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Original Research Article

# Comparative Study of Safety and Efficacy of Alcaftadine 0.25%, Olopatadine Hydrochloride 0.2% and Bepotastine Besilate 1.5% in Allergic Conjunctivitis in Santhal Pargana Jharkhand Population

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**Conflict of interest: Nil**

**Abstract**

**Background:** Allergic conjunctivitis (AC) is an often underdiagnosed, non-infectious subset of conjunctivitis. Signs and symptoms of AC are variable and can be severe, impacting quality of life and potentially threatening vision. Hence, an ideal antiallergenic medication is mandatory to heal such a vision-threatening disease.

**Method:** Out of 90 AC patients, 30 were treated with topical 0.25% Alcaftadine eye drops, 30 patients with topical 0.2% olopatadine, and the remaining 30 with 1.5% Bepotastine besilate eye drops, naming them as groups A, B, C, respectively, and they were followed up on day 1, day 3, 7 day, day 14 and results among all three medications were noted.

**Results:** Day 14 ocular symptom scores and conjunctival hyperemia scores had significant p-values ($p<0.001$).

**Conclusion:** All three topical ophthalmic medications used in the present study are safe. However, bepotastine and alcaftadine are superior to olopatadine in resolving the signs and symptoms of AC.

**Keywords:** Slit lamp, Toss, Hyperalmia, Allergic Conjunctivitis (AC), Ocular Morbidity.



## Introduction

Allergic conjunctivitis (AC) is an inflammation of the conjunctiva that involves an immune mechanism mediated by immunoglobulin (IgE) and mast cells. AC is an often underdiagnosed, noninfectious subset of conjunctivitis [1]. It results from exposure to allergens such as pollen, animal dander, and environmental stimuli.

Seasonal AC and perennial AC are the major subcategories of AC. Seasonal AC makes up 90% of AC cases altogether; other AC includes atopic keratoconjunctivitis (AKC) and vernal keratoconjunctivitis [2]. Signs and symptoms of AC are variable and can be severe, impacting quality of life and potentially threatening vision [3].

Treating this complex and multifactorial condition begins with removing the inciting allergen. This is difficult to do, as it is often in contact with a combination of allergens that produces this response [4]. Anti-allergen drugs alcaftadine 0.25%, olopatadine 0.2%, and Besilate 1.5% were experimented comprehensively to find out an ideal anti-allergic medication.

## Material and Method

90 (ninety) adult patients who regularly visited the ophthalmology department of Sadar Hospital, Dumka, cum the upgraded Phulo Jhamo Medical College, Dumka, Jharkhand 814101, were studied.

**Inclusion Criteria:** Diagnosis of allergic conjunctivitis was made clinically according to signs and symptoms. Toss, all patients above 18 years. The patients who gave their consent for the study in writing were selected.

**Exclusion Criteria:** Patients using topical steroids or topical immunosuppressive eye drops, contact lens wearers, patients with an intraocular pressure more than 2:1 mm Hg in either eye or any type of glaucoma, history of hypersensitivity to the present using drugs (including benzalkonium chloride). History of herpetic infection, an active ocular infection, or any significant illness; taking systemic steroids or antihistamines within seven days; pregnant or lactating mothers were excluded from the study.

**Method: A** total of 90 patients with mild or moderate allergic conjunctivitis were randomized into three groups with an allocation ratio of 1:1:1 using a computer-generated random number sequence to receive topical anti-allergic medications for 14 days as follows.

- Group A: Topical 0.25% Alcaftadine eye drops OD.
- Group B: Topical 0.2% olopatadine eye drops OD
- Topical 1.5% Bepotastine besilate eye drops OD

A complete general physical and ophthalmologic examination was carried out in every patient, and they were examined, and their baseline symptoms and signs (Toss) were recorded. Demographic data, ocular and medical histories, concomitant medications, physical examinations, and clinical examinations, including vital signs, were recorded in a pro forma at the baseline visit. (visit-1) Follow-up visits were on the 3rd day (visit-2), day 7 (visit-3), and day 14 (visit-4) after administration of drugs. At each follow-up visit, data on concomitant medications, ocular symptoms, and ocular signs using hyperaemia scores graded by slit-lamp examination and adverse events were collected. In case of relapse, the patient was asked to visit OPD on day 21. Medication compliance was assessed with the help of a medication compliance card, and the safety of study medications was assessed by adverse drug reactions (ADRs). The duration of the study was from November 2024 to December 2025

**Statistical Analysis:** Baseline demographic studies, total ocular symptoms score (TOSS) at different visits, and conjunctival hyperaemia score at different follow-ups were compared in all three groups. The test is used to study the various parameters. The statistical analysis was carried out using SPSS software. The ratio of male and female was 2:1.

**Observation and Results**

**Table 1:** Total ocular symptoms score (TOSS) and hyperaemia scores grades are mentioned (by WHO)

**Table 2:** Age (years) in all three groups are more or less same hence p value is insignificant (p>0.94).

- In gender study: 19 (63.3%) were male, 11 (36.6%) female in group A, 16 (33.3%) male, 14 (46.6%) female in group B, 22 (73.3%) male, 8 (26.6%) females in group C.
- Toss has more or less same mean values hence p vales has insignificant p value

**Table 3:** In the study ocular symptoms scores at different interval Baseline Day 1, Day 3, Day 7 has insignificant p value (p>0.490) and only Day 14 had highly significant p value (p<0.001).

**Table 4r:** Study of conjunctival hyperaemia scores at different follow-up Day 1, Day 3, Day 7 had insignificant p value (p<0.87) and Day 14 had highly significant p value (p>0.001).

**Table 1: TOSS (Total ocular symptom score) and hyperaemia score grading**

| | |
|---|---|
| (A) | |
| 0 – Indicating no symptoms | |
| 1+ Mild symptoms of discomfort which were just noticeable | |
| 2 + severe symptoms interfering with daily activities | |
| (B) Hyperaemia score – Grading O-No-Normal | |
| 0 – 5 – Trace | Inconsistent rose red hyperaemia |
| 1 – Mild | Reddish color |
| 2 – moderate | Bright red color |
| 3 – severe | Bright and intense diffuse hyperaemia |

**Table 2: Demographic profile of the patients**

| **Patients** | **Group A (30)** | **Group B (30)** | **Group C (30)** | **F value** | **P value** |
|---|---|---|---|---|---|
| Age (years) Mean (±SD) | 28.60 (± 7.8) | 28.60 (± 7.7) | 28.05 (± 6.90) | 0.054 | p>0.90 |
| **Gender (%)** | | | | | |
| Male | 19 (63.3%) | 16 (53.3%) | 22 (73.3%) | -- | -- |
| Female | 11 (36.6%) | 14 (46.6%) | 8 (26.6%) | -- | -- |
| TOSS (Total ocular symptom score) | 7.60 (± 2.30) | 7.64 (± 2.28) | 7.48 (± 2.20) | 0.057 | p>0.944 |

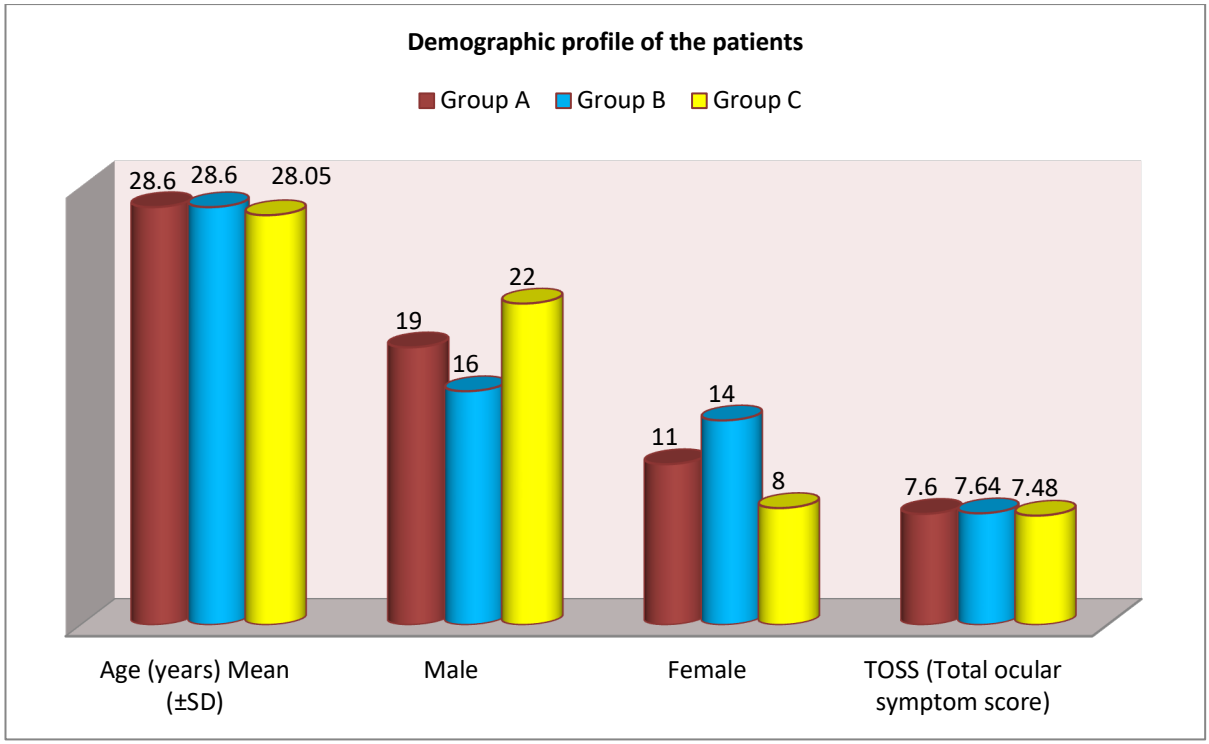


**Figure 1: Demographic profile of the patients**

**Table 3: Total ocular symptom scores at different follow up (ANOVA Test)**

| Details | Group A Alcaftadine Mean (±SD) (30) | Group B Olopatadine Mean (±SD) (30) | Group A Bepotastine Mean (±SD) (30) | F value | P value |
|---|---|---|---|---|---|
| Day 1 Baseline | 7.3 (± 2.30) | 7.3 (± 2.28) | 7.2 (± 2.32) | 0.019 | P>0.981 |
| Day 3 | 5.4 (± 1.58) | 5.4 (± 1.60) | 4.6 (± 1.50) | 2.62 | p>0.078 |
| Day 7 | 2.4 (± 1.03) | 2.5 (± 0.90) | 2.2 (± 1.05) | 0.70 | p>0.496 |
| Day 14 | 0.2 (± 0.04) | 0.4 (± 0.05) | 0.1 (± 0.03) | 420 | P<0.001 |

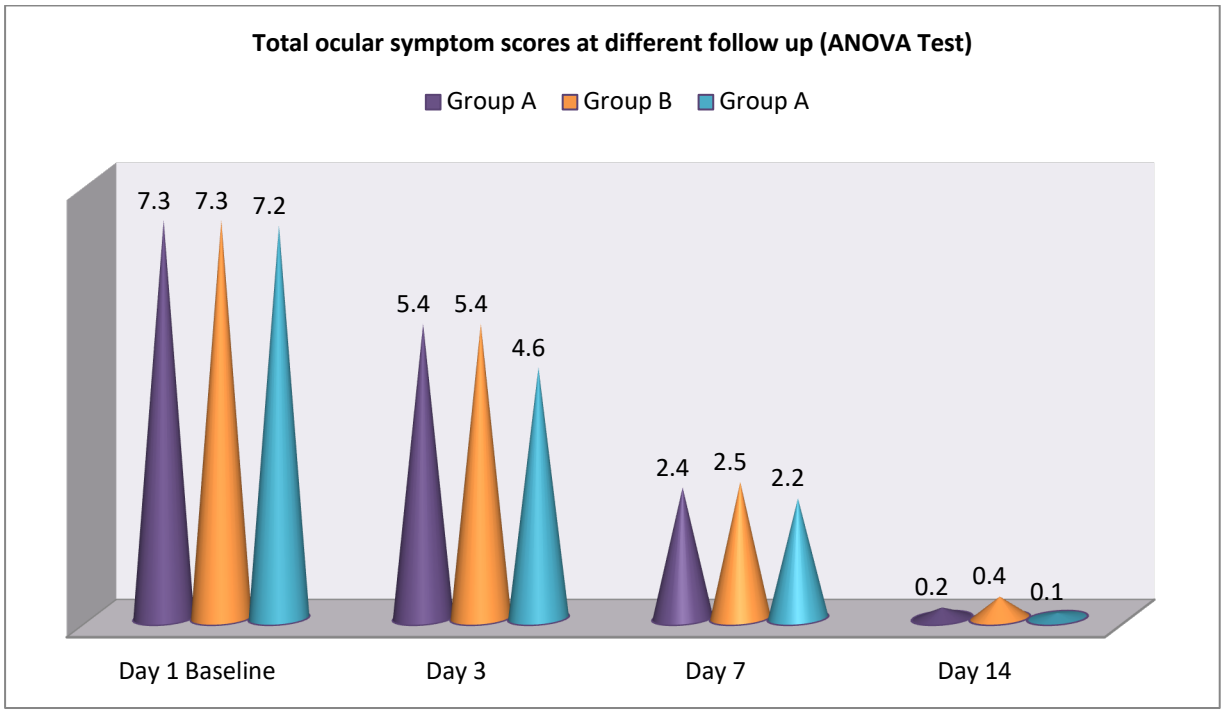


**Figure 2: Total ocular symptom scores at different follow up (ANOVA Test)**

**Table 4: Conjunctival Hyperaemia score at different follow up (ANOVA Test)**

| Details | Group A (30) | Group B (30) | Group C (30) | F value | P value |
|---|---|---|---|---|---|
| Days 1 (Baseline) | 1.2 (± 0.86) | 1.3 (± 0.88) | 1.3 (± 0.82) | 0.137 | p>0.872 |
| Day 3 | 0.7 (± 0.58) | 0.7 (± 0.58) | 0.7 (± 0.55) | 0.00 | p>0.98 |
| Day 7 | 0.3 (± 0.26) | 0.3 (± 0.26) | 0.3 (± 0.26) | 0.00 | p>1.00 |
| Day 14 | 0.009 (± 0.004) | 0.04 (± 0.01) | 0.009 (± 0.02) | 137 | P<0.001 |

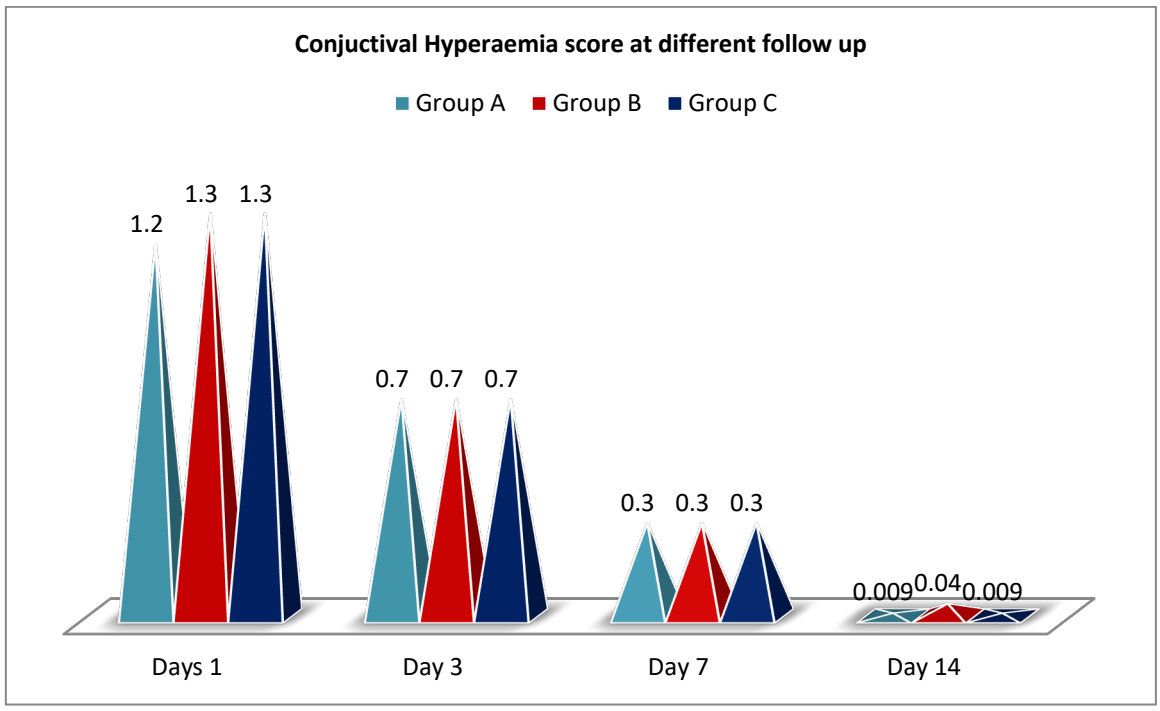


**Figure 3: Conjuctival Hyperaemia score at different follow up**

## Discussion

Present comparative study of safety and efficacy of Alcaftadine 0.25%, Olopatadine hydrochloride 0.2%, and Bepotastine besilate 1.5% in treating allergic conjunctivitis of the Jharkhand population. In the study of total ocular symptom score (TOSS) at different follow-ups on day 14, there was a significant p-value (p<0.001) (Table 3). Similarly, on the day of the 14th visit assessment, the conjunctival hyperaemia score had a significant p-value (p<0.001) (Table 4). These findings are more or less in agreement with previous studies [5,6,7].

Newer topical agents have both antihistamine and mast cell stabilizer action. Their use can control acute symptoms and prevent relapses. The efficacy of these anti-allergic medications over placebo has been proven in a study conducted by previous workers [8].

All three medications showed significant relief in symptoms of redness and itching, which was proved statistically. In a comparative study, it is observed that bepotastine provided better relief for ocular allergy symptoms and non-ocular symptoms associated with allergic conjunctivitis, such as runny nose, compared to olopatadine. It is also noted that a higher percentage of patients preferred bepotastine to olopatadine for treatment [9]. It is also studied that a decrease in the expression of the junctional protein ZO-1, which is caused by allergens, is healed by Alcaftadine compared to olopatadine. In addition to this, Alcaftadine significantly lowered conjunctival eosinophil infiltration caused by allergen challenge in animal studies [10].

In the present study, alcaftadine was able to protect epithelial tight junction protein markers from allergic inflammation-based degradation, but olopatadine failed to protect from degradation [11]. It supported better efficacy of alcaftadine compared to olopatadine for the treatment of allergic conjunctivitis.

## Summary and Conclusion

Present comparative studies of all three topical ophthalmic medications used for the safe and effective therapy of allergic conjunctivitis (Alcaftadine and Bepostatine) obtained better results compared to olopatadine in the resolution of signs and symptoms in allergic conjunctivitis. Conjunctival hyperaemia decreased in all three treatment groups, but there was a significant reduction in the Alcaftadine and Bepotastine groups at the follow-up visit compared to the

Olopatadine group. The present study demands that such studies must be conducted in a large number of patients to confirm present results and findings.

**Limitation of study:** Owing to remote location of research centre, small number of patients lack of latest techniques we have limited finding and results.

This research work was approved by the ethical committee of phulo Jhamo medical college Dumka, Jharkhand 814101.

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