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TO EVALUATE THE EFFECT OF TOPICAL 2% REBAMIPIDE OPHTHALMIC SUSPENSION IN PATIENTS WITH DRY EYE DISEASE.

Dr Shakti Krishan Rajguru[1], Dr. Udesh Rajpurohit[2]

[1]MBBS, MS, Ophthalmology, Junior Specialist, Department of Ophthalmology, Government Medical College, Barmer, Rajasthan
[2]Junior Resident, Government Medical College, Barmer, Rajasthan

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Corresponding author: Dr. Udesh Rajpurohit
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Abstract

Background: Dry eye is an important public health problem causing ocular discomfort, fatigue and visual disturbance that may interfere with daily activities

Methods: It is a prospective, randomized, analytical hospital based study. Minimum Sample size of 80 patients which is randomly allocated in the study (cases) and control group. In the study group topical 2% rebapimide ophthalmic suspension and in control group 0.5% caboxymethyl cellulose ophthalmic solution were given after comprehensive ophthalmic evaluation.

Results: In mild OSDI score chi square test showed p value as 0.07 which was statistically not significant. In moderate OSDI score chi square test showed p value as 0.07 which was statistically not significant. In severe OSDI score chi square test showed p value as 0.04 which was statistically significant.

Conclusion: Rebamipide 2% ophthalmic suspension is an effective treatment in dry eye disease due to mucin deficiency. There was significant improvement in signs and symptoms of dry eye

Keywords: OSDI, Dry eye, Rebamipide 2% ophthalmic suspension

Introduction

Dry eye is an important public health problem causing ocular discomfort, fatigue and visual disturbance that may interfere with daily activities[1].

The International Dry Eye Workshop (DEWS) defined dry eye as 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".[2]

Dry Eye Syndrome (DES) is caused by a chronic lack of sufficient lubrication and moisture on the surface of the eye. Consequences of dry eyes range from constant eye irritation to significant inflammation and even scarring of the front surface of the eye.[3,4]

Material and Method

It is a prospective, randomized, analytical hospital based study. Minimum Sample size of 80 patients which is randomly allocated in the study (cases) and control group. In the study group topical 2% rebapimide ophthalmic suspension and in control group 0.5% caboxymethyl cellulose ophthalmic solution were given after comprehensive ophthalmic evaluation. Patients presenting with the complain of dryness of eyes, foreign body sensation, grittiness have been enrolled for study according to ocular surface disease index (OSDI). A comprehensive ophthalmic evaluation including visual acuity, anterior segment examination was done.

Inclusion criteria:

- Dry eye with any cause.
- Patients having one or more dry eye symptom present often or all the time plus any one following abnormal signs -

1 Schirmer's test results have wetting less than 10 mm at the end of 5 minutes.
2 Tear film breakup time less than 10 second.
3 Positive staining of ocular surface with fluorescein or Rose Bengal dye.

Exclusion criteria

- Patients not willing to give informed consent.
- Patients not giving consent for detail dry eye assessment at baseline and subsequent visits.
- Patients with poor compliance to drug use or follow-up will be excluded from study.
- Acute ocular infection
- Corneal ulcer and extensive corneal scarring.
- Localised epithelial irregularity.

Results

Dry eye patients were 8 (10%) in 15 to 30 years age group, 16 (20%) in 31 to 45 years age group, 33 (41.25%) in 46 to 60 years age group, 18(22.5%) in 61 to 75 years age group and 5(6.25%) were >75 years age group. 47(58.75%) were female and 33(41.25%) were male.

Table 1: Statistical analysis for OSDI score

	Control		Cases		χ^2	P
	Total	Improvement	Total	Improvement		
Mild	11	8	10	9	3.541	0.07
Moderate	15	10	14	14	3.541	0.07
Severe	14	4	16	11	4.82	0.04

In mild OSDI score chi square test showed p value as 0.07 which was statistically not significant.
In moderate OSDI score chi square test showed p value as 0.07 which was statistically not significant.
In severe OSDI score chi square test showed p value as 0.04 which was statistically significant.

Discussion

Dry eye is a disease of the ocular surface, which occur due to quantitative and qualitative changes in tear film. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. The medical treatment and clinical studies performed on dry eye syndrome (DES) have conventionally focused on improvement of epithelium healing and tear film stability.

Although there is variety of drugs being used for dry eye disease, none of the therapy is ideal. In India, artificial tears are the first-line agents and immunosuppressants (Cyclosporine A and steroids) are the second-line agents used for the treatment of dry eyes conventionally.

Recent studies shows 2% rebamipide ophthalmic suspension is also effective in dry eye patients by its effect on ocular surface mucin. Investigations have confirmed that rebamipide increases corneal and conjunctival mucin.

The present randomized case control study was conducted to evaluate the therapeutic effects and side effects of 2% rebamipide ophthalmic suspension and its effect on changes in signs and symptoms of dry eye.

Various questionnaires are often used in epidemiological studies for the assessment of dry eyes. These may be the Ocular Surface Disease Index (OSDI) questionnaire, shortform–12 health survey and the National Eye Institute visual functioning Questionnaire.[5] The Ocular Surface Disease Index (OSDI) is the most frequently used survey instrument for the assessment of ocular surface disease severity in dry eye research.[6] It had been used in a variety of studies, both in the assessment of the severity of dry eye associated with certain conditions and in the investigation of the efficacy of dry eye treatments. [7-9] The OSDI questionnaires was used in our study because it reliably assesses the severity, natural history and effects of dry eye. In a study Schiffman RM et al observed that compared to other questionnaires, the OSDI had a more sensitivity and specificity. However, the accuracy of this method may be affected by the wide range of terms individual subjects use to subscribe their ocular irritation.[10]

In our study, before starting the treatment according to the OSDI score 10 (25%) patients were graded into mild, 14 (35%) into moderate, 16 (40%) into severe dry eye disease in cases. The improvement in OSDI score was remarkable at 12 weeks in these patients. Patient who had mild and moderate OSDI scores almost all are improved which was statistically not significant. Patient who had severe OSDI scores 11 (68.75%) patients showed improvement which was statistically significant. Improved OSDI score also improved the quality of life. The study done by Igarashi et al was used OSDI score for evaluating the symptoms, also showed significant improvement in symptoms after giving 2% rebamipide Ophthalmic suspension.[11]

Conclusion

Rebamipide 2% ophthalmic suspension is an effective treatment in dry eye disease due to mucin deficiency. There was significant improvement in signs and symptoms of dry eye.

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