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MONTELUKAST: NEWER MODALITY IN VERNAL KERATOCONJUNCTIVITIS (VKC)

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Introduction

Vernal Keratoconjunctivitis (VKC) is a chronic, bilateral allergic inflammation of the conjunctiva. The disease is seasonal, recurrent & commonly seen among young boys.

Common symptoms of the disease are redness, itching, lacrimation, photophobia, foreign body sensation & a characteristic ropy discharge. Signs found in VKC are conjunctival congestion, giant papillae involving upper palpebral conjunctiva & the limbus, Tranta's dots & superficial keratitis. (1,2). Patients with VKC frequently have a positive family history or history of allergic diseases like asthma, rhinitis, atopic dermatitis etc.(3).

It is a multifactorial disease with involvement of environmental conditions, immune mechanism & endocrinal system. T2 lymphocytes are thought to be responsible for the pathogenesis of the disease (4). It leads to hyper production of IgE (IL-4) & enhance differentiation and activation of mast cells (IL-3) & eosinophils (IL-5). These cells cause increased production of leukotrienes, which can be detected in tear fluid of VKC patients. If leukotrienes are administered on the surface of the conjunctiva (i.e. LTB4, LTC4 & LTD4), they cause vasodilatation, edema, hyperemia & infiltration of eosinophils & other leucocytes (5,6,7).

The management of VKC includes correct diagnosis, prognostic evaluation and proper therapy. There are many therapeutic options and the selection of the drug depends on the severity of the disease. However at present no drug is available to achieve the ultimate goal of therapy, meaning the complete resolution of the disease & prevention of recurrence. Most commonly used drug is topical steroid which controls effectively the acute phase of the disease but may lead to complications of glaucoma & cataract on prolong use (8, 9). Second line drugs are topical antihistamines, mast cell stabilizers & non steroidal anti-inflammatory drugs (NSAID). Topical cyclosporine 2% is effective in chronic cases but about 6% of patients develop complications of cataract, corneal damage or glaucoma.

Montelukast which is a leukotriene receptor 1 antagonist has the potential to reduce the symptoms of VKC as it has been found that biological activity of leukotriene on conjunctiva produces a similar picture as that of VKC (10).

AIM:

To study the efficacy of oral Montelukast in reducing the symptoms & recurrence in cases of VKC.

MATERIALS & METHODS:

This was a prospective, randomized, control clinical trial. 58 patients of VKC patients attending the outpatient department of Ophthalmology at Muzaffarnagar Medical College from March 2014 to August 2014 were enrolled for the study. The diagnosis of VKC was clinical, based on the symptoms & signs. Exclusion criteria were the patients already on treatment from our department or elsewhere. An informed consent was taken from parents of all the patients. The age & sex distribution was according to Table 1.

Table 1:

SEX	5 YEARS TO 10 YEARS	10 YEARS TO 15 YEARS
MALE 44	18	26
FEMALE 14	4	10

Symptoms (itching, burning sensation, watering, discharge, photophobia & foreign body sensation) and signs (hyperemia/congestion of conjunctiva, tarsal & bulbar papillae, conjunctival chemosis & Tranta's dots) were recorded & graded at every visit. Ocular examination was done using slit lamp by the same physician at the first visit & all subsequent visits. The severity of signs & symptoms were graded at each examination. Grading was done from 0-3; 0- absent, 1-mild, 2- moderate, 3- severe.

All the patients were put on topical olopatadine twice a day; patients with severe disease were also given topical flurometholone three times a day. The patients were randomly assigned to two groups – A & B. Group A patients were additionally given oral motelukast (Montair, Cipla) 5 mg daily at bed time while group B served as control. All the patients were evaluated at interval of 1 week, 3 weeks, 6 weeks & 3 months unless the signs & symptoms totally disappeared earlier. Flurometholone wherever started was discontinued after 2 weeks once acute symptoms & signs regressed. Oral Montelukast was continued for a minimum of 3 weeks.

OBSERVATIONS:

58 patients who were clinically diagnosed as having VKC on the basis of signs & symptoms were distributed according to the grade of severity Table 2.

Table 2:

SEX	AGE	GRADE I	GRADE II	GRADE III
MALE	05 – 10 YEARS	5	11	2
	10 -15 YEARS	7	14	5
FEMALE	05 – 10 YEARS	1	3	0
	10 -15 YEARS	2	7	1

8 patients having Grade III disease were treated with topical flurometholone thrice a day & hence were excluded from the study. Remaining 50 patients were randomly divided in two groups of Group A & B. Group A patients were treated with topical olopatadine twice a day along with oral Motelukast 5 mg once a day at bed time while Group B patients were treated with topical olopatadine twice a day as control group. (Table 3)

Table 3:

SEVERITY	GROUP A	GROUP B
GRADE I	8	7
GRADE II	18	17

At the first follow up after one week, 3 patients from Group A & 2 patients from Group B of Grade 1 severity reported improvement in their symptoms. On slit lamp examination there were no signs of VKC in these patients. 8 patients of Group A & 7 patients of Group B of Grade II severity were found to have decreased symptoms. On slit lamp examination they were observed to have only mild signs, so they were upgraded to Grade I. (Table 4)

Table 4:

SEVERITY	GROUP A	GROUP B
GRADE I	13	12
GRADE II	10	10

At the second follow up after 3 weeks of treatment, all the 13 patients from Group A & 6 patients from Group B of Grade 1 severity showed marked improvement in their symptoms. Slit lamp examination of these patients did not reveal any signs. All the 10 patients of Group A & 4 patients of Group B of Grade 2 severity had decreased symptoms & very mild signs of VKC, hence they were promoted to Grade 1. (Table 5)

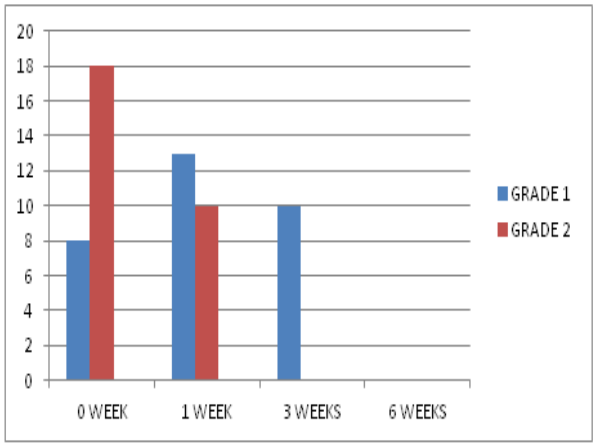
Table 5:

SEVERITY	GROUP A	GROUP B
GRADE I	10	10
GRADE II	NIL	6

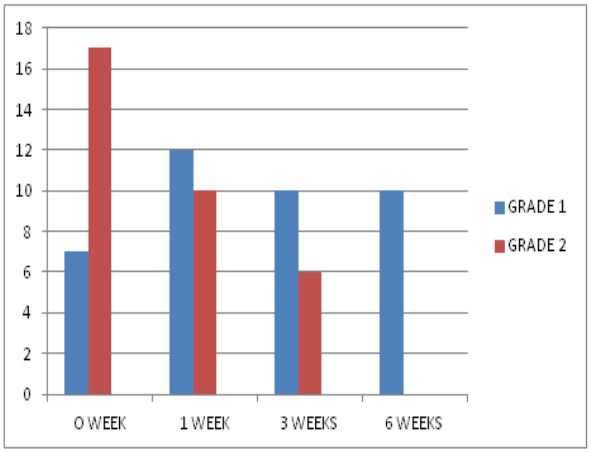
At the conclusion of the study (at 6 weeks of treatment), all the 10 patients of Group A & 6 patients of Group B of Grade 1 severity were found symptom & sign free. 6 patients of Group B of grade 2 severity showed improvement & were so included in Grade 1 severity. Hence after 6 weeks it was observed that all the patients of Group A who were on both topical olopatadine & oral montelukast became totally symptom free. However 10 patients of Group B who were on topical olopatadine alone were still found to have some symptoms & signs of VKC. (Table 6)

Table 6:

SEVERITY	GROUP A	GROUP B
GRADE I	NIL	10
GRADE II	NIL	NIL



Graph 1: CHART DEPECTING PATIENT DISTRIBUTION OF GROUP A



Graph 2: CHART DEPECTING PATIENT DISTRIBUTION OF GROUP B

DISCUSSION:

There is a worldwide increase of allergic conditions of the conjunctiva. One of the main causes is environmental degradation especially in urban cities within the developing countries. Though these conditions are seldom associated with visual loss, however they definitely lead to lot of morbidity. Patients of VKC generally show spontaneous resolution at puberty but corneal involvement is reported in about 9.7% patients. Development of cataract or glaucoma can produce visual impairment.(11, 12)

The signs & symptoms of VKC develop due to ocular surface inflammation represented by the presence of inflammatory substances like leucotrienes, histamines, prostaglandins etc. The present study suggests that Montelukast, a leucotriene receptor 1 antagonist may represent a useful & additional drug for the patients of VKC.

This study has its limitations because of a small sample size & short duration of the study. A long term study is needed to evaluate the effect a long lasting efficacy of the drug as well as its role in prevention of the recurrence. However we feel that despite its limitations, the drug appears to be promising. It should be viewed in context that no such study is reported so far at least from India, to the best of our knowledge.

CONCLUSION:

After the improved knowledge of the pathogenesis of VKC, the use of leukotriene receptor antagonist (Montelukast) as an adjunct is justified. Montelukast 5 mg orally at bed time along with topical olopatadine twice a day showed much more improvement than topical olopatadine used alone in VKC. Combination treatment was more effective & had significant & persistent reduction in signs & symptoms even after the discontinuation of the oral treatment. It was also observed that the effect was long lasting with lesser recurrence.

There were no significant side effects of the oral medication. It is a safe drug when used in 5 mg daily dose in patients less than 15 years of age. However a double masked placebo controlled study is required to confirm the potential of this new treatment modality in vernal kerato conjunctivitis.

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