PREVENTABILITY OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS ADVERSE DRUG REACTION

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Nowadays, non-steroidal anti-inflammatory drugs (NSAIDs) represent one of the most widely prescribed and used drugs in the world. Nevertheless, prescription of NSAIDs is often not appropriate, leading to adverse drug reaction (ADR) that could be preventable.

On the grounds of this consideration, the aim of our study was to assess preventability criteria of ADR related to NSAIDs through an analysis of individual case safety reports (ICSRs) within the Campania Region spontaneous reporting system, from July 2012 to October 2016.

A multidisciplinary team composed of both clinical pharmacologist and pharmacists with pluriannual experience in Pharmacovigilance assessed the preventability of each ICRRs reporting NSAIDs as suspected drug, using the P-method, an algorithm validated by several Pharmacovigilance centres in the program for International Drug Monitoring coordinated by the World Health Organization.

In the period from July 2012 to October 2016, 19,039 ICSRs were sent to Campania Pharmacovigilance Regional Centre. 550 of them reported a NSAIDs as suspected drug.

From our analysis emerged that 94 cases (17,1%) of 550 ICSRs were preventable, according to at least one critical criteria of the P-method, while 456 cases (82,9%) were not preventable.

In 78 (83.0%) out of 94 preventable cases, the underlying mechanism of ADRs was dose-related, while in sixteen preventable cases the underlying mechanism of ADRs was susceptibility (13; 13.8%) and unknown (3; 3.2%), respectively. In the 94 preventable cases, 201 critical criteria were detected of which 182/201 (90.5%) related to healthcare professionals' practices, 0/201 (0.0%) to drug quality, and 19/201 (9.5%) to patient behaviour. In 80 (85.1%) out of 94 cases, pharmacological and/or non-pharmacological treatments, drug switch or withdrawal were required. All 52 out of 94 (55.3%) preventable cases required hospitalization.

In 81 (86.2%) preventable cases, 182 critical criteria related to healthcare professionals' practices were identified. The most detected critical criteria were the necessary medication not given (52/182; 28.6%), labelled drug–drug interaction (36/182; 19.7%), incorrect drug administration duration (31/182; 16.9%), wrong indication (26/182; 14.2%), therapeutic duplication (prescription of two or more medicines with similar ingredients; 18/182; 10.0%), and documented hypersensitivity to administered drug or drug class (10/182; 5.6%).

Since preventing ADRs is a major priority for regulatory agencies we believe that educational activities for promoting an appropriate drug use will pay off in far fewer preventable adverse drug events, far less harm done to patients by medications, and far less cost to the nation's economy. Therefore, a call for action is necessary for regulatory agencies also trough Regional

Pharmacovigilance Centers in order to promote initiatives able to increase the awareness of healthcare professionals on the risk associated with inappropriate use of NSAIDs and, more generally on the risk associated with the drugs more frequently used inappropriately.