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Aspiration Risk After Acute Stroke: Comparison of Clinical Examination and Fiberoptic Endoscopic Evaluation of Swallowing

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Abstract. Aspiration is an important variable related to increased morbidity, mortality, and cost of care for acute stroke patients. This prospective systematic replication study compared a clinical swallowing examination consisting of six clinical identifiers of aspiration risk, i.e., dysphonia, dysarthria, abnormal gag reflex, abnormal volitional cough, cough after swallow, and voice change after swallow, with an instrumental fiberoptic endoscopic evaluation of swallowing (FEES) to determine reliability in identifying aspiration risk following acute stroke. A referred consecutive sample of 49 first-time stroke patients was evaluated within 24 hours poststroke, first with the clinical examination followed immediately by FEES. The endoscopist was blinded to results of clinical testing. The clinical examination correctly identified 19 subjects with aspiration risk, when compared with the criterion standard FEES, but incorrectly identified 3 patients as having no aspiration risk when they did. The clinical examination incorrectly identified 19 subjects with aspiration risk but determined correctly no aspiration risk in 8 patients who did not exhibit aspiration risk on FEES. Clinical examination sensitivity = 86%; specificity = 30%; false negative rate = 14%; false positive rate = 70%; positive predictive value = 50%; and negative predictive value = 73%. It was concluded that the clinical examination, when compared with FEES, underestimated aspiration risk in patients with aspiration risk and overestimated aspiration risk in patients who did not exhibit aspiration risk. Careful consideration of the limitations of clinical testing leads us to believe that a reliable, timely, and cost-effective instrumental swallow evaluation should be available for the majority of patients following acute stroke.

Key words: Stroke — Aspiration — Predictors — Swallowing evaluation — Deglutition — Deglutition disorders.

Aspiration is an important variable related to increased morbidity, mortality, and cost of care for acute stroke patients [1–5]. Although dysphagia has been shown to resolve for many patients within approximately 14 days poststroke [1], determination of aspiration risk during this critical acute phase may prevent pulmonary complications and allow for implementation of appropriate therapeutic interventions to allow for earlier and safer oral intake. The potential to reduce morbidity, mortality, and cost associated with aspiration pneumonia in the acute stroke population, however, is predicated upon reliable information regarding aspiration and aspiration risk.

Prediction of aspiration risk using clinical markers has had varying success [6–12]. Instrumental evaluations, however, identified aspiration in approximately 25% more of the same stroke populations than clinical evaluations [6,7,11,12]. The high incidence of silent aspiration, i.e., 28%–52% [13–16], is one specific reason why clinical examinations have been unreliable predictors of aspiration risk.

A reliable, repeatable, data-based, and cost-effective clinical test with acceptable risk assessment values to test for the presence of aspiration risk is

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needed [17,18]. The purpose of this systematic replication study [19], i.e., replication of a study with minimal variations in design, was to determine if a clinical swallowing examination consisting of six identifiers of aspiration risk, i.e., dysphonia, dysarthria, abnormal gag reflex, abnormal volitional cough, cough after swallow, and voice change after swallow [12], would have acceptably high risk assessment values to predict aspiration risk in the acute stroke population when compared with an instrumental fiberoptic endoscopic evaluation of swallowing (FEES) [20,21].

Methods

Subjects

In a prospective manner, 53 consecutive stroke patients referred by neurology to speech–language pathology for swallowing evaluations were included. Criteria for inclusion were a first-time embolic cerebrovascular accident (CVA), evaluation within 24 hours of admission, determination of the site of the lesion by a board-certified neurologist based on computed tomography (CT) or magnetic resonance imaging (MRI) scans, adequate mental status, i.e., alert and following one-step commands, and ability to complete first the clinical examination and then FEES consecutively. A total of 49 subjects met the criteria (Table 1).

Equipment

Equipment consisted of a 3.6-mm-diameter flexible fiberoptic rhinolaryngoscope (Olympus, ENF-P3), endoscope sheaths (Vision Sciences), light source (Olympus, CLK-4), camera (ELMO, MN401E), and color monitor (Magnavox, RJ4049WA01).

Procedures

As described previously [12], one examiner determined if dysphonia, dysarthria, abnormal volitional cough, and abnormal gag reflex were present. Cough after swallow and voice change after swallow (by phonating "ah") were also scored as either present or absent following single water bolus swallows via straw. No aspiration risk was defined as ≤1 variable identified and aspiration risk was defined as ≥2 variables identified [12].

All subjects had a FEES [20,21] immediately following the clinical examination. Aspiration was defined as the entry of material into the airway below the level of the true vocal folds [22]. Aspiration risk occurred when there was significant spillage or residue of a food bolus into the valleculac, pyriform sinuses, or laryngeal vestibule [20,21]. The endoscopist was blinded to the results of clinical testing.

The standard FEES protocol was followed with slight modifications [20,21]. Briefly, each naris was examined and the scope passed through the most patent naris without administration of a topical anesthetic or vasoconstrictor to the nasal mucosa, thereby eliminating any potential adverse anesthetic reaction and assuring the endoscopist of a safe physiologic examination [23]. The base of the tongue, pharynx, and larynx were viewed and swallowing was evaluated directly with approximately 5-mL-volume food boluses dyed with blue food coloring for contrast. The first food consistency introduced was puree (custard), followed by liquid (milk), and then a solid bolus (cracker), if adequate dentition was present.

Table 1. Subject characteristics

	Left stroke	Right stroke	Bilateral strokes	Total
Males	7	8	5	20
Females	11	9	9	29
Total	18	17	14	49
Mean age (yr)	68	71	72	70

Statistical Analysis

FEES results served as the outcome variable and was the criterion standard to which the six clinical identifiers of aspiration risk were compared. The diagnostic value of a test can be expressed by means of its sensitivity and specificity. Sensitivity is the probability that a diagnostic sign will be positive given that a disease (aspiration risk) is truly present. Specificity is the probability that a diagnostic sign will not be positive given that a disease is truly not present. Predictive value is the chance that persons with a certain test score actually have the disease. A positive predictive value describes which part of the persons under study with a positive test score actually have the disease. A negative predictive value describes which part of the persons under study with a negative test score are healthy. The false negative rate is 1 − sensitivity and is the proportion of disease (aspiration risk) missed by the test. (The false negative rate is almost impossible to calculate under field conditions because persons who test negative are not investigated further and whether they are truly free of disease is not known.) The false positive rate is 1 − specificity and is the proportion of disease-free subjects testing positive by the test. (The false positive rate is more straightforward since persons testing positive are usually thoroughly investigated.)

Results

Table 2 shows sensitivity and specificity values, positive and negative predictive values, and false negative and false positive rates for aspiration risk as determined by comparing the clinical examination with FEES. Since the sample size of the present study was relatively small and aspiration risk as determined by FEES relatively stable, i.e., 4/18 (22%) left CVA, 9/17 (53%) right CVA, and 9/14 (64%) bilateral CVA, the data were pooled and treated statistically as a single sample. The clinical examination correctly identified 19 subjects with aspiration risk, when compared with

Table 2. Comparison of aspiration risk between a clinical swallowing examination and fiberoptic endoscopic evaluation of swallowing (FEES)

	Aspiration risk with FEES		No aspiration risk with FEES		Total
Positive clinical Examination (≥ 2 variables identified)	19	(*a*)	19	(*b*)	38
Negative clinical Examination (≤1 variables identified)	3	(*c*)	8	(*d*)	11
	22		27		49

Sensitivity = $a/(a + c)$ = 19/22 (86%)
Specificity = $d/(b + d)$ = 8/27 (30%)
Positive predictive value = $a/(a + b)$ = 19/38 = 50%
Negative predictive value = $d/(c + d)$ = 8/11 = 73%
False negative rate = 1 − Sensitivity = 1 − 86% = 14%
False positive rate = 1 − Specificity = 1 − 30% = 70%

the criterion standard FEES, but incorrectly identified 3 subjects as having no aspiration risk when they did. The clinical examination incorrectly identified 19 subjects with aspiration risk but determined correctly no aspiration risk in 8 patients who did not exhibit aspiration risk on FEES. Sensitivity of the clinical examination = 86%; specificity = 30%; positive predictive value = 50%; negative predictive value = 73%; false negative rate = 14%; and false positive rate = 70%.

In the no-risk-of-aspiration groups, dysarthria and abnormal volitional cough were the two most frequently cited clinical identifiers. In the risk-of-aspiration groups, dysarthria, abnormal volitional cough, and abnormal gag reflex were the three most frequently cited clinical identifiers.

Discussion

The present study found that a clinical examination [12], when compared with FEES [20,21], underestimated aspiration risk in patients with aspiration risk and overestimated aspiration risk in patients who did not exhibit aspiration risk. These results are in agreement with both a recent investigation of swallowing disorders following acute stroke [24] and previous research reporting that instrumental evaluations identified aspiration in approximately 25% more of the same stroke populations than clinical evaluations [6,7,11,12]. Silent aspiration, which cannot be detected by clinical evaluation [11], may contribute to poor clinical prediction of aspiration risk because in both large prospective [14,15] and retrospective [16] instrumental swallowing studies, incidence of silent aspiration in patients referred for swallowing evaluations in acute-care hospitals was between 25% and 30%.

The clinical consequences of a high false positive rate with low specificity are that oral feedings and medications are incorrectly withheld in a large number of patients until an instrumental test is performed. If videofluoroscopy is used, scheduling delays may occur, possibly resulting in placement of a nasogastric feeding tube prior to testing. If the patient is agitated, restraints may then be required to maintain tube placement contributing to social isolation and distress. FEES is ideally suited for testing because it is portable and done at bedside, thereby allowing timely scheduling for both the endoscopist and patient, requires approximately the same amount of time as a clinical examination, uses less personnel than fluoroscopic evaluations, and is more cost effective than videofluoroscopy [15,20,26]. Time, money, and effort, therefore, are saved without sacrificing accuracy.

Although we are in agreement with the suggestion that swallowing be assessed in all acute stroke patients [25], there is no consensus in the literature regarding either the best type of swallowing assessment to use, i.e., clinical or instrumental, or what specific characteristics acute stroke patients should have in order to benefit from either type of testing. Depending on the questions asked and each clinician's tolerance for inaccuracy, a clinical examination may or may not be suitable to use. If the clinical examination's purpose is only to decide when to refer for an instrumental evaluation, then 86% sensitivity in detecting aspiration risk in patients who are at risk may be acceptable. However, since instrumental evaluations identified aspiration in approximately

25% more of the same stroke populations than clinical evaluations [6,7,11,12], one must accept the fact that a certain percentage of patients at risk to aspirate will be missed. It is up to the individual clinician to decide on the cutoff point of his/her tolerance for inaccuracy. We feel that for a clinical examination to gain widespread acceptance and use, it should have a sensitivity of 95% or greater.

The most frequently cited clinical identifiers of dysphagia were dysarthria, abnormal volitional cough, and abnormal gag reflex. There are concerns, however, that these identifiers may not be good predictors of aspiration risk. Possible reasons for the poor predictive value of clinical examinations [6,7,11,12] are use of predictor variables that have been shown to be either unrelated to swallowing success, e.g., the gag reflex [27–29], or unreliable indicators of laryngeal penetration and aspiration, e.g., wet voice quality [30]. In addition, unsubstantiated correlations, e.g., dysarthria with dysphagia, and weak inter- and intraexaminer reliability, e.g., identification of an abnormal volitional cough, contribute to inaccuracies associated with clinical assessment [18].

One variable that may be of importance in determining type of testing following acute stroke is mental status. Mental status, however, was not included in the clinical examination [12] used in the present study. If resolution of mental status occurs rapidly poststroke, a clinical examination may be appropriate. If mental status changes persist, an instrumental examination may be warranted to determine aspiration risk and make recommendations for therapeutic interventions. More research is needed in this area to determine (1) if mental status is a key variable for swallowing outcome and (2) what specific types and severities of mental status changes impact on swallowing success.

Another question concerns use of a clinical examination to make recommendations for oral feeding. This is, in reality, done all the time, but there is very little evidence to support or reject this practice [4]. What is needed is a prospective, randomized, double-blind trial in which specific recommendations for oral feeding based on a clinical examination are implemented for a given time period. Outcome variables might include aspiration pneumonia, caloric intake, hydration, and need for an instrumental evaluation. However, until this information is available, we feel that even if the clinical examination is negative, visualization of the pharyngeal swallow is necessary. Visualization allows for accurate diagnostic information, e.g., silent aspiration can be determined only by visualization [6,11], and appropriate recommendations for safer oral feeding strategies, e.g., bolus consistency, swallowing steps, and positioning [26].

More research is needed to refine the clinical swallow examination in order to predict aspiration risk more accurately and decrease the false positive rate, i.e., overreferrals, in an effort to decrease health care costs without compromising patient care. How can this be done? The statistical power of the clinical examination must be improved, e.g., increase sample size in order to use multivariate modeling to determine which elements yield results that might be combined for better predictive values. Additional novel predictor variables need to be tested, e.g., mental status. Clinical examinations must be developed that target specific diagnostic categories. An examination suitable for patients with acute stroke may not be suitable for patients in nursing homes, requiring ventilator support, or with traumatic brain injury. Also, a clinical examination should be developed for the pediatric population and, perhaps, subsets in the pediatric population based on age or maturation level.

In addition, timing of a swallow evaluation may be important relative to aspiration risk. The patients in the present study were evaluated within 24 hours poststroke. Since it has been shown that dysphagia and aspiration risk decrease the longer the time period after the stroke [1,2], the results of either a clinical or instrumental assessment may be influenced by when in the recovery process they are performed. Investigation of the optimum time to perform a swallow evaluation is needed. Should evaluations be done within 24 hours or should the patient be evaluated at 48, 72, or 96 hours poststroke? This will require patients to take no nutrition by mouth during this time period and have their hydration monitored carefully. Also, do the results of a swallow evaluation change in the first few days poststroke, and, if so, does type of stroke matter? Since dysphagia has been shown to be an independent predictor of outcome following stroke [4], information regarding changes in swallow function may be useful in predicting both short- and long-term swallowing success as well as general stroke recovery.

Subject selection bias in the present study cannot be ruled out because the neurology service was the referral source. Acute stroke patients at both ends of the continuum were not referred for swallowing evaluations, i.e., they were either considered neurologically intact and in no need of a swallowing evaluation or too obtunded to be able to participate in a swallowing evaluation. The referrals, however, were biased toward swallowing disorders, as these were the patients neurology felt needed formal swallowing evaluations. Future research will include all

admissions to the neurology service in order to obtain a more comprehensive picture of swallowing behaviors following acute stroke.

Conclusion

Careful consideration of the above issues leads us to believe that a reliable, timely, and cost-effective instrumental swallow evaluation remains the most appropriate technique to determine aspiration risk following acute stroke. Additional work is needed in the area of clinical examination in order to improve risk assessment before its widespread acceptance and use occur.

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