RESEARCH ARTICLE
A comparative study of efficacy of fexofenadine with chlorpheniramine maleate in allergic rhinitis in the outpatient department of otorhinolaryngology

Amrutha D Torvi, Soujanya S
Department of Pharmacology, ESIC Medical College, Kalaburagi, Karnataka, India
Correspondence to: Soujanya S, E-mail: soujanya73.ss@gmail.com
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ABSTRACT
Background: Allergic rhinitis is most common non-infectious rhinitis. It is a hypersensitivity disease of nasal mucous membrane mediated by immunoglobulin E characterized by sneezing, itching, watery nasal discharge, and nasal blockade. Allergic rhinitis is condition managed largely in general practice and oral antihistamines are preferred most commonly. Antihistamines differ among each other from potential toxicity perspective, this comparative study between fexofenadine and chlorpheniramine is undertaken to know the differentiating aspects, symptomatic improvements in allergic rhinitis.

Aim and Objective: To study the efficacy of fexofenadine with chlorpheniramine maleate in patients with allergic rhinitis.

Materials and Methods: A comparative study was done on 70 patients of allergic rhinitis after obtaining informed consent in ENT outpatient department where the patients were randomly allocated into one of the following groups: (1) Group A: 35 patients were given Tab. fexofenadine 120 mg and (2) Group B: 35 patients were given Tab. chlorpheniramine 4 mg. Patients were asked to follow up after 2 weeks to know symptomatic improvement assessed before and after the treatment and adverse effects of drugs.

Results: In Group A (fexofenadine), mean age of the patients was 34.95 years, and in Group B (chlorpheniramine), it was 40.17 years. About 57% of patients had intermittent symptoms in Group A and 43% in Group B. There was a significant reduction in severity of individual symptoms in patients in Group A when compared to Group B ($P < 0.001$). Symptoms score has decreased from baseline mean by 100% in Group A as compared to 92% in Group B. Except for nasal itching there was marked reduction in other symptoms in Group A compared to Group B.

Conclusion: Fexofenadine is better with relieving the symptoms than chlorpheniramine, adverse effects were seen more commonly in chlorpheniramine.

KEY WORDS: Fexofenadine; Chlorpheniramine; Allergic Rhinitis

INTRODUCTION

Allergic rhinitis is a common immunologic disease and also chronic disease experienced by humans.[1] Allergic rhinitis is a hypersensitivity disease of the nasal mucous membrane mediated by immunoglobulin E (IgE) which is characterized by sneezing, itching, watery nasal discharge, and nasal obstruction.[2] Other symptoms include lacrimation, conjunctival, nasal, and pharyngeal itching which occurs due to exposure to allergen. In atopic individuals, it often occurs in association with atopic dermatitis, food allergy, urticaria, and asthma.[3] It represents one of the global health problems. About 10–25% of the population is affected worldwide.[2]

The symptoms of allergic rhinitis are most frequently reported in adolescence or young adulthood though it can begin at any...
Incidence of allergic rhinitis is higher in children whose parents experience hypersensitive diseases. If one parent has allergy, the chance of the child having it is 29% and increases to 47% when both have the disease.

Allergic rhinitis is not a life-threatening disease unless associated with severe asthma or anaphylaxis. Morbidity from the condition can be significant.

Atopic individuals who are exposed to aeroallergens usually suffer from allergic rhinitis. Although frequently trivialized by patients and doctors, allergic rhinitis is a common cause of morbidity, social embarrassment, and impaired performance either at school or in the workplace.

Sneezing, watery rhinorrhea, itching of nose, and nasal obstruction are the most characteristic symptoms of allergic rhinitis. Usually, the symptoms occur within 5–15 min after exposure to allergen and sneezing occurs in spasms of 10–20 at a time, which can exhaust the patient. Watery rhinorrhea is usually very profuse. Itching of nose and nasal obstruction of moderate severity is a common complaint. Symptoms of pruritis, nasal obstruction, sneezing, and rhinorrhea are thought to be due to sensory nerve stimulation, mucosal edema, and increased mucus secretion. Varying degrees of loss of smell (anosmia), loss of taste (ageusia), and symptoms associated with the eustachian tube (hearing defects and ear pain) are also accompanied.

The mainstay of treatment of allergic rhinitis involves identification and avoidance of provoking allergens (where possible) and use of topical corticosteroid nasal spray and oral antihistamines. Immunotherapy retains a place in treatment of patients with severe isolated grass pollen allergy. Surgery should not be considered “a last resort” but rather complementary to medical treatment of allergic rhinitis, when this is complicated by structural problems such as deflected septum, nasal polyps, and enlarged turbinates.

Antihistamines were the first efficacious drugs to be used for symptomatic relief of allergic diseases. They are competitive blockers of histamine at H1 receptor. These block the local effect of released histamine from mast cells or basophils. By interfering with this phase, they attenuate inflammatory response mediated by histamine.

The first-generation antihistamines cause sedation which is the most problematic adverse effect because of its lipid soluble property, which allows its penetration into blood–brain barrier.

The second-generation antihistamines have overcome this side effect. Among the second-generation drugs, loratadine and fexofenadine have been approved for use by pilots. A meta-analysis has shown that fexofenadine has not reported sedation in any study so far.

Corticosteroids are presently the most potent medications which are available for the treatment of allergic rhinitis. Intranasal route of administration eliminates the systemic side effects and is more efficacious than the oral preparations.

Intranasal corticosteroids are today the gold standards in treatment of allergic rhinitis.

Intranasal antihistamines are efficacious and equivalent or even superior when compared to oral second-generation antihistamines but are less effective than intranasal corticosteroids.

Commonly administered α-adrenergic agonists such as pseudoephedrine, phenylpropanolamine, and phenylephrine produce vasoconstriction in turbinates, lessening nasal congestion. They are often combined with the first- or second-generation antihistamines.

Since oral antihistamines are more commonly used drugs for allergic rhinitis. Hence, this study was conducted to compare the efficacy between a first-generation antihistamine, chlorpheniramine and second-generation antihistamine, fexofenadine.

**Objective**

The objective of the study was as follows:

- To study the efficacy of chlorpheniramine maleate and fexofenadine.
- To study the effect of chlorpheniramine maleate and fexofenadine on absolute eosinophil count (AEC).

**MATERIALS AND METHODS**

**Source of Data**

This was a prospective observational study conducted in the ENT outpatient department (OPD) of BRIMS Teaching Hospital, Bidar. Relevant data were collected from the department of ENT OPD personally by the investigator as indicated in a specially designed pro forma.

**Methodology and Type of Data Collected**

After taking consent from the patient or the guardian/relatives, the relevant data were collected with details such as:

1. Demographic data: Age, gender, address, occupation, H/o allergy, family H/o allergy, IP/OP number, etc.
2. Disease data: Duration, severity, and coexisting disease if any
3. Data pertaining to drugs: Dose, frequency, route of administration and duration
4. Data pertaining to investigations: Complete blood count (CBC) and AEC.

Inclusion Criteria
1. Male and female patients aged 15 years and above
2. Patient having typical features of allergic rhinitis such as sneezing, watery nasal discharge, itching in nose and nasal blockade.

Exclusion Criteria
The following criteria were excluded from the study:
1. Infection of respiratory tract indicated by the presence of purulent discharge
2. Any past history of hypersensitivity to antihistamines or corticosteroids
3. Pregnant and lactating women
4. Patients aged <15 years of age
5. Patients with impaired kidney and liver function
6. Cancer patients who are terminally ill.

Study Sample Size
70 patients.

Sample Design
Purposive sampling.

Study Design
A comparative study will be done on 70 cases of allergic rhinitis after obtaining informed consent in the ENT OPD where the patients will be divided into two groups, each group consisting of 35 cases, patients will be randomly allocated into one of the following groups.

Group A: 35 patients will be given Tab. fexofenadine 120 mg
Group B: 35 patients will be given Tab. chlorpheniramine maleate 4 mg.

Patients will be asked to follow up after 2 weeks to know symptomatic improvement, CBC & AEC will be assessed before and after the treatment and adverse effects of drugs.

Study Period
12 months.

Place of study: District Government Hospital, Bidar Institute of Medical Sciences, Bidar.

Follow-Up: 14 days
Ethical clearance has been obtained from the “Institutional Ethics Committee” of Bidar Institute of Medical Sciences, Bidar.

Statistical Analysis
The data collected were analyzed statistically using descriptive statistics, namely, mean and standard deviation (SD) of quantitative variables and causal relationship was examined using Z-test. Wherever necessary, the result was depicted in the form of percentage and graphs.

RESULTS
In this study, 70 patients with allergic rhinitis were treated with either fexofenadine hydrochloride or chlorpheniramine maleate for 2 weeks, after randomization. Since allergic rhinitis is commonly seen in the age group of 15–45, patients in this age group, both males and females, were included.

The mean age of the patients who received fexofenadine was 34.95 and those receiving chlorpheniramine were 40.17. Both the groups had statistically same mean age with \( P = 0.149 \).

The reason for this could be lifestyle and activity is more in this age group compared to older age group which will increase the chances of bringing them in contact with a wide variety of allergens.

Duration of illness was statistically similar in both the groups.

Both the treatment groups had a comparable mean total symptoms score at baseline, indicating similar severity of symptoms among all patients at the start of study.

Before treatment, three main symptoms of allergic rhinitis – sneezing, nasal obstruction, and nasal discharge were present in all patients.

Fexofenadine hydrochloride was effective in relieving sneezing, nasal obstruction, and nasal discharge in 78%, 91%, and 97% of patients, respectively, compared to 54%, 66%, and 49% of patients, respectively, on chlorpheniramine treatment.

Nasal itching was present in 77.14% of patients in fexofenadine group and 96% of patients in chlorpheniramine group. Fexofenadine was effective in relieving this symptom in all the patients compared to relief in 96% of patients on chlorpheniramine treatment [Table 1].

Out of 27 patients with nasal itching in fexofenadine group, one patient had persistent nasal itch after the treatment. Since the sample size is small, the effect of chlorpheniramine on nasal itching cannot be commented.
Symptoms such as itching and watering of eyes, itching of palate, and ears were found effectively relieved equally by fexofenadine and chlorpheniramine treatment.

Both the drugs were not effective in reducing Absolute Eosinophil count. Hence, after the treatment, there was no significant difference in AEC in both the Groups A and B [Table 2]. There was no significant difference in all parameters included in CBC in Group A as well as Group B, after the treatment [Table 3].

**DISCUSSION**

In both the treatment groups mean total symptom score decreased, with 100% change in median symptoms score in fexofenadine group and 92.67% change in chlorpheniramine group.

Some second-generation antihistamines have anti-inflammatory effects which were demonstrated by preclinical studies. Data from a study suggested that after nasal provocation, treatment with desloratadine reduces systemic eosinophilia and prevents the increase in circulating eosinophils. Early bronchial clinical response to nasal provocation is reduced by desloratadine significantly.[13]

In this study, there was no significant effect produced by antihistamines on the AEC. Whereas significant fall in AEC and a significant rise in serum IgE levels have been observed by corticosteroids and these findings.[14,15]

Fexofenadine was effective in reducing the nasal obstruction in a study conducted by Bernstein et al.[16] whereas in this study, there was not much effect on this symptom. There was no complain of sedative activity in fexofenadine group, which goes in favor of study conducted by Hindmarch and Shamsi.[9]

With regard to side effects, second-generation antihistamines like fexofenadine are claimed to be better tolerated than first-generation drugs like chlorpheniramine maleate,[17]

*Table 1: Effect of treatment on symptoms*

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group A</th>
<th></th>
<th>Group B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before treatment (%)</td>
<td>After treatment (%)</td>
<td>P-value</td>
<td>Before treatment (%)</td>
</tr>
<tr>
<td>Sneezing</td>
<td>35 (100.0)</td>
<td>8 (22.9)</td>
<td>P&lt;0.01</td>
<td>35 (100.0)</td>
</tr>
<tr>
<td>Nasal obstruction</td>
<td>35 (100.0)</td>
<td>3 (8.6)</td>
<td>P&lt;0.01</td>
<td>35 (100.0)</td>
</tr>
<tr>
<td>Nasal discharge</td>
<td>35 (100.0)</td>
<td>1 (2.9)</td>
<td>P&lt;0.01</td>
<td>35 (100.0)</td>
</tr>
<tr>
<td>Nasal itching</td>
<td>27 (77.14)</td>
<td>1 (2.9)</td>
<td>P&lt;0.01</td>
<td>34 (96.0)</td>
</tr>
<tr>
<td>Itching of eyes</td>
<td>31 (88.6)</td>
<td>-</td>
<td>P&lt;0.01</td>
<td>30 (88.0)</td>
</tr>
<tr>
<td>Watering of Eyes</td>
<td>11 (31.43)</td>
<td>1 (2.9)</td>
<td>P&lt;0.01</td>
<td>19 (56.0)</td>
</tr>
<tr>
<td>Palatal itching</td>
<td>21 (60.0)</td>
<td>-</td>
<td>0.007</td>
<td>22 (57.1)</td>
</tr>
<tr>
<td>Itching of ears</td>
<td>11 (31.43)</td>
<td>-</td>
<td>0.001</td>
<td>15 (44.0)</td>
</tr>
</tbody>
</table>

*Table 2: AEC per mm$^3$ before and after treatment*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th></th>
<th>Group B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment (Mean±SD)</td>
<td>664±30.63</td>
<td>P&lt;0.05</td>
<td>565±26.13</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td>After treatment (Mean±SD)</td>
<td>632±28.52</td>
<td>P&lt;0.05</td>
<td>548±21.14</td>
<td>P&lt;0.05</td>
</tr>
</tbody>
</table>

AEC: Absolute eosinophil count

There was no significant effect of fexofenadine on AEC ($P < 0.02$). The effect of chlorpheniramine was also not significant ($P < 0.1$).

Levocetirizine, an active enantiomer of cetirizine which is also a antihistamine used commonly was found more potent and consistent than other popular H1 antihistamines in potency, consistency, onset and duration of action for blocking the cutaneous response to histamine in other studies. These findings show the efficacy of levocetirizine in treating allergic rhinitis.[18]

All of the newer second-generation antihistamines were compared to see if there were significant differences in their efficacy, a study was conducted and it was found that for the newer non-sedating H1 antagonists there appears to be no clinically relevant differences in activities. Preference of the patient may be the most important factor in making a choice between these drugs.[19]

The effect on all the parameters of CBC was also not significant in both Groups A and B in this study.

In a study conducted by Jonathan Brostoff and Lockhart to compare efficacy and adverse effects of two antihistamines terfenadine and chlorpheniramine maleate and placebo showed that there was significant difference in improvement of symptoms by both the drugs but side effect was more with chlorpheniramine, which was not statistically significant.

The strength of the study was selection of patient by sequential random sampling hence eliminating the selection bias which influences the outcome. The limitation of study was small sample size.
Table 3: CBC before and after treatment

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A Before treatment mean (%)</th>
<th>Group A After treatment mean (%)</th>
<th>Group B Before treatment mean (%)</th>
<th>Group B After treatment mean (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>12.2 (2.85)</td>
<td>13.4 (2.85)</td>
<td>13.7 (2.85)</td>
<td>14 (2.9)</td>
</tr>
<tr>
<td>WBC</td>
<td>8748.57 (2.84)</td>
<td>8728.57 (2.85)</td>
<td>8765.71 (2.85)</td>
<td>8788.57 (2.85)</td>
</tr>
<tr>
<td>Differential count lymphocytes</td>
<td>32 (2.9)</td>
<td>32 (2.85)</td>
<td>32 (2.85)</td>
<td>32 (2.85)</td>
</tr>
<tr>
<td>Monocytes</td>
<td>2.3 (2.83)</td>
<td>2.6 (2.85)</td>
<td>2 (2.85)</td>
<td>2.4 (2.8)</td>
</tr>
<tr>
<td>Eosinophils</td>
<td>3.7 (2.85)</td>
<td>4 (2.85)</td>
<td>4.3 (2.85)</td>
<td>3.4 (2.85)</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>58 (2.83)</td>
<td>58 (2.85)</td>
<td>58 (2.85)</td>
<td>58.3 (2.85)</td>
</tr>
<tr>
<td>ESR</td>
<td>17.4 (2.85)</td>
<td>18.5 (2.85)</td>
<td>18.4 (2.83)</td>
<td>18.8 (2.84)</td>
</tr>
<tr>
<td>PCV</td>
<td>43.2 (2.85)</td>
<td>47.17 (2.85)</td>
<td>42.5 (2.77)</td>
<td>42.5 (2.77)</td>
</tr>
<tr>
<td>Platelet count</td>
<td>2.85 (2.85)</td>
<td>3.85 (2.84)</td>
<td>2.63 (2.81)</td>
<td>2.63 (2.81)</td>
</tr>
</tbody>
</table>

CBC: Complete blood count; WBC: White blood count, ESR: Erythrocyte sedimentation rate, PCV: Packed cell volume

CONCLUSION

The drugs fexofenadine and chlorpheniramine were found to have similar levels of efficacy in controlling the symptoms of allergic rhinitis. The signs improved better with chlorpheniramine. The antihistamines had no significant effect on the AEC.

REFERENCES


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