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ORIGINAL PAPER

Pharyngeal Pressures During Swallowing Within and Across Three Sessions: Within-Subject Variance and Order Effects

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Abstract No studies have investigated within-subject variation in measures of pharyngeal pressures during swallowing across sessions. This study aimed to document the variation in pharyngeal pressures both within and across three sessions. Twenty healthy participants were recruited for three sessions. For each session, peak or nadir pressures were recorded from the upper pharynx (sensor 1), mid-pharynx (sensor 2), and upper esophageal sphincter (sensor 3) during saliva and 10-ml water bolus swallows. Variance was larger across sessions than within sessions for sensors 1 and 2 but comparable for sensor 3. For all sensors there was a high correlation between the variance across sessions and within session ($r = 0.92$, $p < 0.0001$). There were no significant order effects of session or of trial at any sensor with estimated order effects less than 2% and the estimated maximum possible change no larger than 5% for trial and no larger than 12% for session. These data offer direction for longitudinal treatment studies in which pharyngeal pressures are an outcome measurement by (1) providing a basis for power calculations, (2) estimating the likely values of any confounding order effects, and (3) providing suggestions for more reliable data analysis.

Keywords Swallowing · Pharyngeal · Upper esophageal sphincter · Pressures · Variance · Deglutition · Deglutition disorders

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Pharyngeal manometry is frequently used to document the changes associated with various swallowing techniques in both healthy [1–5] and dysphagic participants [6, 7]. These studies have evaluated immediate maneuver effects by comparing the pressure generated for dry swallows with that generated within the same session for maneuver swallows such as the effortful swallow [1–7], Mendelsohn maneuver [7], supraglottic swallow [1, 6, 7], tongue-hold maneuver [7, 8], and chin-tuck maneuver [7, 8]. Changes in pressure have also been evaluated for differing bolus sizes [4, 9]. For these studies, it is assumed that within-session manometric measures are reliable and repeatable provided various maneuver swallows are counterbalanced and catheter placement remains stable throughout the session.

The reliability of pharyngeal pressure measures obtained over separate sessions is not known. One study has reported acquisition of pharyngeal pressures over two sessions but the researchers normalized the data to account for potential intersession variability [3]. Intersession variability could potentially result from discrepancies in catheter position in the pharynx from placement to placement. A study designed to assess the position of a pharyngeal manometric catheter in the pharynx, when placed in one naris and then the other, found the catheter to sit at midline for both placements in only one of ten participants [10]. Furthermore, this study found that in some cases lateral position of the catheter is dependent on the naris in which the catheter is inserted.

Treatment studies that utilize manometry as an outcome measure to document changes in pharyngeal pressure require assurance of measurement stability to attribute any changes to treatment. No studies have investigated the variation that results from simply removing and replacing a manometric catheter in a participant's pharynx.

The aim of this study was to document the variation in pharyngeal manometric measures across swallows within the same session and across three sessions. These data provide information on the variance introduced into pharyngeal pressure measures as a function of catheter placement, thus allowing for elucidation of treatment effects from methodological error in rehabilitation studies using normal participants, and a reference by which to evaluate the variance in dysphagic participants.

Methods

Participants

Twenty healthy participants (gender equally represented, age range 18–35 years) were recruited for this study. They reported no history of dysphagia or neurological impairment. Ethical approval was obtained from the local institutional review board. Informed consent was obtained prior to commencement of data collection.

Instrumentation

A 100-cm-long round catheter, 2.1 mm in diameter (Model CTS3 + EMG, Gaeltec, Hackensack, NJ), was used for manometric data collection. The catheter houses three solid-state, unidirectional, posteriorly oriented sensors (2 × 5 mm), with 20 mm between sensors 1 and 2 and 30 mm between sensors 2 and 3 (as recommended in [11]). Data were collected using the Kay Elemetrics Digital Swallowing Workstation (Kay Elemetrics, Lincoln Park, NJ). Digitized 12-bit samples were obtained with a sampling frequency of 500 Hz and displayed in a −100 to 500-mmHg display window. The system software generates pressure waveforms as a function of time. The catheter was calibrated at 250 mmHg at room temperature. All measurements were displayed on a computer monitor during data collection and digitally recorded for offline analysis.

Procedures

Participants were seated upright in a dental chair. Each participant completed three sessions, with a wide range of intersession intervals (from 30 min to 7 days) to minimize possible bias introduced by a single fixed interval. For session 1, the lubricated intraluminal catheter was inserted into one naris. Once the tip of the catheter reached the upper pharynx, identified by resistance at the posterior pharyngeal wall, the participant ingested water rapidly through a straw until the catheter was pulled down approximately 35 cm into the proximal esophagus. The catheter was then pulled back out at increments of 10 mm, until high pressure in sensor 1, the uppermost sensor, suggested placement in the high-pressure zone of the cricopharyngeus muscle [12]. Pull-through was then done in 5-mm increments, requiring the participant to sit stationary and dry swallow once after a period of approximately 30 s at each increment. Pull-through was continued until correct catheter placement was confirmed through visualization of the typical "M" wave displayed at sensor 3 during swallowing [12]. Standardization of catheter placement using the M wave has been documented in numerous studies [2, 3, 5, 9]. Presence of the M wave indicates placement of the third sensor at the proximal border of the high-pressure zone of the cricopharyngeus muscle [12]. UES measures made with the manometry sensor in this position have been documented to most closely reflect UES measures made using videofluoroscopy [13]. Sensors were oriented toward the posterior pharyngeal wall [2, 3], as confirmed by continuous monitoring of unidirectional markers on the catheter. The catheter was then secured to the nose with medical tape. Sensor 1 was therefore located in the upper pharynx (approximately even with the base of the tongue), sensor 2 in the midpharynx (approximately even with the laryngeal additus), and sensor 3 in the proximal aspect of the tonically contracted UES [14]. The distance from the third sensor to the nose tip for session 1 was noted. For sessions 2 and 3, the catheter was inserted into the same naris and to the same distance in millimeters from the tip of the nose as was determined optimal in session 1. Participants executed five dry swallows and five 10-ml water bolus swallows in each session. A 10-ml water bolus was chosen to provide a contrast in volume to that of saliva swallows, which can be as much as 2 ml [15]. There is also evidence to suggest that bolus volume may reach up to 10–12 ml during natural drinking situations [16]. Participants were prompted to swallow whenever they felt comfortable, following a 30-s rest period. Participants were seated so they were unable to view the waveforms displayed on the computer monitor.

Data Analysis

Peak or nadir pressures for each sensor were obtained offline. These were defined as the highest (sensors 1 and 2) or lowest (sensor 3) recorded pressure during each swallowing event. Due to the open cavity formation of the pharynx, contact pressure recordings were relative to atmospheric pressure. As one of the two conditions evaluated in this study did not involve ingestion of a bolus and as simultaneous fluoroscopy was not performed, pressure measurements reflected contact pressure rather than intra-bolus pressure. Contact pressure represents convergence of the pharyngeal walls or the functional peristaltic wave of the pharynx [17].

Statistical Analysis

Using the R statistical analysis environment [18], mixed-effects models [19, 20] were used to estimate the order effects and variability of the measures (both between sessions and within a session). Confidence intervals were calculated for both the order effects and the variability to indicate the degree of uncertainty in the estimation of the parameters.

Results

Estimated baseline pressures (in mmHg with 95% confidence intervals) for dry swallows were 95 (77–113), 114

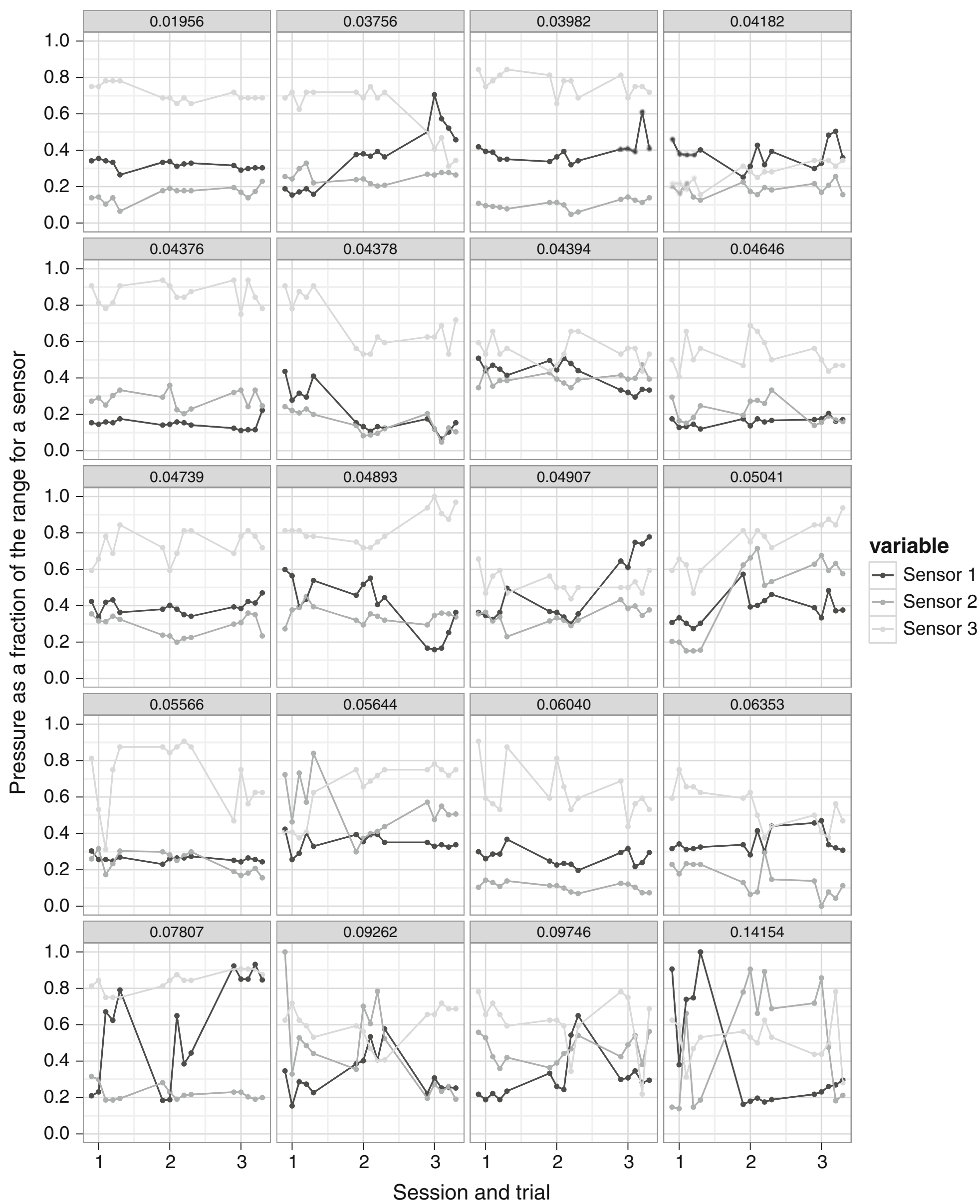

Fig. 1 Individual values for each of the five dry swallow trials at each sensor for sessions 1, 2, and 3, for all 20 participants. Values have been normalized to the range of values at each sensor, to make each value a percentage of the range. Each plot is titled with the individual mean of within-session variance and progresses from least variable to most variable

Table 1 Within- and across-session variability in pharyngeal pressures along with estimated order effects for pharyngeal pressures

Swallow	Sensor	SD across trials (mmHg)	Estimated change per trial (mmHg)	SD across sessions (mmHg)	Estimated change per session (mmHg)
Dry	1	13.4 (12.2–14.8)	0.4 (−1.2 to 2.0)	18.5 (14.5–23.7)	1.0 (−5.2 to 7.2)
Dry	2	17.3 (15.8–18.9)	−0.5 (−1.9 to 0.9)	27.5 (21.7–35.0)	−1.0 (−10.1 to 8.2)
Dry	3	3.0 (2.8–3.3)	−0.1 (−0.5 to 0.2)	3.6 (2.8–4.7)	−0.3 (−1.5 to 1.0)
10-ml	1	16.3 (14.8–17.9)	1.6 (−0.5 to 3.6)	29.4 (23.2–37.2)	1.2 (−8.5 to 10.9)[a]
10-ml	2	17.7 (16.1–19.5)	−1.6 (−3.3 to 0.1)	23.2 (18.1–29.8)	−0.1 (−7.9 to 7.8)
10-ml	3	2.6 (2.4–2.9)	−0.1 (−0.4 to 0.1)[b]	2.8 (2.2–3.7)	−0.1 (−1.1 to 0.8)

Estimated values are shown with 95% confidence intervals in brackets

[a] Greatest change across sessions (12%)

[b] Greatest change across trials (5%)

(93–136), and -13 (-16 to -10) for sensors 1, 2, and 3, respectively, and for 10-ml swallows they were 91 (70–112), 112 (90–133), and -8 (-11 to -5). Figure 1 displays individual values for all 20 participants for each of the five trials plotted across each session for all three sensors for dry swallows only, as dry swallows are representative of both swallow types.

The variability within and across sessions is shown in Table 1 as standard deviations with 95% confidence intervals. Variability is greater across sessions than within sessions for sensors 1 and 2 during both dry and 10-ml swallows. The across-session variance measured at sensor 3 is relatively comparable to that measured within sessions. There were no significant effects of trial or session at any of the sensors for both dry and 10-ml swallows, with the estimated maximum change no larger than 5% for trial and no larger than 12% for session (Table 1).

To examine the relationship between within-session and across-session variability, correlations of the two were completed (Fig. 2). An individual's maximum within-session variance was plotted against the standard deviation for the three sessions for that individual. The two were highly correlated ($r = 0.92$, $p < 0.0001$), with no difference between the correlations for any of the three sensors.

Finally, an analysis was completed to probe the influence of identifying and deleting outliers from the data set. From visual inspection of Fig. 1, sessions with a standard deviation of approximately 20% or greater appeared to be outliers in terms of session variance. Variance at this level is proposed to reflect participant and/or catheter placement issues based on the fact that stable measures could be obtained for the same sensor in another session and/or a different sensor in the same session. The complete data set contains 20 participants, three sessions, three sensors, and two conditions (dry and 10-ml swallows) totaling 360 participant-sensor-condition units. Ten of these units had a within-session standard deviation greater than 20% and were excluded to assess the effect of removing invalid measures, leaving 350 participant-sensor-condition units. Excluding these units reduced the confidence intervals around value estimates; for example, at sensor 1 during 10-ml swallows, the initial 95% confidence interval for the change over sessions of [−8.5 to 10.9] was reduced to [−5.1 to 7.0], a decrease of 40%.

Discussion

This methodological study is the first to have determined the within- and across-session variability of pharyngeal contact pressure recordings during swallowing in normal subjects. This information is important to the emergence of manometry as a viable outcome measure in rehabilitation research. The data presented here represent group variance for pharyngeal and UES pressures during normal swallowing physiology and have relevance in interpreting normative data of pharyngeal pressures provided by previous studies. Documenting this variance is important for studies using healthy participants which investigate changes in pharyngeal function as a result of swallowing maneuvers. These data are also important for formulating power calculations for such studies, and for providing a reference by which to compare dysphagic pharyngeal pressure variation. These data suggest that peak and nadir pressures change less than 2% due to order effects, with the estimated maximal change not likely more than 5% in consecutive trials and not more than 12% in consecutive sessions. The data also suggest that for sensors 1 and 2, variability is greater across sessions than within sessions. Given the increased variability across sessions compared with within a session, these data are important to consider when using manometry for repeated measures to document change as a result of treatments. The within-session variance documented here may also be useful for studies wishing to compare the pressure generation associated with different swallow techniques in the same session. As

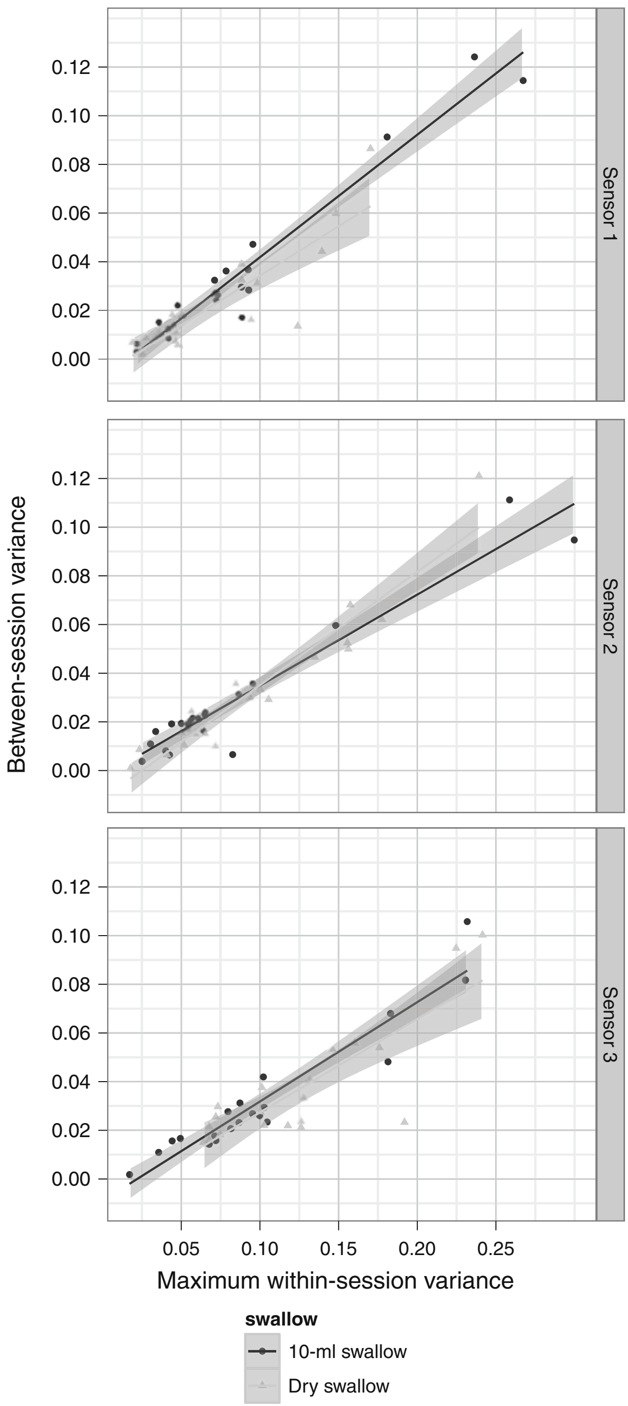

Fig. 2 Scatterplots of the relationship between within- and across-session variability for sensors 1, 2, and 3. Within-session variability reflects the largest individual within-session standard deviation. Across-session variability is the standard deviation of the mean of the three sessions

intrabolus pressure was not measured, the present findings are applicable to contact pressure only.

One consideration in manometric evaluation of pharyngeal pressures is the use of unidirectional versus circumferential sensors. The present study used a 2.1-mm-diameter round catheter housing unidirectional sensors. Evidence of radial asymmetry of pharyngeal and UES pressures suggests that circumferential pressure sensors may be advantageous over unidirectional sensors [21, 22]. There is further evidence suggesting an advantage of an ovoid catheter in negating problems with radial asymmetry [11, 12]; therefore, consideration of the manometry assembly used in this study is warranted. Although circumferential sensors alleviate the issue of radial pressure asymmetry, the increased diameter required to accommodate the sensors may counteract this advantage when looking at pressures in the pharynx. Variation in manometric recordings has been confirmed in relation to an increase in catheter diameter [23], as well as in response to stress [24], which could arguably play a role in the tolerance of a larger catheter. In addition, bolus flow is influenced by catheter diameter [17], suggesting that a smaller-diameter catheter may provide more representative pharyngeal pressures related to swallowing. Previous studies using the same catheter assembly as the present study have shown consistent measures of pharyngeal pressure [25]. Furthermore, the present study highlights that by maintaining sensors in a posterior orientation, pressures within the UES are relatively stable within and across sessions, with no significant order effects and an estimated maximum change of no more than 5% across trials and 12% across sessions for all sensors. There is, however, reasonable variance in pressures measured at all sensors. Comparing the variance seen in the present study with that documented using circumferential sensors would provide insight into how different catheter placements are affected by radial asymmetry in the pharynx.

The variance within and across sessions depicted in Fig. 1 shows a larger variation of values for some sessions than for others, and for some sensors more than others within individuals. In order to provide empirical evidence for dysphagia treatment techniques, outcome measures need to be sensitive to changes in various swallowing parameters. The considerable within- and across-session variability documented in this study suggests that attempts to validate treatments using pharyngeal manometry require either substantial effect sizes and/or participant numbers. If sources of variation can be identified and removed, the application of results from studies incorporating pharyngeal manometry should be improved.

Causes of variation across session may relate to changes in catheter placement. Doeltgen et al. [10] evaluated variation in catheter placement using radiographic still images. In five of ten participants, repeat catheter placement did not change catheter position in the pharynx. If their finding is applied to the present study, with 50% of participants showing varied catheter position in consecutive placements in the pharynx, our data suggest this variance will likely contribute to the increased variability seen in pressures across sessions.

Variability within a participant could be influenced by individual anatomy. Anatomical variations could predispose measurements to the effects of catheter tolerance or radial asymmetry. An interaction of differential catheter placement and anatomical differences may create more variation for one session and/or sensor compared with others, as seen for the participant with mean within-session variance of 0.055 in Fig. 1. Completing a similar investigation using radiographs would further elucidate the influence of catheter placement and anatomical differences on the variation within and across sessions.

The highly predictive relationship between within- and across-session variances suggests that utilizing individual means of pharyngeal pressures for a given session/sensor may not be the optimal first step in analysis of such data. If the goal of the investigation is to reliably document change in swallowing pressures as a result of intervention, then assessing the within-session variability for individuals and excluding high-variability sessions/sensors may result in more definitive results. While excluding data is typically not ideal in group analysis, and not generally possible in the assessment of patients, it may be necessary for the purpose of effective treatment evaluation. So as to avoid bias, exclusion of data must be based on the inference that true values of pharyngeal pressure are not being recorded. Figure 1 shows that while a given sensor may show substantial variability for a given session, other sessions show very reproducible values for the same sensor (see the participant with mean within-session variance of 0.097, sensor 1, Fig. 1). If high variability within sessions reflected true variation inherent in each individual swallow, all sessions should show similar variability for that sensor. The analysis completed on a subset of these data showed that by eliminating units (sensors for a given session and swallow type) that varied more than 20% of the range for that sensor, confidence intervals around values for that sensor were substantially improved. By excluding these highly variable units, it greatly increases the confidence that any change over sessions is small. For treatment studies, large confidence intervals increase the number of participants required to accurately determine the effect of a treatment.

This study did not assess a range of bolus sizes, using only a 10-ml water bolus. Sensor 3, where the lumen surrounding the catheter is much smaller than in the pharynx, is more likely to be influenced by the presence of a bolus. However, within- and across-session variances were comparable across all sensors, for both dry and 10-ml water swallows. Comparing the variations within and across sessions documented in the present study with those of future studies using circumferential sensors and various bolus sizes would be of interest.

Provided that the variation reported in this study is considered in analysis of group treatment effects, pharyngeal pressure recorded using manometry can provide a valuable outcome measure for treatment studies. Because this study did not assess pharyngeal pressures of patients with dysphagia, the values here must be considered to reflect normal swallowing physiology only. A meticulous approach to validation of dysphagia management techniques often involves initially documenting normal physiology [26]. Therefore, although these findings are not generalizable to the patient population per se, the data represent a first step in investigating variability in manometric measures of pharyngeal pressures. These data may serve as a reference for the variability seen in patient groups and a basis for analysis of further studies of healthy participants. These data should also be considered in the interpretation of normative data for pharyngeal pressures. The large within- and across-subject variability documented here suggests that further studies in which this variability is eliminated are needed to gain a clear understanding of treatment effects on pharyngeal pressures before these treatments are applied to patients, where variability may be greater.

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