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ORIGINAL ARTICLE

Validation of the Yale Swallow Protocol: A Prospective Double-Blinded Videofluoroscopic Study

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Abstract The purpose of this prospective, double-blinded, multirater, systematic replication study was to investigate agreement for aspiration risk, in the same individual, between videofluoroscopic swallow studies (VFSS) and the Yale Swallow Protocol. Participants were 25 consecutive adults referred for dysphagia testing who met the inclusion criteria of completion of a brief cognitive assessment, oral mechanism examination, and no tracheotomy tube. First, all participants were administered the Yale Swallow Protocol by two experienced speech-language pathologists trained in protocol administration. Failure criteria were inability to drink the entire amount, interrupted drinking, or coughing during or immediately after drinking. Second, all participants completed a VFSS within 5–10 min of protocol administration. A speech-language pathologist, blinded to protocol results, reviewed the VFSS to determine aspiration status in a binary (yes/no) manner. Inter-rater agreement between two speech-language pathologists was 100 % for identification of aspiration risk with the Yale Swallow Protocol. Inter-rater agreement between the speech-language pathologist and the radiologist for identification of aspiration status with VFSS was 100 %. Twenty percent of VFSS recordings were viewed again 3–6 months after initial data collection, and intrarater agreement for identification of thin liquid aspiration was 100 %. Sensitivity for the Yale Swallow Protocol = 100 %, specificity = 64 %, positive predictive value = 78 %, and negative predictive value = 100 %. Importantly, all participants who passed the protocol did not aspirate during VFSS. Multiple, double-blinded raters and VFSS as the reference standard agreed with previous research with a single, nonblinded rater and FEES as the reference standard for identification of aspiration risk. The clinical usefulness and validity of the Yale Swallow Protocol for determining aspiration risk in a small sample size of male participants has been confirmed. Future research is needed with a larger and more heterogeneous population sample.

Keywords Deglutition · Deglutition disorders · Screening · Aspiration · Videofluoroscopy

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Introduction

Inclusion of a 3-ounce (90 cc) water swallow as a component of a clinical swallow screen was first reported in a small cohort ($n = 44$) of patients in a rehabilitation setting due to stroke [1]. The task required drinking 3 ounces of water directly from a cup without interruption. Coughing during or up to 1 min after completion or a post-swallow, wet-hoarse voice quality indicated failure requiring a referral for objective dysphagia testing.

A recent study expanded upon and generalized use of a 3-ounce water swallow challenge with a larger and heterogeneous population sample of hospitalized individuals ($n = 3{,}000$) with 14 distinct admitting diagnoses [2]. Using

fiberoptic endoscopic evaluation of swallowing (FEES) as the reference standard, it was confirmed that the sensitivity of a 3-ounce challenge for predicting aspiration risk was 96.5 %, the negative predictive value was 97.9 % [2], and the false negative rate was ≤2.0 % [3]. Based on this work, an easily administered, reliable, and validated swallow screening protocol was subsequently developed, hereafter called the Yale Swallow Protocol [4]. It comprised a 3-ounce water swallow challenge [2], a brief cognitive assessment [5], and an oral mechanism examination [6] (see Appendices 1, 2, 3). Importantly, passing this protocol permitted successful, appropriate, and timely oral diet recommendations to be made without the need for further objective dysphagia testing for the vast majority of hospitalized patients regardless of their admitting diagnoses, i.e., trauma requiring intensive care [7], stroke [8], and general hospital, including medical, surgical, and cancer [9].

A limitation of this programmatic line of research was that FEES testing and interpretation were performed in real-time by a single nonblinded rater. This was mitigated, however, by strong post hoc confirmatory intra- and inter-rater reliability for identification of tracheal aspiration. Specifically, intra- and inter-rater agreements of FEES findings were performed with 128 additional participants. Two speech-language pathologists and one otolaryngologist experienced in interpreting FEES results independently and blindly reviewed the swallows on a digital swallowing workstation. Using real-time analysis with repeat viewing as needed, both intra- and inter-rater agreement ratings were 100 % for tracheal aspiration on at least one liquid or puree bolus swallow [6, 10].

In order to resolve methodology concerns related to a single nonblinded rater, corroboration via systematic replication is warranted, i.e., a study that replicates a previous study but also incorporates one or two variations in design [11]. Replication provides two basic functions essential for the substantive base of any scholarly field: verification or disconfirmation, i.e., a fact is not a fact until it is replicable [11]. Therefore, it would be of interest to replicate the protocol with multiple blinded raters and using a different reference standard, i.e., videofluoroscopic swallow study (VFSS). The purpose of this prospective, double-blinded, multirater, systematic replication study was to investigate agreement of aspiration risk between VFSS and the Yale Swallow Protocol.

Methods

Subjects

This study was approved by the Internal Review Board, Veterans Affairs Medical Center, Memphis, TN. Participants were 25 consecutive males (age range = 63–82 years, mean = 70 years) who were referred by their physician for diagnostic dysphagia testing and met the inclusion criteria of adequate cognitive ability to participate safely in a swallowing evaluation [5], completion of an oral mechanism examination [6], and no tracheotomy tube present at time of testing [7]. Table 1 lists participant diagnoses.

Procedures

First, all participants were administered the Yale Swallow Protocol prior to a VFSS by two experienced speech-language pathologists trained in protocol administration. The speech-language pathologists scored the protocol independent of and blinded to each other's ratings. Criteria for success was uninterrupted drinking (assisted or independent) of 3 ounces of water from a cup and without coughing. Criteria for failure were inability to drink the entire amount, interrupted drinking, or coughing during or immediately after drinking.

Second, all participants completed a VFSS within 5–10 min of protocol administration. A different speech-language pathologist and a radiologist, blinded to protocol results and each other's ratings, participated in and reviewed the VFSS independently to determine if tracheal aspiration occurred. Analysis of each test allowed for inter-rater agreement to be determined for both the VFSS and the Yale Swallow Protocol. Aspiration status was determined in a binary (yes/no) manner and defined as entry of material into the airway below the level of the true vocal folds [12].

All VFSS testing was performed with each participant seated upright in the fluoroscopy chair with the head and neck in the neutral position and the chest and abdomen in the true lateral plane (Legacy System, Model 2118104-4, General Electric, Milwaukee, WI). The fluoroscopy images included the lips anteriorly to the pharyngeal wall posteriorly, and the soft palate superiorly to the sixth cervical vertebra inferiorly. Swallowing was evaluated with Varibar thin liquid barium delivered via cup and pudding-thick barium delivered via spoon (E-Z-EM, Lake Success, NY). The presentation order was as follows: 5 mL thin liquid via

Table 1 Participant diagnostic categories

Diagnostic category	No. of participants
Esophageal surgery	2
Head and neck cancer	5
Neurosurgery	3
Medical	8
Neurological (CVA, MS, TBI)	7
Total	25

CVA cerebrovascular accident, *MS* multiple sclerosis, *TBI* traumatic brain injury

cup × 2; 10 mL thin liquid via cup × 2; discrete cup sip of thin liquid × 2; 5 mL pudding × 2; ½ graham cracker coated with pudding; and 3 ounces of thin liquid via cup.

A 2 × 2 contingency table was constructed to compare the results of the Yale Swallow Protocol with those of the VFSS. Inter-rater agreement between the speech-language pathologist and the radiologist for identification of thin liquid aspiration on VFSS and inter-rater agreement between the two speech-language pathologists for identification of thin liquid aspiration risk with the protocol were determined. Blinded intrarater agreement for identification of thin liquid aspiration on VFSS was performed on 5/25 (20 %) randomly selected participants 3–6 months after initial testing.

Results

Table 2 shows the 2 × 2 table for comparing results of the Yale Swallow Protocol to VFSS results. Seven participants passed and 18 failed the 3-ounce water swallow challenge part of the protocol. Of the 18 individuals who failed the protocol, 14 aspirated on VFSS (true positives) and four 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.

Inter-rater agreement for thin-liquid aspiration was 100 % for the speech-language pathologist and the radiologist on VFSS. Inter-rater agreement for thin-liquid aspiration was 100 % for the two speech-language pathologists on the protocol. Intra-rater agreement for the two speech-language pathologists for identification of thin-liquid aspiration during VFSS was also 100 %. Lastly, 20 % of VFSS recordings were viewed again in a blinded manner by the speech-language pathologists 3–6 months after initial data collection and intrarater agreement for identification of thin-liquid aspiration was 100 %.

Discussion

The clinical validity, reliability, and usefulness of the Yale Swallow Protocol to determine aspiration risk has been confirmed. Despite use of a small sample of male participants, there is no evidence that gender influences swallowing success when drinking 3 ounces of water [2]. Multiple, double-blinded raters and VFSS as the reference standard agreed with previous research with a single, nonblinded rater and FEES as the reference standard for identification of aspiration risk. The combination of 100 % sensitivity with 100 % negative predictive value indicates that when the protocol is passed the clinician can be confident that the patient is a minimal (<2 %) aspiration risk [3]. Therefore, this systematic replication study [11] has verified our previous research findings [2] by using videofluoroscopy in a small population of male patients.

These confirmatory data support use of the Yale Swallow Protocol to determine aspiration risk. Also, when using a different criterion standard, i.e., FEES, it was previously shown that when the protocol is passed, specific oral diets can be recommended in the vast majority of hospitalized patients without the need for further objective testing [2, 7–9]. This allows for safe, appropriate, and timely ingestion of oral nutrition, hydration, and medications [13]. When the protocol is failed, the patient is deemed an aspiration risk and either repeat protocol administration in 24 h or referral for objective diagnostic dysphagia testing with FEES or VFSS is recommended [2, 9].

The Yale Swallow Protocol meets the criteria of a simple clinical screen that can be used by a qualified healthcare professional to identify aspiration risk [14]. As suggested by Heffner [15], it is a simple swallow screening tool with known operating characteristics, i.e., 96.5 % sensitivity, 97.9 % negative predictive value [2], and ≤2.0 % false negative rate [3]. When combined with the clinical judgment of a qualified clinician, aspiration risk can be determined confidently in virtually all hospitalized patients who are potential candidates for oral intake [2, 7–9].

Table 2 2 × 2 contingency table comparing results of Yale Swallow Protocol to results of videofluoroscopic swallow study (VFSS)

	Aspiration on VFSS	
Yale Swallow Protocol	Positive	Negative
Positive	14	4
Negative	0	7

Sensitivity = $a/(a + c)$ = 14/(14 + 0) = 100.0 % (95 % CI = 81.2–100.0)

Specificity = $d/(b + d)$ = 7/(4 + 7) = 63.6 % (95 % CI = 39.7–63.6)

Positive predictive value = $a/(a + b)$ = 14/(14 + 4) = 77.8 % (95 % CI = 63.2–77.8)

Negative predictive value = $d/(c + d)$ = 7/(0 + 7) = 100.0 % (95 % CI = 62.5–100.0)

Positive likelihood ratio = sensitivity/(1 − Specificity) = 1.00/(1 − 0.636) = 2.75 (95 % CI = 1.35–2.75)

Negative likelihood ratio = (1 − sensitivity)/specificity = (1 − 1.00)/0.636 = 0.00 (95 % CI = 0.00–0.472)

The clinician has two choices if the Yale Swallow Protocol is failed. First, a FEES or VFSS can be done the same day to determine if unsuccessful sequential drinking is resolved by compensatory strategies, e.g., use of single small (5–10 cc) bolus volumes, positioning, or use of a modified consistency diet incorporating nectar-like thickened liquids [10]. Second, if objective testing is not immediately available, it is recommended that the patient remain nil per os (including medications) [16] and the protocol repeated in 24 h. This is a reasonable approach, as hospitalized patients often demonstrate rapid improvement in swallowing function [17]. If subsequently passed, diet recommendations may be confidently made without the need for further dysphagia testing. If a second swallow protocol is failed, objective endoscopic or fluoroscopic testing should be done to assess for safe oral alimentation and implementation of swallow strategies. In a prior study [2], 71 % of patients who failed a 3-ounce challenge and were assessed with FEES were nonetheless able to safely tolerate single small (5–10 cc) thin-liquid bolus volumes or a modified oral diet of nectar-like thickened liquids and puree consistency foods. The most common reasons that patients failed the Yale Swallow Protocol were generalized deconditioning, reduced endurance, and depressed cognitive functioning.

It is impracticable to perform the 3-ounce water swallow challenge simultaneous with VFSS because water is both invisible during fluoroscopy and has different taste and viscosity characteristics from thin liquid barium. However, all seven participants who passed the 3-ounce challenge also successfully drank 3-ounces of thin liquid barium. Therefore, all participants who passed the protocol, i.e., deemed to have no aspiration risk, also did not aspirate during VFSS.

There is one caveat. The Yale Swallow Protocol is not recommended for patients who require a tracheotomy tube for airway maintenance, ongoing mechanical ventilation, and pulmonary toilet. Although a tracheotomy and placement of a tracheotomy tube are not causal for aspiration [18, 19], if aspiration occurs it is often silent, resulting in a higher false-negative rate. Only objective testing with FEES or VFSS is recommended because silent aspiration occurs more frequently due to laryngeal desensitization from chronic aspiration of secretions [20–22]. All other hospitalized patients, however, are candidates for the protocol.

Strengths, Limitations, and Future Research

This study's major strengths were a randomized design, multiple blinded raters, consecutive participant accrual, and use of a different criterion standard, i.e., VFSS vs. FEES, to determine aspiration risk. Limitations of this study were use of a relatively small and referral-based population of male participants. Future research is needed with a larger and more heterogeneous population sample and to investigate longitudinal success of diet recommendations based on passing the Yale Swallow Protocol.

Conclusion

The clinical validity, reliability, and usefulness of the Yale Swallow Protocol for determining aspiration risk were confirmed. All participants who were deemed not to be an aspiration risk based on results of the protocol also did not aspirate during VFSS. Multiple, double-blinded raters and VFSS as the reference standard confirmed previous research that used a single, nonblinded rater and FEES as the reference standard [2]. These combined results provide strong support for use of the Yale Swallow Protocol to determine aspiration risk in the vast majority of hospitalized patients referred for a swallowing assessment.

Conflict of interest None of the authors have a conflict of interest to declare.

Appendix 1: 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 of 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 °
__ __ Tracheotomy 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.

Appendix 2: Yale Swallow Protocol

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 the 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 (90 cc) 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 [5] and oral mechanism examination [6] provide information on odds of aspiration risk with the 3-ounce water swallow challenge and should not be used as exclusionary criteria for screening.

Appendix 3: Yale Swallow Protocol

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.

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