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Does the efficacy of asenapine in bipolar disorder increase in the presence of comorbidity with a substance use disorder? A naturalistic study.

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Abstract

BACKGROUND:

Asenapine is a second-generation antipsychotic approved in Europe for treating moderate-to-severe manic episodes in adults affected by type I bipolar disorder (BD-I). We aimed to compare its efficacy in psychiatric inpatients with BD-I, with or without substance use disorder (SUD).

METHODS:

We administered flexible asenapine doses ranging from 5-20 mg/day to 119 voluntarily hospitalized patients with Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) BD-I diagnosis, with or without SUD. Patients were assessed with clinician-rated questionnaires [i.e. Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), Hamilton Depression Rating Scale (HDRS), Hamilton Anxiety Rating Scale (HARS), and Global Assessment of Functioning (GAF)]. Assessments were carried out at baseline (T0, prior to treatment), and 3 (T1), 7 (T2), 15 (T3), and 30 days (T4) after starting treatment for all clinical scales and at T0 and T4 for the GAF.

RESULTS:

Patients improved on all scales ($p < 0.001$) across all timepoints, as shown both by paired-sample comparisons and by applying a repeated-measures, generalized linear model (GLM). Patients without comorbid SUD showed greater reductions in BPRS scores at T2 and T3, greater reduction in YMRS scores at T3, and lower HARS scores at all timepoints. HDRS scores did not differ between the two groups at any timepoint. However, the reduction in HARS scores in the comorbid group was stronger than in the BD-I only group, albeit not significantly. Side effects were few and mild-to-moderate.

CONCLUSIONS:

The open-label design and the relatively short observation period may expose to both type I and type II statistical errors (false positive and false negatives). Asenapine showed effectiveness and safety in hospitalized BD-I patients. Its effect was stronger in patients without comorbid SUD.

KEYWORDS:
anxiety; asenapine; atypical antipsychotic drugs; bipolar disorder; substance use disorder