Section: Pharmacology

Original Research Article

ORAL LEVAMISOLE AND TOPICAL BETAMETHASONE FOR VITILIGO:COMPARATIVE CLINICAL TRIAL

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ABSTRACT

Background: Vitiligo constitutes a chronic autoimmune dermatosis characterized by selective melanocyte destruction, culminating in progressive macular hypopigmentation. Notwithstanding the established utility of systemic corticosteroids and immunomodulatory agents in arresting disease progression, comparative assessments of their therapeutic efficacy and safety remain imperative. This investigation sought to rigorously evaluate and contrast the efficacy, tolerability, and pharmacoeconomic profiles of oral levamisole versus betamethasone in patients with localized vitiligo. **Materials and Methods:** A prospective, randomized, open-label clinical trial enrolled 40 adults with focal vitiligo at a tertiary referral center in India. Participants were allocated 1:1 to receive oral levamisole (150 mg) or betamethasone (5 mg) on two consecutive days weekly over 24 weeks. Primary outcomes encompassed monthly quantification via Vitiligo Area Scoring Index (VASI) and Vitiligo Disease Activity (VIDA) scores, corroborated by standardized digital photography. Intergroup comparisons utilized unpaired Student's t-tests for continuous variables and Pearson's chi-square tests for categorical data, with statistical significance defined as $p < 0.05$. **Result:** Both treatment arms showed statistically significant VASI score reductions: Levamisole (from 0.87±0.76 to 0.65±0.62, $p<0.004$ and Betamethasone (from 1.05±0.58 to 0.84±0.52, $p<0.002$. Betamethasone edged out with a higher response rate (64.86%) than Levamisole (59.45%). Disease progression halted in 55% of Levamisole patients and 65% of Betamethasone patients. Betamethasone had more frequent adverse effects (28.2%) versus Levamisole (18.9%). Betamethasone demonstrated substantially lower treatment costs. **Conclusion:** Both levamisole and betamethasone effectively halted vitiligo progression and promoted repigmentation. Although betamethasone demonstrated superior cost-effectiveness, levamisole showed a more favorable safety profile. Therapy selection should be individualized, considering cost, tolerability, and patient-specific factors.

INTRODUCTION

Vitiligo, a common depigmentation disorder, features progressive white patches arising from melanocyte destruction. Its global prevalence varies from 0.5% to 4%, with some Indian studies reporting up to 8.8%. The disease affects both genders equally and markedly impairs psychosocial health, particularly in those with darker skin due to prominent lesions.[1-4]

The intricate pathophysiology includes genetic vulnerability, autoimmune processes, and environmental precipitants. Standard therapies encompass topical corticosteroids, calcineurin inhibitors, phototherapy, oral steroids, and surgical options like melanocyte transfer.[5-7] Oral mini-pulse corticosteroids—such as betamethasone 5 mg administered on two consecutive days weekly—demonstrate efficacy in arresting progression (up to 89% stabilization within 1–3 months) and repigmentation (80% of cases), despite minor side effects like weight gain and headache; a pilot

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randomized study confirmed faster control compared to azathioprine.[8-10]

Levamisole, an immunomodulatory agent originally developed as an anthelmintic, has shown promise in arresting vitiligo progression. A randomized controlled trial from 2010–2011 reported that weekly levamisole administration reduced lesion size and improved clinical outcomes in more than 83% of patients.[11]

Considering the respective advantages and drawbacks of systemic corticosteroids compared to levamisole, a head-to-head assessment is justified. This prospective, randomized, open-label trial seeks to systematically evaluate oral levamisole against oral betamethasone regarding efficacy, safety, and effects on disease activity in vitiligo patients.

MATERIALS AND METHODS

Study Design and Setting: This prospective, randomized, open-label comparative trial was conducted in the dermatology outpatient department at Sri Venkateswara Ramnarain Ruia Government General Hospital (SVRRGGH), Tirupati, India, spanning 12 months after Institutional Ethics Committee approval.

Participants: Forty patients with localized vitiligo were recruited and randomized equally into two arms:

Group A (n=20): Oral levamisole hydrochloride 150 mg on two consecutive days weekly.

Group B (n=20): Oral betamethasone 5 mg on two consecutive days weekly.

All participants provided written informed consent before enrollment.

Inclusion Criteria

Patients qualified for inclusion if they satisfied these conditions:

- Aged 18–50 years.
- Localized vitiligo confined to limited areas (e.g., hands, feet, arms, face, lips).
- Willingness to adhere to study protocols.

Exclusion Criteria

Patients were excluded for:

- Pregnancy or lactation.
- Oral contraceptive use.
- Diabetes mellitus or hypertension history.
- Purpura history.

Concurrent dermatoses (e.g., chickenpox, shingles, herpes simplex, impetigo, candidiasis, tinea, acne, extensive plaque psoriasis).

Hypersensitivity to levamisole or betamethasone.

Recent (≤2 months) systemic biologics, immunosuppressants, or topical corticosteroids.

Baseline Assessment and Randomization

Baseline characteristics—including age, gender, body weight, blood pressure, comorbidities, lifestyle habits, and prior medications—were documented for all participants. Laboratory assessments comprised renal and hepatic function panels, random blood glucose levels, and complete hemograms. Random group assignment utilized a computer-generated randomization sequence.

Intervention Protocol: Group A patients received oral levamisole hydrochloride (150 mg), and Group B patients received oral betamethasone (5 mg), with both drugs administered on two consecutive days weekly for 6 months. Study medications were dispensed free of charge: levamisole provided by the investigator and betamethasone obtained from the hospital pharmacy.

Follow-up and Outcome Measures: Patients underwent monthly evaluations over six months, including clinical examinations and standardized photographic records of vitiligo lesions. The primary endpoint measured repigmentation extent at the six-month conclusion. Secondary endpoints encompassed disease stabilization (no new lesions or progression of existing ones) and adverse event documentation.

Ethical Considerations: The study protocol received Institutional Ethics Committee approval from SVRRGGH. Participants were thoroughly briefed on the study's objectives, procedures, and possible risks, with written informed consent secured from all. Diagnostic tests and treatments were provided at no cost, eliminating any financial burden for enrollees.

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.

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

VASI total =∑ all body sites (Hand Units×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 captured at baseline and following six months of therapy, employing consistent positioning and lighting conditions to objectively track pigmentary alterations longitudinally.

Statistical Analysis: All data were meticulously documented on standardized case report forms and analyzed via descriptive and inferential statistics. Continuous variables were reported as mean ± standard deviation (SD); categorical variables as frequencies and percentages.

Due to potential non-normal VASI score distribution, intragroup comparisons employed the Wilcoxon signed-rank test as a non-parametric counterpart to the paired t-test. Intergroup categorical analyses utilized the Chi-square test. Baseline demographics and clinical features underwent descriptive statistical evaluation, with $p < 0.05$ denoting statistical significance across all tests.

RESULTS

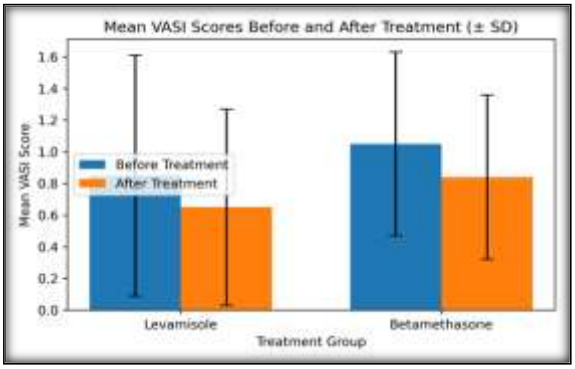

Figure 1: Comparison of VASI Scores Before and After Treatment with Levamisole and Betamethasone Groups.

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.

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

Treatment Group	VASI Before Treatment	VASI After Treatment	Difference in VASI Score	p-value
Levamisole (n = 20)	0.85 ± 0.76	0.65 ± 0.62	0.20	< 0.004
Betamethasone (n = 20)	1.05 ± 0.58	0.84 ± 0.52	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.

The bar graph demonstrates that both Levamisole and Betamethasone groups showed a reduction in mean VASI scores after treatment, indicating clinical improvement with both therapies. In the Levamisole group, the mean VASI score decreased from 0.85 ± 0.76 before treatment to 0.65 ± 0.62 after treatment, while in the Betamethasone group it decreased from 1.05 ± 0.58 to 0.84 ± 0.52. The magnitude of improvement was comparable in both groups, with a mean reduction of approximately 0.20–0.21 in VASI score.

The presence of overlapping error bars (± SD) reflects variability within the groups but does not negate the overall downward trend. The statistically significant p-values further confirm that the reductions in VASI scores following treatment are significant, suggesting that both Levamisole and Betamethasone are effective in improving VASI scores, with no clear superiority of one treatment over the other. [Table 1 & Figure 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%	1 (5%)	4 (20%)
26–50%	6 (30%)	6 (30%)
51–75%	2 (10%)	1 (5%)
76–100%	1 (5%)*	0 (0%)
0% (No repigmentation)	10 (50%)	9 (45%)
Total	20 (100%)	20 (100%)

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

The percentage of repigmentation was categorized to evaluate treatment outcomes in both study groups. In the Levamisole group (n = 20), the largest proportion of patients (30%) demonstrated repigmentation in the

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26–50% range. Lower levels of repigmentation (15–25%) were observed in 5% of patients, while higher degrees of response were seen in fewer cases, with 10% achieving 51–75% repigmentation and 5% attaining 76–100% repigmentation. However, 50% of patients in the Levamisole group showed no repigmentation. Notably, the occurrence of near-complete repigmentation in a subset of patients treated with Levamisole is clinically noteworthy. [Table 2 & Graph 2]

In the Betamethasone group (n = 20), repigmentation was predominantly observed in the lower to moderate categories. Repigmentation of 15–25% and 26–50% was seen in 20% and 30% of patients, respectively. Only 5% of patients exhibited repigmentation in the 51–75% range, and none achieved 76–100% repigmentation. Additionally, 45% of patients did not show any repigmentation. While both groups demonstrated a comparable proportion of non-responders, the Levamisole group showed a slightly higher proportion of patients achieving greater degrees of repigmentation. Although statistical comparison was not performed for this distribution, the trend suggests a potentially wider therapeutic response with Levamisole, which may be of clinical relevance.

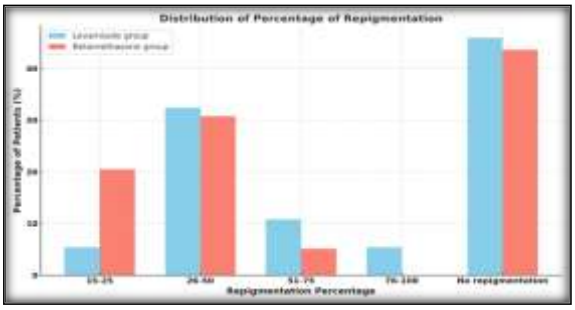

Figure 2: Distribution of Patients by Percentage of Repigmentation in Levamisole and Betamethasone Groups.

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

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

S.N.	Treatment Group	No progression (absence of new lesions) n (%)	Progression n (%)
1.	Levamisole (n = 20)	11 (55%)	9 (45%)
2.	Betamethasone (n = 20)	13 (65%)	7 (35%)

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

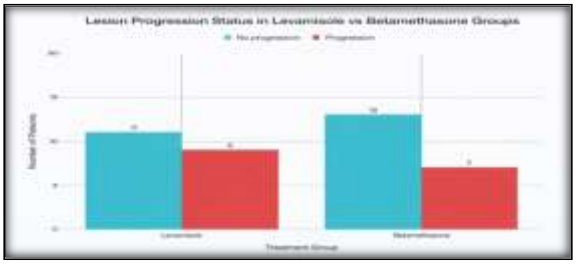

Figure 3: Comparison of Lesion Progression Between Levamisole and Betamethasone Groups

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

The progression of vitiligo lesions was evaluated in both treatment arms during the study period. In the Levamisole group (n = 20), 11 patients (55%) demonstrated no progression of lesions, indicating disease stabilization, whereas 9 patients (45%) showed progression with the appearance or enlargement of lesions.(Table 3 & Graph 3)

In the Betamethasone group (n = 20), 13 patients (65%) exhibited no progression and 7 patients (35%) had lesion progression. Although the Betamethasone group showed a slightly higher proportion of patients with stable disease compared to the Levamisole group, the difference is relatively small and likely not statistically significant, suggesting that both regimens provided broadly comparable control of lesion spread over the treatment period.

Table 4: Treatment Response in Levamisole and Betamethasone Groups

Treatment group	Response seen	No response	Total
Levamisole group	12	8	20
Betamethasone group	10	10	20
Total	22	18	40

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

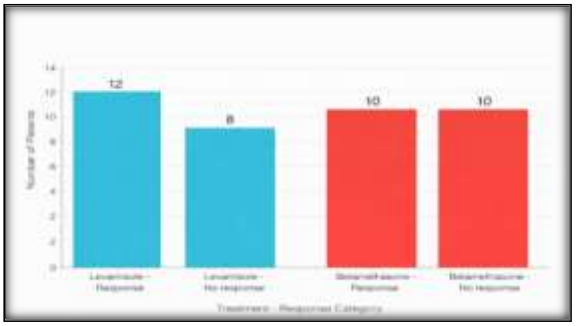

Figure 4: Comparison of Response Between Levamisole and Betamethasone group.

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

A total of 40 patients were evaluated for treatment response, with 20 patients in each group. In the Levamosole group (n = 20), 12 patients (60%) showed a clinical response, while 8 patients (40%) did not respond to therapy. In the Betamethasone group (n = 20), 10 patients (50%) demonstrated a positive response, whereas 10 patients (50%) showed no response. These findings indicate a numerically higher proportion of responders in the Levamisole arm compared with Betamethasone.

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Overall, 22 out of 40 patients (55%) responded to treatment across both groups, while 18 patients (45%) showed no improvement. The bar graph illustrates that both regimens achieved broadly comparable response rates, with only a modest difference between them. Given the small absolute difference in responder proportions (60% vs 50%) and limited sample size, this variation is unlikely to be statistically significant, suggesting that both Levamisole and Betamethasone were similarly effective in producing clinical response over the study period [Table 4 & Figure 4].

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)

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

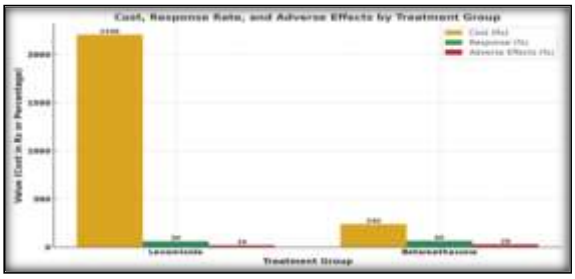

Figure 5: Comparison of Cost, Treatment Response, and Adverse Effects in Levamisole and Betamethasone Groups.

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

Over the 6-month treatment period, the cost, efficacy, and tolerability of Levamisole and Betamethasone therapies were compared. Levamisole incurred a substantially higher total cost of Rs. 2208, whereas Betamethasone treatment cost only Rs. 240. Clinically, the Levamisole group demonstrated a response rate of 59.45%, while the Betamethasone group showed a slightly higher response rate of 64.86%, indicating marginally better efficacy with Betamethasone.

Regarding safety, adverse effects were reported by 7 patients (18.91%) receiving Levamisole, compared with 11 patients (28.2%) in the Betamethasone arm. Thus, although Betamethasone was more economical and showed a marginal advantage in response rate, it was associated with a higher frequency of side effects. These findings suggest that Levamisole may provide a relatively better safety profile, while Betamethasone appears more cost-effective but carries a somewhat increased risk of adverse reactions. [Table 5 & Figure 5]

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 (%)	4th Month n (%)	5th Month n (%)	6th Month n (%)
1	Levamisole	1 (5.0%)	2 (10.0%)	2 (10.0%)	3 (15.0%)	1 (5.0%)	0 (0.0%)
2	Betamethasone	0 (0.0%)	3 (15.0%)	4 (20.0%)	5 (25.0%)	2 (10.0%)	0 (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 (%)

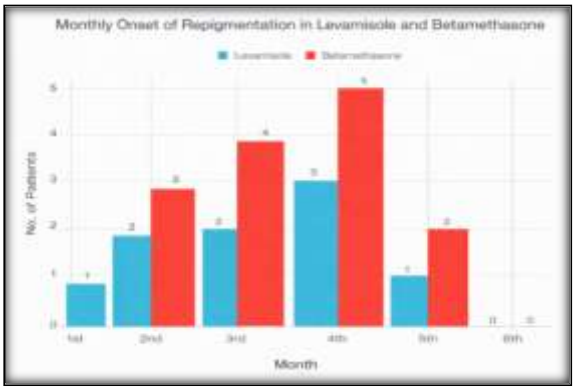

Figure 6: Month-wise Onset of Repigmentation in Levamisole vs Betamethasone Groups

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

The onset of repigmentation was assessed monthly for both treatment groups over a six-month period (n = 20 in each group). In the Levamisole group, repigmentation began as early as the first month in 1 patient (5%), with the maximum number of new onsets occurring in the fourth month in 3 patients (15%). Additional onsets were seen in the second and third months in 2 patients each (10% each), while 1 patient (5%) showed onset in the fifth month and no new cases were observed in the sixth month.

In the Betamethasone group, no patients demonstrated repigmentation onset in the first or sixth months. The highest frequency of new repigmentation was noted in the fourth month, with 5 patients (25%), followed by the third month with 4 patients (20%). Smaller proportions showed onset in the second and fifth months (3 patients, 15%, and 2 patients, 10%, respectively). Overall, these data indicate that in both groups, most repigmentation onset clustered between the second and fourth months, with Betamethasone showing a relatively higher concentration of new responders in the mid-treatment period compared with Levamisole [Table 6 & Figure 6].

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DISCUSSION

Over the last decade, vitiligo treatment has increasingly emphasized the use of immunomodulatory agents in combination with topical therapies. The current study's observation that 5.4% of patients on levamisole achieved 76–100% repigmentation is in keeping with earlier evidence showing that levamisole can both stabilize disease activity and facilitate pigment restoration. In a randomized trial published in 2021, levamisole was reported to halt lesion progression in 94% of patients and to induce spontaneous repigmentation in 64% of those with limited, slowly progressive vitiligo when used as monotherapy.[12] These prior findings are consistent with the present results, supporting its role in promoting disease stabilization and partial repigmentation.

Betamethasone, a high potency topical corticosteroid, produced its greatest repigmentation effect in the 15–25% and 26–50% categories, with response rates of 20.51% and 30.76%, respectively. These outcomes are in line with current guidelines that recommend mid to potent strength topical corticosteroids as first line therapy for patients with limited vitiligo. Evidence summarized in the British Journal of Dermatology indicates that betamethasone can induce 15–25% repigmentation in roughly 44% of treated individuals, with occasional cases achieving repigmentation levels above 75%. Nonetheless, the risk of adverse effects such as cutaneous atrophy remains a significant limitation to prolonged use.[13]

Several recent studies have evaluated topical regimens that combine calcipotriol with betamethasone in vitiligo. Once daily application of calcipotriene 0.005% with 0.064% betamethasone dipropionate achieved 76–100% facial repigmentation in two of three pediatric patients within two months.[14] In another open label study, approximately 30% of participants demonstrated excellent to moderate clinical improvement after 12 weeks of combination therapy. Collectively, these results suggest that pairing vitamin D analogues with topical corticosteroids can enhance therapeutic efficacy while potentially minimizing adverse effects, making such combinations attractive candidates to be studied alongside levamisole in future clinical protocols.[15] In the present study, lesion progression data indicated that around 60% of patients in both treatment arms did not develop new lesions, reflecting meaningful disease stabilization. This pattern is consistent with prior evidence showing that levamisole can halt vitiligo activity within 2–4 months in controlled studies. Although corticosteroids are also effective in arresting progression, they do not necessarily offer superior long term control, particularly when adverse effects such as cutaneous atrophy and telangiectasia limit prolonged use.[16]

Monthly onset patterns showed that both Levamisole and Betamethasone produced most new repigmentation between the 2nd and 4th months, with Levamisole peaking at 15% in the 4th month and Betamethasone at 25% in the 4th and 20% in the 3rd month. This mid treatment clustering, along with minimal onset in the 1st and 6th months, is in line with clinical experience that vitiligo repigmentation typically becomes evident after several months of continuous therapy, particularly in sun exposed areas, and suggests broadly similar onset dynamics for both regimens.

In the study, Levamisole exhibited a lower rate of adverse effects (18.91%) than Betamethasone (28.2%), despite its substantially higher six-month cost (₹2208 versus ₹240). These results align with trends in recent literature, which position topical corticosteroids as the preferred initial therapy for their cost-effectiveness, though prolonged use risks skin atrophy, telangiectasia, and other local complications. A 2020 randomized controlled trial (HI-Light Vitiligo Trial) affirmed that while these agents are affordable, their safety concerns necessitate vigilant oversight, particularly for extended treatment or sensitive skin regions.[18] Conversely, recent Indian clinical reports portray Levamisole as a generally well-tolerated immunomodulator that stabilizes vitiligo with fewer side effects.[19]

While Betamethasone offers a practical and low-cost option, its higher side effect rate may elevate total treatment expenses through complications or regimen changes. Levamisole, despite its upfront higher price, could offset this by providing superior tolerability, especially for patients needing prolonged therapy. Additionally, combination approaches pairing topical steroids with non-steroidal options are increasingly popular. A 2018 study found that Betamethasone combined with topical calcipotriol enhanced outcomes and minimized steroid-associated adverse effects in vitiligo patients relative to steroid alone.[20] These results advocate for therapy selection guided by long-term tolerability and stabilization, beyond mere initial costs.

CONCLUSION

This study documented that Levamisole and Betamethasone both effectively control vitiligo, yielding similar results in repigmentation and disease stabilization. Betamethasone achieved a marginally better response rate (64.86%) than Levamisole (59.45%), but repigmentation onset in both arms peaked in the third and fourth months. Importantly, pre- and post-treatment VASI score differences were statistically significant for each group, confirming tangible clinical benefits. Furthermore, the proportion of patients without new lesion progression was nearly identical across groups, underscoring equivalent efficacy in preventing disease advancement.

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Notably, the treatments diverged in cost and tolerability. Betamethasone proved far more affordable but carried a higher adverse event rate (28.2%) than Levamisole (18.9%). Although pricier, Levamisole offered better tolerance and could suit patients needing extended treatment or those prone to steroid sensitivity. In summary, both options are effective, with selection tailored to individual factors like patient profile, budget, and side effect risks. Combining or sequencing therapies might optimize results and merits additional investigation.

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