Section: ENT & HNS

Original Research Article

EFFICACY OF FLUTICASONE FUROATE IN MANAGING ADENOID HYPERTROPHY IN PEDIATRIC PATIENTS

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ABSTRACT

Background: Adenoid hypertrophy (AH) is a common pediatric condition characterized by the abnormal enlargement of the adenoids, leading to nasal obstruction, sleep disturbances, and recurrent infections. This study aims to compare the efficacy of topical azelastine (137 mcg) and topical fluticasone furoate (27.5 mcg) in managing AH in children aged 6–15 years.

Materials and Methods: A prospective, hospital-based study was conducted at the Department of ENT & HNS, Muzaffarnagar Medical College & Hospital, involving 80 patients, randomly divided into two groups: Group A (Azelastine) and Group B (Fluticasone). Patients were treated for three months, and their progress was monitored at Day 7, Day 14, 1 month, and 3 months using symptom assessment, endoscopic evaluation, and radiological grading.

Results: The study found that both nasal sprays significantly improved nasal congestion, snoring, and sleep disturbances, with fluticasone furoate showing a more rapid onset of symptom relief, particularly in the first 14 days. At 3 months, both groups exhibited comparable symptom resolution rates (95%). Endoscopic and radiological findings revealed a greater reduction in adenoid size in the fluticasone group, making it the preferred option for rapid and sustained improvement. Adverse effects were minimal in both groups, with mild nasal irritation being the most common complaint.

Conclusion: Fluticasone furoate demonstrates superior short-term efficacy in symptom relief, while both treatments are equally effective in long-term management of AH. This study suggests that intranasal corticosteroids may be a more favorable first-line therapy for pediatric AH, potentially reducing the need for surgical intervention. Further research is recommended to explore long-term outcomes and combination therapies.

Keywords: Adenoid Hypertrophy, Nasal Obstruction, Topical Azelastine, Topical Fluticasone Furoate, Corticosteroids, Antihistamines.

INTRODUCTION

Adenoid hypertrophy (AH) is a common condition in children characterized by the abnormal enlargement of the adenoids; a mass of lymphoid tissue located in the nasopharynx. The adenoids play a crucial role in the immune defence system during early childhood but tend to regress after the age of 10 years.[1]

Epidemiological studies indicate that AH is most prevalent between the ages of 2 and 6 years, affecting up to 34% of children globally.[2] The condition can cause nasal obstruction, mouth breathing, snoring, sleep disturbances, and recurrent infections, leading to long-term complications such as obstructive sleep apnea (OSA), craniofacial abnormalities, and cognitive impairments.[3] Pharmacological interventions, particularly intranasal corticosteroids and antihistamines, have emerged as effective alternatives in reducing adenoid size and relieving symptoms without surgical intervention.[4]

Some studies suggest that fluticasone furoate has a faster onset of action and greater anti-inflammatory effects, while others indicate comparable long-term efficacy between both treatments.[5] This study aims to compare the efficacy of topical azelastine (137 mcg) and topical fluticasone furoate (27.5 mcg) in managing AH in children aged 6–15 years.

MATERIALS AND METHODS

This is a hospital-based prospective study to evaluate and compare the effectiveness of topical azelastine (137 mcg) and topical fluticasone furoate (27.5 mcg) nasal sprays in children diagnosed with adenoid hypertrophy (AH) conducted in the Department of ENT & HNS, Muzaffarnagar Medical College & Hospital, Uttar Pradesh, ensuring access to a well-equipped pediatric otolaryngology unit for accurate diagnosis and treatment monitoring. The target population consisted of children aged 6–15 years with a clinical, endoscopy and radiological diagnosis of adenoid hypertrophy. Patients were randomly taken from outpatient and inpatient departments, ensuring diverse representation. An informed consent was taken from all the participants' parents.

A total of 80 patients were enrolled in the study, divided into two groups: Group A: 40 patients receiving Azelastine nasal spray (137 mcg) twice daily for 3 months, applied in each nostril. Group B: 40 patients receiving Fluticasone furoate nasal spray (27.5 mcg) twice daily for 3 months, applied in each nostril.

A purposive sampling technique was employed, selecting patients who met the inclusion criteria and were willing to participate in the study.

Inclusion and Exclusion Criteria Inclusion Criteria

1. Children aged 6–15 years diagnosed with adenoid hypertrophy.
2. Patients with symptoms of nasal congestion, snoring, and sleep disturbances. Patients with radiological and endoscopic confirmation of AH.
3. Patients with no prior history of nasal steroid or antihistamine use in the last 3 months.
4. Willingness of parents/guardians to provide informed written consent for participation.

Exclusion Criteria

1. Children younger than 6 years or older than 15 years.
2. Patients with immunodeficiency disorders, including diabetes mellitus, tuberculosis, or primary immune deficiencies.
3. History of sinonasal diseases such as nasal polyposis, craniofacial malformations, or deviated nasal septum.
4. Patients with a history of recurrent epistaxis or recent upper respiratory infections (within the past two weeks).
5. Allergic or hypersensitive reactions to either azelastine or fluticasone furoate.

Clinical symptoms, treatment response, and imaging findings were recorded in a structured case record form. Follow-up visits were scheduled at Day 7, Day 14, Day 21, 1 Month, and 3 Months.

Statistical Data Analysis & software: Data were entered into Microsoft Excel and analyzed using SPSS software (Version 17/20). A p-value < 0.05 was considered statistically significant, indicating meaningful differences between the treatment groups.

RESULTS

Age distribution is similar between the two groups, ensuring no age-related bias. The majority of participants fall between 9-15 years. There is a slight male predominance in both groups, which is consistent with the higher prevalence of AH in boys.

Table 1: Age Distribution of Study Participants

Age Group (years)	Azelastine Group (n=40)	Fluticasone Group (n=40)	Total (n=80)
6 - 8	10 (25%)	12 (30%)	22 (27.5%)
9 - 11	15 (37.5%)	14 (35%)	29 (36.25%)
12 - 15	15 (37.5%)	14 (35%)	29 (36.25%)
Mean ± SD	9.5 ± 2.5	9.3 ± 2.3	9.4 ± 2.4

Table 2: Gender Distribution of Study Participants

Gender	Azelastine Group (n=40)	Fluticasone Group (n=40)	Total (n=80)
Male	25 (62.5%)	28 (70%)	53 (66.25%)
Female	15 (37.5%)	12 (30%)	27(33.75%)

Fluticasone furoate shows faster symptom relief of nasal congestion at Day 7 and Day 14 ($p < 0.05$, statistically significant).

By 3 months, both treatments have similar efficacy (95% improvement). Fluticasone is more effective for early relief, while long-term outcomes are similar.

Fluticasone provides greater symptom relief of snoring early, with higher improvement at Day 7 and Day 14 ($p < 0.05$).

By 3 months, both treatments provide near- complete relief. Fluticasone furoate shows faster symptom relief of difficulty sleeping at Day 7 and Day 14 ($p < 0.05$, statistically significant). By 3 months, both treatments have similar efficacy (90% and 95% improvement for azelastine and fluticasone furoate respectively). Fluticasone is more effective for early relief, while long-term outcomes are similar.

Table 3: Symptom Relief for Nasal Congestion

Time Point	Azelastine Group (n=40)	Fluticasone Group (n=40)	p-value
Baseline	40 (100%)	40 (100%)	-
Day 7	16 (40%)	22 (55%)	0.045

Day 14	24 (60%)	32 (80%)	0.05
1 Month	32 (80%)	36 (90%)	0.10
3 Months	38 (95%)	38 (95%)	1.00

Table 4: Symptom Relief for Snoring

Time Point	Azelastine Group (n=40)	Fluticasone Group (n=40)	p-value
Baseline	40 (100%)	40 (100%)	-
Day 7	18 (45%)	26 (65%)	0.013
Day 14	24 (60%)	30 (75%)	0.020
1 Month	32 (80%)	34 (85%)	0.45
3 Months	38 (95%)	40 (100%)	0.08

Table 5: Symptom Relief for Difficulty Sleeping

Time Point	Azelastine Group (n=40)	Fluticasone Group (n=40)	p-value
Baseline	40 (100%)	40 (100%)	-
Day 7	12 (30%)	18 (45%)	0.023
Day 14	20 (50%)	28 (70%)	0.013
1 Month	30 (75%)	32 (80%)	0.65
3 Months	36 (90%)	38 (95%)	0.45

Fluticasone shows a greater reduction in adenoid size ($p = 0.04$, statistically significant).on Xray nasopharynx soft tissue lateral view using Cohen and Konak classification. Both groups show significant improvement, but fluticasone is more effective in reducing nasopharyngeal obstruction. On Endoscopy adenoid hypertrophy grade using clemens and mcmurray both treatments reduce adenoid size, but fluticasone is significantly more effective ($p = 0.03$). Both treatments are well tolerated, with mild adverse effects. Azelastine has a slightly higher incidence of nasal irritation. No serious side effects were reported in either group.

Table 6: X-ray Findings – Nasopharyngeal Obstruction (Cohen & Konak Classification)

Time Point	Azelastine Group (n=40)	Fluticasone Group (n=40)	p-value
Baseline	Grade 2.3 ± 0.5	Grade 2.4 ± 0.5	0.07
3 Months	Grade 1.8 ± 0.4	Grade 1.6 ± 0.3	

Table 7: Endoscopic Findings – Adenoid Hypertrophy Grade

Time Point	Azelastine Group (n=40)	Fluticasone Group (n=40)	p-value
Baseline	Grade 3.1 ± 0.6	Grade 3.0 ± 0.5	0.05
3 Months	Grade 2.3 ± 0.5	Grade 2.0 ± 0.4	

Table 8: Adverse Reactions

Adverse Event	Azelastine Group (n=40)	Fluticasone Group (n=40)	p-value
Nasal Irritation	3 (7.5%)	1 (2.5%)	0.30
Headache	2 (5%)	1 (2.5%)	0.67
Dryness in Throat	1 (2.5%)	2 (5%)	0.43

DISCUSSION

Adenoid hypertrophy (AH) is a common pediatric condition with a prevalence ranging from 27% to 50% in children aged 2–6 years, the period when adenoid tissue is most active in immune responses.[2] The prevalence declines after 10 years of age due to physiological regression of adenoidal tissue.[3]

The risk factors associated with AH are multifactorial, including genetic predisposition, recurrent upper respiratory tract infections (URTIs), environmental pollutants, and allergic rhinitis.[6] The results of this study align with existing literature, reinforcing the efficacy of intranasal corticosteroids (fluticasone furoate) over antihistamines (azelastine) in the management of adenoid hypertrophy (AH). The study demonstrated that fluticasone furoate led to faster symptom relief and greater reduction in adenoid size compared to azelastine. These findings are consistent with the study done in 2023, who found that intranasal corticosteroids significantly reduced nasal obstruction and improved sleep quality in pediatric patients.[6] Similarly, a study reported that fluticasone furoate provided faster symptom resolution than antihistamines in children with chronic nasal obstruction due to AH.[5]

The imaging findings in this study, based on Cohen & Konak's X-ray grading and Clemens & McMurray's endoscopic grading, further support the superior anti-inflammatory properties of fluticasone. The significant reduction in adenoid size at 3 months ($p < 0.05$) correlates with previous studies demonstrating corticosteroids' ability to downregulate inflammatory cytokines and reduce lymphoid hyperplasia.[7] While azelastine also showed improvement in nasal congestion, snoring, and sleep difficulties, its slower onset of action suggests that its primary benefit lies in allergic AH cases rather than in inflammatory-driven hypertrophy.[8]

Moreover, azelastine's safety profile showed a slightly higher incidence of nasal irritation, which

aligns with findings by study done in, who noted that antihistamines can cause local irritation due to their impact on nasal epithelial receptors.[9] Overall, both azelastine and fluticasone furoate nasal sprays were safe and effective. However, fluticasone was associated with faster symptom relief and greater adenoid size reduction, making it the preferred first-line therapy for adenoid hypertrophy.[7]

CONCLUSION

Fluticasone furoate demonstrates superior short-term efficacy in symptom relief, while both treatments are equally effective in long-term management of AH. This study suggests that intranasal corticosteroids may be a more favorable first-line therapy for pediatric AH, potentially reducing the need for surgical intervention. Further research is recommended to explore long-term outcomes and combination therapies.

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