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Artigo Original

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Diagnostic precision for bronchopulmonary aspiration in a heterogeneous population

Precisão diagnóstica para o risco de broncoaspiração em população heterogênea

Keywords

Deglutition
Deglutition Disorders
Triage
Protocols
Validation Studies
Sensitivity and Specificity

ABSTRACT

Purpose: The purpose of the present study was to assess the validity of a simple instrument for screening dysphagia used in a large public hospital in Brazil with heterogeneous adult population. **Method:** The Dysphagia Risk Evaluation Protocol (DREP) - screening version contains four items (altered cervical auscultation, altered vocal quality, coughing and choking before / during / after swallowing) that were previously indicated as independent risk factors associated to the presence of dysphagia in the swallowing test with water. Trained speech therapists administered and scored DREP – screening version to consecutive patients referred by hospital's medical team to perform Video Fluoroscopic for Swallowing Study (VFSS). **Results:** 211 patients received the swallowing screen (DREP): 99 failed and 112 passed. One in every five patients was randomized to receive a VFSS. The DREP screening version demonstrated excellent validity with sensitivity at 92.9%, specificity at 75.0%, negative predictive values at 95.5% and an accuracy of 80.9%. **Conclusion:** The DREP - screening version is a simple and accurate tool to identify the risk for penetration and / or aspiration in patients who are not tube-fed, who have a good level of alertness, have no history of recurrent pneumonia, are not on pneumonia, and that do not use a tracheostomy cannula.

Descritores

Deglutição
Transtornos de Deglutição
Triagem
Protocolos
Estudos de Validação
Sensibilidade e Especificidade

RESUMO

Objetivo: O objetivo do presente estudo foi realizar a validação de um instrumento simples de triagem da disfagia utilizado em um hospital público de grande porte no Brasil em população adulta heterogênea. **Método:** O Protocolo de Avaliação de Risco para Disfagia versão de triagem (PARDt) contém quatro itens (ausculta cervical alterada, alteração da qualidade vocal, tosse e engasgo antes/durante/após a deglutição) que foram previamente indicados como fatores de risco independentes associados à presença de disfagia no teste de deglutição com água. Fonoaudiólogos treinados administraram e classificaram o PARDt para pacientes consecutivos encaminhados pela equipe médica do hospital para realizar a videofluoroscopia da deglutição (VDF). **Resultados:** 211 pacientes foram submetidos ao PARDt: 99 falharam e 112 passaram. Um em cada cinco pacientes foram randomicamente selecionados para VDF. O PARDt apresentou excelente validade: sensibilidade de 92,9%; especificidade de 75,0%; valores preditivos negativos de 95,5%; acurácia de 80,9%. **Conclusão:** O PARDt é uma ferramenta simples e precisa para identificar o risco de penetração e/ou aspiração em pacientes que não são alimentados por sonda, que apresentam bom nível de alerta, sem histórico de pneumonias de repetição, que não estejam em vigência de pneumonia e que não façam uso de cânula de traqueostomia.

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INTRODUCTION

Early and accurate identification of dysphagia by screening methods is extremely important in hospitalized patients. Swallowing impairment has been reported in approximately 37% to 78% of patients with acute ischemic and hemorrhagic stroke[1], from 52% to 82% of patients with neurodegenerative diseases, from 42% to 87% of patients after prolonged orotracheal intubation[2], in more than 35% of patients with head and neck diseases[3] and in more than 60% of institutionalized elderlies[4]. Although issues such as nutrition, hydration and quality of life are important aspects involved in dysphagia, aspiration may be the main factor responsible for the significant decline in the outcome of the patient's clinical picture[5].

The literature describes that dysphagia increases the length of hospital stay in all age groups[5], as well as the risk of mortality[1, 6-7]. The impact on hospital resources is substantial, because aspiration leads to the need of using antibiotics and orotracheal intubation[5, 8]. When looking at developing countries, the intensive and prolonged medical and nursing care required by many of these patients puts pressure on the budget, which is usually already quite limited[9-10]. In this sense, although Video Fluoroscopic Swallowing Exam (VFSE) is the gold standard in the study of oral and pharyngeal mechanisms of dysphagia and aspiration[11-12], it is not feasible to perform this test in all patients with suspected dysphagia (age, medical condition, costs, need for specialized professionals, etc.). A simple swallowing screening can be used to identify patients at risk of bronchopulmonary penetration/aspiration[13].

A reliable screening tool should be simple, fast and minimally invasive, and should be able to determine the following factors: risk of aspiration/penetration; need for further assessment of swallowing and safety of oral intake of the patient[14]. Currently there is no consensus on a standard screening method to identify possible risks in the swallowing process[15]. Several meta-analysis reviews were performed with published swallowing screening protocols reporting that these tests have high sensitivity (up to 100%) and low specificity (between 29% and 65%)[16-17]. It allows the detection of bronchopulmonary penetration/aspiration in most patients, but has the disadvantage of having a high rate of false-positive results[18]. In addition, the quality of the studies is variable and does not provide uniform recommendation of the swallowing screening tool[17].

Most existing screening methods have only been validated in patients with dysphagia caused by stroke[19], limiting the application of these tests in patients with dysphagia caused by other diseases. To date, the Toronto Bedside Swallowing Screening Test (TOR-BSST)[20] is one of the few instruments that has shown high sensitivity (from 71.9% to 98.7%) and high negative predictive values (from 89.5% to 93.3%) for early detection of dysphagia in stroke patients. Considering that early detection allows earlier treatment, which shortens the recovery period and reduces overall hospital costs, the aim of this study was to evaluate the validity of a simple screening instrument used in a large public hospital in Brazil.

METHOD

Participants

This research is a cross-sectional observational study, conducted at the *Instituto Central Hospital das Clínicas of the Faculdade de Medicina da Universidade de São Paulo* (ICHC FMUSP), between November 2016 and March 2018. The Ethics Committee for Analysis of Research Projects of ICHC FMUSP (CAPPesq 1,781,177) approved this study. All participants were informed of the objective and procedures of the research and signed the Free and Informed Consent Form (FICF).

The participants of this study were patients referred forVFSE to investigate the possibility of bronchopulmonary aspiration. The inclusion criteria of the participants for this study were: age above 18 years; clinical and respiratory stability according to medical records; Glasgow Coma Scale score ≥ 14; clinical and respiratory stability; absence of tracheostomy; absence of exclusive esophageal dysphagia (i.e., no complaints of high dysphagia); absence of surgical procedures involving head and neck region; absence of medical contraindication for food intake and consistencies used in the clinical and objective evaluation of swallowing; absence of recurrent pneumonia and no pneumonia; absence of exclusive alternative feeding route; absence of physiological contraindications (radiation exposure or allergy to barium) and postural to perform the test, and that had completed swallowing clinical evaluation the first 24 hours prior to VFSE.

Procedures

The clinical evaluation of swallowing was performed by the Speech Therapy Division of ICHC FMUSP. All participating speech therapists successfully passed specific training tests and had experience in the area. In our institution, the clinical evaluation of swallowing is performed according to the Dysphagia Risk Evaluation Protocol (DREP) tool[21]. DREP is a Brazilian protocol indicated for the early assessment of the risk for penetration/aspiration in bedside. This protocol was published in 2007 and has since been used to investigate dysphagia in specific populations[9, 18, 22]. Considering the phases of diagnostic clinical trial, DREP has already completed validation phases 1 and 2.

The DREP included items previously described as effective in identifying patients at high risk for dysphagia. Its application included the supply of controlled volumes of water and puree. The result of the evaluation suggested whether the patient could receive larger volumes of liquids/foods and different food consistencies, besides pointing out whether there was a need for safe feeding monitoring. The protocol was divided into two sections - water swallowing test and puree/solid swallowing test. The results observed during the application were recorded as "passed" or "failed" for each item of the protocol. As determined by the authors, patients were evaluated during swallowing of water volumes measured in 3ml, 5ml and 10ml syringe and 50ml in the cup in free sips, fruit puree offered in the spoon in volumes of 3ml, 5ml and 10ml and half

a piece of bread (the offer was repeated three times for results confirmation). It is noteworthy that the offers were interrupted if the patient showed clinical signs suggesting penetration and/or aspiration. For this study, only the results of the water swallowing test were included.

The items evaluated and the criteria used to interpret the results are described below:

a) Extra oral escape: Water does not escape through the lips, manages the bolus properly – passed; Difficulty in managing the bolus, presence of fluid draining through the mouth - failed;
b) Oral transit time: Swallowing the bolus in up to four seconds - passed; Swallowing the bolus in more than four seconds or no swallowing - failed;
c) Nasal reflux: Water does not escape through the nasal cavity - passed; Water escapes through the nasal cavity - failed;
d) Multiple swallowing per bolus: Presence of a single swallowing per bolus - passed; Presence of more than one swallowing per bolus - failed;
e) Laryngeal elevation (monitored positioning of the index and middle fingers on the hyoid and thyroid cartilage): The larynx reaches, on average, an elevation of two fingers of the examiner - passed; The larynx reaches an elevation of less than two fingers of the examiner – failed;
f) Cervical auscultation (the stethoscope should be positioned on the lateral part of the larynx junction and the trachea, anterior to the carotid): Presence of three sounds characteristic of swallowing, indicating that the bolus passed through the pharynx – two clicks followed by an expiratory sound – passed; When there is no sounds or presence of other sounds not described above - failed;
g) Oxygen saturation (Basal oxygen saturation recorded before swallowing evaluation, using a monitor or pulse oximetry): No changes in oxygen saturation in more than four units – passed; changes in oxygen saturation in more than four units – failed;
h) Vocal quality: Without alterations in the first minute after swallowing - passed; The voice has a bubbling ("wet") sound in the first minute after swallowing – failed;
i) Cough: There is no presence of cough in the first minute after swallowing – passed; Presence of cough (voluntary or not) followed or not by phlegm during the first minute after swallowing - failed;
j) Choking: There is no choking after swallowing – passed; Presence of choking during or after swallowing - failed;
k) Other signs (heart rate and respiratory rate): There are no significant changes in heart rate (60-100 beats per minute) and respiratory rate (12-20 breaths per minute) – passed; Presence of signs such as cyanosis, bronchospasm and significant changes in vital signs – failed.

A study published in 2014[22] sought to elucidate independent risk factors for dysphagia after prolonged orotracheal intubation, based on DREP results in water assessment. The results indicated that specific variables, including multiple swallowing, altered cervical auscultation, altered vocal quality after swallowing, coughs and choking, were significant indicators of high risk of dysphagia onset. Thus, for the present study, it was considered that the patient failed the DREP when in at least one of the following signs presented alteration: cervical auscultation; vocal quality; cough and choking. Based on this result, it could be considered that patients failed DREP screening (DREPs) if they presented at least one of these signs. The item multiple swallowing was not included as a failure criterion, since, according to the literature, it may indicate physiological adaptation of swallowing[23]. In this study, the water-swallowing test was interrupted as soon as the patient presented any of the selected signs, indicating risk of penetration and/or laryngotracheal aspiration, thus being classified as "failure" in the clinical evaluation.

Validation

The objective test used was VFSE, the gold standard in the assessment of swallowing, conducted randomly in the participating patients (one in five patients who underwent evaluation with DREPs and one in five patients who failed the evaluation with DREPs) at the Radiology Institute of the same hospital. The fluoroscopy device used in this study was GE Medical Systems ADVANTX (GE Healthcare, Wakeska, Wisconsin, USA). All VFSE were performed in lateral vision by a radiologist and two trained speech therapists, blind for the clinical evaluation of swallowing. To perform the examination, the selected participants remained standing or seated at an angle of 90º, throughout the examination, with the ingestion of the liquid (barium diluted in water - 70% filtered water, 30% barium contrast). In this study, Bariogel® barium sulfate (BARIOGEL - Cristália Chemicals and Pharmaceuticals LTDA., Brazil) was used at a concentration of 100% - 1g/ml. The protocol adopted for swallowing assessment contains the intake of foods with different consistencies, routinely used in our hospital to investigate swallowing characteristics, especially the presence of aspiration.

In this study, the offers were made in volumes of 3ml, 5ml and 10ml, repeating three times each, and 50ml in free demand. The volumes were measured using a graduated disposable syringe and placed in disposable plastic cups for each offer, and, as in the clinical evaluation, the offer was interrupted if the patient presented penetration and/or aspiration. Swallowing was analyzed by reviewing the scanned images of each swallow.

The determination of penetration and aspiration in the respiratory tree was performed using the Rosenbek scale[24] for each offer. This scale consists of a multidimensional scale of eight points that evaluates the level of penetration/aspiration of the food bolus in the airways and the individual's response to this penetration/aspiration. The scores were assigned as follows: 1 - Contrast does not enter the airways; 2 - Contrast enters the airway, even above the vocal folds (vvff), and is expelled without leaving residues; 3 - Contrast enters the airway, above the vvff, and is not expelled, with visible residue; 4 - Contrast enters the airway, reaches vvff and is expelled, without visible residue; 5 - Contrast enters the airway, reaches vvff and is not

expelled, with visible residue; 6 - Contrast enters the airway, passes the glottis and is expelled, with no visible residue in the larynx or airway; 7 - Contrast enters the airway, passes the glottis, with visible residue in the trachea, not expelled despite the effort; 8 - Contrast enters the airway, passes the glottis, with visible residue in the sub glottis, but the patient does not respond. Patients were classified as failed (presented penetration and/or aspiration) if they received a score greater than or equal to 3.

Despite being accepted as the gold standard in the evaluation of swallowing skills, reliability among specialists remains low[11]. Thus, two speech therapists who were not involved in the swallowing study were chosen, each with more than five years of experience with dysphagia, to review each VFSE. Inter-rater reliability was high, including an Intraclass Correlation Coefficient (ICC) of 0.92.

Data Analysis

The collected data were submitted to statistical analysis in the IBM® SPSS® Statistics software version 25. In addition to descriptive analysis, the accuracy of the clinical protocol was tested using sensitivity, specificity and predictive values in comparison to the gold standard test, i.e., the evaluation of Video Fluoroscopic Swallowing (VFS).

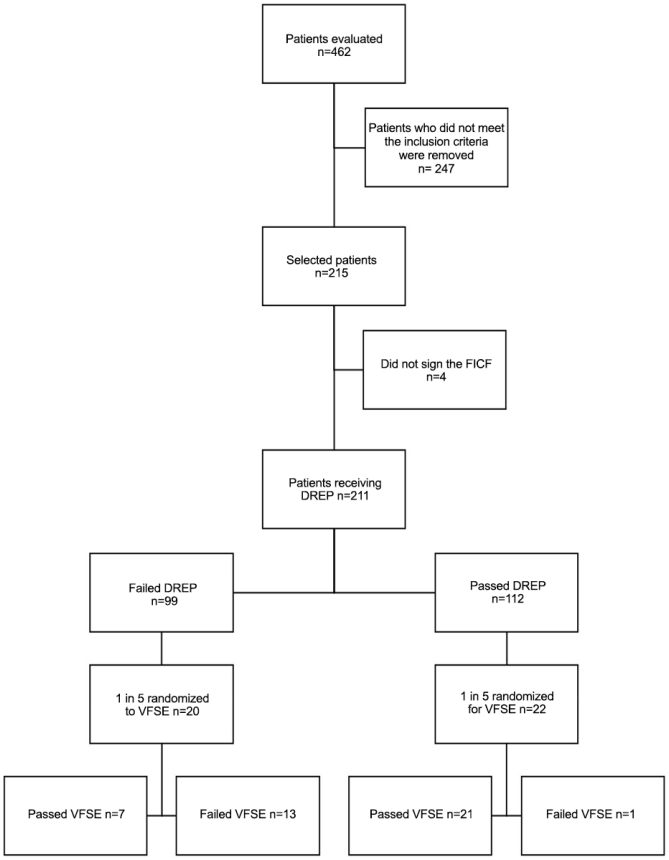
After the accuracy tests, the participants who presented false-positive results were compared with the participants who presented true-positive results in DREPs. Comparisons between groups were performed using the Mann-Whitney U test (for quantitative data) or Pearson's chi-square test (for qualitative data). The level of significance adopted was 5% for all analyses.

RESULTS

Among the 463 patients referred, 211 participants who met the inclusion criteria already described were selected for this study. The sample, randomly selected for the swallowing objective assessment, consisted of 42 patients, 18 men and 24 women, with ages ranging from 24 to 87 years old (62.2±16.0). These patients were diagnosed with the following medical conditions: Gastroesophageal Reflux Diseases (GERD) (n=5); Neurological Diseases (n=28); Lung Diseases (n=3); Cardiovascular Diseases (CVDs) (n=2); Rheumatic Diseases (n=4). Figure 1 shows the flow diagram for patient selection.

The statistical analysis of the data was performed only with the results of the water-swallowing test, because, during the evaluations, all patients who failed swallowing tests with pasty food had already failed the evaluation with water.

Table 1 presents the descriptive results of the altered clinical signs presented by the group of patients who failed the clinical evaluation of swallowing. It is important to emphasize that the same patient may have presented more than one clinical sign; thus, the total number of participants overlaps 20 (i.e., the total number of patients who failed in clinical evaluation).



Captions: n - number of subjects; FICF - Free and Informed Consent Form; DREP - Dysphagia Risk Evaluation Protocol; VFS – Video Fluoroscopic Swallowing

Figure 1. Flow diagram for DREP validation

Table 1. Descriptive analysis of clinical variables associated with penetration and/or aspiration

		N	%
Clinical variable	altered cervical auscultation	2	4.8%
	altered vocal quality	7	16.7%
	cough	18	42.9%
	choking	8	19.0%

Captions: n = number of participants; % percentage of participants

Table 2 shows the descriptive results of the VFSE for the 42 selected patients and the accuracy measures for the comparison between the clinical protocol and the VFSE appear in Table 3. Sensitivity is the probability of a test having a positive result when the disease is present; that is, it evaluates the ability of the test to detect the disease when it is present. In this study, the sensitivity found for DREPs in the diagnosis of penetration and/or aspiration, when compared to the "gold standard" test (VFS), is 92.9% (there was a 7.1% false-negative rate). Specificity is the probability that a test will have a negative result when the disease is absent, that is, it assesses the ability of the test to rule out the disease when it is absent. In this study, the specificity

found for DREPs, when compared to the "gold standard" test (VFS), is 75.0% (there was a 25.0% false-positive rate).

Table 2. VFSE results according to penetration/aspiration scale

		n	%
Rosenbek penetration/ aspiration scale score	1	17	40.5%
	2	11	26.2%
	3*	2	4.8%
	4	4	9.5%
	5	0	0%
	6	4	9.5%
	7	1	2.4%
	8	3	7.1%

Captions: n - number of participants; % - percentage of participants; *cutting line for dysphagia

Table 3. Comparison of the accuracy measures of clinical results and VFS

		VDF		
		Dysphagia (n)	**No dysphagia (n)**	Sensitivity = 92.9%
Clinical protocol	**Dysphagia (n)**	13	7	Specificity = 75.0%
	No dysphagia (n)	1	21	PPV = 65.0%
				NPV = 95.5%
		False-negative = 7.1%	False-positive = 25.0%	Accuracy = 80.9%

Captions: VFSE - Video Fluoroscopic Swallowing Exam; n - number of participants; PPV - Positive Predictive Value; NPV - Negative Predictive Value

The Positive Predictive Value (PPV) is the proportion of true-positive among all individuals with positive tests. This index expresses the probability of a patient with positive DREPs test having dysphagia – in this case, 65.0%. The Negative Predictive Value (NPV) is the proportion of true-negative sums among all individuals with negative tests. This index expresses the probability that a patient with negative DREPs does not have dysphagia – in this case, 95.5%. Finally, the accuracy of the test, that is, the proportion of "correct" results (confirmed by the "gold standard" test, that is, the proportion of true-positive and true-negative results within the sample) is 80.9% (Table 3).

The 20 patients who failed the clinical evaluation of swallowing were divided into two groups: true positive results (13 patients) and false-positive results (seven patients). Comparisons between groups were made for the variables studied (Table 4). The results did not indicate significant differences between the groups.

Table 4. Comparisons between groups of true-positive and false-positive result

	True-positive results (n = 13)	**False-positive results (n = 7)**	**p-valor**
Age in years Average (±SD)	67.7 (±21.1)	62.7 (±9.7)	0.157
Genre Number of participants (percentage)	M = 8 (61.5%) F = 5 (38.5%)	M = 3 (42.9%) F = 4 (51.7%)	0.423
Primary medical diagnoses Number of participants (percentage)	Cardiac = 0 (0%)	Cardiac = 1 (14.3%)	0.070
	Esophagogastric = 0 (0%)	Esophagogastric =1 (14.3%)	
	Neurological = 13 (100%)	Neurological = 4 (57.1%)	
	Pulmonary = 0 (0%)	Pulmonary = 1 (14.3%)	
	Rheumatological = 0 (0%)	Rheumatological = 0 (0%)	
Cough Number of participants (percentage)	12 (92.3%)	6 (85.7%)	0.639
Choking Number of participants (percentage)	6 (46.2%)	2 (28.6%)	0.444
Altered vocal quality Number of participants (percentage)	4 (30.8%)	3 (42.9%)	0.586
Altered cervical auscultation Number of participants (percentage)	1 (7.7%)	1 (14.3%)	0.639

Captions: SD - standard deviation; F - female; M - male; * significant difference, according to the Mann-Whitney U test

DISCUSSION

The main objective of the study was to determine the specificity and sensitivity of a clinical protocol to detect penetration and/or aspiration in a heterogeneous group of patients. The DREP screening (DREPs) is a simple and rapidly applicable clinical tool (less than 15 minutes), sensitive and predictive of the risk of penetration and/or aspiration in adult patients who are not fed through an alternative way, who have a good level of alertness, no history of recurrent pneumonia and no pneumonia at the time of evaluation, and who are not using tracheostomy. The tool presented high sensitivity and high negative predictive values comparable to standards for screening tools published[16, 17].

The use of screening tools plays a central role in diagnostic accuracy. The positive and negative predictive values of a screening tool are considered, by some articles, as more clinically relevant than sensitivity and specificity measures, however, they are considered dependent on the prevalence of the disease and, therefore, should not be generalized to all pathologies[25]. When investigating the accuracy measures using the screening tool in a heterogeneous population, the prevalence of diseases was not taken into account and should be seen as one of the limitations of this study. The literature indicates that sensitivity and specificity do not vary with the prevalence of the disease[26]. In this sense, DREPs presented high sensitivity and specificity to identify the risk of aspiration/penetration. The objective of a swallowing

screening tool is to identify as many cases of dysphagia as possible before penetration and/or aspiration (sensitivity) may occur, which can cause negative impacts including mortality[1, 6-7]. Considering the results of this study, we can affirm that DREPs fulfills this purpose.

We observed that seven patients in our study presented false-positive results in the clinical protocol. However, this does not have a great negative impact on patients, because, during the speech-language evaluation, they will be identified and classified before starting any rehabilitation procedure[20]. These patients may have failed during the application of the swallowing screening instrument due to the presence of pharyngeal residue, retention in pyriform sinuses, and/or secretions/saliva in the airways. In this study, residues were not analyzed after swallowing and VFSE does not evaluate penetration/aspiration of secretions or saliva[27], making it difficult to analyze these findings. In addition, the viscosity of the barium suspension used during VFSE is higher than that of water, therefore, a patient may have handled the thin barium bolus correctly, not by the motor control proper for fine liquids, but because the increased viscosity of the test facilitated bolus control[28].

Only one patient presented false-negative results in DREPs, and an 84-year-old smoker was diagnosed with transient ischemic accident. During VFSE, this patient presented an episode of aspiration with 50ml of water, but was able to effectively clean the airways after completing swallowing (i.e., the patient did not cough or choke). The impact of age on swallowing mechanisms has been widely discussed in the literature. Several studies report alterations in swallowing in the elderly, a condition known as presbyphagia[26]. Normal aging is associated with deterioration of nerve function and decline in muscle mass, which can adversely affect swallowing function[6]. The literature also describes the association between age and the decrease in the function of the mechanisms underlying the coordination between swallowing and breathing, which explains why elderly patients are more vulnerable to penetration/aspiration[29]. In addition, many asymptomatic elderly people demonstrate Video Fluoroscopic alterations of pharyngeal swallowing compared to what is considered normal in healthy young adults[6].

The diagnosis and management of dysphagia require a multidisciplinary approach. For dysphagia, as well as in other pathological conditions, a diagnostic procedure should begin with a screening test. Ideally, nurses in hospital care units should administer the dysphagia-screening instrument, considering that the number of speech therapists in clinical practice is limited[17]. The waiting time for swallowing screening in newly admitted patients can be very long if the tests are performed only by speech therapists. Our study did not verify the reliability of DREPs administration by nurses. It is important to consider the need for training other professionals who can perform the application of the swallowing screening protocol. One of the criteria evaluated in the protocol is cervical auscultation, which is increasingly used to complement the clinical evaluation of swallowing. The sounds associated with swallowing were investigated using accelerometers and microphones to evaluate acoustic characteristics and possible prediction of aspiration[30]. Although a previous study using the full version of DREP, identified altered cervical auscultation as an independent risk factor associated with dysphagia, the literature presents varies results in terms of reliability and validity for this evaluation method compared with imaging exams[30]. Further studies are needed to investigate this technique to assist in the clinical detection of penetration and/or aspiration. For this reason, the suggestion of the present study is to eliminate cervical auscultation (only two patients had altered cervical auscultation after swallowing) of DREPs until we have stronger evidence that this is a sign that relates to penetration and/or aspiration.

Among the limitations in the study, it should be considered that the sample is heterogeneous, because, although all individuals met the inclusion criteria, they had different medical diagnoses, which may have interfered in the positive and negative predictive values of DREPs. DREPs validation with specific populations is under research in our institution. In addition, the results of the study were derived from a hospital cohort of patients from a single institution and may present bias. The administration of the screening tool by professionals from different institutions is desirable to confirm the stability and accuracy of the proposed screening method. Despite these limitations, we believe that DREPs can improve the detection of the risk of penetration and/or aspiration by health professionals in hospital environments, especially the detection of cases requiring in-depth investigation and rehabilitation, because patients with penetration and/or aspiration are up to 10 times more likely to develop pneumonia[5, 12].This will reduce unnecessary radiation exposure and avoid increased expenses and use of invasive procedures.

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MSL and GCM data collection and analysis, initial writing and review of the article; FCS data analysis and writing of the final version and article review; SKJ data analysis and interpretation; CRFA design of the project, writing of the final version and article review.