LETTER TO THE EDITOR

High response rate to BNT162b2 mRNA COVID-19 vaccine among self-care dialysis patients

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Coronavirus disease 2019 (COVID-19) due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is particularly life threatening in patients with kidney failure under dialysis [1–3], with mortality rate at 28 days of 21.2% in the ERA-EDTA registry [4] and 25% in the ERACODA (European Renal Association COVID-19 Database) database [5].

Vaccination campaigns have started in most countries, with a robust humoral response in up to 90% of patients on haemodialysis (HD), albeit delayed and at rates below those achieved in healthy controls [6–8], but higher than in kidney transplant recipients (KTRs) under chronic immunosuppression therapy [7, 9, 10]. Very few data are currently available in patients on self-care dialysis. This peculiar population is younger—except for older patients on peritoneal dialysis (PD)—with few comorbidities and less likely to be infected with COVID-19 than in-centre HD patients, as they can easily achieve efficient social distancing because of their home therapy. However, a significant proportion of self-care dialysis patients is still given chronic immunosuppression, mostly to avoid acute rejection of a failed kidney graft, raising the question of the effectiveness of the vaccination.

We assessed the serological response 28 days after the second dose of the BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech) in all adult patients treated in our self-care dialysis unit, with simultaneously two different electro-chemiluminescent immunoassays using a recombinant nucleocapsid (N) antigen and testing for antibodies against the spike protein receptor-binding, with a cut-off index >1.0 and >0.8 U/mL, respectively.

Out of 91 patients in the unit, 13 (14%) refused the vaccination because of a fear of adverse events and/or in line with the conspiracy theory, and 12 (13%) received a delayed vaccination because of hesitations, organizational difficulties or current medical complications. Six patients (7%) had a previous documented SARS-CoV-2 infection. Sixty-six (72%) patients [54% males, median age 54 (19–82) years, 6% diabetics] received two doses of BNT162b2 mRNA COVID-19 vaccine between 26 February and 9 April 2021. Twenty-one (32%) were on self-care HD (in a satellite unit) (SC-HD), 30 (45%) on home HD and 15 (23%) on PD, respectively (Figure 1).

Ten patients (15%) had antibodies against the N antigen; the six patients with a past SARS-CoV-2 infection and four other patients without previous diagnosis of COVID-19. Sixty-four (97%) vaccinated patients mounted a serological response against the spike protein receptor-binding domain. The response rate is very similar (96%) when considering only the 54 patients without history of COVID-19 and without anti-SARS-CoV-2 N antibody.

The total antibody titers were >250 U/mL in 51 (80%) and between 0.8 and 250 U/mL [median titer 18.8 U/mL (6.4–200.3)] in 13 (20%) of them, respectively. Only two patients did not mount a serological response (titers <0.8 U/mL): a 67-year-old cardiac transplant female recipient with calcineurin inhibitors nephrotoxicity as primary renal disease, on mycophenolic mofetil and...
Self-care dialysis population, n=91
- Home HD, n=46
- SC-HD, n=25
- PD, n=20

Declined or postponed vaccination, n=25
- Home HD, n=16
- SC-HD, n=4
- PD, n=5

Included in analysis, n=66
- Home HD, n=30
- SC-HD, n=21
- PD, n=15

Previous SARS-CoV-2 infection*, n=10
- Home HD, n=5
- SC-HD, n=5
- PD, n=0

No previous SARS-CoV-2 infection*, n=56
- SARS-CoV-2 S >250, n=42
- SARS-CoV-2 S 0.8-250, n=12
- SARS-CoV-2 S <0.8, n=2

Table 1. Characteristics of patients under immunosuppressive therapy with serological response and patients without serological response

| Age | Sex | Diabetes | Cause of ESKD | Immunosuppressive therapy | Dialysis modality | Reason for immunosuppressive therapy |
|-----|-----|----------|----------------|---------------------------|------------------|---------------------------------------|
| Patient 1 | 28 | F | No | Tubulo-interstitial disease | Tac/MMF/Cs | Home HD | Failed renal transplant |
| Patient 2 | 41 | M | No | Tubulo-interstitial disease | Tac/Cs | Home HD | Liver transplant and failed renal transplant |
| Patient 3 | 63 | M | No | Glomerulonephritis | Tac/Cs | Home HD | Faded renal transplant |
| Patient 4 | 50 | M | No | Calcineurin inhibitors nephrotoxicity | Tac | SC-HD | Liver transplant |
| Patient 5 | 48 | F | No | Glomerulonephritis | MMF/Cs | SC-HD | Systemic lupus erythematosus |
| Patient 6 | 34 | F | No | Systemic lupus erythematosus | Csa/Cs | PD | Faded renal transplant |
| Patient 7 | 69 | M | No | Glomerulonephritis | Csa/Cs | Home HD | Faded renal transplant |
| Patient 8 | 64 | M | No | Glomerulonephritis | Csa | Home HD | Faded renal transplant |
| Patient 9 | 54 | F | No | Glomerulonephritis | Csa | Home HD | Faded renal transplant |
| Patient 10 | 46 | M | No | Alport | Csa | PD | Faded renal transplant |
| Patient 11 | 74 | F | No | ADPKD | Cs | SC-HD | Faded renal transplant |
| Patient 12 | 45 | F | No | Tubulo-interstitial disease | Cs | SC-HD | Faded renal transplant |
| Patient 13 | 21 | F | Yes | Renal dysplasia | Cs | Home HD | Prevention of encapsulating peritoneal sclerosis |
| Patient 14 | 49 | M | No | Tubulo-interstitial disease | Cs | Home HD | Faded renal transplant |
| Patient 15 | 69 | F | No | Multiple myeloma | Lenalidomide | PD | Multiple myeloma |
| Patient 16 | 67 | F | No | Calcineurin inhibitors nephrotoxicity | Csa/MMF | PD | Cardiac transplant |
| Patient 17 | 71 | M | Yes | Diabetic nephropathy | / | PD | NA |

ADPKD, autosomal dominant polycystic kidney disease; Cs, corticosteroid; Csa, cyclosporin A; ESKD, end-stage kidney disease; F, female; M, male; MMF, mycophenolate mofetil; NA, not applicable; Tac, tacrolimus.

*Previous SARS-CoV-2 infection defined as positive nasopharyngeal swab or presence of anti-SARS-CoV-2 N antibodies.
cyclosporine as anti-rejection therapy, and a 71-year-old diabetic male, both on PD and older than the patients who mounted a serologic response.

The influence of a chronic immunosuppressive therapy prescription at the time of vaccination was evaluated. Fifty (76%) patients were not given any immunosuppressive therapy: 41 (82%) patients mounted an antibody titer >250 U/mL and 8 patients between 0.8 and 250 [median 59.2 (6.4–200.3)] U/mL, respectively. Sixteen (24%) patients were taking chronic immunosuppressive therapy for various reasons: 10 as a maintenance therapy to avoid acute rejection of a failed kidney transplant, 3 after solid organ (2 liver and 1 heart) transplantation, 1 for multiple myeloma, 1 for systemic lupus erythematosus and 1 as a preventive measure of sclerosing encapsulation peritonitis (Table 1). Fifteen (94%) of them developed a positive serology 28 days after the second vaccine administration, but with lower titers than patients without any immunosuppressive therapy: 10 (67%) had an antibody titer >250 U/mL and 5 between 0.8 and 250 [median 18.8 (7.8–52.2)] U/mL, respectively.

The serological response of patients from our self-care dialysis unit is higher than that of in-centre HD patients [6, 7, 11], suggesting that older age and comorbidities might detrimentally affect the serological response after vaccination, as observed in other populations [12]. Interestingly, 94% of our self-care dialysis patients still given chronic immunosuppression mounted a satisfactory immunization rate, suggesting that the level of immunosuppression and/or the type of immunosuppressant agents used may influence the serologic response, as already suspected [13]. These encouraging results in the efficacy of SARS-CoV-2 vaccination in our self-care dialysis patients emphasize the importance of promoting vaccination in this population.

AUTHORS’ CONTRIBUTIONS

H.G. and E.G. performed the research idea, study design and data analysis. H.G., J.M., A.D., J.D.G., L.B., J.-C.Y., N.K. and E.G. took care of the patients. J.D.G., L.B. and J.-C.Y. organized the vaccination. A.S. and B.K. performed the serologic analysis. All authors discussed and reviewed the manuscript.

CONFLICT OF INTEREST STATEMENT

None declared.

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