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Efficacy and safety of a novel long-acting risperidone formulation

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A new long-acting risperidone microspheres intramuscular formulation was investigated in 370 patients (mean age 38 years) with schizophrenia in a 14-week, multicenter, randomized, double-blind, placebo-controlled trial. Patients received placebo or 25, 50, or 75 mg of long-acting risperidone every 2 weeks for 12 weeks of double-blind treatment. In comparison with placebo, significantly greater changes in total PANSS scores were observed in all long-acting risperidone groups ($p<0.002$ for all doses). Improvements from baseline on the PANSS positive and negative symptom scores were significant in all dose groups ($p<0.05$). Significantly larger proportions of patients with >20% improvement in PANSS scores at endpoint were seen for all doses (25 mg, 47%; 50 mg, 48%; 75 mg, 39%) than for placebo (17%) ($p<0.01$ for all doses). The incidence of extrapyramidal symptoms was similar in the placebo and 25-mg risperidone groups with a nonsignificant increased rate at higher doses. It is concluded that long-acting risperidone was well tolerated and provided continued relief or improvement of symptoms over a 3-month period.

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Long-term safety of long-acting risperidone microspheres

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The safety and efficacy of a long-acting intramuscular formulation of risperidone were investigated in a 1-year, multicenter, open-label trial. Patients with schizophrenia (N=615) or schizoaffective disorder (N=110) who were stable for at least 4 weeks received 25, 50, or 75 mg of long-acting risperidone every 2 weeks for 50 weeks. The most frequently occurring (>10%) reported adverse events (AEs) were anxiety (25%), insomnia (23%), psychosis (18%), depression (16%), headache (13%), hyperkinesia (12%), and rhinitis (11%). Treatment was discontinued because of AEs in 6% of patients. No clinically relevant abnormalities were observed on QTc. The mean increase in weight was 2.7 kg at week 50. Fewer than 1% of patients reported glucose-related AEs. Local injection site reactions were minimal as rated by a VAS and few patients reported pain. In the 670 patients with at least one postbaseline PANSS assessment, total PANSS scores were significantly reduced from baseline at all time points over the 12 months ($P<0.01$). It is concluded that long-acting risperidone was well tolerated and even in these stable patients additional therapeutic benefits were realized.

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UKU-SERS-Pat – the UKU side effect self-rating scale

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A self-rating version of the UKU Side Effect Rating Scale has been developed. The present study examines the agreement between patients' self-assessment of side effects and the attending clinicians' ratings. The patient sample consisted of 63 patients with schizophrenia under maintenance treatment with risperidone, clozapine or classical antipsychotics. Two thirds of the patients used concomitant medication with e.g. benzodiazepines, SSRIs and anticholinergics. Most inter-correlations between scores for single corresponding items, sub-scores of Psychic, Neurological, Autonomic and Other side effects, as well as the Total Score from the self-rating version of the UKU Side Effect Self Rating Scale (UKU-SERS-Pat) and the clinician version (UKU-SERS-Clin) were found to be statistically significant. Patients reported side effects more frequently and/or rated symptoms more severe than the clinicians. The results support the validity of the SERS-Pat and suggest that patient rated side effects may provide important clinical information not detected by clinician rated interviews. Such information can be utilized both in clinical investigations, in development of treatment programs and for individual patients in clinical practice.

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Plasma leptin and weight gain during clozapine treatment

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Objectives: Weight gain is a reported side effect of clozapine, but no predictive factor has been identified. We aimed to investigate whether pretreatment values of circulating leptin or its early changes during clozapine administration could predict the long-term weight gain induced by the drug.

Methods: Body weight and plasma levels of leptin were measured in 22 schizophrenic patients (13 men and 9 women) who had been non-responders to typical antipsychotics. Clozapine was started with dose increments of 25–50 mg every two days to bring patients to the dose of 400 mg/day by the end of the 2nd week. All patients were blood sampled on the day preceding clozapine starting and after 1, 2, 4, 6, 8, 12, 16, 24, and 32 weeks of treatment.

Results: At the end of 2nd week of clozapine administration, plasma levels of leptin increased by 102.5(±32)% while weight gain was 1.6(±0.3)%. Plasma leptin increase was inversely correlated to body weight gain observed after 6 and 8 months of treatment.**Conclusions:** These findings suggest that early changes in leptin secretion may predict long-term weight gain in the course of clozapine administration.

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