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Assessing Sotrovimab's Effectiveness in Mitigating Disease Progression and Mortality among COVID-19 Patients in the Omicron Period: Insights from an Empirical Investigation

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Abstract

Commencing in May 2021, the utilization of sotrovimab in Italy for early-stage treatment of SARS-CoV-2 infection and disease progression prevention has been established. Nevertheless, certain in vitro investigations have cast doubt on its efficacy against Omicron variants. As a result, our objective was to conduct a more extensive inquiry into the real-world efficacy of sotrovimab. Through a retrospective analysis, we gathered medical records of SARS-CoV-2 patients assessed in the infectious diseases units of Sassari, Foggia, and Bari, Italy. Our study encompassed both individuals who received sotrovimab treatment and those who were untreated throughout 2022. Our primary focus was to assess the impact of sotrovimab on curtailing disease progression (defined as the initiation of oxygen supplementation) and COVID-19-related fatalities. Additionally, we sought to evaluate the safety profile of sotrovimab.

Keywords: Sotrovimab • SARS-CoV-2 • COVID-19

Introduction

Our cohort comprised 689 participants; of these, 341 underwent sotrovimab treatment, while 348 remained untreated. The collective findings showcased 161 instances (23.4%) of disease progression and 65 occurrences (9.4%) of mortality. Notably, a statistically significant distinction emerged between the treated and untreated groups (p<0.001). In a multivariate logistic regression analysis, advancing age [OR for each ten-year increment 1.23 (95%CI 1.04-1.45)] was linked to a higher susceptibility to disease progression. Additionally, cardiovascular ailments [OR 1.69 (1.01-2.80)], fever [OR 3.88 (95%CI 2.35-6.38)], and dyspnea [OR 7.24 (95%CI 4.17-12.58)] exhibited associations with elevated disease progression risk. In contrast, factors such as vaccination [OR 0.21 (95%CI 0.12-0.37)] and sotrovimab administration [OR 0.05 (95%CI 0.02-0.11)] displayed links to decreased likelihood of severe COVID-19 development.

Regarding mortality, advanced age [OR for each ten-year increment 1.36 (95%CI 1.09-1.69)] was associated with heightened fatality risk. In the multivariate analysis, cardiovascular disease lost its statistical significance, while individuals undergoing chemotherapy for hematological cancer [OR 4.07 (95%CI 1.45-11.4)] and those presenting with dyspnea at diagnosis [OR 3.63 (95%CI 2.02-6.50)] displayed amplified mortality risk. Conversely, vaccination [OR 0.37 (95%CI 0.20-0.68)] and sotrovimab treatment [OR 0.16 (95%CI 0.06-0.42)] were connected to reduced risk.

Description

Notably, only two adverse events were documented. One individual experienced diarrhea shortly after sotrovimab administration, while another encountered an allergic reaction marked by cutaneous rash and itching. Our investigation conclusively demonstrated that sotrovimab treatment correlated with lowered risk of disease progression and mortality in SARS-CoV-2 patients, a substantial portion of whom were above 65 years of age and exhibited a high vaccination rate. Importantly, this treatment demonstrated remarkable safety. Thus, our findings contribute to the existing body of evidence affirming the efficacy and safety of sotrovimab during the Omicron era within a real-world context.

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), a novel coronavirus initially identified in Wuhan, China, in late 2019 [1], belongs to the larger family of coronaviruses, including SARS-CoV and MERS-CoV, both of which have caused severe respiratory illnesses in humans [2,3]. However, SARS-CoV-2 has demonstrated significantly higher infectivity, resulting in a global pandemic [4,5]. Coronavirus Disease 2019 (COVID-19), stemming from SARS-CoV-2, manifests with a wide range of symptoms, from mild to severe [6]. While fever, cough, and shortness of breath are common, a diverse array of other symptoms such as loss of taste and smell, fatigue, skin lesions, and gastrointestinal issues can also arise. In some instances, the disease escalates to severe pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ dysfunction, leading to substantial morbidity and mortality.

As SARS-CoV-2 has spread globally, its ongoing mutation, typical of RNA viruses, has given rise to numerous variants of concern (VOCs). Variants like Alpha, Beta, Delta, and Omicron have exhibited increased transmissibility, altered disease severity, and potential immune evasion. The Omicron variant, in particular, boasts multiple spike protein mutations, the prime target for many vaccines and therapeutic antibodies, thus triggering apprehensions about the effectiveness of these interventions.

The response to the global COVID-19 pandemic has seen the development of various vaccines and therapeutics in an unparalleled global endeavor. Among antiviral treatments, monlupiravir, nirmatrelvir/ritonavir, and remdesivir gained approval by late 2021 for minimizing severe disease and mortality. Monoclonal antibodies (mAbs) were engineered to counter the SARS-CoV-2 spike protein and hinder viral entry into host cells. Sotrovimab, an mAb, has exhibited encouraging outcomes in clinical trials, holding potential to curtail hospitalization and death in COVID-19 patients.

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Sotrovimab functions by binding to the SARS-CoV-2 spike protein, thwarting viral entry into host cells and thereby impeding replication. Preliminary data underscore its potential effectiveness against earlier VOCs. However, with the emergence of the highly mutated Omicron variant, scrutinizing sotrovimab's real-world efficacy in averting severe disease and fatality becomes paramount. Several in vitro investigations have cast doubts on sotrovimab's Omicron subvariant efficacy. This study aims to assess sotrovimab's effectiveness within the Omicron era, within real-world conditions.

The heightened contagiousness of the Omicron variant and its capacity to evade immunity in previously vaccinated individuals are well-recognized. However, this variant generally entails a lower risk of severe outcomes compared to Delta. This is attributed to intrinsic Omicron characteristics that mitigate infection severity, alongside the protective effects of vaccination.

Notwithstanding the perceived decrease in Omicron's disease severity, the virus's robust transmissibility has strained healthcare systems globally. This is evident in the recent report by the United States' Centers for Disease Control (CDC), revealing sustained levels of emergency department visits, daily hospitalizations, and COVID-19-related death rates. Similar trends are observed in Italy, where new SARS-CoV-2 infections average around 30,000 weekly, while hospitalizations and COVID-19 deaths remain alarmingly high. During the study's inception, the Omicron variant prevalence in Italy stood at approximately 85%, rising to 96% by January 17, 2022 [6].

Conclusion

Our investigation revealed a clear link between sotrovimab treatment and decreased risks of both disease progression and mortality among individuals infected with SARS-CoV-2. Notably, 70% of these individuals were aged over 65 and exhibited a notable vaccination rate. The administration of sotrovimab demonstrated exceptional safety. In essence, our findings serve to strengthen the existing body of evidence highlighting the efficacy and safety of sotrovimab during the Omicron era within a real-world environment.

Acknowledgment

None.

Conflict of Interest

None.

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