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Tear film changes in diabetic retinopathy: A hospital based case control study

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ABSTRACT

Aim: To compare the tear film changes in diabetic population with and without diabetic retinopathy. To study the association of dry eye with different gradings of diabetic retinopathy.
Materials and Methods: A case control study was conducted in 112 eyes in diabetics with and without diabetic retinopathy changes. Tests for tear film changes like Schirmers, TBUT and KES was conducted and the results were compared.
Results: The mean value of Schirmer in diabetic retinopathy group was 10.84 +/- 4.785, mean value of TBUT was 7.73+/- 2.908 and that of KES was 1.34 +/- 0.745 whereas mean value of Schirmers in non DR group was 12.84+/- 2.947, that of TBUT was 10.43+/- 2.035 and that of KES was 0.73+/- 0.726. Significantly poorer Schirmers (p= 0.009), TBUT (p=0.001) and KES(p=0.001) was found in the DR group.
Conclusion: With increasing severity of diabetic retinopathy these signs and symptoms of dry eye have found to increase thereby a significant association between dry eye and grading of DR.

1. Introduction

Diabetic retinopathy is a major cause of blindness among the working age group. The number of cases of adult onset diabetes mellitus is estimated to grow up to 80 million in 2030 as per the estimates of WHO.[1] The Aravind Comprehensive Eye Study reported the prevalence of DR in rural south India to be 10.5%.[2]

A pan India study conducted by AIOS concludes that two – third cases of Diabetic Retinopathy are from the west and south zones.[3]

Diabetes is a systemic risk factor for dry eye syndrome. The Beaver Dams Study reported that approximately 20% of the dry eyes occurred in individuals with type 2 Diabetes. Diabetes has a negative effect on the lacrimal function unit which affects the tear production and changes in composition of tear film. It has been suggested that the association may be due to the diabetic sensory or autonomic neuropathy[4,5] or the occurrence of microvascular changes in lacrimal gland.

The aim of this study is to compare the tear film changes in diabetic population with and without Diabetic retinopathy changes. An insight into the tear film changes in diabetes would enable us to tackle tear film related disorders in diabetics at the earliest.

2. Materials and Methods

Sample size of 112 was estimated considering the article, 'Tear film and ocular surface dysfunction in diabetes mellitus in Indian Population' by Kesarwani et al. using Open epi software version 3. Considering the mean in group 1 as 10.95 and mean in group 2 as 7.63; and considering standard deviation as 6.89 in group 1 and 5.2 in group 2, the sample size was calculated at 95% confidence interval, 80% power of study and taking the ratio of sample size as 1.

The study was conducted in S Nijalingappa Medical College, Bagalkot. 56 patients (a total of 112 eyes) were

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included in the study. All the patients were diagnosed diabetic and were undergoing treatment. The random blood sugar levels of all patients was above 140 mg/dl. 56 patients were divided into two age and gender matched groups consisting of 23 patients (56 eyes each).

The patients were enquired about the symptoms of dry eye such as itching, foreign body sensation, burning. The patients were also enquired about the duration of diabetes and HBA1c status. The patients with other predisposing factors for dry eye like pterygium, trachoma, Vitamin A deficiency, ocular pemphigus, keratoconjunctivitis sicca, patients using topical ocular medications were excluded from the study. Verbal consent was taken from all participants of the test.

The patients were subjected to anterior segment examination by slit lamp examination. The patients were subjected to Schirmers test I, Tear film break up time and Keratoepitheliopathy score in order to assess the tear film changes.

Schirmers test I was conducted in both eyes simultaneously using Schirmers strip. The strip is bent and the smaller end is kept at the junction of lateral one –third and medial two-third of lower eyelid. The patient is asked to keep the eyes open and is permitted to blink. After 5 minutes, readings were noted. A reading between 10mm-20mm was taken as normal and below 10 mm was suggestive of dry eye changes.[6]

Patient's eyes was stained with 2% fluorescein sodium and observed with a cobalt blue filter on a slit lamp. The patient is asked to blink a few times and then stop blinking. The cornea is observed for development of black spots in the pool of fluorescein. The time taken between last blink and appearance of the first randomly distributed black spot is taken as tear film break up time. TBUT $<$ 10 s is considered as feature of dry eye.[7]

In the same sitting the keratoepitheliopathy score was documented based on the area and density of staining. The staining was graded from 0-3

0 – no punctuate staining
1 - 1/3 rd of cornea is stained
2 – 1/3 rd to 2/3 rd
3 - $>$ 2/3 rd of corneal surface[8]

3. Results

The study was intended to compare the values of Schirmers, TBUT and KES among diabetic patients with diabetic retinopathy and without diabetic retinopathy. The mean value of Schirmer in diabetic retinopathy group was 10.84 +/- 4.785, mean value of TBUT was 7.73+/- 2.908 and that of KES was 1.34 +/- 0.745 whereas mean value of Schirmers in nonDR group was 12.84+/- 2.947, that of TBUT was 10.43+/- 2.035 and that of KES was 0.73+/- 0.726. Significantly poorer Schirmers (p= 0.009), TBUT(p=0.001) and KES(p=0.001) was found in the DR group.

The study also found that the values of Schirmers, TBUT and KES deteriorated with increasing grades of diabetic retinopathy.

3.1. Statistical analysis

The difference in Schirmers, TBUT and KES values between diabetics with diabetic retinopathy and without diabetic retinopathy was calculated using independent sample t-test. P value $<$0.05 was considered statistically significant.

The association between the different gradings of diabetic retinopathy and the three tests of dryness was calculated using the Chi Square test (Pearson Square test).

4. Discussion

In the present health scenario, where the number of diabetics is on a rise, Diabetic Retinopathy is becoming a common ocular problem. Studies have proved the association of diabetes with tear film changes. This study was aimed at comparing the tear film changes between diabetic persons with diabetic retinopathy changes and without diabetic retinopathy.

The study was conducted in 112 eyes of diabetics with an average duration of diabetes of 4.2 years. The study consisted of 33 males (66 eyes) and 23 females (46 eyes). Out of these 56 eyes had diabetic retinopathy changes and 56 eyes had normal fundus though they were diabetic. Out of the eyes with diabetic retinopathy, 23 eyes had mild NPDR changes, 20 eyes had moderate NPDR changes and 13 patients had severe NPDR to PDR changes. Out of the 56 eyes with diabetic retinopathy, 40 eyes complained of 2 or more symptoms of dry eye. Out of the 56 eyes without diabetic retinopathy, two or more symptoms of dry eye was reported in 12 eyes.

Though the sensitivity of Schirmers test in assessing dry eye was found to as low as 10-30%, it was considered in our study for assessing dry eye. The mean Schirmers test value in the DR group was 10.84 +/- 4.785 ($p<0.009$) when compared to the mean Schirmers test in the non DR group which was 12.84 +/- 2.947 ($p<0.009$). The study conducted by Kesarwani et al. found a decreased tear secretion in diabetics with diabetic retinopathy.[9] Our study also supports a similar finding. The Schirmers strips showed decreased measurements of wetting as the severity of the stages of DR increased.

The mean TBUT test in DR patients was 7.73 +/- 2.903 whereas in non DR group was 10.43 +/- 2.035 with a p value of $<$ 0.001. This also indicated an ill sustained tear film in DR group in comparison to non DR group. The study conducted by Dogru et al.[8] disagrees with any correlation between TBUT and severity of diabetic retinopathy. Our study finds a significant association between the severity of DR and lesser time of tear film break up time. Even the study

Table 1: Comparison between tear film changes in DR and non DR group.

Tests	DR (n=56)	Non DR (n=56)	P value
Schirmers test	10.84 +/- 4.785	12.84 +/- 2.947	0.009
TBUT	7.73 +/- 2.908	10.43 +/- 2.035	0.001
KES	1.34 +/- 0.745	0.73 +/- 0.726	0.001

Table 2: Comparison of TBUT among different grades of diabetic retinopathy

TBUT	Mild NPDR	Moderate NPDR	Severe NPDR	Normal fundus
		Suggestive of dry eye		
Number	9	17	13	19
Percentage	39.1	85	100	33.9
		Not suggestive of dry eye		
Number	14	3	0	37
Percentage	60.9	15.0	0	66.09
Total	23	20	13	56

P<0.001 at Pearson Chi Square value of 29.194

Table 3: Comparison of Schirmer's test among different grades of diabetic retinopathy

Schirmer's test	Mild NPDR	Moderate NPDR	Severe NPDR	Normal fundus
		Suggestive of dry eye		
Number	7	14	13	10
Percentage	30.4	70	100	17.5
		Not suggestive of dry eye		
Number	16	6	0	46
Percentage	69.6	30.0	0	82.1
Total	23	20	13	56

P<0.001 at Pearson Chi Square value of 38.794

Table 4: Keratoepitheliopathy scoring in different grades of DR

Test	O	1	2	3	Total
Mild NPDR	18	03	01	01	23
Moderate NPDR	02	10	05	03	20
Severe NPDR	0	02	01	09	12

conducted by Saito et al.[10] reported no correlation between TBUT and severity of DR.

The keratoepitheliopathy scores were also found to significantly increase in severity in DR group compared to the non DR group with a mean value in the DR group was 1.34 +/- 0.745 as compared to the mean value of 0.73+/- 0.726 in the non DR group. It was also found that the severity of the KES significantly increased with increasing severity grading of diabetic retinopathy. This is in accordance to the study conducted by K C Yoon et al. where the KES was higher in the diabetic group.[11]

5. Conclusion

Our study shows significant association between the presence of diabetic retinopathy and dry eye symptoms and signs in diabetic patients. With increasing severity of diabetic retinopathy these signs and symptoms of dry eye have found to increase thereby a significant association between dry eye and grading of DR.

This necessitates the need to pharmacologically lubricate the eyes where diabetic retinopathy changes have started and also increase the frequency in accordance with severity of DR. This would decrease the level of discomfort in patients with DR who would already be dealing with visual acuity related problems. Hence the study highlights the need for lubrication in DR patients in accordance to their severity of DR.

6. Abbreviations

DR – Diabetic Retinopathy; NPDR – Non Proliferative Diabetic retinopathy; PDR –Proliferative Diabetic Retinopathy; TBUT – Tearfilm Break Up Time; KES-Kerato epitheliopathy Score.

7. Source of Funding

None.

8. Conflict of Interest

None.

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