

Abstract

Analysis of spontaneous adverse events reports of antiepileptic drugs

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Introduction: Epilepsy is one of the most common neurological diseases, which occurs worldwide. Antiepileptic drugs (AED) suppress the onset of an epileptic seizure. Analysis of spontaneous adverse drug reactions (ADRs) analysis is important data source for generating the potential risks signals in pharmacotherapy.

Objective: The aim of this work was to analyse spontaneous reports of ADRs from the Czech Central Database of ADRs of the State Institute for Drug Control (SÚKL) in the period from June 2004 to October 2017. The analyses of potential drug interactions of all medicinal products mentioned in the reports and the assessment of the reported ADRs expectability was the secondary goal.

Methods: Retrospective analyses of the spontaneous ADR reports of antiepileptic drugs obtained from the SÚKL in the given period. Anonymized data was processed using the descriptive statistics in MS Excel. For example, the patient characteristics or seriousness and expectability of the ADRs were evaluated. The specific adverse drug reactions were divided according to the system organ classes MedDRA. The contraindicated or clinically significant drug interactions were sought after from the Micromedex and UpToDate databases.

Results: There were 303 reports containing 992 ADRs found in total. The reports included 19 different AEDs, lamotrigin (20,8 %) was the most common. Skin ADRs (15,8 %) were the most often, then general ADRs (14,9 %) and nervous system disorders (14,7 %). The reports were predominantly about serious ADRs (89,8 %), death occurred as a result of ADRs in seven cases. There were 280 (28,2 %) unexpected ADRs. Reports were mostly submitted by physicians (68,3 %), least by pharmacists (5,6 %). AEDs were used in monotherapy by 26,7 % of patients. The Micromedex database showed 36,6 % of monitored interactions in polytherapy, the UpToDate database showed 31,0 %.

Conclusion: The trend to report the ADRs has the tendency to grow in the recent years. The reports are submitted most often by physicians. Most of the ADRs were described as serious, however they have usually disappeared or were subsiding. Skin ADRs counts the highest number. There was often the risk of drug interactions registered in the case of polytherapy.