ORIGINAL RESEARCH PAPER

COMPARATIVE EVALUATION OF TOPICAL CYCLOSPORINE (0.05%) AND TOPICAL OLOPATADINE (0.1%) THERAPY IN VERNAL KERATO CONJUNCTIVITIS IN PAEDIATRIC AGE GROUP

Ophthalmology

KEY WORDS: Vernal kerato conjunctivitis (VKC), cyclosporine, olopatadine, chisquare test.

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Introduction :- VKC is a chronic bilateral ocular disease which is a hypersensitivity reaction of type I & type IV. Antihistaminics, mast cell stabilisers, immunomodulators, are commonly used for treatment. Olopatadine (0.1%) (mast cell stabiliser and selective H1 receptor antagonist) has rapid onset and longer action of duration and is cost effective.

Cyclosporine (.05%) is a specific T-cell inhibitor, reduces T-cell activation and expression of T-cell cytokines (IL-2 and IFN). It has a low recurrence rate and is effective for long term control of VKC. So, cyclosporins are effective in recurrent cases and more effective than topical olopatadine in management of VKC patients.

Aims & Objectives :- The aim of the study is to compare the efficacy of cyclosporine (0.05%) and olopatadine (0.1%) in VKC in children in a tertiary health care centre of West Bengal during the period May 2014 to June 2016.

Materials & Methods: - 134 patients with Bilateral VKC were divided into 2 groups and adviced for instillation of drops twice daily for 4 weeks and patients were assessed on 7th, 14th, & 28th day and score was given to each patient for their grades of symptom/sign and by adding up the total, score of each patient was found out.

Results: The data were analysed by Chi-square test. Using paired T-test for comparing the efficacy of group A & group B drugs imply that the study is statistically significant and there is a significant difference in efficacy of both the drugs.

Conclusion :- Topical cyclosporine is more effective than topical olopatadine in management of VKC patients though olopatadine is cost effective.

INTRODUCTION

Topical cyclosporine A is a neutral hydrophobic cyclic undecapeptide metabolite of fungus.¹

Cyclosporine is a specific T-cell inhibitor which causes less improvement of papillae in tarsal conjunctiva normalizes CD4 / CD8 ratio, diminish T cell activation and expression of T-cell cytokines (IL-2 IFN). Application of twice daily doses the

the rapeutic effects are achieved after 2 weeks and maintained long $\mathrm{term}^{2,3,4}$

Olopatadine is both a mast cell Stabiliser and selective H1 receptor antagonist. It has rapid onset and longer duration of action. Application of twice daily doses, it relieves the signs & symptoms of Vernal Keratoconjunctivitis like itching, discharge, redness but less improvement of Papillac in tarsal conjunctiva.

VKC is chronic bilateral ocular disease affecting children mostly during the spring & summer. Peak incidence is between 11-13 years. Boys are affected more than girls. It is an allergic disease, IgE binds with mast cell surface causing degranulation & releasing mediators of inflammation (histamine, IL3, IL4, IL5, IL13, IFN). It is a immunologically both type I & type V hypersensitivity reaction.

Treatment modalities are antihistaminics (topical & systemic) mast cell stabilisers, steroids, immuno modulators along with avoidance of allergens. ⁶

MATERIALS AND METHODS

134 Bilateral VKC were studied upto age of 15 years randomly.

INCLUSION CRITERIA :- Patients having symptoms of itching, redness, Lacrimation, Lid oedema, discharge, Tarsal papillae, Keratopathy.

EXCLUSION CRITERIA: Patient using any topical antiinflammatory anti allergic steroid drug, patient 1st follow up, corneal ulcer having systemic medication, any other ocular disease.

A double blind, randomized control study was conducted to compare the efficacy of Cyclosporine (0.05%) and olopatadine (0.1%) in VKC in children in a tertiary health care centre of West Bengal during the period from May 2014 to June 2016.

Patients were divided into Group A and B and were advised to administer drops twice daily for 4 weeks. Patients were assessed on 7th, 14th and 28th day. Pre and post treatment average symptoms score was noted on each follow up by using a grading scale (Grade 0-3) based on subjective assessment of severity of symptoms and objective assessment of signs. Score was given to each patient for their grades of symptom / sign and by adding up the total score of each patient was found out. The total score of all the patients in the group were added up to find out the total symptom score of each group. The average symptom score was then calculated by dividing the total score with the number of patients in each group. Recurrence rates were assessed in both groups after 8 weeks of treatment.

Grading/scoring of ocular signs and symptoms of VKC in this study.

Crading/scoring of ocular signs and symptoms of vice in this study.									
S/No.	Clinical features	Grade (o)	Grade (1)	Grade (2)	Grade (3)				
1	Itching	Absent	Mild	Moderate	Severe				
2	Lacrimation	Absent	Mild	Moderate	Severe				
3	Redness	Absent	Mild	Moderate	Severe				
4	Lid oedema	Absent	Mild	Moderate	Severe				
5	Discharge	Nil	Present but nomucous strand	Few mucous strands	Many mucouss trands				
6	Tarsal papillae	Absent	Few papillae <0.3 mm	Papillae (0.4 – 1.0 mm)	Giant papillae (>1 mm) Three				

7	Keratopathy	Absent	One	Two	quadrant
	FL stain / slit		quadrant	quadrant	
	lamp				
	examination				

RESULTS

Table - 1 Baseline Characteristics

SL.	Baseline	No. of Pa		
NO.	characteristic	Group – A (Olopatadine)	Group – B (Cyclosporine)	Total
1	No. of patients (%)	N = 70 (52.24%)	N=32 (47.76%)	N= 134
2	SEX Male	46 (65.70%)	42 (65.63%)	88 (65.67%)
	Female	24 (34.29%)	22 (34.38%)	46 (34.33%)
3	Age groups (in year)			
	0-5	6	4	10 (7.46%)
	6-10	12	18	30 (22.39%)
	11-15	52	42	94 (70.15%)

Table - 2 Frequency of Sign and Symptoms

SL.		No. of Patie			
NO.	Clinical features	Group - A (Olopatadine)	Group – B (Cyclosporine)	Total	
1	Itching	64 (91.43%)	54 (84.38 %)	118 (88.06%)	
2	Redness	48 (68.57 %)	42 (65.63 %)	90 (67.16 %)	
3	Lacrimation	46 (65.71%)	36 (56.25 %)	82 (61.19 %)	
4	Lid oedema	32 (47.71 %)	18 (28.13 %)	50 (37.31 %)	
5	Discharge	52 (74.29 %)	42 (65.36 %)	94 (70.15 %)	
6	Tarsal papillae	54 (77.14 %)	44 (68.75 %)	98 (73.13 %)	
7	Keratopathy	16 (22.86 %)	12 (18.75 %)	28 (20.89 %)	

Table – 3: Treatment effects: No. of patients (%) Relieved of symptoms and Signs / Recurrence rates.

		No. of Pat			
Day	Sign / Symptoms	Group – A (Olopatadine)	(Group – B Cyclosporine)	Total	
0	With symptoms	70	64	134	
7	Relieved of symptoms	42 (60%)	28 (46.88%)	70 (52.24%)	
14	Relieved of symptoms	46 (65.71%)	42 (65.63%)	88 (65.67%)	
28	Relieved of symptoms	48 (68.57 %)	50 (78.13 %)	98 (73.13%)	
60	Recurrence	12 (17.14 %)	4 (6.25 %)	16 (0.12 %)	

Table – 4 Score of each symptom / sign in Group A and their (%) improvement pre and post treatment.

Day	Group A (olopatadine) Symptoms score (% improvement)					Group B (cyclosporine) Symptoms score (% improvement)								
	I	R	La	Ld	D	T	K	I	R	La	Ld	D	Т	K
0	204	188	172	104	196	178	18	19	172	166	84	188	172	14
7	104	108	122 (29)	78 (25)	116 (40.8)	(3.37)	16 (11)	92 (56.57)	94 (45.34)	106 (36.14)	62 (26.19)	(39.36)	162 (5.81)	12 (14.28)
14	32 (84.31)	26 (86.17)	44 (74.41)	48 (53.84)	46 (76.53)	138 (22.47)	16 (11)	26 (86.59)	22 (87.2)	42 (74.67)	38 (54.76)	42 (77.65)	68 (60.46)	10 (28.57)
28	6 (97.05)	8 (95.74)	8 (95.34)	10 (90.38)	6 (96.93)	74 (58)	10 (44)	(100)	4 (97.26)	2 (98.79)	4 (95.23)	0 (100)	26 (84.88)	6 (57.19)

ABBREVIATION:-

I – Itching, R – Redness, La – Lacrimation, Ld – Lid Oedema, D – Discharge, T – Tarsal papillae, K – Keratopathy

DISCUSSION

The data was analysed by Chi square test. By comparing proportion of symptomatic relief of both drugs, it appears that Group B is more effective in relieving symptoms of Tarsal Papillae (84% vs 58%). Redness (97% vs 95%), Discharge (100% vs 96%), Itching (100% vs 97%) as compared to Group A after 4 weeks of treatment. Cyclosporine had 46.88% and 65.63% of patients relieved from symptoms in 1st and 2nd week respectively as compared to olopatadine, having 60% in 1st week and 65% in 2nd week. On 4th week follow-up, Cyclosporine showed significant improvement in symptoms score with 78% patients relieved as compared to 68% patients of olopatadine.

Using paired T test for comparing the efficacy of Group A and Group B drugs reveals t Cal = 0.341 > t. tab. = 0.11 at 50%. Level of significance implies that the study is statistically significant and there is significant difference in efficacy of both the drugs.

Side effects of both drugs consisted of mild ocular stinging after initial application but were relieved by 4th / 5th day of treatment, so it is not of much significance in this study. Recurrence rates were lower with cyclosporine as compared to olopatadine.⁵

CONCLUSION

Both the drugs are well tolerated and have similar clinical effects one week after therapy but olopatadine is cost effective. So, it is preferred for initial therapy of VKC cases. Cyclosporine with low recurrence rates is effective for long term control of VKC. So it is effective in recurrent cases. To conclude, topical cyclosporine 0.05% is more effective than topical olopatadine (0.1%) in management of VKC patients.

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