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AGOMELATINE IN THE TREATMENT OF OBSESIVE-COMPULSIVE- DISORDER: POTENTIAL FOR CLINICAL EFFECTIVENESS: AN 4-WEEK, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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Objective: To evaluate the efficacy, safety, and tolerability of fixed-dose agomelatine 25 and 50 mg/d in the treatment of outpatients with obsesive-compulsive disorder (OCD) compared to placebo.
Method: In this 8-week, multicenter, double-blind, parallel-group trial, patients with DSM-IV-defined OCD were randomly assigned (1:1:1) to receive a once-daily dose of agomelatine 25 mg, agomelatine 50 mg, or placebo. The primary efficacy measure was the change from baseline to week 8 in the clinician-rated 17-item Hamilton Depression Rating Scale (HDRS(17)); other efficacy measures were The Yale-Brown Obsessive Compulsive Scale (Y-BOCS) and the Clinical Global Impression scale. The study was conducted between December 2009 and January 2010.
Results: Agomelatine 25 mg/d was more efficacious based on the HDRS(17) total score (P = .01) compared to placebo throughout the treatment period, whereas for agomelatine 50 mg/d, statistically significant reduction in HDRS(17) total score could be observed from weeks 2 to 6 but not at week 8 (P = .144). A higher proportion of patients receiving agomelatine 25 mg/d showed clinical response (P = .013), clinical remission (P = .07), and improvement according to the Clinical Global Impressions-Improvement scale (P = .065) compared to those receiving placebo. No statistically significant difference between patients receiving agomelatine 50 mg/d compared to placebo on clinical response. Both agomelatine doses were safe and well tolerated, although clinically notable aminotransferase elevations were observed transiently in the agomelatine 50 mg/d group.
Conclusions: Agomelatine 50 mg/d provided evidence for its antidepressant efficacy until week 6 and was also safe and well tolerated.

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