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Original Research Article

Role of vitamin D3 supplementation in allergic rhinitis: an outpatient department based prospective analytical observational study

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ABSTRACT

Background: Allergic rhinitis is a common disorder characterized by sneezing, rhinorrhoea, nasal congestion, itching and lacrimation which adversely affect quality of life to a substantial degree. Evidence suggests that low serum vitamin D3 has correlation with severity of allergic rhinitis. The objective of the study was to evaluate whether vitamin D3 supplementation has any role to reduce the severity of disease spectrum among allergic rhinitis patients.
Methods: This prospective analytical observational study was carried out in 6 months in ENT OPD of Midnapore Medical College and Hospital. Only the persistent moderate to severe allergic rhinitis patients as per ARIA-WHO guideline, aged >12 years were included in this study. 64 subjects were randomised into two groups. The test group received oral vitamin D (60000 IU/week for 2 months) along with levocetirizine, fluticasone spray and montelukast while the control group received three drug therapies without vitamin D3. Allergy symptom score (ASS) was assessed at the start and end of the study period.
Results: The study population (n=64) was predominantly female (37) and had a mean age of 39.79 years. The ASS score was 14.06±1.01 in test group and 13.93±1.01 in control group and the post treatment ASS score was 2.65±1.12 and 6.06±0.87 respectively. This difference between groups was significant ($p<0.001$).
Conclusions: There was significant reduction in the allergy symptom score after vitamin D3 supplementation which alters the course of disease towards clinical improvement.

Keywords: Vitamin D3, Allergic rhinitis, Allergy symptom score

INTRODUCTION

Allergic rhinitis (AR) is the most common type of chronic rhinitis, affecting 10-20% of the population, and evidence suggests that the prevalence of the disorder is increasing. Severe AR has been associated with significant impairments in quality of life, sleep and work performance.[1] There are good treatments available for AR, including antihistamines and topical cortico-steroids.[2] Yet, there is a need for new treatment options, particularly aiming at new targets and associated with reduced side effects. The prevalence varies among countries, probably because of geographic and aeroallergen differences.[3-6] In India, AR is considered to be a trivial disease, despite the fact that symptoms of rhinitis were present in 75% of children and 80% of asthmatic adults.[7]

In recent years, the world-wide increase in allergic diseases has been associated with low vitamin D. Schauber et al stated that the association between low serum vitamin D levels and an increase in immune

disorders is not coincidental.[8] Growth in populations has resulted in people spending more times indoors, leading to less sun exposure and less cutaneous vitamin D production.[9]

In recent years, many published studies have examined the relationship between allergic diseases and low serum vitamin D3 levels. The Aim of this study is to investigate whether the severity of the allergic symptoms in allergic rhinitis are reduced by giving Vitamin D3 supplementation in ENT OPD of Midnapore Medical College and Hospital.

Objective

The objective of the study was to evaluate whether vitamin D3 supplementation has any role to reduce the severity of disease spectrum among allergic rhinitis patients.

METHODS

It was a prospective analytical observational study spanning over 24 weeks from June 2018 to January 2018, involving patients of Persistent moderate-severe allergic rhinitis as per ARIA-WHO guideline, aged >12 years of either sex and presented to ENT OPD of Midnapore medical college and Hospital. A total of 70 patients were screened in the study following the inclusion criteria but due to loss to follow up 64 patients were recruited in the study. Pregnant or lactating patients, patients having history of parasitic disease, patients with serious concomitant disease, patients of other class of allergic rhinitis as per ARIA-WHO guideline and patients with low serum vitamin D3 level having symptoms of hypovitaminosis D3 were excluded from the study. Subjects were randomized using computer generated random number table and divided into two groups having 32 patients each. At baseline visit all demographic and biochemical parameters were noted and the allergy symptom scoring (ASS) was also noted. Group 1 (control group) received three drug therapy i.e. levocetirizine (5 mg OD), Fluticasone nasal spray (2 puff BD) and Montelukast (10 mg OD) while the subjects of Group 2 (test group) received four drugs therapy i.e. along with these three drug in same dose and dosing form, Vitamin D3 (60000 IU/week) was also given. After 2 months of therapy at follow up visit the Allergy symptom scoring (ASS) was done in both the groups. The Allergy symptom score (a runny nose, nasal congestion, sneezing, eye symptom and itchy nose) was assessed based on the severity of the symptoms. The severity degree of each symptom was based on the following scores: 0=no symptom; 1=mild, unobtrusive symptoms; 2=moderate, disturbing but tolerable symptoms; and 3=severe, disturbing, perceived to interfere with daily activities/sleep and difficult to tolerate. The maximum total nasal symptom score was 15. Necessary permission was granted by the institutional authorities for the study.

Statistical analysis

Descriptive data were expressed in Mean±SD or median and IQR (in case of numerical variables) and in numbers and percentages (in case of categorical variables). To compare the parametric and non-parametric variables appropriate statistical tests and tools were utilized accordingly. For comparison two tailed P value of less than 0.05 will be considered as significant. Standard statistical software like Microsoft excel, SPSS 21, were utilized for this purpose.

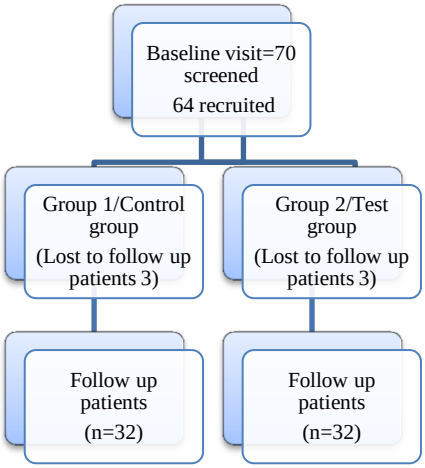

Figure 1: Study flow chart.

RESULTS

The study was conducted to evaluate whether Vitamin D3 supplementation has any role to reduce the severity of disease spectrum among allergic rhinitis patients. Among the patients attending ENT OPD of Midnapore Medical College and Hospital, after randomization 70 patients were screened. But due to lost to follow up 64 patients were recruited in this study. The total no. of male was 27 (42.18%) and female was 37 (57.81%) in this study as depicted in Figure 2. The BMI distribution of study population were 3 (8.82%) underweight, 22 (34.37%) normal weight, 29 (45.31%) overweight and 10 (15.62%) obese as depicted in Table 1.

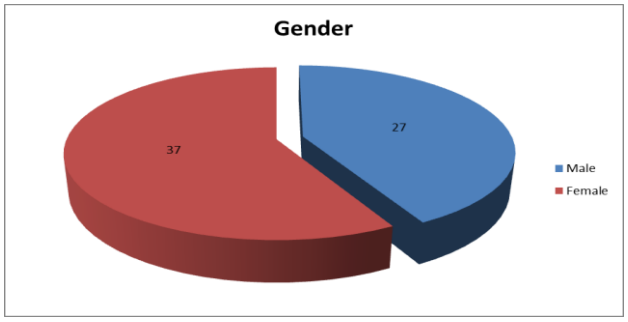

Figure 2: Gender-wise distribution in study population (n=64).

The age of control group was 40.18±7.81years whereas in Test group the mean age±SD was 39.40±7.58 years. The serum IgE was 652.78±127.13 IU/ml and 649.83±128.15 respectively in control and test group. The absolute eosinophil count in two groups was 324.14±68.65 cells/cu-mm and 333.93±69.68 cells/cu-mm respectively. At baseline visit the allergy symptom score in control group and test group were 13.93±1.01 and 14.06±1.01 respectively. The serum Vitamin D3 level was 21.24±2.30 IU/ml in control group and 18.25±3.34 IU/ml in test group respectively. All these data are depicted in Table 2.

Table 1: Categorization of BMI and their distribution in study population (n=64).

Weight status	BMI cut off (kg/m^2)	Number (%)
Underweight	<18.5	3 (8.82)
Healthy weight	18.5 to 22.9	22 (34.37)
Over weight	23 to 24.9	29 (45.31)
obese	≥ 25	10 (15.62)

As per WHO Asia Pacific perspective for Asians WHO IOTF 2003.[16]

Table 2: Baseline parameters of each group.

Parameters	Group 1 (control group) (Mean±SD)	Group 2 (Test group) (Mean±SD)	P value
Age	40.18±7.81	39.40±7.58	0.686
Serum IgE (IU/ml)	652.78±127.13	649.83±128.15	0.927
Absolute eosinophil count (cells/cu-mm)	324.14±68.65	333.93±69.68	0.573
ASS	13.93±1.01	14.06±1.01	0.624
Serum vitamin D3 level (IU/ml)	21.24±2.30	18.25±3.34	0.427

Table 3: Comparison of allergy symptom score between two visits.

	Mean±SD	P value (Chi- square)
ASS at baseline	14.00±1.00	<0.001
ASS at follow up	4.35±1.98	

Table 4: Allergy symptom score at follow up visit in both the group.

Parameters	Group 1 (Control group)	Group 2 (Test group)	P value
ASS at baseline visit	13.93±1.01	14.06±1.01	<0.001
ASS at follow up	6.06±0.87	2.65±1.12	

After 2 months of pharmacotherapy according to the both groups the allergy symptom score was recorded on the basis of the improvement of the patient's allergic symptoms. From Table 3 it was found to be that the ASS scoring was less in follow up visit than the baseline visit ($p<0.001$).

From Table 4 it was clearly noted that the decrease of ASS scoring after pharmacotherapy was much less in test group than control group and the $p<0.001$.

DISCUSSION

In allergic rhinitis, numerous inflammatory cells, including mast cells, CD4-positive T-cells, B-cells, macrophages, and eosinophils, infiltrate the nasal lining on exposure to an inciting allergen (most commonly airborne dust mite particles, cockroach residues, animal dander, molds, and pollens).[10] During the early phase of an immune response to an allergen the mediators and cytokines are released which trigger a further cellular inflammatory response over the next 4-8h (late phase inflammatory response) which results in recurrent symptoms (usually nasal congestion).[11] Infiltration of inflammatory cells is evident in both seasonal and perennial form, though the magnitude of these cellular changes is somehow different in seasonal and perennial AR.[12]

The T-cells infiltrating the nasal mucosa are predominantly T helper (Th 2) 2 in nature and release cytokines (e.g. IL-3, IL-4, IL-5, and IL-13) that promote immunoglobulin E (IgE) production by plasma cells. IgE production, in turn, triggers the release of mediators, such as histamine and leukotriene, which leads to arteriolar dilation, increased vascular permeability, itching, rhinorrhoea (runny nose), mucous secretion, and smooth muscle contraction.[13]

The prevalence of serum vitamin D deficiency was significantly higher in patients with AR than the normal population. In a study performed by Moradzadeh et al the prevalence of severe vitamin D deficiency was significantly greater in patients with Allergic rhinitis than the normal population (30% vs. 5.1%; p=0.03) demonstrating that there is an association between serum vitamin D levels and allergic rhinitis status.[14] This findings is similar to our study where we have found allergic rhinitis patients have low serum vitamin D3 level.

In presented study we supply vitamin D3 (60000IU/ week) for 2 months in test group along with antihistamine, Intranasal Corticosteroid and Leukotriene receptor antagonist while in the control group the patients of persistent moderate- severe category of allergic rhinitis patients only given last three drug therapy i.e. without vitamin D3. The ASS score was 14.06±1.01 in Test group and 13.93±1.01 in Control group. The post treatment ASS score was 2.65±1.12 in Test group and 6.06±0.87 in control group. The Allergy symptom score (ASS) after 2 months of pharmacotherapy in control group and test group were found to be less from baseline ASS but in Test group the ASS score showed much improvement than the control group and the $p<0.001$ i.e. highly significant. Modh et al also found similar findings in their study.[15]

CONCLUSION

There was highly significant reduction in the allergy symptom score (ASS) after supplementation of Vitamin D3. Thus vitamin D3 supplementation alters the course of allergic rhinitis towards clinical improvement. Although more studies with a larger number of patients should be conducted to validate the role of vitamin D supplementation therapy along with initial anti allergic treatment.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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