EVENING AND EARLY MORNING ADMINISTRATION OF ATOMOZETINE IN ADHD CHILDREN: A COMPARISON

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Atomoxetine (A) is a highly selective Norepinephrine-Inhibitors for Attention Deficit Hyperactivity Disorder treatment; its administration early morning brings a significative improvement that lasts till the day after morning. Given that A is not a psychoactive drug,its administration could be in the evening too. This is a placebo-controlled study comparing its effectiveness lasting when administered early in the morning or in the evening. This study was a randomized,multicenter,double-blind,placebo-controlled trial conducted at 12outpatient sites in the United States.197children,6-12years of age,who had been diagnosed as having ADHD,on the basis of the Diagnostic and Statistical Manual of Mental Disorders (4th ed.) criteria,were randomized to receive 8weeks of treatment with A or placebo,dosed once daily in the mornings. ADHD symptoms were assessed with parent and investigator rating scales. The primary outcome measure was the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version:Investigator-Administered and Scored total score. Daily parent assessments of children's home behaviors in the evening and early morning were recorded. This instrument measures 11 specific morning or evening activities,including getting up and out of bed,doing or completing homework,and sitting through dinner. 71% of the children enrolled were male,69% met criteria for the combined subtype (both inattentive and hyperactive/impulsive symptoms),and the most common psychiatric comorbidity was oppositional defiant disorder (35%). Once-daily A (final mean daily dose of 1.3mg/kg) was significantly more effective than placebo in treating core symptoms of ADHD. Mean reductions in the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator-Administered and Scored total score were significantly greater for patients randomized to A,beginning at the first visit after the initiation of treatment and continuing at all subsequent visits. Both inattentive and hyperactive/impulsive symptom clusters were significantly reduced with A,compared with placebo. With continued treatment and dose titrations,core symptoms of ADHD continued to decrease throughout the 8-week study. Mean reductions in the daily parent assessment total scores for patients randomized to A were superior during the first week,beginning with the first day of dosing,and were also superior at endpoint. Efficacy outcomes for the evening hours for A-treated patients were superior to those for placebo-treated patients,as assessed with 2different assessment scales. Decreases in the daily parent assessment morning subscores at endpoint showed a significant reduction in symptoms that lasted into the mornings. Rates of discontinuations attributable to adverse events were <5% for both groups. Adverse events reported significantly more frequently with A were decreased appetite,somnolence,and fatigue. Among children who had been diagnosed as having ADHD,once-daily administration of A in the morning provided safe,rapid,continuous,symptom relief that lasted not only into the evening hours but also into the morning hours. A-treatment was safe and well tolerated.