Pharmacovigilance in oncology: analysis of adverse drug reaction in the last three years

A. Nappi[1], A.C. Bonagura[2], M. Spatarella[1], P. Zuppardi[1]

[1]Hospital Pharmacy "D. Cotugno ", AORN dei Colli, Naples, Italy
[2]Collaborator of Pharmacovigilance Regional Center, Campania region, Italy

The role of the hospital pharmacist, who collaborates with the oncologist, aims at therapy monitoring to deepen drug risk and benefit. In oncology, the pharmacovigilance is important to introduce both innovative therapies and additional monitoring. Our aim was to verify, in the three-years observation, the type and severity of suspect adverse reactions report (ADRs) associated with the use of anticancer drugs, patients types, outcomes, undertaken actions and costs. At 'AORN dei Colli' from 01/05/2012 to 04/30/2015 were analyzed ADRs by RNF relative to anticancer drugs. The ADRs were examined, numbered and divided by severity and outcome. The ADRs were then divided by System Organ Class (SOC) by consulting reports from the archive of the pharmacovigilance office. ADRs received from 01/05/2012 to 30/04/2015 were 336 (male:147; mean age:60.7; females:189, mean age:65.7) of which: 66 in the first year (45 serious and 21 not serious), 159 in the second year (80 serious, 75 not serious and 4 not definite) and 111 in the third year (73 serious, 34 not serious and 4 not defined). The most expressed SOCs were: haemolymphopoietic system disorders (44.5%; respectively: 36.14% in the first year, 45.21% in the second year and 48.87% in the third year), gastrointestinal diseases (12.62% respectively: 7.23%, 11.17%, 14.29%); skin diseases (11.39% respectively: 12.05%; 12.23%; 13.53%) and conditions related to the administration site (6.68% respectively: 8.43% ; 8.51%; 3.01%). The outcome of all reports were: complete resolution 45.67%; improvement 28.9%; not available 18.48% and resolution with hangovers 2.35%. With reference to the haemolymphopoietic system, the most frequent SOC, the undertaken actions were: drugs administration (67.65%), drug dose reduction(2.94%), drug withdrawal (1.96%), diagnostic and laboratory tests (1.9%) and unspecified action (25.49%). The drug treatment has required GCSF administration (65.94%), epoietin administration (14.48%), cortisone administration (10.14%) and blood transfusion (9.43%). Total GCSF expenditure was € 3082.30, with an impact of 56.83% in the first year, 39.46% in the second year and 3.71% in the third year. Total epoietine expenditure was € 1576.80 (60% in the first year, 30% the second year and 10% in the third year). Total cortisone expenditure (administered by os), was not economically significant. The analyzed costs were related to a day of ADR. In the three years an upward trend of the ARD was shown, while SOC is more frequently linked to the haemolymphopoietic system disorders. Almost an half of the ADRs were treated pharmacologically with a total pharmaceutical sum of € 4663.01. In the future, our purpose is to improve reporting in order to have better data quality.