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Original Research Article

Efficacy and Tolerability of Oral Desloratadine (10mg OD), Rupatadine (10mg OD) and Ketotifen (1mg BD) in Seasonal Allergic Rhinitis: A Prospective Randomized Study

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Conflict of interest: Nil

Abstract

Background: Rhinitis is an inflammation of the nasal mucosa that typically manifests as sneezing, runny, or blocked noses. The frequency of allergic rhinitis is higher than that of non-allergic rhinitis. Treatment for SAR is primarily based on antihistamines. The antihistamines that are most frequently administered in our area are desloratadine, rupatadine, and ketotifen. In this study, the effectiveness and tolerability of rupatadine, ketotifen, and desloratadine in SAR were compared.

Methods: From August 2025 to January 2026, a prospective, randomized, three-arm, open-label comparison trial of desloratadine, rupatadine, and ketotifen in SAR was carried out at the Department of ENT, ANMMCH, Gayaji, and Bihar. TNSS was used to gauge the patients' quality of life and the severity of their SAR symptoms. At every visit, adverse effects were tracked during the clinical examination. Desloratadine (DES), rupatadine (RUP), and ketotifen (KET) were the three groups into which study participants were systematically randomized. Oral doses of desloratadine (10 mg OD), rupatadine (10 mg OD), and ketotifen (1 mg BD) were administered according to the designated group. Every drug was administered for four weeks. Every patient had a weekly follow-up during the four-week course of treatment. Change in the mean TNSS from baseline was the primary outcome measure. Individual nasal symptom scores, quality of life, and study medication tolerability were the supplementary outcome measures.

Results: For this study, a total of 150 patients were enrolled and split into three groups. When it came to improving rhinorrhea, nasal congestion, TNSS, and AEC, DES and RUP were equally effective but considerably superior to KET (p=0.05). In terms of improving sneezing, nasal irritation, and quality of life, all medications were similarly beneficial, with no statistically significant intergroup difference. Because there were slightly fewer adverse events overall, RUP seemed to have greater tolerance.

Conclusion: Compared to KET, DES and RUP are more efficient and act more quickly. There were only a few minor, self-limiting, brief side effects that didn't require medical attention, and all of the research drugs were well tolerated.

Keywords: Desloratadine, Rupatadine, Ketotifen, Seasonal Allergic Rhinitis, TNSS, Rhinitis.

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Introduction

Inflammation of the nasal mucosa is called rhinorrhea. It typically manifests as at least two of the following symptoms: sneezing, running nose, blocked nose, and nose itching. Approximately 40% of people worldwide have rhinitis at least once. Both allergy and non-allergic rhinorrhea are possible. Non-allergic rhinitis can be brought on by an illness, a vasomotor imbalance, a medication, etc. One of the main causes of chronic rhinitis is allergic rhinitis, which is more prevalent than non-allergic rhinitis.[1,2] When a sensitized person's nasal mucosa is exposed to an allergen or allergens, IgE-mediated inflammation results, causing allergic rhinitis, a hypersensitivity condition. To be classified as allergic rhinitis, the aforementioned symptoms must be present for more than an hour

every day for a minimum of two weeks. Some patients may also experience related symptoms such lacrimation, eye irritation, anosmia, postnasal drip, or disrupted sleep.[3,4] Conjunctivitis, pharyngitis, sinusitis, asthma, nasal polyposis, otitis media, atopic dermatitis, lower respiratory tract infection, dental occlusion, eczema, lymphoid hyperplasia, and obstructive sleep apnea are just a few of the numerous complications that can accompany allergic rhinitis.[5–8] Each of these increases the patient's morbidity. Seasonal allergic rhinitis (SAR) affects between 09 and 42 percent of people worldwide at least once.[9] It is estimated that 20–30% of Indians have SAR.4 In India, the burden of SAR is growing. Compared to ten years ago, patients are now presenting with greater severity.[10] This should be a cause for concern because many cases go unnoticed and unreported, which frequently affects productivity at work or school and lowers quality of life.[11] SAR significantly affects patients' daily lives because of its bothersome symptoms and comorbidities.[12–15]

Material and Methods

Desloratadine, rupatadine, and ketotifen were compared in this prospective, randomized, three-arm, open-label research for SAR. From August 2025 to January 2026, the study was carried out in the ENT department of Anugrah Narayan Magadh Medical College and Hospital in Gayaji, Bihar. In accordance with our inclusion and exclusion criteria, patients with SAR who visited the ENT OPD department were chosen for this study. The ICH-GCP guidelines and the updated Declaration of Helsinki were followed in conducting this investigation. All participants provided written informed consent after being fully informed about the study's methodology in a language they could understand. People who were not involved in the study or the patient read the informed consent letter to patients who were illiterate. This study included patients with SAR who were between the ages of 18 and 65, had a total Nasal Symptom Score (TNSS) of at least 6, were willing to provide written informed permission, and were available. Patients with non-SAR conditions (such as persistent, vasomotor, infectious, or drug-induced rhinitis), those who had received any medication used to treat SAR within the previous two weeks, those receiving glucocorticoids and/or immunotherapy, those who were known to be hypersensitive to any of the study medications, women who were pregnant, nursing, or intended to become pregnant, those with chronic alcoholism, and those with liver dysfunction were not included in this study. Every patient was questioned about their past, current, and medication histories. Particular attention was paid to any history of allergies, and any exacerbating factors were noted. Both family and personal histories were recorded. The Total Nasal Symptom Score (TNSS), a subjective graded scoring system based on the intensity of nasal symptoms, was used to evaluate the severity of SAR symptoms.[16, 17] Pulse, blood pressure, breathing rate, and other vital signs were measured. At every visit, adverse effects were tracked during the clinical examination. Desloratadine (DES), rupatadine (RUP), and ketotifen (KET) were the three groups into which study participants were systematically randomized while maintaining comparable demographics in each group. Oral doses of desloratadine (10 mg OD), rupatadine (10 mg OD), and ketotifen (1 mg BD) were administered according to the designated group. Every drug was administered for four weeks. Patients who had previously taken any SAR medicine were given a 14-day wash-out period.

Every patient had a weekly follow-up during the four-week course of treatment. After entering the data into an Excel spreadsheet, the mean±SD of each parameter was computed independently for each of the three groups. For categorical data, the chi-square test was employed, and for numerical data, one-way ANOVA was utilized for group analysis. When the data was not normally distributed, the Wilcoxon signed-rank test, Friedman's test, and the Kruskal Wallis H test were employed. For statistical analysis, tables created with Microsoft Excel and SPSS were utilized.

Results

For this study, a total of 150 patients were enrolled, and they were split up into three groups of 50 patients each. The DES group's mean age was 28.6±7.93, the RUP group's was 30.7±10.49, and the KET group's was 29.64±9.03. There was no discernible age difference amongst the study groups, indicating a uniform distribution. There was no statistically significant variation in the gender distribution between the groups. [Table 1] While 26.66% (n=40) of the participants did not have any diurnal symptom exacerbations, the majority of individuals (n=93, 62%) experienced early morning exacerbations of SAR symptoms, and 17.33% (n=26) experienced evening exacerbations. At presentation, symptoms lasted an average of 5.25±2.07 days.

The average duration of SAR symptoms was 4.12±1.59 years. At presentation, the average number of symptoms was 4.46±0.59. There was no statistically significant variation in the TNSS score or average baseline nasal symptom scores among the study groups. In certain cases (n=38, 25.33%), the eosinophil count and AEC were elevated above the normal range. Three participants (n = 3, 2%) had hemoglobin levels less than 10%. [Table 1].

Table 1: Baseline demographics of three groups included patients

	Desloaratdine (n=50)	Rupatadine (n=50)	Ketotifen (n=50)
Mean age in years (%)	28.6±7.93	30.7±10.49	29.64±9.03
No. of females	29(58%)	24(48%)	23(46%)
Diurnal symptom variation*			
Early morning	29(58%)	35(70%)	29(58%)
Afternoon	00	00	02(04%)
Evening	13(26%)	11(22%)	02(04%)
Night	01(02%)	02(04%)	00
Nil	11(22%)	10(20%)	19(38%)
Duration of Symptoms (Days)	5.2±1.95	5.12±2.34	5.44±1.93
No. of Symptoms at Presentation	4.48±0.61	4.5±0.58	4.42±0.57
Severity of symptoms			
Rhinorrhea	1.94+0.31	1.96+0.45	1.90+0.36
Sneezing	1.80+0.45	1.74+0.53	1.72+0.45
Itching	1.24+0.43	1.16+0.37	1.16+0.37
Nasal congestion	1.86+0.50	1.92+0.53	1.90+0.46
TNSS	6.86±0.76	6.80±0.95	6.68±0.71
H/o SAR (years)	4.36±1.54	3.94±1.57	4.08±1.68
Eosinophill Count> 4%	14(28%)	13(26%)	11(22%)
Absolute eosinophil count> 440 cells/mm^3	14(28%)	13(26%)	11(22%)
Hb(<10gm%)	02(04%)	00	01(02%)

Rhinorrhea improved gradually and steadily in all three research groups. In the first two weeks, RUP improved rhinorrhea slightly more quickly than DES (p>0.05), but in the next two weeks, both RUP and DES demonstrated comparable improvements. Over the course of the four-week trial period, KET had a statistically significant (p=0.05) slower response than DES and RUP. Overall, DES and RUP improved rhinorrhea just as well as KET, but significantly better (p=0.05). Over the course of the four-week trial period, all three of the study drugs were successful in reducing sneeze. During the research period, KET responded to sneeze reduction somewhat more slowly than RUP and DES. RUP considerably outperformed KET in terms of reducing sneezing at week one (p=0.015). However, at the conclusion of the research, there was no statistically significant intergroup difference in the improvement of sneezing compared to baseline, and all medications were equally effective (p=0.368). There was no statistically significant difference in the effectiveness of the three trial drugs in reducing nasal irritation (p value=1.00). All three groups saw a slow and progressive improvement in nasal congestion over the course of the trial, with desloratadine and rupatadine outperforming ketotifen in terms of effectiveness and speed at every visit, with a statistically significant difference (p > 0.05). All three groups' mean TNSS increased steadily over the course of the trial, with DES and RUP outperforming KET in terms of effectiveness and speed with a statistically significant difference (p > 0.05) [Table 2].

Table 2: Change in nasal parameters and TNSS from baseline

Mean±SD						
	Baseline	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**P value (Kruskal–Wallis test)**
Rhinorrhea						
Desloratadine	1.94±0.31	0.72±0.54	0.16±0.37	0.1±0.22	0.02±0.15	0.05*
Rupatadine	1.96±0.45	0.56±0.67	0.16±0.42	0.04±0.2	0.04±0.2	
Ketotifen	1.9±0.36	0.94±0.37	0.76±0.52	0.22±0.42	0.15±0.30	
Sneezing						
Desloratadine	1.8±0.45	0.26±0.44	0.15±0.19	0.06±0.21	0.03±0.11	0.368
Rupatadine	1.74±0.53	0.16±0.42	0.04±0.2	0.02±0.14	0.02±0.14	
Ketotifen	1.72±0.45	0.36±0.49	0.16±0.24	0.1±0.32	0.04±0.12	
Nasal Itching						1.00
Desloratadine	1.24±0.43	0.18±0.24	0.08±0.14	0.0±0.0	0.0±0.0	
Rupatadine	1.16±0.37	0.1±0.31	0.02±0.1	0.0±0.0	0.0±0.0	
Ketotifen	1.16±0.42	0.14±0.24	0.04±0.11	0.04±0.11	0.0±0.0	
Nasal Congestion						

Desloratadine	1.86±0.5	0.82±0.56	0.42±0.54	0.06±0.24	0.02±0.14	
Rupatadine	1.92±0.53	0.78±0.68	0.34±0.56	0.04±0.2	0.06±0.24	0.0005*
Ketotifen	1.9±0.46	1.32±0.55	0.96±0.49	0.62±0.53	0.32±0.47	
TNSS						
Desloratadine	6.86±0.76	1.98±1.22	0.66±0.92	0.08±0.24	0.08±0.24	
Rupatadine	6.8±0.95	1.58±1.61	0.58±1.18	0.08±0.4	0.1±0.42	0.0005*
Ketotifen	6.68±0.713	2.66±0.92	1.8±0.93	0.84±0.80	0.62±0.67	

Table 3: Summary of the Treatment outcome at the end of the study period

Symptoms	**Desloratadine**		**Rupatadine**		**Ketotifen**		**P value (Lruskal-Walls test)**
	Change in score from baseline	**% Change from baseline**	**Change in score from baseline**	**% Change from baseline**	**Change in scorefrom baseline**	**% Change from baseline**	
	Mean+SD		Mean+SD		Mean+SD		
Rhinorrhea*	-1.92+0.31	98.96	-1.92+0.45	97.96	-1.75+0.36	92.10	0.05
Sneezing	-1.77+0.22	98.33	-1.72+0.53	98.85	-1.72+0.49	97.10	0.368
Itching	-1.24+0.41	100	-1.16+0.25	100	-1.16+0.37	100	1.000
Nasal congestion+	-1.84+0.5	98.92	-1.88+0.53	96.88	-1.5+0.58	83.16	0.0005
TNSS*	-6.82+0.77	98.83	-6.72+0.97	98.53	-6.06+0.94	90.71	0.0005

Table 4: Effect of study drugs on absolute eosinophil Count

Study Drugs	**Baseline (Mean±SD)**	**Visit 4 (Mean±SD)**	**P value (Wilcoxon Signed Rank Test)**
Desloratadine*	431.2±305	411±280	0.038
Rupatadinet	383.2±277	324.4±266	0.001
Ketotifen	400.6±313	385.8±296	0.055

Table 5: Adverse Effect

ADR	**Desloratadine n(%)**	**Rupatadine n(%)**	**Ketotifen n(%)**
No Adverse Effects	34(68%)	38(76%)	29(58%)
Somnolence	9(18%)	7(14%)	11(22%)
Headache	5(10%)	3(6%)	4(8%)
Fatigue	5(10%)	4(8%)	6(12%)
Dry mouth	2(4%)	-	5(10%)
Nausea	-	1(2%)	-
Dizziness	-	-	1(2%)

Discussion

The mean individual nasal symptom scores and mean TNSS showed a steady decline in the Desloratadine group (DES). Sneezing and nasal itching responded to DES more quickly than rhinorrhea or nasal congestion, which responded more slowly. The mean nasal symptom ratings of rhinorrhea (62.8%), sneezing (85.55%), nasal itching (85.48%), nasal congestion (55.91%), and the mean TNSS (71.14%) decreased at week 1 due to a good response to DES, which was statistically significant (p=0.0005). In comparison to baseline, the response to DES was gradual, progressive, and sustained for the following nasal symptoms: rhinorrhea (98.96%), sneezing (98.33%), nasal itching (100%), nasal congestion (98.92%), and TNSS (98.83%), which was statistically significant (p=0.0005). Our findings are consistent with comparative research and meta-analyses on DES, which show that by the end of three or four weeks of treatment, the severity of nasal symptoms has significantly decreased, ranging from 91% to 95%. [18, 19] DES 10mg OD was taken into consideration in our investigation because DES 5mg showed a shorter onset of action than RUP 10mg in a comparison study.[20]

The mean individual nasal symptom scores and mean TNSS showed a steady decline in the Rupatadine group (RUP). Nasal itching and sneezing in the RUP group responded more quickly than other nasal parameters, much like in the DES group. The mean nasal symptom ratings for rhinorrhea (71.4%), sneezing (90.8%), nasal itching (91.3%), nasal congestion (59.3%), and mean TNSS (76.7%) decreased at week 1 due to a favorable response to RUP, which was statistically significant (p=0.0005). In comparison to baseline, the response to RUP was slow, progressive, and persistent for the following symptoms: rhinorrhea (97.96%), sneezing (98.85%), nasal itching

(100%), nasal congestion (96.88%), and TNSS (98.53%), which was statistically significant (p = 0.0005). Our findings align with earlier research comparing RUP 10mg OD to loratadine 10mg, cetirizine 10mg, levocetirizine 10mg, ebastine 10mg, and desloratadine. A good efficacy profile of RUP 10mg over cetirizine, levocetirizine, and ebastine was reported by 5mg OD. On the other hand, RUP 10mg showed nasal symptom scores that were comparable to those of DES and loratadine.[20, 21–24]

The mean TNSS and mean individual nasal symptom scores showed a gradual decline in the Ketotifen group (KET). Sneezing and nasal itching responded to KET more quickly than nasal congestion or rhinorrhea. The mean nasal symptom ratings for rhinorrhea (50.52%), sneezing (79.06%), nasal itching (87.93%), nasal congestion (30.5%), and mean TNSS (60.17%) decreased at week one due to a positive reaction, which was statistically significant (p=0.0005). In comparison to baseline, the response to KET was gradual, progressive, and sustained for the following symptoms: rhinorrhea (92.10%), sneezing (97.67%), nasal itching (100%), nasal congestion (83.16%), and TNSS (90.71%), which was statistically significant (p = 0.0005).

Rhinorrhea improved gradually and steadily in all three research groups. In the first two weeks, RUP improved rhinorrhea slightly more quickly than DES (p>0.05), but in the next two weeks, both RUP and DES demonstrated comparable improvements. Over the course of the four-week trial period, KET had a statistically significant (p=0.05) slower response than DES and RUP. Overall, DES and RUP improved rhinorrhea just as well as KET, but significantly better (p=0.05). Over the course of the four-week trial period, all three of the study drugs were successful in reducing sneeze. During the research period, KET responded to sneeze reduction somewhat more slowly than RUP and DES. RUP considerably outperformed KET in terms of reducing sneezing at week one (p=0.015).

However, all of the medications were similarly effective by the end of the research (week 4), and there was no statistically significant intergroup difference in the improvement of sneezing compared to baseline (p=0.368).

There was no statistically significant difference in the improvement of nasal irritation between the three trial medicines. All three groups saw a slow and progressive improvement in nasal congestion throughout the course of the trial, with desloratadine and rupatadine outperforming ketotifen in terms of effectiveness and speed at every visit, with a statistically significant difference (p=0.0005). All three groups' mean TNSS increased steadily over the course of the trial, with DES and RUP outperforming KET in terms of effectiveness and speed with a statistically significant difference (p=0.0005).

DES and RUP were found to be significantly more effective than placebo in earlier meta-analyses.[21]. Lukat et al.'s direct comparison research between RUP 10 mg and DES 5 mg indicated no statistically significant difference between DES and RUP in terms of nasal symptom alleviation in SAR, and our investigation likewise produced comparable findings.[20]

Our study's finding that DES and RUP were equally effective is consistent with a meta-analysis of DES that found DES to be just as efficacious in AR/SAR as more recent second-generation antihistamines like levocetirizine and fexofenadine.[25] RUP was found to be much more effective than ebastine, cetirizine, and levocetirizine in a meta-analysis.[21] Oral KET has been utilized in AR/SAR in very few research, and no studies have compared oral KET with oral DES or RUP in AR/SAR. In children with perennial allergic rhinitis, Lai compared oral KET 1 mg BID with cetirizine 10 mg OD and found that cetirizine was significantly more effective than KET in reducing nasal symptoms. This information may corroborate our study's findings that DES and RUP outperformed KET.[26]

The absolute eosinophil count dropped from baseline and was statistically significant for DES (p=0.038) and RUP (p=0.001), but not for KET (p=0.055). DES was considerably inferior than RUP (p <0.05). Prior research evaluating the impact of RUP and DES on AEC reduction demonstrated that RUP was superior to DES and that RUP reduced AEC in a statistically meaningful way. Our investigation yielded similar findings.[21, 22, 27]

Conclusion

NSS and individual nasal symptom scores were significantly reduced by DES, RUP, and KET. When it comes to lowering the key outcome measure, TNSS, DES and RUP are comparatively more effective and faster acting than KET.

Similarly, when it comes to lowering rhinorrhea and nasal congestion scores, DES and RUP are comparatively more effective and faster acting than KET. When it comes to lowering AEC, RUP works better than DES and KET.

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