



Research Article

Safety and Antibody Response to BNT162b2 and ChAdOx1 nCoV-19 Vaccines in Kidney Transplant Recipients

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Abstract

Background and objectives: Corona virus disease 2019 (COVID-19) is associated with significant morbidity and mortality in kidney transplant recipients (KTRs). Therefore, they are considered among the priority group for vaccination. This study presents safety data and antibody response to BNT162b2 and ChAdOx1 nCoV-19 vaccines in KTRs.

Design, setting, participants, and measurements: 230 KTRs received either of the vaccines and were

surveyed about adverse reactions, including timing and duration. 195 KTRs were tested for SARS-CoV-2 spike protein antibodies. Data on COVID-19 breakthrough infections were also collected.

Results: Out of the 230 KTRs, 150 (65.2%) were males, mean age was 46.5 (\pm 14.2) years and 21 had prior COVID-19 infection. Maintenance immune-suppression included prednisone (95.7%), tacrolimus (99.6%), and mycophenolate mofetil (96.1%). 173 (75.2%) received BNT162b2 (45 one dose, 128 two doses), and 57 (24.8%) received ChAdOx1 nCoV-19

(52 one dose, 3 two doses) vaccines. Vaccines were well tolerated with pain at the site of injection, fatigue, and headache reported most in 63.9, 38.3, and 30.4%, respectively. No change in baseline creatinine or biopsy proven rejection. 23.6% developed anti-spike antibodies after one dose and 35.8% after two doses. Prior COVID-19 infection and receiving two doses of vaccine increases the likelihood of seroconversion. 20 patients had COVID-19 breakthrough infection, 17 were seronegative. Hospitalization was required in 11 patients (4 in ICU), and one patient died.

Conclusion: BNT162b2 and ChAdOx1 nCoV-19 vaccines were well tolerated without major adverse events. However, the antibody response was markedly attenuated. More effective vaccination strategies using a third vaccine dose or heterologous vaccination would be warranted.

Keywords: Reverse transcriptase; Heterologous vaccination; Kidney transplant recipients; COVID-19

Abbreviations:

COVID-19: Coronavirus disease 2019; IgG: Immunoglobulin G; ICU: Intensive care unit; KTRs: Kidney transplant recipients; mRNA: micro-ribonucleic acid; rt-PCR: reverse transcriptase-polymerase reaction; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; SOT: Solid organ transplant

1. Introduction

Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2

(SARS-CoV-2), has affected people all over the world. Solid organ transplant (SOT) recipients are more likely to have severe disease with higher rates of hospitalization and mortality [1]. In Saudi Arabia, 55% of kidney transplant recipients (KTRs) with COVID-19 required hospitalization, with a 10.8% mortality rate [2]. As a result, most governmental entities considered SOT recipients a priority in their vaccination programs.

Several clinical trials have demonstrated SARS-CoV-2 vaccination safety and effectiveness [3, 4]. This was also supported by data from real-world reports of vaccine efficacy and protection against severe COVID-19 in the general population [5, 6]. Little is known; however, about the immune response of SOT recipients as they were excluded from major vaccine trials. Based on previous data using other vaccines, the immune response among SOT recipients might be blunted after receiving vaccines [7]. Reports on seroconversion after SARS-CoV-2 vaccination in KTRs are variable. The antibody response to micro-ribonucleic acid (mRNA) vaccines among this population group ranges from 0 to 17% following one dose, and 3 to 59% after 2 doses [8]. The pooled estimate of antibody response after mRNA vaccines first dose was 8% (95% CI, 5– 15%), and 35% (95% CI, 29– 42%) following 2 doses [8]. Several factors were thought to contribute to this poor immune response including older age, less time since kidney transplant, and more intense immunosuppression (triple agent, belatacept and antimetabolites) [9].

In this study we present the safety data and antibody response after receiving mRNA (BNT162b2;

Pfizer/BioNTech) and Adenovirus-vector (ChAdOx1 nCoV-19; Oxford/ AstraZeneca) vaccines among KTRs.

2. Methods

This is a retrospective observational cohort study which recruited 230 kidney KTRs from King Fahad Specialist Hospital in Dammam, Saudi Arabia. All adult KTRs (age >16 years) who had received at least one dose of either BNT162b2 (Pfizer/BioNTech) or ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccines between January 1 and June 15, 2021, were enrolled. The study was approved by hospital institutional review board, and participants provided informed consent.

We collected data on baseline characteristics, immunosuppressive therapy, and prior COVID-19 infection. Prior COVID-19 was defined as any patients with past positive SARS-CoV-2 by real time reverse transcriptase-polymerase reaction (rt-PCR). A questionnaire was used to survey patients about any adverse reactions after receiving the vaccine, including timing and duration of such reactions. Details about COVID-19 breakthrough infections after vaccination were also included. Historical serum creatinine results were collected within ninety days before and thirty to sixty days after vaccination.

To determine response to vaccination, blood samples were collected and tested for immunoglobulin G (IgG) antibodies against the SARS-CoV-2 spike protein at least 30 days after the second vaccine dose. Patients who only had a single dose of the vaccine also had their anti-spike protein antibodies checked

beyond 30 days. This is a qualitative assay and results were interpreted as positive or negative with a threshold index value of 1.5. Data was extracted from the electronic medical records system recorded in a unified data collection form.

3. Statistical Analysis

All data was analyzed using IBM SPSS statistics software (version 24.0) (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean \pm standard deviation. Comparison between groups was assessed by unpaired t-test, paired t-test, Mann-Whitney test, or repeated measures ANOVA. Categorical variables were presented as numbers and percentages and analyzed using the Chi-square or Fisher's exact tests as appropriate. Association between the potential risk factors and the positivity of antibodies response was assessed by means of binary logistic regression analysis. All reported P values are two-sided, and P value less than 0.05 was considered statistically significant.

4. Results

During the study period, 230 kidney transplant recipients who received at least one dose of either BNT162b2 (Pfizer/BioNTech) or ChAdOx1 nCoV-19 (Oxford/AstraZeneca) were identified. Demographics, comorbidities, type of vaccine administered, and number of doses are listed in Table 1. Mean age was 46.5 (\pm 14.2) years and 150 (65.2%) were males. 200 patients had live kidney transplantation and the rest were from deceased donors. Among recipients of living kidney transplantation, 150 patients were from related donors (all of them were from first degree relatives) and the remaining 50 patients from living

unrelated donors. Hypertension was the most common comorbidity at 78.8% while 37.8% of the KTRs were diabetic, and 15% had previous acute allograft rejection. Maintenance immunosuppression included prednisone (95.7%), tacrolimus (99.6%), and mycophenolate mofetil (96.1%). Twenty-one patients

had prior COVID-19 infection, of whom 6 (28.6%) and 2 (9.5%) required hospitalization and intensive care unit (ICU) admission, respectively. Time from COVID-19 infection to receiving first dose of vaccine was 217.9 (± 83.1) days.

Factors	Results(n=230) N (%)
Age	46.5 ± 14.2
Gender	
Female	80 (34.8)
Male	150 (65.2)
Comorbidities	
Diabetes	87 (37.8)
Hypertension	181 (78.7)
Ischemic heart disease	14 (6.1)
Prior rejection	34 (14.8)
Immunosuppression	
Steroid	220 (95.7)
Tacrolimus	229 (99.6)
Mycophenolate	221 (96.1)
Prior COVID-19 infection	
Number	21 (9.1)
Time from infection to first vaccine dose (days)	217.9 ± 83.1
Requirement of hospitalization	6 (28.6)
Requirement of ICU admission	2 (9.5)
Time from transplant to first vaccine dose (years)	5.7 ± 3.8
Type of administered vaccines	
BNT162b2 (Pfizer/BioNTech)	173 (75.2)
ChAdOx1 nCoV-19 (Oxford/AstraZeneca)	57 (24.8)
Number of vaccine doses	
One dose	97 (42.2)
Two doses	133 (57.8)

Table 1: Baseline characteristics.

One hundred and Seventy-Three patients (75.2%) had at least one dose of the BNT162b2 (Pfizer/BioNTech) vaccine, whereas 57 (24.8%) had the ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccine. Ninety-

seven (42.2%) patients received one dose and 133 (57.8%) received two doses of either vaccine. Self-reported local and systemic adverse reactions to vaccines are summarized in Table 2. The most

prevalent reactions among all patients were pain at the site of injection, fatigue, and headache in (63.9, 38.3, and 30.4%, respectively). Most of the adverse reactions occurred within the first 24 hours after vaccination (86%), disappeared within 48 hours in 88 % of the patients, and none of them required hospitalization (Figure 1). There was no statistically significant difference in allograft function as

measured by serum creatinine within ninety days before (109.6 ± 71.5 umol/l) and from thirty to sixty days after vaccination (111.4 ± 85.3 umol/l). The difference in creatinine among patients who received the BNT162b2 (Pfizer/BioNTech) was 2.5 umol/l (± 39.35) and -1.7 umol/l (± 14.55) for the ChAdOx1 nCoV-19 (Oxford/AstraZeneca), $p= 0.439$.

Adverse reactions	Total n (%)	BNT162b2 (Pfizer/BioNTech) n=173 n (%)	ChAdOx1 nCoV-19 (Oxford/AstraZeneca) n=57 n (%)	P value
Pain at site of injection	147 (63.9)	112 (64.7)	35 (61.4)	0.751
Fever or rigors	39 (17)	19 (11)	20 (35.1)	<0.001
Headache	70 (30.4)	45 (26)	25 (43.9)	0.013
Fatigue	88 (38.3)	58 (33.5)	30 (52.6)	0.012
Myalgia	38 (16.5)	19 (11)	19 (33.3)	<0.001
Diarrhea	5 (2.2)	2 (1.2)	3 (5.3)	0.099
Nausea or vomiting	7 (3.0)	1 (0.6)	6 (10.5)	0.001

Table 2: Self-reported adverse reactions.

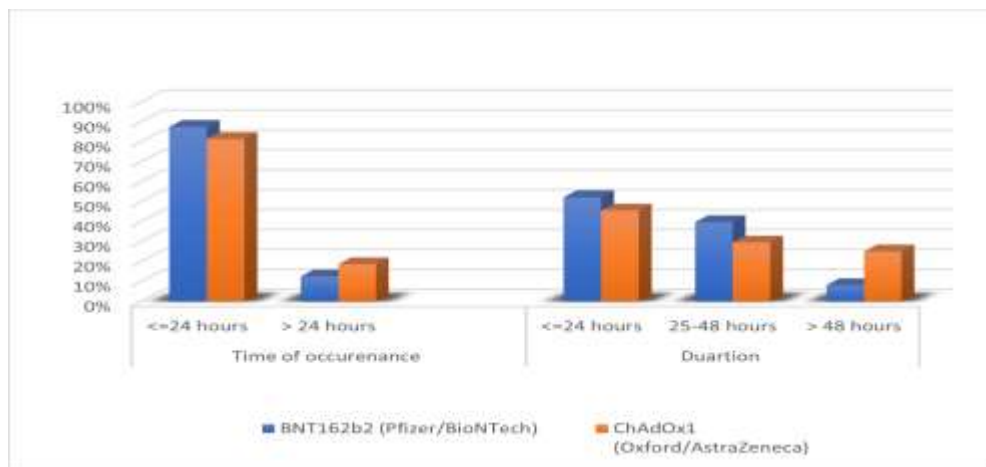


Figure 1: Time of occurrence and duration of adverse reactions.

Testing for SARS-CoV-2 spike protein antibodies was carried out in 195 patients (median time for antibodies testing from the time of vaccination was 32 days (IQR 25-39)). After a single dose of either vaccine, 21/89 (23.6%) of patients developed anti-spike antibodies: BNT162b2 (11/38: 28.9%);

ChAdOx1 nCoV-19 (10/51: 19.6%). While after two doses of either vaccine; 35.8% of patients (38/106) developed anti-spike antibodies (BNT162b2: 36/103 (35%); ChAdOx1 nCoV-19: 2/3 (66.7%) (Figures 2, 3).

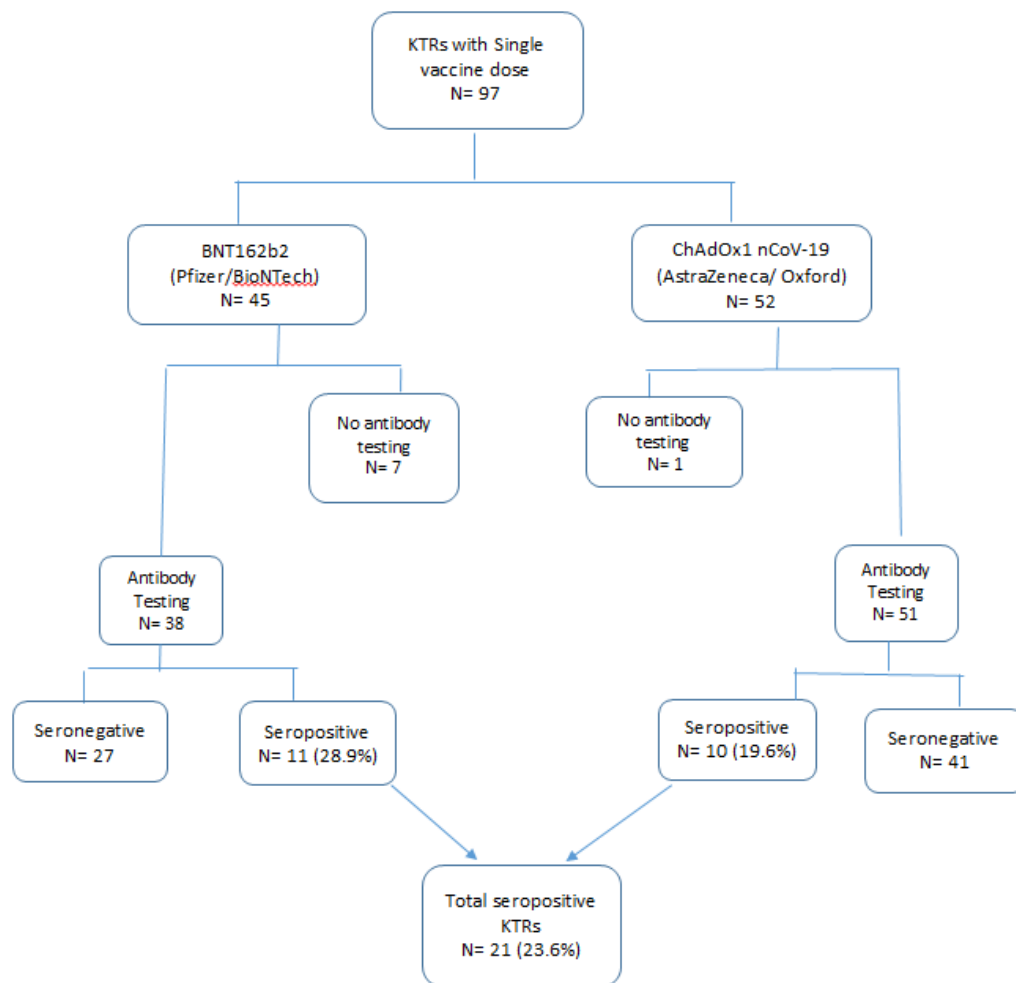


Figure 2: Seroconversion rate among KTRs who received one vaccine dose.

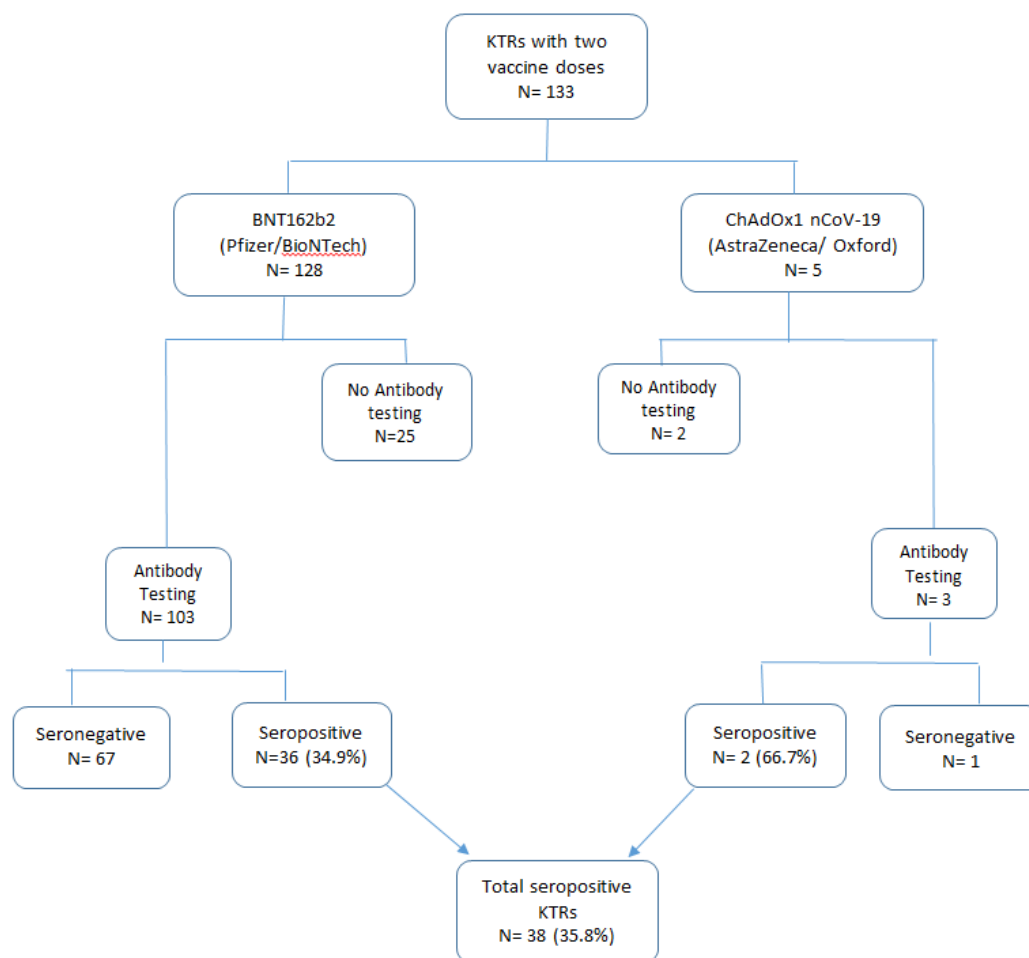


Figure 3: Seroconversion rate among KTRs who received two vaccine doses.

There was no difference in patients characterises, immunosuppression, prior acute rejection, and adverse reactions between seronegative or seropositive patients (p=NS). KTRs with prior COVID-19 were more likely to be seropositive;

27.1% compared to 2.9% seronegative, $p < 0.001$. On multivariate analysis, only prior COVID-19 infection and receiving two doses of vaccine increases the likelihood of seroconversion (Table 3).

Factors	P value	Odds ratio	95% Confidence interval	
Age ≥ 60	0.062	0.425	0.173	1.043
Prior infection	<0.001	19.36	5.367	69.844
BNT162b2 (Pfizer/BioNTech)	0.454	0.659	0.222	1.962
Two doses of vaccine	0.006	4.277	1.512	12.102

Table 3: Multivariate analysis to identify factors associated with positive antibody response.

Twenty patients had COVID-19 breakthrough infection after vaccination. All except one were COVID-19 infection-naïve, and 9 (45%) received two doses of vaccine (Table 4). Mean Time from dose of vaccine to breakthrough infection was 80.7 (± 36.9) days after first dose and 71.6 (± 48.3) days after the

second dose. Most of those patients were seronegative prior to breakthrough infection (n=17). Hospital admission was required in 11 (55%) patients (4 to ICU), while 9 (45%) were managed in the outpatient setting. One patient died of COVID-19 infection.

	No (n=210)	Yes (n=20)	P value
Age	46.5 ± 14.1	47.0 ± 15.7	0.894
Prior COVID-19 infection	20	1	0.703
	9.50%	5.00%	
Type of administered vaccine			
ChAdOx1 nCoV-19 (Oxford/AstraZeneca)	56	1	0.031
	26.70%	5.00%	
BNT162b2 (Pfizer/BioNTech)	154	19	
	73.30%	95.00%	
Number of vaccine Doses			
One dose	86	11	0.244
	41.00%	55.00%	
Two doses	124	9	
	59.00%	45.00%	
Positive anti-spike antibodies	56	3	0.132
	32.00%	15.00%	

Table 4: Breakthrough COVID-19 infection.

5. Discussion

We report on the safety and seroconversion rate after SARS-CoV-2 vaccination in kidney transplant recipients. Our KTRs tolerated the BNT162b2 (Pfizer/BioNTech) and ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccines very well but had a modest antibody response rate to SARS-CoV-2 spike protein. Local and systemic adverse reactions reported by our KTRs were similar to reactions reported by a

comparable cohort of SOT recipients. The reactions were also similar to reactions reported by normal subjects after receiving mRNA [3] or virus-vector [10] SARS-CoV-2 vaccines, however with lower frequency. These lower rates of reported symptoms may reflect the effect of the immunosuppressive medications [11]. More patients reported reactions after receiving ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccine, and this could be

attributed to the platform nature of the SARS-CoV-2 vaccines. Allograft function was stable after receiving either of the vaccines and this was reassuring given the reports of acute rejection following SARS-CoV-2 vaccines [12, 13].

Previous studies suggested a good specific T cell response despite a relatively poor humoral response to two doses of mRNA BNT162b2 vaccine [14]. The antibody response after a single dose of SARS-CoV-2 vaccination reported by several authors showed a lower seroconversion rate that ranged from 2.2 to 17.4% [9, 14-18]. In our study, after one dose of either the BNT162b2 (Pfizer/BioNTech) or ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccines, 21/89 (23.6%) patients developed anti-spike antibodies (11/38 (28.9%) BNT162b2; 10/51 (19.6%) ChAdOx1 nCoV-19). There was a small improvement in seroconversion after the second dose; 38/106 (35.8%) patients (36/103 (35%) BNT162b2, 2/3 (66.7%) ChAdOx1 nCoV-19). Similar earlier studies reported lower rates of seroconversion after 2 doses (17.8%) [14, 19]. Overall seroconversion rate following BNT162b2 vaccine (33.3%) was higher than the ChAdOx1 nCoV-19 vaccine (22.2%), a finding that is consistent with a previous study [20].

Our multivariate analysis showed that previous COVID-19 infection and receiving 2 doses of the vaccine were independent predictors of seroconversion post vaccination. Previous COVID-19 infection was shown to induce a strong T cell response and might play a vital role in producing a long-term immunological memory [21]. Prior priming of the immune system by either COVID-19 infection

or a further challenge by a second dose of the vaccine seemed to result in significant improvement in both the humoral and cellular response to the SARS-CoV-2 vaccine [14, 22]. This, in addition to the modest seroconversion rate after the primary SARS-CoV-2 vaccination may suggest a different approach to SARS-CoV-2 vaccination in organ transplant patients. Alternatives include further booster doses for those patients who do not seroconvert after the conventional two doses of SARS-CoV-2 vaccine regimen, possibly using a third dose from an alternative vaccine formulation. In a study involving 30 SOT recipients, a third dose from different vaccines was given at a median of 67 days following the second dose of their initial vaccine series [23]. One third of the seronegative patients developed antibodies, and all patients with initially low antibody titers had higher levels in a median of 14 days following the third dose. In addition, the vaccine local and systemic reactions were acceptable. In another study, the prevalence of anti-SARS-CoV-2 antibodies in SOT recipients increased from 40% after 2 doses of mRNA vaccines to 68% following a third dose [24]. The authors reported no serious adverse events and no COVID-19 breakthrough infections.

Heterologous vaccination could be another approach to increase the likelihood of seroconversion. Data from Normark and colleagues showed that levels of the S-specific and RBD-specific IgG at 7 to 10 days were 5 and 125 times as high as on the day of the boost using a ChAdOx1 nCoV-19 (Oxford/AstraZeneca) and an mRNA-1273 (Moderna) boost, respectively ($P < 0.001$) [25]. Similar benefits of heterologous vaccination regimen were highlighted in

a randomized open label phase 2 study by Borobia and colleagues [26]. It is not clear if this is an mRNA vaccine class effect or consequence of using different antigenic approaches to stimulate the immune response. In the running COV-POPART study, the heterologous vaccination is being studied in 200 high risk population including SOT recipients [27].

Our patients received the BNT162b2 (Pfizer/BioNTech) or ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccines as per the prevailing national policy at the time of vaccination, which initially offered two doses of either of the vaccines based on availability of stocks. After concerns were raised about the ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccine in certain age groups, its use was restricted to those who already had a first dose of this vaccine. Based on the developing data about using the prime boost strategy in SARS-CoV-2 vaccination, we plan to offer 52 of our patients who had a first dose of the ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccine a second dose of the BNT162b2 (Pfizer/BioNTech) vaccine.

In our study, 11 out of 97 patients (11.3%) who received only a single SARS-CoV-2 vaccine dose developed breakthrough COVID-19 infection during the study period versus 9 of 133 (6.8%) of the 2-dose group. In the study by Caillard and colleagues, 24 out of 25 patients had negative SARS-CoV-2 antibody after the second vaccine dose and before developing COVID-19 infection. Serious COVID-19 infection has been reported after 2 doses of the vaccine [28]. The low seroconversion rate following SARS-CoV-2 vaccines necessitates reinforcing the precautionary

measures of social distancing, hand hygiene and wearing masks. The variable reported rates of COVID-19 breakthrough infections could be attributed to loose precautionary measures follow up. Our study was a retrospective real-life investigation of the outcome of SARS-CoV-2 vaccination and only a handful of patients had the ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccine. In addition, we did not routinely investigate our patients with a COVID-19 rt-PCR or serology for anti-spike antibodies.

In conclusion, both the BNT162b2 (Pfizer/BioNTech) or ChAdOx1 nCoV-19 (Oxford AstraZeneca) vaccines were well tolerated by our kidney transplant recipients. The modest anti-spike antibody response after vaccination coupled with the occurrence of breakthrough COVID-19 infection post vaccination highlight the importance of continuing the non-therapeutic preventive measures against COVID-19 infection. Formal studies of the use of a third vaccine dose and the heterologous vaccination strategy in kidney transplant recipients are urgently needed.

Financial Disclosure

None

Disclaimer

The authors declare no conflicts of interest.

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