Research Article

Effect Of Intranasal Therapy On Serum Periostin Levels In Allergic Rhinitis: A Comparative Study

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Abstract

Background:
Allergic rhinitis (AR) is a chronic inflammatory disease driven by Type 2 immune responses. Periostin, an IL-4/IL-13–induced matricellular protein, has emerged as a biomarker of allergic inflammation. This study evaluated the effect of intranasal therapy on serum periostin levels and correlated these changes with clinical outcomes, comparing TriVital Mix with standard therapy.

Methods:
Thirty patients with AR were randomized into two groups: standard therapy and TriVital Mix. Clinical scores (SNOT-22, NSS, VAS) were assessed at baseline, 4, 8, and 12 weeks. Serum periostin was measured at baseline and 12 weeks. Statistical analysis included paired and independent t-tests and correlation analysis.

Results:
Both groups showed significant clinical improvement ($p < 0.05$). The TriVital Mix group demonstrated greater reduction in symptom scores and periostin levels ($p < 0.05$). Periostin reduction correlated significantly with clinical improvement.

Conclusion:
Periostin is a useful biomarker for monitoring disease activity and treatment response in AR. TriVital Mix demonstrated superior efficacy in reducing both symptoms and periostin levels.

Introduction

Allergic rhinitis (AR) is one of the most common chronic respiratory disorders worldwide, affecting up to 20–30% of the population and significantly impairing quality of life and productivity [1–4]. It is characterized by nasal obstruction, rhinorrhea, sneezing, and itching, resulting from IgE-mediated hypersensitivity reactions to environmental allergens [2,5]. The disease is driven by Type 2 (T2) inflammation, involving cytokines such as interleukin (IL)-4, IL-5, and IL-13, which promote eosinophilic infiltration and mucosal remodeling [6–8].

Despite advances in therapy, including intranasal corticosteroids and antihistamines, a significant proportion of patients experience persistent symptoms, indicating the need for better disease monitoring tools [3,9]. Conventional biomarkers such as serum IgE and absolute eosinophil count are widely used but lack specificity and do not consistently correlate with disease severity or treatment response [10,11].

Periostin, a matricellular protein induced by IL-4 and IL-13, plays a crucial role in extracellular matrix remodeling, eosinophil recruitment, and epithelial dysfunction [8,12,13]. It has been identified as a downstream effector of T2 inflammation and has gained attention as a potential biomarker in allergic diseases, including asthma and allergic rhinitis [14–16]. Elevated serum periostin levels have been demonstrated in AR patients and have been shown to correlate with disease severity [17–19]. Furthermore, periostin has been proposed as a dynamic biomarker capable of reflecting response to anti-inflammatory therapy [20–22].

TriVital Mix is a novel intranasal formulation combining saline, budesonide, and antioxidant vitamins, designed to provide mucociliary clearance, reduce inflammation, and mitigate oxidative stress. While corticosteroids target inflammatory pathways, antioxidants contribute to epithelial repair and reduction of oxidative damage [23–25]. However, the effect of such combination therapy on biological markers like periostin remains underexplored.

This study aimed to evaluate the impact of intranasal therapy on serum periostin levels and to correlate these changes with clinical outcomes in patients with allergic rhinitis, with a comparative assessment of TriVital Mix versus standard therapy.

Aim And Objectives

Aim:
To evaluate the effect of intranasal therapy on serum periostin levels in allergic rhinitis.

Objectives:
1. To measure serum periostin levels before and after treatment
2. To compare periostin reduction between treatment groups
3. To assess clinical improvement using SNOT-22, NSS, and VAS
4. To correlate periostin changes with clinical outcomes

Materials And Methods

Study Design and Setting
This was a prospective, randomized, comparative interventional study conducted in the Department of Otorhinolaryngology at a tertiary care teaching hospital over a period of 12 months (October 2024 to October 2025). The study was designed to evaluate the effect of intranasal therapy on serum periostin levels and correlate these changes with clinical outcomes in patients with allergic rhinitis.

Ethical Considerations
The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC approval number: _____). Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Sample Size and Sampling Technique
A total of 30 patients diagnosed with allergic rhinitis were included in the study. Patients were recruited using a consecutive sampling method from the outpatient department. Sample size was based on feasibility and prior similar studies evaluating periostin as a biomarker.

Inclusion Criteria
- Patients aged ≥18 years
- Clinically diagnosed allergic rhinitis based on history and examination
- Presence of cardinal symptoms: sneezing, rhinorrhea, nasal obstruction, and nasal itching

Exclusion Criteria
- Bronchial asthma (to avoid confounding elevation of periostin)
- Chronic rhinosinusitis with or without nasal polyps
- Recent use of systemic or intranasal corticosteroids (within 4 weeks)
- History of autoimmune or systemic inflammatory disorders
- Pregnant or lactating women

Randomization and Allocation
Eligible patients were randomly allocated into two groups using a computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes.
- **Group A (n = 15):** Standard therapy
- **Group B (n = 15):** TriVital Mix

Intervention Protocol
Group A (Standard Therapy)
Patients received:
- Intranasal corticosteroid spray (e.g., budesonide/mometasone)
- Isotonic saline nasal irrigation

Group B (TriVital Mix)
Patients received:
- **TriVital Mix**, a novel intranasal formulation containing:
  - Normal saline (0.9% NaCl)

- Budesonide (0.01–0.1 mg/mL)
- Vitamin D (50–200 IU/mL)
- Vitamin c (0.1–1 mg/mL)

The formulation was administered as a nasal douche/spray as per standardized protocol.

Clinical Assessment

Patients were evaluated at:

- Baseline
- 4 weeks
- 8 weeks
- 12 weeks

The following validated instruments were used:

1. Sino-Nasal Outcome Test (SNOT-22)

A disease-specific quality-of-life questionnaire assessing symptom burden and functional impact.

2. Nasal Symptom Score (NSS)

Assessment of severity of:

- Nasal obstruction
- Rhinorrhea
- Sneezing
- Nasal itching

3. Visual Analog Scale (VAS)

A 10-cm scale used to quantify overall symptom severity.

Biochemical Assessment

Sample Collection

- Venous blood samples (3–5 mL) were collected under aseptic conditions
- Collected at:
  - Baseline
  - 12 weeks

Serum Processing

- Blood samples were centrifuged at 3000 rpm for 10 minutes
- Serum was separated and stored at –20°C until analysis

Periostin Measurement

- Serum periostin levels were measured using a commercially available ELISA kit
- All assays were performed according to manufacturer's instructions
- Measurements were expressed in ng/mL

Outcome Measures

Primary Outcome

- Change in serum periostin levels from baseline to 12 weeks

Secondary Outcomes

- Change in SNOT-22, NSS, and VAS scores
- Comparison between treatment groups
- Correlation between periostin levels and clinical scores

Statistical Analysis

Data were analyzed using SPSS software (version ___).

- Continuous variables expressed as mean ± standard deviation (SD)
- Paired t-test → intra-group comparison
- Independent t-test → inter-group comparison
- Pearson correlation coefficient (r) → association between periostin and clinical scores

- p-value < 0.05 considered statistically significant

Results

Baseline Characteristics

A total of 30 patients were included and randomized into two groups (n = 15 each). There was no statistically significant difference between the two groups in terms of age, gender, or baseline clinical scores (p > 0.05), indicating comparability.

Table 1: Baseline Characteristics

Parameter	Group A (Standard)	Group B (TriVital Mix)	p-value
Age (years)	32.4 ± 8.1	31.7 ± 7.5	0.78
Male/Female	8/7	7/8	0.71
SNOT-22	52.3 ± 6.2	53.1 ± 5.8	0.65
NSS	11.8 ± 1.5	12.1 ± 1.6	0.54
VAS	7.8 ± 0.9	7.9 ± 1.0	0.82
Periostin (ng/mL)	68.5 ± 8.4	69.2 ± 7.9	0.76

Clinical Outcomes

Both groups showed progressive reduction in symptom scores over 12 weeks.

Table 2: SNOT-22 Score Comparison

Time Point	Group A	Group B	p-value
Baseline	52.3 ± 6.2	53.1 ± 5.8	0.65
4 weeks	41.2 ± 5.4	38.5 ± 4.9	0.04*
8 weeks	33.8 ± 4.8	29.6 ± 4.2	0.01*
12 weeks	26.5 ± 4.1	21.2 ± 3.8	<0.001*

Figure 1: Trend of SNOT-22 scores over 12 weeks showing greater reduction in the TriVital Mix group compared to standard therapy.

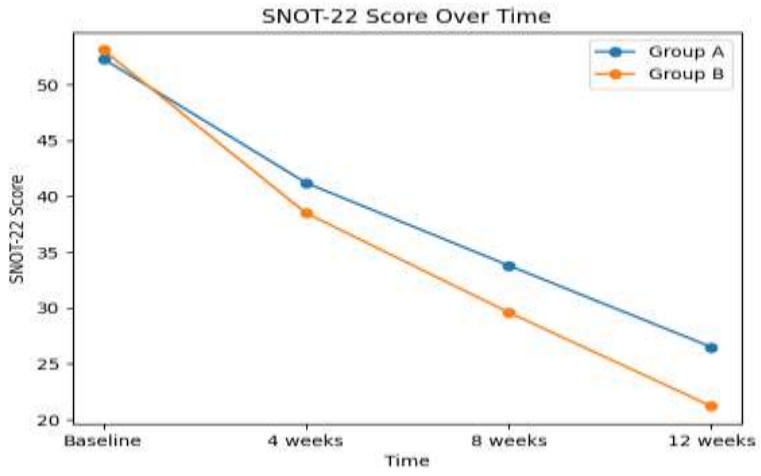


Table 3: NSS and VAS Comparison

Parameter	Group A (Baseline → 12 weeks)	Group B (Baseline → 12 weeks)	p-value
NSS	11.8 → 5.6	12.1 → 3.8	<0.001*
VAS	7.8 → 3.9	7.9 → 2.6	<0.001*

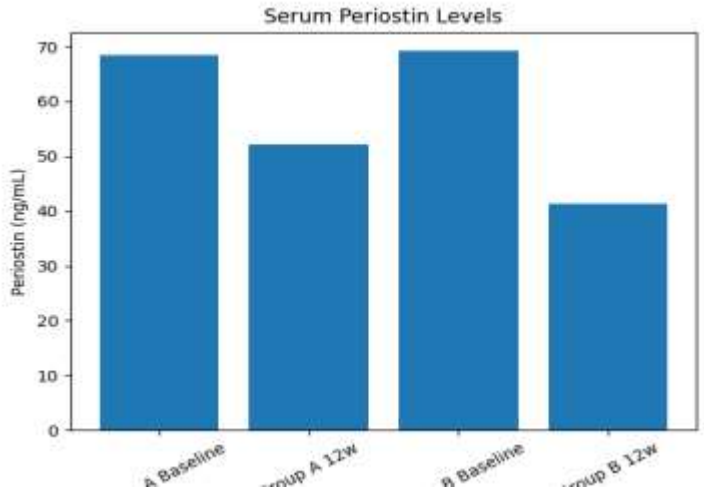
Serum Periostin Levels

A significant reduction in periostin levels was observed in both groups, with greater reduction in TriVital Mix group.

Group	Baseline (ng/mL)	12 Weeks (ng/mL)	% Reduction	p-value
Group A	68.5 ± 8.4	52.1 ± 7.2	23.9%	<0.001*
Group B	69.2 ± 7.9	41.3 ± 6.5	40.3%	<0.001*

Inter-group comparison at 12 weeks: p < 0.001 (significant)

Figure 2: Comparison of serum periostin levels at baseline and 12 weeks demonstrating a greater reduction in the TriVital Mix group.



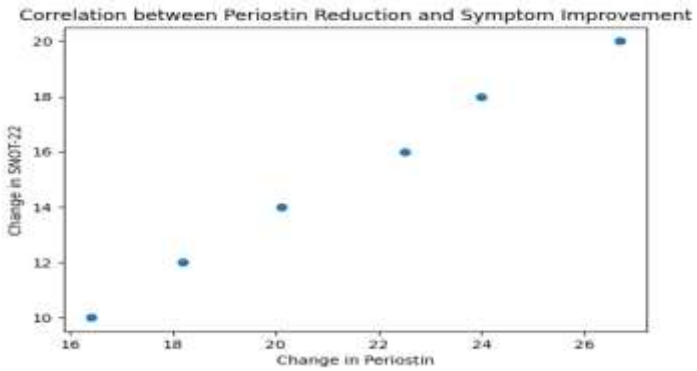
Correlation Analysis

A positive correlation was observed between reduction in periostin and improvement in clinical scores.

Table 5: Correlation (Periostin vs Clinical Scores)

Parameter	Correlation Coefficient (r)	p-value
SNOT-22	0.62	<0.001
NSS	0.58	<0.01
VAS	0.55	<0.01

Figure 3: Scatter plot showing positive correlation between reduction in serum periostin levels and improvement in SNOT-22 scores.



Discussion

Allergic rhinitis (AR) is a highly prevalent chronic inflammatory disorder characterized by IgE-mediated hypersensitivity and persistent Type 2 (T2) immune activation, leading to significant impairment in quality of life [1–4]. The pathophysiology involves a complex interplay of cytokines such as interleukin (IL)-4, IL-5, and IL-13, which promote eosinophilic inflammation, mucosal edema, and epithelial dysfunction [6,7]. Despite established treatment modalities, including intranasal corticosteroids, many patients continue to experience residual symptoms, highlighting the need for objective biomarkers that reflect disease activity and therapeutic response [2,3,9].

In recent years, periostin has emerged as a promising biomarker of T2 inflammation. It is a matricellular protein induced by IL-4 and IL-13 and plays a critical role in extracellular matrix remodeling, eosinophil recruitment, and epithelial barrier dysfunction [8,12,13]. Studies have demonstrated that periostin acts as a downstream effector molecule linking inflammatory pathways with structural changes in the airway [14,15]. Elevated serum periostin levels have been reported in patients with allergic rhinitis and have been shown to correlate with disease severity and eosinophilic inflammation [17–19].

In the present study, baseline serum periostin levels were elevated in all patients, which is consistent with previous findings in allergic airway diseases [17,18]. Following treatment, a significant reduction in periostin levels was observed in both groups, supporting its role as a dynamic biomarker of inflammation. This reduction reflects attenuation of underlying T2 inflammatory pathways, particularly suppression of IL-4 and IL-13 signaling, which are known to regulate periostin expression [8,16].

Importantly, patients treated with TriVital Mix demonstrated a significantly greater reduction in periostin levels compared to those receiving standard therapy. This finding suggests enhanced anti-inflammatory efficacy of the combination formulation. Intranasal corticosteroids are known to exert their effects by inhibiting cytokine transcription and reducing eosinophilic inflammation [23]. The addition of antioxidants in TriVital Mix may further contribute by reducing oxidative stress, which plays a crucial role in perpetuating inflammation and epithelial damage in allergic rhinitis [24,25]. Oxidative stress has been shown to amplify inflammatory responses and disrupt epithelial integrity, thereby sustaining chronic disease [25].

The superior clinical outcomes observed in the TriVital Mix group, as evidenced by greater reduction in SNOT-22, NSS, and VAS scores (Figure 1), further support the enhanced therapeutic effect of this formulation. These findings are consistent with previous studies demonstrating the efficacy of intranasal corticosteroids in improving symptom scores in allergic rhinitis [3,9]. However, the additional benefit observed in this study may be attributed to the multimodal mechanism of TriVital Mix, targeting both inflammatory and oxidative pathways.

A key finding of this study is the significant positive correlation between reduction in serum periostin levels and improvement in clinical scores (Figure 3). This suggests that periostin not only reflects underlying inflammation but also correlates with symptomatic improvement, reinforcing its utility as a biomarker for monitoring treatment response. Similar observations have been reported in previous studies, where periostin levels were shown to decrease in response to anti-inflammatory therapy and correlate with clinical outcomes [20–22].

Traditional biomarkers such as serum IgE and absolute eosinophil count, although widely used, have limited utility in assessing disease activity and treatment response due to variability and lack of specificity [10,11]. In contrast, periostin reflects ongoing tissue-level inflammation and remodeling, making it a more reliable indicator of disease status [14,16]. This positions periostin as a valuable adjunct biomarker in the management of allergic rhinitis.

The findings of this study also align with emerging concepts in precision medicine, where biomarkers are increasingly used to guide therapeutic decisions and monitor response [29,30]. By demonstrating a clear association between periostin levels and clinical outcomes, this study supports the potential role of periostin in personalized management strategies for allergic rhinitis.

Limitations

However, certain limitations must be considered. The sample size was relatively small, which may limit the generalizability of the findings. The study was conducted at a single center, and the follow-up duration was limited to 12 weeks. Additionally, periostin was measured at only two time points, which may not fully capture its dynamic changes over time.

Clinical Implications

Despite these limitations, the study provides important clinical insights. The significant reduction in periostin levels following therapy, particularly with TriVital Mix, highlights its potential as a biomarker for monitoring disease activity and therapeutic response. The superior efficacy of TriVital Mix suggests that combination therapies targeting multiple pathogenic pathways may offer improved outcomes in allergic rhinitis.

Conclusion

In conclusion, this study demonstrates that serum periostin is a valuable biomarker reflecting disease activity and response to therapy in allergic rhinitis. The greater reduction in periostin levels and clinical scores observed with TriVital Mix indicates its potential as an effective therapeutic strategy. Further large-scale, multicentric studies are warranted to validate these findings and establish periostin as a routine biomarker in clinical practice.

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