

Treatment Moderators and Predictors of Outcome in the Treatment of Early Age Mania (TEAM) Study.

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National Institute of Mental Health (NIMH).

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OBJECTIVE:

Both the diagnosis and treatment of bipolar disorder in youth remain the subject of debate. In the Treatment of Early Age Mania (TEAM) study, risperidone was more effective than lithium or divalproex in children diagnosed with bipolar mania and highly comorbid with attention-deficit/hyperactivity disorder (ADHD). We searched for treatment moderators and predictors of outcome.

METHOD:

TEAM was a multi-site, 8-week, randomized clinical trial of risperidone, lithium, or divalproex in 279 medication-naïve patients, aged 6 through 15 years, with a DSM-IV diagnosis of bipolar disorder currently in manic or mixed phase. Outcome measures included binary end-of-treatment responder status and change in the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS) Mania Rating Scale (KMRS). Baseline demographics and clinical characteristics were tested as modifiers of treatment effect and as overall predictors of outcome.

RESULTS:

Moderator effects were detected for site, ADHD, and obesity. Across sites, the response ratio (RR) for risperidone versus lithium ranged from 1.2 (95% confidence interval [CI] = 0.8-1.7) to 8.3 (95% CI = 1.1-60.8), and for risperidone versus divalproex from 1.3 (95% CI = 0.8-2.2) to 10.5 (95% CI = 1.4-77.7). The RR for risperidone versus lithium was 2.1 for patients with ADHD, but 1.0 for those without ADHD, and 2.3 (95% CI = 1.6-3.3) for nonobese patients, but 1.1 (95% CI = 0.6-2.0) for obese ones. Older age and less severe ADHD symptoms were associated with greater improvement on the KMRS.

CONCLUSIONS:

Risperidone was more effective than lithium or divalproex across the demographics and clinical characteristics of the sample, but the magnitude of its effect was influenced by site-related characteristics and presence of ADHD.

Clinical trial registration information-Treatment of Early Age Mania;
<http://clinicaltrials.gov/>; NCT00057681.