AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel or Seroquel Prolong
ACTIVE INGREDIENT: Quetiapine Extend Release (Seroquel Prolong) and Quetiapine Immediate Release (Seroquel)

Study No: NIS-NFI-SER-2009/1
A local non interventional retrospective register study of the current clinical treatment practices and the number of hospitalization days with Seroquel or Seroquel Prolong.

Developmental Phase: N.A.
Study Completion Date: 31 Dec 2010 (LSLV)
Date of Report: 12 Dec 2011

OBJECTIVES:

The primary objectives of the study were:

1. To collect information on the used Quetiapine Immediate Release or Quetiapine Extended Release medication
2. To collect information on duration and number of hospitalisation days
3. Change of GAF* points

The secondary objectives of the study were:

1. To collect information on reasons for latest hospitalization
2. To collect information on pre-hospitalisation treatments
3. To collect information on co-medication
4. To collect information on voluntary vs. involuntary treatments in relationship to used medication
5. To collect background information (e.g. other medical conditions, year of birth, sex, housing, education, employment)
6. To collect information on reasons for medication changes

METHODS:

The patient population consisted of patients who were discharged from the South Karelia Central Hospital between June 2008 and June 2010. There was no need for patient informed consent as this retrospective study was based solely on patient records (i.e. hospital databases) and no intervention in routine care took place. The data was gathered systematically by a trained study nurse and using a structured format. The data collected consisted of basic socio-demographic information (age, gender, living circumstances, employment) and information related to the patient's treatment and characteristics at hospital admission (use of antipsychotics at admission, history of psychosis, voluntary/involuntary hospitalization, global assessment of functioning (GAF) score), during hospitalization (drug use, diagnoses) and at discharge (use of antipsychotics, GAF).

The study population consisted of 156 patients (90 men and 66 women). 43 patients used quetiapine XR, 58 patients used quetiapine IR, and 55 patients used both formulations (XR&IR) either concomitantly or sequentially during their hospital stay. All patients using quetiapine XR or IR during their inpatient stay and having SCZ (ICD-10 codes F20-F29) or BD (F30-F31) diagnosis were included in the study population. No exclusion criteria were applied.

All analyses were performed with Stata (R) statistical software, version 11.1.

RESULTS:

Extended release (XR) and immediate release (IR) quetiapine formulations differ with respect to a number of characteristics including dosing, titration, and plasma concentration profiles. This could lead to a differential use of quetiapine XR and IR in the treatment of schizophrenia spectrum disorders (SCZ) and bipolar disorder (BD). We compared the use of quetiapine XR and IR in SCZ and BD in a naturalistic inpatient setting in order to assess whether they differed with respect to, for instance, daily doses, add-on medication and patient characteristics.
We retrospectively collected registry data on patients discharged between June 2008 and June 2010 from a Finnish psychiatric hospital. Patients with a diagnosis of SCZ (ICD-10 codes F20-F29) or BD (F30-F31) who had used quetiapine in hospital were included in the study. Descriptive statistics and significance tests of differences between groups were performed. To assess the profile of XR versus IR patients, logistic regressions were performed.
Amongst the 156 patients (58% male) included in the study, 43 used quetiapine XR, 58 used quetiapine IR, and 55 used both quetiapine formulations. 102 patients (65%) were diagnosed with SCZ and 54 (35%) with BD; no significant differences in diagnosis were observed between the quetiapine formulations. The mean daily dose of quetiapine XR was significantly higher than that of quetiapine IR (542 mg vs. 328 mg; $p<0.001$). This was also true for the SCZ subgroup (XR: 593 mg vs. IR: 338 mg; $p<0.001$) and the BD subgroup (XR: 466 mg vs. IR: 308 mg; $p=0.009$). 48% of all quetiapine IR patients used a mean dose $\leq$200 mg, compared with 2% of XR patients. Quetiapine IR was sometimes combined with injectable antipsychotic treatment, whereas quetiapine XR was not (12% vs. 0%; $p=0.019$). At discharge quetiapine XR was associated with antipsychotic monotherapy to a greater extent than IR (79% vs. 44%; $p=0.003$). In the logistic

regression analysis, quetiapine XR use was significantly associated with decreasing age and prior XR use.
Among SCZ and BD inpatients, quetiapine XR was used in significantly higher doses than quetiapine IR. Compared with quetiapine XR, quetiapine IR was more often combined with other antipsychotics. Differential use of the quetiapine formulations appears to depend, at least in part, on patient characteristics.