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

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**ABSTRACT**

**PURPOSE:** The purpose of the present study is to determine the dry eye status in Type II diabetes mellitus and normal healthy individual using the Schirmer’s strip.

**OBJECTIVE:** To study the prevalence of dry eyes and dry eye related ocular surface disorders in diabetic patients and normal healthy individual.

**METHODS:**

A cross sectional study was done in Aarupadai Veedu medical college used to detect the profile of dry eye status on 175 diabetic mellitus patients (88 male and 87 female) and 175 healthy individual patients presenting with ocular discomfort, with history of Type 2 Diabetes mellitus. Dry eye symptoms were assessed using questionnaire and graded according to severity. Dry eyes were suspected on the basis of history including ocular discomfort, redness, blurred vision, gritty eyes and other sensation that improved with blinking. The examination for the dry eye was done using Schirmer’s test.

**RESULTS:**

 The prevalence of dry eye in diabetes patient is 177(51%) and normal healthy individual is 87(24.85%). Most of the study participant belonged to the age group of 31-80 years. Although dry eye syndrome was more common in older and female patients, there were significant relation between age sex and duration of diabetes.

1. **INTRODUCTION**

A category of metabolic illnesses known as diabetes are defined by hyperglycemia brought on by deficiencies in insulin secretion, action, or both. Long-term harm, dysfunction, and failure of various organ including the eyes, kidneys, nerves, heart, and blood vessels, are linked to the chronic hyperglycemia of diabetes [1]

The two primary form of DM are Type 1 diabetes mellitus (T1 DM) and Type 2 diabetes mellitus (T2 DM), both of which are typically brought on by faulty insulin secretion (T1 DM) and action (T2 DM). T1 DM often affects kids or teenagers, but T2 DM is likely to affect middle-aged and older individuals who experience chronic hyperglycemia as a result of poor dietary and lifestyle choices.

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]

Diabetes is identified as one of the most common systemic risk factors for Dry Eyes. From the Global Fact Sheet (2019) India has about 77 million adults with diabetes and is the second country after the China with largest diabetic population [3]

A multifactorial illness of the ocular surface is dry eye. It is defined by the loss of tear film homeostasis and is followed by ocular symptoms, the causes of which include tear film instability and hyperosmolarity, ocular surface inflammation, and neurosensory abnormalities [4]

The cornea, conjunctiva, lacrimal gland, meibomian gland, lids, and LFU protect and maintain the tear film and normal function of the ocular surface and the nerves that link their sensory and motor systems. Three layers make up the human tear film: lipid (secreted by the watery meibomian gland) and mucin (secreted by the lacrimal gland, cornea, and conjunctiva) and aqueous layer (secreted by lacrimal gland). Enzymes are present in these three levels, metabolites, signaling molecules, and are crucial in sustaining the ocular surface's physiological function sustaining the ocular surface's physiological function [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. Exposure of diabetic corneas to increased glucose concentration results in accumulation of advanced glycation end products, on the basement membrane lamina.[8]

When the Aqueous tear secretion is deficient such as Sjogren’s or non- Sjogren’s aqueous – deficient type of dry eyes, aqueous component should be provided by artificial tears, hyaluronic acid or tear secretagogues such as diquafosal sodium or using punctual plugs in combination of eye drops [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.

At the beginning of the investigation, all participants answered a subjective symptoms questionnaire.

The subjective complains that were assessed included dry eye, itching, burning, foreign body sensation, eye fatigue, lacrimation, and photophobia. If the individual presented with two or more of these symptoms, the subject was classified as having subjective complaints.

Next, the participants completed a detailed interview assessing basic information (such as age, gender, working situation) and past medical histories of systemic disease (including diabetes, hypertension, 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 analyzed with SPSS statistical software 23.0 version to describe about the data descriptive statistical frequency analysis, percentage analysis will be used categorical variables and for continuous variable the mean and standard direction will be used for all statistical tool the probability value of 0.05 will be considered as significant level.

**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:**

The data collected was analyzed using Microsoft Excel. The results were pictorially expressed in the form of pie chart, percentage, 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 (table 1) is about the sex wise distribution of cases (Diabetes) and controls (non-Diabetes) is Male 88 (176 eyes), Female 87 (174 eyes) and male 77 (154 eyes), female 98 (196 eyes) total 350 (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** |

The (table 2) represents 175 cases in the study had their duration of diabetes between the duration of (87 among the age group of 0 and 5 years, 63 among the age group of 6 and 10 years, 19 among the age group of 11 and 15 years and 6 among the age group of 15 and 20 years). Those patients who had a history of 0-5 years of having diabetes were 87(49.71 %), 6-10 years of having diabetes 63 (36%), 11-15 years of having diabetes 19(10.8%) and the last group constituted 15-20 years 6 (3.4%) of the total case.

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

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

The (table 3) is about the gender characteristics of all the participants of the research and they are characterized into dry eye and non-dry eye group. More number of women (60%) than men (42.02%) is tested with dry eyes proving that women are at a higher risk. Schirmer’s value for diabetes value (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 (table 4) represents the results of the Schirmer’s test. Based on the value obtained on the Schirmer’s strip it was categorized into normal (> 10 mm), mild (8-10 mm), moderate (5-7 mm) and severe (<5 mm). The number of people belonging to each category was represented as percentages. It is observed that 51% of the patients have mild to severe dry eyes proving diabetes as a common risk factor.

**Figure 1: Age characteristics**

The [fig. 1] represents the age distribution of the people who were with dry eye. 40 patients were between 31-40 years, 42 patients were between 41-50 years, 43 patients between 51- 60 years, 36 were between 61-70 years, 14 were between 71-80 years.

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

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

The (table 5) is about the gender characteristics in non-diabetes patient of all the participants of the research and they are characterized into dry eye and non-dry eye group. Total 350 eyes (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 |

The (table 6) represents the results of the Schirmer’s test. Based on the value obtained on the Schirmer’s strip it was categorized into normal (> 10 mm), mild (8-10 mm), moderate (5-7 mm) and severe (<5 mm). The number of people belonging to each category was represented as percentages. It is observed that 24.85% of the patients have mild to severe dry eyes proving diabetes as a common risk factor. Schirmer’s value for non- diabetes patients’ id (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**

Some studies also show no correlation between duration and dry eye like by Dogru et al. and Ozdemir et al. [11] In our study we find that with increasing in HbA1c levels, the Schirmer’s values decreases. That means there is a inverse correlation between glycemic control and Schirmer’s values.

In a study by Pradeep et al, prevalence of dry eye was 32% among type 2 diabetics and showed the prevalence being high in older age groups and with>10 years of duration diabetes mellitus [12] In our study the prevalence of dry eye was 51% among type 2 diabetes patients and also, I agree with increasing the age groups >10 years the prevalence of dry eye also get increased.

In a study by Seifart et al a group of normal, healthy controls with similar numbers, ages, and sexes was compared to 92 patients with diabetes type I and type II who ranged in age from 7 to 69 years. As a result, 52.8% of all diabetic subjects reported having dry eye symptoms, compared to 9.3% of the controls. They concluded close monitoring of diabetic patients and good blood sugar regulation is important for the prevention of dry eye syndrome and retinopathy [13]. I also agree with the result of Seifart et al they also finding similar to my result the difference between the healthy individual and diabetic patients.

The finding of our study is similar to the study conducted by Moss et al ana Yazdani et al which revealed association of dry eye with increasing age [14] Most common clinical features among our study participants were redness of eye, burning sensation, painful eye, blurring of vision and problem in low humid areas.

Current study results showed the significant association between prevalence of dry eye and duration of diabetes. This type of association disease pattern was also reported in Klein et al. [15]

Nepp et al and Ozemir et al reported that abnormal tear function tests were associated with poorer metabolic glucose control in our results, all tear function parameters total and basal secretions were lower in the diabetic group and these abnormalities were related to poor metabolic control.[16]

In Goebel’s study, the results of Schirmer’s Test I and II were significantly lower in diabetic patients compared with controls (37%, P<0.001).[17] I will not agree with Goebel’s study in my study the subject significantly higher in diabetic patients (51%) compared with controls (24.85%).

 The study by the Hom and De land in 2000 showed that 52.9% of patients with either diabetes or borderline diabetes had self-reported clinically relevant dry eye disease in them. Dry eyes were significantly correlated with type 2 diabetes mellitus. [18]. I also agree with study by the Hom and De land, 52% type 2 diabetes mellitus patients 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 results different from that by a recent study by of Beck man who found no difference in the dry eye severity in between diabetes and non-diabetic patients.[20] It was also observed that diabetics had a higher grade of dry eye disease as compared to non-diabetics.

1. **CONCLUSION**

This study proves that there exists a significant association between diabetes mellitus and dry eye. There was statistically significant positive correlation between the duration of diabetes and severity of dry eye. Early diagnosis and timely treatment of diabetes and its control can improve the quality of life. Early treatment of dry eye should be initiated in dry eye positive individuals in order to prevent potential corneal complications. The mainstay of treatment for mild and moderate tear deficiency includes tear substitutes. In case of failure of medical treatment, punctual occlusion can be done to conserve tears. In severe cases, tarsorrhaphy is performed to reduce tear evaporation by reducing the palpebral fissure. Close monitoring of diabetic patients and good blood sugar regulation is important for prevention of dry eye. Potential treatments include antioxidants (i.e., nutrition), ant- inflammatory agents (i.e., topical corticosteroids such as loteprednol, and immune modulatory agents, such as topical cyclosporine and anabolic agents that mimic insulin’s effect such as autologous serum.

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