Validade de face e conteúdo do instrumento LEAPA para descrição morfológica de lesões benignas das pregas vocais

Face validity of the LEAPA instrument for morphologic description of benign organic injury of the vocal folds

Validez aparente del instrumento LEAPA para la descripción morfológica de lesiones orgánicas benignas de las cuerdas vocales

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Resumo
Objetivos: O estudo tem como objetivo apresentar a validação de face e conteúdo do instrumento LEAPA, propondo uma sistematização para descrição estática dos achados laringoscópicos das lesões orgânicas benignas das pregas vocais com ênfase na utilização de elementos-chave da descrição morfológica (localização /L/, extensão /E/, aspecto orgânico /A/, pluralidade /P/, associações /A/). A importância desse instrumento consiste no fato da disfonia ter alta prevalência mundial e em cerca de 50% dos casos ocorrer devido às lesões benignas das
pregas vocais. Assim, a visualização morfo-funcional da laringe por meio das laringoscopias e a capacidade de redigir um laudo técnico confiável dos achados dos exames são essenciais para o correto diagnóstico da disfonia. Métodos: Foi desenvolvida uma avaliação de face por 13 especialistas em laringologia para analisar a confiabilidade do método de descrição das lesões por meio do coeficiente alfa de Cronbach com uso de 17 questões instigantes. Resultados: o instrumento LEAPA obteve alta consistência interna e alta confiabilidade (alfa 0,94). Conclusão: O LEAPA permite a descrição morfológica das lesões benignas das pregas vocais, contribuindo para a elaboração de laudos laringoscópicos concisos, com impressão diagnóstica uniforme, confiável e correta para este grupo de lesões.

Palavras-chave: Disfonia; Laringoscopia; Estudo de validação; Relatório técnico.

Abstract

Objectives: The study aims to present the face and content validation of the LEAPA instrument, proposing a systematization for static description of the laryngoscopic findings of the benign organic lesions of the vocal folds with emphasis on the use of key elements of the morphological description (location / L / , extension / E /, organic aspect / A /, plurality / P /, associations / A /). The importance of this instrument is that dysphonia is highly prevalent world wide and in about 50% of cases it occurs due to benign vocal fold injuries. Thus, the morpho-functional visualization of the larynx through laryngoscopy and the ability to write a reliable technical report of the examination findings are essential for the correct diagnosis of dysphonia. Methods: A face evaluation was developed by 13 laryngology specialists to analyze the reliability of the lesion description method using Cronbach's alpha coefficient using 17 thought-provoking questions. Results: the LEAPA instrument obtained high internal consistency and high reliability (alpha 0.94). Conclusion: LEAPA allows the morphological description of benign vocal fold injuries, contributing to the preparation of concise laryngoscopic reports, with a uniform, reliable and correct diagnostic impression for this group of injuries.

Keywords: Dysphonia; Laryngoscopy; Validation study; Technical report.

Resumen

Objetivos: El estudio tiene como objetivo presentar la validación de rostro y contenido del instrumento LEAPA, proponiendo una sistematización para la descripción estática de los hallazgos laringoscópicos de lesiones orgánicas benignas de las cuerdas vocales con énfasis en el uso de elementos clave de la descripción morfológica (ubicación / L /, extensión / E /, aspecto orgánico / A /, pluralidad / P /, asociaciones / A /). La importancia de este instrumento es que...
la disfonía tiene una alta prevalencia en todo el mundo y en aproximadamente el 50% de los casos se produce debido a lesiones benignas de las cuerdas vocales. Por tanto, la visualización morfofuncional de la laringe mediante laringoscopias y la capacidad de redactar un informe técnico fiable de los hallazgos del examen son fundamentales para el correcto diagnóstico de disfonía.

Métodos: Se desarrolló una evaluación facial por 13 especialistas en laringología para analizar la confiabilidad del método de descripción de la lesión utilizando el coeficiente alfa de Cronbach utilizando 17 preguntas que invitan a la reflexión. Resultados: el instrumento LEAPA obtuvo alta consistencia interna y alta confiabilidad (alfa 0.94). Conclusión: LEAPA permite la descripción morfológica de lesiones benignas de cuerdas vocales, contribuyendo a la elaboración de informes laringoscópicos concisos, con una impresión diagnóstica uniforme, confiable y correcta para este grupo de lesiones.

Palabras clave: Disfonía; Laringoscopia; Estudio de validación; Reporte técnico.

1. Introduction

The larynx is responsible for important physiological activities, being adapted to fulfill such tasks. The so-called basic functions of the larynx include protection of the airways, breathing and phonation. This is exercised, mainly through the vocal folds and its involvement is primarily reflected in the clinic, as dysphonia.

It is estimated that 7% of the world population will have dysphonia at some time in life and that more than 50% of these dysphonia result from benign changes in the vocal folds (Melo, et al., 2001). Different impacts on daily life are felt due to vocal disorders, so that dysphonic individuals consider themselves negatively affected in their social functioning and emotional stability (Ramig & Verdolini, 1998).

Morphological and functional visualization of the larynx is essential to arrive at a correct diagnosis of dysphonia. For this, direct and indirect laryngoscopies stand out, among which they can be performed with rigid or flexible endoscopes and allow to analyze the vocal folds statically and dynamically, making it possible to diagnose organic and functional changes (Frizzarini & Tsuji, 2007).

Despite the importance of these tests in the management of patients with dysphonia, there is no evidence in the literature of a standardized systematization for their reports, nor for the static description of their changes so that they can provide a uniform narrative of the aspects seen during the examination.
This research aims to present the face and content validity of the LEAPA instrument, in which, through a mnemonic instrument, it refers to the morphological characteristics indispensable for a comprehensible description of the benign organic lesions of the vocal folds. This may reproduce, in a systematic way their static evaluation, facilitating, in practical order, the elaboration of laryngoscopy reports by the professionals who perform it, making them concise and clear, allowing them to be understood by all professionals involved in the care of patients with voice disorders.

2. Methods and Materials

The methodological development study is able to build, validate and evaluate research instruments and techniques focused on the development of specific data collection tools, aiming to improve the reliability and validity of these instruments (Borges, et al., 2013). We used a quantitative research method through the application of questionnaires composed of closed questions using the Likert scale for psychometric assessment during face validation (Vieira & Dalmoro, 2008, Pereira, et al., 2018).

Focusing on the morphological characteristics most cited and judged by the authors as fundamental for the description of benign organic lesions of vocal folds in 202 reports of researched laryngoscopies, independent of the performer or the equipment used, a systematization instrument aimed at reports with respect to the morphological description of these lesions. The study was approved by the Research Ethics Committee of the Universitary Hospital of Aracaju, Federal University of Sergipe, under opinion number 1.408.803 CAAE 52725915.1.0000.5546.

This systematization instrument was called LEAPA (Picture 01), an acronym for easy memorization that represents the initials of the key elements considered by researchers as relevant and indispensable for a good narrative of benign glottis lesions, being these: L - location; E - extension; A - (organic) aspect; P - plurality of the main lesion; A - associations (secondary injuries). The specifications of the LEAPA instrument are described in picture 1, however it is worth noting that the instrument systematizes observation points allows the observer to express his subjectivity in addition to the characteristics considered in the object.
Picture 1 – LEAPA instrument.

PROTOCOL FOR THE LARYNGOLOGIC REPORT OF ORGANIC INJURIES OF BENING VOCAL FOLDS – LEAPA INSTRUMENT

INTRODUCTION OF USE:

a) The LEAPA instrument lends itself to the systematic standardization of descriptive reports of videolaryngoscopy for benign organic lesions of the vocal folds;

b) Objective marking of the characters considered to be key elements for the description of the lesion observed in the light of videolaryngoscopy is performed;

c) The narrative of the marked elements is described (descriptive report) followed by the diagnostic impression;

d) If there are associated lesions, a second LEAPA form is used to describe the morphological analysis of the secondary lesion.

( ) Main Injury ( ) Secondary Injury EXAM DATE: ___ / ____ / ___

1) MORPHOLOGICAL ANALYSIS

1.1) Location: 

<table>
<thead>
<tr>
<th>Right vocal fold</th>
<th>Left vocal fold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior 1/3</td>
<td>Medium 1/3</td>
</tr>
<tr>
<td>Posterior 1/3</td>
<td>Posterior 1/3</td>
</tr>
</tbody>
</table>

1.2) Extension: 

<table>
<thead>
<tr>
<th>Anterior</th>
<th>Posterior</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/3 of the vocal folds</td>
<td>1/3 of the vocal folds</td>
<td></td>
</tr>
</tbody>
</table>

1.3) Organic Aspect:

Color: ______Whitish ______Reddish ______Other:
Relief: ______Excavated/ulcerated ______Flat ______Bulging/vegetative ______Other:
Implantation: ______Sessile ______Pediculated ______Other:
Surface: ______Smooth/regular ______Rough/irregular ______Other:
Depth: ______Epitelial ______Subepitelial ______Other:

1.4) Plurality:

<table>
<thead>
<tr>
<th>Focal</th>
<th>Multifocal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral</td>
<td>Bilateral</td>
</tr>
</tbody>
</table>

1.5) Associations:

Yes ______ No

2) DESCRIPTIVE-ANALYTICAL REPORT

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

3) DIAGNOSTIC PRINTING

_________________________________________________________________________

Source: Autor’s data.

Regarding to the specification of each element, the “L” (Location) was proposed, based on the “Anatomical Areas of D’Avila (D’Avila, et al., 2003), shown in Figure 1, which divide the glottic region into anterior, middle and posterior thirds vocal fold plus its respective side, whether right or left. The vowel “E” (Extension) consists of the property of the main
lesion to extend to the adjacent anterior and/or posterior thirds on the longitudinal axis of the vocal fold. Component “A” (Aspect), consists of the description of the macroscopic organic characteristics of the main lesion such as color, implantation mode, surface appearance, depth, and relief. The element “P” (Plurality) refers to the possibility of the main damage presenting itself as an isolated lesion or multiple lesions (unilateral or bilateral). Finally, the last element "A" (Associations), aims to describe the existence of a second type of apparent injury, in addition to the main injury.

**Picture 2 - D’Avila anatomical áreas.**

![Diagram of D’Avila anatomical areas]


**Table 1 – Description of the anatomical areas of D’Avila.**

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area I</td>
<td>Anterior and anterior 1/3 commissure of the vocal folds</td>
</tr>
<tr>
<td>Area II</td>
<td>1/3 average of vocal folds</td>
</tr>
<tr>
<td>Area III</td>
<td>1/3 posterior of the vocal folds and arytenoid regions</td>
</tr>
</tbody>
</table>


The LEAPA instrument's face and content validation stage was developed by 13 judges, who are specialists in otorhinolaryngology and whose public knowledge in laryngology is of public domain (participation in courses or congresses as speakers, debaters, etc. or holder of publications on the studied area) and who freely agreed to participate in the
research in accordance with the technical and ethical criteria that are required, previously signing an authorization term for such purpose (Pereira, et al., 2018).

The evaluators were contacted by e-mail, through the Google Forms virtual form tool, the guidelines regarding the content analysis that was carried out through the observation and critical interpretation of the studied instrument (LEAPA), followed by filling out the questionnaire validation form sent concomitantly and exposed in table 1. This was built based on a study on the scientific quality index for health reports, adapted for this research, consisting of 17 questions of staggered responses with a score of values for each question ranging from 1 to 7 points. It would be up to the end, at the discretion of the evaluator, to make additional comments if deemed appropriate and necessary (Oxman, et al, 1993).

The analysis of the results referring to LEAPA’s content validation was obtained through the average of the grades and its percentage corresponding to the maximum score value of each item of the validation questionnaire, regardless of the evaluator, with the maximum value being 7; the average of the total grades and its percentage corresponding to the maximum score given individually by the evaluators, regardless of the item, the maximum being equal to 119; in addition to calculating the average of the percentages obtained for all items, called the global percentage (PG), which was used as a general measure of LEAPA validity. The interpretation of validity refers to the same cutoff point used in other studies and suggested in a publication on health measurement scales that consider the instrument to have content validity if its PG is greater than 75% (Streiner, et al., 1989, Vilas Boas & Silvany Neto, 2012).

The reliability of the questionnaire using Cronbach's alpha coefficient measured for each item and for the instrument. It reflects the covariance of the items with each other, the internal consistency, and the coherence of the proposed items, being considered reasonable when above 0.8, conferring relevance to the research. It aims to assess the reliability of the instrument among examiners, that is, the degree to which different examiners see the same phenomenon, using the same instrument (Bland & Altman, 1997).
Table 2 – Validation sheet.

**LEAPA Evaluation**

The LEAPA instrument that we are asking for to evaluate was designed to systematize and standardize the morphological description of the benign organic lesions of the vocal folds in a clear and objective way seen through laryngoscopy. We are interested in your opinion about LEAPA and would like you to evaluate its content.

Email address: 

**Agreement: I agree to participate as an evaluator (judge) in the LEAPA protocol content validation process, object of a doctoral thesis entitled “LEAPA - Instrument for the morphological description of benign vocal fold injuries seen at laryngoscopy”. Furthermore, I ratify my position of complete exemption and total absence of any conflict of interest in the face of such participation.**

I ACCEPT ( ) I DO NOT ACCEPT ( )

1) To what extent is LEAPA applicable to morphologically describe benign organic lesions of the vocal folds?

   - Mild 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Severe

2) Otorhinolaryngologists with or without experience in performing laryngoscopies will use LEAPA. In your opinion, will the use of LEAPA by these people be successful?

   - Improbable 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Very probable

3) How do you rate LEAPA in terms of its clarity and simplicity?

   - Unacceptable 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

4) To fill LEAPA with its key elements, how often will information not seen in the light of laryngoscopy be necessary?

   - Very 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Rare

5) To what extent will subjective decisions be required (as opposed to the objective information clearly seen in laryngoscopy), to answer the elements of LEAPA?

   - Big 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Small

6) How can the elements that make up LEAPA be presented generate bias in the responses?

   - Very probable 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Improbable

7) The various key elements of LEAPA aim to systematize and standardize laryngoscopy reports for benign organic lesions of the vocal folds. To what degree will this objective be achieved?

   - Unacceptable 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Very probable

8) The elements of LEAPA are crucial and necessary for a descriptive report, but how many of these are redundant or unnecessary?

   - Very unnecessary 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) None unnecessary

9) Are there important elements for the descriptive report of laryngoscopy in benign organic lesions of the vocal folds that were not included in LEAPA?

   - Important gaps 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Minimal gaps

10) Using the key elements of LEAPA to describe lesions, are these elements sufficient for diagnostic completion?

   - Very improbable 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Very probable

11) How is LEAPA's ability to describe the different benign organic lesions of the vocal folds classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

12) How is LEAPA's ability to describe vocal fold nodules classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

13) How is LEAPA's ability to describe vocal fold polyp classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

14) How is LEAPA's ability to describe vocal fold cyst classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

15) How is LEAPA's ability to describe vocal fold granuloma classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

16) How is LEAPA's ability to describe vocal fold papilloma classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent

17) How is LEAPA's ability to describe vocal fold leukoplakia classified?

   - Too small 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) Excellent
3. Results

Data analysis by calculating the variance of the individual items and the total variance between the items, obtained by the face and content validation questionnaire, generated a Cronbach's alpha coefficient of 0.944. The synthesis of the evaluators' grades showed averages for each item greater than 4.38 (62.5%), reaching a maximum of 6.31 (90.1%), with the average per item being 5.33. This corresponds to 76% and the average per evaluator ranged from 57 (47.9%) to 114 (95.7%), with an average of 89.8, representing 75.4%; therefore, the so-called global percentage was 76%, being considered as having content validity. Table 3 shows the descriptive statistics of the investigated data.

In general, the minimum acceptable value of the coefficient for the reliability of a questionnaire is 0.70; below this value the internal consistency of the scale used is considered low, so the evaluation of the instrument in question indicates reliability by evaluating the internal consistency greater than 0.9, reinforcing the content validity (Oxman, et al, 1993, Streiner, et al., 1989, George & Mallery, 2003).

Table 3 - Descriptive statistics of respondents' responses on LEAPA efficiency.

<table>
<thead>
<tr>
<th>Questionings</th>
<th>Average</th>
<th>SD</th>
<th>Corrected Total Correlation</th>
<th>Cronbach's alpha if item is deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>To which extent is LEAPA applicable to morphologically describe benign organic lesions of vocal folds?</td>
<td>5.85</td>
<td>1.28</td>
<td>0.82</td>
<td>0.93</td>
</tr>
<tr>
<td>Otorhinolaryngologists with or without experience in performing laryngoscopies will use LEAPA. In your opinion, will the use of LEAPA by these people be successful?</td>
<td>5.31</td>
<td>1.49</td>
<td>0.85</td>
<td>0.93</td>
</tr>
<tr>
<td>Question</td>
<td>Mean</td>
<td>SD</td>
<td>Median</td>
<td>SIGMA</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------</td>
<td>-----</td>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td>How do you rate LEAPA in terms of its clarity and simplicity?</td>
<td>5.46</td>
<td>1.39</td>
<td>0.80</td>
<td>0.93</td>
</tr>
<tr>
<td>To fill LEAPA with its key elements, how often will information needed not seen in the light of laryngoscopy be necessary?</td>
<td>5.31</td>
<td>1.32</td>
<td>0.07</td>
<td>0.95</td>
</tr>
<tr>
<td>To what extent will subjective decisions be needed (in contrast to the objective information clearly seen in laryngoscopy), to answer the elements of LEAPA?</td>
<td>5.15</td>
<td>1.57</td>
<td>0.13</td>
<td>0.95</td>
</tr>
<tr>
<td>How can the elements that make up LEAPA be presented generate bias in the response?</td>
<td>4.38</td>
<td>1.80</td>
<td>0.89</td>
<td>0.93</td>
</tr>
<tr>
<td>The various Key elements of LEAPA aim to systematize and standardize laryngoscopy reports for benign organic lesions of the vocal folds. To what degree will this objective be achieved?</td>
<td>5.31</td>
<td>1.44</td>
<td>0.84</td>
<td>0.93</td>
</tr>
<tr>
<td>The elements of LEAPA are crucial and necessary for a descriptive report, but how many of these are redundant or unnecessary?</td>
<td>5.54</td>
<td>1.45</td>
<td>0.67</td>
<td>0.94</td>
</tr>
<tr>
<td>Are there important elements for the descriptive report of laryngoscopy in benign organic lesions of the vocal folds that were not included in LEAPA?</td>
<td>5.00</td>
<td>1.35</td>
<td>0.61</td>
<td>0.94</td>
</tr>
<tr>
<td>Using the LEAPA key elements to describe the lesions, are these elements sufficient for diagnostic completion?</td>
<td>4.62</td>
<td>1.76</td>
<td>0.78</td>
<td>0.93</td>
</tr>
</tbody>
</table>
4. Discussion

Endoscopic examinations of the larynx have revolutionized the investigative methodology of its pathologies, given its clinical applicability, resolvability, and cost/benefit ratio. Various publications assure, due to the large number of subjects pertinent to this topic in question, that endoscopic diagnosis is especially prominent today with tests of sensitivity and specificity in varied values, but encouraging and consistent with its importance (Jerjes, et al., 2011).

The findings obtained are increasingly accurate, with technological devices of image, sound and light that allow the recording and magnification of them, making it possible to highlight organic and functional nuances of the lesions found. However, it is necessary to know how to accurately narrate, expressing in words, what is observed during the exam. The morphological description of the laryngeal lesions, including on the static aspect, as happens in direct laryngoscopies, is a fundamental step in the construction of the reports of the laryngeal exams. However there is no systematization in the literature that standardizes and
unifies this step in order to objectify and optimize the clarity of these texts, diminishing, but not removing, the subjectivity that is inherent in this exams (Neofytou, et al., 2007).

The research in question shows that the LEAPA instrument for the morphological description of benign organic lesions of the vocal folds easily refers, through a mnemonic method, to the key elements (location, extent, organic aspects, plurality and associations). Thus, LEAPA provides a good narrative and presents reliability and content validity, ratifying the instrument as capable of systematizing the description of benign lesions evaluated by laryngoscopy, a step that precedes any other evaluation criteria arising from such an examination.

It is clear that adding to the diagnostic capacity the increment of the laryngoscopy analysis with continuous light and stroboscopic effect for the dynamic (functional) assessment with the parameters of vocal fold mobility and periodicity, presence of mucous wave, glottic closure, symmetry and amplitude of vibration as already known in the literature and ratified in the comments of the judges when face validation has a significant predictive value in the early diagnosis of glottic lesions, including malignant ones, but which transcends the purpose of LEAPA (Rzepakowska, et al., 2017, Krasnodebska, et al., 2018).

Therefore, the existence of a descriptive analysis for laryngeal lesions based on a systematic evaluation with citation of the key elements of benign organic lesions of the vocal folds, allows the elaboration of uniform, reliable and correct laryngoscopy reports for this group of lesions contributing for diagnostic and therapeutic interpretation.

5. Conclusion

The LEAPA instrument has face and content validity. Therefore, it lends itself to the morphological description of benign vocal fold lesions, presenting high reliability and contributing to the systematic elaboration of laryngoscopy reports with an emphasis on the key elements of the examined lesion (location, extent, organic aspect, plurality and associations).

After validating the instrument, we believe that an evaluation with its use in professionals who perform laryngoscopy, comparing the descriptive capacity with videos and images, may be the next step to improve and disseminate the use of LEAPA.
Conflict of Interests

The authors have none to declare.

References


**Percentage of contribution of each author in the manuscript**

Alexandre Augusto Fernandes – 25%
Ricardo Queiroz Gurgel – 25%
Jeferson Sampaio D´Ávila – 25%
Henrique de Paula Bedaque – 25%