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Research Report

Clinical and psychometric validation of the psychotic depression assessment scale

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ABSTRACT

Background: Recent studies have indicated that the 11-item Psychotic Depression Assessment Scale (PDAS), consisting of the 6-item melancholia subscale (HAM-D_6) of the Hamilton Depression Rating Scale and 5 psychosis items from the Brief Psychiatric Rating Scale (BPRS), is a valid measure for the severity of psychotic depression. The aim of this study was to subject the PDAS, and its depression (HAM-D_6) and psychosis ($BPRS_5$) subscales to further validation.

Methods: Patients diagnosed with psychotic depression at Danish psychiatric hospitals participated in semi-structured interviews. Video recordings of these interviews were assessed by two experienced psychiatrists (global severity rating of psychotic depression, depressive symptoms and psychotic symptoms) and by two young physicians (rating on 27 symptom items, including the 11 PDAS items). The clinical validity and responsiveness of the PDAS and its subscales was investigated by Spearman correlation analysis of the global severity ratings and the PDAS, HAM-D_6, and $BPRS_5$ total scores. The unidimensionality of the scales was tested by item response theory analysis (Mokken).

Results: Ratings from 39 participants with unipolar psychotic depression and nine participants with bipolar psychotic depression were included in the analysis. The Spearman correlation analysis indicated that the PDAS, HAM-D_6 and $BPRS_5$ were clinically valid (correlation coefficients from 0.78 to 0.85, $p < 0.001$) and responsive (correlation coefficients from 0.72 to 0.86, $p < 0.001$) measures of psychotic depression. According to the Mokken analysis, all three scales were unidimensional.

Conclusions: The clinical validity, responsiveness and unidimensionality of the PDAS and its subscales were confirmed in an independent sample of patients with psychotic depression.

1. Introduction

Unipolar depression with psychotic symptoms (unipolar psychotic depression (UPD)) is a severe and debilitating condition, which needs intensive treatment and monitoring (Leadholm et al., 2014; Ostergaard et al., 2012b, 2013b; Rothschild, 2009). Although UPD differs significantly from non-psychotic depression in a number of aspects (Benros et al., 2013; Ostergaard et al., 2011, 2012b, 2013c, 2013e; Petrides et al., 2001), most clinical studies of UPD have used various versions of the Hamilton Depression Rating Scale (HAM-D) (Hamilton, 1967) as the main measure for severity and response (Glassman and Roose, 1981; Lykouras et al., 1985; Wijkstra et al., 2010). However, the HAM-D focuses predominantly on depressive symptoms and very few psychotic features are covered by the scale. Some studies have included the Brief Psychiatric Rating Scale (BPRS) (Overall and Gorham, 1962) to allow rating of the severity of the psychotic symptomatology (DeBattista et al., 2006; Furuse and Hashimoto, 2009). The only rating scale designed specifically for use in UPD is the Delusion

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Assessment Scale (DAS) (Meyers et al., 2006), which focuses exclusively on the delusions of the syndrome. The DAS was used in the largest randomized clinical trial in UPD to date, the Study of Pharmacotherapy of Psychotic Depression (STOP-PD) (Meyers et al., 2009), in combination with the 17-item Hamilton Depression Rating Scale (HAM-D_{17}), the BPRS and the Schedule of Affective Disorders and Schizophrenia (SADS) (Spitzer and Endicott, 1979). However, none of these individual scales seem to cover the psychopathology of the entire UPD syndrome (Ostergaard et al., 2012b), and this complicates severity measurement in both clinical practice and research studies (Leadholm et al., 2013; Ostergaard et al., 2014a).

Through analysis of item-level ratings on the HAM-D_{17} and the BPRS from the STOP-PD trial, we have recently constructed and validated a new composite severity rating scale, the "Psychotic Depression Assessment Scale" (PDAS), which covers both the depressive and the psychotic symptoms of UPD (Ostergaard et al., 2014a, 2014b). This scale consists of the 6-item melancholia subscale (HAM-D_6) (Bech et al., 1975), derived from the HAM-D_{17}, plus five psychosis items from the BPRS. The 11 items are: *depressed mood*, *guilt feelings*, *work and activities*, *psychomotor retardation*, *psychic anxiety* and *somatic symptoms (general)* from the HAM-D_6 and *hallucinatory behavior, unusual thought content (delusions), suspiciousness, emotional withdrawal* and *blunted affect* from the BPRS. In our first analysis, the PDAS demonstrated clinical validity, responsiveness and unidimensionality (Ostergaard et al., 2014a). Taken together, this implies that the sum of the individual PDAS item scores (i.e., the total score) is a valid measure for the severity of UPD. In a subsequent analysis we showed that the PDAS was able to detect statistically significant differences in treatment effect between Olanzapine+Sertraline and Olanzapine+Placebo (Olanzapine+Sertraline being superior) in patients with UPD (Ostergaard et al., 2014b). Furthermore, by means of the two PDAS subscales, the HAM-D_6 focusing on the severity of depressive symptoms and the $BPRS_5$ focusing on the severity of psychotic symptoms, we were able to show that the superiority of Olanzapine+Sertraline over Olanzapine+Placebo in UPD was driven by a significantly higher antidepressant effect and not an antipsychotic effect (Ostergaard et al., 2014b). Consequently, the PDAS seems to represent a highly informative alternative to traditional depression scales employed in the measurement of severity in UPD (Fava, 2014).

Since the construction and initial validation of the PDAS was based on the STOP-PD trial, its validity outside this setting has not been established. The participants in STOP-PD all met criteria for UPD according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) (American Psychiatric Association, 1994). In addition, all participants were delusional according to predefined criteria on the DAS and SADS (Meyers et al., 2009). However, not all patients with UPD are delusional. In both the DSM-IV and the recently published DSM-5 (American Psychiatric Association, 2013), patients can also meet criteria for UPD by experiencing hallucinations in addition to a major depressive episode (MDE) (severe MDE in the case of DSM-IV). Furthermore, according to the 10th edition of the International Classification of Disease (ICD-10) (World Health Organization, 1993), patients also meet criteria for UPD (Severe depressive episode with psychotic symptoms) if displaying depressive stupor (a catatonic state characterized by the absence of voluntary movements) in addition to severe depression. Consequently, the validity of the PDAS has only been documented for DSM-IV "delusional depression" in the framework of a highly organized randomized controlled trial (Meyers et al., 2009). The aim of the present study was therefore to test the clinical validity, responsiveness and unidimensionality of the PDAS in UPD as defined by ICD-10 diagnoses assigned as part of routine clinical practice in Danish hospital psychiatry.

2. Methods

2.1. Participants

50 patients with clinical diagnoses of UPD were recruited at Danish psychiatric hospitals. The inclusion criteria were as follows: currently undergoing inpatient or outpatient treatment at a Danish psychiatric hospital; meeting criteria for UPD (ICD-10: F32.3 or F33.3) according to a physician working at the hospital where the patient was undergoing treatment (verified by checklist of ICD-10 criteria); being 18 years of age or older and legally capable; understanding written and spoken Danish; providing written and oral informed consent. The exclusion criteria (evaluated by the referring physician) were: ongoing abuse of psychoactive substances (potentially giving rise to symptoms similar to those seen in UPD); meeting criteria for organic mental disorder, hypomania, mania, mixed affective episode, bipolar disorder, schizophrenia or schizoaffective disorder. The study was approved by the Danish Ethics Committee and the Danish Data Protection Agency. ClinicalTrials.gov Identifier: NCT01518049.

2.2. Interview

All participants were interviewed by the principal investigator (SDØ), using a semi-structured interview constructed specifically to cover the psychopathology of UPD (content validity). The interview aimed at obtaining sufficient information to allow rating on a total of 27 symptom items. The main depressive symptomatology was covered by the 11 items from the Bech–Rafaelsen melancholia scale (MES) (Bech, 2002). Another 16 items derived from the 24-item Hamilton Depression Rating Scale (HAM-D_{24}), the BPRS, and the Comprehensive Psychopathological Rating Scale (CPRS) (Asberg et al., 1978) were added, reaching a total of 27 symptom items. The questions pertaining to each item were asked in the following order, going from unobtrusive to more intrusive aspects, aiming at building a rapport with the participants prior to asking sensitive questions regarding suicidality, hallucinations and delusions etc.: *decreased sleep (MES)*, *tiredness (MES)*, *work and interests (MES)*, *depressed mood (MES)*, *difficulty concentrating (MES)*, *psychic anxiety (MES)*, *emotional withdrawal (inhibition) (MES)*, *guilt feelings (MES)*, *worthlessness (HAM-D_{24})*, *disorientation (BPRS)*, *somatic anxiety (HAM-D_{24})*, *hypochondriasis (HAM-D_{24})*, *obsessions (CPRS)*, *compulsions (rituals) (CPRS)*, *suicidal ideation (MES)*, *suspiciousness (BPRS)*, *hallucinations (BPRS)*, *unusual thought content (BPRS)*, *derealisation/depersonalization (HAM-D_{24})*, *lack of insight (HAM-D_{24})*, *conceptual disorganization (BPRS)*, *decreased verbal activity (MES)*, *decreased motor activity (MES)*, *agitation (HAM-D_{24})*, *catatonia (BPRS)*, *blunted affect (BPRS)*, and *hostility (BPRS)*. All Interviews were video-recorded to allow for subsequent rating by multiple raters. The first 25 participants enrolled in the study who accepted a second interview were interviewed just prior to discharge from the hospital (endpoint) following the exact same procedure as described above. Thus, a total of 75 interviews were conducted.

2.3. Rating

The video-recordings of the interviews were assessed by two independent teams of raters. The raters were selected in order to allow investigation of the clinical validity of the rating scales, which entails comparing ratings on the scales performed by relatively untrained mental health professionals (since rating scales are mainly employed by non-experts in clinical practice) against global ratings of severity performed by very experienced clinicians (considered to be the gold standard for severity measurement in psychiatry) (Bech, 2012; Fava, 2013). Therefore, the