
Oral Presentations

O.02 Hyponatraemia during Psychotropic

Medication: Results from the International

AMSP Project

J.W. van der Velden,^{1,2} E. Jaquenoud Sirof,³ R. Grohmann⁴

1 PharmaNet AG, Zumikon, Switzerland; 2 Universite Libre, Brussels, Belgium; 3 3mediQ, Psychiatrische Dienste Aargau AG, Brugg, Switzerland; 4 Department of Psychiatry, University of Munich, Munich, Germany

Background: The AMSP-Project (Arzneimittelsicherheit in der Psychiatrie) is a prospective multicentre programme for continuous assessment of adverse drug reactions (ADR) of marketed psychotropic drugs in psychiatric inpatients under naturalistic conditions of routine clinical treatment. It corresponds to a dynamic cohort study and currently 55 German, Swiss, Hungarian, Belgian and Austrian hospitals are participating, monitoring approximately 30,000 inpatients per year.

Objective: Hyponatraemia, defined as serum sodium below 130 mmol/L, can be a life threatening medical condition which may lead to severe neurological and psychiatric symptoms. Analyses were set up to measure the incidence and relative risk ratios of hyponatraemia in association with psychotropic treatment.

Methods: All cases of hyponatraemia between the years 1993 through 2005 were reviewed and causality assessment discussed at (inter-)national meetings. Incidence was calculated by number of patients under treatment and relative risks were calculated between the individual treatment regimens.

Results: Out of 208,401 surveyed patients, 66 cases (0.03%) did meet the definition of hyponatraemia. In the cases 124 drugs were judged to be probably causally related; drug combinations were imputed in 45% of all cases. Most cases were observed under treatment with oxcarbazepine with 21 cases (31.8%); followed by treatment with diuretics (18 cases), antiarrhythmics (16 cases) and carbamazepine (15 cases) and venlafaxine (11 cases). An important finding is that the total number of patients treated with oxcarbazepine in this cohort is 1,412 and with carbamazepine is 18,787, showing a significant increased incidence in the oxcarbazepine group. Coadministration of diuretics (18 cases) or ACE-inhibitors (17 cases) was frequent. When clustering by psychotropic class the distribution was: antiepileptic drugs 53%; antidepressants 50%; neuroleptic medication 7.6% and non psychotropic medication 47%.

Discussion: The AMSP project is a valuable tool in detecting and confirming ADR in a psychiatric hospital setting. The pros and cons of the project are equal to intensive spontaneous monitoring systems. The incidence of hyponatraemia is established for the treatment regimens and oxcarbazepine and carbamazepine showed the highest numbers, both in real numbers as well in relative numbers.

Conclusion: The well known benefits of treatment with antiepileptics like oxcarbazepine or antidepressants should be carefully balanced with the problems of hyponatraemia in higher risk patients, e.g. the elderly.