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Validation of the Investigator's Assessment Questionnaire, a new clinical tool for relative assessment of response to antipsychotics in patients with schizophrenia and schizoaffective disorder

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Abstract

The success of long-term therapy in schizophrenia is contingent upon real-world effectiveness or improvements in several domains, including efficacy, safety and tolerability. This report describes the Investigator's Assessment Questionnaire (IAQ), a new 10-item instrument designed to assess relative effectiveness (efficacy, safety and tolerability) of antipsychotic medications in patients with schizophrenia or schizoaffective disorder. To measure content validity, 300 psychiatrists rated the importance of

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the IAQ items. Efficacy (i.e., positive and negative symptoms) was considered most important, but importance scores relative to the mean ranged only from 0.87 to 1.18, suggesting similar importance of the items. Cronbach's coefficient α values showed that the items were internally consistent. Factor analyses indicated that all IAQ items belong to a single domain. Data from the US Broad Effectiveness Trial of Aripiprazole were used for construct validation. Total IAQ score correlated significantly with time to treatment discontinuation ($r = -0.50$), Clinical Global Impressions-Improvement (CGI-I) score ($r = 0.76$) and medication preference of patients ($r = 0.71$) or caregivers ($r = 0.70$). A one-unit decrease in IAQ score corresponded to an additional 1.35 days in the study and a decrease in CGI-I of 0.21 units. These results provide initial validation of the IAQ as a tool for evaluating antipsychotic response in patients with schizophrenia or schizoaffective disorder.

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1. Introduction

While the concept of medication efficacy relates to treatment under ideal conditions, long-term effectiveness is concerned with treatments that demonstrate improvement in several domains (i.e., efficacy, safety and tolerability) under the conditions of routine care (Jaffe and Levine, 2003). Efficacy and safety are deemed predominant. However, since discontinuation is primarily motivated by side effects, tolerability is an equally important component of real-world effectiveness (Collaborative Working Group on Clinical Trial Evaluations, 1998; Freedman, 2003; Nasrallah et al., 2005).

In the treatment of patients with schizophrenia, a validated measure capturing the dimensions of treatment effectiveness (safety, tolerability and relief of symptoms) could be a valuable clinical assessment tool for making meaningful comparisons between existing and novel therapies in a real-world setting. Although many scales have been developed for assessment of medication efficacy [e.g., the Positive and Negative Symptom Scale (PANSS) (Kay et al., 1987) and the Brief Psychiatric Rating Scale (BPRS) (Overall and Gorham, 1962)], most scales do not consider safety or tolerability. One commonly used measure of outcome, the Clinical Global Impressions (CGI) scale (Guy, 1976), allows the physician to include tolerability issues in an overall ranking of patient outcome, but does not specifically rate contributions of tolerability and symptom improvement. No instruments expressly designed to assess overall treatment effectiveness in schizophrenia or schizoaffective disorder were identified.

The Investigator's Assessment Questionnaire (IAQ) was developed to be a simple, easily used

tool that simultaneously evaluates all health concerns associated with antipsychotic use in patients with schizophrenia or schizoaffective disorder. It is a clinician-rated scale that consists of 10 items assessing components of effectiveness including efficacy, tolerability and common side effects of antipsychotics (see Appendix A). The physician is asked to compare the current medication with previous antipsychotic medicine(s) prescribed for the patient's illness, using a five-point Likert scale. Clinicians received assessment instructions that provided descriptions of each item and appropriate anchors for symptom ratings.

The IAQ was used as a secondary endpoint in the recent US Broad Effectiveness Trial with Aripiprazole (US BETA) (Tandon et al., submitted for publication), an open-label naturalistic study that compared the effectiveness of aripiprazole with that of other antipsychotic medications in the management of schizophrenia or schizoaffective disorder. However, no validation studies of the IAQ have been published. Two important components of an instrument's performance are construct validity, which is the correlation of the instrument with conceptually related variables, and content validity, which is the extent to which the instrument represents the domain it is intended to measure (McDowell and Newell, 1996; Busch, 2002). In addition, each domain of the instrument should measure one basic concept (in this case, antipsychotic effectiveness) and should correlate with other measures of this domain. Lastly, within each domain, the instrument must demonstrate internal consistency. That is, the response to one item should be closely related to responses on the other items.

The objective of this work was to use data from the US BETA study and a subsequent survey of psychia-

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