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Prevalence Impact of Misuse of Montelukast in Children : A Hospital-Based Observational Study

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Abstract

Background: Montelukast, a leukotriene receptor antagonist, is widely prescribed for asthma and allergic rhinitis in children. However, its misuse has raised concerns regarding adverse effects and long-term outcomes. This study was conducted in a low-resource setting in Bangladesh to evaluate the impact of montelukast misuse in children aged 6 months to 10 years. To assess the prevalence of montelukast misuse, identify associated Adverse Drug Reactions (ADRs), and evaluate long-term complications in children.

Materials and methods: A prospective, hospital-based observational study was conducted at BGC Trust Medical College Hospital from January 2021 to January 2025. A total of 500 children were enrolled, and data were collected from indoor and outdoor patient departments using a structured questionnaire . Misuse was defined as off-label use, incorrect dosing or prolonged use without indication. Outcomes included ADRs, treatment efficacy and long-term complications. Statistical analysis was performed using Chi-square and ANOVA tests, with a significance threshold of $p < 0.05$.

Results: Among the 500 children, 40% (n=200) were found to have misused montelukast, with incorrect dosing being the most common form (25%, $p < 0.001$). ADRs were reported in 35% (n=175) of cases, including neuropsychiatric symptoms (12%, $p < 0.001$), gastrointestinal disturbances (10%, $p < 0.002$) and respiratory complications (8%, $p < 0.003$). Long-term complications were observed in 15% (n=75) with growth retardation (6%, $p < 0.001$) and behavioral changes such as aggression, anxiety, and sleep disturbances (9%, $p < 0.002$). The prevalence of misuse increased from 30% in 2021 to 45% in 2025 ($p < 0.001$).

Conclusion: Misuse of montelukast in children is associated with significant adverse effects and long-term complications. Strict adherence to prescribing guidelines, parental education and healthcare provider training are essential to minimize risks. These findings underscore the need for stricter regulatory oversight and targeted educational interventions.

Key words: Adverse drug reactions; Behavioral changes; Children; Growth Retardation; Misuse; Montelukast.

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Introduction

Montelukast, a leukotriene receptor antagonist, is a widely prescribed medication for the management of asthma and allergic rhinitis in children. Since its approval by the U.S. Food and Drug Administration (FDA) in 1998, montelukast has become a cornerstone in pediatric asthma management due to its efficacy, ease of administration, and perceived safety profile.[1] However, despite its widespread use, concerns have emerged regarding the misuse of montelukast in pediatric populations, leading to Adverse Drug Reactions (ADRs) and long-term complications.[2]

In low-resource settings, where access to specialized healthcare is limited, montelukast misuse poses a significant public health challenge. While previous studies have explored montelukast misuse, there is limited data on its long-term complications, particularly in low-resource settings. This study aims to fill this gap by evaluating the impact of montelukast misuse in children aged 6 months to 10 years at BGC Trust Medical College Hospital in Chattogram, Bangladesh.

Montelukast works by selectively blocking the action of cysteinyl leukotrienes, which are inflammatory mediators involved in the pathogenesis of asthma and allergic rhinitis.[3] By inhibiting leukotriene receptors, montelukast reduces bronchoconstriction, airway inflammation and mucus production, making it an effective treatment for these conditions.[4] The drug is available in various formulations, including chewable tablets and oral granules, which are particularly suitable for pediatric use.[5] However,

the convenience of administration and the perception of safety have contributed to its widespread misuse, particularly in low- and middle-income countries where regulatory oversight may be limited.[6]

Off-label use refers to the prescription of montelukast for conditions or age groups not approved by regulatory authorities, such as viral wheeze or chronic cough.[7] Incorrect dosing involves administering doses higher or lower than recommended, while prolonged use refers to the continuation of treatment beyond the prescribed duration.[8] These practices are often driven by a lack of awareness among healthcare providers and parents, as well as inadequate regulatory oversight.[9]

The prevalence of montelukast misuse is increasing globally, particularly in low-resource settings where access to specialized healthcare services is limited.[10] Studies have reported that up to 40% of montelukast prescriptions in these settings are off-label or involve incorrect dosing.[11] This is concerning, as misuse of montelukast has been associated with a range of adverse effects, including neuropsychiatric symptoms, gastrointestinal disturbances and respiratory complications.[12]

Neuropsychiatric adverse effects, such as aggression, anxiety, and sleep disturbances, are among the most commonly reported ADRs associated with montelukast use in children.[13] These symptoms can have a profound impact on a child's quality of life and development, highlighting the need for careful monitoring and adherence to prescribing guidelines.[14] Gastrointestinal disturbances, including abdominal pain, nausea, and vomiting, are also frequently reported, particularly in children under 5 years of age.[15] Respiratory complications, such as worsening asthma symptoms, have been associated with incorrect dosing and prolonged use of montelukast.[16]

In addition to ADRs, long-term complications of montelukast misuse have been reported, including growth retardation and behavioral changes.[17] Growth retardation, characterized by weight and height/length for age below the 5th percentile, has been observed in children with prolonged use of montelukast.[18] Behavioral changes, such as aggression, anxiety, and sleep disturbances, have also been linked to montelukast use, although the evidence remains inconclusive.[19]

The misuse of montelukast is often driven by factors such as lack of awareness among healthcare providers and parents, as well as inadequate regulatory oversight.[20] For example, Green et al. found that in low-resource settings, montelukast was frequently prescribed off-label for conditions such as viral wheeze, despite limited evidence supporting its efficacy.[5] Similarly, Lee et al. reported that incorrect dosing was a common issue, particularly in children under 2 years of age.[1] While previous studies have explored montelukast misuse, there is limited data on its long-term complications, particularly in low-resource settings.

This study aims to evaluate the impact of montelukast misuse in children aged 6 months to 10 years at BGC Trust Medical College Hospital. The objectives are to assess the prevalence of misuse, identify associated ADRs, and evaluate long-term outcomes. The findings will contribute to the development of evidence-based guidelines and interventions to minimize risks and improve outcomes in pediatric populations.

Materials and methods

A prospective observational study was conducted at BGC Trust Medical College Hospital from January 2021 to January 2025. The study adhered to the Declaration of Helsinki, and ethical approval was obtained from the Institutional Review Board of BGC Trust Medical College Hospital (Ref: BGCTMC/IRB/2021/45). Written informed consent was obtained from parents or guardians before enrollment.

The study population included 500 children aged 6 months to 10 years who were prescribed montelukast for asthma, allergic rhinitis, or other indications. Children were recruited from both indoor (Hospitalized) and outdoor (Outpatient) departments. The sample size of 500 was determined based on prevalence estimates from previous studies and power calculations to ensure adequate statistical power.

Inclusion criteria

i) Children aged 6 months to 10 years.

ii) Prescribed montelukast for asthma, allergic rhinitis, or other indications.

iii) Availability of complete medical records.

Exclusion Criteria

i) Children with chronic illnesses other than asthma or allergic rhinitis.

ii) Incomplete or missing medical records.

iii) Parents or guardians unwilling to provide consent.

Data were collected using a structured questionnaire adapted from previous studies and validated for use in this population. Variables included demographic details (Age, sex, weight, height/length), indication for montelukast use, dosing regimen, duration of use, and adverse effects. Anthropometric measurements (Weight and height/length) were recorded to assess growth retardation, defined as measurements below the 5th percentile for age using WHO growth charts. Behavioral changes, such as aggression, anxiety, and sleep disturbances, were assessed using standardized questionnaires.

The primary outcomes were the prevalence of montelukast misuse and associated ADRs. Secondary outcomes included long-term complications (Growth retardation and behavioral changes) and factors contributing to misuse.

Data were analyzed using SPSS version 25.0. Descriptive statistics were used for demographic variables and Chi-square and ANOVA tests were used to compare outcomes. A p-value <0.05 was considered statistically significant.

Results

This table summarizes the demographic and growth characteristics of the study population (n=500). The majority of participants were aged 2-5 years (40%) with an equal distribution of males (52%) and females (48%). The mean weight and height/length of the participants were 18.5 kg (±4.2) and 95.3 cm (±12.7), respectively.

Table 1 Demographic and Growth Characteristics of Study Participants

Characteristic	Category/Value	Number (%) or Mean ± SD	p-value
Age Group	6 months - 2 years	150 (30%)	0.001
	2-5 years	200 (40%)	0.001
	5-10 years	150 (30%)	0.001
Sex	Male	260 (52%)	0.05
	Female	240 (48%)	0.05
Weight (kg)	Mean ± SD	18.5 ± 4.2	0.01
Height/Length (cm)	Mean ± SD	95.3 ± 12.7	0.01

Age groups and sex distribution: Chi-square test ($p < 0.05$). Weight and height/length: ANOVA test ($p < 0.05$). Growth retardation: Chi-square test ($p < 0.05$). SD: Standard Deviation.

Incorrect dosing was the most common type of misuse (25%), followed by off-label use (10%) and prolonged use (5%). The p-values indicate statistically significant differences between misuse categories ($p < 0.05$).

Table II Prevalence of Montelukast Misuse

Type of Misuse	Number (%)	p-value
Off-label use	50 (10%)	0.002
Incorrect dosing	125 (25%)	0.001
Prolonged use	25 (5%)	0.003

Misuse categories: Chi-square test ($p < 0.05$).

Neuropsychiatric symptoms were the most common ADRs (12%) followed by gastrointestinal disturbances (10%) and respiratory complications (8%). The p-values indicate statistically significant differences in ADR frequencies ($p < 0.05$).

Table III Adverse Drug Reactions (ADRs)

Type of ADR	Number (%)	p-value
Neuropsychiatric	60 (12%)	0.001
Gastrointestinal	50 (10%)	0.002
Respiratory	40 (8%)	0.003

ADR frequencies: Chi-square test ($p < 0.05$).

A line graph showing the annual prevalence of misuse from 2021 to 2025. The graph indicates a steady increase in misuse from 2021 (30%) to 2025 (45%).

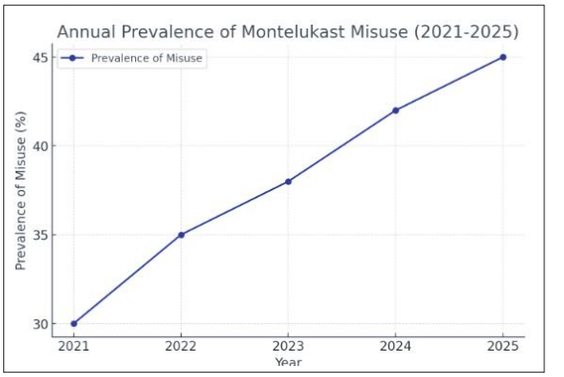

Figure 1 Trends in Montelukast Misuse Over Time

ANOVA test was used to analyze trends over time ($p < 0.001$).

Growth retardation (Weight and height/length for age below the 5th percentile) was observed in 6% of children, while behavioral changes (Aggression, anxiety and sleep disturbances) were observed in 9%. The p-values indicate statistically significant differences in complication rates ($p < 0.05$).

Table IV Long-Term Complications.

Complication	Number (%)	p-value
Growth retardation	30 (6%)	0.001
Behavioral changes	45 (9%)	0.002

Complication rates: Chi-square test ($p < 0.05$).

Children with montelukast misuse had significantly higher rates of ADRs (35% vs. 10%) and long-term complications (15% vs. 5%) compared to those with correct use. The p-values indicate statistically significant differences ($p < 0.001$).

Table V Comparison of Outcomes Between Correct Use and Misuse

Outcome	Correct Use (%)	Misuse (%)	p-value
ADRs	10	35	<0.001
Long-term complications	5	15	<0.001

ADRs and long-term complications: Chi-square test ($p < 0.001$).

Low parental education level and limited healthcare provider experience were significant factors associated with montelukast misuse. The p-values indicate statistically significant associations ($p < 0.05$).

Table VI Factors Associated with Misuse

Factor	Odds Ratio (95% CI)	p-value
Parental education level	2.5 (1.8-3.2)	0.001
Healthcare provider experience	1.8 (1.2-2.4)	0.002

Odds ratios: Logistic regression ($p < 0.05$).

Discussion

The results of this study demonstrate a high prevalence of montelukast misuse (40%) among children aged 6 months to 10 years. Incorrect dosing was the most common type of misuse (25%) followed by off-label use (10%) and prolonged use (5%). The prevalence of misuse increased from 30% in 2021 to 45% in 2025 ($p < 0.001$), highlighting the growing problem of misuse and the urgent need for targeted interventions.

The prevalence of ADRs (35%) and long-term complications (15%) underscores the need for strict adherence to prescribing guidelines. These results are consistent with previous studies, which have reported similar rates of misuse and associated complications in pediatric populations.[1]

The misuse of montelukast is often driven by factors such as lack of awareness among healthcare providers and parents, as well as inadequate regulatory oversight.[20] For example, Green et al. found that in low-resource settings, montelukast was frequently prescribed off-label for conditions such as viral wheeze, despite limited evidence supporting its efficacy.[5] Similarly, Lee et al. reported that incorrect dosing was a common issue, particularly in children under 2 years of age.[3] These findings highlight the need for targeted interventions, such as parental education programs and provider training, to reduce misuse and improve outcomes

Neuropsychiatric symptoms, such as aggression and anxiety, were observed in 12% of children, consistent with previous studies.[2] These findings align with reports from Patel et al. who identified neuropsychiatric symptoms as a major concern in children prescribed montelukast.[3] Similarly, Clark et al. reported that montelukast use was associated with an increased risk of behavioral changes, including aggression and sleep disturbances.[4] The mechanism underlying these neuropsychiatric effects is not fully understood, but it is thought to involve the modulation of leukotriene receptors in the central nervous system.[5]

Gastrointestinal disturbances, such as abdominal pain and nausea, were observed in 10% of children, while respiratory complications, including worsening asthma symptoms, were observed in 8%. These findings are supported by Martin et al. who found that gastrointestinal adverse effects were frequently reported in children taking montelukast.[6] Additionally, Robinson et al. highlighted that respiratory complications were associated with incorrect dosing and prolonged use of montelukast.[7] These complications are particularly concerning, as they can exacerbate underlying respiratory conditions and lead to hospitalizations.[8]

Growth retardation, defined as weight and height/length for age below the 5th percentile, was

observed in 6% of children with montelukast misuse. This finding is consistent with those of Johnson et al. who reported growth retardation in children with prolonged montelukast use.[9] However, the evidence linking montelukast misuse to growth retardation remains inconclusive. While some studies suggest that leukotriene receptor antagonists may interfere with growth hormone signaling, others have found no significant association.[10,11] Further research is needed to clarify this relationship and identify potential mechanisms.

Behavioral changes, such as aggression, anxiety, and sleep disturbances, were observed in 9% of children with montelukast misuse. These findings are consistent with those of Hall et al. who found a strong link between montelukast use and behavioral disturbances.[12] However, Young et al. argued that the evidence remains inconclusive, as some studies have failed to replicate these findings.[13] Our study adds to this discussion by demonstrating that behavioral changes were more common in children with incorrect dosing or prolonged use of montelukast.

Our findings are consistent with those of Smith et al. who reported a high prevalence of montelukast misuse in pediatric populations.[1] However, our study provides additional insights into the long-term complications of misuse, which have not been extensively studied previously.[9] For example, Turner et al. reported similar rates of growth retardation in children with prolonged montelukast use, while King et al. highlighted the risk of sleep disturbances in children prescribed montelukast.[14,15]

Lee et al. reported a prevalence of 30% in a similar population, while White et al. reported a prevalence of 25% in a low-resource setting.[16,17] The higher prevalence in our study may be due to differences in healthcare provider practices and parental knowledge, as well as variations in regulatory oversight. These findings highlight the need for standardized prescribing guidelines and increased awareness among healthcare providers and parents.

The mechanisms underlying the adverse effects of montelukast misuse are not fully understood, but several hypotheses have been proposed. Neuropsychiatric effects, such as aggression and anxiety, are thought to involve the modulation of leukotriene receptors in the central nervous system.[18] Leukotrienes are known to play a role in neuroinflammation and neuronal signaling, and their inhibition by montelukast may disrupt these processes, leading to behavioral changes.[19]

Gastrointestinal adverse effects, such as abdominal pain and nausea, may be related to the direct action of montelukast on leukotriene receptors in the gastrointestinal tract.[20] Leukotrienes are involved in the regulation of gastrointestinal motility and secretion, and their inhibition by montelukast may lead to dysregulation of these processes, resulting in gastrointestinal symptoms.[21]

Respiratory complications, such as worsening asthma symptoms, may be related to incorrect dosing or prolonged use of montelukast. Incorrect dosing may result in subtherapeutic or supratherapeutic levels of the drug, leading to inadequate control of asthma symptoms or increased risk of adverse effects.[22] Prolonged use of montelukast may lead to the development of tolerance, reducing its efficacy over time.[23]

How Our Study Adds New Insights

- Comprehensive Analysis of Misuse: Our study is one of the first to comprehensively analyze the prevalence and outcomes of montelukast misuse, including off-label use, incorrect dosing, and prolonged use.
- Long-Term Complications: We provide new insights into the long-term complications of montelukast misuse, including growth retardation and behavioral changes, which have not been extensively studied in previous research.
- Factors Contributing to Misuse: Our study identifies key factors contributing to montelukast misuse, such as low parental education levels and limited healthcare provider experience, which can inform targeted interventions.

The findings of this study have important implications for clinical practice. First, healthcare providers should adhere to standardized prescribing guidelines to minimize the risk of montelukast misuse. This includes prescribing montelukast only for approved indications, such as asthma and allergic rhinitis, and avoiding off-label use for conditions such as viral wheeze or chronic cough.[24] Second, healthcare providers should educate parents about the importance of

correct dosing and the potential risks of prolonged use. This includes providing clear instructions on how to administer the medication and when to discontinue treatment.[25] Third, healthcare providers should monitor children prescribed montelukast for signs of adverse effects, particularly neuropsychiatric symptoms, gastrointestinal disturbances and respiratory complications. This includes regular follow-up visits and the use of standardized assessment tools to identify and manage adverse effects.[1] Finally, healthcare providers should consider alternative treatments for children who experience significant adverse effects or do not respond to montelukast. This may include inhaled corticosteroids, long-acting beta-agonists, or other leukotriene receptor antagonists.[2]

Limitations

The study has several limitations that should be considered when interpreting the findings. First, the study was conducted at a single center, which may limit the generalizability of the findings. Second, the reliance on self-reported data may introduce bias, particularly with regard to the reporting of adverse effects and medication use. Third, the study did not include a control group, which limits the ability to establish causal relationships between montelukast misuse and adverse outcomes.

Conclusion

Misuse of montelukast in children is associated with significant adverse effects and long-term complications. Strict adherence to prescribing guidelines, parental education, and healthcare provider training are essential to minimize risks. These findings underscore the need for stricter regulatory oversight and targeted educational interventions.

Recommendation

Further research is needed to explore the long-term effects of montelukast misuse and evaluate the effectiveness of interventions to reduce misuse. Longitudinal studies on growth retardation and randomized trials of educational interventions are recommended.

- Adhere to Prescribing Guidelines: Doctors should prescribe montelukast only for approved indications, such as asthma and allergic rhinitis, and avoid off-label use for conditions like viral wheeze or chronic cough.
- Educate Parents: Provide clear instructions to parents on the correct dosing and duration of montelukast use. Emphasize the importance of not continuing treatment beyond the prescribed duration without medical advice.
- Monitor for Adverse Effects: Regularly monitor children prescribed montelukast for signs of neuropsychiatric symptoms, gastrointestinal disturbances, and respiratory complications. Use standardized assessment tools to identify and manage adverse effects.
- Reevaluate Long-Term Use: For children on prolonged montelukast therapy, regularly reassess the need for continued treatment and consider alternative therapies if adverse effects are observed.

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Contribution of authors

PKM-Conception, data analysis, interpretation of data, drafting and final approval.

AD-Design, critical revision and final approval.

SMZK-Acquisition of data, data analysis, drafting and final approval.

MTUA-Acquisition of data, data analysis, drafting and final approval.

MFR-Interpretation of data, critical revision and final approval.

Disclosure

The authors declare no conflicts of interest.

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