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Research article

COMPARATIVE EVALUATION OF AZELASTINE AND FLUOROMETHOLONE IN THE TREATMENT OF SPRING CATARRH (VERNAL CATARRH)

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ABSTRACT

Aim and Objective: To study and compare the efficacy of FML & Azelastin eye drops in relieving symptoms & regressing signs of VKC. **Methodology:** This Prospective Interventional study conducted at Sarojini Devi eye hospital, Hyderabad which is a regional institute of Ophthalmology during the period July 2004 to July 2005. The 100 patients of spring catarrh reported to SD eye hospital during the period were randomly divided into 2 groups of 50 each. Group I were given Fluorometholone 0.25% eye drops four times daily for a period of 4 weeks. Group II were given Azelastine HCl 0.05% eye drops four times daily for a period of 4 weeks. **Results:** Documented by taking symptomatic relief of patient, Clinical improvement of signs, reduction in Eosinophils and Mast cells on histopathological examination. **Conclusion:** This study shows that Fluorometholone is superior to Azelastine in relieving Symptoms and regression of signs in the cases of Vernal catarrh.

Keywords: Vernal keratoconjunctivitis (VKC), FML (Fluorometholone), Azelastine, Eosinophils, Mast cells

INTRODUCTION

Vernal keratoconjunctivitis is a seasonal disease which occurs in summer season in India. Dust, pollens and Ultraviolet rays are considered as aetiological factors. The disease runs a chronic course. The present treatment modalities can provide symptomatic relief for a short duration of time, but not offer any cure. The recurrences every year remains a problem¹.

Fluorometholone is a synthetic corticosteroid. It acts by induction of phospholipase A2 inhibitory proteins which controls synthesis of mediators of inflammation as Prostaglandins and leukotrienes by inhibiting the release of common precursor, Arachidonic acid². Azelastine is a selective H1 antagonist and inhibitor of Histamine and other mediators of inflammation from Mast cells².

Incidence of the disease is common in first and second decade³. Common symptoms are itching, foreign body sensation, and watering⁴. Signs are ropy discharge, cobblestone papillae on tarsal conjunctiva and limbal nodules⁴.



Fig1: Cobblestone papillae on tarsal conjunctiva

Aim and objectives

To study and compare the efficacy of FML and Azelastine eye drops in relieving the symptoms and regressing signs of VKC

MATERIALS AND METHODS

This study has the approved by the ethics committee of Osmania Medical College. There is no financial interest to be disclosed. This study was conducted at Sarojini Devi eye hospital, Hyderabad during the period July 2004 to July 2005. 100 patients of vernal catarrh between the age group of 10-30 years were selected. Of these, 90 were males and 10 were females. The patient didn't receive any treatment for the past one month. 100 patients were randomly divided by simple random technique into two groups of 50 each. Group I were given Fluorometholone 0.25% eye drops 4 times daily for a period of 4 weeks. Group II received Azelastine 0.05% eye drops 4 times daily for 4 weeks. Adult patients were informed about the study and informed consent taken in their mother tongue. Minor patients' attenders (either of the parent) were explained about the study and informed consent taken in front of witness. Patients with complications of VKC⁵ like shield ulcer, glaucoma and other ocular disorders were excluded from the study. The patients were evaluated at 0,1, and 4 weeks using relief from symptoms and improvement of signs using a slit lamp.

The symptoms were Itching, Foreign body sensation, tearing, discomfort which were graded between 0 to grade III^{6,7}. The improvement in signs were classified as Conjunctival hyperaemia, Papillary hypertrophy, Limbal nodules, Quantity of discharge which were graded between 0 to grade III depending upon absence, mild, moderate and severe involvement^{6,7}.

Conjunctival scrapping from palpebral and bulbar conjunctiva were taken from both eyes and Leishman's staining was done to see the Eosinophils and Mast cells in the smear both before and after treatment.

Taking into consideration the probability of a positive outcome was $P = 68\%$ ^{6,7} and the expected fallout or error as $L = 14\%$

$Q = 1 - P = 100 - 68 = 32\%$

Sample size is calculated as:

$$\frac{4PQ}{L^2} = \frac{4 \times 68 \times 32}{14 \times 14} = 44.40816$$

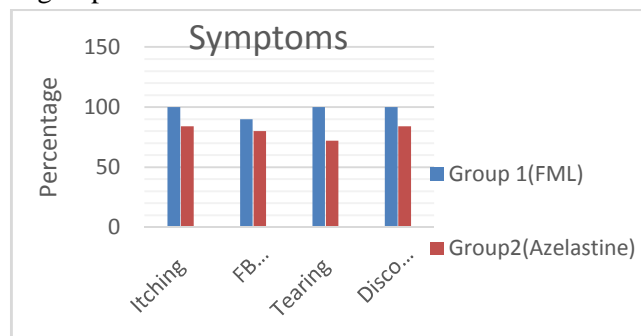
Which is approximately 45, hence a round figure of 50 was taken as sample size.

RESULTS

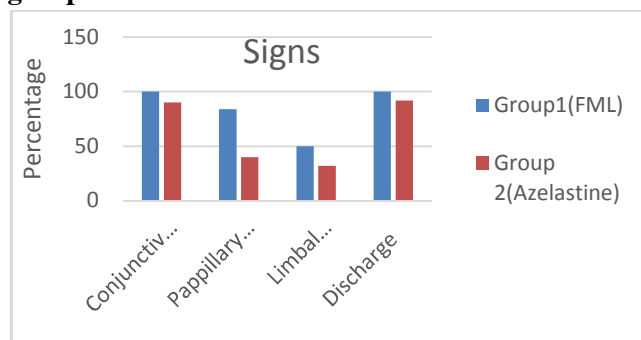
100 patients were studied and treated. Majority of patients were in the age group of 1-10 years ie.50%. 11-20 years formed 45%, whereas 21-30 years group formed 5%. Males were 90% as against 10% females. The earliest symptom to respond to the treatment with both drugs was itching and tearing followed by discomfort. Although the patients responding at the end of the first week were more in group I (Fluorometholone) as compared to group II (Azelastine). At the end of 4 weeks relief from itching, watering and discomfort was 100% with Fluorometholone group, whereas in the Azelastine group only about 80% were relieved.

The earliest sign to show regression after first week of treatment was Conjunctival hyperaemia followed by discharge. Though the patients showing regression were more in Group I.

At the end 4 weeks regression of Conjunctival hyperaemia and discharge was 100% in group I and 92 % in group II. Papillary hypertrophy showed a regression in 84% in group I and 40% in group II at the end of 4 weeks. Limbal nodules have shown regression only in 50% of cases in group I and 32% in group II.



Graph1: Comparison of symptoms in group 1 & group 2 after 4th week.



Graph2: Comparison of signs in group 1 & group 2 after 4th week.

Histopathology at the end of 4 weeks had shown decreased cellularity and complete absence of Eosinophils and Mast cells in Group I, but group II patients had shown persistence of Eosinophils.

In this study Fluorometholone is more effective in relieving subjective complaints of patients and in regression of signs both at the end of 1 week and 4 weeks. Even histopathological study shows the superiority of Fluorometholone when compared to Azelastine.

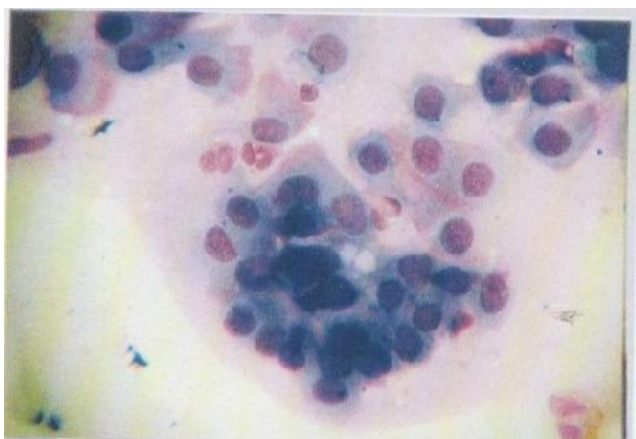


Fig 2: Group1 before treatment showing Eosinophils and mast cells (HPF) 40x

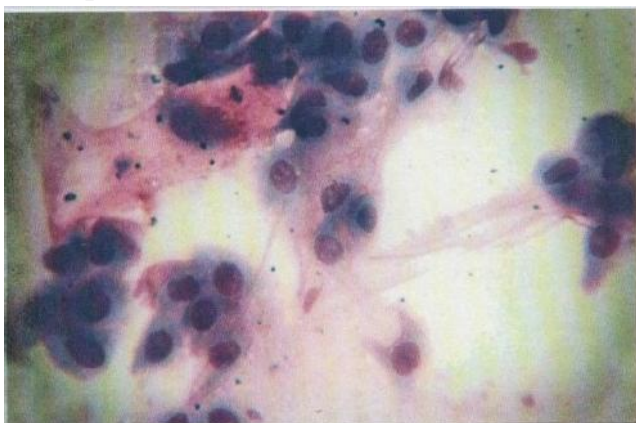


Fig3: Group 1 4 weeks after Treatment with FML showing no eosinophils and mast cells (HPF) 40x

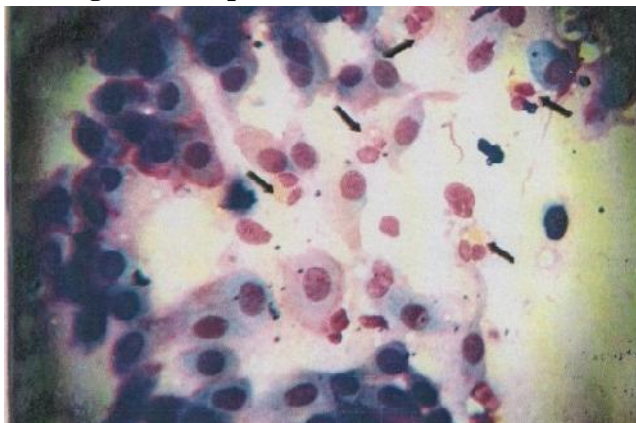


Fig4: Group2 before treatment showing Eosinophils and mast cells (HPF) 40x.

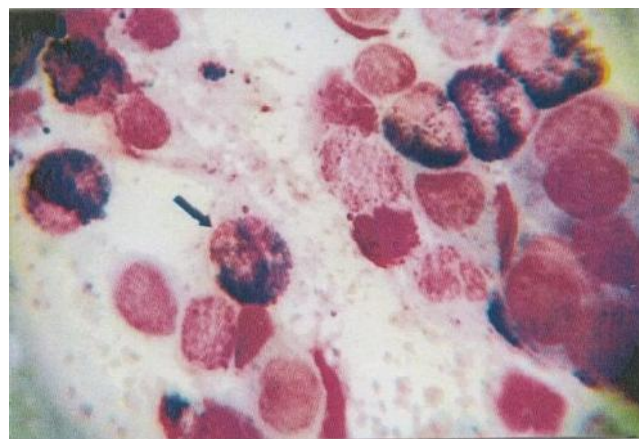


Fig 5: Group 2 after 4 weeks treatment with azelastine still showing occasional eosinophils and mast cells in 40x (HPF)

For testing the statistical significance of above findings Chi square test was performed. Fluorometholone was found to be superior to Azelastine with statistical significance as shown in table for symptoms like itching, tearing, FB sensation and discomfort. Regression of signs like Conjunctival hyperaemia, papillary hypertrophy and discharge was found to be statistically significant as shown in the table. Limbal nodule doesn't show any significant difference between two groups.

Table1: Comparison between symptoms of Group1 & Group2

Symptoms	P' Value
Itching	< 0.0032**
FB Sensation	< 0.1614*
Tearing	< 0.0001***
Discomfort	0.0032**

using Chi-Square test after 4th Week.

Table2: Comparison of signs between Group 1 & Group

Signs	P' Values
Conjunctival Hyperaemia	0.0218**
Papillary Hypertrophy	0.0001*
Limbal Nodules	0.0673***
Discharge	0.0412**

2 using Chi-Square test after 4th week.

*Very Significant ** Significant *** Not significant

DISCUSSION

This study using FML & Azelastine was conducted to show the limitation of Azelastine as first line drug in

the treatment of Spring catarrh. The earliest symptom to respond with both the drug was itching and tearing Followed by discomfort. At the end of one month the relief from itching, tearing and discomfort was 100% in group1, whereas it was only 80% in group 2 patients.

The earliest sign to show regression after 1st week of treatment was conjunctival hyperaemia followed by discharge.70% of patients in group 1 had shown regression in papillary hypertrophy as compared to only 10% in group 2. At the end of one month, the regression in conjunctival hyperaemia and discharge was 100% in group 1 as compared to 92% in group 2.The papillary hypertrophy regressed in 84% in group 1 and 40% in group 2. The Limbal nodules have shown regression only in50% of cases in Group 1 and 32% in group 2.

CONCLUSION

This study shows that Fluorometholone is superior to Azelastine in relieving Symptoms and regression of signs in the cases of Vernal catarrh. It can be used as a drug of first choice to relieve symptoms and signs.

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Conflict of Interest: There is no conflict of interest

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