Risperidone was safe and effective for short term treatment of children with autism and serious behavioural disturbances


QUESTION: In children with autism and serious behavioural disturbances, is risperidone safer and more effective than placebo?

Patients
101 children who were 5–17 years of age (mean age 8.8 y; 81% boys), met the DSM-IV criteria for autistic disorder, and presented with tantrums, aggression, or self injurious behaviour. Other inclusion criteria were weight of ≥ 15 kg, mental age ≥ 18 months, and no serious medical disorders or other psychiatric disorders requiring medication. Children receiving a psychotropic drug that was effective for aggression, tantrums, or self injurious behaviour were excluded. Follow up was complete.

Intervention
Patients were allocated to risperidone (n=49) or placebo (n=52). For children who weighed < 20 kg, the initial dose of risperidone was 0.25 mg/day; for children who weighed 20–45 kg, the initial dose was 0.5 mg at bedtime, increased to 0.5 mg twice/day on day 4, and increased to a maximum of 2.5 mg/day by day 29; for children who weighed > 45 kg, the maximal dose was 1.5 mg in the morning and 2.0 mg at bedtime.

Main outcome measures
The primary outcomes were scores on the Irritability subscale of the Aberrant Behavior Checklist and a rating of much or very much improved on the Clinical Global Impressions – Improvement scale.

Main results
Analysis was by intention to treat. Withdrawal occurred in 6% of the risperidone group and 35% of the placebo group. At 8 weeks, patients who received risperidone had a greater mean decrease from baseline on the Irritability score than did patients who received placebo (14.9 ± 5.6, p < 0.001). More children who received risperidone had a positive response than did children who received placebo (table). Patients in the risperidone group had a greater increase in weight than patients in the placebo group (2.7 ± 0.8 kg, 95% CI for the 1.9 kg difference, 0.88 to 2.97). No serious adverse events occurred in the risperidone group.

Conclusion
In children with autism and serious behavioural disturbances, risperidone was safe and effective for the short term treatment of tantrums, aggression, and self injurious behaviour.

*Risk glossary.
†CI calculated from data in article.