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ORIGINAL ARTICLE

Treatment Efficacy of Vernal Keratoconjunctivitis with 0.1 Percent Fluorometholone and 0.05 Percent Cyclosporine

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ABSTRACT

Objective: The purpose of this study was to evaluate the efficacy of two common treatments for vernal keratoconjunctivitis: fluorometholone (0.1%) and cyclosporine (0.05%).

Study Design: Comparative/prospective study

Methods: Total 86 patients of vernal keratoconjunctivitis were included in this study. Two groups were equally created, group I received fluorometholone (0.1%) in 43 cases and group II received cyclosporine (0.05%)in 43 cases. To find the significant value, chi-square and unpaired t test procedures were employed.

Results: There were 52 (60.5%) males and 34 (39.5%) females among all cases. There were 45 (52.3%) cases had age 5-10 years, 25 (29.1%) cases had age 11-15 years and 16 (18.6%) cases had age 16-20 years. Among all, itching and redness were the most common signs/symptoms. Frequency of efficacy in group I was 39 (90.7%) and in group II efficacy was found in 31 (72.1%) cases with p value <0.003. Frequency of systemic allergy was higher in group I as compared to group II <0.002.

Conclusion: According to these findings, fluorometholone might be an improved option for treating severe vernal keratoconjunctivitis. It is important to take systemic allergy links into account when treating.

Keywords: Cyclosporine, Fluorometholone, Vernal Keratoconjunctivitis

INTRODUCTION

A chronic and recurrent infection of the conjunctiva and corneas, known as vernal keratoconjuctivitis (VKC), can affect children, especially boys. Since VKC is both seasonal and allergic, it tends to flare up more frequently in the warmer months. However, it can arise at any time of year. This uncommon condition primarily affects children and usually resolves itself after puberty[1,2] The presence of conjunctival congestion, papillary hypertrophy, and large papillae in the conjunctiva, as seen under a microscope, helps to confirm the diagnosis. Research has shown that antihistamines and mast cell stabilizers can effectively treat mild to severe cases of VKC. To reduce inflammation in the conjunctiva and cornea, individuals experiencing severe instances are given topical steroids.

Medication is an effective treatment for most cases of ACD. Inhibitors of histamine receptors and stabilizers of mast cells work together to safely and efficiently reduce ACD symptoms.[3,4] Individuals suffering from severe ACD frequently require stronger anti-inflammatory drugs, such as immunomodulators and topical corticosteroids. Despite the positive effects on patients with severe ACD, topical cyclosporine and tacrolimus have some limitations that limit their usage[5,6]. To begin, these nonsteroidal immunomodulators have the potential to generate a significant stinging sensation, which has led some individuals to report poor compliance[7]. Secondly, tacrolimus is an off-label drug, hence it is not yet sold in our countries. Furthermore, there is currently no consensus among writers on the frequency or dosage[7]. In such cases, topical corticosteroids could be applied; however, it is not recommended to use them for extended periods of time due to their negative side effects, which include steroid-induced glaucoma, cataracts, slowed wound healing, and an increased susceptibility to infection or superinfection, especially in children. The rationale behind this is that steroid treatment is more likely to cause an increase in intraocular pressure (IOP) in children (over 60% of whom respond) than in adults. Two distinct classes of steroids are used in ACD, distinguished by their ocular penetrating capabilities. When starting treatment, it is not advisable to use high-potency steroids like 1% prednisolone phosphate or 0.1% dexamethasone sodium phosphate due to the increased risk of side effects. For active VKC cases, it is recommended to use low-potency steroids, such as fluorometholone acetate 0.1%, as they have low intraocular penetration[8]. Regular monitoring of intraocular pressure (IOP) is essential with long-term use of low-potency steroids.

At this time, researchers are still trying to find a topical medication that will cure vernal keratoconjunctivitis (VKC) without causing side effects. In clinical trials, topical cyclosporine showed promise as a first line of treatment for both the limbal and palpebral kinds of vernal keratoconjunctivitis[9-12] However, its efficacy in VKC in comparison to topical steroids is not well documented. Researchers in this study sought to determine if cyclosporine or fluorometholone, two ophthalmic treatments, was safer and more successful in treating vernal keratoconjunctivitis in patients.

We are still in the hunt for an effective topical therapy for VKC management. Examining the efficacy of 0.1% fluorometholone and topical 0.05% cyclosporine in the treatment of VKC is the goal of this study. Information gleaned from the study will help improve healthcare delivery and patient health.

MATERIALS AND METHODS

In this study, 86 individuals with untreated vernal keratoconjunctivitis were enrolled using a non-probabilistic consecutive sampling technique. Using Openepi, we calculated the sample size according to the following parameters: power of test = 90%, confidence interval at 5%, topical fluorometholone efficacy = 93.33%, and topical cyclosporine efficacy = 66.67%.Glaucoma, uveitis, ocular damage, contact lenses, and oral steroids were all included as exclusion factors. One set of subjects was randomly assigned to each patient through a lottery, while the other set of subjects was assigned sequentially to each patient by a systematic sampling technique. Patients in Group I were given a topical solution of 0.1% fluorometholone every two hours, with a rapid tapering off after that, whereas those in Group II were given a solution of 0.05% cyclosporine four times a day. We documented details including names, ages, genders, addresses, and any extra allergies using a pre-made proforma. At the start of treatment, as well as on days 7, 14, and 30, symptoms were scored using a 0–10 scale, as shown in Table 1. A final score of 3 or below was considered indicative of the drug's efficacy on day 30. Data analysis was conducted using SPSS version 24. To illustrate gender, medication effectiveness, and other allergy-related characteristics (such as asthma, rhinitis, and atopic dermatitis), we

utilized percentages and frequencies. This is why a chi-square test was employed to compare the two groups' results. Stratification was used to compensate for effect modifiers and confounders, including age, gender, and baseline score. A chi-square test was performed after stratification with a significance level of P≤0.05.

RESULTS

There were 52 (60.5%) males and 34 (39.5%) females among all cases. There were 45 (52.3%) cases had age 5-10 years, 25 (29.1%) cases had age 11-15 years and 16 (18.6%) cases had age 16-20 years. Among all, itching and redness were the most common signs/symptoms.(Table 1)

Table-1: Demographics of the presented cases

Variables	Frequency	Percentage
Gender		
Male	52	60.5
Female	34	39.5
Age		
5-10 years	45	52.3
11-15 years	25	29.1
16-20 years	16	18.6
Signs/symptoms		
itching	30	34.9
redness	20	23.3
Discharge	10	11.6
Conjunctival sign	15	17.4
Corneal sign	11	12.8

Frequency of efficacy in group I was 39 (90.7%) and in group II efficacy was found in 31 (72.1%) cases with p value <0.003.(table 1)

Table-2: Frequency of efficacy among both groups

Variables	Group I	Group II	P Value
Outcomes			
Effective	39 (90.7%)	31 (72.1%)	0.003
Non-effective	4 (9.3%)	12 (27.9%)	

Frequency of systemic allergy was higher in group I as compared to group II <0.002.(figure 1)

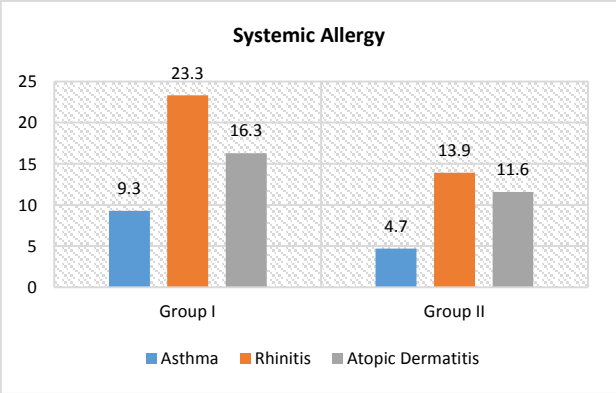

Figure-1: Post-treatment comparison of systemic allergy

DISCUSSION

Complex and affecting people of all ages, VKC can cause irreversible visual loss and severely diminish quality of life. Nevertheless, no universally accepted therapeutic approach has been identified for patients that are particularly severe or resistant. Our investigation discovered that Fluorometholone and Cyclosporine had comparable effects in individuals with moderate sickness (baseline score ≤5). People with severe VKC (baseline score ≥ 6), the effectiveness rate of fluorometholone was 90.7%, whereas that of cyclosporine was 72.1%. The efficacy of steroids and immunomodulators in the treatment of VKC has been the focus of various studies. Gupta et al. found that from day 7 to day 30, both groups of people who were given topical fluorometholone or cyclosporine saw a decrease in their symptoms and sign scores.as mentioned in[13] After considering all patients, it was shown that the fluorometholone group experienced more symptom and sign relief compared to the cyclosporine group (p<0.002).

The use of topical cyclosporine as a steroidsparing agent and a successful treatment for severe allergic conjunctivitis was found in a study by Ozcan et al. This drug is most effective when used at a concentration of 0.5 percent, which is also the most tolerable. Cyclosporin concentrations as high as 2% have been documented in the literature, while 1% is sufficient for severe instances. Topical cyclosporine significantly reduced the need for topical steroids and decreased median signs and symptoms, according to another trial[16]

In addition, with the exception of the change in corneal involvement from week 2 to week 6, the time effect was substantial for all other metrics. Signs of clinical activity include the existence of conjunctival congestion[17]. From week 2 to week 6, both groups showed continuous improvements in conjunctival hyperemia and palpebral conjunctiva papillae. However, there was no significant change in corneal involvement in this study. The corneal epithelium is unable to heal from wounds caused by mechanical abrasions caused by the papillae and by the cytotoxic chemical mediators secreted by eosinophils[17,18]. Until the inflammation goes down, the cornea might not mend until week 6. That is to say, interventions lasting longer than six weeks are typically necessary for cases of severe ACD.

The results of our study are supported by Baisakhiya S and Chaudhry M, who compared the efficacy of olopatadine (0.1%), cyclosporine A (0.05%), and fluorometholone (0.1%) applied topically as a monotherapy for VKC[19] At the conclusion of the first week, the researchers found that all three groups had achieved equal clinical improvement (p>0.01). The fluorometholone group had 86.67% improvement, the olopatadine group had 80%, and the cyclosporine A group had 80%. The recurrence rate at the end of the second month was 33.3% in the olopatadine group, 20% in the cyclosporine A group, and 0% in the fluorometholone group. According to the findings, fluorometholone is the most effective medication for VKC monotherapy.[20]

CONCLUSION

According to these findings, fluorometholone might be an improved option for treating severe vernal kerato-conjunctivitis. It is important to take systemic allergy links into account when treating.

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