

The effect of healthcare practitioner-participant interactions on participant heart rate during esketamine treatment

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Methodological Issue Being Addressed Are vital sign measurements used to assess the safety of esketamine treatment subject to a “white coat effect?”

Introduction Change in hemodynamic function is a side effect of esketamine. Monitoring of vital signs is a central component of the Risk Evaluation and Mitigation Strategy (REMS) protocol that is required for administration of esketamine (marketed as Spravato) for treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. The present work examines whether participants undergoing depression-related esketamine treatment experience “white coat effects” such as additional heart rate (HR) elevation during vital sign measurement interactions with healthcare practitioners (HCPs). These effects may impact determinants of the safety of esketamine treatment for individual participants.

Methods The MindMed Session Monitoring System (MSMS) is a passive monitoring system that continuously collects movement and physiological data from participants undergoing treatment with a consciousness-altering drug. HR was collected passively by the MSMS from 24 participants who completed 129 esketamine sessions. The start of a potentially vital sign altering intervention was defined as an initiation of face-to-face contact with the participant by an HCP prior to vital sign measurement. MSMS HR data were annotated with timestamps marking the start of an intervention based on audio recorded initiation of contact. Times are reported as time post-administration. The participant’s average HR before and after each intervention start was stratified by time windows ranging from 1 to 6 minutes, and the variances of the windows were compared using a paired t test, a nonparametric Wilcoxon signed-rank test, and an F-test.

Results HR was evaluable for 115 sessions across 24 participants and 87 sessions across 23 participants at the 40-minute and 120-minute interventions. At 40-minute interventions, participants had a significantly higher HR in the minute after intervention-start compared to the minute before (increase in HR, BPM: 3.65 ± 5.348 , $p < 0.01$). This effect was consistent at 120-minute interventions (increase in HR, BPM: 5.54 ± 6.652 , $p < 0.01$). A greater reaction to the HCP’s presence was observed at 120-minute interventions compared to 40-minutes (increase in HR, BPM: 1.76 ± 7.725 , $p < 0.05$), with an F-test confirming similar variances in the before-and-after intervention HR distributions. A phenotypical analysis on covariates revealed a higher reaction group and a lower reaction group differentiated by gender, age, and benzodiazepine use.

Conclusion Face-to-face contact of the participant with an HCP to measure vital signs during REMS

monitored esketamine sessions at 40 and 120 minutes post-administration correlates with statistically significant increases in participant HR, with a greater effect at 120-minutes. Furthermore, participant demographics such as gender, age, and concomitant medication may play a role in physiological response. It is therefore important for REMS monitored esketamine HCPs to be aware that REMS procedures involving face-to-face patient interaction while they are under the effect of esketamine may impact the reliability of physiological measurement central to the fulfillment of requirements for esketamine treatment. This data supports the use of continuous passive monitoring to remove or reduce white coat effects.

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