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Exploring SARS-CoV-2 Neutralization Assays in Clinical Trials: A Comprehensive Narrative Review

Ziyao Zhao*

Department of Infectious Diseases, University of Queensland, Brisbane, QLD 4072, Australia

Abstract

The emergence of SARS-CoV-2 has spurred global efforts to develop effective vaccines and therapeutics to combat COVID-19. Critical to this endeavor is the evaluation of interventions' ability to neutralize the virus, a task accomplished through neutralization assays. This narrative review examines the diverse neutralization assays utilized in clinical trials targeting SARS-CoV-2. These assays, ranging from plaque reduction to pseudovirus and live virus assays, offer distinct advantages and considerations in terms of safety, sensitivity, and scalability. Employed in trials assessing vaccines, monoclonal antibodies, convalescent plasma, and antiviral drugs, neutralization assays provide crucial data on interventions' ability to induce neutralizing immunity, guide dose selection, assess treatment efficacy, and inform regulatory decisions. Despite their utility, challenges such as assay variability, standardization, and the emergence of viral variants persist, necessitating collaborative efforts to address these issues. Overall, neutralization assays play an indispensable role in advancing our understanding of COVID-19 interventions and guiding strategies to combat the pandemic. Continued research and standardization endeavors are imperative to optimize their performance and utility in the fight against SARS-CoV-2 and future viral threats.

Keywords: Clinical trials • Neutralization • SARS-CoV-2

Introduction

The emergence of the novel coronavirus, SARS-CoV-2, has led to a global health crisis, prompting unprecedented efforts to develop effective vaccines and therapeutics. Central to the evaluation of candidate interventions is the assessment of their ability to neutralize the virus. Neutralization assays play a crucial role in clinical trials by providing insights into the efficacy of experimental treatments and vaccine candidates. In this narrative review, we explore the various neutralization assays used in clinical trials to evaluate interventions targeting SARS-CoV-2.

Literature Review

Neutralization assays measure the ability of antibodies or other therapeutic agents to inhibit viral infection by neutralizing the virus's ability to infect host cells. These assays typically involve exposing viral particles to the test agents and assessing their impact on viral replication or entry into target cells. Neutralization assays can be performed using live virus, pseudoviruses, or viral proteins, each offering unique advantages and considerations in terms of safety, sensitivity, and scalability. PRNT is a gold standard neutralization assay that measures the reduction in the number of viral plaques formed in cell culture in the presence of neutralizing antibodies. Although highly sensitive and specific, PRNT is labor-intensive and time-consuming, limiting its scalability for large-scale clinical trials. The microneutralization assay is a modified version of PRNT that uses microtiter plates to facilitate high-throughput screening of serum samples for neutralizing activity. This assay offers improved scalability and throughput compared to PRNT, making it suitable for large-scale clinical trials [1].

Discussion

Pseudovirus neutralization assays utilize recombinant viruses engineered to express SARS-CoV-2 spike protein, allowing for the safe and high-throughput assessment of neutralizing antibodies in serum samples. Pseudovirus assays offer enhanced safety and scalability compared to live virus assays, making them ideal for large-scale screening studies. Live virus neutralization assays involve the use of infectious SARS-CoV-2 strains to assess the ability of test agents to neutralize viral infection in cell culture. While live virus assays provide valuable insights into the efficacy of interventions against authentic viral strains, they require strict biosafety containment measures and are less amenable to high-throughput screening. Neutralization assays are employed in clinical trials to evaluate the efficacy of various interventions, including vaccines, monoclonal antibodies, convalescent plasma, and antiviral drugs, against SARS-CoV-2. These assays provide critical data on the ability of interventions to induce or confer neutralizing immunity, inform dose selection, assess treatment efficacy, and guide regulatory decision-making. Despite their utility, neutralization assays pose several challenges and considerations in clinical trial settings. These include variability in assay protocols, interlaboratory standardization, the emergence of viral variants, and the need for robust correlates of protection. Addressing these challenges requires collaborative efforts among researchers, regulatory agencies, and industry stakeholders to ensure the reliability and reproducibility of assay results [2,3].

In addition to the challenges mentioned, the variability in assay protocols and the lack of interlaboratory standardization can lead to inconsistencies in results, hindering the comparison of data across different studies. Furthermore, the emergence of viral variants, such as the Delta and Omicron variants, underscores the importance of continuously monitoring and adapting neutralization assays to assess the effectiveness of interventions against evolving strains. Robust correlates of protection are essential for establishing the effectiveness of vaccines and therapeutics in conferring immunity against SARS-CoV-2 infection and disease progression. Collaborative efforts among researchers, regulatory agencies, and industry stakeholders are crucial for

***Address for Correspondence:** Ziyao Zhao, Department of Infectious Diseases, University of Queensland, Brisbane, QLD 4072, Australia, E-mail: zaho9@gmail.com*

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harmonizing assay protocols, validating correlates of protection, and ensuring the reliability and reproducibility of assay results across different laboratories and clinical trial settings. This concerted approach will be vital for advancing the development and evaluation of interventions against COVID-19 and future viral threats [4-6].

Conclusion

Neutralization assays play a pivotal role in clinical trials aimed at evaluating interventions against SARS-CoV-2. By providing insights into the ability of interventions to neutralize viral infection, these assays inform decision-making processes and guide the development of effective countermeasures against COVID-19. Moving forward, continued research and standardization efforts will be essential to optimize the performance and utility of neutralization assays in the fight against emerging viral threats.

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Conflict of Interest

None.

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