

## **P-201 - EFFECTIVENESS OF QUETIAPINE XR VS. SERTRALINE IN ACUTE BIPOLAR DEPRESSION AS ADD-ON THERAPY TO PREVIOUS MOOD STABILIZER TREATMENT: A PILOT STUDY**

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**Introduction:** Even at therapeutic doses, mood stabilizers do not completely address symptoms in bipolar depression. Some guidelines recommend add-on antidepressant therapy or quetiapine.

**Objectives:** Early effectiveness of quetiapine extended release (quetiapine XR) vs. sertraline in adults with bipolar depression; treated with lithium or valproate at clinically therapeutic blood levels (change from baseline in the MADRS global score at week 2 (LOCF) endpoint). Others (secondary objectives) were measured at week 8.

**Methods:** Prospective, open label, randomized study of 8 weeks follow-up (D1443L00058).

**Results:** 27 patients were randomized to quetiapine XR (14) or sertraline (13). Mean age was 46.07 years. 17 patients (62.96%) were male. 20 (74.07%) were diagnosed with bipolar disorder type I. Mean number of previous events were 9.74. Mean baseline MADRS score was 28.23 (SD 5.86) and 29.50 (SD 5.00) for sertraline and quetiapine XR groups, respectively ( $p=0.59$ ).

Mean change in MADRS score (2 weeks from baseline) was: -6.62 (sertraline group) and -13.14 (quetiapine XR group) ( $p=0.08$ ). Final change from baseline was: -10.62 (sertraline) and -17.14 (quetiapine XR) ( $p=0.1$ ).

Patients with at least one AE and one AE leading to study withdrawal were 12 and 3, respectively (quetiapine XR group); and 9 and 2, respectively (sertraline group). The most frequent AEs were somnolence, dry mouth (35.7%, 21.4%, respectively) (quetiapine XR group), and insomnia, diarrhea, dyspepsia (14.3% for each one) (sertraline group).

**Conclusions:** Numeric differences (though not significant) in favour of quetiapine XR exist for the early effectiveness of quetiapine XR in bipolar depression.

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