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REVIEW ARTICLE

A systematic review of current methodology of high resolution pharyngeal manometry with and without impedance

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Abstract

Purpose This systematic review appraises and summaries methodology documented in studies using high resolution pharyngeal manometry (HRM) with and without impedance technology (HRIM) in adult populations.

Methods Four electronic databases CINAHL, EMBASE, MEDLINE, and Cochrane Library were searched up to, and including March 2017. Studies reporting pharyngeal HRM/HRIM for swallowing and/or phonatory assessment, published in peer-reviewed journals in English, German, or Spanish were assessed for the inclusion criteria. Of the selected studies, methodological aspects of data acquisition and analysis were extracted. Publications were graded based on their level of evidence and quality of methodological aspects was assessed.

Results Sixty-two articles were identified eligible, from which 50 studies reported the use of HRM and 12 studies used HRIM. Of all included manuscripts, the majority utilized the ManoScan™ system (64.5%), a catheter diameter of 4.2 mm was most prevalently documented (30.6%). Most publications reported the application of topical anesthesia (53.2%). For data analysis in studies using HRM, software intrinsic to the recording system was reported most frequently (56%). A minority of the studies using HRM provided data about measurement reliability (10%). This is higher for studies using HRIM (50%).

Conclusions Considerable methodological variability exists regarding data acquisition and analysis in published studies using HRM/HRIM. Lacking reports of methodology make study replications difficult and reduce the comparability across studies. More data regarding the impact of individual methodological aspects on study outcomes are further required for the development of methodological recommendations.

Keywords Deglutition · Manometry · High resolution manometry · Impedance

Introduction

Pharyngeal high resolution manometry (HRM) provides objective pressure data [1], and with the adjunct of impedance technology (HRIM), information about bolus flow during pharyngeal swallowing can be gained non-radiologically [2]. Compared to prior manometric systems, the greater number of sensors allows for increased spatial resolution which is specifically beneficial for evaluation of the upper esophageal sphincter (UES) [3].

Originally developed for measurement of esophageal motility, HRM has been increasingly used in the evaluation of pharyngeal swallowing [1]. Translation of HRM into the context of pharyngeal swallowing requires adaptation of methodology. Importantly, methodological aspects of data acquisition and analysis impact measurements. Thus,

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methods need to be considered in the interpretation of findings in studies using pharyngeal HRM/HRIM. To date, no methodological standards have been defined for assessment of swallowing using pharyngeal HRM [4].

As a contribution to ongoing international efforts towards the development of standards in the methodology of pharyngeal HRM/HRIM, this review will summarize and appraise the status quo of reported methodology of pharyngeal HRM/HRIM in adult populations. This work—based on the existing literature—highlights aspects which require attention for further development and optimal use of pharyngeal HRM/HRIM.

Materials and methods

Protocol and registration

This review was registered in the international prospective register of systematic reviews (PROSPERO) on the 13th of March 2017 (Registration number: CRD42017059144). The review protocol is available from https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=59144. For reporting, guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [5], as well as the Assessment for Multiple Systematic Reviews (AMSTAR) [6], were followed.

Eligibility criteria

Publications reporting HRM or HRIM in the assessment of pharyngeal pressure during swallowing or phonation in adult populations (> 18 years) were included if they reported pharyngeal measures with or without additional report of measures of the UES. Further, documentation of any methodology of data acquisition and analysis was required for inclusion. Studies using 3D HRM systems, water-perfused HRM, or catheters with less than 15 sensors as well as manuscripts reporting only impedance data were excluded. Eligibility for inclusion was restricted to publications in English, German, and Spanish as translation resources were not available. Manuscripts other than peer-reviewed journal articles such as conference abstracts or reviews were excluded. Records were included with no constraint regarding publication year.

Information sources

Four electronic bibliographic databases were searched in and up to March 2017 including MEDLINE, EMBASE, CINAHL, and the Cochrane Library. To identify further relevant publications, the bibliography of all selected publications for this review was screened by their title and tracking of citations via the website Google Scholar was performed.

Search

The search varied slightly according to requirements of the search databases. All included search strings and keywords are listed in Supplementary Material. The search included the keywords ‘swallowing’ and ‘dysphagia’ but not ‘phonation’ or ‘voice’ as the focus of the review is on swallowing. However, any articles reporting pharyngeal pressure measures were eligible for inclusion (even if the manuscript focus was phonation rather than deglutition). Following, the search strategy used in MEDLINE is reported as an example: 1. Deglutition/; 2. swallow*.af.; 3. degluti*.af.; 4. dysphagi*.af.; 5. pharyn*.af.; 6. Esophageal Sphincter, Upper/; 7. (upper esophageal sphincter or upper oesophageal sphincter or UES).af; 8. impedance.af.; 9. Or/1-8; 10. HRM.af.; 11. High resolution manometry.af.; 12. Or/10-11; 13. 9 and 12.

Study selection

Following the initial search, duplicates and records published in a language other than English, German, or Spanish were excluded. For the remaining articles, titles and abstracts were screened for inclusion based on keywords (‘high resolution manometry’/‘HRM’ and/or ‘impedance’, ‘pharynx’/‘pharyngeal’ and ‘upper esophageal sphincter’/‘UES’). A second-stage full-text screening of the remaining publications was performed for further application of the eligibility criteria. Both first- and second-stage examinations were conducted by two independent researchers to minimize bias of individual raters. In the case of initial disagreement, discussion was undertaken to reach a consensus. Reference and citation checking were applied for the publication titles only and based on a reduced number of keywords including ‘high resolution manometry’/‘HRM’ and ‘impedance’.

Data collection process

Data from each article were extracted into a table by two independent reviewers. In total, five reviewers were involved in data collection. Agreement between raters was checked for parameters involving numerical or binary information (yes/no) and discussion was held to reach a consensus.

Data items

Information was extracted based on the following five main categories:

1. General information about the publication (primary author’s name, publication year, journal, and publication language),

2. Information about subjects involved in the study (number of healthy participants or patients and etiology of dysphagia),
3. Data about the HRM/HRIM system and catheter (diameter, number of pressure sensors/impedance segments, spacing between sensors/segments, and measurement direction),
4. Information regarding methodological aspects of data acquisition (use of topical anesthesia including dose and application location, documentation/duration of an adjustment period after catheter placement, participant's position, application of a system-based measurement error correction (relevant only for studies using ManoScan™ system [Medtronic, Minneapolis]), bolus type/administration, and bolus salinity for HRIM studies), as well as
5. Information about methodological aspects of data analysis (type of software, anatomical region of interest, and measurement parameters).

There are methodological aspects such as the use of topical anesthesia which apply to studies using HRM and HRIM. Other methodological facets, such as the impact of bolus properties, differ across the two procedures and were analyzed separately.

Level of evidence and methodological quality assessment of individual studies

The level of evidence of each study was determined according to 'The Oxford Centre for Evidence-based Medicine Levels of Evidence' [7]. Two items specific to the quality of data analysis—blinding and randomization—were coded with a 'yes' or 'no' binary response. Report of inter- and/or intra-rater measurement reliability was assessed. As recommended in the literature, all studies were evaluated by two independent raters and disagreements were discussed to reach a consensus [8].

Results

Study selection

An initial search identified 2133 records; further 66 manuscripts were identified later in the process (37 articles through reference checking, 29 papers through citation tracking). A total of 1575 abstracts were screened by the two raters with an initial agreement of 83%; following

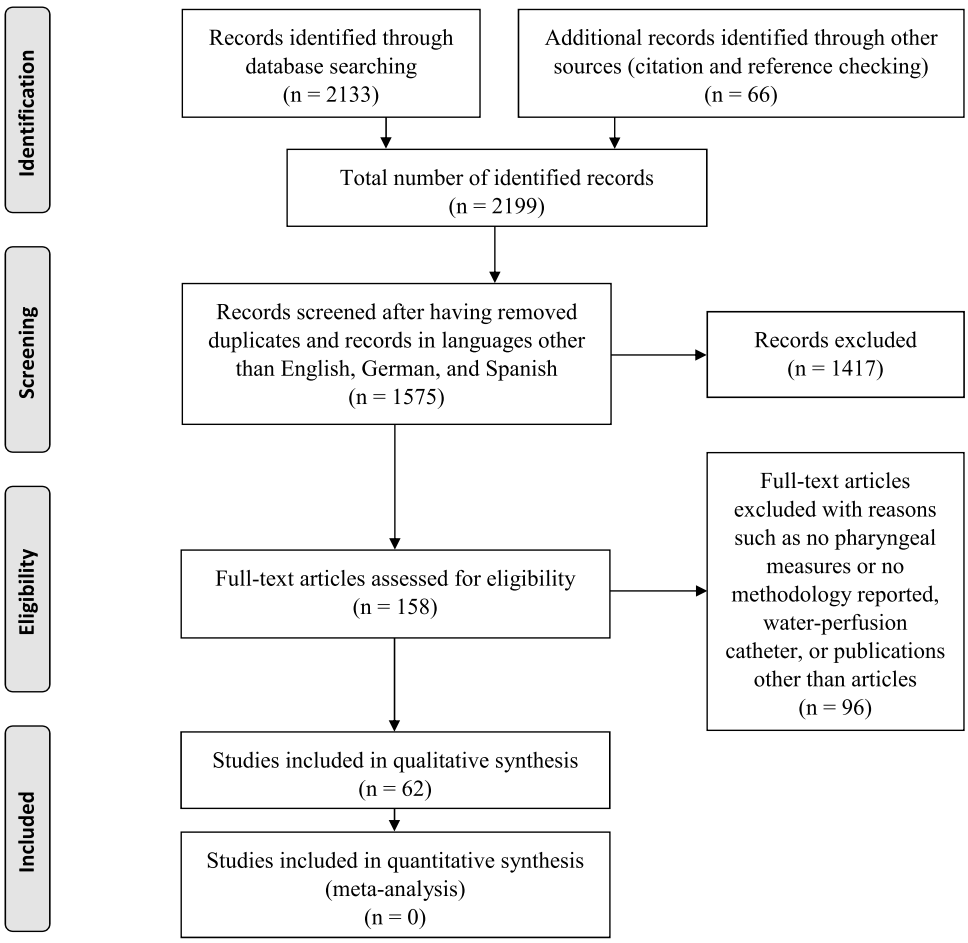

Fig. 1 Adapted PRISMA 2009 Flow Diagram

Table 1 Reported methodology of data acquisition and analysis

General	Subjects	Equipment		Methodological aspects of data acquisition			Methodological aspects of data analysis		Level of evidence
First author (year); language	Number of healthy subjects; patients	System (HRM[a]; HRIM[b]); system name	Catheter diameter; measuring direction; number of pressure sensors; sensor spacing in cm; impedance (number of segments)	Body position	Anesthesia use (type; dose; application location)	Bolus consistency; use of saline	Software	Reported reliability	
Arenaz Bua (2016) [23]; English	0; 13	HRM; ManoScan™	4.2 mm; NR[c]; 36; 1	Seated	Yes (xylocaine; 2%; NR)	Liquid; NA[d]	NR	NR	4
Derrey (2015) [14]; English	0; 16	HRM; MMS	4 mm; circ.[e]; 36; 1	NR	NR	Liquid; NA	System-based	NR	3b
Geng (2013) [28]; English	16; 61	HRM; ManoScan™	4 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal/cath.[f])	Dry/liquid/puree; NA	Matlab™	NR	4
Ghosh (2006) [41]; English	75; 0	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Supine	NR	Dry/liquid; NA	System-based/ Matlab™	NR	4
Hammer (2014) [42]; English	8; 0	HRM; ManoScan™	2.75 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal/cath.)	Dry; NA	Matlab™	NR	4
Hoffman (2010) [43]; English	12; 0	HRM; ManoScan™	4 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%/4%; nasal/ cath./gargle)	Dry/liquid; NA	Matlab™	NR	4
Hoffman (2012) [44]; English	14; 0	HRM; ManoScan™	4 mm; circ.; 36; 1	NR	Yes (lidocaine; 2%/4%; nasal/ cath./gargle)	Liquid; NA	Matlab™	NR	4
Hoffman (2013) [29]; English	0; 30	HRM; ManoScan™	4 mm; NR; 36; NR	Seated	Yes (lidocaine; 2%; nasal/cath.)	Liquid/puree; NA	Matlab™	Unclear	4
Hutcheson (2017) [45]; English	2; 0	HRM; ManoScan™	2.75 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal)	Liquid; NA	Matlab™	NR	4
Jiang (2017) [26]; English	0; 1	HRM; ManoScan™	NR; circ.; 36; NR	Seated	NR	NR; NA	System-based	NR	4
Jones (2016) [15]; English	26; 26	HRM; ManoScan™	2.75 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal)	Liquid; NA	Matlab™	Previously reported	3b
Juan (2013) [9]; English	0; 1	HRM; ManoScan™	2.5 mm; circ.; 36; 1	NR	Yes (lidocaine; 2%; nasal)	Liquid; NA	Matlab™	NR	4
Jungheim (2015) [18]; German	0; 2	HRM; Solar GI™	2 mm; unid.[g]; 20; 0.75/distal sensor 5	Seated	No	Liquid; NA	System-based	NR	4
Jungheim (2015) [46]; German	29; 0	HRM; Solar GI™	2 mm; unid.; 20; 0.75/distal sensor 5	Seated	No	Liquid; NA	System-based	NR	4

Table 1 (continued)

General	Subjects	Equipment		Methodological aspects of data acquisition			Methodological aspects of data analysis		Level of evidence
First author (year); language	Number of healthy subjects; patients	System (HRM[a]; HRIM[b]); system name	Catheter diameter; measuring direction; number of pressure sensors; sensor spacing in cm; impedance (number of segments)	Body position	Anesthesia use (type; dose; application location)	Bolus consistency; use of saline	Software	Reported reliability	
Jungheim (2017) [47]; German	10; 0	HRM; Solar GI™	2 mm; NR; 20; 0.75/distal sensor 5	Seated	No	Liquid; NA	System-based	NR	4
Jungheim (2013) [60]; German	0; 8	HRM; Solar GI™ (MMS)	2 mm; unid.; 20; 0.75/distal sensor 5	Seated	NR	NR; NA	System-based	NR	4
Kim (2015) [48]; English	10; 0	HRM; inSIGHT™	NR; circ.; 32; 1	Seated	Yes (lidocaine; 2%/10%; nasal/cath.)	Liquid; NA	System-based	NR	4
Knigge (2016) [61]; English	0; 37	HRM; NR	NR	NR	NR	Liquid; NA	NR	NR	4
Knigge (2014) [1]; English	0; 3	HRM; ManoScan™	4 mm; NR; 36; NR	NR	Yes (lidocaine; 2%; nasal)	Dry/liquid; NA	NR	NR	5
Lamvik (2016) [62]; English	NR; 0	HRM; ManoScan™	2.75 mm/4.2 mm; NR; 36; NR	NR	NR	Dry/liquid; NA	System-based/ Matlab™	NR	4
Lan (2013) [10]; English	0; 30	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal)	Liquid/puree; NA	System-based	NR	3b
Lan (2015) [11]; English	0; 24	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	NR	Liquid/puree; NA	System-based	NR	4
Lan (2017) [49]; English	34; 0	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	NR	Liquid/puree; NA	System-based	NR	4
Lee (2014) [50]; English	31; 122	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	NR	Liquid; NA	System-based	Unclear	3b
Lee (2017) [12]; English	0; 36	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal)	Liquid; NA	Matlab™	NR	4
Lin (2014) [51]; English	34; 0	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	NR	Liquid/puree; NA	System-based	NR	4
Lippert (2016) [24]; English	6; 6	HRM; ManoScan™	4.2 mm; NR; 36; NR	Seated	Yes (lidocaine; 2%; cath.)	Liquid; NA	Matlab™	NR	3b
Matsubara (2014) [52]; English	30; 0	HRM; ManoScan™	2.64 mm; circ.; 36; 1	Seated	Yes (lidocaine; 4%; nasal/cath./gargle)	Dry/liquid; NA	System-based	NR	4

Table 1 (continued)

General	Subjects	Equipment		Methodological aspects of data acquisition			Methodological aspects of data analysis		Level of evidence
First author (year); language	Number of healthy subjects; patients	System (HRM[a]; HRIM[b]); system name	Catheter diameter; measuring direction; number of pressure sensors; sensor spacing in cm; impedance (number of segments)	Body position	Anesthesia use (type; dose; application location)	Bolus consistency; use of saline	Software	Reported reliability	
Matsubara (2015) [53]; English	30; 0	HRM; ManoScan™	2.64 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%/4%; nasal/cath./gargle)	Dry/liquid; NA	System-based	Yes	4
Matsubara (2016) [54]; English	26; 0	HRM; ManoScan™	2.64 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%/4%; nasal/cath./gargle)	Liquid; NA	System-based	NR	4
McCulloch (2010) [55]; English	7; 0	HRM; ManoScan™	4 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%/4%; nasal/cath./gargle)	Liquid; NA	System-based	NR	4
Menezes (2015) [22]; English	0; 60	HRM; ManoScan™	NR; NR; 36; 1	NR	NR	Liquid; NA	System-based	NR	4
Mielens (2011) [30]; English	12; 3	HRM; ManoScan™	4 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%/4%; nasal/cath./gargle)	Liquid; NA	Matlab™	NR	3b
Mielens (2012) [31]; English	12; 13	HRM; ManoScan™	4.1 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%/4%; nasal/cath./gargle)	Liquid; NA	System-based/Matlab™	NR	3b
Nativ-Zeltzer (2016) [63]; English	44; 0	HRM; ManoScan™	2.75 mm; circ.; 36; 0.75	Seated	Yes (NR; NR; nasal)	Liquid/puree/solid; NA	System-based	NR	4
Noh (2010) [16]; English	0; 1	HRM; NR	NR	Supine	NR	Liquid; NA	System-based	NR	4
Oh (2015) [27]; English	0; 1	HRM; InSIGHT™	NR; NR; NR; 1	Seated	NR	Dry/liquid; NA	NR	NR	4
Park (2016) [32]; English	0; 40	HRM; InSIGHT™	NR; circ.; 32; 1/2	Seated	Yes (lidocaine; 2%/10%; nasal/cath.)	Liquid; NA	System-based	Yes	4
Park (2017) [33]; English	0; 53	HRM; InSIGHT™	NR; circ.; 32; 1/2	Seated	Yes (lidocaine; 2%/10%; nasal/cath.)	Liquid/puree; NA	System-based	Yes	3b
Park (2017) [34]; English	33; 120	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	NR	Liquid; NA	System-based/Matlab™	Yes	3b

Table 1 (continued)

General	Subjects	Equipment		Methodological aspects of data acquisition			Methodological aspects of data analysis		Level of evidence
First author (year); language	Number of healthy subjects; patients	System (HRM[a]; HRIM[b]); system name	Catheter diameter; measuring direction; number of pressure sensors; sensor spacing in cm; impedance (number of segments)	Body position	Anesthesia use (type; dose; application location)	Bolus consistency; use of saline	Software	Reported reliability	
Ryu (2016) [56]; English	10; 0	HRM; InSIGHT™	NR; circ.; 32; 1	Seated	Yes (lidocaine; 2%/10%; nasal/cath.)	Dry/liquid/puree/solid; NA	System-based	NR	4
Silva (2013) [64]; English	40; 0	HRM; ManoScan™	NR; NR; 36; 1	Seated	NR	Liquid; NA	System-based	NR	4
Takasaki (2008) [65]; English	33; 0	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Supine	NR	Dry/liquid; NA	System-based	NR	4
Takasaki (2010) [17]; English	0; 1	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Supine	Yes (NR; NR; nasal)	Dry; NA	System-based	NR	4
Takasaki (2011) [66]; English	18; 0	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Supine	Yes (NR; NR; nasal)	Dry/liquid; NA	System-based	NR	4
Umeki (2009) [67]; English	33; 0	HRM; ManoScan™	4.2 mm; circ.;36; 1	Supine	NR	Dry; NA	System-based	NR	4
Walczak (2017) [68]; English	10; 0	HRM; ManoScan™	2.75 mm; circ.; 36; 1	Seated	Yes (lidocaine; 2%; nasal/cath.)	Liquid; NA	Matlab™	NR	4
Yamaguchi (2017) [20]; English	0; 10	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Supine	NR	Liquid; NA	System-based	NR	4
Yoon (2014) [69]; English	26; 0	HRM; ManoScan™	4.2 mm; circ.; 36; 1	Seated	NR	Liquid/puree; NA	Matlab™	NR	4
Zhang (2016) [25]; English	11; 30	HRM; Solar GI™ (MMS)	3.6 mm; NR; 25; 1	Seated	Yes (lignocaine; 10%; NR)	Liquid; NA	NR	NR	3b
Doeltgen (2016) [57]; English	11; 0	HRIM; ManoScan™	4.2 mm; circ.; 36; 1; impedance (18)	NR	NR	Liquid; yes	Matlab™	NR	4
Ferris (2015) [35]; English	8; 40	HRIM; Solar GI™	3.2 mm; NR; 25; 1; impedance (12)	Seated	Yes (lignocaine; NR; NR)	Liquid/puree/solid; yes	Matlab™	NR	3b
Hoffman (2013) [36]; English	0; 25	HRIM; Solar GI™	3.2 mm; NR; 25; 1; impedance (12)	Seated	Yes (lignocaine; NR; nasal)	Liquid/puree/solid; no	Matlab™	Unclear	4
Lee (2012) [19]; English	26; 1	HRIM; Sandhill Scientific Instruments	4 mm; NR; 32; NR; impedance (6)	Seated	NR	Liquid/puree; yes	System-based	NR	4

Table 1 (continued)

General	Subjects	Equipment		Methodological aspects of data acquisition			Methodological aspects of data analysis		Level of evidence
First author (year); language	Number of healthy subjects; patients	System (HRM[a]; HRIM[b]); system name	Catheter diameter; measuring direction; number of pressure sensors; sensor spacing in cm; impedance (number of segments)	Body position	Anesthesia use (type; dose; application location)	Bolus consistency; use of saline	Software	Reported reliability	
Lee (2014) [37]; English	26; 10	HRIM; Sandhill Scientific Instruments	4 mm; circ./unid.; 32; NR; impedance (6)	Seated	NR	Liquid; yes	NR	Yes	3b
Lee (2014) [13]; English	33; 104	HRIM; ManoScan™	4.2 mm; circ.; 36; 1; impedance (18)	Seated	NR	Liquid; yes	NR	NR	3b
Omari (2016) [58]; English	5; 0	HRIM; ManoScan™	4.2 mm; circ.; 36; 1; impedance (18)	NR	No	Liquid; yes	Matlab™	Yes	4
Omari (2012) [59]; English	20; 0	HRIM; Solar GI™	3.2 mm; NR; 25; 1; impedance (12)	Seated	Yes (lignocaine; NR; NR)	Liquid/puree; yes	Matlab™	NR	4
Omari (2011) [38]; English	8; 18	HRIM, NR	NR	NR	NR	Liquid/puree; yes	Matlab™	Yes	4
Omari (2012) [39]; English	8; 18	HRIM; Solar GI™ (MMS)	3.2 mm; NR; 25; NR; impedance (12)	NR	NR	Liquid/puree; yes	Matlab™	Yes	3b
Omari (2013) [40]; English	0; 40	HRIM; Solar GI™ (MMS)	3.2 mm; NR; 25; 1; impedance (12)	Seated	Yes (lignocaine; NR; NR)	Liquid/puree/solid; yes	Matlab™	Yes	4
Szczesniak (2015) [21]; English	16; 16	HRIM; Solar GI™ (MMS)	3.6 mm; NR; 25; 1; impedance (12)	Seated	Yes (lignocaine; 10%; nasal)	Liquid; yes	Matlab™	Yes	3b

[a]*HRM* high resolution manometry

[b]*HRIM* high resolution impedance manometry

[c]*NR* not reported

[d]*NA* not applicable

[e]*circ.* circumferential

[f]*cath.* catheter

[g]*unid.* unidirectional

discussion, a consensus was reached on 100%. 1417 abstracts were excluded as they did not meet the inclusion criteria. Ultimately, 62 publications met the eligibility criteria. Of these, 50 studies used HRM and 12 studies used HRIM. Information including reasons for exclusion is provided in the adapted PRISMA flow chart [5] (Fig. 1). Selected information of the included studies is depicted in Table 1.

General information

The articles were published between 2006 and 2017, 93.5% in English, 6.5% in German; there were no Spanish manuscripts.

Results of individual studies

Subjects

Manuscripts reported data on healthy adults (41.9%) and patients (32.3%); 24.2% of the articles documented data on both populations. A minority of publications (1.6%) did not provide any information on the subjects recruited. Etiology of dysphagia included stroke [9–13], Parkinson's disease [14, 15], amyotrophic lateral sclerosis [16, 17], myotonic dystrophy [18], Huntington's disease [19], head and neck cancer [20, 21], achalasia [22], as well as status after laryngectomy [23–25], esophageal replacement [26], spinal cord surgery [27], or heterogeneous etiologies [1, 28–40].

HRM system and catheter

The ManoScan™ HRM system was most commonly reported (64.5%). The second most prevalently documented system was Solar GI™ (Medical Measurement Systems/Laborie, Toronto) (19.4%), followed by inSIGHT™ (Sandhill Scientific, Milwaukee) (11.3%). The system used was not reported in 4.8% of the studies. Reports of nine different catheter diameters were found (Table 2). Importantly, 17.7% of all articles did not provide information about the catheter diameter. The number of pressure sensors ranged from 20 to 36, with 36 being the most commonly documented number of sensors (66.1%), followed by 25 sensors (11.3%), 32 sensors (9.6%), and 20 sensors (6.5%); 6.5% of all studies did not specify the number of pressure sensors. For the studies using HRIM, the number of impedance segments ranged from six to 18, with 12 segments being most prevalently reported (50%), followed by 18 segments (25%), and six segments (16.7%); 8.3% of the studies did not report the number of impedance segments. Of the studies using HRM, 72% documented a spacing of 1 cm between pressure sensors, 2% reported 0.75 cm, 12% had different spacing for different sensors and 14% did not provide information regarding the distance between sensors. Of all studies, the majority used catheters measuring pressure circumferentially (61.3%); a minority reported the use of catheters measuring unidirectionally (4.8%). In 32.3% of manuscripts, the measurement direction was not documented, one study reported a catheter including some sensors measuring circumferentially and some unidirectionally (1.6%).

Table 2 Reported catheter sizes

Catheter diameter (mm)	Number of studies	Percentage of studies (%)
4.2	19	30.6
4.1	1	1.6
4	10	16.1
3.6	2	3.2
3.2	5	8.1
2.75	5	8.1
2.64	3	4.8
2.5	1	1.6
2	4	6.5

Methodology of data acquisition

Slightly more than half of the publications utilized topical anesthesia (53.2%); 6.5% of the articles stated that no topical anesthesia was used, and 40.3% of studies did not report whether topical anesthesia was applied. In studies utilizing topical anesthesia, variable administration locations were documented including the nasal passage (33.3%), the catheter (3.1%), or combinations such as 'nasal passage and catheter' (24.2%), or 'nasal passage, catheter, and oral gargle' (24.2%). In 15.2% of the studies reporting the use of topical anesthesia, readers were not informed about the application location. In total, three types of anesthesia were specified including Lidocaine (69.7%), Lignocaine (18.2%), and Xylocaine (3.0%). A minority of 9.1% of studies did not report the type of anesthetic used. Doses of topical anesthesia varied among studies. For example, for Lidocaine, the doses ranged from 2 to 10%. An adjustment period after catheter placement was reported in 53.2% of the papers [10–13, 15, 18, 24, 28–33, 37, 41–59] (durations ranging from 5 to 10 min). In 46.8% of the studies [1, 9, 14, 16, 17, 19–23, 25–27, 34–36, 38–40, 60–69], the reader is not informed if an adjustment period was part of the protocol.

Regarding the positioning of the subjects during the study protocol, a sitting position was reported in 71.0% of the manuscripts, a supine position was documented less frequently (11.3%). In 17.7% of manuscripts, no information on positioning was provided. The following bolus types were documented to be used solely or in

Table 3 Replicability of reported methodology of data acquisition

Methodological aspect	Percentage of manuscripts providing sufficient information for replication
Equipment (HRM[a] system, catheter diameter, number of sensors, sensor spacing, and measuring direction)	58.1% (of all HRM/HRIM[b] studies)
Topical anesthesia (dose and application location)	38.7% (of all HRM/HRIM studies reporting the use of topical anesthesia)
Salinity percentage of bolus	33.3% (of all HRIM studies)

[a]*HRM* high resolution manometry

[b]*HRIM* high resolution impedance manometry

combination: dry swallows (22.6%), liquid (91.9%), puree (27.4%), and solid (8.1%). Of the studies using HRIM, 91.7% reported use of saline while 8.3% did not provide information regarding whether saline was used. Of these studies reporting the use of saline, 36.4% provided information regarding salinity percentage. Table 3 summarizes the number of studies using HRM/HRIM which provided sufficient data regarding methodological aspects of data acquisition to be replicated.

Methodology of data analysis

For studies utilizing HRM, the use of software intrinsic to the recording system was reported more frequently (56%) than the use of external software (Matlab™ [MathWorks, Natick]; 26%). A combination of both system built-in and external software was documented in 8% of the studies; a minority of the publications did not specify the type of software utilized (10%). For studies using HRIM, the majority documented the use of external software (e.g., Matlab™, AIMplot; 75%), whereas the application of the system-based software was documented only in one study (8.3%). No study reported the use of a combination of system-based and external software; 16.7% did not provide information regarding software.

The ManoScan™ system requires correction of a system-based measurement error. In 22.5% of manuscripts, authors reported whether the required correction was applied [11, 17, 41, 50, 51, 62, 65–67]. In the remaining publications utilizing the ManoScan™ system [1, 9, 10, 12, 13, 15, 20, 22–24, 26, 28–31, 34, 42–45, 49, 52–55, 57, 58, 63, 64, 68, 69], it was unclear if the correction was made and not reported, or if a potential error was present in the data.

In studies using HRM, a variety of definitions of the anatomical regions of interest were found. A frequently referenced definition for the velopharynx was "region of swallow-related pressure change, just proximal to the area of continuous nasal cavity quiescence and extending 2 cm" [55] (p. 370). Other authors, in contrast, defined this region as "the boundary between the velopharynx and the meso-hypopharynx", highlighted during verbalisation of "papapa" [54] (p. 439). Various terms were found when referring to the anatomical region between velopharynx and UES, in addition to differing definitions. In some studies, this area was considered as a single region and referred to using terms such as 'pharynx' [10, 11, 14, 16, 23, 49], 'tongue base' [1, 18, 30, 34, 42–44, 46, 47, 55, 60, 61], 'mesopharynx' [12, 15, 20, 24, 29], or 'epiglottis' [22, 64]. In other manuscripts, the anatomical region between velopharynx and UES was divided into sub-regions, such as 'tongue base' and 'low(er) pharynx' [27, 32, 33, 48, 56].

For studies using HRM, measurement parameters reported for the pharynx included pressure amplitude, documented in 90% of the studies. Of these studies, the most frequently reported amplitude measure (91.1%) was maximum/peak pressure [1, 9–11, 15, 17, 18, 20, 22, 24–34, 41, 43–52, 54–56, 60, 61, 63–67]. Various types of timing measures were documented in 52% of the manuscripts. These included one or a combination of the following temporal measures: contraction duration (including 'Kontraktionszeit' in German) [9, 10, 15, 18, 22, 24, 26–34, 42–44, 46–49, 51, 55, 56, 64] (100%), rise and/or fall time [22, 27–29, 32, 33, 48, 56, 64] (34.6%), and time intervals [48, 56] (7.7%). Further, 16% of publications reported an anatomical length measure [18, 43, 46, 47, 52, 65–67] such as the distance from the nostril to the maximum pressure point of the pharynx. Apart from these unidimensional amplitude, timing and distance measures, 52% of the reports documented other types of parameters including multidimensional measures characterized by more than one unit. Of the articles documenting other types of measures, 57.7% reported rate of pressure generation (including 'Geschwindigkeit der Kontraktionswelle' reported in German) [18, 24, 28–31, 43, 44, 46–49, 51, 55, 56], 53.8% reported various types of integral measures [12, 14, 15, 24, 28, 30–34, 44, 56, 63, 69], 19.2% documented velocity of the contraction wave [14, 30, 31, 48, 53], and 7.7% documented pressure gradients [30, 55]. For the UES, 88% of the studies published a type of amplitude measure such as UES pre- or post- opening/nadir pressure [1, 9, 18, 24, 27–33, 42–44, 46–49, 51, 55, 56, 63] (50%), a type of

minimum/nadir UES pressure [1, 9, 12, 14, 15, 24, 27–33, 41–44, 48, 55, 56, 69] (47.7%), residual pressure [10, 11, 18, 22, 23, 26, 46, 47, 49–51, 64] (27.3%), resting pressure [10, 14, 17, 18, 23, 34, 46, 47, 52] (20.5%), or basal pressure [12, 16, 22, 50, 64, 69] (13.6%). In 68% of the publications, a timing measure was documented including UES activity time [9, 18, 24, 27–33, 44, 46–48, 56] (44.1%), UES relaxation duration/interval (including report of 'Relaxationszeit' in German) [10, 12, 18, 22, 26, 34, 41, 46, 47, 49–51, 64, 69] (41.2%), nadir UES duration/UES minimum pressure duration [15, 24, 27–29, 32, 33, 44, 48, 56] (29.4%), or UES opening duration [1, 30, 43, 55] (11.8%). Length measures [22, 52, 63–67] such as the distance from the nostril to the maximum pressure point at the UES were documented in 14% of the reports. Measures other than amplitude and timing were published in 24% of the manuscripts and included measures such as integral measures [12, 24, 28–31, 34, 44, 63] (75%), coefficient of variation [15] (8.3%), or deglutitive sphincter resistance [41] (8.3%). The variation in these timing measures may reflect differences in both measures and terminologies for similar or identical parameters.

The same parameters, according to the terminology used, were measured differently across studies. As an example, the measurement method defining start and endpoint of the 'UES relaxation duration/interval' was in one manuscript defined as "from onset at the point of departure from half the baseline to the offset at the return to half baseline pressure" [12] (p.36). In another study, the start of the measurement period was specified as "a pressure drop by 10%" of the most central UES sensor, and the endpoint was determined "when the same pressure was reached again with the arrival of the pharyngeal contraction wave" [46] (p.603).[1] The measurement period for UES relaxation duration was not only defined differently across studies, but the choice of sensors on which to base the measurement differed as well.

Results of HRIM will be discussed descriptively; a review of existing pressure flow variables exceeds the scope of this present work. Within pharyngeal impedance technology, analysis of HRIM has predominately focused on impedance-only measures (e.g., nadir impedance [35, 57, 58], flow interval [21, 35, 36, 38, 40, 58, 59], ratio of nadir impedance to post-swallow impedance [21, 35, 39, 59]), synergistic measures relating pressure and impedance data (e.g., time from nadir impedance to peak pressure [21, 35, 36, 38, 40, 57–59], pressure at nadir impedance [21, 35, 36, 40, 58, 59]) and composite measures indicating global dysfunction that have been validated against tools, such as video fluoroscopy (e.g., Swallow Risk Index [21, 35, 38–40, 58]). In the sample, only one article reported impedance data as a percentage of incomplete versus complete bolus transit, however, this metric did not appear to be provided with sufficient detail for replication [19] and two studies reported a qualitative visual analysis of the impedance contour color pattern [13, 37]. These studies were the minority, however; consistency in HRIM publications was apparent due to the preponderance of use of standardized external software (e.g., AIMplot) which allows reporting of similar metrics across publications [21, 35, 36, 38, 40, 57–59].

Level of evidence and methodological quality assessment of individual studies

The majority of included articles (74.2%) were case-series (level 4), 24.2% of publications were case-control studies (level 3b), and one single study (1.6%) was classified as expert opinion (level 5). In regard to data analysis, randomization [28, 29, 31, 36, 38, 39, 58, 68] was reported in 12.9% and blinding [9, 10, 13, 15, 21, 34, 35, 37, 39, 40, 58] in 17.7% of the publications. A clear minority of publications using HRM provided data on inter- or intra-rater measurement reliability (10%), whereas the percentage of the studies using HRIM was considerably higher (50%). A final 100% consensus was reached between the two raters for all items considered.

Discussion

This review highlights substantial variability in methodology of data acquisition in studies using HRM. The potential impact of methodology on pressure measurements implies that methodological issues need to be considered in the interpretation of published research. Caution is warranted when comparing data across studies if reported methodology differs. For example, for the width of the catheter in situ, it has been reported that pressure at the UES might be more affected with increasing catheter diameter [63]. Across the studies involved in this review, nine different catheter sizes were documented. Thus, limited comparability across studies needs to be acknowledged. Regarding the body position of the subjects during the procedure, an effect on measurement parameters of the velopharynx and the UES in healthy adults has been documented in the literature [70]. Therefore, caution is warranted when comparing data from studies reporting different positions of the subjects during the assessment. As for the effect of topical anesthesia on pharyngeal pressures, a double-blinded study reported a change in pharyngeal measurement parameters during dry and liquid swallowing in healthy participants when topical anesthesia was applied as compared to a no anesthesia [71]

[1] Original publication language: "Bestimmung anhand des "zentralen Sensors" im oÖS. Ein Druckabfall um 10% markierte den Beginn der Relaxationszeit, das Ende wurde bei Wiedererreichen des gleichen Druckes mit dem Eintreffen der pharyngealen Kontraktionswelle definiert."

condition. This systematic review revealed that the use of anesthesia is common practice. It is recommended that clinicians carefully weigh the influence of anesthesia against the potential benefits of comfort. For studies using HRIM, the conductivity of the bolus depends on its salinity [72], and on the bolus consistency [73]. Dry and solid boluses that have been mixed with barium may have more variable conductivity than pure saline boluses. Ongoing research is needed to clarify how salinity affects the data acquired. Additional data regarding the impact of methodological aspects such as the use of different HRM systems, different catheter features (number of sensors, sensor spacing, or measurement direction), dose and application location of topical anesthesia, and duration of an adjustment period on the acquired data is necessary. Increased understanding of the impact of methodology on data will contribute to a refined decision-making process regarding data acquisition in future research.

Similarly, this review highlights variability of methodology regarding data analysis. The potential impact of aspects of data analysis on study results needs to be incorporated in the interpretation of outcomes. For example, for studies using the most commonly reported ManoScan™ system, it needs to be appreciated that data might vary depending on whether corrections of the system-based measurement errors were applied [62]. The use of system-based software was the most commonly reported in studies using HRM. However, this software was originally developed for evaluation of the esophagus and needs to be critically evaluated if used in the context of pharyngeal swallowing. For example, ManoScan™ system offers built-in software (ManoView™) which provides automated analysis mainly for the esophagus. However, for the pharynx and UES, only limited automated analysis embedded into the recording system is available and poor agreement between automated and manual analysis using this software has been reported for some UES parameters [50]. In contrast, customized methods using external software offer pharynx-specific analyses. However, the various analysis techniques among research and clinical practice restrict the comparability of data [4]. Further development of pharynx-specific system-based software or open-access external software such as Swallow Gateway™ [74], will contribute to a facilitated implementation of HRM/HRIM into clinical practice. Regarding measurement parameters, ability to generate comparisons across studies is considerably limited due to differing terminology and definitions of anatomical regions of interest and measurement parameters, and varying measurement methods. Efforts towards a more standardized terminology might contribute to an improved comparability across studies and to a facilitated communication across research laboratories and clinical institutions. For esophageal manometry, the Chicago Classification was developed for application of standardized metrics and to provide guidance on classification of disorders [75]. Similar guidelines for pharyngeal HRM might contribute to facilitated cooperation across institutions.

Interestingly, the majority of studies included for this review were published by a small number of research laboratories. Considering this fact, the large variability in reported methodology is even more striking. Some observed variability in methodology within research groups arose from inconsistent reporting, such as whether topical anesthesia was used. Hence, it is not clear whether a single research team actually used different methodology across different studies. However, observed methodological differences within research groups may also highlight that development of pharyngeal HRM/HRIM in swallowing assessment remains in the developmental stage.

The impact of methodological aspects of data acquisition and analysis on study results emphasizes the need for detailed reports of methodology in publications using HRM/HRIM. This review revealed a remarkably high number of manuscripts lacking documentation of methodology. Missing methodological information devaluates study results, as interpretation of the data is restricted. Explicit methodological documentations are strongly suggested, enabling readers to understand published data in the context of the selected methodology. Further, detailed methodological reports are required to allow for replication and comparison of data across studies. A particular emphasis on the status quo of reporting reliability is warranted. The number of HRM studies not reporting measurement reliability is striking. Importantly, published studies using HRIM more frequent report reliability analyses. Data regarding reliability are critical for an instrumentation which is translating into clinical practice. Hence, reliability reporting should be standard in future publications for studies using either HRM or HRIM.

Limitations of this review are acknowledged. The search was limited to published articles and to the languages English, German, and Spanish. Reference lists and citations were screened for the words ‘high resolution manometry/HRM’ and ‘impedance’ in their title, only. Further analysis of combined measures of pressure and impedance, as well as inclusion and review of impedance-only studies, should be reviewed in future publications. Due to the variability of terminologies, definitions, and measurement methods of the parameters of interest, a thorough comparison across studies for aspects of data analysis was not feasible.

In conclusion, a thorough evaluation of the existing literature is required as a foundation for the development of pharyngeal HRM/HRIM involving the formulation of methodological standards. Hence, this systematical appraisal of the status quo of published research is a contribution to ongoing international efforts towards an optimized use of pharyngeal HRM/HRIM. Publications providing detailed reports of methodological aspects of data acquisition and analysis add valuable information to an increasing body of research,

which is the base from which future developments arise. International collaboration between researchers, clinicians, and manufacturers is essential, established international working groups are critical to the development of HRM/HRIM. Existing and future open-access analysis platforms contribute to enhanced international collaborations. Further, exploration of topics such as validity, the establishment of normative data, or clinical training is fundamental for optimal use of HRM/HRIM as a diagnostic tool for pharyngeal swallowing.

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Compliance with ethical standards

Conflict of interest Canterbury Medical Research Foundation PRO(16/04). The grant funding was for partial salary. The funding body had no influence on the study design or on the study outcomes.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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