Sotrovimab for Treatment of COVID-19 in Solid Organ Transplant Recipients

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Solid organ transplant recipients (SOTRs) may be at higher risk of developing severe coronavirus disease 2019 (COVID-19).[1] Once hospitalized, SOTRs with COVID-19, when compared with non–COVID-19–related admissions, have higher rates of mechanical ventilation, need for renal replacement therapy, and excess mortality.[1] Early use of anti–severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) monoclonal antibody in SOTRs provides a safe outpatient treatment option to reduce COVID-19–related risk of hospitalization and death.[2] Sotrovimab is a recombinant human immunoglobulin-G1-kappa monoclonal antibody that binds to a conserved epitope on the spike protein receptor-binding domain of SARS-CoV and SARS-CoV-2. Sotrovimab contains a 2 amino acid Fc-modification that is designed to improve bioavailability in the respiratory mucosa and increase half-life with a projected human median elimination half-life of 49 d.[3] Based on clinical studies, in which immunocompromised patients were excluded, it received Emergency Use Authorization by the Food and Drug Administration for the treatment of mild to moderate COVID-19 in May 2021.[4]

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Since November 2020, we have routinely treated all our qualifying SOTRs with available anti–SARS-CoV-2 monoclonal antibodies. In November 2021, based on its favorable pharmacokinetics, we included sotrovimab in our treatment protocols for immunocompromised patients. Since late December 2021, as the Omicron variant dominated in New York, our institution has used sotrovimab exclusively. During the study period from November 19, 2021, to January 17, 2022, 76 SOTRs from the Westchester Medical Center, NY, were diagnosed with COVID-19. Of these, 51 SOTRs (67%) received sotrovimab, 11 (14%) had COVID-19–related hospitalization (4 deaths, 4 ongoing hospitalization), 6 (8%) remained asymptomatic, 3 refused infusion with no progression of mild symptoms, and 5 (6%) had improving symptoms of >7 d at the time of diagnosis. We present our experience regarding the use of sotrovimab in 51 SOTRs (3 during the Delta-predominant period and 48 during the Omicron-predominant period) with at least 21 d of follow-up (Table 1). These include 28 kidney, 11 liver, 9 heart, 2 liver/kidney, and 1 heart/kidney recipients. All 51 patients met the criteria of Emergency Use Authorization by the Food and Drug Administration, had mild to moderate symptoms, and did not require supplemental oxygen and/or hospitalization because of COVID-19. The SOTRs received sotrovimab on average 159 (6–815) mo posttransplant 3.5 (1–9) d after the onset of symptoms, 2 (0–6) d after the laboratory-confirmed diagnosis. Other interventions included lowering or stopping mycophenolate in 34 of 34 (100%) eligible patients for an average of 12 (5–21) d. Other risk factors for progression of COVID-19 included chronic cardiac disease (30/51), chronic kidney disease (27/51), diabetes (16/51), and age of >65 y (8/51). Patients were followed for an average of 39 (21–85) d. One patient experienced progression of COVID-19 symptoms requiring 5-d hospitalization and steroid therapy. Five patients required hospitalization within 21 d of infusion, unrelated to COVID-19 diagnosis. None of the patients required intensive care or experienced death. The infusion was well tolerated with no reported severe adverse events.

Oral antiviral use is limited in SOTRs because of significant drug–drug interaction with nirmatrelvir/ritonavir and observed reduced efficacy of molnupiravir. Therefore, sotrovimab, based on its longer half-life and neutralizing activity against almost all the currently known coronavirus variants, potentially offers another safe and efficacious therapy for outpatient management of SOTRs with mild to moderate COVID-19.

TABLE 1.

Characteristics of solid organ transplant recipients treated with sotrovimab

Age, mean (range), y	50 (19–76)
Male sex, N (%)	29 (57)
Type of organ transplant, N (%)	
Kidney	28 (55)
Liver	11(22)
Heart	9 (17)
Liver-kidney	2 (4)
Heart-kidney	1 (2)
Time from transplant, mean (range), mo	159 (6–815)
Body mass index, mean (range), kg/m^2	29 (19–40)
Duration of symptoms before infusion, mean (range), d	3.5 (1–9)
Time from diagnosis to infusion, mean (range), d	2 (0–6)
Predominant presenting symptoms, N (%)	
Fever	26 (51)
Malaise	23 (45)
Cough	25 (49)
Nasal stuffiness	26 (51)
Oxygen saturation on room air, range	93%–100%
Follow-up period, mean (range), d	39 (21–85)
Progression of COVID-19 symptoms, treatment, N (%)	1 (2) Hospitalized, no ICU stay Oral dexamethasone for 5 d
Hospitalizations not related to COVID-19 within 21 d of infusion, N (%)	5 (10) Syncope, bacterial infections: gastroenteritis, UTI, pneumonia, abdominal pain unspecified
COVID-19 vaccination status, N (%)	
Unvaccinated	10 (20)
Complete doses (at least 3 doses of any mRNA vaccine or 1 Janssen + any booster)	18 (35)
Incomplete doses	23 (45)
Lowered/stopped mycophenolate	34/34 (100) of eligible patients
Duration, mean time (range), d	12 (5–21)
Associated graft rejection/dysfunction, N (%)	0 (0)
Need for intensive care, N (%)	0 (0)
Death during at least 21-d follow-up, N (%)	0 (0)

COVID-19, coronavirus disease 2019; ICU, intensive care unit; UTI, urinary tract infection.

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