

P03-46 - LONG-TERM SAFETY, TOLERABILITY AND EFFICACY OF RISPERIDONE LONG-ACTING INJECTABLE AND ORAL ATYPICAL ANTIPSYCHOTICS IN SCHIZOPHRENIC PATIENTS: TWO YEAR NATURALISTIC STUDY

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Objectives: This non-interventional study (RIS-SCH-4023) examined tolerability and effectiveness of risperidone long-acting injectable (RLAI) versus oral second generation antipsychotics (oSGA: amisulpride, aripiprazole, olanzapine, quetiapine, risperidone or ziprasidone) in schizophrenia under daily routine.

Methods: Outpatients receiving RLAI (n=177) or oSGA (n=257) were followed-up for 2 years (m/f 42%/58%; mean age 34.6 years; duration of disease 2.6 years). Outcome measures included PANSS, CGI, relapse rates, treatment adherence and tolerability. Post-hoc analyses focused on baseline between-group differences.

Results: Multivariable analysis using recursive partitioning showed that upon study entry RLAI patients were 3.7 times (CI=2.48-5.59) more likely than oSGA patients to have switched to study medication due to non-compliance and/or to be substance abusers (RLAI= 59.9%, n=106/177 vs. oSGA=28.6%, n=73/255). Despite these differences, both groups demonstrated significant improvements in efficacy measures with no between-group differences. There were no significant differences in discontinuation of study medication over the two years (RLAI 41.2% vs. oSGA 36.6%) or in yearly relapse rate before change of the initial therapy (RLAI 0.48±1.48 vs. oSGA 0.71±2.63). In patients with high adherence (≥75%) to previous treatment (physicians' estimates, 4-point Likert scale) RLAI vs. oSGA patients had significantly better retention rates (RLAI 57.4 % vs. oSGA 35.1%) and times (527.0±32.6 vs. 424.1±22.3 days). Most frequently reported treatment-related adverse events were weight increase (13.0% vs. 9.7%), EPS (7.9% vs. 5.5%), hyperkinesia (6.2% vs. 3.5%), fatigue (5.7% vs. 9.7%).

Conclusions: Results suggest that factors associated with poor outcomes such as poor compliance and substance abuse may be attenuated by treatment with RLAI.