Journal Homepage: -www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/19575
DOI URL: http://dx.doi.org/10.21474/IJAR01/19575

RESEARCH ARTICLE

A COMPARATIVE STUDY OF PRE-CORNEAL TEAR FILM BETWEEN DIABETICS AND NON-DIABETICSUSING OCULAR SURFACE DISEASE INDEX

Dr. Swati, Dr. Shashi Prabha Prasad and Dr. Sanjeev Verma
Department of Ophthalmology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur.

Manuscript Info

Manuscript History
Received: 30 July 2024
Final Accepted: 31 August 2024
Published: September 2024

Abstract

Purpose: To determine distinctive characteristics of pre-corneal tear film in eyes of diabetics and compare them with non-diabetics.
Design: Hospitalbasedobservationalcross-sectional study.
Methods: The study was done in thedepartmentofophthalmology from July2022-December2023. Patients presenting to outpatient department of ophthalmology who were of age>45 years, have a history of diabetes for more than three years and those without diabetes as control groups were chosen.300patients weretaken forthestudyand dividedinto two groups(150 diabetics and 150 non-diabetics). Sample size was decided based on a convenient sampling method.Ocular surface disease index(OSDI) questionnaire was used to assess symptoms and signs.Corneal sensitivity test, Tear film breakup time(TBUT) and Schirmer tests were done. The corneal and conjunctival stains were used. Chi-square test was used to examine outcomes. Other tests were applied accordingly.
Results: Diabetic patients had poorer OSDI scores compared to Non-diabetic patients(p 0.001*). Patients with diabetes had reduced corneal sensitivity($p<0.05$*). Schirmer II and TBUT values were significantly prolonged in Diabetics compared to Non-diabetcs($p<0.05$*). Duration of diabetes significantly increased the severity of dry eye. Dry eye was more prevalent in diabetic retinopathy patients(p=0.02*). Strong association was found between HbA1C and severity of diabetic retinopathy with P<0.05*.
Conclusion: The duration of diabetes and stage of retinopathy are closely linked to the occurrence and severity of tear film dysfunction. Early detection and treatment are vital for preventing dry eye syndrome and its potential progression to vision-threatening complications, through simple non-invasive methods.

Introduction:-

To preserve the transparency of the cornea, it must be kept moist by a pre- corneal tear film which consists of three layers: lipid layer (outermost), aqueous layer (middle) and mucin layer (innermost). The lipid layer is the outermost layer of the team film secreted by meibomian glands which prevents tear evaporation.[1]The aqueous layer is

Corresponding Author:-Dr. Swati
Address:-Department of Ophthalmology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur.

secreted by the main lacrimal glands and the accessory lacrimal glands of Krause and Wolfring.[2] The mucin layer is the innermost layer which is in direct contact with the corneal epithelium, primarily produced by the goblet cells.

Dry eye occurs when there is inadequate tear volume or function which results in an unstable tear film and ocular surface disease.Dry eye affects a significant percentage of adults globally ranging from 5% to 73.5%.[3] [4] It is more common in women with approximately 3.23 million women and 1.68 million men aged 50 years or older.[5] The prevalence of dry eye is more ranging from 12% to 22% in females.[6] The relation between diabetes mellitus needs a thorough evaluation as dry eye is frequently overlooked or mis- diagnosed in diabetic patients.

Normal blink reflex, contact between the external ocular surface and the eyelids, normal corneal epithelium are required for effective resurfacing of the tear film. The normal production rate of tears is 1.2 μL/min in the range varying from 0.5 to 2.2 μL/ml.[7] The volume of tear film averages about 7 μL with approximately 1.1 μL within the palpebral fissure, 2.9 μL within the marginal strips and 4.5 μL within the fornices.[8]

The Dry Eye Workshop II of the Tear Film and Ocular Surface Society (TFOS DEWS II) defined DED as "A multifactorial disease of the ocular surface characterized by a loss of homeostasis in the tear film and accompanied by ocular symptoms, in which tear film stability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles".[9] The 2017 TFOS DEWS II study provides a detailed classification and description of dry eye disease. The paper classifies DED into aqueous-deficient and evaporative subtypes based on a variety of factors, including inflammation, neurosensory abnormalities, and environmental triggers.[9]

Patients with diabetes often exhibit morphological abnormalities in theireyes, including greater baseline corneal thickness, percentage of hexagonality, reduced endothelial cell density, and an increased coefficient of variation in cell size compared to individuals without diabetes. Changes in corneal morphology due to chronic hyperglycemia leads to reduced corneal sensitivity.[10]

Dry eye in diabetes occurs from inadequate tear production due to autonomic neuropathy affecting the nerves controlling the lacrimal gland. The severity of DES correlates with the severity of diabetic retinopathy.[11]

DES can lead to ocular complications like keratoepitheliopathy and keratitis. Diabetic keratoepitheliopathycan result in abnormalities in tear secretion, leadingto reduced corneal sensitivity and poor adhesion of regenerating epithelial cells.

The detection and monitoring of dry eye disease (DED) can be easily achieved through simple non-invasive testing of the tear film.The OSDI questionnaire which includes both symptoms and signs is used for evaluating and comparing the patient's subjective complaints with objective findings. [12] This study aims to determine the distinctive characteristics of the pre-corneal tear film in the eyes of diabetic individuals and compare them with those of non-diabetics.

Materials and Methods:-

This was a cross-sectional observational study conducted from July 2022-December 2023. Patients presenting to the outpatient department of ophthalmology were chosen based on the inclusion criteria.

Study Design:
Hospital based observational cross-sectional study.

Study location:
Department of ophthalmology, Jaipur

Study period:
July 2022-December 2023

Inclusion criteria

1. Patients willing and giving consent for the study.
2. Patients of age >45 years of both genders.

3. Patients who have a history of diabetes for more than three years.
4. Patients without diabetes as a reference group.

Exclusion criteria

1. Individuals suffering from any other ocular condition known to cause dry eye.
2. Individuals with connective tissue disorders, rheumatoid arthritis, lupus erythematosus, and other systemic conditions (apart from diabetes mellitus) linked to dry eye.
3. Individuals receiving any kind of medication that causes dry eyes (such as NSAIDs, beta-blockers, thiazides, MAO inhibitors, and alpha agonists).
4. Individuals who have had any eye surgery within the previous 24 months.
5. People who wear contact lenses.
6. Smokers.

Sample size estimation:

300 patients were taken for the study and divided into two groups.

Among 300, 150 were diabetics and 150 were non-diabetics who were chosen as the control group. Sample size was decided based on a convenient sampling method.

Methodology:-

Prior informed consent was taken from all the patients. A detailed history, general physical examination, detailed ophthalmologic examination including slit lamp examination of anterior segment and fundus was examined using 90D lens on slit lamp & by indirect fundoscopy. Diabetic retinopathy was classified on the basis of ETDRS (Early treatment diabetic retinopathy study). Fasting blood sugar (FBS) levels and HbA1c were tested for diabetic patients. Ocular surface disease index (OSDI) questionnaire was used to assess the symptoms and signs.

In addition to determine dry eye disease (DED), the following tests were performed:-

1. **Corneal sensitivity test**: A wisp of cotton wool applied to the cornea to induce a blink response was used to assess corneal sensation. The menace reflex was avoided as much as possible. Normal corneal sensation was indicated by a brisk blink response. Reduced corneal sensation was indicated by a weak blink response. Lack of corneal sensation was indicated by an absent blink response.
2. **Tear film Break Up Time (TBUT):** Pre-sterilized strips that are commercially available and impregnated with 1 mg of fluorescein were used to stain the tear film. The test was done in an unanesthetized eye. Using a blue cobalt filter, the cornea was examined under low slit lamp magnification. The patient was advised to blink once or twice before focusing straight ahead without blinking.
3. **Schirmer's test:** The commercial Whatman 41 paper strip 'IO Schirmer's strip' was used for this test. The strip was applied to the lower eyelid's middle and lateral thirds and then removed after 5 minutes. The quantity of wetness on the strip was measured in millimeters.
4. **Dye testing:** The corneal and conjunctival stains were graded using the National Eye Institute (NEI) industry Workshop on Clinical Trials in Dry Eyes grading system. The following dye tests were also performed.

I. **Fluorescein staining:** The inferior conjunctival sac was introduced with a commercially available Fluorescein impregnated strip for staining. To ensure that the dye was evenly distributed over the ocular surface, the patient was instructed to softly close their eyes and roll them around.

II. **Lissamine green strip:** Using a red barrier filter, a strip coated with lissamine green was employed as previously to identify regions of the ocular surface lacking in mucin.

III. **Rose Bengal staining:** The inferior conjunctival sac was stained without anesthesia using a moistened commercial strip loaded with 1.5 mg of Rose Bengal. Examination was done using a green filter on slit lamp.

Grading of DED was done as follows:

1. **Normal:** Schirmer I and II test value >15mm, TBUT >10 seconds and OSDI score of 0-12.
2. **Mild DED:** Schirmer I and II test value between 10mm and 15mm, TBUT value of 10 seconds and OSDI score of 13-22.
3. **Moderate DED:** Schirmer I and II test value between 5mm and 10mm, TBUT value of 5-10 seconds and OSDI score of 23-32.
4. **Severe DED:** Schirmer I and II test value <5mm, TBUT <5 seconds and OSDI score of 33-100.

5. **Data analysis**: The Chi-square test was used to examine the outcomes. Other tests were applied accordingly. MS-Excel and SPSS Version 23 (Statistical Package for Social Science) are the statistical software packages used. P less than 0.05 is regarded as statistically significant.

Results:-

The present study was a cross-sectional study done at Jaipur national university institute for medical sciences and research centre (JNUIMSRC) from July 2022 to December 2023 for 20 months on patients presenting to ophthalmology out patient department. 300 patients, 150 diabetics and 150 non diabetics satisfying the inclusion criteria were included in the study. Prevalence of Dry eye in Diabetics was 40% and in Non-diabetics was 12% in this study population.

Patient demographics are as shown in Table 1. Out of 150 diabetics, 51 patients were in the age group of 51-60 years, whereas out of 150 non-diabetics, 59 patients were in the age group of 61-70 years. Overall male to female ratio in diabetics was 1:1 and non diabetics was 1.3:1.

33diabeticpatientswhowereresidentsofurbanareaand27diabeticpatients who were residents of rural area developed dry eye whereas 9 patients from urban and 9 patients from rural area who had dry eye were non diabetics. There was no statistical significance on comparing residents of urban and rural area who had dry eye (p value=0.709). Out of the 150 cases of Diabetic group, 67 cases had good control with HbA1C levels of 6.0-7.0, 30 cases had fair control and 53 cases had poor control with HbA1C values of>8.0.

28 males and 32 females among diabetic group developed dry eye out of which 41 patients had mild DED, 15 patients had moderate DED, 4 patients had severe DED. 12 males and 6 females among non-diabetic group developed dry eye out of which 10 patients had mild DED, 8 patients had moderate DED and none of the patients had severe DED (Table 1). There were 27 cases of dry eye in the age group of 51-60 years, 23 cases of dry eye in the age group of 61-70 years, 24 cases in 71-80 age group and 4 cases in the age group of 81-90 years. There was no statistical significance which suggests severity doesn't increase with age (p0.427).

40 patients of age group 51-60 years, 32 patients of 61-70 years, 34 patients of 71-80 years and 4 patients of 81-90 years presented with diabetes of duration of6-9 years, whereas 5 patients of age group 51-60 years, 6 patients of 61-70 years, 3 patients of 71-80 years presented with diabetes of duration of >10 years(Table 1).

Corneal sensitivitytest showed 4 diabetic patients had absent blink response, 31 diabetic patients had weak blink response and 115 diabetic patients had brisk blink response. On the other hand 143 non diabetic patients had brisk blinkresponse, 7 non diabetic had weak blink response and none of the non diabetic patients had absent blink response on corneal sensitivity test. There was a statistical significant difference between the diabetic and non diabetic patients (p <0.05*) (Table 2).

The schirmer II test and TBUT values of right and left eye are as shown in Table 3. There was statistical significance on comparing with non diabetics with p<0.05*. Grading was done according to modified NEI score for staining by rose bengal, lissamine and flourescin. An average value of scores for right and left eye are as shown in Table 4.

90 diabetics and 132 non diabetics had normal OSDI score, 41 diabetics and10nondiabeticshadmildOSDIscore,15diabeticsand8nondiabeticshadmoderate OSDI score, whereas 4 diabetics had severe OSDI score (Figure 1). Onapplyingnon-parametrictest(Kruskalwallis)Chisquare11.337,pvalue 0.001*. Outofthe300patients,78patients(26%)hadDryeyedisease(DED) [60 diabetics and 18 Non-diabetics]. Overall 51 patients had mild DED, 22 patients had moderate DED and 4 patients had severe DED (Figure 2a and 2b).

Out of the 16 DR cases, mild non-proliferative diabetic retinopathy (NPDR) was found in 13 eyes (6 right eyes and 7 left eyes), 8 eyes (5 right and 3 left) had moderate NPDR, 7 eyes (4 right and 3 left) had severe NPDR and 4 eyes (1 right and 3 left had PDR) (Figure 3). Among the 32 eyes having diabetic retinopathy, 11 eyes (5 right and 6 left) with mild NPDR had dry eye, 6 eyes (3 right and 3 left) with moderate NPDR, 7 eyes (5 right and 2 left) with severe NPDR and 4 eyes (1 right and 3 left) with PDR had dry eye. P=0.02* showed that dry eye disease was more prevalent in diabetic retinopathy patients (Table 5). Strong association was found when HbA1C was compared with the severity ofdiabeticretinopathywithP<0.05*ondoingOnewayANOVAtestofsignificance (Table 6).

10patientswith>10yearsdurationofdiabetesdevelopeddryeye,43patients with 6-9 years duration of diabetes and 7 patients with <5years duration of diabetes developed dryeye and on comparing with the diabetics who had no dryeye p<0.05* which was statistically significant (Figure 4).

Discussion:-

A cross sectional study was conducted at a tertiary care centre in which 300 patients satisfying the inclusion criteria were included and grouped into 150 diabetic patients and 150 non diabetics who were taken as a control group. Among the 300 patients, the prevalence of Dry eye in Diabetics was 40% and in Non-diabetics was 12%. The overall prevalence of dry eye in this study population was 26%. The frequency of DED in this research was similar to a hospital-based study carried out by Sarkar et al.[13], which indicated 42%, and by Dutta et al.[14], which indicated 48.33%.

In this study 40 % of diabetics and 12% of non diabetics developed dry eye which was comparable to the study done by Seifart U et al.[15] in which the results show that 52.8% of all diabetic patients complained of dry eye, compared with 9.3% of the controls. Similarly Manaviat et al.[16] showed in their study that 108 patients (54.3%) of diabetics suffered from dry eye but they didn't have any controls.

The age of the patients ranged from 51-88 years with a mean age of 67.72±8.671 years. Most of the patients (63.3% of diabetics and 72% of non- diabetics) belonged to the age group of 61-80 years. Among the diabetic patients, a majority (73.33%) had diabetes for 6-9 years duration and 9.33% of cases had diabetes for >10 years duration. The study carried out by Moss et al.[17] revealed that the patients' ages ranged from 48 to 91 years, with a mean age of 65±10 years.

Overall male to female ratio in diabetics was 1:1 and non-diabetics was 1.3:1 in this study. Among the diabetics, 42.11% of females and 37.84% of males developed dry eye. Moss, et al.[17] found that dry eye was more prevalent in females at a rate of 16.7% compared to males at 11.4%. Similarly, fifty-one percent of males and 57.2% of females had dry eye disorder in a study conducted by Shah S et al.[18]

As one ages, dry eye symptoms tend to worsen as a result of reduced tear production and flow, as well as increased evaporation. According to Kaiserman et al.[19], the prevalence of dry eye rises with age. Research indicates that the primarycontributors to dry eyes with age are increased evaporation and the subsequent rise in tear film osmolarity. This points to meibomian gland dysfunction as the main underlying cause.[20] However, in this study, there was no statistically significant difference of dry eye with increasing age suggesting otherwise.

The symptoms of DED increase with the duration of diabetes. A significant association was found between dry eye syndrome and the duration of diabetes. It was more prevalent in diabetics with DR in a study by Manaviat et al.[16] In a study by Pradeep et al.[21], the prevalence of dry eye was 32% among type 2 diabetics. The study showed that the prevalence was higher in older age groups and with more than 10 years of duration of diabetes mellitus. In a study by Pooja HV et al.[22], the prevalence of mild dry eye was as follows: 12.37% (38) in individuals with 5-10 years of diabetes mellitus (DM); 39.53% (17) in those with 11-15 years of DM duration; 37.03% (10) in individuals with 16-20 years of DM; and 42.86% (3) in those who had DM for longer than 20 years.. These studies were comparable to this study 43 (39.09%) out of 110 cases with diabetes of 6-9 years and 10 (71.43%) cases out of 14 cases with diabetes of duration >10yrs developed dry eye with a statistical significance p value<0.05* suggesting the probability of getting dry eye with increasing duration of diabetes.

According to the severity of DED, 51 patients (65.38%) had mild DED, 23 cases (29.49%) had moderate DED and 4 cases (5.13%) had severe DED in this study. In a study conducted by Prasad SC et al.[23], it was found that 33 patients (27.04%) were diagnosed with mild dry eye disease (DED), 72 patients (59.01%) presented with moderate DED, and 17 patients (13.95%) had severe DED.

There was no correlation between patients with dry eye among residents of urban (53.85%) and rural areas (46.15%) even among diabetics in this study.

Prasad et al.[23] discovered significant differences in TBUT and Schirmer's test ($p < 0.05$). They found that 28.5% of the diabetic group had abnormal TBUT values (< 10 sec), and 25% of the diabetic group had abnormal

Schirmer's test values (< 10mm/5 minutes) in their study.. Results from the study by Aljarousha Met al.[24] showed a significant difference in TBUT values between diabetic and non- diabetic subjects. In a study by Khateeb EW et al.[25], in the schirmer test most of them (43%) were having 6-10 mm, followed by 26% who had 11-15 mm, 18% who had more than 15 mm and rest 13% had 0-5 mm. These studies are in conjunction with the present study which had 4 patients out of 150 diabetics had <5 sec TBUT, 32 diabetics had 5-10 sec TBUT and a statistical significance p<0.05* between diabetics and non-diabetics in both the eyes for Schirmer and TBUT.

The Schirmer I test evaluates the lacrimal gland secretory reflex and basal secretion function of the Krause and Wolfring glands. The Schirmer I test is considered normal, if it is 10-30 mm wet and considered dry eye if it is 10 mm or less wet. Schirmer I study of right and left eyes range from 2 to 20 mm with a mean of approximately 8-9 mm in a study by Tribowo A et al.[26]

Corneal morphology is affected in patients with diabetics indicated by reduction of corneal sensitivity. In this study, a weak blink response was seen in 20.7% of diabetics compared to 4.7% of non-diabetics, whereas an absent blink response was seen in 1.3% of diabetics. Schultz et al.[27] reported that 18% of randomly selected diabetic patients had reduced corneal sensitivity. Nielsen NV[28] discovered that 83% of diabetic patients had corneal sensitivity of less than 60 mm, compared to 38% of the control group, using Cochet and Bonnet's aesthesiometer. He stated that there is evidence suggesting that decreased corneal sensitivity is a part of polyneuropathy in diabetes Similarly in a study by Raghavan C et al.[29] Corneal sensitivity was absent in 26.9% of diabetic patients, mild in 20.9%, moderate in 31.3%, and severe in 20.9%. Neuropathy was not present in 10.4% of cases. A notable relationship was found between the duration of diabetes and the reduction in corneal sensation. In a study conducted by Komolafe et al.[30], the average corneal sensitivity in diabetic subjects was found to be 52.4 ± 6.7, a value lower than the55.5 ± 4.9 observed in the control group and was statistically significant (p-value < 0.05).

Among the 32 eyes having diabetic retinopathy in this study, 11 eyes (5 right and 6 left) with mild NPDR had dry eye, 6 eyes (3 right and 3 left) with moderateNPDR, 7 eyes (5 right and 2 left) with severe NPDR and 4 eyes (1 right and 3 left) with PDR had dry eye. P=0.02* showed that dry eye disease was more prevalent in diabetic retinopathy patients. The severity of diabetic retinopathy is correlated with the dry eye disease as seen in this study. Pooja HV et al.[22] unequivocally demonstrated in their study that the prevalence of dry eye disease (DE) among individuals with mild, moderate, severe non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR) was 23.64%, 52.94%, 71.43%, and 66.67% respectively. They confidently established that the prevalence of dry eye increased significantly with the severity of retinopathy. In a research conducted by Najafi et al.[31], a notable association was observed between dry eye disease and diabetic retinopathy (p=0.016). In a study conducted by Nepp et al.[32], it was found that 17.1% of patients with diabetes mellitus (DM) had mild nonproliferative diabetic retinopathy (NPDR), 17.1% had moderate NPDR, 11.1% had severe NPDR, and 25.1% had proliferative diabetic retinopathy (PDR). Another study by Mansuri et al.[33] concluded that dry eye was more prevalent and severe in patients with PDR.

In a research conducted by Nepp et al.[32], it was found that DR is linked to a reduction in tear film function. The PDR group exhibited a significant decrease in both tear break-up time (BUT) and Schirmer's test values compared to the non-DR group. This finding is consistent with this study where diabetic retinopathy patients showed a significant reduction in corneal sensitivity compared to other diabetic patients.

In this study, out of the 150 cases of Diabetic group, 67 cases had good control with HbA1C levels of 6.0-7.0, 30 cases had fair control and 53 cases had poor control with HbA1C values of >8.0. There was statistical significance between HbA1C values and Dry eye symptoms (p=0.045*), however there was no statistical significance between HbA1C values and severity of DED in this study. The research conducted by Prasad SC et al.[23] revealed that the DES group had significantly inferior glycemic control, as indicated by HbA1C values (9.508 ± 2.01), in comparison to the non-DES group (6.387 ± 0.64) (p < 0.001). Meanwhile, a study by Mangoli et al.[10] demonstrated that patients with poor glycemic control were more likely to experience higher grades of dry eye disease (DED). Dutta et al.[14]. conducted research indicating that there is a connection between the frequency of dry eye and inadequate glycemic control in people with diabetes. Seifart et al.[15] found a link between HBA1c levels and the occurrence of dry eye syndrome. They noted that elevated HBA1c levels were linked to a greater incidence of dry eye syndrome.

In this study mean OSDI score was 20.51±6.601 in Dry eye patients compared to 6.14±2.219 in non dry eye patients which was statistically significant (p<0.05*). In a study conducted by Mansuri et al.[33], it was found that the mean

OSDI score was 28.91 ± 9.42 in individuals with dry eye, significantly higher than the score of 10.10 ± 2.03 in those without dry eye (P < 0.0001).

OSDI score:

Ocular Surface Disease Index

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following *during the last week?*	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? . .	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following *during the last week?*	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations *during the last week?*	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned? . . .	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

Add subtotals A, B, and C to obtain D (D = sum of scores for all questions answered) (D)

Total number of questions answered (do not include questions answered N/A) (E)

Tables

Table 1:- Patient demographics.

Patient demographics			
	Diabetics	**Non-diabetics**	**Total**
Age(in years)	65.83±8.66	69.6±8.60	
Gender			

Male	74 (49.33%)	87 (58%)	161(53.67%)
Female	76 (50.67%)	63 (42%)	139(46.33%)
Dry eye in Urban vs Rural population			
Urban	33 (55%)	9 (50%)	42(14%)
Rural	27 (45%)	9 (50%)	36(12%)
HbA1c levels in diabetics			
Good control(6.0-7.0)	67(44.67%)		
Fair control(7.0-8.0)	30(20.00%)		
Poor control(>8.0)	53(35.33%)		
Dry eye in Diabetics and Non diabetics			
Present	60(20.0%)	18(6.0%)	78(26.00%)
Absent	90(30.00%)	132(44.00%)	222(74.00%)
	Duration of diabetes		
Age	**<5years**	**6-9 years**	**>10years**
51-60	6(4.00%)	40(26.67%)	5(3.33%)
61-70	10(6.67%)	32(21.33%)	6(4.0%)
71-80	10(6.67%)	34(22.67%)	3(2.00%)
81-90	0(0.00%)	4(2.67%)	0(0.00%)

Table 2:- Corneal sensitivity test.

Corneal sensitivity	Diabetic	Non diabetic
Brisk blink	**115 (76.7%)**	**143 (95.3%)**
Weak blink	**31 (20.7%)**	**7 (4.7%)**
Absent blink	**4 (1.3%)**	**0 (0%)**
Total	**150 (100%)**	**150 (100%)**

Chi square shows p<0.05* which shows statistical significance between Diabetics and Non diabetics.

Table 3:-Schirmer II and TBUT values.

Schirmer II and TBUT test					
Schirmer II	**Right eye**		**Left eye**		**P value**
	Diabetic	Non diabetic	Diabetic	Non **diabetic**	<0.05*
>15 mm	90 (60%)	132 (88%)	90 (60%)	132 (88%)	
10-15 mm	44 (29.33%)	10 (6.67%)	44 (29.33%)	10 (6.67%)	
5-10 mm	12 (8%)	8 (5.33%)	12 (8%)	8 (5.33%)	
<5 mm	4 (2.67%)	0 (0%)	4 (2.67%)	0 (0%)	
TBUT	**Right eye**		**Left eye**		**P value**
	Diabetic	**Non diabetic**	**Diabetic**	**Non diabetic**	<0.05*
>10 sec	90 (60%)	132 (88%)	90 (60%)	132 (88%)	
10 sec	24 (16%)	0 (0%)	0 (0%)	0 (0%)	
5-10 sec	32 (21.33%)	18 (12%)	56 (37.33%)	18 (12%)	
<5 sec	4 (2.67%)	0 (0%)	4 (2.67%)	0 (0%)	

Table 4:- Staining techniques.

Staining techniques						
	Rose bengal staining grades(Average Right and Left eye)					
	0	**1**	**2**	**3**	**4**	
Diabetic	113(75.33%)	7(4.67%)	15.5(10.33%)	7.5(5.0%)	7(4.67%)	
Non-diabetic	142(94.67%)	0(0.00%)	4(2.67%)	4(2.67%)	0(0.00%)	
	Fluorescein staining grades(Average Right and Left eye)					
	0	**1**	**2**	**2.5**	**3**	**3.5**
Diabetic	90.5(60.33%)	25(16.67%)	10(6.67%)	4.5(3.0%)	6.5(4.33%)	13.5(9.0%)
Non-diabetic	125(83.33%)	17(11.33%)	4(2.67%)	0(0.00%)	4(2.67%)	0(0.00%)
	Lissamine staining grades(Average Right and Left eye)					

	0	1	2	3
Diabetic	115(76.67%)	15.5(10.33%)	9.5(6.33%)	10(6.67%)
Non-diabetic	142(94.60%)	8(5.33%)	0(0.00%)	0(0.00%)

Table 5:- Severity of Diabetic retinopathy in dry eye.

Severity of Diabetic retinopathy vs Dry eye								
Dry eye	**Mild NPDR**		**Mod NPDR**		**Severe NPDR**		**PDR**	
	Right eye	**Left eye**	**Right eye**	**Left eye**	**Right eye**	**Left eye**	**Right eye**	**Left eye**
Present	5	6	3	3	5	2	1	3
Absent	1	1	1	0	0	1	0	0

Pearsonchisquare 0.02*

Table 6:- AssociationbetweenDiabeticretinopathyandHbA1C.

Diabetic retinopathy and HbA1c levels								
	Grades of Diabetic Retinopathy (Right eye)				**Grades of Diabetic Retinopathy (Left eye)**			
HbA1C	**DR mild**	**DR mod**	**DR severe**	**DR PDR**	**DR Mild**	**DR mod**	**DR severe**	**DR PDR**
6.0-7.0	0	0	2	0	0	0	0	2
7.0-8.0	0	0	0	0	0	0	0	0
>8.0	6	4	3	1	7	3	3	1

One way ANOVA test shows $p<0.05$* which is statistically significant for both right and left eye.

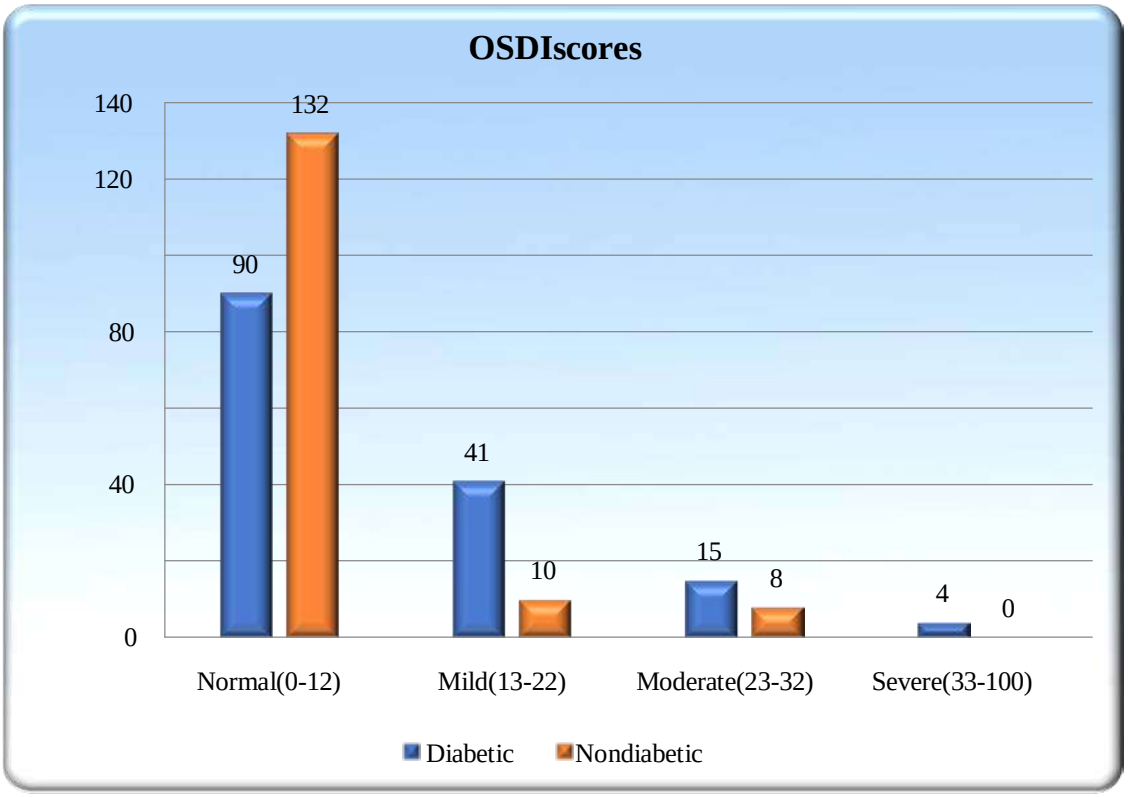

Figure 1:- OSDI scores.

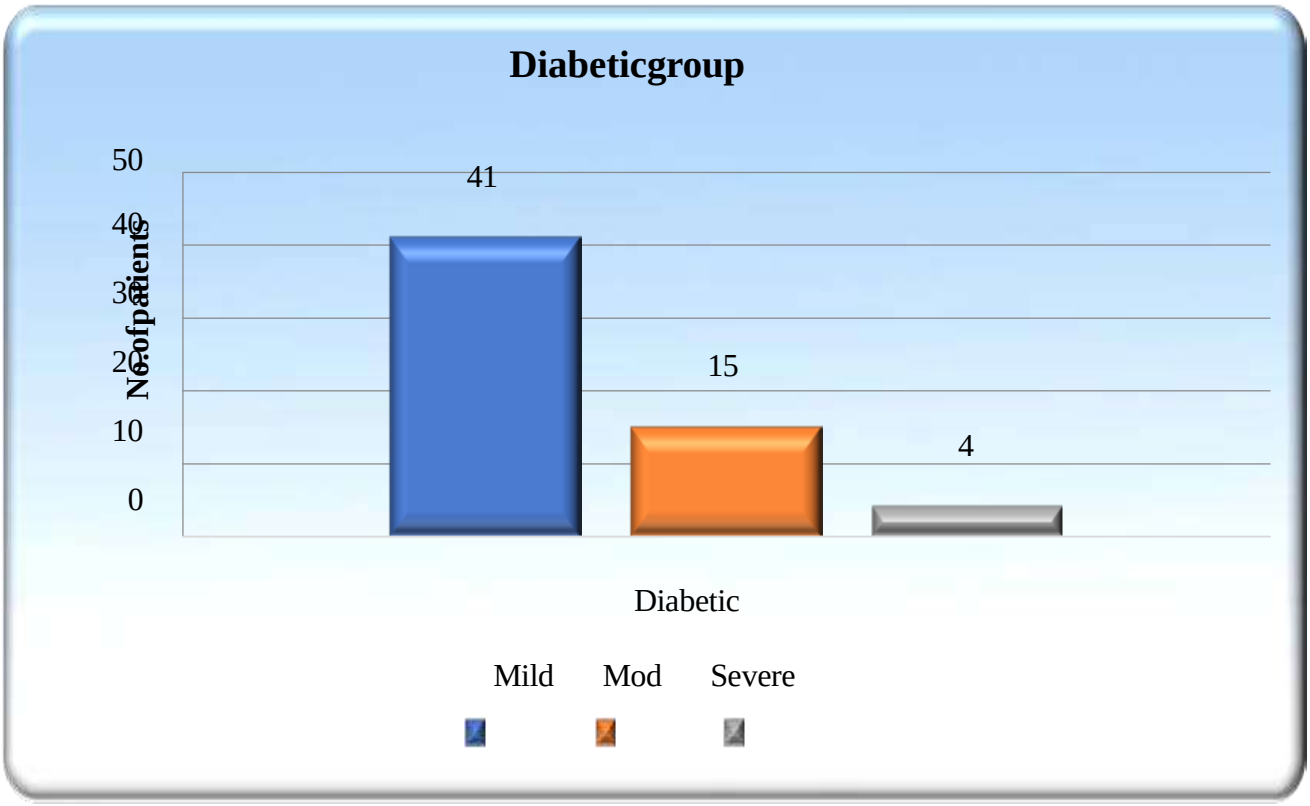

Figure 2a:- Grading of DED-Diabetic group.

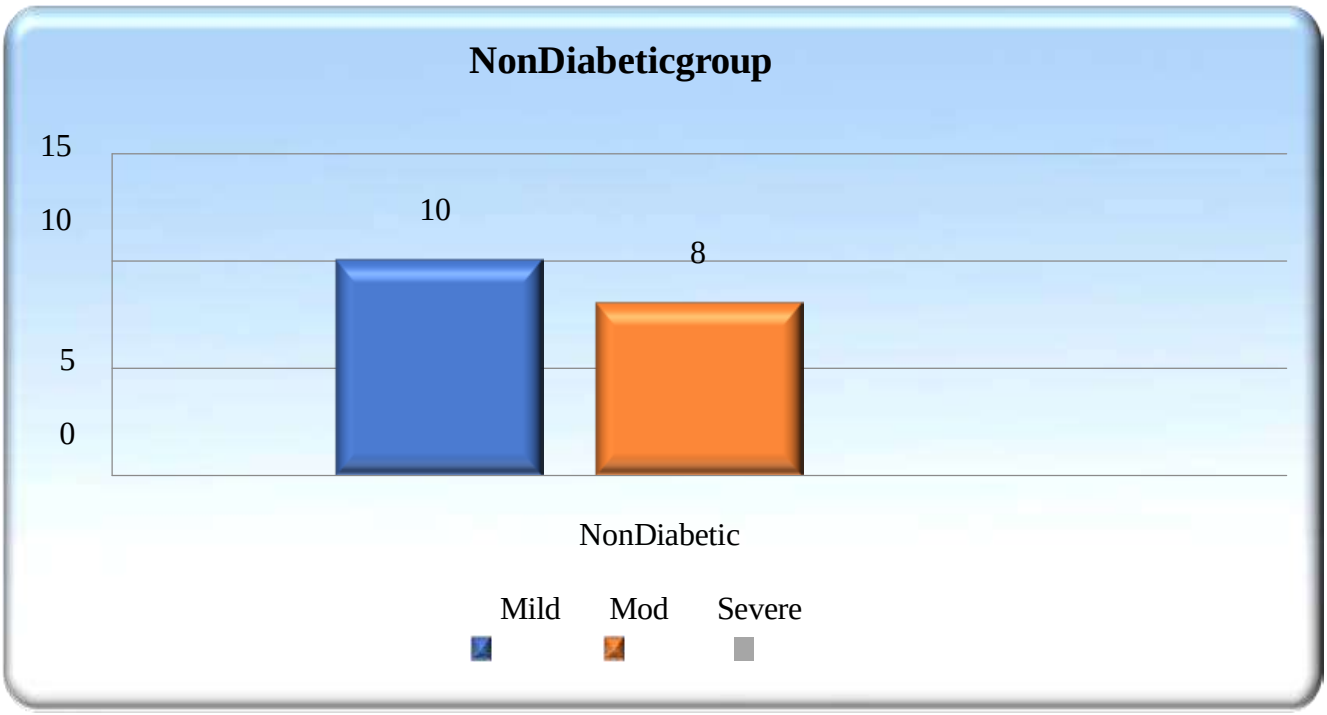

Figure 2b:- GradingofDED-Non-diabeticgroup.

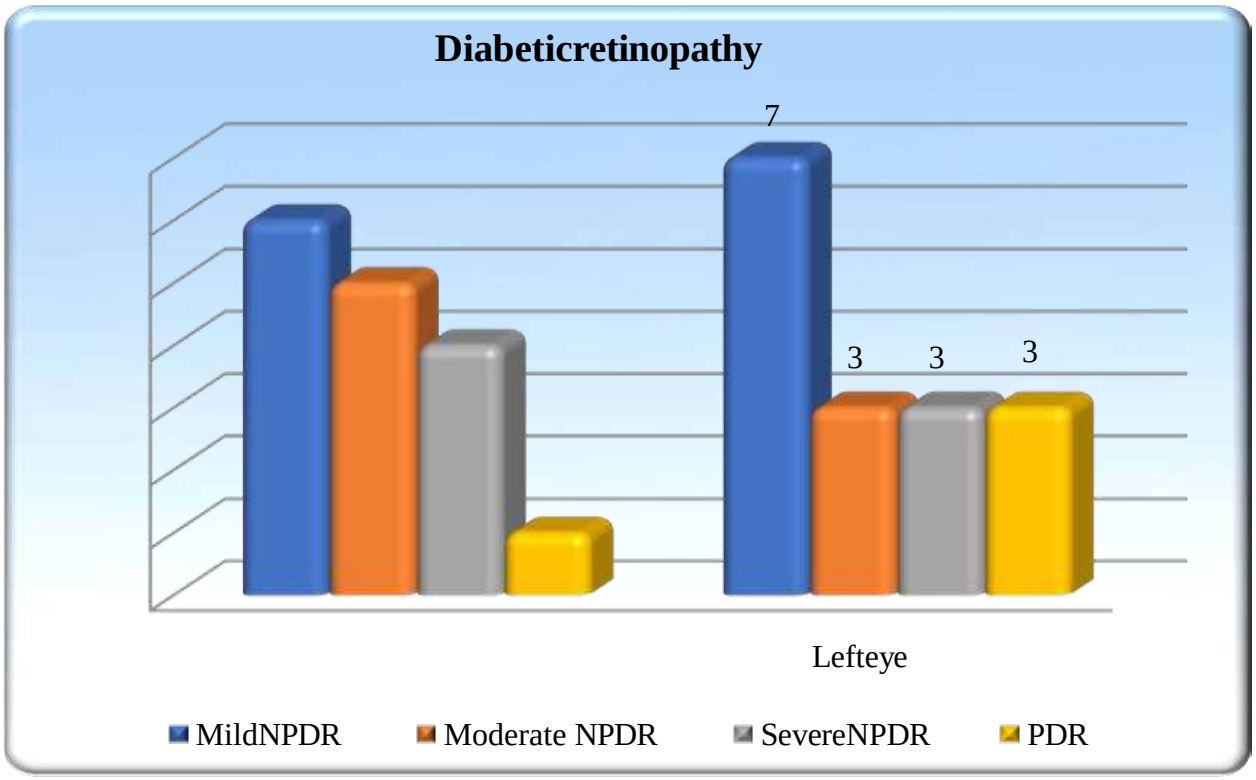

Figure 3:- Distributionofdiabeticretinopathy.

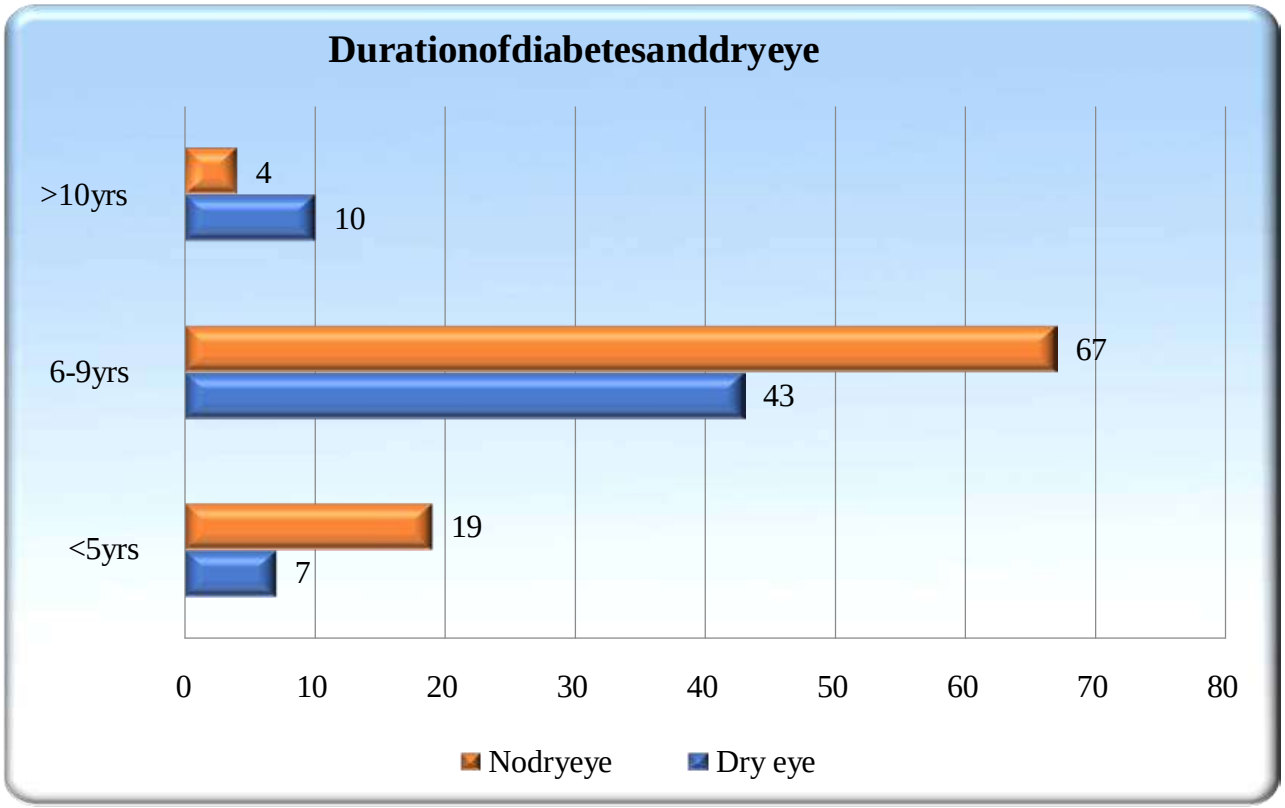

Figure 4:- DurationofdiabetesandDryeye.

Limitations

1. The results of this study may not be broadly applicable to the general population due to ethnic heterogeneity of dry eye disease.
2. The investigations were done on a sample of modest size in a single centre; therefore the effects of modest sample size should be considered while generating the results.
3. Potential bias resulting from the selective sampling of participants from the same hospital and geographic location.

Conclusion:-

Dry eye disease is a significant concern for individuals with diabetes mellitus. The duration of diabetes and the stage of retinopathy are closely linked to the occurrence and severity of tear film dysfunction. It's crucial to routinely test for dry eye, even in asymptomatic patients, through simple non-invasive methods during ophthalmic visits. Early detection and treatment are vital for preventing dry eye syndrome and its potential progression to vision-threatening complications, ultimately enhancing the patient's quality of life. Therefore, it's strongly recommended to include the clinical evaluation of dry eye as a standard part of ocular examinations for diabetic patients.

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