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Columbia-Suicide Severity Rating Scale (C-SSRS) KIT

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The Columbia–Suicide Severity Rating Scale: Initial Validity and Internal Consistency Findings From Three Multisite Studies With Adolescents and Adults

Kelly Posner, Ph.D., **Gregory K. Brown, Ph.D.**, **Barbara Stanley, Ph.D.**, **David A. Brent, M.D.**, **Kseniya V. Yershova, Ph.D.**, **Maria A. Oquendo, M.D.**, **Glenn W. Currier, M.D., M.P.H.**, **Glenn A. Melvin, Ph.D.**, **Laurence Greenhill, M.D.**, **Sa Shen, Ph.D.**, and **J. John Mann, M.D.**
Department of Psychiatry and the Division of Child and Adolescent Psychiatry, Columbia University, College of Physicians and Surgeons, and New York State Psychiatric Institute, New York; Department of Psychiatry, University of Pennsylvania, Philadelphia; University of Pittsburgh School of Medicine and Western Psychiatric Institute and Clinic, Pittsburgh; Department of Psychiatry, University of Rochester Medical Center, Rochester, N.Y.; and the Monash University Centre for Developmental Psychiatry and Psychology, Victoria, Australia

Abstract

Objective—Research on suicide prevention and interventions requires a standard method for assessing both suicidal ideation and behavior to identify those at risk and to track treatment response. The Columbia–Suicide Severity Rating Scale (C-SSRS) was designed to quantify the severity of suicidal ideation and behavior. The authors examined the psychometric properties of the scale.

Method—The C-SSRS's validity relative to other measures of suicidal ideation and behavior and the internal consistency of its intensity of ideation subscale were analyzed in three multisite studies: a treatment study of adolescent suicide attempters (N=124); a medication efficacy trial with depressed adolescents (N=312); and a study of adults presenting to an emergency department for psychiatric reasons (N=237).

Results—The C-SSRS demonstrated good convergent and divergent validity with other multi-informant suicidal ideation and behavior scales and had high sensitivity and specificity for suicidal

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Address correspondence to Dr. Posner (posnerk@nyspi.columbia.edu).

Dr. Posner receives royalty payments for the electronic self-rated versions of the Columbia–Suicide Severity Rating Scale (eC-SSRS) from ERT, Inc., and is the director of the Center for Suicide Risk Assessment, which, as part of an effort to help execute the U.S. Food and Drug Administration's suicidality classification mandates, has received support from Abbott, Albany Molecular Research, Alfresa, Alkermes, Amgen, AstraZeneca, Biodelivery Sciences International, Biomarin, Bristol-Myers Squibb, Canam, Cato Research, Cephalon, Cetero Research, Covance, CRI Worldwide, Depomed, Douglas Pharmaceuticals, Eisai, Euthymics, Forest, GlaxoSmithKline, GW Pharma, Human Genome Sciences, i3 Research, ICON, IntelGenx, Intracellular Therapies, Johnson & Johnson, Kendle Early Stage, Lilly USA, Lundbeck A/S, Lundbeck USA, MedImmune, Medtronic, Merck, Neurosearch, Next Wave Pharmaceuticals, Novartis, Noven, NovoNordisk, Orexigen, Otsuka, Parexel, Pfizer, PGx Health, Pharmaceutical Product Development, Inc., Psyadon, QED, Quintiles, Reckitt Benckiser, Roche, Sanofi-Aventis, Schering-Plough, SCOPE International, Sepracor/Sunovion, Shire, Siena Biotech, Supernus, Synosia Therapeutics, Takeda, Theravance, Upsher-Smith, Valeant, Vivus, World Wide Clinical Trials, and Wyeth Research. Dr. Brown receives royalty payments for eC-SSRS from ERT, Inc. Dr. Stanley receives royalty payments for eC-SSRS from ERT, Inc. Dr. Brent receives research support from NIMH, royalties from Guilford Press, and honoraria for serving on the editorial board of UpToDate and for CME presentations. Dr. Oquendo has received unrestricted educational grants or lecture fees from AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Janssen, Otsuko, Pfizer, Sanofi-Aventis, and Shire, owns equity in Bristol-Myers Squibb, and receives royalty payments for eC-SSRS from ERT, Inc. Dr. Greenhill has received research support from Rhodes Pharmaceutical, National Institute on Drug Abuse, and Johnson & Johnson and study medication and placebo from Shire Pharmaceuticals for an investigator-initiated imaging study. Dr. Mann has received research support from Glaxo-SmithKline and Novartis and receives royalty payments for eC-SSRS from ERT, Inc. The other authors report no financial relationships with commercial interests.

behavior classifications compared with another behavior scale and an independent suicide evaluation board. Both the ideation and behavior subscales were sensitive to change over time. The intensity of ideation subscale demonstrated moderate to strong internal consistency. In the adolescent suicide attempters study, worst-point lifetime suicidal ideation on the C-SSRS predicted suicide attempts during the study, whereas the Scale for Suicide Ideation did not. Participants with the two highest levels of ideation severity (intent or intent with plan) at baseline had higher odds for attempting suicide during the study.

Conclusions—These findings suggest that the C-SSRS is suitable for assessment of suicidal ideation and behavior in clinical and research settings.

Suicide prevention strategies outlined by the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services, and the National Institutes of Health depend on establishing the frequency and severity of suicidal behavior and identifying risk and protective factors (1, 2). Data collection to support these aims must employ valid and reliable assessment tools that allow comparison at local, national, and international levels.

A lack of uniformity in assessment stems in part from the variability of terms referring to similar or even identical behavior. Without a common language for reporting and communicating occurrences of suicidal behavior and ideation, prevention research is undermined in several key areas, including the establishment of reliable incidence and prevalence rates; comparison of data across studies, time periods, and locations; development of adequate tools for identifying and screening patients in primary and other care settings; measurement of risk and benefit in drug trials and postmarketing surveys; and training of health care workers, gatekeepers, and first responders in suicide risk detection (3). Furthermore, the exclusion of individuals with suicidal ideation and behavior from clinical trials has resulted in a dearth of evidence for interventions for these populations, and the methods for determining which patients will be excluded have been variable, making it even more difficult to conduct analyses of these populations on suicide-related questions (4, 5).

Studies of risk factors predicting suicide consistently suggest that suicidal ideation and a history of suicide attempts are among the most salient risk factors for suicide (6–9). Moreover, a structured assessment of suicidal ideation and behavior significantly improves identification of high-risk patients relative to a routine clinical interview (10). However, to date, the field has lacked a single standard measure that assesses both suicidal ideation and behavior (10).

To address inconsistencies in nomenclature, the impact of such inconsistencies on accurate identification, and the need for a single measure to assess the severity of and track changes in suicidal ideation and behavior, a team of investigators from Columbia University, the University of Pennsylvania, and the University of Pittsburgh developed the Columbia–Suicide Severity Rating Scale (C-SSRS).

Suicidal ideation and behavior have traditionally been conceived as a unidimensional construct, with passive ideation, active intent, and behavior existing along a continuum (11, 12). The C-SSRS, however, was designed to distinguish the domains of suicidal ideation and suicidal behavior. Four constructs are measured. The first is the severity of ideation (hereafter referred to as the “severity subscale”), which is rated on a 5-point ordinal scale in which 1=wish to be dead, 2=nonspecific active suicidal thoughts, 3=suicidal thoughts with methods, 4=suicidal intent, and 5=suicidal intent with plan. The second is the intensity of ideation subscale (hereafter referred to as the “intensity subscale”), which comprises 5 items, each rated on a 5-point ordinal scale: frequency, duration, controllability, deterrents,

Columbia–Suicide Severity Rating Scale
Scoring and Administration

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Contributors: Mary E. Nilsson, Shailaja Suryawanshi, Cristiana Gassmann-Mayer, Sarah Dubrava, Paul McSorley, and Kaihong Jiang.

Introduction

The Columbia–Suicide Severity Rating Scale (C-SSRS) is an assessment tool that evaluates suicidal ideation and behavior. This guide outlines the proposed safety outcomes and statistical analysis strategy for the C-SSRS for an individual clinical trial.

The actual tables or combination of tables may vary to be consistent with a sponsor's standards, or to be consistent with the needs of a particular regulatory agency/division. As such this document serves as a general guideline and is not a proposal for mandatory analyses involving the C-SSRS. When analyzing the C-SSRS across studies, the same safety outcomes can be used. However, different statistical methodology would apply to combining data across studies, and is not discussed in this document.

As noted in the August 2012 draft guidance titled "Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials", the FDA has adopted the 11 categories defined in the C-SSRS (five subtypes of suicidal ideation, five subtypes of suicidal behavior, and self-injurious behavior without suicidal intent) as their standard. Some data collected on the C-SSRS are not included in these proposed displays for safety analysis (e.g., suicidal behavior lethality and suicidal ideation intensity), but are used for individual clinical management, safety monitoring, or other research purposes.

Analysis Set:
The analysis set should be defined consistently with the sponsor's standards for the safety analysis set. Frequently, this means including patients who have been exposed to at least one dose of study drug. When analyzing the C-SSRS, it is recommended to include patients having at least 1 post-baseline C-SSRS measurement, regardless of whether they had a baseline C-SSRS measurement. For some analyses of the C-SSRS (e.g., treatment-emergent assessments and shift tables), a pre-treatment C-SSRS measurement is also required.

Outcomes:
There is current debate on whether suicidal ideation and suicidal behavior should be combined and analyzed as a single outcome. Researchers agree on the need for having analyses that keep suicidal ideation and suicidal behavior separate, but disagree on[1]

whether there is value to having any outcome that combines them. This document currently includes the combined outcomes measure.

The following outcomes are C-SSRS categories and have binary responses (yes/no). The categories have been re-ordered from the actual scale to facilitate the definitions of the composite and comparative endpoints, and to enable clarity in the presentation of the results.

Category 1 – Wish to be Dead
Category 2 – Non-specific Active Suicidal Thoughts
Category 3 – Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act
Category 4 – Active Suicidal Ideation with Some Intent to Act, without Specific Plan
Category 5 – Active Suicidal Ideation with Specific Plan and Intent
Category 6 – Preparatory Acts or Behavior
Category 7 – Aborted Attempt
Category 8 – Interrupted Attempt
Category 9 – Actual Attempt (non-fatal)
Category 10 – Completed Suicide

Self-injurious behavior without suicidal intent is also a C-SSRS outcome (athough not suicide-related) and has a binary response (yes/no).

The following outcome is a numerical score derived from the C-SSRS categories. The score is created at each assessment for each patient and is used for determining treatment emergence.

- Suicidal **Ideation** Score: The maximum suicidal ideation category (1-5 on the C-SSRS) present at the assessment. Assign a score of 0 if no ideation is present.

Endpoints:
Composite endpoints based on the above categories are defined below.

- Suicidal **ideation**: A "yes" answer at any time during treatment to any one of the five suicidal ideation questions (Categories 1-5) on the C-SSRS.

- Suicidal **behavior**: A "yes" answer at any time during treatment to any one of the five suicidal behavior questions (Categories 6-10) on the C-SSRS.

- Suicidal **ideation or behavior**: A "yes" answer at any time during treatment to any one of the ten suicidal ideation and behavior questions (Categories 1-10) on the C-SSRS.

Comparative endpoints of interest are defined below. "Treatment emergence" is used for outcomes that include events that first emerge or worsen. "Emergence" is used for outcomes that include events that first emerge.

Columbia Suicide Severity Rating Scale (C-SSRS)

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead
Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

Yes ☐ No ☐

2. Non-Specific Active Suicidal Thoughts
General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

Yes ☐ No ☐

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act
Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

Yes ☐ No ☐

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan
Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

Yes ☐ No ☐

5. Active Suicidal Ideation with Specific Plan and Intent
Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

Yes ☐ No ☐

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe Ideation: ____ _____

Type # (1-5) ***Description of Ideation***

Most Severe

Frequency
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

____

Duration
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

____

This is the end of the SAMPLE C-SSRS questionnaire.
Please return to page 1 to purchase complete version.