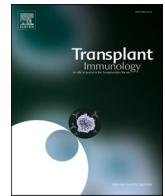




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Brief communication

The effect of COVID 19 vaccination on kidney recipients



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ABSTRACT

Background: Nearly one year from the onset of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, safe and effective vaccines began distribution around the world. This study aimed to assess the rate of COVID-19 disease among vaccinated kidney transplant patients and the types of symptoms found within them. **Design:** This cross-sectional study was performed at the transplant ward and Organ Procurement Unit of Sina Hospital, Tehran, Iran. As a sample size, 159 cadavers' kidney recipients received two doses of the Sinopharm SARS-CoV-2 vaccine. The required data were collected using a checklist via conducting a face-to-face interview. **Results:** The mean age of the vaccinated participants was 49.44 ± 13.87 years old. There were 73 (45.91%) vaccinated cases of SARS-CoV-2 infection during the study period, 18 cases (12.6%) occurred among fully vaccinated individuals, and 53 cases (33.3%) were among individuals who had received only one dose of vaccine.

45% of the fully vaccinated patients (received 2 doses vaccine) contracted SARS-CoV-2 from their families; 35% were infected through participation in social events (35%).

There was a significant difference in disease severity levels between the fully vaccinated group and the one-dose vaccinated ($p < 0.023$). The severe disease occurred in 2 patients after vaccination, who were subsequently admitted to the hospital.

There was a significant difference between the number of kidney transplant days and infection with SARS-CoV-2 before ($P = 0.15$) and after vaccination ($p < 0.015$).

Conclusion: Even after vaccination, kidney recipients are still at the risk of contracting SARS-CoV-2. In addition to these results, the efficacy of vaccination in preventing death caused by SARS-CoV-2 was confirmed.

1. Introduction

According to World Health Organization (WHO), since December 16, 2020, there have been >253 million people infected by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), including >5.1 million deaths. In Iran, from December 2019 to November 2021, over 6.4 million cases of SARS-CoV-2 and over 128,000 deaths were reported [1].

The rates of infection and death associated with this virus require the cross-disciplinary collaboration of transplant surgeons, nephrologists, pulmonologists, anesthesiologists, immunologists, and any other specialists that may be relevant in order to find the best treatment outcomes

for transplant patients [2].

In a recent studies shown that organ transplant recipients who contracted SARS-CoV-2 had a 30% higher risk of death or need for mechanical ventilation compared with normal population [3,4].

Nearly one year from the onset of the SARS-CoV-2 pandemic, the first safe and effective vaccines began distribution around the world with the hope of bringing the SARS-CoV-2 infection pandemic to an end [5]. As the pandemic has continued, further vaccine development has progressed. Based on a report by the WHO, almost 200 vaccine candidates have been evaluated in preclinical animal models and human clinical trials worldwide [6].

Kidney transplant recipients were found to be among the populations

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at a higher risk of SARS-CoV-2 infection [7]. This group is a population with challenging and complex management needs as compared to the general population. Accordingly, due to several risk factors in addition to the immunosuppressant medicines they require, the disease may cause a higher risk of mortality in this group. Although there have been reports of recovery in some cases [2] the mortality rate among kidney transplant recipients varies and management protocol for SARS-CoV-2 post-transplant patients is more complicated than expected [8]. In comparison, the mortality rate for heart transplant recipients is reported to be up to 25% [9]. According to previous studies, kidney transplant recipients are known as a high-risk group for infection with this virus; therefore, effective vaccines are urgently required for these patients [10].

The accessibility and variety of the COVID-19 vaccines have provided an optimistic outlook on the pandemic in organ transplant recipients [11].

In regard to the Centers for Disease Control and Prevention (CDC), vaccination against SARS-COV-2 is a safe way to help prevent the spread of COVID-19 [12].

The United States Food and Drug Administration (FDA) will approve any SARS-COV-2 vaccine that reduces COVID-19 cases by almost 50% compared with a placebo, which is a relatively low efficacy rate for vaccines [13].

Getting a SARS-COV-2 vaccine substantially reduces the rate of infection of COVID-19, decreases the risk of severe symptoms, decreases the risk of transmission to others, and fosters the development of herd immunity [12,14–16]. When vaccines became available, it was hoped that solid-organ transplant recipients would have adequate immune responses to them. This study aimed to assess the rate of SARS-CoV-2 infection in vaccinated transplanted patients and to determine the type of symptoms in these patients in the Sina Organ Procurement Unit, Tehran, Iran.

2. Methods and materials

We performed the current retrospective review on 159 kidney transplant recipients with a median age of 49 (18–83) years old who were vaccinated via either two doses of the Sinopharm or an inactivated SARS-CoV-2 vaccine in 7 months (from May 2021 to Nov 2021) at the transplant ward and Organ Procurement Unit (OPU) of Sina University Hospital, Tehran, Iran.

The Sinopharm vaccine is an inactivated SARS-CoV-2 Vaccine (Vero Cell) [17]. Two doses of this vaccine are given 28 days apart. Therefore, all the vaccinated recipients in this study had at least two months of follow-up from the date of their last vaccination.

After obtaining ethics approval (IR.TUMS.SINAHOSPITAL.REC.1400.095) with a waiver of informed consent from the Tehran University of medical sciences, demographic characteristics of the vaccinated patients, including age, sex, type of transplanted medicine, date of transplant, history of smoking, documentation of SARS-CoV-2 vaccination date, and SARS-CoV-2 symptoms, were extracted by phone interview in the Sina Organ Unit.

All patients were asked to perform a PCR test if a family member or colleague or friend who attended a party with them tested positive. The SARS-CoV-2 diagnosis was confirmed via a nasopharyngeal swab polymerase chain reaction and CT scan for all the patients.

The present study used SPSS software version 16 for all the statistical analyses.

The obtained results were reported as mean, standard deviation, and *p* values. The chi-square or Fisher exact test was used for categorical analyses. The data with normal distribution were analyzed using an unpaired *t*-test. In addition, correlations were analyzed by Spearman. Finally, multivariate analysis on vaccine response was performed using IBM-SPSS Statistics-26. A *p*-value <0.05 was considered statistically significant.

3. Results

Among all the cadavers of kidney transplant recipients in our center, 159 cases were fully vaccinated. The mean age of the vaccinated participants was 49.44 ± 13.87 years old, and the median time of transplanted organs was 130.88 ± 82.61 months (from 12 to 324 Months).

There were 73 cases of SARS-CoV-2 infection during the study period, 18 cases (12.6%) occurred among the fully vaccinated individuals, and 53 cases (33.3%) were among the one-dose group.

Overall, the patients were predominantly male ($n = 58$, 63.5%). Demographics of these patients and details of the cases with breakthrough infection among the fully vaccinated subjects are shown in Table 1.

Eighteen (100%) patients from the fully vaccinated group who received the SARS-CoV-2 infection presented fever, 16 cases (90%) dyspnea, 16 cases (90%) body aches and fatigue, 8 cases (50%) diarrhea, and 2 cases (14.3%) had headache. As shown in Table 2, there was a significant difference between disease severity levels in the fully vaccinated group and the one-dose vaccinated group ($p < 0.023$). In addition, severe illness occurred in 2 patients after full vaccination, who were subsequently admitted to the hospital. The comparison of the severity of disease between the two groups (fully vaccinated and one-dose vaccinated) is shown in Table 2.

No case showed any allergic reaction after SARS-CoV-2 vaccination. In addition, no hospitalizations were reported among the patients who received the SARS-CoV-2 vaccine. Moreover, no cases of organ rejection were reported after the vaccination.

Of note, 45% of the fully vaccinated patients were infected by SARS-CoV-2 by families, followed by those who were infected by participating in social events (35%).

(Fig. 1).

All the patients with the severe disease received dexamethasone and Remdsevir, and 20 (35.6%) patients were still hospitalized at the time of data collection in both groups. There were 2 SARS-CoV-2 related deaths among the fully vaccinated group.

Additionally, there was no significant difference between the type of kidney drugs and infection of SARS-CoV-2 before and after vaccination.

Table 1

Baseline characteristics of 159 recipients who got COVID-19 vaccination.

		Fully vaccinated
Age, years old (mean)		49.44 ± 13.87
Sex	Female	58 (36.5%)
	Male	101 (63.5)
Level of education	illiterate	38 (23.9%)
	High school/ Diploma	90 (56.6%)
	Bachelor's degree	25 (15.7%)
	Master and Doctorate	6 (3.8%)
Smoking	Yes	14 (8.23%)
	No	145 (91.77%)
Use of IV drugs	Yes	6 (3.8%)
	No	153 (96.2%)
Underlying disease	Hypertension	92 (57.86%)
	Diabetes	66 (41.5%)
	CVD	1 (0.64%)
		64 (40.3%)
Cause of ESRD	Hypertension	64 (40.3%)
	Diabetes	16 (10%)
	Infection	10 (6.3%)
	PKD	8 (5.1%)
	Kidney Stone	5 (3.1%)
	Unknown	24 (15.1%)
	Other	32 (20.1)
		70 (44%)
Maintenance immunosuppression	Sandimmun	43 (27%)
	Prograf	159 (100%)
	Prednisolone	86 (54.1%)
	Cellsept	25 (15.7%)
	Myfortic	20 (12.6%)
	Azaram	9 (5.7%)
	Rapamune	9 (5.7%)

Table 2
Baseline characteristics of the kidney recipients who had COVID-19 infection before & after COVID-19 vaccination.

		Before full vaccination (n = 55)	After full vaccination (n = 18)
Disease severity	Mild	33 (63.6%)	16 (88.9%)
	Moderate	9 (16.4%)	–
	Severe	11 (20%)	2 (11.1%)
Maintenance immunosuppression	Cyclosporine	23 (42.6%)	10 (50%)
	Tacrolimus	17(31.5%)	2 (10%)
	Mycophenolate	22 (40.7%)	11 (55%)
	Mofetil (cellcept)		
	Mycophenolate	10 (18.5%)	4 (20%)
	Mofetil (Myfortic)		
	Azathioprine	12 (22.2%)	2 (10%)
Sirolimus	5 (9.4%)	2 (10%)	

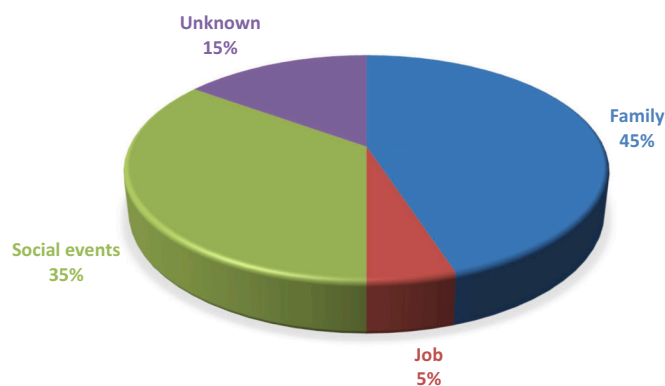


Fig. 1. The source of getting COVID infection in fully-vaccinated patients.

There was a significant difference between the number of kidney transplant days and getting the infection of SARS-CoV-2 before ($P = 0.15$) and after vaccination ($p < 0.015$). In addition, age was found to be significantly related to SARS-CoV-2 infection severity before full vaccination ($P = 0.04$).

There was no significant difference between lung symptoms and age ($p = 0.15$). In addition, there was no significant difference between lung symptoms and underlying disease ($P = 0.68$).

4. Discussion

Universal SARS-CoV-2 vaccination with highly effective vaccines is a critical tool in controlling the outbreak of the disease and saving lives [18]. In May 2021, the Transplant Office of the Ministry of Health in Iran recommended a two-dose regimen of Sinopharm SARS-CoV-2 vaccine to be used for kidney transplant patients. At that time, no data were available on the risks and benefits of SARS-CoV-2 vaccination in transplant recipients [19].

Vaccination in transplant recipients is a challenge, as immunosuppression may reduce the vaccine's efficacy [20].

In this study, we provided the first comparison of SARS-CoV-2 vaccination efficacy among kidney transplant recipients in Iran.

The study by Williams et al. showed that no hospitalizations or no cases of organ rejection (something that is of great concern to transplant recipients) were reported after the mRNA-1273 vaccine. They declared that the benefit of third-dose vaccination appears to outweigh the possible risks [21].

Kidney transplant recipients need to be effectively vaccinated against SARS-CoV-2 due to their increased vulnerability to severe type of this disease [22]. According to our results, none of the vaccinated patients had any symptoms of allergic reactions.

Based on the report by Axelrod et al. of organ transplant recipients, the first dose of the two-dose vaccine series was shown to be safe, with no reports of rejection and rare systemic reactions [20].

Our results show that 18 patients who received full vaccination were infected by SARS-CoV-2. Similarly, Nicole et al. [23] reported a retrospective chart review of 14 solid organ transplant recipients who developed SARS-CoV-2 infection after being fully vaccinated. Therefore, regarding the study by Nicole et al., there is sufficient evidence to issue warnings that immunocompetent populations should continue SARS-CoV-2 precautions post-vaccination.

Recent studies showed that the third dose of the SARS-CoV-2 vaccine increased the seroconversion rate among organ transplant recipients [19,24,25].

Based on our results, 2 (11.2%) fully vaccinated recipients had severe symptoms after SARS-CoV-2 vaccination. There was a significant difference between disease severity levels in fully vaccinated and unvaccinated groups. In another study, Azzi et al. declared that the prevalence rate of SARS-CoV-2 infection was 23.4% in the 975 patients tested either by RT-PCR or SARS-CoV-2 IgG. Of note, the overall mortality rate was 20.5% [26].

Regarding our previous research among kidney transplanted recipients admitted to this center, a 15.2% mortality rate was reported among kidney-transplant recipients with SARS-CoV-2 and 71 cases from 138 patients (51.1%) had moderate to severe symptoms of SARS-CoV-2 [27].

Almost half of the fully vaccinated patients were infected with SARS-CoV-2 by families. According to Kamar, the families of these patients should be encouraged to be vaccinated [24]. Moreover, high ranges of safety and control of SARS-CoV-2 are not possible without paying diligent attention to the other aspects of infection prevention, such as wearing masks, hand hygiene, social contact, and isolation of infected cases [28].

5. Conclusion

The rate and symptomology of SARS-CoV-2 disease between vaccinated and unvaccinated transplant patients are significantly different. Our study shows that despite a good safety profile, the lack of efficacy of the SARS-CoV-2 vaccine is a major problem in the kidney transplant recipient population. The findings of this study suggest that kidney recipients are still at risk of getting SARS-CoV-2 infection even after vaccination. Vaccinated patients were asked to continue preventive measures against SARS-CoV-2 infection, including masking, social distancing, and regular hand hygiene, even after receiving the required doses of the SARS-CoV-2 vaccine [29].

It should be noted that our follow-up observation occurred during the pandemic's peak with the SARS-CoV-2 Delta variant (B.1.617.2), a strain with high transmissibility, which was widespread among our population influencing the high prevalence of SARS-CoV-2 infection in Iran. Overall, vaccination was efficient in the prevention of death as shown by these observational results.

Limitations

The authors of this manuscript have no conflicts of interest to disclose.

Financial disclosure

The authors declare no funding was received for this study.

Declaration of Competing Interest

The authors declare that they have no competing interests.

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