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Research Article

Efficacy and Outcome of Tixagevimab-Cilgavimab Prophylaxis Administration in Kidney Transplant Patients

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Abstract

Background: Kidney transplant recipients are immunocompromised and at high risk of developing COVID-19. Tixagevimab/cilgavimab has been shown to reduce the risk of COVID-19 in immunocompromised individuals. However, information regarding the safety and efficacy of tixagevimab/cilgavimab use in kidney transplant recipients remains limited. Therefore, in this study, we aimed to evaluate the efficacy and safety of tixagevimab/cilgavimab in individuals who have undergone kidney transplantation. *Methods:* A retrospective, single-center study was conducted on all patients who underwent kidney transplantation between June 2022 and January 2023. The recipients were divided into treatment and control groups based on tixagevimab/cilgavimab therapy status. The incidence of COVID-19, acute rejection, hypersensitivity reactions, and cardiac events was compared between the groups. *Results:* A total of 93 patients were included in the study, of whom 38 received tixagevimab/cilgavimab. Prior to drug administration, 38 patients (40.9%) were infected with COVID-19; of these, 12 (31.6%) required hospitalization and two (5.2%) required admission to the intensive care unit (ICU). During the post-administration period, seven patients (7.5%) developed COVID-19; of these patients, four (57%) received tixagevimab/cilgavimab, and three (43%) did not. None of the patients required hospitalization or ICU admission. *Conclusion:* The incidence of COVID-19 was similar across study groups. However, the severity of the infection appeared to be milder in patients who received tixagevimab/cilgavimab.

Keywords

COVID-19, Tixagevimab, Cilgavimab

1. Introduction

Immunocompromised patients, including solid-organ transplant recipients, are highly susceptible to infections. Furthermore, COVID-19 infection is often more severe in immunocompromised patients than in normal patients [1-3]. Immunocompromised individuals may also have a suboptimal response to COVID-19 vaccinations, increasing the risk of infection [4, 5]. Consequently, there is a need for additional preventive and therapeutic measures against COVID-19 infection in these sub-populations.

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Various therapeutic monoclonal antibodies (mAbs) have been evaluated as prophylactic and therapeutic agents against COVID-19 infection [6]. The tixagevimab/cilgavimab primary mechanism of action involves binding of the SARS-CoV-2 spike protein. Tixagevimab and cilgavimab have been proposed as a prophylactic agents to reduce the risk of infection [7]. Tixagevimab and cilgavimab mAbs are administered as separate consecutive intravenous or intramuscular injections at different sites [8]. In 2022, the FDA authorized the use of these mAbs for the pre-exposure prevention of COVID-19 [9].

In immunocompromised patients, including those with organ transplants, tixagevimab/cilgavimab effectively reduces risk of infection [10]. In addition, tixagevimab/cilgavimab use decreases mortality in individuals who do not respond well or respond inadequately to vaccination [11]. However, information regarding the safety and efficacy of tixagevimab/cilgavimab use in individuals with organ transplant remain limited. Therefore, in this study, we aimed to evaluate the efficacy and safety of tixagevimab/cilgavimab in individuals who have undergone kidney transplantation (post-kidney transplant population).

2. Method

2.1. Study Design and Participants

We performed a retrospective cohort study of patients that underwent kidney transplant at King Abdullah Medical City in Makkah, Saudi Arabia, between June 2022 and January 2023. Patients were categorized into two groups: those that were administered tixagevimab/cilgavimab (150 mg or 300; EVUSHELD™) and those that were not administered tixagevimab/cilgavimab. The following patients: transplanted less than one year, those under 18 years of age, individuals with known allergies to tixagevimab/cilgavimab, patients weighing less than 40 kg, and pregnant individuals were excluded. The patient chart is shown in Figure 1. Informed consent was obtained from all study participants before study initiation. This study was approved by the Institutional Review Board of King Abdullah Medical City (approval number: 23-1134).

2.2. Data Collections

We conducted a retrospective chart review and extracted data, including clinical characteristics (age, sex, ABO blood type, comorbidities, and renal disease) and transplant characteristics (induction and maintenance immunosuppression), from the medical records. All transplants were living kidney transplants and the procedure was exclusively performed at our center. Additionally, we recorded the doses of the administered COVID-19 vaccine. Furthermore, after obtaining consent, we directly interviewed patients to identify any COVID-19 symptoms, admissions, and outcomes not documented in their medical records within six months of tixagevimab/cilgavimab administration. We also collected the COVID-19 PCR results from the Central National Laboratory.

2.3. Study Outcomes

This study aimed to determine the incidence of symptomatic COVID-19, confirmed by positive PCR, after intramuscular administration of tixagevimab/cilgavimab in kidney transplant recipients within 6 months of transplantation. The secondary outcomes were acute rejection, hypersensitivity reactions, and cardiac events.

2.4. Statistical Analysis

All data was analyzed using SPSS. The data were reported as continuous, using the mean and standard deviation or median and interquartile range (IQR), and compared using Student's t-test or Mann-Whitney U-test, depending on normality assumptions. Categorical variables are presented as numbers with percentages and were compared using Chi-square or Fisher's Exact tests, as appropriate. A p-value less than 0.05 was considered statistically significant.

3. Results

A total of 93 patients were included in the study. Of these, 38 patients received tixagevimab/cilgavimab (treatment group); 15 patients received 150 mg doses and 23 patients received 300 mg doses. The remaining 55 patients constituted the control group. The majority of participants were male (approximately 60%), with no significant differences in the male-to-female ratio across the groups. The mean age of the participants was 47.1 ± 13.7 years, which was comparable between the study groups; patients who did not receive the drug, those who received 150 mg, and those who received 300 mg (46.6 ± 14.8, 47.5 ± 14.7, and 46.13 ± 15.19, respectively).

Most patients were in blood group O (47.3%), followed by group A (32.3%). The distribution of the blood groups was similar between the treatment and control groups. Patients in the treatment groups (150 mg and 300 mg) received ATG (Antithymocyte Globulin) induction therapy (63.2% and 65%, respectively); however, this difference is probably not indicative because the induction therapy was reported in 43% of the control group.

Unknown causes, diabetes mellitus, and hypertension were the most prevalent reasons for kidney transplantation (32.3%, 23.7%, and 20.4%, respectively) in the study cohort (Table 1). Diabetes mellitus was prevalent in 45.2% of the study population, and of these patients, only 11.8% were smokers. The patients' mean body mass index (BMI) was 28.44 ± 5.8 kg/m², indicating that most patients were overweight. All the study participants were vaccinated, and the vast majority (79.6%) received three COVID-19 vaccine doses, followed by 11.8% who received two doses, 7.5% who received four doses, and 1.1% who received a single vaccine dose. Tacrolimus was the

dominant Calcineurin Inhibitor (CNI) across all groups (100%, 95%, and 94% in 150 mg dose, 300 mg dose, and control groups, respectively). Mycophenolate mofetil and steroids were prescribed universally.

4. Outcome

4.1. COVID-19

Table 2 shows the general characteristics of patients with COVID-19 before and after Tixagevimab/Cilgavimab administration. Thirty-eight of the 93 patients (40.9%) were infected with COVID-19 prior to drug administration, of which 35 (92.1%) were symptomatic. Twelve patients (31.6%) were hospitalized, and two (5.2%) admitted to the intensive care unit (ICU). Before study initiation, the COVID-19 exposure rate ranged from 33-56% among the study groups. Although statistically insignificant, a larger number of patients in the 300 mg-dose group had a previous COVID-19 infection that required hospitalization (21.7%) or ICU admission (4.3%). This difference might be attributed to a higher level of commitment toward prophylactic agents in those who had experienced a more severe form of COVID-19.

During the post-administration period, seven (7.5%) patients were infected with COVID-19; four (57%) received tixagevimab/cilgavimab and three (43%) did not. All patients were symptomatic and none required admission to the hospital or ICU. No deaths were reported before or after drug administration.

Among the study groups, no significant differences were observed in COVID-19 infection incidence, symptoms, or admission to the hospital or ICU before and after drug administration between patients who received tixagevimab/cilgavimab and those who did not (Table 4).

Figures 2 and 3 illustrate the incidence of infection with symptoms and complications before and after drug administration, respectively. They showed a dramatic decrease in the incidence of infection after drug administration, regardless of drug administration.

4.2. Secondary Outcomes

Table 3 shows the side effects of tixagevimab/cilgavimab; three patients (3.2%) developed an anaphylactic reaction, and five (5.5%) developed acute kidney injury (AKI). Two (13%) of these cases received a 150 mg dose, and two (8.7%) a 300 mg dose, and one (1.8%) patient developed AKI in the group that did not receive the drug. There was a tendency toward AKI after tixagevimab/cilgavimab treatment; however, this finding was not statistically significant.

5. Discussion

Different types of monoclonal antibodies have been used for COVID-19 prophylaxis and treatment in the solid-organ transplantation populations [12, 13]. Bamlanivimab was one of the first monoclonal antibodies to be FDA-approved for this purpose, followed by several monoclonal antibodies, either alone or in combination with other agents. Some are authorized for pre-exposure prophylaxis, whereas others are authorized for early management or both [6].

Tixagevimab/cilgavimab are administered intravenously or intramuscularly as two separate injections at two sites [8]. FDA approved the use of Tixagevimab/Cilgavimab in December 2021 under emergency authorization for pre-exposure prophylaxis against SARS-CoV-2. The primary mechanism of action of tixagevimab/cilgavimab involves binding to the receptor-binding domain of the SARS-CoV-2 spike protein [14]. The tixagevimab/cilgavimab induced effect is longer than that of the early produced monoclonal antibodies, with a half-life of 19 days [14].

The efficacy of tixagevimab/cilgavimab as a pre-exposure prophylactic agent in the transplant population remains controversial, especially for the omicrone variant [4, 15-19]. Some studies in immunocompromised populations indicated that tixagevimab/cilgavimab is associated with a lower risk of COVID-19 infection or severe illness [4, 10, 16, 20], whereas other studies showed a weak efficacy response. This weak response was more profound in the Omicron sublineages BA.1 [15], BA.4/BA.5 and BA.2.75 [19]. Andrew H. Karaba and his colleagues showed that the BA.1 neutralizing activity following tixagevimab/cilgavimab in vaccinated solid organ transplant recipients remained low, with a minimal increase from 8% to 16%. Our study did not show a significant difference between patients who received tixagevimab/cilgavimab and those who did not. In a lung transplant study, fewer infections occurred in patients in the tixagevimab/cilgavimab group (31% vs. 40%, $p = 0.004$); however, this did not prevent an outbreak, and there was no difference in the severity of COVID-19 observed between patients with and without tixagevimab/cilgavimab prophylaxis [21]. In our study, although the rate of COVID-19 infection did not differ among the three study groups during the observation period, in the group that received tixagevimab/cilgavimab, there was a tendency toward severe infection alleviation; patients who received tixagevimab/cilgavimab and were infected with COVID-19 did not require Hospitalization or ICU admission. However, this finding cannot be attributed solely to tixagevimab/cilgavimab, because other factors, such as the high multidose vaccination rate and the dominant strain of the virus during the study period, may have contributed to the outcome.

Levin et al. found that a 300 mg dose of tixagevimab/cilgavimab was preventive [4]. Jurdi et. al. reported a breakthrough in the treatment of patients receiving these agents. However, the incidence of infection was lower in patients who received a 300 mg dose of Tixagevimab/Cilgavimab. This finding was consistent with our study observations [16]. Although the optimum dose of Tixagevimab/Cilgavimab is not well established, two separate doses of 150 mg-150 mg would

provide the best protection [22].

Tixagevimab/cilgavimab has a good safety profile [4], with the most common reactions in the post-transplantation population being mild fatigue, headache, and pain at the injection sites. Only 1% of patients who receive tixagevimab/cilgavimab experience rejection [23]. Levin et al. reported a 35% rate of side effects with the use of tixagevimab/cilgavimab, with a 1.8% of severe side effects [4]. In this study, we did not observe any serious adverse effects associated with tixagevimab/cilgavimab administration in a kidney transplant population.

6. Conclusion

Although the rate of COVID-19 infection did not differ among the three study groups during the observation period, in the tixagevimab/cilgavimab group, there was a tendency of severe COVID-19 infection alleviation. This finding cannot be attributed solely to tixagevimab/cilgavimab administration because other factors, such as the high multi-dose vaccination rate and the dominant strain of the virus during the study period, may have contributed to this outcome. Our study has several limitations, including a small sample size, single-center experience, and potential recall bias. Therefore, larger prospective studies are required to validate our findings.

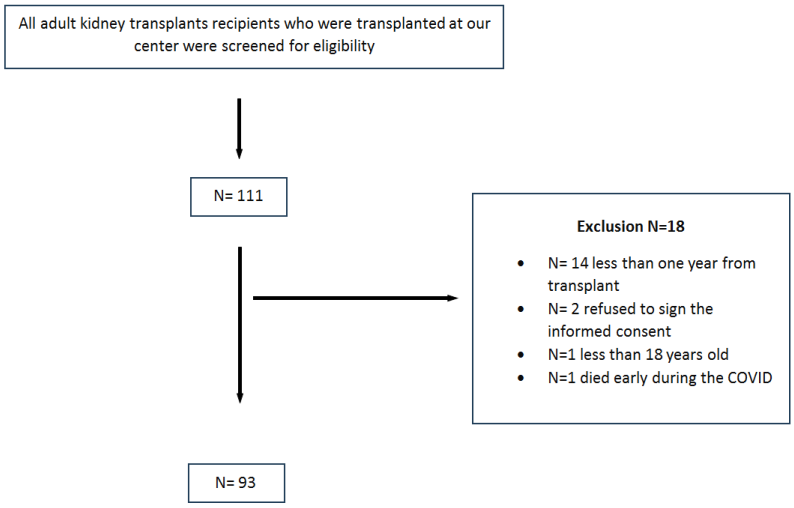

Figure 1. *Chart flow of included patients.*

Table 1. *Patient characteristics according to the hospitalization status.*

Characteristic	Total (n =93)	Received 150 mg. (n=15)	Received 300 mg. (n=23)	Didn't receive (n= 55)
Gender, n (%)				
Female	33 (35.5%)	5 (33.3%)	9 (39.1%)	19 (34.5%)
Male	60 (64.5%)	10 (66.7%)	14 (60.9%)	36 (65.5%)
Age, mean (SD)	47.1 (13.70)	47.5 (14.7)	46.13 (15.19)	46.6 (14.8)
ABO, n (%)				
A	30 (32.3%)	7 (46.7%)	4 (17.4%)	19 (34.5%)
AB	4 (4.3%)	0	2 (8.7%)	2 (3.6%)
B	15 (16.1%)	1 (6.7%)	5 (21.7%)	9 (16.4%)
O	44 (47.3%)	7 (46.7%)	12 (52.2%)	25 (45.5%)
Induction therapy, n (%)				
ATG	43 (46.2%)	9 (60%)	15 (65.2%)	19 (34.5%)
Basiliximab	22 (23.7%)	4 (26.7%)	6 (26.1%)	12 (21.8%)

Characteristic	Total (n =93)	Received 150 mg. (n=15)	Received 300 mg. (n=23)	Didn't receive (n= 55)
Unknown	28 (30.1%)	2 (13.3%)	2 (8.7%)	24 (43.6%)
Renal Disease, n (%)				
Alport	1 (1.1%)	0	0	1 (1.8%)
APCKD	4 (4.3%)	3 (20%)	1 (4.3%)	-
DM	22 (23.7%)	5 (33.3%)	8 (34.8%)	9 (16.4%)
FSGS	4 (4.3%)	0	1 (4.3%)	3 (5.5%)
HTN	19 (20.4%)	2 (13.3%)	4 (17.4%)	13 (23.6%)
IgA	2 (2.2%)	0	0	2 (3.6%)
Lupus nephritis	1 (1.1%)	0	0	1 (1.8%)
other	6 (6.5%)	0	1 (4.3%)	5 (9.1%)
Reflux	4 (4.3%)	0	1 (4.3%)	3 (5.5%)
Unknown	30 (32.3%)	5 (33.3%)	7 (30.4%)	18 (32.7%)
DM, n (%)				
Yes	42 (45.2%)	9 (60%)	10 (43.5%)	23 (41.8%)
Smoker, n (%)				
Yes	11 (11.8%)	3 (20%)	3 (13%)	5 (9.1%)
BMI, mean (SD)	28.44 (5.8)	29.3 (4.5)	28.14 (6.1)	28.6 (5.5)
Dose of vaccine, n (%)				
1	1 (1.1%)	0	0	1 (1.8%)
2	11 (11.8%)	1 (6.7%)	3 (13%)	7 (12.7%)
3	74 (79.6%)	11 (73.3%)	18 (78.3%)	45 (81.8%)
4	7 (7.5%)	3 (20%)	2 (8.7%)	2 (3.6%)
CNI, n (%)				
Cyclo	4 (4.3%)	0	1 (4.3%)	3 (5.5%)
Tac	89 (95.7%)	15 (100%)	22 (95.7%)	52 (94.5%)
MMF, n (%)				
Yes	84 (90.3%)	15 (100%)	21 (91.3%)	48 (87.3%)
Steroid, n (%)				
Yes	91 (97.8%)	15 (100%)	22 (95.7%)	54 (98.2%)

Note: Data are expressed as mean (standard deviation SD) n (%).

Table 2. *Patient COVID-19 and related.*

Characteristic	Total (n =93)	Received 150 mg. (n=15)	Received 300 mg. (n=23)	Didn't receive (n= 55)
Covid Positive before July 2022	38 (40.9%)	5 (13.1%)	13 (34.2%)	20 (52.6%)
Symptomatic	35 (92.1%)	5 (13.1%)	13 (34.2%)	17 (44.7%)

Characteristic	Total (n =93)	Received 150 mg. (n=15)	Received 300 mg. (n=23)	Didn't receive (n= 55)
Required hospitalization	12 (31.6%)	2 (5.2%)	5 (13.1%)	5 (13.1%)
Required ICU admission	2 (5.2%)	0	1 (2.6%)	1 (2.6%)
Death	0	0	0	0
Covid Positive After July 2022	7 (7.5%)	0	4 (57%)	3 (43%)
Symptomatic	7 (100%)	0	4 (57%)	3 (43%)
Required hospitalization	0	0	0	0
Required ICU admission	0	0	0	0
Death	0	0	0	0

Note: Data are expressed as n (%).

Table 3. *Side effects.*

Characteristic	Total (n =93)	Received 150 mg. (n=15)	Received 300 mg. (n=23)	Didn't receive (n= 55)
Anaphylactic reaction	3 (3.2%)	3 (20%)	0	0
Bleeding	0	0	0	0
AKI	5 (5.4%)	2 (13.3%)	2 (8.7%)	1 (1.18%)

Table 4. *Patient COVID-19 received medication or not.*

Characteristic	Receiving		P value
	No (n= 55, 100%)	Yes (n=38, 100%)	
Covid Positive before July 2022	20 (52.6%)	18 (47.4%)	0.391
Symptomatic	17 (48.6%)	18 (51.4%)	0.286
Required hospitalization	5 (41.7%)	7 (58.3%)	0.267
Required ICU admission	1 (50%)	1 (50%)	0.400
Death	0	0	0.109
Covid Positive After July 2022	3 (42.9%)	4 (57.1%)	0.438
Symptomatic	3 (42.9%)	4 (57.1%)	0.152
Required hospitalization	0	0	0.082
Required ICU admission	0	0	0.082
Death	0	0	0.082

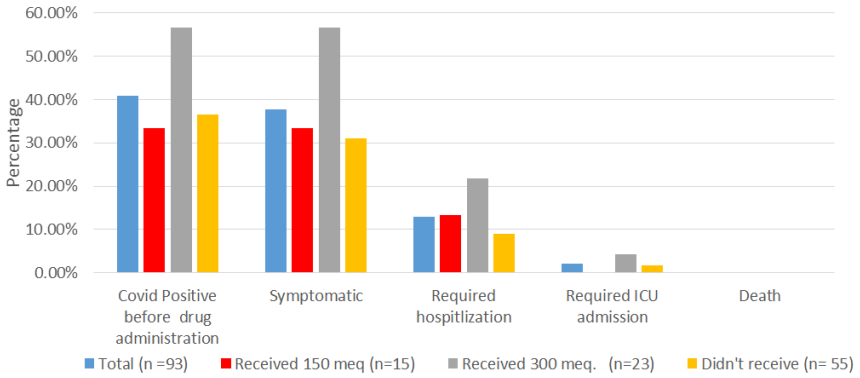

Figure 2. Patient COVID-19 before and related.

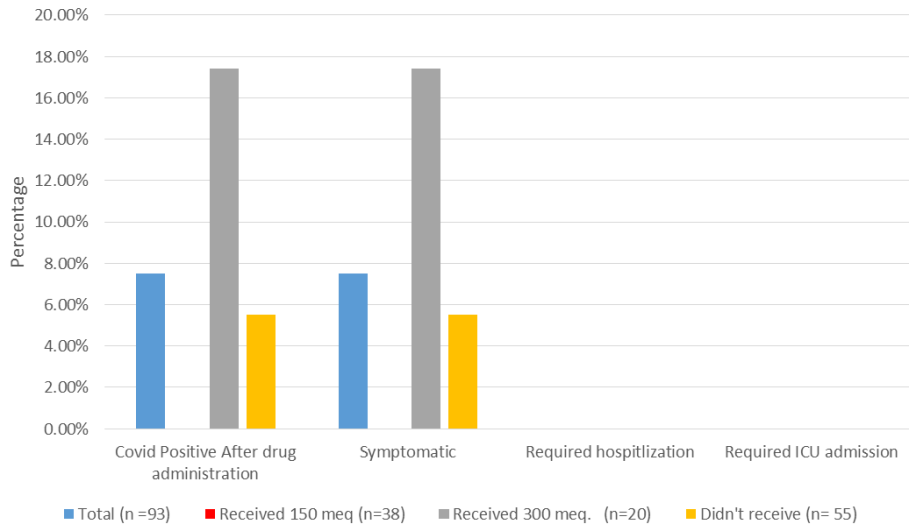

Figure 3. Patient COVID-19 after and related.

Abbreviations

BMI	Body Mass Index
(CNI)	Calcineurin Inhibitor
ATG	Antithymocyte Globulin
AKI	Acute Kidney Injury
ICU	Intensive Care Unit

Author Contributions

Dr. Zainab Habibullah**:** Conceptualization ,Project administration, Writing original Draft.

Dr. Muhammed Bukhari**:** Methodology, Writing – review & editing

Dr.Nouf Al-Otaibi**:** Validation , Formal Analysis.

Mr. Nashat Albadawi: Data curation, Software

Mr. Mohammed Khalil: Data curation

Dr.Abdulhakeem Al-Marwani: Data curation,

Conflicts of 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. The main credit in publication will go to the principal investigator and co-investigators. KAMC will be accredited in publication.

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