Use of REGEN-COV in children after heart transplantation for treatment and post-exposure prophylaxis of COVID-19

Dipankar Gupta1,2, Stephanie A. Clifford1,3 and Frederick J. Fricker1,2

1Congenital Heart Center, Shands Children’s Hospital, University of Florida, Gainesville, FL, USA; 2Department of Pediatrics, College of Medicine, University of Florida, Gainesville, FL, USA and 3College of Nursing, University of Florida, Gainesville, FL, USA

Abstract

COVID-19 pandemic continues to evolve and new variants like Delta and Omicron have been discovered. REGEN-COV is a recombinant human monoclonal antibody to the spike protein of SARS-CoV-2 which received emergency use authorisation for treatment and post-exposure prophylaxis in patients with high risk of progression to severe disease. We review our experience with use of REGEN-COV in paediatric heart transplant patients.

The World Health Organization declared coronavirus disease (COVID-19) secondary to SARS-CoV-2 infection a pandemic on 11 March, 2020. Since then multiple variants including Delta-B.1.617.2 and Omicron-B.1.1.529 have been discovered with variable rates of infection in children. In presence of pre-existing comorbidities including diabetes mellitus, obesity, and cardiovascular disease, COVID-19 is associated with substantial risk of complications including mortality. Limited data is available about the risk and severity of COVID-19 in solid organ transplant patients. Sharma et al. reported a more frequent infection in African American population and higher use of renal replacement therapy in solid organ transplant patients, but the risk of severe disease and death was not higher than age-matched controls. A recent analysis from Pediatric Heart Transplant Society revealed that COVID-19 infection in paediatric heart transplant candidates and recipients leads to a higher rate of hospitalisation when compared to the general paediatric population. Despite higher rates of hospitalisation, the long-term sequelae and mortality remain low in these patients. Similarly, Goss et al. reported no difference in survival in paediatric solid organ transplant patients when compared to immunocompetent patients. Conversely, there have been reports of higher short-term mortality in patients with solid organ transplant as well. Certainly, these reports provide conflicting data, and the results are influenced by the time of infection in context of evolution of the pandemic, geographical area, type of variant, and other clinical features.

The available medical therapies for the management of COVID-19 infection continue to evolve with better understanding of pathophysiology and ongoing research. One such therapy, REGEN-COV, is a recombinant human monoclonal antibody to the spike protein of SARS-CoV-2, comprising Casirivimab and Indevimab. REGEN-COV initially received emergency use authorisation by the US FDA for use as post-exposure prophylaxis for COVID-19 in adult and children (≥12 years and ≥40 kg) at considerable risk for progression to severe COVID-19. It was also authorised for the treatment of mild-to-moderate COVID-19 with positive RT-PCR, in patients at considerable risk for progression to severe COVID-19. With increasing prevalence of Omicron variant and ineffectiveness of REGEN-COV against this variant, FDA revoked the emergency use authorisation stating that REGEN-COV is no longer authorised for treatment or post-exposure prophylaxis in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information such as variant susceptibility to this drug and regional variant frequency. We sought to review our experience with use of REGEN-COV, while it was authorised for use for treatment and post-exposure prophylaxis of COVID-19 in paediatric heart transplant patients.

A retrospective chart review approved by the Institutional Review Board at the University of Florida with waiver of consent was performed to identify patients who received REGEN-COV for post-exposure prophylaxis or as treatment to prevent progression to severe COVID-19. Detailed demographic and clinical data were collected from the electronic medical record. At our centre, six children received REGEN-COV from August to September 2021 during the Delta variant surge. Of these, four received REGEN-COV for the treatment after a positive RT-PCR and two received as post-exposure prophylaxis with a negative RT-PCR. In our cohort, the median age was 16.5 years (range: 15–19) and median time from transplant was 29 months (range: 2–140). There were equal number of males and females. Of those positive for COVID-19, three patients demonstrated mild symptoms (two respiratory and one gastrointestinal) and one
In conclusion, REGEN-COV was tolerated without any complications in our cohort of paediatric heart transplant patients, and no modifications in immunosuppression were required.

Acknowledgements. None.

Author contributions. All authors contributed to the development of the study, data collection, and writing of the manuscript.

Financial support. This research received no specific grant from any funding agency, commercial, or not-for-profit sectors.

Conflicts of interest. None.

Disclosures. Dipankar Gupta MD is on the Scientific Advisory Board of emo-cha Health Inc.

References