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The efficacy and safety of quetiapine in patients with bipolar disorder quetiapine in practice evaluation program (IPEP)

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Background

Bipolar Disorder is a serious mental illness that affects approximately 3–4% of the adult population and is the sixth leading cause of disability in the world. More than half of those patients stop taking their medication at some point during their illness, subjecting themselves to a high risk of relapse and an increased risk of suicide. A medication's overall efficacy and tolerability profile is therefore vital to helping patients comply with their treatments.

Materials and methods

This is a 6-month "In Practice Evaluation Program" that evaluates whether patients with bipolar disorder who were treated with Quetiapine (Seroquel™) were significantly more likely to achieve remission of their mania symptoms.

This open label program was conducted all over Greece by recruiting 517 patients diagnosed with Bipolar I Disorder. Based on clinical program design the recommended titration of daily dosage was 200–800 mg Quetiapine (day 1-day 4) and afterwards the dosage was determined individually in order to achieve remission of their symptoms. The program design included patients' visits during a 6-month period. The treatment efficacy objectives were measured by Clinical Global Impression Scale (CGI). The treatment safety parameters were followed by detailed reporting of adverse drug reactions.

Results

517 patients (50.6% males and 49.4% females) by 78 study sites, aged 39.3+11.3 years were recruited in the program within 6 months period of time (July-Oct 2004). At program initiation 88 (17%) patients were hospitalized, 102 (19.7%) were newly diagnosed and 349 (67.5%) were switched from previous therapies due to experience of limited efficacy (46.7%) and adverse events (68.2%) such as EPS (47.4%), weight gain (46.5%). The mean dose of Quetiapine reached 663 mg/day (min 100, max 1600 mg/day). After 6 months treatment with Quetiapine 90% of patients were evaluated: 14.4% expressed no change, 15.7% low, 33.5% high and 36.1% very high improvement according to CGI scale score ($p = 0.000$, Wilcoxon rank text). The program also demonstrated that the Quetiapine group had significantly greater response compared to previous therapies (severity of illness 59.4% vs. 4.1 %, $p < 0.001$) as defined by the Clinical Global Improvement Score (severity of the illness).

Quetiapine was well tolerated with an incidence of somnolence (0.4%), sedation (0.4%), dizziness (0.2%), and weight gain (0.2%). Compliance to Quetiapine therapy was reported as 97% at final visit.

Discussion

The results of the program show that Quetiapine was superior to previous therapies in reducing symptoms, as measured by CGI scores, in patients with bipolar disorder.

The improvements were noted at every assessment during the 6-month program. In addition, approximately 69.6% of patients receiving Quetiapine achieved remission from their bipolar disorder symptoms.

Quetiapine also demonstrated a good safety profile in this patient population.