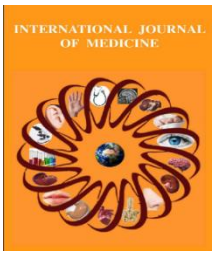
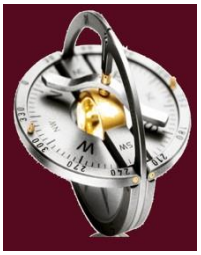


International Journal of Medicine
ISSN (P): 1468-3814; ISSN (e): 2667-7008

https://www.theinternationalmedicine.com



Volume: 7(1) 2025

**Original Research**

# Comparison of topical steroid and antihistamine nasal sprays in the management of allergic rhinitis.

Dr. Sunitha N.[1]*, Dr. Nithin R.[2], Dr. Manu L. S.[3]
[1]*Specialist Officer, Department of ENT, Subdivision Hospital Kollegala, India.*
[2]*Assistant Professor, Department of Nephrology, Sri Chamundeshwari Medical College, India.*
[3]*Consultant Neurologist, Department of Neurology, Sahyadri Narayana Hospital, Shimoga, India.*

Received: 12-11-2024 / Accepted: 08-01- 2025

Abstract
*Background:* Allergic rhinitis is a common inflammatory disorder characterized by sneezing, rhinorrhoea, nasal itching and obstruction, with considerable effects on sleep, daily activities and quality of life. Intranasal corticosteroids provide broad anti-inflammatory activity, whereas intranasal antihistamines have a rapid onset of action. This study compared the effectiveness and safety of topical steroid and antihistamine nasal sprays in patients with allergic rhinitis. *Aim:* To compare the effectiveness and safety of topical steroid and antihistamine nasal sprays in the management of allergic rhinitis. *Materials and Methods:* This prospective, randomized, open-label comparative study included 170 patients with allergic rhinitis. Participants were allocated equally to receive either a topical steroid nasal spray (n=85) or an antihistamine nasal spray (n=85) for four weeks. Total and individual nasal symptom scores, time to noticeable relief, rescue-medication use, Rhinitis Quality of Life Questionnaire (RQLQ) scores, overall clinical response, adherence, satisfaction and adverse effects were assessed. Continuous variables were compared using independent and paired *t* tests, while categorical variables were analysed using the chi-square or Fisher's exact test. Effect estimates were reported with 95% confidence intervals, and P<0.05 was considered statistically significant. *Results:* The mean reduction in Total Nasal Symptom Score was significantly greater with topical steroid than with antihistamine spray (6.12±1.72 versus 5.39±1.83; MD=0.73, 95% CI: 0.19-1.27; P=0.008). Clinical response occurred in 85.9% and 71.8% of patients, respectively (RD=14.1%, 95% CI: 2.0%-26.2%; P=0.024). Topical steroid produced significantly greater reductions in nasal-obstruction and night-time symptom scores (P<0.001 and P=0.001, respectively). Antihistamine spray provided faster noticeable relief (1.98±0.92 versus 3.74±1.31 days; P<0.001). The reduction in RQLQ score was significantly greater in the steroid group (2.19±0.74 versus 1.84±0.79; P=0.003). Clinically meaningful quality-of-life improvement occurred in 89.4% of steroid-treated and 74.1% of antihistamine-treated patients (P=0.010). Adherence to at least 80% of prescribed doses was higher with topical steroids (89.4% versus 77.6%; P=0.039). Any adverse effect occurred in 10.6% and 21.2% of patients, respectively (P=0.059). Bitter taste and somnolence were significantly more frequent with antihistamine spray, while treatment discontinuation was uncommon in both groups. *Conclusion:* Both nasal sprays were effective and generally safe. Topical steroid spray provided superior sustained symptom control, quality-of-life improvement, adherence and patient satisfaction, particularly among patients with nasal obstruction and night-time symptoms. Antihistamine spray produced a faster onset of relief but was associated with more bitter taste and somnolence. Topical steroids may therefore be preferred for sustained management, while antihistamine sprays remain useful when rapid symptom relief is required.

Keywords: *Allergic rhinitis; intranasal corticosteroids; intranasal antihistamines.*

## Introduction

Allergic rhinitis is a common immunoglobulin E-mediated inflammatory disorder of the nasal mucosa that occurs following exposure to allergens such as house-dust mites, pollens, animal dander and moulds. It is clinically characterized by sneezing, nasal itching, rhinorrhoea and nasal obstruction, and may also be associated with ocular itching, watering, sleep disturbance, fatigue and impaired concentration. Although it is not usually life-threatening, allergic rhinitis substantially affects quality of life, academic performance, work productivity and healthcare utilization. It frequently coexists with asthma, sinusitis, conjunctivitis and otitis media, emphasizing the importance of early diagnosis and adequate symptom control.[1,2]

Management includes allergen avoidance, patient education, saline irrigation, pharmacotherapy and, in selected patients, allergen immunotherapy. Intranasal corticosteroids and intranasal antihistamines are among the principal pharmacological treatments. Intranasal corticosteroids suppress multiple inflammatory pathways by reducing inflammatory-cell recruitment, cytokine production, mucosal oedema and vascular permeability. They are particularly effective in controlling nasal obstruction and are recommended as preferred monotherapy for persistent or moderate-to-severe allergic rhinitis. However, their maximum therapeutic effect may require several days of regular administration, and treatment adherence may be affected by nasal irritation, dryness, epistaxis or concerns regarding steroid use.[1,3]

Address for Correspondence Dr. Sunitha N. Specialist Medical Office, Department of ENT, Subdivision Hospital, Kollegala, India. Email: sunithan.hebbal@gmail.com

DOI: 10.61336/im/25-01-17

Intranasal antihistamines block histamine H1 receptors at the nasal mucosa and provide relatively rapid relief from sneezing, itching and rhinorrhoea. They may also improve nasal congestion because of additional anti-inflammatory properties. Their rapid onset makes them useful for patients requiring prompt symptom relief, although bitter taste, nasal discomfort and occasional somnolence may limit acceptability. Evidence suggests that both intranasal corticosteroids and antihistamines are more effective than placebo, but their relative effects may vary according to symptom pattern, disease severity, treatment duration and adherence.[3-5]

Despite the availability of treatment guidelines, direct comparisons of topical steroid and antihistamine nasal sprays in routine clinical settings remain important. Evaluating their effects on total nasal symptoms, individual symptoms, quality of life, treatment adherence and adverse events may help clinicians select an appropriate first-line therapy. Therefore, the present study compared the clinical effectiveness and safety of a topical corticosteroid nasal spray with those of a topical antihistamine nasal spray in patients with allergic rhinitis.

### AIM
To compare the effectiveness and safety of topical steroid and antihistamine nasal sprays in the management of allergic rhinitis.

### OBJECTIVES
1. To compare the reduction in total and individual nasal symptom scores following treatment with topical steroid and antihistamine nasal sprays.
2. To compare the improvement in disease-related quality of life and overall clinical response between the two treatment groups.
3. To compare treatment adherence, patient satisfaction and adverse effects associated with the two nasal sprays.

## Materials and Methods
### Source of Data
The study participants were recruited from patients attending the outpatient Department of Otorhinolaryngology with symptoms suggestive of allergic rhinitis. Patients who fulfilled the eligibility criteria and provided written informed consent were enrolled. Relevant clinical, laboratory and follow-up information was obtained through patient interviews, clinical examinations, investigation reports and a predesigned case-record form.

### Study Design
The study was conducted as a prospective, randomized, open-label, parallel-group comparative clinical study. Eligible participants were randomly allocated in a 1:1 ratio to receive either a topical corticosteroid nasal spray or a topical antihistamine nasal spray.

### Study Location
The study was conducted in the Department of Otorhinolaryngology.

### Study Duration
The study was conducted over 12 months. Each participant was followed for four weeks after treatment initiation.

### Sample Size
A total of 170 patients with allergic rhinitis were included. Participants were allocated equally into two groups:
- **Group A:** 85 patients received topical corticosteroid nasal spray.
- **Group B:** 85 patients received topical antihistamine nasal spray.

The sample size was calculated on the basis of the expected difference in mean reduction of the Total Nasal Symptom Score between the two groups, with a 95% confidence level, 80% statistical power and allowance for possible loss to follow-up.

### Inclusion Criteria
Patients were included when they:
1. Were aged 18-60 years.
2. Had a clinical diagnosis of intermittent or persistent allergic rhinitis based on characteristic symptoms and examination findings.
3. Had at least two symptoms–sneezing, nasal obstruction, rhinorrhoea or nasal itching–for at least one hour on most symptomatic days.
4. Had mild-to-moderate or moderate-to-severe allergic rhinitis requiring pharmacological treatment.
5. Had a baseline Total Nasal Symptom Score sufficient to assess treatment response.
6. Were willing to use the prescribed nasal spray regularly and attend follow-up visits.
7. Provided written informed consent.

### Exclusion Criteria
Patients were excluded when they:
1. Had acute bacterial or viral upper respiratory tract infection at enrolment.
2. Had significant deviated nasal septum, obstructive nasal polyposis, chronic rhinosinusitis, nasal mass or other structural abnormalities affecting nasal airflow.
3. Had undergone nasal or paranasal sinus surgery during the preceding six months.
4. Had used intranasal corticosteroids, intranasal antihistamines or systemic corticosteroids during the predefined washout period.
5. Had known hypersensitivity to either study medication.
6. Had uncontrolled bronchial asthma or another serious respiratory disorder requiring systemic therapy.
7. Had recurrent significant epistaxis, nasal ulceration or mucosal injury.
8. Were pregnant or breastfeeding.
9. Had a severe systemic illness or immunocompromised state.
10. Were unable to comply with treatment or follow-up requirements.

### Procedure and Methodology
The study protocol was initiated after approval from the Institutional Ethics Committee. Written informed consent was obtained from every participant. Confidentiality of participant information was maintained throughout the study.
A detailed history was obtained regarding age, sex, occupation, residence, duration and seasonal pattern of symptoms, suspected allergens, family history of atopy, associated asthma or conjunctivitis, previous treatment and exposure to dust, smoke, pets and other environmental triggers. All patients underwent general examination and complete ear, nose and throat examination. Anterior rhinoscopy was performed to assess mucosal pallor, oedema, turbinate hypertrophy, nasal discharge, septal deviation, polyps and other abnormalities. Diagnostic nasal endoscopy was undertaken when clinically indicated.

The severity of sneezing, rhinorrhoea, nasal obstruction and nasal itching was graded on a four-point scale: 0=no symptom, 1=mild, 2=moderate and 3=severe. The four scores were added to obtain a Total Nasal Symptom Score ranging from 0 to 12. Disease-related quality of life was assessed using a validated rhinitis quality-of-life questionnaire or an institutionally approved equivalent.
Participants were assigned to the two groups using computer-generated random numbers and sequentially numbered allocation envelopes:
- Group A received mometasone furoate nasal spray, 50 µg per actuation, two sprays in each nostril once daily for four weeks.

- Group B received azelastine hydrochloride nasal spray, 0.1%, one spray in each nostril twice daily for four weeks.

The exact dosage was modified, when necessary, according to the approved formulation and institutional protocol. Patients were instructed to shake the bottle, clear the nostrils, keep the head slightly forward, direct the nozzle away from the nasal septum and avoid forceful inhalation during administration. Use of other intranasal corticosteroids, antihistamines or systemic antiallergic drugs was avoided during the study unless required as rescue medication.

Clinical assessments were performed at baseline, two weeks and four weeks. At each visit, the Total Nasal Symptom Score, individual symptom scores, quality-of-life score, adverse events, treatment adherence and requirement for rescue medication were recorded. The primary outcome was the mean change in Total Nasal Symptom Score from baseline to four weeks. Secondary outcomes included changes in individual symptoms and quality-of-life scores, proportion achieving at least 50% symptom reduction, overall clinical response, adherence, satisfaction and adverse effects.

Adherence was evaluated through patient self-reporting and the estimated number of administered or remaining doses. Patients who used at least 80% of the prescribed doses were considered adherent. Adverse effects such as nasal irritation, dryness, epistaxis, headache, unpleasant taste and somnolence were actively assessed.

### Sample Processing

Under aseptic precautions, approximately 3-5 mL of venous blood was collected at baseline when laboratory confirmation was included in the institutional protocol. Blood collected in an EDTA tube was used for complete blood count and absolute eosinophil count. A separate sample was collected in a plain tube, allowed to clot and centrifuged at approximately 3,000 revolutions per minute for 10 minutes. The separated serum was used for total serum immunoglobulin E estimation. When performed, nasal-smear samples were obtained from the inferior turbinate, spread on clean glass slides, air-dried, stained and examined for eosinophils. These investigations supported the diagnosis but were not used as the sole criteria for treatment allocation or response assessment. Samples were labelled with unique identification numbers, processed according to standard laboratory procedures and discarded in accordance with biomedical-waste-management guidelines.

### Data Collection

Data were collected using a predesigned, pretested case-record form. Information included sociodemographic characteristics, clinical history, allergen exposure, examination findings, laboratory results, baseline and follow-up symptom scores, quality-of-life scores, adherence, rescue medication use and adverse events. Each participant was assigned a unique study code. Completed forms were checked for completeness and consistency before entry into an electronic database. Data entry was independently verified to minimize transcription errors.

### Statistical Methods

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics version 28.0. Continuous variables were presented as mean and standard deviation when normally distributed and as median and interquartile range when non-normally distributed. Categorical variables were expressed as frequencies and percentages.

Baseline continuous variables were compared using the independent-samples *t* test or Mann-Whitney U test, as appropriate. Categorical variables were compared using the chi-square test or Fisher's exact test. Changes within each treatment group were assessed using the paired *t* test or Wilcoxon signed-rank test. Differences in symptom scores over multiple follow-up visits were analysed using repeated-measures analysis of variance or an appropriate mixed-effects model. Between-group treatment effects were reported as mean differences, risk differences or relative risks with 95% confidence intervals. Both intention-to-treat and per-protocol analyses were undertaken where applicable. All tests were two-tailed, and a *p* value below 0.05 was considered statistically significant.

## Results

**Table 1: Overall effectiveness and safety of topical steroid versus antihistamine nasal spray (N=170)**

| Outcome at 4 weeks | Total (N=170), n (%) or Mean (SD) | Topical steroid (n=85) | Antihistamine spray (n=85) | Effect estimate (95% CI) | Test of significance | P value |
|---|---|---|---|---|---|---|
| Reduction in Total Nasal Symptom Score | 5.76 (1.81) | 6.12 (1.72) | 5.39 (1.83) | MD=0.73 (0.19-1.27) | t=2.68 | 0.008* |
| Clinical response† | 134 (78.8) | 73 (85.9) | 61 (71.8) | RD=14.1% (2.0%-26.2%) | $\chi^2$=5.07 | 0.024* |
| ≥50% reduction in symptom score | 126 (74.1) | 69 (81.2) | 57 (67.1) | RD=14.1% (1.1%-27.1%) | $\chi^2$=4.42 | 0.036* |
| Time to noticeable symptom relief, days | 2.86 (1.42) | 3.74 (1.31) | 1.98 (0.92) | MD=1.76 days (1.42-2.10) | t=10.14 | <0.001* |
| Required rescue medication | 27 (15.9) | 8 (9.4) | 19 (22.4) | RD=−12.9% (−23.8% to −2.1%) | $\chi^2$=5.33 | 0.021* |
| Experienced any adverse effect | 27 (15.9) | 9 (10.6) | 18 (21.2) | RD=−10.6% (−21.5% to 0.3%) | $\chi^2$=3.57 | 0.059 |

*Statistically significant at P<0.05.
†Clinical response was defined as marked improvement or complete resolution of allergic-rhinitis symptoms. MD: mean difference; RD: risk difference.

Table 1 presents the overall effectiveness and safety of topical steroid and antihistamine nasal sprays after four weeks of treatment. The mean reduction in Total Nasal Symptom Score was significantly greater in the topical steroid group than in the antihistamine group (6.12±1.72 versus 5.39±1.83), with a mean difference of 0.73 (95% CI: 0.19-1.27; t=2.68; P=0.008). A clinical response was achieved by 73 (85.9%) patients receiving topical steroids compared with 61 (71.8%) receiving antihistamine spray, representing an absolute difference of 14.1% (95% CI: 2.0%-26.2%; $\chi^2$=5.07; P=0.024). Similarly, a reduction of at least 50% in symptom score was more frequent with topical steroids than with antihistamines (81.2% versus 67.1%; RD=14.1%, 95% CI: 1.1%-27.1%; P=0.036). However, the antihistamine spray provided significantly faster noticeable symptom relief, with a mean onset of 1.98±0.92 days compared with 3.74±1.31 days for the topical steroid (MD=1.76 days, 95% CI: 1.42-2.10; P<0.001). Rescue medication was required significantly less frequently in the steroid group (9.4% versus 22.4%; P=0.021). Any adverse effect was reported by 10.6% of patients in the steroid group and 21.2% in the antihistamine group; however, this difference did not reach statistical significance (P=0.059).

**Table 2: Reduction in total and individual nasal symptom scores (N=170)**

| Symptom-score reduction from baseline to 4 weeks | Total (N=170), Mean (SD) | Topical steroid (n=85), Mean (SD) | Antihistamine spray (n=85), Mean (SD) | Mean difference (95% CI) | Independent t test | P value |
|---|---|---|---|---|---|---|
| Total Nasal Symptom Score | 5.76 (1.81) | 6.12 (1.72) | 5.39 (1.83) | 0.73 (0.19-1.27) | 2.68 | 0.008* |

| | | | | | | |
|---|---|---|---|---|---|---|
| Sneezing score | 1.47 (0.72) | 1.54 (0.70) | 1.39 (0.73) | 0.15 (−0.07 to 0.37) | 1.37 | 0.173 |
| Rhinorrhoea score | 1.42 (0.70) | 1.49 (0.68) | 1.34 (0.71) | 0.15 (−0.06 to 0.36) | 1.41 | 0.161 |
| Nasal-obstruction score | 1.57 (0.77) | 1.78 (0.72) | 1.36 (0.76) | 0.42 (0.20-0.64) | 3.70 | <0.001* |
| Nasal-itching score | 1.31 (0.65) | 1.31 (0.64) | 1.30 (0.66) | 0.01 (−0.19 to 0.21) | 0.10 | 0.920 |
| Night-time symptom score | 1.38 (0.73) | 1.56 (0.69) | 1.19 (0.72) | 0.37 (0.16-0.58) | 3.42 | 0.001* |
| Ocular symptom score | 1.16 (0.67) | 1.21 (0.66) | 1.11 (0.68) | 0.10 (−0.10 to 0.30) | 0.97 | 0.333 |

*Statistically significant at P<0.05. A positive mean difference favoured the topical steroid group.

Table 2 compares the reductions in total and individual nasal symptom scores from baseline to four weeks. The overall mean reduction in Total Nasal Symptom Score was 5.76±1.81. The reduction was significantly greater with topical steroid spray than with antihistamine spray (6.12±1.72 versus 5.39±1.83; MD=0.73, 95% CI: 0.19-1.27; t=2.68; P=0.008). Among the individual symptoms, the steroid group demonstrated a significantly greater reduction in nasal-obstruction score (1.78±0.72 versus 1.36±0.76; MD=0.42, 95% CI: 0.20-0.64; P<0.001) and night-time symptom score (1.56±0.69 versus 1.19±0.72; MD=0.37, 95% CI: 0.16-0.58; P=0.001). The reductions in sneezing and rhinorrhoea scores were also numerically greater in the steroid group, but the between-group differences were not statistically significant (P=0.173 and P=0.161, respectively). Nasal itching improved almost equally in both groups, with a mean difference of only 0.01 (95% CI: −0.19 to 0.21; P=0.920). Similarly, the difference in ocular-symptom reduction was not significant (MD=0.10, 95% CI: −0.10 to 0.30; P=0.333).

**Table 3: Improvement in disease-related quality of life and overall clinical response (N=170)**

| Outcome at 4 weeks | Total (N=170), n (%) or Mean (SD) | Topical steroid (n=85) | Antihistamine spray (n=85) | Effect estimate (95% CI) | Test of significance | P value |
|---|---|---|---|---|---|---|
| Baseline RQLQ score | 4.18 (0.88) | 4.21 (0.87) | 4.15 (0.89) | MD=0.06 (−0.21 to 0.33) | t=0.44 | 0.658 |
| RQLQ score at 4 weeks | 2.17 (0.82) | 2.02 (0.78) | 2.32 (0.84) | MD=−0.30 (−0.55 to −0.05) | t=−2.41 | 0.017* |
| Reduction in RQLQ score | 2.02 (0.78) | 2.19 (0.74) | 1.84 (0.79) | MD=0.35 (0.12-0.58) | t=2.98 | 0.003* |
| Clinically meaningful RQLQ improvement† | 139 (81.8) | 76 (89.4) | 63 (74.1) | RD=15.3% (3.7%-26.9%) | $\chi^2$=6.69 | 0.010* |
| Excellent/good overall response | 130 (76.5) | 71 (83.5) | 59 (69.4) | RD=14.1% (1.5%-26.7%) | $\chi^2$=4.71 | 0.030* |
| Complete or near-complete symptom control | 111 (65.3) | 63 (74.1) | 48 (56.5) | RD=17.6% (3.6%-31.7%) | $\chi^2$=5.86 | 0.016* |
| Improvement in sleep quality | 123 (72.4) | 68 (80.0) | 55 (64.7) | RD=15.3% (2.0%-28.6%) | $\chi^2$=4.96 | 0.026* |
| Improvement in daily activities | 128 (75.3) | 72 (84.7) | 56 (65.9) | RD=18.8% (6.2%-31.5%) | $\chi^2$=8.10 | 0.004* |

*Statistically significant at P<0.05.
†Clinically meaningful improvement was defined as a reduction of at least 0.5 point in the Rhinitis Quality of Life Questionnaire. RQLQ: Rhinitis Quality of Life Questionnaire.

Table 3 summarizes the improvement in disease-related quality of life and overall clinical response. The baseline Rhinitis Quality of Life Questionnaire scores were comparable between the topical steroid and antihistamine groups (4.21±0.87 versus 4.15±0.89; P=0.658), indicating similar pretreatment impairment. At four weeks, the mean RQLQ score was significantly lower in the steroid group than in the antihistamine group (2.02±0.78 versus 2.32±0.84; MD=−0.30, 95% CI: −0.55 to −0.05; P=0.017). Correspondingly, the reduction in RQLQ score was significantly greater with the topical steroid (2.19±0.74 versus 1.84±0.79; MD=0.35, 95% CI: 0.12-0.58; P=0.003). A clinically meaningful improvement in RQLQ score was observed in 89.4% of steroid-treated patients compared with 74.1% of antihistamine-treated patients (RD=15.3%, 95% CI: 3.7%-26.9%; P=0.010). Excellent or good overall response was also more frequent in the steroid group (83.5% versus 69.4%; P=0.030). Complete or near-complete symptom control was achieved by 74.1% and 56.5% of patients, respectively (P=0.016). Furthermore, improvements in sleep quality (80.0% versus 64.7%; P=0.026) and daily activities (84.7% versus 65.9%; P=0.004) were significantly more frequent with topical steroids.

**Table 4: Treatment adherence, patient satisfaction and adverse effects (N=170)**

| Outcome | Total (N=170), n (%) or Mean (SD) | Topical steroid (n=85) | Antihistamine spray (n=85) | Effect estimate (95% CI) | Test of significance | P value |
|---|---|---|---|---|---|---|
| Adherent to ≥80% of prescribed doses | 142 (83.5) | 76 (89.4) | 66 (77.6) | RD=11.8% (0.8%-22.8%) | $\chi^2$=4.28 | 0.039* |
| Mean treatment adherence, % | 87.9 (10.7) | 90.4 (9.3) | 85.4 (11.4) | MD=5.0% (1.8%-8.2%) | t=3.13 | 0.002* |
| Satisfied/very satisfied | 133 (78.2) | 72 (84.7) | 61 (71.8) | RD=12.9% (0.7%-25.2%) | $\chi^2$=4.18 | 0.041* |
| Willing to continue treatment | 137 (80.6) | 74 (87.1) | 63 (74.1) | RD=12.9% (1.2%-24.7%) | $\chi^2$=4.57 | 0.033* |
| Any adverse effect | 27 (15.9) | 9 (10.6) | 18 (21.2) | RD=−10.6% (−21.5% to 0.3%) | $\chi^2$=3.57 | 0.059 |
| Nasal irritation or dryness | 19 (11.2) | 8 (9.4) | 11 (12.9) | RD=−3.5% (−13.0% to 5.9%) | $\chi^2$=0.53 | 0.465 |
| Epistaxis | 10 (5.9) | 7 (8.2) | 3 (3.5) | RD=4.7% (−2.3% to 11.7%) | $\chi^2$=1.70 | 0.192 |
| Bitter or unpleasant taste | 16 (9.4) | 2 (2.4) | 14 (16.5) | RD=−14.1% (−22.6% to −5.6%) | $\chi^2$=9.94 | 0.002* |
| Somnolence | 8 (4.7) | 1 (1.2) | 7 (8.2) | RD=−7.1% (−13.3% to −0.8%) | $\chi^2$=4.72 | 0.030* |

| | | | | | | |
|---|---|---|---|---|---|---|
| Treatment discontinued because of adverse effects | 7 (4.1) | 2 (2.4) | 5 (5.9) | RD=−3.5% (−9.3% to 2.2%) | Fisher's exact test | 0.443 |

*Statistically significant at P<0.05. MD: mean difference; RD: risk difference.

Table 4 compares treatment adherence, satisfaction and adverse effects. Overall, 142 (83.5%) patients adhered to at least 80% of prescribed doses. The proportion of adherent patients was significantly higher in the topical steroid group than in the antihistamine group (89.4% versus 77.6%; RD=11.8%, 95% CI: 0.8%-22.8%; P=0.039). Mean adherence was also significantly higher with topical steroids (90.4±9.3% versus 85.4±11.4%; MD=5.0%, 95% CI: 1.8%-8.2%; P=0.002). The proportions who were satisfied or very satisfied (84.7% versus 71.8%; P=0.041) and willing to continue treatment (87.1% versus 74.1%; P=0.033) were significantly greater in the steroid group. Any adverse effect was reported by 10.6% of steroid-treated and 21.2% of antihistamine-treated patients, although this difference was not statistically significant (P=0.059). Nasal irritation or dryness occurred in 9.4% and 12.9%, respectively (P=0.465), whereas epistaxis was numerically more frequent with topical steroids (8.2% versus 3.5%; P=0.192); neither difference was significant. Bitter or unpleasant taste was significantly more common with antihistamine spray (16.5% versus 2.4%; P=0.002), as was somnolence (8.2% versus 1.2%; P=0.030). Treatment discontinuation because of adverse effects was uncommon and did not differ significantly between groups (2.4% versus 5.9%; Fisher's exact P=0.443).

## Discussion

### Overall effectiveness and safety

In the present study, both topical steroid and antihistamine nasal sprays produced substantial clinical improvement after four weeks; however, the topical steroid demonstrated superior overall effectiveness. The mean reduction in Total Nasal Symptom Score (TNSS) was significantly greater with topical steroid than with antihistamine spray (6.12±1.72 versus 5.39±1.83; mean difference=0.73, 95% CI: 0.19-1.27; P=0.008). Clinical response was achieved in 85.9% of patients receiving topical steroid compared with 71.8% receiving antihistamine spray, while ≥50% symptom reduction was observed in 81.2% and 67.1%, respectively. These findings agree with the clinical practice guideline by Seidman et al. (2015)[1], which strongly recommended intranasal corticosteroids for patients with allergic rhinitis whose symptoms adversely affected quality of life. Similarly, Brożek et al. (2017)[2] emphasized the overall efficacy of intranasal corticosteroids, particularly for persistent and moderate-to-severe allergic rhinitis.

The greater sustained effectiveness of topical steroid in the present study may be explained by its broad suppression of the allergic inflammatory response. Unlike antihistamines, which primarily block histamine H1 receptors, intranasal corticosteroids inhibit inflammatory cytokines, vascular permeability, mucosal oedema and recruitment of eosinophils and other inflammatory cells. Wallace et al. (2017)[3] recommended intranasal corticosteroid monotherapy as the preferred initial treatment for patients aged ≥12 years with seasonal allergic rhinitis. Dykewicz et al. (2020)[4] also identified intranasal corticosteroids as the preferred monotherapy for persistent allergic rhinitis, while acknowledging intranasal antihistamines as effective treatments for both allergic and nonallergic rhinitis.

The present results are supported by the systematic review of Sousa-Pinto et al. (2024)[5], which found that most intranasal corticosteroids and antihistamines were effective in improving nasal symptoms and quality of life, although differences existed between medications and in the certainty of evidence. In a direct comparative study, Krishnakumar et al. (2022)[6] similarly found that both fluticasone and azelastine nasal sprays improved allergic-rhinitis symptoms, with fluticasone providing better control of several symptom domains. The present study therefore reinforces the superiority of topical steroids for sustained overall disease control.

An important contrasting observation was that antihistamine spray produced noticeable relief significantly earlier than topical steroid spray (1.98±0.92 versus 3.74±1.31 days; P<0.001). This is pharmacologically plausible because topical antihistamines rapidly block nasal H1 receptors, whereas corticosteroids require time to modify inflammatory-gene transcription and suppress the late-phase allergic response. Bousquet et al. (2023)[7] confirmed the rapid clinical efficacy of azelastine in perennial allergic rhinitis. Thus, topical antihistamines may be advantageous when rapid relief is the immediate treatment priority, whereas topical steroids appear more suitable for sustained symptom suppression. Rescue medication was required less frequently with topical steroids (9.4% versus 22.4%; P=0.021), further supporting their more durable therapeutic effect.

### Reduction in total and individual symptoms

The analysis of individual symptoms showed that the principal advantage of topical steroids was in controlling nasal obstruction and night-time symptoms. The reduction in nasal-obstruction score was significantly greater with topical steroid than with antihistamine spray (1.78±0.72 versus 1.36±0.76; mean difference=0.42; P<0.001). The reduction in night-time symptoms was also significantly greater in the steroid group (1.56±0.69 versus 1.19±0.72; P=0.001). These findings are consistent with the anti-inflammatory and anti-oedematous effects of intranasal corticosteroids on the nasal mucosa.

Juel-Berg et al. (2017)[8], in a systematic review and meta-analysis of 990 patients, found that intranasal corticosteroids were superior to nonsedating oral antihistamines for total nasal symptoms and nasal obstruction. Although their comparison involved oral rather than intranasal antihistamines, the findings support the strong effect of topical steroids on congestion. The International Consensus Statement by Wise et al. (2018)[9] similarly recognized intranasal corticosteroids as highly effective across the major nasal-symptom domains and particularly valuable when nasal congestion was prominent.

Differences in the reductions in sneezing, rhinorrhoea and nasal itching were not statistically significant. Sneezing decreased by 1.54±0.70 with topical steroid and 1.39±0.73 with antihistamine spray (P=0.173), while rhinorrhoea decreased by 1.49±0.68 and 1.34±0.71, respectively (P=0.161). Nasal-itching improvement was almost identical between the groups (P=0.920). These results may reflect the central role of histamine in producing itching, sneezing and watery rhinorrhoea, making an intranasal antihistamine particularly effective for these symptoms. Consequently, although the steroid provided broader overall control, both treatments had similar effects on predominantly histamine-mediated complaints.

The between-group difference in ocular-symptom reduction was also nonsignificant (1.21±0.66 versus 1.11±0.68; P=0.333). Juel-Berg et al. (2017)[8] likewise reported no clear superiority of intranasal corticosteroids over antihistamine treatment for ocular symptoms. Therefore, the lack of a significant difference in the present study was consistent with existing evidence and suggested that patients with prominent ocular complaints might require additional ocular or systemic therapy.

### Quality of life and clinical response

Baseline RQLQ scores were comparable between the groups (4.21±0.87 versus 4.15±0.89; P=0.658), supporting the comparability of pretreatment disease burden. After four weeks, the topical steroid group had a significantly lower RQLQ score than the antihistamine group (2.02±0.78 versus 2.32±0.84; P=0.017). The reduction in RQLQ score was also greater with topical steroids (2.19±0.74 versus 1.84±0.79; P=0.003). A clinically meaningful improvement was achieved by 89.4% and 74.1% of participants, respectively (P=0.010).

These results agree with the review by Sousa-Pinto et al. (2024)[5], which demonstrated that intranasal treatments improved both symptom scores and rhinoconjunctivitis-related quality of life. Juel-Berg et al. (2017)[8] also found a greater quality-of-life benefit with intranasal corticosteroids than with oral antihistamines. Calvo-Henríquez et al. (2021)[10] explained that regular intranasal corticosteroid use was associated with improved nasal airflow, symptom control and RQLQ outcomes, supporting the improvements recorded in the present study.

Excellent or good overall response occurred in 83.5% of steroid-treated patients compared with 69.4% of antihistamine-treated patients (P=0.030). Similarly, complete or near-complete symptom control was more frequent with topical steroids (74.1% versus 56.5%; P=0.016). Improvements in sleep quality (80.0% versus 64.7%; P=0.026) and daily activities (84.7% versus 65.9%; P=0.004) were also significantly greater. Brożek et al. (2017)[2] emphasized that adequate control of allergic rhinitis could improve sleep, school and workplace productivity. These findings indicate that the clinical benefit of topical steroids extended beyond nasal symptoms to functional and patient-centred outcomes.

**Adherence, satisfaction and adverse effects**

Adherence to ≥80% of prescribed doses was significantly higher with topical steroid than with antihistamine spray (89.4% versus 77.6%; P=0.039), and mean adherence was 90.4±9.3% and 85.4±11.4%, respectively (P=0.002). Patient satisfaction and willingness to continue treatment were also significantly greater in the steroid group. Singh et al. (2022)[11] reported an intranasal-corticosteroid adherence rate of approximately 59% among allergic-rhinitis patients with comorbidities and identified absence of symptoms, fear of adverse effects, forgetfulness and medication availability as important barriers. The higher adherence in the present study may have resulted from its shorter four-week follow-up, regular monitoring, greater symptom relief and treatment counselling. Nevertheless, it underscores the importance of educating patients regarding correct technique and regular rather than symptom-driven steroid use.

Any adverse effect was less frequent with topical steroid than with antihistamine spray (10.6% versus 21.2%), although the difference narrowly missed statistical significance (P=0.059). Nasal irritation or dryness was comparable between the groups. Epistaxis was numerically more frequent with topical steroids (8.2% versus 3.5%), although this difference was nonsignificant (P=0.192). Wu et al. (2019)[12], in a meta-analysis of 72 randomized trials, reported that intranasal corticosteroids increased the risk of epistaxis relative to placebo (RR=1.48, 95% CI: 1.32-1.67). The present findings were directionally consistent with this known local adverse effect, although the study may not have had sufficient power to detect a difference in an infrequent outcome.

Bitter or unpleasant taste was significantly more common with antihistamine spray (16.5% versus 2.4%; P=0.002), as was somnolence (8.2% versus 1.2%; P=0.030). Krishnakumar et al. (2022)[6] also identified bitter taste as an important adverse effect of azelastine. Bousquet et al. (2023)[7] observed that an unpleasant taste may be related partly to administration technique, particularly excessive posterior deposition caused by tilting the head backward or inhaling forcefully. Appropriate counselling about directing the nozzle laterally, maintaining the head slightly forward and avoiding forceful sniffing may therefore improve acceptability. Treatment discontinuation due to adverse effects was uncommon and did not differ significantly between groups (2.4% versus 5.9%; P=0.443), showing that both treatments were generally well tolerated.

**Conclusion**

Both topical steroid and antihistamine nasal sprays were effective and generally well tolerated in the management of allergic rhinitis. However, the topical steroid spray provided significantly greater overall and sustained symptom control, particularly for nasal obstruction and night-time symptoms. It also produced greater improvement in disease-related quality of life, sleep quality, daily activities and overall clinical response. Patients receiving topical steroids required rescue medication less frequently and demonstrated better treatment adherence and satisfaction.

The antihistamine nasal spray provided significantly faster noticeable symptom relief, indicating its usefulness when rapid control of sneezing, itching and rhinorrhoea is required. Nevertheless, bitter taste and somnolence were more frequent with the antihistamine spray, whereas epistaxis was numerically more common with the topical steroid. Both treatments had low discontinuation rates.

These findings support topical steroid nasal spray as the preferred treatment for sustained control of moderate or persistent allergic rhinitis, especially when nasal obstruction and quality-of-life impairment predominate. Antihistamine nasal spray remains an effective option for patients requiring rapid symptom relief or those who cannot tolerate corticosteroids. Treatment selection should be individualized according to symptom pattern, desired onset of action, tolerability, adherence and patient preference.

**LIMITATIONS**

1. The study was conducted at a single tertiary-care centre; therefore, its findings may not be generalizable to patients treated in primary-care settings or other geographical populations.
2. The sample size was relatively limited and might have been insufficient to identify statistically significant differences in uncommon adverse effects such as epistaxis and treatment discontinuation.
3. The follow-up period was limited to four weeks; therefore, long-term effectiveness, adherence, recurrence and safety could not be evaluated.
4. The open-label design might have introduced performance, reporting and observer bias because the participants and investigators were aware of treatment allocation.
5. Symptom severity, adherence and satisfaction were partly assessed using patient-reported measures and were therefore susceptible to recall and response bias.
6. Treatment adherence was estimated using patient reports and remaining doses rather than electronic medication-monitoring devices.
7. Variations in allergen exposure, seasonal conditions and environmental pollution were not objectively measured or controlled.
8. Allergic sensitization was not uniformly confirmed by skin-prick testing or allergen-specific immunoglobulin E estimation in all participants.
9. The study did not stratify outcomes according to intermittent or persistent disease, allergen type, baseline severity or associated asthma and conjunctivitis.
10. Rescue-medication use and minor variations in nasal-spray administration technique might have influenced treatment outcomes.
11. Objective assessments such as peak nasal inspiratory flow, acoustic rhinometry or rhinomanometry were not employed.
12. Multiple secondary outcomes were analysed without adjustment for multiple comparisons; therefore, some statistically significant findings could have occurred by chance.

**References**

1. Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, et al. Clinical practice guideline: allergic rhinitis. Otolaryngol Head Neck Surg. 2015;152(1 Suppl):S1-S43.
2. Brożek JL, Bousquet J, Agache I, Agarwal A, Bachert C, Bosnic-Anticevich S, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines--2016 revision. J Allergy Clin Immunol. 2017;140(4):950-958.
3. Wallace DV, Dykewicz MS, Oppenheimer J, Portnoy JM, Lang DM. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. Ann Intern Med. 2017;167(12):876-881.
4. Dykewicz MS, Wallace DV, Amrol DJ, Baroody FM, Bernstein JA, Craig TJ, et al. Rhinitis 2020: a practice parameter update. J Allergy Clin Immunol. 2020;146(4):721-767.
5. Sousa-Pinto B, Vieira RJ, Brozek J, Cardoso-Fernandes A, Lourenço-Silva N, Ferreira-da-Silva R, et al. Intranasal antihistamines and corticosteroids in allergic rhinitis: a systematic review and meta-analysis. J Allergy Clin Immunol. 2024;154(2):340-354.
6. Krishnakumar D, Faizal B, Nair AS. Comparison of the effects of azelastine and fluticasone nasal sprays in the treatment of allergic rhinitis. Indian J Otolaryngol Head Neck Surg. 2022;74(Suppl 2):1632-1637.
7. Bousquet J, Klimek L, Kuhl HC, Nguyen DT, Ramalingam RK, Canonica GW, et al. A double-blind, placebo-controlled trial of the efficacy and safety of two doses of azelastine hydrochloride in perennial allergic rhinitis. Front Allergy. 2023;4:1244012.
8. Juel-Berg N, Darling P, Bolvig J, Foss-Skiftesvik MH, Halken S, Winther L, et al. Intranasal corticosteroids compared with oral antihistamines in allergic rhinitis: a systematic review and meta-analysis. Am J Rhinol Allergy. 2017;31(1):e19-e28.
9. Wise SK, Lin SY, Toskala E, Orlandi RR, Akdis CA, Alt JA, et al. International consensus statement on allergy and rhinology: allergic rhinitis. Int Forum Allergy Rhinol. 2018;8(2):108-352.

10. Calvo-Henríquez C, Karkos P, Tsilivigkos C, Fakhry N, Rinaldi V, Lechien JR, et al. The subtle nuances of intranasal corticosteroids. J Otolaryngol Head Neck Surg. 2021;50(1):18.
11. Singh PKM, Krishnan EK, Mat Lazim N, Yaacob NM, Abdullah B. Medication adherence to intranasal corticosteroids in allergic rhinitis patients with comorbid medical conditions. Pharmaceutics. 2022;14(11):2459.
12. Wu EL, Harris WC, Babcock CM, Alexander BH, Riley CA, McCoul ED. Epistaxis risk associated with intranasal corticosteroid sprays: a systematic review and meta-analysis. Otolaryngol Head Neck Surg. 2019;161(1):18-27.