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Translation and Cross-cultural Adaptation of the "Thumb Disability Exam - TDX" questionnaire into Brazilian Portuguese^{*}

Tradução e adaptação cultural do questionário "Thumb Disability Exam – TDX" para o português brasileiro

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 Abstract Keywords ► osteoarthritis ► surveys and questionnaires ► translation ► carpometacarpal joints ► reproducibility of tests 	Objective To perform the translation, cultural adaptation and validation of the Thumb Disability Exam (TDX) questionnaire into Brazilian Portuguese. Method The questionnaire was translated, with reverse translation. The translations were evaluated and synthesized by a committee, resulting in the THUMB DISABILITY EXAM - BRASIL (TDX-BR). A total of 31 patients diagnosed with rhizarthrosis were selected and answered the questionnaire. Quality parameters were evaluated, such as internal consistency, reproducibility and ceiling and floor effect. Results The questionnaires were translated and adapted according to defined protocols. Internal consistency, through the Cronbach α coefficient for the TDX-BR, was 0.962. The reliability of the questionnaire, through intraclass correlation coefficient (ICC)also proved to be quite high, with $\kappa = 0.953$ (0.947–0.959). Agreement, measured using the standard error of measurement, remained with standard values < 5%. There was no ceiling and floor effect. Conclusion Through specific methodology, we consider TDX-BR as translated and valid for the Portuguese language of Brazil.
Resumo	Objetivo Realizar a tradução, adaptação cultural e validação do questionário Thumb Disability Exam (TDX) para o português brasileiro.

Work developed at the Department of Orthopedics and Traumatology, Escola Paulista de Medicina, Universidade Federal de, São Paulo, São Paulo, SP, Brazil.

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Método O questionário foi traduzido, com tradução reversa. As traduções foram avaliadas e sintetizadas por um comitê, chegando ao THUMB DISABILITY EXAM - BRASIL (TDX-BR). Foram selecionados 31 pacientes com diagnóstico de rizartrose que responderam ao questionário. Foram avaliados parâmetros de qualidade, como consistência interna, reprodutibilidade e efeito teto e piso.

Resultados Os questionários foram traduzidos e adaptados conforme protocolos

Palavras-chave

- osteoartrite
- inquéritos e questionários
- ► tradução
- articulações carpometacarpais
- reprodutibilidade dos testes

definidos. A consistência interna, através do coeficiente α de Cronbach para o TDX-BR foi de 0,962. A confiabilidade do questionário, através do coeficiente de correlação intraclasse (CCI) também se mostrou bastante elevada, com $\kappa = 0,953$ (0,947–0,959). A concordância, medida através do erro padrão de medição manteve-se com valores padronizados < 5%. Não houve efeito teto e piso.

de dos **Conclusão** Através de metodologia específica, consideramos o TDX-BR como traduzido e válido para a língua portuguesa do Brasil.

Introduction

Arthrosis of the carpometacarpal joint of the thumb, or rhizarthrosis, is a highly prevalent disease affecting 33% of postmenopausal women and 8 to 12% of the general population. There is a progressive increase in the condition with population aging, reaching a prevalence of 40% in people > 80 years old.¹ It is a potentially limiting disease, which leads to pain in the thumb and reduces the quality of life and independence for work, leisure and daily activities.^{2,3}

Diagnosis is based on clinical signs and symptoms associated with radiographic examination.^{3,4} This condition consists of swelling at the base of the thumb, angular deviation and crackling associated with progressive pain and limited pinching activities. However, the symptoms are often vague and nonspecific.³

Radiographic findings consist of progressive degenerative changes in the carpometacarpal joint of the thumb. Eaton et al. classified this condition through radiographic images of the front and profile of the carpometacarpal joint of the thumb, dividing it into 4 progressive stages.⁴ The Eaton et al. classification, although widely used, ^{5–8} is criticized for its low intra-observer and interobserver reproducibility and for not always corresponding to the symptoms of the patient. Thus, the treatment strategy is often guided subjectively through the perception of limitation by the patient or doctor.^{5,9}

Questionnaires are widely used to systematize and score specific characteristics of each disease. These can categorize subjective variables and thus better guide which stage of clinical limitation each patient is in. They are used for diagnosis or evaluation of clinical evolution after medical care.¹⁰ The Disabilities of the Arm, Shoulder and Hand (DASH) score, as an example, has more than six thousand citations, showing the relevance of the instrument mainly in the comparison of outcomes. However, specific questionnaires are rare in the evaluation of rhizarthrosis, and no questionnaires were found in Portuguese.^{10,11}

Obviously, adaptation to the language of the country where each questionnaire should be applied is essential. The aim of our work is to translate and carry out the cultural adaptation and validation of the Thumb Disability Examination (TDX) questionnaire for the Portuguese language of Brazil. This method is widely used in the literature, as in the DASH score, translated and adapted in 2005.¹²

Materials and Method

The research project was sent to the research ethics committee, being approved in March 2018 (CAAE - 80666617.4.0000.5505). Our work was authorized by the researchers responsible for the original questionnaire.

Noback et al.¹⁰ proposed a specific questionnaire for rhizarthrosis, the TDX, in order to improve accuracy when comparing therapeutic outcomes.^{10,11} The questionnaire evaluates activities performed by patients in the last week and the 20 items are divided into 3 subdivisions, all graded in 5 degrees (following the Likert Scale)¹⁰:

(I) Function assessment (11 items) - ranging from normal function (1 point), to complete dysfunction (5 points).
(II) Pain level (5 items) - considering the absence of pain (1 point) until continuous pain (5 points).

(III) Satisfaction assessment in global hand and thumb characteristics (4 items) - ranging from a lot of dissatisfaction (1 point) to a lot of satisfaction (5 points).

The results obtained are transformed into a variable between 0 and 100, following the formula: *Score* = $\left(\frac{N}{Q-B}-1\right)*25$, where N is the total sum, Q is the number of total questions and B the number of guestions left blank.

The guideline described by Beaton et al. was used¹³ as a guide for the entire translation and adaptation process. First, the original questionnaire was translated into Portuguese by two translators who have Portuguese as their native language, and the two translations were compared and synthesized. Then the reverse translation was done by two native English-speaking translators who did not know the original version, and these two new translations were compared with the original versions. Thus, through a committee of experts, composed of an orthopedist, a specialist English teacher, a physiotherapist, in addition to the two main researchers, the discrepancies were resolved, reaching a prefinal version. Thus, validation was performed

with 31 previously selected patients with a previous diagnosis of rhizarthrosis, the understanding of this prefinal version was evaluated and any changes that the committee deemed necessary to improve the understanding of the target audience were made. Lastly, a Portuguese version was created, the TDX-BR.

A test was carried out, and a retest was applied after 2 to 4 weeks, by e-mail or telephone contact. The questionnaire validation process was performed with the calculation of the psychometric variables. The internal consistency, a measure of the homogeneous relationship of the questionnaire items, was calculated using the Cronbach α coefficient of each of the items, with $\alpha \ge 0.70$, as described by Norman et al.¹⁴ Reliability was assessed using the intraclass correlation coefficient (ICC) obtained through testing and retesting. We used the correlation classification scale according to Landis et al.,¹⁵ through the Cohen kappa coefficient, κ , in which there is variation of -1 to 1, with 1 meaning total agreement, -1 meaning total disagreement and zero meaning randomness. Agreement was assessed using the standard error of measurement (SEM), which reflects the intrinsic error of the instrument. Standard error of measurement is calculated as the standard deviation (SD) of the differences between the scores of the 2 test and retest sessions, divided by the square root of 2.16 The ceiling and floor effect was considered when > 15% of the interviewees reached the maximum or minimum score.¹⁶

Results

After the last stage, the final version was configured and the TDX-BR was arranged in two pages, front and back, in a multiple-choice system, with vertical configuration (\succ Figures 1 and 2). It maintained a total of 20 questions, divided into 3 subdivisions.

Of the 31 patients, 83.9% were women, with a mean age of 63 years old. The results of the psychometric variables evaluated are in **-Table 1**.

Discussion

Rhizarthrosis is a disease of high prevalence and of multidisciplinary interest among rheumatologists, geriatricians, physiotherapists, and orthopedists. It is the most frequently reported form of clinically impacting arthritis in the hand, and the arthritic condition of the upper extremity most frequently treated surgically.¹⁰

From the description of the Eaton stages, which were later adapted by Eaton et al.,⁴ surgeons have been guiding their treatment indications from the radiographic stages. However, we have seen that such a classification often does not reproduce symptoms and limitations, in addition to having weak or moderate reproducibility criteria.^{5,7,8,10,17,18}

The diagnosis of the disease is simple, based on a characteristic clinical picture, associated with imaging exams.⁴ However, ease of diagnosis is not reflected in therapy. The criteria for deciding between nonsurgical therapies or surgical procedures are quite subjective. Such factors make rhizarthrosis a challenge for hand surgeons.^{17,18}

The key issue in the management of any disease is the definition of the best indication for each type of treatment. The questionnaires in clinical practice aim to stratify each case according to the stage of the evolution of the disease, and thus be able to guide the best treatment. A self-administered questionnaire specific to rhizarthrosis is a simple and inexpensive way to, based on the patient's own reports, make it possible to classify the severity of the dysfunction in question and evaluate treatment outcomes in a homogeneous way.¹⁰ Several guidelines are created in order to standardize clinical studies with the primary aim of being able to compare results after conclusions.¹⁹ What we see in the literature is that there is no standardization for rhizarthrosis. Diverse systematic reviews demonstrate inconsistent results that make the authors conclude that there are no differences in outcomes.^{2,17,18}

The aim of our work was to provide an efficient method of evaluating outcomes in rhizarthrosis in the Portuguese language. During the literature review, the TDX questionnaire was considered of good methodological quality. Fernandes et al.²⁰ have already shown that the translation and cultural adaptation of questionnaires is an efficient way for evaluation and comparison for multicenter studies. Translation and adaptation methods are widely described and used in the literature.^{12,13,20-22}

Due to its greater diffusion in the literature, the guideline described by Beaton et al.¹³ was used as a guide for the entire process of translation and adaptation, also following the consensus-based standards for the selection of health status measurement instruments (COSMIN) guidelines.²³

In the original questionnaire, the pagination of the questionnaire was presented in a horizontal model, in which each question corresponded to the answers in a line, in a single table. The multiple-choice longitudinal model for pagination was chosen, as previously proposed by Matsuo et al.²⁴

Only three patients reported that they would add or change items in the questionnaires. Thus, after discussion by the expert committee, it was decided not to change the items already described, nor to add or extinguish any of them. All items were considered to have a correlation of interpretation and semantics with the language of the original questionnaires. No patient left > 2 items blank, keeping within the standard tolerated by TDX (up to 10% of the 20 questions). If there was no complete understanding of at least 10% of patients, the prefinal version (PF1) should be changed. As this did not happen, since only 2 patients (6.5%) did not have a complete understanding, we consider the version PF1 as the final version (F1), considering the process of translation and cultural adaptation complete.²³

The data obtained were then used to perform statistical calculations to validate and assess the reliability of the measurement instrument, translated, and adapted.

Through the Cronbach α coefficient, internal consistency was assessed. The result was considered adequate, with $\alpha =$ 0.962. Internal consistency is an important measurement property for questionnaires that intend to measure a single concept using several items, or even assessing it in subdivisions. In our assessment, when separated into subdivisions of "function", "pain level" and "overall satisfaction", all α values

7. Use a knife to cut food (which is on TDX: This test assesses the function of your the plate) thumbs during the past week. Please answer 1. NO DIFFICULTIES ALL questions. If you have not done any of 2. SOME DIFFICULTY the activities, please make your best estimate 3. MODERATE DIFFICULTY of how much you could do. 4. STRONG DIFFICULTY 5. UNABLE TO PERFORM Please indicate your ability to perform the following tasks with Please indicate how difficult it is to the sick hand: carry out the following tasks with both hands: 1. Turn the key (of a door) 1. NO DIFFICULTIES 2. SOME DIFFICULTY 1. Open a bottle or jar with a 3. MODERATE DIFFICULTY tight or new screw cap 4. STRONG DIFFICULTY 1. NO DIFFICULTIES 5. UNABLE TO PERFORM 2. SOME DIFFICULTY 3. MODERATE DIFFICULTY 2. Pick up a coin with your fingertips 4. STRONG DIFFICULTY 5. UNABLE TO PERFORM 1. NO DIFFICULTIES 2. SOME DIFFICULTY 3. MODERATE DIFFICULTY 2. Buttoning a shirt/blouse 4. STRONG DIFFICULTY button 5. UNABLE TO PERFORM 1. NO DIFFICULTIES 2. SOME DIFFICULTY 3. Write 3. MODERATE DIFFICULTY 1. NO DIFFICULTIES 4. STRONG DIFFICULTY 2. SOME DIFFICULTY 5. UNABLE TO PERFORM 3. MODERATE DIFFICULTY 4. STRONG DIFFICULTY 5. UNABLE TO PERFORM 3. Tie your shoelaces 1. NO DIFFICULTIES 4. Squeeze the toothpaste 2. SOME DIFFICULTY 1. NO DIFFICULTIES 3. MODERATE DIFFICULTY 2. SOME DIFFICULTY 4. STRONG DIFFICULTY 3. MODERATE DIFFICULTY 5. UNABLE TO PERFORM 4. STRONG DIFFICULTY 5. UNABLE TO PERFORM 4. Wring clothes or cloths 5. Holding a glass of water 1. NO DIFFICULTIES 1. NO DIFFICULTIES 2. SOME DIFFICULTY 2. SOME DIFFICULTY 3. MODERATE DIFFICULTY 3. MODERATE DIFFICULTY 4. STRONG DIFFICULTY 4. STRONG DIFFICULTY 5. UNABLE TO PERFORM 5. UNABLE TO PERFORM 6. Rotate the round (ball-type) door handle 1. NO DIFFICULTIES 2. SOME DIFFICULTY 3. MODERATE DIFFICULTY 4. STRONG DIFFICULTY 5. UNABLE TO PERFORM

Fig. 1 Translated and adapted TDX-BR questionnaire, part 1.

remained > 0.70. These subdivisions are the most important clinical factors for defining the treatment of rhizarthrosis. The original questionnaire showed value for internal consistency with $\alpha > 0.79$.¹⁰

No ceiling or floor effect was found in the questionnaire or in the subdivisions. The number of questions and the presence of many alternatives reduce the possibility of this effect. The TDX-BR, with 20 questions and 5 alternatives in each question, leads to many possible answers, considerably reducing this effect. In the original questionnaire, a different parameter than ours was used, with 0-10 (floor) and 90-100 (ceiling) results being considered as ceiling and floor effect. Thus, there was a ceiling effect in only one subdivision, which evaluates patient satisfaction, with 13.2% of patients with scores > 90. However, Terwee et al.¹⁶ consider the ceiling effect as > 15% of patients resulting in the maximum score.^{10,16,25}

The results demonstrated high reproducibility. Values of the ICC > 0.61 are considered as good correlation.²⁶ In our study, these values varied between $\kappa = 0.940$ and $\kappa = 0.968$. These values denote a high correlation between the test and



Fig. 2 Questionnaire translated and adapted TDX-BR, part 2.

the retest, proving the questionnaire to be reliable in reproducing the symptoms. The interval of 2 to 4 weeks between the test and the retest is considered sufficient, so that there is no change in symptoms or disease progression, and also so that the patient cannot remember the answers he had generated in the previous questionnaire.^{25,27} In the original TDX, the ICC values remained between 0.88 and 0.98. Therefore, we got close results.^{10,16,27} The agreement measured through SEM remained with good values, with SEM < 5% in the TDX and in all its subdivisions. These data demonstrate that the instrument has a low intrinsic error, that is, the "true" scores of each patient do not differ by > 5% from the measured scores.

As demonstrated in the literature, works related to the translation and validation of questionnaires are widely used and widely cited.^{5,10,13,16} In addition, disease-specific

Table 1 Internal consistency (Cronbach α), floor and ceiling effects (percentage ≤ 5 or ≥ 95), reliability (intraclass correlation coefficient) and agreement (standard error of measurement) for the questionnaire TDX-BR, (n = 31)

	Cronbach α	Floor/ Ceiling (%)	ICC– к (CI95%)	(SEM %)
TDX	0.962	6.5% / 0,0%	0.953 (0.947–0.959)	3.68
Function	0.912	2.2% / 0,0%	0.940 (0.929–0.950)	4.64
Pain level	0.922	10.9% / 4.3%	0.968 (0.958–0.975)	3.76
Overall satisfaction	0.919	0.0% / 6.5%	0.963 (0.951–0.973)	4.43

Abbreviations: ICC, intraclass correlation coefficient; SEM, standard error of measurement.

questionnaires have been shown to be more consistent than comprehensive questionnaires.¹⁰

Conclusion

We consider the TDX questionnaire as translated into the Portuguese language of Brazil. The TDX-BR version is valid. Following a trend in modern literature, we have an objective method, comparable to the original method, which may in the future be used as a standard in research related to rhizarthrosis in Brazil.

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Conflict of Interests

The authors have no conflict of interests to declare.

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