

P025

Insight as a predicting factor in the early phases of schizophrenia (Eiffel project)

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Introduction and Aim: Insight in schizophrenia shows critical implications for adherence. Non-adherence is particularly relevant in first-episode patients. Few studies have examined insight in early schizophrenia. The aim of this study is to examine relationship between insight, adherence and outcome in patients with early schizophrenia.

Methods: Observational study in patients diagnosed for schizophrenia, schizophreniform, or schizoaffective disorder for less than 5 years. Data are collected retrospectively from first psychotic episode to study start, and prospectively (1 year). Association of demographic data, clinical measures, remission, relapses, and adherence with level of insight (Scale to Assess Unawareness of Mental Disorder and G12 item of PANSS) was evaluated. Adherence was assessed interviewing patients and family. Remission was defined according to Remission in Schizophrenia Working Group criteria. Preliminary data are shown.

Results: 575 patients have been analyzed. Duration of illness was 3.9 ± 1.6 years. According to G12 item of PANSS, almost 50% of patients had moderate to extreme impairment in baseline insight, while this percentage was 15.8% at 12 mo. (N=291). At baseline, 50% of patients showed good adherence to medication (>80%), and adherence rose to 78% at 12 mo. (N=291). Remission (severity criteria) significantly increased from baseline (23.9%, N=574) to 12 mo. (59.5%, N=291; $p < 0.0001$). A significant relationship between insight and remission at baseline ($p < 0.001$) was found. Among patients who reached 12 mo. visit (N=289), hospitalization was more frequent in those with poor baseline insight.

Conclusions: Lack of insight is common in early schizophrenia and may be a relevant predictor of poor outcome.

P026

Therapeutic adherence and treatment strategies: Registry in mental disease (Adhere study)

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Introduction and aim: Non-compliance is very common among patients with mental disorders, especially in schizophrenia. Non-compliance increases risk of relapse, hospitalizations, and suicide attempts, which worsens outcome. The aim of this study is to evaluate adherence to a new-onset therapeutic strategy in patients with schizophrenia, and the methods used to evaluate it. Differences between schizophrenia and other mental disorders will be assessed.

Methodology: Epidemiological study in outpatients diagnosed for schizophrenia, bipolar disorder, depression or personality disorder in which a new therapeutic approach was started (pharmacological or non pharmacological). Retrospective information from the previous three months (sociodemographic and clinical characteristics, treatments, adherence) and prospective data (adherence) for the three months after new therapy start were collected.

Results: Preliminary results from 975 patients with schizophrenia are presented. In 83% of patients with schizophrenia, adherence to pharmacological treatment was assessed through questions to the patient or some relative (caregiver or no direct caregiver), while in 10.5%, 12.6%, 17.3% and 23.7% it was assessed through MARS and DAI scales, MEMS, tablets account, and injections delivery. When patient was asked about his compliance with pharmacological treatment, 48% stated optimal compliance (>80% of doses prescribed), while this percentage is reduced to 44%, 38.5% and 35% when more objective methods were used (tablets account, MARS scale or MEMS, respectively). Compliance rose to 80% in patients treated with long-acting injectable antipsychotics.

Conclusion: Less of 50% of patients with schizophrenia show optimal compliance to oral pharmacological treatment, while this rate is 80% among those treated with long-acting injectable antipsychotics.

P027

Olanzapine-induced metabolic side effects, switching from olanzapine to ziprasidone: A pilot study

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Background: Many outpatients with schizophrenia experience severe metabolic side effects such as metabolic syndrome that occurs frequently in the treatment with some atypical antipsychotics that especially with clozapine and olanzapine.

Objective: To determine whether antipsychotic-associated metabolic abnormalities identified through intensive monitoring can be changed by switching from olanzapine medication to ziprasidone in patients with schizophrenia.

Method: Stable outpatients with metabolic side effects on olanzapine (n=20) therapy were switched to a flexible-dose trial of ziprasidone (40-160 mg/day) in this 13-week naturalistic study. All patients underwent an extensive metabolic evaluation at baseline, at 6 weeks, and at 13 weeks post switch. Metabolic abnormalities included the following medical complications: new onset diabetes impaired fasting glucose, impaired glucose tolerance, metabolic syndrome according to various definitions, and dyslipidemia. After 13 weeks of treatment with ziprasidone (mean daily dose 136.4 mg), there was a significant decrease in body weight, body mass index, and waist circumference. There was a significant reduction in fasting glucose, fasting insulin, and serum lipids levels (cholesterol, triglycerides, low-density lipoprotein (LDL), LDL/HDL, Chol/HDL, and non-HDL cholesterol). The metabolic syndrome was reversed in 70% of patients at 3 months.

Conclusion: Switching stable outpatients with schizophrenia from olanzapine to ziprasidone was generally well tolerated and was associated with improvements at 13 weeks. Results support the reversibility of olanzapine-induced metabolic abnormalities when detected early and followed by a switch to ziprasidone.

P028

Aripiprazole in acute schizophrenics

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Introduction: Schizophrenia requires new antipsychotic that can relieve suffering and improve the prognosis of schizophrenic patients.

Objectives: To study efficacy and safety of Aripiprazole in patients with acute schizophrenia.

Methodology: We studied 16 patients with acute episode of schizophrenia, 6 were first episodes and 10 acute reactivations. We used ARIPRAZOLE for 6 months to evaluate its effectiveness and tolerance. All patients were hospitalised and received Aripiprazole in progressively larger doses, beginning with 10 mg/day and increasing to 30 mg at 10 days. Evaluation measures were PANSS, initial and 6 months, and CGI, initial (severity) and 6 months (evolution-improvement). Side effects were evaluated.

Results: Mean PANSS in first episodes: 85 at onset and 36 at 6 months; in reactivations: 75 at onset and 32 at 6 months. ICG showed a mean severity of 4.6 in the first episodes and 4.2 in reactivations; at 6 months the mean improvement was 2.3 in the first episodes and 2.3 in reactivations. The transitory side effects were found, which did not require discontinuation of the drug: insomnia in 15% of first episodes and in 22% of reactivations; nausea in 16% vs. 22%; a certain disinhibition (not manic) in 83% of first episodes and in 77% of reactivations.

Conclusions: ARIPRAZOLE is an effective antipsychotic in the first and successive episodes of schizophrenia. It improved insight and the subjective feeling of well-being and made the psychotic condition easier to bear. This definitely made it a drug of first choice for acute or reactivated schizophrenia.

P029

Efficacy and safety with long-acting risperidone at medium high doses

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Background and aims: We present the results of one year follow up with 76 schizophrenic patients treated with long-acting risperidone (medium-high dose 50-75mg/biweekly). The efficacy and safety of this new risperidone formulation was the focus of our study.

Methods: We studied during a year follow up, 76 patients diagnosed of schizophrenia (DSM-IV criteria). Long-acting Risperidone was started (day 0) if non-compliance, or relapse with previous treatments in a regimen dose of 50mg. biweekly. Evaluations were performed at day 0, and at 6, 9, and 12 months of follow up. We used as parameters of efficacy: the PANSS, and the CGI.

Results: 65 (85%) kept the initial dose of 50mg biweekly, while 7 patients needed 75mg biweekly at the sixth month, and two patients required supplementary oral dose of 4-6mg of Risperidone. Total mean PANSS at first evaluation was 56 and decreased to a mean of 38 in the group treated with 50mg, 37 points those treated with 75mg. at the end of one year. The CGI changed from an initial 2.8 mean punctuation at baseline to a mean of 1.9 points in the group treated with 50mg, decreased to a mean of 2 points in the group treated with 75mg.

15% of the whole sample relapsed during the follow up of one year and 11 (14.7%) required hospitalisation

Secondary effects when present, were rated as mild.

We hardly believe that long-acting Risperidone at 50-75mg (medium-high doses) is an efficacy and well tolerated treatment, for schizophrenia.

P030

Descriptive analysis of the activity performed at a “Depot Clinic”

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Introduction: Depot Clinic is a relevant tool in the management of chronic psychotic patients in the ambulatory setting, since it allows monitoring attendance to consultation, compliance, and facilitates patient's follow-up.

The aim of this study is to improve knowledge about the Depot Clinic at our Center, checking adherence and retention rates to the treatments.

Methodology: Retrospective review of medical records of all patients that have attended our Center to receive long-acting medication in the last 36 months. Sociodemographic, clinical and treatment data were recorded, as well as information about hospitalizations, compliance with visits, need of additional medication (oral antipsychotics or corrective medication), etc.

Results: Ninety-six patients were included in the analysis. Mean age was 44.8 y and mean time since diagnosis was 17.34 y. Sixty-seven of them were diagnosed with schizophrenia. 55% of patients received risperidone (RLAI), 27% fluphenazine decanoate and 17.7% zuclopentixol. Patients receiving RLAI had been under that treatment for 2.6 y.; those with zuclopentixol and fluphenazine treatments had been receiving them for 6.81 and 11.54 y., respectively. Half of patients treated with RLAI and two thirds of those receiving fluphenazine had oral antipsychotics prescribed as well. Corrective treatment was used in 24%, 64% and 80% of patients receiving RLAI, zuclopentixol and fluphenazine, respectively. Among those patients treated with RLAI, retention rate was 66%, while 9% of patients decided to withdraw the treatment themselves.

Conclusion: RLAI is the most frequently used antipsychotic in our Depot Clinic. This drug has a retention rate over 60% after a 3-year follow-up.

P031

Long-term adherence and health outcomes study with risperidone constant and oral atypicals in the treatment of schizophrenia patients (interim-analysis RIS-SCH-4023)

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Objectives: Two-years naturalistic study investigating adherence to therapy, tolerability, functionality and quality of life (QoL) of 400 patients with early schizophrenia under treatment with the only available atypical depot (CONSTA) and other oral atypicals (OATYP).

Methods: Planned interim-analysis comprised 179 patients (ITT population; baseline to endpoint). Thereof, 89 patients started treatment with CONSTA, 90 patients with one of six OATYP (11 Olanzapin, 16 Quetiapine, 11 Amisulpride, 16 Ziprasidone, 18 Aripiprazole, 18 Risperidone). Mean age was 32.7 for CONSTA and 34.6 years for OATYP cohort. Mean duration of schizophrenia (82%: F20.0) was 2.7 years (SD 1.6) for both groups.

Results: There were baseline differences between CONSTA and OATYP cohort with regard to reasons for starting treatment (non-compliance 56% vs 18%; lack of tolerability 22% vs 31%, respectively) and severity of illness (PANSS total 94 vs 87). With regard to change of therapy, there was a tendency towards higher retention rates and mean study duration in the CONSTA cohort (56% vs 47%, $p=0.23$; 395 vs 342 days). PANSS scores improved significantly for both cohorts (CONSTA -17.2 vs OATYP -16.3). EPS score improved with no significant differences between cohorts. Overall, reported AEs related to schizophrenia (psychosis 14%; agitation 9.5%) were most common, followed by weight gain (9.5%) and fatigue (9%).