

P01.09

Mega-analysis of sertraline vs. fluoxetine in major depression

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Objective: To increase the power to detect efficacy in clinically relevant subgroups, a mega-analysis of pooled data was conducted.

Method: Data were pooled from 8 double-blind, head-to-head studies comparing sertraline and fluoxetine. A "mega-analysis" (Thase et al, Arch Gen Psych, 1997) was conducted on the anxious depression subgroup (defined by a HAM-D-anxiety-somatization factor score > 7), and a high severity subgroup (defined by a 17-item HAM-D total score > 26).

Results: A total of 1,706 patients (65% female; mean age, 49 yrs; baseline HAM-D, 22.7) were randomized to receive at least 6 weeks of double-blind treatment. In the anxious depression subgroup, HAM-D responders (> 50% reduction) for sertraline vs. fluoxetine were 72% vs. 64% (p < 0.05). In the severe depression subgroup, HAM-D responder rates were 72% vs. 56% (p < 0.02). Treatment with sertraline was associated with significantly earlier onset of both clinical response and remission

Conclusion: Mega-analysis represents a promising new method for identifying meaningful clinical differences in the efficacy and tolerability of various antidepressants.

P01.10

Moclobemide in early poststroke depression: an open study

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Objective: Depression is a common problem in rehabilitation and functional recovery after stroke. We have performed an open study of the effect of the RIMA, moclobemide in early poststroke depression.

Method: 157 consecutive admissions to neurological unit were screened for depression and 32 patients were admitted to the study having a HDRS score > or = 15. The patients received 450–600 mg of moclobemide and underwent a neurological and psychiatric examination at 3, 6 weeks and 3, 6 months after the stroke. The antidepressive therapy was finished when a good and stable remission has been achieved.

Results: 450–600 mg of moclobemide were well tolerated and led to > or = 50 % reduction of the HDRS score in 46 % of patients following 6 weeks of treatment and in 70 % of patients following 3 months of treatment. In 6 months observation, moclobemid must have been changed to another antidepressant in 30 % patients.

Conclusions: According to our observation RIMA, moclobemide, is an effective and well-tolerated therapy of depression after stroke and its effectiveness improves during prolonged therapy.

P01.11

Placebo-controlled efficacy comparison of escitalopram and citalopram

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Escitalopram is the single isomer responsible for the inhibition of serotonin reuptake produced by the racemic SSRI antidepressant citalopram. Recently, three placebo-controlled, randomized, 8-week

double-blind trials were completed that employed parallel fixed- or flexible-dose arms of escitalopram (10–20 mg/day), citalopram (20–40 mg/day), or placebo in patients with moderately severe to severe major depressive disorder (MADRS_{fr22}). The MADRS and CGI scales were endpoints in all trials. Both escitalopram and citalopram were effective in reducing depressive symptoms in both scales, and in the percentage of MADRS responders. Analysis of the comprehensive safety database shows that escitalopram was well-tolerated, with only one adverse event (nausea) occurring in more than 10% of patients at a rate greater than placebo, and with a low overall rate of discontinuations due to adverse events.

P01.12

Escitalopram prevents relapse of depressive episodes

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The efficacy of escitalopram in the treatment of MDD was established in several 8-week trials. However, continued antidepressant treatment is necessary to prevent relapse of depression; this was evaluated here with escitalopram.

The trial was an extension study in depressed outpatients who had completed 8 weeks of escitalopram, citalopram, or placebo treatment. It consisted of an 8-week open-label escitalopram (10;V20mg/day) treatment period followed by a randomized, double-blind period. At the end of the open-label period, patients classified as responders (MADRS „T12) were assigned to escitalopram (N=181) or placebo (N=93) for 36 weeks of treatment. The primary efficacy variable was time to depression relapse from the start of the double-blind treatment. Additional efficacy variables included MADRS, HAMD, and HAMA.

Time to depression relapse was significantly longer in escitalopram-treated patients; the risk of relapse was 44% lower in escitalopram- than in placebo-treated patients. Escitalopram-treated patients continued to exhibit low mean ratings of anxiety and depression symptoms during the double-blind period, which were significantly lower than those of placebo-treated patients.

Thus, continuation treatment with escitalopram is effective in preventing relapse of depression.

P01.13

Age specificity in the psychopharmacotherapy of endogenous depressions in adolescence

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Objective: the detection of specific reactions to psychopharmacotherapy in patients with endogenous depressions in adolescence (age group 15–21 years).

Methods: the efficacy of treatment, side effects and complications during psychopharmacotherapy by antidepressive drugs of different classes (TCA, SSRI, NASSA) were studied in 220 adolescent patients with affective disorders (F31–34), compared to that of adults with similar psychotropic therapy and the use of rating scales (CGI, MIDRS, UKU).

Results: it was established that the reactions of adolescents to psychotropic drugs differs from those of adults. Along with the obvious preference of the new generation of antidepressive drugs compared to that of TCA, it also demonstrates a higher frequency and more pronounced adverse reaction, as well as the appearance of complications, which practically are not encountered in adult patients.