Short Communication

Two Methods for Quantifying Pharyngeal Residue on Fluoroscopic Swallow Studies: Reliability Assessment

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Abstract

Objective: To evaluate the reliability of two new tools for quantifying pharyngeal residue on fluoroscopic swallow studies.

Methods: The Bolus Clearance Ratio (BCR) is a measure of radiopaque bolus material pre- and post- swallow. The Pharyngeal Clearing Ratio (PRR) compares bolus post-swallow to the two-dimensional representation of the pharynx at rest. Each is made using tools that permit semi-automatic, quantitative calculations. Three experienced clinicians measured each ratio for 50 dysphagic patients during swallows of a 20ml bolus recorded during fluoroscopic evaluations. One clinician repeated the 50 studies four weeks later.

Results: Intra-class correlation coefficients (ICCs) were used to assess reliability across the three raters for both BCR and PRR. The inter-class correlation for BCR was .916 (p<.000, 95% C.I. = .70-.98); for PRR, the ICC was .923 (p<.000, 95%, C.I. = .85-.95). The intra-class correlation for BCR was .922 (p<.000, 95% C.I. = .80-.98); for PRR, .909 (p<.000, 95% C.I. = .76-.95).

Conclusions: Most assessments of residue are subjective and limited in reliability and application. The quantitative measures described here produced excellent inter- and intra-rater reliability. The utility of BCR and PRR for clinical and investigational purposes is discussed, as are their limitations and plans for future development.

INTRODUCTION

Residue as discussed here refers to bolus material that remains in the oro- and hypopharynx following a swallow as a consequence of incomplete or absent pharyngeal clearing. It represents a significant risk factor for aspiration since it can enter the airway once protective laryngeal structures have relaxed. In a review of more than 6,000 patients seen in our center from 1998-2014 representing diverse etiologies for dysphagia, 2297 were observed to aspirate a total of 2933 times during fluoroscopic swallow evaluations. 56% of these events occurred on aspiration related to residue. This percentage is high, but in fact, the actual number may be higher since the fluoroscopy unit is typically turned off within a few seconds of a swallow. An aspiration event that occurs after this time, in particular, one that does not provoke a cough or throat clearing, may be missed. The significance of aspiration related to residue has also been reported frequently by other investigators [1-6].

Most current fluoroscopic assessments of residue are subjective, involving either equal appearing interval rating scales [7-12] or, more recently, visual-analog scales [13], designed to rate residue along a continuum from “none” to “severe.” These strategies have generally demonstrated only fair reliability, and can fail to reveal small, but possibly significant, changes indicative of deterioration or improvement over time or treatment in individual patients. These shortcomings have complicated our ability to assess residue clinically, and to investigate its impact in various dysphagic populations. More objective techniques involve manually outlining bolus material in the vallecula or pyriform sinuses, respectively, and relating this to anatomical indices that have been normalized, for example, to the height of selected cervical vertebrae [14,15]. These strategies are useful in patients who demonstrate residue restricted to one location, but are difficult to apply when residue is distributed across multiple sites in the pharynx. They also require resources not routinely available in clinical settings. In the current technical report, we describe two new techniques that permit semi-automatic quantification of residue on fluoroscopy, and provide reliability data for both.

METHODS

Subjects

Permission to conduct this study was obtained from the institutional review board. Fifty patients who had previously undergone fluoroscopic exams served as subjects. They were selected to represent a variety of dysphagia etiologies, including head and neck cancer (10), stroke (10), neuromuscular disease (10), trauma (10), and spinal cord disease (10). For purposes of this study, all patients were able to swallow a 20 ml liquid bolus during the fluoroscopic exam. Studies were inspected prior to residue analyses in order to ensure a wide range of residue amounts (non-tot substantially) and distributions (one site, multiple sites, extensive dispersion) across patients. Twenty-seven patients were male; twenty-three, female. No subject was under 18 years of age.

Fluoroscopic Studies

All radiographic studies were conducted in accordance with the routine radiographic protocols approved by the institution. Equipment used included a properly collimated OEC Medical Systems 9800 Radiographic/Fluoroscopic unit that provided a 63 kV, 1.2 mA type output for the full field of view mode (12 in input phosphor diameter). The fluoroscopic study routinely involves completion of a standardized protocol of varying bolus volumes and consistencies, as well as tasks specifically designed for individual patients. The residue measures evaluated here can be used with any bolus volume or consistency. For purposes of this study, however, only swallows of a 20ml liquid (EZ-PAQUE Barium Sulfate Suspension, 60%w/v, 41%w/w, E-Z-EM, Inc., Westbury, NY) were considered. All fluoroscopic studies were archived in accordance with institutional practices and could be downloaded to individual workstations for measurement.

Measurement Techniques

The digital tools used for measurement were developed by the author using tools in a software package, “Swallowtail,” designed to extract mechanical measures from fluoroscopic studies (Beldev Medical, LLC, Arlington Heights, IL). Other software programs, including Adobe Photoshop (Adobe Systems Incorporated, San Jose, CA), MatLab (MathWorks, Natick, MA), and Image J (https://imagej.nih.gov/ij/), include similar capabilities, but are not specifically designed to simply and rapidly process fluoroscopic images. The customized algorithms in Swallowtail are based on Watershed segmentation that uses contours in the image intensity gradient to help define regions of related pixels [16]. In essence, the algorithms permit the grouping of pixels with similar characteristics, in this case, that represent radiopaque contrast material. The two measures developed for residue quantification are described as follows:

a) The first measure is referred to as the “Bolus Clearance Ratio” (BCR). It involves relating quantities of bolus material observed in the pharynx at two different points, before and after a swallow, as viewed in lateral view fluoroscopic images. It provides a percentage estimate of oral intake that fails to clear the pharynx during swallow. To make the measure, the user first identifies the point during a swallow immediately prior to the opening of the upper esophageal sphincter (UES). With this frame identified, a line is drawn through contrast material visible in the pharynx (Figure 1A). The program, as noted, then searches for pixels of similar brightness, or intensity, and outlines the relevant area. The area selected automatically can be edited by using right and left mouse clicks to either add to, or delete from, the field of pixels selected (Figure 1B). When satisfied that the relevant area has been outlined (Figure 1C), the user moves through the study to the frame immediately after the swallow, i.e., the first frame after UES closure. Bolus material that remains un-swallowed, and in the pharynx, is outlined using the same process previously described (Figure 1D). Once these two-dimensional representations of bolus material pre- and post-swallow have been completed, the program calculates the ratio of bolus (or residue) post-swallow to bolus material pre-UES opening. In the case illustrated in Figures 1A-1D, the BCR was 5.80 cm²/14.62 cm² = .40.

b) The second quantification measure involves relating the amount of post-swallow residue to an anatomical referent, rather than to a pre-swallow measure of bolus quantity. This strategy may be particularly useful when values are intended to be

Figure 1 A: The denominator of BCR is defined as the bolus material visible in the two-dimensional representation of the oro- and hypopharynx (in cm²) just prior to opening of the UES (or PES, pharyngo-esophageal segment) shown at the arrow. With this frame identified, a line is drawn through bolus material visible in the pharynx.
B: Area selected is outlined by program, and can then be edited to include or delete selected pixels. Small line shown at the arrow indicates user’s edit to include a small portion of bolus material not represented in the automatic selection.
C: Outline of contrast material pre-UES opening is completed and two-dimensional area calculated (14.62 cm²).
D: With denominator determined, the fluoroscopic study is advanced to the frame that best represents residual bolus material in the oro- and hypo-pharynx after, in this case, one swallow, immediately after UES closure. At this point, a line is again drawn through visible bolus material and representative pixels are automatically identified and outlined, as seen here. Once edits are completed, program determines ratio of bolus area post-swallow to bolus area just prior to UES opening, i.e. Bolus Clearance Ratio. For the case shown, the BCR was 5.80 cm²/14.62 cm² = .40.
considered according to age, gender or size variables for which normative data are available [17]. The measure is referred to as the “Pharyngeal Residue Ratio” (PRR). The denominator in the ratio is determined by outlining the lateral view, two-dimensional pharyngeal air space with a 1 ml bolus held in the oral cavity. The positions of pharyngeal structures with this quantity held in the mouth simulate a uniform resting position that can be easily replicated across patients and trials. It is routinely compared to the two-dimensional area of the pharynx maximally constricted during a swallow, a measure referred to as the Pharyngeal Constriction Ratio, which has been previously described [18-21]. For PRR, the pharynx is outlined semi-automatically as shown in Figure 2A, and the area, in cm², is calculated. The numerator in the ratio is the same as that described in a) for the Bolus Clearance Ratio, that is, the area of bolus remaining in the pharynx after the swallow (Figure 2B). Calculation reveals the Pharyngeal Residue Ratio in this case to be 5.80 cm²/11.72 cm² = .50.

Reliability Analyses

Intra-class correlation coefficients (ICC) were used to assess reliability across the three raters for both BCR and PRR (SPSS 24, IBM Corp). A one-way random ICC was performed for the single rater who measured patients’ BCR and PRR scores twice. Mean times to complete both measures for each subject were also determined.

RESULTS

BCRs across the three raters for the 50 patients were averaged; mean values ranged from .02 to .87 (µ=.32; SD=.27). Mean PRRs across all raters for the same patients ranged from .00 to .64 (µ=.26; SD=.19). The inter-class correlation (two-way random, single measures) for BCR was .916 (p<.000, 95% C.I. = .70-.98); for PRR, the ICC was .923 (p<.000, 95%, C.I. = .85-.95). A one-way random ICC was performed for the single rater who measured patients’ BCR and PRR scores twice. This ICC for BCR was .922 (p<.000, 95% C.I. = .80-.98); for PRR, the ICC was .909 (p<.000, 95% C.I. = .76-.95).

Time involved in loading the clips into Swallowtail and making measurements was also tracked. Mean time across raters for calculation of both measures, for each subject, was 3.49 min (range, 2.38 min – 5.08 min).

DISCUSSION

This study investigated the reliability of two new, semi-automatic measures for quantifying residue on fluoroscopic swallow studies. As noted previously, aspiration related to oro- and hypo-pharyngeal residue is frequently observed in patients undergoing fluoroscopic evaluation and, in fact, may be the most typical kind of aspiration experienced by dysphagic patients who are eating orally. Aspiration, in addition to weight loss and malnutrition, is among the most serious consequences of dysphagia. This evidence notwithstanding, our ability to assess and monitor observations of residue on fluoroscopy, which is typically considered a “gold-standard” in evaluating oral-pharyngeal swallow function, has been limited primarily to subjective descriptions. These strategies have generally demonstrated only modest reliability, and are unable to demonstrate small changes associated with time or treatment [7-12]. Other methods attempt to quantify, manually, residue in the vallecula and relate them to the overall size of the vallecula, or to other anatomic markers [13,14]. Though these strategies may demonstrate improved reliability as compared to subjective impressions, they may not be useful when residue is widely dispersed throughout the pharynx, or localized in more than one site. In addition, they require resources that may be unavailable in many clinical settings.

In contrast, the measures described here demonstrated excellent reliability for samples that included residue localized to one or more sites, as well as material that was widely dispersed throughout the pharynx. As indicated by range data reported, samples analyzed also represented wide variability in residue severity, i.e., from none to substantial. Given these capabilities, BCR and PRR appear to represent a valuable addition to our ability to assess patients clinically, and to objectively monitor changes associated with time or treatment. In addition, they permit quantitative assessments of patients’ swallow integrity that are of value to investigators elaborating the effects of age, disease and treatments in various dysphagic populations. Calculation of both measures can also be done rapidly, which is an advantage in busy clinical settings.

Both the BCR and PRR are obviously limited by the two-dimensional representation of structures possible with lateral-view fluoroscopy. They do not reflect actual volumes, or quantities, of bolus material in the airway. In addition, the current version of Swallowtail does not provide for the automatic calculation of multiple bolus measures in one ratio. For example, post-swallow bolus that appears localized to both the pyriform sinuses and vallecula in an individual patient requires two separate measurements which must be summed manually prior to calculation in either the BCR or PRR ratio. Similarly, if the user wishes to calculate a ratio over a number of clearing swallows, as opposed to after the first swallow, only, the multiple measures are not automatically calculated. This limitation is being addressed in an updated version of the program that will permit multiple measures and automatic summing for the final, calculated ratio.

Currently, we are determining both BCR and PRR for

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**Figure 2 A:** The pharynx, represented by a lateral view fluoroscopic image, is shown with a 1ml bolus held in the oral cavity (PAhold). This position represents a pseudo-rest position of the pharynx and serves as the denominator in the calculation of the Pharyngeal Residue Ratio (PRR).

**B:** Bolus remaining in the pharynx post-swallow is outlined and calculated in cm². This value is used as the numerator in calculations of PRR (as well as BCR). The value in this case is 5.80 cm²/11.72 cm² = .50.
several bolus volumes and consistencies in carefully screened normal, non-dysphagic individuals under and over the age of 65 years. These data will be used in comparisons of patients, and populations of patients, to age- and gender-matched normal subjects. Future studies will investigate the utility of the measures in evaluating patients over time or treatment. Comparisons to commonly utilized subjective rating scales, as well as relationships between the two residue measures and aspiration, are also planned. Reliability of the measures will be further assessed in large groups of patients with residue in a specific location, and with smaller or larger amounts of residue, respectively.

CONCLUSION

BCR and PRR represent quantitative methods for assessing residue, a known risk factor in dysphagic patients, in a highly reliable and clinically feasible manner. In our opinion, they represent a valuable addition to clinical and research efforts directed to dysphagia, in particular, to those attempting to characterize the effects of poor pharyngeal clearing on swallow safety and effectiveness.

REFERENCES
