

Original Research Article

Effects of Cyclosporine 0.05% ophthalmic solution on diagnostic parameters of dry eye disease

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ABSTRACT

Background: Dry eye is a multifactorial disease particularly prevalent in Asia for which there are several treatments. Among anti-inflammatory treatment, cyclosporine 0.05% is preferred therapy. Our study evaluated effects of cyclosporine 0.05% ophthalmic solution on the diagnostic tools of dry eye.

Methods: A prospective study was carried out in ophthalmological outpatient department of ASCOMS and Hospital. Total 60 patients of dry eye disease who fulfilled the inclusion criteria were treated with cyclosporine 0.05% ophthalmic solution twice a day. The diagnostic parameters of dry eye were assessed at baseline, at month 1 and 3. Patients underwent ocular surface disease index (OSDI) score, Schirmer's test, Tear film break up time (TBUT).

Results: After three months, mean OSDI score was significantly improved ($p < 0.001$). There was significant improvement in mean Schirmer score ($p < 0.001$). Baseline TBUT also increased significantly ($p < 0.001$).

Conclusions: Cyclosporine 0.05% ophthalmic solution has significant effect on diagnostic parameters of dry eye disease.

Keywords: Cyclosporine, Dry eye disease, Ocular surface disease index, Schirmer's test

INTRODUCTION

Dry eye is a multifactorial disease of the ocular surface and tear film that results in symptoms of ocular discomfort, visual disturbance and tear film instability. Instability of the tear film is accompanied by T-Cell mediated ocular surface inflammation that plays a major role in disease progression.¹

The prevalence of dry eye disease (DED) is quite higher in Asian studies than American studies i.e. 33.7 % >65 years of age in one study, 27.5% > 21 years of age in other Asian study.^{2,3} DED affects the quality of life by limiting and degrading the performance of common vision related daily activities.^{4,5} Patients of dry eye usually complain of symptoms like blurring of vision,

glare, difficulty while reading, watching television, driving. This has been demonstrated by Ocular surfaces disease index (OSDI) questionnaire.⁶ Thus, DED is diagnosed by the presence of symptoms and various tests like corneal staining with fluorescein, Schirmer's test and tear film break up time (TBUT).

Treatment for DED depends on the severity of the disease itself. Artificial tears or ocular lubricants especially preservative free, are very useful in relieving symptoms in mild cases.⁷ But as it has been studied that inflammation is the key component of the pathogenesis of dry eye, various anti-inflammatory drugs have been used in treatment of dry eye. But among all anti-inflammatory drugs cyclosporine is the only prescribed drug approved by the U.S Food and drug administration specifically for

patients with DED and it is widely used current therapy for DED.⁸ This study involves evaluating the effects of cyclosporine ophthalmic solution on diagnostic parameters of dry eye.

METHODS

The present study was hospital-based prospective study carried out on 60 patients attending ophthalmology OPD, ASCOMS, Jammu. It was carried out after obtaining permission from ethical committee of the institution and was performed according to the tenets of declaration of Helsinki. The written informed consent was obtained from each subject. Inclusion criteria were: Ocular Surface Disease Index (OSDI) score > 12, Schirmer's test score < 10mm /5 min (without anesthesia) in at least one eye and Tear film break up time (TBUT) <10 sec. Worst eye was taken into consideration. Exclusion criteria included any ongoing ocular infection, clinically significant slit lamp findings such as active blepharitis, meibomian gland dysfunction, lid margin inflammation. Apart from that there should be no use of cyclosporine in the patients. Patients with past history of LASIK or any other surgery were also excluded from the study.

On enrollment, all patients underwent complete ophthalmic examination, Schirmer's test without anesthesia, TBUT and fluorescein corneal staining. Twelve item questionnaires were asked to each patient. The patients were asked to instill cyclosporine 0.05% ophthalmic solution, twice daily, bilaterally though worst eye was kept in study plan. The study visits were at 0, 1 and 3 months and at each visit patients underwent measurement of OSDI score, Schirmer test and TBUT.

Paired t-test was used to assess statistical significance. A level of $p < 0.005$ was accepted as statistically significant.

RESULTS

A total of 60 patients were enrolled in the study. The study covered wide range of age (44-70 years). The mean standard deviation (SD) age was $56.1 \text{ years} \pm 8.026$ out of total, 41 (68.33%) were females and 19 (31.66%) were males.

Ocular surface disease index (OSDI)

12 Items questionnaire was asked to all patients at baseline and OSDI score was calculated. Mean (standard error of the mean) OSDI score improved from 39.6 ± 9.24 at baseline to 25.41 ± 6.22 at 3 months (Table 1). There was overall reduction of all ocular symptoms from baseline and it was statistically significant ($p < 0.001$).

Table 1: Mean OSDI Score.

Point of time (Months)	Mean OSDI	SD
0 month	39.6	± 9.24
3 months	25.41	± 6.22

Schirmer's test

Schirmer's test was done in all patients. Mean Schirmer's score at 0 month was $5.83 \text{ mm} \pm 1.56$ and at 3 months it was $9.56 \text{ mm} \pm 1.26$ (Table 2). 18 patients (30%) showed 5 mm improvement in Schirmer's test at 3 months.

Table 2: Mean Schirmer's Score.

Point of time (months)	Mean (mm)	SD
0 month	5.83	± 1.56
3 months	9.56	± 1.26

Tear film breakup time (TBUT)

In present study, baseline mean TBUT was $2.43 \text{ seconds} \pm 0.907$ and it increased to $3.96 \text{ seconds} \pm 1.63$ at 3 months (Table 3). The mean increase in TBUT was statistically significant ($p < 0.001$).

Table 3: Mean TBUT Score.

Point of time (Months)	Mean (sec)	SD
0 month	2.43	± 0.907
3 months	3.96	± 1.63

DISCUSSION

DED continues to be a challenging disease and its therapy depends on its severity. Based on the most recent concept, the armamentarium used to control dry eye disease comprises of a large range of therapeutic strategies.

The recommended treatment for mild dry eye disease are life style changes and the use of artificial tears.^{9,10} However, anti-inflammatory medications are considered to be the first causative therapeutic approach in the treatment plethora of dry eye disease.¹¹ Cyclosporine represents a very promising anti-inflammatory drug.¹² It is a fungal derivative peptide that inhibits T-cell activation and consequently inhibits the inflammatory cytokine production. Our study evaluated effects of cyclosporine 0.05% ophthalmic solution on diagnostic parameters of dry eye.

In present study, female patients outnumbered male patients. The weight of the evidence from large epidemiological studies indicates that the female sex and older age increases the risk for dry eye.¹³

Patients showed significant reduction in the frequency of blurred vision. There was significant improvement in other symptoms like reading, driving, computer or bank machine use and watching television. The finding of improvement in OSDI score in present study is consistent with the study done by Stonecipher KG et al.¹⁴ This study also showed significant improvement in mean Schirmer's score. It was $5.83 \text{ mm} \pm 1.56$ at baseline and improved to

9.56 mm±1.26 at 3 months. The results of our study extend the efficacy findings of earlier clinical trials.¹⁵

At month 3, eyes showed significantly greater improvement in tear film stability resulting in improved performance on tasks related to visual function. Significant improvement in TBUT after instillation of cyclosporine 0.05% ophthalmic solution in post cataract surgery dry eye patients was also observed by Chung YW et al, in their study.¹⁶ There was marked improvement in corneal staining in study eyes at 3 months.

Consistent with previous studies, we found that cyclosporine 0.05% has significant effect on Schirmer's score, OSDI score and TBUT and quality of life.^{14,16,17} The present study also showed that cyclosporine 0.05% ophthalmic solution was well tolerated.

CONCLUSION

The positive effects seen in the present study, in improving the symptoms of dry eye disease, confirm the clinical benefits of cyclosporine 0.05% ophthalmic solution in treatment of dry eye.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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