

STUDY REPORT SUMMARY

ASTRAZENECAPHARMACEUTICALS

FINISHED PRODUCT: Seroquel

ACTIVE INGREDIENT: Quetiapine

Study No: NIS-NHR-SER-2009/1

Developmental phase: Non-interventional study

Study Completion Date: 07/2010

Date of Report: 03/2011.

OBJECTIVES:

Primary Objective:

- to assess severity of illness and global improvement in patients after 6 months of quetiapine therapy using Clinical Global Impression (CGI) scale

Secondary Objective:

- to measure therapeutic response in schizophrenic patients using BPRS scale
- to evaluate compliance with the prescribed antipsychotic treatment
- to evaluate prescribing practices for quetiapine in the treatment of schizophrenia in Croatia
- to evaluate type and frequency of concomitant therapy
- average number of hospitalizations
- to assess severity of illness and global improvement in patients after 3 months of quetiapine therapy using Clinical Global Impression (CGI) scale
- to evaluate frequency of mental illnesses in patients family

METHODS:

Patient population

This study enrolled Male and female patients aged 18 years and older with diagnosis of schizophrenia (outpatients or hospitalised patients) who are already treated with quetiapine for at least 12 weeks according to standard clinical practice

Design

This study was non-interventional, observational, prospective, non-comparative, epidemiological study. Descriptive statistics will be used for evaluation of collected data.

Study was conducted by 42 psychiatrists.

This non-interventional study had two study visits.

Each PCP enrolled 5-20 consecutive patients on quetiapine therapy for at least 12 weeks. When outpatients or hospitalized patients with diagnosis of schizophrenia visited HCP, the study details were explained to patient and he was asked to sign the Informed Consent in line with local regulations.

During the visits investigator filled in Case Report Forms (CRF) with the data obtained from the interview as well as from patient's medical records.

There were two scheduled visits: at inclusion, and 12-14 weeks after first visit. The time between the scheduled visits was determined according to standard clinical practice in Croatia.

During each visit, investigators filled in Case Report Forms for each patient with patient's demographics data, data related to psychiatric diagnosis, history data, clinical data, data related to compliance in taking of medication, concomitant medication, hospitalisation and recommended therapy.

Table 1. Study plan

	<i>Visit 1</i>	<i>Visit 2</i>
Date of the visit	X	X
Date of signing ICF	X	
Date of birth	X	
Gender	X	
Weight	X	X
History data:		
- date of diagnosis	X	
- No of hospitalisations (before quetiapine was prescribed)	X	
- Family history	X	
Retrospective data		
- Date of quetiapine prescription	X	
- Dose of quetiapine	X	
- Status of disease (when quetiapine was prescribed)	X	
- Quetiapine was prescribed in hospital or in outpatient clinic	X	
- Weight when quetiapine was prescribed	X	
- Social status when quetiapine was prescribed	X	
- Antipsychotic therapy before quetiapine	X	
- Reason for change of therapy	X	
CGI-S scale	X	X

CGI-I scale		X
BPRS scale	X	X
Compliance	X	X
Social status	X	X
Recommended therapy	X	X
Concomitant medication	X	X
Hospitalisations	X	X

Study Drug

Quetiapine

Statistical analysis

Descriptive statistical methods were used for data analysis.

RESULTS:

Demographics

In total, 465 patients were enrolled in the study of which 49.7% were male and 50.3% were female.. Most patients were between 30 and 50 years old.

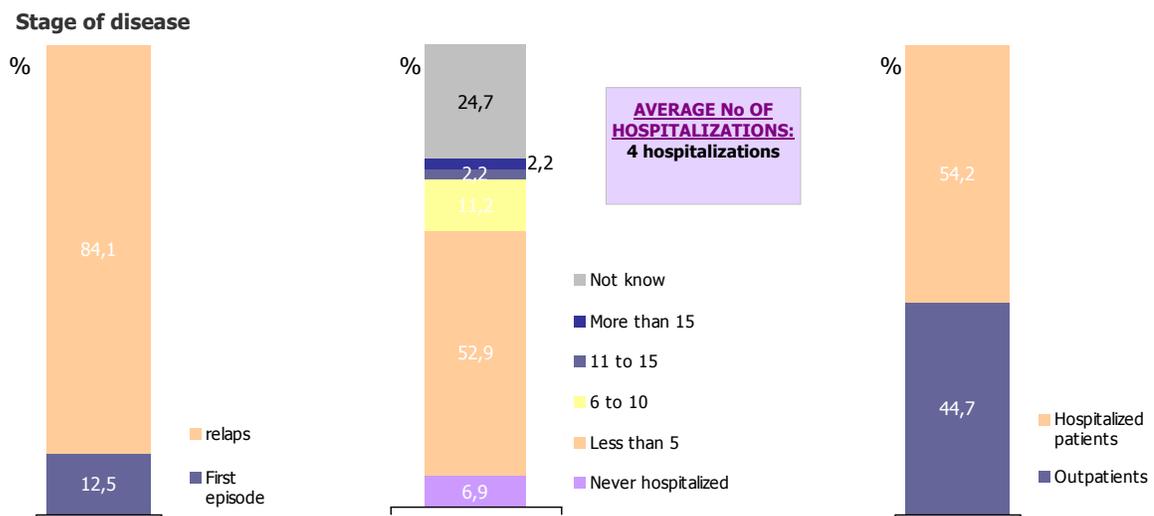
History data

In 25.6% of patients someone of close relatives has psychotics disorder in medical history. Most often it has been mother (32.8%) or father (27.7%) and in majority of cases diagnoses was schizophrenia (50.4%).

Relapse of schizophrenia was entered in 84.1% patients.

Data related to stage of disease and numbers of hospitalizations at the moment of introduction of quetiapine in therapy and the way of introduction are presented in Figure 1.

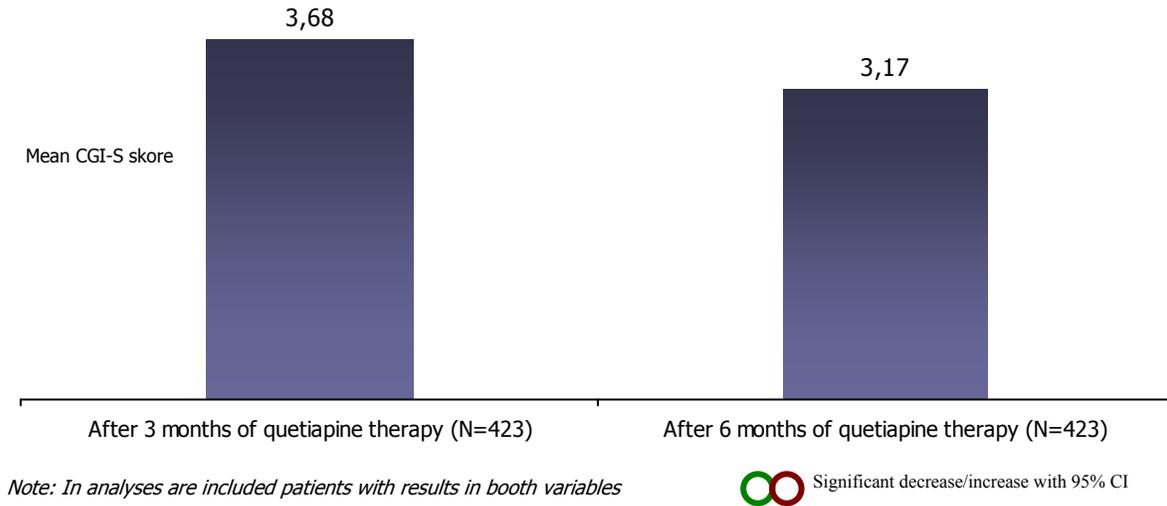
Figure 1. Stage of disease, number of hospitalizations and the way of introduction of quetiapine



Severity of illness and global improvement

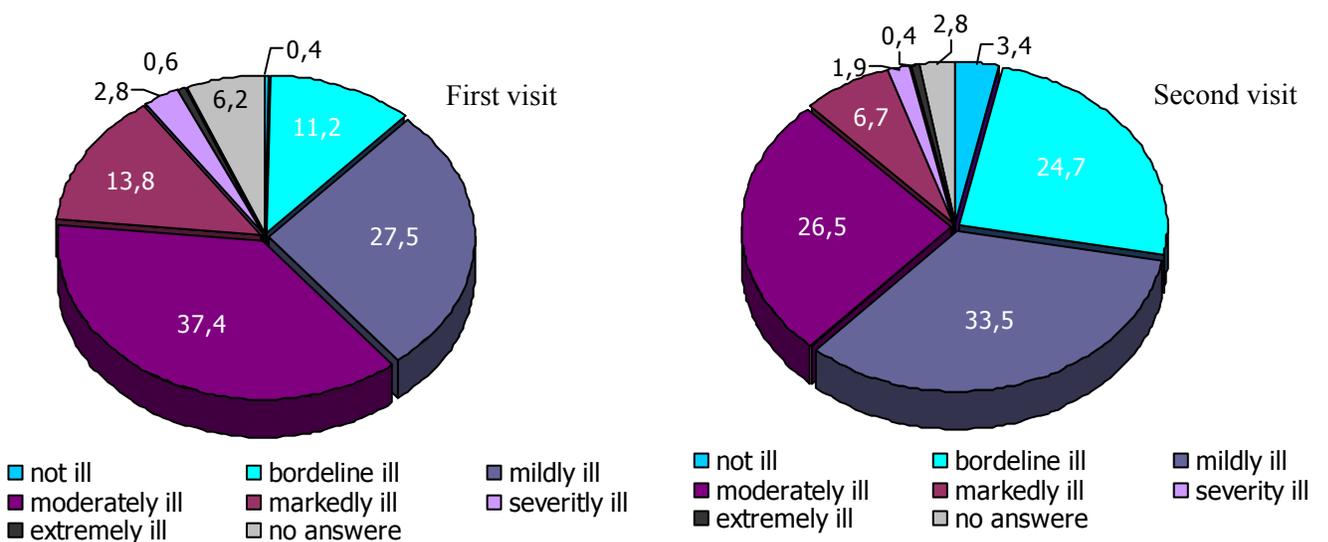
Mean CGI-S score decrease after longer period of quetiapine treatment (Figure 2).

Figure 2.



On first visit the proportion of patients rated as borderline or mild was 38.7% and moderate to severe was 54%. Likewise, on second visit proportion of patients rated as borderline or mild was 58.2% and moderate to severe was 35.1%. (Figure 3)

Figure 3. CGI - Severity of symptoms at visit 1 and 2

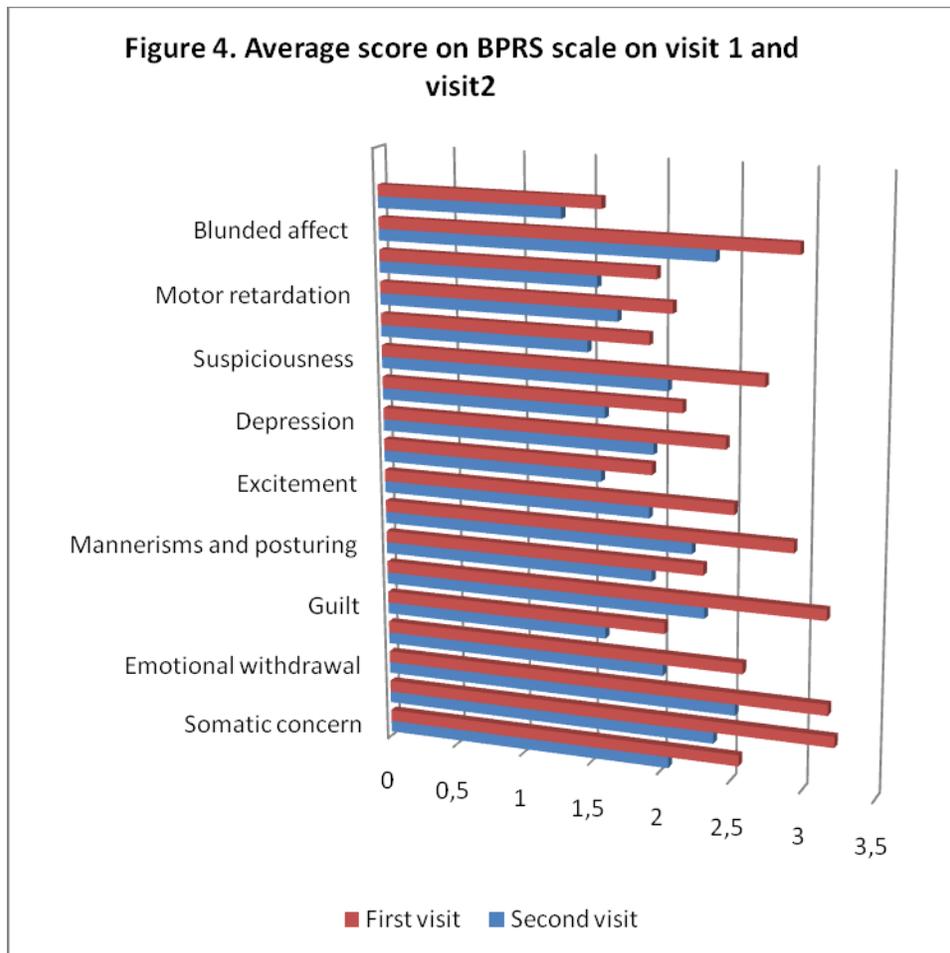


Improvement, assessed on second visit, was recorded in 86.5% of patients. Following CGI-Improvement scale progression of disease was recorded in 2.6% of patients whereas in 6.2% of patients no changes were recorded.

Therapeutic response

Measuring therapeutic response in schizophrenic patients using BPRS scale showed significant differences between visits in mean BPRS total score (after 6 months of quetiapine therapy M=34,4; after 3 months of quetiapine therapy M=44,3).

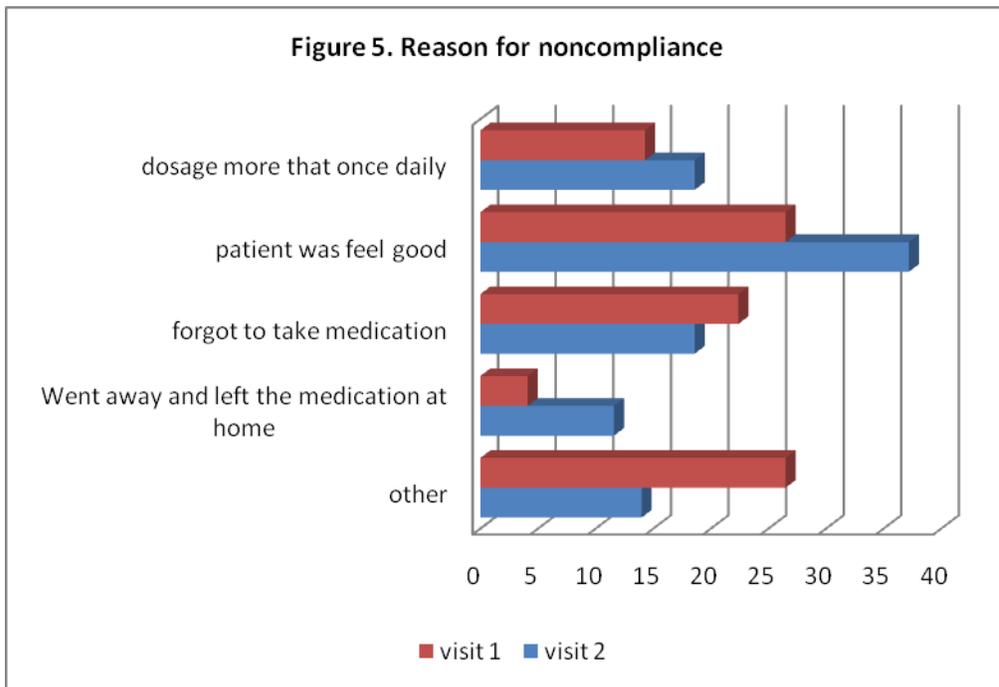
Decreases are recorded in mean points for each symptom (see Figure 4).



Compliance with the prescribed antipsychotic treatment

The overall mean levels of compliance on the first and second visit were 89.7% vs. 90.8%

Reason for noncompliance was shown in Figure 5.



Further therapy with quetiapine

At the visit 2 majority of patients (95.7%) continued quetiapine therapy. Therapy was stop in 13 cases. 4 patients were turn out because of disease progression, 4 because of lack of efficacy and 5 because of other reason (non-compliance, on patient request)

Adverse event

No adverse events were reported in this study.