Pharmacovigilance active project: biological drugs use in the Policlinico Hospital of the Second University of Naples

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Background: Clinical trials of new drugs, based on randomized controlled trials (RCTs), represents only part of the best method available for determining the profile of effectiveness and safety of new drugs; in fact, clinical trials are still significant deficiencies regarding the exact definition of the risk/benefit of a new drug. The target therapy or therapy with biologics represents a new frontier not only in cancer therapy but also in the approach to autoimmune and inflammatory bowel diseases (IBD) [1,2]. Although clinical trials have shown a good safety profile of biological drugs, are still too short to complete this assessment, in fact there are no reliable data on the safety profile of long-term, because is still too short the period of time elapsed since the start of the use in humans and so the length of the major clinical trials. Therefore, coordinated by Campania Regional Centre for Pharmacovigilance and Pharmacoepidemiology, at the Policlinico Hospital of the Second University of Naples was started the project of Pharmacovigilance on the use Biological Drugs. Methods: The project consists of four phases: I) In the first phase was evaluated the Biological Drugs in the PTO Company and subsequent verification of user's department. II) In the second phase, through scheduled meetings, clinicians have been clarified about the procedures, the operational path and objectives of the project and III) In the third phase were intercepted and selected naïve patients from departments identified by the project. Data collection were completed by the analytical description of any adverse reactions (ADRs). All suspected serious adverse reactions and non-serious, known and unknown due to the drug have been reported to responsible for Pharmacovigilance of the Hospital, who inserts the reports into the National Network of Pharmacovigilance (RNF). Results: During the survey period considered (2012-2013), 77 patients were recruited in the study. In particular, 40,2% at the U.O.C. of Oncology, 32,5% at the U.O.C. of Rheumatology, 18,2% at the U.O.C. of Gastroenterology and 14,7% and U.O.C. of Dermatology. The ADRs reported for biological drugs were developed in female and male with the same rate. The patients enrolled in our study were in mean over 65 years old. The total number of events reported was 156 and the results of this analysis showed a prevalence of note reactions (88%) and ADRs not serious (84%). In the specific, the adverse reactions more often reported were diarrhea (11%), nausea (9%), rash (8%) and weakness (6%). Moreover the unknown ADRs were most often associated to Trastuzumab (37%), cetuximab (36%) and bevacizumab (15%). Finally the outcomes of events reported were fully recovered in 62% of cases, getting better in 29% and unchanged in 24%. Conclusion: Our data show therefore an acceptable tolerability profile, especially in view of the fact that the largest number of reported events was already known in the technical and thus more easily manageable by the doctor. The implementation of the project "Pharmacovigilance on biologics" has undoubtedly been a major breakthrough in the management of the safety profile of these drugs.
Keywords: Pharmacovigilance, biological drugs, Policlinico Hospital of the Second University of Naples

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