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Comparing two short versions of the 32-item Hypomania Checklist (HCL-32) for patients with bipolar disorder

Running Head: Screening tools for bipolar disorder

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Abstract

PURPOSE: To compare the sensitivity, specificity, positive predictive value, and negative predictive value between Hypomania Checklist-20 (HCL-20) and HCL-16.

DESIGN AND METHODS: 350 subjects with bipolar disorders (BD) or major depressive disorders (MDD) were included. The sensitivity, specificity, PPV, NPV, and AUC between the HCL-20 and the HCL-16 for BD and its subtypes were compared.

FINDINGS: The HCL-16 demonstrated a superior performance in terms of sensitivity+specificity than the HCL-20. For discriminating BD and BD-I patients from MDD patients, the HCL-16 showed better sensitivity than the HCL-20, while the HCL-20 showed the better specificity than the HCL-16.

PRACTICE IMPLICATIONS: Our results showed that both the HCL-20 and the HCL-16 have a fair screening ability, but the HCL-16 showed a relatively superior performance considering its length.

Keywords: Bipolar disorder, screening, screening, sensitivity, specificity

INTRODUCTION

Bipolar disorder (BD) is a chronic mental illness characterized by depressive and manic/hypomanic episodes (Phillips & Kupfer, 2013). In clinical practice, BD is commonly misdiagnosed as other psychiatric disorders, particularly major depressive disorder (MDD) (Culpepper, 2014; Phillips & Kupfer, 2013), which could lead to adverse consequences, such as high suicide risk (McCombs, Ahn, Tencer, & Shi, 2007) and poor response to antidepressants (Smith, Ghaemi, & Craddock, 2008). Therefore, it is clinically important to improve the identification of BD from other disorders, especially MDD.

Widely used standardized diagnostic instruments, for example, the Structured Clinical Interview for DSM (SCID), are time-consuming and require trained clinical professionals (Zimmerman, Posternak, Chelminski, & Solomon, 2004). In order to detect BD more efficiently, several self-reported questionnaires have been developed, including the 32-item Hypomania Checklist (HCL-32) (Angst et al., 2005) and the Mood Disorder Questionnaire (MDQ) (Hirschfeld et al., 2000). The HCL-32 was developed to identify hypomanic symptoms (Angst et al., 2005) and has been validated in different countries (Gamma et al., 2013;

Meyer et al., 2007; Mosolov et al., 2014; Poon, Chung, Tso, Chang, & Tang, 2012; Yang et al., 2012; Yang et al., 2011).

As the length of the HCL-32 was considered to limit its usefulness (Forty et al., 2010), shortened versions with 16 items (HCL-16) in the UK (Forty et al., 2010) and 20 items (HCL-20) in Denmark (Bech, Christensen, Vinberg, Bech-Andersen, & Kessing, 2011) were developed. Both the HCL-16 and -20 showed satisfactory psychometric properties and could effectively discriminate BD from MDD. The Chinese version of HCL-32 has been validated with satisfactory psychometric properties, and is widely used in clinical settings (Yang et al., 2011), but the psychometric properties of the HCL-20 and the HCL-16 have not yet been tested. Compelling evidence suggested that HCL-32 scores may vary across cultures (Gamma et al., 2013), thus the findings obtained in the West would need to be replicated in different sociocultural contexts (Feng et al., 2017).

In China there are approximately 1.54 million people with BD (Zhang et al., 2017), but China has faced major deficits in mental health resources. For example, by 2015 there were only 27,733 psychiatrists and registrars and 57,591 psychiatric nurses (National Health and Family Planning Commission of China, April 7, 2017). Due to various

reasons, in many areas psychiatric nurses in the outpatient clinics are responsible for early identification of first episode of people with BD in many hospitals. However, to date all screening instruments for BD are excessively long and inconvenient for both patients and nurses.

In this study we aimed to examine the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the curve (AUC) of the HCL-20 and the HCL-16, in comparison with the HCL-32 and the MDQ. In addition, we compared the discriminative properties of the HCL-20 and the HCL-16 in screening out BD-I and BD-II from MDD separately.

METHOD

Study sample and sites

This study is part of a project that tested the usefulness of self-reported tools for BD in China (Feng et al., 2017). A total of 350 patients were recruited from the Beijing Anding Hospital. Inclusion criteria were as following: (1) age of 18-65 years, (2) being diagnosed as BD depression or MDD according to ICD-10 by a review of medical record and a clinical interview, (3) being clinically stable and able to understand the contents of the interview and provide written informed consent. Patients with

depressive disorders associated to major medical conditions were excluded. The study protocol was approved by the Ethics Committee at Beijing Anding Hospital.

Sample size estimation

The subject to item ratio was used in calculating the required sample size in the scale validation. The recommended subject to item ratio should be no lower than 5:1 (Bryant & Yarnold, 1995). Moreover, in estimating the minimum sample size, Comrey and Lee recommended the following: 100 = poor, 200 = fair, 300 = good, 500 = very good, and above 1000 = excellent (Comrey & Lee, 1992). In this study 350 patients were included, which adequately met both of the above criteria.

Instruments and evaluation

DSM-IV diagnoses of MDD and BD were established by an interviewed using the Chinese version of the Mini-International Neuropsychiatric Interview (MINI), Version 5.0 (Sheehan et al., 1998; Si et al., 2009). An inter-rater reliability exercise on use of the MINI between interviewers was conducted and the kappa value was > 0.85.

The HCL-32 is a self-reported scale to identify hypomanic symptoms in depressed patients that consists of 32 hypomanic symptoms with

'yes/no' options (Angst et al., 2005). The Chinese version of the HCL-32 has been validated in Chinese population (Yang et al., 2011) and its sum is computed by adding up all items scores. The HCL-20 is a short version of the HCL-32 that derives 20 items from the HCL-32 (items 1, 2, 4, 5, 7, 8, 9, 10, 11, 15, 18, 20, 21, 23, 25, 27, 28, 29, 31 and 32) (Bech et al., 2011), while the HCL-16 is a short version that derives 16 items from the HCL-32 (items 1, 4, 6, 8, 9, 10, 13, 14, 17, 19, 20, 27, 28, 30, 31 and 32) (Forty et al., 2010). The MDQ is a 13 yes/no items self-reported scale for screening hypomania or mania (Hirschfeld et al., 2000) and the MDQ Chinese version has satisfactory psychometric properties (Hu et al., 2012). The severity of depressive symptoms were assessed using the Chinese version of the Hamilton Depression Rating Scale 17-item (HAMD) (Hamilton, 1960; Xie & Shen, 1984). All the scales were checked once patients completed the assessments, and they were asked to complete the missing items to avoid any missing values.

Statistical analyses

All analyses were performed using the SPSS, 20.0. Criterion validity of the HCL-16 and HCL-20 were estimated with sensitivity, specificity, PPV and NPV. Receiver Operating Characteristic (ROC) curves were calculated to examine the threshold to discriminate between BD and

MDD. Cronbach's alpha was calculated as an indicator of internal consistency. The value of Cronbach's alpha ≥ 0.90 was defined as excellent, 0.80-0.89 as good, and 0.70-0.79 as adequate (Hunsley & Mash, 2008). The level of significance was set at 0.05 (two-sided).

RESULTS

Altogether, 375 patients were screened, and 350 (MDD: n=161, BD-I: n=90 and BD-II: n=99) fulfilled the study entry criteria, completed the assessment and were included in the analysis. Demographic and clinical characteristics are presented in Table 1. Of the 350 patients included, 31.1% were males and 63.7% were married. The patients' mean age was 37.7 (SD=13.0) years old, education level was 12.3 (SD= 5.2) years, and the mean age of onset was 29.6 (SD= 12.6) years.

The Cronbach's alpha for the HCL-32, the HCL-20 and the HCL-16 were 0.93, 0.89, and 0.85, respectively, indicating all the three HCL versions had good reliability. Table 2 presents the sensitivity, specificity, PPV, NPV and AUC of the HCL-32 and the MDQ identifying BD and its subtypes from MDD using the cutoffs suggested by respective validation studies, and also the sensitivity, specificity, PPV, NPV and AUC using the

optimal cut-offs of the HCL-20 and HCL-16 calculated based on the current sample.

All the three HCL versions presents a fair to good screening ability, and the AUC values of both the HCL-20 and the HCL-16 was equal or better than the HCL-32 when identifying BD, BD-I and BD-II. Compared with the HCL-20, the HCL-16 had a higher value of sensitivity+specificity. For discriminating BD and BD-I, the HCL-16 showed better sensitivity, while the HCL-20 showed the better specificity. For discriminating BD-II, the HCL-16 had a better specificity, while the HCL-20 had the better sensitivity.

DISCUSSION

This is the first study to compare the HCL-20 and the HCL-16 in identifying BD, BD-I and BD-II from MDD in Chinese patients. We also compared the screening ability of the short HCL versions for BD in comparisons with the HCL-32 and the MDQ. Compared to the MDQ, both the HCL-20 and the HCL-16 had higher specificity in discriminating BD, BD-I and BD-II, i.e., both the short HCL versions were superior in identifying patients without BD than the MDQ. Unlike previous studies on HCL-20 and HCL-16 (Bech et al., 2011; Forty et al., 2010), we calculated

the optimal cut-offs of both short HCL versions and also compared their screening ability in identifying BD-I and BD-II from MDD. For the HCL-20, its optimal cutoff value was 9, rather than 10 reported in other studies (Bech et al., 2011), in distinguishing BD with MDD in Chinese patients. For the HCL-16, the optimal cutoff in distinguishing BD with MDD was 6 in Chinese population, rather than 8 reported previously (Forty et al., 2010). The discrepancy in the cutoff values of the two short HCL versions across studies could be due to the different loadings of the HCL items across different populations (Fornaro, De Berardis, et al., 2015; Fornaro, Elassy, et al., 2015; Gamma et al., 2013). It should be noted that the HCL-16 (Forty et al., 2010) in the UK and the HCL-20 (Bech et al., 2011) in the Demark selected different items and demonstrated different factor loadings. Several factors could contribute to the discrepancy, including cross-cultural differences and the different psychometric analyses. Therefore, the potential cultural differences and culturally-specific impacts should be taken into account in the items selection.

Several limitations should be acknowledged. First, all patients were recruited in one major psychiatric hospital in China, which may limit the generalization of the findings. Second, following previous study (Bech et

al., 2011), the HCL-20 and the HCL-16 were not administrated in separate samples, instead, the items of the HCL-20 and the HCL-20 were selected from the HCL-32. This could potentially bias the performance of the two short versions since the patients could be influenced by repeated items in the HCL-32. Third, psychiatric diagnoses were established by the MINI, rather than more sophisticated diagnostic battery, such as the SCID. Fourth, depressed mood could impair participants' cognitive performance (Wang et al., 2018). In this study, we recruited clinically stable patients, which was likely to reduce the potential confounding effects of depressed mood on the assessment accuracy.

In conclusion, the current study found that both the HCL-20 and the HCL-16 had acceptable psychometric properties and screening ability in identifying BD and its subtypes. Considering the length, the HCL-16 appears to be an appropriate screening tool for psychiatric nurses to identify patients with BD. The psychometric properties of the HCL-20 and HCL-16 should be further tested in different settings in China.

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Conflict of Interest

All authors have no conflicts of interest to declare.

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Table 1. Basic demographic and clinical characteristics of patients

	The whole sample (n=350)		MDD (n=161)		BD			
					BD-1 (n=90)		BD-2 (n=99)	
	N	%	N	%	N	%	N	%
Male gender	109	31.1	58	36.0	28	31.1	23	23.2
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age (years)	37.7	13.0	40.6	13.2	34.6	12.2	35.7	12.5
Education (years)	12.3	5.2	12.0	6.9	12.5	3.0	12.4	3.1
Age of onset (years)	29.6	12.6	33.1	13.1	26.3	10.5	26.9	12.1
Number of episodes	3.5	3.8	2.8	3.3	3.9	3.3	4.3	4.8
HAMD total	20	7.1	20.7	6.8	20.2	6.7	18.7	7.9

BD=bipolar disorder; MDD=major depressive disorder; HAMD=Hamilton Depression Rating Scale

Table 2. Sensitivity, specificity, PPV, NPV, and Area Under the Curve (AUC) for the HCL with the different measures for bipolar disorders and its subtypes

	Scales	AUC	95% CI	Cut-off value	Sensitivity(SE)	Specificity(SP)	SE+SP	PPV	NPV
BD vs. MDD	HCL-32	0.71	0.65-0.76	14 (Yang et al., 2012)	0.63	0.70	1.33	0.71	0.62
	HCL-20	0.71	0.66-0.77	10 (Bech et al., 2011)	0.52	0.80	1.32	0.75	0.58
				9[a]	0.61	0.73	1.34	0.72	0.61
				8	0.67	0.65	1.32	0.69	0.63
				7	0.73	0.60	1.33	0.68	0.65
	HCL-16	0.71	0.66-0.76	8 (Forty et al., 2010)	0.48	0.81	1.29	0.75	0.57

				7	0.56	0.74	1.30	0.72	0.59
				6[a]	0.68	0.67	1.35	0.71	0.64
				5	0.76	0.55	1.31	0.66	0.65
	MDQ	0.74	0.68-0.79	3 (Hu et al., 2012)	0.90	0.39	1.29	0.63	0.78
BD-I vs. MDD	HCL-32	0.72	0.66-0.79	13 (Yang et al., 2011)	0.69	0.67	1.36	0.54	0.79
	HCL-20	0.73	0.66-0.79	10	0.53	0.80	1.33	0.60	0.75
				9[a]	0.62	0.73	1.35	0.56	0.78
				8	0.69	0.65	1.34	0.51	0.80
				7	0.73	0.60	1.33	0.5	0.8

								1	0
	HCL-16	0.72	0.65-0.78	8	0.48	0.81	1.28	0.59	0.74
				7	0.57	0.74	1.31	0.55	0.76
				6[a]	0.68	0.67	1.35	0.54	0.79
				5	0.76	0.55	1.31	0.49	0.80
	MDQ	0.77	0.71-0.83	5 (Hu et al., 2012)	0.81	0.63	1.44	0.55	0.86
BD-II vs. MDD	HCL-32	0.69	0.63-0.76	12 (Yang et al., 2012)	0.71	0.64	1.35	0.55	0.78
	HCL-20	0.70	0.63-0.76	10	0.50	0.80	1.30	0.61	0.72

			9	0.59	0.73	1.319	0.57	0.74
			8	0.65	0.65	1.30	0.53	0.78
			7[a]	0.72	0.60	1.32	0.53	0.78
HCL-16	0.70	0.64-0.77	8	0.49	0.81	1.30	0.62	0.72
			7	0.56	0.74	1.30	0.57	0.73
			6[a]	0.67	0.67	1.34	0.56	0.77
			5	0.76	0.55	1.31	0.51	0.78
MDQ	0.71	0.64-0.77	3 (Hu et al., 2012)	0.90	0.39	1.29	0.47	0.86

[a]=optimal cutoff in current sample; PPV = Positive Predictive Value, NPV = Negative Predictive Value, AUC = Area under the curve (ROC), CI = 95 % confidence interval for AUC, MDQ = Mood Disorder Questionnaire, and HCL-33 = Hypomania Checklist-33.