Journal of Chemical Health Risks

www.jchr.org

JCHR (2025) 15(5), 944-951 | ISSN:2251-6727

Comparative Study of Effectiveness with Narrowband UVB (NB-UVB) vs NB-UVB with Topical Tacrolimus Ointment (0.1%) in the Treatment of Vitiligo among the Armed Forces Personnel Attending Combined Military Hospital Dhaka

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(Received: 16 July 2025 Revised: 20 August 2025 Accepted: 02 September 2025)

KEYWORDS

Comparative, NB-UVB, Tacrolimus.

ABSTRACT:

Background: Vitiligo is a multifactorial depigmenting disorder caused by melanocyte loss [1–10]. This study evaluates the comparative effectiveness of NB-UVB alone versus NB-UVB combined with 0.1% topical tacrolimus in vitiligo patients.

Aim of the study: The aim of the study was to compare the effecacy of Narrowband UVB (NB-UVB) alone versus NB-UVB combined with 0.1% topical tacrolimus ointment in treating vitiligo.

Methods: This randomized controlled study at the Department of Dermatology and Venereology, CMH Dhaka (Feb–Aug 2021) included 70 patients with stable vitiligo over 14 years, randomized to Group A (0.1% tacrolimus + NB-UVB) or Group B (placebo + NB-UVB). Repigmentation was assessed monthly over three months using a visual analog scale, categorized as excellent (>75%), good (50–75%), moderate (25–49%), or poor (<25%). Data were analyzed with SPSS v23.0 (t-tests, chi-square; $p < 0.05$).

Results: Among 140 patients (70 per group), most were aged 21–30 years (A 38.6%, B 40.0%) and male (A 61.4%, B 67.1%). Disease duration <5 years occurred in 65.7% (A) and 61.4% (B), and non-segmental vitiligo in 90.0% (A) and 87.1% (B). Baseline depigmentation 1–10% was seen in 78.6% (A) and 82.9% (B). At 3 months, excellent response was higher in A (54.3%) than B (31.4%), with overall efficacy 54.3% vs 31.4% ($p < 0.05$).

Conclusion: Treatment with a combination of NB-UVB and topical Tacrolimus ointment (0.1%) is more effective than treatment with NB-UVB alone in vitiligo.

Journal of Chemical Health Risks

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JCHR (2025) 15(5), 944-951 | ISSN:2251-6727

Introduction

Vitiligo is a multifactorial condition influenced by genetic variations, with its exact pathogenesis still not fully clarified [1]. The primary therapeutic goal is to restore pigmentation in depigmented regions of the interfollicular epidermis by facilitating the migration, survival, and melanin production of active melanocytes [2]. The first-line topical therapeutic agents include corticosteroids and calcineurin inhibitors, while NB-UVB, systemic psoralen, and PUVA are considered first-line physical therapies [1]. However, it is not clearly understood to what extent treatments must suppress the autoimmune process and simultaneously stimulate epidermal melanocytic repopulation in order to achieve maximum efficacy.

Vitiligo is an idiopathic, acquired condition distinguished by depigmented patches and macules on the skin, which may or may not be associated with leukotrichia. The disorder is characterized by the depletion of functional melanocytes, leading to a lack of melanin synthesis in the epidermis [3]. The disease has an incidence of 0.5%–2% with no ethnic or sex predilection. It may present as a polygenic or autosomal dominant disorder with incomplete penetrance and variable expression. Based on its clinical association with numerous disorders, vitiligo is considered to be either autoimmune or autoinflammatory in nature [4].

Although vitiligo can appear at any age, it most frequently occurs in individuals under 20 years. The prevalence is estimated at 0.1%–2% in the general population, with a familial incidence of about 30% [5]. The exact cause is not yet known, but hypotheses suggest that genetic predisposition, autoimmunity, and melanocyte destruction by toxic metabolites may play important roles [6]. Despite multiple therapeutic modalities being used, treatment outcomes remain unsatisfactory, posing a therapeutic challenge for dermatologists [7]. Conventional treatment options include topical steroids, ultraviolet B phototherapy (UVB 280–320 nm), and photochemotherapy (PUVA, i.e., psoralen plus UVA 329–400 nm). Excimer laser and topical calcipotriol are also being utilized. NB-UVB alone has been shown to be effective in clinical studies. One study demonstrated that NB-UVB alone resulted in 50% repigmentation in 19.8% of patients [7]. However, combined use of NB-UVB with other modalities has shown more than 75% repigmentation in some patients. Since long-term use of corticosteroids can cause skin atrophy, topical immunomodulators (tacrolimus, pimecrolimus) are recommended as safer and more effective alternatives for long-term management [8]. Tacrolimus has demonstrated efficacy as a monotherapy, with one study reporting over 75% repigmentation in 61% of patients [6]. Additionally, another study observed that combining tacrolimus with NB-UVB resulted in more than 50% repigmentation in 73% of patients [9].

Vitiligo significantly affects the social, psychological, and quality-of-life aspects of patients worldwide, making it an increasing global health concern. In this condition, melanocytes either die or fail to perform their physiological function. Possible contributing factors include autoimmune, genetic, oxidative stress, neural, and viral mechanisms [10]. While a variety of therapeutic options are available, combined treatment with NB-UVB and topical 0.1% tacrolimus ointment has been shown to be more effective and superior to NB-UVB with placebo [11]. Tacrolimus ointment is widely prescribed in vitiligo as it inhibits T-cell activation and pro-inflammatory cytokines. Its therapeutic success rate improves when combined with other treatment modalities, such as NB-UVB microphototherapy, helium-neon laser, or narrow-band excimer laser [8]. From a genetic perspective, the TYR gene has been proposed as a contributing factor.

Although not directly linked to the immune system, tyrosinase—a melanocytic enzyme and melanin biosynthesis catalyst—acts as a major autoantigen in generalized vitiligo. Among environmental risk factors, sunburn, irritation, and radiation exposure are considered important triggers. Vitiligo is also commonly associated with autoimmune and inflammatory disorders including type 1 diabetes mellitus, rheumatoid arthritis, psoriasis, Addison's disease, scleroderma, Hashimoto's thyroiditis, pernicious anemia, alopecia areata, and systemic lupus erythematosus [12]. Although many therapeutic agents have been attempted, none are uniformly effective. The application of steroids in combination with ultraviolet light has been suggested as the best treatment option [13].

UVB lamp exposure of the skin remains a widely used therapeutic modality for vitiligo, employing both broadband and narrowband UV light [14,15]. Studies

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JCHR (2025) 15(5), 944-951 | ISSN:2251-6727

suggest that combination therapy with UVB phototherapy and other topical agents improves clinical outcomes and repigmentation rates. Tacrolimus, when compared with steroids, offers several benefits and is considered highly effective in treating vitiligo and other forms of dermatitis. Given this evidence, evaluating the comparative effectiveness of NB-UVB alone versus NB-UVB combined with topical 0.1% tacrolimus ointment in vitiligo patients is warranted to determine the optimal therapeutic approach.

Objective

- To compare the efficacy of Narrowband UVB (NB-UVB) alone versus NB-UVB combined with 0.1% topical tacrolimus ointment in treating vitiligo.

Methodology & Materials

This randomized controlled study was conducted at the Department of Dermatology and Venereology, Combined Military Hospital (CMH), Dhaka, Bangladesh, from February 2021 to August 2021. A total of 70 patients with vitiligo, selected according to predefined inclusion and exclusion criteria, were enrolled to compare the effectiveness of narrowband ultraviolet B (NB-UVB) therapy alone versus NB-UVB combined with topical tacrolimus ointment (0.1%).

Inclusion Criteria:

- Patients older than 14 years with stable vitiligo
- Provided informed consent

Exclusion Criteria:

- Unwilling to participate
- Pregnant or nursing patients
- Current or recent (within 12 months) use of isotretinoin
- Active vitiligo with new or spreading lesions
- Positive Koebner's phenomenon

Operational definitions included vitiligo as depigmented white patches, melanocytes as melanin-producing cells, and repigmentation as restoration of pigmentation. Patients were randomized into two groups: Group A received 0.1% tacrolimus ointment, and Group B received placebo, both in combination with NB-UVB therapy thrice weekly, starting at 0.1 J/cm² and increasing by 10% per session. Adverse effects were monitored, and phototherapy doses adjusted as needed. Repigmentation was assessed monthly over three months using a visual analog scale divided into four quadrants, categorized as excellent (>75%), good (50–75%), moderate (25–49%), or poor (<25%), and evaluated by two independent observers. Data were analyzed using SPSS version 23.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Independent t-tests and chi-square tests were applied, with $p < 0.05$ considered statistically significant. Quality assurance included pretesting, data verification, and correction of inconsistencies. Ethical standards were maintained throughout, including informed consent, confidentiality, voluntary participation, and approval from the Institutional Review Board of CMH, Dhaka.

Results

Table 1: Distribution of Study Patients by Age (n=140)

Age (years)	Group A (n=70)		Group B (n=70)		P value
	n	%	n	%	
≤20	9	12.9	7	10	0.956^{ns}
21-30	27	38.6	28	40	
31-40	18	25.7	20	28.6	
41-50	11	15.7	9	12.9	
>50	5	7.1	6	8.6	

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JCHR (2025) 15(5), 944-951 | ISSN:2251-6727

Table 1 shows that the majority of patients belonged to the 21–30 years age group in both groups, with 27 (38.6%) in Group A and 28 (40.0%) in Group B. The difference between the two groups was not statistically significant (p > 0.05).

Table 2: Distribution of Study Patients by Sex (n=140)

Sex	Group A (n=70)		Group B (n=70)		P value
	n	%	n	%	
Male	43	61.4	47	67.1	0.480^{ns}
Female	27	38.6	23	32.9	

Table 2 shows that males were 43 (61.4%) in Group A and 47 (67.1%) in Group B, while females were 27 (38.6%) in Group A and 23 (32.9%) in Group B. The difference between the two groups was not statistically significant (p > 0.05).

Table 3: Distribution of Study Patients by Duration of Disease (n=140)

Duration of disease (years)	Group A (n=70)		Group B (n=70)		P value
	n	%	n	%	
<5	46	65.7	43	61.4	0.598^{ns}
≥5	24	34.3	27	38.6	

Table 3 shows that the majority of patients had a disease duration of less than 5 years in both groups, with 46 (65.7%) in Group A and 43 (61.4%) in Group B. The difference between the two groups was not statistically significant (p > 0.05).

Table 4: Distribution of Study Patients by Type of Vitiligo (n=140)

Type of vitiligo	Group A (n=70)		Group B (n=70)		P value
	n	%	n	%	
Segmental	7	10.0	9	12.9	0.595^{ns}
Not segmental	63	90.0	61	87.1	

Table 4 shows that segmental vitiligo was observed in 7 (10.0%) patients in Group A and 9 (12.9%) patients in Group B. Non-segmental vitiligo was found in 63 (90.0%) patients in Group A and 61 (87.1%) patients in Group B. The difference between the two groups was not statistically significant (p > 0.05).

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Table 5: Depigmentation at Baseline of Study Patients (n=140)

Depigmentation (%)	Group A (n=70)		Group B (n=70)		P value
	n	%	n	%	
1-10	55	78.6	58	82.9	0.540[ns]
11-20	14	20	12	17.1	
21-30	1	1.4	0	0	

Table 5 shows that the majority of patients had 1–10% depigmentation in both groups, with 55 (78.6%) in Group A and 58 (82.9%) in Group B. The difference between the two groups was not statistically significant ($p > 0.05$).

Table 6: Response at 3rd Month of Study Patients (n=140)

Response	Group A (n=70)		Group B (n=70)		P value
	n	%	n	%	
Excellent (>75% repigmentation)	38	54.3	22	31.4	0.021[s]
Good (50-75% repigmentation)	23	32.9	29	41.4	
Moderate (25-49% repigmentation)	8	11.4	13	18.6	
Poor (<25% repigmentation)	1	1.4	6	8.6	

Table 6 shows that an excellent response was observed in 38 (54.3%) patients in Group A and 22 (31.4%) patients in Group B. A good response was found in 23 (32.9%) patients in Group A and 29 (41.4%) patients in Group B. A moderate response was seen in 8 (11.4%) patients in Group A and 13 (18.6%) patients in Group B. A poor response was observed in 1 (1.4%) patient in Group A and 6 (8.6%) patients in Group B. The difference between the two groups was statistically significant ($p < 0.05$).

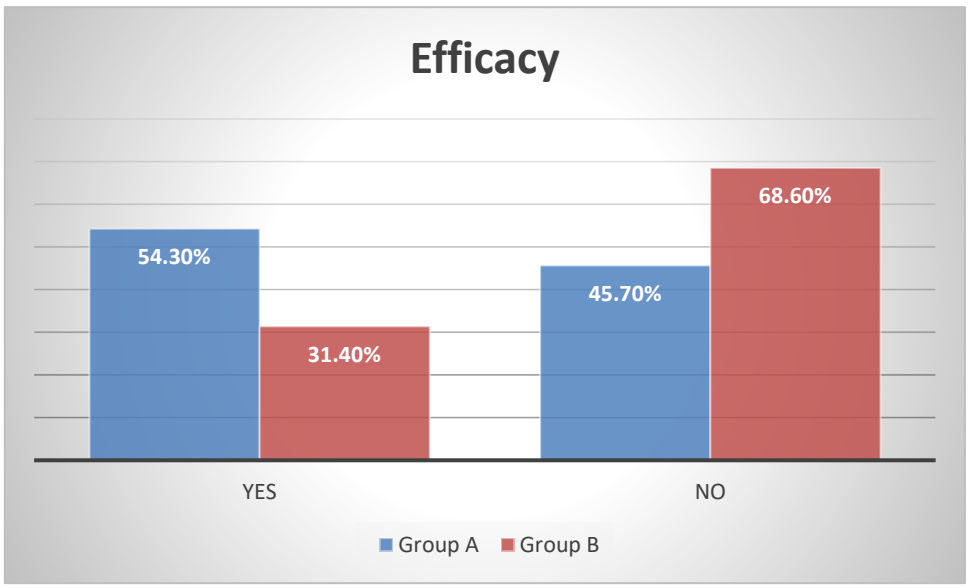

Figure 1: Efficacy of Study Patients (n=140)

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JCHR (2025) 15(5), 944-951 | ISSN:2251-6727

Figure 1 shows that overall efficacy was 38 (54.3%) in Group A and 22 (31.4%) in Group B. The difference between the two groups was statistically significant ($p < 0.05$).

Discussion

This study showed that the majority of patients belonged to the 21–30 years age group in both groups, with 27 (38.6%) in Group A and 28 (40.0%) in Group B, and the difference was not statistically significant ($p > 0.05$). Ullah et al.[16] reported a mean age of 28.59 ± 8.86 years, with a range of 15–51 years. In their study, Group A comprised 14 (29.8%) patients ≤25 years, 27 (57.4%) aged 26–40 years, and 6 (12.8%) >40 years, while Group B had 17 (36.2%) patients ≤25 years, 26 (55.3%) aged 26–40 years, and 4 (8.5%) >40 years. The age distribution was also insignificant ($p = 0.701$). Jamal et al.[17] reported that the majority of patients (46%) were aged 25–34 years, and 39% were 14–24 years, with a mean age of 27.4 ± 12.6 years. Similarly, Putta et al.[3] observed that the most common age group was 20–30 years. The onset age of vitiligo among participants in this study also varied between 20 and 30 years. The mean age of Group B was 37.54 ± 7.04 years, while the mean age of Group A was 38.92 ± 6.35 years, as reported by Bilal et al. [11].

Regarding sex distribution, males accounted for 43 (64.4%) in Group A and 47 (67.1%) in Group B, while females were 27 (38.6%) in Group A and 23 (32.9%) in Group B, with no statistically significant difference. According to Ullah et al. [16], the male-to-female ratio was 0.59:1 ($p = 0.522$), with 16 (34%) men and 31 (66%) females in Group A and 19 (40.4%) males and 28 (59.6%) females in Group B. Jamal et al.[10] observed that vitiligo affects 0.1%–2% of the general population, with a familial incidence of approximately 30%. Putta et al.[3] reported 26 females and 14 males among 40 patients, consistent with prior observations by Handa et al.[17], and Koranne et al.[18] showing female predominance.

Most patients had a disease duration of less than 5 years, with 46 (65.7%) in Group A and 43 (61.4%) in Group B, showing no statistically significant difference ($p > 0.05$). Bilal et al.[11] similarly reported that the majority of patients had a disease course shorter than 3 years (60% in Group A and 53.3% in Group B). Jamal et al.[10] noted that symptom duration ranged from 5 months to 7 years, with 56% of patients presenting after 3–4 years.

Segmental vitiligo was noted in 7 patients (10.0%) in Group A and 9 patients (12.9%) in Group B, whereas non-segmental vitiligo was observed in 63 patients (90.0%) and 61 patients (87.1%), respectively, with no statistically significant difference ($p > 0.05$). Bilal et al.[11] reported segmental vitiligo in 2 (6.7%) patients in Group A and 3 (10%) in Group B, with non-segmental vitiligo comprising the majority (93.3% in Group A and 90% in Group B).

At baseline, 1–10% depigmentation was seen in 55 (78.6%) patients in Group A and 58 (82.9%) in Group B, without a statistically significant difference ($p > 0.05$). According to Njoo et al. [19], following a year of NB-UVB therapy, 27 out of 51 paediatric patients (53%) had > 75% total repigmentation. In the current study, repigmentation began within 6 weeks in 8 patients in Group A and 2 in Group B, while it took more than 6 weeks in 10 patients in Group A and 11 in Group B. According to Bilal et al. [11], the mean baseline depigmentation was 10.5 ± 26.12% in Group A and 8.77 ± 3.81% in Group B. In most patients, depigmentation was between 1 and 10%, and it never went above 30% of the body's surface area.

At the 3rd month, an excellent response (>75% repigmentation) was observed in 38 (54.3%) patients in Group A and 22 (31.4%) in Group B. A good response (50–75%) was seen in 23 (32.9%) patients in Group A and 29 (41.4%) in Group B. Moderate response (25–49%) occurred in 8 (11.4%) patients in Group A and 13 (18.6%) in Group B, while poor response (<25%) was seen in 1 (1.4%) patient in Group A and 6 (8.6%) in Group B, showing a statistically significant difference ($p < 0.05$). Jamal et al.[10] reported similar follow-up outcomes with maximum improvement seen in Group B by the 16th week. Putta et al.[3] observed higher Grade 3 repigmentation in Group A (8 patients) compared to Group B (2 patients), with Grade 1 repigmentation also more prevalent in Group A. Bilal et al.[11] found that over three months, Group A showed superior responses: 16 patients (53.3%) had an excellent response versus 9 patients (30%) in Group B ($p < 0.05$), with comparable distributions for good and moderate responses. Poor response was absent in Group A but seen in 4 patients (13.3%) in Group B.

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JCHR (2025) 15(5), 944-951 | ISSN:2251-6727

In this study, efficacy was observed in 38 (54.3%) patients in Group A and 22 (31.4%) patients in Group B, with the difference between the groups being statistically significant. Bilal et al.[11] reported that in their comparison, 16 (53.5%) patients in Group A showed a favorable response, compared to 9 (30%) patients in Group B ($P < 0.05$). Fai et al.[9] assessed the efficacy and tolerability of combined NB-UVB and topical tacrolimus treatment in vitiligo, reporting a predominant age group of 42 years and over 70% repigmentation. Although clinical response (repigmentation >50%) was achieved, effectiveness on extremities and genital areas was limited. Treatment tolerability was satisfactory, consistent with their results regarding age (mean 38 years) and response rate (60%), although their study lacked a comparative trial component like ours.

Nordal et al.[20] examined the additional benefits of applying tacrolimus ointment (0.1%) once daily alongside NB-UVB therapy and found that combination therapy yielded superior outcomes compared to NB-UVB alone. Similarly, Ullah et al.[16] observed efficacy rates of 87.2% in Group A and 68.1% in Group B, indicating that combination therapy was significantly more effective than monotherapy ($p = 0.022$). In addition, Jamal et al. [10] discovered that topical tacrolimus ointment (0.1%) in conjunction with NB-UVB generated better results than NB-UVB alone. Assessment scores ranged from 0.86 to 3.22 (normal range 0–4), and line graphs demonstrated gradual improvement in vitiligo, with combination therapy consistently producing higher repigmentation than monotherapy.

Tacrolimus may help prevent UVB-induced erythema by modulating early inflammatory processes [21-23]. Fai et al.[9] confirmed significant repigmentation (>70% of lesions) with combined NB-UVB and tacrolimus treatment, while Nordal et al.[20] further supported that adding tacrolimus ointment (0.1%) to NB-UVB therapy improves outcomes in vitiligo compared to NB-UVB alone.

Limitations of the study

This study had several limitations:

- The study population was drawn from a single hospital in Dhaka, which may limit the generalizability of the results to the broader population.
- The small sample size was another limitation. Future studies should consider larger sample sizes to improve the validity of the results.

Conclusion

A significant number of cases exhibited a better response when treated with a combination of NB-UVB and topical tacrolimus ointment (0.1%) compared to NB-UVB therapy alone in vitiligo. Additionally, the combination of NB-UVB with topical tacrolimus (0.1%) proved to be more effective than NB-UVB treatment alone.

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