ORIGINAL ARTICLE

Frequency of efficacy of topical cyclosporine 0.05% eye drops in the management of dry eyes

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ABSTRACT

Aim: To determine the efficacy of cyclosporine 0.05% for the management of patients of dry-eye disease presenting at tertiary care hospital.

Methods: This cross sectional study was conducted at Department of Ophthalmology, Sahiwal Medical College, Sahiwal from March 2020 to September 2020 over the period of 6 months. Total 310 patients of dry eye were included in this study after scrutinized by inclusion criteria. All the selected patients were managed with cyclosporine 0.05% and efficacy of the drug was assessed.

Results: Total 310 patients of dry eye disease were recruited. Mean age was 47.15 ± 3.61 years and mean duration of dry eye disease was 11.10 ± 1.75 months. Out of 310 patients, treatment was found effective in 225 (73%) patients. Efficacy of treatment was noted in 172(96.63%) male patients and in 53(40.15%) female patients. Significantly higher rate of efficacy was noted in male patients as compared to female patients with p value 0.000. **Conclusion:** Results of present study showed higher improvement rate of dry eye symptoms in cases of dry eye managed with cyclosporine 0.05%. Male patients were more victim of dry eye as compared to female patients and statistically significant association of efficacy with gender was observed. No association of efficacy of treatment with age group and duration of disease was observed.

Keywords: Dry eye, cyclosporine, inflammation, immunomodulator agents.

INTRODUCTION

Among ocular morbidities, dry eye (DE) is very common.1Ocular pain, foreign body sensation, sense of dryness and burning are linked with DE. Visual fatigue, blurred vision and photophobia are sometimes associated with DE.2 Pathogenesis of Dry eye has not been completely clarified. Many clinical and pathological changes affecting tear film, lacrimal glands, and eyelids with resulting deficiency in the tear film whether caused by decreased lacrimation or excessive evaporation.3Cells of ocular surface, including inflammatory, epithelial, immune and goblet cells may play a main role in the pathogenesis of DE.4 Many studies propose new concepts of its pathogenesis, including that DE seems to be caused by inflammation mediated by T-cell lymphocytes.5In cases of DE, disorder of cytokine balance, increased osmolarity, tear volume and increased metalloproteinases can be seen commonly. It is observed that apoptosis and inflammation might be play a major role in the progression or development of DE.6 Anti-inflammatory treatments like corticosteroids and topical cyclosporine were recommended for the management of DE.7 There is a link between long time uses of topical corticosteroids and development of cataracts, glaucoma and some other side effects related to use of steroid. In contrast, topical cyclosporine, which specifically blocks T-cell activation, may be a more appropriate long-term therapy because it is not associated with either significant systemic adverse events or the common steroid-related ocular side effects.8

The purpose of the study is to decrease frequency of topical eye dropings from two hourly with other treatment

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modalities to 8 hourly with cyclosporin0.05%, treat ocular surface disease and reduce the inflammation which is the root cause of dry eye thus reducing morbidity of disease.

OPERATIONAL DEFINITION

Efficacy: Defined as: when any 2 out of three tests was negative.

Tear break up time

Negative: tear breakup time > 10 seconds.

Rose Bengal staining:

Negative: if there is no staining:

Schirmer's tests:

Negative: wetting of filter paper >5mm.

MATERIAL AND METHODS

This cross sectional study was conducted at Department of Ophthalmology, Sahiwal Medical College, Sahiwal from March 2020 to September 2020 over the period of 6 months. Total 310 patients of dry eye either male or female having age 30-70 years were included in this study after scrutinized by inclusion criteria. Patients with history of ocular allergic disease, patients with history of previous refractive surgery, patients with systemic connective tissue disease, patients with active ocular disease and patients with prior use of topical cyclosporine were excluded from the study.

Patient's history was taken and 3 tests (tear break up time, rose Bengal staining test and Schirmer's tests) were performed on all selected patients for diagnosis of dry eye.

Cyclosporine 0.05% drops was prescribed to all the selected patients for 3 months. Efficacy (Yes/No) was measured by re-evaluating all the patients which were

prescribed Cyclosporine 0.05% drops previously by applying 3 tests.

Data was entered on computer software SPSS version 16. The quantitative variables of the study i.e. age, duration of symptoms were presented as Mean±SD. The qualitative variables like gender and frequency of efficacy was presented as frequency and percentages. Pie chart was drawn for frequency of efficacy. Stratification was done for age, gender and duration of symptoms. Post stratification chi-square test was applied. P value ≤0.05 was considered as significance.

RESULTS

Total 310 patients of dry eye disease were recruited. Mean age was 47.15 ± 3.61 years and mean duration of dry eye disease was 11.10 ± 1.75 months. Out of 310 patients, treatment was found effective in 225 (73%) patients. (Fig. 1) Age range was 30-70 years. Two age groups30-50 years and 51-70 years were created. In 30-50 years age group, there were 190 (61.29%) patients and in age group 51-70 years, there were 120 (38.71%) patients. Treatment was found effective in 136 (71.58%) patients of age group 30-50 years and in 89 (74.17%) patients of age group 51-70 years. There was insignificant association between efficacy of treatment and age group with p value 0.619. (Table 1)Male patients were 178 (57.42%) and female patients were 132 (42.58%). Efficacy of treatment was noted in 172 (96.63%) male patients and in 53 (40.15%) female patients. Significantly higher rate of efficacy was noted in male patients as compared to female patients with p value 0.000. (Table 2)

Duration of dry eye disease was 1-6 months. Patients were divided into two groups according to duration of disease i.e. 1-3 months and 4-6 months. Out of 151 (48.71%) patients of 1-3 months group, efficacy was found in 109 (72.19%) patients. In 4-6 months group, treatment was found effective in 116 (72.96%) patients. Statistically insignificant association between efficacy and duration of disease was noted with p value 0.879. (Table 3)

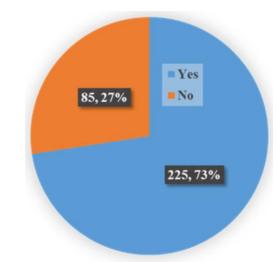


Fig. 1: Frequency of efficacy

Table 1: Stratification for age

Age Group	Efficacy		Total	P value
	Yes	No	Total	r value
30-50	136 (71.58%)	54 (28.42%)	190 (61.29%)	
51-70	89 (74.17%)	31 (25.83%)	120 (38.71%)	0.619
Total	225 (72.58%)	85 (27.42%)	310	

Table 2: Stratification for gender

Gender	Efficacy		Total	P value
Gender	Yes	No	Total	r value
Male	172 (96.63%)	6 (3.37%)	178 (57.42%)	
Female	53 (40.15%)	79 (59.85%)	132 (42.58%)	0.00
Total	225 (72.58%)	85 (27.42%)	310	

Table 3: Stratification for duration of disease

Duration of disease	Efficacy		Total	P value
(months)	Yes	No	Total	r value
1-3	109 (72.19%)	42 (27.81%)	151 (48.71%)	
4-6	116 (72.96%)	43 (27.04%)	159 (51.29%)	0.879
Total	225 (72.58%)	85 (27.42%)	310	

DISCUSSION

Dry eye is a very common disease. In United States, among the patients of dry eye having age over 65 years, 25% of the patients used artificial tears. Ocular irritation was faced by 7.1million people of USA, about 6% population of 4th decade of life and about 15% population of 6th decade of life faced dry eye syndrome. The purpose of the present study was to determine the efficacy of cyclosporine 0.05% in the management of dry-eye disease.

Total 310 patients of dry eye disease were recruited in this study. Mean age was 47.15 ± 3.61 years and mean duration of dry eye disease was 11.10 ± 1.75 months. Out of 310 patients, treatment was found effective in 225 (73%) patients. In 30-50 years age group , there were 190 (61.29%) patients and in age group 51-70 years, there were 120 (38.71%) patients. Treatment was found effective in 136 (71.58%) patients of age group 30-50 years and in 89 (74.17%) patients of age group 51-70 years. There was insignificant association between efficacy of

treatment and age group with p value 0.619. In one study by Byun et al,10 after three months using of Cyclosporine 0.05% in cases of DE, efficacy of treatment was noted in 72% patients which is in accordance with our study. In study of Al-Nashar et al. 11 total 20 patients of dry eye were selected and managed with cyclosporine 0.05% eye drops. In this study age of the patients was between 26-65 years with mean age 37.3 years. In all patients ocular symptoms was significantly improved with treatment of cyclosporine 0.05% eye drops after three months. Prabhasawat et al¹²managed 30 cases of dry eyes with cyclosporine 0.05% eye drops.Out of 30 patients, only 17 patients completed the study and 8 patients withdrew due to intolerable side effects cyclosporine 0.05% and 5 cases lost follow up. Over all efficacy of treatment was 72.1%. In present study male patients were 178 (57.42%) and female patients were 132 (42.58%). Efficacy of treatment was noted in 172 (96.63%) male patients in 53 (40.15%) female patients. Significantly higher rate of efficacy was noted in male patients as compared to female patients with p value 0.000.ln study of Mah et al,¹³ total 35 patients were managed with cyclosporine 0.05% eye drops, most (71.4%) of the patients were female and treatment was found effective in 80% patients. Byunet al14 found significant improvement in cases of dry eye managed with cyclosporine 0.05%. In study of Rao et al, 15 dry eye patients were managed with cyclosporine 0.05% and treatment was found effective in 68% patients.

CONCLUSION

Results of present study showed higher improvement rate of dry eye symptoms in cases of dry eye treated with cyclosporine 0.05%. Male patients were more victim of dry eye as compared to female patients and statistically significant association of treatment efficacy with gender was observed. No association of efficacy of treatment with age group and duration of disease was observed.

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