S14-2 Analysis of safety information on psychotropics using AERS, a large-scale adverse drug reaction database

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Scientific evaluation of drug safety becomes possible with huge post-marketing safety data. Recently, the worldwide situations of drug safety have changed dramatically. Drugs are used based on the evaluation of safety data from clinical practice worldwide. Current issues are how to analyze and use the large-scale safety data. In this study, we analyzed worldwide data on ADRs available through AERS of US FDA (about 3.16 million reports on about 2.4 million patients for 13 years from Q4, 1997 to Q2, 2009). In this symposium, we introduce case analysis on psychotropics including antipsychotics, antiepileptics, and antidepressants. Antipsychotics caused ADRs specific to each drug, and, in combination therapy, increased the incidences of diabetes mellitus, pancreatitis, and neuroleptic malignant syndrome; antiepileptics caused AEs including serious skin reactions such as Stevens-Johnson syndrome (SJS), congenital anomaly, and closed-angle glaucoma; and antidepressants caused AEs including serotonin syndrome, suicidal events, and congenital anomaly. We also introduce AEs occurring at a higher incidence for other indications, drugs often used in the elderly and the associated AEs, and case analysis of AEs in combination therapy. Although the huge data on 440,000 cases per year (2008) are statistically exhaustive, potential biases should always be kept in mind, because AERS is based on spontaneous reports. Thus, analysis of the large-scale ADR database provides clinical practice with important safety information for ensuring drug safety.