Facilitation Of Reporting in hospital Ward (FORWARD): an active monitoring project to improve adverse drug reactions reporting

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Background: Adverse drug reactions (ADRs) are an important public health problem, representing a major cause of morbidity and mortality. ADRs account for 5-10% of all hospital admissions, occur in 10–20% of hospitalized patients and approximately half of ADRs are preventable [1-4]. Due to growing evidence of increased frequency and severity of ADRs, the drugs monitoring programs and preventive measures to reduce ADRs are a public health priority. The aim of the study was to determine the frequency, types, severity and preventability of ADRs both causing hospital admission and occurring among hospitalized patients.

Methods: "Forward" is an active monitoring pharmacovigilance project, carried out between the years 2014 and 2015, in 6 Departments of Internal Medicine in Sicily. A monitor, specialist in clinical pharmacy, was assigned for each hospital ward. All medical records of hospitalized patients were reviewed; identified cases of ADRs were assessed by a scientific committee and reported to the Italian Pharmacovigilance System. The ADRs were classified according to medical dictionary MedDRA and analyzed by System Organ Class (SOC) and preferred term (PT). The preventability of ADRs was assessed according to Schumock and Thornton criteria. Absolute and percentage frequencies with 95% CI were evaluated for ADRs causing hospital admission and occurring during hospital stay.

Results:

During the study period, 4,802 admissions, involving 4,212 patients, were recorded. There were 296 (6.2%) and 153 (3.2%) admissions categorized as ADR cause hospitalization and ADR occurred during hospitalization, respectively. The average length of stay was higher in patients who experienced ADRs during hospitalization compared to patients admitted for ADRs or without ADRs (14.1±8.3 vs 9.6±4.9 vs 10.5±7.1). Patients with ADRs were older than those without ADR (73.4 ±15.8 vs 72.8 ±16.2); most of them are female (61.1% vs 38.9%) ($p<0.001$) and more than half was taking five or more drugs at the time of their hospital admission ($p<0.001$). Overall, the 467 ADR reports included 782 single ADRs (mean 1.7 ADRs per report) and 580 suspected drugs. Altogether, there were 359 (76.9%) serious ADRs and only 74 (15.8%) not-preventable ADRs. In 13 cases (2.8%), a pharmacological interaction was suspected. Among patients who had ADRs during admission, antibiotics (38.2%), diuretics (8.3%) and cardiotonics (9.6%) were the class of drugs most commonly associated with ADRs. Anticoagulants (39%), ACE-inhibitors (13.9%), NSAIDs (11.9%), antidiabetics (9%), antidepressants (6.5%) were often cause of patients hospitalization. According to SOC classification, the most frequently reported ADRs were "gastrointestinal" (18.4% and 2.6% cause and occurred during hospitalization, respectively), "hematological" (17.6% and 2.4%), "cutaneous" (6.0% and 9.4%) "metabolic" (12.0% and 2.8%) and "nervous" disorders (10.7% and 2.6%).

Conclusions: The ADRs represented an important cause of medication-related hospital admissions and a significant number of ADRs are preventable. Our study highlights the need for corrective actions targeted to reduce the impact of ADR in the population.

References

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