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TREATMENT EFFECT OF AGOMELATINE ON DEPRESSIVE SYMPTOMS AND PATIENTS´ COMPLIANCE: RESULTS OF THE NON-INTERVENTIONAL STUDY VITAL OVER 6 MONTHS

M. Lemke[1], *B. Barthel*[2]

[1]Ev. Stiftung Alsterdorf - Psychiatry, Psychotherapy, Psychosomatic Medicine, Hamburg, [2]SERVIER Deutschland GmbH, Munich, Germany

Introduction: Agomelatine, a melatonergic agonist and 5-HT_{2c}-antagonist, has demonstrated antidepressant efficacy in clinical trials.
Aims: Aim of VITAL was to document treatment with agomelatine non-interventionally in daily practice over 6 months.
Objectives: Evaluation of the effectiveness of agomelatine on depressive symptoms, daytime activity, tolerability and compliance in depressed patients under routine conditions.
Methods: 3005 outpatients aged>18 years were observed by 1169 psychiatrists and general practitioners in Germany over 6 months, treated with agomelatine 25-50 mg once daily. Antidepressant effectiveness was evaluated by Beck Depression Inventory (BDI-II), effects on daytime activity by two questions of Circscreen (patient questionnaire), compliance by standardized questions. ADRs were documented every visit.
Results: Included patients (BDI-II total score 31.9) improved during 6 months treatment with agomelatine (BDI-II 9.6). Responder rate (≥50% reduction of BDI-II) rose steadily from 11.7% (2 weeks), 62.0% (12 weeks) to 79.0% (6 months). 55.3% of patients were classified as remitters (BDI ≤9) after 6 months. According to CGI, 20.7% had responded after 2 weeks, 81.6% at study-end (CGI-I≤2). At baseline 53.2% were markedly impaired in normal daily activity compared to 16.1% of patients at the end of study. 64.5% at baseline versus 9.1% after 6 months felt sleepy during daytime (Circscreen). 89.6% of 2511 patients at study-end documented good compliance (regular intake). Adverse drug reactions (mainly headache, dizziness) were reported by 3.6%, 0.6% of patients had reversible ALT/AST>3ULN (n=12).
Conclusion: Antidepressant effectiveness of agomelatine, improvement of daytime activity, good tolerability and good compliance were observed in unselected depressed patients over 6 months.

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