Safety pharmacovigilance of biologicals and differences from small molecules

Anup Choudhury
Novartis Pharmaceuticals, India

Biologics development represents a major modern advancement in the area of healthcare and medicine as promising therapeutic option for many previously incurable diseases because of their huge success rates. Biologics are defined as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood product, blood component or derivative, or an allergenic product used for the prevention, treatment or cure of diseases. A review of development safety and pharmacovigilance of biologics is presented here with their differences from small molecules. Biologics are unique in absorption, distribution, metabolism, and elimination (ADME), which lead to significant differences in their drug development process in comparison to the small molecules or chemical entities. The monoclonal antibodies (mAbs), which are considered to be the most important subset of biologics, bind to their targets by specific or non-specific binding. As the biologics are therapeutic proteins, they have the concern of developing immunogenicity, with possible loss of therapeutic efficacy to severe life threatening adverse events. The safety adverse events can be due to a generalized and intensified immune response or due to cross-reactivity of neutralizing anti-drug antibodies (ADA) with endogenous substances. The most common adverse events in biologics are acute infusion reactions or cytokine release syndrome, also known as cytokine storms, which typically develop within 30 minutes to two hours after the initiation of drug infusion, however, the symptoms, may be delayed for up to 24 hours.

dranupchoudhury@gmail.com

Effect of drug-drug interactions and number of prescribed medications on intensive care unit length of stay

Arezoo Ashnagar1, Mohammad Sistanizad1, Donya Moslemzadeh1 and Sajjad Ashnagar2
1Shahid Beheshti University of Medical Sciences, Iran
2University of Michigan, USA

A drug-drug interaction (DDI) is a type of adverse drug effect (ADE) that is important to be prevented due to its consequences. The aim of this study was to determine the frequency of DDIs during intensive care unit (ICU) stays and to determine whether the frequency of these adverse events was associated with ICU length of stay (LOS). This prospective study was conducted in the ICU of Imam Husain multispecialty teaching hospital. Patients aged >18, with more than a 48 h stay were included in the study. Verification of potential drug interactions was carried out using the online Lexi-Interact TM. The median LOS was determined by the Kaplan-Meier method and cox proportional hazards models were fitted to analyses the relationship between DDI and the LOS. A total of 250 patients (94 females and 156 males) were enrolled in the study and the prescription data of 3986 patients-day entered to the database. The mean age of patients was 52.42±22 years. The mean LOS was 15.9±16.3 days. A total of 50743 potential DDIs have been identified by Lexi-Interact TM, 7425 (14.66%) and 1043 (2.06%) of which were categorized as D and X, respectively. The Pearson’s correlation method showed that a prolonged ICU stay was positively associated with DDIs (p-value<0.001), also the Mann-Whitney test indicates a significant difference in the Los of patients with D and X interactions and patient without D and X interactions (p-value<0.001). This study showed that DDIs are associated with longer ICU stays. By decreasing the number of DDIs, especially type D and X, ICU stays and hospital costs will be decreased. Drug interactions leading to serious adverse effects are to be cautiously watched for when multiple drugs are used simultaneously.

a.ashnagar1993@gmail.com