



A Computer Interview to Increase Diagnostic Confidence for Bipolar Disorders

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Introduction

• Psychiatric illness can be validated (see Robbins and Guze, 1980) based on five dimensions: (1) Episode Characteristic, (2) Age of Onset, (3) Course of Illness, (4) Response to Treatment and (5) Family History. This approach offers the opportunity to create measures of diagnostic confidence based on ordinal scales for each dimension.

The Bipolarity Index (BPx) is a 100 point scale that assesses diagnostic confidence for Bipolar Disorder utilizing the 5 dimensions above.

- Each Dimension is scored 0-20 points. Thus a theoretical classic case with the traits most convincing for bipolar disorder on each Dimension would score 100.
- Data from STEP-BD suggests scores > 60 on BPx are consistent with a confident diagnosis of BPI disorder. (Sachs et al) 92.5 of BPI subjects scored at least 15 on 3 or more BPx dimensions.
- Concordant Rater Systems (CRS) developed a computerized version of The Bipolarity Index. (C-BPx)
- The purpose of this study is to evaluate the utility of utilizing the C-BPx scale in a multi-centered, industry study as a means of validating diagnosis at study entry.

Methods

- Data was obtained from in a multi-centered, industry sponsored study evaluating Bipolar Disorder Type I depression.
- MINI administered by site based personnel was the primary criteria for establishing the diagnosis of BPI. Subjects diagnosed BPI based on the MINI were assessed on a computer interview assessing Lifetime Illness Characteristics. (C-BPx) The responses were scored on the BPx and used to validate the diagnosis (DxV) to confirm eligibility prior to randomization. C-BPx was administered in three countries in 5 languages.
- Each C-BPx was scored by the computer and characterized as highly confident diagnosis or requiring clinical confirmation. Subjects with highly confident diagnosis were confirmed for enrollment without further review. The remainder were reviewed by CRS and a diagnostic validation clinical consensus conference was scheduled (DxV) during which an experienced clinician from CRS reviewed the BP I diagnosis with the clinician who performed the MINI. The BPx score was revised based on information obtained at this consensus conference.
- Subjects granted entry into study based on validation without review (validated-WOR) and based on high scores on each dimension of the C-BPx, were compared to subjects enrolled with diagnoses validated on the basis of clinical consensus conference. (validated-WCC) Subjects not meeting these criteria were not validated (NV) and were deemed ineligible for the study.

- The MADRS administered by a trained site based rater (MADRS_{SBR}) was the primary outcome. The MADRS administered by computer (MADRS_{comp}) was used in parallel with the (MADRS_{SBR}) as part of a rater quality management program.
- Analyses were performed with Chi Square for categorical variables and unpaired t-test for continuous variables. All tests were 2-tailed with the level of significance set at .05.

Results

Table 1: Bipolarity Index Scores for Subjects Enrolled in RCT

Data	n	1. Episode Characteristics	2. Age of Onset	3. Course of Illness	4. Treatment History	5. Family History	TOTAL Bipolarity Index Score	≥ 3 Dimensions 15 or higher (% of n)	≥ 1 Confounder Reported to Computer (% of n)
All subject randomized mean (s.d.)	283	16.62 (± 3.3)	16.17 (± 3.3)	14.34 (± 2.9)	14.24 (± 3.4)	10.69 (± 7.5)	71.86 (± 10.1)	266 (94%)	56 (19.8%)
BP1 diagnosis validated WOR mean (s.d.)	164 (58%)	18.08 (± 2.5)	16.71 (± 3.0)	14.85 (± 2.6)	14.60 (± 3.3)	12.41 (± 7.2)	76.31 (± 9.9)	164 (100%)	33 (20.1%)
BP1 diagnosis validated WCC mean (s.d.)	118 (42%)	14.58 (± 3.2)	15.42 (± 3.6)	13.64 (± 3.2)	13.73 (± 3.5)	8.31 (± 7.4)	65.68 (± 6.6)	102 (81%)	23 (19.5%)
BP1 diagnosis NV not validated mean (s.d.)	27 (8.7% of 310)	13.89 (± 3.5)	15.19 (± 4.8)	12.96 (± 2.9)	9.63 (± 6.2)	7.22 (± 6.7)	58.89 (± 10.1)	16** (60%)	10** (37%)

WOR = Validated without clinician conference; WCC = Validated with clinician conference

Table 2: MADRS_{SBR} and MADRS_{COMP} Comparisons by Diagnostic Validation Status

Data	n	Baseline MADRS mean (s.d)		Δ MADRS Baseline - LOCF		Difference, Δ MADRS _{SBR} - MADRS _{COMP} Baseline - LOCF
		SBR	COMP	SBR	COMP	
All subject randomized mean (s.d.)	283	28.75 (± 6.6)	28.88 (± 9.7)	11.39 (± 10.8)	10.33 (± 12.9)	6.36 (± 5.6)
BP1 diagnosis validated WOR mean (s.d.)	164 (58%)	28.70 (± 6.7)	29.75 (± 9.1)	11.28 (± 10.6)	11.22 (± 12.5)	5.71 (± 5.1)
BP1 diagnosis validated WCC mean (s.d.)	118 (42%)	28.83 (± 6.3)	27.67 (± 10.4)	11.55 (± 11.2)	9.09 (± 13.3)	7.27* (± 6.1)

* P < 0.025 WOR vs WCC

Conclusions

1. Subjects meeting criteria for enrollment without review based on the computer-administered assessment scored higher on the BPx, than those enrolled after consensus conference with site based clinician.
2. Subjects excluded by the diagnostic validation procedures had a significantly higher rate of confounders, and a lower rate of having 3 BPx dimensions scored ≥ 15.
3. The difference between change scores on MADRS_{SBR} and MADRS_{comp} were significantly larger for subjects enrolled after consensus conference with site based clinician than for subjects meeting criteria for enrollment without review.
4. The Computer Administered-BPx may be a useful tool for qualifying subjects for enrollment in randomized clinical trials.

Reference: Sachs, GS, Acta Psychiatr Scand Suppl 2004 : (422);7-17

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