Montelukast and nightmare –
Further characterisation using data from VigiBase

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Background

Montelukast is a selective leukotriene receptor antagonist used to treat asthma. It can induce nightmares and other psychiatric adverse reactions (ADRs).

Objectives

To further characterise montelukast induced nightmare to identify measures to minimise the risks.

Methods

Reports on nightmare contained in VigiBase, the WHO global individual case safety report database at Uppsala Monitoring Centre, were analyzed and narratives reviewed.

Results

By 3rd May 2020, VigiBase contained 25,120 reports for montelukast as suspected, including 8,106 (32%) reporting an ADR of Psychiatric Disorders, thereof 1,118 with nightmare (expected 44). Montelukast was the single suspected in 1,087 cases (97%). Half (51%) of the cases were serious. Most (70%) were below 18 years of age, 82% of whom aged 2 to 10 years. More males were reported for children below 11 years old, but more females for those 11 years or older.

The most co-reported ADR for children aged 2-10 years was aggression, while for teenagers and adults, anxiety, and for those aged 65 and older, insomnia.

The median time from montelukast start to nightmare onset (TTO) was three days, ranging 1h - 10 years, most (65%) within one week. Positive dechallenge was recorded in 88% (486/552) of cases, and positive rechallenge in 23 of the 29 cases which recorded a rechallenge (79%).

Reviewing narratives revealed that vivid nightmares in children could result in extreme fear of sleeping and of being alone. There were descriptions of changed behaviour which affected both family life and the child's ability to cope with school. It was noted that some parents of the children, as well as the caring physicians, were not aware of montelukast psychiatric ADRs, leading to prolonged drug use after the ADR occurrence.

Nightmares usually disappeared within days to weeks after withdrawal of montelukast. However, there were descriptions that the nightmares and co-reported psychiatric ADRs persisted for months, or up to 1.5 years in individual cases.

Five patients were found to have changed the time of montelukast dose from evening to morning. Three of the patients recovered from nightmares, while two reported experiencing no difference when changing to a morning dose.

Conclusions

Although nightmares, together with other psychiatric disorders, are labeled ADRs for montelukast, this study reveals that some young children with these ADRs were reported as having changed behaviour, which affected their daily life and school learning. Prescribers should be aware of these ADRs, and monitor treated patients, in particular children. The benefits and risks of montelukast should be considered before the drug prescription, and re-evaluated when the ADRs occur during treatment.

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