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Original Research

A comparative assessment of Monteleukast and Levocetirizine versus Monteleukast Fexofenadine in cases of Allergic Rhinitis

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ABSTRACT

Background: Allergic rhinitis (AR) is a global health problem. It is the cause of major illness and disability worldwide. The present study compared Monteleukast and Levocetirizine and versus Monteleukast Fexofenadine in cases of allergic rhinitis. **Materials & Methods:** The present study was conducted on 80 patients of allergic rhinitis of both genders. Patients were divided into 2 groups of 40 each. Group I patients were given one tablet of montelukast 10 mg plus levocetirizine 5 mg fixed-dose combination daily and group II patients was treated with fixed-dose combination of montelukast 10 mg plus fexofenadine 120 mg once daily. **Results:** The mean TNSS at baseline in group I was 11.4, at 2 weeks was 5.24 and at 4 weeks was 3.28. The mean TNSS at baseline in group II was 10.5, at 2 weeks was 4.06 and at 4 weeks was 1.16. Cost-effectiveness ratio in group I was significantly lower as compared to group II recorded at 2nd and 4th weeks ($P < 0.05$). Nausea was seen 3 patients in group I and 1 in group II, sedation 1 in group I and 3 in group II and dryness 1 in group I and 4 in group II. The difference was significant ($P < 0.05$). **Conclusion:** Authors found that montelukast-levocetirizine group found to be better than montelukast-fexofenadine group in patients with Allergic rhinitis.

Key words: Allergic rhinitis, Levocetirizine, Montelukast

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INTRODUCTION

Allergic rhinitis (AR) is a global health problem. It is the cause of major illness and disability worldwide.¹ Estimates indicate that 10%–25% of population worldwide is affected by AR. The main symptoms of AR include nasal congestion, rhinorrhea, itching, sneezing, and nonnasal symptoms such as burning, itching and watery eyes, or itching ears and palate. These symptoms can have a considerable toll on patient's quality of life by interfering with cognitive and

emotional functioning. The estimated annual cost attributable to AR in the United States ranges from \$1.4 billion to nearly \$6 billion in direct cost annually.² When an individual is exposed to non-self substance either by injection or infection, a complex series of events are created. Adaptive immunity is created after an interaction of lymphocytes with particular foreign substances which are recognized specifically by those lymphocytes. Allergic rhinitis is basically outcome of body's protective mechanism i.e. immune response

which sends a warning signal whenever there is a foreign invader found in body. An early response starts occurring within a minute after exposure to allergens whereas late response occurs 4 to 8 hours after exposure.³

Today's antiallergic therapy is based on avoidance of the causative allergen, symptomatic pharmacotherapy, specific immunotherapy, and education. Oral/intranasal H₁-antihistaminics, decongestants, leukotrienes receptor antagonists, and intranasal corticosteroids are the pillars in the management of AR. Levocetirizine and fexofenadine is found to be effective in treatment of allergic rhinitis. However many authors have recommended Montelukast, has been effective in improving symptoms in patients with allergic rhinitis.⁴ The present study compared Montelukast and Levocetirizine and versus Montelukast Fexofenadine in cases of allergic rhinitis.

MATERIALS & METHODS

The present study was conducted in the Department of Pharmacology, Rama Medical College Hospital & Research Center, Hapur (UP). It comprised of 80 patients of allergic rhinitis of both genders. All were informed regarding the study and written consent was obtained. Ethical clearance was taken before starting the study.

General information such as name, age, etc. was recorded. Patients were divided into 2 groups of 40 each. Group I patients were given one tablet of montelukast 10 mg plus levocetirizine 5 mg fixed-dose combination daily and group II patients was treated with fixed-dose combination of montelukast 10 mg plus fexofenadine 120 mg once daily. Patient was subjected to total leukocyte count, differential leukocyte count, liver function test, and kidney function test. All patients were recalled regularly and total nasal symptom score, cost-effectiveness ratio and adverse drug reaction was recorded.

The Total Nasal Symptom Score (TNSS) is the sum of scores for each of nasal congestion, sneezing, nasal itching, and rhinorrhea at each time point, using a four point scale (0–3), where 0 indicates no symptoms, a score of 1 for mild symptoms that are easily tolerated, 2 for awareness of symptoms which are bothersome but tolerable and 3 is reserved for severe symptoms that are hard to tolerate and interfere with daily activity. TNSS is calculated by adding the score for each of the symptoms to a total out of 12.

Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Parameters	Group I	Group II
Drug	Montelukast 10 mg plus levocetirizine 5 mg	Montelukast 10 mg plus fexofenadine 120 mg
Male	22	24
Female	18	16

Table I shows that group I patients were given tablet Montelukast 10 mg plus levocetirizine 5 mg and in group II patients, tablet Montelukast 10 mg plus fexofenadine 120 mg was given. There were 22 males and 18 females in group I patients, and 24 males and 16 females in group II.

Table II Total nasal symptom score at baseline and at 2 weeks and 4 weeks

Parameters	Baseline	2 weeks	4 weeks	P value
Group I	11.4	5.24	3.28	0.01
Group II	10.5	4.06	1.16	0.01

Table II, graph I shows that mean TNSS at baseline in group I was 11.4, at 2 weeks was 5.24 and at 4 weeks was 3.28. The mean TNSS at baseline in group II was 10.5, at 2 weeks was 4.06 and at 4 weeks was 1.16. The difference was significant (P< 0.05).

Graph I Total nasal symptom score at baseline and at 2 weeks and 4 weeks

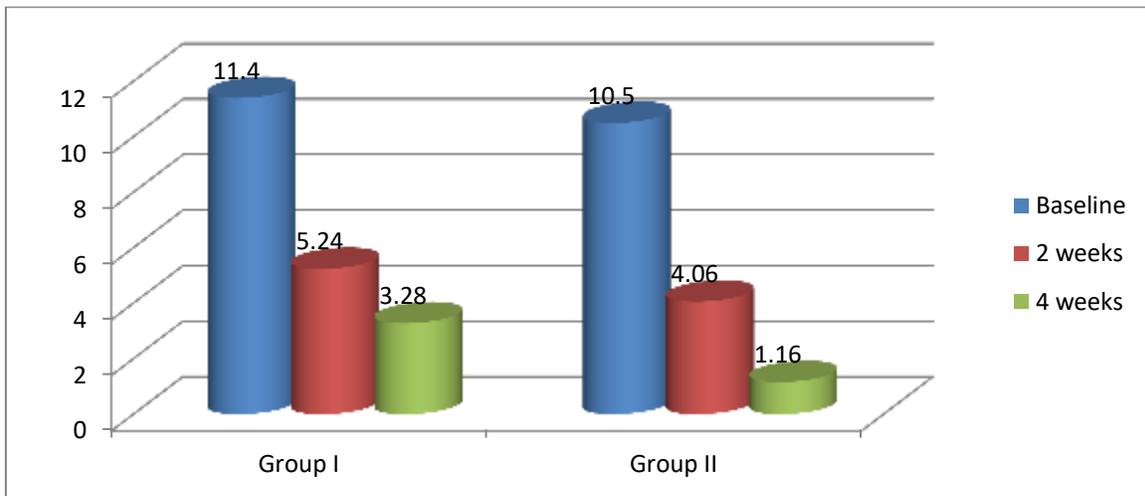
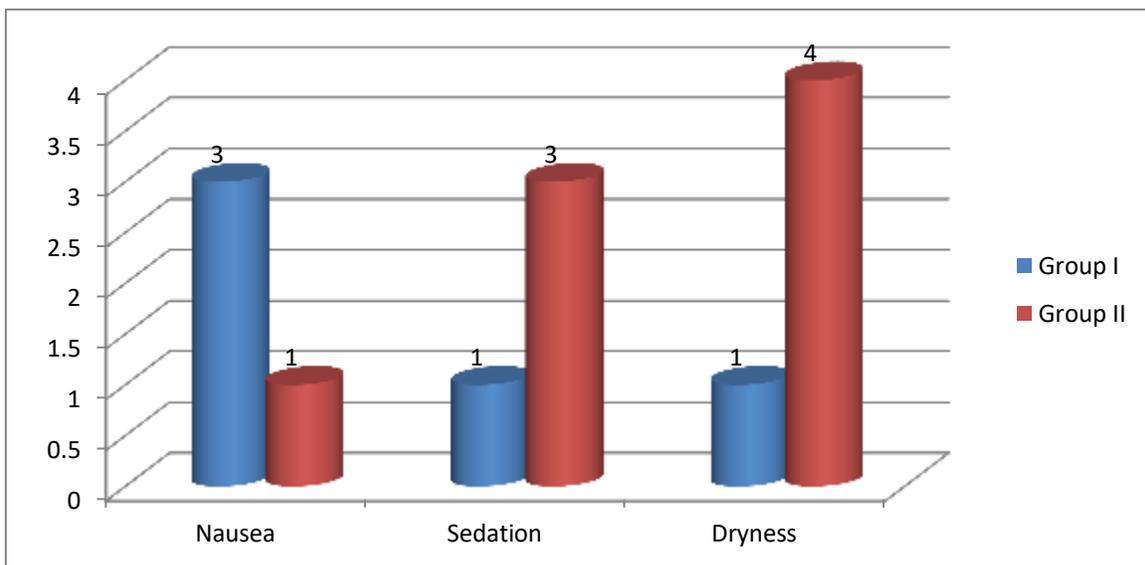


Table III Cost-effectiveness ratio in both groups

Cost-effectiveness ratio	Group I	Group II	P value
At 2 nd week	16.2	23.2	0.02
At 4 th week	24.1	28.4	0.05

Table III shows that cost-effectiveness ratio in group I was significantly lower as compared to group II recorded at 2nd and 4th weeks ($P < 0.05$).

Graph II Adverse drug reactions in both groups



Graph II shows that nausea was seen 3 patients in group I and 1 in group II, sedation 1 in group I and 3 in group II and dryness 1 in group I and 4 in group II. The difference was significant ($P < 0.05$).

DISCUSSION

Allergic rhinitis is inflammation of mucous membrane of nose caused due to allergens like pollen, dust etc. It

is one of the most common condition encountered in day today's life by causing sleep disturbance, irritability, fatigue, reduced work performance etc.⁵

Most common symptoms of allergic rhinitis includes sneezing, itching, rhinorrhea and nasal obstruction few authors reported its association with ocular symptoms. According to world health organisation 10-25% of the adult population and up to 40% of children worldwide are affected by allergic rhinitis.⁶

The goal of the treatment is to control the symptoms and improve patient's quality of life. Allergic rhinitis is also very well known as hay fever in day today's life. It is an allergic reaction mediated by immunoglobulin E (IgE) after exposure from allergen.⁷ Allergic reaction further leads to inflammatory responses caused by inflammatory cells like mast cells and basophiles. Inflammatory cells further release inflammatory mediators like histamines and leukotrienes which leads to symptoms like congestion, irritation sneezing etc.⁸ The present study compared Montelukast and Levocetirizine and versus Monteleukast Fexofenadine in cases of allergic rhinitis.

In present study, group I patients were given tablet Montelukast 10 mg plus levocetirizine 5 mg and in group II patients, tablet Montelukast 10 mg plus fexofenadine 120 mg was given. There were 22 males and 18 females in group I patients, and 24 males and 16 females in group II. Kumari et al⁹ compared the efficacy of Levocetirizine and monteleukast versus fexofenadine and monteleukast in school going children with allergic rhinitis. Sample size selected for the present study was 80 patients suffering from allergic rhinitis. Samples were divided in to two groups (n = 40 Group 1- LM) and (n = 40 Group 2-LF) based on the treatment provided. Out of 80 patients aged between 8 to 15 years. Out of 80 patients 45 were males and 35 females. Reduction in TNSS for Group 1 on 7th day was 52.8% and Group 2 60.8% and for 14th day it was 83.8% for Group 1 and for. 92.1%.

We found that mean TNSS at baseline in group I was 11.4, at 2 weeks was 5.24 and at 4 weeks was 3.28. The mean TNSS at baseline in group I was 10.5, at 2 weeks was 4.06 and at 4 weeks was 1.16. The cost-effectiveness ratio in group I was significantly lower as compared to group II recorded at 2nd and 4th weeks ($P < 0.05$). We found that nausea was seen 3 patients in group I and 1 in group II, sedation 1 in group I and 3 in group II and dryness 1 in group I and 4 in group II.

Mahatme et al¹⁰ included seventy patients with AR participated in a prospective, randomized, double-blind, parallel, active-controlled, comparative 4-week trial. The study inclusion criteria required the patients with total nasal symptom score (TNSS) of 5 or higher. The patients were randomly divided into two treatment groups with montelukast-levocetirizine (10 mg and 5 mg) in one group and montelukast-fexofenadine (10 mg and 120 mg) in another group. TNSS parameter was the main effectiveness parameter. Evaluation of TNSS revealed significant difference ($P < 0.05$) when

compared from baseline to 4th week in both groups. The mean change of TNSS, i.e., 9.46 was significant ($P < 0.05$) in montelukast-fexofenadine group. The cost-effectiveness ratio was less in montelukast-levocetirizine group than in montelukast-fexofenadine group.

CONCLUSION

Authors found that montelukast-levocetirizine group found to be better than montelukast-fexofenadine group in patients with Allergic rhinitis.

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