Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

publish these preliminary findings to highlight the urgent, international need for professional organizations, clinicians, charities, and stakeholder partners to work collaboratively to investigate the factors that influence the immune response following vaccination against COVID-19 in this patient group. There are a myriad of factors that may affect the ability of a patient receiving dialysis to successfully seroconvert following vaccination, and only through a joined-up, standardized approach will we be able to understand and mitigate these factors for dialysis populations around the world. For patients receiving hemodialysis, the United Kingdom has coordinated a multicenter study that will phenotype antibody responses to vaccinations 28 days after the first and second doses of the vaccine with storage and centralized analysis at the Francis-Crick Institute (SP/VACCINE/2021). Centralized analysis using the same antibody assays is an essential component in the design of such studies, and we encourage international communities to conduct similar studies to allow contemporary study of seroconversion rates in response to the spectra of available vaccines, and differing vaccine deployment strategies in populations with different and unique characteristics. We encourage the standardized collection and reporting of clinical variables such that future data syntheses and meta-analyses are possible. Our recommendations for required and desired reporting of clinical measures are shown in Table 2.

The presence or absence of antibodies 28 days after the first vaccine dose in the data we present is not synonymous with protection or absence of protection from COVID-19. Rather, these data should be viewed as a call to arms to all who care for these patients to coordinate collection and standardized analysis of seroconversion following vaccination internationally to understand the immune response and how this relates to subsequent infection rates and outcomes for these patients. These data are essential to inform current and future vaccination programs to protect patients receiving hemodialysis who have had to endure the worst of the pandemic.

SUPPLEMENTARY MATERIAL

Supplementary File (Word)

Supplementary Appendix S1. Methods.

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Neutralizing SARS-CoV-2 antibody response in dialysis patients after the first dose of the BNT162b2 mRNA COVID-19 vaccine: the war is far from being won

see commentary on page 1275

To the editor: On December 21, 2020, the European Commission granted conditional marketing approval to the BNT162b2 coronavirus disease 2019 (COVID-19) mRNA vaccine developed by BioNTech.[1,2] In the general population, the first dose of BNT162b2 was reported to produce a rapid antibody response with 52% efficacy in preventing severe infection, similar to the protection induced by the natural disease.[2,3] There was great hope that vaccination would protect fragile individuals, and societies of nephrology asked that patients with end-stage kidney disease should be given priority in being vaccinated.[4]

The situation of in-center hemodialysis patients is a double challenge: their fragility and their proximity to others have made this population particularly vulnerable. In France, for instance, the cumulative incidence of COVID-19 is now >10% in dialysis patients, with a mortality rate of about 15% in those who tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

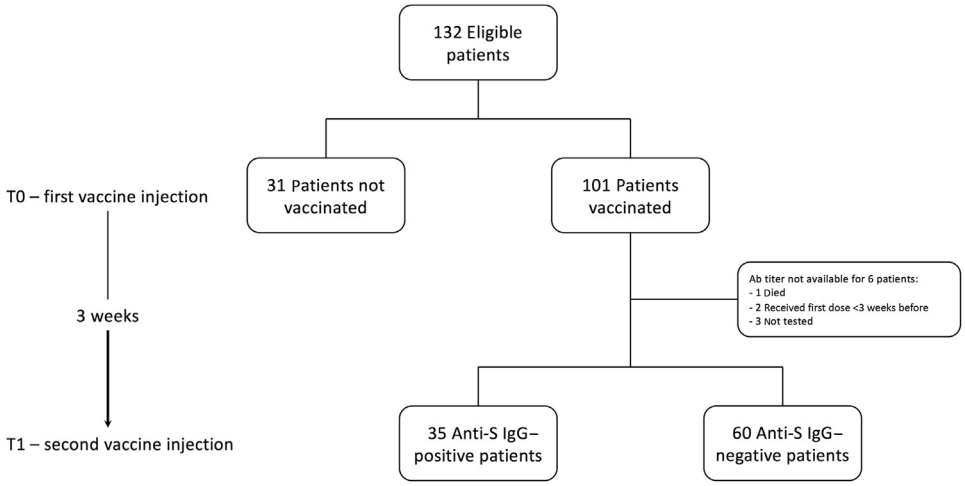

Figure 1 | Flowchart. Ab, antibody; Anti-S, anti-spike.

However, the response to SARS-CoV-2 vaccine in dialysis patients is still unknown, as is the need for a second dose and what its timing should be.[5,6] We therefore wish to report on the antibody response to the first dose of BNT162b2 vaccination in a cohort of high-comorbidity patients on in-center hemodialysis.

All the chronic hemodialysis patients treated in our center between January 1 and February 28, 2021, were enrolled in this observational analysis. We dosed specific IgG anti-spike protein (anti-S IgG) (Elecsys Anti-SARS-CoV-2 S; Roche Diagnostics) at the time of the first vaccine injection (T0) and at the time of the second one (T1) 3 weeks later (Figure 1). Of the 132 eligible patients (mean age, 67.54 ± 15.71 years; 57% males; average dialysis vintage, 2.21 years), 101 (77%) gave their consent to be vaccinated (Table 1). At baseline, only 2 patients tested positive (anti-S IgGs, 1200 and 22 U/ml, respectively). Both had previously had symptomatic COVID-19. At T1, only 35 (35%) of the patients had developed neutralizing antibodies, with a median titer of 8.22 U/ml [interquartile range, 1.73–28.70] (Figure 1). The patients who developed neutralizing antibodies were younger and had a lower comorbidity burden (Table 1). However, in this subset of cases, no correlation was found between antibody titer and age, comorbidity, or dialysis vintage.

To our knowledge, this is the first report on the initial response to COVID-19 vaccine in patients on hemodialysis. At difference with other recent reports in health care workers,[7] our data suggest that only about one-third of hemodialysis patients develop neutralizing antibodies after the first dose of BNT162b2 COVID-19 mRNA vaccine, and that these are at low titers, as could be expected, in a high-comorbidity cohort (median Charlson Comorbidity Index: 8). Younger patients, with lower comorbidity, are more likely to mount an antibody response. Although, because of a shortage of vaccine, some institutions proposed a policy of delayed second-dose administration in the general population,[8,9] a timely second dose of the BNT162b2 COVID-19 mRNA vaccine seems necessary to ensure protection in hemodialysis patients. In the wait for long-term studies on larger groups, needed to enable us to assess the vaccine-induced immune response and kinetic, we considered that this first report could be of help by suggesting that to best

Table 1 | Characteristics of our cohort

Baseline	All	Vaccinated	Not vaccinated	*P*
n (%)	132 (100)	101 (77)	31 (23)	—
Age, yr	67.54 ± 15.71	68.89 ± 14.86	63.13 ± 17.74	0.0739
Male, n (%)	75 (57)	60 (59)	15 (48)	0.3054
Dialysis vintage, yr	2.21 [0.80–4.68]	2.28 [0.81–4.58]	2.21 [0.41–5.97]	0.5637
Charlson Comorbidity Index	8 [5–10]	8 [5–10]	8 [6–9]	0.3649
T1		**Responders**	**Nonresponders**	***P***
No.		35	60	—
Age, yr		62.31 ± 16.20	73.72 ± 11.18	**0.0001**
Male, n (%)		20 (57)	35 (58)	0.9999
Dialysis vintage, yr		1.44 [0.67–3.97]	2.99 [0.96–5.99]	0.3149
Charlson Comorbidity Index		6 [4–8]	9 [7–10]	**0.0006**
Anti–SARS-CoV-2 S IgG titer, U/ml		8.22 [1.73–28.70]	—	—

S, spike; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; T1, time of the second vaccine injection.
Age is expressed as mean ± SD; dialysis vintage and Charlson Comorbidity Index are expressed as median [interquartile range].
Bold *P* values indicate statistically significant variables.

protect dialysis patients, for the time being we cannot let our guard down, even after vaccination.

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Experience with SARS-CoV-2 BNT162b2 mRNA vaccine in dialysis patients

see commentary on page 1275

To the editor: The immune system is profoundly affected by uremia. Patients with end-stage kidney disease (ESKD) may be more vulnerable to infections and may have suboptimal response to vaccination.[1] Patients with ESKD and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease 2019 [COVID-19]) are at increased risk of infection and mortality.[2–4] The first emergency-use authorizations for COVID-19 vaccines were granted by the Food and Drug Administration in December 2020, and clinical trials for the approval of more vaccines are ongoing. However, the representation of patients with chronic kidney disease and ESKD in these trials is low or unreported.[5] The Pfizer BiONTech trial of the BNT162b2 vaccine included 256 patients with renal disease with no further details on the stages of the chronic kidney disease.[6] We investigated dialysis patients and a control group who had completed 2 doses of vaccination with the mRNA BNT162b2 vaccine for anti–spike protein antibody response (LIAISON SARS-CoV-2 S1/S2 IgG; DiaSorin) and observed them for up to 10 weeks (for detailed methods, see the Supplementary Methods).

Table 1 | Participants and response to BNT162b2 mRNA vaccine

Variable	Dialysis patients (n = 160)	Control group (n = 132)	*P* value
Age, median [IQR], yr	69 [62–78]	50.5 [41–60]	<0.001
Male	101 (63)	67 (51)	0.022
Female	59 (37)	65 (49)	
Hemodialysis	127 (79)	—	—
Peritoneal dialysis	33 (21)	—	—
Dialysis vintage, median [IQR], yr	3.21 [1.60–5.39]	—	—
Anti–spike antibody negative (<15 AU/ml)	16 (10)	0	<0.001
Anti–spike antibody level, median [IQR], AU/ml	116.5 [66.0–160.0]	176.5 [142–235]	<0.001
COVID-19 infection after complete vaccination	6 (3.75)	0	0.033

AU, arbitrary unit; COVID-19, coronavirus disease 2019; IQR, interquartile range.
Data are given as n (%), unless otherwise indicated.

A total of 160 chronic dialysis patients (127 hemodialysis and 33 peritoneal dialysis patients) and 132 control group persons were analyzed (Table 1). The median age of the dialysis group was 69 years (interquartile range [IQR], 62–78 years), and of the control group, 50.5 years (IQR, 41–60 years; $P < 0.001$). A total of 63% in the dialysis group and 51% in the control group were men ($P = 0.022$). In the dialysis group, 79% were on hemodialysis and 21% were on peritoneal dialysis. The median dialysis vintage was 3.2 years (IQR, 1.6–5.4 years).

A total of 90% of the dialysis group and 100% of the control group were positive for anti–spike antibodies ($P < 0.0001$). The median level of anti–spike antibody was 116.5 arbitrary unit (AU)/ml (IQR, 66–160 AU/ml) in the dialysis group and 176.5 AU/ml (IQR, 142–235 AU/ml) in the control group ($P < 0.001$).

In the dialysis group, in patients aged ≥75 years, the median anti–spike antibody level was 99.5 AU/ml (IQR, 28.75–139.5 AU/ml), and in patients aged <75 years, the median level was 122 AU/ml (IQR, 72.8–167.0 AU/ml; $P = 0.035$) (Supplementary Figure S1).

In the dialysis group, we compared the lowest anti–spike antibody level quartile group (antibody level, <3.8 to 66 AU/ml) with the highest anti–spike antibody level quartile (160 to >400 AU/ml); the median age in the lowest quartile was 72 years (IQR, 66.25–81.00 years), and in the highest quartile, 67 years (IQR, 56.25–74.00 years; $P = 0.02$). These 2 subgroups did not differ in dialysis modality, dialysis vintage, and sex distribution (Supplementary Table S1).

Six hemodialysis patients (3.75%) and none in the control group developed a new COVID-19 infection (confirmed by positive COVID-19 reverse transcriptase–polymerase chain reaction) >7 days after completion of the recommended vaccination regimen ($P = 0.033$). Epidemiological investigation