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Poster presentation

Quetiapine dose titration in clinical practice

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Background

An 8-week, multicentre, open-label, dose titration study of Quetiapine (Seroquel®) in patients with Schizophrenia was carried out with the objectives to (a) record the titration scheme and maximum achieved dose of Quetiapine for each patient and (b) assess the clinical efficacy and tolerability of Quetiapine as monotherapy.

Material and Methods

The study took place at 45 primary health care and hospital study sites. Patients diagnosed with schizophrenia of mild to moderate severity, hospitalized or outpatients, newly diagnosed or in acute exacerbation of chronic or subchronic schizophrenia were included in the study. All patients were required to score (a) at least 45 on the 18-item BPRS, (b) at least 4 (moderate) on two or more of BPRS items and (c) at least 3 on the CGI Severity of Illness item. Patients should be titrated with the assistance of "the Quetiapine titration pack" and reach the dose of 400 mg by day 5. During follow up the optimum dose for each patient should be reached in order to achieve symptoms' control. Psychopathology was assessed at baseline and at each of the six scheduled visits with the assistance of the BPRS, PANSS, CGI, and SAS scales. An overall assessment scale was also included, asking doctors to rate patients' progress as high, moderate or low improvement. Investigators were allowed to evaluate patients on all or selected rating scales. They were also allowed to prescribe concomitant medication (lorazepam, chloral hydrate, zolpidem). Before study enrollment patients provided written or witnessed verbal informed consent. In an intention to treat analysis, Chi-Square, Fischer's Exact Test and Analysis of Variance (ANOVA) were used as appropriate.

Results

419 patients were eligible for statistical evaluation. Mean age was 37+ 11.5 years. 236 (56.32%) patients were male and 183 (43.68%) female. 68 (16.23%) patients were newly diagnosed and 351 (83.77%) were in acute exacerbation of chronic or subchronic schizophrenia.

Evaluated patients completed the dose titration period as follows: Day 1: 50 mg, Day 2: 100 mg, Day 3: 200 mg, Day 4: 300 mg, Days 5–8: 400 mg, Day 9: 600 mg. At day 56 (end of study period) in 117 patients (27.92%) the dose was maintained at 600 mg, in 239 patients (57.04%) the dose increased to 800 mg and in 63 patients (15.04%) the dose reached 1200 mg/day. Mean Quetiapine dose was 690 mg at day 56. Previous medication wash out was performed by dose decrease from 100% (day 1) to 50% (day 4) and finally 0% (day 8).

Regarding treatment efficacy, 241 (57.51%) patients were evaluated by overall assessment, 70 (16.71%) patients were evaluated by BPRS and 108 (25.78%) patients were evaluated by CGI. Based on psychopathology therapy evaluation 318 (75.89%) patients expressed high improvement score during overall treatment assessment, 83 (19.81%) patients expressed medium improvement score and 18 (4.3%) patients expressed low improvement score ($p = 0.000$). 28 patients (6.68%) recorded the following AEs: sedation (11), mild BP decrease (9), somnolence (8). No other AEs were reported during the study period.

Discussion

1) Dose titration of Quetiapine started at day 1 with 50 mg and reached 600 mg by day 9. Thereafter dose was

individually adjusted and reached a maximum of 1200 mg by day 56. Overall the mean dose for the study population at day 56 was 690 mg of Quetiapine. 2) Overall Quetiapine proved to be effective in improving patients' symptoms as 75.89% of patients showed high improvement according to the overall psychopathology assessment score, 19.81% showed moderate improvement, whereas only 4.3% showed low improvement. 3) Newly diagnosed patients were maintained at lower dose than already diagnosed patients. 4) The rates of recorded AEs were extremely low (6.68%) and not dose dependent.