

# A Study of Levocetirizine and Monteleukast versus Fexofenidine and Monteleukast in School Going Children with Allergic Rhinitis

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## ABSTRACT

**Background:** Allergic rhinitis also called as hay fever is one of the most common allergic respiratory condition. It is often associated with sleep disturbance during night time, drowsiness in day time, nasal congestion and fatigue. Antihistamines like Levocetirizine and fexofenidine along with monteleukast have been used for allergic rhinitis for longer period of time.

**Aim:** To compare the efficacy of Levocetirizine and monteleukast versus fexofenidine and monteleukast in school going children with allergic rhinitis.

**Materials and Methods:** Sample size selected for the present study was 80 patients suffering from allergic rhinitis. Age group selected for current study was school going children aged between 8 to 15years. A detailed case history was obtained and based on the symptoms patients were included in the study. Samples were divided in to two groups (n = 40 Group 1-LM) and (n = 40 Group 2-LF) based on the treatment provided.

**Results:** 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 7<sup>th</sup> day was 52.8% and Group 2 60.8% and for 14<sup>th</sup> day it was 83.8% for Group 1 and for. 92.1%.

**Conclusion:** Fexofenidine and monteleukast can be used as an alternative to Levocetirizine and monteleukast. It showed better result.

**Keywords:** Allergy, Rhinitis, Antihistamine, Leukotrienes Antagonist.

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## INTRODUCTION

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.<sup>1,2</sup> Most common symptoms of allergic rhinitis includes sneezing, itching, rhinorrhea and nasal obstruction few authors reported its association with ocular symptoms.<sup>3,4</sup> According to world health organisation 10-25% of the adult population and up to 40% of children worldwide are affected by allergic rhinitis.<sup>4,5</sup>

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.<sup>3</sup>

Antihistamines are considered as drug of choice for allergic rhinitis. They are available in various forms like oral and intranasal H1 antihistamines, intranasal corticosteroids, oral and intranasal decongestants, intranasal anticholinergics.<sup>4,7,8</sup> antihistamines like Levocetirizine and fexofenidine 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.<sup>7,9</sup> Cingi C et al reported that combination of montelukast plus fexofenadine combination therapy were successful in treating allergic rhinitis.<sup>10</sup> However sufficient data is not available so far, So we aimed to compare the efficacy of Levocetirizine and monteleukast versus fexofenidine and monteleukast in school going children with allergic rhinitis.

**MATERIALS AND METHODS**

Sample size selected for the current study was 80 patients aged between 8 to 15 years. Out of 80 patients 45 were males and 35 females (Table 1). Samples selected were school going children, simple random sampling technique was used. Those willing to participate for the study were selected. Study period selected was for 14 days. Ethical committee clearance was obtained. Patients as well as their parents were provided detailed description of study and were explained about the procedures to be performed. A written informed consent was obtained from the patient and guardians before any procedure. Patients with known drug allergies or hypersensitive patients were not included in the study. Patients were diagnosed for allergic rhinitis. Patients were divided in to two groups based on the treatment provided.

**Group 1:** Levocetirizine plus Monteleukast (LM)

**Group 2:** Fexofenidine plus Monteleukast (FM)

Evaluation criteria was based on total system score (TSS) both total nasal system score (TNSS) and ocular symptom score

(TOSS). The scores were graded on 4-point categoric scale as follows:

- 0 = No symptoms
- 1 = Mild symptoms, but not affecting any activities during the day/sleep at night
- 2 = Moderate symptoms affecting at least one activity or disturbing sleep
- 3 = Severe symptoms affecting >2 daily activities or disturbing sleep all night or most of the night.

Patients were followed up in two intervals i.e. 7<sup>th</sup> day after initiation of treatment and 14<sup>th</sup> day and complete examination was done.

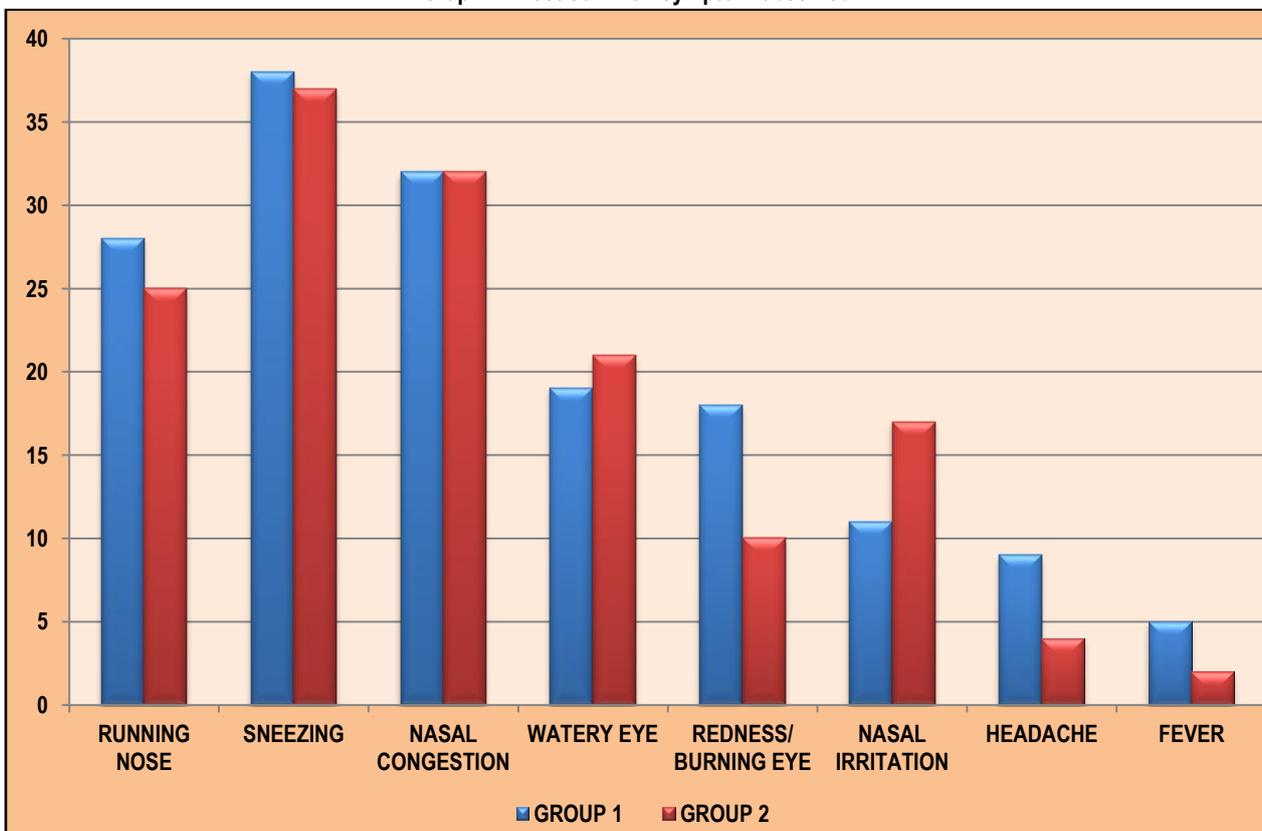
**Statistical Analysis**

All the data was collected and tabulated. Statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 10. One-way analysis of variance (ANOVA) was used to determine differences at the 5 percent significance level (p<0.05). Freidman test was used for comparison and baseline analysis.

**Table 1: Patients demographic details**

Gender	Group 1 (LM)	Percentage	Group 2 (FM)	Percentage
Males	23	57.5%	22	55%
Females	17	42.5%	18	45%
TOTAL	n = 40	100%	n = 40	100%

**Graph 1: Most common symptom observed**



**Table 2: Change In Nasal Symptom Score**

SYMPTOMS	BASELINE	Group 1 (LM)		Group 2 (FM)	
		7 <sup>th</sup> Day	14 <sup>th</sup> Day	7 <sup>th</sup> Day	14 <sup>th</sup> Day
Sneezing	2.19	1.06	0.43	0.82	0.21
Running nose	2.28	0.96	0.29	0.75	0.11
Nasal congestion	2.21	1.03	0.32	0.96	0.23
Nasal irritation	1.11	0.62	0.22	0.52	0.06

Table 3: Change In Ocular Symptom Score

SYMPTOMS	BASELINE	Group 1 (LM)		Group 2 (FM)	
		7 <sup>th</sup> Day	14 <sup>th</sup> Day	7 <sup>th</sup> Day	14 <sup>th</sup> Day
Watery eye	3.22	1.06	0.47	0.99	0.14
Redness/burning eye	3.18	1.13	0.52	1.01	0.12

## RESULTS

A total of 80 patients were selected for the study. Out of 80, 45 were males i.e. 56.25% whereas 35 females i.e. 43.7%. Total sample was divided in two groups (n=80). In Group 1 (LM) there were total 40 patients, 23 males (57.5%) and 17 females (42.5%) and in Group 2 (FM) number of males were 22 (55%) and 18 females (45%). (Table-1) Out of 80 patients 75 complained of sneezing (93.7%), 53/80 running nose (66.25%), 64/80 complained of nasal congestion (80%), 40/80 watery eye (50%), 38/80 redness/burning eye (47.5%), 28/80 nasal irritation (35%), 13/80 reported having headache (16.2%) and 7 complained of fever (8.7%). (Graph-1) The most common symptom found in present study was sneezing, nasal congestion, running nose and watery eye.

The baseline score for total nasal symptom score for the current study was found to be 7.79%. Fall in mean baseline score was observed in both groups. The baseline total nasal symptom score for Group 1 on 7<sup>th</sup> day was 3.67 i.e. there was reduction of 4.12 (52.8%) and Group 2 there was reduction of 4.74 (60.8%). Whereas the baseline score for 14<sup>th</sup> day was 6.53 i.e.83.8% for Group 1 and for Group 2 reduction rate was 7.81 i.e. 92.1%. (Table 2) The total nasal symptom score was found to be reduced significantly in group 2 i.e. fexofenidine plus monteleukast when compared to baseline score ( $p<0.001$ )

The baseline score was total ocular symptom score was 6.4%. The baseline total ocular symptom score for Group 1 on 7<sup>th</sup> day was 2.19 i.e. there was reduction of 4.21 (65.7%) and baseline score for 14<sup>th</sup> day was found to be 0.99 i.e. there was a reduction of 5.41 (84.5%). Whereas total ocular symptom score for Group 2 on 7<sup>th</sup> day was 2 i.e. there was a reduction of 4.4 (68.7%) and on 14<sup>th</sup> day the total ocular symptom score was 0.26 and there was a reduction of 6.14 (95.9%). The total ocular symptom score was also found to be reduced significantly group 2 i.e. fexofenidine plus monteleukast ( $p<0.001$ )

## DISCUSSION

Allergic rhinitis is a global health issue which often affects patient's quality of life. 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.<sup>4</sup> 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.<sup>4,10</sup>

In present study most common symptom observed among patients were sneezing in 93.7%, running nose in 66.25% and nasal congestion in 80% cases. Antihistamines remain the treatment of allergic rhinitis for decades however older antihistamines are replaced by newer generations.<sup>11</sup> Antihistamines block histamine at the H1-receptor level.<sup>4</sup> Tkachyk

SJ in his study recommended that leukotriene receptor antagonists like zafirlukast and montelukast, when taken orally avoid the discomfort of nasal sprays and have lesser side effects.<sup>12</sup> In our study none of the patients complained of any side effects during or after treatment. Recently use of antihistamines and leukotrienes has caught researches eye for better treatment and minimum side effects.

In present study the baseline total nasal symptom score for LM group on 7<sup>th</sup> day was 3.67 i.e. there was reduction of 4.12 (52.8%) and FM there was reduction of 4.74 (60.8%). Whereas the baseline score for 14<sup>th</sup> day was 6.53 i.e.83.8% for LM group and for FM reduction rate was 7.81 i.e. 92.1%. The total ocular symptom score was 6.4%. The baseline total ocular symptom score for LM on 7<sup>th</sup> day was 2.19 i.e. reduction of 65.7% and baseline score for 14<sup>th</sup> day showed reduction of 5.41 i.e. 84.5%. Whereas total ocular symptom score for FM on 7<sup>th</sup> day was 2 i.e. there was a reduction of 68.7% and on 14<sup>th</sup> day the total ocular symptom score was 0.26 and there was a reduction of 95.9%. The total nasal and ocular symptom score was also found to be reduced significantly in fexofenidine plus monteleukast group ( $p<0.001$ ). The combination of fexofenidine and monteleukast showed better results in our study which was similar to those reported by other authors.<sup>13</sup>

## CONCLUSION

Allergic rhinitis is a common allergic condition but can have a severe effect on patients day today's life. Based on the results of present study combination of fexofenidine plus monteleukast, showed better results than Levocetirizine plus monteleukast. No side effects were observed in any patients. However much data is not available in this regard further researches are warranted for the same.

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