ORIGINAL RESEARCH PAPER

Ophthalmology

"PREVALENCE OF DRY EYE DISEASE IN PATIENTS ATTENDING TERTIARY CARE CENTRE- A CROSS SECTIONAL STUDY."

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INTRODUCTION: Dry eye is a very common as well as under-diagnosed ocular disorder. The prevalence of dry eye disease in India is higher than the global prevalence and ranges from 18.4% to 54.3%. Dry eye also leads to increased risk of ocular infections, medication toxicity, intolerance to the contact lens, progressive ocular surface disease, scarring, corneal manifestations, microbial and sterile corneal ulcers leading to perforation and severe visual loss.

AIM: To determine the prevalence of dry eye, in patients attending tertiary care hospital outpatient department of ophthalmology.

DESIGN: A cross sectional study

PLACE AND DURATION OF STUDY: From January, 2019 to June, 2020 (1.5 yea

METHODOLOGY: A cross sectional study was conducted on 800 patients above the age of 20 year attending outpatient department of ophthalmology with the presenting symptoms of dry eye during the study period. All the patients were interviewed with OSDI questionnaire, followed by complete ophthalmic examination, i.e; visual acuity testing and refraction, anterior segment examination and clinical tests. Inter-group comparison (2 groups) was done using t test. Inter-group comparison (>2 groups) was done using one way ANOVA followed by pair wise comparison using post-hoc test.

RESULTS: Among the 800 patients that were included in this study, prevalence of Dysfunctional Tear Syndrome (DTS) was found to be as high as 29.4%. The prevalence of DTS increased with increase in age and was significantly higher among people more than 40 years of age. Prevalence of DTS was higher among females. People with refractive errors, with or without history of spectacle use, had a higher incidence of dry eye. Schirmer's test showed a high sensitivity and specificity, followed by Rose Bengal tests.

CONCLUSION: DTS is an under-diagnosed ophthalmic condition. This is because of the complicated diagnosis and assessment owing to the considerable variation in disease symptoms and lack of definitive diagnostic tests. However, DTS evaluation with standard tests for dry eye helps in accurate diagnosis and treatment of the condition.

INTRODUCTION:

The term 'Dry Eye' can be attributed to the Swedish ophthalmologist Henrik Sjogren who first described the triad of dry eye, dry mouth, and joint pain in the year 1934. With an increasing prevalence in recent years, dry eyes have become one of the commonest reasons for visiting the ophthalmologists. The prevalence of dry eye disease in India is higher than the global prevalence and ranges from 18.4% to 54.3%. (Bron, 2015) (Rege et al., 2013) (Gupta et al., 2010) (Basak et al., 2012). The recent International Dry Eye Workshop (DEWS) report defined dry eye as "A multifactorial disease of the tear film and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. (Basak et al., 2012; Definition, 2002)

The study aims to determine the prevalence of dry eyes, in patients attending tertiary care hospital outpatient department of ophthalmology with clinical objectives to establish the clinical diagnosis of dry eye, to differentiate it from other causes of irritation and redness, to identify the local and systemic causes of dry eye disorder, to prevent further worsening of symptoms and clinical findings and to educate and involve the patient in the management of this disease.

Patients with dry eyes experience difficulties in daily routine activities thus compromising their quality of life. This study was conducted with the aim to evaluate dry eye disease, keeping in view the increasing number of patients presenting in Ophthalmology OPD with the symptoms of Dysfunctional Tear Syndrome. Rapidly changing lifestyle and environment are considered as major causes of dry eye disease. (Messmer, 2015) The development of newer diagnostic techniques and the recent knowledge of the entity make it possible to provide better treatment of the condition. However, a better understanding of important presenting symptoms, the external and systemic factors contributing to dry eye and the

ideal series of tests will help in early diagnosis of this chronic condition, with more efficient and effective treatment and long-term patient satisfaction.

Hot weather, windy air conditions, excessive sun exposure, pollution, smoking, advancing age in females, menopause have been reported as factors associated with dry eyes have been reported that are associated with dry eyes. Recently, dry eye disease has become prevalent among computer users due to decreased blink rate during performance of visual tasks with deep concentration. (Courtin et al., 2016; Rosenfield & Mcoptom, 2016)

Dry eye symptoms sometimes reflect as manifestations for various systemic diseases, hence timely detection might help in early recognition of life–threatening conditions, if any. Subjects with dry eye are prone to potentially blinding infections, such as bacterial keratitis with an increased risk of complications following common procedures such as laser refractive surgery. DTS involves several risk factors that when not paid proper attention, might result in treatment failure and thus, frustration both for the patients and the treating ophthalmologist.

There is an increased risk of ocular infections, medication toxicity, intolerance to the contact lens, progressive ocular surface disease, scarring, corneal manifestations (keratinization, spheroidal degeneration, corneal thinning, vascularization), microbial and sterile corneal ulcers leading to perforation and severe visual loss as a late outcome of dry eyes. Therefore, it becomes crucial to find the exact diagnosis and appropriate management of dry eye. (Begley et al., 2003) The key to prevent the cases from vision-threatening complications of dry eye disease is early diagnosis. The current diagnosis and definition of dry eye disease is based on 3 criteria according to international dry eye workshop guidelines 2007; a. Decrease tear production or increase tear evaporation, b. Damage to the ocular surface, and c.

Associated ocular discomfort or visual disturbance. (Bron, 2015)

This study uses OSDI questionnaire for screening and Schirmer's test and TBUT for diagnosis of dry eye disease, as diagnosis and grading of dry eye disease (DED) on the basis of symptom -based questionnaires such as the ocular surface disease index (OSDI) questionnaire is found to be more reliable than the objective clinical testing for detecting dry eye. (Kallarackal et al., 2002; Milner et al., 2016; Schiffman et al., 2000). DTS evaluation with standard tests for dry eye helps in accurate diagnosis and treatment of the condition. This will go a long way in the effective and successful management of patients with DTS. Early diagnosis and appropriate management of this condition will provide ocular comfort and satisfaction with a better quality of life.

MATERIALS AND METHODS:
After taking informed verbal consent of the patients, a cross sectional study was conducted on 800 patients above the age of 20 year attending outpatient department of ophthalmology with the presenting symptoms of dry eye i.e; ocular discomforts, burning sensation, redness, itching, dryness, etc were included in this study during January, 2019 to June, 2020 (1.5 years). Approval for the study protocol and clearance was obtained from the ethical review committee affiliated with the hospital, where the study was conducted. Subjects who were suffering from any infective condition of ocular adnexa or lid abnormalities or corneal ulcers and the cases who did not give consent for inclusion in the study were excluded.

Complete ophthalmic examination, including visual acuity testing and refraction, anterior segment examination was done. Detailed history and socio-demographic characteristics were studied. Attributable risk factors that cause exacerbation of the symptoms of dry eye are place of residence (rural or urban), excessive wind, sunlight, high temperature, air, pollution, drug, computer worker, office worker/shopkeeper, factory worker, myopia, hypermetropia, etc. Thorough history of medication, ocular disease, operation, treatment, occupation, and medical history was taken.

All the patients underwent through Ocular Surface Disease Index (OSDI) questionnaire. The OSDI is a valid and reliable instrument for measuring dye eye disease (normal to mild to moderate and severe) All the patients were subjected to 12 questions according to OSDI (12), on various components like; eyes that are sensitive to light, eyes that feel gritty, painful or sore eyes, blurred vision, poor vision, reading, driving at night, working with a computer or bank machine (ATM), watching TV, windy conditions, places or areas with low humidity (very dry), areas that are air conditioned. Each question given a score ranging from 0 (none of the time) to 4 (all of the time). The cases were then assessed on a scale of 0 – 100, where higher score represented greater disability. The patients were assigned 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. The cases were classified under various categories based on the score ranging from 0 to 100 as; a. 0–12 representing normal, b. 13–22 representing mild dry eye disease, c. 23–32 representing moderate dry eye disease, d. ≥33 representing severe dry eye disease.

Followed by OSDI, external examination of both eyes was done using torch light and slit lamp. Objective tests i.e; a. Schirmer's test and b. Tear film break up time and c. Rose Bengal test were done. Schirmer's test was performed before the other tests as it had to be done before instillation of anaesthesia. It was done using 5×35mm sterile strips of Whatman No.41 filter paper. Patient was made to sit in relatively dark room with fan switched off. The patient was then asked to look up, lower lid retracted and the test paper inserted in the lower cul-de-sac at the junction of medial 2/3rd and lateral 1/3rd of the lid. TBUT, tear film is stained with

sodium fluorescein 1% and patient was asked not to blink while the tear film was observed under a broad beam of cobalt blue illumination in slit lamp. Time is noted for the first appearance of a "dark" dry spot which is recorded as the TBUT. Subjects went through general and systemic examination to measure vitals and to examine respiratory system, cardiovascular system and central nervous system.

Ocular examination included; a. visual acuity with Snellens test type, b. refraction with the help of retinoscopy, c. frequency of blink rate was noted (increased/ decreased/ normal), d. Proper Closure of lid was examined, whether palpebral fissure is narrow/wide/normal, lid margins examined for any evidence of blepharitis, entropion, and ectropion, conjunctival examination for hyperemia, lymphoid follicle, papillae, cicatrization, and symblepharon, cornea was examined for any evidence of ulcer, epithelial filaments, mucous plaques, opacities, loss of normal luster, corneal sensations were noted by touching the cornea with cotton wisp and tear film was examined for thinning, any debris or mucous strands. Routine investigations like specific blood investigation to check Diabetes thyroid dysfunction and Sjogren's syndrome (SLE). Participants were labeled as having dry eye diseases if at least two out of these diagnostic tests were positive. This criteria of two diagnostic tests to diagnose dry eye disease was adopted in order to increase the detection rate of dry eye and ultimately arrive at an accurate prevalence.

Data obtained was compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States). Data was subjected to statistical analysis using Statistical Package for Social Sciences (SPSS v 26.0, IBM). Descriptive statistics like frequencies and percentage for categorical data, mean and standard deviation for numerical data was depicted. Inter group comparison (2 groups) was done using t test.Inter group comparison (>2 groups) was done using one way ANOVA followed by pair wise comparison using post-hoc test. Comparison of frequencies of categories of variables with groups was done using chi square test. For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

OBSERVATIONS AND RESULTS:
Total of 1579 eyes (800 participants) were included in the study. The relationship of age with prevalence of dysfunctional tear syndrome was studied (Table no. 1). The youngest patient was of 21 years and oldest patient was of 66 years. Mean age of patient was 48.27+/- 11.36 years. Male to female ratio was 2.030. Two-hundred and thirty-two patients were diagnosed to have dry eye disease. The participants were inquired about the history of dry mouth during recruitment in the study. This data was used to assess the number of people presenting with both dry mouth and dry eye. 134 (32.44 %) eyes were found to have both and 271 eyes (67.55 %) had a history only of dry mouth; but no evidence of dry eye. Statistically significant difference was seen when a relationship between conjunctival congestion and dry eye was studied with p=<0.01. There was statistically higher significant (p=<0.001) difference seen between refractive error and dry eyes. When compared between homemaker and farmers, higher prevalence was seen among farmers (36.81%) due to dry wind and temperature and the results were highly significant with P=<0.001. Three-hundred and twenty-nine (64.63%) cases had both higher OSDI and presence of dry eyes. (Figure no. 1) Among 464 cases with dry eye, twenty-four (5.17%) cases OSDI score showed mild dry eye, ninety-six (20.68%) had with moderate dry eye and remaining subjects presented with severe dry eyes.

Schirmer's test:
Of the total, thirty % of eyes gave a wetting of less than 10mm performing Schirmer's test. This was based on predetermined diagnostic criteria with 100 % sensitivity and 86.83 % specificity for the test.

Hundred and twelve eyes (7.09 %) had a wetting of ≤5mm i.e; severe dry eyes; whereas 256 (16.21 %) had wetting between 6-10 mm in one or both the eyes that ranged from moderate to mild dry eye.

TBUT
TBUT was the second test that was performed. It was found to be positive (<10 seconds) in 440 (94.82%) eyes. All the eyes which gave a positive result showed objective evidence of dry eye with 93.09 % sensitivity and 99.28 % specificity.

Rose bengal test:
Among all the eyes; 504 eyes (31.91 %) showed positive staining. Among these, 448 eyes (88.88%) were positive for dry eye considering sensitivity as 96.85 % and specificity as 94.96%. (Table 2)

Out of 464 eyes; 336 patients (72.41%) were given the treatment with artificial tears preferably containing sodium hyaluronate. The frequency was adjusted based on severity of symptoms and signs. 128 (27.58 %) eyes with meibomian gland dysfunction were treated with only Doxycycline.

Table no. 1: Characteristics of study population

| Characteristics	Number
Total number of patients	800 (1579 eyes)
Age Group	≥20 years
Schirmer's test positive (<10sec.)	464
Tear Film Break Up Time positive (<10sec.)	432
Rose Bengal Test Positive (Score >4)	448
Dry eye Present (2 or more tests positive)	232 Patients (464 eyes)
Dry eye absent	556 patients (1115 eyes)

Figure 1: Bar chart depicting Result of osdi score and dry eye

Relation between OSDI Score and dry eye
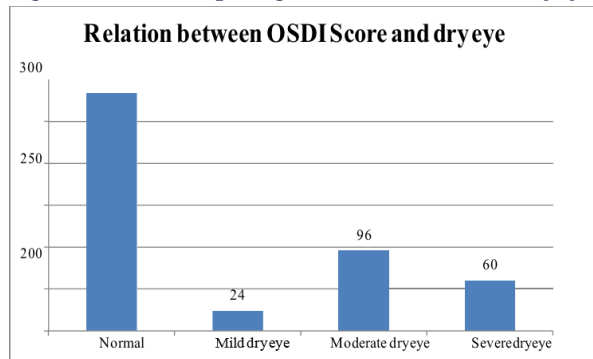
Table 2- Distribution based on the results of Rose Bengal Test

Rose Bengal Test	Dry eye present	Dry eye absent	Total
Positive	448 (88.88 %)	56 (11.11 %)	504
Negative	16 (1.48 %)	1059 (98.51 %)	1075
Total	464	1115	1579

DISCUSSION:
A total sample size in our study was of 800 patients and we found 232 patients to have dry eye evidence either in one or both eyes. The results were based on the positive results of at least two out of four objective tests that were included in the study. The prevalence of dry eye in this study was found to be 29.4 %. A cross sectional study conducted by (Basak et al., 2012) titled "Prevalence of dry eye diseases in hospital-based population in West Bengal, Eastern India" on 3023 patients with age more than 30 years and above in 2012 reported prevalence of 40.8%. With symptoms and at least one sign (TBUT<10 seconds, RB staining score >4 and Schirmer's 1 test=5mm in 5 minutes) they reported a prevalence of dry eye was 26%. A population based study conducted by (Moss et al., 2000) in Indonesia depicted dry eye prevalence of 27.5%. Similar results were found in studies conducted by (Sahai & Malik, 2005) and (McCarty et al., 1998), (Moss et al., 2000), (Jie

et al., 2009) showed the prevalence of 18.4%, 14.6% , 14.4% and 21% respectively. The prevalence of dry eye can vary from 10.8% to 57.1%, there by showing wide difference (Sahai & Malik, 2005). The huge disparity in dry eye prevalence is caused mainly from the different diagnostic criteria employed for the diagnosis of this condition and different cut-off values for the objective dry eye tests. The high prevalence in some studies can be because of objective dry eye tests performed in patients with selection bias or in patients in rheumatoid arthritis and Sjogren's syndrome, which have proven dry eye components. (Lee et al., 2002) conducted a cross sectional study on 39,876 women from 45-84 years and concluded that DES increases with age from 5.7% among women < 50 years old to 9.8% among women aged >75 years. In tihs study, the percentage of people >40years who tested positive for dry eye was found to be 79.52%. The mean age of the participants in this study was 48.27 years similar to the study conducted by (Khurana et al., 1991) where it was 49.19 years.

The prevalence of dry eye was studied, it was found to be significantly higher in patients with age more than 40 years and this was similar to the study done by (Moss et al., 2000). Higher prevalence of DTS was seen in women when compared to men. This was comparable with study conducted by Moss et al[32] where it was 16.7% in women as compared to 11.4% in men and study by (Sahai & Malik, 2005) showed 22.8% in women compared to 14.9% in men.

The most common signs observed in this condition were Conjunctival congestion about 29.74 % of all the patients with conjunctival congestion showed evidence of DTS. Association between DTS and conjunctival congestion was found to be statistically highly significant (p=0.003). Our findings were similar to the findings of Srinivas et al [102]. They also found an increased incidence of bulbar hyperaemia in women with dry eye; which may be used as one of the diagnostic signs for screening of the patients for evidence of DTS. Directly performing the tests may not be required.

It was found that there was significant correlation between the presence of dry eye and refractive errors (p=<0.001). (Sahai & Malik, 2005) exhibited that the prevalence of dry eye was much higher in those with both- corrected as well as uncorrected refractive errors. Study by (Jie et al., 2009) showed that among people with under-corrected refractive errors; there was significantly higher incidence of DTS. It can be attributed to the fact that persons with refractive errors have an increased tendency to rub the eyes. So it introduces infective material and sweat. Also, these people have much more tendency to squeeze the eye, causing instability of tear film, predisposing to dry eye.

Occupation based comparison expressed that there was significantly high dry eye prevalence in farmers (36.81%) due to excessive wind and sunlight exposure. Similar results were observed in the study by (Sahai & Malik, 2005)

OSDI score and dry eye according to The Canadian Dry Eye Epidemiology (Horwath-Winter et al., 2003) based on OSDI questionnaire, 28.7% reported that they had dry eye symptoms, 90% reported having mild symptoms, 7.6% had moderate symptoms and 1.6% had severe symptoms (36). The present study showed that 329 (64.63%) participants, had both dry eye symptom and dry eye. Hundred and eighty (35.36%) patients had higher OSDI score but no presence of dry eye. Hence, OSDI showed highly significant correlation with dry eyes.

Three diagnostic tests were performed on all the participants. Positive findings in two out of these three tests was considered necessary to diagnose the patient as having DTS. As mentioned in the methods section, this procedure was adopted to help the diagnosis in order to increase the detection rate to arrive at an accurate prevalence. Among all the tests included, Schirmer test showed a highest sensitivity,

specificity and predictive values (Both positive and negative). Therefore, it is considered as one of the most frequent tests used in DTS diagnosis in clinical practice. Other studies also showed sensitivity and specificity as high as 85% which corresponded to the results from the present study. Rose bengal test was found out to be the next best test based on the sensitivity and specificity. The characteristic staining of wing shaped area in the interpalpebral area was noted in most of the cases who were positive. Comparison was made between the subjects on the basis of Schirmer test and Rose Bengal test, it was found that, of the total cases, 456 patients tested positive for both the tests, 48 patients (10.52%) were positive only for Rose Bengal test, 155 (33.40%) patients were positive for Schirmer test, but negative for Rose Bengal test. Third test performed was TBUT. It was found to be positive (<10 seconds) for 432 eyes (93.10%). This test was found to have a sensitivity of 93.09% and specificity of 99.28%.

Artificial tears are considered as the mainstay of the therapy for DTS. The aim of using tear substitutes in treatment for DTS was to increase humidity in the ocular surface and to improve lubrication. These tear substitutes provide an environment in which the epithelium can recover to its normal structure and function. A study by (Aragona et al., 2002) showed that long term treatment with artificial tears containing sodium hyaluronate improves Rose Bengal staining with DTS. This suggests that the treatment with this agent promotes healing of corneal and Conjunctival epithelium. This effect was noted after 3 months of starting the treatment. In this study, 128 patients (27.58%) presented with evidence of MGD (meibomian gland disease) were treated with hot fomentation, lid massaging, Doxycycline 100 mg twice daily and the dose was adjusted depending on the resolution of symptoms and signs in subsequent follow-ups.

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