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# Sensitivity and specificity of the Eating Assessment Tool and the Volume-Viscosity Swallow Test for clinical evaluation of oropharyngeal dysphagia

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**Key Messages**

- Oropharyngeal dysphagia (OD) is a very prevalent digestive disorder recognized by the World Health Organization and specifically classified in the International Statistical Classification of Diseases, ICD-9 and ICD-10.
- Videofluoroscopy (VFS) is the gold standard to study oral and pharyngeal mechanisms of OD, swallowing dysfunction and aspiration. However, it is unfeasible to perform a VFS on each patient at risk for OD.
- The aim of the present study was to assess the accuracy of the screening method Eating Assessment Tool (EAT-10) and the clinical bedside method, Volume-Viscosity Swallow Test (V-VST) for detecting OD.
- Results from the present study show that clinical methods for screening (EAT-10) and clinical assessment (V-VST) of OD offer high discriminating ability.

**Abstract**

***Background*** *Oropharyngeal dysphagia (OD) is an underdiagnosed digestive disorder that causes severe nutritional and respiratory complications. Our aim was to determine the accuracy of the Eating Assessment Tool (EAT-10) and the Volume-Viscosity Swallow Test (V-VST) for clinical evaluation of OD.* ***Methods*** *We studied 120 patients with swallowing difficulties and 14 healthy subjects. OD was evaluated by the 10-item screening questionnaire EAT-10 and the bedside method V-VST, videofluoroscopy (VFS) being the reference standard. The V-VST is an effort test that uses boluses of different volumes and viscosities to identify clinical signs of impaired efficacy (impaired labial seal, piecemeal deglutition, and residue) and impaired safety of swallow (cough, voice changes, and oxygen desaturation ≥3%). Discriminating ability was assessed by the AUC of the ROC curve and sensitivity and specificity values.* ***Key Results*** *According to VFS, prevalence of OD was 87%, 75.6% with impaired efficacy and 80.9% with impaired safety of swallow including 17.6% aspirations. The EAT-10 showed a ROC AUC of 0.89 for OD with an optimal cut-off at 2 (0.89 sensitivity and 0.82 specificity). The V-VST showed 0.94 sensitivity and 0.88 specificity for OD, 0.79 sensitivity and 0.75 specificity for impaired efficacy, 0.87 sensitivity and 0.81 specificity for impaired safety, and 0.91 sensitivity and 0.28 specificity for aspirations.* ***Conclusions & Inferences*** *Clinical methods for screening (EAT-10) and assessment (V-VST) of OD offer excellent psychometric proprieties that allow adequate management of OD. Their universal application among at-risk populations*

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*will improve the identification of patients with OD at risk for malnutrition and aspiration pneumonia.*

***Keywords*** *deglutition disorders, ROC curve, screening, sensitivity, specificity.*

## INTRODUCTION

Oropharyngeal dysphagia (OD) is a gastrointestinal motility disorder that includes difficulty or inability to form or move the alimentary bolus safely from the mouth to the esophagus and that can include tracheobronchial aspirations.[1] OD is a highly prevalent condition in 37–78% of patients after a stroke[2] and 23–47.5% of different phenotypes of elderly people.[3,4] It is specifically classified as a digestive condition by the World Health Organization in the International Statistical Classification of Diseases and Related Health Problems ICD-9 and ICD-10.[5] OD is one of the major contributors to malnutrition,[6] a highly prevalent condition among hospital patients that leads to extended hospital stays, prolonged rehabilitation, and diminished quality of life.[4] OD can also lead to respiratory infections and aspiration pneumonia with an associated mortality of up to 50%.[7] 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.

Videofluoroscopy (VFS) is the gold standard to study oral and pharyngeal mechanisms of OD, swallowing dysfunction, and aspiration.[1] However, it is not feasible to perform a VFS on every patient at risk for OD as it requires specific equipment not available in all healthcare facilities. Therefore, the development of clinical methods for easy screening and accurate clinical assessment of OD is necessary. The goal of the screening methods for OD should be quick identification of patients with OD, at risk of aspiration or malnutrition, and who need to be referred for more formal and extensive swallowing assessment. One such screening tool is the Eating Assessment Tool (EAT-10), a 10-item self-administered questionnaire developed to evaluate dysphagia symptoms in persons with a wide variety of causes of dysphagia and in different clinical settings.[8,9] However, these studies were not done against a gold standard and the diagnostic accuracy of the EAT-10 as an OD screening tool has not been established. The goal of the clinical assessment methods for OD should be, in addition to collecting the data necessary to establish a clinical diagnosis, to assess the pathophysiology of the disease, to identify the main signs and symptoms of OD and the mechanism of swallowing dysfunction, and to help to select the most appropriate therapy for those patients (such as elderly patients admitted to nursing homes) who cannot easily undergo VFS. A recent systematic review recommended bedside clinical tests using water or other fluids combined with oximetry, the endpoints being coughing, choking, voice changes, and desaturation to identify patients with OD.[10] The volume-viscosity swallow test (V-VST) fulfills these criteria and shows high diagnostic accuracy in identifying clinical signs and symptoms of impaired efficacy and safety of swallow.[11] In addition, the V-VST establishes the ideal viscosity to be safely administered to patients at risk of OD and aspirations. The V-VST was first validated against VFS by using liquids thickened with a starch-based thickener,[12] however, the diagnostic accuracy of the V-VST using the new generation of thickeners based on xanthan gum has not been established. It is relevant to do so, as the rheological properties of liquids thickened with xanthan gum differ from those of liquids thickened with starch.[13] The inter-rater reliability of the V-VST also needs to be addressed.

The aim of the present study was to validate the screening method EAT-10 and the clinical bedside assessment method V-VST in the detection of OD.

## MATERIALS AND METHODS

### Subjects

A stratified-sampling design was chosen for the study, using the data from previous studies to estimate OD prevalence and subpopulation proportions.[12] Based on this sampling method, data were simulated from the data available using re-sampling techniques.[12] Boot-strapped confidence intervals were then obtained for different sample sizes using the beta-binomial model suggested for the primary analysis. A sample size of 134 (120 at-risk patients and 14 healthy volunteers) was chosen to estimate the sensitivities with 10% margin of error (length of the 95% simultaneous confidence intervals would be at most 20%). This ensured that the margin of errors for estimating the specificities was at most 15%. Thus, 120 patients with a history of swallowing difficulties associated with aging, stroke, and neurodegenerative diseases consecutively referred to the Gastrointestinal Physiology Lab of the Hospital de Mataró (Spain) for swallowing evaluation and 14 adult healthy volunteers (>18 years), were prospectively included in the study between June 2010 and June 2011. The study protocol was approved by the Institutional Review Board of the Hospital de Mataró and was conducted according to the principles and rules laid down in the Declaration of Helsinki and its subsequent amendments. Trial registration: NCT01158313.

### Design

Oropharyngeal dysphagia was clinically evaluated in all patients and controls by means of a screening questionnaire, the EAT-10[8]

and a clinical bedside assessment method, the V-VST.[12] Each test was performed by an independent clinician. The same day, a VFS was also performed on all subjects by a clinician blinded to the results of all clinical evaluations. The results from the VFS are considered as the reference standard for establishing the disease status (presence of OD) and characteristics of swallowing dysfunction (impaired safety and/or efficacy of deglutition). Following the videofluoroscopic study, a second V-VST was performed by another clinician, blinded to the results of the EAT-10, the first V-VST, and the VFS, to assess its test–retest reliability. In addition, socio-demographical, clinical, and nutritional parameters were collected for all participants.

## Index tests

*The Eating Assessment Tool (EAT-10)* The 10-item Spanish-language validated version of the screening questionnaire EAT-10[9] was administered to all patients and healthy volunteers. Patients were instructed to complete the EAT-10 by themselves, but could have guidance by relatives or caregivers if needed. The EAT-10 consists of 10 questions about the severity of symptoms of OD and its clinical and social impact, each question scoring from 0 (no problem) to 4 (severe problem). Normative data from previous studies explored the upper limit of reference interval and suggested that a final EAT-10 score ≥3 was abnormal.[8]

*The volume-viscosity swallow test (V-VST)* The V-VST method was performed as described previously.[14] Briefly, the patients' ability to swallow boluses of different volumes (5, 10, and 20 mL) and viscosities (nectar-like, thin liquid, extreme spoon-thick [EST]) was evaluated following the algorithm in Fig. 1. Signs of impaired efficacy of swallow, such as impaired labial seal, oral residue, piecemeal deglutition (multiple swallows per bolus) and symptoms of pharyngeal residue (auto-reported by the patient as the feeling of having the bolus stuck in the throat after the deglutition), and signs of impaired safety of swallow such as changes in voice quality (including wet voice), cough, and decrease in oxygen saturation ≥3% (measured with a finger pulse-oximeter, Nellcor™ OxiMax™; Philips Medical Systems, Eindhoven, The Netherlands) were evaluated for each patient. A patient who presented one or more signs of impaired efficacy and/or safety of swallow was considered as having OD. All clinical explorations, including oxygen saturation measurements, were filmed with a digital video camera (DVR-PC100E, Mini DV; Sony Corporation, Tokyo, Japan) to allow study traceability.

## Reference test

*Videofluoroscopy* All patients were imaged for the videofluoroscopic study while seated, in a lateral projection which included the oral cavity, pharynx, larynx, and cervical esophagus. Videofluoroscopic recordings were obtained by using a Super XT-20 Toshiba Intensifier (Toshiba Medical Systems Europe, Zoetermeer, The Netherlands) and recorded at 25 frames/s using a Panasonic AG DVX-100B video camera (Matsushita Electric Industrial Co, Osaka, Japan). Digitization, analysis, and measurements of videofluoroscopic images were made using the software Swallowing Observer (Image and Physiology SL, Barcelona, Spain). The ability of the patients to swallow boluses of different volumes and viscosities was also evaluated following the same strategy as in the clinical assessment by the V-VST (Fig. 1). An impairment of the efficacy of swallow was considered when at least one of the following signs was identified during the videofluoroscopic study: impaired labial seal closure, oral residue, pharyngeal residue, or piecemeal deglutition; and an impairment of the safety of swallow was considered when a penetration or an aspiration was detected. The penetrations and aspirations were classified according to the penetration–aspiration scale.[15] A patient who presented an impairment of the efficacy and/or the safety of swallow was considered as having OD.

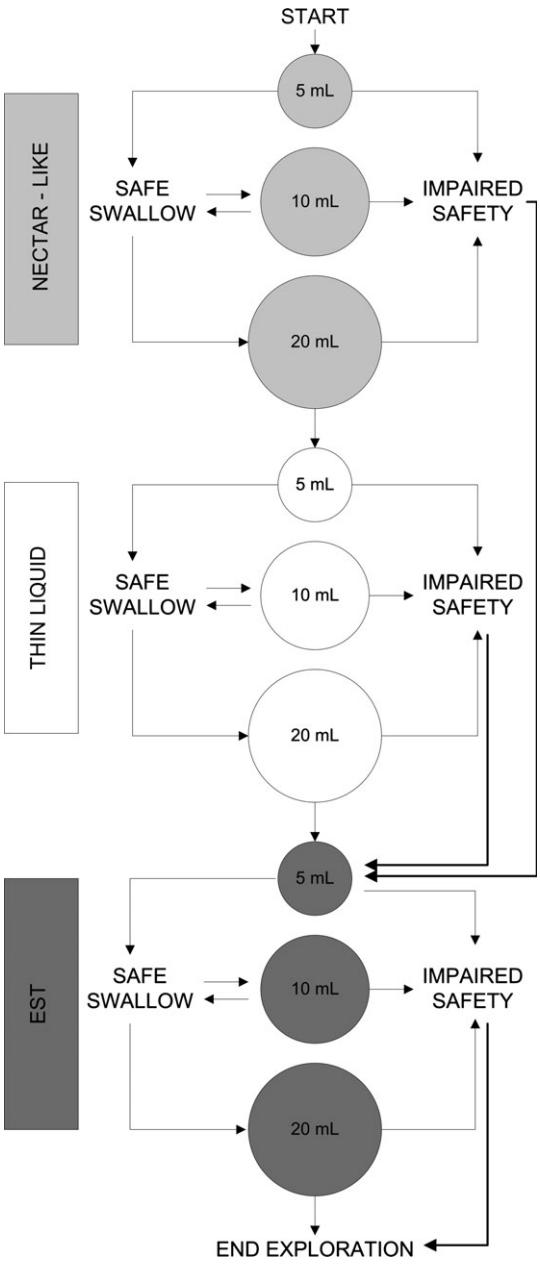


**Figure 1** V-VST algorithm. Patients with safe swallow started the exploration with a 5 mL nectar bolus, followed by 10 and 20 mL nectar boluses, then performed the thin liquid series with boluses of increasing volume and finally completed the pathway with the three EST boluses to explore efficacy of swallow. If the patient presented signs of impaired safety at nectar or thin liquid viscosities, the series was interrupted and the EST series was assessed. EST, extreme spoon-thick.

## Bolus viscosities

Three different viscosities (thin liquid, nectar-like, and EST) were used during V-VST and VFS according to the viscosity ranges of the National Dysphagia Diet Task Force, which are 1–50 mPa s for liquids, 51–350 mPa s for nectar-like, and >1750 mPa s for EST.[16] For V-VST studies, thin viscosity was obtained by using mineral water at room temperature, nectar-like viscosity by adding 1.2 g of thickener (Resource ThickenUp Clear, Nestlé Health Science, Lausanne, Switzerland) to 100 mL mineral water, and EST viscosity by adding 6 g of thickener to 100 mL mineral water. Solutions were prepared 5 min before the test. According to the study protocol, the specific levels of viscosity obtained were 21 mPa s for thin liquids, 238 mPa s for nectar, and 1840 mPa s for EST.[14] For VFS studies, the X-ray contrast Gastrografin (Bayer Hispania SL, Sant Joan Despí, Spain) was diluted 1 : 1 in mineral water, both at room temperature, to obtain the thin viscosity. Dilution avoids any potential damage to lung tissue in case of aspiration. For thickened solutions, the amount of thickener was adjusted to account for the effect of the X-ray contrast to obtain equivalent viscosities to those used in the V-VST. Nectar viscosity was obtained by adding 2.4 g of the thickener to the thin liquid solution containing the X-ray contrast and EST viscosity by adding 5.4 g of the thickener. The solutions for VFS studies were prepared 3 h prior to the videofluoroscopic examination, to obtain stable and equivalent viscosities to those used during the V-VST.[13] Boluses of 5, 10, and 20 mL of each viscosity were carefully placed in the anterior part of the mouth with a syringe to ensure accurate measurement of bolus volume during both V-VST and VFS studies.

## Posttest probabilities

To assess the probability of presenting OD in the target populations after the test result, positive and negative predictive values (PPV and NPV) of EAT-10 and V-VST were assessed for independently living and institutionalized elderly people, respectively. In our population, pretest probability (prevalence of OD) for independently living elderly people is 23%[3] and for institutionalized elderly people, 47.5%.[4]

## Data analysis and statistical methods

Quantitative parameters were described by mean ± SD and qualitative parameters were described by relative and absolute frequencies. To assess the diagnostic accuracy of the EAT-10 relative to VFS, a receiver operating characteristic (ROC) curve was created plotting sensitivity *vs* 1-specificity values for each possible cut-off and calculating the area under the curve (AUC). Sensitivity and specificity of the V-VST relative to the VFS for dysphagia, impaired safety, and impaired efficacy were measured using a conditional likelihood approach and expressed as mean and 95% confidence intervals (CI). The beta-binomial model was used to model the three binary outcomes (dysphagia, impaired safety, and impaired efficacy) with specific covariates comprising the corresponding videofluoroscopic result.[17] As the V-VST for each subject was performed twice by independent blinded readers, a subject-specific random-effect term was added to the beta-binomial model to obtain a mixed-effect model. PPV and NPV were also assessed, taking the mixed beta-binomial estimates for sensitivities and specificities and the prevalence of the particular impairment. The Bayes' theorem was used to compute the PPV and NPV from estimates of the test's sensitivity and specificity and pretest probabilities of OD in the target populations. Using the beta-binomial model, simultaneous confidence intervals for sensitivity and specificity for several parameters were obtained, accounting for the multiplicity. The inter-rater agreement for V-VST in the diagnosis of dysphagia was estimated by means of the Cohen's Kappa coefficient. Statistical analysis was performed using the stats package in R version 2.15 (www.r-project.org). The package bbmle was used to obtain the maximum likelihood estimates for the beta-binomial parameters.

# RESULTS

## Subjects

A total of 134 participants were included in the study. Demographical, clinical, and nutritional characteristics of the study population are described in Table 1. It is worth noting that most patients included in the study presented advanced age (74.4 ± 12.4 years), polymorbidity (Charlson Comorbidity Index 3.04 ± 1.92), high risk of malnutrition (Mini Nutritional Assessment short form, MNA-SF 9.72 ± 2.76), and polymedication (7.77 ± 3.7 drugs/patient). Patients taking drugs with potential effects on swallow function were:

**Table 1** Demographical, clinical, and nutritional characteristics of the study population

| | | | Patients | | |
|---|---|---|---|---|---|
| | HV | Patients | NDD | Stroke | Elderly |
| Subjects | 14 | 120 | 10.8% (13) | 55% (66) | 34.2% (41) |
| Sex (men) | 57.1% (8) | 54.2% (65) | 46.2% (6) | 56.1% (37) | 53.7% (22) |
| Age (years) | 30.5 ± 6.1 | 74.4 ± 12.4 | 64.0 ± 19.6 | 73.5 ± 11.4 | 79.6 ± 8.2 |
| Charlson Index | | | | | |
| 0 | 100% (14) | 10.1% (12) | 17.5% (7) | 0.0% (0) | 38.5% (5) |
| 1–2 | 0% (0) | 31.1% (37) | 40.0% (16) | 25.8% (17) | 30.8% (4) |
| 3–4 | 0% (0) | 37.0% (44) | 35.0% (14) | 39.4% (26) | 30.8% (4) |
| ≥5 | 0% (0) | 21.8% (26) | 7.5% (3) | 34.8% (23) | 0.0% (0) |
| Nutritional status (MNA-SF) | | | | | |
| Malnourished (0–7) | — | 22.9% (27) | 23.1% (3) | 25.8% (17) | 17.9% (7) |
| At risk (8–11) | | 48.3% (57) | 38.5% (5) | 53.0% (35) | 43.6% (17) |
| Well nourished (12–14) | | 28.8% (34) | 38.5% (5) | 21.2% (14) | 38.5% (15) |

HV, Healthy volunteers; NDD, neurodegenerative disease; MNA-SF, Mini Nutritional Assessment short form.



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33.3%, antidepressants; 24.8%, anxiolytics; 16.2%, antiepileptics; 8.5%, sedatives, and 4.3%, antipsychotics. One patient presented a serious adverse event during the study with a severe aspiration during the V-VST resulting in tachycardia. The patient was withdrawn from the study and recovered after a few hours. A second subject wished to withdraw before the study end and a third subject could not be analyzed because the VFS images were damaged.

## Reference test results

*Videofluoroscopy* Videofluoroscopic images for analysis were available from 131 subjects. Prevalence of OD according to the VFS study was 87% (114) of the included subjects, 75.6% (99) of them presenting VFS signs of impaired efficacy, and 80.9% (106) signs of impaired safety of swallow. *Efficacy signs*: impaired labial seal closure was observed in 6.1% (8) of subjects, piecemeal deglutition in 68.7% (90), oral residue in 31.3% (41), and pharyngeal residue in 27.5% (36). *Safety signs:* According to the penetration–aspiration scale,[14] 30.5% (40) of subjects presented score 2 penetrations (material enters the airway, remains above the vocal folds, and is ejected from the airway), 32.1% (42) scores 3–5 (severe penetrations into the laryngeal vestibule not ejected from the airway and/or contacting the vocal folds), and 18.3% (24) scores 6–8 (aspirations into the airway), 62.5% (15) of which were silent (score 8). Increasing bolus viscosity improved the safety of swallow of 80.9% (106) of subjects.

## Index test results

*EAT-10* The median EAT-10 score of the subjects included in the study was 9 with 25–75 percentiles of 3–16. The score of healthy subjects was 0, that of patients with swallowing complaints but normal VFS results, 3 (1–11.5), and the median score of patients diagnosed with OD was 10 (4–16) ($p < 0.001$). Patients with impaired efficacy of swallow presented a median EAT-10 of 11 with 25–75 percentiles of 5–16, and patients with impaired safety 11 (4–16). Up to 75.9% (101) of the 133 subjects that completed the EAT-10 presented a score above the upper limit of the reference interval (≥3; Fig. 2).

*V-VST* Of subjects included in the study, 78.4% (105) presented OD according to the V-VST, 58.2% (78) of them presenting signs of impaired efficacy of swallow, and 73.1% (98) presenting signs of impaired safety (Fig. 3). According to the V-VST, increasing bolus viscosity with thickener improved the safety of swallow of 72.4% (97) subjects and the efficacy of swallow of 1 subject.

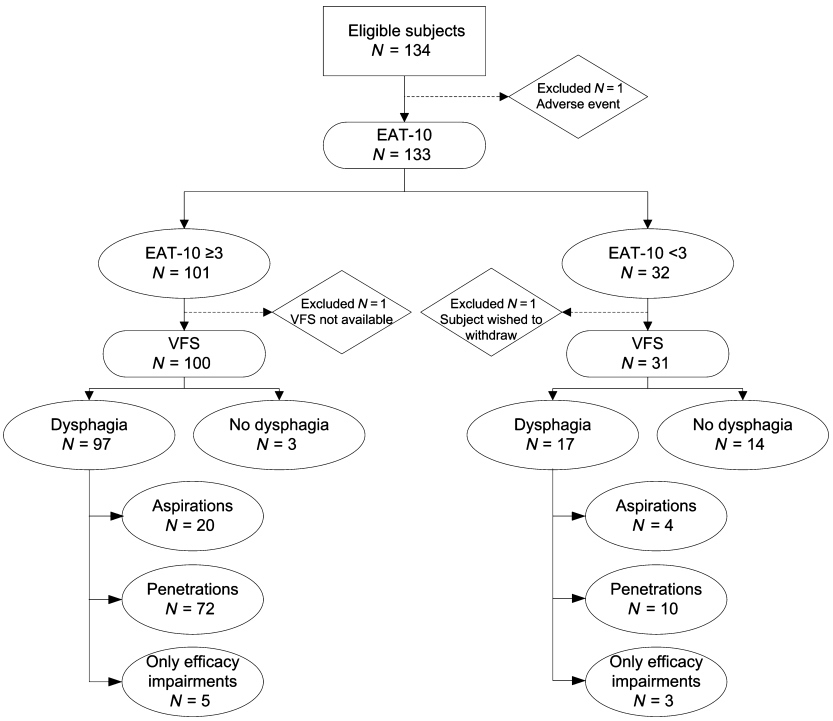


**Figure 2** Flowchart of subjects included in the study that underwent the EAT-10. Subjects stratified by presence of oropharyngeal dysphagia according to the VFS study.

## Accuracy of the EAT-10 and V-VST for detecting OD

*EAT-10* The AUC of the ROC curve for detecting OD was 0.89 (95% CI = 0.802–0.988); for detecting impaired safety, 0.82 (95% CI = 0.719–0.928), and for detecting impaired efficacy, 0.79 (95% CI = 0.682–0.890). The discriminating ability of the EAT-10 for the normative cut-off value (EAT-10 ≥3) to detect dysphagia, impaired efficacy, impaired safety of swallow and aspirations is shown in Table 2. According to the ROC curve, the optimal cut-off to detect dysphagia (0.895 [95% CI = 0.823–0.944] sensitivity and 0.824 [95% CI = 0.566–0.962] specificity), impaired safety of swallow (0.915 [95% CI = 0.845–0.960] sensitivity and 0.680 [95% CI = 0.465–0.850] specificity), and silent aspirations (0.933 [95% CI = 0.680–0.998] sensitivity and 0.215 [95% CI = 0.145–0.301] specificity) was 2, and to detect impaired efficacy of swallow was 4 (0.859 [95% CI = 0.774–0.920] sensitivity and 0.719 [95% CI = 0.532–0.862] specificity; Fig. 4).

*V-VST* The discriminating ability of the V-VST (sensitivity, specificity, and predictive values) for dysphagia, impaired efficacy and safety of swallow, and aspirations is shown in Table 3. Interestingly, any sign of impaired safety of swallow in the V-VST predicts the presence of silent aspirations with a sensitivity of 1.00 (95% CI = 0.782–1.00) and a specificity of 0.320 (95% CI = 0.220–0.394). Moreover, the V-VST showed a sensitivity of 0.821 (95% CI = 0.734–0.888) and a specificity of 0.640 (95% CI = 0.425–0.820) in detecting patients whose swallow improved with the enhancement of bolus viscosity.

## Posttest probabilities

PPV and NPV of OD for EAT-10 in independently living elderly people were 0.603 and 0.963, respectively. For the V-VST in institutionalized elderly people, the PPV and NPV of OD were 0.876 and 0.942, respectively.

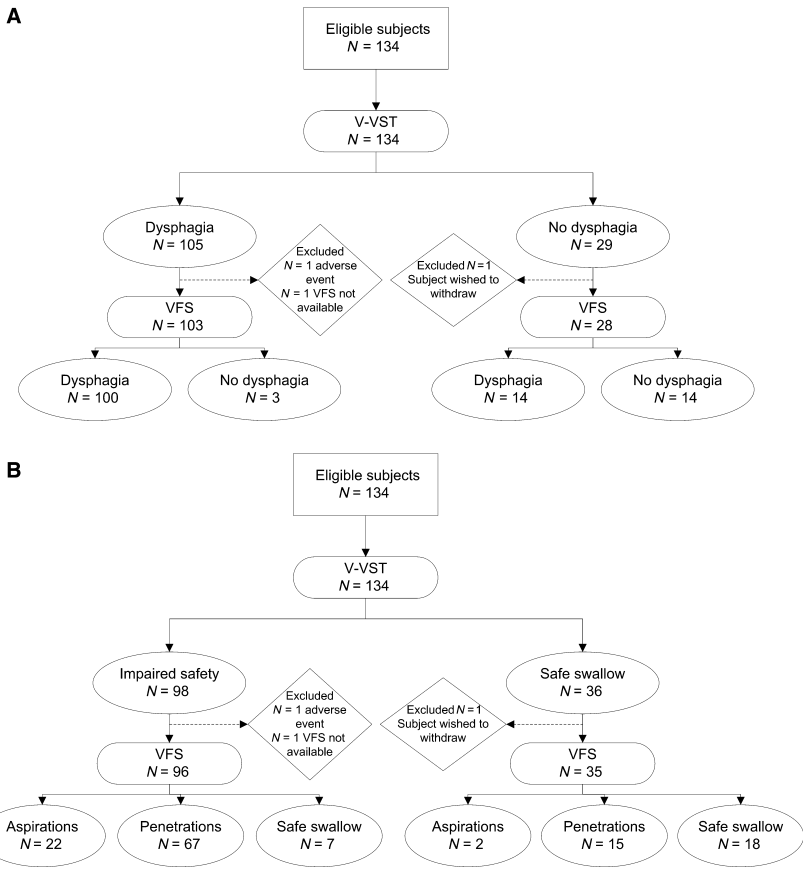


**Figure 3** Flowchart of subjects included in the study that underwent the first V-VST. (A) Subjects stratified by presence of oropharyngeal dysphagia according to the VFS study. (B) Subjects stratified by presence of signs of impaired safety of swallow (penetrations, aspirations, and safe swallow) according to the VFS study. Note that the test was performed twice, to calculate sensitivity and specificity values of the V-VST, so a subject-specific random-effect term was added to the beta-binomial model to obtain the mixed-effect model.



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**Table 2** Accuracy of the EAT-10 in detecting dysphagia, impaired efficacy and safety of swallow, and aspirations at the normative cut-off 3

| | EAT-10 ≥ 3 | | | | | |
|---|---|---|---|---|---|---|
| | Sensitivity (95% CI) | Specificity (95% CI) | PPV | NPV | LHR+ | LHR− |
| OD | 0.85 (0.77–0.91) | 0.82 (0.57–0.96) | 0.828 | 0.847 | 4.72 | 0.183 |
| Impaired efficacy | 0.88 (0.80–0.94) | 0.59 (0.41–0.76) | 0.684 | 0.830 | 2.15 | 0.203 |
| Impaired safety | 0.87 (0.79–0.93) | 0.68 (0.46–0.85) | 0.731 | 0.837 | 3.13 | 0.191 |
| Aspirations | 0.83 (0.61–0.95) | 0.25 (0.17–0.34) | 0.525 | 0.592 | 1.11 | 0.680 |

CI, simultaneous confidence interval; PPV, positive predictive value; NPV, negative predictive value; LHR, likelihood ratio; OD, oropharyngeal dysphagia.

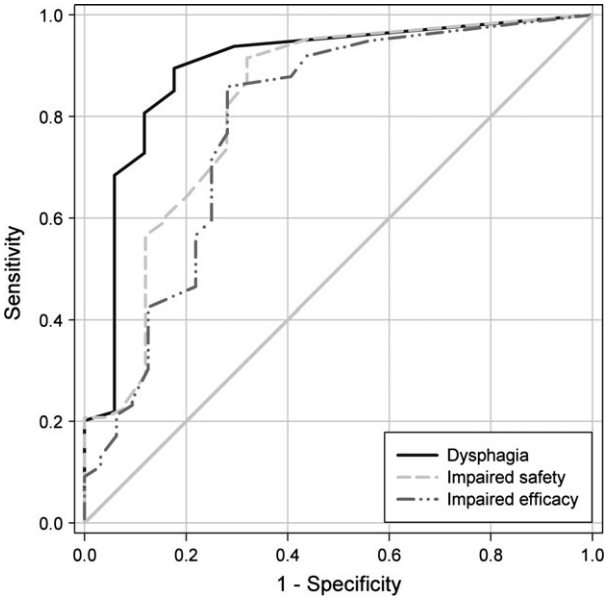


**Figure 4** ROC curves of EAT-10 to detect dysphagia, impaired efficacy, and impaired safety of swallow with respect to VFS findings.

### Inter-rater correlation for V-VST

The V-VST showed a good inter-rater agreement for detecting dysphagia with a Kappa coefficient of 0.628 (95% CI = 0.45–0.78).

## DISCUSSION

The main conclusion of this study is that clinical methods for screening (EAT-10) and assessment (V-VST) of OD offer high discriminating ability. We also found that OD was a serious condition characterized by impairment in oropharyngeal function including frequent silent aspirations, and occurred in vulnerable patients at risk of severe nutritional and respiratory complications. Following these results, we recommend the universal application of these methods among older and neurological patients at risk for OD and nutritional or respiratory complications to identify those that could need a more exhaustive evaluation by instrumental techniques.

Oropharyngeal dysphagia is a prevalent and severe gastrointestinal motility disorder with a very poor prognosis, but the implementation of structured dysphagia programs in hospital settings that systematically evaluate and treat OD reduce the incidence of pneumonia, costs for antibiotics, and mortality rates.[18,19] However, despite the high prevalence, morbidity, mortality, and costs caused by nutritional and respiratory complications, OD is mostly underdiagnosed and undertreated even in tertiary clinical settings providing specialized care of older adults. The low level of awareness among healthcare professionals and the lack of validated and feasible clinical tools for bedside screening and assessment of OD contribute to this situation. In the present study, we provide validated clinical tools to remedy it.

The studied population presented many co-morbidities, low functionality, impaired nutritional status, and high prevalence of OD, most of them presenting signs of both impaired efficacy and safety of swallow. Prevalence of silent aspirations in the studied population was high (11.4%). This is a serious finding that, taken together with the poor health status and high prevalence of malnutrition, put our population at high risk for severe complications including aspiration pneumonia and death.[7,20]

Screening for OD should be an easy, quick, and low cost process able to detect the majority of patients with the disease. At this stage of the diagnostic process, high sensitivity is more desirable than high specificity, as the cost of a more exhaustive swallowing evaluation is preferable to the potentially fatal complications of undetected dysphagia. The 10-item self-administered questionnaire EAT-10 includes questions about dysphagia symptoms in patients with swallowing disorders. In its initial validation study, Belafsky *et al.* found EAT-10 displayed excellent internal consistency, good reproducibility, and criterion-based validity and suggested that an EAT-10 score of 3 or higher should be

**Table 3** Accuracy of the V-VST to detect dysphagia, impaired efficacy and safety of swallow, and aspirations

| | V-VST | | | | | |
|---|---|---|---|---|---|---|
| | Sensitivity (95% CI) | Specificity (95% CI) | PPV | NPV | LHR+ | LHR− |
| OD | 0.94 (0.87–0.98) | 0.88 (0.50–0.99) | 0.98 | 0.70 | 7.83 | 0.068 |
| Impaired efficacy | 0.79 (0.62–0.90) | 0.75 (0.45–0.92) | 0.93 | 0.67 | 3.16 | 0.280 |
| Impaired safety | 0.87 (0.74–0.94) | 0.81 (0.48–0.95) | 0.93 | 0.46 | 4.58 | 0.160 |
| Aspirations | 0.91 (0.78–0.99) | 0.28 (0.17–0.34) | 0.21 | 0.94 | 1.26 | 0.321 |

CI, simultaneous confidence interval; PPV, positive predictive value; NPV, negative predictive value; LHR, likelihood ratio; OD, oropharyngeal dysphagia.

considered abnormal. The score 3 was obtained from the upper limit of reference interval (mean + 2SD) of the healthy volunteers score. However, the drawback is that the upper limit found for negative (healthy) subjects overlaps with the lower limit found for positive (diseased) cases, leading to the misclassification of some dysphagic patients as negatives. According to the results of our ROC curve, reducing the cut-off from 3 to 2 increased the sensitivity of the test nearly 5% without affecting the specificity, resulting in fewer false-negative cases. To the author's knowledge, the accuracy of only one other questionnaire (the Swallowing Disturbance Questionnaire, SDQ)[21] has been previously assessed, using FEES as a reference test, and it presented lower sensitivity and specificity values (71.88% and 78.38%, respectively) than the EAT-10. In addition, posttest probabilities (PPV and NPV) of EAT-10 for OD in independently living elderly people were calculated considering the true prevalence of OD in this population (23%),[3] further confirming the low probability of presenting OD after a negative test (EAT-10 <2). Sensitivity and specificity are intrinsic properties of each diagnostic test, independent of disease prevalence. In contrast, PPV and NPV are dependent on disease prevalence and indicate the probability of having the disease following the test, helping the clinician decide how to manage and treat the patient according to the result of the diagnostic test. Following these results, we recommend the EAT-10 as a first-line tool for systematic screening of at-risk patients, especially in primary care settings, as it is easy and accurate, facilitating its use to general practitioners and allied healthcare professionals not specifically trained in OD. We believe that patients with an EAT-10 ≥2 should be considered for further clinical bedside assessment.

The clinical bedside tests for swallowing assessment of OD should present good psychometric properties, good reliability, a detailed and easy-to-perform protocol designed to protect patients' safety and able to evaluate the safety and efficacy of swallowing, and a system to detect silent aspirations. The V-VST is an accurate bedside assessment method that was designed for this purpose.[12] The V-VST should be administered by trained healthcare professionals at all medical facilities and can be repeated according to the natural progression of the disease. The test presented high diagnostic sensitivity and high positive predictive value to detect OD, impaired safety, and aspirations (including silent aspirations), clearly showing a high discriminating ability. Nevertheless, the specificity for detecting aspirations is low (the test is not able to clearly differentiate between aspirations and penetrations and an instrumental study is needed to discriminate between the two impaired safety signs). However, penetrations scoring 3 or higher in the PAS are also a clinically significant sign of impaired safety of swallow that puts patients at risk of pneumonia.[22] Therefore, the high positive predictive value of the V-VST for impaired safety (penetrations or aspirations) permits the accurate selection of these patients at risk of respiratory complications and the high negative predictive value for aspiration rules out aspiration in a patient with a negative V-VST (posttest probability of 6%). Moreover, the V-VST characterizes the pathophysiology of the impaired swallow function by identifying impaired safety or efficacy of swallow and also detects patients who improve with thickener treatment. In addition, the V-VST establishes the ideal viscosity to safely administer to patients at risk of aspirations, adding value to its diagnostic capacity. In a systematic review, Bours *et al.*[10] recommend a water test combined with oximetry using coughing, choking, and voice alteration as the endpoints as the best method to clinically assess patients for OD. The water tests are one of the most extended and frequently used tests for dysphagia screening. They present a sensitivity of 51–85% and a specificity of 66–75% to detect aspirations, and a sensitivity of 27–79% and specificity of 63–88% to detect impaired safety of swallow (penetrations or aspirations).[23–26] These parameters are inferior to those offered by the V-VST in the present study. Moreover, the water tests involve the continuous swallow of large amounts of water which



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may place the patient at risk for aspiration, can miss silent aspirations if oxygen saturation is not monitored[27,28], and do not assess any parameter related to the efficacy of swallow (residue) nor evaluate the ability of patients to swallow different viscosities. Like the V-VST, several tests have been developed using different viscosities and solids to evaluate aspiration and/or penetration. Sensitivity of these tests range from 41% to 100% and specificity from 57% to 82%.[29–31] Although these tests evaluate patients' ability to swallow material of different consistencies, they are not combined with oxygen desaturation, and therefore silent aspirations can be underdiagnosed. Smith *et al.*[32] recommended a water test combined with oxygen saturation followed by bedside swallowing assessment with a variety of quantities and consistencies. This protocol showed a sensitivity of 80% and specificity of 68% for OD, but did not provide a detailed protocol for the swallow test and only acute poststroke patients were studied. Following these results, we recommend the V-VST for systematic bedside clinical assessment of swallowing function of high-risk populations, such as elderly patients admitted to general hospitals, nursing home residents, and patients with neurological diseases. The V-VST should be performed by trained healthcare professionals. We would like to emphasize that in this study, the viscosities used in the VFS perfectly matched those used in the V-VST and so can be used to prescribe the different levels of thickened liquids for patients with dysphagia.

Differences in ages between the control and patient groups may constitute a limitation of this study because it affects blinding and may influence the researcher's response or diagnosis. Although VFS interpretations were not specifically assessed for reliability in this study, internal controls of our unit found good intra-rater and inter-rater reliability for identification of aspiration and assessment of the Penetration–Aspiration Scale. Similar results were reported in previous studies when the VFS analyses were made by trained clinicians, as they were in our study.[33,34]

In conclusion, our study shows that the discriminating ability of both the EAT-10 questionnaire for clinical screening of OD and the V-VST for clinical bedside assessment is very high and both are useful methods for detecting patients at risk for nutritional and respiratory complications who need more exhaustive instrumental evaluation. We recommend their universal application for populations at risk of OD to ensure comprehensive dysphagia care, to avoid the serious nutritional and respiratory complications associated with OD, to reduce the mortality rates and the economic and social burden associated with this disease, and to improve quality of life of dysphagic patients.

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## DISCLOSURE

PC has served as consultant and received research funding from Nestlé Health Science. LR and VA have served as speakers for Nestlé Health Science. RM is employee of Nestlé Health Science.

## AUTHOR CONTRIBUTION

LR, RM, PC study concept and design; VA selection of patients; LR, VA acquisition of data; LR, VA, PC analysis and interpretation of data; LR, PC drafting of the manuscript; RM statistical planning and analysis; revision for intellectual content and approval of the final version (all authors).

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