VALIDATION OF THE SAFE:

A Prospective, Double-Blind, Comparison of the Findings of The Swallowing Ability and Function Exam (The SAFE) and Fiberoptic Endoscopic Evaluation of Swallowing (FEES)

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About the presenter

- SLP for seven years
- Experience in the school setting, skilled nursing facilities, and critical illness recovery hospital (LTACH)
- Certified endoscopist for the purpose of Fiberoptic Endoscopic Evaluation of Swallowing (FEES)
- Areas of interests: swallowing and swallowing disorders, swallowing research
- No disclosures

Learning Objectives

1. Understand the validity of The SAFE for use in bedside swallowing evaluations.
2. Understand the importance of using validated bedside measures.
3. Understand the limitations of bedside swallowing evaluations for the diagnosis of dysphagia.
4. Understand the importance of utilizing instrumental swallow studies for the diagnosis of dysphagia.

What is The SAFE?

- The Swallowing Ability and Function Examination
- A standardized protocol for the clinical or bedside evaluation of swallowing
- Last published by Pro-Ed in 2003
- By Peggy Kipling and Debra Ross-Swain
- The sample characteristics on which the assessment was developed included 159 individuals from California and Texas aged 32 – 99, diagnosed with dysphagia.

The Swallowing Ability and Function Evaluation (The SAFE)

The SAFE consists of three stages:

1. General information related to swallowing ability.
2. Physical examination of the oropharyngeal mechanism.
3. Functional analysis of swallowing:
   - Oral phase
   - Pharyngeal phase

This research focused solely on the pharyngeal phase subtest.

The Swallowing Ability and Function Evaluation (The SAFE)

- "…based on the findings of the latest research in swallowing disorders…"
- "…identify specific problems during the oral and pharyngeal stages of swallowing…"
- "…suggest the need for referral to other professionals for further assessment…"
- "…for periodic reevaluation and assessment of progress in therapy…"
- "…to serve as a research tool…"
- "When administered before and after skilled dysphagia intervention, it's results can be used to establish the efficacy of various therapies on swallowing ability."
- "…results help generate treatment plans…"
- "…designed to assist in providing a definitive diagnosis or label of dysphagia…"

(Kipling & Ross-Swain, 2003)

Recent literature has shown that bedside evaluations poorly assess pharyngeal swallowing, dysphagia, and aspiration.

- BSEs frequently over and under-identify dysphagia, and therefore cannot be used to replace instrumental assessments to diagnosis dysphagia and aspiration (Steele et al, 2011; Vose et al, 2017).
- Nor do they provide critical information on the pathophysiologies responsible for dysphagia that is necessary to provide effective clinical intervention (Rosenbek et al, 2004).
- Despite this evidence, many clinicians underuse (or may lack access to) instrumental examinations in favor of self-developed assessment techniques when making clinical decisions and recommendations (Carnaby & Harenberg, 2013).

The SAFE is not validated!

Validation is the extent to which a test measures what it claims to measure, it is the test's ability to differentiate persons with and without a specified disorder (Heale & Twycross, 2015).

The SAFE manual cites content and construct validity, yet these methods that are typically employed when no gold standard exists, and adequate substitutes are not available (Guyatt et al, 1986).

The SAFE lacks criterion-related validation, which compares a test to a gold-standard that measures the same variable. An important subset of criterion validity is convergent validity, in which a test highly correlates with the gold-standard criterion (Heale & Twycross, 2015).

For a subjective assessment like The SAFE to truly be validated, it needs to be compared to another objective measurement tool for sensitivity, specificity, and positive/negative predictive value to be calculated.

Without strong sensitivity, specificity, and negative predictive value, an evaluation is lacking in clinical utility (Steele et al, 2011), and one cannot know that the assessment measures what it is affirmed to measure.

SLPs Need Validated Measures for Assessing Swallowing at the Bedside.

- To determine whether the condition of interest, dysphagia, is likely present.
- To assist the clinician in predicting possible impairments and form hypotheses about the possible nature of the patient's dysphagia.
- To add to the value of instrumentation by weaving together several discrete components to produce an overall diagnostic impression.

(Coyle, 2015)

SLPs Need Validated Measures for Assessing Swallowing at the Bedside

- For identifying patients in need of videofluoroscopic and/or endoscopic evaluation of swallowing.
- To reduce over/under referring for instrumentation.
- To determine which gold-standard test, or perhaps both, is/are indicated by the patient's bedside performance.
- To determine improvement or decline in patient swallowing performance as treatment progresses.

Validated Bedside Assessments

- Mann Assessment of Swallowing Ability
  - *Adequate sensitivity, originally validated against VFSS on the CVA population, later validated in a mixed disease population, both studies in the acute care setting (*Girarldo-Cadavid et al, 2020; *Mann, 2002)*
- TOR-BSST
  - *Adequate sensitivity, validated on CVAs only* (Martino et al, 2009)
- Barnes Jewish Hospital Dysphagia Screener
  - *Adequate sensitivity, validated on CVAs only* (Edmiaston et al, 2014)
- Yale Swallow Protocol
  - *Excellent sensitivity, validated on heterogenous population in the acute and post-acute settings* (Suiter et al, 2014; Ward et al, 2020)
- (Be cautious about applying tests to populations for which the test has not been validated on.)

HOW DOES THE SAFE, A SUBJECTIVE ASSESSMENT WHICH HAS NOT BEEN VALIDATED, CORRELATE WITH FEES, AN OBJECTIVE ASSESSMENT?

Method

- Prospective, double-blind design
- The facility was comprised of two short term rehab units, two long term care units, and one assisted living unit.
- Written consent from patients or their power of attorney
- Each participant received serial administration of The SAFE followed by FEES.
- FEES is a gold standard for the evaluation and diagnosis of dysphagia that allows visualization of the bolus, anatomical sites, and vocal fold function, and is a highly sensitive tool for the detection of residue (Langmore et al, 1988; Pisegna & Langmore, 2016).
- Should a high percentage of The SAFE results predicting dysphagia, indeed have pharyngeal dysphagia confirmed by endoscopy, that will be thought to indicate a close correlation to instrumentation and then provide validity to The SAFE.

Participants

- Patients were referred from failed swallowing screens upon admission or patient/staff report of new or worsening symptoms of dysphagia.
- Participants ranged in age from 46 – 95 years, 65% were male, and 35% were female.
- Disease processes included: cerebrovascular accident 30%, falls/generalized weakness 20%, dementia 15%, COPD 15%, infection 15%, and other 5%.

Administration of The SAFE

One speech-language pathologist administered The SAFE to the patient on the same day as and prior to completion of the endoscopic examination of swallowing.

Testing on the same day allowed for control of improved medical status and treatment effect from any interventions the patient had received.

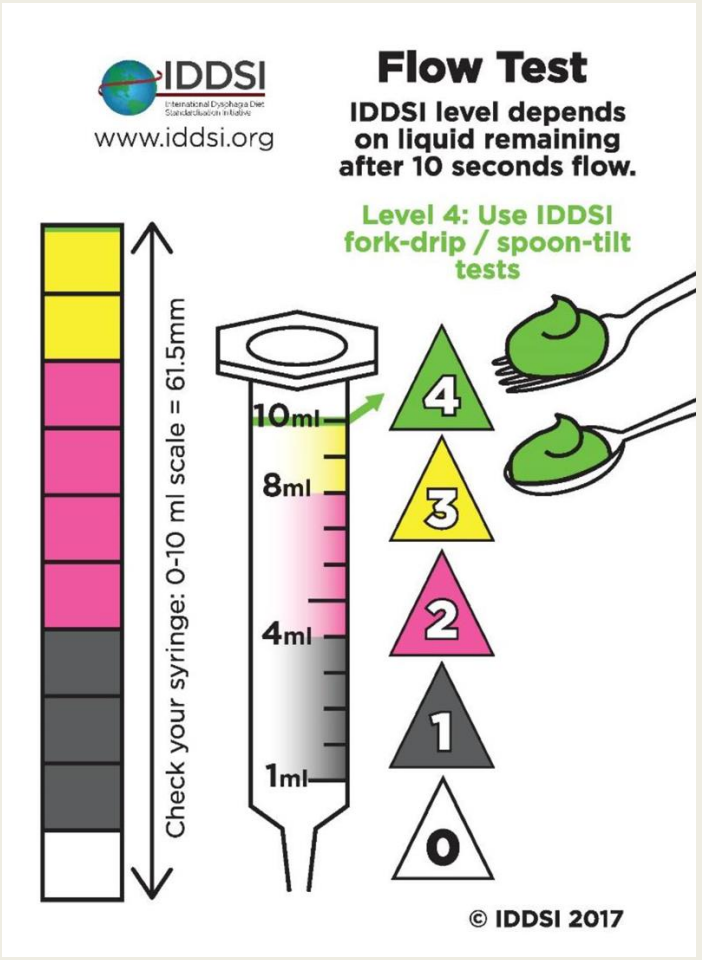
The clinician administering The SAFE was blinded to FEES results, and the endoscopist administering the FEES was blinded to results from The SAFE.

Administration of The SAFE

- Protocol:
  - *1/3 tsp (about 3ml) water presented from a spoon*
  - *Ice chip presented from a spoon*
  - *Sip of nectar/mildly thick liquid from a spoon*
  - *Sip of nectar/mildly thick liquid presented from a cup*
  - *Sip of thin liquid from a cup*
  - *Bite of purée presented from a spoon*
  - *Bite of “custard” presented from a spoon*
  - *Bite of cracker*

Administration of The SAFE

- IDDSI Testing
  - *Flow testing for thin and mildly thick liquids*
  - *Spoon drip test for purée/custard*
  - *Fork-pressure test for cracker- qualifies as “transitional” food*
- Consideration of fat content and temperature for thickened liquids and “custard”



Administration of The SAFE

- Subscale 3: Pharyngeal Phase Swallowing Evaluation
  - *Delay at the pharyngeal level*
  - *Laryngeal elevation*
  - *Coughing/choking before/during/after the swallow*
  - *Repeated swallows*
  - *Complaints of food being “stuck”*
  - *Hoarse/gurgly/wet voice following swallow*
  - *Regurgitation/expectoration of food*

Administration of The SAFE

- Score each item within pharyngeal phase swallowing evaluation (Subscale 3)
- Numerical score of 0 – 3:
  - *0: Severe impairment*
  - *1: Moderate impairment*
  - *2: Mild impairment*
  - *3: Within functional limits*
- Add up for total score on Subscale 3
- Can convert raw score to stanine, percentile rank, and descriptive severity rating

Cervical Auscultation and Pulse Oximetry

- It is recommended that therapists familiar with cervical auscultation and pulse oximetry procedures utilize these techniques during administration of The SAFE.
- However, given the poor reliability of the detection of abnormal swallowing and aspiration using cervical auscultation and pulse oximetry, both measures were excluded (Leslie et al, 2004; Sellers et al, 1998).
- What cervical auscultation can detect and what it contributes to the CSE is not established in the literature (Leslie et al, 2004).
- There is a wide range of auscultation patterns in asymptomatic, healthy people (Leslie et al, 2007).

Cervical auscultation and pulse oximetry

- Interpretation of cervical auscultation is often based more on other aspects of the clinical assessment, medical notes, and previous knowledge (Leslie et al, 1998).
- Sellars, et al, found no clear-cut relationship between changes in arterial oxygenation and aspiration (1998).
- Aspiration does not change SpO2, regardless of the patient's need to receive supplemental oxygen (Leder, 2000).
- A systematic review completed by Britton, et al, found that most studies on pulse oximetry for the detection of aspiration fail to demonstrate an association between observed aspiration and oxygen desaturation (2018).
- Current evidence does not support the use of pulse oximetry in bedside dysphagia assessments (Britton et al, 2018).

FEES Administration

- SA Swallowing Services, PLLC
- A standard protocol for bolus size and number of trials of food and drink consistencies was used with deviation only occurring when trialing compensatory strategies, apprehension regarding patient safety surfaced, or the patient was unable to tolerate the full protocol.
- Video was reviewed using frame-by-frame analysis at a rate of 30 frames per second. Frame-by-frame analysis is necessary for accurate identification of biomechanical impairments underlying a patient's dysphagia, aspiration, and laryngeal penetration (Vose et al, 2018).

Results

- Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated utilizing a two-by-two contingency table.
- 10 subjects were identified as having dysphagia on The SAFE, and 10 were negative for dysphagia on The SAFE.

	Positive on FEES	Negative on FEES
Positive on SAFE	8	2
Negative on SAFE	6	4

Results

True positive = risk for dysphagia identified on SAFE and pharyngeal dysphagia confirmed on FEES

False positive = risk for dysphagia identified on SAFE and pharyngeal swallowing WNL on FEES

False negative= WNL on SAFE and pharyngeal dysphagia confirmed on FEES

True negative= no risk for pharyngeal dysphagia identified on SAFE, pharyngeal swallowing WNL on FEES

Results

Sensitivity was 57%

Specificity was 67%

Positive Predictive Value was 80%

Negative Predictive Value was 40%

Discussion- Sensitivity

Sensitivity and specificity are diagnostic efficiency statistics that evaluate a condition, which in this study was pharyngeal dysphagia.

They are fixed properties of a test that should not change regardless of the characteristics of the population being studied (Streiner, 2003).

Sensitivity is the proportion of people who have the attribute (in this case, pharyngeal dysphagia), who are also detected by the test (The SAFE) (Streiner, 2003).

Discussion- Sensitivity

This study revealed The SAFE to have a sensitivity of 57%, indicating that only 57% of participants who did indeed have pharyngeal dysphagia, were correctly identified as having such during bedside assessment using The SAFE.

These results indicate that The SAFE is not clinically useful and a therapist aiming to decide if their patient is at risk for dysphagia, might as well flip a coin.

Discussion- Specificity

- Specificity is the proportion of people without the attribute who are correctly identified as not having the disease on the test (Streiner, 2003).
- Specificity for The SAFE was 67%, therefore, 67% of patients that did not have dysphagia during FEES, also did not have risk for dysphagia on The SAFE.
- Often when a screening tool presents with low sensitivity, it will result in high specificity, providing it with a useful component. Unfortunately, this was not the case for this assessment.

Discussion- Positive Predictive Value

- Positive and negative predictive value (PPV, NPV) investigate the results of the test and will be variable based upon the population/prevalence of the disorder (Streiner, 2003).
- Screening tests work best when prevalence of the disorder is 50%.
- The prevalence of dysphagia in this group of subjects was 70%.
- PPV for The SAFE was 80%, indicating that if a patient scores positive for dysphagia on The SAFE, there is an 80% chance they will be diagnosed with pharyngeal dysphagia under endoscopy.
- This is the single statistical area where The SAFE may be helpful, in that if a patient scores as positive for dysphagia on The SAFE, there is an 80% chance that they do indeed have pharyngeal dysphagia.

Discussion- Negative Predictive Value

- NPV for The SAFE was 40%, indicating that if a patient is negative on this test, they still very well may have dysphagia.
- With the increased prevalence of dysphagia (70%) in this cohort, clinical utility of PPV and NPV may be limited (Streiner, 2003).
- When prevalence of a disease is high, as it is in this study, it is best to use a test to rule in a disease and not rule it out (Streiner, 2003). The SAFE can be used for neither of these purposes, as sensitivity and specificity were low, and PPV may be inflated by the increased prevalence of dysphagia in this group of skilled nursing facility patients.

Discussion- Aspiration

- Of note, the prevalence of aspiration in this cohort was calculated to be 35%.
- Sensitivity for detecting aspiration was 43%.
- This highlights the need for instrumental imaging of the swallow for detection of dysphagia and aspiration given the frequent sub-clinical nature of aspiration and dysphagia. Unfortunately, The SAFE was even worse at detecting aspiration than dysphagia.
- Given the severe consequences that can result from pharyngeal dysphagia and aspiration, a test that results in a high number of false negatives is quite alarming and lacks clinical utility. When medical complications secondary to a disorder such as dysphagia are serious in nature (i.e., pneumonia and malnutrition), a screening test that would result in over-referral, or a high number of false positives is preferred.

Limitations

Limitations included small sample size, as well as the sample of patients only coming from one level of care, a skilled nursing facility. A larger sample size and patients enrolled from multiple levels of care would strengthen the results.

Additionally, the high prevalence of dysphagia in the cohort is somewhat limiting, as it impacts PPV and NPV.

Conclusion

- The Swallowing Ability and Function Examination poorly correlates to fiberoptic endoscopic evaluation of swallowing.
- It is not a sensitive test to use for the assessment of dysphagia at the bedside, nor is it specific for ruling out dysphagia.
- It results in frequent false negatives that would leave many dysphagic patients undiagnosed and at increased risk for poor outcomes.
- The contention from the manual that The SAFE can be utilized to make treatment recommendations is highly concerning.

Conclusion

- The results of this study are similar to other papers that investigated sensitivity for common bedside measures using instrumental swallow studies as the criterion reference.
- McCullough et al compared several components of CSEs that are like the scored aspects of The SAFE, for example, wet vocal quality, to video fluoroscopy swallow study (VFSS) results in 2005, revealing sensitivity for detecting aspiration at the bedside to be 54%.
- Steele et al in 2011 also found “overt” symptoms of aspiration and thin liquid trials at the bedside to lack appropriate sensitivity/specificity for the detection of dysphagia. As it has been well established in the literature that validated screeners are a crucial component of case-finding dysphagia for best patient outcomes, and given the results of this study, The SAFE should not be utilized for screening, bedside assessment, and particularly not for diagnosis and/or treatment planning.

Conclusion

- CSEs are meant to separate patients who may have dysphagia from those who do not and are not diagnostic in nature (Steele et al, 2011).
- In order to appropriately identify dysphagia and aspiration and prescribe rehabilitative and compensatory measures, a clinician must identify specific biomechanical deficits underlying a patient's dysphagia.
- This is done via videofluoroscopic swallow studies (VFSS) and/or fiberoptic endoscopic evaluations of swallowing (FEES) (Kelly et al, 2007; McCullough et al, 2005; Rangarathnam & McCullough, 2016; Rosenbek et al, 2004; Steele et al, 2011; Vose et al, 2018; Vose & Humbert, 2019; Ward et al, 2020).

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