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REVIEW ARTICLE

Assessment of the diagnostic performance of two new tools versus routine screening instruments for bipolar disorder: a meta-analysis

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Objective: The present meta-analysis was conducted to determine the diagnostic accuracy of the bipolarity index (BI) and Rapid Mode Screener (RMS) as compared with the Bipolar Spectrum Diagnostic Scale (BSDS), the Hypomania Checklist (HCL-32), and the Mood Disorder Questionnaire (MDQ) in people with bipolar disorder (BD).
Methods: We systematically searched five databases using standard search terms, and relevant articles published between May 1990 and November 30, 2021 were collected and reviewed.
Results: Ninety-three original studies were included (n=62,291). At the recommended cutoffs for the BI, HCL-32, BSDS, MDQ, and RMS, the pooled sensitivities were 0.82, 0.75, 0.71, 0.71, and 0.78, respectively, while the corresponding pooled specificities were 0.73, 0.63, 0.73, 0.77, and 0.72, respectively. However, there was evidence that the accuracy of the BI was superior to that of the other tests, with a relative diagnostic odds ratio (RDOR) of 1.22 (0.98-1.52, $p < 0.0001$). The RMS was significantly more accurate than the other tests, with an RDOR (95%CI) of 0.79 (0.67-0.92, $p < 0.0001$) for the detection of BD type I (BD-I). However, there was evidence that the accuracy of the MDQ was superior to that of the other tests, with an RDOR of 1.93 (0.89-2.79, $p = 0.0019$), for the detection of BD type II (BD-II).
Conclusion: The psychometric properties of two new instruments, the BI and RMS, in people with BD were consistent with considerably higher diagnostic accuracy than the HCL-32, BSDS, and MDQ. However, a positive screening should be confirmed by a clinical diagnostic evaluation for BD.

Keywords: Bipolar disorder; screening; accuracy studies; systematic review; meta-analysis

Introduction

The mood disorders encompass a large group of psychiatric diseases, of which major depressive disorders, bipolar disorder (BD), and cyclothymia can be detected on the basis of DSM-IV diagnostic criteria.[1] BDs are often undiagnosed and, thus, often go untreated[2]; delays in diagnosis will delay treatment accordingly. The lifetime prevalence range for BD is 1.4 to 6.4% globally.[3-5] BD is subdivided into type I (BD-I) and type II (BD-II). According to the DSM-5 criteria, the lifetime prevalence of BD-I is about 1% and that of BD-II is 1.3% in the general population.[6-8]

According to earlier reports, some individuals who met criteria for BD were never diagnosed with it, but in comparison, more people were misdiagnosed with BD, with correct diagnosis often being delayed by about 10 years.[9] Accurate and concise tools have since largely improved the diagnosis of BD, including the Mood Disorders Questionnaire (MDQ), a 13-item checklist based on DSM-IV criteria and clinical experience[10]; the Hypomania Checklist-32 (HCL-32), a globally validated self-applied questionnaire to facilitate the diagnosis of BD-II[11]; and the Bipolar Spectrum Diagnostic Scale (BSDS), a self-report questionnaire for BD.[12]

The estimated sensitivity and specificity of the MDQ are in the range of 73-76% and 86-90%, respectively.[13-16] The HCL-32 was reported to have 48-66% and 59-71% sensitivity and specificity respectively for screening BD.[17,18] Thus, both the MDQ and HCL-32 tools have relatively acceptable sensitivity and specificity for BD screening. At lower prevalence or low clinical pretest probability, high negative predictive values were confirmed, indicating that available instruments effectively rule out BD; however, the positive predictive value decreases significantly, leading to a greater number of

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"false positives."[19] Recently, two new instruments for the diagnosis of BD have been introduced: the Bipolarity Index (BI)[20] and the Rapid Mood Screener (RMS).[21] BI, a diagnostic aid, is a clinician-rated tool that focuses on five clinical domains, including signs and symptoms, age at onset, disease course, treatment response, and family history. Considering the clinical domains covered by BI, this diagnostic method may be more conducive than the MDQ, BSDS, and HC-32, of which previous studies reported a specificity of 100% in the differential diagnosis of BD.[22]

Various studies have shown that about 40-50% of patients with BD are undiagnosed at the time of referral and are often treated as having monopolar depression.[23,24] Since a large number of individuals with BD suffer substantial complications and consequences due to this lack of proper diagnosis, a diagnostic tool with appropriate psychometric properties is still needed. The present meta-analysis was conducted to determine the diagnostic accuracy of psychometric properties of the BI and RMS as compared to the BSDS, the HCL-32, and the MDQ in people with BD.

Methods

This systematic review with meta-analysis was conducted according to the Meta-analyses of Observational Studies in Epidemiology,[25] Preferred Reporting Items for Systematic reviews and Meta-Analyses,[26] and Synthesizing Evidence from Diagnostic Accuracy Tests[27] guidelines.

Search strategy

We systematically searched databases including Scopus, ISI Web of Sciences (WOS), PubMed/MEDLINE, EMBASE, and PsycINFO using the standard search terms "Bipolarity index"[Text] AND ("Bipolar Disorder" OR "Bipolar and Related Disorders" OR "Mood Disorders" OR "Mania") OR ("Depression" OR "Depressive Disorder") AND ("Hypomania Checklist" OR "HCL" OR "Hypomania/Mania Symptoms Checklist" OR "Hypomania Symptoms Checklist"). Relevant articles published between May 1990 and November 30, 2021 were collected and reviewed.

Inclusion and exclusion criteria

Prospective, national, population-based studies considering individuals with BD and using the BI tool for diagnosis were included. Articles that had incomplete or unidentified data, various designs (conference abstracts, reviews, case reports, letters), and duplicate publications were excluded.

Study selections

After exclusion of duplicates, two authors (MS and FR) independently screened titles and abstracts of potential papers considering predefined inclusion and exclusion criteria. Any disagreements were resolved by either reevaluation of the source article or consulting a third author (ME).

Data extraction

Information, including authors' names, year of publication, country, age, sample size, and study design were extracted for analysis.

Methodological quality assessment

Two reviewers (MS and FR) assessed the methodological quality of the included studies using the Newcastle-Ottawa Scale and the Quality Assessment of Diagnostic Accuracy Studies tools. Disagreements were resolved by either discussion or reevaluation of the original article with a third reviewer (ME).

Statistical analysis

We retrieved odds ratios (ORs) with 95% confidence intervals (95%CIs) from the eligible studies, and calculated summary ORs with the random-effects or fixed-effect models, depending on the level of heterogeneity, to evaluate the diagnostic utility of the BI in the screening and diagnosis of individuals with BD.[28] We then measured heterogeneity across studies using Cochran's Q statistic and the I^2 test. When the I^2 values exceeded 50%, indicating high heterogeneity, sensitivity and subgroup analyses were performed to discover the source of the heterogeneity. A hierarchical summary receiver-operating characteristic (HSROC) curve and a summary receiver operating characteristic (SROC) curve were constructed. All experiments were viewed with the HSROC curve as a circle and plotted. The area under the curve (AUC) was computed to determine the diagnostic precision. An AUC approaching 1.0 would mean outstanding results, while one approaching 0.5 would denote poor performance. Among numerous subgroups, the 95%CI of the AUC was compared. When the sensitivity and specificity were directly unavailable, they were calculated according to the following formulas: sensitivity = TP / (TP + FN) and specificity = TN / (FP + TN). Publication bias was measured using Deeks' regression test.[29] The analysis was conducted using version 1.4 of the Meta-DiSc software[30] and RevMan 5.3.

Ethics statement

As this systematic review with meta-analysis relied exclusively on previously published studies, ethics committee approval and informed consent were waived.

Results

Search results

Overall, 834 records were found through the initial search. Of 679 articles, 292 duplicates were found and 357 were omitted due to irrelevant titles and abstracts. The remaining 185 entered full-text screening; of these, 94 were excluded due to predefined criteria (Figure 1). Ultimately, 93 studies (n=62,291) were included (Table S1, available as online-only supplementary material).[11-16,20,21-24,31-100]

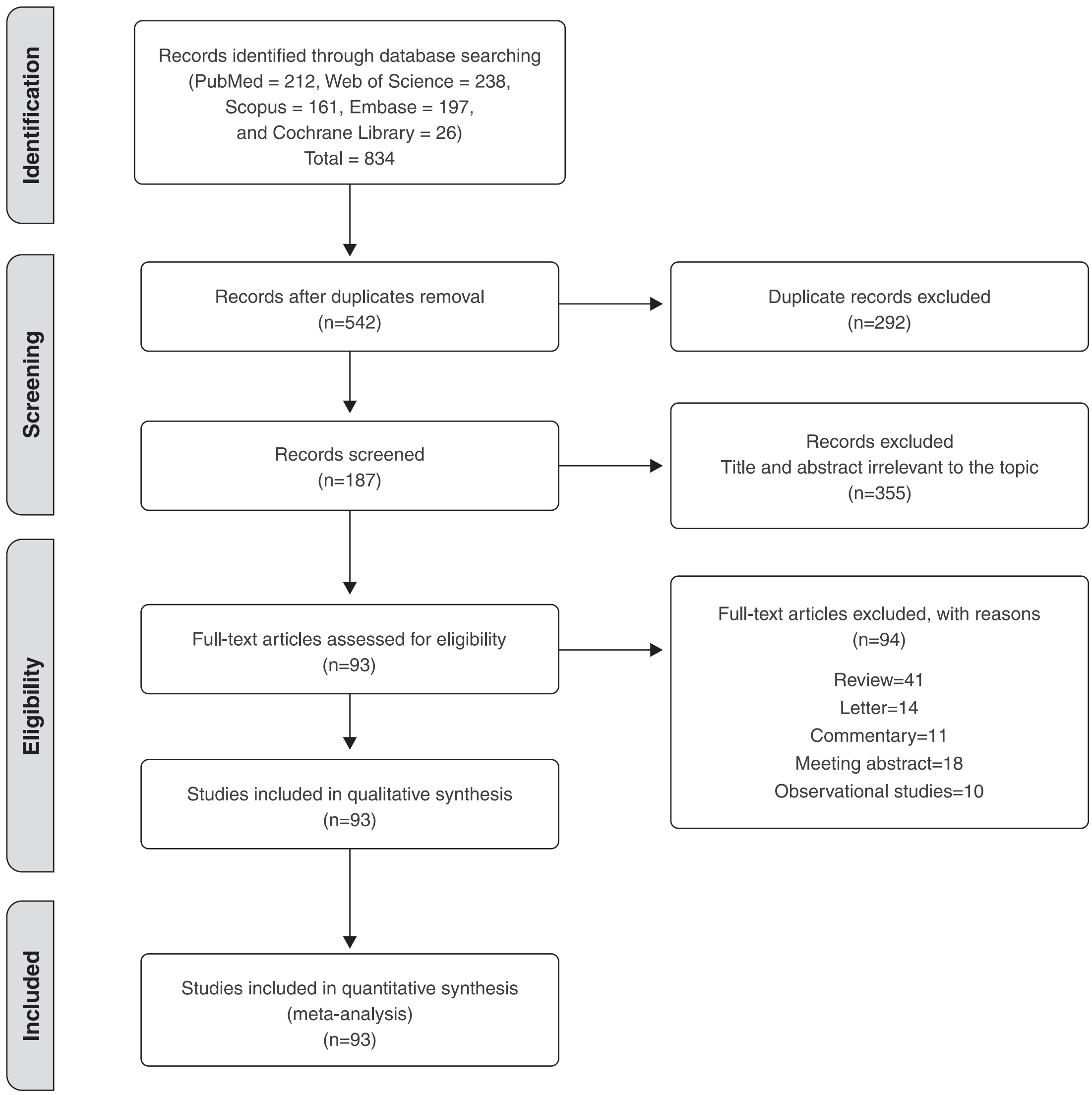

Figure 1 Flow diagram of the selection process.

Methodological quality of included studies

The methodological quality of the included studies is shown in Figure S1, available as online-only supplementary material. A total of nine studies were at high risk of bias in the participant selection domain.[13,24,31,40,41,51,63,64,93] Also nine studies were at high risk of bias in the reference standard domain.[32,39,42,45,46,52,77,86,98] Moreover, a total of two studies were at high risk of bias in the flow and timing domain.[42,107] Three studies were at high risk of bias for all index tests other than one threshold[32,42,77] (Figure 2).

Comparison of the BI, HCL-32, BSDS, MDQ, and RMS for the detection of bipolar disorder (indirect comparison)

The pooled sensitivities and specificities for the BI, HCL-32, BSDS, MDQ, and RMS at specific cutoffs were measured for a separate meta-analysis of each instrument at a common cutoff (Table 1). At the recommended cutoffs for the BI, HCL-32, BSDS, MDQ, and RMS, the pooled sensitivities were 0.82 (95%CI 0.81-0.83), 0.75 (95%CI 0.74-0.76), 0.71 (95%CI 0.69-0.73), 0.71 (95%CI 0.70-0.73), and 0.78 (95%CI 0.73-0.82), respectively. The corresponding pooled specificities were 0.73 (95%CI 0.72-0.74), 0.63 (95%CI 0.62-0.63), 0.73 (95%CI 0.71-0.74), 0.77 (95%CI 0.76-0.78), and 0.72 (95%CI 0.68-0.77), respectively. However, there was evidence that the accuracy of the BI was superior to that of the other tests with a relative diagnostic OR (RDOR) (95%CI) of 1.22 (0.98-1.52, $p < 0.0001$).

We compared the performance of the three existing tools, including the HCL-32 (28 studies), MDQ (55 studies), and BSDS (14 studies), with the two new instruments, BI (nine studies) and RMS (three studies), using all available studies (Figure 3). The pattern of the SROC curves and the accuracy of the screening instruments varied considerably, because accuracy of each tool differed with different cutoffs (Figure 4). Though the

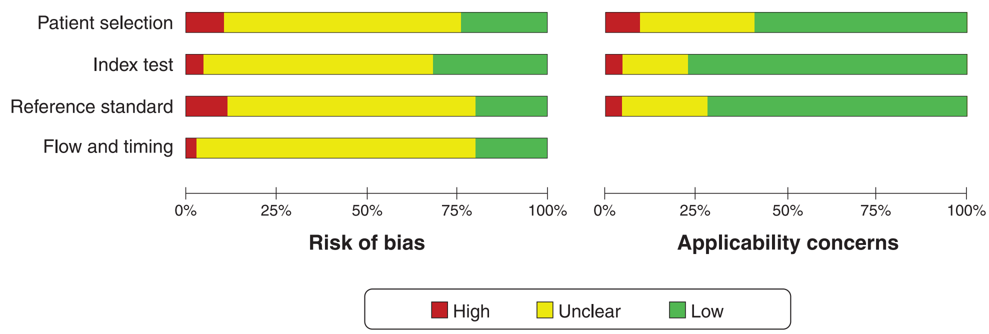

Figure 2 Summary risk of bias and applicability concerns: review authors' judgments regarding each domain of each included study.

number of studies was not comparable, the BI curve was consistently above those of the HCL-32, BSDS, MDQ, and RMS in the region covering maximum observed data at higher values of sensitivity and lower specificity. Both the BSDS and RMS curves were above the HCL-32 and MDQ curves.

Direct comparison

- Comparison of the BI with HCL-32 for the detection of BD: The BI curve was consistently above the HCL-32 curve in the region encompassing most of the observed data (Figure S2).
- Comparison of the BI with BSDS for the detection of BD: The BI curve was consistently above the BSDS curve in the region comprising most of the observed data (Figure S3).
- Comparison of the BI with MDQ for the detection of BD: The BI curve was consistently above the MDQ curve in the region involving most of the observed data (Figure S4).
- Comparison of the RMS with HCL-32 for the detection of BD: The RMS curve was consistently above the HCL-32 curve in the region encompassing most of the observed data (Figure S5).
- Comparison of the RMS with BSDS for the detection of BD: The RMS curve was not consistently above the BSDS curve in the region comprising most of the observed data (Figure S6).
- Comparison of the RMS with MDQ for the detection of BD: The BI curve was consistently above the MDQ curve in the region involving most of the observed data (Figure S7).
- Comparison of the BI with RMS for the detection of BD: The BI curve was consistently above the RMS curve in the region involving most of the observed data (Figure S8).

Detection of BD-I

Overall, 14 studies used various instruments to detect BD-I using the HCL-32 (six studies, 4,799 patients), MDQ (five studies, 4,144 patients), and RMS (three studies, 800 patients) (Figure 5).

Overall, each instrument had acceptable diagnostic accuracy for the detection of BD (Figures S9-12).

At the recommended cutoffs for the HCL-32, MDQ, and RMS, the pooled sensitivities were 0.65 (0.63-0.67), 0.78 (0.76-0.80), and 0.78 (0.73-0.82), respectively. The corresponding pooled specificities were 0.64 (0.62-0.66), 0.67 (0.65-0.69), and 0.72 (0.68-0.77), respectively (Table 2).

Detection of BD-II

Overall, 28 studies used various instruments to detect BD-II: the HCL-32 (10 studies, 6,316 patients), BSDS (five studies, 515 patients), MDQ (14 studies, 3,772 patients), and BI (one study, 800 patients) (Figure 6).

At the recommended cutoffs for the HCL-32, BSDS, and MDQ, the pooled sensitivities were 0.70 (0.68-0.72), 0.78 (0.67-0.87), and 0.52 (0.49-0.56), respectively. The corresponding pooled specificities were 0.65 (0.63-0.66), 0.63 (0.58-0.67), and 0.77 (0.76-0.79), respectively (Table 2).

We compared the test performance and diagnostic accuracies of the BI, HCL-32, BSDS, MDQ, and RMS for detection of BD-I (Figure 7A) vs. BD-II (Figure 7B). The RMS was significantly more accurate than the other tests, with an RDOR (95%CI) of 0.79 (0.67-0.92, $p < 0.0001$), for the detection of BD-I. However, there was evidence that the accuracy of the BI was superior to that of the other tests, with an RDOR of 1.93 (0.89-2.79, $p = 0.0019$), for the detection of BD-II (Table 2). More detailed components of diagnostic accuracy, including sensitivity, specificity, positive and negative predictive values, and likelihood ratios for each test, are given in Supplementary Material S13.

Discussion

The present meta-analysis was conducted to determine the diagnostic accuracy of two new instruments, the BI and RMS, in people with BD, comparing these instruments to already available tools such as the HCL-32, BSDS, and MDQ. The findings showed that the utility and diagnostic accuracy of the BI were significantly superior to those of the other tools, especially for BD-II.

BD and other chronic mental disorders such as schizophrenia are different, but their symptoms are sometimes confused. If a good clinical history is lacking or the context of the patient's current life situation is ignored,

Table 1 Summary diagnostic characteristics of the BI, HCL-32, BSDS, MDQ, and RMS for detection of any type of bipolar disorder in mental health center, primary care, or general community populations

Test	Papers (n)	Participants (n)	Sensitivity			Specificity			Diagnostic OR		
			Pooled (95%CI)	I^2 (%)	p-value	Pooled (95%CI)	I^2 (%)	p-value	Pooled (95%CI)	I^2 (%)	p-value
BI	9	11,474	0.82 (0.81-0.83)	98.9	< 0.0001	0.73 (0.72-0.74)	99.1	< 0.0001	47.20 (12.01-185.52)	99.2	< 0.0001
HCL-32	28	20,837	0.75 (0.74-0.76)	95.9	< 0.0001	0.63 (0.62-0.63)	97.6	< 0.0001	7.50 (5.65-9.95)	92.1	< 0.0001
BSDS	14	7,256	0.71 (0.69-0.73)	80.0	< 0.0001	0.73 (0.71-0.74)	97.0	< 0.0001	13.49 (8.80-20.69)	80.6	< 0.0001
MDQ	55	21,924	0.71 (0.70-0.73)	95.4	< 0.0001	0.77 (0.76-0.78)	95.6	< 0.0001	9.04 (7.32-11.17)	85.6	< 0.0001
RMS	3	800	0.78 (0.73-0.82)	91.4	< 0.0001	0.72 (0.68-0.77)	82.1	0.0038	14.24 (3.16-64.1)	93.7	< 0.0001

95%CI = 95% confidence interval; BI = Bipolarity Index; BSDS = Bipolar Spectrum Diagnostic Scale; DOR = diagnostic odds ratio; HCL-32 = Hypomania Checklist-32; MDQ = Mood Disorder Questionnaire; OR = odds ratio; RMS = Rapid Mood Screener.

misdiagnosis may occur. Substantial misdiagnosis rate between BD and other chronic mental disorders, especially mood disorders, may lead to delay in receiving proper and timely treatment and achieving symptom control.

Overall, for the detection of both types of BD, the BI was significantly more accurate than the HCL-32, MDQ, BSDS, and RMS, while to detect BD-I, the RMS was significantly more accurate, and for the detection of BD-II, the MDQ had superior diagnostic accuracy. Differences in the characteristics of the studied instruments can explain these findings. Our meta-analysis showed 0.82 and 0.73 for the BI at recommended cutoff in psychiatric services, respectively. In this context, Carvalho et al.[18] performed a meta-analysis to compare the diagnostic accuracy of the BSDS, the HCL-32, and the MDQ, and reported summary sensitivities of 81, 66, and 69%, as well as specificities of 67, 79, and 86% for the HCL-32, MDQ, and BSDS in psychiatric services, respectively. Thus, the BI could be more accurate than the other available tools for the detection of BD in primary-care or general-population settings. Given that the BSDS, HCL-32, and MDQ were proposed to improve the diagnosis of less exuberant cases of BD,[12,31] this may explain why the other tools are less accurate than the BI for detection of BD.

Recently, Sun et al.[111] conducted a meta-analysis to assess the diagnostic accuracy of BI for the detection of BD and found diagnostic superiority of the BI, with significant heterogeneity. The pooled sensitivity, specificity, and accuracy of the BI were 93% (95%CI 93-100), 85% (95%CI 69-96), and 86% (95%CI 77-93), respectively.[112] Our meta-analysis of an individual test showed that the pooled sensitivity, specificity, and accuracy of the BI were 82% (95%CI 61-100), 73% (95%CI 52-100), and 93% (95%CI 77-97), respectively. Thus, our meta-analysis also showed a diagnostic superiority of the BI over other instruments, with significant heterogeneity. The Sun et al.[111] meta-analysis included only five studies that used the Chinese version of the BI, but our analysis encompasses studies from America, Asia, and Europe. Wang et al.[17] performed a meta-analysis of studies that directly compared the HCL-32 and the MDQ in detecting BD, and reported that the HCL-32 showed higher sensitivities (82% [95%CI 72-89] vs. 80% [95%CI 71-86]) and lower specificities (57% [95%CI 48-66] vs. 70% [95%CI 59-71]) compared to the MDQ. Our findings are in line with those of Wang et al.[17] in terms of direct comparison of these two instruments, but they included only nine studies, while our meta-analysis included 28 studies using the HCL-32 and 55 using the MDQ. In another meta-analysis, Carvalho et al.[18] assessed the diagnostic accuracy of 53 original studies, both directly and indirectly, and showed that the HCL-32 is consistently more accurate than the MDQ, especially for BD-II. The present meta-analysis showed that the BI has a higher sensitivity for the diagnosis of BD-II compared to other instruments. Given that around 70% of individuals with BD-I are first misdiagnosed, with an average disease onset-to-diagnosis delay of 5 to 10 years, a group of multidisciplinary professionals developed the RMS (a six-item instrument) to offer a pragmatic method to shed light on the necessity for accurate and timely

Bipolarity Index (BI)

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Ter Meulen 2020	1,244	891	613	966	30.0	Europe	0.67 (0.65, 0.69)	0.52 (0.50, 0.54)
Ma 2016	418	141	197	474	40.0	Asia	0.68 (0.64, 0.72)	0.77 (0.74, 0.80)
Aiken 2015	1,684	185	167	1,666	50.0	America	0.91 (0.90, 0.92)	0.90 (0.89, 0.91)
Guo 2014	162	12	14	164	50.0	Asia	0.92 (0.87, 0.96)	0.93 (0.88, 0.96)
He 2014	112	0	8	120	50.0	Asia	0.93 (0.87, 0.97)	1.00 (0.97, 1.00)
Li 2015	102	20	18	100	50.0	Asia	0.85 (0.77, 0.91)	0.83 (0.75, 0.90)
Lin 2011	155	35	21	141	50.0	Asia	0.88 (0.82, 0.92)	0.80 (0.73, 0.86)
Ma 2013	727	218	0	509	50.0	Asia	1.00 (0.99, 1.00)	0.70 (0.67, 0.73)
Zhu 2011	81	35	14	60	50.0	Asia	0.85 (0.77, 0.92)	0.63 (0.53, 0.73)

Hypomania Checklist-32 (HCL-32)

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Chou 2012	7	28	0	24	8.0	Asia	1.00 (0.59, 1.00)	0.46 (0.32, 0.61)
Fei 2021	146	44	6	108	9.0	Asia	0.96 (0.92, 0.99)	0.71 (0.63, 0.78)
Poon 2012	26	82	5	192	11.0	Asia	0.84 (0.66, 0.95)	0.70 (0.64, 0.75)
Carta 2006	20	39	4	60	12.0	Europe	0.83 (0.63, 0.95)	0.61 (0.50, 0.70)
Angst 2005	213	78	53	82	14.0	Europe	0.80 (0.75, 0.85)	0.81 (0.43, 0.59)
Feng 2017	221	105	130	245	14.0	Asia	0.63 (0.58, 0.68)	0.70 (0.65, 0.75)
Huang 2013	288	12	129	581	14.0	Asia	0.69 (0.64, 0.73)	0.98 (0.96, 0.99)
Kim 2018	381	192	133	322	14.0	Asia	0.74 (0.70, 0.78)	0.63 (0.58, 0.67)
Leao 2012	66	66	7	61	14.0	America	0.90 (0.81, 0.96)	0.48 (0.39, 0.57)
Meyer 2011	123	223	17	125	14.0	Europe	0.88 (0.81, 0.93)	0.36 (0.31, 0.41)
Meyer 2017	1,335	685	377	1,027	14.0	Europe	0.78 (0.76, 0.80)	0.60 (0.58, 0.62)
Nallet 2013	30	73	3	46	14.0	Europe	0.91 (0.76, 0.98)	0.39 (0.30, 0.48)
Perugi 2012	485	126	86	445	14.0	Europe	0.85 (0.82, 0.88)	0.78 (0.74, 0.81)
Vieta 2007	201	50	35	186	14.0	Europe	0.85 (0.80, 0.89)	0.79 (0.73, 0.84)
Wang 2019	221	105	130	245	14.0	Asia	0.63 (0.58, 0.68)	0.70 (0.65, 0.75)
Wu 2008	131	13	29	26	14.0	Asia	0.82 (0.75, 0.88)	0.67 (0.50, 0.81)
Yang 2011	222	53	78	103	14.0	Asia	0.74 (0.69, 0.79)	0.66 (0.58, 0.73)
Haghighi 2011	74	5	28	56	14.5	Asia	0.73 (0.63, 0.81)	0.92 (0.82, 0.97)
Gamma 2013	749	2,022	154	2,661	15.0	Europe	0.83 (0.80, 0.85)	0.57 (0.55, 0.58)
Garcia-Castillo 2012	22	52	9	45	15.0	Asia	0.71 (0.52, 0.86)	0.48 (0.36, 0.57)
Sasdelli 2013	60	40	34	54	15.0	Europe	0.64 (0.53, 0.73)	0.57 (0.47, 0.68)
Yoon 2017	319	137	135	317	15.0	Asia	0.70 (0.66, 0.74)	0.70 (0.65, 0.74)
Mosolov 2021	107	47	44	104	16.0	Europe	0.71 (0.63, 0.78)	0.69 (0.61, 0.76)
Camacho 2018	374	299	89	164	17.0	Europe	0.81 (0.77, 0.84)	0.35 (0.31, 0.40)
Bech 2011	53	19	6	44	18.0	Europe	0.90 (0.79, 0.96)	0.70 (0.57, 0.81)
Forty 2010	42	18	17	58	18.0	Europe	0.71 (0.58, 0.82)	0.76 (0.65, 0.85)
Soares 2010	61	18	20	24	18.0	America	0.75 (0.64, 0.84)	0.57 (0.41, 0.72)
Lee 2016	192	96	341	437	19.0	Asia	0.36 (0.32, 0.40)	0.82 (0.78, 0.88)

Bipolar Spectrum Diagnostic Scale (BSDS)

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Zimmerman 2010	81	427	9	444	8.0	America	0.90 (0.82, 0.95)	0.51 (0.48, 0.54)
Lee 2013	83	29	30	84	10.0	Asia	0.73 (0.64, 0.81)	0.74 (0.65, 0.82)
Castelo 2010	55	10	15	34	11.0	America	0.79 (0.67, 0.87)	0.77 (0.62, 0.89)
Nagata 2013	12	19	3	44	11.0	Asia	0.80 (0.52, 0.96)	0.70 (0.57, 0.81)
Shabani 2019	153	64	54	143	11.0	Asia	0.74 (0.67, 0.80)	0.69 (0.62, 0.75)
Aiken 2015	1,314	426	537	1,425	12.0	America	0.71 (0.69, 0.73)	0.77 (0.75, 0.79)
Chu 2010	74	3	26	97	12.0	Asia	0.74 (0.64, 0.82)	0.97 (0.91, 0.99)
Imamura 2015	11	3	17	24	12.0	Asia	0.39 (0.22, 0.59)	0.89 (0.71, 0.98)
Ince 2019	144	24	39	159	12.0	Asia	0.79 (0.72, 0.84)	0.87 (0.81, 0.91)
Sanchez de la Cruz 2018	128	6	72	194	12.0	America	0.64 (0.57, 0.71)	0.97 (0.94, 0.99)
Nassir Ghaemi 2005	52	4	16	23	13.0	America	0.76 (0.65, 0.86)	0.85 (0.66, 0.96)
Vazquez 2010	46	4	19	32	13.0	Asia	0.71 (0.58, 0.81)	0.89 (0.74, 0.97)
Zaratiegui 2011	228	4	113	18	13.0	America	0.67 (0.62, 0.72)	0.82 (0.60, 0.95)
Shabani 2009	59	14	54	54	14.0	Asia	0.52 (0.43, 0.62)	0.79 (0.68, 0.88)

Mood Disorder Questionnaire (MDQ)

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Wang 2009	5	22	1	25	2.0	Asia	0.83 (0.36, 1.00)	0.53 (0.38, 0.68)
Hu 2012	93	94	216	1,084	3.0	Asia	0.30 (0.25, 0.36)	0.92 (0.90, 0.94)
Hughes 2016	146	34	87	199	3.0	Europe	0.63 (0.56, 0.69)	0.85 (0.80, 0.90)
Paterniti 2018	632	219	211	624	3.0	America	0.75 (0.72, 0.78)	0.74 (0.71, 0.77)
Gan 2012	45	16	18	43	4.0	Asia	0.71 (0.59, 0.82)	0.73 (0.60, 0.84)
Poon 2012	20	63	11	211	4.0	Asia	0.65 (0.45, 0.81)	0.77 (0.72, 0.82)
Nagata 2013	10	20	5	43	5.0	Asia	0.67 (0.38, 0.88)	0.68 (0.55, 0.79)
Sasdelli 2013	2	4	9	52	5.0	Europe	0.18 (0.02, 0.52)	0.93 (0.83, 0.98)
Shabani 2009	71	20	42	48	5.0	Asia	0.63 (0.53, 0.72)	0.71 (0.58, 0.81)
Shim 2018	187	17	21	191	5.0	Asia	0.90 (0.85, 0.94)	0.92 (0.87, 0.95)
Thase 2021	136	70	64	130	5.0	America	0.68 (0.61, 0.74)	0.65 (0.58, 0.72)
Vohringer 2016	231	48	29	212	5.0	America	0.89 (0.84, 0.92)	0.82 (0.76, 0.86)
Wang 2020	382	235	70	217	5.0	Asia	0.85 (0.81, 0.88)	0.48 (0.43, 0.53)
Zaratiegui 2011	184	0	157	13	5.0	America	0.54 (0.49, 0.59)	1.00 (0.75, 1.00)
Lin 2011	81	10	14	65	6.0	Asia	0.85 (0.77, 0.92)	0.87 (0.77, 0.93)
Hardoy 2005	35	19	11	89	6.0	Europe	0.76 (0.61, 0.87)	0.82 (0.74, 0.89)
Lee 2013	25	4	56	28	6.0	Asia	0.31 (0.21, 0.42)	0.88 (0.71, 0.96)
Carta 2006	18	14	6	85	6.0	Europe	0.75 (0.53, 0.90)	0.86 (0.77, 0.92)
Waleeprakhon 2014	191	68	59	182	6.0	Asia	0.76 (0.71, 0.82)	0.73 (0.67, 0.78)
Goldberg 2012	87	54	26	59	7.0	America	0.77 (0.68, 0.84)	0.52 (0.43, 0.62)
Gonzalez 2009	9	74	0	116	7.0	Europe	1.00 (0.66, 1.00)	0.61 (0.54, 0.68)
Haghighi 2011	81	17	21	44	7.0	Asia	0.79 (0.70, 0.87)	0.72 (0.59, 0.83)
Hirschfeld 2000	80	9	29	80	7.0	America	0.73 (0.64, 0.81)	0.90 (0.82, 0.95)
Imamura 2015	37	14	18	41	7.0	Asia	0.67 (0.53, 0.79)	0.75 (0.61, 0.85)
Isometsa 2003	17	9	3	8	7.0	Europe	0.85 (0.62, 0.97)	0.47 (0.23, 0.72)
Kim 2008	17	12	42	40	7.0	Asia	0.29 (0.18, 0.42)	0.77 (0.63, 0.87)
Konuk 2007	23	63	13	210	7.0	Asia	0.64 (0.46, 0.79)	0.77 (0.71, 0.82)
Leao 2012	50	47	23	82	7.0	America	0.68 (0.57, 0.79)	0.63 (0.54, 0.71)
Lee 2014	165	91	52	126	7.0	Asia	0.76 (0.70, 0.82)	0.58 (0.51, 0.65)
McIntyre 2021	120	31	19	108	7.0	America	0.86 (0.79, 0.92)	0.78 (0.70, 0.84)
Meyer 2011	112	125	28	223	7.0	Europe	0.80 (0.72, 0.86)	0.64 (0.59, 0.69)
Miller 2004	21	12	16	24	7.0	America	0.57 (0.39, 0.73)	0.67 (0.49, 0.81)
Nallet 2013	22	27	11	92	7.0	Europe	0.67 (0.48, 0.82)	0.77 (0.69, 0.84)
Palmer 2021	634	244	123	513	7.0	America	0.84 (0.81, 0.86)	0.68 (0.64, 0.71)
Aiken 2015	1,370	537	481	1,314	7.0	America	0.74 (0.72, 0.76)	0.71 (0.69, 0.73)
Bech 2011	52	7	7	56	7.0	Europe	0.88 (0.77, 0.95)	0.89 (0.78, 0.95)
Benazzi 2003	57	8	18	15	7.0	Europe	0.76 (0.65, 0.85)	0.65 (0.43, 0.84)
Chou 2012	5	12	2	40	7.0	Asia	0.71 (0.29, 0.96)	0.77 (0.63, 0.87)
Chung 2008	28	2	34	38	7.0	Asia	0.45 (0.32, 0.58)	0.95 (0.83, 0.99)
Chung 2008	0	25	6	83	7.0	Asia	0.00 (0.00, 0.46)	0.77 (0.68, 0.84)
Soares 2010	57	18	24	24	7.0	America	0.70 (0.59, 0.80)	0.57 (0.41, 0.72)
Tafalla 2009	212	161	42	510	7.0	Europe	0.91 (0.87, 0.95)	0.76 (0.73, 0.79)
Vahip 2017	105	45	43	103	7.0	Asia	0.71 (0.63, 0.78)	0.70 (0.62, 0.77)
van Zaane 2012	15	58	20	77	7.0	Europe	0.43 (0.26, 0.61)	0.57 (0.48, 0.66)
Weber Rouget 2005	40	4	14	38	7.0	Europe	0.74 (0.60, 0.85)	0.90 (0.77, 0.97)
Yang 2011	182	27	102	107	7.0	Asia	0.64 (0.58, 0.70)	0.80 (0.72, 0.86)
Yang 2014	68	35	241	1,143	7.0	Asia	0.22 (0.18, 0.27)	0.97 (0.96, 0.98)
Zimmerman 2010	33	64	19	364	7.0	America	0.63 (0.49, 0.76)	0.85 (0.81, 0.88)
Cyprien 2014	51	19	29	96	7.0	Europe	0.64 (0.52, 0.74)	0.83 (0.75, 0.90)
de Dios 2008	8	13	3	83	7.0	Europe	0.73 (0.39, 0.94)	0.86 (0.78, 0.93)
de Sousa Gurgel 2012	36	6	15	96	7.0	America	0.71 (0.56, 0.83)	0.94 (0.88, 0.98)
Dumont 2020	147	14	14	147	7.0	America	0.91 (0.86, 0.95)	0.91 (0.86, 0.95)
Gervasoni 2009	28	17	16	85	7.0	Europe	0.64 (0.48, 0.78)	0.83 (0.75, 0.90)
Castelo 2010	63	13	6	32	8.0	America	0.91 (0.82, 0.97)	0.71 (0.56, 0.84)
Twiss 2008	41	10	12	63	9.0	Europe	0.77 (0.64, 0.88)	0.86 (0.76, 0.93)

Rapid Mood Screener (RMS)

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Montano 2021	122	28	17	111	4.0	America	0.88 (0.81, 0.93)	0.80 (0.72, 0.86)
Thase 2021	136	70	64	130	4.0	America	0.68 (0.61, 0.74)	0.65 (0.58, 0.72)
McIntyre 2021	51	13	7	51	6.0	America	0.88 (0.77, 0.95)	0.80 (0.68, 0.89)

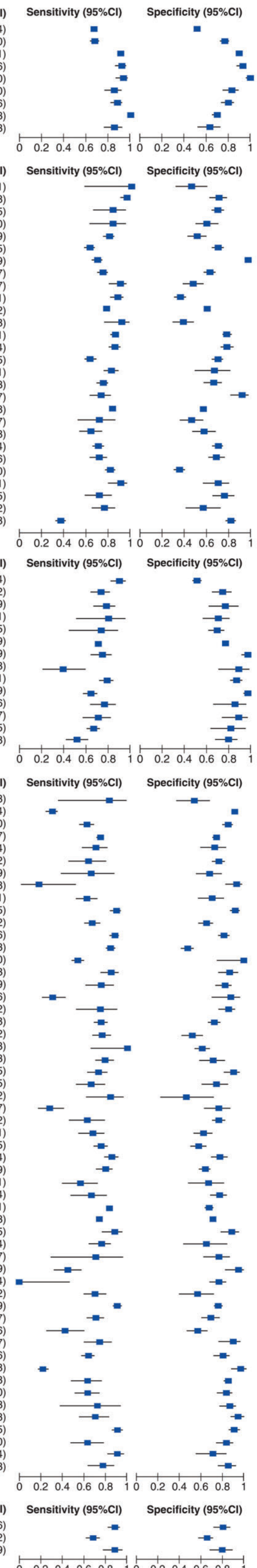

Figure 3 Forest plot of BI, HCL-32, BSDS, MDQ, and RMS, including sensitivity and specificity of included studies. 95%CI = 95% confidence interval; BI = bipolarity index; BSDS = Bipolar Spectrum Diagnostic Scale; FN = false negative; FP = false positive; HCL-32 = Hypomania Checklist-32; MDQ = Mood Disorder Questionnaire; RMS = Rapid Mood Screener; TN = true negative; TP = true positive.

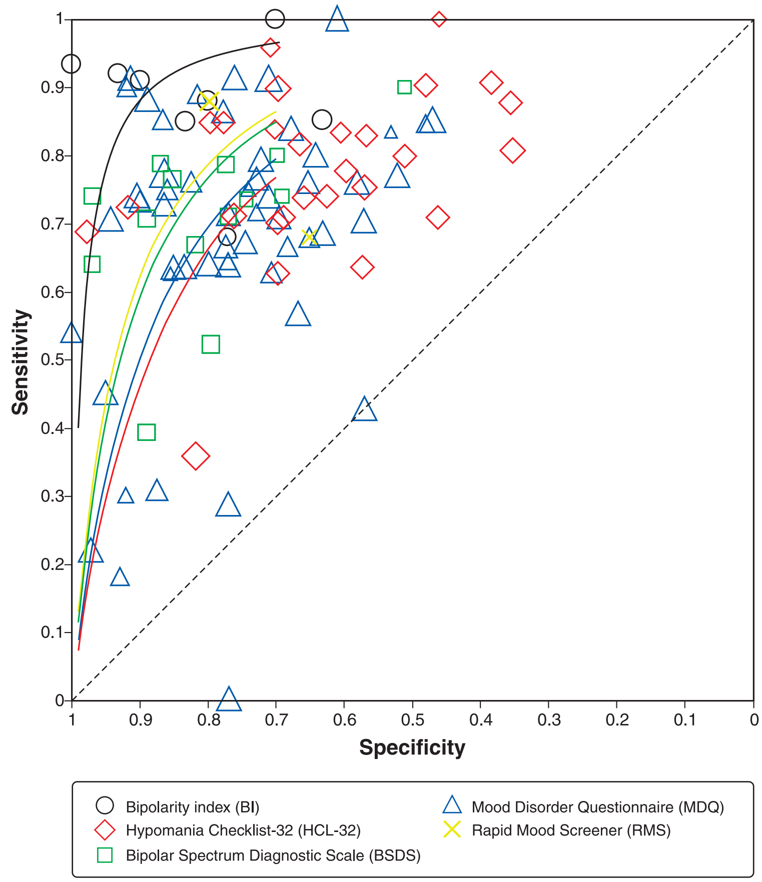

Figure 4 Summary estimates and 95% confidence region of the meta-analyses showing diagnostic test accuracies of BI, HCL-32, BSDS, MDQ, and RMS for detection of any type of bipolar disorder (BD). BI = bipolarity index; BSDS = Bipolar Spectrum Diagnostic Scale; FN = false negative; FP = false positive; HCL-32 = Hypomania Checklist-32; MDQ = Mood Disorder Questionnaire; RMS = Rapid Mood Screener; TN = true negative; TP = true positive.

detection of BD.[21,113,114] In line with our findings, the RMS provided high accuracy for detection of BD-I, with a sensitivity, specificity, and accuracy of 88, 80, and 84%, respectively.[76]

Although this meta-analysis involved a large number of studies and participants, there were some limitations. Comparing the accuracy and diagnostic value of the two new instruments with the three existing ones was prone to confounding due to differences in study characteristics and population.[115] The main limitation of the BI is that the observer is not blind to the results of the Mini International Neuropsychiatric Interview (MINI), which, as a structured diagnostic interview, has become an integral part of psychiatry, not only being considered the diagnostic gold standard in psychiatric research but also increasingly being used to help ensure diagnostic precision in clinical practice.[116] Because several parts of the BI are derived from structured interviews, it is difficult to completely ignore the influence of MINI results. This may limit the generalizations of the findings, but is consistent with how the scale is used in clinical practice. Another limitation is relying on a sole interviewer in a practice environment and the absence of longitudinal follow-up.

The present meta-analysis shows that the diagnostic value and accuracy of a new instrument, the BI, exceeded those of existing instruments including the BSDS, HCL-32, and MDQ. However, it should be noted that these tools should not be considered as a means of definitive diagnosis, because a significant proportion of patients diagnosed with BD do not actually have the disorder.[110] Therefore, it is recommended that a confirmatory diagnostic interview and clinical observation be performed simultaneously. Moreover, cost-benefit analysis to assess the cost of false positives with the use of screening tools not only is important, but failure to account for real cases of BD may lead to erroneous results and suboptimal decision making. Finally, well-designed clinical studies, especially randomized controlled trials (RCT), of BD screening instruments should offer evidence of their impact on patient outcomes.

In conclusion, a large number of patients with BD continue to experience complications and consequences due to a lack of proper diagnosis. To diagnose these disorders accurately, in addition to a clinical interview, a diagnostic tool with appropriate psychometric properties is still needed. Though available BD screening tools have

Table 2 Summary diagnostic characteristics of BI, HCL-32, BSDS, MDQ, and RMS for detection of any type of bipolar disorder in mental health center, primary care, or general community populations

			Sensitivity			Specificity			Diagnostic OR		
Test	Papers (n)	Participants (n)	Pooled (95%CI)	I^2 (%)	p-value	Pooled (95%CI)	I^2 (%)	p-value	Pooled (95%CI)	I^2 (%)	p-value
HCL-32											
BD-I	6	4,799	0.65 (0.63-0.67)	98.3	< 0.0001	0.64 (0.62-0.66)	93.8	< 0.0001	3.48 (2.50-4.85)	84.2	< 0.0001
BD-II	10	6,316	0.70 (0.68-0.72)	97.7	< 0.0001	0.65 (0.63-0.66)	95.5	< 0.0001	5.53 (4.21-7.79)	78.6	< 0.0001
BSDS											
BD-II	4	515	0.78 (0.67-0.87)	0.0	0.9659	0.63 (0.58-0.67)	84.9	0.0002	6.85 (3.72-12.6)	0.0	0.7693
MDQ											
BD-I	5	4,144	0.78 (0.76-0.80)	96.0	< 0.0001	0.67 (0.65-0.69)	91.1	< 0.0001	8.67 (4.44-16.93)	91.6	< 0.0001
BD-II	14	3,772	0.52 (0.49-0.56)	92.6	< 0.0001	0.77 (0.76-0.79)	97.0	< 0.0001	3.93 (4.21-7.79)	60.2	0.0019
RMS											
BD-I	3	800	0.78 (0.73-0.82)	91.4	< 0.0001	0.72 (0.68-0.77)	82.1	0.0038	14.24 (3.16-64.1)	93.7	< 0.0001

95%CI = 95% confidence interval; BD-I = bipolar disorder type I; BD-II = bipolar disorder type II; BI = bipolarity index; BSDS = Bipolar Spectrum Diagnostic Scale; DOR = diagnostic odds ratio; HCL-32 = Hypomania Checklist-32; MDQ = Mood Disorder Questionnaire; OR = odds ratio; RMS = Rapid Mood Screener.

HCL-32-Bipolar I

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Angst 2005	248	121	78	205	14.0	Europe	0.76 (0.71, 0.81)	0.63 (0.57, 0.68)
Feng 2017	235	109	116	242	14.0	Asia	0.67 (0.62, 0.72)	0.69 (0.64, 0.74)
Meyer 2011	122	85	26	55	14.0	Europe	0.88 (0.75, 0.88)	0.39 (0.31, 0.48)
Meyer 2017	632	324	270	486	14.0	Europe	0.70 (0.67, 0.73)	0.60 (0.57, 0.63)
Yang 2011	315	150	141	306	14.0	Asia	0.69 (0.65, 0.73)	0.67 (0.63, 0.71)
Lee 2016	70	40	243	180	19.0	Asia	0.22 (0.18, 0.27)	0.82 (0.76, 0.87)

MDQ-Bipolar I

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Hu 2012	1,204	550	283	937	3.0	Asia	0.81 (0.79, 0.83)	0.63 (0.61, 0.65)
McIntyre 2021	50	14	8	50	7.0	America	0.86 (0.75, 0.94)	0.78 (0.66, 0.87)
Meyer 2011	118	43	30	97	7.0	Europe	0.80 (0.72, 0.86)	0.69 (0.61, 0.77)
Chung 2008	85	50	100	135	7.0	Asia	0.46 (0.39, 0.53)	0.73 (0.66, 0.79)
Cyprien 2014	155	32	40	163	7.0	Europe	0.79 (0.73, 0.85)	0.84 (0.78, 0.88)

RMS-Bipolar I

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Montano 2021	122	28	17	111	4.0	America	0.88 (0.81, 0.93)	0.80 (0.72, 0.86)
Thase 2021	136	70	64	130	4.0	America	0.68 (0.61, 0.74)	0.65 (0.58, 0.72)
McIntyre 2021	51	13	7	51	6.0	America	0.88 (0.77, 0.95)	0.80 (0.68, 0.89)

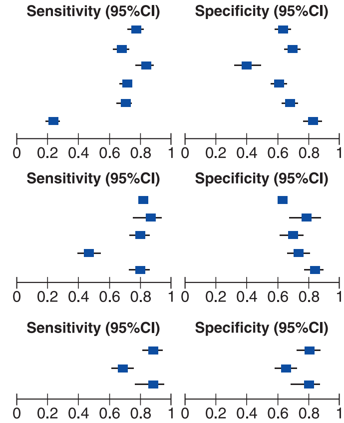

Figure 5 Forest plot of BI, HCL-32, MDQ, and RMS including sensitivity and specificity of included studies on patients with BD-I. 95%CI = 95% confidence interval; BI = Bipolarity Index; FN = false negative; FP = false positive; HCL-32-Bipolar I = Hypomania Checklist-32 (HCL-32)-Bipolar disorder type I; MDQ-Bipolar I = Mood Disorder Questionnaire (MDQ)-Bipolar disorder type I; RMS-Bipolar I = Rapid Mood Screener (RMS)-Bipolar disorder type I; TN = true negative; TP = true positive.

Hypomania Checklist-32 (HCL-32)-Bipolar II

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Carta 2006	8	52	2	61	12.0	Europe	0.80 (0.44, 0.97)	0.51 (0.44, 0.63)
Meyer 2011	126	85	22	55	14.0	Europe	0.85 (0.78, 0.90)	0.39 (0.31, 0.48)
Meyer 2017	689	373	214	437	14.0	Europe	0.76 (0.73, 0.79)	0.54 (0.50, 0.57)
Wu 2008	71	35	23	70	14.0	Asia	0.76 (0.66, 0.84)	0.67 (0.57, 0.76)
Yang 2011	59	59	17	97	14.0	Asia	0.78 (0.67, 0.86)	0.66 (0.61, 0.72)
Angst 2005	231	108	95	218	14.0	Europe	0.71 (0.66, 0.76)	0.67 (0.61, 0.72)
Feng 2017	252	119	98	231	14.0	Asia	0.72 (0.67, 0.77)	0.66 (0.61, 0.71)
Yang 2011	164	402	27	894	14.0	Asia	0.86 (0.80, 0.90)	0.69 (0.66, 0.71)
Mosolov 2021	122	70	25	172	16.0	Europe	0.83 (0.76, 0.89)	0.71 (0.65, 0.77)
Lee 2016	68	15	245	205	19.0	Asia	0.22 (0.17, 0.27)	0.93 (0.89, 0.96)

Bipolar Spectrum Diagnostic Scale (BSDS)-Bipolar II

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Castelo 2010	11	30	4	69	11.0	America	0.73 (0.45, 0.92)	0.70 (0.60, 0.79)
Nagata 2013	12	19	3	44	11.0	Asia	0.80 (0.52, 0.96)	0.70 (0.57, 0.81)
Chu 2010	23	55	6	116	12.0	Asia	0.79 (0.60, 0.92)	0.68 (0.60, 0.75)

Mood Disorder Questionnaire (MDQ)-Bipolar II

Study	TP	FP	FN	TN	Cutoff	Continent	Sensitivity (95%CI)	Specificity (95%CI)
Hu 2012	42	104	149	1,192	3.0	Asia	0.22 (0.16, 0.29)	0.92 (0.90, 0.93)
Gan 2012	32	21	13	56	4.0	Asia	0.71 (0.56, 0.84)	0.73 (0.61, 0.82)
Nagata 2013	10	20	5	43	5.0	Asia	0.67 (0.38, 0.88)	0.68 (0.55, 0.79)
Carta 2006	8	62	2	51	6.0	Europe	0.80 (0.44, 0.97)	0.45 (0.36, 0.55)
Hardoy 2005	16	74	4	60	6.0	Europe	0.80 (0.56, 0.94)	0.45 (0.36, 0.54)
Lin 2011	20	57	5	38	6.0	Asia	0.80 (0.59, 0.93)	0.40 (0.30, 0.51)
Weber Rouget 2005	11	4	10	38	7.0	Europe	0.52 (0.30, 0.74)	0.90 (0.77, 0.97)
Chung 2008	80	54	105	131	7.0	Asia	0.43 (0.36, 0.51)	0.71 (0.64, 0.77)
Cyprien 2014	112	53	83	142	7.0	Europe	0.57 (0.50, 0.64)	0.73 (0.66, 0.79)
de Sousa Gurgel 2012	7	30	5	111	7.0	America	0.58 (0.28, 0.85)	0.79 (0.71, 0.85)
Gonzalez 2009	9	74	0	116	7.0	Europe	1.00 (0.66, 1.00)	0.61 (0.54, 0.68)
Kim 2008	9	18	24	60	7.0	Asia	0.27 (0.13, 0.46)	0.77 (0.66, 0.86)
Meyer 2011	116	43	32	97	7.0	Europe	0.78 (0.71, 0.85)	0.69 (0.61, 0.77)
Castelo 2010	11	30	3	70	8.0	America	0.79 (0.49, 0.95)	0.70 (0.60, 0.79)

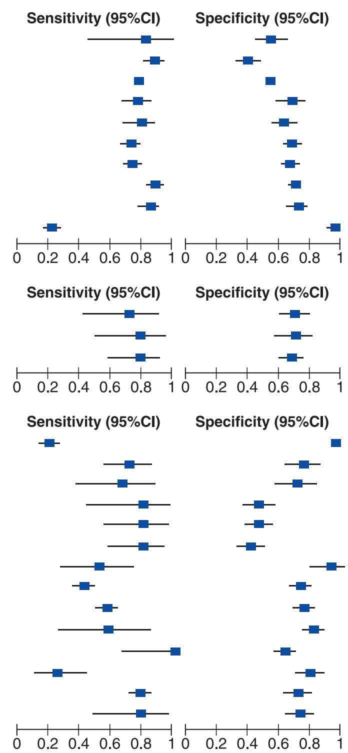

Figure 6 Forest plot of HCL-32, BSDS, MDQ, and BI including sensitivity and specificity of included studies on patients with BD-II. 95%CI = 95% confidence interval; BI = Bipolarity Index; FN = false negative; FP = false positive; HCL-32-Bipolar I = Hypomania Checklist-32 (HCL-32)-Bipolar disorder type I; MDQ-Bipolar II = Mood Disorder Questionnaire (MDQ)-Bipolar disorder type II; RMS-Bipolar I = Rapid Mood Screener (RMS)-Bipolar disorder type I; TN = true negative; TP = true positive.

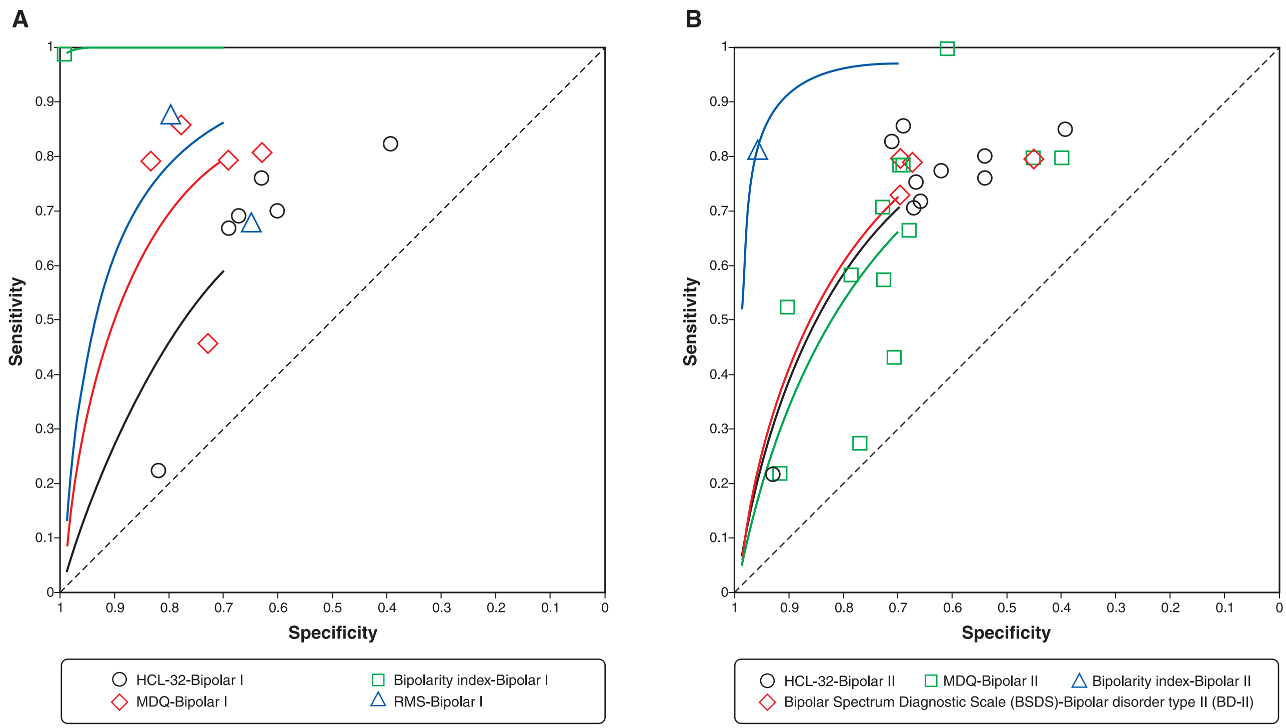

Figure 7 Summary estimates and 95% confidence region of the meta-analyses showing diagnostic test accuracies of BI, HCL-32, BSDS, MDQ, and RMS for detection of any type of BD-I (A) vs. BD-II (B). BD-1 = bipolar disorder type I; BD-II = bipolar disorder type II; HCL-32-Bipolar I = Hypomania Checklist-32 (HCL-32)-Bipolar disorder type I; HCL-32-Bipolar II = Hypomania Checklist-32 (HCL-32)-Bipolar disorder type II; MDQ-Bipolar I = Mood Disorder Questionnaire (MDQ)-Bipolar disorder type I; MDQ-Bipolar II = Mood Disorder Questionnaire (MDQ)-Bipolar disorder type II; RMS-Bipolar I = Rapid Mood Screener (RMS)-Bipolar disorder type I.

acceptable diagnostic accuracy, as shown in previous studies, the results are still not entirely satisfactory because only a limited number of parameters are considered. The present study showed that the diagnostic accuracy of two new instruments, the BI and RMS, is considerably higher than that of available tools such as the HCL-32, BSDS, and MDQ. Nevertheless, a positive screening result should still be confirmed by a clinical diagnostic evaluation for BD.

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Disclosure

The authors report no conflicts of interest.

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