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Controlled trial of cyclosporine (0.05%) versus Olopatadine (0.2%) topical solution in treatment of vernal keratoconjuntivitis

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Abstract
A randomized controlled study was conducted at such sagar medical college, Jabalpur for comparative analysis of topical cyclosporine (0.05%) and olopatadine (0.2%) in patients of vernal keratoconjuctivitis. Total number of patients specified for study was 62 among which 30 patients received cyclosporine and 32 received olopatadine. Improvement in signs and symptoms was assessed for a period of one month. As a result both treatment modalities were found to be safe and effective in treating VKC. In 1st week Olopatadine was more effective but thereafter no statistically significant difference could be observed in their efficacy.

Introduction

Vernal Keratoconjuntivitis (VKC) is a chronic recurrent non infectious allergic disease that generally affects children and young adults[1]. Its onset is most common in spring and summer season i.e. the months of April and August[2]. The condition occurs commonly between 5-20 years of age with peak incidence between 11-13 years of age, males being affected more often than girls.

The three forms of vernal conjunctivitis are palpebral, limbal and mixed. Major symptoms include itching, tearing, photophobia, mucoid or ropy discharge and foreign body sensation. Signs include conjunctival erythema, chemosis, papillae, limbal infiltrates and corneal epithelial disease.

Treatment modalities are topical corticosteroids, antihistaminics, mast cell stabilizers and immunomodulators along with avoidance of allergy. Olopatadine (0.2%) both a mast cell stabilizer and selective H1 –histamine antagonist, has rapid onset and longer duration of action. Cyclosporin-A is a potent immunomodulator that inhibits the corneal expansion of T helper/inducer subsets of lymphocytes and the release of interleukins .Most of the therapeutic effects are achieved after 2 weeks and maintained for long term[3-4].

Materials and Methods

Sixty two patients with VKC were enrolled for the study. All patients received a complete ophthalmic

examination including specific evaluation of symptoms and signs. Patients were randomly allotted into marked study groups. In group 1 (cyclosporine 0.05%) 30 patients and in group 2 (olopatadine 0.2%) 32 patients were included. Signs of VKC were graded separately for each eye. Signs and symptoms were recorded at weekly intervals for a period of one month (at entry, day 7,day 14, day 28).The scores for ocular symptoms were added to give a total symptoms score; the total score for the signs were added to give the total sign score. The symptoms and sign scores were added to give total symptom plus sign (TSS) scores. The symptoms, sign and TSS scores were compared at baseline and at each follow up visit both within and between the groups

Observation and Results

Table No. 1 – Participant flow and follow up

	Group-1 (Cyclosporine)	Group-2 (Olopatadine)	Total
Total no of patients included in study	30	32	62
Age range	5 – 30 yrs	5 – 30 yrs	5 – 30 yrs
Gender Male Female	 15 15	 18 14	 33 29
Discontinued from treatment: missed visits/ personal reasons	5	6	11
Adverse effects	0	0	0
Total no of patients eligible for efficacy analysis	Male – 13 Female – 12	Male – 15 Female – 11	28 23

Table no. 2 Changes in composite scores within the groups

	Group-1 (cyclosporin)			**Group-1 (olopatadine)**		
	Symptoms	**Sign**	**TSS**	**Symptoms**	**Signs**	**TSS**
Day 0	56	43	99	58	44	102
Day 7	48	38	86	41	30	71
Day 14	31	29	60	33	30	63
Day 28	26	21	47	25	22	47

Table no.3 Group analysis by subjective and objective improvements

Subjective evaluation

	None	**Mild**	**Moderate**	**Severe**
Group-1	6	8	4	2
Group-2	7	6	5	2

Objective evaluation

	None	Mild	Moderate	Severe
Group-1	2	5	4	0
Group-2	3	8	3	0

Table no. 4 Comparison of results in both groups

No.of patients relieved		
	Group – 1	**Group - 2**
Day 7	18 (60%)	24 (75%)
Day 14	23 (76%)	25 (78%)
Day 28	23 (76%)	24 (75%)

Discussion

A total of 62 patients registered with 51 completing the study. In our study, it was observed that the disease has more prevalence in male, n=28 (54%) as compared to female, n=23 (45%). This is in concordance with study by Stefano Bonini et al[5].

Cyclosporine had 60% and 76% of patients relieved from symptoms in 1st and 2nd week respectively as compared to Olopatadine having 75% in 1st week and 78% in 2nd week. On 4th week follow up, cyclosporine showed significant improvement in symptom score with 76% patients relieved as compared to 75% in Olopatadine group. None of our evaluation could prove that cyclosporine is superior to Olopatadine in VKC.

Both treatment modalities were found to be safe and effective in treating VKC. In 1st week Olopatadine was more effective but thereafter no statistically significant difference could be observed in their efficacy.

Olopatadine is preferred for initial therapy of VKC cases because of its cost effectiveness. Cyclosporine with low recurrence rates is effective for long term control of VKC.

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