HUMAN VACCINES & IMMUNOTHERAPEUTICS
2020, VOL. 16, NO. 12, 2888–2890
https://doi.org/10.1080/21645515.2020.1847952

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EDITORIAL

Special focus 'SARS-CoV-2 / COVID-19: advances in developing vaccines and immunotherapeutics'

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ARTICLE HISTORY Received 3 November 2020; Accepted 4 November 2020

Introduction

The ongoing coronavirus disease-2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has caused infection in tens of millions while killing over one million people, leading to global health concerns and a worldwide economic crisis. The emergence of COVID-19 has exposed the vulnerability of mankind to pathogenic viruses. This disease evolved from a simple pneumonia of unknown origin to multisystemic diseases leading to the most devastating viral pandemic since 1918. High levels of morbidity and mortality, aggravated by the severity of COVID-19 cases, have resulted in widespread lockdowns to minimize severity, which buy time for developing prophylactics and therapeutics. Rapid and high-level research advances have resulted in the characterization of SARS-CoV-2 and increased scientific and medical understanding of COVID-19. Thus, in less than one year, researchers worldwide have made substantial progress in designing and developing vaccines, immunotherapeutics and drugs to combat COVID-19, many of which have advanced to different phases of clinical trials. Various vaccine platforms and candidates have been explored including RNA, DNA, virus vector, protein subunit, virus-like particles (VLPs), immuno-informatics-based multi-epitope subunit, plant-based, inactivated and attenuated vaccines. Important issues for vaccine testing, viz., efficacy, potency, safety, tolerability, scalability and consistency of production, need to be fulfilled before approving any vaccine for widespread human use. Apart from developing vaccines and drugs, various immune potentiating and immunotherapeutic approaches including convalescent plasma, neutralizing antibodies, monoclonal antibodies, intravenous immunoglobulins, and boosting the immune system via immunomodulatory regimens, have been exploited to lessen the severity of disease in patients. Natural killer (NK) cells, T cells, cytokines, interferons, toll-like receptors (TLRs) for prophylaxis and immunotherapies are also being investigated. Many important research and clinical issues are being addressed, including viral origin, virus characterization, antigen analysis, virulence evaluation, transmission, receptor binding and entry mechanisms, pulmonary and multisystem pathogenesis, inflammatory and immune responses. These aspects are being deciphered at a rapid pace but need to be more fully explored.

This Special Focus 'SARS-CoV-2/COVID-19: Advances in Developing Vaccines and Immunotherapeutics' consists of 20 peer-reviewed articles (Research Articles, Mini-Reviews, Commentaries) covering various developments, trends, and advances in discovering effective vaccines and immunotherapies for SARS-CoV-2/COVID-19 along with presenting the current scenario and future prospects to check the spread of this pandemic. Researchers from different countries including Bahrain, Bangladesh, China, Germany, Hong Kong, India, Indonesia, Japan, Malaysia, Mexico, Morocco, Nepal, Pakistan, Saudi Arabia, Vietnam and USA contributed their valuable insights to this Special Focus.

Vaccines

Yatoo and associates (pp. 2891) in 'COVID-19 – Recent advancements in identifying novel vaccine candidates and current status of upcoming SARS-CoV-2 vaccines' present a comprehensive description of advances in developing vaccines, including some promising vaccines in Phase 2 and 3 clinical trials. This review analyzes previous studies and presents the current status along with future possibilities for producing vaccines.

Yadav and associates (pp. 2905) in 'Recombinant Vaccines for COVID-19′ highlight progress in developing recombinant vaccine as a promising platform for assuring safety and reducing the intricacy of mass production. Important considerations while designing a recombinant vaccine are discussed along with emphasizing the alliance of the recombinant platform to bring more accuracy and efficacy to current vaccine technology.

Dhama and co-workers (pp. 2913) in 'Plant-based vaccines and antibodies to combat COVID-19: Current status and prospects' present overall progress for exploring plants for production of vaccines, monoclonal antibodies and

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immunomodulatory proteins using molecular farming/transient expression system as bioreactors. Methodology and basics of plant biofarming along with their prospective applications for designing effective vaccines and antibodies are discussed. Plant-based formulations could facilitate rapid production for emergency demand, but there are some limitations and challenges to be overcome for clinical application and commercialization of plant-based vaccines.

Mudgal and coworkers (pp. 2921) review 'Prospects for Mucosal Vaccine: Shutting the Door on SARS-CoV-2′ and highlight the importance of oral and nasal mucosal surfaces that play a vital role as a virus portal of entry. Thus, mucosal immunization could be a promising approach for mounting long-lasting systemic and mucosal immunity for SARS-CoV-2.

Vaccines for women and the elderly

The article 'Impact of COVID-19 on women and children and the need for a gendered approach in vaccine development' by Vora et al. (pp. 2932) highlights the vulnerability of women and children during the pandemic. It suggests that data on the effect of the pandemic on pregnant women and newborns remain scarce and that gender disaggregated indicators of mortality and morbidity are not available. The article recommends implementation of a gendered approach to assure the specific needs of women and their newborns during vaccine development. It advocates the importance of taking into account gender-based biological differences and the inclusion of pregnant and lactating mothers in vaccine clinical trials.

The article 'COVID-19 in the elderly people and advances in vaccination approaches' by Dhama et al. (pp. 2938) highlights the present scenario and associated risk factors of SARS-CoV-2 in older people and progress being made in vaccine development, especially for this population. A brief note on the immunomodulatory and immunotherapeutic approaches is also presented to combat risk of infection and lessen the outcome of disease in elderly subjects. The article emphasizes that older subjects should be included in clinical trials to assure efficacy and safety in this population, and associated risks in older age groups should be evaluated along with assessing the need for booster doses.

Adjuvanted vaccines

Sharma and associates (pp. 2944) in 'Exploring the possible use of saponin adjuvants in COVID-19 vaccine' present saponins as immunostimulants for viral vaccines including their applicability to a SARS-CoV-2 vaccine. The authors emphasize the need for more research to develop saponin-adjuvanted recombinant spike or RBD protein subunit vaccine that also might be advantageous for future pandemics associated with other novel coronaviruses.

Hope from BCG vaccine

The article 'BCG vaccine: a hope to control COVID-19 pandemic amidst crisis' by Malik and associates (pp. 2954) covers the use of alternative therapeutic modalities focusing on BCG tuberculosis vaccine that is used in vaccination programs worldwide. The authors highlight the mechanisms underlying BCG-mediated cross-protection of many pathogens through eliciting innate and adaptive immune arms of the host immune system, and review the studies related to the benefits of BCG vaccination in ameliorating morbidity and mortality during the pandemic.

Immunotherapies

Gupta and associates (pp. 2963) in 'COVID-19: Benefits and Risks of Passive Immunotherapeutics' discuss potential passive immunotherapies (convalescent plasma, serum, or hyperimmune immunoglobulin), especially convalescent plasma therapy as a possible lifesaving option in critically ill infected patients, with its ability for virus neutralization and reduction of viremia. The applicability of convalescent blood products in well-designed, randomized, controlled clinical trials along with benefits and risks in the pandemic has been reviewed.

Tawfiq and Arabi (pp. 2973) in 'Convalescent Plasma Therapy for Coronavirus Infection: Experience from MERS and Application in SARS-CoV-2 (COVID-19 disease)' describe the mechanisms and applications of convalescent plasma in mitigating SARS-CoV-2 infection, highlighting the need for clinical trials to show efficacy in affected patients.

Global scenario, public health concerns, prevention and control strategies

O'Connell and Aldhamen (pp. 2980) in 'Systemic innate and adaptive immune responses to SARS-CoV-2 as it relates to other coronaviruses' emphasize the implications of pathological consequences aggravated by altered immune responses as the foremost underlying cause of morbidity and mortality in COVID-19. They summarize the systemic immune responses and prospective immunotherapeutic approaches for SARS-CoV-2.

Ezzikouri and associates (pp. 2992) overview progress and challenges in 'Coronavirus Disease 2019 – Historical Context, Virology, Pathogenesis, Immunotherapy, and Vaccine Development'. They detail the discovery, virus, spread, virology, pathogenesis, and clinical features of disease. They summarize the employable methodologies keeping the main focus on immunotherapies, alternative treatments and vaccine development.

Rizwan and associates (pp. 3001) in 'Current perspective on diagnosis, epidemiological assessment, prevention strategies, and potential therapeutic interventions for severe acute respiratory infections caused by 2019 novel coronavirus (SARS-CoV -2)' provide the current scenario, advances and prospects in virus replication, genetic diversity, transmission, diagnosis, epidemiology and prevention strategies along with potential biotherapeutics, drugs, vaccines, and immunotherapies.

Rabaan and coworkers (pp. 3011) in 'Recent advances in vaccine and immunotherapy for COVID-19′ summarize virus immunopathology and discuss salient advances in developing effective vaccines and immunotherapeutics along with presenting their advantages and limitations and challenges to be overcome.

Barbuddhe and coworkers (pp. 3023) in 'Global scenario, public health concerns and mitigation strategies to counter current ongoing SARS-CoV-2/COVID-19 pandemic' present

an overall global scenario of SARS-CoV-2, important virus features and health concerns. They discuss advances in vaccine development and immunotherapies as well as devising and enforcing mitigation strategies for effective implementation of prevention and pandemic control measures. They emphasize that the involvement of animals as original or intermediate hosts necessitates implementation of One Health approaches for prevention of transmission, controlling further spread, and preventing emergence of such pandemic diseases.

Bilal and Iqbal (pp. 3034) in 'Recent advances in therapeutic modalities and vaccines to counter COVID-19/SARS-CoV-2′comprehend available therapeutic regimens for COVID-19, and emphasize the existing frontiers in viral vaccine development approaches.

Animal models for developing vaccines and immunotherapies

Sharun and coworkers (pp. 3043) in 'Coronavirus disease 2019 (COVID-19) in domestic animals and wildlife: Advances and prospects in the development of animal models for vaccine and therapeutic research' describe the incidence of SARS-CoV-2 infection and transmission in cats, dogs, minks, tiger, ferrets, and other domestic/wild animals. They also summarize the different available animal models for SARS-CoV-2 infection.

Issues related to vaccines

Karthik and coworkers (pp. 3055) in 'Role of Antibody-dependent enhancement (ADE) in the virulence of SARS-CoV-2 and its mitigation strategies for the development of vaccines and immunotherapies to counter COVID-19′ analyze the phenomenon of antibody-dependent enhancement (ADE) in SARS-CoV-2 infection through lessons learned from SARS-CoV and MERS-CoV. They also emphasize different ways to mitigate ADE to enable the development of safe vaccines and immunotherapeutics.

Nainu and coworkers (pp. 3061) in 'SARS-CoV-2 reinfection and implications for vaccine development' review showed evidence of possible reinfection with SARS-CoV-2. They also emphasize the possibility of virus reinfection both from the agent and host perspective, and discuss the implication of reinfection for COVID-19 vaccine development.

Harapan and associates (pp. 3074) raise an important issue regarding cost of payment for vaccines, taking an online survey of respondents in Indonesia as reported in 'Willingness to pay for a COVID-19 vaccine and its associated determinants in Indonesia'. With fear of disease, people are ready to pay, but it would be better if vaccine cost would be partially subsidized to cover less wealthy populations.

Summary

We believe that this Special Focus with high-quality contributions from researchers in different countries will represent an excellent source of information for the readers of this journal. The articles should be useful for medical and veterinary professionals, clinicians, public health experts, researchers, students/scholars, the pharmaceutical industry and biomedicine experts and contribute to designing and adapting effective and safe vaccines and immunotherapeutics for SARS-CoV-2/COVID-19.

We the guest editors would like to express our gratitude to all the contributors for their support and hard work. We also extend a special thanks to all the peer-reviewers for their expertise and rigorous reviews.

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