Original Article

JHSMR Journal of Health Science and Medical Research

Effectiveness of Tixagevimab/cilgavimab for SARS-CoV-2 Pre-exposure Prophylaxis in Hemodialysis Patients: A Retrospective Cohort Study from a Tertiary Hospital in Thailand

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Received 9 June 2025 ● Revised 29 June 2025 ● Accepted 9 July 2025 ● Published online 22 November 2025

Abstract:

Objectives: To evaluate the effectiveness and safety of Tixagevimab/cilgavimab as pre-exposure prophylaxis against coronavirus disease 2019 (COVID-19) in patients with end-stage kidney disease (ESKD) undergoing hemodialysis during the Omicron surge.

Material and Methods: This retrospective cohort study was conducted at Trang Hospital, Thailand, from September 2022 to March 2024. Adult ESKD patients receiving maintenance hemodialysis were included. Patients who received Tixagevimab/cilgavimab were compared with those who did not. The primary outcomes included asymptomatic and symptomatic COVID-19 infection, COVID-19-related hospitalization, and mortality over 18 months. Kaplan-Meier curves and Cox proportional hazards models were used to assess outcomes. The secondary outcome was adverse events after administration.

Results: Among 207 patients (40 intervention, 167 controls), incidence rates of symptomatic infection (0.261 vs. 1.432 per 1,000 person-days) and COVID-19-related hospitalization (0.047 vs. 0.236 per 1,000 person-days) were lower in the intervention group. No COVID-19-related deaths occurred. Tixagevimab/cilgavimab significantly reduced the risk of symptomatic infection (adjusted hazard ratio 0.22; 95% CI, 0.087–0.545). Adverse events were infrequent and mild.

Conclusion: Tixagevimab/cilgavimab was associated with a significant reduction in symptomatic COVID-19 infection among hemodialysis patients during the Omicron wave. Although hospitalization rates were lower in the intervention group, the difference was not statistically significant. The treatment was well tolerated and may provide preventive benefits for high-risk ESKD populations.

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J Health Sci Med Res 2026;44(3):e20251287
doi: 10.31584/jhsmr.20251287
www.jhsmr.org

Keywords: COVID-19, end-stage kidney disease, hemodialysis, pre-exposure prophylaxis, Tixagevimab/cilgavimab

Introduction

Coronavirus disease 2019 (COVID-19), first identified in December 2019 in Wuhan, China, evolved into a global pandemic. The disease, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), can lead to acute respiratory distress syndrome and multiorgan failure in severe cases[1,2]. As of December 2024, the World Health Organization (WHO) reported over 776.8 million confirmed COVID-19 cases and more than 7 million deaths globally[3].

Vaccination remains the primary strategy for preventing severe outcomes associated with COVID-19 infection[4]. However, certain populations, including the elderly, obese individuals, and those with multiple comorbidities, are at an increased risk of developing severe symptoms and requiring intensive care unit admission[5,6]. Among these high-risk groups, patients with end-stage kidney disease (ESKD) undergoing maintenance hemodialysis are particularly vulnerable[7]. These patients face a significantly higher risk of severe symptom progression and mortality, largely due to impaired immunity and frequent exposure to healthcare environments.

Despite the administration of booster doses, vaccine-induced immunity in dialysis patients remains suboptimal and declines over time, particularly with the emergence of new variants[8,9]. Multiple studies have demonstrated that individuals with ESKD often exhibit inadequate humoral responses to COVID-19 vaccines[10,11], underscoring the need for additional preventive strategies tailored to this immunologically compromised population.

Long-acting monoclonal antibodies (LAABs), such as the combination of Tixagevimab and Cilgavimab (Evusheld™, AstraZeneca), have emerged as a promising option for pre-exposure prophylaxis in immunocompromised individuals. These agents bind to the spike protein of SARS-CoV-2 and its variants of concern[12], providing passive immunity against infection. The United States Food and Drug Administration authorized the emergency use of Tixagevimab/cilgavimab as pre-exposure prophylaxis against COVID-19 for adults and pediatric patients (≥12 years of age and weighing ≥40 kg) with moderate or severe immune compromise who are unlikely to mount an adequate response to vaccination[13].

Tixagevimab/cilgavimab has been shown to be effective in reducing the risk of severe symptoms and mortality among unvaccinated adults[14], and has shown a significant protective effect in vaccinated solid organ transplant recipients during the Omicron wave[15]. Preliminary data from ESKD patients on hemodialysis receiving Tixagevimab/cilgavimab reported reduced ICU admission and mortality; however, the follow-up period in these studies was limited to only 6 months[16].

Given the limited data on long-term outcomes, this study aimed to evaluate the effectiveness of Tixagevimab/cilgavimab in preventing asymptomatic and symptomatic COVID-19 infections, hospitalization, and mortality over 18 months during the Omicron surge in ESKD undergoing hemodialysis at a tertiary hospital in Thailand.

Material and Methods

Study design and setting

This retrospective cohort study was conducted at Trang Hospital, a tertiary care center in Thailand. Data were extracted from electronic medical records (EMRs) between September 25, 2022 and March 25, 2024, during the predominance of the SARS-CoV-2 Omicron variant. The study protocol was approved by the Medical Ethics Committee of Trang Hospital (Approval ID 002/01-2568).

Study population

Eligible patients were adults aged ≥18 years with end-stage kidney disease (ESKD) undergoing maintenance in-center hemodialysis. Exclusion criteria applied at baseline included 1) a documented COVID-19 infection within the preceding 3 months, 2) life expectancy less than 6 months, 3) pregnancy or breastfeeding, 4) loss to follow-up, and 5) death unrelated to COVID-19.

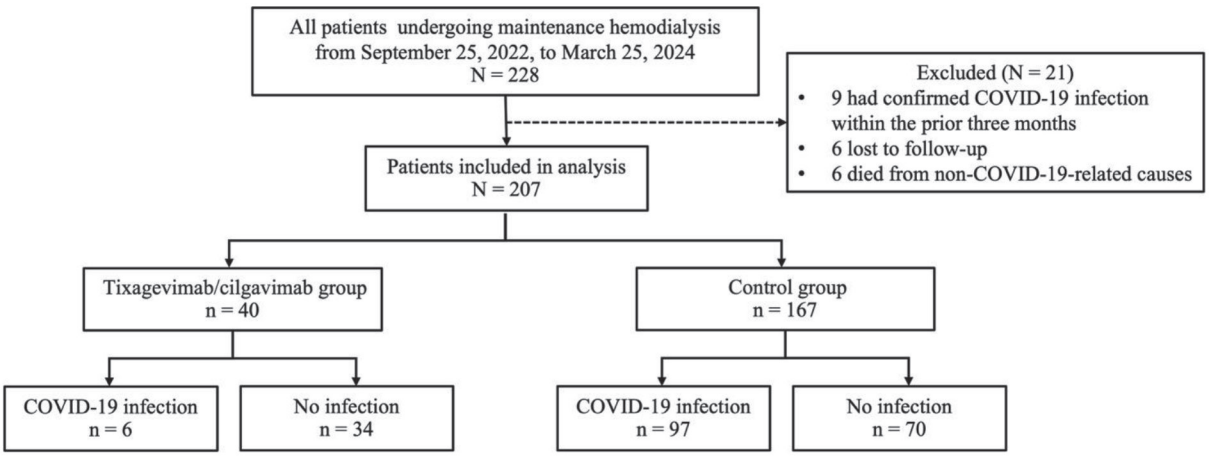
Patients were categorized into 2 cohorts. The intervention cohorts comprised those who received a single 300 mg intramuscular dose of Tixagevimab/cilgavimab, in accordance with the U.S. FDA emergency use authorization[13] and guidelines issued by the Thai Ministry of Public Health[17]. The control cohort included hemodialysis patients who did not receive Tixagevimab/cilgavimab. All patients meeting the inclusion criteria were included in the analysis (Figure 1).

Data collection

Data extracted from EMRs included demographic and clinical characteristics, dialysis treatment profiles, comorbidities, COVID-19 vaccination history, use of immunosuppressive agents (e.g., prednisolone >15 mg/days or equivalent, calcineurin inhibitors, mTOR inhibitors, and cytotoxic agents), and timing and severity of COVID-19 infection. As per institutional policy during the study period, all patients underwent routine COVID-19 screening with either rapid antigen test kit (ATK) or reverse transcription-polymerase chain reaction (RT-PCR) prior to a hemodialysis session. All test results were documented in the EMRs. Adverse events following monoclonal antibody injection were also recorded using routine EMR documentation and follow-up telephone interviews within 30 days post-administration.

Outcomes

The primary outcomes were time-to-event outcomes, measured from the date of Tixagevimab/cilgavimab administration (day 0) to the occurrence of one of the following COVID-19-related events: 1) asymptomatic COVID-19 infection, defined as a positive ATK or RT-PCR results in the absence of clinical symptoms; 2) symptomatic COVID-19 infection, defined as a positive ATK or RT-



COVID-19=coronavirus disease 2019

Figure 1 Study flow diagram

PCR results with clinical symptoms; 3) COVID-19-related hospitalization, defined as hospital admission primarily due to COVID-19 complications; and 4) COVID-19-related mortality, defined as death occurring within 28 days following a COVID-19 diagnosis and hospitalization. These outcomes were monitored over an 18-month (540-day) follow-up period. The secondary outcome was the prevalence of adverse events within 30 days of Tixagevimab/cilgavimab administration.

Statistical analysis

Statistical analyses were performed using STATA version 17.0 (StataCorp LLC, College Station, TX, USA)[18]. Categorical variables were summarized as frequencies and percentages. Continuous variables were reported as means with standard deviations (S.D.) if normally distributed, or as medians with interquartile range (IQR) if not. Between-group comparisons were performed using chi-square tests for categorical variables. For continuous variables, independent t-tests were used when data were normally distributed, while the Mann-Whitney U test was employed for non-normally distributed data

Kaplan-Meier survival curves were generated to compare time-to-event outcomes between the intervention and control groups, with statistical differences assessed using the log-rank test. Cox proportional hazards models were used to estimate adjusted hazard ratios (aHRs) for COVID-19-related outcomes, adjusting for potential confounders including age, sex, diabetes mellitus (DM), number of COVID-19 vaccine doses received, and use of immunosuppressive medications. The proportional hazards assumption for the Cox models was assessed using Schoenfeld residuals, with no significant violations detected (p-value>0.05). A p-value of <0.05 was considered statistically significant.

Results

Patient characteristics

A total of 207 patients undergoing maintenance hemodialysis were included, with 40 (19.3%) receiving Tixagevimab/cilgavimab and 167 (80.7%) serving as controls. The overall mean age was 61.23±14.07 years, and 53.6% were male. Most baseline characteristics were generally comparable between the 2 groups. However, statistically significant differences were observed in the type of vascular access used for hemodialysis (p-value=0.036), the use of immunosuppressive agents (p-value=0.043), and the prevalence of cerebrovascular disease (p-value=0.005) (Table 1). Regarding vaccination, most patients (40.1%) had received 2 doses of the COVID-19 vaccine (Table 2).

Incidence of COVID-19 outcomes

Over the 18-month follow-up period, no asymptomatic infections were detected in the Tixagevimab/cilgavimab group, while 2 cases occurred in the control group (incidence rate: 0.023 per 1,000 person-days). Symptomatic infections occurred in 5 patients in the intervention group (0.261 per 1,000 person-days) and 76 in the control group (1.432 per 1,000 person-days). COVID–19–related hospitalization occurred in 1 patient receiving Tixagevimab/cilgavimab (0.047 per 1,000 person-days) and 19 patients in the control group (0.236 per 1,000 person-days). No COVID–19–related deaths were recorded in either group during the study period (Table 3).

Time-to-event outcomes

Kaplan–Meier survival curves revealed no statistically significant difference in time to asymptomatic COVID-19 infection between the intervention and control groups (log-rank p-value=0.488). However, the time to symptomatic infection was significantly longer in the Tixagevimab/cilgavimab group (log-rank p-value<0.001). For COVID-19–

Table 1 Demographic and clinical characteristics

Characteristic	Total (n=207)	Received Tixagevimab/ cilgavimab (n=40)	Control (n=167)	p-value
Sex, n (%)				
Male	111 (53.6)	21 (52.5)	90 (53.9)	0.874[a]
Female	96 (46.4)	19 (47.5)	77 (46.1)	
Age (year), mean±S.D.	61.23±14.07	60.48±15.95	61.41±13.63	0.706[b]
Weight (kg), median (IQR)	59.0 (51.0-69.0)	61.0 (54.5-75.5)	59.0 (51.0-67.0)	0.091[d]
Height (m), mean±S.D.	1.60±0.09	1.61±0.09	1.60±0.09	0.348[b]
BMI (kg/m^2), median (IQR)	23.1 (20.3-26.0)	23.8 (20.9-26.6)	22.6 (20.3-26.0)	0.269[d]
Type of vascular access for hemodialysis, n (%)				
Arteriovenous Fistula	204 (98.5)	38 (95.0)	166 (99.4)	0.036[a*]
Permanent Catheter	3 (1.4)	2 (5.0)	1 (0.6)	
Frequency of hemodialysis, n (%)				
2 times/week	138 (66.7)	29 (72.5)	109 (65.3)	0.384[a]
3 times/week	69 (33.3)	11 (27.5)	58 (34.7)	
Use of immunosuppressive agents, n (%)				
No,	195 (94.2)	35 (87.5)	160 (95.8)	0.043[a*]
Yes,	12 (5.8)	5 (12.5)	7 (4.2)	
Comorbidity diseases, n (%)				
Hypertension	205 (99.0)	39 (97.5)	166 (99.4)	0.350[c]
Diabetic mellitus	72 (34.8)	12 (30.0)	60 (35.9)	0.480[a]
Cerebrovascular disease	58 (28.0)	4 (10.0)	54 (32.3)	0.005[a*]
Chronic respiratory disease	10 (4.8)	3 (7.5)	7 (4.2)	0.411[c]
Cardiovascular disease	43 (20.8)	8 (20.0)	35 (21.0)	0.893[a]
Hepatic dysfunction	4 (1.9)	1 (2.5)	3 (1.8)	0.579[c]
Hematologic disease	206 (99.5)	40 (100.0)	166 (99.4)	1.000[c]
Malignancy [solid]	6 (2.9)	1 (2.5)	5 (3.0)	1.000[c]
Malignancy [Hematologic]	1 (0.5)	0 (0.0)	1 (0.6)	1.000[c]
Prior organ transplantation	2 (1.0)	0 (0.0)	2 (1.2)	1.000[c]
HIV infection	0 (0.0)	0 (0.0)	0 (0.0)	-

BMI=Body mass index, [a] =Chi-square test, [b]=Independent t-test, [c] =Fisher's exact test, [d]=Mann-Whitney U test, [*]p-value<0.05
n=number of patients, S.D.=standard deviation, kg=kilogram, m2=square metre, IQR=interquartile range

related hospitalization, a numerical difference favoring the intervention group was noted, although it did not reach statistical significance (log-rank p-value=0.089) (Figure 1). Figure 2 Kaplan–Meier survival curves for: (a) asymptomatic infection, (b) symptomatic infection, and (c) hospitalization.

Post-hoc subgroup analysis

The overall hazard ratio (aHR) for symptomatic infection in the Tixagevimab/cilgavimab group was 0.22 (95% CI: 0.087–0.545). Subgroup analyses, the aHR was 0.18 (95% CI: 0.056–0.576) in patients aged ≤75 years, 0.20 (95% CI: 0.062–0.659) in females, and 0.17 (95% CI: 0.053–0.552) in patients without diabetes. Among those who had never used immunosuppressive agents, the aHR was 0.18 (95% CI: 0.068–0.518), while among those who received 0–2 doses of COVID-19 vaccines, the HR was 0.14 (95% CI: 0.035–0.594). No statistically significant interactions were detected between subgroups (Table 4).

Table 2 History of COVID-19 vaccination and interval between COVID-19 vaccination and tixagevimab/cilgavimab (days)

Variables	Total (n=207)	Received tixagevimab/cilgavimab (n=40)	Control (n=167)	p-value
Number of vaccine doses received prior to baseline, n (%)				
1 dose	7 (3.4)	1 (2.5)	6 (3.6)	1.000[b]
2 doses	83 (40.1)	20 (50.0)	63 (37.7)	0.155[a]
3 doses	52 (25.1)	18 (45.0)	34 (20.4)	0.001[a]
4 doses	9 (4.3)	1 (2.5)	8 (4.8)	1.000[b]
Type of vaccine received, n (%)				
Sinopharm BIBP	38 (18.4)	13 (32.5)	25 (15.0)	0.010[a]
Sinovac (CoronaVac)	61 (29.5)	16 (40.0)	45 (26.9)	0.104[a]
Oxford AztraZeneca (Covishield)	87 (42.0)	14 (35.0)	73 (43.7)	0.316[a]
Moderna (Spikevax)	10 (4.8)	3 (7.5)	7 (4.2)	0.411[b]
Pfizer-BioNTech (Comirnaty)	54 (26.1)	15 (37.5)	39 (23.3)	0.067[a]

[a]=Chi-square test, [b]=Fisher's exact test, COVID-19=coronavirus disease 2019, BIBP=Beijing Institute of Biological Products Co., Ltd, n=number of patients

Table 3 Incidence of COVID-19 outcomes in the Tixagevimab/cilgavimab and control groups over 18 months of follow-up

Outcomes	Tixagevimab/cilgavimab (n=40)			Control (n=167)		
	Events	Person-days	Incidence rate (per 1,000 person-days, 95% CI)	Events	Person-days	Incidence rate (per 1,000 person-days, 95% CI)
Asymptomatic infection	0	21, 600	0	2	88, 675	0.023 (0.006-0.09)
Symptomatic infection	5	19, 153	0.261 (0.032-0.490)	76	53, 069	1.432 (1.111-1.753)
Hospitalization	1	21, 142	0.047 (0.007-0.336)	19	80, 642	0.236 (0.150-0.369)
Death	0	21, 600	0	0	90, 180	0

COVID-19=coronavirus disease 2019, CI=confidence interval, n=number of patients

Adverse events

Among the 40 patients who received Tixagevimab/cilgavimab, adverse events were reported in 6 patients (15%). Fatigue was the most commonly reported symptom (5.0%), followed by local injection-site pain, fever, headache, and myalgia; each was reported by 1 patient (2.5%). No serious adverse events were recorded. A total of 34 patients (85.0%) reported no adverse effects following administration (Table 5).

Discussion

This retrospective cohort study evaluated the effectiveness and safety of Tixagevimab/cilgavimab as pre-exposure prophylaxis in preventing breakthrough of COVID-19 in patients with end-stage kidney disease (ESKD) undergoing hemodialysis during the Omicron variant surge at a tertiary hospital in Thailand.

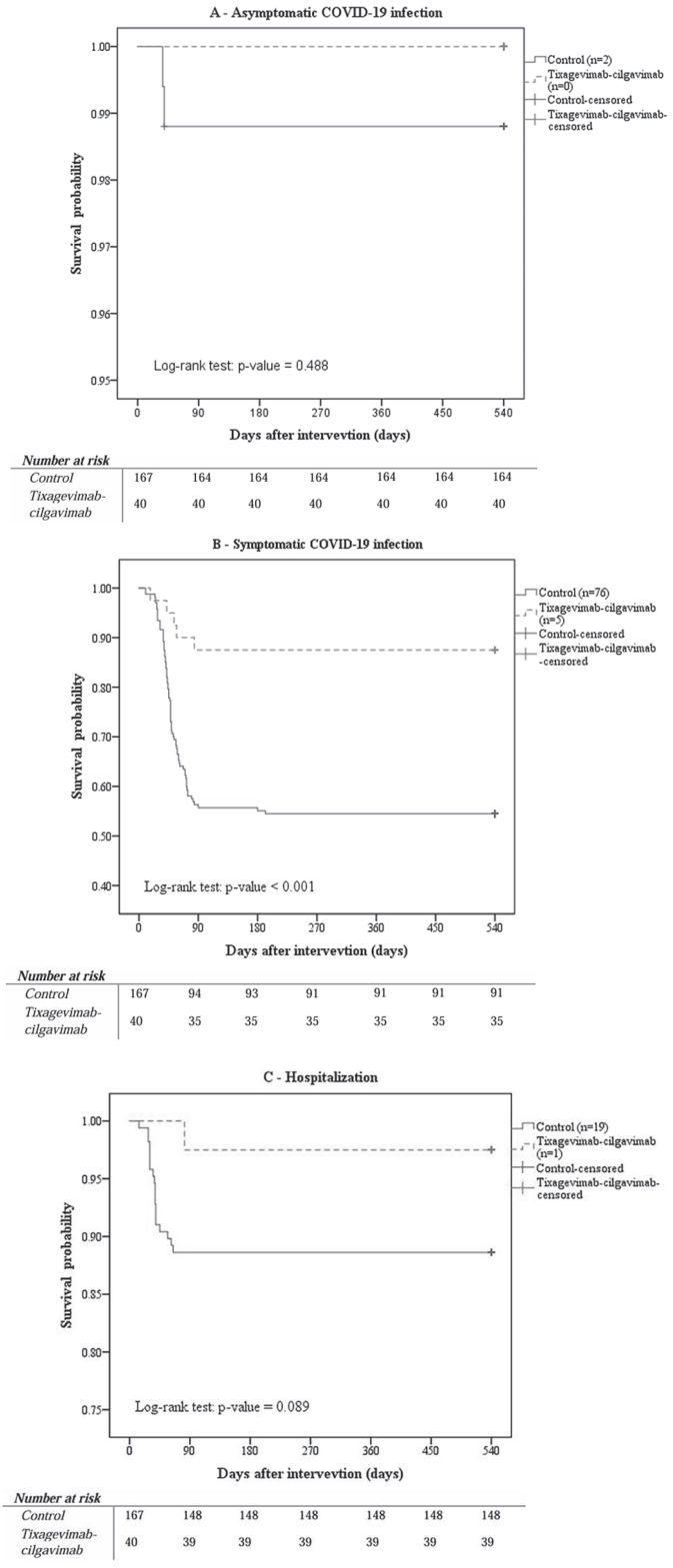


Figure 2 Kaplan–Meier survival curves for: (A) asymptomatic Infection, (B) symptomatic Infection and (C) hospitalization

Table 4 Post-hoc subgroup analysis for symptomatic COVID-19 infection

Factor	n (Tixagevimab/cilgavimab)	HR (95% CI)[a]	Interaction (p-value)
Overall	40	0.22 (0.087-0.545)	
Age (years)			
≤75	31	0.18 (0.056-0.576)*	0.527
>75	9	0.33 (0.073-1.499)	
Sex			
Male	21	0.25 (0.059-1.036)	0.831
female	19	0.20 (0.062-0.659)*	
Diabetes mellitus			
Yes	12	0.37 (0.086-1.567)	0.418
No	28	0.17 (0.053-0.552)*	
Immunosuppressive therapy			
Yes	5	0.72 (0.065-8.094)	0.311
No	35	0.18 (0.068-0.518)*	
COVID-19 vaccine doses			
≤2 doses	21	0.14 (0.035-0.594)*	0.368
>2 doses	19	0.34 (0.099-1.173)	

[a]Cox proportional model adjusted for age, gender, diabetes mellitus (DM), number of COVID-19 vaccine, receiving immune suppressant, *p-value<0.05, COVID-19=coronavirus disease 2019, CI=confidence interval, HR=hazard ratio

Table 5 Adverse events following Tixagevimab/cilgavimab administration

Adverse event	Tixagevimab/cilgavimab (n=40)
Fatigue	2 (5.00)
Injection-site pain	1 (2.50)
Fever	1 (2.50)
Headache	1 (2.50)
Myalgia	1 (2.50)
No Adverse events	34 (85.00)

n=number of patients

Our findings demonstrated that Tixagevimab/cilgavimab was associated with lower incidence rates of asymptomatic infection, symptomatic infection, and COVID-19-related hospitalization compared with the control group. Kaplan-Meier survival analysis revealed a statistically significant difference in time to symptomatic COVID-19 infection between the two groups. These results are consistent with earlier studies during the Alpha, BA.1, and BA.2.75 waves, which reported favorable outcomes following Tixagevimab/cilgavimab administration. Those studies also showed significant increases in neutralizing antibody titers 1 month after injection, with persistence for more than 6 months[16].

Notably, no COVID-19-related deaths occurred in either group throughout the follow-up period. This may reflect the high vaccination coverage among the Thai population, which has been shown to significantly reduce COVID-19 mortality, especially in high-risk groups such as patients with kidney disease[19,20].

The 18-month follow-up period in this study exceeds that of prior reports, which typically followed patients for 3 to 6 months[16,21]. This extended observation aligned with evidence suggesting that SARS-CoV-2 neutralizing monoclonal antibodies may persist in the bloodstream for up to 12 months[12]. Importantly, our study period captured the emergence of immune-evasive Omicron subvariants XBB.1.5 and XBB.1.6[22], offering insights into the sustained

protective effect of Tixagevimab/cilgavimab against evolving viral strains.

Cox proportional hazards analysis, adjusted for potential confounders, confirmed a significantly reduced risk of symptomatic COVID-19 infection in the intervention group. Notably, the observed hazard ratio (HR) was lower than the previous real-world study among immunocompromised populations, which found HRs of approximately 0.7[23]. This difference may reflect variations in patient characteristics, circulating variants, or follow-up duration. Although this analysis included all eligible patient populations, post hoc power calculations using the Schoenfeld formula (assuming a true HR of 0.7) indicated that the study may have been slightly underpowered (power<80%). This should be considered when interpreting the precision of both the overall and subgroup estimates.

In subgroup analyses, greater protective effects were observed in patients aged ≤75 years, without diabetes, and not on immunosuppressive therapy. These trends likely reflect age-related immune decline (immunosenescence) and altered antibody kinetics in older or comorbid individuals. Such findings are consistent with the literature showing reduced vaccine responsiveness in these subgroups[24,25].

Notably, protection was also observed among those with 1 or 2 vaccine doses, a finding that contrasts with existing evidence supporting greater protection from 3 or more doses[26,27]. We suspect this may result from small subgroup sample sizes or unmeasured confounding. Importantly, interaction tests yielded non-significant p-values, indicating no statistical evidence of differential treatment effects across subgroups. According to the best statistical guidance, non-significant interaction results are better interpreted as evidence of consistent treatment effects rather than heterogeneity, thereby supporting the generalizability of the overall findings. These subgroup results should therefore be regarded as exploratory and hypothesis-generating.

Regarding safety, Tixagevimab/cilgavimab was well tolerated. Adverse events were infrequent and mild, including local injection-site pain, fever, headache, and fatigue. These safety profiles align with prior studies on long-acting monoclonal antibodies in patients with compromised immune systems[28-29].

This study has several limitations. First, the retrospective cohort design limits the ability to fully control for confounding. Although we considered applying propensity score methods, these approaches were not feasible due to the modest sample size, which would have further reduced statistical power and precluded subgroup analyses. Instead, we used multivariable Cox regression to adjust for key confounders, preserving analytical power while acknowledging the limitations compared with randomized controlled trials (RCTs). Second, being a single-center study, our limited sample size may restrict the generalizability of the findings and reduce statistical power. Finally, this study did not include anti-SARS-CoV-2 IgG levels, as routine serological testing was not part of hospital policy. Consequently, we could not assess baseline immunity or monitor antibody responses after administration, which may limit the interpretation of Tixagevimab/cilgavimab's immunologic effect.

Nonetheless, this study has several strengths, including its conduct during a critical Omicron variant outbreak, the extended 18-month follow-up period, and the utilization of real-world data from a large regional hospital setting in Thailand. The adjustment for key confounders in time-to-event analyses further enhances the reliability of the findings.

Future studies should prioritize prospective designs, preferably RCTs, to validate these findings. If RCTs are not feasible, large-scale observational methods employing propensity score matching are recommended. Additionally, expanding the sample size through multicenter collaborations could enhance statistical power and improve

the generalizability of findings. To further support policy-level decision-making, future research should also consider incorporating cost-effectiveness analyses to evaluate the economic value of LAAB in high-risk populations.

Conclusion

This retrospective cohort study found that Tixagevimab/cilgavimab significantly reduced the risk of symptomatic COVID-19 infection in patients with ESKD undergoing hemodialysis during the Omicron wave of the COVID-19 pandemic. Although a trend toward reduced COVID-19–related hospitalization was observed, it did not reach statistical significance. The drug therapy was well tolerated and may serve as a useful preventive option in immunocompromised dialysis populations.

Acknowledgement

We gratefully acknowledge the director and staff of Trang Hospital for their support in providing data and necessary facilities, which greatly contributed to the success of this study.

Conflict of interest

The authors declare no conflicts of interest.

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