SHORT COMMUNICATION

Temporal situation of NSAID-related adverse drug reaction reports in Slovak Republic

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Abstract

To make the drug therapy safer and more rational, it is substantial to gain sufficient amount of information concerning the perception of ADRs, especially those related to most "risky" groups such as NSAID. By viewing ADR reporting as a professional responsibility, and recognizing that the quality of submitted information, health professionals can play a major role in improving the public health. ***(Fig. 2, Ref. 5.)***

Key words: temporal situation, NSAID-related adverse drug reaction, drug, Slovakia.

NSAIDs (nonsteroidal anti-inflammatory drugs) are the "Janus-faced" group of drugs. On the one hand, it is one of the most common classes of medications used worldwide. A not neglectable part of them belong to OTC group. They are usually prescribed for antiinflammatory and analgesic indications, although some of them have been increasingly employed for other purposes (e.g. acetylosalicylic acid for antiplatelet therapy, prevention and treatment of colon cancer, treatment of Alzheimer disease) (1).

On the other hand, NSAIDs are at high risk of developing ADRs. Based on frequency and severity of adverse drug reactions (ADRs) they belong to the group of medicines with the most withdrown from the market. The majority of these ADRs would be preventable, if we recognize them and realize the causality. For this reason it is very important to find the proper way through safer therapies and appropriate risk management to reach to the improvement of the safety of NSAIDs.

On the March 18 th, at the postgraduate seminar of Slovak Medical Society for general practitioners "Panel discussion on rational prescription of nonsteroidal antiinflammatory drugs and antirheumatics" was presented the analysis of drug prescription and adverse drug reaction reports. It has been shown, that direct practitioner participation in the ADR reporting system was the most effective source of new ADR reports that led to changes in the product labeling at market withdrawals (2,3,4).

The fact, that the ADR reporting state is relatively low was the reason for encouraging participants to exert more activity in this field. Figure 1 presents the state of NSAID-related ADR reports in 2001 in comparison to the prescription of NSAID in DHD (daily defined doses per 1000 inhabitants and day). It is obvious, that not only the whole number of ADR reports, but also the proportion NSAID related ADR/all ADR reports is very low – 7 % (Fig. 2). Moreover the spectrum of ADRs does not reflect the real situation. The most often reported were dermatologic reactions (62 %), followed by gastrointestinal ADRs (15.2 %) and angioneurotic oedema (12.1 %). Nephrotoxicity due to NSAID was not reported. This all indicates the underestimation of this aspect. The majority of reports were according widely prescribed and well established ibuprofen and diclofenac. Despite low prescription (drug cathegorization limitations) the number of COX-2 inhibitors-related reports was surprising. In may be associated with the "Weber effect", because this group of drugs is relatively new. In 1984 Weber and colleagues observed that number of adverse reactions typically increased to a peak near the end of the second year of marketing and subsequently declined (5). This was consistent with the combined results of 2 temporal changes: an initial rise in reports due to increasing patient exposure as the new drug gained the market share, followed by a later fall in reports as the reporting declined when practitioners became familiar with the medication and lost interest in reporting such events.

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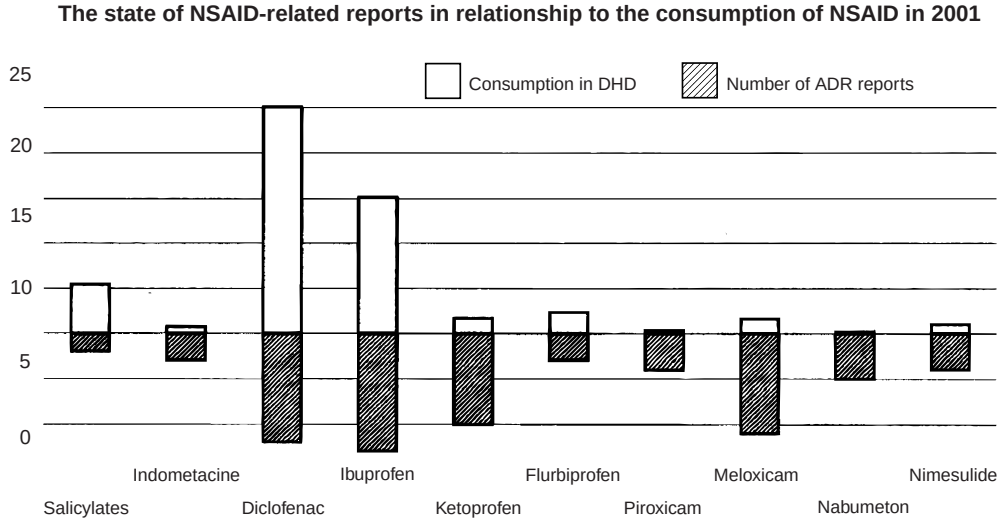

Fig. 1. The state of NSAID-related reports in relationship to the consumption of NSAID in 2001.

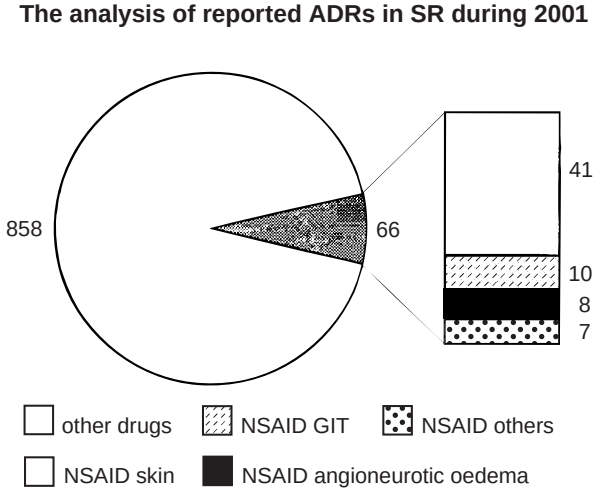

Fig. 2. The analysis of reported ADRs in SR during 2001.

To make the drug therapy safer and more rational, it is substantial to gain sufficient amount of information concerning the perception of ADRs, especially those related to most "risky" groups such as NSAID. By viewing ADR reporting as a professional responsibility, and recognizing that the quality of submitted information, health professionals can play a major role in improving the public health.

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