Screening tool for oropharyngeal dysphagia in stroke – Part I: evidence of validity based on the content and response processes

Instrumento de rastreio para disfagia orofaríngea no Acidente Vascular Encefálico – Part I: evidências de validade baseadas no conteúdo e nos processos de resposta

Keywords
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- Deglutition Disorders
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- Validation Studies

Descritores
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ABSTRACT

Purpose: The aim of the present study was to identify the evidence of validity based on the content and response process of the Rastreamento de Disfagia Orofaríngea no Acidente Vascular Encefálico (RADAVE; “Screening Tool for Oropharyngeal Dysphagia in Stroke”). Methods: The criteria used to elaborate the questions were based on a literature review. A group of judges consisting of 19 different health professionals evaluated the relevance and representativeness of the questions, and the results were analyzed using the Content Validity Index. In order to evidence validity based on the response processes, 23 health professionals administered the screening tool and analyzed the questions using a structured scale and cognitive interview. Results: The RADAVE structured to be applied in two stages. The first version consisted of 18 questions in stage I and 11 questions in stage II. Eight questions in stage I and four in stage II did not reach the minimum Content Validity Index, requiring reformulation by the authors. The cognitive interview demonstrated some misconceptions. New adjustments were made and the final version was produced with 12 questions in stage I and six questions in stage II. Conclusion: It was possible to develop a screening tool for dysphagia in stroke with adequate evidence of validity based on content and response processes. Both validity evidences obtained so far allowed to adjust the screening tool in relation to its construct. The next studies will analyze the other evidences of validity and the measures of accuracy.

RESUMO

Objetivo: Este estudo tem o objetivo de identificar as evidências de validade baseadas no conteúdo e nos processos de resposta de um instrumento de Rastreamento para disfagia orofaríngea no Acidente Vascular Encefálico (RADAVE). Método: Os critérios para elaborar os itens do instrumento foram baseados na revisão de literatura. Um grupo de juízes com 19 profissionais distintos e da área da saúde avaliaram a relevância e representatividade das questões e o resultado foi analisado por meio do índice de validade de conteúdo (IVC). Para evidência de validade baseada nos processos de resposta, 23 profissionais da saúde aplicaram o instrumento e analisaram as questões por meio de escala estruturada e entrevista cognitiva. Resultados: O instrumento foi estruturado para ser aplicado em duas etapas. A primeira versão foi constituída por 18 questões na etapa I e 11 questões na etapa II. Oito questões da etapa I e quatro questões da etapa II não atingiram o IVC mínimo, sendo realizadas reformulações pelos autores. A entrevista cognitiva demonstrou a necessidade de novos ajustes que resultaram na versão final com 12 questões na Etapa I e seis questões na Etapa II. Conclusão: Foi possível desenvolver um instrumento de rastreamento para a disfagia no Acidente Vascular Cerebral com adequadas evidências de validade baseadas no conteúdo e nos processos de resposta. As duas evidências de validade obtidas até o momento permitiram ajustar o instrumento em relação ao seu constructo. Os próximos estudos irão analisar as demais evidências de validade e as medidas de acurácia.
INTRODUCTION

Oropharyngeal dysphagia (OD) is a common symptom in the stroke population, with some health complications occurring in these patients due to the risk of aspiration pneumonia, dehydration, malnutrition and death. Additionally, OD may increase hospitalization time and consequently the health costs. The guidelines of the American Heart Association (AHA) and the American Stroke Association (ASA) indicate that swallowing should be screened in stroke patients prior to any kind of oral feeding, including medications, aiming at the early identification of this symptom and the adequate management to avoid possible complications.

The early identification of OD requires the use of a screening tool that should determine whether the individual would pass or fail it, with selection of those who will need assessment of swallowing. This tool should be accessible to health professionals assisting stroke patients and, in the presence of risk, the patients should be referred to specialized assessment.

In the current literature on screening tools for OD there is no consensus about the parameters on which the tool should be based. In addition, there are still other questions such as who should apply these tools and whether they intend to identify OD or laryngotraheal aspiration, with no clear definition of terms such as screening and assessment.

Another point is that although in recent years there has been a great deal of discussion about the importance of screening tool for OD to provide valid and reliable interpretations of the results they produce, many studies do not mention the steps necessary to construct a measurement instrument, the which includes the obtention of evidence of validity of the instrument.

In view of the absence of consensus in the literature about which is the best screening tool for OD in stroke and the lack of instruments that use a large source of validity evidence in their elaboration, the study of this topic is of great interest. Thus, the aim of the present study was to identify the validity evidence based on the content and response processes of the instrument the Screening for Oropharyngeal Dysphagia in Stroke.

METHODS

This research was approved by the Research Ethics Committee of the Dysphagia Research Center, Marília (protocol No. 0877/2013).

The present study opted to meet the criteria of validity determined by the Standards for Educational and Psychological Testing (APA, AERA, NCME, 2014), for obtaining of the psychometric properties of the screening tool.

Validity evidence based on test content

In order to obtain validity evidence based on test content, two stages were elaborated: development of the questions and evaluation of the questions by an expert committee.

Development of the questions

Before the elaboration of the tool, the researchers worked on an operational definition of dysphagia and screening for OD in stroke. Screening should be a tool for the identification of dysphagia by health professional in different settings, of fast application requiring no specialized procedures. The screening tool for OD will select patients who will need assessment of swallowing by a specialized professional. For the planning and development of the first version of the tool, a theoretical background was used with an extensive review already described in a previous study, the databases that were used MEDLINE, EMBASE, LILACS, SciELO and Cochrane Library in order to determine the risk factors and OD symptoms to be identified by the entire health team in the stroke population. The languages selected were English, Portuguese and Spanish; there was no limitation of the date of publication. The keywords and descriptors used in English were deglutition disorders/diagnosis, stroke, screening, dysphagia, and assessment in different combinations. After selection of all the items present in the screening tool found in the literature, the authors elaborated questions based on all the aspects found and the first version of the RADAVE was defined. The instructional guide was also elaborated with details for the application of each item.

Evaluation of the questions by an expert committee

An expert committee consisted of 19 professionals for OD in the stroke population evaluated the questions. To be considered an expert, a professional had to have at least five years of experience with OD in stroke. The expert committee included 13 speech language pathologists, three doctors, a nutritionist, a nurse and a physiotherapist; all of them with knowledge about OD in stroke. In the invitation sent by email was attached the consent form explaining the objectives of the study and the experts were asked to judge each question as adequate or inadequate regarding the wording, concepts and relevance of the items. In case they judged it as inadequate, they should justify their opinion and suggest changes; they could also make comments or add items they judged relevant and which were not included in the instrument. The Content Validity Index by item (CVI-I) and the Content Validity Index (CVI) were used to analyze the level of agreement among experts about each individual question and about the instrument as a whole, with only values above 0.78 being accepted. The authors analyzed the indexes with lower values as well as all suggestions and after a consensus was reached, modifications were made and the second version of the RADAVE was defined.

Validity evidence based on response processes

This stage was carried out in order to detect possible failures in the elaboration of the questions and to make changes according to the answers observed after application. The RADAVE was applied by 23 health professionals who accepted taking part in the study, including 3 nurses, 6 doctors, 6 nutritionists and 5 physiotherapists. These professionals were selected on the day of the application and were those assisting the selected patient. Eight patients diagnosed with stroke, independent of the type, side and degree of extension, but confirmed by imaging were...
selected. The screening was applied within 48 hours after the diagnosis of stroke. These patients were identified by an active search in the hospitalization sectors of a hospital. Each patient was screened by at least two health professionals from different areas, with a maximum interval of 1 hour between applications in order to determine the performance of professionals of different areas. Before applying the instrument, the researcher provided a standardized and individualized training of five minutes to each professional and accompanied each application individually.

After application of the RADA VE, the professionals evaluated each question in terms of comprehension and applicability using a structured scale with three response options. Doubts and difficulties were to be noted down by the researcher. A directed interview was later held by the main investigator in order to analyze the cognitive processes. The interview was held in order to determine the understanding of the question, the concept and strategies used to provide an answer, as well as suggestions for changes. The researcher took notes of the answers according to what was reported by the professionals. In this stage, a qualitative analysis was carried out with a description of the answers, as well as a quantitative analysis based on relative and absolute frequencies. After analyzing the answers, the authors performed, by consensus, all the changes they judged necessary, thus elaborating the third version of the RADA VE.

**RESULTS**

**Validity evidence based on test content**

**Developing the questions**

The items contained in the instruments reviewed in the literature were divided into those not related to the offer of food and those related to the offer of food. Based on this review, the questions were elaborated on basis of all the aspects found in the instruments reported in the literature. This led to the first version of the instrument (Chart 1), divided into 2 stages. Stage I consisted of 18 questions regarding the risk-predictive factors for OD and Stage II consisted of 11 questions regarding signs of dysphagia with direct observation of the swallowing of

| Chart 1. Questions formulated after the literature review (Version I of the RADA VE) |
|---------------------------------------------------------------|
| Questions Stage I (Predicting factors of risk) | Questions Stage II (Signs and symptoms) - observations of the first meal |
| 1a-Is there difficulty in keeping alert? | 1b-Is there leakage of food or liquid from your oral cavity? |
| 2a-Is there disorientation, confusion, and/or inattentiveness? | 2b-Is there nasal reflux? |
| 3a-Was there intubation for more than 24 hours? | 3b-Is there multiple swallowing? |
| 4a-Do you use a tracheostomy tube? | 4b-Is there throat clearing? |
| 5a-Is there cardiorespiratory difficulty? | 5b-Do you cough during your meals? |
| 6a-Is there history of swallowing difficulty? | 6b-Do you choke during your meals? |
| 7a-Is there difficulty to control your head and torso? | 7b-Is there voice alterations? |
| 8a-Is there motor impairment to the left? | 8b-Is there food residue in your oral cavity? |
| 9a-Is there difficulty in understanding simple verbal commands? | 9b-Does the patient report feeling of saliva and/or food stuck in their throat? |
| 10a-Is there difficulty in speech? | 10b-Does the patient have increased meal time? |
| 11a-Is there alteration in voice quality? | 11b-Is there cardiorespiratory alteration during meal? |
| 12a-Is there alteration in voluntary coughing? | |
| 13a-Is there facial asymmetry? | |
| 14a-Is there soft palate asymmetry? | |
| 15a-Is there deficit in nausea reflex? | |
| 16a-Is there difficulty in moving lips and tongue? | |
| 17a-Is there deficit in tongue strength? | |
| 18a-Is there difficulty in swallowing or managing saliva/secretions swallowing spontaneously or on command? | |
a homogeneous soft diet. The possible answers to the questions in this phase of the study were ‘yes’ and ‘no’. It should be pointed out that stage I is preliminary to stage II, and in case the patient does not pass stage I, it will not be observed during feeding in the next stage. In stage of the research it is still not possible to define the minimum score that will determine whether or not the professional applying the instrument shall proceed to stage II.

**Evaluation of the questions by an expert committee**

The results of the analysis of Stage I and Stage II of the tool by the evaluators are given in Tables 1 and 2. After analyzing the suggestions of the evaluators and the consensus of the authors, modifications were made to stages I and II of the instrument according to Charts 2 and 3 and the second version of the instrument was proposed, with 12 questions in stage I and five questions in stage II.

**Validity evidence based on response processes**

The quantitative analysis of the understanding and applicability of the questions was based on a structured scale, can be found in Table 3 (step 1) and Table 4 (step 2).

The cognitive interview permitted the authors to determine doubts about concepts and misconceptions in application. The results of the cognitive interview are given in Chart 4. After analysis of the doubts, the misconception in applications and suggestions of the applicators, new modifications were performed and the last version of the instrument was elaborated, containing 12 questions in stage I and six questions in stage II according to Chart 5.

### Table 1. Rates of content validity of the RADAVE-analysis of the judges (Stage I)

| Stage I | Number of evaluators who considered the question appropriate | CVI-I |
|---------|-------------------------------------------------------------|------|
| 1a- Is there difficulty in keeping alert?*                  | 14   | 0.73 |
| 2a- Is there disorientation, confusion, and/or inattentiveness?* | 13   | 0.68 |
| 3a- Was there intubation for more than 24 hours?             | 19   | 1.00 |
| 4a- Do you use a tracheostomy tube?                         | 19   | 1.00 |
| 5a- Is there cardiopulmonary difficulty?*                    | 08   | 0.42 |
| 6a- Is there history of swallowing difficulty?              | 19   | 1.00 |
| 7a- Is there difficulty to control your head and torso?      | 17   | 0.89 |
| 8a- Is there motor impairment to the left?*                  | 13   | 0.68 |
| 9a- Is there difficulty in understanding simple verbal commands? | 18   | 0.94 |
| 10a- Is there difficulty in speech?                         | 16   | 0.84 |
| 11a- Is there alteration in voice quality?                   | 16   | 0.84 |
| 12a- Is there alteration in voluntary coughing?*             | 14   | 0.73 |
| 13a- Is there facial asymmetry?                              | 17   | 0.89 |
| 14a- Is there soft palate asymmetry?*                        | 13   | 0.68 |
| 15a- Is there deficit in nausea reflex?*                     | 13   | 0.68 |
| 16a- Is there difficulty in moving lips and tongue?          | 17   | 0.89 |
| 17a- Is there deficit in tongue strength?*                   | 09   | 0.47 |
| 18a- Is there difficulty in swallowing or managing saliva/secretions swallowing spontaneously or on command? | 18   | 0.94 |
| **CVI-T**                                                    |      | 0.80 |

*Items with CVI-I below 0.78

### Table 2. Rates of content validity of the RADAVE-analysis of the judges (Stage II)

| Stage II | Number of evaluators who considered the question appropriate | CVI-I |
|----------|-------------------------------------------------------------|------|
| 1b- Is there leakage of food or liquid through the oral cavity? | 11   | 0.89 |
| 2b- Is there nasal reflux?                                      | 12   | 0.89 |
| 3b- Is there multiple swallowing?*                             | 06   | 0.63 |
| 4b- Is there throat clearing?                                   | 09   | 0.79 |
| 5b- Do you cough during your meals?                            | 09   | 0.79 |
| 6b- Do you choke during your meals?                            | 10   | 0.84 |
| 7b- Is there voice alterations?*                                | 04   | 0.47 |
| 8b- Is there food residue in your oral cavity?                  | 09   | 0.79 |
| 9b- Does the patient report feeling of saliva and/or food stuck in their throat? | 13   | 1.00 |
| 10b- Does the patient have increased meal time?*                | 06   | 0.58 |
| 11b- Is there cardiopulmonary alteration during meal?*          | 04   | 0.37 |
| **CVI-T**                                                      |      | 0.73 |

*Items with CVI-I below 0.78
Chart 2. Questions of Stage I of RADAVE modified by the authors after analyzing the suggestions from the judges

| Questions Stage I – Version 1 | Questions Stage I – Version 2 |
|-------------------------------|-------------------------------|
| 1a- Is there difficulty in keeping alert? | 1a- Is there difficulty in keeping awake? |
| 2a- Is there disorientation, confusion, and/or inattentiveness? | REMOVED |
| 3a- Was there intubation for more than 24 hours? | 2a- Was there intubation for more than 24 hours? |
| 4a- Do you use a tracheostomy tube? | 3a- Do you use a tracheostomy tube? |
| 5a- Is there cardiorespiratory difficulty? | 4a- Are there signs of respiratory discomfort? |
| 6a- Is there history of swallowing difficulty? | 5a- Is there history of swallowing difficulty? |
| 7a- Is there difficulty to control your head and torso? | 6a- Is there difficulty of remaining seated with a straight head? |
| 8a- Is there motor impairment to the left? | REMOVED |
| 9a- Is there difficulty in understanding simple verbal commands? | 7a- Is there difficulty in understanding simple verbal commands? |
| 10a- Is there difficulty in speech? | 8a- Is there difficulty in speech? (distorted speech, difficult understanding) |
| 11a- Is there alteration in voice quality? | 9a- Is there alteration in voice? (hoarseness, weak sound, does not produce voice) |
| 12a- Is there alteration in voluntary coughing? | REMOVED |
| 13a- Is there facial asymmetry? | 10a- Is there facial asymmetry? |
| 14a- Is there soft palate asymmetry? | REMOVED |
| 15a- Is there deficit in nausea reflex? | REMOVED |
| 16a- Is there difficulty in moving lips and tongue? | 11a- Is there difficulty in moving lips and tongue? |
| 17a- Is there deficit in tongue strength? | REMOVED |
| 18a- Is there difficulty in swallowing or managing saliva/secretions swallowing spontaneously or on command? | 12a- Is there difficulty in swallowing or managing saliva/secretions swallowing spontaneously or on command? |

Chart 3. Questions of Stage II of RADAVE modified by the authors after analyzing the suggestions from the judges

| Questions Stage II – Version 1 | Questions Stage II – Version 2 |
|-------------------------------|-------------------------------|
| 1b- Is there leakage of food or liquid from your oral cavity? | 1b- Is there leakage of food or liquid from the oral cavity? |
| 2b- Is there nasal reflux? | REMOVED |
| 3b- Is there multiple swallowing? | 2b- Is there need to swallow 3 times or more the portion of food in the mouth? |
| 4b- Is there throat clearing? | 3b- Is there throat clearing, coughing, and/or choking during meals? |
| 5b- Do you cough during your meals? | REMOVED |
| 6b- Do you choke during your meals? | REMOVED |
| 7b- Is there voice alterations? | REMOVED |
| 8b- Is there food residue in your oral cavity? | 4b- Is there residue of any food consistency in the oral cavity after swallowing? |
| 9b- Does the patient report feeling of saliva and/or food stuck in their throat? | REMOVED |
| 10b- Does the patient have increased meal time? | REMOVED |
| 11b- Is there cardiorespiratory alteration during meal? | 5b- Are there signs of respiratory discomfort? |

Table 3. Analysis of professional applicators on the understanding and applicability of the questions based on the structured scale (Stage I)

| Questions Stage I | % answers- structured scale |
|-------------------|-----------------------------|
| I understood the questions and how to apply them and I did not have doubts | I understood the questions partially and had doubts and/or difficulties of understanding the question and/or how to apply it |
| I did not understand the question and/or did not know how to apply it |
| 1a Is there difficulty in keeping awake? | 100 | - | - |
| 2a Was there intubation for more than 24 hours? | 100 | - | - |
| 3a Do you use a tracheostomy tube? | 100 | - | - |
| 4a Are there signs of respiratory discomfort? | 100 | - | - |
| 5a Is there history of swallowing difficulty? | 78.3 | 21.7 | - |
| 6a Is there difficulty in remaining seated with a straight head? | 95.7 | 4.3 | - |
| 7a Is there difficulty in understanding simple verbal commands? | 100 | - | - |
| 8a Is there difficulty in speech? (distorted speech, difficult understanding)? | 100 | - | - |
| 9a Is there alteration in voice? | 95.7 | 4.3 | - |
| 10a Is there facial asymmetry? | 100 | - | - |
| 11a Is there difficulty in moving lips and tongue? | 78.3 | 21.7 | - |
| 12a Is there difficulty in swallowing or managing saliva/secretions, swallowing spontaneously or on command? | 91.3 | 8.7 | - |
Table 4. Analysis of professional applicators on the understanding and applicability of the questions based on the structured scale (Stage II)

| Questions Stage II | % answers- structured scale |
|--------------------|----------------------------|
| I understood the questions and how to apply them and I did not have doubts | I understood the questions partially and had doubts and/or difficulties of understanding the question and/or how to apply it | I did not understand the question and/or did not know how to apply it |
| 1b Is there leakage of any food consistency from the oral cavity? | 100 | - | - |
| 2b Is there need to swallow 3 times or more the portion of food in the mouth? | 90.47 | 9.52 | - |
| 3b Is there throat clearing, coughing, and/or choking during meals? | 100 | - | - |
| 4b Is there residue of any consistency in the oral cavity after swallowing? | 100 | - | - |
| 5b Are there signs of respiratory discomfort during meals? | 95.24 | 4.76 | - |

Chart 4. Analysis of the cognitive answer-interview process

| Questions | Analysis of the response processes |
|-----------|-----------------------------------|
| 6a-Is there difficulty of remaining seated with a straight head? | 1 applicator requested the patient to rise from the bed to check if the patient could seat without support |
| | 1 applicator considered the discomfort (pain) reported by the patient remaining seated with difficulty |
| | 2 applicators considered the difficulty of positioning patients sitting down due to excess weight as a difficulty |
| 8a- Is there difficulty in speech? (distorted speech, difficult understanding) | 1 applicator considered speech as a language, reporting having reached their conclusion because the patient would speak well by forming coherent sentences |
| 9a-Is there alteration in voice? (hoarse voice, weak voice, no voice production) | 1 applicator did not understand the difference between speech and voice, stating that if the speech in the previous question was appropriate then voice would also automatically be |
| 12a- Is there difficulty in swallowing or managing saliva/secretions swallowing spontaneously or on command? | 3 applicators considered a difficulty when patients did not swallow their saliva when requested and 1 when the patient took too long to follow the command (patient with understanding deficit). They did not consider reflex swallowing and other signs such as absence of oral leakage, coughing, and/or choking. |
| 2b- Is there need to swallow 3 times or more the portion of food in the mouth? | 1 applicator did not understand the concept of multiple swallowing. The patient did not swallow the volume placed in their oral cavity and the professional understood this patient would need various swallowing commands in order to be able to swallow it. |
| 5b-Are there signs of respiratory discomfort during meals? | 1 applicator considered a longer breathing after swallowing as a sign of respiratory discomfort |
| | 2 applicators considered the respiratory discomfort previous to feeding as a sign observed during feeding |

Chart 5. Final version of the RADAVE elaborated after evaluating response processes

| Instructions | Questions | Possible outcomes | Yes | No | Does not apply |
|--------------|-----------|------------------|-----|----|---------------|
| Call the patient by their name and observe | Is there difficulty in keeping awake? | Does not respond, drowsy, needs verbal and tactile stimulation in order to stay alert |
| Check their clinical history | Was there intubation for more than 24 hours? | - |
| Check their clinical history and observe the patient | Was there use of a tracheostomy tube? | - |
| Observe the respiratory pattern | Are there signs of respiratory discomfort? | Shortage of breath, difficulty to breath, tiredness, use of accessory muscles, increased respiratory frequency |
| Ask the patient, Escort or check the patient’s chart | Is there history of swallowing difficulty? | Choking, coughing during feeding, use of alternative feeding pathway, need to previously adapt the diet. |
| Position the patient sitting down with their elevated decubitus | Is there difficulty in being sitting down with a straight head? | Does not control the head and/or torso even when supported |

Note: The English language translation was done only for publication purposes. There are still no translation and cultural adaptation of the RADAVE for the English language.
Stage I (Predicting factors of risk)

| Instructions                                                                 | Questions                                                                                                                                  | Possible outcomes                                                                                     | Yes | No | Does not apply |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------|----|----------------|
| Ask the patient their names and request them to open and close their eyes    | Is there difficulty in understanding simple verbal commands?                                                                               | Is not able to respond, cannot or has difficulties to follow commands, needs gestures in order to perform the commands |      |    |                |
| Observe the voice of the patient during the conversation                     | Is there alteration in voice?                                                                                                               | Hoarse voice, no sonorization, or little sonorization                                                  |      |    |                |
| Observe the speech and language of the patient during the spontaneous conversation | Is there difficulty in speech and/or language?                                                                                             | Does not speak, dragged speech, alterations in articulation (dysarthria), difficulty to understand the speech, fragmented oral expressions, incoherent speech |      |    |                |
| Observe their face at rest and request a pout and a smile                    | Is there facial asymmetry?                                                                                                                 | Reduction or total absence of movement of one of the sides of the face                                 |      |    |                |
| Ask the patient to move their lips and tongue                                | Is there difficulty in moving lips and tongue?                                                                                                | Does not present movement, slow movements, movement deviation                                          |      |    |                |
| Observe if the patient swallows their saliva (rising larynx movement)        | Is there difficulty in swallowing or managing saliva/secretions swallowing spontaneously or on command?                                 | Does not observe swallowing, saliva accumulation in the oral cavity, drooling, wet voice, noises in respiratory tract |      |    |                |

Stage II (Signs and symptoms)- observations of the first meal

| Instructions                                                                 | Questions                                                                                                                                  | Possible outcomes                                                                                     | Yes | No | Does not apply |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------|----|----------------|
| Observe the swallowing of food (larynx rising)                               | Is there difficulty in swallowing the volume in the mouth?                                                                               | Take too long to swallow, does not swallow, needs constant verbal orientation to swallow               |      |    |                |
| Observe the oral region                                                       | Is there leakage of any food consistency from the oral cavity?                                                                            | Leakage of food from the mouth                                                                        |      |    |                |
| Observe the larynx rising                                                     | Was there swallowing of more than 3 times the portion placed in the mouth?                                                                | Swallows more than 3 times                                                                            |      |    |                |
| Observe the signs                                                              | Is there throat clearing, coughing, and/or choking during meals?                                                                           | Coughing, throat clearing, and/or choking during meals                                                 |      |    |                |
| After the patient swallows, observe their oral cavity                        | Is there residue of any food consistency in the oral cavity after swallowing?                                                             | Food accumulation inside the mouth                                                                     |      |    |                |
| Observe the respiratory pattern during the meal (disregard previous discomfort)| Are there signs of respiratory discomfort during meals?                                                                                    | Shortage of breath, difficulty to breath, tiredness, use of accessory muscles, increased respiratory frequency, fall in oxygen saturation |      |    |                |

Note: The English language translation was done only for publication purposes. There are still no translation and cultural adaptation of the RADAVE for the English language.

DISCUSSION

It was observed that some screening tools for OD available in the literature are called screening, but classify the severity of OD and determine the consistency of the oral diet, thus mixing the objectives of assessment of swallowing by a professional expert in dysphagia[8,16].

The screening tool of the present study was developed in order to be applied by any health professional to screen for OD in patients with stroke and to refer them, when the result was positive, to specific assessment of swallowing to be conducted by a professional expert.

Currently, the importance of the OD screening tools for a valid interpretation of their results is discussed[11]. However, most of the tools have poor psychometric measures, which highlight only one type of validity evidence, i.e., that based on the relation to other variables, where there is comparison of the screening results to other methods such as clinical evaluation of swallowing, nasoendoscopy or videofluoroscopy[9,10,17].

The evidence of validity is essential for the elaboration of an instrument, and the screening tool for OD proposed here and in the initial validation stage fulfilled the stages for obtaining evidence of validity of the content and response process.

The validity evidence based on test content is considered to be an important stage of the validation process and the analysis of a committee formed by professionals of distinct health areas with experience in the OD area allowed the improvement and modification of the first version of the RADAVE[13].

Only two of the instruments found in the literature showed the analysis of the evaluators, who included speech language
therapists, doctors and nurses. The research groups analyzed the suggestions and performed modifications, as also done in the present study(18).

In the present study, the analysis of the evaluators permitted the exclusion of questions they considered to be difficult for identification and observation by the health team even though they were trained. Others were excluded because of the lack of scientific proof of the relation of dysphagia with voluntary cough, nausea reflex(19,20) and laterality of the injury(21,22).

After the analysis of the experts, the authors also performed exclusions they considered pertinent considering clinical practice. Other suggestions such as terminology adjustments also permitted the authors to improve the contents of the instrument.

Regarding the validity evidence based on response processes, it was observed that the team took little time for application, 5 minutes on average, and that they had very few doubts regarding comprehension of the questions and applicability. The doubts presented referred to the question regarding the history of difficulty in swallowing, when the patient was not in a position to answer the question due to clinical reasons, when the escort was not present, or when there were no data in the patient’s chart. Some of the professionals suggested including the item “not applicable” in the questionnaire, which could solve this difficulty. The other doubts referred to the mobility of the lip and the difficulty of observing the laryngeal elevation.

The method of interview with the professionals who applied the questionnaire was chosen in order to evaluate the response processes(23). The questions addressed in the cognitive interview permitted the authors to determine how much the professionals really understood the questions.

In the cognitive interview there were a few misconceptions such as those regarding questions about the control of trunk and neck, concepts of speech, voice and observation of saliva swallowing.

Only one of the screening tool found in the literature showed validity evidence based on the response process. In the elaboration of the TOR-BSST tool(19), a pilot test was conducted in which the author concluded that high rates of applicability of administration and interpretation of the questions were reached. It is noteworthy that the possible failures in its applicability were not described and speech-language therapists conducted the pilot, but the tool was developed to be used by nurses.

A recent study evaluated the implementation of a screening tool by interviewing professionals who reported difficulties such as lack of time to document the results, difficulty in recalling all screening items and misinterpretation such as mistaking drowsiness for disorientation and offering water in a syringe rather than in a glass(24).

Some changes were made in order to solve some flaws observed in application, such as the addition of the specific aspect of language to the speech question and adding a question to stage II related to the difficulty of initiating swallowing. Instructions were added preceding the questions in order to facilitate application, considering that most applicators did not look into the guide and only used their previous experience for application.

It is believed that the doubts and failures found were related to the lack of experience of the health professionals in the specific fields of communication and swallowing, in addition to previous concepts related to the experience of the professionals in their specific fields.

CONCLUSION

It was possible to elaborate a screening tool for OD in stroke with validity evidence based on the content and response processes. The evidence of validity studied so far permitted relevant changes and led this screening tool for OD in stroke appropriate to its construct. It is necessary to continue the validation process in order to analyze other evidence of validity.

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REFERENCES

1. Wade DT, Hewer RL. Motor loss and swallowing difficulty after stroke: frequency, recovery, and prognosis. Acta Neurol Scand. 1987;76(1):50-4. PMid:3630644. http://dx.doi.org/10.1111/j.1600-0404.1987.tb0343.x.
2. Smithard DG, O’Neill PA, Park C, Morris J, Wyatt R, England R, et al. Complications and outcome after acute stroke - does dysphagia matter? Stroke. 1996;27(7):1200-4. PMid:8685928. http://dx.doi.org/10.1161/01.STR.27.7.1200.
3. McHorney CA, Robbins J, Lomax K, Rosenbek JC, Chignell K, Kramer AE, et al. The SWAL–QOL and SWAL–CARE outcomes tool for oropharyngeal dysphagia in adults: III. Documentation of reliability and validity. Dysphagia. 2002;17(2):97-114. PMid:11956835. http://dx.doi.org/10.1007/s00455-001-0109-1.
4. Brogan E, Langdon C, Brooks K, Budgeon C, Blacker D. Dysphagia and factors associated with respiratory infections in the first week post stroke. Neuroepidemiology. 2014;43(2):140-4. PMid:25402187. http://dx.doi.org/10.1159/000366423.
5. Adams HP Jr, del Zoppo G, Alberts MJ, Bhatt DL, Brass L, Furlan A, et al. Guidelines for the early management of adults with ischemic stroke - a guideline from the American Heart Association/American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care outcomes in research interdiscplinary working groups: the american academy of neurology affirms the value of this guideline as an educational tool for neurologists. Circulation. 2007;115(20):e78-534. PMid:17515473. http://dx.doi.org/10.1161/CIRCULATIONAHA.107.181486.
6. Martino R, Pron G, Diamant NE. Screening for oropharyngeal dysphagia in stroke: insufficient evidence for guidelines. Dysphagia. 2000;15(1):19-30. PMid:10594255. http://dx.doi.org/10.1007/s004559910006.
7. ASHA: American Speech-Language-Hearing Association. Preferred practice patterns for the profession of speech-language pathology. Rockville: American Speech-Language-Hearing; 2004. http://dx.doi.org/10.1044/policy.PP2004-00191.
8. Trapl M, Enderle P, Nowotny M, Teuschl Y, Matz K, Dachenhansen A, et al. Dysphagia bedside screening for acute-stroke patients: the gugging swallowing screen. Stroke. 2007;38(11):2948-52. PMid:17885261. http://dx.doi.org/10.1161/STROKEAHA.107.483933.
9. Martino R, Silver F, Teasell R, Bayley M, Nicholson G, Streiner DL, et al. The Toronto Bedside Swallowing Screening Test (TOR-BSST) development and validation of a dysphagia screening tool for patients with stroke. Stroke. 2009;40(2):555-61. PMid:19074483. http://dx.doi.org/10.1161/STROKEAHA.107.510370.
10. Edmiaston J, Connor LT, Steger-May K, Ford AL. A simple bedside stroke dysphagia screen, validated against videofluoroscopy, detects dysphagia and aspiration with high sensitivity. J Stroke Cerebrovasc Dis. 2014;23(4):712-6. PMid:23910514. http://dx.doi.org/10.1016/j.jstrokecerebrovasdis.2013.06.030.
11. Donovan NJ, Daniels SK, Edmiaston J, Weinhardt J, Summers D, Mitchell PH. American Heart Association Council on Cardiovascular Nursing and Stroke Council. Dysphagia Screening: state of the art - Invitational Conference Proceeding from the State-of-the-Art Nursing Symposium, International Stroke Conference 2012. Stroke. 2013;44(4):e24-31. PMid:23412377. 
   http://dx.doi.org/10.1161/STR.0b013e3182877f57.

12. American Educational Research Association, American Psychological Association, National Council on Measurement in Education. Standards for educational and psychological testing. Washington: American Educational Research Association; 2014.

13. Alexandre NMC, Coluci MZO. Validade de conteúdo nos processos de construção e adaptação de instrumentos de medidas. Ciênc. saúde coletiva. 2011;16(7):3061-3068. http://dx.doi.org/10.1590/S1413-81232011000800006.

14. Almeida TM, Cola PC, Pernambuco LA, Magalhães HV Jr, Silva RG. Screening tools for oropharyngeal dysphagia in stroke. Audiol, Commun Res. 2015;20(4):361-70. http://dx.doi.org/10.1590/2317-6431-2015-1571.

15. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Res Nurs Health. 2007;30(4):459-67. PMid:17654487. http://dx.doi.org/10.1002/nur.20199.

16. Courtney BA, Flier LA. RN dysphagia screening, a stepwise approach. J Neurosci Nurs. 2009;41(1):28-38. PMid:19368069. http://dx.doi.org/10.1097/JNN.0b013e31819345ac.

17. Nishiwaki K, Tsuji T, Liu M, Hase K, Tanaka N, Fujiwara T. Identification of a simple screening tool for dysphagia in patients with stroke using factor analysis of multiple dysphagia variables. J Rehabil Med. 2005;37(4):247-51. PMid:16024482. http://dx.doi.org/10.1080/16501970510026999.

18. Massey R, Jedlicka D. The massey bedside swallowing screen. J Neurosci Nurs. 2002;34(5):252-3, 257-60. PMid:12391741. http://dx.doi.org/10.1097/01376517-200210000-00005.

19. Leder SB. Videofluoroscopic evaluation of aspiration with visual examination of the gag reflex and velar movement. Dysphagia. 1997;12(1):21-3. PMid:8997829. http://dx.doi.org/10.1007/PL00009514.

20. Linden P, Kuhlmeier KV, Patterson C. The probability of correctly predicting subglottic penetration from clinical observations. Dysphagia. 1993;8(3):170-9. PMid:8359036. http://dx.doi.org/10.1007/BF01354535.

21. Barer DH. The natural history and functional consequences of dysphagia after hemispheric stroke. J Neurol Neurosurg Psychiatry. 1989;52(2):236-41. PMid:2564884. http://dx.doi.org/10.1136/jnnp.52.2.236.

22. Power ML, Hamdy S, Goulermas JY, Tyrrell PJ, Turnbull I, Thompson DG. Predicting aspiration after hemispheric stroke from timing measures of oropharyngeal bolus flow and laryngeal closure. Dysphagia. 2009;24(3):257-64. PMid:19252944. http://dx.doi.org/10.1007/s00455-008-9198-4.

23. Padilla JL, Benitez J. Validity evidence based on response processes. Psicothema. 2014;26(1):136-44. PMid:24444741.

24. Daniels SK, Anderson JA, Petersen NJ. Implementation of stroke dysphagia screening in the emergency department. Nursing research and practice. 2013; 2013(2013):304190. http://dx.doi.org/10.1155/2013/304190.

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TMA participated in the study design and research, obtaining and interpreting the data and writing the manuscript; PCC participated in the study design and research, critical review of the manuscript; LAP participated in the study design and research, critical review of the manuscript; HVMJ participated in the study design and research, critical review of the manuscript; CDM participated in the critical review of the manuscript; RGS participated in the study design and research, critical review of the manuscript.