

Alcaftadine 0.25% Vs Olapatadine 0.2% Ophthalmic Solutions in Allergic Conjunctivitis: A Study in a Clinical Setting in South India

Dr Akash R¹, Dr Panimalar A Veeramani², Dr.Taarika G^{3*}

¹ Junior Resident, Department of Ophthalmology, Saveetha Medical College, Thandalam, Chennai, Tamil Nadu, India

² Associate Professor, Department of Ophthalmology, Saveetha Medical College, Thandalam, Chennai, Tamil Nadu, India

³ Junior Resident, Department of Ophthalmology, Saveetha Medical College, Thandalam, Chennai, Tamil Nadu, India

Abstract: Objective: Although allergic conjunctivitis seldom causes visual impairment, it holds significance due to its frequency and severity. This study was carried out to compare the safety and efficacy of Alcaftadine 0.25% and Olapatadine 0.2% ophthalmic solutions in treating the symptoms and signs of allergic conjunctivitis as there is not much literature comparing these two drugs directly. **Materials and methods:** This is a prospective, observer masked study of 80 patients with allergic conjunctivitis assigned to two groups-Group I: 40 patients received Alcaftadine 0.25% and Group II:40 patients received Olapatadine 0.2% ophthalmic solution and relief of symptoms were noted and assessed with a follow at 1 week and 1 month. **Results:** Eyes treated with Alcaftadine 0.25% had significantly low mean itch score of 0.6 compared to Olapatadine 0.2% ophthalmic solution which was 1. Eyes treated with both Alcaftadine 0.25% and Olapatadine 0.2% ophthalmic solutions reduced lid swelling, redness and discharge; safe and no serious adverse effects were encountered. **Conclusion:** Both Alcaftadine 0.25% and Olapatadine 0.2% ophthalmic solutions used in the study are safe and effective in treating the symptoms and signs of Allergic conjunctivitis. However, Alcaftadine 0.25% ophthalmic solution is comparatively more efficacious.

Keywords: Alcaftadine 0.25% , Olapatadine 0.2%, Safety, Efficacy, Allergic conjunctivitis.

1. INTRODUCTION

Conjunctivitis, defined as an inflammation of the conjunctiva presents itself in many types. Based on the conjunctival response, it is classified into follicular (viral, chlamydial), papillary (allergic) and granulomatous (fungal, parasitic, foreign body) types¹. Allergy is relatively very common among the general population accounting to more than 15% globally⁸. Allergic conjunctivitis is very rarely followed by visual impairment like several deadly ocular diseases. The importance given to it arises from its frequency and severity.

The allergic reaction in the conjunctiva maybe acute like seasonal allergic or 'hay fever conjunctivitis', perennial allergic conjunctivitis or chronic like the vernal conjunctivitis, giant papillary conjunctivitis and atopic keratoconjunctivitis². Contact lens associated giant papillary conjunctivitis is not considered among the group of diseases causing ocular allergy by some experts. They rather consider it as a chronic ocular micro-trauma related disorder³.

The main etiological factors that trigger allergic conjunctivitis are natural allergens like dust , mites, grass and tree pollen; change in climate, pollutants from fuel combustion and tobacco smoke⁵. The clinical symptoms and signs seen in allergic conjunctivitis are due to allergy or hypersensitivity reactions which maybe immediate (humoral) or delayed (cellular).

Simple allergic conjunctivitis (Seasonal and Perennial allergic conjunctivitis) is Type-1 hypersensitivity reaction mediated by IgE and subsequent activation of mast cells³. Vernal keratoconjunctivitis is regarded mainly due to Th2

lymphocyte alteration and the IgE mediated response due to allergens is considered secondary. Both IgE (Type I hypersensitivity reaction) and cell mediated immune mechanisms (Type IV hypersensitivity reaction) are responsible for atopic keratoconjunctivitis⁶.

It was observed recently that the tight junctions contribute to the pathogenesis of allergic conjunctivitis through the presence of proteolytic enzymes in fecal pellets of mites leading to cleavage of tight junction and thereby increasing epithelial permeability⁷.

Ocular itching, the hallmark symptom of allergic conjunctivitis is due to activation of H1 receptors on the conjunctiva by histamine released from activation of mast cells. Dilatation of the vascular endothelium seen as redness is due to the binding of histamine to H1 and H2 receptors⁸. The symptoms like itching, redness, burning, lacrimation is seen to cause personality and behavioral changes as patients keep their faces away from light especially in severe cases of allergic conjunctivitis⁴.

In recent years, in addition to avoidance of allergens and using lubricants, the treatment modalities for allergic conjunctivitis has markedly expanded enabling more focused specific therapy, but often leaving both clinicians and patients confused over the wide range of options⁹. It encompasses a wide group of drugs like antihistamines, mast cell stabilizers, vasoconstrictors, corticosteroids, non steroidal anti inflammatory drugs and sodium chromoglycate⁸.

As monotherapy, antihistamines have become a comparatively better choice for many early and some late allergic reactions because of its dual function of acting on both the inflammation process and allergic events⁹. Relief due to topical vasoconstrictors is short lived and its overuse may cause rebound hyperemia and irritation. Mast cell stabilizers have a very slow onset of action. Steroids are rarely preferred for chronic allergy due to its significant side effects like raised intraocular pressure and cataract formation.

Alcaftadine, a chemical entity developed as an antiallergic stands out from other antihistamines as it was also found to have anti inflammatory action against infiltrated eosinophils in a guinea pig model of allergic conjunctivitis along with unique spectrum of histamine receptor sensitivity¹⁰. Olapatadine ophthalmic solution is found to be safe and effective in the treatment of allergic conjunctivitis, with 0.1% being optimal. This study has been undertaken with the main objective of comparing the efficacy and safety of Alcaftadine 0.25% and Olapatadine 0.2% ophthalmic solutions in treating the signs and symptoms of allergic conjunctivitis as there is not much literature comparing these directly done in Southern India.

2. METHODOLOGY

Study design:

This was a prospective, observer masked study conducted in a single tertiary care centre in South India between January, 2021 and September, 2021. The study proposal and informed consent was approved by the institutional ethical committee (IEC). Studies were conducted according to Helsinki declaration revised in 2008. Patients presenting to Ophthalmology outpatient department with allergic conjunctivitis willing to participate in the study were informed beforehand about the objective of the study and were asked to sign the informed consent form ensuring them that their participation was totally voluntary.

Study eligibility criteria:

Patients presenting to Ophthalmology outpatient department with allergic conjunctivitis willing to participate in the study were included. History of allergy or sensitivity to the study medications, contact lens wearers, Presence of an active ocular infection and other ocular conditions like red eye, pregnant or lactating women, actively taking antihistamines or steroids or undergoing any ocular surgery during the time of study were taken as exclusion criteria.

Treatment and assessments:

Patients were assigned to two groups randomly.

Group I: Received topical 0.25% Alcaftadine ophthalmic solution BD

Group II: Received topical 0.2% Olapatadine ophthalmic solution BD

Before initiating treatment and assessment, patients were asked to fill out a questionnaire grading their symptoms and the signs were assessed by a masked investigator.

Ocular redness,itching and discharge were graded using a 4-point scale (0-3).

GRADING	Ocular redness	Discharge	Itching
Grade 0	No redness	No discharge	No itching
Grade 1	Mild redness	Mild discharge	Mild itching
Grade 2	Moderate redness	Moderate discharge	Moderate itching
Grade 3	Severe redness	Severe discharge	Severe itching

The first dose of antihistamines both Alcaftadine 0.25% and Opatadine 0.2% was done at Ophthalmology outpatient department.After 15 minutes of instillation,patients were asked to fill out the same questionnaire grading their symptoms which would give way to the relief attained.The same was followed the next day,at 1 week and 1 month in addition to which the signs were assessed by the masked investigator.

Data analysis and statistical methods:

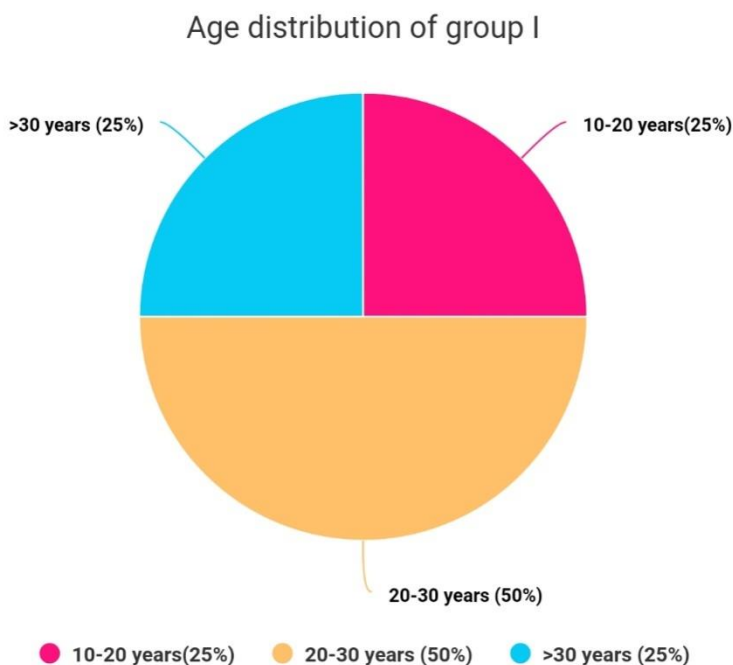
The data obtained was analyzed using Microsoft Excel and Statistical Package for the Social Sciences(SPSS)version 25.

Categorical variables were summarized using frequencies and percentages. Continuous variables were summarized using descriptive statistics which comprises of the number of observations, mean, median, standard deviation, minimum and maximum values. For tests of significance, Chi-squared test was used for qualitative data and one way ANOVA for qualitative data. All P values were kept at a significance level of 0.05%.

3. RESULTS:

Socio demographic details:

A total of 80 patients participated in the study. There was no study drop out as all patients were regularly followed up. Among the 40 patients enrolled in group I, 25(62.5%) are males and 15(37.5%) are females. In group II, 20(50%) are males and 20(50%)are females. The age distribution of patients assigned in groups I and II are given in figure 1.



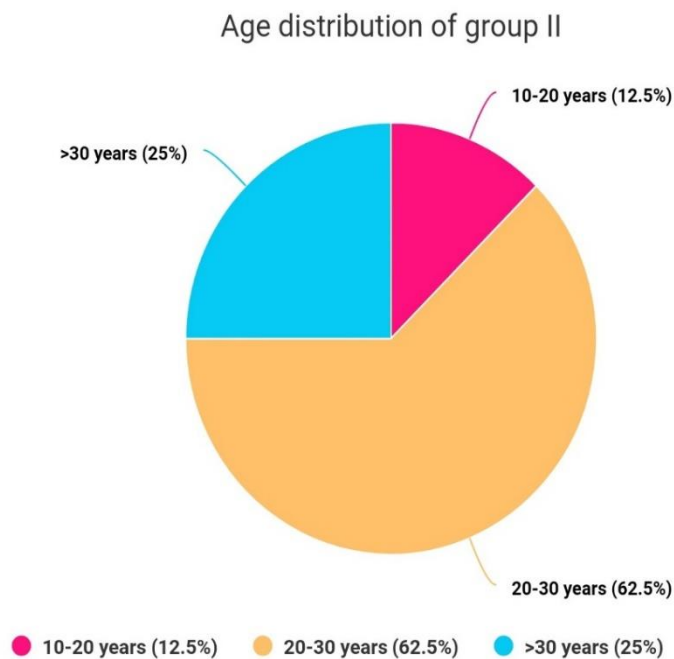


Figure 1: Age distribution of patients enrolled in group I and II.

Efficacy outcome measures:

For the primary efficacy end point, ocular itching 15 minutes after instilling the ophthalmic solutions were recorded and then followed up at 1 day, 1 week and a month. Mean itch score at baseline was 2.5 for group I and 2.7 for group II (figure 2).

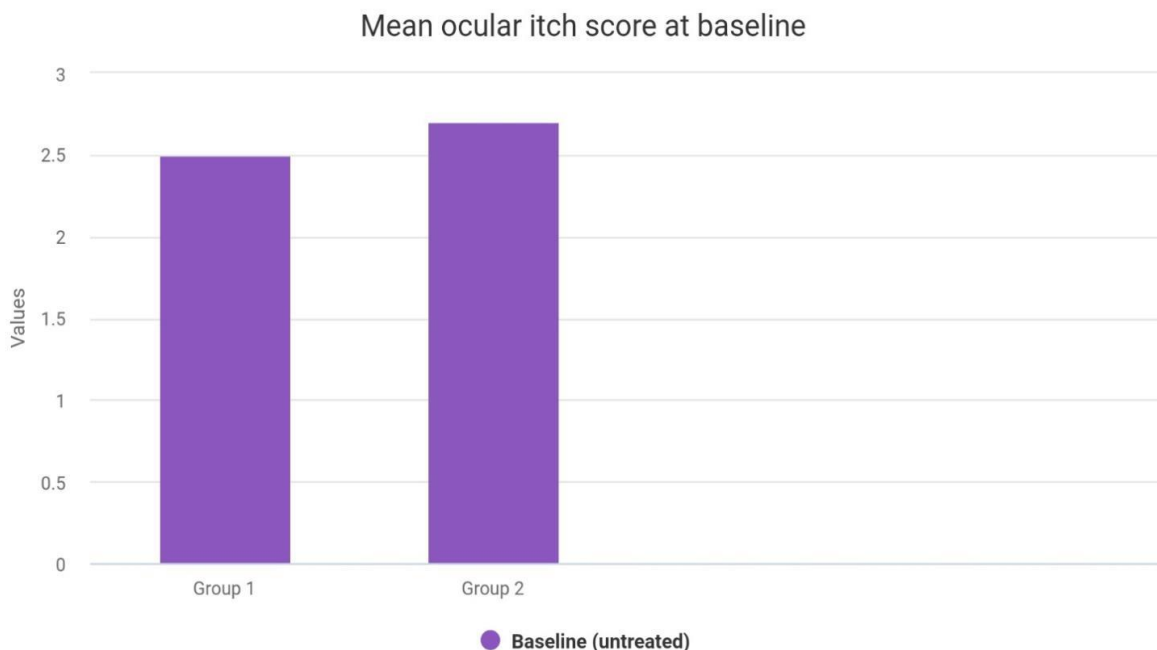


Figure 2: Mean ocular itch score at baseline.

It was seen that 15 minutes after instillation of Alcaftadine 0.25% ophthalmic solution in group I, mean itch score improved to 0.6. In group II, 15 minutes after instilling Olapatadine ophthalmic solution, the mean itch score was 1 (figure 3).

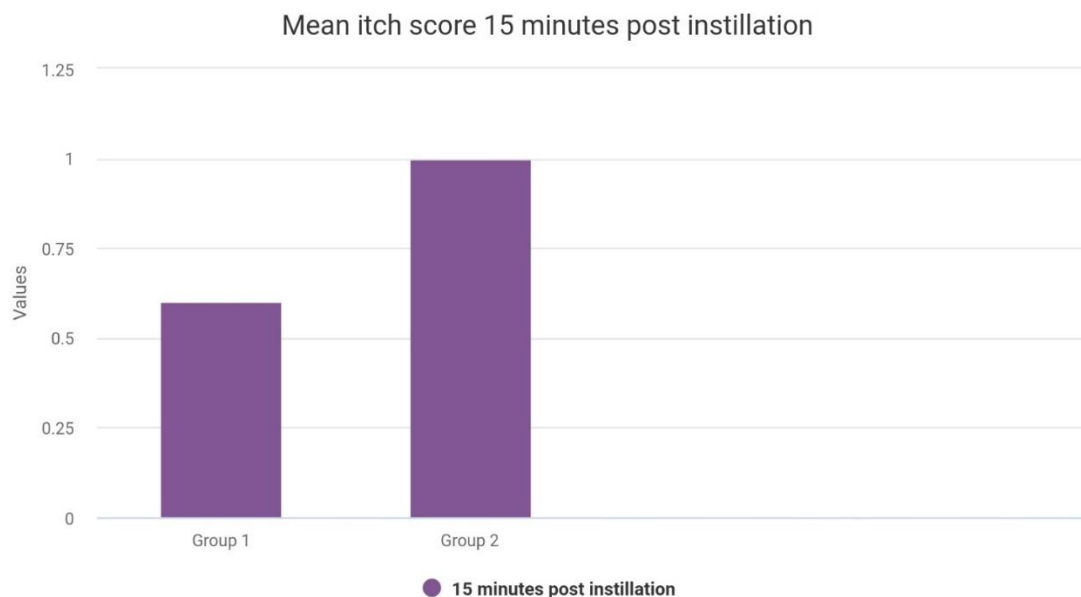


Figure 3: Mean itch score 15 minutes post instillation.

Redness, lid swelling and discharge relief was almost the same in both the group of patients. None of the patients required alternate line of pharmacological therapy for worsening of symptoms and there were no serious adverse reactions to these drugs encountered.

4. DISCUSSION

According to a study conducted by Dudeja L et al., Alcaftadine 0.25% and Olapatadine 0.2% was proved to be equally efficacious¹³ which contradicts the results in our study where Alcaftadine 0.25% showed better efficacy in treating the signs and symptoms of allergic conjunctivitis when compared to Olapatadine 0.2% ophthalmic solution. Similar superiority of Alcaftadine 0.25% over Olapatadine 0.2% was also seen in a study conducted by Mclaurin EB et al., where it was found that Alcaftadine had a lower overall mean itch score at 3,5,7 minutes than the patients treated with Olapatadine^{12,13}.

Analogous to other studies conducted to compare the efficacy of Alcaftadine 0.25% and Olapatadine 0.2% this study also found the both the ophthalmic solutions were generally well tolerated and there were no serious adverse effects^{11,13}.

In a study conducted by Greiner JV et al., Alcaftadine 0.25% had a rapid onset of action superior to Olapatadine 0.1% which is seen in this study too⁸. Quick onset and longer duration of action which are key aspects in treating the signs and symptoms of allergic conjunctivitis are observed to be established by Alcaftadine 0.25% ophthalmic solution in our study which goes along with other studies done¹¹.

Although a very meticulous follow up and evaluation of the findings was done, the sample size is small. Also, this study was conducted in a single tertiary care centre. This limitation hampers the representativeness of the data and its generalizability. Future research based on large sample size and more study setting will validate our findings.

5. CONCLUSION

Both Alcaftadine 0.25% and Olapatadine 0.2% ophthalmic solutions are safe and effective in treating the symptoms and signs of Allergic conjunctivitis. However, Alcaftadine 0.25% ophthalmic solution was found to be comparatively more efficacious.

6. REFERENCES

- [1] Sihota R, Tandon R. Parsons' Diseases of the Eye. Elsevier India; 2011.
- [2] Ono SJ, Abelson MB. Allergic conjunctivitis: update on pathophysiology and prospects for future treatment. Journal of Allergy and Clinical Immunology. 2005 Jan 1;115(1):118-22.

- [3] La Rosa M, Lionetti E, Reibaldi M, Russo A, Longo A, Leonardi S, Tomarchio S, Avitabile T, Reibaldi A. Allergic conjunctivitis: a comprehensive review of the literature. *Italian journal of pediatrics*. 2013 Dec;39(1):1-8.
- [4] Kosrirukvongs P, Visitsunthorn N, Vichyanond P, Bunnag C. Allergic conjunctivitis. *Asian Pacific journal of allergy and immunology*. 2001 Dec 1;19(4):237.
- [5] Thong BY. Allergic conjunctivitis in Asia. *Asia Pacific Allergy*. 2017 Apr 1;7(2):57-64.
- [6] 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 design, development and therapy*. 2011;5:77.
- [7] Wan H, Winton HL, Soeller C, Taylor GW, Gruenert DC, Thompson PJ, Cannell MB, Stewart GA, Garrod DR, Robinson C. The transmembrane protein occludin of epithelial tight junctions is a functional target for serine peptidases from faecal pellets of *Dermatophagoides pteronyssinus*. *Clinical & Experimental Allergy*. 2001 Feb;31(2):279-94.
- [8] Greiner JV, Edwards-Swanson K, Ingerman A. Evaluation of alcaftadine 0.25% ophthalmic solution in acute allergic conjunctivitis at 15 minutes and 16 hours after instillation versus placebo and olopatadine 0.1%. *Clinical ophthalmology (Auckland, NZ)*. 2011;5:87.
- [9] Ciprandi G, Buscaglia S, Cerqueti PM, Canonica GW. Drug treatment of allergic conjunctivitis. *Drugs*. 1992 Feb;43(2):154-76.
- [10] Bohets H, McGowan C, Mannens G, Schroeder N, Edwards-Swanson K, Shapiro A. Clinical pharmacology of alcaftadine, a novel antihistamine for the prevention of allergic conjunctivitis. *Journal of ocular pharmacology and therapeutics*. 2011 Apr 1;27(2):187-95.
- [11] Ackerman S, D'Ambrosio Jr F, Greiner JV, Villanueva L, Ciolino JB, Hollander DA. A multicenter evaluation of the efficacy and duration of action of alcaftadine 0.25% and olopatadine 0.2% in the conjunctival allergen challenge model. *Journal of asthma and allergy*. 2013;6:43.
- [12] McLaurin EB, Marsico NP, Ciolino JB, Villanueva L, Williams JM, Hollander DA. Alcaftadine 0.25% versus olopatadine 0.2% in prevention of ocular itching in allergic conjunctivitis. *Journal of Allergy and Clinical Immunology*. 2014 Feb 1;133(2):AB278.
- [13] Dudeja L, Janakiraman A, Dudeja I, Sane K, Babu M. Observer-masked trial comparing efficacy of topical olopatadine (0.1%), bepotastine (1.5%), and alcaftadine (0.25%) in mild to moderate allergic conjunctivitis. *Indian journal of ophthalmology*. 2019 Sep;67(9):1400.
- [14] Torkildsen G, Shedden A. The safety and efficacy of alcaftadine 0.25% ophthalmic solution for the prevention of itching associated with allergic conjunctivitis. *Current medical research and opinion*. 2011 Mar 1;27(3):623-31.

DOI: <https://doi.org/10.15379/ijmst.v10i1.2675>

This is an open access article licensed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>), which permits unrestricted, non-commercial use, distribution and reproduction in any medium, provided the work is properly cited.