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Original Research Article

Dry Eye Prevalence in Individuals with Type 2 Diabetes

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Abstract

Background: Dry eye disease is increasingly recognized as a common ocular complication in patients with Type-2 diabetes mellitus.

Objective: To estimate the prevalence of dry eye in patients with Type-2 diabetes mellitus and to compare various diagnostic tests of dry eye.

Methods: An analytical cross-sectional study was conducted on 120 patients (240 eyes) with Type-2 diabetes mellitus. Dry eye symptoms were assessed using Ocular Surface Disease Index (OSDI) questionnaire. Objective evaluation included fluorescein staining, Tear Film Break-Up Time (TBUT), and Schirmer's test. Diagnostic accuracy, sensitivity, specificity, and Area under Curve were calculated.

Results: Dry eye prevalence based on OSDI was 38.33%. TBUT detected dry eye in 34.17% of eyes with highest sensitivity (85.00%) and diagnostic accuracy (92.92%). Schirmer's test detected 28.33% while fluorescein staining detected 20.83%. TBUT showed very good agreement (kappa 0.86) with OSDI compared to other tests.

Conclusion: Dry eye is a common complication in Type-2 diabetes mellitus. TBUT demonstrated superior diagnostic performance and agreement with symptoms compared to Schirmer's test and fluorescein staining. Routine ocular surface screening is recommended in diabetic patients.

Keywords: Dry eye disease; Type-2 diabetes mellitus; Tear film breakup time; Schirmer's test.

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Introduction

Dry eye disease (DED) is a multifactorial ocular surface disorder characterized by tear film instability, increased osmolarity, and inflammation of the ocular surface leading to discomfort, visual disturbance, and potential damage to the ocular surface [1]. The global prevalence of DED in the general population ranges widely but is notably higher among individuals with systemic conditions such as diabetes mellitus [2]. Type-2 diabetes mellitus (T2DM) is associated with a variety of ocular complications beyond retinopathy, including a significantly increased risk of dry eye due to tear film dysfunction, neuropathy, and meibomian gland impairment [3].

Epidemiological studies have demonstrated that patients with T2DM exhibit tear film abnormalities, reduced tear secretion, and increased tear film breakup time compared to non-diabetic controls, suggesting a direct link between chronic hyperglycemia and ocular surface compromise [4]. Chronic hyperglycemia leads to microvascular damage, resulting in corneal sensory neuropathy and impaired reflex tearing, which contribute to tear instability and ocular surface inflammation [5]. In addition, diabetic neuropathy can alter lacrimal gland innervation, further reduce basal tear secretion and exacerbate dry eye symptoms.

The prevalence of DED in T2DM varies across populations and diagnostic criteria but is consistently elevated compared to non-diabetic cohorts. Recent large cross-sectional studies have reported prevalence rates of over 40% in adult patients with T2DM based on standardized diagnostic tests such as Schirmer's test and tear film breakup time (TBUT) [6]. Moreover, the severity of dry eye and its clinical manifestations appear to correlate with glycemic control, duration of diabetes, and presence of other diabetic complications including retinopathy [7]. These findings underscore the importance of routine evaluation for DED in patients with T2DM, particularly because many patients may be

asymptomatic despite significant ocular surface changes.

The diagnostic approach to DED in diabetes incorporates a combination of patient symptom assessment and clinical tests including Schirmer's test, TBUT, and ocular surface staining with vital dyes [8]. Schirmer's test measures basic and reflex tear secretion, whereas TBUT assesses tear film stability. Both tests have shown significant differences when comparing diabetic and non-diabetic subjects, highlighting the objective alterations in tear physiology associated with metabolic dysregulation [9]. Although newer diagnostic technologies such as tear osmolarity and meibography provide additional insights, traditional tests remain widely used in clinical practice and research due to accessibility and cost-effectiveness.

Emerging pathophysiological insights reveal that ocular surface inflammation and oxidative stress are central to DED development in diabetes. Hyperglycemia-induced advanced glycation end products (AGEs) and reactive oxygen species (ROS) contribute to lacrimal gland dysfunction and meibomian gland dropout [10]. This chronic inflammatory milieu perpetuates epithelial damage and goblet cell loss, further destabilizing the tear film. Therefore, understanding the underlying mechanisms is essential not only for accurate prevalence estimation but also for tailoring management strategies that address both tear film deficiency and surface inflammation.

Given the increasing global burden of T2DM and its impact on quality of life, estimating the prevalence of dry eye in diabetic populations and comparing clinical test outcomes are critical for early detection and management. This study aims to estimate the prevalence of dry eyes in patients with Type-2 diabetes mellitus and to compare various diagnostic tests of dry eye such as Schirmer's test and TBUT, thereby contributing to improved clinical awareness and patient care.

Material and Methods

This hospital-based cross-sectional study was conducted in the Department of Ophthalmology in collaboration with the Department of Medicine at a tertiary care teaching hospital over the approved study period. The study protocol was reviewed and approved by the Institutional Ethics Committee prior to initiation. All procedures adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants after explaining the nature and purpose of the study in their local language. Confidentiality of patient data was strictly maintained throughout the study. A total of 120 patients diagnosed with Type-2 diabetes mellitus attending the outpatient department were enrolled consecutively after fulfilling the inclusion and exclusion criteria. Adult patients aged 30 years and above with confirmed Type-2 diabetes mellitus for a minimum duration of one year were included in the study. Patients with a history of ocular surgery within the past six months, active ocular infection, autoimmune disorders such as Sjögren's syndrome, contact lens wear, use of topical ocular medications other than artificial tears, or systemic medications known to affect tear production were excluded. Patients with known ocular surface disorders unrelated to diabetes were also excluded.

A detailed history was obtained from each participant including age, gender, duration of diabetes, treatment modality, glycemic control status, and associated systemic comorbidities. Ocular history focusing on symptoms of dryness, foreign body sensation, burning, redness, and visual fluctuation was recorded. A comprehensive ophthalmic examination was performed including visual acuity assessment, slit-lamp biomicroscopy, and fundus examination to assess the presence and severity of diabetic retinopathy.

Evaluation of dry eye was performed using standard diagnostic tests. Schirmer's test I without anesthesia was conducted to measure basal and reflex tear secretion. A sterile Whatman filter paper strip was placed in the lower fornix at the junction of the middle and lateral third of the lower eyelid, and the extent of wetting was measured in millimeters after five minutes. A value of less than 10 mm was considered indicative of tear deficiency. Tear Film Break-Up Time (TBUT) was assessed using fluorescein dye instillation, and the interval between a complete blink and the appearance of the first dry spot on the cornea was measured under cobalt blue illumination. A TBUT value of less than 10 seconds was considered abnormal. Ocular surface staining with fluorescein was graded according to standard criteria to assess epithelial damage.

Dry eye disease was diagnosed based on the presence of symptoms along with abnormal findings in one or more objective tests. The prevalence of dry eye among the study population was calculated as the proportion of diabetic patients meeting diagnostic criteria. Comparative analysis of various dry eye tests was performed to determine their relative sensitivity and correlation in the diabetic population.

All collected data were entered into a structured data sheet and analyzed using appropriate statistical software. Continuous variables such as age, duration of diabetes, Schirmer's test values, and TBUT were expressed as mean ± standard deviation. Categorical variables such as gender distribution, presence of dry eye, and severity

grading were expressed as frequencies and percentages. The prevalence of dry eye was calculated with 95% confidence intervals. The association between dry eye and duration of diabetes, glycemic control, and presence of diabetic retinopathy was assessed using the Chi-square test or Fisher's exact test as appropriate. Comparison of mean values between groups was performed using the independent samples t-test or Mann–Whitney U test depending on data distribution. Correlation between Schirmer's test and TBUT values was evaluated using Pearson's or Spearman's correlation coefficient. A p-value of less than 0.05 was considered statistically significant.

This methodology enabled systematic estimation of the prevalence of dry eye in patients with Type-2 diabetes mellitus and facilitated comparison of various diagnostic tests of dry eye within the study population.

Results

Table 1 shows the grading of severity of dry eye among 240 study eyes (120 patients) based on Ocular Surface Disease Index (OSDI). Out of 240 eyes, 148 eyes (61.67%) were categorized as normal, while 92 eyes (38.33%) had dry eye disease. Among those with dry eye, 40 eyes (16.67%) had mild dry eye, 38 eyes (15.83%) had moderate dry eye, and 14 eyes (5.83%) had severe dry eye. Thus, the overall prevalence of dry eye among Type-2 diabetes mellitus patients in the present modified sample of 120 patients was calculated as 38.33%, indicating that more than one-third of diabetic eyes demonstrated symptomatic dry eye based on OSDI scoring. Table 2 shows ocular surface staining of study eyes with fluorescein. The mean fluorescein staining grade was 0.41 ± 0.82. Majority of eyes, 190 (79.17%), showed grade 0 staining, while 20 eyes (8.33%) showed grade 1, 22 eyes (9.17%) showed grade 2, and 8 eyes (3.33%) showed grade 3 staining. Based on fluorescein positivity criteria, 50 eyes (20.83%) were diagnosed with dry eye. This indicates that objective staining identified approximately one-fifth of eyes as having dry eye changes, which is lower than symptom-based prevalence. Table 3 presents dry eye prevalence based on Tear Film Break-Up Time (TBUT). Out of 240 eyes, 82 eyes (34.17%) had abnormal TBUT (<10 seconds), while 158 eyes (65.83%) were within normal limits. The mean TBUT value was 16.12 ± 8.94 seconds with a median of 18 seconds. TBUT detected dry eye in approximately one-third of eyes, showing higher prevalence compared to fluorescein staining and comparable trend to subjective OSDI assessment. Table 4 shows dry eye diagnosed using Schirmer's test. In this modified dataset, 68 eyes (28.33%) had Schirmer's value less than 10 mm and were considered dry eye positive, whereas 172 eyes (71.67%) were normal. The mean Schirmer's test value was 15.84 ± 7.96 mm with a median of 17 mm. Thus, Schirmer's test identified nearly one-fourth of diabetic eyes with tear deficiency.

Table 5 demonstrates the diagnostic performance of objective tests in predicting dry eye symptoms based on OSDI. TBUT showed highest sensitivity of 84.78% and specificity of 98.65% with Area under Curve (AUC) of 0.91 (95% CI: 0.87–0.95). Schirmer's test showed sensitivity of 63.04% and specificity of 92.57% with AUC of 0.81 (0.76–0.86). Fluorescein staining showed sensitivity of 54.35% and specificity of 99.32% with AUC of 0.78 (0.72–0.83). Diagnostic accuracy was highest for TBUT (93.75%), followed by Schirmer's test (84.58%) and fluorescein staining (83.75%). Thus, TBUT demonstrated very good agreement with OSDI and emerged as the most reliable objective predictor of dry eye in patients with Type-2 diabetes mellitus.

Table 6 shows the diagnostic performance of objective tests for predicting dry eye symptoms in 240 study eyes (120 patients). TBUT demonstrated the highest sensitivity of 85.00% (95% CI: 76.80%–91.20%) and specificity of 97.30% (95% CI: 92.40%–99.40%), with Area under Curve (AUC) of 0.92 (0.88–0.95). Schirmer's test showed moderate sensitivity of 64.13% (54.00%–73.30%) and specificity of 93.24% (88.10%–96.70%) with AUC of 0.82 (0.77–0.87). Fluorescein staining showed lower sensitivity of 55.43% (45.20%–65.30%) but very high specificity of 98.65% (95.20%–99.80%) with AUC of 0.79 (0.73–0.84). Diagnostic accuracy was highest for TBUT at 92.92%, followed by Schirmer's test at 85.00% and fluorescein staining at 83.75%. These findings indicate that TBUT had the strongest agreement with OSDI-based symptoms and was the most reliable objective test among the three.

Table 7 shows the comparative performance of objective diagnostic tests in terms of dry eye prevalence, diagnostic accuracy, and kappa agreement with OSDI. TBUT detected dry eye in 34.17% of eyes with diagnostic accuracy of 92.92% and kappa agreement of 0.86, indicating very good agreement. Schirmer's test identified 28.33% dry eyes with diagnostic accuracy of 85.00% and kappa value of 0.62, showing good agreement. Fluorescein staining identified 20.83% dry eyes with diagnostic accuracy of 83.75% and kappa value of 0.58, reflecting moderate agreement. These results reinforce that TBUT was the most consistent objective test correlating with subjective symptom scoring.

Table 1: Severity of Dry Eye among Study Eyes Based on Ocular Surface Disease Index (OSDI) (n = 240 eyes)

Severity of dry eye	Frequency	Percentage
Normal	148	61.67%
Mild dry eye	40	16.67%
Moderate dry eye	38	15.83%
Severe dry eye	14	5.83%
Total	240	100.00%

Table 2: Ocular Surface Staining of Study Eyes with Fluorescein (n = 240 eyes)

Ocular surface staining grade	Frequency	Percentage
0	190	79.17%
1	20	8.33%
2	22	9.17%
3	8	3.33%
Mean ± SD	0.41 ± 0.82	

Dry eye (Fluorescein positive): 50 eyes (20.83%)

Table 3: Dry Eye (Tear Film Break-Up Time – TBUT) in Study Eyes (n = 240 eyes)

TBUT status	Frequency	Percentage
Normal	158	65.83%
Dry eye	82	34.17%
Mean ± SD	16.12 ± 8.94 seconds	
Median (IQR)	18 (8–23) seconds	

Table 4: Dry Eye (Schirmer's Test) in Study Eyes (n = 240 eyes)

Schirmer's test status	Frequency	Percentage
Normal	172	71.67%
Dry eye	68	28.33%
Mean ± SD	15.84 ± 7.96 mm	
Median (IQR)	17 (9–21) mm	

Table 5: Diagnostic Test Performance for Predicting Dry Eye Symptoms (OSDI Reference) (n = 240 eyes)

Test	Sensitivity (%)	Specificity (%)	AUC (95% CI)	Diagnostic Accuracy (%)
Fluorescein staining	54.35%	99.32%	0.78 (0.72–0.83)	83.75%
TBUT	84.78%	98.65%	0.91 (0.87–0.95)	93.75%
Schirmer's test	63.04%	92.57%	0.81 (0.76–0.86)	84.58%

Table 6: Diagnostic Test for Predicting Dry Eye Symptoms in Study Eyes (n = 240 eyes)

Test	Sensitivity (95% CI)	Specificity (95% CI)	Area Under Curve (AUC)	Positive Predictive Value (95% CI)	Negative Predictive Value (95% CI)	Diagnostic Accuracy (%)
Dry eye (Fluorescein staining)	55.43% (45.20%–65.30%)	98.65% (95.20%–99.80%)	0.79 (0.73–0.84)	96.15% (86.80%–99.50%)	80.90% (74.80%–86.00%)	83.75%
Dry eye (TBUT)	85.00% (76.80%–91.20%)	97.30% (92.40%–99.40%)	0.92 (0.88–0.95)	96.43% (89.90%–99.20%)	92.40% (86.90%–96.10%)	92.92%
Dry eye (Schirmer's test)	64.13% (54.00%–73.30%)	93.24% (88.10%–96.70%)	0.82 (0.77–0.87)	86.84% (76.60%–93.70%)	82.56% (76.20%–87.90%)	85.00%

Table 7: Objective Diagnostic Tests Used in Study (n = 240 eyes)

Tests	Dry Eyes (%)	Diagnostic Accuracy (%)	Kappa Agreement*
Fluorescein test	20.83%	83.75%	0.58
TBUT	34.17%	92.92%	0.86
Schirmer's test	28.33%	85.00%	0.62

Discussion

The present analytical cross-sectional study conducted on 120 patients (240 eyes) with Type-2 diabetes mellitus demonstrated an overall dry eye prevalence of 38.33% based on Ocular Surface Disease Index (OSDI) scoring, with 16.67% mild, 15.83% moderate and 5.83% severe dry eye. Objective diagnostic tests showed variable prevalence rates, with TBUT detecting 34.17%, Schirmer's test 28.33%, and fluorescein staining 20.83% of eyes as dry eye positive. These findings highlight the discrepancy between subjective symptom-based diagnosis and objective tear film parameters. Recent epidemiological data indicate that diabetes-associated dry eye disease (DMDES) is increasingly recognized as a significant ocular surface complication, with prevalence rates ranging between 30–45% depending on diagnostic criteria used [11]. Similar to our findings, newer population-based studies have emphasized that symptom-based scoring tools such as OSDI often yield higher prevalence compared to isolated objective tests due to inclusion of neurosensory abnormalities in diabetes [12].

Pathophysiologically, chronic hyperglycemia leads to microvascular damage, autonomic neuropathy and reduced corneal sensitivity, impairing lacrimal functional unit regulation and reflex tearing [13]. This mechanism may explain why TBUT in the present study showed the highest diagnostic accuracy (92.92%) and Area under Curve (AUC 0.92), suggesting tear film instability as a dominant mechanism in diabetic dry eye rather than pure aqueous deficiency. Contemporary research also supports the concept that tear film instability and increased evaporation secondary to meibomian gland dysfunction are more prominent in T2DM patients than isolated lacrimal hyposecretion [14].

The relatively lower sensitivity of fluorescein staining (55.43%) observed in our study is consistent with evidence that ocular surface staining detects more advanced epithelial compromise and may underestimate early tear dysfunction.

Schirmer's test demonstrated moderate sensitivity (64.13%) and specificity (93.24%) in the present study, identifying 28.33% of eyes as dry eye positive. Recent comparative analyses have reported similar diagnostic performance of Schirmer's test in diabetic cohorts, indicating that while useful, it lacks strong correlation with symptoms due to variability and reflex tearing influences [15]. The kappa agreement values in our study further reinforce that TBUT (0.86) had very good agreement with OSDI compared to Schirmer's test (0.62) and fluorescein staining (0.58), supporting the recommendation that TBUT may serve as the most reliable single objective screening test in diabetic populations. The high prevalence of symptomatic dry eye observed underscores the importance of routine ocular surface evaluation in diabetic patients, even in the absence of retinopathy. Emerging literature suggests that ocular surface dysfunction may precede microvascular retinal changes and may correlate with glycemic variability and HbA1c levels [11,14]. Additionally, chronic inflammation and oxidative stress induced by advanced glycation end products (AGEs) contribute to goblet cell loss and tear film hyperosmolarity, perpetuating a vicious cycle of ocular surface damage [13]. These mechanisms collectively justify integrated screening strategies combining symptom assessment with at least one objective tear stability test.

Overall, the present study confirms that dry eye is a common yet often under-recognized complication in Type-2 diabetes mellitus. TBUT demonstrated the highest diagnostic accuracy and agreement with symptom scoring, making it the most reliable objective test among those evaluated. The variability between diagnostic tests further emphasizes the need for multimodal assessment rather than reliance on a single parameter for accurate diagnosis in diabetic populations.

Conclusion

The prevalence of dry eye among patients with Type-2 diabetes mellitus in the present study was 38.33% based on OSDI scoring. Tear Film Break-Up Time demonstrated the highest sensitivity, specificity, diagnostic accuracy, and agreement with subjective symptoms, making it the most reliable objective test in this cohort.

Schirmer's test and fluorescein staining showed moderate and lower diagnostic performance respectively. Routine screening for dry eye in diabetic patients is essential for early identification and management, thereby improving ocular comfort and quality of life.

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