Postoperative Dysphagia Following Esophagogastric Fundoplication - Does the Timing to First Dilation Matter?

Running head: Dilation for dysphagia after fundoplication

Dimitrios I. Athanasiadis MD [a], Don Selzer MD [a], Dimitrios Stefanidis MD PhD [a], Jennifer N. Choi MD [a], Ambar Banerjee MD [a]

[a] Department of Surgery, Indiana University School of Medicine, Indianapolis, IN, USA

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Corresponding author:

Ambar Banerjee, MD

11725 N Illinois St, Suite 350

Carmel, IN 46032

Telephone: (317) 944 0960

Fax: (317) 968 1127

Email: banerjam@iupui.edu

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Abstract

Background: Postoperative dysphagia after anti-reflux surgery typically resolves in a few weeks. However, even after the initial swelling has resolved at 6 weeks, dysphagia can persist in 30% of patients necessitating esophageal dilation. The purpose of this study was to investigate the effect of esophageal dilation on postoperative dysphagia, the recurrence of reflux symptoms, and the efficacy of pneumatic dilations on post-operative dysphagia.

Methods: A prospectively collected database was reviewed for patients who underwent partial/complete fundoplication with/without paraesophageal hernia repair between 2006-2014. Patient age, sex, BMI, DeMeester score, procedure type, procedure duration, length of stay, postoperative dysphagia, time to first pneumatic dilation, number of dilations, and the need for reoperations were collected.

Results: The study included 902 consecutive patients, 71.3% females, with a mean age of 57.8±14.7 years. Postoperative dysphagia was noted in 26.3% of patients, of whom 89% had complete fundoplication ($p<0.01$). Endoscopic dilation was performed in 93 patients (10.3%) with 59 (63.4%) demonstrating persistent dysphagia. Recurrent reflux symptoms occurred in 35 (38%) patients who underwent endoscopic dilation.

Patients who underwent a dilation had a smaller revision rate than patients who did not undergo a dilation before revision (17.2% vs 41.7%, respectively, $p<0.001$) in the four-year follow-up period. The duration of initial dilation from surgery was inversely related to the need for

revisional surgery (*p=0.047*), while more than one dilation was not associated with additive benefit.

Conclusion: One attempt at endoscopic dilation of the esophagogastric fundoplication may provide relief in patients with postoperative dysphagia and can be used as a predictive factor for the need of revision. However, there is an increased risk for recurrent reflux symptoms and revisional surgery may ultimately be indicated for control of symptoms.

Keywords: dysphagia, dilation, reoperation, fundoplication, recurrent reflux

Introduction

Surgical treatment of gastroesophageal reflux disease (GERD) has become common in the laparoscopic era with a technique proven to be both safe and effective [1, 2]. However, most patients develop transient dysphagia in the postoperative period which typically resolves in the first weeks to months after surgery [3]. In fact, dietary progression attempts to avoid post-operative dysphagia by starting with liquids followed by pureed and soft mechanical foods until a regular diet is commonly reached 4-6 weeks later. Persistent dysphagia (beyond 6 weeks postoperatively) has been reported in 3-30% of patients after anti-reflux surgery [4]. While some patients with early post-operative dysphagia symptoms have complete resolution and good long-term success [5], those with persistent dysphagia are often dissatisfied with their quality of life [6]. Many of those patients require further intervention, including esophageal dilation, and even revisional surgery to relieve their symptoms [7, 8]. However, some patients who undergo esophageal dilations for persistent postoperative dysphagia have been noted to develop recurrent reflux symptoms with or without resolution of their dysphagia [9]. Studies that assess efficacy of endoscopic intervention for post-fundoplication dysphagia are limited [10].

This study aims to

(1) Identify patients with postoperative dysphagia following gastric fundoplication and assess the efficacy of esophageal dilation in those patients, and

(2) Investigate the relationship between timing of the first dilation from original surgery, the total number of dilations, and requirement for revisional surgery.

Materials and Methods

Following institutional review board approval, a prospectively collected database was reviewed for patients who underwent partial/complete fundoplication with/without paraesophageal hernia repair between January 2006 and January 2014. This date range was specifically chosen to include patients who were operated by the same group of surgeons and had at least four years of postoperative data available for review. Data points included age, gender, baseline body mass index (BMI), preoperative DeMeester score, type of fundoplication (Nissen or Toupet), and concomitant repair of a hiatal hernia. Furthermore, the procedure time, the length of stay in the hospital (LOS), and complications such as postoperative dysphagia, and persistent dysphagia or recurrent reflux symptoms following pneumatic dilation for dysphagia were noted. Additionally, the need for repeat pneumatic dilations or reoperation was recorded along with the specific timing of that occurrence in relation to the primary operation. Postoperative dysphagia or recurrent reflux symptoms were defined as those persisting for more than 6 weeks after surgery/dilation[4, 11]. These were identified from subjective symptoms assessed by surgeons and the use of a GERD and dysphagia questionnaire (Figure 1) along with objective studies including upper gastrointestinal tract radiographs esophageal manometry and esophagogastroduodenoscopy, when obtained. Prior to revisional surgery all of the aforementioned studies were being utilized along with the use of pH/impedance study in selected cases. These data were not collected as the aim of this study was to investigate the association of postoperative endoscopic dilation with symptom resolution and subsequent revisional surgery. In our practice, pneumatic dilations are delivered with through the scope (TTS) balloons of 18-20mm diameter. Demographics and other baseline patient characteristics were analyzed with descriptive statistics. The statistical significance of the relationships of the nominal and continuous variables were calculated with student t-test, Mann-

Whitney test (depending on the distribution of the data), and Chi-square test. If univariate analysis revealed a significant difference between cohorts ($p < 0.05$), a multivariate analysis was performed. A logistic bivariate regression was utilized accounting for confounders such as the procedure type, age, and gender. Statistical analysis of the data was performed using the SPSS statistical software, version 26.0 (SPSS Inc., Chicago, IL).

Results

Nine hundred and two consecutive patients, with a mean age of 57.8 ± 14.7 years were included in the study and followed for up to four years, with females comprising 71.3% of the population (Table 1). Laparoscopic Nissen fundoplication and laparoscopic paraesophageal hernia repair with Nissen fundoplication were performed in 436 and 190 patients respectively. Laparoscopic Toupet fundoplication and laparoscopic paraesophageal hernia repair with Toupet fundoplication were performed in 10 and 83 patients respectively. 183 patients underwent revisional anti-reflux procedures (20.3%) (Figure 2). The mean operative time was 101.8 ± 50.9 minutes and the median LOS was 1 day ranging up to 37 days. Subjective postoperative dysphagia was noted in 237 of 902 patients (26.3%) (Table 2), which led to an esophagogastroduodenoscopy in 163 of them. The rest of the patients did not undergo an endoscopy as their symptoms gradually improved and no anatomical problems were suspected. 89% of the patients with postoperative dysphagia had Nissen fundoplication while the rest underwent Toupet fundoplication ($p<0.01$). The overall rate of revisional surgery was 13.5% in the index study population (n=122/902) out of whom only 3 had a prior Toupet fundoplication and were revised due to recurrent hernia. The rate was higher in the sub-group of patients who had developed postoperative dysphagia (35% vs 6%, $p<0.001$).

One or more endoscopic dilations of the fundoplication were performed in 93 patients (n=93/902, 10.3%) with dysphagia resolution in 34 (36.6%) and persistent symptoms of dysphagia in 59 (63.4%) (Table 2). Only 6 patients from the Toupet group underwent a dilation. Recurrent reflux symptoms were reported in 35 patients (37.6%).

Post-dilation patients with resolution of dysphagia had a median of 1 (range 1-3) dilation while those without resolution of dysphagia had a median of 2 (range 1-7, $p<0.001$). The

multivariable analysis confirmed that additional dilations following the first did not provide additional benefit. (Table 3) Patients who underwent at least one dilation experienced a lower revision rate (n=16/93) than those who proceeded to revision immediately (n=60/144) (17.2 vs 41.7%, p<0.001). The results remained significant even after controlling for potential confounders such as age, gender, and BMI. Patients who were revised without undergoing a dilation were found to have a recurrent hiatal hernia/slipped fundoplication through upper gastrointestinal tract radiographs and esophagogastroduodenoscopy.

Regarding the incidence of reflux recurrence following pneumatic dilations, we identified that it was irrelevant of the number of dilations performed as both patients, with or without post-dilation reflux symptoms, received similar number of dilations (1.86 vs 1.85, p=0.987, respectively).

Finally, the need for an early dilation was associated with a higher rate of revision compared to patients who did not require one (*p=0.03*). (Table 4) The total number of pneumatic dilations though was not different between patients who required revision and those who did not (p=0.702).

Discussion

Since its successful introduction, laparoscopic fundoplication has become the gold standard of management for patients with moderate to severe gastroesophageal reflux disease[12]. The safety and efficacy of this procedure has further allowed it to become a treatment option for those who present with earlier stages of the disease[13]. Post-operative dysphagia, however, is one of the most common sequelae of gastroesophageal fundoplication in both Nissen and Toupet fundoplication [14, 15]. This issue is commonly attributed to anatomical issues such as recurrence of a hiatal hernia and tight wrap[16] and functional defects like slow esophageal transit[4, 17]. Dilations are commonly used to alleviate the symptoms, with the success ranging from 50-67% while many patients requiring multiple dilations [9, 16, 18, 19]. More importantly, in concordance with our results, recurrent reflux following pneumatic dilations in achalasia studies is commonly reported in more than 20-25% of the patients[20, 21]. Additionally, most studies have failed to demonstrate useful criteria by which post fundoplication dysphagia can be anticipated [22], and the knowledge regarding the efficacy of pneumatic dilations for the post-fundoplication dysphagia is lacking[3].

The data show that post-fundoplication dysphagia is more common in patients undergoing Nissen fundoplication, and pneumatic dilations can alleviate dysphagia. However, any additional attempts following the first dilation do not provide added benefit and seem to only delay revisional, corrective surgery. Finally, if needed early following the primary operation, endoscopic dilation may be an indicator for the need of revisional surgery due to persistent dysphagia.

These findings are congruent with systematic reviews that have demonstrated that Nissen fundoplication leads to higher rates of postoperative dysphagia than Toupet fundoplication (89% vs 11%, $p<0.01$) [23].Further, the percentage of patients who required endoscopic dilation to

palliate dysphagia (10.3%) is similar to that reported in the literature [9] [12] [24] [25]. Sobrino et al. [24] reported one case series in which 12.4% of the patients who underwent gastroesophageal fundoplication required from 1 to 5 dilations to provide some relief of postoperative dysphagia. The authors also reported the resolution of post-operative dysphagia in 67% of their cases following endoscopic dilation. Hui et al. [9] reported good clinical response in dysphagia patients after balloon pneumatic dilation (64% of patients experienced symptomatic relief). However, the literature shows dilation for post-fundoplication dysphagia achieves variable resolution between 50%-67% [19] [24]. Here, symptomatic relief of symptoms for more than 6-weeks after pneumatic dilation was observed in 36.6%. While endoscopic dilations can help improve dysphagia symptoms, they can also unfortunately lead to recurrent reflux symptoms[20, 21]. Indeed, in our study, 38% of our patients reported subjective reflux symptoms following the dilations. As Min at al. [21] had reported, even in patients with worse dysphagia symptoms such as in patients with achalasia, the recurrence of reflux symptoms was as high as 26.6% following pneumatic dilation. It has also been suggested in the literature, in concordance with our results, that repeat dilations are unlikely to be effective in the case of absence of symptom relief after the initial dilation, [26].

In this group, most patients who required reoperation for dysphagia did not undergo dilation and were offered revision to partial posterior fundoplication directly (41.7% vs 17.2%). A recent systematic review [23] supported this strategy as partial fundoplication offered similar reflux remission and less postoperative dysphagia than NF. Many studies have reported that revisional surgery success rates are as high as 86 to 96%. [12, 13, 25, 27-29] Specifically, Frantzides et al. [29] demonstrated that revision of laparoscopic fundoplication yielded excellent results approaching the success rates of primary operations. Hence, revisional surgery should be

considered for symptomatic control with excellent success rates and improved quality of life irrespective of the etiology of dysphagia.

Studies have also shown that the use of dilations can be beneficial for patients helping them avoid another operation[24]. Pneumatic dilations alleviate dysphagia symptoms in a majority of patients while reducing the number of patients requiring revision. However, dilation should be limited to one attempt to avoid delays to likely therapeutic and needed reoperation. At the same time, patients should be cautioned about the possibility of recurrence of reflux symptoms. Finally, the time to the first dilation can be used by the surgeon as a warning sign for the need for revisional surgery. Patients who eventually required reoperation for dysphagia symptoms received the first dilation much earlier (median 94, IQR 209) than those who did not undergo a reoperation (Median 163, IQR 275) (p=0.047).

This study does not come without limitations, most of which are related to its retrospective design. Data was sourced from a single institutional data set, including multiple surgeons utilizing varying known approaches for the creation of fundoplication. It also relied on the patients' self-reported symptoms and surgeons' clinical judgment, in many instances, likely without the use of an objective testing for dysphagia or reflux other than an esophagogastroduodenoscopy. It is well established that both dysphagia and reflux symptoms tend to be highly subjective [30], and thus might have been under- or over-reported. Lastly, we did not record the use of bougie in our reported cases; however, it is debatable in the literature if the use of bougie or not is related to postoperative dysphagia[31, 32].

Conclusion

Dysphagia following esophagogastric fundoplication is a common sequela of anti-reflux surgery. The incidence of symptoms observed can vary depending on the type of fundoplication performed. One endoscopic dilation of esophagogastric fundoplication may provide some relief in patients complaining of postoperative dysphagia, at the expense of development of recurrent reflux symptoms in some patients. Additionally, time to the first dilation can be used as a tool to estimate the severity of dysphagia, as the early need for dilation may signal the need for a reoperation. However, when physiologic abnormalities and/or anatomic defects are present, revisional surgery may ultimately be indicated to control the symptoms of dysphagia.

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Disclosures

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Figure Legends

Figure 1. GERD and dysphagia Questionnaire

Figure 2. Procedures

Table 1. Patient characteristics

N	902
Age, years, mean ± SD	57.8 ± 14.7
Females, n (%)	643 (71.3%)
Baseline BMI, mean ± SD	29.5 ± 5.5
Preoperative DeMeester Score, median, range	35, 1-331

SD, Standard deviation

Table 1. Intra- and post-operative information

Operative time, minutes, mean ± SD	101.8 ± 50.9
Length of stay, days, median, range	1, 1-36
Postoperative dysphagia, n (%)	237 (26.3%)
Endoscopic dilation of wrap, n (%)	93 (10.3%)
Number of dilations per patient, mean ± SD	1.86 ± 1.3
Persistent dysphagia after dilations, n (%)	59 (63.4%)

SD, Standard deviation

Table 1. Multivariable analysis regarding dysphagia resolution

Dependent variable	Odds Ratio	95% Confidence Interval	p-value
Number of dilations	0.133	0.30-0.587	*0.008*
Age	0.987	0.943-1.032	0.564
Gender	1.257	0.317-4.990	0.745
BMI	1.037	0.930-1.157	0.512

Our parameter is comparing resolution of dysphagia to a reference of no-resolution.
BMI; body mass index

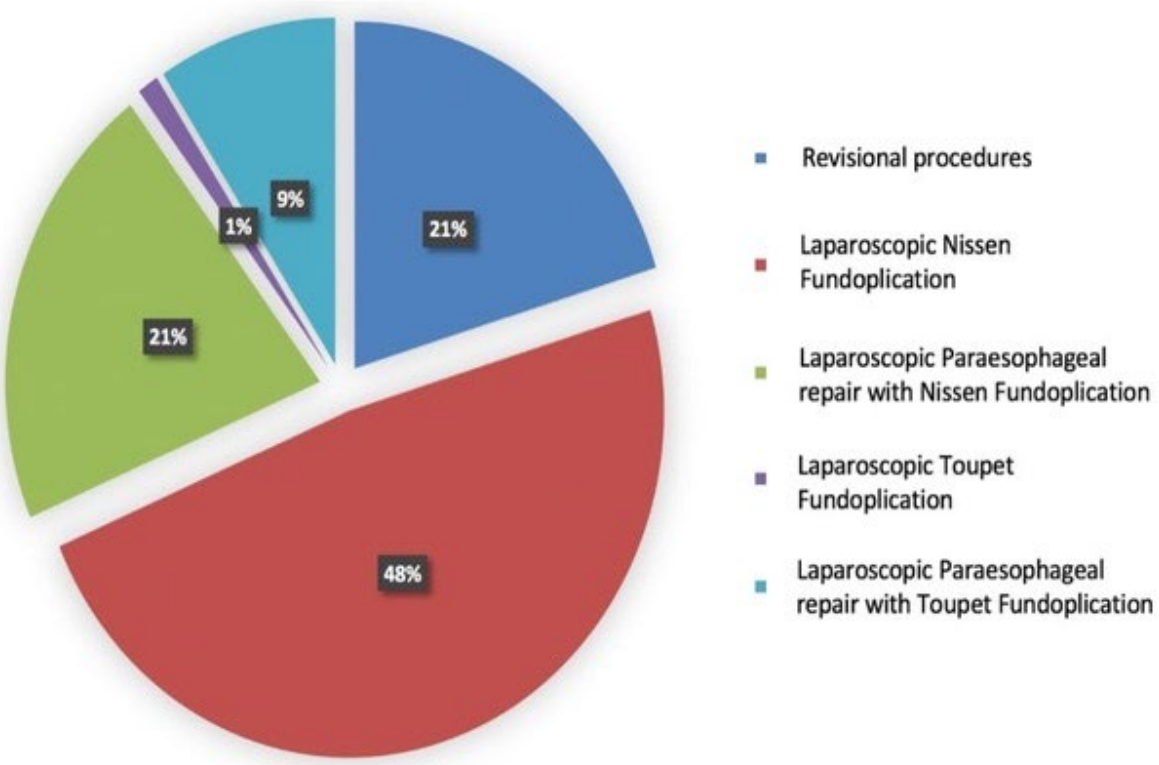
Table 4. Comparison of patients regarding the need for revisional surgery

	Revisional surgery	No revisional surgery	p-value
Duration from initial surgery to first dilation (days) median, IQR	94, 209	163, 275	*0.047*
Number of dilations	1.9 ± 1.1	1.8 ± 1.4	0.702

IQR, interquartile range;

Reflux / Esophageal Disorders Questionnaire			
Do you experience heartburn/reflux?	No	Yes	If yes, please circle the number of days per week that you experience heartburn/reflux **Days:** 0 1 2 3 4 5 6 7
On a scale of 0 to 10 how severe is your heartburn or acid reflux on the average?			**(0 being none and 10 being the most severe)** 0 1 2 3 4 5 6 7 8 9 10
Do you have upper abdominal pain with your acid reflux?	No	Yes	Please rate any upper abdominal pain on a scale of 0 to 10 **(0 being none and 10 being the most severe)** 0 1 2 3 4 5 6 7 8 9 10
Do you have chest pain with your acid reflux?	No	Yes	Please rate any upper abdominal pain on a scale of 0 to 10 **(0 being none and 10 being the most severe)** 0 1 2 3 4 5 6 7 8 9 10
Is your heartburn or acid reflux worsened by any of these certain factors?			☐ Large meals ☐ Spicy foods ☐ Caffeine ☐ Chocolates ☐ Bending over ☐ Lying down ☐ Stressful situations ☐ Other:_____
Do you have difficulty swallowing?	No	Yes	If yes, check if you have difficulty with swallowing liquids, solids, or both. ☐ Liquids ☐ Solids ☐ Both
How often do you have difficulty swallowing?			☐ Never ☐ Frequently ☐ Rarely ☐ With every swallow ☐ Occasionally
Do you have regurgitation (vomiting or spitting up)?	No	Yes	If yes, check when this happens ☐ Lying down ☐ Bending over ☐ After meals ☐ Anytime
How often do you have regurgitation?			☐ Never ☐ Frequently ☐ Rarely ☐ With every swallow ☐ Occasionally
Does your acid reflux cause you to have any of these other symptoms?			☐ Coughing ☐ Choking ☐ Asthma ☐ Wheezing ☐ Hoarseness ☐ Nausea ☐ Indigestion ☐ Bloating ☐ Increased belching ☐ Other:_____
Has your acid reflux caused you to have and problems with certain activities?	No	Yes	If yes, check off the activities that apply ☐ Avoidance of foods ☐ Filling up more quickly than usual ☐ Interference with sexual relations ☐ Need to sleep more upright ☐ Other: _____
Have you had tests or procedures performed for evaluation of your heartburn or acid reflux?	No	Yes	If yes, please check those that apply ☐ Upper GI (Barium Swallow) x-ray ☐ Upper GI Endoscopy (Scope – EGD) ☐ Dilation or "stretching" of the esophagus ☐ pH or Bravo probe testing to measure acid over 24 to 48 hours ☐ Esophageal Manometry/Motility Studyto measure swallowing strength ☐ Botox injection of the esophagus ☐ Stretta radiofrequency ☐ Enteryx injection

Date:_____ Completed By:_____ Please see other side


21%
48%
21%
1%
9%
Revisional procedures
Laparoscopic Nissen Fundoplication
Laparoscopic Paraesophageal repair with Nissen Fundoplication
Laparoscopic Toupet Fundoplication
Laparoscopic Paraesophageal repair with Toupet Fundoplication