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Original Research Article

Comparison of efficacy of topical alcaftadine (0.25%) versus olopatadine (0.1%) in allergic conjunctivitis

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ABSTRACT

Purpose: The most common atopic ocular condition in clinical practice is allergic conjunctivitis. One of the preferred treatment options for allergic conjunctivitis is anti histamines eye drops. The study purpose is to compare the clinical efficacy between topical alcaftadine 0.25% and olopatadine hydrochloride 0.1% in allergic conjunctivitis patients.

Materials and Methods: A prospective, randomized, open label, parallel group, comparative study was conducted on 60 Patients with bilateral allergic conjunctivitis (30 in each group) after taking an informed written consent and was evaluated from May 2018 to November 2018. Patients were randomized into 2 groups of 30 each, group A received topical Alcaftadine 0.25% twice daily and patients in Group B received topical olopatadine hydrochloride 0.1% twice daily for 2 weeks. The patients were evaluated on first visit (baseline) followed by 7th and 14th day after starting the treatment. At each visit signs and symptoms were evaluated and rated using a scale from 0-3(0-Absent, 1- mild, 2 moderate and 3- severe). The change from baseline in the mean scores of itching, hyperemia, photophobia and tearing on day 14 is the primary outcome variable.

Results: The signs and symptoms of allergic conjunctivitis were reduced by 2 weeks from baseline after using both the drugs. Relative significant efficacy was achieved in alcaftadine group for Itching, hyperemia and photophobia, but not for tearing (p=0.3).

Conclusion: When compared to 0.1% olopatadine hydrochloride, 0.25% alcaftadine is more effective in reducing the symptoms of all types of allergic conjunctivitis except those mentioned in exclusion criteria.

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1. Introduction

Allergic conjunctivitis is one of the most common atopic ocular conditions encountered in clinical practice. Early phase reactions of allergic conjunctivitis are mediated majorly by Histamine.¹ Human conjunctiva is rich in Mast cells which play vital role in pathogenesis of allergic conjunctivitis.^{2,3} Degranulation of mast cells occur in conjunctiva of susceptible individuals following exposure to allergens leading to cross linking of pairs of Ig-E and release of inflammatory mediators like leukotrienes,

tryptase, histamine, cytokines and PAF.²

Allergic tissues showed five times over expressions of H4 receptors followed by H1 and H2 receptors as demonstrated by semi-quantitative RT-PCR. A Primary treatment for allergic conjunctivitis being topical antihistamines, Alcaftadine has broad-spectrum action on H1, H2 and H4 receptor and also has immune modulation action on cell recruitment and stabilizes the mast cell.⁴ Olopatadine hydrochloride is a dual-acting drug with selective H₁ receptor antagonistic action and mast cell stabilization action.⁵

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2. Materials and Methods

A prospective, randomized, open label, parallel group, comparative study was conducted in Bangalore at a tertiary care centre. Institutional ethical committee approval was obtained for the study. 60 consecutive patients of bilateral allergic conjunctivitis (30 in group A and 30 in group B) attending OPD and willing to participate after signed informed consent were enrolled. Exclusion criteria was patients on topical / oral corticosteroids within 2 weeks of enrollment, on lubricants, dry eye disease, past contact lens wearers, ocular surgeries, previous herpes infection, bacterial or viral conjunctivitis, severe allergic conjunctivitis like atopic keratoconjunctivitis, vernal keratoconjunctivitis, pregnant & lactating women, subjects already taking the study drugs and known hypersensitivity to it.

Allergic conjunctivitis subjects were selected and randomized into 2 groups of 30 each by simple random sampling into Group- A and Group- B. Patients in Group - A received topical Alcaftadine 0.25% 1 drop to each eye twice daily and patients in Group-B received topical Olopatadine Hydrochloride 0.1% 1 drop to each eye twice daily for 2 weeks in both the group. Detailed history and clinical examination – slit lamp examination were performed and documented in a prescribed format in each visit. For uniform grading of symptoms and signs at each visit, we used scoring scales from 0-3 (0-Absent, 1- mild, 2-moderate, 3- severe).⁶ 30 subjects per group was the sample size. Statistical Package for the Social Sciences (SPSS) version 11.5 and Microsoft excel were used to analyse the data. Mean and SD for analysing descriptive data and Paired sample T Test for analyzing of significance. Two tailed P values at a significance level of 0.05.

3. Results

Age distribution of patients in our study (Figure 1), there were higher number of patients between the age group of 21 to 24 years than in age group above 28 years. 66.66% of our study groups were males and 33.33% were females (Figure 2). 63.33% of the study population was from the urban areas and 36.66% were from the rural areas.

Itching scores in Group A receiving alcaftadine 0.25%, the Mean and SD on day 14 for Itching was 0.23 and 0.430 versus 0.67 and 0.711 in Group B receiving olopatadine hydrochloride 0.1% (p-0.008 statistically significant). (Figure 4) hyperaemia scores in Group A receiving alcaftadine 0.25%, the Mean and SD on day 14 for hyperaemia was 0.23 and 0.430 versus 1.10 and 0.885 in Group B receiving olopatadine hydrochloride 0.1% (p-0.002 statistically significant). (Figure 5)

In case of Photophobia the study groups could not be compared as all study subjects were symptom free in Group A, hence we could not arrive at the statistical Significance.

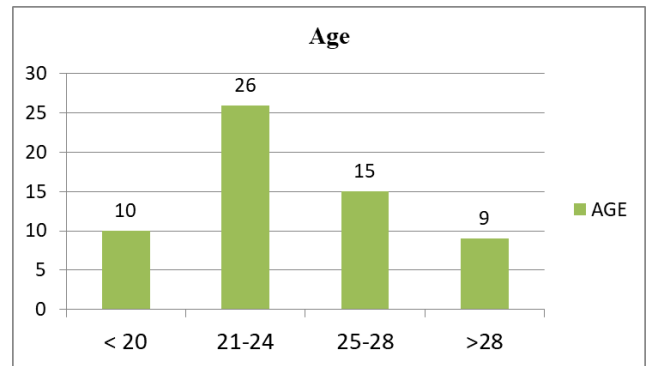


Fig. 1: Age distribution in the study population

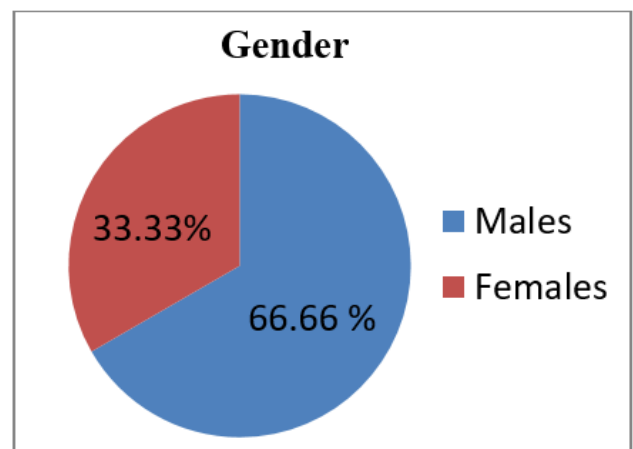


Fig. 2: Gender distribution in the study population

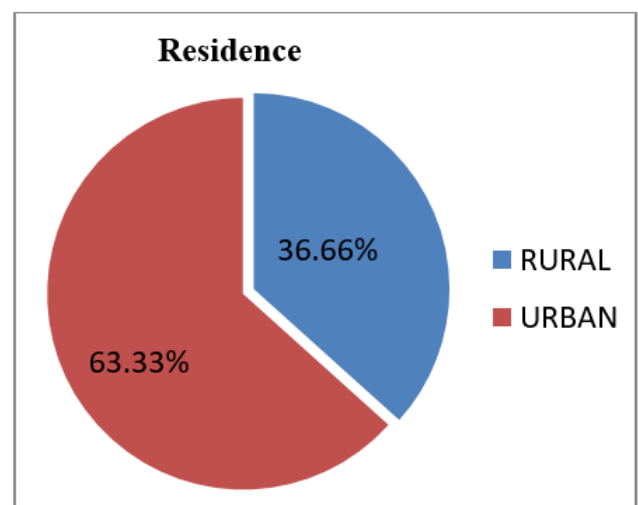


Fig. 3: Distribution of residence in the study population

Table 1: Scoring of signs and symptoms of allergic conjunctivitis.⁶

Signs & Symptoms	Scoring of Signs and Symptoms of Allergic Conjunctivitis			
	0-Absent	1-Mild	2-Moderate	3-Severe
Itching	Absent	Occasional itching without tendency to rub eyes	Frequent itching with tendency to rub eyes	Continuous itching, frequently rubbing eyes
Hyperaemia	Absent	Slightly dilated blood vessels, pink	More Apparent vessel dilatation, more intense color	Numerous and obvious dilated vessels, color deep red
Photophobia	Absent	Occasional	Continuously Photophobic	Eye responds with blepharospasm on exposure to light
Tearing	Absent	Occasional no complaints of discomfort	Frequent, feeling of discomfort	Persistent accompanied by swabbing of eyes

Table 2: Statistical table for the signs and symptoms on Day 0, 7 & 14 in the study population

Symptom	Days	Group-A		Group-B		P value (<0.05-Statistically Significant)
		MEAN	SD	MEAN	SD	
Itching	D0	2.73	0.583	2.73	0.521	0.54
	D7	1.93	0.828	1.97	0.928	0.54
	D14	0.23	0.430	0.67	0.711	0.008
Tearing	D0	1.13	0.346	1.03	1.159	0.01
	D7	0.13	0.346	0.23	0.430	0.24
	D14	0.07	0.254	0.10	0.305	0.3
Hyperaemia	D0	2.87	0.346	2.70	0.596	0.004
	D7	2.67	0.479	2.63	0.615	0.184
	D14	0.23	0.430	1.10	0.885	0.002
Photophobia	D0	0.67	0.959	0.80	0.997	0.83
	D7	0.43	0.817	0.53	0.900	0.60
	D14	0.00	0.00	0.007	0.254	

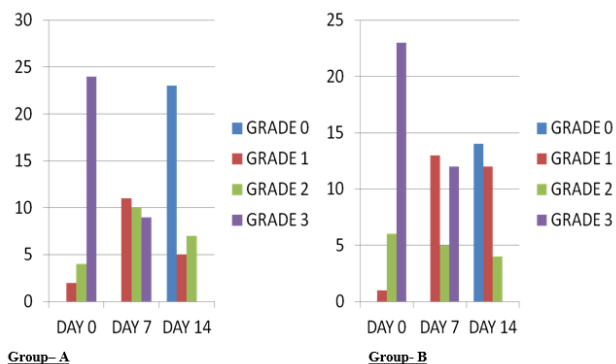


Fig. 4: Itching scores in the study population

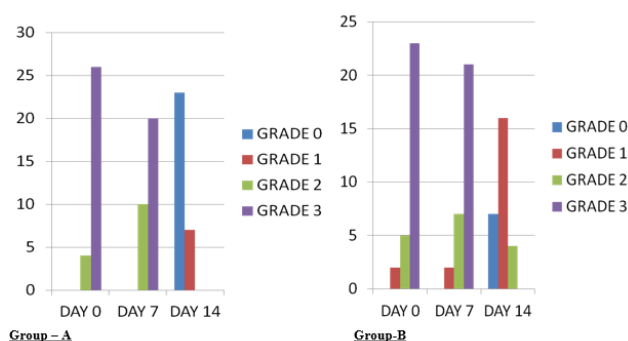


Fig. 5: Hyperaemia scores in the study population

For tearing, Group A Receiving Alcaftadine 0.25% the Mean and SD on day 14 for Tearing was 0.07 and 0.254 Versus 0.10 and 0.305 in Group B receiving Olopatadine Hydrochloride 0.1% (p-0.3 not statistically significant).

4. Discussion

We conducted a prospective, randomized, open label, parallel group, comparative study to find out whether topical Alcaftadine is more effective than olopatadine 0.1% eye drop for managing allergic conjunctivitis. The aim of the study is to improve the quality of life by reducing the signs and symptoms effectively. Analysis of Data from 60 patients

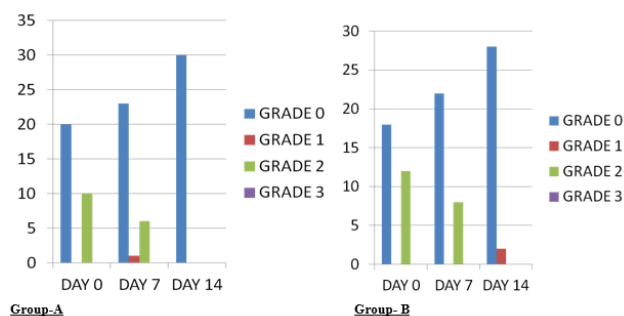


Fig. 6: Photophobia scores in the study population

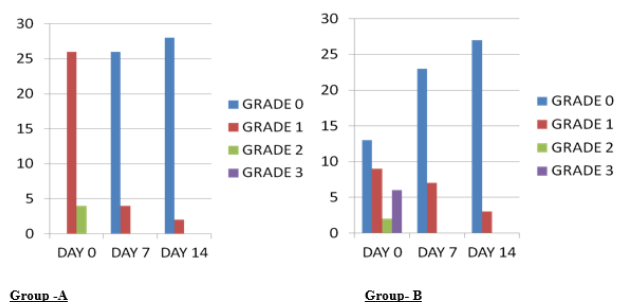


Fig. 7: Tearing scores in the study population

(30 in group A and 30 in group B) for overall efficacy in reducing the signs and symptoms of allergic conjunctivitis at 2 weeks after instillation, we found that Alcaftadine 0.25% efficacy was statistically significantly higher compared to olopatadine 0.1% eye drops.

In another comparative study which enrolled 285 subjects following conjunctival allergen challenge test it was noted that the mean itch score was lower at 3, 5 and 7 minute in Alcaftadine group when compared to olopatadine group.⁷

Another study test in mice showed Alcaftadine treated animals had reduced conjunctival eosinophil infiltration.⁸

Alcaftadine displays other therapeutic properties such as ability to reduce conjunctival eosinophil recruitment and a protective effect on epithelial tight junction protein expression.⁸

Primary outcome was that Alcaftadine 0.25% is more effective in treating itching, hyperemia and photophobia than 0.1% olopatadine hydrochloride.

Secondary outcome was that patients were comfortable with Alcaftadine 0.25% during the study and showed good response after 2 weeks of study than 0.1% olopatadine hydrochloride.

Literature reviews shows that Alcaftadine 0.25% is more effective and safer than 0.1% olopatadine hydrochloride.

No adverse effect noted in patients during the study period in both the groups.

5. Strengths of the Study

We have selected a newer generation antihistaminic which can play predominant role in reducing allergic conjunctivitis.

6. Conclusion

Reduction of signs and symptoms of allergic conjunctivitis at 2 weeks from baseline was noted in both the groups but Alcaftadine 0.25% group showed more significantly effective reduction.

7. Limitations

Fewer study subjects, different ethnic groups not included.

8. Source of Funding

None.

9. Conflict of Interest

The authors declare no conflict of interest.

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