

# The clinical profile and prevalence of dry eye in tertiary care hospital-based population

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## ABSTRACT

**Background:** Dry eye is recognized as a growing public health problem and one of the most frequent reasons for visiting an ophthalmologist in middle and old age people. **Objectives:** To the best of our knowledge, very less study has been undertaken in central India on dry eye. The present study was designed to study clinical profile and to evaluate the true prevalence and risk factors of dry eye in central India. **Materials and Methods:** A total of 1562 participants aged 30 years or more visiting ophthalmology department in a tertiary care rural hospital enrolled in a study. Study duration was 18 months. The study design was a prospective, cross-sectional, and observational study. An ocular surface disease index (OSDI) questionnaire was administered to all participants and individuals with OSDI score greater than 12 were further evaluated with dry eye tests in sequence of tear break-up time, lissamine green staining, Schirmer-1 test, and slit-lamp examination for meibomian gland dysfunction. The participants with OSDI Score  $\geq 13$  were diagnosed to be having dry eye. The data were compiled and subjected to statistical analysis using SPSS v.17.0 software (SPSS Inc., Chicago, Illinois, USA).  $P < 0.05$  was considered to be statistically significant. **Results:** Prevalence of dry eye in our study was 24.7%. Prevalence of lipid layer, aqueous layer, and mucin layer deficiency dry eye was 13.8%, 5.2%, and 7.8%, respectively. Increasing age, illiteracy, and menopause were the significant risk factors and female sex, urban habitat, and laborer and factory worker were insignificant risk factors for dry eye. **Conclusion:** Prevalence of dry eye in our study is higher than reported in literature in central India. Lipid anomaly dry eye was the most prevalent, followed by mucin layer deficiency and lastly aqueous tear deficiency.


**KEY WORDS:** Dry Eye; Ocular Surface Disease Index Score; Schirmer's Test; Tear Breakup Time; Meibomian Gland Dysfunction

## INTRODUCTION

Dry eye is recognized as a growing public health problem and one of the most frequent reasons for visiting an ophthalmologist in middle and old age people. The tear film and ocular surface society dry eye workshop II (TFOS DEWS II).<sup>[1]</sup> Redefined

dry eye as a “multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.”

Dry eye may lead to progressive ocular surface disease, increases risk of infections, contact lens intolerance, development of epithelial defects, superficial punctate keratitis, filamentary keratitis, scarring, ocular surface keratinization, sterile corneal ulceration, corneal thinning, sterile corneal melting leading to perforation, and severe visual loss. Hence, correct diagnosis and appropriate management of dry eye are essential.

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## Objective

To the best of our knowledge, very few studies have been undertaken in central India on dry eye. The present study was designed to evaluate the true prevalence of dry eye in central India using standard ocular surface disease index (OSDI) questionnaire and to assess risk factors in the general population so that appropriate treatment is to be administered before it reaches to the stage of corneal blindness.

## MATERIALS AND METHODS

A total of 1562 patients aged 30 years or more enrolled in the study. The study was carried out at the Department of Ophthalmology, Mahatma Gandhi Institute of Medical Sciences, Sevagram (Maharashtra) from May 2014 to December 2015. Approval from Institutional Ethical Committee of Mahatma Gandhi Institute of Medical Sciences was obtained. The study design was a prospective, cross-sectional, and observational study. Written informed consent was taken before enrolling the patients in the study. Patients with history of extra- and intra-ocular surgery within past 6 months, gross lid abnormalities, contact lens users, history of allergic conjunctivitis, and history of acute ocular infections excluded from the study.

A scientifically validated OSDI questionnaire<sup>[2]</sup> was administered to all eligible participants to assess the symptoms of dry eye. The grading of dry eye was made on the basis of OSDI score as mild (13–22), moderate (23–32), and severe (33–100). Data regarding systemic risk factors causing or triggering dry eyes such as connective tissue diseases, Sjögren's syndrome, systemic lupus erythematosis, thyroid disease, leukemia, lymphoma, leprosy, tuberculosis, syphilis, mumps, Vitamin A deficiency, jaundice, cirrhosis, diabetes, and hypertension were recorded. History of chronic use of systemic and ocular medications was noted. Use of contact lens and intravenous drug use data was also recorded. Female patients were specifically asked for usage of oral contraceptives and gynecological history about menopause.

Individuals with OSDI score greater than 12 were further evaluated in detail. Unaided, aided, and best-corrected visual acuity were recorded using visual acuity charts including Snellen's test type for educated patients and Landolt's broken ring type for uneducated patients. Unaided, aided, and pinhole improvement of visual acuity were recorded. Lid, lacrimal apparatus, sclera, conjunctiva, and cornea examined with slit lamp and fundus evaluation done by direct and indirect ophthalmoscopy. Objective test for dry eye carried out in sequence of tear breakup time, lissamine green staining, Schirmer-1 test, and slit-lamp examination for meibomian gland dysfunction performed.

## Tear Breakup Time

A 2% fluorescein strip was moistened with normal saline or antibiotics drops and placed in the lateral one-third of lower lid in a non-anesthetized eye and patient was asked to blink only once or twice to avoid pooling of fluorescein. The stopwatch was set for 10 s. The patient cornea was focused by diffuse illumination using the cobalt blue light of the slit lamp and patient was asked to blink. The time-lapse between the last blink and the appearance of the first randomly distributed dark discontinuity in the fluorescein-stained tear film was noted. Three such readings were taken, and average for these three was recorded. Tear breakup time <10 s was considered positive, indicative of tear film instability and dry eye.

## Lissamine Green Staining

With the help of tear substitute, the impregnated strip was moistened and applied to lower palpebral conjunctiva. After 15 s of staining of ocular surface, conjunctiva and cornea were examined under red-free filter of slit lamp. Van Bijsterveld scoring system was used to grade the staining. The ocular surface was divided into three zones: Nasal bulbar conjunctiva, temporal bulbar conjunctiva, and cornea. Each zone was evaluated and graded from 0 to 3, with 0 for "no staining," 1 for "mild staining," 2 for "moderate staining," and 3 for "extensive staining." An additive score of three or more constituted a positive test for mucin deficiency dry eye.

## Schirmer-1 Test

Pre sterilized a standard Schirmer's strip which is made up of Whatman#41 filter paper measuring 35 by 5 mm was placed at the junction of lateral one-third and medial two-third of lower lid without instilling any anesthetic drops. Inner 5 mm semicircular portion of the strip was folded inside at the posterior lid margin. The patient was advised to avoid squeezing the lids, looking up or moving eyes excessively. The patient was asked to look straight and does natural blinking.

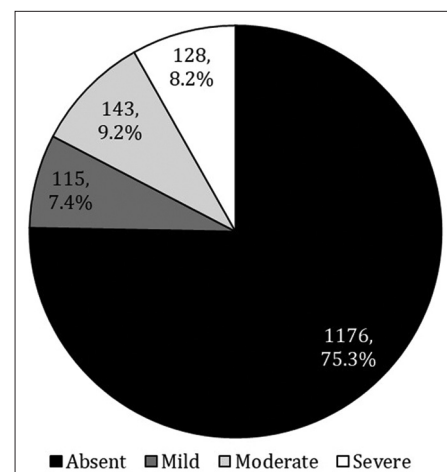


Figure 1: Prevalence of severity of the dry eye

After 5 min, the level of strip wetting (in mm) was noted. Reading <5 mm wetting was considered as positive Schirmer's test and patient is having aqueous deficiency dry eye.

### Slit-Lamp Examination

Patient's upper and lower lid margins were examined under slit lamp for eyelashes, lid thickening, punctum, and meibomian gland orifices. The patient was asked to look up and lower lid just below the margin was pressed against the globe with focusing over the meibomian gland orifices to see if it is blocked or open and type of material expressed out. It was graded from Grade 0 to Grade 3. Grade 0 – for no obstruction, 1 – orifices plugged with serous secretion, 2 – plugged with viscous/toothpaste-like secretion, and 3 – plugged/blocked with no secretion on pressing. Grade of 2 “or” 3 considered as positive for dry eye and suffering from meibomian gland dysfunction.

The data were compiled and subjected to statistical analysis using SPSS v.17.0 software (SPSS Inc., Chicago, Illinois, USA).  $P < 0.05$  was considered to be statistically significant. Categorical variables were analyzed between groups using Chi-square test, and continuous variables were analyzed between groups using independent sample *t*-test.

**Table 1:** Baseline characteristics of study population ( $n=1562$ )

Characteristics	Number	Percentage
Age groups (in years)		
30–39	282	18.1
40–49	467	29.9
50–59	332	21.3
60–69	331	21.2
≥70	150	9.6
Sex		
Male	721	46.2
Female	841	53.8
Place of residence		
Rural	647	41.4
Urban	915	58.6
Occupation		
Agriculture	430	27.5
Homemaker	408	26.1
Laborer/Factory worker	289	18.5
Office worker	10	0.6
Others*	425	27.2
Education level		
Illiterate	366	23.4
Elementary school	242	15.5
High school	474	30.4
College and above	480	30.7

\*Retired, idle, jobless, househusbands, and tailors

## RESULTS

A total of 1562 patients participated in the study. The base line characteristic of study population is described in Table 1. The prevalence of dry eye in our study is 24.7% (386). The dry eye symptoms reported in our study are described in Table 2.

The severity of dry eye among study participants according to grade is shown in Figure 1. Most of the study participants had moderate dry eye (9.2%). Dry eye severity was significantly ( $P = 0.006$ ) more in females compared to males. Females had more prevalence of moderate (87 of 143) and severe dry eye (84 of 128) whereas males had more prevalence of mild dry eye (62 of 115).

The population diagnosed to be having dry eye had significantly ( $P = 0.001$ ) higher average age 54.4 years ( $SD \pm 12.8$  years) compared to no dry eye group 51.0 years ( $SD \pm 12.4$  years). The prevalence of dry eye was increased significantly with age and was significantly higher in patients in 6<sup>th</sup> decade (32.0%) compared to all other age groups ( $\chi^2 15.68$  and  $P = 0.003$ ). We also found statistical significant higher prevalence of dry eye among illiterates (29.8%;  $P = 0.039$ ). The dry eye is more prevalent among female gender (26.6%), residents in urban area (25.6%), and laborer and factory workers (26.3%) but we did not find any statistical difference among these groups [Table 3]. Dry eye is most common among postmenopausal female 69.6% (156/224) compared to non-menopausal female.

Systemic risk factors associated with dry eye are hypertension (7.8%), diabetes mellitus (2.9%), thyroid disorder (2.6%), Sjögren's syndrome (1.6%), other connective tissue diseases (1.8%), Steven Johnson syndrome (0.5%), leprosy (0.3%), and tuberculosis (0.3%). About 5.2% of patients were affected with more than one diseases.

**Table 2:** Dry eye symptoms

Dry eye symptoms	Total study population ( $n=1562$ ) (%)
Uncomfortable in windy conditions	53.0
Gritty eyes	52.7
Problem in watching television	34.8
Uncomfortable in low humidity area	29.7
Sore eyes	24.8
Blurred vision	23.2
Sensitive to light	21.5
Problem in reading	19.8
Problem in driving at night	11.5
Poor vision	8.5
Problem in computer use	5.0
Uncomfortable in air condition	2.8

**Table 3:** Prevalence of dry eye according to age, sex, place of residence, and educational level

Variables	Number of subjects	Dry eye subjects	Prevalence %	P-value (x <sup>2</sup> )
Age groups (in years)				
30–39	282	58	20.6	0.003
40–49	467	104	22.3	
50–59	332	75	22.6	
60–69	331	106	32.0	
≥70	150	43	28.7	
Sex				
Male	721	162	22.5	0.057
Female	841	224	26.6	
Place of residence				
Rural	647	153	23.7	0.412
Urban	915	233	25.6	
Occupation				
Agriculture	430	101	23.5	0.092
Homemaker	408	103	25.3	
Laborer/Factory worker	289	76	26.3	
Office worker	10	2	20.0	
Others*	425	104	24.5	
Education level				
Illiterate	366	109	29.8	0.039
Elementary school	242	64	26.5	
High school	474	474	25.6	
College and above	480	106	22.1	

\*Retired, idle, jobless, househusbands, and tailors

Most of the dry eye patients in our study had normal vision (70.0%), followed by mild to moderate vision loss (17.4%), severe vision loss (7.8%), total blindness (2.6%), near-total blindness (2.1%), and least had profound vision loss (0.8%).

Ocular morbidity among dry eye patients is shown in Table 4 according to frequency of their occurrence.

The association of dry eye disease with different diagnostic dry eye tests including tear breakup time, slit-lamp examination, Schirmer's, and lissamine green staining was summarized in Table 5. The results demonstrated higher percentage of tear breakup time test positive (93.3%) in dry eye patients compared to other diagnostic tests. Tear breakup time t positive among different age group of 30–39, 40–49, 50–59, 60–69, and ≥70 years was 94.8%, 98.1%, 98.7%, 88.7%, and 83.7%. It was more prevalence in 5<sup>th</sup> decade. Among gender it was significantly ( $P = 0.003$ ) more prevalent among female (95.5%) compared to male (90.1%).

Prevalence of lipid layer deficient dry eye disorder was 55.7% in dry eye patients (386) and 13.8% in total screened population (1562). The lipid layer deficiency among dry eye patients of the different age group of 30–39, 40–49,

**Table 4:** Ocular morbidity in dry eye patients (386)

Disorder	Number of subjects	Percentage
Meibomianitis	57	14.8
Xerosis	12	3.1
Pterygium	12	3.1
Blepharitis	11	2.9
Decreased corneal sensation	8	2.1
Bitot spots	7	1.8
Alacrimia	5	1.3
Corneal opacity	6	1.6
Corneal filament	4	1.0
Trichiasis	3	0.8
Lid retraction	1	0.3
Ectropion	1	0.3
Symblepharon	1	0.3
Conjunctival fibrosis	1	0.3
Corneal infiltration	1	0.3
Adherent leukoma	1	0.3
Multiple disorder*	11	2.9

\*Eyelid, corneal disorder

50–59, 60–69, and ≥70 years was 50.0%, 60.6%, 45.3%, 64.2%, and 58.1%, respectively, with more prevalence in 6<sup>th</sup> decade. We did not find any statistically significant



**Table 5:** Dry eye test results

Test	Positive	Percentage of dry eye (386)	Percentage of total population (1562)
Tear breakup time	360	93.3	23.1
Slit-lamp examination (Lipid layer deficiency)	215	55.7	13.8
Lissamine green staining (Mucin layer deficiency)	122	31.6	7.8
Schirmer's test (Aqueous layer deficiency)	81	21.0	5.2

among age group whereas it was high in male (57.1%) compared to female (54.9%) without any statistical significance.

Prevalence of aqueous layer deficient dry eye disorder was 21.0% in dry eye patients (386) and 5.2% in total screened population (1562). The aqueous layer deficiency among dry eye patients between age group of 30–39, 40–49, 50–59, 60–69, and  $\geq 70$  years was 17.2%, 24.0%, 22.7%, 21.7%, and 16.3%, respectively, with more prevalent in 4<sup>th</sup> decade. We did not find any statistically significant among age group whereas female (25.0%) had more prevalence of aqueous layer deficiency compared to male (16.1%) which was statistically significant ( $P = 0.023$ ).

Prevalence of mucin layer deficient dry eye disorder was 31.6% in dry eye patients (386) and 7.8% in total screened population (1562). Prevalence between age group of 30–39, 40–49, 50–59, 60–69, and  $\geq 70$  years was 36.2%, 33.7%, 36.0%, 28.3%, and 27.9%, respectively, with more prevalent in 5<sup>th</sup> decade. However, it was not statistically significant among different age groups. Whereas among gender, females (35.7%) had more prevalence of mucin layer deficiency compared to male (25.9%). The results demonstrate female sex was the most significant ( $P = 0.041$ ) risk factors for mucin layer deficiency dry eye disorder compared to males. The result demonstrated most of the dry eye patients are affected by lipid layer deficiency followed by mucin and aqueous layer deficiency.

## DISCUSSION

The prevalence of dry eye on the basis of OSDI questionnaire in our study was 24.7% (386 dry eye patients out of total screened population of 1562). Demographic data analysis showed that dry eye is most prevalent among older age population (32.0% in 6<sup>th</sup> decade) and illiterates (29.8%) with  $P < 0.05$ . We did not found any statistically significant difference in prevalence of dry eye among participant based on their gender, occupation, and residence. Sub analysis of severity of dry eye among gender, we found females are mostly affected by severe grade of dry eye disease compared to male ( $P = 0.006$ ). We found most common symptom reported by dry eye patients were uncomfortable in windy conditions (53.0%) followed by gritty eyes (52.7%). Meibomianitis (14.8%) is the most common ocular morbidity found in dry eye

patients. Tear breakup time was found positive in 93.3% of dry eye patients, which was very useful tool for diagnosis of dry eye. We found lipid layer deficiency (57.7%) is most common tear film abnormality followed by Mucin (31.6%) and aqueous layer deficiency (21.0%) in dry eye patients.

The tear film and ocular surface society dry eye workshop II<sup>[3]</sup> epidemiology report stated globally prevalence of dry eye ranges from 5 to 50%. In our study, the prevalence of dry eye was 24.7%. However, Gupta *et al.*<sup>[4]</sup> study reported higher prevalence (29.3%) compared to our study as this study included older study participants ( $>40$  years) compared to our study which might be a reason for higher prevalence as dry eye is more prevalent in older age groups. Whereas Sahai and Malik<sup>[5]</sup> study reported that lower prevalence (18.4%) of dry eye compared to our study might be due to inclusion of younger age group (2<sup>nd</sup> decade). Rege *et al.*<sup>[6]</sup> study reported prevalence of 15.4% with McMonnies questionnaire. Choudhary *et al.*<sup>[7]</sup> reported the prevalence of dry eye in Madhya Pradesh was 9.6%. Beaver dam eye study<sup>[8]</sup> reported that prevalence of dry eye was 14.4%. Beijing eye study<sup>[9]</sup> reported a prevalence of 21.0% based on dry eye symptoms. The wide disparity in prevalence of dry eye due to lack of standardization of type of patients enrolled in the study, dry eye questionnaires, objective tests, and diagnostic criteria. Despite availability of numerous clinical and objective tools, no gold standard diagnostic tests exist. The prevalence of dry eye was increased significantly with age with relative peak in 6<sup>th</sup> decade (32.0%). Rege *et al.*<sup>[6]</sup> study reported similar trends with relative peak in 6<sup>th</sup> decade. However, Sahai and Malik<sup>[5]</sup> reported similar trend but relative peak in 3<sup>rd</sup> decade (20.0%) while Gupta *et al.*<sup>[4]</sup> study reported peak in 8<sup>th</sup> decade (41.2%). Beaver dam eye study<sup>[8]</sup> reported variation from 8.4% in younger than 60 years to 19.0% in older than 80 years. Among gender, females had higher prevalence of dry eye (26.6%) compared to males (22.5%) with dry eye severity was significantly more in females compared to males. Similarly, Sahai and Malik<sup>[5]</sup> study based on 13 symptoms questionnaire reported that females (22.8%) had significantly higher prevalence than males (14.9%). Gupta *et al.*<sup>[4]</sup> study based on OSDI questionnaire found higher prevalence of dry eye in female (34.3%) compared to male (31.0%). Gupta *et al.*<sup>[4]</sup> in their study reported higher prevalence of dry eye in females (27.4%) compared with males (11.8%). Moss *et al.*<sup>[8]</sup> also reported higher prevalence of dry eye in women (17.0%) compared with men (11.1%) and this difference was persisted across all ages. Beijing eye study<sup>[9]</sup> reported in their multivariate analysis that females had more prevalence of dry eye symptoms than males. Physician health studies<sup>[10]</sup>

estimated the prevalence and risk factors of dry eye among American men and compared with similar cohort of females and reported that significant higher prevalence of dry eye among women in all age groups. However, Lee *et al.*<sup>[11]</sup> study ( $n = 1058$ ) based on six items dry eye symptom questionnaire reported prevalence of dry eye symptoms in male (32.7%) significantly ( $P < 0.001$ ) higher than females (22.8%). In our study, dry eye is more prevalent among residents in urban area (25.3%) than rural area (23.7%). In contrast, Sahai and Malik<sup>[5]</sup> reported more prevalence in rural area (19.6%) compared to urban area (17.5%). Dry eye is more prevalent among laborer and factory workers (26.3%), followed by homemakers (25.3%), agriculture (23.5%), and office workers (20.0%). In Sahai and Malik<sup>[5]</sup> study farmers/laborer (25.3%) affected more, followed by homemakers (20.5%), factory workers (14.3%), office workers (12.8%). Choudhary *et al.*<sup>[7]</sup> study reported laborer/farmers most affected by dry eye followed by office workers and homemakers. Dry eye is most common among postmenopausal female 69.6% (156/224) compared to non-menopausal female. Estrogen deficiency in menopausal female leads to decrease in tear production from lacrimal gland eventually making postmenopausal female more prone for dry eye disorder. Similarly, Jamaliah and Fathilah<sup>[12]</sup> reported 51.3% (59/115) postmenopausal females with dry eye disorder, whereas Sahai and Malik<sup>[5]</sup> reported equal distribution of dry eye among both post and non-menopausal females (22.8%). Systemic risk factors associated with dry eye patients are hypertension (7.8%), diabetes mellitus (2.9%), thyroid disorder (2.6%), Sjögren's syndrome (1.6%), other connective tissue diseases (1.8%), Steven Johnson syndrome (0.5%), leprosy (0.3%), and tuberculosis (0.3%), whereas Beaver dam eye study<sup>[8]</sup> reported risk factors independently and significantly associated with dry eye disease was arthritis, smoking, caffeine use, thyroid disease, gout, diabetes, multivitamin use, and total to high-density lipoprotein cholesterol ratio. Tomsic *et al.*<sup>[13]</sup> in their study reported the prevalence of Sjögren's syndrome dry eye of 0.1% whereas we found that 1.6% of total dry eye patients were suffering from Sjögren's syndrome. In our study, 93.3% of dry eye patients were positive for tear breakup time which was higher compared to other objective diagnostic tests. Similarly, Gupta *et al.*<sup>[4]</sup> reported that 96.0% of dry eye patients were positive for tear breakup time. Rege *et al.*<sup>[6]</sup> reported 82.5% positive for tear breakup time. The overall prevalence of tear breakup time in screened population was 23.1%. Most of the dry eye patients are affected by lipid layer deficiency (55.7%) followed by mucin layer (31.6%) and aqueous layer deficiency (21.0%). The overall prevalence of these anomalies in our screened population was 13.8% had lipid layer followed by 7.8% mucin layer and 5.2% aqueous layer deficiency. However, in contrast to our study Rege *et al.*<sup>[6]</sup> reported prevalence of lipid layer deficiency as 14.5%, followed by aqueous layer (13.4%) and mucin layer deficiency (3.5%).

Strength of the present study was reasonable number of sample size, diagnosis of dry eye based on scientifically

validated OSDI questionnaire along with relevant objective diagnostic tools being used. We included wider age group of population. The demographic population are representative of central India where we found higher prevalence of dry eye comparative to other geographical area reported in literature which might be due to different environmental conditions unique to that particular geographic region. The limitation of present study was hospital-based population.

## CONCLUSION

Prevalence of dry eye in our study was 24.7% which is higher than reported in literature in central India. Prevalence of lipid layer, aqueous layer, and mucin layer deficiency dry eye disorder was 13.8%, 5.2%, and 7.8%, respectively. Lipid layer deficiency dry eye was the most prevalent followed by mucin layer deficiency and lastly aqueous tear deficiency. Increasing age, illiteracy, and menopause were the significant risk factors and female sex, urban habitat, and laborer/factory worker were insignificant risk factors for dry eye. More studies have to be done in future to evaluate correlation of dry eye symptoms and signs as in our study we could not find a strong relationship between the two.

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