

safety of venlafaxine extended-release (XR) in preventing recurrence of depression.

**Methods:** Patients with recurrent unipolar depression (N=1096) were randomly assigned in a 3:1 ratio to 10-week treatment with venlafaxine XR (75 mg/d to 300 mg/d) or fluoxetine (20 mg/d to 60 mg/d). Responders (HAM-D17 total score  $\leq 12$  and  $\geq 50\%$  decrease from baseline) entered a 6-month, double-blind, continuation phase on the same medication. Continuation phase responders enrolled into the maintenance treatment period consisting of 2 consecutive 12-month phases. At the start of each maintenance phase, venlafaxine XR responders were randomly assigned to double-blind treatment with venlafaxine XR or placebo; fluoxetine responders continued for each period. Time to recurrence (HAM-D17 total score  $> 12$  and  $< 50\%$  reduction from acute phase baseline at 2 consecutive visits or the last visit prior to discontinuation) was evaluated using Kaplan-Meier methods and compared between groups using log-rank tests.

**Results:** At the end of the continuation phase, venlafaxine XR responders were randomly assigned to venlafaxine XR (n=164) or placebo (n=172); 129 patients in each group were evaluated for efficacy. The cumulative probability of recurrence through 12 months was 23.1% (95% CI: 15.3, 30.9) for venlafaxine XR and 42.0% (95% CI: 31.8, 52.2) for placebo (P=0.005).

**Conclusions:** Twelve months of venlafaxine XR maintenance treatment was effective in preventing recurrence in depressed patients who had been successfully treated with venlafaxine XR during acute and continuation therapy.

## P068

Two-year placebo-controlled maintenance study to assess recurrence prevention with venlafaxine XR in patients with recurrent unipolar major depression

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**Objectives:** This study evaluated the efficacy and safety of venlafaxine extended-release (XR) in preventing recurrence of depression.

**Methods:** Outpatients with recurrent unipolar depression (N=1096) were randomly assigned in a 3:1 ratio to 10-week treatment with venlafaxine XR (75 mg/d to 300 mg/d) or fluoxetine (20 mg/d to 60 mg/d). Responders (HAM-D17  $\leq 12$  and  $\geq 50\%$  decrease from baseline) entered a 6-month, double-blind, continuation phase on the same medication. Continuation phase responders enrolled into maintenance treatment consisting of 2 consecutive 12-month phases. At the start of each maintenance phase, venlafaxine XR responders were randomized to double-blind treatment with venlafaxine XR or placebo; fluoxetine responders continued on fluoxetine. Time to recurrence (HAM-D17  $> 12$  and  $< 50\%$  reduction from acute

phase baseline at 2 consecutive visits or the last valid visit prior to discontinuation) was evaluated using Kaplan-Meier methods and compared between groups using log-rank tests.

**Results:** In the second maintenance phase, the cumulative probabilities of recurrence through 12 months in the venlafaxine XR (n=43) and placebo (n=40) groups were 8.0% (95% CI: 0.0, 16.8) and 44.8% (95% CI: 27.6, 62.0), respectively (P<0.001). The probabilities of recurrence over 24 months for patients assigned to venlafaxine XR (n=129) or placebo (n=129) for the first maintenance phase were 28.5% (95% CI 18.3, 37.8) and 47.3% (95% CI 36.4, 58.2), respectively (P=0.005).

**Conclusions:** An additional 12 months of venlafaxine XR maintenance therapy was effective in preventing recurrence in depressed patients who had responded to venlafaxine XR after acute, continuation, and 12 months' initial maintenance therapy.

## P069

Treatment of depressive syndrome in patients with psychosomatic disorders

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We analyzed a comparative evaluation of the effectiveness of the use of the antidepressant "Zoloft" in the complex treatment of depressive syndrome in 112 patients with psychosomatic disorders. Such patients lose interest in treatment, at the same time steadfast attention to their internal condition is noticed. Very frequently in these patients under the background of low mood, great anxiety, fear concerning the condition of their health is noticed.

Taking into account the above symptoms, we included "Zoloft" in the complex pharmacotherapeutic treatment. This choice was made because "Zoloft's" possibility of taking it once in a day, high safety, lack of dependence, insignificant side effects. The average therapeutic dosage was consisted of 50 mg/day duration of use — up to 4 months.

As the results, we found the regression of depressive symptoms in 89% of patients in this group was noticed at the end of the first week from the beginning of taking the drug. At the beginning this concerned anxieties and fears; mood was raised, active desire for prolonging the treatment was noticed. Sleep at night was better, psychotherapeutic correction was adequately effective. Fast regress of somatic complains were also noticed.

Thus, the results testify to a high efficiency of the Zoloft and good compatibility with psychocorrective work. Catamnestic data of from 2 to 4 years allow us to believe in the excellence (reliability) of our results.

## P070

Use of antiepileptic drugs in psychiatry

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**Introduction:** Antiepileptic drugs have been more and more used by psychiatrists in treatment of disorders not related to epilepsy. Valproate and carbamazepine are approved in the treatment of Bipolar Disorder, as mood stabilizers. Lamotrigine also showed efficacy in bipolar depression, and gabapentine is a promising drug in treatment of anxiety disorders. This drugs are also being studied in other psychiatry disorders, as borderline personality, Schizophrenia, and agitation related to dementia.

**Objectives:** The authors make a review about the use of antiepileptic drugs in Psychiatry disorders, with focus on mechanisms of action, pharmacokinetics, adverse effects and efficacy.

**Conclusions:** In the past, Antiepileptic drugs were exclusively for epilepsy. Now-a-days, they are used in a variety of Psychiatry disorders. This is a good example about the connexion between Psychiatry and Neurology.

## P071

Child neurodevelopment following exposure to venlafaxine in utero, unexposed siblings as comparison groups: Preliminary results

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**Background/Aim:** Venlafaxine (VLF) is an antidepressant drug often used by pregnant women. Its possible adverse effects on fetal CNS development have not been studied. The present study will fill the knowledge gap.

**Aim:** To assess neurodevelopment of children exposed to VLF during gestation.

**Methods:** Cohort study -controlled, matched, and blinded. Assessment of 5 groups of mother-child pairs: exposed to VLF (n=32) or other SRIs (n=29), healthy controls (n=42), and 2 groups of siblings (n=15). Siblings were unexposed relatives of children from the VLF or 'other SRIs' groups. Primary outcome: WPPSI-III Scales of Intelligence. VLF exposed children will be compared with those of children in control groups and their non-exposed siblings.

**Results:** There were no differences in Full Scale IQ, Performance IQ and Verbal IQ between the VLF and SRIs groups (103+10vs105+12; 102+11vs102+15; 103+11vs105+12), VLF group and their siblings (105+12vs100+8; 102+15vs105+7; 105+12vs95+10), or the the SRIs group and their siblings (103+10vs104+8; 102+10vs104+8; 103+11vs106+12). Healthy controls scored significantly higher than the VLF group and the other 3 groups in Full Scale IQ, Performance IQ and Verbal IQ (P= 0.011; 0.041; and 0.028 respectively).

**Conclusion:** Preliminary results show that factors such as maternal depression, genetics, and environment (not necessarily the antidepressant) are strongly associated with the child's cognitive abilities. Assessment of siblings helps to verify the impact of these factors and is possibly the strongest evidence in drug safety studies.

**Support:** Wyeth Pharmaceuticals

## P072

Correlation of functioning level with level of anxiety, depression and hopelessness in patients under the treatment with psychopharmacotherapy

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In our prospective study we analyzed 30 of patients (20 females) with anxious depressive disorders, mean age  $37,6 \pm 10,8$  (20-57) years, treated with antidepressive agents. For 18 months there have been used Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Back Hopelessness Scale (BHS) and GAF on the beginning, at the end of treatment (after 12 months), and 6 months after

treatment. At the beginning of treatment next mean values were observed: BDI  $42,5 \pm 13,1$ , BAI  $32,6 \pm 14,7$ , BHS  $9,2 \pm 6,9$ , and GAF  $51,9 \pm 9,1$ .

GAF showed negative correlation in comparison with BAI (-0,60), BDI (-0,66), and BHS (-0,54). After one year of medication mean value of improvements were: for BDI  $31,7 \pm 10,8$ , for BAI  $24,1 \pm 13,3$ , for BHS  $7,5 \pm 5,8$ , and for GAF  $13,2 \pm 5,4$ . GAF still highly correlated with BDI (-0,69), with BAI (-0,56) and with BSB (-0,44). Six months after all parameters were significantly worsen: BDI  $5,1 \pm 2,3$ , BAI  $4,2 \pm 2,8$ , BHS  $1,5 \pm 1,8$ , and GAF  $-5,0 \pm 1,4$ . GAF still correlated with BDI (-0,41), BAI (-0,39), but correlation rate with BHS was very low (-0,23).

**Conclusion:** Due to negative correlation rates with level of depression, anxiety and hopelessness it is possible to apply GAF like measure of assessment of patient's depression and anxiety, and useful follow up tool of patients treatment with psychopharmacotherapy.

## P073

Duloxetine in major depressed patients resistant to SSRIs or venlafaxine

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**Introduction:** The management of treatment-resistant depression remains a major public health problem. Several acute depression trials suggest that only 45% of the patients achieve remission state with antidepressant monotherapy. An increasing body of evidence is emerging suggesting that multi-action antidepressants might be more effective in treatment-resistant depressed patients than single-action agents. In this context, the purpose of the study was to assess the effectiveness of duloxetine in treatment-resistant major depressed outpatients.

**Methods:** We performed a prospective study assessing the efficacy of duloxetine in major depressed outpatients who did not achieve full symptom remission (CGI-S (severity)  $\geq 3$ ) after treatment of adequate dose and duration (more than 8 weeks) with at least either one SSRI or the SNRI venlafaxine. We excluded patients with a severe medical illness and a personality disorder. CGI-S was used as a measure of symptom severity and administered before the administration of duloxetine and 6 weeks later. Five patients had been treated with venlafaxine and the others with a SSRI (Fluoxetine, Paroxetine, Citalopram).

**Results:** The sample included 10 patients (3 M, 7 F). We observed a very significant decrease in CGI-S scores ( $5 \pm 0,45$  to  $1,2 \pm 0,63$ ,  $p < 0,0001$ ) after treatment with duloxetine (dose between 20 and 60 mg). Remission was achieved in 90% of the patients. The tolerance was excellent.

**Conclusion:** This study suggests the potential interest of duloxetine in treatment-resistant depressed patients.

## P074

Affective patients in residential setting

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Several studies have demonstrated that Mood Disorders are threatening, widespread disorders characterized by poor outcome and chronic development. This study was undertaken to examine the features of affective patients in long-term residential care.