

## Original Research

### A comparative study of olopatadine 0.1% ophthalmic drops with bepotastine besilate 1.5% ophthalmic drops in patients with vernal keratoconjunctivitis

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#### ABSTRACT:

**Background:** Vernal keratoconjunctivitis is a persistent, bilateral, occasionally asymmetric, cyclically worsened, allergic ocular surface inflammation that includes bulbar and/or tarsal conjunctiva. The present study compared olopatadine 0.1% ophthalmic drops with bepotastine besilate 1.5% ophthalmic drops in patients with vernal keratoconjunctivitis (VKC). **Materials & Methods:** 60 patients of vernal keratoconjunctivitis was prescribed olopatadine 0.1% ophthalmic drops and group II bepotastine besilate 1.5% ophthalmic drops, one drop each in the affected eye twice daily for 5 weeks. Ocular symptoms such as itching, discomfort, and watering were recorded. **Results:** The mean itching score at 1st week was 2.90 and 2.87, at 3<sup>rd</sup> week was 2.14 and 2.10 and at 5th week was 1.54 and 1.16 in group I and II respectively. Ocular discomfort score was at 1st week was 2.78 and 2.68, at 3rd week was 2.00 and 1.82 and at 5th week was 1.24 and 0.68 in group I and II respectively. Watering score was 2.72 and 2.60, at 3rd week was 1.68 and 1.26 and at 5th week was 1.12 and 0.47. Conjunctival hyperaemia scores at 1st week was 2.52 and 2.80, at 3rd week was 1.30 and 1.84 and at 5th week was 1.06 and 0.36 in group I and II respectively. The difference was significant ( $P < 0.05$ ). **Conclusion:** Authors found that bepotastine eye drops proved quicker relief of symptoms and signs compared to olopatadine eye drops in patients with vernal keratoconjunctivitis.

**Key words:** Bepotastine, olopatadine, vernal keratoconjunctivitis.

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#### INTRODUCTION

The conjunctiva of the eye is continually exposed to a variety of airborne antigens that can lead to inflammation, termed allergic conjunctivitis which is an ocular surface inflammatory disease that affects approximately 40% of the global population.<sup>1</sup> It is predominantly Ig E-mediated Type I hypersensitivity reaction where allergen binds to specific Ig E molecules, triggers mast cell degranulation and subsequent increase in histamine leading to activation of both H<sub>1</sub> and H<sub>2</sub> types of histamine receptors.<sup>2</sup> Vernal keratoconjunctivitis is a persistent, bilateral, occasionally asymmetric, cyclically worsened, allergic ocular surface inflammation that includes bulbar and/or tarsal conjunctiva.

Pharmacological treatment of allergic conjunctivitis includes H<sub>1</sub> receptor blockade, mast cell stabilization, and blocking of cytokine production and prostaglandin formation.<sup>3</sup> Olopatadine hydrochloride is a second-generation antihistamine (as well as anticholinergic and mast cell stabilizer) that exerts comprehensive pharmacological actions such as histamine H<sub>1</sub> receptor antagonism, chemical mediator suppression, tachykinin release inhibitory action, and eosinophil infiltrative suppression. Bepotastine is a second-generation nonsedating antihistamine with diverse mechanisms being appropriately investigated in both animal studies and clinical trials.<sup>4</sup> The US Food and Drug Administration accepted its use in the management of allergic conjunctivitis, with the dose

of twice daily in patients 2 years of age and above in 2009. It is a double-acting agent with both extremely selective histamine H1 receptor antagonism and mast cell-stabilizing effects. It exerts anti-inflammatory actions by inhibiting leukotriene B and improving eosinophilic chemotaxis and activation.<sup>5</sup> The present study compared olopatadine 0.1% ophthalmic drops with bepotastine besilate 1.5% ophthalmic drops in patients with vernal keratoconjunctivitis (VKC).

## MATERIALS & METHODS

The present study comprised of 60 patients of vernal keratoconjunctivitis of both genders. All were informed and their written consent was obtained.

Demographic data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 30 each. Group I were prescribed olopatadine 0.1% ophthalmic drops and group II bepotastine besilate 1.5% ophthalmic drops, one drop each in the affected eye twice daily for 5 weeks. Clinical and slit-lamp examination of eyes were performed. The ocular signs such as conjunctival hyperemia and papillary hypertrophy were evaluated. The gradings was used such as absence of signs- grade 0, mild signs- grade 1, moderate signs- grade 2, and severe signs- grade 3. Ocular symptoms such as itching, discomfort, and watering were recorded. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

## RESULTS

**Table I Distribution of patients**

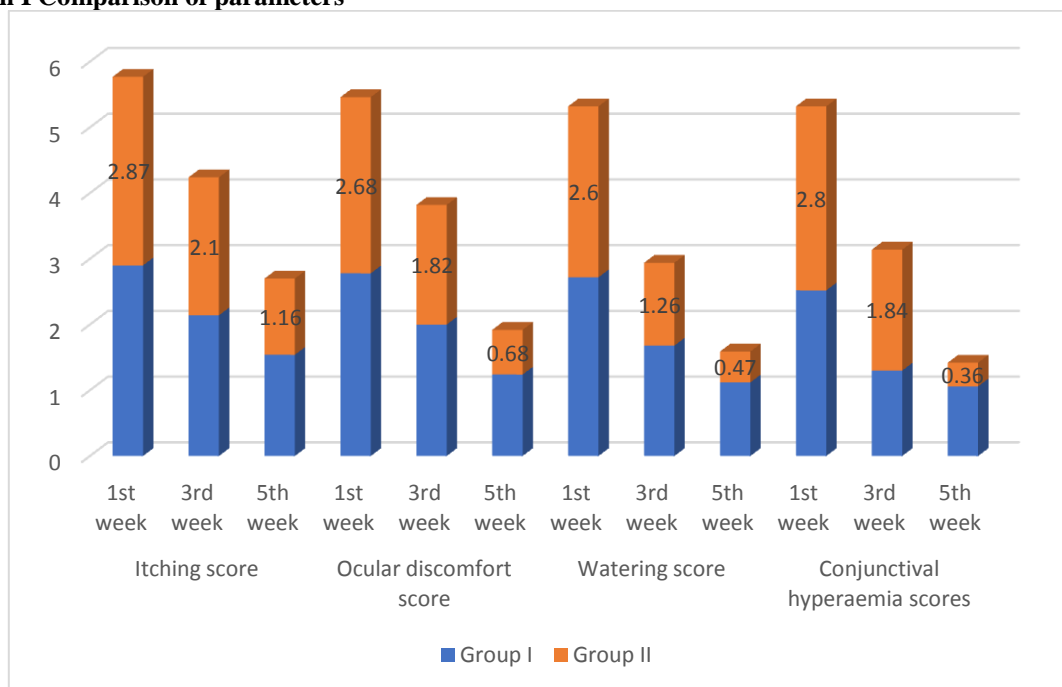
Groups	Group I	Group II
Drug	Olopatadine 0.1%	Bepotastine besilate 1.5%
M:F	16:14	17:13

Table I shows that group I had 16 males and 14 females and group II had 17 males and 13 females.

**Table II Comparison of parameters**

Parameters	Variables	Group I	Group II	P value
Itching score	1 <sup>st</sup> week	2.90	2.87	0.05
	3 <sup>rd</sup> week	2.14	2.10	
	5 <sup>th</sup> week	1.54	1.16	
Ocular discomfort score	1 <sup>st</sup> week	2.78	2.68	0.02
	3 <sup>rd</sup> week	2.00	1.82	
	5 <sup>th</sup> week	1.24	0.68	
Watering score	1 <sup>st</sup> week	2.72	2.60	0.01
	3 <sup>rd</sup> week	1.68	1.26	
	5 <sup>th</sup> week	1.12	0.47	
Conjunctival hyperaemia scores	1 <sup>st</sup> week	2.52	2.80	0.04
	3 <sup>rd</sup> week	1.30	1.84	
	5 <sup>th</sup> week	1.06	0.36	

Table II, graph I shows that mean itching score at 1<sup>st</sup> week was 2.90 and 2.87, at 3<sup>rd</sup> week was 2.14 and 2.10 and at 5<sup>th</sup> week was 1.54 and 1.16 in group I and II respectively. Ocular discomfort score was at 1<sup>st</sup> week was 2.78 and 2.68, at 3<sup>rd</sup> week was 2.00 and 1.82 and at 5<sup>th</sup> week was 1.24 and 0.68 in group I and II respectively. Watering score was 2.72 and 2.60, at 3<sup>rd</sup> week was 1.68 and 1.26 and at 5<sup>th</sup> week was 1.12 and 0.47. Conjunctival hyperaemia scores at 1<sup>st</sup> week was 2.52 and 2.80, at 3<sup>rd</sup> week was 1.30 and 1.84 and at 5<sup>th</sup> week was 1.06 and 0.36 in group I and II respectively. The difference was significant (P< 0.05).

**Graph I Comparison of parameters**

## DISCUSSION

Ocular allergy is a commonly encountered pathology in clinical practice, with an increase in the number of patients noticed in the last decade with a prevalence of approximately 40% of the population globally.<sup>6</sup> Avoidance of allergens plays a key role in the prevention of allergic conjunctivitis. Addition of anti-histamine reduces inflammation, whereas mast cell stabilizers prevent mast cell degranulation on an exposure to allergens.<sup>7</sup> Topical corticosteroids are the most potent agents to control inflammatory symptoms of allergic conjunctivitis but there is a risk of many side-effects.<sup>8</sup> Newer topical agents have both anti-histamine and mast cell stabilization action. Their use can control acute symptoms and prevent relapses.<sup>9</sup> The present study compared olopatadine 0.1% ophthalmic drops with bepotastine besilate 1.5% ophthalmic drops in patients with vernal keratoconjunctivitis (VKC).

In present study, group I had 16 males and 14 females and group II had 17 males and 13 females. Sruthi et al<sup>10</sup> included 50 patients diagnosed with VKC, of which Group A and Group B were given olopatadine 0.1% ophthalmic drops and bepotastine besilate 1.5% ophthalmic drops, respectively, twice a day for 8 weeks. The reduction in signs and symptoms in both groups was compared. Overall, 50 cases were included in the study, 72% of total patients were in the age group of 5–10 years, and 28% were in the age group of 11–15 years. There were 39 males and 11 females. After 8 weeks of follow-up, the mean reduction in the scoring of symptoms and signs provided better and quicker relief of watering, ocular discomfort, and conjunctival hyperemia with bepotastine 1.5% eye drops. Olopatadine 0.1% eye drops provided faster improvement in papillary

hypertrophy. Both drugs were equally effective in reducing itching. Laboratory findings of absolute eosinophil count had no statistical significance in between the two groups.

In present study we found that mean itching score at 1st week was 2.90 and 2.87, at 3<sup>rd</sup> week was 2.14 and 2.10 and at 5th week was 1.54 and 1.16 in group I and II respectively. Ocular discomfort score was at 1st week was 2.78 and 2.68, at 3rd week was 2.00 and 1.82 and at 5th week was 1.24 and 0.68 in group I and II respectively. Watering score was 2.72 and 2.60, at 3rd week was 1.68 and 1.26 and at 5th week was 1.12 and 0.47. Conjunctival hyperaemia scores at 1st week was 2.52 and 2.80, at 3rd week was 1.30 and 1.84 and at 5th week was 1.06 and 0.36 in group I and II respectively. Ayyappanavar et al<sup>11</sup> compared the efficacy and safety of Alcaftadine 0.25%, Olopatadine hydrochloride 0.2%, and Bepotastine besilate 1.5% ophthalmic solutions in the treatment of allergic conjunctivitis. 180 patients with mild to moderate allergic conjunctivitis, randomized into three groups of 60 patients each. Each group was assigned to be treated with one of the three treatment options namely Alcaftadine 0.25%, Olopatadine hydrochloride 0.2% and Bepotastine besilate 1.5% ophthalmic solutions. Patients were followed-up at regular intervals with relief and resolution of symptoms and signs noted using Total Ocular Scoring System (TOSS) and hyperaemia scale. All three topical medications were effective in resolving symptoms of the patients with mild to moderate allergic conjunctivitis. Baseline mean TOSS scores for Alcaftadine group, Olopatadine group and Bepotastine besilate group were (7.68±2.32), (7.65±2.32) and (7.45±2.27) respectively as compared to the corresponding TOSS scores on 14th Day (4th visit) which were (0.2 ±

0.43), ( $0.4 \pm 0.56$ ) and ( $0.1 \pm 0.36$ ) respectively. The resolution of symptoms in the Bepotastine and Alcaftadine groups was significantly profound as compared to the Olopatadine group ( $p = 0.008$ ). Bepotastine and Alcaftadine groups significantly reduced allergic conjunctivitis symptoms compared to Olopatadine group ( $p = 0.008$ ).

## CONCLUSION

Authors found that bepotastine eye drops proved quicker relief of symptoms and signs compared to olopatadine eye drops in patients with vernal keratoconjunctivitis.

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