

Original Article

# Prevalence of Dry Eye Disease Among Type II Diabetes Mellitus and its Association with Glycosylated Hemoglobin in Patients Attending Tertiary Care Hospital

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## ABSTRACT

**Introduction:** Dry eye is one of the most troublesome conditions affecting the tear and ocular surface. It can cause symptoms like ocular discomfort, visual disturbance, and tear film instability, potentially damaging the ocular surface. Dry eye is more common in diabetic patients which may be brought on by neuropathy, metabolic dysfunction, or aberrant lacrimal secretions. The aim was to determine the prevalence of dry eye disease among type II diabetes mellitus based on Schirmer's test, tear film break-up time, tear meniscus height, corneal fluorescence staining, and ocular surface disease index scoring and its association with glycosylated hemoglobin.

**Materials and methods:** A hospital-based, observational, cross-sectional, and prospective study was conducted by recruiting 121 patients with type II DM aged 18 years or older. Proforma was used to collect data from patient interviews, and the dry eye was identified using Schirmer's test, TBUT, TMH, corneal fluorescence staining, and OSDI scoring. HbA1c was sent to all patients.

**Results:** Prevalence of dry eye in type II DM was 84.30% based on the Schirmer's test, 87.60% based on TBUT, 89.30% based on corneal staining with fluorescein, 41.30% based on TMH, and 76.00% based on OSDI. Hence, the overall prevalence of dry eye in type II DM was 75.70%.

**Conclusion:** DED was associated with an increased level of HbA1c. Hence, dry eye screening should be part of the visual assessment of diabetic patients.

**Keywords:** Dry eye disease; Diabetes mellitus; HbA1c; Schirmer's test

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## INTRODUCTION

Diabetes mellitus is a metabolic disease characterized by hyperglycemia caused by defects in insulin secretion, insulin action, or both.<sup>1</sup> and relationship between dry eye and glycosylated haemoglobin (HbA1c) it is a systemic condition that can lead to ocular problems, including Dry Eye Disease (DED), keratopathy, cataracts, glaucoma, and diabetic retinopathy. Dry eye symptoms in diabetic patients may be brought on by neuropathy, metabolic dysfunction, or aberrant lacrimal secretions.<sup>2</sup> Due to decreased goblet cells and mucin production, the ocular surface's hydrophilic nature can lead to tear film instability, which may harm the corneal and conjunctival epithelium.<sup>3</sup>

Global prevalence of Diabetes in adults in 2017 was 8.8% of the world population, with the anticipation of a further increase to 9.9% by 2045.<sup>4</sup> HbA1c reflects the average plasma glucose level over the past three months, and both blood glucose and HbA1c are related to the prevalence of DED.<sup>5,6</sup> The incidence of dry eye is positively correlated with the level of HbA1c, so the higher the level of HbA1c, the higher the incidence of dry eye.<sup>7</sup> The global prevalence of DED was 76% among diabetic patients.<sup>8</sup>

Dry eye is a multifactorial disease of the tear and ocular surface that can cause symptoms like ocular discomfort, visual disturbance, and tear film instability, as well as potential damage to the ocular surface.<sup>9</sup> The tear film consists of three layers: the outermost layer is the lipid layer, which is the thinnest and is produced by the meibomian glands, the middle layer is the aqueous layer, accounting for 90% of the tear film, and is produced by the main lacrimal gland as well as the accessory lacrimal glands of Krause and Wolfring. Dry eyes are most commonly caused by a deficiency in aqueous tears. The deepest layer is the mucous layer, which is created by conjunctival goblet cells.<sup>10</sup>

Though the problem of dry eye is connected to the fluctuation of HbA1c, there is a lack of such a large clinical study. Only a limited number of studies have been conducted in Nepal in the past. This prospective, cross-sectional study will help to identify the burden of the disease and help with the timely prevention of sight-threatening complications.

## MATERIALS AND METHODS

This study was approved by KISTMCTH IRC with ref no. 078/079/30, Nepal. It was a hospital-based, observational, cross-sectional, and prospective study conducted at the Outpatient Department (OPD) of Ophthalmology and patients referred from various Departments in KIST Medical College and Teaching Hospital, between 18 months from 21st October 2021 to 18<sup>th</sup> April 2023, on 121 diabetic patients. Non-probability sampling was used and patients with Type II DM aged >18 years who had given written as well as verbal consent were included in this study whereas patients with Type I DM or having any other complications of diabetics like diabetic nephropathy, diabetic retinopathy, having any other systemic diseases like hypertension, thyroid disorders, having chemical injury or trauma or wearing contact lens and those who are using medications such as antihistamines or antidepressants, and diuretics were excluded.

A detailed history was taken, followed by a thorough ophthalmic

examination of both eyes. Visual acuity was assessed in distant vision by Snellen's chart and near vision by Jaeger's chart. A detailed slit lamp biomicroscopic examination of the anterior segment and dilated retinal status evaluation by 90 D lens was done. Diabetic patients were then requested to do HbA1c at the time of presentation in KIST Medical College and Teaching Hospital, and only one time test was done through ion-exchange high-performance liquid chromatography (HPLC).

Dry eyes were suspected based on a history of soreness, gritty sensation, itching, redness, and blurred vision. The symptoms were assessed using the OSDI questionnaire.

**Ocular surface disease index (OSDI) questionnaire:** It is a self-administered 12-item questionnaire; values to determine dry eye severity were calculated using the OSDI formula (Sum of scores divided by total number of questions answered and multiplied by 25). The score ranges from 0 to 100. After calculating the score, patients were graded according to severity as:<sup>3</sup> **Normal** =0-12 points; **Mild dry eye** =13-22 points; **Moderate dry eye** =23-32 points ; **Severe dry eye** =33-100 points

In this study, dry eyes were assessed by using: 1) **Schirmer's test (Type II):** It was performed after the instillation of xylocaine. Graded as:<sup>11</sup> **Normal:** >15mm; **Mild dry eye:** <15mm; **Moderate dry eye:** <10; and **Severe dry eye:** <5mm. 2) **Tear film breakup time (TBUT):** It was observed by using a wet fluorescein-impregnated strip placed in the lower fornix using a cobalt blue filter. Appearance of a dry spot or line before 10 seconds was considered abnormal and documented as dry eye.<sup>12</sup> **Normal:** >10sec; **Mild dry eye:** 8-10sec; **Moderate dry eye:** 5-7sec. and **Severe dry eye:** <5sec, 3) **Corneal staining pattern with fluorescein:** It was observed 1-2 minutes after the insertion of a strip of 2% fluorescein into the lower fornix of each eye using cobalt blue light and graded as;<sup>3</sup> **No staining:** 0; **Mild staining occupying < 1/3 of corneal epithelial surface:** 1; **Moderate staining occupying < 1/2 of corneal epithelial surface:** 2; and **Severe staining of > 1/2 of the corneal epithelial surface:** 3. 4) **Tear meniscus height (TMH):** **Normal TMH :** 0.3 mm, **Suggestive of dry eye:** < 0.25 mm<sup>13</sup> and tear meniscus height (TMH)

All data were entered and analyzed in the statistical package for the Social Sciences (SPSS) 17. Mean and Pearson chi-square tests were the statistical methods used to analyze the data and a *p*-value of <0.05 was considered to be statistically significant

## RESULTS

121 diabetic patients who were under oral hyperglycemic drugs were enrolled in this study. The mean age of the patients was 57 ± 11.84 years. The maximum number of cases was from the age group 40-59 (49.60%), and the minimum number of cases was from the age group 18-39 (8.30%), with a male-to-female ratio of 0.7:1. The majority of participants had complaints of blurring of vision, as seen in 42 (34.70%) patients. ( Table 1)

**Table 1: Demographic parameters**

Parameters		Frequency (N)	Percentage (%)
Age group	18-39	10	8.30%
	40-59	60	49.60%
	≥60	51	42.10%
Gender	Male	50	41.30%
	Female	71	58.70%
Presenting symptoms	Blurring of vision	42	34.70%
	FB sensation	19	15.70%
	Burning sensation	21	17.40%
	Watering of eye	14	11.60%
	Redness of eye	15	12.40%
	None	10	8.30%
Glycemic status	<6	5	4.10%
	6-6.7	25	20.70%
	6.8-7.6	33	27.30%
	>7.6	58	47.90%

Based on Schirmer's test, 17(14.00%) cases had severe dry eye whereas by TBUT 24(19.80%) had severe dry eye. Similarly, corneal staining with fluorescein detected 14(11.60%) cases with severe dry eye. OSDI could detect severe dry eye in 28(23.10%) cases. 50 cases had dry eye based on TMH. According to Schirmer's test, TBUT, and corneal staining with fluorescein, there was a maximum of moderate dry eyes and a maximum of mild dry eyes according to the OSDI score. Association of severity of dry eye with the level HbA1c based on Schirmer's test, TBUT, corneal staining with fluorescein, OSDI is shown in table 3. Significant association was observed between HbA1c level and Schirmer's test ( $p<0.001$ ), TBUT ( $p<0.05$ ), corneal staining with fluorescein ( $<0.001$ ), and OSDI ( $p<0.05$ ). We found a moderately strong correlation between the severity of dry eye and increasing levels of HbA1c. (Table 4) The overall prevalence of dry eye in type II DM was 75.70%. (Table 5) Among the study population among the patient with type II diabetes mellitus, corneal staining with fluorescein could detect dry eye in 108 (89.30%) cases followed by TBUT which detected dry eye in 106 (87.60%) patients.

**Table 2: Frequency of dry eye based on Schirmer's test, TBUT, corneal staining with fluorescein, TMH, OSDI**

Indices showing dry eye	Severity of dry eye	N(%)
Schirmer's Test	Normal	19(15.70%)
	Mild	29(24.00%)
	Moderate	56(46.30%)
	Severe	17(14.00%)
TBUT	Normal	15(12.40%)
	Mild	38(31.40%)
	Moderate	44(36.40%)
	Severe	24(19.80%)
Corneal Staining with Fluorescein	Normal	13(10.70%)
	Mild	42(34.70%)
	Moderate	52(43.00%)
	Severe	14(11.60%)
TMH	Normal	71(58.70%)
	Dry eye	50(41.30%)
OSDI	Normal	29(24.00%)
	Mild	33(27.30%)
	Moderate	31(25.60%)
	Severe	28(23.10%)

**Table 3: Association of severity of dry eye with the level HbA1c based on Schirmer's test, TBUT, corneal staining with fluorescein, OSDI**

HbA1c	Grading of dry eye	Schirmers test n(%)	TBUT n(%)	Corneal staining with fluorescein n(%)	OSDI n(%)
<6.0	Normal	4(80.00%)	3(60.00%)	3(60.00%)	3(60.00%)
	Mild	1(20.00%)	2(40.00%)	2(40.00%)	1(20.00%)
	Moderate	-	-	-	1(20.00%)
	Severe	-	-	-	-
6.0-6.7	Normal	6(24.00%)	5(20.00%)	5(20.00%)	12(48.00%)
	Mild	9(36.00%)	12(48.00%)	15(60.00%)	8(32.00%)
	Moderate	8(32.00%)	5(20.00%)	4(16.00%)	3(12.00%)
	Severe	2(8.00%)	3(12.00%)	1(4.00%)	2(8.00%)
6.8-7.6	Normal	4(12.10%)	3(9.10%)	2(6.10%)	6(18.20%)
	Mild	6(18.20%)	9(27.30%)	12(36.40%)	10(30.30%)
	Moderate	21(63.60%)	16(48.50%)	17(51.50%)	10(30.30%)
	Severe	2(6.10%)	5(15.20%)	2(6.10%)	7(21.20%)
>7.6	Normal	5(8.60%)	4(6.90%)	3(5.20%)	8(13.80%)
	Mild	13(22.40%)	15(25.90%)	13(22.40%)	14(24.10%)
	Moderate	27(46.60%)	23(39.70%)	31(53.40%)	17(29.30%)
	Severe	13(22.40%)	16(27.60%)	11(19.00%)	19(32.80%)
*p value		0.001	0.004	0.001	0.014

\*Pearson chi-square test

**Table 4: Association of severity of dry eye with the level HbA1c based on TMH**

HbA1c	Normal(0.33)	Dry eye(<0.25mm)	p value
<6.0	5(100.0%)	-	0.005
6.0-6.7	20(80.0%)	5(20.0%)	
6.8-7.6	20(60.6%)	13(39.4%)	
>7.6	26(44.8%)	32(55.2%)	
Total	71(58.7%)	50(41.3%)	

\*Pearson chi-square test

**Table 5: Prevalence of dry eye in type II DM based on Schirmer's test, TBUT, corneal staining with fluorescein, TMH, OSDI**

Indices showing dry eye	Frequency (n)	Percentage (%)
Schirmer's test	102	84.30%
TBUT	106	87.60%
Corneal staining with fluorescein	108	89.30%
TMH	50	41.30%
OSDI	92	76.00%

## DISCUSSION

This observational cross-sectional study demonstrated a correlation between HbA1c and dry eye. Among various risk factors for dry eye, hyperglycemia is also regarded as one of

the risk factors however evidence is still lacking, and it is still a controversial issue. In this study, the association between dry eye and its severity with HbA1c in diabetic patients visiting tertiary care hospitals for dry eye management has been established.

This study found that the prevalence of dry eye was 84.30% based on Schirmer's test. Our study found that the Schirmer value decreases with increased HbA1c levels. This indicates an inverse correlation between glycemic control and Schirmer's test values. A related study by Ramalakshmi et al. revealed that around 54% of diabetics have DED.<sup>14</sup> This may be because of autonomic neuropathy and microvascular problems of the lacrimal gland, which interfere with its function and cause dry eyes in diabetics. Another comparable cross-sectional study done in 2021 revealed a statistically significant correlation between the subject's HbA1c level and the Schirmer score of that eye.<sup>15</sup> The prevalence of dry eye is higher in our study than in other studies; this might be due to the longer duration of diabetes (52% of patients having more than 5 years duration of type II DM) in most of the patients in this study.

Out of 121 patients in our study, the prevalence of dry eye was 87.60% based on TBUT and 76% based on OSDI score. A cross-sectional study carried out in 2018 demonstrated the relationships between TBUT and OSDI scores and long-term glycemic management. The chances of DED for an increased proportion of HbA1c were 20% among the Chinese type II DM population. The prevalence of dry eye was too low as compared to this study; this may be because the dry eye was observed only based on TBUT and OSDI scores.<sup>16</sup> Reddy et al. did a study on 70 patients with type II DM in 2020. Dry eye was analyzed using TBUT and Schirmer's tests, and the prevalence of dry eye was found in 52.80%.<sup>17</sup> A comparable study was done using the TBUT and Schirmer's test, and it was shown that when the HbA1c level increased, the mean values of the TBUT and the Schirmer test decreased.<sup>18</sup>

The prevalence of dry eye among 121 diabetic patients was 89.30% based on corneal staining with fluorescein. Additionally, increased HbA1c levels were significantly correlated with the severity of dry eye. A study done by Mohammed et al. revealed significant variations in corneal staining and TBUT between diabetes individuals and non-diabetic subjects with the percentage of dry eye being 63% in diabetics.<sup>19</sup> A cross-sectional study was conducted on 100 type II diabetic patients attending a medical college in Raichur, India, from July 2011 to June 2013. Dry eyes

were examined using Schirmer's test, TBUT, fluorescein staining, rose bengal staining, and OSDI. The results showed that 36% of the diabetic patients had dry eye.<sup>20</sup>

In our study, the prevalence of dry eye was 41.30% based on TMH. A similar study was done to detect dry eye syndrome among patients with type II DM in South India. Tear volume was measured using Schirmer's test and TMH. The prevalence of dry eye was 61% among type II DM.<sup>21</sup>

In this study, the prevalence of dry eye was 76% based on OSDI. Aggarwal et al. did a similar study in which the OSDI questionnaire was used to examine dry eyes, where the prevalence of DED among diabetics was found to be 36%.<sup>3</sup> Another study by Dutta et al. found that 58 (32%) eyes had mild dry eyes, 20 (11.11%) eyes had moderate dry eyes, and 10 (5%) eyes had severe dry eyes according to the OSDI score.<sup>22</sup> Almohammed et al. did a retrospective study where the prevalence and severity of DED were measured by OSDI. The overall prevalence of DED was found to be 51.7%.<sup>23</sup>

In this study based on our findings, the overall prevalence of dry eye in type II DM was 75.70%. In a similar study, Waris et al. concluded that 43% of patients with type II diabetes had dry eyes and about 95% association was found between HbA1c and dry eye.<sup>24</sup> Another study by Mansuri et al included an assessment of dry eye by OSDI, Schirmer's test, TBUT, and fluorescein staining of cornea and conjunctiva which showed a prevalence of DED in type II DM to be 43.81%.<sup>25</sup>

This study was limited to a single center with a small sample size. Similarly, other dry eye tests like tear osmolarity, conjunctival impression cytology, biomarkers, and ocular surface thermography were not incorporated.

## CONCLUSIONS

We found that type II DM patients with increased levels of HbA1c are directly related to dry eye. Diabetic patients were screened for dry eye and found to have a significant association using tests like Schirmer's test, TBUT, TMH, corneal staining with fluorescein, and OSDI. Hence, our findings recommend that dry eye screening should be a part of the visual assessment of diabetic patients to prevent sight-threatening complications.

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