

## ORIGINAL ARTICLE

# Prevalence of Dry Eye in Type II Diabetic Patients in Upper Egypt

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### ABSTRACT

Keywords: Dry Eye;  
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break up time test; Type II  
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**Background:** Diabetes mellitus is a group of metabolic disorders that is characterized by hyperglycemia due to either impaired insulin secretion or impaired insulin action or both. **Objective:** To determine the prevalence of dry eye in type II diabetic patients in Upper Egypt. **Methods:** our study included a total of 150 eyes of 75 persons, where 100 eyes of 50 diabetic patients were considered as group I (cases), while 50 eyes of 25 non-diabetic persons were considered as group II (control). All patients in the study had comprehensive ophthalmic examination including Schirmer's test and Break-up time (BUT). **Results:** regarding the severity of dry eye measured by Schirmer's test, there was a significant difference between cases and controls p value was 0.021 regarding the severity of dry eye measured by BUT, there was a significant difference between cases and controls p value 0.046. Additionally, testing the correlation between Schirmer's and BUT tests showed that there is a statistically significant correlation between both tests. **Conclusion:** Our findings support the impression that diabetic patients have an elevated prevalence of dry eye syndrome. Diabetes and dry eyes appear to have a common association. Early examination of diabetic patients for detecting ocular surface disorders is indicated.

### INTRODUCTION

Diabetes has become a growing major public health problem both in developing and developed countries and its global prevalence will be expected to reach 380 million by 2025<sup>(1)</sup>.

Some studies showed that type II Diabetes Mellitus is one of the risk factors of dry eye disease and as the prevalence of diabetes increases the development of dry eye disease may increase, the prevalence of dry eye disease has been reported up to 54.3 % in diabetic patients<sup>(2)</sup>.

Dry eye disease is multifactorial disease characterized by decrease tear production and/or increase tear evaporation<sup>(3)</sup>.

Dry eye disease is manifested with signs and symptoms of ocular discomfort such as stinging, sandy sensation, feeling of dryness, itching and /or redness which may cause serious irritation to the cornea. Dry eye disease affects the quality of life of patients by inducing ocular discomfort,

visual disturbances and ultimately blindness in diabetic people which was reported in age of 20-74 years <sup>(4)</sup>.

Other study reported approximately 20 % of dry eyes occurred in individuals with type II diabetics aged between 43-86 years. Furthermore, significant relationship between dry eyes and diabetes were documented from hospital-based studies <sup>(5)</sup>.

There are few researchers who studied prevalence and relation between dry eye disease and diabetes in Egypt <sup>(6)</sup>.

So there is need to study prevalence and relation between dry eye disease and diabetes in Upper Egypt, which has different climatic and environmental conditions.

## **MATERIAL AND METHODS**

In this epidemiological study, we included 100 eyes of patients suffering from DM type II who were diagnosed for at least 3 years and aging between 35-45 years and 50 eyes of healthy volunteers. All patients in the study were undergone comprehensive ophthalmic examination including; Complete history taking including baseline information included patient's age, race, gender, underlying ocular disease, glaucoma medications and other ocular surgeries; complete ophthalmological examination including visual acuity, refraction, IOP measurement and slit lamp examination. Dry eye was diagnosed by Schirmer's test and Break up time (BUT) test. Diagnosis was established by positivity of one or both tests.

- Schirmer's test without topical anesthesia was carried out with standardized strips. The strip was folded at the notch and placed at the junction of the middle and lateral thirds of the lower eye lids for 5 minutes with patient's eyes gently closed. More than 10mm of wetting after 5 min was considered normal, 8-10 mm of wetting after 5 min was considered mild dryness, 5-7 mm of wetting after 5 min was considered moderate dryness, and less than 5mm of wetting was considered severe dryness at the end of 5 min.

- Tear break up time (BUT) test with 2% stain fluorescein was introduced into the conjunctival sac the individuals were then instructed to blink several times for few seconds. The tear film was examined with broad beam and cobalt blue filter and the interval between the last blink and the appearance of first corneal black spot or line in the stained tear film was measured using stop watch. Value more than 10 seconds was normal, value of 8-10 seconds was considered mild dryness, 5-7seconds was considered moderate dryness, and value less than 5 seconds was considered severe dryness.

- Patients were enrolled in the study according to the following criteria: Type II diabetes that have glycated hemoglobin A1C test 6.5 % or higher on two separate tests, fasting blood sugar test more than 125 mg/dl, oral glucose tolerance test of 200 mg /dl or higher after two hours and random blood sugar test of 200 mg/dl or higher and the age between 35-45 years. Diagnosed diabetes mellitus II should be at least 3 years. While the exclusion criteria were using medications such as antihistamines, antidepressants, oral contraceptives and diuretics, who had undergone LASIK surgery, wear contact lenses, patients have Sjogren's syndrome, rheumatoid arthritis, systemic lupus erythematosus, Parkinson's disease or any other diseases associated with KCS, patients who smoke. Other exclusion criteria are patients with vitamin A deficiency, pregnant women, patients age more than 45 and less 35 years, who were diagnosed as diabetes mellitus II less than 3 years, patients with ocular surface diseases or any eyelid deformity that may interfere with tear film or anterior ocular surfaces.

## **Statistical analysis**

The analysis was done using SPSS version 26 (IBM Inc., Chicago, Illinois, USA). Inferential analysis was conducted using Chi square test to investigate the correlation between the severity level of both Schirmer's and BUT tests and DM while Student's t Test to compare pre- and post-intervention change. Confidence interval level was set to 95% where a corresponding p value threshold was identified as 0.05 where any output p below 0.05 was interpreted as an indicator of statistical significance.

## RESULTS

A total of 150 eyes of 75 persons were recruited in the current study, where 100 eyes of 50 diabetic patients were considered as group I (cases), while 50 eyes of 25 non-diabetic persons were considered as group II (control). Among group 1, males 27 (54%) were slightly exceeding females 23 (46%), meanwhile, among controls, males 15 (60%) that also constituted the majority of this group exceeding females 10 (40%). However, there were no statistically significant difference as regards gender between groups ( $p=0.622$ ). While in terms of age in group 1 a mean (SD) age of 41.9 (3.3), [35 – 45] years, in group 2 the mean (SD) age of 39.7 (3.4), [35 – 45] years, despite the relatively small difference in mean age, controls were found to be significantly younger than cases ( $p<0.0001$ ). As regards visual acuity and refraction, group1 had a mean (SD) visual acuity (VA) of 0.68 (0.26), [0.04 – 1.0], while controls had a mean VA of 0.57 (0.29), [0.08 – 1.0] with a significant difference ( $p=0.027$ ). Refraction-wise, cases had a mean (SD) spherical equivalent (SE) of -0.41 (1.8), [-3.9 – 3.8] while it was -2.2 (3.0), [-13.3 – 2.8] among controls,  $p=0.001$  (Table 1).

The mean intraocular pressure (IOP) was found to be 15.8 (2.6), [11- 22] in group1 which was less than that in controls 16.4 (2.1), [12 – 22]. However, it was insignificant  $p=0.144$  (Table 2).

Ophthalmic examination revealed unremarkable fundus examination in both cases and controls. Meanwhile, comparing the lens status of both groups showed that the prevalence of cataract among cases 17 (17%) was significantly higher than such prevalence among controls 2 (4%), ( $p=0.024$ ). Details of clinical indices in both cases and controls are demonstrated in table (3).

Detection of the prevalence of eyes with Schirmer's test positive of dry eye syndrome showed that 64 (64%) of the cases (eyes) were suffering dry eye syndrome which is greater than the same prevalence in controls 22 (44%). Such difference was found to be statistically significant  $p=0.019$  (Figure 1).

As regards to the severity of dry eye measured by Schirmer's test showed that in group1 was mild in 17% of cases, moderate in 36% of cases and severe in 11% of cases. While in controls, mild dry eye was detected in 10% of cases, moderate in 34% of cases and no severe subjects were found. There was a statistically significant difference between cases and controls  $p$  value 0.021 in Schirmer's test Table (4).

Moreover, BUT showed that the prevalence of positive cases of dry eye syndrome was 76 (76%) and it was higher than that prevalence in controls 30 (60%). However, such difference was not found to be statistically significant  $p=0.157$  (Figure 2).

As regards to severity of dry eye measured by BUT showed that in group1, mild in 19% of cases, moderate in 41% of cases and severe in 16% of cases. While in controls, mild degree was detected in 20% of cases, moderate in 20% of cases and severe in 20% of cases. There was a statistically significant difference between cases and controls  $p$  value 0.046 in BUT test. Table (5).

The mean (SD) of the duration of diabetes among subjects was 6.4 (4.7) [1–17] years. Furthermore, categorization of the diabetic duration into four groups showed that among the duration of [1-4] years, there were 29 normal subjects while dry eye was detected in 23 patients. In duration of [5-9] years, there were 2 normal subjects and 16 dry eye patients. In duration of [10-14] years, there were 2 normal subjects and 16 dry eye patients. In duration of [15+] years, there were 3 normal subjects and 9 dry eye patients. Testing the correlation of such categories with Schirmer's test showed that there is statistically significant reverse correlation where  $R= -0.401$ ,  $p$  values of ( $p<0.0001$ ). Table (6) demonstrates these associations in details.

Categorization of the diabetic duration into four groups [1-4], [5-9], [10-14] and [15+] years and testing the correlation of such categories with BUT test showed that in duration of [1-4] years, 18 normal subjects and 34 dry eye subjects. In duration of [5-9] years, no normal subjects was detected while 18 dry eye patients were found. In duration of [10-14] years, there were 2 normal subjects and 16 dry eye patients. In duration of [15+] years, there were 4 normal subjects and 8 dry eye patients. Testing the correlation of such categories with BUT test showed that there is statistically significant

inverse correlation where  $R=-0.406$ ,  $p$  values of 0.013. Table (7) demonstrates these associations in details.

Additionally, testing the correlation between Schirmer's and BUT tests showed that there is a statistically significant correlation between both tests ( $R=0.953$ ,  $p<0.0001$ ).

## DISCUSSION

Dry eye syndrome is common among patients with DM type 2 that causes tear film instability by affecting the aqueous layer and the mucin layer of tear film that is necessary for tear film spreading and wetting<sup>(7)</sup>.

In recent study among group 1, males (27) (54%) were slightly exceeding females (23) (46%). Meanwhile among controls males (15) (60%) that also constituted the majority of this group exceeding females (10) (40%). However, there was no statistically significant difference as regard gender between groups. Manaviat had shown that prevalence of dry eye syndrome has no significant relation between dry eye in type II diabetes and sex as (58%) were females and (48.8%) were males<sup>(8)</sup>.

In Alawlaqi and Hammadeh study, women were more likely to experience dry eye disease, with increased prevalence after menopause. As there were changes in balance of sex hormones as both androgen and estrogen have effects on synthesis and components of tear film<sup>(9)</sup>.

While in terms of age in group1 a mean (SD) age 41.9 (35-45) years, in group2 the mean (SD) age of (39.7) (35-45) years, despite the relatively small difference in mean age, controls were found to be significantly younger than cases. In Moss study showed that dry eye developed with association of age as a history of dry eye developed in 322 of 2414 subjects for an incidence of (13.3%) was significantly associated with age<sup>(10,11)</sup>.

In the recent study the most of controls are myopic and there is no relation between it and presence of dry eye disease. In Fahmy study showed that the prevalence of dry eye was 24.6%, 36.5% and 17.4% in emmetropes, myopes and hypermetropes respectively. BUT has negative correlation with hypermetropes and positive correlation with myopia<sup>(12)</sup>.

Also, in the recent study comparing the lens status of both groups showed that the prevalence of cataract among cases (17) (17%) was significantly higher than such prevalence among controls (2) (4%). Also, in Manaviat study showed that diabetic cataract is one of diabetic complications that occurs earlier<sup>(8)</sup>.

In this study, it is found that there is statistically significant reverse correlation between Schirmer's test results with presence of diabetes. As Schirmer's test values are significant lower in diabetic patients compared with control group. Also, BUT test values are significantly lower in diabetic patients compared with control group. In Goebbel study the results of Schirmer's test and BUT test was lower also in diabetic patients than controls<sup>(13)</sup>.

Also, in recent study there is high incidence of dry eye in controls as in Upper Egypt the environment play role in presence of dry eye disease, as temperature is high and that is considered one of the risk factors of dry eye. In India there was study of Radhika that was done on 9735 people as the prevalence of dry eye disease was (26.2%) was higher in plains (41.3%) as temperature was high compared to hilly (24.0%) and costal area (9.9%) as temperature was less ( $p<0.001$ )<sup>(11)</sup>.

In recent study there are four categorizations of diabetic duration in years (1-4), (5-9), (10-14), (15+) and testing the association of such categories with both Schirmer's test and BUT test showed that statistically significant reverse correlation between their results and duration of diabetes. In hospital based study of Manaviat (45%) of those with diabetes had dry eye syndrome and there was significant correlation between dry eye syndrome and duration of diabetes<sup>(8)</sup>.

Also in the recent study there is statistically significant correlation between Schirmer's test results and BUT test results. Xinrong Zou showed also the same correlation and the same results<sup>(14)</sup>.

The advantages of using Schirmer's and BUT tests are cheap, available, high sensitivity and specificity to another dry eye measurements so the researchers recommend them in dry eye screening<sup>(15)</sup>.

The recent study has some limitations as tear osmolality measurement was not included in dry eye diagnosis. It is important for diagnosis of dry eye; however it is not widely used in Upper Egypt. Furthermore, it is difficult to carry out tear osmolality measurement which takes long time and costs high in such community based epidemiological investigation. Also, among limitations of the present study are the relatively few number of the study sample due to long list of exclusion criteria.

## CONCLUSION

Our findings support the impression that diabetic patients have an elevated prevalence of dry eye syndrome. Diabetes and dry eyes appear to have a common association. The results of the recent study and most of other similar studies suggest that diabetic patients are more prone to suffering from dry eye than normal individuals and there for these symptoms should be monitored. Early examination of diabetic patients for detecting ocular surface disorders is indicated.

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**Tables**

**Table 1: Comparison between visual acuity and refraction among cases and controls.**

Variable	Case N: 100		Control N: 50		P value*
	Mean (SD)	Rang [min – max]	Mean (SD)	Rang [min – max]	
Visual Acuity	0.68 (0.26)	[0.04 – 1.0]	0.57 (0.29)	[0.08 – 1.0]	0.027
Spherical Equivalent	-0.41 (1.8)	[-3.9 – 3.8]	-2.2 (3.0)	[-13.3 - 2.8]	0.001

\*Student's t test

**Table 2: Comparison between intraocular pressure among cases and controls.**

Intraocular Pressure	Case N: 100		Control N: 50		P value*
	Mean (SD)	Rang [min – max]	Mean (SD)	Rang [min – max]	
	15.8 (2.6)	[11.0 – 22.0]	16.4 (2.1)	[12.0 – 22.0]	

\*Student's t test

**Table 3: Comparison between lens status among cases and controls.**

Lens Status	Case N: 100		Control N: 50		P value*	
	Category	No. (%)	Category	No. (%)		
	Clear	83 (83%)	Clear	48 (96%)		0.024
	Cataract	17 (17%)	Cataract	2 (4%)		

\*Student's t test

**Table 4: Schirmer's test categories according to severity.**

Schirmer's Test	Category	Cases	Controls	P value*
	Normal	36 (36)	28 (56)	
	Mild	17 (17)	5 (10)	
	Moderate	36 (36)	17 (34)	
	Severe	11 (11)	0 (0)	
<b>Total</b>		<b>100</b>	<b>50</b>	

\*Chi<sup>2</sup> test

**Table 5: Break up time test categories according to severity.**

Break up time Test	Category	Cases	Controls	P value*
	Normal	24 ( 24)	20 (40)	
	Mild	19 ( 19)	10 (20)	
	Moderate	41 (41)	10 (20)	
	Severe	16 (16)	10 (20)	
<b>Total</b>		<b>100</b>	<b>50</b>	

\* Chi<sup>2</sup> test

**Table 6: Schirmer's test results and diabetes mellitus duration.**

Diabetes mellitus Duration (years)	Schirmer's Test		Total	p value*
	Normal	Dry		
[1 - 4]	29	23	52	<0.0001
[5 - 9]	2	16	18	
[10 - 14]	2	16	18	
[ 15+ ]	3	9	12	
<b>Total</b>	<b>36</b>	<b>64</b>	<b>100</b>	

\*Student's t test

**Table 7: Break up time test results and diabetes mellitus duration.**

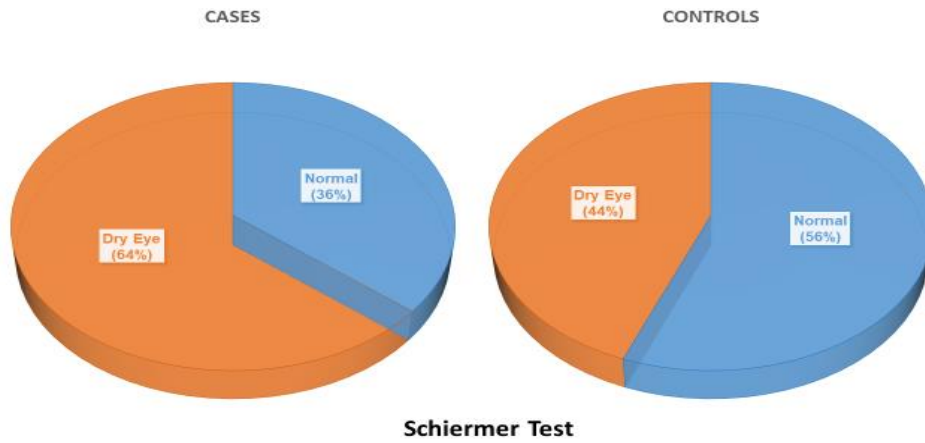
Diabetes mellitus Duration (years)	Break up time Test		Total	p value*
	Normal	Dry		
[1 - 4]	18	34	52	0.013
[5 - 9]	0	18	18	
[10 - 14]	2	16	18	
[ 15+ ]	4	8	12	
<b>Total</b>	<b>24</b>	<b>76</b>	<b>100</b>	

\*Student's t test



**Figures**

**Figure 1:** Comparing cases to controls in terms of Schirmer’s test.



**Figure 2:** Comparing cases and controls in terms of break up time test.

