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Safety of the First Dose of SARS-CoV-2 Vaccination in Solid Organ Transplant Recipients

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DISCLOSURE

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ABBREVIATIONS

SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

SOTR: solid organ transplant recipient

COVID-19: Coronavirus disease 2019

PCR: polymerase chain reaction

The safety of the SARS-CoV-2 mRNA vaccines in solid organ transplant recipients (SOTRs) is unknown because immunosuppressed individuals were generally excluded from phase 1-3 studies. To better understand perivaccination reactogenicity in immunosuppressed individuals, we studied SOTRs who underwent early vaccination.

SOTRs in the United States were recruited to participate in this study by invitation through their transplant centers or social media. Participants completed a detailed online questionnaire 1 week following their first dose. This study was approved by the Institutional Review Board at the Johns Hopkins School of Medicine.

We studied 187 SOTRs who received their first SARS-CoV-2 vaccination dose between December 16, 2020 and January 16, 2021, of whom 64% identified as front-line healthcare workers. Median (IQR) age was 48 (37-59) years; 69% were female, and 87% were White, and 6% Hispanic/Latino. Median (IQR) years since transplantation was 6 (3-13); 52% were kidney, 19% liver, 14% heart, 9% lung, 3% kidney/pancreas, and 3% other multiorgan recipients. Maintenance immunosuppression included tacrolimus (87%), mycophenolate (69%) or azathioprine (11%), and steroids (55%).

Participants received the Pfizer/BioNTech (50%) or Moderna (50%) mRNA vaccines. There were no self-reported cases of PCR-confirmed SARS-CoV-2 diagnoses between vaccination and study participation, nor were there any reported cases of acute rejection, neurological diagnoses (Guillain-Barré syndrome, Bell's Palsy or neuropathy) or allergic reactions requiring epinephrine. Two participants reported development of a new infection (1 was acute-on-chronic pouchitis, the second was influenza A) requiring treatment. Local site reactions included mild pain (61%), mild redness (7%), and mild swelling (16%) (Table 1). Systemic reactions such as

fever and chills were uncommon (4% and 9%), although more-than-baseline fatigue was reported by 38%, headache by 32%, and myalgias by 15%.

Similar to the randomized trials of these vaccines,[1,2] adverse events were largely consistent with expected vaccine reactogenicity, with mostly mild local reactions such as injection-site pain; systemic reactions, such as fever, were uncommon.[3] Furthermore, transplant rejection, which remains a theoretical concern triggered by vaccination, was not seen during early follow-up.[4]

Strengths of this study include a national sample and novel, early data to inform major concerns among SOTRs and their providers.[5] Limitations include a relatively small sample size, lack of longer-term safety data and less granular ascertainment of side effects than the original trials. Further study will be needed to explore unexpected safety issues, and longer-term follow-up is vital to explore additional adverse effects. It is also important to note that this was a nonrandomized, early, observational study leveraging a convenience sample of SOTRs with access to the vaccine, and as such not designed to evaluate vaccine efficacy.

In this first group of SOTRs to be vaccinated against SARS-CoV-2 in the United States, we observed expected, typically mild, minimal perivaccine reactogenicity after the first dose, similar to reported rates in non-SOTRs. There were no reported episodes of acute rejection, SARS-CoV-2 diagnoses, neurological diagnoses or major allergic reactions. These early, reassuring safety data in SOTRs may ease anxiety among patients and providers and provide some evidence for targeted counseling to address critical concerns such as vaccine refusal and hesitancy.

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