Original Research Article

Comparative study of intranasal steroids sprays alone v/s intranasal steroids with intranasal antihistamines sprays in patients with allergic rhinitis

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Abstract

Background: Allergic rhinitis, is one of the most common respiratory problems encountered in the clinical practice. The treatment includes combination of allergen avoidance and pharmacotherapy i.e, antihistaminics, corticosteroids and mast cell stabilizers. Present study was aimed to compare intranasal steroids sprays alone v/s intranasal steroids with intranasal antihistamines sprays in patients with allergic rhinitis. **Material and Methods:** Present study was conducted in patients from 18-45 years of age group, either gender, attending the ENT outpatient clinic, clinically diagnosed with allergic rhinitis. The patient was examined with the assessment scales for nasal congestion and obstruction using the Nasal obstruction Symptom Evaluation (NOSE) scale. 80 patients by computer generated chits randomly allocated to Group S (50 mcg of fluticasone propionate in each spray) and Group SA (Azelastine Hydrochloride 140 mcg, Fluticasone Propionate 50 mcg in each nasal spray) **Results:** Age and gender distribution was comparable among both groups and difference was not significant statistically. Group S had baseline NOSE score as 80.79 ± 12.22 and at 6 weeks score was 81.88 ± 10.49 and difference was statistically significant (p <0.001). Group SA had baseline NOSE score as 81.88 ± 10.49 and at 6 weeks score was 28.29 ± 8.21 and difference was statistically significant (p <0.001). At baseline NOSE score in group S was 80.79 ± 12.22 while in group SA was 81.88 ± 10.49, difference was not significant statistically (p - 0.078). After 6 weeks, NOSE score in group S was 53.32 ± 9.33 while in group SA was 28.29 ± 8.21, difference was statistically significant (p - 0.023). **Conclusion:** Combination of intranasal steroids with intranasal antihistamines sprays has significant reduction of symptoms when compared to intranasal steroids spray alone in the management of allergic rhinitis.

Keywords: allergic rhinitis, intranasal steroids, intranasal antihistamines sprays, NOSE score.

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INTRODUCTION

Allergic rhinitis is clinically defined as a symptomatic disorder of the nasal membranes and surrounding tissues induced by an IgE mediated inflammation aOer the exposure of the nasal membranes to an allergen.[1,2] Allergic rhinitis, is one of the most common respiratory problems encountered in the clinical practice. Estimates of the prevalence of the allergic rhinitis in different countries vary from 0.5% to 28.0%.[3] Around 20–30 % Indian population suffers from allergic rhinitis and prevalence is increasing over past few years.[4] Common manifestations of the allergic rhinitis include paroxysmal sneezing, nasal blockage, and watery nasal discharge. In clinical examination there may be pale or bluish boggy inferior

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turbinates with watery nasal discharge. The conjunctivae may be hyperemic and edematous. The treatment includes combination of allergen avoidance and pharmacotherapy i.e, antihistaminics, corticosteroids and mast cell stabilizers. Newer second-generation drugs like levocetrizine, desloratidine, and azelastine are preferred due to rapid onset of action and symptomatic improvement and decreased incidence of side effects compared to first generation antihistaminics.[5]

Topical corticosteriods are effective in controlling nasal symptoms of allergic rhinitis, they control sneezing, rhinorrhoe nasal congestion/pruritus. Corticosteriods like Mometasone Beclomethasone, Budesonide and Fluticesone available as Aqueous nasal sprays, better tolerated, have better local distribution with in the nasal cavity.[6] Present study was aimed to compare intranasal steroids sprays alone v/s intranasal steroids with intranasal antihistamines sprays in patients with allergic rhinitis.

MATERIAL AND METHODS

Present study was conducted in Department of ENT, KIMS Medical College, Chaitanya Nagar, Amalapuram, India. Study type was comparative, prospective study of 2 years duration. Study approval was obtained from institutional ethical committee.

Inclusion criteria

- Patients from 18-45 years of age group, either gender, attending the ENT outpatient clinic, clinically diagnosed with allergic rhinitis, willing to participate in present study.

Exclusion criteria

- Patients with Hypersensitivity to Antihistamines or Corticosteroids.
- Patients with structural abnormalities in nose i.e., grossly deviated nasal septum, nasal polyps or nasal tumors.
- Use of systemic/oral corticosteroids within 30 days of first visit
- Patients with significant medical (i.e. asthma, chronic sinusitis, tuberculosis, carcinoma of lung, pneumonia and upper respiratory tract infections), surgical or psychiatric disease which can affect participant's safety or influence the study outcome
- Patients with history of blood disorders like nonallergic eosinophilic syndrome, tropical eosinophilia syndrome.

Study was explained to patients in local language and written consent was taken for participation and study. General data such as age, gender, medical history, any co-morbidity, symptoms of allergic rhinitis were noted in the study proforma. Base line investigations such as Complete blood picture, absolute eosinophil count were done. The patient was examined with the assessment scales for nasal congestion and obstruction using the Nasal obstruction Symptom Evaluation (NOSE) scale.

In present study, 80 patients by computer generated chits randomly allocated to group S and group SA.

- Group S (n=40) patients were asked to administer the dose of 2 sprays (50 mcg of fluticasone propionate in each spray) in each nostril once daily (total daily dose, 200 mcg) in the morning. This drug was given for a period of 4 weeks.
- Group SA (n=40) patients were asked to administer 1 spray (Azelastine Hydrochloride 140 mcg, Fluticasone Propionate 50 mcg in each nasal spray) in each nostril twice daily (total daily dose 560 mcg of Azelastine hydrochloride and 200 mcg of fluticasone propionate) in the morning and evening.

Both groups receive treatment for a period of 6 weeks. Patients were instructed on proper technique for administering the nasal sprays, before starting the treatment. The follow up was done for checking the alleviation of symptoms after 6 weeks of start of the treatment.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS

In present study, 80 patients were randomly divided in group S (n=40) and group SA (n=40). Age and gender distribution was comparable among both groups and difference was not significant statistically.

Table 1: General characteristics

Characteristics	Group S - No. of patients (%)	Group SA - No. of patients (%)	P value
Age groups (in years)			0.081
18-25	18 (45 %)	16 (40 %)	
26-35	14 (35 %)	14 (35 %)	
36-45	8 (20 %)	10 (25 %)	

Mean age (mean ± SD)	32.24 ± 9.45	31.95 ± 10.03	
Gender			0.092
Male	18 (45 %)	19 (47.75 %)	
Female	22 (55 %)	21 (52.25 %)	

In present study, Group S had baseline NOSE score as 80.79 ± 12.22 and at 6 weeks score was 81.88 ± 10.49 and difference was statistically significant (p <0.001). Group SA had baseline NOSE score as 81.88 ± 10.49 and at 6 weeks score was 28.29 ± 8.21 and difference was statistically significant (p <0.001).

At baseline NOSE score in group S was 80.79 ± 12.22 while in group SA was 81.88 ± 10.49, difference was not significant statistically (p - 0.078). After 6 weeks, NOSE score in group S was 53.32 ± 9.33 while in group SA was 28.29 ± 8.21, difference was statistically significant (p - 0.023).

Table 2: NOSE score

Groups	Group S	Group SA	P value
Base line	80.79 ± 12.22	81.88 ± 10.49	0.078
After 6 weeks	53.32 ± 9.33	28.29 ± 8.21	0.023
P value	<0.001	<0.001	

DISCUSSION

Allergic rhinitis (AR) or hay fever is a chronic inflammation of nasopharynx that occurs as a response against inhaled allergen exposure triggered by immunoglobulin E (IgE)-mediated inflammation of nasal membranes.[8,9] Severe AR deteriorates the quality of life leading to impairment of daily activity and its prevalence is on increase.[10] Patients with AR can also experience fatigue, sleep disturbance, social function impairment, depressed mood, anxiety, learning, attention impairment, increased work or school absenteeism, decreased work or school performance and productivity. The impact is made worse because of co-morbidities such as sinusitis, otitis media with effusion, allergic conjunctivitis, bronchial asthma and dental disorders.[11] AR represents as a part of systemic airway disease involving the entire respiratory tract and is no more a localized disorder of nasal cavity as thought earlier.[12] Nasal steroids and antihistamines have been considered as gold standard treatment of choice in moderate to severe AR.[13] In order to avoid possible systemic effects while concentrating the therapeutic effect on the diseased tissue, the topical nasal administration of drugs has become popular. Azelastine, a phthalazinone derivative, is an antiallergic drug with multiple activities. Azelastine inhibits antigen induced production of leukotrienes (LTC4 and LTD4), which inhibits the 5-lipoxygenase pathway of arachidonic acid metabolism.[14,15] Sahana G N *et al..*,[16] studied 60 patients, randomly assigned into a group received fluticasone (n=30) and the other group received fluticasone + azelastine (n=30), both the groups had statistical improvement in TNSS and RQLQ scores when compared to baseline within the groups (p < 0.0001). They concluded that the combination therapy showed better improvement in TNSS when compared to fluticasone alone. The improvement in combination therapy might be due to different mechanism of action of the drugs and also intranasal drug delivery targets nasal mucosa and reduces the risk in allergic rhinitis. A study by Dhanush HC *et al..*,[17] also observed the significant reduction in individual symptoms of allergic rhinitis among the patients treated with topical azelastine. In study by Deepa Shivnani,[18] allergic rhinitis was found to be more common in younger age group. Combination Nasal Sprays (Intra-nasal corticosteroids with intranasal antihistamines) were found to be statistically superior when compared to only intranasal steroid sprays. Raisha G. *et al..*,[19] noted that after four weeks, both TSS and individual symptom score were reduced in either group (p<0.05). TSS decreased by an average of 84.14% in Group-I (i.e. treated with Fluticasone propionate) was less effective than 91.16% in Group–II (i.e. treated with Fluticasone propionate and Azelastine hydrochloride I in a combination). In study by Somasundaram S *et al..*,[20] 60 patients randomly allocated to group S (intranasal steroids) and group SA (intranasal steroids and intranasal antihistamines). Baseline NOSE score (Group S - 82.17 ± 10.52 and Group SA - 83.75 ± 11.94) were comparable and difference was not significant statistically (p - 0.078). At 6 weeks a significant fall in Absolute eosinophil count was noted in groups S (82.17 ± 10.52 vs 49.28 ± 7.56) as well as group SA (83.75 ± 11.94 vs 22.2 ± 6.97) and difference was statistically significant (p<0.001). At 6 weeks, less NOSE score was noted in group SA (22.2 ± 6.97) as compared to group S (49.28 ± 7.56) and difference was statistically significant (p - 0.021). Standard of care for AR includes a treatment plan that considers patient preferences, the severity of the disease, and most essentially involves a shared decision-making process between patient and provider. National and international guidelines recommend topical treatment, intranasal sprays, as targeted therapy for AR The primary advantage of topical therapy is direct delivery to the site of the disease, the nasal mucosa. Reduction in the likelihood of systemic adverse effects is a secondary benefit. [21,22] Intranasal

corticosteroids are considered first-line agents for the treatment of allergic rhinitis, especially for patients with moderate to severe symptoms. Consensus guidelines do not recommend the use of one intranasal corticosteroid product over another. Intranasal corticosteroids combined with intranasal antihistamines are considered to be more effective than either alone in the treatment of allergic rhinitis. [23,24]

CONCLUSION

The management of AR includes patient education on avoidance of allergen as well as pharmacotherapy and allergen specific immunotherapy. Combination of intranasal steroids with intranasal antihistamines sprays has significant reduction of symptoms when compared to intranasal steroids spray alone. The goals of treatment are to provide the patient with symptomatic relief and improve the quality of life with minimal adverse effects.

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