AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel XR/IR
ACTIVE INGREDIENT: Quetiapine XR/IR

Study No: NIS-NSE-SER-2010/1, NCT number NCT01214135

Developmental Phase: IV
Study Completion Date: 31 Dec 2010
Date of Report: 3 Nov 2011

OBJECTIVES:

In a retrospective, non-interventional setting, we examined the real life use of quetiapine XR/IR for treatment of hospitalized patients with schizophrenia. The study included assessment of dose levels, add-on therapy and simultaneous use, as well as concomitant medication, disease severity and co-morbidity in these patients.

METHODS:

This study was conducted at 14 sites of in-patient care in Sweden. Patients of both sexes aged 18 - 65 years and diagnosed with schizophrenia (ICD10 diagnosis codes F20, F23.1, F23.2, and F25) could be enrolled.
They had to have been hospitalized for psychotic symptoms (admission and discharge dates available) and received at least one dose of quetiapine XR and/or quetiapine IR at any time during hospitalization (regardless of dose).
Data were collected retrospectively by reviewing medical records during the study period (1st July, 2009 - 30th September, 2010).

Each study site performed a manual search in the medical record system for all patients with schizophrenia who were admitted to hospital due to psychotic symptoms and had received at least one dose of quetiapine XR or quetiapine IR during hospitalization. All patients who fulfilled the eligibility criteria were enrolled into either the quetiapine XR group or the quetiapine IR group. If a subject had received both Seroquel XR and Seroquel IR simultaneously the highest dose determined which group the patient was enrolled in.

All data were entered into a web based data capture system according to study protocol, and was kept anonymous and identified only by an enrolment code.

All analyses were pre-specified in a statistical analysis plan and performed using the SAS software, version 9.2. Means were compared by a t-test, except for GAF values where an analysis of variance was used with least squared means (LSM) and baseline GAF as co-variate.

Proportions were compared using a chi-2 test. The percent of patients treated with concomitant drugs were calculated using a Poison regression with length of hospital stay as offset variable.

The statistical null hypothesis was that the groups had the same average value or proportion and p-values for rejecting this hypothesis were calculated. A p-value below 0.05 was considered as significant.

RESULTS:

A total of 178 patients were included in the study, where 118 (66 %) received quetiapine XR and 60 (34 %) received quetiapine IR. Demographic data were equal for the two treatment groups.

Based on mean daily dose, XR was used as antipsychotic medication in 64% of patients compared to 40% of IR patients (dose $\geq$ 400 mg/d; p=0.002) and in higher doses than IR (494 mg/d vs. 345 mg/d; p=0.001; calculated averages). Schizophrenia was more commonly reported as reason for use for XR than IR (20% vs 0%; p=0.0003). Patients with co-morbid substance abuse and/or somatic disease were more likely to receive XR (p=0.003; p=0.03). Treatment cessation due to non-adherence was less common in XR patients (3.4% vs. 12%; p=0.03). Polypharmacy was seen in 98% of patients.