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Enhancing the cross-cultural adaptation and validation process: linguistic and psychometric testing of the Brazilian–Portuguese version of a self-report measure for dry eye

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Abstract

Objectives: To provide a reliable, validated, and culturally adapted instrument that may be used in monitoring dry eye in Brazilian patients and to discuss the strategies for the enhancement of the cross-cultural adaptation and validation process of a self-report measure for dry eye.

Methods: The cross-cultural adaptation process (CCAP) of the original Ocular Surface Disease Index (OSDI) into Brazilian–Portuguese was conducted using a 9-step guideline. The synthesis of translations was tested twice, for face and content validity, by different subjects (focus groups and cognitive interviews). The expert committee contributed on several steps, and back translations were based on the final rather than the prefinal version. For validation, the adapted version was applied in a prospective longitudinal study to 101 patients from the Dry Eye Clinic at the General Hospital of the University of São Paulo, Brazil. Simultaneously to the OSDI, patients answered the short form-36 health survey (SF-36) and the 25-item visual function questionnaire (VFQ-25) and underwent clinical evaluation. Internal consistency, test–retest reliability, and measure validity were assessed.

Results: Cronbach's alpha value of the cross-culturally adapted Brazilian–Portuguese version of the OSDI was 0.905, and the intraclass correlation coefficient was 0.801. There was a statistically significant difference between OSDI scores in patients with dry eye (41.15 ± 27.40) and without dry eye (17.88 ± 17.09). There was a negative association between OSDI and VFQ-25 total score ($P < 0.01$) and between the OSDI and five SF-36 domains. OSDI scores correlated positively with lissamine green and fluorescein staining scores ($P < 0.001$) and negatively with Schirmer test I and tear break-up time values ($P < 0.001$).

Conclusion: Although most of the reviewed guidelines on CCAP involve well-defined steps (translation, synthesis/reconciliation, back translation, expert committee review, pretesting), the proposed methodological steps have not been applied in a uniform way. The translation and adaptation process requires skill, knowledge, experience, and a considerable investment of time to maximize the attainment of semantic, idiomatic, experiential, and conceptual equivalence between the source and target questionnaires. A well-established guideline resulted in a culturally adapted Brazilian–Portuguese version of the OSDI, tested and validated on a sample of Brazilian population, and proved to be a valid and reliable instrument for assessing patients with dry eye syndrome in Brazil.

Keywords: Questionnaires; Self-report measure; Ocular Surface Disease Index; Cross-cultural adaptation; Validation studies; Translation; Dry eye

1. Introduction

Dry eye is a highly prevalent condition all over the world, which progressively impairs the patients' quality of life, as symptoms increase. Thus, symptom questionnaires are among the most repeatable of the commonly used diagnostic tests. The Report of the International Dry Eye Work Shop (DEWS), in 2007, selected fourteen questionnaires as dry eye symptom and quality-of-life instruments [1]. One of them, the Ocular Surface Disease Index (OSDI), is a patient-reported outcomes (PROs) questionnaire designed to provide a rapid assessment of symptoms of ocular irritation consistent with dry eye disease and their impact on vision-related functioning, developed by The Outcomes Research Group at Allergan Inc. (Irvine,

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What is new?

Key findings

- Lack of cultural adapted, valid, and suitable Brazilian–Portuguese version of self-report measure for dry eye and their impact on vision-related quality of life.

What this adds to what was known?

- An enhanced process for the cross-cultural adaptation of a self-report measure and a suggested 9-step guideline.

What is the implication and what should change now?

- A reliable, validated, and culturally adapted instrument that may be used in monitoring dry eye in Brazilian patients, especially in clinical trials testing efficacy of treatments to manage this condition and as tool that enables international comparative studies.

CA, USA) [2]. Schiffman et al. [3] tested the OSDI for validity, reliability, and reproducibility. The goals of the OSDI are to make the diagnosis of ocular surface disease easier and quicker and to provide evidence of differences in ocular disability due to dry eye disease [4].

Therefore, to better diagnose and monitor patients with dry eye, the use of a questionnaire to assess this condition that is cross-culturally adapted and validated for the target population is essential. The OSDI was translated and validated into French, German, Swedish, and UK English [5], and numerous studies have used this questionnaire to assess dry eye patients [4,6–9]. At this time, translated versions of the OSDI are available in 20 countries but not all of them have undergone a full linguistic validation process [10].

The objective of this study was to describe the cross-cultural adaptation process (CCAP) and validation of the Brazilian–Portuguese OSDI version providing a cross-culturally adapted, validated, and suitable questionnaire to assess dry eye and their impact on vision-related quality of life, especially in clinical trials testing efficacy of treatments to manage this condition in Brazilian patients.

2. Patients and methods

2.1. Participants

The Ethics Committee of the General Hospital of the University of São Paulo, School of Medicine (HCFMUSP), São Paulo, Brazil, approved the study, and all subjects signed an informed consent form before being enrolled in this study.

A total of 26 patients from the Dry Eye Clinic of the Department of Ophthalmology of HCFMUSP were enrolled for the pilot test during the cross-cultural adaptation phase of the OSDI (phase1). For validation process (phase 2), 101 patients from the Dry Eye Clinic were randomly recruited.

2.2. The Ocular Surface Disease Index

The OSDI is a 12-item PRO questionnaire designed to provide a rapid assessment of the range of ocular surface symptoms related to chronic dry eye, their severity, and their effect on the patient's ability to function. The OSDI is a valid and reliable instrument, and it possesses the necessary psychometric properties to be used as an end point in clinical trials [3]. The OSDI has an overall score and three scale's scores: ocular symptoms (items 1, 2, 3), vision-related function (items 4, 5, 6, 7, 8, 9), and environmental triggers (items 10, 11, 12) [2,3]. Scores may be compared with other outcome measures, such as clinical findings and clinical tests.

2.3. The cross-cultural adaptation process (phase 1)

Anytime a measure is used with a population that differs qualitatively from the one for which it was originally developed, one must check its continued validity and usefulness in the new population [11]. Based on the model described by Herdman et al. [12], Guillemin et al. [13] presented an extensive review in 1993, followed by an update and a more formal presentation in 2000 [14]. The American Association of Orthopedic Surgeons Outcomes Committee currently endorsed these guidelines, which are applied in most studies on the process of cross-cultural adaptation of self-report measures.

The methodology for CCAP is discussed in a companion article [15]. In the present study, we adopted a 9-step guideline, shown in Fig. 1. To identify the concepts to be measured, the first step was to review the publications involving the OSDI and the particularities of CCAP in this setting, which were discussed by an expert committee of cultural adaptation, comprising three ophthalmologists experts in dry eye, one translator, and one health professional in eye care (step 1). Then, translations of the original US English version of the OSDI into Portuguese were performed by two independent translators, native in the target language with good understanding of the original language (one of them with medical background and the other, a naive translator, with no medical background and not aware nor informed of the concepts being examined in the questionnaire) to obtain semantic and idiomatic equivalence (step 2). A synthesis version of these translations was then reviewed by the experts for assessment of conceptual equivalence and was agreed on by consensus (step 3). The synthesis version was applied to three focus groups of five patients of the target population, assessing the