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ORIGINAL ARTICLE

Comparison of the clinical efficacy of preserved and preservative-free hydroxypropyl methylcellulose-dextran-containing eyedrops

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KEYWORDS
Hydroxypropyl methylcellulose;
Artificial tear drops;
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Abstract
Purpose: This study aimed to compare the efficacy of two sustained-release formulation of artificial tear drops.
Patients and methods: This is a randomized patient-masked clinical trial, a total 88 patients into two group A ($n=41$; with single dose of artificial tear, containing dextran 70, 1 mg/ml and hypromellose, 3 mg/ml hydroxypropyl methylcellulose (HPMC) and group B ($n=47$; with multidose of artificial tear, containing 0.3 g HPMC and 0.1 g of dextran 70, with 0.01% benzalkonium chloride (BAK) as preservative) were completed the study. The ocular surface disease index (OSDI) questionnaire, tear break up time (TBUT), corneal and conjunctival staining and Schirmer test, were performed. Repeated measures ANOVA was used to assess the differences among the two products. A p-value less than 0.05 was considered significant.
Results: The mean of age of the participants in the Group A and B was 44.08 ± 6.29 (range, 33–58 years) years and 45.83 ± 8.42 (31–60 years), respectively. 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 ($p=0.339$, $p=0.640$, $p=0.334$, $p=0.807$ and $p=0.676$, 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 ($p=0.115$, $p=0.013$, respectively).

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Conclusion: Our outcomes indicated that improvement occurred with use of both products but there was no statistically significant difference between them.

PALABRAS CLAVE
Hidroxipropil metilcelulosa;
Lágrimas artificiales;
Síndrome de ojo seco

Comparación de la eficacia clínica de los colirios con conservantes y los colirios con contenido de hidroxipropil metilcelulosa-dextran sin conservantes

Resumen
Objetivo: El objetivo de este estudio fue comparar la eficacia de dos fórmulas de lágrimas artificiales de liberación sostenida.
Pacientes y Métodos: Ensayo clínico aleatorizado y enmascarado para el paciente, se incluyó a un total de 88 pacientes distribuidos en dos grupos: el grupo A (n = 41; con una dosis única de lágrima artificial con contenido de Dextran 70,1 mg/ml e hipromelosa, 3 mg/ml hidroxipropil metilcelulosa (HPMC), y el grupo B (n = 47; con multidosis de lágrima artificial, con contenido de 0,3 g HPMC y 0,1 g de Dextran 70, y 0,01% de cloruro de benzalconio (BAK) como conservante). Se realizaron las siguientes pruebas: cuestionario del índice de enfermedad de la superficie ocular (OSDI), tear break-up time (TBUT), tinción corneal y conjuntival y prueba de Schirmer. Para el análisis estadístico se utilizó ANOVA para mediciones repetidas, a fin de evaluar las diferencias entre los dos productos. Se consideró significativo un valor p inferior a 0,05.
Resultados: La media de edad de los participantes de los grupos A y B fue de 44,08 ± 6,29 (rango de 33 a 58 años) y 45,83 ± 8,42 (de 31 a 60 años), respectivamente. Al comparar los dos grupos antes de la intervención, las puntuaciones OSDI, TBUT, las de tinción conjuntival y corneal, y las de la prueba de Schirmer no reflejaron diferencias estadísticamente significativas (p = 0,339, p = 0,640, p = 0,334, p = 0,807 y p = 0,676, respectivamente). Transcurridas cuatro semanas, las puntuaciones OSDI y las de tinción conjuntival y corneal reflejaron una mejora en comparación a las puntuaciones anteriores a la intervención (p < 0,001). Pero las diferencias en cuanto a las puntuaciones de la prueba de Schirmer y TBUT no fueron significativas (p = 0,115, p = 0,013, respectivamente).
Conclusión: Nuestros resultados indican que se produjo una mejora con el uso de ambos productos, pero que no se produjo una diferencia estadísticamente significativa entre ambos.

Introduction

Dry eye syndrome (DES) is a multifactorial disease of the ocular surface. Rapid evaporation of tear film, inadequate production of tears, and inflammation of the ocular surface are among the causes of this syndrome. This condition can result in the ocular symptoms of foreign body sensation, redness, and discomfort, as well as the signs of surface damage in the cornea and conjunctiva, all leading to detrimental visual performance.[1–4] DES is a common problem worldwide and can reduce the working efficiency of an individual. Dry eye is therefore a frequent complaint that patient present to eye care clinics. Common patient's complaints related to dry eye include reduced vision, difficulty reading, difficulty driving at night and difficulty doing computer work.[5] A key principle for the management of dry eye disease is augmentation of the tear film through the topical administration of artificial tear substitutes. These products enhance tear stability thus reducing loss by evaporation; this, in turn, helps to retain moisture in the eye and relieve the chronic ocular inflammation associated with dry eyes. Artificial tear substitutes help to reduce patient discomfort, improve quality of life and reduce the risk of damage to the corneal epithelium.[6] Artificial tears are among the first line of therapy in management of DES.[8] 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.[9] Frequent eye care visits and different treatment options impose high costs to patients and health care systems.[10] Due to their non-invasive nature and low side effect profile, artificial tears have remained the main stay of therapy for DES.[11] Almost all tear substitutes rapidly replace the moisture layer of tears[12] and quickly reduce the symptoms. In USA, approximately 7 to 10 million Americans spend 320 million dollars per year on artificial tear products.[13] In USA, many clinical trials have been conducted to evaluate their efficacy and to compare them with each other.[14] In report of Dry Eye WorkShop (DEWS) was concluded that although many topical lubricants with various

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