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EFFECTIVENESS OF MAZINDOL IN CHILDREN WITH ADHD : OPEN-LABEL STUDY

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Mazindol is a central nervous system stimulant, which blocks reuptake of dopamine and norepinephrine. Mazindol (1-6 mg/d) has previously been studied in the treatment of excessive daytime sleepiness with relative therapeutic benefit. Our hypothesis suggests that mazindol may be effective for the treatment of Attention Deficit Hyperactivity Disorder symptoms.

Based on clinical assessments after oral administration of mazindol to 24 children (9-12 years) with ADHD (according to DSM-IVTR criteria), this open-label study evaluates the efficacy, safety and tolerability of mazindol (1mg/d, 7 days). Safety evaluations included routine hematology, electrocardiograms, blood pressure, and pulse rate. Efficacy rating measurements included ADHD-RS score (primary outcome measure), CPRS-R:L, CGI-S and CGI-I (secondary outcome measures). This clinical trial reports data obtained from 21 boys (10±1 years).

Based on primary outcome (ADHD-RS), change in ADHD-RS mean total score after one week of mazindol was -24.6 ($p < 0.0001$) ; greater than a 90% improvement from baseline. Change in CPRS-R:L (80 items) mean total score after one week of mazindol was -55.5 ($p < 0.0001$); CGI-S after one week of mazindol was -3,02 ($p < 0.01$). Adverse events were mild to moderate in severity and decreased appetite, weight loss, headache, and abdominal pain were most common (95%).

Changes in laboratory values, ECG, blood pressure, pulse rate and body weight were not clinically meaningful. Blood pressure and pulse rate were unchanged ($p > 0.05$) after one week of treatment.

This preliminary investigation suggests that mazindol is still a new well-tolerated and active psychostimulant for the treatment of ADHD in children.

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