

# Clinical characteristics of patients with SARS-CoV-2 Omicron variant and COVID-19 vaccination with clinical outcome findings in Shanghai, China: a single center, retrospective, observational study

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## Background

- In march 2022, a severe outbreak of the SARS-COV-2 omicron variant occurred in shanghai. The entire city was forced to enter a phased stage of lockdowns starting by the end of march and the total number of reported infections and deaths were 626,811 and 588 respectively until June.
- Highly effective vaccination is an important tool to prevent infectious diseases and decrease the impact of the pandemic. In some countries, vaccination has reduced the disease burden of COVID-19, with most severe COVID-19 illnesses and deaths occurring among unvaccinated patients.
- Although the vaccination programs had been effective in containing pre-omicron outbreaks, peer reviewed data describing its effectiveness against omicron in China is thus far limited.

## Objective

This study aimed to determine disease severity, clinical features, clinical outcome in hospitalized patients with the omicron variant and evaluate the effectiveness of one-dose, two-dose, and three-dose inactivated vaccines in reducing viral loads, disease course, ICU admissions and severe diseases.

## Methods

- Retrospective cohort analysis was performed on 5,170 adult patients identified as severe acute respiratory syndrome coronavirus 2 positive admitted at shanghai medical center for gerontology between march 2022 and June 2022.
- Data were collected from patients' electronic medical records, including age, sex, marital status, comorbidities, clinical severity, clinical symptoms, vaccination (dose of vaccine and manufacturer), the cycle threshold (Ct) value of RT-PCR, treatment and clinical outcomes. The detection limit value of Ct was set to be 35.0. Samples with Ct of less than 35.0 were considered positive and positive with a high viral load respectively.

## Results

Of 5,170 confirmed COVID-19 patients, the median age was 53.0 and 55.3% were male. The most common comorbidities were hypertension (21.2%), followed by diabetes (9.3%), Solid malignancies (2.8%), coronary heart disease (2.4%), nerve system disease (1.9%), and Chronic lung disease (1.2%). 71.0% were mild COVID-19 cases, while 22.6% were Asymptomatic. Among the patients, most of those had symptoms (77.4%), while 22.6% cases had no symptoms.

**Table 1 Characteristics of patients tested positive for SARS-CoV-2 Omicron variant (n=5170)**

Demographic and Clinical Characteristics		Frequency (%)
Age		52.94 ± 19.54
Gender	Male	2,861 (55.3)
	Female	2,309 (44.7)
Marital status	Married	3,365 (88.5)
	Single	397 (10.4)
	Other (Including divorce, widowhood)	41 (1.1)
	Missing	1,367(26.4)
Comorbidities	Hypertension	1,092 (21.2)
	Diabetes	477 (9.3)
	Solid malignancies	146 (2.8)
	Coronary heart disease	124 (2.4)
	Nerve nerve system disease	99 (1.9)
	Chronic lung disease	60 (1.2)
	Atrial fibrillation	51 (1.0)
	Renal insufficiency	44 (0.9)
	Cardiac insufficiency	36 (0.7)
	Autoimmune disease	15 (0.3)
	Hematologic malignancy	12 (0.2)
	Rheumatism	5 (0.1)
	Myocardial infarction	8 (0.2)
	Missing	24(0.5)
Classification of admission	Asymptomatic	1,090 (22.6)
	Mild	3,423 (71.0)
	Moderate	248 (5.1)
	Severe	41 (0.9)
	Critical	16 (0.3)
Symptoms	Missing	342(6.8)
	Cough	1,137 (22.0)
	Fever	592 (11.5)
	Sore throat	510 (9.9)
	Expectoration	279 (5.4)
	Fatigue	334 (6.5)
	Loss of taste	52 (1.0)
Treatment	Loss of smell	36 (0.7)
	Paxlovid	389 (7.5)
	Ordinary oxygen therapy	401 (7.8)
	High-flow oxygen	72 (1.4)
	Prone Ventilation	63 (1.2)
	Noninvasive ventilation	22 (0.4)
	Invasive ventilation	27 (0.5)

At the third day, fifth day, seventh day, fourteenth day after admission, Ct values were 26.7±6.5, 30.4±6.2, 33.0±5.3 and 35.1±3.4 respectively. About one-quarter of the patients had a high viral load (Ct value< 20), while they were hospitalized.

**Table 2 Distribution of Ct values in patients tested positive for SARS-CoV-2 Omicron variant (n=2170)**

Nucleic acid test for novel coronavirus	Ct value	Frequency (%)
Ct value at 3 days after admission	<35	1,646 (75.9)
	>=35	219 (10.1)
	Discharged	305 (14.1)
Ct value at 5 days after admission	<35	1,300 (59.9)
	>=35	514 (23.7)
	Discharged	356 (16.4)
Ct value at 7 days after admission	<35	903 (41.6)
	>=35	583 (26.9)
	Discharged	684 (31.5)
Ct value at 14 days after admission	<35	35.1±3.4
	>=35	99 ( 4.6)
	Discharged	109 ( 5.0)
Ct minimum value after admission	<20	589 (27.1)
	>=20	1,581 (72.9)

2% of these patients were transferred to the intensive care unit after admission and the length for the negative to positive (NTP) interval was 5.7 ± 3.4 days. 97.1% patients were cured or showed an improvement in symptoms and 0.9% died.

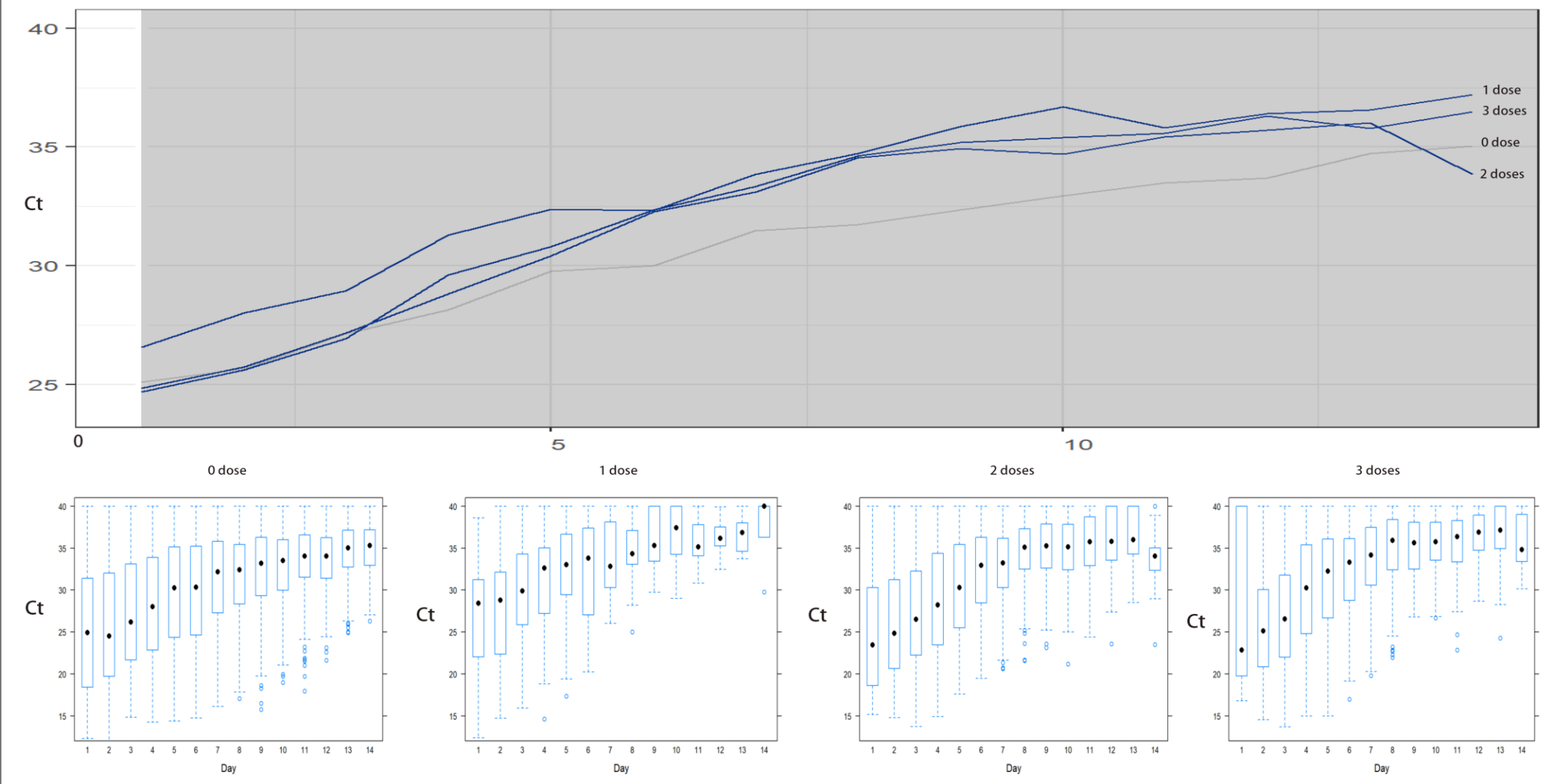
**Table 3 Clinical efficacy of patients tested positive for SARS-CoV-2 Omicron variant (n=5170)**

Clinical efficacy	Classification	Frequency (%)
Transfer to intensive care unit	No	5,065 (98.0)
	Yes	105 (2.0)
Rebound in hospital	No Rebound	1,980 (73.0)
	Rebound	733 (27.0)
	Missing	2,997(47.5)
	Length for NTP interval, days	5.7 ± 3.4
Clinical outcome	cure	4,444 (93.2)
	improve	187 (3.9)
	death	43 (0.9)
	other	94 (2.0)
	Missing	402(7.8)
Hospital stay, days		8.7 ± 4.5

Ct values of patients vaccinated remained higher than patients unvaccinated most of the time, and vaccination, especially 2 or 3 doses of vaccination, was clear in reaching the limit value of cycle threshold (Ct=35) earlier, which showed that Vaccine has a positive effect on the prognosis of patients and discharge management.

**Table 4 Distribution of vaccine doses in patients with novel coronavirus pneumonia (n=5170)**

	Vaccination status	Frequency (%)
Vaccination status	No	1,396 (27.0)
	Yes	3,774 (73.0)
Vaccination dose	Not vaccinated	1,396 (30.3)
	One dose	137 (3.0)
	Two doses	1,106 (24.0)
	Three doses	1,968 (42.7)
	Missing	563(10.9)
Vaccine manufacturers	Sinopharm Beijing Biotech	535 (30.4)
	Sinovac	474 (26.9)
	Other	96 (5.4)
	Unknown	657 (37.3)
	Missing	3,408(65.9)



**Figure 1 The trend of Ct value between different vaccination doses**

## Conclusions

In summary, the most of patients who contracted SARSCoV-2 omicron variant had mild clinical features and patients with vaccination took less time to lower viral loads. As the COVID-19 pandemic progressed, an older and less vaccinated population was associated with higher risk for ICU admission and severe disease.