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# Retrospective Evaluation of COVID-19 Infection and COVID-19 Vaccines in Heart Transplant Patients

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## **ABSTRACT**

Background. Patients who have performed solid organ transplantation in terms of COVID-19 infection are included in the high-risk group. In this study, it was aimed to evaluate the relationship between vaccination and retrospective evaluation of 32 patients who underwent a heart transplant in the clinic and tested positive for SARS-CoV-2 polymerase chain reaction.

Methods. In this study, demographic characteristics of the cases, comorbidities, timing of heart transplantation, immunosuppressive treatments, symptoms of COVID-19 infection, lung imaging findings, follow-up (outpatient/inpatient), treatments, 1-month mortality, and vaccination histories against COVID-19 infection were evaluated. The data obtained from the study were analyzed with SPSS version 25.0.

Results. The 3 most common symptoms are cough (37.5%), myalgia (28.1%), and fever (21.8%). COVID-19 infection was severe in 6.2% of the patients, moderate in 37.5%, and mild in 56.2%. Hospitalization was required in 5 patients (15.6%, 1 in the intensive care unit), and the other patients were followed up as an outpatient. Severe COVID-19 infection was seen more in 33% of unvaccinated patients; 93.5% were vaccinated. Nineteen patients (68%) were vaccinated before COVID-19 infection. Our patients received the CoronoVac (Sinovac, China) vaccine.

Conclusion. COVID-19 infection is more likely to be severe and mortal in patients with heart transplant recipients. It is also crucial to comply with preventive measures other than immunization in this group of patients. This study is the largest series investigating COVID-19 infection in heart transplant recipient patients in our country.

OVID-19, which was declared an epidemic on January 30, 2020, and a pandemic on March 11, 2020 by the World Health Organization, has affected the whole world.

The first case in our country was detected on March 11, 2020. As of May 7, 2022, 14,775,634 people were diagnosed with COVID-19 infection, and 97,666 people died in our country [1]. Incubation time and clinical features may change in variants that develop because of virus mutation. The most common findings are fever, weakness, myalgia, sore throat, eating disorder, nausea/vomiting, anosmia and dysgeusia, cough, and dyspnea. Complications such as pneumonia, respiratory failure, kidney failure, and heart damage may develop in more critical cases. It is known that it can progress to acute respiratory distress

syndrome and multiorgan failure, especially in people with increased age and underlying risk factors [2]. In a meta-analysis evaluating the groups with the highest risk of mortality, acute renal failure, chronic obstructive pulmonary disease, diabetes mellitus, hypertension, cardiovascular disease, cancer, increased D-dimer, male sex, increased age, active smoker, and obesity were found to be associated with increased mortality [3]. Organ transplant recipient patients are also among the high-

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risk groups for COVID-19 infection [4,5]. Studies in our country on the risk of COVID-19 infection caused by prolonged immunosuppression and comorbidity in heart transplant recipient are few in number and in the form of case reports [6,7]. The clinical manifestations of COVID-19 in heart transplant recipient patients are similar to those in immunocompromised patients but may be variable. Although the diagnosis and treatment are the same as in the general population, care should be taken, especially regarding treatment management and drug interactions [8].

Vaccination is the most effective method to protect against COVID-19 infection. In a very short time after the pandemic started, COVID-19 vaccines were developed and started to be used all over the world [4]. In our country, vaccination for increased age and high-risk groups started in January 2021. Organ transplant recipient patients were also included in the priority vaccination group [1].

In this study, we aimed to evaluate the clinical features and COVID-19 vaccination status of patients who underwent heart transplantation at Ege University Hospital and whose SARS-CoV-2 polymerase chain reaction test was positive retrospectively.

#### MATERIALS AND METHODS

The records of cases with COVID-19 infection who underwent heart transplantation between 2005 and January 2022 in the Cardiovascular Surgery clinic of our hospital and who were found to have positive SARS-CoV-2 polymerase chain reaction since March 2020 were retrospectively examined from the hospital data processing system and patient files. Demographic characteristics of the cases, comorbidities, timing of heart transplantation, immunosuppressive treatments, symptoms of COVID-19 infection, lung imaging findings, follow-up method (outpatient/inpatient), treatments, 1-month mortality, and vaccination histories for COVID-19 infection were recorded. The severity of COVID-19 infection was evaluated according to the World Health Organization criteria [9]. The data obtained from the study were first entered into Excel (Microsoft, Corp, Redmond, Wash, United States) and then transferred to the SPSS version 25.0 program (IBM SPSS, Inc, Armonk, NY, United States) and analyzed with this program. Mean, SD, median, minimum, and maximum values for quantitative variables were presented. The conformity of continuous variables to normal distribution was investigated, and it was decided that not all variables fit the normal distribution. Nonparametric methods were used to compare these variables. Independent groups were compared with the Mann-Whitney U test. Qualitative variables were presented in crosstabs as

frequencies and percentages. Ege University Faculty of Medicine Clinical Research Ethics Committee approved this study on April 22, 2022, with protocol no. E-99166796-050.06.04-668751361.

#### **RESULTS**

Our hospital had 245 heart transplant recipient patients between 2005 and January 2022. Among the patients who underwent heart transplantation, 32 patients (13%) were diagnosed with COVID-19 infection between September 2020 and January 2022. Nine (28.1%) of the patients were diagnosed in the second wave of the epidemic in our country, 3 (9.3%) were diagnosed in the third wave, and 20 (62.5%) were diagnosed in the fourth wave. Twenty-two patients (68.7%) were male, and 10 patients (31.2%) were female (mean age, 47 ± 17 years; minimum, 19; maximum, 66). The reasons for transplantation were dilated cardiomyopathy (n = 25; 78%), ischemic cardiomyopathy (n = 4; 12.5%), restrictive cardiomyopathy (n = 2; 6.2%), and arrhythmogenic right ventricular dysplasia (n = 1; 3.1%). There is a minimum of 1 month to a maximum of 17 years between COVID-19 disease and the time of transplantation.

Although 26 of the patients (81.2%) did not have any other accompanying disease, 2 patients (6.2%) had type 2 diabetes mellitus, and 1 patient (3.1%) had acute kidney failure, chronic kidney failure, HIV infection, and coronary artery disease.

The most common clinical complaints in patients were cough (n = 12; 37.5%), myalgia (n = 9; 28.1%), fever (n = 7; 21.8%), dysgeusia (n = 5; 15.6%), anosmia (n = 5; 15.6%), sore throat (n = 3; 9.3%), and dyspnea (n = 1; 3.1%). COVID-19 infection was severe in 2 patients (6.2%), moderate in 12 patients (37.5%), and mild in 18 patients (56.2%). The clinical features of the patients before and after vaccination are presented in Table 1.

Although 5 patients (15.6%; 1 patient in the intensive care unit) were followed up with hospitalization, the other patients were followed up as an outpatient. Severe COVID-19 infection was seen more in 33% of unvaccinated patients. The probability of severe COVID-19 infection was found to be 3.1% in those vaccinated.

Favipiravir was given to 13 patients (40.6%). Chest X-rays were taken in 10 patients (involvement in 3 patients), and computed tomography scans in 6 patients (involvement in 4 patients) of 11 patients (34.3%) who underwent lung imaging.

Table 1. Clinical Features of the Cases Before and After COVID-19 Vaccination

	Prevaccination Diagnosis(N = 9)	Postvaccination Diagnosis(N = 19)
Most common clinical symptom	Cough 4/9 (44.4%)	Cough 7/19 (36.8%)
	• • • •	Myalgia 7/19 (36.8%)
COVID-19 infection severity	Mild 6/9 (66.6%)	Mild 10/19 (52.6%)
·	Moderate 3/9 (33.3%)	Moderate 10/19 (42.1%)
	Severe 0/9 (0%)	Severe 1/19 (5.2%)
Lung involvement	1/4 (25%)	3/7 (42.8%)
Hospitalization	1/9 (11.1%)	3/19 (15.7%)
One-month mortality	0/9 (0%)	0/19 (0%)

One patient died because of COVID-19 infection. The 1-month mortality rate was 3.1%. The 3-month mortality rate in the follow-up was 3.1%. Heart transplant cases infected with COVID-19 are presented in Table 2.

Death case was a 63-year-old male patient who underwent heart transplantation in 2006 because of dilated cardiomyopathy. The patient with concomitant renal failure received basiliximab, mycophenolate mofetil, and corticosteroid treatments as immunosuppressive treatments. He was admitted to the hospital with dyspnea and cough and was followed up with a severe infection.

Because 1 patient was died before COVID-19 vaccination, the COVID-19 vaccination data of 31 patients were obtained. Vaccination was administered in 29 patients (93.5%). Nineteen patients (68%) were vaccinated before COVID-19 infection. After the COVID-19 infection, 9 patients (32%) were vaccinated.

Our patients received the CoronoVac (Sinovac, China) vaccine. Fourteen patients (50%) were vaccinated with the CoronoVac vaccine. The Biontech vaccine was given to 7 (25%) patients.

Twenty-five percent of patients were inoculated with CoronoVac and Biontech vaccines, the first doses of which were Coronovac. Two patients (6.8%) received a single dose, 7 patients (24.1%) received 2 doses, 14 patients (48.2%) received 3 doses, and 6 patients (20.6%) received 4 doses of COVID-19 vaccine. In our patients, COVID-19 infection was seen between September 6, 2020 and February 2, 2022. One of our patients who was not vaccinated was died on December 1, 2020. The patient had the Delta variant of the COVID-19 infection. Nineteen patients (68%) were diagnosed with COVID-19 infection after vaccination. A comparison of heart transplant cases infected with COVID-19 vs uninfected with COVID-19 is presented in Table 3.

## DISCUSSION

Studies are still ongoing to research the increased risks of arteriovenous thrombosis, myocarditis, and myocardial infarction on the cardiovascular system of COVID-19 infection [10]. In patients with preexisting cardiovascular disease, heart transplant recipient patients come to the forefront in relation to chronic immunosuppression and increased morbidity risk. However, because of studies with small sample sizes, the incidence and prognosis of COVID-19 infection in heart transplant recipient patients have not been well characterized. Although there are studies reported as case reports from our country, our study is the largest series evaluating COVID-19 infection in patients who underwent heart transplantation in our country.

In a systematic review and meta-analysis study in which a total of 5588 heart transplant recipient patients, including 10 studies published in 2021, were included to evaluate the risk and prognosis of COVID-19 in heart transplant recipients, the frequency of COVID-19 infection was found to be 2.54%. The probability of COVID-19 infection was found to be significantly higher in heart transplant recipient patients compared with the general population (odds ratio, 5.47; 95% CI, 3.03-9.89; P < .001) [11].

In a study published in 2021, in which 20 heart transplant recipients followed up with the diagnosis of COVID-19

infection in a tertiary hospital in Spain between February 2020 and February 2021 were examined, the prevalence of COVID-19 infection was 5.2% [12].

In our study, the incidence of COVID-19 was found to be 13%. According to the literature, the increased incidence rate was thought to be because our cases were mostly infected in the fourth wave period after June 2020. After June 2020, flexibility has been made in the restrictive preventions applied for COVID-19 infection in our country, resulting in an increase in cases in heart transplant recipient patients and the general population. Experience in managing COVID-19 infection in solid organ transplant recipients in the early stages of the pandemic was quite limited. In addition, the clinical spectrum of COVID-19 in heart transplant recipient patients has not been fully defined because of asymptomatic and subclinical cases. Demographic features, comorbidities, and symptoms were found to be similar to those in the literature in the cases in our study [11].

In studies, the mortality rate of solid organ transplant recipients infected with SARS-CoV-2 was found to be 3% to 50% in different case series [13–16]. A mortality rate of 20% to 30% has been reported in patients who have undergone heart and lung transplantation [17,18]. In our study, 1-month mortality was 3.1%. The reason for the low mortality rate in our study is that we close follow-up of heart transplant recipients.

In various studies, risk factors for mortality from COVID-19 infection and severe infections were found to be increased age, comorbidities, obesity, and dyspnea at admission [19,20]. Our death case had similar features. He was an advanced-age patient with kidney failure admitted to the hospital with dyspnea. Also, in our study, severe COVID-19 infection was seen in 33% of unvaccinated patients. The probability of severe COVID-19 infection was found to be 3.1% in those vaccinated.

The Alpha variant was first seen in the United Kingdom in December 2020. The Beta variant started to appear in South Africa in December 2020. The Gamma variant has been seen in Brazil since December 2020. The Delta variant started appearing in India in May 2021. The Omicron variant started to appear in November 2021 [21]. In our country, the vaccine was started on January 14, 2021. In our patients, COVID-19 infection was seen between September 6, 2020 and February 6, 2022. One of our patients, who was not vaccinated, died on December 1, 2020. The patient had the Delta variant of the COVID-19 virus.

Lymphopenia has also been independently associated with higher mortality [22,23]. In a multicenter retrospective cohort study published in 2020 in China, 191 patients diagnosed with COVID-19 infection without underlying immunosuppressive disease were included in the study [22]. Lymphopenia was detected in 40% of the patients, and it was found to be a statistically significant (P < .0001) variable in the mortality analysis [22]. In our study, because most of the patients had mild infections, laboratory examination was not performed, and those living outside the province could not apply to our hospital during the pandemic, so no evaluation could be made about lymphopenia.

Studies on SARS-CoV-2 vaccines have also shown that vaccines are safe and effective in transplant recipients [24]. In a study of 189 patients published in 2021 on COVID-19

Table 2. Heart Transplant Cases Infected With COVID-19

	Time After			Imaging findings andcomputer		In- or		
Cases	Transplant (d)	Immunosuppressant Treatment	Symptoms	tomography	Treatment	Outpatient	Mortality	Vaccination
1	3679	mycophenolate mofetil + cortisone + mycophenolate mofetil	Anosmia Dysgeusia	None	Favipiravir + paracetamol	Outpatient	None	3 doses Sinovac
2	4360	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	2 doses Biontech
3	5632	Mycophenolate mofetil + cortisone	Fever myalgia	Positive	Favipiravir + paracetamol	Inpatient	None	2 doses Sinovac 1 dose Biontech
4	6172	Basiliximab + mycophenolate mofetil + cortisone	Dyspnea	None	None	Inpatient	Death	None
5	6478	Mycophenolate mofetil + cortisone	Cough	None	Favipiravir + paracetamol	Outpatient	None	2 doses Biontech
6	1643	Mycophenolate mofetil + cortisone	Cough	None	Favipiravir + paracetamol	Outpatient	None	2 doses Biontech
7	3234	Mycophenolate mofetil + cortisone	Cough	None	None	Outpatient	None	2 doses Biontech
8	5633	Mycophenolate mofetil + cortisone	Anosmia Dysgeusia	None	Favipiravir	Outpatient	None	3 doses Biontech
9	4795	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	None
10	5133	Mycophenolate mofetil + cortisone	Fever myalgia	None	Favipiravir	Outpatient	None	2 doses Sinovac 2 doses Biontech
11	4328	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	3 doses Sinovac 1 dose Biontech
12	5536	Daclizumab + cortisone	Myalgia	None	None	Outpatient	None	2 doses Sinovac
13	4745	Mycophenolate mofetil + cortisone	Cough + fever	None	Favipiravir	Outpatient	None	1 dose Sinovac
14	3313	Mycophenolate mofetil + cortisone	Cough + myalgia	None	Favipiravir	In patient	None	2 doses Sinovac 2 doses Biontech
15	2128	Mycophenolate mofetil + cortisone	Anosmia Dysgeusia	None	Favipiravir + enoxaparin sodium	Outpatient	None	2 doses Sinovac
16	1596	Mycophenolate mofetil + cortisone	Anosmia Dysgeusia	Positive	Favipiravir + enoxaparin sodium + acetylsalicylic acid	Inpatient	None	2 doses Sinovac 2 doses Biontech
17	4452	Mycophenolate mofetil + cortisone	Cough	Positive	Favipiravir	Inpatient	None	3 doses Biontech
18	5032	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	1 dose Biontech
19	6284	Mycophenolic acid + cortisone	None	None	None	Outpatient	None	2 doses Sinovac 1 dose Biontech
20	5837	Basiliximab + mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	3 doses Sinovac
21	1971	Mycophenolate mofetil + cortisone	Anosmia Dysgeusia	None	None	Outpatient	None	3 doses Sinovac
22	2116	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	3 doses Sinovac
23	4214	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	3 doses Sinovac
24	3873	Mycophenolate mofetil + cortisone	Cough + myalgia	None	None	Outpatient	None	3 doses Sinovac
25	3110	Mycophenolate mofetil + cortisone	Cough + myalgia	None	None	Outpatient	None	2 doses Sinovac
26	6563	Mycophenolic acid + basiliximab	Fever myalgia	Positive	Favipiravir	Outpatient	None	3 doses Sinovac
27	2957	Mycophenolate mofetil + cortisone	Cough + fever	None	Favipiravir	Outpatient	None	3 doses Sinovac
28	6154	Basiliximab + mycophenolate mofetil + cortisone	Fever myalgia	None	None	Outpatient	None	2 doses Sinovac 1 dose Biontech
29	5362	Mycophenolate mofetil + cortisone	Fever myalgia	None	None	Outpatient	None	3 doses Sinovac
30	459	Mycophenolate mofetil + cortisone	None	None	None	Outpatient	None	3 doses Sinovac
31	3995	Mycophenolate mofetil + cortisone	Cough	None	Dirithromycin	Outpatient	None	None
32	3734	Mycophenolate mofetil + cortisone	Throat sore	None	paracetamol	Outpatient	None	4 doses Sinovac

	Mean Age (y)	Sex	Mean Time After Transplant (y)	Vaccination History (Vaccinated)	Etiology of Heart Disease	Diabetes	Tacrolimus	Mycophenolate mofetil	Cyclosporine	Steroid
Infected COVID-19	47.75	31.2%Female	11.6	93.5%	78% dilated CMP 12.5% ischemic CMP	6.2%	3.1%	93.75%	0	100%
Noninfected COVID-19	45.7	19.2%Female	10.4	70.5%	64% dilated CMP 24.3% ischemic CMP	5.1%	8.9%	91%	1.2%	100%

Table 3. Comparison of Heart Transplant Cases Infected With COVID-19 vs Uninfected With COVID-19

CMP, cardiomyopathy.

vaccination rates at a German transplant center, 133 patients (71%) accepted the vaccination offer and were vaccinated [25]. Vaccination acceptance was 74% in heart transplant recipient patients, 72% in waiting list patients, and 56% in patients with a ventricular assist device [25]. In our study, 93.5% of heart transplant recipient patients for COVID-19 infection were vaccinated.

The limitations of our study are that it was retrospectively planned, mortality risk factors could not be evaluated because of the low number of death cases, laboratory findings were not examined, and antibody levels were not checked after COVID-19 vaccination.

## CONCLUSIONS

COVID-19 infection is more likely to be severe and cause death in heart transplant recipients. Our study is the largest series examining COVID-19 infection in patients who underwent heart transplantation in our country. Mortality rates are the same in the study group and the normal population in our study. However, multivariate large-scale cohort studies are needed for clinical prognostic markers and factors affecting mortality. The probability of severe COVID-19 infection with vaccination in heart transplant patients was found to be significantly lower than in unvaccinated patients. In this group of patients, it is especially important to obey preventive precautions other than immunization and to closely follow up with heart transplant recipient patients.

# DATA AVAILABILITY

Data will be made available on request.

## **DECLARATION OF COMPETING INTEREST**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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