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Atomoxetine treatment of attention-deficit/hyperactivity disorder in young adults with assessment of functional outcomes: a randomized, double-blind, placebo-controlled clinical trial.

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BACKGROUND:
Attention-deficit/hyperactivity disorder (ADHD) is associated with significant impairment in multiple functional domains. This trial evaluated efficacy in ADHD symptoms and functional outcomes in young adults treated with atomoxetine.

METHODS:
Young adults (18-30 years old) with ADHD were randomized to 12 weeks of double-blind treatment with atomoxetine (n = 220) or placebo (n = 225). The primary efficacy measure of ADHD symptom change was Conners' Adult ADHD Rating Scale (CAARS): Investigator-Rated: Screening Version Total ADHD Symptoms score with adult prompts. Secondary outcomes scales included the Adult ADHD Quality of Life-29, Clinical Global Impression-ADHD-Severity, Patient Global Impression-Improvement, CAARS Self-Report, Behavior Rating Inventory of Executive Function-Adult Version Self-Report, and assessments of depression, anxiety, sleepiness, driving behaviors, social adaptation, and substance use.

RESULTS:
Atomoxetine was superior to placebo on CAARS: Investigator-Rated: Screening Version (atomoxetine [least-squares mean ± SE, -13.6 ± 0.8] vs placebo [-9.3 ± 0.8], 95% confidence interval [-6.35 to -2.37], P < 0.001), Clinical Global Impression-ADHD-Severity (atomoxetine [-1.1 ± 0.1] vs placebo [-0.7 ± 0.1], 95% confidence interval [-0.63 to -0.24], P < 0.001), and CAARS

Self-Report (atomoxetine [-11.9 ± 0.8] vs placebo [-7.8 ± 0.7], 95% confidence interval [-5.94 to -2.15], $P < 0.001$) but not on Patient Global Impression-Improvement. In addition, atomoxetine was superior to placebo on Adult ADHD Quality of Life-29 and Behavior Rating Inventory of Executive Function-Adult Version Self-Report. Additional assessments failed to detect significant differences ($P \geq 0.05$) between atomoxetine and placebo. The adverse event profile was similar to that observed in other atomoxetine studies. Nausea, decreased appetite, insomnia, dry mouth, irritability, dizziness, and dyspepsia were reported significantly more often with atomoxetine than with placebo.

CONCLUSIONS:
Atomoxetine reduced ADHD symptoms and improved quality of life and executive functioning deficits in young adults compared with placebo. Atomoxetine was also generally well tolerated.