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Research Article

Effect of Vitamin D Supplementation on Clinical Outcomes in Patients with Allergic Rhinitis

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ABSTRACT:

Background: Allergic rhinitis (AR) is a prevalent IgE-mediated inflammatory condition of the nasal mucosa, recognized for its substantial negative impact on patients' quality of life. Vitamin D possesses immunomodulatory capabilities that suggest a potential role in mitigating allergic inflammation and enhancing clinical outcomes in individuals afflicted with AR. The objective of the study was to evaluate the effect of adjunctive vitamin D supplementation on symptom severity and serum 25-hydroxyvitamin D [25(OH)D] concentrations in patients with allergic rhinitis.

Methods: Eighty patients, aged 18–55 years, presenting with clinically diagnosed allergic rhinitis were randomly assigned to one of two treatment arms: oral cholecalciferol (60,000 IU weekly for 8 weeks) combined with standard anti-allergic therapy (n = 40), or standard anti-allergic therapy alone (n = 40). Clinical efficacy was evaluated using the Total Nasal Symptom Score (TNSS) and Visual Analogue Scale (VAS), with serum 25(OH)D concentrations quantified at baseline and following 8 weeks of intervention.

Results: Baseline demographic and clinical characteristics were comparable between the two groups. Following 8 weeks of treatment, the vitamin D supplementation group demonstrated significantly greater reductions in TNSS and VAS scores than the control group. Serum 25(OH)D concentrations increased significantly in the vitamin D group, whereas no significant change was observed in the control group.

Vitamin D supplementation was well tolerated, with no serious adverse events or hypercalcemia reported.

Conclusion: Adjunctive vitamin D supplementation significantly improved symptom severity and corrected vitamin D insufficiency in patients with allergic rhinitis receiving standard therapy. These findings suggest that vitamin D supplementation may serve as a safe and effective adjunctive treatment.

Keywords: Allergic rhinitis; Vitamin D supplementation; Cholecalciferol; Total Nasal Symptom Score; Visual Analogue Scale.

Introduction:

Allergic rhinitis (AR) is a chronic immunoglobulin E (IgE)-mediated inflammatory disorder of the nasal mucosa characterized by sneezing, rhinorrhea, nasal obstruction, and nasal itching following exposure to inhaled allergens. It affects approximately 10–30% of the global population and represents one of the most prevalent chronic respiratory disorders, imposing a substantial burden on quality of life, sleep, school and work performance, and healthcare utilization [1, 2]. Furthermore, AR frequently coexists with asthma and other atopic diseases, emphasizing the concept of a unified airway inflammatory response [1].

The pathophysiology of allergic rhinitis involves a complex interplay between environmental allergens and the host immune system. Exposure to allergens triggers the activation of antigen-presenting cells, leading to the differentiation of T-helper 2 (Th2) lymphocytes and the subsequent production of cytokines, including interleukin (IL)-4, IL-5, and IL-13. These cytokines stimulate immunoglobulin E (IgE) synthesis and promote eosinophilic inflammation. Further activation of mast cells and basophils results in the release of histamine and other inflammatory mediators, which are responsible for the characteristic nasal symptoms [3]. Intranasal corticosteroids and oral antihistamines constitute the primary treatment modalities; however, a significant number of patients continue to report persistent symptoms despite receiving appropriate therapy, underscoring the necessity for effective adjunctive therapeutic strategies [1, 4].

Vitamin D, a fat-soluble secosteroid hormone, has long been recognized for its crucial role in calcium and bone homeostasis. Nevertheless, a growing body of evidence indicates that vitamin D also possesses significant immunomodulatory properties, influencing both innate and adaptive immune responses. The widespread expression of vitamin D

receptors on various immune cells, including dendritic cells, macrophages, B lymphocytes, and activated T lymphocytes, underscores its diverse regulatory functions. Within these cells, vitamin D has been shown to modulate antigen presentation, suppress the production of pro-inflammatory cytokines, promote the differentiation of regulatory T-cells, and attenuate Th2-mediated allergic inflammation [5, 6]. These multifaceted biological effects have stimulated considerable interest in exploring the potential therapeutic implications of vitamin D in allergic diseases.

Vitamin D insufficiency is a widespread global health concern, exhibiting strong associations with a range of allergic conditions, notably asthma, atopic dermatitis, and allergic rhinitis [7]. Numerous observational investigations have documented reduced serum 25-hydroxyvitamin D [25(OH)D] concentrations in individuals afflicted with allergic rhinitis when contrasted with healthy controls. Furthermore, these studies indicate an inverse correlation between vitamin D levels and both disease severity and symptom management [8, 9]. Despite these findings, the therapeutic efficacy of vitamin D supplementation in the management of allergic rhinitis remains a subject of considerable debate. While certain clinical trials have demonstrated improvements in symptom severity and quality of life subsequent to vitamin D supplementation, other studies have reported minimal or no discernible benefit beyond that conferred by conventional anti-allergic pharmacotherapy [10-12]. These discrepancies may arise from variations in study demographics, baseline vitamin D status, supplementation protocols, treatment durations, and selected outcome parameters.

Given the immunomodulatory properties of vitamin D and the inconsistent evidence regarding its clinical efficacy in allergic rhinitis, further clinical studies are warranted to clarify its therapeutic role. Therefore, the present study was undertaken to evaluate the effect of adjunctive vitamin D supplementation on symptom severity, assessed using the Total Nasal Symptom Score (TNSS) and Visual Analogue Scale (VAS), as well as serum 25-hydroxyvitamin D concentrations and treatment safety in patients with allergic rhinitis receiving standard anti-allergic therapy.

Materials and Methods:

Study Design and Setting:

This randomized controlled study was conducted at the Department of ENT and Head and Neck Surgery, Venkateshwara Institute of Medical Sciences, Gajraula,

Uttar Pradesh, India, from January 2025 to December 2025. The study aimed to evaluate the efficacy of vitamin D supplementation as an adjunct to standard therapy for symptom management in patients with allergic rhinitis.

Study Participants:

A total of 80 patients aged 18–55 years, of either sex, with clinically diagnosed allergic rhinitis were enrolled. The diagnosis of allergic rhinitis was established according to the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines, based on a compatible clinical history and characteristic symptoms, including sneezing, rhinorrhea, nasal itching, and nasal obstruction, supported by clinical examination [1].

Patients with chronic kidney disease, chronic liver disease, autoimmune disorders, pregnancy or lactation, hypercalcemia, malignancy, systemic corticosteroid therapy, allergen immunotherapy, current vitamin D supplementation, or any chronic inflammatory disease capable of influencing vitamin D metabolism were excluded from the study.

Randomization and Intervention:

Eligible participants were randomly assigned in a 1:1 ratio to one of two groups using a computer-generated randomization sequence. The Vitamin D group (n = 40) received oral cholecalciferol 60,000 IU once weekly for eight weeks in addition to standard anti-allergic therapy, whereas the control group (n = 40) received standard anti-allergic therapy alone.

Standard anti-allergic treatment consisted of oral levocetirizine 5 mg once daily and intranasal fluticasone propionate (100 µg/day) for eight weeks, in accordance with current recommendations for the management of allergic rhinitis [1].

Outcome Measures:

The primary outcome was the change in Total Nasal Symptom Score (TNSS) after 8 weeks of treatment.

Secondary outcomes included:

a) Serum 25-hydroxyvitamin D concentration
b) Visual Analogue Scale (VAS) for symptom severity
c) Treatment-related adverse events

The TNSS was calculated by summing scores for sneezing, rhinorrhea, nasal itching, and nasal obstruction, with each symptom graded on a four-point scale from 0 (no symptoms) to 3 (severe symptoms), giving a maximum possible score of 12 [3]. Symptom severity was also evaluated using a 10-cm Visual Analogue Scale (VAS), where 0 indicated no symptoms and 10 represented the worst imaginable symptoms [13].

Laboratory Analysis:

Venous blood samples were collected at baseline and after 8 weeks of treatment. Serum 25-hydroxyvitamin D [25(OH)D] concentrations were measured using a chemiluminescent immunoassay (CLIA) according to the manufacturer's instructions.

Statistical Analysis:

Continuous variables were expressed as mean ± standard deviation (SD). Categorical variables were presented as frequency and percentage. Baseline characteristics were compared using the independent Student's *t*-test or chi-square test as appropriate. Within-group comparisons were performed using the paired *t*-test, whereas post-treatment differences between the two groups were analysed using the independent Student's *t*-test. A two-sided *P* value <0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS version 20.

Results:

A total of 80 participants were enrolled in the study, comprising 40 patients in each of the vitamin D supplementation and control groups. The baseline demographic and clinical characteristics of the two groups are presented in **Table 1**. The mean age of participants was comparable between the vitamin D and control groups. Similarly, no significant differences were observed in sex distribution, body mass index, duration of allergic rhinitis, baseline serum 25-hydroxyvitamin D concentration, Total Nasal Symptom Score (TNSS), or Visual Analogue Scale (VAS) score between the two groups (all $P > 0.05$). These findings indicate that the groups were well matched before the initiation of treatment

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Table 1: Baseline characteristics of the studied subjects.

Variables	Vitamin D group (n=40)	Control group (n=40)	p-value
Age (years)	32.80±8.70	33.50±9.10	0.726
Male/Female	18/22	19/21	0.822
BMI (kg/m²)	24.35 ± 2.8	24.77 ± 3.1	0.527
Duration of AR (years)	4.2 ± 2.1	4.5 ± 2.4	0.554
Vitamin D (ng/mL)	20.13± 4.48	19.47 ± 5.47	0.559
TNSS	9.44 ± 1.53	9.17 ± 1.71	0.472
VAS Score	8.21 ± 1.01	7.85 ± 0.81	0.083

The clinical outcomes following 8 weeks of treatment are summarized in **Table 2**. At baseline, there were no significant differences between the vitamin D supplementation and control groups with respect to TNSS ($P = 0.472$) or VAS score

(P = 0.083). After 8 weeks of treatment, both groups demonstrated significant improvements in symptom severity compared with baseline (both $P < 0.001$). However, patients receiving vitamin D supplementation exhibited significantly lower TNSS (3.40 ± 1.10 vs. 4.97 ± 1.56, $P < 0.001$) and VAS scores (2.79 ± 1.15 vs. 4.47 ± 1.29, $P < 0.001$) than those receiving standard anti-allergic therapy alone, indicating greater improvement in allergic rhinitis symptoms with adjunctive vitamin D therapy.

Table 2: Clinical outcomes before and after 8 weeks of treatment.

Time Point	Vitamin D group (n=40)	Control group (n=40)	*P* value†
TNSS (Baseline)	9.44 ± 1.53	9.17 ± 1.71	0.472
TNSS (Week 8)	3.40 ±1.10	4.97± 1.56	<0.001
p-value‡	<0.001	<0.001	-
VAS (Baseline)	8.21 ± 1.01	7.85 ± 0.81	0.083
VAS (Week 8)	2.79±1.15	4.47±1.29	<0.001
p-value‡	<0.001	<0.001	-

†Between-group comparison using the independent Student's *t*-test. ‡Within-group comparison between baseline and Week 8 using the paired Student's *t*-test.

Table 3 and **Figure 1** present the alterations in serum 25-hydroxyvitamin D concentrations observed after an 8-week intervention period. Baseline serum vitamin D levels were comparable between the vitamin D supplementation group and the control group (20.13 ± 4.48 vs. 19.47 ± 5.47 ng/mL, P = 0.559). Following 8 weeks of intervention, the vitamin D supplementation group exhibited a statistically significant increase in serum vitamin D concentration, escalating from 20.13 ± 4.48 ng/mL to 36.55 ± 6.34 ng/mL ($P < 0.001$). Conversely, the control group demonstrated no significant change in serum vitamin D levels (19.47 ± 5.47 ng/mL at baseline vs. 19.68 ± 4.71 ng/mL at Week 8; P = 0.858). By the conclusion of the study, serum vitamin D concentrations were significantly elevated in the vitamin D supplementation group compared to the control group ($P < 0.001$), thereby substantiating the efficacy of cholecalciferol supplementation in ameliorating vitamin D insufficiency.

Table 3. Comparison of serum 25-hydroxyvitamin D concentrations before and after 8 weeks of treatment.

Time Point	Vitamin D group (n=40)	Control group (n=40)	*P* value†
Vitamin D (Baseline)	**20.13± 4.48**	**19.47 ± 5.47**	**0.559**
Vitamin D (Week 8)	**36.55± 6.34**	**19.68 ± 4.71**	**<0.001**
p- value‡	**<0.001**	**0.858**	**-**

†Between-group comparison using the independent Student's *t*-test. ‡Within-group comparison between baseline and Week 8 using the paired Student's *t*-test.

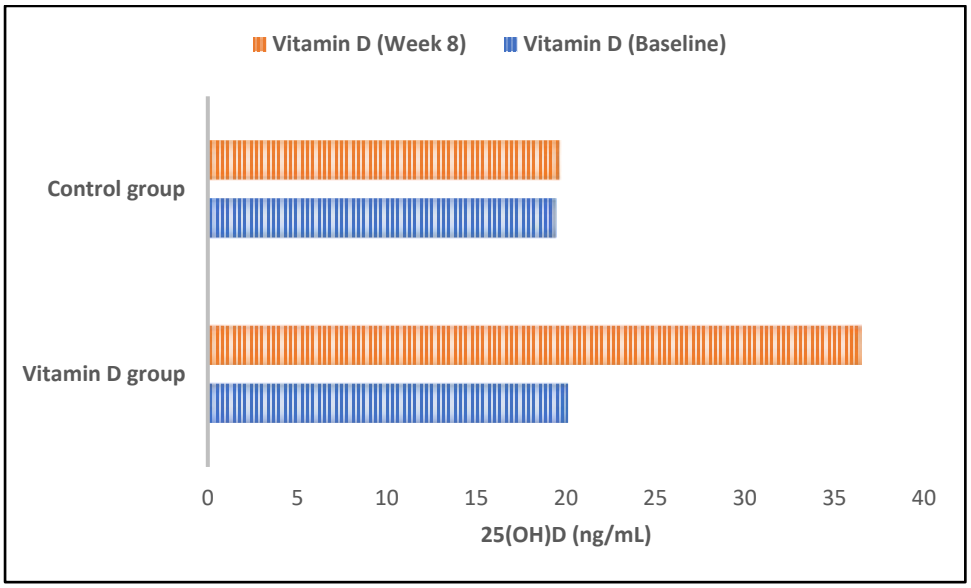

Figure 1: Comparison of serum 25-hydroxyvitamin D concentrations before and after 8 weeks of treatment.

Treatment-related adverse events observed during the study are summarized in **Table 4**. Vitamin D supplementation was generally well tolerated throughout the 8-week treatment period. Mild gastrointestinal discomfort was reported in three patients (7.5%) in the vitamin D group and two patients (5.0%) in the control group. Mild headache occurred in one participant (2.5%) receiving vitamin D supplementation and in two participants (5.0%) in the control group. No cases of hypercalcemia or serious adverse events were reported in either group. None of the participants discontinued treatment due to adverse events, indicating that vitamin D supplementation was safe and well-tolerated when administered alongside standard anti-allergic therapy.

Table 4: Comparison of treatment-related adverse events between the vitamin D supplementation and control groups.

Adverse Event	Vitamin D Group n (%)	Control Group n (%)
Gastrointestinal discomfort	3 (7.5)	2 (5)
Mild headache	1 (2.5)	2 (5)

Hypercalcemia	0	0
Serious adverse events	0	0

Discussion:

The present study evaluated the effect of adjunctive vitamin D supplementation on symptom severity and serum 25(OH)D concentrations in patients with allergic rhinitis receiving standard anti-allergic therapy. The principal findings demonstrated that vitamin D supplementation resulted in significantly greater reductions in TNSS and VAS scores compared with standard therapy alone. Furthermore, serum 25(OH)D concentrations increased significantly in the supplementation group, whereas no significant change was observed in the control group. Vitamin D supplementation was also well tolerated, with only mild adverse events reported and no cases of hypercalcemia or serious treatment-related complications.

The two study groups had comparable baseline characteristics, including age, sex, body mass index, duration of allergic rhinitis, baseline serum vitamin D concentrations, TNSS, and VAS scores. This lack of significant baseline differences indicates successful randomization and minimizes the likelihood that demographic or clinical factors influenced the observed treatment effects. Such comparability enhances the study's internal validity, supporting the conclusion that post-treatment differences were primarily attributable to vitamin D supplementation rather than baseline imbalances.

Vitamin D supplementation yielded a significant amelioration of clinical symptoms, substantiated by reduced TNSS and VAS following eight weeks of intervention. These findings suggest that vitamin D may augment the therapeutic response when administered as an adjunct to conventional anti-allergic therapy. The observed beneficial effects in this study are biologically plausible given vitamin D's established immunomodulatory properties. Vitamin D receptors are expressed on various immune cells, including dendritic cells, macrophages, B lymphocytes, and activated T lymphocytes, allowing vitamin D to regulate both innate and adaptive immune responses. Specifically, active vitamin D has been shown to suppress dendritic cell maturation, promote regulatory T-cell differentiation, inhibit Th1 and Th17 inflammatory responses, and modulate Th2-mediated cytokine production, including interleukin (IL)-4, IL-5, and IL-13, which are central to allergic inflammation [5, 6]. Moreover, vitamin D has demonstrated the capacity to reduce eosinophilic inflammation, stabilize

epithelial barrier function, and suppress IgE-mediated immune responses [11]. These actions collectively suggest a potential mechanism by which vitamin D could mitigate nasal mucosal inflammation and alleviate symptom severity in allergic rhinitis.

Our findings align with existing literature. Upadhyay and Jain demonstrated that vitamin D supplementation in children with allergic rhinitis significantly reduced TNSS and increased serum vitamin D concentrations compared with conventional therapy alone [10]. Similarly, Modh et al. reported that oral vitamin D supplementation improved clinical symptoms and quality of life in patients with allergic rhinitis, suggesting that correcting vitamin D deficiency may enhance the response to conventional treatment [9]. Furthermore, observational studies by Arshi et al. revealed significantly lower serum vitamin D concentrations in patients with allergic rhinitis compared to healthy controls, further substantiating an association between vitamin D deficiency and allergic disease severity [8]. Collectively, these studies support the hypothesis that vitamin D deficiency contributes to allergic inflammation and that supplementation may offer clinical benefits in appropriately selected patient populations.

One of the strengths of the present study is the prospective comparison of clinical symptom scores together with objective assessment of serum 25(OH)D concentrations before and after treatment. The inclusion of both TNSS and VAS provided complementary measures of symptom severity, while monitoring serum vitamin D concentrations confirmed treatment adherence and biological response to supplementation. In addition, the intervention was well tolerated, and no serious adverse events or hypercalcemia were observed, supporting the short-term safety of vitamin D supplementation in adults with allergic rhinitis.

Nevertheless, several limitations should be acknowledged. First, the study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. Second, the follow-up period was limited to eight weeks, preventing assessment of the long-term sustainability of symptom improvement. Finally, immunological biomarkers such as serum IgE, eosinophil count, cytokine profiles, and markers of eosinophilic inflammation were not evaluated, which precluded exploration of the precise immunological mechanisms underlying the observed clinical benefits.

Conclusion:

In conclusion, adjunctive vitamin D supplementation significantly ameliorated symptom severity and augmented serum 25(OH)D concentrations in patients with allergic rhinitis undergoing conventional anti-allergic therapy. The intervention demonstrated a favourable safety and tolerability profile, with an absence of serious adverse events. These findings posit that the rectification of vitamin D insufficiency may constitute a valuable adjunctive strategy for enhancing clinical outcomes in allergic rhinitis. Nevertheless, larger-scale, multicenter, randomized controlled trials incorporating extended follow-up durations and comprehensive immunological evaluations are imperative to corroborate these preliminary findings and further delineate the precise role of vitamin D supplementation in the therapeutic paradigm of allergic rhinitis.

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