CLINICAL AND EXPERIMENTAL VACCINE RESEARCH

Clin Exp Vaccine Res 2024;13:309-314
https://doi.org/10.7774/cevr.2024.13.4.309
pISSN 2287-3651 • eISSN 2287-366X

Clinical presentation, associated factors, and course of cutaneous reaction after the booster dose of COVID-19 vaccination

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Received: March 25, 2024
Accepted: July 15, 2024

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No potential conflict of interest relevant to this article was reported.

The authors acknowledge Associate Prof. Dr. Chulaluk Komoltri and Ms. Nerisa Thornsi for their assistance with the statistical analyzes.

Purpose: A booster coronavirus disease 2019 (COVID-19) vaccination was proposed to preserve immunity and prevent new variants of the severe acute respiratory syndrome coronavirus 2 virus. The objectives of this study are to investigate clinical manifestations, associated factors and course of cutaneous reactions after the booster dose of COVID-19 vaccination, compared to the recommended 1st and 2nd doses.

Materials and Methods: This retrospective cohort study was conducted at Siriraj Hospital, Bangkok. Adult patients who reported cutaneous reactions after COVID-19 vaccination from April 2021 to February 2022 were included. Data were collected from electronic medical records and analyzed.

Results: A total of 521 subjects with a median age of 38 years were included. Females predominated (80.2%). Most reactions were reported after receiving CoronaVac (49.1%) and ChAdOx1 nCoV-19 (46.3%). The injection site reaction was the most reported. Twenty-one patients reported rash after the 3rd booster dose, with messenger RNA vaccines in most cases. Patients in this group had significantly fewer injection site reactions compared to those with the 1st and 2nd vaccination (70.6% vs. 91.5%) with an increasing proportion of new-onset urticaria (17.6% vs. 5.4%, p=0.023). The rash after the 3rd booster vaccination tended to have a longer duration of reactions (p=0.001). Boosting with a vaccine different from the 1st dose may not affect the reaction. Age and sex did not affect booster rash. In this study, no serious cutaneous reactions were found.

Conclusion: Most adverse cutaneous reactions after COVID-19 vaccination are mild in severity, especially after booster vaccination, and should not discourage the benefits of getting vaccinated.

Keywords: COVID-19 vaccination, Cutaneous reaction, Booster dose

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Introduction

Coronavirus disease 2019 (COVID-19) is a global public health problem. In Thailand, according to the latest information from the Department of Disease Control, as of November 14, 2022, the number of confirmed cases was 4,698,373 [1]. Vaccination against COVID-19 for the population is therefore essential because if most of the population has immunity, it will help control and prevent the spread of the disease. A booster dose was proposed to preserve immunity against a new variant of the severe acute respiratory syndrome coronavirus 2 virus [2,3].

According to research conducted in the United States that focused on 414 healthcare

workers with skin reactions after COVID-19 vaccination, 83% of subjects received messenger RNA (mRNA)-1273 (Moderna, Cambridge, MA, USA), and 17% received BNT162b2 (Pfizer, New York, NY, USA). For vaccination with mRNA-1273, the most common rashes were delayed large local reactions, which were 65.5% after the 1st dose and 30.4% after the 2nd dose. Other reported reactions were local injection site reactions, urticarial eruptions, and morbilliform eruptions. Of the BNT162b2-treated subjects, urticarial eruptions were reported as the most common reactions, which were 23.5% after the 1st dose and 15% after the 2nd dose. The local injection site reactions and morbilliform eruptions were the most reported, respectively [4]. Forty-three percent of people whose rash developed after the 1st vaccination dose will develop a rash after receiving the 2nd dose.

The ChAdOx1 nCoV-19 vaccine was the vaccine with the most reported injection site reactions. Other rare side effects have been reported after this vaccine, including severe cellulitis, vaccine-induced psoriasis, rosacea, vitiligo, and Raynaud's phenomenon [5]. Morbilliform eruption was reported after the booster dose without cutaneous reaction reported after receiving the 1st dose [6].

At the time of starting this investigation in Thailand, there were readily available vaccines for people, namely CoronaVac (Sinovac, Beijing, China), BBIBP-CorV (Sinopharm, Beijing, China), and ChAdOx1 nCoV-19 (AstraZeneca-Oxford, Cambridge, UK). The mRNA vaccines were available as the 3rd booster dose for those previously vaccinated with CoronaVac or ChAdOx1 nCoV-19. Previously, limited data were published that examined the clinical manifestation, associated factors, and course of cutaneous reactions that occur after the booster dose of COVID-19 vaccination in Thailand, especially rashes after the 3rd or more booster doses. Therefore, we conducted this retrospective study to address these issues.

Materials and Methods

This retrospective cohort study was conducted in the Dermatology Clinic of the Department of Dermatology Siriraj Hospital, the Adverse Drug Reaction (ADR) Unit of the Pharmacy Department Siriraj Hospital, and the COVID-19 vaccination unit of Siriraj Hospital, Bangkok, Thailand, from April 2021 to February 2022. Adult patients aged 18 years or older who were vaccinated with the COVID-19 vaccine at Siriraj Hospital, Bangkok, Thailand and reported adverse cutaneous reactions after vaccination were enrolled in the study. Subjects were excluded if cutaneous reactions were found to be due to any other causes by the dermatologist in the research team. Retrospective data in electronic medical record systems since April 2021 were collected from the Dermatology Clinic of the Department of Dermatology Siriraj Hospital, ADR Unit of the Pharmacy Department Siriraj Hospital and the COVID-19 vaccination unit of Siriraj Hospital. These data include demographic data, the date of vaccination, the name of the vaccine, the number of vaccination doses, the onset of the rash, the diagnosis, and the duration of the rash. The onset and duration of the rash were classified as less than 1 day, between 1 and 7 days, and more than 7 days due to the data received from the ADR Unit and the COVID-19 vaccination unit being collected in this format.

This study was ethically approved by the Siriraj Institutional Review Board of the Faculty of Medicine of Siriraj Hospital, Mahidol University (COA SI 1022/2021). Informed consent was obtained from all individual participants included in the study.

Descriptive statistics describe demographic data, diagnosis, onset, and duration of cutaneous adverse reactions. Normally distributed continuous data are presented as mean± standard deviation, non-normally distributed continuous data as median and interquartile range, and categorical data as number and percentage. Chi-square or Fisher's exact tests were used to compare group differences. Analyses were performed with PASW SPSS Statistics for Windows ver. 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Five hundred and twenty-one subjects were enrolled in the study. Among 1,646 patients who reported reaction after vaccination from the COVID-19 vaccination unit, 470 patients (28.6%) had cutaneous reactions. The rest come from the dermatology clinic (40 patients) and the ADR Unit (11 patients). The median age (interquartile range) was 38 (27–52) years, ranging from 14 to 89 years. Three hundred and eighty-eight patients (80.2%) were female. Most of the patients reported the rash after receiving CoronaVac (49.1%) and ChAdOx1 nCoV-19 (46.3%), and a minority after receiving BNT162b2 (17%), BBIBP-CorV (1.2%), and mRNA-1273 (0.2%). Three hundred and ninety-two patients (75.5%) reported a rash after the 1st dose, which was from ChAdOx1 nCoV-19 in 215 patients (54.8%), CoronaVac in 172 patients (43.9%), BBIBP-

CorV in four patients (1.0%), and BNT162b2 in one patient (0.3%). One hundred and six patients (20.4%) reported rash after the 2nd dose, which was CoronaVac in 84 patients (79.2%), ChAdOx1 nCoV-19 in 16 patients (15.1%), BNT162b2 in four patients (3.8%), and BBIBP-CorV in two patients (1.9%). Twenty-one patients (4.0%) reported rash after the 3rd dose, which was of BNT162b2 in 11 patients (52.4%), ChAdOx1 nCoV-19 in nine patients (42.9%), and mRNA-1273 in one patient (4.8%). No one reported a rash after the fourth dose of vaccination.

Among 521 patients who reported cutaneous reactions, 57 patients' data from the COVID-19 vaccination unit were inadequate to diagnose the cutaneous reactions. For the other 464 patients, diagnoses were injection site reactions (90.5%), followed by urticaria (6.0%), eczema (0.6%), maculopapular rash (0.6%), and herpes zoster (0.4%). The other diagnoses were two cases of urticarial vasculitis, one case each of vitiligo, aphthous ulcer, unspecified vesicular eruption, miliaria rubra, folliculitis, and leukocytoclastic vasculitis. Most of the patients had a new onset of cutaneous reaction. Among the 127 patients who reported cutaneous reactions after the 2nd or 3rd dose of vaccination, nine patients had recurrent injection site reactions and three patients had recurrent urticaria. These cases were first vaccinated with CoronaVac and received the booster dose with the 2nd CoronaVac dose. Most of the patients (94.6%) reported the onset of the rash within 1 day, 5.2% reported the onset between 1–7 days, and only one patient (0.2%) reported the onset of the rash after 7 days. More than half of the patients (79.6%) reported a duration of the rash of less than 1 day, 72 patients (16.9%) reported a duration of 1–7 days, and 15 patients (3.5%) reported more than 7 days.

The descriptive statistics of all diagnoses related to the name of the vaccine and the onset of the rash are shown in Table 1. Injection site reactions were diagnosed most frequently in almost all subject groups divided by vaccine name (91.3%, 90.3%, 92.3%, 80.0%, and 0% in the CoronaVac, ChAdOx1 nCoV-19, BNT162b2, BBIBP-CorV, and mRNA-1273 group, respectively). Urticaria comprised half (50%) of the rash, with onset within 7 days after vaccination. Eczema is the only diagnosis with an onset of more than 7 days.

Table 2 shows the comparison of the disease characteristics between patients who received the 3rd booster doses and those who received less than three doses of vaccination. Age and sex were not significantly different between the two groups. Among patients who received the 3rd booster doses of vaccination, the most diagnosed conditions were injection site reactions (70.6%), followed by urticaria (17.6%) and maculopapular rash (5.9%). However, in the group that received less than three doses, the most diagnosed conditions were also injection site reactions (91.5%), followed by urticaria (5.4%). There was a statistically significant difference between the diagnosis of these two groups (p=0.023). There were no statistically significant differences in disease onset compared between these groups. The duration of reactions after receiving the 3rd booster dose of vaccination reported resolution within 1 day in 40%, within 1–7 days in 53.3%, and more than 7 days in 6.7%, while another group reported resolution with-

Table 1. Descriptive statistics of all diagnoses related to the name of the vaccine and the onset of the rash

Diagnosis	Vaccine name					Onset of the reaction		
	CoronaVac (N=229)	ChAdOx1 nCoV-19 (N=216)	BNT162b2 (N=13)	mRNA-1273 (N=1)	BBIBP-CorV (N=5)	<1 day (N=443)	1–7 days (N=20)	>7 days (N=1)
Injection site reaction	209 (91.3)	195 (90.3)	12 (92.3)	0	4 (80.0)	418 (94.4)	2 (10.0)	0
Urticaria	8 (3.5)	18 (8.3)	0	1 (100.0)	1 (20.0)	18 (4.1)	10 (50.0)	0
Eczema	2 (0.9)	1 (0.5)	0	0	0	2 (0.0)	0	1 (100.0)
Maculopapular rash	2 (0.9)	0	1 (7.7)	0	0	2 (0.5)	1 (5.0)	0
Reactivation of herpes zoster	1 (0.4)	1 (0.5)	0	0	0	0	2 (10.0)	0
Urticarial vasculitis	2 (0.9)	0	0	0	0	1 (0.2)	1 (5.0)	0
Vitiligo	1 (0.4)	0	0	0	0	0	1 (5.0)	0
Aphthous ulcer	1 (0.4)	0	0	0	0	1 (0.2)	0	0
Unspecified vesicular lesion	1 (0.4)	0	0	0	0	0	1 (5.0)	0
Miliaria rubra	1 (0.4)	0	0	0	0	1 (0.2)	0	0
Pityrosporum folliculitis	0	1 (0.5)	0	0	0	0	1 (5.0)	0
Leukocytoclastic vasculitis	1 (0.4)	0	0	0	0	0	1 (5.0)	0

Values are presented as number (%).

Table 2. Comparison of disease characteristics between patients who received three or more booster doses of vaccination and patients who received less than three doses of vaccination

Characteristic	Rash after the 3rd booster dose (N=21)	Rash after the 1st or 2nd dose (N=497)	p-value
Age (yr)	37 (26.5–44.5)	38 (27.0–53.0)	0.310
Sex			1.000
Male	4/21 (19.0)	92/461 (20.0)	
Female	17/21 (81.0)	369/461 (80.0)	
Diagnosis			0.023*
Injection site reaction	12/17 (70.6)	407/445 (91.5)	
Urticaria	3/17 (17.6)	24/445 (5.4)	
Maculopapular rash	1/17 (5.9)	2/445 (0.4)	
Eczema	0	3/445 (0.7)	
Reactivation of herpes zoster	0	2/445 (0.4)	
Others	1/17 (5.9)	7/445 (1.6)	
Onset of the reaction (day)			0.119
<1	18/21 (85.7)	473/497 (95.2)	
1–7	3/21 (14.3)	23/487 (4.6)	
>7	0	1/497 (0.2)	
Duration of the reaction (day)			0.001*
<1	6/15 (40.0)	333/410 (81.2)	
1–7	8/15 (53.3)	64/410 (15.6)	
>7	1/15 (6.7)	13/410 (3.2)	

Values are presented as median (interquartile range) or number/total numbers (%).
*p<0.05 (statistical significance).

in 1 day in 81.2%, within 1–7 days in 15.6%, and more than 7 days in 3.2%. There is a statistically significant difference between these two groups in the duration of the disease (p=0.001).

In the group of patients whose cutaneous reactions occurred after receiving the 2nd dose of vaccination with the ChAdOx1 nCoV-19 vaccine, comparing patients who were first vaccinated with the CoronaVac vaccine and the ChAdOx1 nCoV19 vaccine revealed no statistically significant differences in the diagnosis, onset, and duration of reactions, as shown in Table 3.

Table 3. Comparison within the group of patients whose cutaneous reactions occurred after receiving the 2nd dose of vaccination with the ChAdOx1 nCoV-19 vaccine: between patients who were first vaccinated with the CoronaVac vaccine and the ChAdOx1 nCoV-19 vaccine

Characteristic	First vaccinated by CoronaVac (N=3)	First vaccinated by ChAdOx1 nCoV-19 (N=10)	p-value
Diagnosis			1.000
Injection site reaction	2 (66.7)	8/10 (80.0)	
Urticaria	1 (33.3)	2/10 (20.0)	
Onset of the reaction (day)			1.000
<1	2 (66.7)	8/10 (80.0)	
1–7	1 (33.3)	2/10 (20.0)	
Duration of the reaction (day)			0.375
<1	0	5/7 (71.4)	
1–7	0	0/7 (0.0)	
>7	1 (100.0)	2/7 (28.6)	

Values are presented as number/total numbers (%).

Discussion

During the COVID-19 pandemic, Thailand encouraged its citizens to be vaccinated. In April 2021, only CoronaVac and ChAdOx1 nCoV-19 were available in Thailand. People were aware of these vaccines because they were new vaccines and people were still concerned about their efficacy and side effects. Therefore, most of the patients in this study demonstrated cutaneous reactions mainly due to these two types of vaccine in a similar proportion. In August 2021, the mRNA or ChAdOx1 nCoV-19 vaccines were officially recommended as the additional booster dose (the 3rd dose) for people who were completely vaccinated with previous CoronaVac and ChAdOx1 nCoV-19 for maintenance of effectiveness [7,8].

 https://doi.org/10.7774/cevr.2024.13.4.309

However, our study reported a lower rate of cutaneous reaction after the 3rd booster dose, which corresponded to previous studies [9,10]. The mechanism explaining this has not yet been established. Our proposed mechanism is that by receiving multiple doses of vaccination, the previously stimulated immune system is now familiar with the constituent of the vaccine, resulting in fewer adverse reactions.

In our study, we found that the most reported adverse cutaneous reactions were injection site reactions in almost all vaccines, followed by urticaria and eczema. This finding contrasts with the study mentioned earlier [11], which found that the most common diagnosis was urticaria followed by an eczematous reaction and angioedema, respectively, after vaccination with CoronaVac and ChAdOx1 nCoV-19. However, this finding is consistent with a systematic review that reported that the most common adverse cutaneous reaction reported after COVID-19 vaccination was at the injection site [12]. Furthermore, our results are consistent with the previous systematic review [12], in which COVID-19 vaccination can be associated with skin conditions such as herpes zoster, vasculitis, and vitiligo, although in rare cases. Most cutaneous reactions were mild in severity and lasted for less than 1 day. We did not observe any previously reported life-threatening conditions, such as anaphylaxis [11,12].

The diagnosis of adverse cutaneous reactions after the 3rd booster of the COVID-19 vaccine differed from the 1st or 2nd dose of vaccination. In this group, there was an increased proportion of new-onset urticaria, an increased proportion of a longer onset of more than 1 day, and also an increased proportion of a longer overall duration of the rash. These findings corresponded with the previous questionnaire-based study in Switzerland that reported that chronic spontaneous urticaria could start after the booster dose (at the 3rd dose) of the COVID-19 vaccine with a median onset of 10 days after vaccination [13]. Some authors suggested that the highest responses of humoral and cellular immunity induced by a booster dose of vaccination and the production of histamine-releasing autoantibodies may play a role in this reaction [14]. Age and sex did not affect the rash after the 3rd dose booster. However, our findings on diagnosis were in contrast to recent studies, which reported higher percentages of patients who had injection site reactions after receiving the COVID-19 booster dose than in the 1st or 2nd doses [15,16].

According to the 2nd booster of the ChAdOx1 nCoV-19 vaccine, there were no statistically significant differences in cutaneous reactions, onset and the duration of reactions between patients who received the 1st vaccination with the CoronaVac vaccine or the ChAdOx1 nCoV-19 vaccine. This suggests that receiving the booster dose with a different vaccine from the 1st dose may not affect the reaction. However, this study had few participants in each arm. A study in a larger population is needed to explain this.

Our main limitations in this study are that we do not have data on total doses of COVID-19 vaccines injected during those periods, so we could not calculate the prevalence of reported adverse cutaneous reactions. In addition, there were not many mRNA vaccines injected at that time because it was just introduced in Thailand. The total number of subjects had reached the amount required when the mRNA vaccines were readily available, so our subgroup of data on adverse cutaneous reactions after injection of the mRNA vaccine was small and all statistical analyzes involving this subgroup had less statistical power. Some data on the type of vaccine previously vaccinated were missing. The subgroup analysis of the booster dose was small, making significant differences difficult to interpret. This may be due to the fact that people have begun to understand that most reactions are likely to be self-limiting. As a result, the side effects of vaccination may be underreported compared to the early days when the COVID-19 vaccine was still a new issue.

In conclusion, in Thailand, many types of COVID-19 vaccines are used with many different protocols. After the 3rd booster vaccination, there is a lower rate of cutaneous reaction compared to the 1st and 2nd doses. Age and sex did not affect the booster rash. The most common adverse cutaneous reaction was the injection site reaction, with a significantly increasing proportion of new-onset urticaria. The rash after the booster vaccination tended to last longer. A booster with a vaccine different from the 1st dose did not affect the reaction. Finally, the booster vaccine is safe, and patients should not be discouraged from vaccinating.

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