International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

IJMRP

Original Research Article.

Study of Evaluation of Safety and Efficacy of Alcaftadine 0.25% in the Management of Allergic Conjunctivitis at a Tertiary Care Hospital

Sahil Sarpal[1], Amol Chawhan[2*]

[1]Assistant Professor, Department of Ophthalmology,
Meenakshi Medical College Hospital and Research Institute, Kanchipuram, Tamil Nadu, India.
[2*]Associate Professor, Department of Ophthalmology,
Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar, Telangana, India.

ABSTRACT

Background: Ocular allergies are usually categorized into acute or chronic allergic disorders based on their pathological mechanism and clinical expression of the allergic response on the ocular surface. Hence; the present study was conducted for assessing the safety and efficacy of Alcaftadine 0.25%, in the management of allergic conjunctivitis.

Materials & Methods: A total of 20 patients were enrolled. Visits 1 and 2 were screening visits during which the conjunctival allergen challenge (CAC) was conducted, and subjects' eligibility was assessed. During the third visit alcaftadine 0.25% was given. 16 hours after the study medication instillation at visit 3, a CAC was performed to assess duration of action. All the results were recorded in Microsoft excel sheet and were analysed by SPSS software.

Results: Mean age of the patients was 51.2 years. 55 percent of the patients were males. At 3 mins, 5 mins and 7 mins, mean ocular itch scores post- CAC was 0.29, 0.42 and 0.39 respectively. Abnormal eye sensation, Photophobia and Asthenopia were seen in 5 percent of the patients each.

Conclusion: Alcaftadine 0.25% ophthalmic solution was effective and prevented both the symptom of ocular itching and the sign of conjunctival redness of the CAC-induced allergic response.

Key words: Alcaftadine, Allergic Conjunctivitis, Ophthalmic.

***Correspondence to:**

Dr. Amol Chawhan,
Associate Professor,
Department of Ophthalmology,
Chalmeda Anand Rao Institute of Medical Sciences,
Karimnagar, Telangana, India.

Article History:

Received: 28-03-2020, **Revised:** 15-04-2020, **Accepted:** 10-05-2020

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2020.6.3.048	

INTRODUCTION

Allergic disorders of the ocular surface are primarily characterized as IgE-medicated and/or T-lymphocyte-mediated disorders that affect the ocular surface, including the cornea, conjunctiva, and eyelid. Ocular allergies are usually categorized into acute or chronic allergic disorders based on their pathological mechanism and clinical expression of the allergic response on the ocular surface. The acute form includes seasonal allergic conjunctivitis (SAC) and perennial allergic conjunctivitis (PAC). Chronic forms are vernal keratoconjunctivitis (VKC) and atopic keratoconjunctivitis.[1-3]

Allergic conjunctivitis is the most prevalent form of ocular allergy. It is predominantly an IgE-mediated ocular allergy that occurs when airborne allergens induce allergic expression on the ocular surface.[4,5] The treatment and management goals of allergic conjunctivitis are to prevent or minimize the inflammatory cascade associated with allergic response in the early stages of the pathological mechanism. It is of note that activation of histamine receptors on immune and nonimmune cells are associated with allergen- induced inflammation of the conjunctiva and its associated ocular allergic manifestations, including itching, edema, hyperemia, and tearing.[6,7] Hence; the present study was conducted for assessing the safety and efficacy of Alcaftadine 0.25%, in the management of allergic conjunctivitis.

MATERIALS & METHODS

The present study was conducted in the Department of Ophthalmology, Meenakshi Medical College Hospital & Research Institute, Kanchipuram, Tamil Nadu (India) for assessing the safety and efficacy of Alcaftadine 0.25%, in the management of allergic conjunctivitis. A total of 20 patients were enrolled. Visits 1 and 2 were screening visits during which the conjunctival allergen challenge (CAC) was conducted, and subjects' eligibility was assessed. Titration of the allergen dose was done at visit 1; a positive response was defined as a score of ≥2 on a 0–4 scale for both ocular itching and redness in at least two of the three vessel beds at 10 minutes after an allergen challenge. During the third visit alcaftadine 0.25% was given. 16 hours after the study medication instillation at visit 3, a CAC was performed to assess duration of action. All the results were recorded in Microsoft excel sheet and were analysed by SPSS software.

Table 1: Demographic data

Variable		Number	Percentage
Age group	**Less than 45 years**	8	40
	More than 45 years	12	60
Gender	**Males**	11	55
	Females	9	45

Table 2: Ocular itch scores post – CAC

Time point	Mean	SD
3 mins	0.29	0.15
5 mins	0.42	0.21
7 mins	0.39	0.19

Table 3: Incidence of ocular adverse events

Ocular adverse events	Number	Percentage
Abnormal eye sensation	1	5
Photophobia	1	5
Asthenopia	1	5

RESULTS

In the present study, 20 patients were assessed. Mean age of the patients was 51.2 years. 55 percent of the patients were males. At 3 mins, 5 mins and 7 mins, mean ocular itch scores post- CAC was 0.29, 0.42 and 0.39 respectively. Abnormal eye sensation, Photophobia and Asthenopia were seen in 5 percent of the patients each.

DISCUSSION

Allergic disorders of the ocular surface are primarily characterized as IgE- and/or T-lymphocyte-mediated disorders that affect the cornea, conjunctiva, and eyelid. Seasonal allergic conjunctivitis is the most prevalent type of allergic conjunctivitis that impacts the quality of life of patients. Alcaftadine is an efficacious multiple action antiallergic therapeutic agent with inverse agonist activity on H1, H2, and H4 receptors, as well as anti-inflammatory and mast cell stabilizing effects that could provide therapeutic benefits to patients with allergic conjunctivitis.[7- 9]

In the present study, 20 patients were assessed. Mean age of the patients was 51.2 years. 55 percent of the patients were males. At 3 mins, 5 mins and 7 mins, mean ocular itch scores post- CAC was 0.29, 0.42 and 0.39 respectively. McLaurin EB et al evaluated the safety of the once-daily topical ophthalmic solutions, alcaftadine 0.25% and olopatadine 0.2%, in preventing ocular itching associated with allergic conjunctivitis. Subjects were randomized 1:1:1 to receive alcaftadine 0.25%, olopatadine 0.2%, or placebo. Alcaftadine demonstrated a significantly lower mean itch score over all time points compared with olopatadine (0.68 vs. 0.92, respectively; P = 0.0390); both alcaftadine- and olopatadine-treated subjects achieved significantly lower overall mean ocular itching scores compared with placebo (2.10; P < 0.0001 for both actives). Minimal itch over all time points was reported by 76.1% of alcaftadine-treated subjects compared with 58.1% of olopatadine-treated subjects (P = 0.0121). Treatment with alcaftadine 0.25% and olopatadine 0.2% was safe and well tolerated; no serious adverse events were reported. Once-daily alcaftadine 0.25% ophthalmic solution demonstrated greater efficacy in prevention of ocular itching compared with olopatadine 0.2 % at 3 min post- CAC (primary endpoint), and over all time points, 16 h post-treatment instillation.[10] Abnormal eye sensation, Photophobia and Asthenopia were seen in 5 percent of the patients each. In a previous study conducted by Torkildsen G et al, authors evaluated the safety and clinical efficacy of alcaftadine 0.25% ophthalmic solution, a new topical anti-allergic agent for the prevention of the signs and symptoms of allergic conjunctivitis induced by conjunctival allergen challenge (CAC). After 16 hours (Visit 3) and 15 minutes (Visit 4), a CAC was performed, and ocular and nasal symptoms of allergy were graded over a 20-minute period. Clinical and statistical significance were evaluated. Alcaftadine was effective in the prevention of ocular itching based on both clinically relevant and statistically significant differences compared with vehicle (placebo). With an onset of action within 3 minutes and a duration of action of at least 16 hours, the statistically and clinically significant effect of alcaftadine 0.25% on itching make it an important addition to therapy for ocular allergy.[11] Two previous studies have examined the therapeutic effects of both alcaftadine and olopatadine. An early CAC-based clinical study found alcaftadine 0.25% was superior to olopatadine 0.1% for both onset and duration of anti-itch effects.19 The faster onset of effect is consistent with the findings of the present study in which statistically significant lower itch scores were seen at the 3-minute time point post allergen challenge (16 hours post instillation). In another preclinical study, alcaftadine was shown to have a greater effect than olopatadine on both eosinophil recruitment and epithelial junctional protein stability, suggesting a potential for greater efficacy in late-phase allergy. This result, together with an examination of inflammation-induced disruptions in ocular epithelial stability, suggest that efficacy differences between alcaftadine and olopatadine may be related to the greater ability of alcaftadine to prevent the disruption to the ocular surface that follows allergen exposure.[12, 13]

CONCLUSION

From the above results, it can be concluded that alcaftadine 0.25% ophthalmic solution was effective and prevented both the symptom of ocular itching and the sign of conjunctival redness of the CAC-induced allergic response.

REFERENCES

1. Abelson MB, Udell IJ. H2-receptors in the human ocular surface. Arch Ophthalmol. 1981;99(2):302–4.
2. Nakano Y, Takahashi Y, Ono R, et al. Role of histamine H4 receptor in allergic conjunctivitis in mice. Eur J Pharmacol. 2009;608(1–3):71–5.
3. Thurmond RL, Gelfand EW, Dunford PJ. The role of histamine H1 and H4 receptors in allergic inflammation: The search for new antihistamines. Nat Rev Drug Discov. 2008;7(1):41–53.
4. Scoper SV, Berdy GJ, Lichtenstein SJ, Rubin JM, Bloomenstein M, Prouty RE, et al. Perception and quality of life associated with the use of olopatadine 0.2% (Pataday) in patients with active allergic conjunctivitis. Adv Ther. 2007;24:1221–32.
5. Wade L, Bielory L, Rudner S. Ophthalmic antihistamines and H1–H4 receptors. Curr Opin Allergy Clin Immunol. 2012;12:510–6.
6. Abelson MB, Chambers WA, Smith LM. Conjunctival allergen challenge. A clinical approach to studying allergic conjunctivitis. Arch Ophthalmol. 1990;108:84–8.
7. Abelson MB, Loeffler O. Conjunctival allergen challenge: models in the investigation of ocular allergy. Curr Allergy Asthma Rep. 2003;3:363–8.
8. Abelson MB. Evaluation of olopatadine, a new ophthalmic antiallergic agent with dual activity, using the conjunctival allergen challenge model. Ann Allergy Asthma Immunol. 1998;81:211–8.
9. Zampeli E, Thurmond RL, Tiligada E. The histamine H4 receptor antagonist JNJ7777120 induces increases in the histamine content of the rat conjunctiva. Inflamm Res. 2009;58(6):285–91.
10. McLaurin EB et al. Ocular Itch Relief with Alcaftadine 0.25% Versus Olopatadine 0.2% in Allergic Conjunctivitis: Pooled Analysis of Two Multicenter Randomized Clinical Trials. Adv Ther. 2014; 31(10): 1059–71.
11. Torkildsen G, Shedden A. The safety and efficacy of alcaftadine 0.25% ophthalmic solution for the prevention of itching associated with allergic conjunctivitis. Curr Med Res Opin. 2011 Mar;27(3):623-31.
12. Ono SJ, Lane K. Comparison of effects of alcaftadine and olopatadine on conjunctival epithelium and eosinophil recruitment in a murine model of allergic conjunctivitis. Drug Des Devel Ther. 2011;5:77–84.
13. Contreras-Ruiz L, Schulze U, García-Posadas L, et al. Structural and functional alteration of corneal epithelial barrier under inflammatory conditions. Curr Eye Res. 2012;37(11):971–81.

Source of Support: Nil. **Conflict of Interest:** None Declared.

Cite this article as: Sahil Sarpal, Amol Chawhan. Study of Evaluation of Safety and Efficacy of Alcaftadine 0.25% in the Management of Allergic Conjunctivitis at a Tertiary Care Hospital. Int J Med Res Prof. 2020 May; 6(3): 217-19.
DOI:10.21276/ijmrp.2020.6.3.048