Statistically significant age-related distribution was found for 5 side effects: bradycardia, nausea, diarrhea, sweating and headache. Bradycardia was more prevalent in elderly (>65 years) patients as compared to younger population (2.4% vs 0.2%, $p < 0.05$), while gastrointestinal side effects, sweating and headache were less prevalevt in the elderly. The age-related differences in the side effect profile may be attributable to altered sensitivity of the serotonergic system.

P01.05

Antidepressant remeron in the treatment of alcoholism

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Antidepressant medications have lately been used successfully to treat chronic alcoholism. At the same time, there is no information concerning the usefulness of a new antidepressant Remeron (mirtazapin) in this respect. So the aim of the present work was to study the effect of Remeron in treating pathological craving for alcohol and affective (depressive) disorders related to alcohol dependence. Thirty male alcoholic patients between the ages of 28 to 54 with the developed alcohol dependence (ICD-10) and alcohol related affective (depressive) disorders were entered into the study. The illness duration varied from 5 to 20 years. Remeron was given in tablets of 30 mg/day for 4 weeks. The therapeutic effect of Remeron was noted as early as the very first days of the treatment course. The study has revealed high therapeutic efficacy of Remeron in the treatment of pathological craving for alcohol and alcohol related affective disorders. Remeron has also anxiolytic, hypnotic and vegetostabilizing effects. So Remeron might be recommended as an effective and harmless medication to be included in the complex therapeutic programs for treating alcoholic patients.

P01.06

Lithium augmentation in venlafaxine non-responders: an open study

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Thirteen major depressive patients not responding (less than 50% decrease of their baseline MADRS score) to a four-week venlafaxine 300mg treatment were eligible for a four-week open trial of lithium addition. These patients were part of an initial group of 50 patients. If the patients had an insomnia resistant to the allowed sedatives (zopiclone, clorazepate), trazodone could be added to venlafaxine at bedtime during the prelithium phase: 7 of the 13 patients received trazodone. Lithium dose was individually determined according to 24 hrs single dose plasma level: the mean steady state plasma levels ranged between 0.75 and 0.81 mmol/L. Two patients had to stop lithium before the end of the study. Among the 11 other subjects, five patients became responders, including one patient with a dramatic response (dropping of the MADRS score from 40 to 14 in four days) and two patients had a semi-rapid response (within two weeks). The two patients who dropped out did so for similar reasons involving a mixed-manic switch, nausea and trembling. Retrospectively we believe that these may have been moderate cases of serotonin syndrome.

P01.07

Antidepressant and anxiolytic effect of St. John's wort extract ZE-117

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Objectives: The anxio-antidepressant efficacy of ZE-117 was evaluated in depressive patients.

Methods: Three prospective, randomized, multicentre, double-blind controlled studies were conducted in accordance to GCP. Patients (ICD-10 F32.0, F32.1) were treated 6 weeks with 2x250mg/day ZE-117 (Esbericum® forte) or Placebo, Fluoxetine (20mg/day) resp. Imipramine (150mg/day). Severity of depressive complaints was measured by Hamilton Depression Scale (HAMD); anxiety symptoms were evaluated by corresponding subgroup analysis. Secondary variables were Clinical Global Impression (CGI) I-III, analog scales and adverse events (AE).

Results:

Demographic and anamnestic data were comparable.

Based on HAMD-responders ZE-117 was superior to Placebo (56% versus 15%) and Fluoxetine (60% versus 40%) and equivalent to Imipramine (ZE-117: 43; TCA: 40%).

There was a marked decrease of anxiety symptoms during therapy with ZE-117. This relieve was comparable with Fluoxetine and Imipramine and superior to Placebo.

AE were more frequent in patients treated with Fluoxetine or Imipramine in comparison with ZE-117 ($p<0.01$); and approximately in the same frequency as under Placebo.

Conclusions: ZE-117 shows a favourable benefit-risk ratio in the treatment of the anxio-depressive syndrome in depressive patients

P01.08

Efficacy and tolerability of mirtazapine in HIV-1 infected outpatients

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Objective: Prospective, longitudinal, open-label, observational study to assess the efficacy and tolerability of mirtazapine in the treatment of major depression in HIV-1 infected outpatients. Methods: Twenty-seven HIV-1 infected patients with major depression were assessed at baseline and after 1, 2, 4, 8 and 16 weeks of treatment with mirtazapine using Hospital Anxiety and Depression Scale (HADS), Beck Depression Inventory (BDI), and the Global Clinical Impression (GCI). Side effects were recorded. Outcome of completing patients was analysed using univariate repeated-measures analysis of variance (ANOVA) or Friedman test.

Results: Sixteen patients dropped-out before reaching the last visit, mainly due to somnolence and dizziness (5 patients). Completing patients (41%) showed a significant ($p<0.05$) improvement in all measures: 58% on GCI, 53% on BDI, and 46% on HADS depression subscale. Most of all the patients improved their insomnia during the first week of treatment. No side effects on sexual functioning were observed. No significant changes on weight were observed.

Conclusions: Despite the risk of abandonment due to side-effects, mirtazapine should be considered in the treatment of depressed HIV-1 infected patients because its rapid improving effect on all measures of depression, especially on sleep disturbances.

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