ABSTRACT

Analysis of spontaneous adverse drug reactions reporting hormonal contraception and hormone replacement therapy

Author: Vendula Ryndová

Supervisor: PharmDr. Kateřina Malá, Ph.D.

Consultant: PharmDr. Eva Zimčíková, Ph.D.

Department of Social and Clinical Pharmacy, Faculty of Pharmacy in Hradec Králové, Charles University

Introduction: Hormonal contraception (HC) is the most widely used method to prevent pregnancy worldwide. In addition to pregnancy planning and other non-contraceptional benefits, it also has certain risks. Hormone replacement therapy (HRT) is used primarily for treatment of estrogen deficiency in postmenopausal women. HRT is associated with a number of risks, in particularly for women 60+ of age. Analysis of spontaneous adverse drug reactions (ADRs) reporting contribute to detection of potential risks associated with pharmacotherapy, thereby increases the safety of the drugs.

Aim: The aim of this thesis was to analyse spontaneous ADRs reports of HC and HRT registered in the Czech Central Database of ADRs of the State Institute for Drug Control (SÚKL).

Methods: Retrospective analysis of the spontaneous ADRs reports of HC and HRT registered in the database of SÚKL from 10/2004 to 6/2017. Mainly, method of receiving the report, reporting person, patient information, seriousness, and consequences of the ADRs were evaluated. ADRs were determined according to the MedDRA system organ classes and the active substances according to the ATC classification. Data were analyzed using descriptive statistics.

Results: There were 556 reports on HC containing 1333 ADRs in total. The reports included 15 different active substances. The most frequent were ADRs related to reproductive system and breast disorders (19.1%), product issues (11.9%), and vascular disorders (10.7%). The reports were dominantly serious ADRs (93.7%), death occurred as a result of ADRs in 5 cases. The most frequent were levonorgestrel intrauterine system (50.9%) and combined contraceptives (32.8%).

There were 13 reports on HRT containing 32 ADRs in total. The most frequent ADRs were related to nervous system disorders (12.5%) and general disorders (12.5%). The reports were dominantly evaluated serious ADRs (92.3%). The most frequent reports were associated with combined treatment (59.4%) and estradiol (37.5%). Half of the ADRs were unexpected.

Conclusions: Analysis of spontaneously reported ADRs of HC and HRT provided informations about the most frequent reactions. This study highlighted the importance of spontaneous reporting for drug safety.

Key words: hormonal contraception, hormone replacement therapy, pharmacovigilance, spontaneous adverse events reporting