Original Article

A Comparative Study of Diclofenac Sodium with Ketorolac Tromethamine Ophthalmic Solution in Treatment of Allergic Conjunctivitis

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Abstract

Allergic conjunctivitis is inflammation of the conjunctiva (the membrane covering the white part of the eye) due to allergy. The conjunctiva is a thin membrane that covers the eye. When an allergen irritates the conjunctiva, common symptoms that occur in the eye include: ocular itching, eyelid swelling, tearing, photophobia, watery discharge, and foreign body sensation. The cause of allergic conjunctivitis is an allergic reaction of the body's immune system to an allergen. Allergic conjunctivitis is common in people who have other signs of allergic disease such as hay fever, asthma and eczema. Among the most common allergens that cause conjunctivitis are Pollen from trees, grass and ragweed, Animal skin and secretions such as saliva, Perfumes, Cosmetics and someskin medicines. **Aims and Objectives:** To study the effect of Diclofenac Sodium with That of Ketorolac Tromethamine Ophthalmic Solution in the treatment of Allergic Conjunctivitis. **Methodology:** After approval from Institutional Ethical Committee, a prospective clinical trial in the 70 patients was carried out. Patients having symptoms of Allergic Conjunctivitis were informed about both these treatment modalities and effectiveness and limitations. After having consent of the patients; they were included into the study. All the Patients were given treatment first time and those who were having history of use of any drugs e.g.Like steroids used in past were excluded from the study. Patients were given treatment randomly by Diclofenac (0.5%) and Ketorolac (0.1%) by computer generated random numbers. All the patients were evaluated by physician using a scales scores at baseline (day 0), mid-week (day 3), day 7 and day 14 after the initiation of the therapy. At each visit, the signs and symptoms were rated by the physician using a scale from 0-3(mild-1, moderate-2, and severe-3). **Result:** The mean age in Diclofenac group was 17±3.4 Yrs. And in Ketorolac group was 18± 4.2 Yrs. There were 25 Males and 10 Females in Diclofenac group and 27 Males and 8 Females in Ketorolac group. Mean duration of Disease in both the groups were 2.9±2.1 Months. And 3.1±2.5 Months respectively in Diclofenac and Ketorolac group all these characteristics are comparable to each other. Ocular-itching, Burning sensation, Discharge, Photophobia, Foreign body sensation, Swollen eye all these characters were compared in Diclofenac and Ketorolac group at Baseline, at Day -3, Day-7, Day14 by Physicians scale score were significantly lower in the Diclofenac group and Ketorolac group at all the three times ($P<0.05$;Unpaired t-test was used for statistical analysis. **Conclusion:** Use of either Diclofenac or Ketorolac; both of them reduces symptoms of allergic conjunctivitis drastically, but the reduction of symptoms were significantly more marked— in Diclofenac group as compared to the ketorolac group so topical use of Diclofenac is better than Ketorolac in the management of Allergic conjunctivitis.

Key words: Allergic Conjunctivitis (AC), Diclofenac Sodium, Ketorolac Tromethamine.

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INTRODUCTION

Allergic conjunctivitis is inflammation of the conjunctiva (the membrane covering the white part of the eye) due to allergy.[1]The conjunctiva is a thin membrane that covers the eye. When an allergen irritates the conjunctiva, common symptoms that occur in the eye include: ocularitching, eyelid swelling, tearing, photophobia, watery discharge, and foreign body sensation (with pain).[1,2] The cause of allergic conjunctivitis is an allergic

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reaction of the body's immune system to an allergen. Allergic conjunctivitis is common in people who have other signs of allergic disease such as hay fever, asthma and eczema.[4] Among the most common allergens that cause conjunctivitis are Pollen from trees, grass and ragweedAnimal skin and secretions such as saliva, Perfumes, Cosmetics, Skin medicines, Air pollutionSmokeDust mitesBalsam of Peru (used in food and drink for flavoring, in perfumes and toiletries for fragrance, and in medicine and pharmaceutical items for healing properties)Eye drops. Most cases of seasonal conjunctivitis are due to pollen and occur in the hay fever season, grass pollens in early summer and various other pollens and moulds may cause symptoms later in the summer.[5] Itching is the most typical symptom of ocular allergy, and more than 75% of patients report this symptom when seeking treatment.[2] Symptoms are usually worse for patients when the weather is warm and dry, whereas cooler weather with lower temperatures and rain tend to assuage symptoms.[1] Signs in phlyctenularkeratoconjunctivitis include small yellow nodules that develop over the cornea, which ulcerate after a few days.[3] Seasonal Allergic Conjunctivitis (SAC) is the most common and most prevalent of allergic disorders which afflict the ocular surface.[6,7] Susceptible individuals typically have a family or personal history of environmental allergies, asthma, bronchitis, food allergies or eczema.[7] Such atopic persons when exposed to airborne allergens, sometimes show debilitating ocular symptoms such as itching, tearing, photophobia or discharge. Chemosis, conjunctival injection and swelling of eyelids commonly occur in association with these symptoms. These signs and symptoms are a result of the actions of chemical mediators released in a cascade of response following exposure to an offending allergen. SAC is classical type I anaphylactic hypersensitivity reaction.[8] Allergy has a great impact on society, influencing many quality of life (QOL) parameters.[9]Patients of SAC experience QOL reductions in general health and specific aspects of vision, and also suffer from economic consequences as a result of the disease.[6,10] The loss of productivity contributes to the economic burden of the disease in the same manner as the shared costs of the treatments.[6]The direct and indirect expenditure related to ocular allergy prescriptions have risen from $6 million in 1990s to more than $300 million in the new millennium.[11] Treatment of acute SAC may include systemic medications (antihistamines, mast cell stabilizing agents or corticosteroids), immunotherapy or desensitization injections, as well as topical ocular medications. Topical decongestants, antihistamine agents, mast cell stabilizing agents, corticosteroids or nonsteroidal anti-inflammatory agents have all been used With variable results in the treatment of acute Seasonal Allergic Conjunctivitis.[12-18] More recently, dual action ophthalmic drugs like Olopatadine with both antihistaminic and mast cell stabilizing activity have been used.[19] Multi-action therapies like Ketotifen which inhibit eosinophil activation in addition to functioning as an antihistaminic with mast cell stabilization are useful.[20,21]

AIMS AND OBJECTIVES

To study the effect of Diclofenac Sodium with That of Ketorolac Tromethamine Ophthalmic Solution in Treatment of Allergic Conjunctivitis.

METHODOLOGY

After approval from Institutional Ethical Committee, a prospective clinical trial in the 70 patients was carried out. Patients having symptoms of Allergic Conjunctivitis were informed about both these treatment modalities and effectiveness and limitations, after having consent of the patients they were included into the study. All the Patients were given treatment first time and those who were having history of use of any drugs e.g. Like steroids in past were excluded from the study. Patients were given treatment randomly by Diclofenac Sodium (0.5%) and Ketorolac (0.1%) topical drops by computer generated random numbers. All the patients were Evaluated by physician using a scale scores at baseline(day 0), mid-week (day 3), day 7 and day 14 after the initiation of the therapy. At each visit, the signs and symptoms were rated by the physician using a scale from 0-3(mild-1, moderate-2, severe-3) as described in [22].

RESULT

Table 1: Distribution of the Patients as per the Demographic Factors

	Diclofenac	Ketorolac
Age (Mean± SD)	17± 3.4 Yrs.	18± 4.2 Yrs.
Sex		
Male	25	27
Female	10	8
Duration of Disease (Mean±SD)	2.9± 2.1 Mnths.	3.1± 2.5Mnths.

From Table 1: The mean age in Diclofenac group was 17± 3.4 Yrs. And in Ketorolac group was 18± 4.2 Yrs. There were 25 Males and 10 Females in Diclofenac group and 27 Males and 8 Females in Ketorolac group. Mean duration of Disease in both the groups were 2.9± 2.1 Mnths. And 3.1± 2.5 Mnths. respectively in Diclofenac and Ketorolac group all these characteristics are comparable to each other.

Table 2: Distribution of the Patients as per the Symptoms of Allergic conjunctivitis in Patients

Symptoms	Drugs	Baseline (Mean±SD)	p-value	Day -3 (Mean± SD)	p-value	Day-7 (Mean± SD)	p-value	Day14 (Mean± SD)	p-value
Ocular-itching	Diclofenac	1.9± 1.2	P<0.05	1.45±1.2	P<0.05	1.21±0.81	P<0.05	0.9± 0.2	P<0.05
	Ketorolac	3.1±1.1		2.98 ± 1.1		2.75±0.78		2.1± 0.3	
Burning sensation	Diclofenac	1.8±1.1	P<0.05	1.21± 0.85	P<0.05	1.11±0.21	P<0.05	0.85±0.5	P<0.05
	Ketorolac	2.8± 1.3		2.98±0.12		2.89± 0.14		1.2±0.65	
Discharge	Diclofenac	2.1 ± 1.5		1.02± 1.3		0.98± 0.13	P<0.05	0.85±0.2	P<0.05
	Ketorolac	1.9±1.2	P<0.05	2.56± 1.2	P<0.05	2.48± 0.21		1.3± 0.32	
Photophobia	Diclofenac	1.7± 1.1	P<0.05	1.05±1.23		0.99± 0.12	P<0.05	0.64±0.12	P<0.05
	Ketorolac	1.82±1.3		3.1± 1.12	P<0.05	2.95± 0.25		1.5± 0.25	
Foreign body sensation	Diclofenac	1.1± 1.5	P<0.05	1.1± 1.1	P<0.05	0.92±0.11	P<0.05	0.55±0.12	P<0.05
	Ketorolac	1.9± 1.2		2.98± 2.1		2.82±0.21		1.21±1.1	
Swollen eye	Diclofenac	1.45± 0.9		1.31± 1.21		0.93±0.45	P<0.05	0.45±0.21	P<0.05
	Ketorolac	1.21±0.87	P<0.05	2.89± 2.41	P<0.05	2.75±0.32		1.32±1.5	

Unpaired t-test were used for analysis.(sd=Standard deviation)

Ocular-itching, Burning sensation, Discharge, Photophobia, Foreign body sensation, Swollen eye all these characters were compared in Diclofenac and Ketorolac group at Baseline, at Day -3, Day-7, Day14 by Physicians scale score were significantly lower in the Diclofenac group and Ketorolac group at all the three times (P<0.05;Unpaired t-test was used)

DISCUSSION

In the United States, the National Health and Nutrition Examination Survey III(NHANES III) found that ocular symptoms, defined as "episodes of tearing and ocular itching", affected 40% of the adult population, with no significant differences according to age [23], though with a predominance in the south versus other regions of the country. Exposure to aeroallergens (animal epithelia, pollen and mites) triggered more ocular symptoms than nasal manifestations. Thus, during the months of May and August, in relation to the environmental pollen levels, ocular symptoms were seen to predominate over nasal symptoms. On examining the prevalence of ocular allergy in relation to the results of the skin tests made with the mentioned environmental aeroallergens [24], the authors found patients with AC to have greater skin reactivity than patients with allergic rhinitis. In Italy [25], a study involving 898 new patients visiting an allergy clinic found 40% of the subjects to report symptoms compatible with AC, and 66% of them were also diagnosed with seasonal allergic rhinitis. A Japanese study [26] in turn found 90% of all patients with pollen allergy to present AC. For the treatment the side effects of topical corticosteroids are well known. While the efficacy of these agents for the treatment of allergic disease is excellent, serious limitations to their chronic use include: elevation of intraocular pressure, accelerated development of cataract, decreased resistance to infection, mydriasis, delayed corneal wound healing, ptosis and optic atrophy.[27] In our study use of either Diclofenac or Ketorolac both of them reduced symptoms of allergic conjunctivitis drastically, but the reduction of symptoms were significantly more marked in Diclofenac group as compared to the ketorolac group the study is in confirmation with Navdeep Dehar *et al*[22].

CONCLUSION

Use of either Diclofenac or Ketorolac both of them reduces symptoms of allergic conjunctivitis drastically, but the reduction of symptoms were significantly more marked in Diclofenac group as compared to the ketorolac group so Topical use of Diclofenac is better than Ketorolac in the management of Allergic conjunctivitis.

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