Measuring Remission and Response using CDRS-R and MADRS: An Analysis in Adolescents with MDD and Imminent Risk for Suicide

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Methodological Issue Being Addressed Examination of the correspondence between the CDRS-R and MADRS scales in measuring response and remission in adolescents with major depressive disorder (MDD) who were at imminent risk for suicide.

Introduction The Children's Depression Rating Scale, Revised (CDRS-R), is used widely as the primary efficacy endpoint in clinical trials in children and adolescents with depressive disorders. With the development of rapidly acting antidepressant medications (RAADs), it is important to evaluate CDRS-R as a measure for rapid onset of antidepressant effects. The Montgomery-Asberg Depression Rating Scale (MADRS) has been validated for use to assess RAADs in adults with depression (Johnson et al., 2016) and used as the primary endpoint in esketamine studies to assess rapid reduction in depressive symptoms. Thus, it is of interest to examine the correspondence of these scales. To our knowledge, there is only one analysis that compares the properties of the MADRS and CDRS-R scales in the pediatric population (Jain et al., 2007). The goal of this analysis is to assess agreement of these scales using data from a recently completed study and further extend the knowledge on efficacy measures in adolescent population.

Methods We use data from a double-blind, randomized, psychoactive placebo-controlled (midazolam) trial of intranasal esketamine, plus standard of care, in adolescents (n=145) ages 12-17 with MDD who were assessed to be at imminent risk for suicide. This analysis examines the agreement between CDRS-R and MADRS in measuring response (≥50 % reduction of total score from baseline on either scale) and remission (total score ≤28 for CDRS-R or ≤12 for MADRS). The percentage of responders and remitters on each scale (and both scales) on Day 2 (24 hours after first treatment) and Day 25 (end point after last treatment) was also calculated. Criteria of response and remission were based on published literature. Pearson correlation coefficient (PCC) was calculated for change from baseline in CDRS-R and MADRS total scores.

Results Our results show that 54% (assessed by CDRS-R) and 54% (assessed by MADRS) of the participants were responders with 86% agreement (responders on both scales) at Day 2. While 90% (CDRS-R) and 87% (MADRS) of participants were responders with 92% agreement at Day 25. For remission, 14% (CDRS-R) and 26% (MADRS) of participants were remitters at Day 2 with 53% agreement. At Day 25, 52% (CDRS-R) and 74% (MADRS) of participants were remitters with 69% agreement. The PCC for change from baseline in CDRS-R and MADRS total score at Day 2 and Day

25 was 0.88 and 0.76, respectively.

Conclusion The data support the use of the CDRS-R in detecting rapid change in adolescents. There is a high agreement between responders and high correlation between the change from baseline in CDRS-R and MADRS. There was lower agreement for remitters, which is not unexpected as the remission criteria used did not represent the same level of symptoms based on Jain et al.'s proposed equivalence of CDRS-R and MADRS. Additional work is needed to further define the cut off scores for remission in adolescents.

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