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**Background and aims:** Agitation is a common symptom in schizophrenia and bipolar mania, causing marked distress and posing considerable risks for patients. Intramuscular formulations of psychotropic medication can provide a fast acting treatment of severe agitation in patients with acute episodes of schizophrenia or mania. As effective as these treatments are, particular antipsychotics can be associated with a heightened risk of dystonia and related Extrapyramidal Symptoms (EPS). Patients presenting to emergency care settings are also likely to have coexisting intoxications and medical conditions that may contribute to this risk.

**Methods:** The aim of this observational prospective study was to document the safety and effectiveness of all IM psychotropic drugs during the 24 hours following an initial injection in acutely agitated patients suffering from schizophrenia or bipolar disorder under naturalistic conditions.

**Results:** Two-hundred-thirty-two (232) participating investigator sites (12 European countries) observed 1940 patients (mean age: 39 y, 42% female, 66% schizophrenia diagnosis). The primary endpoint was the occurrence of extrapyramidal symptoms (EPS), further endpoints were clinical severity measured by PANSS-EC and CGI-S. A total of 1311 (68%) patients received a monotherapy injection at baseline. Within 24 hours after the first injection, 190 (10%) of all 1940 patients experienced EPS. All intramuscular psychotropic drugs were shown to be effective in reducing measures of acute agitation.

**Conclusion:** This study provides favourable results on EPS related adverse events and effectiveness of intramuscular psychotropic medication for the management of acute agitation in patients within a naturalistic setting during the first 24 hours of treatment.

## P165

Schizophrenia and substance use disorders: Effects of zypasidone treatment

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**Background and aims:** The risk of abuse/dependence of alcohol or drugs in schizophrenia have been estimated about 4 times the prevalence in general population. This fact difficults the treatment results and efficacy: more relapses, more treatments withdrawal and poorer prognosis. The aims of our study is to evaluate the effect of Zypasidone, an atypical antipsychotic with 5HT properties, in patients with schizophrenia and comorbid substance use disorder in a single, open, prospective-naturalistic design.

**Method:** 36 outpatients were selected with Schizophrenic disorder diagnosis (DSMIV) and abuse/dependence of at least 1 substance in which Zypasidone was recommended (inefficacy, intolerance of prior treatments,...). They were evaluated clinically and data about actual consum and craving were collected at initial visit and follow-up monthly (3 to 6 months). Results were analyzed with SPSS pack.

**Results:** The mean follow-up period was 3 month. 28 patients finished the evaluation showing a decrease in clinical measures (PANSS, ICG) with good tolerance (only 4 drop-outs associated to undesirable effects). The most frequent drug use disorder was tobacco followed by alcohol and cannabis. The results on number and frequency of drug use shows a slow tendency to reduce at the end of the evaluation

as well the craving measures but no significant differences were found.

**Conclusions:** Our exploratory study with Zypasidone, although metodological limitations, suggests that clinical schizophrenic symptoms can improve but also drug pattern use. Naturalistic studies of schizophrenia with comorbid substance use disorder can be useful to show the efficacy of antipsychotics in real clinical practice

## P166

Changes in prolactin in olanzapine-treated adolescents with schizophrenia or bipolar mania: A pooled analysis of 4 studies

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**Introduction:** Prolactin (PRL) data from adolescents treated with olanzapine are presented.

**Methods:** Data from 454 adolescents (13-18, mean=15.9 yrs) with schizophrenia or bipolar mania were pooled from 4 olanzapine (2.5-20.0mg/day) studies (4-32 weeks; 2 double-blind, placebo-controlled studies [combined for acute phase endpoint PRL levels] with open-label extensions; 2 open-label studies). Age- and sex-specific Covance reference ranges defined normal PRL; categorical increases were based on multiples of the upper limit of normal (ULN). Baseline-to-endpoint PRL changes in adolescents were compared with data pooled from 84 olanzapine clinical trials in adults with schizophrenia or bipolar disorder.

**Results:** Olanzapine-treated adolescents had mean PRL increases at both the acute (11.4µg/L) and open-label endpoints (4.7µg/L). Of those patients with normal PRL levels at baseline (N=311), high PRL occurred in 54.7% at anytime; 32.2% at endpoint. The percentage of patients in which PRL levels shifted from normal-to-abnormal was smaller at endpoint than at anytime during treatment; 26.7% shifted to a higher category. Among patients with normal baseline PRL, 32.7% remained ≤1X ULN; 32.3% increased to 1-<=2X; 6.0%, >2-<=3X; and 1.2%, >3X at anytime; 4.6% had at ≥=1 potentially PRL-related adverse event. Adolescents had significantly higher mean changes at endpoint (p=.004), and a greater incidence of high PRL levels at anytime during olanzapine treatment (p<.001) versus adults.

**Conclusion:** Incidence of high PRL was significantly higher, and mean increases in PRL were significantly greater in adolescents versus adults. Mean increases and high PRL incidence were lower at the open-label compared with the acute phase endpoint.

## P167

Changes in metabolic parameters in olanzapine-treated adolescents with schizophrenia or bipolar I disorder: A pooled analysis of 4 studies

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