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Original Research Paper

Ophthalmology

A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF 1.5% BEPOTASTINE BESILATE VERSUS 0.1% OLOPATADINE HYDROCHLORIDE IN ALLERGIC CONJUNCTIVITIS

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ABSTRACT

OBJECTIVE: To compare the efficacy of 1.5% bepotastine besilate versus 0.1% olopatadine hydrochloride in patients of allergic conjunctivitis

METHODS: This randomized single center study included 40 patients with allergic conjunctivitis. The patients were divided into two groups (20 patients each). Group I was treated with bepotastine besilate 1.5% twice daily and Group II with olopatadine hydrochloride 0.1% twice daily for 14 days.

RESULTS: Out of 40 patients of allergic conjunctivitis, 25 were male and 15 were female. All the patients were in the age group of 18 to 45 years. Majority of the patients (57.5%) who participated in the study were living in urban area. On Day 1, the total mean score of all the parameters were comparable in both groups (p-value > 0.01). On Day 7, there was significant ($p < 0.01$) reduction in itching and epiphora in group I patients as compared to group II. On Day 14, these symptoms got markedly improved in Group I patients.

CONCLUSION: 1.5% bepotastine besilate topical drops are better in alleviating the symptoms of allergic conjunctivitis as compared to 0.1% olopatadine topical drops

KEYWORDS : allergic conjunctivitis; bepotastine besilate; olopatadine hydrochloride

INTRODUCTION:

Most common allergic disorder of eye is allergic conjunctivitis.[1] The number of patients presenting with ocular discomfort due to allergic conjunctivitis is substantial.[2] Quite frequently, symptoms complex of allergic conjunctivitis includes ocular itching and conjunctival hyperemia, which are sometimes associated with conjunctival papillae, chemosis, lid swelling, and tearing, rhinorrhea and other nasal symptoms.[3] Pollen, dust mites, molds, or animal danders are most common allergens.[4] Allergic conjunctivitis is a type 1 hypersensitivity reaction (i.e IgE-mediated) and is seen in previously sensitized individuals.[5]

Allergic response can be acute or chronic. Acute phase occurs immediately and is due to histamine release caused by antigen-evoked mast cell degranulation. Chronic phase manifests in hours or days and it is due to pro-inflammatory mediators, eosinophils and neutrophils.[3,4]

The signs and symptoms are primarily caused by the action of histamine, acting on histamine H_1 receptors present in ocular tissues.[6] Therefore, drugs preventing mast cell degranulation or those that antagonize the action of histamine at its receptors are the first-line therapy.[7] They have an improved safety profile and increased therapeutic effect compared to older topical agents (eg, pheniramine maleate) used in the treatment of allergic conjunctivitis.[8]

These symptoms have a negative impact on quality of life of patients and result in hampering of performance and productivity, so it is important to study allergic conjunctivitis and its proper treatment.[9]

Various treatments are recommended for treatment of allergic conjunctivitis like avoiding the allergens, topical mast cell stabilizers, antihistamines and steroids.[10] Bepotastine besilate and Olopatadine both are histamine H_1 receptor antagonists and mast cell-stabilizing agents.[11,12] The anti-inflammatory actions of bepotastine include inhibition of eosinophil migration, interleukin-5, leukotrienes and platelet-activating factor.[11] Olopatadine also acts by decreased chemotaxis and inhibition of eosinophil activation.[12] Both these drugs are approved by US FDA for use in treatment of allergic conjunctivitis.

Present study is designed to compare the efficacy of these newest topical anti-allergy drugs bepotastine and olopatadine in allergic conjunctivitis.

MATERIALS AND METHODS:

40 patients of allergic conjunctivitis, who presented in outpatient department of Ophthalmology, Government Medical College and Hospital, Jammu in the months of May and June, 2018 were enrolled. All the included patients were at least 18 years of age, had a diagnosis of allergic conjunctivitis with no other unrelated ocular diseases. Patients taking steroids or antihistamines, were pregnant, or nursing/lactating, having any ocular infection were excluded. Patients using contact lenses were advised to use glasses during study period. All patients signed an informed consent form.

Patients were randomly assigned to either of the two study groups. They were all instructed to instill bepotastine 1.5% (Group I) and olopatadine 0.1% (group II) twice daily for a period of 14 days. Patients were asked to grade the following items (graded on 0 to 3 scale) ocular itch, epiphora, conjuctival chemosis and conjunctival hyperemia on Day 1, 7 and Day 14 and were noted and a total score was calculated to measure the effectiveness of the drug (Table 1). Statistical analysis using paired t-test was performed.

Table 1: Scoring of signs and symptoms of allergic conjunctivitis

Signs and Symptoms	Score 0	Score 1	Score 2	Score 3
Itching	Absent	Occasional itching, without tendency to scratch or rub the eyes	Frequent itching with tendency to scratch or rub the eyes	Continuous itching, frequently rubbing of eyes
Epiphora	Absent	Occasional, no discomfort	Frequent, mild discomfort	Persistent, frequent swabbing of the eye

Hyperemia	Absent	Slightly dilated blood vessels, pink in color	More apparent vessel dilatation, vessel color is more intense, involves most of vessel bed	Numerous and obvious dilated blood vessels, color deep red
Chemosis	Absent	Mild	Moderate	Severe

RESULTS:

The present study included 40 patients of allergic conjunctivitis, out of which 25 were male and 15 were female. All the patients were in the age group of 18 to 45 years. Mean age in group I was 23.7 and in group II it was 21.7 and p-value being 0.270749. Majority of the patients (57.5%) who participated in the study were living in urban area. All the demographic data is represented in Table 2.

Table 2: Demographic data

Characteristics	Group I (n=20)	Group II (n=20)
Mean Age	23.7	21.7
Male	60%	65%
Female	40%	35%
Urban dwelling	55%	60%
Rural dewelling	45%	40%

On Day 1, the total mean score of all the parameters were comparable in both groups and p-value was more than 0.01. On Day 7, there was significant ($p < 0.01$) reduction in itching and epiphora in group II patients. On Day 14, these symptoms got markedly improved in Group II patients. Hyperemia and chemosis were reported in only few patients but the improvement in these signs was statistically insignificant ($p > 0.01$).

Table 3: Comparison of total mean score

Signs and Symptoms	Day1			Day7			Day14		
	Group I	Group II	p-value	Group I	Group II	p-value	Group I	Group II	p-value
Itching	2.7	2.8	0.239002	1.4	2.2	0.001451	0.5	1.2	<0.00001
Epiphora	2	2.1	0.268601	0.7	1.6	0.000066	0.5	1	0.005105
Hyperemia	1.6	2	0.03236	1.3	1.6	0.029331	0.6	1	0.017783
Chemosis	0.6	0.8	0.215539	0.1	0.2	0.194402	0	0.1	0.077221

DISCUSSION:

Of all the ocular affections, allergic conjunctivitis is quite common and cumbersome, as it is recurrent in nature and hampers the general lifestyle of the patients. It is not a vision threatening condition but in some cases, it can lead to ocular surface disease. It is mast cell degranulation mediated hypersensitivity (type I) reaction in response to action of IgE.

In addition to use of dark glasses and cool compresses, various drug options are available depending on the severity of disease. Mainstays of treatment are lubricants, antihistaminics and mast cell stabilisers.

In past, various studies have been done comparing the efficacy of olopatadine hydrochloride with placebo, mast cell stabilizers, NSAIDs and some other drugs Spangler et al.2001[48] Yaylali et al. 2003[39] Leonardi & Zafirakis 2004[13]. There is dearth of data comparing olopatadine with bepotastine, so we designed a single centre randomized trial, to compare the efficacy of 0.1% olopatadine hydrochloride with 1.5% bepotastine besilate eye drop in allergic conjunctivitis patients.

Yaylali et al conducted a study on 40 patients of allergic conjunctivitis, 21 were male and 19 were female. Their average age was 19 years (range 15–25 years).[13] In a study done by Chaudhary et al , 43% patients were male and the mean age was 28 ± 12 years.[14] In our study there were 40 patients, out of whom 25 were male and all patients were in the age group of 18 to 45 years.

In our study, 23 patients were from the urban part of the city and rest of them was living in the rural area. In a study by Meena et al, most of the patients were outdoor worker.[15]

In the present study, we observed that mean scores for itching and epiphora on the day of presentation (Day 1) were comparable in both the groups (p-value > 0.01). On 7th day, there was definite decrease in the mean score of both the groups but the marked improvement is seen in patients using bepotastine (p-value < 0.01). On day 14, similar results were seen in all patients but they were more marked in bepotastine group (p-value < 0.01). Hyperemia and chemosis were equally improved in both the groups (p-value > 0.01).

Our study concluded that 1.5% bepotastine besilate topical drops are better in alleviating the symtoms of allergic conjunctivitis when compared with 0.1% olopatadine topical drops. As our sample size was small, in future more studies with larger sample size are required to earmark the superiority of either of the drug.

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