



ADJUNCTIVE VITAMIN D IN ALLERGIC RHINITIS: A RANDOMIZED CONTROLLED STUDY

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Received:- 04/07/2026

Revised:-05/08/2026

Accepted:-12/08/2026

Published:-20/08/2026

Abstract

Allergic rhinitis (AR) is a very common chronic inflammatory condition of the nasal mucosa, which has a negative impact on life, sleep and productivity. The immunomodulatory effects of vitamin D (Vit D) have been well established and its effects on allergic inflammation are likely but the effects of Vit D as an adjunctive therapy for AR is still being studied. We conducted a randomized controlled trial to assess the effectiveness of Vit D supplementation, in addition to intranasal corticosteroid therapy, in Vit D deficient patients with allergic rhinitis. A total of 300 patients were evaluated and 110 who had 20-29 ng/mL of serum 25-hydroxyVit D were randomly divided into two groups of 55 patients. Fluticasone alone was given to Group A and fluticasone in combination with Vit D to Group B. Total Nasal Symptom Score (TNSS) was evaluated at baseline, 4 weeks and 8 weeks, and the serum Vit D was measured. 80% of screened patients were found to have hypovitaminosis D. The TNSS gradually decreased in both groups, but Group B showed more improvement from 8.15 at baseline to 4.90 at 4 weeks and 2.77 at 8 weeks, while Group A went from 8.35 at baseline to 6.80 at 4 weeks and 5.24 at 8 weeks. There was a significant difference between the two groups in the post-treatment ($p < 0.0001$). Vit D could thus be an adjunctive medication providing extra symptomatic relief in Vit D deficient allergic rhinitis patients.

Keywords: Allergic rhinitis; Vitamin D; Total Nasal Symptom Score; Fluticasone; Supplementation

1. Introduction

Diagnostic radiology forms a critical part of contemporary clinical practice, contributing to the diagnosis and Sneezing, rhinorrhoea, nasal blockage, nasal itching, and frequently eye symptoms are all signs of allergic rhinorrhoea (AR), a common chronic inflammatory condition of the nasal mucosa. It is an immunoglobulin E (IgE) mediated reaction to environmental allergens which adds significantly to morbidity in various age groups (Bousquet et al., 2008). It is an important allergy worldwide due to its prevalence, recurrent nature and association with asthma and other atopic diseases (Pawankar et al., 2011). AR can last into adulthood and strongly affect functioning in everyday life, sleep, school and work performance (Greiner et al., 2011). The concept of a unified airway also underlines the close association between upper- and lower-airway allergic inflammation (Grossman, 1997).

The Allergic Rhinitis and its Impact on Asthma (ARIA) framework categorizes AR into intermittent and persistent, and mild and moderate-to-severe by duration and severity of symptoms, respectively (Bousquet et al., 2001). New ARIA recommendations focus on personalized care depending on the severity and duration of symptoms, comorbidities and treatment response (Brożek et al., 2017). As of today, AR is regarded as a complex inflammatory condition that is based on genetic susceptibility, environmental exposure, epithelial dysfunction and dysregulated immune responses (Akdis & Agache, 2014). New developments have been made and several molecular and cellular mechanisms leading to the initiation and persistence of disease have been identified (Singh et al., 2025).

Type 1 hypersensitivity response is the predominant mechanism in the pathogenesis of AR. After allergen exposure, antigen-presenting cells influence the differentiation of T-helper cells to a Th2 phenotype leading to IgE production through cytokines (Galli et al., 2008). To produce the typical nasal symptoms, mast cells are activated upon re-exposure to the allergen, leading to the release of histamine, leukotrienes and other mediators (Wallace et al., 2008). Chronic inflammation leads to mucosal hyperresponsiveness and increased chronic symptom burden (Small et al., 2018). Allergic disease has been on the rise in India contributing to urbanization, lifestyle changes, environmental pollution, and an increase in allergen exposure (Mahesh et al., 2023). Allergic respiratory disorders may be further affected by changes in pollen distribution and fungal sporulation as a result of climate change (Demain et al., 2021).

AR has also significant indirect costs due to less productivity and absenteeism (Blais, 2010). Antihistamines, intranasal corticosteroids, leukotriene-receptor antagonists, allergen immunotherapy, and allergen avoidance are all part of conventional treatment. Such therapies are effective in controlling symptoms, but there has been growing interest in adding therapies that can alter underlying immune responses (Small et al., 2018). Vitamin D (Vit D) has been of special interest in allergic diseases due to its immunomodulatory properties (Zhang et al., 2024). Several studies have demonstrated hypovitaminosis D in AR (Arshi et al., 2012). There is also epidemiological evidence that Vit D deficiency is associated with chronic rhinitis (Park & Park, 2024). The same associations were previously observed between serum Vit D level and the occurrence of AR (Wjst & Hyppönen, 2007). Vit D may regulate allergic inflammation via regulatory T cells (Tregs), dendritic cells, epithelial barrier function, and Th2-mediated responses (Tian & Cheng, 2017). Thus, clinical trials have been conducted to see if Vit D supplementation would help to enhance the outcomes of AR. Vit D supplementation was found to have clinical benefits in AR patients by Modh et al (2014). Also, Bhardwaj and Singh (2021) found that Vit D was beneficial when used as an adjunct. Bakhshaei et al. (2019) showed a beneficial effect in a randomized clinical trial. Guo (2023) reported on the increased therapeutic effect of Vit D plus intranasal mometasone.

The effect of Vit D status can also impact on the response to allergen immunotherapy (Li et al., 2023). House dust mites are a good reason for using oral supplementation during house dust mite allergy treatment (Chiewchalerm Sri et al., 2023). However, more recent studies have showed some differences in treatment response based on baseline Vit D status, the use of concomitant therapy, Vit D supplementation regimens and the length of follow-up (Kawada et al., 2025).

The variability confirms the need for additional controlled assessment of Vit D as an adjunct and not a replacement for the standard AR therapy. The purpose of present study was to assess the effectiveness of Vit D supplementation as an adjunctive treatment in AR patients. The study was limited to those with Vit D insufficiency treated with either fluticasone alone or fluticasone and Vit D supplementation. The aims were to evaluate changes in Total Nasal Symptom Score (TNSS) and to measure serum 25-hydroxyVit D (25-VD) levels, which were to compare the symptomatic recovery in both treatment groups.

2. Materials and Methods

2.1 Study Design and Setting

Randomized controlled study was conducted in the Otorhinolaryngology department at “National Institute of Medical Sciences and Research, NIMS University, Jaipur, Rajasthan” to assess the efficacy of “Vit D” as an adjunctive therapy to standard treatment of patients with allergic rhinitis. The study was undertaken after obtaining permission from the Scientific and Ethics Committee of the institution. All subjects signed informed consent forms after a study protocol was explained.

2.2 Screening and Study Population

300 AR patients attending the ENT OPD were screened for serum Vit D. Of these, 60 patients were Vit D normal (above 30 ng/mL), 130 patients were Vit D deficient (below 20 ng/mL) and 110 patients had Vit D insufficiency (between 20 and 29 ng/mL). The randomized study included just the 110 patients who had Vit D insufficiency. Patients with a normal Vit D level and those with Vit D deficiency were not randomized; the Vit D deficient patients needed to be treated with Vit D due to their deficiency.

2.3 Sample Size and Group Allocation

The final sample was comprised of 110 patients, divided into two groups of 55 patients. Patients were divided into Group A (standard treatment of fluticasone) and Group B (fluticasone with adjunctive Vit D). The study is indicated in the thesis as being randomized, but the method for the generation of the random allocation sequence, for concealment of allocation, and for blinding of the participants and investigators is not reported.

2.4 Inclusion Criteria

Patients were selected if they:

- had an AR allergy diagnosis;
- was either a male or female and of any age;
- had moderate-to-severe persistent allergic rhinitis;
- had serum 25-hydroxyvitamin D levels between 20 and 29 ng/mL; Had no clinical signs or symptoms of Vit D deficiency; and

While one statement in the thesis mentions “vitamin D deficiency,” the screening and participant-selection data provided indicate that only those with 'vitamin D insufficiency' (20-29 ng/mL) were recruited in the randomized comparison.

2.5 Exclusion Criteria

Patients with systemic comorbidities were excluded if they had, which may have an impact on Vit D levels, including Crohn's disease, thyroid dysfunction, ulcerative colitis, rickets, cystic fibrosis, and juvenile idiopathic arthritis. Those who were pregnant or breastfeeding were not included. Patients who had taken Vit D or omega 3 supplements in the last three months were also not included in the study.

2.6 Diagnostic Assessment and Data Collection

AR was diagnosed based on the guidelines from the AR and its Impact on Asthma and in line with clinical history and investigation. Specially designed a semi-structured proforma was used to obtain sociodemographic and clinical details. Allergic history, environment stimuli and past treatments were recorded.

2.7 Measurement of Serum Vitamin D

The concentration of serum 25-hydroxyvitamin D was determined by chemiluminescence immunoassay. Normal Vit D levels were defined as >30 ng/mL, Vit D deficiency was defined as <20 ng/mL, and Vit D insufficiency was defined as 20-29 ng/mL. Biochemical improvement was evaluated by measuring serum Vit D levels before and following treatment.

2.8 Clinical Assessment

AR symptoms were assessed by the TNSS. To determine the impact of symptoms on quality of life, the Rhino conjunctivitis Quality of Life Questionnaire was also part of the study protocol. TNSS and RQLQ scores were taken prior to treatment (baseline scores) and following the period of the study (post-intervention scores). TNSS was evaluated at 0, 4 and 8 weeks. The main clinical result was the change in TNSS during the study period and the difference in improvement in symptoms between the two treatment groups.

2.9 Intervention

Group A was treated with standard fluticasone treatment. Patients in Group B were given the fluticasone along with Vit D as an adjunctive therapy. Both groups were followed for 8 weeks and clinical assessment done at baseline, 4 weeks and 8 weeks. The dosage of Vit D supplementation, whether in the form of a supplement, injection, or from sunlight, is not specified, nor is the dosage regimen of fluticasone. These details should be provided upon submission of the research article from the original treatment protocol, prescription or case record forms.

2.10 Outcome Measures

Change in the TNSS from the baseline to 4 and 8 weeks after the intervention was the primary outcome measure. The secondary outcome measures were:

- change in serum Vit D levels after treatment;

- comparison of post-treatment TNSS between the two groups;
- change in RQLQ scores; and
- occurrence of adverse events during treatment.

During follow up serum Vit D was measured, along with symptom scores and adverse events, as reported in the thesis.

2.11 Statistical Analysis

Descriptive and inferential statistics were used to analyse the collected data. Frequencies and percentages were used to summarize categorical variables and mean values with relevant measures of dispersion were used to summarize continuous variables. Baseline and post treatments were compared within each group by paired t-tests. Independent-samples t-tests were performed to determine whether there was a difference in the TNSS and in serum Vit D level between the two treatment groups. The thesis does not provide details about the statistical software, software version, level of significance, confidence interval, the way the statistical assumptions were checked, or how missing data was handled. These should be included in the original statistical analysis plan prior to submission to the Journal.

3. Results

AR patients (n=300) were screened for serum Vit D status. Among them, 60 patients (20.0%) had normal Vit D levels, 130 (43.3%) were deficient, and 110 (36.7%) were insufficient. So, 80.0% of the population screened was hypovitaminosis D with 110 patients in each group (Group A and Group B) for the randomized study. Table 1 shows the distribution of Vit D status among the 300 screened patients, with 43.3% classified as deficient, 36.7% as insufficient, and only 20.0% having normal Vit D levels, indicating an overall hypovitaminosis D prevalence of 80%. Figure 1 shows the distribution of Vit D status among screened patients, visually highlighting that Vit D deficiency was the most common category, followed by insufficiency and normal Vit D status.

3.1 Vitamin D Status of Screened Patients

Table 1. Distribution of vitamin D status among screened patients

Vitamin D status	Number, n	Percentage
Normal (>30 ng/mL)	60	20.0%
Deficient (<20 ng/mL)	130	43.3%
Insufficient (20–29 ng/mL)	110	36.7%
Total	300	100.0%

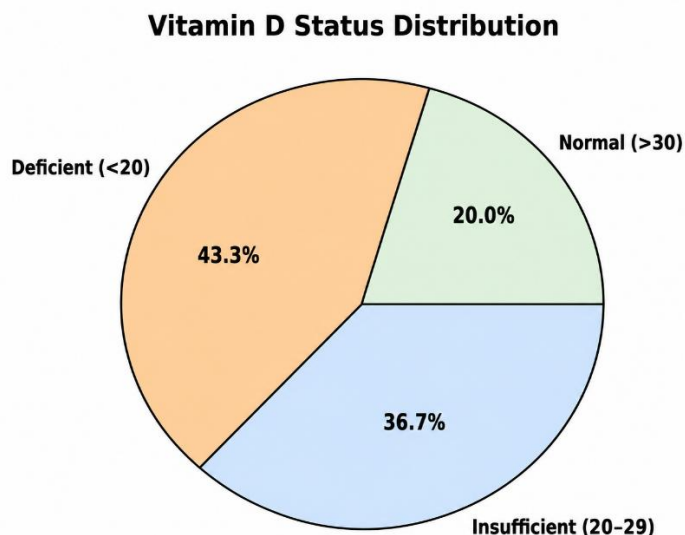


Figure 1. Distribution of vitamin D status among screened patients.

3.2 Demographic and Baseline Characteristics

Male participants accounted for 62 of the 110 total participants in the study, while females made up 48 out of 110 participants in the study. The highest age group was 41 - 50 years with 32 participants, followed by 31 - 40 years (27 participants) and 21 - 30 years (25 participants). All of the groups had similar baseline characteristics. The mean age for Group A and Group B was 36.27 years and 37.90 years, respectively, while

mean baseline serum Vit D level was 20.96 ng/mL and 21.02 ng/mL, respectively. The mean baseline TNSS for Group A and B was 8.35 and 8.15 respectively. There was no significant difference in TNSS between the baseline ($t = 0.904$, $p = 0.368$). Table 2 shows that the two treatment groups were comparable at baseline with respect to sample size, mean age, serum Vit D levels, and TNSS, with no significant difference in baseline TNSS ($p = 0.368$). Figure 2 shows the baseline comparison between the two treatment groups. Panel A presents the mean age, which was 36.27 years in Group A and 37.90 years in Group B; Panel B shows similar baseline serum Vit D levels of 20.96 ng/mL and 21.02 ng/mL, respectively; and Panel C demonstrates comparable baseline TNSS values of 8.35 in Group A and 8.15 in Group B.

Table 2. Demographic and baseline characteristics of the study participants

Characteristic	Group A: Fluticasone	Group B: Fluticasone + vitamin D
Number of participants	55	55
Mean age, years	36.27	37.90
Mean baseline vitamin D, ng/mL	20.96	21.02
Mean baseline TNSS	8.35	8.15
Baseline TNSS comparison	$t = 0.904$, $p = 0.368$	

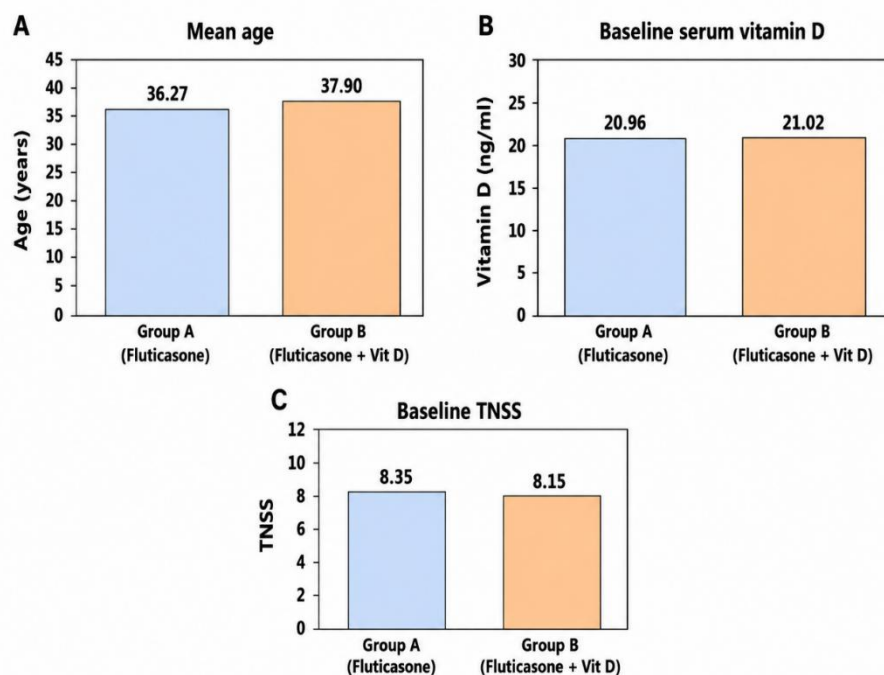


Figure 2. Baseline comparison of (A) mean age, (B) serum vitamin D levels, and (C) Total Nasal Symptom Score (TNSS) between Group A (Fluticasone) and Group B (Fluticasone + Vitamin D).

3.3 Changes in Total Nasal Symptom Score

TNSS gradually decreased in both groups throughout the 8 weeks follow-up. For Group A, the mean TNSS at baseline was 8.35, and at 4 and 8 weeks was 6.80 and 5.24, respectively. In group B, the mean TNSS was 8.15 at baseline, 4.90 at 4 weeks and 2.77 at 8 weeks. Reduction from baseline to 8wk was statistically significant for both groups in the context of the reduction in TNSS. The paired-samples analysis gave a t -value of 26.39, and the p value was < 0.0001 in Group A. In Group B, the corresponding t -value was 34.61 with $p < 0.0001$. The post-treatment TNSS was significantly different between the groups at 8 weeks ($p < 0.0001$, $t = 8.43$) favouring Group B. Table 3 shows a progressive reduction in TNSS in both groups from baseline to 8 weeks, with a greater decline in Group B receiving fluticasone plus Vit D than in Group A receiving fluticasone alone. Figure 3 shows the change in mean TNSS at baseline, 4 weeks, and 8 weeks, demonstrating a steeper and more sustained reduction in symptom severity in Group B compared with Group A.

Table 3. Comparison of TNSS between treatment groups over time

Time point	Group A: Fluticasone	Group B: Fluticasone + vitamin D
Baseline	8.35	8.15
4 weeks	6.80	4.90
8 weeks	5.24	2.77
Change from baseline to 8 weeks	-3.11	-5.38

Within-group statistical result	$t = 26.39, p < 0.0001$	$t = 34.61, p < 0.0001$
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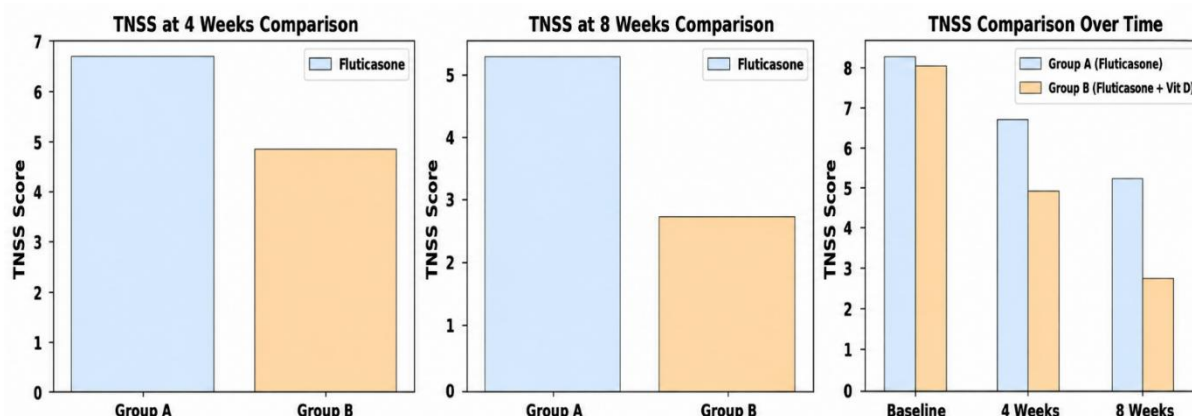


Figure 3. Change in mean TNSS at baseline, 4 weeks, and 8 weeks in both treatment groups.

3.4 Changes in Serum Vitamin D Levels

The initial Vit D levels were similar for both groups. The serum Vit D level rose significantly in Group A from 20.96 to 38.64 ng/mL, and in Group B from 21.02 to 39.15 ng/mL at follow-up. Corresponding increase were 17.68 and 18.13 ng/mL, respectively. Both groups had significant improvement in Vit D levels, but the change in Vit D between the groups was not statistically significant ($t = -0.42, P = 0.678$). Table 4 shows that serum Vit D levels increased substantially after treatment in both groups, although the difference in the magnitude of improvement between the groups was not statistically significant ($p = 0.678$). Figure 4 shows the baseline and post-treatment serum Vit D levels in both treatment groups, illustrating marked biochemical improvement in each group with only a minimal difference between them.

Table 4. Comparison of serum vitamin D levels before and after treatment

Measurement	Group A: Fluticasone	Group B: Fluticasone + vitamin D
Baseline vitamin D, ng/mL	20.96	21.02
Post-treatment vitamin D, ng/mL	38.64	39.15
Mean change, ng/mL	+17.68	+18.13
Between-group comparison of change	$t = -0.42, p = 0.678$	

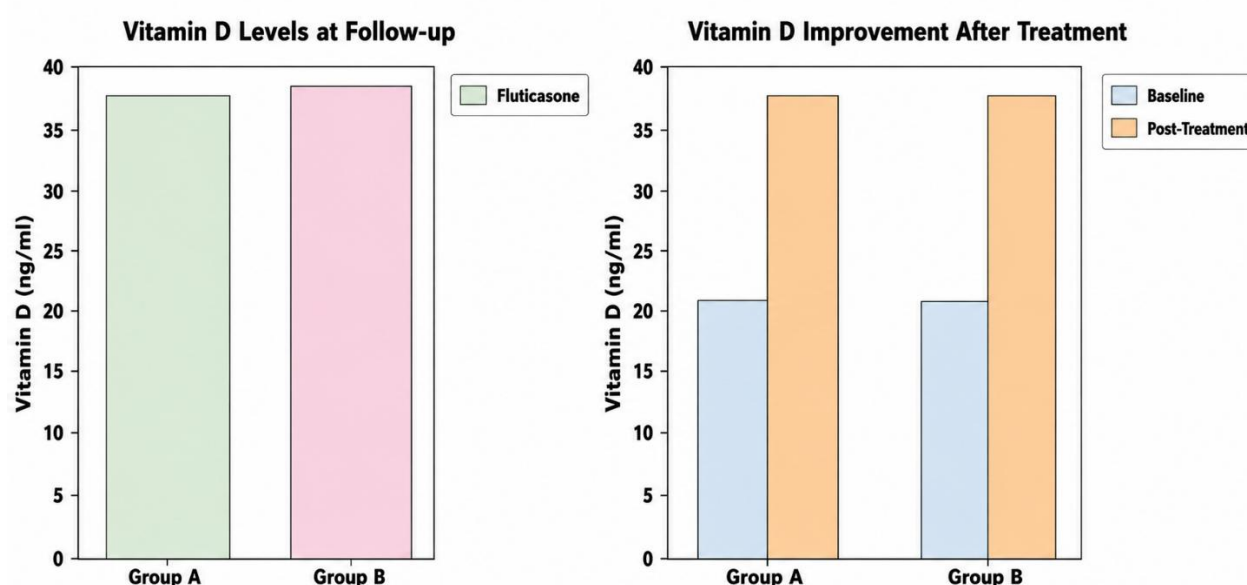


Figure 4. Baseline and post-treatment serum vitamin D levels in Group A and Group B.

3.5 Adverse Events

Overall treatment was well tolerated. The adverse effects were not reported by 72 subjects (65.5%). Mild headache was experienced by 21 (19.1 %) and the nose irritation by 17 (15.5%) participants. No serious or life-threatening side effects were reported.

4. Discussion

AR is a chronic disorder of IgE mediated inflammatory nature of nasal mucosa which negatively impacts sleep, daily activities, work productivity and quality of life. Besides the traditional pharmacologic therapy, Vit D has gained more and more interest as a potential immunomodulatory agent involved in allergic inflammation.

The present study aimed to assess the impact of Vit D supplementation added to fluticasone therapy in AR and Vit D deficient patients. The study population was predominantly middle-aged, with 41–50 years being the most prevalent age group followed by the 31–40 years age group and the 21–30 years age group. This distribution shows that AR is still clinically significant for people in their economically active age groups. This is consistent with previous reports of the significant burden of AR in adults (Small et al., 2018). Another finding of the study was that the two sexes were reasonably represented with a slight male predominance. Similar trend was reported in patients who received Vit D supplements for AR (Bhardwaj & Singh, 2021). However, the prevalence of AR is thought to be equal between males and females and may be different in various populations and environments (Tian & Cheng, 2017).

Baseline Vit D levels were low in all age groups and there was minimal difference between boys and girls. The mean serum Vit D level was 20.99 ng/mL, indicating Vit D insufficiency in the subjects of this study. Reduced levels of Vit D have been documented in allergy patients with AR (Arshi et al., 2012) as well. Epidemiological studies have also found an association between Vit D status and AR (Wjst & Hyppönen, 2007). Further, more recent evidence has indicated that low Vit D levels may be associated with chronic rhinitis, especially in adults (Park & Park, 2024). There were no significant differences between the two groups with respect to age, serum Vit D levels or TNSS at baseline. There was no significant difference in baseline TNSS, which was used to confirm the pre-treatment comparability of the groups. In randomized studies, comparable baseline characteristics play a crucial role as they enable a more reliable interpretation of the differences after treatment as treatment-related differences.

The Vit D supplementation group showed more symptom improvement compared to the other group, with both showing progressive decreases of TNSS in follow-up. After 8 weeks, the mean TNSS scores were 5.24 and 2.77 for Group A and Group B, respectively. This consistent improvement with adjunctive Vit D treatment is in agreement with earlier evidence of Vit D supplementation beneficial in the symptomatic treatment of AR (Modh et al., 2014). This improvement has been shown with the use of Vit D in combination with conventional treatment (Bhardwaj & Singh, 2021). Vit D was also shown to have therapeutic effects after supplementation in AR in a randomized trial (Bakhshaei et al., 2019). Similar results have been described in the use of intranasal corticosteroid therapy plus Vit D (Guo, 2023). Both groups showed highly significant between-group differences in TNSS from baseline to 8 weeks, with a significant advantage for the combination therapy.

These results indicate that fluticasone worked in both groups, and that Vit D in combination with fluticasone resulted in more symptomatic improvement. Vit D could do this via controlling regulatory T cells, the function of dendritic cells, cytokine expression and Th2-mediated allergic responses (Zhang et al., 2024). It has also been highlighted in previous mechanistic reviews in AR (Tian & Cheng, 2017). Both groups experienced significant rises in serum Vit D levels with the magnitude of this rise not being significantly different between groups. This suggests that the greater rise in Vit D in Group B does not account for the better symptomatic effect. This discovery could instead prove beneficial for an immunomodulatory role of Vit D in symptom control. Recent meta-analytic data suggest, however, that there is some variability in outcomes based on baseline Vit D status and Vit D supplement regimen, concomitant therapy, and study duration (Kawada et al., 2025).

Overall, treatment was well-tolerated, with most participants reporting no treatment-related side effects, and mild headache or nasal irritation in those who did experience treatment-related events. In conclusion, the results are overall positive for the potential use of ADJVITD in controlling AR symptoms. The major strength of the study was the randomized controlled design, inclusion of baseline assessment of serum Vit D, and direct comparison of treatment groups. Some limitations were the, relatively small, number of patients (n = 60), the short follow-up time (8 weeks) and the single-center design, exclusion of Vit D levels less than 20 ng/mL and the absence of evaluation of potential confounders including sun exposure and lifestyle/diet.

5. Conclusion

This current study aimed to assess the effectiveness of Vit D supplementation in addition to intranasal corticosteroid (INCS) for AR patients. Hypovitaminosis D was frequently found regardless of age and gender, suggesting that hypovitaminosis D is a significant problem in AR patients. In both treatment groups the TNSS improved significantly during the study period, indicating the efficacy of the standard intranasal corticosteroid treatment. Patients taking fluticasone and adjunctive Vit D, however, showed a greater, more rapid and sustained decrease in TNSS at 4 and 8 weeks than those taking fluticasone alone. The difference between the groups after the post treatment was statistically significant in favor of an added clinical advantage of the Vit D supplementation. There was a rise in serum Vit D in both groups with the difference in biochemical improvement between the groups not being significant. This indicates that the additional symptoms improvement seen with adjunctive Vit D is not only due to increased serum Vit D but may also be due to the immunomodulatory properties. The adverse effects were mild and both treatments were well tolerated. In conclusion, Vit D supplementation seems to be safe and clinically beneficial as an addition to conventional treatment in allergic rhinitis, especially in people with underlying Vit D deficiency. The results also underline the need to be aware of and treat hypovitaminosis D in this population.

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