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Research report

The Bipolar Comprehensive Outcomes Study (BCOS): Baseline findings of an Australian cohort study

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Abstract

Background: The Bipolar Comprehensive Outcomes Study (BCOS) is a 2-year, observational study of participants with bipolar I or schizoaffective disorder examining clinical, functional, and economic outcomes associated with naturalistic treatment.
Methods: Participants prescribed mood stabilisers were assessed using various measures, including the Young Mania Rating Scale (YMRS), 21-item Hamilton Depression Rating scale ($HAMD_{21}$), Clinical Global Impressions-Bipolar Version Severity of Illness scale (CGI-BP), and the EuroQol instrument (EQ-5D).
Results: 240 participants were recruited from two sites. On average, participants were 41.8±12.7 years of age (mean±SD), 58.3% were female, and 73.3% had a diagnosis of bipolar I disorder at study entry. The majority of participants were moderately ill, with an average CGI-BP Overall score of 3.8±1.3. Most participants had subthreshold mania and depression symptoms, indicated by $HAMD_{21}$ Total 13.4±8.6, CGI-BP Depression 3.2±1.3, YMRS Total 8.2±8.5 and CGI-BP Mania 3.0±1.6 average scores. For bipolar participants, 94.6% of hospitalisations for psychiatric treatment in the past 3 months were single admissions (vs. 65.2% for schizoaffective participants, $p=.002$). Bipolar participants rated their overall health state higher (EQ-5D scores: 68.2±18.8 vs. 61.6±22.7, $p=.023$), had a higher mean weekly wage ($500–$999, 21.3% vs. 6.3%), lower unemployment (22.2% vs. 48.4%), and higher romantic relationship status (47.1% vs. 26.6%).
Limitations: The observational design and small sample size may have limited the causal relationships and generalisability within the current findings.
Conclusions: Participants were characterised by social and occupational dysfunction at entry, but schizoaffective participants appeared to be more severely affected. Effective treatment is required to address both clinical and functional impairment.

Keywords: Bipolar disorder; Schizoaffective disorder; Mood stabilizers; Non-interventional; Observational study; Naturalistic design

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1. Introduction

Bipolar I and schizoaffective disorders are debilitating, long-term, and recurrent conditions, respectively affecting approximately 0.3–1.5% and less than 0.5% of the worldwide population (Weissman et al., 1996). These disorders have a significantly adverse impact on quality of life and are often associated with considerable personal, social, and societal costs (Bauer et al., 2001). Furthermore, people with bipolar I disorder are 15 times more likely to commit suicide (Harris and Barraclough, 1997) and two times more likely to divorce (Coryell et al., 1993) compared with the general population. Bipolar I disorder is a mood disorder characterised by acute, affective episodes which may be manic, depressed, or mixed, with full or partial inter-episode remission. Schizoaffective disorder has overlapping phenomenology with bipolar disorder in that it presents with symptoms that meet criteria for a mood episode, but is additionally accompanied by delusions, hallucinations, and/or significant disturbed thinking (American Psychiatric Association, 2000). In both disorders, diminished life satisfaction persists even during periods of sustained euthymia (Goldberg and Harrow, 2005). Thus, treatment of bipolar I and schizoaffective disorders should ideally aim to restore patients to full general health, as well as satisfactory quality of life.

Adequate management of manic and depressive symptoms is complicated, but can be achieved through long-term treatment with mood stabilisers as monotherapy, or in combination with antidepressant or antipsychotic agents (Malhi and Berk, 2002). Atypical antipsychotics are increasingly prescribed for patients with bipolar I and schizoaffective disorders, as they provide better control over acute manic symptoms and are better tolerated than their typical counterparts (Schillevoort et al., 2001). However, few studies have assessed atypical antipsychotics in the long-term treatment of bipolar and schizoaffective disorders, particularly in regard to quality of life, long-term medication adherence rates, long-term clinical outcomes, service use and pharmacoeconomic issues.

The chronic and usually progressive courses of bipolar and schizoaffective disorders require comprehensive and flexible assessment methods. Patients with these illnesses are often excluded from randomised clinical trials (RCTs), as their limited awareness of their condition can produce difficulties with consent (Gomez et al., 2000). These patients are also likely to have concomitant psychiatric disorders, which are also excluded from many RCTs (Collaborative Working Group on Clinical Trial Evaluation, 1998). By comparison, observational studies typically have fewer inclusion and exclusion criteria than RCTs, providing the option of more naturalistic studies, using a broader range of participants and for longer time periods. However, many previous observational studies of participants with bipolar I and schizoaffective disorders have been of limited size, duration, and scope. Therefore, prospective observational studies are necessary to evaluate the clinical, functional, and economic impact of antipsychotic treatments in a "real-life" (naturalistic) context. Various observational studies using bipolar I participants are in progress or have recently been completed, such as the European Mania in Bipolar Longitudinal Evaluation of Medication (EMBLEM, Goetz et al., 2007), Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD, Kogan et al., 2004), Texas Medication Algorithm Project (TMAP, Rush et al., 2003) and the VA Cooperative Study (Bauer et al., 2001). The Bipolar Comprehensive Outcomes Study (BCOS) has been initiated to provide a more comprehensive assessment of this therapeutic area using a naturalistic design.

BCOS is a prospective, longitudinal (2-year), observational study of health outcomes associated with mood stabiliser treatment in participants with bipolar I and schizoaffective disorders. The primary objective of BCOS is to compare the proportion of participants who experience symptomatic relapse following treatment with various mood stabilisers in oral form. Secondary objectives include comparing time to relapse and remission, changes in quality of life scales, as well as direct and indirect health care costs. BCOS is the first prospective observational study evaluating the actual care of participants with bipolar I and schizoaffective disorders to be conducted in Australia, and is also the first study to measure the costs of health care in this population. The aims of this paper are to provide an overview of the study design as well as the baseline characteristics and clinical status of BCOS participants.

2. Methods

2.1. Study population

Participants were considered eligible for study entry if they provided written consent, met the study inclusion criteria and their diagnosis was confirmed by the Mini-International Neuropsychiatric Review, Version 5 (MINI, Sheehan et al., 1998). The study inclusion criteria were: a primary diagnosis of bipolar I disorder (manic, mixed or depressed episode) or schizoaffective disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision (DSM-IV-TR,