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Brief Communication

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SARS-CoV-2 Breakthrough Infection after mRNA-1273 Booster among CoronaVac-Vaccinated Healthcare Workers

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This study was approved by the Mochtar Riady Institute for Nanotechnology Ethical

ABSTRACT

It remains unknown whether the Indonesian healthcare workers (HCWs) who had received two doses of CoronaVac vaccine and one dose of mRNA-1273 booster could be protected during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron wave. In total, 125 infection-naïve and 10 previously infected HCWs were recruited. The mRNA-1273 booster substantially increased titer of anti-SARS-CoV-2 spike protein receptor-binding domain antibodies. However, the monitoring revealed that 34 out of 125 infection-naïve (27.2%) and 3 out of 10 previously infected HCWs (30.0%) were infected during the Omicron wave. All infected HCWs were either asymptomatic or having mild coronavirus disease 2019 (COVID-19) and subsequently fully recovered, supporting the heterologous prime-boost strategy against COVID-19.

Keywords: SARS-CoV-2 variant; COVID-19 vaccines; Heterologous prime-boost; Breakthrough infection

CoronaVac (Sinovac Life Sciences, Beijing, China), which is an inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine, was utilized in the coronavirus disease 2019 (COVID-19) emergency vaccination program for healthcare workers (HCWs) in Indonesia [1]. The protective antibody titers induced by two doses of CoronaVac were noted to be relatively low and significantly waned over 6 months [2, 3]. This has prompted the Ministry of Health of the Republic of Indonesia to provide one dose (100 μg) of mRNA-1273 vaccine (Moderna, Inc., Cambridge, MA, USA) for the Indonesian HCWs since mid-July 2021. As per reports, it was found that one dose of mRNA-1273 booster can significantly increase titer of anti-SARS-CoV-2 S-RBD antibodies, the surrogate of protective humoral immunity, among infection-naïve, CoronaVac-vaccinated HCWs [4]. However, as the SARS-CoV-2 Omicron variant has swiftly replaced the Delta variant that resulted in the latest wave of COVID-19 cases globally, this study was conducted to assess the breakthrough infection rate during the Omicron wave and its severity among Indonesian HCWs who had received primary vaccination with CoronaVac and a booster with mRNA-1273 vaccine.

This observational study was conducted at the Siloam Hospitals Lippo Cikarang, Indonesia. Of note, a part of this study had been reported, describing a strong induction of anti-SARS-

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Conflict of Interest

No conflict of interest.

Author Contributions

Conceptualization: TS, LK, BDS, JJ. Data curation: TS, JJ. Formal analysis: TS, JJ. Investigation: TS, JJ. Methodology: TS, LK, BDS, JJ. Software: JJ. Validation: TS, JJ. Writing – original draft: JJ. Writing – review & editing: TS, LK, BDS, JJ.

CoV-2 spike protein receptor-binding domain (S-RBD) antibodies with mild and transient reactogenicity upon mRNA-1273 booster among CoronaVac-vaccinated, infection-naïve subjects [5]. In this current study, further assessment on the CoronaVac-vaccinated HCWs with mRNA-1273 booster and the follow-up on those study subjects during the outbreak of Omicron variant in Indonesia were reported (January - March 2022). Two groups were assessed and compared in this current study: the first group, which comprised 125 infection-naïve HCWs who received two doses of CoronaVac and one dose of mRNA-1273 booster ("infection-naïve"), and the second group, which consisted of 10 CoronaVac-vaccinated HCWs who had been infected with SARS-CoV-2 during the outbreak of Delta variant in Indonesia (June - August 2021) and subsequently received one dose of mRNA-1273 booster ("previously infected"). The duration between the second dose of CoronaVac and the mRNA-1273 booster was between 5.5 and 6.5 months. The Elecsys® Anti-SARS-CoV-2 S assay (Roche Diagnostics, Mannheim, Germany) was used to measure the total antibodies against receptor-binding domain of the S1 protein, approximately on 7 days before and on 28 days after receiving one dose of mRNA-1273 vaccine. All 135 individuals were subsequently monitored by the surveillance unit of the Siloam Hospitals Lippo Cikarang for any breakthrough infection with SARS-CoV-2 until March 31, 2022. According to its standard operating procedure, the surveillance unit conducted a weekly screening by using the Elecsys® SARS-CoV-2 Antigen (Roche Diagnostics, Germany), in which a positive result would be verified via a reverse transcription-quantitative polymerase chain reaction (RT-qPCR) assay on a nasopharyngeal swab specimen.

Before booster shots were administered, titers of anti-SARS-CoV-2 S-RBD antibodies were higher among previously infected subjects (geometric mean titer/GMT = 13,122 U/mL) than among infection-naïve subjects (GMT = 65.57 U/mL). This was unsurprising, as the infection had occurred less than 3 months (*i.e.*, 35 - 85 days) before the booster. A contrasting result was observed after the booster, in which the titers were higher in the group of infection-naïve subjects (GMT = 47,445 U/mL) than in the group of previously infected subjects (GMT = 31,281 U/mL). This could be due to the limited time interval between the previous infection and the booster in the latter group,[6,7] presumably due to the suppression of naïve B-cell activation by the existing immunoglobulin G during the secondary immune response (*i.e.*, the booster) [8]. Irrespective of the groups, the post-booster titers were higher than the pre-booster ones (**Fig. 1A**). Of note, within the infection-naïve group, HCWs with lower pre-booster titers were observed to have higher fold increments of anti-SARS-CoV-2 S-RBD antibodies after the booster (**Fig. 1B**). This was in line with the observation that the previously infected HCWs had lower post-booster titers on average than the infection-naïve subjects. Taken together, the heterologous prime-boost with the mRNA-1273 vaccine has substantially increased the humoral immunity among CoronaVac-vaccinated individuals, irrespective of the history of infection.

Higher titers of anti-S antibodies upon vaccination, including anti S-RBD antibodies, were correlated with a better protection against SARS-CoV-2 infection, both in adults and elderlies [2, 7, 9, 10]. The neutralizing activity of those antibodies were reduced against the Omicron, however, than against the original, Beta or Delta variant [7, 9, 10]. Despite the very high titer of anti-SARS-CoV-2 S-RBD antibodies measured on around 28 days post-booster in this study (*i.e.*, September - October 2021), a substantial portion of HCWs were infected during the Omicron wave (**Table 1**). From January to March 2022, 27.2% and 30.0% in the infection-naïve and the previously infected groups, respectively, were infected by SARS-CoV-2. Moreover, 32 out of 37 breakthrough cases (29 infection-naïve and 3 previously

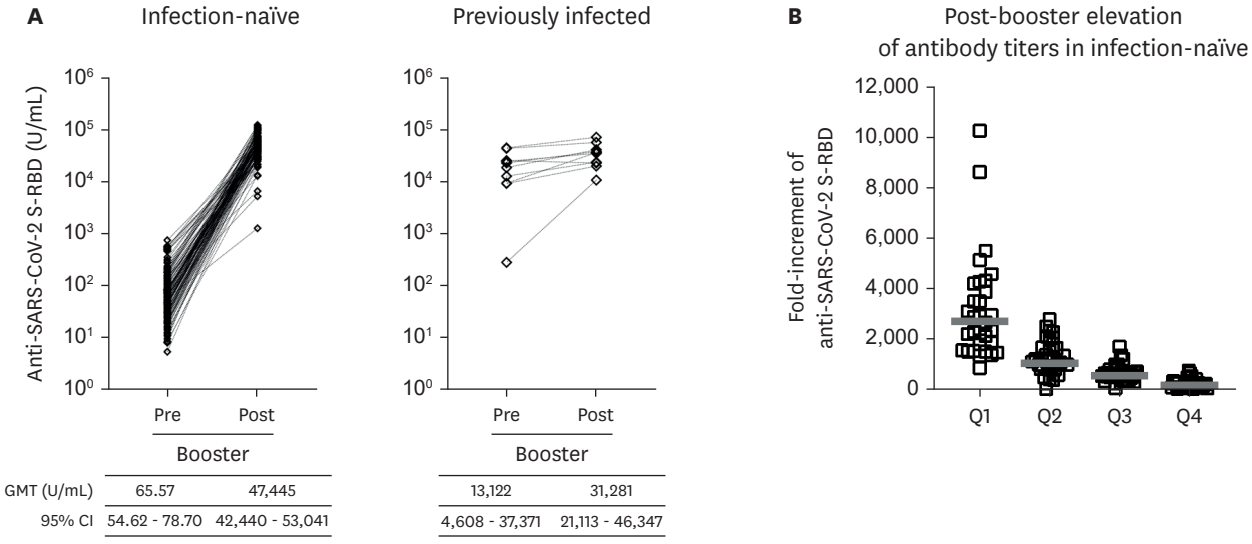

Figure 1. Titer of anti-SARS-CoV-2 S-RBD antibodies among healthcare workers following the heterologous prime-boost strategy.
(A) Antibody titers within the groups of CoronaVac (Sinovac Life Sciences, Beijing, China)-vaccinated infection-naïve (n = 125) and previously infected (n = 10) healthcare workers were presented as before (pre-booster) and after (post-booster) mRNA-1273 booster in the logarithmic scale. The pre- and post-booster titers from each individual were connected with dotted lines. The geometric mean titer (GMT) and 95% confidence interval (95% CI) of antibody titers from each condition were presented below the graph. (B) The infection-naïve healthcare workers (n = 125) were stratified into four groups. Q1 (n = 31) comprised healthcare workers with pre-booster titers ranging from the minimum (5.48 U/mL) and up to the 25th percentile (31.55 U/mL); Q2 (n = 32) comprised subjects with pre-booster titers ranging from beyond the 25th percentile and up to the median titer (61.77 U/mL); Q3 (n = 31) comprised healthcare workers with pre-booster titers ranging from beyond the median titer and up to the 75th percentile (133.1 U/mL); and Q4 (n = 31) comprised subjects with pre-booster titers ranging from beyond the 75th percentile and up to the maximum titer (765.3 U/mL). The fold increment was calculated by dividing post-booster titer with pre-booster titer for each subject. The gray line indicates the geometric mean of fold increments.
SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; S-RBD, spike protein receptor-binding domain; CI, confidence interval.

infected HCWs) were confirmed by the RT-qPCR results, while the remaining 5 cases (5 infection-naïve HCWs) were suspected to have contracted Omicron based on their Elecsys® SARS-CoV-2 Antigen's (Roche Diagnostic, Germany) positive results and their clinical symptoms of upper respiratory tract infection. These five cases were not verified via the RT-qPCR because the hospital was unfortunately overwhelmed by the number of COVID-19 cases during the Omicron wave; thus, the surveillance unit decided to instruct those HCWs to serve immediate self-isolation for a minimum of 10 days without doing the RT-qPCR. This finding highlights the extensive ability of the B.1.1.529 Omicron variant to evade the neutralizing antibodies, presumably due to accumulation of multiple mutations in its spike protein [9, 11, 12]. We were tempted to speculate that the hybrid immunity of vaccination plus natural infection was sub-optimal in preventing the Omicron infection, but this interpretation might be skewed by the limited number of subjects in the previously infected group. Another possibility was the decline in vaccine-induced antibody titers over time (despite no available data on the titers prior to the infection) as the median duration from booster dates to confirmed dates of infection were already 178.5 and 159.0 days in the infection-naïve and the previously infected groups, respectively. It was important to note, nonetheless, that all individuals with breakthrough infection were either asymptomatic or having mild COVID-19 (mainly symptoms of upper respiratory tract infection and fever) and that all were able to fully recover without hospitalization. The less severe disease was presumably due to the well-preservation of T-cell responses to spike protein across multiple variants.[13] Nonetheless, the less severity during the Omicron wave could be also attributed to the adult age range and healthy condition of the study subjects (**Table 1**, **Supplementary Table 1**).

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Table 1. Characteristics of healthcare workers infected during the Omicron wave

Variables	Infection-naïve (n = 34)	Previously infected (n = 3)
Age [median (min-max)], years	32 (22 - 52)	42 (24 - 47)
Sex		
Male [n (%)]	9 (26.5%)	0 (0.0%)
Female [n (%)]	25 (73.5%)	3 (100.0%)
Comorbidity[a]		
Chronic obstructive pulmonary disease [n]	0	0
Coronary heart disease [n]	0	0
Chronic kidney disease [n]	0	0
Chronic liver disease [n]	0	0
Diabetes mellitus [n]	0	0
Obesity [n]	0	0
Hypertension [n]	0	0
Cerebrovascular disease [n]	0	0
Malignancy [n]	0	0
Other[b] [n]	0	1
Duration from booster date to confirmed date of infection [median (min-max)], days	178.5 (122 - 207)	159.0 (147 - 194)
Symptom[cd]		
None [n (%)]	2 (5.9%)	0 (0.0%)
Fever [n (%)]	14 (41.2%)	0 (0.0%)
Fatigue [n (%)]	5 (14.7%)	0 (0.0%)
Nausea [n (%)]	2 (5.9%)	0 (0.0%)
Headache [n (%)]	1 (2.9%)	0 (0.0%)
Dizziness [n (%)]	3 (8.8%)	0 (0.0%)
Rhinitis [n (%)]	16 (47.1%)	3 (100.0%)
Cough [n (%)]	26 (76.5%)	1 (33.3%)
Sore throat [n (%)]	20 (58.8%)	2 (66.7%)

[a]Any comorbidity of subjects with breakthrough infection was presented.
[b]One subject was suspected to have systemic lupus erythematosus.
[c]Each subject can report more than one symptom.
[d]Frequency of each symptom was calculated over total breakthrough infection cases per group.

The Omicron variant effectively thwarted the vaccine effectiveness in reducing the symptomatic infection as well as the severity and fatality of COVID-19 [14]. Regarding the CoronaVac vaccination, it has been reported that the primary vaccination and homologous booster with CoronaVac were ineffective in neutralizing the Omicron infection [9, 10, 15, 16]. Accumulating evidence indeed suggested that heterologous prime-boost among individuals receiving two doses of CoronaVac was more effective in providing a protection against the Omicron infection. The published laboratory and clinical data suggested that heterologous booster with AZD1222, BNT162b2 or mRNA-1273 improved the host protection against the Omicron variant [7, 9, 10, 15, 16], which support our finding. Of note, Assawakosri et al. [7] reported that mRNA-1273 appeared to be the most effective booster, as compared to BNT162b2 or AZD1222, for healthy Thai adults with CoronaVac primary vaccination. This finding was in line with other studies, demonstrating that homologous booster, but not the primary vaccination, with mRNA-1273 vaccine substantially improved the host ability to reduce symptomatic infection and to prevent severity and fatality of the Omicron infection [17-19]. Taken together, despite the immune evasiveness of the Omicron variant, the HCWs who had been vaccinated with CoronaVac and subsequently boosted with mRNA-1273 were reasonably protected against SARS-CoV-2 infection and COVID-19 severity.

This study had several limitations, including a single-center study with small sample size and no data of T-cell response and neutralizing antibodies. This study faced a difficulty to recruit a proper control group (*i.e.*, subjects receiving a booster with CoronaVac or non-mRNA-based vaccine) as all HCWs at the Siloam Hospitals Lippo Cikarang followed the

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governmental instruction to receive mRNA-1273 booster. No sequencing result was available from those breakthrough cases, although the Omicron variant was likely the pathogen based on the available sequencing data from Indonesia, as per the GISAID initiative (**Fig. 2**) [20].

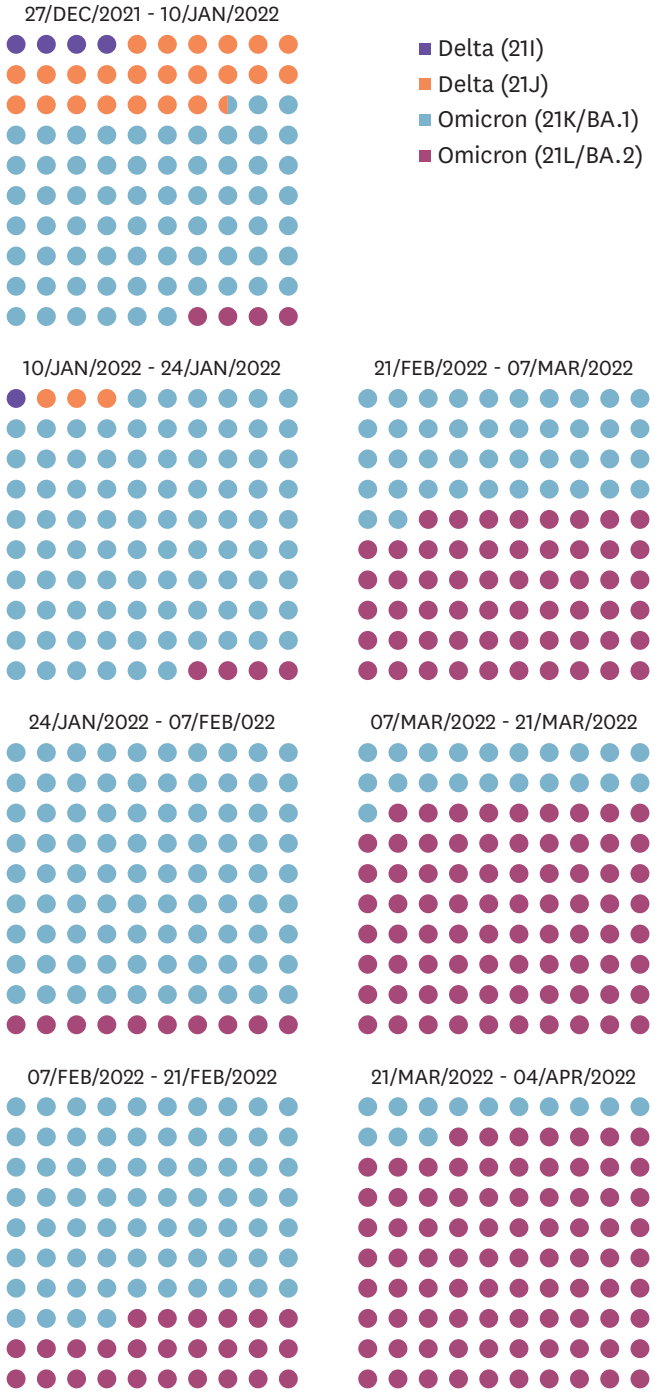

Figure 2. Distribution of SARS-CoV-2 Variants of Concern in Indonesia between December 27, 2021 and April 4, 2022.
Data of SARS-CoV-2 variants of concern in Indonesia were presented in seven time periods, *i.e.*, 27/DEC/2021 - 10/JAN/2022; 10/JAN/2022 - 24/JAN/2022; 24/JAN/2022 - 07/FEB/022; 07/FEB/2022 - 21/FEB/2022; 21/FEB/2022 - 07/MAR/2022; 07/MAR/2022 - 21/MAR/2022; and 21/MAR/2022 - 04/APR/2022. Delta (21I) and Delta (21J) were represented by dark grey and light grey circles, respectively. Omicron (BA.1) and Omicron (BA.2) were represented by white and black circles, respectively. One circle indicates one percent. Proportions of the SARS-CoV-2 genomes in Indonesia submitted to the GISAID initiative was obtained from the https://covariants.org/. SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

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In conclusion, we suggested that the heterologous prime-boost with one dose of mRNA-1273 vaccine among CoronaVac-vaccinated HCWs substantially increased titer of anti-SARS-CoV-2 S-RBD antibodies and that this strategy might be able to mitigate the severity of COVID-19, despite the relatively high rate of breakthrough infection during the Omicron wave. As the general population in Indonesia primarily received the inactivated or viral vector-based SARS-CoV-2 vaccine, the heterologous prime-boost strategy with the mRNA-based vaccine can be expanded to provide a better protection against COVID-19.

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SUPPLEMENTARY MATERIAL

Supplementary Table 1

Demographic profiles of healthcare workers participating in this study

Click here to view

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