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A Comparative Cross-Sectional Study of Short-term Clinical Outcomes of Topical Clobetasol versus its Combination with Calcipotriol in Mild-to-Moderate Plaque Psoriasis

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Abstract

Background:

Plaque psoriasis is a chronic immune-mediated inflammatory disorder that significantly affects quality of life. Combination topical therapy may improve treatment outcomes compared to corticosteroid monotherapy. This study compared the short-term efficacy and safety of topical clobetasol alone versus clobetasol combined with calcipotriol.

Methods:

This observational cross-sectional study was conducted over six months at Narayan Medical College and Hospital, Bihar, India. Sixty adults with mild-to-moderate plaque psoriasis were equally divided into Group A (clobetasol 0.05%) and Group B (clobetasol 0.05% + calcipotriol 0.005%). Treatments were applied once daily for three weeks and on alternate days for the next three weeks. Efficacy was assessed using PASI, PGA, and DSS scores at baseline, week 3, and week 6. Statistical analysis included an unpaired t-test, Fisher's exact test, and Cohen's d effect size.

Results:

Both groups were comparable at baseline. Group B demonstrated significantly greater PASI reduction at week 3 ($p=0.0140$) and week 6 ($p=0.0067$). PGA scores were significantly lower in Group B at week 6 ($p=0.0002$). DSS reduction was greater in the combination group, but not statistically significant. Adverse effects were mild and comparable between groups.

Conclusion:

Combination therapy of clobetasol with calcipotriol demonstrated superior short-term efficacy compared to clobetasol alone without increased adverse effects.

Recommendation:

Combination therapy may be considered a preferred short-term treatment option in mild-to-moderate plaque psoriasis to achieve faster and greater clinical improvement.

Keywords: Calcipotriol, clobetasol propionate, Dermatology Sum Score, Physician Global Assessment, Plaque psoriasis, Psoriasis Area and Severity Index score
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INTRODUCTION

Plaque psoriasis is a chronic autoimmune condition that manifests primarily on the skin as raised, red patches covered with silvery-white scales [1,2]. It affects approximately 2–3% of the global population, with varying prevalence across regions, and often begins in early adulthood, demonstrating a chronic, relapsing course [3,4]. These plaques result from an accelerated skin cell turnover, where immune system dysfunction prompts skin cells to proliferate far more rapidly than

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normal [5]. The condition often follows a relapsing-remitting course and may be triggered or exacerbated by factors such as stress, infections, skin injuries, and certain medications [1]. While not contagious, it can significantly impact quality of life due to its physical discomfort and psychosocial visibility.

Management focuses on controlling symptoms and minimizing flare-ups through a combination of topical therapies, phototherapy, and systemic treatments, including biologics that target specific immune pathways [6-9]. The pathogenesis of psoriasis is multifactorial, involving genetic predispositions and environmental triggers that lead to the dysregulation of the immune system, particularly the over-activation of T-cells and the subsequent release of pro-inflammatory cytokines such as TNF-α and interleukins [1,2].

Clobetasol propionate is a highly potent topical corticosteroid used in the management of plaque psoriasis to alleviate inflammation, itching, and scaling. Typically prescribed for short-term use or in intermittent cycles, clobetasol is often reserved for more severe or resistant cases due to its strong anti-inflammatory effect. Overuse or prolonged application, especially on thin-skinned areas like the face or groin, can lead to adverse effects such as skin atrophy, striae, or systemic absorption [10,11].

However, prolonged use of Clobetasol is associated with adverse effects, including skin thinning, telangiectasia, and hypothalamic-pituitary-adrenal (HPA) axis suppression, especially when used over large areas or for extended periods [12]. This has led to the exploration of combination therapies to improve therapeutic outcomes while minimizing side effects. One such combination is Clobetasol with Vitamin D3 (Calcipotriol), which has emerged as a promising alternative due to the complementary mechanisms of action of both agents. Calcipotriol, a synthetic analogue of vitamin D3, modulates keratinocyte proliferation and differentiation while also exerting mild immunomodulatory effects [13,14].

The combination of calcipotriol with clobetasol propionate offers a synergistic approach to managing plaque psoriasis. Used together-often in fixed-dose formulations such as ointments or gels—this regimen enhances therapeutic efficacy while minimizing the adverse effects associated with long-term steroid use. Calcipotriol helps offset steroid-induced skin changes and improves patient adherence through its complementary mechanism [15,16].

The Psoriasis Area and Severity Index (PASI) score is widely used to validate outcome measures of psoriasis manifestation and improvement after treatment [9]. PASI score is applied to determine a single estimate of a patient's disease severity at a given time based on induration, erythema, and scaling of the skin [17].

Existing evidence suggests that the combination of topical clobetasol with calcipotriol offers improved clinical outcomes in plaque psoriasis compared to clobetasol monotherapy, particularly in reducing lesion severity, enhancing patient adherence, and minimizing steroid-associated adverse effects. Randomized controlled trials and meta-analyses have demonstrated superior efficacy and safety profiles for the combination, highlighting synergistic mechanisms of action. However, lacunae remain in understanding long-term remission rates, optimal treatment duration, and comparative outcomes across different ethnic and age groups. [18-21]

The objective of this study was to compare the short-term efficacy, safety, and patient tolerability of the two treatment regimens, thereby informing evidence-based clinical decisions and highlighting the potential advantages of integrated topical therapies in plaque psoriasis management.

METHODS

Study design

This was an **observational cross-sectional study** conducted over six months (March 2025–August 2025) at Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar, a tertiary care teaching hospital offering dermatology outpatient and inpatient services.

Study Protocol

The study involved patients diagnosed with mild-to-moderate plaque psoriasis from the Dermatology OPD. The study protocol was approved by the "Institutional Human Ethics Committee", adhering to international ethical guidelines. Informed consent was obtained from all participants after explaining the study details via "a locally translated Participant Information Sheet."

Study Design

Group A: Topical clobetasol propionate (0.05%) monotherapy, applied once daily for 3 weeks and alternate days for the next 3 weeks at night.

Group B: Combination therapy (clobetasol 0.05% + calcipotriol 0.005%), applied once daily for 3 weeks and alternate days for the next 3 weeks at night.

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Study Population

Inclusion Criteria:

(1) Adults aged 18–60 years of both sexes.
(2) Clinically diagnosed mild-to-moderate plaque psoriasis (localized lesions).
(3) Patients prescribed topical clobetasol monotherapy or combination therapy (clobetasol + calcipotriol).
(4) Willing to provide informed consent and comply with follow-up visits.

Exclusion Criteria:

(1) Severe/very severe psoriasis or systemic involvement.
(2) Systemic psoriasis treatments within 4 weeks prior to enrollment.
(3) Pregnant/lactating women, children, or immunocompromised patients (e.g., HIV, cancer).
(4) Co-morbidities like tuberculosis, leprosy, or other autoimmune/infectious skin diseases.
(5) Known hypersensitivity to clobetasol or calcipotriol.

Sample Size:

The sample size was calculated using the Cochrane formula for prevalence studies: $N = Z_\alpha^2 \times p \times q / d^2$, where: $Z_\alpha = 1.96$ (95% confidence level), $p = 2.8\%$ (maximum prevalence of psoriasis in India) [22], $q = 97.2\%$, $d = 5\%$ (absolute precision). The estimated sample size was 42, adjusted to 54 (including a maximum of 30% non-response rate). The study enrolled 34 and 35 patients for groups "A" and "B" via a purposive sampling method based on study criteria during the 6-month study period. But, 60 patients (Equally 30 per group) were finally taken into consideration after completing follow-up assessment as described in the study plan in Figure 1.

Methodology:

The clinical scoring was performed at baseline on the initial visit and at the 3rd week and 6th week-end follow-up visit of the respective patients, directed by the dermatologists who had pre-discussed assessment tests as per study requirements. The scores assigned to each patient of both treatment groups for all assessment tests under study were recorded for further analysis.

Baseline Assessment:

(1) Demographic and clinical data recorded (age, gender, family history, etc.).
(2) Psoriasis severity evaluated using "the Psoriasis Area and Severity Index (PASI) at day 0. Four areas were selected (Head, trunk, upper limb and, lower limb). Each area was evaluated on a 5- point scale at each visit." (0=No symptoms, 1= Slight, 2= Moderate, 3= Marked, 4= Very marked) [23,24]
(3) Global assessment of improvement was done clinically by the dermatologist: using "Physician Global Assessment (PGA) Score" at each visit. A five-point ordinal scale was used, where 1 = no improvement or worsening, 2 = minimal improvement, 3 = moderate improvement, 4 = marked improvement, and 5 = highly improved (maximum efficacy). [24]
(4) "Dermatological sum score" (DSS) was the sum of erythema, plaque elevation, and scaling of the target lesion. Each sign was evaluated on a 5-point scale at each visit (0= absent; 1 = mild; 2 = moderate; 3 = marked; 4 = very marked). [23]

Follow-up:

All scoring system scores were reassessed at the 3rd and 6th week to monitor clinical improvement, if any. Possible adverse effects were also noticed and documented.

Data Collection:

Prescription details sourced from DVL department records and as provided by concerned dermatologists. All scores, treatment responses, and adverse drug reactions noted were entered into a Microsoft Excel Sheet Version for further assessment.

Statistical Analysis:

The study employed descriptive and inferential statistical methods to assess clinical outcomes between treatment groups. Demographic and baseline clinical variables were analysed using means, standard deviations, and frequency distributions. Group comparisons were performed using unpaired t-tests for continuous variables (e.g., age, PASI scores, PGA, DSS) and Fisher's exact test for categorical variables (e.g., gender, family history, adverse events). The PASI, PGA, and DSS scores were compared at baseline, and at the end of the 3rd week, and 6th week to evaluate treatment efficacy. A *p-value less than 0.05* was considered statistically significant.

RESULTS

Participant Flow
69 patients assessed for eligibility
9 excluded (did not complete follow-up)
60 completed study
30 in Group A

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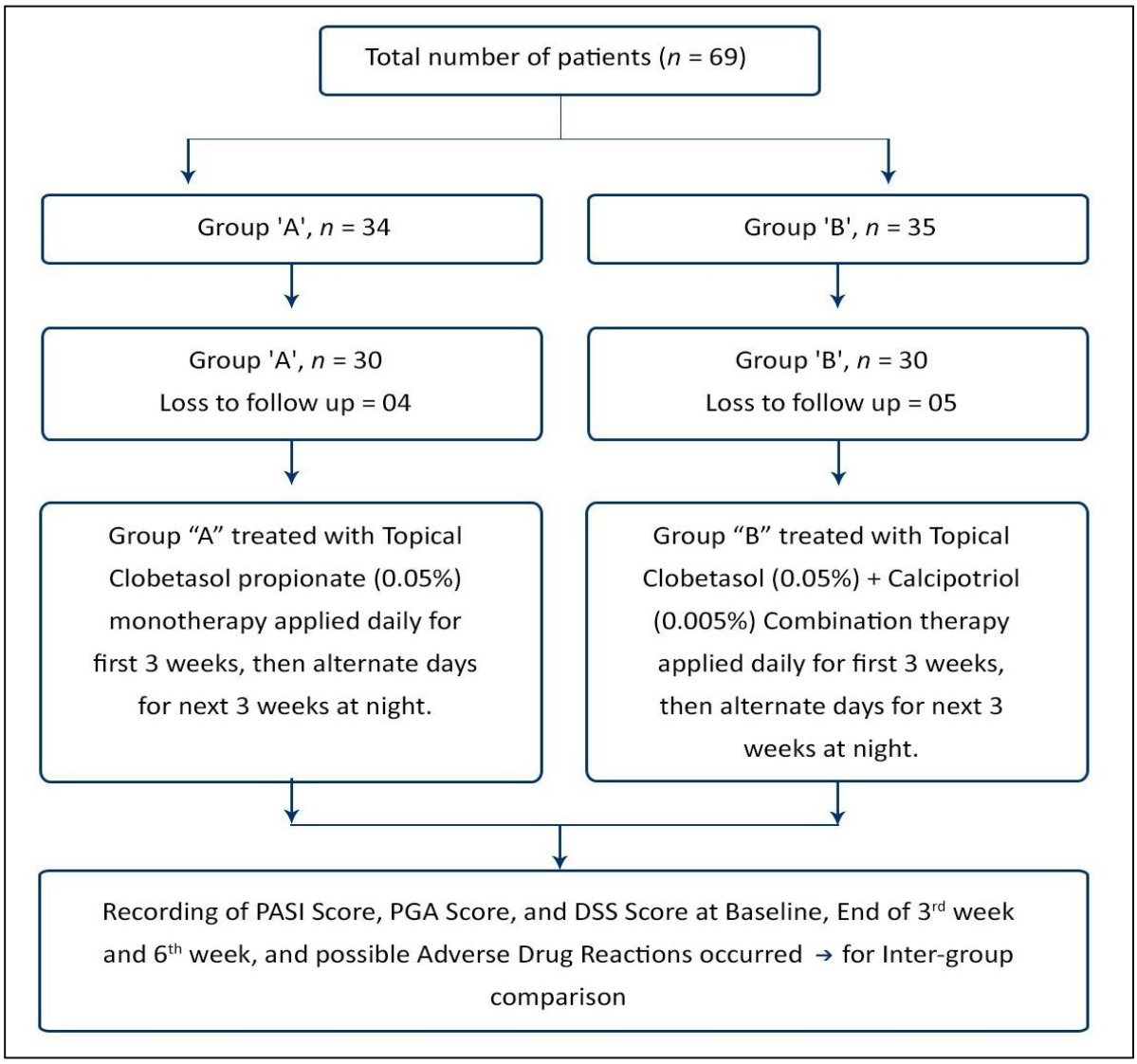
30 in Group B



30 patients of plaque psoriasis in Group A received topical clobetasol propionate (0.05%) monotherapy, applied once daily for 3 weeks and alternate days for the next 3 weeks at night. Whereas, Group B (30 patients) received combination therapy (clobetasol 0.05% + calcipotriol 0.005%), applied once daily for 3 weeks and alternate days for the next 3 weeks at night. The mean age, gender distribution, duration of disease, and family history of psoriasis were similar between the groups, with no statistically significant differences (p-values > 0.05). This indicates that the groups were well-matched at baseline, ensuring that any differences in outcomes observed later are likely due to the treatments rather than pre-existing disparities in patient demographics or disease severity [Table 1].

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Table 1: Clinico-demographic Data comparison between Group A and Group B

A: Comparison of Demographic Characteristics between Group A & B				
Variable		**Group A (*n*=30)**	**Group B (*n*=30)**	***p*-value**
Age in Years, mean ± SD		39.57 ± 7.84	40.13 ± 6.98	0.7712*
Gender	Male, *n* (%)	22 (73.33)	20 (66.67)	0.7787**
	Female, *n* (%)	8(26.67)	10 (33.33)	
B: Comparison of Clinical Characteristics between Group A & B				
Duration of Disease in Years, Mean ± SD		6.73 ± 1.59	6.90 ± 1.64	0.6850*
Family History of Psoriasis	Positive, *n* (%)	8 (26.67)	7 (23.33)	>0.9999**
	Negative, *n* (%)	22(75.33)	23(76.67)	

* Unpaired t-test; **Fisher's Exact Test

The Psoriasis Area and Severity Index (PASI) scores were comparable at baseline for both groups (p = 0.5692). However, at 3rd and 6th weeks, Group B (combination therapy) showed significantly greater reductions in PASI scores compared to Group A (p = 0.0140 and p = 0.0067, respectively). This suggests that the combination of clobetasol and calcipotriol is more effective in reducing psoriasis severity than clobetasol alone over the short-term treatment period [Table 2].

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Table 2: Comparison of PASI Score between Group A and Group B

Patient Visit	PASI Score in Mean ± SD		*p*-Value (Unpaired t- test)	*δ*- Value (Cohen's d – Effect Size Test)
	Group A (*n*=30)	Group B (*n*=30)		
Baseline (Day "0")	7.83 ± 1.17	8.00 ± 1.13	0.5692	-0.15
End of 3 Weeks	6.47 ± 1.08	5.77 ± 1.06	0.0140	+0.65
End of 6 Weeks	5.10 ± 1.03	4.37 ± 0.98	0.0067	+0.73

The Physician Global Assessment (PGA) scores were similar at baseline (p = 0.3932). By week 6, Group B demonstrated a significantly lower mean PGA score than Group A (p = 0.0002), indicating that the combination therapy led to a more pronounced improvement in the overall clinical appearance of psoriasis lesions as assessed by dermatologists. The trend of greater improvement in Group B was already noticeable at week 3, though not statistically significant (p = 0.0625) [Table 3].

Table 3: Comparison of PGA Score between Group A and Group B

Patient Visit	PGA Score in Mean ± SD		*p*-Value (Unpaired t- test)	*δ*- Value (Cohen's d – Effect Size Test)
	Group A (*n*=30)	Group B (*n*=30)		
Baseline (Day "0")	3.53 ± 0.61	3.67 ± 0.65	0.3932	-0.22
End of 3 Weeks	3.06 ± 0.54	2.80 ± 0.52	0.0625	+0.49
End of 6 Weeks	2.67 ± 0.49	2.23 ± 0.36	0.0002	+1.02

The Dermatology Life Quality Index (DLQI) or Disease Severity Score (DSS) showed no significant differences at baseline (p = 0.8732). While both groups exhibited reductions in DSS scores over time, the differences between groups at the end of weeks 3rd and 6th did not reach statistical significance (p = 0.0775 and p = 0.0614, respectively). This implies that both therapies improved disease-related quality of life or severity, but the combination therapy did not show a clear advantage in this specific measure [Table 4].

Table 4: Comparison of DSS Score between Group A and Group B

Patient Visit	DSS Score in Mean ± SD		*p*-Value (Unpaired t- test)	*δ*- Value (Cohen's d – Effect Size Test)
	Group A (*n*=30)	Group B (*n*=30)		
Baseline (Day "0")	38.60 ± 6.49	38.87 ± 6.56	0.8732	-0.04
End of 3 Weeks	34.77 ± 6.15	31.93 ± 6.09	0.0775	+0.46
End of 6 Weeks	31.33 ± 5.88	28.50 ± 5.61	0.0614	+0.47

Total Adverse drug reactions observed were only n=22. Among these, most frequently seen was skin discolouration (27.27%), followed by skin dryness, burning sensation, and itching sensation, which were equally noticed (18.18%). Flushing (4.55%) occurred least commonly (Fig. 2).

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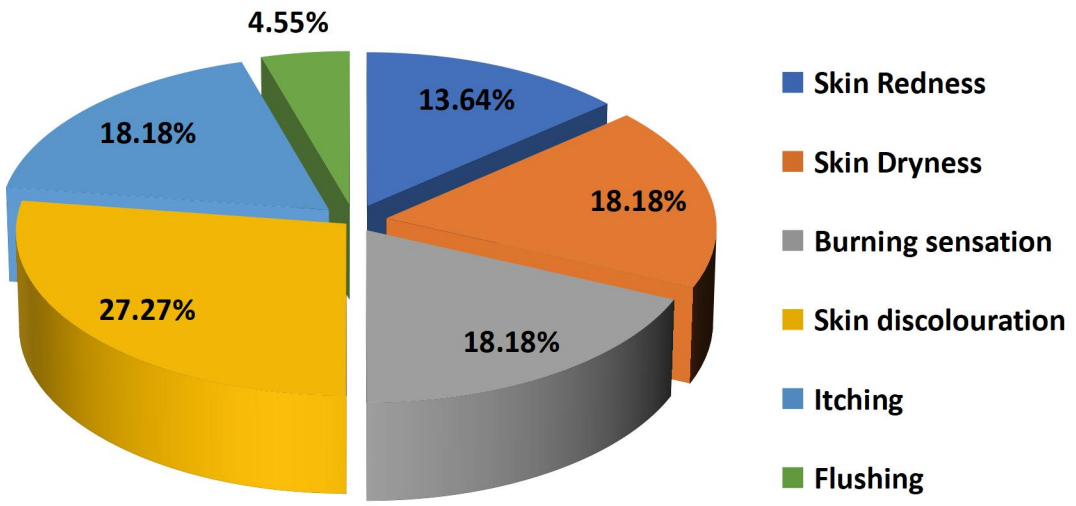
Fig. 2: Percentage of different ADRs noticed during the study period (Total ADRs, *n*=22)



However, the incidence of adverse events, including skin redness, dryness, burning sensation, discoloration, itching, and flushing, was low and comparable between the two groups, with no statistically significant differences (*p*-value > 0.05). This suggested that the addition of calcipotriol to clobetasol did not increase the risk of adverse effects, and both treatments were almost equally well-tolerated throughout the study period [Table 5].

Table 5: Comparison of Incidence of Adverse Drug Reactions between Group A and Group B

Adverse Drug Reactions	Group A (*n*=30)	Group B (*n*=30)	*p*-Value (Fisher's Exact Test)
	Number of Patients, *n* (%) [Out of the total 30 patients]		
Skin Redness	1 (3.33)	2 (6.67)	>0.9999
Skin Dryness	3 (10.0)	1 (3.33)	0.6120
Burning sensation	3 (10.0)	1 (3.33)	0.6120
Skin discoloration	2 (6.67)	4 (13.33)	0.6707
Itching	2 (6.67)	2 (6.67)	>0.9999
Flushing	0	1 (3.33)	>0.9999

DISCUSSION

Psoriasis is a chronic inflammatory skin disorder driven by immune dysregulation, particularly involving the T-helper cell 17 pathways and overexpression of pro-inflammatory cytokines like IL-17 and IL-23. This results in abnormal keratinocyte proliferation, leading to

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the characteristic thick, scaly plaques. Topical corticosteroids, such as clobetasol propionate, are highly effective due to their potent anti-inflammatory and immunosuppressive effects. However, long-term use can cause skin atrophy and rebound flares [25]. Vitamin D analogues like calcipotriol offer a complementary mechanism by normalizing keratinocyte differentiation and exerting anti-inflammatory effects. Combining these agents targets multiple pathological pathways, potentially enhancing efficacy while minimizing adverse effects associated with prolonged steroid use [26].

The present study demonstrated middle-aged group (Group A=39.57 ± 7.84 years and Group B= 40.13±6.98 years) and male preponderance (73.33%) with female to male gender ratio of 1:4. Also, approximately 25% patients had a positive family history of psoriasis with >6 years old of illness. Keerthy et al. (2025) in their study found similar results as the majority of the subjects belonged to the age group 30 to 40 years, with mean age in Group A & Group B being 37.17 years and 35.5 years, respectively. The male-to-female ratio is 2:1, having 32% of patients with psoriasis family history [27]. Sidgiddi et al (2021) showed parallel findings with a higher prevalence of middle-aged patients and a significant positive family history of psoriasis [28]. This study also noticed that the combination of clobetasol and calcipotriol led to significantly greater improvements in PASI and PGA scores compared to clobetasol monotherapy over 6 weeks. These results highlighted the synergistic effects of the two agents, with the combination providing faster and more pronounced clinical benefits. Importantly, both treatments were well-tolerated, with no significant differences in adverse events. This supported the use of combination therapy as a first-line approach for moderate plaque psoriasis, particularly in cases where rapid symptom control was desired [29].

These findings were not only aligned with existing literature but also offered new insights. Yazali et al. (2022) reported comparable efficacy between calcipotriol and clobetasol monotherapy, whereas the present study showed superior outcome with combination therapy [19]. This discrepancy may be due to differences in study duration or patient demographics. Upalekar TS et al. (2024) reinforced our conclusions through a systematic review, confirming that steroid-vitamin D combinations outperform monotherapy in both efficacy and safety [18]. Similarly, Heim Marjorie et al. (2022) provided mechanistic evidence, showing that calcipotriol enhances the anti-inflammatory effects of steroids by reducing immune cell infiltration in psoriatic lesions [20].

Devaux S et al. (2012) conducted a meta-analysis demonstrating that vitamin D-steroid combinations were twice as effective as vitamin D alone, further validating the result of the present study [21]. Meanwhile, Feldman et al. (2012) showed that calcipotriol foam monotherapy had modest success rates (14–27%), underscoring the advantage of combining it with a potent steroid like clobetasol for better outcomes [30].

The collective evidence solidified the role of steroid-vitamin D combinations as a gold standard for plaque psoriasis. These regimens offer rapid symptom control, sustained efficacy, and a favourable safety profile. However, subsequent research should explore long-term outcomes, cost-effectiveness, and optimal dosing strategies to refine treatment protocols. Additionally, investigating the effects of newer formulations, such as foams or sprays, could further improve patient adherence and therapeutic outcomes.

In summary, the findings of the present study contributed to the growing body of evidence supporting the superiority of clobetasol-calcipotriol combination therapy in psoriasis management. By leveraging the complementary mechanisms of both agents, this approach achieves superior clinical results while maintaining an excellent safety profile. As such, it should be considered a first-line option for patients with moderate to severe plaque psoriasis, offering a balanced and effective treatment strategy.

Generalizability

Although conducted in a single tertiary-care center in eastern India, the demographic and clinical characteristics of participants are comparable to those of psoriasis populations reported in other Indian and international studies. Therefore, the findings may be applicable to similar clinical settings managing mild-to-moderate plaque psoriasis, particularly in resource-limited environments where topical therapy remains first-line treatment.

Strength and Limitation

This study has some limitations, as the sample size was relatively small and confined to a specific geographic region and demographic section, even though the sample size for this study was calculated based on estimated prevalence data. As a result, such findings

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may limit the potential for assessment of long-term outcomes such as relapse rates or cumulative side effects of prolonged steroid use. Future research in this direction at large scale on more diverse populations could add to the validity and applicability of these findings.

Conclusion

The study concluded that the combination therapy of clobetasol propionate (0.05%) and calcipotriol (0.005%) applied for 6 weeks was more effective than clobetasol monotherapy in improving psoriasis severity, as evidenced by significantly greater reductions in PASI scores at 3rd and 6th weeks from baseline and a markedly lower PGA score by the end of 6th week. Adverse events were minor and similar in both groups, indicating that the combination therapy was well-tolerated. These findings supported the superiority of the combination therapy in managing plaque psoriasis over the short term, particularly in reducing clinical severity and improving lesion appearance.

Limitations

This study had a relatively small sample size and a short follow-up duration of six weeks. Long-term outcomes, relapse rates, and cumulative adverse effects could not be evaluated. Additionally, being a single-center study, external validity may be limited.

Recommendations

Future multicenter studies with larger sample sizes and longer follow-up durations are recommended to evaluate long-term remission rates and safety. Comparative cost-effectiveness studies and evaluation of newer formulations, such as foam or gel preparations, may further optimize psoriasis management strategies.

List of Abbreviations

PASI – Psoriasis Area and Severity Index
PGA – Physician Global Assessment
DSS – Dermatological Sum Score
DLQI – Dermatology Life Quality Index
DVL – Dermatology, Venereology and Leprosy
HPA – Hypothalamic-Pituitary-Adrenal

Conflict of Interest

The authors declare that there are no financial or non-financial conflicts of interest related to this study.

Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

Dipti Singh: Conceptualization, methodology, data collection, manuscript drafting.
Mukesh Kumar: Statistical analysis, software handling, manuscript preparation.
Sushma Kumari: Study supervision, validation, and critical revision.
Shashikala Kumari: Resources, visualization, manuscript editing.
Mahboob Alam: Clinical supervision, dermatological assessment, patient management.
All authors reviewed and approved the final manuscript.

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Author Contribution

Dipti Singh: Conceptualization, Methodology, the investigation and data curation; Shashi Kala Kumari: Resources and writing-review & editing; S. Kumari produced the visualizations; Mehboob Alam: Supervision and Project administration. Mukesh Kumar: Software, formal analysis, and the original draft writing; Sushma Kumari: Validation and visualization; All authors read, revised, and approved the final version of the manuscript.

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Declaration of competing interest

The authors declared that they have no relevant financial or non-financial conflicts of interest to disclose. This research was conducted independently. No commercial entity had a role in study design, data collection, data analysis, result interpretation, or manuscript preparation.

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Ethics Statement

The study was approved by the Institutional Ethics Committee (Vide letter No-NMCH/IEC/2024/107). Informed consent was obtained from the study participants.

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