Predictors of relapse or maintenance of response in pediatric and adult patients with attention-deficit/hyperactivity disorder following discontinuation of long-term treatment with atomoxetine

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Abstract

We identified relapse/maintenance-of-response (MOR) predictors following discontinuation of long-term atomoxetine treatment in pediatric and adult patients with attention-deficit/hyperactivity disorder (ADHD) and assessed correlations between ADHD symptoms and quality of life (QoL). Post hoc analyses of data from two randomized, double-blind, placebo-controlled, phase 3 withdrawal studies in patients with ADHD meeting predefined response criteria before randomization. Study 1: patients (N = 163; 6–15 years) received atomoxetine (1.2–1.8 mg/kg/day) for 1 year, followed by randomization to atomoxetine (n = 81) or placebo (n = 82) for 6 months. Study 2: patients (N = 524; 18–50 years) received atomoxetine (80–100 mg/day) for ~6 months, followed by randomization to atomoxetine (n = 266) or placebo (n = 258) for ~6 months. Placebo patients were used for the analyses. Relapse: ≥50% worsening of pre-randomization improvement in ADHD symptoms and ≥2 level severity increase on the Clinical Global Impression-Severity (CGI-S) scale at 2 consecutive visits; MOR: retaining ≥75% of pre-randomization symptom improvement and CGI-S ≤ 2 at all visits (study 1); retaining ≥70% of pre-randomization symptom improvement and CGI-S ≤ 3 at all visits (study 2). In adults, statistically significantly (P ≤ .05) increased the likelihood of relapse was associated with pre-randomization presence of Conners’ Adult Attention-Deficit/Hyperactivity Disorder Rating Scale-Investigator-Rated:Screening Version (CAARS-Inv:SV) items “difficulty awaiting turn” and “careless mistakes.” In pediatric patients, less MOR was associated with the pre-randomization presence of ADHD Rating Scale-IV-Parent Version Investigator-Rated item “does not listen”; in adults, less MOR was associated with the pre-randomization presence of CAARS-Inv:SV items “loses things” and “difficulty awaiting turn.” Changes in patients’ QoL after withdrawal from atomoxetine moderately correlated with changes in ADHD symptoms in pediatric patients and mildly in adults.