

as having low (<4) or high (≥4) insomnia. Baseline-to-endpoint reduction in this score was used as a measure of improvement. The frequency of treatment-emergent insomnia (appeared or worsened during treatment) was also determined.

**Results:** Fluoxetine-treated patients with high baseline insomnia experienced significant reductions in their HAMD-Sleep Disturbance Factor score compared with placebo-treated patients (fluoxetine, -2.129; placebo, -1.616;  $p < .001$ ). Patients with low baseline insomnia showed a slightly decreased (NS) Sleep Disturbance score in both treatment groups (fluoxetine, -0.243; placebo, -0.272). Improvement in mean HAMD total scores for fluoxetine-treated patients (total, high, and low insomnia) was statistically significantly greater compared with placebo-treated patients. Frequency of treatment-emergent insomnia with fluoxetine treatment was similar regardless of baseline Sleep Disturbance score (low insomnia, 15.7%; high insomnia, 16.0%).

**Conclusion:** These findings demonstrate that fluoxetine-treated patients with high baseline insomnia experience improvement in insomnia symptoms as their overall depression improves. Treatment-emergent insomnia in fluoxetine-treated patients cannot be predicted based on a patient's presenting sleep disturbance.

### Tues-P43

FLUOXETINE VERSUS SERTRALINE AND PAROXETINE IN MAJOR DEPRESSION: TOLERABILITY AND EFFICACY IN PATIENTS WITH LOW AND HIGH BASELINE INSOMNIA

M. Fava<sup>1</sup>, J.F. Rosenbaum<sup>1</sup>, S.L. Hoog<sup>2\*</sup>, R.G. Tepner<sup>2</sup>, J.B. Kopp<sup>2</sup>, M. Saylor<sup>2</sup>. *The Fluoxetine Collaborative Study Group; <sup>1</sup>Massachusetts General Hospital, Boston, MA; <sup>2</sup>Eli Lilly and Company, Indianapolis, IN, USA*

**Objective:** Assess whether fluoxetine, sertraline, and paroxetine differ in efficacy and tolerability in depressed patients with low or high baseline insomnia.

**Methods:** Patients (N = 284) with DSM-IV depression were randomized to fluoxetine, paroxetine, or sertraline treatment in double-blind fashion. Using HAMD-Sleep Disturbance Factor score, patients were categorized as having low insomnia (<4) or high insomnia (≥ 4) at baseline. Changes in overall depression and insomnia were assessed.

**Results:** Within both low/high insomnia subgroups, patients demonstrated similar HAMD-17 improvement (low insomnia: fluoxetine, -10.4, ± 7.1; sertraline, -12.2, ± 7.7; and paroxetine, -11.9, ± 6.6;  $p = 0.392$  and high insomnia: fluoxetine, -13.2, ± 8.2; sertraline, -14.7, ± 7.5; and paroxetine, -12.9, ± 8.5;  $p = 0.545$ ) and HAMD Sleep Disturbance Factor improvement (low insomnia subgroup: fluoxetine, -0.6, ± 1.5; sertraline, -0.7, ± 1.6; and paroxetine, -0.7, ± 1.8;  $p = 0.996$  and high insomnia: fluoxetine, -3.1, ± 2.0; sertraline, -3.3, ± 1.8; and paroxetine, -2.9, ± 2.4;  $p = 0.705$ ). There were no significant differences between treatments in percentages of patients with substantial worsening, any worsening, worsening at endpoint, or improvement in the HAMD-Sleep Disturbance Factor score, in either subgroup. Treatments were well tolerated in both subgroups.

**Conclusion:** These data show no significant differences in efficacy and tolerability of fluoxetine, sertraline, and paroxetine in patients with low or high baseline insomnia during acute treatment of major depression.

### Tues-P44

FLUOXETINE VERSUS SERTRALINE AND PAROXETINE IN MAJOR DEPRESSION: TOLERABILITY AND EFFICACY IN PATIENTS WITH HIGH AND LOW BASELINE ANXIETY

M. Fava<sup>1</sup>, J.F. Rosenbaum<sup>1</sup>, S.L. Hoog<sup>2\*</sup>, R.G. Tepner<sup>2</sup>, J.B. Kopp<sup>2</sup>, M. Saylor<sup>2</sup>. *The Fluoxetine Collaborative Study Group; <sup>1</sup>Massachusetts General Hospital, Boston, MA 02114; <sup>2</sup>Eli Lilly and Company, Indianapolis, IN 46285, USA*

**Objective:** Assess whether fluoxetine, sertraline, and paroxetine differ in efficacy and tolerability in depressed patients with high/low associated anxiety.

**Methods:** Patients (N = 284) with DSM-IV depression were randomized to fluoxetine, paroxetine, or sertraline treatment in a double-blind fashion. Using HAMD Anxiety/Somatization Factor score, patients were categorized as having high (≥ 7) or low anxiety (<7) at baseline. Changes in overall depression and anxiety were assessed.

**Results:** Within both subgroups, patients demonstrated similar HAMD-17 improvement (high anxiety subgroup: fluoxetine, -14.4, ± 7.4; sertraline, -16.8, ± 6.2; and paroxetine, -15.4, ± 7.6;  $p = 0.323$  and low anxiety subgroup: fluoxetine, -9.9, ± 7.2; sertraline, -10.4, ± 7.6; and paroxetine, -11.0, ± 7.1;  $p = 0.700$ ) and HAMD Anxiety/Somatization Factor improvement (high anxiety subgroup: fluoxetine, -4.7, ± 2.6; sertraline, -5.8, ± 2.6; and paroxetine, -5.3, ± 2.7;  $p = 0.199$  and low anxiety subgroup: fluoxetine, -2.5, ± 2.4; sertraline, -2.6, ± 2.4; and paroxetine, -2.7, ± 2.2;  $p = 0.935$ ). There were no significant differences between treatments in percentages of patients with substantial emergence, any worsening, worsening at endpoint, or improvement in items 9 (agitation), 10 (psychic anxiety), and 11 (somatic anxiety) in either subgroup. Treatments were well tolerated in patients with both high and low baseline anxiety.

**Conclusion:** These data showed no significant differences in efficacy and tolerability of fluoxetine, sertraline, and paroxetine in patients with high/low baseline anxiety symptoms during the acute treatment of major depression.

### Tues-P45

COMBINED MOCLOBEMID, PROMAZINE ADMINISTRATION — A SAFETY TREATMENT IN ELDERLY DEPRESSIVE AGITATION

D. Marinković. *Institute of Psychiatry, UCC, Belgrade, Serbia, Yugoslavia*

Elderly depressives are often difficult to be treated, due to somatic obstacles. The moclobemide efficacy is proved to be safety choice in the inhibited depressive forms. The sample consisted of endogenous depressives and patients suffering from unipolar and bipolar depressive form. All inpatients were treated with moclobemide, dose range 450–600 mg/day. Due to severe agitation, at the same time was administrated promazine 25–100 mg/day, chlorpromazine 25–100 mg/day and diazepam 15–30 mg/day. Moderate therapeutic effect has been achieved in 22.2% treated. The therapeutic response was good in 66.7%. Because of poor therapy response 11.1% were dropped out. Total HRDS score and CGI analysis pointed out that significant therapeutic effect is achieved yet on 14<sup>th</sup> day of treatment ( $p < 0.01$ ). Cluster items monitoring agitation, psychic and somatic anxiety and suicidal tendency demonstrated the significant score reduction at the end of second week following discontinuation of concomitant therapy. There were no severe adverse effects. The results pointed out good efficacy and safety of moclobemide in the treatment of agitated, psychotic depression in aged patients.