Original Article

A Comparison of Safety and Efficacy Between Sodium Cromoglycate 2% and Fluorometholone 0.1% in Management of Vernal Keratoconjunctivitis

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ABSTRACT

Objective: To compare the safety and efficacy of sodium cromoglycate 2% eye drops with fluorometholone 0.1% eye drops in patients with bilateral vernal keratoconjunctivitis (limbal and conjunctival palpebral or mixed).

Study Design: Quasi Experimental Study

Place and duration of Study: This study was carried out in Department of Ophthalmology, Combined Military Hospital, Multan from 20th May 2009 to 20th June 2009.

Patients and Methods: This was hospital based study conducted on 60 diagnosed cases of vernal keratoconjunctivitis attending the OPD of Eye Department Combined Military Hospital, Multan in year 2009. Cases were divided in to two groups of 30 patients each. Group 2 was treated with sodium Cromoglycate while Group 1 was given Fluoro metholone 0.1%. Ocular complaints were noted and graded. Slit lamp examination was done at the start of treatment and at the end of the treatment.

Results: After first week of treatment in group 2 (sodium cromoglycate 2%) 22 patients had mucoidal discharge with photophobia, redness and itching while in group 1 (Fluorometholone 0.1%) none of the patient had mucoidal discharge. At the end of study 24 patients had itching, redness and photophobia in group 2 but in group 1 only 16 patients had these symptoms. It was also revealed that 6 patients in group 2 had watering and mucoid discharge but none of the patient in group 1 had watering and mucoid discharge at the end of study. ($p < 0.001$)

Conclusion: Patients treated with fluorometholone 0.1% got better results than patients treated with sodium cromoglycate 2% in the management of vernal Keratoconjunctivitis

Key Words: Vernal keratoconjunctivitis, Sodium cromoglycate, Fluorometholone

INTRODUCTION

Vernal conjunctivitis is a bilateral, recurrent inflammation of the conjunctiva that tends to occur during warm weather, with peak onset in the spring and summer.

It may be a seasonal, external ocular inflammatory disease of unknown cause. Afflicted patients experience intense itching, tearing, photophobia and mucous discharge or a thick, ropy, yellow, mucoid discharge[1] and usually demonstrate large cobblestone papillae on their superior tarsal conjunctiva and limbal conjunctiva[1]. Although usually self-limited, vernal conjunctivitis can result in potentially blinding corneal complications. The condition occurs mainly in children and young adults in the age range of 5-25 years[2], with peak incidence in the age range 11-13 years. Boys are affected twice as frequently as girls[3]. Three forms of the disease occurs which are palpebral, limbal and mixed[1]. The palpebral form is marked by cobblestone papillae on the superior tarsal conjunctiva, while the lower lid is affected minimally[4]. The limbal form is marked by a broad, thickened, gelatinous opacification of the superior limbus that can override the cornea. A very characteristic manifestation of limbal vernal conjunctivitis is the presence of Horner-Trantas dots[5].

The drug treatment options for allergic conjunctivitis have markedly expanded over the last few years, providing opportunities for more focused therapy, but unfortunately often leaving both patient and doctor confused over the variety of options. This overview attempts to simplify the pharmacological treatment options based on the current understanding of drugs and their mechanisms of action. Simple therapeutic options will be eluded in the final suggested 'stepcare' approach. Cromolyn sodium: This compound is beneficial in the treatment of seasonal and perennial allergic conjunctivitis, giant papillary conjunctivitis, vernal and atopic keratoconjunctivitis. It is extremely well tolerated in the eye and the risks of long-term use are negligible. Its long safety record (up to 10 years of continuous use) makes it the drug of choice for many clinicians in long term use[6]. Fluoromethalone 0.1% (FML, Flucon) is a structured analogue of progesterone and is very effective in reducing ocular surface

inflammation with a low potential for IOP elevation. It is therefore a popular choice for surface disease[6,13].

The chronic nature of the disease must be considered when the treatment is decided. Treatment of chronic forms of ocular allergies may necessitate collaborative efforts between the ophthalmologist and the allergist or immunologist[6].

MATERIALS AND METHODS

This was quasi experimental study carried on 60 cases of primary vernal keratoconjunctivitis reporting Department of Ophthalmology in Combined Military Hospital, Multan during year 2009. The study included patients between 6 to 14 years of age and included both sexes. Those patients with history of dry eye other forms of allergic conjunctivitis, ocular surgery within 2 months before study, corneal ulcer of infectious origin, active ocular herpes, abnormality of nasolacrimal drainage apparatus and severe systemic allergy requiring systemic treatment were excluded and only patients having primary vernal keratoconjunctivitis were included in the study. After informed consent the procedure was explained and disease highlighted. Personal data including age and gender was noted and entered in proforma. Different symptoms (itching, tearing, burning, redness and mucoidal discharge) and signs (limbal hypertrophy, conjunctival chemosis, and presence of follicle) of VKC was noted and graded on slit lamp examination at the time of their enrolment (day zero) and at different times after starting the treatment (days 7, 15, and 30).

These patients were divided into two groups of 30 each. Group 2 had 30 patients who were treated with topical sodium cromoglycate (2%) and group 1 (30 patients) treated with topical floromethalone (1%). Follow up visits were planned to see response on 1st ,2nd ,3rd and 4th week**.** Cases were assessed for the overall effect of treatment using a five point grading system starting from Excellent to bad for variables of irritation, photophobia,watering and mucidal discharge.Data was analyzed by using SPSS version 11.T-test was applied to compare the two groups. Descriptive statistics were used to calculate mean and SD.

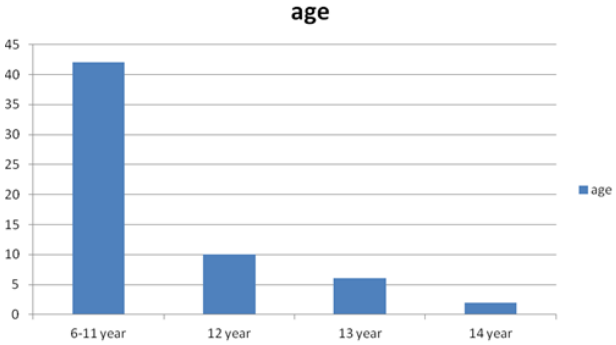
RESULTS

There was no drop out from our patients because they were included in study after detailed work up. All the patients were followed as outdoor cases. None of the patients required any hospital admission. There were a total of 48 male (80%) patients and 12 (20%) female patients. 42 (70%) patients were in age group 6-11, 10 (16.66%) in 12 years of age,6 (10%) of 13 years and 2 (3.33%) of 14 years of age. Most of the patients were from a younger age group. Age distribution is given in graph 1. No patients were found to have unilateral vernal keratoconjunctivits. Out of 60 patients, 36 (60%) had palpebral VKC, 5 patients (8.33%) had limbal VKC while 19 (31.66%) of patients had mixed VKC.

After first week, in group 2 (sodium cromoglycate 2%), out of 30 patients, 7 (23.33%) had itching and redness, 8 (26.66%) had itching, redness and photophobia. While 22 (73.33%) had mucoidal discharge with photophobia, redness and itching. In group 1 (Fluorometholone 0.1%), 4 (13.33%) had itching and redness, 3 (10%) had photophobia but none of the patient had mucoidal discharge.

After 2nd week of treatment in group 2, none of the patient complained of itching but 3 (10%) had redness with itching and 19 (63.33%) had itching, redness, photophobia and mucoidal discharge. In group 1 patients 3 (10%) had itching, 17 (56.66%) had redness but none of the patients had photophobia or mucoidal discharge.

At the end of 3rd week, out of 30 patients of group 2, 10 (33.33%) had redness and itching ,14 (46.66%) were photophobic and 10 (33.33%) had some mucoidal discharge with other symptoms. In group 1, 20 (66.66%) had some itching and redness but no patient was photophobic, or had any watering and mucoidal discharge. At the end of study 24 (80%) had itching, redness and photophobia in group 2 but in group 1 only 16 (53.3%) had these symptoms and 6 patient in group 2 had watering and mucoid discharge but none of patient in group 1 had watering and mucoid discharge.



Graph 1. Age distribution

Table No.1: Symptoms – At the End of Study.

Drug	Symptoms				Total
	Itching & redness	Itching, redness & photphobia	Itching, redness, photphobia & watering	Itching, redness, photphobia, watering, mucoidal discharge	
Sodium Cromoglycate 2%	10	14	4	2	30
Fluorometholone 0.1%	24	6	-	-	30
Total	**34**	**20**	**4**	**2**	**60**

DISCUSSION

The hypothesis of this study was that fluorometholone 0.1% was more effective than sodium cromoglycate 2% in the management of Vernal Keratoconjunctivitis. The study was conducted on 60 patients. There seemed to be was a male preponderance (95%). The results are comparable to a similar study conducted in Swat by Sheikh et al (82%)[7]. It was a retrospective study which was carried over 73 patients of Vernal Kerato-conjunctivitis (VKC) in Swat from July 1998 to April 1999. Most patients were between 4 years to 18 years. 64 out of these were male patients. The authors observed that 10 years or below and males patients were more affected. A similar study done at Karachi by Syed Shahab Ali also had similar results, showing (92%) male preponderance[8]. In Italy a study done by Gormaz et al[9] showed a 90% male preponderance.

Majority of the patients presented in first decade of their life between ages of 6-11 (60%). A study conducted in Peshawar showed similar results (61%)[9]. Another study done in Italy had the same result (65%)[10] which depicts that the disease is more common in young age group and presents before puberty.

The most common form of vernal keratoconjunctivitis encountered was palpebral (75%), and then the mixed type and a few cases of limbal were also seen. These results are comparable to the results shown by Iqbal et al.[9]

The most common symptom seen in the study was itching which all the patients reported (n=100%). The second common symptom was mucoid discharge. These findings are comparable to data given by Syed Shahab Ali at Karachi and Bisht R[8] in India. Photophobia was reported by only a few patients. This symptom is more associated when cornea is involved and as in our study there was less corneal complications so the result is explainable.

In our study after 4 weeks of treatment none of the patients complained of photophobia and mucoidal discharge. In a study done by Mentalli et al[11] Improvement in the watering, discharge, conjunctival hyperaemia, papillary hypertrophy, and Trantas' dots was noted in both groups, but overall fluorometholone was significantly more effective than nedocromil. Eyes treated with fluorometholone showed a significant decrease in ocular surface temperature compared with nedocromil treated eyes[6]. But in a study done by Greg et al. According to him significant improvement in all signs and symptoms except photophobia was observed after topical treatment for active VKC. Comparision of the efficacy of different drugs was not possible due to lack of standardized criteria among studies.[12]

In another study done in London was more effective in combating the acute stage of VKC and giving more rapid relief to the patient.

As the duration of our study was 4 weeks for each patient so the results were more in favour of flourometholone. A more comprehensive study of longer duration is therefore required to clearly understand the effect of both these medicines.

CONCLUSION

Vernal keratoconjunctivitis is a common form of ocular allergy in our part of the world The patients are usually young males in their early years of life. As the disease has a course of many years so it is a financial burden on the patients and their families. Many treatments are available but none so far have proven to be a better option than fluorometholone in its management. The need of the hour is to do more and more research so that we come up with a final solution to decrease the misery of the patient.

REFERENCES

1. Leonardi A, Motterle L, Bortolotti M. Allergy and the eye. Clin Exp Immunol 2008;153 Suppl: 17–21.
2. Bonini S, Coassin M, Aronni S, Lambiase A. Vernal keratoconjunctivitis. Eye 2004;(4):345-51.
3. Leonardi A, Motterle L, Bortolotti M. Allergy and the eye.Clin Exp Immunol 2008;153 Suppl:17-21.
4. Bremond-Gignac D, Donadieu J, Leonardi A, Pouliquen P, Doan S, Chiambarretta F, et al. Prevalence of Vernal Keratoconjunctivitis: A Rare Disease? Br J Ophthalmol 2008;92:1097-102.
5. Shady T, Awwad M, Najjar DM, Aouad A, Randa S, Haddad. Vernal keratoconjunctivitis presenting unilaterally. J Pediatr Ophthalmol Strabismus 2006;43(3):179-80.
6. Jun J, Bielory L, Raizman MB. Vernal Conjunctivitis. Immunol Allergy Clin 2008; 28(1): 59-82.
7. Kanski JJ, Clinical Ophthalmology A Systematic Approach. Publisher: Butterworth-Heinemann Medical; 2007.
8. Hu Y, Matsumoto Y, Dogru M, Okada N, Igarashi A, Fukagawa K, et al. The differences of tear function and ocular surface findings in patients with atopic keratoconjunctivitis and vernal keratoconjunctivitis. Allergy 2007;62(8):917-25.
9. Koczman JM, Thomas A, Oetting M. Vernal Keratoconjunctivitis: 8 year-old asthmatic male with reduced vision 2007 [cited 2007 June 25]; Available from: http://webeye.ophth.uiowa.edu.
10. Knop N, Knop E. Conjunctiva-associated lymphoid tissue in the human eye. Invest Ophthalmol Vis Sci 2000;41(6):1270-9.
11. Tiffany J. The Normal Tear Film. In: Geerling G, Brewitt H, editors. Surgery for the Dry Eye. Dev Ophthalmol. 41st ed. Basel: Karger; 2008.p.1-20.
12. Ghavami S, Hashemi M, de Serres FJ, Bajestani SN, Mehrabifar H, Leonardi A, et al. Trypsin inhibitory capacity in vernal keratoconjunctivitis. Invest Ophthalmol Vis Sci 2007;48(1)264-9.
13. Keklikci U, Soker SI, Soker CS, Ozkul S, Sakalar YB. Unilateral vernal keratoconjunctivitis: a case report. Eur J Ophthalmol 2007;17(6):973-5.

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