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Perspective

Antiviral Permeability and Tolerance Screening

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ABOUT THE STUDY

RNA viruses have always posed a significant threat to human civilization, and they have evolved in tandem with human progress. In the meantime, this large group of viruses poses a significant challenge to humanity, which has not yet been adequately prepared. The COVID-19 pandemic (SARS-CoV-2) has provided irrefutable proof of this fact, resulting in immeasurable economic costs and thousands of deaths worldwide. Other viruses, such as Hepatitis C (HCV), Influenza (INFV), HIV, Ebola (EBOV), Marburg (MARV), Zika (ZIKV), MERS- and SARS-CoV, were able to leave their negative marks on the history of our modern society. All of these viruses contain RNA as genetic material, which can be single-stranded or double-stranded. Furthermore, their viral life cycle contains a plethora of promising antiviral targets, such as RNA-dependent RNA polymerase (RdRp) and various proteases. A significant number of existing and new clinical trials target different stages of the viral life cycle. Several research groups have dedicated their scientific efforts in this context to discovering new potential biological targets, improving the structural data of known targets, repurposing drugs, and developing synthetic and/or natural compounds. Thus, great advances in the field of medicinal chemistry focused on the development of new antiviral agents have been made in the last few decades. Then, this special volume was created to bring some of the most recent advances in this field that may inspire researchers worldwide.

The COVID-19 pandemic serves as a timely reminder of the critical need for antivirals. Antiviral drug development has historically lagged behind that of other diseases such as cancer, neurodegenerative diseases, inflammatory diseases, and others. In retrospect, if the 2003 SARS-CoV-1 had raised the alarm about the need for coronavirus vaccines and antivirals, we would have been in a much better position to fight the SARS-CoV-2. Antivirals currently approved by the FDA only target a small number of viruses known to infect humans. Unfortunately, many viruses with pandemic potential or known to cause severe diseases, such as enterovirus A71 and D68, Zika virus (ZIKV), Nipah virus, Ebola, Marburg, and Lassa Fever virus, do not yet have vaccines or antivirals. Furthermore, viruses are constantly mutating, either naturally or as a result of drug selection pressure. As a result, newer antiviral generations with novel mechanisms of action are required to combat drug resistance. HIV antivirals, which transformed a once-terminal disease into a chronic yet manageable disease, and SARS-CoV-2 antivirals such as remdesivir, molnupiravir, and PAXLOVID, which have proven effective in preventing severe symptoms and lowering mortality rates, have undeniably demonstrated the therapeutic benefits of antivirals.

Hepatitis C Virus (HCV) should be eliminated as a public health threat, according to the World Health Organization (WHO). To achieve this goal, it is recommended that new infections be reduced by 90% and liver-related mortality be reduced by 65%. Direct-acting Antiviral Agents (DAA) that are highly effective play a significant role in this elimination. Unfortunately, DAA treatment fails 2.5-5% of patients, most of whom have Resistance-Associated Substitutions (RAS). This could eventually result in 1.8-3.6 million first-line DAA failures. RAS may jeopardize the elimination goals for a variety of reasons, the most important of which is that virus transmission and infection progression will continue. More data are needed to properly handle RAS and identify mutational patterns that cause resistance. Currently, sample sizes are small, data is dispersed, and methods are heterogeneous. As a result, collaboration is essential, and a European collaboration, such as HEPCARE, should provide a solution. To achieve the goal of eliminating hepatitis C (HCV) by 2030, mass production of low-cost, generic Direct-Acting Antivirals (DAAs) will be required.

The pharmaceutical companies Gilead and Bristol-Myers Squibb have granted generic companies Voluntary Licences (VLs) to mass produce the DAAs sofosbuvir and daclatasvir at a low cost. To meet World Health Organization prequalification standards, generic manufacturers must demonstrate bioequivalent pharmacokinetics for their DAAs when compared to the originator versions. The purpose of this study was to see if generic versions of sofosbuvir and daclatasvir had bioequivalent pharmacokinetics to the original forms.

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