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COMPARATIVE EFFICACY OF INTRANASAL FLUTICASONE SPRAY VERSUS AZELASTINE SPRAY VERSUS FLUTICASONE AND AZELASTINE NASAL SPRAY IN TREATMENT OF ALLERGIC RHINITIS – A 3 ARM, RANDOMIZED CONTROLLED STUDY

Otorhinolaryngology

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ABSTRACT

Aim: To compare the effectiveness of fluticasone nasal spray, azelastine nasal spray, and their combination in the treatment of allergic rhinitis. Additionally, to assess changes in AEC and serum IgE levels, and the improvement in Total Nasal Symptom Score (TNSS) after 3 months of treatment. **Background:** Allergic rhinitis (AR) is a prevalent condition characterized by inflammation of the nasal mucosa due to an allergic response to environmental allergens. Allergic Rhinitis significantly impacts quality of life, causing symptoms such as nasal congestion, sneezing, rhinorrhea and itching. Despite various treatment options, the management of Allergic rhinits remains challenging, especially in cases with poor response to conventional therapies. **Methodology:** This hospital-based, randomized controlled prospective study included 60 allergic rhinitis patients. Serum IgE levels, AEC, and Total Nasal Symptom Score (TNSS) was assessed at baseline and after 3 months. Patients were randomly assigned to one of three groups:

1. Fluticasone nasal spray
2. Azelastine nasal spray
3. Combination of both

Results: In this study, The mean age for Group 1 is 32.45 ± 8.95 years, while Group 2 shows a mean age of 32.80 ± 11.31 years, and Group 3 records a mean age of 32.95 ± 11.00 years. When considering the total sample (N = 60), the overall mean age is 32.73 ± 10.30 years. The significant differences in all the three groups from start of treatment to 3 months shows that In Group 1, serum IgE levels decreased significantly by 246.60 ± 185.99 (p = 0.001), AEC levels reduced by 346.35 ± 242.45 (p = 0.001), and TNSS improved markedly with a decrease of 1.75 ± 0.72 (p = 0.001). Similarly, Group 2 showed significant reductions, with serum IgE levels decreasing by 95.35 ± 130.40 (p = 0.004), AEC levels dropping by 146.70 ± 160.47 (p = 0.001), and TNSS improving by 0.65 ± 0.81 (p = 0.002). In Group 3, the improvements were also statistically significant, with serum IgE levels decreasing by 195.75 ± 231.60 (p = 0.001), AEC levels reducing by 321.75 ± 239.73 (p = 0.001), and TNSS showing the greatest improvement, with a decrease of 2.00 ± 0.65 (p = 0.001). **Conclusion:** This study aims to evaluate and compare the effectiveness of fluticasone nasal spray, azelastine nasal spray, and their combination in the management of allergic rhinitis. By assessing changes in serum IgE, AEC levels, and Total Nasal Symptom Score (TNSS) over a 3-month period, the results will provide valuable insights into the optimal treatment approach for patients with allergic rhinitis

KEYWORDS

Allergic Rhinitis, IgE, Total Nasal Symptom Score

INTRODUCTION

Allergic rhinitis (AR) is a common inflammatory condition of the nasal mucosa caused by an immunoglobulin E (IgE)-mediated hypersensitivity reaction to allergens such as pollen, dust mites, and pet dander[1]. It is characterized by symptoms like nasal congestion, rhinorrhea, sneezing, and nasal itching, significantly impacting the quality of life and productivity of affected individuals [2]. Intranasal corticosteroids (INCS) and antihistamines are the cornerstone of AR management. Fluticasone, a second-generation corticosteroid, is widely used for its potent anti-inflammatory properties, reducing nasal congestion and inflammation[3,4]. Azelastine, a second-generation intranasal antihistamine, provides rapid relief by blocking histamine receptors and exerting anti-inflammatory effects [5].

Recent studies suggest that combining intranasal corticosteroids and antihistamines may offer superior efficacy compared to monotherapy. The combination of fluticasone and azelastine may provide enhanced symptom control due to their complementary mechanisms of action. However, direct comparisons of their efficacy in allergic rhinitis are limited[6,7].

This study aims to evaluate and compare the efficacy of fluticasone nasal spray, azelastine nasal spray, and their combination in the management of allergic rhinitis, assessing improvements in symptom severity, patient-reported outcomes, and potential adverse effects. The findings will contribute to optimizing treatment strategies for allergic rhinitis and improving patient care[8,9].

MATERIALS AND METHODS

This hospital-based, randomized controlled prospective study was conducted in Department of ENT, S Nijalingappa Medical college. The participants included 60 allergic rhinitis patients. After a detailed history and ENT examination, diagnostic nasal endoscopy was done to rule out other conditions. Serum IgE levels, AEC, and Total Nasal Symptom Score (TNSS) was assessed at baseline and after 3 months. Patients were randomly assigned to one of three groups:

1. Fluticasone nasal spray
2. Azelastine nasal spray
3. Combination of both

The treatment lasted 3 months, and outcomes were compared across groups.

Inclusion Criteria–

1. All the patient between age group 15-75years with complaints of sneezing, rhinorrhoea, headache, nasal block with or without inferior turbinate hypertrophy
2. Patient giving consent for the study

Exclusion Criteria –

1. Patients with age less than 15 years or more than 75 years
2. Anatomic defect of nose like marked Deviation of nasal septum
3. Chronic respiratory illness
4. Nasal polyps
5. Recent nasal surgeries
6. Nasal mass
7. Sinusitis patients
8. Patients not giving consent for the study

Parameters Assessed

- Serum IgE levels
- AEC
- TNSS

RESULTS

Data was entered into Microsoft Excel spreadsheet and was checked for any discrepancies. Summarized data was presented using Tables and Graphs. The data was analysed by SPSS (21.0 version, Amork, NY USA). Shapiro Wilk test was used to check which all variables were

following normal distribution. Data was normally distributed therefore, inferential statistics were performed using the parametric test. For Intergroup comparison, one way ANOVA was used followed by post hoc tukeys test for pairwise comparison. Paired t test was used for intragroup comparison. Level of statistical significance was set at p-value less than 0.05

Table 1 presents the mean age, standard deviation, and sample size for three groups evaluated in this study. The mean age for Group 1 is 32.45 ± 8.95 years, while Group 2 shows a mean age of 32.80 ± 11.31 years, and Group 3 records a mean age of 32.95 ± 11.00 years. When considering the total sample (N = 60), the overall mean age is 32.73 ± 10.30 years.

Table 1: Mean Age

GROUP	Mean	N	Std. Deviation
GROUP 1	32.45	20	8.953
GROUP 2	32.80	20	11.312
GROUP 3	32.95	20	11.000
Total	32.73	60	10.297

Table 2 illustrates the gender distribution across the three groups in the study. In Group 1, there are 6 females (30.0%) and 14 males (70.0%), making a total of 20 participants. Group 2 has a higher proportion of females, with 12 females (60.0%) and 8 males (40.0%). In Group 3, the distribution is more balanced, with 9 females (45.0%) and 11 males (55.0%).

Table 2: Gender Wise Distribution

			GENDER		Total
			F	M	
GROUP	GROUP 1	N	6	14	20
		%	30.0%	70.0%	100.0%
	GROUP 2	N	12	8	20
		%	60.0%	40.0%	100.0%
	GROUP 3	N	9	11	20
		%	45.0%	55.0%	100.0%
Total		N	27	33	60
		%	45.0%	55.0%	100.0%

Table 3 provides a comparative analysis of serum IgE levels, absolute eosinophil count (AEC) levels, and total nasal symptom scores (TNSS) at baseline across three groups.

For serum IgE levels, Group 1 recorded a mean value of 493.60 ± 277.94, while Group 2 had a mean of 407.25 ± 254.07, and Group 3 reported a mean of 442.00 ± 324.07. The differences in IgE levels among the groups were not statistically significant (p = 0.634).

Regarding AEC levels, Group 1 showed a mean of 582.15 ± 273.20, Group 2 had a higher mean of 652.65 ± 482.18, and Group 3 demonstrated a mean of 577.45 ± 254.09. The p-value for AEC levels was 0.752, indicating no significant difference between the groups.

For the total nasal symptom score (TNSS), Group 1 had a mean score of 2.40 ± 0.50, Group 2 recorded 2.45 ± 0.61, and Group 3 reported 2.30 ± 0.47. The comparison of TNSS across the groups also showed no significant difference (p = 0.661).

Table 3: Intergroup Comparison of Serum IGE, ACE and Total Nasal Symptom Score at Baseline

		Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		P Value
					Lower Bound	Upper Bound	
Serum IGE Level	Group 1	493.60	277.937	62.149	363.52	623.68	0.634
	Group 2	407.25	254.070	56.812	288.34	526.16	
	Group 3	442.00	324.069	72.464	290.33	593.67	
AEC Levels	Group 1	582.15	273.203	61.090	454.29	710.01	0.752
	Group 2	652.65	482.179	107.818	426.98	878.32	
	Group 3	577.45	254.089	56.816	458.53	696.37	
Total Nasal Symptom Score	Group 1	2.40	.503	.112	2.16	2.64	0.661
	Group 2	2.45	.605	.135	2.17	2.73	
	Group 3	2.30	.470	.105	2.08	2.52	

Interpretation of Table 4

Table 4 presents the intergroup comparison of serum IgE levels, absolute eosinophil count (AEC) levels, and total nasal symptom scores (TNSS) at the 3-month follow-up.

For serum IgE levels, no statistically significant difference was observed among the groups (p = 0.333). Group 1 recorded a mean IgE level of 247.00 ± 131.86, Group 2 had 311.90 ± 180.24, and Group 3 reported 246.25 ± 161.98.

In contrast, a statistically significant difference was found in AEC levels (p = 0.001). Group 2 had the highest AEC levels, with a mean of 505.95 ± 362.66, which was significantly higher than both Group 1 (235.80 ± 98.05) and Group 3 (255.70 ± 131.05), as indicated by post hoc analysis (2 > 3,1).

Similarly, a significant difference was observed in TNSS (p = 0.001). Group 2 exhibited the highest symptom scores, with a mean of 1.80 ± 0.70, which was significantly greater than Group 1 (0.65 ± 0.49) and Group 3 (0.30 ± 0.47) based on post hoc analysis (2 > 3,1).

Table 4: Intergroup Comparison of Serum IGE, ACE and Total Nasal Symptom Score at 3 Months

		Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		P Value	Post hoc
					Lower Bound	Upper Bound		
SERUM IGE LEVEL	GROUP 1	247.00	131.855	29.484	185.29	308.71	0.333	-
	GROUP 2	311.90	180.239	40.303	227.55	396.25		
	GROUP 3	246.25	161.984	36.221	170.44	322.06		
AEC LEVELS	GROUP 1	235.80	98.047	21.924	189.91	281.69	0.001	2>3,1
	GROUP 2	505.95	362.664	81.094	336.22	675.68		
	GROUP 3	255.70	131.050	29.304	194.37	317.03		
TOTAL NASAL SYMPTOM SCORE	GROUP 1	.65	.489	.109	.42	.88	0.001	2>3,1
	GROUP 2	1.80	.696	.156	1.47	2.13		
	GROUP 3	.30	.470	.105	.08	.52		

Table 5 highlights the significant intragroup reductions in serum IgE levels, absolute eosinophil count (AEC) levels, and total nasal symptom scores (TNSS) from baseline to 3 months across all three groups.

In Group 1, serum IgE levels decreased significantly by 246.60 ± 185.99 (p = 0.001), AEC levels reduced by 346.35 ± 242.45 (p = 0.001), and TNSS improved markedly with a decrease of 1.75 ± 0.72 (p = 0.001). Similarly, Group 2 showed significant reductions, with serum IgE levels decreasing by 95.35 ± 130.40 (p = 0.004), AEC levels dropping by 146.70 ± 160.47 (p = 0.001), and TNSS improving by 0.65 ± 0.81 (p = 0.002). In Group 3, the improvements were also statistically significant, with serum IgE levels decreasing by 195.75 ± 231.60 (p = 0.001), AEC levels reducing by 321.75 ± 239.73 (p = 0.001), and TNSS showing the greatest improvement, with a decrease of 2.00 ± 0.65 (p = 0.001).

Table 5: Intragroup Comparison of Serum IGE, AEC and Total Nasal Symptom Score (from Baseline to 3 Months)

DIFFERENCE FROM BASELINE TO 3 MONTHS		Paired Differences					t	df	P Value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
GROUP 1	SERUM IGE LEVEL	246.600	185.990	41.589	159.554	333.646	5.930	19	.001*
	AEC LEVEL	346.350	242.449	54.213	232.880	459.820	6.389	19	.001*

	TOTAL NASAL SYMPTOM SCORE	1.750	.716	.160	1.415	2.085	10.925	19	.001*
GROUP 2	SERUM IGE LEVEL	95.350	130.398	29.158	34.322	156.378	3.270	19	.004*
	AEC LEVEL	146.700	160.472	35.883	71.597	221.803	4.088	19	.001*
	TOTAL NASAL SYMPTOM SCORE	.650	.813	.182	.270	1.030	3.577	19	.002*
GROUP 3	SERUM IGE LEVEL	195.750	231.603	51.788	87.357	304.143	3.780	19	.001*
	AEC LEVEL	321.750	239.725	53.604	209.555	433.945	6.002	19	.001*
	TOTAL NASAL SYMPTOM SCORE	2.000	.649	.145	1.696	2.304	13.784	19	.001*

DISCUSSION

This study compared the efficacy of fluticasone nasal spray, azelastine nasal spray, and their combination in allergic rhinitis over a 3-month period. The findings suggest that while all three treatments significantly improved allergic rhinitis symptoms, the combination therapy of fluticasone + azelastine (Group 3) demonstrated superior efficacy.

Reduction in Serum IgE Levels- Serum IgE levels significantly declined in all groups, indicating that each treatment effectively reduced the allergic response. However, the greatest reduction was observed in Group 1 (Fluticasone) and Group 3 (Combination therapy), suggesting that corticosteroids play a primary role in lowering IgE levels.

Reduction in Absolute Eosinophil Count (AEC)- AEC levels also significantly decreased in all groups, with the most substantial reductions seen in Group 1 and Group 3. Group 2 (Azelastine) showed the least reduction, suggesting that while antihistamines may alleviate symptoms, corticosteroids have a stronger anti-inflammatory effect in reducing eosinophil levels.

Improvement in Total Nasal Symptom Score (TNSS)- The TNSS improved in all groups, but the greatest symptom relief was seen in Group 3 (Combination therapy), followed by Group 1 (Fluticasone) and then Group 2 (Azelastine). The statistically significant differences suggest that the combination of fluticasone and azelastine provides a synergistic effect, offering better symptom control than either agent alone.

Clinical Implications

- Fluticasone alone is effective in reducing inflammatory markers and symptoms but does not provide the rapid relief of antihistamines.
- Azelastine alone is beneficial for immediate symptom relief but lacks the long-term anti-inflammatory effects of corticosteroids.
- Combination therapy (Fluticasone + Azelastine) provides the most comprehensive benefit, improving both inflammatory markers and symptom scores more effectively than monotherapy.

Limitations and Future Directions

While this study provides valuable insights into the comparative efficacy of these treatments, some limitations should be considered:

1. The sample size was relatively small (N=60), warranting larger-scale studies for more generalizable results.
2. The study duration was limited to 3 months, and long-term effects remain unknown.
3. Patient adherence and variations in allergen exposure were not controlled, which could influence symptom outcomes.

CONCLUSION

This study demonstrated that all three treatment modalities—fluticasone nasal spray, azelastine nasal spray, and their combination—are effective in managing allergic rhinitis. However, the combination therapy of fluticasone and azelastine provided the most significant improvement in allergic symptoms, as reflected in total nasal symptom scores (TNSS), absolute eosinophil count (AEC), and serum IgE levels over a 3-month period.

Fluticasone alone effectively reduced inflammation and allergic markers, making it a strong standalone option. Azelastine alone provided symptom relief but had a lesser impact on inflammatory markers compared to fluticasone. Fluticasone + Azelastine combination therapy resulted in the greatest overall improvement, suggesting a synergistic effect.

Given the superior outcomes observed with combination therapy, this approach should be considered for patients with moderate to severe allergic rhinitis, particularly those requiring both rapid symptom relief and long-term inflammation control. Further research is warranted to evaluate its long-term safety, cost-effectiveness, and impact on quality of life in broader patient populations.

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