RESEARCH

COMPARATIVE EVALUATION OF 0.01% OLOPATADINE HYDROCHLORIDE VERSUS 0.5% KETEROLAC TROMETHAMINE OPHTHALMIC SOLUTION IN THE MANAGEMENT OF ALLERGIC CONJUNCTIVITIS IN PATIENTS OF KARNATAKA

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Abstract

Background: Allergic conjunctivitis a group of hyper sensitivity disorders which involves eyelid, conjunctivitis and cornea with common pathogenesis. It presents itching, redness, tearing, swelling, burning, oedema, rarely blurred vision. It needs to be treated efficiently due to restless of patient's condition. **Materials and Methods:** Out of 100 patients having allergic conjunctivitis 50 (fifty) patients were treated with 0.1% olopatadine HC% and 50 patients with 0.5% Ketorolac Tromethamine for the period of 14 days. The prognosis of the both groups was recorded at different intervals, 30 minutes, 2nd day, 7th day and 14th day pros and cons of both eye drops was recorded and compared. **Result:** Although both eye drops were useful to treat allergic conductivities but 0.1%. Olopatadine hydrochloride had marginally faster relief of sign and symptoms compared to 0.5% Ketorolac fumarate. Few patients receiving Ketorolac had increase in hyperaemia and stinging sensation. **Conclusion:** It is revealed that, patients receiving 0.1% oiopatadine HCL had a marginally faster relief of signs and symptoms compared to 0.5% Ketorolac fumarate, though it is not significant statistically. However both drugs improved the patient's conditions to similar extents. It needs further clinical trials to ensure the accuracy of present results.

INTRODUCTION

Allergic conjunctivitis is a group of hypersensitivity disorders involving eyelid, conjunctiva and cornea sharing a common pathogenesis.[1] In this condition patients suffer with itching, redness, tearing, swelling, burning, a sensation of fullness in the eye leading to rubbing of the eye, rarely blurred vision.[2] This condition presents in episodes and is associated with symptoms and signs such as lid Oedema, conjunctival hyperaemia, chemosis and papillary reactions.

Topically applied ophthalmic agents are the principle treatment method for allergic conjunctivitis frequently used topical drugs includes H1 anti-histamines, mast cell stabilizers and non-steroidal anti-inflammatory drugs, steroids.

Olopatadine is a novel drug which has been shown clinically to have therapeutic value in treatment of allergic conjunctivitis. It has dual action of most cell mediator release with blocking of histamine H1 receptor.[3] Ketorolac tromethamine 0.5% ophthalmic solution, potent NSAID that inhibits the enzyme cyclo-oxygenises and decreases the synthesis of prostaglandins.[4] Hence efficacy of both ophthalmic drops has been of compared in patients with allergic conjunctivitis.

MATERIALS AND METHODS

100 adult patients regularly visiting to ophthalmology department of Medical Sciences, Khaja Banda Nawaz University Kalaburgi-585103 were studied.

Inclusive Criteria

Patient above age group of 18 years having ocular itching hyperaemia, mucous discharge and clinically proven allergic conjunctivitis, palpebral or bulbar conjunctival manifestation associated with allergic rhinitis, bronchial asthma.

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Exclusion Criteria

Patients below 18 years with bacteria or viral conjunctivitis or any infective aetiology. Patients with Keratitis, scleritis, Uveitis, herpes, pregnant or lactating mothers were excluded from study.

Method: The ocular examination was performed in every patient included slit lamp Bio-microscopy to evaluate conjunctival and corneal involvement Intra ocular pressure was measured by using non-contact Tonometer. Fundus examination was carried out by using indirect opthalalmoscopy.

After establishing the diagnosis, the patients were divided in two groups A and B. Group-A patients were treated with Olopatadine and B group treated with Ketorolac and drugs were installed twice daily. Both groups' patients were evaluated for clinical signs and symptoms at base line and at 30 minutes 2nd day, 7th and 14th day of installation of eye drops.

Duration of study May-2019 to June-2021

Statistical analysis

Tropical installation of different eye drops in both group (A and B) and their effects on itching, hyperaemia, at different intervals were studied with compared chi-square and positive results were noted. The statistical analysis was carried out in SPSS software. The ratio of male and females was 2:1.

RESULTS

[Table 1] Comparison of proportion of groups itching in both groups.

- At 30 minutes of interval after installation of eye drops 54% proportion was in group- A, 34% in group-B.
- At 2nd day, 0.8% proportion was in group-A, 58% in group-B at 30 minutes p value was 0.04 ($p<0.04$) and p value was highly significant but there was 100% in itching from base line.

[Table 2] (A) Comparative study of percentage of Non-responders for itching in both groups – Base line and 7th Days – 12% in group-A, 14% in group-B and ($p<0.001$) p value was highly significant

(B) Comparative percentage of Non-responding for itching between base line and 14th day. Group-A 2% and group-B 2% and $p<0.0001$ p value was highly significant in both groups

[Table 3] Addition observations in drug groups – Itching group-A Nil, group-B Nil Hyperaemia group-A Nil, group-B increased in 3 patients at 30 minutes of installation.

Table 1: Comparison of proportion of group-A and group-B for itching

Groups	Group-A	Groups-B	Group-A	Groups-B
Proportion	54%	34%	68%	56%
Interval	At 30 minutes		At 2 days	
Chi. Square	4.018		1.513	
DF	1		1	
Significance	0.045		0.2187	

($p<0.04$) p value was highly significant at 30 minutes of installation. Hence there was significant difference between two drugs for reducing itching.

Table 2(a): Comparison percentage of non-responders for itching in group-A and group-B between baseline and day 7

Groups	Group-A	Group-B
Baseline and Day 7	12%	14%
Chi square	77.78%	74.684
DF	1	1
Significance	<0.0001	<0.0001

($p<0.001$) p value was highly significant in non-responders

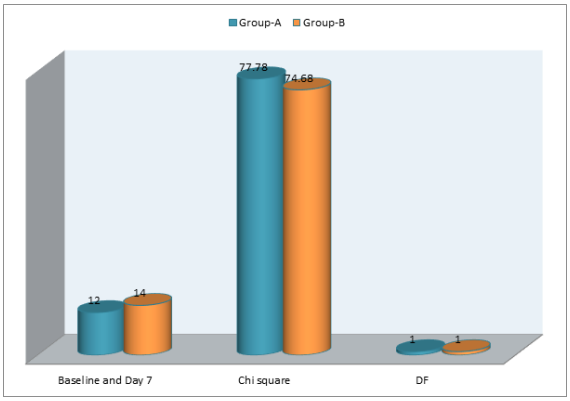

Figure 1: (A) Comparison percentage of non-responders for itching in group-A and group-B between baseline and day 7

Table 2(b): Comparing percentage of non-responders for itching in group-A and group-B between and day 14

Groups	Group-A	Group-B
Baseline and Day 14	2%	4%
Chi square	95.118	91.385
DF	1	1
Significance	<0.0001	<0.0001

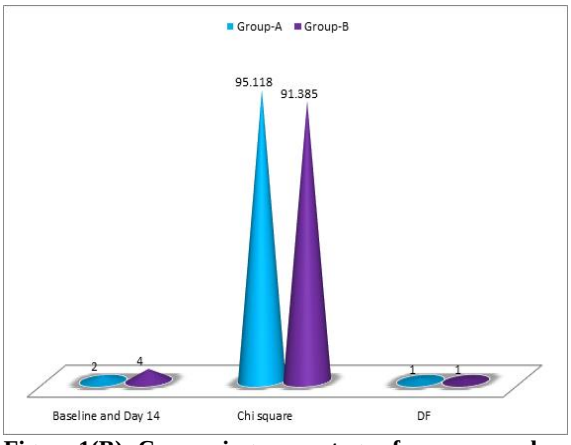

Figure 1(B): Comparing percentage of non-responders for itching in group-A and group-B between and day 14

Table 3: Additional observations in drug groups

Clinical finding	Group-A	Group-B
Itching	Nil	Nil
Hyperaemia	Nil	Increased in 3 patients

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DISCUSSION

Present comparative evaluation of 0.1% Olopatadine hydrochloride versus 0.5% Ketorolac tromethamine ophthalmic solution in the management of allergic conjunctivitis in north Karnataka Population. The present comparative study of proportions itching in group-A and B, in group-A 54%, group-B had 34% at 30 minutes and p value was highly significant ($p<0.04$) [Table 1]. The comparison of percentage in both non-responders (groups-A and B) i.e. between baseline, Day 7. Group-A had 12%, group-B had 14% non-responder and p value was highly significant ($p<0.001$). In comparison of non-responders for itching in group-A and B between base line and day 14th Group-A had 2% non-responders group-B had 4% non-responders and p value was highly significant ($p<0.001$) [Table 2].

The additional observation was itching was nil in both A and B groups. Hyperaemia was nil in group-A, and increased in 3 patients in group-B [Table 3]. These findings are more or less in agreement with previous studies.[5,6,7]

The "Allergy" terms was coined by two Greek words allos meaning other and "ergon" meaning reaction and it was confirmed that patient is sensitive to particular entity is called allergic.[8] A topical steroid is useful especially in temperate climate to manage allergy.

It was also reported that severe form of chronic Kerato-conjunctivitis associated with atopic dermatitis. Ocular allergy comprises various disease entities classified as seasonal allergic conjunctivitis, perennial allergic conjunctivitis, Vernal Kerato-conjunctivitis, atopic Kerato-conjunctivitis and giant papillary conjunctivitis.[9]

With the up surge in industrialization and global trends in climatic change, led to polluted atmosphere in developing countries have increased rate of allergic conjunctivitis. Moreover due to mal-nutrition and lower economic status have reduced immunity will drastically increase the ocular allergies especially allergic conjunctivitis. It is also reported that the causes of allergic conjunctivitis are contributed by hereditary factors, environmental impact, male gender, because male is more exposed environment than female, use of high potency antibiotics in childhood have positive correlated with allergic disorders. Obesity due to hormonal changes alters the T-lymphocyte, especially BMI more than 30. Higher consumption of junk foods and lower consumption of omega-3 fatly acids, chronic alcoholism causes shift in cytokines production results in reduced immunity. Moreover auto-immune disorders smoking associated with increased IgE levels also enhance allergic disorders.[10]

Pathologically allergic conjunctivitis is a bilateral and self-limiting inflammation. Inflammatory response in which the allergens interact with IgE which is in term bound to sensitized mast cells resulting in the clinical ocular allergic expression. The immune-pathogenesis of allergic conjunctivitis is predominantly IgE medicated hyper sensitivity reaction. Late phase reactions are characterized by infiltration of Neutrophils, Esinophils, Macrophages, and Th2 cells, probably in response to cytokines released by activated most cells.

Ocular conjunctivitis has to e differentiated from other form of ocular allergy like AKC, VKC, GPC, CDC which share the symptoms such as itching tearing and conjunctivitis hyperaemia.

Several topical agents are available for the treatment and prophylaxis of ocular allergy. These include vasoconstrictors; antihistamine, mast-cell stabilizers, and anti-inflammatory agents efficacy of these drugs vary from patients to patients and other factors such as drug compliance. The primary treatment algorithm includes avoidance of allergens, colloid comprise and lubrication

CONCLUSION

As allergic conjunctivitis has multiple aetiologies hence both drugs i.e. 0.1% Olopatadine hydrochloride and 0.5% Ketorolac tromethamine ophthalmic solution are useful to treat but olopatadine improved itching symptoms slightly better than Keratolac at 30 minutes and 2 days of installation however patients of both group had improvement in itching symptoms on 7th and 14th day. As itching is due to irritation of superficial or cutaneous nerves, hence olopatadine proved efficient as compared to Keratolac. Similarly olopatadine improved hyperaemic signs slightly better than keratolac at 30 minutes and 2 day of installation but there was no statistical significant in itching symptoms of both groups.

The present study demands further clinical trials in large number of patients of both sexes at different age groups to ensure the accuracy of present comparative study results of both drugs

Limitation of Study

Owing to tertiary location of research hospital. Small number of patients and lack of latest technology we have limited research results.

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