

Efficacy of Topical 0.05% Cyclosporine in Vernal Keratoconjunctivitis in Children Aged 5-15 Years Visiting Outpatient Department



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ABSTRACT

Purpose: To assess the effectiveness and safety of short-term use of topical 0.05% cyclosporine in children with Vernal Keratoconjunctivitis (VKC).

Study Design: Quasi experimental study.

Place and Duration of Study: Sheikh Zayed Medical College and Hospital in Rahim Yar Khan from April 2025 to September 2026.

Methods: A Consecutive sampling was done to include 78 children of 5-15 years of age who had clinically identified VKC. The analysis involved one eye of each patient. They were treated with the topical cyclosporine 0.05% eye drops four times per day for one month. The severity of the disease was evaluated using a validated clinical scoring system that included symptoms and indicators at baseline and after one month. Treatment was considered effective if there was at least one point improvement in the total VKC score from baseline.

Results: There were 65.4% males. The total VKC score dropped significantly from the baseline of 10.0 [IQR: 8.0-13.0] to 4.0 [IQR: 2.0-6.0] after one month ($p < 0.001$). Clinical improvement was noted in 69 patients (88.5%). No substantial differences in treatment response were observed based on age, gender, duration of symptoms, or daily computer usage. A mild, temporary burning sensation was observed in 7% of individuals.

Conclusion: Topical 0.05% cyclosporine provided substantial short-term therapeutic improvement and exhibited a positive safety profile in pediatric patients with VKC. Larger, randomized controlled trials with longer follow-up are needed to confirm these preliminary findings and to establish the long-term role of this treatment in VKC management.

Keywords: Vernal Keratoconjunctivitis, Cyclosporine, Pediatric Ophthalmology, Immunosuppressive Agents.

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INTRODUCTION

Vernal keratoconjunctivitis (VKC) is a chronic, bilateral, and recurrent allergic inflammatory condition

that predominantly affects the ocular surface in children and young adults. It is defined by a type I hypersensitivity reaction, facilitated by immunoglobulin E (IgE) and the activation of mast cells, eosinophils, and T-lymphocytes inside the conjunctival tissue.¹ Clinical presentation is often severe, with excessive lacrimation, photophobia, and the formation of gigantic cobblestone papillae on the tarsal conjunctiva, Horner-Trantas spots at the limbus, and potential corneal sequelae that endanger sight, such as shield ulcers.^{2,3} The disease exhibits a certain demographic and geographic density, being more

prevalent in arid and warm areas like South Asia, Central Africa, and South America, and is more prevalent in males than females.⁴⁻⁶

VKC is a significant therapeutic challenge to manage. Topical antihistamines and mast cell stabilizers are the first line of treatment for mild cases; more severe VKC usually needs topical corticosteroids to deal with extensive inflammation. The long-term use of corticosteroids is, however, greatly limited by the known ocular side effects, which include cataract formation, glaucoma, and secondary infections.^{4,7} This has been a major limitation, which has seen the quest to come up with effective steroid-sparing therapies that can effectively manage chronic inflammation. Topical immunomodulators, e.g., cyclosporine A (CsA), have emerged as an essential treatment of steroid-dependent or resistant VKC. CsA acts by inhibiting calcineurin that inhibits the activation of T-lymphocytes and the production of pro-inflammatory cytokines.^{8,9} Though there has been 0.1% concentration of cyclosporine allowed in VKC in some regions, research on the lower levels, including 0.05%, should be done to strike a balance between effectiveness and local tolerance. The present study offers promising results with varied data on the efficacy of topical 0.05% CsA. In one of the studies, 52.8% full-healing rate was found in the span of one month (10), whereas in the other, it was found to have a higher rate of 70.5%.^{10,11} This inconsistency underscores the need to conduct more studies on specific demographics of patients.

This study was conducted to have localized evidence in treating VKC. The area around Rahim Yar Khan, a district of Pakistan, has a hot and humid climate which is a predisposing factor of VKC among the pediatric population. Currently, not much information exists on the effectiveness of 0.05 percent cyclosporine when applied to this demographic and environmental context. The proposed study will determine the efficacy of topical 0.05% cyclosporine among children aged between 5 and 15 years with VKC. The results aim at providing meaningful information to the local health care professionals and policymakers, offering a safe and effective substitute to corticosteroids, and thus increasing the quality of treatment of the children with this systemic allergic eye disease in the area.

METHODS

The study was conducted at outpatient department of ophthalmology at Sheikh Zayed Medical College and

Hospital, Rahim Yar Khan from April 2025 to September 2025. The Institutional Review Board (**Reference No. 555/IRB/SZMC/SZH**) approved the study. The research was compliant with the Declaration of Helsinki.

The children of 5-15 years of age, diagnosed with VKC were included. Patients who had previously been diagnosed with hypersensitivity to cyclosporine, had suffered a head injury or eye operation, had an active eye infection (e.g., infectious keratitis), or had any other inflammatory eye condition (e.g., uveitis or glaucoma) were excluded. A total of 78 patients were recruited using a non-probability consecutive sampling. We included one eye from one patient (the more severely affected eye). Sample size was calculated using WHO sample size calculator, with expected efficacy of 52.8%, level of confidence of 95%, and margin of error of 10%.

After obtaining verbal informed consent from parents or guardians, demographic and clinical data was recorded including age, gender, duration of symptoms, and relevant ocular history. Each participant underwent a comprehensive ocular examination. Visual acuity was assessed using a Log MAR chart, intraocular pressure was measured with Goldmann applanation tonometer and slit-lamp biomicroscopy was done for anterior segment examination and dilated fundus examination using 1% tropicamide eye drops. VKC severity was determined by a standardized clinical scoring system adapted from Bonini et al, which evaluates symptoms (itching, tearing, photophobia, and discharge) and signs (conjunctival hyperemia, tarsal papillae, limbal papillae, and corneal involvement).¹² Each patient was recorded on a baseline score before the treatment started.

The participants were prescribed topical cyclosporine 0.05% eye drops four times a day for one month. Other topical ocular medications (including antihistamines, mast cell stabilizers, corticosteroids, or vasoconstrictors) were stopped during the study period. Data analysis was done using SPSS version 26.0. The Shapiro-Wilk test was used to assess normality of the data. Continuous variables were presented in mean, standard deviation, or median interquartile range (IQR). Frequencies and percentages were used to present categorical variables. The signed-rank Wilcoxon test was used to compare the before and after treatment of VKC. Stratified analysis was done to determine efficacy in terms of age, gender,

duration of symptoms, and computer use. Chi-square test or Fisher's exact test was used for group comparisons, where a p-value of ≤ 0.05 was considered statistically significant.

RESULTS

The mean age of the patients was 10.2 ± 3.1 years, and 65.4% were males ($n = 51$). The median duration of symptoms was 12 months (IQR: 6-18 months). The basic demographic and clinical features of the patients are provided in Table 1.

After one month of treatment with topical 0.05% cyclosporine eye drops, significant improvement in both subjective symptoms and objective clinical signs

Table 1: Demographic and Clinical Characteristics of Study Participants at Baseline ($n = 78$).

Characteristic	Value
Age (years), Mean \pm SD	10.2 \pm 3.1
Gender, n (%)	
Male	51 (65.4%)
Female	27 (34.6%)
Duration of Symptoms (months), Median [IQR]	12.0 [6.0–18.0]
Daily Computer Use >6 hours, n (%)	22 (28.2%)
Baseline Total VKC Score, Median [IQR]	10.0 [8.0–13.0]
Baseline Total VKC Score, Mean \pm SD	10.0 \pm 1.4
Baseline Disease Severity, n (%)	
Mild (Total Score 1-7)	0 (0%)
Moderate (Total Score 8-14)	78 (100%)
Severe (Total Score 15-24)	0 (0%)

Table 2: Comparison of VKC Clinical Scores at Baseline and After One Month of Treatment ($n = 78$).

Variable	Baseline Score, Median [IQR]	Score at 1 Month, Median [IQR]	p-value
Total VKC Score	10.0 [8.0–13.0]	4.0 [2.0–6.0]	<0.001*
Symptom Sub score	5.0 [4.0–7.0]	2.0 [1.0–3.0]	<0.001*
Sign Sub score	5.0 [4.0–6.0]	2.0 [1.0–3.0]	<0.001*

Wilcoxon signed-rank test

was noticed. The median total VKC score significantly declined to 4.0 (IQR: 2.0–6.0) during the one-month follow-up ($p < 0.001$). These changes are shown in Table 2.

According to the predefined criterion for treatment effectiveness, 69 out of 78 patients (88.5%) demonstrated clinical improvement after one month of therapy. Stratified analysis has been done to measure the uniformity of treatment response among various patient subgroups. No statistically significant differences in the efficacy of the treatment were found when patients were stratified by age, gender, duration

Fisher's exact test/ Chi-square

of symptoms, or daily computer usage more than six hours ($p > 0.05$ in all cases of comparison).

Topical cyclosporine was well tolerated, considering safety. The research period was free of any significant negative events. Seven percent of the patients complained of a minor and short burning sensation on instillation of eye drops, which resolved on its own, and did not require a termination of treatment.

DISCUSSION

The research assessed the short-term clinical efficacy and safety of topical 0.05% cyclosporine in children with VKC in a tertiary care center in southern Punjab, Pakistan. The results revealed that symptoms and sign score significantly improved one month after therapy, and 88.5% of the patients achieved clinically significant changes.

Such findings are congruent with the past studies in different geographical regions. Indian research showed significant clinical improvement in steroid-resistant VKC patients who used topical cyclosporine.^{13,14} Other studies highlighted the immunomodulatory role of cyclosporine in

Table 3: Treatment Efficacy Stratified by Patient Characteristics ($n = 78$).

Variable	Patients Improved n/N (%)	p-value
Age ≤ 10 years	30/35 (85.7%)	0.418
Age > 10 years	39/43 (90.7%)	
Gender (Male)	44/51 (86.3%)	0.532
Gender (Female)	25/27 (92.6%)	
Duration of Symptom ≤ 12 months	33/38 (86.8%)	0.367
Duration of Symptom > 12 months	36/40 (90.0%)	
Computer Use > 6 h/day	20/22 (90.9%)	0.489
Computer Use ≤ 6 h/day	49/56 (87.5%)	

suppressing T-cell-mediated inflammation that is central to the pathogenesis of VKC.^{15,16} Our study registered a higher rate of effectiveness compared to previous studies.^{10,17,18} This could be because of the difference in defining outcomes. Even though they took an extreme approach in defining cure, the present research employed a reduction in a standardized clinical measure, which could be more indicative of a remarkable change in a chronic, relapsing disease like VKC.

The safety profile seen is consistent with previous research in China and Japan, where a moderate burning sensation was the commonest side effect, which is due to the drug vehicle and not to cyclosporine.^{19,20} There were no observed serious adverse events or discontinuation of treatment in the current sample.

Our study has several limitations. First, the single-arm, non-controlled design limits the strength of our conclusions, as we cannot rule out the effects of the natural history of VKC, regression to the mean, or a placebo effect. Second, the follow-up period was short (one month), which does not allow for assessment of long-term efficacy, safety, or relapse rates. Third, the sample size was relatively small, which may have limited our ability to detect significant differences in subgroup analyses. A relevant consideration is the standardization of disease severity in the study cohort. While the protocol did not formally stratify inclusion by severity, post-hoc analysis revealed that all participants (100%) presented with 'moderate' disease at baseline according to the VKC severity scale. This unintended homogeneity in baseline severity strengthens the internal validity of our findings, as it reduces outcome variability attributable to extremes of disease severity and suggests that the reported treatment effect is reasonably representative for children with moderate VKC. Finally, as a single-center study, the results may not be generalizable to other settings or populations.

CONCLUSION

This short-term, single-arm study suggests that topical 0.05% cyclosporine is associated with significant clinical improvement and appears to be safe and well-tolerated in children with moderate VKC over one-month period. The majority of patients showed a reduction in clinical scores with minimal side effects. Larger, randomized controlled trials with longer

follow-up are needed to confirm these preliminary findings and to establish the long-term role of this treatment in VKC management.

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Patient's Consent: Researchers followed the guidelines set forth in the Declaration of Helsinki.

Conflict of Interest: Authors declared no conflict of interest.

Ethical Approval: The study was approved by the Institutional review board/Ethical review board (555/IRB/SZMC/SZH).

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Authors Designation and Contribution

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