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Comparative Clinical Efficacy of Bepotastine Besilate versus Olopatadine Hcl in Seasonal Allergic Conjuctivitis.

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ABSTRACT

Background: Aim-To study comparative efficacy of bepotastine besilate 1.5% vs olopatadine hcl 0.1% in seasonal allergic conjunctivitis. **Methods:** In this randomized, placebo controlled study 128 patients with the clinical diagnosis of SAC were assigned into two groups. First group received olopatadine in one eye and placebo in the contralateral eye whereas second group received bepotastine in one eye and placebo in the contralateral. Olopatadine hydrochloride 0.1%, bepotastine 1.5% ophthalmic solutions were used in twice daily dosing. Preservative free artificial tear drops were used as placebo. Patients with clinical diagnosis of allergic conjunctivitis with no concurrent ocular disease were enrolled in this stud. Patients with severe allergic conjunctivitis with involvement of cornea or requiring systemic therapy for same, history of hypersensitivity to either of agent. Prior history of ocular herpes infection, retinal detachment or diabetic retinopathy, dry eye, prior or current use of systemic or topical steroids, NSAIDs, anticholinergics, immunosuppressants or antihistamines and ocular surgery within 2 weeks were excluded from the study. Eligible patients underwent full ophthalmological examination and were randomly allocated to the two groups. Objective signs and subjective symptoms were observed at baseline (before treatment) and on 3rd, 7th and15th day after treatment initiation. The clinical signs (chemosis, hyperemia,mucus secretion, eyelid edema, papillary hyperplasia) and symptoms(itching and tearing) were evaluated summing up the score using a 3-point scale. **Results:** At the day 3,some ocular symptoms like itching,redness ,mucous secretion improved in the patients using bepotastine. However foreign body sensation ,papillary reaction was not subsided .in patients using olopatadine 0.1%,70% of cases showed improvement at day 3 follow up. At the end of 7 days all the symptoms and signs subsided in the patients using bepotastine,but in case olopatadine foreign body sensation and papillary reaction did not improve in some cases (12%). At the end of day 15, all the signs and symptoms improved in all patients either using bepotastine or olopatadine. Whereas the eyes with placebo treatment did not show any significant improvement at the end of day 3,7,15.. **Conclusion:** Bepotastine 1.5 % appears to be better than olopatadine 0.2% in improving ocular symptoms due to seasonal allergic conjunctivitis.

Keywords: Bepotastine Besilate, Olopatadine, Seasonal Allergic Conjuctivitis.

INTRODUCTION

Seasonal and perennial allergic conjunctivitis represent the majority of diagnoses in ocular allergic cases. Seasonal and perennial allergic rhinitis and conjunctivitis cause disruption in daily activities, which is reflected by diminished quality of life measures. Managing allergy effectively requires adequate relief of symptoms and prevention of future symptoms. With this approach, patients have reported enhanced quality of life.[1]

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Allergic conjunctivitis is typically a type 1 IgE-mediated hypersensitivity reaction. The ocular allergic response is a cascade of events that are co-ordinated by mast cells. The presence of an allergen makes the body to be an antigen specific response, releasing cytokines and producing antigen-specific immunoglobulin E (IgE). Then IgE binds to mast cells with release of histamine and further release of cytokines, prostaglandins and platelet-activating factor with other intermediaries. These intermediaries cause an allergic inflammation and symptoms through the activation of inflammatory cells. This process could be progress to chronic allergic inflammation where there is proliferation of fibroblast in the conjunctiva with development of papillae in some patients.[2]

The comparatively large surface area of the conjunctiva, which is rich in vascular supply, and degranulation of mast cells make allergic conjunctivitis a particularly vexing form of allergy for affected patients. As such, appropriate diagnosis and effective treatment can have a positive impact on patient's quality of life and disease management. Also meeting a patient's perceived needs is paramount for effective allergy management,

particularly with ocular allergy, due to the eyes habitual with exposure to the environment.[3]

Topically applied ophthalmic agents are the principal treatment method for SAC. Olopatadine is a first generation anti-histamine, dual action, in terms of both mast cell degranulation inhibition and histamine H1 receptor blockage. This agent has a rapid onset due to antihistamine activity and prolonged duration of action due to mast cell stabilization, which allows for a twice daily dosage. Whereas bepotastine besilate is second generation anti-histaminic, H1 receptor blocker. Both the drugs used in this study are effective in alleviating the symptoms of SAC as shown in previous studies and being used routinely for treating SAC.[4] This study compares the efficacy between Bepatostine eye drops and olopatadine in inhibiting the signs and symptoms of SAC.

MATERIALS AND METHODS

In this randomized, placebo controlled study 128 patients with the clinical diagnosis of SAC were assigned into two groups. First group received olopatadine in one eye and placebo in the contralateral eye, whereas second group received bepotastine in one eye and placebo in the contralateral. Olopatadine hydrochloride 0.1%, bepotastine 0.3% ophthalmic solutions were used in twice daily dosing. Preservative free artificial tear drops were used as placebo.

Subjects with severe allergic conjunctivitis with involvement of cornea or requiring systemic therapy for same, prior history of ocular herpes infection, retinal detachment or diabetic retinopathy, dry eye, prior or current use of systemic or topical steroids, NSAIDs, anticholinergics, immunosuppressants or antihistamines and ocular surgery within 8 weeks were excluded from the study.

Eligible patients underwent full ophthalmological examination and were randomly allocated to the two groups. Objective signs and subjective symptoms were observed at baseline (before treatment) and on 3rd, 7th and15th day after treatment initiation. The clinical signs (chemosis, hyperemia,mucus secretion, eyelid oedema, papillary hyperplasia) and symptoms(itching and tearing) were evaluated summing up the score using a 3-point scale.

Inclusion Criteria

1. Patients with clinical diagnosis of refractive VKC whose symptoms did not subside with antihistaminic/mast-cell stabilizer/topical steroids.
2. Patients who respond to steroid but develop steroid toxicity

Exclusion Criteria

1. Patient having one useful eye
2. Patients using contact lens
3. Patients with any other active ocular inflammatory condition
4. Patients with hypersensitivity reaction
5. Those patient who lost to follow-up

Table 1: Scoring of Signs and Symptoms of Allergic Conjunctivitis.[5-7]

Score

Itching

0 – None

1 – Intermittent tickling sensation, involving more than corner of the eye

2 – Mild continuous itch, without desire to rub

3 – Severe itch with desire to rub

Hyperaemia

0 – None

1 – Mild, slightly dilated blood vessels, pink in colour, may be quadrantal

2 – Moderate, more apparent vessel dilation, vessel colour is more intense and involves most of vessel bed

3 – Severe, numerous and obvious dilated blood vessels, colour deep red and not quadrantic

Chemosis

0 – None

1 – Minimal

2 – Localised areas of chemosis

3 – Diffuse obvious chemosis

Mucus secretion

0 – None

1 – Present at medial canthus / caruncle

2 – Strands of mucus visible in interpalpebral area

3 – Visible accumulation of stringy mucus on lower lid margin

Eyelid oedema 0 – None

1 – Minimal

2 – Moderate

3 – Severe

Papillary hyperplasia

0 – None

1 – Size 0.1 to 0.2mm

2 – Size 0.3 to 0.5mm

3 – Size more than or equal to 0.6mm

Tearing 0 – None

1 - Occasional

2 – Frequent but not hampers quality of vision

3 – All day long hampering quality of vision

RESULTS

There were no significant differences among the groups regarding baseline scores. At all follow up visits, in both groups, scores for ocular itching, conjunctival redness, tearing, chemosis, mucus secretion, eyelid swelling and papillary hyperplasia were significantly improved in drug-treated eyes compared with placebo-treated eyes ($p<0.03$ for olopatadine group and $p < 0.01$ for bepotastine group). All parameters improved less on 3rd day of

the treatment in both groups, however, significant reduction in clinical signs and symptoms were seen on7th and 15th day compared with those receiving placebo. Bepotastine was found superior to Olopatadine in reducing itching (p=0.021), hyperaemia (p=0.016), mucus secretion (p=0.034), chemosis (p=0.031), eyelid edema (p=0.013) and papillary hyperplasia (p=0.031) and both drugs were similar in alleviating tearing (p =0.103).

DISCUSSION

The increasing prevalence of allergic conjunctivitis and its deleterious effects on vision and ocular comfort necessitates the use of a safe, highly effective, and comfortable topical medicine. However, the current literature is lacking comparative data to assist the eye care professional in selecting the appropriate initial topical treatment.[8.9] The majority of patients presenting at the clinical site of this study report that over-the-counter agents are not very effective.[10] This observation prompted initiation of this single centre, randomized, observer masked, crossover trial to examine the differences in patient satisfaction regarding symptom relief and comfort of two commonly prescribed allergy eye drops, bepotastine besilate 1.5% twice daily and olopatadine hydrochloride 0.2% twice daily.[11]

CONCLUSION

Bepotastine 1.5 % appears to be better in improving ocular symptoms, due to seasonal allergic conjunctivitis than olopatadine. At study end, patients were asked for which drop they will prefer to continue as treatment. A total of 65% of patients stated that they would prefer to continue with Bepotastine besilate1.5% compared with 35% of patients who preferred to treat with olopatadine hydrochloride 0.2%

Foot Notes

Disclosure: No author has a financial or proprietary interest in any material or method mentioned in this work.

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