

Original article:

Evaluating the role of glycerin as an adjuvant in tear substitute eye drops in patients of dry eye

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ABSTRACT:

PURPOSE: To evaluate the role of glycerin 0.9% as adjuvant in tear substitute eye drops in patients of dry eye.

METHODS: A single centric randomized study was conducted in the outpatient department of Government Medical College, Jammu. 60 patients of dry eye were randomly distributed into two groups. Group I received commercially available fixed dose combination of carboxymethylcellulose 0.5% and glycerin 0.9% eye drops and Group II patients received carboxymethylcellulose 0.5%. All patients were instructed to instill eye drops at least twice daily for a period of four weeks.

RESULTS: Group I patients with dry eye reported earlier relief of symptoms and significant improvement (p-value < 0.01) in tear break-up time (TBUT) on Day 7, compared to baseline. On Day 28, both groups showed comparable improvement of symptoms and TBUT.

CONCLUSIONS: Both the formulations were equally effective in alleviating dry eye symptoms. Carboxymethylcellulose 0.5% and glycerin 0.9% eyedrops caused earlier relief in the symptoms as compared to carboxymethylcellulose 0.5% alone.

KEYWORDS: glycerin, substitute, tears, commercially

INTRODUCTION:

Dry eye disease is a multi factorial disease.¹ It is one of the most common ophthalmological pathologies associated with tear film hyperosmolarity. It affects about 5%–50% of the global population.² Dry eye impacts daily function and there by diminishes quality of life.^{3,4} Symptoms of dry eye are watering, burning sensation, grittiness, foreign-body sensation, blurred vision, and photophobia.⁵ Tear Substitutes are the primary therapy for the dry eye disease.⁶ They include cellulose derivatives, carbomers, polyvinyl alcohol, glycerine, sodium hyaluronate, autologous serum, povidone and sodium chloride.^{7,8} Carboxymethylcellulose is available in 0.5% and 1% concentration, and is the most frequently used cellulose derivative. It binds to corneal epithelial cells and increases the viscosity of the tears. Glycerine is available in 0.1% - 1% concentrations. It is a demulcent, lubricant, humectant and it promotes epithelial cell growth.

This study was done to evaluate the role of glycerine as an adjuvant to carboxymethylcellulose eye drops.

MATERIALS AND METHODS:

Present study was a randomized, prospective, single centre study conducted in outpatient department of ophthalmology, Government Medical College Jammu in the months of March and April, 2019. All the patients of dry eye who were symptomatic, had tear film break-up time of less than 10 seconds, Schirmer's test (without

anaesthesia) less than 10 millimetres after 5 minute and age more than 18 years were included in the study. Patients instilling any kind of eye drops or those with any history of ocular surgery or ocular trauma within 6 months were excluded.

All the patients underwent complete ocular examination. Schirmer’s test and tear film break-up time were noted. Subject to inclusion and exclusion criteria, all participants signed written informed consent. 60 patients of dry eye were randomly distributed into two groups. Group I included 30 patients, they received commercially available fixed dose combination of carboxymethylcellulose 0.5% and glycerine 0.9% eye drops. Group II also included 30 patients; they received carboxymethylcellulose 0.5% eye drops. All the patients were instructed to instil eye drops at least twice daily for a period of four weeks. Patients were examined on Day 1, Day 7 and Day 28. Data was recorded and statistically analysed using t-test and a p-value < 0.01 was considered statistically significant.

RESULTS:

| Parameter | | DAY 1 | | |
|----------------------------------|------------|-----------------|-------------------|---------|
| | | Group I n=30 | Group II n =30 | p-value |
| Mean Age (years) | | 44 | 42.7 | 0.418 |
| Sex | Male (%) | 40 | 36.6 | 0.574 |
| | Female (%) | 60 | 63.3 | |
| Mean TBUT (sec) | | 5.9 | 5.8 | 0.461 |
| Mean Schirmer’s Test (mm /5 min) | | 8.1 | 8.2 | 0.422 |

Table 1: Baseline parameters of all the patients

| Parameter | | DAY 7 | | DAY 28 | |
|-----------------|----------|--|--|--|--|
| | | p-value (compared with baseline) | p-value (between group comparison) | p-value (compared with baseline) | p-value (between group comparison) |
| TBUT | GROUP I | p < 0.001 | p < 0.001 | p < 0.001 | 0.412 |
| | GROUP II | 0.485 | | p < 0.001 | |
| Schirmer’s Test | GROUP I | p < 0.001 | p < 0.001 | p < 0.001 | 0.567 |
| | GROUP II | 0.496 | | p < 0.001 | |

Table 2: Inter group comparison and comparison with baseline parameters on Day 7 and Day 28

DISCUSSION:

In dry eye disease, artificial tears are the first line of therapy. These drugs work by enhancing the tear stability.⁹ Various formulations are available and this present study evaluates the role of glycerin 0.9% in artificial tears. The present study demonstrated that both carboxymethylcellulose 0.5% and carboxymethylcellulose 0.5% with 0.9% glycerin improved the reading in Schirmer's test and tear film break-up time also improved. There was significant improvement when compared with the baseline on Day 7 and Day 28. But when compared with other groups, statistically significant difference was noted on Day 7 ($p < 0.001$) but no difference was noted on Day 28 ($p > 0.01$), this stands for both the parameters evaluated. This implied that carboxymethylcellulose 0.5% with 0.9% glycerin showed earlier improvement when compared with carboxymethylcellulose 0.5% alone.

A multicenter, investigator-masked, randomized, parallel-group, active-controlled, clinical study was conducted by Hans-Walter Roth et al.¹⁰ in which they enrolled patients with mild to moderate dry eye symptoms. They compared CMC 0.5% and Glycerin 0.9% vs Sodium Hyaluronate 0.18%. At day 7 and 14, both CMC/glycerin and sodium hyaluronate effectively relieved dry eye symptoms. Scores were consistently similar across all measures, and both treatment were highly acceptable to patients.

Kaercher et al.¹¹ conducted a multicenter, non- interventional, observational, open-label study. The purpose was to evaluate the efficacy and tolerability of a dry eye product containing Sodium CMC (0.5%) and glycerol (pure glycerin) (0.9%), in 5277 patients with keratoconjunctivitis sicca. 85.4% of the total patients reported improvement in local comfort where as 75.1% of patients felt an improvement in symptoms after changing their treatment. They concluded the eye drops with Sodium CMC 0.5% with Glycerol 0.9 % was well tolerated and improved dry eye scoring.

CONCLUSION:

Both the formulations were equally effective in alleviating dry eye symptoms. Carboxymethylcellulose 0.5% and glycerin 0.9% eyedrops caused earlier relief in the symptoms as compared to carboxymethylcellulose 0.5% alone.

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