Research, Society and Development, v. 9, n. 11, e83691110498, 2020
(CC BY 4.0) | ISSN 2525-3409 | DOI: http://dx.doi.org/10.33448/rsd-v9i11.10498

Construction and validation of a simplified questionnaire for screening of patients with temporomandibular disorder

Construção e validação de um questionário simplificado para o diagnóstico de pacientes com disfunção temporomandibular

Construcción y validación de un cuestionario simplificado para el diagnóstico de pacientes con trastornos temporomandibulares

Received: 11/24/2020 | Reviewed: 11/27/2020 | Accept: 12/01/2020 | Published: 12/05/2020

Angela Maria Fernandes Vieira de Paiva
ORCID: https://orcid.org/0000-0001-8331-9989
Universidade Federal do Rio Grande do Norte, Brasil
E-mail: paivahjam@hotmail.com
Laércio Almeida de Melo
ORCID: https://orcid.org/0000-0002-9276-0116
Universidade Federal do Rio Grande do Norte, Brasil
E-mail: laercio_melo91@hotmail.com
Erika Oliveira de Almeida
ORCID: https://orcid.org/0000-0003-1279-1842
Universidade Federal do Rio Grande do Norte, Brasil
E-mail: erika.almeida.protese@gmail.com
Helson José de Paiva
ORCID: https://orcid.org/0000-0001-5980-3869
Universidade Federal do Rio Grande do Norte, Brasil
E-mail: paivahjam@hotmail.com
Kenio Costa de Lima
ORCID: https://orcid.org/0000-0002-5668-4398
Universidade Federal do Rio Grande do Norte, Brasil
E-mail: limke@uol.com.br

Abstract

Objective: Develop and validate a diagnostic tool of temporomandibular disorders (TMD) compared to the gold standard (RDC/TMD). Methods: Construction and validation of the

questionnaire followed a series of steps: test validation, face validity, factorial validity and validation in comparison to the gold standard. Stability of the questionnaires with 5 and 7 items was tested by Intraclass Correlation Coefficient. Results: 130 individuals participated for the factorial validation and 99 for the validation in comparison to the gold standard. The instrument stability was 0.923 for both questionnaires. Considering the total score of the questions for the questionnaire with 7 items, the best result for TMD was assumed for scores from 10 to 21, while 85.1% was also positive in RDC/TMD. Scores from 7 to 9 revealed no TMD, and 96.2% was also negative in RDC/TMD with accuracy of 90.1%. Sensitivity was 95% and specificity 87%. For the questionnaire with 5 items, the best result for TMD was assumed for scores from 7 to 15 while no TMD was associated to scores 5 and 6, with accuracy of 85.8%. Sensitivity was 88% and specificity 84%. Conclusion: Simple and fast questionnaires with reliability for the diagnosis of temporomandibular disorder were obtained.
Keywords: Temporomandibular joint Dysfunction syndrome; Temporomandibular joint; Questionnaire.

Resumo

Objetivo: Desenvolver e validar um instrumento de diagnóstico das disfunções temporomandibulares (DTM) em comparação ao padrão ouro (RDC/TMD). Metodologia: A construção e validação do questionário seguiram uma série de etapas: validação de teste, validação facial, validação fatorial e validação em comparação com o padrão ouro. A estabilidade dos questionários com 5 e 7 itens foi testada pelo Coeficiente de Correlação Intraclasse. Resultados: 130 indivíduos participaram da validação fatorial e 99 da validação em comparação ao padrão ouro. A estabilidade do instrumento foi de 0,923 para ambos os questionários. Considerando a pontuação total das questões do questionário de 7 itens, o melhor resultado para DTM foi assumido para pontuações de 10 a 21, enquanto 85,1% também foi positivo no RDC/TMD. Escores de 7 a 9 não revelaram DTM e 96,2% também foram negativos no RDC/TMD com acurácia de 90,1%. A sensibilidade foi de 95% e a especificidade de 87%. Para o questionário com 5 itens, o melhor resultado para DTM foi assumido para escores de 7 a 15, enquanto nenhuma DTM foi associada aos escores 5 e 6, com acerto de 85,8%. A sensibilidade foi de 88% e a especificidade de 84%. Conclusão: Foram obtidos questionários simples e rápidos com confiabilidade para o diagnóstico de disfunção temporomandibular.
Palavras-chave: Síndrome da disfunção da articulação temporomandibular; Articulação temporomandibular; Questionário.

Resumen

Objetivo: Desarrollar y validar un instrumento para el diagnóstico de trastornos temporomandibulares (TMD) en comparación con el estándar de oro (RDC / TMD). Metodología: La construcción y validación del cuestionario siguió una serie de pasos: validación de prueba, validación facial, validación factorial y validación en comparación con el estándar de oro. La estabilidad de los cuestionarios con 5 y 7 ítems fue probada por el Coeficiente de Correlación Intraclase. Resultados: 130 individuos participaron en la validación factorial y 99 en la validación en comparación con el patrón oro. La estabilidad del instrumento fue de 0,923 para ambos cuestionarios. Considerando el puntaje total de las preguntas del cuestionario de 7 ítems, el mejor resultado para TMD se asumió para puntajes de 10 a 21, mientras que el 85.1% también fue positivo en el RDC / TMD. Las puntuaciones de 7 a 9 no revelaron TMD y el 96,2% también fueron negativas en el RDC / TMD con una precisión del 90,1%. La sensibilidad fue del 95% y la especificidad fue del 87%. Para el cuestionario de 5 ítems, se asumió el mejor resultado para DTM para puntuaciones de 7 a 15, mientras que ninguna DTM se asoció con puntuaciones 5 y 6, con 85,8% de precisión. La sensibilidad fue del 88% y la especificidad del 84%. Conclusión: Se obtuvieron cuestionarios sencillos, rápidos y confiables para el diagnóstico de trastorno temporomandibular.

Palabras clave: Síndrome de la disfunción de articulación temporomandibular; Cuestionario.

1. Introduction

Temporomandibular disorder is a set of changes that mainly involve the joints of the mouth (called temporomandibular disorders - TMD) and the muscles that work in the movements of the jaw (Schiffman et al., 2014). Since its introduction in 2014, the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) has been a widely used tool for clinical trials in TMD (Schiffman et al., 2014; Hasanain et al., 2009). It assumes a multiaxial protocol, evaluating clinical factors in axis I and psychological and psychosocial features in axis II (Lucena et al., 2006).

Epidemiological and clinical studies on TMD have demonstrated controversial results about its prevalence and frequency as a consequence of mistakes in methodology and lack of standardized diagnostic criteria (Sessle, 2009). Thus, reliable and validated tools for measuring the frequency and severity of TMD are essential for comparison of the results from different clinical trials (Lucena et al., 2006; Nomura et al., 2007; Campos et al., 2009; Zhao et al., 2011).

Although the clinical use of RDC/TMD remains as a reliable, validated and updated tool (Visscher et al., 2010); it limits the approach since exams and deeper knowledge about pain are necessary in dental and medical clinical routine. So, a simplified screening tool was created for evaluation of patients with TMD-related pain based on the RDC/TMD (Svenson, 2009; Palla and Farella, 2010). However, the 20-30 minutes spent for application turns it inappropriate for screening of TMD patients (Zhao et al., 2011).

Despite of the knowledge in the last decades about the diagnosis and treatment of different TMDs and the development of a tool validated by psychometric methodology for identification of TMD-related pain, such disorders remain subdiagnosed because of the lack of simple screening tools (Araújo et al., 2010; Gonzalez et al., 2011). So, the aim of this study was to develop and validate a diagnostic tool of temporomandibular disorders (TMD) compared to the gold standard with seven and five items.

2. Methods

Study design

The present study is characterized by a cross-sectional and observational research for development and validation of a simplified and easy questionnaire. The study was approved by the Institutional Ethical Committee (protocol number 107/2011).

Instrument Construction

In the first step, an exhaustive bibliographic search was done in order to develop a questionnaire for easy understanding and application. Initially, the authors have selected some questions from previous surveys: the Helkimo Index, Research Diagnostic Criteria for TMD (RDC/TMD), the Questionnaire on Temporomandibular Disorders of the American Academy of Orofacial Pain (AAOP) and the Anamnesic index proposed by Fonseca (Fonseca et al., 1994). Other questions were based on the signs and symptoms most frequently reported by the patients, resulting in a preliminary questionnaire consisting of 15 questions.

Construction and validation of the questionnaire followed the methodology "Measuring Health: A Guide to Rating Scales and Questionnaires" (McDowell, 2006). Questionnaires are commonly validated using a series of steps: development of questions and assessment of questions by a committee of experts (Test validation); assessment of the

comprehensiveness of the scale (Face validity) and correlational evidence, which is often presented in association with factor analysis of the items making up the scale (Factorial validity).

Participants

Patients and students of the Department of Dentistry of Federal University of Rio Grande do Norte – UFRN and patients from private dental practice were recruited. Sample composition was performed according to the peculiarities of each phase of the validation process: Factorial validity - Sample size followed the recommended classic proportion of at least 10 individuals per item of the instrument (Nunnaly, 1978). The number of established individuals aimed to resembled the sample data distribution with the population distribution; Validation in comparison to the gold standard - Sample size calculation considered a 95% confidence interval with an amplitude ≤ 10% from the prevalence of TMD.

Test validation

In the second step, a test validation was done through an evaluation by 9 experts in Temporomandibular Disorders and Orofacial Pain, Epidemiology and Psychology. The professionals analyzed and discussed the questions. Then, they presented their judgment and suggestions about each question. Upon any inadequacy, the experts made comments and suggestions, including the final number of questions that should compose the questionnaire to be validated. As a result, a questionnaire in Portuguese language consisting of 7 items was developed and applied in the present study.

Face validity of the instrument

The third stage of the study was equivalent to the face validation. The questionnaire obtained in the previous step had seven questions and it was administered by the principal investigator and research collaborators in an intentional sample of 30 individuals with different socioeconomic factors and different educational levels. The understanding of the questions was tested (between "understandable" and "not understandable"). Then, it was possible to make terminological adjustments to the questions, producing a new questionnaire with the same number of questions as previous.

Factorial validity of the instrument

At the fourth stage of the construction of the questionnaire, the new previously elaborated instrument was applied. This phase aimed to test the internal consistency of the questions. In order to verify the reproducibility of the instrument, from the total patients in this phase, a sample of 30% was taken to evaluate the stability of the questions. This was done by repeating the application of the same questionnaire, under similar conditions, after 5 days of the initial application.

In the questionnaire with 7 questions, the factors explaining the total variance were obtained. Then, two questions which variance was not explained by the extracted factors were eliminated and a questionnaire with 5 questions was obtained.

Validation in comparison to the gold standard

The patients answered to the questionnaires with seven and five items. A clinical evaluation was also done based on the RDC/TMD version translated and validated to Portuguese in order to get reliable parameters for identification of patients with TMD or not (Pereira et al., 2004). The examiners were previously calibrated and the patients reporting any type of TMD-related orofacial pain were instructed about the treatment. Only adults with no systemic disease influencing the answers to the questions were included in the study. After screening, the patients were classified according to the diagnosis, based on the RDC/TMD, into “no TMD” or “TMD” (muscular, articular or mixed) and compared to the results of the suggested questionnaire. For easier data collection, three answering alternatives (“always”, “sometimes”, and “never”) were determined and scored (always=3, sometimes=2, and never=1).

Statistic Analysis

The internal consistency of the questions was tested by Cronbach's alpha coefficient and their adequacy to the construct studied by Confirmatory Factor Analysis. The reproducibility and stability of the proposed instrument was evaluated by the intraclass correlation coefficient for the total score.

In validation in comparison to the gold standard, a sum of scores was calculated in order to determine the better range or value to represent TMD diagnosis. The sensitivity,

specificity, positive predictive value, negative predictive value and likelihood ratio were calculated for validation of the results.

For the questionnaire with 7 items, the values ranged from 7 to 21. Then, the following intervals were assumed for testing: 9 – 21; 10 – 21; 11 – 21 and 12 – 21. For the questionnaire with 5 items, the values ranged from 5 to 15; and the intervals 6 – 15, 7 – 15 and 8 – 15 were tested according to the same method.

For assessing the association of gender and social economic condition on TMD, chi-squared test at 5% level of significance was used. For age, the "TMD" and "no TMD" groups were compared using Student's t-test. All tests were considered significant at a confidence level of 95%.

3. Results

A final questionnaire with seven items was created based on a careful evaluation of previous questionnaires, experts' analysis and testing about questions understanding. 130 individuals participated for the factorial validation and 99 for the validation in comparison to the gold standard. The internal consistency of the questionnaire was 0.752. Table 1 shows data about the commonalities obtained by the factor analysis of the questionnaire with seven items.

Table 1. Commonalities obtained for each of the 7 questions.

Do you have pain or difficulty in opening the mouth? (Você tem dor ou dificuldade de abrir a boca?) (Tiene dolor o dificultad para abrir la boca?)	0.693
Do you have clicks or sounds in the jaw joints when opening or closing the mouth? (Você possui cliques ou sons ao abrir e fechar a boca?) (Tiene clics o sonidos al abrir y cerrar la boca?)	0.386
Does your jaw lock when opening or closing the mouth? (Sua mandíbula trava ao abrir e fechar a boca?) (Su mandíbula se bloquea al abrir y cerrar la boca?)	0.709
Dou you have ear pain or pain around the ears? (Você tem dor de ouvido ou ao redor dele?) (Tiene dolor de oído dentro o alrededor de él?)	0.545
Do you have pain in the forehead or beside it? (Você tem dor na fronte ou ao redor dela?) (Tiene dolor en la frente o alrededor de ella?)	0.814
Do you have pain in the cheek region (Você tem dor na região das bochechas?) (Tiene dolor en el área de las mejillas?)	0.528
Do you feel your jaws tired throughout the day? (Você sente seus maxilares cansados ao longo do dia?) (Sientes tu mandíbula cansada durante el día?)	0.400

Source: Authors.

Among the seven questions, two factors were produced explaining 58.2% of the total variance. Then, the two questions (i.e., Popping or noises in the joints when opening or closing the mouth; and Jaws worn throughout the day), which variance was not explained by the extracted factors, were eliminated and a new analysis was performed. So, a final questionnaire with five items was obtained and its internal consistency was 0.694. Table 2 shows data about the commonalities obtained by the factor analysis of the questionnaire with five items.

Table 2. Commonalities obtained for each of the 5 questions.

Do you have pain or difficulty in opening the mouth? (Você tem dor ou dificuldade de abrir a boca?) (Tiene dolor o dificultad para abrir la boca?)	0.696
Does your jaw lock when opening or closing the mouth? (Sua mandíbula trava ao abrir e fechar a boca?) (Su mandíbula se bloquea al abrir y cerrar la boca?)	0.791
Dou you have ear pain or pain around the ears? (Você tem dor de ouvido ou ao redor dele?) (Tiene dolor de oído dentro o alrededor de él?)	0.620
Do you have pain in the forehead or beside it? (Você tem dor na fronte ou ao redor dela?) (Tiene dolor en la frente o alrededor de ella?)	0.824
Do you have pain in the cheek region (Você tem dor na região das bochechas?) (Tiene dolor en el área de las mejillas?)	0.589

Source: Authors.

The five questions produced two factors explaining 70.4% of the total variance. The instrument stability, tested by the Intraclass Correlation Coefficient, was 0.923 for both questionnaires containing seven and five items.

For the validation in comparison to the gold standard, the sample included 99 individuals and most of them (69=69.7%) were patients and students of the Dental Faculty at the UFRN. The remaining individuals (30=30.3%) were patients from private dental practice without specific complaint about orofacial pain.

The mean age of the individuals was 39.9 years (±13.14), including 73 (73.7%) women and 26 (26.3%) men. According to the symptoms and RDC/TMD findings, used as a gold standard for TMD diagnosis, 57.6% did not present TMD. Among the TMD patients, 69% presented articular TMD, 11.9% muscular TMD and 19% mixed TMD (muscular and articular).

For the questionnaire with 7 items, Table 1 shows the score range used for statistical measures of sensitivity, specificity, positive and negative predictive value, as well as accuracy

and likelihood ratio. Within the score range, the best result for TMD diagnosis was from 10 to 21, with three answers “sometimes” at least. For no TMD diagnosis, the best result was from 7 to 8, with only one answer “sometimes”, as shown in Table 3.

Table 3. Measures of diagnosis for the questionnaire with 7 items.

Score range	Measures of diagnosis					
	Sensitivity (IC 95%)	Specificity (IC 95%)	Positive predictive value (%)	Negative predictive value (%)	Accuracy (%)	Likelihood ratio
9-21	95 (91-99)	71 (63-79.9)	71	95	81.8	LR+ =3.27 LR- =14.2
10-21	95 (91-99)	87 (81-93)	85	96	90.1	LR+ =7.3 LR- =17.4
11-21	83 (76-90)	89 (83-95)	85	87	86.8	LR+ =7.5 LR- =5.23
12-21	66.6 (57-75)	94 (90-98)	90	79	82.8	LR+ =11.1 LR- =2.82

Measures for the questionnaire QST/TMD with 7 items. All measures were calculated based on TMD diagnosis using RDC, assumed as the gold standard. Source: Authors.

For the questionnaire with 5 items, the score range was also tested on statistical measures of sensitivity, specificity, positive and negative predictive value, as well as accuracy and likelihood ratio (Table 4). Furthermore, the best score range for TMD diagnosis was from 7 to 15, with two answers “sometimes” at least. For no TMD diagnosis, the best score range was from 5 to 6, with only one answer “sometimes”.

Table 4. Measures of diagnosis for the questionnaire with 5 items.

Score range	Measures of diagnosis					
	Sensitivity (IC 95%)	Specificity (IC 95%)	Positive predictive value (%)	Negative predictive value (%)	Accuracy (%)	Likelihood ratio
6-15	100 (-)	59,6 (50-69.2)	64.6	100	76.7	LR+ =2.47 LR- = -
7-15	88 (81.6-94.4)	84 (76.8-91.2)	80	90.5	85.8	LR+ =5.5 LR- =7.0
8-15	71 (62.1-79.9)	92 (86.7-97.3)	88	81.5	83.8	LR+ =8.87 LR- =3.17

Measures for the questionnaire QST/TMD with 5 items. All measures were calculated based on TMD diagnosis using RDC, assumed as the gold standard. Source: Authors.

Considering the effect of some factors on TMD, only gender was a significant influence (p=0.036) and women presented higher frequency of dysfunction.

4. Discussion

The validation process of a simplified questionnaire based on the RDC/TMD (axis II) was possible. The results showed a reproducible and easily applicable instrument for the Brazilian population, being an innovative and standardized method for conducting TMD epidemiological studies.

Considering that the epidemiological and clinical studies of TMD are subject to several errors associated mainly with methodological aspects, it is understood that the evaluation of the consistency and reproducibility of the used instruments is of great importance in order to achieve a correct diagnosis (Campos et al., 2009). Consistency and reproducibility were characteristics found in the questionnaire proposed in the present study.

In the evaluation of the questionnaire with 7 items, assuming the total score of the questions (QST/TMD) in four conditions, the best result for TMD was in the range from 10 to 21 and no TMD was found in the range from 7 to 9. Both conditions were in accordance with the RDC/TMD results. For the QST/TMD with only 5 items, the best range was from 7 to 15, also in accordance with the RDC/TMD results (gold standard).

In the present study, although the questionnaire with 7 items has presented better

results for a diagnostic study, its psychometric properties were not as satisfactory as in the questionnaire with 5 items. The questionnaire with 5 items properly identifies the truly positive and negative. The most important feature in screening and population diagnostic studies is the accurate identification of patients presenting real TMD and exclusion of those patients without dysfunction. The questionnaire with only 5 items also presented reliability and reproducibility when compared to the gold standard.

The development of a simplified questionnaire with fewer questions aims to avoid overlap of items and false-positive results causing overtreatment. In addition, its simplification spreads the use of QST/TMD as a safe and practical tool for TMD diagnosis in dental clinics and epidemiological studies.

Some simplified diagnostic instruments have been proposed in the literature. However, these questionnaires had 10 or more questions or excluded the possibility of diagnosing TMD through disc displacement (Fonseca et al., 1994; Araújo et al., 2010). The index suggested by Fonseca with 10 questions is interesting for epidemiological studies because of its simplicity, quickness, low cost and possibility of phone screening (Fonseca et al., 1994). However, this study suggests a reduction in the number of questions to 5 (1 – pain or difficulty during mouth opening; 2 – mandible locking during mouth opening or closing; 3 – earache or pain surrounding the ears; 4 – pain on forehead or laterally; and 5 – pain on cheek region) in order to make it simple and faster (Campos et al., 2009; DeLeeuw, 2010).

The literature suggests a simplified questionnaire for screening of patients with TMD-related orofacial pain with only 4 items (1 – pain on cheek region; 2 – pain on head lateral region; 3 – pain during wide mouth opening; and 4 – mandible tired or painful during chewing) (Araújo et al., 2010). The authors highlighted that two questions are related to pain location and the other two are related to mandibular function-related pain, as recommended by the AAOP (Araújo et al., 2010). It was found similarity comparing the 5 items tested in the present study with those from the previous research. In addition, the question about mandibular locking in the QST/TMD provides wider screening since mandibular locking is a frequent symptom for intra-articular dysfunction type disc displacement with reduction (DDwR) and periodical locking. When locking occurs, mandibular opening and/or closing becomes difficult. It is noteworthy that it is difficult to accurately diagnose the intra-articular dysfunctions using the RDC/TMD (Manfredini et al., 2012). In addition, the segments described as “cheek region” and “head lateral region” were more appropriate for identification of TMD and also observed in the present study (Araújo et al., 2010).

The developed questionnaire allows its application in a simple way by clinicians,

researchers and other health professionals. Consequently, this instrument has an important clinical relevance. Clinicians, clinic secretaries and dental assistants can apply the questionnaire. In addition, the instrument allows a simple and fast diagnosis. Another important advantage is the accuracy of the instrument. The questions direct to identify problems related to TMD.

5. Conclusion

The simplified questionnaire validated in this study (QST/TMD) is in accordance with the gold standard (RDC/TMD). The simplicity of this questionnaire with only 5 items allows its use as an initial screening tool on orofacial pain and temporomandibular dysfunction, providing appropriate understanding and application in epidemiological studies.

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Percentage of contribution of each author in the manuscript

Angela Maria Fernandes Vieira de Paiva – 50%

Laércio Almeida de Melo – 10%

Erika Oliveira de Almeida – 10%

Helson José de Paiva – 10%

Kenio Costa de Lima – 20%