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## Variability in endoscopic assessment of Nissen fundoplication wrap integrity and hiatus herniation

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**SUMMARY. Background:** Upper endoscopy (EGD) is frequently performed in patients with esophageal complaints following anti-reflux surgery such as fundoplication. Endoscopic evaluation of fundoplication wrap integrity can be challenging. Our primary aim in this pilot study was to evaluate the accuracy and confidence of assessing Nissen fundoplication integrity and hiatus herniation among gastroenterology (GI) fellows, subspecialists, and foregut surgeons. **Methods:** Five variations of post-Nissen fundoplication anatomy were included in a survey of 20 sets of EGD images that was completed by GI fellows, general GI attendings, esophagologists, and foregut surgeons. Accuracy, diagnostic confidence, and inter-rater agreement across providers were evaluated. **Results:** There were 31 respondents in the final cohort. Confidence in pre-survey diagnostics significantly differed by provider type (mean confidence out of 5 was 1.8 for GI fellows, 2.7 for general GI attendings, 3.6 for esophagologists, and 3.6 for foregut surgeons,  $P = 0.01$ ). The mean overall accuracy was 45.9%, which significantly differed by provider type with the lowest rate among GI fellows (37%) and highest among esophagologists (53%;  $P = 0.01$ ). The accuracy was highest among esophagologists across all wrap integrity variations. Inter-rater agreement was low across wrap integrity variations (Krippendorff's alpha <0.30), indicating low to no agreement between providers. **Conclusion:** In this multi-center survey study, GI fellows had the lowest accuracy and confidence in assessing EGD images after Nissen fundoplication, whereas esophagologists had the highest. Diagnostic confidence varied considerably and inter-rater agreement was poor. These findings suggest experience may improve confidence, but highlight the need to improve the evaluation of fundoplication wraps.

**KEY WORDS:** anti-reflux surgery, endoscopy, gastroesophageal reflux disease, Nissen fundoplication, trainees.

### INTRODUCTION

Gastroesophageal reflux disease is common and proton pump inhibitors (PPIs) are first-line therapy for erosive esophagitis and esophageal symptoms such as heartburn.<sup>1,2</sup> However, approximately 32–45%

of patients have inadequate symptomatic response with medical therapy alone.<sup>3</sup> As a result, anti-reflux surgery (ARS) is frequently performed in patients who are intolerant of, unwilling to use, or unresponsive to PPIs.<sup>4</sup>

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Laparoscopic Nissen fundoplication is the most commonly performed ARS.<sup>5,6</sup> Although largely effective,<sup>7–9</sup> Nissen fundoplication is associated with several side effects such as dysphagia and gas bloat syndrome related to properties of the operative intervention itself. However, after surgery, as many as 64% of patients can have recurrence of reflux symptoms,<sup>9,10</sup> which may result from breakdown of the crural repair, laxity or migration of the wrap, hiatal herniation, or other reasons. Because between 3 and 10% of patients will eventually undergo surgical revision,<sup>11–13</sup> investigating post-operative esophageal complaints to determine wrap integrity is important.<sup>14</sup>

Upper endoscopy (EGD) is frequently performed<sup>10,15–17</sup> to elucidate whether the wrap may be too tight, loose, migrated, or disrupted.<sup>6,9,18</sup> However, previous studies comparing post-operative endoscopic findings between referring physicians and esophageal experts reported high rates of misinterpretation of endoscopic findings.<sup>19</sup> As a result, radiographic or esophageal function tests are often added to the diagnostic evaluation,<sup>20,21</sup> though these data are complementary and may result in incomplete detail or conflicting reports, as well as disagreements among interpreting providers.<sup>22</sup> Endoscopy therefore remains routine. There are no data, though, comparing the endoscopic evaluation post-fundoplication among different specialties and by levels of experience nor are there any data on diagnostic confidence among providers. In this study, we aimed to assess for differences in accuracy and confidence among esophagologists, general gastroenterology (GI) attendings, GI fellows, and foregut surgeons in interpreting endoscopic images of patients following Nissen fundoplication.

## METHODS

### Study population and sampling strategy

Participants were invited from six geographically diverse academic medical centers and their community-affiliated hospitals, including North Carolina, Minnesota, Illinois, Michigan, California, and New York. Inclusion criteria included current GI or foregut surgery clinical practice, though no restrictions were made on frequency of clinical care. Self-identified esophagologists, general GI attendings, GI fellows, and foregut surgeons were recruited, none of whom participated in study development. Eligible participants were identified from participating institutions with GI training programs. Subjects were recruited via an email introduction with details of the study and those who completed at least 11 of the 20 questions (with at least 1 question of each image type) were included in the final analysis.

The first email invitation was sent on October 26, 2020, and a single reminder email was sent to non-

responders before the survey was closed in November 11, 2020. There was no compensation provided for survey completion.

All authors had access to the study data and reviewed and approved the final manuscript. This study was reviewed and deemed exempt by the institutional review boards at Duke University, University of California San Diego, University of Michigan, Zucker School of Medicine at Hofstra/Northwell, Mayo Clinic, and Northwestern University.

### Survey development and distribution

We developed a 28-question survey instrument. Survey domains included demographic information such as self-identified gender, number of years since training was completed, and primary practice area.

Post-Nissen fundoplication EGD images from at least three retroflexed views were collected retrospectively from the participating tertiary care medical centers. Images included representations of five variations in wrap integrity (intact without hernia; disrupted without hernia; disrupted with paraesophageal hernia (PEH); intact with sliding hernia; disrupted with sliding hernia). Although there is no universally accepted system for evaluating post-fundoplication anatomy endoscopically,<sup>14</sup> these categories were thought to capture the major anatomic complications.<sup>10</sup> Because barium esophagram or operative results, which could be considered definitive of wrap orientation, were not uniformly available, the gold standard used in our study was expert consensus. Only images with unanimous wrap integrity agreement among the esophagologist study investigators were included to ensure accuracy of the EGD diagnosis.

Using these de-identified images, the survey was distributed through individual email via a secure REDCap (Research Electronic Data Capture, Nashville, TN) hosted at Duke University,<sup>23,24</sup> which is a secure, web-based software platform designed to support data capture for research. One set of training images was provided. The final survey included 20 unique sets of images. Additionally, 8 image sets repeated to assess for intra-rater agreement, resulting in a total of 28 case vignettes (examples in [Supplementary Materials](#)). When available, images included the following views: (i) en face immediately above the GEJ, (ii) retroflexion in neutral position, (iii) left lateral, (iv) right lateral, and/or (v) near-view images. The evaluation of Nissen fundoplication integrity was assessed by multiple choice options. Respondents assessed their confidence in endoscopic assessment of fundoplication wraps at the onset of the study, and for each set of images throughout the survey using a 5-point Likert scale. No patient-specific data, complementary imaging, or clinical

information such as presenting symptoms were included with the images.

### Statistical analysis

The primary aim of the study was to determine diagnostic accuracy in assessing Nissen fundoplication wrap integrity with endoscopic images. The analysis was stratified by provider type. Secondary aims included evaluating diagnostic confidence and determining inter-rater agreement. An exploratory aim was evaluating intra-rater reliability among duplicate images. For diagnostic confidence, scores on a Likert scale were evaluated as a continuous variable. To minimize confounding, the response to a second image in a duplicate pair was not included in the analysis for accuracy, confidence, or inter-rater reliability and was only used to assess intra-rater agreement. For each respondent, average proportion correct (mean across answered questions) was calculated for each image type. Accuracy and confidence for each image type and by provider type was evaluated using Chi-square, Kruskal-Wallis, or ANOVA F test as appropriate. For inter-rater agreement, Krippendorff's alpha<sup>25,26</sup> was used to measure the agreement among raters within practice type and image type. To assess intra-rater agreement, Cohen's kappa was calculated for each image pair. All analysis was performed using SAS version 9.4 (Cary, NC).

### RESULTS

Of 256 survey invitations sent via email, there were 48 (19%) responses. Ultimately 31 (65%) respondents from six academic institutions met inclusion criteria and were included in the analysis. Years in training ranged from 'currently in training' to greater than 20 years since completion of fellowship. At least six respondents from each of the provider types were included in the final analysis (Table 1).

Diagnostic confidence assessed prior to starting the survey varied significantly by provider type ( $P=0.01$ ). Specifically, confidence was lowest among GI fellows (mean 1.8, standard deviation [SD] 0.8) and highest among foregut surgeons (mean 3.6, SD 1.1) and esophagologists (mean 3.8, SD 0.9). This pattern in pre-survey confidence was consistent and significant for each wrap integrity variation, with the lowest confidence in fellows and the highest confidence in esophagologists and foregut surgeons regardless of the wrap integrity variation (Fig. 1).

Overall accuracy was subjectively low, with an average of 45.9% of cases correctly identified across all providers (Fig. 2). There was a significant difference in overall accuracy between providers ( $P=0.01$ ), with esophagologists having the highest overall accuracy

**Table 1** Demographic characteristics (N = 31)

Provider type	
Esophagologists	8 (25.8%)
General GI attendings	9 (29.0%)
GI fellows	9 (29.0%)
Foregut surgeons	5 (16.1%)
Gender identity	
Male	20 (64.5%)
Female	11 (35.5%)
Numbers of years since training completed	
Currently in training	9 (29.0%)
1–5	8 (25.8%)
6–10	2 (6.5%)
11–15	1 (3.2%)
16–20	8 (25.8%)
>20	3 (9.7%)

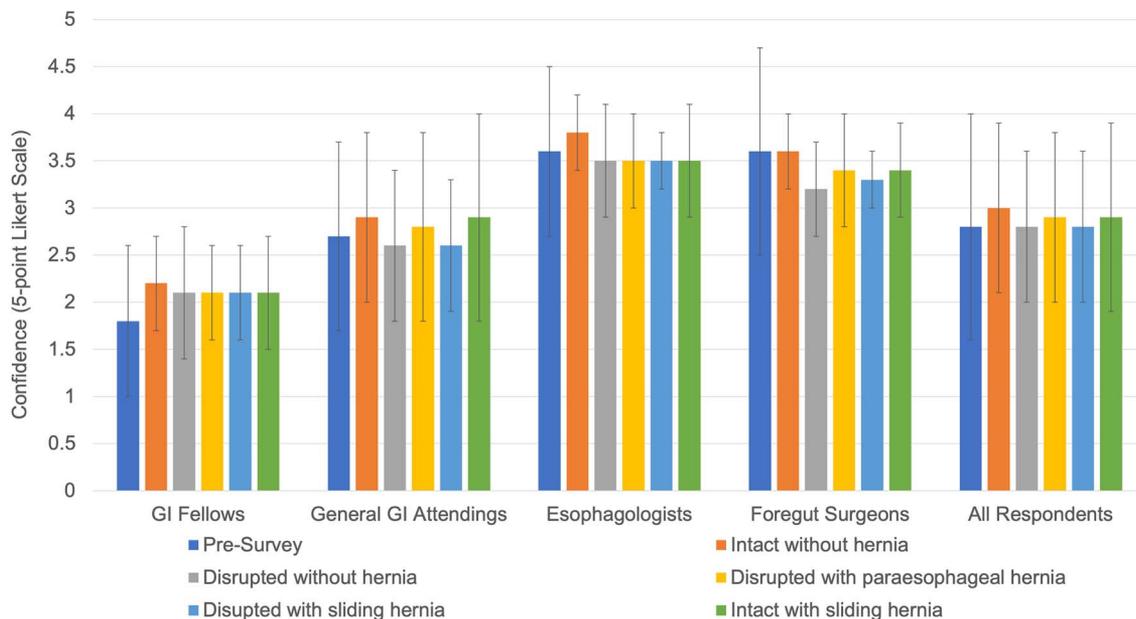
Thirty-one respondents were included in the final study. Respondents spanned two specialties (GI and foregut surgery) with up to 20 years in practice. The nine fellows still in training who responded to the survey were not stratified by training year due to small sample size.

(mean 52.5% correct, SD 11.0%) and GI fellows the lowest (mean 37.0% correct, SD 10.3%). Accuracy by provider type did not differ significantly within wrap integrity variation, but across all providers was highest accuracy was assessing intact wraps without hernia (mean accuracy 82.4%, SD 19.7%) and lowest for disrupted wraps with PEH (mean accuracy 22.3%, SD 17.8%). There were notable, although not statistically significant, differences between fellow and esophageal attending accuracy for identifying disrupted wraps with sliding hernias (20.4% vs. 41.7%, respectively). There was less of a difference between fellow and esophageal attending accuracy for identifying disrupted wraps with PEH (23.3% vs. 27.5%).

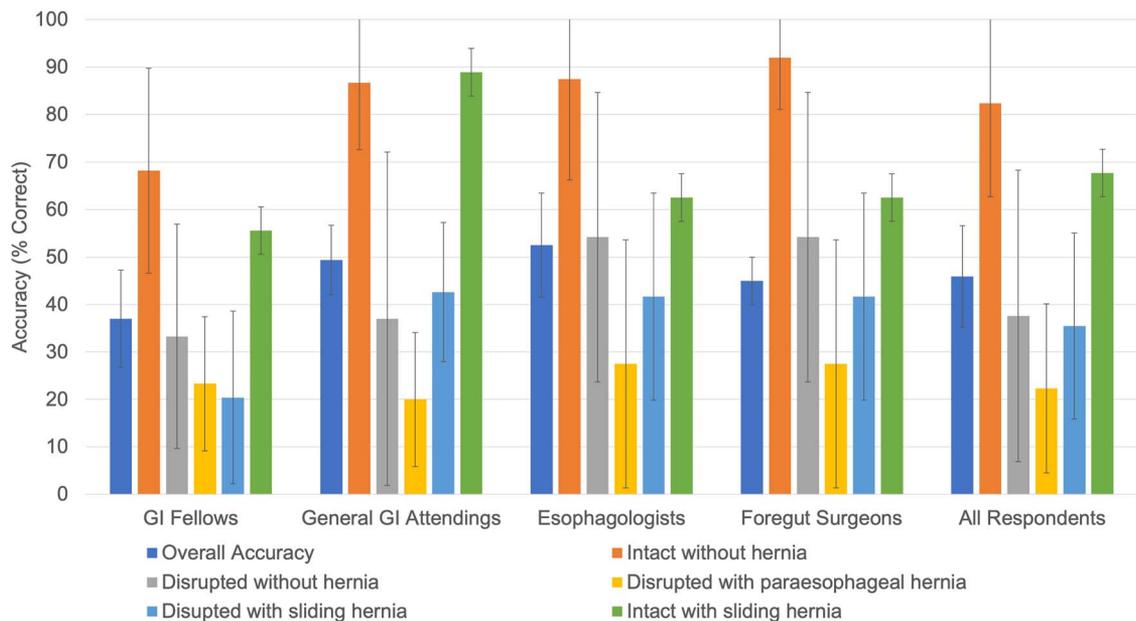
Inter-rater agreement was low across all provider groups and wrap integrity variations (Table 2). Krippendorff's alpha typically ranges from 0 to 1, with 1 indicating perfect agreement. Negative values are possible and indicate less than chance disagreement. Across each wrap integrity variation, provider inter-rater reliability was alpha <0.30, indicating low to no agreement between providers within each provider type. Intra-rater reliability between paired images ranged from kappa = 0.00 to 0.67, or none to moderate agreement between paired responses (Supplementary Material 2).

### DISCUSSION

Nissen fundoplication is the most common ARS performed and many patients undergo endoscopic evaluation post-operatively if esophageal symptoms such as heartburn, chest pain, regurgitation, and/or dysphagia occur after surgery. Endoscopic evaluation may vary by provider despite its value for determining wrap integrity. Our study evaluated both accuracy and confidence in the endoscopic assessment of wrap



**Fig. 1** Confidence in endoscopic evaluation of Nissen fundoplication integrity. *P*-values were calculated for pre-survey and by image type, across provider groups: pre-survey ( $P = 0.01^*$ ), intact without hernia ( $P < 0.01^*$ ), disrupted without hernia ( $P < 0.01^*$ ), disrupted with PEH ( $P < 0.01^{**}$ ), disrupted with sliding hernia ( $P < 0.01^*$ ) and intact with sliding hernia ( $P = 0.01^*$ ). \*Kruskal-Wallis test. \*\*ANOVA F-test.



**Fig. 2** Accuracy in endoscopic evaluation of Nissen fundoplication integrity. Bars represent mean accuracy in percentages. Error lines represent standard deviation. *P*-values were calculated for overall accuracy and by image type, across provider groups: pre-survey ( $P = 0.01^*$ ), intact without hernia ( $P = 0.07^{**}$ ), disrupted without hernia ( $P = 0.25^*$ ), disrupted with PEH ( $P = 0.80^*$ ), disrupted with sliding hernia ( $P = 0.07^*$ ), and intact with sliding hernia ( $P = 0.46^*$ ). \*Kruskal-Wallis test. \*\*ANOVA F-test.

integrity after surgery by multiple specialists and by levels of training. In this multi-center survey study, we found that GI fellows had the lowest accuracy and confidence in assessing EGD images after Nissen fundoplication, whereas esophagologists had the highest. Despite the differences in confidence, overall accuracy was low for all wrap variations except when intact without hernia.

The importance of accurate diagnostic interpretation of the endoscopic view of a fundoplication

and consistent nomenclature for describing findings has been previously affirmed. Although data are limited, prior studies demonstrated substantial variations in endoscopic wrap interpretation.<sup>14,19</sup> Our present study confirms the variation in interpreting endoscopic images of a Nissen fundoplication. Furthermore, we found these differences are more pronounced by practitioner type. Although it is not unexpected that esophagologists would have higher accuracy and confidence compared to trainees,

**Table 2** Inter-rater reliability in endoscopic evaluation of Nissen fundoplication integrity

Reliability (95% CI) <sup>†</sup>	Esophagologists (N = 8)	General GI attendings (N = 9)	GI fellows (N = 9)	Foregut surgeons (N = 5)
Intact without hernia	-0.05 (-0.40, 0.27)	0.20 (-0.03, 0.46)	0.20 (0.04, 0.34)	-0.04 (-0.70, 0.61)
Disrupted without hernia	0.29 (0.08, 0.47)	-0.03 (-0.224, 0.178)	-0.03 (-0.21, 0.18)	-0.17 (-0.65, 0.32)
Disrupted with PEH	0.14 (-0.05, 0.34)	0.02 (-0.19, 0.22)	-0.01 (-0.19, 0.20)	0.29 (-0.14, 0.71)
Disrupted with sliding hernia	-0.01 (-0.16, 0.15)	0.24 (0.10, 0.37)	0.12 (-0.07, 0.32)	-0.14 (-0.41, 0.13)
Intact with sliding hernia	0.00 (-0.33, 0.33)	0.00 (-0.75, 0.63)	0.00 (-0.25, 0.30)	0.00 (-0.50, 0.50)

<sup>†</sup>Krippendorff's alpha.

Inter-rater agreement was low across all provider groups and wrap integrity variations. Krippendorff's alpha was used to measure the agreement among raters within practice type and image type. Across each wrap integrity variation, provider inter-rater reliability was alpha <0.3.

this highlights an important knowledge gap and opportunity for improvement.

It is less clear, however, why the overall accuracy was consistently poor with the exception of normal appearing wraps. As others have argued, the terminology to describe endoscopic Nissen findings is variable<sup>19</sup> and several classifications including the Hinder and Horgan exist, which are not necessarily congruent.<sup>6,27</sup> As a result, the poor accuracy we found may be due in part to the lack of clear language used to describe anatomy following ARS.<sup>28</sup> Although we did not include a set of definitions in the survey to which respondents could refer, the inclusion of a training example and use of standardize multiple choice answers is expected to have minimized potential variation. In addition to the differences observed among practitioner types, we identified notable differences by wrap integrity variation. Variations in wrap breakdown and migration resulted in overall poor accuracy, ranging from 22.3 to 62.5% in wraps with complications, compared to 82.4% mean accuracy in normal wraps that were intact without hernia. Examples of normal post-operative images are widely available, though many variations of abnormal exist<sup>10</sup> so our findings may be due in part to the lack of easily recalled examples of abnormal paradigms.

An accurate diagnosis of esophageal symptoms after Nissen fundoplication relies on the integration of a patient's history and a multi-modal diagnostic work-up. Although barium radiography and endoscopy are often adjunctive for a diagnosis, interpretation variability has been identified when comparing surgical and radiographic assessments of wrap integrity.<sup>29</sup> Although it is therefore possible that some of the low confidence and accuracy identified was due to the nature of the task which asked respondents to make an assessment of the endoscopic findings alone, our study aimed to specifically assess such a scenario to minimize the potential bias that additional clinical data would introduce.

The need for ancillary information in order to make an accurate diagnosis may be more pronounced with less experience. This observation could explain

the significantly lower confidence and accuracy among trainees. However, the use of additional testing does not always clarify the nature of the fundoplication failure or symptom etiology. In a small study, endoscopic evaluation was able to detect more post-fundoplication abnormalities compared to the barium esophagram.<sup>22</sup> Newer technologies such as the endolumenal functional lumen imaging probe (EndoFLIP, Crospon, Galway, Ireland), which can measure the esophageal cross-sectional area, motility, and intraluminal pressure of the esophagus when distended,<sup>30</sup> are commonly integrated into this diagnostic algorithm. Although data support its use intra-operatively during wrap creation,<sup>31</sup> its role for evaluating recurrent symptoms is not yet clear. The use of traditional esophageal function tests is also imperfect.<sup>32</sup>

Ultimately, confidence in the endoscopic evaluation is critical but appears lacking. In 2007, a questionnaire study showed large variability in the interpretation of endoscopy images assessing the distal esophagus and pyloric antrum.<sup>33</sup> In this study, a higher level of experience did not imply higher levels of inter or intra-observer agreement. We did evaluate for intra-rater reliability, which was inconsistent. These data were exploratory in nature and given the small sample size would caution against making any larger conclusions from these results other than further study is needed in this regard. Even still, our findings suggest that an emphasis on tracking trainee skill in assessing commonly encountered anatomic variations may also be valuable.

Our study, however, is not without limitations. Firstly, as previously acknowledged, an assessment of fundoplication integrity after surgery frequently involves integrating several data points that were not available to respondents. Further, assessment was made based on static images, rather than video. Similar studies have been conducted in the past,<sup>33-35</sup> and there is no intrinsic reason to believe video would provide superior assessment; indeed, static image reports are standard when seeing patients as referrals in this clinical context. No definitions were provided

to respondents for reference, and establishing a consensus terminology has been identified as an important goal for improving post-fundoplication assessment. Based on our conclusions, an area of future investigation should be aimed at defining the language used to describe endoscopic images following fundoplication. Having standardized reporting of endoscopic findings in these scenarios would help establish best practices in this patient population.

Further, our overall response rate was low and sample size limited. However, this was an exploratory study aimed to identify an area in which improvement is needed. Indeed, we were still able to determine important and significant differences even within this limited sample, which was well-balanced across provider types. Future studies are needed to affirm these findings and further evaluate the impact standardize terms have on reliable endoscopic assessment of fundoplication wraps. Given the small sample size, GI fellows were not stratified by training year. Finally, our study was conducted only in academic centers, focusing exclusively on Nissen fundoplication, and therefore the generalizability may be limited. But, there are no data that other variations in anti-reflux surgical wraps would be more or less difficult to assess so we chose to minimize confounding by limiting to Nissen fundoplication only, which are the most widely utilized surgical approach.

In conclusion, our study revealed GI fellows had both the lowest accuracy and confidence in assessing EGD images following a Nissen fundoplication. Esophagologists had the highest confidence; however, overall accuracy was low for all wrap variations. These findings support that experience, and clinical focus may improve provider confidence. Increased diagnostic accuracy at EGD in the evaluation of wrap integrity and hiatus herniation after fundoplication remains an area of need throughout all training levels.

## ABBREVIATIONS

GI	gastroenterology
EGD	upper endoscopy
ARS	anti-reflux surgery
PPI	proton pump inhibitor

## SUPPLEMENTARY DATA

Supplementary data mentioned in the text are available to subscribers in DOTESO online.

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