Risk of gastrointestinal complications associated to NSAIDs, low-dose aspirin and their combinations: Results of a pharmacovigilance reporting system

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Gastrointestinal (GI) complications are one of the most limiting cause of use of NSAIDs. Beyond others well defined factors, history of peptic ulcer, older age, Helicobacter pylori infection and use of gastrotoxic drugs may affect their GI safety profile. In particular, the risk of GI complications associated to the use of antiplatelet drugs, especially low-dose acetylsalicylic acid (LDA) should deserve much attention. However, only few studies have focused on the effect of combination LDA/NSAIDs on the GI tract compared with the monotherapy and much less studies assessed this effect with multiple NSAIDs use. We aimed to characterize the GI safety profile of NSAIDs and LDA as monotherapy or their combinations in real-life conditions by analyzing spontaneous adverse drug reactions (ADRs) reporting system in a Southern Italy. We used the case/non-case method in the Italian Pharmacovigilance Network (RNF). Cases were reports of GI events in the RNF between January 2007 and December 2011. Non-cases were all other reports during the same period. The association between NSAID and suspected GI ADRs was calculated using the reporting odds ratio (ROR) with 95% confidence intervals as a measure of disproportionality while adjusting for age, and concomitant use of antineoplastic agents or drugs for cardiovascular diseases. Sub-analyses were performed within the NSAID class. Among the 2816 adverse drug reactions recorded, we identified 374 (13.3%) cases of GI complications. Upper GI complications were the most frequently reported type of events. The highest associations were found for the combined use of NSAIDs and/or LDA, whilst the lowest associations were for their respective monotherapy. Looking at individual NSAIDs the highest association with GI events was observed for ketorolac exposure followed by nimesulide, diclofenac, aspirin, Ketoprofen, and ibuprofen. This study highlights the primary role of the national spontaneous reporting system to bring out potential signals, such as the inappropriate drug use pattern, which however, have to be furtherly studied in-depth with ad hoc population-based studies.

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Biography

Cristina Scavone is a pharmacist attending the last year of PhD in translational medicine. She plays her scientific research as a PhD student at the Department of Experimental Medicine of University of Campania "Luigi Vanvitelli" and at the Pharmacovigilance and Pharmacoepidemiology Center. Her research activities are directed to the topic of pharmacovigilance and pharmaco epidemiology. Since 2014, she is a member of the Italian Society of Pharmacology.

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