bei Patienten der beiden Gruppen. 36 Patienten wurden mit Mianserin (Lerivon), Dosis 7.5–15 mg/Tag (max 30 mg/Tag) 46-mit Alprazolam (Cassadan), Dosis 0.06–0.125 mg/Tag (max 0.25 mg/Tag) behandelt. Bei der Behandlung mit Mianserin wurde eine positive Wirkung bei 83.3% der Kranken gefunden, bei der Behandlung mit Alprazolam - bei 78.3% Patienten. Die Dynamik des Patienten-zustandes wahrend der Behandlung war ahnlich. Unterschiedlich war die Auspragung der antidepressiven Wirkung (Mianserin starker, als Alprazolam).

Tues-P39

VENLAFAXINE IN ELDERLY DEPRESSED PATIENTS. A MULTICENTER STUDY

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Objective: To study the possible differences in the management of depression with Venlafaxine between patients aged 65 years and over, and patients under 65.

Design: A nation-wide observational, prospective, longitudinal study.

Subjects: 5012 Out-patients with DSM-IV major depression, with age ranging from 18 to 97 years, 30.6% male and 69.4% female, who received treatment with Venlafaxine for 6 months. 577 patients were^3 65 years old, of which 75.3% were female and 24.7% male.

Assessment of depression was carried out over a total of 5 visits using Hamilton's 17 items scale and Clinical Global Impression Scale (CGI).

Results: The score in Hamilton's scale at baseline was 22.8 and 5.3 in the final visit at six months for patients^3 65 versus 23.2 and 5.6, respectively, for patients <65 (NS). Total CGI at 6 months resulted in "a great deal of improvement or much improved" in 84.88% for patients^3 65 versus 84.36% for patients <65 (NS). Mean dosing was 101.9 mg/day for patients^3 65 versus 107.8 for patients <65 (p = 0.006).

Compliance with treatment was 94% for both age groups.

Out of the total 577 elderly patients, only 63 (10.9%) reported side-effects. For patients <65, the percent of side-effects was 11.8% (NS). The most frequent events were: nausea and vomiting, constipation, nervousness, tremors and dry-mouth.

Conclusions: Outcome of elderly patients being treated for depression does not vary in relation to that of the remaining population, either in terms of efficacy or tolerance.

Tues-P40

OPTIMAL LENGTH OF CONTINUATION THERAPY: A PROSPECTIVE ASSESSMENT DURING FLUOXETINE LONG-TERM TREATMENT OF MAJOR DEPRESSIVE DISORDER

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Objective: To prospectively determine optimal length of fluoxetine continuation therapy following successful acute treatment of major depressive disorder.

Design: Outpatients were treated for 12 to 14 weeks with fluoxetine (20 mg/day). Patients meeting response criteria were randomized to 50 weeks of double-blind continuation therapy comprised of placebo crossover periods as follows:

- immediate placebo crossover for 50 weeks (crossover group-1);
- fluoxetine for 14 weeks followed by placebo crossover for 36 weeks (crossover group-2);
- fluoxetine for 38 weeks followed by placebo crossover for 12 weeks (crossover group-3);
- fluoxetine for 50 weeks (no crossover).

Actual relapse rates and Kaplan-Meier estimates were determined during three fixed 12-week time intervals following each placebo crossover.

Results: Relapse rates were statistically significantly higher in patients initiating placebo in crossover group-1 (48.6% vs. 26.4% $p < 0.001$) and crossover group-2 (23.2% vs. 9.0% $p < 0.05$) than in patients remaining on fluoxetine. Relapse rates were not statistically significantly higher in patients initiating placebo in crossover group-3 than in patients remaining on fluoxetine (16.2% vs. 10.7%, NS).

Conclusions: These data suggest that following a successful 12-week course of acute therapy, additional protection against relapse is associated with continuation therapy of at least 26 further weeks (38 weeks total).

Tues-P41

ADVERSE EVENT PROFILES ASSOCIATED WITH LONG-TERM FLUOXETINE TREATMENT

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Background: The Agency for Health Care Policy and Research Guideline state that "most patients should receive the full therapeutic dosage of antidepressant drug for 4 to 9 months of continuation therapy after symptom remission is achieved." We examined the safety of fluoxetine 20 mg/day in long-term treatment in a large, prospective trial and report a comparison of early and late adverse events (AEs) and the course of AEs over time.

Design: AEs were recorded at each visit in a uniform format by open-ended questioning, regardless of perceived causality. The frequencies of common new/worsened AEs reported in the first four weeks (early) or the 22nd–26th weeks of treatment (late) were compared using McNemar's test.

Results: 299 patients with major depressive disorder responded to 12 weeks of fluoxetine treatment and entered continuation therapy and 174 completed 26 weeks of therapy. All early events which occurred in $\geq$ 5% of patients declined significantly ($p < .05$) over time and no events occurred significantly more frequently during continuation therapy.

Conclusions: Common adverse events associated with initiating fluoxetine in depressed patients resolve in the majority of patients and are significantly less frequent with ongoing treatment. Overall, therapy with fluoxetine 20 mg daily is well tolerated over a 6 month period.

Tues-P42

CHANGES IN INSOMNIA DURING TREATMENT OF DEPRESSION: ANALYSIS OF FLUOXETINE DOUBLE-BLIND, PLACEBO-CONTROLLED TRIALS

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Objective: Examine the effects of fluoxetine, a nonsedating antidepressant, on depression related insomnia symptoms.

Method: Retrospective analysis of data from 7 double-blind clinical trials of 2456 patients with major depression randomly assigned to fluoxetine or placebo treatment. Baseline HAMD-Sleep Disturbance Factor score was used to categorize patients