**COMPARATIVE STUDY OF DRY EYE STATUS IN NORMAL HEALTHY INDIVIDUAL AND TYPE-II DIABETES MELLITUS**

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**ABSTRACT**

**PURPOSE:** The current study's goal is to use the Schirmer's strip to assess the dry eye state in people with Type II diabetes mellitus and in otherwise healthy people.

**OBJECTIVE:** to investigate the frequency of ocular surface diseases associated with dry eyes and diabetes in both healthy individuals and those without the condition.

**METHODS:**

A cross-sectional study was conducted at Aarupadai Veedu Medical College to assess the dry eye status in a total of 175 patients with diabetes mellitus (88 male and 87 female), as well as 175 healthy individuals who presented with ocular discomfort and had a history of Type 2 Diabetes mellitus. Dry eye symptoms were evaluated through a questionnaire and classified based on their severity. Dry eye conditions were suspected based on historical factors such as ocular discomfort, redness, blurred vision, gritty sensations, and other discomfort that improved with blinking. The evaluation for dry eye was performed using the Schirmer's test.

**RESULTS:**

 The occurrence of dry eye among diabetes patients was observed in 51% (177 cases), while it was noted in 24.85% (87 cases) of normal, healthy individuals. The majority of the study participants fell within the age bracket of 31-80 years. Although dry eye syndrome was more prevalent in older individuals and among females, there was a notable association between age, gender, and the duration of diabetes.

1. **INTRODUCTION**

Diabetes is a class of metabolic diseases characterized by hyperglycemia resulting from insufficient insulin secretion, action, or both. Diabetes's chronic hyperglycemia is associated with long-term damage, dysfunction, and failure of many organs, including the kidneys, eyes, nerves, heart, and blood vessels [1].

There are two main forms of diabetes mellitus: Type 1 diabetes mellitus (T1 DM) and Type 2 diabetes mellitus (T2 DM), both of which are typically triggered by defects in insulin secretion (T1 DM) and insulin action (T2 DM). T1 DM frequently affects children or adolescents, while T2 DM is more commonly observed in middle-aged and older individuals who develop chronic hyperglycemia due to unhealthy dietary and lifestyle habits.

In T2 DM, an imbalance between insulin levels and insulin sensitivity results in a functional deficit of insulin, this has a more subtly developing start. The causes of insulin resistance are numerous, but fat and ageing are the two most prominent ones [2]

One of the most prevalent systemic risk factors for dry eyes is diabetes. According to the Global Fact Sheet (2019), India is the second-largest diabetic population after China, with around 77 million individuals living with the disease. [/3]

Dry eye is a multifactorial ocular surface disorder. It is characterized by the breakdown of tear film homeostasis, which is followed by ocular symptoms. Ocular surface inflammation, tear film instability and hyperosmolarity, and abnormalities related to the nervous system are the sources of these symptoms. \*[4]

The tear film, the regular operation of the ocular surface, the nerves connecting their sensory and motor systems, the cornea, conjunctiva, lacrimal gland, meibomian gland, lids, and LFU are all protected and maintained by these structures. The human tear film is composed of three layers: the aqueous layer (secreted by the lacrimal gland), mucin (secreted by the cornea, conjunctiva, and watery meibomian gland), and lipid (secreted by the lacrimal gland). These three levels—enzymes, metabolites, and signaling molecules—all have an important role to play in maintaining the physiological function of the ocular surface [5].

Inflammation, blurred vision, grittiness and irritation, instability of the tear film, and latent ocular surface degradation are all symptoms of the multifactorial condition known as dry eye syndrome, which also affects the lacrimal gland and ocular surface [6]

The International Dry Eye Work Shop (DEWS) claims that the diminished corneal sensitivity supports the development of DES. In two ways: first, by lowering the reflex-induced lacrimal secretion and second, slowing down blinking, and increasing evaporative tear loss [7]

Insulin has significant impact on the growth, proliferation, and metabolism of the corneal and lacrimal glands. Diabetes patients with low insulin levels have biomechanical problems. Hyperglycemia causes inflammatory changes, which in turn cause subsequently affects the regular tear secretion. When diabetic corneas are exposed to elevated glucose concentrations, advanced glycation end products build up on the basement membrane lamina.(8)

For cases of Sjogren's or non-Sjogren's aqueous-deficient dry eyes, artificial tears, hyaluronic acid, tear secretagogues such diquafosal sodium, or the use of punctual plugs in conjunction with eye drops should be used to supply the aqueous component. In [9]

1. **AIM AND OBJECTIVES**

My long-term objective with this project is determined whether or not Diabetes cause dry eye.

* To study the prevalence of dry eyes and dry eye related ocular surface disorders in diabetic patients and normal healthy individual.
* Compare the dry eye for Diabetes Patients and non-Diabetes patients.

**OBJECTIVES:**

The aim of the study is prevalence of dry eyes and dry eye related ocular surface disorders in diabetic patients and normal healthy individual.

1. **METHODOLOGY**

**STEPS INVOLVED IN THIS STUDY:**

**SELECTION OF SUBJECTS**:

This study comprises of 350 eyes with age group of 31 to 80 years.

**STUDY AREA:**

Aarupadai Veedu Medical college Hospital, Pondicherry

 **STUDY DESIGN:**

ACross sectional study consisting 350 patients was undertaken to study the dry eye status in DM patients and normal healthy patients**.**

**SAMPLE SIZE:**

A total of 175 diabetic patients and 175 normal healthy patients attending AVMC ophthalmology OPD type II DM of either sex were screened for dry eye with and without diabetes.

 **INCLUSION CRITERIA**

1. Both diabetes and Non diabetes patient.

2. Definite type 2 diagnosis of diabetes patient.

3. Patients of either sex, in age group between 35- 80 years.

**EXCLUSION CRITERIA**

1. Patients who wear Contact lens user
2. Patients who have undergone ocular surgeries in the past.
3. Amblyopia
4. Allergies
5. **PROCEDURE**

This is a Prospective cross-sectional study which will performed at Department of Ophthalmology in AVMC Hospital, Pondicherry. This study will include totally 700 eyes.

Each participant completed a subjective symptoms questionnaire at the start of the study.

The following subjective complaints were evaluated: photophobia, lacrimation, dry eyes, burning, itching, and alien body sensation. The participant was labeled as having subjective complaints if they displayed two or more of these symptoms.

Subsequently, the participants underwent a comprehensive interview during which they answered questions about their age, gender, employment status, and past medical histories related to systemic diseases such as diabetes, hypertension, and rheumatoid arthritis.

The duration of illnesses and medication were noted. The subject also underwent the Schirmer’s examination to evaluate whether the patient having dry eye or not

**PLAN FOR ANALYSIS:**

Analysis the prevalence of dry eye status by using Schirmer’s test with age group of 31-80 years.

**STATISTICAL TOOL DETAILS:**

The collected data will be subjected to analysis using SPSS statistical software version 23.0. To provide descriptive statistical information about the data, categorical variables will be analyzed using frequency analysis, percentage analysis, and mean and standard deviation for continuous variables. A significance level of 0.05 will be applied to all statistical tools.

**CONFLICT OF INTEREST:**

There is no conflict of interest released to this study.

**FUNDING:** No funding is sought; only research and ethics approval are sough.

**STATISTICAL ANALYSIS:**

Excel was used to examine the gathered data. The outcomes were represented graphically using percentage charts, pie charts, and tabular columns.

1. **RESULTS**

**Table 1: Sex wise distribution of cases and controls taken into the study**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **MALE** | **FEMALE** | **TOTAL** |
| **CASE** | 88 | 87 | 175 |
| **CONTROL** | 77 | 98 | 175 |
| **TOTAL** | 165 | 185 | 350 |

The sex-wise distribution of cases (diabetes) and controls (non-diabetes) is shown in Table 1. A total of 350 eyes are made up of male 88 (176 eyes), female 87 (174 eyes), male 77 (154 eyes), and female 98 (196 eyes) (700 eyes).

**Table 2: Duration of diabetes and age in year**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Age of cases in year** | **No. of patients** | **Duration of diabetes in year** | **Duration of diabetes in year** | **Duration of diabetes in year** | **Duration of diabetes in year** |
| **0 – 5** | **6 – 10** | **11 - 15** | **15 – 20** |
| **31 – 40** | **40** | **32** | **7** | **1** | **-** |
| **41 – 50** | **42** | **24** | **16** | **2** | **-** |
| **51 – 60** | **43** | **21** | **14** | **5** | **3** |
| **61 – 70** | **36** | **10** | **16** | **8** | **2** |
| **71 – 80** | **14** | **-** | **10** | **3** | **1** |
| **Total** | **175** | **87** | **63** | **19** | **6** |

Table 2 shows that 175 individuals in the study had diabetes for a length of between (87 cases in the 0–5 year age group, 63 cases in the 6–10 year age group, 19 cases in the 11–15 year age group, and 6 cases in the 15–20 year age group). Patients with a history of diabetes for 0–5 years comprised 87 (49.71%), 6–10 years, 63 (36%), 11–15 years, 19 (10.8%), and the final group, comprising 6 (3.4%) of patients with a history of 15-20 years, made up the total cases.

**Table 3: Gender characteristics [Diabetes patients]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Gender** | **Total** | **Dry eye** | **Non- dry eyes** |
| **Male** | **176** | **74** | **102** |
| **Female** | **174** | **103** | **71** |

Table 3 details the gender characteristics of all research participants, who are classified into two groups: those with dry eyes and those without. Women are more likely to test positive for dry eyes than males are (42.02% vs. 60%), indicating that women are more vulnerable. Diabetes value according to Schirmer (p=0.371).

**Table 4: Schirmer’s test for diabetes patient**

|  |  |  |
| --- | --- | --- |
| **Type** | **Range** | **% of patient eyes** |
| Normal | >10 mm | 173 |
| Mild | 8 - 10 mm | 30 |
| Moderate | 5 - 7 mm | 55 |
| Severe | <5 mm | 92 |

The Schirmer's test results are shown in (table 4). The results of the Schirmer's strip were used to classify the results into four categories: normal (> 10 mm), mild (8-10 mm), moderate (5-7 mm), and severe (<5 mm). The percentages indicated how many persons fell into each category. Diabetes is frequently associated with mild to severe dry eyes, as evidenced by the observation that 51% of patients experience this condition.

**Figure 1: Agecharacteristics**

[Fig. 1] displays the age distribution of patients with dry eyes. Forty patients fell between the ages of thirty and forty, forty-two between forty and fifty, forty-three between fifty and sixty, thirty-six between sixty and seventy, and fourteen between seventy-one and eighty.

**Table 5: Gender characteristics [non-Diabetes patients]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Gender** | **Total** | **Dry Eye** | **Non-Dry eye** |
| **Male** | 196 | 46 | 150 |
| **Female** | 154 | 41 | 113 |

Table 5 details the gender characteristics of all research participants who do not have diabetes and are classified into two groups: those with dry eyes and those without. 350 eyeballs in total, 196 ± 46 male and 154 ± 41 female.

**Table 6: Schirmer’s test for non-diabetes patient**

|  |  |  |
| --- | --- | --- |
| **Type** | **Range** | **% of patient eyes** |
| **Normal** | >10 mm | 263 |
| **Mild** | 8-10 mm | 25 |
| **Moderate** | 5-7 mm | 30 |
| **Severe** | <5 mm | 32 |

(Table 6) displays the findings from the Schirmer's test. The results were categorized based on the values obtained on the Schirmer's strip into the following groups: normal (>10 mm), mild (8-10 mm), moderate (5-7 mm), and severe (<5 mm). The distribution of individuals in each category was represented as percentages. Notably, it was observed that 24.85% of the patients exhibited mild to severe dry eyes, underscoring diabetes as a prevalent risk factor. The Schirmer's value for non-diabetic patients was noted to be (p=0.08).

**Symptoms of patients in the two groups**

Amongst the symptoms it was observed that foreign body sensation, blurry vision and grittiness were the most common symptoms. Amongst diabetics, grittiness was the predominant symptom being seen

1. **DISCUSSION**

Certain studies, such as those conducted by Dogru et al. and Ozdemir et al. [11], have reported no significant correlation between the duration of diabetes and the occurrence of dry eye. However, in our study, we have identified that as HbA1c levels increase, Schirmer's values tend to decrease. This suggests an inverse relationship between glycemic control and Schirmer's values.

A study conducted by Pradeep et al. found that the prevalence of dry eye was 32% among individuals with type 2 diabetes. Their research indicated a higher prevalence in older age groups and among those with diabetes mellitus lasting more than 10 years [12]. In our study, we observed a dry eye prevalence of 51% among type 2 diabetes patients. Additionally, our findings align with the notion that as age groups exceed 10 years of diabetes duration, the prevalence of dry eye also tends to increase.

In a study conducted by Seifart et al., a cohort of healthy, normal controls, matched in terms of numbers, ages, and genders, was compared to a group of 92 patients with both type I and type II diabetes, spanning an age range from 7 to 69 years. Their findings revealed that 52.8% of all diabetic subjects reported experiencing dry eye symptoms, in contrast to only 9.3% of the controls. Their conclusion emphasized the importance of vigilant monitoring of diabetic patients and effective blood sugar regulation in preventing dry eye syndrome and retinopathy [13]. I concur with the results of Seifart et al., as they align with the observations in my study, highlighting the notable difference between healthy individuals and diabetic patients in relation to dry eye symptoms.

The results of our study correspond with the investigations carried out by Moss et al. and Yazdani et al., demonstrating a connection between dry eye and advancing age [14]. Among the participants in our study, the most prevalent clinical features included eye redness, burning sensations, eye pain, blurred vision, and difficulties experienced in low-humidity environments.

The findings of the current investigation demonstrated a strong correlation between the length of diabetes and the prevalence of dry eye. Klein et al. also reported this type of association illness pattern. In [15]

Nepp et al. and Ozemir et al. both observed that abnormal tear function tests were linked to suboptimal glucose control in metabolic terms. Our study likewise revealed that all tear function parameters, including total and basal secretions, were reduced in the diabetic group, and these irregularities were connected to subpar metabolic control [16].

Schirmer's Test I and II outcomes in diabetes patients were considerably lower than those in controls in Goebel's study (37%, P<0.001).(17) I disagree with Goebel's findings since in my research, the percentage of diabetes patients (51%) was much greater than that of the control group (24.85%).

The research conducted by Hom and De Land in 2000 revealed that 52.9% of patients, whether diagnosed with diabetes or borderline diabetes, self-reported experiencing clinically significant dry eye disease. There was a notable correlation between dry eyes and type 2 diabetes mellitus [18]. Our study findings align with Hom and De Land's research, indicating that 52% of type 2 diabetes mellitus patients are affected by dry eye.

The study by Segun Isaac Olaniyan et al reported Dry eye was more common among males (25.5%, 95% C.I, 14.3-36.5) than females (20.0%, 95% C.i, 13.1-26.9) [19]. I will not agree with Segun Issac Olaniyan et al but this was not statistically significant with my result females (58.8%) than males (42.2%). Kaisermann et al and Fuerst et al. also noted higher frequencies were found in females.

Our study's findings differ from a previous study by Beckman, which revealed no difference in the severity of dry eye symptoms between patients with and without diabetes.20] Additionally, compared to non-diabetics, diabetics were shown to have a greater grade of dry eye illness.

1. **CONCLUSION**

This research establishes a strong correlation between dry eye and diabetes mellitus. A statistically significant positive connection was seen between the severity of dry eye and the length of diabetes. The quality of life can be enhanced by diabetes control through early diagnosis, prompt treatment, and management. In order to avoid potential corneal problems, people who test positive for dry eye should begin treatment as soon as possible. Tear replacements are the cornerstone of care for mild to moderate tear shortage. Timely occlusion can be used to preserve tears in the event that medical treatment is unsuccessful. In extreme situations, tarsorrhaphy is used to narrow the palpebral fissure, which lowers tear evaporation. Prevention of dry eye is mostly dependent on close observation of diabetic patients and appropriate blood sugar control. Antioxidants (diet), ant-inflammatory drugs (topical corticosteroids like loteprednol), immunological modulators (topical cyclosporine), and anabolic drugs that imitate the effects of insulin (autologous serum) are examples of potential treatments.

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