



Social functioning and quality of life as measures of effectiveness in the treatment of schizophrenia

JUN SOO KWON, JUNG-SEOK CHOI

Department of Psychiatry, Seoul National University
College of Medicine, 101 Daehak-no, Chongno-gu,
Seoul, Korea

From the perspective of health care practitioners, the most useful clinical trials are those that assess the effectiveness of a drug, that is, determine how well the drug works under conditions of actual clinical practice. Clinical trials designed to determine effectiveness should use outcome measures that have the greatest clinical significance for practitioners, with the goal of maximizing generalizability and addressing practical questions about the risks, benefits, and costs of an intervention in routine clinical practice (1). Here we would like to emphasize the importance of social functioning and quality of life (QOL) as outcome variables in clinical trials in patients with schizophrenia.

Recent research has shown that atypical antipsychotics improve QOL in patients with schizophrenia (2). However, studies that incorporate QOL in the assessment of long-term effectiveness are limited and inconsistent. Fleischhacker and Goodwin summarize the results

of the Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS) (3), which employed the Quality of Life Scale (4) as the primary outcome measure for evaluating the effectiveness of treatment. The CUtLASS found no disadvantage of first-generation antipsychotics in comparison to non-clozapine second-generation antipsychotics. Similarly, in a double-blind, randomized controlled trial, Rosenheck et al (5) reported that measures of effectiveness demonstrated no advantage for olanzapine compared with haloperidol in overall QOL. In contrast, a naturalistic observational study on patients with schizophrenia undergoing usual care indicated that ziprasidone treatment resulted in improved satisfaction with general activity as measured by the Quality of Life Enjoyment and Satisfaction Questionnaire (6).

When measuring QOL in patients taking antipsychotics, it is important to acknowledge that a variety of factors may influence QOL outcomes: these include side effects and daily dosage of the antipsychotic, depressive and negative symptoms, duration of treatment, and subjective tolerability. In a natural-

istic comparative study, Ritsner et al (7) found no significant difference in general QOL between patients using atypical vs. typical antipsychotics. However, after adjusting for daily dosage, duration of treatment, and subjective tolerability, QOL measures indicated that atypical antipsychotics (olanzapine and risperidone) were superior to typical ones.

Some randomized controlled trials of antipsychotics have used a social functioning scale as an outcome measure, such as the Social and Occupational Functioning Assessment Scale (8,9), the Medical Outcomes Study Short-Form 36 Health Survey (10), or the Personal and Social Performance scale (PSP) (11). However, these trials have largely involved short-term interventions, limiting their ability to detect meaningful changes in the social functioning of patients. We are currently undertaking a randomized, controlled, open-label clinical trial in Korea to evaluate improvement in social functioning in patients with schizophrenia or schizoaffective disorder. The study compares long-acting injectable vs. oral risperidone using a hybrid model to assess both efficacy and effectiveness after one year of treatment. Primary outcome measures in this study are the PSP and the Social Functioning Scale.

The scales used to assess social functioning and QOL in clinical trials must be appropriate to the study population and the clinical condition, and should measure several dimensions of social functioning and QOL. Furthermore, we need to develop scales that measure functioning independently from symptoms, and that are sensitive to changes over the course of the illness.

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