

## To Compare the Efficacy of Montelukast Levocetirizine and Montelukast Fexofenadine in Patients of Allergic Rhinitis at a Tertiary Care Centre

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### ABSTRACT

**Background:** Allergic rhinitis is a common inflammatory condition of the upper respiratory tract and is characterized by one or more symptoms including sneezing, itching, nasal congestion, and rhinorrhoea. Hence; the present study was conducted for comparing the efficacy of montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis.

**Materials & Methods:** A total of 40 subjects with presence of allergic rhinitis were enrolled. Patients with total nasal symptom score (TNSS) of 5 or higher were enrolled. All the patients were broadly divided into two study groups as follows: Group A: 20 patients who were treated with montelukast levocetirizine, and Group B: 20 patients who were treated with montelukast fexofenadine. All the patients were given medication once daily. The patients were given an 8-day symptom diary at visit one (screening visit). A recording of TNSS parameter was expected from the patients. Efficacy was evaluated by the change in TNSS from baseline. Improvement in the scores by two or more points was considered significant.

**Results:** Mean TNSS at baseline among group A and group B was 11.29 and 11.08 respectively. Mean TLC count among group A and group B was 8436.1 and 8469.8 respectively. Mean TSS among patients of group A at 2 weeks, and 4 weeks

was 5.31 and 3.85 respectively. Mean TSS among patients of group B at 2 weeks, and 4 weeks was 4.86 and 1.18 respectively. Significant results were obtained while comparing the mean TNSS at different time intervals.

**Conclusion:** From the above results, the authors conclude that decline in TNSS was more in montelukast-fexofenadine group. Hence; it is a comparatively better option in treating allergic rhinitis patients.

**Key words:** Montelukast, Fexofenadine, Allergic Rhinitis.

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### Article History:

**Received:** 02-04-2019, **Revised:** 27-04-2019, **Accepted:** 18-05-2019

### Access this article online

Website: <a href="http://www.ijmrp.com">www.ijmrp.com</a>	Quick Response code 
DOI: 10.21276/ijmrp.2019.5.3.079	

### INTRODUCTION

Allergic rhinitis is a common inflammatory condition of the upper respiratory tract and is characterized by one or more symptoms including sneezing, itching, nasal congestion, and rhinorrhoea. The symptoms of allergic rhinitis result from a complex allergen-driven mucosal inflammation caused by interplay between resident and infiltrating inflammatory cells and a number of vasoactive and pro-inflammatory mediators. Seasonal allergic rhinitis (SAR) is one type of allergic rhinitis and is commonly referred to as 'hay fever'. Seasonal allergic rhinitis is caused by an IgE-mediated reaction to seasonal aeroallergens and is fairly easy to identify because of the rapid and reproducible onset and offset of symptoms in association with pollen exposure.<sup>1-3</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. antihistamines like 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.<sup>4-6</sup> Hence; the present study was conducted for comparing the efficacy of montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis.

### MATERIALS & METHODS

The present study was conducted at Department of Pharmacology, Hind Institute of Medical Sciences, Mau, Ataria, Sitapur, Uttar Pradesh (India) for comparing the efficacy of

montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis. A total of 40 subjects with presence of allergic rhinitis were enrolled. Patients with total nasal symptom score (TNSS) of 5 or higher were enrolled. TNSS is the intensity of nasal symptoms (rhinorrhea, nasal itching, nasal obstruction, and sneezing) using a 4-point Likert scale from 0 to 3 (0 = no symptom, 1 = mild, 2 = moderate, and 3 = severe). All the patients were broadly divided into two study groups as follows:

**Group A:** 20 patients who were treated with montelukast levocetirizine, and

**Group B:** 20 patients who were treated with montelukast fexofenadine

All the patients were given medication once daily. The patients were given an 8-day symptom diary at visit one (screening visit). A recording of TNSS parameter was expected from the patients. Efficacy was evaluated by the change in TNSS from baseline. Improvement in the scores by two or more points was considered significant.

All the results were recorded in Microsoft excel sheet and were analysed by SPSS software.

**Table 1: Demographic data**

Variable	Group A	Group B
Mean age (years)	34.6	36.2
Males (n)	12	13
Females (n)	8	7

**Table 2: Comparison of baseline variables**

Variable	Group A	Group B
TNSS at baseline	11.29	11.08
Total leukocyte count	8436.1	8469.8

**Table 3: Comparison of TNSS at different time intervals**

TNSS	Group A	Group B	p- value
Baseline	11.29	11.08	0.12
2 weeks	5.31	4.86	0.45
4 weeks	3.85	1.18	0.00 (Significant)

## RESULTS

Out of 40 subjects, 20 subjects belonged to group A and the remaining 20 subjects belonged to group B. Mean age of the patients of group A and group B was 34.6 years and 36.2 years respectively. There were 12 males and 8 females in group A. There were 13 males and 7 females in group B. Mean TNSS at baseline among group A and group B was 11.29 and 11.08 respectively. Mean TLC count among group A and group B was 8436.1 and 8469.8 respectively. Mean TSS among patients of group A at 2 weeks, and 4 weeks was 5.31 and 3.85 respectively. Mean TSS among patients of group B at 2 weeks, and 4 weeks was 4.86 and 1.18 respectively. Significant results were obtained while comparing the mean TNSS at different time intervals.

## DISCUSSION

Allergic Rhinitis is a symptomatic disorder of the nose induced after allergen exposure due to an IgE-mediated inflammation of membranes lining the nose. It is clinically defined as a symptomatic condition with four major symptoms as anterior or posterior rhinorrhoea, sneezing, nasal itching & nasal congestion. Allergic Rhinitis symptoms result in sleep disturbance, fatigue, depressed mood and cognitive function compromise that impairs quality of life and productivity. There may be associated conjunctivitis, postnasal drip, Eustachian tube dysfunction, otitis media, sinusitis & in children, dental malocclusions & facial deformities also. Triggers of Allergic rhinitis are domestic allergens

as mites, domestic animals, insects or of plant origin; common outdoor allergens include pollens and moulds; occupational triggers as latex; tobacco smoke; automobile exhaust include ozone, oxides of nitrogen and sulphur dioxide; aspirin and other non-steroidal anti-inflammatory drugs.<sup>6-9</sup> The present study was conducted for comparing the efficacy of montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis.

Out of 40 subjects, 20 subjects belonged to group A and the remaining 20 subjects belonged to group B. Mean age of the patients of group A and group B was 34.6 years and 36.2 years respectively. There were 12 males and 8 females in group A. There were 13 males and 7 females in group B. Mean TNSS at baseline among group A and group B was 11.29 and 11.08 respectively. Mean TLC count among group A and group B was 8436.1 and 8469.8 respectively. Mahatme MS et al compared the efficacy, safety, and cost-effectiveness of montelukast-levocetirizine and montelukast-fexofenadine combination in patients of AR. 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. The decrease in TNSS was more in montelukast-fexofenadine group, but the cost-effectiveness is more with montelukast-levocetirizine combination.<sup>10</sup>

Mean TSS among patients of group A at 2 weeks, and 4 weeks was 5.31 and 3.85 respectively. Mean TSS among patients of group B at 2 weeks, and 4 weeks was 4.86 and 1.18 respectively. Significant results were obtained while comparing the mean TNSS at different time intervals. Abha Kumari et al compare the efficacy of Levocetirizine and montelukast versus fexofenadine and montelukast in school going children with allergic rhinitis. 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 15 years. 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 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%. Fexofenadine and montelukast can be used as an alternative to Levocetirizine and montelukast. It showed better result.<sup>11</sup>

## CONCLUSION

From the above results, the authors conclude that decline in TNSS was more in montelukast-fexofenadine group. Hence; it is a comparatively better option in treating allergic rhinitis patients.

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**Source of Support:** Nil. **Conflict of Interest:** None Declared.

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**Cite this article as:** Anurag Pathak, Hemant Garg, Rajesh Kumar Suman, Arun Kumar Adhikari. To Compare the Efficacy of Montelukast Levocetirizine and Montelukast Fexofenadine in Patients of Allergic Rhinitis at a Tertiary Care Centre. *Int J Med Res Prof*. 2019 May; 5(3): 337-39. DOI:10.21276/ijmrp.2019.5.3.079