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Web-based longitudinal remote assessment of dry eye symptoms

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ABSTRACT

Purpose: To investigate the feasibility of remote assessment and follow-up of dry eye symptoms using electronic versions of two validated questionnaires.

Methods: We conducted a prospective study of consecutive patients with dry eye disease (DED). Patients were enrolled during a clinical visit and were explained how to respond electronic versions of the Ocular surface Disease Index (OSDI) and the Symptom Assessment in Dry Eye (SANDE) questionnaires using a computer in the presence of investigators. A secure link to both questionnaires was sent to each patient every 2 weeks in order to respond and submit their symptoms over a 3-month period.

We analyzed the number of patients who responded to both questionnaires, the recurrence, and the symptoms scores reported.

Results: A total of 1121 questionnaires were collected; 103 patients (85%) reported their symptoms at least once during the 3-month study duration. The majority of participants who completed the study (71.6%) responded remotely at least once per month during the 3-month duration of the study. The mean OSDI and SANDE scores from the total of remote evaluations were 34.9 ± 21.9 (range 0–97.5) and 50.3 ± 24.9 (range 0–100), respectively. There was a statistically significant correlation between the total scores collected with the two questionnaires ($R = 0.67$, $P < 0.001$).

Conclusions: Patients are motivated to report DED symptoms while away from the clinic. Distance-based evaluation of DED symptoms is both feasible and convenient, and can be implemented to follow symptoms in large populations with chronic dry eye.

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1. Introduction

Dry eye disease (DED) is a multifactorial disorder of the ocular surface that affects millions of people in the United States and around the world [1–3]. It represents one of the most frequent reasons for ophthalmic consultations, with 5%–30% of the general population affected, depending on the diagnostic criteria used [3,4]. DED symptoms severely affect patients' activities of daily living, either continuously or triggered by specific tasks such as computer use or driving [5]. These symptoms include discomfort, blurred vision, burning sensation, irritation, photophobia, and contact lens intolerance [6,7]. The measurement of patient's signs and symptoms, and their impact on patients' quality of life are critical aspects in DED evaluation. A combination of signs and symptoms are commonly used as diagnostic criteria [7–10].

Questionnaires that assess patients' symptoms are very useful

during the diagnosis and follow-up of dry eye disease [7,8]. Symptoms in DED are characterized by their fluctuation and variability, which do not always correspond with fluctuations of clinical signs. Although evaluation of symptoms is critical for ocular surface disease treatment and follow-up, often due to time constraints, consistent and comprehensive assessment of DED symptoms is not performed.

We have evaluated and confirmed the performance and correlation between two DED symptoms questionnaires that are accessible and clinically validated tools for measuring ocular surface symptoms [11]. The Ocular Surface Disease Index (OSDI; Allergan Inc., Irvine, CA) [12] and the Symptom Assessment Questionnaire in Dry Eye (SANDE) [13]. The OSDI is a frequently used instrument comprised of 12 questions that evaluate the frequency of dry eye symptoms, with a score that ranges between 0 and 100. Based on the score, the patients' symptoms can be categorized as normal (0–12), mild dry eye (13–22), moderate dry eye (23–32), or severe dry eye (33–100) [12,14,15]. The SANDE is a short and intuitive questionnaire that quantifies both, the severity and frequency of dry eye symptoms, and is comprised of two questions based on a

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100 mm horizontal linear visual analog scale. The SANDE measures symptom frequency from “rarely” to “all of the time” and symptoms severity from “very mild” to “very severe,” with a score that ranges between 0 and 100 [13,16].

Based on the critical value of ocular surface symptoms in DED management and the factors that limit their recurring assessment, we investigated the feasibility of remote longitudinal assessment of ocular surface symptoms using electronic versions of the OSDI and SANDE questionnaires. We conducted a prospective study to assess dry eye symptoms in a cohort of patients with ocular surface disease and evaluated their response to remote web-based symptoms assessment.

2. Methods

In this prospective, cohorts-based study we collected patients' baseline data on DED symptoms at the Cornea Service, MEEI, as well as follow-up data remotely through a secure internet protocol and web interface. Consecutive patients who attended our clinic, a specialized ocular surface unit, with a previous diagnosis of dry eye disease were included in the study. Patients of any age, level of education or occupation, as well as with any type of DED or treatment were invited to participate. In general, we included any patient who would have been a candidate to receive the same paper-based symptoms questionnaires in the clinic. All patients included in the study reported having a current email address that they used regularly, and familiarity with the use of internet and computers. The study was conducted in compliance with the Institutional Review Board (IRB) at the Massachusetts Eye and Ear Infirmary (#14-210H), Boston, in accordance with the tenets of the Declaration of Helsinki and written informed consent was obtained from all participants.

Patients responded to two questionnaires, the Ocular surface Disease Index (OSDI) and the Symptom Assessment in Dry Eye (SANDE). The 12-item OSDI contains 3 ocular symptom questions, 6 vision-related function questions, and 3 environmental trigger questions. Each question score ranges from 0 (“none of the time”) to 4 (“all of the time”). The total score ranges between 0 and 100 and is calculated based on the following formula: $OSDI = ([\text{sum of scores for all questions answered} \times 100] / [\text{total number of questions answered} \times 4])$ [11]. The SANDE questionnaire scores range between 0 and 100 and is comprised of two questions: 1) How often do your eyes feel dry and/or irritated? And 2) How severe you feel your symptoms of dryness and/or irritation are? Each question uses a 100 mm horizontal line where patients are asked to respond by sliding a button in accord to their perception of ocular discomfort. Frequency of symptoms ranges from “rarely” to “all of the time” and the severity of symptoms ranges from “very mild” to “very severe.” [12,14].

We created an electronic version of both questionnaires with a user-friendly interface that could be accessed over the internet (Figs. 1 and 2). For the baseline symptom assessment, both questionnaires were presented to patients in the clinic with a desktop computer using a web application that provides a secure internet connection for data capture and exchange. For the recurrent home-based assessments we created a web interface that was compatible with personal computers and mobile devices, providing flexibility and mobility to patients for submitting their answers. After enrollment and baseline symptom evaluation, the electronic OSDI and SANDE questionnaires were sent to all participants twice a month over a period of three months. Participants received a link through an automated email that allowed them to respond and submit their responses. The two electronic questionnaires were self-explanatory and contained a series of features that prevented

incomplete submissions. A line for questions and technical support was provided to all the participants during the study. Finally, the patients were asked if they considered that the electronic versions of the OSDI and SANDE questionnaires were clear and easy to understand. Patients were explained that in order to avoid bias in the subsequent evaluations symptoms scores would not be displayed after submission of the two questionnaires. Patients' responses were submitted through a secure internet protocol and the study was compliant with the HIPAA privacy rules.

2.1. Data analysis

We evaluated the number of participants that reported their symptoms with both questionnaires at least once over the 3-month period duration of the study. We evaluated the proportion of cases in which patients reported their dry eye symptoms in the first, second, and third months following their last clinical evaluation. Additionally we calculated the level of association between the two electronic questionnaires using the Spearman coefficient of correlation, where a *P* value of less than 0.05 was considered statistically significant.

3. Results

A total of 1121 ocular surface symptoms evaluations from 103 patients were collected and analyzed. These evaluations correspond to patients who, apart from the baseline measurement, reported their ocular surface symptoms at least once remotely during the study duration. The number of patients who responded at least once remotely ($n = 103$) represented 85% of the 125 participants who originally agreed to remotely report their DED symptoms. The participants' mean age was 56 (± 13) years (range 22–77), female participants accounted for 59% of the study population and male participants accounted for 41%.

We collected 563 OSDI questionnaires and 558 SANDE questionnaires. From the total number of evaluations collected, only five questionnaires were incomplete (<1%). The majority of the participants who completed the study (71.6%) responded remotely at least once per month during the 3-month duration of the study, 19.6% responded at least once per month for two consecutive months, and 8.8% responded at least on one occasion over the duration of the study.

The mean OSDI score from the total of remote evaluations received was 34.9 ± 21.9 units (range 0–97.5), and the median OSDI score was 31.3 units. In 10 of the 12 items evaluated by the OSDI questionnaire the most recurrent response was “Some of the time” (score 1), which, after “None of the time” (score 0), is the lower frequency option available in the questionnaire. In the other two items of the OSDI the most common response was “None of the time.” Both, “None of the time” and “Some of the time” accounted for 59.5% of the responses from all the collected evaluations. The proportion of responses for each OSDI item is presented in Table 1.

The mean SANDE score from the total of remote evaluations received was 50.3 ± 24.9 units (range 0–100), and the median SANDE score was 51.5 units. From the items evaluated by the SANDE questionnaire, “Frequency of dry eye symptoms” received a majority of responses that fell between 61 and 80 units in a 0–100 scale. The item “Severity of dry eye symptoms” received a majority of responses that fell between 41 and 60 units. The total SANDE score (0–100 scale), which combines both the frequency and severity items, was higher than 41 units in more than 64% of the responses. The proportion of responses for each OSDI item is presented in Table 2.

In regard to perception and comfort using the remote electronic

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