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THE BOSTON RESIDUE AND CLEARANCE SCALE (BRACS): CRITERION VALIDITY TESTING

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ABSTRACT

PURPOSE: Despite evidence that residue is the most significant problem separate from aspiration in dysphagia patients with head and neck cancer (HNC) post-radiation (Agarwal, et al., 2011), there is currently no standardized scale with which to rate residue. The purpose of this project is to assess the Boston Residue and Clearance Scale (BRACS), which has previously undergone initial reliability and validity testing, for criterion validity with HNC patients.

METHODS: BRACS is an 11-point multidimensional scale developed to determine the severity of residue as detected during a Flexible Endoscopic Evaluation of Swallowing (FEES). The BRACS score is uniquely derived from three aspects: 1) amount and location of residue, 2) presence of spontaneous clearing swallows, and 3) efficacy of clearing swallows. Excellent inter-rater and test-retest reliability, internal consistency and concurrent validity were confirmed by preliminary data (Kaneoka, 2013). In order to further validate BRACS by confirming its criterion validity with HNC patients post-radiation, BRACS scores were compared to scores on other previously validated measures of dysphagia severity: 1) degree of penetration/aspiration via scores on the Penetration-Aspiration Scale (PAS; Rosenbek, et al., 1996), 2) quality-of-life impairment via scores on the M. D. Anderson Dysphagia Inventory (MDADI; Chen, et al., 2001), and 3) diet status via scores on the Performance Status Scale for Head and Neck Cancer -

Normalcy of Diet scale (PSSHNC-ND; List, et al., 1990). Nine patients post-radiation at Boston Medical Center who have a history but are currently free of HNC underwent a FEES exam and completed the MDADI and PSSHNC-ND scales. During the FEES, patients were presented with boluses of liquid, applesauce, and cracker as tolerated. Each of the 24 total collected swallows were reviewed and assigned a PAS and BRACS score by an expert clinician. Using Spearman's rank correlation coefficient, all variables were analyzed for significant associations. Discriminant analyses were also conducted between the scores to determine how accurately different combinations of variables were able to predict diet status on the PSSHNC-ND scale.

RESULTS: A significant correlation of -0.32 was found between BRACS and PSSHNC Normalcy of Diet scores when analyzing all bolus consistencies (p=.10). Significant correlations were found between BRACS and PAS scores when analyzing applesauce (0.555) and liquid (0.582) swallows only. With cracker boluses, a significant correlation between BRACS and MDADI scores (-0.556) and between BRACS and PSSHNC-ND (-0.738) were found. Discriminant analyses determined that BRACS combined with the quality-of-life and penetration-aspiration variables had a much higher accuracy rate (95.8%) of predicting the PSSHNC-ND score than MDADI (87.5%), PAS (75.0%), or BRACS (70.8%) alone.

CONCLUSION: BRACS measures a parameter distinct from the commonly used PAS in individuals with HNC. The strong correlation between BRACS scores of cracker boluses and PSSHNC Normalcy of Diet scores indicate that BRACS is most useful for detecting residue severity in more solid consistencies in these patients. Discriminant

analysis revealed that BRACS, like PAS and MDADI, makes a substantial contribution to the accurate prediction of a HNC patient's functional diet outcome. Criterion validity was confirmed by preliminary data with HNC patients post-radiation.

TABLE OF CONTENTS

List of Tables

List of Figures

INTRODUCTION

It is important to establish valid and reliable tools for clinicians and researchers to measure all aspects of dysphagia in order to understand the problem thoroughly and provide the most accurate and effective treatments for individuals with swallowing disorders. There are three major types of swallowing problems experienced by patients with pharyngeal dysphagia: (1) aspiration, which means food or liquid spill into the airway; (2) food or drink spill into the pharynx before the onset of the swallow, which can lead to aspiration; and (3) poor pharyngeal clearance of the food or drink bolus leaving residue in the pharynx, which can also lead to aspiration. The Penetration-Aspiration Scale (PAS; Rosenbek, et al., 1996) is a validated measure of the severity of the problem of penetration and aspiration and has been commonly used by clinicians and researchers around the world. Quantifying temporal measures of "pharyngeal delay" (i.e., measuring the seconds between spillage and swallow onset) can be compared to normative data (Kim, et al., 2005). However, there is currently no validated and reliable measure of residue severity. The purpose of this paper is to provide preliminary data to support criterion validity of the Boston Residue and Clearance Scale (BRACS). We elected to enroll only head and neck cancer (HNC) patients who are post-radiation therapy as residue is the most commonly visualized indicator of dysphagia on instrumental swallow studies for this population (Agarwal, et al., 2011).

Issues associated with pharyngeal dysphagia.

Individuals with dysphagia are at higher risk for a variety of health problems than individuals without dysphagia. The most frequently referenced problem faced by this population is aspiration pneumonia (Rosenbek, et al., 1996). A strong association has been found between swallowing dysfunction and aspiration pneumonia (Martin, et al., 1994; Langmore, et al., 1998). Aspiration before, during, or after the swallow can be caused by poor airway protection, pharyngeal delay of swallow, the presence of pharyngeal residue, or a combination thereof. Aspiration of food or liquid at any time can result in a fatal pneumonia (Martino, et al., 2005). Patients with dysphagia are at an increased risk for developing pneumonia, especially in the presence of other risk factors (e.g., dependence for feeding and oral care, poor oral hygiene, tube feeding, smoking; Langmore, et al., 1998). In the United States, pneumonia is the sixth leading cause of death with an annual cost of $10 billion (Welte, 2012). Critically ill patients hospitalized with pneumonia have mortality rates ranging from 5% to as high as 50% (Bartlett, et al., 2000; Fine, et al., 1997; Pinner, et al., 1996). Individuals with dysphagia have also been shown to have longer average hospital stays than individuals without dysphagia (Odderson, et al., 1995).

In addition to being at an increased risk for aspiration pneumonia, individuals with dysphagia are at high risk for malnutrition and decreased and/or altered food intake (Lin, et al., 2005; Foley, et al., 2009; List, et al., 1990; Martino, et al., 2005). Partially associated with this decrease in functional diet status, these individuals are at higher risk for impaired quality-of-life (Chen, et al., 2009; van der Berg, et al., 2013). It is critical to evaluate the issues faced by persons with dysphagia using reliable and effective tools. Validated measures of pharyngeal dysphagia are necessary for clinicians to make evidence-based decisions regarding assessment and treatment. Currently, validated scales exist to measure penetration/aspiration and pharyngeal delay time, but not to measure residue. Because pharyngeal residue can lead to a dangerous pneumonia or a decrease in function and quality-of-life (Perlman, et al., 1994; Eisenhuber, et al., 2002; Han, et al., 2001), it is important for clinicians to confidently and accurately measure residue severity.

Visualization of pharyngeal residue.

Pharyngeal residue can be the result of one or more physiological abnormalities. Commonly cited deficits are as follows: (a) reduced strength of squeeze by pharyngeal constrictor muscles (Dejaeger, et al., 1997; Teguh, et al., 2008; Eisenhuber, et al., 2002; Batth, et al., 2012), (b) reduced base of tongue retraction toward the posterior pharyngeal wall (Dejaeger, et al., 1997; Ono, et al., 2007), (c) reduced opening of the upper esophageal sphincter (UES; Logemann, et al., 1989), or (d) reduced hyolaryngeal excursion (McCullough, et al., 2012). Although small amounts of pharyngeal residue can be the result of the normal aging process (Perlman, et al., 1994), Kelly, et al. (2008) found that substantial amounts of residue in any population is abnormal and most likely indicates a swallowing problem. Residue is most commonly visualized by clinicians using radiographic or nasoendoscopic instrumental swallowing procedures.

Radiographic studies, called videofluorographic swallow studies (VFSS; Palmer, et al., 1993) are instrumental examinations of swallow function wherein the patient consumes different consistencies of food and liquid coated with barium contrast while the swallows are video-recorded using radiography. VFSS can be administered in the anterior-posterior position but is most commonly administered in the lateral position.

The lateral position includes visualization of the oral stage, pharyngeal stage, and partial esophageal stage of the swallow. Anatomical visualization of the pharynx includes profile views of the base of tongue, vallecular space, epiglottis, posterior pharyngeal wall, airway, arytenoid cartilages, pyriform sinuses, hyoid bone and the UES. VFSS also offers good visualization of the coordination of the peristaltic pharyngeal squeeze with hyolaryngeal excursion, airway protection and UES opening. VFSS was considered the gold standard of swallowing evaluations (Logemann, et al., 1988) prior to the Flexible Endoscopic Evaluation of Swallowing (FEES; Langmore, et al., 1988), and is still used more commonly because many clinicians prefer a more comprehensive view of the entire swallow mechanism (oral, pharyngeal and esophageal swallow stages). During the FEES procedure, a flexible endoscope is passed transnasally into the hypopharynx to record swallows of food and liquids. Visualization in FEES is limited to the pharyngeal stage of the swallow; however, it has been shown to be equally if not more sensitive than VFSS in detecting aspiration (Aviv, et al., 2000; Kelly, et al., 2008) and has been found to be more sensitive than VFSS in detecting amount and location of residue (Kelly, et al., 2006). This increase in sensitivity to residue is most likely related to the axial view of the oropharynx, hypopharynx and larynx, which enables a superior view of the bolus location.

Clinical assessment of pharyngeal residue.

A residue problem can be described in three dimensions: amount, location, and response. The amount of residue left in the throat after the swallow can be related to the increasing risk of laryngeal penetration and aspiration and amount of material that may be aspirated after the swallow. The location of the residue is meaningful because the lower the site of residue (or the closer the residue is to the airway), the greater the risk of aspiration, regardless of the quantity (Farneti, et al., 2008). The location may also provide the clinician with insight into a structural or physiological reason for the dysphagia. Copious amounts of residue on the base of tongue may suggest to the clinician that the tongue base retraction or pharyngeal squeeze is weak, providing input for dysphagia treatment goal areas. Another parameter to note is the spontaneous response to the observed residue (i.e., clearing swallow). This is important for clinicians to describe because the risk of residue aspiration and functional impairment will naturally decrease as the individual is able to clear the residue from the pharynx.

Because there is currently no standardized or validated method for rating residue severity, most clinicians score the residue visualized via VFSS or FEES using perceptual scales that are inconsistent across clinicians. Binary methods (*absent* or *present*) provide clinicians and researchers with the benefit of high levels of reliability between different clinicians (inter-rater reliability) as well as between the same clinician at different points in time (test-retest reliability; Perlman, et al., 1992; Dejaeger, et al., 1997). However, a measure of the existence of pharyngeal residue in the absence of amount or location provides little clinical utility. For example, a small amount of residue does not necessarily predict aspiration and may be attributed to the normal aging process (Ono, et al., 2007). Conversely, a large amount of residue in the valleculae may not be near the airway but can indicate significant functional diet and quality-of-life impairments. Binary perceptual ratings are therefore a weak means of monitoring and documenting patient progress or decline in swallowing function or severity of aspiration risk in terms of pharyngeal residue. Because of the need for more meaningful methods of rating residue, several researchers have attempted to establish more reliable residue scales by providing detailed descriptions of rating categories.

Many scales that have been used in the literature to perceptually quantify or rate solely the amount of the residue have been found to be scored quickly, inexpensively, and with a high level of test-retest reliability. Some scales define the amount category using ordinal scales (e.g., *none, mild, moderate,* or *severe*; Kelly, et al., 2006; Hind, et al., 2001; Kuhlemeier, et al., 1998; 2001). Others attempted to further describe the categories, making subjective ratings dependent on more specific criteria in order to promote inter-rater reliability; for example, ordinal scales were based on the perceived percent of the bolus remaining or perceived amount of the residue in cm^2 (Han, et al., 2001; Ono, et al., 2007). In an attempt to be more objective about the amount of residue, one study reported residue outcomes as a proportion of the amount of the bolus to the size of the cavity as determined by Picture Archiving Communication System (PACS) image measurement tools (Dyer, et al., 2008). Other more objective measures of residue have been calculated using scintigraphy, which is a tool that measures the amount of radiation emitted from residue containing radioisotopes on two-dimensional images (Bogaardt, et al., 2007; Logemann, et al., 2005). The studies examining perceptual ratings of amount all reported poor to moderate inter-rater reliability. The scintigraphy studies generally reported high inter-rater reliability, but had poor diagnostic accuracy in determining swallowing disorders and other timing measurements. This may be attributed to the fact that in scintigraphy, the location of the residue is not addressed and the number of swallows that can be observed is substantially limited. Scintigraphy outcomes have not yet been associated with degree of dysphagia severity, offering little clinical utility (Bogaardt, et al., 2007; Logemann, et al., 2005).

Two studies explored the use of a residue scale in which location, instead of amount, was the sole parameter used to quantify residue severity (*valleculae*, *pyriform sinuses*, or *both*) (Dejaeger, et al., 1997; McCullough et al., 2001). Six studies examined a residue scale that assessed both ordinal amount and location of the residue in order to determine severity (Eisenhuber, et al., 2002; Tohara, et al., 2010; Kelly, et al., 2008; Barquist, et al., 2001; Perlman, et al., 1994; Stoeckli, et al., 2003). All scales describe slightly different procedures for rating the severity of residue amount. Similar to amount-only scales, these amount-and-location studies demonstrated poor to moderate inter-rater reliability, indicating that ratings vary widely between clinicians.

Only two studies to date (O'Neil, et al., 1999; Farneti, et al., 2008) have included a *response to residue* category as a factor in the rating of a residue problem. The 'response' to residue was the presence of dry swallows to clear the residue. Unfortunately, O'Neil, et al.'s (1999) scale did not allow clinicians to take the location of the residue into account, and also did not thoroughly define each level of amount (i.e., amount was quantified using the imprecise terms *mild, moderate,* or *severe*). Farneti, et al.'s (2008) scale is the only established scale to report on all three parameters of amount, location and response to residue. The scale assigned five different pharyngeal locations with higher scores as the proximity to the airway increases. Amount could be assigned *coating, minimum* (less than half the cavity) or *maximum* (full or overflowing cavity), with assigned scores also increasing with perceived severity of the residue problem. Three levels of residue management could be assigned: <2 clearing attempts, 2>5 clearing attempts, and >5 clearing attempts. This scale does not consider if the swallows are spontaneous or cued, which would reflect a more functional description of the clearance problem. It also does not account for locations that are not cavities to be filled, such as the posterior pharyngeal wall or base of tongue. Though Farneti, et al.'s (2008) scale considers all three aspects of the residue, no reliability or validation data has currently been reported.

Of all the reported residue scales, Logemann, et al.'s (2005) is the only scale known to provide evidence of criterion validity (i.e., correlated with an external measure). In this study, the perceived percentage of the bolus remaining in the pharynx after the swallow during VFSS was highly associated with measures found in scintigraphy; however, because the perceived percent residue volume was determined according to only one clinician's judgment on VFSS, the generalizability of results across different clinicians and researchers must be called into question.

Description of the Boston Residue and Clearance Scale (BRACS).

BRACS is an 11-point multidimensional scale of residue, meaning more than one aspect of the problem is being judged (see Appendix A). BRACS is distinct from previously proposed residue scales because it accounts for all aspects of the residue (amount, location, response) and has previously demonstrated excellent test-retest and inter-rater reliability as well as confirmed concurrent validity and internal consistency

(Kaneoka, 2013). BRACS was created for use with FEES rather than VFSS because of the tendency of VFSS to underestimate the amount of residue as well as the inferior anatomical visualization of the location of the bolus in the hypopharynx (Kelly, et al., 2006). The scale was assembled to be ordinal; as BRACS scores increase, the behaviors identified by those scores are assumed to be a more severe sign of dysphagia than the behaviors identified in the lower scores. The scale specifically defines amount categorization (*mild* = covering/filling < 1/3 of the location; *moderate* = covering/filling 1/3 – 2/3 of the location; *severe* = covering/filling > 2/3 of the location). It provides four location zones to score, with specific anatomical landmarks listed, wherein scores increase as proximity to the airway increases. An extra point is added if residue is noted in four or more anatomical regions. An additional point is added if residue is at any time noted to be present inside the vestibule, placing the individual at highest risk for aspiration after the swallow. If residue is observed and the individual demonstrates no spontaneous clearing swallows, an extra point is added to account for the apparent lack of pharyngeal sensation. Cued or spontaneous swallows are then judged for effectiveness (*yes* = 80-100% cleared, *partially* = 20-80% cleared, *no* = 0-20% cleared). One aspect that makes BRACS distinct from other scales is that it is accompanied by thorough scoring instructions for each parameter (see Appendix B). These scoring instructions provide raters with detailed directions on how and when to score each section and is aimed at increasing inter-rater reliability. Though other previous ordinal scales across the literature reported low reliability, BRACS demonstrated excellent reliability during initial testing. During initial reliability and validity testing, BRACS was shown to have higher inter-rater reliability than clinical judgments of residue severity of *none, mild, moderate* or *severe* (Kaneoka, 2013), but currently no attempts have been made to fully establish the criterion validity of BRACS.

Criterion validity of a scale.

A test is said to have criterion-related validity when the test has demonstrated its ability to effectively predict criterion or indicators of a construct or theoretical trait (Cronbach, et al., 1955). BRACS is difficult to validate against an outside criterion because currently, there is no gold standard for rating the severity of the residue problem. Because residue is one of the three principle problems of pharyngeal dysphagia (i.e., premature spillage, aspiration, residue), we have chosen to validate BRACS as a measure of one aspect of dysphagia severity against other validated measures of dysphagia severity. Validated measures of penetration-aspiration (Rosenbek, et al., 1996), swallowing-related quality-of-life (Chen, et al., 2001), and diet status (List, et al., 1999) were the chosen measures of dysphagia severity. The quality-of-life and diet measures used in this study were designed specifically for use with HNC patients. We have chosen to enroll only HNC patients post-radiation in this study because residue is the most common swallowing-related problem in this population, occurring more frequently than aspiration on instrumental swallowing examinations (Agarwal, et al., 2011).

Radiation-induced swallowing difficulties.

Patients with head and neck squamous cell carcinoma have traditionally been treated with surgery alone, surgery followed by radiotherapy (SRT) and more recently with aggressive concomitant chemotherapy and radiation therapy (CRT; Batth, et al., 2012; List, et al., 1999; Nguyen, et al., 2001). While a substantial body of evidence shows that RT or CRT leads to organ preservation, increased survival and increased quality-of-life compared to surgery alone (Agarwal, et al., 2008; Murphy & Gilbert, 2009), any form of radiation to the head and neck region presents a significant treatment challenge due to the tumor's close proximity to several structures vital for swallowing. There is often some degree of chronic swallowing impairment post-radiation even if the treatment successfully eradicates the cancer (Murphy & Gilbert, 2009; List, et al., 1990; Francis, et al., 2009). Radiation is based on the principle of killing cancerous cells, but normal cells are also negatively affected (Johns, et al., 2012). This can cause acute issues such as mucositis, which is the painful inflammation of mucous membranes in the throat, making swallowing a distressing experience. Many patients have a feeding tube placed before radiation treatment to ensure they are able to maintain adequate nutrition during the painful effects of radiation (Murphy & Gilbert, 2009). Discomfort during swallowing often leads patients to rely exclusively on the feeding tube, thus neglecting to use and exercise their swallowing mechanism. For this reason, many patients experience long-term weakness and ineffectiveness of the swallow after the acute effects of radiation have resolved (Rosenthal, et al., 2006). This lack of use of the swallowing mechanism combined with immobility caused by fibrosis contributes to long-term difficulty in swallowing, diet modification, an increased risk of aspiration pneumonia, and a pronounced reduction in swallowing-related quality-of life (Agarwal, et al., 2008; Murphy & Gilbert, 2009).

Months or even years after radiation treatments have concluded, a patient's tissues may continue to produce excess abnormal scar tissue, or fibrosis (Murphy & Gilbert, 2009). When pharyngeal tissues become fibrotic, structures undergo a significant reduction in function and range of motion, further complicating the swallow (Li, et al., 2009; Batth, et al., 2012; Nguyen, et al., 2002; Lin, et al., 2005). Swallowing function in these patients continues to decline during the first 12 months after radiation therapy due to the delayed effects of gradual fibrosis of pharyngeal tissues (Johns, et al., 2012). Commonly cited swallow deficits in patients post-radiation to the head and neck include a reduction in lingual range of motion, a reduction in base of tongue retraction to the posterior pharyngeal wall, a weakening of the pharyngeal constrictor muscles, and a pronounced reduction in laryngeal elevation during the swallow (Nguyen, et al., 2002; Batth, et al., 2012; Teguh, et al., 2008). All of these dysfunctions can lead to increased aspiration risk with the primary reason being excessive pharyngeal residue remaining in the hypopharynx after the swallow.

Residue in head and neck cancer patients post-radiation.

Though not a frequently studied problem, residue is the most commonly visualized swallowing problem in patients after radiation to the head and neck (Agarwal, et al., 2011). Two studies evaluated swallowing in HNC patients post-radiation using VFSS (Agarwal, et al., 2011; Gillespie, et al., 2005). Agarwal, et al. (2011) found that in 47 HNC patients, 48% had residue while only 23% showed aspiration at two months post-radiation. Twelve months post-radiation, 59% showed residue, whereas only 29.5% showed aspiration. As expected, thin barium swallows were more closely associated with aspiration whereas thick barium swallows were more closely associated with residue.

Among the 34 patients who had relatively normal baseline PAS scores before radiation (PAS ≤ 2), only 21% had aspiration after radiation (PAS scores of 6 or 7). None of these patients received a score of 8 to indicate silent aspiration. The majority of these patients (47%) received scores of 1 (no penetration or aspiration). Penetration was observed in 32% of these patients (PAS scores of 2 to 5), meaning that material passed into the laryngeal vestibule and either was ejected or remained in the airway after the swallow. Penetration of material that is not ejected is essentially residue; however, the dichotomous residue scoring system used in this study (*present* or *absent*) provided no information about the location, amount or response to the residual material. Despite the lack of information reported regarding residue, the presence of residue was consistently reported more frequently than the presence of aspiration in irradiated HNC patients.

Gillespie, et al. (2005) conducted a prospective study of 21 subjects with oropharygeal cancer comparing the treatment effects of SRT to the effects of CRT by conducting VFSS evaluations before and at least 12 months after treatment. Outcomes included PAS score, quality of life (M. D. Anderson Dysphagia Inventory, MDADI) (Chen, et al., 2001), and diet (*normal* or *altered*). No significant associations were found between PAS and MDADI scores. With a 5-mL bolus of thin liquids, 2/11 SRT patients aspirated on the post-treatment VFSS exam. Mean PAS scores for this group were 3.1, which means that material enters the airway but is safely ejected. Of the 10 patients who completed chemoradiation therapy, no one aspirated on the post-treatment VFSS exam. Mean PAS scores for this group were 1.4, meaning material either does not enter the airway at all or penetrates transiently. Diet, however, was found to be substantially affected in both SRT and CRT groups. At the time of diagnosis, 95% of subjects consumed a normal diet with no restrictions (one patient consumed soft solids and liquids only). At the time of the study at least twelve months after radiation, only 48% were consuming a normal diet while 33% consumed only soft solids and liquids, 14% consumed only ground solids and purees with liquids, and 5% received only tube feeds, indicating that diet alteration was a significantly larger problem for this population than aspiration.

Research shows that the presence of residue, diet modification and reduced quality of life are consistently found in HNC patients post-RT (Agarwal, et al., 2011; Gillespie, et al., 2005). These studies also suggest that aspiration in this population is not the most common and significant problem. Therefore, residue scores may not be strongly associated with PAS scores, particularly with liquids (Agarwal, et al., 2011). Residue severity in this population may be more closely associated with quality-of-life measures (MDADI) and diet measures (PSSHNC-ND) validated specifically with HNC patients.

Description of other measures serving as dysphagia criterion.

Penetration-Aspiration Scale (PAS). The PAS (Rosenbek, et al., 1996) was developed to describe the depth to which material passes into the airway and whether or not that material is expelled. Rosenbek, et al. (1996) established both intra- and interjudge reliability. *Penetration* is defined as the passage of material into the laryngeal vestibule (airway) but not below the vocal folds. *Aspiration* is defined as the passage of material below the vocal folds. The PAS is an 8-point scale where no penetration/aspiration receives a score of 1 and silent aspiration (material passing below the vocal folds with no effort made to eject) receives a score of 8 (see Appendix C). It assesses the depth of bolus invasion into the airway, response to the invasion, and effectiveness of the response.

It was developed for use in videofluoroscopic swallow studies (VFSS) and has subsequently been validated for use with Flexible Endoscopic Evaluation of Swallowing (FEES; Colodny, 2002). Of note, Rosenbek, et al. (1996) states that while the PAS is a validated measure of penetration and aspiration, "it does not quantify all such events nor was it intended to. Users are left to use other systems to specify the amount and timing of penetration and aspiration events" (p. 97). A scale to help quantify the amount and location of residue remaining in the pharynx would be especially important to determine the risk of penetration and aspiration *after* the swallow.

M. D. Anderson Dysphagia Inventory (MDADI). The importance of quality-of-life (QOL) outcomes in HNC patients after radiation is evidenced by the proliferation of instruments quantifying QOL. Since 1989, there have been more than 300 studies in the head and neck literature that refer specifically to QOL (Schwartz, et al., 2001). Because radiotherapy often results in functional and psychosocial dysfunction regardless of cancer elimination (List, et al., 1999; Batth, et al., 2012), evaluation of HNC treatment outcomes must also include QOL and functional end points. The MDADI (Chen, et al., 2001) (see Appendix D) is a questionnaire that was designed to assess dysphagia's effects on the HNC patient's overall quality-of-life. The MDADI is a 20-question form that assesses a patient's emotional (6 questions), physical (8 questions), functional (5 questions) and global (1 question) symptoms; these four individual components are called "domains."

The MDADI was found to have excellent internal consistency and test-retest reliability. Construct and criterion validity were also confirmed. The MDADI was also shown to identify characteristic differences between cancer of the oropharynx and cancer of the larynx and hypopharynx (Chen, et al., 2001). The five possible responses to each question (*strongly agree, agree, no opinion, disagree*, and *strongly disagree*) are scored on a scale of 1 to 5 with 1 being *strongly agree* and 5 being *strongly disagree*. One item on the emotional subscale and one item on the functional subscale are scored as 5 points for *strongly agree* and 1 point for *strongly disagree* with 100 possible points indicating no impairment in swallowing-related quality-of-life.

Performance Status Scale for Head and Neck Cancer – Normalcy of Diet. The Performance Status Scale for Head and Neck Cancer Patients (PSSHNC) is a functional status measure designed to assess the unique disabilities of head and neck cancer patients in areas of eating and speaking (List, et al., 1990; see Appendix E). The PSSHNC is a clinician-rated assessment tool consisting of three subscales: Understandability of Speech, Normalcy of Diet and Eating in Public. Each section contains a list of hierarchical items arranged to describe a continuum with total incapacity at one end and normal functioning at the other. The clinician rates the patient in all three areas after an informal interview, each score out of a possible 100 points. All three subscales were validated independently. The Normalcy of Diet subscale was found to have the highest levels of interrater reliability (Kappa=0.88), and the scale in its entirety was found to be reliable, specific to head and neck cancer patients, and able to distinguish between different levels of functioning across these patients.

The Normalcy of Diet subscale examines the degree to which a patient is consuming a normal diet. The scale has ten categories with "full diet" at the top of the hierarchy, meriting 100 points, and nonoral or tube feeding at the bottom of the list, meriting 0 points. Foods are listed in between, ranked from most difficult to swallow through easiest to swallow (i.e., peanuts through cold liquids). Ratings are assigned based on the highest-ranking food that the patient discloses they are able to eat. The Functional Oral Intake Scale for Dysphagia (FOIS) (Crary, et al. 2005), which is another measure of diet not specifically designed for HNC patients, was found to be significantly associated with overall dysphagia severity but not aspiration severity. This evidence suggests that it is appropriate to utilize the PSSHNC Normalcy of Diet scale as a measure of dysphagia severity independent of the PAS. As an outcome measure for this study, the PSSHNC Normalcy of Diet scale may provide insight into which discrete dysphagia parameters (e.g., penetration-aspiration, residue, QOL) contribute most highly to the overall picture of the dysphagia, here represented by what the patient is functionally able to eat.

Because there are many dysphagic patients for whom residue is the most severe aspect of the swallowing problem, there is a strong need for a reliable and validated measure of pharyngeal residue severity taking into account amount, location and response to residue. Such a scale would assist clinicians with monitoring functional status and patient response to treatment. It would also provide dysphagia researchers with a meaningful residue outcome to aid in a variety of evaluation and treatment studies. HNC patients post-radiation were chosen for this study because research has shown that residue is commonly the largest factor contributing to dysphagia in these individuals. Taken in comparison to external dysphagia criteria (QOL, penetration-aspiration and diet), it is believed that BRACS can be shown to be a valid and distinct measure of the problem of pharyngeal residue.

METHODOLOGY

Experimental protocol.

Subjects. Approval for this project was obtained from the Boston University Medical Center Institutional Review Board prior to enrollment. Nine adult patients from Boston Medical Center were then identified via medical chart reviews and upcoming clinic visits to Otolaryngology or Speech Pathology and were prospectively consented for enrollment in this study. These patients constituted a convenience sample, meaning they were enrolled consecutively, if they met the following inclusion criteria: currently free of HNC, completed radiation therapy at least 3 months prior to participation, speak English, and able and willing to participate in the protocol. A history of HNC surgery was acceptable so long as it was limited to less than half the oral, laryngeal or pharyngeal structures.

Table 1. Characteristics of nine subjects at the time of enrollment and examination.

Subject Characteristics	
Age mean (SD)	64 (6)
Sex	7 males, 2 females
Surgical resection	7
Chemotherapy	8
Time post-RT, mean (SD) in years; months	3;9 (3;4)
Time post-RT, range in years; months	0;4 – 12;2
Time post-surgery, mean (SD), n=7 in years; months	2;10 (1;4)

Completion of MDADI and PSSHNC Normalcy of Diet scales. The nine patients gave their consent for participation in this study during a routine follow-up dysphagia evaluation with an SLP. At the time of consent, patients were provided with an identification number known only to the graduate student researcher. Subjects completed the MDADI questionnaire independently, and the PSSHNC Normalcy of Diet scale was scored by a clinician during an informal interview. The MDADI and PSSHNC forms were labeled with the subject's identification number by the student researcher at the end of the visit. Confidential patient identifying information was stored in a secure location at Boston Medical Center.

Endoscopic methods. An outpatient FEES exam was conducted for each patient by a speech pathologist as is standard of care at Boston Medical Center. Equipment consisted of a flexible distal chip nasopharyngoscope (PENTAX, VNL-1070STK endoscopes) used with a KayPENTAX FEES system. The nasopharyngoscope was passed trans-nasally into the nasopharynx, oropharynx, and hyopharynx in order to adequately visualize the structures involved in swallowing. Up to two sprays of a topical anesthetic (Lidocaine) and two sprays of a nasal decongestant (Neo-Synephrine) were administered to subjects for comfort, totaling not more than 0.2 mL. Subjects were presented with ½ - 1 teaspoon of liquid, ½ - 1 teaspoon of puree, and a quarter of a saltine cracker as tolerated. Two patients could not tolerate a cracker bolus and one patient could not tolerate a liquid bolus per individual diet restrictions. Boluses were dyed green with one drop of food coloring to aid in visualization on the screen. Following delivery of the boluses administered for the purposes of this protocol, additional PO trials, non-swallowing assessment of structures and movements, and compensatory swallowing strategies were employed as warranted as part of the clinical FEES exam but were not included in the study. The 24 total collected swallows were de-identified by a student researcher prior to being reviewed at a later date by the expert clinician. The expert clinician was blinded to the identity of the subjects being rated. She assigned each swallow a PAS score and a BRACS score. PAS, BRACS, MDADI, and PSSHNC Diet scores were all recorded in a de-identified spreadsheet according to patient ID number, consistency, and individual swallow ID number.

Statistical analysis.

Using the statistical analysis software package *IBM SPSS Statistics* (IBM Corp., 2012), Spearman's rank correlation coefficients were calculated among all variables (PAS, BRACS, MDADI, and PSSHNC Diet). Spearman's rho is a nonparametric measure of statistical dependence between two variables which calculates the correlations of the rank orders of variables, meaning outliers will have less have less effect on the calculation. It was chosen because the variables in this relatively small sample size were not normally distributed. Separate correlations were found for (a) all swallows (n=24), (b) for applesauce boluses only (n=9), (c) for liquid boluses only (n=8), and (d) for cracker boluses only (n=7). Because this was an exploratory study with a small sample size, an alpha of .10 was used. Many researchers support the practice of selecting a less conservative level of significance when sample size is small (Sauley & Bedeian, 1989; Kervin, 1992; Sproull, 2002).

Discriminant analyses were conducted in order to assess which variable, or combination of variables (MDADI, PAS or BRACS), had the highest level of accuracy at predicting diet category as represented by PSSHNC Normalcy of Diet scores. Discriminant statistics offer a powerful technique for examining differences between two or more groups, considering multiple variables simultaneously, and can be useful in predicting or explaining the predefined category to which an individual will belong based on their differences across several variables (Solberg, 1978). Diet status was assumed to reflect a more functional outcome of dysphagia severity and was therefore used here as an independent variable. Diet scores were dichotomized using a median split resulting in 15 cases of scores greater than 90 and 9 cases of scores less than 90. MacCallum, Zhang, Preacher & Rucker (2002) describe justifications for use of a median split in the practice of scientific research. On average, this approach tends to result in lower reliability; however, it is generally deemed appropriate for exploratory or descriptive purposes as in this study. Scores of 90 or 100 on the PSSHNC-ND represented one category, indicating a grossly normal diet with no significant restrictions. The other diet category was described as below the median cutoff of 90, indicating a range of more severe diet impairment or alteration. Group identification accuracy rates were reported as a percentage for all combinations of predictor variables. Klecka (1980) supports the use of discriminant statistics even in the case of non-normal distribution because they can yield useful pattern identification.

Because quality-of-life is highly variable from patient to patient (Schwartz, et al., 2001), it is difficult to predict quality-of-life from any swallowing-related measures. Therefore, we decided to use the MDADI as a predictor variable, as is the case with BRACS and PAS, instead of as an independent variable, as with the PSSHNC-ND. In concert with swallowing-related variables, quality-of-life may be helpful in predicting an individual's diet restrictions.

RESULTS

From 9 subjects, a total of 24 swallows were collected, made up of 9 applesauce, 8 liquid, and 7 cracker boluses. Corresponding BRACS, PAS, MDADI, and PSSHNC Diet raw scores for each subject and swallow number can be visualized in Table 2.

Table 2. Subject raw scores on BRACS, PAS, MDADI, and PSSHNC Normalcy of Diet for all boluses.

ID#	Bolus #	Consistency	BRACS (out of 10)	PAS (out of 8)	MDADI (out of 100)	PSSHNC-ND (out of 100)
1	1	Applesauce	5	1	97	100
	2	Liquid	5	1		
	3	Cracker	1	1		
2	4	Applesauce	0	1	64	90
	5	Liquid	0	1		
	6	Cracker	3	1		
3	7	Applesauce	3	1	49	40
	8	Liquid	3	8		
	XXX	Cracker	XXX	XXX		
4	9	Applesauce	1	1	94	100
	10	Liquid	0	1		
	11	Cracker	5	1		
5	12	Applesauce	6	3	57	20
	13	Liquid	3	8		
	XXX	Cracker	XXX	XXX		
6	14	Applesauce	1	1	82	100
	15	Liquid	0	1		
	16	Cracker	0	1		
7	17	Applesauce	3	1	40	60
	18	Liquid	0	1		
	19	Cracker	5	1		
8	20	Applesauce	5	1	76	90
	21	Liquid	0	1		
	22	Cracker	5	1		
9	23	Applesauce	4	1	63	50
	XXX	Liquid	XXX	XXX		
	24	Cracker	7	1		

Note: XXX indicates that the subject's diet restrictions did not allow the safe presentation of the particular consistency.

Average BRACS scores increased (worsened) as consistency moved from liquid to applesauce to cracker (see Figure 1). The average BRACS score for liquid was 1.4, for applesauce was 3.1 and for cracker was 3.7.

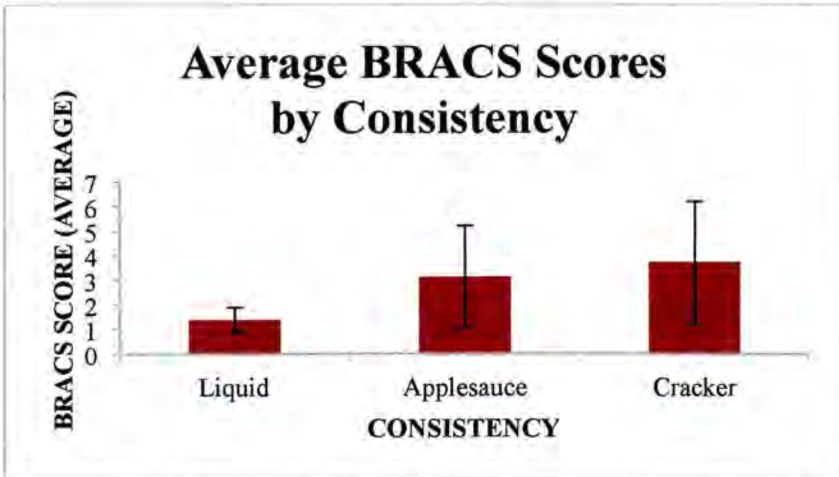

Figure 1. Average BRACS scores displayed by consistency type. Error bars indicate +/- the standard deviation.

Conversely, average PAS scores decreased (improved) as consistency moved from liquid to applesauce to cracker (see Figure 2). The average PAS score for liquid was 2.8, for applesauce was 1.2, and for cracker was 1. Of note, only scores of 1 (no penetration or aspiration) were obtained for applesauce and cracker with the exception of applesauce swallow #12 receiving a score of 3 (penetration above the level of the vocal folds that was not ejected; see Appendix C).

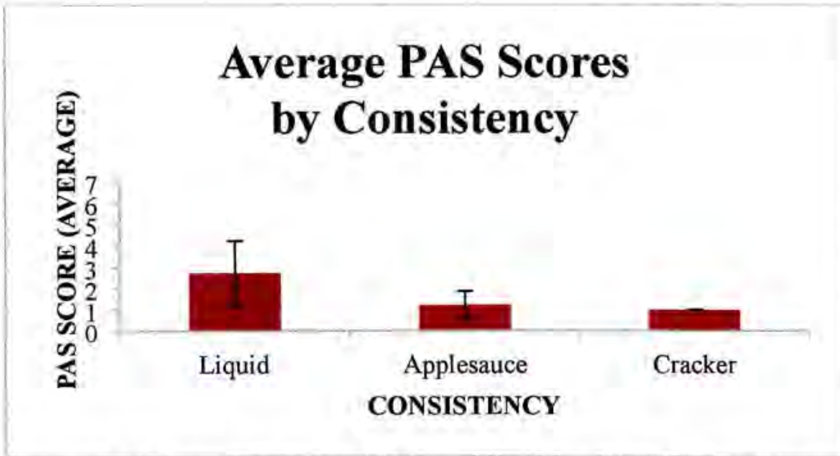

Figure 2. Average PAS scores displayed by consistency type. Error bars calculated based on standard deviation.

Spearman's rank correlation coefficients.

When pooling all consistencies together, a significant negative correlation was found between BRACS and PSSHNC Normalcy of Diet scores (see Table 3). Significant positive correlations were found between BRACS and PAS scores with liquid (see Table 4) and applesauce (see Table 5) boluses. For cracker boluses, correlations could not be found for PAS scores because there was no distribution of scores (all cracker boluses received a PAS score of 1 for no penetration or aspiration). Significant negative correlations for cracker boluses were found between BRACS scores and both MDADI and PSSHNC Diet scores (see Table 6).

Table 3. Spearman's rank correlation coefficients for all bolus consistencies.

	BRACS	PAS	MDADI
PAS	0.199		
MDADI	-0.099	*-0.367*	
PSS	*-0.317*	*-0.582*	*0.889*

n=24; r critical value=.270
Items in italics=statistically significant (p<.10)

Table 4. Spearman's rank correlation coefficients for all liquid boluses.

	BRACS	PAS	MDADI
PAS	*0.582*		
MDADI	0.096	*-0.504*	
PSS	-0.241	*-0.779*	*0.872*

n=8; *r* critical value=.476
Items in italics=statistically significant (p<.10)

Table 5. Spearman's rank correlation coefficients for all applesauce boluses.

	BRACS	PAS	MDADI
PAS	*0.555*		
MDADI	-0.093	-0.274	
PSS	-0.418	*-0.560*	*0.860*

n=9; *r* critical value=.467
Items in italics=statistically significant (p<.10)

Table 6. Spearman's rank correlation coefficients for all cracker boluses.

	BRACS	PAS	MDADI
PAS	XXX		
MDADI	*-0.556*	XXX	
PSS	*-0.738*	XXX	*0.917*

n=7; *r* critical value=.538
Items in italics=statistically significant (p<.10)
Note: PAS correlations could not be determined due to inadequate distribution (only scores of 1 existed).

The strong negative association between BRACS and PSSHNC-ND scores for cracker boluses can be appreciated in Figure 3. It is important to note that the association is not perfectly linear because of the variability of the data for BRACS=5, but a definite trend can be seen as demonstrated by the best-fit line. As BRACS scores worsen (increase) with this consistency, Normalcy of Diet scores also worsen (decrease).

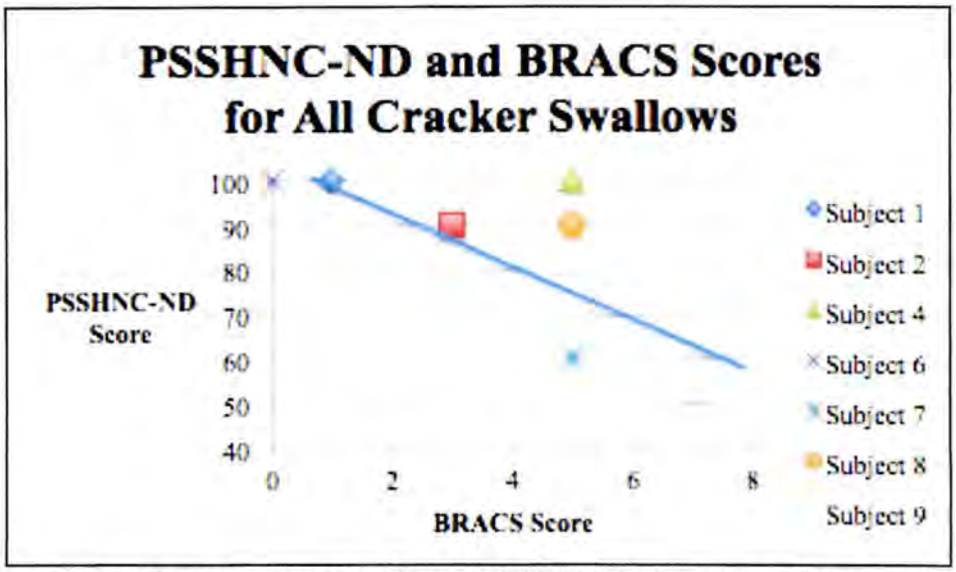

Figure 3. Association between BRACS and PSSHNC-ND scores with cracker boluses.

Discriminant analysis.

Discriminant analysis was used to determine how BRACS, PAS and MDADI contribute to predicting PSSHNC-ND category of above/below the median of 90. This analysis is a pattern recognition technique that does not rely exclusively on normal distribution of scores. Diet score categorization resulted in 15 cases of scores greater than or equal to 90 and 9 cases of scores less than 90. The chi-square test was used to determine the accuracy with which different combinations of the predictor variables (BRACS, PAC, MDADI) were able to predict diet category (above/below the median). The differences between the expected frequencies and the actual frequencies of diet categorization can be appreciated in Tables 7 through 12.

Table 7. Chi-square analysis examining accuracy of BRACS scores in predicting PSSHNC-ND category.

	Predicted Group Membership 0	1	Total
0	8*	1	9
1	6	9*	15

Note: The category of PSSHNC-ND scores below 90 is represented by 0, whereas the category of PSSHNC-ND scores above 90 is represented by 1.
*70.8% (17) of original grouped cases were correctly classified.

Table 8. Chi-square analysis examining accuracy of PAS scores in predicting PSSHNC-ND category.

	Predicted Group Membership 0	1	Total
0	3*	6	9
1	0	15*	15

Note: The category of PSSHNC-ND scores below 90 is represented by 0, whereas the category of PSSHNC-ND scores above 90 is represented by 1.
*75.0% (18) of original grouped cases were correctly classified.

Table 9. Chi-square analysis examining accuracy of combined BRACS and PAS scores in predicting PSSHNC-ND category.

	Predicted Group Membership 0	1	Total
0	5*	4	9
1	5	10*	15

Note: The category of PSSHNC-ND scores below 90 is represented by 0, whereas the category of PSSHNC-ND scores above 90 is represented by 1.
*62.5% (15) of original grouped cases were correctly classified.

Table 10. Chi-square analysis examining accuracy of MDADI scores in predicting PSSHNC-ND category.

	Predicted Group Membership 0	1	Total
0	9*	0	9
1	3	12*	15

Note: The category of PSSHNC-ND scores below 90 is represented by 0, whereas the category of PSSHNC-ND scores above 90 is represented by 1.
*87.5% (21) of original grouped cases were correctly classified.

Table 11. Chi-square analysis examining accuracy of combined MDADI and PAS scores in predicting PSSHNC-ND category.

	Predicted Group Membership 0	1	Total
0	9*	0	9
1	3	12*	15

Note: The category of PSSHNC-ND scores below 90 is represented by 0, whereas the category of PSSHNC-ND scores above 90 is represented by 1.
*87.5% (21) of original grouped cases were correctly classified.

Table 12. Chi-square analysis examining accuracy of combined MDADI and BRACS scores in predicting PSSHNC-ND category.

	Predicted Group Membership 0	1	Total
0	9*	0	9
1	1	14*	15

Note: The category of PSSHNC-ND scores below 90 is represented by 0, whereas the category of PSSHNC-ND scores above 90 is represented by 1.
*95.8% (23) of original grouped cases were correctly classified.

When predicting the PSSHNC Normalcy of Diet score category, total BRACS scores pooling all consistencies had an accuracy rate of 70.8%, PAS was 75.0%, and MDADI was 87.5%. Interestingly, combined BRACS and PAS scores lowered predictive accuracy (62.5%) from when both measures were taken alone. BRACS tended to underestimate diet category while PAS tended to overestimate diet category (see Tables 7 and 8). MDADI and PAS, when taken together, had a predictive accuracy rate of 87.5%, which was not improved from the MDADI predictive accuracy rate alone. MDADI and BRACS together had an accuracy rate of 95.8%, correctly predicting diet category in 23 out of 24 cases. Thus, the best predictor of diet as measured from the PSS was BRACS and MDADI combined (see Table 12).

Table 13. Accuracy rate of different test score variables when predicting diet category.

	PSSHNCD Prediction Accuracy Rate
MDADI	87.5%
BRACS	70.8%
PAS	75.0%
BRACS + PAS	62.5%
MDADI + BRACS	95.8%
MDADI + PAS	87.5%
MDADI + BRACS + PAS	95.8%

Note: Diet category determined using median split discriminant analysis as above/below a score of 90.

DISCUSSION

Criterion validity.

To date, BRACS is the only scale for rating severity of pharyngeal residue that has reported excellent inter-rater reliability, test-retest reliability, and evidence of concurrent validity and internal consistency (Kaneoka, 2013). Criterion validity, which is the measure of validity tested in this project, determines how well one variable or set of variables predicts an outcome based on information from other variables. It is important for all measures of dysphagia to confirm criterion validity to ensure that the measure being validated is related to some external indicator of that function, allowing the measure to be used confidently and effectively. This preliminary study investigated the ability of BRACS to accurately reflect the residue problem in nine irradiated HNC patients by comparing BRACS outcomes to validated measures of quality-of-life (Chen, et al., 2001), penetration-aspiration (Rosenbek, et al., 1996), and diet status (List, et al., 1990). Our prediction was that BRACS would be most closely related to external measures of diet normalcy and quality of life, which was confirmed.

A measure separate from PAS. The PAS is a valid means of determining the degree to which material passes into the airway, but is not useful for determining the severity of pharyngeal residue. While dysphagic HNC patients post-radiation can suffer from problems related to aspiration of material, the most immediate problem for these individuals and the problem that is most commonly visualized by clinicians is the retention of food and liquid in the throat after the swallow (Agarwal, et al., 2011; Gillespie, et al., 2005). The inverse relationship between BRACS and PAS scores in regards to bolus thickness (see Figure 1 and Figure 2) highlights that the two measures are rating very different parameters. As bolus propulsion through the pharyngeal cavities becomes easier (e.g., liquid), there is a smaller chance of pharyngeal retention but a higher chance of penetration and aspiration into the airway. As the bolus increases in thickness and therefore creates more propulsion difficulty (e.g., cracker), there is a smaller chance of penetration and aspiration but a higher chance of pharyngeal retention. No penetration/aspiration was observed in this study with any cracker boluses, but significant BRACS scores were observed with this consistency. These findings suggest that BRACS is a tool that measures a parameter of dysphagia that is unique from what is measured in the PAS scale.

Correlations between BRACS and PAS, QOL, and PSSHNC-ND. Over all 24 collected swallows, BRACS scores demonstrated a significant correlation with diet as measured by the PSSHNC-ND scores. Because the PSSHNC-ND scale reflects what types of food and liquid the individual is currently consuming in everyday life, it is logical that residue scores would be associated with these, especially if pharyngeal residue is so significant that it impacts the individual's comfort, safety, and/or ability to eat specific foods due to poor bolus clearance. No significant correlation was found between BRACS and PSSHNC-ND for liquid or applesauce boluses, which may reflect the fact that these consistencies are generally easier to propel through the pharynx, leaving little or no residue. With cracker boluses, however, a significant correlation was found between the BRACS and the quality-of-life score as measured by the MDADI as well as between the BRACS and the PSSHNC-ND score. This is consistent with the notion that individuals who are unable to fully clear the pharynx of regular solid foods may experience significantly altered diet status and, perhaps as a result, may experience decreased swallowing-related quality-of-life. These results suggest that the BRACS scale is most useful for detecting severity of pharyngeal retention with tougher consistencies requiring mastication and a stronger pharyngeal squeeze.

Combining measures of dysphagia to predict diet. Diet status was chosen to represent global dysphagia in discriminant analysis because it is not intrinsically tied to one cause of pharyngeal dysphagia (i.e., penetration-aspiration, swallow delay, or residue). All three aspects of the dysphagia cause can result in significantly altered diet and quality-of-life. However, because QOL can have such a widely subjective variability (Schwartz, et al., 2001) and diet is a more objective measure of what the individual is functionally eating, it was decided that PSSHNC Normalcy of Diet scores would be the best outcome with which to analyze the other predictor variables. The two swallowing measures, BRACS (70.8%) and PAS (75%), had similar accuracy rates at predicting diet when taken alone. When taken together, BRACS and PAS yielded a lower accuracy rate at predicting diet (62.5%), most likely because the two measures are assessing very different aspects of the swallowing problem (see Figure 1 and Figure 2). This is why it is necessary to pair these swallowing measures with a quality-of-life measure; swallowing ability as visualized in the isolated event of an instrumental examination cannot fully reflect the functional swallowing problem in everyday life, especially when aspiration of residue may be occurring long after the swallow. The QOL measure alone (MDADI) had 87.5% accuracy in predicting diet. When BRACS was added to the MDADI, the prediction accuracy rate increased to 95.8%. When PAS was added to the MDADI, accuracy rates did not improve from 87.5%. When added to the combined BRACS and MDADI scores, the PAS did not improve the 95.8% accuracy rate of diet category prediction. One possible explanation for this is the poor distribution of PAS scores (e.g., only scores of 1 received for cracker boluses and most applesauce boluses). This data shows that scores on MDADI (quality-of-life) and BRACS (residue clearance) together are excellent predictors of what the individual is able to eat functionally as a result of the radiation-induced dysphagia.

Limitations and further studies.

This is a preliminary study to investigate the criterion validity of BRACS. As such, it has several limitations. The sample size was very small with only nine patients and 24 swallows. The alpha level of significance (.10) was also set very high to adjust for the small sample size and poor distribution. The relatively older age of our subjects (mean of 64) complicates the differentiation between normal aging and functional abnormalities (Ono, et al., 2007). All subjects were at least two-years post-radiation except for one (Subject #2), who was enrolled in the study 4 months post-radiation. Because it can take a year or longer for acute swallowing sequelae from RT to resolve (Johns, et al., 2012), this patient's acute radiation symptoms such as mucositis may not have fully resolved, negatively impacting his/her swallowing abilities separate from a fibrosis-related decrease in pharyngeal squeeze and range of motion. The poor distribution in severity across collected swallows resulted in a disproportionate number of swallows that showed no or little penetration/aspiration. Therefore, statistical analysis could not be reliably completed with regard to PAS outcomes. Also, this study only investigated patients with a history of HNC post-RT, and so results cannot be generalized to other dysphagia etiologies in which aspiration is more frequently observed on VFSS or FEES.

Future prospective studies with FEES should include a much larger sample size with heterogeneous patient populations of various medical diagnoses (e.g., neurologic, respiratory, post-intubation). Analysis should be conducted on data to determine if BRACS has a high predictive value for determining regional dysfunction (e.g., base of tongue retraction vs. weak pharyngeal contraction) in order to assist in specific treatment recommendations. Criterion validity testing should compare BRACS scores to other measures of pharyngeal dysphagia (e.g., temporal measures of delay and penetration-aspiration), a non-disorder-specific quality-of-life scale, and a non-disorder-specific diet scale. Because it is more common for settings to use VFSS as a means of instrumental swallow examination than to use FEES, BRACS reliability and validity testing using VFSS should also be explored in future studies in order to increase the clinical relevance and importance of a validated measure of pharyngeal residue.

CONCLUSION

BRACS was confirmed to characterize a separate and important parameter of pharyngeal dysphagia from the commonly used PAS assessment tool. With cracker boluses, highly significant correlations were found between BRACS scores and quality-of-life (MDADI) and diet (PSSHNC-ND) scores, indicating that BRACS is most useful for detecting residue severity in more solid than in less solid consistencies. In concert with quality-of-life (MDADI) scores, BRACS was found to have excellent predictive accuracy in predicting the normalcy of the patient's diet. Preliminary data suggests that criterion validity of BRACS is confirmed in the HNC population. Further validity testing with a larger and more heterogeneous sample is required to fully establish BRACS as a reliable and meaningful measure of severity of pharyngeal residue with FEES.

Appendix A

The Boston Residue and Clearance Scale (BRACS)

The Boston Residue and Clearance Scale (BRACS) V. 9-20-12

	Bolus 1:				Bolus 2:				Bolus 3:				Bolus 4:			
Q1. LOCATION & AMOUNT OF RESIDUE – mark all that apply, and then indicate the worst score attained from any location in the last row.	None Coat	Mild <1/3	Mod 1/3-2/3	Sev. >2/3	None Coat	Mild <1/3	Mod 1/3-2/3	Sev. >2/3	None Coat	Mild <1/3	Mod 1/3-2/3	Sev. >2/3	None Coat	Mild <1/3	Mod 1/3-2/3	Sev. >2/3
Zone 1																
Lateral pharyngeal wall, Posterior pharyngeal wall	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Base of Tongue	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Valleculae, Tip of epiglottis	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Zone 2																
Left Lateral channel & Left Piriform recess	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Right Lateral chanel & Right Piriform recess	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Post-cricoid region	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Zone 3																
Left Arytenoid & Left AE fold	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Right Arytenoid & Right AE fold	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Inter-arytenoid space	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Zone 4																
Laryngeal surface of epiglottis	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Laryngeal surface (side walls) of AE fold & False vocal folds	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Anterior Commissure, True vocal folds, Posterior Commissure	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Circle the Worst Score Indicated Above →	**0**	**1**	**2**	**3**	**0**	**1**	**2**	**3**	**0**	**1**	**2**	**3**	**0**	**1**	**2**	**3**
Q2. WAS THERE RESIDUE IN 4 OR MORE REGIONS?																
No	**0**				**0**				**0**				**0**			
Yes	**1**				**1**				**1**				**1**			
Q3. WAS THERE RESIDUE (more than a speck) IN THE VESTIBULE AT ANY TIME?																
No	**0**				**0**				**0**				**0**			
Yes	**1**				**1**				**1**				**1**			
Q4. DID PATIENT EXECUTE ANY SPONTANEOUS CLEARING SWALLOWS IN RESPONSE TO RESIDUE AT ANY TIME?																
Yes (or N/A since there was never any residue)	**0**				**0**				**0**				**0**			
No	**1**				**1**				**1**				**1**			
Q5. WERE SPONTANEOUS OR CUED SWALLOWS EFFECTIVE AT CLEARING THE RESIDUE BY THE 3RD SWALLOW (AS COMPARED TO AMOUNT PRESENT DURING Q1)?																
Yes – All or almost all cleared (~80-100% cleared)	**0**				**0**				**0**				**0**			
Partially – Noticeable amount cleared (~20-80% cleared)	**2**				**2**				**2**				**2**			
No – None or little cleared (~0-20% cleared)	**4**				**4**				**4**				**4**			
TOTAL SCORE = (Worst Score from Q1 + Scores from Q2-5) →																

Appendix B
BRACS Instructions

1. Score Q1 and Q2 after the patient's initial swallow(s), as soon as you can clearly visualize the larynx at the first natural pause.

   Q1: Rate the amount of residue (none/coating, <1/3, 1/3-2/3, >2/3) covering or filling each location.
   - ❖ If a location cannot be visualized at this time, assume "None/Coat" unless it is later visualized.
   - ❖ If a "location" consists of several areas (i.e. Left Lateral channel & Left Piriform recess), those areas are considered one collective unit when rating how much residue is covering or filling that "location".
   - ❖ When judging residue covering or filling bilateral structures, left and right sides are considered as one aggregate structure (i.e. the Laryngeal surface of AE fold refers to both left and right AE fold surfaces collectively; so if the left surface is completely covered, but the right one has no residue, that location would be scored as moderate since about ½ of the collective location is filled.)

   Q2: Indicate yes if 4 or more of the 12 locations in Q1 have mild, moderate, or severe residue.
2. Score Q3-5 after watching the rest of the clearing swallows for that bolus (if any).

   Q3: Indicate whether there was any residue in the vestibule at any time. A tiny inconsequential bit / speck of residue in the vestibule should not be counted.

   Q4: Indicate if the patient had any spontaneous swallows at any time during the trial.

   Q5: Give your general impression on how effective the spontaneous and/or cued swallows were. This impression should be based on a "reasonable" number of swallows (about 3).
   - ❖ Yes, effective means that by the 3rd swallow, the residue is either completely cleared, or there is very little left as compared to the amount of residue present when scoring Q1.
   - ❖ Partly effective means that it is obvious that some of the residue has been cleared as compared to the amount of residue present when scoring Q1, but the swallow is not efficient enough to clear all, or almost all, of the residue by the 3rd swallow.
   - ❖ No, not effective means that, as compared to the amount of residue present when scoring Q1, very little or none of it has been cleared by the 3rd swallow. The swallow just is not efficient enough to eliminate whatever bolus has been presented within a reasonable number of attempts.

Appendix C

Penetration-Aspiration Scale (PAS) (Rosenbek, et al., 1996)

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1. Material does not enter the airway
2. Material enters the airway, remains above the vocal folds, and is ejected from the airway
3. Material enters the airway, remains above the vocal folds, and is not ejected from the airway
4. Material enters the airway, contacts the vocal folds, and is ejected from the airway
5. Material enters the airway, contacts the vocal folds, and is not ejected from the airway
6. Material enters the airway, passes below the vocal folds and is ejected into the larynx or out of the airway
7. Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort
8. Material enters the airway, passes below the vocal folds, and no effort is made to eject

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Appendix D

M. D. Anderson Dysphagia Inventory (MDADI) (Chen, et al., 2001)

This questionnaire asks for your views about your swallowing ability. This information will help us understand how you feel about swallowing.

The following statements have been made by people who have problems with their swallowing. Some of the statements may apply to you.

Please read each statement and circle the response which best reflects your experience in the past week.

My swallowing ability limits my day-to-day activities.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

E2. I am embarrassed by my eating habits.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

F1. People have difficulty cooking for me.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P2. Swallowing is more difficult at the end of the day.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

*E7. I do not feel self-conscious when I eat.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

E4. I am upset by my swallowing problem.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P6. Swallowing takes great effort.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

E5. I do not go out because of my swallowing problem.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

F5. My swallowing difficulty has caused me to lose income.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P7. It takes me longer to eat because of my swallowing problem.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P3. People ask me, "Why can't you eat that?"

StronglyAgree Agree No Opinion Disagree StronglyDisagree

E3. Other people are irritated by my eating problem.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P8. I cough when I try to drink liquids.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

F3. My swallowing problems limit my social and personal life.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

*F2. I feel free to go out to eat with my friends, neighbors, and relatives.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P5. I limit my food intake because of my swallowing difficulty.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P1. I cannot maintain my weight because of my swallowing problem.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

E6. I have low self-esteem because of my swallowing problem.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

P4. I feel that I am swallowing a huge amount of food.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

F4. I feel excluded because of my eating habits.

StronglyAgree Agree No Opinion Disagree StronglyDisagree

Appendix E

The Performance Status Scale for Head and Neck Cancer (List, et al., 1990)

Eating in public
- 100 No restriction of place, food, or companion (eats out at any opportunity)
- 75 No restriction of place, but restricts diet when in public (eats anywhere, but may limit intake to less "messy" foods, *e.g.*, liquids)
- 50 Eats only in presence of selected persons in selected places
- 25 Eats only at home in presence of selected persons
- 0 Always eats alone

Understandability of speech
- 100 Always understandable
- 75 Understandable most of the time; occasional repetition necessary
- 50 Usually understandable; face-to-face contact necessary
- 25 Difficult to understand
- 0 Never understandable; may use written communication

Normalcy of diet
- 100 Full diet (no restrictions)
- 90 Peanuts
- 80 All meat
- 70 Carrots, celery
- 60 Dry bread and crackers
- 50 Soft, chewable foods (*e.g.*, macaroni, canned/soft fruits, cooked vegetables, fish, hamburger, small pieces of meat)
- 40 Soft foods requiring no chewing (*e.g.*, mashed potatoes, apple sauce, pudding)
- 30 Pureed foods (in blender)
- 20 Warm liquids
- 10 Cold liquids
- 0 Nonoral feeding (tube fed)

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