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Evaluating the Efficacy of Intranasal Montelukast in Pediatric Acute Asthma Attacks: A Single-blinded, Placebo-controlled Clinical Trial

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ABSTRACT

Asthma is a common chronic respiratory disease in children, often leading to acute exacerbations marked by dyspnea, cough, and wheezing, which frequently necessitate emergency medical care. While standard therapies are effective, the exploration of novel drug delivery routes continues. Oral montelukast is a recognized treatment, but the efficacy of its intranasal formulation for acute attacks remains underexplored. This study aimed to evaluate the clinical effectiveness of intranasal montelukast as an adjunct therapy for pediatric asthma exacerbations.

A single-blinded, placebo-controlled, single-center trial was conducted involving children aged 2-12 years hospitalized with moderate to severe acute asthma. Participants were randomized to receive either intranasal montelukast or a placebo alongside standard care. Key outcomes, including the Pulmonary Index Score (PIS), respiratory rate, oxygen saturation, and length of hospital stay, were systematically assessed.

The analysis of 25 patients in each group revealed no significant baseline differences. The intranasal montelukast group demonstrated a statistically significant and sustained reduction in PIS scores at critical intervals (8, 12, and 24 hours) compared to the placebo group. Improvements in respiratory rate and oxygen saturation were also more pronounced with the active treatment. Notably, the mean hospital stay was significantly shorter for the montelukast group (2.16 days) than the placebo group (3.12 days).

In conclusion, intranasal montelukast shows significant promise as an effective adjunct therapy for acute pediatric asthma, correlating with accelerated clinical improvement and a reduced duration of hospitalization. These encouraging results justify further investigation through larger, multicenter trials to definitively establish its efficacy and safety profile.

Keywords: Asthma attack; Montelukast; Pediatric asthma; Pulmonary index scores

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INTRODUCTION

Asthma is a prevalent chronic condition in children. Despite the preventability of acute episodes, emergency

visits and hospitalizations most frequently occur due to acute exacerbations of asthma.[1] Asthma is a chronic inflammatory respiratory condition characterized by the hallmark symptoms of intermittent dyspnea, cough, and wheezing.[2] Estimates indicate that over 300 million individuals worldwide suffer from asthma, with projections indicating that over 400 million individuals will develop asthma in the future. Asthma prevalence in children shows geographical diversity, with global rates ranging from 9.1% to 9.5% in children and 9.1% to 10.4% in adolescents.[3] Various elements, such as age, gender, financial situation, genetic makeup, and contact with pollutants, appear to influence the occurrence of asthma.[4] Asthma results in stunted growth, heightened healthcare expenses, diminished quality of life, and school absenteeism, among other issues. The adoption of suitable approaches to understand asthma's epidemiology and subsequently administer proper treatment has significantly reduced the impact of the disease.[5] Vitamin D deficiency, alterations in gastrointestinal and respiratory microbiomes, tobacco smoke exposure, air pollution, and genetic factors have been proposed as potential risk factors for the development of asthma.[6–10] Pediatric asthma management involves a combination of lifestyle modifications and medications, including bronchodilators and corticosteroids.[11] Poor asthma control could be a major risk factor for asthma attacks.[12] An asthma attack is characterized by a sudden or gradual worsening of asthma symptoms that can significantly compromise the patient's quality of life or potentially lead to life-threatening situations.[13,14] The main part of the management strategy for acute asthma includes short- and long-acting beta-agonists and inhaled and systemic corticosteroids. However, other agents, such as leukotriene receptor antagonists, methylxanthines, and monoclonal antibody immune-modulating drugs, could be administered as other therapeutic options.[15] Leukotriene receptor antagonists, such as montelukast and zafirlukast, are some of the therapeutic agents used for asthma attack management.[16] Montelukast is a distinctly targeted and specific antagonist of cysteinyl leukotriene receptors (CysLTRA). By attaching to leukotriene receptors, it alleviates bronchospasms and airway mucosal swelling, consequently decreasing the infiltration of inflammatory cells and mucus production, which aids in the enhancement of the disease condition.[17] Montelukast is conventionally administered orally; however, research on the efficacy of intranasal montelukast for managing asthma attacks is limited. It is hypothesized that intranasal drug administration could provide a more rapid route for drug delivery, potentially facilitating and accelerating treatment and achieving quicker control of acute exacerbations. Therefore, this study aims to evaluate the clinical effectiveness of intranasal montelukast in managing pediatric asthma attacks.

MATERIALS AND METHODS

This single-blinded, placebo-controlled, single-center clinical trial aimed to examine the efficacy of intranasal montelukast in children with acute asthma attacks. The study was conducted at Imam Hossein Pediatric Hospital, affiliated with Isfahan University of Medical Sciences, in 2022-2023. The study population comprised all children admitted to the emergency room or the asthma and allergy ward of Imam Hossein Hospital due to an acute asthma attack. This clinical trial was registered with the Iranian Clinical Trial Registry under the registration code IRCT20220119053760N2.

Inclusion Criteria

The following criteria were used for inclusion:1. Children aged 2-12 admitted with moderate (Pulmonary index score [PIS] 7-11) to severe (PIS>12) acute asthma attacks (Supplementary Table 1).

2. No history of systemic corticosteroids or anti-leukotrienes administration at least four weeks prior to admission.

3. No other probable diagnosis, such as pneumonia or cystic fibrosis.

4. No history of chronic respiratory diseases, airway anatomical abnormalities, or congenital cardiovascular diseases.

5. No history of administration of anticonvulsant or immunosuppressive drugs.

Patients with life-threatening asthma (those tending to respiratory failure or needing intubation), allergy to montelukast, or lack of consent for participation or continuation in the study were excluded.

Study Procedure

Upon admission, patients were assessed for baseline characteristics, including demographics, chronic diseases, and medical history related to asthma. Also, patients were evaluated for asthma severity and clinical status using the PIS. Patients were informed about the

study's objectives, and informed consent was obtained from the parents or guardians of the children for their participation in the study. After initial assessment, patients were randomized to treatment and control groups. Both groups received standard treatment based on the severity of their asthma attack. For moderate asthma attacks, the treatment included oxygen therapy, albuterol nebulizer, and systemic glucocorticoids. Severe cases received oxygen therapy, salbutamol and ipratropium nebulizers, systemic glucocorticoids, and intravenous magnesium sulfate. Patients in the treatment group also received intranasal montelukast.

The intranasal montelukast was formulated by an expert pharmacologist using montelukast sodium hydrate drug powder (Sigma-Aldrich,USA). Carboxymethyl cellulose was used as a suspending agent, with propylparaben and methylparaben as antimicrobial and antifungal agents. A phosphate buffer was used for pH adjustment. The final dosage of montelukast was 1 mg per puff. The prepared solution was packaged as a nasal spray.[18,19] The placebo had the same formulation, excluding montelukast, and was packaged identically.

The formulated drug was administered to patients upon admission and continued daily thereafter. Patients aged 2 to 6 years received 2 puffs of the drug in each nostril daily, while patients older than 6 years received 2 puffs in one nostril and 3 puffs in the other. The drug administration began at hospital admission and adhered to the prescribed daily dosage. The control group was given a placebo in a bottle identical to that used for the treatment group.

Outcome Measurement

The primary outcome was the PIS score, an objective clinical score for evaluating pulmonary function in pediatric asthma. The PIS consists of five components: respiratory rate, wheezing severity, inspiratory/expiratory ratio, O_2 saturation, and accessory muscle use. Each component is scored from 0 to 3, with a total score of 15 indicating higher severity. Researchers examined the PIS score every four hours until 12 hours after admission on the first day and daily thereafter. The secondary outcome was the length of hospital stay.

Sample Size

The sample size was calculated to be 24 for each group, considering a 95% confidence interval (CI), a power of 0.80, and the mean difference in post-treatment forced expiratory volume in 1 second between patients receiving oral montelukast and those receiving a placebo.

Randomization

Patients were randomized into treatment and control groups based on their national ID numbers. Patients with even ID numbers were allocated to the treatment group, while those with odd ID numbers were allocated to the control group.

Blinding

This was a single-blinded study. The patients were unaware of the type of treatment they received, but the physicians, clinical examiners, and statistical analysts were aware of the treatment allocations.

Statistical Analysis

Statistical analysis was performed using SPSS version 26. Categorical variables were described by frequency and rate, and continuous variables by mean and standard deviation (SD). The normal distribution of continuous variables was examined using the Kolmogorov-Smirnov test. The comparison of categorical variables between groups was conducted using the chi-square test, and continuous variables were compared using the t-test. The PIS score comparison between groups was conducted using the chi-square test, and the efficacy of treatment over time was examined using the Friedman test. All statistical analyses were conducted with a 95% CI.

RESULTS

A total of 25 patients were examined in each group (Figure 1). Statistical analysis showed no significant differences between the groups regarding demographic variables, such as age and sex. Additionally, there were no significant differences between the groups in terms of past medical history, family history of asthma, history of dermatitis, and history of hospitalization due to asthma attacks. The comparison of asthma attack severity based on the PIS score also showed no statistically significant difference between the placebo and treatment groups (Table 1).

Patients' respiratory rates were categorized based on the PIS score into four categories scored from 0 to 3. The comparison of the respiratory score distribution of

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patients showed no significant difference between the groups prior to treatment and 4 hours after treatment. However, the comparison of respiratory rates at 8 hours, 12 hours, and on the second and third days after drug administration showed higher frequencies of lower respiratory scores in the montelukast group. The Friedman test showed a significantly higher frequency of lower respiratory scores over time in both groups (Table 2).

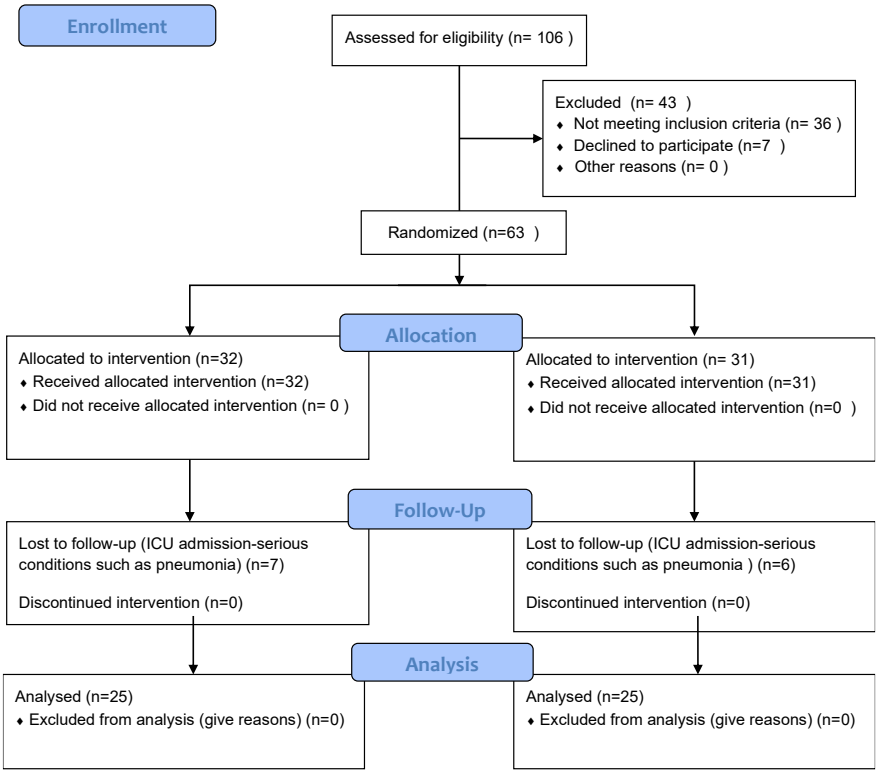

Figure 1. CONSORT flow diagram of patients.

Table 1. Comparison of baseline characteristics between treatment and placebo groups.

Variable	Montelukast (n=25)	Placebo (n=25)	*p*
Age, y	5.77 ± 2.75	5.78 ± 2.72	0.988[a]
Sex, No. (%)			1.000[b]
Male	18 (72)	18 (72)	
Female	7 (28)	7 (28)	
PMH, No. (%)	10 (40)	9 (36)	0.605[b]
Family history of asthma, No. (%)	12 (48)	14 (56)	0.778[b]
History of dermatitis, No. (%)	5 (20)	3 (12)	0.702[b]
Hospitalization due to asthma, No. (%)	7 (28)	3 (12)	0.202[b]
Asthma severity, No. (%)			0.765[b]
Moderate	17 (68)	16 (64)	
Severe	8 (32)	9 (36)	

The comparison was conducted using independent t-test. The comparison was conducted using chi-square test.
PMH: past medical history.

Patients' O_2 saturation scores were also evaluated using the PIS score. Statistical analysis showed no significant difference between the groups before montelukast administration. The comparison of O_2 saturation scores on the first day after drug administration revealed lower scores in the montelukast group, but the statistical analysis showed no significance. However, the comparison of O_2 saturation scores on the second and third days after drug administration revealed significantly higher frequencies of lower scores in the montelukast group (Table 3).

The PIS scores were also compared between groups. The PIS score at the time of admission was lower in the montelukast group, but there was no significant difference between the groups. The PIS score of patients in the montelukast group at the 4th hour after drug administration was lower, but the statistical analysis showed no significant difference. However, the PIS score was significantly lower in the montelukast group in all the other follow-up visits (Table 4) (Figure 2).

Table 2. Comparison of respiratory rate score between treatment and placebo groups.

Variable	Score	Montelukast (n=25), No. (%)	Placebo (n=25), No. (%)	*p*[a]
Respiratory rate score upon admission	0	1 (4)	0 (0)	0.085
	1	12 (48)	8 (32)	
	2	12 (48)	16 (64)	
	3	0 (0)	1 (4)	
Respiratory rate score 4 hours after drug administration	0	1 (4)	1 (4)	0.08
	1	20 (80)	14 (56)	
	2	4 (16)	9 (36)	
	3	0 (0)	1 (4)	
Respiratory rate score 8 hours after drug administration	0	6 (24)	1 (4)	0.007
	1	19 (76)	20 (80)	
	2	0 (0)	1 (4)	
	3	0 (0)	0 (0)	
Respiratory rate score 12 hours after drug administration	0	8 (32)	2 (8)	0.004
	1	17 (68)	18 (72)	
	2	0 (0)	5 (20)	
	3	0 (0)	0 (0)	
Respiratory rate score second day after drug administration	0	12 (48)	7 (28)	0.038
	1	13 (52)	14 (56)	
	2	0 (0)	4 (16)	
	3	0 (0)	0 (0)	
Respiratory rate score third day after drug administration	0	23 (92)	15 (60)	0.009
	1	2 (8)	10 (40)	
	2	0 (0)	0 (0)	
	3	0 (0)	0 (0)	
p value[b]		<0.001	<0.001	

[a]The comparison was conducted using chi-square test.

[b]The comparison was conducted using Friedman test.

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Table 3. Comparison of O_2 saturation scores between treatment and placebo groups.

Variable	Score	Montelukast (n=25), No. (%)	Placebo (n=25), No. (%)	*p* [a]
O2 saturation score upon admission	0	0 (0)	0 (0)	0.503
	1	1 (4)	0 (0)	
	2	3 (12)	3 (12)	
	3	21 (84)	22 (88)	
O2 saturation score 4 hours after drug administration	0	0 (0)	0 (0)	0.402
	1	1 (4)	1 (4)	
	2	5 (20)	2 (8)	
	3	19 (76)	22 (88)	
O2 saturation score 8 hours after drug administration	0	0 (0)	0 (0)	0.370
	1	3 (12)	1 (4)	
	2	5 (20)	5 (20)	
	3	17 (68)	19 (76)	
O2 saturation score 12 hours after drug administration	0	2 (8)	0 (0)	0.164
	1	3 (12)	1 (4)	
	2	6 (24)	8 (32)	
	3	14 (56)	16 (64)	
O2 saturation score second day after drug administration	0	5 (20)	0 (0)	0.006
	1	7 (28)	4 (16)	
	2	9 (36)	12 (48)	
	3	4 (16)	5 (20)	
O2 saturation score third day after drug administration	0	16 (64)	5 (20)	0.002
	1	2 (8)	6 (24)	
	2	7 (28)	9 (36)	
	3	0 (0)	5 (20)	
p value[b]		<0.001	<0.001	

[a]The comparison was conducted using chi-square test.
[b]The comparison was conducted using Friedman test.

Table 4. Comparison of PIS score between treatment and placebo groups.

Variable	Montelukast (n=25), mean ± SD	Placebo (n=25), mean ± SD	*p*
PIS score upon admission	9.76 ± 2.01	10.2 ± 1.76	0.413
PIS score 4 hours after drug administration	7.56 ± 1.42	8.08 ± 1.73	0.251
PIS score 8 hours after drug administration	5.96 ± 1.77	6.92 ± 1.55	0.047
PIS score 12 hours after drug administration	5.13 ± 1.6	6.4 ± 1.63	0.009
PIS score second day after drug administration	3.55 ± 1.23	5.08 ± 2.1	0.006
PIS score third day after drug administration	2.78 ± 0.44	4 ± 1.65	0.005

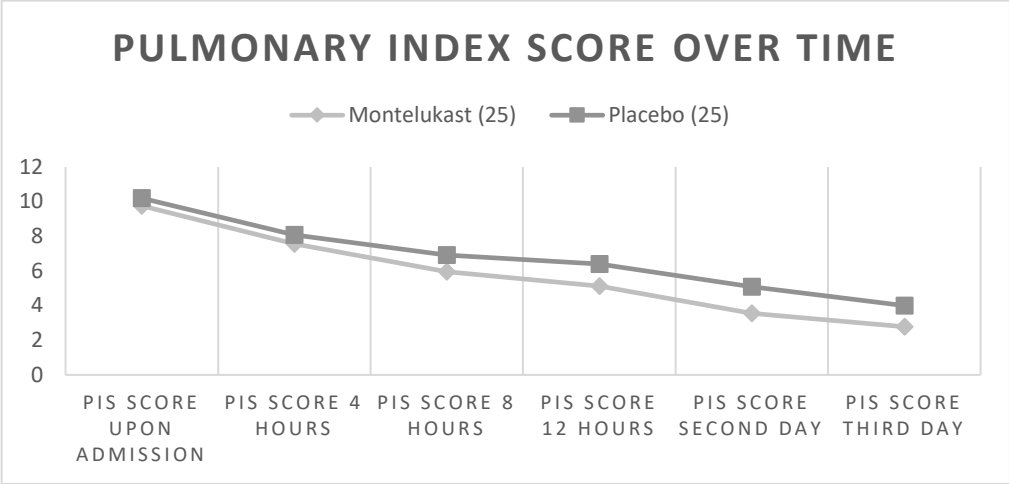

Figure 2. Diagram of PIS score over time.

The secondary outcome of the current research was the length of hospital stay. The mean length of stay in the montelukast group was 2.16 (±0.8) days, compared to 3.12 (±0.83) days in the control group. Statistical analysis using the independent t-test showed a significantly shorter length of stay in the montelukast group (p<0.001).

DISCUSSION

This single-blind, placebo-controlled, single-center clinical trial evaluated the efficacy of intranasal montelukast in managing pediatric asthma attacks. The findings demonstrate that intranasal montelukast significantly reduces patients' PIS scores, respiratory scores, and O_2 saturation levels. To the best of our knowledge, there are no other studies that specifically assess the clinical efficacy of intranasal montelukast in pediatric patients.

Montelukast, a leukotriene receptor antagonist commonly used for chronic asthma control, has been studied in its oral form for asthma attacks. However, results regarding its efficacy have been inconsistent. For instance, a recent double-blind, placebo-controlled trial by Jafari et al (2023) found no statistically significant effect of oral montelukast on asthma severity scores, O_2 saturation, or length of hospital stay compared to the control group.[20] Similarly, Zubairi et al conducted a trial examining the addition of oral montelukast to standard treatment in adolescents and adults, which also reported no significant benefits regarding spirometry metrics or length of stay.[21] Additionally, a study by Akbas found no significant effects of oral montelukast on length of stay, discharge time, clinical asthma score, or O_2 saturation.[22]

In contrast, other studies have reported positive results with oral montelukast. Chaudhury et al (2017) demonstrated the clinical efficacy of oral montelukast in improving forced expiratory volume (FEV) and other spirometry outcomes after four weeks of treatment.[23] Ramsay's 2010 study also reported improved spirometry metrics, such as peak expiratory flow, in the montelukast treatment group compared to controls.[24] Furthermore, another trial indicated a significantly lower PIS score in patients receiving a single 4-mg dose of montelukast compared to the placebo group.[25] These discrepancies may be attributed to variations in clinical outcome measurements among different studies.

The efficacy of montelukast therapy may be explained by its selective inhibition of cysteinyl leukotriene receptors, particularly D4 and E4, leading to reduced airway inflammation and bronchodilation through smooth muscle relaxation.[26] Notably, there was no significant difference between groups until the fourth hour post-admission, which could be attributed to the peak plasma concentration time of montelukast, which has been reported to occur 2 to 4 hours after oral administration (Singulair (Montelukast Sodium). The absence of data on the half-life and peak plasma time for the nasal form of montelukast is a limitation. Moreover, the impact of standard therapy on the results may introduce bias.

Another notable finding of this study is the significantly shorter length of stay in the montelukast group, which may be due to reduced asthma severity facilitating earlier discharge.

This study has limitations, including a small sample size, a single-center design, and incomplete blinding, which may affect the results. Furthermore, the lack of additional outcome measurements, such as spirometry or inflammatory markers, represents another limitation.

In conclusion, intranasal montelukast could be a potential adjunct therapy for managing asthma attacks in pediatric patients, potentially reducing hospital length of stay. However, further multicenter, double- or triple-blinded studies with larger sample sizes and more comprehensive outcome measurements are needed to better assess the efficacy of intranasal montelukast for acute asthma attacks.

STATEMENT OF ETHICS

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences (Approval Code: IR.MUI.MED.REC.1401.076). The trial was registered in the Iranian Clinical Trial Registry (code: IRCT20220119053760N2). Informed consent was obtained from the parents or legal guardians of all participating children prior to their inclusion in the study. The study was conducted in accordance with the principles of the Declaration of Helsinki.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest regarding the publication of this study. No financial or personal relationships influenced the design, execution, analysis, or reporting of this research.

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DATA AVAILABILITY

The data that support the findings of this study are not publicly available due to privacy and ethical restrictions, as they contain information that could compromise the privacy of the research participants. However, the data are available from the corresponding author upon reasonable request.

AI ASSISTANCE DISCLOSURE

The authors utilized AI Assistance for grammar and language editing.

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