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A COMPARATIVE STUDY OF FEXOFENADINE WITH CHLORPHENIRAMINE MALEATE AND BETAMETHASONE IN ALLERGIC RHINITIS

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ABSTRACT

Objectives: This study was undertaken to compare the efficacy and safety of fexofenadine with chlorpheniramine and betamethasone in allergic rhinitis. *Methods*: This was a prospective observational study on 75 patients of allergic rhinitis. They were randomly divided into 3 groups of 25 patients each for receiving fexofenadine, chlorpheniramine and betamethasone respectively. Improvement of symptoms after treatment was assessed in each group. Changes in absolute eosinophil count and serum IgE levels were also recorded. *Results*: Symptomatic improvement was similar with all the 3 drugs. Physical signs of nasal allergy reduced more with chlorpheniramine. Only betamethasone produced a significant fall in absolute eosiniphil count and a significant rise in serum IgE levels. Chlorpheniramine caused more adverse effects, mainly drowsiness and dry mouth. *Conclusion*: Fexofenadine was better tolerated by patients as it caused lesser adverse effects. All the three drugs in this study showed similar efficacy in controlling the symptoms of allergic rhinitis.

KEY WORDS: **Fexofenadine, Chlorpheniramine, Betamethasone, Allergic rhinitis.**

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INTRODUCTION

Allergic rhinitis is an IgE mediated hypersensitivity disease of the mucous membranes of the nasal airways characterized by sneezing, itching, watery nasal discharge and nasal blockade.[1] The disease is extremely common and causes discomfort, impaired work performance and social embarrassment. Estimated prevalence of the disease varies from 10% to 20% with a peak age distribution in young adulthood.[1] Allergic rhinitis occurs in a topic individuals who are exposed to aeroallergens like dust or pollen grains. It is broadly divided into seasonal and perennial.[2] Seasonal allergic rhinitis, also called Hay fever in some cases, is usually due to pollen grains and occurs at the time of pollination. Perennial allergic rhinitis affects the patient throughout the year and is commonly due to house dust, pet animals or occupational allergens. Perennial rhinitis with seasonal exacerbations may occur. The paranasal sinuses may also be involved as their mucosal lining is continuous with that of nasal cavity. Associated allergic conjunctivitis and bronchial asthma may occur. The treatment options for allergic rhinitis include oral antihistamines, inhaled corticosteroids, oral corticosteroids (short course), inhaled anticholinergics and immunotherapy (desensitization). Of all these options, antihistamines continues to be the most commonly prescribed drugs in allergic rhinitis. The second generation antihistamines like fexofenadine are claimed to be better tolerated than first generation drugs like chlorpheniramine maleate with regard to the side effects.[3]

AIM OF THE STUDY

1. To compare the efficacy and safety of fexofenadine with chlorpheniramine maleate and betamethasone in allergic rhinitis.
2. To study the effects of fexofenadine, chlorpheniramine maleate and betamethasone on eosinophil count and serum IgE levels.

MATERIALS AND METHODS

This study was done at the allergy clinic of a teaching hospital in Hyderabad, India. Patients having signs and symptoms suggestive of allergic rhinitis were considered for the study as per the following inclusion and exclusion criteria.

Inclusion criteria

a) Patients in the age group of 15 to 45 years, both males and females, were included because allergic rhinitis is mostly seen in this age group.[4] Secondly, in patients above 45 years of age, the reactivity to skin test for allergy is reduced[5] and inconsistent.

b) Patients having the typical features of allergic rhinitis such as sneezing, watery nasal discharge, itching in the nose and nasal blockade were included. The duration of these symptoms had to be of at least one month duration, to rule out common cold or other minor infections of the upper respiratory tract.

Exclusion criteria

a) Infections of the respiratory tract as indicated by purulent discharge or fever.
b) Patients who had used antihistamines in the past 48 hours or topical steroids in the past 2 weeks or systemic steroids in the past 4 weeks. The above drugs can alter the clinical picture and also interfere with the skin test for allergy.
c) Any previous history of hypersensitivity to antihistamines or corticosteroids.
d) Evidence of major systemic disease.
e) Pregnant / lactating women.
f) Patients undergoing desensitization (immunotherapy).

This study was approved by the institutional ethics committee and informed consent was obtained from the subjects prior to their inclusion in this study. A total of 75 patients were included in this study based on the above criteria. They were randomly divided into 3 groups of 25 patients each for receiving fexofenadine, chlorpheniramine and betamethasone respectively. Patient data including the presenting complaints, history of

exposure to common allergens and family history of allergies was recorded. General and ENT examination of the patients was done. Then the following investigations were carried out:

i. Complete blood picture
ii. Absolute eosinophil count
iii. X-ray of the paranasal sinuses (Water's view)
iv. Skin test for allergy
v. IgE levels in the serum

Skin test for allergy

Skin tests are sometimes helpful in identifying the cause of allergic rhinitis. In this test, a number of sterilized allergen extracts (antigens) are injected intradermally on the forearm of the patient. The allergen test kit used in this study was purchased from Curewell Limited, New Delhi. It is contained the following common allergens:

Dust allergens	Plant allergens	Fungal allergens
House dust	Parthenium	Aspergillus fumigatus
House dust mite	Ricinus communis	Aspergillus flavus
Paper dust		Aspergillus niger
Rice dust		Mucor mucedo

Technique of skin testing

The modified prick test was performed on all patients. After cleaning the skin of the forearm with spirit, one drop of each of the allergen extracts was placed on the skin in a linear way, about 2 cm apart from each other. Using a sterile needle of no. 26 gauge, a small prick was made into the skin through the drop of the allergen extract. The tip of the needle just enters the skin thereby introducing the allergen into the skin. This method causes minimal injury to the skin and hence the chances of a false positive reaction due to needle injury to the skin are minimized.

Reading the skin test reactions

The reactions were read after 20 minutes. The diameter of the wheal (swelling) was measured directly by placing a transparent plastic scale on the skin and recording its size in millimeters. The size of the wheals were compared with that of the control (normal saline). Only those reactions (wheals) which were greater than the control were considered as positive.

Treatment prescribed and follow up

Patients in Group-I received Tab. Fexofenadine 120 mg once daily at bed time for 14 days.[6] Patients in Group-II received Tab. Chlorpheniramine maleate 4 mg once daily at bed time for 14 days. Patients in Group-III received Tab. Betamethasone 0.5 mg twice daily for 7 days. Patients in groups I and II were initially given tablets for 7 days after which they reported at the allergy clinic for assessment of clinical improvement of symptoms and adverse effects if any. Then they were provided tablets for 7 more days. After completion of the total duration of 14 days of treatment[7] , the patients again reported at the allergy clinic. They were followed up with regard to clinical improvement, any adverse effects reported and also by repeating all the investigations done before starting the treatment.

Patients in group-III were given 14 tablets of betamethasone sufficient for 7 days. After that they reported at the allergy clinic for assessment of clinical improvement of symptoms and adverse effects if any. All the investigations done before starting the treatment were repeated. The patients in all the groups were instructed not to take any medicine other than the tablets provided to them during the study period. In assessing the improvement of symptoms after treatment, the patient was told to express his/her improvement as 25%, 50%, 75% or 100% of the initial intensity of that symptom. If there was no improvement in the patient's opinion, it was recorded as 0% while total relief of the symptom was recorded as 100% improvement. Along with the patient's own

assessment, the ENT specialist's assessment was also recorded. Similarly the investigation parameters before and after the treatment were recorded in tabular form.

RESULTS

Table-1
Demographic data of patients

Drug given	No. of males	No. of females	Mean age in years
Fexofenadine n=25	15 (60%)	10 (40%)	27 (±8)
Chlorpheniramine n=25	10 (40%)	15 (60%)	27 (±8)
Betamethasone n=25	12 (48%)	13 (52%)	29 (±8)

Table-2
Incidence of various symptoms in the patients (n=75)

Symptom	No. of cases	Percentage of incidence
Sneezing	75	100
Watery nasal discharge	69	92
Itching in nose/palate/throat	34	45.33
Nasal blockade	48	64
Loss of smell (anosmia)	14	18.66

Table-3
Overall improvement in symptoms after treatment

Drug given	Sneezing	Nasal discharge	Itching in nose/palate/throat	Nasal blockade	Anosmia
Fexofenadine	73%	76.08%	60.41%	53.33%	75%
Chlorpheniramine	70%	78.26%	85.41%	54.68%	91.66%
Betamethasone	65%	73.91%	87.50%	44.11%	65%

Table-4
Summary of skin test results

Drug given	No. of cases with positive reaction before treatment	No. of cases with absent reaction after treatment	No. of cases with reduced reaction after treatment	Mean % reduction of skin reaction
Fexofenadine	22	16	6	93.36%
Chlorpheniramine	23	14	9	81.82%
Betamethasone	21	17	4	92.09%

Table-5
Serum IgE levels in IU/ml before and after treatment

Drug given		Before treatment	After treatment	P value
Fexofenadine	Mean	199	195	P > 0.5
	± S.D.	156	159	Not
	± S.E.	31	32	significant
Chlorpheniramine	Mean	263	260	P > 0.5
	± S.D.	196	213	Not
	± S.E.	39	43	significant
Betamethasone	Mean	176	208	P < 0.001
	± S.D.	83	111	Very
	± S.E.	17	22	significant

Table - 6
Absolute eosinophil count per mm^3 before and after treatment

Drug given		Before treatment	After treatment	P value
Fexofenadine	Mean	787	755	P < 0.02
	± S.D.	492	468	Not significant
	± S.E.	98	94	
Chlorpheniramine	Mean	575	558	P < 0.1
	± S.D.	382	335	Not significant
	± S.E.	76	67	
Betamethasone	Mean	536	386	P < 0.001
	± S.D.	319	249	Very significant
	± S.E.	64	50	

Table-7
Adverse effects reported during treatment

Drug given	No. of patients who reported adverse effects	Dryness of mouth/throat	Drowsiness	Others
Fexofenadine	5	4	1	Nil
Chlorpheniramine	12	5	7	Nil
Betamethasone	3	Nil	Nil	Loss of appetite = 1 Headache = 1 Burning sensation in stomach = 1

SUMMARY AND CONCLUSION

Symptomatic improvement of sneezing and nasal discharge were similar with all the 3 drugs. Sneezing reduced by 73% with fexofenadine, 70% with chlorpheniramine and 65% with betamethasone. Nasal discharge reduced by 76% with fexofenadine, 78% with chlorpheniramine and 74% with betamethasone. Itching was better controlled

by betamethasone (88%) when compared to chlorpheniramine (85%) and fexofenadine (60%). Relief of nasal blockade was around 50% with each of these drugs. Relief of anosmia was 75% with fexofenadine, 92% with chlorpheniramine and 65% with betamethasone. Physical signs of allergy in the nose disappeared better with chlorpheniramine (53% of patients) than with fexofenadine (36%) or betamethasone (35%). In the skin test for allergy, the mean percentage reduction of skin reaction was 93% with fexofenadine, 82% with chlorpheniramine and 92% with betamethasone. The effect of fexofenadine on absolute eosinophil count was not significant ($P < 0.02$). The effect of chlorpheniramine was also not significant ($P < 0.1$), but betamethasone caused significant reduction in absolute eosinophil count ($P < 0.001$).

The effect of on serum IgE levels was not significant with fexofenadine ($P > 0.5$) and chlorpheniramine ($P > 0.5$). But betamethasone produced a significant rise in serum IgE levels ($P < 0.001$). Adverse effects were reported by more patients on chlorpheniramine (12 cases) than with fexofenadine (5 cases) or betamethasone (3 cases). Some patients on antihistamines reported either dryness of mouth or drowsiness while the reported adverse effects with betamethasone included burning sensation in stomach, loss of appetite and headache (1 case each). In all these cases, the adverse effects were mild and lasted only for a few days. In conclusion, the three drugs namely fexofenadine, chlorpheniramine and betamethasone were found to have similar levels of efficacy in controlling the symptoms of allergic rhinitis. The signs improved better with chlorpheniramine. Fexofenadine was the most effective in suppressing the skin reaction to allergens. It was closely followed by betamethasone and then chlorpheniramine. The antihistamines had no significant effect on the absolute eosinophil count and serum IgE levels. Whereas betamethasone produced a significant fall in absolute eosinophil count and a significant rise in serum IgE levels. These findings are similar to the results of previous studies.[8,9] Adverse effects were found to be more with chlorpheniramine than the other two drugs. Considering this factor and also the fact that long term use of systemic corticosteroids like betamethasone is undesirable, fexofenadine appears to be a better choice in the treatment of allergic rhinitis. Though fexofenadine is relatively costlier, it appears to be better tolerated than chlorpheniramine and betamethasone.

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