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Causality assessment methods of hepatic adverse drug reactions: Opportunities for enhancement

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Causality assessment of hepatic adverse drug reactions is pivotal for patient safety. Methods for causality assessment of hepatic adverse drug reactions include global introspection, algorithms, and probabilistic analysis. Algorithms are different and show variable inter-rater and multi-rater agreements. Naranjo, WHO-UMC, Roussel-Uclaf, Maria and Victorino, and Drug-Induced Liver Injury Network are few examples of the algorithms used in assessment of causality for drug-induced liver injuries. Comparison of these algorithms demonstrates the advantages and limitations for each. Recent algorithms that introduce pharmacogenetics in causality assessment of hepatic adverse drug reactions haven't been practiced on a wider scale yet. Reliability of their probability scores is questionable. Theoretically, drug-induced liver injuries can be predicted with a highly sensitive and specific robust causality assessment method that integrates pharmacogenetics with pharmacovigilance and applies a holistic approach. Challenges that face the development of this algorithm are numerous and may include understanding of gene regulation and DNA-protein interaction, knowledge of computational tools as next-generation sequencing and bioinformatics, and streamlining genetic and safety data collection. Pharmacogenetics-based algorithms used for causality assessment of hepatic adverse reactions have a potential invaluable impact on drug development. Applying the valid reliable data and probability scores generated by these novel algorithms will enhance the cost-effectiveness analysis of microdose clinical trials and reflect on selection of the next in sequence drug candidate.

Biography

Bassem Toeama received his MD degree from Cairo University, Egypt. He has worked in clinical medicine as an oncologist, in academia, and in pharmaceutical industry over the past 20 years. His experience has been primarily in oncology, pharmacovigilance, clinical research, and lab research. He holds an MSc degree in Experimental Therapeutics at the University of Oxford, UK and an MSc degree in Experimental Medicine at McGill University, Canada. He is a PhD candidate in health technology assessment at the University of Toronto, Canada. Bassem is a pharmacovigilance consultant, a clinical research instructor, and a lead medical writer.

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