

The Effectiveness and Safety of Amisulpride in Chinese Patients with Schizophrenia

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Introduction: Clinical studies and practical use of amisulpride in Chinese population were rarely reported.

Objectives: To evaluate the efficacy and safety profile of amisulpride in Chinese patients with schizophrenia.

Aims: To assess the change of the Positive and Negative Symptom Scale (PANSS) and adverse events emerged during the study.

Methods: In this national, prospective, open-label, multicenter, single arm study, 316 patients with ICD-10 diagnosis schizophrenia were treated with amisulpride for 8 weeks. The PANSS was primarily used for efficacy evaluation.

Results: Of the 295 patients included for efficacy analysis, 66.8% reached a decrease of $\geq 50\%$ PANSS total score at week 8. The mean (SD) baseline PANSS total score was 89.1 (13.7), as the study proceeded, the score decreased to 73.0 (17.7), 60.7 (17.6) and 51.0 (14.6) at week 2, 4 and 8 visits, respectively. The mean (SD) PANSS positive subscale score decreased from 23.8 (5.7) at baseline to 18.1 (6.2) at week 2, 14.1 (5.5) at week 4, and 11.1 (4.1) at week 8. The mean (SD) PANSS negative subscale score decreased from 23.7 (7.9) at baseline to 20.7 (8.0) at week 2, 17.8 (7.8) at week 4, and 15.2 (7.0) at week 8. All above measures were significantly improved at each post-baseline visit compared with baseline ($P < 0.05$). Extrapyramidal disorder (25.9%) and blood prolactin increase (25.9%) were the most frequently reported adverse events, but the incidence of endocrine disorders (8.2%) was relatively low.

Conclusion: Amisulpride had both good clinical efficacy and safety profile for Chinese schizophrenic patients.