Original Article

Translation and validation of the Portuguese version of a dry eye disease symptom questionnaire

Tradução e validação da versão em português de um questionário para sintomas de olho seco

Julia Silvestre de Castro[1], Iara Borin Selegatto[1], Rosane Silvestre de Castro[2], José Paulo Cabral de Vasconcelos[2], Carlos Eduardo Leite Arieta[2], Mônica Alves[2]

ABSTRACT

Purposes: A symptom questionnaire is an important tool used to quantify and qualify the impact of a disease on a patient's related quality of life and to estimate the prevalence of a certain condition within a population. Ophthalmologists frequently encounter patients with dry eye disease (DED), and therefore, evaluating the symptoms reported by these patients influences diagnosis, therapeutic monitoring, and evaluations of disease progression. The latest consensus on dry eye (Dry Eye Workshop, DEWS), published in 2007, led to the standardization of several questionnaires and a better understanding of the prevalence, severity, and overall effect of DED on the patient's quality of life.

Methods: In this study, we translated into Portuguese a symptom questionnaire from DEWS that has already been used in several other population-based studies. For subsequent validation, the translated questionnaire was applied by two independent observers to a population of 30 subjects, and the results were compared in a concordance analysis.

Results: The processes of translating to Portuguese and back translating the dry eye symptom questionnaire were conducted without difficulty. The high-correlation coefficients obtained when comparing the results of the initial application and the re-administration of this questionnaire to a sample of 30 individuals indicated excellent concordance with regard to results, repeatability, and reliability.

Conclusions: This translated and validated questionnaire can be applied to a larger population with the intent to determine the prevalence of DED symptoms in the overall Brazilian population, as well as in distinct regions of the country.

Keywords: Dry eye syndromes/diagnosis; Diagnostic techniques, ophthalmological; Sickness impact profile; Surveys and questionnaires; Symptom assessment

RESUMO

Objetivos: A aplicação de questionários sobre os sintomas é uma forma de quantificar e qualificar o impacto de uma determinada doença na qualidade de vida dos pacientes portadores e ainda de estimar a prevalência de uma determinada condição na população estudada. O olho seco é uma condição ocular muito prevalente na prática oftalmológica e a avaliação dos sintomas reportados pelos pacientes é uma importante ferramenta propedêutica e de acompanhamento terapêutico e evolução da doença. De acordo com o último consenso sobre olho seco (Dry Eye Worshop, DEWS) publicado em 2007, diversos questionários foram padronizados e tem sido utilizados para o melhor entendimento sobre a prevalência, gravidade e impacto na qualidade de vida dos pacientes.

Métodos: Foi realizada a tradução para o português de um dos questionários de sintomas reportado no DEWS, seguido de sua validação. Trata-se de um questionário de sintomas de olho seco já utilizado em diversos outros estudos populacionais. O questionário traduzido foi aplicado em uma população de 30 indivíduos por dois observadores diferentes e os resultados foram comparados para verificação de concordância.

Resultados: O processo de tradução e contra tradução do questionário de sintomas de olho seco para a língua portuguesa foi realizada sem dificuldades. A análise dos resultados obtidos na aplicação teste e re-teste do questionário em uma amostra de 30 indivíduos apresentou coeficientes de correlação altos demonstrando excelente concordância de resultados, reprodutibilidade e confiabilidade.

Conclusões: A tradução e validação deste questionário permitirá sua aplicação em estudos de prevalência dos sintomas de olho seco na população brasileira, bem como comparação em diversas regiões do país.

Descritores: Síndromes do olho seco/diagnóstico; Técnicas de diagnóstico oftalmológico; Perfil de impacto da doença; Inquéritos e questionários; Avaliação de sintomas

INTRODUCTION

Dry eye disease (DED), a multifactorial disorder, is among the most prevalent ocular conditions encountered by ophthalmologists. This condition is characterized by changes in the tear composition and volume, as well as the ocular surface integrity, and manifests with a broad range of symptoms and associated risk factors[1]. Symptoms of DED largely affect patients' quality of vision and may therefore have profound effects on daily activities[1,2]. The chronic and heterogeneous nature of DED, with respect to both etiology and clinical presentation, introduces many challenges in terms of patient evaluation[3]. In addition, multiple studies have reported poor correlations between clinical tests and with associated symptoms related to the severity and progression of the disease[4,5].

Surveys are an important tool used in health-related research, as well as research pertaining to other fields, such as human and social sciences. For example, symptom questionnaires have been increasingly implemented to assess the quality of life related to a specific disease, quantify symptoms, evaluate natural disease courses, and

determine the impacts of treatment strategies. The widespread use of validated questionnaires in distinct populations warrants translated and language-adapted versions. To expedite this task, many translation guidelines have been published in an attempt to ensure equivalence between the original and translated versions[6,7].

As DED can occur without major clinical signs of tissue damage, it is considered to be a symptom-based condition, especially in mild to moderate cases. The prevalence of DED varies considerably among different populations, and a complete understanding of the global and South American prevalence is lacking[8-13]. Hence, validated questionnaires that fully investigate and refine patients' reports of DED symptoms are important for the objective measurement of symptoms and the evaluation of general prevalence in population-based studies[14].

In this study, we aimed to validate the Portuguese language version of a simple, comprehensive and patient-reported dry eye symptom questionnaire. This short questionnaire comprises of two direct questions regarding DED symptoms and a third question concerning a previous clinical diagnosis of DED. According to previous studies, this questionnaire has been applied to various populations and has yielded a sensitivity of 77% and specificity of 83% for clinical DED diagnosis, using a Schirmer 1 value cutoff point of ≤10 mm or tear breakup time <10 seconds[15]. In other words, this short DED questionnaire is sensitive, repeatable, and easily administered in large epidemiologic studies, as well as during clinical research[11,12,16,17]. We hope that our validated Portuguese language version will facilitate a better understanding of the prevalence of DED symptoms in the Brazilian population.

METHODS

This study was conducted in the Department of Ophthalmology at the University of Campinas, after receiving approval from the Faculty of Heath Sciences Ethics Committee. To obtain a scientifically accurate translation and transcultural validation of the original English version of the questionnaire into the target Portuguese language version, we followed a three-phase process initially proposed by Beaton and Gjersing[6,7]. First, the initial translation and transcultural adaptation of the English version to the Portuguese language was performed by two independent translators, followed by an interdisciplinary panel evaluation of the translated version. Second, the Portuguese version was back translated into English by two independent native speakers, followed by evaluation and comparison with the original English version by the same interdisciplinary panel. Third, the final version of the questionnaire was applied to a selected population to verify inter- and intra-observer concordance. Our validation process, listed below, was based on the above guidelines. We ensured that the following tasks were completed:

1. Two native Portuguese speakers translated the original English language version of the questionnaire to the Portuguese language.
2. An interdisciplinary committee, comprising two ophthalmologists (a general ophthalmologist and dry eye specialist), two residents, and one medical student, evaluated both the English and Portuguese language versions to ensure an adequate translation and transcultural adaptation without altering the applicability of the questionnaire.
3. Two native English speakers back translated the final questionnaire after committee approval.
4. The interdisciplinary committee revaluated the back translated document via comparison with the original version.
5. Two independent observers applied the Portuguese language questionnaire to a sample of 30 persons at distinct time points separated by an interval of two days. Participants included volunteers from among the hospital staff and medical students.

6. A cohort of 30 subjects who responded to the questionnaires applied by both observers were duly informed about the aims of the study and gave their signed informed consent.
7. Statistical analysis of the responses was used to determine correlations and Kappa agreement values. Here, the minimum and maximum agreement scores were 0 and 1, respectively. Interclass correlation coefficients (ICC) values were classified as follows: <0.4, good; 0.4-0.59, moderate; 0.6-0.79, substantial; and >0.8, excellent. The values observed for each response are described in tables 1 and 2.

Kappa coefficients were calculated by evaluating the agreement between responses to each question at two distinct times of application. Continuous variables were compared using the Mann-Whitney U test, categorical variables were assessed using the chi-square test, and correlations were determined using Spearman correlation coefficients. Differences were considered significant at p<0.05. All analyses were performed using Prism statistics software, version 5.0 (GraphPad, Inc., San Diego, CA, USA). The study design is summarized in figure 1.

The selected DED symptom questionnaire included two questions about symptoms: How often do your eyes feel dry? And how often do your eyes feel irritated? Regarding the incidence of symptoms, scores of 0, 1, 2, and 3 indicated never, sometimes, often, and constantly, respectively. DED symptoms were classified as absent if "never" was the response to both questions, and mild, moderate, or severe if "sometimes", "often" or "constantly" was marked as a response, respectively, as previously described[15]. A third yes or no question addressed previous DED diagnoses: Have you ever been diagnosed (by a clinician) as having dry eye syndrome? (Figure 2).

RESULTS

The Portuguese version of this DED symptom questionnaire was applied twice by two different observers to a population comprising 30 medical students (mean age, 22.93 ± 2.81 years). No difficulties emerged during the translation and adaptation steps because the questionnaire comprised simple and direct queries. Similarly, the remaining steps of the process did not raise any controversies. The overall results are presented in table 1 and table 2. The correlation coefficient values were consistently high and statistically significant for all three items: 0.92 for dry eye symptoms; 0.90 for irritation; and 1.0 for previous diagnosis of dry eye (Table 1). The Kappa concordance values exceeded 0.79, indicating substantial to excellent concordance (Table 2).

Table 1. Descriptive statistics and internal consistency of the Portuguese version of the dry eye disease (DED) symptom questionnaire

Sample (n=30)	Total score (Mann-Whitney)	Correlation coefficients (Spearman)
Question 1: dry eye symptom	0.87 ± 0.85*	0.92*
Question 2: irritation symptom	1.17 ± 0.75*	0.90*
Question 3: previous DED diagnosis	1/29 (3.3%)*	1.00*

*= P<0.0001.

Table 2. Analysis of inter-observer agreement regarding the Portuguese version of the dry eye disease (DED) symptom questionnaire

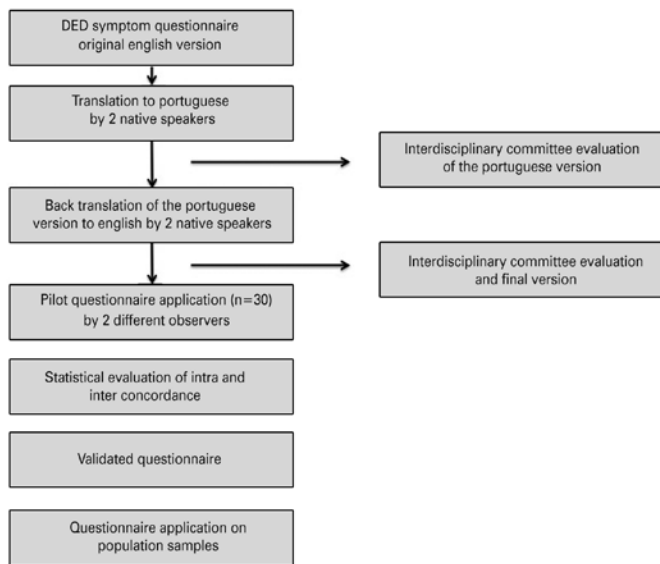| Sample (n=30)	Kappa value	P value
Question 1: dry eye symptom	0.84	<0.0001
Question 2: irritation symptom	0.79	<0.0001
Question 3: previous DED diagnosis	1.00	<0.0001

Figure 1. Study design.

Figure 2. Original English and Portuguese versions of the symptom questionnaire.

DISCUSSION

Despite the frequent incidence of DED, its prevalence in the Brazilian population is poorly understood. The present study indicates that the Portuguese translation and adaptation of this DED symptom questionnaire yielded a reliable tool, as evidenced by the high internal consistency of the answers obtained and the high correlation coefficients. To develop this tool, we followed guidelines used pre-

viously in similar endeavors, including a scientifically rigorous translation and adaptation process. Although the chosen questionnaire comprised simple and direct questions, the use of two independent translators for each language translation was very useful because it allowed the multidisciplinary assessment panel to validate the questionnaire through comparisons and discussion. The inclusion of members with distinct areas of expertise in this assessment panel was crucial as it allowed comparisons from different points of view and solved discrepancies with the aims of consensus and proper adaptation. Accordingly, our results demonstrate that this validated questionnaire is both reliable and reproducible and can be applied in future population-based studies to determine the prevalence of DED symptoms.

In conclusion, there remains a significant lack of knowledge about the current prevalence of DED in Brazil and the distinct regions within this very large country. This simple questionnaire appears to be a feasible, powerful instrument that will contribute epidemiological information about this common ocular condition on both local and more widespread levels.

REFERENCES

1. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf. 2007; 5(2):75-92.
2. Research in dry eye: report of the Research Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf. 2007;5(2):179-93.
3. Methodologies to diagnose and monitor dry eye disease: report of the Diagnostic Methodology Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf. 2007;5(2):108-52.
4. Alves M, Reinach PS, Paula JS, Vellasco e Cruz AA, Bachette L, Faustino J, et al. Comparison of diagnostic tests in distinct well-defined conditions related to dry eye disease. PloS One. 2014;9(5):e97921.
5. Design and conduct of clinical trials: report of the Clinical Trials Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf. 2007;5(2):153-62.
6. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 2000;25(24):3186-91.
7. Gjersing L, Caplehorn JR, Clausen T. Cross-cultural adaptation of research instruments: language, setting, time and statistical considerations. BMC Med Res Methodol. 2010;10:13.
8. Amparo F, Schaumberg DA, Dana R. Comparison of Two Questionnaires for Dry Eye Symptom Assessment: The Ocular Surface Disease Index and the Symptom Assessment in Dry Eye. Ophthalmology. 2015;122(7):1498-503.
9. Lienert JP, Tarko L, Uchino M, Christen WG, Schaumberg DA. Long-term natural history of dry eye disease from the patient's perspective. Ophthalmology. 2016;123(2):425-33.
10. Chia EM, Mitchell P, Rochtchina E, Lee AJ, Maroun R, Wang JJ. Prevalence and associations of dry eye syndrome in an older population: the Blue Mountains Eye Study. Clin Exp Ophthalmol. 2003;31(3):229-32.
11. Uchino M, Nishiwaki Y, Michikawa T, Shirakawa K, Kuwahara E, Yamada M, et al. Prevalence and risk factors of dry eye disease in Japan: Koumi study. Ophthalmology. 2011;118(12):2361-7.
12. Uchino M, Yokoi N, Uchino Y, Dogru M, Kawashima M, Komuro A, et al. Prevalence of dry eye disease and its risk factors in visual display terminal users: the Osaka study. Am J Ophthalmol. 2013;156(4):759-66.
13. Na KS, Han K, Park YG, Na C, Joo CK. Depression, stress, quality of life, and dry eye disease in korean women: a population-based study. Cornea. 2015;34(7):733-8.
14. The epidemiology of dry eye disease: report of the Epidemiology Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf. 2007;5(2):93-107.
15. Gulati A, Sullivan R, Buring JE, Sullivan DA, Dana R, Schaumberg DA. Validation and repeatability of a short questionnaire for dry eye syndrome. Am J Ophthalmol. 2006; 142(1):125-31.
16. Schaumberg DA, Dana R, Buring JE, Sullivan DA. Prevalence of dry eye disease among US men: estimates from the physicians' health studies. Arch Ophthalmol. 2009;127(6): 763-8.
17. Uchino M, Schaumberg DA, Dogru M, Uchino Y, Fukagawa K, Shimmura S, et al. Prevalence of dry eye disease among Japanese visual display terminal users. Ophthalmology. 2008;115(11):1982-8.