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Defining Pharyngeal and Upper Esophageal Sphincter Disorders on High-Resolution Manometry-Impedance: The Leuven Consensus

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ABSTRACT

Introduction: The *Leuven Consensus* provides a classification scheme for the diagnosis of pharyngeal and upper esophageal sphincter (UES) motor disorders using metrics derived from pharyngeal high-resolution manometry-impedance (P-HRM-I).

Methods: Twenty-six experts with broad multidisciplinary backgrounds contributed their knowledge and experience to this initiative via a formal deliberative Delphi process. Guidance on a swallow assessment protocol as well as diagnostic criteria for UES dysfunction and pharyngeal contractile dysfunction is provided.

Results: For UES dysfunction, the stepwise evaluation of UES and intrabolus pressure metrics under increasing bolus volume and/or viscosity conditions is used to confirm failure of manometric relaxation and opening of the UES region. For pharyngeal contractile dysfunction, the evaluation of contractile metrics is used to define pharyngeal hypocontractility or hypercontractility.

Conclusion: These recommendations complement routine instrumental investigations and provide a standardized process, criteria, and nomenclature for P-HRM-I assessment of patients reporting symptoms of oropharyngeal dysphagia.

1 | Introduction

Diagnostic pharyngeal high-resolution manometry-impedance systems (P-HRM-I) are now being incorporated into clinical practice for evaluation of deglutitive neuromuscular function in patients with oropharyngeal dysphagia. In 2020, the *International Pharyngeal HRM Working Group* published a Core Outcome Set (COS) of P-HRM-I metrics that provided a minimum dataset foundation for describing pharyngeal swallowing physiology. The COS metrics can identify swallowing dysfunction, with the intention of standardizing reporting and to enable research comparisons [1]. The metrics were separated into those relevant to assessing the opening function of the pharyngoesophageal segment (PES); more commonly referred to as the "upper esophageal sphincter" (UES) region, and the bolus propulsion and clearance functions of sequential contraction of the pharynx.

Guidance on and agreement of diagnostic protocols as well as criteria, including normal values, and descriptive nomenclature for pharyngeal disorders are needed for translation of P-HRM-I into widespread clinical practice. To address this gap, the International Pharyngeal HRM Working Group undertook a deliberative process to develop recommendations for performing P-HRM-I swallowing assessments and how these should be analyzed and reported, taking into account variability of equipment systems and geographic differences for researchers and clinicians.

2 | Methods

Delphi consensus methodology was used to reach agreement on a final set of recommendations. Criteria used to achieve consensus were based on that previously used for determination of the recommended COS of metrics [1]. A voting score within the range of 1–9 was used to determine consensus, where 1–3 indicated decreasing levels of clear disagreement (1 = absolute disagreement), 4 indicated slight disagreement, 5 was neutral, 6 indicated slight agreement, and 7–9 indicated increasing levels of clear agreement (9 = absolute agreement). If statements were not scored, these were assigned as neutral (5). Consensus required that at least 70% of the Working Group agreed with the statement (scoring 7–9) and no more than 20% disagreed with the statement (scoring 1–3). All other score distributions were taken to indicate no consensus. The Working Group was also invited to provide comments, which helped to inform further discussion.

The process of developing recommendations commenced in December 2023. A 15-member subgroup with relevant publication track record in pharyngeal manometry was tasked with developing initial proposals via online discussions. These initial proposals were finalized (August 17, 2024) and the associated information circulated for consideration by the full multidisciplinary Working Group (all 26 authors). An in-person meeting of the Working Group was convened in Leuven, Belgium (September 21, 2024).

Prior to the Leuven meeting, the first round of voting on Delphi statements occurred, with results and associated commentary circulated. The statements were discussed at the Leuven meeting, revised, and recirculated. A second round of voting proved sufficient to achieve the threshold for consensus agreement on all statements, allowing synthesis of a final set of consensus recommendations. The level of agreement on the Delphi statements ranged from 74% to 100% and disagreement ranged from 0% to 4% (see Supporting Information for full list of statements and aggregate voting scores which are the basis for what is reported in the entire consensus).

This document summarizes the final recommendations of the International Pharyngeal HRM Working Group, which include:

1. A defined Swallow Challenge Protocol
2. Criteria for diagnosing UES Dysfunction
3. Criteria for diagnosing Pharyngeal Contractile Dysfunction

There are three important caveats to the recommendations:

1. Complementary instrumental investigations for visualization of swallow function (as described in Section 3 below) are an essential adjunct as they may identify abnormalities such as altered bolus transit and/or airway protection not identified by manometric assessment. Therefore, if not previously performed, they should be performed simultaneously or scheduled prior to the time of P-HRM-I assessment.
2. Patients without dysfunction based on these recommendations cannot be considered to have "normal" swallowing function, and abnormalities of the esophageal phase of swallow should also be considered.
3. At this stage, guidance for clinical intervention decisions is not provided. P-HRM-I can measure change following interventions (see *Indications*); however, the Working Group did not consider whether therapeutic or surgical interventions based on these recommendations may be effective.

Many additional topics were also raised during Working Group deliberations, including the role of (a) puree and solid consistency challenges (i.e., a real food that is more palatable), (b) natural swallowing challenges (sip [2] and drinking challenges [3]), (c) sensory stimulation [4], (d) volitional swallowing tasks [5, 6–9], and (e) biofeedback training [10]. No recommendations are provided on these aspects; while potentially relevant to P-HRM-I swallowing assessment, they were considered to represent future directions for evidence-based research.

Summary

- The Leuven Consensus provides a classification scheme for diagnosis of pharyngeal and upper esophageal sphincter (UES) motor disorders.
- The scheme utilizes metrics derived by pharyngeal high-resolution manometry-impedance (P-HRM-I).
- These recommendations complement routine instrumental investigations and provide a standardized process, criteria and nomenclature.

3 | Indications for Pharyngeal Manometry

The nature of oropharyngeal swallowing dysfunction is complex, and accurate interpretation of swallowing assessments requires collective input from a multidisciplinary clinical team (otolaryngology, gastroenterology, rehabilitation medicine and speech pathology/deglutology). In this context, pharyngeal high-resolution manometry is most often used as a complementary diagnostic test following a videofluoroscopic swallow study (VFSS) or flexible endoscopic evaluation of swallow (FEES). Manometry is used to obtain additional objective information on swallowing function that cannot be gained through these more common swallowing assessment methodologies. A multimodal assessment, where manometry is performed simultaneously with fluoroscopic imaging (i.e., videomanometry/manofluorography), can streamline the assessment process and allow a comprehensive single assessment of swallowing. Where possible, pharyngeal manometry should be used in conjunction with impedance (P-HRM-I) to allow derivation of all recommended COS metrics [1] and provide objective information regarding bolus position and transit. A decision tree for the utility and timing for P-HRM-I is provided in Figure 1.

At all times, prior to undertaking P-HRM-I, the clinical situation must be well understood, oropharyngeal anatomy examined under laryngoscopic or X-ray guidance, and aspiration risk ascertained. Guidance on indications and contraindications for P-HRM-I as a complementary swallowing assessment modality is provided in Table 1. This includes indications where P-HRM-I is strongly recommended with established evidence, suggested for use with emerging evidence, or where use is contraindicated. There are also situations where the usual protocol cannot be easily executed (see * in lower right box of Table 1). In these circumstances, P-HRM-I may still be possible; however, extra precautions are required.

4 | Recommended Measures of Swallowing Function

Pharyngeal high-resolution manometric swallowing assessment utilizes swallowing measures that objectively assess different aspects of pharyngo-UES motor function. When combined with *impedance* technology (P-HRM-I) bolus distension during deglutitive bolus transit can be assessed without simultaneous imaging. Metrics that describe upper esophageal sphincter relaxation and opening and pharyngeal contractile strength are defined in Table 2, and Figure 2 illustrates how they are derived, based on separate examples of analysis of pharyngeal pressure-only and pressure-impedance recordings. The algorithmic derivation of objective swallowing measures appears reliable [11–15] and has been extensively used to assess normal and disordered swallowing function in large datasets [16–20]. Consistent with other diagnostic frameworks, such as the *Chicago Classification* of esophageal motility disorders [21], swallow function metrics determined to be outside the normal range indicate specific dysfunctions that, when recognized, allow for a diagnosis of a pharyngeal and/or UES motor disorder. Normative values for swallow function

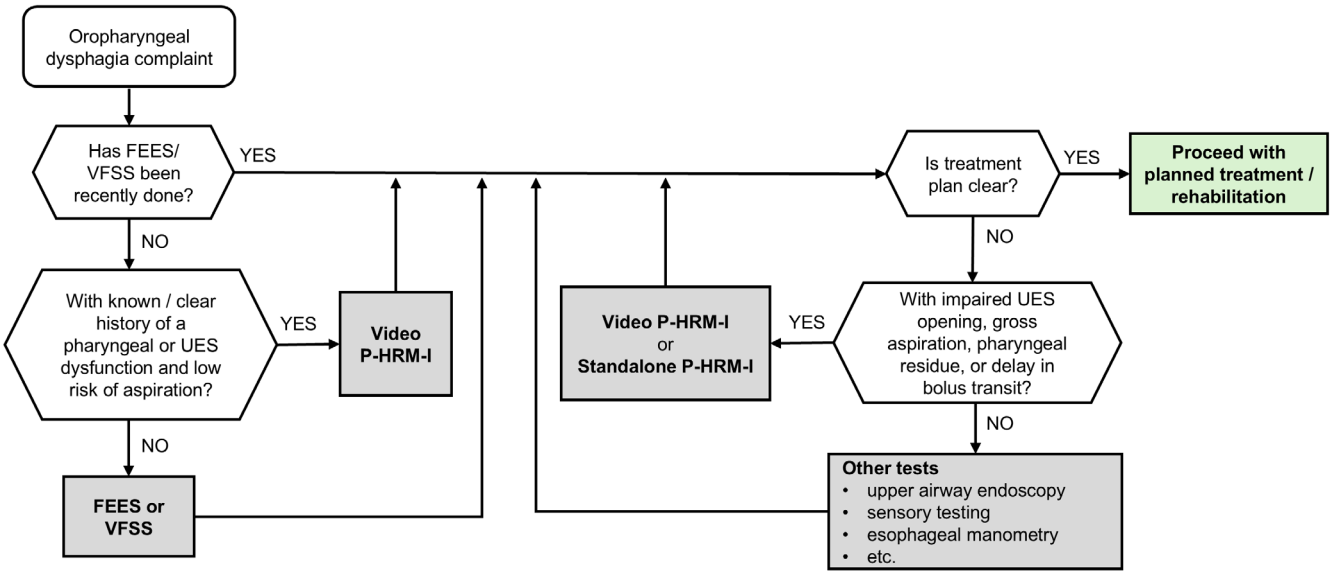


FIGURE 1 | A decision tree defining the utility, timing, and the additional clinical information gained using P-HRM-I, alongside the more frequently applied swallowing assessments, VFSS and FEES. Most patients with oropharyngeal dysphagia will have undergone VFSS/FEES prior to P-HRM-I; if this has not occurred, it is strongly recommended that P-HRM be performed simultaneously with VFSS (i.e., Video P-HRM-I). If VFSS/FEES has been performed, then P-HRM-I can proceed as a stand-alone procedure.

TABLE 1 | Suggested indications and contraindications for P-HRM-I.

	Do P-HRM-I	Do NOT do P-HRM-I
Strongly recommended	• When suspecting UES Dysfunction based on history or other instrumental tests (VFSS/FEES) • When quantification of propulsive and restrictive forces is needed to guide treatment decisions or to determine baseline swallowing function • To measure change following interventions (e.g., myotomy, botulinum toxin injection, dilatation) or as objective biofeedback during rehabilitative treatment	• Known significant nasal obstruction • History of trauma to the nasal cavity, sinonasal surgery, recent clinically significant epistaxis, skull base or mid-facial fractures • High risk of bleeding
Suggested	• When VFSS is difficult or cannot be performed (e.g., patient cannot be transported to VFSS, contrast allergy) • To rule out any swallowing dysfunction in the context of possible functional dysphagia • To quantify the progression of a degenerative or neuromuscular disorder • To monitor objective changes to swallowing function over time • To identify subtle changes in swallowing when previous instrumental assessments are deemed normal or do not provide explanation for symptoms	• Inability to comprehend or follow instructions or agitation • Inability to tolerate manometry catheter due to discomfort or gagging • Severe restriction (e.g., stricture) of pharyngoesophageal segment* • High aspiration risk that cannot be mitigated by controlling bolus size, compensatory techniques*

Note: *Standalone manometry is not recommended in these circumstances, however, may be deemed safe to perform with concurrent direct vision/guidance (x-ray/flexible endoscopy) to ensure safety.

metrics, while requiring standardization, are now emerging in the literature [19, 20, 22].

4.1 | Metrics of Upper Esophageal Sphincter Relaxation and Opening

Deglutitive UES relaxation and pharyngo-esophageal segment (PES) opening are essential for swallowed bolus transfer into the esophagus. During deglutition, deactivation of the tonically active UES muscle (cricopharyngeus, receiving neural inputs via CN X) leads to pressure relaxation of the UES region effectively reducing restrictive forces that impede bolus flow. Intraluminal bolus forces, extrinsic expansive traction forces exerted by the hyolaryngeal muscles (mylohyoid, anterior digastric, and posterior digastric) and intrinsic tissue compliance are the main determinants of UES opening when a competent palate and larynx are present to ensure "pressure chamber" closure [23]. The metrics used to distinguish normal from incomplete UES relaxation are the *Integrated Relaxation Pressure* (UES IRP) and *Relaxation Time* (UES RT). UES opening can also be determined if simultaneous videofluoroscopy imaging is performed, or opening inferred from the impedance recording. The metrics used to distinguish normal from impaired UES opening/distensibility are the *UES Maximum Admittance* (UES Max Ad), which is indicative of maximum bolus cross-sectional area, and hypopharyngeal *Intrabolus Pressure* (IBP) proximal to the UES, which indicates the luminal pressure at peak bolus distension of the hypopharynx.

4.2 | Bolus Pressurization Patterns

Impaired UES relaxation and/or luminal opening resists bolus flow and often leads to patterns of bolus pressurization of the pharyngeal chamber upstream of (proximal to) the UES that are readily observable on pharyngeal pressure topography plots. The lower margin of the zone of pressurization approximates the position of a high-pressure gradient, a useful clinical physiological measure that may identify and localize a pathologically restricted UES opening [24]. Corresponding impedance plots, which confirm luminal bolus distension, can be used to distinguish bolus pressurizations from lumen-occluding pharyngeal contractions, and it has been proposed that these patterns are suggestive of a disorder of pharyngeal outflow when the bolus pressurization peak exceeds 20 mmHg above the predeglutitive hypopharyngeal baseline [18].

Three different bolus pressurization patterns have been characterized (Figure 3). While all patterns provide an unequivocal biomechanical signature of outflow obstruction, the determination of pattern type is to some extent subjective, and the importance of making this distinction needs to be established. Pharyngeal *pan-pressurization* (Type 1) and *distal-compartmentalized-pressurization* (Type 2) are indicative of sustained restriction at the UES during bolus transit that are never, or rarely, seen in healthy swallowing [18]. The functional basis for *transient-pressurization* (Type 3) requires further exploration; while this pattern may reflect inappropriate activation or delayed deactivation of the cricopharyngeal muscle (i.e., timing abnormalities), it can also be apparent in patients with a structurally restricted

TABLE 2 | Swallow function metrics that define UES relaxation and opening and pharyngeal contractile strength.

Metric		Abbreviation (units)	Definition	Interpretation
UES Relaxation and Opening.	Hypopharyngeal Intrabolus Pressure	IBP (mmHg)	IBP is defined by the pressure 1 cm superior of UES apogee position at the time of maximum hypopharyngeal distension deduced from impedance.	Abnormally high value indicates elevated hypopharyngeal pressure within the bolus proximal of the UES.
	UES Integrated Relaxation Pressure	UES IRP (mmHg)	UES IRP is a measure of the extent of UES relaxation. UES IRP is the median of the lowest nonconsecutive 0.20–0.25 s of e-sleeve pressure.	Abnormally high value indicates elevated residual pressure during UES relaxation as the bolus transits the UES.
	UES Maximum Admittance	UES MaxAd (mS)	UES MaxAd is a measure of extent of UES opening. UES MaxAd is the highest admittance value recorded during trans-sphincteric bolus flow.	Abnormally low value indicates diminished distension area of the bolus as it transits the UES.
	UES Relaxation Time	UES RT (s)	UES RT is a measure of the duration of UES relaxation. UES RT is the e-sleeve pressure interval below 50% of baseline or 35 mmHg, whichever is lower.	Abnormally short value indicates diminished interval of UES relaxation.
Pharyngeal Contractile Strength	Velopharyngeal Contractile Integral	VCI (mmHg.s.cm)	VCI is a measure of contractile vigor within a space–time box on the pressure topography plot spanning the velopharyngeal region only. VCI is the mean pressure within this domain multiplied by duration (s) and length (cm).	Abnormally low value indicates velopharyngeal hypocontractility (observed on pressure topography as ABSENT or LOW). Abnormally high value indicates velopharyngeal hypercontractility
	Mesopharyngeal Contractile Integral	MCI (mmHg.s.cm)	MCI is a measure of contractile vigor within a space–time box on the pressure topography plot spanning the mesopharyngeal region only. MCI is the mean pressure within this domain multiplied by duration (s) and length (cm).	Abnormally low value indicates mesopharyngeal hypocontractility (observed on pressure topography as ABSENT or LOW). Abnormally high value indicates mesopharyngeal hypercontractility
	Hypopharyngeal Contractile Integral	HPCI (mmHg.s.cm)	HPCI is a measure of contractile vigor within a space–time box on the pressure topography plot spanning the hypopharyngeal region only. HCI is the mean pressure within this domain multiplied by duration (s) and length (cm).	Abnormally low value indicates hypopharyngeal hypocontractility (observed on pressure topography as ABSENT or LOW). Abnormally high value indicates hypopharyngeal hypercontractility
	Hypopharyngeal Peak Pressure	HPeakP (mmHg)	HPeakP is a measure of contractile vigor within the hypopharyngeal space–time box. HPeakP is the mean of pressure peaks along the length of this domain.	

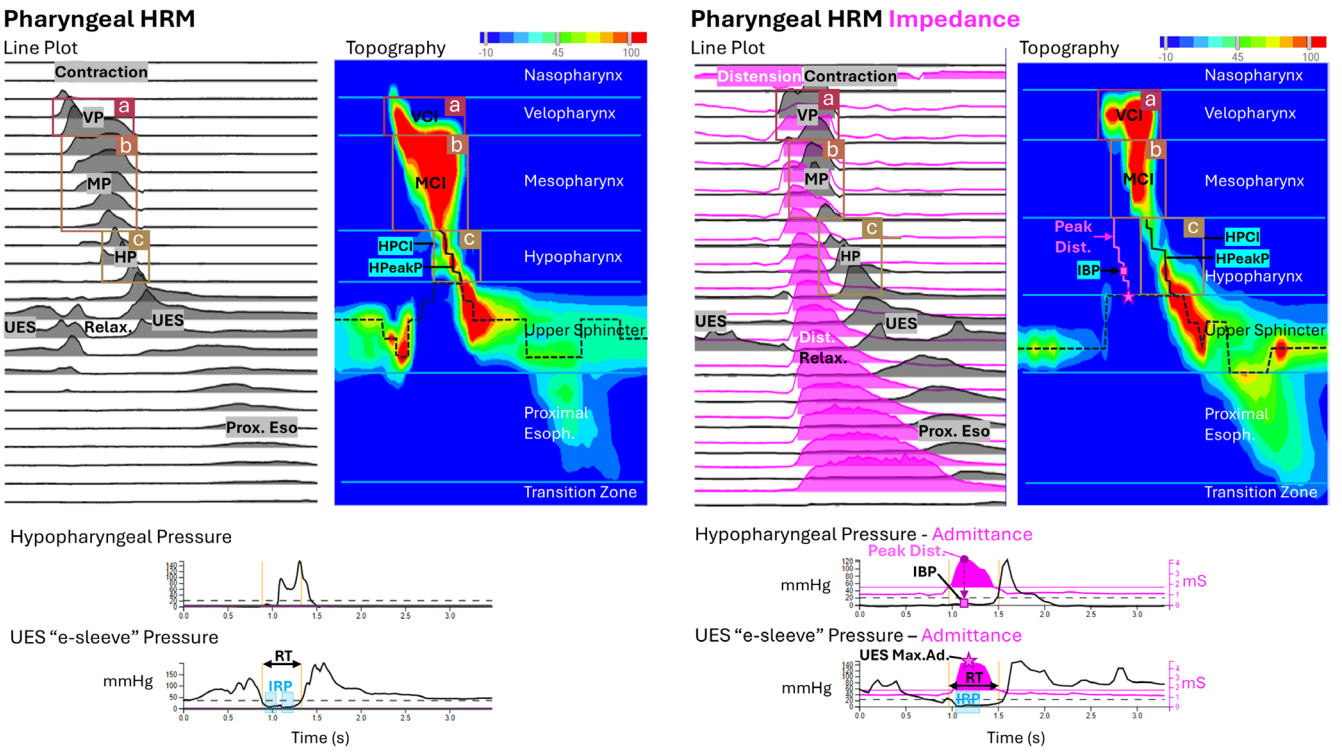


FIGURE 2 | Swallow function measures derived from pressure only (P-HRM, left) and pressure-impedance (P-HRM-I, right) analysis. Metrics are algorithmically derived from pressure-impedance data that can be displayed qualitatively as a Line Plot or Topography Plot. Line plots show pressure (contraction/relaxation) and admittance (distension) associated with deglutitive bolus transit from velum to esophageal transition zone. Boxes show the span and duration of different pharyngeal segments (a—velopharynx, b—mesopharynx and c—hypopharynx); these are analyst-defined, based on their location, and waveform characteristics. To assess pharyngeal contractility, pressures within these pharyngeal segment regions are used to derive contractile integrals for the velopharynx (VCI, box a), mesopharynx (MCI box b) and hypopharynx (HPCI box c), as well as the mean hypopharyngeal peak pressure (HPeakP, black line within box c). The plots below show the time-profiles recorded within the hypopharynx and UES. Hypopharyngeal Pressure is measured 1 cm proximal of the UES apogee. UES pressure is measured within the boundaries of UES region based on the e-sleeve method (i.e., measuring the maximum axial pressure within the UES region over time). To assess UES function, pressure analysis allows derivation of the UES Integrated Relaxation Pressure (IRP) and UES Relaxation Time (RT). The addition of impedance, to detect timing and extent of bolus distension, allows derivation of hypopharyngeal Intrabolus Pressure (IBP) and the UES Maximum Admittance (UES MaxAd). Metric definitions and their interpretation are also provided in Table 2.

PES opening. The pattern may also be influenced by other factors, such as poor orolingual control and impaired hyolaryngeal elevation [18, 20, 25].

4.3 | Metrics of Pharyngeal Contractile Dysfunction

The sequential pharyngeal contraction generated during deglutition is essential for bolus propulsion and clearance, the relative importance of the former and latter functions being dependent on bolus size and viscosity. Kahrilas (1993) [26] demonstrated how the pharyngeal propulsive chamber is mechanically optimized for larger volumes. Lingual forces alone can propel the head of a large fluid bolus beyond the UES, meaning that pharyngeal contraction at the bolus tail serves only to clear any remaining bolus material from the distal pharynx. In contrast, for small volumes, the propulsive chamber capacity is unused, and lingual forces are only able to propel the bolus to the distal pharynx. The pharyngeal stripping contraction is therefore needed to both propel and clear the small volume bolus from the pharynx, and bolus passage through the UES is subsequently delayed when compared to larger volumes.

Metrics of pharyngeal contractility summarize the strength of lumen-occlusive pharyngeal squeeze within three functionally distinct regions (or "segments"); velopharynx, mesopharynx, and hypopharynx. Pharyngeal hypocontractility usually indicates impaired neuromuscular function, often of clinical relevance as it may be associated with incomplete pharyngeal bolus clearance, resulting in residue and postswallow aspiration of such residue [27]. Pharyngeal hypercontractility, on the other hand, may occur as a compensatory, upstream response to disorders of pharyngeal bolus outflow, as has been reported in patients with Parkinson's disease [28] and also obstructive sleep apnea [29]. The metrics used to assess the function of the specific pharyngeal segments are described below.

Velopharyngeal contraction closes and seals the proximal margin of the pharyngeal propulsive chamber, thus it may exert an indirect effect on the capacity of the pharyngeal chamber to generate bolus driving forces. On pressure topography, the

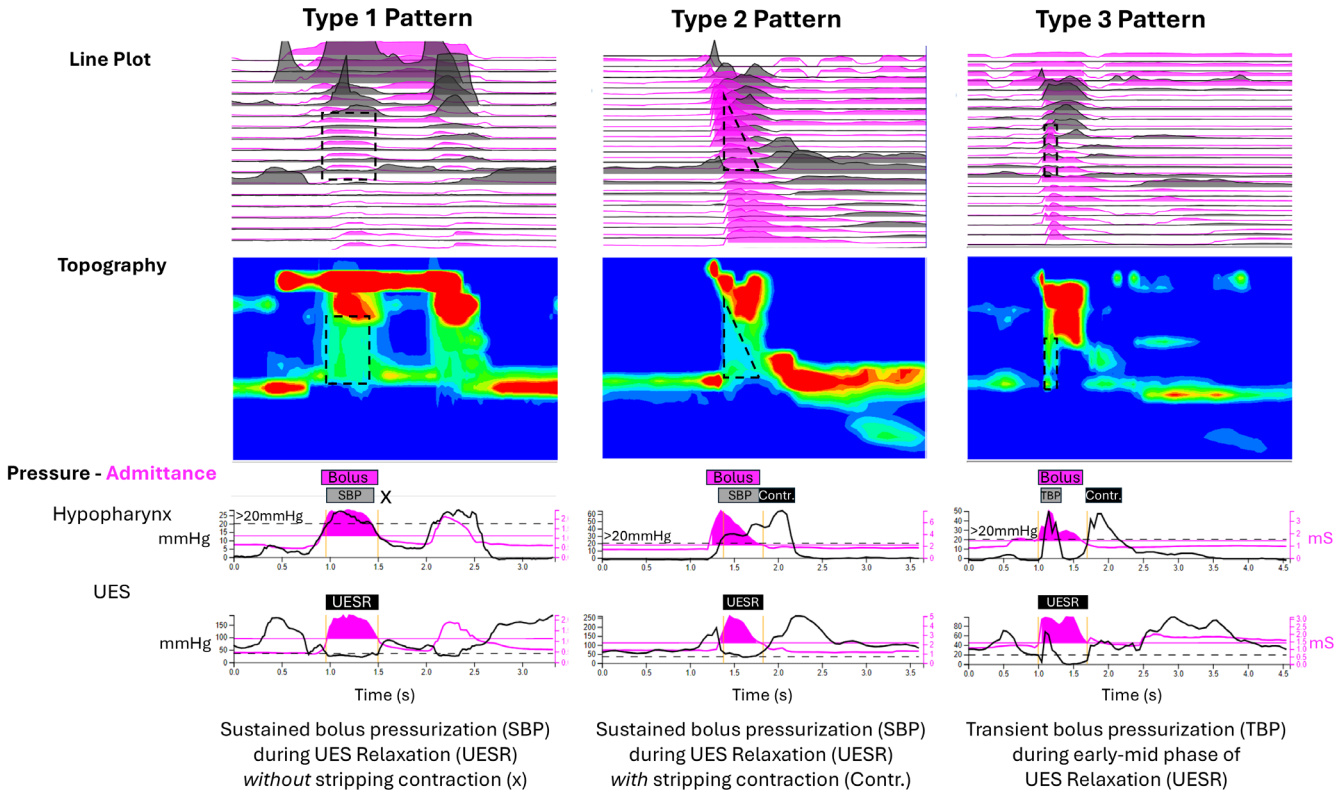


FIGURE 3 | Examples of swallows demonstrating three different pharyngeal pressurization patterns during UES relaxation. Type 1—sustained pan-pressurization, Type 2—sustained distal compartmentalized pressurization, and Type 3—transient pressurization. Boxes (dotted) on the topography and line plots show the region of pressurization > 20 mmHg above hypopharyngeal baseline. The lower margin of the zone of pressurization approximates the position of a high-pressure gradient that may help to localize a pathologically restricted UES opening. The plots bottom show hypopharyngeal and UES pressure-admittance profiles over time for each swallow (per Figure 2). Each example can be visually assessed for the presence of pressurization patterns during UES relaxation. The three different pressurization patterns can be distinguished based upon: (i) the duration of pressurization relative to UES relaxation, that is, sustained pressurization during relaxation (Type 1 and Type 2) vs. transient, nonsustained pressurization during early-mid relaxation (Type 3), and (ii) the presence of a lumen occlusive hypopharyngeal stripping contraction following bolus transit, that is, no visible stripping contraction and simultaneous pan-pressurization (Type 1) vs. stripping contraction with compartmentalized pressurization of the distal pharynx (Type 2).

velopharynx appears as a sustained pressure wave resulting initially from contact forces that are generated by velum elevation through contraction of the velopharyngeal muscles (tensor veli palatini, levator veli palatini, and palatopharyngeus). Afterward, tongue base retraction (genioglossus) also generates contact forces that are transferred from the posterior superior aspect of the tongue to the velum and catheter. These multiple and superimposed forces produce a waveform that is both prolonged and often multimodal in shape [30]. Due to these properties, the *Velopharyngeal Contractile Integral* (VCI) is used to assess the vigor of the velopharyngeal contraction as this considers the strength, length, and duration of the contraction.

Mesopharyngeal contraction defines the onset of the pharyngeal clearance phase that follows lingual propulsion. On pressure topography, mesopharyngeal activity appears as a sustained pressure wave [30] resulting from contact forces that are generated by mesopharyngeal muscle contraction (superior pharyngeal constrictor) and apposition of the base of the tongue (genioglossus) and posterior pharyngeal wall (stylopharyngeus, palatopharyngeus, salpinogpharyngeus). As force generation is prolonged, the *Mesopharyngeal Contractile Integral* (MCI) is used to assess the vigor of the mesopharyngeal contraction because this considers the strength, length, and duration of the contraction.

Hypopharyngeal contraction follows mesopharyngeal contraction sequentially and continues the process of pharyngeal clearance. On pressure topography, hypopharyngeal activity appears as a brief single-peaked pressure wave [30] resulting from contact forces that are generated by sequential hypopharyngeal muscle contraction (inferior pharyngeal constrictor) and laryngeal contact with the catheter against the spine. Effective contraction of the distal pharynx is also reliant on axial shortening of the distal pharyngeal wall (palatopharyngeus, salpingopharyngeus and mainly stylopharyngeus).

Due to the waveform characteristics of the hypopharyngeal contraction (i.e., brief and single peaked), a metric that considers the size and duration of the contraction may not be needed and both the *Hypopharyngeal Contractile Integral* (HPCI) and the *mean Hypopharyngeal Peak Pressure* (HPeakP) have been used to assess the vigor of the hypopharyngeal contraction. Head-to-head comparisons of HPCI vs. HPeakP suggest that the latter may exhibit superior statistical confidence for distinguishing patients from controls and for predicting aspiration

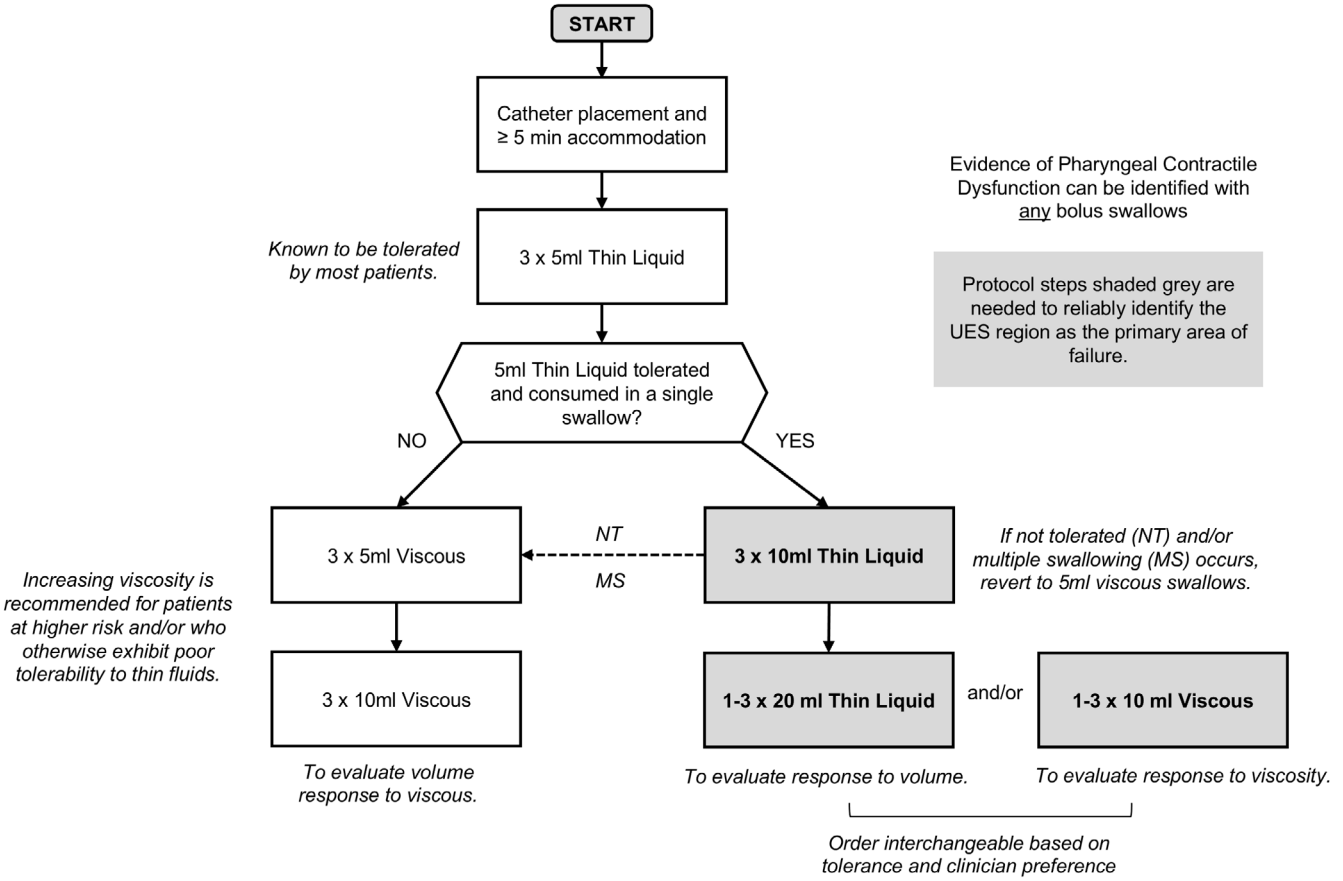


FIGURE 4 | Recommended swallow challenge protocol. Pharyngo-UES function is assessed based upon cued fixed-volume swallows, starting with a thin liquid bolus, followed by more challenging boluses of greater volume and/or a viscosity. Adherence to bolus volumes and the order of swallow challenges is advisable; however, it can be altered, case by case, based on safety considerations and tolerance.

and postswallow residue [18, 27]. HPeakP has also been directly validated as a measure for assessing the adequacy of pharyngeal propulsion in the context of postradiotherapy cricopharyngeal stricture [31].

5 | Consensus Recommendations on Swallow Challenge Protocol

The goal of the swallow challenge protocol is to assess pharyngeal swallowing and UES function by capturing a minimum number of tolerated and analyzable swallows safely and effectively. The Working Group recommendation for a protocol is shown in Figure 4 and has been designed to assess pharyngo-UES function using cued fixed-volume fluid bolus challenges, ideally consumed in a single discrete swallow.

During the swallowing assessment, ongoing monitoring of a patient's status is recommended, and the protocol may need to be truncated if the patient reports feeling "full" or fatigued or exhibits poor tolerance of the procedure. Poor tolerance of the procedure is indicated when a patient is unable or unwilling to consume bolus challenges, experiences significant pain, demonstrates overt signs or symptoms of aspiration or respiratory distress, and/or any overt changes in their state of arousal (e.g., vagal response).

For internal consistency and to achieve meaningful assessment of swallowing physiology, each bolus challenge should ideally be repeated a minimum of three times. Swallow challenges should include thin liquid (International Dysphagia Diet Standardization Initiative (IDDSI) Level 0) and then a thickened liquid (IDDSI levels 2, 3, and/or 4). Increasing bolus thickness to mild, moderate, or extremely thick (IDDSI levels 2, 3, and/or 4) can also be considered for patients at higher risk and/or who otherwise exhibit poor tolerability to thin fluids.

The physiological and therapeutic effects of thickened fluids using thickening products are directly related to the shear viscosity obtained, and not the IDDSI Level achieved [20, 32]. However, the Working Group did not specify an optimal viscosity for P-HRM-I, as this is currently unknown. Therefore, to ensure that datasets and normal values will be comparable for thickened liquid challenges, it is preferable to use fluids with known shear rheology. Specifically, the viscosity should be measured in SI units (mPa.s, Pa·s or cP) at representative shear rates of $50\,s^{-1}$ for the oral phase and $300\,s^{-1}$ for the pharyngeal phase, consistent with other established protocols for assessing thickened fluids [33].

Being a biomechanically based assessment, it is important to employ bolus challenges of a sufficient volume to test the

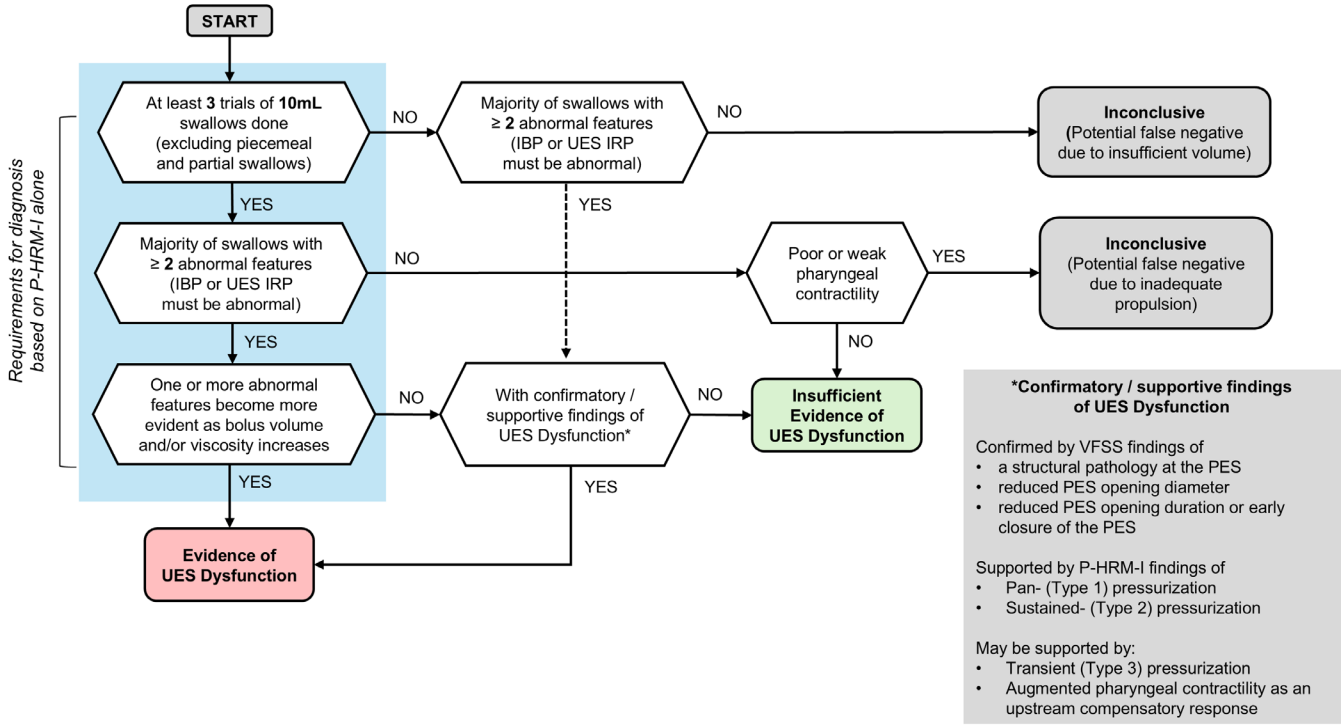


FIGURE 5 | Diagnosis of UES dysfunction. UES dysfunction is optimally diagnosed by a protocol that includes single intact swallows of at least 10 mL volume as well as swallows of differing volumes and/or viscosity. Diagnosis of UES dysfunction based on P-HRM-I alone requires reproducible abnormal UES features and a stimulus–response to bolus volume and/or viscosity. Otherwise, other confirmatory/supportive findings are required.

entire swallowing system in a manner that will be tolerated by most patients. In the first instance, a thin liquid bolus is recommended, followed by more challenging boluses of greater volume and/or a viscosity that may further reveal abnormalities. The protocol may include dry (saliva) swallows; however, it should always include 5 mL thin liquid (IDDSI Level 0) swallows as a conservative starting challenge. The protocol should always aim to include 10 mL thin liquid swallows as well as 5 mL and/or 10 mL thickened liquid swallows. Finally, the protocol should aim to include 20 mL thin liquid swallows when tolerated.

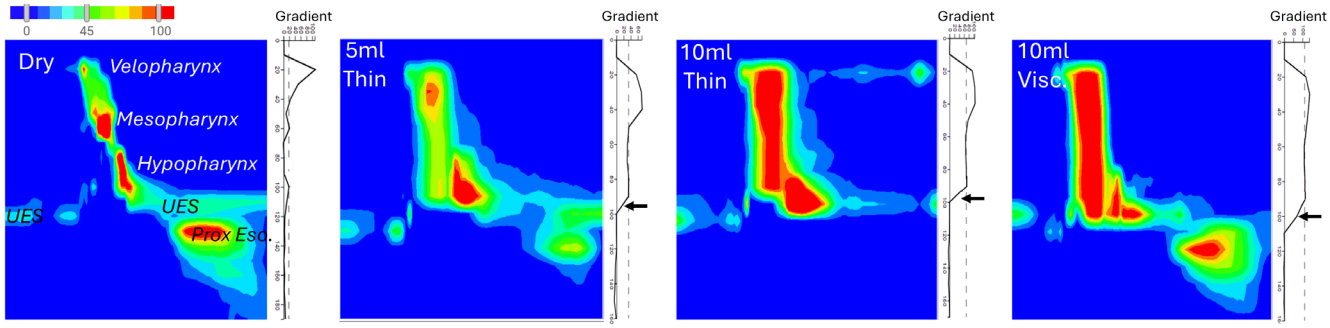
Bolus challenges may be administered via a spoon or syringe, and a patient should be instructed to swallow a bolus all at once; noting that challenges that generate multiple swallowing events may affect the volume consumed per swallow and therefore should be redone if pharyngeal function is considered sufficient to allow consumption with a single swallow. Examples of multiple swallow events include piecemeal and partial deglutition, defined as the division of the orally administered bolus volume across two or more successive swallows, and clearing swallows, defined by incomplete pharyngeal bolus transfer on the first swallow attempt that requires subsequent swallows to clear bolus residue [34]. Single swallows that fail to completely empty bolus residual from the pharyngeal chamber, due to poor or weak pharyngeal contractility, may also impact the volume consumed per challenge.

The recommended order of swallow challenges should be followed for standardization purposes. However, this can be modified for individual patients, based on safety and tolerance. The protocol also includes recommendations for adjusting volumes and viscosity on a case-by-case basis to optimize the ability to capture discrete swallowing events for later analysis.

6 | Consensus Recommendations on Diagnosis of UES Dysfunction

Normal relaxation and opening of the UES region is governed by cricopharyngeal muscle structure and function, in combination with secondary pharyngeal factors, such as extrinsic traction associated with elevation and anterior excursion of the hyolaryngeal complex as well as passive luminal distension by bolus-driving pharyngeal contractile forces [23]. The criteria to reach a diagnosis of UES dysfunction have been specifically tailored to reveal the relaxation and opening of the UES region as the *primary area of failure* while accounting for potential confounders related to secondary mechanisms. A flowchart summarizing the Working Group recommendations for diagnosis of UES dysfunction and representative examples of UES dysfunction has been provided (Figures 5–7A,B).

UES dysfunction is defined by the failure of normal manometric relaxation and/or distension of the PES region. Evidence of UES dysfunction is best identified by higher volume (≥ 10 mL) swallows that align with self-selected swallow volume [2] and pharyngeal chamber volume [26] and therefore maximize the ability of the propulsive forces to drive the bolus through the UES, while minimizing the potential confounding impact of swallowed air [26]. Additionally, submental muscle EMG activity and UES opening have been found to correlate most optimally during higher volume swallows [35]. In some patients,



UES Metric	Challenge		
	5ml Thin	*10ml Thin*	*10ml Visc.*
IBP (mmHg)	**19**	**21↑**	**98↑**
UES IRP (mmHg)	**25**	**34↑**	**63↑**
UES Max.Ad. (mS)	**3.1**	**3.5**	**3.8**
UES RT (s)	0.66	0.69	0.63

Pharyngeal Metric	Challenge		
	5ml Thin	*10ml Thin*	*10ml Visc.*
VCI (mmHg.cm.s)	59	74	64
MCI (mmHg.cm.s)	197	**223↑**	202
HPCI (mmHg.cm.s)	102	140	114
HPeakP (mmHg)	104	112	112

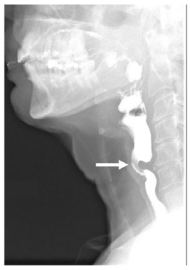


FIGURE 6 | Example of unequivocal UES dysfunction. Panels show representative pressure topography for dry, 5 mL and 10 mL thin liquid and 10 mL viscous liquid swallows (International Dysphagia Diet Standardization Initiative (IDDSI) Level 4, extremely thick, with mean viscosity of 600 mPa.s at $50s^{-1}$ and 160 mPa.s at $300s^{-1}$). 20 mL volume was not tested due to tolerance. The axial pressure gradients seen as the bolus transits the UES region are shown right of each plot, where the position of a high-pressure gradient (arrows) localizes the pathologically restricted UES opening. The median values for metrics are shown in the Tables bottom. Challenge-specific abnormal findings are highlighted in red text. Evidence of UES dysfunction is clearly identified by three metrics being abnormal for all challenges. A stimulus–response to volume and viscosity was also apparent (↑). Supportive evidence was also provided by a pan-pressurization pattern becoming more apparent with the 10 mL liquid challenges and augmented mesopharyngeal contractility as an upstream compensatory response. UES dysfunction is also confirmed by VFSS findings of structural pathology (cricopharyngeal bar—see image). *Based upon Flinders Medical Centre Motility Service normal ranges (Author TO).

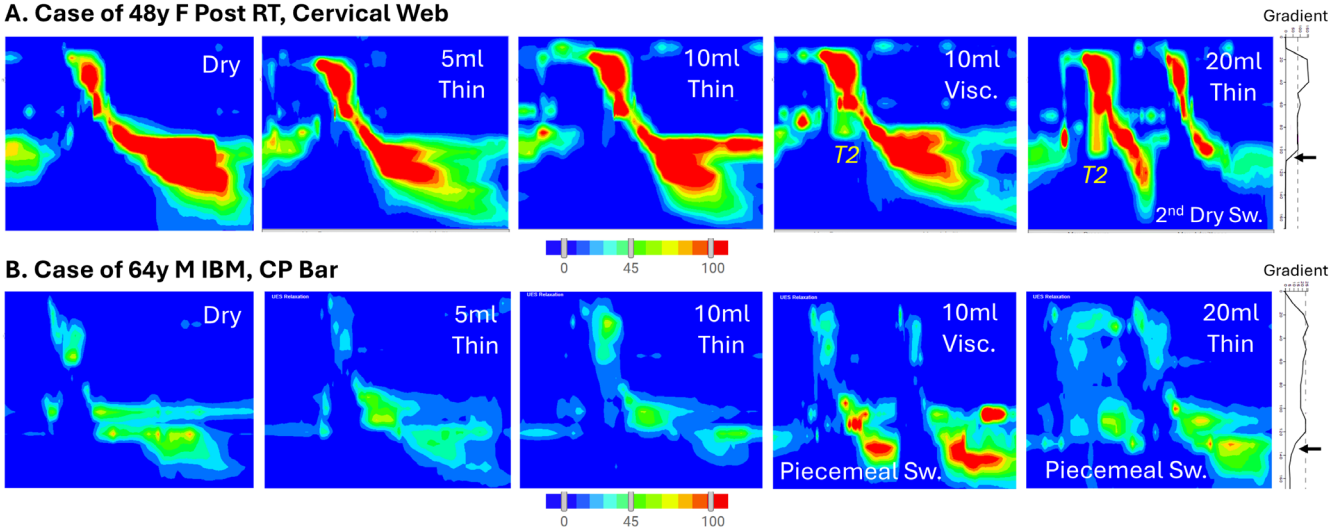
evidence of UES dysfunction can be apparent with a small volume swallow (see Figure 6), for many patients, evidence of UES dysfunction that is potentially amenable to cricopharyngeal disruption will be missed unless swallows of larger volumes (≥ 10 mL) are included in the protocol [36] (see Figure 7A). This potential for a false negative finding (of normal UES function) will be exacerbated in patients with inadequate propulsion [37] and/or piecemeal/partial swallows (see Figure 7B).

A diagnosis of UES dysfunction (see flowchart Figure 5) requires that the majority of ≥ 10 mL swallows (two out of three; excluding piecemeal/partial swallows) demonstrate two or more of the following abnormal COS [1] metrics: High IBP, High UES IRP, Low UES Max Admittance, or Short UES RT. Of these features, UES dysfunction is most strongly supported by High IBP and/or UES IRP and should remain unconfirmed if both UES IRP and IBP are normal, even if UES Max Ad and UES RT are abnormal. Additionally, in order to demonstrate the failure of adaptative UES opening [38], a diagnosis of UES dysfunction requires that abnormal parameters show a stimulus–response, becoming more evident as bolus volume (size) and/or viscosity increases.

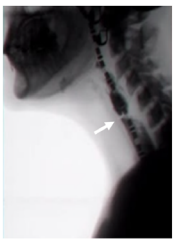
Evidence of UES dysfunction may not be reliably identified with dry swallows and low volume (< 10 mL) swallows (see Figure 7). Therefore, UES dysfunction should remain unconfirmed if abnormal relaxation and/or distension are only found with dry swallows, low volume swallow challenges (5 mL) and swallows typically associated with incomplete single swallow bolus transfer, such as piecemeal/partial swallows and swallows showing pharyngeal hypocontractility. UES dysfunction should also remain unconfirmed if evidence of a stimulus–response to volume or viscosity is lacking.

For cases of unconfirmed UES dysfunction, dysfunction may be supported by VFSS findings of structural pathology at the PES, reduced PES opening diameter, reduced PES opening duration, or early closure of the PES. UES dysfunction is supported by pan- (Type 1) and distal-compartmentalized (Type 2) [18] bolus pressurization patterns on pharyngeal pressure topography and may be supported by a transient (Type 3) [25] bolus pressurization pattern. UES dysfunction may also be supported by augmented pharyngeal contractility as an upstream compensatory response to obstructed bolus outflow (see Figures 6 and 7A).

The Working Group considered the potential role of functional luminal imaging probe (EndoFLIP) to confirm UES dysfunction by evaluating the compliance of the PES. EndoFLIP has been shown to accurately detect abnormally reduced PES distensibility in patients with structural pathologies (e.g., radiation-induced stricture [39] and Zenker's diverticulum [40]). It can be used as a research tool in patients undergoing endoscopy; however, its role is unclear in other settings. Importantly, optimal use requires that patients are sedated. Under these conditions, the effect of sedation level and muscle relaxant on PES distensibility remains incompletely understood, and there is also a paucity of normative range data. As most of the Working Group also



Example A	Challenge			
Metric	*5ml Thin*	*10ml Thin*	*10ml Visc.*	*20ml Thin*
IBP (mmHg)	1	5↑	37↑	54↑
UES IRP (mmHg)	2	1	9↑	20↑
UES Max.Ad. (mS)	3.0	3.8	4.6	4.4
UES RT (s)	0.69	0.76	0.74	0.79



Example B	Challenge			
Metric	*5ml Thin*	*10ml Thin*	*10ml Visc.*	*20ml Thin*
IBP (mmHg)	5	6	6	15↑
UES IRP (mmHg)	1	6↑	4	11↑
UES Max.Ad. (mS)	2.1	2.7	3.5	3.2
UES RT (s)	0.44	0.46	0.57	0.60

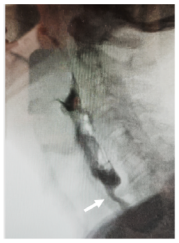


FIGURE 7 | Examples of UES dysfunction revealed by increased volume and viscosity. Panels show representative pressure topography for different swallow challenges. The axial pressure gradient seen as the 20 mL thin bolus transits the UES region is shown far right. The median values for UES metrics are shown in the Tables bottom. Challenge-specific abnormal findings* are highlighted in red text. Evidence of UES dysfunction is best identified by higher volume (≥10 mL) swallows (shaded gray in Table). The viscous bolus challenges were International Dysphagia Diet Standardization Initiative (IDDSI) Level 3–4 (moderately—extremely thick) with mean viscosity in the range of 400–600 mPa.s at $50s^{-1}$ and 140–160 mPa.s at $300s^{-1}$. *Based upon Flinders Medical Centre Motility Service normal ranges (Author TO).
Case A. Patient post radiotherapy (only) for left vocal fold carcinoma. Only one UES metric (UES Max.Ad.) was abnormal for 5 mL thin, and no metrics were abnormal for 10 mL thin. However, three metrics were abnormal for both 10 mL viscous and 20 mL thin. A stimulus–response to volume and viscosity was also apparent (↑). Multiple swallowing was seen for 20 mL thin liquid volumes; in this case, the pattern had no impact because the bulk of the bolus was consumed with the first swallow (secondary dry pattern on impedance). Supportive evidence was also provided by a transient Type 2 pressurization pattern (T2) notably only apparent with the 10 mL viscous and 20 mL thin challenges, and augmented mesopharyngeal contractility with 10 mL thin, 10 mL viscous, and 20 mL thin (MCI 174, 186 and 260 mmHg.cms, respectively). This example illustrates why caution is required when interpreting normal findings for low-volume swallows and highlights the need to additionally evaluate viscous liquids. Together, these data provide a diagnosis of UES dysfunction confirmed by VFSS findings of structural pathology (pharyngeal web—see image).
Case B. Patient with inclusion body myositis (10-year history) with oropharyngeal dysphagia symptoms and swallowing fatigue that has gradually worsened over time. Only one UES metric (UES Max.Ad.) was abnormal for 5 ml thin, while two metrics were abnormal for 10 ml and 20 ml thin. A stimulus-response to volume was apparent (↑). In contrast, a stimulus response to viscosity was not observed, possibly related to piecemeal swallowing and hypopharyngeal weakness (HPeakP range 26-34 mmHg) which would have reduced the volume consumed per swallow and increased likelihood of transit being incomplete. Piecemeal swallowing was also seen for 20 ml thin liquid volumes, however values for both UES IRP and UES Max.Ad. remained abnormal, with the abnormal UES IRP becoming more evident with the increased volume. Whilst IBP also increased with volume, IBP was always normal, consistent with pharyngeal propulsive weakness. This example illustrates why some caution is required when interpreting low volume swallows, partial swallows and swallows with poor or weak pharyngeal contractility. However, when considered together, the data for this case meet the evidence threshold required to provide for a diagnosis of UES Dysfunction confirmed by VFSS findings of structural pathology (cricopharyngeal bar – see image).

lacked sufficient direct experience with EndoFLIP, no specific recommendations could be provided.

7 | Consensus Recommendations on Diagnosis of Pharyngeal Contractile Dysfunction

Pharyngeal contractile dysfunction is primarily defined as an abnormal sequential segmental contraction. Since the diagnosis of pharyngeal contractile dysfunction is focused on vigor only, timing and coordination aspects are not captured by the current suite of recommended pharyngeal contractile COS metrics. The Working Group recommendations for the diagnosis of pharyngeal contractile dysfunction are summarized in Figure 8. Examples are provided in Figure 9.

A diagnosis of pharyngeal contractile dysfunction requires that the majority of bolus swallows (two out of three) demonstrate ABSENT or LOW contractile pressures in one or more pharyngeal segments. If the majority of bolus swallows demonstrate

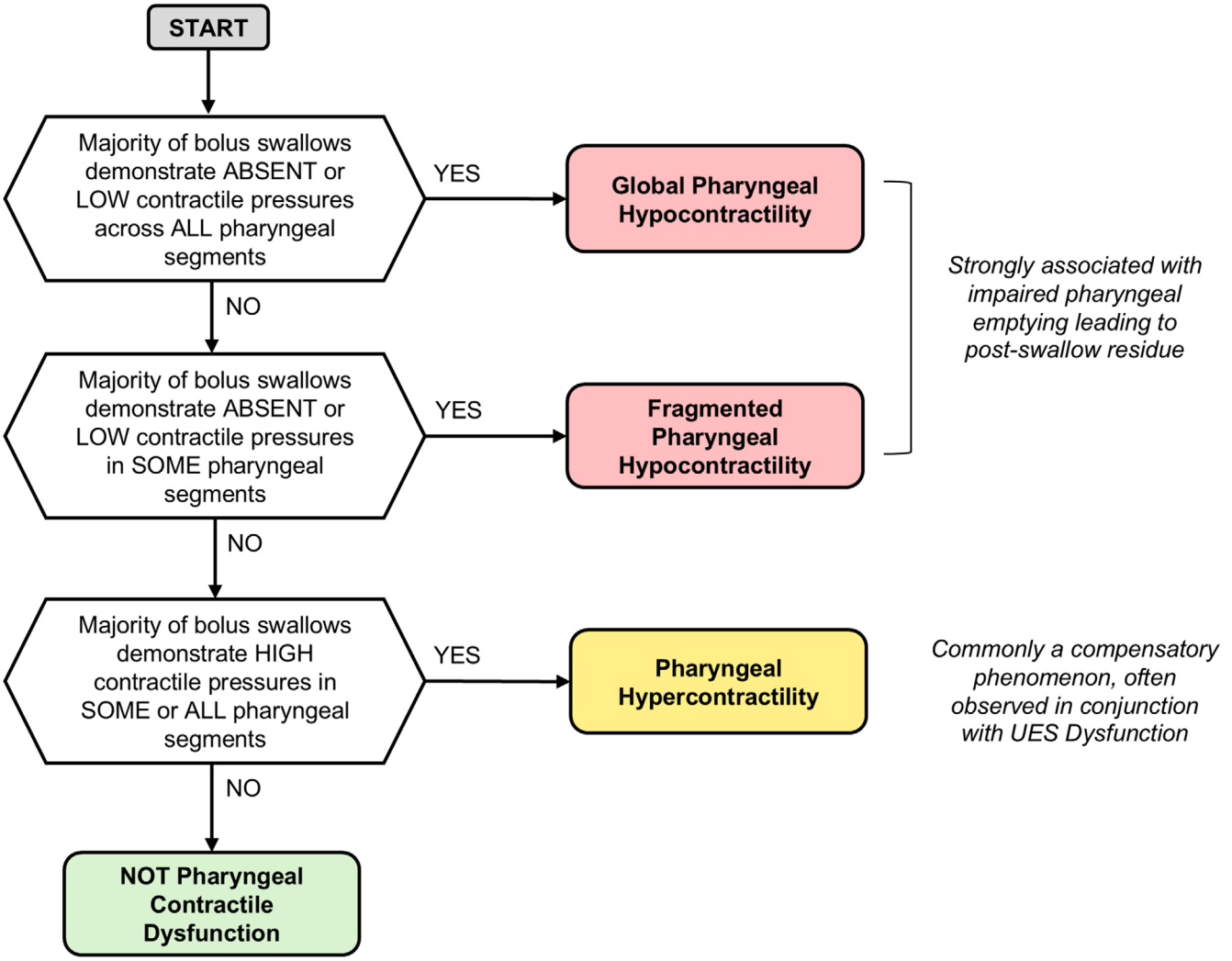


FIGURE 8 | Diagnosis of pharyngeal contractile dysfunction. A diagnosis requires that the majority of bolus swallows of any volume demonstrate ABSENT or LOW, or HIGH contractile pressures in one or more pharyngeal segments.

HIGH contractile pressures in one or more pharyngeal segments, then pharyngeal contractility is usually compensatory, although this may represent dysfunction.

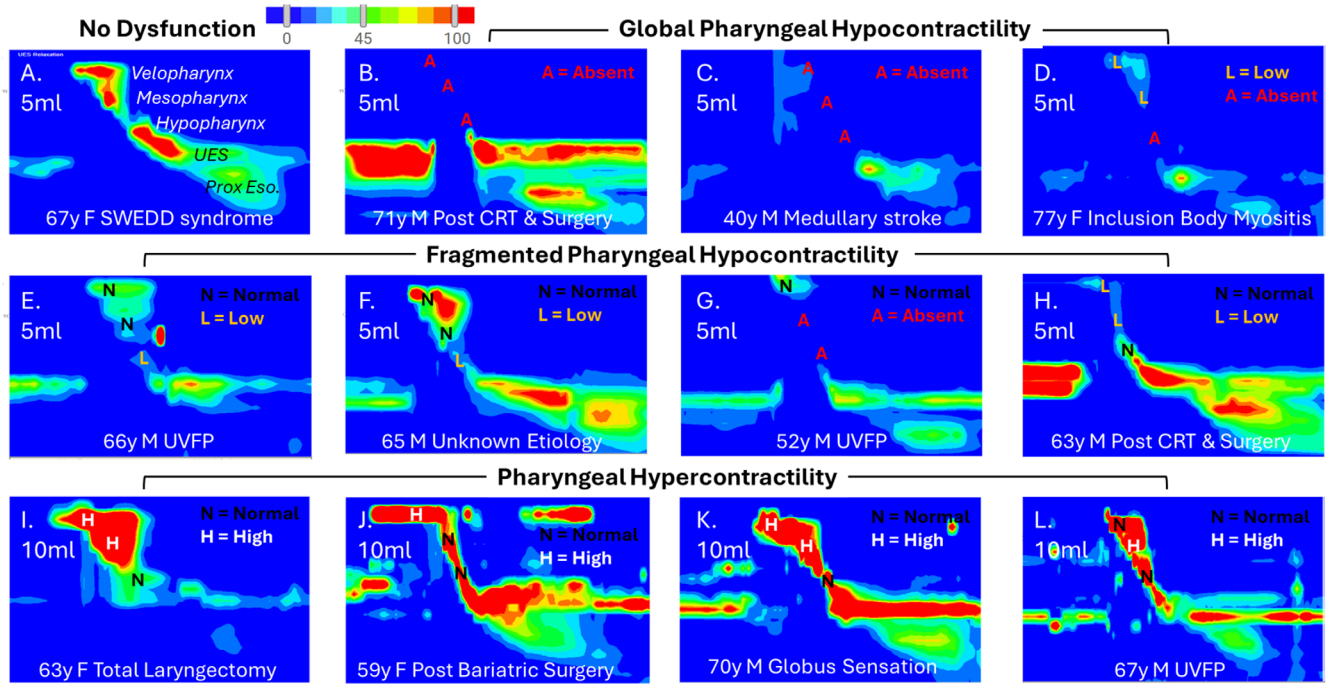
Evidence of pharyngeal contractile dysfunction can be identified with any bolus swallows and may be identified with dry swallows. Velopharyngeal, mesopharyngeal, and hypopharyngeal contractile integral (VCI, MCI, HPCI) and the mean hypopharyngeal peak pressure (HPeakP) are recommended as measurements of pharyngeal contractile strength. Other metrics of pharyngeal contractility are also available, and until further data emerge, analysts should use their discretion regarding what metrics of pharyngeal contractility should be used.

Pharyngeal hypocontractility is strongly associated with impaired pharyngeal emptying, leading to postswallow residue [27]. Global pharyngeal hypocontractility is diagnosed when the majority of bolus swallows demonstrate ABSENT or LOW contractile pressures across all pharyngeal segments (i.e., velopharynx, mesopharynx, and hypopharynx—see Figure 9B–D).

Fragmented pharyngeal hypocontractility is diagnosed when the majority of bolus swallows demonstrate ABSENT or LOW contractile pressures in some pharyngeal segments (see Figure 9E–H).

Pharyngeal hypercontractility that is unrelated to a swallowing maneuver (e.g., effortful swallow) can be global or fragmented and is commonly a compensatory phenomenon, often observed in conjunction with UES dysfunction. Pharyngeal hypercontractility is diagnosed when the majority of bolus swallows demonstrate HIGH contractile pressures in some or all pharyngeal segments (see Figure 9I–L). When the majority of bolus swallows demonstrate a mixture of BOTH hypocontractile and hypercontractile features among different pharyngeal segments, then fragmented pharyngeal hypocontractility is diagnosed.

A combined pharyngeal and UES disorder is considered if UES dysfunction criteria are also met. As hypercontractility can be a compensatory "upstream" response to obstructed bolus outflow, patients with hypercontractility and UES dysfunction



Abnormal Pattern Type	None	Global Hypocontractility			Fragmented Hypocontractility				Hypercontractility			
Case	A	B	C	D	E	F	G	H	I	J	K	L
VCI (mmHg.cm.s)	86	-2↓	4↓	11↓	43	77	19	16↓	311↑	239↑	325↑	203
MCI (mmHg.cm.s)	80	1↓	6↓	9↓	43	91	5↓	5↓	240↑	141	241↑	240↑
HPCI (mmHg.cm.s)	34	17↓	6↓	0↓	10↓	11↓	12↓	52	35	41	80	74
HPeakP (mmHg)	81	37↓	9↓	1↓	18↓	25↓	17↓	61	63	159	287	127

FIGURE 9 | Examples of pharyngeal contractile dysfunction. Representative pharyngeal pressure topography plots from 12 patients (Cases A–L). Each swallow can be qualitatively assessed to determine whether pressures generated by each pharyngeal segment are low (suggestive of a weak, lumen occlusive, pharyngeal contraction) or absent (suggestive of a nonocclusive contraction). Objective confirmation is provided by metrics of pharyngeal contractile strength (see Table for median values from 3 to 5 thin liquid swallows. Abnormal findings* are highlighted in red text). *Based on Flinders Medical Centre Motility Service normal ranges (Author TO).

(see Figures 6 and 7A) should fall within the spectrum of UES dysfunction. However, patients with hypocontractility and UES dysfunction (see Figure 7B) are considered a combined disorder where visual instrumental investigations such as videofluoroscopy are essential for a complete diagnostic assessment.

8 | Clinical Relevance

This guideline promotes a physiologically based approach to understanding oropharyngeal swallowing dysfunction that will refine treatment recommendations and enable integration of P-HRM-I into clinical practice. Confirming the cause and severity of pharyngeal dysphagia is oftentimes difficult in the clinical setting when patient symptoms conflict with a single assessment such as an isolated VFSS, particularly if standardized protocols or quantitative measures are not utilized. A test battery approach, obtaining corroborating or supplementary physiological information regarding the swallow, can provide direct guidance for management selection and treatment targets. The use of P-HRM-I swallowing assessment guided by the recommendations and algorithms provided will improve the diagnostic categorization of individual patients. High-quality, objective, complete information allows confirmation of the pathophysiology of a clinically reported dysphagia concern and adds rigor to causal assumptions that are often made prior to treatment initiation. These recommendations, combined with additional supportive studies, clinical history, and physical findings, will raise patient and clinician confidence and improve the likelihood of treatment success, reducing both risk and cost of care.

9 | Conclusion

The International Pharyngeal Manometry Working Group has considered a range of research and clinical evidence and herein provides a preliminary set of consensus-based recommendations and algorithms to classify pharyngeal motor disorders utilizing P-HRM-I swallowing assessment. To identify and define dysfunction, the diagnostic process involves a stepwise evaluation of bolus challenges, ranging from thin liquids to more challenging volumes and viscosities, alongside other appropriate swallowing assessments. For diagnosis, the classification

categorizes disorders into UES dysfunction, pharyngeal contractile dysfunction, or a combination of both.

The *Leuven Consensus* attempts to address the need for guidance on a standardized approach and nomenclature for interpreting and reporting P-HRM-I results. This foundational work is expected to undergo iterative revision as more knowledge and experience is gained. A paucity of universally available system-specific normal values is acknowledged, as is the need for further research to evaluate the validity and utility of these recommendations, including clinical trials to assess whether interventions based on these recommendations are effective.

Author Contributions

T.I.O., C.C., T.M.M., N.N.Z., A.K.O., M.M.S., P.I.W., and N.R. were members of the organizing committee. T.I.O., C.C., T.M.M., N.N.Z., A.K.O., M.M.S., P.I.W., J.A., H.H.G.B., K.D., C.J., J.C.F.M., G.N.P., and N.R. developed preliminary proposals. All Authors actively participated in the Leuven consensus meeting and Delphi voting rounds. T.I.O., J.C.F.M., C.C., T.M.M., P.I.W., J.A., H.H.G.B., S.C., and N.R. wrote sections of the manuscript. T.I.O., C.C., M.S., M.M.S., P.I.W., and J.C.F.M. contributed clinical case examples. A.K.O., N.N.Z., G.N.P., M.R.C., S.H., R.H., J.P.S., and A.R. critically revised the manuscript for important intellectual content. All authors approved the final version of the manuscript.

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Conflicts of Interest

T.I.O., inventorship of relevant patents and software. A.K.O., Research Grant: Laborie Medical Inc. Consultant: Laborie Medical Inc. Educational Conference Support: Medtronic Inc., Laborie Medical. SH, chief scientific officer of the company Phagenesis Ltd., which focuses on dysphagia therapies, and holds stocks and shares in that company. NR, inventorship of relevant patents. All other authors report no conflicts of interest.

Data Availability Statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.