

Olanzapine/Fluoxetine and Olanzapine Treatment for Bipolar Depression: Open-Label Continuation in Rapid Cycling Patients

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Objective: Olanzapine/fluoxetine combination (OFC) has demonstrated efficacy in the treatment of bipolar depression. This secondary analysis of patients with a history of rapid cycling (RC) examines the efficacy of OFC and olanzapine (OLZ) during a 6-month open-label (O-L) extension.

Methods: 833 subjects with an index depressive episode were enrolled in an 8-week, double-blind, randomized trial with 315 RC patients receiving OFC (n=37), OLZ (n=140), or placebo (n=138). Patients achieving remission (MADRSE⁸; YMRS¹²) entered O-L treatment and received OLZ initially and switched to OFC any time after one week, as needed.

Results: During double-blind treatment, mean change from baseline to endpoint in total MADRS score revealed that OFC-treated RC patients improved significantly (-15.7± 1.6) compared with placebo and OLZ; 34.3% of rapid cycling patients achieved remission (12 of 35). During the O-L phase, 64.7% of RC patients (22 of 34) remained free from relapse (vs. 61.9% for non-RC patients). Mean time to relapse (MADRSE¹⁶; YMRS¹⁵) into any mood episode was 141 days for rapid cyclers and 177 days for non-rapid cyclers. Mania relapse occurred in 12% of RC patients.

Conclusion: As management of depression is the primary unmet need in RC patients, OFC may represent an efficacious treatment for bipolar depression in patients with a history of rapid cycling.