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Original article

A cluster-analytical approach toward real-world outcome in outpatients with stable schizophrenia



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ABSTRACT

Background: This study aims to empirically identify profiles of functioning, and the correlates of those profiles in a sample of patients with stable schizophrenia in a real-world setting. The second aim was to assess factors associated with best profile membership.

Methods: Three hundred and twenty-three outpatients were enrolled in a cross-sectional study. A twostep cluster analysis was used to define groups of patients by using baseline values for the Heinrichs-Carpenter Quality of Life Scale (QLS) total score. Logistic regression was used to construct models of class membership.

Results: Our study identified three distinct clusters: 50.4% of patients were classified in the "moderate" cluster, 27.9% in the "poor" cluster, 21.7% in the "good" cluster. Membership in the "good" cluster versus the "poor" cluster was characterized by less severe negative (OR = .832) and depressive symptoms (OR = .848), being employed (OR = 2.414), having a long-term relationship (OR = .256), and treatment with second-generation antipsychotics (SGAs) (OR = 3.831). Nagelkerke R² for this model was .777. Conclusions: Understanding which factors are associated with better outcomes may direct specific and additional therapeutic interventions, such as treatment with SGAs and supported employment, in order to enhance benefits for patients, as well as to improve the delivery of care in the community.

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1. Introduction

Despite innovations in therapeutic and psychosocial interventions, schizophrenia remains a highly disabling illness, affecting multiple areas of everyday functioning, such as social, vocational and residential domains, even during symptom remission [1].

Heterogeneity of response and outcome is common among patients with schizophrenia [2]. It has been suggested that the definition of "outcome" in schizophrenia may need to be broadened beyond symptom severity to also include quality of life (QOL), subjective well-being, health status, use of healthcare services, and measures of the patients' level of functioning [3–5].

In particular, QOL measurements are increasingly considered to be an important way of evaluating the treatments and care provided to patients with schizophrenia [6,7]. Using QOL measures may provide clinicians with information regarding the general health

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status of their patients that might otherwise go unrecognized thereby improving patient satisfaction and health outcomes [8].

At present, the health-related quality of life instrument used most frequently in schizophrenia research is the Heinrichs-Carpenter Quality of Life Scale (QLS) [9], a clinician-rated scale of patients' social, occupational, and psychological functioning.

QLS is one of the 6 functional outcome scales selected in the Validation of Everyday Outcomes (VALERO) [10,11].

Matching an individual patient to a subgroup of patients with a similar functioning profile may help clinicians tailor treatment alternatives that best meet individual patients' long-term needs and facilitate the translation of the evaluation of the patient into terms that can be easily communicated to the patients and their families [12–14]. The practical implications of this process in clinical routine care could be the identification of very disabled patients that need more intensive special rehabilitation in residential facilities or through home visits [15].

A few previous attempts have been made to classify schizophrenia patient functioning according to severity [4,16], but none have used an empirically driven approach that focused only on functioning. While Lipkovich et al. [4] created a data-driven classification that combined symptomatology and functioning

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using the QLS and the Positive and Negative Syndrome Scale [17], Stahl et al. [16] used theoretically based criteria to classify patients using the OLS.

Ascher-Svanum et al. [12] used an empirical approach to identify and validate the classification of patients with schizophrenia in "good", "moderate" or "poor" functioning groups based on the assessment of functional measures, the QLS, the 36-item Short-Form Health Survey (SF-36) [18] Mental Component Summary Score, and a productivity measure.

In the current study, we sought to explore whether we could use the QLS to identify different profiles of functioning in a sample of patients with stable schizophrenia in a real-world setting and to determine whether participants with these different profiles have different levels of clinical severity, depression, insight, and different associations with functional variables including the "occupational/vocational" status and "social relationships", assigned treatment or socio-demographic variables. Further aim was to assess factors associated with cluster affiliation.

In line with previous research, we predicted that patients with lower psychotic symptomatology severity and with less severe depressive symptoms [19] would exhibit better functional level. Moreover, given work linking first-generation antipsychotics (FGAs) compared to second-generation ones (SGAs) [20] and poorer insight to poorer social [21–23] we anticipated that patients receiving FGAs, compared to SGAs, and with poorer insight would have poorer social functioning.

2. Materials and methods

2.1. Participants

The study has been conducted at the Department of Neuroscience, University of Turin, Struttura Semplice di Coordinamento a Valenza Dipartimentale (SSCVD), Department of Mental Health ASL TO1- A.O.U. Città della Salute e della Scienza di Torino, Italy, during the period between July 2008 and July 2011.

Patients were initially evaluated by a clinician-psychiatrist, and if they met Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) [24], they were seen subsequently by our research team (C.M., M.S.). Of these, a sample of consecutive subjects routinely treated in a community setting and fulfilling the following criteria were included in the study:

- men and women in the 18-65 years age group;
- diagnosis of schizophrenia according to the DSM-IV-TR, confirmed by two expert clinicians (C.M., M.S.) using the Structured Clinical Interview for DSM-IV disorders (SCID) [25]. Subjects were excluded if they had a current disorder other than schizophrenia on Axis I of the DSM-IV-TR, a current or past codiagnosis of autistic disorder or another pervasive developmental disorder, a history of severe head injury (coma ≥ 48 hours) and a diagnosis of a psychiatric disorder due to a general medical condition;
- patients with stable schizophrenia (no increase in symptomatology/no change in antipsychotic regimen for at least 6 months). The choice of antipsychotic drug prescribed and dosage were left to the discretion of the treating physicians.

Patients were evaluated using a semistructured interview to assess demographic features. All patients were submitted to standard care (Standard of Care-SoC), provided in community mental health centers in Italy, including pharmacological treatment as recommended by the guidelines [26,27], clinical monitoring at least on a monthly basis, home care when required, and psychological interventions tailored to patient's needs.

Written informed consent was obtained from all subjects after a complete description of the study. The study was carried out in accordance with Declaration of Helsinki 1995 (as revised in Edinburgh 2000) and was approved by the Local Research Ethics Committee (LREC).

2.2. Psychiatric assessment

Overall severity of illness was rated using the Clinical Global Impression-Severity scale, CGI-S [28].

Current levels of psychopathological symptoms were assessed using the Positive and Negative Syndrome Scale (PANSS), which includes Positive Symptoms (PANSS-P), Negative Symptoms (PANSS-N), and General Psychopathology (PANSS-G) subscales [29]. Depressive symptoms were evaluated using the Calgary Depression Scale for Schizophrenia (CDSS) [30].

To quantify patients' global functioning, we used the Global Assessment of Functioning scale (GAF) [31]. For the purpose of our study, raters were instructed to use the GAF to measure only psychosocial functioning in the month before rating [32–34].

We used the Scale for the Assessment of Unawareness of Mental Disorder, SUMD, to assess insight [35]. For the purposes of this study, we used three items of the SUMD:

- awareness of mental illness (SUMD 1);
- awareness of the need for treatment (SUMD 2);
- awareness of the social consequences of disorder (SUMD 3).

Real-world functioning was assessed using the QLS [9]. It includes 21 items rated by the clinician on 7-point scales in 4 domains: interpersonal relations and social network (IRSN), instrumental role functioning (IRF), intrapsychic foundations (IF), and common objects and activities (COA). We chose to use only QLS total score as clustering indicator because the primary endpoint of many psychopharmacological studies of treatments for schizophrenia was change from baseline to endpoint on the QLS total score [36–42]. Moreover, the QLS total score measures effects beyond functioning in patients with schizophrenia; it also assesses the richness of personal experience, the quality of interpersonal relations, and productivity in occupational roles.

2.3. Functional milestones achievements

Functional milestones were defined in line with Harvey et al. [43] and included social outcomes such as ever being married, currently or previously engaged, which we categorized as current or former relationship vs none. Vocational outcome was categorized as employed vs not employed.

We collected information from patients, informants, and medical records on the achievement of functional milestones. In cases of uncertainty, a consensus was obtained through discussion with the principal investigator (P.R.) and the interviewer.

Clinical ratings were done by research psychiatrists who were well-trained and experienced in the rating scales. In order to maintain high inter-rater reliability and to prevent rater drift, raters met at least once a month for training and reliability retesting.

2.4. Statistical analysis

Statistical analyses were performed using the software Statistical Package for the Social Sciences, SPSS, version 21 for Windows (SPSS, Chicago, IL, USA).

Data are presented as means \pm standard deviations (SD) or percentages (%), unless stated otherwise.

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