

6.86%). In PAT families the parent-offspring transmission was significant ( $p=0.046$ ), while the sibling effect (that includes parent-offspring correlation and environmental influences) was not significant ( $p=0.22$ ). In MAT families the parent-offspring transmission was not significant ( $p=0.41$ ), while the sibling effect was significant ( $p=0.0022$ ).

**Conclusion:** Our data show that sex and parent-of-origin may modify the liability to psychotic BP. Genetic factors seem to be stronger in PAT families.

## P0125

Suicide in bipolar patients: is it possible to predict & prevent?

S. Guloksuz, E.T. Oral, N. Kocal, E. Erten, E. Kurt, A. Hariri, P. Gokalp. *Bakirkoy Prof Dr Mazhar Osman State Research & Teaching Hospital for Neurology and Psychiatry Rasit Tahsin Mood Disorders Outpatient Clinic, Istanbul, Turkey*

**Background and Aim:** Risk of suicide in bipolar disorder (BP) patients is one of the highest in psychiatric disorders. It is stated that long term treatment with lithium, selectively, can reduce the risk of suicide commitments and attempts. In our study, rates of suicide attempts of BP patients before and after treatment with a mood stabilizer (MS) and the relationship between suicide and other risk factors are investigated in a specialized tertiary outpatient mood disorder clinic in Istanbul, Turkey.

**Method:** Charts of 608 bipolar disorder patients (DSM-IV) followed in our outpatient mood disorder clinic were evaluated retrospectively and 89 containing incomplete or unreliable data about the suicide history were excluded.

**Results and Conclusion:** Lifetime rates of suicide attempts were 19.9% for BP-I patients ( $n=95$ ), 50% for BP-II patients ( $n=8$ ), 8.3% for BP-NOS patients ( $n=2$ ) respectively. The rate of suicide was higher in BP-II patients. Duration of illness and onset as depressive episode were found as significant predictors of suicide attempt in logistic regression analysis. The rate of suicide attempt before treatment with MS was higher than the rate after treatment with MS (15.6% vs. 6.2%;  $p<0.001$ ). Our findings suggest that the risk of suicide attempts in bipolar patients and especially in BP-II is highly increased, predicting the factors of suicide earlier and treating patients adequately could prevent this risk efficiently.

## P0126

Aripiprazole monotherapy in acute bipolar I mania: A randomized, placebo- & lithium-controlled study (Cn138-135)

L. Hanssens<sup>1</sup>, A. Torbeyns<sup>1</sup>, R.N. Marcus<sup>2</sup>, R.D. McQuade<sup>3</sup>, R. Sanchez<sup>4</sup>. <sup>1</sup>*Bristol-Myers Squibb Company, Braine L'Alleud, Belgium* <sup>2</sup>*Bristol-Myers Squibb Company, Wallingford, CT, USA* <sup>3</sup>*Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA* <sup>4</sup>*Bristol-Myers Squibb Company, Rueil-Malmaison Cedex, France*

**Purpose:** To evaluate the efficacy and safety of aripiprazole monotherapy as acute and continuation therapy for acute bipolar I mania.

**Methods:** Patients with acute bipolar I mania were randomized (1:1:1) to double-blind aripiprazole (15–30 mg/day;  $n=155$ ), placebo ( $n=165$ ) or lithium (900–1500 mg/day;  $n=160$ ) for 3 weeks. At the end of Week 3, patients randomized to placebo were blindly switched

to aripiprazole. Key efficacy outcome measures were mean change from baseline in YMRS Total score at Week 3 (LOCF; primary endpoint) and Week 12.

**Results:** Improvements in YMRS Total scores from baseline were significantly greater versus placebo as early as Day 2 with aripiprazole ( $p=0.003$ ) and Day 7 with lithium ( $p=0.040$ ; LOCF). At Week 3, improvements from baseline in mean YMRS Total scores were significantly greater with aripiprazole ( $-12.96$ ;  $p<0.001$ ) and lithium ( $-12.03$ ;  $p=0.005$ ) versus placebo ( $-9.01$ ; LOCF). These improvements were maintained to Week 12 (LOCF) with both aripiprazole ( $-14.48$ ) and lithium ( $-12.71$ ). Response rate was significantly greater versus placebo as early as Day 2 with aripiprazole ( $p=0.026$ ), and Day 10 with lithium ( $p=0.006$ ; LOCF). Response rates continued to increase over the study period and at Week 12 were 56.5% with aripiprazole and 49.0% with lithium.

**Conclusions:** Aripiprazole significantly improved symptoms as early as Day 2 and throughout the 3-week, placebo-controlled portion of this study in acutely manic patients. The beneficial effects of aripiprazole were sustained through Week 12 and were similar to lithium, confirming the robust efficacy of aripiprazole in these patients.

## P0127

Treatment of acute manic and mixed episodes in bipolar disorders

H. Grunze<sup>1</sup>, N. Klose<sup>2</sup>, B. Ibach<sup>2</sup>. <sup>1</sup>*Department of Psychiatry, Ludwig-Maximilians-University, Munich, Germany* <sup>2</sup>*Therapeutic Area CNS, Medical & Scientific Affairs, Janssen-Cilag, Neuss, Germany*

**Objective:** Risperidone has shown to be effective and generally well tolerated in the treatment of patients with acute manic episodes in bipolar disorder when given as monotherapy or in combination in randomized-controlled-trials. This non-interventional study served to add evidence for therapeutic benefit of risperidone in this indication in a clinical routine-setting.

**Methods:** Prospective, multi-center non-interventional trial (RIS-BIM-4001) performed in Germany. Inpatients with a baseline score  $\geq 20$  in the Young-Mania-Rating-Scale (YMRS) were eligible for enrollment. All patients were evaluated based on intent-to-treat-analysis (ITT).

**Results:** 251 patients were evaluated (54% female, median age 46 years). The most frequent concomitant medications during the study were valproic acid (40%), lorazepam (36%), diazepam (33%) and lithium (24%). The mean daily dose of risperidone at endpoint was  $4.5 \pm 1.5$  mg/day. Mean YMRS total score improved significantly from baseline to endpoint ( $33.6 \pm 8.5$  to  $14.6 \pm 8.8$ ;  $p<0.0001$ ), also mean MADRS total score ( $13.14 \pm 5.83$  to  $7.18 \pm 5.8$ ;  $p<0.0001$ ) and mean BPRS total score ( $13.5 \pm 5.1$  to  $7.4 \pm 3.6$ ;  $p<0.0001$ ). A total of 185 AEs was documented in 100 (39.84% out of the total ITT-patients), thereof 102 AEs (55.1%) in 59 patients (23.51%) were evaluated by the physicians an at least possible causal relationship to risperidone. Most frequent were EPS (6.4%).

**Conclusions:** In this non-interventional trial oral risperidone treatment was associated with a significant and clinically relevant improvement of psychopathology. These data are in line with the results of previous randomized controlled trials and support the good tolerability and safety of risperidone in the treatment of bipolar inpatients with acute moderate to severe manic symptoms.