

Complejo Hospitalario Universitario de Vigo, Vigo, Spain ² Janssen-Cilag Spain, Madrid, Spain ³ Janssen Pharmaceutica, Beerse, Belgium ⁴ SGS Life Science Services, Wavre, Belgium ⁵ Johnson & Johnson Pharmaceutical Services, Toronto, ON, Canada ⁶ Johnson & Johnson Pharmaceutical Services, Raritan, NJ, USA

Objectives: Assess clinical and functioning treatment outcomes of risperidone long-acting injection (RLAI) versus oral antipsychotics for patients participating in the electronic Schizophrenia Treatment Adherence Registry (e-STAR) in Spain.

Methods: e-STAR is a 2-year, multi-national, prospective, observational study of patients with schizophrenia who were initiated on RLAI or an oral antipsychotic. Data were collected retrospectively (1-year) and prospectively every three months (2 years). Outcomes included clinical effectiveness measured by Clinical Global Impression of Illness Severity (CGI-S) and patient functioning assessed by Global Assessment of Functioning (GAF) scale. Clinical and functional outcomes are analyzed using a linear mixed model controlling for age, gender, disease duration, baseline hospitalization status and antipsychotic treatment patterns. Results presented are based on the complete e-STAR data from Spain.

Results: 1,622 patients (63.6% male, mean age 38.4±11.2 years) participated in e-STAR from Spain, 1,345 were initiated on RLAI and 277 on oral antipsychotics. RLAI treated patients had significantly longer disease duration (12.6±9.5 years vs. 10.9±9.7, $p<0.01$) than those treated with oral antipsychotics. During the 2-year study, clinical symptoms and functioning improved in both groups. As revealed by the mixed-model regression, RLAI patients, compared to oral patients, had significantly greater improvement on CGI-S scores (-1.10 vs. -0.88, $p<0.02$) and GAF scores (16.4 vs. 14.6, $p<0.03$). Baseline hospitalization status and disease duration were significant explanatory variables in the mixed model regression.

Conclusions: This 2-year, prospective, observational study showed that compared to oral antipsychotics, RLAI treatment was associated with greater improvement in clinical symptoms and functioning in patients with schizophrenia.

P0158

Clinical and functional improvements with risperidone long-acting injection treatment: 6-month results from the electronic schizophrenia treatment adherence registry in Sweden

L. Eriksson ¹, M. Povey ², B. Eriksson ³, A. Lam ⁴, Z. Zhongyun ⁵. ¹ SU/Östra RPV, Hisings-Backa, Sweden ² SGS Life Science Services, Wavre, Belgium ³ Janssen-Cilag Sweden, Onsala, Sweden ⁴ Johnson and Johnson Pharmaceutical Services, Toronto, ON, Canada ⁵ Johnson & Johnson Pharmaceutical Services, Raritan, NJ, USA

Objectives: Evaluate clinical and functional treatment outcomes in patients initiated on risperidone long-acting injection (RLAI) during routine clinical practice and followed up for at least 6-months.

Methods: e-STAR is a multi-national, prospective, observational study of patients with schizophrenia who have been initiated with RLAI. Data are collected both retrospectively (1 year) and prospectively (2 years). Clinical outcome measured by Clinical Global Impression-Severity (CGI-S) scale and functioning measured by Global Assessment of Functioning (GAF) scale were assessed at baseline and every 3 months. Results presented are based on data from patients enrolled in e-STAR in Sweden and have at least 6-months of follow-up data available.

Results: To date 102 patients have been enrolled in e-STAR in Sweden, of which 83 had at least 6-months of follow-up data available and were included in this analysis. Majority were male (63.9%) with mean age of 46.3±13.2 years. 71.1% had diagnosis of schizophrenia, 13.3% schizoaffective and 15.7 related psychosis and mean time since diagnosis of 12.5±10.1 years. Most important reasons for switching to RLAI were lack of efficacy (31.3%) and lack of compliance (27.7%) with previous therapy. At 6 months, 92.8% of patients were still on RLAI treatment. Mean CGI-S score significantly decreased from 4.21±1.08 at baseline to 3.60±1.13 at 6 months ($p<0.001$). Additionally, the mean GAF score significantly improved from 40.7±11.9 at baseline to 51.8±12.8 at 6 months ($p=0.006$).

Conclusion: These 6-month interim results showed that treatment with risperidone long-acting injection was associated with significant reduction in disease severity and improvement in patient functioning.

P0159

Reduction in suicidal ideation and violent behavior after treatment with risperidone long-acting injection from the e-star project in The Netherlands

M. van Kooten ¹, H. bij de Weg ², E. de Groot-Stam ³, C.L. Mulder ⁴, M. Povey ⁵, M. Manders ⁶, A. Lam ⁷, Z. Zhao ⁸. ¹ Ambulant ACT, de Geestgronden-Buitenamstel, Hoofddorp, The Netherlands ² GGZ Friesland, Leeuwarden, The Netherlands ³ Gelderse Roos, RIAGG, Veenendaal, The Netherlands ⁴ BAVO Europoort, Rotterdam, The Netherlands ⁵ SGS Life Science Services, Wavre, Belgium ⁶ Janssen-Cilag Netherlands, Tilburg, The Netherlands ⁷ Johnson and Johnson Pharmaceutical Services, Toronto, ON, Canada ⁸ Johnson & Johnson Pharmaceutical Services, Raritan, NJ, USA

Objectives: To assess the incidence of suicidal ideation, violent behaviour, and deliberate self-harm in patients with schizophrenia 12-months after initiating treatment with risperidone long-acting injection (RLAI) who are enrolled in the electronic-Schizophrenia Treatment Adherence Registry (e-STAR) in the Netherlands.

Methods: e-STAR is an international, prospective, observational study of patients with schizophrenia who have been initiated with RLAI. Data are collected retrospectively (1 year) and prospectively (2 years). The incidence of suicidal ideation, violent behaviour, and self-injury was evaluated by the treating physician based on the presence or absence of these events at baseline and prospectively every 3 months. Patients with at least 12 months of available follow-up data from the Netherlands were included in this analysis.

Results: To date a total of 190 patients have been enrolled in the Netherlands and 118 patients with 12 months of available data were analyzed. The majority were male (62.7%) with a mean age of 37.7±11.5 years and a mean time since schizophrenia diagnosis of 11.1±21.5 years. Compared to baseline, statistically significant decreases were observed in the occurrence of suicidal ideation (15.1% to 4.3%, $p=0.006$) and violent behaviour (12.9% to 2.2%, $p=0.006$) at 12 months. The incidence of self-injury also decreased from 4.3% to 3.2%, but the reduction was not statistically significant.

Conclusion: These 12-month interim results showed significant decrease in the incidence of suicidal ideation and violent behaviour was observed in patients with schizophrenia after initiating treatment with risperidone long-acting injection.

P0160

Does computerized cognitive remediation change brain activation patterns in schizophrenia: fMRI pilot data

J. Lindenmayer^{1,2,3}, S. Kaushik^{2,3}, C. Branch², S. McGurk⁴, A. Khan^{2,3,5}, H. Li³, L. Hoffman³. ¹New York University School of Medicine, New York, NY, USA ²Nathan Kline Institute for Psychiatric Research, Orangeburg, NY, USA ³Manhattan Psychiatric Center, New York, NY, USA ⁴Dartmouth College, Hanover, NH, USA ⁵Fordham University, New York, NY, USA

Background: Attention, working memory (WM), information processing and memory deficits are important features of schizophrenia. WM functions appear to be mediated by the dorsolateral prefrontal cortex (DLPFC). Functional imaging studies have shown a failure to activate the DLPFC during working memory tasks in patients with chronic schizophrenia. The primary aim of this study is to determine whether there are brain activation changes in the dorso-lateral prefrontal cortex (DLPFC) as a result of engaging in a randomized, controlled 12 week course of cognitive remediation therapy (CRT) in inpatients with chronic schizophrenia.

Methods: Patients with DSM IV schizophrenia are randomized to a 12 week trial of Cognitive Remediation (CR) using a Computerized CR program (COGPACK) or to a 12-week control condition. Patients receive at baseline and endpoint an fMRI scan with a cognitive task (N-back task), a neuropsychological test battery (MATRICS), functional and symptom assessments.

Results: Preliminary results of this ongoing study show that patients after 12 weeks of CR showed (1) significantly more improvement in WM functions than patients who participated in the control group and (2) improvement in accuracy on the verbal letter 2-back task during the fMRI scan. Signal difference between 2-back and 0-back was not present or only present minimally at baseline (Pre-CR); however, at endpoint (Post-CR) there was signal difference present, which corresponds to an increase in activation in the areas of the DLPFC. This increase in activation pattern may be reflective of the effects of the exposure to the CR intervention.

P0161

Assessment of body fat % in patients treated with sertindole or olanzapine

Y. Linne von Hausswolff-Juhlin¹, S. Rossner², M. Neovius². ¹Department of Psychiatry, Karolinska University Hospital, Dept of Medicine, Karolinska Institute, Stockholm, Sweden ²Department of Medicine, Karolinska Institute, Stockholm, Sweden

Background: Treatment with antipsychotic agents may result in changes in body composition. Highly accurate measurement techniques are expensive and may be associated with safety concerns, e.g. radiation exposure. Cheaper alternatives are available, but their accuracy in the patient population of interest has been investigated little.

Objective: To compare two methods for estimating body fat % (%BF) in patients treated with atypical antipsychotics.

Methods: Data on %BF measured at baseline and 1 month in six patients participating in a randomized trial of olanzapine and sertindole were collected. Eight-electrode bio-electrical impedance (BIA8) and dual energy x-ray absorptiometry (DEXA) equipments were used to measure %BF.

Results: At baseline, the mean %BF_{BIA8} was 26% compared to 35% for DEXA, indicating a large underestimation by BIA8. After

one month, the means were unchanged, although individual patients changed between +1.7 to -1.5%BF_{BIA}, and +1.5 to -1.3%BF_{DEXA}. The assessed median change at one month was similar for the two methods, with an increase of 0.3%BF_{BIA} compared to 0.2%BF_{DEXA}. The median between methods difference was 0%BF (range -3.0 to +1.3).

Conclusion: Large discrepancies in absolute levels of %BF were seen between the two measurement methods. The discrepancies were, however, constant over time. Therefore the change estimates were almost identical. Judging from this small sample, it appears as assessment of change in body composition may be estimated using the cheaper and faster BIA method, although the absolute values may be large underestimates. Caution in the interpretation must be exercised due to the small sample and small magnitude of change.

P0162

Immune parameters and aminotransferase blood serum level in dynamics of atypical neuroleptics treatment of schizophrenic patients

O.A. Lobacheva¹, T.P. Vetlugina¹, A.V. Semke², T.A. Popova³. ¹Psychoneuroimmunology Laboratory, Mental Health Research Institute, Tomsk, Russia ²Endogenous Disorders Department, Mental Health Research Institute, Tomsk, Russia ³Biochemical Laboratory, Mental Health Research Institute, Tomsk, Russia

Objective: The features of atypical neuroleptics influence on immune parameters and aspartate and alanine aminotransferases blood serum level of schizophrenics during 6-week therapy.

Methods: We examined 52 schizophrenics: 20 patients were treated by quetiapine, 12 - by olanzapine, 10 - by rispolept, 10 - by amisulpride. Scales PANSS and CGI was used at clinical examination. We defined the parameters of cellular, humoral immunity, serum levels of aminotransferases. Control group – 36 healthy people.

Results: The data of favorable influence on positive, negative, general psychopathological symptoms of patients was observed.

Before therapy T-cell immunodeficiency with reduction of CD2+, CD4+, CD16+-cells was observed among schizophrenics (comparing to control). Authentically high aminotransferases levels in first point were observed in groups of patients treated by olanzapine and quetiapine.

During 6 weeks of quetiapine treatment indices of aHLA-DR+-cells quantity, CD16+-cells, IgA, IC level tend to those of control indices, the normalization of aminotransferases levels was observed.

During olanzapine treatment the normalization of CD2+, CD8+-cells was observed; we determined the increase of IgA and IgM in the process of normalization of IgG and IC level. Aminotransferases levels reduced up to control indices.

During rispolept treatment the normalization of lymphocytes, CD4+, CD16+-cells, was observed; during amisulpride treatment the reduction of CD2+, aHLA-DR+-lymphocytes the increase of IC level, the normalization of CD16+-cells quantity and the increase of aminotransferases levels was revealed.

Summary: Was observed priority data about render various effects on immune parameters of atypical neuroleptics; dynamics of aminotransferases level which depends on their initial level is revealed.

P0163

Genious study: The use of ziprasidone for the treatment of patients with schizophrenia