OMICS International
conferenceseries.com

J Pharmacovigilance 2015, 3:4
http://dx.doi.org/10.4172/2329-6887.S1.018

4th International Conference and Exhibition on

Pharmacovigilance & Clinical Trials

August 10-12, 2015 London, UK

The safety of biological medicines for rheumatoid arthritis & their economic consequences

Giannis Papadopoulos[1], **K Demetzos**[1], **S Markantoni-Kyroudi**[1] and **K Souliotis**[2]
[1]University of Athens, Greece
[2]University of Peloponnese, Greece

Introduction: Biotechnological medicines have improved the treatment of various diseases and the quality of life of patients. The administration of a drug may lead to adverse events that may or may not be documented. These events affect disease progression and health expenditures. Rheumatoid Arthritis (R.A.) is an autoimmune disease for which biotechnological medicines are prescribed. RA has serious economic impact. Especially, the annual cost of RA is 41billion Euros in the U.S.A. and 45billion Euros in Europe, which are increasing dramatically with appearance of an adverse event.

Aims: To record the ADR of biotechnological drugs prescribed for R.A., to assess their possible effects on both patient & health system and to develop a tool aiming the efficient use of biological medicines.

Methodology: A review of existing literature on adverse events of biotechnological medicines for RA & analysis of all available data from Eudravigilinance were conducted. The collection of adverse events data from rheumatology clinics of various hospitals will be conducted. Finally, any algorithm/tool currently utilized to guide the selection of the most appropriate treatment will be assessed.

Results: 60% of patients are female aged 18-65 years. 20% of reports indicated that an infection has occurred, 15% highlighted the existence of inflammation at the site of injection and 12.5% reported a gastrointestinal disorder. The occurrence of musculoskeletal problems, hyperplasia and nervous disorder estimated at 10% of the reports and the respiratory problems approximately 8%.

Conclusion: Infection or inflammation at the site of injection is the most common adverse events altering microbiological profile of patient. Possible relationships/associations between certain parameters (for example genome and the appearance of an adverse event) which will contribute to the safer and efficient use of biological drugs will be examined. In addition, the total average medical costs were reported to range from 5720$ to 5822$, while the average number of days absent from work due to a person's RA was reported to range from 2, 7 to 30 days /years. The appearance of adverse events increases dramatically the therapeutic costs.

gianpapadopoulos@gmail.com

Frequency of adverse events in plateletpheresis donors in regional transfusion centre in North India

Gopal Kumar Patidar, Ratti Ram Sharma and **Neelam Marwaha**
Post Graduate Institute of Medical Education and Research, India

We planned this prospective study to look into donor safety aspect by studying adverse events in normal healthy plateletpheresis donors. In this study we included 500 healthy, first-time (n=301) and repeat (n=199) plateletpheresis donors after informed consent. The plateletpheresis procedures were performed on TrimaAccel (5.1 version, GAMBRO BCT) and Amicus (3.2 version FENWAL) cell separators. The adverse events during procedure were recorded and classified according to their nature. In results we found a total of 18% (n=90) adverse events were recorded in 500 plateletpheresis donors, of which 9% of were hypocalcaemia in nature followed by hematoma (7.4%), vasovagal reaction (0.8%) and kit related adverse events in (0.8%). There was significant postprocedure drop in Hb, Hct, platelet count of the donors ($p<0.0001$) whereas WBC count showed a statistically significant rise ($p<0.0001$). Divalent cations (iCa+, TCa+, TMg+) also showed a statistically significant decline after donation ($p<0.0001$). However there were no statistically significance differences between adverse events in TrimaAccel (5.1 version, GAMBRO BCT) and Amicus (3.2 version FENWAL) cell separators. Donor reactions can adversely affect the voluntary donor recruitment strategies to increase the public awareness regarding constant need for blood and blood products. Commonly observed adverse events in plateletpheresis donors were hypocalcemia, hematoma formation and vasovagal reactions which can be prevented by pre-donation education of the donors and change of machine configuration.

drgpatidar@gmail.com