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Early onset of antipsychotic action and outcome of Ziprasidone treatment in placebo-controlled bipolar mania trials

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Background and Aims: Recent research indicates intramuscular ziprasidone produces a significant, early (within 24 hours) improvement in psychotic symptoms. In this analysis, we evaluated the potential for an early antipsychotic response to oral ziprasidone in subjects with acute bipolar mania.

Methods: We conducted a pooled analysis of two 3-week, randomized, double-blind, placebo-controlled trials of ziprasidone (40-160 mg/d) in hospitalized patients (N=415) with bipolar I disorder, and a current manic (N=257) or mixed episode (N=158), with (N=151) or without (N=245) psychotic features. Efficacy assessments included the Mania Rating Scale (MRS, derived from the SADS-C). Remission was defined as achieving a MRS score <= 12. Improvement in psychosis was evaluated by a sum of the three SADS-C psychosis items (delusions, hallucinations, and suspiciousness). MMRM and logistic regression analyses were applied to estimate the time course of response.

Results: Significantly greater response rate (>50% decrease from baseline) and improvement in the SADS-C psychosis score were observed in the ziprasidone group (versus placebo) as early as Day 4 ($p<0.01$), and the magnitude of improvement increased with time ($p<0.003$). At Day 21, remission rate with ziprasidone monotherapy was 49% versus 36% in the placebo group ($p=0.02$). Early antipsychotic response at Day 4 was an accurate predictor of remission at Day 21 ($p<0.01$, ROC=0.76).

Conclusions: Ziprasidone was associated with a rapid onset of response in psychotic symptoms in patients with acute bipolar mania. This early reduction in psychotic symptoms was found to mediate overall improvement in manic symptoms and predict remission at endpoint.

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The prevalence of mixed episodes during the course of illness in bipolar disorder

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Aim: To investigate the prevalence of mixed episodes during the course of illness in bipolar disorder.

Methods: A total of 1620 patients with an ICD-10 diagnosis of bipolar affective disorder at the first psychiatric contact were identified in a period from 1994 to 2003 in Denmark and the prevalence of mixed, depressive and hypomanic/manic episodes were calculated at each episode.

Results: The prevalence of mixed episodes increased from the first episode to the tenth episode, however, only for women (6.7 % of the first episodes leading to psychiatric care compared to 18.2 % of the tenth episodes). For men, the prevalence of mixed episodes was constantly low. At all episodes, the presence of a current mixed episode increased the risk substantially of getting a future mixed episode.

Conclusion: Clinicians should pay more attention to mixed episodes, especially among women, as they may represent an increasing treatment challenge as the illness progress.

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Outcomes of acute mania: 12 month results from the french EMBLEM cohort

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Objectives: To describe 12 month outcomes of French patients enrolled in EMBLEM (European Mania in Bipolar Longitudinal Evaluation of Medication).

Methods: EMBLEM is a prospective, observational study on outcomes of manic/mixed episode. Adult patients were enrolled within the standard course of care if they initiated/changed oral medication for treatment of acute mania. All treatment decisions were at the discretion of the treating psychiatrist. 530 psychiatrists (126 French) enrolled 3459 eligible patients (771 French). 12 months results of the French cohort will be presented.

Results: At baseline, mean age was 45.5 years (sd 13.6) and 59% were female. 68% were outpatients and 34% had a mixed episode. 76% of French patients were eligible for follow-up at 12 months. 80% improved (CGI-BP overall decrease >2) during follow-up whereas 47% patients never achieved recovery (two consecutive CGI-BP overall <2). 37% of patients presented with no medication at baseline. 41.6% were started on monotherapy and 58.4% on combination therapy; of those 54% and 28% respectively remained on their initial medication throughout the 12 months. 25% were treated with antidepressants in addition to their new oral medication, which increased to 35% at 12 months.

Conclusions: In this naturalistic study, less than half of French patients achieved recovery during 12 months follow-up. Antidepressant was frequent at baseline and use increased during follow-up. Twice as many patients remained on the same monotherapy as those on the same combination therapy

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Low serum total cholesterol in bipolar disorder

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Background and Aims: Low serum total cholesterol has been reported to be assotiated with risk of suicidal, violent and impulsive behaviours. To date there are no laboratory tests for diagnosing bipolar disorder (BD). Case vignette to illustrate the clinical observation of changes of serum total cholesterol (STChol) and mood disturbaces of patient with bipolar disorder (BD) at admission and in remission was used.

Methods: A 23- years old, healthy and drug-free female met the ICD-10 criteria for bipolar disorder. She was assesed during two mixed episodes to explore change in serum cholesterol (Chol) levels at admission (A) of first (1e) episode and after remission (R), one month later. The readmission due to second consecutive mixed episode (2e) was 19 months later. MADRS scale for depression and YMRS scale for mania were applied, and body mass index (BMI) was assessed.

Results: Chol-1eA 2,50 mmol/l (normal range 3,63-6,20 mmol/l), Chol-1eR 3,90 mmol/l; Chol- 2eA 3,05 mmol/l. BMI-1e 20,5 BMI-2e

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