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DESCRIPTIVE ANALYSES OF THE ARIPIPRAZOLE ARM IN THE RISPERIDONE LONG-ACTING INJECTABLE VERSUS QUETIAPINE RELAPSE PREVENTION TRIAL (CONSTATRE)

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Objective: A recent randomized, open-label, relapse prevention trial (ConstaTRE) of risperidone long-acting injectable (RLAI) versus quetiapine and the oral atypical antipsychotic aripiprazole was carried out. Here we report the descriptive analysis of the aripiprazole arm.

Methods: Clinically stable adults with schizophrenia or schizoaffective disorder previously treated with oral risperidone, olanzapine, or oral conventional antipsychotic were randomized to treatment with RLAI, quetiapine, or aripiprazole (in some countries). Efficacy and tolerability were monitored for up to 24 months of treatment.

Results: A total of 45 patients were treated with aripiprazole (10-30 mg/day) and 329 patients with RLAI. Relapse occurred in 27.3% aripiprazole and 16.5% RLAI-treated patients. Kaplan-Meier estimates of mean relapse-free period were 314 versus 607 days for aripiprazole and RLAI patients, respectively. Full-remission, as defined by Andreasen *et al*, (2005), was achieved by 34% aripiprazole and 51% RLAI patients and was maintained until the end of the trial by 30% aripiprazole and 44% RLAI patients. According to Clinical Global Impression-Severity, there were 61% aripiprazole and 62% RLAI patients moderately ill or worse at baseline, and 59% aripiprazole and 45% RLAI at endpoint, respectively. Tolerability was generally similar between aripiprazole and RLAI treatment groups. However, weight gain, extrapyramidal adverse events (AEs), and possibly prolactin-related AEs were more common with RLAI treatment. Gastrointestinal disorders were more common in aripiprazole-treated patients.

Conclusions: Time-to-relapse in stable patients with schizophrenia or schizoaffective disorder tended to be longer in RLAI-treated patients when compared with aripiprazole-treated patients. Both RLAI and aripiprazole treatments were generally well tolerated.

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