Original article

Outbreak, Surveillance, Investigation & Response (OSIR) Journal
ISSN 2651-1061 (Online)
https://he02.tci-thaijo.org/index.php/OSIR
Email: osireditor@osirjournal.net

March 2026
Volume 19, Issue 1
Article no. 279468

Effectiveness of Pre-exposure Prophylaxis with Tixagevimab–Cilgavimab for COVID-19 Hospitalization among Chronic Kidney Disease Patients in Thailand: A Retrospective Cohort Study, August 2022 to May 2023

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Received: 23 Dec 2025; Revised: 29 Jan 2026; Accepted: 12 Feb 2026
https://doi.org/10.59096/osir.v19i1.279468

Abstract

Objectives: To evaluate the effectiveness of tixagevimab–cilgavimab in preventing COVID-19-related hospitalizations among chronic kidney disease (CKD) patients in Thailand from 1 Aug 2022 to 30 May 2023.

Methods: We conducted a retrospective cohort study using secondary data from Thailand's national health databases among CKD patients aged ≥12 years under the Universal Coverage Scheme who were followed from 1 Aug 2022 to 30 May 2023. The primary outcome was time until COVID-19 hospitalization, analyzed using Cox regression, and adjusted for age, gender, vaccination status, and comorbidities. Receiving tixagevimab–cilgavimab at a dose of either 300 mg or 600 mg was the main explanatory variable. A stratified analysis was also conducted by history of dialysis.

Results: Among 1,018,175 CKD patients, tixagevimab–cilgavimab recipients had a higher hazard of hospitalization compared to non-recipients (adjusted hazard ratio 1.70; 95% confidence interval (CI) 1.40–2.06). Among dialysis patients, administration of tixagevimab–cilgavimab was associated with a non-significant reduction in the risk of hospitalization (effectiveness 18.15%; 95% CI: -12.82–40.62) while COVID-19 vaccination was strongly protective in both groups, with five doses showing an effectiveness of 79.18% (95% CI 61.28–88.80). Tixagevimab–cilgavimab did not significantly reduce the hazard of hospitalization overall but showed a non-significant trend toward a benefit among dialysis patients.

Public Health Recommendations: Tailored prophylaxis strategies are needed for immunocompromised populations during evolving waves of COVID-19 variants. Further studies should assess effectiveness by variant period and underlying risk profile to better identify subgroups most likely benefit from the interventions.

Keywords: tixagevimab–cilgavimab, COVID-19, chronic kidney disease, dialysis, prophylaxis, effectiveness

Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has dramatically affected global health, especially among individuals with pre-existing medical conditions.[1–6] Individuals with chronic kidney disease (CKD) and end-stage kidney disease (ESKD) on maintenance dialysis are particularly vulnerable to coronavirus disease 2019 (COVID-19) and tend to experience more severe clinical outcomes than the general population.[1–4] This increased susceptibility underscores the necessity for targeted preventive strategies for high-risk populations such as those with CKD and ESKD.

Vaccination has been a crucial tool in combating COVID-19, significantly reducing disease severity and the number of hospitalizations. However, vaccine effectiveness for CKD and ESKD patients may be reduced due to their immunocompromised status, resulting in suboptimal immune responses. Studies indicate that CKD patients, particularly those on dialysis, often show lower seroconversion rates post-vaccination compared to the general population.[7–13] This diminished response highlights the need for additional protective measures to safeguard these high-risk individuals.

Monoclonal antibody cocktails have emerged as a tool for the prevention and treatment of COVID-19. Among these, the combination of tixagevimab and cilgavimab has shown promise in providing prolonged protection against SARS-CoV-2.[14,15] Tixagevimab–cilgavimab works by targeting distinct sites on the virus, thereby neutralizing its ability to infect human cells and offering long-term prophylactic benefits.[16,17] The Thai Food and Drug Administration authorized tixagevimab–cilgavimab on 27 Jun 2022 and it was introduced to the Thai population on 1 Aug 2022.[18] Initially, Thai authorities recommended 300 mg of tixagevimab–cilgavimab (150 mg tixagevimab + 150 mg cilgavimab) for immunocompromised individuals, later increasing the dose to 600 mg (300 mg + 300 mg) in November 2022.[19,20]

However, studies investigating the real-world effectiveness of tixagevimab–cilgavimab in Thailand remain limited, especially among CKD patients, who are the primary target of the policy. This study therefore evaluated the effectiveness of tixagevimab–cilgavimab in preventing COVID-19-related hospitalizations among CKD patients in Thailand from 1 Aug 2022 to 30 May 2023.

Methods

Study Design and Population

A retrospective cohort study using secondary data was conducted among Thai individuals aged ≥12 years who were members of the Universal Coverage Scheme—the main public health insurance arrangement for the Thai populations—and had at least one recorded diagnosis of chronic kidney disease (ICD-10: N18) during the period from 1 Oct 2021 to 30 Sep 2022, regardless of whether this represented a new or follow-up diagnosis.

The exposure status was determined based on tixagevimab–cilgavimab administration history. Individuals who received both 300 mg and 600 mg does during the study period were excluded.

Participants with a record of COVID-19 diagnosis from inpatient departments from 1 Aug 2022 to 30 May 2023 were classified as COVID-19 hospitalized cases.

Data Sources

We retrieved secondary data on 15 Jun 2024 from two national health databases: the National Health Security Office (NHSO) database and the Ministry of Public Health Immunization Center (MOPH-IC). The NHSO is responsible for monitoring population diagnosis and treatment within the Universal Coverage Scheme, while the MOPH-IC, the national immunization information center under the Office of Permanent Secretary, is responsible for compiling data on COVID-19 immunization and tixagevimab–cilgavimab administration.

Demographic data, underlying health conditions and the outcome of individuals were extracted from the NHSO database. Data on tixagevimab–cilgavimab and COVID-19 vaccination were obtained from the MOPH-IC database.

Statistical Analysis

Cases aged ≥120 years were excluded as these ages were deemed implausible. For descriptive analysis, categorical data were summarized using frequency and proportion, while continuous data were summarized using the mean and standard deviation (SD). The primary independent variable of interest was tixagevimab–cilgavimab administration status, categorized into three groups: not received, received 300 mg, and received 600 mg. Other variables collected included gender, age, history of dialysis, and underlying diseases, such as chronic lung disease (emphysema and chronic obstructive disease), cancer,

diabetes, hypertension, liver diseases (chronic hepatitis and cirrhosis of liver), human immunodeficiency virus infection, and COVID-19 vaccine status. Recipients of the COVID-19 vaccine were those who had received the vaccine at least fourteen days prior to the outcome or 30 May 2023, which is the end of the follow-up time. Vaccinations administered less than 14 days before the outcome were ignored, and such individuals were classified according to their prior vaccine status. Participants were censored at the time of COVID-19 diagnosis with hospitalization.

To identify factors associated with time to COVID-19 hospitalization, a Cox regression model was employed. The proportional hazards assumption was assessed using Kaplan-Meier curves. A separate stratified analysis was conducted among patients with and without a history of dialysis as dialysis status is a predictor of COVID-19 severity and may modify the effect of prophylaxis on hospitalization risk. An adjusted hazard ratio (HR) was calculated with 95% confidence interval (CI) adjusted for age group (12–59 years, 60–79 years, 80–99 years and ≥100 years), gender, and underlying diseases. The effectiveness of tixagevimab–cilgavimab and COVID-19 vaccine was calculated as one minus the adjusted HR multiplied by one hundred percent.

Results

A total of 1,018,175 CKD participants were included in the study. The characteristics of the study population stratified by tixagevimab–cilgavimab administration status are shown in Table 1. The proportions of subjects who were hospitalized increased with age, especially among individuals aged 80 years and above, with the highest proportion (5.36%) observed in the 80–99-year age group receiving tixagevimab–cilgavimab 300 mg. Across all groups, females had slightly higher proportions of COVID-19 hospitalization than males. For underlying health conditions, dialysis patients in the control group had the highest proportion of hospitalizations (4.52%), while diabetes and hypertension were more frequent among cases who received tixagevimab–cilgavimab, especially those receiving a dose of 600 mg (33.33% and 21.43% for 300 mg and 600 mg, respectively).

Table 1. Percentage of COVID-19 hospitalization by patient characteristics and tixagevimab–cilgavimab administration status in Thailand, 1 Aug 2022–30 May 2023 (n=1,018,175).

Characteristic	Did not receive (n=1,010,824)		Received 300 mg (n=7,234)		Received 600 mg (n=117)	
	n	%	n	%	n	%
Length of follow-up (days)						
Mean (SD)	294 (40)		174 (63)		142 (55)	
Gender						
Female	7,246	1.67	124	3.58	2	3.70
Male	8,497	1.47	117	3.11	1	1.59
Age group (years)						
12–59	2,362	1.20	92	3.03	1	1.49
60–79	8,684	1.45	124	3.32	2	4.17
80–99	4,657	2.20	25	5.36	0	0.00
100 or more	30	3.74	0	0.00	0	NA
Underlying disease						
Diabetes mellitus						
No	9,985	1.33	139	2.78	0	0.00
Yes	5,758	2.22	102	4.57	3	33.33
Hypertension						
No	8,407	1.32	110	2.64	0	0.00
Yes	7,336	1.97	131	4.28	3	21.43
Chronic lung disease						
No	15,396	1.54	240	3.33	3	2.56
Yes	348	3.78	1	3.23	0	NA
Human immunodeficiency virus (HIV)						
No	15,731	1.56	241	3.33	3	2.59
Yes	12	0.84	0	0.00	0	0.00
Hepatic disease						
No	15,720	1.56	241	3.34	3	2.56
Yes	23	5.34	0	0.00	0	NA

Table 1. Percentage of COVID-19 hospitalization by patient characteristics and tixagevimab–cilgavimab administration status in Thailand, 1 Aug 2022–30 May 2023 (n=1,018,175)(cont.).

Characteristic	Did not receive (n=1,010,824)		Received 300 mg (n=7,234)		Received 600 mg (n=117)	
	n	%	n	%	n	%
Cancer						
No	15,610	1.55	241	3.35	3	2.56
Yes	133	3.15	0	0.00	0	NA
History of dialysis						
No	14,695	1.49	168	3.23	2	5.41
Yes	1,048	4.52	73	3.58	1	1.25
Number of COVID-19 vaccine doses received*						
None	4,747	2.62	31	5.42	1	14.29
One	978	2.06	13	4.73	0	0.00
Two	5,846	1.48	70	3.36	0	0.00
Three	3,779	1.14	108	3.10	2	3.39
Four	375	0.76	18	2.33	0	0.00
Five	11	0.24	1	1.92	0	0.00
Six	7	3.27	0	0.00	0	NA

**Prior to COVID-19 hospitalization or end of follow-up time. NA: not applicable as the denominator was zero. SD: standard deviation.*

Individuals who received tixagevimab–cilgavimab had a 70% higher hazard of COVID-19 hospitalization compared to those who did not (adjusted HR 1.70; 95% CI 1.40–2.06). COVID-19 vaccination was associated with a reduced hazard of hospitalization in a dose-dependent manner. Compared to unvaccinated individuals, those who had received one to five doses of the vaccine had lower hazards, with the greatest protection seen in individuals who received five doses (adjusted HR 0.21; 95% CI 0.12–0.39), corresponding to a vaccine effectiveness of 78.58% (95% CI 61.30%–88.14%) (Table 2).

Table 2. Factors associated with time to COVID-19 hospitalization among chronic kidney disease patients in Thailand, 1 Aug 2022–30 May 2023.

Factor	Adjusted HR	95% CI
Tixagevimab–cilgavimab administration status		
Not received	Ref	
Received	1.70	1.40–2.06
Number of COVID-19 vaccine doses received*		
None	Ref	
One	0.77	0.72–0.83
Two	0.58	0.56–0.61
Three	0.45	0.43–0.47
Four	0.41	0.37–0.46
Five	0.21	0.12–0.39
Gender		
Female	Ref	
Male	1.23	1.20–1.27
Age group (years)		
12–59	Ref	
60–79	1.28	1.22–1.34
80–99	1.89	1.80–1.99
100 or more	2.95	2.06–4.24
Underlying disease		
Diabetes mellitus		
No	Ref	
Yes	1.66	1.60–1.72
Hypertension		
No	Ref	
Yes	1.22	1.17–1.26
Chronic lung disease		
No	Ref	
Yes	1.93	1.73–2.15
Human immunodeficiency virus (HIV)		
No	Ref	
Yes	0.63	0.35–1.14
Hepatic diseases		
No	Ref	
Yes	2.65	1.75–4.01
Cancer		
No	Ref	
Yes	1.74	1.46 – 2.07
History of dialysis		
No	Ref	
Yes	3.33	3.11 - 3.55

**Those receiving six doses of the vaccine were excluded due to a small sample size. Ref: reference group. HR: hazard ratio. CI: confidence interval.*

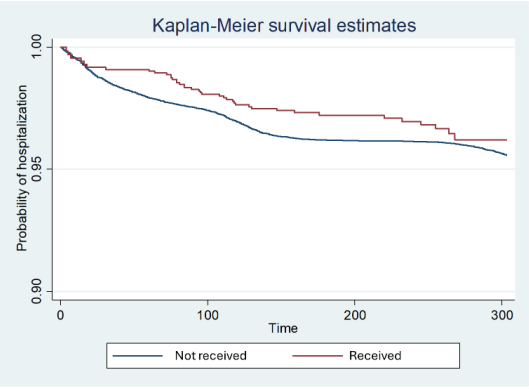
Stratified analysis revealed differing effects of tixagevimab–cilgavimab and COVID-19 vaccination between individuals with and without a history of dialysis. Among patients with a history of dialysis, the effectiveness of tixagevimab–cilgavimab against COVID-19 hospitalization was 18.15% (95% CI -12.82–40.62). Similarly, COVID-19 vaccination—ranging from one to four doses—was not significant, although all point estimates suggested a trend toward a reduced risk. In contrast, among patients without a history of dialysis, tixagevimab–cilgavimab administration was associated with a significantly increased hazard of COVID-19 hospitalization (adjusted HR 2.96; 95% CI 2.37–3.71). COVID-19 vaccination was significantly associated with a lower hazard, with stronger protection seen with increasing doses. The vaccine effectiveness ranged from 22.54% (95% CI 16.73–27.94) for one dose to 79.18% (95% CI 61.28–88.80) for five doses (Table 3).

Table 3. Adjusted hazard ratios of tixagevimab–cilgavimab and COVID-19 vaccine status against COVID-19 hospitalization among chronic kidney disease patients in Thailand stratified by history of dialysis, 1 Aug 2022–30 May 2023.*

Factor	Patients with a history of dialysis		Patients with no history of dialysis	
	Adjusted HR*	95% CI	Adjusted HR†	95% CI
Tixagevimab–cilgavimab administration status				
Did not receive	Ref		Ref	
Received	0.82	0.59–1.13	2.96	2.37–3.71
Number of COVID-19 vaccine doses received				
None	Ref		Ref	
One	0.89	0.69–1.15	0.77	0.72–0.83
Two	0.88	0.74–1.03	0.57	0.55–0.59
Three	0.87	0.73–1.04	0.43	0.41–0.45
Four	0.97	0.71–1.34	0.39	0.34–0.43
Five	0.36	0.05–2.51	0.21	0.11–0.39

**Those receiving six doses of the COVID-19 vaccine were excluded due to a limited sample size. †Adjusted for gender, age group, and underlying diseases (diabetes mellitus, hypertension, chronic lung disease, human immunodeficiency virus infection, hepatic disease, and cancer). Ref: reference group. HR: hazard ratio. CI: confidence interval.*

As shown in Figure 1, dialysis patients who received tixagevimab–cilgavimab, regardless of dosage, had a slightly higher probability of remaining free from COVID-19 hospitalization over time compared to those who did not. The survival curve for tixagevimab–cilgavimab status did not cross, indicating that the proportional hazards assumption of the Cox model was not violated (Figure 1).



Received: tixagevimab–cilgavimab administered at a dose of either 300 mg or 600 mg.

Figure 1. Kaplan–Meier survival curve of COVID-19 hospitalization among dialysis patients in Thailand stratified by tixagevimab–cilgavimab administration status, 1 Aug 2022–30 May 2023.

Discussion

The findings of our study showed that tixagevimab–cilgavimab did not reduce the hazard of COVID-19 hospitalization among Thai CKD patients during the late Omicron period. This contrasts with previous studies, such as the PROVENT trial and several observational cohorts, that demonstrated the effectiveness of tixagevimab–cilgavimab in preventing both COVID-19 infection and severity among high-risk populations, including patients with CKD, older adults, and immunocompromised individuals.[21–23] This might be explained by the difference in circulating SARS-CoV-2 variants. Previous studies were primarily conducted during the dominance of variants such as Alpha or Omicron BA.1, against which tixagevimab–cilgavimab retained strong neutralizing activity. Additionally, the clinical guidelines of the Thai healthcare system may have emphasized that the high-risk individuals should be given tixagevimab–cilgavimab, leading to a higher likelihood of hospitalization among this group compared to their lower-risk counterparts, who were encouraged to practice self-care.[19,20] Tixagevimab–cilgavimab was also specifically administered to immunocompromised individuals, particularly those with CKD or ESKD—

representing the highest-risk subgroup. This distinction may explain why tixagevimab–cilgavimab recipients exhibited a higher hospitalization rate.

Our study findings contrast with a retro-prospective cohort study conducted in Thailand in 2024 that followed high-risk individuals, including CKD patients. That study found a limited protective effect of tixagevimab–cilgavimab against COVID-19 outcomes.[24] A reason for the difference of effect may be the dosing approach: while that study focused exclusively on patients who received the updated 600 mg dose, our study combined recipients of both 300 mg and 600 mg, reflecting the transitional dosing guidelines in place during the study period. It is possible that the lower dose provided insufficient protection, particularly during a time when immune-evasive variants were circulating and might have further compromised the effectiveness of tixagevimab–cilgavimab.

Our findings indicated that tixagevimab–cilgavimab was associated with a lower hazard of COVID-19 hospitalization among dialysis patients, with a vaccine effectiveness estimate of 18.15% (95% CI -12.82–40.62), although without statistical significance. This contrasts with a previous study conducted in Thailand among dialysis patients enrolled between November 2022 and February 2023, with a follow-up through September 2023, which reported a statistically significant reduction in hospitalization risk associated with tixagevimab–cilgavimab use (incidence rate ratio 0.094, 95% CI 0.002–0.779).[25] This corresponds to an approximate 91% lower hospitalization rate in that study. Notably, both studies were conducted during a period when similar Omicron variants were circulating, such as XBB.1.5 and XBB.1.6.[26] However, that study focused exclusively on breakthrough symptomatic COVID-19 cases, whereas our study included all hospitalized cases, regardless of symptom status. It is possible that some individuals in our cohort were admitted to hospital as a precautionary measure due to their high-risk profile, even if they were asymptomatic or had mild symptoms, which conformed to the Thai clinical practice guideline discussed earlier.

Limitations

Several limitations should be considered when interpreting the results. The major limitation of our study is confounding by indication. Tixagevimab–cilgavimab was preferentially administered to patients perceived by clinicians to be at a particularly high risk of severe COVID-19 outcomes, such as those with advanced comorbidities or greater clinical frailty, resulting in an underestimation of the drug's effectiveness, pulling the observed association toward the null value. Although we adjusted for age, gender, dialysis status, vaccination status, and major comorbidities, residual confounding from unmeasured factors including functional status, prior SARS-CoV-2 infection, or health-seeking behavior may have remained. Furthermore, nondifferential misclassification of both tixagevimab–cilgavimab and COVID-19 hospitalization status may have occurred due to errors in diagnostic coding for COVID-19 hospitalizations or delays in coding drugs within national registries. Since these errors are unlikely to differ systematically by hospitalization status, such misclassification would dilute the observed associations, resulting in an underestimation of the study drug's effectiveness.

Despite these limitations, our findings remain trustworthy. Since the primary sources of bias—confounding by indication and misclassification—both tend to underestimate the drug's effectiveness, our reported effectiveness represents a conservative estimate of what tixagevimab–cilgavimab can achieve in practice. In addition, the use of two nationwide databases provided a large sample size, enhancing statistical power to detect differences in hospitalization risk and reducing the influence of random errors.

Public Health Recommendations

Prophylactic strategies for immunocompromised populations, particularly CKD patients and those receiving dialysis, should be regularly reassessed in response to evolving SARS-CoV-2 variants. As monoclonal antibodies such as tixagevimab–cilgavimab may have reduced neutralizing activity against emerging variants, national clinical guidelines should incorporate up-to-date evidence on variant-specific effectiveness. COVID-19 vaccination should remain the cornerstone of prevention for CKD patients, as our findings demonstrated strong protection from multiple vaccine doses; therefore, maintaining high vaccine coverage and booster uptake among CKD and dialysis patients should continue to be prioritized within the Thai healthcare system. In addition, prophylactic monoclonal antibody use should be targeted toward the highest-risk groups, particularly patients undergoing dialysis or those with severe immunocompromise, rather than applying a uniform approach across all CKD patients. Strengthening the use of national health databases to monitor the real-world effectiveness of preventive interventions is also important to support timely policy adjustments. Further research is needed to evaluate the

effectiveness of updated prophylactic agents and dosing strategies in the context of emerging SARS-CoV-2 variants, particularly among patients with advanced kidney disease who may have limited vaccine-induced immunity.

Conclusion

Tixagevimab–cilgavimab prophylaxis did not significantly reduce COVID-19 hospitalizations among CKD patients overall during the late-Omicron era. However, among dialysis patients, there was a non-significant protective effect, with an estimated effectiveness of 18.15% (95% CI -12.82 to 40.62). While tixagevimab–cilgavimab showed promise in clinical trials and other studies, its real-world impact in our CKD cohort was limited. These findings suggest that a one-size-fits-all approach to pre-exposure prophylaxis may not be appropriate for heterogeneous and immunocompromised populations. A more targeted, variant-responsive strategy is essential. Continued surveillance and further research are critical to ensure optimal protection for high-risk kidney disease patients, particularly those on dialysis, who may have limited vaccine-induced immunity.

Acknowledgements

We would like to thank the National Health Security Office for providing access to the data and supporting information used in this study. In addition, we extend our sincere thanks to Dr. Somchai Peeraprakorn for his valuable recommendations during the proposal development and for the opportunity to carry out this study.

Authors Contributions

Natthaprang Nittayasoot: Conceptualization, methodology, formal analysis, writing—original draft. **Panithee Thammawijaya:** Conceptualization, methodology, writing—review & editing, supervision. **Suphanat Wongsanuphat:** Methodology, formal analysis, data curation. **Rapeepong Suphanchaimat:** Methodology, formal analysis, writing—review & editing. **Supansa Suriya:** Data curation. **Chakkarat Pitayawonganon:** Conceptualization, writing—review & editing, supervision.

Ethical Approval

This study was reviewed and approved by the Institute for the Development of Human Research Protections (IHRP) Ethics Committee, Ministry of Public Health, Nonthaburi, Thailand on 14 Sep 2023 (Approval No. IHRP 104–2566).

Informed Consent

Patient consent was waived because this study used secondary data from national health databases, which involved no direct contact with participants. All individual information was treated anonymously and kept confidential. The waiver of informed consent was approved by the Institute for the IHRP Ethics Committee.

Data Availability

The data that support the findings of this study are available from the Ministry of Public Health, Thailand, but restrictions apply to its availability, which were used under license for the current study and are not publicly available. Data access requests must be made directly to the Ministry of Public Health, Thailand, in accordance with their data access policies.

Conflicts of Interest

The author declares no conflicts of interest.

Funding Support

This study received financial support from AstraZeneca (Thailand) Company Limited (Grant number E-520777 to the Department of Disease Control Foundation, Thailand). The funder had no role in the study design, data collection, data analysis, manuscript preparation, or decision to publish.

Declaration of Generative-AI and AI-assisted Technologies in the Writing Process

During the preparation of this work, the authors used ChatGPT to correct grammatical errors and to improve the clarity and flow of the manuscript. The content produced by this tool was reviewed, edited, and validated by the authors.

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