ADVERSE EVENTS DETECTED IN EMERGENCY ROOM OF AN UNIVERSITY HOSPITAL

Costanza Furlanetto[1] , Agnese Princi[1] , Irene D'Este[1] , Sara Dereani[2] , Paola Rossi[2] , Irene Fregonese[3] , Catia Tavano[3] , Ranieri Giuseppe Cravero[3] , Germana Modesti[1]

[1] SOC. Farmacia Ospedale Santa Maria della Misericordia, Azienda Sanitaria Universitaria Integrata di Udine, Udine - Italy, [2] Servizio Assistenza Farmaceutica Regione Friuli Venezia Giulia, Trieste - Italy, [3] SOC Pronto Soccorso Azienda Sanitaria Universitaria Integrata di Udine, Udine - Italy

Introduction: With the support of The Italian Medicines Agency (AIFA) an active pharmacovigilance program is operative in the Emergency Room (ER) of Integrated University Hospital "Santa Maria della Misericordia" (Udine, Italy). This project has two important goals: to report the suspected adverse events to drugs (ADE) or vaccines (AEFI) leading outpatients to ER and to analyze the ADEs "in toto", in order to share the results with the involved health care professionals.

Matherials and methods: The pharmacovigilance program dates back to 2015 and since February 2018 the pharmacist have been analyzing daily the ER accesses for ADEs to drugs or vaccines. The pharmacist investigated the records of the Intraoperative Emergency System (SEI), checked the causes that led outpatients to hospital and selected only the ones potentially related to ADE/AEFI. The selected cases were reviewed with the ER medical staff. Once confirmed, ADEs are entered, then validated by the pharmacist and finally recorded into the AIFA National Pharmaceutical Monitoring Network (RNF). ADEs were evaluated using the Adverse Drug Reaction Probability Scale (Naranjo) and analyzed respect to time, age, sex, category of ADE, seriousness, suspected medicines, type of reporter, off-label use, overdose, misuse and abuse. The reports of suspected/unexpected adverse reactions were further collected in an internal database, used for data analysis. The database items were drug, pharmacotherapeutic subgroup, adverse drug description, gravity, notoriety.

Results: Over a 1-year period (from february 2018 to january 2019) 345 ADEs were reported. Among them 132 were classified as non-serious (38.3%) and 212 serious (SAEs) (61.4%). Between SAEs only one caused death (0.3%), the others were related with unchanged or worsened reactions (2.3%), with partial (45.3%) or complete resolution (33.9%) or with an unknown outcome (18.8%). The ADR resulting in death occurred with edoxaban, which firstly caused to the patient a profuse melena, than a coma, that led to a failure evolution. The most frequently pharmacotherapeutic subgroups envolved in ADEs were anti-platelets and anticoagulants agents (TAO/NAO), which counted for 34.2% of all the reports. Psychotropic drugs counted for 20%, antimicrobials for 17.1%, cardiovascular apparatus agents for 8.4%, musculoskeletal system drugs for 7.8% and oncologic/immunomodulatory medications for 4.9%. Bleeding (97.4%) was mostly related with antiplatelets and anticoagulants agents, allergic reactions (88.1%) with antimicrobials, nausea, dizziness, epigastralgia (17.4%), skin reactions (11.6%) with psychotropic drugs, that induced central nervous system depression (44.9%) in case of abuse. The Naranjo causality scale, applied by Regional Pharmacovigilance Center (CRFV) phamacists for the SAEs, demonstrated that 161 reactions were possible (75.9%), 50 probable (23.4%) and 2 doubtful (0.9%). Regarding reported reactions notoriety we detected 15 reactions, corresponding to 4.3% of the total, that were not present in the Product's Summary of Product Characteristics (SPC).

Discussion and conclusions: Adverse drug events in the outpatient setting are common. In this report we describe the collaboration of two units, pharmacy and ER, to develop an ADE monitoring. This project demonstrated that active post-marketing pharmacovigilance programs, in real life setting, are a valid strategy to increase healthcare professionals' awareness of pharmacologic therapy, reduce underreporting and provide more information on drug safety. Next goals will concern the identification of specific drugs associations, related with ADE that lead to hospitalization or admission to ER, and the production of educational material for health professionals.