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# VACCINATION AGAINST SARS-COV-2 AND MORTALITY IN HEMODIALYSIS PATIENTS: THREE IS GOOD


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**Abstract:** This study has investigated the vaccination rates against SARS-CoV-2 infection, antibody response to vaccine types, and factors affecting mortality in maintenance hemodialysis patients.98 of 143 patients undergoing hemodialysis in our clinic had 3 doses of BNT162b2 (Pfizer-BioNTechh) or CoronaVac (Sinovac Life Sciences) vaccine. Of these 98 patients, blood samples were obtained from 52 patients who agreed to obtain serum samples before and after vaccination. The serum samples were analyzed using the Abbott SARS-CoV-2 immunoassay designed to detect IgG antibodies against the receptor-binding domain of the S1 subunit of the spike protein of SARS-CoV-2. The rate of vaccination with at least one dose of vaccine was 85.3%, and the frequency of SARS-CoV-2 infection was 58.7%. The patients whose antibody titer was obtained after the third dose of vaccine (n=52) were divided into two groups according to the last vaccine type, as BioNTechh group of 16 patients and the Sinovac group of 36 patients. Considering all 52 patients with 3 doses of vaccine, the median antibody level was 397.3 (min-max) (4.5-40000) before the third vaccine dose, while 1325.3 (min-max) (10.5-40000) after the third vaccine dose (P<0.001). In patients with the last vaccine dose of Sinovac (n=36), the median antibody titer was 168.2 (min-max) (4.5-40000) before the third vaccine dose, while 851.7 (min-max) (55.2-40.000) after the third vaccine dose (P<0.01). In patients with the last vaccine dose of BioNTechh, the median antibody titer was 2738.6 (min-max) (9.4-37723.4) before the third vaccine dose, while 37575.8 (min-max) (10.5-40000) after the third vaccine dose (P=0.002). The frequency of SARS-CoV-2 infection (P=0.001) and SARS-CoV-2 infection-related mortality rates were significantly lower in vaccinated patients than in unvaccinated patients (P<0.001). SARS-CoV-2 vaccine doses elicited a high seropositive response in patients receiving maintenance dialysis. Those who received the last (3rd) dose of vaccine with BNT162b2 had higher antibody levels than those with CoronaVac/Sinovac. In addition, regardless of the vaccine type, being vaccinated with any of them decreased the incidence of SARS-CoV-2 infection and the mortality rate.



**Keywords:** COVID-19 vaccination, SARS-CoV-2, Maintenance hemodialysis, Mortality



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## 1. Introduction

Hemodialysis (HD) patients are at higher risk for acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection than the healthy population due to their comorbidities, frequent invasive procedures, and presence in crowded dialysis environments (Shimada et al., 2021; Yen et al., 2021). Vaccination, mask, social distancing, and hygiene are the most important weapons in the fight against SARS-CoV-2. However, it is known that the immune response to vaccination is low in patients with chronic renal failure due to impaired immunity (Asan et al., 2017). The accumulation of uremic toxins and the weakening of the immune response due to chronic inflammation cause this (Asan et al., 2017). Studies show that the third dose of vaccine administration may be beneficial for the vaccine-induced humoral response in the fight against SARS-CoV-2 infection in HD patients, due to the variants and antibody titer decrement over time (Cao et al., 2021; Espi et al., 2021).

The first new coronavirus disease (COVID-19) vaccine campaign in Türkiye has started in January 2021 with the CoronaVac (Sinovac Life Sciences) regimen, a chemically inactivated whole virus vaccine for healthcare workers (Bayram et al., 2021; Önder, 2020). The second vaccine dose was administered 21 days after the first dose, and the scope of the vaccine was extended over time to include the elderly, chronic patients, and immunocompromised patients (Yavuz et al., 2022). As of June 2021, approximately four and a half months after

the first vaccination, the Turkish Ministry of Health has started the 3rd dose booster-dose vaccination campaign for healthcare workers and the entire population over 50 years of age (Yavuz et al., 2022). By September 2021, more than 9 million Turkish citizens had the third dose of the CoronaVac or BNT162b2 vaccine (URL1).

It is known that only 75% of hemodialysis patients show an immune response after two doses of the Covid-19 vaccine (Ducloux et al., 2021). Besides, the significance of a third dose Covid-19 vaccine is emphasized in both the healthy population and HD patients (Ducloux et al., 2021; Keskin et al., 2022). Our study aimed to compare the humoral response to the 3rd dose BNT162b2 (Pfizer-BioNTechh) and CoronaVac (Sinovac Life Sciences) COVID-19 vaccines in HD patients and investigate the relationship between serum antibody titer, frequency of SARS-CoV-2 infection and mortality.

## 2. Materials and Methods

The study included 143 volunteer HD patients who were followed up in the HD program in our hospital for at least six months, agreed to be vaccinated between March 2021 and November 2021 and were over the age of 18. The patients' sociodemographic characteristics, SARS-CoV-2 infection frequency, mortality related-SARS-CoV-2 infection, COVID-19 vaccination status, number of vaccinations, and the date and vaccination type were obtained from the clinical file records. The hospital's electronic medical record system was used to access laboratory test information and reverse transcriptase-polymerase chain reaction (rRT-PCR) results studied in routine follow-ups.

Pre- and post-vaccine serum samples could be obtained from 52 of 98 who received the 3rd dose vaccine (BNT162b2 vaccine or CoronaVac) in a total of 143 patients who underwent HD in our clinic. A written informed consent form was obtained from all patients. Two venous blood samples were obtained from the participants, the first on the day of the third booster dose before vaccination, and the second 28 days after the third vaccination. These samples were centrifuged shortly after collection and stored at -20 °C until studied. The humoral response was analyzed using the Abbott, SARS-CoV-2 immunoassay designed to detect IgG antibodies directed against the receptor-binding domain of the S1 subunit of the spike protein of SARS-CoV-2. Antibody levels of 50 AU/mL and above are considered positive in this immunoassay.

The study was conducted in compliance with the criteria of the Helsinki Declaration and after the approval of the Health Sciences University Samsun Training and Research Hospital Local Ethics Committee with the date and number of GOKA/2021/16/1.

### 2.1. Statistical Analysis

Categorical variables were expressed as n (%). Continuous variables were expressed as mean ± standard deviation (SD) if normally distributed, and as median (min-max) if non-normally distributed. Chi-square and Fisher's exact tests were used to compare categorical variables. Wilcoxon signed ranks test was used to compare continuous variables. Spearman correlation analysis was used to test the correlation between age and antibody titers. The P value less than 0.05 was considered statistically significant (Önder, 2018). IBM SPSS Statistics 22 program was used for statistical analysis.

## 3. Results

A total of 143 hemodialysis patients undergoing dialysis in our clinic were included in the study. The mean age of all patients [91 (63.6%) male and 52 (36.4%) female] was 62.4 ± 13.2 years. The median dialysis time of the patients was 39 (6–409) months. The laboratory values of the patients were as follows; Urea: 124±34.5 mg/dL, Creatinine: 7.1±2.4 mg/dL, Albumin: 3.5±0.4 g/dL, ALT: 16 (7–44) U/L, Sodium: 137.5±3.3 mmol/L, Potassium: 4.9±0.7 mmol/L, Calcium: 8.5±0.7 mg/dL, Phosphorus: 4.9±1.1 mg/dL, Hemoglobin: 10.7±1.4 g/dL, White blood cell: 6238±1979 106/L, Platelet: 204269±70202 106 /L, CRP: 8 (0.4–197) mg/L, Ferritin: 282 (28–826) ng/mL.

The vaccination rate with at least one dose of vaccine was 85.3% (122/143 patients), and the frequency of SARS-CoV-2 infection was 58.7% (84/143 patients). The SARS-CoV-2 infection mortality rate was 28.6% (24/84 patients). Of the 24 patients dying from SARS-CoV-2 infection, 16 died before vaccination, and only one of the other 8 patients had received all three doses of vaccine on time. The other 7 patients did not have their vaccine boosters done on time and delayed it. 2 doses of vaccine were administered to 3 of these 7 patients and only a single dose to 4.

98 of 143 patients agreed to receive the 3rd dose of vaccine and 8 also the 4th dose of vaccine until the end of the study. 52 of the 98 patients receiving the 3rd dose of vaccine (BNT162b2 vaccine or CoronaVac), allowed venous blood sampling. When the patients whose antibody titer was studied after the third dose of vaccine (n=52) were divided into two groups according to the last vaccine type, it was observed that the 3rd vaccine was BioNTechh in 16 patients (7 patients: first two vaccines Sinovac, last vaccine BioNTechh; 2 patients: first vaccine Sinovac, last 2 vaccines BioNTechh; 7 patients: three vaccines BioNTechh) and Sinovac in 36 patients.

The SARS-CoV-2 IgG antibody titers studied after the 3rd dose vaccination were seropositive in 51 (98.1%) of 52 patients and seronegative in only 1 (1.9%). Considering all 52 patients receiving 3 doses of vaccine, the median antibody level was 397.3 (min-max) (4.5-40000) pre-3rd vaccination, while 1325.3 (min-max) (10.5-40000) post-3rd vaccination. The increase in antibody titer measured pre-and-post-3rd dose was statistically significant ($P<0.001$). Considering the change in antibody titers before and after the 3rd vaccine dose, the median antibody titer in patients receiving the last vaccine dose as Sinovac was 168.2 (min-max) (4.5-40000) pre-vaccine and 851.7 (min-max) (55.2-40.000) post-vaccine

(P<0.01) (Table 1). The median antibody titer in patients receiving the last vaccine dose as BioNTechh was 2738.6 (min-max) (9.4-37723.4) pre-vaccine and 37575.8 (min-max) (10.5-40000) post-vaccine (P=0.002) (Table 1). Besides, there was no difference between the two groups in terms of SARS-CoV-2 infection frequency (P>0.05). In addition, when compared in terms of antibody titers after the 3rd vaccine dose, the difference between the two groups was statistically significant (P<0.001).

Regardless of the last dose vaccine type, when the effects of gender and age on the antibody titer after the 3rd dose vaccination were examined, no significant difference was found between the groups.

The frequency of both SARS-CoV-2 infection (Table 2) and SARS-CoV-2 infection-related mortality rates was significantly lower in vaccinated patients than in unvaccinated patients (Table 3) and this difference between the groups was statistically significant in all booster vaccine doses (Table 2 and Table 3). In addition, as the number of booster vaccine doses increased, the frequency of SARS-CoV-2 infection did not change while the mortality rates of SARS-CoV-2 infection decreased linearly (Table 3).

When those vaccinated with BNT162b2 alone, CoronaVac/Sinovac alone, and CoronaVac/Sinovac + BNT162b2 in combination with at least 2 doses were compared in terms of frequency of SARS-CoV-2 infection and SARS-CoV-2 infection-related mortality rates, no statistically significant difference was found between the groups (P>0.05) (Table 4).

**Table 1.** Comparison of the two groups in terms of median SARS-CoV-2 IgG antibody titers analyzed after the 3rd vaccine dose

| | BNT162b2(Pfizer/BioNTech) (n:16) (min-max) | CoronaVac/Sinovac (n:36) (min-max) | Sig. |
|---|---|---|---|
| Pre-vaccine SARS-CoV-2 IgG Antibody titers (AU/mL) | 2738.6 (9.4-37723) | 168.2 (4.5-40000) | P<0.001 |
| Post-vaccine SARS-CoV-2 IgG Antibody titreş (AU/mL) | 37575.8 (10.5–40000) | 851.7 (55.2–40000) | P<0.001 |
| Sig. | P=0.002 | P< 0.01 | |

**Table 2.** The relationship between vaccination and SARS-CoV-2 infection frequency

| Vaccination frequency | SARS-CoV-2 infection frequency | | Sig. |
|---|---|---|---|
| | Vaccinated (n, %) | Unvaccinated (n, %) | |
| At least 1 dose | 65 / 122 (53.3%) | 19 / 21 (90.5%) | 0.001 |
| At least 2 dose | 61 / 115 (53%) | 19 / 21 (90,5%) | 0.001 |
| At least 3 dose | 52 / 98 (53.1%) | 19 / 21 (90.5%) | 0.002 |

**Table 3.** The relationship between the vaccination frequency and the mortality related-SARS-CoV-2 infection

| Vaccination frequency | The SARS-CoV-2 infection-related mortality rate | | Sig. |
|---|---|---|---|
| | Vaccinated (n, %) | Unvaccinated (n, %) | |
| At least 1 dose | 8 / 122 (6.6%) | 16 / 21 (76.2%) | <0.001 |
| At least 2 dose | 4 / 115 (3.5%) | 16 / 21 (76.2%) | <0.001 |
| At least 3 dose | 1 / 98 (1.02%) | 16 / 21 (76.2%) | <0.001 |

**Table 4.** The relationship between SARS-CoV-2 infection frequency and related mortality rate in patients who received at least two doses of the vaccine

| | BNT162b2(Pfizer/BioNTech) (n : 26) (%) | CoronaVac/Sinovac (n : 62) (%) | Combined (n:27) (%) | Sig. |
|---|---|---|---|---|
| SARS-CoV-2 infection frequency | 11 (42.3%) | 36 (58.1%) | 14 (51.9%) | 0.397 |
| SARS-CoV-2 infection-related mortality rate | 1 (3.8%) | 3 (4.8%) | 0 (0%) | 0.515 |

## 4. Discussion

In our study, anti-SARS-CoV-2 IgG SP antibody titers after the second dose of the COVID-19 vaccine regimen in hemodialysis patients were higher in those with BNT162b2 (Pfizer/BioNTech) vaccine than those with CoronaVac/Sinovac vaccine. Vaccination against SARS-CoV-2 infection with any of the BNT162b2 (Pfizer/BioNTech) or CoronaVac/Sinovac vaccines reduced the frequency of SARS-CoV-2 infection and mortality rate in hemodialysis patients. The reduction of SARS-CoV-2 infection in patients receiving at least two doses of the vaccine was independent of the vaccine type.

In a study conducted in a healthy population, Keskin et al. investigated the SARS-CoV2-specific antibody response one month after the 3rd vaccination (Keskin et al., 2022).

They found the median SARS-CoV-2 IgG SP titer to be significantly higher in post-BNT162b2 Pfizer/BioNTechh vaccine as 31277.9 AU/ml (min-max) (5999 AU/ml, 102290 AU/ml) than in post-CoronaVac/Sinovac vaccine as 215.8 AU/ml (min-max) (242 AU/ml, 2900.9AU/ml). Again, in a recent study conducted in a healthy population by Yavuz et al., the SARS-CoV-2 IgG SP titer was detected higher in people receiving BNT162b2 Pfizer/BioNTechh vaccine as a booster dose than in those receiving CoronaVac/Sinovac vaccine (Yavuz et al., 2022). In our study, similar to the healthy population, the SARS-CoV-2 IgG SP titer was higher in people receiving BNT162b2 Pfizer/BioNTechh vaccine as a booster dose than in those receiving CoronaVac/Sinovac vaccine, but as expected, the SARS-CoV-2 IgG SP titer was lower than the healthy population. Abbott Laboratories kits were used in our study and the two studies mentioned above. However, we would like to mention that we did not continue with serial dilutions to measure titers above 40000 AU/ml in our study.

Among hemodialysis patients, the third dose of mRNA SARS-CoV-2 vaccine is associated with a high seroconversion, and the BNT162b2/Pfizer studies have shown that a third dose was administered shortly after the second dose is associated with increased seropositivity (Ducloux et al., 2021; Longlune et al., 2021; Dekervel et al., 2021; Bensouna et al., 2022). However, although the immunity formed in HD patients decreases over, the persistence of the seropositive response after the third dose is still obscured (Hsu et al., 2022). Perhaps, as recommended for seronegative kidney transplant recipients, a fourth additional dose of vaccine will be recommended for seronegative HD patients in the future (Caillard et al., 2022).

In-hospital case-fatality rates reported in previous general population SARS-CoV-2 infection studies were 10.2%, 15.6%, and 20.3%, respectively (Goyal et al., 2020; Myers et al., 2020; Rosenberg et al., 2020). In our study, the SARS-CoV2 infection related-mortality rate was 28.6%, indicating that the SARS-CoV2 infection related-mortality rate in hemodialysis patients was higher than that of the general population. It is well known that the primary mode of transmission of SARS-CoV-2 infection is person-to-person contact (Lai et al., 2020). Despite the mask-distance-hygiene defense methods against SARS-CoV-2 infection, hemodialysis patients are at higher risk of infection due to their multiple comorbidities, frequent invasive procedures, and crowded dialysis environments. Therefore, the primary way to disease prevention is to increase the vaccination rate in addition to social isolation and protection from droplets (Yen et al., 2021). In our study, both the SARS-CoV-2 infection frequency and SARS-CoV-2 infection-related mortality rates were significantly lower in vaccinated patients than in unvaccinated ones. Besides, as the number of vaccine boosters increased, the frequency of SARS-CoV-2 infection remained unchanged while the related mortality rates decreased linearly.

Seroimmunity against SARS-CoV-2 is known to reduce both new-onset infections and person-to-person transmission, as well as hospitalizations (Earle et al., 2021; Harris et al., 2021), and this is crucial for HD patients at high risk. Considering the continued high rates of SARS-CoV-2 infection and rapidly declining immunity after the first vaccine series, in addition to all the precautions available to all HD patients, a booster dose of the SARS-CoV-2 vaccine will provide essential benefits for patients in disease prevention. In our study, since the first case of SARS-CoV-2 infection in Türkiye was detected in March 2020, 16 of 24 patients in our clinic died from SARS-CoV-2 infection before the vaccine accessibility in the last year and a half. Of the other 8 patients who died, three doses of vaccine were administered to 1 person, two doses to 3 persons, and only a single dose to 4 people. Only one of these patients received all three booster doses on time, while the other 7 patients did not. Considering the 52 patients whose SARS-CoV-2 IgG antibody titers were studied after the 3rd dose of vaccine, 98.1% of the patients were seropositive and the number of patients who died after the 3rd dose of vaccine was only one. This situation reveals once again how crucial for HD patients to be vaccinated.

In a previous study, there was a significant inverse correlation between advanced age and SARS-CoV-2 IgG Antibody titers (Grupper et al., 2021; Speer et al., 2021), and two seronegative patients were male in the same study. In our study, regardless of the vaccine type administered, no correlation was found between SARS-CoV-2 IgG antibody titers and age, and this may be due to the low number of cases.

In our study, there was no correlation between SARS-CoV-2 IgG antibody titers and gender, but the gender of a seronegative patient was also male, similar to the previous study (Grupper et al., 2021). In addition, this seronegative male patient was also negative for Hepatitis-B antibody. HD patients with end-stage renal disease tend to have a low immune response to infection or vaccination, as demonstrated by the hepatitis B virus vaccine (Asan et al., 2017). Therefore, higher vaccine dosage or repetitive vaccine program changes are often needed in these patients (Asan et al., 2017).

The most important limitation of our study is the lack of healthy control group and small sample size. The number of our patients was not at the desired level, since all 143 hemodialysis patients did not receive a third dose of vaccine and some of the patients who had three doses of vaccine did not give their consent to participate in this prospective study. However, it is important to demonstrate that repeated doses of vaccine cause better response in hemodialysis patients.

## 5. Conclusion

In conclusion, additional doses of SARS-CoV-2 vaccines elicited a high seropositive response in patients receiving maintenance dialysis. Those who received the last (3rd)

dose of vaccine with BNT162b2 had higher antibody levels than those with CoronaVac/Sinovac. In addition, regardless of the vaccine type, being vaccinated with any of them decreased the incidence of SARS-CoV-2 infection and the related mortality rate. We believe that the administration of additional vaccine doses in hemodialysis patients plays an important role in increasing and maintaining protection against SARS-CoV-2 infection.

**List of abbreviations**

BNT162b2: Pfizer-BioNTechh vaccine
CoronaVac: Sinovac Life Sciences vaccine
COVID-19: New coronavirus disease 2019
HD: Hemodialysis
Ig G: Immunoglobulin G
mRNA: messenger ribonucleic acid
SARS-CoV-2: Acute respiratory syndrome coronavirus 2

**Author Contributions**

The percentage of the author(s) contributions is present below. All authors reviewed and approved final version of the manuscript.

| | D.Y. | D.S.K.Ö. | E.B. | M.B. | M.D.D. |
|---|---|---|---|---|---|
| C | 30 | 20 | 30 | 30 | 20 |
| D | 100 | | | | |
| S | 100 | | | | |
| DCP | 25 | 25 | 25 | 25 | |
| DAI | 20 | 20 | 20 | 20 | 20 |
| L | 20 | 20 | 20 | 20 | 20 |
| W | 20 | 20 | 20 | 20 | 20 |
| CR | 30 | 30 | 20 | 20 | 30 |
| SR | 10 | 60 | 10 | 10 | 10 |
| PM | 20 | 20 | 20 | 20 | 20 |
| FA | 20 | 20 | 20 | 20 | 20 |

C=Concept, D= design, S= supervision, DCP= data collection and/or processing, DAI= data analysis and/or interpretation, L= literature search, W= writing, CR= critical review, SR= submission and revision, PM= project management, FA= funding acquisition.

**Conflict of Interest**

The author declared that there is no conflict of interest.

**Ethical Approval/Informed Consent**

This study was approved by Health Sciences University Samsun Research and Training Hospital ethics committee (approval date: December 12, 2021, protocol code: GOKA/2021/16/1). All participants signed written informed consent about the study.

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