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Proposed Catheter Standards for Pharyngeal Manofluorography (Videomanometry)

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Abstract. With the recent introduction of commercially available pharyngeal manofluorography systems, catheter design should be standardized. Catheters of different designs can produce different data because of their design characteristics. A standard catheter design should make results between investigators comparable and facilitate acceptable normal values. The authors' combined laboratory experience with many catheter designs was reviewed and the literature consulted. For pharyngeal manofluorography, the proposed standard catheter should be 2 × 4 mm in diameter, ovoid, and 100 cm long. The catheter should be marked in centimeters with an anterior and posterior orientation. There should be a slightly malleable, 3- to 4-cm length without sensors beyond the most distal sensor. Solid state transducer sensors should be three or four in number and placed in the pharyngoesophageal segment, midhypopharynx, and tongue base (esophagus for fourth sensor). Sensor spacing should be 3 cm, except 2 cm between the midhypopharynx and tongue base. Unidirectional, in-line, posteriorly oriented sensors with the option of a single circumferential sensor in the cricopharyngeus are currently preferred over circumferential sensors because of their small diameter (patient comfort).

Key words: Catheter — Manometry — Pharynx — Standards — Videofluoroscopy — Deglutition — Deglutition disorders.

Several techniques have evolved in the evaluation of patients with suspected oropharyngeal swallowing dysfunction. The modified barium swallow (video swallowing fluoroscopy) has been well standardized and is currently the accepted standard procedure for clinical pharyngeal swallowing analysis [1–3]. However, other than for timing of events, the clinical modified barium swallow remains largely subjective. Descriptive terms such as ''mild,'' ''moderate,'' and ''severe'' are used for quantification. Pharyngeal manometry objectively quantifies pressure and timing measurements to pharyngeal function. Although first advocated as a research tool, pharyngeal manometry is now moving into clinical practice. Research studies into pharyngeal function with manometry have often used unique catheter designs, so that results from various laboratories are difficult to compare [4–10]. These variations in manometry technology and catheter designs contribute to the varying, and sometimes conflicting results obtained by different laboratories [4,8,9,11,12]. Clinical application of pharyngeal manometry without simultaneous videofluoroscopy has been commercially ''standardized'' by Synetics with use of the Castell method [10,13–17]. This method uses one unidirectional and two sequential circumferential solid state sensors with spacing of 3 cm and 2 cm. The most distal sensor is placed manometrically in the proximal pharyngoesophageal segment (the upper esophageal sphincter) (UES).

Pharyngeal manometry without fluoroscopy, however, has been criticized as having limited clinical usefulness [4,13,18–21]. Problems correlating results of pharyngeal manometry with those of modified barium swallow have led to the development of combined studies (manofluorography) [13,18,20,22–24]. Many research [4,7,8,23,25–27] and all clinical [18,22,24,28–31] manofluorography studies have used variations of the McConnel method, in which four unidirectional solid state sensors are separated by 3-cm spaces. The second sensor is placed in the distal hypopharynx at the bottom of the air column. This location puts the third sensor in

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the middle of the UES (at rest). The addition of simultaneous videofluoroscopy (manofluorography or videomanometry) and the recent introduction of commercially available manofluorography systems (Synetics, Medical Measurement Systems: Kay Elemetrics Corp., Lincoln Park, NJ) are the two critical factors behind a new interest in pharyngeal manometry as a clinically useful tool.

Standardization of pharyngeal manofluorography or any diagnostic test is desirable to (1) compare test and retest results for an individual patient, (2) establish ''normal range'' and standard deviations for a given population, and (3) evaluate ''abnormal'' results in relation to diagnosis and outcome. Such universal standards allow meaningful comparisons of results from different laboratories, institutions, and countries. With the advent of these commercially available manofluorography systems, it is important to establish a standard catheter design and placement. Such a standard will facilitate establishment of acceptable normal values and enhance comparison of studies among centers.

Materials and Methods

The following information is based on a thorough review of the English literature and our combined personal experience of 21 years (J.R.S., 4 years; K.R.D., 7 years; F.M.S.M., 10 years) using a variety of catheter designs. These include perfusion and solid state sensors, unidirectional and circumferential solid state sensors, and round and ovoid cross-sectional catheters in a variety of sensor numbers and spacings. The most commonly used catheter techniques in the authors' experience are the McConnel method (F.M.S.M. and J.R.S.) and the Castell method (K.R.D. and J.R.S.), as previously described.

Results

Sensor Type

Most research studies over the past 5 years have used solid state transducer sensors rather than perfusion catheters with strain gauges. Solid state transducers are more sensitive to the rapid timing and pressure changes of the pharynx (particularly for amplitude) than are perfusion systems [9]. Solid state transducer systems are also much easier to set up and operate and avoid the introduction of fluid artifacts into the pharynx. The disadvantage of solid state systems is that they are initially more expensive than perfusion systems. In our experience, this expense is more than offset by time saved. We have solid state catheters that are more than 4 years old and that have been used in more than 300 studies.

Catheter Diameter

The diameter of the catheter should be as small as possible. Nasal and pharyngeal discomfort increase significantly with increase in diameter. As patient discomfort and catheter diameter increase, cricopharyngeal resting pressure and pharyngeal contraction forces increase in normal subjects [11,32]. In addition, an uncomfortable patient may alter swallowing and make clinical studies more difficult and time consuming. We and others have found that if two catheters of different diameter are used sequentially in the same patient, different values result [4,8,11,12]. From a purely biomechanical perspective, catheter diameter may affect flow rates (and therefore pressures) through the relatively narrow UES [19,33].

The limiting factor in solid state catheter diameter is sensor diameter. At present, the smallest diameter for solid state sensors used in pharyngeal manometry is 2 mm (length of 7.5 mm), which is found in unidirectional systems (Sones W, personal communication, 1996). The smallest circumferential sensors are 2.2 mm in diameter and 8 mm in length, but the limit is one per catheter (additional unidirectional sensors may be added). The two sequential circumferential sensors used in the Castell method are significantly larger, 5 or 6 mm in diameter by 13 mm long. Smaller solid state transducers have been made for other applications, such as cardiologic procedures and biliary manometry, but have not yet been applied to pharyngeal manometry (Robertson RA, personal communication, 1996). As technology advances, we expect size and number limitations to change and costs to decrease.

Sensor Spacing and Placement

Previous studies (modified barium swallow) have established three important anatomic areas that provide clinically valuable data in the pharyngeal phase of swallowing: (1) the tongue base, (2) the low hypopharynx (laryngeal inlet), and (3) the cricopharyngeal segment [1–3]. These areas have been the focus of pharyngeal manometry with and without videofluoroscopy [9,17,21, 23,27]. A fourth, perhaps less significant, area is the upper cervical esophagus. The cervical esophagus is sometimes useful clinically in markedly abnormal swallowing to indicate a swallow that leads to cervical-esophageal peristalsis from uncoordinated pharyngeal attempts at swallowing. It should be recognized that the one cervical-esophageal transducer provides limited esophageal information. Solid state catheters have fixed (nonadjustable) sensor spacings because of radial stability, catheter size, and cost concerns. To enable pressure measurements at the three or four important anatomic areas, sensor spacing in the adult subject is commonly at 3-cm intervals or at 3- and 2-cm intervals. The variability of sensor spacing depends on precisely where sensors are placed in the pharynx and on the patient's anatomy. For example, the Castell method [4,17] places the most distal sensor (sensor 3) in the ''proximal cricopharyngeal region.'' These studies are not usually done with simultaneous fluoroscopy, so the location of the catheter is based on the typical configuration seen in this most distal sensor. Through use of simultaneous videofluoroscopy with Castell's catheter placement, the most distal sensor (sensor 3) is located in the pharynx at the level of the vocal cords during quiet respiration [4]. Sensor 2 is 3 cm proximal, in the midhypopharynx. This midhypopharyngeal position may result in an epiglottic spike artifact [4,9], which results in pressure spikes of up to 600 mmHg because the epiglottis hits the sensor during the epiglottic ''tilt.'' Sensor 1 (tongue base) is an additional 2 cm proximal at the level of the tip of the epiglottis (Fig. 1).

The McConnel method [7,8,23,26] places sensor 3 in the midcricopharyngeal region during quiet respiration, about 1–1½ cm below the corresponding 3 sensor of Castell's system. McConnel sensor 2 is 3 cm above sensor 3 in the low hypopharynx. At rest, this location is just above the bottom of the air column in the hypopharynx, behind and slightly above the tip of the arytenoid (Fig. 1). The epiglottic spike occurs less commonly in this lower position. McConnel's sensor 2 is 1–1½ cm below Castell's sensor 2. The most proximal McConnel sensor, 1 (tongue base), is 3 cm above 2 (hypopharynx). This location corresponds to the tip of the epiglottis and is only 0–0.5 cm below the most proximal sensor, 1, of Castell. McConnel uses an additional sensor (4) in the cervical esophagus, 3 cm below the cricopharyngeal sensor, 3.

Spacing is thus 3 cm, 3 cm, and 3 cm for the McConnel method and 3 cm and 2 cm for the Castell. Sensors 1 and 2 give similar tracings in both systems, but sensor 3 shows different configurations between each system. The rationale for a higher sensor 3 (cricopharyngeal) placement by Castell is that the sensor is expected to be in the middle of the cricopharyngeus at the superior apex of the swallow [8,34] because in normal subjects the larynx rises more than the catheter from the rise of the soft palate. The rationale for a lower sensor 3 placement by McConnel is that in dysphagic patients, laryngeal elevation is commonly impaired more than palatal elevation. A lower position therefore gives a better representative reading of the UES. This may be a moot point, however, since both the Castell and the McConnel positions give reliable negative nadirs in normal patients. A negative nadir is an important manometric variable in pharyngeal manofluorography. In both positions, the nadir is preceded by an elevation pressure wave and followed by a clearing pressure wave. However, the amplitude and to some extent the timing of the latter two waves appear differently between sensor positions within the UES [8]. A consensus for placement of the cricopharyngeal sensor (3) is difficult to attain. The answer to

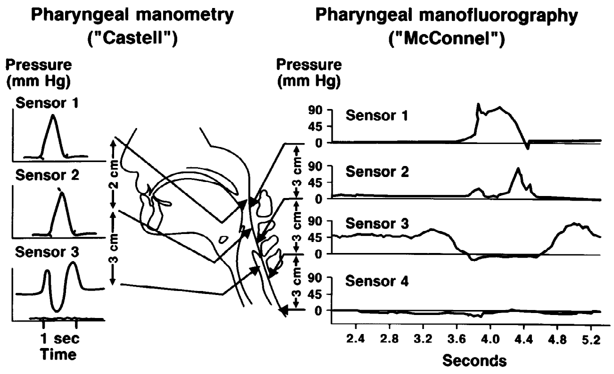

Fig. 1. Sensor locations for pharyngeal manometry and pharyngeal manofluorography as determined by fluoroscopy.

which is ''best'' is not supported by clinical studies or our personal experience. The work of Kahrilas et al. [8] and Gerhardt et al. [35] suggests that an appropriate compromise would be to raise the McConnel cricopharyngeal sensor 0.5 to 1 cm in normal persons.

These spacings are for an ''average'' adult. For waveform analysis, a spacing difference of 1 to 2 cm for sensors 1 and 2 is not significant, since the variation of pharyngeal length among individuals exceeds these dimensions. There are two exceptions. First, the previously mentioned epiglottic spike artifact occurs when sensor 2 is in the midhypopharynx [4,9]. Second, in a patient with a very short neck, sensor 1 lies behind the soft palate. This position yields a significantly abnormal tongue base wave compared with a location at or below the tip of the epiglottis [4]. Therefore, the recommended spacing for McConnel's catheter should change to 2 cm between sensors 2 and 1. The recommended spacing for the Castell catheter would then be 2 cm between sensors 3 and 2 and 2 cm between sensors 2 and 1. This change would locate sensors 1 and 2 in both the McConnel and the Castell catheters at nearly identical anatomic sites. There is, however, a mechanical limitation for sensor spacing on a single catheter (Sones W, personal communication, 1996; Robertson RA, personal communication, 1996). Sequential circumferential sensors are 13 mm long. To maintain catheter flexibility, spacing between sensors must be more than 2.5 cm. Currently used unidirectional sensors are 7.5 mm long and must be 2 cm apart, although new technology will enable 1-cm spacing. It is also doubtful that the Castell sensor configuration will change, since this configuration has already been commercially standardized. We think that changing the McConnel configuration to 3 cm, 3 cm, and 2 cm at this time is not a problem and will not significantly alter normal data for sensor 1 (unless it lies behind the soft palate).

In summary, we believe that the ideal sensor spacing for manofluorography is 3 cm, 3 cm, and 2 cm (i.e., 3 cm between the esophageal sensor (sensor 4), and the cricopharyngeal sensor (sensor 3); 3 cm between the cricopharyngeal sensor (3), and the hypopharyngeal sensor (2); and 2 cm between the hypopharyngeal sensor (2) and the tongue base sensor (1). The catheter should be positioned so that the cricopharyngeal sensor is 0.5–1.5 cm below the inferior margin of the vocal cords at rest. This placement should be adjusted, depending on the patient's anatomy and deficiencies in laryngeal or palatal elevation, to keep sensor 3 within 1–2 cm below the vocal cords at maximal laryngeal elevation. With new sensor technology that allows 1-cm spacing, placing two sensors in the cricopharyngeal segment 1 cm apart should give cricopharyngeal measurements at the apex of laryngeal elevation in both normal persons and dysphagic patients with minimal or no catheter adjustment (sensor 3a, located at the vocal cords in the Castell method, and sensor 3b, 1 cm below the vocal cords in the McConnel method).

Catheter Length

The length of the catheter from tip to connector should be about 100 cm. This length allows the connectors to be taped to the upright fluoroscopy table above the level of the patient's head or to be held by the patient and still provide ample length for patient positioning. With this length, also, enough catheter is available for esophageal measurements. Having the catheter clearly marked in centimeters, with its most distal sensor at 0 cm, is very helpful. This marking should indicate anterior and posterior surfaces, since by previously established convention all unidirectional catheters should be placed facing posteriorly. We have found that it is important to have a 3- to 4-cm, slightly malleable segment without sensors past the most distal sensor. A slight bend in this end length facilitates catheter placement through the genu of the nasopharynx. It also solves the problem of placement through the cricopharyngeus into the esophagus when Zenker's diverticula or other pharyngeal ''dead ends'' (postsurgical) are present [15,36]. We also believe that a length of the catheter should extend through the cricopharyngeus into the esophagus. This feature helps stabilize the catheter laterally and horizontally in the hypopharynx and avoids dislocation and ''stimulation'' of an object entering or leaving the cricopharyngeus as the larynx rises and falls with the swallow [4,12,17]. Lastly, the catheter should have a slightly ovoid shape to help maintain a constant radial orientation. This is important only for unidirectional sensors, since the radial pressures in the pharynx are asymmetrical [25,35].

Unidirectional and Circumferential Sensors Compared

A common debate in pharyngeal manometry is whether the sensors should be unidirectional or circumferential. Both the Castell and the McConnel catheter systems use a posteriorly oriented unidirectional sensor for the tongue base (sensor 1) (epiglottis tip in a resting position). The McConnel method uses all unidirectional, posterior-facing sensors, whereas the Castell method uses circumferential sensors for the hypopharynx (sensor 2) and the cricopharyngeus (sensor 3). The advantage of circumferential sensors is that known radial asymmetries in the pharynx and cricopharyngeus [25,35] are averaged, so that catheter rotation is not a variable [4,17]. The disadvantage of sequential circumferential sensors is that because the diameters are larger (5–6 mm), the patient is more uncomfortable.

The advantage of unidirectional sensors is that they are smaller in diameter (2 mm) and therefore more comfortable for patients. They also produce less flow resistance through the UES than sensors of larger diameter [19]. Small (2.2 mm in diameter by 8 mm in length) circumferential sensors are available but are currently limited to one per catheter and must be placed at the distal or secondmost distal location. A single unidirectional sensor may be placed distal, and multiple unidirectional sensors may be placed proximal, to this small circumferential sensor (Sones W, personal communication, 1996). The disadvantage of unidirectional sensors is that radial orientation is important. We have found that rotational stability is excellent with an ovoid catheter, especially with fluoroscopic confirmation. Since both the Castell and the McConnel catheters have unidirectional sensors, radial orientation is important in both systems. Reliable and stable measurements are obtained with both unidirectional and circumferential sensors. Because of size and patient comfort, the unidirectional sensors are currently preferred. In nonfluorographic studies, especially with a round catheter, the problem of orientation becomes great enough to suggest a more important role for the circumferential sensors. If future developments lead to less expensive and smaller sequential circumferential sensors, they will then be the obvious choice.

Conclusions

The ideal standard pharyngeal manometry catheter (Fig. 2) used in manofluorography should be 2 × 4 mm (or smaller, 1.5 × 3 mm) in diameter, ovoid in shape, and 100 cm long. The catheter should be marked in centimeters with an anterior and posterior orientation. A slightly malleable, 3- to 4-cm length of catheter without sensors should remain beyond the most distal sensor. Solid state transducers should be used, and one sensor each should be placed in three or four locations: cricopharyngeus, hypopharynx, and tongue base (esophagus for the fourth sensor). Sensor spacing should be 3 cm between crico-

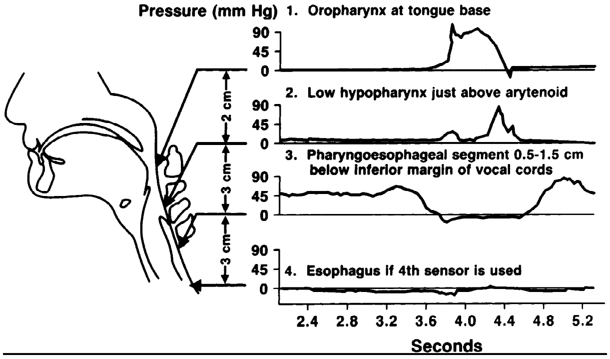

Fig. 2. Proposed standard catheter spacing and placement.

pharyngeus and hypopharynx and 2 cm between hypopharynx and tongue base. The option of two sensors in the cricopharyngeus 1 cm apart enables UES measurements at the apex of laryngeal elevation in both normal persons and dysphagic patients without catheter adjustments. If an esophageal sensor is added, the location should be 3 cm below the (first) cricopharyngeal sensor. Unidirectional, in-line, posteriorly oriented sensors with the option of a single small circumferential sensor in the cricopharyngeus are currently preferred over circumferential sensors because of their small size and patient comfort.

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