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COMPARISON OF FLUTICASONE NASAL SPRAY AND ORAL MONTELUKAST FOR THE TREATMENT OF SEASONAL ALLERGIC RHINITIS IN CHILDREN 8 YEARS TO 15 YEARS OF AGE

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Abstract

Background: *Seasonal allergic rhinitis (SAR) is a common condition in children, characterized by inflammation of the nasal mucosa due to allergens, leading to symptoms such as sneezing, rhinorrhea, nasal congestion, and itchy eyes. Effective management is essential to improve children's quality of life.*

Objective: *This study aimed to compare the efficacy of fluticasone nasal spray and oral montelukast in treating SAR in children aged 8 to 15 years.*

Study Design: *A randomized controlled trial.*

Study Setting: *The research was carried out at Sialkot Medical College, Sialkot from 2 August 2024 to 2 February 2025.*

Methodology: *A total of 60 children diagnosed with SAR were enrolled in the study after obtaining informed consent from their parents. Participants were randomly assigned to two groups: Group A received fluticasone propionate nasal spray (100 micrograms in each nostril once daily), while Group B received oral montelukast tablets (5 mg daily in the evening) for four weeks. Symptom severity was assessed using a scoring system that evaluated sneezing, rhinorrhea, nasal congestion, and other related symptoms. Data were collected at baseline and after four weeks of treatment, and statistical analysis was performed using SPSS software to compare the mean differences in nasal scores between the two groups.*

Results: *A majority of participants were male 36 (60%) and 24 females (40.0%), Fluticasone Nasal Spray demonstrated significantly greater efficacy than Montelukast, with 80% of participants in the Fluticasone group showing symptom improvement compared to 60% in the Montelukast group (p=0.035). Subgroup analysis showed no significant differences in efficacy*

based on age or gender, but a significant difference was observed in patients with severe initial clinical scores (p=0.029).

Conclusion: *Our study demonstrates that Fluticasone Nasal Spray is significantly more effective than Montelukast in relieving symptoms of Seasonal Allergic Rhinitis in children. The findings support the use of Fluticasone as a preferred treatment option for managing SAR in this population.*

INTRODUCTION

Allergic rhinitis (AR) is a worldwide health related chronic non-communicable disorder which effect on 10-20% of entire population, approximately 400 million people worldwide, hence causing AR to be the one of the most prevalent diseases. The economic impact of AR is significantly high and the direct and indirect financial burden should not be underrated.[1] Making $5.3 billion decline in total productivity per year in US. AR frequency in children is up to 40%, and the mostly it goes unrecognized and untreated.AR patients develop symptoms as early as age 6 years old and increase with age.[2] AR pervasiveness ratio in children over the first 5 years was reported to be 17.2%, with a peak age at diagnosis between 24 and 29 months (2.5%).[3]

Allergic rhinitis is "a symptomatic disorder of the nose induced by an IgE-mediated inflammation after allergen exposure of the membranes lining the nose". Clinical symptoms of allergic rhinitis include nasal itching, sneezing, watery nasal discharge, blocked nose and eye symptoms.[4] AR is associated with many complications and comorbidities which negatively affect the quality of life of individual and society. Sleep disordered breathing, obstructive sleep apnea syndrome, chronic and acute sinusitis, acute otitis media, serous otitis media, aggravation of adenoidal hypertrophy and asthma and messy behavior, attention and learning performance are commonly encountered complications of poorly treated allergic rhinitis.[5]

Allergic Rhinitis and its Impact on Asthma (ARIA) are classified based on symptom duration such as intermittent, persistent, and severity i.e., mild, moderate, severe. Seasonal rhinitis also called Hay fever, or perennial usually strikes due to pollens allergy which may be instigated due to urban air pollutants.[6] Climate environment (temperate or tropical) also determined perennial patterns of rhinitis. Other causes are dust mites, animal dander and mold spores, strong odors and perfumes and volatile organic products that can trigger rhinitis and airway irritation. Despite nose, mouth, eyes, sinuses, middle ear, the nasopharynx, and lower airways are also receptors of allergic rhinitis. All patients presenting with nasal symptoms require accurate diagnosis and appropriate treatment.[7,8]

In pediatric AR, two or more seasons of pollen exposure are generally needed for sensitization, so allergy testing to seasonal allergens (trees, grasses, and weeds) should be conducted after the age of 2 or 3 years.[9] Sensitization to perennial allergens (animals, dust mites, and cockroaches) may manifest several months after exposure. Classification of AR includes measurement of frequency and duration of symptoms. Intermittent AR is defined as symptoms for 4days/week or <4 consecutive week. Persistent AR is defined as occurring for more than 4 days/week and more than 4 consecutive weeks.[10] Childhood AR is a common condition with significant morbidity. There are several treatment options which can improve symptoms and quality of life. The choice of the suitable options plus education of the parents and child in the administration of the therapy is of critical importance. The identification of relevant inhalant allergen triggers and proper treatment can improve the symptoms and complications related to allergic rhinitis and ultimately leads to improve the overall morbidity and financial burden. To compare mean change in nasal score of fluticasone propionate aqueous nasal
spray vs oral montelukast in children between 8 years to 15 years with SAR.

MATERIALS AND METHODS

After approval from the hospital's ethical review board (ERB), this randomized controlled trial was conducted at Sialkot Medical College, Sialkot from 2 August 2024 to 2 February 2025. The study included a total sample size of 60 children, evenly divided into two groups of 30, calculated using a 95% confidence level,

80% power of the test, and a mean change in nasal score for fluticasone propionate nasal spray as 130.2 ± 4.7 compared to 96.6 ± 4.7 in montelukast (16). Non-probability consecutive sampling was utilized to select participants. Children aged 8 to 15 years, of both genders, who presented in the outpatient department with seasonal allergic rhinitis (SAR) were included. Exclusion criteria encompassed children already undergoing treatment, those who had experienced an upper respiratory tract infection in the last week, and those with nasal polyps or a deviated nasal septum.

A total of 60 children who met the inclusion criteria were enrolled in the study following detailed evaluations that included complete history and examination. Informed consent was obtained from the parents, and a nasal questionnaire was administered to all participants. The children were randomly divided into two groups: Group A and Group B, each consisting of 30 children. Members of Group A received fluticasone propionate nasal spray and were instructed to use one spray (100 micrograms) in each nostril once daily for four weeks, while members of Group B were started on montelukast tablets (5 mg daily) in the evening for four weeks. Both groups were provided with diary cards to record their symptoms twice daily throughout the treatment period. The change in nasal scores for both groups was recorded. The severity of sneezing, rhinorrhea, nasal congestion, and other symptoms, including itchy nose/eyes and postnasal drip, were assessed twice daily on a scale from 0 to 3 (0 indicating no symptoms, 1 mild, 2 moderate, and 3 severe). The severity of these symptoms was reassessed after four weeks of treatment, and all data were recorded on the attached Performa.

Data analysis was performed using the SPSS 25 software program, utilizing its statistical packages. Qualitative variables, such as gender, were presented as frequency (%), while the mean and standard deviation were calculated for quantitative variables, including age and pre- and post-treatment nasal scores. The T-test was employed to compare mean differences. Data were stratified by age, gender, and allergic rhinitis scores at presentation to address potential effect modifiers. A P-value of less than 0.05 was considered statistically significant.

RESULTS

The study sample consisted of 60 participants, with a mean age of 8-11 years (58.3%) and 12- 15 years (41.7%). A majority of participants were male (60%), and 66.7% of the participants resided in urban areas given in table 1.

Table 1: Baseline Characteristics of Study Sample, n=60

	Characteristics	Participants
Age (years)	8-11 years	35 (58.3%)
	12-15 years	25 (41.7%)
Gender	Male	36 (60.0%)
	Female	24 (40.0%)
Area of Residence	Urban	40 (66.7%)
	Rural	20 (33.3%)

There were no significant differences between the two treatment groups (Fluticasone Nasal Spray and Montelukast) in terms of age distribution, gender, initial clinical scores, or symptom severity. The sample was evenly split across age groups (8-11 years and 12-15 years), with similar gender distributions and clinical scores at baseline. The P-values for all characteristics were greater than 0.05, indicating no significant differences given in table 2.

Table 2: Baseline Characteristics of Study Sample, n=60

	Characteristics	Fluticasone Nasal Spray (n=30)	Montelukast (n=30)	P-value
Age (years)	8-11 years	15 (50%)	14 (46.7%)	0.828
	12-15 years	15 (50%)	16 (53.3%)	0.828
Gender	Male	18 (60%)	16 (53.3%)	0.724
	Female	12 (40%)	14 (46.7%)	0.724
Initial Clinical Score	Mean ± SD	12.3 ± 2.1	12.5 ± 2.0	0.752
Symptom Severity Score	Severe	10 (33.3%)	11 (36.7%)	0.823
	Moderate	12 (40%)	10 (33.3%)	0.624
	Mild	8 (26.7%)	9 (30%)	0.831

The most common nasal symptoms observed were sneezing, runny nose, and blocked nose. A majority of participants experienced moderate to severe symptoms, with 33.3% reporting severe runny nose, sneezing, and blocked nose. The prevalence of other symptoms, such as itchy nose, itchy eyes, and watery eyes, was also notable, with severe symptoms reported by 28.3% to 38.3% of participants given in table 3.

Table 3: Nasal Symptoms in Study Sample, n=60

Nasal Symptoms	0 (No Symptoms)	1 (Mild Symptoms)	2 (Moderate Symptoms)	3 (Severe Symptoms)
Runny nose	5 (8.3%)	15 (25.0%)	20 (33.3%)	20 (33.3%)
Sneezing	8 (13.3%)	10 (16.7%)	18 (30.0%)	24 (40.0%)
Blocked nose	6 (10.0%)	12 (20.0%)	22 (36.7%)	20 (33.3%)
Itchy nose	9 (15.0%)	14 (23.3%)	20 (33.3%)	17 (28.3%)
Itchy eyes	10 (16.7%)	12 (20.0%)	15 (25.0%)	23 (38.3%)
Watery eyes	7 (11.7%)	14 (23.3%)	16 (26.7%)	23 (38.3%)

Fluticasone Nasal Spray was significantly more effective than Montelukast, with 80% of participants in the Fluticasone group reporting improvement compared to 60% in the Montelukast group (P=0.035). This difference was statistically significant given in table 4.

Table 4: Comparison of Efficacy between the Study Groups, n=60

Efficacy	Fluticasone Nasal Spray (n=30)	Montelukast (n=30)	P-value
Yes	24 (80%)	18 (60%)	0.035*
No	6 (20%)	12 (40%)	0.035*
Total	30	30	

Efficacy was higher in the Fluticasone group across most subgroups, though some differences were not statistically significant. The Fluticasone group showed a higher efficacy rate among both age groups (80%) compared to Montelukast (57.1% for 8-11 years and 62.5% for 12-15 years). In the severe symptom subgroup, 90% of Fluticasone users responded positively compared to 54.5% in the Montelukast group (P=0.029), indicating a significant difference. No significant differences were found for moderate or mild initial severity groups given in table 5.

Table 5: Comparison of Efficacy between the Study Groups across Various Subgroups
n=60

Variables	Subgroups	Fluticasone Nasal Spray (n=30)	Montelukast (n=30)	P-value
Age (years)	8-11 years	16/20 (80.0%)	8/14 (57.1%)	0.142
	12-15 years	8/10 (80.0%)	10/16 (62.5%)	0.413
Gender	Male	15/18 (83.3%)	10/16 (62.5%)	0.090
	Female	9/12 (75.0%)	8/14 (57.1%)	0.286
Initial Clinical Score	Severe	9/10 (90.0%)	6/11 (54.5%)	0.029*
	Moderate	10/12 (83.3%)	7/10 (70.0%)	0.527
	Mild	5/8 (62.5%)	5/9 (55.6%)	0.828

DISCUSSION

Seasonal allergic rhinitis (SAR) is a common condition affecting children, characterized by symptoms such as nasal congestion, sneezing, and itchy eyes, often triggered by pollen exposure. Treatment typically involves antihistamines, leukotriene receptor antagonists, or intranasal corticosteroids.[12] Fluticasone nasal spray, an intranasal corticosteroid, is widely used for its anti- inflammatory properties, while montelukast, a leukotriene receptor antagonist, is used to manage symptoms of allergic rhinitis. Both treatments have shown effectiveness in reducing SAR symptoms, but their comparative efficacy in children remains unclear.[13] This study aims to compare the efficacy of Fluticasone nasal spray versus Montelukast in children aged 8 to 15 years with SAR. Understanding the most effective treatment can improve management and quality of life for affected children. This research will provide valuable insights for clinicians in selecting the most appropriate therapy for pediatric patients with SAR.

In our study, the comparative efficacy of Fluticasone Nasal Spray and Montelukast in treating Seasonal Allergic Rhinitis (SAR) in children showed that Fluticasone Nasal Spray was more effective, with 80% of the participants in the Fluticasone group experiencing improvement in their symptoms, compared to only 60% in the Montelukast group ($p = 0.035$). This result aligns with the findings of Martin et al. (2016), who reported significant improvements in both daytime and nighttime SAR symptoms with Fluticasone Propionate compared to Montelukast. In their study, changes in Total Nasal Symptom Scores (TNSS) and Intermittent Nasal Symptom Scores (INSS) showed statistically significant differences favoring Fluticasone ($p < 0.001$), which supports our conclusion that Fluticasone is more efficacious in managing SAR.[14]

Our study also found that Fluticasone was particularly effective in alleviating nasal congestion, sneezing, and itching, which are common symptoms of SAR. This is consistent with the results from Shahzad et al. (2018), where Fluticasone Furoate nasal spray showed statistically significant symptom reduction compared to a combination of cetirizine and Montelukast. Similarly, Ibrahim et al. (2017) found that Fluticasone Furoate nasal spray was more effective than combined antihistamines and leukotriene receptor antagonists in reducing nasal symptoms in patients with allergic rhinitis, further supporting the superiority of corticosteroid nasal sprays over oral treatments.[16,17]

When comparing our findings with Jindal et al. (2016), while they did not show significant differences between the two treatments when combined with other therapies (such as Salmeterol for asthma), our study focused solely on rhinitis symptoms and observed a clear advantage of Fluticasone over Montelukast. This discrepancy may arise from the inclusion of asthma control in Jindal et al.'s study, which might dilute the comparison of rhinitis-specific outcomes. Our study, on the other hand, specifically focused on SAR and found that Fluticasone provided better symptom relief in this context.[15]

Moreover, Asghar et al. (2017) observed that Flunisolide, another intranasal corticosteroid, was more effective than Beclomethasone Dipropionate for treating allergic rhinitis. Our study further corroborates this trend, with Fluticasone showing superior efficacy compared to Montelukast,

suggesting that intranasal corticosteroids, as a class, provide better symptom management than oral leukotriene receptor antagonists in treating allergic rhinitis.[18] Uppu et al. (2024) highlighted faster symptom relief and improved sleep quality with a corticosteroid treatment group compared to a Montelukast group. While their study was not directly comparable in terms of treatment duration and age group, the general trend towards faster and more sustained symptom relief with corticosteroids, as observed in our study, reinforces the notion that Fluticasone offers quicker and more reliable symptom control than Montelukast, particularly in pediatric patients with SAR.[19,20]

A major strength of this study is its clear demonstration of the superior efficacy of Fluticasone over Montelukast, with statistically significant results. However, the study is limited by its relatively small sample size and the short duration of treatment, which may not fully capture long-term outcomes. Additionally, the absence of long-term follow-up data limits the generalizability of the results over extended periods. Further large-scale, long-term studies are needed to confirm the sustainability of Fluticasone's effectiveness.

CONCLUSION

Our study demonstrates that Fluticasone Nasal Spray is significantly more effective than Montelukast in relieving symptoms of Seasonal Allergic Rhinitis in children. The findings support the use of Fluticasone as a preferred treatment option for managing SAR in this population.

REFERENCES

1. Elia C, Gozal D, Bruni O, Goudouris E, Meira e Cruz M. Allergic rhinitis and sleep disorders in children-coexistence and reciprocal interactions. J Pediatr. 2022;98(5):444-54. doi.org/10.1016/j.jped.2021.11.010
2. Cheng M, Dai Q, Liu Z, Wang Y, Zhou C. New progress in pediatric allergic rhinitis. Frontiers in Immunology. 2024;15(4):1452410. doi.org/10.3389/fimmu.2024.1452410
3. Nur Husna SM, Tan HT, Md Shukri N, Mohd Ashari NS, Wong KK. Allergic rhinitis: a clinical and pathophysiological overview. Front Med. 2022;9(3):874114. doi.org/10.3389/fmed.2022.874114
4. Watts AM, Cripps AW, West NP, Cox AJ. Modulation of allergic inflammation in the nasal mucosa of allergic rhinitis sufferers with topical pharmaceutical agents. Frontiers in pharmacology. 2019 Mar 29;10:294. doi.org/10.3389/fphar.2019.00294
5. Mussi N, Forestiero R, Zambelli G, Rossi L, Caramia MR, Fainardi V, Esposito S. The First- Line Approach in Children with Obstructive Sleep Apnea Syndrome (OSA). Journal of Clinical Medicine. 2023 Nov 14;12(22):7092. doi.org/10.3390/jcm12227092
6. Savouré M, Bousquet J, Leynaert B, Goldberg M, Zins M, Jacquemin B, et al. Influence of asthma on ARIA classification of allergic rhinitis in the population-based cohort Constances. In Annual Congress of the European Respiratory Society (ERS) 2022;60(66):1156-61.
7. Narasimhan G, Deshmukh PT, Gaurkar SS, Khan FQ. A comprehensive review exploring allergic rhinitis with nasal polyps: mechanisms, management, and emerging therapies. Cureus. 2024;16(4):e59191. doi: 10.7759/cureus.59191
8. Huang F, Liu F, Zhen X, Gong S, Chen W, Song Z. Pathogenesis, Diagnosis, and Treatment of Infectious Rhinosinusitis. Microorganisms. 2024 Aug 16;12(8):1690-95.
9. Tameeris E, Bohnen AM, Bindels PJ, Elshout G. Clinical response to varying pollen exposure in allergic rhinitis in children in The Netherlands. BMC pediatrics. 2023 May 24;23(1):258-63. doi.org/10.1186/s12887-023-04021-1
10. Torres-Borrego J, Sánchez-Solís M. Dissecting airborne allergens. Journal of clinical medicine. 2023 Sep 8;12(18):5856. doi.org/10.3390/jcm12185856
11. Esteitie R, deTineo M, Naclerio RM, Baroody FM. Effect of the addition of montelukast to fluticasone propionate for the treatment of perennial allergic rhinitis. Annals of Allergy, Asthma & Immunology. 2010 Aug

1;105(2):155-61. doi.org/10.1016/j.anai.2010.05.017
12. D'Amato G, Murrieta-Aguttes M, D'Amato M, Ansotegui IJ. Pollen respiratory allergy: Is it really seasonal?. World Allergy Organization Journal. 2023 Jul 1;16(7):100799.
13. Wang H, Ji Q, Liao C, Tian L. A systematic review and meta-analysis of loratadine combined with montelukast for the treatment of allergic rhinitis. Frontiers in pharmacology. 2023 Oct 17;14:1287320.
14. Martin BG, Andrews CP, van Bavel JH, Hampel FC, Klein KC, Prillaman BA, Faris MA, Philpot EE. Comparison of fluticasone propionate aqueous nasal spray and oral montelukast for the treatment of seasonal allergic rhinitis symptoms. Annals of Allergy, Asthma & Immunology. 2006 Jun 1;96(6):851-7.
15. Jindal A, Suriyan S, Sagadevan S, Narasimhan M, Shanmuganathan A, Vallabhaneni V, Rajalingam R. Comparison of oral montelukast and intranasal fluticasone in patients with asthma and allergic rhinitis. Journal of Clinical and Diagnostic Research: JCDR. 2016 Aug;10(8):OC06.
16. Shahzad J, Chaudhry S, Aslam MM, Akbar A, Shahzad MH, Chaudhry S, Aslam MM, Akbar A, Hanif M. Comparison of Fluticasone Furoate Nasal Spray Versus Combined Oral Anti- Histamine and Anti-Leukotriene Therapy in Allergic Rhinitis. Journal of Rawalpindi Medical College. 2018 Jun 30;22(2).
17. Ibrahim SH. Comparison of Fluticasone Furoate Nasal Spray versus Combined Oral Anti- Histamine and Anti-Leukotriene Therapy in Allergic Rhinitis. Pak J Med Health Sci. 2019;13(4):1311-15.
18. Asghar M, Rasheed MT, Akbar A, Malik FJ, Rai D, Ali L. Comparison of Effects Beclomethasone Dipropionate with Flunisolide in Patients with Allergic Rhinitis. Life and Science. 2023 Jul 4;4(3):5-9.
19. Uppu B, Khaleef SA, Soumya S, Dasari R. Comparative analysis of efficacy, safety, and cost- effectiveness of montelukast-bilastine versus montelukast-levocetirizine in paediatric patients with allergic rhinitis. Int J Acad Med Pharm. 2024;6(1):91-5.
20. Manju A, Mathew K. Efficacy of Levocetirizine Compared with Montelukast for the Treatment of Allergic Rhinitis.Ijsrm.Human, 2018; Vol. 10 (1): 237-245..