Doctoral Thesis

Oropharyngeal dysphagia after stroke: assessment and treatment

Anna Guillén-Solà

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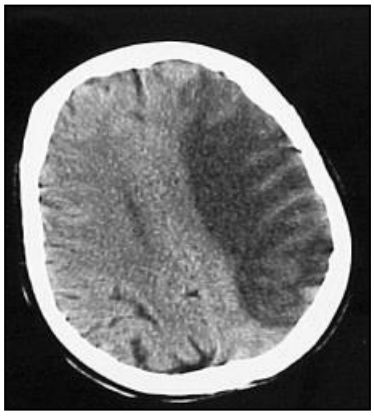
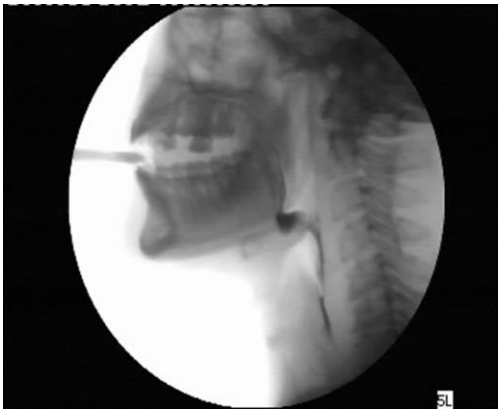
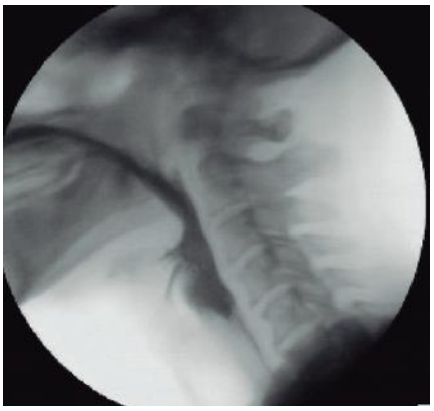

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FAN CONSTAR:

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SUMMARY

SUMMARY page

0 ABBREVIATIONS

- CCT: Citric cough test
- EMT: Expiratory muscle training
- FEES: Flexible endoscopic evaluation of swallowing
- GUSS: Gugging swallowing screen
- HRM: High resolution manometry
- IC: Interval of confidence
- IEMT: Inspiratory and expiratory muscle training
- MASA: Mann assessment of swallowing ability
- MMASA: Modified Mann assessment of swallowing ability
- NMES: Neuromuscular electrical stimulation
- NPO: Nil per mouth
- NPV: Negative predictive value
- OR: Odds ratio
- PAS: Penetration-aspiration scale
- PEmax: Maximal expiratory measure
- PImax: Maximal inspiratory measure
- PPV: Positive predictive value
- RMT: Respiratory muscle training
- UES: Upper esophageal sphincter
- TOR-BSST: Toronto bedside swallowing screening test
- VFSSS: Videofluoroscopic swallowing study
- VMBS: Videofluoroscopic modified barium swallow
- V-VST: Volume-Viscosity swallow test
- WST: Water swallow test

1 INTRODUCTION

1.1 Dysphagia after stroke: what is the relevance?

1.1.1 Dysphagia and aspiration post-stroke. Epidemiology.

Oropharyngeal dysphagia is a common morbidity in stroke survivors and it is associated with increased mortality and morbidity such as malnutrition, dehydration and respiratory complications (1)(2)(3)(4)(5). In Catalonia, there are 15,000 strokes per year, 60% of which will attend some type of physical or cognitive sequel. Eighty percent of strokes are secondary to ischemia, and hemorrhage accounts for 20%. Dysphagia has an impact on patients with acute stroke ranging from 29 to 67% (2)(6), depending on series and decreases around 20-25% at 6 months post-stroke (5). This variability is due to the definition of dysphagia, evaluation methods used, time post-onset or patient selection methods (7).

Bronchoaspiration after stroke represents the most visible symptom of dysphagia. Both bronchoaspiration and dysphagia are associated to lung infections and death, hospital stays and healthcare costs (8)(9). Bronchoaspirative pneumonia is the second cause of death during the acute phase of stroke, reaching 20% mortality along the first year after stroke onset (10)(11) and aspiration represents an 11-fold increased risk of lung infections in stroke survivors (2)(12). Available evidence suggests that screening dysphagia in the early stages of stroke onset reduces the risk of bronchoaspiration and is essential to determine the best therapeutic strategies.

1.1.2 Normal swallowing and relationship between aspiration, dysphagia and pneumonia in the rehabilitation early stage of stroke

Normal swallowing consists of four sequential and coordinated phases: oral preparatory phase, the oral propulsive phase, the pharyngeal phase and the esophageal phase (7)(13).

Dysphagia after stroke is defined as incoordination, delayed and reduced function of swallowing muscles, mainly the pharyngeal muscles (14)(15), as a consequence of the loss of central nervous system control; in fact, specific cortical lesions seem to be related to the presence of dysphagia and aspiration (16). Difficulty for swallowing pills, drooling, loss of food from mouth, reflux or pocketing on food in cheeks are frequent signs observed in the clinical practice (10).

Aspiration is the entry of food material below the true vocal folds. Some studies have suggested the relationship between dysphagia and pneumonia with aspiration of food or liquids (10)(17)(18). Changes in voice quality, coughing during or after feeding, delay in swallow reflex might be clinical manifestations of aspiration (9). **Silent aspiration** is the presence of food or liquids below the true vocal folds without any symptoms, cough or other signs of swallowing difficulty (18)(19)(20). Silent aspiration in acute stroke runs between 9 to 39% of patients (19)(21) an for its detection, instrumental studies as Videofluoroscopy (18)(22) or Flexible endoscopic evaluation of swallowing (FEES) (23) are required.

The diagnostic criteria of **bronchoaspirative pneumonia** used in the literature is based on documentation of three of the following indicators: abnormal chest X-Ray, fever (>38ºC), purulent sputum, tachypnea (>22 breaths per minute), tachycardia, arterial hypoxemia, inspiratory crackles and presence of pathogen and leukocytosis (24)(25).

Although there is a close relationship between dysphagia, bronchoaspiration and aspiration pneumonia, their differences are not always well-reflected in the available studies. Other risk factors for developing pneumonia include: dependence for feeding (26)(27), brainstem stroke, recurrent lower respiratory infections, weak voice and cough compromised immune system (26), difficulty to swallowing oral secretions, wet-horse voice quality, lower-grade fever or leukocytosis, age over 65 years, dysarthria or aphasia, a modified Rankin score ≥4, failure in the Water Swallow Test (WST) (28)(29),

gastric reflux, slower pharyngeal transit time, aspiration on instrumental evaluation, nasogastric tubes (due to mechanical interference in cardiac sphincter), aspiration of oral colonized flora (30)(31)(32,33), and attenuated cough reflex (34)(35). Aspiration over 10% of bolus administered or the presence of severe signs of oral or pharyngeal stages in the instrumental evaluation have been classically considered as high risk of aspiration pneumonia (22), nevertheless a recent review reports higher incidence of pneumonia in patients with dysphagia (OR 2.8, IC 95%: 1.44 to 3.61), this incidence is even higher en patients with aspiration (OR 6.53, IC 95%: 2.91 to 14.64) (15). These results imply that the presence of aspiration is associated with 4.5-fold increased risk of pneumonia while dysphagia represents a 3-fold increase in pneumonia.

1.2 Assessment methods: screening and diagnosis

1.2.1 Clinical and bedside screening methods for the assessment of dysphagia

Swallowing screening protocols should identify patients who need a formal evaluation of swallowing. They should be able to distinguish normal patients who can eat safely and take medications by mouth from those with alterations which predispose to medical complications as malnutrition, dehydration and lung infections (36).

The implementation of dysphagia screening protocols has shown to be effective to decrease the risk of lung infections in stroke patients. The relative risk reduction for bronchoaspirative pneumonia reaches 80% and for mortality exceeds 70% (12)(37)(38). Despite this, no standards for constructing a valid dysphagia screening tool have been defined yet and further clinical trials should be performed to identify the best one (39).

The ideal screening test for dysphagia must be sensitive and specific and meet only one goal: to identify patients at risk of aspiration (39). Nowadays, there are a wide variety of high-sensitivity tests which can be administered by different healthcare professionals. A good test should be quick and minimally invasive, provide information about safety of oral feeding, identify the optimal management strategies for oral feeding and determine the need of instrumental evaluations. Screening should be performed within the 3-first days of stroke onset and be re-administered every time that health-status of the patient changes (15). The consequence of no-identifying a dysphagic patient (false negative) might result in increased morbidity (i.e. respiratory complications). The consequence of a positive identification for dysphagia but not real (false positive) leads to patient's discomfort and delay in orally intaken food or drugs (26).

Sensitivity and specificity of screening test for dysphagia, compared to VFSS measures, do not exceed 85% and 60%. These tests can be applied at bedside and are based on the administration of water or other substances at different viscosities while clinical signs are controlled. There is no consensus regarding the screening test to be applied in stroke. However, none of these measures tests is perfect, which has resulted in a high number of tests (40)(41). A summary of the most frequently used screening test for dysphagia are described below.

The Water Swallow Test

The WST, since it first appeared in the medical literature in 1992 as part of the Burke Dysphagia Screening Test, has become the most studied screening test for dysphagia. It requires to swallow a 3-oz of water (90 ml) from a cup without interruptions. Presence of coughing during or at least 1-minute after ending the test or the presence of wet-voice was considered abnormal. The WST detects aspiration with a sensitivity of 76%

and specificity of 59% (42), compared with the Videofluoroscopic Modified Barium Swallow (VMBS) study. Some variations of the test have been developed:

- A 50-ml WST (swallow in 10 ml aliquots until 50 ml) combined with a desaturation test increases sensitivity and specificity to 100% and 70.8%, respectively, with a relative risk to develop pneumonia of 1.24 (43).
- A 50-ml WST associated to a desaturation with a fixed cut-off in >2%, in comparison with FEES using different food consistencies, sensitivity increases to 94.1% and specificity to 62.5% and attains a PPV 84.2% and NPV of 83.3% (44).
- A simplified 30-ml WST compared with VMBS reports sensitivity and specificity of 72% and 67%, respectively (45).

The use of pulse oxymetry combined to WST is still controversial. The physiological apnea during breathing/swallowing-coordinated tasks can induce a desaturation (46)(47)(48), so that some authors consider the WST alone as the best method to detect dysphagia and bronchoaspiration risk in acute neurological patients (40)(49). Available evidence reports that drops of oxygen saturations of 4% and moderate to severely abnormal respiratory function are more common in aspirators than non-aspirators (50)(51)(52)(53).

Finally, given that water is the least secure viscosity for oral feeding, the risk of bronchoaspiration when performing a WST should be considered. Acute stroke patients are in an unstable phase with a high prevalence of swallowing disorders which suppose doubts about the need of exposing them to an induced-bronchoaspiration (54).

Signs of Daniels: "Any of two"

The clinical signs of dysphagia described by Daniels are: dysphonia, dysarthria, abnormal volitional cough, abnormal gag reflex, cough and voice changes after the

screening test. The presence of two of these clinical features distinguishes subjects with normal swallow or slight alterations of those with mild or severe dysphagia. When compared with the VMBS, the presence of two signs of Daniels achieves a sensitivity of 92% and specificity of 67% (27)(29).

Logemann Protocol

The Logemann's protocol consists of 28 items grouped in 5 categories: medical history, behavior variables, gross motor variables, oromotor testing, and observations in the swallowing trial. Authors found that throat clearing was the best predictor of aspiration with sensitivity and specificity of 78% and 58%, respectively, whilst dysarthria was better to predict oral stage dysfunction with sensitivity of 64% and specificity of 75% in comparison with the VMBS exam (55).

The Gugging Swallowing Screen

The Gugging Swallowing Screen (GUSS) consists of a combination of a preliminary assessment of swallow (based on saliva swallow trial), a direct swallowing test with different consistencies and diet recommendations. Results were compared with FEES. The sensitivity for aspiration achieved 100% and specificity 50%. In a second evaluation, they obtained the same sensitivity and a higher specificity of 69% (56).

The Toronto Bedside Swallowing Screening Test

This is a simple and accurate screening test based on different groups of items: tongue movement, pharyngeal sensation, water swallows and voice before and after water trial. It can be administered, scored and placed on medical chart in approximately 10 minutes. The test obtained an excellent validity with sensitivity at 91% (IC 71.9 to 98.7) and NPV at 93.3% in acute rehabilitation settings with a prevalence of dysphagia 39% when compared to VMBS exam (57).

The Mann Assessment of Swallowing Ability

The Mann Assessment of Swallowing Ability (MASA) includes 24 items for evaluating oral phase preparation (lip seal, control of saliva, tongue strength, preparation, respiration assessment), oral deglutition (gag reflex, palatal movement, oral transit time, bolus clearance) and pharyngeal phase (pharyngeal pooling, voluntary cough, laryngeal elevation, voice quality), as well as the administration of WST. The MASA sensitivity and specificity are 71% and 72%, respectively, for the assessment of dysphagia, and 93% and 53% for assessing aspiration (58). A modified MASA of 12 items, in comparison with the original MASA, achieved sensitivity of 87%, specificity of 86% and good reliability (*kappa* index of 0.76) (59).

The Volume Viscosity Swallow Test

The Volume-Viscosity Swallow Test (V-VST) is a non-invasive bedside screening method for detecting dysphagia and bronchoaspiration that evaluates different food consistencies and liquids at different volumes and viscosities under pulse oximetry control. Changes in the predefined security signs of swallowing (tone of voice, coughing or reduced oxygen saturation a >3% of the basal parameter) suggests bronchoaspiration to be confirmed by an instrumental technique (60)(61). The V-VST was tested in a non-homogenous sample of patients showing sensitivity of 100% for bronchoaspiration, but specificity of 28.8%; for penetration, sensitivity and specificity were 83.7% and 34.7%, respectively.

Cough Reflex Testing

Voluntary cough is cortically driven. Nevertheless, the non-volitional urge-to-cough induced by chemical or mechanical agents triggers a cough reflex that, when the irritant agent is strong enough, cannot be cortically modulated and supressed (62)(63)(64). Neurological patients often present with reduced voluntary cough, reduced laryngeal expiratory reflex and reduced cough sensitivity. Patients with dysphagia and lung-

infections have a lower cough peak flow than dysphagic patients without pulmonary complications (34)(35). A relationship between reduced cough reflex and swallowing disturbances has been pointed to more likely develop pneumonia. Sensitivity and specificity of cough to detect bronchoaspiration varies from 52-82.4% and 54-86%, respectively (65)(66)(67). The absence of a cough response in 68% of patients with known-aspirations and the fact that clinical swallowing assessment can only identify 45% of aspirating patients should also be considered (29)(68).

The European Research Society Guidelines on the assessment of cough highlights the lack of standardization of cough testing protocols and tussive agent dosage (35). Several agents have been tested from tartaric acid to citric acid or capsaicin at different concentrations (34)(35)(69)(70)(71), but to date, no normative data are available. Passive inhalation of citric acid at 0.8 mol/L induces natural cough in healthy individuals, from which 68% of them can suppress cough, but not at 1.2 mol/L solution (34). Some authors report sensitivity of 0.87 and specificity of 0.89 for citric cough test at 1 mol/L in combination with a WST, in suspected non-homogeneous dysphagic patients (72), while others describe good results for detecting silent aspiration at lower concentrations: 0.4 mol/L for risk stroke-population and 0.8 mol/L for non-risk population providing good predictive values (34).

1.2.2 Instrumental methods for diagnosing dysphagia and aspiration

1.2.2.1 Videofluoroscopic Swallowing Studies

The VFSS study is the gold standard examination for swallowing disorders (22)(40)(54)(68). This dynamic radiological technique affords a real time analysis of the three swallowing phases. It is performed with patient in a lateral sitting position in chest X-ray chamber. While patient swallows different boluses consistencies of food

impregnated with radio-opaque contrast, the researcher can evaluate the different phases of swallowing and detect penetration or aspiration to the respiratory tract; it

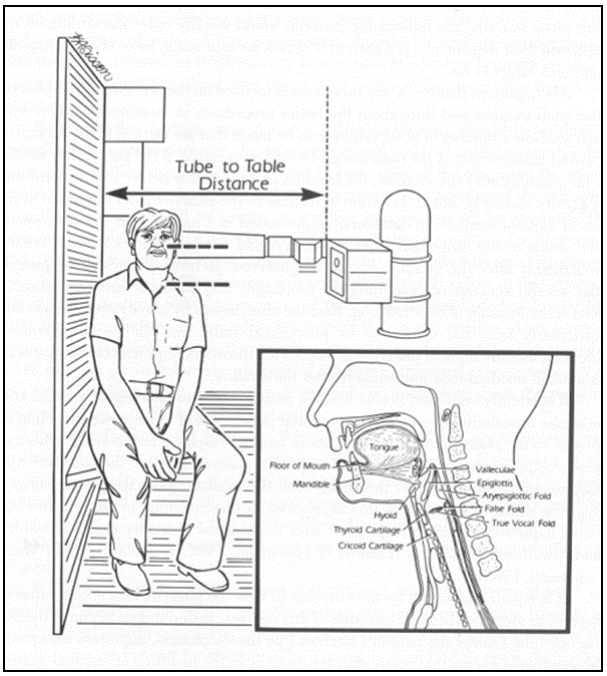


Fig 1. VFSS positioning in X-Ray Chamber

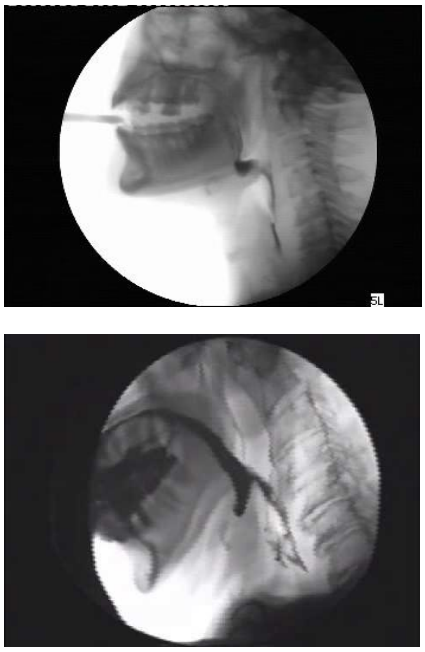


Fig.2. VFSS images

assesses not only the path of the bolus, but also the effect of positional changes in protecting the airway (13). Different soluble-X-ray contrast had been used to performed the exploration (73)(74)(75). Barium constrasts are usually used in North America, but in Europe Iodine contrasts are preferred given that barium cannot be removed from the respiratory tract once has been aspirated.

The main disadvantages of the VFSS study include: relatively expensive resource which requires a high investment of time, lack of availability in all settings, radiation exposure, difficult performance in patients unable to sit upright and difficulties in image interpretation (18). The capacity of VFSS to assess biomechanical swallow function, to test different consistencies, to detect microbronchoaspirations (76), to quantify the vallecullae and pyriform sinus residue, and to define an evidence-based rehabilitation plan are their strongest points (75).

1.2.2.2 Flexible Endoscopic Evaluation of Swallowing

The FEES is a useful and recognized technique described by Susan Langmore in 1988 (77)(23) in which a flexible fiberoptic tube passes through the nose to visualize throat while swallowing (78). FEES procedure allows a direct viewing of the oral, pharyngeal and laryngeal anatomy and function. The sensibility of the mucosa innervated by superior laryngeal nerve can be assessed adding a sensory test based on air pulses (FEES Sensory Testing, FEESST). Some authors have speculated that this sensory component results in better prediction of respiratory complications (78), whilst others prefer direct touch to assess throat sensory (79). Other authors have used FEES as the gold standard to assess the accuracy of bedside screening tests (43)(44)(80).

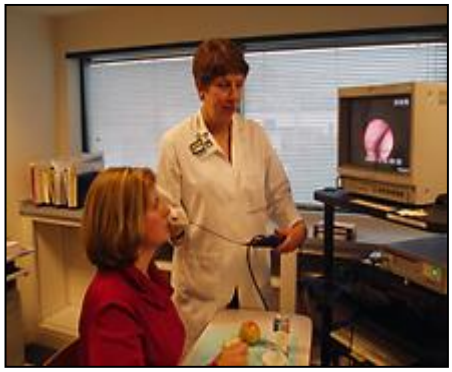


Fig 3. Susan Langmore perfoming a FEES

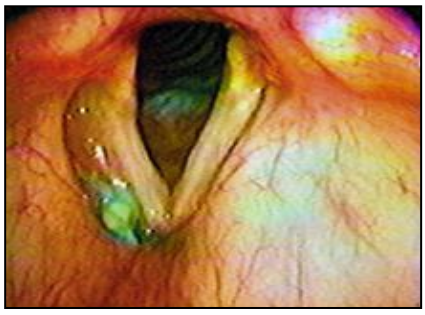


Fig 4. FEES vision

Main advantages respect the VFSS include no-radiation exposure, direct visualization of the anatomy implied in swallowing and possibility to perform a sensory evaluation. The no evaluation of oral phase, hyoid and laryngeal elevation, opening of the superior sphincter esophageal and worse tolerance in patients with cognitive impairment are recognized disadvantages (81).

In summary, VFSS and FEES provide similar and complementary information about penetration and aspiration. The clinician should consider which is the most appropriate for every patient in every setting, since both of them are valid methods for assessing dysphagia.

1.2.2.3 Manometry and High-resolution manometry

Esophageal manometry is an instrumental technique that measures the motor esophageal activity in basal condition and during swallowing. It provides extra information about pharyngeal propulsion, upper esophageal sphincter tone and swallowing coordination (82). The introduction of practical high-resolution manometry (HRM) and the development of sophisticated algorithms to display the expanded manometric dataset as pressure topography plots (83)(84) provides high and reliable information about the pharyngeal, esophageal and sphincter physiology and show high accuracy in classifying swallows as safe or unsafe in patients with dysphagia. This method could be used in the clinical practice to screen patients at risk of penetration or aspiration (85) and quantifies the swallow dysfunction with the use of a swallow risk index (86)(87)(88), but this technique, when available, is reserved to the study of esophageal disorders.

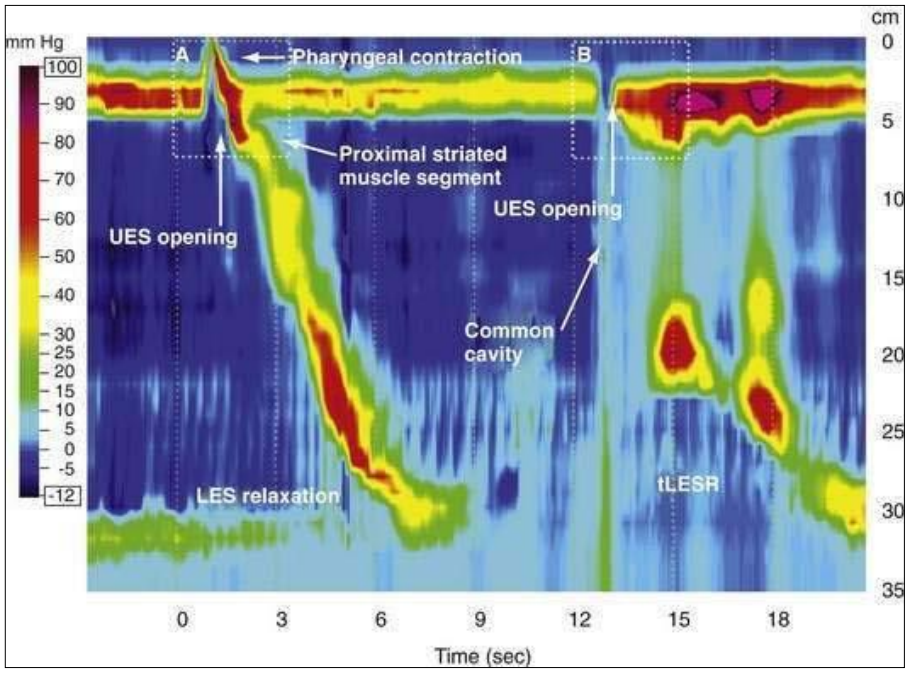


Fig 5. HMR result

1.3 Treatment of dysphagia in stroke

1.3.1 Best Practice Guidelines for managing Dysphagia

A good understanding of the swallowing physiology and points of disruption detected by screening methods and/or instrumental techniques are essential to design the best strategy to manage every swallowing disorder.

Most of the practice guidelines for dysphagia management recommends (89)(90):

- All stroke survivors should remained in NPO (nil-per-mouth) until swallowing ability will be evaluated by a trained assessor.
- Regular oral care is necessary to avoid critical oral bacteria.
- Acute stroke survivors should be screened before the beginning of oral feeding once they are alert and awake
- Instrumental evaluation must be performed in all patients with failed swallowing screening tests.
- Aspiration of >10% of the boluses administrated is considered, in general, an indication of non-oral feeding.
- Feeding assistance and supervision should be provided to any patient with risk of aspiration after stroke.
- Stroke patients with failed screening test should be also assessed regularly by a nutritionist in order to avoid malnutrition and dehydration.
- It is necessary to educate patient and family concerning oral and non-oral nutrition and provide information of the choices in every case.
- Stroke survivors should be encouraged to feed themselves.

1.3.2 Specific interventions

Oropharyngeal dysphagia treatments have been focused historically in diet modifications and compensatory strategies and postural manoeuvers to protect the airway and performing manoeuvers offsetting (swallowing forced manoeuver Mendelhson, increased input sensorial- changes the bolus: volume Tª flavour substances, cold, acidic flavors, mechanical stimulation of the tongue) (75)(91) in order to prevent broncho-aspiration and to improve the effectiveness and efficiency of swallowing, as well as, diet adaptations. Additional considerations are needed for the performance of these manoeuvers as cognitive and comprehension capabilities of the patient as well as physical condition.

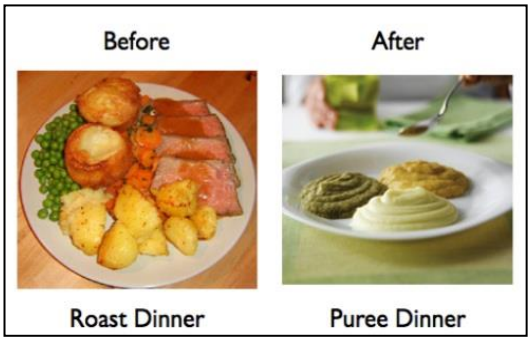
In recent decades specific techniques of rehabilitation have been developed to treat/accelerate the recovering of swallowing function: EMT (expiratory muscle training) (92), exercise toning and lingual strength, NMES (Neuromuscular electrical stimulation) (30)(93), magnetic cerebral stimulation and pharyngeal stimulation (94)(95).

1.3.3 Dietary modifications

Modification and diet adaptation are aimed to decrease the risk of aspiration and reduce lung infections, to ensure an equilibrated provision of nutrients and fluids and progressively reintroduce feeding and avoid the deterioration of the swallowing function (96)(97).

Diet adaptation consists of modifying consistencies for a best oral and pharyngeal management of the food (Image 6). Mainly, the most restrictive adaptations are made in the first stages of the stroke onset and changes can be determined by clinical swallowing assessment unless in silent aspirators, in which case, is recommended to repeat an instrumental study, VFSS or FEES, for modifying consistencies.

Fig 6. Nectar, honey and pudding consistencies.



Diet adaptations.

One of the most important restrictions is related to the fluid intake. The use of jelly water or thickeners (98)(99) might be unpleasant for patients and result in dehydration (100). The risk of dehydration is higher in dysphagic stroke patients during the rehabilitation period: peak blood urea nitrogen (BUN) ≥45 with an *odds ratio* (OR) of 4.2 (95% IC: 2.1-8.3), being even higher in patients with VFSS-detected aspiration in which a modified diet is indicated: OR: 7.2 (95% IC 3.6-14.3) (101).

Diet modifications usually reduce the enjoyment of feeding in most of the individuals and results in a decreased oral intake and subsequently, to patient's malnutrition and higher risk of dehydration (9)(90)(99)(102)(103). Dietician advice is important to ensure adequate and equilibrated diet modifications, mainly in very restrictive diets, in order to ensure a correct imbalance diet. Dietary management should be performed after reviewing VFSS/FEES results. Despite limited evidence that dysphagia diets can reduce pneumonia, there is a consensus that dysphagic patients should be provided with an appropriate diet and nutritionist's control (15).

1.3.4 Swallowing treatment programs: classical approach

Research to improve swallowing function and avoid aspiration has focused on the use of postural compensation and compensatory manoeuvers. Postural compensations such as position of head and neck (7)(104) and manoeuvres such as double

swallowing, coughing after swallowing (19), Mendelsohn manoeuver (patients hold the larynx up using neck muscles or their hands during swallow) (105), Shaker exercise (78)(106) or Masako manoeuver (patients protude tongue and then swallow) (107) may be employed and have shown benefits to this end (108). Not always the postural compensation manoeuvers are effective, for example, the chin tuck manoeuver was effective in only 50% of patients (109).

The time that material remains in the pharynx before swallow (either because of pharyngeal delay or residue from the previous swallow) (50) and a shorter opening duration of the upper esophageal sphincter (UES) are related with aspiration (110). Training programs should be addressed to improve kinematic and temporal swallowing factors, but to date, it is not well-defined in the published literature.

An only randomized clinical trial failed to show benefits of dysphagia therapy, but the 2-week intervention was probably too short to find changes (111). Programs with higher level of swallowing rehabilitation seems to be more effective to decrease the need of diet modifications and faster return to non-compensatory at 6-month follow-up (25). Evidence that short rehabilitation programs are not effective in improving clinical dysphagia outcomes while a longer intervention may reduce chest infections and diet adaptations at 6-month follow-up is limited (15). Traditional programs have been generally unsuccessful to restoring swallow in severe dysphagia (93)(25).

1.3.5 New approaches

1.3.5.1 Neuromuscular Electrical Stimulation

The NMES aims to improve strength of muscle groups with preserved motor innervation but disabled by stroke. It is contraindicated in patients with pacemakers, superficial metal implants, skin breakdowns, oropahryngeal cancer, seizure disorder, impaired peripheral nerve conduction and pregnancy.

This technique, first described by Freed (112) to improve laryngeal elevation and decreased aspiration, was approved in 2001 by the US Food and Drug Administration (88). To date, available studies report contradictory results (113)(114)(115)(116). Discrepancy in research outcomes has divided researchers and clinicians points of view, whilst some authors report that sensory and motor stimulation of peripheral nerves can accelerate swallowing recovery, others consider that surface electrical stimulation can reduce hyo-laryngeal elevation during swallowing therapy, depending on electrodes modality position (117)(118)(119).

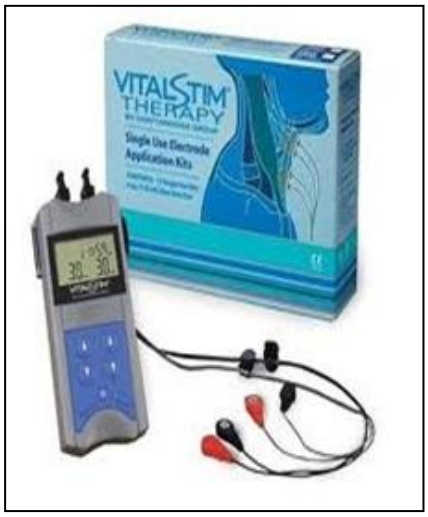


Fig 7. Vital Stim system

Improvements in recovery for patients with mild-to-moderate dysphagia but not for severe and tube-dependent feeding at 3-month follow-up have been reported (93)(120). These results might indicate that NMES is effective when stimulated muscles preserve some volitional movement (30). Three systematic reviews conclude that NMES is a promising technique but high-quality trials are required to recommend the extensive use of the device (114)(118)(119). The combination of NMES (in motor or sensitive threshold) and traditional swallowing therapy (classical oropharyngeal exercises and thermo-tactile stimulation) provides better swallow functional results (121)(122). In summary, the use of NMES is theoretically well-supported, but well-designed studies are necessary to determine its real efficacy and safety (30)(123)(124).

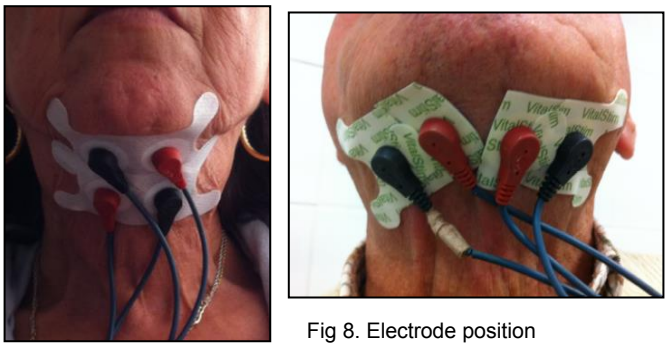


Fig 8. Electrode position

1.3.5.2 Respiratory Muscle Training

The effect of strength training of skeletal muscles has widely been demonstrated. In the past decade, animal and human models have suggested an adaptation in response to loading conditions for the mastication muscles (97).

EMT emerges as a potential treatment in dysphagia rehabilitation (92)(125)(126). EMT entails the patient to exhale through a device with a spring-loaded pressure valve that has a threshold sited between 60-80% of the individual's maximal expiratory pressure. This threshold can be re-evaluated and adjusted throughout the training program. Electromyographic studies have shown the potential effect of EMT in suprahyoid muscle recruitment and improve expiratory driving pressures for cough (127).

Fig 8. RMT device

Cough is an important mechanism to guard against aspiration and its effectiveness depends upon the coordinated activation of respiratory and intrinsic laryngeal muscles (64)(128). A significant impairment of cough and respiratory muscle function occurs in acute and subacute stroke (129)(130)(131). Impairment of cough function is likely related to respiratory muscle weakness rather than intrinsic laryngeal muscle dysfunction. Thus, an intervention targeting stroke-induced respiratory muscle weakness may improve cough effectiveness and reduce the risk of aspiration.

Fig 9. Respiratory training

Inspiratory muscles expand the thoracic cage generating the negative alveolar pressure that results in inspiratory flow. When additional effort is required to exhale, the expiratory muscles contract, increasing the alveolar-atmosphere pressure gradient. Whilst inspiratory muscles ensure an appropriate level of ventilation to facilitate pulmonary gas exchange,

malfunction of expiratory muscles will give rise to difficulties upon exertion, coughing and attempts to expectorate secretions from the airways (132).

Benefits following respiratory training have been evidenced in young healthy adults (125)(126) and in different neurological pathologies as Parkinson disease (133)(134), and multiple sclerosis (135). Inspiratory and expiratory muscle training (IEMT) has shown to be effective to increase maximal expiratory pressures (PEmax) and reduce respiratory complications in subacute stroke patients with an absolute risk reduction of 11.5% in respiratory complications at 6-month follow-up (136). Nevertheless, swallowing disturbances were not considered in this study. Otherwise, a single-blind trial evaluating respiratory muscle training (RMT) concluded that respiratory muscle function and cough flow increase as a part of natural history of stroke evolution, and RMT did not suppose a better or extended improvement in respiratory strength or flow cough; but once more dysphagia was not specifically considered (137).

2 RATIONALE FOR THESIS COMPENDIA

This compendium of papers is part of a global project entitled "Oropharyngeal Dysphagia after Stroke: Assessment and Treatment". Two published studies aimed to evaluate the clinical screening capacity of two tests, V-VST and CCT, for detecting oropharyngeal dysphagia and aspiration have been included. Under the hypothesis that the combination of both tests might result in a better approach for swallowing disorders in the clinical practice, our first investigations were focused on the assessment of dysphagia. These studies along with others in progress, have contributed to dysphagia has become a priority line in the Rehabilitation Research Group of the *Institut Hospital del Mar d'Investigacions Mèdiques* (IMIM). As a result of these first studies, the V-VST has been included in the dysphagia screening protocol used in further investigations.

In addition, as a part of our research, we report some data about new emerging therapeutic modalities for dysphagia recovery, the neuromuscular stimulation (NMES) and the respiratory training (RMT). To date, most of available studies on NMES have been conducted in patients with chronic stroke with controversial results. The few studies conducted in acute stroke perform a clinical, but not instrumental evaluation of dysphagia. Otherwise, the effect over the submental muscles and swallowing functions of the RMT shown in previous studies conducted in healthy volunteers and patients with multiple sclerosis, myasthenia gravis or Alzheimer's disease lead us to test this promising intervention in stroke patients.

Although we are just in the beginning, I do sincerely believe that we are set on a good path.

Enjoy reading

3 HYPOTHESIS and OBJECTIVES

HYPOTHESIS

- Hypothesis 1: The use of CT and V-VST provides a secure framework for assessing dysphagia in subacute stroke patients
- Hypothesis 2: Innovative interventions as electrical stimulation and respiratory muscle training might improve swallowing functional parameters and potentially help to reduce the number of respiratory complications.

MAIN OBJECTIVES

First study:

- To determine the usefulness of the Volume-Viscosity Swallow Test in subacute ischemic stroke patients admitted to a rehabilitation ward.

Second study:

- To validate a cough reflex test as a standalone tool, using a 1 mol/L citric acid solution to detect silent aspiration in subacute stroke patients, confirmed by videofluoroscopic study as the criterion standard.

Other objectives:

- To evaluate the effectiveness of a 3-week Neuromuscular Electrical Stimulation or Inspiratory and Expiratory Muscle Training therapies to improve dysphagia in stroke.

4 STUDIES

STUDY 1:

Usefulness of the volume-viscosity swallow test for screening dysphagia in subacute stroke patients in rehabilitation income

Guillén-Solà A, Marco E, Martínez-Orfila J, Donaire-Mejías MF, Depolo-Passalacqua M, Duarte E, Escalada F.

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Usefulness of the volume-viscosity swallow test for screening dysphagia in subacute stroke patients in rehabilitation income

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Abstract.
BACKGROUND: Swallowing disorders affect up to 35–85% of patients with stroke. Dysphagia complications can lead to malnutrition, dehydration, bronchoaspirative pneumonia and death, and have impact on health care costs.
OBJECTIVE: To evaluate the clinical screening capacity of the Volume Viscosity Swallow Test (V-VST) for oropharyngeal dysphagia and aspiration in a homogeneous stroke patient sample.
METHODS: Cohort study of 52 stroke patients in a subacute phase. Piecemeal deglutition and oropharyngeal residue were considered signs of impaired efficacy and cough, fall in oxygen saturation and voice changes, signs of impaired safety. Sensitivity, specificity, positive and negative predictive values, accuracy and likelihood ratios were calculated for V-VST results and compared with those of videofluoroscopy (VFS), the gold standard for studies on swallowing disorders.
RESULTS: The V-VST is a highly sensitive and specific test to detect aspiration with sensitivity of 88.2% and specificity of 71.4%; negative predictive value was 92.6%; accuracy index was 0.74. Sensitivity and specificity for penetration were 34.3% and 70.6%, respectively; accuracy was 32%.
CONCLUSIONS: The V-VST is low in cost, easy to use and very sensitive, meeting the requirements of oropharyngeal dysphagia and aspiration screening test in subacute stroke patients.

Keywords: Stroke, oropharyngeal dysphagia, volume viscosity swallow test, pulse oximetry, screening, sensitivity, specificity

1. Introduction

Oropharyngeal dysphagia, defined as difficulty in preparing the food bolus and/or transport from the mouth to the stomach, is present in up to 55% of acute stroke patients (Martino et al., 2005; Kumar et al., 2010) and decreases to 2–25% at 6 months after stroke

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(Terre 2006). Silent aspiration in dysphagic patients in the subacute stroke is present in 15–39% (Ramsey et al., 2005). Oropharyngeal dysphagia is associated with increased medical complications, bronchial pneumonia, malnutrition, dehydration and death (Terre & Mearin, 2006; Indredavik et al. 2008; Rofes et al. 2012). It represents a major economic burden for health systems due to greater demand for care, higher incidence of hospital admissions, and longer, more expensive hospital stays (Hong et al., 2008).

Videofluoroscopy (VFS) (Carnaby-Mann & Lenius, 2008; Bours 2009) is the gold standard test in the study of swallowing disorders. Using boluses of different viscosities and consistencies, it assesses not only the path of the bolus, but also the effect of positional changes in protecting airway. Nevertheless, VFS is a relatively expensive resource, requires a high investment of time and is not always available in all settings. A variety of dysphagia screening tests can be applied at the bedside, but their sensitivity and specificity do not exceed 85% and 60%, of VFS measures. None of these available measures is perfect (Bours et al., 2009; Daniels et al., 2012) and therefore, better knowledge would be useful to improve diagnosis and treatment of dysphagia in stroke patients (Bours et al., 2009).

Bedside clinical assessment of dysphagia (Carnaby-Mann & Lenius, 2008; Daniels et al., 2012) is useful for determining the sequence of actions to be taken depending on the alteration detected. This is cost-effective, non-invasive and method offers the possibility to start treating dysphagia promptly. The Volume Viscosity Swallow Test (V-VST) is a non-invasive method for evaluating dysphagia that involves giving food at different volumes and viscosities under pulse oximetry control (Logemann et al., 1998; Clave 2008; Ramsey et al., 2006, Zaidi et al., 1995). Changes in any of the safety signs (tone of voice, coughing or reduced oxygen saturation) indicate a positive test suggesting passage of food into the airway. It has the advantage of allowing the rehabilitation team to detect early clinical signs and adjust diet to minimize the risk of complications while awaiting instrumental examinations. A good screening tool should be valid, reliable and feasible (Daniels at al. 2012), should identify patients with risk of swallowing disorders and not patients without risk, and must prove its accuracy in a determined sample of patients.

The V-VST has reported a sensitivity of 100% and specificity of 28.8% in aspiration and 83.7% and 34.7%, respectively for penetration in an heterogeneous sample of patients (Clave et al., 2008; Clave et al., 2006). The aim of this study was to determine the usefulness of the V-VST in an homogeneous sample of acute/subacute ischemic stroke patients admitted to a rehabilitation ward.

2. Methods

2.1. Design

Cohort study of consecutive stroke patients admitted to an inpatient neurorehabilitation unit of an acute-care university hospital in Barcelona, Catalonia, Spain.

2.2. Participants

The inclusion criteria were: 1) subacute stroke patients within 3 weeks of stroke, 2) V-VST and VFS performed during hospital stay, and 3) no history of a previous neurological condition that could cause oropharyngeal dysphagia. We excluded patients whose general and/or cognitive condition prevented administration of the various diagnostic tests.

2.3. Main outcomes

The main outcome variables for V-VST analysis were the indexes that determine reliability and the overall value of a screening method:

- Sensitivity: Probability that the test is positive (food passing into the airway) in patients with penetration and/or aspiration confirmed by VFS.
- Specificity: Probability that the test is negative (no food passing into the airway) in patients without penetration or aspiration in VFS.
- Positive predictive value (PPV): the probability that an individual presents food passage into the airway when the diagnostic test result is positive.
- Negative predictive value (NPV): The probability that an individual has no passage of food into the airway when the diagnostic test result is negative.
- The diagnostic accuracy index: The proportion of true results (positive and negative) for all tests performed.
- Likelihood ratios: Used to assess the value of performing a diagnostic test and compare the probability of obtaining a particular result in an individual (e.g. detection of food into the airway) compared to a non-affected patient. Two versions of the likelihood ratio exist, one for positive and one for negative test result. The positive likelihood

ratio (LR+) is the probability of positive test in a person who has the disease divided by the probability of a positive test in a person who does not have the disease.

2.4. Swallow assessment

Volume Viscosity Swallow Test: Changes in security signs are recorded in tone of voice, coughing during or after eating, or desaturation of more than 3% compared to baseline pulse oximetry. Piecemeal deglutition and oropharyngeal residue were signs of impaired efficacy. The V-VST is performed at the patient's bedside using food boluses of different viscosities (liquid, nectar or 'single cream' and pudding) at increasing volumes (5, 10 and 20 ml). Liquid viscosity is assessed with mineral water at room temperature; nectar viscosity is obtained by adding 4.5 g of thickener (Resource ThickenUp®, Nestlé, Barcelona, Spain) to 100 ml of mineral water; and pudding viscosity by adding 9 g of thickener to 100 ml mineral water (Clave 2008). The test starts at nectar viscosity and, if any of the safety variables is altered, it continues with pudding viscosity. If no alterations are observed, the test is repeated at liquid viscosity.

Videofluoroscopy: This dynamic imaging technique involves obtaining a sequence of lateral and anteroposterior images of the intake of different volumes (5, 10 and 20 ml) of water-soluble X-ray contrast (Gastrografin®, Schering, Spain) at 3 different viscosities (liquid, nectar and pudding) (11,12). Liquid viscosity is obtained by mixing 1:1 mineral water and the X-ray contrast both at room temperature; nectar viscosity by adding 3.5 g of thickener Resource ThickenUp® (Nestlé, Barcelona, Spain) to the liquid solution; and finally pudding viscosity is obtained by adding 8 g of the thickener to the 1:1 solution (Clave 2008, Clave 2006). VFS signs recorded are: airway penetration (presence of radiographic contrast in the laryngeal vestibule above the vocal cords), aspiration (presence of contrast below the vocal cords) and silent aspiration (presence of contrast below the vocal cords without clinical response) (Logemann 1998).

2.5. Procedure

On admission to rehabilitation, V-VST was performed to evaluate dysphagia in all patients with acute stroke. VFS was only indicated in cases of posterior territory stroke and whenever any of the safety parameters (changes in tone of voice, coughing, or desaturation) were present.

The V-VST data were recorded as follows: alteration or normality in efficacy in the oral phase, efficacy in the pharyngeal phase, safety signs, suspicious of aspiration and suspicious of penetration. Efficacy in the oral phase is defined by lips sealing, oral residue and fractionated swallowing; efficacy in the pharyngeal phase is defined by the pharyngeal residue sensation; and safety signs by the presence of changes in voice, cough and/or desaturation.

Videofluoroscopy was scored with the 8-point Penetration Aspiration Scale (PAS). As depicted in Fig. 1, a PAS score of 1 indicates a normal test, scores from 2 to 5 indicate passage of material into the larynx that does not pass below the vocal folds (penetration) and scores from 6 to 8 indicate passage of material below the level of vocal folds (aspiration) (Rosenbeck et al., 1996).

Other demographic and clinical variables collected include topographic classification and aetiology of stroke, respiratory complications, time elapsed between stroke event and completion of VFS, display and removal of nasogastric tube and/or gastrostomy, changes in diet, prescription of speech therapy and functional assessment using the Barthel index (Mahoney & Barthel, 1965).

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

Fig. 1. The 8-point Penetration-Aspiration Scale

2.6. Statistical analysis

Sensitivity, specificity, PPV, NPV, accuracy and positive likelihood ratio are described in percentages. Other descriptive categorical variables are shown as absolute values and percentages, and quantitative variables are presented with their mean and standard deviation (SD). Contingency tables are used to calculate the indexes for determining the reliability of the V-VST as a screening method for penetration and/or aspiration in patients with oropharyngeal dysphagia. Each 2 × 2 contingency table contains two rows (V-VST: positive or negative) and two columns (penetration or aspiration evidenced by VFS: yes or no).

3. Results

Of the 127 eligible patients screened for inclusion, 52 (40.9%) were recruited to the study from November 2009 to November 2011. Principal reasons for exclusion were: drowsy/too unwell to participate ($n = 17$); unable to give consent because of aphasia or lack of comprehension ($n = 22$) and previous dysphagia and/or stroke ($n = 11$). Sixteen additional patients were excluded for lack of VFS data (this screening was not routinely performed in patients with normal V-VST at admission).

The general characteristics of the sample are described in Table 1. Clinical assessment was performed at 13.8 (SD 8.86) days after the stroke coinciding with admission in the neurorehabilitation ward. The time elapsed from stroke onset until VFS was performed were 26.7 (SD 10.6) days. The time from neurorehabilitation admission to VFS was 7.9 (SD 4.37). Acute pneumonia (before admission to rehabilitation) occurred in 10 (19.2%) patients. No patient developed pneumonia during the neurorehabilitation stay.

Table 2 groups the contingency tables to compare the V-VST and VFS frequency distribution.

Table 3 summarizes the values of sensitivity, specificity, PPV, NPV, accuracy and LR+ for efficacy and safety signs. When the same analysis is separately performed for each safety sign (voice changes, cough and desaturation), desaturation >3% accurately identifies cases of penetration and aspiration with high specificity. The sensitivity and specificity of the V-VST to assess the efficacy signs in the oral phase was 93.7% and 65%, respectively. The accuracy was of 79.6% and LR+ was 2.67. Similar values were achieved in assessment of the safety signs. The presence of wet voice with the V-VST suggested penetration with a sensitivity of 34.3% and specificity of 70.6%. Similarly, the presence of cough and desaturation suggested aspiration with a sensitivity of 88.2% and specificity of 71.4%. Although sensitivity of desaturation in the V-VST was relatively low, specificity was 97.1% and LR+ was 14.41.

4. Discussion

This study evaluated the screening ability and overall value of the V-VST, a method for clinical assessment of dysphagia, and compared it results with the gold standard of fluoroscopic detection of aspiration in patients with oropharyngeal dysphagia after acute/subacute stroke, a typical patient in a rehabilitation setting. Some considerations must first be made regarding the characteristics of the sample that could have influenced the outcome. It is well known that samples from rehabilitation units have an initial bias because their patients tend to be pre-selected for their potential to pursue a course of treatment. Two groups of patients are not included: those with good initial recovery who are discharged directly home and those whose initial physical, cognitive or functional recovery prevents them from following a rehabilitation program. Another selection bias is that the sample includes only those patients with dysphagia who underwent VFS assessment; those patients with an initial V-VST within the ranges of normality or with very slight alterations did not require further evaluation. This further excluded patients on the "good initial status" end of spectrum. Despite these biases, this study was designed to provide an overview of our results in a homogeneous sample of acute/subacute ischemic stroke patients. Further study including a control group would be necessary to validate this approach.

The prevalence of neurogenic dysphagia varies between 25% and 85% depending on the series and the time of evaluation (Terré 2006; Ramsey et al., 2005; Daniels et al., 2012; Mann et al., 1999). In our sample of 127 patients, prevalence in the first 2 weeks after stroke onset was 53.5% (52 study participants plus 16 with only slightly altered V-VST results). Prevalence data reported elsewhere are heterogeneous in the timing and type of clinical evaluation and tests based on each author's choices based on scientific evidence and their own clinical experience (Mann 1999). This makes comparisons very difficult. Many tests are described in the literature for the early detection of dysphagic patients (Daniels et al., 2012; Logemann et al., 1998; Clave

Table 1
Demographic and clinical variables of the sample ($n = 52$)

Age	68.1 (SD 11.4)
Sex:	
Female	12 (23.1%)
Male	40 (76.9%)
Laterality of stroke	
Right	27 (51.9%)
Left	21 (40.4%)
Bilateral	4 (7.7%)
Topographic classification:	
Anterior total circulation	9 (17.3%)
Anterior partial circulation	20 (38.5%)
Lacunar	4 (7.7%)
Posterior circulation	19 (36.5%)
Respiratory complications:	
Acute phase (during stay in Neurology)	10 (19.2%)
Subacute phase (during stay in Rehabilitation)	0 (0%)
Time (in days) elapsed from:	
Stroke to videofluoroscopy	21.7 (SD 10.6)
Stroke to Rehabilitation admission	13.8 (SD 8.9)
Rehabilitation admission to videofluoroscopy	7.9 (SD 4.33)
Functional assessment:	
Barthel at admission to Rehabilitation	42.0 (SD 22.1)
Barthel at discharge from Rehabilitation	64.4 (SD 26.05)
Diet at admission to Rehabilitation:	
Normal diet	5 (9.6%)
Soft diet with thickeners in liquids	19 (36.5%)
Dysphagic diet	23 (44.2%)
Nasogastric tube	4 (7.7%)
Percutaneous gastrostomy	1 (1.9%)
Diet at discharge from Rehabilitation	
Normal Diet	22 (42.3%)
Soft diet with thickeners	16 (30.8%)
Dysphagic diet	11 (21.2%)
Percutaneous gastrostomy (total diet)	1 (1.9%)
Percutaneous gastrostomy (oral / gastrostomy diet)	2 (3.8%)

et al., 2008; Ramsey et al., 2006; Mann et al. 1999; Logemann et al. 1999). All of them are designed to detect individuals who aspirate and to make dietary adjustments to prevent additional medical complications. The ideal screening test should respond with a sensitivity of 100% and the highest possible specificity. However, clinical practice almost never has access to perfect tests and diagnostic procedures; clinicians must be satisfied with getting as close as possible to their population. The sensitivity of diagnostic tests for the detection of a potentially serious, but treatable condition, must be as high as possible. High sensitivity will over-treat patients, but incorrect diagnosis will simply result in repeated dietary adjustments and the use of temporary thickening. This is obviously less serious than under-diagnosed cases, which might lead to serious complications such as pneumonia. Nevertheless, the presence of dysphagia is associated with pneumonia, although other risk factors also must be considered (Langmore 1998).

In our study the presence of coughing during or after swallowing had a sensitivity of 82.4% and a specificity of 54.3% for aspiration, whereas Mari et al. (Mari et al. 1997) report a sensitivity of 52% and specificity of 86% using a 25 item form to check for symptoms of dysphagia and 3oz water swallow test. For dysphonia and changes in tone of voice, other authors report sensitivity values of 60–97% and specificity of 29–45% (Carnaby-Mann 2008), fully consistent with those observed in our study (sensitivity 80%, specificity 50%). Finally, other authors report desaturation sensitivities of 13–75% and specificities of 83–95% (Ramsey 2005, Carnaby-Mann 2008, Mari 1997), while our results were 41.2% for sensitivity and 97.1% for specificity. Usefulness of other

Table 2
Contingency tables showing the frequency distribution of the Volume Viscosity Swallow Test and Videofluoroscopy

		VFS - Efficacy Oral Phase				VFS - Efficacy Pharyngeal Phase			
		No	Yes			No	Yes		
V-VST Efficacy Oral Phase	No	13	2	V-VST Efficacy Pharyngeal Phase	No	19	15		
	Yes	7	30		Yes	8	10		
		VFS- Security Signs				VFS - PAS			
		No	Yes			Penetration	Aspiration		
V-VST Alteration of Security Signs	No	9	6	V-VST Penetration suspicious	No	23	12		
	Yes	5	32		Yes	12	5		
		VFS - PAS				VFS - PAS			
		Penetration	Aspiration			Penetration	Aspiration		
V-VST Aspiration suspicious	No	25	2	V-VST Cough	No	19	3		
	Yes	10	15		Yes	16	14		
		VFS – PAS				VFS - PAS			
		Penetration	Aspiration			Penetration	Aspiration		
V-VST Voice changes	No	15	2	V-VST desaturation	No	34	10		
	Yes	15	8		Yes	1	7		

V-VST: Volume-Viscosity Swallow Test; VFS: videofluoroscopy; PAS: Penetration Aspiration Scale.

Table 3
Sensitivity, specificity, predictive values, accuracy and positive likelihood ratio of parameters determining the overall value of the volume viscosity swallow test

	VIDEOFLUOROSCOPY					
	Se(%)	Sp(%)	PPV(%)	NPV(%)	Accuracy(%)	LR+
V-VST:						
Efficacy signs in oral phase:	93.7	65	81.1	86.6	79.6	2.67
Efficacy signs in pharyngeal phase	40	70.8	55.5	55.9	43.3	1.35
Impaired safety:	84.2	64.3	86.4	60	70.7	2.35
Penetration (PAS 2–5)	34.3	70.6	70.6	34.3	32	1.16
Aspiration (PAS >5)	88.2	71.4	60	92.6	74.1	3.08
Clinical Signs:						
Cough	82.4	54.3	46.7	86.4	60	1.08
Voice changes	80	50	34.8	88.2	54.86	1.6
Desaturation >3 basal	41.2	97.1	88	77.3	66.1	14.41

V-VST: volume viscosity swallow test; Se: sensitivity; Sp: specificity; PPV: positive predictive value; NPV: negative predictive value.

diagnostic methods such as the water swallowing test (WST) and its variants (Mann et al. 1999; DePippo et al. 1992; Nishiwaki et al. 2005), are controversial because they expose a labile patient to risk of aspiration. Furthermore, these tests have a high NPV, so the risk/benefit ratio is rather poor (Carnaby-Mann 2008).

The V-VST results reported by Clavé (Clave, 2006, 2008) show 100% sensitivity for aspiration, but a low specificity 28.8%. It is noteworthy that our study sample is more homogeneous in terms of aetiology. Of 85 patients who participated in the study by Clavé, only 23 were stroke patients and it remains unclear if they were in an acute, subacute or chronic phase; the remainder were geriatric patients with tumours of the head or neck, or neurodegenerative diseases. In our sample, the clinical signs defined by Clavé have a low sensitivity to suspect penetration. However, sensitivity and specificity to suspect aspiration are 88.2% and 71.4%, respectively. Accuracy for aspiration reaches 74.1%, which provides a good framework to take the first medical decisions.

The V-VST is an easily implemented test that detects the viscosities and volumes at which the patient is at risk, and allows early dietary adjustments. It also offers the ability to track daily or weekly status, as appropriate, and make progressive adjustments according to patient progress. There were no complications from aspiration during admission in our rehabilitation unit, even though about 20% of the sample had a record of bronchial pneumonia in the acute stroke.

5. Conclusion

This study analyses the usefulness of V-VST in a homogeneous simple of ischemic stroke patients. The results are quite good but further investigation with larger samples is required to confirm our observations. Moreover, as this is a cohort study, systematic data collection and forecasting, as well as establishing a control group is needed to validate these results at population level.

The V-VST is low in cost, easy to use, and has high sensitivity and specificity. It meets the requirements of a clinical screening test for dysphagia in subacute ischemic stroke patients.

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Conflict of interest

All authors declare they do not have any financial and personal relationships with other people or organisations that could inappropriately influence their work.

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STUDY 2:

Usefulness of Citric Cough Test for screening silent aspiration in subacute stroke patients: a prospective study.

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ORIGINAL RESEARCH

Usefulness of Citric Cough Test for Screening of Silent Aspiration in Subacute Stroke Patients: A Prospective Study

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Abstract

Objective: To detect silent aspiration in a homogeneous sample of stroke patients using the citric acid cough test.

Design: Prospective study.

Setting: Public university tertiary hospital.

Participants: Consecutive subacute stroke patients (N=134; 74 men, 60 women; mean age ± SD, 62.2±11.9y; 11.7±9.9d after stroke) who had complained of dysphagic symptoms, referred for rehabilitation from December 2010 to October 2012.

Intervention: All patients were administered a citric acid cough test and underwent a videofluoroscopic swallowing study (VFSS). A reduced or an absent response on the citric acid cough test was considered when cough peaks were ≤4. A control group of healthy volunteers was also screened.

Main Outcome Measures: The citric acid cough test results were compared with the VFSS results, which were used as a criterion standard.

Results: There were 36 patients with a positive citric acid cough test, of which the VFSS revealed penetration in 14 cases (38.9%), aspiration in 5 (13.9%), silent aspiration in 5 (13.9%), and normality in 12 patients (33.3%). The sensitivity and specificity indexes for the reliability of citric acid cough test as a screening method for silent aspiration in comparison with the VFSS were .19 and .71, respectively. Other comparisons were made between silent aspirators (Penetration Aspiration Scale=8) and different subgroups of patients, but values remained poor.

Conclusions: The citric acid cough test using 1.0 (weight by volume)% for 1 minute does not seem to be a useful standalone tool to screen for silent aspiration in subacute stroke patients with suspected dysphagia.

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Dysphagia is present in a significant proportion of subacute stroke patients, up to 85% depending on the series,[1-6] and is associated with an increase in medical complications such as aspiration pneumonia, malnutrition, and death.[7,8] Aspiration pneumonia, the most common respiratory complication, is responsible for approximately half of the deaths that occur in these patients; moreover, dysphagia triples the risk of developing pneumonia.[4]

Most studies suggest that weakness or absence of the cough reflex is correlated with an increased risk of pneumonia.[1] Silent aspiration is defined as the passage of a food bolus or airway secretions below the true vocal cords without triggering any clinical response such as coughing or respiratory distress; it has been described in 15% to 54% of stroke patients.[9-11] Coughing acts as a protective mechanism in the airway, removing waste by generating an expiratory flow.[8,12] The mechanisms associated with silent aspiration include poor pharyngeal muscle

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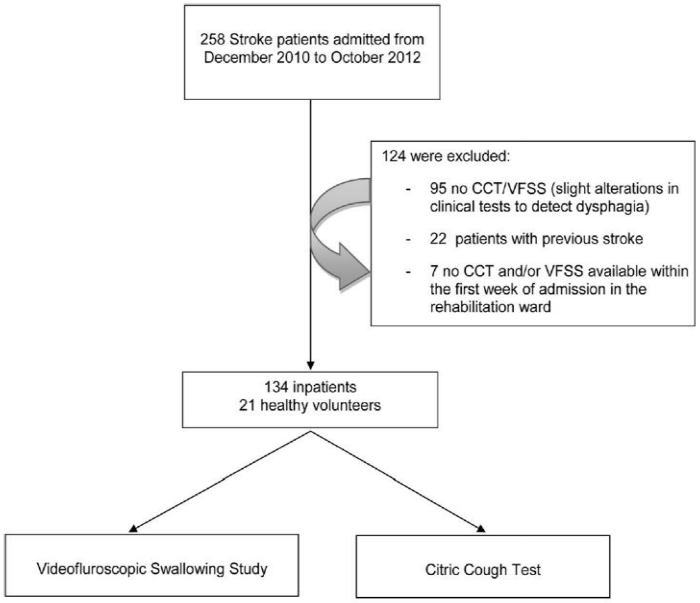

Fig 1 Study flowchart.

coordination, decreased sensitivity, and low laryngeal capacity to induce cough.[13,14]

The bedside clinical assessment of dysphagia is a cost-effective, noninvasive method that offers the possibility to begin prompt treatment of dysphagia.[15,16] Some validated screening protocols include Logemann's method,[17,18] Modified Assessment Swallowing Ability,[19,20] Toronto Bedside Swallowing Screening Test,[21] and Gugging Swallowing Screen.[22] However, none of these have the ability to detect silent aspiration, which is an interesting endpoint.[23] Only Leder et al[24] describes silent aspiration as volume dependent in a prospective and nonhomogeneous sample.

The European Respiratory Society guidelines on the assessment of cough highlight the lack of standardization of cough testing protocols and tussive agent dosage.[23] To date, several tussive agents—citric acid, capsaicin, and tartaric acid—have been used to assess the cough reflex,[13,25-28] but the lack of validated protocols makes it difficult to include them in the clinical assessment of dysphagia.

Wakasugi et al[13] report that a citric acid cough test, in combination with a water swallowing test, is useful in screening for silent aspiration in a nonhomogeneous sample of patients, with a sensitivity of .87 and specificity of .89. The administration of inhaled citric acid in a 0.8mol/L concentration inhibits cough in 68% of healthy volunteers, while a cough response is observed with the use of a 1.2mol/L concentration in 80% of individuals.[25] Miles,[25] Miles,[29] and colleagues describe good results when comparing cough reflex testing and instrumental assessment using both fiberendoscopic evaluation of swallowing and videofluoroscopic swallowing study (VFSS). Both studies show that lower concentrations of citric acid (0.4mol/L) provide better predictive values for silent aspiration in higher-risk populations, while higher concentrations (0.8mol/L) are useful as a screening tool in a low-risk population.[27]

Considering the properties of validity, reliability, feasibility, and accuracy of screening tests, we designed a prospective study to validate a cough reflex test as a standalone tool, using a 1mol/L citric acid cough test to detect silent aspiration in a homogeneous stroke sample, confirmed by VFSS as the criterion standard.

List of abbreviations:

NPV negative predictive value
PAS Penetration Aspiration Scale
PPV positive predictive value
VFSS videofluoroscopic swallowing study
w/v weight by volume

Methods

Study design and participants

A prospective study of 258 consecutive stroke patients admitted to an inpatient intensive rehabilitation ward in a university's tertiary hospital was conducted from December 2010 to October 2012. Patients were eligible for inclusion if they met the following criteria: (1) they had a subacute stroke within 1 to 3 weeks of evolution; (2) they had a swallowing disorder suspected on clinical examination, based on the volume-viscosity swallow test[30,31]; and (3) there was no history of previous neurologic diseases.

Of the 258 patients admitted to the rehabilitation ward, 134 met the inclusion criteria. As summarized in figure 1, patients were excluded for the following reasons: (1) they had a low risk of silent aspiration defined by normal or nearly normal findings on

Table 1 General characteristics of patients (n=134) and control group (n=21)

Characteristics	Patients (n=134)	Healthy Controls (n=21)	*P*
Age (y)	62.2±11.9	63.7±12	NS
Sex			
Female	74 (54.2)	11 (52.4)	NS
Male	60 (44.8)	10 (47.6)	
Cardiovascular risk factors			
Hypertension	87 (64.9)	6 (28.6)	<.001
Diabetes mellitus	43 (32.1)	1 (4.8)	NS
Cholesterol	69 (51.5)	9 (42.9)	NS
Atrial fibrillation	26 (19.4)	2 (9.5)	NS
Tobacco smoking			
Smokers	46 (34.3)	4 (19)	NS
Ex-smokers	25 (18.7)	6 (28.6)	
Nonsmokers	52 (38.8)	11 (52.4)	
Unknown	11 (8.2)	0 (0)	

NOTE. Values are mean ± SD, n (%), or as otherwise indicated.
Abbreviation: NS, not significant.

clinical examination, except for those with posterior circulation strokes (n=95) in which silent aspiration is highly prevalent; (2) they had a previous stroke or other neurologic diseases (n=22); and (3) there was a lack of a VFSS, a CCT, or both, within the first week of admission to the rehabilitation ward (n=7). Patients with a score >3 on the Spanish version of the Short Portable Mental Status Questionnaire also were excluded.[32] A control group of 21 healthy volunteers of the same age and sex distribution was also tested to confirm that the presence of a cough in healthy subjects is not related to VFSS disorders.

Description of the cohort included demographic variables (age, sex) and clinical variables (topographic classification, stroke etiology [Trial of Org 10172 in Acute Stroke Treatment classification],[33] arterial occlusion [Oxford Scale],[34] and cardiovascular risk factors). Functional outcomes and disability at admission were assessed by the National Institutes of Health Stroke Scale,[35] the Rankin Scale,[36] and the Barthel Index.[37]

Diagnostic tools

Citric acid cough test

The citric acid cough test consists of oral inhalation of a 1.0 (weight by volume [w/v])% mixture of saline and citric acid for 1 minute through an ultrasonic nebulizer (OMRON NE-U17[a]) and the counting of cough peaks that result. For the purpose of this study, the particle size was 1 to 8μm, and the output rate was 3mL/min. Patients were asked to breathe normally for 1 minute and cough as needed. Following the European Respiratory Society Task Force Guidelines for Cough Assessment,[27] cough was defined as a 3-phase process of inspiration, forceful expiratory effort against a closed glottis, and reopening of the glottis and fast expiratory airflow. A researcher counted the cough peaks performed by the patient during the citric acid cough test, following instructions provided by Wakasugi.[13] Patients with ≥5 cough peaks were considered as normal citric acid cough test responders, whereas those with ≤4 were considered as reduced or absent citric acid cough test responders.[38,39] No audio recording was performed.

Table 2 Clinical and functional assessment at admission in rehabilitation ward

Characteristics	Values
Time elapsed from stroke to rehabilitation admission (d)	12.7±9.8
Etiology	
Hemorrhagic	18 (13.4)
Ischemic	116 (86.6)
TOAST classification	
Atherosclerosis	24 (17.9)
Cardioembolism	22 (16.4)
Lacunar	15 (11.2)
Other etiology	5 (3.7)
Undetermined etiology	31 (23.1)
No data available	20 (14.2)
Laterality of stroke	
Right	73 (54.5)
Left	57 (42.5)
Bilateral	4 (3)
Topographic classification	
Anterior total circulation	4 (3)
Anterior partial circulation	87 (65.4)
Posterior circulation	16 (12)
Brainstem	26 (19.5)
Oxford Stroke classification	
TACI	19 (14.2)
PACI	12 (9)
LACI	18 (13.4)
POCI	10 (7.5)
No data available	52 (42.5)
Impairment assessment (NIHSS)	6.3±4.2
Disability (modified Rankin Scale)	
No significant disability	3 (2.2)
Slight disability	11 (8.2)
Moderate disability	32 (23.9)
Moderately severe disability	45 (33.6)
Severe disability	6 (4.5)
No data available	37 (27.6)
Functional assessment (Barthel Index)	42.8±18.6
Prevalence of silent aspiration (%)	34.57
Respiratory complications in acute stroke phase (during stay in neurology)	22 (16.4)

NOTE. Values are mean ± SD, n (%), or as otherwise indicated.
Abbreviations: LACI, lacunar infarct; NIHSS, National institutes of Health Stroke Scale; PACI, partial anterior circulation infarct; POCI, posterior circulation infarct; TACI, total anterior circulation infarct; TOAST, Trial of Org 10172 in Acute Stroke Treatment.

Videofluoroscopic swallowing study

The VFSS is a dynamic imaging technique that is considered the criterion standard for the study of swallowing disorders. A lateral-profile sequence of the intake of different volumes of 3 distinct viscosities (liquid, nectar, pudding) was obtained with Thickener Resource ThickenUp[b] and water-soluble contrast (Visipaque[c]) as described by Logemann.[18] Water-soluble contrast is available in bottles of 50mL (16mg iodine) or 320mg/mL. Liquid viscosity

Table 3 Cough test in silent aspirators (PAS=8) versus rest of sample (N=134)

	VFSS	
CCT	True Silent Aspirators	Rest of Sample
No_CCT_resp	5	31
CCT_resp	21	77

NOTE. Sensitivity, .192; specificity, .71; efficiency, .612; PPV, .138; NPV, .785.
Abbreviations: CCT, citric acid cough test; CCT_resp, CCT responders (≥5 cough peaks); No_CCT_resp, absent or reduced CCT responders (<4 cough peaks).

was obtained by mixing 1:1 mineral water and water-soluble contrast at room temperature (100mL/16mg iodine); thickener was added to the liquid solution in a mixing tin to obtain nectar and pudding viscosity (3.5g and 8g of thickener, respectively). Solutions were prepared 10 minutes before measurement. For each viscosity and soft solid, boluses in increasing volumes of 5, 10, and 20mL were offered to patients with a syringe.

The presence of radiographic contrast in the laryngeal vestibule above the vocal cords was classified as penetration; below the vocal cords, as aspiration; and below the vocal cords without a clinical response, as silent aspiration. The 8-point Penetration Aspiration Scale (PAS) was used to quantify selected penetration and aspiration events. PAS scores were determined by the depth reached by swallowed material and by whether or not material entering the airway was expelled. For the purpose of this study, we used the VFSS results (classified with Penetration Aspiration Scale by Rosenbeck[40]) in 4 groups: (1) normal test results (PAS=1); (2) passage into the larynx but not below the vocal folds (penetration; PAS=2–5); (3) passage below the vocal folds (aspiration; PAS=6–7); and (4) passage below the vocal folds without clinical signs such as cough or desaturation (PAS=8).[40,41] For a global interpretation of the results, participants were also classified following the convention used by Power et al: healthy (PAS=1–2), and disordered (PAS score ≥3).[42] A group of silent aspirators (PAS>8) was also considered.

Both VFSS and citric acid cough test were conducted between 1 and 6 days after admission. One researcher administered the citric acid cough test, and immediately afterward the VFSS was performed by another researcher who was blind to citric acid cough test results. The worst PAS score was used for analysis, regardless of the associated volume or viscosity.

Table 4 Cough test in silent aspirators (PAS=8) versus aspirators (PAS=6–7)

	VFSS	
CCT	True Silent Aspirators	Sample With PAS=6–7
No_CCT_resp	5	5
CCT_resp	21	14

NOTE. Sensitivity, .192; specificity, .736; efficiency, .42; PPV, 0.5; NPV, 0.4.
Abbreviations: CCT, citric acid cough test; CCT_resp, CCT responders (≥5 cough peaks); No_CCT_resp, absent or reduced CCT responders (<4 cough peaks).

Main outcomes

The main outcome variables for analysis of the diagnostic capacity of the citric acid cough test were the 5 indexes that determine a method's reliability and overall diagnostic value: (1) Sensitivity: Probability that the test is positive (food passing into the airway) in patients with penetration, aspiration, or both, confirmed by VFSS. (2) Specificity: Probability that the test is negative (no food passing into the airway) in patients without penetration or aspiration in VFSS. (3) Positive predictive value (PPV): Probability of food passage into the airway when the diagnostic test result is positive. (4) Negative predictive value (NPV): Probability of no passage of the food into the airway when the diagnostic test result is negative. (5) Diagnostic accuracy index (or efficiency): Proportion of true results (positive and negative) among all tests performed.

Data analysis

Categorical variables are shown as absolute values and percentages. Quantitative variables are presented with their mean and SD. Two-by-2 contingency tables were used to calculate the 5 indexes determining the reliability of a screening test: sensitivity, specificity, PPV, NPV, and the accuracy index. Every contingency table contained 2 rows (citric acid cough test: positive/negative) and 2 columns (penetration/aspiration evidenced by VFSS: yes/no). Pre- and posttest probabilities were also calculated using Bayes' theorem.[43] For this purpose, patients were classified into 2 groups according to the convention used by Power[42]: normal laryngeal protection (PAS score, 1–2) and abnormal laryngeal protection (aspirators/disordered swallowing) if they scored >3 on the PAS. Statistical significance was set at .05 for all hypothesis testing. Data were analyzed using the SPSS Statistics 21[d] program.

Results

The general characteristics of the sample (n=134) are summarized in table 1. Three of the cardiovascular risk factors—hypertension, hypercholesterolemia, and smoking—were present in more than half of the patients. Table 2 describes the clinical and functional characteristics of patients on admission to rehabilitation, at a mean ± SD of 12.7±9.8 days from stroke onset. The mean ± SD National Institutes of Health Stroke Scale score was 6.3±4.2, and the Barthel Index was 42.8±18.6. Disability was moderately severe in 33.6% of patients, assessed with the modified Rankin Scale. There was a moderate negative correlation between PAS and Barthel Index at admission ($r=-.369$, $P<.001$) and at discharge ($r=-.430$, $P<.001$). Acute pneumonia had occurred before admission to rehabilitation in 22 patients (16.4%), of whom only 9 (40.9%) had a positive citric acid cough test. On the other hand, the VFSS showed normality in 2 (9.1%) of these 22 patients, penetration in the airway in 9 (40.9%), aspiration in 6 (27.3%), and silent aspiration in 5 (22.7%). Notably, of the 5 patients with silent aspiration under the criterion standard, only 2 had a positive citric acid cough test.

Age, sex distribution, and cardiovascular risk factors are pooled with the patient population and summarized in table 1. Swallow assessment results were as follows: 2 healthy volunteers had a positive citric acid cough test and were classified by VFSS assessment as having airway penetration (PAS=5) and a normal PAS, respectively. Six healthy individuals had penetration of a liquid bolus (PAS=2–5). No aspiration or silent aspiration was detected in any healthy control. The only difference in

cardiovascular risk factors between controls and patients was the significantly lower prevalence of hypertension among healthy controls (28.6% vs 64.9%, respectively).

Of the 36 patients (26.8%) with a positive citric acid cough test, the VFSS revealed penetration in 14 cases (38.9%), aspiration in 5 (13.9%), silent aspiration in 5 (13.9%), and normal swallowing in 12 patients (33.3%). The VFSS demonstrated silent aspiration in 26 patients (19.4%), only 5 of whom had a positive citric acid cough test. The indexes for determining the reliability of the citric acid cough test as a screening method for silent aspiration in comparison with the VFSS were calculated from contingency tables (table 3). Sensitivity and specificity were .19 and .71, respectively. Other contingency tables were constructed to compare silent aspirators (PAS=8) with various patient subgroups (tables 4 and 5), but sensitivity, specificity, efficiency, and predictive values remained very poor.

Table 6 shows contingency tables and reliability indexes for the citric acid cough test when participants were classified according to healthy or disordered VFSS.[42] The new calculated reliability indexes remained equally poor. In fact, the values obtained in the posttest odds were no better than the pretest, which indicates poor quality as a diagnostic or screening test. When the same analyses were repeated for the group of patients with disordered VFSS—that is, silent aspirators (PAS=8) compared with other VFSS disorders (PAS=3–7)—a slight improvement was obtained in specificity and NPV at the expense of decreased sensitivity.

Table 5 Cough test in aspirators (PAS=6–8) versus non-aspirators (PAS=1–5) (N=134)

	VFSS	
CCT	Aspirators	Sample With PAS=1–5
No_CCT_resp	10	26
CCT_resp	35	63

NOTE. Sensitivity, .22; specificity, .71; efficiency, .535; PPV, .278; NPV, .642.
Abbreviations: CCT, citric acid cough test; CCT_resp, CCT responders (≥5 cough peaks); No_CCT_resp, absent or reduced CCT responders (<4 cough peaks).

Discussion

This study assessed the citric acid cough test as a screening tool to detect silent aspiration in patients with oropharyngeal dysphagia after stroke, compared with the criterion-standard VFSS test. The strengths of the study include its prospective design, the homogeneity of dysphagia etiology (only stroke patients were included), the time elapsed from stroke onset (mean ± SD, 12.7±9.9d), and a control group tested to detect any associations between a positive/negative cough test and VFSS disorders. Age, sex, and cardiovascular distribution were similar to the patient sample.

The prevalence of silent aspiration is 34.6%, which is consistent with published studies in which the prevalence varies from 24% to 52% in the acute phase, 15% to 39% in subacute dysphagic patients, and 2% to 25% in unselected stroke patients.[9,44,45] In the control group, none of the healthy volunteers had aspiration or silent aspiration, but the VFSS demonstrated airway penetration in 6 cases (28.6%). Data available from other samples of healthy individuals reported the presence of penetration in 11.4% of healthy adults.[41]

The citric acid cough test efficacy for detecting silent aspiration in dysphagic stroke patients requires further investigation, as previously reported results are controversial. Wakasugi[13] studied 107 patients with documented aspiration, reporting citric acid cough test sensitivity of .67, specificity of .98, accuracy of .89, PPV of .98, and NPV of .61 as a standalone test. When the citric acid cough test was used in combination with a water swallowing test, the sensitivity increased to 88.2%. These results were obtained from an heterogeneous sample of Asian patients with severe symptoms of dysphagia. The same authors conducted a new study in a similar heterogeneous sample to verify the reproducibility of the method and investigate the usefulness of a portable handheld nebulizer. Of 160 patients, 36% had cerebrovascular diseases, 25% neuromuscular diseases, 14% head and neck cancer, 8% respiratory diseases, and 17% other diseases.[38] Once again they obtained good sensitivity, specificity, and predictive values—.86, .71, .53 (PPV), and .93 (NPV), respectively—and concluded that the citric acid cough test using 1.0 (w/v)% is a good standalone method to detect silent aspirators. Disappointingly, our study has not been able to reproduce these results in patients with subacute stroke. Apart from ethnic differences between Asian and Mediterranean populations and sample heterogeneity, the observed differences cannot be explained by methodological features, and we are unable to find other reasons for this large discrepancy.[13,38,39] The use of a receiver operating characteristic curve based on citric acid cough test peaks to determine the best cutoff points for sensitivity might help to provide an explanation. Unfortunately, we recorded the number of cough spikes as a dichotomous variable (≥5 or <5 cough spikes) instead of as a continuous variable, making it impossible to conduct the receiver operating characteristic curve analysis.

Table 6 Contingency tables used to calculate reliability indexes of the cough test when compared with the criterion standard

	VFSS		
CCT	Disordered (PAS=3–8)	Healthy (PAS=1–2)	Total
No_CCT_resp	15	21	36
CCT_resp	56	42	98
Total	71	63	134

NOTE. Reliability indexes: Sensitivity, .21; specificity, .67; efficiency, .42; PPV, .42; NPV, .43; LR+, .63; LR−, 1.183; pretest odds, .31; posttest odds, .16.

	Disordered VFSS		
CCT	PAS 8	PAS 3-7	Total
No_CCT_resp	5	10	15
CCT_resp	21	35	56
Total	26	45	71

NOTE. Reliability indexes: Sensitivity, .19; specificity, .78; efficiency, .56; PPV, .33; NPV, .62; LR+, .86; LR−, 1.038; pretest odds, .32; posttest odds, .25
Abbreviations: CCT, citric acid cough test; CCT_resp, CCT responders (≥5 cough peaks); LR, likelihood ratio; No_CCT_resp, absent or reduced CCT responders (<4 cough peaks).

The main methods of citric acid delivery during cough testing are single-dose and dose-response methods.[27] In the first, a single concentration of citric acid is used. The dose-response method involves the administration of incremental concentrations of tussive agent over a fixed period, usually 15 to 60 seconds. In most studies, the single-dose response method is preferred because of the accuracy and reproducibility of the dose administered and the ease to determine a tussive response.[27]

Miles,[25] Miles,[29] and colleagues and Miles and Huckabee[46] obtained good results when comparing dose-response cough reflex tests using citric acid (0.4 and 0.8mol/L) with fiberendoscopic evaluation of swallowing/VFSS. These authors suggest that the use of citric acid (0.4mol/L) provides good predictive values for silent aspiration in high-risk populations, while higher concentrations (0.8mol/L) are more useful for the screening of silent aspiration in low-risk populations typically requiring more stimuli to trigger the cough reflex. Nevertheless, in our sample of high-risk dysphagia patients, a citric acid concentration of 1mol/L was not sufficient to trigger this reflex. The use of different citric acid concentrations and the single-dose versus dose-response method could offer a possible explanation for the observed discrepancies.[13] The study by Miles[29] was aimed at assessing the usefulness of the citric acid cough test to reduce the incidence of pneumonia in patients with poststroke dysphagia. Although this end goal was not achieved, the administration of the citric acid cough test influenced diet adaptations and referrals for instrumental assessment.

Addington et al[47] obtained high specificity (100%) and low sensitivity (17%) when assessing the laryngeal cough reflex in stroke patients with L-tartaric acid stimulation. These results are more consistent with ours and show good specificity but poor sensitivity. Regarding the control group, only 6 volunteers (28.6%) had airway penetration, and none had aspiration or silent aspiration, following another study[41] in which 11.4% of 149 healthy volunteers assessed by VFSS had penetration.

The relationship between tobacco and the cough reflex has not been well demonstrated.[19,48,49] Studies in chronic smokers reveal a diminished cough reflex sensitivity to capsaicin compared with nonsmokers,[49] while other authors report that smokers show higher cough thresholds than nonsmokers.[49,50] To pursue this hypothesis, we stratified the analysis by smokers and nonsmokers. Sensitivity, specificity, and predictive values remained low overall, despite our clinical experience suggesting a worse response among smokers.

Aspiration and silent aspiration are not independent predictors of aspiration pneumonia, while other factors might be involved.[9,51] Moreover, the full consequences of silent aspiration are not well established. We do know that pneumonia has a direct relationship with antibiotic treatments, length of hospital stay, and mortality rates. Therefore, major efforts should be directed to the development of a simple and effective tool to detect silent aspiration.[26]

Study limitations

Samples drawn from rehabilitation units have an initial bias because patients tend to be preselected for their potential to pursue a course of treatment. Another selection bias is that the sample did not include all stroke patients, but only stroke patients with suspected dysphagia. Since all assessments were performed by the same experienced physician, interrater reliability indexes cannot be provided, which represents a major limitation of this study. Finally, the citric acid concentration and its method of administration might also represent a limiting factor.

Conclusions

The citric acid cough test using 1.0 w/v% citric acid concentrations for 1 minute does not seem to be useful as a standalone test for the screening of silent aspiration in this sample of subacute stroke patients with suspected dysphagia. Despite the increased information available regarding the reproducibility of inhalation cough methods in the last decade, further research to improve standardization of testing methodology is required.

Suppliers

a. Omron NE-U17; OMRON Healthcare Europe.
b. Thickener Resource ThickenUp; Nestlé.
c. Visipaque; GE Healthcare Bio-Sciences.
d. SPSS Statistics 21; IBM Corp.

Keywords

Cough; Deglutition disorders; Diagnosis; Rehabilitation; Respiratory aspiration

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5 GLOBAL RESULTS

5.1 Assessment of dysphagia

Volume-Viscosity Swallow Test

Of the 127 eligible patients screened for inclusion, 52 (40.9%) were recruited to the study from November 2009 to November 2011. Principal reasons for exclusion were: drowsy/too unwell to participate (*n* = 17); unable to give consent because of aphasia or lack of comprehension (*n* = 22) and previous dysphagia and/or stroke (*n* = 11). Sixteen additional patients were excluded for lack of VFSS data (this screening was not routinely performed in patients with normal V-VST at admission).

The general characteristics of the sample are described in Table 1 (pag.53-*635-).* Clinical assessment was performed at 13.8 (SD 8.86) days after the stroke coinciding with admission in the neurorehabilitation ward. The time elapsed from stroke onset until VFSS was performed were 26.7 (SD 10.6) days. The time from neurorehabilitation admission to VFSS was 7.9 (SD 4.37). Acute pneumonia (before admission to rehabilitation) occurred in 10 (19.2%) patients. No patient developed pneumonia during the neurorehabilitation stay.

Table 2 (pag.54-*636-)* groups the contingency tables to compare the V-VST and VFSS frequency distribution. And Table 3 (pag.55-*637-)* summarizes the values of sensitivity, specificity, PPV, NPV, accuracy and LR+ for efficacy and safety signs. When the same analysis is separately performed for each safety sign (voice changes, cough and desaturation), desaturation >3% accurately identifies cases of penetration and aspiration with high specificity. The sensitivity and specificity of the V-VST to assess the efficacy signs in the oral phase was 93.7% and 65%, respectively. The accuracy was of 79.6% and LR+ was 2.67. Similar values were achieved in assessment of the safety signs. The presence of wet voice with the V-VST suggested penetration with a sensitivity of 34.3% and specificity of 70.6%. Similarly, the presence of cough and desaturation suggested aspiration with a sensitivity of 88.2% and specificity of 71.4%.

Although sensitivity of desaturation in the V-VST was relatively low, specificity was 97.1% and LR+ was 14.41.

Cough Test

The general characteristics of the sample (n=134) are summarized in table 1 (pag.61-*1279-)*. Three of the cardiovascular risk factors hypertension, hypercholesterolemia, and smoking were present in more than half of the patients. Table 2 (pag.61-*1279-)* describes the clinical and functional characteristics of patients on admission to rehabilitation, at a mean ±SD of 12.7(±9.8) days from stroke onset. The mean ±SD National Institutes of Health Stroke Scale score was 6.3±4.2, and the Barthel Index was 42.8±18.6. Disability was moderately severe in 33.6% of patients, assessed with the modified Rankin Scale. There was a moderate negative correlation between PAS and Barthel Index at admission (r=-.369, P<.001) and at discharge (r=-.430, P<.001). Acute pneumonia had occurred before admission to rehabilitation in 22 patients (16.4%), of whom only 9 (40.9%) had a positive citric acid cough test. On the other hand, the VFSSS showed normality in 2 (9.1%) of these 22 patients, penetration in the airway in 9 (40.9%), aspiration in 6 (27.3%), and silent aspiration in 5 (22.7%). Notably, of the 5 patients with silent aspiration under the criterion standard, only 2 had a positive citric acid cough test Age, sex distribution, and cardiovascular risk factors are pooled with the patient population and summarized in table 1. (pag.61-*1279-)*.

Swallow assessment results were as follows: 2 healthy volunteers had a positive citric acid cough test and were classified by VFSSS assessment as having airway penetration (PAS=5) and a normal PAS, respectively. Six healthy individuals had penetration of a liquid bolus (PAS=2-5). No aspiration or silent aspiration was detected in any healthy control. The only difference in cardiovascular risk factors between controls and patients was the significantly lower prevalence of hypertension among healthy controls (28.6% vs 64.9%, respectively). Of the 36 patients (26.8%) with a

positive citric acid cough test, the VFSSS revealed penetration in 14 cases (38.9%), aspiration in 5 (13.9%), silent aspiration in 5 (13.9%), and normal swallowing in 12 patients (33.3%). The VFSSS demonstrated silent aspiration in 26 patients (19.4%), only 5 of whom had a positive citric acid cough test. The indexes for determining the reliability of the citric acid cough test as a screening method for silent aspiration in comparison with the VFSSS were calculated from contingency tables (table 3) (pag.62-*1280-)*.Sensitivity and specificity were .19 and .71, respectively. Other contingency tables were constructed to compare silent aspirators (PAS=8) with various patient subgroups (tables 4 and 5) (pag.62-*1280-) (*pag.63-*1281-)*, but sensitivity, specificity, efficiency, and predictive values remained very poor. Table 6 (pag.63-*1281-)*.shows contingency tables and reliability indexes for the citric acid cough test when participants were classified according to healthy or disordered VFSSS. The new calculated reliability indexes remained equally poor. In fact, the values obtained in the posttest odds were no better than the pretest, which indicates poor quality as a diagnostic or screening test. When the same analyses were repeated for the group of patients with disordered VFSSS - that is, silent aspirators (PAS=8) compared with other VFSSS disorders (PAS= 3-7) - a slight improvement was obtained in specificity and NPV at the expense of decreased sensitivity.

5.2 Application of Volume-Viscosity Test on research

A randomized trial was designed for evaluate the effectiveness of two therapies that aim to improve dysphagia outcomes in a sample of subacute stroke patients. Patients were allocated in standard swallow therapy (SST), in NMES or in RMT group. The SST consisted of an educational intervention aimed to improve self-management of dysphagia and protect the airway, oral exercises to improve lingual praxis, and compensatory techniques based on VFSS findings; the RMT consisted of 5 sets of 10 respirations followed by 1 minute of unloaded recovery breathing off the spring-loaded

valve, twice a day, 5 days per week for 3 weeks; and the NMES was based on 80 Hz of transcutaneous electrical stimulus with two electrodes placed on suprahyoid muscles in 40-minute daily sessions (5 days per week, during 3 weeks).

The main outcome measures (at 3-week and 3-month follow-up) were analyzed by intention-to-treat. Twenty-three patients were not able to perform the respiratory and/or swallowing assessment after the 3-week intervention. Twelve of these patients were lost to 3-month follow-up and no clinical information was available from their medical records for analysis: 1 patient in the SST was transferred to acute care due to a medical complication; 3 patients in the SST group, 2 in the IEMT group, and 2 in the NMES group failed to perform the volitional respiratory assessment maneuver; 2 patients allocated to the NMES group were dropped because of technical and/or organizational problems resulting in discontinued intervention; and 2 patients allocated to IEMT did not complete a minimum of 80% of training sessions. The remaining 11 patients were transferred to an intermediate care unit before the 3-week respiratory assessment, but were not excluded from the 3-month follow-up analysis because all of them had performed more than 80% of the sessions and underwent the clinical swallowing assessment before discharge.

At recruitment, patients had a mean age of 69 (SD 8.7) years; gender distribution was 38 men and 24 women. The majority of strokes were in the anterior circulation (61.3%); atherosclerosis, cardio-embolism, and undetermined origin were the predominant etiologies; and mean severity was moderate (NIHSS 6.8, SD 3.8). Time elapsed since stroke onset and admission to the rehabilitation unit was 10.4 (SD 6.5) days (Table 1).

Table 1 *(pg 77)* shows a comparison of IEMT, SST, and NMES treatment effect changes over time. Greater improvements in respiratory muscle strength were observed in the IEMT group after the 3-week intervention. Nevertheless, at 3-month follow-up, this improvement remained in the IEMT group.

***Table 1**. Treatment effect of the inspiratory and expiratory muscle training upon beginning the intervention period and at 3-month follow-up, compared to standard swallow and neuromuscular electrical stimulation therapies*

	IEMT	SST	Treatment effect, change (95% CI)	p	IEMT	NMES	Treatment effect, change (95% CI)	p
Respiratory muscle strength at 3 weeks:								
- Δ PImax (cmH_2O)	21.1 (SD 13.1)	8.2 (SD 7.2)	12.9 (4.5 to 21.2)	**0.004**	21.1 (SD 13.1)	9.6 (SD 6.4)	11.5 (2.7 to 20.2)	**0.015**
- Δ %PImax	21.1 (SD 11.8)	8.0 (SD 7.5)	13.1 (5.2 to 20.9)	**0.004**	21.1 (SD 11.8)	10.4 (SD 6.8)	10.7 (2.5 to 18.8)	**0.014**
- Δ PEmax (cmH_2O)	26.4 (SD 16.9)	7.1 (SD 8.6)	19.3 (8.5 to 30.3)	**0.001**	26.4 (SD 16.9)	13.5 (12.9)	12.9 (0.4 to 25.4)	**0.044**
- Δ %PEmax	16.8 (SD 11.0)	6.4 (SD 3.7)	10.3 (3.7 to 17.0)	**0.006**	16.8 (SD 11.0)	9.8 (SD 8.8)	7.5 (-0.8 to 15.8)	0.076
Respiratory muscle strength at 3 months:								
- Δ PImax (cmH_2O)	18.3 (SD 14.5)	9.4 (SD 12.5)	12.4 (3.07 to 21.6)	**0.011**	18.31 (SD 14.55)	13.82 (SD 15.51)	4.48 (-6.2 to 15.1)	0.399
- Δ %PImax	17.0 (SD 15.8)	6.9 (SD 14.1)	10.0 (0.25 to 20.3)	**0.056**	17.01 (SD 15.82)	14.46 (SD 17.37)	2.55 (-9.3 to 14.4)	0.662
- Δ PEmax (cmH_2O)	32.4 (SD 21.2)	18.1 (SD 19.2)	14.3 (0.33 to 28.2)	**0.045**	32.43 (SD 21.23)	24.17 (SD 22.5)	8.26 (-7.2 to 23.8)	0.287
- Δ %PEmax	19.5 (SD 16.5)	12.4 (SD 12.8)	7.11 (2.96 to 17.2)	0.160	19.52 (SD 16.50)	15.34 (SD 13.99)	4.17 (-6.7 to 15.0)	0.438

(*) Quantitative variables are presented as mean and standard deviation (in parentheses)
***Abbreviations: IEMT**, Inspiratory and expiratory muscle training**; SST,** Standard Swallow Therapy; **NMES**, Neuromuscular Electrical Stimulation; **CI**, Confidence interval; **PImax**, maximal inspiratory pressure; **PEmax**, maximal expiratory pressure.*

Patient distribution according to disorders in security and efficacy signs of deglution along the study protocol is described in Table 2. After the 3-week intervention, patients in both NMES and IEMT groups had significantly improved security signs (p= 0.049), but this beneficial effect was lost at 3-month follow-up. At 3 months, it seems to be an improvement in efficacy signs in both intervention groups (p= 0.079).

Table 2. *Disorders in security and efficacy signs of deglutition at admission to rehabilitation, upon study completion, and at three-month follow-up: comparison of neuromuscular electrical stimulation and respiratory muscle training with standard swallow therapy.*

	SST	**NMES**	**p**	**SST**	**RMT**	**p**
Baseline:						
- V-VST security signs altered	17	17	0.757	17	16	0.5
- V-VST efficacy signs altered	15	18	0.114	15	16	0.5
3 weeks:						
- V-VST security signs altered	16	10	**0.049**	16	9	**0.011**
- V-VST efficacy signs altered	14	13	0.620	14	15	0.5
3 months:						
- V-VST security signs altered	6	2	0.112	6	3	0.219
- V-VST efficacy signs altered	13	8	0.078	13	7	**0.037**

Results for VFSS were dichotomized as aspirators (PAS ≥5) and non-aspirators (PAS <5) at admission to the rehabilitation unit and at 3-month follow-up. The number of non-aspirators improved at 3 months, but no statistical significant differences were observed among groups. The FOIS improved 0.76 (SD 1.1) after completing the intervention, and 1.76 (SD 1.1) at 3-month follow-up. The mean improvement of the DOSS at 3 months was 0.96 (SD 1.4). No significant differences in the FOIS and the DOSS were observed among the study groups. During the intervention period, only 2 (3.2%) patients in the Group I presented lung infections. At 3-month follow-up, there were 13 patients with medical complications: 2 new strokes (1 fatality), 1 hip fracture, 1 seizure, and 9 respiratory events. Therefore, lung infections represented 15.5% of the

dysphagic sample and distribution by study group was 4 in SST, 3 in NMES, and 2 in RMT. There were no reported adverse effects during the trial. Patient acceptance was considerably good, only a few patients in the NMES group reported any discomfort related to the electrode position and motor stimulation threshold, but none withdrew from the study. Three patients in the IEMT group reported dizziness related to hyperventilation, with no clinical impact.

6 DISCUSSION

6.1 Discussion for assessment of dysphagia

Volume viscosity swallow test

This study evaluated the screening ability and overall value of the V-VST, a method for clinical assessment of dysphagia, and compared it results with the gold standard of fluoroscopic detection of aspiration in patients with oropharyngeal dysphagia after acute/subacute stroke, a typical patient in a rehabilitation setting. Some considerations must first be made regarding the characteristics of the sample that could have influenced the outcome. It is well known that samples from rehabilitation units have an initial bias because their patients tend to be pre-selected for their potential to pursue a course of treatment. Two groups of patients are not included: those with good initial recovery who are discharged directly home and those whose initial physical, cognitive or functional recovery prevents them from following a rehabilitation program. Another selection bias is that the sample includes only those patients with dysphagia who underwent VFSS assessment; those patients with an initial V-VST within the ranges of normality or with very slight alterations did not require further evaluation. This further excluded patients on the “good initial status” end of spectrum. Despite these biases, this study was designed to provide an overview of our results in a homogeneous sample of acute/subacute ischemic stroke patients. Further study including a control group would be necessary to validate this approach. The prevalence of neurogenic dysphagia varies between 25% and 85% depending on the series and the time of evaluation (5)(41)(51)(138). In our sample of 127 patients, prevalence in the first 2 weeks after stroke onset was 53.5% (52 study participants plus 16 with only slightly altered V-VST results). Prevalence data reported elsewhere are heterogeneous in the timing and type of clinical evaluation and tests based on each author’s choices based on scientific evidence and their own clinical experience (138). This makes comparisons very difficult. Many tests are described in the literature for the early detection of dysphagic patients (13)(21)(41)(55)(60). All of them are designed to detect individuals

who aspirate and to make dietary adjustments to prevent additional medical complications. The ideal screening test should respond with a sensitivity of 100% and the highest possible specificity. However, clinical practice almost never has access to perfect tests and diagnostic procedures; clinicians must be satisfied with getting as close as possible to their population. The sensitivity of diagnostic tests for the detection of a potentially serious, but treatable condition, must be as high as possible. High sensitivity will over-treat patients, but incorrect diagnosis will simply result in repeated dietary adjustments and the use of temporary thickening. This is obviously less serious than under-diagnosed cases, which might lead to serious complications such as pneumonia. Nevertheless, the presence of dysphagia is associated with pneumonia, although other risk factors also must be considered (26). In our study the presence of coughing during or after swallowing had a sensitivity of 82.4% and a specificity of 54.3% for aspiration, whereas Mari et al. (65) report a sensitivity of 52% and specificity of 86%using a 25 item form to check for symptoms of dysphagia and 3oz water swallow test. For dysphonia and changes in tone of voice, other authors report sensitivity values of 60–97% and specificity of 29–45% (54), fully consistent with those observed in our study (sensitivity 80%, specificity 50%). Finally, other authors report desaturation sensitivities of 13–75% and specificities of 83–95% (21)(54)(65), while our results were 41.2% for sensitivity and 97.1% for specificity. Usefulness of other diagnostic methods such as the water swallowing test (WST) and its variants (42)(45)(138), are controversial because they expose a labile patient to risk of aspiration. Furthermore, these tests have a high NPV, so the risk/benefit ratio is rather poor (54).

The V-VST results reported by Clavé (60)(139) show 100% sensitivity for aspiration, but a low specificity 28.8%. It is noteworthy that our study sample is more homogeneous in terms of aetiology. Of 85 patients who participated in the study by Clavé, only 23 were stroke patients and it remains unclear if they were in an acute, subacute or chronic phase; the remainder were geriatric patients with tumours of the

head or neck, or neurodegenerative diseases. In our sample, the clinical signs defined by Clavé have a low sensitivity to suspect penetration. However, sensitivity and specificity to suspect aspiration are 88.2% and 71.4%, respectively. Accuracy for aspiration reaches 74.1%, which provides a good framework to take the first medical decisions. The V-VST is an easily implemented test that detects the viscosities and volumes at which the patient is at risk, and allows early dietary adjustments. It also offers the ability to track daily or weekly status, as appropriate, and make progressive adjustments according to patient progress. There were no complications from aspiration during admission in our rehabilitation unit, even though about 20% of the sample had a record of bronchial pneumonia in the acute stroke.

Citric Cough test

This study assessed the citric acid cough test as a screening tool to detect silent aspiration in patients with oropharyngeal dysphagia after stroke, compared with the criterion-standard VFSSS test. The strengths of the study include its prospective design, the homogeneity of dysphagia etiology (only stroke patients were included), the time elapsed from stroke onset (mean ± SD of 12.7 ± 9.9 d), and a control group tested to detect any associations between a positive/negative cough test and VFSSS disorders. Age, sex, and cardiovascular distribution were similar to the patient sample. The prevalence of silent aspiration is 34.6%, which is consistent with published studies in which the prevalence varies from 24% to 52% in the acute phase, 15% to 39% in subacute dysphagic patients, and 2% to 25% in unselected stroke patients (21)(111)(139). In the control group, none of the healthy volunteers had aspiration or silent aspiration, but the VFSSS demonstrated airway penetration in 6 cases (28.6%). Data available from other samples of healthy individuals reported the presence of penetration in 11.4% of healthy adults (81).

The citric acid cough test efficacy for detecting silent aspiration in dysphagic stroke patients requires further investigation, as previously reported results are controversial. Wakasugi (72) studied 107 patients with documented aspiration, reporting citric acid cough test sensitivity of .67, specificity of .98, accuracy of .89, PPV of .98, and NPV of .61 as a standalone test. When the citric acid cough test was used in combination with a water swallowing test, the sensitivity increased to 88.2%. These results were obtained from a heterogeneous sample of Asian patients with severe symptoms of dysphagia. The same authors conducted a new study in a similar heterogeneous sample to verify the reproducibility of the method and investigate the usefulness of a portable handheld nebulizer. Of 160 patients, 36% had cerebrovascular diseases, 25% neuromuscular diseases, 14% head and neck cancer, 8% respiratory diseases, and 17% other diseases (140). Once again they obtained good sensitivity, specificity, and predictive values, 0.86, 0.71, 0.53 (PPV), and 0.93 (NPV), respectively and concluded that the citric acid cough test using 1.0 (w/v) % is a good standalone method to detect silent aspirators. Disappointingly, our study has not been able to reproduce these results in patients with subacute stroke. Apart from ethnic differences between Asian and Mediterranean populations and sample heterogeneity, the observed differences cannot be explained by methodological features, and we are unable to find other reasons for this large discrepancy (72)(140)(141). The use of a receiver operating characteristic curve based on citric acid cough test peaks to determine the best cutoff points for sensitivity might help to provide an explanation. Unfortunately, we recorded the number of cough spikes as a dichotomous variable (≥5 or <5 cough spikes) instead of as a continuous variable, making it impossible to conduct the receiver operating characteristic curve analysis.

Study limitations

Samples drawn from rehabilitation units have an initial bias because patients tend to be preselected for their potential to pursue a course of treatment. Another selection bias is that the sample did not include all stroke patients, but only stroke patients with

suspected dysphagia. Since all assessments were performed by the same experienced physician, inter-rater reliability indexes cannot be provided, which represents a major limitation of this study. Finally, the citric acid concentration and its method of administration might also represent a limiting factor.

6.2 Discussion for new approaches

The results of an unpublished but submitted trial which pretends to compare the effectiveness of two innovative therapies that aim to improve dysphagia outcomes in a sample of subacute stroke patients, previously presented, are discussed. After a 3-week intervention, both IEMT and NMES benefits were associated with improvement in respiratory muscle strength and clinical signs of security in swallowing. At 3-month follow-up, respiratory muscle strength remained higher in the intervention groups, although it remains to be seen whether this improvement is associated with fewer respiratory complications and/or better dysphagia outcomes.

A systematic review published in 2009 reported promising results on the use of surface NMES as a motor and sensory facilitation modality (114). A meta-analysis that aimed to evaluate the effect of NMES on swallowing rehabilitation revealed a small but significant effect size for NMES in the treatment of swallowing disorders (121). Most of the studies included in these reviews had been carried out in chronic stroke samples, but evidence regarding subacute stroke is much more limited: the combination of NMES and conventional therapy has been shown to improve swallowing function assessed with the Functional Dysphagia Scale, but not in terms of FOIS and PAS (121); another (122) randomized trial that compared the effect of adding thermo-tactile stimulation to NMES showed greater improvement in the PAS of patients who underwent the combined therapy. A clinical trial conducted in acute stroke patients randomly assigned to NMES or usual dysphagia therapy showed a mean FOIS gain of

1.4 points at 3 weeks and 2.4 points at 6 weeks, but did not provide information on videofluoroscopic parameters (142). Finally, a non-randomized study reported improvements in diet and patients' satisfaction, as well as reduced respiratory complications (143).

Over the past decade, many authors have investigated the effects of respiratory muscle training on the management of dysphagia. The finding of increased motor unit recruitment of the submental muscle complex in healthy volunteers after EMT opened the discussion of a potential benefit of EMT in patients with dysphagia (62)(125). Thereafter, other studies carried out in patients with Parkinson disease (134), multiple sclerosis (127), and myasthenia gravis (144) have also shown improved swallowing function after EMT. To the authors' knowledge, two randomized clinical trials have evaluated the effect of IEMT in subacute stroke: the first concluded that improvements observed in respiratory muscle function and cough flow are part of the natural history of stroke and are not influenced by respiratory muscle training (137); the second found that IEMT induces a significant improvement in respiratory muscle strength, which could have had a role in reducing the number of respiratory complications observed at 6-month follow-up (136). These studies were conducted in subacute stroke, but none focused specifically on dysphagic patients.

The present study also showed improvements in the security signs assessed with V-VST at the end of the intervention in both the NMES and IEMT groups. Nevertheless, the lack of differences between groups at 3-month follow-up might be explained by the reversibility of the training effect and/or the natural evolution of dysphagia. The distribution of patients with impaired efficacy signs remains unchanged at the end of the 3-week interventions, although an improvement was observed in IEMT patients at 3 months. We cannot offer a definitive explanation for this finding, although sample size might have been a factor somehow.

The prevalence of lung infections in this study is surprisingly low, especially when considering it was conducted in a selected sample of patients with dysphagia. The continuous supervision of patients participating in clinical trials might have contributed to this low prevalence. Dysphagia and aspiration are probably the most important factors predisposing to lung infections, but are not the only ones (26). In our study, only 9 patients had lung infections at 3-month follow-up and distribution was similar among the study groups. The lack of differences cannot be exclusively attributed to the intervention, since our sample size estimation was not powered to predict lung infections. The sample size required to show a 5% decrease in post-stroke pneumonia has been estimated to exceed 22,000 patients (137), which provides a good rationale for a larger study adequately powered to assess respiratory complications.

There are some limitations to be considered in this trial. It includes stroke patients with dysphagia diagnosed with the VFSS approach and without previous history of disorders in swallowing or respiratory muscle function. Apart from the initial bias inherent to samples from rehabilitation units, in which patients tend to be pre-selected for their potential to follow a rehabilitation program, some potential limitations concerning the assessment methods should be considered. The determination of PImax and PEmax requires volitional maneuvers that are influenced by individuals' cooperation as well as their ability to make an airtight seal around the manometer mouthpiece, which often requires the assistance of a therapist. In order to minimize unnecessary patient exposure to radiation according to the 'as-low-as-reasonably achievable' (ALARA) principle (145), VFSS was not repeated at the end of the 3-week intervention. Although previous studies have shown the reliability of the V-VST compared with VFSS (60)(61), the V-VST can be useful in clinical practice but cannot replace VFSS. Another potential limitation is that NMES electrodes positioning could affect the potential to achieve better results (117): the thyrohyoid position used in this study has been evaluated in other studies with good results, although a depressive

effect on the hyolaryngeal complex has been described and authors have recommended a submental position (123)(146).

In our opinion, it might be useful to search for indirect indicators associated with the presence of lung infections, such as delayed triggering pharyngeal reflex and number of bronchoaspirations in the videofluoroscopic assessment, or peak cough flow, among others. Further research should include larger samples of both subacute and chronic patients in order to avoid confounding factors due to natural stroke evolution during the first weeks after event onset.

In conclusion, a 3-week intervention of both IEMT and NMES added to SST improves respiratory muscle strength and security in swallowing during the subacute stroke phase, although higher effectiveness of either of these innovative therapies could not be established from the observed differences. The use of combined therapies in the management of dysphagia appeared to accelerate swallowing recovery. The low prevalence of bronchoaspirative events prevented the evaluation of potential impact on the presence of respiratory complications.

7 CONCLUSIONS

CONCLUSIONS

- The Volume Viscosity swallow test is a low-cost test, easy to apply screening method to include as a standard method to evaluate stroke patients at income.
- The Volume Viscosity swallow test has a high sensitivity and specificity in ischemic stroke patient with a good inter-reliability between new explorers respect the gold standard.
- The Citric Cough test at 1mol/L solution is not useful as stand-alone test for the screening of silent aspiration or aspiration.
- NMES and IEMT appear to be useful interventions to improve respiratory muscle weakness and swallowing security after only 3-weeks protocol treatment
- The influence of NMES and IEMT on the appearance of respiratory complications remains unknown

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9 ANNEXES

9.1 First paper submitted in a non-indexed journal

Cribaje de la disfagia en el paciente con Ictus: utilidad de los signos clínicos y el método de exploración clínica de volumen viscosidad en comparación con la videofluoroscopia.

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ORIGINAL

Cribaje de la disfagia en el ictus: utilidad de los signos clínicos y el método de exploración clínica de volumen viscosidad en comparación con la videofluoroscopia

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PALABRAS CLAVE
Ictus;
Disfagia;
Cribaje clínico;
Videofluoroscopia;
Rehabilitación

Resumen
Introducción: La presencia de disfagia condiciona complicaciones como la desnutrición, deshidratación, neumonia e incluso la muerte del paciente, repercutiendo en los costes sanitarios. Existen métodos de detección precoz de la disfagia basados en signos clínicos y métodos instrumentados que pueden aplicarse en la cabecera del enfermo.
Objetivos: Determinar la utilidad del la valoración de Signos Clínicos y del Método de Exploración Clínica de Volumen-Viscosidad (MECV-V) y evaluar su eficiencia para detectar la broncoaspiración en la fase aguda y subaguda del ictus.
Pacientes y métodos: Estudio retrospectivo de una cohorte de 79 pacientes. Se comparan los parámetros clínicos y el MECV-V con los resultados objetivados con la videofluoroscopia (VFC). Se calculan las variables que determinan la fiabilidad y el valor global de un método diagnóstico: sensibilidad, especificidad y valores predictivos.
Resultados: Los signos clínicos para detectar disfagia grave (aspiración) obtuvimos una sensibilidad del 69% y una especificidad del 28,8%, El MECV-V detectó aspiración con una sensibilidad del 100% y una especificidad del 13,6%. El valor predictivo negativo fue respectivamente del 62,5 y 100%, la eficiencia diagnóstica fue de 0,38 y del 0,44% respectivamente.
Conclusión: La valoración del paciente disfágico basado en los datos de exploración clínica y el MECV-V resulta en un cribaje de bajo coste, de fácil aplicación y muy sensible. El MECV-V presenta mayor sensibilidad, especificidad y eficiencia, permitiendo ajustar dietas precozmente y decidir si precisa de una valoración instrumentada.

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KEYWORDS
Stroke;
Dysphagia;
Screening test;
Videofluoroscopy;
Rehabilitation

Screening of swallowing disorders in stroke: utility of clinical signs and clinical examination method of volume-viscosity in comparison with videofluoroscopy

Abstract
Introduction: The presence of dysphagia has been associated to dehydration, nutritional disorders, pneumonia and even death of the patient, this having an affect on the health care costs. There are methods to detect dysphagia early based on evaluation of the clinical signs and methods that can be used at the bedside of the patient.
Objectives: To determine the utility of the evaluation of the clinical signs (CS) and the volume-viscosity test (V-VST) and evaluate their efficacy to detect risk of aspiration in the acute and subacute phase of stroke.
Patients and method: A retrospective evaluation of a cohort of 79 stroke patients was performed. We compared the clinical signs and V-VST with the results observed with the videofluoroscopy (VFC). The variables that determine accuracy and overall value of a diagnostic method, that is, sensitivity, specificity, and positive (PPV) and negative (NPP) predictive values, were calculated.
Results: A sensitivity of 69% and specificity of 28.8% was obtained for the Clinical Signs to detect severe dysphagia (Aspiration). V-VST detected aspiration with 100% sensitivity and 13.6% specificity. NPP was 62.5% and 100%, respectively. Diagnostic accuracy was 0.38 for clinical signs and 0.48 for V-VST.
Conclusion: Using CS and V-VST for the evaluation of the dysphagic patient is a low-cost screening method that is easy to apply and highly sensitive. The V-VST offers a higher sensitivity, specificity and accuracy and makes it possible to modify the diet early and to decide whether instrumental assessment is indicated.

Introducción

La disfagia o las dificultades en la deglución están presentes entre el 25-85% de los pacientes tras un ictus agudo[1–5], dependiendo de las series publicadas. La neumonía broncoaspirativa se estima en un riesgo tres veces superior en los pacientes con disfagia, respecto a los que no presentan clínica, y en 11 veces superior en los pacientes con signos severos de alteración de la deglución[4]. La malnutrición[6–11], la deshidratación y la muerte post-ictus [12,13], son parte de las complicaciones habituales, y generan mayor demanda asistencial y mayor incidencia de ingresos hospitalarios, con estancias hospitalarias más largas y costosas[14,15].

Existe una gran variedad de métodos de detección precoz o cribaje que se extienden desde las clásicas *check lists*, basadas en la presencia de signos y síntomas clínicos, a los métodos de evaluación en la cabecera del enfermo (*clinical bedisde assesment:* test del agua, control de la saturación,...), con los que se obtienen una sensibilidad y especifidad entre el 85 y 60% respectivamente, comparadas con *el gold standard*, la videofluoroscopia (VFC)[16–18]. Estudios recientes[19] demuestran la gran utilidad de los test de valoración. Así sabemos que el cribaje tiende a realizarse en el paciente con mayor severidad de ictus, aunque vemos que las ratios de neumonías broncoaspirativas son más altas en los pacientes no explorados comparados con los que pasaron el test de cribaje correctamente y más bajas que los que lo pasaron y resultó alterado.

La VFC es el *gold standard* en el estudio de los trastornos de la deglución. Consiste en la administración de volúmenes crecientes de bolo alimentario a distintas viscosidades y consistencias, y permite evaluar el trayecto del bolo alimentario, así como el efecto de los cambios posicionales para la protección de la vía respiratoria. Es un recurso caro, puesto que se realiza en las instalaciones de radioescopia, requiere una alta inversión en tiempo y no está a disposición de todos los clínicos. Por todo ello, es necesario disponer de un método de cribaje protocolizado y no-instrumentalizado que ayude a optimizar el diagnóstico y el tratamiento de la disfagia en los pacientes con ictus[17,19–22].

La valoración de la disfagia en la cabecera del paciente (*clinical bedside assessment*)[16,21,22] es coste-efectivo, no invasivo y ofrece la posibilidad de instaurar un tratamiento para la disfagia mientras se valora si precisa de una valoración instumentalizada para completar el diagnóstico.

La evaluación propuesta por Daniels[1,7] donde la presencia de dos signos clínicos (alteración en el reflejo tusígeno, el reflejo nauseoso, la disfonía, la disartria, los cambios en el tono de voz en la ingesta y la tos durante o postdeglución), permite dividir a los pacientes en dos grandes grupos de disfagia moderada-severa y disfagia leve-no disfagia es de fácil y rápida aplicación.

Otro método clínico no invasivo de valoración de la disfagia consiste en administrar alimentos a diferentes volúmenes y viscosidades[17,23], parecido al método expuesto por Logemann[17] en la valoración videofluoroscópica. Clavé[24,25] asocia la pulsioximetría[26–28] al test clínico con distintos volúmenes y viscosidades, definiendo el método de Exploración Clínica de Volumen-Viscosidad (MECV-V). Los cambios en cualquiera de los signos de seguridad (tono de voz, tos o desaturación) etiquetan la prueba de positiva e indican la necesidad de realizar la VFC. Este test permite ajustar la dieta para evitar complicaciones médicas mientras no se pueda realizar una exploración más completa.

Aunque cada vez más, la valoración de la disfagia en el ictus se realiza de manera sistemática en los servicios de Neurología y de Rehabilitación Neurológica, existe gran disparidad entre las diferentes pruebas clínicas[19]. En base a estas consideraciones, se diseña un estudio con el objetivo de evaluar la utilidad de los signos clínicos descritos por Daniels[1,7] y del MECV-V para detectar la broncoaspiración en pacientes con disfagia orofaríngea secundaria a ictus en comparación con la VFC que es el *gold standard* para su diagnóstico y, secundariamente, conocer la correlación entre las diferentes pruebas utilizadas.

Pacientes y métodos

Estudio retrospectivo de una cohorte de pacientes consecutivos con ictus admitidos en una Unidad de Hospitalización para Rehabilitación Intensiva en un hospital universitario de tercer nivel con área de influencia en la ciudad de Barcelona durante el año 2009.

Los criterios de inclusión en el estudio fueron: 1) pacientes con ictus agudo de menos de tres semanas de evolución, 2) registro de los signos clínicos, MECV-V y videofluoroscopia en la historia clínica, y 3) no historia previa de enfermedades neurológicas que pudieran condicionar disfagia orofaríngea.

Se excluyeron aquellos pacientes que por su estado general y/o cognitivo no pudieran colaborar en la realización de las diferentes pruebas diagnósticas.

Del total de pacientes ingresados durante 2009, 150 pacientes, 79 (52,66%) cumplían los criterios de inclusión previamente descritos. (fig. 1).

Los instrumentos diagnósticos/cribaje utilizados son:

- Signos clínicos de Daniels[1,7]: reflejo tusígeno, reflejo nauseoso, disfonía, disartria, tos postdeglución o cambios en el tono de voz tras la ingesta). La presencia de dos de estos signos permite diferenciar a los pacientes en dos grandes grupos, los afectos de disfagia moderada-severa de aquellos con disfagia leve-sin disfagia, con una sensibilidad del 93% y una especificidad del 66,7%.
- MECV-V[25]: recoge la alteración de los parámetros de seguridad (cambio del tono de voz, tos durante o tras la ingesta o desaturación superior al 3% respecto a la pulsioximetría basal). Se realiza con el paciente en sedestación y se administran bolos alimentarios de diferentes viscosidades (líquidos finos, néctar y *pudding*) a volúmenes crecientes (5,10 y 20 ml) que se preparan mezclando agua y espesante Resource® (Novartis Consumer Health S.A, Barcelona, Spain). La exploración se inicia a viscosidad néctar y se observa si aparece algún parámetro de seguridad alterado. En caso afirmativo, se continúa la exploración con la viscosidad *pudding* y si ésta no está alterada, puede procederse a la administración de líquidos finos. El autor reporta una sensibilidad del 100% y una especificidad del 28% para el diagnóstico de aspiración (paso de alimento a las vías respiratorias) y, una sensibilidad del 83% y especificidad del 64,7% para el diagnóstico de penetración (presencia de alimento por encima de las cuerdas vocales).
- Evaluación con VFC[17,29]: técnica radiológica dinámica que consiste en la obtención de una secuencia en perfil lateral y anteroposterior de la ingesta de diferentes volúmenes (5, 10 y 20 ml) de tres viscosidades diferentes (líquido, néctar y *pudding*) de contraste hidrosoluble Gastrografin® (Schering, Spain). Los signos videofluoroscópicos recogidos fueron: penetración a vía respiratoria (presencia de contraste radiológico en el vestíbulo laríngeo por encima de las cuerdas vocales), aspiración (presencia de contraste por debajo de las cuerdas vocales) y aspiración silente (presencia de contraste por debajo de las cuerdas vocales sin respuesta clínica por parte del paciente).

En este estudio, y únicamente para el manejo analítico, se tratará la clasificación de Daniels[1,7] como una prueba diagnóstica de paso de alimento a vía respiratoria (penetración y/o broncoaspiración), considerando como resultado positivo si los pacientes se clasifican en el grupo de disfagia moderada o severa y como resultado negativo, si los pacientes se clasifican en el grupo de disfagia leve o no disfagia.

Las variables de resultados son la sensibilidad, la especificidad, los valores predictivos y positivo expresados en porcentaje; y, para estimar el valor de de los test realizados se han calculado las razones de probabilidad positiva y negativa, así como el cálculo de la eficiencia diagnóstica o *accuracy*.

Otras variables recogidas fueron:

- Datos demográficos: edad, sexo.
- Variables clínicas: clasificación topográfica y etiología del ictus, complicaciones respiratorias, tiempo transcurrido desde el ictus hasta la realización de la VFC, indicación y retirada de sonda nasogástrica y/o de gastrostomía, modificaciones en la dieta y prescripción de logoterapia.
- Valoración funcional mediante el uso de la escala de Barthel[30].

Análisis estadístico

Las variables categóricas se presentan en valores absolutos y en porcentajes, mientras que las cuantitativas se presentan con su media y DE. Se utilizan tablas de contingencia, a partir de las cuales se calculan los índices que determinan la fiabilidad de los signos clínicos descritos por Daniels[1,7] y del MECV-V como método diagnóstico de aspiración en pacientes con disfagia orofaríngea.

Para analizar la capacidad de los métodos diagnósticos utilizados[31] se calculan los índices que determinan la fiabilidad diagnóstica de un método, expresados en porcentajes, que en el caso del presente estudio se definen como:

- Sensibilidad: probabilidad que la prueba sea positiva (paso de alimento a la vía respiratoria) en pacientes que presentan penetración y/o broncoaspiración confirmadas mediante la prueba *gold standard*.
- Especificidad: probabilidad que la prueba sea negativa (no paso de alimento a la vía respiratoria) en pacientes que no presentan penetración ni broncoaspiración en la prueba *gold standard*.
- Valor predictivo positivo (VPP): es la probabilidad que tiene un individuo de presentar paso de alimento a la vía respiratoria cuando el resultado de la prueba diagnóstica es positiva.

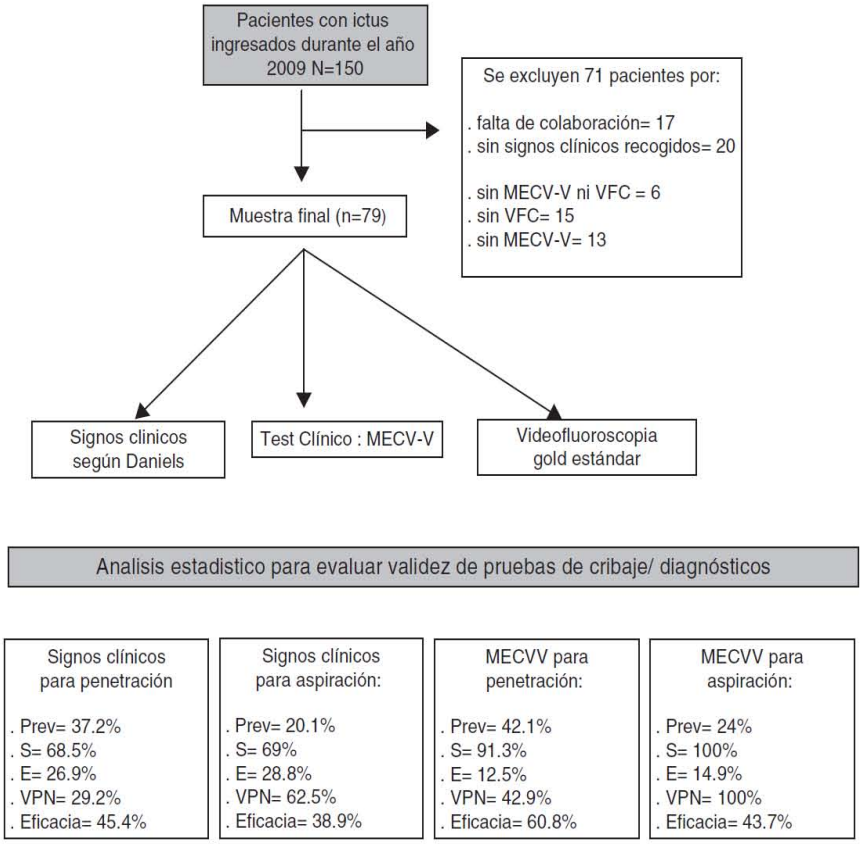

Figura 1 Diagrama de flujo del estudio.

- Valor predictivo negativo (VPN): es la probabilidad que tiene un individuo de no presentar paso de alimento a la vía respiratoria cuando el resultado de la prueba diagnóstica es negativa.

Las razones de probabilidad permiten un mejor entendimiento de los resultados de una prueba ya que muestra con qué fuerza el resultado positivo de la prueba indica la presencia real de la enfermedad (por ejemplo, broncoaspiración). En otras palabras, las razones de probabilidad indican como el resultado de la prueba hace cambiar la probabilidad pretest a la probabilidad postest en el paciente. Para convertir la probabilidad pretest de tener una enfermedad a la probabilidad postest, usando la razón de probabilidad.

Para estimar el valor global de los métodos diagnósticos se utilizaron diferentes índices:

- Índice de exactitud o eficacia diagnóstica: es la proporción de resultados verdaderos (positivos y negativos) entre la totalidad de pruebas efectuadas.
- Razones de probabilidad (*likelihood ratios*): comparan la probabilidad de obtener determinado resultado en un individuo que presente paso de alimento a la vía respiratoria, con relación a la de obtenerlo en otro que no la tenga. La razón de probabilidad de una prueba positiva (RPP) indica el número de veces que es más probable hallar un resultado positivo de la prueba en un individuo enfermo, con relación a otro no enfermo y es el resultado de dividir la proporción de casos con resultado positivo entre los que presentan paso de alimento a vía respiratoria (sensibilidad) entre la proporción de casos con resultado positivo y que no presentan la enfermedad (tasa de falsos positivos). La razón de probabilidad de una prueba negativa (RPN) es el resultado de dividir la proporción de casos con resultado negativo entre los que presentan paso de alimento a vía respiratoria (100 - sensibilidad) entre la proporción de casos con resultado negativo entre los que no presentan la condición (especificidad).

Resultados

En el año 2009 se realizaron 154 valoraciones videofluoroscópicas, de las cuales 79 correspondían a pacientes con ictus agudo que cumplían los criterios de inclusión. Las características generales de la muestra se describen en la tabla 1. La edad media fue de 64,7 (DE 13,2) años y la distribución por sexos fue de 60 hombres frente a 19 mujeres. La valoración clínica se realizó a los 14,8 (DE 11,8) días del ictus coincidiendo con el ingreso en la Unidad de Rehabilitación, mientras que el tiempo transcurrido desde el ictus hasta la realización de la videofluoroscopia fue de 23,1 (DE 13,6) días. A su llegada a Rehabilitación, hubo 4 pacientes que eran portadores de sonda nasogástrica y dos de sonda de gastrostomía. Del total de pacientes, constaba una neumonía broncoaspirativa en la fase aguda del ictus en 14 (17,7%) casos.

Tabla 1 Variables clínicas y demográficas de la muestra (n = 79)

Edad	64,7 (DE 13,2)
Sexo	
Mujer	19 (24%)
Hombre	60 (76%)
Lateralidad del ictus	
Derecho	40 (50,6%)
Izquierdo	33 (41,8%)
Bilateral	6 (7,6%)
Clasificación topográfica	
Circulación total anterior	10 (12,7%)
Circulación parcial anterior	35 (44,3%)
Lacunar	6 (7,6%)
Circulación posterior	28 (35,4%)
Etiología	
Isquémico	59 (74,7%)
Hemorrágico	15 (9%)
Isquémico con transformación hemorrágica	5 (6,3%)
Complicaciones respiratorias	
En fase aguda (durante ingreso en Neurología)	14 (17,7%)
En fase subaguda (durante ingreso en Rehabilitación)	1 (3,7%)
Días transcurridos desde	
Ictus a la realización de la Videofluoroscopia	23,1 (DE 13,6)
Ictus al ingreso en Rehabilitación	14,8 (DE 11,8)
Ingreso en Rehabilitación a la V videofluoroscopia	8,3 (DE 6,5)
Estado funcional	
Índice de Barthel al ingreso en Rehabilitación	43,2 (DE 21,5)
Índice de Barthel al alta de Rehabilitación	65,4 (DE 25,6)
Tipo de alimentació al ingreso en Rehabilitación	
Dieta normal	13 (16,5%)
Dieta blanda con espesantes en los líquidos	24 (30,4%)
Diesta disfágica	36 (45,6%)
Alimentación por sonda nasogástrica	4 (5,1%)
Alimentación por gastrostomía percutánea	2 (2,6%)

La tabla 2 describe los resultados de la clasificación según los signos clínicos descritos por Daniels[1,7] y del MECV-V, respecto a la VFC. Destaca que casi la mitad de la muestra presentaban dos o más signos clínicos alterados siendo clasificados en el grupo de disfagia moderada-severa de Daniels[1,7], de los cuales hubo 22 pacientes en los que se confirmó paso de contraste a vía aérea mediante la VFC. Por otra parte, en la misma tabla se detalla el número de pacientes que al ser evaluados con el MECV-V, presentaron cambios en el tono de voz, tos durante o tras la ingesta y/o desaturación superior al 3% en cualquiera de las consistencias exploradas.

En la tabla 3 quedan especificadas la prevalencia, la sensibilidad, la especificidad, el VPP y el VPN respecto al *gold standard*. La prevalencia de broncoaspiración del grupo de pacientes con disfagia moderada o severa fue del 20,1% con una sensibilidad del 69% y una especificidad del 28,8%. La prevalencia de broncoaspiración en el grupo de pacientes que dieron positivo en el MECV-V fue del 24% con una sensibilidad del 100% y una especificidad del 14,9%. El VPN fue del 62,5% para la clasificación de Daniels[1,7] y del 100% para el MECV-V.

En la tabla 4 se describen los resultados para la capacidad diagnóstica de los métodos clínicos utilizados, definidos con parámetros de prevalencia y la razones de probabilidad positiva y negativa para cada prueba. Destacar una eficacia del 60,8% para el MECV-V en relación a la penetración y del 43,7% para la aspiración. En cuanto a las razones de probabilidad destacar la desaturación > 3% con una RPP de 6,26 para penetración y de 7,18 para aspiración, así como un RPP del 9,04 para los cambios en el tono de voz en la aspiración. El resto de valores se mueven en razones cercanas al uno.

Discusión

El presente estudio evalúa la capacidad diagnóstica de la clasificación según los signos clínicos descritos por Daniels[1,7]y del MECVV para detectar la broncoaspiración en pacientes con disfagia orofaríngea secundaria a ictus en comparación con la prueba *gold standard*.

El «VPN» y el «VPP» de una prueba diagnóstica están determinados por la especificidad y la sensibilidad de la prueba y por la prevalencia de la condición estudiada en la población. Cuanto más sensible sea una prueba, mejor será el VPN y cuanto más específica, mejor será el VPP. Para una sensibilidad y especificidad determinadas, a medida que aumenta la prevalencia, aumenta la capacidad predictiva positiva de una prueba y disminuye la capacidad predictiva negativa. Por el contrario, a medida que disminuye la prevalencia, disminuye la capacidad predictiva positiva y aumenta la capacidad predictiva negativa.

Las «razones de probabilidad» son especialmente atractivas en la evaluación de las pruebas diagnósticas ya que relacionan sensibilidad y especificidad en un único índice y no se afectan por los cambios de la prevalencia[31]. En cambio, la «eficiencia diagnóstica» tiene el inconveniente de asignar el mismo valor a los falsos positivos que a los falsos negativos, cuando en realidad la importancia de cada uno de ellos es variable según la situación clínica y el propósito de la prueba (cribado, confirmación o exclusión de una enfermedad o condición).

Nuestra muestra tiene una prevalencia de disfagia del 52,6%[3,6–8]. No es fácil hacer comparativas con otros estudios publicados puesto que existe disparidad de criterios en cuánto al momento y el tipo de evaluación clínica y cada centro tiende a utilizar una batería de tests propia, basada en la literatura y complementada según la experiencia clínica del autor[2,19,32,33]. Existen múltiples y variados tests en la literatura para la detección precoz del paciente disfágico[7,22–24,26,32]. El objetivo en todos es detectar a los pacientes que aspiran y poder ajustar las dietas para evitar

Tabla 2 Descripción de las pruebas diagnósticas utilizadas (n = 79)

	Videofluoroscopia			
	Penetración		Aspiración	
	Sí	No	Sí	No
Signos clínicos Daniels				
Clasificación en dos grupos				
Disfagia moderada-severa	42 (53,2%)	20 (25,3%)	22 (27,9%)	40 (50,6%)
Disfagia leve-no disfagia	11 (13,9%)	6 (7,6%)	5 (6,3%)	12 (15,2%)
MECV-V				
Resultado global				
Positivo	42 (60%)	21 (30%)	23 (32,9%)	40 (57,1%)
Negativo	4 (5,7%)	3 (4,3%)	0 (0%)	7 (10%)
Cambios en el tono de voz				
Sí	23 (40,35%)	13 (22,8%)	12 (21,1%)	24 (42,1%)
No	14 (24,6%)	7 (12,3%)	2 (3,5%)	19 (33,3%)
Tos ingesta o post-ingesta				
Sí	29 (41,4%)	10 (14,3%)	20 (28,6%)	19 (27,1%)
No	17 (24,3%)	14 (20%)	3 (4,3%)	28 (40%)
Desaturación > 3% basal				
Sí	12 (17,1%)	1 (1,4%)	10 (14,3%)	3 (4,3%)
No	34 (48,6%)	23 (32,9%)	13 (18,6%)	44 (62,8%)

E: especificidad; MECV-V: Método de Exploración Clínica de Volumen-Viscosidad; S: sensibilidad; VPN: valor predictivo negativo; VPP: valor predictivo positivo.

así las complicaciones médicas derivadas en un paciente que ya es lábil. El test ideal debería responder a una sensibilidad del 100% y a una especificidad lo más alta posible. Pero, puestos a renunciar mejor una alta sensibilidad que una alta especificidad. Con una alta sensibilidad habrá pacientes sobretratados, pero un ajuste de dieta y el uso de espesantes de forma temporal tienen menos riesgo que el pasar desapercibido y presentar cómo complicación una neumonía broncoaspirativa.

Si comparamos los datos obtenidos por Daniels et al.[1,7] en la evaluación de los signos clínicos y en su combinación para la detección del paciente disfágico, nos alejamos de

Tabla 3 Análisis de la capacidad para detectar penetración y aspiración de la clasificación según los signos de Daniels y el MECV-V en comparación con la videofluoroscopia (n = 79)

	Penetración					Aspiración				
	PREV	S	E	VPP	VPN	PREV	S	E	VPP	VPN
Clasificación en los grupos de disfagia moderada-severa o disfagia leve-no disfagia	37,2%	68,5%	26,9%	66,1%	29,2%	20,1%	69%	28,8%	35,1%	62,5%
MECV-V										
Resultado global del MECV-V	42,1%	91,3%	12,5%	66,7%	42,9%	24%	100%	14,9%	37,5%	100%
Por signos desglosados										
Cambios en el tono de voz:	23,2%	62,2%	35,0%	63,9%	33,3%	13%	86,7%	44,2%	35,1%	90,5%
Tos ingesta o post-ingesta:	29,2%	63,0%	58,3%	74,4%	45,2%	21%	87,5%	59,6%	52,5%	90,3%
Desaturación superior al 3% respecto la pulsioximetría basal	12,5%	26,1%	95,8%	92,3%	40,4%	11,2%	45,8%	93,6%	78,6%	77,2%

E: Especificidad; MECV-V: Método de Exploración de Volumen-Viscosidad; S: sensibilidad; VPN: valor predictivo negativo; VPP: valor predictivo positivo.

Tabla 4 Capacidad diagnóstica de los métodos clínicos utilizados

VFC	Penetración			Aspiración		
	Eficacia	RPP	RPN	Eficacia	RPP	RPN
Clasificación en los grupos de disfagia moderada-severa o disfagia leve-no disfagia	45,4%	0,94	1,16	38,9%	0,97	1,08
MECV-V						
Resultado global del MECV-V	60,8%	1,04	0,69	43,7%	1,18	0
Por signos desglosados						
Cambios en el tono de voz	42,3%	0,95	1,08	53,3%	1,55	0,30
Tos ingesta o post-ingesta	40,2%	1,51	0,63	66,2%	9,04	0,13
Desaturación superior al 3% respecto la pulsioximetría basal	33,7%	6,26	0,77	65,5%	7,18	0,58

MECV-V: Método de Exploración de Volumen-Viscosidad; RPN: razón de probabilidad negativa; RPP: razón de probabilidad positiva.

la sensibilidad y la especificidad publicadas, en que presentaba sensibilidad del 93% y una especificidad del 66,7% en la detección de pacientes disfágicos leves o moderados graves con la asociación de dos o más de los seis signos clínicos evaluados. Si revisamos los resultados publicados por otros autores en la presencia de tos en la deglución, publicaba Mari et al.[34] una sensibilidad del 52% y una especificidad del 86% o para la disfonía, según Stanners et al.[35] con una sensibilidad del 60% y una especificidad del 45%; según Horner et al.[36] una sensibilidad del 97% y una especificidad del 29%. O si nos fijamos en la desaturación Zaidi et al.[37] y tomamos como referencia los resultados de Lim et al.[18] en la comparación con el FEES con una sensibilidad del 76,9% y una especificidad del 83,3% y con un índice de correlación kappa del 0,601. Nuestros resultados no son nada despreciables y se colocan en las medias de los ya publicados. El uso de otros métodos diagnósticos como los tests del agua (*Water Swallowing Test* [WST]) y sus variantes[22], resulta controvertido por exponer a la broncoaspiración a un paciente lábil y de riesgo. Además, estos tests han demostrado tener alto valor predictivo negativo, por lo que la ratio riesgo/beneficio es más bien pobre[38].

El nuevo protocolo establecido en nuestra Unidad basada en la valoración de los signos clínicos y el MECV-V, vemos que su aplicación permite una detección precoz de las viscosidades y volúmenes a las que el paciente está en riesgo y ajustar así la dieta, y nos ofrece la posibilidad de realizar un seguimiento diario o semanal, según requiera el paciente, para ajustar progresivamente la dieta. Así mismo, destacar solo un 1,5% de complicaciones por broncoaspiración en el 2009, cuándo cerca del 20% del los pacientes eran trasladados con episodios de neumonía previa. Parece pues, que sí somos capaces de establecer un buen algoritmo en la valoración y diagnóstico, probablemente en un futuro no muy lejano podremos acotar bien los pacientes a los que realizamos el estudio de VFC, dejándolo restringido a los casos altamente dudosos en la valoración clínica o a los de alto riesgo de aspiración silente.

Si nos fijamos en los resultados publicados por Clavé et al.[24,25] para al MECV-V, obtenemos también un 100% de sensibilidad la aspiración, pero un 14,9% de especificidad, respecto el 28,8% del autor. En este caso hay que destacar que nuestra muestra es homogénea en cuanto a etiología respecto a la utilizada por el autor del MECV-V, que presenta una muestra de 85 pacientes (con 12 voluntarios sanos de grupo control) de los cuales solo 23 están clasificados como afectos de accidente cerebrovascular, correspondiéndose el resto a pacientes geriátricos, afección tumoral de cabeza y cuello o enfermedades neurodegenerativas. Pero, aún con una especificidad baja, el MECV-V presenta una capacidad diagnóstica alta. Si desglosamos los parámetros evaluados obtenemos una razón de probabilidad positiva (probabilidad de presentar penetración y aspiración respecto al paciente sano) de 6,25 veces para penetración y de 7,18 para aspiración y de 9,04 veces en la tos respecto a la aspiración.

Los datos de correlación del MECV-V con la VFC, aunque precisan de un estudio prospectivo, apuntan datos interesantes comparados con la literatura y creemos que es de gran utilidad para la primera valoración el la cabecera del enfermo puesto que nos ayuda a definir la dieta según las alteraciones detectadas a las distintas viscosidades, evitando a sí complicaciones mayores.

En cuánto a las limitaciones del estudio hay que destacar:

- Nuestra muestra padece un sesgo importante de base. Pacientes preselecionados para el traslado en régimen de ingreso (se descartan los pacientes con buena recuperación funcional inicial que regresaron a domicilio y los de situación grado de colaboración muy deficitario que no se consideraron tributarios a traslado para pauta de rehabilitación intensiva).
- Se escogen a los pacientes que durante el ingreso se estudiaron con signos clínicos según Daniels[1,7], MECV-V y VFC, descartándose a los que les faltaban datos.
- No tenemos grupo control puesto que no era el objetivo del estudio en su inicio.
- Creemos que es necesario aumentar el tamaño de la muestra para confirmar las diferencias en los datos obtenidos en los signos clínicos de Daniels[1,7] frente la valoración VFC.

Dado que es un estudio retrospectivo, es necesario plantear un recogida sistematizada y prospectiva y establecer un grupo control que nos permita validar los tests en nuestra población, aunque el autor del test ya lo presenta en su publicación del 2008 donde trabaja con un grupo control de 12 pacientes.

En conclusión, la asociación del MECV-V pulsioximetría a parámetros clínicos constituyen un buena herramienta para el abordaje clínico de la población potencialmente disfágica, ayudando en el diagnóstico, la nutrición y para establecer la necesidad de pruebas instrumentadas. Ofrecen una buena alternativa de valoración en centros donde no se dispone de la valoración instrumentalizada, trabajando en la línea que preconizan las últimas revisiones de asociar un test clínico y la pulsioximetría a la valoración del paciente potencialmente disfágico[29].

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Los autores declaran que los procedimientos seguidos se conformaron a las normas éticas del comité de experimentación humana responsable y de acuerdo con la Asociación Médica Mundial y la Declaración de Helsinki.

Confidencialidad de los datos. Los autores declaran que han seguido los protocolos de su centro de trabajo sobre la publicación de datos de pacientes y que todos los pacientes incluidos en el estudio han recibido información suficiente y han dado su consentimiento informado por escrito para participar en dicho estudio.

Derecho a la privacidad y consentimiento informado. Los autores declaran que en este artículo no aparecen datos de pacientes.

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9.2 Posters of merit related to paper 1 and paper 2.

Presented in the ESSD, *5th European Congress in Swallowing disorders.*

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Poster 1:

Accuracy of the volume-viscosity swallow test among healthcare professionals in a stroke rehabilitation unit

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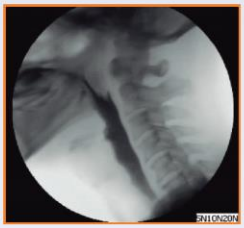
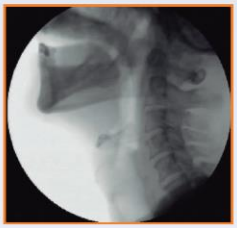
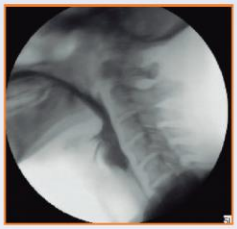
Introduction

Oropharyngeal dysphagia (OD) is a highly prevalent condition in patients after a stroke and it is an underdiagnosed disorder that causes severe nutritional and respiratory complications. Despite its high prevalence and severe complications, OD is not always systematically explored and detected, and most patients are not even diagnosed and do not receive any treatment for this condition.
Bedside assessment for OD should be done to an earlier identification of dysphagic patients. Videofluoroscopy (VFS) is the gold standard to study oral and pharyngeal mechanisms of OD, swallowing dysfunction and aspiration.
The implementation of dysphagia programs, including screening, results in substantial reductions in pneumonia rates.
The Volume-Viscosity Swallow Test (V-VST) shows high diagnostic accuracy in identifying clinical signs and symptoms of impaired efficacy and safety of swallow.
The main purpose of the study was to assess inter-ratercorrelation of V-VST between two healthcare professionals working in a post-acute stroke rehabilitation unit versus the VFS.

Materials & Methods

Twenty-seven post-acute stroke patients with swallowing difficulties or suspected dysphagia were studied.
The V-VST was performed at the same time by two healthcare professionals with different degrees of expertise; one-year Rehabilitation medical resident (A), and a new Rehabilitation resident (with a two hours formation) (B). They scored their results separately, determined the functional oral intake scale (FOIS) and estimated the clinical penetration aspiration scale (PAS).
The day after, VFS was performed by a physiatrist with eight-year expertise in swallowing disorders, blinded to clinical results.

Results

A total of twenty-seven patients with a mean age of 66.3 years were recruited. Of these, 63.6% presented ischemic stroke and 27.3% were hemorrhagic.
Researcher A, using the V-VST, detected 55.6% of impaired safety and 40% of impaired efficacy of swallow with respect to VFS findings. Researcher B, detected 65% and 57% respectively.
The Kappa coefficient was 0.60 for impaired safety and 0.78 for impaired efficacy.
The estimated PAS alteration that the researchers detected was 75% (researcher A) and 77.8% (researcher B) with respect to VFS with a Kappa coefficient of 0.762.

Table 1. Demographical and clinical characteristics of the study population.

	Patients (n=27)
Age (years)	66.33 (DE 10.35)
Sex:	
- Male	19 (70.37%)
- Female	8 (29.63%)
Stroke etiology	
- Ischemic	63.6%
- Hemorrhagic	27.3%
NIHSS	6.50 (DE 4.43)
TOAST:	
- Atherothrombotic	12.5%
- Cardioembolic	18.8%
- Lacunar	18.8%
- Unusual	25.0%
- Undetermined	25.0%
mRSincome	3,45 (DE 0.99)
Oxford classification:	
- TACI	18.8%
- PACI	18.8%
- LACI	37.5%
- POCI	25.0%
Clinical signs:	
- Dysphonia	48.1%
- Dysarthria	40.7%
- Absent gag reflex	51.9%
- Absent voluntary cough	11.1%

NIHSS: National institute of Health Stroke Scale; TOAST: Trial of Org 10172 in Acute Stroke Treatment; mRS: modified Rankin Scale; TACI: total anterior circulation infarcts; PACI: partial anterior circulation infarcts; LACI: lacunar circulation infarcts; POCI: posterior circulation infarcts

Table 2. Accuracy of the V-VST to detect dysphagia, impaired safety and efficacy of swallow and aspirations with respect to VFS findings.

	Impaired safety	Impaired efficacy	Estimated PAS
Researcher A	55.6%	40.0%	75.0%
Researcher B	65.0%	57.0%	77.8%

Researcher A: one-year Rehabilitation medical resident; Researcher B: new Rehabilitation resident; PAS: Penetration Aspiration Scale.

Conclusions

A good inter-rater correlation and high accuracy have been found between two short-expertise medical residents in V-VST application for screening swallowing disorders in stroke patients.

The V-VST is an easy and reproducible test to detect swallowing disorders in a risk population of stroke patients.

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Poster 2:

Citric cough test for screening of aspiration in subacute stroke patients

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Introduction

Dysphagia is present in 85% of subacute stroke patients and is associated with an increased medical complications such as aspiration pneumonia, malnutrition and death. Cough is an important protective mechanism responsible for maintaining the patency of the airways. Cough clears the airways through the generation of high expiratory flow. A decreased or absent cough reflex in stroke patients with swallowing disorders has been pointed to more likely to develop pneumonia.
Acid Citric Cough Test (CCT) has been reported as a useful screening for silent aspiration, in combination with a water swallowing test. CCT compared with Videofluoroscopy (VFS) has been described with good results to detect silent aspirations. According to European Respiratory Task Force Guidelines for Cough Assessment (1) the number of consecutive cough peaks to consider a failed response is not well determined.
The aim of this study was to compare the 2 versus 5 cough threshold (C2 and C5 respectively) to detect silent aspiration in subacute stroke patients.

Materials and Methods

A prospective study of stroke patients admitted to an inpatient intensive rehabilitation unit in a university hospital. All patients were examined with the Viscosity-Swallow-Test (V-VST). CCT and VFS were conducted in all patients with failed V-VST.
Dysphagia was confirmed with VFS (gold standard). The severity of dysphagia was assessed with the Penetration-Aspiration-Scale (PAS). For a global interpretation of the results, participants were also classified following the convention used by Power et al: healthy (PAS= 1-2), and disordered (PAS ≥3). (2)

CITRIC ACID COUGH TEST: (3)
The CCT consist of oral inhalation of a 1.0(w/v) % mixture of saline and citric acid for 1 minute through an ultrasonic nebulizer (ORMON NE-U17) and the counting of cough peaks that result. For the purpose of this study, the particle size was 1 to 8µm, and the output rate was 3mL/min. Patients were asked to breathe normally for 1 minute and cough as needed. Following the European Respiratory Task Force Guidelines for Cough Assessment, cough was defined as a 3-phase process of inspiration, forceful expiratory effort against a closed glottis, and reopening of the glottis and fast expiratory airflow.
The number of cough peaks triggered by patient (C2 and C5) was recorded.
Patients with ≥2 or ≥5 cough peaks were considered as normal CCT responders in C2 and C5 respectively, and with <2 or <5 cough peaks were considered as reduced or absent CCT responders. No audio recording was performed.

Results

Forty-nine patients were enrolled in the study. The baseline demographic and clinical characteristics are shown in Table 1. The mean age was 67.89 years; gender distribution was 71.4% men. Acute hemispheric infarction was present in thirty-six patients. Most of these patients (30.6%) presented infarction on posterior circulation (POCI).
At C2 threshold, 4 patients were no-CCT-responders (75% with PAS≥3) and 43 triggered 2 or more cough (63% with PAS≥3).
At C5 threshold, 12 patients were no-CCT-responders (67% with PAS≥3) and 34 patients triggered 5 or more cough (65% with PAS≥3).
Table 2 shows contingency tables for the CCT when participants were classified according to healthy or disordered VFS.
ROC curves were constructed without achieving significance differences between C2 and C5 threshold, neither for diagnosing aspiration (Table 3).

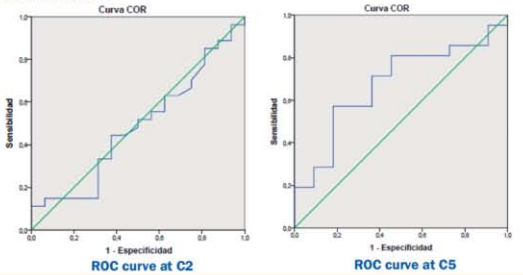
Table 1: Baseline demographic and clinical characteristics of the sample

Characteristics		Patients (n=49)
Age (y)		67.89
Sex		
	- Female	14 (28.6%)
	- Male	35 (71.4%)
Tabacco smoking		
	- Smokers	9 (18.4%)
	- Ex-smokers	12 (24.5%)
	- Nonsmokers	19 (38.8%)
	- Unknown	9 (18.4%)
Stroke etiology		
	- Isquemic	36 (73.5%)
	- Hemorrhagic	13 (26.5%)
Oxford Stroke classification		
	- TACI	10 (20.4%)
	- PACI	6 (12.2%)
	- LACI	5 (10.2%)
	- POCI	15 (30.6%)
	- No data availabe	7 (14.2%)

Table 2: Contingency tables for C2 and C5 threshold vs Penetration-Aspiration-Scale

C2	PAS<3	PAS≥3	
Cough <2	1 (25%)	3 (75%)	4
Cough ≥2	16 (37%)	27 (63%)	43
C5	**PAS <3**	**PAS ≥ 3**	
Cough <5	4 (33%)	8 (67%)	12
Cough ≥5	12 (35%)	22 (65%)	34

Table 3: ROC curve



ROC curve at C2 ROC curve at C5

Conclusions

CCT at 1.0mol/L evaluated at C5 and C2 does not seem to be a useful standalone tool to detect aspiration in subacute stroke patients.

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3- Wakasugi Y, Tohara H, Nakane A, Murata S, Mikushi S, Susa C, et al. Usefulness of a handheld nebulizer in cough test to screen for silent aspiration. Odontology. 2014;102(1):76–80.

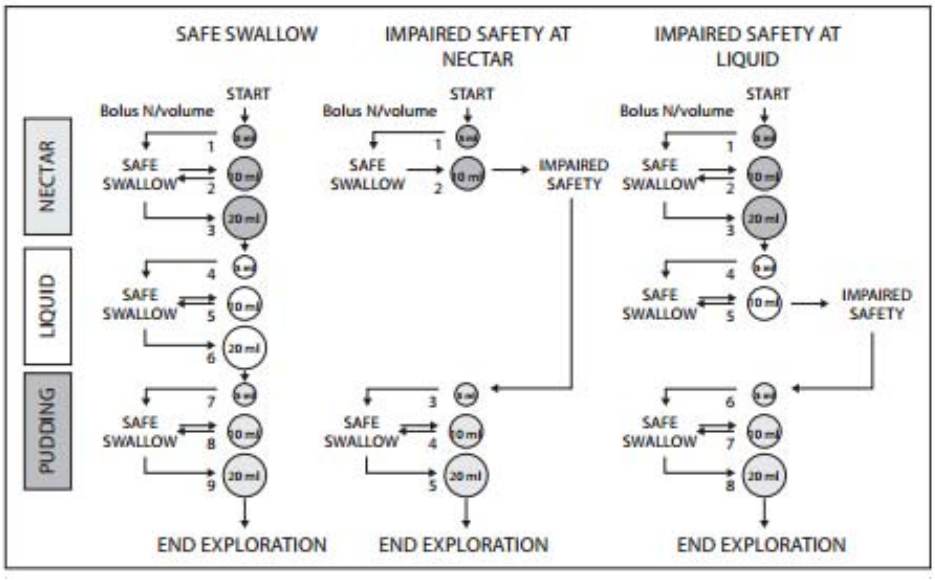
9.3 The 8-point Penetration-Aspiration Scale

Table 2. Scoring system for Penetration-Aspiration Scale

Category	Score	Description
Penetration		
	1	Contrast does not enter airway
	2	Contrast enters airway, remains above vocal folds, no residue
	3	Contrast remains above vocal folds, visible residue remains
	4	Contrast contacts vocal folds, no residue
	5	Contrast contacts vocal folds, visible residue remains
Aspiration		
	6	Contrast passes through glottis, no subglottic residue visible
	7	Contrast passes through glottis, visible subglottic residue despite patient response
	8	Contrast passes through glottis, visible subglottic residue, no patient response

Rosenbek, JC, Robbins, J, Roecker EV, Coyle, JL, & Woods, JL. A Penetration-Aspiration Scale. Dysphagia 11:93-98, 1996.

9.4 The Volume Viscosity Swallow test



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9.5 The Dysphagia outcome severity scale

Table 1. Dysphagia outcome and severity scale—final revision

Full per-oral nutrition (P.O): Normal diet

Level 7: Normal in all situations
- Normal diet
- No strategies or extra time needed

Level 6: Within functional limits/modified independence
- Normal diet, functional swallow
- Patient may have mild oral or pharyngeal delay, retention or trace epiglottal undercoating but independently and spontaneously compensates/clears
- May need extra time for meal
- Have no aspiration or penetration across consistencies

Full P.O: Modified diet and/or independence

Level 5: Mild dysphagia: Distant supervision, may need one diet consistency restricted
- May exhibit one or more of the following
  - Aspiration of thin liquids only but with strong reflexive cough to clear completely
  - Airway penetration midway to cords with one or more consistency or to cords with one consistency but clears spontaneously
  - Retention in pharynx that is cleared spontaneously
  - Mild oral dysphagia with reduced mastication and/or oral retention that is cleared spontaneously

Level 4: Mild–moderate dysphagia: Intermittent supervision/cueing, one or two consistencies restricted
- May exhibit one or more of the following
  - Retention in pharynx cleared with cue
  - Retention in the oral cavity that is cleared with cue
  - Aspiration with one consistency, with weak or no reflexive cough
    - Or airway penetration to the level of the vocal cords with cough with two consistencies
    - Or airway penetration to the level of the vocal cords without cought with one consistency

Level 3: Moderate dysphagia: Total assist, supervision, or strategies, two or more diet consistencies restricted
- May exhibit one or more of the following
  - Moderate retention in pharynx, cleared with cue
  - Moderate retention in oral cavity, cleared with cue
  - Airway penetration to the level of the vocal cords without cough with two or more consistencies
    - Or aspiration with two consistencies, with weak or no reflexive cough
    - Or aspiration with one consistency, no cough and airway penetration to cords with one, no cough

Nonoral nutrition necessary

Level 2: Moderately severe dysphagia: Maximum assistance or use of strategies with partial P.O. only (tolerates at least one consistency safely with total use of strategies)
- May exhibit one or more of the following
  - Severe retention in pharynx, unable to clear or needs multiple cues
  - Severe oral stage bolus loss or retention, unable to clear or needs multiple cues
  - Aspiration with two or more consistencies, no reflexive cough, weak volitional cough
    - Or aspiration with one or more consistency, no cough and airway penetration to cords with one or more consistency, no cough

Level 1: Severe dysphagia: NPO: Unable to tolerate any P.O. safely
- May exhibit one or more of the following
  - Severe retention in pharynx, unable to clear
  - Severe oral stage bolus loss or retention, unable to clear
  - Silent aspiration with two or more consistencies, nonfunctional volitional cough
  - Or unable to achieve swallow

O'Neil KH, Purdy M, Falk J, Gallo L. The dysphagia outcome and severity scale. Dysphagia. 1999;14:139–451

9.6 The Functional Oral Intake Scale.

Level	Type of Intake
1	Nothing by mouth
2	Tube dependent with minimal attempts of food or liquid
3	Tube dependent with consistent oral intake of food or liquid
4	Total oral diet of a single consistency
5	Total oral diet with multiple consistencies but requiring special preparation or compensations
6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
7	Total oral diet with no restrictions

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