Sotrovimab in Solid Organ Transplant Patients With Early, Mild/Moderate SARS-CoV-2 Infection: A Single-center Experience

Biagio Pinchera, MD,[1] Antonio Riccardo Buonomo, MD,[1] Riccardo Scotto, MD,[1] Rosa Carrano, MD,[2] Fabrizio Salemi, MD,[2] Fabiana Galluccio, MD,[2] Maria Guarino, MD,[3] Giulio Viceconte, MD,[1] Nicola Schiano Moriello, MD,[1] Agnese Giaccone, MD,[1] Antonella Gallicchio, MD,[1] Emanuela Zappulo, MD,[1] Riccardo Villari, MD,[1] and Ivan Gentile, PhD[1]; Federico II COVID team*

The administration of monoclonal antibodies against SARS-CoV-2 reduce the risk of COVID-19–related hospitalization and death.[1] Solid organ transplant (SOT) patients with SARS-CoV-2 infection have higher rates of severe disease progression compared with the general population. The availability of such treatments could represent a key therapeutic tool in the fight against COVID-19 and its sequelae. Nevertheless, real world data regarding the use of monoclonal antibodies in these patients are scarce[2] and are limited to few case series based on Casirivimab/Imdevimab or Bamlanivimab/Etesevimab administration.[3,4] No published study evaluated efficacy and safety of Sotrovimab in this setting so far.

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[1] *Department of Clinical Medicine and Surgery, Section of Infectious Diseases, University of Naples "Federico II," Naples, Italy.*

[2] *Department of Public Health, Section of Nephrology, University of Naples "Federico II," Naples, Italy.*

[3] *Department of Clinical Medicine and Surgery, Gastroenterology and Hepatology Unit, University of Naples "Federico II," Naples, Italy.*

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We present a small case series of SOT recipients diagnosed with SARS-CoV-2 infection (positive SARS-CoV-2 RNA detection by RT-PCR on rhino-oropharyngeal swab) treated with sotrovimab (single 500 mg IV dose) at the Division of Infectious Diseases of Federico II University Hospital of Naples, Italy, between December 15, 2021, and January 15, 2022.

Since Omicron variant of concern became an epidemiological concern in that period, Sotrovimab was administered to all outpatients with early mild/moderate symptoms of COVID-19, high risk of disease progression, and no need of oxygen therapy or hospitalization (Ordinal Scale for Clinical Improvement score: 0–2).[5]

For each patient, main clinical and laboratory data were collected before the administration of Sotrovimab and 7 d later. Rate of hospitalization, need of oxygen supplementation, and death were evaluated at day +28.

During the study period, a total of 15 SOTs recipients received Sotrovimab. Baseline demographic and clinical variables are summarized in Table 1. Thirteen patients (86%) had received mRNA COVID-19 vaccines. Nine patients had received 2 doses, 3 patients had received booster dose, and 1 patient a single dose: protective preinfusion SARS-CoV-2 IgG titers (Roche Diagnostics GmbH, Mannheim, positive threshold >15 BAU/mL) were found in only 61.5% of patients.

At the time of infusion, 13 (87%) patients had a mild disease, 2 (13%) a moderate disease, and none showed a severe COVID-19. No allergic reaction or other adverse events were reported during the infusion or in the next 4 wk. Two patients (13%) needed hospitalization (after 1 and 3 d) because of rapidly progressive respiratory distress requiring oxygen supplementation.

A week after, SARS-CoV-2 RNA on rhino-oropharyngeal swab was still detectable in all patients; however, 87% of patients reported clinical recovery.

At day +28, 10 patients (66.7%) achieved virologic clearance. The median time to SARS-CoV-2 undetectability at nasal swab was 20 d (interquartile range: 11–40) from symptoms onset and 14 d (interquartile range: 9–16) after infusion. All patients showed resolution of COVID-19–related clinical symptoms at the end of follow-up.

In this real-life study carried out on 15 SOT patients with COVID-19 receiving Sotrovimab, the rates of hospitalization, oxygen supplementation, and death were 13%, 13%, and 0%, respectively. Sotrovimab infusion was

TABLE 1.

Characteristics of enrolled patients

	TOE (N = 15)	T1 (N = 15)
Age (median, IQR)	49 (27–67)	
Gender, n (%)		
M	11 (73.3)	
F	4 (26.7)	
Symptoms, n (%)		
Fever	11 (79)	
Malaise	6 (43)	
Cough	10 (72)	
Nausea/diarrhea	2 (14)	
Shortness of breath	1 (7)	
Headache	3 (22)	
Nasal stuffiness	1 (7)	
Anosmia	1 (7)	
dysgeusia	1 (7)	
Type of transplant, n (%)		
Kidney transplant	14 (93.1)	
Liver transplant	1 (6.7)	
Time from transplant (mo), mean (IQR)	9 (3–240)	
Immunosuppressive therapy at diagnosis, n (%)		
Tacrolimus-mycophenolate-steroids	7 (46)	
Tacrolimus-everolimus-steroids	1 (7)	
Cyclosporine-mycophenolate-steroids	2 (13)	
Tacrolimus-mycophenolate	2 (13)	
Tacrolimus-everolimus	1 (7)	
Tacrolimus-steroids	1 (7)	
Tacrolimus	1 (7)	
COVID-19 vaccination, n (%)		
Yes	13 (87)	
No	2 (13)	
Timeframe between last vaccination dose and infection (mo), mean (IQR)	7 (1–9)	
Ig anti-SARS-CoV-2 titer presotrovimab infusion (BAU/mL), n (%)		
Negative	7 (46)	
Positive	8 (54)	
Asymptomatic infection	0/15	13/15 (87%)
WBC (cell/μL; median, IQR)	6410 (2450–13 420)	9165 (3100–12 630)
Neutrophil count (cell/μL; median, IQR)	4030 (1490–11 550)	7350 (1810–10 260)
Lymphocyte count (cell/μL; median, IQR)	885 (330–1.920)	835 (120–1910)
PLT (cell/μL; median, IQR)	218 000 (79 000–347 000)	295 000 (72 000–483 000)
D-dimer (ng/mL; median, IQR)	631 (212–3.307)	468 (94–5582)
Fibrinogenemia (mg/dL; median, IQR)	330 (253–498)	204 (173–448)
CRP (mg/L; median, IQR)	9.7 (0–126.5)	3.5 (0–51.9)
LDH (U/L; median, IQR)	214 (163–670)	240 (188–441)

COVID-19, coronavirus disease 2019; CRP, C-reactive protein; F, female; Ig, immunoglobulin; IQR, interquartile range; LDH, lactic dehydrogenase; M, male; PLT, platelet; T1, time of 7 d postsotrovimab; TOE, time of enrollment presotrovimab; WBC, white blood cell.

well-tolerated with no reported adverse events. Our results confirm the activity and safety of monoclonal antibody therapy demonstrated in other real-life series.[3,4] However, to our best knowledge, ours is the first report focusing on Sotrovimab-favorable tolerability and efficacy profile in transplant patients, a very interesting clinical finding considering its preserved activity against Omicron variant.

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