

## Comparative Study of Efficacy & Tolerability of Oral Montelukast & Azelastine Nasal Spray in Allergic Rhinitis

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**Abstract:** A prospective, comparative study was done in the Dept. of ENT, Pravara Rural hospital, Loni to compare efficacy & tolerability of oral montelukast & nasal azelastine and to compare their effect on eosinophil count in patients of allergic rhinitis from Sept 2009 to 2011 with follow up upto 6 weeks. Total 100 patients with allergic rhinitis were enrolled in two categories, A (n=50) & B (n= 50) Both drugs were found to be highly effective & safe in treatment of allergic rhinitis as well as equally efficacious in reducing rhinorrhea. However, azelastine was found to be more effective for sneezing & nasal congestion, more efficacious in the first 3 weeks of treatment and better than montelukast for reduction of ABEC. Montelukast was found in my study to be a better drug for treatment of symptom of itchy nose. However, sedation was noted with montelukast which needs further evaluation. All in all in the present study, Azelastine unequivocally came out as the effective & safe drug in treatment of allergic rhinitis for the first 3 weeks while Montelukast can be added for patients with symptoms of itchy nose in allergic rhinitis. Montelukast stands out as the more efficacious and safe drug for later weeks of treatment of allergic rhinitis. In view of these results Azelastine is recommended for the acute treatment of allergic rhinitis and Montelukast for the late phase of treatment of allergic rhinitis.

**Keywords:** Absolute blood eosinophil count ( ABEC ), Allergic rhinitis

### I. Introduction:-

“Spring is in the air at last!”

Most of us look forward to the end of the cold dark winter months and all the delights of the spring season, but for the patients of allergic rhinitis, it is the worst time of the year.

Rhinitis is defined as inflammation of the nasal mucosa and is characterized by symptoms of congestion, rhinorrhoea, itching of the nose, postnasal drip, and sneezing. Rhinitis can be divided broadly into following major categories:

Allergic, Nonallergic and Infective.<sup>1,2</sup>

Allergic rhinitis, which is best, defined as that adverse pathophysiological response of the nose and adjacent organs that result from the interaction of allergen with antibody in a host sensitized by previous exposure to that allergen.<sup>3,4</sup> Allergic rhinitis is the most common atopic disorder affecting large number of adults worldwide.<sup>2,4,5,6</sup> Estimates of the prevalence of the allergic rhinitis in different countries vary from 0.5% to 28.0%.<sup>3,7</sup> The high prevalence of allergic rhinitis and its effect on quality of life have led to its being classified as a major chronic respiratory disease.

Common manifestations of the allergic rhinitis include paroxysmal sneezing, nasal blockage, and watery nasal discharge. In clinical examination there may be pale or bluish boggy inferior turbinates with watery nasal discharge. The conjunctivae may be hyperaemic and oedematous.<sup>3,4</sup>

### AIMS & OBJECTIVES

1. To compare the efficacy of Oral Montelukast and Nasal Azelastine in patients of allergic rhinitis.
2. To compare the tolerability of Oral Montelukast and Nasal Azelastine in patients of allergic rhinitis.
3. To compare the effect of Oral Montelukast and Nasal Azelastine on eosinophil count in patients of allergic rhinitis.

### II. Material And Methods

This prospective clinical study was done in the Department of ENT, Pravara Rural Hospital, Loni. The Institutional ethical committee approval was obtained in August 2009 and then the study was carried out for a period of 2 years from September 2009 - 2011.

Patients were diagnosed and assessed by ENT surgeons with allergic rhinitis disease were enrolled for the study according to the following inclusion and exclusion criteria. Written informed consent was taken from each patient.

**INCLUSION CRITERIA:**

1. Patients ready to give informed consent.
2. Patients 6 years and above.
3. Patients of either sex.
4. Patients of all types of allergic rhinitis, seasonal as well as perennial

**EXCLUSION CRITERIA:**

1. Patients not ready to give informed consent.
2. Patients below the age of 6 years.
3. Patients who were hypersensitive to drug.
4. Patients of infectious rhinitis.
5. Patients having any chronic illness like diabetes, hypertension etc.
6. Patients on any other medication.
7. Patients not following the protocol.

**STUDY CONDUCT**

This is a prospective, open, active treatment controlled, comparative study with follow-up up to 6 weeks. Total of 100 patients with allergic rhinitis of any cause and type, having typical symptoms such as sneezing, nasal congestion, nasal itching, and rhinorrhea & with a history of exposure to allergen were enrolled. Enrolled patients were categorized into 2 groups:

**Group A:** Patients between age of 6-14 years received Montelukast tablet 5 mg at bed time and patients aged 15 years and above received Montelukast tablet 10 mg at bed time.<sup>8</sup>

**Group B:** Patients between age group of 6-11 years received one puff of Azelastine 0.14 mg in each nostril twice daily and patients aged 12 years and above received two puffs of Azelastine in each nostril twice daily.<sup>9, 10</sup>

- During the treatment and follow up the efficacy was assessed by using TNSS scale and tolerability by MTTES scale weekly for a period of 6 weeks scores for the following symptoms of TNSS and MTTES were recorded from 0 to 3.

**TOTAL NASAL SYMPTOM SCORE (TNSS):**

Under TNSS scale following symptoms :

- a. Rhinorrhea, Sneezing, Itchy nose, Nasal congestion were assessed and scores were recorded from 0-3 (absent-severe)<sup>4,10,11,12,13</sup>

Scores	Definitions	Symptoms For
0	Absent Symptom is not present	•Rhinorrhea. •Sneezing. •Itchy nose. Nasal congestion.
1	Mild Symptom is present but is not annoying or troublesome	
2	Moderate Symptom is frequently troublesome but would not interfere with normal daily activity or sleep	
3	Severe Symptom is sufficiently troublesome to interfere with normal	

**MODIFIED TREATMENT TOLERABILITY EVALUATION SCORE (MTTES):**

Under MTTES scale following symptoms :

- a. Vomiting, dislikeness for meals, daytime sleep and additional medication were assessed and scores were recorded from 0-3 (absent-severe)<sup>4,10,11,12,13</sup>

SCORES	Definitions	SYMPTOMS FOR MTTES
0	Absent Symptom is not present	Vomiting.
1	Mild Symptom is present but is not annoying or troublesome	Dislikeness for meals
2	Moderate Symptom is frequently troublesome but would not interfere with normal daily activity or sleep	Day Time Sleeping
3	Severe Symptom is sufficiently troublesome to interfere with normal daily activity or sleep	Additional Medication

The primary efficacy and tolerability end points were change from baseline in the total nasal symptom score (TNSS) and modified treatment tolerability evaluation score (MTTES) respectively. The data was pooled and observations were recorded. I

The effect of Montelukast and Azelastine on Absolute Eosinophil count in blood was recorded at 0 and 6 weeks in both the groups.

**Absolute Eosinophil count**

- 0 weeks : Before the start of the therapy (first Visit)
- 6 week : After the completion of therapy (last Visit)

**SAMPLE SIZE:**

- 50 patients were included in each group according to inclusion and exclusion criteria.
- Total sample size: 100 patients of allergic rhinitis STUDY PERIOD:
- Two years starting from the date of approval of the study. Institutional Ethical approval August 2009 (vide letter no PMT/RMC/RC/80/2009)

**STATISTICAL ANALYSIS:**

The data was collected and subjected to statistical analyses by applying "Z" test of significance and based on these results the conclusions were drawn

**OBSERVATIONS**

TABLE NO.1

Age and Sex wise distribution of the patients of Allergic Rhinitis under Study

**Graph la**

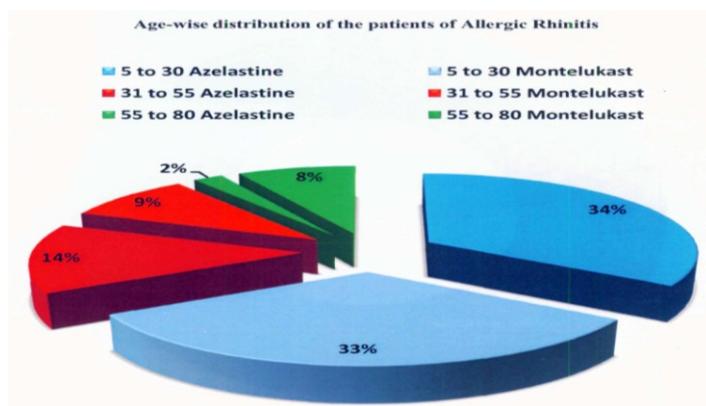
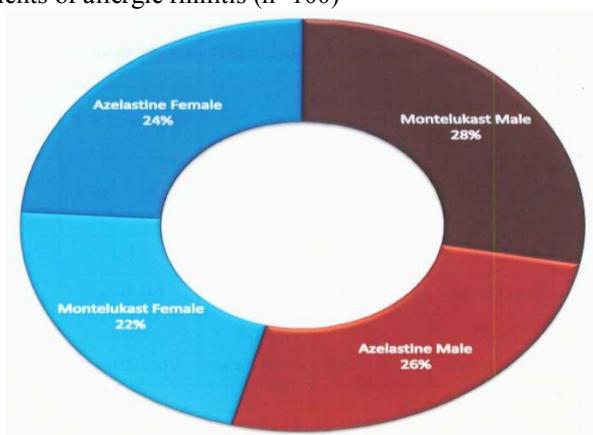


TABLE NO.1:

Age and Sex wise distribution of the patients of Allergic Rhinitis under study

**Graphlb**

Sex-wise distribution of patients of allergic rhinitis (n=100)



**Table no.2:**

Mean baseline Total nasal symptom scores (TNSS) of patients of allergic rhinitis

Mean individual nasal symptom scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week:

Week	Group	Rhinorrhea	Sneezing	Itchy	Nasal	TNSS
0	Montelukast	2.32	2.42	2.3	2.6	9.64
	Azelastine	2.46	2.38	2.44	2.52	9.80

1	Montelukast	2.16	2.28	2.08	2.48	9.00
	Azelastine	2.2	1.7	2.32	1.98	8.20
2	Montelukast	1.98	2.12	1.84	2.42	8.36
	Azelastine	1.88	1.46	2.18	1.68	7.20
3	Montelukast	1.44	1.78	1.82	2.18	7.22
	Azelastine	1.52	1.22	2.08	1.48	6.30
4	Montelukast	1.16	1.46	1.66	1.88	6.16
	Azelastine	1.8	1.04	1.94	1.22	5.28
5	Montelukast	0.8	1.18	1.42	1.54	4.94
	Azelastine	0.9	0.86	1.8	1.08	4.64
6	Montelukast	0.54	0.88	1.08	1.3	3.80
	Azelastine	0.66	0.62	1.6	0.82	3.70

Graph no.2

Mean baseline Total nasal symptom scores (TNSS) of patients of Allergic Rhinitis

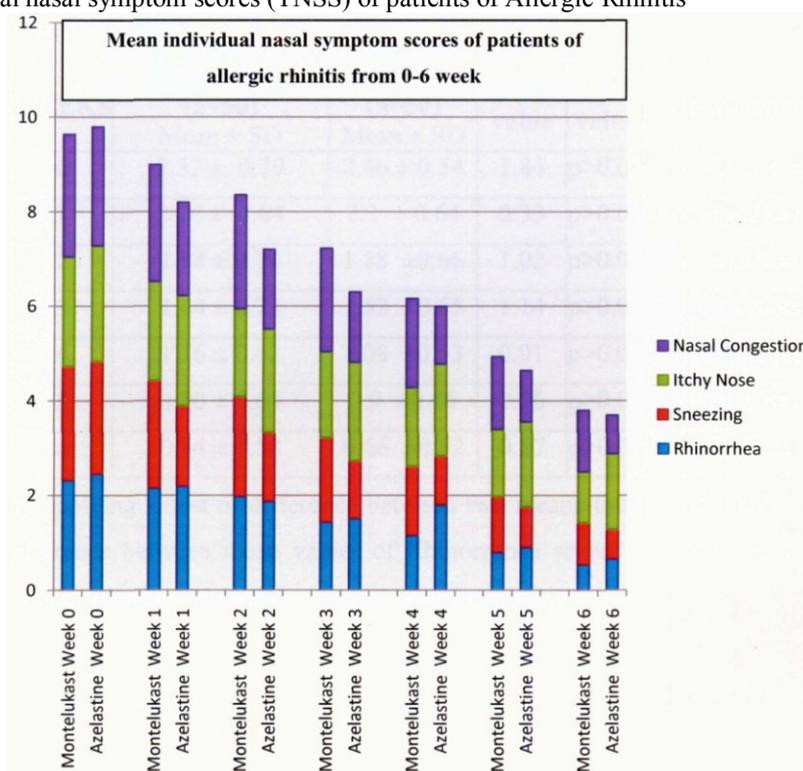


Table no.3:

Comparison of mean baseline Individual symptomscores of patients of Allergic Rhinitis

Table 3a:

The comparison of mean baseline Rhinorrhoea scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week

WEEKS	Montelukast (n=50)	Azelastine (n=50)	Ztest value	'P' value	Significance
0	2.32 ± 0.79	2.46 ± 0.54	1.84	p>0.05	Not
1	2.16 ± 0.84	2.2 ± 0.64	0.33	p>0.05	Not
2	1.98 ± 0.74	1.88 ± 0.66	1.02	p>0.05	Not
3	1.44 ± 0.73	1.52 ± 0.65	1.14	p>0.05	Not
4	1.16 ± 0.62	1.08 ± 0.53	0.91	p>0.05	Not
5	0.80 ± 0.64	0.9 ± 0.46	0.56	p>0.05	Not
6	0.54 ± 0.58	0.66 ± 0.52	0.87	p>0.05	Not

By applying Z test of difference between two means there is no significant difference between mean values of Rhinorrhoea scores (i.e. p>0.05) at 0-6weeks between Montelukast and Azelastine group.

Graph 3a

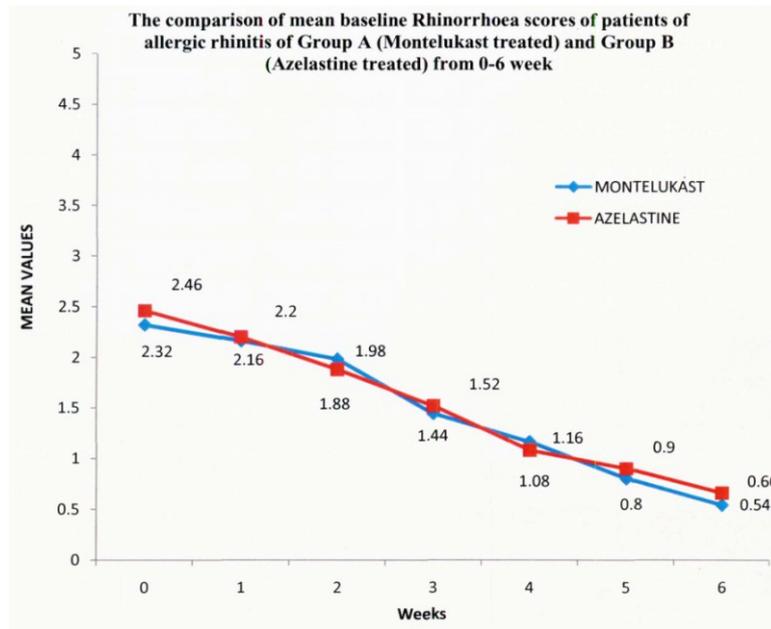


Table 3b:

The comparison of mean baseline Sneezing scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week

WEEKS	Montelukast (n=50)	Azelastine (n=50)	Ztest value	'P' value	Significance
0	2.42 ±0.54	2.38 ±0.49	0.329	p>0.05	Not significant
1	2.28 ±0.50	1.70 ±0.61	5.22	P<0.01	Highly
2	2.12 ±0.52	1.46 ±0.58	6.0	P<0.01	Highly
3	1.78 ±0.50	1.22 ±0.58	8.0	P<0.01	Highly
4	1.46 ±0.60	1.04 ±0.49	3.92	P<0.01	Highly
5	1.18 ±0.44	0.86 ±0.40	3.81	P<0.01	Highly
6	0.88 ±0.48	0.62 ±0.53	2.57	P<0.01	Highly

By applying Z test of difference between two means there is highly significant difference between mean baseline Sneezing scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 1-6 week (pO.O1)

Graph 3b

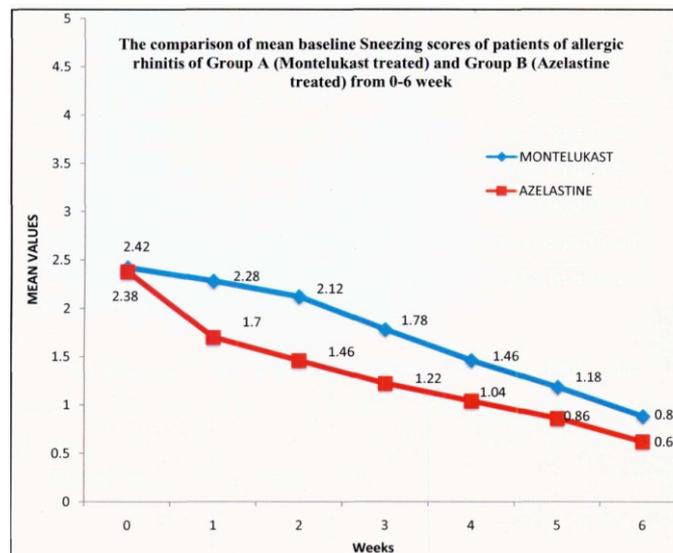


Table 3c

The comparison of mean baseline Itchy nose scores rhinitis of Group A (Montelukast treated) and Group from 0-6 week of patients of allergic B (Azelastine treated)

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	'P' value	Significance
0	2.30 ±0.50	2.44 ±0.50	1.4	p>0.05	Not significant
1	2.08 ±0.49	2.32 ±0.47	2.5	p<0.01	Highly
2	1.84 ±0.42	2.18 ±0.52	3.54	p<0.01	Highly
3	1.82 ±0.52	2.08 ±0.44	4.33	p<0.01	Highly
4	1.66 ±0.52	1.94 ±0.42	2.98	p<0.01	Highly
5	1.42 ±0.50	1.80 ±0.40	4.27	p<0.01	Highly
6	1.08 ±0.49	1.60 ±0.49	5.31	p<0.01	Highly

By applying 'Z' test of difference between two means there is highly significant difference between mean baseline Itchy nose scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 1-6 week (pO.OI)

Graph 3c

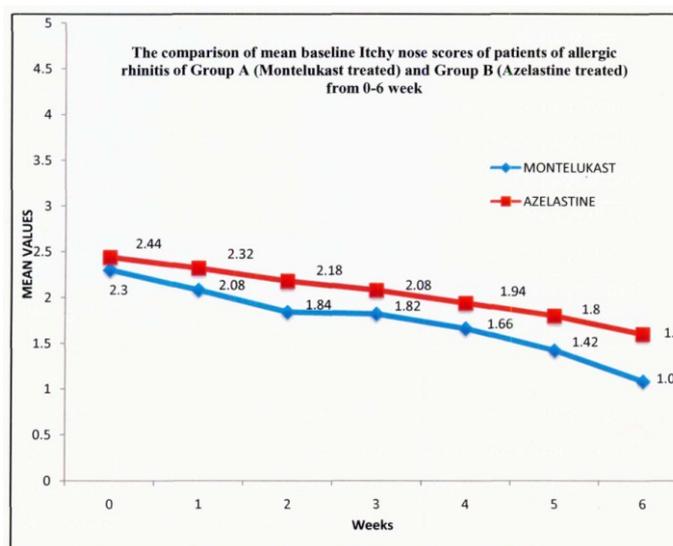


Table 3d:

The comparison of mean baseline Nasal congestion scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	'P' value	Significance
0	2.60 ±0.50	2.52 ±0.50	1.52	p<0.01	Not significant
1	2.48 ±0.50	1.98 ±0.59	6.02	p<0.01	Highly
2	2.42 ±0.54	1.68 ±0.55	6.85	p<0.01	Highly
3	2.18 ±0.52	1.48 ±0.50	6.86	p<0.01	Highly
4	1.88 ±0.43	1.22 ±0.42	7.76	p<0.01	Highly
5	1.54 ±0.50	1.08 ±0.39	5.13	p<0.01	Highly
6	1.30 ±0.46	0.82 ±0.44	8.36	p<0.01	Highly

By applying 'Z' test of difference between two means there is highly significant difference between mean baseline nasal congestion scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 1-6 week (p<0.01)

Graph 3d :

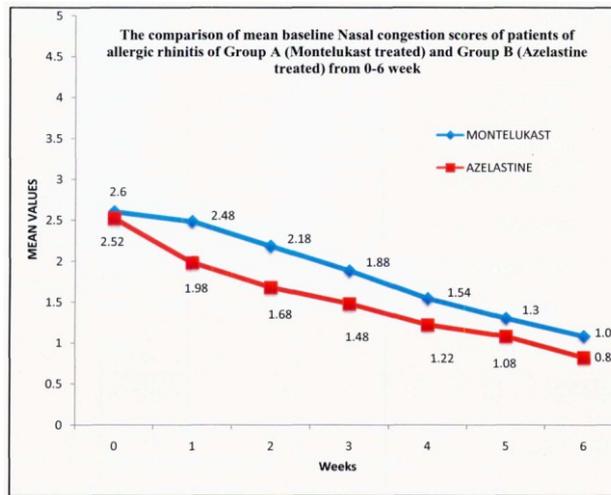


Table 3e:

The comparison of mean baseline TNSS scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week

WEEKS	Montelukast (n=50)	Azelastine (n=50)	Ztest	'P'	Significance
0	9.64 ± 1.73	9.80 ± 1.51	0.2	p>0.05	Not significant
1	9.00 ± 1.79	8.20 ± 1.28	2.57	p<0.01	Highly
2	8.36 ± 1.69	7.20 ± 1.30	6.26	p<0.01	Highly
3	7.22 ± 1.68	6.30 ± 1.01	3.32	p<0.01	Highly
4	6.16 ± 1.50	5.28 ± 1.03	3.42	p<0.01	Highly
5	4.94 ± 1.48	4.64 ± 0.80	1.26	p<0.01	Highly
6	3.80 ± 1.37	3.70 ± 1.03	5.31	p<0.01	Highly

By applying 'Z' test of difference between two means there is highly significant difference between mean TNSS of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 1-6 week(p<0.01)

Graph 3e:

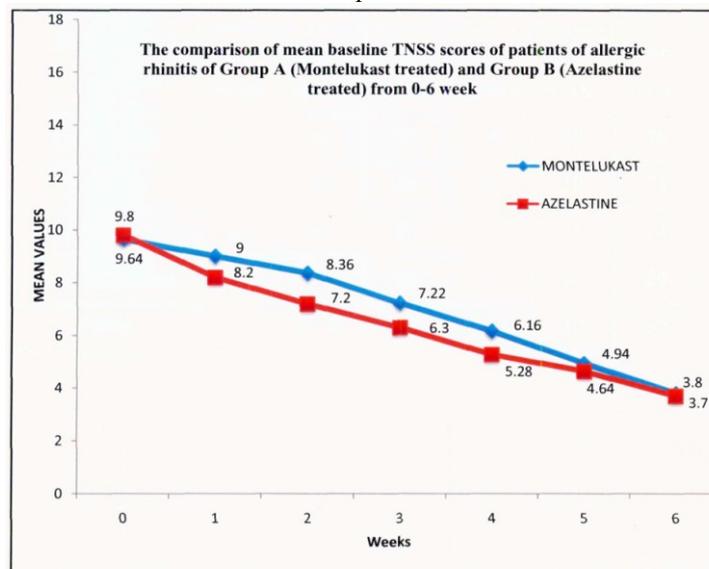


Table 3f:

Comparison of percent change in mean baseline Individual symptomand TNSS scores of patients of Allergic Rhinitis from 0-3, 3-6 and 0-6 weeks

Symptom Parameter	Percentage (%) Change					
	Montelukast (n=50)			Azelastine(n=50)		
	0-3 weeks	3-6 weeks	0-6 weeks	0-3 weeks	3-6 weeks	0-6 weeks
Rhinorrhoea	38	63	77	38	57	76
Sneezing	27	51	64	49	50	74
Itchy nose	21	41	53	15	23	34
Nasal congestion	16	31	50	36	45	67
TNSS	25	47.36	60	35	42	62

Table no.4:

Comparison of mean Absolute Eosinophil count at 0 and 6 weeks of Group A (Montelukast treated) and Group B (Azelastine treated) patients of Allergic Rhinitis

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	'P' value	Significance
0	7.90 ±0.95	7.70 ±1.43	0.83	p<0.05	Not significant
6	4.60 ± 0.97	3.12 ±0.77	8.46	p<0.01	Highly significant

By applying Z test of difference between two sample means there is no significant difference between mean values of absolute eosinophil count at 0 week in group A and group B (i.e.p>0.05) and there is highly significant difference between mean values of absolute eosinophil count at 6 week in group A and group B (i.e. p <0.01)

Graph no 4

Comparison of mean Absolute Eosinophil count at 0 and 6 weeks of Group A (Montelukast treated) and Group B (Azelastine treated) patients of Allergic

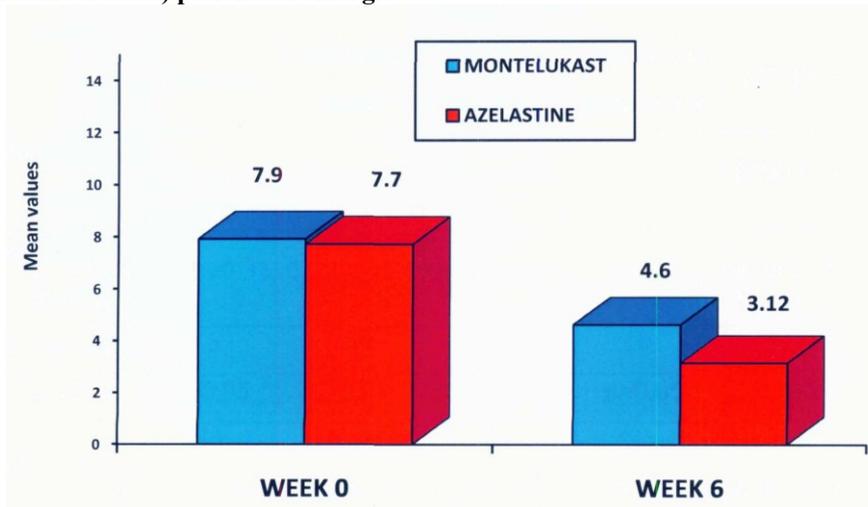


Table no.6:

Comparison of mean baseline Individual tolerabilityscores of patients of Allergic Rhinitis

Table 6a:

The comparison of mean baseline tolerability Vomiting scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week:

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	value	Significance
0	0.16 ±0.37	0.12 ±0.33	0.57	p>0.05	Not significant
1	0.18 ±0.39	0.12 ±0.33	13	p>0.05	Not significant
2	0.22±0.42	0.14±0.35	1.03	p>0.05	Not significant
3	0.24±0.43	0.14±0.35	1.28	p>0.05	Not significant
4	0.18 ±0.39	0.10±0.30	1.91	p>0.05	Not significant
5	0.14±0.35	0.08 ±0.27	1.58	p>0.05	Not significant
6	0.14±0.35	0.08 ±0.26	1.58	p>0.05	Not significant

By applying Z test of difference between two means there is no significant difference between mean values of Vomiting scores (i.e.  $p > 0.05$ ) at 0-5 weeks between Montelukast and Azelastine group.

Graph 6a

The comparison of mean baseline tolerability vomiting scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week

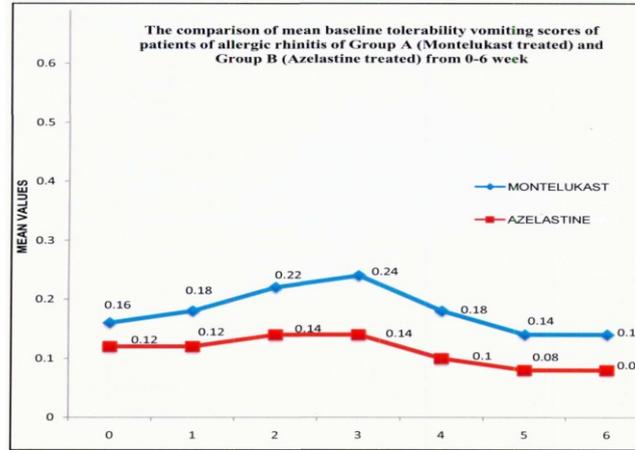


Table 6b:

The comparison of mean baseline tolerability **Dislikeness meal** scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week:

WEEKS	Montelukast (n=50) Mean $\pm$ SD	Azelastine (n=50) Mean $\pm$ SD	Ztest value	value	Significance
0	0.08 $\pm$ 0.27	0.06 $\pm$ 0.24	0.59	$p > 0.05$	Not significant
1	0.16 $\pm$ 0.37	0.2 $\pm$ 0.45	0.63	$p > 0.05$	Not significant
2	0.16 $\pm$ 0.37	0.22 $\pm$ 0.46	0.52	$p > 0.05$	Not significant
3	0.18 $\pm$ 0.39	0.22 $\pm$ 0.42	0.67	$p > 0.05$	Not significant
4	0.14 $\pm$ 0.35	0.18 $\pm$ 0.39	0.73	$p > 0.05$	Not significant
5	0.10 $\pm$ 0.30	0.14 $\pm$ 0.35	0.82	$p > 0.05$	Not significant
6	0.06 $\pm$ 0.24	0.10 $\pm$ 0.30	0.74	$p > 0.05$	Not significant

By applying Z test of difference between two means there is no significant difference between mean values of Dislikeness meal scores (i.e.  $p > 0.05$ ) at 0-6 weeks between Montelukast and Azelastine group

Graph 6b

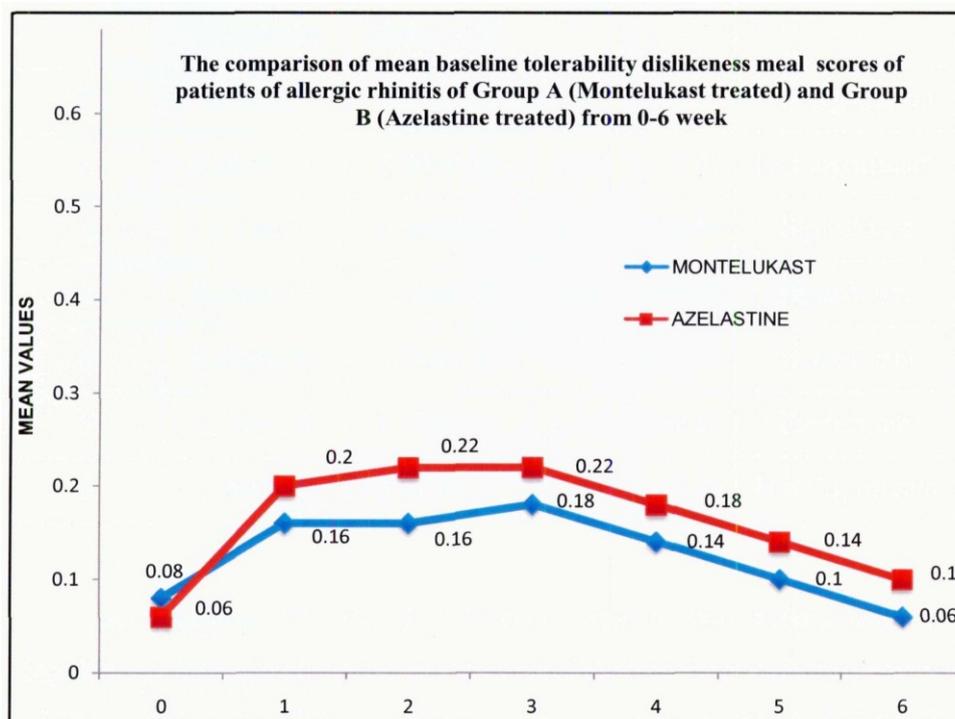


Table 6c:

The comparison of mean baseline tolerability Day time sleeping scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week:

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	P value	Significance
0	0.04±0.2	0.08±0.27	0.51	p>0.05	Not
1	0.08±0.27	0.06±0.24	0.56	p>0.05	Not
2	0.1±0.3	0.04±0.20	2.14	p<0.05	Significant
3	0.12±0.33	0.04±0.20	2.86	p<0.05	Significant
4	0.14±0.35	0.04±0.20	3.57	p<0.05	Significant
5	0.10±0.30	0.02±0.14	4.21	p<0.05	Significant
6	0.08±0.27	0.02±0.14	1.39	p>0.05	Not

By applying 'Z' test of difference between two means there is Significant difference between mean tolerability Day time sleeping scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 2-5 week (p<0.05). There is no significant difference in mean tolerability Day time sleeping scores at 0, 1 and 6 weeks.

Graph 6c

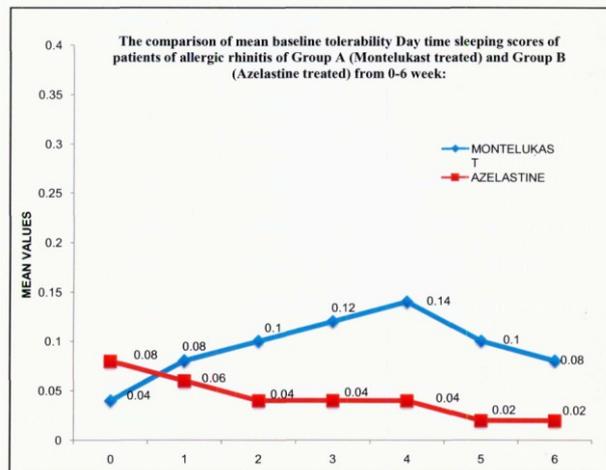


Table 6d:

The comparison of mean baseline tolerability Additional medication scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week:

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	p value	Significance
0	0±0	0±0	0	p>0.05	Not significant
1	0±0	0.02±0.14	0.1	p>0.05	Not significant
2	0±0	0.04±0.2	1.42	p>0.05	Not significant
3	0.02±0.14	0.04±0.2	0.54	p>0.05	Not significant
4	0.04±0.2	0.06±0.24	0.4	p>0.05	Not significant
5	0.06±0.24	0.06±0.24	0	p>0.05	Not significant
6	0.06±0.31	0.06±0.24	0	p>0.05	Not significant

By applying Z test of difference between two means there is no significant difference between mean values of Additional medication scores (i.e. p>0.05) at 0-6weeks between Montelukast and Azelastine group

Graph 6d

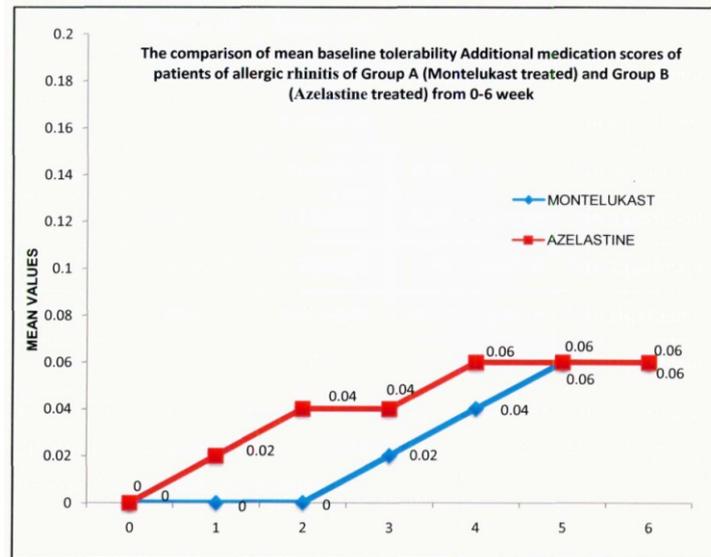


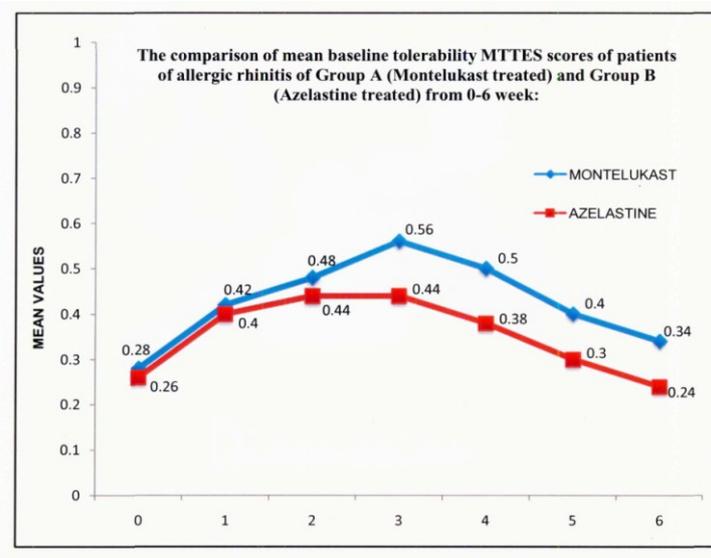
Table 6e:

The comparison of mean baseline tolerability MTES scores of patients of allergic rhinitis of Group A (Montelukast treated) and Group B (Azelastine treated) from 0-6 week:

WEEKS	Montelukast (n=50) Mean ± SD	Azelastine (n=50) Mean ± SD	Ztest value	P value	Significance
0	0.28±0.5	0.26±0.49	0.49	p>0.05	Not significant
1	0.42±0.61	0.40±0.67	0.12	p>0.05	Not significant
2	0.48±0.65	0.44±0.7	0.98	p>0.05	Not significant
3	0.56±0.73	0.44±0.61	0.47	p>0.05	Not significant
4	0.50±0.70	0.38±0.57	1.48	p>0.05	Not significant
5	0.40±0.64	0.30±0.46	0.12	p>0.05	Not significant
6	0.34±0.66	0.24±0.43	0.13	p>0.05	Not significant

By applying Z test of difference between two means there is no significant difference between mean values of MTES scores (i.e. p>0.05) at 0-6weeks between Montelukast and Azelastine group.

Graph 6e



### III. Discussion

In the present study total of 100 patients with allergic rhinitis (n=100) of any cause and type, having typical symptoms such as sneezing, nasal congestion, nasal itching, and rhinorrhea, & with a history of exposure to allergen were enrolled.

The mean Sneezing scores were reduced from baseline  $2.42 \pm 0.54$  at 0 weeks to  $0.88 \pm 0.48$  (64%) at 6 weeks with Montelukast whereas with Azelastine treated patients the mean score was reduced from  $2.38 \pm 0.49$  at 0 week to  $0.62 \pm 0.53$  at 6 weeks (74%)

The mean itchy nose scores were reduced from baseline  $2.30 \pm 0.50$  at 0 weeks to  $0.08 \pm 0.49$  (53%) at 6 weeks with Montelukast whereas with Azelastine treated patients the mean score was reduced from  $2.44 \pm 0.50$  at 0 week to  $1.60 \pm 0.53$  (34%) at 6 weeks.

The mean nasal congestionscores were reduced from baseline  $2.60 \pm 0.50$  at 0 weeks to  $1.30 \pm 0.46$  (50%) at 6 weeks with Montelukast whereas with Azelastine treated patients the mean score was reduced from  $2.52 \pm 0.50$  at 0 week to  $0.82 \pm 0.44$  (65%) at 6 weeks.

The mean baseline TNSS with Montelukast were reduced from baseline  $9.64 \pm 1.73$  at 0 weeks to  $3.80 \pm 1.37$  at 6 weeks (60%) whereas with Azelastine treated patients the mean score was reduced from  $9.80 \pm 1.51$  at 0 week to  $3.70 \pm 1.03$  at 6 weeks (62%)

The inter weekly comparison of reduction in TNSS with Azelastine (35%) was greater than Montelukast (25%) in 0-3 weeks whereas in 3-6 week reduction in TNSS was found more with Montelukast (48%) than with Azelastine (42%).

The mean absolute eosinophil count in Group A (Montelukast treated) was  $7.90 \pm 0.95$  and in Group B (Azelastine treated) was  $7.70 \pm 1.43$  suggestive of Absolute Eosinophilia. On Comparison of mean Absolute Eosinophil count at 0 weeks of Group A (Montelukast treated) and Group B (Azelastine treated) patients of Allergic Rhinitis there was no significant difference between mean values of absolute eosinophil count in group A and group B (i.e.  $p > 0.05$ )

At 6 week both the drugs decreased eosinophil count and it was reduced to  $4.60 \pm 0.97$  with Group A (Montelukast treated) and  $3.12 \pm 0.77$  in Group B (Azelastine treated). Thus on comparison there was highly significant (i.e.  $p < 0.01$ ) decrease in absolute eosinophil count in Azelastine treated patients of Allergic Rhinitis

Azelastine was better drug in the first 3 weeks for TNSS than Montelukast. The reduction in TNSS in 3-6 weeks was more with Montelukast than Azelastine. The overall improvement in TNSS from 0-6 week was equal in both Montelukast and Azelastine

It can be very well concluded that Azelastine proved to be more efficacious than Montelukast in 1-3 week. This is accord with the various studies revealing that Azelastine is a nasally administered second generation antihistamine that has been shown to be effective for the treatment of seasonal and perennial allergic rhinitis. It has following advantages in allergic rhinitis:<sup>14</sup>

### IV. Summary And Conclusions

This study was undertaken primarily to find out which agent amongst Montelukast and Azelastine is better in the context of efficacy and tolerability in patients suffering from allergic rhinitis by assessing various parameters.

The study can be very well summarized and concluded as follows:

1. Azelastine and Montelukast, both the drugs are highly effective and safe in the treatment of allergic rhinitis.
2. Azelastine and Montelukast are equally efficacious in reducing Rhinorrhea in allergic rhinitis.
3. Azelastine is more effective for sneezing and nasal congestion than Montelukast in allergic rhinitis.
4. Montelukast is better drug for the treatment of symptom of itchy nose in allergic rhinitis.
5. Azelastine seems more efficacious than Montelukast in the first 3 weeks of treatment.
6. Montelukast seems better alternative in the later weeks (after 3<sup>rd</sup> week) in the treatment of allergic Rhinitis.
7. Both the drugs decreased eosinophil count but Azelastine was better out of the two for reduction of absolute eosinophil count.
8. Montelukast and Azelastine, both the drugs are well tolerated.
9. Few incidences of Sedation are noted with Montelukast which needs to be evaluated further.

All in all in the present study, Azelastine unequivocally came out as the effective and safe drug in the treatment of Allergic rhinitis for the first 3 weeks while Montelukast can be added for patients with symptom of severe itchy nose in allergic rhinitis. Montelukast stands out as the more efficacious and safe drug for later weeks of treatment of allergic rhinitis.

In view of these results Azelastine is recommended for the acute treatment of Allergic rhinitis and Montelukast for the late phase of treatment of Allergic rhinitis.

### References

- [1]. G. K. Scadding et al. BSACI guidelines for the management of allergic and non-allergic rhinitis. *Clinical and Experimental Allergy* 2008; 38: 19-42.
- [2]. Jayant M Pinto and Seema Jeswani. Rhinitis in the geriatric population. *Allergy, Asthma & Clinical Immunology* 2010; 6:10.
- [3]. Anand Ghimire et al. Comparative efficacy of steroid nasal spray versus antihistamine nasal spray in allergic rhinitis. *Nepal Medical College Journal* 2007; 9(1):4-7.
- [4]. Michael Benninger et al. Evaluating approved medications to treat allergic rhinitis in the United States. An evidence-based review of efficacy for nasal symptoms by class. *Ann Allergy Asthma Immunol.* 2010; 104:13-29.
- [5]. Vipin Gupta and Prithpal Singh Matreja. Efficacy of Montelukast and Levocetirizine as treatment for Allergic Rhinitis. *J Aller Ther an open access journal* Volume 1. Issue 1:16-28.
- [6]. M. Kurowski et al. Montelukast plus cetirizine in the prophylactic treatment of seasonal allergic rhinitis, influence on clinical symptoms and nasal allergic inflammation. *Allergy* 2004;59: 280-288
- [7]. William storms et al. Allergic rhinitis induced nasal congestion: its impact on sleep quality. *Primary Care Respiratory Journal* (2008); 17.
- [8]. Merck and co. highlights of prescribing information - Singulair: Revised: April 2011:3-21
- [9]. Merck and co. highlights of prescribing information - ASTEPRO: Revised; July 2011:36-56.
- [10]. Shailen shah et al. Efficacy and safety of azelastine 0.15% nasal spray and azelastine 0.10% nasal spray in patients with SAR. *Allergy Asthma proc* 2009 ; 30 : 628 -633
- [11]. Dr Martin A Stern et al. Nasal budesonide offers superior symptom relief in perennial allergic rhinitis in comparison to nasal azelastine. *Ann Allergy Asthma Immunol* 1998; 81:354-358.
- [12]. Bikash Medhi. Efficacy of Fexofenadine in the Indian Population suffering from Allergic Rhinitis & Chronic Urticaria. *JK science*: April-June 2006; Vol. 8 No. 2: 83-85.
- [13]. Ralph Mosges et al. Efficacy and tolerability of levocabastine and azelastine nasal sprays for the treatment of allergic rhinitis, *Mediators of Inflammation* .1995; vol 4: S11-S15.
- [14]. Wu AY et al. Anti-inflammatory effects of high-dose Montelukast in an animal model of acute asthma. *Clin Exp Allergy* 2003; 33:359- 366.