



Original Research Article

A Comparative Study of Tear Film Stability & Secretion in Pterygium Patients - Diabetic vs. Non-diabetic

Ashutosh S. Ganeshpuri¹, B. S. Kamble², Preeti Patil³, S. P. Wadgaonkar⁴

¹P.G., ³rd year, M.S (Ophthalmology), ²Professor, ³Lecturer, ⁴Associate Professor, Department of Ophthalmology, ACPM Medical College & Hospital, Sakri Road, Dhule, Maharashtra, India.

Corresponding Author: Ashutosh S. Ganeshpuri

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ABSTRACT

Aims, settings & design: The present prospective study was conducted on 62 ophthalmology patients over a period of 1 year, between May 2012 to April 2013 in rural set up to compare Schirmer's test's and the tear film breakup time test's diagnostic utility to detect tear film abnormalities in pterygium patients having diabetes vs control group

Materials & Methods: Our study involved 62 pterygium patients equally categorized into two groups. Group A comprised of diabetic patients & Group B of non-diabetic patients. The tear film stability & secretion were estimated in patients of both the groups.

Results: The mean Schirmer's test 1, mean Schirmer's test 2 & mean tear film breakup time values were 13.64 mm, 11.23 mm & 12.76 sec in Group A & 17.63 mm, 14.51 mm & 17.73 sec in Group B respectively. There was a statistically significant difference in the dry eye results between both the groups (p value < 0.05). Additionally there was a positive correlation between diabetic retinopathy, dry eye syndrome, decreased corneal sensation especially when associated with pterygium.

Conclusion: This study shows that dry eye syndrome is an important manifestation of diabetes & highlights the fact that tear film stability & secretion are greatly affected in patients having pterygium in comparison with non-diabetic pterygium patients.

Keywords: pterygium, Schirmer's test, TBUT, diabetes, tear film stability, tear film secretion

INTRODUCTION

Pterygium is a degenerative condition resulting in the formation of fibrovascular wing shaped tissue that develops from the conjunctiva & encroaches on to the cornea. [1] UVR-A & UVE-B are most important in the pathogenesis. [2-4] Pterygium takes its name from the Greek word for wing and was first described by Hippocrates. Its development is unrelated to antecedent injury or inflammation and

ninety percent of pterygia are located nasally. [5]

One of the theories is that the tear film abnormalities causes local drying of the cornea & conjunctiva which in turn predisposes to these new growths and exposes epithelium directly to the destructive effect of UV rays. [6] Precorneal tear film is formed of three layers as shown in Figure 1. Outer lipid layer, secreted by the meibomian glands and its function is to

prevent rapid evaporation of tears and lubricates the eyelids over the globe, middle aqueous layer, secreted by the lacrimal gland and its function is to supply oxygen to the corneal epithelium and antibacterial as it contains lysozymes, inner mucinous layer, secreted by the goblet cells and functions to make the corneal epithelium hydrophilic. [7]

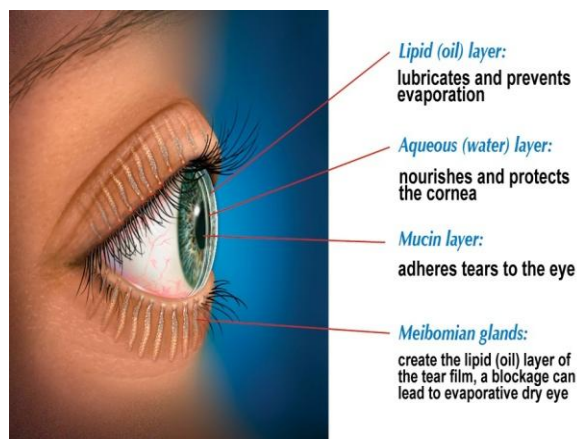


Figure 1: Layers of Precorneal tear film.

There is a worldwide distribution of Pterygium, but it is seen more commonly in the areas which have warm and dry climate. [8] The incidence of Pterygium is fairly high in this part of the world. [9] Pterygium is commonly seen in India, which is a part of the “Pterygium belt” which was described by Cameron. [10] Despite this fact, there is a relative paucity of current information about the prevalence of pterygium in the population. The prevalence of the lesion increases with age, the highest incidence occurs between the age of 20 and 49 years. [10]

Researchers have documented various ocular manifestations of diabetes mellitus to include large fluctuations in refraction, premature cataractogenesis and non proliferative and proliferative retinopathy. [11] It has also been noted that many diabetic patients complain of dry eye symptoms such as burning or foreign body sensation, and dryness. [12] Conjunctival features include tortuous & dilated vessels

(which are commonly found in the inferior bulbar region), pingueculae, & pterygia. Keratoconjunctivitis sicca has been reported to be more common amongst diabetic patients. [13]

In addition, many diabetic patients complain of typical dry eye symptoms, such as burning and/or foreign body sensation. Thus, the question arises as to whether diabetes mellitus is correlated with tear film anomalies or a disturbance of the function of the tear film. [14]

Tear film changes seen in DM : DM is a systemic disease often accompanied by microvascular complications, like that of conjunctival microvasculature & this in turn result in the clinical condition of dry eye.

Diabetic individuals are reported to have a greater tendency for developing dry eye syndrome than non-diabetics. [15] Prevalence of dry eye increases with age & duration of diabetes. The longer the duration of diabetes the higher is the incidence. [16,17]

Goebbel has reported that schirmer's reading significantly reduces in diabetic pts. [7]

In 1995, the National Eye Institute/Industry Workshop published the definition of dry eye states and a new classification. This definition of dry eye states that

“Dry eye is a disorder of the tear film due to tear deficiency or excessive tear evaporation which causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort”.

There is no single, readily available diagnostic test that has a high degree of sensitivity and specificity for the diagnosis of dry eye or its classification. The diagnosis, therefore, depends on the history, examination, and a combination of diagnostic studies. The clinical tests used are careful slit-lamp examination, the Schirmer's test, the tear film breakup time

(TBUT) and the Rose Bengal Test. Tear breakup time test is the standard clinical procedure that was introduced by Norn and its high sensitivity suggests a strong connection to the dry eye. [8] The other dry eye test includes tear film osmolarity, [18] lysozyme and lactoferrin, [19,20,21] impression cytology [22] and conjunctival biopsy. Although there are so many tests available for detection and diagnosis of dry eye, clinically, only three tests are used routinely. These are the Schirmer's test, the tear film break up time (TBUT) and the Rose Bengal test. The latter is reserved for use in severe dry eye patients with corneal signs of dry eye. The Schirmer's test measures the quantity of tear production and the TBUT measures the quality of the tear. The TBUT is also considered to be a measurement of the mucin and lipid layer integrity.

This study was done to compare Schirmer's test and the tear film breakup time test diagnostic utility to detect tear film abnormalities in pterygium patients having diabetes vs control group.

MATERIALS & METHODS

Type of Study : Prospective

Period of Study : May 2012 to April 2013

Sample Size : 62 cases

Patients Selection : A total of 62 patients were selected which comprised of 26 females and 36 males. Patients were diagnosed and those satisfying the inclusion and exclusion criteria were included in the study group.

Inclusion criteria:

Among the pterygium patients presenting to the OPD during the study period, both diabetic (Type 2 diabetes mellitus or non-insulin dependent diabetes mellitus (NIDDM)) and non-diabetic patients were included. Non-diabetic for the controls.

Exclusion Criteria:

Patients having other adnexal, anterior or posterior segment diseases that could alter tear secretion & stability or patients who refused to participate in the study & for the controls all other diseases of the eye except refractive errors.

- Secondary pterygium, Recurrent pterygium and pseudo pterygium.
- Age below 20 years and more than 80 years.
- History of any surgery done on eye.
- History of trauma, chemical or mechanical.
- Any clinical evidence suggestive of glaucoma.
- Active scleritis/ clinical evidence of thinned out sclera.
- Eyes with evidence of any ocular surface disorder or any ocular adnexal disorders or evidence of any high intraocular pressure.
- History of pemphigus, collagen vascular disease or Steven Johnson's syndrome.
- Abnormal anterior segment or posterior segment examination status except for pterygium.

Method of Collection of Data:

All the patients were evaluated as follows.

1. History
Patients were asked about their age, sex, occupation (laborers, farmers, welders etc.), duration of exposure, onset of pterygium, ocular symptoms (foreign body sensation, ocular irritation, recurrent inflammation, redness, cosmetic discomfort) of the disease, history of any surgery or trauma, history of glaucoma, hypertension and any other systemic illness. Detailed history of known cases of diabetes was taken.
2. Ocular Examination
A detailed ocular examination of the patient was done including visual

acuity and intraocular pressure. Slit lamp examination was done to check the nature and the extent of the pterygium, any fluorescein staining of the cornea, tear film abnormality, corneal scarring and anterior segment inflammation. Fundus examination was done to look for any vision threatening lesion, in particular to exclude glaucomatous patients to avoid sacrificing conjunctiva in the useful area (superior limbal region) which may be required later on for filtration surgery in these patients. Anterior segment, photographs were taken preoperatively and on follow up visits postoperatively.

3. Vision and Refraction

The best uncorrected visual acuity, best corrected visual acuity and refraction were recorded for all cases both preoperatively and postoperatively using Snellen's chart. Visual Acuity was recorded in decimals for ease of pre-op and post-op comparison..

4. Investigations

These included complete blood examination, complete urine examination, blood sugar, bleeding time and clotting time.

5. Grading of Pterygium

Grading of pterygium was partially adapted form of the simple grading system introduced by Tan DH et al in 1997. [23] Our grading criteria is described in Table 1.

Table 1 : Grading Criteria.

Grade 1	pterygia in which episcleral vessels underlying the body of pterygia were unobscured and clearly distinguished.
Grade 3	pterygia in which episcleral vessels underlying the body of pterygium were totally obscured.
Grade 2	includes all other pterygia not falling under the above mentioned grades.

6 . Staging of Pterygium

Staging of pterygium is mentioned in a few studies [23,24] and a modified and more objective staging has been used. Staging is used as an index of spread of the pterygium and its relation to recurrence is studied.

The length between limbus and center of cornea is arbitrarily divided into three parts. Staging criteria is as described in Table 2.

Table 2 : Staging Criteria

Stage I	The pterygium apex lying within the 1/3 rd adjacent to limbus.
Stage II	The pterygium apex lying within the middle 1/3 rd .
Stage III	The pterygium apex lying within the 1/3 rd adjacent to corneal center.

7. Exposure situations

Considering an average working duration of 6 hours per day, daily actinic exposure is classified as shown in Table 3.

Table 3 : Exposure situation classification.

Indoor	> 5 hours spent indoors
Mainly indoors	> 3 hours spent indoors
Mainly outdoor	< 3 hours spent indoors
Outdoor	< 1 hour spent indoors

Statistical Analysis

- The current study is hospital based prospective comparative study. The test of significance for association of different characteristics was Pearson's Chi Square test. The statistical significant, p value was calculated and a value less than 0.05 was considered significant. SPSS 16 was used to analyse the data.
- A case-controlled study was conducted in Department of Ophthalmology, of our Hospital between May 2012 & April 2013. The tear secretion & the tear film stability were estimated in Diabetic patients presenting with Pterygium & these findings were compared with those from control subjects with

Pterygium & non-diabetic matched for the age & gender.

- There is no single, readily available test that has a high degree of sensitivity & specificity for the diagnosis of dry eye or its classification, so the diagnosis, depends on the history, examination, & a combination of diagnostic studies.
- Although there are so many tests available for detection & diagnosis of dry eye, clinically, only three tests are used routinely. These are the Schirmer's test, the tear film break up time (TBUT) & the Rose Bengal test. The latter is reserved for use in severe dry eye patients with corneal signs of dry eye.
- The Schirmer's test measures the quantity of tear production & the TBUT measures the quality of the tear. The TBUT is also considered to be a measurement of the mucin & lipid layer integrity.
- The main aim of this study was to compare tear secretion & tear film instability in patients with pterygium in diabetic vs non-diabetic subjects .
- In both the Groups, the tear secretion & its stability were tested by performing the following tests.
 - Tear film break up time (TBUT)
 - Schirmer's test 1
 - Schirmer's test 2

METHODOLOGY

- TBUT: Manipulation of the eyelid or instillation of the anesthetics may affect the tear film break up time. So, the TBUT test was performed before other dry eye tests & recorded after fluorescein staining. Care was taken to avoid contact with the cornea to

prevent an excessive reflex secretion of tear. The end of a fluorescein strip was moistened with one drop of distilled water and applied to the subject's temporal bulbar conjunctiva. The subject was asked to blink several times to spread the dye over the corneal and conjunctival surfaces and then asked to keep the eyes open looking straight ahead. The cobalt blue filter was used to scan the entire cornea looking for dry areas which appeared as dark spots or streaks as shown in Figure 2. The time in seconds between the last blink and the first appearance of a dry spot was recorded with a stopwatch as the TBUT. The mean of three consecutive TBUT was taken. A TBUT of less than 10 seconds was indicative of an unstable tear film.

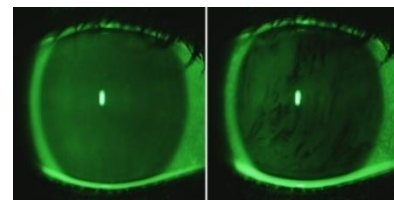


Figure 2 : TBUT Test

- Schirmer's test
 - a. Without anesthesia (Schirmer's test 1), &
 - b. After anesthesia (Schirmer's test 2 or Basal Secretion)
- The Schirmer test was performed after a thorough slit-lamp examination so that ocular irritation by the test strip would not interfere with other examination results as shown in the Figure 3. After 5 minutes, the strips were removed & the amount of wetting in millimeters was recorded.

- The Schirmer 1 test (without anesthesia) was considered positive if the length of the wetting was less than 10mm at the end of 5 minutes. The Schirmer test 2 after anesthesia (Basal secretion) was performed after the instillation of topical 4% xylocaine & (wiping the lower fornix with cotton), in the same manner as the Schirmer 1 test.
- After testing tear secretion & its stability, both the groups of patients were categorized under following Headings.
 - a) Normal Schirmer, Normal TBUT,
 - b) Abnormal Schirmer, Normal TBUT
 - c) Abnormal TBUT, Normal Schirmer
 - d) Abnormal Schirmer, Abnormal TBUT



Figure 3 : Schirmer's Test.

Data was entered in the Microsoft Excel Sheet. The means of both Schirmer's tests & TBUT, in patients were calculated in the study & control group.

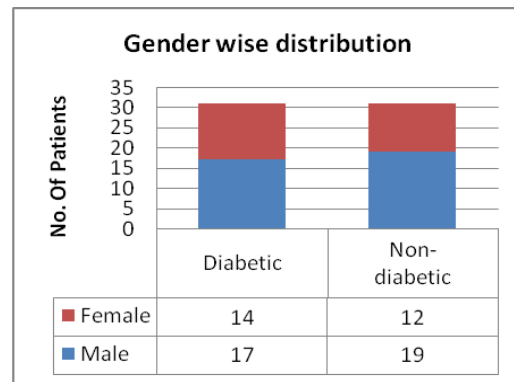
Case data:

Our study involved 62 pterygium patients equally categorized into two groups. Group A comprised of diabetic patients & Group B of non-diabetic patients. The tear film stability & secretion were estimated in patients of both the groups.

OBSERVATIONS & RESULTS

Gender wise distribution

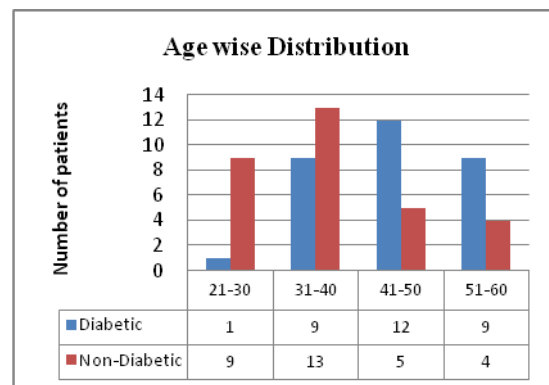
Out of 62 patients 26 (41.94%) were female and 36 (58.06%) were male. As seen in Graph 1, Of female patients 14 (53.85%) were diabetic patients and remaining 12 (46.15%) were non-diabetic. Of male patients 17 (47.22%) were diabetic patients and remaining 19 (52.78%) were non-diabetic.



Graph 1 : Gender Wise Distribution

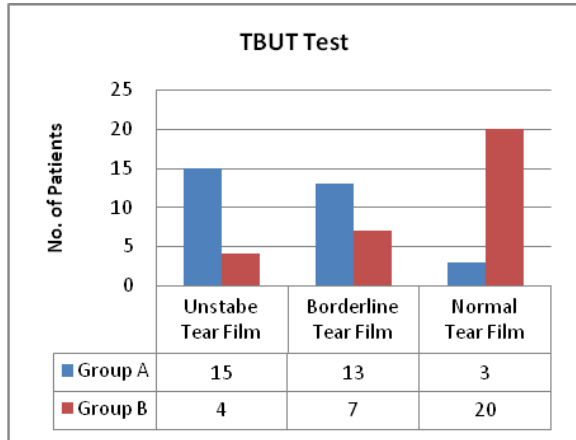
Age wise distribution

Patients were divided into age group of 10 years intervals. As seen in Graph 2, a total of 10 (16.13%) patients belonged to 21-30 years of which 1 patient was diabetic and remaining 9 were non-diabetic. 22 patients were included in age group of 31-40 of which 9 were diabetic and rest 13 were non-diabetic. In age group 41-50 comprised of 17 patients, 12 diabetic and 5 non-diabetic. 13 patients belonged to the age group of 51-60 years of which 9 were diabetic and 4 were non-diabetic.

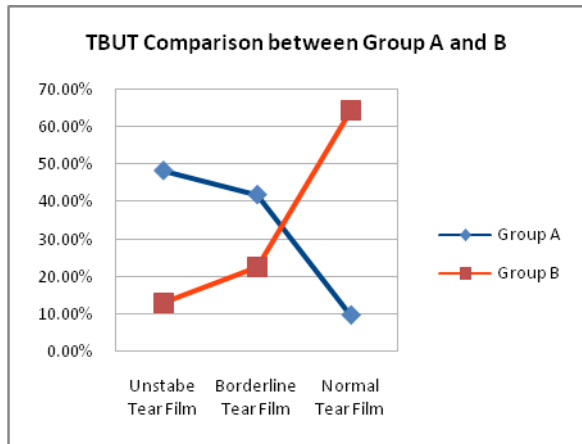


Graph 2 : Age Wise Distribution.

TBUT Test:



Graph 3 : TBUT Test



Graph 4 : TBUT Comparison between Group A and B

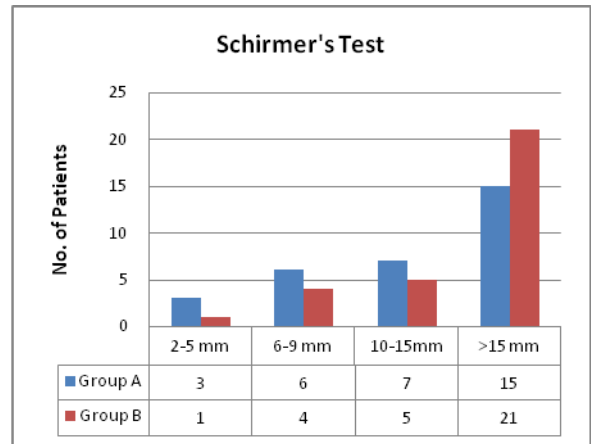
The TBUT test conducted & analyzed showed 15(48.39%) unstable tear film, 13(41.94%) borderline & 3(9.68%) normal tear film in Group A patients as shown in Graph 3. Similarly 4(12.90%) showed unstable tear film, 7(22.58%) borderline & 20 (64.52 %) normal tear film in the Group B. The TBUT Comparison between the two groups A and B is shown in Graph 4.

Schirmer's Test:

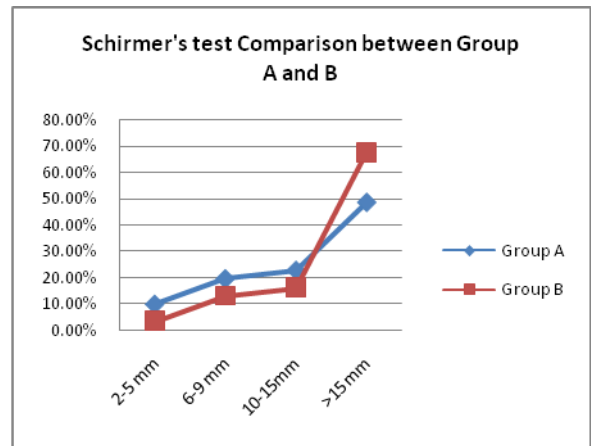
Regarding the degree of dry eye, a Schirmer's test of less than 2 mm was not seen in both the case & control groups, whereas in the Group A, the Schirmer's test 2-5 mm was in 3(9.68%), 6 – 9 mm in 6 (19.35%), 10 - 15 mm in 7 (22.58%), 15 mm

or above in 15 (48.39%) as shown in Graph 5. In the control group, the Schirmer's test of 2 – 5 mm was in 1 (3.23%), 6 - 9 mm in 4(12.90%), 10 – 15 mm in 5(16.13 %) & 15 mm & above in 21(67.74%) patients . Comparison of the Schirmer's test between the two groups A and B is shown in Graph 6.

There was a statistically significant difference between the two groups (P<0.05).



Graph 5 : Schirmer's Test.



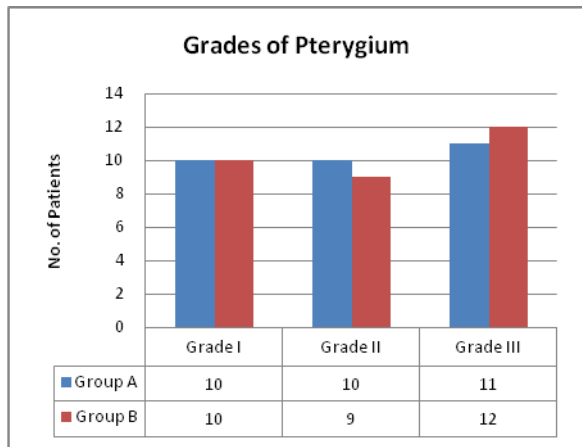
Graph 6 : Schirmer's test Comparison between Group A and B.

Table 4 : Comparative Outcome of Tests between the two Groups.

	Schirmer's 1 (mm)	Schirmer's 2 (mm)	TBUT (sec)
Diabetic	13.64	11.23	12.76
Non-diabetic	17.63	14.51	17.73

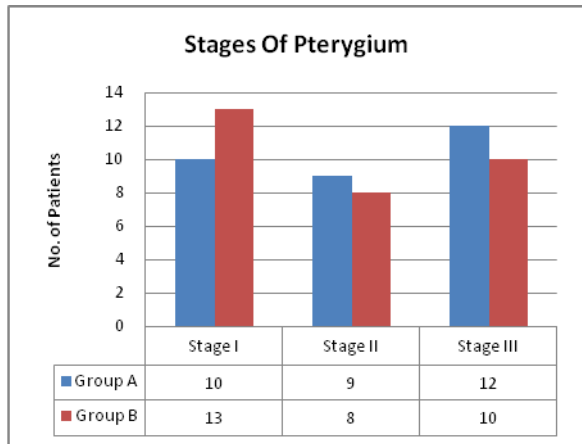
All the measurements for the Schirmer's test 1, 2 and TBUT test are shown in Table 4.

Grades and Stages of Pterygium patients:



Graph 7 : Grades of Pterygium

In Group A, 10 patients belonged to Grade I, 10 in Grade II and 11 patients in Grade III. In Group B, 10 patients belonged to Grade I, 9 in Grade II and 12 patients in Grade III as seen in Graph 7.

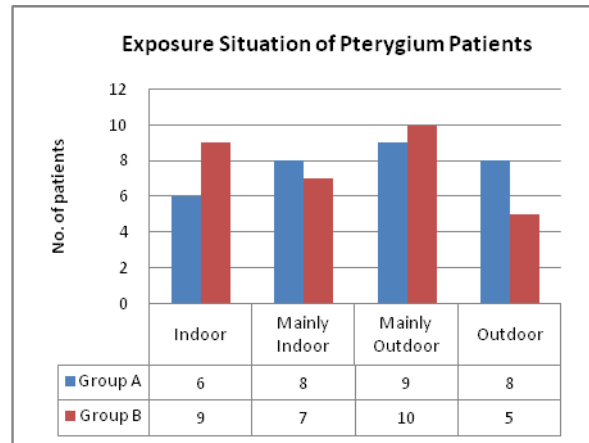


Graph 8 : Stages of Pterygium

In Group A, 10 patients belonged to Stage I, 9 in Stage II and 12 patients in Stage III. In Group B, 13 patients belonged to Stage I, 8 in Stage II and 10 patients in Stage III as seen in Graph 8.

Pterygium in relation to exposure:

There was no significant difference based of the exposure situation as per our categorization as shown in Graph 9.



Graph 9 : Exposure Situation of Pterygium Patients

DISCUSSION

A review of the literature has shown that so far no earlier studies have clearly shown a relationship between diabetes, dry eye & pterygium unequivocally.

Studies have either analyzed only the relationship between symptoms of dry eye & pterygium or correlated TBUT & pterygium or studied tear secretion & pterygium. While some of these studies showed a correlation between dry eye & pterygium [25] others did not find any correlation between these two conditions. [17]

Some studies, [26, 27] have shown the prevalence of dry eye & pterygium to be more common in males & others [28] have found no sex differences. In the present study, males were more affected (58.07%) than females (41.94%) which are similar to three recent studies conducted in Thailand, China & India. [29] The prevalence of pterygium was common in the 4th to 6th decades of life in this study, similar to other studies.

In this study, the mean Schirmer I was 13.64 mm (range 2.5 – 35 mm) in group A & 17.63 mm (range 4.5 mm - 35mm) in the group B (p<0.05). The mean basal

secretion value was 11.23mm (range 1 mm – 27.5mm) in group A & 14.51mm (range 0 mm - 28 mm) in the group B ($p < 0.05$). The mean TBUT was 12.76 sec in group A & 17.73 sec in group B.

In a study from India (Mithal et al, 1991) [30] when Schirmer's test was done in two groups of patients, they found that the mean wetting of the filter paper was 12.6 mm (range 11 - 16 mm) & 5.2 mm (range 3 - 9.4 mm) respectively in normal healthy eyes & the eyes of patients with pterygium, they concluded that both the values were found to be significantly reduced in cases of pterygium indicating the inadequacy of tear film in these pterygium patients.

According to a study by Martin Gobels [7] Schirmer test values were found to be significantly decreased in the diabetic group when compared with the non-diabetic control group which was in correlation with our study.

In the study by FK Idu et al. the mean basal secretion and the mean total secretion had a slightly decreased rate in the diabetic group in comparison with control group. Also the mean TBUT was significantly lower in the diabetic group. [29] We also recorded similar findings in the diabetic and non-diabetic group patients.

In a paper by Indu Gupta et al [31] the TF BUT was significantly lower in the diabetics as compared with the controls. The mean Schirmer 1 test value was 8.99 millimeters and 15.8 mm in diabetic group and control group respectively. However, in our study the mean Schirmer 1 test value was 13.64 millimeters and 17.63 mm in diabetic group and control group respectively. Both their and our studies showed significantly lower Schirmer 1 test value in the diabetic group as compared with the controls.

Chaidaroon & Pogmoragot in Thailand [32] assessed Schirmer's test with

anesthesia (basal secretion) in both the eyes of patients with unilateral pterygium.

Ishioka et al (2001) [33] showed that Schirmer's test with anesthesia was shortened & was decreased in the eye with pterygium with marginal significance. They concluded that there is a correlation between pterygium formation & unstable tear film.

CONCLUSION

- Pterygium was more common in male & in outdoor workers.
- The largest number of pterygia was found in the fourth to sixth decades of life in both sexes.
- There was no relation between dry eye with sex & occupation.
- Burning sensation was the most common symptom of pterygium patients followed by grittiness & redness.
- Most of the patients in this study presented in late stages & the average encroachment of pterygium into the cornea was 2.04 mm & average width of pterygium at the corneal junction was 3.74 mm.
- Patients with decreased tear production are more prone to the damaging effects of UV rays in the sunlight. Conservatively the progress of pterygium can be stopped or slowed down by using lubricant eye drops as a substitute for tear.
- Our study demonstrated high sensitivity of the TBUT test compared to the Schirmer's test. Thus, it could be used as an initial screening tool in out-patient departments to detect tear film instability in patients with pterygium.
- The ocular surface changes found in diabetics could at least partially be the result of a primary surface

disease or of metabolic alterations of the conjunctival epithelial cells independent of tear film abnormalities.

- The trophic function of the tear film could be disturbed in diabetics, leading to chronic trophic damage of the conjunctival surface, which may be a causative factor for pterygium. More investigations are however recommended for tear production. These results suggest that diabetic patients are more prone to suffering from dry eye symptoms than normal subjects and therefore eye care practitioners are advised to watch out for these symptoms.
- The decreased mean Tear film break up time indicates increased instability of the tear film in the diabetic patients. The lower Schirmer 1 test value demonstrates decreased total (basal and reflex) tear secretion in the diabetic patients. The pronounced degree of metaplasia in the diabetics revealed compromised condition of the conjunctiva. Early examination of the diabetic patients for the detection of the ocular surface disorders is indicated.

Recommendation

- This study has clearly demonstrated that there is a strong relationship between dry eye, diabetes & pterygium. Therefore, evaluation & treatment of dry eye should also be part of diabetes & pterygium management. As both evaporative & hyposecretory types of dry eye was associated with pterygium, all three tests of dry eye (TBUT, Schirmer 1 & Schirmer 2 or Basal Secretion) should be performed in pterygium patients & appropriate tear substitute should be prescribed based on these

results. Appropriate precautions should be taken by all dry eye patients such as use of UV protective glasses, hats & umbrellas to protect their eyes from developing pterygia. They should also avoid exposure of their eyes to strong winds & heat from open flames.

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