IMPLEMENTING A PHARMACOVIGILANCE PROGRAM IN ONCOLOGY

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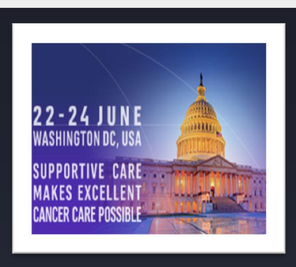


Background

Adverse Drug Reactions (ADRs) may result in hospitalization, disability or death of the patient. The occurrence of ADRs has high morbidity and mortality, accounting for the 5th leading cause of death in industrialized countries. Post-marketing evaluation of drugs completes the safety and efficacy profile of the drug, since it allows the inclusion of a large number of individuals, like pregnant women and nursing mothers, children and elderly patients, and produces chronic exposure and toxicity data. In fact, the safety profile of a drug may vary over time. The implementation of intensive monitoring programs allows identification of early occurrence of ADRs, in a comprehensive and exhaustive way. Since it´s a resource consuming activity, the drug selection criteria should be well defined.

Purpose

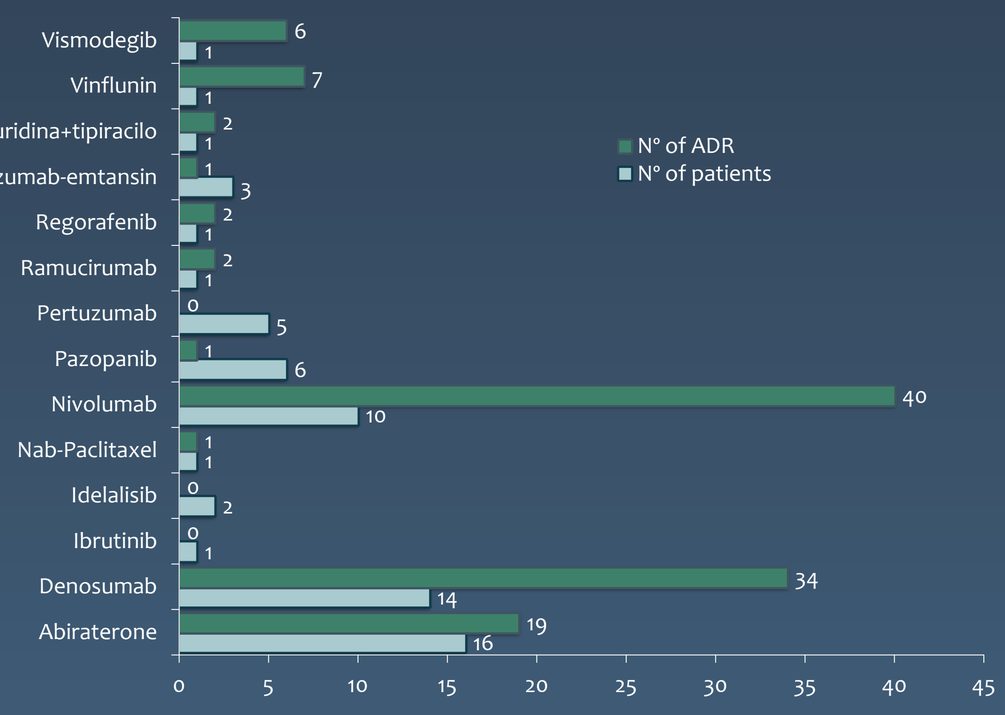
To describe and characterize an Intensive Pharmacovigilance Program in CHLO oncology department

Material and Methods

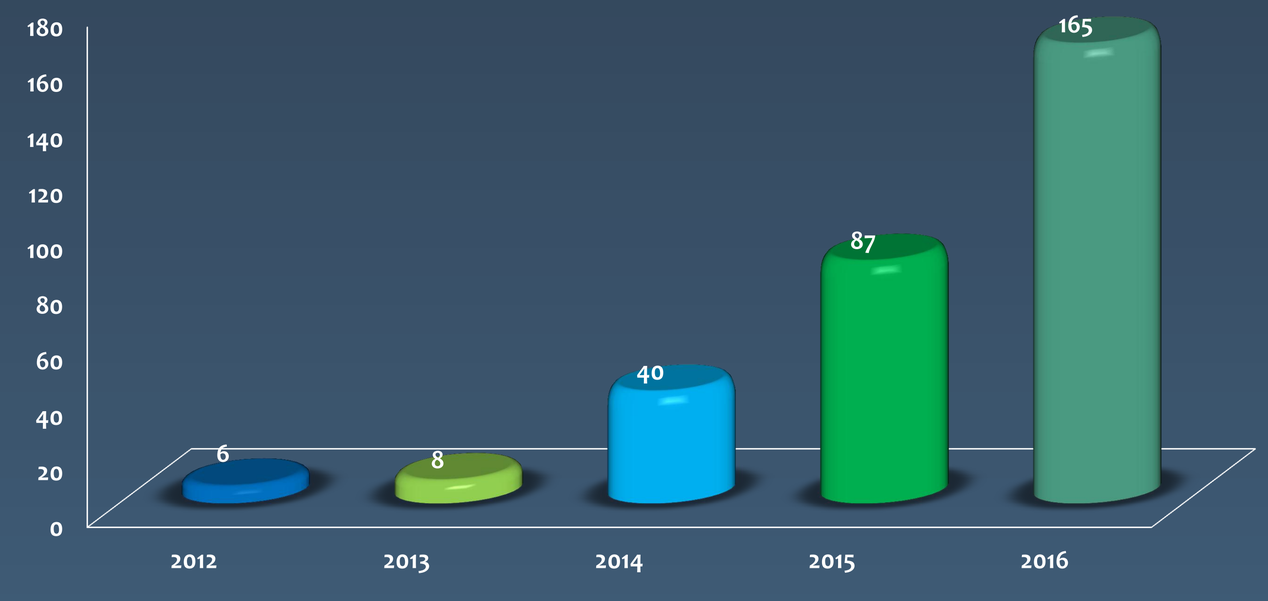
Analysis of the implementation of an Active Pharmacovigilance Program through a descriptive, observational study, with retrospective analysis, conducted between January 2012 and December 2016, in the oncology sector of a general central hospital. The antineoplastic and immunomodulators included in this program were selected by Pharmacy and Therapeutic Committee. Data were collected by patient interview and hospital records review and analyzed using SPSS V17.0. Detected ADRs were notified to the regulatory agency.

Results

During the study period, 14 drugs were included in the Active Pharmacovigilance Program (abiraterone, denosumab, ibrutinib, idelalisib, albumin-bound paclitaxel, nivolumab, pazopanib, pertuzumab, ramucirumab, regorafenib, trastuzumab-emtansine, trifluridine+tipiracil, vinflunin and vismodegib). We monitored 63 patients and performed 306 follow-ups, with an average of 5 follow-ups/ patient (min = 1, max = 21).

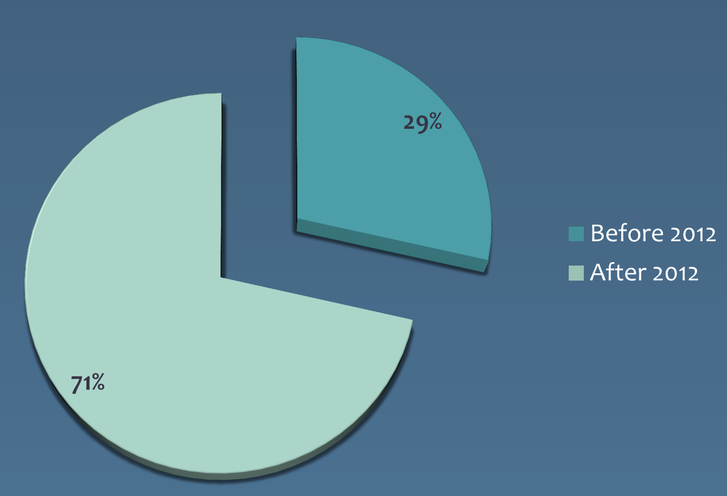


Graffic 1: N° of patients included by drug

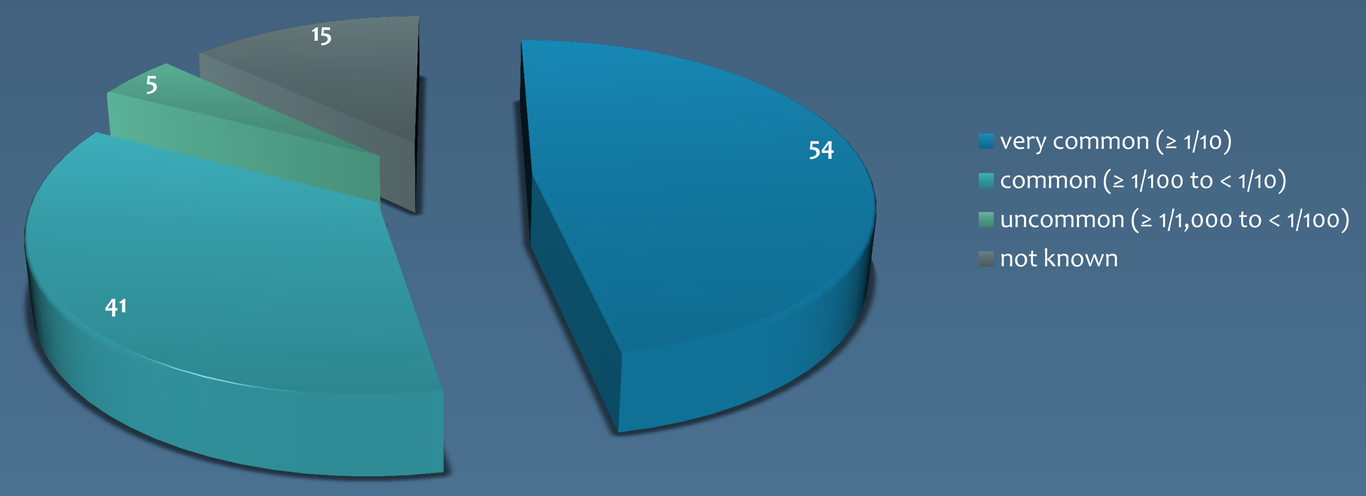


Graffic 2: N° of follow-ups/ year

The majority of drugs included in this active pharmacovigilance program had an approval date before 2012. We identified ADRs in 69% of the follow-ups, corresponding to 115 ADRs.



Graffic 3: Approval date of the drugs included



Graffic 4: N° of ADR by frequency

Most ADRs identified were described in summary of product characteristics as very common or common. But we were also able to identify 15 ADR that were not described in the summary of product characteristics and 5 uncommon ADR.

Conclusions

Clinical trials usually include a small number of patients and that are followed for a relative short period of time, therefore it's important to monitor the safety of drugs in clinical practice. The use of intensive monitoring programs to identify and assess potential safety signals, which could not be otherwise identified by the spontaneous reporting process, gives an enormous contribution to the safe use of drugs. It is challenging to identify ADR, given the high frequency of symptoms, the substantial burden of chronic illness, and the frequent use of multiple medications. Although it is a resource-consuming activity, the importance of pharmacovigilance needs to be regarded with more attention by health care professionals, since the identification of ADR is related to patient safety and quality of life.

References:

1 – McClure L. Improving Drug Safety: Active Surveillance Systems Should be Paramount. Pharm Med 2009; 23 (3): 127-130;
2 – Lazarou J, Pomeranz B, Corey P. Incidence of Adverse Drug Reactions in Hospitalized Patients. JAMA 1998; 279 (15): 1200-1205;
3 – Haas J *et al*. Active Pharmacovigilance and Healthcare Utilization. The American Journal of Managed Care 2012; 18: 423-428

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