LETTERS TO THE EDITOR


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Authors’ Reply: Clinical Studies of Vaccine Efficacy

We thank Ashby for his interest in our study. Our data clearly demonstrate a two-dose coronavirus disease 2019 (COVID-19) vaccination regimen is insufficient protection for patients either on dialysis or with a kidney transplant. This finding is entirely in keeping with other emergent data demonstrating higher COVID-19 mortality in double-vaccinated patients with kidney failure when compared with other patients who are clinically vulnerable.1-3 Vaccine efficacy differs between studies in patients with kidney failure depending on the population studied, degree of immunosuppression, vaccination regimen, mechanism of reporting of positive COVID-19 infection, and infectivity of the prevalent variant of severe acute respiratory syndrome coronavirus 2. However, the totality of evidence supports that, although two-dose vaccination may improve outcomes to some degree, there is still an unacceptably high proportion of double-vaccinated patients with kidney failure dying or being hospitalized within 28–30 days of a positive COVID-19 test; this proportion is reported at 9% and 34%, respectively, up until September 21, 2021 in our study1 and 9.5% and 30%, respectively, in Canada, albeit with a follow-up only until June 30, 2021.4 To date, there are still comparatively few reports of the effect of COVID-19 vaccination on clinical outcomes rather than serologic markers of response in this population.

We acknowledge the lack of consideration of time at risk in our study as a potential problem. Although we note the merits of this approach, it does pose challenges when implementing in a highly vaccinated population. We do not feel that including person-time would significantly affect the analyses because the follow-up period is short (March–October) and patients are classed as fully vaccinated 2 weeks after their second dose. We have used March 1, 2021 as the date when we included both patients who were vaccinated and those who were unvaccinated for our vaccine effectiveness calculation because this was the point at which all patients would have had the opportunity to be vaccinated. It was suggested that, by not accounting for person-time exposed, we are underestimating vaccine efficacy. If this is the case, as the population progressively transitions to double-vaccinated status, it is likely that those who are double vaccinated will be slightly less exposed to COVID-19 than those who are unvaccinated, and so vaccinated individuals have slightly less follow-up time, thereby slightly overestimating vaccine effectiveness (if at all) in our study. The total number of infections from the beginning of the pandemic in March 2020 was 814 (apologies for a typographic error in one listing of the date in the paper for which we have submitted a correction). Individuals who had two doses had 357 of the infections, compared with 25 cases among those who were not vaccinated. Individuals who were partially vaccinated were excluded. In terms of the second point with regards to defining groups as of September 19, we have repeated the analyses according to the suggested permutations. Vaccine effectiveness was slightly lower rather than underestimated. We have clearly described the limitations of the methodology we used and presented the accompanying confidence intervals as a measure of precision. We feel that our paper reinforces a very important message: Two doses of COVID-19 vaccine in patients receiving kidney replacement therapy provide insufficient protection. Patients should be encouraged to take up additional vaccine doses and continue to implement other preventive measures.

DISCLOSURES

S. Bell reports receiving honoraria from AstraZeneca. P. Mark reports receiving honoraria from Astellas, AstraZeneca, Boehringer Ingelheim, Napp, Novartis, Pharmacosmos, and Vifor; and receiving research funding from Boehringer Ingelheim. All remaining authors have nothing to disclose.

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AUTHOR CONTRIBUTIONS

S. Bell, J. Campbell, E. Lambou, and P. Mark reviewed and edited the manuscript; S. Bell and P. Mark wrote the original draft and were responsible for methodology; J. Campbell was responsible for data curation; and J. Campbell and E. Lambou were responsible for formal analysis.
REFERENCES

