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Original Research Article

An Experiment Comparative Assessment of Intranasal Steroids Sprays Alone V/S Intranasal Steroids with Intranasal Antihistamines Sprays in Patients with Allergic Rhinitis

Priyanka Patel[1], Urvishbhai Patel[2], Amit B. Chavda[3], Kritika Nigam[4]

[1]Senior Resident, Department of ENT (Otorhinolaryngology), GMERS Medical College, Himmatnagar, Gujarat, India

[2]3rd Year Resident, Department of Otorhinolaryngology, GMERS Medical College and Civil Hospital, Himmatnagar, Gujarat, India

[3]Assistant Professor, Department of ENT (Otorhinolaryngology), GMERS Medical College, Himmatnagar, Gujarat, India

[4]1st Year Resident, Department of ENT (Otorhinolaryngology), GMERS Medical College, Himmatnagar, Gujarat, India

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Corresponding author: Dr. Urvishbhai Patel

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Abstract

Aim: The aim of the present study was to compare intranasal steroids sprays alone v/s intranasal steroids with intranasal antihistamines sprays in patients with allergic rhinitis.

Methods: The Present study was conducted in Department of ENT, GMERS Medical College, Himmatnagar, Gujarat, India. Study type was comparative, prospective study of one year duration.

Results: In present study, 200 patients were randomly divided in group A (n=100) and group B (n=100). Majority of the patients belonged to 18-25 years age group. Age and gender distribution was comparable among both groups and difference was not significant statistically. All the parameters of TNSS before treatment, after 2weeks of treatment and after 4 weeks of treatment were analysed using ANOVA test (as it was found to be parametric in distribution) in the subjects treated with combination therapy and it was noted that statistically significant difference was found in all the parameters of all three groups ($p < 0.0001$). It was found that two groups were matched for activities, practical problem, nose symptoms, other symptoms. Eye symptoms were found to be significantly higher in steroid therapy group compared to combination therapy group. It was observed that in the steroid therapy group, mean percentage improvement was found to be 16% (0 weeks to 2 weeks) and 4% (2 weeks to 4 weeks) whereas for combination therapy group, the same was found to be 30% (0 weeks to 2 weeks) and 22% (2 weeks to 4 weeks).

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.

Keywords: allergic rhinitis, intranasal steroids, intranasal antihistamines sprays

Introduction

Allergic rhinitis is a disease characterized by nasal obstruction, rhinorrhea, sneezing and nasal itch and often accompanied by conjunctivitis. It is elicited by IgE-mediated allergic inflammation of the nasal mucosa. The disease prevalence is 10–20% of the population in industrialized countries [1] and seems to be increasing. [2,3] Although allergic rhinitis is not a life-threatening disease, it can severely affect patients' quality of life [4-6] and can cause comorbidity from other diseases, such as asthma, sinusitis, otitis media and conjunctivitis. [7] Allergic rhinitis can be either seasonal, i.e. present at certain times of the year such as during the pollen season, or perennial, i.e. present at all times of the year. Applicable therapeutic initiatives in allergic rhinitis are allergen avoidance, allergen immunotherapy and pharmacological intervention.

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%. [8] Around 20–30 % Indian population suffers from allergic rhinitis and prevalence is increasing over past few years. [9] 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 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. [10] 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. [11]

The aim of the present study was to compare intranasal steroids sprays alone v/s intranasal steroids with intranasal antihistamines sprays in patients with allergic rhinitis.

Materials and Methods

The Present study was conducted in Department of ENT, GMERS Medical College, Himmatnagar, Gujarat, India. Study type was comparative, prospective study of one year duration.

Inclusion criteria

- Patients complaining of sneezing, running nose or blocked nose and itching sensation in the nose which are hallmark symptoms of allergic rhinitis with moderate or severe grade of symptoms, having more than 5 TNSS were included in the study.
- 18 - 45 years old Patients irrespective of sex, religion and economical status
- All types of Allergic Rhinitis i.e., Seasonal, Perennial or Intermittent/Persistent.
- Able to provide written informed consent.

Exclusion criteria

- Age more than 45 years.
- Patients complaining of symptoms due to structural abnormalities i.e., grossly deviated nasal septum, nasal polyps or nasal tumors.
- Use of systemic/oral corticosteroids within 30 days of first visit
- Hypersensitivity to Antihistamines or Corticosteroids.
- 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 non-allergic eosinophilic syndrome, tropical eosinophilia syndrome.
- Patients with mild symptoms of AR with TNSS less than 5 were excluded from this study.
- 200 subjects were taken up for this study, 100 in each group after fulfilling the inclusion and exclusion criteria. The study was conducted in following two groups based on drug given;

Group A

In this group, 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 B

In this group 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. This drug was given for a period of 4 weeks. Instruction on proper technique for administering the nasal sprays was given before starting the treatment. Patients were explained in detail about the procedure and informed written consent was taken from all patients. Observation on parameters was done on 2nd and 4th week of the treatment. Analysis of symptoms was done statistically on the basis of improvement of TNSS and MiniRQLQ in case of allergic rhinitis.

The purpose of this study was to determine if greater efficacy could be achieved with the combination of azelastine hydrochloride nasal spray and fluticasone propionate nasal spray compared with the efficacy of fluticasone propionate nasal spray alone and also to ascertain whether the combination nasal sprays should be prescribed as a standard medical management for allergic rhinitis or not, as to achieve better quality of life after treatment with maximum improvement in TNSS.

Data collection techniques and tools

Patients presenting with sneezing, watery nasal discharge, nasal obstruction and itching sensation in the nose were carefully evaluated by means of a predesigned proforma, used to record the relevant information like Patient's data, Clinical findings and TNSS (Total Nasal Symptom Score) from the individual patient shortlisted with inclusion and exclusion criteria.

TNSS

Intensity of nasal symptoms (rhinorrhea, nasal itching, nasal obstruction and sneezing) using a 4-point Likert scale from 0 to 3 (0 = no symptom, 1 =

mild, 2 = moderate, 3 = severe). The TNSS was obtained from the sum of all 4 individual symptom scores, with a total possible score ranging from 0 (no symptoms) to 12(maximum symptom intensity). Patients with a TNSS of 5 or higher, not treated with antihistamines in the previous week or with topical corticosteroids in the previous 2 weeks, was included in the study.

Mini RQLQ

Disease-specific questionnaires are the instruments most widely used in order to "measure the quality of life", because they more accurately describe the problems associated with the disease and are more responsive to possible alterations in the quality of life, when compared with generic questionnaires. In the case of allergic rhinitis, the disease-specific questionnaire most commonly used is the Mini Rhino-conjunctivitis Quality of Life Questionnaire (Mini-RQLQ).

Mini rhino-conjunctivitis quality of life questionnaire

This self-administered, 14-item questionnaire has been validated to measure the functional impact of rhino-conjunctivitis in five domains (activity limitation, practical problems, nose symptoms, eye symptoms and other symptoms). Patients score their experiences during the previous week on a 7-point scale (0 = not troubled, 6 = extremely troubled) with total possible score ranging from 0 to 84.

Analysis of data

A database was created which includes the Patient's Name, Age, Sex, Hospital Number, Parameters of TNSS and Mini RQLQ scores before and after 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 was tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

Table 1: Demographic details

Age in years	**Group A**	**Group B**	**P Value**
18-25 years	46	44	0.070
26-35 years	34	30	
36-45 years	20	26	
Gender			
Male	48	46	0.095
Female	52	54	

In present study, 200 patients were randomly divided in group A (n=100) and group B (n=100). Majority of the patients belonged to 18-25 years age group. Age and gender distribution was comparable among both groups and difference was not significant statistically.

Table 2: Comparison of TNSS values at different interval of treatment with combination therapy

Characteristics Before treatment		**In subjects treated with combination therapy**		
		After 2 Weeks ofTreatment	**After 4 Weeks oftreatment**	**p Value**
TNSS in (Mean ± S.D)	Rhinorrhea	2.32 ± 0.56	0.34 ± 0.42	<0.0001
	Itching	2.04 ± 0.64	1.04 ± 0.70	<0.0001
	Nasal Obstruction	1.46 ± 0.80	0.54 ± 0.68	<0.0001
	Sneezing	2.48 ± 0.62	0.64 ± 0.49	<0.0001

All the parameters of TNSS before treatment, after 2weeks of treatment and after 4 weeks of treatment were analysed using ANOVA test (as it was found to be parametric in distribution) in the subjects treated with combination therapy and it was noted that statistically significant difference was found in all the parameters of all three groups ($p < 0.0001$).

Characteristics Before treatment		In subjects treated with steroids alone		p Value
		After 2 Weeks of Treatment	After 4 Weeks of treatment	
Mini RQLQ (Mean ± S.D)	Activities	12.38 ± 2.58	10.32 ± 2.60	<0.01
	Practical Problems	9.41 ± 2.6	7.33 ± 2.28	<0.001
	Nose Symptoms	11.61 ± 3.14	9.71 ± 3.19	<0.01
	Eye Symptoms	11.09 ± 2.48	10.08 ± 1.46	<0.01
	Other Symptoms	12.16 ± 3.16	10.18 ± 3.14	<0.01

Table 3: Comparison of MiniRQLQ Values at Different Interval of Treatment with Steroids alone

It was found that two groups were matched for activities, practical problem, nose symptoms, other symptoms. Eye symptoms were found to be significantly higher in steroid therapy group compared to combination therapy group.

Table 4: Comparison of MiniRQLQ Values at Different Interval of Treatment with Combination Therapy.

Characteristics Before treatment		In subjects treated with combination therapy		p Value
		After 2 Weeks ofTreatment	After 4 Weeks oftreatment	
Mini RQLQ (Mean ± S.D)	Activities	12.32 ± 3.43	10.32 ± 3.43	<0.0001
	Practical Problems	9.76 ± 2.19	6.76 ± 2.19	<0.0001
	Nose Symptoms	12 ± 2.9	8 ± 2.9	<0.0001
	Eye Symptoms	8.64 ± 1.98	4.64 ± 1.98	<0.0001
	Other Symptoms	12.04 ± 3.2	9.04 ± 3.2	<0.0001

In this study, mean percentage improvement in MiniRQLQ score was calculated for both Steroid Therapy group and combination therapy group. The improvement was calculated over period of 0 weeks to 2 weeks and then from 2 weeks to 4 weeks of treatment. Respective MiniRQLQ scores for zero week (before the start of treatment), 2 weeks after the start of treatment and 4 weeks after the start of treatment were considered for same.

Table 5: Improvement

Improvement	Steroid therapy %	Combination Therapy %
0 weeks to 2 weeks	16	30
2 weeks to 4 weeks	4	22

It was observed that in the steroid therapy group, mean percentage improvement was found to be 16% (0 weeks to 2 weeks) and 4% (2 weeks to 4 weeks) whereas for combination therapy group, the same was found to be 30% (0 weeks to 2 weeks) and 22% (2 weeks to 4 weeks).

Discussion

Traditionally, AR is classified as seasonal or perennial and as either mild, moderate, or severe. Mild AR involves no sleep interruption, no impairment of daily activities, and no troublesome symptoms. Moderate-to-severe AR involves one or more of those factors. A newer classification system specifies that AR be characterized as intermittent or persistent. Intermittent disease involves symptoms for fewer than 4 days per week or for the duration of fewer than 4 weeks. Persistent disease involves symptoms that occur more than 4 days per week and are present for longer than 4 weeks. [12-14]

In present study, 200 patients were randomly divided in group A (n=100) and group B (n=100). Majority of the patients belonged to 18-25 years age group. Age and gender distribution was comparable among both groups and difference was not significant statistically. In the self-report questionnaire study on adults from Stockholm, Sweden, there were no statistically significant gender differences in the prevalence of either allergic or nonallergic symptoms. [15] Severe AR deteriorates the quality of life leading to impairment of daily activity and its prevalence is on increase. [16] 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. [17] 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. [18] Nasal steroids

and antihistamines have been considered as gold standard treatment of choice in moderate to severe AR. [19]

All the parameters of TNSS before treatment, after 2weeks of treatment and after 4 weeks of treatment were analysed using ANOVA test (as it was found to be parametric in distribution) in the subjects treated with combination therapy and it was noted that statistically significant difference was found in all the parameters of all three groups ($p < 0.0001$). It was found that two groups were matched for activities, practical problem, nose symptoms, other symptoms. Eye symptoms were found to be significantly higher in steroid therapy group compared to combination therapy group. In this study, mean percentage improvement in Mini RQLQ score was calculated for both Steroid Therapy group and combination therapy group. The improvement was calculated over period of 0 weeks to 2 weeks and then from 2 weeks to 4 weeks of treatment. Respective Mini RQLQ scores for zero week (before the start of treatment), 2 weeks after the start of treatment and 4 weeks after the start of treatment were considered for same. Sahana G N et al [20] 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 [21] also observed the significant reduction in individual symptoms of allergic rhinitis among the patients treated with topical azelastine.

It was observed that in the steroid therapy group, mean percentage improvement was found to be 16% (0 weeks to 2 weeks) and 4% (2 weeks to 4 weeks) whereas for combination therapy group, the same was found to be 30% (0 weeks to 2 weeks) and 22% (2 weeks to 4 weeks).

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.

References

1. International Rhinitis Management Working Group. International consensus report on the diagnosis and management of rhinitis. Allergy. 1994; 49(19):5-34.
2. Sibbald BO, Rink EL, D'Souza MI. Is the prevalence of atopy increasing? British Journal of General Practice. 1990 Aug 1;40(337):338-40.
3. Åberg N, Sundell J, Eriksson B, Hesselmaf B, Åberg B. Prevalence of allergic diseases in schoolchildren in relation to family history, upper respiratory infections, and residential characteristics. Allergy. 1996 Apr;51 (4)0020:232-7.
4. Bousquet J, Bullinger M, Fayol C, Marquis P, Valentin B, Burtin B. Assessment of quality of life in patients with perennial allergic rhinitis with the French version of the SF-36 Health Status Questionnaire. Journal of allergy and clinical immunology. 1994 Aug 1;94(2):182-8.
5. Juniper EF, Guyatt GH, Dolovich J. Assessment of quality of life in adolescents with allergic rhinoconjunctivitis: development and testing of a questionnaire for clinical trials. Journal of allergy and clinical immunology. 1994 Feb 1;93(2):413-23
6. Simons FE. Learning impairment and allergic rhinitis. InAllergy and asthma proceedings 1996 Jul 1 (Vol. 17, No. 4, p. 185). OceanSide Publications.
7. Spector SL. Overview of comorbid associations of allergic rhinitis. Journal of allergy and clinical immunology. 1997 Feb 1;99(2):S773-80.
8. Ghimire A, Das BP, Mishra SC. Comparative efficacy of steroid nasal spray versus antihistamine nasal spray in allergic rhinitis. Nepal Med Coll J. 2007 Mar 1;9(1):17-21.
9. Chandrika D. Allergic rhinitis in India-an overview.
10. Hansen J, Klimek L, Hörmann K. Pharmacological management of allergic rhinitis in the elderly: safety issues with oral antihistamines. Drugs & aging. 2005 Apr;22:289-96.
11. Skidgel RA, Erdos EG. Histamine, bradykinin, and their antagonists. Goodman and Gilman's the pharmacological bases of therapeutics. McGraw-Hill medical publishing division, New York. 2006:629-52.
12. Facts A. Figures-Asthma and Allergy Foundation of America.
13. Leynaert B, Neukirch C, Liard R, Bousquet J, Neukirch F. Quality of life in allergic rhinitis and asthma: a population-based study of young adults. American journal of respiratory and critical care medicine. 2000 Oct 1; 162(4):1391-6.

14. Meltzer EO, Nathan RA, Seiner JC, Storms W. Quality of life and rhinitic symptoms: results of a nationwide survey with the SF-36 and RQLQ questionnaires. Journal of allergy and clinical immunology. 1997 Jun 1;99(6) :S815-9.
15. Hampel FC, Ratner PH, Van Bavel J, Amar NJ, Daftary P, Wheeler W, Sacks H. Double-blind, placebo-controlled study of azelastine and fluticasone in a single nasal spray delivery device. Annals of Allergy, Asthma & Immunology. 2010 Aug 1; 105(2):168-73.
16. Dykewicz MS, Hamilos DL. Rhinitis and sinusitis. J Allergy Clin Immunol 2010; 125(2 Suppl 2):S103-15.
17. Giavina-Bianchi P, Agondi R, Stelmach R, Cukier A, Kalil J. 2008. Fluticasone furoate nasal spray in the treatment of allergic rhinitis. Ther Clin Risk Manag. 2008;4(2):465-72.
18. Bourdin A, Gras D, Vachier I, Chanez P. Upper airway: Allergic rhinitis and asthma: united disease through epithelial cells. Thorax 2009; 64(11): 999-1004.
19. Gangaraju SS, Pillai N, Manthal V. A comparative study to evaluate the effects of intranasal steroid spray, isotonic saline nasal irrigation and combination therapy in patients with allergic rhinitis. Int J Otorhinolaryngol Head Neck Surg 2021;7:1004-9.
20. Sahana G N, Fidelis G. Dass A, Nalini G K, Ragavendra Prasad K U, A comparative study of fluticasone alone and fluticasone combined with azelastine nasal spray in patients with allergic rhinitis, Pharmacology and Clinical Pharmacy Research, 6 (3) December 2021.
21. Dhanush HC, Malashetti S, Chandrashekharayya SH, Khavasi P. Comparative study of fluticasone propionate combined with azelastine versus fluticasone propionate alone as nasal spray in allergic rhinitis. Int J Otorhinolaryngol Head Neck Surg 2021;7:487-92.