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# EFFICACY EVALUATION OF MONTELUKAST FOR CHILDHOOD PERENNIAL ALLERGIC RHINITIS AT A TERTIARY CARE CENTRE

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### Abstract

Background: Allergic Rhinitis is a symptomatic disorder of the nose induced after allergen exposure due to an IgE-mediated inflammation of membranes lining the nose. Montelukast is an orally active, highly selective cysteinyl leukotriene type-1 receptor antagonist of leukotreine D4, with affinities approximately two-fold greater than the natural ligand. Hence; the present study was conducted for efficacy evaluation of montelukast for childhood perennial allergic rhinitis at a tertiary care centre. Materials & Methods: 60 eligible children were consecutively enrolled in the study after taking prior informed consent/assent from the parents/child. Demographic profile, relevant information of individual patient was collected using well-structured proforma by interviewing the parents/attendant. At the time of enrollment, detailed history and physical examination was performed in the OPD. Case record form/proforma including nasal symptom score was filled at enrollment and subsequently on the first and second follow up at the end of the 1st and the 4th week respectively. all the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. Results: A total of 60 patients were evaluated. Majority patients belong to the age group of 11 to 15 years. The mean age of the patients was 11.9 years. 60 percent of the patients were boys while the remaining were girls. Family history was positive in 42 percent of the patients. Mean nasal symptom score among patients at baseline, 1 week and 4 weeks was 8.9, 6.9 and 4.1 respectively; on comparing significant results were obtained. Epistaxis, Nasal burning/irritation and Headache were seen by 1.67 percent, 5 percent, and 3.33 percent of the patients respectively. Conclusion: Montelukast is a cysteinyl leukotriene receptor 1 antagonist used to treat allergic rhinitis (AR). Significant results were obtained in relation to Montelukast among AR patients.

## **INTRODUCTION**

Allergic Rhinitis is a symptomatic disorder of the nose induced after allergen exposure due to an IgEmediated 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 nonsteroidal anti-inflammatory drugs.<sup>[1,2]</sup>

It can also be associated with co-morbid conditions as Asthma, Atopic Dermatitis & Nasal polyps. AR is a global health problem also with considerable economic & societal burdens. About 40 % of the world's population is atopic, and allergic rhinitis is the commonest preservation of this atopic tendency. The reported incidence of allergic rhinitis in the western countries is 1.4-39.7 %. The indirect costs resulting from Allergic Rhinitis associated absenteeism and presenteeism result in losses to employers that exceed those for other common conditions such as migraine, diabetes and asthma.<sup>[1,2]</sup> Previous data also suggest that AR is the most common chronic disorder in the pediatric population with up to 40% of children affected. The disease along with associated co-morbidities has a profound impact on the daily lives of children. Irritability, sadness, impairment of sleep and limitation of activities at school as well as home are often seen in these children. AR results in day-time fatigue and impairment of cognition and memory in children which significantly affect the learning process and thus impact on school performance and all these aspects upset the family. Many of these problems go completely unnoticed as children often fail to share them at home or at school. Furthermore, adverse effects of medications used for treatment of AR often compound these problems. Although AR greatly impacts life at home, school and even while sleeping, it is treated as a trivial and a commonplace disorder. Consequently, it does not receive the attention it deserves from the patient, the family as well as the health care professionals, especially in developing countries like India.[3-5]

Montelukast is an orally active, highly selective cysteinyl leukotriene type-1 receptor antagonist of leukotreine D4, with affinities approximately two-fold greater than the natural ligand. It is rapidly absorbed achieving peak plasma concentration (Cmax) in 3 to 4 hours and with a mean bioavailability of 64% following a 10 mg oral administration.<sup>[6,7]</sup> Hence; the present study was

conducted for efficacy evaluation of montelukast for childhood perennial allergic rhinitis at a tertiary care centre.

# **MATERIALS AND METHODS**

60 eligible children were consecutively enrolled in the study after taking prior informed consent/assent from the parents/child. Demographic profile, relevant information of individual patient was collected using well-structured proforma by interviewing the parents/attendant. At the time of enrollment, detailed history and physical examination was performed in the OPD. Case record form/proforma including nasal symptom score was filled at enrollment and subsequently on the first and second follow up at the end of the 1st and the 4th week respectively. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

#### RESULTS

A total of 60 patients were evaluated. Majority patients belong to the age group of 11 to 15 years. The mean age of the patients was 11.9 years. 60 percent of the patients were boys while the remaining were girls. Family history was positive in 42 percent of the patients. Mean nasal symptom score among patients at baseline, 1 week and 4 weeks was 8.9, 6.9 and 4.1 respectively; on comparing significant results were obtained. Epistaxis, Nasal burning/irritation and Headache were seen by 1.67 percent, 5 percent, and 3.33 percent of the patients respectively.

Table 1: Distribution of patients according to Nasal symptoms score at baseline				
Nasal symptoms	Study group			
	Mean	SD		
Rhinorrhea	2.6	1.3		
Nasal stuffiness	2.1	1.2		
Nasal itching	2.1	1.3		
Sneezing	2.1	1.5		
Total	8.9	1.9		

Table 2: Distribution of patients according to Nasal symptoms score at 1 week.

Nasal symptoms	Study group		
	Mean	SD	
Rhinorrhea	2.1	1.3	
Nasal stuffiness	1.8	0.8	
Nasal itching	1.5	0.8	
Sneezing	1.5	0.7	
Total	6.9	0.7	
*: Significant			

Table 3: Distribution of patients according to Nasal symptoms score at 4 weeks.

Nasal symptoms	Study group		
	Mean	SD	
Rhinorrhea	1.4	0.6	
Nasal stuffiness	1.1	0.5	
Nasal itching	0.8	0.4	
Sneezing	0.8	0.4	
Total	4.1	1.8	

*: Significant	

Table 4: Comparison of total nasal symptom score.					
Variable	Baseline	1 week	4 weeks		
Total nasal symptom score	8.9	6.9	4.1		
p-value	0.0001 (Significant)				

Table 5: Side effects

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Group		Intubating Co	Intubating Condition		p-value
		Excellent	Good		
А	Count	18	2	20	
	% within Group alloted to patient	90.0%	10.0%	100.0%	
В	Count	17	3	20	>0.05
	% within Group alloted to patient	85%	15%	100.0%	
С	Count	16	4	20	
	% within Group alloted to patient	80.0%	20.0%	100.0%	

### **DISCUSSION**

The frequency of common colds in childhood means that AR may be misdiagnosed or ignored. AR is diagnosed by a detailed history, supported by examination of the patient as a whole as well as the nose, plus, if necessary, testing for allergen- specific IgE. The clinical history should note where and when nasal symptoms occur, plus exacerbating and relieving factors. In addition, other symptoms, particularly those of asthma, eczema, ENT problems and food allergy should be sought, plus any effects of all these upon sleep and quality of life. A history or a family history of allergic disease and/or immune problems together with social history, including a review of treatments tried, those currently being taken and their efficacy, should be taken.<sup>[7-9]</sup>

A total of 60 patients were evaluated. Majority patients belong to the age group of 11 to 15 years. The mean age of the patients was 11.9 years. 60 percent of the patients were boys while remaining were girls. Family history was positive in 42 percent of the patients. Mean nasal symptom score among patients at baseline, 1 week and 4 weeks was 8.9, 6.9 and 4.1 respectively; on comparing significant results were obtained. Epistaxis, Nasal burning/irritation and Headache were seen 1.67 percent, 5 percent, and 3.33 percent of the patients respectively. The data comparing intranasal corticosteroids with monotherapy of montelukast or antihistamine show nasal steroids to have a greater efficacy on daytime and nighttime symptoms (Pullerits et al 2002; Martin et al 2005). However, when intranasal corticosteroids are compared with combination therapy with montelukast and antihistamines, results vary depending on the antihistamine chosen (ie, cetirizine vs loratadine) and which intranasal corticosteroid was used (ie, fluticasone vs budesonide vs mometasone). In one study comparing fluticasone with a combination of montelukast and loratadine, both groups showed improvements in daytime nasal allergic symptoms compared with placebo, but fluticasone was superior in controlling nighttime symptoms (Pullerits et al 2002). Conversely, the combination of montelukast and cetirizine was as

effective as intranasal mometasone in patients with allergic rhinitis, and intranasal budesonide in patients with seasonal AR and asthma (Wilson, Orr, et al 2001; Wilson, Sims, et al 2001). Lastly, further benefit is shown in patients already treated with intranasal corticosteroids and antihistamines when montelukast is added for uncontrolled symptoms of AR.[11-13] Van Adelsberg J et al evaluated the efficacy and tolerability of montelukast, a cysteinyl leukotriene receptor antagonist, given once daily in the morning for treatment of seasonal (fall) allergic rhinitis for 4 weeks. Patients (n = 1079) with a history of allergic rhinitis and a positive skin test to seasonal pollen allergens were assigned to placebo, montelukast 10 mg, or loratadine 10 mg. Symptoms were assessed with a daily diary. Montelukast was more effective than placebo in improving scores for the primary endpoint of daytime nasal symptoms (P = 0.003) and the secondary endpoints of night-time. composite, and daytime eye symptoms, patient's and physician's global evaluations of allergic rhinitis, and rhinoconjunctivitis quality-of-life (P </= 0.006). The positive control loratadine also improved scores for the primary endpoint (P </= 0.001) and the majority of the secondary endpoints (P < 0.03). When analyzed by week, the treatment effect of montelukast was more persistent than loratadine over all 4 weeks of treatment. Montelukast provided effective relief of seasonal allergic rhinitis symptoms when given once daily in the morning, showed significant and sustained improvement in symptoms of allergic rhinitis over 4 weeks of treatment, and was well-tolerated.[14]

# **CONCLUSION**

Montelukast is a cysteinyl leukotriene receptor 1 antagonist used to treat allergic rhinitis (AR). Significant results were obtained in relation to Montelukast among AR patients.

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