Original Article

Prevalence and risk factors of dry eye disease in North India: Ocular surface disease index-based cross-sectional hospital study

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Purpose: This study aims to study the prevalence of DED and analyze risk factors in North Indian population. **Methods:** This was a cross-section hospital-based, observational study. Cases enrolled over 2 years (systematic random sampling) were administered ocular surface disease index questionnaire to evaluate the prevalence and risk factors of DED. Schirmer's test and tear break-up time were performed only in the subset of patients giving consent. Categorical data were assessed with Chi-square/Fisher's Exact test, and odds ratio was analyzed using bivariate and multivariate logistic regression. $P < 0.05$ was statistically significant. **Results:** A total of 15,625 patients were screened. The prevalence of DED was 32% (5000/15625); 9.9% (496/5000) had mild DED; 61.2% (3060/5000) had moderate DED; and 28.9% (1444/5000) had severe DED. Age group of 21–40 years, male sex, urban region, and desk job were associated with increased risk of DED. Hours of visual display terminal (VDT) usage significantly correlated with DED ($P < 0.001$), and 89.98% of patients with 4 h or more of VDT use had severe dry eye. Cigarette smoking and contact lens usage had increased odds of developing severe DED ($P < 0.001$). Objective tests were undertaken in 552 patients; of these, 81.3% (449/552) had severe DED. **Conclusions:** The prevalence of DED in North India is 32%, with the age group of 21–40 years affected most commonly. VDT use, smoking, and contact lens use were associated with increased odds of developing DED.

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Dry eye disease (DED) is a chronic ocular pathology and a major global health problem that manifests as a plethora of symptoms such as burning, photophobia, tearing, and grittiness. Patients with DED experience difficulties in daily routine activities thus compromising their quality of life.[1]

The subjective symptoms and discomfort experienced by the patients with DED poorly correlates with the objective clinical tests.[2] The diagnosis and grading of DED on the basis of symptom-based questionnaires such as the ocular surface disease index (OSDI) questionnaire (Allergen Inc, Irvine, Calif, USA) is more reliable than based on clinical tests.[2-5]

The prevalence of DED is greatly influenced by geographic location, climatic conditions, and lifestyle of the people and ranges from 5% to 35%.[6-8] However, different definitions of dry eye are employed in various epidemiological studies which may not be standardized, and limited data exist on the potential effect of race or ethnicity on dry eye prevalence. There is a need to expand epidemiological studies to more geographic regions using standardized questionnaires and uniform diagnostic criteria. Very few studies have described the epidemiology of DED from the Indian subcontinent.[9-13] We describe the prevalence of DED and the demographic profile of individuals with DED reporting to a tertiary care center in North India.

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Methods

A cross-section hospital-based, observational study was conducted at an apex tertiary care ophthalmic institution. Patients presenting to the outdoor patient department over a period of 2 years (June 2014–May 2016) were evaluated. Ethical clearance was obtained from the Institutional Review Board. Informed consent was obtained, and the study adhered to the tenets of the Declaration of Helsinki.

Systematic random sampling was performed to enroll patients, wherein the first patient was selected randomly, and subsequently, every fifth patient was enrolled in the study. All consenting patients above 10 years of age were included in the study and divided into four groups based on age: ≤20 years, 21–40 years, and >40 years. Patients younger than 10 years or not providing consent were excluded from the study.

Verbal informed consent was obtained before administering the OSDI score. Written informed consent was obtained only from patients willing to undergo objective tests.

The primary objective of the study was to analyze the prevalence of symptomatic DED based on the OSDI questionnaire and to analyze the associated risk factors. The

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secondary objective was to assess the tear film stability and secretion in patients with symptoms of DED.

Comprehensive history was obtained from all the patients with emphasis on history pertaining to dry eye. In addition, history of visual display terminals (VDT) usage including television, smartphones, tablets, laptops, etc., was also elicited and analyzed.

OSDI questionnaire was administered to all patients. The questionnaire was administered by a single examiner. To those who were nonconversant in English, the questions were explained to the patients in their local language. The OSDI questionnaire has 12 items, with each question given a score ranging from 0 (none of the time) to 4 (all of the time). The patients had to assign a score based on the duration of symptoms experienced over the preceding week. The final score was calculated by multiplying the sum of all the scores by 25 and then dividing the total by the number of questions answered. Scores range from 0 to 100 with 0–12 representing normal, 13–22 representing mild DED, 23–32 representing moderate DED, and ≥33 representing severe DED.[5,14]

The objective tests were undertaken only in patients with DED (based on the OSDI questionnaire) who gave consent for further investigations. These patients underwent tear film break up time (TBUT) and Schirmer test. The tests were carried out in the same room by a single examiner, with similar temperature and humidity conditions for all patients. The room temperature was maintained at 25°C–26.5°C, with 60%–65% humidity during examination.

Tear break up time

Fluorescein was applied to the ocular surface. The patient was asked to blink a few times before examination. Slit lamp biomicroscopy with a cobalt blue filter was used to investigate the tear film layer, and the interval from the last blink to the appearance of the first random dry spot on the cornea was noted. The test was repeated thrice and the mean value was calculated. Value of <10 s was considered as indicative of tear film instability.[15]

Schirmer's test

Whatman filter paper no 41 (measuring 5 mm × 35 mm) was placed in the lower fornix at the lateral one-third of the lower lid margin. The extent of wetting of the strip was measured after 5 min. Less than 5.5 mm of wetting was diagnostic of severe dry eye.[16] Schirmer's test was done without anesthesia. To avoid the influence of conjunctiva-corneal staining on the Schirmer test, it was carried out at an interval of 10 min after the TBUT test.

Statistical analysis

The data were analyzed using Stata 14.0 (StataCorp LP, College Station, TX, USA). Chi-square test/Fischer Exact test were used to establish the association between categorical data. Bivariate logistic regression analysis was used to calculate the odds ratio (OR). Multivariate analysis was performed to identify independent risk factors. $P < 0.05$ was considered statistically significant.

No formal sample size calculation was done. As per statistical experts, at least 10 subjects per potential risk factor should be enrolled to constitute an adequate sample size for risk factor studies. We have studied only 19 potent risk factors in our study, and the sample size is more than adequate to estimate the strength of association for each risk factor.

Results

A total of 15625 patients were administered the OSDI questionnaire over a period of 2 years, and their demographic profile is elaborated in Table 1. Clinically, significant DED was detected in 32% (5000/15,625) patients. Of these, 9.9% (496/5000) had mild DED, 61.2% (3060/5000) had moderate DED, and 28.9% (1444/5000) had severe DED. The demographic details of the patients with DED are described in Table 2. The OSDI questionnaire consists of 12 questions, and 66% (3300/5000) answered all 12 questions, whereas 1.58% (79/5000) answered 11 questions, 32.34% (1617/5000) answered 10 questions, and 0.08% (4/5000) answered 9 questions. The mean OSDI scores were 20.59 ± 1.14 in cases with mild DED, 28.60 ± 2.68 in cases with moderate DED and 42.32 ± 7.82 in cases with severe DED. The scores for the three domains of OSDI, namely, ocular symptoms, vision-related functions, and environmental triggers is summarized in Table 3.

The prevalence of DED was more in males (65.3% males, 34.7% females) and in patients between 21 and 40 years of age (52.1%). Majority of patients belonged to the urban areas (65.02%) as compared to a rural background (34.98%).

Table 1: Demographic profile of 15,625 patients who were administered the Ocular Surface Disease Index questionnaire

Demographic characteristics	Number of patients (%)
Age	
≤20	1997 (12.78)
21-40	7625 (48.80)
>40	6003 (38.42)
Sex	
Male	11,211 (71.75)
Female	4414 (28.25)

Table 2: Demographic profile of patients presenting with dry eye disease to a tertiary care ophthalmic setup

Demographic characteristics	Number of patients (%)
Age	
≤20	392 (7.84)
21-40	2605 (52.1)
>40	2003 (40.06)
Sex	
Male	3264 (65.28)
Female	1736 (34.72)
Occupation	
Desk job with computer use	171 (3.42)
Not involving desk job and computer use	4829 (96.58)
Severity of DED	
Mild	496 (9.92)
Moderate	3069 (61.2)
Severe	1444 (28.88)

DED: Dry eye disease

Patients involved in desk jobs with computer use were more predisposed to develop DED.

A bivariate analysis of the risk factors associated with the development of severe DED as well as a multivariate analysis of risk factors associated with DED was undertaken. Significant odds of having severe DED were associated with age, occupation, VDT use, cigarette smoking, and contact lens use [Table 4].

There was no significant difference in the severity of the disease between males and females (P = 0.18). Occupation involving desk job with regular computer usage was associated with the development of dry eye, with 89.47% of computer users having severe DED. Hours of video display terminal (including computers, television, and mobile phone screens) usage significantly correlated with DED (P < 0.001), and 89.98% patients with 4 h or more of VDT use had severe dry eye (adjusted OR 60.2; 95% confidence interval [CI] 43.9–82.7).

Cigarette smoking (P < 0.001, OR 1.5; 95% CI 1.19–1.88) and contact lens usage (P < 0.001, OR 6.4; 95% CI 3.31–12.65) were identified as significant risk factors for severe DED.

There was no significant association between severe DED and the presence of systemic disease, systemic or ocular allergy, previous ocular surgery, alcohol intake or any systemic, or topical medications including steroid use.

Objective tests were undertaken in 552 patients (1104 eyes) with DED. Of these, 18.65% (103/552) had nonsevere DED (mild and moderate), and the remaining 81.3% (449/552) had severe DED. The mean Schirmer's test values were 25.0 ± 8.4 mm in cases with mild DED, 16.9 ± 6.6 mm in cases with moderate DED, and 14.5 ± 7.1 mm in cases with severe DED. The mean TBUT was 10.5 ± 1.6 s in cases with mild DED, 7.1 ± 2.0 s in cases with moderate DED and 4.9 ± 2.3 s in cases with severe DED. A Schirmer's test value of <5.5 mm (indicative of severe DED) was observed in only 5.3% cases (58 eyes). TBUT of <10 s (indicative of tear film instability) was observed in 95.8% cases (1058 eyes).

Discussion

DED is one of the most prevalent ophthalmic disorders and may have an adverse impact on the quality of life. In addition to causing various disabling symptoms, it may also compromise

Table 3: Mean Ocular Surface Disease Index scores and domain scores in patients with dry eye disease

Severity of DED	Number of patients	Mean OSDI score	Domain A score (ocular symptoms)	Domain B Score (vision related functions)	Domain C score (environmental triggers)
Mild	496	20.59±1.14	4.5±0.5	1.62±0.56	2.7±0.79
Moderate	3060	28.60±2.68	5.52±0.76	3.28±1.1	4.05±1.09
Severe	1444	42.32±7.82	7.73±2.48	6.1±3.77	5.46±1.40

OSDI: Ocular Surface Disease Index, DED: Dry eye disease

Table 4: Bivariate and multivariate analysis of factors associated with severity of dry eye disease

Risk factor (s)	Severe DED (n=1444)	Nonsevere DED (n=3556)	P	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age (years)					
≤20	94	298	0.01	1.0	1.0
21-40	832	1773		1.5 (1.1-1.9)	1.46 (1.1-1.9)
≥40	518	1485		1.1 (0.9-1.4)	1.73 (1.2-2.3)
Female gender	481	1255	0.18	0.9 (0.8-1.04)	1.2 (1.08-1.47)
Desk job with computer use	153	18	<0.001	23.2 (14.2-38.1)	5.8 (3.0-11.0)
VDT users (hours of usage)					
0-<2 h	200	1423	<0.001	1	1
2-<4 h	705	2073		2.4 (2.0-2.8)	2.5 (2.1-2.9)
≥4 h	539	60		63.9 (47.1-86.7)	60.2 (43.9-82.7)
Presence of systemic disease	221	617	0.07	0.8 (0.7-1.01)	
Steroid use	6	31	0.88	0.4 (0.19-1.)	
Smoking	130	220	<0.001	1.5 (1.19-1.88)	2.14 (1.6-2.7)
Alcohol	10	16	0.20	1.5 (0.6-3.4)	
Systemic allergy	19	30	0.13	1.5 (0.8-2.79)	1.79 (0.93-3.4)
Ocular allergy	8	15	0.50	1.31 (0.5-3.1)	
Use of topical medications	4	7	0.50	1.4 (0.41-4.81)	
Use of systemic medications	122	334	0.29	0.8 (0.7-1.1)	
Contact lens use	31	12	<0.001	6.4 (3.3-12.6)	5.1 (2.1-12.4)
Previous ocular surgery	89		0.20	1.17 (0.9-1.5)	

OR: Odds ratio, CI: Confidence interval, VDT: Visual display terminal

the results of the corneal, cataract, and refractive surgical procedures.

Several objective tests have been developed to diagnose and grade the severity of DED. However, these tests show poor repeatability, significant interobserver variability and correlate poorly with the patient symptoms as well as the quality of life.[2-4] Different patient-reported outcome (PRO) questionnaires have been developed to assess the quality of life in patients with DED, which act as a useful tool to aid in the screening, monitoring, and management of DED.[5,17] Two validated, reliable dry eye questionnaires are currently available that are in accordance with the FDA PRO guidelines: OSDI and the impact of dry eye on everyday life questionnaire.[5,17-20] In our study, we used the OSDI questionnaire as the basic tool for screening the patients. Its shorter completion time, easy comprehension by patients, and no additional cost make it ideal for clinical use in the outpatient department.[5,20]

The prevalence of dry eye in our study based on OSDI questionnaire is 32%. The prevalence of DED in India is higher than the global prevalence and ranges from 18.4% to 54.3%.[9,13] The vast disparity in the prevalence of DED may be attributed to endemic geographic variations as well as the use of different diagnostic criteria by various studies. Moreover, we relied on only symptoms to estimate the prevalence of DED, which may have resulted in an overestimation of the prevalence of DED.

In our study, the majority of patients with DED were in the age group of 21–40 years. The previous epidemiological studies often exclude this age group, and may, therefore, have underestimated the true prevalence of DED.[6,9,10] A selection bias toward the younger population cannot be ruled out, as the older population visiting the hospital for ocular pathologies such as cataract is less likely to consent to answering the questionnaire.

Females are affected more commonly than males in a majority of studies.[6-13] We observed a significantly higher occurrence of DED in males. Since ours was a hospital-based study, this trend could be attributed to the lack of treatment-seeking behavior among females in the developing countries. The Salisbury Eye Evaluation study also reported males to be more commonly affected than females; however, it included only patients more than 65 years of age.[21]

Desk job with computer use was significantly associated with the risk of developing severe DED. The low-relative humidity in indoor office environment and air-conditioned rooms negatively impacts the tear film by causing desiccation of the eye. We observed a strong association between VDT usage and severe DED. Computer use for more than 8 h a day has been reported as a significant risk factor for DED, mainly attributed to the decrease in blink rate while using these devices, thereby hampering the uniform distribution of the tear film over the ocular surface.[22] Since the main route of tear elimination is through evaporation, longer periods of eye opening and the higher gaze angle when viewing a computer screen results in faster tear loss which further worsens the dry eye. We observed 89.98% of dry eye cases with 4 h or more of VDT usage had severe DED. Increasing use of computers, laptops, tablets, smartphones and television has led to an increase in the prevalence of DED in the younger population.

We observed a significant association of DED with contact lens usage as well as smoking. Contact lens usage may cause dry eye or aggravate preexisting DED.[23,24] Nearly 50% of contact lens users may complain of symptoms of dryness, discomfort, grittiness, irritation, burning, or foreign body sensation.[23,24] Smoking may affect the tear film stability as well as ocular surface sensitivity, and a significant association has been reported between smoking and DED.[25]

We did not observe any association with systemic comorbidities, allergies, previous ocular surgery, alcohol or medication use, either systemic or topical.

Only 552 patients consented to undergo objective tests for the evaluation of DED. The patients answering the questionnaire were visiting the hospital for a specific ocular purpose and were less likely to consent for contact examination after answering the questionnaire. The prevalence of severe dry eye was found to be 81.3%% in this subgroup as against 28.88% when classified on the basis of questionnaire. This may be explained on the basis that patients with severe DED were more likely to give consent for further invasive clinical tests as compared to patients with mild-moderate DED. This further highlights the superiority of questionnaires over objective tests as a screening tool for DED. A Schirmer's test value of < 5.5 mm (indicative of severe DED) was observed in only 5.3% cases (58 eyes), and the mean Schirmer's test value was more than 10 mm in all severity grades of DED. This may be a result of reflex tearing during the examination and is also indicative of less prevalence of aqueous tear deficiency type dry eye in our study. A tear-film instability was observed in 95.8% patients with DED. A mean TBUT of 10 s or more was observed in cases with mild TBUT, which may indicate an overestimation of the prevalence of DED by the OSDI questionnaire.

The inherent bias associated with hospital-based studies is a limitation of our study. Rural population staying in far-flung areas with limited access to healthcare, females and elderly are less likely to visit the hospital due to sociocultural environment prevalent in developing nations. Moreover, the patients had come for specific reasons mostly not pertaining to DED, and these patients were usually not willing to undergo further examination.

To the best of our knowledge, ours is one of the largest studies which screened 15625 individuals and identified the presence of DED in 5000 individuals based on a validated subjective questionnaire. We included all patients more than 10 years of age. Majority of epidemiology studies have included patients more than 40 years of age.[6,9,10] However, with the increasing use of VDT by the younger age group, specifically teenagers, there is a need for the epidemiological studies to broaden their inclusion criteria to obtain an accurate estimate of the prevalence of DED.

Conclusions

We observed the prevalence of DED in North India to be 32%, with the age group of 21–40 years affected most commonly. VDT use, smoking, and contact lens use were associated with increased odds of developing DED.

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Conflicts of interest

There are no conflicts of interest.

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