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ORIGINAL ARTICLE

# Assessment of Rhinitis Control Assessment Test Score after Vitamin D Supplementation along with Standard Regimen in Patients of Allergic Rhinitis – A Prospective Randomized Control Trial

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**Background:** Allergic rhinitis (AR) affects 10%–20% of the global population, significantly impacting daily activities and quality of life. It has varied clinical presentations including sneezing, nasal discharge, and watering and itching in the eyes. The role of Vitamin D supplementation has been considered nowadays as one of the important aspects in the management of AR, and the same was assessed in the present study. **Aim:** Assessment and comparison of Rhinitis Control Assessment Test (RCAT) and TNSS score in patients of AR in both the groups. **Methods:** This 18-month randomized controlled trial was conducted in 160 patients of AR divided into two groups (Group A = standard regimen and Group B = Vitamin D supplementation along with standard regimen). The study was carried out to assess the RCAT and TNSS scores post-Vitamin D supplementation along with standard regimen. The collected data were analyzed using SPSS software. **Results:** The pre- and posttreatment TNSS were calculated for both the groups (pretreatment Group A = 10.06 ± 1.56 and Group B = 11.59 ± 1.29; posttreatment Group A = 5.01 ± 0.01, Group B = 2.59 ± 0.49). The posttreatment RCAT scores were significantly higher in Group B (28.60 ± 0.98) as compared to Group A (20.96 ± 1.40). Therefore, Group B showed statistically significant improvement in both RCAT and TNSS scores compared to Group A implying a positive effect of Vitamin D supplementation. **Conclusion:** Vitamin D supplementation along with standard regimen showed significant improvement in the symptomatology and quality of life in AR patients due to its immunomodulation property as assessed by TNSS and RCAT score.

Key words: Allergic rhinitis, Vitamin $D_3$, Rhinitis Control Assessment Test, Total Nasal Symptom Score

## INTRODUCTION

Allergic rhinitis (AR) affects 10%–20% of the global population. Despite its negative impact on quality of life and work performance, very few percentages of individuals seek medical advice. Therefore, as a result of patients' negligience, allergic rhinitis is being underdiagnosed and inadequately managed.[1,2] Frequent symptoms of AR include nasal congestion, sneezing, and redness and itching in the eyes. These symptoms are considered to be originating because of an immunologic overreaction to common allergens such as pollen, dust, hay, and dander. AR burden can be possibly estimated by its frequent co-occurrence with asthma. Almost 40% of the population suffering from AR is at risk of developing asthma in their lifetime. This highlights the need for integrated management of these upper and lower respiratory tract allergies and infections.[3] The condition's increased prevalence and negative impact on daily routine life have sparked extensive research into its management strategies, with a particular focus on the role of micronutrients such as Vitamin $D_3$. Vitamin $D_3$, which has been traditionally known for its crucial role in bone health, has now been increasingly identified as a modulator of immune responses, thus alleviating allergic symptoms. Recent studies suggest that Vitamin D deficiency may be linked to heightened susceptibility to allergic diseases by influencing immune system regulation, particularly within the mucosal barriers of airway.

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Therefore, it offers a potentially valuable adjunct to standard pharmacological treatments for AR. The common Vitamin D exogenous sources include ultraviolet B radiation-induced skin synthesis, diet, and supplements.[4-6] Vitamin D endogenous production is influenced by genetic determinants, latitude, season, skin pigmentation and lifestyle.[7]

Comprehensive management of AR involves antihistamines, corticosteroids (oral and topical), and immunotherapy. The relationship between Vitamin D and allergic diseases including asthma has been a subject of numerous studies. Yet, the outcomes remain inconclusive, necessitating further exploration to establish a clearer understanding of the role of Vitamin D in managing allergic rhinitis (AR).[7] The purpose of this study was to understand the role of Vitamin D in the management of AR by assessing and comparing the Rhinitis Control Assessment Test (RCAT) and TNSS scores in both the groups.

## MATERIALS AND METHODS

A prospective randomized controlled trial was done on 160 patients aged 18–60 years divided into two matched groups. The participants were divided according to stratified randomization and single blinding was ensured. The patients having classical symptoms of AR were included in the study; however, patients with non-AR, nasal comorbidities, and taking Vitamin D-affecting medications (e.g., lipid-lowering drugs) were excluded from the study. Patient demographic factors and other confounding factors were duly considered prior to the commencement of the study. Group A received topical steroid in the form of spray + antihistamines and Group B received topical steroids + antihistamines + Vitamin D (60,000 IU once weekly) for 4 weeks each. All patients were reviewed at the 5$^{th}$ week, after 4 weeks of completion of therapy.

Levels of serum Vitamin D and Total Nasal Symptom Score (TNSS) were measured both before and after the treatment period for both the groups. The RCAT data were collected posttreatment.

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of Bhagat Phool Singh Government Medical College for Women, Khanpur Kalan, Sonipat (Protocol no. BPSGMCW/RC836/IEC/22, Dated:18/11/2022). Written informed consent was obtained from the participants in a designed proforma.

Data collected were subjected to the mean and standard deviation (mean ± SD) calculation for quantitative data. For comparison between mean differences of Group A and Group B, statistical Package for the Social Sciences (SPSS, IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. IBM Corp., Armonk, NY, USA) was used. $P < 0.05$ was considered significant. Treatment efficacy was assessed using Total Nasal Symptom Scores (TNSS) and the RCAT.

TNSS score includes the following four parameters:

- Nasal congestion
- Sneezing
- Rhinorrhea
- Nasal itching.

Scores were graded from 0 (none) to 3 (very severe).

Posttreatment RCAT questionnaire included six questions:

- During the past week, how often did you have nasal congestion?
- During the past week, how often did you sneeze?
- During the past week, how often did you have watery eyes?
- During the past week, to what extent did nasal or other allergy symptoms interfere with your sleep?
- During the past week, how often did you avoid any activities because of nasal or other allergy symptoms?
- During the past week, how well your nasal or other allergy symptoms were controlled?

The responses were graded from never (0) to extremely often.[5]

## RESULTS

The present study was conducted on 160 patients divided across two matched groups: Group A, following the standard regimen, and Group B, receiving Vitamin D in addition to the standard regimen. The sociodemographic characteristics of the participants in this study were analyzed. Majority of the patients belonged to 40–49 years of age group in both the groups: Group A had 34 (42.5%); Group B had 38 (47.5%). Group A had male predominance, and Group B had female predominance. On the basis of education, majority of Group A participants were illiterate (43.8%), followed by middle school education (20.0%), while in Group B, the highest percentage also belonged to illiterate (47.5%), with (21%) receiving middle school education. Regarding occupation, the most common category in both the groups was unemployed/homemaker (43.8% in Group A and 42.5% in Group B), followed by semiprofessional and semiskilled workers. According to socio-economic status, maximum number of Group A participants (68.8%) belonged to the middle socio-economic status, followed by lower (26.8%), and upper (5.0%) socio-economic status. Similarly, in Group B maximum participants belonged to middle socio-economic status (70.0%), followed by lower (23.8%), and upper (6.3%) socio-economic status. Overall, the distribution of socio-demographic characteristics between the two groups were similar.

Rhinorrhea was the most common presenting symptom (Group A = 70% and Group B = 77.5%), followed by sneezing (Group A = 52.5% and Group B = 56.3%), itchy nose (Group A = 25% and Group B = 31.3%), and itching and watery eyes (Group A = 15% and Group B = 16.3%). Family history played a significant role in 70% of patients in Group A and 67.5% in Group B as they had a positive family history of AR. Pollen exposure was the most common allergen exposure among both the groups (Group A = 41.35 and Group B = 43.8%), with animal dander exposure, flooring, mold, and tobacco exposure being the other less common allergen exposure in both the groups. Baseline serum Vitamin $D_3$ levels were calculated for both the groups outlined in Table 1 and Figure 1. The details of posttreatment Vitamin $D_3$ levels among Group B are outlined in Table 2. The comparison of pre- and posttreatment mean Vitamin D levels was done for Group B, as mentioned in Table 3. Pre- and posttreatment TNSS and posttreatment RCAT scores were calculated for all the cases in both the groups. Vitamin $D_3$ supplementation in Group B revealed significant improvement in their symptoms, as shown by improved TNSS and RCAT scores. The details of pre- and posttreatment TNSS are outlined in Table 4 and Figure 2. The posttreatment RCAT score details are outlined in Table 5 (posttreatment).

Table 1: Distribution of study subjects according to baseline Vitamin $D_3$ levels

| Vitamin $D_3$ levels | Group A (standard regimen) - frequency, *n* (%) | Group B (Vitamin-D + standard regimen) - frequency, *n* (%) |
|---|---|---|
| 30–100 ng/mL (sufficient) | 25 (31.3) | 24 (30.0) |
| 20–29 ng/mL (insufficient) | 36 (45.0) | 38 (47.5) |
| <20 ng/mL (deficient) | 19 (23.8) | 18 (22.5) |
| Total | 80 (100.0) | 80 (100.0) |

Table 2: Posttreatment Vitamin $D_3$ levels in Group B

| Vitamin $D_3$ levels | Group B (Vitamin-D + standard regimen) - frequency, n (%) |
|---|---|
| 30–100 ng/mL (sufficient) | 43 (53.8) |
| 20–29 ng/mL (insufficient) | 24 (30.0) |
| <20 ng/mL (deficient) | 13 (16.2) |
| Total | 80 (100.0) |

Table 3: Comparison of mean Vitamin D levels pre- and posttreatment in Group B

| Variables | Pretreatment | Posttreatment | *t* (unpaired *t*-test) | *P* |
|---|---|---|---|---|
| Serum Vitamin-$D_3$ levels (IU/mL) | 24.54±9.80 | 30.62±14.49 | −6.756 | <0.01 |

## DISCUSSION

In the present study, 80 participants were recruited in two groups (Groups A and B). Group A participants received standard treatment regimen i.e. antihistamines and steroid nasal spray, while Group B, along with standard regimen received Vitamin D supplementation also. Maximum number of patients belonged to 40–49 years of age group (Group A = 34 [42.5%] and Group B = 38 [47.5%]), followed by 30–39 years of age group (Group A = 31 [38.7%] and Group B = 23 [28.7%]), 50–60 years of age group (Group A = 12 [15%] and Group B = 16 [21.3%]) and 3 (3.8%) individuals 18–29 years of age group (Group A = 3 [3.8%] and Group B = 2 [2.5%]). Group A had male predominance (62.5%), while Group B had female predominance (55%). In accordance with a study done by Restimulia *et al*.,[8] 36 patients having AR with Vitamin D deficiency were selected and divided into two groups: experimental group (*n* = 19) having 10 males and 9 females received Vitamin $D_3$ along with fluticasone furoate nasal spray, whereas control group (*n* = 17) having eight males and nine females was given placebo along with fluticasone furoate.

In the present study, the effects of two different treatment regimens were assessed on symptomatology and rhinitis control in the form of two scoring systems: TNSS (pre- and posttreatment) and RCAT (posttreatment). The mean TNSS (pretreatment) for Group A was 10.06 ± 1.56, while Group B scored 11.59 ± 1.29. The results showed that Group B had higher Total Nasal Symptom Scores (TNSS) suggesting more severe symptoms and poorer rhinitis control compared to Group A. While assessing the posttreatment scores, the findings were quite reversed; Group B showed improved scores in both TNSS and RCAT compared to Group A, suggesting a beneficial effect of Vitamin D supplementation. The TNSS decreased to 2.59 ± 0.49 in Group B and Group A had 5.01 ± 0.01. RCAT scores were improved markedly to 28.60 ± 0.98 in Group B compared to 20.96 ± 1.40 in Group A. A similar study by

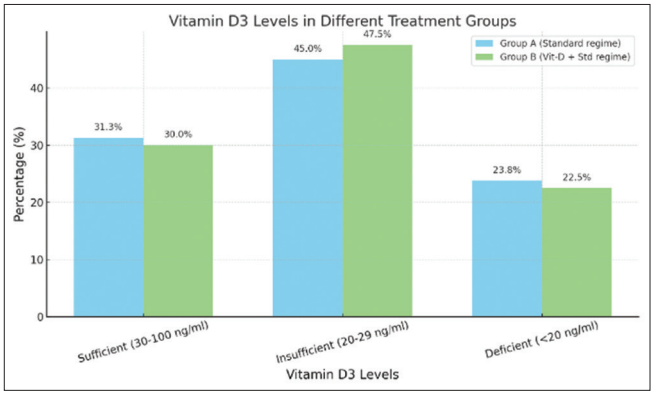


**Figure 1:** Serum Vitamin $D_3$ levels pretreatment in Groups A and B

Table 4: Pre- and posttreatment Total Nasal Symptom Score in Groups A and B

| Scores | Group A (standard regimen), mean±SD | Group B (Vitamin-D + standard regimen), mean±SD | *P* |
|---|---|---|---|
| Pretreatment | 10.06±1.56 | 11.59±1.29 | <0.01 |
| Posttreatment | 5.01±0.01 | 2.59±0.49 | 0.000172 |

SD=Standard deviation

Table 5: Posttreatment Rhinitis Control Assessment Test score in Groups A and B

| Scores | Group A (standard regimen), mean±SD | Group B (Vitamin D + standard regimen), mean±SD | *P* |
|---|---|---|---|
| RCAT score | 20.96±1.40 | 28.60±0.98 | 0.00532 |

RCAT=Rhinitis Control Assessment Test; SD=Standard deviation

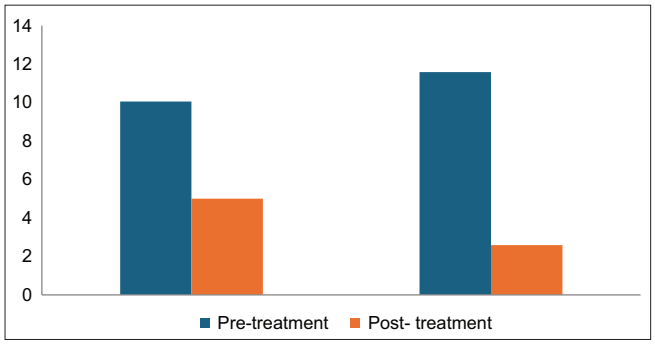


**Figure 2:** Pre- and posttreatment TNSS scores in Groups A and B

Bhardwaj *et al.*[9] included 89 patients of AR divided into two groups (Group A = received fluticasone nasal spray and Group B = fluticasone spray with Vitamin D supplementation). Pre- and posttreatment TNSS and posttreatment RCAT scores were calculated among both the groups. The mean pretreatment and posttreatment TNSS score in Group A was 12.5 ± 2.68 and 8.98 ± 1.009 and Group B (11.64 ± 3.09 and 6.3 ± 1.45), respectively. The difference of pretreatment and posttreatment score improvement was more in Group B (5.34) as compared to Group A (3.52). The mean posttreatment RCAT score in Group A and Group B was 28.2 ± 1.53 and 19.72 ± 2.84, respectively, showing marked improvement of symptom control in Group B. In a study carried by Restimulia *et al.,*[8] patients were divided into placebo group(receiving standard treatment) and experimental group (receiving standard treatment + Vitamin D supplementation). The TNSS score was calculated for both the groups. In the placebo group, TNSS score was 6.47 pre-treatment and was 3.94 post treatment while in experimental group it was 7.16 pre-treatment and 2.58 post treatment. This proves that Vitamin D supplementation has positive role in managing patients of allergic rhinitis as shown by improved TNSS score. This proves that Vitamin D supplementation has a positive role in managing patients of AR as shown by improved TNSS score.

In a similar study by Modh *et al.,*[10] comprising 21 patients suffering from AR in each control and test group. In Test group, Tab Fexofenadine was given to patient with TNSS score < 10 and Fluticasone nasal spray in patients with TNSS score >11 which was then followed by Oral Vitamin $D_3$ supplementation (Cholecalciferol 1000 IU) for 21 days in cases of Vit D deficiency, while in the patients of Control group received same treatment without Vitamin $D_3$ supplementation. Pre and post treatment TNSS score were assessed. In the test group, mean TNSS score pre-treatment was 10.6±2.65 and post treatment it significantly reduced to 2.76±1.6. Therefore, supporting the role of Vitamin $D_3$ supplementation in patients of allergic rhinitis. Pre- and posttreatment TNSS scores were assessed. In the test group, the mean TNSS score pretreatment was 10.6 ± 2.65, and posttreatment, it significantly reduced to 2.76 ± 1.6, as seen in the present study, thus supporting the role of Vitamin $D_3$ supplementation in patients of AR.

## CONCLUSION

This study concluded that Vitamin D supplementation along with the standard regimen alters the natural course of disease due to its immunomodulation property, thereby enhancing the treatment efficacy and better outcomes in AR patients. However, more studies with a larger sample size are required to be conducted to validate the role of Vitamin D supplementation in AR.

### Data availability statement

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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