FC05-02

TRANSLATION OF RANDOMISED CONTROLLED TRIAL FINDINGS INTO CLINICAL PRACTICE: COMPARISON OF OLANZAPINE AND VALPROATE IN THE EMBLEM STUDY

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Aims: To contrast the outcomes of olanzapine- and valproate-treated patients in an observational study of acute mania with the results of a RCT assessing the same treatments (Tohen et al., 2002).

Methods: EMBLEM (European Mania in Bipolar Evaluation of Medication) was a 2-year, prospective, observational study of health outcomes associated with treatment of mania. Severity of mania and depression was assessed at baseline and 6 weeks using the YMRS and 5-item version of the HAMD, respectively. The RCT was a 3-week, randomised, double-blind comparison of olanzapine (n=125) and divalproate-treated (n=123) patients hospitalised for acute manic or mixed episodes. The YMRS and HAMD were used to quantify manic and depressive symptoms, respectively.

Results: 621 EMBLEM patients were analysed (n=107 valproate, n=514 olanzapine). Both observed groups improved from baseline to 6 weeks in mean YMRS and HAMD-5 total scores, with significantly greater mean improvements in the olanzapine compared with the valproate group using linear regression to adjust for baseline differences. The RCT reported significantly greater mean YMRS improvement (but not HAMD) in the olanzapine-treated group. EMBLEM patients treated with olanzapine experienced significantly greater weight gain than patients treated with valproate, similar to RCT results. There was a significantly greater incidence of treatment-emergent gastrointestinal adverse events in EMBLEM patients treated with valproate.

Conclusions: The EMBLEM results support those of the RCT, which suggest that olanzapine monotherapy may be more effective than valproate monotherapy in the treatment of acute mania. Contrasting observational and RCT results present methodological challenges but can provide important complementary information.

https://doi.org/10.1016/S0924-9338(09)70547-4 Published online by Cambridge University Press