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Comparative Study on the Therapeutic Efficacy of Topical Bimatoprost (0.03%) Ophthalmic Solution and Tacrolimus (0.1%) Ointment in Stable Vitiligo

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ABSTRACT

Introduction: Vitiligo is a chronic autoimmune skin disorder characterized by loss of melanocytes, leading to depigmented patches. Although not associated with physical morbidity, its appearance causes significant psychological distress, especially in dark-skinned individuals. Tacrolimus, a topical calcineurin inhibitor, is first-line treatment for localized, stable vitiligo. However, bimatoprost, a prostaglandin analog known for its melanin-stimulating activity, is emerging as a potential alternative.

Objectives:

Primary Objective: To compare the efficacy of topical bimatoprost 0.03% ophthalmic solution versus tacrolimus 0.1% ointment in stable vitiligo.

Secondary Objective: To evaluate the clinical response of bimatoprost 0.03% ophthalmic solution versus tacrolimus 0.1% ointment and to assess their safety and adverse effects in stable vitiligo.

Material & Methods: A randomized comparative study was conducted over 24 months in the Department of Dermatology at Era's Lucknow Medical College. Fifty clinically stable vitiligo patients (aged >18 years, <5% BSA involvement) were randomized into two groups: Group A received topical bimatoprost 0.03%, and Group B received topical tacrolimus 0.1%, both applied twice daily over the

lesions. Treatment was continued for 12 weeks, with follow-up every four weeks. Efficacy was assessed using the Vitiligo Area Scoring Index (VASI), subjective score, and photographic documentation. Any side effect was documented at each follow-up.

Results: Both groups showed clinical improvement, with Group A demonstrating faster onset of repigmentation, particularly in facial lesions. Bimatoprost was well tolerated, with minimal side effects such as local hypertrichosis, while tacrolimus was associated with mild burning sensation in some cases.

Conclusion: Topical bimatoprost 0.03% is a safe and effective alternative to tacrolimus 0.1% ointment in treating stable vitiligo, especially for cosmetically sensitive areas. Therefore, it can be considered as a treatment option in stable vitiligo.

Introduction

Vitiligo is a chronic autoimmune skin disorder characterized by depigmented patches resulting from melanocyte loss. It affects individuals of all ages, sexes, and ethnicities worldwide and significantly impairs quality of life due to stigma and psychosocial distress [1,2]. Clinically, it presents as pale-to-milky-white macules involving skin and mucous membranes [3]. Globally, the lifetime prevalence is ~0.36%, with higher rates in the Indian subcontinent, Mexico, and Japan; incidence is greater in adults and more conspicuous in darker-skinned individuals [4-6].

Vitiligo is classified into segmental (SV) and non-segmental (NSV) types, with NSV in children showing stronger associations with thyroid disorders [7,8]. Multiple pathogenetic models—genetic, neural, metabolic, and autoimmune—have been unified under the convergence theory, suggesting multifactorial origins. Key contributors include genetic predisposition, oxidative and emotional stress, toxic melanin precursors (e.g., DOPA, dopachrome, 5,6-dihydroxyindole), altered melanocyte homeostasis (e.g., calcium imbalance), and autoimmunity [9,10].

Management encompasses medical, surgical, and psychological approaches. Topical corticosteroids and calcineurin inhibitors are widely used for localized disease, while phototherapy and systemic therapies are options for extensive cases [11-13].

Among various treatment modalities, topical therapy is the first-line and most preferred option. While corticosteroids are the first-line treatment for management of unstable vitiligo [14], the use of corticosteroids is not free from adverse effects.

Topical corticosteroids can cause local and systemic adverse effects, including atrophy of skin, infections, hypertrichosis, contact dermatitis, telangiectasia, striae, bruising, rosacea, facial erythema, and ocular problems like glaucoma and cataract, if used near eyes [14].

Calcineurin inhibitors, particularly tacrolimus and pimecrolimus, offer a safer and effective alternative for stable vitiligo [15].

Tacrolimus, a macrolide derived from *Streptomyces tsukubaensis*, has immunomodulatory properties which act by selectively inhibiting calcineurin, an intracellular protein involved in T-cell activation.12 However, concerns have been raised over the past two decades regarding their potential risk of developing lymphoma, nonmelanoma skin cancer, and skin cancer [16,17].

Bimatoprost is a synthetic prostaglandin analogue used to lower intraocular pressure in glaucoma. It has potential to induce melanogenesis and is hence considered a suitable alternative topical pharmacotherapy for the management of vitiligo. Preliminary evidence from clinical studies shows it to be a safe and effective treatment for management of vitiligo [18,19].

Although preliminary studies regarding the use of bimatoprost are promising, there is a lack of comparative studies evaluating its performance against other established topical pharmacological treatments for vitiligo such as topical tacrolimus. Hence, the present study was conducted to compare therapeutic efficacy of topical bimatoprost (0.03%) ophthalmic solution and tacrolimus (0.1%) ointment in stable vitiligo.

Methods

The present randomized comparative study was conducted over 24 months at the Department of Dermatology, Era's Lucknow Medical College and hospital, a tertiary care center in North India. The sample size was estimated at 90% power and 5% level of significance based on the difference in percentage body surface area reduction between the two treatment groups. Accounting for a 20% loss to follow-up, a sample size of 50 patients was calculated, with 25 patients in each group.

A total of 50 clinically diagnosed patients with stable vitiligo meeting inclusion/exclusion criteria were enrolled after informed consent. Inclusion criteria: age ≥18 years, stable vitiligo with <5% BSA involvement, and no treatment in the preceding three months. Exclusion criteria: pregnancy,

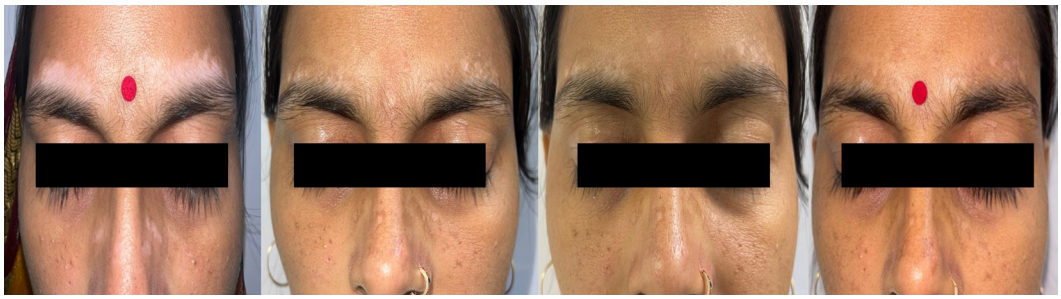

Figure 1. Clinical images of Group A (bimatoprost 0.03%) at baseline, 4, 8, and 12 weeks.

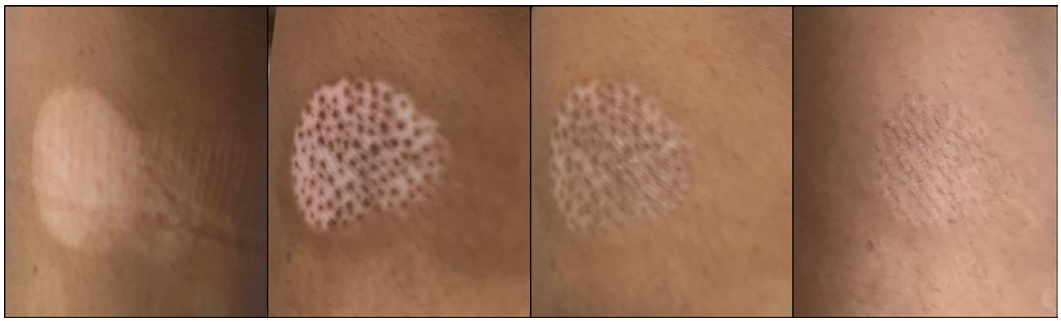

Figure 2. Clinical images of Group A (bimatoprost 0.03%) at baseline, 4, 8, and 12 weeks.

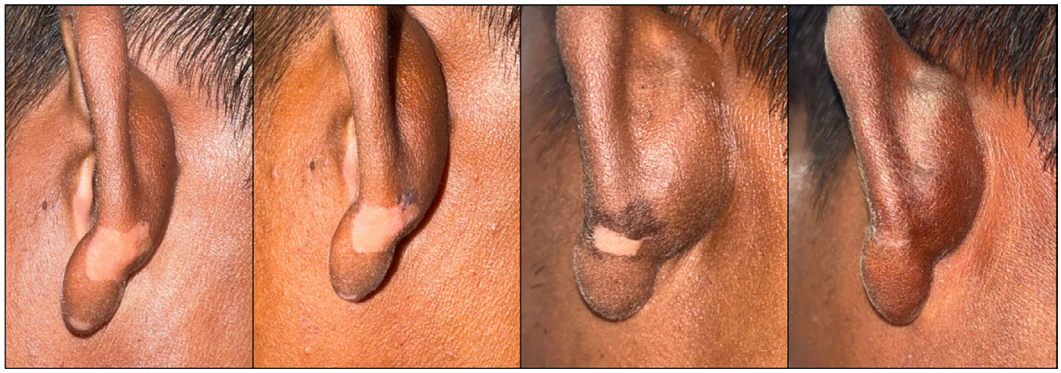

Figure 3. Clinical images of Group B (tacrolimus 0.1%) at baseline, 4, 8, and 12 weeks.

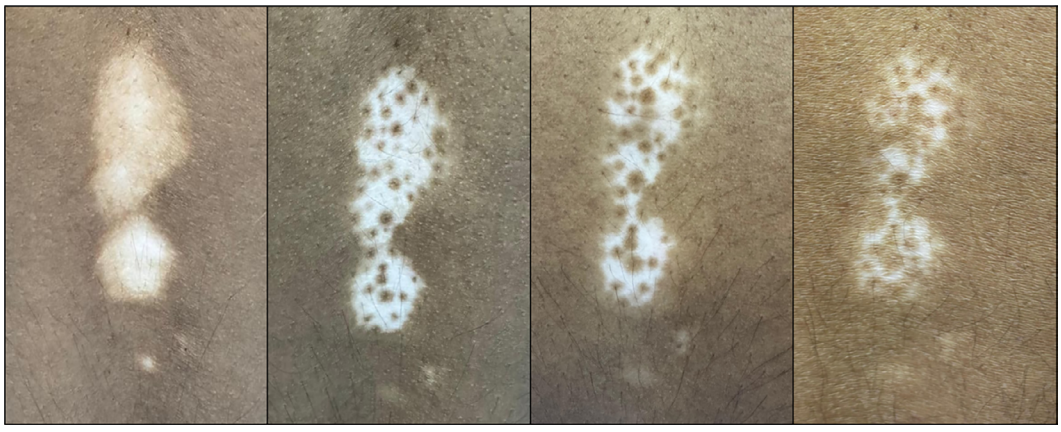

Figure 4. Clinical images of Group B (tacrolimus 0.1%) at baseline, 4, 8, and 12 weeks.

Table 1. Intragroup comparison of change in VASI at different follow-up intervals.

Time	Group A				Group B				Inter-group comparison (unpaired t-test)
	Mean VASI± SD	Mean change in VASI ±SD	% change	p-value (paired t-test)	Mean VASI± SD	Mean change in VASI ±SD	% change	p-value (Paired t-test)	
Baseline	1.23± 1.39	-	-	-	1.40± 1.43	-	-	-	t=0.421; p=0.676
4 weeks	0.76± 0.83	-0.46± 0.62	-37.4	t=3.75; p=0.001	1.00± 1.03	-0.40± 0.55	-28.6	t=3.63; p=0.001	t=0.877; p=0.385
8 weeks	0.47± 0.49	-0.76± 0.99	-61.8	t=3.82; p=0.001	0.65± 0.76	-0.74± 0.95	-52.9	t=3.93; p=0.001	t=1.000; p=0.322
12 weeks	0.21± 0.23	-1.02± 1.22	-82.9	t=4.17; p<0.001	0.30± 0.35	-1.10± 1.26	-78.6	t=4.35; p<0.001	t=1.013; p=0.316

Table 2. Comparison of subjective outcome between two study groups at 4,8, and 12 weeks.

Outcome	4 weeks		8 weeks		12 weeks	
	Group A (N=25)	Group B (N=25)	Group A (N=25)	Group B (N=25)	Group A (N=25)	Group B (N=25)
Excellent	1 (4.0%)	0	0	0	2 (10.0%)	3 (12.0%)
Good	7 (28.0%)	7 (28.0%)	7 (28.0%)	9 (36.0%)	13 (52.0%)	13 (52.0%)
Moderate	9 (36.0%)	10 (40.0%)	11 (44.0%)	11 (44.0%)	8 (32.0%)	7 (28.0%)
Poor	8 (32.0%)	8 (32.0%)	7 (28.0%)	5 (20.0%)	2 (8.0%)	2 (8.0%)
p-value	0.789		0.747		0.966	

lactation, or hypersensitivity to tacrolimus or bimatoprost. Demographic and clinical data, including disease duration, family history, and comorbidities, were recorded.

A detailed dermatological examination under both natural and wood's lamp illumination was done to assess lesion distribution, symmetry, pattern, and extent of depigmentation. Severity and activity of vitiligo were quantified using Vitiligo Area Scoring Index (VASI). Patients were then randomized using block randomization into two groups of 25 each. Group A received topical bimatoprost ophthalmic solution (0.03%) and Group B received topical tacrolimus ointment (0.1%), both applied twice daily for 12 weeks. Follow-up assessments were conducted at 4, 8, and 12 weeks, which included photographic documentation, VASI, and subjective scoring. Adverse effects such as itching, burning, and hypertrichosis were noted, and patient-rated treatment response was recorded. Data were analyzed using SPSS Version 21.0 with appropriate statistical tests applied; a p-value <0.05 was considered statistically significant.

Results

Out of a total of 50 patients enrolled in the study, 25 (50%) made up Group A (0.03% bimatoprost ophthalmic solution) and 25 (50%) to Group B (0.1% tacrolimus ointment); both groups applied treatment over lesions twice daily for 12 weeks. Mean age of patients in Groups A and B was 35.64±17.28 and 33.84±15.81 years, respectively (*P*>0.05). In both groups, the majority of patients were female (Group A: 56%, Group B: 60%; *P*=0.774).

Mean disease duration was 5.68±2.85 months in Group A and 5.24±2.89 months in Group B (*P*=0.591). The face and back were the most affected in Group A (24% each), followed by the abdomen (16%) and feet (12%), and other sites (32%). In Group B, the abdomen was the most common (16%), then face and back (12% each), feet (8%), and other sites (52%). Family history was positive in 32% of Group B and 20% of Group A (*P*=0.333). Mean BSA involved was 1.43±1.51% in Group A vs. 1.73±1.68% in Group B (*P*=0.524). Visible lesions were present in 60% of Group A and 68% of Group B (*P*=0.557). Asymmetry was found in 80% of Group A patients and 60% of Group B patients (*P*=0.123). Leukotrichia was seen in 24% and 16% of patients in Group A and B, respectively (*P*=0.480). In Group A, 8% had alopecia areata and 12% had diabetes mellitus. In Group B, alopecia areata and thyroid disorder were 8% each; diabetes was 16% (*P*>0.05).

In Group A, mean VASI was 1.23±1.39 at baseline and decreased to 0.76±0.83, 0.47±0.49, and 0.21±0.23 at 4, 8, and 12 weeks, respectively, showing absolute reductions of 0.46±0.62, 0.76±0.99, and 1.02±1.22. Mean corresponding percent reductions were 37.4%, 61.8%, and 82.9%. At all

time intervals, the change from baseline was significant statistically (P<0.001).

In Group B, baseline VASI was 1.40±1.43, decreasing to 1.00±1.03, 0.65±0.76, and 0.30±0.35 at 4, 8, and 12 weeks, with absolute reductions of 0.40±0.55, 0.74±0.95, and 1.10±1.26. Percent reductions were 28.6%, 52.9%, and 78.6% (Table 3); all statistically significant (P<0.001).

Comparison between groups showed no significant difference in VASI at baseline, 4, 8, or 12 weeks follow-up (P>0.05) (Table 4).

At 4 weeks, 32% of Group A and 28% of Group B reported good-to-excellent subjective outcomes (P=0.789), whereas 28% and 36% did so at 8 weeks (P=0.747) and 62% and 64% at 12 weeks (P=0.966), indicating no significant difference in perceived response (Table 5).

Adverse effects included itching in Group A (20% at 4 weeks, 12% at 8 weeks) and Group B (32% at 4 weeks, 4% at 8 weeks); none at 12 weeks. Burning sensation was seen in 12% (Group A) and 24% (Group B) at 4 weeks and in 8% (Group B) at 8 weeks; none thereafter. Hypertrichosis was observed only in Group A (16% at 4 weeks, 4% at 8 weeks), with a significant difference at 4 weeks (P=0.037). No other adverse effect was reported

Discussion

The present randomized controlled trial was conducted to compare therapeutic efficacy of topical bimatoprost (0.03%) ophthalmic solution with tacrolimus (0.1%) ointment in stable vitiligo. There are only a few studies that have compared these drugs, mostly as pilot single-blind trials [20,21]. The sample size of present study is exactly comparable to that of Kumari et al.,22 who also carried out their study as a randomized controlled trial and included a total of 50 patients randomized to two groups.

In the present study, the age of patients ranged from 18 to 75 years, and mean age of patients was 35.64 and 33.84 years, respectively, in the two groups. Overall, 58% of patients were female, and there was no significant difference between the two groups in terms of age or sex. In other studies, the mean age of patients ranged from 35.34 to 45.5 years, and the proportion of females ranged from 56% to 80% [20,22,23]. The age and sex profiles of our patients are comparable to those reported by Kumari et al.,22 who reported the mean age of patients in the two groups as 35.34 and 37.28 years, respectively, and had 58% females. As such, no age- or sex-related impact on efficacy and safety of either of two drugs has been reported in any earlier study. A higher dominance of females in different studies could be owing to the cosmetic concerns in vitiligo in the social context [24].

In the present study, patients were matched for demographic and clinical characteristics. Pruettivorawongse et al. [21] provided information regarding baseline body surface area and reported median values as 4.59 and 2.87 cm2 in bimatoprost and tacrolimus groups. In the present study, these values were 1.43 and 1.73 cm2, respectively, thereby showing that the level of body surface area involved in the present study was smaller than in their study.

In the study by Kanokrungsee et al. [20], the mean duration of disease was five years. In our study, the mean duration was 5.68 and 5.24 years in the two groups. Those authors reported a family history in 20% cases as compared to 20% and 36% patients, respectively, in bimatoprost and tacrolimus groups in our study. In their study, generalized type of vitiligo was the most common (40%). In the present study, both localized and multifocal types were equal in number in the overall study population (50% each). They reported hyperthyroidism in 20% of patients; in our study, it was positive in only 8% of tacrolimus group patients, but we had other comorbidities, like diabetes mellitus and alopecia areata, that were present in 8% and 14% of the study population. They did not provide a comparative analysis of demographic or clinical characteristics between their groups. However, for the outcome measure, they compared the Vitiligo Surface Area at baseline, reporting mean values of 3.72 and 3.52 in the two groups, with no statistically significant difference.

Kumari et al. [22] in their study described the mean duration to be 5.03 and 5.11 years, respectively, in bimatoprost and tacrolimus groups. This is quite close to the 5.68 and 5.24 years, respectively, in our study. In their study, the face was the most common site involved in both groups, whereas in the present study, other body parts (lower and upper limbs) were the most commonly involved.

With respect to sites involved, Kanokrungsee et al. [21] and Zaky et al. [23] included patients with facial vitiligo only; however, in the present study, facial vitiligo comprised only 18% of total study population, and sites other than the face were more commonly involved.

In the present study, treatment efficacy was assessed both objectively through changes in VASI scores and subjectively. In Group A, the mean VASI decreased from 1.23 ± 1.39 at baseline to 0.21 ± 0.23 at 12 weeks. Group B showed a reduction from 1.40 ± 1.43 to 0.30 ± 0.35 at 12 weeks. Both groups showed significant VASI reductions from baseline to 12 weeks (P<0.001), indicating effective treatment in both groups. Although bimatoprost showed a slightly faster initial response, the overall difference in effectiveness between the two treatments remained statistically non-significant throughout the study. Subjective outcomes also aligned closely, with a comparable proportion of patients in both groups reporting good-to-excellent improvement by the end of the treatment period. These findings suggest that both agents are effective in managing stable vitiligo, with

no significant advantage of one over the other in terms of clinical efficacy or patient satisfaction.

Compared to the present study, Pruettivorawongse et al. [21] in their study reported outcomes in terms of percentage reduction in affected body surface area and grading score improvement. In their study, the percentage reduction in body surface area in bimatoprost and tacrolimus groups was 16.35% and 16.85%, respectively, showing no statistically significant difference between the two groups. Kanokrungsee et al. reported >50% improvement in 14.29% of patients treated with bimatoprost compared to 7.14% in the tacrolimus group. Although the overall percentage reduction in body surface area between the two groups was minimal (0.50%), the higher proportion of bimatoprost patients achieving >50% improvement suggests a faster therapeutic response, consistent with the findings observed in our study at the first follow-up interval.

Kanokrungsee et al. [20], in a similar study following a comparable dosage and treatment duration protocol to the present study, reported a reduction in VSA of 23.83% in the bimatoprost group and 31.71% in the tacrolimus group after 12 weeks of therapy. The percentage reduction in VSA seemed to be higher in the tacrolimus group as compared to that in the bimatoprost group; however, with respect to outcomes in terms of repigmentation, they found >50% repigmentation in 20% of bimatoprost as compared to 10% of tacrolimus group patients. However, in statistical terms, neither reduction in VSA nor repigmentation outcomes showed a significant difference between the two groups. As far as VSA reduction at 12 weeks is concerned, their results showed a relatively much lower reduction in size over 12 weeks in both of the two groups (23.83% and 31.71%, respectively) than that observed in the present study (>75% in both groups). The reason for this could be relatively lower VASI scores as well as body surface area involvement in the present study as compared to their study. However, with respect to relative performance of the two drugs, the results in the present study fully endorse their study, with no statistically significant difference between the two groups.

In their study, Zaky et al. [23] described the outcome in terms of proportion of patients achieving good-to-excellent repigmentation and reported it to be 66.7% in the bimatoprost group as compared to 79.1% in tacrolimus group; they did not find a significant difference between the two groups. In their study, in terms of the proportion of those achieving good-to-excellent response, tacrolimus outperformed bimatoprost by 12.4%. In the present study, at the final assessment in terms of subjective response, we also found tacrolimus to outperform bimatoprost but only by 2%.

Among other studies, only Kumari et al. [22] report a statistically significant difference in clinical outcome and found the VSA at 6-month follow-up to be significantly lower in the bimatoprost group compared to that in the tacrolimus group. This could be owing to a longer treatment duration, as none of the other studies lasted more than three months. However, even in their study, for graded response, the difference between two groups was not significant statistically. Furthermore, at three-month assessment, the results in their study were similar to those observed in the present study and other studies that had a treatment duration of 12 weeks. Thus, for clinical outcome, the results in the present study conform to most of the other studies that evaluated the outcomes at 12 weeks.

In the present study, adverse effects such as itching and burning sensation were observed only during initial follow-up intervals (4 and 8 weeks), with complete resolution by the end of the 12-week period in both groups. Notably, hypertrichosis was significantly more frequent in the bimatoprost group during the first follow-up, aligning with findings by Kumari et al.22, who also reported a slightly lower but comparable incidence of hypertrichosis in the bimatoprost group and none in the tacrolimus group, though their assessment was limited to the final visit. Similarly, Zaky et al. [24] described only mild, tolerable side effects across treatment groups without providing group-specific details, reporting side effects like irritation, desquamation, and occasional vesicles, all of which resolved without serious complications. Consistent with these findings, the present study reported all adverse events as mild and self-limiting, requiring neither dose adjustment nor treatment discontinuation, thereby supporting the overall safety and tolerability of both treatment modalities.

Conclusion

Topical bimatoprost (0.03%) ophthalmic solution is as effective as tacrolimus (0.1%) ointment in the treatment of stable vitiligo, with both agents showing significant clinical improvement and comparable patient-reported outcomes over 12 weeks. The safety profile of both treatments was favorable, with minimal and self-limited adverse effects. Bimatoprost had a slightly faster initial response, but overall efficacy was comparable. These findings support the potential role of bimatoprost as an alternative therapeutic option. However, larger-scale studies with longer follow-up durations as well as the inclusion of quality of life assessments and cost-effectiveness analyses are warranted to substantiate and expand upon these results.

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