

A STUDY OF EFFICACY, SAFETY AND TOLERABILITY OF ORAL VITAMIN D SUPPLEMENTATION IN PATIENTS WITH MILD TO MODERATE PSORIASIS

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ABSTRACT

Background: Psoriasis is a chronic inflammatory skin disorder characterised by keratinocyte hyperproliferation and immune dysregulation. Vitamin D plays key roles in immune modulation, keratinocyte differentiation, and calcium homeostasis. While topical vitamin D analogues are well established in psoriasis management, the effects of oral supplementation remain less defined. This study aimed to evaluate the efficacy, safety, and tolerability of oral vitamin D supplementation in patients with mild to moderate psoriasis. **Materials and Methods:** This single-centre, open-label, prospective study was conducted at Government Rajaji Hospital, Madurai, from October 2020 to September 2021. Sixty patients with mild-to-moderate psoriasis were divided into two groups of 30 patients each. Group A received oral cholecalciferol 60,000 IU weekly plus topical betamethasone 0.1%, whereas Group B received only topical therapy for six months. Serum 25-hydroxy vitamin D and calcium levels and PASI scores were assessed at baseline and at 2, 4, and 6 months. Data were analysed using repeated measures ANOVA and unpaired t-test; $p \leq 0.05$ was considered significant. **Result:** In the case group, serum vitamin D increased from 18.78 ± 6.20 ng/ml at baseline to 23.89 ± 6.95 ng/ml at six months, while the control group decreased from 18.98 ± 5.85 ng/ml to 16.95 ± 5.55 ng/ml ($p < 0.001$ at 4 and 6 months). Serum calcium rose in the case group from 8.85 ± 0.49 mg/dl to 9.75 ± 0.69 mg/dl, versus a decline in control (9.06 ± 0.87 mg/dl to 8.40 ± 0.65 mg/dl; $p < 0.001$). PASI scores decreased from 20.06 ± 4.58 to 15.49 ± 4.54 in the case group, compared with 20.04 ± 1.94 to 17.54 ± 1.84 in the control ($p < 0.001$). **Conclusion:** Oral vitamin D supplementation effectively increased serum vitamin D and calcium levels and reduced disease severity in patients with mild-to-moderate psoriasis.

INTRODUCTION

Psoriasis is a long-standing inflammatory skin condition shaped by both hereditary and environmental influences. It presents with well-defined, raised, erythematous plaques covered by silvery scales, most often involving the extensor regions and the scalp.^[1] Disease severity, extent, and frequency vary among patients. In India, reported prevalence estimates for psoriasis among adults range from about 0.44% to 2.8%.^[2] A bimodal age distribution, with approximately 20% of cases occurring before 20 years of age and 58% before 30 years.^[3] Both sexes are equally affected, and first-degree relatives of affected are at higher risk. The pathogenesis of psoriasis is immune-mediated and

mainly involves T-helper 1 (Th1) lymphocytes. Activation leads to the release of cytokines such as IFN- γ , IL-2, IL-12, IL-17, and TNF- α , resulting in conscription of neutrophils, endothelial cells, and other inflammatory mediators, which ultimately drive keratinocyte hyperproliferation.^[4]

Vitamin D is a steroid-derived hormone produced mainly in the skin following exposure to ultraviolet-B light. It is vital for maintaining calcium balance and bone health and also contributes to the regulation of immune function.^[5] Vitamin D deficiency, defined as serum 25(OH)D levels below 30 nmol/L, is a global health concern and is highly prevalent among patients with psoriasis. Vitamin D deficient and calcium have been associated with keratinocyte hyper proliferation

and impaired cell differentiation, causing to severity.^[6]

Studies have indicated that vitamin D uses immunomodulatory effects by inhibiting T-cell proliferation, helping regulatory T-cell function, and modulating cytokine release. In keratinocytes, calcitriol, the active form of vitamin D, supports terminal differentiation and reduces proliferation.^[7] Previous studies suggest that lower serum 25(OH)D levels associated with increased psoriasis activity.^[8] Oral vitamin D are well-established treatments for mild to moderate psoriasis owing to their efficacy and safety. However, the effect of oral vitamin D supplementation remains unclear. Oral supplementation may offer broader immunomodulatory benefits, potentially improve disease activity, while maintain safety and tolerability. Several studies have explored the potential efficacy of oral vitamin D in psoriasis, although standardised protocols and comprehensive safety assessments are limited.^[8-10] Therefore, this study aimed to evaluate the efficacy, safety, and tolerability of oral vitamin D supplementation in patients with mild to moderate psoriasis.

MATERIALS AND METHODS

This single-centre, open-label, prospective study was conducted in the Department of Dermatology, in collaboration with the Institute of Pharmacology and the Departments of Dermatology and Biochemistry at Government Rajaji Hospital, Madurai, from October 2020 to September 2021. Institutional Ethics Committee of the Government Rajaji Hospital, Madurai approved the study and written informed consent was obtained from all patients.

Inclusion and exclusion criteria

Patients aged 18–70 years of either sex with mild to moderate psoriasis, defined by a PASI score of 1–20, and serum 25-hydroxy vitamin D₃ levels (20–

30 ng/ml). Only patients willing to provide written informed consent were enrolled.

Patients with severe psoriasis, renal or liver disease, malignancy, or hyperparathyroidism, or those taking microsomal enzyme inducers or inhibitors were excluded.

Methods: Sixty patients were divided into two groups of 30 patients each. Group A received oral cholecalciferol 60,000 IU once weekly for six months, along with topical betamethasone 0.1% and emollients, whereas Group B received only topical betamethasone 0.1% and emollients for the same duration. Data collected included PASI (Psoriasis Area and Severity Index) scores, serum calcium levels, and serum 25-hydroxy vitamin D₃ levels. Venous blood samples were obtained from the antecubital vein and collected in vacutainers, following standard hospital procedures. Serum vitamin D₃ levels were measured using ELISA, and the PASI scores were assessed at baseline and at 2, 4, and 6 months to monitor disease severity. Efficacy was evaluated based on changes in PASI scores, and biochemical responses were assessed by measuring serum vitamin D₃ and calcium levels.

Statistical analysis: Continuous data were summarised as mean ± standard deviation, while categorical variables were expressed as counts and percentages. Changes within each group were examined using repeated-measures ANOVA, and comparisons between groups were performed with the unpaired t-test. A p-value of ≤ 0.05 was considered statistically significant. All analyses were carried out using IBM SPSS Statistics version 27.

RESULTS

Most patients were between 40 and 60 years of age (56.7%), and females were higher (65%). Mild psoriasis was more common, 70% of cases, while 30% had moderate disease severity [Table 1].

Table 1: Demographic and clinical characteristics

Parameter		N (%)
Age (years)	20 – 40	26 (43.3%)
	40 – 60	34 (56.7%)
Gender	Male	21 (35%)
	Female	39 (65%)
Mild Psoriasis		42 (70%)
Moderate Psoriasis		18 (30%)

Vitamin D levels showed no significant difference at baseline to 6 months in case and control (p = 0.614, p = 0.895). A significant difference in serum calcium level at baseline to 6 months in case and control (p = 0.004, p < 0.001). The PASI scores decreased over

time in both groups, with no significant difference in either the control (p = 0.102) or case group (p = 0.123), although the case group showed improvement by six months [Table 2].

Table 2: Longitudinal changes in vitamin D, serum calcium, and PASI score in groups

Parameter	Time point	Control	P value	Case	P value
Vitamin D (ng/mL)	Baseline	18.98 ± 5.85	0.614	18.08 ± 6.20	0.895
	2 months	18.50 ± 5.85		18.20 ± 6.32	
	4 months	17.04 ± 5.52		21.63 ± 6.45	
	6 months	16.95 ± 5.55		23.89 ± 6.95	
Serum calcium (mg/dL)	Baseline	9.06 ± 0.87	0.004	8.85 ± 0.49	<0.001
	2 months	8.99 ± 0.78		9.01 ± 0.51	
	4 months	8.74 ± 0.71		9.28 ± 0.58	
	6 months	8.40 ± 0.65		9.75 ± 0.69	
PASI Score	Baseline	20.04 ± 1.94	0.102	20.06 ± 4.53	0.123
	2 months	19.85 ± 1.97		19.50 ± 4.57	
	4 months	18.96 ± 1.87		17.60 ± 4.57	
	6 months	17.54 ± 1.84		15.49 ± 4.54	

In case group, mean serum vitamin D levels increased from 18.78 ± 6.20 ng/ml at baseline to 21.63 ± 6.45 ng/ml at four months and 23.89 ± 6.95 ng/ml at six months. In contrast, the control group showed a decrease from 18.98 ± 5.85 ng/ml at baseline to 16.95 ± 5.55 ng/ml at six months, with no significant at baseline ($p = 0.113$) and two months ($p = 0.152$) but were significant at four and six months ($p < 0.001$).

Serum calcium increased in the case group from 8.85 ± 0.49 mg/dl to 9.75 ± 0.69 mg/dl, while

decreasing in the control group from 9.06 ± 0.87 mg/dl to 8.40 ± 0.65 mg/dl, with significant differences at 4 and 6 months ($p = 0.002$ and $p < 0.001$).

PASI scores reduced in the case group from 20.06 ± 4.58 to 15.49 ± 4.54, compared with a decrease from 20.04 ± 1.94 to 17.54 ± 1.84 in the control group, with significant differences at all follow-up points ($p < 0.001$ at 4 and 6 months) [Table 3].

Table 3: Comparison of serum vitamin D, serum calcium, and PASI scores between groups over time

Parameter	Time Point	Control (Mean ± SD)	Case (Mean ± SD)	P value
Serum vitamin D (ng/mL)	Baseline	18.98 ± 5.85	18.78 ± 6.20	0.113
	2 months	18.50 ± 5.85	18.20 ± 6.32	0.152
	4 months	17.04 ± 5.52	21.63 ± 6.45	< 0.001
	6 months	16.95 ± 5.55	23.89 ± 6.95	< 0.001
Serum calcium (mg/dL)	Baseline	9.06 ± 0.87	8.85 ± 0.49	0.255
	2 months	8.99 ± 0.78	9.01 ± 0.51	0.922
	4 months	8.74 ± 0.71	9.28 ± 0.58	0.002
	6 months	8.40 ± 0.65	9.75 ± 0.69	< 0.001
PASI Score	Baseline	20.04 ± 1.94	20.06 ± 4.58	0.012
	2 months	19.85 ± 1.97	19.50 ± 4.57	0.011
	4 months	18.96 ± 1.87	17.60 ± 4.57	< 0.001
	6 months	17.54 ± 1.84	15.49 ± 4.54	< 0.001

DISCUSSION

Psoriasis is a chronic inflammatory skin disease marked by dysregulated immune activity and excessive keratinocyte proliferation. Vitamin D plays crucial roles in immune modulation, keratinocyte differentiation, and calcium homeostasis. Although topical vitamin D is well established for the managing of mild to moderate psoriasis, the effects of oral supplementation on disease severity, biochemical markers, and tolerability remain poorly defined. In this study, oral vitamin D supplementation for six months significantly increased serum vitamin D and calcium levels while reducing PASI scores compared with the control. Treatment was well tolerated, with no major adverse effects, indicating that oral vitamin D is effective, safe, and beneficial for mild-to-moderate psoriasis.

In our study, oral vitamin D supplementation significantly increased serum levels over six months compared with a declining trend in the control group. Similarly, Disphanurat et al., psoriasis patients receiving oral vitamin D₂ (60,000 IU every two

weeks) for six months showed an increase in mean serum 25(OH)D from approximately 24.8 ng/mL to 27.4 ng/mL ($p = 0.029$).^[11] McCullough et al., psoriasis patients received high-dose vitamin D₃ (35,000 IU/day) for six months, and their mean serum 25-OH-D levels increased from 14.9 ± 7.4 ng/mL to 106.3 ± 31.9 ng/mL.^[12] Lourencetti et al. found that oral active vitamin D metabolites (1,25-OH₂D₃ or 1 α -OH-D₃) improved moderate-to-severe psoriasis in most patients within 2–8 months, with doses 0.25–2 μ g/day, high doses (35,000 IU/day) tolerated; hypercalciuria was the main side effect.^[13] Therefore, oral vitamin D effectively raises serum levels in psoriasis patients; regular monitoring is advised to ensure safety and prevent hypercalciuria.

Our study showed that oral vitamin D supplementation significantly increased serum calcium levels, while levels declined in the control group over six months. Chaudhari et al. reported comparable serum calcium levels across mild, moderate, and severe psoriasis, with no significant differences.^[14] Qadim et al. reported that approximately 37% of psoriasis patients had low

serum calcium, showing a possible calcium imbalance that could be improved with vitamin D supplementation.^[15] Sinha et al. reported that at baseline, 86.6% had normal serum calcium, and 13.3% had low levels; after 12 weeks of treatment, all patients (100%) had normal calcium levels ($p < 0.05$).^[16] Thus, oral vitamin D improves calcium levels in patients with psoriasis; regular monitoring is recommended to maintain optimal calcium balance. Oral vitamin D supplementation significantly reduced PASI scores compared to the control group, showing improvement over six months. Similarly, Bhati et al. in a six-month study of weekly oral vitamin D₃ (60,000 IU) showed mean PASI scores decreased from 8.84 to 3.69 ($p < 0.001$).^[17] Overall, oral vitamin D effectively reduces psoriasis severity; reliable supplementation may enhance clinical outcomes alongside standard topical therapy.

Limitations: Our study's small, single-centre, open-label design limits its generalisability and may introduce bias. A six-month follow-up may be insufficient, and uncontrolled factors, such as sun exposure, diet, adherence, and lack of inflammatory marker assessment, could influence outcomes.

CONCLUSION

Oral vitamin D supplementation for six months improved serum vitamin D and calcium levels and was associated with a decrease in PASI scores compared with standard topical therapy alone. The treatment was well tolerated, suggesting that oral vitamin D may serve as a useful adjunct for patients with mild to moderate psoriasis. Larger controlled studies are needed to confirm these findings and to define optimal dosing and monitoring strategies.

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