

Improvements in Global Functioning in Bipolar Patients: Results from an Open-Label Risperidone Study

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Objective: Examination of risperidone monotherapy on global functioning in patients with bipolar mania.

Conclusions: Treatment with risperidone resulted in significant and clinically meaningful improvements in overall functioning. Patients initially on placebo improved to a level of mild impairment. Patients receiving risperidone for the entire 12 weeks improved to a level of minimal or no impairment, supporting the role of risperidone in helping patients achieve restoration of their functioning.

Methods: A 9-week, open-label (OL) extension trial of risperidone was conducted in patients previously randomized to 3 weeks of either placebo or risperidone monotherapy for treatment of acute mania. The Global Assessment Scale (GAS) assessed overall functioning.

Results: Participants included 105 patients originally randomized to placebo (PLA/RIS), and 134 to risperidone (RIS/RIS). Mean age was 35.2; mean modal risperidone dose was 4.7 mg. Mean (SD) OL baseline GAS score was 56.1 (17.6) for PLA/RIS patients, and 66.9 (13.0) for RIS/RIS patients. At OL endpoint, mean (SD) scores improved to 66.8 (21.7) and 77.7 (14.7), an improvement of 10.6 and 10.8 points, respectively (both $P < .001$). Median scores at OL endpoint were 70.0 and 80.0, respectively. Relative to double-blind baseline, the RIS/RIS group improved by 41.9 points, and the PLA/RIS group by 31.1 points.