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Assessment of Safety and Immunogenicity of BBIBP-CorV (Myancopharm) COVID-19 Vaccine as a Third Dose (Booster) among Workers of Pharmaceutical Factory (Insein) in Yangon, Myanmar

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Vaccination is an important strategy to stop the pandemic situation of COVID-19 infection. This study was conducted to determine the safety and immunogenicity of BBIBP-CorV (Myancopharm) as a third dose (booster) among factory workers in Yangon. A single group prospective cohort study was conducted in Pharmaceutical Factory (Insein), Yangon, 2022. A total of 306 workers who had received two doses of any kind of COVID-19 vaccine before 6 months of the screening were enrolled. Adverse Events (AEs) were assessed and recorded by phone interviewing using Kobo Collect software. Safety hematological and biochemical parameters were also assessed. Immunogenicity was assessed by antibody (Ab) to SARS-CoV-2 spike antigen by Enzyme Linked Fluorescent Assay (VIDAS® SARS-COV-2 IgG assay, Biomerieux, France). Among 306 participants, the mean age was 45.8±8.1 years and male to female ratio was 1:2.73. During the seven days after vaccination, solicited local and systematic AEs were reported by 46(47.7%) and 97(31.7%) participants, respectively. All AEs and laboratory parameters were mild to moderate in severity. No serious adverse events were reported. On baseline assessment, 295/306 (96.4%) participants were anti-SARS-CoV-2 IgG Ab positive. On Day-28 post vaccination, 306/306 (100%) showed a positive IgG Ab response. In all 306 participants, there was a significant rise in Geometric Mean Concentration of anti-SARS-CoV2 IgG Ab after the booster dose from 257.96 to 305.43 BAU/ml ($p<0.001$). The BBIBP-CorV (Myancopharm) vaccine is safe and there is significant increase in antibody levels in the participant population after a booster dose.

Keywords: Safety, Immunogenicity, BBIBP-CorV (Myancopharm), COVID-19 vaccine, Booster dose, Myanmar

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INTRODUCTION

A novel coronavirus disease, caused by SARS-CoV-2, has emerged and started from a family cluster in China to an international outbreak in 2019. It was named COVID-19 by World Health Organization (WHO) and due to the rapid spread and the nature of the disease, the WHO declared a pandemic on 11 March 2020.[1] Vaccines play an important role in increasing population immunity, preventing severe disease, and reducing the ongoing health crisis.[2] All countries tried to get the vaccines as early as possible and vaccinate the people according to the priority list for stopping the pandemic situation. There are various types of vaccines and policy makers need to choose the effective vaccines which are suitable for storage and transportation within the country.

Due to the reducing levels of protective antibodies against the SARS-CoV-2 virus and the emergence of new variants, a remarkable increase in case numbers were reported in many countries.[3] As protection against SARS-CoV-2 infection waned after a two-dose schedule of COVID-19 vaccines, policy-makers considered and started implementing a third dose, also known as a booster, vaccination against COVID-19 to protect the most vulnerable and high-risk people, and mitigate health-care and economic impacts. Many studies also reported that both homologous and heterologous COVID-19 booster dose vaccination enhanced the anti-SARS-CoV-2 IgG antibody and neutralizing antibody levels to reduce the morbidity and mortality caused by the disease.[4, 5] WHO also recommended a booster dose immunization and the Expanded Programme on Immunization (EPI), Ministry of Health, Myanmar started booster dose immunization for COVID-19 infection to all above 12 years old beginning from 1st June, 2022.[6]

In response to vaccine requirements, BBIBP-CorV (Myancopharm) vaccine was produced according to the same formula and procedures of BBIBP-CorV (manufactured by Sinopharm) from the final bulk stage to fill finish at Hepatitis B Vaccine Plant under the Ministry of Industry, Myanmar. The inactivated Sinopharm/ BBIBP-CorV vaccine had already been approved by WHO for emergency use and shown to be 79% effective against symptomatic cases and 100% against severe cases.[7]

Moreover, it has been used in 89 countries including Myanmar. The Expanded Program on Immunization (EPI), Ministry of Health, added BBIBP-CorV (Myancopharm) vaccine to the list of COVID-19 vaccines in Myanmar for use in both primary series and booster immunization. Moreover, there were no previous studies about the safety and immunogenicity of the BBIBP-CorV (Myancopharm) vaccine in Myanmar. The findings of the study will help to estimate the safety and immunogenicity of the BBIBP-CorV (Myancopharm) vaccine in Myanmar people and will provide useful evidence-based information for effective usage of vaccine in immunization of the whole population in Myanmar.

Thus, the present study was conducted to determine the safety and immunogenicity of BBIBP-CorV (Myanco-pharm) vaccine as a third dose (booster) among factory workers in Myanmar, to detect the anti-spike protein IgG Antibody (Ab) levels and adverse events (AEs) after the booster dose.

MATERIALS AND METHODS

An observational study (Single group prospective cohort study) was conducted among factory workers of Pharmaceutical Factory (Insein), Yangon, Myanmar during June-July, 2022. A total of 306 factory workers (18-59 years old) with stable medical conditions who received two doses of any kind of COVID-19 vaccine as a primary series vaccination before 6 months of the screening period were enrolled. The exclusion criteria were subjects with signs of active COVID-19 infection at the screening visit, history of COVID-19 infection within one month, pregnancy or lactation or willingness to become pregnant within 30 days after study vaccine, subjects who

receive immuno-suppressive or cytotoxic medications, history of severe allergic reactions after previous vaccinations or hypersensitivity to any components of the study vaccine and subjects who have any known bleeding disorders or, in the investigator's opinion, have any contraindications for an intramuscular injection. (Fig. 1)

The recruitment process was initiated one week before actual field implementation. Before enrollment, potential participants were invited for voluntary participation without any enforcement. After that, the researchers requested staff lists who were interested to participate in the study from the factory. The screening log sheet was prepared and the screening of the potential participants was conducted from the list of the factory workers. Then, confirmation of the eligible participants with inclusion criteria and exclusion criteria of the study and a list of eligible participants was prepared as the sampling frame. Then, written informed consent was obtained from each participant after a detailed explanation of the study procedures, risks and benefits for participating in the recruitment process. All data were collected by using tablets with Kobo collect software. All members of the research team were trained for blood sampling, interviewing and recording AEs in a two-day training workshop. Then, a detailed schedule was prepared and booster immunization was done. In this study, the BBIBP-CorV (Myancopharm) vaccine (Batch No-22VM01, Expired Date- March, 2023) was used.

Before the booster vaccination, all participants were checked for body temperature, blood pressure and vital signs. Venous blood collection was done for three times at Day 0 (before booster vaccination) for baseline data, Day-7 for safety laboratory parameters and Day-28 for assessment of immunogenicity after vaccination. All safety laboratory investigations for safety parameters were done at National Health Laboratory which is the national standard laboratory with well-established internal and external quality control assessment.

Assessment of safety

Participants were closely observed for 30 minutes post-vaccination to assess any immediate local and systemic adverse events (reactogenicity). Solicited adverse events were collected through 7 days following the vaccination. Unsolicited adverse events and serious adverse events (SAE) were also recorded till 28 days after the vaccination. Routine daily telephone calls were done by trained interviewers in the first seven days after vaccination, and the participants were asked to report by phone if they have some condition between day 8 and day 28 after vaccination.

Solicited local AE included pain/tenderness, induration/swelling, erythema and itching at the injection site, and localized axillary swelling or tenderness ipsilateral to the injection arm. Solicited systemic AEs were fever, chills/rigors, fatigue, headache, dizziness, myalgia, arthralgia, nausea, vomiting, diarrhea and skin rash. Solicited adverse events with onset after the 7day solicitation period were reported as unsolicited adverse events.

Serious adverse events were defined as events that are fatal or life-threatening; cause or prolong hospitalization; result in a significant, persistent, or permanent disability; produce a congenital anomaly; or require intervention to prevent permanent impairment or damage. Any abnormal changes on laboratory measures at day 7 after the booster dose were also used as a safety parameter. The severity of the adverse events and laboratory parameters were categorized from grade 1 to grade 4 based on Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials from the United States Food and Drug Administration (FDA).

Assessment of immunogenicity

Immunogenicity of booster dose of BBIBP-CorV (Myancopharm) vaccine was assessed by antibodies to SARS-CoV-2 spike antigen by VIDAS® SARS-COV-2 IgG II (9COG) (Biomerieux, France) assay (Lot no.

1009094860, Expired Date- 11/11/2022). The RFV (Relative Fluorescence Value) was calculated by subtracting the background reading from the final result. The sample RFV/ Standard RFV more than equal to 1 was used as positive.

According to the WHO international standard for anti-SARS-CoV-2 Ab, the Ab levels were expressed with Binding Antibody Unit (BAU/ml). All RFV were multiplied by 20.33 BAU/mL and geometric mean concentration of SARS-CoV-2 IgG Antibody were analyzed. The Ab titers at 28 days after the booster dose were used to assess the immunogenicity after the BBIBP-CorV (Myancopharm) booster dose vaccination compared with the antibody titers collected at Day 0 before the booster vaccination. A significant correlation between anti-RBD/S IgG levels using the VIDAS® SARS-COV-2 IgG II assay and neutralizing antibody titres using a conventional virus neutralization test, have been reported for a cohort of COVID-19 positive health care workers followed in France over for a period of 6 months and a cohort study of COVID-19 positive patients in Qatar. [8, 9]

Statistical analysis

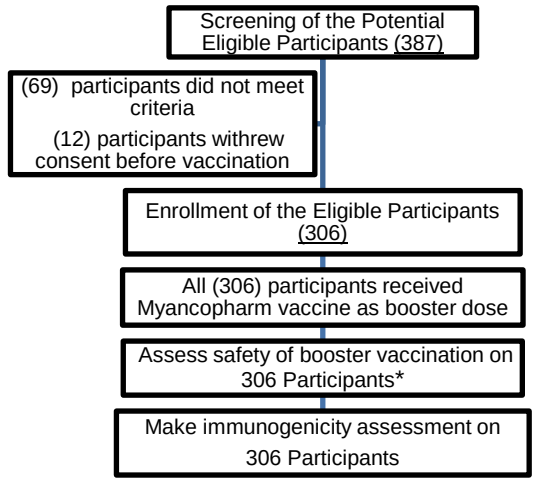
Data entry was done using ODK software and all the analyses were done using STATA software (version 15 STATA Corp., College Station, TX, USA). All AE were described in percentage. All Ab data were transformed to log and geometric mean concentration (GMC) were calculated. The GMC between different groups were analyzed using Paired-t test. P value <0.05 was used as the significant cut-off point in this study.

Ethical consideration

This study was approved by the Institutional Review Board of Department of Medical Research with the approval number (Ethics/DMR/2022/02). The study was conducted in full compliance with the Declaration of Helsinki, Council for International Organizations of Medical Sciences guidelines and International Conference on Harmonization in Good Clinical Practice guidelines. Written informed consent was provided by each participant before the enrollment.

RESULTS

In this study, 387 volunteers were screened for the eligibility of the participants and 69 factory workers did not meet the study criteria. Twelve participants withdrew their consent before vaccination (Fig. 1).



*For safety assessment of the booster dose vaccination, AE were assessed on 306 participants by phone interviewing from Day-0 to Day-7 but for laboratory parameters, only 305 participants were checked at Day-7 after booster dose vaccination

Fig. 1. Flow chart of the study

A total of 306 participants were enrolled and all participants were included for immunogenicity analysis and 306 volunteers participated in safety of the booster vaccination. The mean age of the participants was 45.8±81 years (SD). Male to Female Ratio was (MF=1:2.73). Among the participants, 119/306 (38.9%) had history of COVID-19 infection. The background socio-clinical characteristics of all vaccinated participants is shown in Table 1.

Safety of BBIBP-CorV (Myancopharm)

Among 306 participants who received BBIBP-CorV (Myancopharm) as booster (third) dose, 146 (47.7%) reported local

Table 1. Background characteristics of participants at baseline

Variables	Number of participants (%)
Age	
18-24 years	8(2.6)
25-34 years	11(3.6)
35-44 years	101(33.0)
45-54 years	142(46.4)
>54 years	44(14.4)
Gender	
Male	82(26.8)
Female	224(73.2)
Type of Primary Series vaccination	
BBIBP-CorV (Sinopharm)	291(95.0)
SII-ChAdOx1 nCoV 19	13(4.3)
Coronavac	2(0.7)
History of previous COVID-19 infection*	
No	187(61.1)
During first wave	8(2.6)
During second wave	45(14.7)
During third wave	55(18.0)
During fourth wave	26(8.5)
History of hospitalization due to COVID-19 infection (n=119)	
No	112(94.1)
Yes	7(5.9)
History of falling oxygen saturation due to COVID-19 infection (n=119)	
No	104(87.4)
Yes	15(12.6)
Requirement of oxygen due to COVID infection (n=119)	
No	110(92.4)
Yes	9(7.6)
Past medical history**	
Diabetes Mellitus	16(5.2)
Hypertension	79(25.8)
COPD/Asthma	14(4.6)
Cardiovascular diseases	37(12.1)
Others	42(13.7)
Regular medication prescribed by doctors	
No	81(26.5)
Yes	225(73.5)

*Some participants had more than one time of history of infections

**Participants had more than one disease.

adverse reactions and 97(31.7%) had systemic adverse reactions during 7 days after vacci-nation. All solicited adverse reactions were grade 1 (mild) or grade 2 (moderate) in severity and they resolved within 1-4 days. Among local adverse reactions, pain/ tenderness (143, 46.7%) at the vaccine injection site was the commonest followed by itching, swelling, induration and erythema. For systemic adverse reactions, dizziness, headache and fatigue were common and fever, chills/rigors, nausea/vomiting, diarrhea and arthralgia were also noted. No serious adverse events (SAEs) were reported within this period. The solicited adverse reactions following the vaccination are shown in Table 2.

In this study, 25(8.2%) had unsolicited adverse events during 28 days after vacci-nation. All events were mild (grade 1). No serious adverse events (SAE) were reported within 28 days post vaccination in this study. Haematological and biochemical parameters among vaccinated people (n=305) were assessed after 7 days of post vaccination. Most events were changed from baseline (Normal Value) to grade-1 except three cases. Two participant showed abnormal neutrophil count (grade-2) and one showed increased Alanine aminotransferase Enzyme (ALT) raised up to grade-3. Although abnormal (abnormal neutrophil counts and high ALT) levels were seen, all were clinically asymptomatic throughout the study period.

Immunogenicity of BBIBP-CorV (Myanco-pharm)

Regarding the history of previous primary series COVID-19 vaccination, 291(95.1%) were received BBIBP-CorV vaccine which was manufactured from Sinopharm and only 15 received either SII-ChAdOx1nCoV19 or Coronavac vaccine which was produced from Serum Institute of India and Sinovac, respectively. At baseline investigations of antiSARS-CoV-2 IgG Ab, 295/306 (96.4%) showed positive and only 11/306 (3.6%) were negative. On investigation at Day-28 post vaccination serum samples, 306/306 (100%) showed positive on IgG Ab. All vaccinated people who were negative at baseline (11/11, 100%) became positive after booster vacci-nation. One participant who was negative at baseline (<20.33 BAU/ml) became positive and the anti-SARS-CoV-2 Ab reached at 779.05 BAU/ml. There was a significant rise in geometric mean concentration (GMC) of anti-SARS-CoV2 IgG Ab among vaccinated people from 257.96 BAU/ml to 305.43 BAU/ml ($p<0.001$) (Table 3).

Table 2. Adverse reactions and changes in laboratory parameters following vaccination

	Total, n (%)	Grade 1, n (%)	Grade 2, n (%)	Grade 3, n (%)
A. Solicited Adverse Reactions				
I. *Local Adverse Reactions*				
Any	146 (47.7)	145 (47.4)	1 (0.3)	-
Pain/tenderness	144 (47.0)	143 (46.7)	1 (0.3)	-
Induration	4 (1.3)	4 (1.3)	-	-
Swelling	7 (2.3)	7 (2.3)	-	-
Erythema	4 (1.3)	4 (1.3)	-	-
Itching	11 (3.6)	11 (3.6)	-	-
II. *Systemic Adverse Reactions*				
Any	97 (31.7)	92 (30.1)	5 (1.6)	-
Fever	14 (4.6)	14 (4.6)	-	-
Chills/rigors	19 (6.2)	19 (6.2)	-	-
Fatigue	29 (9.5)	27 (8.8)	2 (0.7)	-
Headache	29 (9.5)	29 (9.5)	-	-
Dizziness	33 (10.8)	31 (9.8)	2 (0.7)	-
Myalgia	21 (6.9)	21 (6.9)	-	-
Arthralgia	9 (2.9)	9 (2.9)	-	-
Nausea/vomiting	7 (2.3)	7 (2.3)	-	-
Diarrhoea	6 (1.9)	5 (1.6)	1 (0.3)	-
B. Laboratory parameters[##]				
I. *Haematology*				
Decreased Haemoglobin level* (n=260)	9 (3.5)	9 (3.5)	-	-
Leucocytosis (n=295)	5 (1.7)	4 (1.4)	1 (0.3)	-
Neutropenia (n=299)	5 (1.7)	4 (1.4)	1 (0.3)	-
Eosinophilia (n=278)	12 (5.4)	12 (5.4)	-	-
Thrombocytopenia (n=303)	1 (0.3)	1 (0.3)	-	-
II. *Biochemical parameters*				
Hypernatraemia (n=301)	1 (0.3)	1 (0.3)	-	-
Hyperbilirubinameia (n=302)	2 (0.7)	2 (0.7)	-	-
Increased ALP level (n=288) *	3 (1.0)	3 (1.0)	-	-
Increased ALT level (n=273) *	6 (2.2)	5 (1.8)	-	1 (0.4)
Increased AST level (n=272) *	4 (1.5)	4 (1.5)	-	-

*cut-off value differed by gender, ALP=Alkaline Phosphatase Level, ALT=Alanine amino-transferase level, AST=Aspartate aminotransferase level

[##]For laboratory parameters, the number of participa nts who were normal at baseline changed to abnormal after one week following booster vaccination were analyzed and described as (n).

Table 3. Geometric Men Concentration of anti-SARS-CoV-2 IgG Ab between different groups

Group	GMC of Anti-SARS-CoV-2 IgG Ab at Day-0	GMC of Anti-SARS-CoV-2 IgG Ab at Day-28	P value
All participants [#]	257.96 (231.19, 287.83)	305.43 (284.87, 327.48)	<0.001*
Age			
<45 years (n=120)	238.10 (95%CI, 200.22, 283.14)	263.39 (95%CI, 235.08 - 295.11)	0.046*
≥45 years (n=186)	270.82 (95%CI, 234.78, 312.39)	335.76 (95%CI, 307.95, 366.08)	<0.001*
Gender			
Male (n=82)	187.80 (95%CI, 143.6, 245.59)	257.24 (95%CI, 221.45, 298.82)	0.003*
Female (n=224)	289.75 (95%CI, 259.42, 323.62)	325.25 (95%CI, 301.16, 351.26)	0.001*
History of COVID-19 infection			
Yes (n=119)	305.33 (95%CI, 261.53, 356.48)	336.25 (95%CI, 301.72, 374.73)	0.034*
No (n=187)	231.62 (95%CI, 199.39, 269.05)	287.80 (95%CI, 262.79, 315.18)	<0.001*

GMC=Geometric Mean Concentration, Ab levels were described by BAU/ml, *p value<0.05 was used as significant point in this study. [#]Among 306 vaccinated people, only 15 participants received heterologous type booster vaccination.

The significant increase the GMC of IgG ab levels were noted in both <45 years and ≥45 years. The GMC of Ab levels were also increased in both male and female group ($p<0.05$). Moreover, regardless of the history of COVID-19 infection, the GMC of IgG Ab were significantly raised on both groups ($p<0.05$). The GMC of IgG Ab at different subgroups are also shown in Table 3.

DISCUSSION

Many variants of SARS-CoV-2 virus have emerged and with the recommendation of the WHO, booster immunization among high risk people began worldwide including Myanmar. Now, Ministry of Health, Myanmar is giving COVID-19 booster vaccination to all adults (more than 12 years old) who have completed two doses of primary vaccination.

During the seven days after vaccination, solicited local and systematic adverse reactions were reported by 146(47.7%) and 97(31.7%) participants, respectively. These results were comparable with a safety and immunogenicity study of a third-dose homologus BBIBP-CorV boosting vaccination by Ai J, *et al*, 2022 which described that 44.4% of participants had injection site adverse reactions and 22.2% had systemic adverse reactions.[10] A double-blind placebo control trial of BBIBP-CorV vaccine for primary series vaccination in China during 2020, 46% had solicited adverse events in Phase-1 and 37% in Phase-2.[11] The safety and immunogenicity of BBIBP-CorV (Sino-pharm) among Thai adolescents aged 12-17 years revealed that the vaccine was safe and effective.[12]

According to WHO Strategic Advisory Group on COVID-19 vaccine evidence assessment on BBIBP-CorV (Sinopharm), most AEs were mild to moderate and there was no safety concern. This study also noted that most AEs were mild and the commonest were pain/tenderness at the injection site and fatigue. Those results were also similar to the previous published data.[13] Furthermore, there was no serious adverse event in this study. According to previous studies showed that BBIBP-CorV (Sinopharm) vaccines were safe even in young children (2-12 years) and HIV infected people with Anti-retroviral treatment.[14, 15]

In this study, Geometric Mean Concentration (GMC) of the anti-spike protein IgG Ab levels of SARS-CoV-2 virus were significantly raised after the booster vaccination among factory workers. Moreover, all the participants who were negative anti-SARS-CoV-2 IgG Ab at the baseline became Ab positive after the booster vaccination. During the 28-day study period, the trend of local transmission of COVID-19 infection was low and the positive rate was less than 0.5% of tested samples according to the daily report of Ministry of Health since 1st April, 2022. Therefore, the rise in Ab levels after the booster dose is unlikely to be attributed by natural infection and thus regarded as the effect of booster immunization.

In this study, to determine the immunogenicity of the booster dose, only IgG Ab levels were assessed. The reason for measuring only Anti-SARS-Cov2 IgG is according to a study conducted in China during June 2021, although IgM, IgA and IgG Ab were produced after three doses of BBIBP-CorV vaccination the increase in IgG Ab alone was significant.[4] Moreover, previous studies also reported that the test used in this study (VIDAS® SARS-COV-2 IgG (9COG) (Biomerieux, France assay) which measured for anti-spike protein Ab was well correlated with neutralizing Ab titers.[8]

Regarding the baseline Ab concentration, a study in China conducted in 2021 described that the median of IgG Ab level was only 9.98 (3.09-18.10) BAU/ml at the baseline.[10] One study in Thailand described that baseline anti receptor-binding domain (RBD) Ab was in the range of 33-38 BAU/ml at the Coronavac prime group and 90-116 BAU/ml at ChAdOx1 prime group.[16] Compared to these studies, the baseline GMC of Ab among participants in this study were high, 257.96 BAU/ml (95% CI, 231.19, 287.83). This may be due to the high intensity of Omicron variant infection and this study was

conducted within six months of the fourth wave of COVID-19 infection in Myanmar although only 119 participants (38.9%) had history of natural infection.

The limitation of this study was that neutralizing Ab levels could not be measured using gold standard neutralizing antibody assay as live virus could not be handled due to the limited facility of Biosafety Level-3 laboratory.

Conclusion

The BBIBP-CorV (Myancopharm) vaccine is safe and there is significant increase in antibody levels in the participant population after a booster dose. This study will support the data for the stakeholders to choose the appropriate and effective vaccine and making policy and guidelines for the prevention and control of COVID-19 infection and to stop the pandemic situation.

Competing interests

There were no competing interests.

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