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Advancing Dysphagia Screening: A Comparison of Patient-Reported Outcome Measures and Bolus-Driven Screenings in Aspiration Prediction

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ADVANCING DYSPHAGIA SCREENING: A COMPARISON OF PATIENT-REPORTED OUTCOME MEASURES AND BOLUS-DRIVEN SCREENINGS IN ASPIRATION PREDICTION

THESIS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Science in Communication Sciences and Disorders in the College of Health Sciences
at the University of Kentucky

By

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ABSTRACT OF THESIS

ADVANCING DYSPHAGIA SCREENING: A COMPARISON OF PATIENT-REPORTED OUTCOME MEASURES AND BOLUS-DRIVEN SCREENINGS IN ASPIRATION PREDICTION

It is known that dysphagia impacts an individual's health and quality of life. Due to this, early identification of dysphagia is crucial. There are many different dysphagia screening tools with no consensus. This study aimed to compare the two most frequently used dysphagia screenings, a patient-reported outcome measure (PROM), the EAT-10, and bolus-driven swallow screening, the Yale Swallow Protocol, to determine if one tool is superior in aspiration prediction on a videofluoroscopic swallow study (VFSS). This study also aimed to discover the best cutoff score on the EAT-10 for aspiration prediction. A total of 66 participants were recruited after physician referral for a VFSS at the University of Kentucky Voice and Swallow Clinic. Each participant completed the EAT-10, Yale Swallow Protocol, and a VFSS. The original EAT-10 cutoff score of 3 was found to have a sensitivity of 100% and specificity of 12.07%. Due to the poor specificity, this study discovered that the cutoff value of 19 balanced the sensitivity to 75% and specificity to 58.62%. The Yale Swallow Protocol was found to have a sensitivity of 87.5% and specificity of 62.07% which indicates that the bolus-driven swallow screening, the Yale Swallow Protocol, is superior in aspiration prediction.

KEYWORDS: dysphagia, screening, EAT-10, Yale Swallow Protocol, aspiration

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DEDICATION

To Grandma – You are my angel.

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CHAPTER 1. INTRODUCTION

Swallowing is a daily function that is crucial to survival. Difficulty with the complex function of moving any food or liquid from the mouth to the stomach is termed dysphagia and should be taken with serious concern (Logemann, 1998). Dysphagia prevalence is difficult to determine; however, analysis of the 2012 National Health Interview Survey concluded dysphagia prevalence as occurring with 1 in 25 adults (Bhattacharyya, 2014). There are many causes for dysphagia, strokes being the leading cause with 42% to 67% of patients experiencing dysphagia within the first 3 days (Katzan et al., 2003). Other causes for dysphagia in descending prevalence include but are not limited to, neurological disease (Parkinson's, Alzheimer's, etc.), head and neck cancer, advancing age, head and neck injury, prescription medication or drugs, congestive heart failure, arthritic changes in the neck, chronic obstructive pulmonary disease, or something else. These are comorbid diagnoses that put an individual at risk for developing dysphagia which increases the risk of hospitalization, mortality, and more. (Bhattacharyya).

Dysphagia is profoundly important due to the possibility of mild to severe social, psychological, physical, economical, and survival consequences that may impact an individual's quality of life. Regarding social and psychological consequences, 41% of individuals with dysphagia reported feeling anxious during mealtimes and 35% avoided eating around others altogether. This concludes that a diminished quality of life is associated with dysphagia (Ekberg et al., 2002). The physical consequences of dysphagia are talked about more often and include dehydration, malnutrition, and aspiration pneumonia. These physical consequences may lead to economical and survival

consequences such as prolonged hospitalization, expensive medical care, and occasionally death (Altman, 2011 & Langmore et al., 1998). Altogether, the social, psychological, physical, economical, and survival consequences of dysphagia not only impact the individual's quality of life but can also impact their caregivers and the healthcare system (Dziewas et al., 2017).

Due to the significant impact on individuals' health and quality of life, early identification of dysphagia is crucial for all comorbidities, so that dysphagia does not go unrecognized. The identification of dysphagia occurs along a continuum beginning with a screening then possibly advancing to a clinical swallow evaluation and all the way to an instrumental examination. An instrumental examination is the gold standard swallow assessment since it is the most accurate examination available to determine if a patient is aspirating (Palmer et al., 1993). Additionally, an instrumental examination is crucial for accurately planning swallow therapy (Logemann, 1997). However, instrumental examinations are invasive exams that require specialized expensive equipment and trained staff that is not available to everyone (Linden et al., 1993).

Due to the expensive and invasive nature of an instrumental swallow examination, a screening must first be completed to identify individuals who are at risk for dysphagia and need further evaluation. The swallow screening plays a crucial role in the continuum as a quick and affordable tool to decrease over-referral and over-utilization of resources. The American Speech-Language-Hearing Association (ASHA, 2004) defines a screening as, "a pass/fail procedure to identify individuals who require a comprehensive assessment of swallowing function or a referral for other professional and/or medical services."

There are two widely used types of dysphagia screenings. One being a patient reported outcome measure (PROM) and the other a bolus-driven swallow screening. To begin with PROMs, the Food and Drug Administration (FDA) and National Quality Forum (NQF) defines it as, "a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else." There are many different tools available for dysphagia screenings; however, the Eating Assessment Tool (EAT-10) is the most common tool utilized (Carnaby et al., 2024). There are barriers to using any PROM as a screening tool. The patient's perception of their dysphagia and the correlation to the actual swallow physiology has not been well-defined due to conflicting research results (Rogus-Pulia et al., 2014).

Due to this issue and the fact that the swallow is not observed with PROMs, some professionals are deciding to use a bolus-driven swallow screening in addition or in replacement. This screening is more objective due to it including administration of one or more boluses. These boluses can vary in volume depending on the type of swallow screening being completed but most often include a water swallow test (Daniels et al., 2016; DePippo et al., 1992; Edmiaston et al., 2014; Leder & Suiter, 2014; Martino et al., 2009). The most common bolus-driven swallow screening used is the Yale Swallow Protocol (Carnaby et al., 2024). There are also barriers with bolus-driven swallow screenings including reports of patients unable to swallow continuously and the inability to identify silent aspiration (Garand et al., 2021). Issues with both PROMs and bolus-driven swallow screenings lead to a lack of consensus on which one clinicians should use.

Statement of the Problem

It is neither practical nor feasible to perform a complete evaluation on every patient at risk for dysphagia. Therefore, a dysphagia screening is the crucial first step to identifying individuals with dysphagia who need further evaluation (Suiter, 2018). Early identification is important to decrease the chance of known negative impacts on an individual's health quality of life (Suiter et al., 2020). An accurate dysphagia screening correlates to shorter hospital stays, reduced costs, and a decreased chance of aspiration pneumonia (Hinchey et al., 2005; Odderson et al., 1995; Titsworth et al., 2013).

If you look at the current literature, there are thousands of ways to screen an individual for dysphagia and no standardization. There have been attempts to create formal dysphagia screening guidelines including The Joint Commission implementing a requirement in 2006 for any patients with ischemic or hemorrhagic strokes. These individuals were required to undergo a dysphagia screening before any nutrition or medication by mouth. However, in 2010, this requirement was eliminated due to lack of agreement of what constitutes a dysphagia screening tool and lack of standardization. Now each facility must independently decide which dysphagia screening tool to implement (Maharay et al., 2018).

Coming to an agreement on what constitutes a dysphagia screening tool and creating standardization may prevent half of post stroke aspiration pneumonias, accounting for prevention of 40,000 aspiration pneumonias and saving around 8,300 lives (Hinchey et al., 2005). With screening protocols ranging from PROMs and bolus-driven swallow screenings, further investigation must be completed to determine how each

screening correlates to the actual physiology. It is crucial to unveil the optimum dysphagia screening to decrease over-referral and over-utilization of resources.

Purpose of the Study

Although it is known that dysphagia can have a profound impact on an individual's health and quality of life, less is known on the correlation between PROMs and bolus-driven tools as screenings to identify dysphagia in a timely manner and decrease the known impact. The PROM, the EAT-10, and the bolus-driven swallow screening, the Yale Swallow Protocol, are the two most frequently used screening tools (Carnaby et al., 2024). There is a lot of literature currently available regarding the correlation of the EAT-10 to aspiration prediction and the Yale Swallow Protocol to aspiration prediction. There is less research comparing PROMs and bolus-driven swallow screenings to determine which is superior in aspiration prediction. Both screening tools have advantages and disadvantages, and it remains unclear which tool is superior. This study aims to compare a PROM, the EAT-10, and a bolus-driven swallow screening, the Yale Swallow Protocol, to determine if one is superior in the identification of aspiration risk. This study also aims to determine the superior cutoff score for the EAT-10 in aspiration prediction.

Chapter Summary

Chapter one sought to establish the profound impact dysphagia has on an individual's quality of life and the importance of completing a screening. Chapter 2 will encompass a review of the literature currently available on the importance of screening and the utilization of popular dysphagia screening tools.

CHAPTER 2. LITERATURE REVIEW

This literature review intends to outline the current literature available on the importance of dysphagia, how screening fits into the continuum, patient-reported outcome measures (PROMs), and bolus driven swallow screening.

Importance of Dysphagia

Dysphagia can have a profound impact on an individual's health and quality of life. This impact can be divided into the categories of economic, survival, physical, social and psychological. Beginning with the economic and survival burdens associated with dysphagia, there is a higher cost with dysphagia cases when compared to non-cases which accounts for an additional $4.3 to $7.1 billion spent annually in the hospital setting (Patel et al., 2018). The reason for this higher cost is the longer hospital stays, expensive examinations, and costly treatment (Patel et al.). More specifically, dysphagia adds 43% longer hospital stays (Patel et al.).

The economic and survival burdens correlate to the physical consequences associated with dysphagia. These consequences are discussed more often including risk of dehydration, malnutrition, and aspiration pneumonia. Although these consequences are severe and may increase mortality rates, it is important to note that these are not the only factors to consider in evaluating and treating an individual with dysphagia. It has been discovered that over 50% of patients with dysphagia reported eating less and 44% reported weight loss placing the patients at risk for dehydration and malnutrition (Ekberg et al., 2002). Dehydration and malnutrition should be seen with serious concern due to the finding that after a year with a dysphagia diagnosis, geriatric patients that presented with dehydration and malnutrition had a mortality rate of 65.8% (Carrion et al., 2015).

Malnutrition can also lead to someone feeling lethargic resulting in decreased work, socialization, mobility, and ability to perform hygiene (Ekberg et al.).

Aspiration pneumonia is typically one of the upmost concerns for an individual with dysphagia. Dysphagia and presence of aspiration places an individual at risk of developing aspiration pneumonia, but they are not sufficient to cause aspiration pneumonia alone. Risk factors for developing aspiration pneumonia include but are not limited to more debilitated patients, individuals aspirating food instead of liquid, tube fed patients, esophageal dysmotility, and dependence with oral care (Langmore et al., 1998). Nonetheless, aspiration pneumonia is a huge problem that has severe consequences itself, including hospital admissions, expensive treatment, and sometimes death (Langmore et al.).

The social and psychological consequences associated with dysphagia are not talked about often, but also severely impact an individual's quality of life just as much as the other consequences. Eating is often a social experience that is pleasurable and may even be the focus of many events individuals consistently attend (Ekberg et al., 2002). Dysphagia may take away this pleasurable everyday experience and instead cause social isolation leading to feeling excluded, anxious, decreased dignity, and decreased self-esteem (Ekberg et al.). Current research has proven that 36% of patients reported avoiding eating around other individuals and 41% of patients reported anxiety or panic throughout their mealtimes (Ekberg et al.).

Altogether, the social, psychological, physical, survival, and economic burdens associated with dysphagia combine to profoundly impact individuals' health and quality of life and should be seen with importance.

How Screening Fits into the Continuum

As mentioned previously the identification of dysphagia occurs along a continuum. Screening is the first step of the continuum. The American Speech-Language-Hearing Association (ASHA, 2004) defines dysphagia screening as, "a pass/fail procedure to identify individuals who require a comprehensive assessment of swallowing function or a referral for other professional and/or medical services." It is important to outline how a screening differs from the evaluation portion of the continuum (Suiter, 2018). There are three important features to determine this differentiation. The first being that a screening is generally given to a large number of individuals who are at risk for dysphagia such as individuals diagnosed with strokes, head and neck cancer, etc. (Suiter). The next feature is that a screening is a pass/fail procedure while an evaluation is not (Suiter). Finally, the screenings are administered by a variety of different professionals quickly and inexpensively (Suiter).

There are three main purposes of screening tools. The screening tool should determine at risk individuals, determine the requirement of a more formal evaluation, and determine when the patient can safely return to an oral diet (Suiter et al., 2020). Also, the screening tool would be accurate, expressed with the terms true negative, true positive, false positive, and false negative (Suiter, 2018). True negative means the individual passed the screening tool and does not have dysphagia or aspiration events. True positive means the individual failed the screening tool and has dysphagia or aspiration events. False positive means the individual failed the screening tool but does not have dysphagia or aspiration events. Finally, false negative means the individual passed the screening tool but has dysphagia or aspiration events (Suiter). These terms correlate to the

screening tool's sensitivity and specificity. Sensitivity correlates to the true positives. Specificity represents the ability for the screening tool to identify individuals without dysphagia or aspiration events. High sensitivity and high specificity are ideal for all screening tools (Suiter). The two types of screening tools to identify dysphagia and aspiration risk are patient-reported outcome measures and bolus-driven swallow screenings.

Patient Reported Outcome Measures

Patient Reported Outcomes Measures (PROMs) are beginning to be used more frequently as an essential tool to incorporate the patient's perception (Churruca et al., 2021). They provide the clinician with an evaluation of the patient's quality of life and treatment progress in the form of a questionnaire (Moloney et al., 2022). There are many benefits to using PROMs in clinical practice including an increase in patient empowerment since they can feel more a part of their evaluation, diagnostic, treatment, decision-making, and monitoring process (Carfora et al.).

Patient Reported Outcome Measures (PROMs) are used across many different professions. An example of this is the Voice Handicap Index developed by Barbara H. Jacobson in 1997. This tool is a psychometrically validated tool that is used to measure the effects of someone's voice disorder. The Voice Handicap Index is intended to be used as a tool to evaluate the patient's perception of the impact of their voice on their daily living. Also, this tool is intended to be used as an evaluation to determine the effectiveness of the voice treatment provided (Jacobson et al., 1997).

Of interest, PROMs additionally are used in the dysphagia population. If you look at the current literature, there are copious types of PROMs used as current dysphagia

screening tools including The Eating Assessment Tool (Belafsky et al., 2008), the Munich Dysphagia Test–Parkinson's Disease (Simons et al., 2014), the Dysphagia Handicap Index (Silbergleit et al., 2012), and the Sydney Swallow Questionnaire (Wallace et al., 2000). However, a recent survey has discovered that the EAT-10 is the most used dysphagia screening tool utilized to date (Carnaby et al., 2024).

Issues with Patient Reported Outcome Measures

There are barriers to patient reported outcome measures that professionals must consider. Research has identified technical, social, cultural, legal, and logistical barriers to use of PROMs (Nelson et al., 2015). Since PROMs are questionnaire-based screenings, there is risk for under identification of aspiration or dysphagia because patients frequently underreport their symptoms (Ding & Logemann, 2008). This is commonly found with several reports of disconnects between patient perception and physiologic findings (Rogus-Pulia et al., 2014). Patient's perception of their dysphagia and the correlation to the actual swallow physiology has not been well-defined due to conflicting research results (Rogus-Pulia et al.). Specifically, with the head and neck cancer population, sensory deficits decrease the patient's ability to be aware of their symptoms (Rogus-Pulia et al.). Similarly, recent literature has found that older individuals aged 65 and up tend to report inaccurate symptoms (Namasivayan-MacDonald et al., 2019). Other barriers to consider include the patient's capacity to answer, question relevance and validity, inconsistencies on how the PROMs are used in clinical practice, and whether the patient understands the purpose of the PROM (Carfora et al., 2022). Still, it has been found that patient reports of impairment are driving the referral for further assessments rather than etiology and comorbidities (Arrese et al., 2017).

EAT-10

The EAT-10 was developed by Peter C. Belafsky in 2008 due to a clinical need for a quick (estimated time being 2 minutes) and easy (worded to make it simple to read) dysphagia instrument appropriate for any population. The EAT-10 is a self-administered questionnaire that establishes the patient's perspective. The individual answers ten questions by rating each on a scale of 0 to 4. The initial normative data discovered an overall score of 3 or greater to be abnormal. Belafsky originally discovered that the patient's score would be useful in documenting dysphagia severity and monitoring treatment responses (Belafsky et al., 2008).

Since development of the EAT-10, the tool has been translated into many different languages such as Chinese (Wang et al., 2015), Spanish (Burgos et al., 2012), Swedish (Möller et al., 2016), Italian (Schindler et al., 2013), Brazilian Portuguese (Gonçalves et al., 2013), European Portuguese (Nogueira et al., 2015), Hebrew (Shapira-Galitz et al., 2019), Greek (Printza et al., 2018), and French (Lechien et al., 2019). Additionally, the tool is being used to predict aspiration across all patient populations with no consensus on the foremost cutoff value used (Zhang et al., 2022). For example, when determining aspiration risk for patients with unilateral vocal fold paralysis, a cutoff value of 9 was found to have a sensitivity of 77.8% and specificity of 73.1 (Zuniga et al., 2018). Similarly, a cutoff value of 9 accurately predicted aspiration in individuals with COPD. With this cut-off value, 77% of individuals aspirated (Regan et al., 2017).

When looking more specifically at use of the EAT-10 with individuals with neurological diseases, there are mixed findings. With the stroke population, correlation between the EAT-10 and physiology were moderate (Bartlett et al., 2022). Then, a cutoff

value of 8 had a sensitivity of 86% and a specificity of 72% for the amyotrophic lateral sclerosis (ALS) population (Plowman et al., 2017). When looking at swallow safety and efficiency in the ALS population, the accuracy found was 67% when using the original cutoff score of 3 (Donohue et al., 2022). With the Parkinson's population, a cutoff value of 6 was found to predict penetration and aspiration but only had a sensitivity of 58% (Schlickewei et al., 2021).

In contrast, when comparing all etiologies, associations between aspiration and penetration to the EAT-10 score were found with the head and neck population but not the Parkinson's or stroke population (Bartlett et al., 2022). Conclusions that patient reports alone are not reliable with the head and neck cancer population were made, given correlations only being found with the pretreatment through 1-year post treatment group (Arrese et al., 2017). In the population of individuals with an overall diagnosis of oropharyngeal dysphagia, a cutoff score of 15 was discovered to identify individuals at risk of aspiration. This cutoff score was associated with a sensitivity of 71% (Cheney et al., 2015). On the other hand, there is literature stating that reducing the cutoff value from 3 to 2 correlates to an increased sensitivity by 5% and less false negatives (Rofes et al., 2014). Of important note, aspiration is not the only factor to screen for. A cutoff score of 19 points identified pharyngeal residue in the head and neck population. (Florie et al., 2021).

Although there are a variety of cutoff values being utilized, a systematic review concluded that a cutoff score of 2 and 3 demonstrated the premier performance to screen individuals (Zhang et al., 2022). There is an overall consensus within the literature that a

higher overall EAT-10 score correlates to a higher overall chance of individuals penetrating or aspirating (Cheney & Rofes & Plowman).

Bolus-Driven Swallow Screening

Bolus-driven swallow screenings are the other type of swallow screening being used to identify individuals with dysphagia. This type of swallow screening includes presentation of a bolus. As with the PROMs, there are many different bolus-driven swallow screenings used clinically. Most include some sort of water test, but each varies in the volume and procedure utilized. The criteria for the common 3-ounce water test includes giving the patient 3 ounces of water and instructing them to drink it without interruption. If the patient coughs throughout the consumption, coughs within 1 minute post completion, or has a wet-hoarse voice quality then they fail (DePippo et al., 1992). Other bolus sizes are also used including the Toronto Bedside Swallow Screening Tool (Martino et al., 2009), which utilizes a smaller bolus volume. Another bolus-driven swallow screening is the GUGGING which is validated for the acute stroke population (Trapl et al., 2007). Overall, the most widely used bolus-driven screening is the Yale Swallow Protocol (Carnaby et al., 2024).

Issues with Bolus-Driven Swallow Screenings

There are also barriers to bolus-driven swallow screenings that professionals must be aware of. Since screenings are developed to discover the need for further evaluation, an issue with bolus-driven swallow screenings such as the 3-ounce water test is that it over-refers patients leading to unnecessary diet restrictions for nearly half of the patients (Suiter & Leder, 2008). Additionally, there are still no current tools to identify silent aspiration (Garand et al., 2021). Silent aspiration is evidence of material below the level

of the vocal folds with no coughing or signs of aspiration occurring (Ramsey et al., 2005). Due to the increased risk of silent aspiration, head and neck cancer, and tracheostomy patients should be evaluated with an instrumental examination rather than a bolus-driven swallow screening (Leder et al., 2011). Additional barriers include that the Yale Swallow Protocol does not outline the exact length of time when stating a failure as coughing "immediately" after. Subsequently, the terms "coughing and choking" are not defined (Morrissey, 2022). Overall, a continual barrier to bolus-driven swallow screenings is the inability to drink the 3 ounces without stopping (Garand et al.). Populations found to have difficulty with the 3-ounce water test include individuals with dementia and generalized deconditioning (Suiter & Leder).

Yale Swallow Protocol

The Yale Swallow Protocol was developed by Steven Leder and Debra Suiter in 2014. This bolus-driven swallow screening consists of a 3-ounce water test, a brief cognitive assessment, and an oral mechanism examination. The 3-ounce water test is the only pass/fail component of the Yale Swallow Protocol. Passing includes drinking 3 ounces of water without coughing or stopping (Suiter et al., 2014). Additionally, passing the protocol allows for recommendations of an oral diet without the need for further examinations (Suiter & Leder, 2008 & Leder et al., 2011 & Leder et al., 2012 & Leder et al., 2012). On the other hand, failing includes interrupted drinking, inability to finish the whole 3 ounces, and coughing during or directly after (Suiter et al.). Failing the protocol results in referral for an instrumental examination (Suiter & Leder). The one caveat to the Yale Swallow Protocol is that it is not recommended for a specific population of individuals with tracheostomy tubes (Suiter et al.). The Yale Swallow Protocol was

originally found to have 100% sensitivity and 64% specificity (Suiter et al.). Additionally, the Yale Swallow Protocol has been translated to languages such as Danish (Nielsen et al., 2020). The one caveat to the Yale Swallow Protocol is that it is not recommended for individuals with tracheostomy tubes. However, the protocol can be administered to all other populations (Suiter et al.).

In a subsequent study, the Yale Swallow Protocol correctly determined aspiration risk and was followed by 5 days of successful oral alimentation in the acute setting without needing an instrumental swallow examination (Leder & Suiter, 2014 & Leder et al., 2016). Additionally, Ward et al. (2020) discovered that the Yale Swallow Protocol had a sensitivity of more than 95% in the post-acute care population. The Yale Swallow Protocol has been recommended for use in patients post-extubation (Brodsky et al., 2020). Additionally, with the motor neuron disease population, the Yale Swallow Protocol had a sensitivity of 80% but specificity of 33.3% when identify risk of aspiration (Garand et al., 2021). The Yale Swallow Protocol has also been validated for use by nurses and other trained healthcare professionals with inter-rater agreement of 98.01% (Leder & Suiter, 2014 & Warner et al., 2014).

Altogether, PROMs and bolus-driven swallow screenings are most frequently used. There are advantages and disadvantages to using each type of swallow screening and there is no consensus to which type is superior. Thus, the purpose of this study is to compare a PROM, the EAT-10, and a bolus-driven swallow study, the Yale Swallow Protocol, to determine if one of the screeners are superior in identifying aspiration.

Research Hypotheses

1. A higher cutoff value will be needed when using a PROM, the EAT-10, to predict aspiration.
2. When comparing a bolus-driven swallow screening to a PROM, the bolus-driven swallow screening will be superior in aspiration prediction.

Chapter Summary

Chapter 2 provided an overview of the current literature available on the dysphagia screenings tools currently used and the issues with the current screenings. Chapter 3 will describe the methodology of the study.

CHAPTER 3. METHODOLOGY

The study was conducted at the University of Kentucky Voice and Swallow Clinic. It was approved by the University of Kentucky International Review Board (IRB).

Design

This prospective, cross sectional study design investigated the two most frequently used swallow screenings, a patient-reported outcome measure (PROM), the Eating Assessment Tool (EAT-10), and a bolus-driven swallow screening, the Yale Swallow Protocol to determine their ability to predict aspiration during a videofluoroscopic swallow study (VFSS). Participants were recruited for this study when their physician referred them for an outpatient VFSS at the University of Kentucky Voice and Swallow Clinic. The standard of care evaluation in the clinic includes a history, cranial nerve examination, EAT-10, Yale Swallow Protocol, and a videofluoroscopic swallow study. At the time of the individual's appointment, this evaluation was completed regardless of their decision to participate in this study. If the individual decided to participate, they were enrolled in the study and completed all study procedures during their appointment time, on one date, and were not required to return to complete additional procedures.

Participants

This study included 66 participants recruited to participate between February 2021 and September 2023. The participants completed an EAT-10, Yale Swallow Protocol, and VFSS if eligible to participate in this study. Participants were recruited during their scheduled VFSS appointment at the University of Kentucky Voice and Swallow Clinic. Specific inclusion and exclusion criteria needed to be met before consenting to participate in this study during their appointment. Eligible participants met the following inclusion

criteria: (1) 18 years and older with a history of dysphagia or suspected dysphagia and (2) referred for a VFSS. The first inclusion criteria could be determined prior to the individual's appointment via a chart review. All patients scheduled for a VFSS with the University of Kentucky Voice and Swallow Clinic met the second inclusion criteria. This study was not advertised to individuals in the general community. Individuals were unable to participate in the study if they met any of the following exclusion criteria: (1) younger than 18 years of age, (2) tracheostomy tube in place, and (3) unable to understand or speak English. Most exclusion criteria could be determined prior to their scheduled appointment via chart review within the electronic medical records.

If an individual met the above inclusion criteria, they were informed of the nature and purpose of the study once they arrived for their scheduled appointment. The individuals were then asked to participate. If the individual decided to participate, the participant signed a Consent and Authorization Form (see Appendix A) prior to beginning study procedures. A randomized number for each participant was assigned for deidentification. The physical forms for the study, such as consent forms, EAT-10 forms, Yale Swallow Protocol results, and videofluoroscopic results, were stored in a locked office in the University of Kentucky College of Heath Sciences. If the individual decided to not participate in the study, they still completed the VFSS as scheduled.

Procedures

This study examined a patient-reported outcome measure and a bolus-driven swallow screening. The patient-reported outcome measure used for this study was The Eating Assessment Tool (EAT-10, see Appendix B) since it is the swallow screening most widely used (Carnaby et al., 2024). After consent, the EAT-10 was provided to the

patient to fill-out independently, via a speech-language pathologist who is a board-certified specialist in swallowing and swallowing disorders. The EAT-10 is a dysphagia screening survey that is symptom-specific (Belafsky et al., 2008). There are 10 questions that the individual rates on a scale of 0 (no problem) to 4 (severe problem). The total score is then calculated by adding together the ratings from all 10 questions. The total score may range anywhere from 0 to 40. To date, the EAT-10 has been validated to conclude that an abnormal score consists of any total score that is greater than 3 (Belafsky et al).

Next, the bolus-driven swallow screening was administered by the same speech-language pathologist who is a board-certified specialist in swallowing and swallow disorders. The screening tool used was the Yale Swallow Protocol (see Appendix C) since it is the bolus-driven swallow screening tool that is used most frequently (Carnaby et al., 2024). The Yale Swallow Protocol is a pass/fail tool that includes three orientation questions: What is your name? What year is it? Where are we?, a brief oral mechanism examination: Open your mouth, Stick out your tongue, Smile, and a 3-ounce water swallow test. During the water swallow test, the individual is asked to drink 3-ounces of water without stopping. The individual fails the screening if they are unable to drink the 3-ounces of water without stopping or if they cough immediately after. The Yale Swallow Protocol has been validated for its ability to predict aspiration risk with a sensitivity of 100% and specificity of 64% (Suiter et al., 2014).

After the two dysphagia screenings were administered, a VFSS was completed by the same speech-language pathologist who is a board-certified specialist in swallowing and swallow disorders. All VFSS were recorded at 30 frames per second to allow optimal

visualization of swallow physiology. Participants sat upright in a chair for the initial portion of the swallow study to obtain lateral views; they stood for the last portion of the swallow study to obtain an antero-posterior position view. The material used during the VFSS included Varibar thin and nectar liquid barium and pudding-thick barium (E-Z-EM, Lake Success, NY). The videos were recorded using the TIMS system to allow for post procedure review.

During the VFSS, a standardized protocol, the Modified Barium Swallow Study Impairment Profile (MBSImP, see Appendix D), was used as a systematic way of evaluating 17 different physiologic events occurring during the swallow. A 90 mL bolus was presented for the continuous cup drinking trial since it is the bolus size used for the Yale Swallow Protocol. This trial was used to determine whether the patient aspirated, which is defined as material entering the airway below the true vocal folds (Logemann, 1998). A binary (yes/no) value was given based on the presence or absence of aspiration. To determine inter-rater reliability for identification of aspiration, a second rater, a speech-language pathology graduate student, blinded from the results and the speech-language pathologist's ratings, reviewed 20% of the VFSS videos for the 90mL barium trials.

Outcome Measures

This study's primary outcome measures included the total score obtained from the patient-reported outcome measure (EAT-10), the results of the bolus-driven swallow screening (Yale Swallow Protocol), and whether the participant aspirated when taking the 90 mL thin liquid bolus during the videofluoroscopic swallow screening. The participant's EAT-10 score was documented as 0-40. The results of the Yale Swallow

Protocol were documented as a pass or fail. The participant was determined to be an aspirator or non-aspirator based on their VFSS.

Statistical Analysis

All statistical analysis used SPSS 28.0. A 2 x 2 contingency table was constructed for EAT-10 total scores of 3 to the binary aspiration results since this is the cutoff score originally discovered (Belafsky et al., 2008). An area under the curve analysis of the EAT-10 overall was completed. Results determined if a new EAT-10 cutoff point was superior for identification of aspiration. Once the cutoff point was determined, a 2 x 2 contingency table was constructed to compare the chosen EAT-10 cutoff score to the binary aspiration results. If participants' score on the EAT-10 fell above the cutoff score and aspiration was documented during the VFSS, a *true-positive* value was found. If participants' score on the EAT-10 fell below the cutoff score and aspiration was not documented during the VFSS, a *true-negative* value was found. If participants' score on the EAT-10 fell above the cutoff score and aspiration was not documented during the VFSS, a *false-positive* value was found. Finally, if participants' score on the EAT-10 fell below the cutoff score and aspiration was documented during the VFSS, a *false-negative* value was found. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were calculated for the EAT-10. This study focused on the sensitivity and specificity values because positive predictive value and negative predictive value are impacted by number of aspirators. Since this study found few aspirators, these values are not as meaningful.

The binary results of the Yale Swallow Protocol were compared to the binary aspiration results using a 2 x 2 contingency table. If participants failed the Yale Swallow

Protocol and aspiration was documented during the VFSS, a *true-positive* value was found. If participants passed the Yale Swallow Protocol and aspiration was not documented during the VFSS, a *true-negative* value was found. If participants failed the Yale Swallow Protocol and aspiration was not documented during the VFSS, a *false-positive* value was found. Finally, if participants passed the Yale Swallow Protocol and aspiration was documented during the VFSS, a *false-negative* value was found. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were calculated for the Yale Swallow Protocol, but this study focused on the sensitivity and specificity values.

Chapter Summary

Chapter three presented the methodology used to investigate whether the two most used screening tools, the Eat-10 for patient reported outcome measures, and the Yale Swallow Protocol for bolus-driven swallow screening predict aspiration on a videofluoroscopic swallow study. Chapter four entails the study's results.

CHAPTER 4. RESULTS

Participants

In this prospective, cross-sectional study, 66 individuals were consecutively referred to an outpatient voice and swallow clinic for a videofluoroscopic swallow study between February 2021 and September 2023. All participants completed the Eating Assessment Tool (EAT-10), the Yale Swallow Protocol, and a videofluoroscopic swallow study (VFSS). Participant demographics, including diagnosis associated with the referral, are provided in Table 4.1.

Eight of 66 (12%) participants aspirated when taking the 90 mL thin liquid bolus during their videofluoroscopic swallow study. Results for predictive ability of the EAT10 and the Yale Swallow Protocol for identifying aspiration risk are shown below.

TABLE 4.1: Participant Demographics

	Males (N = 27)	**Females (N = 39)**
Mean Age ± SD (Y)	50 ± 16	58 ± 15
Diagnoses		
Cardiovascular	0	1
Central Nervous System	3	7
Dermatology	0	0
Ear/Nose/Throat	4	8
Endocrine	1	1
Gastrointestinal	3	3
Hematology	0	0
HIV/AIDS	0	0
Infectious Disease	0	1
Nephrology/Urology	0	0
Obstetrics/Gynecology	0	0
Oncology	9	12
Ophthalmology	0	0
Plastic Surgery	0	0
Psychiatry	0	0
Respiratory (including Pneumonia)	5	1
Rheumatology/Orthopedics	0	0
Trauma	0	0
Other	2	1
Sepsis-excluding pneumonia	0	0

Inter-rater Reliability

Inter-rater reliability between the speech language pathologist who is a board-certified specialist in swallowing and swallowing disorders and the speech language pathology graduate student was determined for aspiration during the 90mL trial. This was performed on 13/66 (20%) randomly selected participants during the analysis of this study, 2-5 months after the completion of testing. 100% agreement was found which may be due to the small number of aspirators in the study. This study also had excellent intra-rater reliability when the speech language pathologist when back and rated the videos for the second time, 2-5 months after completion of testing.

EAT-10 in Predicting Aspiration

The average EAT-10 score for individuals who did not aspirate during the VFSS was 15.38 (SD = 10.8). The average EAT-10 score for participants who aspirated was 20.25 (SD = 8.84). 89.4% (59/66) of the participants scored higher than the original cutoff value of 3, but only 12% (8/66) of the participants aspirated on the instrumental examination. A 2 x 2 contingency table was used to determine the sensitivity and specificity of EAT-10 total scores of 3 or greater for predicting aspiration on a VFSS. The results are presented in Table 4.2. The sensitivity of an EAT-10 total score of 3 or greater for predicting aspiration was 100% (95% CI, 63.06-100.0%); specificity was 12.07% (95% CI, 4.99%-23.30%); positive predictive value was 13.56% (95% CI, 12.48-14.72%); negative predictive value was 100.0% (95% CI, 59.04-100.0%); accuracy was 22.73% (95% CI, 13.31-34.70%) which is also presented in Table 4.3.

TABLE 4.2: 2 x 2 Contingency table for the EAT-10 total scores of 3 or higher to predict aspiration.

EAT-10 Total Score	**Aspiration of VFSS**	
	Positive	**Negative**
>3	8 a=true positive	51 b=false positive
<3	0 c=false negative	7 d=true negative

TABLE 4.3: Sensitivity of EAT-10 scores of 3 or higher.

	SENS	**SPEC**	**PPV**	**NPV**	**ACC**
EAT-10	100% (95% CI, 63.06-100.0%)	12.07% (95% CI, 4.99-23.30%)	13.56% (95% CI, 12.48-14.72%)	100% (95% CI, 59.04-100.0%)	22.73% (95% CI, 13.31-34.70%)

SENS=Sensitivity; SPEC=Specificity; PPV=Positive Predictive Value; NPV=Negative Predictive Value

To determine a cutoff value when comparing the EAT-10 total scores to the binary aspiration results of this study, the ROC curve is shown in Figure 4.1 and ROC analysis is available (see Appendix E). Based on this analysis, a cutoff value of 19 was chosen. A 2 x 2 contingency table was used to determine sensitivity and specificity of EAT-10 scores of 19 or greater for predicting aspiration on instrumental assessment. Results are presented in Table 4.4. Sensitivity of EAT-10 of greater than 19 for predicting aspiration was 75% (95% CI = 34.81-96.81%); specificity was 58.62% (95% CI, 44.93-71.40%); positive predictive value was 20.00% (95% CI, 13.12-29.27%); negative predictive value was 94.44% (95% CI, 83.39%-98.29%); accuracy was 60.61% (95% CI, 47.81%-72.42%) which is also presented in Table 4.5.

FIGURE 4.1: The receiver operating characteristics (ROC) curve for EAT-10 in predicting aspiration.

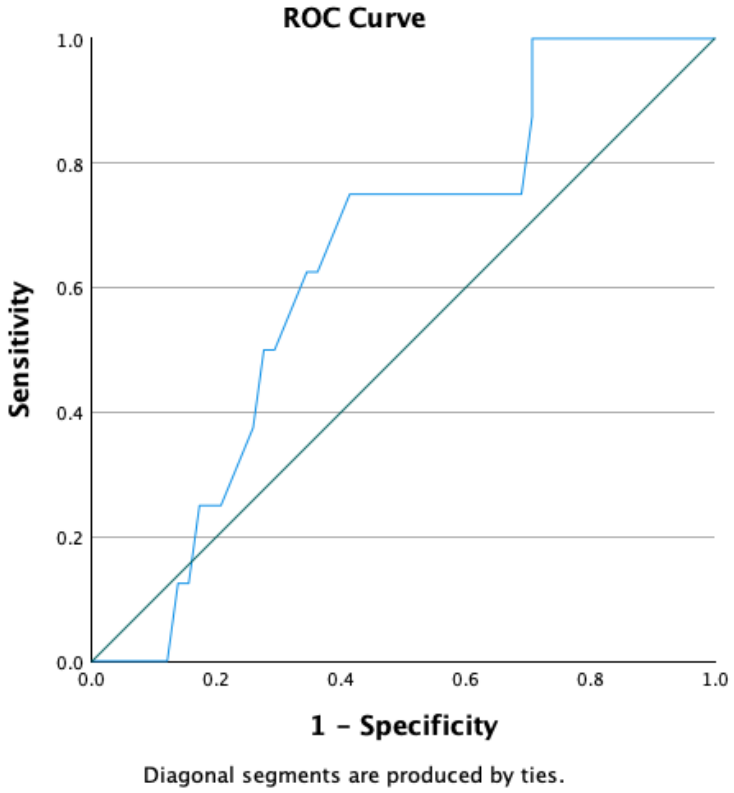


TABLE 4.4: 2 x 2 Contingency table for EAT-10 total scores of 19 or higher to predict aspiration.

EAT-10 Total Score	**Aspiration of VFSS**	
	Positive	**Negative**
>19	6 a=true positive	24 b=false positive
<19	2 c=false negative	34 d=true negative

TABLE 4.5: Sensitivity of EAT-10 scores of 19 or higher.

	SENS	**SPEC**	**PPV**	**NPV**	**ACC**
EAT-10	75% (95% CI, 34.81-96.81%)	58.62% (95% CI, 44.93-71.40%)	20% (95% CI, 13.12-29.27%)	94.44% (95% CI, 83.39-98.29%)	60.61% (95% CI, 47.81-72.42%)

SENS=Sensitivity; SPEC=Specificity; PPV=Positive Predictive Value; NPV=Negative Predictive Value

Yale Swallow Protocol in Predicting Aspiration

A total of 44% (29/66) of the participants failed the Yale Swallow Protocol. The results of the Yale Swallow Protocol predicting aspiration are shown in Figure 4.2. A 2 x 2 contingency table was used to determine sensitivity and specificity of the Yale Swallow Protocol for predicting aspiration on an instrumental assessment. Results are presented in Table 4.6. Sensitivity of the Yale Swallow Protocol for predicting aspiration was 87.5% (95% CI = 47.35-99.68%); specificity was 62.07% (95% CI, 48.37-74.49%); positive predictive value was 24.14% (95% CI, 17.28-32.64%); negative predictive value was 97.30% (95% CI, 85.06%-99.56%); accuracy was 65.16% (95% CI, 52.42%-76.47%). The results of this analysis are presented in Table 4.7.

FIGURE 4.2: The receiver operating characteristics (ROC) curve for the Yale Swallow Protocol predicting aspiration.

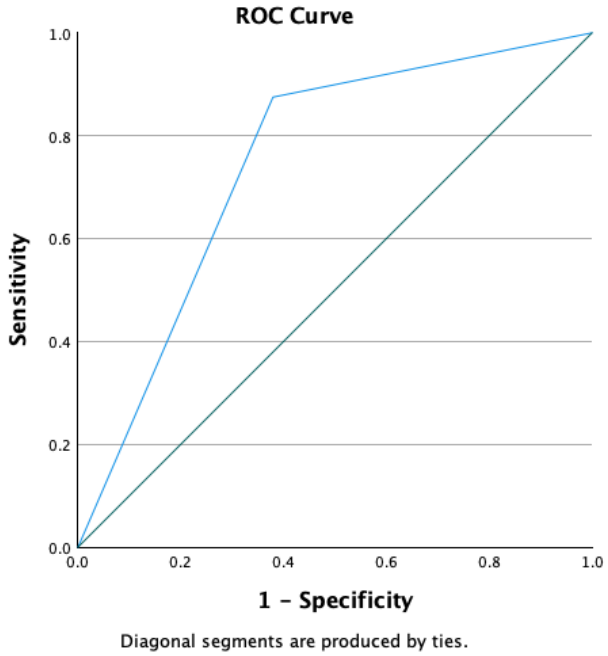


TABLE 4.6: 2 x 2 Contingency table for the ability of the Yale Swallow Protocol to predict aspiration.

Yale Swallow Protocol	**Aspiration of VFSS**	
	Positive	**Negative**
Fail	7 a=true positive	22 b=false positive
Pass	1 c=false negative	34 d=true negative

TABLE 4.7: Sensitivity of the Yale Swallow Protocol.

	SENS	**SPEC**	**PPV**	**NPV**	**ACC**
YSP	87.50% (95% CI, 47.35-99.68%)	62.07% (95% CI, 48.37-74.49%)	24.14% (95% CI, 17.28-32.64%)	97.30% (95% CI, 85.06-99.56%)	65.16% (95% CI, 52.42-76.47%)

SENS=Sensitivity; SPEC=Specificity; PPV=Positive Predictive Value; NPV=Negative Predictive Value

Chapter Summary

Chapter four entailed the results of the cross-sectional study. The final fifth chapter includes the discussion, limitations, implications for future research, and conclusions.

CHAPTER 5. DISCUSSION

Review of Purpose

It is known that dysphagia impacts an individual's health and quality of life. Due to this, early identification of dysphagia is crucial. The first step of the continuum for identifying dysphagia is a screening to determine the need for further examinations. There are patient-reported outcome measures (PROMs) and bolus-driven swallow screenings. Within each screening type, there are multiple screening tools currently being used. The two most frequently used swallow screenings include a PROM, the EAT-10, and a bolus-driven swallow screening, the Yale Swallow Protocol (Carnaby et al., 2024). There are advantages and disadvantages to using each of the screening tools, so it is unclear which tool is superior. To date, there are no studies that have investigated both the EAT-10 and Yale Swallow Protocol in aspiration prediction on an instrumental examination. Consequently, this study aims to compare a PROM, the EAT-10, and a bolus-driven swallow screening, the Yale Swallow Protocol, to determine if one tool is superior in the identification of aspiration risk.

Review of Methodology

This prospective, cross-sectional study recruited sixty-six individuals to participate. Participants were recruited during their scheduled videofluoroscopic swallow study (VFSS) appointment at the University of Kentucky Voice and Swallow Clinic. If an individual was eligible and decided to participate, they completed a PROM, the EAT-10, a bolus-driven swallow screening, the Yale Swallow Protocol, and videofluoroscopic swallow study (VFSS) on the date of their scheduled appointment.

Discussion of Results

This study investigated two hypotheses. The first hypothesis, a higher cutoff value will be needed when using a PROM, the EAT-10, to predict aspiration, was supported. The second hypothesis, a bolus-driven swallow screening will be superior in aspiration prediction, was supported.

EAT-10

This study investigated the ability of the EAT-10 to predict aspiration. The EAT-10 has been validated for a cutoff score of 3 or greater to be abnormal (Belafsky et al., 2008). An analysis using the original cutoff value of 3 was completed for this study to determine the accuracy in predicting aspiration. This study discovered a high sensitivity of 100% (95% CI, 63.06-100.0%), but an extremely low specificity of 12.07% (95% CI, 4.99%-23.30). The sensitivity demonstrates that 100% of the individuals who aspirated on the instrumental, scored above 3 on the EAT-10. This high sensitivity correlates to a low rate of false negatives which is consistent with the zero false negatives found in this study. The specificity demonstrates that 12.07% of the individuals did not aspirate on the instrumental and scored below the cutoff score of 3 on the EAT-10. A high specificity typically correlates to a low number of false positives, but this study found a high number of false positives. In other terms, using the cutoff score of 3, it correctly identified all 8 of the aspirators but incorrectly identified 51 non-aspirators out of the 59 individuals scoring 3 or greater on the EAT-10. This study found that the average score for participants who did not aspirate was 15.38 (SD=10.8) which is already above the original cutoff value of 3. 89.4% of the participants scored above the original cutoff value, but only 12% of the participants aspirated on the instrumental examination. This finding is consistent with

previous literature which discovered 17% of healthy individuals reported swallowing difficulties (Bloem et al., 1990).

An area under the curve analysis was completed to further investigate the EAT-10 in aspiration prediction. This study found an area under the curve value of 0.637 which indicates the EAT-10 is a poor predictor of aspiration overall. Since an extremely poor specificity was found in this study with the original cutoff score of 3 and the area under the curve indicated that the EAT-10 was a poor predictor of aspiration, further investigation was completed to determine if a new cutoff score would better predict aspiration. See Appendix E for the table used to find a new cutoff value. A balance was found by using the cutoff score of 19, with a sensitivity of 75% (95% CI = 34.81-96.81%) and specificity of 58.62% (95% CI, 44.93-71.40%). This new cutoff score raises the specificity above a 50/50 chance. This study found that the new cutoff score of 19 is a fair predictor of aspiration. Thus, this study's hypothesis that the original cutoff value will need to be raised for the EAT-10, was supported. Using the new cutoff score of 19, 6 of the aspirators were correctly identified and only 24 non-aspirators were incorrectly identified which reduced the amount of overidentified individuals. Despite this, raising the cutoff score to 19 incorrectly identified 2 of the aspirators which places these individuals at risk for going undiagnosed. In order to catch all of the individuals who aspirated, many individuals would be over-referred.

The cutoff value found in this study is the same cutoff value that Florie et al (2021), discovered in their study but their cutoff value was used to predict post swallow pharyngeal residue in the head and neck cancer population. To date, there is a multitude of research within different patient populations that each discovered a new cutoff value.

Bartlett et al (2021), studied the correlation of EAT-10 scores to penetration aspiration scores (PAS) on an instrumental examination and found significant correlation with the head and neck cancer population but not the Parkinson's Disease population within an outpatient clinic. Our study combined all populations in the sample size, but further research may be of interest to determine a cutoff value and agreement for each population.

The EAT-10 is the dysphagia screening tool with the most current research in aspiration prediction. This study focused only on the PROM, the EAT-10, but there are around 34 different dysphagia PROMs. Other PROMs mentioned previously such as the Munich Dysphagia Test – Parkinson's Disease have limited research on their correlation to aspiration prediction. In one study by Buhmann et al (2019), it was concluded that the Munich Dysphagia Test – Parkinson's Disease cannot predict aspiration. Another dysphagia screening tool is the Sydney Swallow Questionnaire. The normative values for this screening tool were developed to determine the patient's overall severity rather than aspiration prediction (Szczesniak et al., 2014). Overall, a systematic review of the 34 different PROMs discovered that most PROMs are typically used to monitor symptoms and treatment over time (Patel et al., 2017). The EAT-10 is the dysphagia tool that is frequently being researched and used to predict aspiration.

We know that PROMs are important to include to gain information about the patient's perspective and the impact on their quality of life. The EAT-10 and many others are questionnaires that may be used to gain this type of information. Having said that, if the EAT-10 is used to predict aspiration, the total score should be used with caution.

Yale Swallow Protocol

The hypothesis that the bolus-driven swallow screening will be superior to predict aspiration was supported. When investigating the ability of the Yale Swallow Protocol to predict aspiration, the sensitivity of 87.5% (95% CI = 47.35-99.68%) and specificity of 62.07% (95% CI, 48.37-74.49%) was found. The specificity correlates to a lower rate of false positives. The Yale Swallow Protocol did still have 22 false positives, but this number is much lower than the amount found with the EAT-10. This sensitivity and specificity along with the area under the curve value of 0.748 indicate that the Yale Swallow Protocol is an acceptable predictor of aspiration which is superior to the EAT-10 being a fair predictor of aspiration.

The sensitivity and specificity of the Yale Swallow Protocol in this study was found to be less than the original values of 100% sensitivity and 64% specificity (Suiter et al., 2014). This may be due to the small sample size used for this study. It is important to note that this study found one false negative with the Yale Swallow Protocol which means that participant passed the Yale Swallow Protocol but aspirated on the instrumental examination. This is different than the original study that did not find any false negatives.

Limitations

This study is a small study that is part of a larger study that is still ongoing. As such, a limitation to this study is the small sample size. The larger study is currently continuing to grow, and a larger sample size should be used for further research to further determine the superior dysphagia screening tool. An additional limitation of this study is the small number of aspirators included in this study. This study included 66 participants,

but only 12% (8/66) of the participants aspirated on the instrumental examination. This percentage is consistent with the larger study currently ongoing. Another limitation of this study is the fact that it was a referred sample since individuals were only included if they were referred to the University of Kentucky Voice and Swallow Clinic for a videofluoroscopic swallow study by their physician.

Additional limitations of this study include the same clinician completing all study procedures with the participant and not randomizing participant numbers. Inter-rater agreement was found to be 100% though. This study did not randomize the order of the participants but rather numbered them chronologically which is another limitation that is recognized.

Implications for Future Research

There is currently no consensus on the definition of dysphagia. Without a definition of dysphagia, it is unclear what we screen and what we treat. A clinician may treat patients based on their reported symptoms, due to the impact on quality of life. Another clinician may only treat the objective findings of a bolus-driven swallow screening. This is a preliminary study aiming to compare the PROMs to bolus-driven swallow screenings. Continued research should be completed to develop a consensus definition for dysphagia and which screening tools to use.

Additionally, further research should determine a consensus for the EAT-10 cutoff value used to predict aspiration overall and within each patient population. There is currently a lot of research available with many different cutoff values found. Further research should also be completed to determine if certain EAT-10 questions correlate to aspiration prediction. Most research is currently being conducted regarding the

correlation to the total score of the EAT-10 rather than specific questions. Lastly, it may be beneficial for further research to determine if combining a PROM and bolus-driven swallow screening results in better aspiration prediction.

Conclusions

In conclusion, the patient's perspectives of their symptoms are important to determine the impact on their quality of life. The preliminary results of this study indicate that the EAT-10 is a fair predictor of aspiration, which means that if the EAT-10 is used as a screening tool to predict aspiration, it should be used with caution. On the other hand, a bolus-driven swallow screening such as the Yale Swallow Protocol was found to be a good predictor of aspiration.

Chapter Summary

Chapter five included the discussion, limitations, implications, and conclusions.

APPENDIX A. Consent Forms

IRB Approval
6/13/2023
IRB # 52311
IRB3

Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR CLINICAL UTILITY OF A SWALLOW SCREEN IN AN OUTPATIENT CLINICAL SETTING:

We are asking you to choose whether or not to volunteer for a research study about the usefulness of a swallow screening protocol in an outpatient clinical setting. We are asking you because your doctor referred you to our clinic for an x-ray test of your swallowing, also known as a modified barium swallow study. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The usefulness of a brief swallow screening protocol in an outpatient setting is not known. This research is being done to study the effectiveness of a brief screening for swallowing problems in outpatient clinics. Resutls of this study will be compared with your x-ray swallow test.

By doing this study, we hope to learn whether a brief screening test is useful for determining risk of swallowing problems for patients seen in an outpatient clinic. Your participation in this research will last about 1 hour.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will not benefit directly from participating in this study. Information gained from this study will be useful in helping to identify individuals at risk for swallowing difficulty who need a full evaluation of swallowing. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There are no expected physical risks or discomforts associated with participation in this study. The Yale Swallow Protocol is standard of care for our patients. As with any assessment of swallow function, there is a risk that liquid may go down the wrong tube (also known as aspiration). You are here for a swallow study because your doctor suspects you are having difficulty swallowing. Drinking water, including 3 ounces of water, is part of our usual study protocol and is necessary to accurately assess your swallow function. You would be completing the Yale Swallow Protocol regardless of your decision to participate in this study. If you choose not to participate in this study, we will not include the information from the results of the Yale Swallow Protocol or the results of your swallow study in our data analysis.

You may choose not to participate in this study. If you do not participate, your clinical care will not be affected.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Debra Suiter, PhD, CCC-SLP, BCS-S, Principal Investigator, of the University of Kentucky, Department of Communication Sciences and Disorders at 859-218-5323.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You do not qualify for this study if you are under 18 years of age or have a tracheostomy tube in place or if you do not understand or speak English.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted in the Radiology Department at UK Medical Center. You will need to come 1 time for the swallow study for which you were referred. Participation in this study will not necessitate any additional clinic visits. The time it takes to complete your x-ray swallow study will not be affected by your participation in this study. The typical amount of time it takes to complete your entire swallow study appointment is 30 minutes.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to complete a brief screening protocol prior to completion of the swallow study for which your doctor referred you to us. This screen includes brief questions and a water swallow test in which you will be asked to swallow 3 ounces of water. The total time for this screening protocol is approximately 10 minutes or less, and it is considered standard of care in our clinic. Following completion of the screening, we will proceed with the swallow test that your doctor ordered. You will complete the screening test and the x-ray test of your swallowing even if you choose not to participate in this study. We are asking to be allowed to use your data as part of our research study, which means we will compare the results of the screening protocol to the results of your swallow study. This will not involve an additional time commitment or additional clinical procedures on your part.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no expected physical risks or discomforts associated with this study. This study will collect data from your medical record and swallow test results. Study information will be kept in locked officed, locked filing cabinets for paper records. Electronic files will be kept on encrypted and password protected computers and stored on encrypted and password protected servers at the University of Kentucky. All of your identifying information will be removed before the data are analyzed. Only research study personnel who are required to directly interact with the medical record and/or you will know the linkage between the unique identifier and identifying information. All of your information in our database will remain confidential in compliance with federal and state laws.

There is always a chance that any medical procedure can harm you. The research procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no direct benefit to you from being in this study. However, if you take part in this study, information learned may help others with swallowing difficulty.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

This study is being done in collaboration with researchers at Johns Hopkins University. Only the video recording of your x-ray swallow test will be shared. We will not share your name or any other personal information with researchers at Johns Hopkins. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. This study will collect data from your medical record and swallow test results. Study information will be kept in locked officed, locked filing cabinets for paper records. Electronic files will be kept on encrypted and password protected computers and stored on encrypted and password protected servers at the University of Kentucky. All of your identifying information will be removed before the data are analyzed. Only research study personnel who are required to directly interact with the medical record and/or you will know the linkage between the unique identifier and identifying information. All of your information in our database will remain confidential in compliance with federal and state laws.

You should know that in some cases we may have to show your information to other people.

For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

To ensure the study is conducted properly, officials of the University of Kentucky may look at or copy pertinent portions of records that identify you. We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Debra Suiter, Principal Investigator at 859-218-5323 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

- Medical costs related to your care and treatment because of study-related harm may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); ***or***
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with individual research results (i.e., results of the screening protocol).

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 600 people to do so nationally, and one of 300 at the University of Kentucky.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information stored, it will be available indefinitely and cannot be removed due to the inability to identify them.

AUTHORIZATION TO USE OR DISCLOSE YOUR INDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Name, age, results of your swallow study, and medical history.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- Johns Hopkins Medical Center

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Debra Suiter, 900 S.Limestone Avenue, CTW124K, Lexington, KY 40536 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- ☐ **Key Information Page**
- ☐ **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject** *or, if applicable, *research subject's legal representative*	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	_____ Date

APPENDIX B. Eating Assessment Tool (EAT-10)

EATING ASSESSMENT TOOL (EAT-10)

Date:_____

Name: _____MR#: _____

Height:_____Weight:_____

Please briefly describe your swallowing problem.

Please list any swallowing tests you have had, including where, when, and the results.

To what extent are the following scenarios problematic for you?

Circle the appropriate response	0 = No problem				4 = Severe problem
1. My swallowing problem has caused me to lose weight.	0	1	2	3	4
2. My swallowing problem interferes with my ability to go out for meals.	0	1	2	3	4
3. Swallowing liquids takes extra effort.	0	1	2	3	4
4. Swallowing solids takes extra effort.	0	1	2	3	4
5. Swallowing pills takes extra effort.	0	1	2	3	4
6. Swallowing is painful.	0	1	2	3	4
7. The pleasure of eating is affected by my swallowing.	0	1	2	3	4
8. When I swallow food sticks in my throat.	0	1	2	3	4
9. I cough when I eat.	0	1	2	3	4
10. Swallowing is stressful.	0	1	2	3	4
Total EAT-10:					

APPENDIX C. Yale Swallow Protocol

Yale Swallow Protocol

Step 1: Exclusion Criteria

___ Yale Swallow Protocol Deferred due to NO concern for aspiration risk.

Any YES answer to the following risk factors will also defer administration to protocol:

Yes	No	
___	___	Unable to remain alert for testing.
___	___	Eating a modified diet (thickened liquids) due to pre-existing dysphagia.
___	___	Existing enteral tube feeding via stomach or nose.
___	___	Head-of-bed restrictions <30°.
___	___	Tracheostomy tube present.
___	___	Nil per os by physician order.

If the patient's clinical status changes resulting in a new risk for aspiration, the protocol must be readministered before oral alimentation or medications are ordered.

Step 2: Administration Instructions

If patient is deemed an aspiration risk and all exclusion criteria in Step 1 are checked "NO," proceed with protocol:

- Brief Cognitive Screen:

  What is your name?
  Where are you right now?
  What year is it?

- Oral-Mechanism Examination

  Labial closure
  Lingual range of motion
  Facial symmetry (smile/pucker)

- Perform 3-ounce water swallow challenge:

  Sit patient upright at 80-90° (or as high as tolerated >30°).
  Ask patient to drink the entire 3 ounces (90cc) of water from a cup or with a straw, in sequential swallows, and slow and steady but without stopping. (Note: Cup or straw can be held by clinician or patient.) Assess patient for interrupted drinking and coughing or choking during or immediately after completion of drinking.

  Note: Information from the brief cognitive screen and oral mechanism examination provide information on odds of aspiration risk with the 3-ounce water swallow challenge and should not be used as exclusionary criteria for screening.

Information Provided by SA Swallowing Services, PLLC., 2014

Step 3: Pass/Fail Criteria

Results and Recommendations

____ PASS: Complete and uninterrupted drinking of all 3 ounces of water without overt signs of aspiration, i.e., coughing or choking, either during or immediately after completion.

- If patient passes, collaborate with MD/PA/LIP to order appropriate oral diet. If dentate, order a soft solid consistency or regular consistency diet. If edentulous, order a liquid and puree diet.

____ FAIL: Inability to drink the entire 3 ounces in sequential swallows due to stopping/starting or patient exhibits overt signs of aspiration, i.e., coughing or choking, either during or immediately after completion.

- If patient fails, keep nil per os (including medications) and discuss with the MD/PA/LIP the need for an objective swallowing evaluation by speech-language pathologist.
- Readminister the protocol in 24 h if patient shows clinical improvement.

(Taken from: Suiter, D.M., Sloggy, J., & Leder, S.B. (2014). Validation of the Yale Swallow Protocol: A prospective double-blinded videofluoroscopic study. *Dysphagia, 29,* 199-203.)

Validation Information

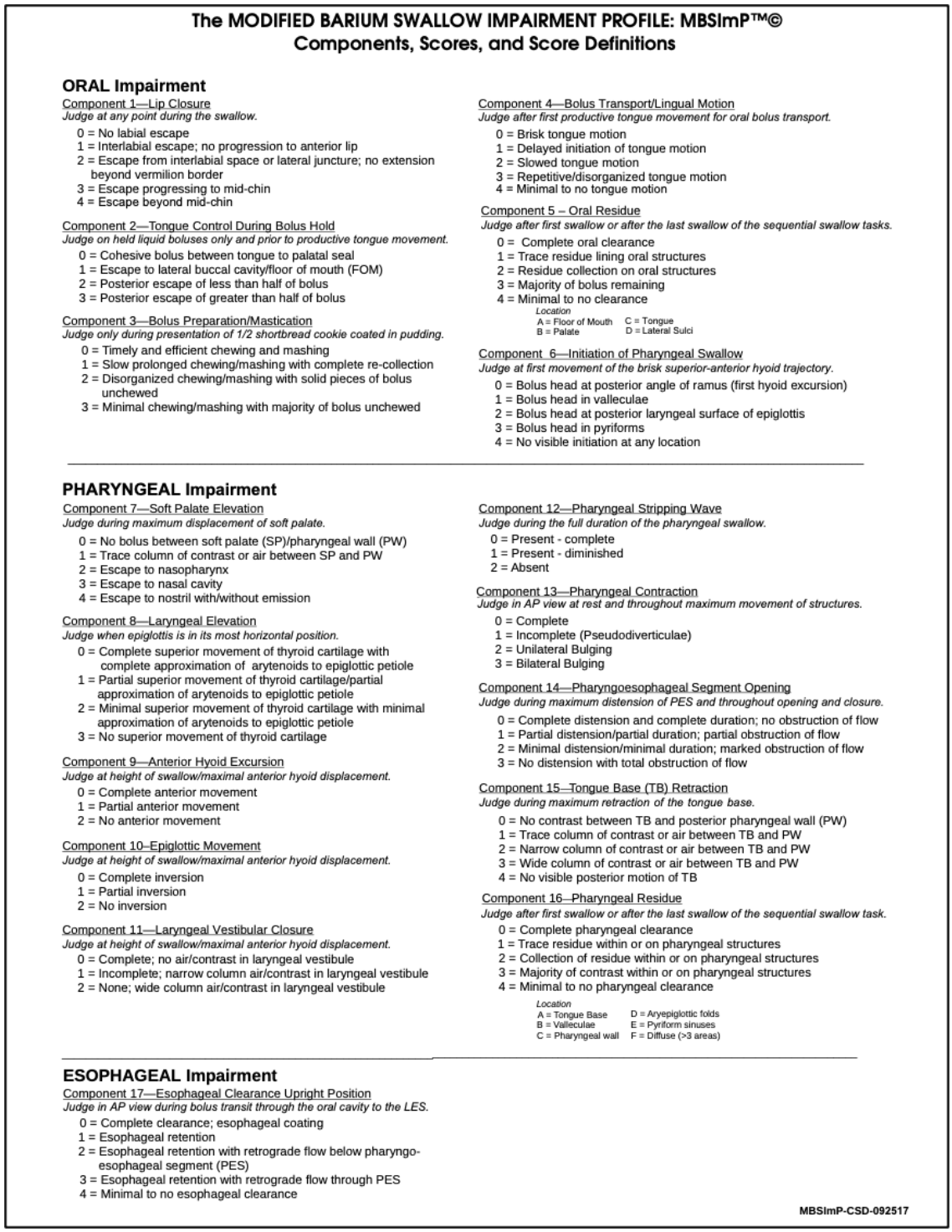
1. Three-ounce water swallow test validation first reported on 44 stroke patients by DePippo et al. (1992). Failure required referral for objective (VFSS) dysphagia test.

2. A revised 3-ounce water swallow challenge administered to 3,000 hospitalized patients with 14 distinct diagnoses and referenced with FEES as the standard correctly predicted aspiration 96.5% of the time, with a negative predictive value of 97.9%, and a false negative rate of ≤2.0%. (Suiter, D.B. & Leder, S.B. [2008]. Clinical utility of the 3-ounce water swallow test. *Dysphagia, 23*, 244-250.)

3. Validation study of Yale Swallow Protocol was reported using 25 subjects with categorical diagnoses of esophageal surgery, head & neck cancer, neurosurgery, medical issues, or neurological (CAV, MS, TBI) and using VFSS as the standard reference. Seven participants passed and 18 failed the 3-ounce swallow challenge. Of the 18 who failed, 14 aspirated on VFSS (true positives) and 4 did not aspirate on VFSS (false positives). Sensitivity for the protocol = 100%, specificity = 64%, positive predictive value = 78%, and negative predictive value = 100%. All participants who passed the protocol, i.e., deemed to have no aspiration risk, also did not aspirate during VFSS. (Suiter, D.M., Sloggy, J., & Leder, S.B. [2014). Validation of the Yale Swallow Protocol: A prospective double-blinded videofluoroscopic study. *Dysphagia, 29,* 199-203.)

Information Provided by SA Swallowing Services, PLLC., 2014

APPENDIX D. The Modified Barium Swallow Impairment Profile (MBSImP)



The MODIFIED BARIUM SWALLOW IMPAIRMENT PROFILE: MBSImP™©
Components, Scores, and Score Definitions

ORAL Impairment

Component 1—Lip Closure
Judge at any point during the swallow.
- 0 = No labial escape
- 1 = Interlabial escape; no progression to anterior lip
- 2 = Escape from interlabial space or lateral juncture; no extension beyond vermilion border
- 3 = Escape progressing to mid-chin
- 4 = Escape beyond mid-chin

Component 2—Tongue Control During Bolus Hold
Judge on held liquid boluses only and prior to productive tongue movement.
- 0 = Cohesive bolus between tongue to palatal seal
- 1 = Escape to lateral buccal cavity/floor of mouth (FOM)
- 2 = Posterior escape of less than half of bolus
- 3 = Posterior escape of greater than half of bolus

Component 3—Bolus Preparation/Mastication
Judge only during presentation of 1/2 shortbread cookie coated in pudding.
- 0 = Timely and efficient chewing and mashing
- 1 = Slow prolonged chewing/mashing with complete re-collection
- 2 = Disorganized chewing/mashing with solid pieces of bolus unchewed
- 3 = Minimal chewing/mashing with majority of bolus unchewed

Component 4—Bolus Transport/Lingual Motion
Judge after first productive tongue movement for oral bolus transport.
- 0 = Brisk tongue motion
- 1 = Delayed initiation of tongue motion
- 2 = Slowed tongue motion
- 3 = Repetitive/disorganized tongue motion
- 4 = Minimal to no tongue motion

Component 5 – Oral Residue
Judge after first swallow or after the last swallow of the sequential swallow tasks.
- 0 = Complete oral clearance
- 1 = Trace residue lining oral structures
- 2 = Residue collection on oral structures
- 3 = Majority of bolus remaining
- 4 = Minimal to no clearance

Location
A = Floor of Mouth C = Tongue
B = Palate D = Lateral Sulci

Component 6—Initiation of Pharyngeal Swallow
Judge at first movement of the brisk superior-anterior hyoid trajectory.
- 0 = Bolus head at posterior angle of ramus (first hyoid excursion)
- 1 = Bolus head in valleculae
- 2 = Bolus head at posterior laryngeal surface of epiglottis
- 3 = Bolus head in pyriforms
- 4 = No visible initiation at any location

PHARYNGEAL Impairment

Component 7—Soft Palate Elevation
Judge during maximum displacement of soft palate.
- 0 = No bolus between soft palate (SP)/pharyngeal wall (PW)
- 1 = Trace column of contrast or air between SP and PW
- 2 = Escape to nasopharynx
- 3 = Escape to nasal cavity
- 4 = Escape to nostril with/without emission

Component 8—Laryngeal Elevation
Judge when epiglottis is in its most horizontal position.
- 0 = Complete superior movement of thyroid cartilage with complete approximation of arytenoids to epiglottic petiole
- 1 = Partial superior movement of thyroid cartilage/partial approximation of arytenoids to epiglottic petiole
- 2 = Minimal superior movement of thyroid cartilage with minimal approximation of arytenoids to epiglottic petiole
- 3 = No superior movement of thyroid cartilage

Component 9—Anterior Hyoid Excursion
Judge at height of swallow/maximal anterior hyoid displacement.
- 0 = Complete anterior movement
- 1 = Partial anterior movement
- 2 = No anterior movement

Component 10–Epiglottic Movement
Judge at height of swallow/maximal anterior hyoid displacement.
- 0 = Complete inversion
- 1 = Partial inversion
- 2 = No inversion

Component 11—Laryngeal Vestibular Closure
Judge at height of swallow/maximal anterior hyoid displacement.
- 0 = Complete; no air/contrast in laryngeal vestibule
- 1 = Incomplete; narrow column air/contrast in laryngeal vestibule
- 2 = None; wide column air/contrast in laryngeal vestibule

Component 12—Pharyngeal Stripping Wave
Judge during the full duration of the pharyngeal swallow.
- 0 = Present - complete
- 1 = Present - diminished
- 2 = Absent

Component 13—Pharyngeal Contraction
Judge in AP view at rest and throughout maximum movement of structures.
- 0 = Complete
- 1 = Incomplete (Pseudodiverticulae)
- 2 = Unilateral Bulging
- 3 = Bilateral Bulging

Component 14—Pharyngoesophageal Segment Opening
Judge during maximum distension of PES and throughout opening and closure.
- 0 = Complete distension and complete duration; no obstruction of flow
- 1 = Partial distension/partial duration; partial obstruction of flow
- 2 = Minimal distension/minimal duration; marked obstruction of flow
- 3 = No distension with total obstruction of flow

Component 15—Tongue Base (TB) Retraction
Judge during maximum retraction of the tongue base.
- 0 = No contrast between TB and posterior pharyngeal wall (PW)
- 1 = Trace column of contrast or air between TB and PW
- 2 = Narrow column of contrast or air between TB and PW
- 3 = Wide column of contrast or air between TB and PW
- 4 = No visible posterior motion of TB

Component 16—Pharyngeal Residue
Judge after first swallow or after the last swallow of the sequential swallow task.
- 0 = Complete pharyngeal clearance
- 1 = Trace residue within or on pharyngeal structures
- 2 = Collection of residue within or on pharyngeal structures
- 3 = Majority of contrast within or on pharyngeal structures
- 4 = Minimal to no pharyngeal clearance

Location
A = Tongue Base D = Aryepiglottic folds
B = Valleculae E = Pyriform sinuses
C = Pharyngeal wall F = Diffuse (>3 areas)

ESOPHAGEAL Impairment

Component 17—Esophageal Clearance Upright Position
Judge in AP view during bolus transit through the oral cavity to the LES.
- 0 = Complete clearance; esophageal coating
- 1 = Esophageal retention
- 2 = Esophageal retention with retrograde flow below pharyngo-esophageal segment (PES)
- 3 = Esophageal retention with retrograde flow through PES
- 4 = Minimal to no esophageal clearance

MBSImP-CSD-092517

APPENDIX E. Supplemental Data

The ability for the EAT-10 to predict aspiration measures.

EAT-10 Total Score	Sensitivity	1-Specificity
.50	1.000	.948
1.50	1.000	.914
2.50	1.000	.879
4.00	1.000	.810
5.50	1.000	.741
6.50	1.000	.707
7.50	.875	.707
8.50	.750	.690
10.00	.750	.638
12.00	.750	.621
13.50	.750	.586
14.50	.750	.552
15.50	.750	.517
16.50	.750	.500
17.50	.750	.448
18.50	.750	.414
19.50	.625	.362
20.50	.625	.345
21.50	.500	.293
22.50	.500	.276
23.50	.375	.259
24.50	. 250	.207
25.50	. 250	.190
27.50	.250	.172
29.00	. 125	.155
31.00	.125	.138
32.50	.000	.121
33.50	.000	.069
35.00	.000	.017
37.00	.000	.000

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