



A CLINICAL STUDY OF DRY EYE DISEASE AMONG DIABETIC AND NON-DIABETIC PERSONS

Ophthalmology

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ABSTRACT

Purpose: The aim of the study was to investigate the prevalence of dry eye disease among diabetic patients and to compare it with non-diabetic persons.

Material and Methods: This was a randomized cross-sectional study of 224 randomly selected patients between 31 to 60 years of age diagnosed to have diabetes and age, sex matched 224 non-diabetic normal persons as controls, done in a tertiary care hospital from January 2018 to June 2019. Standard patient evaluation of eye dryness (SPEED) questionnaire, Schirmer's test, tear film break-up time (TFBUT) and Rose Bengal staining tests were used for diagnosis of DED.

Results: Out of total 224 diabetic patients, 88 (39.3%) were males, 136 (60.7%) were female and out of 224 non-diabetic subjects 90 (40.2%) were males, 134 (59.8%) were female. Mean age of the diabetic patients was 56 ± 10.4 years and was 53 ± 9.8 years in non-diabetic persons. The SPEED questionnaires score equal or greater than six was found in 48 (21.4%) diabetics and in 23 (10.3%) cases of non-diabetic persons. The Schirmer test value was less than 10 mm in 39 (17.4%) diabetic patients and in 20 (8.9%) control cases. The TFBUT was less than 10 seconds in 35 (15.6%) diabetic patients and in 17 (7.6%) cases non-diabetics. Rose Bengal score was more than four in 14 (6.3%) patients with diabetes and in 4 (1.8%) control cases. The prevalence of DED was found to be in 35 (15.6%) patients with diabetes and in 17 (7.6%) cases of non-diabetics.

Conclusions: Diabetic patients had a significantly higher prevalence of DED in comparison to age and sex matched non-diabetic controls.

KEYWORDS

Dry eye disease, SPEED questionnaire, Schirmer test, tear film break-up time

INTRODUCTION

India is stated to be the world's capital of diabetes mellitus (DM). The diabetic population in the country is estimated to be close to 69.9 million by 2025 and 80 million by 2030. Diabetes has become the fifth leading cause of blindness across the globe.¹ It is estimated that about 70 % of DM cases live in middle- and low-income countries.² In patients with DM, chronic hyperglycemia is the most important factor related to microvascular complications like retinopathy and nephropathy.^{3,4}

The Definition and Classification Subcommittee of the International Dry Eye Workshop (DEWS) in 2007 created a comprehensive definition in lacrimal function unit (LFU) dysfunction for dry eye disease (DED), which is most widely accepted till date. DED is defined as 'a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tears film instability with potential damage to the ocular surface.'⁵ The pathogenesis of DED begins with disorder of tears circulation and subsequently tears film instability. This causes surface epithelial lesions which leads to decreased tear production by the tear gland and subsequently aggravation of the DED symptoms with induction of an inflammatory response.⁶

The LFU is composed of the cornea, conjunctiva, lacrimal gland, meibomian gland, lids and the sensory and motor nerves that connect them.⁷ LFU has a regulatory role in tear secretion and tear film formation and maintains the normal physiology of the ocular surface. The damage to any component of LFU can cause tear deficiency or evaporative DED. The effects of hyperglycemia on any component of the LFU may be transferred to the entire system via neural connections, leading to insufficient tear production or excess tear loss, abnormalities in blinking, and changes in tear film composition to cause DED.

In the diagnosis of DED, symptoms play an important role. The common symptoms of DED are dryness, grittiness, soreness or irritation, burning or watering, eye fatigue due to either reduced production of tears or increased tear evaporation rate.⁸ It has also been reported that both ocular discomfort and psychological stress of DED adversely affects the quality of life of a person which ultimately leads to decrease an individual's productivity.⁹ The reported prevalence of DED in the literature varies from 10.8% to 57.1%.¹⁰

The diagnosis of DED is mainly based on subjective symptoms without an objective clinical diagnosis. SPEED questionnaire¹¹ has

demonstrated good validity, objectivity and consistency when compared to other questionnaires to evaluate a case of DED. The numeric value for each answer is simply added with scores ranging from zero to 28. Patient's evaluation for DED should be started even if without complaints of dry eye when score is six or more on the SPEED questionnaire.

There is no consistency among symptoms and signs of DED, various test results also don't correlate with each other. Schirmer test with or without anesthesia assess quantity of aqueous production. Tear film break up time evaluate lipid layer, thus the stability of tear film. The abnormalities of corneal and conjunctival staining with different dye give an idea of both aqueous tear deficiency and evaporative dry eye. The present study was aimed to assess the prevalence of dry eye disease among patients with DM and to compare it with non-diabetic subjects.

MATERIAL AND METHODS

This was a case control study which included randomly selected 224 patients with diabetes between 31 to 60 years were done from January 2018 to June 2019. Age and sex matched 224 non-diabetic persons from ophthalmology department were taken as controls for the study. The study subjects outside the mentioned age group, having lid abnormalities, features of anterior segment inflammation, history of ocular surgery, connective tissue disorders and thyroid disease were excluded from the study. They were informed about the study and their consent was taken. This research protocol was approved by the Institutional ethics committee.

A detailed history regarding age, gender, duration of diabetes was taken from diabetic persons. Visual acuity of all study subjects was recorded with Snellen's chart and if needed refractive error was corrected. A thorough anterior segment examination was done with slitlamp biomicroscope and posterior segment evaluation was done with 90D and indirect ophthalmoscope.

The study subjects were interviewed with SPEED questionnaires (Annexure I) to evaluate dry eye disease. The subjects with possible answers score of six or more with SPEED questionnaires were suggestive to have DED.

Annexure I SPEED Questionnaire

Name: _____, Sex: M / F
Age ____ / ____ / ____

How **FREQUENTLY** do you experience the following dry eye symptoms?

Symptoms	Never (0)	Sometimes (1)	Often (2)	Constant (3)
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

How **SEVERE** are your dry eye symptoms?

Symptoms	No problems (0)	Tolerable – not perfect but not uncomfortable (1)	Uncomfortable – irritating but does not interfere with my day (2)	Bothersome – irritating and interferes with my day (3)	Intolerable – unable to perform my daily tasks (4)
Dryness, Grittiness or Scratchiness					
Soreness or Irritation					
Burning or Watering					
Eye Fatigue					

Total SPEED score (Frequency + Severity) = ____/28

Tear film was evaluated with Schirmer's I test, tear film breakup time (TFBUT) and Rose Bengal staining. Schirmer test was done by placing a small strip of Whatman's filter paper No 41 inside the inferior fornix. The eyes were closed for 5 minutes. Then the paper was removed and the amount of moisture part was measured. Less than 10 mm was suggestive of dry eye.

The tear film breakup time (TFBUT) test measured time the tears took to breakup in the eyes. After application of fluorescein 1% dye in the lower fornix the patient is asked not to blink while the tear film is observed under a broad beam of cobalt blue illumination of a slitlamp. The TFBUT was recorded as the number of seconds elapsed between the last blink and the appearance of first dry spot in the tear film over cornea. A TFBUT less than 10 seconds was considered abnormal and positive for DED.

Rose Bengal staining was done with sterile Rose Bengal strips. A modified Van Bijsterveld grading was employed. A grade greater than four was taken as positive for DED.

Patients with two or more positive tests had been considered for DED group and others were included in the non-DED group. Statistical analysis were done by Statistical software SPSS version 20.0

RESULTS

A total 224 diabetics and 224 non-diabetic persons were screened for DED in this study (Table-1).

Table-1: Basic characteristics of the study population

	Diabetic persons(n=224)	Non-diabetic persons (n=224)
Mean age in years(SD)	56(10.4)	53(9.8)
Sex (%)		
Male	88(39.3)	90(40.2)
Female	136(60.7)	134(59.8)
Outdoor workers (%)	52(23.2)	43(19.2)

It included 88 (39.3 %) males, 136 (60.7%) female diabetic patients and 90 (40.2 %) males, 134 (59.8%) female non-diabetic persons. Male to female ratio in diabetic group was 1:1.54 and in non-diabetic group it was 1:1.48. Mean age of the diabetic patients was 56 ±10.4 years and 53±9.8 years in non-diabetic persons. Fifty-two (46.4%) diabetic subjects and 43(19.2%) non-diabetic persons worked more than four hours in outdoor daily.

In this study, 48(21.4%) diabetic patients had dry eye subjective symptoms with SPEED questionnaires while 23(10.3%) non-diabetics were positive for symptoms of dry eye. Most common symptoms were dryness, grittiness or scratchiness in 37(33.03%) diabetics and in 18(16.07%) non-diabetics.

The Schirmer's test value less than 10 mm was associated in 39 (17.4%),TFBUT value was less than 10 seconds in 35 (15.6%) and rose Bengal staining was positive in 14(6.3%) diabetic patients. The Schirmer's test value less than 10 mm was present in 20 (8.9%), TFBUT value was less than 10 seconds in 17 (7.6%) and rose Bengal staining was positive in 4(1.8%) non-diabetic persons(Table-2).

Table-2: Comparison between diabetic patients and non-diabetic controls

	Diabetic patients(n=224)	Non-diabetics (n=224)	P -value
SPEED questionnaire (score ≥ 6)	48(21.4%)	23(10.3%)	.00062
Schirmer's test (< 10 mm)	39(17.4%)	20(8.9%)	.00402
TFBUT (< 10 seconds)	35(15.6%)	17(7.6%)	.004.2
Rose Bengal grade (Grade > 4)	12(5.3%)	4(1.8%)	.02068

Therefore, out of the study population of 224 diabetics, 35(15.6%) patients with DM and out of equal number of controls, 17(7.6%) non-diabetic subjects were diagnosed to have DED.

DISCUSSION

The DED is a serious but neglected health problem in ophthalmology practice with limited treatment options. It affects millions of people worldwide. In this study, 224 diabetic patients and 224 non-diabetic persons were screened for DED. It included 88 (39.3 %) males, 136 (60.7%) female diabetic patients and 90(40.2 %) males, 134(59.8%) female non-diabetic persons. Male to female ratio in diabetic group was 1:1.54 and in non-diabetic it was 1:1.48. The female diabetic patients were more in our study than male patients, correlating to Sahai A et al.¹² study from Jaipur where females were also more affected than males. Mean age of the diabetic patients in this study was 56 ±10.4 years and was 53±9.8 years in non-diabetic persons. Environmental exposure plays a role in the development of DED. But in our study, more than four hours of outdoor work was done by only 52(23.2%) diabetic subjects and by 43(19.2%) non-diabetic persons. Out of 224 diabetic patients, funduscopy revealed 33(14.7%) patients had evidence of diabetic retinopathy.

In this study, 48(21.4%) diabetic patients had dry eye subjective symptoms with SPEED questionnaires while 23(10.3%) non-diabetics had symptoms of dry eye. The symptoms of DED were more common in diabetic patients compared with the non-diabetic subjects. Most common symptoms were dryness, grittiness or scratchiness in 37(33.03%) diabetic patients and in 18(16.07%) non-diabetic persons.

TFBUT value was less than 10 seconds in 35 (15.6%) diabetic patients. We found lower TFBUT value in patients with diabetic retinopathy compared to patients without diabetic retinopathy.

The Schirmer's test value was positive in 39 (17.4%) and Rose Bengal staining was positive in 34(15.2%) diabetic patients. But the Schirmer's test value was positive in 20 (8.9%), TFBUT value was less than 10 seconds in 17 (7.6%) and Rose Bengal staining was positive in 14(6.2%) non-diabetic persons (Table-2). There is no single clinical test to accurately diagnose DED. We therefore combined subjective symptoms with SPEED questionnaire, assessed ocular anterior ocular surface with slitlamp examination, and performed objective tests of Schirmer's test, TFBUT test and Rose Bengal staining for diagnosis of DED.

Therefore, out of the study population of 224 diabetics, 35(15.6%) diabetic patient were diagnosed to have DED and out of 224 non-diabetic subjects 17(7.6%) were diagnosed to have DED. The incidence of DED in our study correlates with the study of Sudha R et al¹³ and Agarwal P et al¹⁴. The results of this study enhance the

understanding of the relationship between diabetes mellitus and tear functions.

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