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 baseline BMI and both treatments were found to be well tolerated. Hence, Lumateperone can be considered as valuable treatment option in management of Bipolar II depression.

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

EPP088

Insulin Resistance and Suicidal Behaviors: Insights into Mood Disorders

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Introduction: Compared to the general population, mood disorders (MD) patients show an increased risk of developing type II diabetes and obesity, which are associated with changes in brain correlates and a worse clinical outcome[1]. According to the literature, MD patients with a dysregulated metabolic system are characterized by a reduction in white matter (WM) integrity, lower global functioning, and suicidal behaviors (SB) [2],[3],[4]. However, little is known about the impact of early stages of metabolic dysregulation, namely insulin resistance (IR), in relation to the clinical course of MD[1].
Objectives: Therefore, the present study aims to investigate the effect of IR on WM integrity in MD patients with suicidal behaviors (s-BP, s-UP) compared to those without suicidal behaviors (ns-BP, ns-UP). Finally, we have hypothesized that obesity may be linked to SB through a biological pathway involving inflammatory and IR markers.
Methods: Our sample was composed of 184 depressed patients (92 BP, 92 UP) who were assessed for SB via the Beck Suicidal Scale (BSS). Patients underwent 3T Magnetic Resonance imaging, and blood samples were collected to determine levels of insulin and glucose and blood cell counts. The Homeostatic Model Assessment for Insulin Resistance (HOMA) and systemic-immune-inflammation index (SII) were then computed. To investigate the effect of HOMA and SII on WM microstructure, we performed voxelwise DTI analyses: first, we tested whether the relation between HOMA, SII, and DTI measures differed between s-BP and ns-BP patients; then, post-hoc analyses were performed for analyzing the effect of HOMA, and SII separately in 40 s-BP and 52 ns-BP. The same analyses were replicated on 43 s-UP and 49 ns-UP. Moderated mediation analyses were performed with the macro PROCESS for SPSS.
Results: The relationship between BMI and suicidal behaviors was fully serial mediated by SII and HOMA only in BP (b=0,031, 95% BCa CI [0.003, 0.088]). Specifically, we found that higher BMI was sequentially associated with increased SII and HOMA levels, ultimately leading to higher BSS scores. A significant interaction between s-BP and ns-BP was identified for the effect of (1) HOMA on mean diffusivity (MD), axial (AD), and radial diffusivity (RD). However, no significant interaction was found for the effect of IR and SII markers in UP. Performing the analyses separately in the two groups, s-BP showed (1) a negative widespread association between HOMA and FA, and a positive effect between HOMA and RD, AD, and MD. In ns-BP, no significant results were found.
Conclusions: These findings may suggest that IR may play a key role in the biological pathway underlying suicidal behaviors in BP but not in UP. Therefore, metabolic system dysregulation should be taken into consideration during the treatment.

Disclosure of Interest: None Declared

EPP089

Efficacy and Safety of Lumateperone compared to Quetiapine in Indian patients with Bipolar II depression: A subgroup analysis based on prior hypomanic episodes

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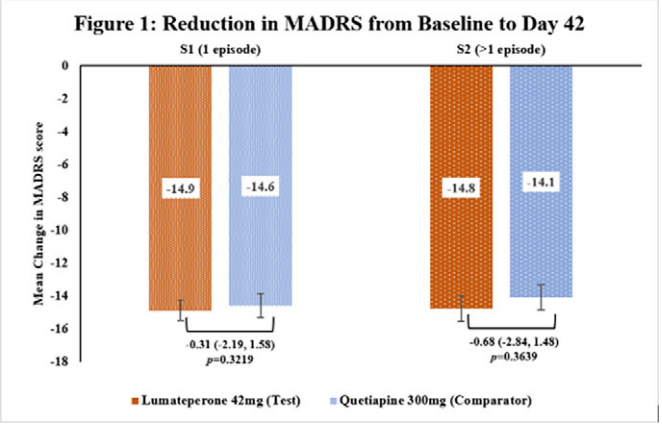
Introduction: Lumateperone, an atypical antipsychotic drug, has a dual mechanism of action by combination of activity at central serotonin (5-HT2A) and dopamine (D2) receptors.
Objectives: This subgroup analysis of an Indian Phase 3 study was conducted to evaluate the efficacy and safety of Lumateperone 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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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.