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SURVEY OF SAFETY AND EFFICACY OF LONG-ACTING INJECTABLE RISPERIDONE IN DAILY PRACTICE: AN OPEN-LABEL, NON-INTERVENTIONAL PROSPECTIVE STUDY

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Objective: This post-authorization safety survey evaluated the long-term safety, tolerability, and efficacy of risperidone long-acting injectable (RLAI) in routine clinical practice.

Methods: In this 6-month, multicenter, European, naturalistic survey, patients were included if, during routine clinical practice, long-term antipsychotic therapy with RLAI was deemed necessary by the treating physician. Efficacy measures (at baseline and after 1, 3, 6 months) included Clinical Global Impression-Severity (CGI-S) and Global Assessment of Functioning (GAF). Safety was evaluated by recording treatment-emergent adverse events (TEAEs) at every visit.

Results: RLAI was initiated in 5,134 predominantly male (58.6%) patients (aged 14-94 years) with a diagnosis of paranoid schizophrenia (69.8%). RLAI initial doses were 25 mg every-two-weeks in 37.0%, or 50 mg in 44.4% of patients. At endpoint, RLAI dosages were 50 mg in 49.3% of patients, 25 mg in 27.0%, and 37.5 mg in 22.1%. Six-month treatment with RLAI was completed by 4,314 patients (84.0%). RLAI was discontinued due to loss to follow-up (n=346;6.7%), insufficient response (n=116;2.3%), and AEs (n=106;2.1%). CGI-S significantly improved from baseline to endpoint ($p < 0.001$). Patient functioning in the GAF scale also significantly improved from baseline to endpoint (45.4±16.0 versus 62.4±17.7, respectively, $p < 0.001$). TEAEs were recorded by 20% of patients. AEs occurring in ≥5% of patients were akathisia, extrapyramidal disorders, depression, psychotic disorder, anxiety, and weight gain. Serious AEs were reported by 384 (8%) patients.

Conclusions: This large prospective survey confirms the good safety, tolerability, and efficacy of RLAI as reported in previous controlled clinical trials when used in routine clinical practice.

https://doi.org/10.1016/S0924-9338(09)71258-1 Published online by Cambridge University Press