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COMPARITIVE STUDIES ON UTILIZATION OF MONTELUKAST BILASTINE VS MONTELUKAST LEVOCETIRIZINE IN A TERITARY CARE HOSPITAL – AN AMBI DIRECTIONAL STUDY

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ABSTRACT

Background: Antihistamines and leuckotriene receptors antagonist layout the foundation of pharmacological management while compilations such as montelukast with levocetrizine are used widely, newer combinations like montelukast with bilastine are obtaining focus because of the capability for safety and tolerability however evaluating the comparitive data of safety and efficacy remain limited especially in real world clinical settings. Objective: To evaluate and compare safety efficacy of montelukast +levocetrizine V/S montelukast +bilastine in a hospital- based setting, Materials and methods: An ambi directional study was conducted about six months at the mallige hospital crescent road. A total of 200 sample sizes were taken to compare the efficacy and safety efficacy assessed based on laboratory parameters and safety was monitored through adverse drug reaction and drug interactions. Results: The results showed, Out of 200 patients 111(55.5%) were male and 89 were (44.5%) female out of which a mean age of 56 to 65 yrs indicated a bit higher progress of sedation for Montelukast Levocetirizine compared to Montelukast Bilastine. Conclusion: Both Montelukast Levocetrizine and Montelukast Bilastine showed better efficacy and safety in terms of reducing sedation and has a clinical advantage in long term management.

Keywords: Montelukast Bilastine, Montelukast Levocetirizine

INTRODUCTION

Allergic diseases are increasing world-wide with 20% to 30% of the population Allergic disease may consist of anaphylaxis, asthma, food allergy, eczema, urticaria, angioedema. This should be treated properly to avoid chronic life-long disease. The severity of the symptoms can be examined byIgE (immunoglobin E), serum AEC (absolute eosinophil count) levels **[1]**. Allergic rhinitis is the most common chronic disease and its characteristics management are nasal itching, sneezing, rhinorrhea and nasal obstruction **[2]**. Chronic urticaria causes itchy circular swellings which lasts for about 6 weeks. Prevalence of urticaria is approximately 0.5% to 1.0% in different population. The occurrence of wheals and pruritic are due to the activation of high affinity IgE receptor **[3]**. Antihistamines are used to treat allergic diseases. H1 antihistamines causes sedation by crossing the BBB because of this effect it is undesired causing concerns while driving a car or operating machines it affects daily activities. Non-sedating second-antihistamine provides symptomatic treatment and non-sedating properties at therapeutic doses **[4]**. Leukotriene receptor antagonist provides exclusive outcomes to treat inflammatory symptoms when combined with antihistamines, a broad symptomatic relief. This combination aims many inflammatory pathways for therapeutic effectiveness. Montelukast- Bilastine and Montelukast-Levocetirizine is compared while Bilastine a new generation antihistamine provides a promising effectiveness and safety profile **[5]**.

MATERIALS AND METHODS

We conclude this prospective, observational, comparative study was carried out over a period of six months in the Department of Pulmonology/Allergy at Mallige Hospital, a tertiary care center, following approval from the Institutional Ethics Committee. A total of 200 patients aged 18 years or older, of either gender, diagnosed with asthma or allergic rhinitis/urticaria and requiring treatment with montelukast in combination with either levocetirizine or bilastine, were included after obtaining written informed consent. The patients were ran7domly allocated into two groups of 100 each: Group A (ML), who received montelukast with levocetirizine, and Group B (MB), who received montelukast with bilastine. Patients who were pregnant or lactating, on concomitant medications known to interact with levocetirizine or bilastine (such as strong CYP3A4 inhibitors or QT-prolonging agents), or with severe comorbidities including renal or hepatic impairment and uncontrolled cardiovascular

disease, as well as those with known hypersensitivity to study drugs **[6]**, were excluded. Data were recorded in a pretested case record form (CRF), which captured demographic details (age, sex, occupation, and medical history), clinical profile and diagnosis, treatment details (drug dosage, frequency, and duration), laboratory investigations (complete blood count, liver and renal function tests, and serum IgE wherever available), adverse drug reactions (ADRs) assessed by WHO causality assessment and Hartwig's severity scale, and potential drug–drug interactions identified through Lexicomp and Micromedex databases. The primary outcome was to compare the safety and efficacy of montelukast + levocetirizine versus montelukast + bilastine, while secondary outcomes included identifying the most commonly prescribed combinations, evaluating the incidence and severity of ADRs, and detecting clinically relevant drug–drug interactions **[7]**. Efficacy was assessed using validated scales including the Total Symptom Score (TSS) for allergic rhinitis and the Asthma Control Test (ACT) for asthma, along with patient-reported outcomes related to quality of life, sleep disturbance, and daytime productivity, whereas rationality of prescriptions was evaluated using WHO prescribing indicators **[8]**.

Statistical Analysis

Data entry was performed in Microsoft Excel and statistical analysis was carried out using SPSS software. Descriptive statistics such as mean, standard deviation, and percentages were used for demographic and baseline variables. Categorical variables including ADR incidence were analyzed using Chi-square test or Fisher's exact test, as appropriate.

RESULTS

A Total of 200 candidates were assessed to compare the safety and efficacy of Montelukast Levocetirizine Versus Montelukast Bilastine and Evaluated based on the Laboratory parameters and safety was observed through adverse drug reaction and drug interaction. Out of 200 Patients, 111 Male patients (55.5%) and 89 Female patients (44.5%) a slight increase in male preference is seen in **(Figure 1, Table 1)**. In Sex distribution maximum use is seen in males, Aged between 56–65 years (21.5%), then between 76–85 years (16%), and between 66–75 years (15.5%) **(Figure 2, 4; Table 2, 4)**.

HOSPITAL STAY

Fewer patients receiving Montelukast + Bilastine were admitted for shorter duration (1–2 days: 27.5%) compared to Montelukast

+ Levocetirizine (15.5%). It suggests relatively higher efficacy of Bilastine combination to reduce hospital stay **(Figure 3, Table 3)**.

EXPERIMENTAL DATA

PaO_2: Montelukast + Bilastine had more patients in normal (38%) and moderate (16%) ranges, whereas Levocetirizine was better in mild hypoxia (54%). Severe hypoxia (<40 mmHg) occurred only in Bilastine (3%) **[9] (Figure 5, Table 5)**.

IgE: Bilastine group contained higher patients having mild elevations (56%), while Levocetirizine contained higher patients having normal levels (12%) but higher in very high ranges (7%) **[10] (Figure 6, Table 6)**.

SpO_2: Bilastine covered wider severity intervals such as severe/critical cases while the levocetirizine group showed better normal/mild intervals (45%) **(Figure 7, Table 7)**.

Eosinophils: Levocetirizine had higher normal counts (35%), while Bilastine group showed higher number of patients in moderate/severe **(Figure 8, Table 8)**.

Lymphocytes: Levocetirizine was within stability (more in normal/mild range), whereas Bilastine patients were in low to severe range **(Figure 9, Table 9)**.

Basophils & ESR: Basophil and ESR levels of Levocetirizine were most consistent within normal range while Bilastine covered predominantly moderate to severe cases **(Figure 10, 11; Table 10, 11)**.

DRUGS INTERACTIONS

Montelukast + Bilastine showed fewer interactions (91% no interaction) compared with Levocetirizine (74%). Levocetirizine had notable interactions with hydroxyzine (7%) and carbamazepine (6%) **(Figure 12, Table 12)**.

NEGATIVE EFFECT

Montelukast + Bilastine: Most common was headache (26%) and dry mouth (18%). Interestingly, 38% stated no side effects **(Figure 13, Table 13)**.

Montelukast + Levocetirine: Most common side effect was sedation (45%), fewer patients (9%) without any side effects **(Figure 14, Table 14)**.

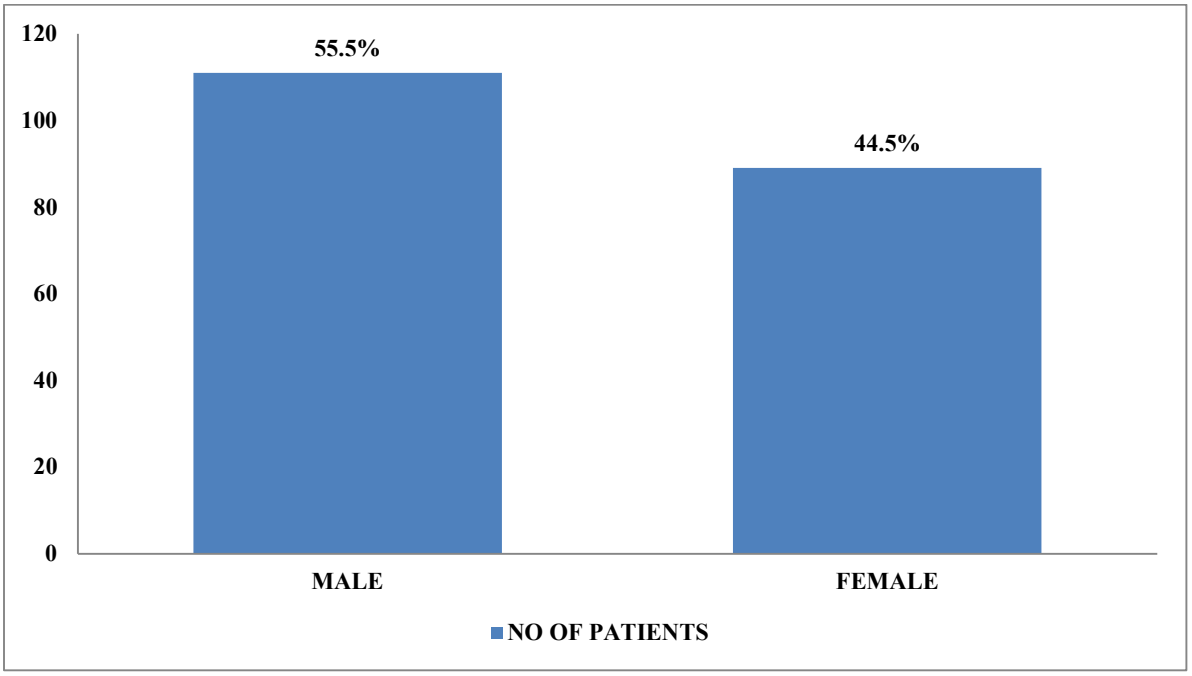


Figure 1: Percentage of Anti-histmine Prescribed based on Gender

Table 1: Anti-histamine Prescribed based on Gender

Gender	Number of patients	Percentage
Male	111	55.5%
Female	89	44.5%
TOTAL	200	100%

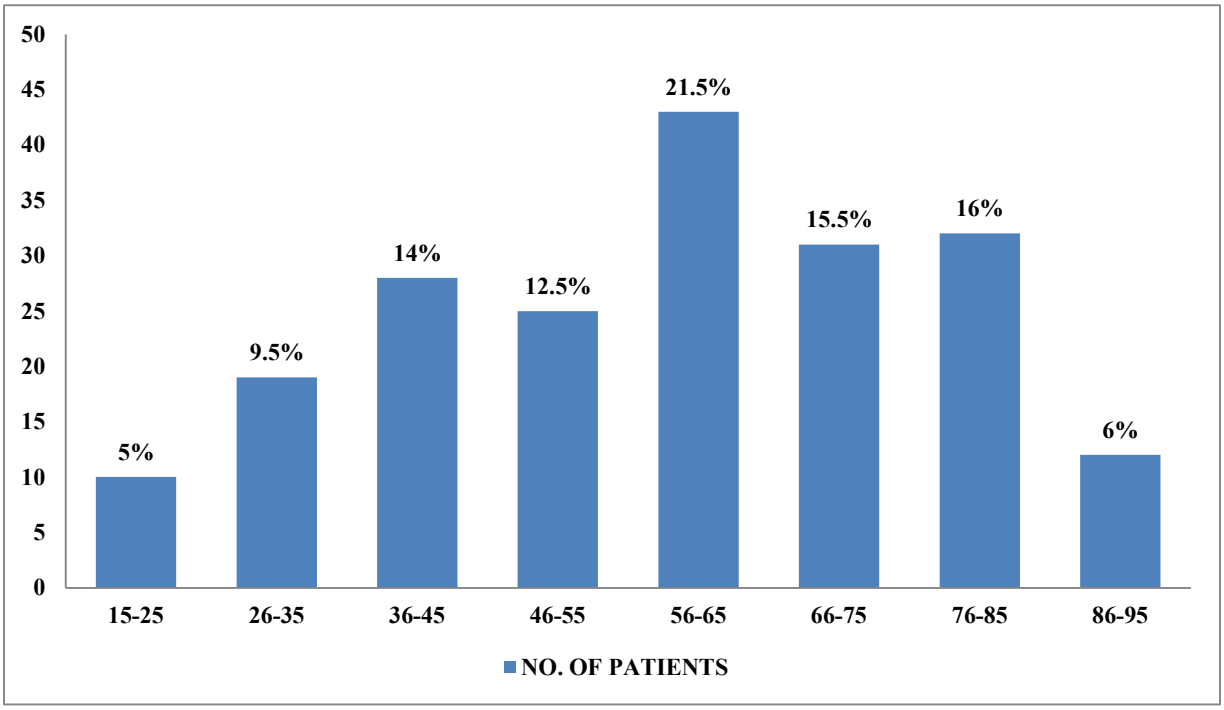


Figure 2: Number of Patients Based on Anti-histamine Prescribed based on Age of Patients in Years

Table 2: Anti-histamine Prescribed based on Age of Patients in Years

Age group	No. of Patients	Percentage
15-25 years	10	5 %
26-35 years	19	9.5 %
36-45 years	28	14 %
46-55 years	25	12.5%
56-65 years	43	21.5%
66-75 years	31	15.5%
76-85 years	32	16%
86-95 years	12	6%
TOTAL	200	100%

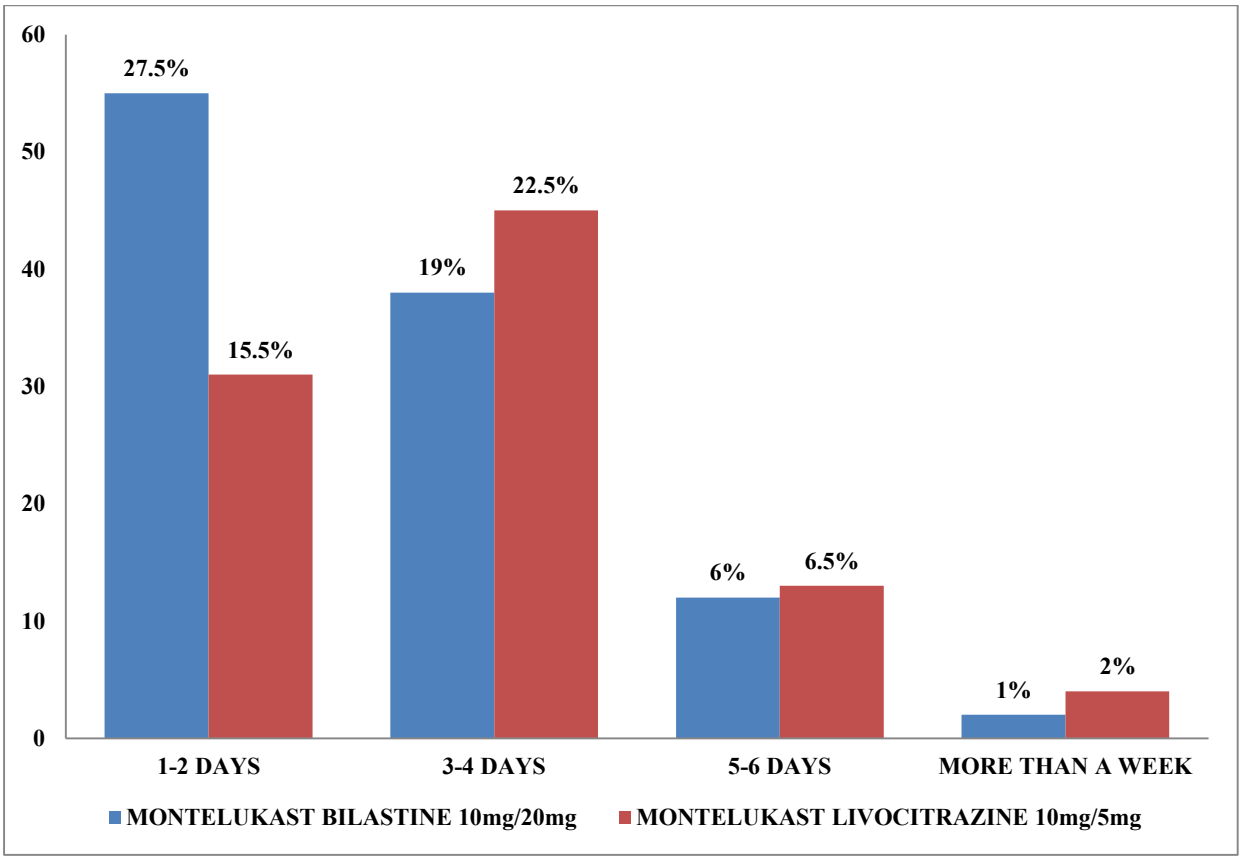


Figure 3: Number of Patients staying in Hospital based on Number of Days

Table 3: Percentage of Patients staying in Hospital based on Number of Days

Hospital Stay	No. of patients with Montelukast Bilastine	No. of patients with Montelukast Levocitrazine	Percentage of Montelukast Bilastine	Percentage of Montelukast Levocitrazine
1-2days	55	31	27.5%	15.5%
3-4days	38	45	19%	22.5%
5-6days	12	13	6%	6.5%
More than a week	2	4	1%	2%
TOTAL	100	100	53.5%	46.5%

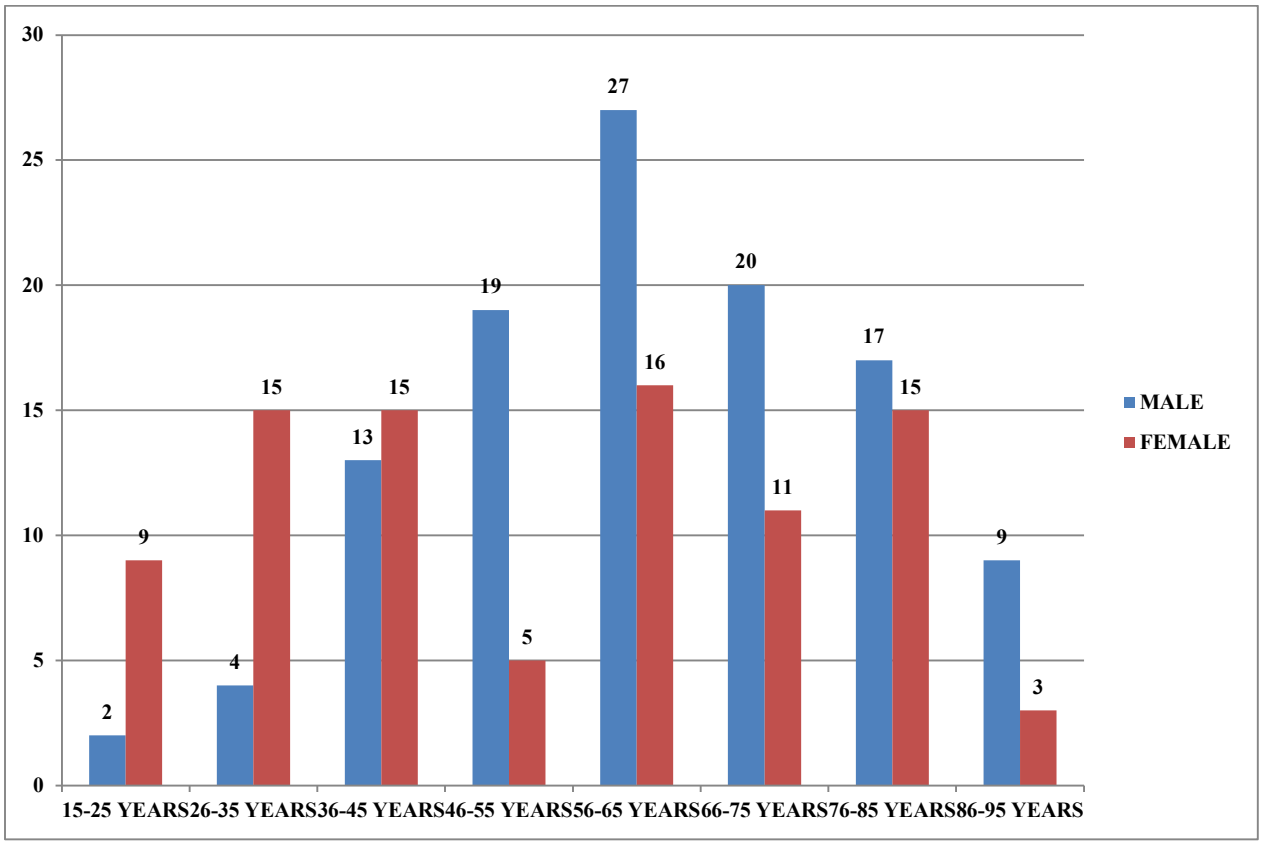


Figure 4: Number of patients according to there age group

Table 4: Chart of number of patients according to there age group

AGE	MALE	MALE %	FEMALE	FEMALE %
15-25 YEARS	2	1%	9	4.5%
26-35 YEARS	4	2%	15	7.5%
36-45 YEARS	13	6.5%	15	7.5%
46-55 YEARS	19	9.5%	5	2.5%
56-65 YEARS	27	13.5%	16	8%
66-75 YEARS	20	10%	11	5.5%
76-85 YEARS	17	8.5%	15	7.5%
86-95 YEARS	9	4.5%	3	1.5%
TOTAL	111	55.5%	89	44.5%

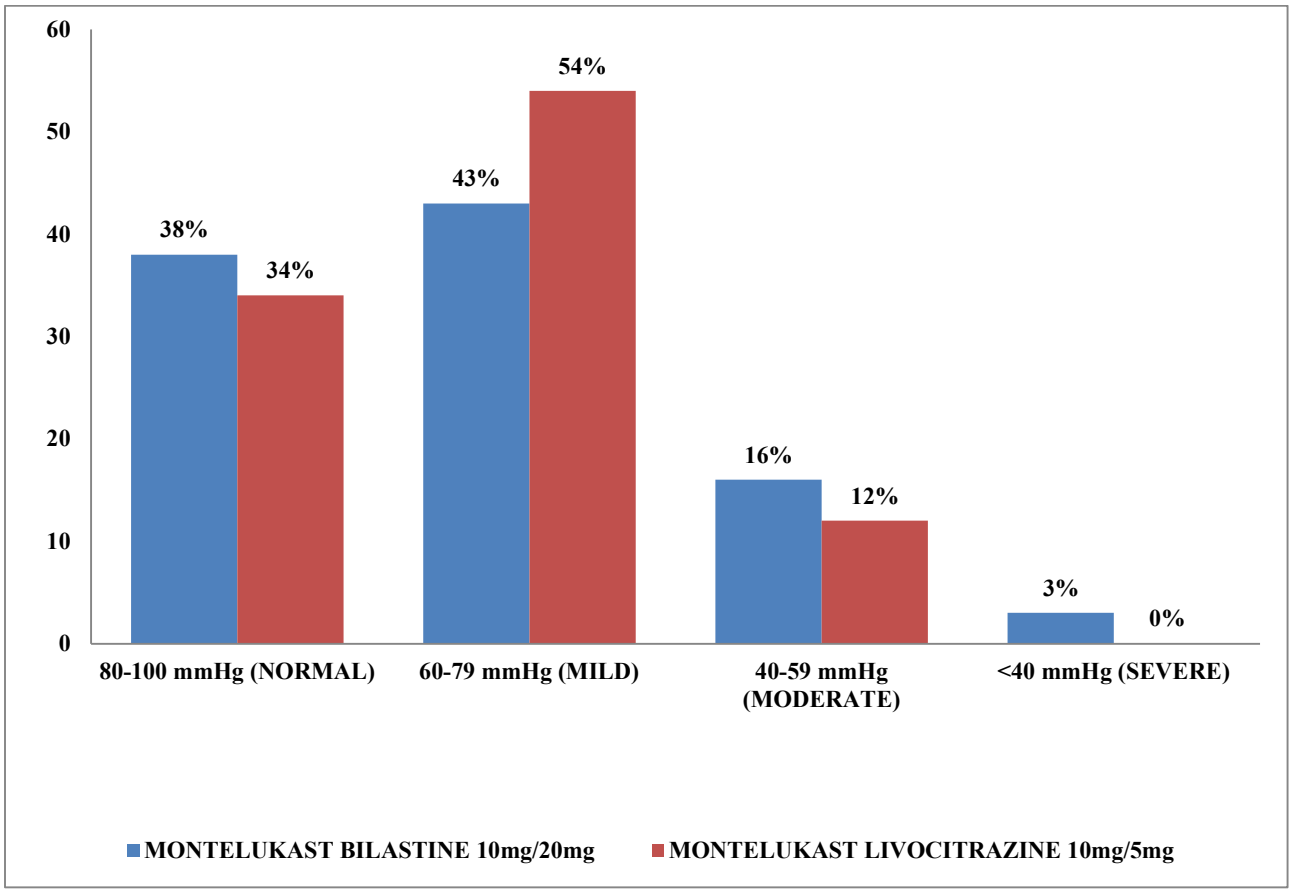


Figure 5: Percent of abnormal PaO2 for each montelukast Bilastine and montelukast levocetirizine

Table 5: No of patients PaO2 reading for patients with montelukast bilastine and montelukast levocetirizine

PaO2 READING	PATIENT WITH MONTELUKAST BILASTINE	PATIENT WITH MONTELUKAST LEVOCETIRIZINE	PERCENTAGE FOR MONTELUKAST BILASTINE	PERCENTAGE OF MONTELUKAST LEVOCETIRIZINE
80-100 mmHg (NORMAL)	38	34	38%	34%
60-79 mmHg (MILD)	43	54	43%	54%
40-59 mmHg (MODERATE)	16	12	16%	12%
<40 mmHg (SEVERE)	3	0	3%	0%
TOTAL	100	100	100%	100%

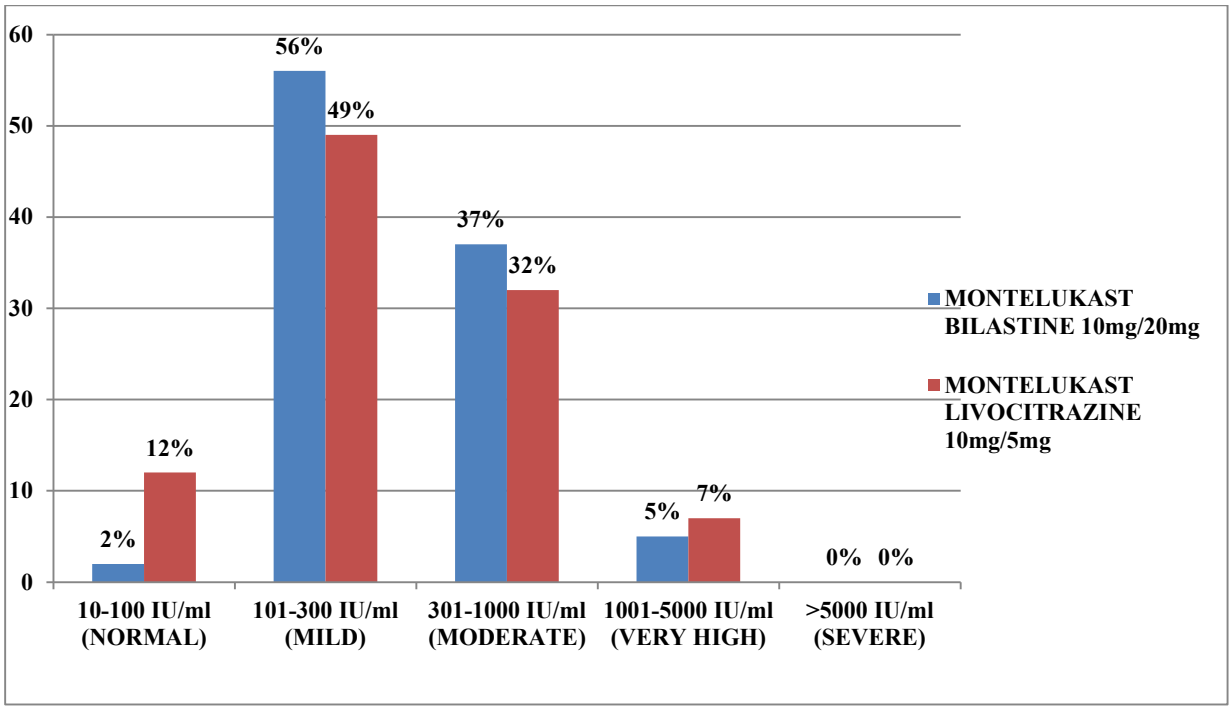


Figure 6: Percentage of IgE level in patients with montelukast bilastine and montelukast ievocitrazine

Table 6: Chart of Percentage of IgE levelin patients with montelukast bilastine and montelukast levocitrazine

IgE LEVEL	PATIENT WITH MONTELUKAST BILASTINE	PERCENTAGE OF PATIENTS MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCITRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
10-100 IU/ml	2	1%	12	6%
101-300 IU/ml	56	28%	49	24.5%
301-1000 IU/ml	37	18.5%	32	16%
1001-5000 IU/ml	5	2.5%	7	3.5%
>5000 IU/ml	0	0%	0	0%
TOTAL	100	50%	100	50%

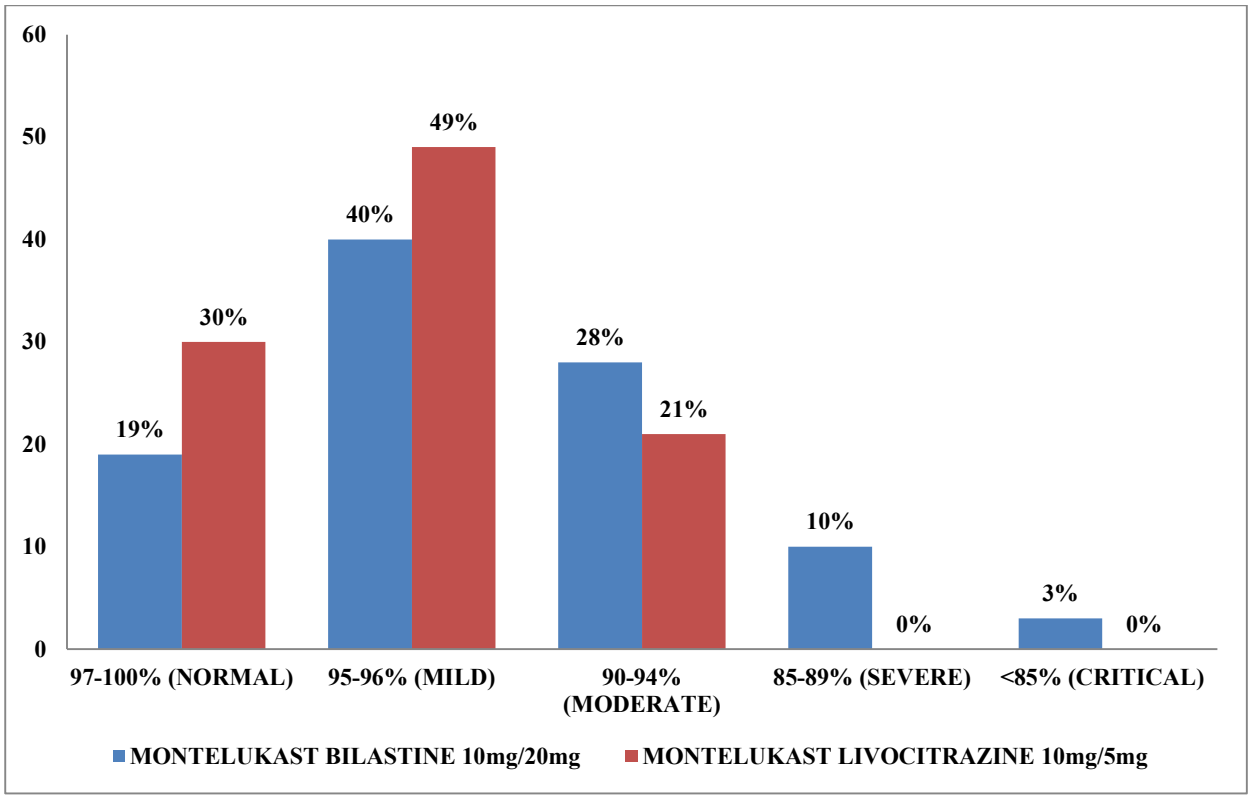


Figure 7: Graph of percentage of SPO2 level in patients with montelukast bilastine and montelukast levocitrazine

Table 7: Chart of percentage of SPO2 level in patients with montelukast bilastine and montelukast levocitrazine

SPO2 LEVEL	PATIENTS WITH MONTELUKAST BILASTINE	PERCENTAGE OF PATIENTS MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCETIRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
97-100% (NORMAL)	19	9.5%	30	15%
95-96% (MILD)	40	20%	49	24.5%
90-94%(MODERATE)	28	14%	21	10.5%
85-89%(SEVERE)	10	5%	0	0%
<85%(CRITICAL)	3	1.5%	0	0%
TOTAL	100	50%	100	50%

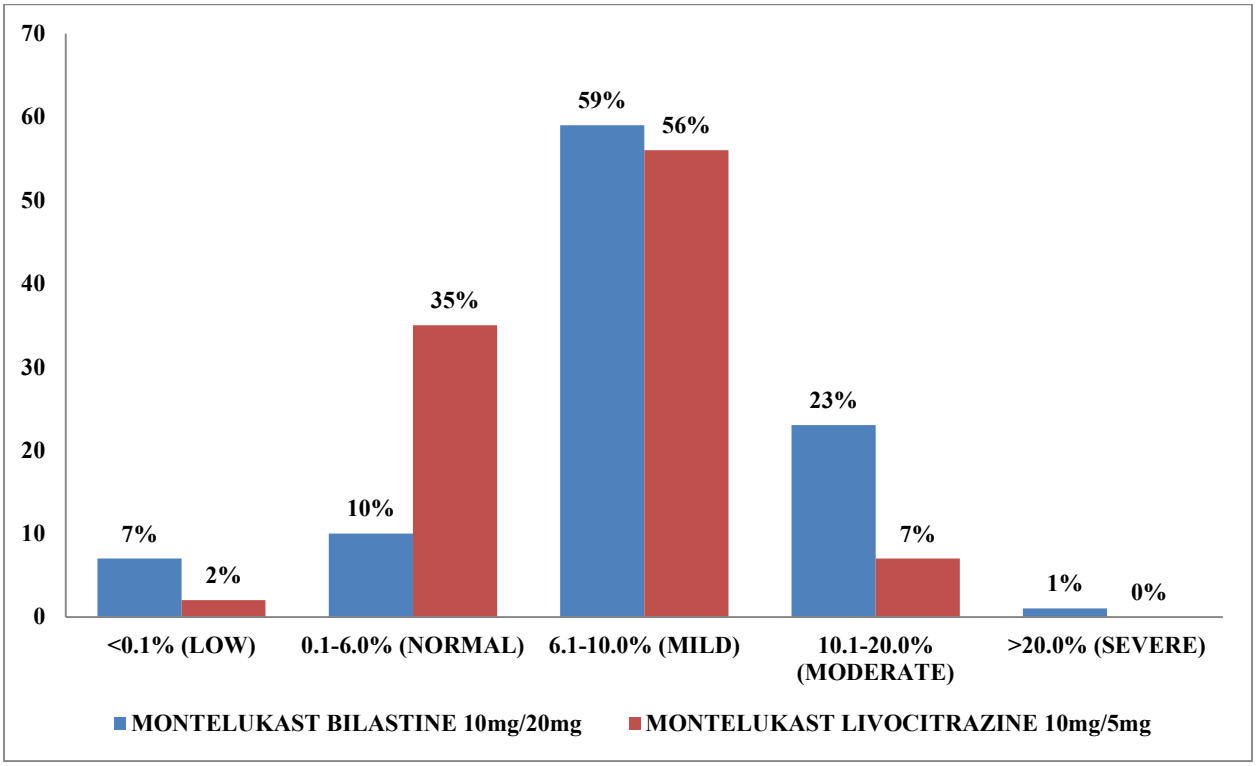


Figure 8: Graph of percentage of Eosinophils leve lin patients with montelukast bilastine and montelukast levocirazine

Table 8: Chart of percentage of Eosinophils level in patients with montelukast bilastine and montelukast levocirazine

EOSINOPHILS LEVEL	PATIENTS WITH MONTELUKAST BILASTINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCITRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
<0.1%(LOW)	7	3.5%	2	1%
0.1-6.0%(NORMAL)	10	5%	35	17.5%
6.1-10.0%(MILD)	59	29.5%	56	28%
10.1-20.0%(MODERATE)	23	11.5%	7	3.5%
>20.0%(SEVERE)	1	0.5%	0	0%
TOTAL	100	50%	100	50%

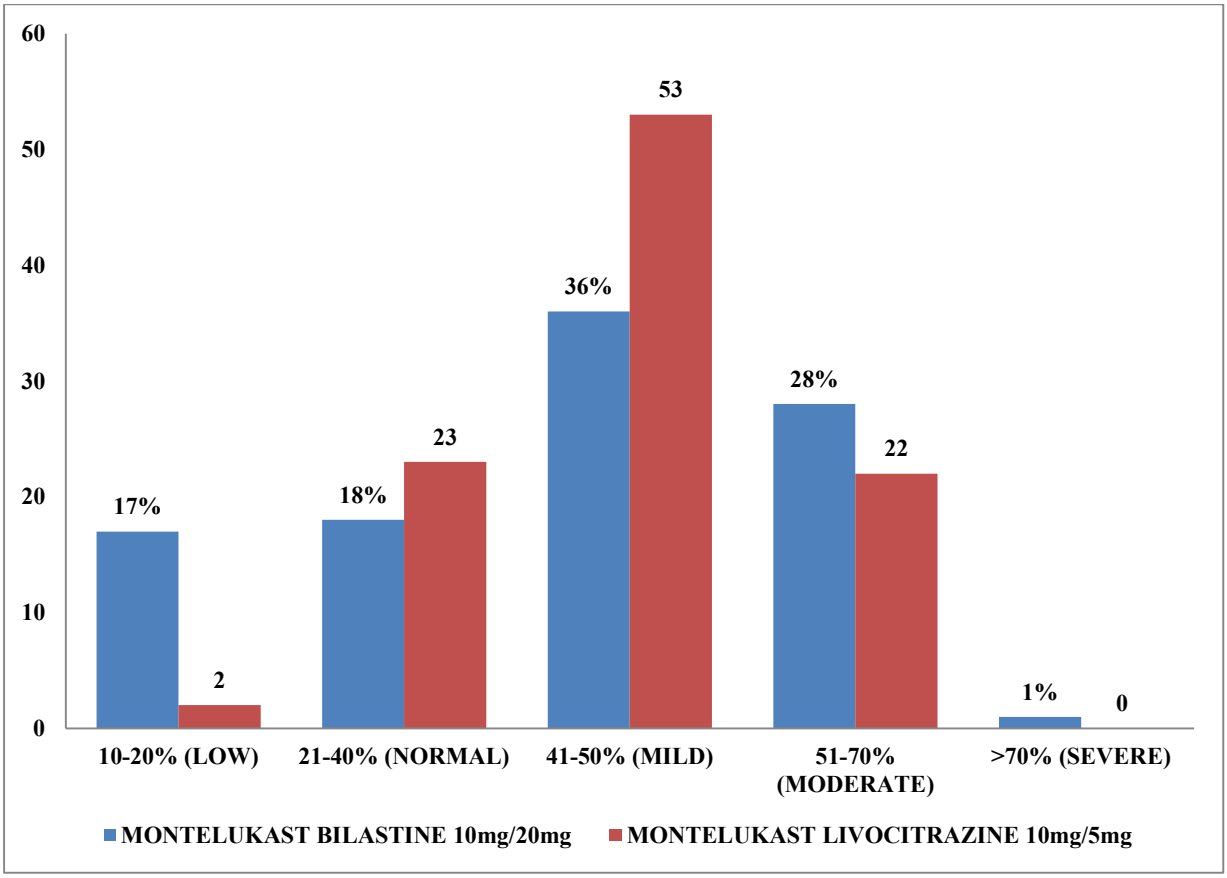


Figure 9: Graph of percentage ofLymphocites level in patients with montelukast bilastine and montelukast levocirazine

Table 9: Table of percentage of Lymphocites level in patients with montelukast bilastine and montelukast levocirazine

LYMPHOCYTE LEVEL	PATIENTS WITH MONTELUKAST BILSTINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCITRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
10-20%(LOW)	17	8.5%	2	1%
21-40%(NORMAL)	18	9%	23	11.5%
41-50%(MILD)	36	18%	53	26.5%
51-70%(MODERATE)	28	14%	22	11%
>70%(SEVERE)	1	0.5%	0	0%
TOTAL	100	50%	100	50%

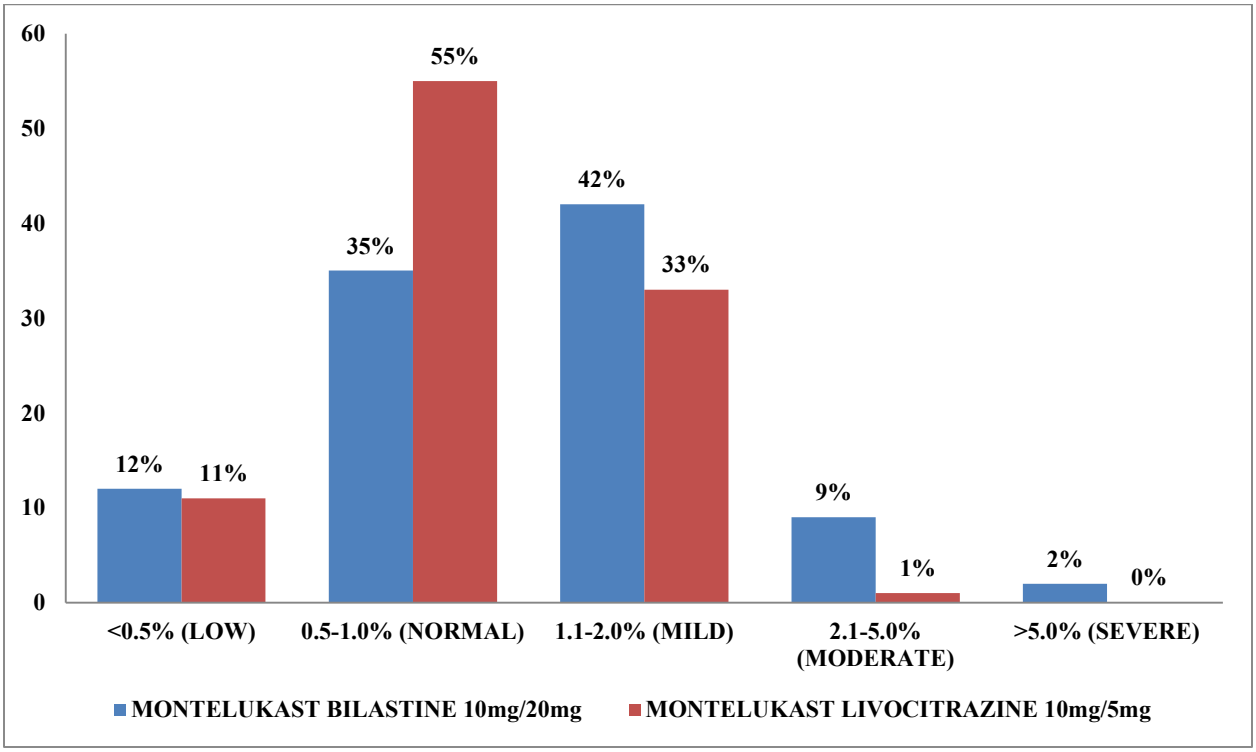


Figure 10: Graph of percentage of Basophils level in patients with montelukast bilastine and montelukast levocirazine

Table 10: Table for percentage of Basophil level in patients with montelukast bilastine and montelukast levocirazine

BASOPHILS LEVEL	PATIENTS WITH MONTELUKAST BILSTINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCITRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
<0.5%(LOW)	12	6%	11	5.5%
0.5-1.0%(NORMAL)	35	17.5%	55	27.5%
1.1-2.0%(MILD)	42	21%	33	16.5%
2.1-5.0%(MODERATE)	9	4.5%	1	0.5%
>5.0%(SEVERE)	2	1%	0	0%
TOTAL	100	50%	100	50%

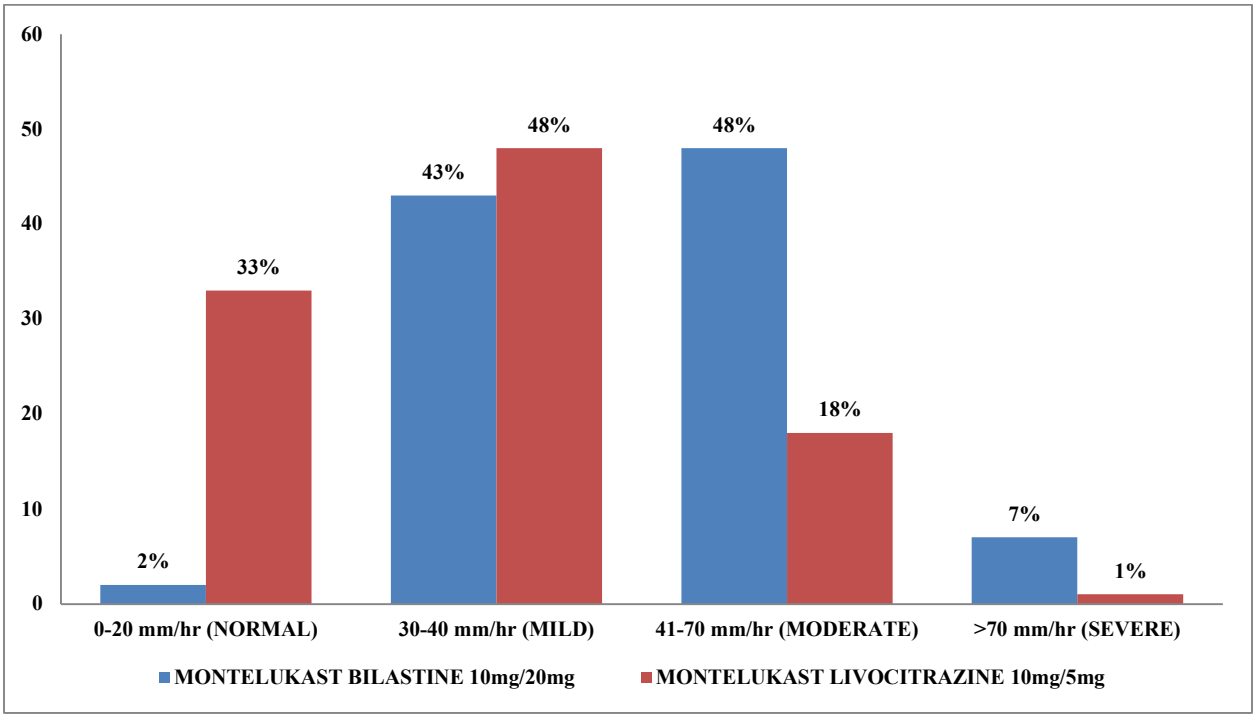


Figure 11: Graph for percentage of ESRlevel in patients with montelukast bilastine and montelukast levocirazine

Table 11: Table for percentage of ESR level in patients with montelukast bilastine and montelukast levocirazine

ESR LEVEL	PATIENTS WITH MONTELUKAST BILSTINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCITRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
0-20 mm/hr(NORMAL)	2	1%	33	16.5%
30-40 mm/hr(MILD)	43	21.5%	48	24%
41-70 mm/hr(MODERATE)	48	24%	18	9%
>70 mm/hr(SEVERE)	7	3.5%	1	0.5%
TOTAL	100	50%	100	50%

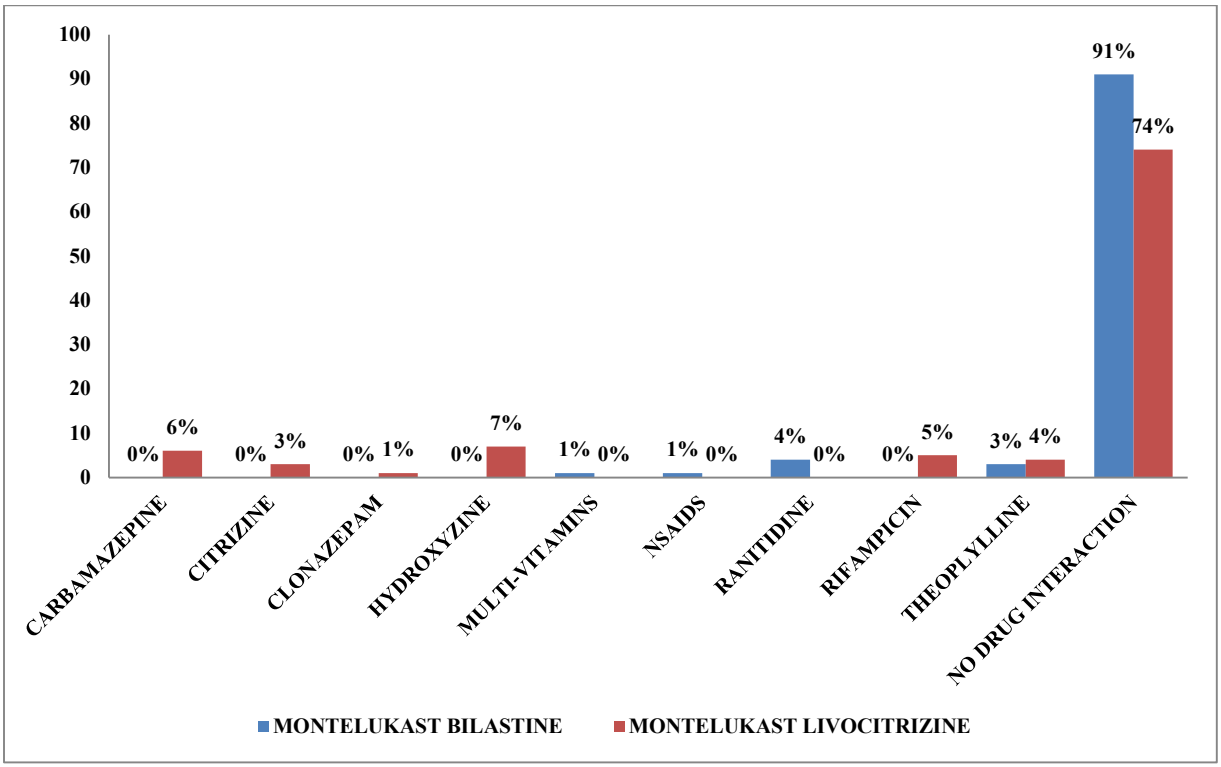


Figure 12: Graph for percentage of drug interaction in patients with montelukast bilastine and montelukast levocirazine

Table 12: Percentage of drug interaction in patients with montelukast bilastine and montelukast levocirazine

DRUG INTERACTING WITH	PATIENTS WITH MONTELUKAST BILSTINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST BILASTINE	PATIENTS WITH MONTELUKAST LEVOCITRIZINE	PERCENTAGE OF PATIENTS WITH MONTELUKAST LEVOCITRIZINE
CARBAMAZEPINE	0	0%	6	3%
CITRIZINE	0	0%	3	1.5%
CLONAZEPAM	0	0%	1	0.5%
HYDROXYZINE	0	0%	7	3.5%
MULTI-VITAMINS	1	0.5%	0	0%
NSAIDS	1	0.5%	0	0%
RANITIDINE	4	2%	0	0%
RIFAMPICIN	0	0%	5	2.5%
THEOPYLLINE	3	1.5%	4	2%
NO DRUG INTERACTION	91	45.5%	74	37%
TOTAL	100	50%	100	50%

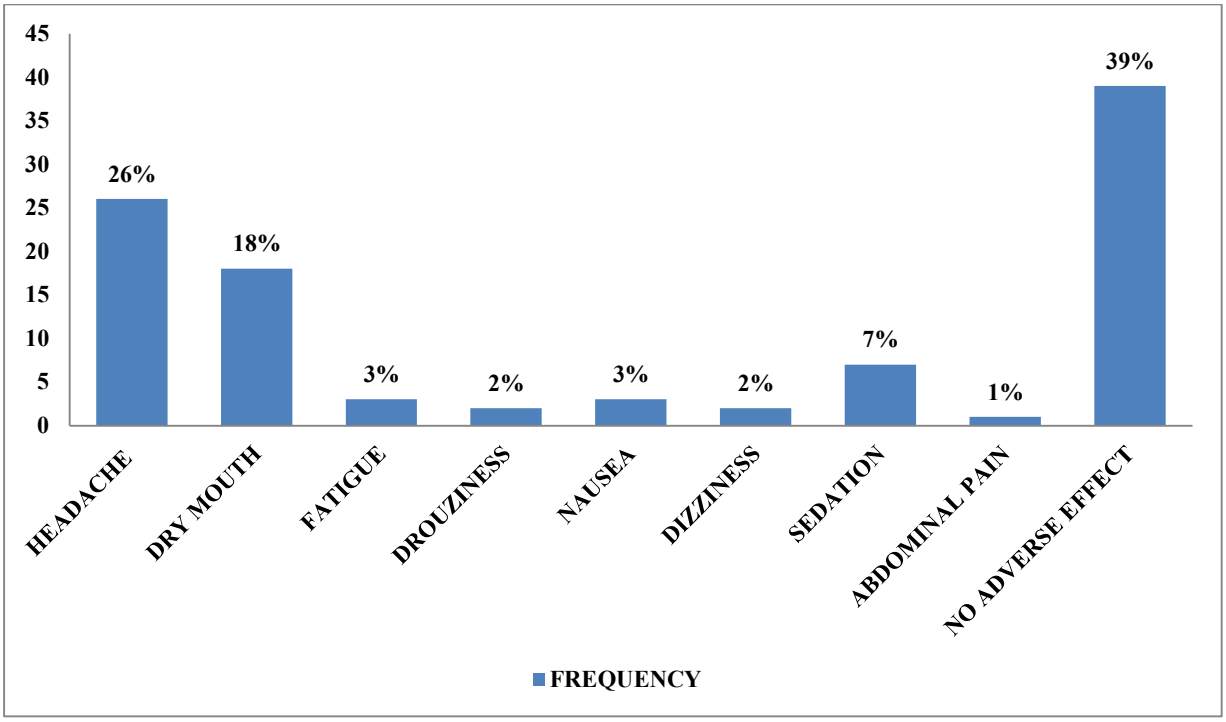


Figure 13: Percentage of adverse effect in patients with montelukast bilastine

Table 13: Percentage of adverse effect in patients with montelukast bilastine

ADVERSE EFFECT OF MONTELUKAST BILASTINE	FREQUENCY	PERCENTAGE
HEADACHE	26	26%
DRY MOUTH	18	18%
FATIGUE	3	3%
DROWZINESS	2	2%
NAUSEA	3	3%
DIZZINESS	2	2%
SEDATION	7	7%
ABDOMINAL PAIN	1	1%
NO ADVERSE EFFECT	38	38%
TOTAL	100	100%

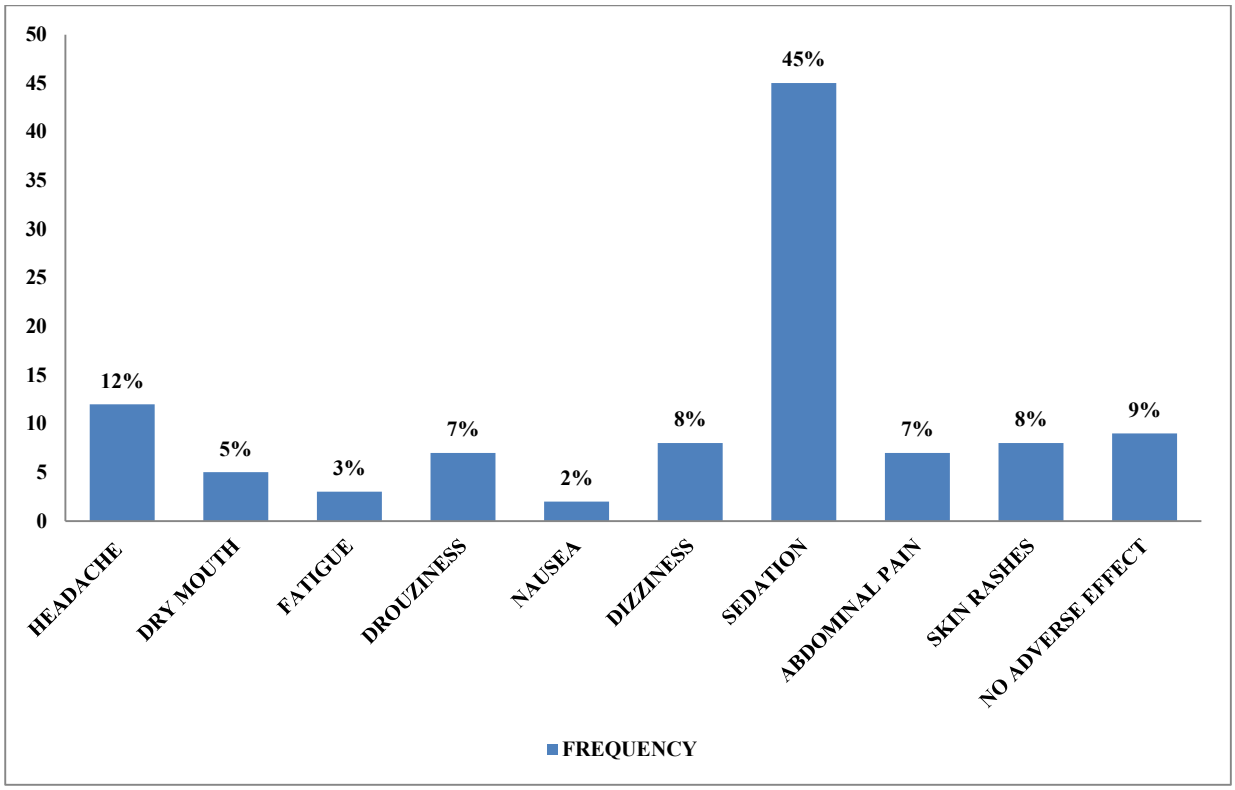


Figure 14: Percentage of adverse effect in patients with montelukast levocitrazine

Table 14: Percentage of adverse effect in patients with montelukast levocitrazine

COMMON ADVERSE EFFECT OF MONTILUKAST LI LEVOCITRIZINE	FREQUENCY	PERCENTAGE
HEADACHE	12	12%
DRY MOUTH	5	5%
FATIGUE	3	3%
DROUZINESS	7	7%
NAUSEA	2	2%
DIZZINESS	8	8%
SEDATION	45	45%
ABDOMINAL PAIN	7	7%
SKIN RASHES	8	8%
NO ADVERSE EFFECT	3	3%
TOTAL	100	100%

DISCUSSION

This comparative study assessed the safety and efficacy of Montelukast Bilastine in comparison to Montelukast Levocetirizine in patients with asthma and allergic diseases, based on clinical outcomes, laboratory parameters, and adverse effect profiles. Both combinations exhibited clinical benefit, in accordance with previously reported evidence favoring adjunctive use of leukotriene receptor antagonists along with second-generation antihistamines in allergic airway disorders **[11]**.

The current results indicate that Montelukast Bilastine provided better symptom control, reduced hospital stay, and better respiratory parameters, especially in patients with moderate to severe hypoxia. This is concordant with Bilastine's pharmacological profile, characterized by high selectivity for peripheral H1 receptors **[12]** and very limited central nervous system penetration, which might be responsible for its good tolerability and reduced sedation rates. Conversely, Montelukast Levocetirizine patients most commonly complained of sedation and tiredness, symptoms that might compromise adherence and activities of daily living.

Laboratory values also accentuated therapeutic differences. Montelukast Bilastine exhibited more uniform IgE **[10] (Figure 6, Table 6)** and PaO_2 control **(Figure 5, Table 5)**, implying greater immunological and respiratory gain in more allergic and inflammatory-loaded patients. In contrast, Montelukast Levocetirizine exhibited relative superiority in preserving SpO_2 **(Figure 7, Table 7)**, eosinophil count **(Figure 8, Table 8)**, and lymphocyte stability **(Figure 9, Table 9)**, implying possible use in less severe or more stable disease manifestations. Such differences might be due to prescribing patterns **[13]**, with Bilastine used in more serious disease presentations.

Study of drug interaction showed a safety benefit in favor of Montelukast Bilastine, with 91% of patients having no interaction versus only 74% in the Levocetirizine **(Figure 12, Table 12)**. The increased rate of interactions seen with Levocetirizine, especially with CNS depressants and enzyme-inducing drugs, should be taken into account in polypharmacy **[14]**.

Together, the results indicate that Montelukast Bilastine is preferable in patients who have moderate to severe allergic respiratory diseases or are at risk of sedation-related side effects, whereas Montelukast Levocetirizine can still be used for stable patients who need eosinophilic control but with less concern regarding sedation **(Figure 13, 14; Table 13,14)**. Both treatments were generally safe,

but their different profiles confirm the need to use individualized therapy choice **[15]**.

CONCLUSION

Both fixed combinations Montelukast Bilastine and Montelukast Levocetirizine were both effective in managing asthma and allergic symtoms. Montelukast Bilastine was however accompanied by shorter hospital stay, fewer interactions with drugs, and better tolerability and hence better adapted to moderate-to-severe cases **[15]**. Montelukast Levocetirizine could still be employed in stable patients, but due to a higher incidence of sedation accompanying it, wider use is not feasible.

Acknowledgements

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