Once a day Concerta methylphenidate was equivalent to 3 times daily methylphenidate in children with ADHD


QUESTION: In children with attention deficit hyperactivity disorder (ADHD), is once daily extended release methylphenidate (MPH) as effective as 3 times daily dosing?

**Design**
Randomised (unclear allocation concealment8), blinded (patients/parents and outcome assessors)*, placebo controlled crossover trial with 7 days of follow up for each treatment condition.

**Setting**
State University of New York at Buffalo, Buffalo, New York, USA.

**Patients**
70 children between 6 and 12 years of age (mean age 9 y, 89% boys) with ADHD receiving a stable dose of MPH for >4 weeks. Exclusion criteria included contraindication to stimulant medication, any condition that would interfere with participation in laboratory classroom assessment, receiving any other medication for ADHD, and having reached menarche. 2 children were discontinued from the study.

**Intervention**
Crossover comparison of placebo, immediate release (IR) MPH 3 times a day (tid), and Concerta, a once daily MPH formulation taken in the morning. Each child's dose concentration was based on that child's MPH dosing before the study. 3 dosing concentrations of medication were used: 5 mg IR MPH tid/18 mg Concerta once a day; 10 mg IR MPH tid/36 mg Concerta once a day; and 15 mg IR MPH tid/54 mg Concerta once a day. Children received each medication condition for 7 days. Parents received behavioural parent training and teachers were taught to establish a school home daily report card.

**Main outcome measures**
Change in ADHD symptoms, social behaviour and academic performance in both naturalistic (home and school) and laboratory environments (on Saturday); and side effects.

**Main results**
On all measures in all settings, both drug conditions were statistically different from placebo (p<0.001 for all measures) with little difference between drug conditions. In the natural setting, effect sizes (magnitude of the drug effects relative to placebo) on ADHD symptoms were 2.0, on oppositional defiant disorder symptoms 1.5, and on peer relation problems 1.4. Both medications improved behaviour as measured by teacher ratings and individualised target behaviours. These effects continued on into the evening as measured by parent ratings. In the laboratory setting Concerta was equivalent to IR MPH and both were statistically different from placebo. Effect sizes for both active drugs ranged from 0.4 to 0.8 on measures of rule violation frequency, negative behaviour frequency, observed disruptive behaviours, and individualised target behaviours. Side effects on children's sleep and appetite were similar for the 2 drug conditions.

**Conclusion**
Once a day Concerta methylphenidate was equivalent to 3 times daily methylphenidate in children with attention deficit hyperactivity disorder.

*See glossary.