ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES
Knowledge to Innovation

Vol 17, Issue 12, 2024

Online - 2455-3891
Print - 0974-2441

Research Article

A COMPARATIVE STUDY OF ORAL PSORALEN VS METHYLPREDNISOLONE WITH NARROW BAND UVB THERAPY IN VITILIGO

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Received: 02 October 2024, Revised and Accepted: 14 November 2024

ABSTRACT

Objective: The efficacy and safety evaluation of oral Psoralen and of oral Methylprednisolone along with narrow-band ultraviolet B (NB-UVB). To observe the safety and efficacy of oral Psoralen in patients of Vitiligo. To observe the safety and efficacy of oral Methylprednisolone along with NB-UVB in patients of Vitiligo. To compare the safety and efficacy of oral Psoralen and oral Methylprednisolone along with NB-UVB during the study. To assess the dermatological life quality index (DLQI) in patients of Vitiligo before, during treatment, and after treatment.

Methodology: A randomized controlled trial was conducted involving 76 patients diagnosed with generalized vitiligo. Patients were randomly assigned to either Group A or Group B. Group A received oral psoralen (0.3–0.6 mg/kg) followed by Twice-weekly sessions of NB-UVB therapy along with methylprednisolone.

Results: As per the observations, the DLQI of the patients treated with the methylprednisolone with NB-UVB were showing better results as compared to the oral psoralen group.

Conclusion: Even though vitiligo does not pose a direct threat to a person's physical or mental health, it does cause a great deal of suffering for those who suffer from it and their loved ones. Therefore, treatment is necessary. While there are a number of systemic and topical treatments for this condition, phototherapy – and particularly NB-UVB – is among the most effective and safest options.

Keywords: Vitiligo, Phototherapy, NB-UVB, Dermatological life quality index, Oral Psoralen, Methylprednisolone.

 DOI: http://dx.doi.org/10.22159/ajpcr.2024v17i12.53085. Journal homepage: https://innovareacademics.in/journals/index.php/ajpcr

INTRODUCTION

Vitiligo is a skin disease of the skin causing that causes depigmentation. It occurs due to the impairment of melanocytes. There are different causes of vitiligo; they are autoimmune disease, hereditary, neural, viral infections, and oxidative stress. It can be categorized into two types: Chemical and idiopathic. The main reasons for vitiligo are autoimmune disease, genetic factors, neural influences, viral infections, and oxidative stress contribute to generalized vitiligo or non-segmental vitiligo (NSV). The patients will have a white patch that may spread all over the body. Segmental vitiligo is a chronic disease with hyperpigmentation disorder having a white color patch with a unilateral distribution [1]. The symptoms of vitiligo are depigmentation with white color skin patches seen all over the body. It gets distributed all over the face, hands, and wrists. Some of the patients may get depression.

Vitiligo is the most dangerous disease-causing decrease in the pigmentation of the skin in 0.5–2% population in both males and females [1,2]. In the year of 1977, Isle of Bornholm, Denmark reported that 0.38% of patients were affected mostly [3]. A low prevalence of 0.093% was found in China and a higher prevalence of 8.8% was found in India [4,5]. Among 50 global studies, the frequency of vitiligo varied from as little as 0.06% to as much as 2.28% [6]. Both males and females are equally affected. 25% of vitiligo was found in 10 years of age [7]. As per the study conducted on the age group, they were stating that 70–80% of diseases were found in 30 years. Below 30 years, 80% and 10 years, 41.3% were affected mostly. According to Hann and Lee *et al*. [8] the average range of patients was 15.6 years.

The primary causes of vitiligo are biochemical changes, cytotoxic, neural, and autoimmune factors. Biochemical/cytotoxic vitiligo occurs due to the destruction of melanocytes and their cytotoxic precursors by inhibiting melanin synthesis [9]. The neural cause of vitiligo is due to nerve injury at the infected site, leading to segmental vitiligo that may interact with melanocytes and melanocytotoxic substrates. Vitiligo is due to hereditary, autoimmune disorders, this disease may be version due to toxic compounds, infections, mutations, cellular changes, and deficiency in melanocyte [10].

Several studies that examined lesions, perilesional, and non-lesional skin biopsies from vitiligo patients with immune infiltration have observed that T cells in the skin of vitiligo patients were found to target and destroy melanocytes. 20–30% of vitiligo patients have a family history [11].

Vitiligo was divided into different types: (1) Non-segmental, (2) Segmental, (3) Mixed (NSV + SV), and (4) Unclassified vitiligo. There are five distinct treatment types for vitiligo: Surgery, local and oral immunosuppressants, and phototherapy [12]. Topical corticosteroids, Calcineurin Inhibitors, Vitamin D3 Analogues (D3A), Phototherapy: Narrow-Band UVB (NBUVB) phototherapy, and PUVA irradiation were used as a treatment for vitiligo.

The findings across multiple studies indicated that vitiligo significantly impacts patients' quality of life, with other studies reported moderately to severely impactful effects [13]. As per previous studies, they observed significant reductions ($p<0.05$) in depigmented areas and stabilization of vitiligo lesions after 6 months of treatment using Methylprednisolone and NBUVB, as well as oral minipulse betamethasone and NBUVB [14] and superior repigmentation outcomes with NB-UVB compared to PUVASOL, with similar stability observed post-treatment cessation [15].

This study was conducted to determine which oral medication, Psoralen or Methylprednisolone combined with NB-UVB therapy is more effective in re-pigmenting vitiligo lesions. Evaluate the safety profiles of oral Psoralen and Methylprednisolone to minimize adverse effects and enhance treatment compliance. Assess the impact of treatments on the dermatological life quality index (DLQI) to improve psychological and emotional well-being in vitiligo patients. Investigate the sustainability of treatment outcomes over a 12 weeks to guide long-term management strategies. Provide evidence-based data to support clinical decision-making and optimize personalized treatment approaches for vitiligo at the ground level of practice.

METHODS

The current study was conducted in the Department of Pharmacology and Therapeutics in collaboration with the Department of Dermatology at S.N. Medical College and its affiliated hospital in Agra (U.P.).

Study design

It was an observational, prospective, comparative study of Oral Psoralen versus Methylprednisolone with Narrow-Band UVB therapy in Vitiligo.

Inclusion criteria

1. Patients diagnosed with both dermatomal and non-dermatomal vitiligo.
2. Vitiligo subjects aged between 12 and 60 years.
3. Patients must have at least 25–50% body surface area involvement as diagnosed by the investigator.
4. Patients ready to give written informed consent form.

Exclusion criteria

1. Patients already treatment for vitiligo with other medications within the past 2 months.
2. Subjects unwilling to provide written informed consent.
3. History of drug or alcohol abuse, chronic smokers unwilling to abstain from smoking during the study period.
4. Significant hepatic or renal disease.
5. Pregnancy or lactation.
6. Diagnosed cases of autoimmune disorders or immunocompromised states.
7. History of hypersensitivity to any of the investigational drugs.

Sample size calculation

A total of 76 patients as per inclusion criteria randomly selected suffering from vitiligo attending skin OPD of the hospital will be included in the study. In case of qualitative study, the sample size will calculate by using the OpenEpi online sample size calculator.

Study groups

- Group 1: Patients with vitiligo will receive oral methoxy psoralen as prescribed by a dermatologist.
- Group 2: Patients with vitiligo will receive oral methylprednisolone in combination with NB UVB therapy.

Dosing

Methoxypsoralen: 0.3–0.6 mg/kg/day

Methylprednisolone: 0.25–0.5 mg/kg will be administered for twice weekly along with NB UVB therapy at a dose of 0.25–3 J/cm^2 twice weekly.

Duration of study

The study was carried for 1 year after taking approval from the Ethics Committee.

Pre-treatment evaluation

1. Complete Blood Count (CBC)
2. Liver Function Tests (LFT)
3. Kidney Function Tests (KFT)

Follow-Up

Data were collected from patients on the first visit and followed for 4, 8, and 12 weeks.

Evaluation of safety (Tables 1 and 2)

1. Assessment of safety – Estimation of efficacy.
2. Assessment of effectiveness – Assessment of DLQI.
3. Evaluation of effect on quality of life – Evaluation and estimation of adverse effects.

Evaluation of efficacy will include – Re-pigmentation of vitiliginous areas was graded as follows:

- Grade 0: No pigmentation
- Grade 1: Minimum re-pigmentation (1–25%)
- Grade 2: Mild re-pigmentation (26–50%)
- Grade 3: Moderate re-pigmentation (51–75%)
- Grade 4: Excellent re-pigmentation (76–100%)

The color of the re-pigmented area was compared with that of the patient's unaffected skin, and the degree of matching was assessed in both treatments.

RESULTS

In our study, a total of 76 individuals were diagnosed with vitiligo; 38 of these patients received oral methoxy psoralen (Group A), while another 38 received methylprednisolone with narrow-band UVB therapy (Group B).

Table 3 shows the number of people in each age group for groups A and B; in group A, there are 12 people between the ages of 12 and 21, while in group B, there are 16 people in that age group. The number of males and females in each group, in group A, there are 16 males and 22 females, while in group B, there are 14 males and 24 females. The number of people in each group who have the condition for <1 year, 1–3 years, or more than 3 years, in group A, there are 5 people who have had the condition for <1 year, while in group B, there are 7 people in that group. Group A, 18 people have vitiligo on the face and neck, while in group B, there are 16 people in that group, in group A, there are 7 people who have a positive family history, while in group B, there are 9 people in that group.

The demographic characteristics, duration of sickness, and body area affected by vitiligo are displayed in Figs. 1-4.

Table 4 compares pre and post-treatment values for CBC, LFT, and KFT in Group A and Group B. Each parameter is presented with

Table 1: Dermatology life quality index

Total score	Significance
0–1	No effects
2–5	Small effects
6–10	Moderate effects
11–20	Very large effects
21–30	Extremely large effects

Table 2: Distribution of patients based on VASI

Degree of depigmentation (%)	VASI (Interpretation)
100	Complete depigmentation, no pigment presents
90	Specks of pigments present
75	Depigmented area exceeds pigmented area
50	Pigmented and depigmented areas are equal
25	Pigmented area exceeds depigmented area.
10	Only specks of depigmented presents

VASI: Vitiligo area severity index

its mean and standard deviation (SD). Group A and Group B show improvements in hemoglobin, white blood cells, and platelet counts after treatment. Liver function markers (ALT, AST, ALP, and bilirubin) and kidney function markers (BUN, creatinine, and GFR) also indicate better outcomes post-treatment for both groups. The data suggests that both treatments were effective in improving the overall health parameters of the patients.

Table 3: Demographic characteristics of the patient

Characteristic	Group-A (n=38)	Group-B (n=38)
Age		
12–21 years	12 (31.58)	16 (42.11)
22–31 years	6 (15.79)	4 (10.53)
32–41 years	11 (28.95)	8 (21.05)
>42 years	9 (23.68)	10 (26.32)
Gender		
Male	16 (42.11)	14 (36.84)
Female	22 (57.89)	24 (63.16)
Duration of Illness		
<1 year	5 (13.16)	7 (18.42)
1–3 years	26 (68.42)	21 (55.26)
>3 years	7 (18.42)	10 (26.32)
Body area involved		
Face and Neck	18 (47.37)	16 (42.11)
Upper extremity	6 (15.79)	8 (21.05)
Lower extremity	8 (21.05)	6 (15.79)
Trunk	6 (15.79)	8 (21.05)
Positive family history	7 (18.42)	9 (23.68)

Table 4: Comparison of CBC, LFT, KFT between groups

Test	Group A	Group B
Complete blood count (CBC)*		
Hemoglobin (g/dL)	13.02±1.16	13.29±1.24
White blood cells (WBC) (cells/mm^3)	6,848±451	7,236±477*
Platelets (cells/mm^3)	205,246±14,198	215,482±15,516*
Liver function test (LFT)**		
Alanine aminotransferase (ALT) (U/L)	28.68±4.64	29.46±5.57*
Aspartate aminotransferase (AST) (U/L)	26.78±3.46	27.67±4.58
Alkaline phosphatase (ALP) (U/L)	68.25±8.57	72.75±10.68*
Bilirubin (Total) (mg/dL)	0.77±0.11	0.86±0.17*
Kidney function test (KFT)***		
Blood urea nitrogen (BUN) (mg/dL)	14.34±1.56	15.31±2.95
Creatinine (mg/dL)	0.97±0.15	1.04±0.14*
Glomerular filtration rate (GFR) (mL/min)	92.26±4.31	90.32±5.27

Un paired t test, Significance levels: p<0.001*, p<0.01**, p<0.05***.

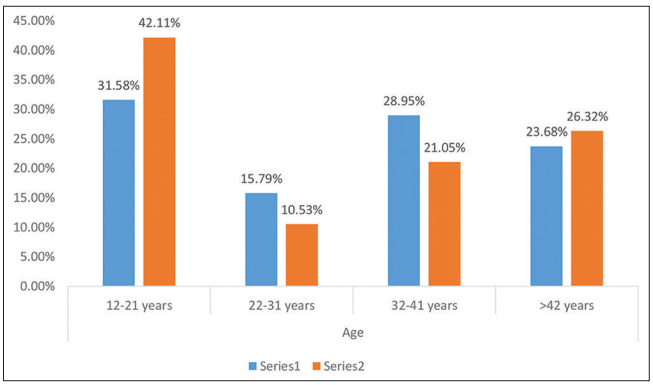

Fig. 1: Demographic profile of the patients based on age

Table 5 and Fig. 5 display the count of patients in each group according to their level of repigmentation (none, minimal, mild, moderate, and excellent) at different time intervals. It also presents the average area of repigmentation and the percentage of repigmentation for each group at each interval. A p<0.05 indicates a statistically significant difference between the groups in terms of repigmentation.

The data reveal a statistically significant difference between groups A and B at all three time points. At 4 weeks, group A had more patients with no repigmentation, whereas group B had more patients with minimal, mild, and moderate repigmentation. This pattern continued at 8 weeks,

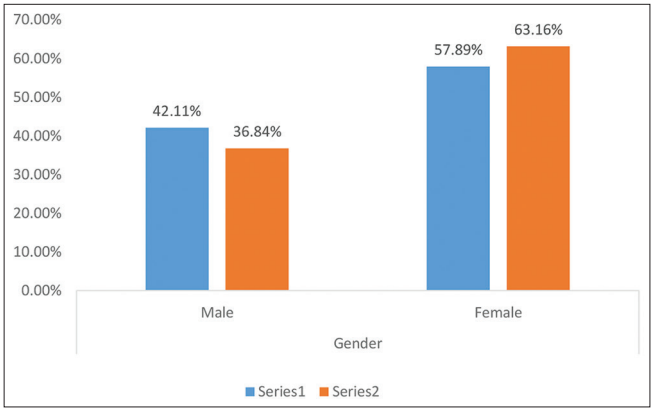

Fig. 2: Demographic profile of the patients based on gender

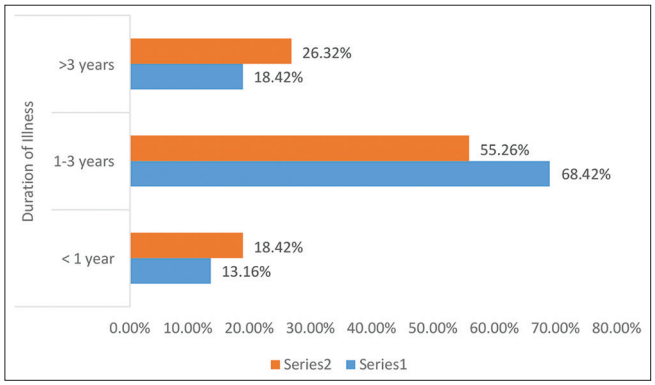

Fig. 3: Demographic profile of the patients based on duration of illness

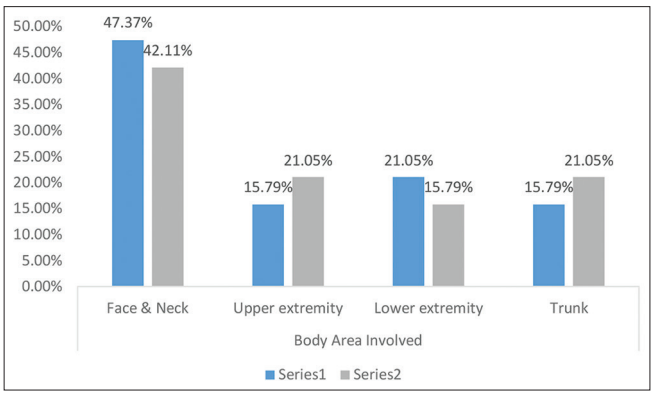

Fig. 4: Demographic profile of the patients based on body area involved

Table 5: Treatment Outcomes Over Follow-Up

	Group A Frequency and Percentage (%)	Group B Frequency & Percentage	p-value
Repigmentation level at 4 weeks*			
None (0)	7 (21.87)	0 (0)	0.03
Minimal (1–25%)	12 (37.5)	13 (40.62)	
Mild (26–50%)	8 (25)	9 (28.12)	
Moderate (51–75%)	5 (15.62)	7 (21.87)	
Excellent (76–100%)	0 (0)	3 (9.37)	
Average Area of Re-pigmentation (%)	1.97	2.79	
Repigmentation level at 8 weeks**			
None (0)	3 (9.3)	0 (0)	0.03
Minimal (1-25%)	12 (37.5)	7 (21.87)	
Mild (26-50%)	9 (28.12)	9 (28.12)	
Moderate (51-75%)	8 (25)	10 (31.25)	
Excellent (76-100%)	0 (0)	6 (18.75)	
Average Area of Re-pigmentation (%)	2.82	4.17	
Repigmentation level at 12 weeks***			
None (0)	0 (0)	0 (0)	0.17
Minimal (1-25%)	9 (28.12)	3 (9.37)	
Mild (26-50%)	10 (31.25)	9 (28.12)	
Moderate (51–75%)	6 (18.75)	7 (21.87)	
Excellent (76–100%)	7 (21.87)	13 (40.62)	
Average Area of Re-pigmentation (%)	2.82	4.17	

Chi-square test - Significance levels: p<0.001*, p<0.01**, p<0.05***.

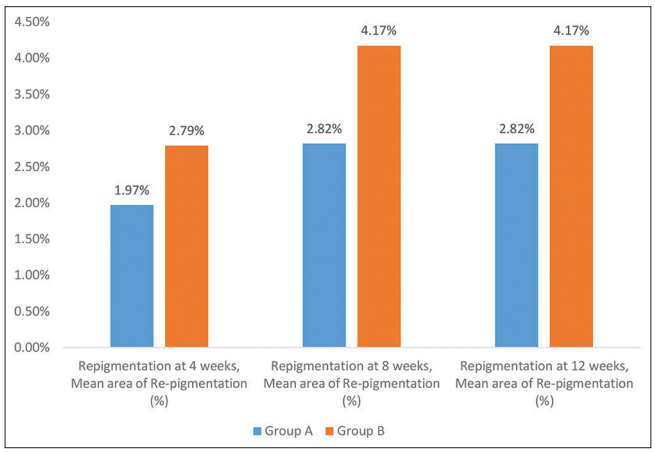

Fig. 5: Repigmentation at 4, 8, 12 weeks of mean area of Re-pigmentation (%)

with group A still having more patients with no repigmentation, and group B having higher numbers of patients with minimal, mild, and moderate repigmentation. By 12 weeks, group A maintained higher numbers of patients with no repigmentation, while group B showed more patients with minimal, mild, and excellent repigmentation. Across the board, group B exhibited higher mean repigmentation areas and percentages than group A at all three time points.

The mean DLQI score in group A was 5.12 at the initial visit and decreased to 2.31 at the 12-week mark. In group B, the mean DLQI score started at 2.81 at the first visit and reduced to 1.40 at 12 weeks. The table also includes the outcomes of an unpaired t-test, which is used to compare the means between the two groups. A p-value below is considered statistically significant. The p-value for the t-test at the initial visit is 0.86, indicating no significant difference between the mean DLQI scores of the two groups at this time point. However, the p-value at 12 weeks is 0.01, indicating a significant difference between the mean DLQI scores of the two groups at the 12-week follow-up, which is shown in Table 6.

Safety

Comparing short-term safety profiles, methylprednisolone appears to be the safer option due to a lower frequency of side effects such as nausea, vomiting, erythema, and itching/burning compared to oral psoralen. While both medications can cause nausea and vomiting, oral psoralen additionally carries risks of headaches and dizziness. The potential for striae with methylprednisolone should also be considered, but it may be less common, and transient compared to the cumulative adverse effects of oral psoralen.

DISCUSSION

Despite vitiligo being a common skin disorder, there is no universally accepted definition. The Vitiligo European Task Force (VETF) has provided consensus definitions for clarity. Vitiligo vulgaris is defined as an acquired pigmentation disorder characterized by symmetrically distributed depigmented patches that gradually increase in size, associated with the loss of melanocytes from both the follicular and epidermal layers (NSV). Segmental vitiligo may follow a dermatome pattern or present unilaterally as asymmetric vitiligo.

There is limited clinical experience with narrow-band UVB (NB-UVB) for vitiligo. To our knowledge, no comparative trial has been conducted between oral Psoralen and methylprednisolone combined with NB-UVB therapy for vitiligo treatment. Both therapies can achieve repigmentation of the affected skin.

The table shows the distribution of patients in each group according to their repigmentation levels (none, minimal, mild, moderate, and excellent) at various time points. It also details the mean repigmentation area and the percentage of repigmentation for each group at these intervals. A p<0.05 is considered statistically significant, indicating a significant difference between the two groups regarding repigmentation.

At all three time points, there is a notable difference between groups A and B in terms of repigmentation. At 4 weeks, group A had more patients with no repigmentation, whereas group B had more patients with minimal, mild, and moderate repigmentation. This pattern persisted at 8 weeks, with group A showing higher numbers of patients with no repigmentation, and group B showing higher numbers of patients with minimal, mild, and moderate repigmentation. By 12 weeks, group A still had more patients with no repigmentation, while group B had more patients with minimal, mild, and excellent repigmentation. Group B consistently exhibited higher mean repigmentation areas and percentages than group A at all three time points.

The table also compares pre- and post-treatment values for CBC, LFT, and KFT in Group A and Group B. Each parameter is presented with

Table 6: Dermatology life quality index

DLQI	Group A	Group B	p-value
First visit	5.12±2.80	5±2.81	0.86
12 weeks	2.31±1.6*	1.40±1.39**	0.01***

DLQI: Dermatological life quality index. Un paired t test, Significance levels: p<0.001*, p<0.01**, p<0.05***.

its mean and SD. Post-treatment, both groups showed improvements in hemoglobin levels, white blood cell counts, and platelet counts. Liver function markers (ALT, AST, ALP, and bilirubin) and kidney function markers (BUN, creatinine, and GFR) also indicated better outcomes for both groups. These results suggest that the treatments were effective in improving the overall health parameters of the patients.

Previous studies have shown similar trends. Anabar *et al*. 2020 at the end of 6 months, 14 of 20 patients achieved more than 75% repigmentation, whereas 4 patients showed 50% repigmentation and 2 patients showed 25% repigmentation after treatments. Adverse effects were limited and transient [16].

Westerhof *et al*. first provided encouraging results in favor of NB UVB in vitiligo in which 63% of their patients achieved 75% or greater repigmentation after 12 months of twice weekly therapy when compared with 46% of patients achieving similar degree of repigmentation with topical PUVA [17].

Parsad *et al*. in 2006 reported significant repigmentation in 23.6% of PUVA-treated patients and 41.9% of NB-UVB-treated patients, with moderate improvement in 36.8% and 32.2% of patients, respectively [18].

The p-value for the t-test at 12 weeks is 0.01, indicating a significant difference between the mean DLQI scores of the two groups at this time point. In a 2007 study by Yones *et al*. on the treatment of vitiligo, NB-UVB therapy was found to be superior to oral PUVA therapy. In 2013, El Mofty *et al*. conducted a randomized controlled trial comparing broadband UVA to psoralen UVA, concluding that broadband UVA at a dose of 15 J/cm^2/session yields comparable results to PUVA, making it a viable option when oral psoralens are contraindicated [19].

In our study, the stability of repigmentation with surrounding skin was observed up to 12 weeks and found to be almost equal in both groups. However, retrospective analysis showed that stability of repigmentation after 12 weeks was significantly better in the methylprednisolone with NB-UVB treated group compared to the oral PUVA treated group.

Strength of study

Clinical relevance

Addressing a clinically significant question in dermatology regarding the efficacy and safety of two commonly used treatments for vitiligo.

Treatment comparison

Provides a direct comparison between two different treatment modalities, allowing for insights into their respective effectiveness, side effects, and patient outcomes.

Evidence-based medicine

Contributes to evidence-based decision-making by evaluating treatments that are currently in use, thereby potentially influencing clinical guidelines and practice.

Patient-centered outcomes

Focuses on outcomes that matter to patients such as repigmentation rates, treatment adherence, and quality of life improvements, which are crucial for informing patient care.

Methodological rigor

Opportunity to design a robust study with appropriate randomization, blinding (if applicable), and control of confounding variables, ensuring reliable and valid results.

Generalizability

Depending on the study design, findings may apply to a broad range of vitiligo patients, enhancing the study's external validity.

Ethical considerations

Ensures that patients receive standard of care while participating in research, adhering to ethical principles of beneficence and non-maleficence.

Limitation of study

Patient variability

Vitiligo is a heterogeneous condition with variability in patient characteristics (e.g., age, skin type, duration, and extent of vitiligo), which may influence treatment outcomes and complicate direct comparisons.

Sample size constraints

Achieving adequate sample sizes for robust statistical analysis can be challenging in dermatological studies, potentially limiting the study's power to detect significant differences between treatments.

Treatment adherence

Variability in patient adherence to treatment protocols (e.g., medication adherence and compliance with phototherapy schedules) may affect outcomes and introduce bias.

Duration of follow-up

Short-term follow-up periods may not capture long-term outcomes and relapse rates, limiting the study's ability to assess treatment durability and sustainability over time.

CONCLUSION

This study assessed the effectiveness of PUVASOL (psoralen followed by sun exposure) versus NBUVB therapy in treating vitiligo. Various factors, including CBC, LFT, KFT, treatment efficacy, speed of repigmentation, stability of repigmentation, and side effects, were examined to identify the superior treatment method. The results demonstrated that NBUVB therapy was more effective overall compared to Psoralen.

In detail, NBUVB therapy led to more significant improvements in repigmentation at various follow-up intervals (4, 8, and 12 weeks). Group B, treated with NBUVB, exhibited higher mean repigmentation areas and percentages across all time points, indicating a more robust and sustained response compared to the Psoralen group.

In addition, the DLQI scores improved more significantly in the NBUVB group, reflecting a better quality of life for patients undergoing this treatment. The statistical analysis showed that the differences in DLQI scores between the groups were significant at the 12-week mark, further underscoring the efficacy of NBUVB therapy.

Safety profiles were also favorable for NBUVB therapy, with fewer adverse effects reported compared to Psoralen. This finding suggests that NBUVB not only offers superior efficacy but also maintains a better safety profile, making it a preferable option for patients.

However, the evidence supports the use of NBUVB therapy as a more effective and safer alternative to Psoralen for the treatment of vitiligo. The enhanced repigmentation results, improved patient quality of life, and reduced side effects highlight the advantages of NB-UVB therapy in clinical practice.

ABBREVIATIONS

NB-UVB: narrow-band ultraviolet B, DLQI: Dermatological life quality index, NSV: Non-segmental vitiligo, SV: segmental vitiligo, D3A: Vitamin D3 Analogues , PUVA: photochemotherapy, PUVASOL: Psoralen And UVA by Nuclear Solar, VETF: Vitiligo European Task Force, CBC: Complete Blood Count, LFT: Liver Function Test, KFT: Kidney Function Test, SD: Standard deviation

ACKNOWLEDGEMENTS

We would like to dedicate this work to respected Dean of Sarojini Naidu Medical College, Agra, Dr. Prashant Gupta; Associate Professor and In charge Head of Pharmacology Department, Sarojini Naidu Medical College, Dr. Anurag Jain; Associate Professor of Pharmacology Department, Sarojini Naidu Medical College, Dr. Vipin Kumar; Professor and HOD of Pharmacology and Therapeutics Department, F.H Medical College, Tundla, Dr. Anupam Sharma; Professor and HOD of Skin and VD Department, Sarojini Naidu Medical College, Dr. Yatendra Singh Chaha; Patients of Skin and VD Department, Sarojini Naidu Medical College, Agra.

FUNDING

None.

CONFLICTS OF INTEREST

None Declared

AUTHOR CONTRIBUTIONS

Conceptualization: Dr. Rahul Kumar Pal, Dr. Vipin Kumar, Dr. Anurag Jain, Dr. Yatendra Singh Chahar; Data curation: Dr. Rahul Kumar Pal, Dr. Vipin Kumar, Dr. Anurag Jain; Methodology: Dr. Rahul Kumar Pal, Dr. Vipin Kumar; Project administration: Dr. Rahul Kumar Pal, Dr. Vipin Kumar, Dr. Anurag Jain, Dr. Yatendra Singh Chahar; Visualization: Dr. Rahul Kumar Pal, Dr. Vipin Kumar; Writing – original draft: Dr. Krunal Natvarlal Chauhan, Dr. Rahul Kumar Pal, Dr. Vipin Kumar; Writing – review and editing: Dr. Krunal Natvarlal Chauhan, Dr. Rahul Kumar Pal, Dr. Vipin Kumar.

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