A RANDOMIZED, DOUBLE BLIND STUDY OF ATOMOXETINE FOR ADHD IN CHILDREN AND ADOLESCENTS: RELAPSE PRENTION AFTER ONE YEAR

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Despite the fact that ADHD is a chronic disorder, systematic assessments of efficacy in ADHD have mainly taken place in trials limited to several weeks in duration. Few prospective studies have examined the value of continued treatment in subjects who have had a satisfactory initial response to treatment.
A study was conducted at 33 academic investigative centers in Europe, Israel, South Africa, and Australia: after a parent or guardian for each patient provided written informed consent, 614 patients aged 6 to 15 years meeting *DSM-IV* criteria for ADHD confirmed by a structured interview (K-SADS-PL) were prescribed with Atomoxetine (0.5-1.8 mg/kg/ day) a nonstimulant treatment for ADHD (Buitelaar et al. 2004). A total of 416 patients responded to an initial 12-week, open-label period of treatment they were randomized to continued atomoxetine treatment or placebo for 9 months under double-blind. At end point, atomoxetine was superior to placebo in preventing relapse defined as a return to 90% of baseline symptom severity (proportion relapsing: atomoxetine 65 of 292 [22.3%], placebo 47 of 124 [37.9%], p = .002). The proportion of patients with a 50% worsening in symptoms post-randomization was also lower on atomoxetine (atomoxetine 83 of 292 [28.4%], placebo 59 of 124 [47.6%], $p <$ .001; Michelson et al. 2004).
Subjects who had completed 1 year of double-blind atomoxetine treatment were then randomly assigned in double-blind fashion to continued atomoxetine or placebo substitution for further 6 months. Atomoxetine was superior to placebo in preventing relapse (Wilcoxon test, p = .008) and in maintaining symptom response (ADHD Rating Scale IV score, p < .001). Among subjects assigned to discontinuation, the magnitude of symptom return was generally to a level of severity less than that observed at study entry. There was, However, a considerable variability between individuals in the magnitude of symptom return after drug discontinuation, suggesting that some subjects treated with atomoxetine for a year with good results may consolidate gains made during drug treatment and could benefit from a medication-free trial to assess the need for ongoing drug treatment.

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