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Original Research Paper

Ophthalomology

A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF CARBOXYMETHYLCELLULOSE AND POLYETHYLENE GLYCOL ARTIFICIAL TEARS ON SUBJECTIVE AND OBJECTIVE PARAMETERS OF DRY EYE DISEASE

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ABSTRACT **Purpose:** To compare the changes in Ocular Surface Disease Index (OSDI) and Tear Film Break up Time (TBUT) with carboxymethylcellulose and polyethylene glycol containing artificial tears in patients of dry eye disease (DED). **Methods:** This prospective randomized study consisted of patients above 18 years of age diagnosed as a case of dry eye disease. The patients were equally divided into two groups; Group A & Group B. Participants in Group A were prescribed carboxymethylcellulose (0.5%) containing artificial tears while participants in Group B were prescribed polyethylene glycol (0.4%) containing artificial tears. OSDI and TBUT scores were recorded at baseline, at 1 week and then at 6 weeks. **Results:** OSDI and TBUT scores were comparable at baseline in both the groups. Group B had significantly improved OSDI and TBUT scores compared to Group A after 1 week and also after 6 weeks. **Conclusion:** Polyethylene glycol (0.4%) artificial tears are superior to Carboxymethylcellulose (0.5%) artificial tears in improving OSDI as well as TBUT scores in DED patients.

KEYWORDS : dry eye disease, carboxymethylcellulose, polyethylene glycol, osdi, tbut

INTRODUCTION

Dry eye disease (DED) is one of the most common causes of ocular morbidity in patients presenting to an ophthalmology outpatient department. In epidemiological studies conducted around the world, prevalence in the range of 5 to 50% has been calculated depending upon the diagnostic criteria applied(1). A prevalence of 32% has been reported in the North Indian population(2). Recent data has suggested that our country is on the brink of an epidemic(3) .

Patients with DED have complaints of foreign body sensation, burning & stinging sensation, eye pain and visual disturbance(4). Treatment of DED is focused on improving the patient's comfort, relieving the symptoms, returning the ocular surface and tear film to normal state, and, preventing corneal damage(5). Traditionally, the mainstay of treatment for DED has been by tear replacement with ocular lubricants which are also known as "artificial tears"(6).

Ocular lubricants have a range of reported mechanisms which make them beneficial to the ocular surface in Dry Eye Disease. These mechanisms include promotion of tear retention at ocular surface, increasing tear film thickness, protection against desiccation, improvement of goblet cell density and the maintenance of physiological corneal thickness(7). "The active pharmaceutical ingredient (API) of most commonly prescribed artificial tears are carbo xymethylcellulose (CMC), hydroxypropyl methyl cellulose (HPMC), polyethylene glycol (PEG), propylene glycol (PPG) and sodium hyaluronate (SH)"(8). Carboxymethylcellulose (CMC) is a high molecular weight polysaccharide and is one of the commonest active ingredient used in lubricating eye drops. The prolonged retention time of CMC is attributed to its viscous and mucoadhesive properties(9). Polyethylene glycol (PEG) is a polyether compound which is postulated to work by binding to damaged hydrophobic areas of epithelial cells followed by attachment of a protective gel matrix which restores health of the ocular surface(10). This study was undertaken to compare Carboxymethylcellulose (0.5%) and Polyethylene Glycol (0.4%) in improving subjective and objective parameters of Dry Eye Disease (DED).

MATERIAL AND METHODS

This was a prospective comparative study conducted in the Department of Ophthalmology at Netaji Subhash Chandra Bose Subharti Medical College, Swami Vivekanand Subharti University, Meerut and a total of 80 patients were enrolled. A thorough history was taken from all the cases and a comprehensive ocular evaluation was performed which included visual acuity assessment using Snellen chart, slit lamp examination of eyelids, tear film, conjunctiva and cornea. An informed consent was taken from each subject and prior ethical clearance was taken from the institutional ethical committee. Subjects with an Ocular Surface Disease Index (OSDI) > 12 and a Tear Film Break up Time (TBUT) <10 seconds were classified as patients with Dry Eye Disease, randomization was done, dividing patients equally into 2 groups i.e.,

Group A comprising of 40 cases was given 0.5% Carboxymethylcellulose (CMC) Eyedrops 4 times/day from 1st day till the end of 6th week.

Group B comprising of 40 cases was given 0.4% Polyethylene Glycol (PEG) Eyedrops 4 times/day from 1st day till the end of 6th week.

Patients above 18 years of age of both sexes regardless of previous treatment status were included in the study. Patients on systemic medications that have been associated with causing dry eye, history of any ocular or refractive surgery, patients having pathology of anterior segment e.g., Trichiasis, Conjunctivitis, Corneal Pathologies, Blepharitis were excluded from the study.

Ocular Surface Disease Index (OSDI) was used as a subject parameter and Tear film breakup time (TBUT) was used as a of objective parameter of Dry Eye Disease and both were recorded at day 1, 1st week and 6th week.

To perform Tear Film Breakup Time (TBUT) test firstly an impregnated fluorescein strip was wetted with a single drop of sterile saline and excess fluid was removed by shaking the strip briskly. The wet impregnated fluorescein strip was then used to stain the ocular surface. Patients were then instructed to blink several times to distribute the stain evenly. The ocular surface was then examined using the cobalt blue light of a slit lamp. Then the patient was asked to stop blinking and the time

was measured from the last blink till a dry or a dark spot appeared over the cornea. This time interval (in seconds) was recorded as the TBUT. TBUT was measured 3 times for both the eyes, and the average of the findings recorded was registered as the mean TBUT. A value of <10 seconds was considered as a diagnosis of DED.

OSDI score was recorded after asking the patients all the 12 questions as given in the OSDI questionnaire. To calculate OSDI score sum of scores of all questions that were answered was multiplied by 25 and the result was divided by the total number of answered questions.

Data collected was tabulated in Microsoft Excel spread sheet and analyzed using the statistical package for the MedCalc statistical Software version 20.115 for windows edition. Qualitative data were presented as number, percentage and Quantitative data were presented as mean±SD. Comparison between groups was done by χ2-test for qualitative data and by t test for quantitative data. A statistically significant result was considered when the P value was < 0.05.

RESULTS

Mean age in group A and B was found to be 52.45±9.44 and 54.82±9.44 years respectively. Maximum subjects were from the age group of >50 years followed by 31-50 years. No significant difference was found between group A and B with respect to age (P=0.224). Approximately equal distribution of male and females were revealed among both the groups in the present study, (47.50% males in Group A and 55% males in Group B whereas, 52.50% females in Group A and 45% females in Group B).

At baseline, mean OSDI level was 34.89±5.26 and 35.70±5.00 in group A and group B respectively (P=0.485). After 1 week, OSDI score decreased in both the groups but reduction in score was more in group B as compared to group A. After 6 weeks, OSDI score further decreased in both the groups. When OSDI score was compared in group A and B at one week and six weeks, statistically significant difference was found (P=0.040, P<0.0001 respectively) indicating that OSDI score decreased more in subjects receiving PEG tear substitutes (table 1).

Table – 1 Comparison of OSDI among the study groups at different intervals

OSDI	Group A (CMC)		Group B (PEG)		P value
	Mean	SD	Mean	SD	
Baseline	34.89	5.26	35.70	5.00	0.485
1st Week	30.5	5.55	28.07	4.80	0.040
6th Week	25.51	5.49	18.86	4.67	<0.0001

At baseline, mean TBUT score was 5.8±1.66 seconds and 6.07±1.76 seconds in group A and group B respectively (P=0.475). After 1 week, mean TBUT score increased in group A as well B. After 6 weeks, TBUT score further increased in both the groups. When TBUT score was compared in group A and B at the end of first and sixth week, Group B was found to have a significantly better reduction in TBUT score compared to Group A (P=0.034, P=0.008 respectively) (table 2).

Table – 2 Comparison of TBUT among the study groups at different intervals

TBUT (in seconds)	Group A (CMC)		Group B (PEG)		p value
	Mean	SD	Mean	SD	
Baseline	5.8	1.66	6.07	1.76	0.475
1st Week	6.85	1.35	7.55	1.55	0.034
6th Week	7.95	1.31	8.77	1.40	0.008

DISCUSSION

The instability of tear film is regarded as the hallmark of Dry Eye Disease. This instability leads to either subclinical or clinically apparent ocular surface inflammation. Due to the inflammation, there occurs epithelial damage of the ocular surface which is turn augments the tear film instability, establishing the vicious cycle. The main goal of DED treatment is to break this vicious cycle. Tear substitutes have been the conventional treatment for dry eye patients for improving their symptoms(11). Tear substitutes account for about half a billion dollars in sales all over the world every year, this popularity is accounted to their non-invasive nature and good safety profile(12).

Ocular Surface Disease Index (OSDI) is a 12 item questionnaire which assesses ocular symptoms associated with Dry Eye and their influence on vision related functioning(13). In our study, PEG tear substitutes produced significantly better subjective improvement in terms of OSDI score compared to CMC tear substitutes after 1 week and also after 6 weeks of initiating treatment. These results were consistent with the findings of a study conducted by Christensen MT et al who concluded that PEG containing eyedrops were superior in alleviating dry eye symptoms(14).

Tear Film Breakup Time (TBUT) is used to evaluate tear film stability. In the current study, one week after initiating the treatment mean TBUT score increased in group A as well group B. After 6 weeks mean TBUT score increased further in Group A and also in Group B. However, the increment in TBUT score was significantly more in group B as compared to group A at 1 week and also at 6 weeks suggesting that PEG containing tear substitutes are better at improving tear film stability compared to CMC containing tear substitutes. Maharana PK et al had compared CMC 0.5%, hydroxypropyl-guar containing PEG eye drops and found PEG to be better than CMC in terms of improvement in TBUT after 1 week and also after 4 weeks of initiating treatment(15).

CONCLUSION

Despite a high prevalence of Dry Eye Disease all over the world only a limited number of studies have compared the various types of ocular lubricants available in the market, which are the mainstay of treatment in patients of DED(16). This prospective comparative study demonstrated improvement in subjective parameter (OSDI) as well as objective parameter (TBUT) with both Carboxymethycellulose 0.5% & Polyethylene Glycol 0.4% tear substitutes in Dry Eye Disease. The Polyethylene group, however, had a statistically significant improvement in OSDI and TBUT scores over Carboxymethylcellulose group. Both the treatments were well tolerated by the patients and no serious adverse drug reaction was observed.

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