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Böbrek Transplant Hastalarında COVID-19 Hastalığın Uzun Süreli Takip Sonuçları ve COVID-19 İnaktif Aşısının Etkisi Araştırılması

Investigation of Long-Term Follow-up Results of COVID-19 Disease in Kidney Transplant Patients and the Effect of Inactive COVID-19 Vaccine

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ÖZ

Amaç: COVID-19 tedavisi gören böbrek nakli alıcılarının uzun dönem greft fonksiyonlarını değerlendirmeyi ve hastalığın klinik seyrinde inaktive aşının rolünü araştırmayı amaçladık.

Materyal ve Metot: Mart 2020-Eylül 2021 tarihler arasında COVID-19 pnömonisi geçiren böbrek nakli olmuş hastalar çalışmaya dahil edildi.. Aşı olan hastalarda hastalığın klinik seyri değerlendirildi ve aşı olmayanlar ile karşılaştırıldı. Hastaların hastaneye başvuru anı, hastalığı geçirdikten 6 ay ve 12 ay sonraki laboratuvar bilgileri kaydedildi.

Bulgular: Çalışmaya COVID-19 enfeksiyonu olan hastaların 56'sı (%67,5) erkek olmak üzere toplam 83 hasta katıldı. Aşıdan sonra 20 hastada COVID-19 hastalığı gelişti. Aşı; akut böbrek hasarı (ABH) gelişimini 5,9 kat ve yoğun bakıma yatışı 1,4 kat azaltmıştır ($p<0.05$). İzlemde 10 hasta hastaneye ilk başvuruda öldü ve ilk yıl içinde geç ölüm kaydedilmedi. 5 hastaya greft kaybı nedeniyle diyaliz tedavisi başlandı.

Sonuç: Böbrek nakli hastalarında COVID-19 enfeksiyonu sonrası greft disfonksiyonu gelişebilir. Bununla birlikte, COVID-19 inaktif aşısı; hastaneye yatış, ABHve yoğun bakıma yatış risklerini azaltabilir.

Anahtar Kelimeler: Böbrek nakli, COVID-19, inaktif aşı, kronik böbrek yetmezliği

ABSTRACT

Objective: We aimed to evaluate the long-term graft functions of kidney transplant recepients (KTR) who have been cured of the COVID-19 and to investigate the role of inactivated COVID-19 vaccine in the clinical course of the disease.

Materials and Methods: KTR who had COVID-19 pneumonia between March 2020 and September 2021 were included in the study.. The clinical course of the disease was evaluated in vaccinated patients and compared with those who were not vaccinated. The laboratory information of the patients at the time of admission to the hospital, 6 months and 12 months after the disease was recorded.

Results: Of the 83 patients included, 67.5% were male. COVID-19 disease developed in 20 patients after vaccination. Vaccine; it decreased the development of acute kidney injury (AKI) 5.9 fold and hospitalization in the intensive care unit (ICU) 1.4 times fold ($p<0.05$). In the follow-up, 10 patients died at the first admission to the hospital and no late death was recorded in the first year. Dialysis treatment was started in 5 patients due to graft loss.

Conclusion: In kidney transplant patients, graft dysfunction may develop after COVID-19 infection. However, the inactivated COVID-19 vaccine; it can reduce the risks of hospitalization, AKI, and ICU admission.

Keywords: Chronic kidney failure, COVID-19, inactivated vaccine, kidney transplant

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INTRODUCTION

Since the first case was reported in December 2019, a new type of Coronavirus has caused a major pandemic all over the world, causing severe acute respiratory syndrome with a high risk of death.[1] Disease-related mortality was higher in advanced age and male gender, and higher mortality rates were also reported in the presence of comorbid diseases such as cardiovascular diseases, diabetes, chronic kidney disease, chronic lung diseases, and hypertension.[2] Mortality rates due to COVID-19 pneumonia in patients with kidney transplantation are also much higher than in the normal population.[3] The main treatment of renal transplant patients with COVID-19 disease is recommended as discontinuation or dose reduction of immunosuppressive drugs together with oxygen support therapy. Among the immunosuppressants, primarily discontinuation of antimetabolites, dose reduction/stopping of calcineurin inhibitors, and increasing maintenance steroid doses or switching to dexamethasone, if necessary.[4–6] Depending on these treatment protocols, many complications such as acute rejection, de novo DSA occurrence, and graft loss may occur in the short and long term. In this case, a decrease in graft and patient survival rates may occur.

In COVID-19 disease, the most effective approach to prevent the disease and overcome the disease is vaccination. Current guidelines so far recommend vaccination of transplant candidates and recipients.[7] It is known that hospitalization and death rates of vaccinated renal transplant patients are significantly lower than non-vaccinated patients. In addition, patients who use immunosuppressive drugs due to renal transplantation (RTX) may improve with milder disease attacks, and treatment changes such as interrupting immunosuppressive doses for a shorter time or reducing the dose may reduce the risk of possible long-term complications.

The aim of this study is to evaluate the late effects of treatment protocols applied for COVID-19 infection in kidney transplant patients on graft function, and also to investigate the possible benefits of inactivated vaccine in kidney transplant patients vaccinated with COVID-19 vaccine.

MATERIALS AND METHODS

Ethics Committee Approval: In the study, it was approved by the Non-İnterventional Ethics Committee in Medical Faculty, Sakarya University (Date: 01/10/2021, decision no: 426). The study was conducted in accordance with international declaration, guideline, etc.

A total of 83 kidney transplant patients who had COVID-19 pneumonia between March 2020 and September 2021 were included in the study retrospectively. Demographic characteristics of the patients such as age, gender, body mass index (BMI), primary disease, and blood groups were recorded. Information about COVID-19 disease treatment protocols was obtained from patient files. Patients were aged >18 years, had positive nasopharyngeal swabs of real-time reverse transcriptase-polymerase chain reaction (RT-PCR) test and, whose files were accessed were included in the study. Patients were aged <18 years and whose RT-PCR was negative were excluded. Complications such as acute graft dysfunction, biopsy-proven acute rejection, mechanical ventilator requirement, re-hospitalization, and death were investigated. After excluding patients who died and patients who returned to dialysis, the laboratory information of the other patients at the time of admission to the hospital, 6 months and 12 months after the disease was recorded and compared.

Information on vaccination, outpatient follow-up, hospitalization, admission to the intensive care unit, supportive treatments used, and changes in immunosuppressive protocols of patients diagnosed with COVID-19 were recorded. According to the severity of the disease, antimetabolites were discontinued/dose reduced, CNI dose reduced/ interrupted, and maintenance steroid dose increased or switched to dexamethasone. Intravenous immunoglobulin (IVIG) and convalescent plasma therapy were administered to some patients who were resistant to treatment.

With the launch of the COVID-19 vaccine, our kidney transplant patients started to be vaccinated as of March 1, 2021. The data of the patients who had the infection without the COVID-19 vaccine and the patients who had the COVID-19 disease after being vaccinated were compared.

Statistical Analysis: Statistical analyses were performed using SPSS version 21 software. The suitability of the variables to normal distribution was examined using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov). Categorical variables were expressed as the number of cases (percentage in brackets). Non-parametrics variables were expressed as median (1st

-3rd encounters). Feridman test was used for more than two dependent nonparametric continuous numerical variables and Cohran's Q test was used for more than two dependent categorical variables. Odd's was checked for risk analysis in binary categoricals. The level of significance was defined as $p<0.05$.

RESULTS

56 (67.5%) of the 83 kidney transplant patients with COVID-19 infection were male and the median age was 49 years. The mean body mass index (BMI) of the patients was 26 (23-29) kg/m^2. Hypertension (43.4%) and diabetes mellitus (27.7%) were the most common accompanying systemic diseases. The median follow-up period of the patients was 9.1 (5.9 -12.3) months. In terms of symptoms, cough, shortness of breath, myalgia, and fever were observed in approximately >60% of the patients. Among the patients, COVID-19 disease was

Table 1. Demographic characteristics, treatment protocols, and complications of kidney transplant patients who develop COVID-19 disease.

Characteristics	Value
Sex (Male/Female) n (%)	56/27 (67.5/32.5)
	Median (1st-3rd.)
Age (years),	49 (38-58)
Body Mass Index, kg/m^2	26 (23-29)
Follow-up time, months	9.1 (5.9-12.3)
Dialysis duration before transplantation, months	36 (12-76)
	n (%)
Transplant Type	
Living	69 (83,1)
Deceased	14 (16.9)
Primary Disease	
Diabetes Mellitus	23 (27.7)
Hypertension	36 (43.4)
Chronic Glomerulonephritis	6 (7.2)
Nefrolithiasis	4 (4.8)
Polychystic kidney Disease	1 (1.2)
Others	13 (15.7)
Symptoms	
Fever	49 (59)
Cough	60 (72.3)
Shortness of breath	51 (61.4)
Myalgia	50 (60.2)
Anosmia	7 (8.4)
Nausea-vomiting	20 (24.1)
Blood groups	
A	41 (49.4)
B	15 (18.1)
AB	4 (4.8)
O	23 (27.7)
Vaccination status before contracting COVID-19 disease	20 (24.1)
İmmunosupresion changing	
İncreasing steroid doses	80 (96.4)
Decreasing/withdrawal CNI dose	17 (20.5)
Withdrawal MMF	76 (91.6)
Decreasing of m-TORi dose	1 (1.2)
Supportive Treatment	
Favipiravir	77 (92.8)
Dexamethasone	45 (54.2)
Convalescent plasma	25 (30.1)
IVIG	21 (25.3)
Complications	
Recuirement to the intensive care unit	15 (18.1)
Rehospitalization	8 (9.6)
Acute kidney injury	27 (32.5)
Return to hemodialysis	5 (6)
Biopsy proven acute rejection	7 (8.4)
Recruitment to the non-invasive mechanical ventilation	21 (25.3)
Recuirement to the mechanical ventilation	10 (12)

detected most frequently in patients with A RH(+) blood group. In most of the cases, steroid dose was increased and mycophenolate mofetil (MMF) treatment was discontinued (Table 1).

With respect to supportive care, most of the cases were received favipiravir antiviral therapy, and more than half of them were witched to dexamethasone therapy. In terms of disease-related complications, 32.5% of patients developed acute kidney injury (AKI), 25.3% needed the non-invasive mechanical ventilator, 18.1% needed the intensive care unit, 12% needed the mechanical ventilator and 8.4% developed acute rejection (Table 1).

Table 2. Laboratory outcomes at baseline, sixth and twelfth months of kidney transplant patients who developed COVID-19 disease.

Characteristic	Basal	6'th months	12'th months	p
	Median (1st-3rd)	Median (1st-3rd)	Median (1st-3rd)	
WBC (μ/L)	5.6 (4.1-7.8)	7.6 (6.3-8.9)	7.5 (6.3-8.9)	<0.001*
Hemoglobin (g/l)	12.8(10.8-13.8)	13 (11.3-14.1)	12.9 (11.5-14.3)	0.511*
Lymphocyte (10^3/ul)	1.2 (0.7-1.7)	2.3 (1.7-2.6)	2.1 (1.8-2.6)	<0.001*
Neutrophil (10^3/ul)	3.9 (2.8-5.3)	4.6 (3.5-5.4)	4.4 (3.6-5.2)	0.029*
Lymphocyte neutrophil ratio	0.3 (0.2-0.5)	0.5 (0.3-0.7)	0.5 (0.4-0.6)	<0.001*
Platelet (10^3/ul)	180 (143-249)	224 (176-287)	241 (198-295)	<0.001*
Ferritine (ml/ng)	204 (92-706)	55 (20-165)	58 (23-157)	<0.001*
Glucose (mg/dl)	113 (94-128)	97 (90-112)	96 (91-106)	<0.001*
Serum creatinine (mg/dl)	1.2 (1-1.7)	1.2 (1-1.8)	1.2 (1-1.8)	0.220*
Uric acid (mg/dl)	6.2 (5-7.5)	6.4 (4.8-7.4)	6 (5-7.3)	0.878*
Albumin (g/dl)	34 (31-39)	42 (39-44)	41 (40-44)	<0.001*
LDH (U/L)	247 (200-342)	203 (198-251)	200 (182-210)	<0.001*
CRP (mg/L)	29 (15-59)	3.6 (3.3-5.9)	3.3 (3-6)	<0.001*
Mycroskopic hematuria (n %)	13 (%22)	9 (%14)	8 (%13)	0.368**
Protein to creatinine ratio	417 (221-858)	219 (123-527)	210 (111-445)	<0.001*

*: Cohran's Q test, **: Feridman test CRP: C-reactive protein; WBC: White blood cell; LDH: Lactate Dehydrogenase. p <0.05.

In terms of biochemical parameters, statistically, significant improvements were recorded in the patients' hematological, organ function tests, and coagulation tests at the sixth and twelfth months compared to the basal values (p<0.05) (Table 2). While the median protein/creatinine ratio in basal spot urine was 417 (221-858) g/g, and decreased significantly at the 6th and 12th months, respectively; 219 (123-527) and 210 (111-445) g/g (p<0.001)(Table 2).

During the follow-up, 10 (12%) patients died in the first hospitalization, while no late death was recorded in the first year. The median time to antimetabolite re-initiation of the patients was 2 (1-5 weeks) weeks. Biopsy-proven acute cellular rejection attacks were detected in 7 (8.4%) patients and were detected within the first 4 months after discharge from the hospital. Acute antibody-mediated rejection was not detected in any patient (Table 3).

Table 3. Comparison of patients with and without COVID-19 inactivated vaccine in terms of possible complications.

	Vaccinated Group N=20 (%)	Non-vaccinated Group N=63 (%)	p
Rehospitalization (n)	0 (0)	8 (12.7)	0.189
AKI (n)	2 (10)	25 (39.7)	**0.014**
Mechanical ventilator (n)	0 (0)	10 (15.9)	0.108
Non-invasive mechanical ventilator (n)	1 (5)	20 (31.7)	**0.018**
Acute rejection (n)	2 (10)	5 (7.9)	0.673
Hemodialysis requirement (n)	0 (0)	5 (7.9)	0.330
ICU (n)	0 (0)	15 (23.8)	**0.017**
Sepsis (n)	0 (0)	12 (19)	0.061
Mortality (n)	0 (0)	10 (15.9)	0.108
MMF restart (n) (≤2 week)	18 (90)	24 (47.1)	**0.001**

Chi-squared test; ICU: Intensive care unit; AKI: Acute kidney injury.

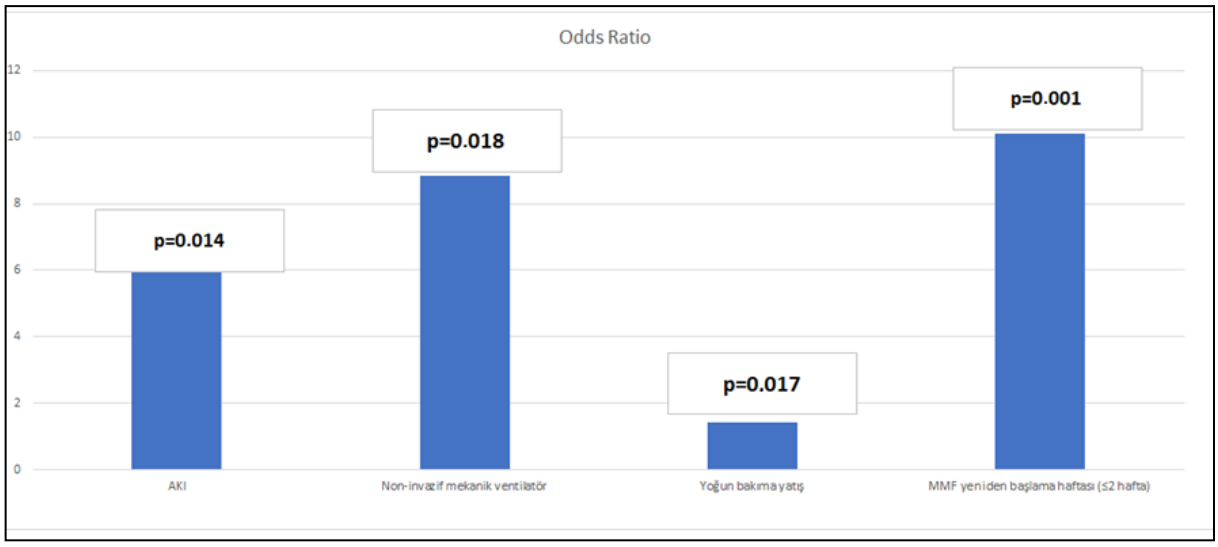

Figure 1: Odds ratios with respect to the probability of protecting the COVID-19 vaccine from possible complications of the disease.

The number of patients with a history of inactivated Sinovac vaccine was 20 (24.1%), and these patients were diagnosed with COVID-19 after vaccination. Compared with unvaccinated patients, getting vaccinated was found to be more protective with respect to; AKI development as 5.9 times (1.3-27.8) (p=0.014), need for a non-invasive mechanical ventilator as 8.8 (1.1-71.4) (p =0.018) times, need for intensive care admission as 1.4 times (1.2-1.7) (p=0.017) and resumption of antimetabolite therapy in a shorter time (<2 weeks) as 10.1 times (2.1-47.6) (p=0.001) (Table 3) (Figure 1).

DISCUSSION AND CONCLUSION

In this study, we investigated the post-COVID long-term results of kidney transplant patients with a definitive diagnosis of COVID-19 disease and investigated the characteristics of patients who contracted COVID-19 disease after receiving the inactive COVID-19 vaccine. In the early post-COVID-19 period of patients, in terms of disease-related complications, 32.5% of patients developed AKI, 25.3% needed the non-invasive mechanical ventilator, 18.1% needed the intensive care unit, 12% needed the mechanical ventilator and 8.4% developed acute rejection. In the literature data, the incidence of AKI has been shown to be 30-83%.[4,8–10] COVID-19 infection causes AKI and is an independent risk factor for mortality. In a study evaluating the extrapulmonary symptoms and sequelae of COVID-19, it was stated that 13% of patients who did not develop acute kidney injury during their hospital stay and had normal kidney function had a decrease in kidney function during their follow-up.[11] In long-term follow-up, no decrease in kidney function was observed in our patients. We comment that the reason for this is that we excluded patients who died and patients who returned to dialysis due to graft loss and that transplant patients should pay more attention to their current health status. In our study population, complete recovery in AKI was noted in all patients who survived during the follow-up period.

Although COVID-19 infection primarily affects the lungs, it can affect other organs, including the kidney.[12] Kidney damage may occur due to dehydration secondary to fever and diarrhea caused by infection, cytokine-mediated inflammatory damage, nephrotoxic effects of the drugs used, and hemodynamic disorders in severe cases, and this damage is seen at a higher rate in kidney transplant patients compared to the normal population.[13,14] Acute rejection may develop due to the reduction of immunosuppressive therapy doses. Acute rejection with COVID-19 disease was seen in 20% of patients.[15] Discontinuation of immunosuppressant drugs such as calcineurin inhibitors and antimetabolite drugs used in transplant patients may cause rejection and thus graft loss may occur. Graft loss occurred in 5 of our patients. There are insufficient data on possible long-term complications due to discontinuation/dose reduction of immunosuppressives in kidney transplant patients with COVID-19. In our study, biopsy-proven acute

cellular rejection was detected in 8.4% of the patients and developed within the first 4 months of post-COVID-19. All patients who developed acute rejection responded to anti-rejection therapy. We showed that the patients did not develop any permanent hematologic or organ dysfunction during the follow-up period.

Depending on the severity of the disease, lymphopenia, thrombocytopenia, and leukocytosis are observed as hematological biomarkers.[16] In our patients, leukocyte, lymphocyte, and thrombocyte levels at the time of covid-19 infection were significantly lower than at the 6-month follow-up. We attributed the inconsistency of leukocyte values with the literature data to the immunosuppressant drugs used, and not all of our patients had a severe covid-19 infection.

Low albumin levels and high C-reactive protein and LDH levels are expected in COVID-19 patients.[17] As expected, high CRP and LDH levels and low albumin levels were detected in the 6-month follow-up of our patients.

With the production of the vaccine against COVID-19 infection, our patients began to be vaccinated. The first vaccines administered to our patients were the state-sponsored Sinovac vaccine. 20 of our vaccinated patients were infected with the coronavirus. Literature data mostly gives information on mRNA vaccines. In a study examining the humoral response to mRNA vaccine administered in 2 consecutive doses in transplant patients, it was reported that the antibody response was low after the first dose and that the antibody response was mostly detectable after the second dose.[18] However, it should be kept in mind that antimetabolites used for immunosuppression may prevent the development of neutralizing antibodies in this patient group. For this reason, considering that the probability of antibody formation after vaccination may be lower than in the normal population, a recommendation has been made to increase the dose of the vaccine in order to create an adequate humoral response.[19] In addition, COVID-19 infection was reported in transplant recipients who received two doses of vaccine in studies, and the third dose was recommended in this immunocompromised patient group.[20,21]

When COVID-19 infected patients were compared with those who were not vaccinated, there was no hospitalization in the intensive care unit and no death in these patients. In addition, it was observed that the discontinued antimetabolite treatment was started earlier and the disease was milder. As a result, although the vaccine does not fully protect against infection, it is thought that the patient recovers from the infection more easily. However, a large proportion of patients still remain at risk for COVID-19 infection. Therefore, patients should take the necessary personal protective measures to avoid infection and encourage their relatives to be vaccinated.

Limiting aspects of our study; the fact that it is retrospective and, the number of patients with inactivated COVID-19 vaccine is low.

In conclusion, post-COVID-19 short-term morbidity -mortality rates are high in renal transplant patients. However, no permanent damage or organ dysfunction developed in the medium-long term. We can say that inactivated COVID-19 vaccine can provide positive advantages in terms of decreasing the requirement of intensive care units, decreasing of development of AKI, and resumption of early antimetabolites in patients with a history of COVID-19 disease.

Ethics Committee Approval: In study, it was approved by the Non-İnterventional Ethics Committee in Medical Faculty, Sakarya University (Date: 01/10/2021, decision no: 426). The study was conducted in accordance with international declaration, guideline, etc.

Conflict of Interest: No conflict of interest was declared by the authors.

Author Contributions: Concept – NF, HD; Supervision – HD, OK, SS; Materials - EA, AT, SY; Data Collection and/or Processing - ACG, MP, ABG; Analysis and/or Interpretation – HD, NF; Writing – NF,HD.

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