td>10</td>
<td>7.1</td>
<td></td>
</tr>
</tbody>
</table>

*P > .05 was not statistically significant for all patient characteristics. All values are expressed as mean (SD) unless otherwise indicated.

**Table 4. Operative and Early Postoperative Complications**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Bougie Group</th>
<th>No Bougie Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule tear</td>
<td>6 (7.4)</td>
<td>10 (11)</td>
<td>16 (9.4)</td>
</tr>
</tbody>
</table>

TABLE 4. Operative and Early Postoperative Complications


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continuing source of postprocedural morbidity with laparoscopic antireflux procedures. In fact, the advent of laparoscopic antireflux surgery may have decreased the tolerance for postoperative dysphagia. Inflated expectations of a rapid easy recovery from a less invasive approach have, to some extent, elevated dysphagia from the status of a natural side effect of the procedure to an actual complication. The technique of the Nissen fundoplication has evolved over time specifically to minimize this complication. Several surgeons have contributed significant modifications to Nissen’s original technique. The most widely quoted article on such modifications is DeMeester’s 1986 study of 100 fundoplications, which has influenced the practice of this technique worldwide.

DeMeester reported 3 modifications to Nissen’s original technique that decreased the incidence of persistent postoperative dysphagia from 21% to 3%. First, the length of the fundoplication was reduced from 4.0 to 1.0 cm. Second, the short gastric vessels were divided to ensure complete mobilization of the gastric fundus and to guarantee a tension-free wrap. Finally, the esophageal bougie used to calibrate the wrap was increased from 36F to 60F. DeMeester claimed that increasing the diameter of the esophageal bougie decreased the incidence of transient swallowing discomfort from 83% to 40%. It is important, however, to recognize the limitations of such an uncontrolled study. Any 1 or any combination of the 3 modifications to the technique, or simply the surgeon’s greater experience in later cases, could have been responsible for the decrease in long-term dysphagia. Despite the lack of scientific evidence for these modifications to the Nissen fundoplication technique, they have become surgical dogma and only recently has there been critical reassessment of the technical elements of fundoplication.

Several recent studies have critically evaluated the need to divide the short gastric vessels, primarily because the difficulty of performing this procedure laparoscopically has encouraged surgeons to determine whether it is actually beneficial. Watson et al enrolled 102 patients in a double-blind randomized trial to determine the efficacy of short gastric vessel division in reducing dysphagia. They found no difference in postoperative dysphagia or overall patient satisfaction. Loustarinen et al performed a similar, smaller study of short gastric vessel division during open Nissen fundoplication, and also failed to identify an outcome difference. This study has been criticized for its lack of power because only 25 patients were enrolled.

In contrast, perhaps because it appears technically simple and innocuous, the use of the esophageal bougie has not previously been subjected to a prospective randomized trial. However, scientific evidence to support use of this invasive technique is required since it has been associated with serious complications, particularly esophageal perforation.

The incidence of perforation of the esophagus or the gastroesophageal junction is reported to be 0.8% during laparoscopic Nissen fundoplication; whereas, it was rarely reported during the open Nissen fundoplication era.

### Table 5. Dysphagia Frequency and Severity Scores*

<table>
<thead>
<tr>
<th>Dysphagia</th>
<th>Bougie Group</th>
<th>No Bougie Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td>1.1 (1.6)</td>
<td>0.81 (1.5)</td>
<td>.26</td>
</tr>
<tr>
<td>Frequency</td>
<td>1.5 (2.0)</td>
<td>1.0 (1.8)</td>
<td>.08</td>
</tr>
<tr>
<td>Frequency + severity</td>
<td>2.6 (3.4)</td>
<td>1.8 (3.2)</td>
<td>.13</td>
</tr>
<tr>
<td>Early postoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td>1.5 (1.6)</td>
<td>1.7 (1.8)</td>
<td>.43</td>
</tr>
<tr>
<td>Frequency</td>
<td>2.6 (2.1)</td>
<td>2.8 (2.1)</td>
<td>.63</td>
</tr>
<tr>
<td>Frequency + severity</td>
<td>4.1 (3.3)</td>
<td>4.5 (3.6)</td>
<td>.49</td>
</tr>
<tr>
<td>Late postoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td>0.32 (0.87)</td>
<td>0.59 (1.1)</td>
<td>.09</td>
</tr>
<tr>
<td>Frequency</td>
<td>0.36 (0.91)</td>
<td>0.76 (1.3)</td>
<td>.03</td>
</tr>
<tr>
<td>Frequency + severity</td>
<td>0.67 (1.7)</td>
<td>1.4 (2.2)</td>
<td>.04</td>
</tr>
</tbody>
</table>

*All values are expressed as mean (SD).

### Table 6. Effect of Laparoscopic Nissen Fundoplication on Dysphagia Frequency, Severity, and Overall Score*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Improved</th>
<th>Worse</th>
<th>No Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>49</td>
<td>25</td>
<td>80</td>
</tr>
<tr>
<td>Frequency</td>
<td>51</td>
<td>25</td>
<td>78</td>
</tr>
<tr>
<td>Frequency + severity</td>
<td>52</td>
<td>25</td>
<td>77</td>
</tr>
</tbody>
</table>

*All values are expressed as the number of patients who rated their dysphagia in the late postoperative phase compared with the preoperative phase. All P < .001.

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The lack of direct manual guidance of the bougie tip through the gastroesophageal junction, and anterior angulation of the distal aspect of the esophagus after posterior hiatal closure are believed to be the primary factors leading to bougie perforation.6,12

The results of this trial confirmed that the presence of a 56F bougie in the distal aspect of the esophagus during construction of a 360° fundoplication substantially reduces the incidence of long-term dysphagia. There is a less marked effect on severe dysphagia. Since this was a randomized trial and the 2 groups of patients were equivalent for demographics, presentation, physiology, and disease severity, we were surprised to find a possible source of bias in the additional operative procedures performed. Seven patients in the bougie group and none in the no bougie group underwent laparoscopic pyloroplasty. Delayed gastric emptying in these patients may have been a confounding variable for postoperative dysphagia. However, when the data were reanalyzed excluding all patients with additional procedures, notably more patients in the no bougie group still had postoperative dysphagia. An additional confounding variable could be the presence of motility disorders of the esophagus that are a well-known cause of dysphagia. Patients who had severe motility disorders, as we define it, were excluded from participation in this study. There were still patients in both study arms having nonspecific motor disorders that fell above our conservative cutoff (10% in the bougie group and 7.1% in the no bougie group; P = .13), but none of these patients had postoperative dysphagia at long-term follow-up. This seems to imply that mild motility disorders are not a particular risk factor for postoperative dysphagia following a laparoscopic Nissen fundoplication.

We should point out a difficulty in clinical interpretation and outcome reporting of postoperative dysphagia. Almost every study, including this one, uses a different method of dysphagia assessment.6,12,13,33-35 In addition, results are affected not only by the clinical tool used, but also by the person who applies the tool. Significant bias could be introduced if follow-up is performed by the operating surgeon.6 The development and validation of a dysphagia assessment tool that is widely accepted by surgeons, and easily applied by independent investigators, would be valuable.

The dysphagia assessment tool that we used is very sensitive at detecting any dysphagia if it is present, even occasional dysphagia to dry solids is detected. The apparently high rates of postoperative dysphagia in this study are likely owing to the sensitivity of our scoring system. Similar incidences have been reported in other studies where the presence of any postoperative dysphagia was sought, including mild symptoms.34 Dysphagia incidence is much lower when only moderate or severe dysphagia is reported.15,33

Overall, there was a significant reduction in dysphagia scores, both in frequency and severity, following laparoscopic Nissen fundoplication. This phenomenon has been reported by others, in addition to the finding that preoperative dysphagia does not predict the occurrence of postoperative dysphagia.15,34-37 None of the other preoperative variables examined were found to be predictors of postoperative dysphagia. Sex, esophagitis, motility disorders, and strictures have been analyzed by others as predictors of dysphagia, with similar negative results.33,39

The actual mechanism of the bougie in the minimization of dysphagia is unknown. Intuitively, wraps performed without a bougie may simply be too tight, despite all efforts by experienced surgeons to create a consistent floppy wrap. If this is the case, it should be detectable with postoperative manometric studies. We have recently completed a case-matched analysis of patients in this study group looking at the lower esophageal sphincter characteristics of those with and those without postoperative dysphagia. Our findings showed no difference in the groups and no evidence of “tight” or dysfunctional wraps.50 Another report, however, involving 381 patients found a significant increase in the esophageal basal and nadir lower esophageal sphincter pressures in 97 patients with postoperative dysphagia who were followed up for 2 years.54 It is also possible that the use of a large esophageal bougie prevents dysphagia by dilating a subclinical stricture. Thus, the patients in the bougie arm of this study could be viewed as having prophylactically received the standard therapy for postoperative dysphagia.

In all likelihood, the mechanism for prolonged dysphagia following fundoplication is multifactorial. Dysphagia may be caused by a wrap that is too tight or too long, a wrap that fails to relax adequately, or an undetected esophageal stricture. The use of an esophageal bougie will help to create a wrap of adequate diameter, and will serve to dilate a preexisting stricture. However, it will not affect the length of the fundoplication, nor will it ensure that the wrap will manifest appropriate receptive relaxation. Therefore, while use of a bougie will decrease the rate of postoperative dysphagia, it will not eliminate this clinical problem.

CONCLUSION

The use of an esophageal bougie during laparoscopic Nissen fundoplication significantly reduces the incidence of long-term postoperative dysphagia. This advantage of esophageal bougie use, however, must be weighed against its risks, including esophageal perforation.

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REFERENCES


DISCUSSION

Lawrence W. Way, MD, San Francisco, Calif: In this study, Dr Swanstrom and his colleagues performed Nissen fundoplications on 171 patients randomly assigned to having or not having a bougie in the esophagus as the tightness of the wrap was gauged. A dysphagia scale was created, and a nurse who was unaware of the patients’ treatment group assignment assessed the severity of dysphagia at intervals postoperatively. With minor exceptions, the groups were well matched preoperatively.

One month after the operation, dysphagia was present in about 70% of patients regardless of whether or not a bougie was used. At late follow-up (ie, at least 3 months after surgery), dysphagia was present in 30% of the no bougie group and 17% of the bougie group, a statistically significant difference. Severe dysphagia, defined as a dysphagia score of 5 or more, was present in 5% of the bougie group and 14% of the no bougie group, an insignificant difference.

While the authors have made a valuable attempt to answer an important technical question, I am not convinced their experiment was as successful as it first appears. This may partly stem from their being so experienced at performing laparoscopic Nissen fundoplication that they compensated readily for the absence of a bougie when performing the wrap in the no bougie group.

A central concern in this analysis is the definition of dysphagia that emanates from using the rating scale. Presumably what the surgeon and patient are really interested in is dysphagia that affects patient satisfaction—clinically relevant dysphagia. In this regard, the dysphagia scale appears to be hypersensitive, and the figures it generated suggested that postoperative dysphagia was a greater problem than was truly the case. The scale’s hypersensitivity, however, may have been necessary to produce the statistically significant differences between the groups. How else can one interpret the fact that in late follow-up, 16 patients were said by the nurse to have severe dysphagia, yet neither the surgeons nor the patients believe that treatment was indicated?

An alternative approach would be to say that dysphagia was severe when it was bad enough to call for esophageal dilatation, and data on this point are contained in the paper. Looked at in this way, severe dysphagia occurred within 3 months of surgery in about 9% of both groups, and with few exceptions, it was corrected by the dilatation. Thus, the nurse’s assessment using the dysphagia scale gave a high and lopsided incidence of severe dysphagia on late follow-up, whereas the more realistic form of severe dysphagia that got treated was evenly distributed, uncommon, transient, and largely confined to the early postoperative period.

Despite all of this, I know the authors truly believe that using a bougie is the best method of sizing the wrap, and I agree with them.

Bruce M. Wolfe, MD, Sacramento, Calif: This is an excellent example of a study of one component of an operation that is ultimately a technical event that has important impact for the patient. Long-term dysphagia is certainly troublesome, even if not severe. I have some questions for the authors. How was the injury of the esophageal mucosa detected? Did you routinely use an endoscope for all of these patients after the procedure such that this bougie injury was detected? Is it possible that there are more bougie injuries than we know of clinically?
Have you considered using a partial or 270° wrap more often as a result of this finding of the greater frequency of dysphagia with a more sensitive monitor? Have you considered alternatives to the standard bougie? There are 2 devices being marketed now. One is a balloon that is inflated so it is not quite as big when you put it in, and another is a bougie that goes over a soft nasogastric tube so hopefully the path has already been identified before the bougie is placed, thereby reducing risk.

Finally, could you comment on your explanation for this outcome? I know this is not what you expected to find. Do you think we are really doing the wraps too tight without the bougie or is there some other phenomenon going on here?

Ed Phillips, MD, Los Angeles, Calif: Since you standardized the diameter of the bougie, I guess you have proven size matters. Considering all of the factors that result in postoperative dysphagia, does the use of a bougie help in the construction of the wrap or the dilation of the esophagus? Regarding wrap construction: though you standardized the length of the wrap, was the length actually measured? It is very difficult to "eyeball" the actual length. Also, did you record how many times a wrap was actually modified because of the use of a bougie? Finally, regarding the issue of esophageal dilation: the incidence of stricture was moderately high in both groups, but was the degree of stricture quantified? Were patients with strictures analyzed separately? In other words, were patients with strictures randomized to the no bougie procedure disproportionately responsible for the early or late postoperative dysphagia in the no bougie group? And did these patients receive postoperative dilation and, if so, did they respond? For those of us who perform laparoscopic fundoplication frequently, the risk of esophageal perforation from placement of a bougie seems out of proportion to any benefit. An esophageal perforation rate of 0.5% is too high. Using a less sensitive definition of dysphagia, our incidence is considerably lower than you have presented. If the patients who have persistent postoperative dysphagia respond to dilation, it seems safer to dilate the few postoperative patients that need it than to risk a complication on the greater number of patients that don’t.

Mark Vierra, MD, Stanford, Calif: One comment and one question. My first comment is to echo what Dr Way suggested. You really could throw away the differences between the bougie and no bougie groups and retitled this article "Fundoplication Diminishes Dysphagia in Patients With Gastroesophageal Reflux" because the way I look at it, this clearly did improve overall dysphagia among patients with reflux. My question really has to do with the mechanism by which the bougie might be affecting the incidence of dysphagia. I can think of 2 mechanisms by which this might occur. One is that you are simply increasing the volume of the wrap, and the other is that it may prevent you from angulating the wrap. We have had the opportunity to operate on a couple of patients done elsewhere with bougies who had persistent postoperative dysphagia unexplained by swallow manometry. The thing that helped us to explain the dysphagia was the retroflexed view of the wrap. The wrap was torqued or angulated, and I wonder whether the bougie might help to diminish the incidence of torque or angulation of the wrap rather than simply increasing the diameter of the esophagus during the performance of it.

Jeffrey E. Doty, MD, San Jose, Calif: There are bougies and then there are bougies. We did our first hundred with a Maloney bougie and then switched to the Hurst because the Maloney tended to distort the greater curvature in the wrap. We found that the Hurst dilator was extremely dangerous. There is no calibration on it. It was very difficult to communicate with the anesthesiologist where they were in terms of the gastroesophageal junction, and the blunt tip would either dissect down behind the shelf created by the posterior cruel repair or would flip anteriorly as it would come through the hiatus and go anteriorly as your picture demonstrated. So my question is, which dilator do you use and how do you communicate with your anesthesiologist?

Second, as you recall, DeMeester described using a 60 bougie and was very clear in his paper that he would be able to slip his finger between the wrap and the bougie in the esophagus and that there would be no band compressing on his finger. How do you accomplish that laparoscopically?

Dr Swanström: Dr Way mentioned experience, and it is important to know that this was done by experienced surgeons. It was certainly our feeling that a surgeon who has done a few hundred fundoplications would do the repair the same way regardless of having a bougie in place. I think that is really relevant, and this is certainly directed more toward people in their learning curve. Is it needed or not?

I agree that one of the flaws in our study is that the dysphagia scale is very sensitive. There is 2 ways of looking at this: one is that if you ask somebody if they have a symptom, you will often get a yes response. If you never ask, they will only tell you about it if it is bad enough to require treatment. Therefore, in a clinical outcomes study, when you start asking, you up the sensitivity.

Did we construct the score to generate good P values? Not really. It is a score we have used for some time. It is simply overly sensitive and, when addressed to patients, they frequently feel like they have to answer at least part of it yes. This, I believe, accounts for our high rates of dysphagia. Clinically significant dysphagia occurs in about 2% or 3% of our experience.

Dr Wolfe was also kind enough to review the manuscript. He asks: How was the injury detected? We do not obtain a routine follow-up swallow or endoscopy and really found this injury by accident. He complained about more pain than usual immediately after surgery, so we did get an upper GI on him.

Partial fundoplications. As many of you know I was initially fond of Toupet fundoplications but they really have turned out to be a poor antireflux procedure. We have written several papers that document the poor long-term results of partial wraps. To give patients a mediocre antireflux surgery to avoid a transient dysphagia which is easily treated with dilation is probably not a good choice.

Several people asked what kind of bougies we use. Typically we would use a Maloney-Hurst, but if the patient has a risk factor, we would do intraoperative endoscopy and use a Savory dilator over a guide wire. These new dilator systems that insert over the NG [nasogastric] tube or have balloons that inflate are exciting and, I hope, will avoid perforations. Unfortunately they do tend to be more expensive, and that is always a drawback.

Both Drs Vierra and Wolfe asked what I think is a critical question which is why these patients have dysphagia. Last year at SSAT we presented a detailed manometric assessment trying to find what was different between patients who had postoperative dysphagia and a group who were treated the same way who did not, thinking that the wraps must be nonrelaxing, or have a higher pressure or that patients with dysphagia would have preoperative histories of stricture or dysmotility. Neither was true. There was no difference in preoperative history and, manometrically all wraps were the same. In fact, as pointed out by Dr Vierra, Nissen actually improve dysphagia in patients presenting that way. Our theory based on that study and this one is that it is not so much the construction of the wrap that is affected by the bougie. I know I am doing the wrap the same whether there is a bougie in there or not, but, in fact, we may be dilating subclinical strictures or spasm that were not otherwise apparent.

Length of wrap was standardized in all cases. We actually did not document it individually, but all wraps were measured at completion and confirmed to be between 1.5 and 2 cm. How do we check for looseness? We insert two 5-mm instruments after we have removed the bougie and lift up to ensure floppiness. That is our equivalent, in the laparoscopic world, of inserting a finger between the esophagus and wrap.