Water-perfused esophageal high-resolution manometry; normal values and validation

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(internal reference number MEC 2012_017 ) and was approved on the 19th of February 2012. All subjects
provided informed consent for the study.
Abstract:

Background: Water-perfused high-resolution manometry (HRM) catheters with 36 unidirectional pressure channels have recently been developed but normal values are not yet available. Furthermore, the technique has not been validated and compared with solid-state HRM. We therefore aimed to develop normal values for water-perfused HRM and to assess the level of agreement between water-perfused HRM and solid-state HRM.

Methods: We included 50 healthy volunteers (Mean age: 35 years, range: 21 – 64 years, 15 female). Water-perfused HRM and solid-state HRM were performed in a randomized order. Normal values were calculated as 5th and 95th percentile ranges and agreement between the two systems was assessed using intra-class correlations coefficient (ICC) statistics.

Results: The 5–95th percentile range for contractile front velocity (CFV) was 3.0 – 6.6 cm s⁻¹, for distal contractile integral (DCI) 141.6 – 3674 mmHg·s·cm, for distal contraction latency (DL) 6.2 – 8.7 s and for integrated relaxation pressure (IRP4s) 1.0 – 18.8 mmHg. Mean (SD) and ICC for water-perfused HRM and solid-state HRM were for CFV 4.4 (1.1) vs 3.9 (0.9) cm s⁻¹, ICC: 0.49, for DCI 1189 (1023) vs 1092 (1019) mmHg·s·cm, ICC: 0.90, for DL 7.4 (0.8) vs 6.9 (0.9) s, ICC: 0.50 and for IRP4s 8.1 (4.8) vs 7.9 (5.1), ICC:0.39.

Conclusions: The normal values for this water-perfused HRM system are only slightly different from previously published values with solid state HRM and moderate to good agreement was observed between the two systems with only small differences in outcome measures.
**Abbreviations**

EGJ: esophagogastric junction

HRM: High-resolution manometry

CFV: contractile front velocity

DCI: distal contractile integral

DL: distal contraction latency

IBP: intrabolus pressure

IRP: integrated relaxation pressure

UES: upper esophageal sphincter
Introduction

Since its introduction in the early 1950s, esophageal manometry has contributed to a better understanding of esophageal motor function and has currently become a widely performed technique in clinical practice. The first manometry systems used a catheter which contained water-perfused channels which opened to the lumen at several points along the catheter. These water-perfused pressure channels were driven by a pneumatic pump and connected to external pressure sensors. Water-perfused manometry catheters were hindered by large intervals between the pressure sensors which could result in an inadequate assessment of sphincter pressure and peristaltic abnormalities. This shortcoming was partly overcome by adding a sleeve sensor, which measured the highest pressure exerted along a segment of several centimeters. This allowed for a reliable measurement of the esophagogastric junction (EGJ), even though the EGJ moves up and down the catheter during inspiration or during swallowing. However, the esophageal pressure was still measured with a low level of detail and adding more pressure channels would require more water-perfused channels through the catheter and thus a larger diameter of the catheter and a significant amount of water being administered to a patient during the measurement. Furthermore, the response rate of water-perfused manometry is relatively low which results in difficulties when measuring rapidly changing pressures. Smaller caliber capillaries have partly overcome these shortcomings, making it now possible to create catheters with much more pressure sensors.

The second type of esophageal manometry system uses a solid-state catheter which has electronic pressure sensors within the catheter itself. With the use of this technique a high-resolution manometry (HRM) catheter was developed which showed a high level of detail at the EGJ and the esophagus by using 36 pressure sensors. The currently available solid-state high-resolution manometry catheters often use circumferential pressure sensors and it has been suggested that the latter increases the accuracy of measuring the pressure of the asymmetric EGJ. Furthermore, the response rate of solid-state manometry is considerably higher. However, solid-state manometry catheters are relatively expensive and more vulnerable to damage compared to water-perfused manometry.
The solid-state manometry catheter is currently being considered as the gold standard for esophageal HRM and analysis is performed using the Chicago classification.(3, 7, 8) The normal values presented in this classification have therefore specifically been developed for the use of solid-state catheters.

Despite the advantages of solid-state HRM, water-perfused HRM systems are still being used frequently, and it is estimated that approximately 400-500 centres worldwide currently use a water-perfused HRM assembly. Their popularity is the result of the relatively low costs of the catheter and the fact that the external pressure transducers result in a high durability of the system. These advantages may outweigh the concomitant practical disadvantages of water-perfused systems. These include a longer preparation time of the system before a measurement due to the necessity to perfuse the catheter until all air is removed from the capillaries and the need to sterilize the catheter after use. Recently, a water-perfused HRM catheter has been developed with 36 channels rendering a pressure measurement resolution equal to that of the solid state catheters. However, no normal values for this technique are available which limited the use of water-perfused HRM in clinical practice this far. Furthermore, the level of agreement between water-perfused HRM and solid-state HRM is currently unknown. The aim of this study was therefore to develop normal values for water-perfused high-resolution manometry for the parameters defined by the Chicago classification and to assess the level of agreement between water-perfused HRM and solid-state HRM.
Methods

Subjects

We included 50 healthy volunteers (mean age: 35 years, range: 21 – 64 years, 15 females) without a history of upper gastrointestinal complaints. Subjects who used medication which could affect upper gastrointestinal motility or subjects with a history of upper gastrointestinal surgery were excluded. All subjects provided written informed consent. This study has been reviewed by the ethics committee of the Academic Medical Center (internal reference number MEC 2012_017) and was approved on the 19th of February 2012.

High-resolution manometry

Water-perfused HRM and solid-state HRM were consecutively performed in a randomized order. Subjects reported to the hospital after fasting for a minimum of 3 hours. For each manometric study, the manometry catheter was introduced transnasally and positioned to record from hypopharynx to stomach. Subjects were placed in supine position and received 10 boluses of 5 ml water with an interval of 20 seconds.

The water-perfused high-resolution manometry assembly consisted of a 36-channel water-perfused catheter (Dentsleeve, Mississauga, Ontario, Canada). The luminal diameter of each perfusion capillary was 0.4 mm and the total diameter of the catheter was 4.7 mm. The perfusion pressure during the entire manometric study was maintained at 0.15 ml/min. Pressures were recorded with external pressure transducers (Argon Medical Devices, Plano, TX, USA). The catheter was zeroed to atmospheric pressure before the catheter was introduced. The manometric signals were recorded with a frequency of 20 Hz and were stored on a personal computer.

Solid-state HRM was carried out using a solid-state HRM assembly with 36 circumferential pressure sensors spaced at 1-cm intervals (Given Imaging, Los Angeles, CA, USA). A sampling frequency of 37 Hz was used to record HRM signals with the solid-state catheter. Before the onset of the measurement, the HRM pressure
tracings were calibrated at 0 and 300 mmHg.

Data analysis

Water-perfused high-resolution manometry data were analyzed using dedicated software (Medical Measurements Systems (MMS), Enschede, The Netherlands). Solid-state high-resolution manometry data were also analyzed using dedicated software (Given Imaging, Los Angeles, CA, USA). Esophageal motility was assessed using the Chicago criteria. Assessment of EGJ relaxation pressure, resting pressure and upper esophageal sphincter (UES) resting pressure and relaxation pressure was automatically performed using dedicated software after manual inspection of the tracings and the correct placement of analysis markers during a period of non-swallowing, directly following the 10 liquid swallows (QuickView Measurement and analysis software v 8.23a, MMS, Enschede, the Netherlands). EGJ pressure was referenced to gastric pressure whereas the esophageal contraction parameters and UES pressures were referenced to atmospheric pressure. Breaks in the esophageal contraction wave were defined as segments within the esophageal contraction wave with an amplitude below the 20-mmHg isobaric contour. Average break length was defined as the mean break length during the 10 swallows. The contractile front velocity (CFV) was defined as the slope of the line connecting the points on the 30-mmHg isobaric contour at the proximal and the distal margin of the distal esophageal segment. Distal contractile latency (DL) was defined as the time between deglutitive UES relaxation and the contractile deceleration point (CDP: the inflection point along the 30-mmHg isobaric contour where propagation velocity slows demarcating the tubular esophagus from the phrenic ampulla). The distal contractile integral (DCI) was calculated by multiplying the length of the smooth muscle esophagus by the duration of propagation of the contractile wave front, and the mean pressure in the manually placed frame excluding pressures below 20 mmHg. Deglutitive relaxation of the EGJ was assessed with the Integrated relaxation pressures (IRP) which measured the lowest 4-s cumulative pressure values that occurred during a 10-s postdeglutition time window in the electronically generated e-sleeve signal through the anatomic zone defining the EGJ. There is currently no general consensus for the assessment of deglutitive relaxation of the UES, we therefore...
assessed UES relaxation with the Integrated relaxation pressures (IRP) during the lowest 0.2-s and 0.8-s cumulative pressure values that occurred during a 3-s window in the electronically generated e-sleeve signal through the UES. Furthermore, UES relaxation was assessed by calculating the UES residual pressure (intrabolus pressure at the level of the UES during a swallow) automatically during the manually placed marker during UES relaxation. Esophageal intrabolus pressure (IBP) was measured between the peristaltic wavefront and the EGJ.

**Statistical analysis**

Normal values were defined as the interval between the 5th and 95th percentile of values. The levels of agreement between the two systems were assessed using intra-class correlation coefficient statistics. Data are presented as mean±SD, median and 5th and 95th percentiles.
Results

Subjects

Measurements were successfully performed in all subjects and none of the subjects met the criteria for achalasia or esophageal spasm.

Normal values for water-perfused HRM

EGJ, esophageal and UES parameters are shown in table 1. The 5–95th percentile range for the IRP 4s was 1.0 – 18.8 mmHg. For the basal pressure of the EGJ (respiratory minimum) the 5–95th percentile range was 3.0 – 29.8 mmHg. The 5–95th percentile range for CFV was 3.0 – 6.6 cm s^-1, for DCI 141.6 – 3674 mmHg*s*cm and for DL 6.2 – 8.7 s. Total break length in the esophageal contraction length was 3.0 cm and its 5–95th percentile range was 0.0 - 9.5 cm. The 5–95th percentile range for basal pressure of the UES (mean) was 28.8 – 199.3 mmHg, for UES residual pressure 1.7 – 30.7 mmHg, and for the UES IRP 0.2s 1.1 – 28.9 mmHg.

Agreement between solid-state HRM and water-perfused HRM

The levels of agreement between water-perfused HRM and solid-state HRM are shown in table 2. Fair agreement between the two measurement techniques was observed for the IRP4s values (ICC = 0.39), with a slightly higher 95th percentile of 18.8 mmHg using water-perfused HRM compared to 15.5 mmHg measured with solid-state HRM. The Bland-Altman plot did not demonstrate a consistent trend (increased or decreased value) in IRP4s difference between the two measurement techniques (figure 2B). Slight agreement between the two techniques was observed for EGJ resting pressures (ICC = 0.16). Again, the Bland-Altman plot did not demonstrate a consistent trend in LES resting pressure difference between the two measurement techniques and similar 5th percentile and 95th percentiles were observed (figure 2A).

Table 2 also shows the esophageal parameters as measured by water-perfused HRM and solid-state HRM and their respective intra-class coefficient values. The agreement between DCI values as measured by the...
two techniques was almost perfect (ICC = 0.90). Moderate agreement was observed between the two
techniques for CFV (ICC = 0.49) and DL (ICC = 0.50), and the Bland-Altman plots did not demonstrate a
consistent trend (increased or decreased value) between the techniques for these measures (figure 3A-C).
No agreement (ICC = -0.07) was observed between the IBP values as measured by the two techniques.
There was slight agreement in UES resting pressure as measured with between the two techniques (ICC = -
0.11). In general, a markedly higher 95th percentile was observed for water-perfused HRM compared to
solid-state HRM (199.3 vs 137.7 mmHg). A consistent trend (increased or decreased value) in resting UES
pressure differences between the two techniques was not identified using the Bland-Altman plots (figure
1A). Slight agreement between the two techniques was observed for UES residual pressures (ICC = 0.15).
The 95th percentile of UES residual pressure was 30.7 mmHg using water-perfused HRM compared to 8.5
mmHg using solid-state HRM. Moreover, the Bland-Altman plot demonstrated that the residual UES
pressure measured with the solid-state catheter is consistently lower compared to the water-perfused
catheter (figure 1B).
Discussion

This study provides normal values for water-perfused high-resolution manometry of the esophagus. The normal values for the most important parameters, DL, CFV and IRP 4s, acquired by a water-perfused catheter are comparable to previously published described criteria and a moderate to good agreement was observed compared to solid-state HRM performed in the same subject on the same day. Furthermore, even though the normal values for DCI appear to be markedly lower compared to previously published criteria, an almost perfect ICC was observed between water-perfused HRM and solid-state HRM. Basal pressure of the EGJ and UES appear to be markedly different between water-perfused HRM and solid-state HRM, a finding which is also reflected by a poor ICC. However, the latter two parameters do not form part of the Chicago classification and the relevance of these observations for clinical practice is considered limited and parameters expressing relaxation of the sphincters is much more important.

The values obtained with the water-perfused HRM catheter in the current study were slightly different from the solid state HRM performed at the same day and also slightly different from the normal values measured with solid state HRM previously in Chicago.(3, 7–9) However, it should be mentioned that the solid-state HRM values we measured in the current study with the same catheter as used in Chicago were also slightly different from those historic values measured in Chicago with that type of catheter. It is likely that part of the differences found can not be attributed to the system used, but are the result of the large variability within subjects and groups. Although we performed the measurements consecutively and in a randomized order, we cannot exclude the presence of a considerable intra-individual variability, as was also demonstrated in a recent study by Bogte et al. It is likely that this is responsible for a large part of the differences between the 2 consecutive measurements in the same subject, and only smaller differences can be accounted by differences in measurement technique.(1)

The water-perfused catheter used in this study incorporates unilateral pressure sensors in contrast to the circumferential pressure sensors of the solid-state catheter used in previous publications.(3, 7, 8) Since the EGJ is asymmetric, the latter could explain the poor agreement between water-perfused HRM and solid-state HRM.
state HRM for measuring pressure in the sphincter. However, a recent study which also incorporated unilateral pressure sensors did not observe such a low EGJ resting pressure. Moreover, using this unilaterally sensitive solid-state catheter, a markedly higher IRP4s was observed, a finding which was also not observed in our study. The use of unilateral pressure sensors is therefore not likely to cause a consistent increase or decrease in resting pressure of the EGJ, however, it is possible that it results in more variation compared to the circumferential catheters in which a circumferential average is reported.

The response rate of water-perfused systems is markedly slower compared to solid-state systems. Since the UES is composed of striated muscle, pressure changes are much more rapid than pressure changes in the esophagus or in the EGJ. The slower response rate of water-perfused HRM is likely the cause of the large differences and poor agreement between the UES residual pressure as measured by solid-state HRM and water-perfused HRM. Another reason for differences in UES parameters might be the existence of the pharyngo-UES reflex. It has been shown that both rapid and continuous slow perfusion of the pharynx with water can increase UES pressure. For these reasons we believe that manometric measurements of the UES obtained with water-perfused HRM might overestimate UES resting pressure and UES relaxation pressure and, consequently, that water-perfused HRM is not well suited for exact pressure measurements of the UES. Since the presented normal values for UES relaxation were developed specifically for water-perfused systems, we advice caution when these values are used for UES relaxation using solid-state systems.

Water-perfused catheters with a high-resolution segment only at the position of the EGJ are also available. These catheters measure pressure at the EGJ similarly to the catheter used in our study but have a larger spacing between the sensors positioned at the level of the esophageal lumen. We therefore propose that centers which use these catheters adopt our proposed values for EGJ measurement. However, we advice to use caution with using our proposed criteria for esophageal parameters until future studies evaluate the effect of larger sensor spacing on HRM parameters defined by the Chicago classification.

The current normal values for water-perfused manometry and the moderate to good agreement between
water-perfused and solid-state manometry for the most relevant HRM parameters, suggests the
uncomplicated use of this technique in the diagnostic assessment of patients with dysphagia. However, the
usefulness of normal values is always determined by the likelihood that an abnormal value can indeed be
considered pathological and responsible for symptoms and while this seems clear for well-studied
parameters such as IRP, it is much less clear for other parameters such as break size, DCI and CFV.

In conclusion, in this study we have established normal values for a water-perfused high-resolution
manometry system. The normal values which we propose are only slightly different from previously
obtained normal values and a moderate to high level of agreement between measurements with water-
perfused HRM and solid-state HRM was observed for CFV, DL, DCI and IRP4s, i.e. for measurements
performed at the same day in the same subject. The presented normal values allow physicians to use water-
perfused HRM catheters in clinical practice and help to define normal and abnormal. However, the results of
our study also confirm that differences in measurement outcome exist between different manometric
systems, and that normal values must be determined for each different manometric system.
## Tables

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<th></th>
<th>mean</th>
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<th>5th</th>
<th>95th</th>
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<td>7</td>
<td>1</td>
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<td>76</td>
<td>28.8</td>
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<td>11.5</td>
<td>1.7</td>
<td>30.7</td>
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<td>7.9</td>
<td>9.5</td>
<td>1.1</td>
<td>28.9</td>
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<td>IRP 0.8s (mmHg)</td>
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<td>10.5</td>
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<td>8.0</td>
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<td>CFV (cm s⁻¹)</td>
<td>4.4</td>
<td>1.1</td>
<td>4.2</td>
<td>3.0</td>
<td>6.6</td>
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<td>970</td>
<td>141.6</td>
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<td>3.5</td>
<td>6.0</td>
<td>0.0</td>
<td>12.0</td>
<td>&lt;15</td>
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<td>Total break length (cm)</td>
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<td>2.7</td>
<td>2.3</td>
<td>0.0</td>
<td>9.5</td>
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Table 1. Esophageal parameters, EGJ parameters and UES parameters as measured by water-perfused HRM.
### Table 2. Esophageal parameters, EGJ parameters and UES parameters as measured by water-perfused HRM and solid-state HRM. ICC = Intra-class correlation coefficient, 5<sup>th</sup> - 95<sup>th</sup> = 5<sup>th</sup> percentile - 95<sup>th</sup> percentile.

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<td>Mean (SD)</td>
<td>5&lt;sup&gt;th&lt;/sup&gt; - 95&lt;sup&gt;th&lt;/sup&gt;</td>
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<td>Resting pressure</td>
<td>75.8 (32.2)</td>
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<td>1.7 - 30.7</td>
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<td><strong>EGJ parameters</strong></td>
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<tr>
<td>Resting pressure</td>
<td>14.7 (8.3)</td>
<td>3.0 - 31.2</td>
<td>11.6 (8.1)</td>
<td>3.0 - 29.8</td>
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<td>IRP4s (mmHg)</td>
<td>7.9 (5.1)</td>
<td>2.0 - 15.5</td>
<td>8.1 (4.8)</td>
<td>1.0 - 18.8</td>
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<td><strong>Esophageal parameters</strong></td>
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<tr>
<td>DCI (mmHg·s·cm)</td>
<td>1092 (1019)</td>
<td>178 - 2828</td>
<td>1189 (1023)</td>
<td>142 - 3674</td>
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<td>CFV (cm s&lt;sup&gt;-1&lt;/sup&gt;)</td>
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<td>5.7 (3.5)</td>
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**Figure Legends**

Figure 1. Bland Altman plots of A: IRP4s, B: EGJ resting pressure. +95% = 95% upper limit of agreement. -95% = 95% lower limit of agreement. Bias = average difference between outcomes obtained by water-perfused HRM and solid-state HRM.

Figure 2. Bland Altman plots of A: distal contractile integral (DCI), B: contractile front velocity (CFV), C: distal latency (DL). +95% = 95% upper limit of agreement. -95% = 95% lower limit of agreement. Bias = average difference between outcomes obtained by water-perfused HRM and solid-state HRM.

Figure 3. Bland Altman plots of A: UES resting pressure, B: UES residual pressure. +95% = 95% upper limit of agreement. -95% = 95% lower limit of agreement. Bias = average difference between outcomes obtained by water-perfused HRM and solid-state HRM.
References


