NEW RESEARCH

NEW RESEARCH ABSTRACTS

AMERICAN PSYCHIATRIC ASSOCIATION

2002 ANNUAL MEETING

Philadelphia, PA ■ May 18-23, 2002

ABSTRACTS

haloperidol, IM ziprasidone was consistently associated with a lower movement disorder burden (eg, akathisia, dystonia, EPS, hypertonia) at all doses investigated. In all studies, clinically significant changes in blood pressure and heart rate associated with IM ziprasidone were isolated and transient; treatment-emergent postural hypotension was observed in one ziprasidone-treated patient in one study. There were no QTc values ≥500 msec with IM ziprasidone.

Conclusion: In clinical trials, IM ziprasidone in divided doses up to 80 mg/day was well tolerated, with low incidences of AE-related discontinuations and movement disorder AEs.

NR313 Wednesday, May 22, 12:00 p.m.-2:00 p.m.

Olanzapine Improves Tardive Dyskinesia in Patients with Schizophrenia

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Summary:

Objective: We report preliminary findings of the effects of olanzapine (OLZ) treatment upon tardive dyskinesia TD.

Methods: Eligible schizophrenic subjects met restricted Research Diagnosis Tardive Dyskinesia criteria (restricted RD-TD) that specified for abnormal involuntary movements to be of at least moderate severity. Subjects received OLZ, 5–20 mg/day for 8 months within a double-blind design that included up to 2 medication reduction (75%) periods of 2 weeks duration. TD was assessed with the Abnormal Involuntary Movement Scale (AIMS) and psychopathology with the Positive and Negative Syndrome Scale (PANSS).

Results: A significant reduction in mean AIMS Total score was demonstrated (N=95; BL=11.9; EP=7.5; p<.001; LOCF). Nearly 70% of subjects no longer met the restricted RD-TD criteria after up to 8 months of treatment, with greater than 50% improving as early as 8 weeks. No statistically significant rebound worsening of TD was found during the blinded drug reduction periods. A significant improvement in the PANSS occurred (BL=68.2; EP=59.7; p<.001, LOCF).

Conclusion: These data, suggesting an ameliorative, rather than masking effect, and the concurrent further improvement in clinical status suggests that OLZ may offer a potential treatment alternative for managing the schizophrenic patient with pre-existing TD.

NR314 Wednesday, May 22, 12:00 p.m.-2:00 p.m.

Aripiprazole Versus Placebo in Acute Mania

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Summary:

Objective: To compare the efficacy and safety of aripiprazole, the first next-generation atypical antipsychotic with a unique mechanism of action (dopamine-serotonin system stabilizer) to placebo in patients with acute bipolar mania.

Methods: This Phase III, multicenter, double-blind, placebo-controlled study randomized 262 patients with acute mania to aripiprazole 30 mg (reduced to 15 mg if unable to tolerate) or placebo for 3 weeks. Patients remained hospitalized for a minimum of two weeks of the treatment phase. The primary measure of efficacy was the change in Y-MRS Total score. Response was defined as a decrease of ≥50% in Y-MRS Total score.

Results: Aripiprazole produced statistically significant improvements in Y-MRS Total score (–8.15 vs. –3.35, p≤0.01) compared to placebo. The response rate was significantly higher in the aripiprazole group than the placebo group (40% vs. 19%, p≤0.01). For all efficacy variables, aripiprazole separated from placebo by day 4. Discontinuations due to adverse events did not differ between the aripiprazole and placebo groups, and there were no significant changes in weight versus placebo.

Conclusion: Aripiprazole was effective and well tolerated in the treatment of acute mania in patients with bipolar disorder in this randomized, placebo-controlled trial.

NR315 Wednesday, May 22, 12:00 p.m.-2:00 p.m.

Ziprasidone Versus Olanzapine in Schizophrenia: Six-Month Continuation Study

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Summary:

Objective: To compare long-term efficacy and tolerability of ziprasidone and olanzapine in schizophrenia or schizoaffective disorder.

Methods: This 6-month, blinded continuation study followed hospitalized patients who had completed a 6-week randomized trial with satisfactory clinical response (CGI-I ≤2 or ≥20% reduction in symptom severity by PANSS Total) and were discharged on olanzapine 5–15 mg QD (n=71) or ziprasidone 40–80 mg BID (n=62). Primary efficacy measures were BPRS and CGI-S; secondary variables included PANSS Total and Positive and Negative Subscale scores. Tolerability assessments included fasting lipids, insulin, glucose, and weight.

Results: Ziprasidone- and olanzapine-treated patients demonstrated comparable changes in BPRS, CGI-S, and PANSS Total and Subscale scores from baseline of 6-week study to endpoint of 6-month continuation. Changes during continuation phase did not differ significantly between groups. Olanzapine-treated patients exhibited significant mean increases versus ziprasidone in endpoint weight (P<0.001) and BMI (P=0.001), and significant median increases versus baseline in LDL-C (P<0.01), insulin (P<0.05), glucose (P=0.05), and fasting liver enzymes (P<0.05). Both agents displayed low incidence of movement disorders. No patients had QTc ≥500 msec.

Conclusions: Ziprasidone and olanzapine demonstrated comparable antipsychotic efficacy in long-term treatment. Olanzapine patients alone exhibited sustained weight gain and deleterious metabolic changes.

NR316 Wednesday, May 22, 12:00 p.m.-2:00 p.m.

Antipsychotic Monotherapy Versus Combination Treatment with Valporate in Hospitalized Patients with Acute Schizophrenia: A Double-Blind, Multi-Center Study

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Summary:

Objective: This study compared the efficacy and safety of atypical antipsychotic monotherapy (olanzapine or risperidone) versus combination treatment with valproate (divalproex sodium) in patients with an acute episode of schizophrenia.