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Comparative evaluation of topical Chloroquine Phosphate and Cyclosporine A in mild to moderate Dry Eye disease

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ABSTRACT

Purpose: This study was aimed at comparing the efficacy of topical Chloroquine phosphate (CHQ) 0.03% and topical Cyclosporine A 0.05% in mild to moderate dry eye disease. The study also assessed the side effect profile of these drugs over the course of treatment.
Design: A prospective comparative study.
Methods: A subset of 70 patients with mild to moderate dry eye disease (DED) were taken up and divided into 2 groups (35 each). DED parameters including Ocular Surface disease index (OSDI), Tear film breakup time (TBUT), Schirmer's test (ST) and Corneal Fluorescein stain (CFS) were recorded at baseline. Group 1 was started on topical Chloroquine phosphate 0.03% twice a day and Group 2 was started on topical Cyclosporine A 0.05% twice a day, for a total duration of 6 months. Patients were followed up at 1 month, 3 months and 6 months and all parameters were repeated.
Results: At the end of 3 months no statistically significant difference in improvement was noted in mean OSDI score as well as mean TBUT and mean ST for R/E and L/E in CHQ group as compared with CSA group. At the end of 6 months a statistically significant difference was noted in mean OSDI score improvement in CSA group as compared with CHQ group, whereas for mean TBUT and mean ST no significant difference was noted at 6 month as well. CFS was negative for both the groups at baseline and all follow up visits. For the side effects, 2 patients noted mild irritation by 3 months and 4 by 6 months in CHQ group while 1 patient noted mild irritation by 3 months and 2 by 6 months in CSA group, with no statistically significant difference between the groups.
Conclusion: Thus this study supports the role of topical Chloroquine phosphate 0.03% and topical Cyclosporine A 0.05% in the management of mild to moderate dry eye disease with similar efficacy in 3 months use and significantly better subjective efficacy in 6 months for Cyclosporine A 0.05%, as well as their good safety profile and tolerability in longterm use.

Keywords: Dry eye disease, topical chloroquine phosphate, topical cyclosporine A, ocular surface disease index, tear film breakup time, Schirmer's test

INTRODUCTION

The ocular surface consists of a three layered tear film with a topmost lipid layer, a middle aqueous layer and a basal mucin layer. This tear film is a part of the ocular surface and has a key role in rendering protection to the exposed part of eye. Any disruption at any level of tear dynamic gives rise to ocular symptoms. One such pathology is Dry Eye Disease (DED). As defined by the Tear Film and Ocular Surface society's Dry Eye Workshop II (TFOS DEWS II) Definition and Classification Subcommittee, DED is a multifactorial disease of the ocular surface characterized by loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles. Ocular surface inflammation is now being recognized as the underlying pathophysiology resulting in the chronic nature of the disease. A decrease in aqueous production or increased evaporation causes an increase in tear film osmolarity. This activates Mitogen-activated protein kinase (MAP-kinase) and Neurokinin-B (NK-B). Inflammatory markers like Interleukins (IL-1,6), Tumor Necrosis Factor (TNF)-alpha and Matrix Metalloproteinase-9 (MMP-9) are released and cause inflammation. This leads to goblet cell apoptosis, thus adding to the tear film instability. DED prevalence ranges from 5 to 50% globally, with that in South east Asian countries ranging from 20 to 52.4%. This may go upto 75% in adults over 40 yr age, with women being most affected [1, 2].

Lubricating topical drugs for the management of DED are used unanimously, but most of the times they fail to provide relief after discontinuation. This is because topical lubricating drugs don't cater to the inflammatory pathophysiology of the disease. Moderate DED usually benefits by the use of anti-inflammatory topical therapy to break the vicious circle of surface damage and inflammation [3]. Topical drugs in this category like corticosteroids (E.g. Loteprednol 0.5%) in low dosage, cyclosporine A (0.05%, 0.1% drops), tacrolimus (0.03%, 0.1% ointment), chloroquine phosphate (0.03% drops) are being prescribed. Oral tetracycline and macrolides are given for antibiotic and anti-inflammatory role in blepharitis associated DED [4]. Severe dry eye disease usually warrants more aggressive anti-inflammatory and lubricating therapy. Eye drops made from patient's own serum (autologous serum eye drops) in concentration on 20-100% have been used due to its abundance in epithelial growth factors and anti-inflammatory substances [5]. Temporary occlusion of tear ducts by silicone plugs (Punctal plugs) are also used in very severe dry eye disease patients [6].

Various anti-inflammatory agents are currently in use for mild to moderate dry eye disease. One such drug being used for dry eye is topical Chloroquine phosphate (CHQ). The lysosomotropic effects of CHQ are widely believed to be responsible for its anti- inflammatory properties and effectiveness in the treatment of some autoimmune diseases. It is reported that CHQ decreases the production of the pro-inflammatory cytokine tumour necrosis factor-alpha (TNF-alpha), and interleukin-6 (IL-6) in Lipopolysacharide (LPS)-or phytohemagglutinin stimulated peripheral blood mononuclear cells, and also augmented LPS-induced expression of TNF-alpha and IL-6 in monocytic and microglial cells [7]

Cyclosporine a (CSA) is a cyclic peptide produced by the fungi Tolypocladium inflatum and Beauveria nevus, and is a powerful immune-modulator and anti-inflammatory agent. Topical cyclosporine has been shown to reduce T-lymphocyte activation, conjunctival epithelium apoptosis marker expression, and pro inflammatory cytokine production in patients with dry eye disease. In addition, conjunctival goblet cell density is increased and squamous metaplasia is decreased [8]
This study was aimed at comparing the efficacy and safety of topical Chloroquine Phosphate 0.03% eye drops and topical Cyclosporine A 0.05% eye drops in mild to moderate dry eye disease. Due to the paucity of literature comparing these two drugs in mild to moderate DED, we conducted this study.

Methods

This prospective comparative study enrolled 70 patients aged 18-75 years with mild to moderate DED presenting to the outpatient department of RIO, Pt. B.D Sharma PGIMS Rohtak, Haryana. The patients were recruited from September 2023 over a period of 1 year. Ethical clearance was obtained from the institutional review board. Written and informed consent was obtained from all patients and the study adhered to the tenets of the declaration of Helsinki.

The patients presented with various ocular symptoms like transient blurred vision, burning sensation, light sensitivity, gritty sensation and poor tolerance to wind/air conditioner. The diagnosis of DED was based on the presence of signs and symptoms of DED. The severity of symptoms was assessed using Ocular Surface Disease Index (OSDI) questionnaire [9] and the signs were assessed by Tear film breakup time (TBUT), Schirmer's test (ST) and Corneal Fluorescein staining (CFS). Patients with an OSDI score of >13, TBUT of <10 seconds and Schirmer's test of <15mm were diagnosed to have DED. The classification into mild, moderate and severe disease was done on the basis of OSDI score, and only patients with mild to moderate DED (OSDI score of 13-32) were eligible for participation in the study.

Patients with age of 18-75 years with mild to moderate DED (OSDI score 13-32) along with the presence of at-least one sign amongst TBUT, ST and CFS were included in the study. Exclusion criteria were patients with ocular allergies or chronic ocular bacterial or viral infections or any non dry eye ocular inflammation, history of trauma or ocular surgery in a period of last 6 months, patients with corneal degenerations or dystrophies, uncontrolled systemic disease, known case

of hypersensitivity to chloroquine or cyclosporine, pregnant women, nursing women, chronic alcoholics or patients receiving concurrent treatment that could interfere with interpretation of the study results.

The patients were allocated into two treatment groups. Group 1 (n= 35) was started on topical Chloroquine phosphate (CHQ) 0.03% twice a day and Group 2 (n=35) was started on topical Cyclosporine A (CSA) 0.05% twice a day. Detailed history was taken and the symptoms of DED experienced by the patient were noted. OSDI questionnaire was evaluated as well and the score was recorded at baseline. A comprehensive ocular examination was done for all patients, including uncorrected and best corrected visual acuity testing, slit lamp examination and detailed fundus examination to rule out posterior segment pathology. This was followed by objective tests for DED assessment including TBUT, ST without anesthesia and CFS for both the eyes of each patient. A gap of 10-15 minutes was given between two consecutive examinations. Record of the baseline readings were kept and patients were then followed up at 1 month, 3 months and 6 months. The same battery of subjective (OSDI score) and objective tests (TBUT, ST, CFS) were evaluated at each follow up visit. Any ocular adverse effect like irritation, tingling or burning, redness, ocular pain or any systemic side effects if present at any point of time were also recorded. Patient compliance was ensured at each follow up visit [10, 11]

Statistical Analysis

The data was coded and entered into Microsoft Excel spreadsheet. Statistical analysis was done using Microsoft Excel. Normally distributed continuous variables were expressed as Mean ± standard deviation and were compared using independent samples t-test. Descriptive statistics included computation of percentages, means and standard deviations. Level of significance was set at $P \leq 0.05$.

Results

The mean demographic details of the CHQ and CSA group, and the mean baseline parameters including OSDI, TBUT R/E and L/E and ST R/E and L/E are summarised in Table 1. The quantitative and quantitative parameters were comparable at baseline with no statistically significant difference (Table 1). The CFS test was negative for all our patients at baseline and at all follow up visits, thus not giving any relevant inference in our study. Explain the study design, population/sample, procedures, and statistical methods used.

Table 1: CHQ vs CSA (baseline and demography)

	CHQ	**CSA**
Mean Age and range (yrs)	35.26 ± 10.92 (20-56)	39.86 ± 12.79 (18-65)
Sex Ratio (M:F)	11:24	17:18
OSDI Score	27.3 ± 5.07	27.74 ± 4.88
TBUT R/E	7.14 ± 1.52	7 ± 1.53
TBUT L/E	7.14 ± 1.56	6.97 ± 1.65
ST R/E	8.54 ± 2.37	8.2 ± 3.1
ST L/E	8.63 ± 2.6	8.2 ± 3.12

Table 2: CHQ vs CSA 1 month

Mean Values	**CHQ**	**CSA**	**p value**
OSDI score	24.03 ± 3.67	23.88 ± 2.94	0.975
TBUT R/E	7.83 ± 0.99	7.54 ± 1.17	0.458
TBUT L/E	7.8 ± 1.11	7.49 ± 1.29	0.434
ST R/E	8.74 ± 2.19	8.26 ± 3.06	0.653
ST L/E	8.77 ± 2.46	8.4 ± 2.99	0.796

Table 3: CHQ vs CSA 3 month

Mean Values	**CHQ**	**CSA**	**p value**

OSDI score	19.36 ± 2.44	19.67 ± 1.54	0.768
TBUT R/E	8.49 ± 0.82	8.6 ± 0.65	0.77
TBUT L/E	8.6 ± 0.78	8.43 ± 0.74	0.612
ST R/E	9.14 ± 2.28	8.57 ± 2.86	0.533
ST L/E	9.2 ± 2.19	8.71 ± 2.77	0.628

Table 4: CHQ vs CSA 6 month

Mean Values	CHQ	CSA	p value
OSDI score	17.62 ± 1.79	16.69 ± 1.39	0.025
TBUT R/E	8.8 ± 0.83	9.03 ± 0.62	0.33
TBUT L/E	9.14 ± 0.65	9 ± 0.64	0.614
ST R/E	9.97 ± 2.04	9.57 ± 2.4	0.657
ST L/E	9.74 ± 2.19	9.69 ± 2.56	0.993

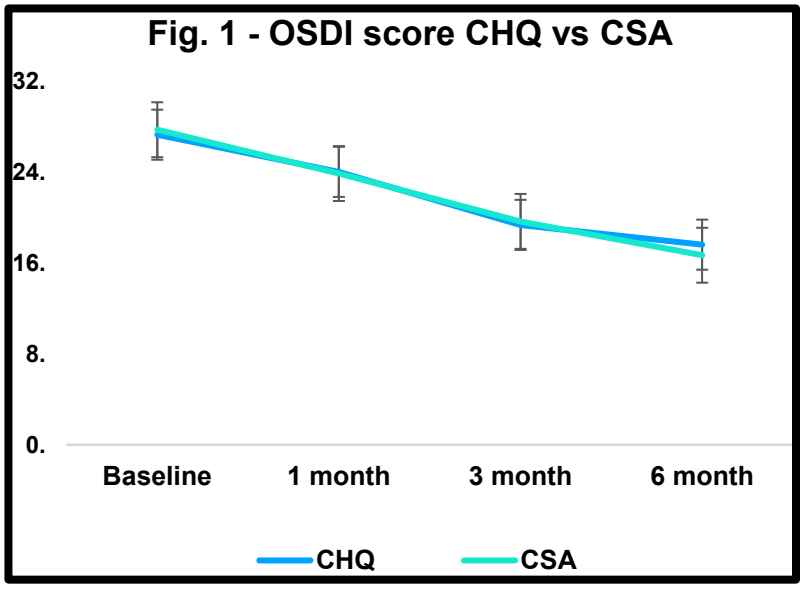

Fig 1: OSDI score CHQ vs CSA

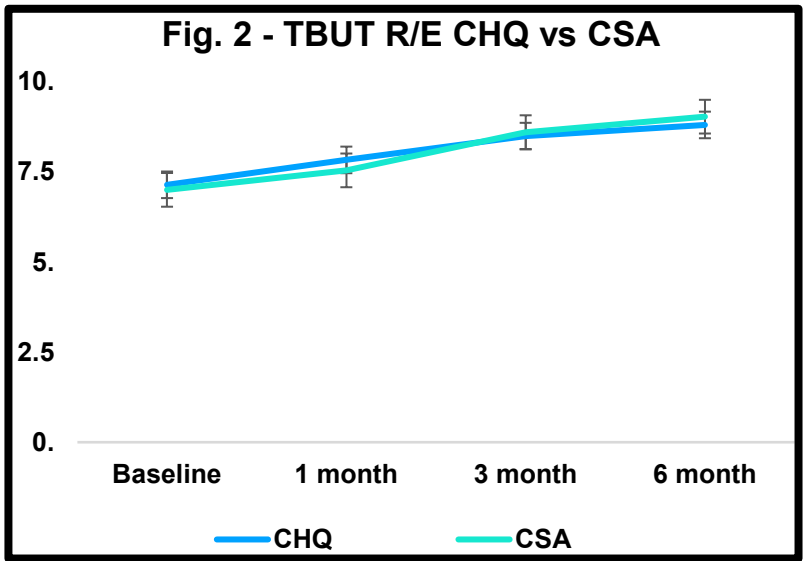

Fig 2: TBUT R/E CHQ vs CSA

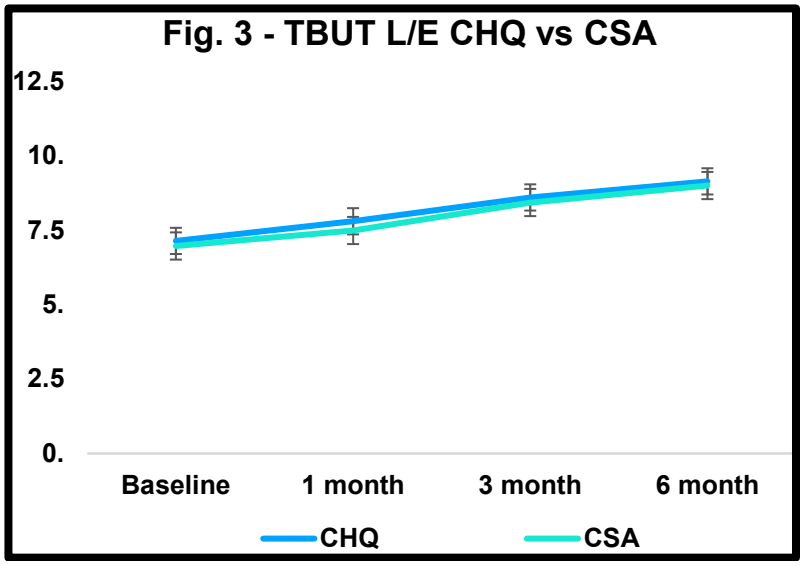

Fig 3: TBUT L/E CHQ vs CSA

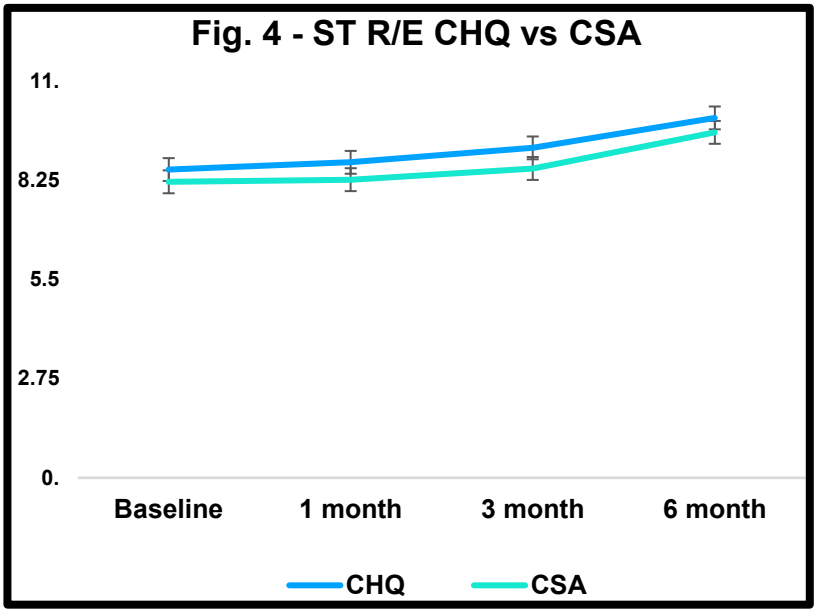

Fig 4: ST R/E CHQ vs CSA

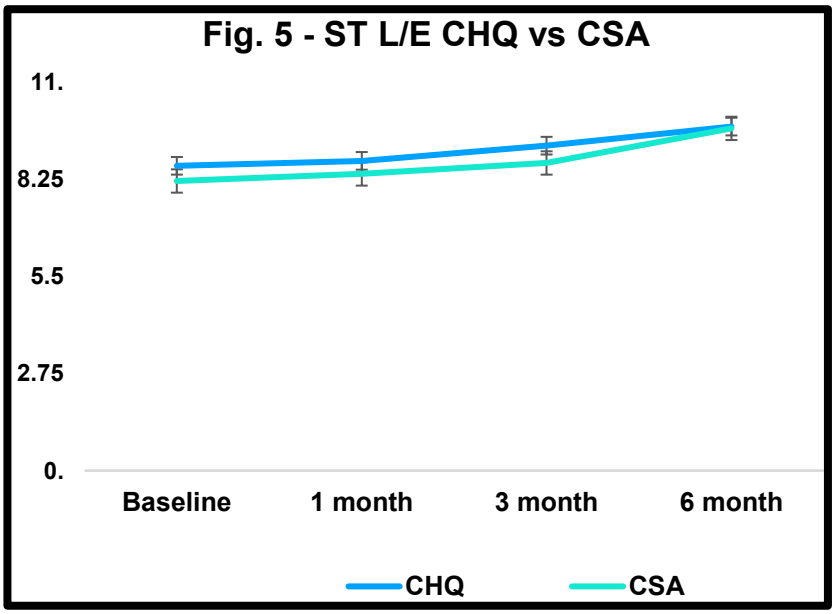

Fig 5: ST L/E CHQ vs CSA

The qualitative and quantitative parameters at 1 month, 3 months and 6 months are summarised in Table 2, Table 3 and Table 4 respectively. The mean OSDI score at the end of 1 month for the CHQ group was 24.03 ± 3.67 and for CSA group was 23.88 ± 2.94 which did not show any statistically significant difference (p= 0.975). This persisted at the end of 3 months as well when the mean OSDI score for CHQ group was 19.36 ± 2.44 as compared with the CSA group score of 19.67 ± 1.54, (p= 0.768). But by the end of 6 months, a statistically difference in improvement between the two groups was noted (CHQ group 17.62 ± 1.79 and CSA group 16.69 ± 1.39), (p= 0.025) (Fig. 1)

The mean TBUT for the Right eye at the end of 1 month for the CHQ group was 7.83 ± 0.99 and for the CSA group was 7.54 ± 1.17 which did not show any statistically significant difference (p= 0.458). The TBUT R/E by the end of 3 months (CHQ group 8.49 ± 0.82 and CSA group 8.6 ± 0.65) and by the end of 6 months as well (CHQ group 8.8 ± 0.83 and CSA group 9.03 ± 0.62), had no statistically significant difference (p= 0.77, p= 0.33 respectively) (Fig. 2).

The mean TBUT for the Left eye at the end of 1 month for the CHQ group was 7.8 ± 1.11 and for the CSA group was 7.49 ± 1.29 which did not show any statistically significant difference (p= 0.434). The TBUT L/E by the end of 3 months (CHQ group 8.6 ± 0.78 and CSA group 8.43 ± 0.74) and by the end of 6 months as well (CHQ group 9.14 ± 0.65 and CSA group 9 ± 0.64), had no statistically significant difference (p= 0.612, p= 0.614 respectively) (Fig. 3).

The mean ST for the Right eye at the end of 1 month for the CHQ group was 8.74 ± 2.19 and for the CSA group was 8.26 ± 3.06 which did not show any statistically significant difference (p= 0.653). The ST R/E by the end of 3 months (CHQ group 9.14 ± 2.28 and CSA group 8.57 ± 2.86) and by the end of 6 months as well (CHQ group 9.97 ± 2.04 and CSA group 9.57 ± 2.4), had no statistically significant difference (p= 0.533, p= 0.657 respectively) (Fig. 4).

The mean ST for the Left eye at the end of 1 month for the CHQ group was 8.77 ± 2.46 and for the CSA group was 8.4 ± 2.99 which did not show any statistically significant difference (p= 0.796). The ST L/E by the end of 3 months (CHQ group 9.2 ± 2.19 and CSA group 8.71 ± 2.77) and by the end of 6 months as well (CHQ group 9.74 ± 2.19 and CSA group 9.69 ± 2.56), had no statistically significant difference (p= 0.628, p= 0.993 respectively) (Fig. 5).

For side effect profile of the drugs it was recorded that by 3 months, 2 (5.7%) patients in CHQ group complained of mild irritation while using the drug, which relieved on washing the eyes with cold water and no discontinuation of therapy was required. Whereas 1 (2.9%) patient had similar complain in CSA group, and the difference was not statistically significant (p= 0.323). By 6 months, 4 (11.4%) patients in CHQ group and 2 (5.7%) patients in CSA group complained of mild irritation with the use of drug, while the difference was again not statistically significant (p= 0.230).

Discussion

Dry eye disease (DED) is by far the most common ocular surface pathology, yet it is an easily overlooked condition in its mild form and frequently under-treated in mild to moderate form as well. The role of anti-inflammatory topical agents like topical chloroquine phosphate and cyclosporine A have been used in severe dry eye disease patients for a long time. In recent studies, these agents have been used in patients with mild to moderate disease as well, and have proven to give better results than routinely used lubricating drugs [12].

Singh KK in 2022 conducted a comparative study of efficacy of chloroquine phosphate 0.03% and sodium carboxymethylcellulose 1% in dry eye disease patients on 200 eyes of 100 patients. The protocol was composed of 2 phases: a 3-week treatment phase, and a 1-week post treatment phase. The efficacy measures were in terms of LGSS (Lissamine Green staining), FLSS (Fluorescein staining), Schirmer's test and the global assessment scoring system - OSDI. The findings of this study support the continued investigation of the use of topical CHQ as a safe and effective treatment for DED, thus concluding that Chloroquine Phosphate eye drops can be a novel therapeutic approach for the restoration of tear formation for DED [7].

Gao M *et al* in 2023 conducted a study to evaluate the efficacy and safety of 0.05% cyclosporine eye drops for the treatment of primary Sjögren's syndrome-associated dry eye (PSSDE). Sixty patients with PSSDE were randomly divided into three groups of 20 each. They received treatment with 0.05% cyclosporine (C group), preservative free hyaluronic acid artificial tears (S group) or their combination (CS group). The evaluation indicators were evaluated at baseline and at weeks 2, 4 and 12. The study found that the symptoms of C and CS groups were reduced significantly. The signs [schirmer I test ($F = 4.838$, $p = .011$), ocular staining score ($F = 7.961$, $p = .001$) and tear break-up time ($F = 9.283$, $p < .001$)] were significantly different between S and C groups as well as S and CS groups. The tear meniscus height ($F = 3.197$, $p = .048$) was significantly different between S and CS groups. No serious adverse events occurred. The study concluded that topical Cyclosporine A 0.05% is an efficacious and safe way to treat patients with PSSDE [13].

Titiyal *et al* in 2023 conducted a study to compare effect of topical cyclosporine-A 0.05% (CsA) and chloroquine phosphate 0.03% (CHQ) as an adjunct to standard therapy in maintaining post-laser assisted *in situ* keratomileusis (LASIK) ocular surface stability. The study was a randomised control trial including 100 patients undergoing femtosecond-LASIK from

18-70 years. Study subjects were randomized into three groups: 33 eyes in Group I (Standard Treatment group, topical moxifloxacin, topical prednisolone and carboxymethyl cellulose), 34 eyes in Group II (CsA group, CsA 0.05% twice daily for three months in addition to standard treatment) and 33 eyes in Group III (CHQ group, topical CHQ 0.03% twice daily for three months in addition to standard treatment). The study concluded that both CHQ and CsA are useful adjuncts to standard therapy in maintaining ocular surface stability after refractive surgery. Also, topical Cyclosporine A was found to be superior to topical Chloroquine phosphate as with better tear osmolarity and TBUT at 6 months, thus having sustained anti-inflammatory effect with less ocular irritative effects. The limitation has been a shorter follow up and small sample size, thus long term follow up studies for the same are warranted [14].

Our current study was aimed at comparing the efficacy of two anti-inflammatory drugs (topical CHQ and topical CSA) in mild to moderate DED and compare the improvements in patient signs and symptoms over a period of 6 months.
It was found in our study that by the end of 3 months, no statistically significant difference was noted in the OSDI score among the two groups. The difference in improvement of OSDI was statistically significant at the end of 6 months (p= 0.025) with CSA giving an extra edge. This differs from the study by Titiyal JS *et al* (2023), where the result in terms of OSDI score were seen to be significantly high in control group as compared to CHQ and CsA groups at 6 months, whereas no statistically significant difference was noted between the improvement in CsA and CHQ group was noted.

For the parameter TBUT for the right and left eye both, by the end of 3 months and 6 months no statistically significant difference in improvement was noted in both the CHQ and CSA groups for both eyes (R/E p= 0.77, L/E p= 0.612 at 3 months; R/E p= 0.33, L/E p= 0.614 at 6 months). Whereas in the study by Titiyal *et al* (2023) wherein TBUT improvement at 6 months was noted to be significantly higher with CsA as compared with CHQ group.

For the parameter ST for the right eye and left eye both, by the end of 3 months and 6 months, no statistically significant difference in improvement was noted in both the CHQ and CSA groups for both eyes (R/E p= 0.533, L/E p= 0.628 at 3 months; R/E p= 0.657, L/E p= 0.993 at 6 months). In the study by Titiyal *et al* (2023) similar picture was noted for Schirmer's test values at 6 months with no significant difference between improvement in CsA and CHQ group [14].

This study also concluded that side effects were noted to be only mild irritation for 5.7% patients in CHQ group and 2.9% patients in CSA group at 3 months (p= 0.323) and 11.4% in CHQ group and 5.7% in CSA group at 6 months, with no statistically significant difference (p= 0.230). The side effect was transient and didn't warrant a discontinuation of drug in any of our patients. No other side effects like persistent irritation, tingling or burning, redness, ocular pain or any systemic side effects were noted in either of the drugs at any time. In the study by Singh KK (2022), in a 3 week treatment period, 4 patients in CHQ group and 3 patients in CMC group experienced symptoms like conjunctival hyperemia, burning, pain and visual disturbance [7]. In the study by Gao M *et al* (2023) After 2, 4 and 12 weeks of treatment, no patients in the three groups (C, S and CS) had any major side effects with drug use. In the CS group, only one patient experienced eye irritation within 1-3 days and resolved after 2 days. No other adverse events were found [13].

Conclusion

Our current study concluded that both the topical anti-inflammatory drugs, Chloroquine phosphate (CHQ) 0.03% and Cyclosporine A (CSA) 0.05% have a significant benefit in the management of mild to moderate dry eye disease as a monotherapy. A significant difference in improvement of OSDI score was noted with the topical CSA when compared with topical CHQ on longterm use only (6 months), while the TBUT and Schirmer's test showed no significant difference at 3 months and 6 months of use. This study also noted no significant side effects with the use of either of the drugs in majority of the patients. Thus this study suggests comparable efficacy of these two in the management of mild to moderate dry eye disease, with benefit in reducing both symptoms and signs of DED as well as their safety and longterm tolerability. Using it alone or in combination with topical lubricating drugs can give early and better symptomatic improvements in mild to moderate dry eye disease as well.

Limitations

Limitations of this study are its relatively small sample size which may have limited the generalisability of the findings to larger population. Also the study was conducted in a single centre and the findings may be influenced by the specific characteristics of study population and the diagnostic and treatment protocols employed.

Scope of Improvement

Larger sample size could have been taken and some more diagnostic tests could be added to the study.

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Nil

Conflicts of Interest

There are no conflicts of interest

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