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Comparative Efficacy of Intranasal Corticosteroids vs. Antihistamines in Allergic Rhinitis: A Randomized Biochemical-Based Study

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Abstract

Allergic rhinitis (AR) significantly impairs quality of life and presents with chronic nasal inflammation. This randomized open-label study compared intranasal corticosteroids (INCS) and oral second-generation antihistamines (AH) in 120 adult patients over 8 weeks. Patients were randomized 1:1 to receive intranasal fluticasone propionate 200 µg/day or oral cetirizine 10 mg/day. Clinical efficacy was assessed via Total Nasal Symptom Scores (TNSS) and visual analogue scales (VAS); biochemical endpoints were serum eosinophil cationic protein (ECP), interleukin-4 (IL-4), and immunoglobulin E (IgE). After 8 weeks, the INCS group demonstrated significantly greater TNSS reduction (–65% vs. –40%, $p < .001$) and VAS improvement (–5.6 vs. –3.2, $p < .001$). Serum ECP, IL-4, and IgE levels dropped more in the INCS arm: ECP (–50% vs. –28%, $p = .004$), IL-4 (–42% vs. –21%, $p = .006$), IgE (–38% vs. –18%, $p = .008$). Both treatments were well tolerated. These results indicate that intranasal corticosteroids offer superior clinical and immunological control compared to antihistamines in moderate-to-severe AR. Future studies should explore combination therapy and long-term impacts on airway remodeling.

Keywords: allergic rhinitis, intranasal corticosteroids, antihistamine, eosinophil cationic protein, interleukin-4, immunoglobulin E

Introduction

Allergic rhinitis (AR) is a prevalent immunoglobulin E (IgE)-mediated inflammatory disease affecting nasal mucosa, with widespread impact on sleep quality, productivity, and comorbidities such as asthma. Standard treatment includes intranasal corticosteroids (INCS) and second-generation oral antihistamines (AH). INCS are recognized for potent anti-inflammatory effects—suppressing pro-inflammatory cytokines, blocking eosinophil degranulation, and modulating adaptive immunity. Conversely, AH primarily antagonize H1 receptors, reducing histamine-mediated symptoms but demonstrating limited anti-inflammatory activity.1-4

Previous comparative trials have focused on symptom resolution; few have evaluated immunomodulatory differences using biochemical markers. Biomarkers such as eosinophil cationic protein (ECP), interleukin-4 (IL-4), and total IgE reflect eosinophilic activation, Th2 polarization, and allergic burden. Observational evidence suggests that INCS reduce ECP and IL-4 more effectively than AH, but controlled randomized data are scarce, particularly in adults with moderate-to-severe AR.5-8

This study aimed to compare INCS versus AH over an 8-week period, with objective and immunological endpoints. The hypothesis was that INCS would achieve superior reduction in both clinical symptoms and biochemical markers of allergic inflammation.

Methodology

A randomized open-label trial was conducted at a Fatima Jinnah Medical University Lahore . Adult patients (18–60 years) with moderate-to-severe AR (as per ARIA classification) and positive skin prick test or serum-specific IgE were recruited. Exclusion criteria included perennial corticosteroid use, immunodeficiency, pregnancy, chronic rhinosinusitis with polyps, or systemic disease. Sample size ($n = 60$ per group) provided 80% power to detect a 25% difference in TNSS at $\alpha = .05$.

Participants were randomized to Group A (INCS: fluticasone propionate 200 µg/day) or Group B (AH: cetirizine 10 mg/day) for 8 weeks. Baseline and 8-week assessments included TNSS, VAS (0–10), and serum biomarkers: ECP (ELISA), IL-4 (chemiluminescence), and total IgE (ImmunoCAP). Safety and adverse events were monitored throughout.

Data were analyzed via SPSS v27. Continuous variables were expressed as mean ± SD; percentage reductions were calculated. Intergroup comparisons used independent t-tests; intragroup changes used paired t-tests. A p-value $< .05$ denoted statistical significance.

Results

Demographic & Baseline Data

Parameter	INCS (n = 60)	AH (n = 60)	p-value
Age (yrs), mean ± SD	35.4 ± 10.2	36.1 ± 9.8	.72
Male, n (%)	32 (53%)	34 (57%)	.68
Baseline TNSS (0–12)	8.5 ± 1.2	8.3 ± 1.0	.34
Baseline VAS (0–10)	7.2 ± 1.1	7.1 ± 1.0	.58
Baseline ECP (µg/L)	24.5 ± 5.3	25.1 ± 5.1	.61
Baseline IL-4 (pg/mL)	18.2 ± 4.4	18.7 ± 4.6	.59
Baseline IgE (kU/L)	320 ± 80	330 ± 85	.57

Symptom Scores & Quality of Life

Measure	INCS Baseline → 8wks	% Change	AH Baseline → 8wks	% Change	p-value
TNSS	8.5 → 3.0	–65%	8.3 → 5.0	–40%	<.001
VAS	7.2 → 1.6	–78%	7.1 → 3.9	–45%	<.001

Biochemical Marker Changes

Marker	INCS Baseline → 8wks	% Change	AH Baseline → 8wks	% Change	p-value
ECP (µg/L)	24.5 → 12.2	–50%	25.1 → 18.1	–28%	.004
IL-4 (pg/mL)	18.2 → 10.6	–42%	18.7 → 14.8	–21%	.006
IgE (kU/L)	320 → 198	–38%	330 → 272	–18%	.008

All paired comparisons were significant ($p < .001$) within each group.

Discussion

1. **Symptom Relief and QoL**

   INCS produced significantly greater symptom improvement than AH, reflecting corticosteroids' comprehensive anti-inflammatory mechanism compared to mere antihistaminic action.9-10

2. **Immunological Impact**

   The INCS group showed superior reductions in ECP, IL-4, and IgE, indicating effective

eosinophil degranulation suppression, decreased Th2 activity, and reduction in overall allergy burden—findings in line with prior mechanistic studies.11-12

3. **Clinical Implications**

   The superior biochemical modulation suggests that INCS provide more durable disease control, with potential implications for reducing long-term tissue remodeling and preventing comorbid asthma.13-15

4. **AH Utility**

   Antihistamines, while less effective, still produced moderate improvements in symptoms and ECP, supporting their role in mild cases or as adjunctive therapy where corticosteroids are contraindicated.16-18

5. **Future Directions**

   A next step involves comparing combination therapy (INCS + AH) over 12 months, assessing airway remodeling via nasal biopsy, and exploring cost-benefit impacts.19-20

6. **Study Strengths & Limitations**

   Strengths include objective biochemical endpoints and clear symptom scales. Limitations are the open-label design and moderate sample size; future studies should be double-blind and multicentric.

7. **Safety Profile**

   Both treatments were well tolerated. No significant adverse events occurred, affirming safety of INCS and AH when used over 8 weeks.

Conclusion

Intranasal corticosteroids are superior to antihistamines in moderating both clinical symptoms and biochemical markers of allergic rhinitis. Oral antihistamines offer moderate benefit, underscoring their role in mild disease or in combination regimens. Future research should explore long-term outcomes and molecular biomarkers of airway remodeling.

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