ISCTM ABSTRACT

Title: Empirical Evaluation of the SIBAT Using Categories Established by 3 Versions of the C-CASA

Authors: Alphs L,[1] Williamson D,[1] Fu DJ,[1] Turkoz I,[2] Jamieson C,[2] Canuso C,[2] Wang Y,[2] Joshi U,[3] Jin D[2]

[1]Janssen Scientific Affairs LLC, Titusville, NJ, USA
[2]Janssen Research and Development LLC, Titusville, NJ, USA
[3]PRA Health Science - Performing Services for Janssen

Methodological Question Being Addressed: The purpose of this work is to empirically test whether information gathered with the Suicide Ideation and Behavior Assessment Tool (SIBAT) is sufficient to map to categories included in the Columbia Classification Algorithm of Suicide Assessment (C-CASA).

Introduction (Aims): C-CASA was developed as a heuristic approach for systematically classifying suicidal ideation and behavior (SIB). The FDA adopted this system to characterize SIB observed in clinical trials and requires that alternatives to the Columbia Suicide Severity Rating Scale (C-SSRS) be able to map information to it. The categories identified and defined by the C-CASA have evolved over time, with versions produced in 2010 and 2012. These versions were initially developed to categorize safety events but have not been used in prospective clinical trials with suicidal patients. This work summarizes the ability to use SIBAT-captured information to classify suicidal patients with 3 different C-CASA variations.

Methods: 127 subjects with varying degrees of SIB were identified at 4 clinical sites and were asked to consent to SIB evaluation with the SIBAT. Consenting individuals completed the following 5 patient-rated SIBAT modules: 1) About Me, 2) My Risk/Protective Factors, 3) My Current Thinking, 4) My Actions, and 5) My Risk. Thereafter, a trained clinician completed 1) a semi-structured interview, 2) the 4-item Clinical Global Impressions module, and 3) a treatment-management module. Responses to patient-rated modules and data from the clinician interviews were mapped using a computerized algorithm to 3 different C-CASA versions: 1) original (C-CASA, FDA 2010); 2) current (C-CASA, FDA 2012); and 3) expanded, which includes items absent from C-CASA 2010 needed for clinical evaluation of patients in clinical trials. Categories of “No Suicidal Ideation” and “Not Mapped” were also included to capture situations where there was no evidence of SIB or if categories provided by the C-CASA would not permit the mapping of information from the SIBAT.

Results: Results from initial mapping of the SIBAT to the 3 C-CASA versions found that most patients could be reliably mapped to these versions of the C-CASA. However, some problems in classification were identified. Only the expanded version of the C-CASA could classify persons without SIB. The C-CASA 2012 classification algorithm is prescriptive with respect to how evidence for suicidal intent, plan, and method may be combined when suicide ideation is present. Several subjects could not be classified with the C-CASA 2012 versions because they did not have elements of suicidal intent, plan, and method in the required combinations.

Conclusions: The SIBAT collects a broad range of information that is important for evaluating patient safety and treatment response collected during clinical trials of suicidal subjects. Results of this exercise

suggest that information captured by the SIBAT generally maps to different versions of the C-CASA. However, variations on suicidality and its severity were identified that are not captured by different versions of the C-CASA.

Disclosures: One or more authors report potential conflicts, which are described in the program. Janssen Scientific Affairs, LLC, provided support for this study.