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## When Preschool Children Have ADHD

*Stimulant medication is effective for treatment of preschool children with ADHD, but it's associated with a high rate of adverse events.*

Results of small studies have reported benefits from methylphenidate (MPH) for treating core ADHD behaviors in preschool children. Now, results of the Preschool ADHD Treatment Study (PATS), a NIMH-funded, six-center, randomized trial of the efficacy and safety of MPH in preschool children, have been reported in four articles.

Investigators enrolled 303 children (age range, 3–5.5 years) who met DSM-IV criteria for combined-type ADHD in an intensive 10-week behavioral therapy program with their parents. Children whose behaviors had not improved after behavioral therapy and whose parents agreed to a medication trial entered a 5-week, placebo-controlled, double-blind trial in which 165 children were randomized to receive placebo or 1.25 mg, 2.5 mg, 5.0 mg, or 7.5 mg of immediate-release MPH three times daily. Outcomes were measured with standardized ADHD questionnaires completed by parents and teachers. Compared with controls, children who received the 2.5 mg, 5.0 mg, and 7.5 mg doses of MPH had significant reductions in ADHD symptoms ( $P<0.01$ ,  $P<0.001$ ,  $P<0.001$ , respectively). The mean effective *total* daily dose of MPH was 14.2 (+/–8.1) mg/day.

After the controlled phase, 140 children entered a 10-month open-label maintenance trial. By the end of the maintenance phase, the mean effective *total* daily dose of MPH rose from 14.2 mg/day to 20.5 mg/day. Thirty percent of parents reported moderate-to-severe adverse effects (including emotional outbursts, difficulty falling asleep, repetitive behaviors and thoughts, appetite suppression, and irritability). Eleven percent of children in this phase discontinued MPH. Among the 95 children who remained on MPH, annual growth rates were 20% lower than expected for height (–1.38 cm/year) and 55% lower for weight (–1.32 kg/year).

**Comment:** The results of this large, placebo-controlled trial demonstrate the effectiveness of stimulant medication in the treatment of preschool children with ADHD. The strengths of the study include a meticulous diagnostic process, participation of all parents in an intensive behavioral management program before considering medication, randomization to different medication doses, and long-term follow-up to assess safety.

ADHD remains a challenging diagnosis because the core symptoms — hyperactivity, impulsivity, and inattentiveness — are consistent with typical developmental variations in preschool children. Clinicians must decide which children fall outside expected behavioral norms. In preschool children with ADHD, frequent and unremitting disruptive behaviors in the classroom and at home that are not responsive to behavioral management often suggest the diagnosis of ADHD. However, psychosocial deprivation, sexual abuse, autistic spectrum disorder, and early bipolar disease are some other conditions that might be associated with similar behavior patterns. Primary care pediatricians should use caution before prescribing medication for ADHD in a preschool child and should weigh the potential benefits of MPH against the relatively high rate of adverse events.

— *Martin T. Stein, MD*

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Kollins S et al. Rationale, design, and methods of the Preschool ADHD Treatment Study (PATS). *J Am Acad Child Adolesc*

*Psychiatry* 2006 Nov; 45:1275-83.

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