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RELAPSE PREVENTION IN SCHIZOPHRENIA AND SCHIZOAFFECTIVE DISORDER WITH RISPERIDONE LONG-ACTING INJECTABLE VERSUS QUETIAPINE: RANDOMIZED, LONG-TERM, OPEN-LABEL, CLINICAL TRIAL RESULTS (CONSTATRE)

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Objective: The ConstaTRE study was designed to compare long-term relapse in stable patients treated with risperidone long-acting injectable (RLAI) or the oral atypical antipsychotic quetiapine.

Methods: This was a randomized, open-label, prospective, active-controlled, multicenter, 2-year trial in symptomatically stable patients with schizophrenia or related disorder who were switched from stable treatment with oral risperidone, olanzapine, or oral conventional antipsychotic to RLAI or quetiapine. Primary efficacy measure was time-to-relapse. Positive and Negative Syndrome Scale (PANSS) scores and safety (adverse events [AEs] and Extrapyramidal Symptom Rating Scale [ESRS]) evaluations were reported.

Results: 710 patients were randomized (n=355 per group), with 666 patients (n=329 RLAI and n=337 quetiapine) being evaluable. Mean doses were 32.8±8.0 mg every-two-weeks for RLAI and 396.8±141.9 mg/day for quetiapine. Kaplan-Meier analysis indicated a significantly longer relapse-free period with RLAI treatment (log rank: p< 0.0001). Relapse occurred in 16.5% of RLAI and 31.3% of quetiapine patients. Mean duration of treatment was 483.8±277.8 and 400.7±290.6 days for RLAI and quetiapine, respectively. Total PANSS scores improved significantly from baseline to endpoint for the RLAI-treated group (p< 0.001). The endpoint difference favors RLAI over quetiapine (p< 0.001). Treatment-emergent AEs were similar between groups. ESRS total scores decreased for both groups. Possibly prolactin-related AEs occurred more often with RLAI than quetiapine (4.6% versus 1.5%, respectively). Somnolence was reported less often with RLAI than quetiapine (1.8% versus 11.3%, respectively).

Conclusions: Time-to-relapse was significantly longer and relapse rates were significantly lower for RLAI compared with quetiapine. Both treatments were well tolerated.