

## Self-Report on the SIBAT: Sensitivity to Rapid Change in Thinking Related to Suicide

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**Methodological Question Being Addressed:** Sensitivity of the My Suicidal Thinking Module of the Suicidal Ideation and Behavior Assessment Tool to changes in thoughts related to suicide 4- and 24-hours after initiation of treatment.

**Introduction:** A number of scales are available to assess suicidal ideation; however, none of these have been explicitly designed to be sensitive to the rapid changes in suicidal ideation that one may observe in an acute psychiatric care setting subsequent to admission due to suicidal thoughts or behaviors. As this epoch has been targeted by recent treatments, appropriate measurement tools must be developed and validated. The Suicidal Ideation and Behavior Assessment Tool (SIBAT) is a 10-module tool combining clinician report, patient report, and patient performance components, some of which are expected to change rapidly and some of which are not. This project examines the sensitivity of the My Suicidal Thinking (MST) module to changes in suicidal thinking 4 and 24 hours after initiation of standard-of-care and standard-of-care + esketamine treatment.

**Methods:** The SIBAT was used in a small (n=66), Phase 2a proof-of-concept study, the outcomes of which have been reported elsewhere. Given the nature of this trial and the in-development status of this measure, the study was not powered to detect significance of a drug effect on this scale. The MST module of the SIBAT is a patient-report component of the SIBAT that assesses a range of suicide-related thoughts and beliefs, each scored on a 5-point Likert scale. Subjects completed the MST module with other measures at baseline prior to treatment and again 4- and 24-hours after the initiation of treatment. Items from the MST module demonstrated to load negatively on a primary Suicidality factor were reverse-scored, and all items were summed to yield a total score. Total MST score was analyzed using repeated measures an analysis of covariance (ANCOVA) model, with visit (baseline, 4 hours, 24 hours) and treatment (standard of care or standard of care + esketamine or placebo) treated as factors and baseline MST score treated as a continuous covariate.

**Results:** Total MST score proved quite sensitive to changes at 4 hours ( $p < .001$ ) and 24 hours ( $p < .001$ ) as compared to baseline. All mean changes were in the direction of less severe suicide-related thinking.

**Conclusions:** Total MST score from the SIBAT appears to be quite sensitive to acute changes in thoughts and beliefs related to suicide as soon as four hours after initiation of care in an Emergent Care setting. Preliminary results also suggest potential as a patient-reported outcome measure in adequately-powered clinical trials.

**Disclosures:** L. Alphas and D. Williamson are employed by Janssen Scientific Affairs, LLC, and are Johnson & Johnson stockholders. C. Canuso, D. J. Fu, Y. Zang, and R. Lane are employed by Janssen Research and Development and are Johnson & Johnson stockholders.