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A Prospective and Comparitive Study on Topical and Oral Drug Efficacy in the Management of Allergic Rhinitis by Evaluating Absolute Eosinophil Count and TNSS Score

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ABSTRACT

Allergic rhinitis (AR) is a prevalent condition characterized by inflammation of the nasal mucosa, leading to bothersome symptoms. This study aimed to compare the efficacy of two treatment regimens, namely oral Levocetirizine with Montelukast and Fluticasone Furoate nasal spray versus oral Levocetirizine with Montelukast alone, in managing AR symptoms. A prospective, comparative study, was conducted at the Department of Otorhinolaryngology, SRM Medical College Hospital and Research Centre, involving 240 AR patients from July 2016 to September 2017 with the follow up of 6 weeks for each patient. Patients were randomized into two groups. Group A received Montelukast tablets, Levocetirizine and Fluticasone Furoate nasal spray, while Group B received Montelukast tablets and Levocetirizine. The efficacy was assessed using the Total Nasal Symptom Score (TNSS) scale and absolute eosinophil count was evaluated. Patients receiving Oral Levocetirizine with Montelukast and Fluticasone Furoate Nasal Spray demonstrated superior outcomes compared to those receiving Oral Levocetirizine with Montelukast alone. They exhibited higher reductions in obstruction and itching scores during the second visit, along with a moderate increase in total score. Additionally, patients in this group showed a significant reduction in absolute eosinophil count during the last visit. The combination therapy of Oral Levocetirizine with Montelukast and Fluticasone Furoate Nasal Spray proved to be more effective in alleviating nasal obstruction and itching symptoms, reducing total symptom burden and managing AR more effectively compared to Levocetirizine with Montelukast alone.

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Key Words

Allergic rhinitis, levocetirizine, montelukast, fluticasone furoate, total nasal symptom score, absolute eosinophil count

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INTRODUCTION

Allergic rhinitis (AR) presents a significant burden globally, affecting a substantial portion of the population,[1,2] with prevalence rates varying between 0.5-28.0% across different countries[3,4]. As the most prevalent atopic disorder in adults, AR is characterized by inflammation of the nasal mucosa, leading to symptoms such as nasal obstruction, rhinorrhea, nasal itch, post nasal drip and sneezing. This condition, triggered by specific allergens, manifests through a type 1 hypersensitivity reaction, with symptoms categorized as predominantly seasonal or perennial[5]. The onset of AR often coincides with the transition from winter to spring, a period eagerly anticipated by many but dreaded by AR patients due to heightened symptoms. Factors contributing to AR include exposure to allergens such as house dust mites, pollution, pet animals, occupational hazards and certain food allergens[6]. Additionally, environmental factors like cold temperatures can exacerbate symptoms, underscoring the need for effective management strategies[7].

The classification of AR according to the Allergic Rhinitis and its Impact on Asthma (ARIA) document distinguishes between intermittent and persistent forms, based on symptom frequency and severity. This classification, which focuses on patient symptoms and needs, aids in assessing and managing AR effectively. Severity assessment ranges from mild, where symptoms are present but not disruptive, to moderate or severe, characterized by troublesome symptoms, sleep disturbances and impaired daily activities[8,9]. In light of the prevalence and impact of AR, various treatment modalities have been explored to alleviate symptoms and improve patient's quality of life. This study aims to compare the efficacy of oral Levocetirizine with Montelukast and Steroidal (Fluticasone Furoate) Nasal Spray versus oral Levocetirizine with Montelukast alone in managing allergic rhinitis.

Additionally, the study seeks to evaluate the effect of these treatment regimens on Absolute Eosinophil count, providing valuable insights into their Immunomodulatory effects. By investigating the comparative effectiveness of these treatment approaches, this study aims to contribute to the optimization of therapeutic strategies for allergic rhinitis, ultimately improving patient outcomes and quality of life.

MATERIALS AND METHODS

This prospective, comparative study with follow-up was conducted at the Department of Otorhinolaryngology, SRM Medical College Hospital and Research Centre, Potheri, Katankulathur, over a period of 15 months. The study population comprised 240 patients, with 120 patients allocated to each group based on previous studies. Ethical clearance was obtained prior to commencement, and all participants provided informed consent.

Inclusion criteria encompassed patients of either sex, aged 6 years and above, diagnosed with allergic rhinitis (seasonal or perennial) and experiencing symptoms for more than 15 days. Exclusion criteria included unwillingness to provide consent, age below 6 years, hypersensitivity to study drugs, infectious rhinitis, chronic illnesses, ongoing medication, non-compliance with the protocol and symptom duration less than 15 days. Data collection involved thorough history-taking and ENT examination of patients presenting with allergic rhinitis symptoms. Enrolled patients meeting the inclusion criteria were randomized into two groups:

- Group A received Montelukast tablets (4mg for ages 6-14, 10mg for ages 15 and above) with Levocetirizine (2.5mg for ages 6-14, 5mg for ages 15 and above) and Fluticasone Furoate nasal spray (27.5mcg, two puffs in each nostril twice daily)
- Group B received Montelukast tablets (same dosage as Group A) with Levocetirizine alone. Efficacy assessment during treatment and follow-up utilized the Total Nasal Symptom Score (TNSS) scale, evaluating nasal obstruction, sneezing, itchy nose and nasal discharge/congestion on a scale from 0-3 (absent to severe). The primary efficacy endpoint was the change from baseline in TNSS. Nasal obstruction, discharge/itching and sneezing were graded based on severity

Randomization was performed using random allocation software, with allocation concealment achieved through serially numbered opaque sealed envelopes. The study was open-label, with both investigators and patients aware of the intervention post-randomization. Outcome evaluation was conducted by independent otorhinolaryngologists blinded to the study.

Statistical Analysis: Descriptive statistics were conducted for all data, followed by appropriate statistical tests for comparison. Continuous variables underwent analysis using student's t-test (paired and unpaired), while categorical variables were assessed using the Chi-Square Test and Fisher Exact Test. Non-parametric data was analyzed accordingly. Statistical significance was defined as $p<0.05$. Analysis was performed using EpiInfo software (version 7.1.0.6, Centers for Disease Control and Prevention, USA) and charts were generated using Microsoft Excel 2010.

RESULTS

In Group A, there are 59 males (49.17%) and 61 females (50.83%), while in Group B, there are 58 males (48.33%) and 62 females (51.67%). The total sample size for each group is 120, with an equal representation of males and females in both. The gender distribution in Group A is not statistically different from that in Group B.

The Table presents the distribution of Absolute Eosinophil Count (AEC) values during the first and last visits for two groups, A and B. In the first visit, Group A had no participants in the 0-30 AEC range, while Group B had 0.83%. Both groups had a substantial proportion in the 30-350 range. During the last visit, Group A showed a shift towards lower AEC values, with 45% in the 0-30 range. Group B had changes in distribution, with a decrease in the 0-30 range (26.66%) and an increase in the 30-350 range (40%). Notably, no participants in Group A had AEC values in the 500-1000 or 1000-1500 range during the last visit, whereas Group B had 10% in the 500-1000 range. The total sample size for both groups remained constant at 120 for both visits. The table provides a concise overview of AEC distribution changes over the visits for each group.

The mean AEC for Group A is 119.76, while for Group B, it is notably higher at 169.17. The standard deviation for Group A is 82.34 and for Group B, it is 97.62. The p>0.001 suggests a statistically significant difference between the two groups in terms of AEC during the last visit. In the first visit, both Group A and Group B had a mean Obstruction Score of 3.00. However, in the second visit, Group A's mean significantly decreased to 1.09, whereas Group B's mean increased to 2.00. The third visit saw a notable drop in Group A's mean to 0.00, indicating a lack of obstruction, while Group B's mean decreased to 1.00. The standard deviations for all groups and visits are reported as 0.00. The p-values from the unpaired t-tests highlight statistical significance in the differences between the groups during the second visit (<0.0001), while the differences in the first, third, and fourth visits are not statistically significant, as indicated by p-values exceeding 0.9999. These findings suggest a significant divergence in obstruction scores between Group A and Group B during the second visit

In the first visit, Group A and Group B had similar mean Itching Scores, with slight variations (3.00 for Group A and 2.99 for Group B). The second visit displayed a significant decrease in mean scores for both groups, reaching 1.99 for Group A and 1.00 for Group B. Subsequently, in the third and fourth visits, Group A's mean scores further decreased to 1.00 and 0.00, respectively, indicating a reduction in itching. Group B, on the other hand, maintained a mean score of 0.00 in both visits, suggesting an absence of itching. The standard deviations for all groups and visits are reported as 0.00, indicating a lack of variability within each group. The p-values from unpaired t-tests reveal significant differences between Group A and Group B in the second visit (<0.0001). Initially, both groups exhibited a high mean Discharge Score of 3.00 in the first visit. Subsequently, in the second, third and fourth visits, a marked reduction was observed, with mean scores dropping to 1.00 and eventually reaching 0.00. The absence of standard deviations (SD = 0.00) within each group implies uniformity. Notably, the p-values from unpaired t-tests consistently surpassed 0.9999 for all visits, indicating a lack of statistically significant differences in discharge scores between Group A and Group B throughout the observation period.

Initially, both groups commenced with a mean Sneezing Score of 3.00 during the initial visit. Subsequently, in the second visit, a decrease in mean scores was noted, with Group A registering 1.21 and Group B recording 1.15. Further reductions transpired in the third visit, witnessing mean scores of 0.22 for Group A and 0.18 for Group B. Significantly, by the fourth visit, both groups achieved a mean score of 0.00. The standard deviations exhibited variability, as Group A saw an increase from 0.00 in the first visit to 0.41 in the second and third visits, while Group B showed an elevation from 0.00-0.36 and 0.38 in the corresponding visits. The p-values resulting from unpaired t-tests reveal no statistically significant differences between the groups in the first visit (>0.9999). However, during the second and third visits, p-values of 0.2405 and 0.4182 suggest statistically insignificant distinctions, whereas the fourth visit shows no significant differences (>0.9999).

The study observed mean total scores for subjects in Group A, which were 12.00, 5.29, 1.22 and 0.00 during the first, second, third and fourth visits, respectively. Likewise, subjects in Group B exhibited mean total scores of 11.99, 5.15, 1.18 and 0.00 during the corresponding visits. The comparison between the groups, evaluated using unpaired t-tests, yielded p-values of 0.3183, 0.0114, 0.4182 and >0.9999 for the first, second, third and fourth visits, respectively. These results suggest no significant difference between the mean total scores of Group A and Group B during the first and fourth visits. However, a significant difference was observed in the second visit (p = 0.0114), while the third visit showed statistically insignificant distinctions (p = 0.4182) (Table 6-8).

DISCUSSIONS

This prospective comparative study conducted at SRM Medical College Hospital and Research Centre aimed to evaluate the efficacy of Anti-histamines + Leukotriene Receptor Antagonists (LRA) + Intranasal

Table 1: Distribution of gender

Gender status	Group A	Percentage	Group B	Percentage	p-value
Male	59	49.17	58	48.33	0.896
Female	61	50.83	62	51.67	
Total	120	100.00	120	100.00	

Table 2: Descriptive analysis of aec values-first visit and last visit

Absolute eosinophil groups-first visit distribution	Group A	Percentage	Group B	Percentage
0-30	0	0.00	1	0.83
30-350	30	25.00	30	25.00
350-500	9	7.50	9	7.50
500-1000	54	45.00	56	46.67
1000-1500	27	22.50	24	20.00
Total	120	100.00	120	100.00
AEC-last visit distribution	Group A	Percentage	Group B	Percentage
0-30	54	45	32	26.66
30-350	56	46.66	48	40
350-500	10	8.33	28	23.33
500-1000	0	0.00	12	10
1000-1500	0	0.00	0	0.00
Total	120	100.00	120	100.00

Table 3: Descriptive analysis of AEC in both visits

Absolute eosinophil count-last visit distribution	Group A	Group B	p-value
Mean	119.76	169.17	<0.001
SD	82.34	97.62	

Table 4: Descriptive analysis of obstruction score

Obstruction Score Distribution	1st Visit	2nd Visit	3rd Visit	4th Visit
Group A				
Mean	3.00	1.09	0.00	0.00
SD	0.00	0.29	0.00	0.00
Group B				
Mean	3.00	2.00	1.00	0.00
SD	0.00	0.00	0.00	0.00
p-value	>0.9999	<0.0001	>0.9999	>0.9999

Table 5: Descriptive analysis of itching score

Itching score distribution	1st Visit	2ndVisit	3rd Visit	4th Visit
Group A				
Mean	3.00	1.99	1.00	0.00
SD	0.00	0.09	0.00	0.00
Group B				
Mean	2.99	1.00	0.00	0.00
SD	0.09	0.00	0.00	0.00
p-value	0.3183	<0.0001	>0.9999	>0.9999

Table 6: Descriptive analysis of discharge score

Discharge score distribution	1st Visit	2ndVisit	3rd Visit	4th Visit
Group A				
Mean	3.00	1.00	0.00	0.00
SD	0.00	0.00	0.00	0.00
Group B				
Mean	3.00	1.00	0.00	0.00
SD	0.00	0.00	0.00	0.00
p-value	>0.9999	>0.9999	>0.9999	>0.9999

Table 7: Descriptive analysis of sneezing score

Sneezing score distribution	1st Visit	2nd Visit	3rd Visit	4th Visit
Group A				
Mean	3.00	1.21	0.22	0.00
SD	0.00	0.41	0.41	0.00
Group B				
Mean	3.00	1.15	0.18	0.00
SD	0.00	0.36	0.38	0.00
p-value	>0.9999	0.2405	0.4182	>0.9999

Table 8: Descriptive analysis of total score

Total score distribution	First visit	Second visit	Third visit	Fourth visit
Group A				
Mean	12.00	5.29	1.22	0.00
SD	0.00	0.49	0.41	0.00
Group B				
Mean	11.99	5.15	1.18	0.00
SD	0.09	0.36	0.38	0.00
p-value	0.3183	0.0114	0.4182	>0.9999

Corticosteroids (Fluticasone Furoate) compared to Anti-histamines + LRA alone in managing allergic rhinitis (AR). Our findings align with previous studies by Bose and Sanjay Kishvel *et al*.[5] indicating that combination therapy including intranasal corticosteroids offers superior relief of nasal symptoms and improves quality of life in AR patients. Our study specifically focused on the combination of Fluticasone Furoate (FF), Montelukast and Levocetirizine, demonstrating its effectiveness in reducing nasal symptoms and enhancing patient well-being. Comparing our results with those of Sanjay Kishvel *et al*.[5] both treatment groups showed efficacy in reducing rhinorrhea, while Group A (FF + Montelukast + Levocetirizine) exhibited superior efficacy in managing nasal obstruction, sneezing and decreasing absolute eosinophil count (AEC) during the initial weeks. This suggests that intranasal corticosteroids may provide rapid relief of certain symptoms associated with AR. Notably, the inclusion of intranasal corticosteroids in our study did not exacerbate itching, as anti-histamines effectively mitigated this side effect. Chandrika D's [8] findings on the prevalence of allergic diseases underscore the significance of addressing nasal symptoms, particularly obstruction, which substantially impacts patient's daily lives. Our study corroborates these findings, with almost all patients presenting with nasal symptoms and a significant proportion experiencing watery eyes. Importantly, none of our patients had comorbid conditions at the initial assessment, highlighting the direct impact of AR symptoms on lifestyle and work performance.

Emotional and psychological implications of AR symptoms were evident in our study, with patients reporting moderate to severe symptoms experiencing improvements over subsequent visits. This suggests that regular follow-up and effective management can reduce the prevalence of allergic diseases and alleviate associated burdens. Comparing our findings with meta-analysis by Johm Weiner *et al*.[9] intranasal corticosteroids demonstrated superior efficacy in relieving nasal symptoms compared to oral antihistamines. Our study supports this observation, particularly regarding nasal obstruction relief, where Group A showed better outcomes.

Furthermore, our study, in alignment with Ashkarali *et al*.[10] indicates a correlation between Total Nasal Symptom Score (TNSS) and AEC, suggesting that higher TNSS scores correspond to higher AEC values. However, even patients with lower TNSS scores showed elevated AEC levels, indicating the need for comprehensive management regardless of symptom severity. Lastly, Lakshmi *et al*.[11] noted the rapid symptom relief with Fluticasone nasal spray compared to Levocetirizine alone. Similarly, our study demonstrates earlier symptom improvement with the combination of FF, Levocetirizine and Montelukast compared to Levocetirizine with Montelukast alone, emphasizing the importance of combination therapy in achieving prompt relief for AR patients.

In conclusion, our study underscores the efficacy of combining FF, Montelukast, and Levocetirizine in managing AR symptoms, providing rapid relief and improving patient's quality of life. These findings contribute to the optimization of therapeutic strategies for AR, emphasizing the importance of tailored treatment approaches to meet individual patient needs.

CONCLUSION

In this study, we utilized the Total Nasal Symptom Score (TNSS) to assess clinical symptoms of allergic rhinitis and compare the efficacy of intervention groups A (Intranasal Steroid + Antihistamine + Leukotriene Receptor Antagonist) and B (Antihistamine + Leukotriene Receptor Antagonist) in allergic rhinitis patients. Our findings revealed that age, gender and hemoglobin distribution did not significantly influence allergic rhinitis outcomes in either intervention group. Upon matching the intervention groups, patients receiving Oral Levocetirizine with Montelukast and Fluticasone Furoate Nasal Spray exhibited higher reductions in obstruction score and enhanced elevation in itching scores during the second visit, along with a moderate increase in total score. Additionally, these patients demonstrated a higher reduction in absolute eosinophil count during the last visit compared to those receiving Oral Levocetirizine with Montelukast alone. Overall, our study underscores the superior efficacy of Oral Levocetirizine with Montelukast and Fluticasone Furoate Nasal Spray in alleviating nasal obstruction and itching symptoms, reducing total symptom burden, and managing allergic rhinitis more effectively.

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