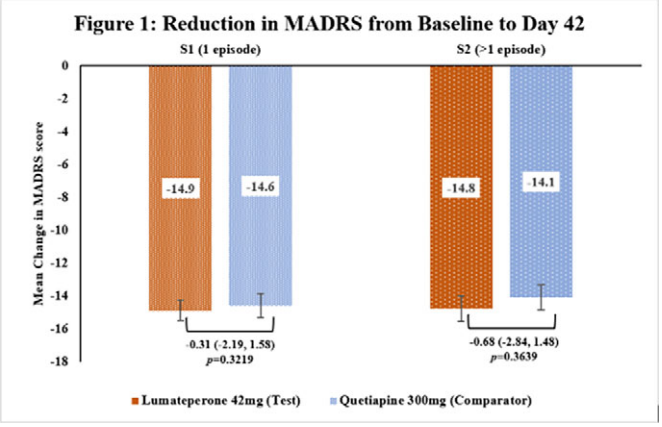
Introduction: Lumateperone, an atypical antipsychotic drug, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors.
Objectives: This subgroup analysis of an Indian Phase 3 study was conducted to evaluate the efficacy and safety of Lumateperone 42mg compared to Quetiapine 300mg in treatment of Bipolar II depression when stratified based on prior hypomanic episodes.
Methods: The phase-III, randomized, multi-centric, assessor-blind, parallel-group, active-controlled, comparative, non-inferiority study included Indian patients with Bipolar II depression with moderate severity having a Montgomery-Asberg depression rating scale (MADRS) score ≥20 and Clinical global impression–bipolar version–severity (CGI-BP-S) score ≥4. The study was conducted after receiving regulatory and ethics committee approvals. The patients were randomized (1:1) to either receive Lumateperone 42mg [Test] or Quetiapine 300mg [Comparator] for 6 weeks. The patients were stratified based on number of prior hypomanic episodes in lifetime: Subgroup 1 [S1]: 1 episode and Subgroup 2 [S2]: >1 episode. For efficacy outcomes MADRS score, CGI-BP-S (total score, depression subscore and overall bipolar illness subscore), and Quality of life enjoyment and satisfaction-short form questionnaire (Q-LES-Q-SF) score were evaluated and for safety outcomes treatment emergent adverse events (TEAEs) were assessed. [Clinical trial registration: CTRI/2023/10/058583]
Results: This subgroup analysis included 462 patients, out of which 251 in S1[Test=129; Comparator=122] and 211 in S2[Test=102; Comparator=109]. The baseline demographic characteristics were comparable in between treatment arms across subgroups. The primary endpoint of reduction in MADRS score from baseline to Day 42 in Test arm was non-inferior to Comparator arm in both subgroups [Figure 1] as the upper 95% CI was below the predefined margin of 3.0. The reduction of CGI-BP-S (total score, depression subscore and overall bipolar illness subscore) from Day 14 to Day 42 were comparable in both Test and Comparator arms in both subgroups. The improvement in Q-LES-Q-SF score from baseline to Day 42 were comparable in both Test and Comparator arms in both subgroups. The incidence of TEAEs were similar in both treatment arms [S1: Test=37.2% and Comparator=35.2%; S2: Test=31.4% and Comparator=35.8%] and no serious adverse events were reported.

Image 1:



Conclusions: This subgroup analysis demonstrated that Lumateperone 42mg is non-inferior to Quetiapine 300mg in treatment of Bipolar II depression as assessed via MADRS score from baseline to Day 42, irrespective of number of previous hypomanic episodes and both treatments were found to be well tolerated.

Disclosure of Interest: A. Dharmadhikari: None Declared, P. Chaurasia: None Declared, Y. Patel: None Declared, D. Choudhary: None Declared, P. Dasud: None Declared, M. Bhirud: None Declared, P. Meena: None Declared, F. Shah: None Declared, G. Ganesan: None Declared, B. P. Rathour: None Declared, K. Mistry: None Declared, M. Dutta: None Declared, A. Ramaraju: None Declared, S. Mangalwedhe: None Declared, S. G. Goyal: None Declared, G. Kulkarni: None Declared, A. Mukhopadhyay: None Declared, P. Chaudhary: None Declared, G. T. Harsha: None Declared, M. Parikh: None Declared, S. Dey: None Declared, S. Sarkhel: None Declared, N. Jyothi: None Declared, A. Kumar: None Declared, N. Sooch: None Declared, A. Shetty Employee of: Sun Pharma, S. Saha Employee of: Sun Pharma, P. Devkare Employee of: Sun Pharma, A. Shetty Employee of: Sun Pharma, D. Patil Employee of: Sun Pharma, P. Ghadge Employee of: Sun Pharma, A. Mane Employee of: Sun Pharma, S. Mehta Employee of: Sun Pharma.

EPP090

Differences in Electrodermal Activity in Depressed Bipolar Patients with High and Low Anxiety Levels

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doi: 10.1192/j.eurpsy.2025.441

Introduction: Electrodermal activity (EDA) measures the skin's electrical properties. It varies according to the sweat gland's activity which responds to the sympathetic nervous system (Boucsein W. Electrodermal Activity. Berlin: Plenum Press; 2012). Previous literature has reported lower EDA during bipolar and unipolar depressive episodes (Sarchiapone M, et al. BMC Psychiatry 2018; 18: 22 & Valenzuela-Pascual C, et al. Acta Psychiatr Scand 2024). Historically, heightened anxiety has been correlated with increased EDA, although findings in this area have been inconsistent (Naveteur J, et al. Int J Psychophysiol 2005; 56(3): 261–269).
Objectives: This study aimed to determine whether significant differences in EDA exist among depressed patients based on their levels of anxiety.
Methods: We analysed EDA recordings from an E4 wearable device utilised by 29 depressed patients with bipolar disorder. They wore the device for a period of 48 hours without altering their daily routines. The tonic mean and phasic peaks parameters of EDA were extracted and analysed via a mixed-effects model for repeated measures, incorporating sleep state and anxiety level as variables. Anxiety levels were assessed based on the scores from item 10 on the Hamilton Rating Scale for depression, which reflects psychic anxiety.

Results: The results indicated that anxiety levels did not significantly influence any of the models examined. However, in the phasic peaks model, there is a noteworthy interaction between anxiety level and sleep status ($p < 0.01$). Both models demonstrated a tendency towards increased EDA values in the high anxiety group although these findings did not reach statistical significance. This trend was consistent across both sleep states for the tonic mean model (Image 1). In contrast, the high anxiety group exhibited higher phasic peaks values (M [SD] = 2.33 [0.80-3.86]) compared to the low anxiety group (M [SD] = 2.33 [0.80-3.86]) only during wakefulness, although this difference was not statistically significant ($p > 0.05$) (Image 2).

Image 1:

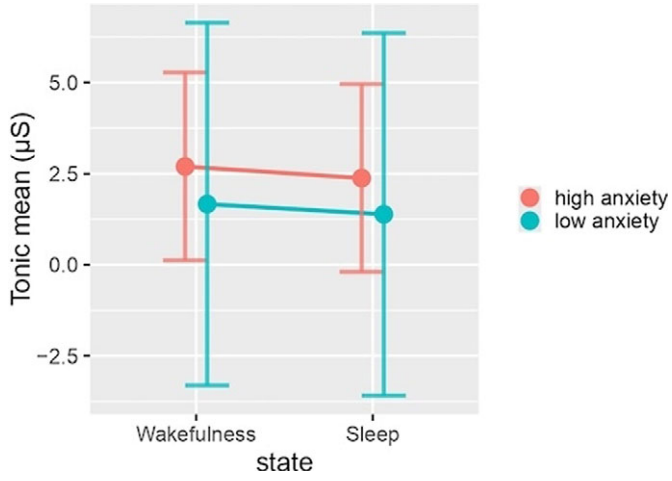
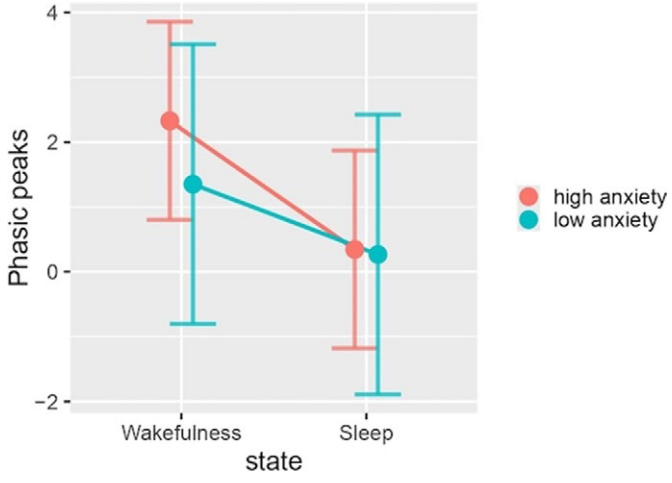


Image 2:



Conclusions: These findings should be interpreted with caution due to the small sample size and the imbalance in the distribution of low (17%) versus high anxiety (83%) participants. Furthermore, anxiety is a multifaceted symptom that should be evaluated using a more comprehensive assessment tool. To validate these preliminary observations, it is essential to increase the sample size and use a more precise measure of anxiety.

Disclosure of Interest: None Declared

EPP091

Do Second-Generation Antipsychotics Protect Against the Emergence of (Hypo)mania in Depressed Patients with Mixed Features?

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doi: 10.1192/j.eurpsy.2025.442

Introduction: Five medications have been approved for the treatment of bipolar depression, though no medication has been approved for the treatment of depression with mixed features. Post-hoc analyses of the bipolar depression trials examined efficacy in depressed patients with and without mixed features. Each study also examined the emergence of manic symptoms as a possible negative outcome, and each found that the frequency of emergent manic symptoms was more frequent in the patients treated with placebo than with medication though in no study was the difference statistically significant. However, the studies were not powered to detect a significant difference in treatment emergent (hypo)manic episodes thereby prompting the current pooled analysis.

Objectives: The goal of the present pooled analysis was to examine whether second-generation antipsychotics that have been found effective in treating depression with mixed features protect against the emergence of (hypo)manic episodes in depressed patients with concurrent manic symptoms.

Methods: Five placebo-controlled studies of the effectiveness of second-generation antipsychotics in the treatment of depressed patients with mixed features reported information on the emergence of manic symptoms.

Results: The 5 studies included 1,829 depressed patients with mixed features—1,620 with bipolar disorder and 209 with major depressive disorder. In each study, the frequency of treatment-emergent manic episodes was higher in the group treated with placebo, though in no study was this difference significant. Summed across studies, the frequency of treatment emergent (hypo)manic episodes was higher in the patients receiving placebo (4.0% vs. 2.4%, X^2=3.66, p=.056). Excluding the patients treated with olanzapine, which has not been found to be effective in treating bipolar depression, the frequency of emergent (hypo)manic episodes was significantly higher in the patients receiving placebo, (4.0% vs. 1.8%, X^2=7.31, p=.007).

Conclusions: The results of the present analysis suggest that the second-generation antipsychotics that are effective in treating bipolar depression also protect against a (hypo)manic switch in depressed patients with mixed features.

Disclosure of Interest: None Declared

Child and Adolescent Psychiatry

EPP092

Cyberbullying Among Middle School Students in Sousse, Tunisia: Prevalence and associated factors

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