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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Dry eye examination – benefits of Ocular Surface Disease Index (OSDI) questionnaire with clinical testing

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SUMMARY

Introduction/Objective Dry eye is a multifactorial disease with incidence up to 50% in the general population. It is characterized by a loss of homeostasis of the tear film and accompanied by ocular symptoms. Ocular Surface Disease Index (OSDI) questionnaire is designed to provide a rapid assessment of the symptoms. The aim of this study was to evaluate the diagnostic capacity of OSDI.

Methods A prospective, randomized and observational study was conducted at the Clinic for Eye Disease, University Clinical Center of Serbia, between December 2018 and February 2019. The OSDI questionnaire was used to rate the severity of dry eye disease. Schirmer I test, tear break-up time test (TBUT), Rose Bengal test and lid-parallel conjunctival folds (LIPCOF) test were performed as a clinical proof of the symptoms.

Results A total of 27 patients, 15 male (55.4%) and 12 female (44.6%), with mean age of 60 ± 15 years were included in the study. The average value of OSDI score was 26.37 ± 23.98 (0–80). Schirmer I test and Rose Bengal test for the right and the left eye, as well as the TBUT test for the left eye were positively correlated with OSDI score (Spearman correlation coefficient).

Conclusion OSDI questionnaire is a fast, reliable, and inexpensive test. In our study we have found a correlation between the OSDI score and other clinical tests, except with LIPCOF test. At this moment, the questionnaire that could be the gold standard for dry eye disease diagnosis does not exist, therefore further studies concerning this topic are needed.

Keywords: dry eye; OSDI questionnaire; LIPCOF; Schirmer test; TBUT test; Rose Bengal test

INTRODUCTION

Dry eye is multifactorial eye surface disease, characterized by the loss of tear film homeostasis and eye symptoms [1]. It is one of the most frequent reasons for visiting an ophthalmologist, so it represents a significant outlay for the health care system [2]. Most of the patients have mild symptoms, but sometimes very complex interventions are necessary to avoid further progression to corneal ulcer and conjunctival scaring [3]. Contact lens wear and refractive surgery can cause a dry eye [4]. In the etiology of dry eye main factors are tear film instability, hyperosmolarity, inflammation, eye surface damage, and neurosensory abnormalities [1]. Sjögren syndrome, transplantation (graft versus host reaction), and aging can also cause dry eye [5].

Following present knowledge, ocular and lacrimal inflammation take the main role because they are making defects of corneal and conjunctival cells and causing symptoms [1]. What occurs has been proven on the molecular and biochemical level, where it has also been shown that lower levels of androgen and higher levels of pro-inflammatory cytokines followed by the loss of immunologic homeostasis of the lacrimal gland and the eye surface lead to pathological changes [6]. Neurogenic mechanisms – loss of innervation and lower sensitivity – can also cause dry eye [4]. Dry eye disease is one of the most prevalent ophthalmic disorders in the general population, which can go up to 50% in different studies [2].

In the classification of dry eye disease, we have two large categories: aqueous tear-deficient dry eye (Sjögren syndrome dry eye) and evaporative dry eye (non-Sjögren syndrome dry eye) [7]. Aqueous tear-deficient dry eye implies that dry eye is due to a failure of lacrimal tear secretion, and it represents about 10% of all cases. Evaporative dry eye is due to deficiency in lipid part of tear film, which is manifested with higher evaporation. The main cause is Meibomian gland disfunction, and it represents 85% of all cases [8]. Blepharitis, eyelid margin inflammation is a cause, as well as a consequence, of Meibomian gland disfunction, but in differential diagnosis we also need to think of rosacea, atopy, seborrheic dermatitis and staphylococcal infection [1].

Etiologically important factors in dry eye disease are female sex and ageing (low levels of androgen play the main role in Meibomian gland disfunction) [8]. Except those, important factors are also lagophthalmos, decreased blinking, systemic autoimmune diseases, atopy,

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vitamin A deficiency, and external conditions with low air humidity [9]. A number of questionnaires have been developed, and they are in use in combination to help make a dry eye diagnosis, but none of them, separately, has required sensitivity and specificity to be a gold standard [10]. The clinical presentation of dry eye disease varies a great deal, which makes a diagnosis even more difficult. Patients frequently have unspecific symptoms, such as visual disturbance, ocular discomfort, photophobia, itching, and irritation. Patients can sometimes experience excessive tearing due to discomfort. Symptoms do not have a strong correlation with clinical findings, especially if there is low pain tolerance [11]. For the purpose of reaching a diagnosis, checking severity of the disease, starting treatment and follow-up, many questionnaires have been made, and among them are the Dry Eye Questionnaire (DEQ-5) and the Ocular Surface Disease Index (OSDI) [12, 13].

The OSDI questionnaire has been made by the Outcomes Research Group at Allergan Inc. in order to provide fast evaluation of ocular irritation symptoms in connection with dry eye disease and their impact on vision [13]. Therefore, the aim of this study was to evaluate diagnostic capacity the OSDI questionnaire in assessment of dry eye disease and the severity of the disease relative to clinical diagnostic procedures.

METHODS

This was a prospective, randomized, and observational study, conducted at the at the Department of Cornea and External Eye Disease, Clinic for Eye Disease, University Clinical Center of Serbia, between December 2018 and February 2019. Patients were randomized upon the arrival for a clinical examination such as cataract or blepharitis, and had no previous history of dry eye treatment. Anamnestic characteristics were collected at the beginning of the study. Participation was voluntary and informed consent was obtained from each participant. Ethical approval was obtained from the Institutional Review Board.

The 12-item OSDI questionnaire is a self-administered questionnaire used to rate the severity of dry eye disease. Responses to each item were scored on a five-point Likert scale, where 0 indicates "none of the time"; 1 indicates "some of the time"; 2 indicates "half of the time"; 3 indicates "most of the time," and 4 indicates "all of the time." The OSDI score calculates on the basis of the given formula: OSDI = ((sum of scores for all questions answered) × 100) / ((total number of questions answered) × 4)). The OSDI is assessed on a scale of 0 to 100, with higher scores representing greater disability [14].

For the purpose of this study, additional clinical measures were performed.

Schirmer I test

The Schirmer I test was used to determine the flow of tears produced by the tear glands and measures the basal and reflex secretions of the main and accessory glands. It is performed using calibrated, bent strips of non-toxic filter paper. On the lateral and middle-third of the lower eyelid, a shorter folded end is attached, in order to avoid irritation of the cornea. This test is performed without previously applied anesthesia, and on both simultaneously. The test length is 5 minutes, and after removing the strips from the lower eyelids, we measured the amount of wetting of the paper strips. The limit values of Schirmer I test for dry eye disease are ≤ 10 mm / 5 minutes [15].

Tear break-up time test

Tear break-up time (TBUT) is a clinical test used to assess the stability of the tear film. It is performed by instilling a small amount of fluorescein on the ocular surface of the lower eyelid, after which the respondent was asked to blink in order to spread the fluorescein evenly across the surface of the eye. Then, patient is instructed to keep their eyes opened, without blinking. Using cobalt blue illumination, the TBUT is recorded as the number of seconds elapsed between the patients last blink of an eye and presence of the first defect in the tear film. The normal values of the TBUT test are over 10 seconds, and the results below this value indicate that there is a disruption in the quality of the tear film [15].

Rose Bengal test

The Rose Bengal test is used to indirectly measure the presence of reduced tear volume, detecting damaged and devitalized epithelial cells that have lost the role of creating tears. The results of this test can be read immediately. On the surface of the eye, we observe three zones: the cornea, the nasal, and the temporal part of conjunctival staining. Points from 0 to 3 are assigned to each of these zones, depending on whether there is coloring – if there are few colored dots, lots of colored dots, or if confused zones are present. The positive result of this test are four or more points for all three zones combined, with a maximum of nine points [16].

LIPCOF test

Small folds parallel to the lower lid margin in the infero-nasal and infero-temporal quadrants of the bulbar conjunctiva are defined as lid-parallel conjunctival folds (LIPCOF), and they were first described by Höh et al. [17]. LIPCOF correlates with reduced mucin production and with epitheliopathy of the eyelid edge. Using the method described by Höh et al., the LIPCOF test graded 0–3, by the slit lamp examination [17]. According to the comparison of the number of conjunctival folds with the height of the normal tear meniscus height there is a scale of grading. In grade 0, no fold appears; in 1, a single small fold appears, smaller than the normal tear film meniscus; in grade 2, multiple folds up to the height of the normal tear meniscus appear; in grade 3, multiple folds higher than the normal tear meniscus appear.

Statistical analysis

Numerical data were presented as an arithmetic mean and median with corresponding measures of variability (standard deviation, minimal and maximal value, range). Categorical data were presented as absolute numbers with frequencies. Differences of the OSDI questionnaire results according to sex were analyzed by the Mann–Whitney U test. Spearman correlation coefficients were calculated to explore the relationship between the LIPCOF test grade and the patient's age. The p-value < 0.05 was considered statistically significant. Statistical analysis was done using the IPSS 1.3 program.

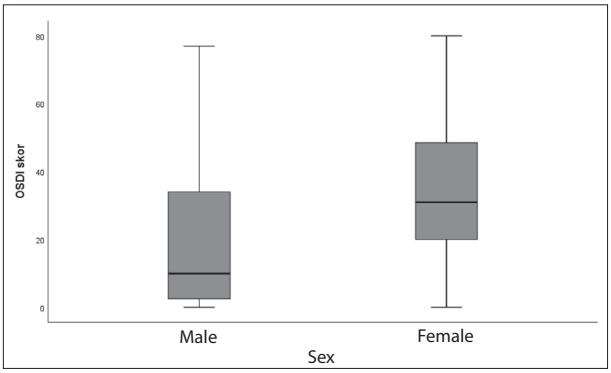


Figure 1. Ocular Surface Disease Index (OSDI) score according to sex

RESULTS

A total of 27 patients, 15 male (55.4%) and 12 female (44.6%), with a mean age of 60 ± 15 years (ranging 22–82 years) were included in the study (Table 1).

Table 1. Demographic characteristics of the patients

Sex, n (%)	
Male	15 (55.4)
Female	12 (44.6)
Age, mean ± SD	60 ± 15

The average value of the OSDI score in our study population was 26.37 ± 23.98, ranging 0–80. The median value of Schirmer I test was 6 for the right eye (ranging 0–12), and 3 for the left eye (ranging 0–10). The median values of the LIPCOF test, the Rose Bengal test, and the TBUT test are presented in Table 2.

The correlations between the OSDI score and age, as well as Schirmer I, LIPCOF, Rose Bengal, and TBUT test results are presented in Table 3. As shown in Table 3, Schirmer I test results for the right and the left eye were positively correlated with the OSDI score: rho = 0.639; p < 0.001 and rho = 0.540, p = 0.004, respectively. Rose Bengal test (OD rho = 0.458, p = 0.016; OS rho = 0.193, p = 0.334), and TBUT test for the left eye (rho = 0.439, p = 0.022) were also positively correlated with the OSDI score (Table 3).

No statistically significant difference was found between the OSDI score and sex (p = 0.136) (Figure 1). Also, no correlation between the age of the respondents and the OSDI score was found (rho = 0.099, p = 0.623).

DISCUSSION

The results of this study showed that the OSDI score was positively correlated with Schirmer I, Rose Bengal and TBUT test results. Also, no statistically significant difference was found between the OSDI score and sex and no correlation between the age of the respondents and the OSDI score. This study is limited by the small group of patients, so further testing within bigger groups is suggested for better validation of the findings.

The core pathophysiological mechanisms of dry eye are lower tear production, higher evaporation, or their combination, with tear film hyperosmolarity and eye surface inflammation [1]. In clinical observation it was found that patients usually do not meet the criteria of making the diagnosis of the disease by all the tests, so more classifications were made, of which the one from Copenhagen is the most popular. This phenomenon is probably a consequence of multifactorial etiology of dry eye. Copenhagen criteria include three main factors – changes in the aqueous layer (Schirmer), higher level of evaporation (TBUT), and eye surface defects (Rose Bengal staining) [3]. By using more tests, the chance of making correct diagnosis is

Table 2. Median test values for Schirmer I, lid-parallel conjunctival folds (LIPCOF), Rose Bengal, and tear break-up time (TBUT) tests

Test	n	mean	SD	median	minimum	maximum
Schirmer OD	27	5.57	3.03	6.0	0	12
Schirmer OS	27	4.09	2.95	3.00	0	10
LIPCOF OD	27	0.7	0.77	1.00	0	2
LIPCOF OS	27	0.59	0.64	1.00	0	2
Rose Bengal OD	27	1.89	2.21	1.00	0	8
Rose Bengal OS	27	1.30	1.2	1.00	0	4
TBUT OD	27	4.81	3.17	5.00	1	10
TBUT OS	27	4.7	3.66	3.00	1	14

OD – right eye; OS – left eye

Table 3. Correlation between Ocular Surface Disease Index (OSDI) score and age, Schirmer I, lid-parallel conjunctival folds (LIPCOF), Rose Bengal, and tear break-up time (TBUT) tests

Variable	OSDI score	
	ρ	p
Age	0.099	0.623
Schirmer OD	0.639	**0.001**
Schirmer OS	0.540	**0.004**
LIPCOF OD	0.114	0.572
LIPCOF OS	-0.130	0.517
Rose Bengal OD	0.458	**0.016**
Rose Bengal OS	0.193	0.334
TBUT OD	-0.064	0.749
TBUT OS	0.439	**0.022**

OD – right eye; OS – left eye

rising, but there is no consensus on which combination, besides best specificity and sensitivity, would cover other aspects, such as severity, quality of life, and follow-up [3]. To overcome this problem, questionnaires like the DEQ-5, McMonnies, and the OSDI are added to the battery of clinical examinations [10].

In this study, in which 27 patients took part, the OSDI score values match OSDI scores of other studies in this field. The mean age of patients in our study is slightly higher than that in other studies [18]. In the literature overview, we found that the significant correlations between the OSDI questionnaire and clinical examinations are common [19]. In general, a positive correlation is most common between the OSDI score and the TBUT test [19, 20, 21]. The positive correlation between these tests is very valuable for clinicians in order to easily establish the dry eye diagnosis and to promptly advise proper therapy.

When we analyzed the LIPCOF clinical test results, we have found that almost 50% of the patients had negative results, and just 20% of the patients were positive to this test, with similar results found by other studies. It is not in correlation to positive findings between the OSDI score and the LIPCOF grade in our study [21]. Further study of etiopathogenic mechanisms, symptoms, and different aspects that any single test evaluates, as well as more patients included, would help in the clarification of these differences.

CONCLUSION

The OSDI questionnaire is a quick, reliable, and inexpensive test, which is a great tool in the evaluation of the first symptoms of dry eye disease. In our study, we have found a correlation between the OSDI score and the most common clinical diagnostic tests, whereas only the LIPCOF test had been without statistical significance. A questionnaire for dry eye disease that could be considered the gold standard still does not exist – therefore, further studies with greater number of participants concerning this topic are needed.

Conflict of interest: None declared.

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Испитивање сувог ока – предности упитника индекса болести предње површине ока са клиничким тестовима

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САЖЕТАК

Увод/Циљ Суво око је болест са инциденцом и до 50% у популацији. То је мултифакторијална болест површине ока где губитак хомеостазе сузног филма прати очне симптоме. Упитник индекса болести површине ока (ИБПО) омогућава брзо постављање дијагнозе.

Циљ овог рада је процена дијагностичке вредности теста ИБПО у болести сувог ока и градацији тежине у односу на налаз релевантних клиничких тестова.

Методе Проспективна, рандомизована и опсервациона студија обављена је на Клиници за очне болести Универзитетског клиничког центра Србије, у периоду од децембра 2018. до фебруара 2019. године. Упитник ИБПО је коришћен ради евалуације симптома и корелације са клиничким тестовима. Клинички тестови примењени у овој студији су Ширмеров тест I, тест прекида сузног филма, тест *Rose Bengal* и тест набора конјунктиве паралелних ивици капка.

Резултати Укупно је било 27 болесника – 15 мушкараца (55,4%) и 12 жена (44,6%), просечне старости 60 ± 15 година. Просечна вредност скора ИБПО у студији била је 26,37 ± 23,98 (0–80). Пронађена је позитивна корелација са скором ИБПО између Ширмеровог I теста и теста *Rose Bengal* за десно и лево око, као и теста прекида сузног филма за лево око (Спирманов коефицијент корелације).

Закључак Упитник ИБПО је брз, поуздан и јефтин тест који добро процењује постојање и тежину сувог ока. У нашој студији пронађена је корелација упитника ИБПО са свим клиничким тестовима у дијагностици сувог ока, изузев теста набора конјунктиве паралелних ивици капка. Тренутно не постоји упитник који би представљао златни стандард у дијагностици сувог ока, те су даља истраживања у овом смеру неопходна.

Кључне речи: суво око; упитник индекса болести површине ока; набори конјунктиве паралелни ивици капка; Ширмеров тест; тест прекида сузног филма; тест *Rose Bengal*