The Ocular Surface 15 (2017) 202–210

Contents lists available at ScienceDirect

The Ocular Surface

journal homepage: www.theocularsurface.com

Rasch analysis of three dry eye questionnaires and correlates with objective clinical tests

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ARTICLE INFO

Article history:
Received 25 September 2016
Received in revised form
22 January 2017
Accepted 22 January 2017

Keywords:
Dry eye
Ocular Comfort Index
Ocular Surface Disease Index
Questionnaires
Rasch analysis

ABSTRACT

Purpose: To assess the psychometric properties of Chinese versions of the Ocular Comfort Index (OCI), Ocular Surface Disease Index (OSDI) and McMonnies questionnaires. Further, to assess the correlation between questionnaire scores and objective dry eye disease (DED) clinical tests.
Methods: Translated versions of the OCI, OSDI and McMonnies questionnaires were completed in a random order by 238 participants with DED. Objective clinical tests included visual acuity (VA), fluorescein tear film break-up time (TBUT), corneal fluorescein staining, Schirmer I testing and meibomian gland grading. Rasch analysis was used to assess questionnaire psychometrics and spearman rank for correlations.
Results: For the OCI, the person separation was 2.31, item infit and outfit statistics ranged from 0.74−1.14 and 0.75−1.32, respectively, and targeting 1.54 logits. For the OSDI, person separation was 0.94. None of the three subscales provided valid measurements based on Rasch analysis. For the McMonnies questionnaire, person separation was 1.17, item infit and outfit statistics ranged from 0.7 to 1.21 and 0.51 −3.49, respectively. There were weak correlations between questionnaire scores and clinical tests. There were weak correlations between OSDI scores and VA, fluorescein TBUT, Schirmer I testing and corneal fluorescein staining. There were weak correlations between McMonnies scores and VA, fluorescein TBUT, Schirmer I testing, and corneal fluorescein staining and meibomian gland grading.
Conclusions: The OCI questionnaire was the only questionnaire that provided valid measurement on the basis of Rasch analysis, although slight multidimensionality was found. There were weak correlations between OCI scores and fluorescein TBUT, Schirmer I testing, and corneal fluorescein staining. Due to this paradoxical disconnect between symptoms and signs and the repeatability of tests, the use of both subjective and objective markers in the clinical management of patients or as endpoints in clinical trials would appear prudent.

1. Introduction

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by inflammation of the ocular surface [1,2]. The disease affects between 5% and 35% of people [3], increasing in prevalence with age. There are two main subtypes of the disease: evaporative and aqueous-deficient dry eye [4]. The lacrimal

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http://dx.doi.org/10.1016/j.jtos.2017.01.005
1542-0124/

functional unit (LFU) consists of the cornea, conjunctiva, lacrimal and meibomian glands and the lacrimal drainage system, connected reflexively by a neural network [5]. The LFU maintains ocular surface homeostasis via regulation of tear flow, hence conserving the tear film and corneal transparency. The failure of the LFU to respond adequately to desiccating stress is a key initiator of dry eye [5,6].

A key challenge in the field of dry eye disease (DED) is adequate assessment of the patient in terms of diagnosis and grading of disease severity. To this end, there are a myriad of tests available. One such includes tear osmolarity testing, which appears to provide the best objective marker for the disease across the various severity levels and subtypes [7,8]. However, this is an expensive test and not routinely used in most clinical practices. More traditional objective testing includes fluorescein tear film breakup time (TBUT), fluorescein corneal staining, Schirmer testing, and meibomian gland dysfunction grading. However, the clinical signs of the disease are poorly correlated with patient symptoms, largely due to reduced surface sensitivity in advanced ocular surface disease [9,10]. Thus, it is important that symptoms are assessed appropriately with valid questionnaires. Examples of questionnaires used in the subjective assessment of dry eye include the Ocular Comfort Index (OCI) [11], the Ocular Surface Disease Index (OSDI) [12], and the McMonnies questionnaire [13].

The OCI is a 12-item instrument which measures ocular surface irritation on a linear interval scale. It was developed and is scored via Rasch analysis. It has demonstrated robust psychometric properties and has also been shown to detect improvement in symptoms of dry eye in individuals before and after treatment [11]. The OSDI was developed to measure the severity of DED; it consists of 12 items and is scored on an ordinal scale in accordance with classic test theory [12]. This form of scoring has a number of disadvantages [14]. In comparison to Rasch analysis, it cannot be presumed that the difficulty of items is comparable and that the difficulty step between each category is constant. Therefore, the scaling may not be linearly related to symptom severity. Further, it is not suited to arithmetic operations and the handling of omitted items is inadequate. The McMonnies questionnaire is used to assess the symptoms of ocular surface disease to aid in the diagnosis of DED. It incorporates epidemiological risk factors, frequency of symptoms of ocular irritation, and sensitivity to environmental triggers [13]. Initial scoring was summed, but later amendments were made to the scoring system [15,16].

The aim of the present study was to assess the psychometric properties of the OCI, OSDI, and McMonnies questionnaire with Rasch analysis. Further, each questionnaire is compared to the objective clinical tests of fluorescein TBUT, corneal staining, Schirmer I testing and meibomian gland dysfunction grading.

2. Methods

2.1. Questionnaires

The OCI was developed using Rasch analysis and introduced in 2007 [11]. The OCI queries the frequency and intensity of six symptoms (*dryness, grittiness, stinging, tiredness, pain* and *itching*) over the past week. Response options are on a 0–6 scale (*never* to *always/severe*). The OSDI was introduced in 1997 by the Outcomes Research Group at Allergan Inc. (Irvine, CA) [12]. Its 12 items are formatted three subscales that assess symptoms, functional limitations, and environmental factors related to DED. There are five response options for the first subscale (*All of the time; Most of the time; Half of the time; Some of the time; None of the time*). The remaining two subscales have an additional response option (Not applicable). The McMonnies questionnaire was introduced in 1986 by McMonnies [13] and also consists of 12 items with variable response options and formatting. The questions incorporate risk factors, frequency of symptoms, and sensitivity to environmental triggers. Items 1, 4–6, 8, and 10–12 have three response options; items 2 and 7 have cumulative response options; and items 3 and 9 have four response options.

2.2. Translations

The OCI and McMonnies instruments were translated from English into Mandarin independently by two ophthalmologists who are proficient in both languages. The two versions were reconciled by a panel of experts to form a second draft. A third translator who was blinded to the original questionnaires then back-translated into English. The panel of experts compared the back-translated version with the original English version to identify any discrepancies. The Mandarin-translated OCI and McMonnies questionnaires were then pilot-studied in 20 patients with DED for comprehension and understanding. Further modifications and revisions to the wording of each item were carried out on the basis of patient feedback to produce the final translated versions. Permission was obtained from Allergan to use their Mandarin version of the OSDI (1995 Allergan, Inc. Irvine. CA, U.S.A. OSDI - China/Mandarin - Version of 22 Sep 15 – Mapi. All Rights Reserved).

2.3. Participants

In total, 238 participants aged 18 years or older with a confirmed diagnosis of DED were recruited from the Eye Hospital of the Wenzhou Medical University, Wenzhou, China. The ordering of questionnaires was randomized prior to commencement of the study, using a random number generation (generating 3 integers [1, 2 and 3] corresponding to each questionnaire), and each subject self-administered the three questionnaires in random order. The approximate time needed to complete the three questionnaires ranged from 3 to 5 min. One trained examiner coordinated this questionnaire completion process for each participant in the same standardized fashion. Exclusion criteria were language barriers to understanding, significant cognitive impairment, significant ocular pathology apart from DED, and best corrected visual acuity worse than 6/9 in either eye. The study was approved by the Review Board of the Eye Hospital of Wenzhou Medical University, and informed consent was obtained from all participants. Research adhered to the tenets of the Declaration of Helsinki.

2.4. Objective measurements

After completion of the questionnaires, all participants underwent specific objective dry eye investigations. First, best corrected logMAR visual acuity was performed in the right eye, then the left eye. Then fluorescein (Fluor Strip Test [TianJin Jingming new technological development Co., Ltd. China]) was instilled in the right eye (a single saline drop was placed on the impregnated tip of the strip, the excess fluid shaken off and the drop instilled on inferior palpebral conjunctiva) and the TBUT was measured followed by fluorescein staining (FL). The fluorescein TBUT was measured three times and the average of the three measurements recorded. Fluorescein was then instilled in the left eye and TBUT was measured followed by FL. The Ora Calibra Fluorescein Staining Scale was used to grade corneal staining. The scale uses a 0 to 4 grading system based on number of punctate dots, where 0 = *none* and 4 = *severe confluent staining* [17]. A 15-min washout period preceded Schirmer I testing, which was performed first in the right eye, then in the left eye. One eye drop of proparacaine hydrochloride (15 ml:75 mg, S.A. Alcon-Couvreur N.V.) was instilled in the