ORIGINAL ARTICLE OPEN ACCESS

Efficacy of Tacrolimus 0.03% Ointment Vs. Olopatadine 0.2% Eye Drops in Vernal Keratoconjunctivitis: A Comparative Study

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ABSTRACT

Background: Vernal keratoconjunctivitis (VKC) is a chronic, vision-threatening eye inflammation typically starting in early childhood and often resolving by puberty, though it can begin earlier and persist into adulthood. This study aimed to evaluate the efficacy and safety of Tacrolimus 0.03% ointment versus Olopatadine 0.2% eye drops in the management of VKC.

Methods: A cross-sectional study was conducted at the Department of Ophthalmology, Mardan Medical Complex, Mardan from June 2023 to August 2024, encompassing 288 patients with VKC, who were randomly assigned to receive either Tacrolimus 0.03% ointment (n=144) or Olopatadine 0.2% eye drops (n=144). Demographic data, symptom severity, side effects, and patient satisfaction were assessed. Data were analyzed using SPSS 26.0 with descriptive statistics, t-tests for continuous variables, chi-square for categorical variables, and significance set at $P < 0.05$.

Results: In a study of 288 VKC patients (mean age 12.6 ± 3.5 years, 73.6% male) treated with Tacrolimus 0.03% ointment or Olopatadine 0.2% drops, Tacrolimus showed greater improvement in pruritus (75.3% vs. 58.3%), photophobia (75.6% vs. 61.0%), and lacrimation (66.7% vs. 51.4%) ($P < 0.001$), with more complete symptom relief (77.8% vs. 58.3%, $P < 0.001$) and shorter time to improvement (14.2 vs. 21.6 days, $P < 0.001$); adverse events were more common with Tacrolimus (63.9% vs. 20.8%, $P < 0.001$), including burning (33.3%), ocular pain (25.0%), and skin irritation (5.6%), though patient satisfaction was higher (76.4% vs. 59.7%, $P = 0.002$), confirming its superior efficacy.

Conclusion: Tacrolimus 0.03% ointment exhibits more efficacy than Olopatadine 0.2% eye drops in the treatment of VKC, offering more rapid and significant symptom relief.

Keywords: Olopatadine, Tacrolimus, Vernal Keratoconjunctivitis, Patient Satisfaction, Adverse Effects, Comparative Study.

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Doi: https://doi.org/10.36283/ziun-pjmd14-3/048.

How to cite: Sultan M, Hamza SA, Ali MS, Tariq M Efficacy of Tacrolimus 0.03% Ointment Vs. Olopatadine 0.2% Eye Drops in Vernal Keratoconjunctivitis: A Comparative Study. Pak J Med Dent. 2025 July ;14(3): 314-320. Doi: https://doi.org/10.36283/ziun-pjmd14-3/048 .

Received: Sat, May 24, 2025 **Accepted:**Sun, July 20, 2025 **Published:** Mon, July 21, 2025

INTRODUCTION

Vernal keratoconjunctivitis (VKC) is a persistent inflammatory ocular condition that endangers vision, commonly observed in adolescents and young adults[1]. It often commences at age five and endures for 2 to 10 years, resolving by puberty; however, it may initiate earlier and persist into adulthood[2]. The male-to-female ratio in this context is about. The disease predominantly occurs in tropical regions, including the Indian subcontinent, the Middle East, the Mediterranean, West African countries, and Japan[3].

The prevalence of VKC in tropical regions may reach 5%3. Despite the term "vernal" implying seasonality, this allergic condition can sometimes persist year-round. Patients may undergo varying stages because to differences in the inflammatory process of the disease, potentially leading to diminished quality of life and irreversible corneal damage[4]. Patients experience visual impairment resulting from intense pruritus, characterized by lacrimation, mucoid discharge, photophobia, burning sensations, and eyelid heaviness due to involvement of the tarsal conjunctiva[5].

Conjunctival manifestations encompass hyperemia, widespread fine papillary hypertrophy, macro papillae, extensive cobblestone tarsal papillae in particular configurations, and limbal papillae linked to Horner-Trantas dots[6]. Once regarded only as an IgE-mediated condition, current investigations into VKC and conjunctival scraping cultures indicate a complex aetiology, primarily including Th2 lymphocytes with mast cells, eosinophils, basophils, plasma cells, and macrophages[7]. The papillary reaction and tissue remodelling in the tarsal conjunctiva of patients are promoted by IL-4, IL-5, IL-13, and several growth factors and cytokines secreted by Th2 cells[7,8]. At present, olopatadine is among the most often recommended antihistamines for allergic conjunctivitis[9]. Tacrolimus, conversely, is an immunosuppressive agent increasingly utilised as a steroid-sparing therapeutic alternative in VKC[10].

Multiple studies have assessed the efficiency of tacrolimus for VKC; however, our review of various research databases found no studies comparing the effectiveness of tacrolimus with olopatadine, both of which are employed for long-term symptomatic relief in VKC patients. Moreover, most research on tacrolimus evaluated the effects of relatively high concentrations of the medication (topical tacrolimus 0.1%). The application of high-dose topical tacrolimus was linked to recurrent burning sensations and pain. In Pakistan, multiple instances of VKC have been recorded, especially in arid climatic zones[11,12,13].

This climatic zone is characterized by extreme heat, aridity, and dust storms. Over the past two decades, this region has had a rise in external ocular illnesses, notably VKC, attributed to global warming. Elevated temperatures and arid conditions, together with dust exposure, are the principal causes leading to this rise, as they have a high correlation with VKC and other external ocular disorders. In light of the absence of an ocular formulation of tacrolimus in Pakistan, the study employed the lowest accessible concentration of tacrolimus skin ointment, namely 0.03%. This study aimed to evaluate the efficacy and safety of Tacrolimus 0.03% ointment versus Olopatadine 0.2% eye drops in the management of VKC.

METHODS

This cross-sectional study was conducted at the Department of Ophthalmology at Mardan Medical Complex (MMC), Mardan, from June 2023 to August 2024 after approval from the institutional review board under reference # 2162/BKMC. The study included individuals diagnosed with VKC who visited the outpatient department of MMC throughout the research period. Participants were chosen based on the defined inclusion and exclusion criteria. The inclusion criteria for the study comprised patients aged 5 to 18 years who were diagnosed with vernal keratoconjunctivitis (VKC) based on clinical symptoms such as itching, redness, tearing, and photophobia, along with signs including conjunctival hyperemia, papillary hypertrophy, or Horner-Trantas dots. Eligible participants had not used any anti-inflammatory or anti-allergic medications in the two weeks preceding the study. Exclusion criteria included the presence of systemic or ocular infections, a history of ocular surgery within the past three months, use of contact lenses, known hypersensitivity to either Tacrolimus or Olopatadine, and co-existing ocular conditions such as glaucoma or cataract.

A total of 288 patients were included in the trial, divided into two equal groups of 144 people each. A sequential sampling strategy was employed, asking all qualified patients who appeared during the study period to participate. The Institutional Ethical Review Board of Mardan Medical Complex in Mardan approved the study. Informed consent, either verbal or written, was collected from every participant or guardian involved. Their identity was kept confidential throughout the entire study. Participating subjects were educated about and risks, their possible advantages, and how the methods would be conducted in the study. The sample population of participants came from the Ophthalmology Outpatient Department of Mardan Medical Complex in Mardan. Patients who qualified were located with the set inclusion and exclusion criteria. After receiving informed consent, a baseline

evaluation was completed. This initial assessment consisted of taking a thorough medical history, performing a detailed ophthalmological examination with slit lamp biomicroscopy, and classifying the Vernal Keratoconjunctivitis (VKC) severity. The symptom scores for pruritus, erythema, and lacrimation were noted using a visual analog scale (VAS) ranging from 0 to 10, in which 0 means the absence of symptoms while 10 is the worst possible level of symptoms. Other data, such as demographics, which included age, gender, and how long they have been suffering from VKC, were also collected.

Participants were further divided into two groups based on which treatment was easier to have and to administer: One group was given Tacrolimus 0.03% ointment while the other group was given Olopatadine 0.2% eye drops. Participants were given specific directions regarding the way they were supposed to administer their medication, which was to be done two times a day.

All data were recorded in a standardised proforma to ensure consistency and completeness. The gathered data included baseline parameters, follow-up symptom assessments, clinical outcomes, and adverse effects. Data were entered and analyzed using SPSS (26.0). Descriptive statistics (mean ± SD, frequency, and percentages) were used to summarize demographic and baseline characteristics. The independent t-test was applied to compare continuous variables, and the chi-square test was used for categorical variables. A P-value < 0.05 was considered statistically significant.

RESULTS

Table -1: Demographic Characteristics

Variable	Tacrolimus 0.03% Ointment (n=144)	Olopatadine 0.2% Eye Drops (n=144)	Total (n=288)
Age (years)			
Mean ± SD	12.5 ± 3.4	12.8 ± 3.6	12.6 ± 3.5
Range	5–18	5–18	5–18
Gender			
Male, n (%)	104 (72.2%)	108 (75.0%)	212 (73.6%)
Female, n (%)	40 (27.8%)	36 (25.0%)	76 (26.4%)
Duration of VKC (years)			
Mean ± SD	3.1 ± 1.5	3.0 ± 1.6	3.1 ± 1.5
Range	1–8	1–7	1–8
History of Atopy			
Yes, n (%)	92 (63.9%)	88 (61.1%)	180 (62.5%)
No, n (%)	52 (36.1%)	56 (38.9%)	108 (37.5%)
Severity of VKC			
Mild, n (%)	28 (19.4%)	32 (22.2%)	60 (20.8%)
Moderate, n (%)	78 (54.2%)	76 (52.8%)	154 (53.5%)
Severe, n (%)	38 (26.4%)	36 (25.0%)	74 (25.7%)

There was little difference between the two groups in terms of demographics and clinical features. Participant ages ranged from 5 to 18 years old, and the Tacrolimus group had an average age of 12.5 ± 3.4 years, whereas the Olopatadine group had an average age of 12.8 ± 3.6 years. With a somewhat lower number of females in both groups, the majority of participants were males (72.2%) in the Tacrolimus group and 75.0% in the Olopatadine group. With a range of 1-8 years for the Tacrolimus group and 1-7 years for the Olopatadine group, the average duration of VKC was 3.1 ± 1.5 years and 3.0 ± 1.6 years, respectively. It appears that the prevalence of atopy was equal between the Tacrolimus and Olopatadine groups, as 63.9% and 61.1% of the respective groups had a history of the condition. Both the Tacrolimus group (54.2%) and the Olopatadine group (52.8%) had moderate VKC severity. Mild VKC accounted for 19.4% of instances and severe VKC for 25.0% of cases in the Tacrolimus cohort and 22.2% of cases in the Olopatadine cohort, respectively. Both groups may be easily compared for further research thanks to the balanced baseline characteristics **(Table 1)**.

 DOI: https://doi.org/10.36283/ziun-pjmd 14-3/048

Table 2: Baseline and Post-Treatment Symptom Scores

Symptom	Baseline Mean ± SD	Post-Treatment Mean ± SD	% Improvement	P-value
Itching				
Tacrolimus	8.5 ± 1.2	2.1 ± 1.0	75.30%	<0.001
Olopatadine	8.4 ± 1.3	3.5 ± 1.4	58.30%	<0.001
Redness				
Tacrolimus	7.8 ± 1.5	1.9 ± 0.8	75.60%	<0.001
Olopatadine	7.7 ± 1.4	3.0 ± 1.2	61.00%	<0.001
Tearing				
Tacrolimus	7.5 ± 1.2	2.5 ± 1.1	66.70%	<0.001
Olopatadine	7.4 ± 1.3	3.6 ± 1.2	51.40%	<0.001

The results demonstrated that both patient cohorts had a noticeable reduction in itching, redness, and lacrimation after the therapy. Tacrolimus demonstrated greater improvements than Olopatadine. The two groups' baseline average itching scores were 8.4 ± 1.3 for olopatadine and 8.5 ± 1.2 for tacrolimus. Post-medication scores' means were 2.1 ± 1.0 and 3.5 ± 1.4, respectively, which means that Tacrolimus improved the condition by 75.3% and Olopatadine improved it by 58.3% ($P < 0.001$ for both). The mean redness score was improved by 75.6% in the Tacrolimus group and by 61.0% in the Olopatadine group, both treatments having $P < 0.001$. The decrease in tearing in the Tacrolimus group was 66.7%, from 7.5 ± 1.2 to 2.5 ± 1.1, and in the Olopatadine group, it was 51.4%, from 7.4 ± 1.3 to 3.6 ± 1.2, both of which were statistically significant at $P < 0.001$ **(Table 2)**.

Table -3: Clinical Outcomes at Week 12

Outcome	Tacrolimus (n=144)	Olopatadine (n=144)	P-value
Complete Symptom Resolution	112 (77.8%)	84 (58.3%)	<0.001
Partial Symptom Resolution	28 (19.4%)	48 (33.3%)	0.012
No Improvement	4 (2.8%)	12 (8.3%)	0.045
Mean Time to Improvement (days)	14.2 ± 2.3	21.6 ± 3.1	<0.001

Tacrolimus significantly outperformed Olopatadine in completely relieving symptoms in patients with Vernal Keratoconjunctivitis (VKC), according to the trial results. Compared to 58.3% of patients who received Olopatadine, 77.8% of patients who were given Tacrolimus experienced complete symptom alleviation ($P < 0.001$). There was a significant difference ($P = 0.012$) between the two groups in terms of the percentage of patients who reported some improvement from their symptoms; 19.4% in the Tacrolimus group and 33.3% in the Olopatadine group. A small number of patients showed no improvement; specifically, 8.3% of Olopatadine patients and 2.8% of Tacrolimus patients ($P = 0.045$). The Tacrolimus group showed significantly faster symptom relief, with an average length of 14.2 ± 2.3 days, compared to the Olopatadine group, which took 21.6 ± 3.1 days ($P < 0.001$). The results show that compared to Olopatadine, Tacrolimus is more effective and takes less time to alleviate VKC symptoms **(Table 3)**.

Table- 4: Adverse Effects

Adverse Effect	Tacrolimus (n=144)	Olopatadine (n=144)	P-value
Burning Sensation, n (%)	48 (33.3%)	12 (8.3%)	<0.001
Eye Discomfort, n (%)	36 (25.0%)	18 (12.5%)	0.018
Skin Irritation, n (%)	8 (5.6%)	0 (0.0%)	0.007
Total Adverse Events	92 (63.9%)	30 (20.8%)	<0.001

Compared to the Olopatadine group, the Tacrolimus group had significantly more side effects, according to the analysis of these effects. In the Tacrolimus group, 33.3% of patients reported a burning sensation, compared to 8.3% in the Olopatadine group (P < 0.001). One quarter of patients given Tacrolimus and one quarter of patients given Olopatadine experienced eye discomfort (P = 0.018). In contrast to the Olopatadine group, 5.6% of those on Tacrolimus experienced skin irritation (P = 0.007). With a p-value of less than 0.001, the incidence of adverse events was significantly higher in the Tacrolimus group (63.9% vs. 20.8% in the Olopatadine group). While Tacrolimus did a better job of reducing symptoms than Olopatadine, the results showed that it was associated with more side effects **(Table 4)**.

Table -5: Patient Satisfaction at Week 12

Satisfaction Level	Tacrolimus (n=144)	Olopatadine (n=144)	P-value
Very Satisfied, n (%)	110 (76.4%)	86 (59.7%)	0.002
Satisfied, n (%)	30 (20.8%)	50 (34.7%)	0.015
Neutral, n (%)	4 (2.8%)	8 (5.6%)	0.224
Dissatisfied, n (%)	0 (0.0%)	0 (0.0%)	-

Tacrolimus had much higher patient satisfaction rates than Olopatadine, according to the study on patient satisfaction levels. In the Tacrolimus group, 76.4% of patients were "very satisfied" with their treatment, compared to 59.7% in the Olopatadine group (P = 0.002). Patients in the Olopatadine group were more likely to report being "satisfied" than those in the Tacrolimus group (34.7% vs. 20.8%, P = 0.015). There was no statistically significant difference between the Tacrolimus and Olopatadine groups about the percentage of patients reporting neutral satisfaction (2.8% and 5.6%, respectively; P = 0.224). Notably, not a single patient in either group was dissatisfied with the care they received **(Table 5)**.

DISCUSSION

Preventative, pharmacological, and surgical approaches are commonly used to control VKC. Surgery involves removing the top tarsal big papillae or debriding non-healing shield ulcers; however, this is only done in extreme cases; preventative options include immunisation and avoiding allergens such as home dust mites, pollen, and dust[14]. Pharmacological management is preferred in cases of acute VKC. The main therapy options include topical antihistamines, mucolytics, lubricants, and mast cell stabilisers[15]. Managing symptoms in severe and chronic cases requires the use of topical corticosteroid drops and supratarsal steroid injections. Glaucoma, cataracts, and secondary infections can develop from the improper and extended use of topical steroids[16]. The most typically affected age group, children with VKC, are also the most likely to experience steroid-induced complications[17]. Currently, the gold standard for treating VKC is second-generation antiallergic medicine, which has the added benefit of stabilising mast cells and acting as an antihistamine[18]. Olopatadine stabilises mast cells and decreases histamine release by acting as a selective antagonist of the histamine H1 receptor. Along with topical steroids, it is currently the drug of choice for treating allergic conjunctivitis [19,20].

The US Food and Drug Administration licensed it for the treatment of allergic conjunctivitis at concentrations of 0.1%, 0.2%, and 0.7% [20]. Tacrolimus, an immunosuppressant produced from Streptomyces tsukubaensis, is 100 times more effective than cyclosporine[21]. It is a nonsteroidal macrolide. The exact way tacrolimus works is still not fully understood; however, it is thought to suppress the activation of Th2 lymphocytes (the key cells in VKC), the proliferation of B cells mediated by T helper cells, and the creation of cytokines. Its primary use was as an immunosuppressant in transplants of the liver, but it has since found its way into other organ transplants as well22. It is currently being used to treat a variety of skin diseases, including vitiligo and atopic dermatitis. Various forms and quantities of tacrolimus have been studied, and the conclusions regarding its safety and efficacy have been contradictory[21]. Both 0.03% tacrolimus and 0.2% olopatadine were effective in this trial, significantly reducing the severity of symptoms in patients with VKC; hence, these drugs are highly recommended. After three months of treatment, the tacrolimus group showed fewer residual signs and symptoms compared to the olopatadine group. This difference was statistically significant[21,22].

Consistent with this investigation, a study showed that moderate to severe VKC could be safely and effectively treated with topical administration of 0.03% tacrolimus ointment[23]. Tacrolimus was used in a different experiment to treat severe VKC for the long term without serious side effects[21]. Symptoms and papillary hyperplasia were both reduced with prolonged tacrolimus treatment[24]. According to a comparative study that included 21 patients with

severe VKC, adding olopatadine to 0.03% tacrolimus had no further effects[25].

Despite demonstrating the efficacy of Tacrolimus 0.03% and Olopatadine 0.2% in managing VKC, this study has several limitations. It was conducted over a relatively short period of three months, which may not adequately reflect long-term safety and efficacy, especially for a chronic and recurrent condition like VKC. The reliance on subjective symptom reporting introduces potential bias, as patient perception can vary. The absence of a placebo control group limits the ability to determine the true effect size of each treatment. Furthermore, the study did not stratify patients based on VKC severity (mild, moderate, or severe), which may limit applicability across the full clinical spectrum. Adverse events were self-reported and not graded by severity, which could affect the precision of safety assessments. Lastly, the single-center nature and limited demographic diversity may reduce the generalizability of the findings. Therefore, additional multicenter studies with larger, more diverse populations and longer follow-up periods are needed to further validate the long-term safety and efficacy of these treatments.

CONCLUSION

In the treatment of Vernal Keratoconjunctivitis, Tacrolimus 0.03% ointment is more effective than Olopatadine 0.2% eye drops, leading to faster symptom relief and better overall efficacy. However, it has been associated with a higher incidence of mild side effects. Tacrolimus, on the other hand, had higher patient satisfaction, so it's a better option for controlling VKC when effectiveness is more important than tolerability. It is recommended to closely monitor to reduce the likelihood of negative consequences.

ACKNOWLEDGEMENT

The authors would like to thank the hospital's administration and everyone who helped complete this study.

FUNDING

None

CONFLICT OF INTEREST

None

ETHICAL APPROVAL

The Institutional Ethical Review Board of Mardan Medical Complex in Mardan approved the study under reference # 2162/BKMC.

AUTHORS' CONTRIBUTION

M.S. conceived and designed the study. **M.S.A.** was responsible for drafting the manuscript. Data analysis was performed by **S.A.H.**, while **M.T.** conducted the critical review. The final version of the manuscript was approved by **M.S**.

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