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Analysis of adverse drug reactions in hospitalized patients reported to pharmacovigilance center in a teaching hospital

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Abstract

Purpose: This study was carried out to assess the rate and pattern of ADRs reporting in hospitalized patients at a teaching hospital. Method: A retrospective cross-sectional study was conducted in Balcalı Hospital at Adana, Turkey during one year. The reports were examined on the basis of demographics, ADRs type, causality, severity, seriousness, drug characteristics and outcomes. WHO-UMC/ Naranjo algorithm scale, Hartwig and Siegel severity scale and pharmacovigilance contact point (PVCP) criteria were used to assess the causality, severity and seriousness of ADRs respectively. The data was double checked and then entered into SPSS (version 22.0) for mean, standard deviation (SD), frequency and percentage. Results: A total of 61105 hospitalized patients were admitted to the hospital and only 20 spontaneous ADRS were submitted to PVCP with an incidence rate of 0.03%. Of these, 18 eligible ADR reporting forms were reviewed according to inclusion criteria. ADRs related to antibiotics (38.8%) were most frequently reported followed by antineoplastic agents (22.2%). Most of the ADRs were related to skin (33.3%). In causality assessment, almost 50% of the reported ADRs were possible and 55.5% were moderate in severity. Moreover, about 83.3% of the ADRs were found to be serious according to PVCP criteria. Among the total patients, 55.5% have recovered from the reactions. ADRs were reported by physicians (66.7%) followed by an assistant doctor (16.7%). Conclusion: This study shows that ADRs are a significant problem in hospitalized patients. Monitoring and management of severe and serious types of ADRs would be valuable for improved patient care.

Keywords

Adverse drug reactions, antibiotics, pharmacovigilance, hospital, Turkey

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Details