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Original Article

Preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops in dry eye disease

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ABSTRACT:

Background: Dry eye syndrome (keratoconjunctivitis sicca) is a common condition characterized by inflammation of the ocular surface and lacrimal glands. The present study compared preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops in dry eye patients. **Materials & Methods:** 60 patients of dry eyes disease were divided into 2 groups. Group I were prescribed dextran 70, 1 mg/ml and hypromellose, 3 mg/ml hydroxypropyl methylcellulose (HPMC) and group II 0.3 g HPMC and 0.1 g of dextran 70, with 0.01% benzalkonium chloride. The ocular surface disease index (OSDI) questionnaire, tear break up time (TBUT), corneal and conjunctival staining and Schirmer test were performed. **Results:** Themean conjunctival score at baseline was 6.72 and 7.30 and at 4 weeks was 5.30 and 5.42 in group I and II respectively, corneal score at baseline was 1.45 and 1.22 and at 4 weeks was 0.50and 0.43 in group I and II respectively, schirmer test (mm) at baseline was 6.09 and 6.14 and at 4 weeks was 6.82 and 7.28 in group I and II respectively. OSDI score at baseline was 42.2 and 39.2 and at 4 weeks was 32.4 and 28.3 in group I and II respectively, TBUT (sec) at baseline was 7.6 and7.8 and at 4 weeks was 7.2 and 8.5 in group I and II respectively. The difference was significant ($P< 0.05$). **Conclusion:** Both preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops were efficient in reducing symptoms of dry eyes disease.

Key words: Dry eyes, Schirmer test, conjunctival staining

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INTRODUCTION

Dry eye syndrome (keratoconjunctivitis sicca) is a common condition characterized by inflammation of the ocular surface and lacrimal glands. Dry eye symptoms may be a manifestation of a systemic disease, therefore timely detection may lead to recognition of a life–threatening condition.[1] Additionally, patients with dry eye are prone to potentially blinding infections, such as bacterial keratitis and at an increased risk of complications following common procedures such as laser refractive surgery.Dry eye may develop secondary to inflammatory disease (e.g. vascular, allergic), environmental conditions (e.g. allergens, cigarette smoke, dry climate), hormonal imbalance (e.g. perimenopausal women and patients under hormone replacement therapy), and contact lens wear.[2]

Artificial tears are among the first line of therapy in management of dry eye syndrome. They may be used along with other treatments such oral omega-3 essential fatty acid supplements, mucin secretagogues, short term steroids and daily cyclosporine A, to combat the inflammatory nature of the disease. Frequent eye care visits and different treatment options impose high costs to patients and health care systems.[3] Due to their non-invasive nature and low side effect profile, artificial tears have remained the main stay of therapy for DES. Almost all tear substitutes rapidly replace the moisture layer of tears and quickly reduce the symptoms.[4,5] Benzalkonium chloride (BAK) is a preservative frequently used in ophthalmic preparations. In patients with mild dry eye, benzalkonium chloride containing products may be well tolerated when used four to six times a day or less.[6] The present study compared preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops in dry eye patients.

MATERIALS & METHODS

The present study comprised of 60 patients of dry eyes disease of both genders. All were informed and their written consent was obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 30each. Group I were prescribed dextran 70, 1 mg/ml and hypromellose, 3 mg/ml hydroxypropyl methylcellulose (HPMC) and group II 0.3 g HPMC and 0.1 g of dextran 70, with 0.01% benzalkonium chloride (BAK). The ocular surface disease index (OSDI) questionnaire, tear break up time (TBUT), corneal and conjunctival staining and Schirmer test, were performed. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Drug	Hydroxypropyl methylcellulose	Benzalkonium chloride
M:F	12:18	14:16

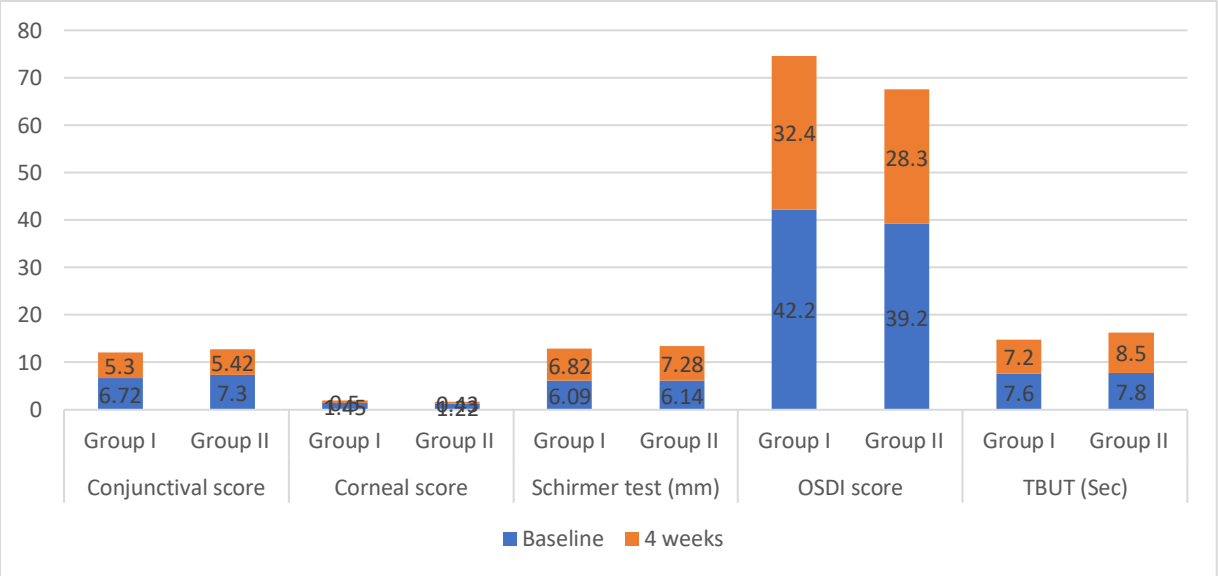
Table I shows that group I had 12 males and 18 females and group II had 14 males and 16 females.

Table II Comparison of parameters

Parameters	Groups	Baseline	4 weeks	P value
Conjunctival score	Group I	6.72	5.30	0.01
	Group II	7.30	5.42	
Corneal score	Group I	1.45	0.50	0.02
	Group II	1.22	0.43	
Schirmer test (mm)	Group I	6.09	6.82	0.02
	Group II	6.14	7.28	
OSDI score	Group I	42.2	32.4	0.05
	Group II	39.2	28.3	
TBUT (Sec)	Group I	7.6	7.2	0.04
	Group II	7.8	8.5	

Table II, graph I shows that mean conjunctival score at baseline was 6.72 and 7.30 and at 4 weeks was 5.30 and 5.42 in group I and II respectively, corneal score at baseline was 1.45 and 1.22 and at 4 weeks was 0.50and 0.43 in group I and II respectively, schirmer test (mm) at baseline was 6.09 and 6.14 and at 4 weeks was 6.82 and 7.28 in group I and II respectively. OSDI score at baseline was 42.2 and 39.2 and at 4 weeks was 32.4 and 28.3 in group I and II respectively, TBUT (sec) at baseline was 7.6 and7.8 and at 4 weeks was 7.2 and 8.5 in group I and II respectively. The difference was significant (P< 0.05).

Graph I Comparison of parameters



DISCUSSION

Dry eye is a disorder of the tear film which occurs due to tear deficiency or excessive tear evaporation; it causes damage to the interpalpebral ocular surface and is associated with a variety of symptoms reflecting ocular discomfort.[7] The precorneal tear film is an essential component of the ocular surface and can be subdivided into an anterior lipid layer, a middle aqueous layer and an innermost mucin layer.[8] These layers are produced by the meibomian glands, the lacrimal gland and goblet cells of the conjunctiva, respectively.[9] The tear film lubricates the eye, maintains nutrition and oxygenation of ocular structures, acts as a refractive component and helps remove debris from the ocular surface.[10] In terms of tear production, dry eye can be divided into tear deficient and evaporative type. Dry eye syndrome is associated with a long list of causes which can be divided into primary and secondary.[11]The present study compared preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops in dry eye patients.

We found that group I had 12 males and 18 females and group II had 14 males and 16 females.Ozdemir et al[12] in his study found that TBUT and Schirmer's test values were significantly lower in diabetic patients compared with controls. In the diabetic group, more individuals had abnormal fluorescein stain compared

with the control group (P<0.001). Abnormal tear function tests were associated with poorer metabolic glucose control and proliferative diabetic retinopathy (P<0.05) but not with duration of diabetes (P>0.05). It was concluded that poor metabolic control and proliferative diabetic retinopathy are high risk factors for ocular surface disorders in type 2 diabetes.

We observed that mean conjunctival score at baseline was 6.72 and 7.30 and at 4 weeks was 5.30 and 5.42 in group I and II respectively, corneal score at baseline was 1.45 and 1.22 and at 4 weeks was 0.50and 0.43 in group I and II respectively, schirmer test (mm) at baseline was 6.09 and 6.14 and at 4 weeks was 6.82 and 7.28 in group I and II respectively. OSDI score at baseline was 42.2 and 39.2 and at 4 weeks was 32.4 and 28.3 in group I and II respectively, TBUT (sec) at baseline was 7.6 and7.8 and at 4 weeks was 7.2 and 8.5 in group I and II respectively. Shobja P et al[13] found that in comparing two groups before the intervention, the OSDI scores, the TBUT scores, the conjunctival and corneal staining scores and the Schirmer scores did not show statistically significant differences. The mean of age of the participants in the group I and II was 44.08 years and 45.83, respectively. After 4 weeks, the OSDI scores, conjunctival and corneal staining scores showed improvement in compare to those before the intervention ($p < 0.001$). But, the differences for the Schirmer test score and TBUT score was not significant.

Preservative free formulations are also indicated for those with a known history of allergy to preservatives and those who wear contact lenses. The limitation of the study is small sample size.

CONCLUSION

Authors found that both preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops were efficient in reducing symptoms of dry eyes disease.

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