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Dry eye and its correlation to diabetes microvascular complications in people with type 2 diabetes mellitus☆,☆☆,★,★★

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ABSTRACT

Aims: This study was performed to investigate the correlation between dry eye disease and diabetes microvascular complications.
Methods: In this study 243 people with type 2 diabetes were enrolled. Tear osmolarity was measured using tear lab osmolarity system. All of the participants were evaluated for diabetes microvascular complications. The Michigan neuropathy screening instrument was used for detection of peripheral neuropathy, and the albumin/creatinine ratio in a spot urine sample was considered to diagnose diabetic nephropathy.
Results: The prevalence of dry eye disease was 27.7%. The mean value for tear osmolarity was 301.97 ± 13.52 mOsm/L. We found a significant correlation between dry eye disease and diabetic retinopathy (P = 0.01). However no significant correlation was found between dry eye disease, diabetic neuropathy, and diabetic nephropathy.
Dry eye disease was more prevalent in people with proliferative diabetic retinopathy and/or clinically significant macular edema (0.006). In a binary logistic regression analysis model, there was a significant correlation between dry eye disease and retinopathy (OR = 2.29, CI = 1.16–4.52, P = 0.016). In addition, both dry eye and retinopathy had significant correlation with HbA1C.
Conclusions: Dry eye disease is common in people with type 2 diabetes, especially in those with diabetic retinopathy. In addition, it is more prevalent in people who suffer from advanced stages of diabetic retinopathy.
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1. Introduction

Diabetes mellitus is a common systemic disease characterized by chronic hyperglycemia which leads to major chronic complications. Peripheral neuropathy, nephropathy, and retinopathy are well known microvascular complications of diabetes. A number of ocular complications accompany diabetes mellitus. These include cataract, glaucoma, retinopathy, punctuate keratitis, and recurrent corneal lesions (Inoue et al., 2001; Rehany, Ishii, Lahav, & Rumelt, 2000). Diabetes is the leading cause of blindness in industrialized countries in people between the ages of 25 and 74 years and the fourth cause of blindness in developing countries (Robinson & News, 2012). Cataract, glaucoma, and macular degeneration are more likely to cause vision loss than diabetic retinopathy (Idil, Caliskan, & Ocaktan, 2004).

Dry eye disease (DED) is a common ocular disease among the adult population (Moss, Klein, & Klein, 2000; Moss, Klein, & Klein, 2004). Diabetic patients might exhibit dry eye symptoms probably due to neuropathy, metabolic dysfunction, or abnormal lacrimal secretions (Inoue et al., 2001; Dogru, Katakami, & Inoue, 2001; Sánchez Thorin, 1998). It has been shown that the composition of tear proteins in diabetic people is different from healthy subjects (Herber, Grus, Sabuncuo, & Augustin, 2001; Herber, Grus, Sabuncuo, & Augustin, 2002; Grus, Sabuncuo, Dick, Augustin, & Pfeiffer, 2002). Damage to the microvasculature of the lacrimal gland accompanied with autonomic neuropathy might impair lacrimation in long standing diabetes mellitus. Patients with diabetic retinopathy do not complain of dry eye symptoms, however, they have clinical and pathological manifestations of Keratoconjunctivitis Sicca (KCS) (Nielsen & Lund, 1979).

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Several previous studies have investigated the relationship between dry eye disease, diabetes, and diabetic retinopathy (Moss et al., 2000; Seifart & Strempel, 1994; Manaviat, Rashidi, Afkhami-Ardekani, & Shoja, 2008; Nepp, Abela, Polzer, Derbolav, & Wedrich, 2000). However, the prevalence of DED varied according to the methods used for diagnosis of dry eye and it was not clear whether there is a correlation between DED and other microvascular complications of diabetes.

Our purpose was to investigate the prevalence of dry eye disease based on osmolarmeter as a gold standard method for diagnosis of tear hyperosmolarity and explore if peripheral neuropathy, nephropathy, and diabetic retinopathy have any correlation with dry eye disease in people with type 2 diabetes mellitus.

2. Subjects, materials and methods

We studied 243 people with type 2 diabetes at Institute of endocrinology and metabolism from August 2011 to November 2012. This study was a part of a diagnostic accuracy survey comparing various methods for diagnosis of dry eye disease. Demographic and clinical data of the patients were recorded including sex, age, duration of diabetes, BMI, blood pressure, and the type of treatment for diabetes control. Exclusion criteria included use of medications or history of any other ocular or systemic disease that can affect tear production or quality, anterior segment surgery, Keratorefractive procedures (LASIK, LASEK, PRK) within the 2 years prior to enrollment, trauma, contact lens wear, glaucoma, pregnancy, use of ocular medications or nutritional tear supplements. Serum samples were sent for measurement of fasting glucose, lipids and glycosylated hemoglobin (HbA1C). Tear osmolarity was measured using tear lab osmolarity system, (BON Co. Germany), according to the randomization table for one eye. A tear sample, approximately 50 nl, was collected from the inferior lateral tear meniscus of the ocular surface. The 308 mOsm/L cutoff was used to diagnose dry eye disease (Foulks, Lemp, Berg, Bhola, & Sullivan, 2009).

Retinal status was evaluated by retinal color photography and indirect ophthalmoscopy exam with dilated pupils following the administration of Tropicamide Ophthalmic drop (Mydrax 1%). Diabetic retinopathy was classified according to the early treatment diabetic retinopathy study (ETDRS) criteria (Early Treatment Diabetic Retinopathy Study Research Group, 1991) by two specialists. Michigan neuropathy screening instrument (MNSI) was used for diagnosis peripheral neuropathy (Diabetes Research & Center, 2000); a score greater than 2 points on a 10 point scale was defined as neuropathy. A urine sample was sent for measurement of urine albumin and creatinine. Albumin/creatinine ratio greater than 30 μg/mg identified microalbuminuria. For diagnosis of macroalbuminuria, a ratio greater than 300 μg/mg was the considered cut point.

All of the participants signed the written informed consent and the ethics committee of Tehran University of Medical Sciences approved the study protocol.

3. Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS version 18.0, Chicago IL). Descriptive statistics methods were used for baseline characteristics (means ± SD and proportions). Chi square test, logistic regression and Spearmen's correlation coefficients were used to compare discrete variables. Significance was considered to be $P < 0.05$. Results were given with their 95% CIs.

4. Results

Two hundred forty three people with type 2 diabetes, 141 (58%) female and 102 (42%) male, were enrolled in this study. The mean age of the participants was 55.80 ± 10.33, and the mean duration of diabetes was 9.08 ± 7.9 years. 13.5% of the participants were current smoker. The mean for BMI was 29.2 ± 4.9 (27.4 ± 3.99 in male and 30.59 ± 5.02 in female; P-value = 0.000). The mean for fasting blood glucose was 152.4 ± 59.6 mg/dl, and for HbA1C was 7.55% ± 1.73%. Table 1 illustrated the baseline characteristics of the participants.

Table 1
Baseline characteristics of the participants, according to diabetic microvascular complications.

Characteristic	Diabetic retinopathy	Diabetic nephropathy	Diabetic neuropathy
Age (years)	56.52 ± 9.73	60.27 ± 11.07	58.66 ± 10.23
Female, *n* (%)	26(53%)	25(45%)	24(58%)
BMI (kg/m^2)	29.41 ± 5.38	28.73 ± 4.88	29.23 ± 4.68
Diabetes duration (years)	13.68 ± 9.28	11.53 ± 8.71	11.66 ± 9.20
Systolic BP (mmHg)	133.83 ± 19.98	132.82 ± 21.29	131.46 ± 24.7
Diastolic BP (mmHg)	81.06 ± 11.27	79.82 ± 9.13	80.49 ± 12.69
FBS (mg/dl)	161.28 ± 77.88	178.64 ± 74.78	162.9 ± 76.98
HbA1C (%)	8.28 ± 2.09	8.27 ± 2.02	7.79 ± 2.17
HDL (mg/dl)	42.98 ± 10.21	44.78 ± 12.88	42.05 ± 11.43
LDL (mg/dl)	100.67 ± 29.19	97.11 ± 40.99	96.87 ± 30.03
TG (mg/dl)	136.86 ± 66.99	130.82 ± 58.96	131.67 ± 70

Data are mean ± SD unless otherwise indicated.

The means for systolic blood pressure and diastolic blood pressure were 127.3 ± 19.27 mmHg and 78.34 ± 10.7 mmHg respectively.

Oral glucose lowering drugs (OGLDs) were used by 69.4% of the participants, while 10.5% were on insulin only, 15.5% were on both and 4.6 % were on diet only.

There was no correlation between the type of treatment for diabetes and dry eye disease or diabetes microvascular complications (Table 2). In addition, no significant correlation was found between cigarette smoking and dry eye disease (P = 0.12).

The mean value for the tear osmolarity was 301.97 ± 13.52 mOsm/L. The prevalence of dry eye disease was 27.7% in total, 10.2% in male, and 17.4% in female participants. Table 3 illustrates the prevalence of dry eye disease and diabetes microvascular complications according to sex and age of the participants.

We found a significant correlation between dry eye disease and retinopathy (P = 0.01). Considering diabetes retinopathy classification into nonproliferative diabetic retinopathy (NPDR), proliferative diabetic retinopathy (PDR), and clinically significant macular edema (CSME); NPDR was observed in 12.6% of the patients, while PDR and CSME were present in 2.8% and 7.5%; respectively.

Using binary logistic regression analysis, we found a significant odds ratio for dry eye disease (dependent variable) and retinopathy; (OR = 2.29, CI = 1.16–4.52, P = 0.016). In addition, the binary logistic regression between stage of retinopathy (NPDR and PDR, CSME, CME) and dry eye (dependent variable) showed a significant odds ratio for dry eye and more advanced stages of diabetic retinopathy (OR = 4.41, CI = 1.28–15.17, P = 0.019). Similarly significant odds were found between dry eye disease and HbA1C; OR = 1.19, CI = 1.008–1.41, P = 0.04. However, no significant

Table 2
Frequency of dry eye disease and other diabetes microvascular complications according to the type of treatment.

Complications	OGLDs	Insulin	OGLDs + Insulin	P-value(χ^2-test)
Dry eye disease	43/160 (26%)	8/25 (32%)	10/37 (27%)	0.86
Retinopathy	28/147 (19%)	6/24 (25%)	9/30 (30%)	0.37
Neuropathy	25/106 (23%)	6/17 (35%)	8/23 (35%)	0.38
Nephropathy	36/143 (25%)	7/18 (39%)	8/31 (26%)	0.46

Data are shown as n (%).

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