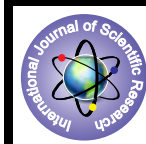


A Comparative Study to Evaluate the Efficacy of Oral Fexofenadine Hydrochloride and Topical Mometasone Furoate in Decreasing Symptoms of Moderate-Severe Allergic Rhinitis.



Medical Science

KEYWORDS : Allergic rhinitis, treatment outcome, nasal spray, histamine analogue.

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ABSTRACT

Objectives-Allergic rhinitis is a common and debilitating disease that has major effect on health related quality of life. For several years, there has been discussions of whether first line pharmacological treatment of moderate-severe allergic rhinitis should be antihistamines or intranasal corticosteroids. Hence, this study was done to clinically evaluate the efficacy of fexofenadine hydrochloride and topical mometasone furoate in treatment of moderate-severe allergic rhinitis. Methods- 100 patients aged between 12-65 years with moderate-severe allergic rhinitis who fulfilled the inclusion criteria were sequentially randomized into two groups and treated with either topical mometasone furoate spray or fexofenadine hydrochloride for 4 weeks. Patients were given a symptom diary to record the efficacy of their treatment on daily basis. Results- Significant reduction in severity of individual symptoms in mometasone group compared to fexofenadine group was noted ($p < 0.01$). Symptoms score decreased from baseline mean by 99-100% in mometasone group compared to 90-91% in fexofenadine group. Fexofenadine hydrochloride had rapid onset of action compared to mometasone furoate. Conclusion- Mometasone furoate is superior in relieving symptoms compared to fexofenadine hydrochloride.

Introduction:

Allergic Rhinitis is an IgE mediated hypersensitivity disease of the mucous membrane of nasal airway characterized by sneezing, itching, watery nasal discharge and sensation of nasal obstruction¹. It represents a global health problem affecting 10 to 25% of population¹. While allergic Rhinitis itself is not life threatening (unless accompanied by severe asthma or anaphylaxis), morbidity from the condition can be significant which includes chronic rhinosinusitis, nasal polypi, serous otitis media, bronchial asthma, orthodontic problems and other ill effects of prolonged mouth breathing, especially in children². According to management of moderate-severe allergic rhinitis adapted by ARIA guidelines¹, antihistamines or intranasal corticosteroids are the first line of treatment of choice. Fexofenadine hydrochloride is one of the newer second generation antihistamines which is shown in many studies to be efficacious against nasal stuffiness along with additional advantage of having systemic effects and therefore effective for conjunctival, palatal and pharyngeal symptoms³. On the other hand, appreciation of effectiveness of nasal steroid sprays in relieving nasal symptoms of allergic rhinitis has grown steadily over last several years, including relief of sneezing, congestion, nasal pruritis, and allergic eye symptoms. One of the recent corticosteroids, mometasone furoate nasal spray, has been shown to be effective in both adults and children without any effect on HPA axis⁴ or adverse tissue changes in nasal mucosa⁵.

Hence, this study was done to compare both these drugs.

Materials and Methods:

For this study, 100 subjects who were aged between 12-65 years with moderate - severe symptoms of allergic rhinitis were chosen among outpatients attending Department of E.N.T, Kempegowda Institute of Medical Science, Bangalore. Patients who were willing to participate in the study were evaluated by means of proper history taking with help of a proforma, clinical examination and relevant laboratory investigations. Patients with three or more of following symptoms - sneezing, nasal obstruction, nasal discharge, itching of nose, itching of eyes, watering of eyes and palatal itching were selected. Only those with at least one moderate - severe degree of above symptoms were selected. Those patients with laboratory investigations showing absolute eosinophilic count more than 400 cells/mm³, nasal smear study showing > 15% of eosinophils and with positive skin prick test for atleast one allergen were included in the study.

Patients were excluded from the study if they had any of the following-

- Co-existing upper respiratory tract infection including sinusitis
- Pregnant and lactating women
- Mild symptoms of allergic rhinitis
- Co-existing systemic diseases
- Use of oral/intranasal corticosteroids or antihistamines within one month of presentation to outpatient department

Baseline symptoms scores were recorded in the diary from which were provided to them, explained about it and asked to maintain it throughout the study period of 4 weeks.

Table-1 – showing symptom evaluation score.

Symptom evaluation score	Description	Definition
0	Absent	No symptoms
+	Mild	Symptoms present but not troublesome
++	Moderate	Symptoms frequently troublesome but not disturbing daily activity or sleep
+++	Severe	Symptoms disturbing daily activity

Patients were sequentially randomized into two groups- Group1 (50 patients) received topical mometasone furoate nasal sprays 2 puffs once daily and Group2 (50 patients) received oral fexofenadine hydrochloride 10 mg once daily for 4weeks. During 4 weeks treatment period, patients were evaluated at weekly intervals.

Results:

Mean age of patients in Group1 was 30.64 and Group2 was 34.72. Both the groups had statistically same mean age group with $p=0.187$. There were 18 males and 32 females in Group1 and 34 males and 16 females in Group2. The duration of illness is statistically similar between the two groups (Group1-2.60+/-1.35 and Group2-2.08+/-1.04) with $p=0.134$. 26 patients (52%) had intermittent symptoms in Group1 compared to 24 patients (48%) in Group2 and 24 patients (48%) had persistent symptoms in Group1 compared to 26 patients (52%) in Group2 and the distribution in the two groups were statistically similar with $p=0.777$. 6 patients had family history of allergy in Group1 and 4 patients in Group2.

Both treatment groups had comparable mean total symptoms scores at baseline indicating, similar severity of symptoms among all patients at the start of study. There was 100% change

of median symptoms score in Group1 compared to 91.67% in Group2 post treatment. Sneezing was present in all subjects included in the study in both groups. Mometasone was effective in relieving sneezing in 36 patients (76%) as compared to fexofenadine in 28 patients (66%). Nasal obstruction was present in all the patients in both groups. 4 patients had persistent nasal obstruction in Group1 and 18 patients in Group2. 46 patients(92%) in Group1 compared to 36 patients (64%) in Group2 were relieved of nasal obstruction.

Nasal discharge was present in all the patients with relief of symptoms in 96% of patients who were on mometasone treatment compared to 48% on fexofenadine treatment. Nasal itching was present in 38 patients (67.9%) in Group I and in 48 patients (96%) in Group II. Fexofenadine was effective in relieving this symptom in all the patients compared to relief in 48 patients(96%) on mometasone treatment. In other symptoms - itching of eyes, watering of eyes, palatal itching and itching of ears, both drugs are equally effective.

Table-2- showing effect of treatment on individual symptoms

Symptoms	Group I			Group II		
	Before treatment	After treatment	P value	Before treatment	After treatment	P value
Sneezing	50 (100.0%)	12 (24.0%)	P<0.01	50 (100.0%)	22 (44.0%)	0.007
Nasal obstruction	50 (100.0%)	4 (8.0%)	P<0.01	50 (100.0%)	18 (36.0%)	0.001
Nasal discharge	50 (100.0%)	2 (4.0%)	P<0.01	50 (100.0%)	26 (52.0%)	0.023
Nasal Itching	38 (67.9%)	2 (4.0%)	P<0.01	48 (96.0%)	-	P<0.01
Itching of eyes	44 (88.0%)	-	P<0.01	44 (88.0%)	-	P<0.01
Watering of eyes	16 (32.0%)	2 (4.0%)	P<0.01	28 (56.0%)	2 (4.0%)	P<0.01
Palatal itching	30 (60.0%)	-	0.007	32 (57.1%)	-	P<0.01
Itching of ears	16 (32.0%)	-	0.001	22 (44.0%)	-	P<0.01

Discussion:

Both mometasone furoate and fexofenadine hydrochloride have been demonstrated to be effective in treating allergic rhinitis in studies, conducted by David Bernstein et al⁶ and Marianns Friere et al⁷ respectively. In this study, 100 patients with moderate to severe allergic rhinitis were treated with either mometasone furoate nasal spray (50patients) or oral fexofenadine hydrochloride (50patients) for 4 weeks, after sequential randomization. The mean age of patients receiving topical mometasone was 30.64 years and those receiving oral fexofenadine was 34.72. Both the groups has statistically same mean age group with p=0.187. The may be attributed to the life style and activity in this age group, which is more compared to older age group, which will increase the chances of bringing them into contact with a wide variety of allergens. There were more number of females (32) in mometasone group compared to fexofenadine group in which males were more in number (34). However, allergic rhinitis per se does not differ in its presentation and clinical course between males and females and no ethical variations are reported¹. Hence, this difference in sex does not affect the comparison of two groups, who were selected after randomization.

Mometasone furoate was effective in relieving sneezing, nasal obstruction and nasal discharge in 76%, 92% and 96% of patients respectively compared to 66%, 64% and 48% of patients respectively on fexofenadine treatment. Nasal itching was present in 67.9% of patients in mometasone group and 96% of patients in fexofenadine group. All the patients were relieved of this symptom in fexofenadine group compared to 96%(48patients) in mometasone group. Though considerable reduction in severity of individual symptoms in each patients seen in both

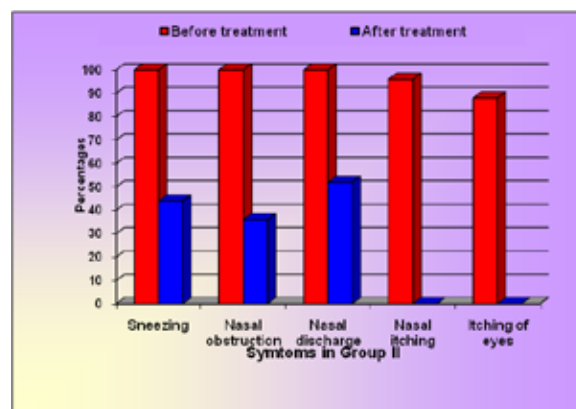
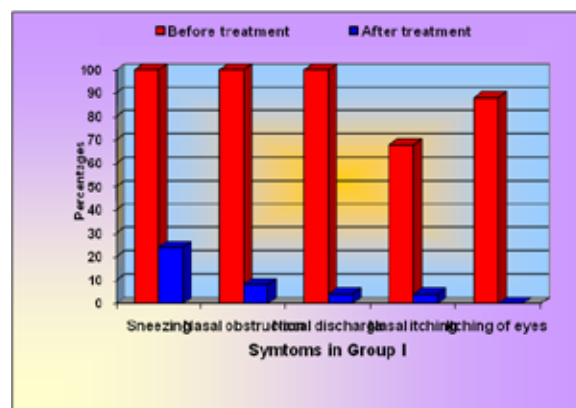
treatment group, the mometasone group had higher degree of reduction. Mean total symptom score decreased in both treatment groups after 4-week study period with 100% change in median symptoms score in mometasone group and 91.67% change in fexofenadine group. This goes in favour of study conducted by Tsang et al⁸ on efficacy of topical mometasone on allergic rhinitis patients.

Rapid onset of action within minutes of oral fexofenadine treatment compared to 1-2 days delay in onset of action in case of topical mometasone group. As against the study conducted by David Bernstein et al⁶, where fexofenadine was effective on nasal obstruction, this study shows not much effect on this symptom (64% as against 92% in mometasone group). No patients in fexofenadine group complained of sedative activity of the drug, which goes in favour of study conducted by Hind March and Shamsi³.

This study compares favourably with meta analysis of randomized controlled trials conducted worldwide and published between 1966 and 1977, which was done by John Weiner et al⁹, which showed intranasal corticosteroids produced significant relief compared to antihistamines.

Hence, we conclude that mometasone furoate nasal spray is superior in relieving moderate-severe symptoms of allergic rhinitis compared to oral fexofenadine and intranasal steroids should be regarded as effective first line treatment.

Graphs 1&2.



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