

Admitting (Un)Known (Biosimilar-) Drugs Affects Thrombosis and Haemostasis Processes

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Accidental admitting and using (un-) known drugs might manipulate health and/or disease(s) of a subject in a positive (healing) and/or negative way (increased mortality and morbidity rate). Now a days, different kinds of drug development technologies are available, which might help affect global health. Though, the psychiatric comorbid disorders were important risk factors for premature drug-related deaths despite so many developed tools and technologies [1].

From the invention of the chemical drugs and their usage, the side effects are also induced, simultaneously. Recent studies have indicated that other new non-chemical drugs also have own remarkable 'side effects' in different ways of actions. The known risk factors for increased premature death in different drugs and substance abusers are

1. Types of drugs or substance,
2. Immature systemic organ developments at a young age and
3. Polydrugs synergistic side effects and abuse [1-4].

Besides, there are two types of drugs in general that are being used for cure and care namely

1. Biologic (herbal, blood-derived) and
2. Non-biologic (chemical and/or bio-similar) drugs. Both types have own (dis-) advantages. In the 21st Century, one might expect that regulatory affairs have for any novel substance and drugs have an appropriate regulation before introducing in the market. Remarkably, with new speed regulations, some prerequisite researches skipped, however. Here, it is tried to highlight more about different

drugs' potential side effects at human platelet function and survival (thrombocytopenic and thrombolytic side effects), which could be the main cause of different (ir-) responsiveness and (hyper-) activity towards thrombosis and bleeding disorders [5]. Recent European Commission investigation about Cancer- Associated-Thrombosis (CAT) showed that side effects of chemotherapy and radiotherapy might increase thrombosis risk of cancer patients without reference to their treating Medical Practitioner.

On one hand, the main formulation of non-biologic chemical drugs (NBCD) supposed to be known and the standard formula with final concentration, and their so-called "final added elements and concentration" (FAEC) could be measured, tracked, changed by the different technologies and interventions. On the other hand, the FAEC's infections in either biologic and/or non-biologic drugs could be managed by different developed technologies, ultimately. I have introduced novel technologies to quality control (QC) and quality assurance (QA) before admitting to the patients but unfortunately, it is refused to implement it, however.

Other kinds of drugs are herbal medicines, which are mainly made from different pieces of 1. Trees 2. Plants and 3. Vegetables. In the Oriental agricultural regions, almost all segments of trees and plants are used either as dietary supplements or as a Medicine i.e. fruits, flowers, leaves, roots, and their extracts; irrespective of thrombosis and hemostasis. There is no gold standard for the usage of herbal medicines, globally. All side effects and allergic reactions are also not described and determined appropriately.

It is best-known that the bio-similar and biological drugs

have unknown (final) formulation, which might cause small traces that are not being measured, -traced, -changed by any certain Medicine because of insensitive /unspecific available tools, locally. Simultaneously, the primary assumption to use such herbal/ blood-driven drugs was that biological drugs have no side effects. The transfection of antigens by bio-similar / biological drugs becomes a major halt of unassuming intravenous transfusions.

In the last decades' research and developments opened new ways to isolate and fabricate the biological blood-derived drugs (BBDD) prepared from 1. Human whole blood 2. White blood cells 3. Red blood cells 4. Platelets 5. Plasma proteins and 6. Waste product electrolytes. In general, these kinds of BBDD are used directly unprocessed, and/or separated to components- stored for a while, up to months under cold conditions. The BBDD with limited additives and anticoagulants and/or in combination admitted unassumingly and without human leukocyte antigens/human platelet antigens (HLA/HPA) matching, intravenously. Moreover, the BBDD that got potentially contaminated with different kinds of blood-borne antigens either biological or non-biologic transfused to the recipients, however. The biological types of antigens might induce mild- to lethal allergic reactions, transfusion-related acute lung injury (TRALI) and autoimmune diseases, post transfusion. Besides, the BBDD final concentration and formulation due to either different donor sources or patient's diversity should be classified under unknown biologic drugs with high risk.

My group relevant basic research (in *ex-vivo*) have shown that after all, when post-transfusion's immune reactions are induced under certain circumstances (recipient's model system), (ir-)responsiveness and (hyper)activity of platelets function changes unpredictably [6]. When the recipient got identical antigens transfused, the memory B- and T-cells might react immediately, and produce (auto-) antibodies against transfused antigens and own cells and tissues. This kind of memory antibodies might develop autoimmune disease, eventually. How the lymphocytes B- and T-cells respond to a new antigen and/or tolerate other antigens is intensively studied. When patients' immune system and (auto-)antibodies attacks own platelets, a patient gets either thrombosis or thrombocytopenia so-called 'Immune thrombocytopenia (ITP)' and 'Thrombotic thrombocytopenic purpura (TTP)' that ends in the most cases to a severe bleeding disorder, and/or heart-brain-gut thrombosis, consequently. How? And why acute ITP changes in chronically forms of fatal autoimmune disease are not elucidated completely [5].

One might speculate that autoimmune disease might be derived from side effects of unknown diet supplement and/or biosimilar- biological drugs available in the

market. Although all kinds of authorities prevent unknown supplements and (biosimilar) drug marketing but still so much unknown food supplements and drugs are merchandising in the pharmacies and big drug stores that one scares from uncontrolled offers Online.

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