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A COMPARATIVE STUDY ON THE EFFECTIVENESS OF SODIUM HYALURONATE, CARBOXYMETHYL CELLULOSE, AND POLYETHYLENE GLYCOL–PROPYLENE GLYCOL IN PATIENTS WITH MODERATE TO SEVERE DRY EYE DISEASE

Ophthalomology

Dr Spoorthi S Post Graduate, Department of Ophthalmology, Akash Institute of Medical Sciences and Research Centre, Bangalore-562110, Karnataka, India

Dr Varun Y Raju Consultant Ophthalmologist Manjunatha Nethralaya Eye Hospital Hesarghatta RD, T Dasarahalli Bengaluru-560057

ABSTRACT

Background: Dry eye disease (DED) is a multifactorial disorder of the tear film and ocular surface resulting in discomfort, visual disturbance, and tear film instability. Artificial tear preparations remain the mainstay of treatment for moderate to severe dry eye. This study aimed to compare the effectiveness of sodium hyaluronate, carboxymethyl cellulose, and polyethylene glycol–propylene glycol formulations in patients with moderate to severe dry eye disease. **Objective:** To comparatively evaluate the effectiveness of sodium hyaluronate, carboxymethyl cellulose, and polyethylene glycol–propylene glycol eye drops in patients with moderate to severe dry eye disease. To evaluate changes in tear film stability using Tear Break-Up Time (TBUT) following treatment with each formulation. To assess tear secretion using the Schirmer test before and after treatment **Methods:** This prospective comparative single-centre study was conducted from January 2024 to December 2024. A total of 75 patients aged 20–80 years diagnosed with moderate to severe dry eye disease based on the DEWS II classification were included. Patients were randomly allocated into three groups: Group A received sodium hyaluronate 0.1%, Group B received carboxymethyl cellulose 0.5%, and Group C received polyethylene glycol 0.4% with propylene glycol 0.3%, with 25 patients in each group. Evaluation was performed at baseline and at 4-week intervals using Schirmer's test I, Schirmer's test II, and tear break-up time (TBUT). Statistical analysis was performed using SPSS version 25. Chi-square test and one-way ANOVA were used for analysis, and a p-value <0.05 was considered statistically significant. **Results:** All three treatment groups showed statistically significant improvement in Schirmer's test values and TBUT at follow-up compared to baseline ($p<0.05$). Among the three groups, sodium hyaluronate demonstrated the greatest improvement in tear film stability and tear secretion, followed by polyethylene glycol–propylene glycol and carboxymethyl cellulose. **Conclusion:** Sodium hyaluronate 0.1% was found to be more effective in improving tear film parameters in patients with moderate to severe dry eye disease when compared to carboxymethyl cellulose and polyethylene glycol–propylene glycol formulations. Regular follow-up and appropriate selection of tear substitutes can significantly improve patient outcomes.

KEYWORDS

Dry Eye Disease, Sodium Hyaluronate, Carboxymethyl Cellulose, Polyethylene Glycol, TBUT, Schirmer's test.

INTRODUCTION

Dry eye disease (DED) is a common ocular surface disorder characterized by loss of tear film homeostasis, resulting in ocular discomfort, visual disturbance, and inflammation of the ocular surface. According to the Tear Film and Ocular Surface Society Dry Eye Workshop II (TFOS DEWS II), dry eye disease is a multifactorial condition involving tear film instability, hyperosmolarity, ocular surface inflammation, and neurosensory abnormalities.

Artificial tear substitutes are the first-line treatment for moderate to severe dry eye disease. Various formulations are available, including sodium hyaluronate, carboxymethyl cellulose, and polyethylene glycol–propylene glycol combinations, each differing in viscosity, retention time, and ocular surface interaction. This study aims to compare the effectiveness of these commonly used tear substitutes in improving tear film stability and tear secretion.

MATERIALS AND METHODS

This prospective comparative single-centre study was conducted in the Department of Ophthalmology from January 2024 to December 2024 after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrolment. A total of 75 patients aged between 20 and 80 years diagnosed with moderate to severe dry eye disease based on the DEWS II classification were included. Patients were divided into three treatment groups with 25 patients in each group. Group A received sodium hyaluronate 0.1%, Group B received carboxymethyl cellulose 0.5%, and Group C received polyethylene glycol 0.4% with propylene glycol 0.3%. A total of 75 patients completed the study. Baseline demographic and clinical characteristics were comparable across the three treatment groups, with no statistically significant differences in baseline Schirmer's test values or TBUT ($p>0.05$). At baseline, the mean Schirmer's test I values were 6.2 ± 1.4 mm, 6.0 ± 1.5 mm, and 6.1 ± 1.3 mm in the sodium hyaluronate, carboxymethyl cellulose, and polyethylene glycol–propylene glycol groups, respectively. At 12 weeks, these values improved to 11.8 ± 2.1 mm, 9.6 ± 1.9 mm, and 10.4 ± 2.0 mm, respectively. The improvement was statistically significant within all groups ($p<0.05$), with the greatest improvement observed in the sodium hyaluronate group.

Mean TBUT values at baseline were 5.1 ± 1.0 seconds, 5.0 ± 1.1 seconds, and 5.2 ± 1.0 seconds in Groups A, B, and C respectively. At the final follow-up, TBUT improved to 9.4 ± 1.5 seconds in the sodium hyaluronate group, 7.8 ± 1.4 seconds in the carboxymethyl cellulose group, and 8.5 ± 1.3 seconds in the polyethylene glycol–propylene glycol group. Intergroup comparison using one-way ANOVA demonstrated statistically significant differences favoring sodium hyaluronate ($p<0.05$).

Statistical Analysis

Data were entered and analyzed using SPSS version 25. Quantitative variables were expressed as mean ± standard deviation. One-way ANOVA was used to compare continuous variables among groups, and Chi-square test was used for categorical variables. A p-value of less than 0.05 was considered statistically significant.

RESULTS

All three treatment groups demonstrated statistically significant improvement in Schirmer's test values and TBUT at follow-up compared to baseline. The sodium hyaluronate group showed the maximum improvement in tear secretion and tear film stability, followed by the polyethylene glycol–propylene glycol group and the carboxymethyl cellulose group. Intergroup comparison using ANOVA revealed statistically significant differences favouring sodium hyaluronate ($p<0.05$).

Table 1: Comparison of Schirmer's Test I (mm) Among Study Groups:

Group	Baseline (Mean ± SD)	12 Weeks (Mean ± SD)	p-value
Sodium hyaluronate 0.1%	6.2 ± 1.4	11.8 ± 2.1	<0.05
Carboxymethyl cellulose 0.5%	6.0 ± 1.5	9.6 ± 1.9	<0.05
PEG 0.4% + PG 0.3%	6.1 ± 1.3	10.4 ± 2.0	<0.05

Table 2: Comparison of Tear Break-Up Time (Seconds) Among Study Groups:

Group	Baseline (Mean ± SD)	12 Weeks (Mean ± SD)	p-value
Sodium hyaluronate 0.1%	5.1 ± 1.0	9.4 ± 1.5	<0.05
Carboxymethyl cellulose 0.5%	5.0 ± 1.1	7.8 ± 1.4	<0.05
PEG 0.4% + PG 0.3%	5.2 ± 1.0	8.5 ± 1.3	<0.05

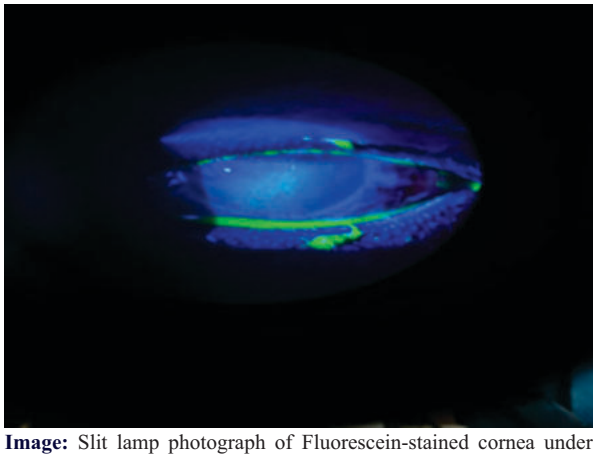

Image: Slit lamp photograph of Fluorescein-stained cornea under cobalt blue light showing superficial punctate keratitis (SPK), indicative of ocular surface epithelial damage in dry eye disease.

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