Nephrol Dial Transplant (2021) 36: 1756–1757
doi: 10.1093/ndt/gfab165
Advance Access publication 25 April 2021

RESEARCH LETTER

Efficacy of the BNT162b2 mRNA COVID-19 vaccine in a haemodialysis cohort

Luc Frantzen [1], Guilhem Cavaillé[1], Sandrine Thibeaut[2] and Yohan El-Haik[3]

[1]Service de Néphrologie, Hôpital Saint Joseph Marseille, Marseille, France, [2]Laboratoire de Biologie Médicale, Hôpital Saint Joseph Marseille, Marseille, France and [3]Pharmacie, Centre de Dialyse DIAVERUM, Hôpital Saint Joseph Marseille, Marseille, France

Correspondence to: Luc Frantzen; E-mail: lfrantzen@mac.com

INTRODUCTION

Nephrologists call for priority access to coronavirus disease 2019 (COVID-19) vaccination in patients receiving in-centre haemodialysis [1] for two main reasons: a very high risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection compared with the general population (5–16 times more likely [2] because they travel to their dialysis centre three times a week and are surrounded by other patients and caregivers) and also a particular high mortality rate (close to 20%) when infected by SARS-CoV-2 [3].

Our team is taking care of 470 in-centre haemodialysis patients in Marseille and its surroundings, a region severely affected by COVID-19. As soon as vaccination was prioritized for our patients, we proceeded to a large-scale campaign as of 18 January 2021, when the first injections were administered.

Nevertheless, a major downside is vaccine hyporesponsiveness among such immune-compromised patients, who often show disappointing seroconversion rates (e.g. a 44% rate following a double-dose vaccination schedule for hepatitis B [4]).

In this context and given the lack of data on COVID-19 vaccination in dialysis, we decided to evaluate the vaccine response of our patients by serology testing in order to optimize their future management.

MATERIALS AND METHODS

We proposed the COVID-19 vaccination—two injections 3 weeks apart of the BNT162b2 mRNA COVID-19 vaccine—to all our in-centre haemodialysis patients. The exclusion criteria were a lack of consent or a SARS-CoV-2 infection less than 3 months ago. The patients were vaccinated in their dialysis centre (the majority during their dialysis session).

Vaccination efficacy was assessed 1 month after the second injection by quantifying antibodies directed against the Spike protein using the Elecsys® Anti SARS-CoV-2 S enzyme immunoassay (which presents a high correlation with neutralizing antibodies).

Table 1. Patient characteristics and immune response after two doses of the BNT162b2 mRNA COVID-19 vaccine

Patient characteristics	Total
	$n = 244$
Age, mean (IQR), years[a]	71 (63–80)
Male, *n* (%)	170 (70)
Obesity (BMI >30 kg/m^2), *n* (%)	55 (23)
Comorbidity, *n* (%)	
Diabetes mellitus	90 (37)
Hypertension	212 (87)
Heart disease	86 (35)
Cancer/haemopathy[b]	3 (1)
Chronic obstructive pulmonary disease	16 (6)
Immunosuppression therapy, *n*	1[c]
Previous SARS-CoV-2 infection, *n* (%)	32 (13)
Positive antibody response >15 U/mL, *n* (%)	221 (91)
> 250 U/mL	142 (58)
200–249 U/mL	4 (2)
150–199 U/mL	8 (3)
100–149 U/mL	20 (8)
50–99 U/mL	24 (10)
15–49 U/mL	23 (9)
Negative antibody response <15 U/mL, *n* (%)	23 (9)

[a]Interquartile range (IQR).
[b]With ongoing treatment.
[c]Pancreatic graft.
BMI, body mass index.

RESULTS

As of early March, 70% of our cohort (326 patients) had received the two injections (3 weeks apart) of the BNT162b2 mRNA COVID-19 vaccine. Vaccine tolerability was excellent, with no serious adverse event in the overall cohort.

The first results, regarding 244 patients, show a very high response rate: 91% present a positive antibody titer (with a cut-off fixed at 15 U/mL for the Elecsys® Anti SARS-CoV-2 S test).

The baseline characteristics of the patients and their immune response are shown in Tables 1 and 2.

Older patients were less likely to present an antibody response. There was also no response to vaccination among all

Table 2. Demographic and clinical characteristics of patients stratified by immune response

	Antibody level		
	>15 U/mL ($n = 221$)	<15 U/mL ($n = 23$)	P-value
Age, median (IQR), years	70 (63–79)	77 (72–85)	**0.005**
Male, *n* (%)	158 (71)	12 (52)	0.25
Obesity (BMI >30 kg/m^2), *n* (%)	51 (23)	4 (17)	0.53
Comorbidity, *n* (%)			
Diabetes mellitus	85 (38)	5 (22)	0.11
Hypertension	192 (87)	20 (87)	0.99
Heart disease	81 (37)	5 (22)	0.15
Cancer/haemopathy	0	3 (13)	**<0.001**
Chronic obstructive pulmonary disease	15 (7)	1 (4)	0.65
Immunosuppression therapy, *n*	0	1	**0.002**
Previous SARS-CoV-2 infection, *n* (%)	31 (14)	1 (4)	0.19

Descriptive statistics included the percentages for categorical variables and the median [interquartile range (IQR)] for continuous variables according to the distribution. Comparisons between the two groups according to the presence or absence of a significant antibody level for continuous variables were made using the Student's *t*-test or the Mann–Whitney test, according to the variable distribution. Comparisons between the two groups for categorical variables were made using the Pearson's chi-square test or Fisher's exact test. A P-value <0.05 was considered significant (shown in bold). The statistical analysis was conducted using R version 3.6.0 R Development Core Team (2019). BMI, body mass index.

the patients undergoing chemotherapy (3/3) or under immunosuppression (1/1).

DISCUSSION

These results go far beyond what is usually seen with other vaccines in this hyporesponsive population, with a 91% antibody positivity rate, with 60% of the patients presenting an antibody level >200 U/mL correlating to maximal neutralizing capacity in the neutralization assays for the Elecsys® Anti SARS-CoV-2 S test.

However, some of our patients showed a rather weak response, and a recent study [5] reported lower antibody levels in dialysis patients compared with the general population. The consequences may be a lower vaccine efficacy and a shorter period of immunoprotection. It is therefore necessary to consider reinforced vaccination schedules.

Nevertheless, in parallel to these biological results, we have witnessed a spectacular decrease in new case occurrences as of mid-February (3 weeks after the first injections) in our dialysis centres.

This clinical and biological response to a mRNA COVID-19 vaccination among a highly vulnerable population is extremely promising. Studies to assess vaccine efficacy in this population in the real-word setting are needed.

CONFLICT OF INTEREST STATEMENT

The authors declare that the results presented in this paper have not been published previously in whole or part. None of the authors presents a conflict of interest.

REFERENCES

1. Francis A, Baigent C, Ikizler T *et al.* The urgent need to vaccinate dialysis patients against severe acute respiratory syndrome coronavirus 2: a call to action. *Kidney Int* 2021; 99: 791–793
2. De Meester J, De Bacquer D, Naesens M *et al.* Incidence, characteristics, and outcome of COVID-19 in adults on kidney replacement therapy: a region-wide registry study. *J Am Soc Nephrol* 2021; 32: 385–396
3. Savino M, Casula A, Santhakumaran S *et al.* Sociodemographic features and mortality of individuals on haemodialysis treatment who test positive for SARS-CoV-2: a UK Renal Registry data analysis. *PLoS ONE* 2020; 15: e0241263
4. Krueger KM, Ison MG, Ghossein C. Practical guide to vaccination in all stages of CKD, including patients treated by dialysis or kidney transplantation. *Am J Kidney Dis* 2020; 75: 417–425
5. Grupper A, Sharon N, Finn T *et al.* Humoral response to the Pfizer BNT162b2 vaccine in patients undergoing maintenance hemodialysis. *Clin J Am Soc Nephrol* 2021; 16: doi: 10.2215/CJN.03500321 (online ahead of print)

Received: 19.4.2021; Editorial decision: 21.4.2021