Journal of Pharmacovigilance
ISSN: 2329-6887

Yiannakopoulou, J Pharmacovigilance 2014, 2:1
DOI: 10.4172/2329-6887.1000e116

Editorial Open Access

Pharmacovigilance and NSAIDs

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Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most commonly prescribed medications. In addition, over the counter use of ibuprofen and diclofenac is a common practice in many countries. Adverse drug reactions are the fifth cause of death in developed countries. Thus, the risk of adverse drug reactions associated with the use of NSAIDs including gastrointestinal, cardiovascular, renal, hepatic toxicities, anaphylactic reactions, remains a serious public health concern. Some of these adverse drug reactions are serious and even fatal. Gastrointestinal injuries ranging from dyspepsia to fatal upper gastrointestinal bleeding and perforation are among the most common adverse events of NSAIDs. On the other hand, rare adverse events as agranulocytosis and aplastic anemia, Stevens Johnson and Lyell's Syndromes have also been reported. Yet, special populations as old patients, patients with comorbidities, pregnant women and children are under-represented in the clinical studies. A number of NSAIDs have been withdrawn because of adverse events detected through pharmacovigilance, i.e. withdrawal of rofecoxib and valdecoxib due to cardio toxicity, bromfenac, ibufenac, and benoxaprofen due to hepatotoxicity.

Preclinical studies cannot predict reliably the safety profile of NSAIDS. On the other hand, clinical studies, although appropriate for the evaluation of the efficacy of a drug, have difficulty in identifying the adverse events of a drug. Reporting of safety data has been inadequate even in well-scheduled RCTs, rendering systematic review of safety data not feasible. It has been suggested that reporting of safety data would be clinically and statistically meaningful if all of the following data were provided: the number of patients who suffered from adverse events, a report of all adverse events that appeared, frequency of 10 more common adverse events, the number of patients who suffered from serious adverse events, a list of all serious events that appeared, the number of patients who suffered from irreversible adverse events, the number of patients who withdrew because of adverse events, the number of patients who suffered from 1, 2–5, 6–10 and >10 adverse events, and, finally, safety data for the number of patients who completed the study [1,2].

Pharmacovigilance is designed to monitor drugs continuously after their approval and commercialization, aiming at assessing and improving their safety profile. The main objective of pharmacovigilance is the increase of the spontaneous reporting of adverse drug reactions, i.e. reporting of suspecting adverse drug reactions by the medical stuff to a national coordinating center. Pharmacovigilance contributes to the early identification of signals leading to the formation of hypotheses and further investigation through observational studies or large prospective studies. Taking into account all the aspects outlined above, the contribution of pharmacovigilance is vital for the improvement of the safety of NSAIDs. All relevant authorities should take action towards reporting of adverse drug reactions associated with NSAID use and towards dissemination of this information to the scientific community.

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Received February 17, 2014; **Accepted** February 19, 2014; **Published** February 28, 2014

Citation: Yiannakopoulou ECh (2014) Pharmacovigilance and NSAIDs J Pharmacovigilance 2: e116. doi:10.4172/2329-6887.1000e116