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Evaluation of spontaneous adverse drug reaction reporting related with nephrotoxicity and its causality assessment

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Objectives: The purpose of the present study is to evaluate the clinical characteristics, reporting quality of spontaneous adverse drug reaction (ADR) reporting related with nephrotoxicity, with respect to the three reporter groups - physicians, nurses, and pharmacists.

Methods: Records of spontaneous ADR related with nephrotoxicity from 2010 to 2017 at Seoul National University Hospital were reviewed. We collected data of demographics, the type of ADRs related with nephrotoxicity, causative drugs, reporters, seriousness, other clinical characteristics, and quality of reporting. We included ADRs of “certain”, “probable”, or “possible” categories as per the World Health Organization causality definitions in our analysis. We excluded “unlikely”, “unclassified”, and “unclassifiable” causality ADRs from the analysis.

Results: After excluding 25 ADRs of “unlikely” causality, 1,170 ADR records related with nephrotoxicity (707 male and 463 female patients) were finally selected for analysis. Among them, 314 ADR records were submitted by physicians, 556 by nurses, and 325 by pharmacists. Total reporting frequency has increased over time. The types of ADRs related with nephrotoxicity include acute kidney injury (n=560, 47.9%), urinary symptom (n=178, 15.2%), and electrolyte imbalance (n=432, 36.9%). By definition, urinary symptom includes urinary retention, urinary frequency, hematuria, proteinuria, and polyuria. Physicians and pharmacists most frequently reported AKI (80.6%, and 59.1%, respectively) and nurses most frequently reported electrolyte imbalances (56.8%). Physicians, nurses and pharmacists did not differ in the proportion of reporting ADR of “unlikely” causality - 2.9%, 2.2%, and 1.2%, respectively (P=0.244).

Conclusions: In our spontaneous ADR reporting system, the pattern of ADR is significantly different among the three reporter groups – physicians, nurses and pharmacists. However, the quality of reporting was similar among the three reporter groups.