THE MANAGEMENT OF BIPOLAR MANIA: A NATIONAL SURVEY OF BASELINE DATA FROM THE EMBLEM STUDY

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The 12-week acute phase of the 24-month EMBLEM naturalistic study evaluated the changes of manic symptoms, clinical and functional status in patients treated for a manic or mixed bipolar episode. In Italy, 186 adult in-patients and 369out-patients (2unknown) that started or changed any oral medication for the treatment of manic or mixed bipolar episode, took part in the acute phase of the study.Prescribed and concomitant medications, clinical and functional status were recorded at baseline and after 1, 2, 3, 6 and 12 weeks. A total of 521patients (93.5%) completed the 12weeks acute phase. Change of psychiatrist was the main reason for discontinuation, as well as severity of mania was a risk factor for early withdrawals. Twenty-one patients (3.8%), 3 of which more than once, attempted suicide in the 12-week period, compared to 4.5% in the 12 months before baseline. The mean(±SD) CGI-BP mania score decreased from 4.4±0.9 to 2.4±1.1. Improvement (decrease≤2 points in the overall CGI-BP at any time) was reported in 49.7% of patients in total population, in 51.1% of those receiving and kept in combined therapy, in 37.2% of those kept in monotherapy, in 56.3% of those switched from mono- to combined therapy and in 53.6% of those switched from combined to monotherapy. The corresponding rates of worsening (increase of at least one point to a minimum of 3 in the overall CGI-BP at any time) were 25.0%, 23.3%, 20.9%, 27.1% and 29.8%, respectively. The total score of the 5-items HAM-D scale was 3.0±2.5 at baseline and 2.0±2.1 at 12 weeks. The total score of the Young Mania Rating Scale decreased from 23.1±10.2 to 5.9±6.6 and marked improvements were observed for all items. The compliance to prescribed drug was sub-optimal in 55.8% of patients at baseline and in 86.4 at 12weeks. The rates of patients who changed therapy during the 12-week period were 39.6% for patients treated with monotherapy and 67.7% for those treated with combined therapy. Switch from mania to depression was observed in 36 patients (6.5%). A progressive improvement of the most frequent side effects reported at baseline (e.g. akatisia,insomnia, sedation, loss of memory) was observed and concomitant medications (i.e. anticholinergics, benzodiazepines and other hypnotics) were progressively reduced.The results of the acute phase of the EMBLEM study in Italy showed that the start/change of the prescribed therapy produced marked relief of symptoms of mania and functional status, with improved compliance to medication, improved tolerability and reduced use of concomitant medications. Long-term results are necessary to confirm such acute data in the maintenance period.