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Comparison of Clinical Use of Ocular-surface Disease Index Questionnaire, Tear Film Break-up time, and Schirmer Tests in Diagnosing Dry-eye

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Authors' contributions

This work was carried out in collaboration between both authors. Author SS designed the study, performed the statistical analysis, interpreted and prepared the manuscript. Author PG managed the literature searches. Both authors read and approved the final manuscript.

Article Information

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Opinion Article

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ABSTRACT

Aims: To evaluate and compare the diagnostic values and clinical utility of the Ocular Surface Disease Index (OSDI) questionnaire, the tear film break-up time test (TBUT), and the Schirmer's test in diagnosing dry eye disease in patients presenting with dry eye symptoms.

Study Design: A prospective observational study.

Place and Duration of Study: Department of Ophthalmology, AIIMS Jodhpur, Rajasthan, India. Two-month period between July 2016 and September 2016.

Methodology: We have included 100 patients aged >20 years having foreign body sensations, burning sensations, pain, dryness, blurred vision, photophobia, redness in the study. Routine ophthalmological examination was performed after OSDI questionnaire, followed by TBUT and Schirmer's test and outcomes were evaluated.

Results: The mean age of 100 participants was 43 ± 15.97 years (range 20–78 years). The mean OSDI, TBUT, and Schirmer's test scores were 58.67 ± 12.12 (range 30.0-88.9), 5.77 ± 3.49 seconds (range 0–17 seconds), and 09.78 ± 7.93 mm (range 0–32.5 mm), respectively. There was a



statistically highly significant inverse correlation between the OSDI and TBUT (r = -0.597, P = <0.0001), statistically significant correlation between TBUT and Schirmer test (r = -0.227, p = 0.023), whereas no significant correlation noted between the OSDI and Schirmer's test (r = -0.142, p = 0.158).

Conclusion: The prevalence of dry eye disease (DED) is increasing these days. For early recognition and treatment, we need rapid, reliable and less invasive diagnostic test in daily practice. The OSDI together with the TBUT is less time consuming, easy to perform and can be useful in diagnosis of DED.

Keywords: Dry eye disease; tear film; ocular surface.

1. INTRODUCTION

Presently, there is no single "gold standard" test for clinical diagnosis of dry eye disease (DED) [1]. Most diagnostic tests used in clinical practice are still poorly standardized. Symptom based questionnaires are more repeatable and reliable than the objective tests. However, same symptoms can be experienced in other ocular surface conditions.

The aim of this study was to investigate the prevalence of dry eye disease in different age group of patients presenting with symptoms of dry eye, to evaluate and compare the diagnostic efficacy and clinical utility of the Ocular Surface Disease Index questionnaire, tear film break-up time test and Schirmer's test in diagnosing dry eye disease.

2. MATERIALS AND METHODS

A prospective observational study was performed in two-month period between July 2016 and September 2016 among the patients who attended the outdoor of our hospital and fulfilled the inclusion criteria. The study was approved by the Institute's Ethics Committee. We have included 100 patients in this study. The study protocol was explained to all the participants and written informed consent was received.

2.1 Subjects

Patients aged \geq 20 years old were included in the study. Subjects previously diagnosed with DED were excluded from the study.

2.1.1 Inclusion criteria

- 1. Patients having foreign body sensations, burning sensations, pain, dryness, blurred vision, photophobia, redness.
- 2. Age ≥20 years

3. Willing to give consent for study and follow up.

2.1.2 Exclusion criteria

- 1. Contact lens user.
- 2. Subjects who have undergone ocular surgery in previous 6 months.
- 3. Acute ocular infection with extensive corneal or conjunctival pathology.
- 4. Subjects who had had any previous ocularsurface disorders or intraocular surgery.
- 5. Who had nasolacrimal duct obstruction, or who were using topical ophthalmic drugs and/or systemic medications.

2.2 Ophthalmological Examination and Measurements

The Ocular Surface Disease Index (OSDI) questionnaire was performed before ophthalmic examination. The OSDI questionnaire is composed of twelve questions that provide a rapid assessment of the symptoms of ocular irritation in dry eye and their impact on vision-related functioning. The OSDI score was assessed on a scale of 0 to 100, with higher scores representing greater disability. The cut-off OSDI score for diagnosis was accepted as \geq 35.

After the OSDI questionnaire, subjects underwent a detailed ophthalmic examination, including best-corrected visual acuity, intraocular pressure measurement, anterior segment examination with slit lamp biomicroscope and fundus examination with indirect ophthalmoscope.

Following the OSDI questionnaire and ophthalmic examination, the tear film breakup time test (TBUT) and the Schirmer's Test were performed.

To measure tear film breakup time, a sterile strip of fluorescein was applied in the lower eyelid fornix and then removed. The subject was asked to blink three times and then look straight forward, without blinking. The tear film was observed under the cobalt blue filtered light of the slit lamp microscope and the time span between the last blink and appearance of the first break in the tear film was recorded with a stopwatch. A tear film breakup time of <10 seconds was considered consistent with DED. The mean TBUT score of the right and left eyes was used for statistical analysis.

Ten minutes after the TBUT, Schirmer I test (without anaesthesia) was performed to evaluate basal and reflex tear secretion. In the Schirmer I test, a filter paper strip $(35 \times 5 \text{ mm})$ was used to measure the amount of tears produced over 5 minutes. The strip was placed at the junction of the middle and the lateral thirds of the lower eyelid. The test was performed under ambient light. The patients were instructed to look forward and to blink normally during the course of the test (5 minutes), and then wetting of the filter paper in 5 minutes was recorded. Wetting \leq 10 mm was considered consistent with dry eye. The mean Schirmer's Test score of the right and left eyes was used for statistical analysis.

2.3 Study Protocol

The OSDI questionnaire was performed first and the OSDI scores were calculated. Following routine ophthalmologic examination, the TBUT and Schirmer's test were performed and test scores noted. The patients who were diagnosed as dry eye disease were prescribed tear substitutes.

2.4 Statistical Analysis

Descriptive statistics of the study population were noted. Correlation analysis was performed between the OSDI, TBUT and Schirmer's test scores using Pearson's correlation coefficient. A P value of <0.05 was considered significant.

3. RESULTS

The study included 100 subjects; 60 of them were male and 40 were female (male: female ratio 3:2). The age of patients ranged between 20-78 years (the mean age 43 ± 15.97 years).

The mean OSDI, TBUT, and Schirmer's test scores were 58.67 ± 12.12 (range 30.0-88.9), 5.77 ± 3.49 seconds (range 0-17 seconds), and 09.78 ± 7.93 mm (range 0-32.5 mm), respectively. There was a statistically highly significant inverse correlation between the OSDI

and TBUT (r = -0.597, *P* = <0.0001), statistically significant correlation between TBUT and Schirmer's test (r= -0.227, p= 0.023), and no significant correlation noted between the OSDI and Schirmer's test (r= -0.142, p= 0.158) (Table 1).

The most sensitive test was OSDI among the three; 99% patients were diagnosed as dry eye disease by OSDI with the cut-off OSDI score ≥35, 90% of the patients were diagnosed by TBUT, while, 69% of patients were diagnosed by Schirmer test (Table 2).

A relative peak in dry eye prevalence was noted among the age group 20-29 years (26% according to OSDI and 21% according to TBUT) followed by age group 30-39 years (23% according to OSDI and 19% according to TBUT results). Whereas the age group 50-59 years were most afflicted with DED according to Schirmer test (16%) followed by age group 20-29 years (14%). In elderly subjects results of all the three tests were more comparable (patients diagnosed as DED were 36% with OSDI, 36% with TBUT, 33% with Schirmer test age group 50-79 years) than in younger subjects (patients diagnosed as DED were 63% with OSDI, 55% with TBUT, 36% with Schirmer test in age group 20-49 years) (Table 2).

4. DISCUSSION

According to the International Dry Eye Work Shop (2007) definition, Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbances, and tear film instability with potential damage to the ocular surface. It is accompanied with increased osmolarity of the tear film and inflammation of the ocular surface [1].

Prevalence of dry eye ranges from 5% to 35% in various age groups worldwide [2-10]. Increasing age and female gender is associated with increased prevalence of DED. It is one of the most common reasons for eye care clinic visits. DED is a chronic disease and advanced dry eyes may affect the ocular surface and cause visual impairment. The public health burden of DED may be considerable, affecting visual function, activities of daily life, physical functioning and social life, workplace productivity, and quality of life [11].

The appropriateness of currently used tests to diagnose DED has been extensively discussed in literature; however, there is no gold standard test

or even a panel of tests or well-established cutoff values for the available tests [12]. The most common objective diagnostic test for dry eye; the Schirmer test is in use for more than 100 years [13]. It measures tear production but the evaporative aspect of dry eye is overlooked [14, 15]. The Schirmer's Test is easy to perform but gives variable results and has low sensitivity for detecting dry eyes [16,17]. Another widely used test is tear film Break up time Test (TBUT) to assess the tear film stability [18,19]. It is minimally invasive, repeatable and reliable test for the diagnosis of DED. The Ocular Surface Disease Index (OSDI) questionnaire provide a rapid assessment of the symptoms of ocular irritation and their impact on vision-related functioning; has good-to-excellent test-retest reliability [20]. However, symptoms alone are inadequate for the diagnosis of DED, because the same symptoms can be experienced in other ocular surface conditions and reduction in tear production may not be associated with ocular symptoms. A poor correlation between the symptoms and results of diagnostic tests in patients with DED is reported by Nichols et al. [21].

Studies on the test of tear function, including Schirmer's test and TBUT have generally reported lower prevalence rates as compare to guestionnaire based studies [2,4].

In this study, we performed three tests for confirmation of the diagnosis; 99% of the patients were diagnosed as DED according to the results of the OSDI, 90% patients according to TBUT and 69% patients according to Schirmer test. The lower prevalence rate by diagnostic tests may be because the symptoms and signs of DED do not correlate well and can vary depending on the environmental conditions to which patients are exposed in their daily lives. Only 57% of symptomatic patients have been shown to have objective signs of dry eye [4,21-23].

There was good correlation between OSDI and the TBUT results. We found that the TBUT results were also well correlated with Schirmer test, possibly because the results of TBUT depend on many factors like ocular surface exposed area, tear film volume and clearance, and no widely accepted standard cut-off values.

 Table 1. Correlation between Ocular-Surface Disease Index (OSDI), tear film breakup time test (TBUT), and Schirmer's test

		OSDI	TBUT	Schirmer test
OSDI	Pearson correlation	1	597(**)	142
	Sig. (2-tailed)		.000	.158
	Ν	100	100	100
TBUT	Pearson correlation	597(**)	1	.227(*)
	Sig. (2-tailed)	.000		.023
	N	100	100	100
Schirmer	Pearson correlation	142	.227(*)	1
test	Sig. (2-tailed)	.158	.023	
	Ν	100	100	100

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

" Correlation is significant at the 0.05 level (2-tailed)

Table 2. Distribution	of pati	ents in	different	age groups
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Age group (years) (20-79)	Total No. of patients (100)	% of patients with OSDI score >35 (99)	% of patients with TBUT <10 second (90)	% of patients with Schirmer Test <10 mm (69)
20-29	26	26	21	14
30-39	23	23	19	13
40-49	15	14	15	09
50-59	16	16	15	16
60-69	14	14	14	11
70-79	06	06	06	06

Cihan et al. [24] compared the diagnostic values of the Schirmer's test. TBUT and OSDI in drveye syndrome and reported a significant inverse correlation between the OSDI and TBUT scores (r = -0.385, P = 0.022) and no significant correlation between the OSDI and Schirmer's test scores. Alves et al. [25] reported that DED diagnostic test results were variable among different conditions. Vital staining and TBUT correlated best and the best test combination to detect DED was OSDI/TBUT/Schirmer, Lam, et al. [6] revealed no significant correlation between the OSDI and Schirmer's test (Spearman rho = 0.075, p = 0.44). Elderly subjects (aged 46-55 years) had a significantly higher mean index score compare to the younger subjects (aged 18-25 years, p = 0.006). An inverse correlation between daily hours of computer use and Schirmer's test scores was reported (Spearman rho = -0.20, p = 0.032) by Moss SE et al. [5].

Various studies in the literature have shown a lack of correlation between the dry eye symptoms that patients experience and the results of selected clinical tests for dry eye. No single diagnostic test can reliably distinguish individuals with and without the disease.

Only 69% patients had a positive Schirmer's test result of < 10 mm in this study. This might be due to reflex epiphora resulting in the misdiagnosis of dry-eye. Singh reported that reflex epiphora changed the results of Schirmer's test; therefore, no correlation with symptoms in patients of dry eye syndrome was noted [26]. The Schirmer test has been considered inaccurate, unrepeatable and not inclusive of the evaporative aspect of DED in the previous studies [27]. In our study, the Schirmer test results were closer to TBUT and OSDI in elderly subjects (patients diagnosed as DED were 36% with OSDI, 36% with TBUT, 33% with Schirmer test in age group 50-79 years) as compare to younger subjects (patients diagnosed as DED were 63% with OSDI, 55% with TBUT, 36% with Schirmer test in age group 20-49 years). This explains that decreased reflex tear secretion capacity in older age could not affect the results of Schirmer test in elderly subjects, and reflex tearing developed during the Schirmer test procedure may be the underlying cause of the absence of correlation between the OSDI and Schirmer's test scores in our study.

Prevalence of DED has been reported to increase with age in many population-based studies [2,5,6]. In our study the age group 20-29 years showed a relative peak in dry eye prevalence (26%) according to OSDI and (21%)

according to TBUT followed by age group 30-39 years (23%) according to OSDI and (19%) according to TBUT results. That may be because of dramatic increase in the use of digital devices such as computer and smart phones, resulted in an increase in DED in the younger population [9,28,29]. Dry-eye disease in visual display terminals users may be due to decreased blinking rate and consequent increase in the rate of tear evaporation [30]. The age group 50-59 years were most afflicted with dry eye according to Schirmer test (16%) followed by age group 20-29 years (14%). That may be due to more reflex tearing in younger subjects.

5. CONCLUSION

Dry eye disease is one of the most frequently diagnosed condition and tear substitutes are more commonly prescribed (abused) eye drops by ophthalmologists. The prevalence of DED is increasing in the digital era. Early diagnosis and treatment are essential to avoid visual impairment and to improve quality of life. Based on this study, we conclude that the OSDI together with the TBUT is less time consuming, easy to perform and can be useful in diagnosis of DED. Further studies would be useful for better understanding of mechanism and diagnosis of DED.

6. LIMITATION OF STUDY

Limitation of our study is the absence of age and gender matched control group of healthy subjects to evaluate the specificity of the tests. This can be included in future studies. Lack of well-established cut-off values for the available diagnostic tests and symptoms based questionnaire scores may have had likely influence on the test results.

CONSENT

Written informed consent was obtained from all the participants.

ETHICAL APPROVAL

The study was approved by the Institute's Ethics Committee.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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