

Conclusions: These findings suggest that patients requiring a change in antipsychotic therapy may experience cognitive improvements following a switch to ziprasidone.

P02.04

Ziprasidone vs olanzapine for cognitive function in schizophrenia

P.D. Harvey¹, G. Simpson², R. Horne³, P.J. Weiden⁴, M. Bari⁵, S.J. Romano⁶. ¹*Mount Sinai School of Medicine, New York*; ²*LAC & USC Medical Center, Los Angeles*; ³*Lake Mead Hospital, Las Vegas*; ⁴*SUNY Health Sciences Center, Brooklyn*; ⁵*Synergy Clinical Research Center, Crula Vista*; ⁶*Pfizer, Inc., New York, USA*

Objective: To compare cognitive changes in patients treated with ziprasidone versus olanzapine.

Methods: Patients with schizophrenia or schizoaffective disorder were randomly assigned to 6 weeks' double-blind therapy with olanzapine (n=133) or ziprasidone (n=136) therapy. Cognitive tests – at baseline and end of week 6 or early termination – included measures of vigilance, executive functioning, verbal learning and memory, verbal fluency, and visuo-motor speed. Endpoint data were available for at least 49 ziprasidone patients and 60 olanzapine patients (numbers varied by test administered).

Results: There were statistically significant improvements from baseline for both groups in vigilance, visuo-motor speed, verbal learning and delayed recall, and category fluency, but no improvements in letter fluency or executive functioning. Olanzapine patients had statistically greater improvement (p=0.015) in category fluency, a finding that would not have withstood correction for overall number of tests performed.

Conclusions: Ziprasidone exerts a beneficial effect on several domains of cognition known to affect functional outcome in schizophrenia. Few notable differences were detected between ziprasidone and olanzapine, suggesting that ziprasidone has cognition-enhancing effects similar to those of other newer antipsychotics.

P02.05

Health status indices in stable outpatients switched to ziprasidone

P.J. Weiden¹*, D.G. Daniel², G. Simpson³, S.J. Romano⁴. ¹*SUNY Health Sciences Center, Brooklyn*; ²*Comprehensive Neuroscience, Inc., Falls Church*; ³*LAC & USC Medical Center, Los Angeles*; ⁴*Pfizer, Inc., New York, USA*

Objective: To assess ziprasidone's impact on health indices in outpatients switched from other antipsychotics.

Methods: Stable, symptomatic outpatients with schizophrenia were switched to ziprasidone (40–160 mg/day) from conventional antipsychotics (n=108), olanzapine (n=104), or risperidone (n=58) in 3 identical, 6-week, open-label trials, using random assignment to 1 of 3 crossover strategies. Primary outcome was mean change from baseline to endpoint in total cholesterol, triglycerides, prolactin (nonfasting); weight and BMI; and movement disorders.

Results: Patients switched from olanzapine experienced significant mean weight loss (–3.5 lb; P<0.001) and BMI (P<0.0001). Significant improvements in total cholesterol and triglycerides occurred in patients switched from olanzapine (P<0.0001) and risperidone (P<0.01). Significant decreases in prolactin occurred in patients switched from conventional antipsychotics (P=0.05) and risperidone (P<0.0001). Movement disorders were infrequent with ziprasidone, with significant improvement noted after switch from conventional antipsychotics (P<0.0001) and risperidone (P<0.01). Ziprasidone was well tolerated, with discontinuations from AEs ranging from 6–11%.

Conclusions: Switching to ziprasidone from conventional antipsychotics, olanzapine, or risperidone resulted in significant improvement in several important indices of health status.

P02.06

Therapeutic response in stable outpatients switched to ziprasidone

P.J. Weiden¹*, G. Simpson², S.G. Potkin³, S.J. Romano⁴. ¹*SUNY Health Sciences Center, Brooklyn*; ²*LAC & USC Medical Center, Los Angeles*; ³*University of California, Irvine*; ⁴*Pfizer, Inc., New York, USA*

Objectives: To determine the influence of previous maintenance antipsychotic therapy and speed of cross-taper technique on post-switch efficacy and tolerability of ziprasidone in outpatients with schizophrenia.

Methods: Three identical, 6-week, open-label, randomized trials were conducted in stable, symptomatic outpatients with schizophrenia switched to ziprasidone (40–160 mg/day) from conventional agents (n=108), olanzapine (n=104), or risperidone (n=58). Subjects were randomized to one of three cross-taper schedules – fast, slow, or abrupt discontinuation – for week 1 on ziprasidone. Baseline and outcome assessments included PANSS and CGI-S.

Results: All three crossover schedules were well tolerated, showing no outcome differences by crossover method. Significant symptom improvement from baseline occurred in total PANSS and CGI-I in all three studies. Prior antipsychotic medication did not influence degree of improvement seen.

Conclusions: Stable but symptomatic outpatients switched from other first-line antipsychotics to ziprasidone usually found ziprasidone to be tolerable and effective. Most patients showed symptom improvements within the 6-week treatment period, whether they were switched from conventional or first-line atypical antipsychotics. These results indicate that many patients will experience clinical improvements after being switched to ziprasidone.

P02.07

Ziprasidone vs haloperidol for IM/oral therapy of acute schizophrenia

S. Brook¹*, W. Jorge², I. Benattia³. ¹*Sterkfontein Hospital, South Africa*; ²*University of Freiburg, Germany*; ³*Pfizer, Inc., New York, USA*

Objectives: To compare efficacy and tolerability of sequential IM/oral ziprasidone versus haloperidol in acute schizophrenia.

Methods: 6-week flexible-dose, randomized trial of ziprasidone (<40 mg IM, 80–160 mg oral; n=429) and haloperidol (<10 mg/day IM, 5–20 mg/day oral; n=138). Primary outcomes (change from baseline: BPRS, CGI-S, CGI-I. Secondary outcomes (assessed throughout): Covi, ESRs, BAS, AEs.

Results: Change in BPRS total was significant for ziprasidone versus haloperidol at visit 1 (P<0.005), comparable thereafter. Endpoint CGI-S, frequency distribution of CGI-I, and change in BPRS anxiety scores were comparable throughout. CGI-I scores were “much” or “minimally” improved for most patients, with significantly more ziprasidone completers responding on visits 1 (P<0.05) and 2 (P<0.01). Haloperidol patients had greater mean change from baseline BAS and ESRs scores at all visits (both P<0.0001). Treatment-emergent AEs in >10% of patients included anxiety, insomnia, somnolence – ziprasidone; and akathisia, dystonia, EPS, hypertonia, tremor, insomnia – haloperidol.