Using PANSS negative subscale to select patients less likely to relapse

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What is the Methodological Issue Being Addressed? Identifying baseline symptom criteria that predict relapse is important for both schizophrenia trial design and clinical practice. Depending on a trial's objective, enrollment criteria should either select patients at sufficient relapse risk to detect a relapse-prevention effect or, in studies targeting negative symptoms or cognition, select patients at lower relapse risk so psychotic relapse does not obscure treatment effects. Symptom profile at entry into double-blind treatment may therefore provide prognostic information for enrichment or stratification. Clarifying which baseline symptoms predict time to relapse could refine eligibility criteria and improve trial efficiency.

Introduction We aimed to determine whether baseline psychopathology, measured on entry into double-blind treatment, predicts survival time to relapse among patients randomized to placebo in antipsychotic relapse-prevention studies. Specifically, we examined the independent associations of positive, negative, and general psychopathology symptoms with relapse risk.

Methods We combined individual-patient data on participants randomized to placebo (n=557) from five placebo-controlled relapse-prevention studies of antipsychotic medications, accessed through the Vivli and YODA data-sharing platforms. The association between baseline symptoms and survival time to relapse was modelled using Cox proportional-hazards regression. Predictors entered as continuous variables were the Positive and Negative Syndrome Scale (PANSS) Positive, Negative, and General Psychopathology subscale scores at baseline, together with age and sex. Relapse was defined as a 12-point increase on the PANSS total score.

Results Higher baseline positive symptoms were associated with an increased risk of relapse, indicating shorter survival time to relapse with greater positive-symptom severity at entry (HR=1.06, p=.05). In contrast, higher baseline negative symptoms were associated with a decreased risk of relapse (HR=0.94, p=0.01), indicating longer survival time. Age and sex were retained as covariates in the model.

Conclusion Among placebo-treated patients, the baseline symptom profile predicted relapse risk in opposing directions: severity of positive symptoms conferred higher risk, whereas severity of negative symptoms appeared to delay or protect against relapse. These findings suggest that baseline PANSS positive and negative subscale scores could be used to refine eligibility and enrichment criteria in trials—favoring inclusion of patients with residual positive symptoms—to increase the likelihood of observing relapse and improve trial efficiency and the opposite for negative symptoms and cognition trials. Prospective validation is warranted.

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Keywords

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Disclosures Jonathan Rabinowitz, Michael Davidson and Remy Luthringer are employed by Minerva Neurosciences and share or option holders. Helene Speyer has no disclosures.

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