Tues-P28

MIRTAZAPINE VS FLUOXETINE: EFFICACY ON SYMPTOMS ASSOCIATED WITH DEPRESSION

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Aim: To compare the efficacy of mirtazapine and fluoxetine on depressed mood, as well as on anxiety, sleep and retardation symptoms in depressed in- and outpatients.

Methods: Patients with a Major Depressive Episode (DSM-IIIR), a baseline score of ≥ 21 on the 17 item-HAMD and ≥ 2 on depressed mood item, were randomized to a 6 week treatment with either mirtazapine (n = 66; 15–60 mg/day) or fluoxetine (n = 67; 20–40 mg/day). Changes from baseline in depressed mood were assessed by item 1 ('depressed mood') of the HAMD, while anxiety disturbances, sleep disturbances and retardation symptoms were respectively assessed by anxiety/somatization, sleep disturbance and retardation factors of the HAMD. The efficacy analyses were performed on the Intent-To-Treat Group using the Last Observation Carried Forward method.

Results: On all efficacy variables treatment with mirtazapine has resulted in a larger magnitude of change from baseline than treatment with fluoxetine. During the first two weeks of treatment, the largest magnitude of change was observed in the anxiety/somatization and sleep disturbance factors, The changes in the 'depressed mood' and the retardation factor were similar in both groups. From week 2 onwards changes favoring mirtazapine were particularly prominent in the 'depressed mood' item and the retardation factor. The difference on the 'depressed mood' item favoring mirtazapine reached statistical significance at week 4.

Conclusion: The results demonstrate that treatment with mirtazapine is superior to fluoxetine in improving depressed mood. Pharmacological properties of mirtazapine, especially its specific actions on postsynaptic 5-HT receptors, may account for the consistent improvements in anxiety and sleep disturbances throughout the treatment period.

Tues-P29

A NATURALISTIC STUDY OF MIRTAZAPINE IN THE GERMAN PSYCHIATRIC PRACTICE

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Aim: To assess clinical efficacy and tolerability of mirtazapine in everyday clinical practice in Germany.

Methods: Depressed in and outpatients (n = 2460) of both sexes, older than 18 years, were treated with mirtazapine (15–45 mg/day) for 6 weeks in an open label-study. Clinical efficacy was assessed after 1, 3 and 6 weeks of treatment by a German version of the CGI-Severity of illness and Global improvement scales. Tolerability was assessed by registering treatment-emergent adverse events.

Results: Forty eight percent of patients had an ICD-X diagnosis of a recurrent depressive episode at baseline, while 73% were treated with antidepressants prior to inclusion in the study. The most common reason for switching to mirtazapine was lack of efficacy. After 6 weeks of treatment with mean dose of 30 mg/day of mirtazapine, 72% of patients were classified as CGI responders. At the same time point, in 45.4% the severity of illness was assessed as 'mild', and in 22.6% as 'moderate'. Eighty-one percent of patients have not reported any treatment emergent adverse events. Somnolence was reported by 6% of patients, dizziness by 2.7, weight gain by 2.1% and restlessness by 2.1% of patients. Each of the remaining adverse events was reported by less than 2% of patients.

Conclusion: Mirtazapine was effective and well tolerated treatment in everyday clinical practice. Despite the methodological limitation, our results are in line with previously reported double-blind randomized studies of mirtazapine.

Tues-P30

ECONOMIC IMPACT OF USING MIRTAZAPINE

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Aim: To estimate the cost-effectiveness of mirtazapine vs amitriptyline and fluoxetine in management of moderate and severe depression in France.

Method: Clinical decision analysis techniques were used for retrospective estimate of the direct and indirect healthcare costs per patient; a cost-effectiveness analysis was performed to determine costs per successfully treated patient. Treatment paths for management of depression were developed from clinical data, interviews with French psychiatrists and published literature.

Results: After 28 weeks of treatment, both direct costs to Social Security and indirect costs to French society per patient were higher with amitriptyline than with mirtazapine (FF 786 and FF 4.814, respectively). A cost-effectiveness analysis shows that the expected direct costs to Social Security per patient successfully treated with mirtazapine are FF 24.212 less than for a patient successfully treated with amitriptyline. Estimates after 6 months of treatment with fluoxetine show that although direct costs are FF117 higher with mirtazapine, indirect costs are FF427 higher with fluoxetine. In addition, a cost-effectiveness analyses shows that the expected direct costs are FF25.914 less with mirtazapine compared to fluoxetine. Social Security payments to patients during their time off work emerged as the main cost driver and accounted for 86% of the direct cost per patient. In contrast, acquisition costs of antidepressants accounted for 1 to 3% of the expected costs per patient.

Conclusion: Mirtazapine is more cost-effective antidepressant compared to amitriptyline or fluoxetine. The cost per patient successfully treated with mirtazapine is FF24.212 lower than with amitriptyline, and FF25.914 lower than with fluoxetine.

Tues-P31

THE CLINICAL COURSE AND RESOLUTION OF MIRTAZAPINE-INDUCED EDEMA

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Objective: Edema is rare a adverse event reported with majority of antidepressants, with incidence ranging between 1%–11%. In placebo-controlled studies of mirtazapine, edema was reported in 1% of patients. We present 2 cases of edema with mirtazapine successfully resolved after dosage increase.

Method: Chart review of two outpatients presenting with facial edema.

Results: A 27-year old woman with the ICD-10 diagnosis of severe depression without psychotic symptoms, previously unsuccessfully treated with moclobemide and fluoxetine, started treatment with mirtazapine 30 mg/day. After one week there was a substantial improvement in sleep and anxiety, but facial edema appeared in the morning. The dose was increased to 45 mg/day,

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