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Case Study

A Case Report On Montelukast And Fexofenadine Induced Depression And Nightmares

Christeena Mary Viji¹, Karun Kumar²

¹Pharm D Intern, Nazareth college of pharmacy, Othera,

²Assistant Professor Department of Pharmacology, Palakkad Institute of Medical Sciences, Palakkad

*Author for Correspondence: Dr. Karun Kumar

Email: karun_kumar@live.in

 Abstract	
Published on: 04 Mar 2025	Depression and nightmares are caused by Montelukast. Montelukast is a selective leukotriene receptor antagonist (LRTA) and US-FDA issued a black box warning in 2020. In this case report, a 14 year old female was prescribed a combination of Tab. Montelukast and Tab. Fexofenadine for the treatment of bronchial asthma exacerbations. After this, she started experiencing multiple episodes of depression and nightmares. The patient was asked to avoid Montelukast after which the patient's condition improved and she was started on MDI Formoterol fumarate and Budesonide powder for inhalation and Tab. Desloratadine for further management. After stopping the drug, her condition improved. This case underlines the importance of monitoring for rare but serious side effects of leukotriene receptor antagonist and highlights the need for further research into their mechanisms and risk factors.
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2025 All rights reserved.  Creative Commons Attribution 4.0 International License.	Keywords: Montelukast, depression, nightmare, bronchial asthma, Fexofenadine

INTRODUCTION

Dream disturbances, such as nightmares, along with psychiatric conditions like hallucinations, aggressive behaviour, depression, and suicidal thoughts or behaviours were not reported in Montelukast clinical trials^[2-5]. A nightmare is a long, intensely distressing dream, often centred around attempts to escape threats to survival, safety, or physical well-being. However, according to the product labelling, nightmares are categorized as an uncommon adverse drug reaction (ADR), occurring at a frequency of $\geq 1/1000$ to $<1/100$ ^[1].

Depressive disorder, or depression, is a common mental health condition that can happen to anyone. It is characterized by low mood or loss of pleasure or interest in activities for long periods of time^[18]. Depression is an uncommon is an uncommon adverse drug reaction (ADR) occurring at a frequency of $\geq 1/1000$ to $<1/100$ people taking the medication^[7].

CASE REPORT

A 14-year-old female patient came to the Department of General Medicine with complaints of tiredness and dyspnoea on 26th August 2024. She had bronchial asthma since her childhood and frequent exacerbations since November, 2023. She also had complaints of dust allergy and was unable to tolerate scents and paint smell. She was started on treatment for bronchial asthma with Tab. Montelukast and Tab. Fexofenadine 10/120 mg once a day at night time on 24th June 2024. She developed depression and nightmares while on treatment with Tab. Montelukast and Tab. Fexofenadine 10/120 mg. She experienced nightmares and depressive episodes with a feeling of weakness. Upon consultation, the patient had depressive episodes and nightmares frequently. Tab. Montelukast and Tab. Fexofenadine was withdrawn and the patient was started on MDI Formoterol fumarate and Budesonide powder for inhalation 400 1 puff 2 times a day and Tab. Desloratadine 5 once a day at bedtime. Now her condition has improved.

Upon evaluation at our Adverse Drug Reaction (ADR) Monitoring Center, the causality was determined to be “probable” using the WHO-UMC Causality Assessment Scale^[12]. The type of ADR was classified as “Type B” according to the Rawlins–Thompson^[9] classification and was assessed as “Level 3, Moderate” in terms of severity based on Hartwig’s scale. As per the WHO criteria, the seriousness of the reaction was categorized as “nonserious,” and the outcome of the reaction was “Recovering.” In addition, according to the Schumock and Thornton scale, the ADR was deemed “nonpreventable” As per Naranjo’s adverse drug reaction probability assessment scale it is “probable” ADR. The assessment of causality and other attributes of the ADR was conducted using established scales.

DISCUSSIONS

Tab. Montelukast and Tab. Fexofenadine are leukotriene receptor antagonists (LTRAs) and nonsedating H1 receptor antagonists respectively^[19]. When Tab. Montelukast and Tab. Fexofenadine 10/120 mg was administered to this patient for the treatment of exacerbations of bronchial asthma, after which the patient experienced depression and nightmares. After withdrawal of the drug, the patient’s condition improved which indicates that the the drug may have caused depression and nightmares^[6,7]. However, Vigiaccess shows a total of 32,506 ADRs reported. Amongst them, 10,977 are psychiatric disorders. Depression was reported in 2,265 ADRs and nightmares in 1,607 ADRs^[17]. Depression and nightmares should be carefully assessed and closely monitored in children receiving montelukast, as these symptoms may develop during the treatment.

CONCLUSION

Although Montelukast is marked beneficial but the adverse neuropsychiatric drug reactions are more prevalent than those documented in the literature. The health professional should focus on collecting the patient’s history regarding previous exposure to the drug and drug provocation testing. They should also emphasize on the management of the adverse effects.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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