Incidence of Antipsychotic-Associated Side Effects: Impact of Clinician vs. Patient Ratings and Absolute vs. Change Scores

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The Methodological Question Being Addressed: Which of (1) clinician or patient rating, and which of (2) change or absolute score definition is superior for the detection of antipsychotic-associated side effects?
Introduction (Aims): There are two means by which treatment-related adverse events, reflecting severity, can be reported. One is "absolute score", where side effects are defined by a certain cut-off point (e.g., a score of more than mild). The second option represents "change in score", where side effects are defined as a higher score on a scale when compared to baseline. The absolute score definition is commonly used for treatment-related adverse events in randomized controlled trials on antipsychotics in schizophrenia, whereas the change score definition is less commonly employed. To our knowledge, however, there have been no studies concurrently comparing the two definitions. The present study aimed to compare (1) detection rates of antipsychotic-associated side effects between clinician and patient ratings, and (2) concurrent detection rates of side effects for clinicians and patients using the change and absolute score definitions.
Methods: Data from phase 1 of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE, N=1,460) were analyzed. In this trial eighteen adverse events were systematically and concurrently assessed by clinicians and patients using a 4-point severity scale ranging from 0 (Absent) to 3 (Severe). The incidence of antipsychotic-associated side effects was calculated according to two definitions: change (i.e., higher score on the scale versus baseline) and absolute score (a score of 2 or 3 on the scale). In addition, patient and clinician concurrent detection rates were examined.
Results: The differences in incidence of antipsychotic-associated side effects between clinician and patient ratings were as small as 5.7% across the two definitions. The incidence of all side effects across clinician and patient ratings was approximately two times higher when using the change vs. absolute score definition. Among the side effects detected by patients, 11 side effects were identified more frequently by clinicians with 14.3%-30.2% differences when using the change vs. absolute score definition. Conversely, there was no difference $\geq$10% in patient or clinician concurrent detection rate on any item when using the absolute vs. change score definition.
Conclusions: Our findings suggest that patient ratings are in line with clinician ratings, and that the change score definition may be superior for the assessment of antipsychotic-associated side effects in clinical studies.

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