Observational Study

Medicine

OPEN

Humoral response to vaccination against SARS-CoV-2 in patients undergoing dialysis

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Abstract

Patients undergoing maintenance dialysis have a higher mortality rate associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and response rates to vaccination against SARS-CoV-2 vary from 29.6% to 96.4% in such patients. This study aimed to assess the immunogenicity of SARS-CoV-2 vaccination in Korean patients undergoing dialysis. We enrolled 70 SARS-CoV-2-vaccinated patients undergoing dialysis, with 11 healthcare workers serving as healthy control subjects. Thirty-two patients had received a third vaccination, whereas 38 had received 2 vaccinations. The healthy control subjects completed the second vaccination. Immunoglobulin G (IgG) antibodies targeting the receptor-binding domain of the S1 subunit of the SARS-CoV-2 spike protein were measured The vaccination responder rates were 86% (37/43), 96% (26/27), and 91% (10/11) in the patients undergoing hemodialysis and peritoneal dialysis and healthy controls, respectively. IgG antibody levels were significantly higher when a third dose was administered, independent of the type of vaccine or the time interval between vaccination and the subsequent blood sampling date. When a third dose of vaccine was administered, there was no difference in IgG antibody levels between those receiving cross-vaccination or a single vaccine. There was no significant difference in IgG antibodies between healthy controls and patients undergoing dialysis. Patients on dialysis exhibited a sufficient antibody-related response to vaccination against SARS-CoV-2, even in those receiving cross-vaccination, and the antibody titer was higher after a third vaccination. Therefore, it is necessary to administer a third vaccine dose to Korean patients undergoing dialysis.

Abbreviations: ESRD = end-stage renal disease, IgG = immunoglobulin G, IRB = Institutional Review Board, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Keywords: hemodialysis, peritoneal dialysis, SARS-CoV-2, vaccination

1. Introduction

When suffering from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, mortality rates are higher in patients with underlying disorders.[1] In particular, kidney disease significantly increases the risk associated with SARS-CoV-2 infection.[2] Vaccines are currently the only tool for controlling ongoing infections and reducing patient mortality, as other classes of therapeutic agents for SARS-CoV-2 infection remain in the research and development stage.

In the case of the hepatitis B vaccine, the degree of antibody response is low in patients undergoing dialysis,[3] and the Korean guidelines for prevention and control of infection in hemodialysis units recommend a vaccine dose that differs from that recommended for the general population. Similarly, previous studies have confirmed that the response to the influenza vaccine was also lower in patients on dialysis than in the general population.[4] With regards to the SARS-CoV-2 vaccine, if the degree of antibody response exhibited is lower than that of the general population and the efficacy is low,[5–7] other countermeasures are necessary to improve protection against illness. Studies have been published in the United States and Europe comparing the extent of the antibody response by vaccine type or frequency of vaccination. However, in South Korea, vaccination policies differ from those of other countries, including those related to cross-vaccination and vaccination intervals, and further analysis and research involving Korean patients is required. Therefore, in this study, we aimed to investigate potential differences in the antibody response to SARS-CoV-2 vaccines in patients undergoing dialysis in South Korea in order to assess the efficacy of vaccines in situations involving cross-vaccination and the administration of third vaccine doses in particular.

2. Methods

2.1. Subjects

We enrolled SARS-CoV-2-vaccinated patients who were undergoing hemodialysis or peritoneal dialysis at Haeundae Paik Hospital, Busan, South Korea from December 2021 to January

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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How to cite this article: Lee YJ, Park BS, Heo CM, Park S, Yu S, Kim YW. Humoral response to vaccination against SARS-CoV-2 in patients undergoing dialysis. Medicine 2022;101:50(e32152).

Received: 12 October 2022 / Received in final form: 10 November 2022 / Accepted: 11 November 2022

http://dx.doi.org/10.1097/MD.0000000000032152

2022. These patients were defined as follows: those who were receiving maintenance dialysis; and those who had been vaccinated against SARS-CoV-2 at least twice. Patients receiving the BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and ChAdOx1 (Oxford-AstraZeneca) vaccines were included in the study. Those who received the first and second doses of the same vaccine and a third dose of a different vaccine were included in the study; however, those who received the first and second doses of different vaccines were excluded, as were those who had a previous SARS-CoV-2 infection. Eleven healthy healthcare workers who had been vaccinated with the ChAdOx1 vaccine comprised the group of healthy control subjects.

2.2. Evaluation of antibody responses

Sera obtained from the centrifugation of blood samples collected in VACUETTE® CAT Serum Separator Clot Activators (Greiner Bio-One GmbH, Kremsmünster, Austria) at 1680 × g for 10 minutes were aliquoted and stored at – 80 °C until analysis. Immunoglobulin G (IgG) antibodies to the receptor-binding domain of the S1 subunit of the spike protein of SARS-CoV-2 were measured by chemiluminescent microparticle immunoassay (CMIA) using an ARCHITECT i2000SR immunoassay analyzer (Abbott Laboratories, IL) and SARS-CoV-2 IgG II Quant assay kits (Abbott Laboratories, Sligo, Ireland). The manufacturer-defined analytical measurement interval was 21–40,000 AU/mL (3.0 BAU/mL—5680.0 BAU/mL as WHO unit), with a positivity cutoff ≥ 50 AU/mL (7.1 BAU/mL as WHO unit). The conversion from Abbott AU/mL unit to the WHO BAU/mL unit was followed the equation of BAU/mL = 0.142 AU/mL. All procedures were performed according to the manufacturer's instructions.

2.3. Statistical analysis

The data are presented as the median and interquartile range for continuous variables. Differences in variables were compared across subgroups using the Mann–Whitney *U* test or Kruskal–Wallis test for continuous variables as appropriate, and the Bonferroni correction was applied in the post hoc analyses. To assess whether the distribution was normal for each variable, the Shapiro–Wilk test was used. The Spearman's correlation coefficient between the antibody and the period from the second inoculation to the time of blood collection was analyzed. Univariate logistic regression analyses were performed to identify the prognostic factors independently related to presence of absence of antibody production. All statistical analyses were carried out using Statistical Package for the Social Sciences version 25.0 software, and *P* values less than .05 were considered statistically significant.

2.4. Ethics statement

This study was performed in accordance with the Declaration of Helsinki. This study was approved by the Institutional Review Board (IRB) of Inje University Haeundae Paik Hospital (IRB number: 2021-10-027). A written informed consent form was completed by all participants.

3. Results

Table 1 shows the clinical characteristics of the patients. Seventy SARS-CoV-2-vaccinated patients undergoing dialysis were included in the study. Of the 70 patients with end-stage renal disease (ESRD), 43 underwent hemodialysis as a renal replacement therapy, whereas 27 patients underwent peritoneal dialysis. Of the patients who participated in the study, 39 received the ChAdOx1 vaccine, 6 were administered the mRNA-1273 vaccine, and 37 received the BNT162b2 vaccine for the first and second vaccine doses. Thirty-two individuals received a third vaccine dose, 11 and 21 of whom received the mRNA-1273 and BNT162b2 vaccines, respectively. Of the 11 patients who received the mRNA-1273 vaccine for the third inoculation, 9 had previously received the ChAdOx1 vaccine as the first and second doses, whereas the other 2 received the mRNA-1273 vaccine. Of the 21 patients who received the BNT162b2 vaccine as the third dose, 6 had previously received the ChAdOx1 vaccine at the first and second doses, whereas 15 received

Table 1

Clinical characteristics of the patients who received up to a second or third dose of a vaccine.

	Second dose	Third dose	Total	
	(N = 38)	(N = 32)	(N = 70)	*P* value
Gender, male (%)	23 (60.5%)	20 (62.5%)	43 (61.4%)	0.989
Age, yr	68.6 ± 11.6	70.4 ± 10.2	69.4 ± 10.9	0.483
Dialysis modality, HD	27 (71.1%)	16 (50.0%)	43 (61.4%)	0.120
DM, n (%)	20 (52.6%)	21 (65.6%)	41 (58.6%)	0.392
Dialysis vintage, month	53.1 ± 37.4	44.6 ± 30.2	49.2 ± 34.3	0.304
Kt/V	1.7 ± 0.5	1.9 ± 0.8	1.8 ± 0.6	.206
Anti-HBs Ab titer (IU/mL)	107.7 ± 209.4	118.1 ± 209.6	112.4 ± 208.1	.837
Hemoglobin (d/dL)	10.4 ± 1.1	10.4 ± 0.8	10.4 ± 1.0	.864
Leukocyte (L)	7000 ± 2600	6800 ± 2400	6900 ± 2500	.761
CRP (mg/L)	0.4 ± 0.8	0.2 ± 0.3	0.3 ± 0.6	.154
Albumin (g/dL)	3.9 ± 0.4	3.8 ± 0.4	3.9 ± 0.4	.523

Ab = antibody; CRP = C-reactive protein; DM = diabetes mellitus; HD = hemodialysis.

Table 2

Antibody titers based on whether individuals received a third dose of a vaccine and the type of vaccine administered.

		Antibody titers	*P* value
Third dose	Yes (n = 32)	13764.85 (5444.20-40000.00)	<.001*
	No (n = 38)	775.85 (94.88-5015.98)	
type of vaccine	mRNA-1273 (n = 11)	17403.70 (10171.00-40000.00)	0.457*
	BNT162b2 (n = 21)	13645.80 (5015.75-37465.85)	

*Mann–Whitney's *U* test.

the BNT162b2 vaccine. The inoculation interval between the first and second vaccine doses was 81.85 ± 10.42 days for the ChAdOx1 vaccine, 30 ± 12.52 days for the BNT162b2 vaccine, and 47.17 ± 5 days for the mRNA-1273 vaccine. The interval between the second and third doses was 127.54 ± 34.24 days for the mRNA-1273 vaccine and 139.47 ± 31.18 days for the BNT162b2 vaccine. The interval between the final inoculation date and the blood sampling date was 77.97 ± 57.46 days for all groups. More specifically, the interval was 120.52 ± 44.82 days for patients who received up to a second vaccine dose, 27.43 ± 11.55 days for patients who received up to a third vaccine dose, and 75.54 ± 4.85 days for the healthy controls.

The vaccination responder rates were 86 % (37/43) in patients undergoing hemodialysis, 96 % (26/27) in patients receiving peritoneal dialysis, and 91 % (10/11) in the healthy controls. In the case of IgG antibodies, the patients who received a third vaccine dose had an antibody titer of 1594.6 BAU/mL (773.1–5680.0 BAU/mL); in those who received up to a second vaccine dose, the titer was 110.2 BAU/mL (13.5–712.3 AU/mL). The patients who received a third vaccine dose exhibited significantly higher titers ($P < .001$) (Table 2). The antibody titers did not differ depending on which vaccine was administered as the third dose; the titers were 2471.3 BAU/mL (1444.3–5680.0 BAU/mL) for the mRNA-1273 vaccine and 1937.7 AU/mL (712.2-5320.2 AU/mL) for the BNT162b2 vaccine ($P = .457$) (Table 2). When a subgroup analysis was performed on patients who received up to a second vaccine dose, the antibody titer was significantly lower in those who received the ChAdOx1 vaccine (than in those who were administered the BNT162b2 vaccine ($P = .004$); however, there was no difference between those who received the ChAdOx1 and mRNA-1273 vaccines or between those who received the mRNA-1273 and the BNT162b2 vaccines (Table 3). There was no statistically significant relationship between the elapsed time from the second vaccine dose to the date of blood sampling and the antibody titers, and a long period of time did not necessarily mean that the titers would be low ($R = 0.260$, $P = .114$). When a subgroup analysis was performed on those who were administered a third vaccine dose, the antibody titers did not significantly differ from those of the group who received up to the second vaccine doses, nor did the titers differ between those who received a different vaccine for the third dose and those who received a third dose with the same vaccine ($P = .455$) (Table 4). There was no significant difference in the antibody titers between the healthy control patients who received the ChAdOx1 vaccine up to the second dose and the patients with ESRD who received up to a second vaccine dose ($P = .905$) (Table 5). There was no significant association between any of the patients' baseline characteristics and the presence or absence of antibody production after vaccination (Table 6).

4. Discussion

In this study, we investigated the antibody response after vaccination against SARS-CoV-2 in patients undergoing hemodialysis and peritoneal dialysis. To the best of our knowledge, no previous studies have assessed the responses to all 3 vaccines—BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and ChAdOx1 (Oxford-AstraZeneca)—in Korean patients undergoing hemodialysis and peritoneal dialysis or among those receiving up to the second or third doses. Considering the widespread immune dysfunction observed in patients dependent on dialysis,[8] it was hypothesized that there would be a difference in the degree of antibody production in response to the vaccines compared to those in the general population. Previous studies have reported that more than one in 5 patients on dialysis exhibited evidence of a weakened immune response to SARS-CoV-2 vaccines.[9] In a meta-analysis, patients who underwent dialysis after receiving the first and second doses of a SARS-CoV-2 vaccine were less likely to develop a sufficient antibody response than the group that did not receive dialysis. However, in the present study, there was no difference in the antibody titers between the patients with ESRD who received up to a second dose and those in the healthy control group who received the ChAdOx1 vaccine up to the second dose. This result is consistent with that of a previous meta-analysis, which confirmed that the difference in antibody response between the nondialysis population and the dialysis population was diminished when a second dose of vaccine had been administered. In Koreans, it can be said that even patients with ESRD exhibited the same rate of antibody production as

Table 3

Antibody titers by vaccine used for the second dose.

	Type of second dose			
	ChAdOx1 (n = 12)	mRNA-1273 (n = 4)	BNT162b2 (n = 22)	*P* value
Titers	113.90 (31.18–592.00)	3291.70 (961.83–4775.28)	2275.00 (423.78–10826.43)	.004*

*Kruskal–Wallis test. Bonferroni's post hoc test was used for multiple comparisons between vaccine groups. ChAdOx1 was significantly different to BNT162b2 ($P = .004$). There was no statistically significant difference between the ChAdOx1 and mRNA-1273 ($P = .084$), and between the mRNA-1273 and BNT162b2 ($P = 1.000$).

Table 4

Comparison of antibody titers between those who received different or same vaccine for the third dose.

	Different vaccine (n = 15)	Same vaccine (n = 17)	*P* value
Titers	12796.30 (4241.40–40000.00)	30479.40 (6813.90–40000.00)	.455*

*Mann–Whitney's *U* test.

Table 5

Comparison of antibody titers between the group administered up to a second dose of a vaccine and the healthy control group.

	Second dose (n = 38)	Normal healthy control (n = 11)	*P* value
Titers	775.85 (94.88–5015.98)	705.10 (353.50–1842.40)	.905*

*Mann–Whitney's *U* test.

Table 6

Patients' baseline characteristics and levels of antibody production.

	OR (95% CI)	*P* value
Gender, male (%)	0.608 (0.109–3.381)	.570
Age, yr	1.011 (0.941–1.085)	.769
Dialysis modality, HD	0.237 (0.027–2.089)	.195
DM, n (%)	2.027 (0.418–9.837)	.381
Dialysis vintage, month	1.029 (0.994–1.065)	.108
Kt/V	3.061 (0.320–29.245)	.331
Anti-HBs Ab titer (IU/mL)	0.997 (0.994–1.000)	.137
Hemoglobin (d/dL)	0.596 (0.246–1.444)	.252
Leukocyte (L)	1.064 (0.759–1.491)	.720
CRP (mg/L)	4.112 (0.144–117.515)	.409
Albumin (g/dL)	0.930 (0.126–6.852)	.943

Ab = antibody; CRP = C-reactive protein; DM = diabetes mellitus; HD = hemodialysis.

healthy controls, and it can be argued that there should be a benefit from receiving a second dose of a vaccine in patients undergoing dialysis. In the present study, the antibody titers were significantly higher when a third dose of vaccine was administered, although this change was not related to the specific vaccine selected. A study conducted in Israel confirmed a decreased and weakened humoral response following vaccination against SARS-CoV-2 in patients on dialysis,[10] and a study conducted in France found that a third dose of a vaccine significantly increased antibody levels in patients receiving maintenance dialysis.[11] Considering the results of these previous studies and the possibility of reduced vaccine effectiveness against mutated forms of the virus, it is reasonable to consider the use of booster doses in patients with ESRD. In Korea, due to policy changes related to the vaccine supply process, individuals are typically inoculated with a different vaccine at the time of the second and third vaccinations. The difference between the present study and others is that we included patients who received different vaccines for the second and third doses. The results confirmed that the antibody response was sufficient in these patients, even if the same vaccine was not used for the third dose, and it can be expected that there will be benefits related to booster vaccinations.

In this study, when comparing the level of antibody production in patients who received up to the second vaccine dose, the antibody titers were significantly lower in those who were inoculated with the ChAdOx1 vaccine than in those inoculated with the BNT162b2 vaccine, although no differences were observed between the other vaccines. This may be due to the fact that there were only 4 individuals vaccinated with the mRNA-1273 vaccine as the second dose, and it is thought that the difference may be related to the period of time between the second inoculation and the time of sample collection. The duration of antibody protection after the second vaccination remains unclear. In a study investigating the correlation between the antibody response and protection after the second dose of either the ChAdOx1 or BNT162b2 vaccine in the general population in the UK, it was estimated that the duration of the antibody response was 2–3 months after 2 doses of ChAdOx1 and 5–8 months after 2 doses of BNT162b2.[12] It is thought that this is related to the fact that blood was collected, on average, 137.77 days after BNT162b2 inoculation and 93.72 days after ChAdOx1 inoculation, and the present study observed no difference in antibody titers. Follow-up studies are required to determine if that is the case.

In the present study, no statistically significant associations were observed with respect to the presence or absence of antibody production and sex, age, the presence of diabetes, the method or vintage of dialysis, the fractional urea clearance ratio Kt/V, hepatitis B antibody titers, or the levels of hemoglobin, leukocytes, C-reactive protein, and albumin. In the case of other vaccines, in a study that confirmed the presence of an antibody response after vaccination with a hepatitis B vaccine in patients with ESRD, correlations were confirmed between the antibody response and older age, the presence of diabetes mellitus or obesity, and vaccine dose.[13] In a study that confirmed the presence of a humoral immune response after influenza vaccination, there was also a correlation between age and the immune response.[14] Other previous studies related to SARS-CoV-2 vaccines have shown that female sex, young age, living in long-term care facilities, potential immunosuppression due to immunodeficiency disorders, heart failure, covaccination with a hepatitis B vaccine, and being hospitalized at the time of vaccination were factors related to the absence of a response to vaccination.[15] It has also been reported that low hemoglobin or a history of diabetes is associated with a poor antibody response to SARS-CoV-2 vaccination.[16] The reason that there were no significant factors related to the presence or absence of antibody production in the present study is thought to be related to the fact that 63 out of 70 patients exhibited a positive antibody response; therefore, the number of patients may not have provided sufficient power to observe a statistically significant effect. To address this possibility, further studies involving a larger number of patients would be required.

This study has several limitations. First, there was a large difference in the time until blood collection after vaccination between patients who received up to a second vaccine dose and those who received up to a third dose. Second, since the patients chose for themselves whether to get vaccinated, there may be clinical differences between those who received up to a third inoculation and those who received up to a second inoculation, as the reason for selecting the number of vaccinations would have varied on an individual basis. In addition, since the individuals included in the study could not select the type of vaccine they wished to receive for policy reasons, head-to-head comparisons could not be performed between those who received different vaccines. Third, the antibody titers were not determined for each individual prior to vaccination. Finally, since the SARS-CoV-2 N antibody was not measured, unnoticed COVID-19 was unknown.

The present study provides data on antibody production after SARS-CoV-2 vaccination in patients undergoing hemodialysis or peritoneal dialysis. Further studies are required to explain the differences in efficacy of various vaccines and to optimize the vaccination policy for patients with ESRD. In particular, this study involving patients with ESRD will prove to be meaningful, as it is expected that a continuous response to the pandemic will be required moving forward. The present study provides the information needed to devise strategies for improving response rates to vaccines, such as the administration of additional doses or the use of higher vaccine doses in patients with ESRD. It is important to note, however, that antibody titers are only one

way to assess the immunological response to vaccination. Whether a measurable antibody response correlates with protection from infection is not yet known, and further research is required.

Ultimately, this study shows that patients receiving dialysis exhibited a sufficient antibody-related response to SARS-CoV-2 vaccines, even in the case of cross-vaccination, and the antibody titer was higher after a third dose of vaccine was administered. Therefore, it is necessary to administer SARS-CoV-2 vaccines to Korean patients undergoing dialysis to ensure optimal protection.

Acknowledgments

We would like to thank Editage (www.editage.co.kr) for English language editing. This study was supported by Inje University Haeundae Paik Hospital and a research grant from the Inje University in 2018 (No. 20180167).

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