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European Society for Neurogastroenterology and Motility (ESNM) recommendations for the use of high-resolution manometry of the esophagus

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Abstract

Background: Several patients in gastroenterology practice present with esophageal symptoms, and in case of normal endoscopy with biopsies, high-resolution manometry (HRM) is often the next step. Our aim was to develop a European consensus on the clinical application of esophageal HRM, to offer the clinician guidance in selecting patients for HRM and using its results to optimize clinical outcome.

Methods: A Delphi consensus was initiated with 38 multidisciplinary experts from 16 European countries who conducted a literature summary and voting process on 71 statements. Quality of evidence was evaluated using grading of recommendations assessment, development, and evaluation (GRADE) criteria. Consensus (defined as >80% agreement) was reached for 33 statements.

Results: The process generated guidance on when to consider esophageal HRM, how to perform it, and how to generate the report. The Delphi process also identified several areas of uncertainty, such as the choice of catheters, the duration of fasting and the position in which HRM is performed, but recommended to perform at least 10 5-ml swallows in supine position for each study. Postprandial combined HRM impedance is considered useful for diagnosing rumination. There is a large lack of consensus on treatment implications of HRM findings, which is probably the single area requiring future targeted research.

Conclusions and inferences: A multinational and multidisciplinary group of European experts summarized the current state of consensus on technical aspects, indications, performance, analysis, diagnosis, and therapeutic implications of esophageal HRM.

KEYWORDS
achalasia, belching, chest pain, Chicago classification, esophageal manometry, impedance manometry, rumination, solid state catheter, spasm

1 | INTRODUCTION

A large number of patients in gastroenterology practice present with esophageal symptoms, including dysphagia, regurgitation, heartburn, chest pain, and belching, among others.[1,2] Most of these patients will undergo upper endoscopy with biopsies, but if this is negative, esophageal manometry is a key investigation. Standard esophageal manometry was already introduced in the 1960s and has

ESNM HRM consensus group authors listed in Appendix 1.

seen wide application in gastroenterology practice.[3] High-resolution esophageal manometry (HRM), which uses a high number of closely apposed pressure sensors, was first described by Ray Clouse and co-workers in 2000.[4] Commercially available HRM equipment and the development of a standardized diagnostic approach to these results as described in the Chicago classification [5-7] allowed increasingly broad application of esophageal HRM in clinical practice. However, major variation exists between clinical practices on technical aspects, patient selection, and implications of HRM studies.

The aim of this project was to develop a European consensus on the clinical application of esophageal HRM, which could offer the clinician guidance in selecting patients for esophageal HRM and using its results to optimize clinical outcome.

2 | METHODS

The European Society for Neurogastroenterology and Motility (ESNM) initiated a Delphi process, to develop consensus statements for the use of esophageal HRM in clinical practice. The Delphi approach, which combines the principles of evidence-based medicine, supported by systematic literature reviews and a voting process, aims at determining consensus for complex problems in medicine for which evidence from controlled trials is lacking.[8]

The principal steps in the process were as follows: 1) selection of a Working Group of 5 ESNM members with expertise in HRM and/or Delphi consensus processes; 2) selection of an international Consensus Group consisting of experts in esophageal disease and HRM from 16 different European countries, recruited through the ESNM board; 3) drafting of statements allowing to evaluate the current knowledge on the use of esophageal HRM; 4) systematic literature reviews to identify evidence to support each statement; 5) three rounds of repeated voting of the statements and voting discussion until a stable level of consensus voting was reached; and 6) grading of the strength using accepted criteria.

For the Consensus Group, ESNM board members nominated experts from their respective national societies for participation. A total of 38 experts from 16 European countries agreed to participate. Members had a background of expertise in gastroenterology, surgery, esophageal physiology, or speech pathology.

The 5-member Working Group made a list of statements that were evaluated in a first voting round by all members after the summer of 2017, who also gave feedback on clarity of the statement and made suggestions for adapting or splitting the statement into 2 or more questions, or for adding additional statements on a given topic. Next, the 5-member Working Group drafted a new list of statements and composed working teams of 3 to 4 members who were allocated 4 to 7 statements for which they conducted a literature search (Medical Subject Headings not shared with the other groups) and wrote a scholarly review in the course of the year 2018. After all literature surveys with literature reference list were collected, they were put into a suitable framework for a new voting round. For voting, each statement was presented with the evidence summary, and then, the entire panel indicated the degree of agreement for the statement using a 6-point Likert scale (Table 1). When 80% of the Consensus Group agreed (A+ or A) with a statement, this was defined as consensus. All votes were mutually anonymous. The strength of evidence for each statement was scored using the GRADE system (Table 2).[9]

The final voting round was conducted in the summer of 2019, after which the manuscript was drafted and circulated for final approval of the participants. The references cited in this chapter are only a selection of the articles reviewed in each area, chosen to clarify the discussion.

Key Messages

- In patients with esophageal symptoms and a normal endoscopy with biopsies, high-resolution manometry (HRM) is often the next step.
- Our aim was to develop a European consensus to offer the clinician guidance in selecting patients for HRM, in performing the investigation and using its results to optimize clinical outcome.
- A Delphi consensus was initiated with 38 multidisciplinary experts from 16 European countries who conducted a literature summary and voting process on 71 statements.
- This Delphi process summarized the current state of consensus on technical aspects, indications, performance, analysis, diagnosis, and therapeutic implications of esophageal high-resolution manometry.

3 | RESULTS

3.1 | Equipment

1. **High-resolution manometry is the gold standard for the diagnosis of esophageal motility disorders.**
   STATEMENT ENDORSED, overall agreement 100%: A + 91%, A 9%, A− 0%, D− 0%, D 0%, D+ 0%. GRADE A.
2. **Solid state pressure sensors and water-perfused sensors are equivalent to evaluate esophageal body and OGJ motility.**
   STATEMENT NOT ENDORSED, overall agreement 50%: A + 12%, A 47%, A− 24%, D− 6%, D 9%, D+ 3%. GRADE B.
3. **21 to 36 pressure sensors are necessary to accurately evaluate esophageal body and OGJ motility.**
   STATEMENT ENDORSED, overall agreement 94%: A+ 50%, A 44%, A− 6%, D− 0%, D 0%, D+ 0%. GRADE B.
4. **When high-resolution manometry is not available, use of a water-perfused catheter with Dent sleeve is preferable.**
   STATEMENT ENDORSED, overall agreement 92%: A+ 53%, A 29%, A− 18%, D− 0%, D 0%, D+ 0%. GRADE B.

Neurogastroenterology & Motility NGM -WILEY

TABLE 1 6-point Likert scale.

Point	Description
A+	Agree strongly
A	Agree with minor reservation
A−	Agree with major reservation
D−	Disagree with major reservation
D	Disagree with minor reservation
D+	Disagree strongly

5. **Disinfection of the catheter should be performed after each procedure according to manufacturer's guidelines.**
   STATEMENT ENDORSED, overall agreement 100: A+ 88%, A 12%, A− 0%, D− 0%, D 0%, D+ 0%. GRADE B.
6. **Representation as topographical esophageal pressure plots (Clouse plots) facilitates data interpretation.**
   STATEMENT ENDORSED, overall agreement 97%: A+ 85%, A 12%, A− 3%, D− 0%, D 0%, D+ 0%. GRADE A.
7. **Representation as topographical esophageal pressure plots (Clouse plots) improves interobserver agreement.**
   STATEMENT ENDORSED, overall agreement 94%: A+ 62%, A 32%, A− 6%, D− 0%, D 0%, D+ 0%. GRADE A.
8. **Representation as topographical esophageal pressure plots (Clouse plots) improves intra-observer agreement.**
   STATEMENT ENDORSED, overall agreement 91%: A+ 59%, A 32%, A− 3%, D− 6%, D 0%, D+ 0%. GRADE A.
9. **Combined HRM impedance allows the evaluation of bolus clearance and the relationship between bolus movement and intraluminal pressures.**
   STATEMENT ENDORSED, overall agreement 88%: A+ 65%, A 24%, A− 9%, D− 0%, D 0%, D+ 3%. GRADE B.
10. **The combined-impedance manometry device requires a specific disinfection protocol.**
   STATEMENT NOT ENDORSED, overall agreement 47%: A+ 26%, A 21%, A− 15%, D− 21%, D 6%, D+ 12%. GRADE B.
11. **The tolerability of the different available HRM catheters is not similar.**
   STATEMENT NOT ENDORSED, overall agreement 76%: A+ 50%, A 26%, A− 15%, D− 9%, D 0%, D+ 0%. GRADE A.
12. **The performance characteristics are specific to each type of catheter.**
   STATEMENT ENDORSED, overall agreement 88%: A+ 42%, A 45%, A− 9%, D− 3%, D 0%, D+ 0%. GRADE A.

Several national guidelines consider esophageal manometry the gold standard test for the assessment of esophageal motility when endoscopy identifies no mechanical obstruction or mucosal disease.[10-13] Furthermore, HRM is superior to conventional manometry for detecting abnormal motility and detects esophageal motility disorders like achalasia earlier than conventional manometry.[14,15] Whether esophageal body and esophagogastric junction (OGJ) parameters obtained with solid state pressure sensors and water-perfused sensors are equivalent is controversial and requires further comparative studies.[16] The normal values for water-perfused catheters with 36 pressure channels are only slightly different from previously published values with solid state HRM, and moderate-to-good agreement was observed between the two systems, with relatively small differences in outcome measures.[17-19] One study, however, reported a significant difference in the definition of the lower esophageal sphincter (LOS) upper margin, LOS relaxation ratio, and integrated relaxation pressure in 4 seconds (IRP.[20] De Schepper and colleagues studied the effect of increasing the spacing between adjacent sensors, and found that increasing the distance to 3 or more cm induced (minor) discrepancies with the 1 cm data.[15]

With conventional manometry, it can be difficult to distinguish a fall in pressure that is caused by movement of a single pressure sensor (or side hole) from the OGJ into the stomach or the

TABLE 2 Grading of recommendations assessment, development, and evaluation system[9]

Code	Quality of evidence	Definition
A	High	Further research is very unlikely to change our confidence in the estimate of effect • Several high-quality studies with consistent results • In special cases: one large, high-quality multicenter trial
B	Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. • One high-quality study • Several studies with some limitations
C	Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. • One or more studies with severe limitations
D	Very low	Any estimate of effect is very uncertain. • Expert opinion • No direct research evidence • One or more studies with very severe limitations

esophageal body from a true relaxation of the lower esophageal sphincter (LES). This is particularly relevant in the manometric diagnosis of achalasia, where 4 out of 26 patients with achalasia were erroneously diagnosed with aperistalsis when using single-sensor LOS pressure tracings.[11] Ghosh et al. reported that the single-sensor method of assessing OGJ relaxation had a sensitivity of only 52% for detecting achalasia and that one of the most important causes for this was esophageal shortening.[21] The perfused Dent sleeve is a device that measures the highest pressure exerted anywhere along its length (6 cm).[22] It allows for prolonged recording of LOS pressures.

Esophageal manometry probes are considered semi-critical items that contact mucous membranes and should be free from all microorganisms, although small numbers of bacterial spores are permissible. The Center for Disease Control (CDC) establishes disinfection strategies for semi-critical devices. The guidelines for cleaning and disinfecting are partly derived from methods used for dental unit water lines. Appropriate cleaning and equipment maintenance should be regularly employed per local infection control and manufacturer's instructions to assure high-level disinfection. Cleaning should always precede high-level disinfection and sterilization.[23] An alternative is the use of a disposable catheter sheath, a single-use, hygienic catheter protector cover, which prevents gross contamination and reduces cleaning and disinfecting efforts. The sheath is not compatible with water-perfused catheters or with impedance measurements and seems infrequently used. It seems adequate to consult with the Hygiene Department of the hospital about the most appropriate cleaning and disinfection method in specific cases such as incorporated impedance rings (Table 3).

Multichannel HRM with color plotting simplifies the performance of a motility study, facilitates positioning of the catheter, and improves the interpretation of the tracings.[4] Spatiotemporal plotting also allows faster and more accurate analysis of manometry data by manometry-naive individuals compared to the line plot format.[24] Using the Chicago classification, HRM has not only superior inter-rater agreement and is easier to learn, but also has higher diagnostic accuracy, with a significantly lower chance of an incorrect diagnosis compared to conventional manometry, both for experts and non-experts.[25,26] On the other hand, manometric diagnoses of conditions other than normal or achalasia are variable and have poor interobserver agreement.[26] Interobserver and intra-observer agreement for differentiating achalasia from non-achalasia patients using HRM and the Chicago classification ranges from very good to excellent.[27] The largest variation was observed in classification between type I and type II achalasia, which have similar characteristics.[20]

Validation studies with combined measurement of manometry, impedance, and video-fluoroscopy have demonstrated that bolus clearance can be depicted by combined HRM impedance.[28-30] Initial studies defined bolus entry by a 50% drop in impedance relative to the preswallow baseline, and bolus clearance by return of impedance to 50% of baseline.[28] Disturbed bolus transit was documented by combined HRM impedance in patients with scleroderma, and subsets of patients with ineffective esophageal motility or distal esophageal spasm (pre-Chicago nomenclature).[31-34] Integrating impedance and manometric patterns identifies a number of quantitative parameters reflecting bolus transport and uphold, which can increase the diagnostic yield of manometry in patients with dysphagia and no major motor abnormality according to the Chicago classification.[35-42]

Catheters from different manufacturers have their own design and properties. The tolerability of esophageal manometry catheters may differ depending on the diameter and stiffness of the probe.[43] The normal values also depend of the type of the pressure sensors (solid state, water-perfused system, unidirectional, or circumferential) and of catheter (diameter) used.[17,44-46] Investigators should take into account the specific normal values of their equipment (catheter and system) as summarized in the Chicago consensus.[7]

3.2 | Study protocol

1. **Calibration should be performed before each procedure.**
   STATEMENT ENDORSED, overall agreement 91%: A+ 74%, A 18%, A− 6%, D− 0%, D 3%, D+ 0%. GRADE A
2. **At least 4 h of fasting prior to esophageal manometry is recommended.**
   STATEMENT NOT ENDORSED, overall agreement 76%: A+ 55%, A 21%, A− 21%, D− 3%, D 0%, D+ 0%. GRADE B
3. **When achalasia is suspected, the fasting period prior to manometry should be longer.**
   STATEMENT ENDORSED, overall agreement 88%: A+ 65%, A 24%, A− 12%, D− 0%, D 0%, D+ 0%. GRADE B
4. **Preferably, the manometric probe is inserted transnasally.**
   STATEMENT ENDORSED, overall agreement 100%: A+ 94%, A 6%, A− 0%, D− 0%, D 0%, D+ 0%. GRADE A
5. **Catheter insertion without anesthesia is feasible.**
   STATEMENT ENDORSED, overall agreement 91%: A+ 65%, A 26%, A− 6%, D− 0%, D 0%, D+ 0%. GRADE B
6. **Local anesthesia improves the catheter tolerance.**
   STATEMENT NOT ENDORSED, overall agreement 76%: A+ 59%, A 18%, A− 18%, D− 6%, D 0%, D+ 0%. GRADE A
7. **In patients with a normal body height, at least one or two pressure sensors should be in the pharynx and three in the stomach.**
   STATEMENT ENDORSED, overall agreement 94%: A+ 71%, A 23%, A− 3%, D− 0%, D 3%, D+ 0%. GRADE B
8. **In tall patients, the probe should be moved to monitor esophageal body and esophagogastric junction pressures first and upper esophageal sphincter and pharyngeal pressures later.**
   STATEMENT ENDORSED, overall agreement 97%: A+ 68%, A 29%, A− 3%, D− 0%, D 0%, D+ 0%. GRADE B
9. **A deep breath maneuver should be performed at the beginning of the study to ensure that the catheter has passed through the esophagogastric junction.**

TABLE 3 All statements with endorsement and references.

Statement	Consensus	References
Equipment		
1. High-resolution manometry is the gold standard for the diagnosis of esophageal motility disorders.	Endorsed	10-15
2. Solid state pressure sensors and water-perfused sensors are equivalent to evaluate esophageal body and OGJ motility.	*Not* endorsed	16-20
3. 21 to 36 pressure sensors are necessary to accurately evaluate esophageal body and OGJ motility.	Endorsed	15
4. When high-resolution manometry is not available, use of a water-perfused catheter with Dent sleeve is preferable	Endorsed	21,22
5. Disinfection of the catheter should be performed after each procedure according to manufacturer's guidelines.	Endorsed	23
6. Representation as topographical esophageal pressure plots (Clouse plots) facilitates data interpretation.	Endorsed	24,25
7. Representation as topographical esophageal pressure plots (Clouse plots) improves inter-observer agreement.	Endorsed	26,27
8. Representation as topographical esophageal pressure plots (Clouse plots) improves intra-observer agreement.	Endorsed	27
9. Combined HRM impedance allows the evaluation of bolus clearance and the relationship between bolus movement and intraluminal pressures.	Endorsed	28-42
10. The combined-impedance manometry device requires a specific disinfection protocol.	*Not* endorsed	23
11. The tolerability of the different available HRM catheters is not similar.	*Not* endorsed	43
12. The performance characteristics are specific to each type of catheter.	Endorsed	44-46
Study protocol		
13. Calibration should be performed before each procedure.	*Not* endorsed	47,48
14. At least 4 h of fasting prior to esophageal manometry is recommended.	*Not* endorsed	10,49
15. When achalasia is suspected, the fasting period prior to manometry should be longer.	Endorsed	10,49
16. Preferably, the manometric probe is inserted transnasally.	Endorsed	49,50
17. Catheter insertion without anesthesia is feasible.	Endorsed	49-51
18. Local anesthesia improves the catheter tolerance.	*Not* endorsed	53-55
19. In patients with a normal body height, at least one or two pressure sensors should be in the pharynx and three in the stomach.	Endorsed	10,51,56,57
20. In tall patients, the probe should be moved to monitor esophageal body and esophagogastric junction pressures first and upper esophageal sphincter and pharyngeal pressures later.	Endorsed	10,51,56,57
21. A deep breath maneuver should be performed at the beginning of the study to ensure that the catheter has passed through the esophagogastric junction.	Endorsed	57
22. HRM studies should be preferentially performed in supine position.	*Not* endorsed	58-63
23. When a vascular artifact is suspected at the level of the OGJ, the patient's position should be changed.	*Not* endorsed	64
24. The standard HRM protocol includes a 30-s period without swallowing.	Endorsed	7
25. The standard HRM protocol encompasses 10 5-ml water swallows performed in supine position.	Endorsed	5-7,65-67
26. The interval between 2 consecutive swallows should be at least 20 seconds.	Endorsed	68,69
27. Testing the response to multiple rapid swallows (consisting of five 2-ml water swallows 1 to 2 s apart), provides additional information on contractile reserve.	Endorsed	71-78
28. The Rapid Drink Challenge test (RDC), consisting of drinking 200 ml of water, provides additional information to evaluate obstruction.	Endorsed	72,79,80
29. Semi-solid swallows help to detect esophageal motility disorders beyond water swallows.	*Not* endorsed	81-84
30. Solid swallows help to detect esophageal motility disorders beyond water swallows.	*Not* endorsed	81-84
Measurement quality		

(Continues)

Table 3 (Continued)

Statement	Consensus	References
31. A test meal helps to detect esophageal motility disorders beyond water swallows.	*Not* endorsed	85,86
32. Double swallows are not suitable for analysis.	*Not* endorsed	49,87
33. The presence of artifacts caused by coughing, belching, gagging, hiccups, etcetera, just before or after a swallow makes the swallow not suitable for analysis.	*Not* endorsed	49
34. At least 7 swallows are needed for a reliable analysis of HRM.	*Not* endorsed	49
35. A vascular artifact at the level of OGJ makes reliable analysis with reliable interpretation of the OGJ impossible.	*Not* endorsed	64
Study analysis		
36. Metrics provided by the Chicago Classification are a common basis for interpreting HRM recordings.	Endorsed	5-7,88
37. The Chicago Classification is the basis for diagnosis of motility disorders.	Endorsed	5-7,88
38. Not all motility disorders are identified by the Chicago Classification.	*Not* endorsed	5-7,87,89
39. OGJ morphology is assessed in a period without swallowing	Endorsed	5-7
40. OGJ morphology is described according to three subtypes in the Chicago classification v3.0.	Endorsed	90-92
41. OGJ resting pressure is assessed over a 30-s period without swallow.	Endorsed	90-92
42. Quantification of OGJ resting pressure should be measured as the end-expiratory or mean baseline pressure.	Endorsed	90-92
43. Analysis of swallows is performed individually for each swallow and consists of the analysis of the OGJ relaxation and the analysis of the contractile vigor and the contractile pattern.	Endorsed	5-7,21,66,90,97-101
44. The outcome of additional tests (MRS, RDC, solid swallows, test meal) should be reported separately.	Endorsed	91
45. The manometry report should mention the equipment, the catheter and the protocol used.	Endorsed	44,45,67
Indications		
46. Esophageal manometry is only indicated after obstruction and esophageal mucosal lesions have been ruled out, preferably by upper gastro-intestinal endoscopy.	Endorsed	7,97
47. Esophageal manometry is indicated in patients with dysphagia when obstruction and esophageal mucosal lesion have been ruled out.	Endorsed	7,97
48. Esophageal manometry is indicated with non-cardiac chest pain when a cardiac cause has been ruled out, and mechanical obstruction, esophageal mucosal lesions, and reflux disease.	Endorsed	7,97
49. Manometry is imperative before reflux testing (pH or pH-impedance monitoring) to accurately localize the OGJ.	Endorsed	98-100
50. Esophageal manometry is mandatory in the work up prior to antireflux surgery.	Endorsed	101-103
51. Esophageal manometry is indicated in connective tissue disorders.	*Not* endorsed	104
52. An edrophonium provocation test is indicated in patients with non-cardiac chest pain.	*Not* endorsed	105
53. Amyl nitrite administration is useful in patients to distinguish post-surgical stenosis from achalasia (example achalasia vs Dor fundoplication).	*Not* endorsed	106
54. Esophageal manometry with meal is indicated when rumination is suspected.	*Not* endorsed	107-110
55. Postprandial manometry helps to diagnose the rumination syndrome.	Endorsed	107-110
56. Combined HRM impedance is required for the diagnosis of rumination syndrome.	Endorsed	107-110
57. Postprandial manometry helps to diagnose belching disorders.	*Not* endorsed	107,110-112
58. Combined HRM impedance is required for the diagnosis of belching disorders.	*Not* endorsed	107,110-112
Therapeutic implications		
59. Absent peristalsis is a contra-indication for antireflux surgery.	*Not* endorsed	37,101,113-115
60. When Ineffective Esophageal Motility (IOM) is present, antireflux surgery must be tailored.	*Not* endorsed	37,101,113-115
61. Achalasia subtyping determines the choice of treatment in achalasia.	*Not* endorsed	116-120
62. Type III achalasia should be preferentially treated with myotomy.	Endorsed	116-120
63. OGJ outflow obstruction in patients with dysphagia should be treated with bougie or through-the-scope dilation.	*Not* endorsed	120-122

(Continues)

Table 3 (Continued)

Statement	Consensus	References
64. OGJ outflow obstruction in patients with dysphagia should be treated like achalasia.	*Not* endorsed	120-122
65. Spasm in patients with dysphagia and/or non-cardiac chest pain should be treated with botulinum toxin injection.	*Not* endorsed	124,125
66. Spasm in patients with dysphagia and/or non-cardiac chest pain should be treated with myotomy.	*Not* endorsed	123-128
67. Spasm in patients with dysphagia and/or non-cardiac chest pain should be treated with bougie dilation.	*Not* endorsed	123
68. Jackhammer esophagus in patients with dysphagia and/or chest pain should be treated with botulinum toxin injection.	*Not* endorsed	124,125
69. Jackhammer esophagus in patients with dysphagia and/or chest pain should be treated with myotomy.	*Not* endorsed	126-128
70. Calcium channel blockers and NO donors are recommended in patients with spastic motility disorders (spasm, jackhammer esophagus).	*Not* endorsed	123
71. IOM in patients with dysphagia should be treated with prokinetics.	*Not* endorsed	129-132

STATEMENT ENDORSED, overall agreement 88%: A+ 71%, A 18%, A− 12%, D− 0%, D 0%, D+ 0%. GRADE A

10. **HRM studies should be preferentially performed in supine position.**

    STATEMENT NOT ENDORSED, overall agreement 62%: A+ 29%, A 32%, A− 26%, D− 3%, D 6%, D+ 3%. GRADE C

11. **When a vascular artifact is suspected at the level of the OGJ, the patient's position should be changed.**

    STATEMENT NOT ENDORSED, overall agreement 79%: A+ 53%, A 26%, A− 15%, D− 6%, D 0%, D+ 0%. GRADE B

12. **The standard HRM protocol includes a 30-s period without swallowing.**

    STATEMENT ENDORSED, overall agreement 82%: A+ 48%, A 33%, A− 12%, D− 3%, D 3%, D+ 0%. GRADE A

13. **The standard HRM protocol encompasses 10 5-ml water swallows performed in supine position.**

    STATEMENT ENDORSED, overall agreement 97%: A+ 76%, A 21%, A− 3%, D− 0%, D 0%, D+ 0%. GRADE B

14. **The interval between 2 consecutive swallows should be at least 20 seconds.**

    STATEMENT ENDORSED, overall agreement 97%: A+ 71%, A 26%, A− 0%, D− 3%, D 0%, D+ 0%. GRADE B

15. **Testing the response to multiple rapid swallows (consisting of five 2-ml water swallows 1 to 2 s apart), provides additional information on contractile reserve.**

    STATEMENT ENDORSED, overall agreement 91%: A+ 62%, A 29%, A− 9%, D− 0%, D 0%, D+ 0%. GRADE B

16. **The Rapid Drink Challenge test (RDC), consisting of drinking 200 ml of water, provides additional information to evaluate obstruction.**

    STATEMENT ENDORSED, overall agreement 88%: A+ 59%, A 29%, A− 12%, D− 0%, D 0%, D+ 0%. GRADE B

17. **Semi-solid swallows help to detect esophageal motility disorders beyond water swallows.**

    STATEMENT NOT ENDORSED, overall agreement 58%: A+ 26%, A 32%, A− 21%, D− 15%, D 6%, D+ 0%. GRADE B

18. **Solid swallows help to detect esophageal motility disorders beyond water swallows.**

    STATEMENT NOT ENDORSED, overall agreement 68%: A+ 35%, A 32%, A− 21%, D− 9%, D 3%, D+ 0%. GRADE B

19. **A test meal helps to detect esophageal motility disorders beyond water swallows.**

    STATEMENT NOT ENDORSED, overall agreement 65%: A+ 38%, A 26%, A− 21%, D− 9%, D 6%, D+ 0%. GRADE B

Calibration procedures are described by the manufacturer. Guidelines recommend performing calibration before each procedure.[47] With some devices, a post-procedure calibration is also recommended ("thermal compensation") to compensate measurement drift over time.[48]

The HRM catheter is usually inserted in a conscious patient in an upright position, but can also be placed in a sedated patient during endoscopy.[49] Although one could argue that an absolute fasting is not necessary, medical literature reports that at least 6 h fasting for solids before testing is preferable, with the option to reduce to only 2 h fasting when only liquids were ingested.[10] The transnasal approach is preferred as it gives the patient the feeling of control, possibility to freely swallow and it also offers a protection to the catheter. The most common problems are irritation of nose and throat, but sedation is rarely needed.[50] Very rarely, when the patient is extremely anxious, low-dose sedation (eg, 1–2 mg midazolam or 10–30 mg oxazepam) can be considered to insert/place the catheter, but this may be associated with nonspecific changes in HRM metrics.[51,52] Most often local nasal anesthesia is used, in the form of an anesthetic gel (lidocaine 2%) or a transnasal spray (lignocaine 4%) to reduce discomfort caused by insertion of nasogastric tubes without any increase in difficulty of its placement.[53-57] The efficacy of this approach and whether it has an effect on motility parameters are poorly studied.

The catheter should be positioned by observing the recording, adjusting it such that the proximal one or two pressure sensors are in the pharynx and the distal three pressure sensors are subdiaphragmatic.[10,51] This is not always possible, especially in case of large hiatal hernias, achalasia, or in particularly tall patients.[56] In the former cases, an endoscopy-assisted placement should be considered, which is often easier with a flaccid water-perfused catheter. Correct catheter placement, as confirmed by identifying the pressure inversion point (PIP), is necessary to observe both upper esophageal sphincter (UOS) and OGJ.[57] Alternatively, one should evaluate separately the mid-distal esophageal body, including the OGJ, and the proximal esophageal body, with the UOS movements.

The OGJ is made up of the LES and crural diaphragm. During breathing, the LOS and crural diaphragm move together. During inspiration, there is an increase in negative intra-esophageal pressure and in gastric positive pressure. In order to prevent gastro-esophageal reflux, OGJ pressure increases. This increase is due to the crural diaphragm contraction and is related to the depth of inspiration. Therefore, if the OGJ impression is not easily identified, the patient can be asked to take a deep breath, which will magnify these pressure changes.[57]

Esophageal manometry was initially performed using water-perfused systems, which required the supine position during the examination in order to ensure a proper alignment of the catheter with external sensors. The body position during esophageal manometry remains a matter of debate. The supine position is considered the standard for performing high-resolution esophageal manometry, and all the metrics included in the Chicago classification are based on the scoring of 10 swallows performed in supine position.[7] However, as drinking and eating in this position are not physiological, some authors have additionally used other body positions such as left lateral decubitus, or upright with a mild inclination (30–45°).[58] It is clear that body position influences esophageal function metrics, as contraction amplitude, duration, percentage of multipeaked contraction, and the resting pressure of the LOS are significantly reduced in sitting as compared to supine position, probably reflecting effects of gravity on bolus progression and changes in intragastric pressure in the upright position.[59] Furthermore, hiatal hernia may be more frequently found in a sitting position.[59]

When using the solid state HRM probes, there is no necessity of horizontal alignment of patients with external sensors. The upright position also allows easier and more physiological application of multiple rapid water swallows (MRS), solid test meals, and rapid drink challenge.[60-62] However, findings of abnormal motility may differ between positions, even when normal values for the sitting position are applied.[63] Besides a need for determining robust normal values for HRM in upright position, the diagnostic metrics as used in the Chicago classification will need to be revised or updated for measurements in this position. Hence, when using upright swallows this may be done in addition to a standardized supine series. Vascular artifacts may interfere with data interpretation of HRM. If suspicion of vascular artifacts exists, the investigator might try to change the position of the patient, for instance for correct determination of the IRP.[64]

Esophageal HRM starts with a swallow-free period to characterize UOS and OGJ resting dynamics. According to the Chicago classification v3, calculation of inspiratory and expiratory OGJ pressure and of OGJ-contractile integral (OGJ-CI) requires a minimum of 3 respiratory cycles during a period of recording free of swallows.[7] With some margin, 20–30 seconds seems like a sufficient swallow-free time period to study resting pressures when the respiratory rate is normal.

By convention, the standard HRM protocol and its normal values are based on ten 5-ml water swallows.[5-7,65-67] These characteristics were transferred from conventional esophageal manometry, although there are no formal data available to support the minimal number or volume of wet swallows required for HRM. A retrospective study suggests that a lower number of technically perfect swallows (single swallows without belching or retching) could still be sufficient to diagnose major motility disturbances, especially achalasia, but prospective data are lacking.[49] Especially considering the frequent occurrence of intermittent dysmotility, 10 swallows seem like a logical minimum to maintain HRM diagnostic sensitivity. Normal values for standard HRM and hence for Chicago interpretation are also based on measurements in supine position.[65-67]

The swallow-induced neural control mechanism is characterized by a postswallow period of refractoriness which lasts 10 seconds, during which the esophageal muscle is unable to display coordinated and efficient motor activity.[68,69] Therefore, an interval of 20–30 seconds without swallowing is recommended. Longer intervals between swallows are not required and not recommended, due to the risk of spontaneous dry swallows.

The phenomenon of deglutitive inhibition accounts for inhibition of the esophageal body when multiple swallows are taken in rapid succession, after which a full peristaltic contraction occurs.[70] Multiple rapid water swallows (MRS) are a simple provocative maneuver that involves ingestion of five swallows (2 ml of water per swallow) in rapid sequence (<10 s).[61,71] The test augments central and peripheral deglutitive inhibition, hence suppressing contractions in the esophageal body, and relaxation of the LOS. The last swallow of the MRS series is followed by a powerful peristaltic sequence in the esophageal body together with a contraction in the LOS and reflects the contraction reserve in the esophageal body.[61,69-72] At least three MRS are needed to reliably assess contraction reserve.[73] Abnormal results include incomplete inhibition of the OGJ or the peristaltic contractility during swallows or an abnormal contraction after the swallows.[70,72,73] The failure of post-MRS peristaltic augmentation seen in ineffective esophageal motility (IOM) offers a number of prognostic possibilities: It is associated with higher acid exposure time in non-erosive reflux disease, late postoperative dysphagia following antireflux surgery (ARS), presence or development of IOM post-ARS, and possibly failure of promotility agents.[70-78] Poor post-MRS contraction is also the most common manometric finding in systemic sclerosis.[78]

The multiple water swallow test, or rapid 200-ml drinking challenge test (RDC), is performed in upright position and mainly applied for evaluating OGJ resistance. RDC in achalasia leads to sustained pressurizations along the entire esophageal body (pan-esophageal pressurizations) and exaggerates the existing large pressure gradient across a non-relaxed OGJ. In OGJ obstruction, a more variable pattern is observed, which may reflect the inability of the OGJ to relax.[72,79,80] The RDC is also helpful for identifying increased resistance to OGJ outflow, and uncovering latent hypercontractility.[81] Addition of RDC and a solid meal during HRM in symptomatic patients post-ARS helps identifying outlet obstruction alongside potential benefit from dilation.[75]

Challenges with semi-solid (or viscous) and solid boluses have also been proposed for use during HRM testing as they mimic esophageal pressures generated during normal drinking and eating. Limited available studies suggest that semi-solid and solid swallows increase sensitivity to identify an abnormality in patients presenting with dysphagia.[81-84] However, normative values for manometric parameters with semi-solid and solid swallows are limited. Similarly, a standardized test meal may improve diagnostic sensitivity of HRM and has the potential to alter the diagnosis beyond what was found with standard water swallows.[85,86] However, there is no standardization to date.

3.3 | Measurement quality

1.Double swallows are not suitable for analysis.
STATEMENT NOT ENDORSED, overall agreement 76%: A+ 38%, A 38%, A− 12%, D− 6%, D 6%, D+ 0%. GRADE B

2.The presence of artifacts caused by coughing, belching, gagging, hiccups, etc., just before or after a swallow makes the swallow not suitable for analysis.
STATEMENT NOT ENDORSED, overall agreement 79%: A+ 53%, A 26%, A− 18%, D− 3%, D 0%, D+ 0%. GRADE B

3.At least 7 swallows are needed for a reliable analysis of HRM.
STATEMENT NOT ENDORSED, overall agreement 68%: A+ 26%, A 41%, A− 15%, D− 12%, D 3%, D+ 3%. GRADE B

4.A vascular artifact at the level of OGJ makes reliable analysis with reliable interpretation of the OGJ impossible.
STATEMENT NOT ENDORSED, overall agreement 53%: A+ 21%, A 32%, A− 18%, D− 18%, D 12%, D+ 0%. GRADE B

Only one paper assessed the impact of “technically imperfect” manometric studies.[49] Among 2000 consecutive studies performed by the Chicago group, 21% were considered as technically imperfect, and most of them (58%) attributed to fewer than 7 evaluable swallows. Double swallows are one of the main criteria for categorizing a study as technically imperfect and should not be considered and reported as a limitation of the esophageal manometry, except probably in the case of achalasia, where double swallows are frequent.[49] Moreover, there is limited evidence that rapid double swallows occurring within 4 seconds normally only induce one peristaltic wave. Accordingly, they might be evaluated in patients who cannot suppress double swallows.[87] Artifacts such as belching, gagging, coughing, and hiccups are limiting factors in the performance and interpretation of manometry tracings and cause significant discomfort to the patient. The impact may be limited if the artifact occurs after the peristaltic wave has run through the esophageal body, or in the case of a swallow that occurs after an artifact but elicits an intact peristalsis. In the particular case of achalasia, the presence of these artifacts will not influence the diagnosis.[49] The gold standard should probably remain at 10 swallows for a reliable diagnosis, but when the diagnosis of achalasia is obvious, less than 10 swallows is acceptable. Vascular artifact may increase the distal contractile integral (DCI) or IRP, but this may be fixed by changing the patient's position.[64]

3.4 | Study analysis

See Appendix S1.

3.5 | Indications

See Appendix S1.

3.6 | Therapeutic implications

See Appendix S1.

4 | RECOMMENDATIONS

Based on the statements that achieved consensus, a number of recommendations for clinical application of esophageal HRM can be made. These are summarized in Table 4 in the supplement file and provide important guidance on when to consider esophageal HRM, how to perform it and how to generate the report.

The Delphi process also identified several areas of uncertainty, which require additional evidence or further research. The thought that water-perfused sensors are not equally performant as solid state sensors (statement[2]) is important as the water-perfused sensors are still widely used due to cost considerations. There is also uncertainty as to whether different catheters are differently tolerated (statement[11]), and whether HRM impedance catheters require different disinfection protocols (statement[10]).

There is no consensus on the duration of fasting before esophageal manometry (statement[14]) and on whether local anesthesia facilitates catheter positioning (statement[18]). Most important, there is no consensus that supine is the preferred position for HRM (statement[22]), although all normal values and diagnostic guidances available were generated for that position. Probably based on that consideration, there is a recommendation to perform at least 10 5-ml swallows in supine position for each study (statement[25]). There is no consensus on added value of semi-solid or solid boluses (statements[29,30]) or on the use of a test meal (statement[31]).

There is no consensus on a minimum of 7 swallows being needed for interpreting a manometry (statement[34]). There is no agreement that double swallows, vascular artifacts, or swallows in proximity of artifacts from cough, belching, gagging, hiccups, etc., are not suitable for analysis (statements[32,33,35]).

There is also no agreement on the need for esophageal manometry in suspected connective tissue disorders, on the usefulness of edrophonium provocative testing, or on the use of amyl nitrite to distinguish functional from anatomical obstruction at the OGJ (statements[51-53]). The postprandial combined HRM impedance is considered useful for rumination (statements[55,56]), but not for belching disorders (statements[57,58]).

The biggest area of lack of consensus is the section on treatment implications (statements[59-61,63-71]). The only treatment statements to reach consensus are the one advocating myotomy for the treatment of type 3 achalasia (statement[62]) and even there the evidence is scarce due to the rare occurrence of this condition. The voting on these statements clearly establishes the need for therapeutic trials in esophageal motility disorders beyond achalasia, preferably in a multicenter setting as for many entities the number of patients at single centers is low.

5 | CONCLUSION

Esophageal motility disorders are often considered in clinical practice, and many patients will be referred for esophageal (high-resolution) manometry. This consensus process used a multinational and multidisciplinary group of European experts to summarize the current state of consensus on technical aspects, indications, performance, analysis, diagnosis, and therapeutic implications of esophageal high-resolution manometry. The Consensus Group voted on several statements that may guide clinicians using or referring for esophageal manometry. The statements with consensus offer guidance for esophageal manometry in clinical practice, whereas the statements without consensus identify areas requiring further research.

AUTHOR CONTRIBUTIONS

Jan Tack initiated the process, drafted consensus questions, wrote manuscript sections, participated in voting, wrote manuscript, and reviewed and corrected content. Ans Pauwels wrote manuscript sections, participated in voting, wrote manuscript, and reviewed and corrected content. Sabine Roman, Edoardo Savarino, André Smout, and all members of ESNM HRM consensus group drafted consensus questions, wrote manuscript sections, participated in voting, and reviewed and corrected content. ESNM HRM consensus group are as follows: Filiz Akyuz, Ion Bancila, Silvia Barrias, Serhat Bor, Jan Borovicka, Albert J Bredenoord, Charlene Brochard, Martin Buckley, Dan Carter, Constanca Ciriza de los Rios, Jose Conchillo, Nicola De Bortoli, Heiko De Schepper, Ram Dickman, Dan Dumatriscu, Jan Hatlebakk, Dag Arne Hoff, Dragan Jurcic, Jutta Keller, Luis Novais, Christian Pehl, Roberto Penagini, Nathalie Rommel, Yishai Ron, Cecilio Santander Vaquero, Daniel Sifrim, Paulo Souto, Olga Storonova, Rosana Troskot, Alexander Trukhmanov, Radu Tutuian, Philip Woodland, and Frank Zerbib.

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SUPPORTING INFORMATION

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

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APPENDIX 1

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