Research Article

The prevalence and clinical profile of dry eye in tertiary hospital based normal healthy population in Uttarakhand, India

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ABSTRACT

Background: Dry eye is a multifactorial disorder of the tear film due to lack of tears or its excessive evaporation which can potentially damage the ocular surface and is associated with symptoms of ocular discomfort as defined by the National Eye Institute (NEI) Industry workshop in 1995. Objective of the study was to study the prevalence and the clinical profile of dry eye in hospital-based normal healthy population.

Methods: In this observational study, 503 patients were screened for dry eye on the basis of questionnaire adopted from Dry Eye Workshop questionnaire which included five symptoms. On the basis of two or more than two symptoms, patients were divided into two groups Group I and Group II respectively. All patients underwent routine ophthalmological examination along with evaluation of tear parameters like Schirmer's test I, tear film break-up time, slit lamp assisted tear meniscus height measurement, Rose Bengal staining and tear film thinning time. On the basis of questionnaire and tear parameters, 235 patients were found eligible for the study. Final grading of dry eye into four grades was done according to Dry Eye Workshop. Severity of dry eye was divided into three grades as mild, moderate and severe with total score of <3, 3-4, >4 respectively. The data was analysed by using Pearson’s correlation of coefficient and multiple comparison tests with SPSS 22 version. P value<0.05 was taken statistically significant.

Results: The prevalence of dry eye in our study was found to be 46.71%. Mean age of the patients was 47.80±16.37 years. Mild, moderate and severe dry eye was seen in 136 (57.87%), 92 (39.14%) and 3 (1.27%) patients respectively. Mean standard value of Schirmer’s test I, tear film break-up time, tear meniscus height and tear film thinning time were 13.59±6.65, 9.66±2.45, 0.39±0.15 and 10.15±2.24 respectively. The P values of all tear parameters were 0.001 which were statistically significant.

Conclusions: Dry eye disease prevale in greater extent even in asymptomatic healthy patients and its reliable diagnosis can be done on the basis of both symptoms and tear parameters. Screening of symptomatic patients without any sign of dry eye in the preclinical phase is important for its early detection.

Keywords: Dry eye, Tear film break-up time, Schirmer's test I, Dry eye questionnaire

INTRODUCTION

Dry eye is a multifactorial disorder of the tear film due to lack of tears or its excessive evaporation which can potentially damage the ocular surface and is associated with symptoms of ocular discomfort as defined by the national eye institute (NEI) industry workshop in 1995. Dry eye is a disturbance of lacrimal function unit (LFU) which is an integrated system comprising of lacrimal glands, ocular surface, lids, sensory and motor nerves that connect them. Symptom assessment is a key component of diagnosis of clinical dry eye and may provide a more integrated view of clinical condition over time. Few
standardized symptom questionnaires has been designed for formal research purposes which are most repeatable of the commonly used diagnostic tests.2

Besides questionnaire, several tests include Schirmer’s test, Tear film break up time (TBUT) and Rose bengal staining are being used for dry eyes assessment. The objective of the study was to estimate the prevalence of dry eye and to evaluate the relationship of its clinical profile and various tear parameters in normal healthy population.

METHODS

The research was approved by institutional research ethical committee and was in accordance to the tenets set forth in Declaration of Helsinki. The present observational study was conducted from May 2013-July 2015 in the department of Ophthalmology of a tertiary eye care centre in Himalayan Institute of medical sciences, Dehradun, Uttarakhand, India.

The normal healthy 503 subjects with symptoms of dry eyes without any prior treatment were included in study after obtaining informed written consent. Patients suffering from acute ocular infections with corneal or conjunctival pathology, contact lens users, systemic ailments like diabetes, hypertension, cardiac illnesses, thyroid disorders, rheumatoid arthritis, sjogren syndrome and those who had undergone extraocular or intraocular surgery were excluded from the study.

All the patients having symptoms of dry eye underwent interview in form of questionnaire adopted from Dry Eye Workshop (DEWS) questionnaire which included five symptoms (Table 1).

Table 1: Questionnaire.

| Symptom                      | Yes | No |
|------------------------------|-----|----|
| Foreign body sensation       |     |    |
| Dryness                      |     |    |
| Photophobia                  |     |    |
| Burning sensation            |     |    |
| Blurred vision after prolonged reading |     |    |

When the subject reported a symptom to occur sometimes, often or all the time was positive response and it was negative when reported to occur rarely or never. According to the response to each of the questions, the symptom score was calculated. On the basis of above given questionnaire patients were divided into two groups-

- Group I: Patients having any of the two symptoms of dry eye.
- Group II: Patients having more than two symptoms of dry eye.3

The same examiner performed all the tests. Ocular examination included lid surface, lid position and meibomian gland evaluation. Best corrected visual acuity (BCVA), Slit lamp biomicroscopy and Schirmer’s test I were done for all the subjects. Tear film thinning time (TTT) was done by observing the time of distortion of corneal mires on manual keratometer in between two blinks.

Schirmer’s test I was performed by placing a Schirmer’s strip (Whatman filter paper no. 41 5x 35 mm) at the junction of the mid and the lateral third of lower eyelid.

After 5 minutes, Schirmer strip was removed ,wet strip was measured and dryness was graded as follows mild<10 mm, moderate <5 mm and severe <2mm. TBUT was recorded in seconds, from the time of eyelid opening to the appearance of first black spot in between two blinks. Tear meniscus height (TMH) was measured in mm on slit lamp from the centre of lower lid to upper limit of tear lake as shown in Figure 1 A,B,C.

Van Bisterveld scoring was done by observing the staining pattern of ocular surface by using Rose Bengal stained strips. Ocular surface was divided into three zones as Zone 1 if stains only cornea, Zone 2 if stains nasal bulbar conjunctiva and Zone 3 if stains temporal bulbar conjunctiva as shown in Figure 2 A, B, C. Score 0-3 given for each zone on the basis of staining pattern (0 = normal, 3= highest)

- Score: 1+ few separated spots
- Score: 2+ many separated spots
- Score: 3+ confluent spots
Maximum score: 9 which indicates severity.

On the basis of questionnaire and tear parameters, 235 patients were found eligible for this study. Final grading of dry eye was done according to DEWS.³

- Grade 1-mild discomfort, TBUT variable, Schirmer’s score variable
- Grade 2-moderate discomfort, TBUT <10 sec, Schirmer’s score <10mm
- Grade 3-severe discomfort, TBUT <5sec, Schirmer’s score <5mm
- Grade 4-disabling discomfort, TBUT immediate, Schirmer score <2mm

(Grade 4 must have symptoms and signs)

Severity was divided into three grades on the basis of DEWS grade scoring explained above as Mild grade: total score of <3, Moderate grade: score 3-4, Severe grade score >4 (Table 2).

**Statistical analysis**

The data thus obtained was subjected to analysis using Statistical Package for Social Sciences (SPSS) software version 22. The descriptive statistics was used to express data in terms of frequency and percentage.

To avoid statistical complications from correlation between the right and left eyes, measurements from only the right eye of each patient were analyzed. Data analysis was done using multiple comparison tests. Tear parameters were correlated and compared using Pearson’s correlation of coefficient and multiple comparison tests respectively. P value < 0.05 was taken as statistically significant.

**RESULTS**

In this study, 503 patients were taken on the basis of symptoms of dry eye. 235 (46.71%) were found eligible for this study as per tear parameters. The prevalence of dry eye in the present study was found to be 46.71%. In a total of 503 patients prevalence of dry eye was maximum (66.37%) in the age group of 21 to 40 years in males (48.8%) with mean age of 47.80±16.37 years.

Out of 235 eligible patients maximum 98 (41.70%) patients were between the age group of 41 to 60 years. Males and females were 122 (51.91%) and 113 (48.08%) respectively.

**Table 2: Grading according to DEWS (2007).**

| Symptoms          | 1 | 2 | 3 | 4 |
|-------------------|---|---|---|---|
| Schirmer’s score  |   |   |   |   |
| Mild              | <3|   |   |   |
| Moderate          | 3-4|  |   |   |
| Severe            | >4|   |   |   |
| TBUT              |   |   |   |   |
| Male              | 250 (49.7%) | 122 (51.91%) | 48.8 |
| Female            | 253 (50.2%) | 113 (48.08%) | 44.66 |
| Age               |   |   |   |   |
| <20year           | 33 (6.5) | 8 (3.40) | 24.24 |
| 21-40year         | 113 (22.4) | 75 (31.91) | 66.37 |
| 41-60year         | 169 (33.5) | 98 (41.70) | 57.98 |
| >60year           | 188 (37.3) | 54 (22.97) | 28.72 |

**Table 3: Prevalence of dry eye according to age and sex.**

**Table 4: Grading of dry eye according to Schirmer’s I test and tear film breakup time (TBUT).**

| Grading of dry eye | Number of patients (n) | Schirmer’s (mm/5min)% | TBUT (sec)% |
|--------------------|------------------------|-----------------------|-------------|
| Normal (>15)       | 78 (33.19)             | 5 (2.12)              |
| Mild (10-15)       | 89 (37.87)             | 136 (57.87)           |
| Moderate (5-9)     | 58 (24.68)             | 92 (39.14)            |
| Severe (<5)        | 10 (4.25)              | 3 (1.27)              |
| Total              | 235                    | 235                   |

Male female ratio was 1.06:1 as shown in Table 3. On the basis of symptoms, patients were divided into two groups- group I and group II and maximum 126 (53.61%) patients were in group II.
Table 4 revealed that maximum patients 89 (37.87%) 136 (57.87%) were seen with mild dry eye on the basis of Schirmer’s I and TBUT respectively. Mean standard value of Schirmer’s test I, TBUT, TMH and TTT were 13.59±6.65, 9.66±2.45, 0.39±0.15 and 10.15±2.24 respectively as shown in Table 5. Maximum patients 105 (44.68%) were seen with moderate severity of dry eye according to DEWS grading as shown in Table 6.

### Table 5: Correlation of various tear parameters.

| Dry eye test                                    | Range   | Mean±SD   |
|------------------------------------------------|---------|-----------|
| Schirmer’s test I (mm)                          | 3-35    | 13.59±6.65|
| Tear film breakup time (sec)                   | 4-16    | 9.66±2.45 |
| Tear meniscus height (mm)                      | 0.2-0.8 | 0.39±0.15 |
| Tear film thinning time (sec)                  | 5-16    | 10.15±2.24|

### Table 6: Severity of dry eye according to dry eye work shop (DEWS).

| Grading of dry eye | Number of patients(n) | Percentage % |
|--------------------|------------------------|--------------|
| Mild               | 84                     | 35.74        |
| Moderate           | 105                    | 44.68        |
| Severe             | 46                     | 19.57        |
| Total              | 235                    | 100          |

### Table 7: Correlation between grading of dry eye and tear parameters.

| Grading of dry eye | Schirmer’s I (Mean±SD) | Tear film breakup time (Mean±SD) | Tear meniscus height (Mean±SD) | Tear film thinning time (Mean±SD) |
|--------------------|------------------------|---------------------------------|--------------------------------|----------------------------------|
| Mild (n=84)         | 16.54±6.25             | 11.00±2.20                      | 0.52±0.11                      | 11.35±2.08                      |
| Moderate (n=105)    | 14.02±6.26             | 9.58±2.15                       | 0.38±0.12                      | 10.14±1.94                      |
| Severe (n=46)       | 7.19±3.00              | 7.43±1.77                       | 0.22±0.07                      | 8.00±1.38                       |
| p* value            | 0.001                  | 0.001                           | 0.001                          | 0.001                           |

p* - p value statistically significant calculated by multiple comparison test.

The mean standard values of Schirmer’s test I, TBUT, TMH and TTT for mild, moderate and severe dry eye were 16.54±6.25, 11.00±2.20, 0.52±0.11, 11.35±2.08, 14.02±6.26, 9.58±2.15, 0.38±0.12, 10.14±1.94. And 7.19±3.00, 7.43±1.77, 0.22±0.07, 8.00±1.38 respectively shown in Table 7. The p values for all tear parameters were 0.001 which was statistically significant.

**DISCUSSION**

In present study prevalence of dry eye was 46.71% which falls within this range of 6.7% to 66.2% as reported. Maximum patients 126 (53.61%) were in Group II with more than two symptoms of dry eye which may be due to irregularities in the corneal surface caused at high altitudes due to increased evaporation, low humidity and winds leading to poor wetting of the ocular surface as reported by Sahai et al. Mean age of the patients in our study was 47.80±16.37 years. The prevalence of dry eye increased progressively with age. 98 (41.70%) patients were in age group of 41 - 60 years, which is consistent with findings in other studies. In this study the prevalence of dry eye was seen more in males 122 (51.91%), similar male preponderance has been reported in study done by Tseng et al. Exposure to excessive wind, sunlight or high temperature and air pollution were significantly related to dry eye. The hot and dry atmosphere aggravate symptoms of dry eye like grittiness, sandy and foreign body sensations which might compel the patient to seek advice.

Smoking and drugs have been suggested as risk factors in various studies. 14 (5.95%) patients were smokers, exposure to tobacco smoke or cigarette smoke predisposes tear film instability by its direct irritant action on the eyes with eventual decrease TBUT by 30-40%. Smoking represents a modifiable risk factor in dry eye causation. Gupta et al reported no significant association of dry eye with systemic disease, use of ocular or oral medications and exposure to alcohol or cigarette smoking.

In this study, 13 (5.53%) of the patients used topical drugs off and on for minor ocular ailments. It has been seen that topical drugs with added preservatives may disrupt one or more components of the tear film leading...
In accordance, noninvasive tear film instability is a significant issue. The present study demonstrated that dry eye was more prevalent in emmetropes (51.06%) than in ammetropes (48.93%). However, past studies have mentioned that prevalence of dry eye was more in those with refractive error (corrected and uncorrected) as compared to emmetropes.

It has been postulated that persons with refractive errors have tendency to rub their eyes and apart from the introduction of infective material, sebum, sweat and particulate foreign substances into the eye predispose to tear film instability as stated by Sahai et al. It has been postulated in the studies by Sahai et al and Gupta et al that presence of dry eye symptoms and environmental influences (temperature, humidity, wind, irritants, contact lens wear), systemic inflammatory conditions are important in determining the degree of disease manifestation. 5,9,12

In the present study moderate dry eye was detected in 105 (44.68%) symptomatic patients without any sign of dry eye as concluded by Gupta et al that less than 60% of subjects with other objective evidence of dry eye are symptomatic. 9 Screening of patients in the preclinical phase when symptomatic without any sign of dry eye is important for its early detection. 10 But the use of symptoms alone will result in missing a significant percentage of dry eye patients so combined approach with symptoms and signs of dry eye is important tool for diagnosis of dry eye. 7

It has been observed that due to poor correlation between patient symptoms and clinical signs, diagnosis of dry eye require the use of multiple tests. Most of the time, two or more tests are used to diagnose dry eye. Symptom questionnaires and objective dry eye tests are used to help to establish a diagnosis of dry eye syndrome and to assess the effects of treatments or to grade disease severity as published in the studies by Schein et al. 9 In this study on the basis of tear parameters maximum patient were having mild dry eye but in collaboration with the symptoms moderate dry eye was seen in maximum subjects.

In this study grading of dry eye was done on the basis of symptoms and tear parameters as mild, moderate and severe. The correlation between all the tear parameters was found statistically significant (P=0.001). In the present study there was significant positive correlation between all tear parameters Schirmer’s I, TBUT, TMH and TTT for mild, moderate and severe dry eye which shows an agreement with Wang and Ibrahim et al who reported a positive correlation between TBUT and lower TMH. 13,14 Li et al found strong correlation between lower tear meniscus and clinical parameters like TBUT, noninvasive TIBUT and Schirmer’s I which was in accordance with the present study. 15

In this study, a positive correlation was found between TBUT and TTT as both of these tests are used for qualitative analysis of the tear film. On the contrary according to published literature there was poor correlation between the objective dry eye tests and severity of dry eye, as there is no standardization on the guidelines for the diagnosis. Low degree of standardization and the invasive nature of diagnostic tests can make interpretation challenging which further makes it difficult to compare the results of dry eye tests.

This may be due to the lack of well-defined cut-off values which enables a distinction to be made between healthy and affected eyes as stated in the studies by Schein et al.9 Cynthia et al reported higher tear volume in meobomian gland disease which led to greater corneal epithelial damage due to various changes in tear compositions.16

The present study is unique as it explored the relationship between the clinical symptoms and tear parameters in healthy individuals.

**Limitations**

The limitation of the present study was the fact that all cases of severe corneal /conjunctival pathology, contact lens users, systemic ailments like diabeties, thyroid disorders, rheumatoid arthritis and sjogren syndrome were excluded from the study leading to an underestimation of prevalence of dry eye. In these cases the interpretation of dry eye tests could have been difficult and nonconclusive.

**CONCLUSION**

The prevalence of dry eye in normal healthy population to the tune of 46.71% is suggestive of the fact that dry eye is underdiagnosed disease. Evaluation of tear parameters alone can be misleading in diagnosis of dry eye. Combined approach with the use of clinical symptoms and various tear parameters, a reliable diagnosis of dry eye can be done.

The clinical symptoms and various tear parameters shows positive relationship according to the severity of dry eye in healthy population.

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