약물이상반응(Adverse Drug Reactions: ADRs)의 인과성 평가를 위한 한국형 알고리즘의 개발

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According to the study conducted on hospitalized patient in the United States by Lazarou et al.(JAMA. 1998), there are more than 2,000,000 serious ADRs in hospitalized patients, causing over 100,000 deaths annually. If true, then ADR is the 4th leading cause of death. Now in Korea, there is no active ADR monitoring system, but ADR monitoring system in the Seoul National University Hospital and Korean Medical Association, representing the nationwide clinicians, was initiated on May 2001 and on May 2002 respectively. Until Oct 1st 2002, only 30 cases, 16 cases from the Seoul National University Hospital and 14 cases from the Korean Medical Association, were reported. At present, rapid and valid review, resulting in helpful feedback to the reporters, is essential for the activation of ADRs monitoring system in Korea. In the same context, the algorithm, easy-to-use and in Korean, for the initial causality assessment became necessary. In this study, we first made a draft algorithm after reviewing the three current algorithms: Naranjo, French, and RUCAM. Then we conducted a test to evaluate the validity and reliability of the algorithm. The test was done with three target users, a physician majoring in internal medicine , a general physician and pharmacist majoring in pharmacoepidemiology, assessed the causality of the reported 14 ADR cases with the algorithm. Finally, the results were compared with the gold standard, the conclusion of the committee for drug safety within the Korean Medical Association. The average sensitivity and specificity was 100%, 50.0% respectively, and the average difference from gold-standard in mean scores was 0.65 (Min;-0.15, Max;1.40) points. Finally, we developed the Korean Alogorithm for ADR causality assessment.

Key words: adverse drug reactions, algorithm, causality assessment, validity, reliability