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## PREVALENCE OF DRY EYE DISEASE IN TYPE 2 DIABETIC PATIENTS AND ITS ASSOCIATION WITH RETINOPATHY

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**ABSTRACT:** Type 2 diabetes (T2D) is one of the risk factor for dry eye disease (DED) and known factor for diabetic retinopathy (DR). There are few studies have been already reported the prevalence of DED nevertheless studies shown prevalence of DED and DR by sex in patients with T2D. The study was carried out with 100 T2D patients. DED was assessed with Tear break up time and Schirmer tests. All the subjects were examined by slit lamp bio-microscopy and colored fundus photographs. Diabetic retinopathy (DR) was graded according to early Treatment Diabetic Retinopathy (ETDRS) criteria. Out of 100 T2D patients, the prevalence of DED was noticed in 53 patients. Out of 53 DED cases, 14 (43.8%) were males and 39 (57.4%) were females. Next we assessed the association of DED with DR and it was found 47.6% in males and 69.4% in females. In our study, the prevalence of DED was high in T2D patients and showed to have a high correlation with DR. Prevalence of DED was more in females as compared to males with DR but severity of DR was more in males as compared to females with DR. As T2D and dry eye seems to have a common association, further studies are needed to establish the underlying etiologic relationship with large sample size. Ophthalmologists may increase their role to ensure comprehensive eye care to the people by examining dry eye which is an imperative part of the evaluation of diabetic eye disease.

**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 2 diabetes (T2D) is one of the risk factor for dry eye disease (DED) and as the prevalence of T2D increases the development of DED may increase<sup>2-6</sup>. The prevalence of DED has been reported up to 54.3% in diabetic patients<sup>2</sup>.

DED is a multifactorial disease characterized by a progressive dysfunction of meibomian gland which leads to decreased tear production and /or increased tear evaporation, respectively<sup>7, 8</sup>. DED is manifested with signs and symptoms of ocular

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discomfort such as stinging, sandy sensation, feeling of dryness, itching and redness which may cause serious irritation to the cornea. In recent years, diabetic patients have also been reported for corneal complications including superficial punctuate keratopathy, trophic ulceration, and persistent epithelial defect<sup>2</sup>.

DED affects the quality of life of patients by inducing ocular discomfort, visual disturbances and ultimately blindness in diabetics people which was reported in the age of 20-74 years<sup>9</sup> and a study reported approximately 20% of dry eyes occurred in individuals with T2D aged between 43 and 86 years. Furthermore significant relationship between dry eyes and diabetes were documented from hospital based studies<sup>10, 11</sup>. The prevalence of this creating awareness among the public to be taken care of their life style changes, westernized diet and medications, usage of electronic items like computer etc as well as hormonal status which may increase the risk for both diabetes and DED.

Diabetic retinopathy (DR) presents with micro-vascular complications and is a well-known ocular complication of diabetes is considered as the leading cause of visual disability and acquired blindness globally<sup>12, 13</sup>. It is well established that progression of DR increases with duration of diabetes and significant association between DR and DED in T2D patients 2-4. It is reported from hospital based study that dry eye syndrome (DES) is more prevalent in DR patients as compared to non-DR group. Further both DES and retinopathy were significantly associated with HbA1c<sup>2, 3</sup>.

Considering the increasing prevalence of DED in T2D patients, it is mandatory to prevent and manage the DED and complications of diabetes. Patients with signs and symptoms of DED must approach ophthalmologists to seek comprehensive eye care. Hence it has been emerging as crucial outcome measures for clinicians to detect DED earlier and to look- forward treatment in early stages itself so as to prevent the further adverse complications of dry eye in diabetic patients. Therefore it is aimed to study the prevalence of DED in diabetic patients and its association with progression of DR. There are few studies have been already reported the prevalence of DED in association with DR nevertheless studies shown on

gender wise prevalence of DED and DR in patients with T2D.

**MATERIALS AND METHODS:** The study was carried out with 100 T2D patients who attended outpatient and in-patient department, Department of Ophthalmology in collaboration with Department of Biochemistry Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry from December 2014-November 2016.

The age group selected for the study was 35-80 years. The study was approved by Institutional human ethical committee. An informed consent was obtained from all the patients employed for the study.

The presence of T2D was confirmed by investigating fasting blood glucose level (normal limit < 110 mg/dl) in all the individuals. Based on the test results, new and review cases of T2D were included for the study. Patients with Type 1 diabetes, secondary diabetes and those who are on medications such as antihistamines, tricyclic anti-depressants, oral contraceptives and diuretics were excluded from the study. Further cigarette smokers, contact lens users, patients underwent lasik surgery, having Sjogren's syndrome and rheumatoid arthritis were on the exclusion criteria list.

Clinical information of all patients including sex, age, duration of diabetes, ocular symptoms and presence of other diseases were obtained from the medical records and direct patient interview. All T2D patients were assessed for dry eye status and presence of any signs of DR.

**Evaluation of Dry Eye:** Patients with complaints of ocular discomfort, gritty sensation, itchiness, redness, and excessive tearing was further confirmed by Tear break-up time [t-BUT], Schirmer's test with 5×35 mm strip of Whatman-41 filter paper. Based on the test results, the dry eye patients were graded in to three groups mild, moderate and severe DED and the prevalence in gender was noticed. Dry eye patients were further evaluated by slit lamp for blepharitis and the degree of MGD. After complete ocular examination patients were grouped as DED and non-DED patients.

**Assessment of DR:** Fundus examination was performed in all the individuals to assess the retinal changes. With dilated fundus, the diagnosis and grading of DR were done by slit lamp biomicroscopy and colored fundus photographs using a Topcon TRC- 50DX fundus camera (Topcon Medical systems, Inc. NJ, USA) according to Early Treatment of Diabetic Retinopathy Study (ETDRS) criteria. Based on the fundus examination, patients were divided in to diabetes with signs of DR and those without signs of DR. Patients with retinopathy (DR group) were classified into NPDR and PDR and NDPR.

#### Sample Preparation and Biochemical Assays:

About 5ml of fasting blood sample was taken in EDTA-coated wells from all individuals to assay fasting blood sugar (FBS), post-prandial blood

sugar (PPBS) and HbA1C. FBS and PPBS were estimated by glucose oxidase- peroxidase method and HbA1C by turbidometric method.

**Statistical Analysis:** Data analysis was performed using SPSS statistical software (Version 22, SPSS, Inc., Chicago, Illinois, USA). Data were presented as mean  $\pm$  SD. Chi square test were used to assess the significance between discrete variables. Significance was set to  $P < 0.05$ .

**RESULTS:** Table 1 shows the frequency of DED by age and sex. Out of 100 patients (32 males, 68 females), the presence of DED was noticed in 53 patients. Out of 53 DED cases, 14 (43.8%) were males and 39 (57.4%) were females. There was a significant association between sex and prevalence of DED ( $p < 0.04$ ).

**TABLE 1: PREVALENCE OF DED BY AGE AND SEX IN T2D PATIENTS**

Age in years	Prevalence of DED in 100 T2D patients		Total	p-value
	Total no. of male (n=32)	Total no. of female (n=68)		
35-50	4	11	15	0.04
51-60	7	16	23	
61-70	2	09	11	
71-80	1	04	05	
Total	14 (43.8%)	39 (57.4%)	53 (53%)	

Prevalence of DR by age and sex were given in Tables 2 and 3. Out of 100 patients, 43 were Non - DR and 57 patients were DR. The retinopathy was mild in 19 (33.3%) patients consisting of 8 males and 11 females, whereas 25 (43.8%) patients had moderate NPDR consisting of 10 males and 15 females, 8 (14%) had sever NPDR consists of 2 males and 6 females and 5 (8.8%) had PDR consists of 1 male and 4 females. Prevalence of grades of DR was found high especially in the age group of 51-60 (59.5%) years old and low in 35-50 (28.5%) year's old group (Table 2). The

prevalence of DR in male was 65.6% and it was 53% in females (Table 3). There was a significant association between sex and grades of DR ( $p < 0.03$ ). Table 4 represents the association between duration of diabetes and presence of DED by sex. Of 100 patients, DED was seen in 53 patients with increased duration of diabetes. A significant association was observed between frequency of DED and the duration of diabetes in females ( $p < 0.02$ ) as compared to males ( $p < 0.03$ ). This data indicating that prevalence of DED increases with increase in the duration of diabetes.

**TABLE 2: FREQUENCY OF GRADES OF DR BY AGE IN T2D PATIENTS**

Age in years	Non-DR (n=43)		DR (n=57)								Total
			Mild NDPR (n=19) 33.3%		Moderate NDPR (n= 25) 43.8%		Severe NDPR (n=8) 14.1%		PDR (n=5) 8.8%		
	Male (n=11)	Female (n=32)	Male (n=8)	Female (n=11)	Male (n=10)	Female (n=15)	Male (n=02)	Female (n=06)	Male (n=01)	Female (n=04)	
35-50	3	07	1	1	1	1	-	-	-	-	14
51-60	5	12	4	5	5	7	-	3	-	1	42
61-70	2	11	2	3	3	5	1	2	1	2	32
71-80	1	2	1	2	1	2	1	1	-	1	12
Total	11	32	08	11	10	15	02	06	01	04	100

**TABLE 3: FREQUENCY OF GRADES OF DR BY SEX AND IN T2D PATIENTS**

Grading of DR	No. of patients			Chi square test P-value
	Male	Female	Total	
Non- DR	11 (34.4%)	32 (47%)	43 (43%)	0.03
Mild NPDR	08 (25%)	11 (16.2)	19 (33.2%)	
Moderate NPDR	10 (31.2%)	15 (22%)	25 (43.9%)	
Severe NPDR	02 (6.2%)	06 (8.8%)	08 (14%)	
PDR	01 (3.1%)	04 (5.9)	05 (8.9%)	
Total	32 (65.6%)	68 (53%)	100	

Non-DR- Non-diabetic retinopathy, DR-diabetic retinopathy, NPDR non-proliferative DR and PDR-proliferative DR P < 0.05-significant

**TABLE 4: ASSOCIATION BETWEEN DURATION OF DIABETES AND PRESENCE OF DED BY SEX IN T2D PATIENTS**

Duration of diabetes (in years)	Patients with DED			Total no. of patients		Grand Total of no. of patients	Chi square test P-value Male; Female	
	No. of males	No. of females	Total no. of DED	Males	Females			
≤ 5 years	02 (14.2%)	10 (25.6%)	12 (22.7%)	7	15	22	0.003	0.002
6-10	03 (21.4%)	17 (43.6%)	20 (37.7%)	9	26	35		
11-15	06 (42.8%)	06 (15.4%)	12 (22.6%)	11	16	27		
16-20	02 (14.2%)	05 (12.8%)	07 (13.2%)	03	08	11		
>20	01 (7.1%)	01 (2.6%)	02 (3.8%)	02	03	05		
Total	14 (43.8%)	39 (57.4%)	53 (53%)	32	68	100		

Prevalence of DED by sex and its association with DR and Non-DR is given in **Table 5**. Out of 100 T2D patients, 57 patients are with signs of DR and rests of them are non-DR. Of 57 DR patients DED was seen in 35 patients (61.4%) consisting of 10 males and 25 females. When comparing the association of DED with severity of DR between males and females, we found higher prevalence in female (69.5%) as compared to males (48.9%). In

non-DR group, we had 43 patients and observed 19 DED cases from both sex. Thus frequency of DED was observed highly significant in DR patients than Non-DR (P < 0.02). This table indicates as the severity of retinopathy increases the prevalence of DED also increases. From the tables, it is evident that although severity of DR is more in males, the frequency of DED is high in females as compared to males with DED.

**TABLE 5: ASSOCIATION BETWEEN PREVALENCE OF DED AND GRADES OF DR BY SEX IN T2D PATIENTS**

Gender	DR (n=57)			Non-DR (n=43)			P-value
	Male (n=21)	Female (n=36)	Total no. of DED	Male (n=11)	Female (n=32)	Total no of DED	
DED	10 (47.6%)	25 (69.4%)	35 (61.4%)	4 (36.4)	15 (46.9%)	19 (44.2%)	0.02
Non- DED	11(52.4%)	11 (30.6%)	22 (38.6%)	7 (63.6)	17 (53.1%)	24 (55.8%)	

Non-DR- Non-diabetic retinopathy, DR-diabetic retinopathy, DED-dry eye disease; P<0.02- significant.

Mean values of FBS, PPBS and HbA1c by sex and its association with and without DED was given in **Table 6**. Patients with DED showed increased levels in the aforementioned biochemical investigations as compared to Non-DED group.

There was a significant association between glycemic control and DED by sex. Females had higher / significant association with DED as compared to males.

**TABLE 6: MEAN VALUES OF FBS, PPBS AND HBA1C IN PATIENTS WITH DED AND WITHOUT DED**

DED		FBS (mg/dl)	PPBS (mg/dl)	HbA1c (%)
Present (46)	Male (n=26)	146±12.08	244±15.6	8.2±2.9
	Female (n=20)	172±13.11	302±17.37	10.8±3.17
	P value	0.000**	0.000**	0.01*
Absent (54)	Male (n=39)	130±11.40	201±14.17	7.1±2.6
	Female (n=15)	142±11.91	216±14.69	7.5±2.7
	P value	0.001	0.001	0.6184

DED-dry eye disease, FBS-fasting blood glucose, PPBS-post-prandial blood glucose; \*P<0.05-Significant; \*\*P<0.000-highly significant.

As meibomian gland dysfunction is the leading cause of DED, the present study assessed the MGD in DED and Non-DED patients. Out of 100 patients, 53 patients were prevalent to DED and 47 were Non-DED patients. Among the patients with MGD, 15 patients (28.3%) had mild disease, 28 patients (52.8%) had moderate disease while 10 (18.8%) patients showed a severe degree of MGD (Table 7).

Among 53 patients with grades of DED, 32 (60.3%) patients of both sex had meibomian gland disease. The higher number (n = 23) was noted in females and it accounts for 43.4% as compared to males with DED (16.9%) in presence of MGD (Table 8). In Non-DED group, both sex (n=20) showed meibomian gland disease and it accounts for 42.6%. This was found statistically significant ( $p < 0.002$ ).

**TABLE 7: ASSOCIATION BETWEEN MGD AND SEVERITY OF DED IN DIABETIC PATIENTS**

MGD	DED (n = 53)						Non-DED (n = 47)		Total (100)
	Mild (n=15) 28.3%		Moderate (n= 28) 52.8%		Severe (n=10) 18.8%		Male (n=18)	Female (n=29)	
	Male (n=06)	Female (n=09)	Male (n=11)	Female (n=17)	Male (n=03)	Female (n=07)			
Present	2	6	6	13	1	4	7	13	52
Absent	4	3	5	4	2	3	11	16	48
Total	06	09	11	17	03	07	18	29	100

DED-dry eye disease, MGD-meimobian gland disease

**TABLE 8: CORRELATION BETWEEN MGD AND DED BY SEX IN DIABETIC PATIENTS**

MGD	DED (n=53)			Non-DED (n=47)			p-value
	Male	Female	Total	Male	Female	Total	
Present	9 (16.9%)	23 (43.4%)	32 (60.3%)	7 (14.9%)	13 (27.7%)	20 (42.6%)	0.002
Absent	11 (20.8%)	10 (18.9%)	21 (39.6%)	11 (23.4%)	16 (34%)	27 (57.4%)	

DED-dry eye disease, MGD-meimobian gland disease;  $P < 0.002$ -highly significant.

**DISCUSSION:** Dry eye is a disorder of tear film which could cause tear deficiency or excessive tear evaporation which in turn causes damage to the ocular surface and leads to symptoms of ocular discomfort. Ocular disorder was noticed in 28% of the adults who presents with DED and found common in the general population<sup>14</sup>.

Dry eye is generally not curable and its management needs proper control of symptoms and prevention of ocular surface damage. Dry eye is a significant feature of diabetes and patients with diabetes have DES more often than those without diabetes<sup>2</sup>. Chronic blood glucose levels leading autonomic neuropathy not only affects the tear gland but also affects the quality of tears by disrupting their normal chemical composition with increasing amount of glucose which contributes to symptoms of dry eye. Hence tightly controlled blood glucose level might be the prime factor for preventing and remedying DED association with T2D.

In the present study, out of 100 patients, we observed 53% of DED and could be seen in all ages of sex. The prevalence of DED is more in females as compared to males. Relationship between

prevalence of DED with respect to age was reported very recently by Ranjan *et al.*, 2016<sup>15</sup>. This increase may be due to association between hormonal status and pre and postmenopausal period. Our study suggests that hormones may influence the prevalence of DED in pre and post menopausal women. In our study the number of severity of DR significantly increased with respect to age and we also found relationship between sex and grades of DR. As compared to females, males are more prevalent to DR such a relation was found in Zhang *et al.*, 2016 and Ozawa *et al.*, 2015<sup>2,16</sup>.

Duration of diabetes is one major risk factor for acquiring DED. Our study showed significantly higher prevalence of DED in longer duration of diabetes and it was noted in females (57.4%) as compared to males (43.8%). Further it was observed that sex and age also seemed to affect DED. Our findings are consistent with Zhang *et al.*, 2016<sup>2</sup> and Burda *et al.*, 2013<sup>14</sup> who reported a significant association between duration of diabetes and DED prevalence and suggested as the duration increased the prevalence of dry eye also increased.

The study found association between DED and DR in T2D patients. Out of 100 patients, DR was found

in 57 patients who included 21 males and 36 females. Between males and females with DR, the prevalence of DED was found significantly higher in females. In consistent with this, a high incidence of dry eye among females as compared to males was reported<sup>17</sup>. Also many studies reported the significant correlation between DED and stages of DR<sup>2-5</sup>. From findings we inferred that DED is more prevalent among females with DR while the severity of DR was found high in males with less prevalence of DED when compared to females. Recently Ozawa *et al* in the years 2012 and 2015 strongly suggested that the severity of DR in males of T2D were attributed to abnormalities in neuro-retinal function<sup>16, 18</sup>. In our study frequency of DED was higher in T2D with DR, which was not noticed in previous studies<sup>2-5</sup>.

Glycemic control is one preventing factor for the development of DED. Our results showed that glycemic status was not under control especially in females with DED as compared to males. It implies that gender plays an important role in showing close association between poor glycemic control and prevalence of DED. Studies by Shaikh 2015<sup>4</sup> and Najafi *et al.*, 2013<sup>5</sup> found correlation between the HbA1c values and the presence of DED. Further Shaikh reported that glycemic status of the patient definitely had an impact on the prevalence of DED in diabetics<sup>4</sup>. Recently Najafi *et al.*, 2013 documented that both dry eye and retinopathy had significant correlation with HbA1c<sup>5</sup> and strongly suggested that surveillance of diabetic patients and good control over blood glucose are necessary key factors for prevention of dry eye syndrome and retinopathy.

Normal microbial flora present on the conjunctiva contributes to the defense of ocular surface. In pathological conditions likely diabetic patients may be inclined for the increased risk for opportunistic colonization of the eyelids, resulting in blepharitic presentations. Further these developments lead to a compromised tear film lipid layer with increased evaporation and decreased tear secretion. Ghasemi, 2008 confirmed that diabetes might be a possible predisposer for blepharitis<sup>19</sup>. Further Shaikh 2015 found correlation between MGD and DED in diabetic patients and reported that peripheral neuropathy causes aqueous deficiency dry eye and meibominitis results in evaporative dry eye<sup>4</sup>. In

support of this, the present study observed the association between presence of MGD and severity of DED in T2D patients, females showed higher predominance as compared to males. A higher percentage of prevalence of DED with respect to meibomian gland disease was noted than previous studies. Finis *et al.*, 2012 reported that MGD is more common in women and its incidence increases with age and it is influenced by the hormonal status<sup>20</sup>.

**CONCLUSION:** In our study, the prevalence of DED was high in T2D patients and showed to have a high correlation with DR and Prevalence of DED was observed more in females as compared to males with DR but severity of DR was observed more in males with DR as compared to females. Higher prevalence of DED in females may be due to influence of hormones and severity of DR in males might be due to abnormalities in local neuroretinal function but the exact principal mechanism have to be studied as a future study. This study registered the higher prevalence of DED in 100 T2D patients associated with DR than reported in earlier studies. As T2D and dry eye seems to have a common association, further studies are needed to establish the underlying etiologic relationship with large sample size. MGD is the most common causative factor for dry eye in diabetics. Hence other important tests could be employed to assess MGD and DED as a future study. Ophthalmologists may increase their role to ensure comprehensive eye care to the people by examining dry eye which is an imperative part of the evaluation of diabetic eye disease.

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**CONFLICT OF INTEREST:** None.

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