

#### 47. Detection and Incidence of Drug-Induced Agranulocytosis in French and Spanish Hospital: a Prospective Analysis from Laboratory Signals

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**Aims:** Our objectives were to assess the detection and incidence of drug-induced agranulocytosis in a University Hospital using hematology laboratory data.

**Methods:** A prospective study was undertaken at Toulouse University Hospital in France and Navarra University Hospital in Spain during 1 year from 1<sup>st</sup> May 2004 to 30<sup>th</sup> April 2005. Patients were selected by computerised process using hematology laboratory data, based on neutrophil count (< 500/mm<sup>3</sup>). Medical records of all selected patients were then consulted.

**Results:** During the period of the study, 225,659 neutrophil counts were performed in both hospitals among which 2,835 (1.26%) met the inclusion criteria corresponding to 739 patients. Seventeen patients were excluded because of lack of data and 20 cases due to infants younger than 3 months. Among these patients (n = 702), 23 cases of drug-induced agranulocytosis were suspected. All cases were classified as "serious" since they led to death in two cases, hospitalisation or prolongation of hospitalisation in 19 cases and threatening of vital prognosis in 2 cases. Withdrawal of suspected drugs was done in all cases with regression of neutropenia in 21 cases. According to hospitalisation data, the annual incidence of drug-induced agranulocytosis was 1.62 [1.0-2.6] per 10,000 inpatients in Toulouse University hospital and 3.24 [0.9-8.3] per 10,000 inpatients in Navarra University Hospital. The involved drugs were mainly: antibacterial (30.4%), immunosuppressive (17.4%), antithyroid (13.0%), antiplatelet (8.7%) and non-steroidal antiinflammatory (8.7%) drugs. Only 7 cases of Toulouse University Hospital were spontaneously reported by physicians during the same period. Thus, the underreporting coefficient (U) was 2.71.

**Conclusion:** Our survey allowed to identify the suspected drug-induced agranulocytosis through a prospective study in a large sample of inpatients only by using laboratory data analysis and to note an important underreporting rate of this serious adverse drug reaction (ADR) to the official French Pharmacovigilance system. Laboratory data analysis could be used for identifying serious ADRs.