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COMPARISON OF THERAPEUTIC ROLE OF N. SATIVA SEEDS WITH LEUKOTRIENE RECEPTOR BLOCKER MONTELUKAST AMONG PERIODIC ALLERGIC RHINITIS PATIENTS

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Abstract:
Objective: *The study was held for comparing the therapeutic role of N. Sativa seeds with leukotriene receptor blocker Montelukast in patients with periodic allergic rhinitis.*
Methods: *We carried out this research at Jinnah Hospital, Lahore from October 2017 to June 2018. A total number of forty-seven participants who were patients of seasonal allergic rhinitis and looking for outpatient administration were evaluated through comparative uncontrolled single-blind clinical assessment. All participants belonged to different primary health care points. After the registration process, the participants were divided into a single-blind approach for obtaining Montelukast. Group A, (10 mg/day, n=24) and group B (250 mg/day of N. Sativa, n=24) verbally for fourteen days. All Patients joining up the research study had accomplished therapeutic directions.*
Results: *An obvious as well as an early decline was observed in both of N. Sativa and Montelukast in the time of day and also as ophthalmic signs, while montelukast displayed late and moderated effects in symptoms of nighttime after comparison with N. Sativa. Additionally, montelukast is also found behind drug-associated side effects as that of heat burn, headache, and faintness.*
Conclusion: *N. Sativa is harmless and there are no threats related to serious and hostile effects. Thus, it is found beneficial for seasonal allergic rhinitis patients as a dependable alternative method for management.* ***Keywords:*** *Leukotriene Receptor Blocker, Montelukast, Nigella Sativa, SAR (Seasonal Allergic Rhinitis), Central Nervous System.*

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INTRODUCTION:

A large number of inhabitants are being disturbed with the common disorder of SAR throughout the whole world [1 – 3]. In SAR pathogenesis, Leukotrienes have been managed to put forth convincing challenging effects in the elementally participate and within the upper respiratory zone [4]. It's an immunoglobulin (E, IgE)-mediated provocative reaction by the mucous membrane within the upper respiratory tract due to allergens [5]. Amongst susceptible persons the involvement to convinced unfamiliar proteins at last ends to sensitization with allergy, in accordance with following by particular IgE synthesis within the opposition to these proteins. In nasal mucosa, the mast cells have a special receptors group which fascinate such immunoglobulins. When the specific pollen grains inhalation occurs, they get assembled along with the IgE on mast-cells, producing an immediate quantity of mediators discharge as like histamine and leukotrienes, the leading cause of indications related to SAR [6, 7]. The first-generation time-honored antihistamines are effective within the treatment of the symptoms of SAR but it is observed that susceptibility to pass through the blood-brain barrier can produce opposed effects of CNS [3, 8, 9]. Consequently, the leukotriene receptor apposite montelukast was overcome to diminish as of opposing effects in the absence of cooperating therapeutic properties [10]. Still, it approves a propensity for producing side effects associated with drugs [11]. In consequences of old-fashioned medication, the utilization of herbal and natural drugs as an additional remedial method for treatment of various health issues was rising [1, 3, 12]. Therefore, natural and herbal treatments have better results when utilized against numerous disorders of allergy. N. Sativa is related to the family' Ranunculaceae and its very effective herb having a wealthy spiritual as well as chronological practice [13]. It is already mentioned that primordial Egyptian and Greek physicians affirmed the seed of Kalonji or N. Sativa for the treatment of various diseases as it has been previously mentioned in primordial [14]. There are many research studies that represent anti-histaminic and anti-inflammatory [15] effects of seeds of N. Sativa [16, 17]. Recently, different scientists have also examined the influence of the seed of N. Sativa on human immunity [13]. An obvious organic detection of the N. Sativa seeds is revealed due to thymoquinone which is basic component related to the fixed as well as essential oil [16, 18] that reduces the IgE availability, urine cortisol and the plasma, consequently, expressing valuable beneficial element for conditions of allergy [19]. Resultantly, the study was focused on the comparison of the therapeutic outcome and safe-way related to leukotriene receptor against montelukast with N. Sativa for the remedial methods of allergic rhinitis.

METHODS:

We carried out this research at Jinnah Hospital, Lahore from October 2017 to June 2018. A total number of forty-eight male and female untreated patients, seeking outpatient administration for SAR were enrolled and registered for this single-blind research study. Patients with a recent history of cardiac and liver illness, past precedence of foremost psychiatric issues or any drug addicted were excluded from the study. N. Sativa is a foodstuff, and healthy persons commonly use it and Montelukast has commonly used medication for various allergic conditions so, ethical permission was not required at any of the ethical issues was present in this study. The study duration comprised over two weeks for each patient. Assessment on visits was carried out for the patients on a daily basis. Demographic data was documented relevant to disease, lab reports of previous treatments and physiological evaluations were documented. Two groups were formed up amongst the Patients found with signs of SAR for receiving montelukast, 10mg per day, Group A (n=23) and 250 mg per day of N. Sativa, Group B (n=23) verbally for fourteen days. The patients showed the signs of allergic rhinitis, within the research study duration through a questionnaire related to seventeen distinctive symptoms, which were further divided into three groups: Symptoms related to daytime which included itching, nasal obstruction, ear pressure, postnasal drip, sneezing anosmia, restlessness, daytime drowsiness. The second group comprised over symptoms related to ophthalmic which included read eyes, lacrimation, puffiness, burning. The third group contained symptoms of nighttime showing intricacy in sleeping, nasal hindrance upon nocturnal arousing nighttime, rhinorrhea, all patients showed each symptom up to an extent. each symptom was ranked as per the intensity and incidence 5-point range, in this: 0- No Signs of disease, 1- insignificant signs, 2- reasonable signs, 3-abstemiously very little and 4-obvious signs. Different symptom's score was added to obtain multiple symptom scores. Physical shades, including the rate of pulse, the temperature of the body, diastolic, systolic blood pressures were evaluated. Peripheral blood eosinophils were calculated with the help of [Mithic-18] automatic hematological analyzer, C2 Analytic, France]. Total results expressed in SEM + means. The Mean significance evaluated through the average of the matching t-test of the student. The software SPSS for data analysis with 'P' value (considered significant) lower than or equal to 0.05 For all results.

RESULTS:

A total number of seventy-five patients got examined, out of the fifty-two patients were incorporated into our study and at the end, forty-six patients (23 among Group-A and 23 among Group-B) accomplished the study program for a duration of two weeks in compliance with study procedure. Five persons were omitted from the study due to failure in the completion of follow up visits. The age range of the patients included in the study was 21 – 46 years. Amongst the patients of Group-A and B, indications of SAR, montelukast's effect and usage of N. Sativa to decrease day time-related symptoms found statistically noteworthy as $P < 0.001$, at the time of matching with the baseline before-treatment duration of the research study. Similar to the relief of signs of ophthalmic, it had significant statistics within two groups as $P < 0.001$, when matched with a baseline before-treatment duration of the study. Among Group-A patients the night-time symptoms score indicated a non-significant decrease on the seventh day $P = 0.082$ and statistically significant decline found at the fourteenth day, $P = 0.006$, And among Group-B patients with higher statistics, significant $P = 0.001$, after the remedy decline within night time signs was noted after-treatment at the seventh day. The amount of peripheral eosinophil was also reduced expressively within study groups. But the total count of peripheral eosinophil did not show the severity of the symptom. In a few patient conspicuous symptoms showed a minor rise in eosinophil count, but the rise was observed in the majority of the patients within the count of eosinophil from its reference values. Blood pressure and rate of pulse remained the same. On the other hand, an obvious change was seen in the body temperature in both groups. Treatment conformity was found lower among Group-A whereas many patients in Group-A revealed side effects associated to the drug, such as dizziness, and lethargy, while in Group-B, only one patient was found with insomnia and two patients were found with daytime lethargy.

Table – I: Treatment Outcomes Comparison Among Groups

Study Group-I (Montelukast)				**Study Group-II (N. Sativa)**			
Study Days	Day 0	Day 7	Day 14	Study Days	Day 0	Day 7	Day 14
Daytime	25.04	19.2	4.2	Daytime	23.86	13.12	2.9
Symptom Score	± 1.35	± 1.33	± 0.22	Symptom Score	± 1.60	± 0.80	± 0.22
P- Value	-	<0.001	<0.001	P- Value	-	<0.001	<0.001
Ophthalmic	13.61	10.31	7.6	Ophthalmic	13.9	9.63	2.15
Symptom Score	± 0.31	± 0.01	± 0.20	Symptom Score	± 0.11	± 0.01	± 0.41
P- Value	-	<0.001	<0.001	P- Value	-	<0.001	<0.001
Nighttime	12.25	12.13	11.58	Nighttime	12.98	11.41	6.32
Symptom Score	± 0.29	± 0.19	± 0.33	Symptom Score	± 0.13	± 0.35	± 0.51
P- Value		0.639	0.006	P- Value		0.001	<0.001
Total Eosinophil	8.23	5.16	4.3	Total Eosinophil	7.7	4.6	3.1
Count (% /cu mm)	± 0.20	± 0.30	± 0.10	Count (% /cu mm)	± 0.40	± 0.40	± 0.10
P- Value		**0.029**	**0.003**	**P- Value**		**0.037**	**0.007**

Table – II: Physiological Shades (Group-Wise)

Study Groups	Group-I (Montelukast) (24)					Group-II (N. Sativa) (23)				
Physiological Constraints	Day-0		Day-14		P-Value	Day-0		Day-14		P-Value
	Mean	±SD	Mean	±SD		Mean	±SD	Mean	±SD	
Systolic Blood Pressure (mm of Hg)	122.4	0.30	122.6	0.01	0.109	125.2	0.80	124.5	0.40	0.181
Diastolic Blood Pressure (mm of Hg)	76.4	0.10	75.8	0.10	0.095	74.1	0.30	74.2	0.10	0.849
Pulse Rate (Beats / Minute)	99.1	0.20	95.2	0.01	< 0.001	98.7	0.20	91.4	0.40	< 0.001
Temperature (° F)	99.4	0.90	98.2	0.01	< 0.001	99.8	0.10	98	0.03	< 0.001

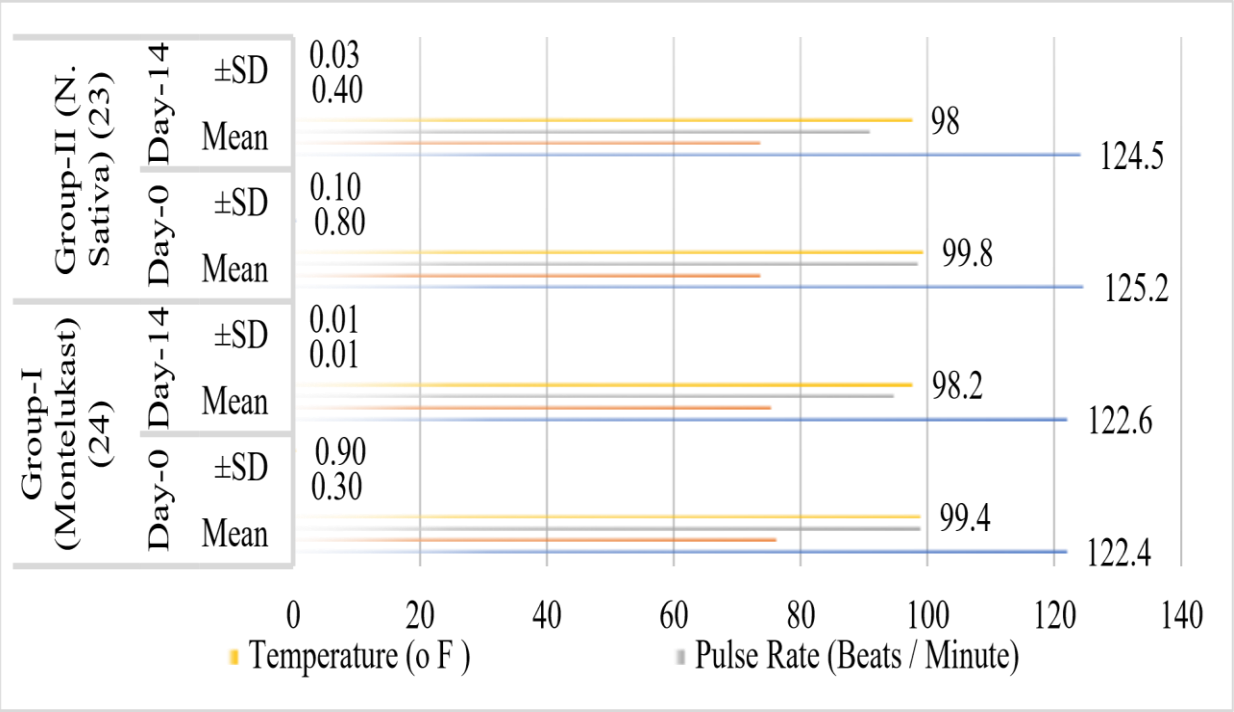


Table – III: Outcomes Comparison

Study Day			0	7	14
Daytime Symptom Score	Montelukast	Mean	25.04	19.2	4.2
		±SD	1.35	1.33	0.22
	N. Sativa	Mean	23.86	13.12	2.9
		±SD	1.6	0.8	0.22
	P-Value		0.208	< 0.0001	< 0.0001
Ophthalmic Symptom Score	Montelukast	Mean	13.61	10.31	7.45
		±SD	0.31	0.01	0.2
	N. Sativa P-Value	Mean	13.9	9.63	2.15
		±SD	0.11	0.01	0.41
	P-Value		0.236	0.002	< 0.0001
Nighttime Symptom Score	Montelukast	Mean	12.25	12.13	11.58
		±SD	0.29	0.19	0.33
	N. Sativa P-Value	Mean	12.98	11.41	6.32
		±SD	0.13	0.35	0.51
	P-Value		0.343	< 0.0001	< 0.0001
Total Eosinophil Count (% /cu mm)	Montelukast	Mean	8.23	5.16	4.3
		±SD	0.2	0.3	0.1
	N. Sativa P-Value	Mean	7.7	4.6	3.1
		±SD	0.4	0.4	0.1
	P-Value		0.149	0.04	0.002

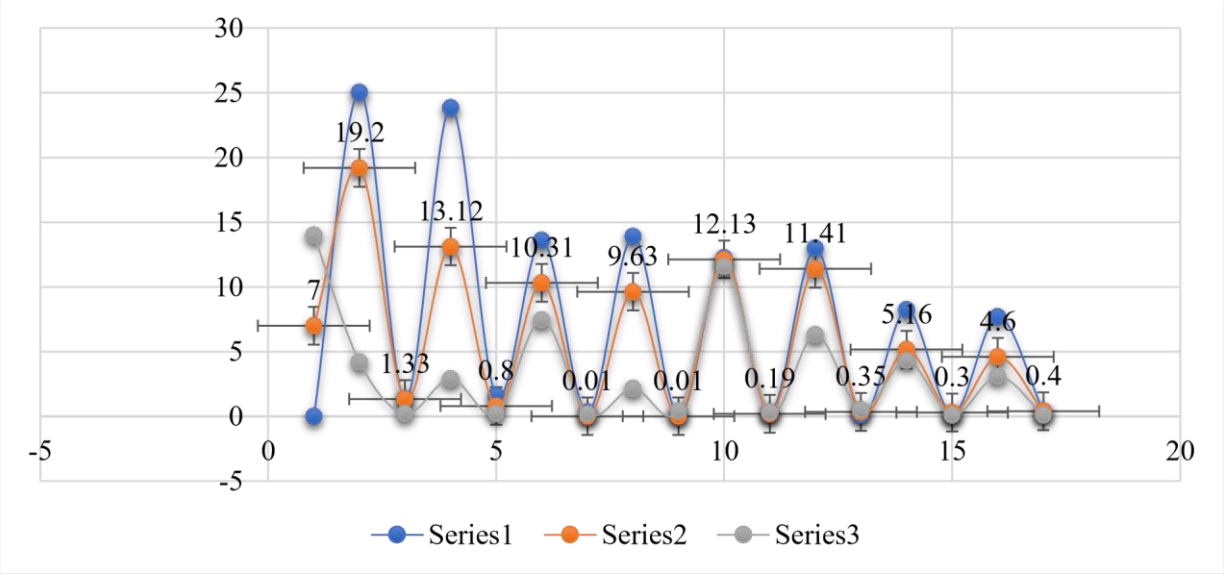
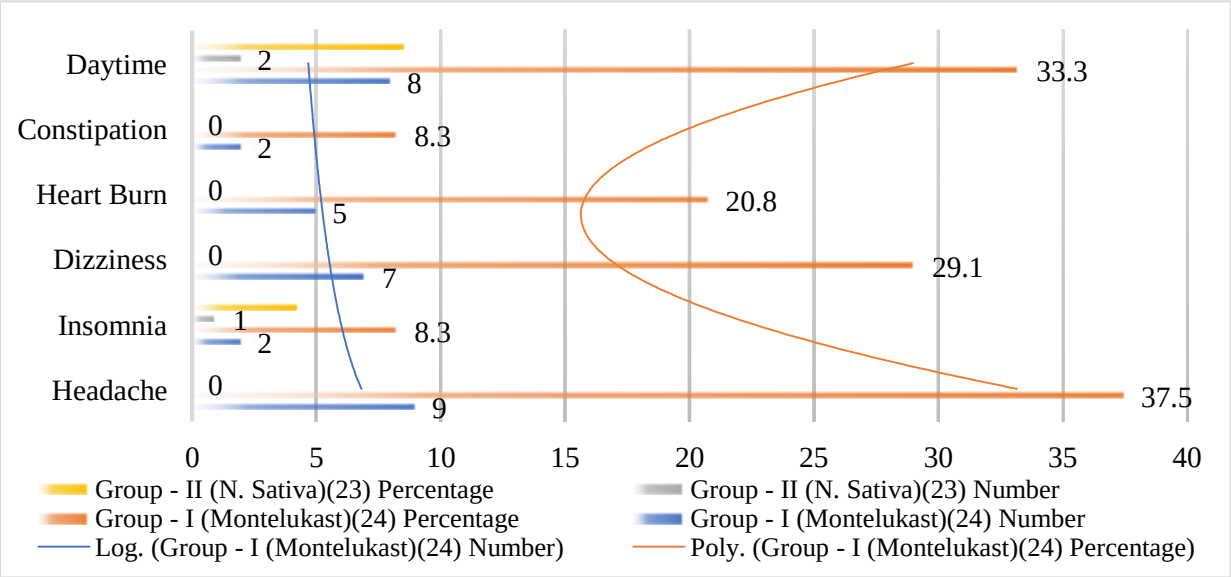


Table – IV: Group Wise Effect of Drugs

Study Group/ Side Effects	Group - I (Montelukast) (24)		Group - II (N. Sativa) (23)	
	Number	Percentage	Number	Percentage
Headache	9	37.5	0	0.0
Insomnia	2	8.3	1	4.3
Dizziness	7	29.1	0	0.0
Heart Burn	5	20.8	0	0.0
Constipation	2	8.3	0	0.0
Daytime	8	33.3	2	8.6



DISCUSSION:

The important concern of herbal as well as conventional therapeutic decisions to manage SAR was highlighted in this research study. SAR provides grounds for an enormous uneasiness and has serious effects on the quality of a patient's life. A large number, about 91% of patients consider SAR as the factor behind disturbed professional performance [1 – 3]. The tendency to form up allergic, reactions to extrinsic allergens are having a hereditary module. Within susceptible persons, link with convinced distant proteins develops allergic indications caused by the formation of distinctive IgE, directed opposite to this mass of proteins. Furthermore, within the nasal-mucosa, this IgE pelts the mast cells exterior [20]. An exact protein is capable of binding to the IgE on the mast-cells which further causes discharge of mediators as like of histamine and leukotrienes, which rings the central signs of SAR [7]. The result indicated that N. Sativa and montelukast seeds reduced the ophthalmic and daytime SAR symptoms to an equivalent position. Whereas, the montelukast is having postponed impressions on night-time indications. It also has side effects. The anti-allergic, effects of seeds of N. Sativa can be presented to its apposite histaminic process [21, 22], N. Sativa decreases intracellular calcium which holds protein kinase C, a known element to speed up the histamine discharge [23] and maybe by stopping the receptors of histamine [16] elucidating the harmless, in conventional medical usage in the track to SAR.

CONCLUSION:

This research study validates that the N. Sativa is an effective treatment for curing of all symptom groups of SAR; however, montelukast is having very few

impression on nocturnal signs and causes headache and many more adverse effects. So, on the other hand, N. Sativa is thought to be the safe treatment of SAR patients, a leading reason for huge discomfiture for various individuals. As a result, it is necessary that basic care health centers must be adequately familiar regarding managing this common health issue.

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