

patients. A 2 x 2 repeated measures analysis of variance (ANOVA) contrasting the comparison group to the clozapine patients both before and after the index date indicates a significant time by group interaction, thus documenting the greater relative decrease in rehospitalization rate in the clozapine gr.

We also used a compliance scale pre and post-beginning of treatment with clozapine for evaluate the adherence to treatment. Clozapine improve the compliance of treatment, in comparison to the neuroleptics that patient has taken before.

Conclusions: the clozapine seems to be more effective than other antipsychotics in decrease the risk of hospitalizations, and improve the adherence to treatment

P0261

Comparative mortality associated with ziprasidone vs. olanzapine in real-world use: The ziprasidone observational study of cardiac outcomes (zodiac)

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Background: Whether the modest QTc-prolonging effect of ziprasidone increases cardiovascular event risk is unknown.

Methods: The Ziprasidone Observational Study of Cardiac Outcomes (ZODIAC), an open-label, randomized, postmarketing study, enrolled patients with schizophrenia from routine clinical practice settings in 18 countries. The primary outcome was non-suicide mortality in the year after initiation of assigned treatment. A total of 18,154 subjects were randomized to ziprasidone or olanzapine, dosed according to enrolling physician's clinical judgment. A physician-administered baseline questionnaire collected information on demographics, medical and psychiatric history, and concomitant medication use. Brief follow-up questionnaires elicited hospitalization data since the last study visit, vital status, study medication continuation, and concomitant antipsychotic medication(s) use. ZODIAC study subjects reflected the general population of patients with schizophrenia.

Results: The incidence of nonsuicide mortality within one year of initiating therapy was 0.91% for the ziprasidone group and 0.90% for the olanzapine group (both n = 9,077), relative risk (95% confidence interval [CI]) of 1.01 (0.75, 1.37). This finding was robust in numerous secondary and sensitivity analyses. Regarding secondary endpoints, the risk of all-cause mortality or cardiovascular mortality was similar among ziprasidone and olanzapine users; the incidence of all-cause hospitalizations was higher among ziprasidone users. The proportion of patients remaining on treatment at 6 months was lower for the ziprasidone group.

Conclusions: ZODIAC is one of the largest randomized studies conducted to date of patients with schizophrenia. With substantial statistical power, the study found no difference in risk of nonsuicide death associated with the use of ziprasidone vs. olanzapine.

P0262

Risperidone and liver function tests in children and adolescents: A short term prospective study

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Objective: Revealing of unknown adverse effects of atypical antipsychotics on pediatric population may take a long period of time. The purpose of this prospective study is to document changes in the liver function tests (LFTs) associated with Risperidone usage in a group of children and adolescents.

Method: Study subjects consist of 120 youths with ages ranging from 3-17 years. For this study, patients' baseline and follow-up weight and liver function tests (LFT) including alanine aminotransferases (ALT) and aspartat aminotransferases (AST), gamma glutamyl transesterase (GGT), alkaline phosphatase (ALP) and serum bilirubin levels were measured before and after the treatment period of one month.

Results: Only one eight years old male patient's ALT levels increased up to three-fold and AST levels increased up to two-fold of the basal levels. First month mean levels of liver enzymes and bilirubin of the patients were significantly higher than the baseline. One or more of the liver enzymes and/or bilirubin levels of sixty-three patients (52,5%) showed an asymptomatic increase in the first month of this study. Weight gain was observed in 58 patients (57.4%). There was no significant association between changes in weight and liver enzymes and bilirubin levels.

Conclusion: We found asymptomatic LFT abnormalities mostly in the form of ALP elevation in 52.5% and marked liver enzymes elevation in 0.8% of risperidone treated subjects. These findings suggest that risperidone treatment in the short term commonly leads to liver function changes however it rarely may induce a serious hepatic toxicity at therapeutic doses in children and adolescents.

P0263

Effect of risperidone long-acting injection on hospitalisation: A mirror image analysis

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The aim of this study was to assess the effect of risperidone long-acting injection (RLAI) on hospitalisation using a mirror image analysis.

Data on the number of admissions and number of days in hospital were analysed during the two-year period before starting RLAI and the duration of therapy in 56 patients.

Admission rates and length of hospitalisation both decreased for approximately 60% of patients during RLAI therapy.

The time in hospital was significantly lower (p=0.002) during RLAI therapy compared to the previous two years. During the pre-

RLAI phase, 59% of patients spent more than one month per year in hospital; in the RLAI phase this was reduced to 23%.

The median number of admissions was also lower, but although 55% of patients had no admissions there were also several patients with multiple admissions during RLAI therapy. During the pre-RLAI phase, no patients had an admission rate above 1.5 admissions per year, but in the post phase 10 patients (18%) had admission rates above 1.5. These results are partially explained by the fact that hospitalisation tended to be shorter during RLAI than in the previous 2 years (average 75 days per admission pre-RLAI vs. 34 days during RLAI).

As there was no control group the results should be interpreted cautiously. Any differences could be caused by other confounding factors which changed with time, and there was wide variation between patients.

In summary, RLAI significantly reduced hospitalisation and this may result in substantial cost savings.

P0264

Efficacy and tolerability of quetiapine in the treatment of schizoaffective disorder: A retrospective study

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Background and Aims: The efficacy of QTP in the treatment of schizophrenia has been well established in randomised, double-blind, placebo-controlled trials, but there is a lack of data concerning its efficacy in the medium- term management of schizoaffective disorder. Aim of the study was to evaluate retrospectively the efficacy and tolerability of QTP in preventing relapses of Schizoaffective Disorder (1,2).

Methods: The study involved 18 outpatients (4 males and 14 females), at least 18 years of age, with a diagnosis of Schizoaffective Disorder, based on the DSM-IV-TR criteria.

Patients were evaluated by using BPRS, CDSS and CGI-S. Clinical evaluation was assessed retrospectively through the data obtained by the clinical records. Evaluation started when QTP was prescribed (T0), and was performed after six months (T6). Moreover, a clinical evaluation was assessed six months before the start of QTP treatment by using the same rating scale (T-6). The main outcome measure evaluated was the rate of hospitalization caused by depressive, manic or psychotic relapses.

Results: At the end of the study (T6), a significant reduction in CGI-S, BPRS and CDSS scores was observed. CDSS mean scores showed a 60% amelioration vs T0. No patients dropped out because of side effects. The mean dosage of quetiapine in our study was 544 mg/die.

Conclusions: QTP, alone or in association with benzodiazepines and/or mood stabilizers, seems to be an effective tool in the treatment of Schizoaffective Disorder and in prevention of relapses and consistent with several researches it seems effective in reduction of depressive symptoms.

P0265

Auricular acupuncture experience among dual diagnosis patients: Randomized controlled pilot clinical trial

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Background: The auricular acupuncture (AA) detoxification was first introduced in 1974. Over the past thirty years this technique has been extensively studied, expanded and improved. Unfortunately, there is no empirical evidence to recommend the use of AA for dual diagnosis patients (DDP). The absent data on the efficacy and safety of the AA leads to inappropriate use of this therapeutic intervention in DDP.

Methods: Randomized controlled parallel groups clinical trial aimed to investigate the effectiveness and safety of AA in DDP for the management of both psychiatric and addiction issues. The study population group [10 AA treatments at least 20 minutes 4-5 times a week] comprised 10 subjects (9 males (90.0%), mean age 28.8 years (SD=5.7)). The control population group (without AA) comprised 3 subjects (3 males (100.0%), mean age 29.5 years (SD=7.8)). Antipsychotic efficacy was measured by CGI-Severity & CGI-Improvement scales, craving was measured by Drug-DALI and treatment compliance was measured by DAI-10.

Results: There were no differences between the groups according to demographic and clinical measures at the beginning of the study. The mean DALI score change in study population was -3.7 (SD=3.9; p<.06), the mean DAI score change was 3.9 (SD=4.6; p<.06) in comparison to -6.0 (SD=4.2; NS) and 5.5 (SD=10.6; NS) in a control population, respectively. There were no differences in CGI-I (NS). There were no adverse events in both populations.

Conclusions: There is a trend for effect of AA to craving decrease and a trend for effect to improvement of treatment-compliance in DDP.

P0266

Metabolic side effects of atypical antipsychotics in early onset schizophrenia: One year follow-up pilot study

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Objective: To assess weight gain in adolescents treated with antipsychotic drugs for early onset schizophrenia (EOS).

Method: One-year follow-up of 13 consecutive adolescents (10 male, 3 females, age range: 11-16) treated with atypical antipsychotics for early onset schizophrenia (according to DSM-IV criteria). The main outcome measure is sex- and age-adjusted Z scores of Body Mass Index (BMI).

Results: BMI, sex- and age-adjusted BMI percentiles and BMI Z scores are significantly increased in schizophrenic adolescents after prescription of atypical antipsychotics (p= 0.025).

Conclusions: Despite the limited number of children included, this pilot study confirms a significant link between prescription of risperidone in early onset schizophrenia and increase of adjusted BMIZ scores. Clinicians and caregivers are to be aware of potential metabolic adverse effects of these medications. These findings suggest a regular health monitoring in adolescents treated with atypical antipsychotics, before and along the prescription.