## P02.24

QTc intervals: IM olanzapine treatment in acutely agitated patients

M. Tohen\*, S.R. David, C.M. Beasley Jr., K. Alaka. Lilly Research Laboratories, Indianapolis, USA

Objective: QTc interval data during IM treatment were analyzed among patients with schizophrenia, bipolar mania, and dementia.

Method: In four double-blind trials, patients received 1-3 IM injections of olanzapine (2.5-10 mg/injection), haloperidol (7.5 mg/injection), or placebo over 24 hours. Databases included: placebo-controlled (2-schizophrenia, 1-bipolar), haloperidol-controlled (2-schizophrenia), and geriatric placebo-controlled (1-dementia). Mean QTc interval changes from baseline and prolonged QTc intervals (endpoint  $\geq$ =99% of healthy adults or increase  $\geq$ =60 msec or endpoint  $\geq$ =500 msec) were analyzed.

**Results:** Overall, QTc interval changes in IM olanzapine-treated patients were small and not significantly greater than placebo. There were significant (p<0.05) between-group mean change differences in the haloperidol-controlled database at 2 hours and geriatric placebo-controlled database at 2 and 24 hours after the first injection. The incidences of prolonged QTc intervals for olanzapine-treated patients were never significantly greater than placebo and were <=3% in all databases (exception: <=11% geriatric).

**Conclusions:** Changes in QTc intervals in IM olanzapine-treated patients were no worse than with placebo, suggesting that IM olanzapine has a favorable QTc interval profile in acutely agitated patients with schizophrenia, bipolar mania, or dementia.

## P02.25

Risperidone and olanzapine in inpatient treatment of bipolar disorder

A. Mehnert<sup>1\*</sup>, M. Jones<sup>2</sup>. <sup>1</sup>Janssen Research Foundation, Belgium <sup>2</sup>Department of Psychology, Macquarie University, Sydney, Australia

**Objective:** To compare drug usage, costs and outcomes in inpatient treatment of bipolar disorder with risperidone (RIS) or olanzapine (OLA).

Method: A retrospective multicenter cohort study using patient chart review. Inclusion criteria were: diagnosis of bipolar disorder, discharged or at least 120 days of follow-up,  $\ge 65$  years of age and treated with either RIS or OLA.

**Results:** 62 patients (RIS=30, OLA=32) were included. Demographic characteristics for the two samples were similar. The median time to onset of efficacy was 9 days for RIS and 12 days for OLA. The average daily dose for RIS was 3.0 mg and with OLA 11.0 mg. 10% of RIS-treated and 16% of OLA-treated patients discontinued therapy.

Daily costs of the studied medication were 4.6 USD for OLA and 2.0 USD for RIS (p<0.0001). Daily costs for all in-patient drug use were 6.2 USD in the OLA group and 2.9 USD in the RIS group (p<0.0001).

**Conclusions:** RIS and OLA were both effective in the bipolar patients studied. Drug costs for patients receiving RIS were significantly lower than costs for patients receiving OLA.

## P02.26

Atypical antipsychotics in schizophrenia and mood disorder

A. Mehnert<sup>1</sup>\*, M. Jones<sup>2</sup>. <sup>1</sup>Janssen Research Foundation. Belgium <sup>2</sup>Department of Psychology, Macquarie University, Sydney, Australia

**Objective:** To compare the outcomes associated with atypical antipsychotic treatment in inpatients with schizophrenia and mood disorder.

Method: A retrospective cohort study using patient chart review was undertaken in inpatients diagnosed with schizophrenia or mood disorder, under 66 years of age and treated with either risperidone (RIS) or olanzapine (OLA).

**Results:** 2013 patients with schizophrenia (N=1901) and mood disorders (N=112) were included. Schizophrenia patients typically had an earlier age of onset of symptoms (24.5 years) than those with mood disorder (30.1 years, p=0.0002), and were commonly taking more antipsychotics on admission. Mood disorder patients received lower doses of RIS or OLA (p<0.0001), had a shorter time to achieve efficacy (p=0.01), were more often discharged within 120 days (p=0.02) and had a shorter median time-to discharge (p<0.0001) than patients with schizophrenia. Adjusting for background factors had little impact on the dose comparison, time-to discharge or time-to efficacy analyses.

**Conclusions:** Patients with mood disorders generally required lower doses of atypical antipsychotic and were discharged faster than schizophrenic patients. Differences in clinical outcomes were not explained by differences in background characteristics.

## P02.27

Meta-analysis of the efficacy of aripiprazole in schizophrenia

W.H. Carson<sup>1</sup>\*, E. Stock<sup>1</sup>, A.R. Saha<sup>2</sup>, M.W. Ali<sup>2</sup>, R.D. McQuade<sup>1</sup>, M.J. Kujawa<sup>1</sup>, G. Ingenito<sup>2</sup>. <sup>1</sup>Bristol-Myers Squibb, Wallingford, CT; <sup>2</sup>Otsuka Maryland Research Institute, USA

Aripiprazole is the first of the next generation of atypical antipsychotics. This meta-analysis presents efficacy data from four 4to 6-week multicenter, double-blind, controlled studies involving 1540 patients hospitalized with acute relapse of schizophrenia or schizoaffective disorder. Patients were randomized to aripiprazole (n=893), placebo (n=380), or active control (haloperidol 10 mg/day [n=167] or risperidone 6 mg/day [n=100]). Daily aripiprazole doses were 2 mg (n=59); 10 mg (n=165); 15 mg (n=207); 20 mg (n=199); 30 mg (n=263). Weekly efficacy assessments included PANSS and CGI. Aripiprazole demonstrated statistically superior antipsychotic efficacy to placebo, as did haloperidol and risperidone. In the metaanalysis, aripiprazole doses over 2 mg produced significant improvement in PANSS-total score by week 1 (p<0.05). In individual studies, aripiprazole 15, 20 and 30 mg consistently produced significant improvements in PANSS-total score, with similar changes from baseline observed for all treatment groups. Aripiprazole 15, 20 and 30 mg consistently produced significant improvements in other efficacy scores compared with placebo. These data suggest that aripiprazole improved positive and negative symptoms of schizophrenia disorder, with significant effects present one week after starting treatment.