P-213 - EARLY IMPROVEMENT AS A PREDICTOR OF OUTCOME IN MANIC/ MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER: POST-HOC ANALYSES OF ASENAPINE STUDIES

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Introduction & objective: To determine whether early manic symptom improvement predicts outcome in bipolar I disorder patients experiencing manic or mixed episodes.
Methods: Pooled data from two 3-week trials; asenapine (5 or 10 mg BID; n=372), olanzapine (5-20 mg QD; n=391), or placebo (n=197). Early improvement (YMRS total score changes from baseline ≥15%, ≥20%, and ≥25%) was assessed at days 2, 4, and 7. Associations between early improvement and week 3 outcomes (YMRS response [≥50% total score reduction] and remission [total score ≤12]) were calculated using Fisher's exact tests; odds ratios classified their relative strength. Sensitivity (SN), specificity (SP), and positive (PPV) and negative (NPV) predictive values were calculated as previously described (*J_Clin_Psychiatry*_2009;70:344-353).
Results: Early improvement was strongly associated with positive outcomes. The earliest positive associations across all cutoffs occurred with asenapine at day 2 (response, all $P< 0.04$; remission, all $P< 0.007$), olanzapine at day 4 for response (all $P< 0.02$) and day 2 for remission (all $P< 0.002$), and placebo on day 7 (response, all $P< 0.003$; remission, all $P\leq 0.0005$). Odds ratios were higher for asenapine (1.8-9.1) than olanzapine (1.4-3.5) and placebo (1.3-8.0). Respective day 4 remission values for SN, SP, PPV, and NPV at the ≥15% cut-off were 80%, 58%, 48%, and 85% for asenapine; 76%, 43%, 49%, and 71% for olanzapine; and 50%, 67%, 31%, and 82% for placebo.
Conclusion: Early improvement was strongly associated with week 3 response and remission; high NPVs indicated little chance of stable remission in the absence of early improvement.

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