Original Article

Pattern of Schirmer test, TBUT test and OSDI score in Diabetic Retinopathy- A Hospital Based Observational Study

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Abstract

Background: This study aims to determine the relationship between dry eye disease and diabetic retinopathy. The study design is cross-sectional observational study. **Material and Methods:** 300 patients with type 2 diabetes mellitus, aged between 18 and 65 years of either sex, were recruited. A comprehensive ophthalmological examination was done in each case, including fundus photography and optical coherence tomography. Diabetic retinopathy was graded according to Early Treatment Diabetic Retinopathy (ETDRS) criteria. Blood was tested for Hb1Ac%. Tear Break Up Time, the Schirmer test, and the Ocular Surface Disease Index were used to evaluate dry eye syndrome and classify it into four categories: normal, mild, moderate, and severe. The SPSS version was used for the statistical analysis. The significance of the results was determined using an ANOVA test. **Results:** 153 of 300 diabetic patients (51%) had dry eye disease. There was a significant association between dry eye and the duration of diabetes mellitus ($P < 0.0001$). The diabetic retinopathy group had significantly lower Schirmer values compared with the diabetic retinopathy population ($p=0.0004$). A considerably lower TBUT score was observed in the diabetic retinopathy population ($p=0.0001$). In our study, patients with diabetic retinopathy showed a strong positive association with the ocular surface disease index ($p < 0.0001$). **Conclusion:** Dry eye disease is strongly associated with more severe diabetic retinopathy in later life. Schirmer test, TBUT test, and OSDI score value were significantly abnormal when diabetic patients also had diabetic retinopathy. Any diabetic patient who complains about dry eye symptoms must be thoroughly screened for the probable presence of diabetic retinopathy and vice versa. Clinical examination of dry eye disease, such as the Schirmer test, TBUT test, and OSDI scoring, should be an integral part of diabetic eye assessment.

Keywords: Diabetes mellitus, Diabetic Retinopathy, Ocular surface disease index, Schirmer test, Tear film break up time.

Received: 01 November 2025 **Revised: 25 November 2025** **Accepted: 10 December 2025** **Published: 23 December 2025**

Introduction

Diabetes mellitus is now a major public health problem worldwide, with a global prevalence rate of 11.1%. According to the International Diabetes Federation, approximately 853 million people will be affected by diabetes worldwide in 2050. India is also not an exception.

Data from 2019 shows that the incidence in India increased from 7.1% in 2009 to 8.9% in 2019.[1]

Glycosylated hemoglobin (HbA1c) and the existence of dry eye syndrome were found to be positively correlated in one earlier investigation. They concluded that the prevalence of dry eye syndrome increased with higher HbA1c levels.[2]

The multifactorial ocular surface disease known as dry eye disease (DED) is characterized by a loss of tear film homeostasis and associated ocular symptoms. The etiology of DED includes tear film hyperosmolarity, instability, ocular surface damage and inflammation, and neurosensory abnormalities.[3]

When it comes to diabetes, screening for diabetic retinopathy is given far greater priority than ocular surface inspection. However, subsequent bacterial infections, corneal perforation, scarring, and vision loss can result from dry eye. Such vision-threatening complications will be less common if this condition is identified and treated early. Patients' quality of life is significantly affected by dry eye disease, which also impairs everyday activities and work productivity.[4]

However, there isn't enough research in eastern India to assess the dry eye condition in people with type 2 diabetes. To identify potential ocular surface illness and its correlation with diabetic retinopathy, the current study is evaluating tear volume, tear film stability, and ocular surface condition in patients with the condition.

Materials and Methods

It was a prospective, comparative, observational study conducted at the Department of Ophthalmology of a tertiary

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DOI:
10.21276/amit.2025.v12.i3.261

How to cite this article: Bala B, Nag S, Biswas S. Pattern of Schirmer test, TBUT test and OSDI score in Diabetic Retinopathy- A Hospital Based Observational Study. Acta Med Int. 2025;12(3):1227-1231.

care government medical college in Kolkata, West Bengal. The study period was 18 months (April 2023 to October 2024). All recruited patients were diagnosed with type 2 diabetes mellitus according to the American Diabetes Association criteria. The diagnosis of diabetes was made by the physician at our General Medicine OPD clinic. All type 2 Diabetes patients aged 40 years or older, of any gender, who attend our Ophthalmology OPD and provide valid consent to participate in the study were included as study participants. All participants provided informed consent, and the study was conducted in compliance with the Declaration of Helsinki.

Exclusion criteria included Type 1 DM, Diabetes with other ocular or systemic disease, and patients with raised IOP. Those who are smokers use contact lenses, and pregnant women were excluded from this current study. Patients who undergo any ocular surgery were excluded from this study.

All patients were interviewed, and data were collected by reviewing medical records, including age, sex, duration of diabetes, history of other diseases, and medication history.

All patients undergo a comprehensive ophthalmological examination, including detailed history taking, recording of best corrected visual acuity, slit lamp examination, gonioscopy, and IOP measurement. The fundus was clinically evaluated with a 90D lens and indirect ophthalmoscopy.

To know the status of diabetes, we have checked Fasting blood sugar (FBS), postprandial blood sugar (PPBS), and the level of glycosylated hemoglobin (Hb1Ac).

All the clinically detected cases of diabetic retinopathy were further evaluated by fundus photography, optical coherence tomography, and optical coherence tomography angiography.

All recruited study subjects were evaluated for dry eye using tear film break-up time (TBUT), Schirmer test, and ocular surface disease index (OSDI) scoring, as per the guidelines of the American Academy of Ophthalmology. Diagnosis of dry eye disease was established when at least one test became abnormal.

Using a slit lamp, the tear meniscus height and the presence of debris (mucus, oil droplets, and detritus) were measured to evaluate the tear film.

Three types of dry eye were distinguished: mild, moderate, and severe. Over 10 mm of wetness after 5 minutes was deemed normal for the Schirmer test; mild dryness was defined as 8–10 mm of wetting; moderate dryness as 5-7 mm; and severe dryness as less than 5 mm of wetting after 5 minutes.

The time, in seconds, between the final blink and the emergence of the first dry area is known as the tear film break-up time. A tear film break-up time of less than 10 seconds was considered a favorable sign of dry eye. Negative was defined as more than or equal to 10 seconds.

Each patient was given the Ocular Surface Disease Index questionnaire, and their score was recorded. A higher score indicates a larger degree of ocular surface illness. Patients were divided into four groups based on their OSDI scores. A score of 0–12 indicates normal dry eye, 13–22 indicates mild, 23–32 indicates moderate, and 33–100 indicates severe.

The Early Treatment Diabetic Retinopathy Study (ETDRS) criteria were used to classify diabetic retinopathy into five categories: proliferative diabetic retinopathy (PDR), mild nonproliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, and no diabetic retinopathy.

After compiling and entering all collected data into a spreadsheet application (Microsoft Excel 2019), SPSS (Statistical Package for the Social Sciences, version 27.0.1) was used to analyze the data. An appropriate statistical test (e.g., the Chi-square test, t-test, ANOVA) was used. Statistical significance was defined as a P value < 0.05.

Results

In this study, 300 diabetic patients were recruited after strict adherence to the inclusion and exclusion criteria. Out of the 300 study subjects, 165 (55%) were male, and the remaining 135 (45%) were female.

Most of our study population was aged 50 years or older (67%). The average age of the patients was 52.18 ± 10.08 years.

Of these 300 patients, 159 (53%) had clinically detected diabetic retinopathy. In our study population, 147 patients (49%) had diabetes for less than 5 years. But 20% study population had diabetes for more than 10 years.

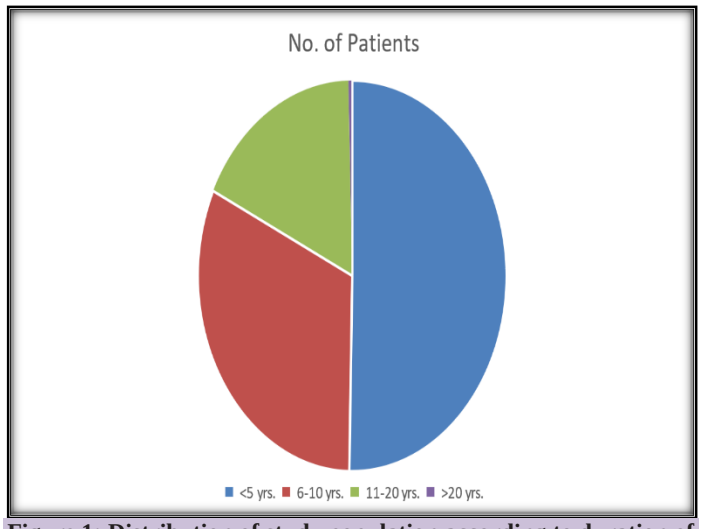

Figure 1: Distribution of study population according to duration of Diabetes

There was a significant correlation ($p<0.05$) between diabetes duration and dry eye [Table 1]. The prevalence of dry eye was 82.4% among people with diabetes who had had the disease for more than 10 years, and 71% among those with diabetes who had had it for more than 6 years.

Of these 300 patients, the glycosylated hemoglobin (HbA1c) percentage was less than 6% in 78 patients, between 6% and 8% in 150 patients, and greater than 8% in 72 patients. There was a significant association between the HbA1c level and the grade of diabetic retinopathy.

Table 1: Association of dry eye with mean duration of diabetes

Dry Eye	No. of Patients	Duration of Diabetes In years. (mean± SD)	P value
Positive	153	7.79 ± 5.93	<0.0001
Negative	147	4.10 ± 3.94	

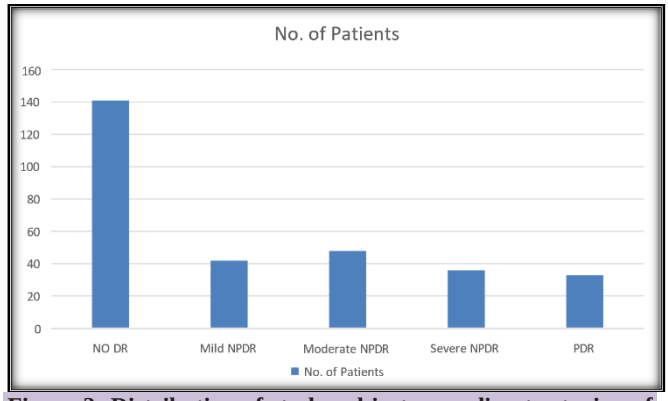

Figure 2: Distribution of study subject according to staging of Diabetic Retinopathy

In our study, 141 patients (47%) showed no signs of diabetic retinopathy; 42 had mild non-proliferative diabetic retinopathy (NPDR); 48 had moderate NPDR; 36 had severe NPDR; and 33 had proliferative diabetic retinopathy (PDR) [Figure 2].

Patients without retinopathy had a mean diabetes duration of 4.86 ± 5.23 years [Table 3], whereas patients with retinopathy had a mean diabetes duration of 8.79 ± 5.53 years. Diabetes with or without retinopathy had mean HbA1c values of 8.85 ± 2.41% and 9.20 ± 2.27%, respectively. HbA1c level and the presence of diabetic retinopathy did not correlate significantly (p value = 0.196). The mean Schirmer score in the No DR group was 11.67 ± 4.41 mm of wetting, while this value was 10.04 ± 3.42 in the diabetic retinopathy group. In the no-DR group, 95.7% of subjects had Schirmer values within normal limits, while only six patients showed a mild decrease. In mild and moderate degrees of NPDR, a mild to moderate degree of low Schirmer value was noted in 68.8% cases, but in severe NPDR and PDR cases, the frequency of severely low Schirmer value was indicated in 14.7% cases.

Table 2: Distribution of study subjects according to clinical characteristics

Characteristic	Diabetes with No Retinopathy	Diabetes with Diabetic Retinopathy	
	Mean ± SD	Mean ± SD	P value
Age (yr)	53.72 ± 9.88	57.55 ± 8.93	0.0005
DM duration (yrs.)	4.86 ±5.23	8.79 ± 5.53	<0.0001
HbA1c%	8.85 ± 2.41	9.20 ±2.27	0.1964
Schirmer (mm)	11.67 ± 4.41	10.04 ± 3.42	0.0004
TBUT (Sec)	13.94 ± 4.66	11.44 ± 4.23	0.0001
OSDI	8.04 ± 8.26	21.37 ± 12.16	<0.0001

Table 3: Tear break up time pattern in study population

	>10 sec	5-10 sec	<5 sec
NO DR	137	4	0
Mild NPDR	10	32	0
Moderate NPDR	13	33	2
Severe NPDR	6	26	4
PDR	4	22	7

In the no diabetic retinopathy group, 97.1% of patients had tear film break-up without any abnormality [Table 4], while only four patients had a mild degree of abnormality. But as diabetic retinopathy progresses, the severity of TBUT abnormality also increases. In mild to moderate NPDR, most of the study subjects have a mild variety of TBUT abnormality, while in severe NPDR or in proliferative diabetic retinopathy, most study subjects suffered from a severe degree of TBUT abnormality.

Table 4: Schirmer test score in different grade of Diabetic Retinopathy

	>10 mm	5-10 mm	<5 mm
No DR	135	6	0
Mild NPDR	12	30	0
Moderate NPDR	13	32	3
Severe NPDR	4	28	4
PDR	3	24	6

The Schirmer test [Table 5] showed little abnormality in the No DR group and in the patient with mild NPDR. Only 19.67% of No DR and mild NPDR cases showed a mild to moderate degree of abnormal Schirmer score. In contrast, in

moderate-to-severe NPDR and PDR cases, 82.90% showed a moderate-to-severe degree of abnormal Schirmer values.

Table 5: Result of ocular surface disease index in study population

Diabetic Retinopathy (DR)		Ocular surface disease index				
		Normal	Mild	Moderate	Severe	Total
No DR	N	108	24	6	3	141
	%	76.60	17.02	4.26	2.13	100
Mild NPDR	N	27	6	9	0	42
	%	64.29	14.29	21.43	0	100
Moderate NPDR	N	12	15	18	3	48
	%	25	31.25	37.50	6.25	100
Severe NPDR	N	0	15	12	9	36
	%	0	41.67	33.33	25	100
PDR	N	0	0	15	18	33
	%	0	0	45.45	54.55	100
Total	N	147	60	60	33	300

Of the 300 study participants, 153 (51%) had abnormal ocular surface disease. Ocular surface disease index was significantly abnormal in patients with diabetic retinopathy, especially in the advanced stage of diabetic retinopathy. In mild NPDR, 35.7% patients had abnormal OSDI score, while in moderate NPDR, it was 75%. Interestingly, in severe NPDR and PDR cases, all the affected individuals show abnormally high OSDI scores.

Of 300 subjects, 153 (51%) had dry eye syndrome; 93 (60.78%) were female, and 60 (39.21%) were male. No significant association was observed between gender and dry eye frequency in the diabetic population (p=021).

The frequency of dry eye syndrome was highest in patients aged 60 years or older and lowest in the 30-40 years age group, but this correlation was also not significant (p=0.89).

Discussion

In our study, 300 consecutive patients with type 2 diabetes mellitus were examined, and of them, 159 (53%) had diabetic retinopathy. We have assessed dry eye disease in all 300 subjects. Our study population was slightly male predominant (M: F=11:9). 67% our study population was above 50 years of age. A recent study from Western India showed a similar kind, with a mean age of 7 ± 9.06 years.[5]

53% of the study population had clinically detected diabetic retinopathy in our study. The duration of diabetes mellitus shows a strong, statistically significant correlation with diabetic retinopathy ($p < 0.0001$). A recent study in Bangladesh also showed a strong association between diabetes duration and diabetic retinopathy.[6]

In the non-DR group, 97.1% had normal TBUT time, with a mean of 13.94 ± 4.66 seconds. 95.7% had normal Schirmer value with an average value of 11.67 ± 4.41 mm of wetting after 5 minutes, and 76.6% had normal ocular surface disease index score. However, in the DR group, this dry eye parameter shifted toward dry eye disease, and the results clearly indicate that dry eye disease severity is closely associated with diabetic retinopathy severity.

Our study shows that 72.9% of moderate NPDR patients, 88.8% of severe NPDR patients, and 90.9% of PDR patients showed abnormality in their Schirmer test. Patients without DR had an average Schirmer score of 11.64 ± 4.41 mm, while those with diabetic retinopathy had an average Schirmer score of 10.04 ± 3.42 mm after 5 minutes. In our study, the diabetic retinopathy group had significantly low Schirmer value in comparison with the diabetic retinopathy population (p= 0.0004).

Goebbels reported a significantly low Schirmer score in Type 1 diabetes mellitus.[7]

In a study by Moss et al., the prevalence of Dry eye among the diabetic population was 14.4%, and it increased with age.

A similar kind of observation was also noted in the tear film breakup time test. 72.9% moderate NPDR, 83.3% severe NPDR, and 87. 8% of patients 8% PDR had low tear film breakup time. The TBUT in the No DR group was 13.94 ± 4.66 seconds, while patients with diabetic retinopathy had an average TBUT of 11.44 ± 4.23 seconds.

Abnormal TBUT (<10 sec) was observed in 126 patients, and most had mild to moderate abnormality. Again, here patients with diabetic retinopathy had significantly low TBUT score in comparison to patients without diabetic retinopathy (p=0.0001). Jin et al,[9] studied 100 patients with type 2 DM II along with an 80-person population and a control group. The tear film break-up time was significantly shorter in patients with type 2 diabetes mellitus.

Based on the ocular surface disease index symptom scores among 300 diabetic patients, 153 (51%) were symptomatic. Among them, 60 patients had mild symptoms, 60 had moderate symptoms, and 33 had severe symptoms. Manaviat et al,[10] reported that 54% of diabetic patients had dry eye-related symptoms.

According to the ocular surface disease index, more than 60% of patients had mild to moderate abnormality. In contrast, in the severe NPDR group, almost 60% had a moderate-to-severe abnormal OSDI score. In PDR patients, more than 90% had a moderate-to-severe abnormal OSDI score. In our study, patients with diabetic retinopathy showed a strong positive association with the ocular surface disease index ($p < 0.0001$). The mean ocular surface disease index score was 8.04 ± 8.26 in the no diabetic retinopathy group, while it was 21.37 ± 12.16 in the diabetic retinopathy group.

In the Mansuri et al,[5] study, the mean OSDI score in the dry eye disease group was 28.91 ± 9.42, while in the non-dry eye group, it was 10.10 ± 2.03, and the difference was statistically

significant ($p < 0.001$).

In our study, out of 300 study subjects, 153 (51%) had dry eye disease. One recently concluded cross-sectional study in Bangladesh showed a prevalence of 44.6%.[6] A case-control study of South India reported 54% dry eye disease among the diabetic population.[7] But another study from western India reported a 36% prevalence of dry eye among the diabetic population.[8]

As per Moss et al,[8] study, the overall prevalence of dry eye was 14.4%. It was 8.4% among patients aged <60 years but increased to 19% among patients aged 80 years.

Seifert et al.2 examined 92 patients with Diabetes mellitus, both type 1 and type 2. They found 52.8% of them had dry eye disease in the Diabetes mellitus group, while it was only 9.3% in the control group.

Jain,[11] studied 400 patients with dry eye; 80 had DM. He concluded DM itself was a risk factor for DED.

Ozdemir et al conducted a case-control study and found that Tear film BUT and Schirmer test values were significantly lower in diabetic patients than in control subjects ($P < 0.001$).[12-15]

In this study, the prevalence of dry eyes among diabetic retinopathy patients was significantly higher than that among diabetic patients without retinopathy. Seifert et al.2 also found similar kinds of results in their study. A study conducted in Pakistan shows a statistically significant association between dry eye symptoms and increasing age and diabetic retinopathy.[12]

Dry eye is more common among people with diabetes, most likely due to autonomic dysfunction, changes in tear film dynamics, decreased corneal sensitivity, and microvascular damage to the lacrimal gland.

Limitations of the study

As our study was hospital-based and cross-sectional, it may not accurately reflect the true prevalence of dry eye disease in patients with diabetic retinopathy. A multi-center study with a large sample size will be better.

Conclusion

The presence of increased severity of diabetic retinopathy in older age is significantly associated with dry eye disease. Schirmer test, TBUT test, and OSDI score value were significantly abnormal when diabetic patients also had diabetic retinopathy. Any diabetic patient who complains of dry eye symptoms must be thoroughly screened for the possible presence of diabetic retinopathy, and vice versa. Clinical examination of dry eye disease, such as the Schirmer test, TBUT test, and OSDI scoring, should be an integral part of diabetic eye assessment.

Acknowledgement: We are thankful to all participating patients in this study and to all the staff in our department.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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