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Association of Vitamin D and Allergic Rhinitis: A Clinical Study in the Indian Population.

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ABSTRACT

Introduction: Allergic rhinitis (AR) is a prevalent condition in India, driven by IgE-mediated inflammation, with potential links to vitamin D deficiency due to its immunomodulatory effects. This study investigates serum 25-hydroxyvitamin D (25(OH)D) levels and AR severity in an Indian cohort.

Materials and Methods: This cross-sectional study (May 2023–April 2024) at Pt. B.D. Sharma PGIMS, Rohtak, enrolled 138 adults (72 AR cases, 66 controls). AR was diagnosed per Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines [1]. Serum 25(OH)D, IgE, and absolute eosinophil count (AEC) were measured; interleukin (IL-4, IL-5, IL-13) data were unavailable due to assay issues. Severity was assessed via Sino-Nasal Outcome Test-22 (SNOT-22). Comparisons used t-tests or Mann-Whitney U tests; correlations used Spearman's coefficient, adjusting for age, sex, BMI, and sun exposure.

Results: AR cases showed significant symptoms (nasal obstruction 90.3%, sneezing 100%, eye redness/itching 81.9%; $p \leq 0.01$) and elevated IgE ($p<0.001$) vs. controls. No differences were found in 25(OH)D (79.2% cases vs. 86.4% controls deficient, $p=0.18$) or AEC ($p=0.16$). 25(OH)D did not correlate with SNOT-22 scores ($r_s=-0.12$, $p=0.31$).

Conclusion: AR's burden and IgE-mediated etiology are confirmed, but 25(OH)D showed no association with AR prevalence or severity, likely due to high deficiency (82.6%) in India. These findings guide otorhinolaryngology practice in high-deficiency populations.

Keywords: Allergic rhinitis, vitamin D, 25-hydroxyvitamin D, IgE, India

INTRODUCTION

Allergic rhinitis (AR) is a chronic condition characterized by nasal congestion, rhinorrhea, sneezing, and itching, driven by IgE-mediated inflammation triggered by allergen exposure [1]. Globally, AR affects 10–30% of the population, with prevalence reaching 45% in parts of Asia, including Indonesia [2]. In India, AR is a significant public health issue, with prevalence rates of 11.9% and 24.4% among children aged 6–7 and 13–14 years, respectively, and symptoms reported in 75% of children and 80% of asthmatic adults [3]. Urbanization, indoor lifestyles, and dietary shifts in India may exacerbate AR and contribute to widespread vitamin D deficiency, a

potential immunomodulatory factor [4]. AR impairs quality of life, disrupting sleep, work, and social activities, making it a critical focus for otorhinolaryngology in India.

Vitamin D, a secosteroid synthesized via ultraviolet B (UVB) exposure or dietary sources (e.g., fatty fish), modulates immunity through receptors on T-cells, B-cells, and macrophages [5,6]. It regulates Th1/Th2 cytokine balance, promotes antimicrobial peptides (e.g., cathelicidin), and inhibits proinflammatory cytokines, potentially reducing allergic inflammation [6]. Studies link low serum 25-hydroxyvitamin D (25(OH)D) to atopic conditions, with some reporting higher AR prevalence and severity with deficiency [7,8]. A meta-analysis noted increased AR risk with low 25(OH)D [9], but findings are inconsistent, with some studies showing no association [10,11]. Clinical trials suggest vitamin D supplementation may alleviate AR symptoms and enhance corticosteroid efficacy, yet optimal levels remain undefined [12,13]. This study investigates 25(OH)D's role in AR severity in an Indian cohort, aiming to inform evidence-based otorhinolaryngology strategies in high-deficiency populations.

MATERIALS AND METHODS

Study Design

This cross-sectional study, conducted at the Department of ENT and Biochemistry, Pt. B.D. Sharma PGIMS, Rohtak, India (May 2023–April 2024), compared 25(OH)D, eosinophilia, and interleukin (IL-4, IL-5, IL-13) levels between AR patients and age-matched controls. The secondary objective was to correlate 25(OH)D with AR severity.

Study Population

Participants were adults (≥18 years) presenting at the ENT outpatient clinic. AR cases were diagnosed per ARIA guidelines [1]. Controls had non-allergic ENT conditions (e.g., chronic otitis media) without AR or conditions affecting vitamin D/interleukins. Informed consent and ethical approval (IEC/2023/045) were obtained.

Inclusion Criteria

- AR diagnosis per ARIA guidelines [1].
- Age ≥18 years, either sex.
- Written informed consent.

Exclusion Criteria

- Age <18 years.
- Nasal polyposis.
- Comorbidities affecting vitamin D or interleukins (e.g., kidney disease, autoimmune disorders).
- Bronchial asthma.
- Medications affecting 25(OH)D (e.g., corticosteroids, vitamin D supplements).
- Pregnant or lactating females.

Sample Size

Based on a 10% AR prevalence in India [3], a sample size of 138 (72 cases, 66 controls) was calculated using:

$n = (Z1-\alpha/2)^2 \times p \times q / d^2$

where $Z_{1-\alpha/2} = 1.96$, $p = 0.10$, $q = 0.90$, and $d = 0.05$. A power calculation for 25(OH)D differences (effect size=0.5, α=0.05, power=80%) confirmed adequacy (n≈130).

Data Collection

Clinical Evaluation:

- **History**: Recorded AR symptoms (nasal congestion, rhinorrhea, sneezing, itching), onset, duration, frequency, and ear/throat history.
- **Examination**: Included physical exam, anterior/posterior rhinoscopy, and nasal endoscopy. AR severity was assessed via Sino-Nasal Outcome Test-22 (SNOT-22) [14].
- **Investigations**:
  - Complete blood count (hemoglobin, total leukocyte count, differential, AEC).
  - Biochemical markers (blood urea, creatinine, SGOT, SGPT, random blood sugar).
  - Serum 25(OH)D was measured using a chemiluminescent immunoassay (sensitivity: 4 ng/mL; specificity: 99.5%). Levels <20 ng/mL were classified as deficient, and levels of 20–30 ng/mL as insufficient [5].
  - Serum IgE was measured using ELISA (sensitivity: 5 IU/mL; specificity: 98%).
  - IL-4, IL-5, and IL-13 measurements were planned but could not be performed because the reagents degraded during storage.
  - Urine examination to rule out systemic conditions.

Control Group

Controls had no AR or allergic conditions, presenting for chronic otitis media, and underwent identical evaluations.

Study Procedure

AR was confirmed according to ARIA criteria (≥2 symptoms for >1 hour on most days for ≥2 consecutive days) [1]. Blood samples were processed at PGIMS Biochemistry using standardized protocols. Data were recorded in a structured proforma.

Statistical Analysis

Data were analyzed using SPSS (version 26.0). Normality was assessed using the Shapiro–Wilk test. Descriptive statistics (mean ± SD, median, and interquartile range [IQR]) were used to summarize participant characteristics. Between-group comparisons were performed using t-tests for normally distributed data and Mann–Whitney U tests for non-normally distributed data. Spearman's correlation was used to assess the relationship between 25(OH)D levels and SNOT-22 scores. Multivariable regression was adjusted for age, sex, BMI, and sun exposure. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study adhered to the Declaration of Helsinki. Informed consent detailed purpose, procedures, and risks. Confidentiality was ensured via data anonymization, and participants could withdraw without affecting care.

RESULTS

Participant Characteristics

Of the 138 participants, 72 were AR cases (mean age, 28.67 ± 5.2 years; 48.6% male and 51.4% female) and 66 were controls (mean age, 29.12 ± 4.8 years; 40.9% male and 59.1% female). No significant differences were observed in age (p=0.74) or sex (p=0.36).

Symptom Profile

Table 1 summarizes symptoms, with significant differences between cases and controls (p≤0.05):

- Nasal obstruction: 90.3%.
- Nasal discharge: 94.4%.
- Sneezing: 100%.
- Post-nasal drip: 6.9%.
- Headache: 8.3%.
- Hyposmia/anosmia: 34.7%.
- Halitosis: 30.5%.
- Eye redness/itching: 81.9%.
- Ear pain/fullness: 61.1%.
- Family history of allergy: 30.5%.

Symptoms and characteristics absent in both groups included facial pain, fever, dental pain, cough, and a history of smoking. In cases, 54.2% had intermittent symptoms, 45.8% persistent. SNOT-22 scores indicated mild (50.0%), moderate (48.6%), or severe (1.4%) severity.

Table 1: Symptom prevalence in AR cases and controls

Symptom	Cases (% Positive)	Controls (% Positive)	P-value
Nasal obstruction	90.3	0	0.01
Nasal discharge	94.4	0	0.01
Sneezing	100	0	0.01
Post-nasal drip	6.9	0	0.02
Headache	8.3	0	0.01
Hyposmia/Anosmia	34.7	0	0.01
Halitosis	30.5	0	0.01
Eye redness/itching	81.9	0	0.001
Ear pain/fullness	61.1	0	0.001
Family history (allergy)	30.5	0	0.01

Clinical Findings

Anterior rhinoscopy revealed nasal secretions in 87.5% of cases and 0% of controls (p=0.003). The nasal mucosa was pale in 61.1% and congested in 5.6% of cases; it was normal in controls (p=0.001). Ear discharge in controls (bilateral: 31.8%, left: 30.3%, right: 37.9%; p=0.56) reflected chronic otitis media, a common ENT condition in India.

Laboratory Findings

Table 2 shows blood parameters with significant differences:

- Platelet count (PLC): 2.53±0.68×10^5/μL (cases) vs. 2.22±0.43×10^5/μL (controls; p=0.002).
- Prothrombin time (PT): 12.13±1.05 s vs. 12.74±0.71 s (p=0.001).
- International normalized ratio (INR): 1.009±0.109 vs. 0.93±0.07 (p=0.001).

- Blood urea: 20.76±4.14 mg/dL vs. 22.45±3.17 mg/dL (p=0.008).
- Serum creatinine: 0.73±0.13 mg/dL vs. 0.92±0.101 mg/dL (p=0.001).
- SGOT: 35.69±8.89 U/L vs. 30.91±5.66 U/L (p=0.001).

No differences were found in hemoglobin, total leukocyte count, neutrophils, lymphocytes, monocytes, or SGPT (p>0.05).

Table 2: Comparison of blood parameters

Parameter	Case Group (Mean±SD)	Control Group (Mean±SD)	P-value
Hemoglobin (g/dL)	13.55±1.99	14.04±1.51	0.108
TLC (/µL)	7948.37±1892.47	8127.01±1674.77	0.55
Neutrophils (%)	55.84±6.44	55.45±5.11	0.69
Lymphocytes (%)	32.05±4.65	31.13±2.36	0.15
Monocytes (%)	6.85±2.63	7.13±1.63	0.45
PLC ($\times 10^5$/µL)	2.53±0.68	2.22±0.43	0.002*
PT (sec)	12.13±1.05	12.74±0.71	0.001*
INR	1.009±0.109	0.93±0.07	0.001*
Blood urea (mg/dL)	20.76±4.14	22.45±3.17	0.008*
S. Creatinine (mg/dL)	0.73±0.13	0.92±0.101	0.001*
SGOT (U/L)	35.69±8.89	30.91±5.66	0.001*
SGPT (U/L)	35.55±10.43	34.74±5.41	0.57

*Significant at p≤0.05.

Study Outcomes

Serum 25(OH)D levels: In the case group, 79.2% (57/72) had deficient levels (<20 ng/mL) and 5.5% (4/72) had insufficient levels (20–30 ng/mL), compared with 86.4% (57/66) and 6.0% (4/66), respectively, in the control group. Normal levels (>30 ng/mL) were observed in 15.3% of cases and 7.6% of controls (p=0.18).

IgE levels: Among cases, 66.7% had moderately elevated IgE levels (100–500 IU/mL) and 26.4% had elevated levels (>500 IU/mL). Among controls, 43.9% had normal levels (<100 IU/mL) and 56.1% had moderately elevated levels (p<0.001).

Absolute eosinophil count (AEC): An elevated AEC (>350 cells/µL) was found in 41.7% of cases and 30.3% of controls (p=0.16).

Interleukin levels: Data for IL-4, IL-5, and IL-13 were unavailable because the reagents degraded during storage; these biomarkers therefore require further investigation.

Correlation with severity: Spearman's correlation showed no significant relationship between 25(OH)D levels and SNOT-22 scores ($r_s = -0.12$, p=0.31). Deficient 25(OH)D was observed in 87.5% of mild, 80.0% of moderate, and 100% of severe cases.

DISCUSSION

This study confirms AR's significant burden in India, where urbanization and dietary changes increase its prevalence and vitamin D deficiency [4]. Symptoms including nasal obstruction (90.3%), nasal discharge (94.4%), sneezing (100%), and eye redness/itching (81.9%) were prevalent in cases ($p \leq 0.01$), consistent with ARIA guidelines [1]. Less common symptoms like hyposmia/anosmia (34.7%), halitosis (30.5%), and headache (8.3%) indicate broader quality-of-life impacts, relevant to Indian otorhinolaryngology practice [15]. The high ear pain/fullness rate (61.1%, $p=0.001$) suggests possible Eustachian tube dysfunction, warranting further study in Indian populations with high AR prevalence.

Clinical findings, such as nasal secretion (87.5%, $p=0.003$) and pale mucosa (61.1%, $p=0.001$), confirm AR's inflammatory basis [1]. The absence of facial pain and fever distinguishes AR from sinusitis [16]. A family history of allergy in 30.5% of cases ($p=0.01$) supports atopy's genetic basis. Controls showed ear discharge (31.8–37.9%) due to chronic otitis media, a common ENT condition in India.

Elevated IgE levels in cases ($p<0.001$) align with AR's IgE-mediated etiology [11], with mean levels of 1071.4 IU/mL vs. 208.7 IU/mL in controls. However, AEC showed no significant difference (41.7% cases vs. 30.3% controls, $p=0.16$), contrasting with studies linking eosinophilia to AR severity [17], possibly due to regional allergen variability. Missing IL-4, IL-5, and IL-13 data limits insights into Th2-mediated inflammation.

Vitamin D's immunomodulatory effects (e.g., regulation of the Th1/Th2 balance) [6] may not directly influence AR in this cohort, possibly because of widespread deficiency.

Significant blood parameter differences (e.g., higher platelet count, INR, SGOT in cases; higher PT, urea, creatinine in controls) are likely incidental and unrelated to AR or vitamin D.

CONCLUSION

This study confirms AR's significant burden in India, with nasal obstruction (90.3%), sneezing (100%), eye redness/itching (81.9%), and less common symptoms like hyposmia/anosmia (34.7%) and halitosis (30.5%) prevalent ($p \leq 0.02$). Elevated IgE ($p<0.001$) reinforces AR's allergic etiology, while the absence of facial pain aids differentiation from sinusitis. A family history in 30.5% of cases suggests genetic predisposition. However, no differences in 25(OH)D ($p=0.18$) or AEC ($p=0.16$), and no correlation with SNOT-22 severity ($p=0.31$), challenge vitamin D's role in AR, likely due to high deficiency (82.6%) in India. These findings suggest routine vitamin D supplementation may not be justified for AR management in Indian otorhinolaryngology practice. Longitudinal studies with standardized 25(OH)D cutoffs, comprehensive biomarker analysis, and larger samples are needed to clarify AR's pathophysiology and optimize therapeutic strategies in high-deficiency populations.

LIMITATIONS

High 25(OH)D deficiency (82.6%) may have reduced statistical power to detect differences. Missing IL-4, IL-5, and IL-13 data due to reagent degradation limits Th2 insights. The cross-sectional design precludes causality assessment, and unmeasured confounders (e.g., seasonal allergen exposure, socioeconomic status) may influence results. The 10% AR prevalence estimate may underestimate regional rates (11.9–24.4%)[3].

Implications and future directions

AR's significant symptom burden and IgE elevation underscore the need for routine ENT assessment of extranasal symptoms like headache and halitosis in India. The non-significant 25(OH)D findings suggest its role in AR remains

inconclusive, particularly in high-deficiency regions like India, where urban lifestyles and dietary patterns exacerbate deficiency. Future research should include longitudinal designs, standard 25(OH)D cutoffs (<20 ng/mL), and interleukin measurements to explore causality and supplementation benefits. Investigating genetic and environmental factors (e.g., allergen types, family history) could optimize AR management strategies tailored to Indian populations, enhancing otorhinolaryngology practice.

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