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Comparative Study of Oral Levamisole versus Oral Betamethasone in Vitiligo: A Prospective Analysis.

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Abstract:

Background: Vitiligo is a chronic depigmenting disorder characterized by the destruction of melanocytes, resulting in progressive hypopigmented macules. Although oral corticosteroids and immunomodulators are widely used for disease control, their comparative efficacy and safety profiles require further evaluation.

Aim: This study aimed to compare the efficacy, safety, and cost-effectiveness of oral Levamisole and Betamethasone in the management of localized vitiligo.

Methodology: A prospective, randomized, open-label study was conducted on 80 patients with localized vitiligo at a tertiary care center in India. Patients were randomly assigned to receive either Levamisole 150 mg or Betamethasone 5 mg, both administered orally on two consecutive days per week for six months. Clinical response was assessed monthly using VASI (Vitiligo Area Scoring Index), VIDA (Vitiligo Disease Activity), and standardized digital photography. Statistical analysis was performed using Student's t-test and Chi-square test; $p < 0.05$ was considered statistically significant.

Results: Both groups demonstrated statistically significant improvement in VASI scores: Levamisole group (0.87 ± 0.79 to 0.67 ± 0.65, $p < 0.004$) and Betamethasone group (1.07 ± 0.61 to 0.86 ± 0.54, $p < 0.002$). The response rate was slightly higher with Betamethasone (64.86%) versus Levamisole (59.45%). Lesion progression was arrested in 59.5% (Levamisole) and 61.5% (Betamethasone) of patients. Adverse effects were more common with Betamethasone (28.2%) compared to Levamisole (18.9%). Treatment cost was significantly lower with Betamethasone.

Conclusion: Both Levamisole and Betamethasone were effective in controlling vitiligo progression and inducing repigmentation. While Betamethasone was more cost-effective, Levamisole exhibited a better safety profile. Individualized therapy selection is recommended based on cost, tolerability, and patient-specific factors.

Keywords:

Vitiligo, Levamisole, Betamethasone, Repigmentation, Immunomodulator therapy.

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Introduction

Vitiligo is a prevalent depigmentation disorder marked by progressive hypopigmented patches from melanocyte destruction. Globally, incidence ranges between 0.5% and 4%; Indian prevalence has been reported up to 8.8% in select studies. The condition affects both sexes equally and significantly impacts psychosocial well-being, especially in individuals with darker skin tones due to the visibility of lesions.(1-4)

The complex pathogenesis involves genetic susceptibility, autoimmune mechanisms, and environmental triggers. Conventional treatments include topical corticosteroids, calcineurin inhibitors, phototherapy, systemic steroids, and surgical techniques like melanocyte transplantation.(5-7) Oral corticosteroids in mini-pulse regimens—typically 5 mg betamethasone given for two consecutive days weekly—have proven effective in halting disease progression, with arrest rates up to 89% observed within 1–3 months; repigmentation occurred in 80% of cases, though side effects such as weight gain and headache were reported in a minority. A pilot randomized trial also compared betamethasone mini-pulse therapy with azathioprine, showing faster progression control with steroids.(8-10)

Levamisole, an immunomodulator traditionally used as an anti-helminthic, has demonstrated efficacy in halting vitiligo progression. A randomized controlled trial conducted between 2010 and 2011 found that weekly levamisole therapy led to lesion size reduction and clinical improvement in over 83% of participants.(11)

Given the benefits and limitations of systemic corticosteroids versus levamisole, a direct comparative evaluation is warranted. This prospective, randomized, open-label study aims to rigorously compare oral levamisole with oral betamethasone in terms of efficacy, safety, and impact on disease progression in vitiligo patients.

Materials and Methods

Study Design and Setting

This was a prospective, randomized, open-label, comparative clinical study conducted in the outpatient dermatology department at Sri Venkateswara Ramnarain Ruia Government General Hospital (SVRRGGH), Tirupati, India. The study was carried out over a 12-month period following approval by the Institutional Ethics Committee.

Participants

A total of 80 patients diagnosed with localized vitiligo were enrolled and randomized into two treatment groups:

- **Group A (n = 40):** Received oral Levamisole hydrochloride 150 mg, administered on two consecutive days per week.
- **Group B (n = 40):** Received oral Betamethasone 5 mg, also administered on two consecutive days per week.

All patients provided written informed consent prior to participation.

Inclusion Criteria

Participants were eligible for the study if they met the following criteria:

- Age between 18 and 50 years.
- Presence of localized vitiligo with depigmented patches limited to a few areas such as hands, feet, arms, face, or lips.
- Willingness to participate and comply with study procedures.

Exclusion Criteria

The following exclusion criteria were applied:

- Pregnant or lactating women.
- Use of oral contraceptives.
- History of diabetes mellitus or hypertension.
- History of purpura.
- Presence of co-existing skin conditions (e.g., chickenpox, shingles, herpes simplex, impetigo, candidiasis, tinea, acne, or extensive plaque psoriasis).
- Known hypersensitivity to Levamisole or Betamethasone.
- Recent (within 2 months) use of systemic biologics, systemic or topical immunosuppressive agents, or topical corticosteroids.

Baseline Assessment and Randomization

Baseline demographic data (age, sex, body weight, blood pressure, comorbid conditions, personal habits, and medication history) were recorded. Laboratory evaluations included renal function tests, liver function tests, random blood

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Journal of Dermatological Case Reports

glucose, and complete blood counts. Randomization into the two groups was performed using a computer-generated random allocation sequence.

Intervention Protocol

Group A received Levamisole hydrochloride (150 mg) and Group B received Betamethasone (5 mg) orally, both administered on two consecutive days each week for six months. Study medications were provided at no cost: Levamisole was supplied by the investigator, while Betamethasone was sourced from the hospital pharmacy.

Follow-up and Outcome Measures

Patients were evaluated monthly for six months. At each follow-up, clinical assessment and standardized photographic documentation of vitiligo lesions were conducted. The primary outcome was the extent of repigmentation assessed at the end of six months. Secondary outcomes included stabilization of disease (defined as the absence of new lesions and no progression of existing patches) and adverse event reporting.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee of SVRRGGH. All participants were informed about the study's purpose, procedures, and potential risks. Written informed consent was obtained. Investigations and treatment were conducted free of charge, ensuring no financial burden on participants.

Data Analysis

Variables and Assessment Tools

Following administration of the assigned treatments, patients in both groups were evaluated based on the following clinical parameters:

- **Demographic characteristics:** Age and sex.
- **Disease parameters:** Number of vitiligo lesions and the diameter of individual lesions.
- **Scoring systems used for evaluation of vitiligo severity and activity included:**

1. **Vitiligo European Task Force (VETF) Classification**

Patients were categorized into clinical stages based on the extent of depigmentation and hair involvement:

- **Stage 0:** Normal pigmentation.
- **Stage 1:** Incomplete depigmentation.
- **Stage 2:** Complete depigmentation with <30% hair whitening.
- **Stage 3:** Complete depigmentation with >30% hair whitening.

2. **Vitiligo Area Scoring Index (VASI)**

The VASI score estimates the extent of depigmentation using predefined percentage categories:

- **100%:** Complete depigmentation (no pigment present).
- **90%:** Specks of repigmentation.
- **75%:** Depigmented area > pigmented area.
- **50%:** Equal pigmented and depigmented areas.
- **25%:** Pigmented area > depigmented area.
- **10%:** Only minimal depigmentation (specks) present.

The total body VASI score was calculated by summing the contributions of each body region based on lesion area and percentage depigmentation.

$$\text{VASI total} = \sum_{\text{all body sites}} (\text{Hand Units} \times \text{Depigmentation Percentage})$$

3. Vitiligo Disease Activity Score (VIDA)

The VIDA score, based on patient-reported disease activity, was used to assess temporal progression:

- **+4:** Activity within ≤6 weeks.
- **+3:** Activity within 6 weeks to 3 months.
- **+2:** Activity within 3 to 6 months.
- **+1:** Activity within 6 to 12 months.
- **0:** Stable for ≥1 year.
- **–1:** Stable for ≥1 year with spontaneous repigmentation.

4. Digital Photography

Standardized digital photographs were obtained at baseline and after six months of treatment using identical positioning and lighting to

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Journal of Dermatological Case Reports

objectively document pigmentary changes over time.

Statistical Analysis

All data were systematically recorded in a standardized case report form and subsequently analyzed using both descriptive and inferential statistical methods. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were summarized as frequencies and percentages.

Given the potential non-normal distribution of VASI scores, within-group comparisons were performed using the Wilcoxon signed-rank test, a non-parametric alternative to the paired t-test. Between-group comparisons for categorical variables were analyzed using the Chi-square test.Descriptive statistics were utilized to characterize the baseline demographic and clinical parameters. A p-value < 0.05 was considered to indicate statistical significance for all analyses.

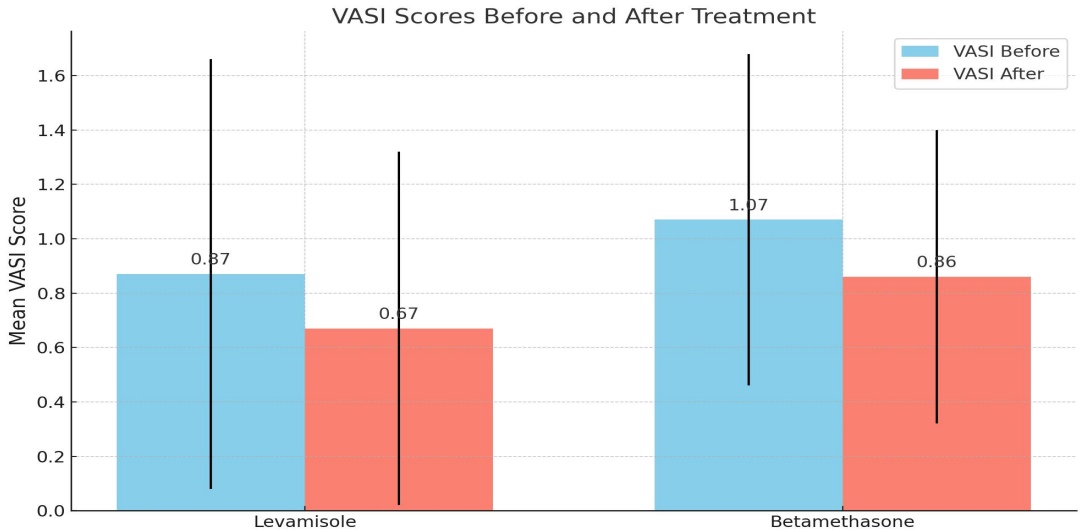
OBSERVATIONS AND RESULTS:

Table 1: Comparison of VASI Scores Before and After Treatment with Levamisole and Betamethasone Groups.

Treatment Group	VASI Before Treatment	VASI After Treatment	Difference in VASI Score	p-value
Levamisole (n = 37)	**0.87 ± 0.79**	**0.67 ± 0.65**	**0.20**	**< 0.004**
Betamethasone (n = 39)	**1.07 ± 0.61**	**0.86 ± 0.54**	**0.21**	**< 0.002**

Data was expressed as mean ± standard deviation (SD)
Test: Student's t test and post hoc Tukey's test
P<0.05 significant, P<0.01 highly significant.

Graph1: Comparison of VASI Scores Before and After Treatment with Levamisole and Betamethasone Groups.



Data was expressed as mean ± standard deviation (SD)
Test: Student's t test and post hoc Tukey's test
P<0.05 significant, P<0.01 highly significant,

Both the Levamisole and Betamethasone groups showed a statistically significant reduction in VASI scores after 6 months of treatment. In the Levamisole group (n = 37), the mean VASI

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Journal of Dermatological Case Reports

score decreased from 0.87 ± 0.79 before treatment to 0.67 ± 0.65 after treatment, with a mean difference of 0.20 and a p-value < 0.004, indicating a highly significant improvement. Similarly, in the Betamethasone group (n = 39), the VASI score reduced from 1.07 ± 0.61 to 0.86 ± 0.54, with a mean difference of 0.21 and a p-value < 0.002, which is also highly significant.

The statistical analysis was conducted using the Student's t-test and post hoc Tukey's test, confirming that the changes observed were not due to chance. Although both treatments led to comparable improvements in VASI scores, Betamethasone showed a slightly higher absolute reduction. However, the difference between the two groups was minimal, suggesting that both Levamisole and Betamethasone are equally effective in reducing vitiligo severity, with high statistical significance ($p < 0.01$). (Table 1 & graph 1)

Table 2: Distribution of Patients by Percentage of Repigmentation in Levamisole and Betamethasone Groups.

Repigmentation percentage	Levamisole group n (%)	Betamethasone group n (%)
15-25	2(5.40)	8(20.51)
26-50	12(32.43)	12(30.76)
51-75	4(10.81)	2(5.12)
76-100	2(5.40)*	0(0)
0 (Norepigmentation)	17(45.94)	17(43.58)
Total	37(100)	39(100)

Data was expressed as numbers(n) and percentage(%)

Graph 2: Distribution of Patients by Percentage of Repigmentation in Levamisole and Betamethasone Groups.

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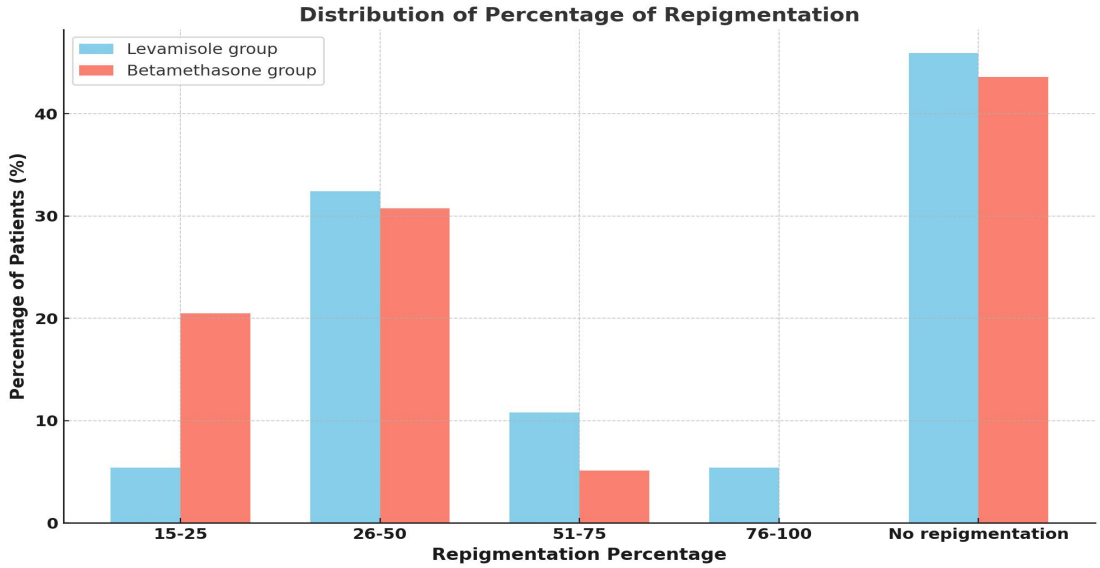
Journal of Dermatological Case Reports



Dara was expressed as numbers(n) and percentage(%)

The percentage of repigmentation was categorized to assess treatment outcomes in both groups. In the Levamisole group (n = 37), the highest proportion of patients (32.43%) experienced repigmentation in the 26–50% range. A smaller number of patients showed 51–75% repigmentation (10.81%), and 5.40% achieved 76–100% repigmentation. However, 45.94% of the patients did not show any repigmentation. The presence of patients achieving up to 100% repigmentation in the Levamisole group is clinically notable.(Table 2 & Graph 2)

In the Betamethasone group (n = 39), most patients had repigmentation between 15–50%, with 20.51% in the 15–25% range and 30.76% in the 26–50% range. Only 5.12% of patients showed 51–75% repigmentation, and none achieved 76–100%. Similarly, 43.58% of the patients in this group did not respond. While both groups had a comparable number of non-responders, the Levamisole group demonstrated a slightly higher proportion of patients with greater repigmentation. Although the difference was not subjected to statistical testing in this table, the trend suggests a potentially broader response range in the Levamisole group, which may be clinically significant.

Table 3: Comparison of Lesion Progression Between Levamisole and Betamethasone Groups

S.N.	Treatment Group	No progression of lesions (absence of new lesions) n(%)	Progression of lesions n(%)
1.	Levamisole (n=37)	22(59.54)	15(40.54)
2.	Betamethasone (n=39)	24(61.53)	15(38.46)

Dara was expressed as numbers(n) and percentage(%)

Graph 3: Comparison of Lesion Progression Between Levamisole and Betamethasone Groups

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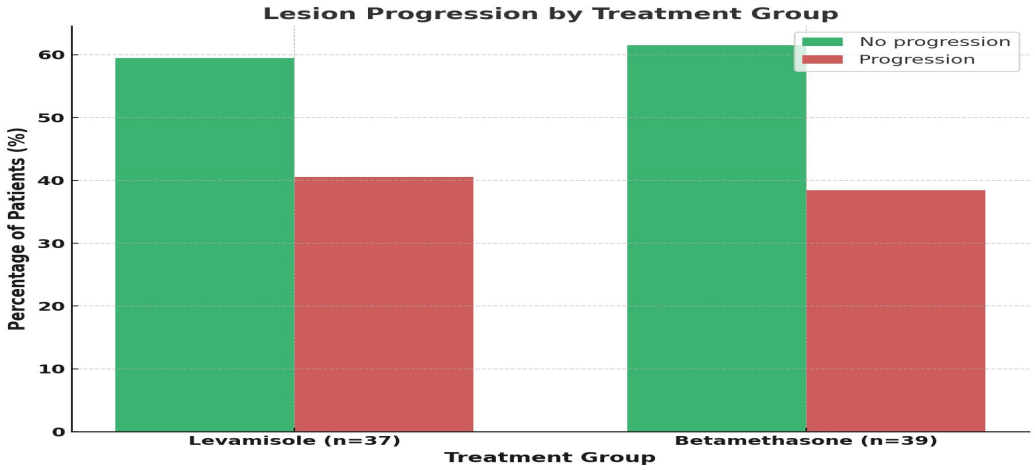


Dara was expressed as numbers(n) and percentage(%)

The progression of vitiligo lesions was assessed in both treatment groups over the study period. In the Levamisole group (n = 37), 22 patients (59.54%) showed no progression of lesions, indicating stabilization of the disease, while 15 patients (40.54%) experienced progression in the form of new lesions.(Table 3 & Graph 3)

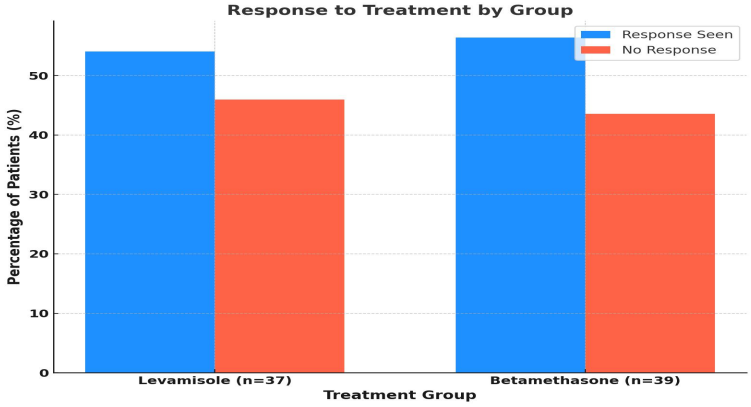
In the Betamethasone group (n = 39), 24 patients (61.53%) showed no progression and 15 patients (38.46%) demonstrated progression. The proportions of patients with stable disease versus progression were nearly the same in both groups. Although the Betamethasone group had a slightly higher percentage of patients without lesion progression, the difference was minimal and likely not statistically significant. This suggests that both treatments were comparably effective in preventing the spread of new lesions during the treatment period.

Table 4: Treatment Response in Levamisole and Betamethasone Groups

Treatment group	Response seen	No response	Total
Levamisole group	**20**	**17**	**37**
Betamethasone group	**22**	**17**	**39**
Total	**42**	**34**	**76**

Dara was expressed as numbers(n) and percentage(%)

Graph 4: Comparison of Response Between Levamisole and Betamethasone group.



Dara was expressed as numbers(n) and percentage(%)

A total of 76 patients were assessed for clinical response to treatment. In the Levamisole group (n = 37), 20 patients (54.05%) showed a positive treatment response, while 17 patients (45.95%) showed no response. In the Betamethasone group (n = 39), 22 patients (56.41%) responded

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Journal of Dermatological Case Reports

to treatment, whereas 17 patients (43.59%) did not.

The overall response rate across both groups was 42 out of 76 patients (55.26%). Both treatment groups showed a similar proportion of responders and non-responders, with a slightly higher response observed in the Betamethasone group. However, the difference in response rates between the two groups was small and may not be statistically significant, suggesting that both Levamisole and Betamethasone were comparably effective in inducing a clinicalesponse over the study period.(Table 4 & Graph 4)

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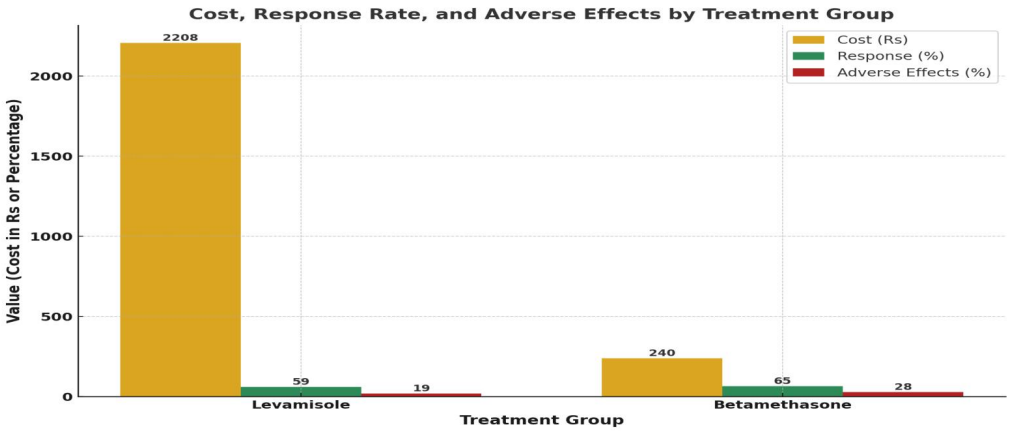
Journal of Dermatological Case Reports

Table 5: Comparison of Cost, Treatment Response, and Adverse Effects in Levamisole and Betamethasone Groups.

S.No.	Treatment group	Cost for 6 months (Rs)	Response (%)	Adverse Effects n(%)
1.	Levamisole	2208*	59.45	7(18.91)
2.	Betamethasone	240**	64.86	11(28.2)

Dara was expressed as numbers(n) and percentage(%).

Graph 5: Comparison of Cost, Treatment Response, and Adverse Effects in Levamisole and Betamethasone Groups.



Dara was expressed as numbers(n) and percentage(%).

The cost of treatment, response rate, and adverse effects were compared between the Levamisole and Betamethasone groups over a 6-month period. The total cost for Levamisole therapy was substantially higher at Rs. 2208, compared to Rs. 240 for Betamethasone. Despite the higher cost, the response rate in the Levamisole group was 59.45%, while the Betamethasone group had a slightly higher response rate of 64.86%.

In terms of safety, 7 patients (18.91%) in the Levamisole group reported adverse effects, compared to 11 patients (28.2%) in the Betamethasone group. While Betamethasone was more economical and showed a marginally better response rate, it was associated with a higher incidence of adverse effects. This suggests that Levamisole may offer a better safety profile, whereas Betamethasone may be more cost-effective but with a slightly greater risk of side effect

Table 6: Month-wise Onset of Repigmentation in Levamisole and Betamethasone Groups.

S.No	Treatment Group	1st Month n (%)	2nd Month n (%)	3rd Month n (%)	4thMonth n (%)	5thMonth n (%)	6thMonth n (%)
1.	Levamisole	1(2.7)	4(10.8)	7(18.9)	7(18.9)	1(2.7)	0(0)
2.	Betamethasone	0(0)	3(7.69)	8(20.5)	8(20.5)	3(7.69)	0(0)

Maximum number of patients had onset of repigmentation during the 3rd and 4th month.
Data was expressed as number of patients (n) and percentage (%)

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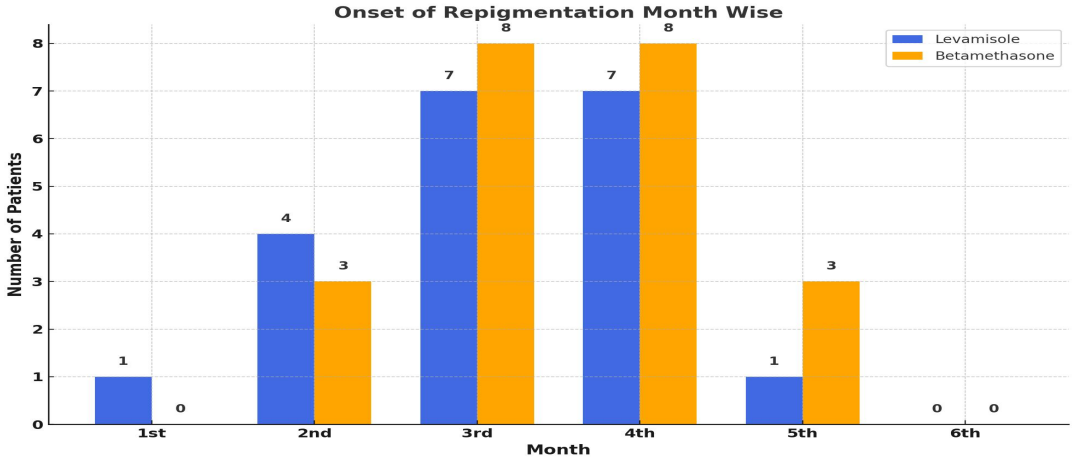
Journal of Dermatological Case Reports

Graph 6:Month-wise Onset of Repigmentation in Levamisole vs Betamethasone Groups



Data was expressed as number of patients (n) and percentage (%)

The onset of repigmentation was recorded monthly for both treatment groups over a six-month period. In the Levamisole group, the earliest signs of repigmentation were observed in the first month in 1 patient (2.7%). The highest number of patients began showing repigmentation in the third and fourth months, with 7 patients (18.9%) each. A smaller number showed onset in the second (10.8%) and fifth (2.7%) months, while no repigmentation was observed initiating in the sixth month.

In the Betamethasone group, no patients showed repigmentation in the first month. The peak onset was observed in the third and fourth months, with 8 patients (20.5%) each beginning to repigment. Fewer patients showed onset in the second and fifth months (7.69% each), and none showed new repigmentation in the sixth month. These findings suggest that for both treatments, the majority of repigmentation onset occurred between the second and fourth months, with Betamethasone having a slightly earlier peak response but a similar overall timeline compared to Levamisole.(Table 6 & Graph 6

Discussion:

Over the past decade, vitiligo management has increasingly focused on combining immunomodulatory agents with topical therapies. The present study finding that levamisole led to 5.4% of patients attaining 76–100% repigmentation aligns with older but relevant evidence that levamisole can stabilize the disease and promote pigment restoration. In a 2021 randomized trial, levamisole halted lesion progression in 94% of patients and yielded spontaneous repigmentation in 64% when used alone for limited, slowly progressive vitiligo.(12)These outcomes support present observation of disease stabilization and partial repigmentation.

Betamethasone, a potent topical corticosteroid, demonstrated peak repigmentation (20.51% at 15–25%, and 30.76% at 26–50%). This is consistent with guideline recommendations endorsing mid- to potent topical steroids as first-line therapy for limited vitiligo.(13) Studies reviewed by Britisher Journal of Dermatology found betamethasone induced 15–25% repigmentation in ~44% of subjects, and occasional >75% repigmentation. However, side effects such as skin atrophy remain a concern.(13)

Several recent clinical trials have explored topical combinations involving calcipotriol and betamethasone. For instance, once-daily calcipotriene 0.005% with 0.064% betamethasone dipropionate elicited 76–100% facial repigmentation in two out of three children within two months. (14) Another open-label trial reported excellent to moderate response in nearly 30% of patients treated over 12 weeks.(15) These findings imply that combining vitamin D analogues with corticosteroids may improve efficacy and reduce adverse events, a strategy worth exploring alongside levamisole in future trials.Present lesion progression data showed no new lesions in roughly 60% of patients in both treatment groups. This stabilization echoes evidence that levamisole can arrest disease activity within 2–4 months in

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Journal of Dermatological Case Reports

controlled trials.(16) Corticosteroids also arrest progression but are not necessarily superior, especially when side effects such as skin atrophy and telangiectasia limit long-term use .

Regarding speed of repigmentation, both groups peaked at the third and fourth months (Levamisole: 18.9% each month; Betamethasone: 20.5%), mirroring recent patient reports that repigmentation onset typically occurs between 3–6 months, particularly in sun-exposed areas.(17) The similar timelines suggest comparable onset dynamics, although combinations with UVB or immunomodulators could accelerate response .

In this study, Levamisole showed fewer adverse effects (18.9%) compared to Betamethasone (28.2%), though it incurred a significantly higher cost over six months (₹2208 vs ₹240). These findings reflect the general trend noted in recent literature, where topical corticosteroids remain the first-line treatment due to cost-effectiveness but are associated with skin atrophy, telangiectasia, and other local side effects when used long-term. A 2020 randomized controlled trial (HI-Light Vitiligo Trial) concluded that while topical corticosteroids are economical, their safety limitations require careful monitoring, especially in long-term use or on sensitive skin areas.(18) On the other hand, Levamisole has been described in recent Indian clinical experience as a relatively well-tolerated immunomodulator that can help stabilize vitiligo with a lower incidence of adverse events.(19)

Although Betamethasone remains a practical and affordable treatment, the increased frequency of side effects could raise overall treatment costs due to complications or therapy adjustments. Levamisole, though more expensive initially, may reduce this burden by offering a better safety profile, particularly in patients requiring long-term management. Moreover, combination therapy using topical steroids and non-steroidal agents is gaining traction. A 2018 study reported that combining topical calcipotriol with Betamethasone significantly improved efficacy and reduced steroid-related side effects in vitiligo patients compared to steroid monotherapy.(20) These findings support the tailored use of therapy based not just on initial cost but on overall tolerability and disease stabilization.

Conclusion:

The present study demonstrates that both Levamisole and Betamethasone are effective in managing vitiligo, with comparable outcomes in terms of repigmentation and disease stabilization. While Betamethasone showed a slightly higher response rate (64.86%) compared to Levamisole (59.45%), the onset of repigmentation in both groups peaked during the third and fourth months of treatment. Notably, the difference in VASI score before and after treatment was statistically significant for both groups, indicating measurable clinical improvement. Additionally, the number of patients with no progression of new lesions was nearly the same in both groups, suggesting comparable effectiveness in halting disease activity. However, differences were observed in cost and safety profiles. Betamethasone, though significantly more economical, was associated with a higher rate of adverse effects (28.2%) compared to Levamisole (18.9%). Levamisole, while costlier, was better tolerated and may be preferable in patients requiring long-term therapy or with sensitivity to steroids. Overall, the findings suggest that both treatments are viable options, and the choice should be individualized based on patient characteristics, affordability, and risk of side effects. Combination or sequential therapy may offer enhanced outcomes and warrants further study.

Conflict of interest: none

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Journal of Dermatological Case Reports

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