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# **Manifestations of vernal keratoconjunctivitis and comparison study of efficacy of different monotherapy with topical corticosteroid, cyclosporine and alcaftadine in its management in Sln Medical College, Odisha, India**

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**Abstract**--Objective: The purpose was to study the ocular manifestations pattern and complications of vernal keratoconjunctivitis (VKC) and efficacy of corticosteroid, cyclosporine, alcaftadine. Material and methods: A Prospective study was done taking 227 patients from 15<sup>th</sup> Oct 2021 to 15<sup>th</sup> Mar 2022 in Department of Ophthalmology SLN Medical College and Hospital. Vernal Keratoconjunctivitis (VKC) was diagnosed basing on clinical presentation and scoring of signs and symptoms. Various investigations like slit-lamp biomicroscopy, keratometry, retinoscopy, distant direct, direct ophthalmoscopy and Corneal topography, fundus examination with +90D +20DVolk lenses done. Patients were allocated

in 3 groups randomly for studying the efficacy of topical corticosteroid, cyclosporine and alcaftadine as monotherapy and first line therapy too. The results were analyzed after 4, 8 & 12 weeks. Visual acuity and ocular complications were recorded. Results: Most common age group involved was 5 year to 9 year and least were more than of 20 years. Among the patients, 171 (75.4%) were male and 56 (24.6%) were female between 1-30 years. Most common presentation was limbal form. Complications like shield ulcer found in 11 and keratoconus in 2 patients. There was significant reduction in sign and symptom score in topical corticosteroid and topical cyclosporine group. Conclusion: Severe VKC is potentially blinding .visual loss may occur due to keratoconus and corneal scars. Topical cyclosporine 0.05% and topical alcaftadine 0.25% which can help to reduce corticosteroid usage, is an effective and safe alternative for the treatment of VKC.

**Keywords**---Vernal Kerato Conjunctivitis, corticosteroid, cyclosporine, alcaftadine.

## **Introduction**

Vernal keratoconjunctivitis (VKC) is an ocular allergic disease,observed in children and young adults presenting. Usually patients complain of severe itching and photophobia also accompanied by ocular discomfort and lacrimation [1,2]. It is a chronic ocular allergy. It mostly affects children and adolescents living in warm or hot climatic conditions [3]. The eye is frequent target for local as well as systemic inflammation. Vernal Keratoconjunctivitis (VKC) is a seasonally recurring, bilateral inflammation of the cornea and conjunctiva that occurs predominantly in male children. Patients frequently, but not invariably, have a personal or family history of atopy. The disease may persist year-round in tropical climates i.e hot and humid climate. An immune mechanism is reported to be involved in its development [4].

Several types of corneal changes associated with upper-tarsal lesions may also develop in VKC. Punctate epithelial erosions in the superior and central cornea are frequently observed. Pannus occurs most commonly in the superior cornea, but occasionally 360° corneal vascularisation may develop. Non infectious epithelial ulcers with an oval or shield-like shape (the so-called shield ulcer) with underlying stromal opacification may develop in the superior or central cornea. Vernal corneal plaques result due to coating of bare areas of epithelial macroerosions with a layer of altered exudates. An association between VKC and keratoconus has been reported. Stem cell deficiency may also occur in severe cases. Signs are consistent with the dry-eye syndrome.

Moderate to severe VKC needs repeated topical steroid treatment to downregulate conjunctival inflammation. Persistent severe symptoms, thick mucous discharge with moderate to severe corneal involvement, numerous and inflamed limbal infiltrates and/or giant papillae, indicate a need for corticosteroids [5]. Topical cyclosporine has immunomodulatory effects, has recently received attention for

its ability to reduce corticosteroid usage and its potential as an alternative treatment for corticosteroid resistant cases. It reduces ocular inflammation by inhibiting Th2 lymphocyte proliferation, interleukin2 production, and histamine release from mast cells and basophils.

Alcaftadine is an antiallergic therapeutic agent that has inverse agonist effects on H3, H2, and H4 receptors, as well as mast cell-stabilizing effects. In doing so, antihistaminic effect provides relief from itching associated with early phase of ocular allergic response, whereas mast cell stabilization inhibits the release of mediators such as cytokines and lipid mediators that play a role in late-phase response of allergic conjunctivitis. Although many studies have been done regarding this disease but very few, regarding visual problems and ocular complications and role of newer drugs in management of VKC has been compared. Hence this study was undertaken to find out effect of different monotherapies on symptom and sign scores of VKC.

### **Materials and Methods**

This is a prospective study conducted in the Department of Ophthalmology SLN Medical College and hospital, Odisha from 15<sup>th</sup> October 21 to 15<sup>th</sup> March 22. The study population was 227 VKC patients. Informed consent was taken from major patients and from parents of minor patients within this study period. The study was undertaken after taking approval from institutional ethical committee (IEC). The diagnosis of VKC was made on the history of severity of itching, with giant papillae on the palpebral conjunctiva and Horner-Trantas dots. Other corneal signs including pseudogerontoxon and punctate epithelial keratitis were noted. VKC was categorized as palpebral, limbal, or mixed.

The diagnosis of keratoconus was based on slit-lamp biomicroscopy, keratometry, retinoscopy, distant direct and direct ophthalmoscopy. Corneal topography was done in adjacent higher center and were quantitatively analyzed by using modified Robinowitz-McDonnell criteria, that is- patients with average stimulated keratometry of more than 46D, central corneal power of more than 47.3 D or infero-superior asymmetry (I-S) higher than 1/4 D were considered to have keratoconus.

All 227 patients underwent recording of visual acuity with Snelens chart and children under 5 years with key picture chart. Anterior segment examination was done under slit-lamp followed by plain mirror retinoscopy, and fundus examination with +90D +20D Volk lenses along with distant direct and direct ophthalmoscopic examination. 275 out of 277 (leaving 2 keratoconus patient) were randomly distributed in 3 groups. Group A-corticosteroid (loteprednol) alone with 91 patients, Group - B-Topical cyclosporine 0.5% 4 times daily with 92 patients, Group C-Topical alcaftadine 0.25% twice daily with 92 patient. The patients were evaluated at Weeks 4, 8 and 12 after the initiation of therapy. Symptoms and signs before and after treatment, during the four-week intervals, were recorded and scores between 0 and 3 were assigned. Symptom scores were calculated by grading of itching, discomfort (i.e. foreign body sensation, stinging and burning), tearing, discharge and photophobia. Sign scores were calculated by grading conjunctival hyperaemia, tarsal papillae, limbal papillae, keratopathy and

corneal neovascularisation. Extensiveness and size were considered when grading the tarsal conjunctival and limbal papillae. Corneal signs were scored according to the extensiveness of punctate epithelial keratitis and/or presence of ulceration. Corneal neovascularisation was graded according to corneal quadrants and by measuring the dimension from the limbus to the central cornea.

Table-1: Scoring method for signs and symptoms of Vernal keratoconjunctivitis

Variable	Score			
Symptom	0	1	2	3
Itching	None	Occasional	Frequent	Constant
Discomfort	None	Mild	Moderate	Severe
Tearing	None	Impression of wet eyes, without tears on the face	Intermittent tears on the face	Constant tear on face
Discharge	None	'Small I amount	Moderate	Constant
Photophobia	None	Mild	Moderate	Severe
Sign	0	1	2	3
Conjunctival hyperaemia	None	Mild	Moderate	Severe
Tarsal papilla	None	<1 mm	1-3mm	>3mm
Limbal papilla	None	<90° or <2mm	90°- 180° or 2-4 mm	180° or 4 mm
Keratopathy	None	Mild and localized punctate epithelial keratitis	Two quadrants of epithelial keratitis	Three or more quadrants of epithelial keratitis and/or corneal ulcer
Corneal neovascularization	None	<90° or <1mm	90°- 180° or 1-3 mm	>180° or >4 mm

### Statistical Analysis

All the data were analysed by Graph pad prism 5 software. Quantitative data were analysed by percentage and median. Data were compared for statistical significance using Chi-square test, Student's t-test and one-way ANOVA, as appropriate. A p value <0.05 was considered statistically significant.

### Results

Total number of patients with VKC were 227. The majority of them were males with number of 171 and females were minority with number of 56. The male: female ratio in this study came out to be approximately 3:1. Table 1 shows the gender distribution in this study. Age wise distribution of VKC is given in Table-2. All patients had bilateral disease, out of 227, 11 presented with shield ulcer in one eye and 2 presented with keratoconus in one eye. Table 6, 7 and 8 shows efficacy of topical corticosteroid, topical cyclosporine, topical alcaftadine in 3 month time period.

Table – 2 Age and Gender wise distribution of VKC

Age group (year)	Male	Female	Total
1– 4	11	6	17 (7.4%)
5 – 9	69	26	95 (41.8%)
10 – 14	59	17	76 (33.4%)
15 – 19	27	6	33(14.5%)
20 – 30	5	1	6 (2.6%)

Majority of cases belong to the age group of less than 9 years.

Table – 3 Gender and Pattern statistics of VKC in this study

Pattern of VKC	LIMBAL (53%)	PALPEBRAL (31%)	MIXED (16%)	TOTAL
Gender				
MALE	79 (46%)	57 (33%)	35 (21%)	171
FEMALE	34 (61%)	13 (24%)	9 (15%)	56
TOTAL	121	70	36	227

Most common type of VKC is Limbal type in our study.

Table – 4: Number of eyes with complication

Pseudogerontoxon	151
Punctate epithelial keratitis	159
Shield ulcer	11
Keratoconus	2

Table – 5: Visual Acuity in patients with VKC

>6/24	161
6/24->6/60	53
6/60-3/60	13 (Keratoconus and shield ulcer)

Table – 6: Sign and symptom score in VKC

Monotherapy treatment groups	Group-A-Topical corticosteroid	Group-B-topical cyclosporine	Group-C-Alcaftadine
Variable	Median Symptom score	Median Symptom score	Median Symptom score
Baseline	10	10	10.5
Week 4	4	5	8
Week 8	2	4	6
Week 12	1	3	5
	Median Sign score	Median Sign score	Median Sign score
Baseline	7	6	6.5
Week 4	3	3	5

Week 8	2.5	2	4.5
Week 12	1	2	3

## Discussion

Allergic diseases are very common in southern odisha. Majority of cases with VKC examined under this study were between the age of 5-9 years[41.8%] while very few seen to be suffering from VKC in adult age group that is above 20 year[2.6%]. (Table -2). A hospital-based study [6] reported a low prevalence of only 6% of patients with VKC to be above the age of 20 years and study [7] also reported only 4% of patients to be more than 20 years of age. However, an Indian study [8] has reported 12% of patients to be above 20 years of age. In tropical regions limbal disease may be severe. Boys are affected more often as girls. Here majority of cases were males with male:female ratio of 3:1. Most of the studies have reported similar male preponderance [9,10] However, a study by Ukponmwan [11] from Nigeria reported that more females affected as compared to male (1:1.3) which contradicts our study.

Diagnosis is of VKC was based on patient clinical history and presence of typical signs and symptoms .The most common clinical type of VKC in this study was limbal followed by by palpebral then mixed (Table-3). Majority of the patients had punctate epithelial keratitis as complication of VKC. 13 of them had complications like shield ulcer and keratoconus. Important fact is that all of them had visual acuity in range of 6/60-3/60 which was visually disabling according to WHO.

Before using topical corticosteroid the median value of symptom score was 10 and sign score was 7, which markedly reduced to symptom and sign score of 4 and 3 respectively by the end of week 4 and reduced to 2 and 1 respectively by the end of 8 week and 12 week. Before using topical cyclosporine the median value of symptom and sign score was 10 and 6 respectively, by the end of 12 week it reduced to 3 and 2 respectively. Before using topical Alcaftadine, the median of symptom and sign score was 10.5 and 6.5 respectively which reduced to 5 and 3 respectively by the end of 12 weeks.

## Limitations of study

There was no immunological diagnostic test done to these group of patients because of limitation in facility. And also History of other associated allergic disease and family history of allergic disease were not documented. Side effects with the medications were not documented.

## Conclusion

VKC is not a rare disease and severe form of VKC is potentially blinding .There is need to a disease severity grading to develop standardised therapeutic guidelines based on the stage of VKC. Visual loss occurs due to corneal scars and keratoconus. Corticosteroid is usually used as main drug for treatment of VKC but is associated with several complications of its long term use and according to the results of the above study, the use of topical cyclosporine 0.05% four times a

day is an effective and safe alternative therapy for VKC .Further studies are needed to determine the optimal duration of therapy and examine the likelihood of recurrence after the cessation of cyclosporine. Even newer antihistaminics, Alcaftadine, also showed improvement in VKC but not that significant. So, studies are needed to determine the optimal duration of therapy with Alcaftadine.

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