

Original Research

To compare the efficacy of montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis

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ABSTRACT:

Background: Sneezing, itching, congestion of the nose, and rhinorrhea are just a few of the symptoms of allergic rhinitis, a common inflammatory illness of the upper respiratory tract. In order to compare the effectiveness of montelukast levocetirizine and montelukast fexofenadine in patients with allergic rhinitis, the current study was carried out. **Materials & methods:** Overall 100 subjects with allergic rhinitis were recruited. Subjects having with total nasal symptom score (TNSS) of five or greater had been recruited were. All the subjects had been categorized into 2 study cohorts. Group 1 comprised of 50 subjects who were treated with montelukast levocetirizine, and Group 2 consisted of 50 patients who were treated with montelukast fexofenadine. All the patients were given medication once daily. Improvement in the scores by two or more points was considered significant. **Results:** Mean TNSS at baseline among group 1 and group 2 was 12.01 and 12.24 respectively. Mean TLC count among group 1 and group 2 was 8452.9 and 8473.3 respectively. Mean TSS among patients of group 1 at 2 weeks, and 4 weeks was 6.47 and 5.75 respectively. Mean TSS among patients of group 2 at 2 weeks, and 4 weeks was 5.87 and 2.36 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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INTRODUCTION

Allergic rhinitis (AR) is an atopic disease characterized by symptoms of nasal congestion, clear rhinorrhea, sneezing, postnasal drip, and nasal pruritis. It affects one in six individuals and is associated with significant morbidity, loss of productivity, and healthcare costs. Historically, AR was thought to be a disease process of the nasal airway alone. Still, the development of the unified airway theory has classified AR as a component of systemic allergic response, with other associated conditions, such as asthma and atopic dermatitis, sharing an underlying systemic pathology.¹ AR can be classified as either seasonal (intermittent) or perennial (chronic), with approximately 20% of cases being seasonal, 40% perennial, and 40% with features of both.² In addition to nasal symptoms, patients with AR may also present with associated allergic conjunctivitis, non-productive cough, Eustachian tube

dysfunction, and chronic sinusitis. Once diagnosed, AR is treatable with a variety of modalities, with intra-nasal glucocorticoids being first-line therapy.

AR is characterized by the presence of nasal and non-nasal symptoms. Nasal symptoms include anterior or posterior rhinorrhea, sneezing, nasal blockage and/or itching of the nose.³ These symptoms may persist for hours after allergic reaction upon the exposure of allergens that cause mucosal inflammation.⁴ In consequences, the mucosa is rendered more reactive to the triggering allergen as well as to other allergens and to non-allergenic stimuli (e.g., strong odors and other irritants). Non-nasal symptoms are characterized by ocular symptoms such as allergic rhinoconjunctivitis (i.e., itching and redness of the eyes and tearing) which frequently occurs in AR patients.⁵ Other symptoms include itching of the palate, postnasal drip and cough.

Hence; the present study was conducted for comparing the efficacy of montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis.

MATERIALS & METHODS

The current study was carried out for comparing the effectiveness of montelukast levocetirizine as well as montelukast fexofenadine in subjects having allergic rhinitis. Overall, 100 subjects having allergic rhinitis had been recruited. Subjects having total nasal symptom score (TNSS) of five or greater had been recruited. TNSS represents the degree of nasal symptoms using a 4-point Likert scale from 0 to 3 (0 = no symptom, 1 = mild, 2 = moderate, and 3 = severe). All the subjects had been categorized into 2 cohorts. Group 1 comprised of 50 subjects who were treated with montelukast levocetirizine, and Group 2 consisted of 50 patients who were treated with montelukast fexofenadine. All the patients were given medication once daily. 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.

RESULTS

Out of 100 subjects, 50 subjects belonged to group 1 and the remaining 50 subjects belonged to group 2. Mean age of the patients of group 1 and group 2 was 35.7 years and 36.3 years respectively. There were 40 males and 10 females in group 1. There were 42 males and 8 females in group 2. Mean TNSS at baseline among group 1 and group 2 was 12.01 and 12.24 respectively. Mean TLC count among group 1 and group 2 was 8452.9 and 8473.3 respectively. Mean TSS among patients of group 1 at 2 weeks, and 4 weeks was 6.74 and 5.75 respectively. Mean TSS among patients of group 2 at 2 weeks, and 4 weeks was 5.87 and 2.36 respectively. Significant results were obtained while comparing the mean TNSS at different time intervals.

Table 1: Demographic data

Variable	Group 1	Group 2
Mean age (years)	35.7	36.3
Males (n)	40	42
Females (n)	10	8

Table 2: Comparison of baseline variables

Variable	Group 1	Group 2
TNSS at baseline	12.01	12.24
Total leukocyte count	8452.9	8473.3

Table 3: Comparison of TNSS at different time intervals

TNSS	Group 1	Group 2	p- value
Baseline	12.01	12.24	0.14
2 weeks	6.74	5.87	0.49
4 weeks	5.75	2.36	0.00 (Significant)

DISCUSSION

Allergic rhinitis (AR) is a common disorder that afflicts 400 million people worldwide and it represents a global concern as its prevalence has increased over the years.⁶ AR usually comorbid with other diseases such as asthma⁷, leading to impaired quality of life, school or work performance, and significant financial impact.^{8,9} AR is shown to be caused by aberrantly high Th2 cytokines, and recent findings on the cause of AR are directed toward impairment of the nasal epithelial barrier integrity.¹⁰⁻¹³ In this review, we summarize the well-established yet important concepts of AR including the epidemiology, clinical and laboratory diagnostic criteria, pathophysiology of AR including allergens as well as Th2 responses in AR. Allergic rhinitis prevalence has increased significantly since the 1990s.¹⁴⁻¹⁶ It is reported to affect approximately 25 and 40% of children and adult globally, respectively. Approximately 80% of AR symptoms develop before the age of 20 years¹⁷ and peak at age 20–40 years before gradually declining.¹⁸ The incidence rate of AR in children over the first 5 years of life was reported to be 17.2%, with a peak age at diagnosis between 24 and 29 months (2.5%). Meta-analysis studies have shown the sex-specific differences in the prevalence of AR with male predominance in childhood and a female predominance in adolescents.^{19,20}

Prevalence of AR has increased with years due to several risk factors including global urbanization as shown by several studies comparing AR prevalence in urban settings with rural areas.^{21,22} This is mainly caused by increased levels of pollutants [e.g., traffic-related pollutants and particulate matter 2.5 (PM_{2.5})] that can exacerbate pollen-sensitized AR.^{23,24,25} It has been reported that AR is more prevalent in urban areas compared with rural areas.²⁶ Climate changes also prolong pollen season as reported in Europe over the last three decades along with more frequent seasonal allergies.²⁷

The present study was conducted for comparing the efficacy of montelukast levocetirizine and montelukast fexofenadine in patients of allergic rhinitis.

Out of 100 subjects, 50 subjects belonged to group 1 and the remaining 50 subjects belonged to group 2. Mean age of the patients of group 1 and group 2 was 35.7 years and 36.3 years respectively. There were 40 males and 10 females in group 1. There were 42 males and 8 females in group 2. Mean TNSS at baseline among group 1 and group 2 was 12.01 and 12.24 respectively. Mean TLC count among group 1 and group 2 was 8452.9 and 8473.3 respectively. Mean TSS among patients of group 1 at 2 weeks, and 4 weeks was 6.74 and 5.75 respectively. Mean TSS among patients of group 2 at 2 weeks, and 4 weeks was 5.87 and 2.36 respectively. Significant results were obtained while comparing the mean TNSS at different time intervals.

Mahatme MSet al²⁸ compared the efficacy, safety, as well as cost-effectiveness of montelukast-

levocetirizine and montelukast-fexofenadine combination in patients of AR. 70 patients with AR participated in a prospective, randomized, double-blind, parallel, active-controlled, comparative 4-week trial. The patients between the age group of 18–65 years of either gender having moderate-severe intermittent or mild persistent AR were included in the study. 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

From the aforementioned outcomes, it was concluded that the decrease in TNSS had been more in montelukast-fexofenadine group. Therefore, it is a relatively better option for managing allergic rhinitis subjects.

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