ADVERSE REACTIONS TO CONTRAST MEDIA: AN ANALYSIS FROM SPONTANEOUS REPORTING DATA

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Diagnostic contrast media (CM) are a widely used class of drugs with poor information regarding their safety. Nevertheless, as for the other class of drugs, epidemiological studies showed that CM cause adverse reactions, which are commonly considered unpreventable and unavoidable. Because spontaneous reporting is a valuable methodology for better defining the safety profile of drugs after their approval, we analysed the spontaneous reports of suspected adverse reactions attributed to CM (CM-ARs) sent to the Sicilian Regional Centre for the Spontaneous Reporting of Adverse Drug Reactions (ADRs) during the period from 1996 to 2006, with the aim to identify their most important features. One hundred ADR reports (out of 3471) involved CM (2.9%); 29 reports were serious, including one fatal case. Reported CM-ARs were equally distributed between females and males. However, when considering only serious reactions, a greater vulnerability in women seems to be confirmed, although this difference is not statistically significant, probably because of the small size of the database.
Skin, respiratory system and gastrointestinal tract were most frequently affected sites. The majority of reports described hypersensitivity reactions with immediate onset. Iopromide (52.5%), iopamidol (13.9%) and iomeprol (11.9%) were the drugs with the highest number of reports.
Despite contrast media are used in much higher concentrations and total doses than any other intravascular drugs, we observed that the rate of serious CM-ARs is minor in comparison to other drug categories in the whole database. This low proportion could be explained both by the protective role of the preventive management and by the presence of established protocols for the prompt treatment of serious reactions after CM administration by radiologists. Moreover, our data shows that specific therapy is far more used to treat CM adverse reactions, than for those caused by the other drugs, although the value of preventive pharmacological measures is uncertain.
In conclusion, case reports collected by the Sicilian Regional Centre showed that CM-ARs are not common or not commonly signalled; however, in agreement with previous published reports, analysis of data suggests that they are generally allergic-like reactions. Further investigations are needed within post-marketing surveillance to identify and prevent the consequences of CM-ARs and interactions. Awareness about CM safety should be promoted among all healthcare professionals.