ITALIAN EMERGENCY DEPARTMENT VISITS AND HOSPITALIZATIONS FOR OUTPATIENTS' ADVERSE DRUG EVENTS: THE MEREAFAPS STUDY

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Introduction: Adverse drug events (ADEs) are the most common cause of iatrogenic harm in healthcare and they have recently received attention in national patient safety initiatives worldwide. Moreover, ADEs are a significant cause of emergency department (ED) visits and consequent hospitalization. Preventing ADEs and their related ED visits in outpatients remains a public health safety challenge. In this context, the aims of the present study were to describe frequency, seriousness and preventability of outpatients' ADE-related ED visits and hospitalizations in the Italian general population, and to identify the presence of potential predictors of ADE-related hospitalization.

Material and methods: We performed a National multicentre retrospective study based on reports of suspected ADEs collected between January 1st, 2007and December 31st, 2018in the 94EDs involved in the MEREAFaPS project. Patients' demographic characteristics, their clinical status, suspected and concomitant drugs, ADE description, and its degree of seriousness, were collected. Causality and preventability were assessed using validated algorithms, and logistic regression analyses were used to estimate the reporting odds ratios (RORs) with 95% confidence intervals (CIs) of ADE-related hospitalization, considering the following covariates: age, sex, ethnicity, number of implicated medications, parenteral administration, presence of interaction, therapeutic error, and/or complementary and alternative medicines, complementary and alternative medicine (CAM).

Results: Within 12years, 61,855reports of suspected ADE were collected, of which 18,918(30.6%) resulted in hospitalization (ADE defined as serious). Patients were mostly female (56.6%) and caucasians (87.7%), with a mean age of 57.5±25.0 years. 58% of patients were treated with more than two drugs, and 47% of ADEs leading to hospitalization were preventable. Anticoagulants, antibiotics, and nonsteroidal anti-inflammatory drugs (NSAIDs) were the most frequently implicated agents for ED visits and/or hospitalization, which included clinically significant ADEs, such as haemorrhage (for anticoagulants), moderate to severe allergic reactions (for antibiotics), and dermatologic reactions and gastrointestinal disturbances (for NSAIDs). Older age (1.54[1.48-1.60]), higher number of concomitantly taken drugs (2.22[2.14-2.31]), the presence of drug-drug interactions (1.52[1.28-1.81]), and therapeutic error (1.54[1.34-1.78]), were significantly associated with an increased risk of hospitalization. Sex, ethnicity, parenteral drug administration and presence of CAM, were not associated with an higher risk of hospitalization.

Discussion and conclusions: Our long-term multicentre pharmacovigilance study in ED provided a valid estimation of ADE-related hospitalization in Italy, describing the seriousness, preventability, and clinical impact of ADEs in a representative sample of the European general population.