Clinical Pharmaceutical Research; Challenge or Dilemma

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Abstract

Comprehensive discovery of Immune Complex Antigens (IC-antigens) is helpful for elucidating pathophysiology and may serve as the foundation for new diagnostic and therapeutic approaches for a variety of immune-related disorders. A technique for completely recognising and analysing IC-antigens in bodily fluids is immune complexome analysis (such as serum and cerebrospinal fluid). We used this method to examine circulating ICs in cancer, viral illnesses, and autoimmune disorders such as rheumatoid arthritis, Sjogren's syndrome, systemic scleroderma, and systemic lupus erythematosus. Proteins are fluorogenic derivatized, followed by HPLC of the derivatized proteins, isolation of the proteins differentially expressed in a particular group, enzymatic digestion of the isolated proteins, and LC-tandem MS employing a database-searching algorithm for protein identification.

Keywords: IC-antigens • Serum • Cerebrospinal fluid • HPLC

Introduction

Globally, the healthcare system, the economy, and sociocultural interactions are being progressively impacted by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-associated coronavirus disease 2019 (COVID-19 rapid)'s pandemic expansion [1]. These include big platform clinical trials (such as the SOLIDARITY trial by the World Health Organization and the Discovery trial by INSERM) that examine already available antiviral and adjunctive immunomodulatory medications. While the severity of the threat presents a significant challenge to the healthcare system. It also has an impact on thousands of current clinical studies trying to create novel treatments for illnesses with high unmet medical needs in various therapeutic fields [2]. Self-medication with potentially active treatments without a documented positive benefit/risk profile also raises concerns for the overall public health. This is crucial in regions of the world where there may be lax regulations on distribution, which could allow elderly. Despite containment efforts, the COVID-19 pandemic has persisted, hampering clinical trial infrastructure globally with quarantines and lockdowns. The US Food and Drug Administration (FDA) and the European Medicines Agency have both issued regulatory guidelines to support clinical trials during the COVID-19 pandemic (EMA). Missed appointments, missing or drastically reduced data collection for safety, effectiveness, and pharmacokinetic endpoints, as well as increased patient dropout, are some effects that compromise the validity of trials, the interpretation of data, and the support of evidence [3, 4]. Clinical trialists have addressed these issues in a number of novel ways. These include in-home nurse visits, telemedicine assessments conducted via telephone or video contact rather than in-person visits, and opportunities for remote source data verification through access to electronic health records when in-person site visits are not practical. On-site visits with careful planning for appropriate distancing/isolation of trial participants to avoid mixing with potentially infectious patients are also included in this list. We identify opportunities from a quantitative clinical pharmacology perspective to maximize the value of data, complementing statistical methodologic innovations that have been described to address interruptions in clinical trials, even though case-by-case assessments of risk, impact, and mitigation are required [5].

Conclusion

Public health and drug development are facing unprecedented difficulties as a result of the COVID-19 pandemic. Utilizing a Totality of Evidence strategy, clinical pharmacologists and model-informed drug developers are in a prime position to take advantage of opportunities to improve therapy optimization, provide guidance for difficult decisions faced by healthcare professionals and clinical trialists, and lessen the effects of disruptions in ongoing clinical trials for non-COVID-19 drug development. In the long run, we anticipate that the improvements in clinical trial design and model-informed adaptive evidence production made possible by this strategy would speed up access to medicines by enhancing efficiency and reducing the length of time required for overall drug development.

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