ABSTRACT

Analysis of Spontaneous Adverse Events Reports after Tick-Borne Encephalitis Vaccine

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Introduction and aim: Tick-borne meningoencephalitis is one of the most frequent causes of viral meningitis in Europe. In recent years, the number of cases of this infection in the Czech Republic has begun to rise. Vaccination is the only reliable protection against infection, but it also comes with some risks. Analysis of spontaneous adverse reaction reports is a key source of information for signal detection, which is used to identify drug risks. The aim of this thesis was to analyse the spontaneous reporting of suspected adverse drug reactions (ADRs), using the data from the Central Database of ADRs provided by the State Institute for Drug Control.

Methodology: Descriptive statistics were performed from reporting data in the period from June 2004 to October 2017. For example, the total number of reports, the number of ADRs and the patient characteristics were analysed. We compared the adverse reactions with the Vigibase database and evaluated the expectability of reported reactions.

Results: During the reporting period, 184 reports were received, of which 79,9 % were related to the FSME-IMMUN® vaccine. A total of 659 ADRs were reported. Most ADRs fall into the categories *General disorders and administration site condition* (23,4 %), *Nervous system disorders* (21,7 %) and *Musculoskeletal and connective tissue disorders* (10,2 %). For the most part, these were serious ADRs (89,1 %), which disappeared in more than half of the patients (51,6 %). Most reports were received from physicians (81 %) and the least from other healthcare professionals and pharmacists (3,3 %). There are also 2 suspected deaths in the report. During the assessment of expectability of ADRs, we encountered 157 unexpected ADRs (23,8 %). Compared to the Vigibase database, the representation of ADRs in the organ classes did not differ too much.

Conclusion: Analysis of spontaneous reporting of ADRs allows us to detect possible signals for further evaluation. These signals may be unexpected ADRs or deaths after vaccination.