Efficacy of the BNT162b2 mRNA Covid-19 Vaccine in a hemodialysis cohort

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Introduction

Nephrologists call for priority access to COVID-19 vaccination in patients receiving in-center hemodialysis [1] for two main reasons: a very high risk of SARS-CoV-2 infection compared with the general population (5-16 times more likely [2] because they travel to their dialysis center 3 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-center hemodialysis patients in Marseille and its surroundings, a region severely affected by COVID-19. As soon as vaccination has been prioritized for our patients, we proceeded to a large-scale campaign as of January 18th 2021, when the first injections were administered.

Nevertheless, a major downside is the vaccine hyporesponsiveness among such immune-compromised patients often showing disappointing seroconversion rates (for example 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.

Methods

We proposed the COVID-19 vaccination - two injections three weeks apart of the BNT162b2 mRNA COVID-19 vaccine - to all our in-center hemodialysis patients. The exclusion criteria were a lack of consent or a SARS-CoV-2 infection less than three months old. The patients were vaccinated in their dialysis center (the vast 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).

Results

As of early March, 70% of our cohort (326 patients) had received the two injections (three weeks apart) of the BNT162b2 mRNA COVID-19 vaccine. Vaccine tolerability was excellent with no serious adverse event on 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 Table 1 and 2.

Older patients were less likely to present an antibody response. There was also no response to vaccination among all the patients undergoing chemotherapy (3/3) or under immunosuppression (1/1).

Discussion

The 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 above 200 U/ml correlating with maximal neutralizing capacity in the neutralization assays for the Elecsys® Anti SARS-CoV-2 S test.

However, some of our patients show a rather weak response and a recent study [5] reported lower antibody levels in dialysis patients compared to 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 (three weeks after the first injections) in our dialysis centers.
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 does present a conflict of interest.

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Table 1 - Patient characteristics and immune response after 2 doses of the BNT162b2 mRNA COVID-19 vaccine

Patient Characteristics	**Total (n = 244)**
Age, mean (SD), years	76 (13)
Male - n (%)	170 (70)
Obesity (IMC > 30) - n (%)	55 (23)
Comorbidity - n (%)	
Diabetes mellitus	90 (37)
Hypertension	212 (87)
Heart Disease	86 (35)
Cancer/hemopathy [a]	3 (1)
Chronic obstructive pulmonary disease	16 (6)
Immunosuppression therapy - n	1 [b]
Previous SARS-CoV-2 infection - n (%)	32 (13)
Immune response	**(n = 244)**
Positive antibody response - n (%)	
Antibody level > 15 U/ml	**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 - n (%)	
Antibody level < 15 U/ml	**23 (9)**

[a] *With ongoing treatment*

[b] *Pancreatic graft*

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 [a]**
Age, mean (SD), years	70 (13)	77 (10)	**0.005**
Male - n (%)	158 (71)	12 (52)	0.25
Obesity (IMC > 30) - 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/hemopathy	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

[a] *Descriptive statistics included the percentages for categorical variables and the mean (± standard deviation) or median [interquartile ranges] 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. The statistical analysis was conducted using R version 3.6.0 R development Core team (2019).*