Calibrating the Optimized Pediatric PANSS10 Short Form in Three Independent Clinical Trials

Submitter Josh Langfus

Affiliation University of North Carolina at Chapel Hill

SUBMISSION DETAILS

I agree to provide poster pdf for attendee download. Yes

Poster PDF for download <blank>

Methodological Issue Being Addressed The relative lack of pediatric-specific scales for psychopharmacology trials poses significant challenges for ensuring valid and reliable assessment of intervention efficacy. The adult Positive and Negative Syndrome Scale (PANSS) is the most-used primary efficacy measure in pediatric schizophrenia trials; however, the original 30-item scale has significant limitations. It is a long and complex measure, requiring highly trained raters to reliably integrate information from caregivers, youth, and their own observations. To address these concerns, our group has developed a 10-item optimized PANSS (the PANSS10) that retains the content coverage of the original measure, achieves excellent reliability and validity in a pediatric population, and realizes a significant reduction in administration length. Here we assess whether scores on the PANSS10 are well-calibrated compared to scores on the 30-item PANSS and examine consistency between the original and optimized version at clinical trial entry criteria scores.

Introduction We report the calibration of the PANSS10 versus the 30-item PANSS in data from three clinical trials and also show that PANSS10 scores separate active treatment from placebo.

Methods Secondary analyses included data from three registered, masked, multi-arm, multi-site, pediatric schizophrenia trials[1–3]; one had a placebo arm[2]. In each study, patients were administered the 30-item PANSS weekly. Bland-Altman analyses examined the calibration of the extracted PANSS10 items' scores versus the 30-item PANSS at baseline, probing the difference between two as a function of their average. This approach can reveal whether the PANSS10 differs on average from the 30-item PANSS as well as evidence of score-dependent bias. We also examined expected differences between PANSS10 and 30-item PANSS scores at study inclusion criteria (equivalent to 30-item PANSS total scores of 60 and 120). We used item averages instead of sum scores to enable comparisons across forms of different lengths. Finally, in the trial with a placebo arm, we replicated ANCOVA analyses showing treatment separation therefrom.

Results Bland-Altman results across all samples showed a consistent pattern of calibration for the PANSS10. On average, scores on the PANSS10 were higher by .0006 average points (max=0.095, min=-0.14), equivalent to .0018 points on (max=2.9, min=-4.2) the 30-item PANSS, indicating very small overall bias. In terms of score-dependent bias, there were small but statistically significant effects suggesting that the PANSS10 is more sensitive than the 30-item PANSS. At study inclusion thresholds, the average PANSS10 difference from the 30-item PANSS was 0.18 at the 60-point threshold (max=2.79, min=-1.3) and 6.6 points at the 120-point threshold (max=10.1, min=3.4).

Replicating analyses for the trial comparing 3 doses of Paliperidone ER to placebo, we found a significant change from baseline in the Medium Dose group for the PANSS10 (B=-0.2661, p=.02) – cf. the 30-item PANSS (B=-0.2577, p=.01).

Conclusion The results of this post-hoc analysis suggest that the optimized pediatric PANSS10 is well-calibrated compared to the original PANSS at study inclusion thresholds and just as sensitive in detecting treatment efficacy. This supports the use of the optimized form as an inclusion criterion assessment and efficacy measure in clinical trials.

Co-Authors

* Presenting Author

First Name	Last Name	Affiliation
Josh *	Langfus *	University of North Carolina at Chapel Hill
Joan	Busner	Signant Health, Virginia Commonwealth University
David	Daniel	Signant Health
Eric	Youngstrom	Institute of Mental and Behavioral Health, Nationwide Children's Hospital and The Ohio State University; Helping Give Away Psychological Science
Robert	Findling	Virginia Commonwealth University

Keywords

Keywords
PANSS
Schizophrenia
Assessment
Clinical Trials
Pediatric

Guidelines I have read and understand the Poster Guidelines

Disclosures This study, carried out under YODA Project 2020-4528, used data obtained from the Yale University Open Data Access Project, which has an agreement with JANSSEN RESEARCH & DEVELOPMENT, L.L.C.. The interpretation and reporting of research using this data are solely the responsibility of the authors and do not necessarily represent the official views of the Yale

University Open Data Access Project or JANSSEN RESEARCH & DEVELOPMENT, L.L.C.

Mr. Langfus has no potential conflicts of interests to disclose. Dr. Findling receives or has received research support, acted as a consultant and/or has received honoraria from Abbvie, Acadia, Adamas, Afecta, Ajna, Akili, Alkermes, American Academy of Child & Adolescent Psychiatry, American Psychiatric Press, Arbor, BioXcel, Idorsia, Iqvia, Karuna, Lundbeck, Merck, MJH Life Sciences, Neurim, NIH, Novartis, Otsuka, Oxford University Press, PaxMedica, PCORI, Pfizer, Physicians' Postgraduate Press, Radius, Receptor Life Sciences, Sage, Signant Health, Sumitomo Pharma, Sunovion, Supernus Pharmaceuticals, Syneos, Takeda, Tris, and Viatris. Dr. Busner is a full time employee of Signant Health. Dr. Daniel serves as an Executive Advisor to Signant Health and is President of Bioniche Global Development, LLC. Dr. Youngstrom has received royalties from the American Psychological Association and Guilford Press, consulted with Signant Health about psychological assessment, and received funding from NIMH. He is the founder and Executive Director of Helping Give Away Psychological Science (HGAPS.org).

Related Tables and Supporting Materials ISCTM 2024 Poster References.docx