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Adverse drug events (ADEs) in adult patients with cancer: an analysis of the jordanian national pharmacovigilance database

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Introduction: Adverse drug events (ADEs) in patients with cancer are an important cause of morbidity and mortality as anticancer drugs are designed to be cytotoxic and thus often injure normal cells (1). However, few epidemiologic studies were conducted regarding ADEs in oncology using data submitted during routine pharmacovigilance practice. The aim of this study was to assess the incidence, predictability, preventability and severity of ADEs in patients with cancer.

Methods: All spontaneous reports of adverse drug events (ADEs) in adult patients (i.e. > 18 years) recorded in the National Jordanian Pharmacovigilance Programme Database between January 2011 and December 2012 were investigated. Reports with incomplete or missing information were excluded. The Naranjo probability scale was used to evaluate the causality relationship between a likely ADE (2). Preventability was determined using criteria adopted from Schumock and Thornton scale (3). The severity of the reaction was determined according to Hartwig Scale (4). Predictability criteria were adapted from previous published work (5). Results: Between January 2011 and December 2012, 821 valid ADEs in 751 patients were reported to the Jordanian Pharmacovigilance Program. Amongst all reported ADEs, 401 (48.8%) events occurred in hospitalized patients. The most common drug classes associated with ADEs were: anticancer (52.3%), opioid analgesic (18.5%), antibiotics (14.3%), and immunosupressants (11.5%). Overall, the most frequently reported adverse drug events: were gastrointestinal (21.2 %), neurological (18.9%), and respiratory (11.5%). The ten most common events types were: pain, neutropenia, rash and itching, nausea and vomiting, and shortness of breath. Collectively they comprised 50.3% of ADEs identified. The majority of ADEs (72.6%) were assessed as probable in its causality. Total of 561 (68.3%) of the reported ADEs were moderate in severity. Of the reported ADEs, 80% were considered predictable of which 13% were preventable. Furthermore, the majority of preventable ADEs (n=72, 77%) were significantly higher in hospitalized patients ($P < 0.05$).

Conclusion: Patients with cancer are at high risk of developing ADEs. Strategies that reduce the incidence and severity of ADEs especially in hospitalized patients are essential to improve the outcomes.

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