



A Comparative Study To Evaluate The Efficacy of Levocetirizine and Fexofenadine Hydrochloride in Allergic Rhinitis

KEYWORDS

Allergic rhinitis, Levocetirizine, Fexofenadine, treatment outcome

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ABSTRACT Objectives-Allergic rhinitis is a common and debilitating disease that has major effect on health related quality of life. Antihistamines are the main stay of treatment and are recommended for all types of intermittent and persistent allergic rhinitis. Compared with older antihistamines, newer antihistamines are shown to be more potent. This study was done to compare two newer antihistamines- levocetirizine and fexofenadine.

Methods- 100 patients aged between 12-65 years with allergic rhinitis who fulfilled the inclusion criteria were sequentially randomized into two groups and treated with either levocetirizine 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 levocetirizine group compared to fexofenadine group was noted ($p < 0.01$). Symptoms score decreased from baseline mean by 99-100% in levocetirizine group compared to 90-91% in fexofenadine group. Fexofenadine hydrochloride had rapid onset of action compared to levocetirizine.

Conclusion- Levocetirizine is more effective than fexofenadine in relieving symptoms of allergic rhinitis.

Introduction:

Allergic rhinitis is the most common atopic IgE mediated hypersensitivity disease of the nasal airway mucous membrane. It represents a global health problem affecting 18% to 40% of adults worldwide¹. Antihistamines are the main stay of treatment and are recommended for all types of intermittent and persistent allergic rhinitis². Compared with older antihistamines, newer antihistamines are shown to be more potent. One of these antihistamines is levocetirizine which is shown in many studies to be highly selective H1 antihistamine which has additional benefits of nasal decongestion, improving nasal airflow and is cost effective^{3,4}. Similar results have also been shown in case of another newer anti histamine- fexofenadine hydrochloride⁵. 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. 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
- 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.

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

Table-1 – showing symptom evaluation score.

Patients were sequentially randomized into two groups- Group1 (50 patients) received levocetirizine 5mg once daily and Group2 (50 patients) received fexofenadine hydrochloride 120mg once daily for 4 weeks. 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 symp-

toms 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. Levocetizine 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 levocetizine 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 levocetizine treatment. In other symptoms – itching of eyes, watering of eyes, palatal itching and itching of ears, both drugs are equally effective. Incidence of sedation was noted to be equal in both the groups (3.8%).

Total Symptoms score	Group 1	Group 2	P value
	Mean (Median)		
Before treatment	10.96(11) Min=7: Max=15	11.88(12) Min=8:Max=14	P>0.05
After treatment	0.32(0) Min=0:Max=2	1.96(1) Min=0:Max=9	0.001
P value	P<0.001	P<0.001	-
% Change of median Symptom score	100.0%	91.67%	-

Table 2- showing total symptoms score.

Symptoms	Treatment	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	P value
Sneezing	Before	2.48±0.65	2.76±0.52	P<0.001
	After	0.24±0.44	0.52±0.65	
Nasal obstruction	Before	2.44±0.65	2.44±0.51	P<0.001
	After	0.08±0.27	0.40±0.57	

Nasal discharge	Before	2.56±0.65	2.44±0.58	P<0.001
	After	0.04±0.20	0.72±0.84	
Nasal Itching	Before	1.37±0.59	1.33±0.56	P<0.001
	After	0.04±0.20	0	
Itching of eyes	Before	1.27±0.46	1.09±0.43	P<0.001
	After	0	0.08±0.04	

Table 3 – showing mean pattern of symptoms score.

Discussion:

Both levocetizine and fexofenadine hydrochloride have been demonstrated to be effective in treating allergic rhinitis. In our study, the mean age of patients in both the groups was 30.64-34.72 years. This 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.

Levocetizine 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 levocetizine group and 96% of patients in fexofenadine group. All the patients were relieved of this symptom in fexofenadine group compared to 96% (48 patients) in levocetizine group. Though considerable reduction in severity of individual symptoms in each patients seen in both treatment group, the levocetizine group had higher degree of reduction. Fexofenadine showed faster onset of action within minutes compared to levocetizine which took around half an hour to an hour. But, the activity of levocetizine lasted longer compared to fexofenadine. This goes in favour of studies done by Simons and Simons⁵, Michael Larbig et al⁷ and Friedrich H et al⁸ who have also noted the same results. Levocetizine was effective in reducing nasal obstruction in 92% which goes in favour with other studies^{3,4}. As against the study conducted by David Bernstein et al⁵ where fexofenadine was effective on nasal obstruction, this study showed not much effect in this symptom (64%). Popoyet al⁹ and Wilson et al¹⁰ found levocetizine an effective tool not only for immediate short term allergic manifestation but also for long term symptomatic relief. Our study goes in favour with comparative studies done by Friedrich H et al⁸ and Michael Larbig et al⁷ and also a study by De Vos C et al¹¹ who compared treatment satisfaction in patients treated with antihistamines.

Hence, we conclude that although both levocetizine and fexofenadine are effective H1 receptor inverse agonists, levocetizine is more effective than fexofenadine.

REFERENCE

1. Bousquet J, Van Cauwenberge P et al. Allergic Rhinitis and its impact on asthma. *J Allergy Clin Immunol* 2001; 108: S147-334. | 2. Simons FE. Advances in H1-antihistamines. *N Engl J Med*. 2004;351:2203-17. | 3. Ciprandi G, Cirillo I, Vizzaccaro A, Tosca MA. Levocetizine improves nasal symptoms and airflow in patients with persistent allergic rhinitis; a pilot study. *Allerg Immunol* 2005; 37: 25-9. | 4. Bousquet J, Demarteau N, Mullol J, Van Daymme, Van Gee, Bachert C. Costs associated with persistent allergic rhinitis are reduced by levocetizine. *Allergy* 2005; 60: 788-94. | 5. Bernstein DI et al. Efficacy and safety of fexofenadine hydrochloride for treatment of seasonal allergic rhinitis. *Ann Allergy Asthma Immunol*. 1997; 79: 443-448. | 6. Simons FER, Simons KJ. Peripheral H1-Blockade effect of fexofenadine. *Ann Allergy Asthma Immunol*. 1997; 79: 530-532. | 7. Michael L, Bernard B, Laurent M, Holger S et al. Facial thermography is a sensitive tool to determine antihistamine activity: comparison of levocetizine and fexofenadine. *Br J Clin Pharmacol*. 2005; 62: 158-164. | 8. Friedrich H, Petra UZ, Ziegelmayer R, Kavina A, Lemell P. Levocetizine has a longer duration of action on improving total nasal symptoms score than fexofenadine after single administration. *Br J Clin Pharmacol*. 2005; 60(1): 24-31. | 9. Popoy TA, Dumitrascu D, Bachvarova A, Bocsan C, Dimitrov V, Church MK. A comparison of levocetizine and desloratadine in the histamine-induced wheal and flare response in human skin in vitro. *Inflamm Res*. 2006;55:241-44. | 10. Wilson AM, Byrne PM, Parameshwaran K. Leukotriene receptor antagonists for allergic rhinitis: a systematic review and meta-analysis. *Am J Med*. 2004;116:338-44. | 11. De Vos C, Mitchev K, Pinelli ME, Derde MP, Boev R. Non-interventional study comparing treatment satisfaction in patients treated with antihistamines. *Clin Drug Invest*. 2008;28(4):221-30. |