

NEWS ARTICLE

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Link to depression in kids on risperidone

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Symptoms of depression may develop in children receiving the antipsychotic drug risperidone, an Intensive Medicines Monitoring Programme (IMMP) study reveals.

Although the association of risperidone (Risperdal and Ridal) with depression needs further study and the study's authors do not want to be alarmist, IMMP director Mira Harrison-Woolrych says the data indicate this is a new adverse reaction for risperidone in children and clinicians need to be aware of because of the potentially serious consequences.

Published in *Drug Safety* (2007;30[7]:569–579), the IMMP study is a nationwide prospective cohort looking at the safety and use of atypical antipsychotic medicines in children. The study found symptoms of depression developed in children without previous mood disorders, who were being treated for indications not usually associated with depression.

Four cases of depression related to risperidone were identified, equivalent to an incidence of eight cases per 1000 patient-years of treatment.

The authors say the incidence may be an underestimate as other cases of suicidality and self-harm were also identified. Depression was only recorded as an event if doctors specifically reported those symptoms and researchers could confirm the child had developed symptoms of depression.

Study coauthor Juan Garcia-Quiroga, a child and adolescent psychiatrist, points out there is evidence that these medicines are useful in managing children and this study simply looked at the safety and use of the medicines, not efficacy. It is often difficult to diagnose depression in children who are likely to be using these medicines as there are usually many confounding issues, Dr Garcia-Quiroga says.

The authors say this research is the first study internationally that provides a comprehensive "real picture of how these medicines are used in children and their safety profile. Other studies have been conducted for short periods while there was virtually no exclusion of children in the IMMP study and long-term follow-up.

Clozapine, olanzapine and quetiapine were also monitored in the study, but 93 per cent of the 420 children involved were taking risperidone.

The study looked at all children aged two to 15 years who were prescribed antipsychotic medicine in New Zealand. They were followed up for at least a year after they began the medication, with intensive follow-up events reported by both GPs and from hospital admissions. On average, children were using these medications for 18 months.

The antipsychotics were most frequently used for aggression (47 per cent), behavioural difficulties and anxiety (17). Diagnoses for their use were most commonly disruptive disorders (43 per cent), pervasive developmental disorders like autism and Asperger's syndrome (34) and cognitive impairment (17). Investigation of the symptoms targeted by these medicines identified unexpected use for the treatment of sleep disorders.

About 30 per cent of the children experienced an adverse event with about one-third of the events considered to be related to the antipsychotic medicine. A total of 352 clinical events were recorded, 331 occurred in children taking risperidone.

The most frequent adverse events reported were weight gain, severe dental caries and somnolence. From a medical monitoring point of view, Dr Harrison-Woolrych says these rates are not surprising. Weight gain and sleepiness were expected reactions, although the finding that about 6 per cent of the children had hospital admissions for dental caries was unexpected.

Onset or worsening of diabetes was also expected, although the authors say the sample size is small.



larger study population is needed to study this issue further.

They are grateful to the many GPs and specialists who provide the information and because of this early release of the study details to *New Zealand Doctor*. The Medicines Adverse Reactions Committee considered the findings and decided no changes are required to the medicine's data sheet. This is available at www.medsafe.govt.nz/profs/Datasheet/DSForm.asp

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