The Role of High-Resolution Manometry Before and Following Antireflux Surgery

The Padova Consensus

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Background: In the last 2 decades the development of high-resolution manometry (HRM) has changed and revolutionized the diagnostic assessment of patients complain foregut symptoms. The role of HRM before and after antireflux procedure remains unclear, especially in surgical practice, where a clear understanding of esophageal physiology and hiatus anatomy is essential for optimal outcome of antireflux surgery (ARS). Surgeons and gastroenterologists (GIs) agree that assessing patients following antireflux procedures can be challenging. Although endoscopy and barium-swallow can reveal anatomic abnormalities, physiological information on HRM allowing insight into the cause of eventually recurrent symptoms could be key to clinical decision-making.

Methods: A multidisciplinary international working group (14 surgeons and 15 GIs) collaborated to develop consensus on the role of HRM pre-ARS and post-ARS, and to develop a postoperative classification to interpret HRM findings. The method utilized was detailed literature review to develop statements, and the RAND/University of California, Los Angeles Appropriateness Methodology (RAM) to assess agreement with the statements. Only

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NIH K23 DK125266 (R.Y., Primary Investigator). NIH K23DK131317 (A.J. Co-Investigator).

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Supplemental Digital Content is available for this article. Direct URL citations are provided in the HTML and PDF versions of this article on the journal's website, www.annalsofsurgery.com.

DOI: 10.1097/SLA.0000000000006297

statements with an approval rate >80% or a final ranking with a median score of 7 were accepted in the consensus. The working groups evaluated the role of HRM before ARS and the role of HRM following ARS.

Conclusions: This international initiative developed by surgeons and GIs together, summarizes the state of our knowledge of the use of HRM pre-ARS and post-ARS. The Padova Classification was developed to facilitate the interpretation of HRM studies of patients underwent ARS.

Keywords: achalasia, bariatric surgery, foregut surgery, fundoplication, gastroesophageal reflux disease

(*Ann Surg* 2025;281:124–135)

BACKGROUND

Over the past 20 years, high resolution manometry (HRM) has become an essential component of the algorithm for assessing patients with unexplained foregut symptoms, especially dysphagia and chest pain. The hierarchical value of HRM to diagnose esophageal motility disorders is well defined by the Chicago Classification (CC), now in its fourth iteration. However, the role of HRM before and after antireflux surgery remains unclear, especially in surgical practice, where a clear understanding of esophageal physiology and foregut anatomy is essential for optimal outcome of antireflux surgery (ARS). Further, assessing patients following ARS can be challenging. Although endoscopy and barium esophagram can reveal anatomic abnormalities, physiological information from HRM may provide insight into the mechanisms of recurrent symptoms, with potential value in clinical decision-making. However, whether HRM can be used to differentiate the causes of recurrent symptoms or failure of foregut surgery is still a matter of debate.

A multidisciplinary international working group of foregut surgeons and gastroenterologists collaborated to develop consensus on the role of HRM pre-ARS and post-ARS, and to develop a postoperative classification to interpret HRM findings after laparoscopic fundoplication.

METHODS

The Padova initiative was a prospective multidisciplinary international initiative conducted over 3 years (July 2020 to June 2023) that utilized a detailed literature review to develop statements, and the RAND/University of California, Los Angeles Appropriateness Methodology (RAM) to assess agreement with the statements. The Padova Working Group is comprised of 29 members (14 foregut surgeons and 15 gastroenterologists) from 22 centers across North American and Europe. The selection criteria included leadership in the field of foregut surgery, peer-reviewed publications and diversity of geography and practice setting. The overarching aim was to generate recommendation statements regarding the role of HRM in ARS and bariatric surgery. This paper presents the statements regarding ARS.

The ARS working groups consisted of 3 subgroups, each evaluating one of the following sections: (1) candidacy for ARS, (2) role of HRM before ARS, (3) role of HRM following ARS. Each subgroup, co-chaired by a gastroenterologist and foregut surgeon, proposed a list of recommendation statements specific to their group. Four nonvoting members (2 gastroenterologists and 2 foregut surgeons) were recruited to perform an external literature review supporting the recommendation statements.

The first working group meeting was conducted virtually on October 27, 2020. Statements in the sections of Role of HRM before ARS and Role of HRM following ARS underwent voting per RAM protocol. Between meetings 1 and 2 the members independently ranked the proposed statements using an electronic survey generated using REDCap (University of California San Diego). As per RAM protocol, the panel members were explicitly instructed not to consider cost implications or the feasibility of implementing the recommendations in their rankings. The panelists were advised to apply their ranking to the average patient presenting to the average physician at an average facility. Each statement was ranked on a 9-point interval scale where a score of 1 to 3 was considered inappropriate, 4 to 6 was of uncertain appropriateness and 7 to 9 was deemed appropriate. The panelists also had the opportunity to provide comments regarding each proposed statement and suggest modifications. The second meeting was conducted virtually on September 15, 2022. Before this meeting, a folder with individual summary results of the initial rankings with overall aggregated ranking results was provided to each panelist, along with a summary of the literature review for each suggested statement. During this meeting, 2 panelists reviewed existing literature and discussed areas of disagreement followed by rewording statements when applicable. The panelists then reranked each statement for their perceived levels of appropriateness. Per RAM protocol, statements met definition as appropriate when the final ranking had a median score of 7 or greater with 80% or more in agreement that the statement was appropriate.

ROLE OF HRM BEFORE AND FOLLOWING ANTIREFLUX SURGERY

Candidacy for Antireflux Surgery

A discussion surrounding candidacy for ARS is presented before the recommendation statements regarding the role of HRM in relation to ARS to highlight the recommended approach in considering candidacy for ARS.

According to available literature, ARS is indicated for patients with typical gastro-esophageal reflux disease (GERD) symptoms (heartburn and/or regurgitation) with objective evidence of pathologic reflux on endoscopy and/or on ambulatory reflux monitoring.[1–4] The best candidates for ARS include patients who respond to proton pump inhibitors (PPIs), have objective evidence of reflux on endoscopy (Los Angeles Grade B or higher; long-segment Barrett esophagus), and/or a hiatal hernia, and correlation between symptoms and reflux events on ambulatory reflux monitoring.[5–9] For patients with chest pain a negative cardiac evaluation should be confirmed preoperatively.[10–15] Of note, ARS can also be offered to patients not responding to PPI and/or with extraesophageal symptoms in the setting of an abnormal reflux burden defined by abnormal esophageal acid exposure, and/or a positive symptom-reflux association for regurgitation-predominant symptoms with a clinically significant hiatal hernia. Overall, such patients should be counseled regarding the potential for persistence of symptoms after ARS, potential dysphagia, inability to belch, flatulence, and bowel symptoms.[16–25]

Preoperative evaluation of all patients being considered for ARS should include endoscopy, barium esophagogram, esophageal manometry, and reflux monitoring OFF PPI therapy (unless objective evidence of reflux is present on endoscopy).[5–9] The use of additional tests such as gastric emptying studies and functional lumen imaging probe (FLIP) may be useful preoperatively in the setting of dyspepsia or to evaluate the compliance of the lower esophageal sphincter (LES), respectively, but no evidence exists to associate results of these tests with ARS outcomes.[26,27] Prospective studies are needed to evaluate the value of these tests in predicting post-ARS outcome.

In patients presenting with large hiatal hernia (HH) as the primary abnormality, surgical risk related to age and comorbidities should be thoroughly weighed against the risk of complications from HH morphology and size. In patients with: large paraesophageal HH (type 2), combined axial and paraesophageal HH (type 3) or massive herniation of bowel and intra-abdominal organs (type 4), gastric volvulus represents an absolute indication for emergency surgical treatment. In truly asymptomatic subjects with isolated paraesophageal HH (type 2), available data suggest that the likelihood of life-threatening complications is relatively low, therefore the need for elective surgery should be carefully weighed. Age and ASA score are the major determinants of the postoperative morbidity.[28–34] Large type 3 or type 4 hernias are rarely asymptomatic, with risk of acute life-threatening events like gastric bleeding or perforation due to hypoperfusion from gastric volvulus. Elective laparoscopic repair is safe, even in elderly patients, where prevention of these life-threatening adverse events needs to be factored in to decision-making for surgical treatment. In high-risk asymptomatic patients with mild or no symptoms, a "watchful waiting" strategy could be considered, due to the relatively high recurrence rate after surgery.[28–43] Conversely, the risk of an axial HH (type 1) progressing to a large symptomatic hernia or leading to life-threatening complications is very low. Therefore, in absence of reflux symptoms, surgical treatment is not routinely indicated for small axial HH (type 1).[44,45]

The role of high body mass index (BMI) in increasing the risk of complications following ARS for HH continues to be debated. While older reports suggested a higher risk of recurrence and adverse events following fundoplication for HH in overweight patients, current evidence suggests that antireflux procedures can be performed safely both in the overweight (BMI = 25–30 kg/m^2) and in the obese patients (BMI > 30 kg/m^2), with short-term outcomes comparable to that in normal-weight subjects. The long-term durability of reflux control, however, is worse among obese patients and no conclusive data exists regarding choice of fundoplication type, although Nissen fundoplication is more frequently performed. Moreover, the indication of fundoplication for BMI > 35 kg/m^2 subjects should be thoroughly evaluated since bariatric procedures may be more suitable in such patients. Indeed, Roux-en-Y gastric bypass has been demonstrated to effectively control reflux and is therefore currently recommended as the procedure of choice for obese patients with BMI > 35 kg/m^2 and GERD.[46–59]

HRM Before Antireflux Surgery

The following recommendation statements discuss the contemporary role of HRM before ARS (Table 1, Figure 1).

The evaluation of esophageal motility with HRM is essential to exclude motor disorders not amenable to antireflux surgery (median score 9, 89% agreement)

HRM is particularly important before ARS as transit symptoms such as dysphagia can escalate if ARS is performed in patients with disorders of esophageal outflow, particularly those in the achalasia spectrum. In a study of over 1000 patients undergoing HRM before ARS, 3% were found to have esophagogastric (EGJ) obstruction suspicious for achalasia-spectrum disorders where standard ARS would have significantly worsened esophageal transit.[18] Another study of 524 achalasia patients reported that 29% had been referred for ARS because of incomplete response to GERD management.[60] Identification of achalasia on HRM changes the management strategy in these instances. Since the integrated relaxation pressure (IRP) can be within the normal range infrequently in achalasia,[1] the diagnosis of absent contractility in the context of dysphagia requires alternate testing with barium radiography or FLIP to objectively exclude achalasia before ARS.

A finding of LES obstruction, as defined by the updated manometric criteria of EGJOO in CC v4.0, must be addressed before undertaking antireflux surgery (median score 8, 86%)

Of particular importance, EGJ outflow obstruction (EGJOO) is a heterogenous motor pattern that could

TABLE 1. Recommendations in Padova Classification for Role of HRM Before Antireflux Surgery

Statement	Median	Range	Ranked appropriate (%)
HRM before antireflux procedure			
The evaluation of esophageal motility with HRM is essential to exclude motor disorders not amenable to antireflux surgery	9	5, 9	89
A finding of LES obstruction, as defined by the updated manometric criteria of EGJOO in CC v4.0, must be addressed before undertaking antireflux surgery	8	4, 9	86
In presence of objective evidence of GERD patients with hypercontractile esophagus, as defined by CC v4.0 criteria, with typical reflux symptoms, with at least partial symptom improvement with antisuppresion medications, can be referred for antireflux surgery.	7	5, 9	81
Antireflux surgery should be considered with caution in patients with distal esophageal spasm on manometry in the setting of obstructive symptoms of dysphagia and/or chest pain	8	2, 9	95
In presence of objective evidence of GERD and in the absence of obstructive symptoms patients with distal esophageal spasm can be referred for antireflux surgery.	7	5, 9	81
EGJ barrier function should be assessed by HRM, using the metrics of LES end expiratory pressure, LES baseline pressure or EGJ-CI and including the presence of a hiatal hernia (LES-CD separation)	8	3, 9	85

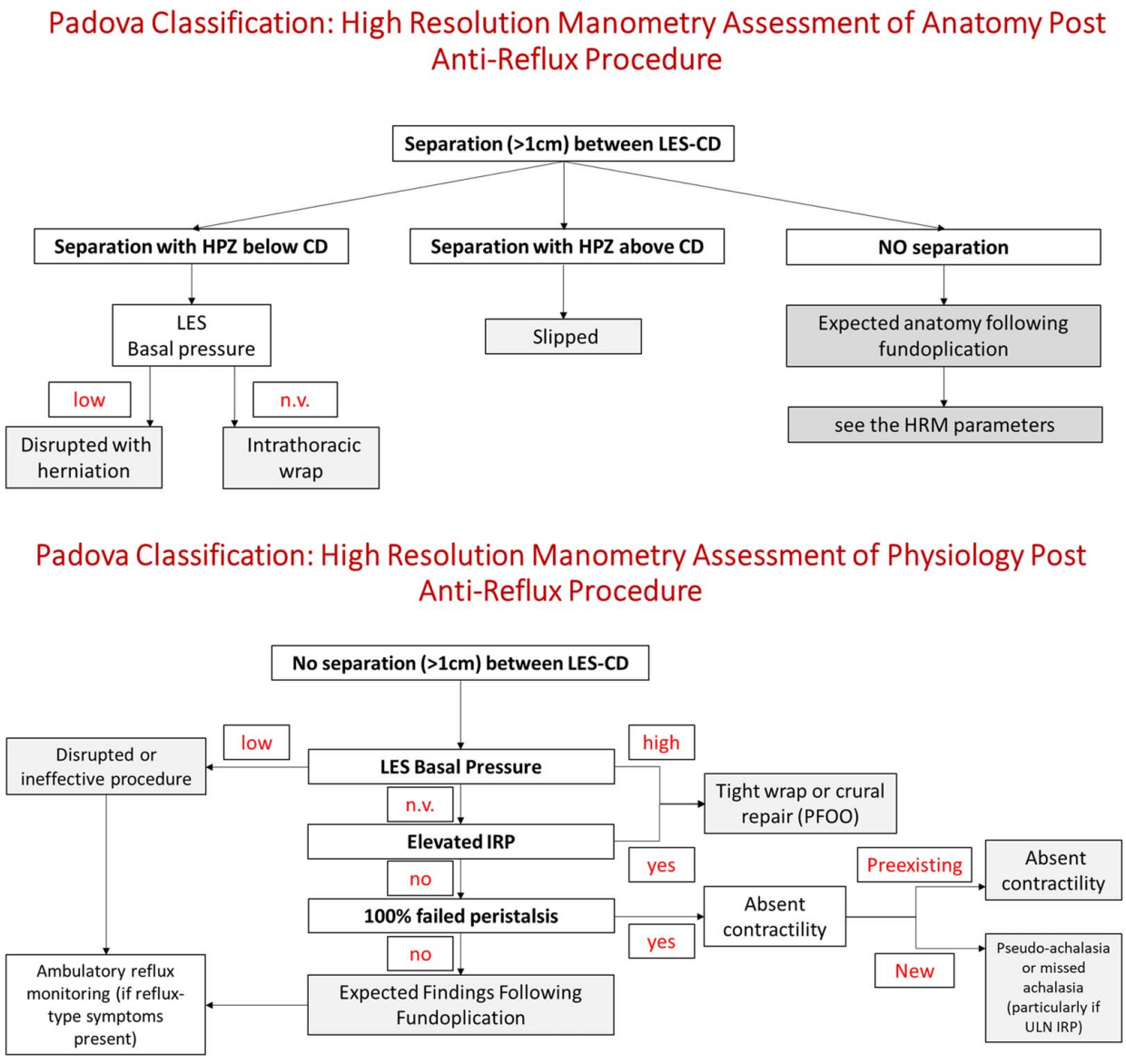


FIGURE 1. Padova Classification. The algorithm for the interpretation of HRM study in patient underwent ARS.

include LES obstruction as one of the underlying mechanisms, in addition to mechanical etiologies (such as a paraesophageal hernia) and artifact. The CC 4.0 adds specificity to EGJOO diagnostic criteria by requiring confirmation with an alternate test (including timed barium esophagram or FLIP) as well as specific obstructive symptoms such as dysphagia or chest pain,[61] both of which are frequently reported in association with GERD. Therefore, a diagnosis of EGJOO needs to be thoroughly evaluated before ARS with confirmatory testing, and if motor obstruction is definitively identified, this needs to be addressed.

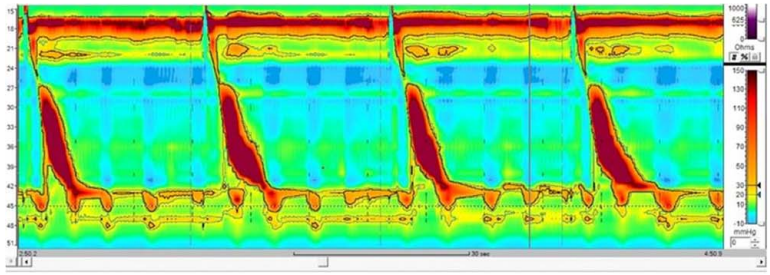
In presence of objective evidence of GERD patients with hypercontractile esophagus, as defined by CC v4.0 criteria, with typical reflux symptoms, with at least partial symptom improvement with acid-suppression medications, can be referred for antireflux surgery (median score 7, 81% agreement)

In contrast, disorders of peristalsis such as hypercontractile esophagus without EGJOO can be associated with GERD.[62] In the presence of typical reflux symptoms, objective GERD evidence and at least partial improvement with medical reflux management, hypercontractile esophagus is not necessarily a contraindication, and further evaluation for ARS can proceed (Fig. 2).

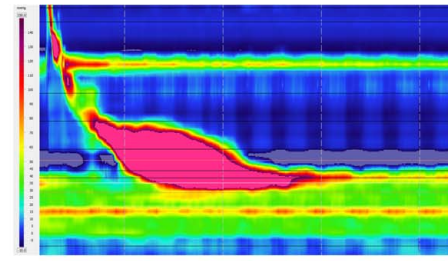
Antireflux surgery should be considered with caution in patients with distal esophageal spasm on manometry in the setting of obstructive symptoms of dysphagia and/or chest pain (median score 8, 95% agreement)

In presence of objective evidence of GERD and in the absence of obstructive symptoms patients with distal esophageal spasm can be referred for antireflux surgery (median score 7, 81% agreement)

The pattern of distal esophageal spasm should be approached with high scrutiny. Often, distal esophageal spasm on HRM exists as a spastic reactive motility



Courtesy of Motility Laboratory from University of Washington



Courtesy of Motility Laboratory from Norton Thoracic Institute

FIGURE 2. Hypercontractile esophagus with hiatal hernia: In both HRM examples there is a separation between the crural diaphragm and LES with single-peaked hypercontractility in the esophagus characterized by a distal contractile integral > 8000 mm Hg·s·cm.

response in the setting of GERD. However, distal esophageal spasm on HRM in the setting of symptoms such as dysphagia or noncardiac chest pain may represent an entity on the spectrum of type 3 (spastic) achalasia. These findings have also been described with chronic opioid use, and treatment other than ARS may need to be considered.

EGJ barrier function should be assessed by HRM, using the metrics of LES end expiratory pressure, LES baseline pressure or EGJ-CI, and including the presence of a hiatal hernia (LES-CD separation) (median score 8, 85% agreement)

The resting EGJ barrier consists of intact LES tone and superimposed crural diaphragm (CD); compromise in either or both of these can be associated with abnormal reflux burden. Useful HRM metrics consist of LES end expiratory pressure, LES baseline pressure, EGJ contractile integral and EGJ morphology (determining the presence of a HH by measuring separation between the LES and crural diaphragm).[63] The finding of LES-CD separation on HRM correlates well with identification of HH during laparoscopic surgery.[2] There was agreement that assessing these metrics are useful before ARS.

HRM Following Antireflux Surgery

Approximately 5% to 15% of patients have recurrence of reflux symptoms and/or pathologic acid reflux following ARS in the short and long terms.[17,18,60,64,65] Persistent postprocedure dysphagia has been reported by up to 12% to 25% of patients, leading to impaired quality of life.[61,66,67] The following statements characterize the significance of HRM in the assessment of the neo-LES and the hiatal morphology for patients with fundoplication failure (Table 2).

HRM has a diagnostic role in patients with unsuccessful fundoplication (persistent or new-onset reflux symptoms and/or dysphagia) unless a large recurrent hernia necessitates reoperation (median score 8; 85% agreement)

HRM can characterize esophageal motility as well as EGJ morphology and function in patients with persistent or new-onset reflux symptoms and/or dysphagia after fundoplication.[62] Thus, manometry may explain the mechanism of postoperative complications and/or surgical

TABLE 2. Recommendations in Padova Classification for Role of HRM Following Antireflux Surgery

Statement	Median	Range	Ranked appropriate (%)
HRM following antireflux procedure			
HRM has a diagnostic role in patients with unsuccessful fundoplication (persistent or new-onset reflux symptoms and/or dysphagia) unless a large recurrent hernia necessitates reoperation.	8	1, 9	85
No manometry finding is an absolute indication for the need for reoperative fundoplication, but HRM plays a role in decision-making when used in adjunct with endoscopic, pH monitoring, and barium studies.	9	1, 9	96
HRM findings after a successful fundoplication show a single distal high pressure zone (reflecting normal LES-CD configuration) with appropriate deglutitive relaxation.	8	2, 9	89
Nissen (360°) fundoplication tends to be associated with higher EGJ resting pressures, higher IRP and higher esophageal contractility compared with partial fundoplication.	8	2, 9	81
A combination of high intrabolus pressure (IBP) and high integrated relaxation pressure (IRP) may be indicative of postfundoplication outflow obstruction (PFOO).	8	5, 9	93
A very prominent single HPZ with impaired or failed deglutitive relaxation can indicate twisted or too tight fundoplication.	8	6, 9	86
HRM findings correlating with slipped fundoplication include a dual HPZ, where the upper HPZ shows normal deglutitive relaxation while distal HPZ (combination of crus and slipped fundoplication) is generally a uniform pressure band.	7	1, 9	80
HRM findings correlating with an intrathoracic fundoplication include a dual HPZ, where the lower HPZ (crus) shows the expected respiratory pattern (as in surgery-naive hiatus hernia patients), while the upper HPZ associated with herniated fundoplication may show deglutitive relaxation	7	4, 9	81
In patients with new-onset dysphagia and normal endoscopic findings, timed barium swallow (with tablet) and functional luminal imaging probe (FLIP) technology may help to clarify the etiology of symptoms, in particular if manometric findings are equivocal.	8	6, 9	93

failure. Particularly in patients with postoperative dysphagia, HRM can differentiate between underlying outflow obstruction and other causes such as esophageal dysmotility and may thereby guide further management.[62,63,68] In patients with large recurrent HHs necessitating reoperation, HRM rarely contributes to clinical decision-making. However, it may help guide re-do fundoplication by identifying disorders of esophageal peristalsis, if any.

No manometry finding is an absolute indication for the need for reoperative fundoplication, but HRM plays a role in decision-making when used in adjunct with endoscopic, pH monitoring and barium studies (median score 9, 96% agreement)

Almost all experts agreed that there is insufficient evidence to suggest that a specific manometry finding could be used as an indication for reoperative fundoplication.[69] Instead, HRM is an integral part of the diagnostic evaluation required for treatment stratification.

HRM findings after a successful fundoplication show a single distal high pressure zone (reflecting normal LES-CD configuration) with appropriate deglutitive relaxation (median score 8, 89% agreement)

Several studies confirm an increase in LES and EGJ metrics postoperatively, including IRP.[66,68,70] Asymptomatic patients (no reflux symptoms, no dysphagia) investigated 3 months after partial or complete fundoplication invariably demonstrated a single high pressure zone on HRM.[3] Integrated relaxation pressure (IRP) is typically higher after ARS than in surgery-naive patients, especially after a 360-degree fundoplication, but passage of contrast to the stomach on barium studies is typically normal. Moreover, normal EGJ morphology and LES metrics on HRM indicate the absence of anatomic abnormalities at the level of the fundoplication wrap such as herniation or dislocation[66,71] (Supplemental Digital Content 1, Table 1, http://links.lww.com/SLA/F77).

Nissen (360 degrees) fundoplication tends to be associated with higher EGJ resting pressures, higher IRP and higher esophageal contractility compared with partial fundoplication (median score 8, 81% agreement)

There are a few studies that compared fundoplication characteristics after Nissen and Toupet fundoplication. Similar to earlier studies using conventional esophageal manometry,[64] studies using HRM showed higher EGJ resting pressure, higher IRP and higher distal contractile integral following Nissen fundoplication.[70] The latter was attributed to the tighter wrap which induces a stronger peristaltic response. By contrast, Müller et al observed no significant differences for IRP following complete or partial fundoplication.[66] Moreover, variable esophageal contractility after full and partial fundoplication may also be due to tailoring the type of fundoplication to preoperative motility patterns (Fig. 3).

A combination of high intrabolus pressure and high integrated relaxation pressure (IRP) may be indicative of postfundoplication outflow obstruction (PFOO) (median score 8, 93% agreement)

Normative IRP values of the neo-LES after fundoplication are expected to be higher than in surgery-naive patients. There is minimal data on expected "normal" IRP in totally asymptomatic postfundoplication patients —with variance to be expected between types of fundoplication and manometry system used—but can be expected to be higher than normal values used in current manometry systems which are for nonoperated patients. For this reason reliance on IRP alone may be insufficient to assess for outflow obstructive physiology. A combination of high intrabolus pressure and high IRP however are indicative of a postfundoplication outflow obstruction (PFOO) (Fig. 4).

A very prominent single high pressure zone (HPZ) with impaired or failed deglutitive relaxation can indicate twisted or too tight fundoplication (median score 8, 86% agreement)

A high LES pressure with inadequate relaxation (PFOO) can be seen in patients with twisted fundoplication or a tight fundoplication/crus closure. The "normal" IRP value in postsurgery patients is expected to be greater than in surgery-naive patients so any value <15 mm Hg using Medtronic systems is consistent with normal though even a higher value may be within normal limits.

HRM findings correlating with slipped fundoplication include a dual HPZ, where the upper HPZ shows normal deglutitive relaxation while distal HPZ (combination of crus and slipped fundoplication) is generally a uniform pressure band (median score 7, 80% agreement)

A dual HPZ noted in postfundoplication patients is abnormal and can reflect the native EGJ, the fundoplication and the crus closure. In a slipped fundoplication (where the fundoplication encircles the proximal stomach rather than the EGJ) the proximal HPZ is the native EGJ, while the distal HPZ represents the fundoplication and is generally also at the level of the diaphragmatic crus. In addition, Hoshino et al[62] demonstrated that the distal HPZ does not show deglutitive relaxation in a slipped fundoplication (Fig. 5A).

HRM findings correlating with an intrathoracic fundoplication include a dual HPZ, where the lower HPZ (crus) shows the expected respiratory pattern (as in surgery-naive hiatus hernia patients) while the upper HPZ associated with herniated fundoplication may show deglutitive relaxation (median score 7, 81% agreement)

A fundoplication is normally positioned around the native EGJ but the entire EGJ- fundoplication complex may migrate into the chest—this is called an "intrathoracic fundoplication." HRM findings in such a patient will also show a dual HPZ with the proximal HPZ corresponding to the native EGJ/ fundoplication complex and may relax with deglutition, while the distal HPZ corresponds to crus and shows respiration pattern as in surgery-naive hiatus hernia[62,69] (Fig. 5B).

In patients with new-onset dysphagia and normal endoscopic findings, timed barium swallow (with tablet) and FLIP technology may help to clarify the etiology of symptoms, in particular if manometric findings are equivocal (median score 8, 93% agreement)

Neither timed barium swallow (with tablet) nor FLIP have been tested specifically in patients with failed fundoplication. However, these technologies may help to identify patients with clinically relevant PFOO and are generally suggested as adjunctive investigations for corroboration of clinical relevance of PFOO along the same lines as use of these techniques are recommended for EGJOO diagnosis by the CC v4.0.[72,73] However, normative post-surgery values for distensibility index and EGJ diameter using FLIP have not been established.

The Padova Classification

The working group was tasked with developing a practical classification for HRM assessment following ARS known as the "Padova Classification" (Fig. 1, Supplemental Digital Content 1, Table 2, http://links.lww.com/SLA/F77).

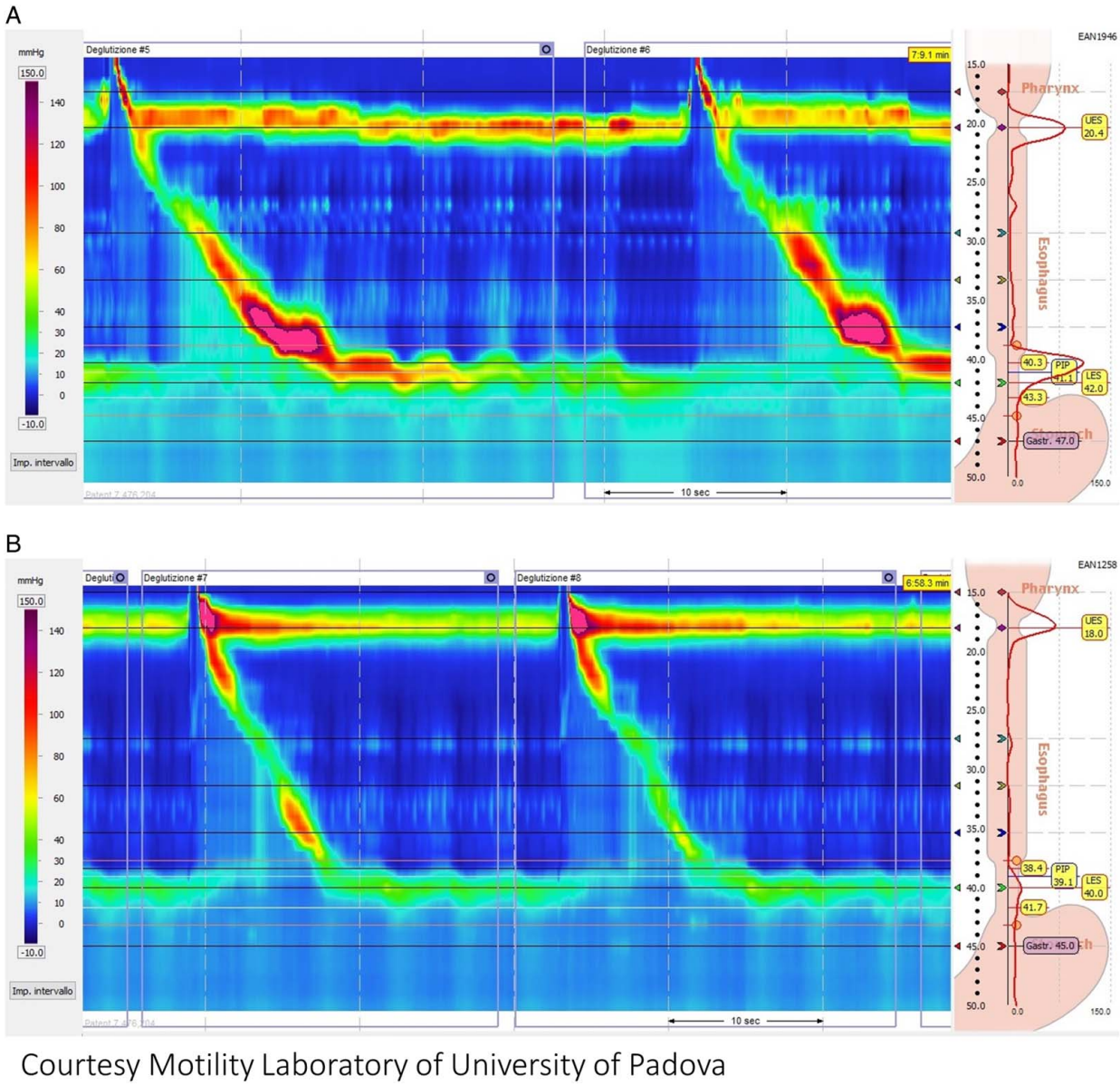
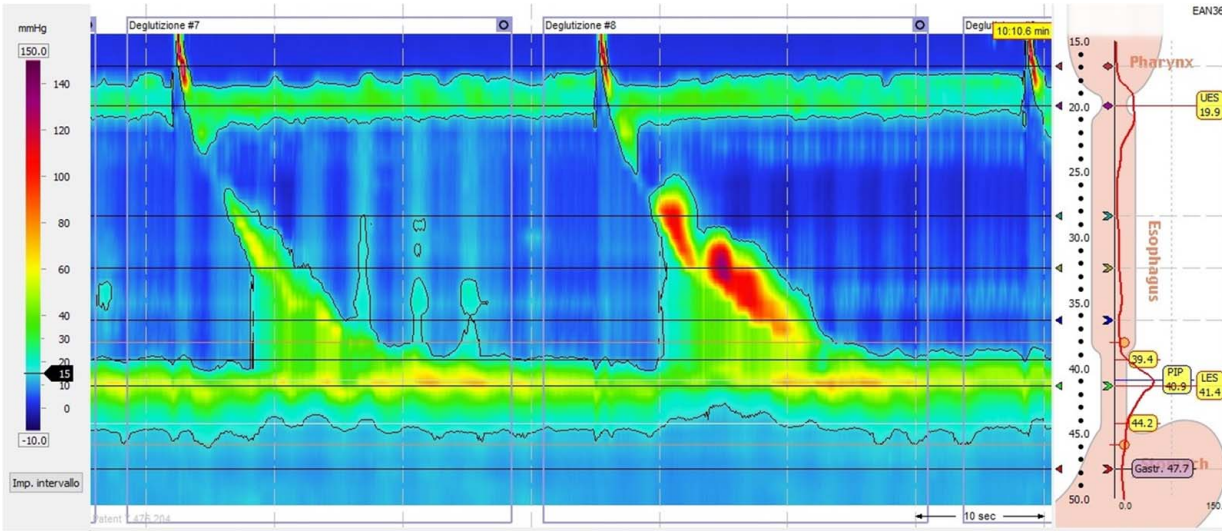


FIGURE 3. Expected findings following fundoplication: There is a single distal esophageal high pressure zone (HPZ). The wrap, the native LES, and the crura are in the same position as the pressure inversion point (PIP). Following Nissen fundoplication (A-top figure) and following Toupet fundoplication (B -bottom figure).

In patients with symptoms following ARS, initial evaluation includes endoscopy and barium esophagram. Data from HRM is generally considered alongside symptom presentation and findings on endoscopy and barium esophagram to guide management.

In the Padova Classification, the fundamental question is whether post-ARS anatomy is abnormal (Fig. 1A), determined by the relationship between the neo-LES and CD. Separation of the HPZ ≥ 1 cm below the CD indicates a slipped fundoplication. If the HPZ is ≥ 1 cm above the CD, the neo-LES resting/basal pressure is assessed; a hypotensive neo-LES indicates a disrupted fundoplication with herniation whereas a normotensive neo-LES indicates a herniated wrap (without disrupted fundoplication). Absence of separation suggests against abnormal anatomy post-ARS.

The next question is whether post-ARS physiology across the neo-LES and esophageal body is abnormal (Fig. 1B), and begins with assessment of the neo-LES resting/basal pressure. A hypotensive neo-LES indicates a disrupted/ineffective ARS for which reflux monitoring may be considered to assess for recurrent GERD, if clinically indicated. In contrast, a hypertensive LES indicates a PFOO. Similarly, a normotensive LES with elevated LES relaxation pressure (ie, elevated IRP) also indicates a PFOO. The presence of intrabolus pressurization increases confidence in the diagnosis of PFOO. If basal pressure and IRP across the neo-LES are normal, the next step is the assessment of esophageal peristalsis. Failed peristalsis in 100% of swallows indicates absent contractility. Corroboration with preoperative HRM can help discern whether the absent contractility was



Courtesy Motility Laboratory of University of Padova

FIGURE 4. PFOO: There is a single distal HPZ and high basal pressure across the neo-LES as well as high IRP. Compartmentalized intrabolus pressurization is evident in the distal esophageal body. The bolus becomes trapped between the progressing peristaltic contraction and the outflow obstruction caused by a poorly relaxing of the neo-LES in a patient underwent laparoscopic Nissen fundoplication.

preexisting or is newly detected. Pseudoachalasia related to the ARS or a missed achalasia are potential sources of a newly detected absent contractility. The presence of at least some contractility indicates expected findings following fundoplication; in this scenario reflux monitoring may be considered to assess for recurrent GERD, if clinically indicated.

Statements not meeting agreement and considerations for future evaluation (Supplemental Digital Content 1, Table 3, http:// http://links.lww.com/SLA/F77**).**

In studies evaluating provocative maneuvers, there is uniform demonstration of complementary clinically useful information from these additional tests beyond the interpretation of the 10-swallow protocol alone.[11–17] However, there was no agreement that EGJ obstruction demonstrated by provocative measures alone was enough to prompt further evaluation before ARS.[17]

In the conventional manometry era one of the eternal dilemmas was whether the evaluation of esophageal contraction vigor and peristaltic breaks may be helpful in choosing a partial or a complete fundoplication to reduce the risk of postoperative dysphagia.[74] In this initiative, evaluation of contraction vigor using presence of ineffective swallows, peristaltic breaks, or response to multiple rapid swallows (MRS) did not meet agreement in guiding the tailoring of a specific ARS procedure (eg, total vs partial fundoplication) or predicting post-ARS dysphagia.[11] Retrospective, uncontrolled data demonstrate the clinical value of determining esophageal contraction reserve using MRS in esophageal hypomotility disorders (absent contractility and ineffective esophageal motility).[11,22] Lack of contraction reserve has been associated with higher likelihood of dysphagia after standard ARS, higher reflux burden, and higher likelihood of persistence of ineffective esophageal motility after surgery. Further studies are needed to decide if lack of contraction reserve on MRS should translate into tailoring of ARS. (Tables 1, 2, Fig. 1).

The role of behavioral disorders such as rumination syndrome in esophageal symptoms mimicking or overlapping with GERD continues to be investigated using esophageal physiological testing,[18,19] but postprandial HRM did not reach agreement as a useful adjunctive tool in PPI nonresponsive patients. Further, the value of impedance metrics used in conjunction with standard HRM remains inconclusive in workup before ARS.

The straight leg raise maneuver continues to be investigated as a HRM provocative maneuver that can predict esophageal reflux burden,[20,21] but its value before ARS has not been established. Esophageal pressurization during the straight leg raise maneuver has been associated with a higher likelihood of abnormal reflux burden in single center as well as multicenter studies.[20,21,23] While this HRM maneuver is simple to perform, whether an abnormal result predicts a better response to ARS remains to be researched.

DISCUSSION

In the last 2 decades the advent of esophageal HRM has improved the study of esophageal motor function, with a better identification of clinically relevant esophageal motility diagnoses. Indeed, the CC, now at its fourth revision, has revolutionized the classification of esophageal motor disorders[1] and it is, at present, widely accepted in nearly all esophageal centers. However, the CC was developed for the evaluation of patients with dysphagia and noncardiac chest pain, without additional guidance in the assessment of patients in the presurgical and postsurgical setting. Indeed, little is known on the role of esophageal function as assessed by HRM before and after antireflux and/or bariatric surgery. Thus, this multidisciplinary international working group developed the first consensus, following the systematic review of current medical literature, on the role of HRM before and after antireflux surgery and a postoperative classification of HRM findings.

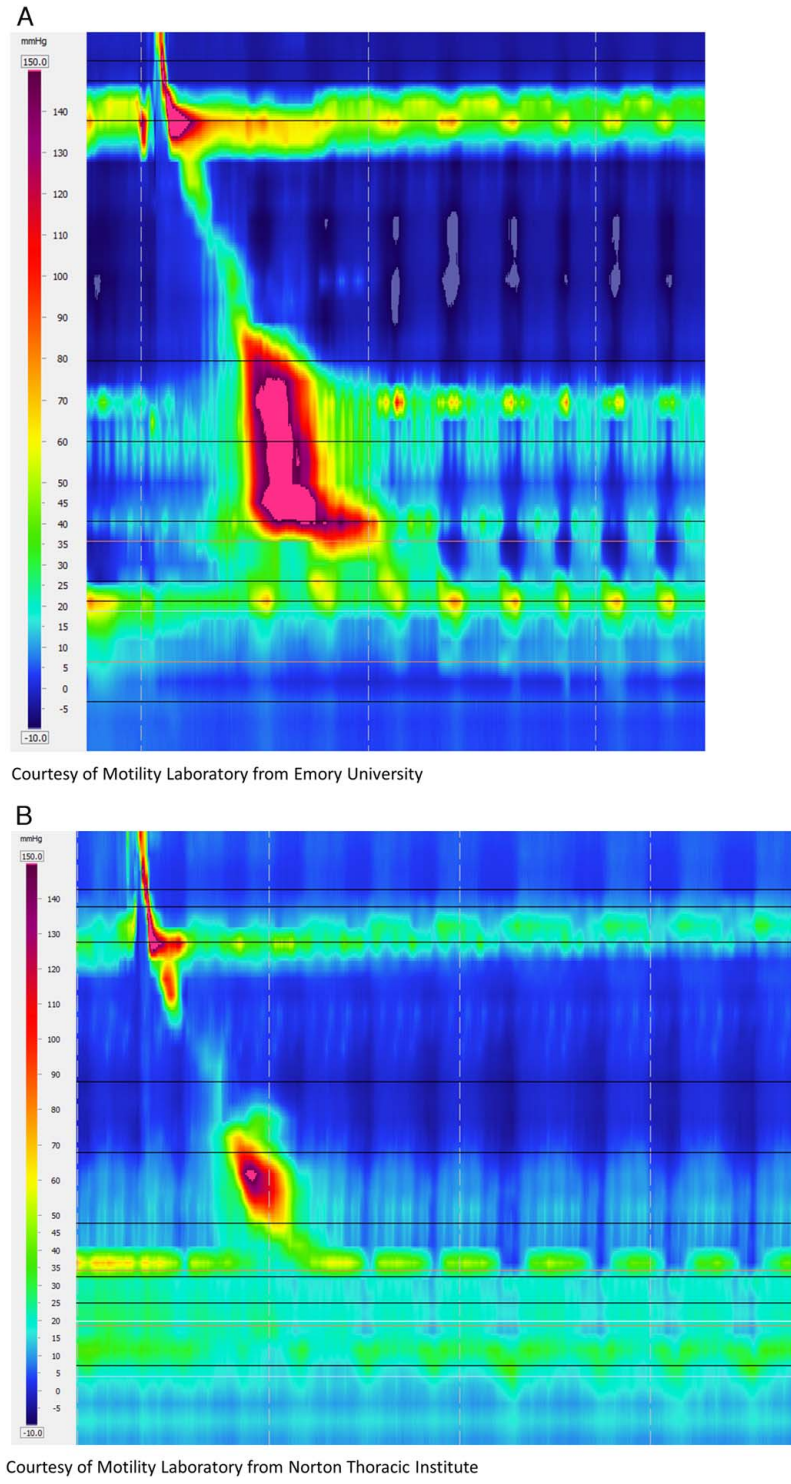


FIGURE 5. Anatomic disruption following fundoplication. A, Slipped fundoplication: There is presence of a distinct double-hump configuration. The native LES (proximal HPZ) migrates above the wrap (distal HPZ). In this type of HRM morphology, the fundoplication is slipped at the gastric body level and is represented by the distal HPZ. The distal HPZ does not relax and does not change according with respiratory variations, while the proximal HPZ relaxes during swallows. The PIP is located above the distal HPZ. B, Intrathoracic fundoplication: presence of a distinct double-hump configuration. The distal HPZ represents the crus and the proximal HPZ is the wrap around the native LES. In this HRM subtype, the distal HPZ does not relax during swallow and respiratory variations are evident, while in the proximal HPZ the relaxation of the sphincter is well-represented. In these cases, the PIP coincides with the distal HPZ.

The Padova Classification of postoperative HRM assessment was developed to facilitate the interpretation of HRM studies of patients underwent ARS. The Padova initiative confirms that HRM evaluation is essential before ARS to assess esophageal motility and EGJ morphology. The consensus agreed that ARS alone need not be avoided in patients with disorders of peristalsis, such as hypercontractile esophagus, when accompanied by objective evidence of GERD, and in the absence of dysphagia or other obstructive symptoms. However, the consensus emphasizes caution and further evaluation of EGJOO or distal esophageal spasm on HRM before consideration of ARS. Moreover, this initiative provides consensus among GIs and surgeons on the issue of abnormal esophageal motility and tailoring of fundoplication; at this time, available evidence indicates that the evaluation of esophageal contraction vigor and peristaltic

breaks should not be the key in choosing a partial or a complete wrap, since reduction of the risk of postoperative dysphagia has not been conclusively demonstrated on prospective studies. The consensus also describes and categorizes post-ARS normal and abnormal HRM findings. To our knowledge, this is the first attempt to organize and classify HRM patterns before and after ARS.

In the past, within the limitations of perfused traditional manometry, few efforts evaluated the characteristics of the LES in GERD[2] with the aim to identify patients that would benefit from fundoplication.[3] Some studies reported an increased relaxation pressure of the neo-LES after Nissen fundoplication[4] and its relationship with postoperative dysphagia.[5] Other old reports focused on esophageal motility before and after fundoplication, showing partial recovery of peristalsis in most patients[6,7] and questioning the relevance of disordered esophageal peristalsis in planning surgery.[7] These papers were flawed in some aspects (most single center retrospective series from surgical groups, seldom replicated by other centers and never fully accepted by the scientific community). Above all, the diagnostic technique then available prevented the evaluation of different parameters that are now possible with HRM.

In recent years several studies report on esophageal function on HRM before and after fundoplication,[17,61–75] with some even attempting to identify normative values to which symptomatic patients after fundoplication could be compared.[8] However, none of these papers provide a guide on the utility of HRM in planning surgery, nor interpretation of HRM to evaluate the different anatomical aspects of a "normal" or a "failed" fundoplication.

The Padova consensus confirmed that HRM plays a key role in decision-making when used in adjunct with endoscopic, pH monitoring and barium studies in postoperative symptomatic patients. In particular, when radiologic or endoscopic assessment cannot clearly explain the persistence of postoperative symptoms, HRM has a diagnostic role and can clearly reflect the "anatomical situation" as either too tight (PFOO), slipped or a migration of the wrap.

The main limitations of this consensus were: (a) the agreement was based on existing literature, and may reflect the flaws of the evaluated studies, (b) the limited levels of evidence as the majority of data is derived from observational data as opposed to randomized controlled trials or meta-analysis, often with small sample sizes and single center experiences, and, (c) the lack of outcomes data to confirm recommendations.

The Padova initiative and classification summarizes the state of our knowledge of the use of HRM pre-ARS and post-ARS, evaluated by a multidisciplinary international working group of surgeons and gastroenterologists gathered with the aim to develop consensus on role of HRM preforegut and postforegut surgery.

The first branching point is whether there is >1 cm separation between the neo-LES and the CD. A separation with an HPZ below the CD presents a *slipped fundoplication*. When the HPZ is above the CD the entire neo-LES fundoplication complex is migrated into the chest. A normal basal LES pressure identifies an *intrathoracic fundoplication*, while a lower value of resting pressure represents a *disrupted fundoplication with herniation*.

In cases of no separation between the neo-LES and CD, the evaluation first begins with assessment of the neo-LES resting and relaxation pressures. A lower value of basal neo-LES pressure represents a *disrupted wrap* or *an ineffective procedure* and a clinically relevant conclusive diagnosis requires additional information which may include ambulatory reflux monitoring. If the neo-LES shows a higher resting pressure, the patient has a tight wrap or crura repair and the manometric diagnosis is referred to as a postfundoplication outflow obstruction (PFOO). This condition is also diagnosed if the neo-sphincter has defective relaxation (elevated median IRP). The last point in the algorithm is to assess peristalsis where 100% failed peristalsis is abnormal. If this condition was preexisting the patient has a preoperative diagnosis of absent contractility (see the CC), otherwise it may present a pseudoachalasia or missed achalasia (particularly if upper limit of normal IRP). Finally, if none of the above parameters are met, these manometric findings are consistent with expected findings following fundoplication.

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