Research of the month : June 2015

Effect of 0.3 % Hydroxypropyl Methylcellulose/Dextran Versus 0.18 % Sodium Hyaluronate in the Treatment of Ocular Surface Disease in Glaucoma Patients: A Randomized, Double-Blind, and Controlled Study

Clinical research

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JOURNAL OF OCULAR PHARMACOLOGY AND THERAPEUTICS
Volume 31, Number 6, 2015
DOI: 10.1089/jop.2014.0115

Impact factor = 1.47

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ABSTRACT

Purpose: To compare the efficacy and safety of 0.3% hydroxypropyl methylcellulose/dextran (HPMC/dextran) and 0.18% sodium hyaluronate (SH) in the treatment of ocular surface disease in patients using antiglaucoma drugs containing preservatives.
Methods: This was a double-blind, randomized, parallel-group study in 70 glaucoma patients with Ocular Surface Disease Index (OSDI) score greater than 20 points and/or presence of ocular signs. Patients were randomized to receive either preservative-free 0.3% HPMC/dextran ($n=35$) or preservative-free 0.18% SH ($n=35$). Treatment was 1 drop in each eye, 4 times a day. Data were collected at baseline, at day 7 and day 28.
Results: The groups were homogeneous at baseline. At day 28, both treatments showed significant improvements ($P<0.05$) in the mean OSDI score, lid skin and lid margin inflammation, conjunctival injection, and expressibility of meibomian glands, corneal staining score, fluorescein tear breakup time (FBUT), and Schirmer I test. However, the mean OSDI score, lid margin inflammation and conjunctival injection showed significant improvements ($P<0.05$) in the SH group at days 7 and 28, compared to the HPMC/dextran group. FBUT and the Schirmer I test also showed significant improvements ($P<0.05$) in the SH group compared to the HPMC/dextran group, at day 28. No adverse reactions were observed in either group.
Conclusions: Preservative-free artificial tear, 0.3% HPMC/dextran, and 0.18% SH, caused a significant relief of the ocular surface disease in glaucoma patients. However, 0.18% SH led to a greater improvement in ocular signs and symptoms than 0.3% HPMC/dextran.

Introduction

GLAUCOMA IS THE SECOND leading cause of blindness in Thailand, and more generally worldwide.[1,2] Nowadays, various medications are mandatory for the treatment of glaucoma to prevent blindness from hypertensive optic nerve damage. Eye drops usually containing preservatives, are the mainstay of treatment. However, the long-term duration of such treatments can also cause ocular surface disease, especially dry eye. Several previous studies[3–9] have shown that the presence of preservatives in antiglaucoma medications is a main cause of ocular surface problems such as keratopathy, conjunctival inflammation, abnormal tear film production, tear film instability, and meibomian gland dysfunction. These adverse effects can lead to poor adherence to treatment.

Thus, given the need to continue glaucoma treatments and concern for the ocular surface damage they cause, it is important to find a medication that would decrease these ocular surface side effects. Previous reports have demonstrated the efficacy of nonpreserved artificial tears in increasing tear film production, tear film stability, and improving ocular surface in dry eye patients.[10–14] Sodium hyaluronate (SH) was shown *in vitro* to reduce ocular toxicity due to benzalkonium chloride (BAK), a preservative often used in antiglaucoma

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Table 1: Demographic Data and Baseline Characteristics.

Characteristics	*HPMC/dextran (Group A) (n=35)*	*SH (Group B) (n=35)*
Gender		
Male, *n* (%)	10 (28.6)	13 (37.1)
Female, *n* (%)	25 (71.4)	22 (62.9)
Signs		
Lid margin inflammation severity, *n* (%)		
No injection	4 (11.4)	6 (17.1)
Mild inflammation	28 (80.0)	23 (65.8)
Moderate inflammation, telangiectasia	3 (8.6)	6 (17.1)
Severe inflammation, marked telangiectasia	0	0
Meibomian gland secretion, *n* (%)		
Clear fluid	8 (22.9)	8 (22.9)
Cloudy fluid	22 (62.9)	25 (71.4)
Cloudy/particulate fluid	4 (11.4)	2 (5.7)
Inspissated/ toothpaste-like	1 (2.9)	0
Expressibility of meibomian gland *n* (%)		
Well express	8 (22.9)	12 (34.3)
2/3 expressibility	20 (57.1)	14 (40.0)
1/3–2/3 expressibility	7 (20.0)	8 (22.9)
< 1/3 expressibility	0	1 (2.9)
Bulbar conjunctival injection *n* (%)		
No injection	5 (14.3)	8 (22.9)
Mild injection	26 (74.3)	23 (65.7)
Moderate injection	4 (11.4)	4 (11.4)
Follicle *n* (%)		
None	15 (42.9)	15 (42.9)
Presence	20 (57.1)	20 (57.1)
Corneal fluorescein score (mean ± SD)	5.86 ± 3.33	6.37 ± 4.27
Corneal Rose Bengal score (mean ± SD)	0.37 ± 0.69	0.37 ± 0.84
Fluorescein tear breakup time, s (mean ± SD)	3.83 ± 1.54	4.65 ± 1.85
Schirmer's I test, mm (mean ± SD)	6.60 ± 2.55	6.46 ± 2.56
Symptoms		
OSDI [mean ± SD]	31.47 ± 11.11	31.50 ± 13.60

Table 2 : Antiglaucoma Medications Before Inclusion.

Antiglaucoma medications	*No. of eyes (%)*
β-blockers	48 (68.6)
Prostaglandin analogs	43 (61.4)
α-agonists	31 (44.3)
Topical CAIs	8 (11.4)
Fixed-combinations	9 (12.9)

Table 3 : Relationship Between Frequency of Antiglaucoma Eye Drops Administration and Mean OSDI Score at Baseline.

No. of drops/day	*No. of patients (%)*	*Mean OSDI baseline*
1–2	23 (32.9)	29.3
3–4	28 (40.0)	31.4
5–7	19 (27.1)	34.2

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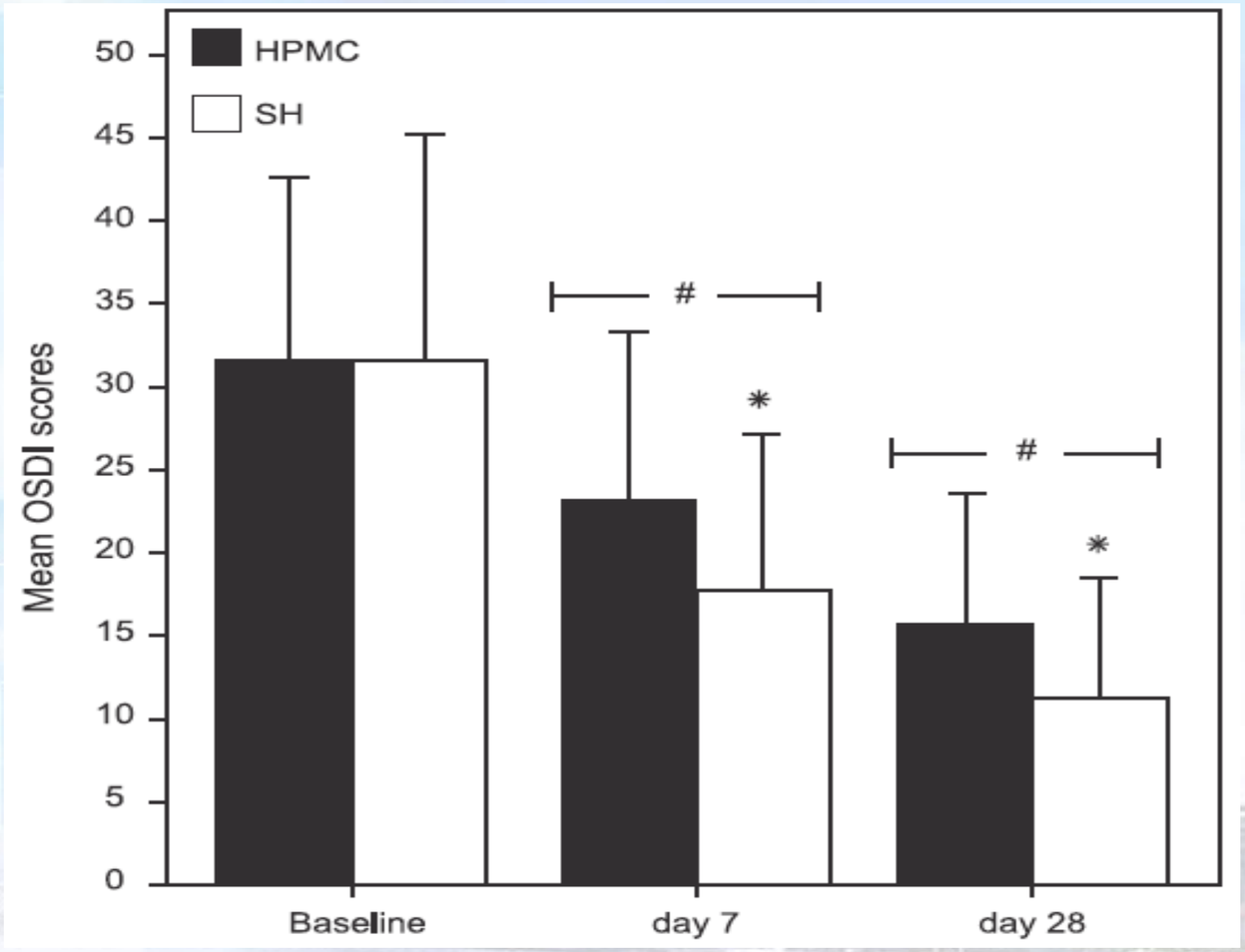

Figure 1: Mean ocular surface disease index (OSDI) scores at baseline, D7 and D28 in both groups.

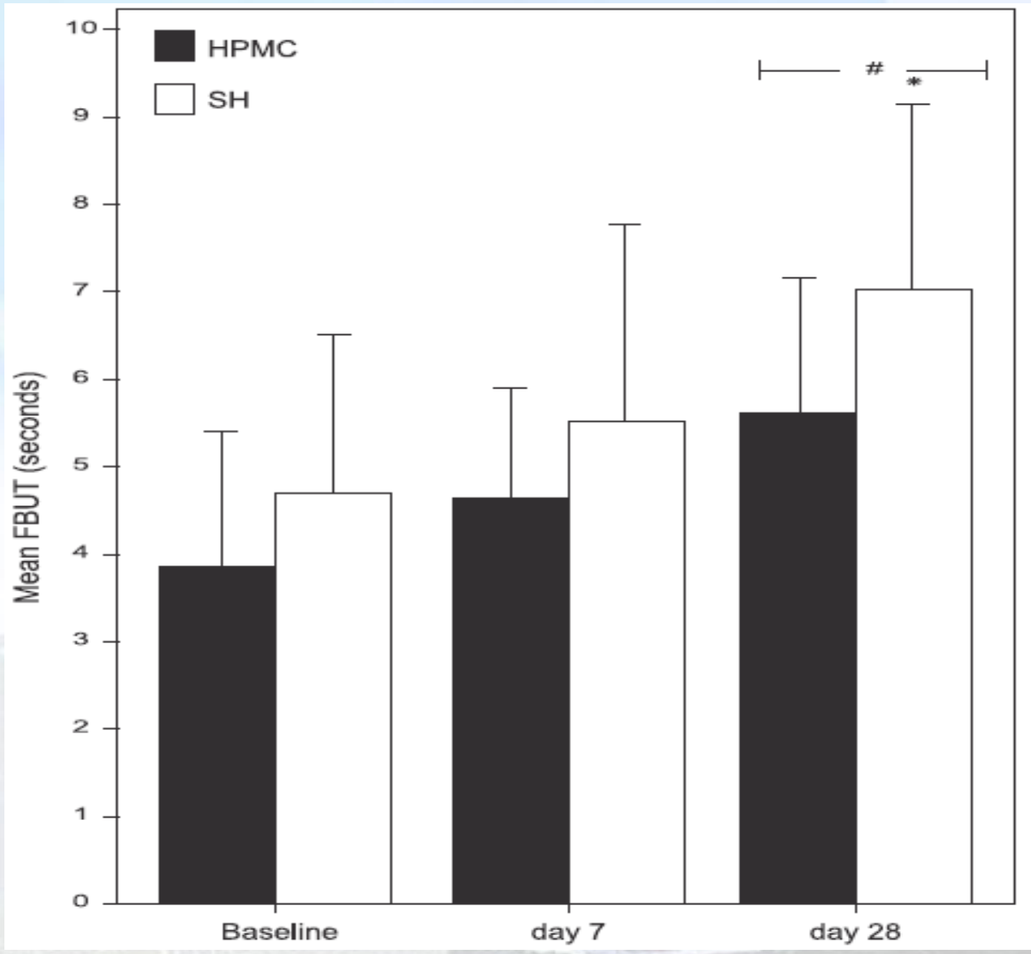

Figure 2: Mean fluorescein tear breakup time (FBUT) at baseline, D7 and D28 in both groups.

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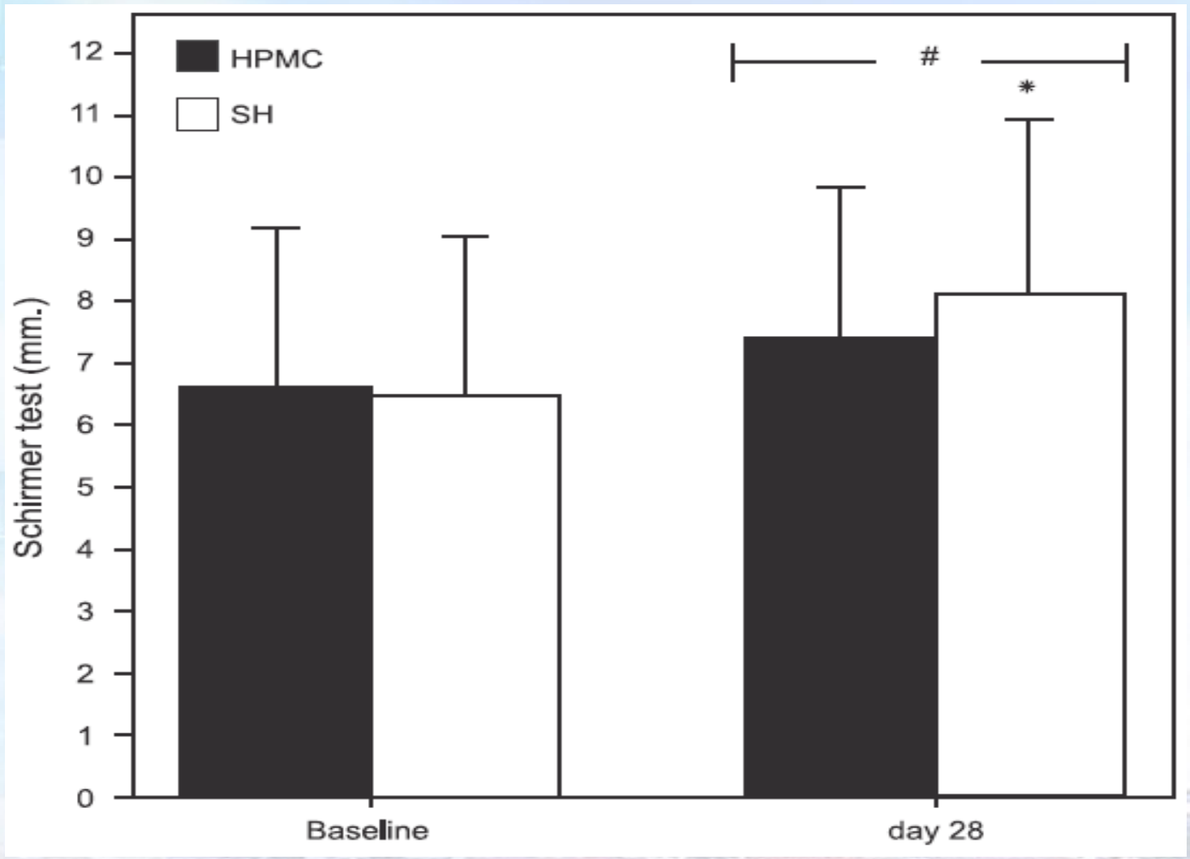

Figure 3: Mean Schirmer's test value at baseline and D28 in both groups.

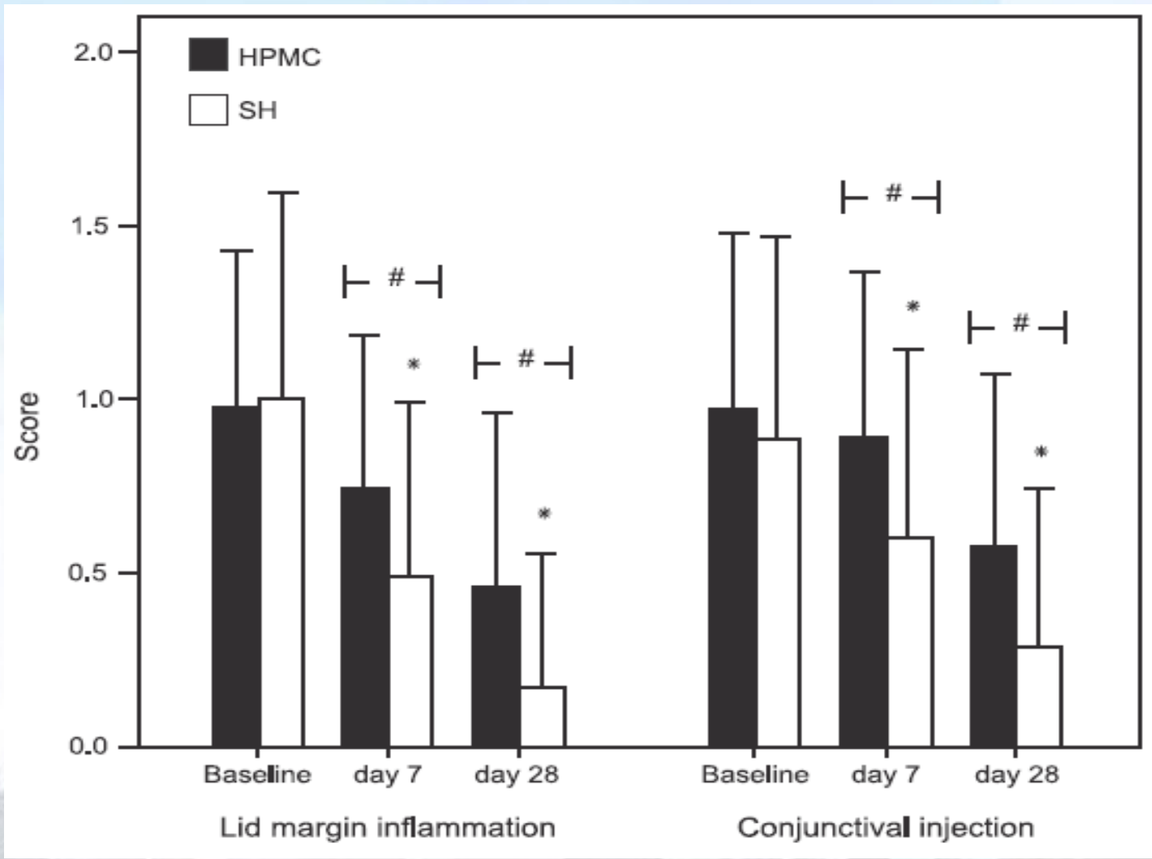

Figure 4: Mean lid margin inflammation and conjunctival injection scores at baseline, D7 and D28 in both groups.