Early improvement as a predictor of treatment response and remission in patients with schizophrenia: a pooled, post-hoc analysis from the asenapine development program.

The purpose of this study was to assess whether early symptom improvement predicts later treatment outcome in patients with schizophrenia. Data were pooled from intent-to-treat (ITT) populations of three six-week randomized controlled studies with fixed doses of asenapine (ASE; n=470), olanzapine (OLA; n=95), risperidone (RIS; n=56), haloperidol (HAL; n=112), or placebo (PLA; n=275). Early improvement was defined as a 20% reduction of Positive and Negative Syndrome Scale (PANSS) total score at week 2, compared to baseline (primary criterion). Treatment outcome at week 6 was defined as response (PANSS: >=50% score reduction) or remission (PANSS item score <=3 on selected items at week 6). Odds ratios (ORs) and predictive performance statistics were calculated. Statistically significant associations between early improvement (at week 2) and treatment outcome (at week 6) were observed for all treatment groups except OLA; as evidenced by increased ORs for response. Analysis of associations between early improvement and remission, as defined by Andreasen et al. (2005), revealed a statistically significant relationship for ASE and PLA-treated patients only. Predictive performance statistics revealed higher negative predictive value (NPV) and sensitivity rates, and comparably lower positive predictive value (PPV) and specificity rates across treatment groups for both
response and remission. It is suggested that absence of improvement within two weeks of treatment may predict the unlikely success of subsequent pharmacological intervention.