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Montelukast Suspected Adverse Reaction in Children

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Abstract

Leukotriene receptor antagonist (LTRA) montelukast is frequently used for breathing difficulties associated with sleep, allergic rhinitis, and asthma. Recent investigations have documented a number of negative outcomes in kids, including neuropsychiatric problems and sleep difficulties. Objective: To learn more about the safety profile of montelukast for kids with allergies, hay fever, and breathing problems related to sleep. Method and findings: Over a two-year period, we retrospectively examined all adverse medication reactions to montelukast among 385 kids aged 6 months and older in six tertiary centres. 89.6% of patients had asthma, 50% had allergic rhinitis, and 13.6% had breathing problems linked to sleep. Singulair was the most widely used form of montelukast, accounting for 67.9% of all prescriptions. According to this study, there were 123 individuals who experienced adverse medication responses, and the majority of them were in those toddlers (22.8%) and those between the ages of 4 and 9 (52.8%) were the next two age groups. 9.8% of the children had two (ADRs) documented, whereas 5.5% had three or more. The most frequent adverse drug reactions (ADRs), which affected 15.1% of participants (overlap was widespread; 5.5% of kids had trouble sleeping, 4.4% had trouble falling asleep or staying asleep, and 1.82% had nightmares), were agitation (10.4%), pain (9.4%), and hyperactivity (6.8%).

Keywords: Montelukast • Singular • Neuropsychiatry • Side effect • Adverse effect

Introduction

One of the most widely prescribed drugs for asthma and other medical disorders is montelukast, a leukotriene receptor antagonist (LTRA). LTRAs are typically administered as an adjuvant medicine to inhaled corticosteroids for individuals with stage 3 or higher asthma, while they may also be prescribed as an alternative to inhaled corticosteroids for moderate asthma. LTRAs work by suppressing inflammatory mediators of bronchoconstriction. The US Food and Drug Administration (FDA) issued a montelukast use warning to doctors in 2009, citing a number of significant observations that could result in neuropsychiatric abnormalities. Due to the significant prevalence of childhood asthma and the serious side effects of montelukast, we made the decision to find out if this well-known drug, which is frequently prescribed for children under certain circumstances, actually works [1]. is linked to any neuropsychiatric incident in kids in Saudi Arabia's six largest cities. The prevalence of asthma in children has increased from 8 to 23% over the past 20 years. The southern portion of the kingdom (Abha) in Saudi Arabia has the lowest prevalence (7%), and Hafoof has the greatest prevalence (33%). Unfortunately, according to data from Dr. Jahdali et al. utilising the Asthma Control Test (ACT), the majority of asthma cases in the Kingdom of Saudi Arabia are uncontrolled. In a comparable study, Dr. Aslan et al. found that 50% of children's asthma cases in a Riyadh tertiary centre were uncontrolled. Asthma is a frequently diverse disease with a variety of asthma phenotypes and presentations ranging from a simple cough to a severe exacerbation A lower age group and an older age group are frequently used to categorise asthma cases [2].

Materials and Methods

Among children aged 6 months to 17 years, we retrospectively assessed all possible adverse drug reactions (ADRs) to montelukast. The Prince Sultan Military Medical City (PSMMC) in Riyadh, Qassim University, Imam Abdulrahman Bin Faisal University in Dammam, Dr. Suleiman Fakeeh Hospital, King Abdul-Aziz University Hospital in Jeddah, and Maternity and Children Hospital in Abha, Saudi Arabia, were the six tertiary centres where this study was carried out among kids with a doctor-confirmed diagnosis of asthma, allergic rhinit Epitools was used to determine the sample size (accessed on 1 September 2022) (https://epitools.ausvet.com.au/oneproportion). The lowest sample size needed to determine the prevalence of side effects with a 95% confidence interval and a sample size of 80% was a sample of 385 children on montelukast. accuracy of 5%. All patients were given an electronic questionnaire, but the focus was on kids with signs of asthma, allergies to the nose, or breathing problems associated with sleep. It was also noted when montelukast was used alone or in conjunction with long-acting bronchial agonists and/or inhaled corticosteroids [3].

Children with recognised problems of the central nervous system (CNS), concomitant conditions, or those who did not take montelukast were not included. Three different questioning techniques were used to evaluate the frequency of adverse medication reactions linked to montelukast. First, parents were questioned regarding their familiarity with montelukast, its many forms, potential side effects, and the three possible indications for its use. But for those kids with respiratory problems related to sleep, we double-checked to see if the signs got worse after being prescribed montelukast since the illness itself can have side effects that are comparable to those of the medication. Version 21.0 of SPSS for Windows was used to conduct the statistical analysis (SPSS Inc., Chicago, IL, USA). Frequencies and proportions are used to present the data. For variables with a nonnormal distribution, a nonparametric test was used. In order to compare data between individuals of various ages, independent sample t tests were utilised. Categorical groups were compared using chi-square testing. A 95% confidence interval and a p value of 0.05 were used to determine statistical significance [4].

Discussion

A cysteinyl leukotriene receptor (D4 and E4) antagonist called montelukast is frequently used to treat allergic rhinitis, sleep-related breathing problems, and asthma as a preventative measure. In this study, 123 individuals experienced a significant rate of adverse medication reactions (31.9%), with sleep disturbance being the most frequent (ADRs). Since 2008, there have been more reports of possible adverse drug reactions to montelukast, such as irritability, aggression, and sleep difficulties. These reactions typically start 1 week after starting

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therapy and can affect up to 10% of children. Numerous negative effects were noted in the World Health Organization's (WHO) pharmacovigilance database, including hostility, suicidal ideation, anxiety, insomnia, aberrant behaviour, nightmares, shortness of breath, stomach discomfort, nausea, rash, dizziness, myalgia, and muscle pain. spasm. Due to the risk for adverse neuropsychiatric events (such as depression and suicidality), the FDA suggested caution when montelukast and other LTRAs are administered. However, a sizable nested case-control research with 1920 asthmatics matched for age, sex, and area failed to find a significant link between montelukast and neuropsychiatric episodes in children [5].

Conclusion

The safety of montelukast in clinical practise is well covered in this article. This study supports the worry that individuals using montelukast have a high prevalence of negative neuropsychiatric side effects, particularly agitation, sleep disturbance, pain, and hyperactivity. When montelukast is recommended, families and doctors should be informed of its (ADRs); fortunately, no major side effects have been documented. There are still many misconceptions about montelukast, therefore educating the families is essential. It is vitally necessary to do additional epidemiological research to estimate the risk for management.

Acknowledgement

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Conflict of Interest

None.

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