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Original Research Article

Efficacy of Mometasone Furoate and Fluticasone Furoate Nasal Sprays in Children Aged 6 To 18 Years with Allergic Rhinitis: A Double-Blind Randomized Control Trial

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Conflict of interest: Nil

Abstract

Introduction: Allergic rhinitis (AR) is a globally prevalent IgE mediated inflammatory disorder of the nasal mucosal membranes. Symptoms of nasal congestion, rhinorrhoea, sneezing, nasal and ocular itching affect quality of life. Intranasal corticosteroids are first-line therapy for allergic rhinitis with mometasone furoate and fluticasone propionate nasal spray.

Methods: A double-blind randomized control trial was conducted from February 2021 to July 2022, on 130 children aged 6 to 18 years at the department of Paediatrics Geetanjali medical college and hospital, Udaipur. Patients were randomized into two groups, Group A received Mometasone Furoate (MF) nasal spray, and Group B received Fluticasone furoate (FF) nasal spray for 4 weeks. Total Nasal Symptom Score (TNSS) and Total Non-nasal symptoms score (TNNS) were filled at baseline and at follow up. Data was analysed and statistically evaluated.

Results: Statistically significant difference found at 4 weeks $p<0.001$ in the mean value of TNSS for FF group. Mean value of TNNS at baseline was 14.10, at 1 week was 4.07 and at 4 week was 0.67 which was found statistically significant. Nasal stuffiness, nasal itching and sneezing found at 1 week $p = 0.001$- and 4-week $p = 0.001$ was statistically significant in FF group.

Discussion: Fluticasone demonstrated a better control of nasal and ocular symptoms. Both the agents showed comparable effectiveness, though Fluticasone trended towards better Sneezing and nasal itching control due to localized anti-inflammatory action.

Keywords: Rhinitis, intranasal corticosteroids, inflammation, nasal score.

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Introduction

Allergic Rhinitis (AR) is IgE mediated inflammation of membrane lining of the nose induced by allergen exposure. [1] Allergic Rhinitis involves symptoms like rhinorrhoea, sneezing, nasal itching & nasal congestion. [1] It is common chronic childhood illnesses, strongly influenced by urban air pollution and frequently presents with comorbid conditions like asthma, atopic dermatitis and nasal polyps. [2] It impacts quality of life of children causing fatigue, irritability, sleep disturbances and poor school performance and limitation in outdoor physical activities. [2]

Prevalence is often reported as 7.7%–11.3% for younger children (6–7 years) and rises to 23.5%–24.4% for adolescents (13–14 years). [3] Studies have demonstrated that intranasal corticosteroids are currently most potent medication available for treatment of allergic rhinitis. [4] More effective than antihistaminic and leukotriene receptors antagonists. [4] Intranasal corticosteroids like Mometasone furoate (MF) has greater affinity for glucocorticoids receptors than dexamethasone. [5] Mometasone inhibits mast cells, eosinophils, histamine, leukotrienes, interleukin-1, IL-4, IL-5, interferon-γ and TNF-α.5 Fluticasone furoate (FF) is local vasoconstrictor with direct anti-inflammatory effect and is approved by FDA for treatment of allergic rhinitis in children. The onset of action of FF nasal spray is rapid and is observed 8 h after the first dose of medication. [5]

Research Gap: Very few large centres randomized control trials (RCTs) have been done on Indian children comparing efficacy of FF and MM nasal spray in allergic rhinitis. In fact, fewer RCTs have been done on children than adults including Total nasal symptoms score (TNSS) and total ocular

symptoms score.6 This may be due to inability to recruit enough participants, ethical consideration and limited funding. The number of studies from India are still limited compared with international literature. Long-term safety of intranasal steroids in children, its effect on quality of life, growth monitoring and its adherence with parental perception is still under research in India.6

The current study analyses the efficacy of MF and FF nasal sprays in treatment of allergic rhinitis in children aged 6-18 years over 4 weeks. The recommended starting dosage in children is 55 mcg once daily administered as one spray (27.5 mcg/spray) in each nostril.

Study design and Settings: This study was conducted as double-blind randomized control trial in the department of Paediatrics of Geetanjali medical college and hospital, Udaipur, Rajasthan. This study was carried out over a period of 18 months from, February 2021 – July 2022.

Inclusion criteria: Children from 6 to 18 years of either sex diagnosed with allergic rhinitis were enrolled in the study. Symptoms like nasal blockage, rhinorrhoea, sneezing and itching; any 2 of the above 4 symptoms must be present for >1 hr every day, for >2 weeks for diagnosis. Those who were able to adhere to the dosing and visit schedules.

Exclusion criteria: Children with history of nasal polyp, fever, already being treated with intranasal corticosteroids were excluded.

Methodology

According to figure 1, a total of 144 participants were assessed for eligibility, of whom 14 were excluded (8 did not meet the diagnostic criteria and 6 declined participation).

Randomization and Intervention: The remaining 130 participants were randomized equally into two treatment groups: Group A received Mometasone Furoate (n=65) and Group B received Fluticasone Furoate (n=65). During follow-up, 5 participants from each group were lost to follow-up. Finally, 60 participants in each group were analysed. Demographic profile of patient was collected.

Randomization was done using small square slips with computer generated numbers from 1 to 120. Odd numbers were assigned to Mometasone furoate group [group A], while even numbers were assigned to fluticasone furoate group [group B]. They were folded and shuffled and were put in a serially numbered opaque envelop and sealed. Both participant/patient and researcher did not know which spray is being administered. Both drugs were administered intranasally once daily for 4 weeks. Adherence to treatment was monitored through self-reported diaries and follow-up visits.

Outcome Measures -The primary outcome was the change in Total Nasal Symptom Score (TNSS) which includes nasal congestion, rhinorrhoea, sneezing, and nasal itching, each graded on a 4-point scale (0–3). [7]

TNSS Scoring system- 0: No symptoms,

- 1: Mild (awareness but not bothered),
- 2: Moderate (Troublesome but not interfering daily activities/sleep),
- 3: Severe (Interferes with daily activities/sleep).

Total Non-Nasal Symptoms Score (TNNS) measures symptoms outside the nose like Ocular symptoms-itching-eyes, eye congestion, sleep disturbances rated 0-3 with high scores indicating severity. [7]

Assessment and Follow-up: Participants were assessed at baseline, week 1 and week 4. Symptom severity and quality of life scores were recorded at each visit. Adverse events such as nasal burning and headache were documented.

Statistical analysis: Data was entered in Microsoft Excel, analysed and evaluated using SPSS-PC-28 version. Quantitative data was expressed in mean, standard deviation and difference between two comparable groups, were tested by student's t-test (unpaired) while quantitative data were expressed in percentage. Statistical differences between the proportions were tested by chi-square or Fisher's exact test. P-value less than 0.05 was considered statistically significant.

Results

According to table 1, the mean age of patients with MF was 11.58 years (SD = 3.62) and mean age of patients with FF was 11.28 years (SD = 3.46) with no statistically significant difference between both groups (p=0.644). No significant association between gender in each group (p=0.713). Family history was found in the 58.3% patients in group MF and 65.0% in FF group, with no significant association (p=0.453).

According to table 2, the mean value of Rhinorrhoea at baseline for MF group was 3.60 (SD = 0.49) and at 4 week was 1.03 (SD = 0.823). For FF group, mean value of Rhinorrhoea at baseline was 3.52 (SD = 0.50) and at 4 week was 0.15 (SD = 0.36) with statistically significant difference at weeks. Nasal stuffiness, nasal itching and sneezing at 4 weeks (p<0.001). As per table 3, incidence of nasal burning was 23.33% in MF group and 15.0% in FF, showing no significant association between groups (p = 0.073). Incidence of headache was also not significant. According to figure 2, both the groups had comparable baseline TNSS values (14.03 vs 14.10). Reduction in TNSS was greater in FF group and improvement in nasal

symptoms with FF was significant ($p<0.001$). According to figure 3, findings suggest superior efficacy of FF in reducing non-nasal symptoms (TNNS) over study period.

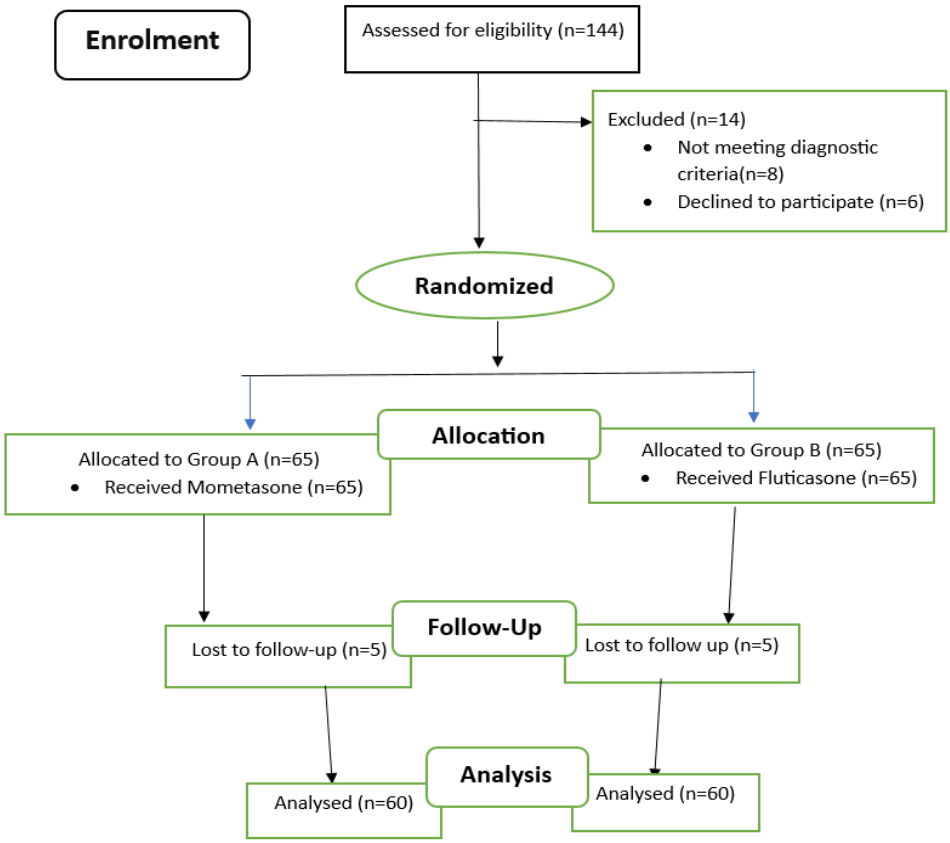

Figure 1: CONSORT flow diagram depicting participant recruitment, randomization, allocation, follow-up and analysis

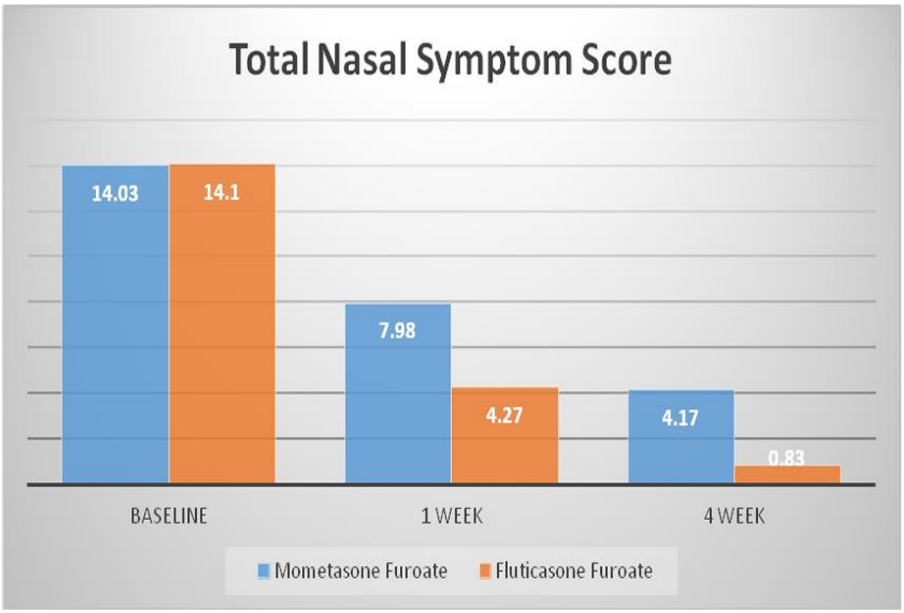

Figure 2: Comparison of Total Nasal Symptoms Score (TNSS) between Mometasone Furoate and Fluticasone Furoate at baseline, 1 week and 4 weeks.

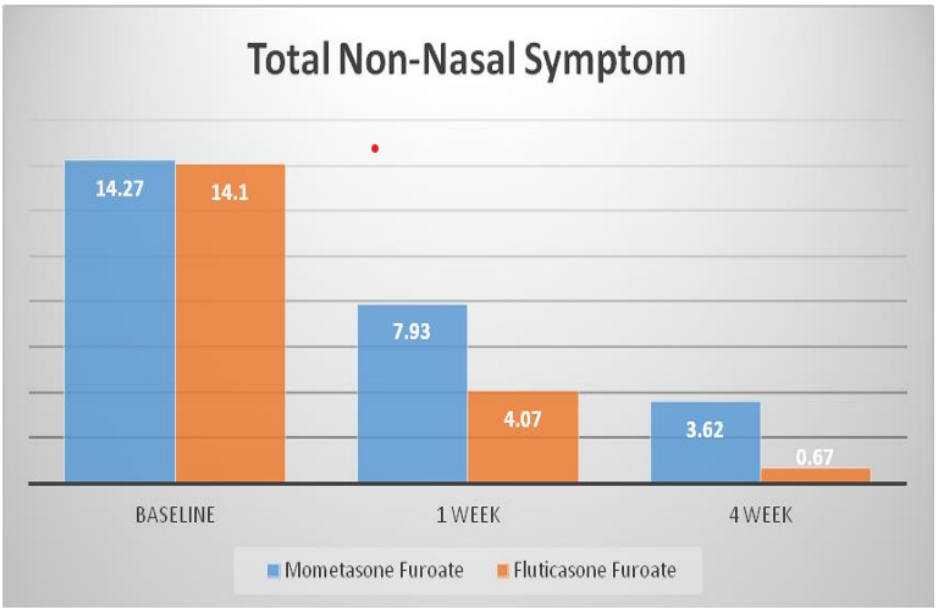

Figure 3: Comparison of Total Non-Nasal Symptoms Score (TNNSS) between Mometasone Furoate and Fluticasone Furoate at baseline, 1 week and 4 weeks.

Table 1: Demographics of patients

Characteristics	Group A (Mometasone)	Group B (Fluticasone)	p-value
Mean Age in years ± SD	11.58±3.623	11.28±3.465	0.644
Male: Female Ratio	35:25	33:27	0.713
Height (cm) Mean ± SD	125.235±17.5907	124.665±18.5299	0.863
Weight (kgs) Mean ± SD	33.97±13.311	32.02±13.262	0.423
Family history of AR(Yes)	35 (58.3)	39 (65)	0.453

Table 2: Severity scores in both the groups.

Symptoms	*Severity Scores (Mean + SD)	p-value
	Group A (Mometasone) Group B (Fluticasone)	
Total Nasal Symptoms-		
1.**Sneezing**	3.52±0.504 (at baseline) 3.47±0.503 (at baseline) 1.12±0.783 (at 4 weeks) 0.28±0.454 (at 4 weeks)	0.294 **<0.001**
2.**Rhinorrhoea**	3.60±0.494 3.52±0.504 1.03±0.823 0.15±0.360	0.181 **<0.001**
3.**Nasal Itching**	3.45±0.502 3.58±0.497 0.97±0.843 0.20±0.403	0.073 **<0.001**
4.**Nasal stuffiness**	3.47±0.503 3.53±0.503 1.05±0.872 0.27±0.703	0.235 **<0.001**
Total Non-Nasal Symptoms-		
1.**Eye Itching**	3.65±0.481 3.55±0.502 0.95±0.872 0.17±0.156	0.134 **<0.001**
2.**Eye Congestion**	3.48±0.504 3.42±0.497 0.73±0.733 0.17±0.342	0.234 **<0.001**
3.**Sleep disturbances**	2.13±1.556 1.17±1.556 0.75±0.856 0.07±0.456	0.543 **<0.001**

*** 0: No symptoms, 1: Mild (awareness but not bothered), 2: Moderate (Troublesome but not interfering daily activities/sleep), 3: Severe (Interferes with daily activities/sleep).**

Table 3: Safety comparison in both the groups.

Adverse effect	Group A Mometasone Furoate (n=60)	Group B Fluticasone Furoate(n=60)	p-value
Nasal burning	14 (23.33%)	9 (15.1%)	0.073
Headache	3 (5%)	2 (3.3%)	0.51

Discussion

This randomized clinical trial assessed the efficacy and safety of two intranasal corticosteroids INCSs—FF and MF in managing paediatric allergic rhinitis. Our findings were indicating that INCSs significantly reduced Total Nasal Symptom Scores (TNSS) over the 4-week study period, with FF demonstrating a superior efficacy towards better sneezing and nasal itching control. The efficacy of Fluticasone observed in our study aligns with previous research. [8]

The Allergic Rhinitis and its Impact on Asthma (ARIA 2024-2025) guidelines recommends the use of Intranasal corticosteroids over antihistaminic. [9] In the survey, 89.12% ENT specialists believe INCS are the most effective treatment, 62.24% consistently prescribe INCS for management. [10] 84.48% of them prefer fluticasone furoate. 76.00% routinely educate patients on proper nasal spray techniques. [10]

Our findings align with randomized study conducted by Barasara PP et al, in 2025 comparing efficacy of MF and FF nasal spray in reducing the nasal and ocular symptoms of allergic rhinitis. [11] According to their results there was a statistically significant reduction in the TNSS scores with Fluticasone furoate. [11] Hamid et al, in 2020 conducted a study and found improvement in nasal symptoms in both the groups from base line to week 8. TNSS for MF group (10.18 at baseline; 2.50 at week 8) was better than FF group (9.46 at baseline; 2.71 at week 8), but the difference was not significant ($p>0.05$). [12]

Fluticasone showed lower incidence of adverse effects particularly for nasal burning and headache. Previous Indian study from West Bengal also demonstrated no statistically significant increase in Intraocular pressure (IOP) after giving FFNS in Indian population. [13] Fluticasone is efficacious due to localized anti-inflammatory action on eosinophils, mast cells directly in nasal mucosa and minimal systemic absorption making it safe. [14]

Strengths and Limitation: Strengths of the study include its randomized design, adequate sample size, and the inclusion of subjective (TNSS) measures. The follow-up period was limited to four weeks. The use of patient-recorded Total Nasal Symptom Score (TNSS) was subjective.

Conclusion

Both fluticasone furoate and mometasone furoate are effective in reducing symptoms of allergic rhinitis. However, we found fluticasone furoate to be more effective in reducing nasal symptoms and thus improving the quality of life of children on the basis of TNSS. We also found lower incidence of side effects in fluticasone furoate as compared to Mometasone Furoate nasal spray.

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