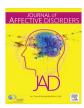
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#### Research paper

# A tool to predict suicidal ideation and behavior in bipolar disorder: The Concise Health Risk Tracking Self-Report



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#### ABSTRACT

Background: Few brief, self-report measures exist that can reliably predict adverse suicidality outcomes in patients with BD. This study utilized the Concise Health Risk Tracking Self-Report (CHRT) to assess suicidality in patients with BD and examined its psychometric performance, clinical correlates, and prospective value in predicting adverse events related to suicidality.

Methods: The CHRT was administered at baseline and follow-up to 482 adult patients in Bipolar CHOICE, a 6-month randomized comparative effectiveness trial. The Columbia Suicide Severity Rating Scale (CSSRS) was used at baseline to assess lifetime history of suicide attempts and related behaviors. Clinician-rated measures of mood (Bipolar Inventory of Symptoms Scale) and bipolar symptoms (Clinical Global Impressions-Bipolar Version) were conducted at baseline and follow-up.

Results: The CHRT showed excellent internal consistency and construct validity and was highly correlated with clinician ratings of depression, anxiety, and overall functioning at baseline and throughout the study. Baseline CHRT scores significantly predicted risk of subsequent suicidality-related Serious Adverse Events (sSAEs), after controlling for mood and comorbidity. Specifically, the hazard of a sSAE increased by 76% for every 10-point increase in baseline CHRT score. Past history of suicide attempts and related behaviors, as assessed by the CSSRS, did not predict subsequent sSAEs.

*Limitations*: The CSSRS was used to assess static risk factors in terms of past suicidal behaviors and may have been a more powerful predictor over longer-term follow-up.

Conclusions: The CHRT offers a quick and robust self-report tool for assessing suicidal risk and has important implications for future research and clinical practice.

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#### 1. Introduction

Bipolar disorder (BD) is associated with standardized mortality

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ratios between 1.6 and 2.1 (Osby et al., 2001), mostly due to high rates of suicide and cardiovascular disease (Roshanaei-Moghaddam and Katon, 2009). Patients with BD have about an eightfold higher risk of suicide and a two-fold increased risk of death from chronic medical illnesses as compared to those in the general population (Cerimele et al., 2013). Major depressive episodes associated with BD are the most lethal phase of the disorder, associated with the majority of lifetime suicide attempts, which occur in 25% to 56% of patients, and deaths by suicide, which occur in 10% to 19% (Nierenberg et al., 2001). Thus, close monitoring of suicidality in BD is undoubtedly essential; however, this is limited by the lack of brief, reliable, self-report ratings of suicidal ideation and behavior.

Although there are clinician-rated measures that track suicidality in BD (e.g. the Columbia Suicide Severity Rating Scale (CSSRS); (Posner et al., 2011)), these measures require intensive training and have significant limitations since patients may not feel comfortable speaking directly to clinicians about suicidal thoughts. Given the sensitive nature of suicidal ideation and behavior, it is important to get the patients' honest report of their current state. Self-report measures involve less in-person confrontation, and hence could provide more insight into suicidality and allow patients to disclose with more candor. Even the CSSRS, which is often viewed as the gold standard for assessing suicidality, has recently been formulated into an electronic, self-report version to reduce clinician burden and encourage patient self-disclosure (Mundt et al., 2013).

While self-report scales may offer significant advantages in assessing suicidal ideation, the value of positively predicting suicidal acts must also be considered. In a study of 191 patients with BD, suicidal ideation was assessed at baseline using the self-report Beck Depression Inventory – item 9 (BDI; Beck and Steer, 1990), and two clinician-rated measures: the Scale for Suicidal Ideation (SSI; Beck et al., 1979) and the Hamilton Depression Scale – item 3 (HAM-D; Hamilton, 1960). The predictive value of these different measures was investigated during a six-month follow-up, with a baseline SSI score  $\geq 8$  having the best combination of sensitivity and specificity and a positive predictive value of 32% for an attempted suicide during follow-up (Valtonen et al., 2009).

The Concise Health Risk Tracking Scale (CHRT) is a novel selfreport measure initially developed to assess suicidality in patients with unipolar major depressive disorder (Trivedi et al., 2011). The measure includes questions about hopelessness, self-worth, pessimism about the future, perception of social support, and active suicidal plans. The items are scored on 5 point Likert scales, ranging from "Strongly Disagree" to "Strongly Agree." Previous studies with unipolar major depressive disorder samples have demonstrated that the CHRT has excellent psychometric properties, with an internal consistency (Chronbach alpha) of 0.78 and a consistent factor structure with 3 independent factors (current suicidal thoughts and plans, perceived lack of social support, and hopelessness) (Trivedi et al., 2011). These three factors are consistent with the findings of Beck and colleagues, linking suicidal ideation/ plans, perceived lack of social support, and hopelessness with eventual suicide (Beck et al., 1974, 1976, 1990; Brown et al., 2000). In developing the CHRT, Trivedi et al. (2011) found that suicidal thoughts and plans were more likely to be endorsed by patient self-report than by clinician assessment (they compared 2 versions of the CHRT: one clinician rated and one self-report by the patient), and clinicians compared to patients were less likely to use the more extreme rating ("strongly agree"). These results suggested the possibility that patients may be more willing to endorse suicidal ideation on self-report assessments or that some physicians may inadequately record suicidal ideation.

One previous study used the CHRT to evaluate suicidality in BD and found excellent initial support for its psychometric properties

(Ostacher et al., 2015). This paper further explores the CHRT's psychometric properties and clinical correlates in Bipolar CHOICE and it is the first paper to examine the prospective value of the CHRT in predicting adverse events related to suicidality in patients with BD.

#### 2. Methods

#### 2.1. Procedure

The Bipolar CHOICE (Clinical and Health Outcomes Initiative in Comparative Effectiveness) study (Nierenberg et al., 2014) was a six-month nationwide multi-site, randomized comparative effectiveness trial comparing lithium, a classic mood stabilizer, to quetiapine, a second generation antipsychotic approved by the Food and Drug Administration to treat BD. Study physicians were able to prescribe additional medications as needed (regardless of treatment assignment) as long as it was consistent with an established BD treatment guideline (Suppes et al., 2005) and personalized to the needs of the patient given their current symptoms and functioning (Asao et al., 2006). The rationale, design, and methods of the Bipolar CHOICE study are reported elsewhere (Nierenberg et al., 2014).

#### 2.2. Participants

The Institutional Review Boards of the eleven study sites approved the study protocol. The Bipolar CHOICE study enrolled 482 individuals between the ages of 18 and 68 years, with 58.7% females. In terms of race, 72.2% were White, 19.9% were Black, 3.3% were Asian, and 4.6% were other. In terms of ethnicity, 11% were Hispanic or Latino. Limited inclusion and exclusion criteria were designed to maximize generalizability (Nierenberg et al., 2014), but participants were required to have a DSM-IV TR BPI or BPII diagnosis and to be at least mildly symptomatic (CGI-BP  $\geq$  3) at intake. All participants supplied written informed consent after receiving a full description of the study.

#### 2.3. Assessments

DSM-IV TR diagnoses were determined by trained raters using the Extended Mini-International Neuropsychiatric Interview (MINI), an electronic version of a validated structured diagnostic interview (Sheehan et al., 1998). The MINI suicide module also assessed suicidal risk at baseline, classifying risk levels as none, low, moderate, and high. The Clinical Global Impressions-Bipolar Version (CGI-BP) assessed BP illness severity and comprised three separate severity scores, ranging from 1 to 7 (normal to very severely ill), for mania, depression, and overall bipolar illness (Spearing et al., 1997). Symptom severity was also measured with the clinician-administered Bipolar Inventory of Symptoms Scale (BISS) (Bowden et al., 2007; Gonzalez et al., 2008) from which a total score and depression, mania, anxiety, irritability, and psychosis domain scores were derived. Clinical interviews obtained demographic information, psychiatric/medical history, and current medications. Serious adverse events (SAEs) were systematically recorded during the study. The Clinical Events Committee, chaired by the Director of Training and Assessments (AuthorNR-H), classified each SAE as related or unrelated to suicidal behavior, while blind to randomization status. Suicidal ideation was assessed at baseline and at each follow-up visit using the Concise Health Risk Tracking Scale (CHRT) (Trivedi et al., 2011). A 14-item self-report version of the CHRT was used, which includes 2 items related to impulsivity. Fig. 1 displays the scale items, with the 7 items that comprise the short version listed in bold. The Columbia Suicide

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