

# Correlation Analysis of the Timing of Administration of Paxlovid on the Prognosis of Elderly Patients Infected with the Novel Omicron Variant

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**Received Date:** March 20, 2026 | **Accepted Date:** April 17, 2026 | **Published Date:** May 04, 2026

**Citation:** Yanyu Pei, Ying Gu, (2026), Correlation Analysis of the Timing of Administration of Paxlovid on the Prognosis of Elderly Patients Infected with the Novel Omicron Variant, *International Journal of Clinical Case Reports and Reviews*, 35(4); DOI:10.31579/2690-4861/1075

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## Abstract:

**Background:** To explore the effect of the timing of administration of Paxlovid (Nirmatrelvir/Ritonavir) on the prognosis of elderly patients infected with the Omicron variant.

**Materials and Methods:** This retrospective study included 125 elderly patients with COVID-19 admitted to our hospital from May 1, 2023 to April 30, 2024 as the research subjects. Among them, 57 patients initiated Paxlovid treatment  $\leq 5$  days after symptoms appeared (Treatment Group 1), and 68 patients initiated Paxlovid treatment  $> 5$  days after symptoms appeared (Treatment Group 2). We compared the all-cause mortality rate, treatment efficacy, clinical indicators, inflammation-related indicators, immune-related indicators, ferritin, and D-dimer levels between the two groups.

**Results:** There were no statistically significant differences in all-cause mortality rate (8.77% vs 17.65%) and treatment efficacy rate (91.23% vs 80.88%) between Treatment Group 1 and Treatment Group 2 ( $P > 0.05$ ). Compared with Treatment Group 2, patients in Treatment Group 1 had significantly shorter time to nucleic acid negative conversion and total hospitalization time ( $P < 0.05$ ). The levels of CRP, ESR, and PCT in Treatment Group 1 were significantly lower than those in Treatment Group 2 after 5 days of medication and at discharge ( $P < 0.05$ ). The average levels of NLR and IL-6 in patients in Treatment Group 1 were significantly lower than those in Treatment Group 2 after 5 days of medication and discharge ( $P < 0.05$ ). The serum ferritin and D-dimer levels of patients in Treatment Group 1 were significantly lower than those in Treatment Group 2 after 5 days of medication and discharge ( $P < 0.05$ ).

**Conclusion:** In elderly patients infected with the Omicron variant, the use of Paxlovid when initiated within  $\leq 5$  days of symptom onset did not change all-cause mortality and treatment efficacy, but was when initiated  $> 5$  days after symptom onset in improving clinical progression, reducing inflammatory response, and lowering related risk indicators.

**Key words:** omicron; elderly patients; nirmatrelvir; ritonavir; timing of medication; prognosis

## Introduction

Since the outbreak of the coronavirus disease 2019 (COVID-19) in late 2019, the disease has rapidly spread worldwide, causing significant impacts on human health and socioeconomic conditions. Over time, the SARS-CoV-2 virus has undergone continuous mutations, with the Omicron variant emerging as one of the predominant strains. This variant is characterized by rapid transmission and strong concealment, posing substantial challenges to epidemic control [1-2]. Elderly individuals, due to declining physical functions and weakened immunity, often have multiple chronic underlying conditions such as cardiovascular diseases, diabetes, and chronic pulmonary diseases, making them a high-risk

population for severe disease progression and mortality following SARS-CoV-2 infection. Paxlovid is an oral small-molecule antiviral agent composed of nirmatrelvir and ritonavir. Nirmatrelvir inhibits the activity of enzymes required for SARS-CoV-2 replication, thereby suppressing viral replication, while ritonavir slows the metabolism or degradation of nirmatrelvir to prolong its therapeutic duration [3-4]. Studies [5]. have demonstrated that Paxlovid exhibits certain efficacy in treating mild to moderate COVID-19 patients with high-risk factors for progression to severe disease, reducing the risk of hospitalization or death. However, there is limited research on the impact of the timing of Paxlovid administration on the prognosis of elderly patients infected with the Omicron variant, and this remains controversial. This study aims to

investigate the impact of Paxlovid on the prognosis of elderly patients infected with the Omicron variant under different administration timing, providing a scientific basis for clinical treatment. The specific findings are as follows:

## Materials and Methods:

### 1. General Information

This study employed a retrospective research method, selecting elderly COVID-19 patients hospitalized in our hospital from May 1, 2023, to April 30, 2024 as the study subjects. A total of 125 patients were enrolled, including 69 males and 56 females; the age range was 65–97 years, with a median age of 76 years and a mean age of  $(75.89 \pm 5.17)$  years. Inclusion criteria: ① Presence of clinical manifestations related to SARS-CoV-2 infection. ② Possession of one or more of the following etiological or serological test results: positive SARS-CoV-2 nucleic acid test; positive SARS-CoV-2 antigen test; positive SARS-CoV-2 isolation and culture; or recovery-phase SARS-CoV-2-specific IgG antibody levels elevated to four times or more than those in the acute phase. ③ Age  $\geq 65$  years. Exclusion criteria: ① Patients with concurrent malignant tumors or pulmonary tuberculosis; ② Patients with concurrent autoimmune diseases or hematologic disorders; ③ Patients using other antiviral medications such as Azvudine tablets.

### 2. Methods

All patients received standard basic treatment, including bed rest, ensuring adequate energy and nutrient intake, maintaining water and electrolyte balance, and providing symptomatic treatment based on the patient's symptoms. For patients with hypoxemia, oxygen therapy was administered to maintain oxygen saturation  $\geq 93\%$ . Simultaneously, vital signs such as body temperature, respiratory rate, heart rate, and blood pressure were closely monitored, along with changes in the patient's condition, such as worsening symptoms or the onset of dyspnea, to promptly adjust the treatment plan. If complications such as bacterial infection occurred, antibiotics were administered appropriately based on the patient's condition. During conventional basic treatment, patients who initiated Paxlovid antiviral therapy within  $\leq 5$  days of symptom onset were designated as Treatment Group 1, while those who started Paxlovid therapy after  $>5$  days were assigned to Treatment Group 2. The specific regimen involved Nirmatrelvir 300 mg ( $150 \text{ mg} \times 2$  tablets) combined with Ritonavir 100 mg ( $100 \text{ mg} \times 1$  tablet), administered orally every 12 h for 5 consecutive days. Throughout the medication period, close monitoring was conducted to assess potential adverse drug reactions (ADRs), such as taste inversion, diarrhea, dyspepsia, dizziness, and elevated liver enzymes. If adverse reactions occurred, their severity was promptly evaluated, and appropriate measures were taken. For mild adverse reactions, close observation was sufficient without immediate intervention. However, for severe adverse reactions that significantly impacted the patient's quality of life or health, such as severe diarrhea leading to dehydration or markedly elevated liver enzymes—medication suspension or treatment regimen adjustment was considered, along with symptomatic management. Concurrently, vital signs and disease progression were continuously monitored to evaluate treatment efficacy.

### 3. Observation Indicators

The primary endpoints were all-cause mortality and treatment efficacy rate, while secondary endpoints included laboratory test results, time to negative nucleic acid conversion after medication, and total

hospitalization duration. ① All-cause mortality: The number of deaths during the entire treatment course and follow-up period in each group was counted, and the proportion of deaths relative to the total number of patients in each group was calculated. ② Treatment efficacy rate: Calculated as: Treatment efficacy rate = Number of patients discharged after recovery (excluding those who developed severe/critical conditions after medication and those receiving immunotherapy) / Total number of patients in the group  $\times 100\%$ . ③ Time to negative nucleic acid conversion: Defined as the number of days from the initiation of Paxlovid treatment to the time when the SARS-CoV-2 nucleic acid test result turned negative. ④ Total hospitalization duration: The total number of days from admission to discharge. ⑤ Inflammation-related indicators: A 5 mL fasting venous blood sample was collected, and serum was separated using the corresponding instrument and kit to measure C-reactive protein (CRP) by immunoturbidimetry. Additionally, erythrocyte sedimentation rate (ESR) was measured by the Weil method, and procalcitonin (PCT) was detected by electrochemiluminescence immunoassay. Measurements were performed before medication, 5 days after medication, and at discharge. ⑥ Immune-related indicators: A 5 mL fasting venous blood sample was collected, and an automated hematology analyzer was used to measure neutrophil count and lymphocyte count, calculate the neutrophil/lymphocyte ratio (NLR), and detect interleukin-6 (IL-6) by enzyme-linked immunosorbent assay. ⑦ Serum ferritin and D-dimer. Collect 5 mL of fasting lower venous blood from the patient, centrifuge at 3000 r/min for 15 minutes (radius 10 cm), and separate the serum. Measure serum ferritin using chemiluminescence immunoassay and detect D-dimer levels with enzyme-linked immunosorbent assay (ELISA). ⑧ Disease outcome indicators. Detailed records of disease outcomes for each patient in both groups were compiled, categorized into three types: complete recovery with discharge, progression to severe/critical condition, and death. By comparing the distribution of patients with different outcome types in both groups, the impact of different administration timing of Paxlovid on the final clinical outcomes was evaluated.

### 4. Statistical Methods

Data were analyzed using SPSS 32.0 statistical software. Measurement data conforming to normal distribution were expressed as (mean  $\pm$  standard deviation), with intergroup comparisons performed using the two-sample t-test; measurement data non-conforming to normal distribution were expressed as mean (P25, P75), with intergroup comparisons using nonparametric tests; count data were expressed as [n (%)], with intergroup comparisons performed using the  $\chi^2$  test or Fisher's exact probability method. A P-value  $<0.05$  was considered statistically significant.

## Results

### 1. General Information

Among the 125 enrolled patients, 57 began Paxlovid treatment within 5 days of symptom onset (Treatment Group 1), while 68 patients started treatment more than 5 days after symptom onset (Treatment Group 2). In Treatment Group 1, there were 36 males and 21 females, with an age range of 65–97 years and a mean age of  $75.41 \pm 4.98$  years. In Treatment Group 2, there were 33 males and 35 females, with an age range of 65–97 years and a mean age of  $76.37 \pm 5.32$  years. No significant differences were observed in baseline characteristics between the two groups ( $P>0.05$ ).

2. Comparison of all-cause mortality and treatment efficacy rates between the two groups

No statistically significant differences were observed between Treatment Group 1 and Treatment Group 2 in terms of all-cause mortality (8.77% vs 17.65%) or treatment efficacy rate (91.23% vs 80.88%) ( $P>0.05$ ). See Table 1.

| group             | n  | all cause mortality | Effective treatment | Progress to severe/critical condition |
|-------------------|----|---------------------|---------------------|---------------------------------------|
| Treatment Group 1 | 57 | 5 (8.77)            | 52 (91.23)          | 0 (0.00)                              |
| Treatment Group 2 | 68 | 12 (17.65)          | 55 (80.88)          | 1 (1.47)                              |
| $X^2$             |    | 2.079               | 1.917               | 0.008                                 |
| P                 |    | 0.149               | 0.166               | 0.929                                 |

**Table 1:** Comparison of all-cause mortality and treatment efficacy rates between the two groups, n (%)

3. Comparison of nucleic acid conversion time and total hospitalization duration between the two groups. Compared with Treatment Group 2, Treatment Group 1 exhibited significantly shorter time to negative nucleic acid conversion and total hospitalization time ( $P<0.05$ ). See Table 2.

| group             | n  | Time to nucleic acid conversion | Total hospital stay |
|-------------------|----|---------------------------------|---------------------|
| Treatment Group 1 | 57 | 12.22±3.15                      | 18.04±5.12          |
| Treatment Group 2 | 68 | 15.87±4.08                      | 22.89±6.25          |
| t                 |    | 5.514                           | 4.686               |
| P                 |    | 0.000                           | 0.000               |

**Table 2:** Comparison of nucleic acid test negative turnaround time and total hospitalization duration between the two groups (±s, d)

4. Comparison of inflammatory markers between the two groups. The levels of CRP, ESR, and PCT in Treatment Group 1 were significantly lower than those in Treatment Group 2 at 5 days of medication and upon discharge ( $P<0.05$ ). See Table 3.

| metric      | group             | n  | Before medication | 5 days of medication | At discharge |
|-------------|-------------------|----|-------------------|----------------------|--------------|
| CRP (mg/L)  | Treatment Group 1 | 52 | 77.34±31.78       | 44.56±19.87*         | 20.23±9.76*  |
|             | Treatment Group 2 | 55 | 76.12±30.64       | 56.34±26.12*         | 28.78±13.15* |
|             | t                 |    | 0.202             | 2.614                | 3.802        |
|             | P                 |    | 0.840             | 0.010                | 0.000        |
| ESR (mm/h)  | Treatment Group 1 | 52 | 35.67±12.95       | 28.25±9.98*          | 19.78±7.95*  |
|             | Treatment Group 2 | 55 | 36.12±12.76       | 32.78±11.95*         | 24.25±9.98*  |
|             | t                 |    | 0.181             | 2.122                | 2.553        |
|             | P                 |    | 0.857             | 0.036                | 0.012        |
| PCT (ng/mL) | Treatment Group 1 | 52 | 0.47±0.22         | 0.34±0.15*           | 0.24±0.09*   |
|             | Treatment Group 2 | 55 | 0.46±0.21         | 0.41±0.17*           | 0.31±0.11*   |
|             | t                 |    | 0.241             | 2.254                | 3.591        |
|             | P                 |    | 0.810             | 0.026                | 0.001        |

**Table 3:** Comparison of Inflammatory Markers Between the Two Groups (±s)

Note: Compared with the pre-treatment level in this group, \* $P<0.05$ .

#### 5. Comparison of immune-related indicators between the two groups

The NLR and IL-6 levels in Treatment Group 1 were significantly lower than those in Treatment Group 2 at 5 days of medication and upon discharge ( $P<0.05$ ). See Table 4

| metric       | group             | n  | Before medication | 5 days of medication | At discharge |
|--------------|-------------------|----|-------------------|----------------------|--------------|
| NLR          | Treatment Group 1 | 52 | 6.48±2.42         | 5.73±1.18            | 4.88±1.08*   |
|              | Treatment Group 2 | 55 | 6.62±2.58         | 6.42±1.32            | 5.62±1.28*   |
|              | t                 |    | 0.289             | 2.845                | 3.223        |
|              | P                 |    | 0.773             | 0.005                | 0.002        |
| IL-6 (pg/mL) | Treatment Group 1 | 52 | 12.85±5.25        | 8.21±3.38*           | 4.85±1.75*   |
|              | Treatment Group 2 | 55 | 12.65±4.85        | 10.20±4.65*          | 7.24±3.23*   |
|              | t                 |    | 0.205             | 2.520                | 4.720        |
|              | P                 |    | 0.838             | 0.013                | 0.000        |

**Table 4:** Comparison of immune-related indicators between the two groups ( ±s)

Note: Compared with the pre-treatment level in this group, \*P<0.05.

#### 6. Comparison of serum ferritin and d-dimer levels between the two groups

The serum ferritin and D-dimer levels in Treatment Group 1 were significantly lower than those in Treatment Group 2 at 5 days of medication and upon discharge (P<0.05). See Table 5.

| metric   | group             | n  | Before medication | 5 days of medication | At discharge   |
|----------|-------------------|----|-------------------|----------------------|----------------|
| ferritin | Treatment Group 1 | 52 | 355.91±115.34     | 295.67±105.45*       | 225.34±95.16*  |
|          | Treatment Group 2 | 55 | 352.45±112.23     | 335.56±101.08        | 285.67±115.09* |
|          | t                 |    | 0.157             | 1.998                | 2.946          |
|          | P                 |    | 0.875             | 0.048                | 0.004          |
| D- dimer | treatment group 1 | 52 | 360.45±125.61     | 275.78±95.89*        | 195.45±90.37*  |
|          | Treatment Group 2 | 55 | 355.34±122.36     | 325.67±92.78         | 245.78±97.09*  |
|          | t                 |    | 0.213             | 2.735                | 2.772          |
|          | P                 |    | 0.832             | 0.007                | 0.007          |

**Table 5:** Comparison of serum ferritin and D-dimer levels between the two groups ( ±s, ng/mL)

Note: Compared with the pre-treatment level in this group, \*P<0.05.

### Discussion

Nirmatrelvir is a peptidoid compound that specifically targets the 3CL protease of SARS-CoV-2. The 3CL protease plays a critical role in the viral life cycle by cleaving the viral polyprotein precursor, a process that is critical for viral replication and assembly[6-8]. Nirmatrelvir binds tightly to the active site of the 3CL protease, effectively inhibiting its activity and preventing the normal cleavage of the viral polyprotein precursor. This blocks the virus from completing its replication and assembly processes, significantly reducing its replication capacity in patients[9]. Ritonavir in Paxlovid acts as a "synergist," inhibiting the activity of cytochrome P450 3A (CYP3A) enzyme, thereby maintaining higher effective concentrations of nirmatrelvir in vivo and enhancing its antiviral efficacy [10-11]. The results of this study showed that the all-cause mortality rate in Treatment Group 1 was lower than that in Treatment Group 2, and the treatment efficacy rate was higher in

Treatment Group 1 than in Treatment Group 2, but neither differences were statistically significant (P>0.05). This indicates that the timing of Paxlovid administration has a comparable impact on the efficacy and prognosis of elderly patients infected with the Omicron variant. This finding differs from some early studies on Paxlovid, which suggested that early use of Paxlovid could significantly reduce the risk of hospitalization and death in patients [12]. The potential reasons for this may include: ① All patients in the study sample were aged ≥65 years, representing a high-risk population for severe illness and death following SARS-CoV-2 infection. Moreover, they were infected with the Omicron variant, which exhibits strong transmissibility and high immune evasion capacity, thereby partially diminishing the significant efficacy of early Paxlovid administration in reducing all-cause mortality and improving treatment response rates; ② The limited sample size of this study introduced certain statistical biases in the results, necessitating further validation through expanded enrollment in subsequent studies. In terms of clinical

improvement, patients in Treatment Group 1 showed significantly shorter nucleic acid clearance time and total hospitalization duration ( $P<0.05$ ), indicating that initiating Paxlovid therapy within  $\leq 5$  days of symptom onset could more rapidly suppress viral replication, promote nucleic acid clearance, shorten viral shedding duration, and reduce transmission risk. Pathophysiologically, early-stage viral load in the body is in a phase of rapid increase. At this stage, Paxlovid can promptly block viral replication, preventing extensive viral proliferation from causing further damage to tissues and organs, thereby more effectively promoting clinical symptom relief and disease recovery[13]. CRP is an acute-phase protein, which the liver synthesizes in large quantities when the body is infected or stimulated by inflammation, reflecting the body's inflammatory state; ESR reflects the sedimentation rate of red blood cells under certain conditions, typically associated with inflammation and infection; PCT levels in serum are extremely low but significantly elevated in bacterial infections, sepsis, and severe viral infections leading to systemic inflammatory response syndrome[14-17]. The results of this study showed that after 5 days of treatment, CRP, ESR, and PCT levels in Treatment Group 1 were significantly lower than those in Treatment Group 2 after 5 days of treatment and at discharge ( $P<0.05$ ), indicating that early treatment is more conducive to controlling inflammation and reducing excessive inflammatory states induced by viral infections. Previous studies [18-19]. have indicated that IL-6 is closely associated with the synthesis of CRP. After binding to its receptor, IL-6 phosphorylates and activates receptor-associated JAK kinases, which subsequently phosphorylate the signal transducer and transcriptional activator 3 (STAT3). The phosphorylated STAT3 forms dimers, translocates into the nucleus, and binds to specific sequences in the promoter region of the CRP gene, thereby enhancing CRP gene transcription. In Treatment Group 1, early administration of the drug effectively controlled viral infection, reduced the secretion of IL-6 by immune cells, restricted the activation of the JAK-STAT signaling pathway, and prevented STAT3 from being extensively phosphorylated and binding to the CRP gene promoter, thereby decreasing CRP synthesis. Immunological indicators also demonstrated that the levels of NLR and IL-6 in Treatment Group 1 were significantly lower than those in Treatment Group 2 ( $P<0.05$ ), indicating that early administration of the drug better regulated the body's immune response and avoided immune imbalance caused by excessive inflammation. Serum ferritin is the storage form of iron in the human body and can increase under various conditions such as inflammation, infection, and tumors. D-dimer is a specific degradation product generated when fibrin monomers are cross-linked by activating factor XIII and then hydrolyzed by plasmin, serving as an important indicator of hypercoagulability and hyperfibrinolysis in the body. In patients infected with SARS-CoV-2, elevated levels of D-dimer suggest possible coagulation dysfunction [20]. The results of this study demonstrated that the serum ferritin and D-dimer levels in Treatment Group 1 were significantly lower than those in Treatment Group 2 after 5 days of treatment and at discharge ( $P<0.05$ ). This indicates that early administration of Paxlovid helps maintain normal coagulation function in patients and reduces the risk of thrombotic complications. The limitations of this study include: First, the study employed a retrospective method, and the results may be influenced by various confounding factors. Second, the sample size was relatively small, with only 125 patients included, which may lead to insufficient representativeness of the study results and fail to fully reflect the true efficacy of different medication timing in a larger population of elderly patients infected with the Omicron variant. Third, the observation period was limited, primarily focusing on

the evaluation of various indicators during hospitalization and at discharge, and further follow-up and research are needed for the long-term prognosis after discharge.

## Conclusion:

In conclusion, for elderly patients infected with the Omicron variant, although the use of Paxlovid tablets for  $\leq 5$  days did not alter all-cause mortality or treatment efficacy, it was superior to medication initiated  $>5$  days after symptom onset in improving clinical progression, reducing inflammatory responses, and lowering related risk indicators.

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