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Persistent dysphagia rate after antireflux surgery is similar for Nissen and partial fundoplication

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Abstract

Introduction: Laparoscopic fundoplication is the gold standard operation for treatment of gastroesophageal reflux disease (GERD). It has been suggested that persistent postoperative dysphagia is increased following Nissen fundoplication compared to partial fundoplication. We aimed to determine risk factors for persistent postoperative dysphagia, specifically examining type of fundoplication.

Methods: Patients experiencing GERD symptoms who underwent laparoscopic Nissen, Toupet, or Dor fundoplication from 2009–2016 were identified from a single institutional database. A dysphagia score was obtained as part of the GERD-Health Related Quality of Life questionnaire. Persistent dysphagia was defined as a difficulty swallowing score ≥ 1 (noticeable) on a scale from 0–5 at least one year postoperatively. Odds ratios of persistent dysphagia among those who underwent anti-reflux surgery were calculated in a multivariate logistic regression model adjusted for fundoplication type, sex, age, body mass index, and redo operation.

Results: Of the 441 patients who met inclusion criteria, 255 had ≥ 1 year of follow-up (57.8%). The median duration of follow-up was 3 years. 45.1% of patients underwent Nissen fundoplication, and 54.9% underwent partial fundoplication. Persistent postoperative dysphagia was present in 25.9% (n=66) of patients. On adjusted analysis, there was no statistically significant

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association between the type of fundoplication (Nissen vs. partial) and the likelihood of postoperative dysphagia.

Conclusions: Persistent postoperative dysphagia after anti-reflux surgery occurred in approximately one-quarter of patients and did not differ by the type of fundoplication. These findings suggest both Nissen and partial fundoplication are reasonable choices for an anti-reflux operation for properly selected patients.

Keywords

Nissen fundoplication; Toupet fundoplication; Dor fundoplication; gastroesophageal reflux disease; postoperative dysphagia; persistent dysphagia

Introduction

Gastroesophageal reflux disease (GERD) has a prevalence of 18.1–27.8% and places a substantial burden on the United States healthcare system with estimated costs of \$12.1 billion.^{1,2} While GERD can often be managed with lifestyle modifications and acid-blocking medications, surgical intervention can be considered in several scenarios: 1) when medical management fails to control symptoms, 2) when patients do not want to take proton pump inhibitors long-term, 3) when there are complications of GERD (Barrett's esophagus, peptic stricture), or 4) when there are extra-esophageal manifestations of GERD (asthma, hoarseness, cough, chest pain).^{3,4,5} The gold standard operation for GERD is laparoscopic fundoplication, which has been shown to provide effective long-term relief of symptoms.^{6,7} Several complications can occur after laparoscopic fundoplication including gas-bloat, inability to vomit, and dysphagia. While postoperative dysphagia is common and typically improves within weeks of the operation, 8–35% of patients experience persistent postoperative dysphagia beyond one 1 year.^{8,9}

Efforts have been made to understand the risk factors for developing persistent postoperative dysphagia, yet uncertainty remains. Several preoperative factors have been shown to increase the risk of persistent postoperative dysphagia, including the presence of preoperative dysphagia and delayed esophageal transit by barium swallow.^{10,11} Prior work has also demonstrated that preoperative manometry results have no relation to the development of persistent postoperative dysphagia.¹⁰ However, there has been continued debate in the literature as to whether the type of operation (Nissen fundoplication vs. partial fundoplication) affects the risk of postoperative dysphagia.^{8,9,12–19} Some studies have suggested that Nissen fundoplication has an increased risk of postoperative dysphagia and gas-bloat compared to partial fundoplication.^{9,16,18,20} Conversely, other studies suggest that rates of postoperative dysphagia are similar between Nissen and partial fundoplication, and there is superior reflux control with Nissen fundoplication.^{13–15,17,19,21–23}

The appropriate selection of patients for an antireflux operation is imperative for optimal patient care. While we understand some of the risk factors for persistent postoperative dysphagia, considerable debate remains on whether a Nissen fundoplication or partial fundoplication should be performed. Our aim was to identify the preoperative risk factors for persistent postoperative dysphagia after primary laparoscopic antireflux surgery with

specific examination of the type of fundoplication (Nissen vs. partial). We hypothesized that Nissen fundoplication would result in an increased rate of postoperative dysphagia after antireflux surgery.

Methods

Study population:

The University of Wisconsin Hospital & Clinics Division of Minimally Invasive Surgery maintains a database that includes all patients who undergo benign foregut operations. Retrospective data collection was performed until prospective data collection began on June 9, 2014. REDCap (Research Electronic Data Capture), a secure web-based data capture tool hosted at the University of Wisconsin School of Medicine and Public Health, was used to collect and manage study data. Data collection was performed through administration of preoperative and postoperative questionnaires by clinic staff and review of the electronic medical record by a database manager.

Patients with gastroesophageal reflux disease who underwent elective laparoscopic Nissen, Toupet, or Dor fundoplication between January 2009 and July 2016 were identified from the University of Wisconsin Hospital and Clinics foregut surgery database and included in the study. Only patients who had at least one year follow up were included. Patients with achalasia or patients who underwent Enterra placement, per oral endoscopic myotomy (POEM), LINX placement, Heller myotomy, transoral incisionless fundoplication (TIF), roux-en-y gastric bypass (RYGB), gastrectomy or vagotomy were excluded from the study. University of Wisconsin Institutional review board approval was obtained for this study with a waiver of consent.

Variables:

The baseline characteristics included were sex, age (as both continuous and categorical variable: <60, 60–70, and ≥70], body mass index (BMI, as both continuous and categorical variable: <30 or ≥30], number of reflux episodes on esophageal impedance pH monitoring, and ineffective esophageal motility (defined as having either greater than 60% failed contractions or an average amplitude of contraction in the distal esophagus <45mm). The operative information included was type of fundoplication, primary vs. redo operation, and mesh use. Patients who underwent Nissen fundoplication were compared with those who underwent partial fundoplication (Toupet or Dor fundoplication) on baseline demographic and clinical characteristics.

The previously validated GERD-Health Related Quality of Life questionnaire (GERD-HRQL) was administered in clinic or by telephone to obtain postoperative outcomes.²⁴ A postoperative dysphagia score was obtained by using the “difficulty swallowing” question from the GERD-HRQL. Persistent postoperative dysphagia was defined as a difficulty swallowing score ≥1 (noticeable but not bothersome symptoms) on a scale from 0 (no symptoms) to 5 (incapacitating symptoms) at least one year postoperatively.

A postoperative bloating score was obtained using the bloating question from the GERD-HRQL on a scale of 0 (no symptoms) to 5 (incapacitating symptoms). No bloating was

defined as a score of 0, mild bloating was defined as a score of 1 or 2, and moderate/severe bloating was defined as a score between 3–5 at least one year postoperatively. The postoperative reflux score was calculated from nine acid reflux questions on the GERD-HRQL questionnaire which were administered at least one year postoperatively. Each question was scored on a scale of 0–5 (no symptoms-incapacitating symptoms) for a total reflux score between 0 and 45.

Statistical analysis:

Demographic and clinical characteristics were compared between patients who underwent Nissen and partial fundoplication. Demographic and clinical characteristics were also compared between those with persistent postoperative dysphagia which was mild (difficulty swallowing score of 1 or 2: noticeable but not bothersome everyday) and those with more severe dysphagia (difficulty swallowing score >2: symptoms that were bothersome everyday, affected daily activity, or were incapacitating). The proportion of patients with no bloating, mild bloating, and moderate/severe bloating were compared in those who underwent Nissen and partial fundoplication. The mean reflux score in patients who underwent each type of fundoplication was also compared. Pearson's chi-square test was used for categorical variables and Student's t-test for continuous variables (Wilcoxon test was used for continuous variables that were not normally distributed).

Multivariate logistic regression was performed to investigate whether the type of fundoplication (Nissen vs. partial) was associated with persistent postoperative dysphagia among patients who underwent laparoscopic fundoplication surgery for GERD. The variables included in the logistic regression model were defined a priori and included sex, age (categorical: <60, 60–70, and ≥70], BMI (categorical: <30 or ≥30], and primary (or re-do) operation. Adjusted odds ratios (OR) of persistent dysphagia among those who underwent Nissen compared to partial fundoplication with 95% confidence intervals (CI) were calculated in the multivariate logistic regression models. Statistical significance was defined at $p < 0.05$. Analysis was performed using STATA SE 15.0.

Results

There were 441 patients identified who underwent elective laparoscopic fundoplication for GERD. Of these patients, 255 had at least one year of follow-up (57.8%). The median follow-up time was 3 years. There were 115 (45.1%) patients in the Nissen fundoplication group and 140 (54.9%) patients in the partial fundoplication group. Baseline demographic and clinical characteristics were significantly different between the Nissen fundoplication and partial fundoplication groups (Table 1). The partial fundoplication group had more females, older patients, increased ineffective esophageal motility, and increased mesh use. In the Nissen fundoplication group, a bougie was used in 68 (59.1%) patients and ranged in size from 52–60 French.

Of the 255 patients included in the study, 25.9% had persistent postoperative dysphagia (Figure 1). Persistent postoperative dysphagia was present in 31/115 (27.0%) of those who underwent Nissen fundoplication and 35/140 (25.0%) of those who underwent partial fundoplication (Table 2). Of those with persistent postoperative dysphagia, 27/66 (40.9%)

had a difficulty swallowing score of 1 and 3/66 (4.5%) had a difficulty swallowing score of 5. As the difficulty swallowing score increased, the frequency of patients reporting that score decreased. Those with more severe dysphagia were more likely to be older than 60 years old compared to those with mild dysphagia (68.2% vs. 38.7%, $p=0.009$). Data on hiatal hernia type was present in 159/255 patients. There were 47/159 (29.6%) with a type I or II hiatal hernia and 112/159 (70.4%) with a type III or IV hiatal hernia. There was no difference in persistent postoperative dysphagia between the two hiatal hernia groups ($p=0.32$). In addition, there was no difference in other baseline demographic and clinical characteristics between the severity of dysphagia groups.

No postoperative bloating was present in 65/115 (56.5%) of those who underwent Nissen fundoplication and in 87/140 (62.1%) of those who underwent partial fundoplication. Moderate/severe postoperative bloating was present in 29/115 (25.2%) of those who underwent Nissen fundoplication and 32/140 (22.9%) of those who underwent partial fundoplication (Table 2). There was no significant difference in bloating between the Nissen and partial fundoplication groups ($p=0.64$). The mean postoperative reflux score was 2.85 in those who underwent Nissen fundoplication and was 3.17 in those who underwent partial fundoplication (Table 2). There was no significant difference in postoperative reflux score between the fundoplication types ($p=0.65$).

Univariate analyses of sex, age, BMI, primary vs. re-do operation, and Nissen vs. partial fundoplication with persistent postoperative dysphagia showed no significant risk factors. In the multivariate logistic regression model (including sex, age, BMI, primary vs. redo operation, and type of fundoplication), none of the factors were found to be significantly associated with persistent postoperative dysphagia (Table 3).

Discussion

In our cohort of patients, nearly one in four patients had persistent postoperative dysphagia. In patients that had persistent postoperative dysphagia, most had mild dysphagia. Those with more severe dysphagia were more likely to be older than 60. There was no statistically significant difference in rates of persistent postoperative dysphagia between those who underwent Nissen fundoplication and those who underwent partial fundoplication. In addition, none of the other variables used in our multivariate model including age, sex, BMI, and primary vs redo operation were significant predictors of persistent postoperative dysphagia. There was also no statistically significant difference in rates of postoperative bloating or reflux.

This study adds to the current debate over whether to perform a Nissen fundoplication or a partial fundoplication for patients with GERD. Several randomized controlled trials with follow-up of at least one year have also shown no difference in persistent postoperative dysphagia when only comparing Nissen fundoplication to Toupet fundoplication.^{13,15,17,19} A few of these same randomized controlled trials also showed an increase in postoperative dysphagia within the first weeks to months after the operation in those who underwent Nissen fundoplication compared to Toupet fundoplication, which is a difference that disappeared over the long-term.^{13,15} However, there have also been several randomized

controlled trials which show an increase in persistent postoperative dysphagia in those who underwent Nissen fundoplication compared to those who underwent Toupet fundoplication.^{9,16,18}

A number of meta-analyses have been performed to combine this data and more definitively answer this question.^{20,25} However, there continues to be mixed results even among meta-analyses. The meta-analysis performed by Broeders et al. in 2010 showed that persistent postoperative dysphagia was increased with Nissen fundoplication with a risk ratio of 1.61 and there was an increase in the need for dilation.²⁰ However, only two of the studies included in the dysphagia analysis had follow-up greater than one year and no study had follow-up extending to three years. The median follow-up in our study was three years and provided longer follow-up than this meta-analysis. In 2016, a meta-analysis was performed by Du et al. which incorporated several more recent studies and showed an increase in short term postoperative dysphagia (follow-up < 36 months) in the Nissen fundoplication group, but no significant difference in postoperative dysphagia when follow-up was increased to > 36 months.²⁵

In addition to the wide range in published rate of persistent postoperative dysphagia, there is disagreement over the effectiveness of reflux control between the operations. Some literature has suggested that Toupet fundoplication has a higher failure rate and that Nissen fundoplication better controls reflux.^{21–23} Others suggest that symptom control is equal between the operations.^{14,25} Another aspect of fundoplication to consider is the risk of gas-bloat. Most studies suggest that Nissen fundoplication has an increased risk of gas-bloat compared to Toupet fundoplication.^{20,25} The risk of persistent postoperative dysphagia, the effectiveness of reflux control, and the risk of postoperative gas-bloat are all important outcomes of an antireflux operation and important factors to consider.

Given the findings in our study combined with the results of prior work, we believe that both Nissen and partial fundoplication are suitable choices for an antireflux operation in properly selected patients. In this study, there were no set criteria for the choice of type of fundoplication for a given patient. This decision was made at the discretion of the surgeon. The patients in the partial and Nissen fundoplication groups differed in the proportion of females, older patients, patients with ineffective esophageal motility, and those with mesh, which may represent criteria that some surgeons use. In the future, it will be useful to better understand the selection criteria that surgeons at our institution use to select a given patient for Nissen or partial fundoplication. These unmeasured criteria may be important in predicting the success of an antireflux operation and could assist in the selection of the optimal operation for each patient. It will also be important to continue long-term follow-up of patients so that we can understand how persistent postoperative dysphagia may change over time.

There are several limitations to this study. We did not have complete information on which patients had preoperative dysphagia, which has been shown in prior studies to increase the risk of persistent postoperative dysphagia.^{10,11} In addition, we had incomplete data on if patients had early postoperative dysphagia that resolved before one year, which could be an additional predictor of persistent postoperative dysphagia. We also had incomplete data on

preoperative manometry and pH studies, which prohibited their use in our analysis. However, several studies have shown that manometry results or abnormal esophageal motility has not predicted the risk for persistent postoperative dysphagia.^{10,25,26} In addition, we were unable to include mesh use in the multivariable logistic regression model since we were limited in the number of variables to include by our sample size and the number of events of persistent postoperative dysphagia. This is a retrospective study and selection bias may have affected our primary outcome since there is variation in surgeon preference in how to choose the type of fundoplication for a given patient. Lastly, while we were able to obtain follow-up information on 57.8% of patients, there are some patients lost to follow-up which may introduce bias to our results.

Conclusion

Close to one-quarter of anti-reflux surgery patients experienced some degree of dysphagia that persisted for at least one-year after surgery. Our findings suggest that the choice of fundoplication was not associated with this persistent dysphagia in properly selected patients. Tailoring the type of fundoplication to patient characteristics is a reasonable treatment approach.

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Figure 1.
Distribution of difficulty swallowing scores from the GERD-HRQL questionnaire

Table 1.

Demographic and clinical characteristics of antireflux surgery patients with follow-up > 1 year.

Characteristic	Total (N=255)	Nissen (N=115)	Toupet/Dor (N=140)	p-value
Female (%)	185 (72.5)	74 (64.3)	111 (79.3)	0.008
Age (mean±SD) ^a	58.3±14.0	52.6±13.2	63.0±12.9	<0.001
Age group (%)				
<60	127 (49.8)	77 (67.0)	50 (35.7)	<0.001
60–70	79 (31.0)	34 (29.6)	45 (32.1)	
70	49 (19.2)	4 (3.5)	45 (32.1)	
BMI (mean±SD) ^a	30.4±5.4	30.6±5.2	30.2±5.5	0.251
BMI ≥30 vs. <30 (%)	128 (50.2)	61 (53.0)	67 (47.9)	0.410
Number of Reflux episodes (mean±SD) ^{a b}	75.8±44.7	74.5±47.2	77.7±41.3	0.612
Ineffective esophageal motility (%) ^c	30 (22.4)	9 (12.7)	21 (33.3)	0.004
Primary vs. re-do (%)	211 (82.8)	101 (87.8)	110 (78.6)	0.052
Mesh (%)	103 (40.4)	34 (29.6)	69 (49.3)	0.001

^aWilcoxon test was used because of non-normal distribution.^bMissing=159.^cMissing=121

Table 2.

Postoperative outcomes in Nissen and partial fundoplication patients with follow-up > 1 year.

	Nissen (n=115)	Toupet/Dor (n=140)	P-value
Persistent Postoperative Dysphagia (%)	31 (26.7)	35 (25.0)	0.72
Postoperative Bloating (%)			0.64
None	65 (56.5)	87 (62.1)	
Mild	21 (18.3)	21 (15.0)	
Moderate/Severe	29 (25.2)	32 (22.9)	
Postoperative reflux score (mean±SD)	2.85±5.77	3.17±5.57	0.65

Table 3.

Logistic regression analysis of predictive factors for persistent dysphagia (difficulty swallowing > 0).

Characteristic	Univariate (n=255)			Multivariate (n=255)		
	OR	95% CI	P-value	OR	95% CI	P-value
Age (vs. <60)	ref	-	-	ref	-	-
[60, 70)	1.06	0.56, 1.98	0.866	1.00	0.52, 1.91	0.994
70	0.70	0.32, 1.56	0.384	0.69	0.29, 1.65	0.402
BMI 30 (vs. <30]	0.99	0.56, 1.73	0.970	0.90	0.51, 1.61	0.726
Female (vs. male)	1.40	0.72, 2.69	0.319	1.48	0.75, 2.94	0.260
Primary (vs. re-do)	0.80	0.39, 1.64	0.542	0.77	0.37, 1.60	0.482
<i>Total (vs. partial) fundoplication</i>	<i>1.11</i>	<i>0.63, 1.94</i>	<i>0.723</i>	<i>1.09</i>	<i>0.59, 2.03</i>	<i>0.777</i>