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LONG-TERM SAFETY AND EFFICACY OF ATOMOXETINE IN ADULT ADHD JAPANESE PATIENTS

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Introduction: Research has shown that ADHD symptoms and functional impairment often persist beyond childhood into adulthood. Thus an effective therapy that can be tolerated over long-term use in adults is needed. This is the first long term safety and tolerability study of an adult ADHD medication in Asia.
Objectives: Assess long-term safety, tolerability, and efficacy of atomoxetine (ATX) in adult Japanese ADHD patients.
Aims: Demonstrate the safety and tolerability of long-term ATX.
Methods: ATX (40-120 mg/day) was evaluated based on integrated analyses of a 10 week double-blind (DB) study and a 48 week open-label long term (LT) extension study. Long-term safety and tolerability were assessed by adverse events, discontinuation rate, and vital-signs. Efficacy measures included change from baseline in Conners' Adult ADHD Rating Scale-Investigator Rated (CAARS-Inv:SV) total symptoms score, behavior Rating Inventory of Executive Function (BRIEF-A), and Adult ADHD/QoL Measure (AAQoL).
Results: 233 patients took ATX (LT mean final prescribed dose: 108.3 mg/day). AEs leading to discontinuations were seen in 37 (15.9%) patients, the most common being nausea in 10 (4.3%) patients. Statistically significant baseline-to-endpoint reductions in mean CAARS-Inv:SV total symptoms score during in the DB study continued throughout the LT study. Similar reductions were seen in BRIEF-A Self Report scores. These findings along with AAQoL results indicated that patients perceived improvements in both QoL and Executive Function.
Conclusions: Long-term ATX treatment was shown to be generally safe and tolerable in Japanese adult ADHD patients. Results also suggested ATX improved ADHD core symptoms, QoL and Executive Functions.

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