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

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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) types. Allergy is relatively very common among the general population accounting to more than 15% globally. 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 keratoconjunctivitis. 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 disorder.

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 smoke. 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 cells. 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 keratoconjunctivitis.

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 permeability.

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 receptors. 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 conjunctivitis.

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 options. It encompasses a wide group of drugs like antihistamines, mast cell stabilizers, vasoconstrictors, corticosteroids, non steroidal anti inflammatory drugs and sodium chromoglycate.

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 events. 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 sensitivity. 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).

<table>
<thead>
<tr>
<th>GRADING</th>
<th>Ocular redness</th>
<th>Discharge</th>
<th>Itching</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No redness</td>
<td>No discharge</td>
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</tr>
<tr>
<td>Grade 1</td>
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</tr>
<tr>
<td>Grade 2</td>
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</tr>
<tr>
<td>Grade 3</td>
<td>Severe redness</td>
<td>Severe discharge</td>
<td>Severe itching</td>
</tr>
</tbody>
</table>

The first dose of antihistamines both Alcaftadine 0.25% and Olapatadine 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).
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 efficacious\(^1\) 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\(^1\)\(^2\)\(^3\).

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\(^1\)\(^2\)\(^3\).

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 too\(^8\). 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 done\(^1\)\(^1\)\(^1\).

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


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