

## Efficacy and Tolerability of Pregabalin vs Sertraline in Generalised Anxiety Disorder Concise Communication

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Generalised Anxiety Disorder (GAD) represents a chronic mental illness characterized with pathological fear, extremely persistent worry usually about minor everyday problems and with numerous vegetative symptoms [1-17]. It represents a difficult problem in Mental Health, as the life occurrence of GAD is 5-7%. Symptoms of GAD, according to ICD-X and DSM-V even today can be misdiagnosed, and inadequately treated [8-24]. If the symptoms are long-lasting and untreated, often comorbidity with depression, alcohol abuse, and high suicidality level make an extremely serious mental problem [2-9]. GAD interfered significantly with everyday activities and causes substantial personal distress so proper diagnosis and adequate treatment have to become a priority in medical practice. WFSBP (World Federation of Societies of Biological Psychiatry) recommends SSRI (Selective Serotonin Reuptake Inhibitors), SNRI (Serotonin and Norepinephrine Reuptake Inhibitors) and pregabalin, atypical anxiolytic as first-line treatment, in combination with psychotherapy [7-19]. In the present study, efficacy and tolerability of pregabalin vs. sertraline in patients with diagnoses of GAD was observed. The study included 107 in-patients aged 20-60, both genders. Duration of disorder was on average 4,7±0,3 years in the group of patients treated with sertraline and about 4,6±0,4 in the group treated with pregabalin. In previous episodes, 98% of all included patients were treated with SSRI and SNRI, in adequately therapeutic doses. Actually, patients were admitted to daily treatment due to a new episode of GAD. In included patients, wash-up period was one week. At the beginning of the study, all patients were required to have a Covi Anxiety Scale, total score >9 and total score on HAMA (Hamilton Anxiety Scale) >20. In the first group, patients were treated with sertraline, (doses began from 50 mg up to a mean value of 150 mg/die). Doses were titrated during one week. In the second group, patients were treated with pregabalin, doses at the first day were 75 mg, and titrated to 225 mg/die during one week. In all included patients, cognitive-behavioral therapy, individual and group was performed, during investigation. The primary analysis was change in Hamilton Rating Scale for Anxiety (HAMA), a total score from baseline to endpoint. Secondary indicators of efficacy were change in HAMA psychic (emotional) and somatic (physical) scores weekly till endpoint. Global clinical assessment was conducted by using the Clinical Global Impression change rating (CGI).

HAMA was repeated every week to evaluate therapeutic effects used by two independent psychiatrists. Each patient was randomly assigned to 4 weeks of treatment with pregabalin (n=47) or sertraline (n=60). Adverse events were reported in 26% of all patients, with no significant differences among two groups of patients. Among patients treated with sertraline, the most common adverse event was nausea (13%) and dizziness (5%), and in the group there also appeared dizziness (13%) and somnolence (10%). In these patients, adverse events were short-lasting, dose-dependent and mild intensity. With reduction of doses, adverse events disappeared and therapeutic effects persisted. There were no withdrawal events during this study.

Results of this study showed that both pregabalin and sertraline showed good effect in treating symptoms of Generalized Anxiety Disorder. Time of acting onset was shorter in treatment with pregabalin compared to treatment with sertraline. In the patient treated with sertraline, anxiolytic effect was detectable after at least 14 days in the present

study, and pregabalin showed first good results during the first week of treatment. Adverse effects were reported in 28% of patients treated with pregabalin and 27% of patients treated with sertraline, with no significant difference.

In the present study, efficacy and tolerability of pregabalin were high. Compared to sertraline, pregabalin showed more rapid time of action and equal efficacy. Adverse events are short-lasting and dose-dependent. Our investigation showed that pregabalin, an atypical anxiolytic, is efficacious and well-tolerable in the treatment of G.A.D.

In perspective, longer-term studies will be required to assess the long-term safety and efficacy of pregabalin in the treatment of GAD.

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