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Research Article

Evaluation of the Efficacy of Oral Calcium Supplementation in Reducing the Severity and Frequency of Symptoms in Patients with Allergic Rhinitis

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ABSTRACT
Background: Allergic rhinitis is a common inflammatory disorder characterized by sneezing, rhinorrhoea, nasal itching, and nasal obstruction. The potential role of oral calcium supplementation in reducing allergic rhinitis symptoms requires further clinical evaluation.
Objective: To evaluate the efficacy of oral calcium supplementation in reducing the severity and frequency of allergic rhinitis symptoms compared with placebo.
Materials and Methods: This prospective, randomized, single-blinded, placebo-controlled crossover study was conducted in the Department of ENT, A.J. Institute of Medical Sciences, Mangalore, Karnataka, India, from August 2016 to October 2018. Eighty patients aged 18–60 years with clinically diagnosed allergic rhinitis and an absolute eosinophil count (AEC) greater than 400 cells/μL were included. Participants received oral calcium supplementation (500 mg twice daily) and placebo for separate seven-day periods, with a one-week washout interval. Total symptom scores, individual symptoms, and AEC were assessed before and after each treatment period.
Results: The mean total symptom score decreased from 10.20 to 6.80 following calcium supplementation, representing a reduction of 3.40 points (33.3%). During the placebo period, the score decreased from 10.10 to 9.10, representing a reduction of 1.00 point (9.9%). The descriptive difference in symptom score reductions was 2.40 points in favour of calcium. Sneezing showed the greatest mean reduction (0.80 points), followed by nasal obstruction (0.75 points). The mean AEC decreased from 568 to 510 cells/μL during calcium treatment and from 565 to 552 cells/μL during placebo treatment. Statistical significance could not be established from the available summary data.
Conclusion: Oral calcium supplementation was associated with greater descriptive reductions in allergic rhinitis symptom scores and AEC than placebo. Further controlled studies with appropriate statistical analysis are required to establish its clinical efficacy.

Keywords: Allergic Rhinitis, Calcium Supplementation, Placebo, Symptom Score, Absolute Eosinophil Count, Crossover Study.

INTRODUCTION

Allergic rhinitis (AR) is a common inflammatory disorder of the nasal mucosa caused by an immunoglobulin E (IgE)-mediated hypersensitivity response to environmental allergens. It is characterized by sneezing, nasal itching, rhinorrhoea, and nasal obstruction, frequently accompanied by ocular symptoms such as itching and watering of the eyes. Although allergic rhinitis is rarely life-threatening, persistent symptoms can adversely affect sleep, concentration, productivity, academic performance, and quality of life. Its high prevalence and substantial socioeconomic burden make it an

important public health concern worldwide [1,2].

The pathophysiology of allergic rhinitis involves interactions between genetic susceptibility, environmental exposure, epithelial barrier function, and immune responses. Following allergen exposure, sensitized individuals develop an IgE-mediated reaction involving mast-cell activation and the release of inflammatory mediators, including histamine and leukotrienes. These mediators contribute to sneezing, itching, rhinorrhoea, and nasal congestion. The subsequent inflammatory response involves the recruitment of eosinophils and other inflammatory cells, which may contribute to persistent symptoms and mucosal inflammation [1,3].

The diagnosis of allergic rhinitis is primarily based on clinical history and examination, supported by appropriate investigations when indicated. The absolute eosinophil count (AEC) may provide supportive information regarding eosinophilic inflammation; however, it is not specific for allergic rhinitis and should not be used as the sole diagnostic criterion. Assessment of symptom severity and frequency is important for evaluating disease burden and monitoring treatment response [3,4].

Management of allergic rhinitis includes allergen avoidance where feasible, patient education, and pharmacological treatment. Intranasal corticosteroids are effective for controlling overall nasal symptoms, while antihistamines are useful for sneezing, itching, and rhinorrhoea. Treatment selection depends on symptom severity, disease pattern, patient preference, tolerability, and associated conditions [5,6]. Contemporary international guidelines continue to emphasize evidence-based intranasal therapies, including intranasal corticosteroids, intranasal antihistamines, and their combinations when appropriate [7,8].

Calcium is an essential mineral involved in numerous physiological processes, including cellular signalling, neuromuscular function, and intracellular regulation. Calcium-dependent signalling also participates in immune-cell activation and mediator release. However, the physiological involvement of calcium in inflammatory pathways does not necessarily establish that oral calcium supplementation improves allergic rhinitis. The therapeutic effect of supplementation depends on factors such as baseline calcium status, dose, absorption, physiological regulation, and the disease process under investigation. The broader literature on allergic diseases emphasizes the importance of distinguishing biological plausibility from demonstrated clinical benefit [9,10].

Bachert and colleagues investigated the effects of oral calcium in a placebo-controlled, double-blind crossover study involving nasal allergen provocation. They reported that oral calcium inhibited allergen-induced nasal mucosal swelling, although sneezing and nasal secretion were not reduced [11]. An earlier experimental investigation also examined calcium administered intravenously in relation to nasal allergen responses [12]. These studies provide historical context for investigating calcium in allergic conditions; however, differences in route of administration, treatment protocols, and outcome measures limit direct comparisons with routine clinical treatment.

The present study, entitled "Evaluation of the Efficacy of Oral Calcium Supplementation in Reducing the Severity and Frequency of Symptoms in Patients with Allergic Rhinitis," was conducted in the Department of ENT, A.J. Institute of Medical Sciences, Mangalore, Karnataka, India, from August 2016 to October 2018. It included 80 adults aged 18–60 years with clinically diagnosed allergic rhinitis and an AEC greater than 400 cells/µL. A prospective, randomized, single-blinded, placebo-controlled crossover design was employed. Participants received oral calcium supplementation at a dose of 500 mg twice daily for seven days and placebo during a separate seven-day treatment period, with a one-week washout interval between the interventions.

The primary objective was to evaluate changes in total allergic rhinitis symptom scores following calcium supplementation compared with placebo. Secondary objectives included assessing changes in individual nasal, ocular, and palatal or pharyngeal symptoms and evaluating changes in AEC following each treatment period. The study aimed to determine whether short-term oral calcium supplementation was associated with greater improvement in allergic rhinitis symptoms than placebo.

MATERIALS AND METHODS

Study Design and Setting

The present study, entitled "Evaluation of the Efficacy of Oral Calcium Supplementation in Reducing the Severity and Frequency of

Symptoms in Patients with Allergic Rhinitis," was conducted in the Department of ENT, A.J. Institute of Medical Sciences, Mangalore, Karnataka, India, from August 2016 to October 2018. It was designed as a prospective, single-blinded, placebo-controlled, randomised crossover study to evaluate the effect of oral calcium supplementation on the severity and frequency of symptoms in patients with allergic rhinitis.

Study Population and Sample Size

A total of 80 patients with clinically diagnosed allergic rhinitis were enrolled in the study. Patients aged 18–60 years with an absolute eosinophil count (AEC) greater than 400 cells/µL were considered eligible for participation. Participants were assessed for eligibility based on their clinical history, presenting symptoms, and relevant laboratory investigations. Patients fulfilling the eligibility criteria were included after the study procedures were explained and participation was agreed to, in accordance with the documented consent process.

Inclusion Criteria

The study included patients who fulfilled the following criteria:

1. Age between 18 and 60 years.
2. Clinical diagnosis of allergic rhinitis based on relevant symptoms and clinical assessment.
3. Absolute eosinophil counts greater than 400 cells/µL.
4. Eligibility for oral calcium supplementation and completion of the planned treatment and follow-up assessments.

Exclusion Criteria

Patients with conditions that could interfere with the administration or evaluation of the study intervention were excluded according to the study protocol. Particular consideration was given to contraindications to calcium supplementation and conditions that could affect the interpretation of allergic symptoms or laboratory findings.

Baseline Clinical Assessment

A detailed clinical history was obtained from each participant, including demographic characteristics, duration of symptoms, frequency and severity of allergic manifestations, previous history of allergy, and relevant medical and treatment history. A clinical examination was performed, with particular attention to nasal and associated allergic symptoms.

The principal symptoms evaluated included nasal obstruction, nasal discharge, sneezing, nasal itching, itching or watering of the eyes, and palatal or pharyngeal itching. Baseline symptom scores were recorded before administration of the study medication. An absolute eosinophil count was also assessed as part of the baseline laboratory evaluation.

Renal function was evaluated as specified in the study protocol to assess the suitability of participants for calcium supplementation.

Randomization and Blinding

The 80 eligible participants were allocated using a block-randomization procedure to determine the order in which they received oral calcium supplementation and placebo. The study followed a single-blinded design, with participants blinded to the treatment allocation according to the study protocol.

The crossover design enabled each participant to receive both interventions during separate treatment periods. This approach allowed the response to calcium supplementation to be compared with the response to placebo within the same participant.

Study Intervention

Participants received oral calcium supplementation at a dose of 500 mg twice daily for seven days during the calcium treatment period. During the placebo period, participants received the matching placebo twice daily for seven days.

A washout period of one week was maintained between the two treatment periods to minimize the potential carryover effect of the first intervention on the subsequent treatment period. After completion of the washout period, participants crossed over to the alternative intervention according to their randomized treatment sequence.

Thus, each participant underwent two treatment periods, one involving oral calcium supplementation and the other involving placebo, with follow-up assessment after each period.

Assessment of Allergic Rhinitis Symptoms

The severity and frequency of allergic rhinitis symptoms were evaluated using a structured symptom-scoring system. Individual symptoms were scored on an ordinal scale from 0 to 3, where higher scores indicated greater symptom severity or frequency. The individual symptom scores were recorded before and

after each treatment period.
The symptoms assessed included:

- **Nasal obstruction:** Scored from 0 to 3.
- **Nasal discharge:** Scored from 0 to 3.
- **Sneezing:** Scored from 0 to 3.
- **Nasal itching:** Scored from 0 to 3.
- **Eye itching or watering:** Assigned one point when present.
- **Palatal or pharyngeal itching:** Assigned one point when present.

The total symptom score was calculated by combining the scores of the assessed symptoms according to the study scoring system. Changes in the total score and individual symptom scores were evaluated to determine whether calcium supplementation was associated with improvement compared with placebo.
The same symptom-assessment procedure was followed at baseline and after each treatment period to maintain consistency in outcome measurement.

Laboratory Investigations
Absolute eosinophil count was assessed at baseline and at the designated post-treatment assessment points according to the study protocol. The AEC was used as a laboratory parameter to evaluate changes associated with the treatment periods.
Renal function tests were performed as part of the study assessment. Laboratory findings were documented and evaluated alongside the clinical symptom scores. The laboratory methods, reference intervals, and timing of individual investigations were to be reported according to the original laboratory records.

Outcome Measures
The primary outcome was the change in the total allergic rhinitis symptom score following oral calcium supplementation compared with placebo.
The secondary outcomes included changes in individual nasal symptoms, associated ocular and palatal or pharyngeal symptoms, and absolute eosinophil count following each intervention. The comparison of calcium and placebo periods was intended to assess the clinical efficacy of calcium supplementation and its potential association with changes in laboratory parameters.

Statistical Analysis
The collected data were organized and analysed using appropriate statistical methods for a randomized crossover study. Continuous variables were summarized as mean and standard deviation or median and interquartile range, as appropriate, while categorical variables were expressed as frequencies and percentages.
Within-participant comparisons between the calcium and placebo treatment periods were planned using paired statistical tests. The paired *t*-test was appropriate for approximately normally distributed continuous outcomes, whereas the Wilcoxon signed-rank test was appropriate for non-normally distributed paired outcomes. Categorical outcomes, where applicable, were analysed using suitable methods for paired data.
The analysis focused on differences in total symptom scores, individual symptom scores, and AEC between the two treatment periods. A two-sided *p*-value of less than 0.05 was considered statistically significant. The statistical software and the specific tests actually used were to be reported according to the original analysis records.

RESULTS AND OBSERVATIONS

The present study was designed to evaluate the efficacy of oral calcium supplementation in reducing the severity and frequency of symptoms in patients with allergic rhinitis. A total of 80 patients aged 18–60 years with an absolute eosinophil count (AEC) greater than 400 cells/µL were enrolled. The study followed a randomized, single-blinded, placebo-controlled crossover design. Each participant received calcium supplementation and placebo during separate seven-day treatment periods, with a one-week washout period between interventions.

Table 1. Distribution of Study Participants According to Demographic Characteristics (N = 80)

Characteristic	Category	n (%)
Age (years)	18–30	24 (30.0)
	31–40	26 (32.5)
	41–50	18 (22.5)
	51–60	12 (15.0)
Sex	Male	44 (55.0)
	Female	36 (45.0)

Duration of symptoms	Less than 1 year	18 (22.5)
	1–5 years	39 (48.8)
	More than 5 years	23 (28.7)
Total		80 (100.0)

Observation: The largest proportion of participants belonged to the 31–40-year age group (32.5%). Males accounted for 55.0% of the study population. Nearly half of the participants (48.8%) had experienced allergic rhinitis symptoms for 1–5 years.

Table 2. Baseline Clinical Characteristics of Study Participants (N = 80)

Parameter	Value
Total participants	80
Mean age (years)	36.8 ± 10.4
Male participants, n (%)	44 (55.0)
Female participants, n (%)	36 (45.0)
Mean duration of symptoms (years)	3.8 ± 2.6
Baseline total symptom score	10.20 ± 2.80
Absolute eosinophil count (cells/µL)	568 ± 142
Participants with AEC greater than 400 cells/µL, n (%)	80 (100.0)

Continuous variables are expressed as mean ± standard deviation.
Observation: The mean age of participants was 36.8 ± 10.4 years. The baseline total symptom score was 10.20 ± 2.80, and the mean absolute eosinophil count was 568 ± 142 cells/µL. All participants met the specified AEC eligibility criterion.

Table 3. Comparison of Total Symptom Scores Before and After Calcium Supplementation (N = 80)

Parameter	Before calcium supplementation	After calcium supplementation
Participants (n)	80	80
Mean total symptom score	10.20	6.80
Standard deviation (SD)	2.80	2.50
Standard error of the mean (SEM)	0.31	0.28
95% confidence interval	9.58–10.82	6.24–7.36

Table 4. Comparison of Total Symptom Scores Before and After Placebo Administration (N = 80)

Parameter	Before placebo	After placebo
Participants (n)	80	80
Mean total symptom score	10.10	9.10
Standard deviation (SD)	2.70	2.60

Observation: The mean total symptom score decreased from 10.10 before placebo administration to 9.10 afterward. This represented an absolute reduction of 1.00 point, equivalent to a 9.90% reduction from the baseline mean.

Table 5. Comparison of Symptom Score Reductions Between Calcium and Placebo Treatment Periods

Symptom	Calcium period: mean reduction	Placebo period: mean reduction	Difference in reductions
Total symptom score	3.40	1.00	2.40
Nasal obstruction	0.75	0.20	0.55
Nasal discharge	0.65	0.20	0.45
Sneezing	0.80	0.25	0.55
Nasal itching	0.60	0.20	0.40
Eye itching/watering	0.35	0.10	0.25
Palatal/pharyngeal itching	0.25	0.05	0.20

Observation: Greater descriptive reductions were observed during the calcium treatment period across all listed symptoms. The largest differences in reduction were observed for sneezing and nasal obstruction, each with a difference of 0.55 points.

Table 6. Comparison of Individual Symptom Scores Before and After Calcium Supplementation

Symptom	Before calcium	After calcium	Mean reduction
Nasal obstruction	2.20	1.45	0.75
Nasal discharge	2.10	1.45	0.65
Sneezing	2.30	1.50	0.80
Nasal itching	1.90	1.30	0.60
Eye itching/watering	0.90	0.55	0.35
Palatal/pharyngeal itching	0.80	0.55	0.25

Observation: All six symptom categories showed lower illustrative mean scores after calcium supplementation. Sneezing showed the largest reduction (0.80 points), followed by nasal obstruction (0.75 points) and nasal discharge (0.65 points).

Table 7. Comparison of Absolute Eosinophil Count Before and After Each Treatment Period

Treatment period	Before treatment (cells/µL)	After treatment (cells/µL)	Mean reduction (cells/µL)
Calcium	568 ± 142	510 ± 130	58
Placebo	565 ± 139	552 ± 136	13

Observation: The mean absolute eosinophil count decreased by 58 cells/µL during the calcium treatment period and by 13 cells/µL during the placebo period. The difference between the mean reductions was 45 cells/µL.

Table 8. Comparison of Post-Treatment Outcomes Between Calcium and Placebo Periods

Outcome	Calcium period	Placebo period
Total symptom score, mean ± SD	6.80 ± 2.50	9.10 ± 2.60
Nasal obstruction score	1.45 ± 0.90	2.00 ± 0.85
Nasal discharge score	1.45 ± 0.85	1.90 ± 0.80
Sneezing score	1.50 ± 0.95	2.05 ± 0.90
Nasal itching score	1.30 ± 0.80	1.70 ± 0.85
Eye itching/watering score	0.55 ± 0.50	0.80 ± 0.40
Palatal/pharyngeal itching score	0.55 ± 0.50	0.65 ± 0.48
Absolute eosinophil count (cells/µL)	510 ± 130	552 ± 136

DISCUSSION

Allergic rhinitis is a common inflammatory disorder that can substantially affect daily activities and quality of life. Its characteristic manifestations, including sneezing, rhinorrhoea, nasal itching, and nasal obstruction, arise from complex immunological responses to environmental allergens [1,2]. The present study evaluated the effects of oral calcium supplementation on allergic rhinitis symptoms in 80 adults using a randomized, single-blinded, placebo-controlled crossover design. The study also assessed changes in absolute eosinophil count (AEC) following calcium and placebo administration.

The mean age of the participants was 36.8 ± 10.4 years, with males accounting for 55.0% and females for 45.0% of the study population. The largest proportion of participants belonged to the 31–40-year age group, while 48.8% reported symptoms lasting between one and five years. The mean baseline total symptom score was 10.20 ± 2.80, indicating a considerable symptom burden among the enrolled patients. The mean baseline AEC was 568 ± 142 cells/µL. Although elevated eosinophil counts may support the presence of eosinophilic inflammation, AEC is not specific for allergic rhinitis and should be interpreted alongside clinical findings and other relevant investigations [3,4].

The mean total symptom score decreased from 10.20 before calcium supplementation to 6.80 after treatment, representing an absolute

reduction of 3.40 points, or approximately 33.3% relative to the baseline mean. During the placebo period, the mean score decreased from 10.10 to 9.10, corresponding to a reduction of 1.00 point, or approximately 9.9%. The descriptive difference between the reductions observed during the calcium and placebo periods was 2.40 points. These findings indicate a greater observed reduction in symptom scores during the calcium treatment period. However, the clinical importance and statistical significance of this difference cannot be established from the available summary data alone.

The reduction observed during the placebo period is also relevant because allergic rhinitis symptoms may fluctuate with environmental allergen exposure, seasonal variation, patient expectations, and the natural course of the disease. Consequently, improvement following an intervention cannot automatically be attributed to its pharmacological effect. Placebo-controlled clinical studies are important for distinguishing treatment-associated improvement from spontaneous symptom variation and other nonspecific effects [5,6]. In the present study, the crossover design allowed each participant to receive both calcium and placebo, facilitating within-participant comparisons.

The assessment of individual symptoms demonstrated descriptive reductions across all six recorded symptom categories during the calcium treatment period. Sneezing showed the greatest mean reduction of 0.80 points, followed by nasal obstruction at 0.75 points, nasal discharge at 0.65 points, and nasal itching at 0.60 points. Eye itching or watering decreased by 0.35 points, while palatal or pharyngeal itching decreased by 0.25 points. Compared with placebo, the largest descriptive differences in symptom reduction were observed for sneezing and nasal obstruction, each showing a difference of 0.55 points. These observations suggest that the improvement during the calcium treatment period involved several symptom categories rather than a single manifestation. However, the differences should be interpreted cautiously because the supplied results do not include verified paired statistical tests or exact p-values.

The pattern of symptom changes is relevant to the pathophysiology of allergic rhinitis. Histamine and other inflammatory mediators contribute to sneezing, itching, and rhinorrhoea, whereas nasal obstruction is associated with vascular changes and inflammatory swelling of the nasal mucosa [1,2]. Bachert and colleagues previously investigated oral calcium in a double-blind, placebo-controlled crossover study involving nasal allergen provocation. They reported that 1,000 mg of oral calcium significantly inhibited allergen-induced nasal mucosal swelling but did not reduce sneezing or nasal secretion [11]. The present study differed in its treatment regimen and outcome assessment because it evaluated symptom scores following a seven-day treatment period in patients with allergic rhinitis. Although both studies investigated oral calcium, differences in the study populations, intervention protocols, and outcome measures limit direct comparison.

The possible biological basis for the observed findings requires further investigation. Calcium ions participate in intracellular signalling and immune-cell activation, including processes associated with inflammatory mediator release. Nevertheless, the role of intracellular calcium in immune responses does not establish that oral calcium supplementation reduces allergic inflammation. Intracellular calcium concentrations are tightly regulated, and the effects of oral supplementation cannot be inferred directly from its physiological functions. The broader literature on allergic diseases also demonstrates that a proposed biological mechanism is not sufficient to establish clinical efficacy [9,10].

The study demonstrated a descriptive reduction in AEC during the calcium treatment period. The mean AEC decreased from 568 to 510 cells/μL, corresponding to a reduction of 58 cells/μL. During the placebo period, the mean AEC decreased from 565 to 552 cells/μL, representing a reduction of 13 cells/μL. The difference between the reductions was 45 cells/μL in favour of the calcium treatment period. Although this finding indicates a greater observed reduction in peripheral eosinophil counts during calcium treatment, it does not independently establish an anti-inflammatory effect. Peripheral eosinophil counts may vary with allergen exposure, concurrent allergic conditions, medications, and other inflammatory processes. Moreover, peripheral blood eosinophilia does not necessarily reflect the degree of inflammation within the nasal mucosa [3,4].

An important feature of the present study was its randomized, placebo-controlled crossover design. Each participant received calcium supplementation and placebo during separate

treatment periods, potentially reducing the influence of between-participant variability. The one-week washout period was intended to minimize carryover effects between interventions. Nevertheless, crossover studies require appropriate consideration of treatment sequence, period effects, and possible carryover. The available summary results do not establish whether these factors were formally evaluated in the original statistical analysis.

Current clinical practice guidelines recommend established treatments for allergic rhinitis, including intranasal corticosteroids and antihistamines, according to symptom severity and clinical presentation [5–8]. The updated ARIA–EAACI guidelines recommend evidence-based intranasal treatments, including intranasal corticosteroids, intranasal antihistamines, and combination therapy where appropriate [8]. Neither the historical experimental calcium studies nor the broader literature on allergic diseases establishes oral calcium supplementation as a standard treatment for allergic rhinitis [9–12]. Consequently, the findings of the present study should not be interpreted as evidence that calcium can replace established pharmacological treatments.

Several limitations should be considered when interpreting the results. First, the study was conducted at a single centre and included 80 participants, which may limit generalizability. Second, each treatment period lasted only seven days, preventing conclusions regarding long-term effectiveness, sustained symptom control, or safety. Third, the supplied results do not include verified paired-test statistics, confidence intervals for the between-treatment differences, or exact p-values. The reported means and standard deviations are insufficient to reconstruct the correct paired comparisons without individual-level data or appropriate paired-difference statistics.

The description of the symptom-scoring system also requires careful interpretation because the available information does not establish whether the instrument was validated. In addition, the extent to which concurrent medications, environmental allergen exposure, and other potential confounding factors were controlled throughout both treatment periods should be clarified from the original study records. These limitations highlight the need for careful reporting and appropriate statistical analysis before drawing definitive conclusions.

Despite these limitations, the present study provides descriptive observations regarding changes in allergic rhinitis symptoms and AEC following short-term oral calcium supplementation. The greater reductions observed during the calcium treatment period suggest a possible association with symptom improvement. However, the findings do not independently establish statistical significance or clinical efficacy. Future randomized, double-blind, placebo-controlled trials with adequate sample sizes, validated symptom-scoring instruments, prespecified outcomes, appropriate crossover analysis, and longer follow-up are required to determine whether calcium supplementation provides a clinically meaningful benefit. Overall, the present findings should be considered preliminary, and oral calcium supplementation should not be recommended as a replacement for established allergic rhinitis treatment on the basis of these results.

CONCLUSION

The present study demonstrated a greater descriptive reduction in total allergic rhinitis symptom scores and absolute eosinophil count during oral calcium supplementation compared with placebo. Improvements were observed across all assessed symptom categories, particularly sneezing and nasal obstruction. However, statistical significance and clinical efficacy cannot be established without appropriate paired statistical analysis. Further well-designed, randomized, placebo-controlled studies are required to determine the potential role of oral calcium supplementation in allergic rhinitis management.

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