

Introduction: Numerous authors have proposed “responder” criteria for patients with schizophrenia treated with antipsychotic monotherapy (Leucht, S et al 2009; 438 7-14; Suzuki T et al, 2012; 197 1-6; Kane J et al 1988; 45 789-96). These suggest reductions greater than 30% on the PANSS total score, improvements of 1 category or more on the CGI-S, or CGI-C ratings of very much, much or minimally improved, as well as various permutations and combinations of the above. No study has met the responder definition of Kane et al in the last 30 years in monotherapy studies in TRS patients. However, a widely accepted definition of response in patients with TRS treated with a putative antipsychotic added to their background antipsychotic monotherapy, is not currently available, and more work is needed on this highly relevant topic (Suzuki, T et al 2011; 133 1-3).

Objectives: Combining PANSS (30-item anchored scale), CGI-C and CGI-S (both 7-point Likert scales), three of the most accepted scales to evaluate patients with schizophrenia worldwide, we propose two different definitions of response in TRS population

Methods: Study 014 was designed to evaluate the safety and preliminary evidence of efficacy of evenamide, a NCE added to an antipsychotic monotherapy, given orally at 3 fixed doses (7.5, 15 and 30 mg bid) in patients with TRS not adequately responding to a therapeutic dose of an AP. Assessment of efficacy was based on changes of the PANSS and CGI-S/C. We reviewed the efficacy data of the first 100 patients at various timepoints up to 30 weeks.

Results: We assessed multiple definitions involving all the three measures (PANSS, CGI-S, and CGI-C) to determine one that would define a “responder” by categories that may be clinically meaningful. Review of the data indicated two definitions of responders based on the different combinations of the individual measures. “Full responder” was defined as PANSS total score improvement $\geq 20\%$; CGI-C at least much improved (i.e. 1,2); CGI-S at least one point improvement and reaching at least mildly ill (i.e. a score of at least 3 or less). “Partial responder” was defined as PANSS total score improvement $\geq 15\%$; CGI-C rated as any improvement (i.e. 1,2,3); CGI-S at least one point improvement. These two categories are alternatively true and patients not fulfilling the criteria for the above categories are considered as “non-responders”. Further descriptive analysis will be presented.

Conclusions: These definitions may change the selection of compounds used as add-on therapy for TRS patients as well as the study designs to evaluate them.

Disclosure of Interest: None Declared

EPP1057

Biomarkers as Proxies for Cognitive Reserve: the role of high density lipoprotein cholesterol in first episode of psychosis

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Introduction: The proxies used to compose cognitive reserve (CR) in first episode of psychosis (FEP) have varied in the literature.

The development of FEP is linked to the peripheral pathways of the central nervous system (Leboyer *et al.* Psychopharmacology 2016; 233(9) 1651-60) Furthermore, schizophrenia has been linked to the metabolic system, indicating that alterations in the levels of biological parameters, in particular high-density lipoproteins (HDL) (Gjerde *et al.* Eur Arch Psychiatry Clin Neurosci 2020; 270 (1) 49-58) cause worse global functioning and cognitive impairment (Adamowicz *et al.* J Clin Med 2020; 9(2) 537). Despite this knowledge, no research has considered the introduction of biomarkers as proxies for CR.

Objectives: The present study aimed to create a quantifiable and objective CR index that adjusts for the multifactorial nature of FEP.

Methods: We included 668 patients who had FEP and 217 healthy controls who were assessed for sociodemographic information and levels of biological parameters: waist circumference, hypertension and levels of HDL, triglycerides and glucose. The main analyses were multiple regression analysis, principal component analysis (PCA) and exploratory factor analysis (EFA).

Results: Regression analyses showed that HDL was the top performing biological parameter in a model containing years of education and unemployment ($F=11.80$; $p<0.001$) while also outperforming other parameters in a correlation analysis with a composite of the same variables ($r=0.21$; $p<0.001$). In EFA analyses combining all possible components, we found that the most optimal proxies for the composition of biological CR were years of education and HDL. The results using PCA indicated that biological CR would have a greater explanatory power for the phenomenon than classical CR, increasing 7.27% of the explanation for FEP patients and 16.08% for healthy controls.

Conclusions: This article proposes an objective and quantifiable method to measure CR, taking into account endogenous and exogenous factors. This index, introducing biomarkers as proxies could provide a more accurate CR score for FEP patients.

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EPP1058

Positive and Negative Syndrome Scale (PANSS) predictors of hospitalization during home treatment on 1045 patients with schizophrenia in acute crisis

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Introduction: Several factors related to the risk of requiring psychiatric hospitalization have been described in patients diagnosed with schizophrenia treated with methods other than home treatment. With regard to the symptoms, high global illness severity and positive symptoms of schizophrenia have been most frequently

related to the risk of hospitalization in patients with schizophrenia. However, there are no studies describing which clinical factors increase the likelihood of being hospitalized while undergoing home follow-up.

Objectives: To determine which of the clinical factors assessed in the PANSS predict the risk of hospitalization in patients diagnosed with schizophrenia following a home treatment program.

Methods: All patients with schizophrenia who were visited by a home treatment team in Barcelona between January 2017 and December 2021 were included in the study. A comparative, bivariate analysis of each item of the PANSS and of the global results of each category was conducted on those who were hospitalized and those who were not hospitalized. Finally, a logistic regression of each category of the PANSS was done on both groups, controlling for other socio-demographic and clinical factors.

Results: A total of 1045 patients with schizophrenia were evaluated in this study. PANSS positive symptom subscale (PANSS-S), PANSS General Psychopathology, PANSS Excited Component and PANSS Global Score scored higher in patients who were finally hospitalized in a conventional acute treatment unit. Regarding the PANSS negative symptom subscale, no significant differences were found between the two groups.

In patients who required hospitalization, the scores of all the PANSS positive symptom subscale (PANSS-P) items and all items on the PANSS excited component (excitement, tension, hostility, uncooperativeness and poor impulse control) were significantly higher. Some items regarding general psychopathology (Somatic concern, anxiety, guilt feelings, tension, and mannerisms) were also significantly higher in the hospitalization group. Only 3 items—blunted affect, guilt feelings and motor retardation—scored significantly higher in patients who did not require hospitalization. In the logistic regression, only the global score of the PANSS-P reached statistical significance ($P = 0.001$).

Conclusions: Positive symptoms scored in the PANSS seem to be the most predictive factors of hospitalization regarding clinical symptoms in patients with Schizophrenia following home treatment. Other items regarding exciting symptoms and general psychopathology also showed as relevant regarding the risk of conventional hospitalization in those patients.

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EPP1059

Clinical Global Impression of Cariprazine in Negative Symptom Schizophrenia Patients: Comparison of clinical trial data vs. real-world evidence

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Introduction: There is an increasing need to understand the effectiveness of novel medications in real-world context since despite being the gold standard, double-blind trials have their own limitations as well. Clinical Global Impression is a simple tool for clinicians to assess the severity of an illness (CGI-Severity) as well as to rate how much the patient's disorder has improved or worsened

relative to baseline (CGI-Improvement). In this poster, cariprazine, a third-generation antipsychotic medication that was found to be effective in the treatment of negative symptoms in schizophrenia will be evaluated.

Objectives: To compare the effectiveness of cariprazine in clinical trial vs real-world setting via the CGI-S and CGI-I scales in negative symptom schizophrenia patients.

Methods: We compared the results of a clinical trial (Németh et al. Lancet 2017; 389:1103-13) and an observational study (Rancans et al. Int Clin Psychopharmacol. 2021;36(3):154-161). The latter was an open-label, flexible-dose, 16-week, observational study of cariprazine involving 116 outpatients in Latvia. Adult patients who have been diagnosed with schizophrenia, exhibited negative symptoms based on clinical judgement, were at least mildly ill according to the CGI-S scale and have not previously received cariprazine were eligible to take part in the study. Dosing of cariprazine was based on clinical judgement. The clinical trial was a randomized, double-blind, multi-centred, 26-week study with adults aged 18–65 years with long-term (>2 year), stable schizophrenia and predominant negative symptoms (>6 months). Patients were randomly assigned to monotherapy with cariprazine 4.5 mg/day or risperidone 4.0 mg/day.

Results: 116 patients on flexible dose cariprazine (observational study) were compared with 227 patients on cariprazine 4.5 mg/day and 229 on risperidone 4.0 mg/day (clinical trial). Baseline severity of illness as measured by the CGI-S was between moderately and markedly ill in all three groups. By the end of the 26-week trial, cariprazine reduced the CGI-S score significantly (LS Mean Change: -0.9, $p < 0.01$). In contrast, the risperidone group achieved only -0.7-point change from baseline. In the observational study, cariprazine also achieved significant change (-0.9, $p < 0.001$) but by week 16. In terms of improvement, patients on cariprazine improved minimally to much in both the clinical trial and real-world setting.

Conclusions: The effectiveness of cariprazine in clinical trial and real-world setting do not seem to differ as measured by the scales in negative symptom patients.

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EPP1060

Relationship between CAINS negative symptoms and cognition, psychosocial functioning and quality of life in patients with a first psychotic episode of schizophrenia

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