Suspected adverse reactions to contrast media in Campania Region (Italy): results from 14 years of post-marketing surveillance

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Objective: During the last years in Italy and both Campania Region, there was increase in use of contrast media (CM), which led to an increase in number of patients potentially at risk of adverse drug reactions (ADR). This aspect stressed the necessity to monitor CM-induced ADR carefully, also in our Regional territory. The main objective of the present study was to give a preliminary evaluation of all Spontaneous Reports of ADRs (SRA) attributed to CM sent to Campania Pharmacovigilance Regional Center (CRFVC) in 14 years of post-marketing surveillance (from 2001 to 2014).
Research design and methods: We analyzed all SRA related to CM sent to CRFVC from 01/01/2001 to 31/10/2014. For each SRA we aimed to evaluate: frequency and source of reports, ADRs onset, time to event, seriousness and outcome of CM-induced ADRs, socio-demographic characteristics of cases, most frequently reported risk factors and the most reported type of CM (checking for pharmacodynamic and/or pharmacokinetic interactions).
Results: During study period, 111 SRA were sent to CRFVC; specialist in radiology was the main source of reports. Ninety-seven SRA (87.3%) were referable to hypersensitivity reactions. Thirty-four SRA (30.6%) reported serious ADRs. The most reported CM were iopamidol and iopromide among iodates and gadobenic acid and gadoteric acid among gadolinium-based contrast agents. We identified two SRA induced by pharmacokinetic and/or pharmacodynamic interactions.
Conclusions: During 14 years of post-marketing surveillance, only few SRA concerning CM-induced ADRs were sent to CRFVC probably due to underreporting. We aim to improve monitoring activity on CM-induced ADRs especially in hospitals. Most reported ADR and CM were in line with current body of literature and with other National scenarios.

References:

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