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Statistical analysis and safe use of drug following by adverse drug reaction

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The USA, Japan and other nations have an established spontaneous reporting system for adverse drug reactions (ADR), enabling them to quickly detect and apply in clinical settings as critical abnormal reactions occur. Korea, on the other hand, has a low awareness of reporting on adverse drug reactions and has not yet developed systematic analytical methods. We have created a database based on the Korea Food and Drug Administration's (KFDA) voluntary reports on adverse drug reactions and Health Insurance Review Agency's insurance claims. We analyzed 5321 cases of KFDA's voluntary reports ADRs from 2001 to July 2006, as well as a total of 171,593,093 cases of medical prescriptions for people 65 years or older and children 16 years or younger patients hospitalized in Seoul for the year of 2005. We selected and analyzed celecoxib, alendornate, ribostamycin, ciprofloxacin, and ofloxacins as model drugs based on their potential to produce clinically useful results. We classified the ADRs as side-effect, toxicity, idiosyncratic effect, hypersensitivity, others, and medication error according to mechanisms, which were further classified into mild, moderate, and severe according to levels of seriousness. We also classified them according to frequency, namely 10% or more, 2 ~ 10%, 0.1 ~ 2%, and 0.1% or under. Following the classification, we developed the methods to measure the prominent ADRs by drug, and with regard to the signal index. We confirmed the statistical signals using PRR, ROR, and information component (IC). Although there was a formalized report form for the KFDA's voluntary ADR reports used in this research, a considerable number of reports were not accurately filled out as required, making it difficult to utilize for the statistics. Through this research, we have programmed reports on ADRs of drugs sold in Korea, and have confirmed statistical signals of

model drugs. The results indicate that there is an urgent need to apply methods for data analysis using data concerning ADRs. By applying the results of this research, we have confirmed the possibility of creating a systematic structure that can be used in the early detection of critical ADRs.

Key words: Drug, ADR (adverse drug reaction), Causal relationship, Statistical analysis