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Role of Chloroquine Phosphate Eye Drop in Dry Eye Disease

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Abstract
Background: *Dry Eye is the most common cause of ocular discomfort with wide variety of symptoms from mild irritation to diminuation of vision even blindness. With recent COVID pandemic use of gadgets and electronic devices have increased prevalence of the disease further. So it is essential to provide patients satisfactory results. So we conducted a study to lookl for role of chloroquine phosphate eye drop in Dry Eye Disease.*
Material And Methods : *A prospective, randomized, case control study was conducted on 200 patients which were assigned into 2 groups-*
Group: 1 Carboxymethyl Cellulose (CMC) (0.5 %, 2-4 t / day)
Group: 2 Chloroquine phosphate (0.03%,2 t/ day).
Main outcome measures included efficacy aspects like; TBUT, Fluorescein Staining of Cornea Schirmer test along with subjective findings of ocular discomfort.
Result: *Statistically significant difference was seen in improvement of subjective symptoms objective findings, signifying positive role of chloroquine Phosphate eye drop in Dry Eye Disease.*
Key Words- *Dry Eye Disease, TBUT, Fluorescein Stain.*

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I. Introduction

Dry eye disease (DED) is one of the most frequently encountered ocular morbidity especially post COVID period.. The new definition of dry eye is "Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.[1,"] Main causative factor of the disorder is thought to be immunological component. Cytokine and receptor mediated inflammatory cascade disintegrates the tear film layer by affecting the lacrimal gland acini and ducts and disturbs ocular surface homeostasis.[2] Apoptosis has an important role in the pathogenesis of dry eyes.[3]

The prevalence of DES in India varies from 10.8% to 57.1% with wide disparity[4.] Prevalence increases with age. Women are affected approximately twice as frequently as men[5]. Various factors are responsible for this condition. The understanding of the pathogenesis of dry eyes disease has proceeded from the mere recognition of lack of tears and consideration of their quality to the concept of wetting of the ocular surface. The underlying cause of tear film dysfunction is the alteration of tear's aqueous, mucin and lipid components. Apoptosis has also been implicated in the pathogenesis of dry eyes.

Current therapies for the management of dry eye include drugs for tear supplementation, retention, and stimulation; anti- inflammatory agents; and environmental strategies.[6] Palliative therapies like tear substitutes are currently the most common choice of treatment but having a drawback of only symptomatic improvement and not treating underlying cause of disease. The major anti-inflammatory agents currently in use include topical corticosteroids and immunomodulatory agents.[6,7]

Topical chloroquine may not only improve the symptoms of dry eye disease but also significantly target the inflammatory processes leading to disease pathogenesis.[8] The present study was carried out to compare the efficacy & patient tolerability of topical chloroquine phosphate (0.03%) with artificial tear.

II. Material & Methods

Study Design

A prospective, randomized, open label,two way, split plot design study was conducted on 200 eyes of 100 patients at Department of ophthalmology, MBS Hospital, Kota,taking permission from institutional review board regulations and taking informed consent from subjects.

Inclusion and exclusion criteria

Inclusion criteria

1 Age – between 18- 60 years

2 One or more moderate dry eye–related symptoms, including foreign body sensation ,dryness, itching burning, blurred vision, ,intolerance to bright light, and soreness i.e. a Ocular Surface Disease Index [OSDI] score between 13 and 100,best visual acuity of 6/18 or better in each eye. Both eyes were treated and included in all analysis (see statistical analysis).

3 Schirmer test-1 score less than 10 mm/5min.

4 Tear Break up time of less than 10 seconds.

5 Flouroscein stain score more than 3.5.

6 Written informed consents from participants.

Exclusion Criteria

1. Patients with any ocular condition which in opinion of the investigator makes the patients unsuitable for inclusion.
2. Patients infected with Chronic bacterial or viral ocular infections.
3. Patient presented with corneal degeneration and dystrophy .
4. Patient with history of any ocular disorder including ocular injury, infection,Non dry eye ocular inflammation
5. Patients requiring surgical correction of dry eye.
6. Patients who had history of any trauma, surgery within period of six month and any uncontrolled systemic diseases or significant illness.
7. Contact lens users ,
8. Known case of hypersensitivity to chloroquine ,
9. Pregnant women, willing to get pregnant,nursing women, chronic alcoholic.

Sequence and duration of all study periods

Patients were randomly assigned into 2 different treatment groups-

Group1: CarboxymethylCellulose(CMC)(0.5%, 2-4t/day)

Group 2: Chloroquine phosphate(0.03%,2t/day).

All the subjects received treatment for 21 days during which they were evaluated on visit 1(day 0), visit 2(day 7), visit 3(day 14) and visit 4(day 21). Seven days after termination of the treatment subjects were assessed on visit 5(day 28).

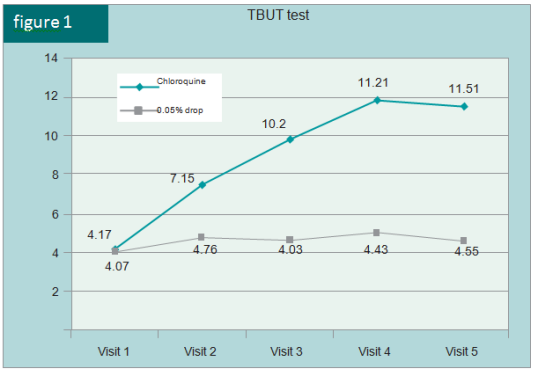
III. Observation And Results

Observation was made in terms of objective and subjective findings noted on every visit.

A. OBJECTIVE FINDINGS

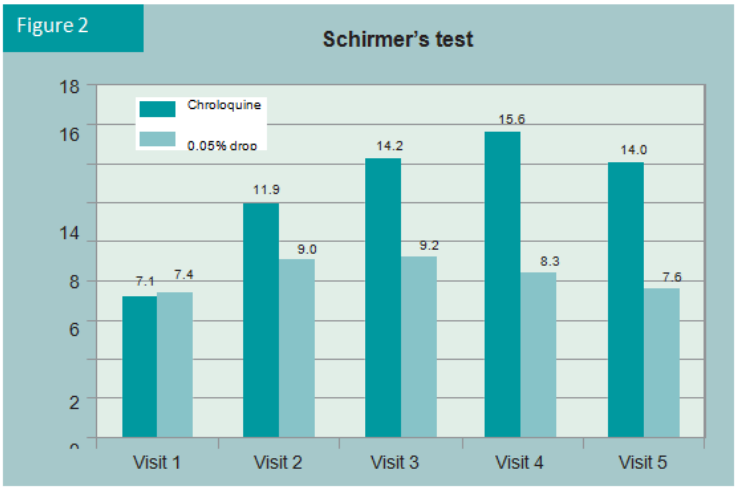
1. TBUT (Tear Film Breakup Test)

Starting with similar baseline TBUT values. Statistically difference between TBUT values in group 1 & 2 were seen with statistically significant improvement in group 1 (chloroquine 0.03%) as shown in figure 1. Average TBUT of 2 groups have been compared on all visits.



2.Schirmer's Test

Schirmer test values were not significantly different in two groups at baseline. The difference was statistically significant at all subsequent Visits (V2,3,4 and 5). Values in group 1 were significantly more at all these visits compared to group 2.



There was a statistically significant increase in Schirmer test values from baseline in first group 1.The same was not statistically significant in group 2 as discussed in figure 2.

3. FLUORESCEIN STAINING OF CORNEA

Starting with similar baseline pattern of baseline fluorescein patterns, statistically significant difference was seen in favour of Group 1 and the comparison with Group 2 has been shown in table 1

	Multiple small regions with no single quadrant free		Multiple small regions with at least one quadrant free		Single small (<1.5mm) area		No affected region	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Visit 1	28	30	47	46	11	12	14	12
Visit 3	11	21	14	36	27	14	48	29
Visit 5	3	10	7	5	38	36	62	49

Table 1 showing difference between staining pattern difference of two groups at subsequent visits.

B. SUBJECTIVE FINDINGS

Two groups were compared for improvement in various symptoms like photophobia, tearing, eye strain, discharge, intolerance to wind and difficulty in watching TV.

It was observed that reductions in burning and itching were significantly more in chloroquine group. Otherwise no significant difference in two groups for rest of the symptoms symptoms was seen.

IV. Conclusion

Our study demonstrated that use of chloroquine phosphate eye drops (0.03%) had favourable impact on disease with significant improvement in symptoms (foreign body sensation, burning and itching and signs (TBUT, Schirmer's, fluorescein staining of cornea). Hence, can be used as better alternative than a normal lubricating (0.5%) drops .

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