Factors Associated with Adverse Event Following Immunization of First Dose of COVID-19 Vaccination in Bamrasnaradura Infectious Disease Institute, Thailand

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Abstract

With the emergence of the Coronavirus disease 2019 (COVID-19) pandemic. The new vaccines are emergency using including Thailand. There are 4 types of vaccines authorized for use, inactivated vaccine (Sinovac and Sinopharm), Viral vector vaccine (AstraZeneca, Janssen), mRNA vaccine (Pfizer and Moderna), and Protein based vaccine (Novavax). However, many people who received the vaccine develop adverse events following immunization (AEFI). Because it was emergency using the study about the AEFI still limited. This study aims to investigate and evaluate associated AEFI factor of first dose of COVID-19 vaccine in Bamrasnaradura Infectious Disease Institute, Thailand. We conducted a cross-sectional study. Data were collected from individuals who received vaccine in Bamrasnaradura Infectious Disease Institute and reported in MoPH IC between March1st and September 30th, 2021. The study found that most participants were female (64.44%), no underlying disease (90.52%), young adult (49.17%), and received AstraZeneca vaccine (59.07%). The common symptoms found in this study were fever (43.7%), myalgia (41.37%), headache (38.50%), fatigue (24.44%), pain-swelling-redness at injection site (18.77%), and drowsiness (13.74%). Overall, the most common factors associated with AEFI in this study were: people who do not have an underlying disease, females, and the young adult group. In conclusion, the AEFI symptoms usually happen in people who received AstraZeneca followed by Sinovac, and Pfizer. This study found that there were many variables associated with AEFI. The finding important implications for the ongoing COVID-19 vaccination campaign in Thailand.

Keywords*: *AEFI, COVID-19, COVID-19 vaccine, Sinovac, AstraZeneca, and Pfizer.

1. Introduction

With the emerging of Coronavirus disease 2019 (COVID-19) pandemic, the WHO Director General declared on January 30th, 2020, following by the recommendations of the Emergency Committee, that the outbreak constitutes a Public Health Emergency of International Concern (PHEIC) (World Health Organization (WHO), 2020a). The world is working rapidly to find ways to stop this outbreak. Its aim is to give more people around the world access to safe, effective, and cheap COVID-19 diagnostics, treatments, and vaccinations (WHO, 2020b and Chen et.al., 2020).

Coronavirus disease vaccination helps herd immunity and COVID-19 spread. On February 24, 2021, Thailand began distributed COVID-19 shots. COVID-19 vaccines were given to 13 high-risk provinces, and they began by vaccinating front-line health care workers and volunteers, followed by high-risk patients, including the elderly (60 years and older), pregnant women, chronic disease patients, and those over 90 kg. Vaccinating high-risk individuals reduces the risk of severe disease and death (WHO, 2021; Thai DDC, 2021a).

Thailand authorizes four emergency vaccines. Firstly, inactivated vaccines in the name Sinovac and Sinopharm. Secondly, AstraZeneca in the group of viral vector vaccine. Thirdly, Pfizer and Moderna are mRNA vaccines. Lastly, protein subunit vaccine in the name of Novavax (Thai DDC, 2021b).

The Bamrasnaradura Infectious Disease Institute, under the Department of Disease Control, Ministry of Public Health, Thailand, distributes COVID-19 vaccinations. Bamrasnaradura Infectious Disease Institute distributes 2,000 vaccine doses daily and has a strong vaccination distribution protocol (Thai DDC, 2021a).

Adverse events following immunization (AEFI) is unfavorable medical events that occur after vaccination (WHO, 2021). Vaccine-related stress reactions, accidents, and routine errors can cause AEFI. AEFI problems are closely related to public perceptions of the vaccine's effectiveness and safety. Increasing immunization coverage is accompanied by adverse events following immunization (AEFI), which are unfavorable medical occurrences that occur after vaccination but are not necessarily caused by vaccine use (Center for Disease Control and Prevention (CDC), 2021; Thai DDC, 2021). There are not only vaccine-related AEFI, but also anxiety-related AEFI caused by vaccination stress reaction, accident, or procedural error (WHO, 2022a and b; Thai DDC, 2021a). AEFI problems are closely related to public perceptions of the vaccine's effectiveness and safety. This is one of the factors affecting whether the community accepts or rejects the vaccination. Refusing to get vaccinated lowers the number of people who get vaccinated and lowers herd immunity (VAERS, 2021; WHO, 2021; Thai DDC, 2021a). This can lead to centralized outbreaks or pockets of infection in such groups.

In Thailand, we have two platforms for reporting AEFI symptoms. First, the Thai Ministry of Public Health created the MoPH Prompt application for vaccine reservation, monitoring, and COVID-19 information. It monitors adverse symptoms post-vaccination. The second is the AEFI reporting sheet, which collects data from patients in the hospital with any symptom after vaccination (VAERS, 2021; Thai DDC, 2021a).

WHO studies found that most COVID-19 vaccine side effects were mild, such as Fever, cough, injection-site pain, and redness (VAERS, 2021). The main AEFI were also difference. However, because of its emergency use during the pandemic, information on AEFI is still limited.

Previous studies have shown that most of the side effects were mild, such as, pain, and redness at the injection site, fever, headache (Subedi, Yadav, Paudel, Regmi, & Pyakurel, 2021). Also, the main group of AEFI that were shown were varies. However, because of its emergency use during pandemic, information on AEFI is still limited. The aim of this study to research the incident of adverse events following immunization with the COVID-19 vaccine in Bamrasnaradura Infectious Disease Institute (Thai general population). The data of this study included 125,344 participants who received their dose of COVID-19 at Bamrasnaradura Infectious Disease Institute between March1st and September 30th, 2021. The data was collected from the MoPH Prompt application and the AEFI reported sheet.

2. Objectives

1. To investigate the AEFI prevalence of first dose of COVID-19 vaccine at BIDI.
2. To evaluate associated AEFI factor of first dose of COVID-19 vaccine at BIDI.

3. Materials and Methods

3.1 Study design and participants

Our cross-sectional study was conducted from March 1st to September 30th, 2021 at the Bamrasnaradura Infectious Disease Institute under the Department of Disease Control, Ministry of Public Health, Thailand. Over the course of the study, a total of 125,344 participants received the Sinovac, AstraZeneca, and Pfizer vaccines.

3.2 Data collection

Data were collected from AEFI surveillance in Thailand was used. The AEFI surveillance was conducted for the two doses for 30 days each dose using the Ministry of Public Health Immunization Centre (MoPH Prompt application) and AEFI1 reported sheet. 30 days after the first dose, the second dose was given. The whole country of Thailand uses the MoPH Prompt application which developed by Thai Ministry of Public Health. People can log in by using the number on their ID card and their phone number. It is only in the database of the Ministry of Health Immunization. An application for using COVID-19 in Thailand under

the supervision of the Thai Ministry of Public Health that checks the vaccine history and test results. It has the 6 functions: Show the latest COVID-19 test results, book a COVID19 vaccine, Schedule a COVID-19 vaccination, Show COVID19 vaccination history, Show COVID19 vaccination certificate, and records self-reported any symptoms after receiving COVID19 vaccine (Thai DDC, 2021a). Participants were asked if they had been COVID-19 vaccinated and, if so, to record the type of vaccine and date of administration. Users reporting vaccination were then asked 3 times for the following (day1, day2-14, and day15-30) whether they experienced adverse effects, including both systemic and local effects, for example, headache, fatigue, chills and shiver, diarrhea, fever, arthralgia, myalgia, nausea, local pain, swelling, tenderness, redness, itch, warmth, and swollen armpit glands. Users could also leave the box unchecked to say that they had no symptoms (Thai DDC, 2021a).

The Ministry of Public Health Immunization and the AEFI-1 reporting center (MoPH Prompt application) are passive reporting of adverse events following immunization (AEFI) by healthcare professionals in the hospital is the primary mechanism for phase IV surveillance of vaccine safety (Thai DDC, 2021a).

3.3 Data Analysis

The data were analyzed by using Python programming, which is a statistical programming language. For the data description, which includes gender, age, underlying disease, and vaccine type details. We present this data as frequencies and percentages. Moreover, we performed bivariate tests between the dependent and independent variables. In this step, the dummy underlying disease variables are converted to "Yes" or "None" to simplify the analysis. Lastly, we used the Chi-square test and P value to screen the relationship of variables, which is a statistical method that helps to identify whether there is a significant association between variables.

4. Results and Discussion

In table 1, we present demographic and clinical characteristics of participants who experienced AEFI. The number of patients with AEFI was 16,779. The majority of participants were female (64.44%) and had underlying medical conditions (9.48%), with respiratory conditions and cardiovascular being the most common. Approximately 49.17% of participants who experienced adverse events following immunization were young adults (18 – 40 years old).

The majority of people who received first dose of vaccine type in this study are Sinovac (52.77%), AstraZeneca (47.01%), and Pfizer (0.11%). For those who received the first dose of COVID-19 vaccine and experienced AEFI, the majority received AstraZeneca (59.07%), Sinovac (40.87%), and Pfizer (0.06%). Moreover, the majority of AEFI symptoms were mild and self-resolvable, such as fever (43.7%), myalgia (41.37%), headache (38.50%), fatigue (24.44%), pain, swelling, redness at the injection site (18.77%), and drowsiness (13.74%).

Table 1 Demographic, clinical characteristic, and clinical of AEFIs table.

Variables	Categories	Number (Persons)	Percent (%)
Gender	Men	5,966	35.56
	Women	10,813	64.44
	Gender_total	16,779	100.00
Age	Young Adult (18-39 years)	8,251	49.17
	Middle Adult (40-59 years)	6,970	41.54
	Elderly (60-79 years)	1,455	8.67
	Senior elderly (80 years and older)	103	0.61
	Age_total	16,779	100.00
Underlying	Kidney disease	40	0.24
	Respiratory disease	463	2.76
	Diabetes	281	1.67
	Cancer	110	0.66

Variables	Categories	Number (Persons)	Percent (%)
	Cerebrovascular disease	35	0.21
	Cardiovascular disease	277	1.65
	Obesity	378	2.25
	Neurological disease	4	0.02
	Underlying_total	1,591	9.48
Other conditions	Pregnancy	3	0.02
No underlying disease and other condition		15,188	90.52
	Condition_total	16,779	100.00
Vaccine type	AstraZeneca	9,912	59.07
	Sinovac	6,857	40.87
	Pfizer	10	0.06
	Sum_vaccine	16,779	100.00
AEFIS	Pain, swelling and redness at Injection Site	3,149	18.77
	Fever	7,347	43.79
	Headache	6,460	38.50
	Fatigue	4,100	24.44
	Myalgia	6,941	41.37
	Weakness	733	4.37
	Nausea	1,201	7.16
	Vomiting	389	2.32
	Diarrhea	858	5.11
	Rash	570	3.40
	Drowsiness	2,305	13.74
	Joint pain	480	2.86
	Numbness	242	1.44
	Hemorrhagic spot	48	0.29
	Blurred vision	131	0.78
	Dyspnea	224	1.34
	Other	1,931	11.51
	Sum_AEFIs	16,779	100.00

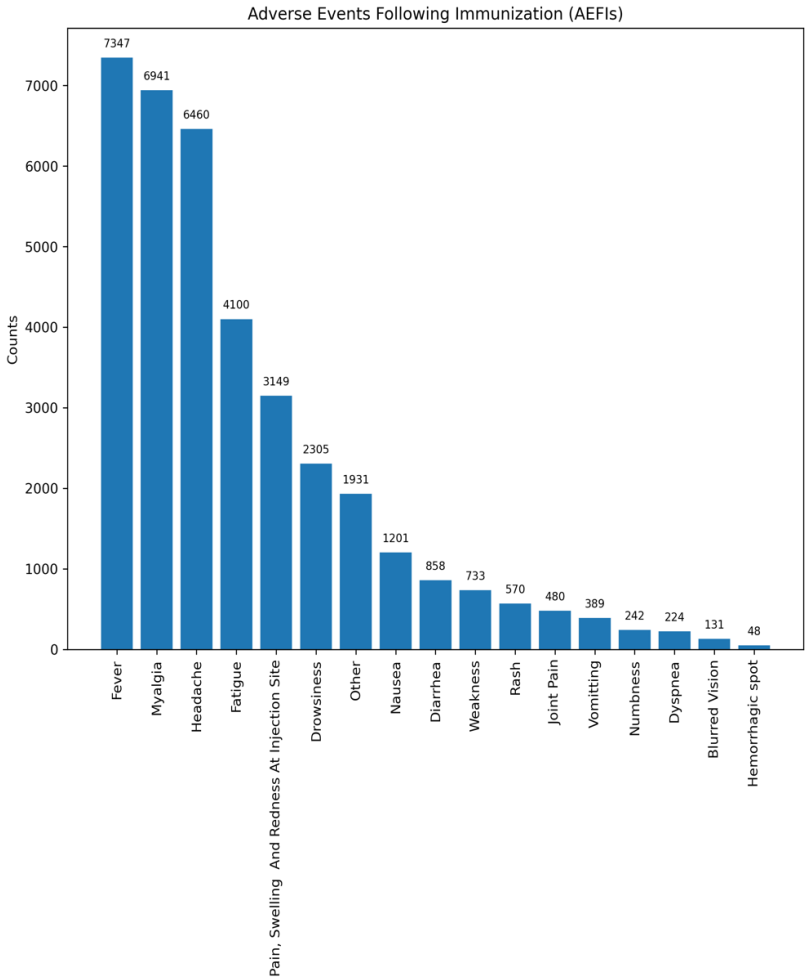

Figure 1 Number of people who have AEFI after received COVID19 vaccine in Bamrasnaradura Infectious Disease Institute.

Figure1 shows the number of AEFI symptoms after receiving COVID-19 vaccine in BIDI between March 1st and September 30th, 2021, within 30 days. The unit is measured in persons.

Table 2 Characteristics of participants that related with AEFI after receiving their first dose of COVID-19 vaccine. P value, a significance level of <0.05 (*).

AEFIs	Gender			Age groups					Underlying disease			Vaccine type			
	Male	Female	χ^2 (p)	YA	MA	ED	SED	χ^2 (p)	Yes	No	χ^2 (p)	AZ	SV	PZ	χ^2 (p)
Pain, swelling and redness at injection site	6.3	12.52	8.400 **(.004)***	9.5	7.5	1.7	0.1	10.722 **(.013)***	1.77	17.0	0.005 (.941)	12.4	6.3	0.0	83.070 **(<.001)***
Fever	16.2	27.6	11.249 **(.001)***	23.1	16.9	3.5	0.2	69.597 **(<.001)***	5.58	39.9	5.012 **(.025)***	33.8	10.0	0.0	1757.991 **(<.001)***
Headache	10.9	27.56	232.887 **(<.001)***	20.9	14.8	2.7	0.2	127.190 **(<.001)***	6.19	35.2	10.223 **(.001)***	25.3	13.2	0.0	190.890 **(<.001)***
Fatigue	8.2	16.22	8.861	15.1	7.8	1.4	0.1	353.513	7.40	22.4	5.507	16.2	8.2	0.0	118.297

		48.22	**(.003)***				0.5	**(<.001)***			**(.019)***				**(<.001)***
Myalgia	14.6	26.8	0.591	21.8	15.9	3.4	0.3	62.842	5.60	37.5	0.127	27.9	13.4	0.0	346.940
		37.64	(.442)				0.4	**(<.001)***			(.722)				**(<.001)***
Weakness	1.9	2.48	19.435	2.9	1.3	0.1	0.0	100.076	9.14	4.0	2.013	3.1	1.3	0.0	46.828
		61.96	**(<.001)***					**(<.001)***			(.156)				**(<.001)***
Nausea	1.3	5.84	165.338	3.9	2.6	0.6	0.1	16.700	8.90	6.6	2.803	4.4	2.8	0.0	4.135
		58.6	**(<.001)***				0.6	**(.001)***			(.094)				(.126)
Vomiting	0.4	1.95	67.768	1.3	0.8	0.2	0.0	6.512	9.33	2.2	3.307	1.6	0.7	0.0	13.634
		62.49	**(<.001)***	47.9		8.5	0.6	(.089)			(.069)				**(.001)***
Diarrhea	1.9	3.24	0.381	2.9	2.0	0.3	0.0	28.227	8.96	4.6	0.540	3.0	2.1	0.0	0.732
		61.2	(.537)	46.3		8.4	0.6	**(<.001)***			(.462)				(.694)
Rash	0.9	2.53	25.007	1.6	1.5	0.3	0.0	2.949	9.23	3.2	2.822	1.7	1.7	0.0	26.453
		61.92	**(<.001)***	47.6		8.4	0.6	(0.400)			(.093)				**(<.001)***
Drowsiness	4.5	9.26	10.171	7.6	5.6	0.5	0.1	99.507	8.21	12.5	0.150	9.0	4.7	0.0	55.783
		55.18	**(.001)***			8.2	0.6	**(<.001)***			(.698)				**(<.001)***
Joint pain	1.0	1.85	0.000	1.5	1.3	0.1	0.0	23.046	9.20	2.6	0.099	2.2	0.6	0.0	74.265
		62.6	(0.987)				0.6	**(<.001)***			(.754)				**(<.001)***
Numbness	0.5	0.98	1.336	0.8	0.6	0.1	0.0	9.645	9.27	1.2	7.698	1.0	0.4	0.0	15.614
		63.46	(0.248)				0.6	**(.022)***			**(.006)***				**(<.001)***
Hemorrhagic spot	0.1	0.22	2.826	0.2	0.1	0.0	0.0	1.300	9.47	0.3	1.024	0.2	0.1	0.0	0.063
		64.22	(.093)					(.729)			(.311)				(.969)
Blurred vision	0.3	0.5	0.000	0.4	0.3	0.1	0.0	2.019	9.42	0.7	0.331	0.5	0.3	0.0	14.944
		63.94	(.988)					(.568)			(.565)				**(.001)***
Dyspnea	0.4	0.97	6.502	0.7	0.6	0.1	0.0	5.976	9.37	1.2	0.160	1.0	0.3	0.0	26.611
		63.47	**(.011)**					(.113)			(.690)				**(<.001)***
Others	3.7	7.84	12.548	4.3	5.7	1.4	0.1	122.008	8.21	10.2	5.894	5.2	6.3	0.0	176.294
		56.61	**(<.001)***					**(<.001)***			**(.015)***				**(<.001)***

AZ= AstraZeneca vaccine, SV= Sinovac vaccine, PZ= Pfizer vaccine, YA= Young Adult (18-39 years), MA= Middle Adult (40-59 years), EA= Elderly (60-79 years), and SE= Senior Elderly (80 years and older).

Table 2 presents information on the sample size, number of AEFI symptoms, AEFI proportion, chi-square test statistic, and p-value for each of the variables are considered. The bivariate tests include a chi-square test for independence to determine whether there is a significant relationship between each variable and the occurrence of AEFI. To begin with the independent variables that associated with headache are gender (χ^2= 232.88, p <.001), age (χ^2= 69.59, p <0.001), disease history (χ^2= 10.22, p = 0.0013), and type of vaccine (χ^2= 190.89, p <.001). Next, the independent variables that associated with fever are gender (χ^2= 232.88, p <.001), age (χ^2= 127.189, p <.001), disease history (χ^2= 5.011, p = 0.025), and type of vaccine (χ^2= 1757.99, p <.001). Next, the independent variables that associated with muscle pain are age (χ^2= 62.842, p <.001), and type of vaccine (χ^2= 346.93, p <.001). Next, the independent variables that associated with fatigue are gender (χ^2=8.861, p =.003), age (χ^2= 353.513, p <.001), disease history (χ^2= 5.0506, p = 0.019), and type of vaccine (χ^2= 118.297, p <.001) Next, the independent variables that associated with fatigue are gender (χ^2=8.861, p =.003), age (χ^2= 353.513, p <.001), disease history (χ^2= 5.0506, p = 0.019), and type of vaccine (χ^2= 118.297, p <.001). Factors associated with the incidence of nausea were gender (χ^2=165.338, p <.001), and age (χ^2=, 16.700, p =0.001) Factors associated with the incidence of vomit were gender (χ^2= 67.768, p <.001), and type of vaccine (χ^2=13.63, p =0.001). Factors associated with the incidence of diarrhea was age (χ^2=28.227, p <.001). Factors associated with the incidence of rash were gender (χ^2= 25.007, p <.001and type of vaccine (χ^2=26.45, p <.001). Factors associated with the incidence of feeling sleepy were gender (χ^2= 10.171, p <.001), age (χ^2=99.507, p <.001), and type of vaccine (χ^2=55.78, p <.001). Factors associated with the incidence of joint pain were age (χ^2=23.046, p <.001) and type of vaccine (χ^2=74.26, p <0.001). Factors associated with the incidence of numbness were age (χ^2=9.645, p =0.022), disease history (χ^2=7.69, p = 0.005),

and type of vaccine (χ^2=15.61, p <.001). Factors associated with the incidence of difficult breathing were gender (χ^2=6.502, p =0.011), and type of vaccine (χ^2=26.61, p < 0.001). Lastly, factors associated with the incidence of blur vision was type of vaccine (χ^2=14.94, p =0.001).

4. Discussion

Thailand began the COVID-19 vaccination campaign on February 28th, 2021. The initial vaccine used was the Sinovac vaccine, followed by AstraZeneca vaccine and Pfizer vaccine in March 2021 and July 2021, respectively. A total of administered first dose of vaccine between March 1st to September 30th, 2021, at Bamrasnaradura Infectious Disease Institute were 125,344 persons. The rate of AEFI from the MoPH Prompt IC at this period was 16,799, which was 13.40%. However, there are studies about AEFI from many countries, the majority of AEFI reported were mild, including pain-swelling-redness at injection site, fever, headache, and fatigue (Public Health Ontario, 2020; Tran , 2021; Supangat, 2021). These studies also found that females, young adults individuals, those with no underlying diseases, and those who received the AstraZeneca vaccine had an increased risk of AEFI after the first dose of COVID-19 vaccination (Kant et al., 2022; Wang et al., 2021). Our findings are consistent with previous studies that have identified similar risk factors for AEFI, including women and young adult group. The higher risk of AEFI among females may be due to biological factors such as differences in immune response to vaccines (Kant et al., 2022). The higher risk among younger people with no underlying diseases may be due to their higher immunity (Wang et al., 2021).

Previous studies showed the majority of side effects is pain, redness and swelling at injection side, following by fever, myalgia or muscle pain, and headache (Supangat, 2021; Subedi et al., 2021; Lee et al., 2021). This is different from our study, pain, redness and swelling at injection side is in rank fived of our study. In our study, the most common symptom that people reported is fever following by myalgia, headache, fatigue, and pain, redness and swelling at injection site, respectively.

The study has some limitation. The number of people who received Pfizer in this study is very different from others. This is because in Thailand, we imported Pfizer after Sinovac and AstraZeneca vaccine. The risk group of people, received as the other vaccines already. As a result, the number of people who received Pfizer are lower than other groups. Next, our respondents have to reported in the application MoPH Prompt or in the hospital, so many people may not report symptom because it is very mild and resolvable. Next, this study cannot conclude that which variables are commonly the AEFI symptom. We must use further statistics to calculate it. Lastly, we finished the follow-up questionnaire four weeks after the vaccination. In order to evaluate the late symptoms of immunization, long-term follow-up is required.

5. Conclusion

This study found headache, fatigue, and fever are associated with gender, young adult, no underlying disease and received AstraZeneca vaccine. For the weakness symptom, and pain-swelling -redness at injection site are associated with gender, young adult, and AstraZeneca. For the numbness symptom is associated with young adult, no underlying disease and received AstraZeneca vaccine. Moving on to myalgia, it is associated with young adult and received AstraZeneca vaccine. Nausea is associated gender and young adult. For vomiting, it is associated with gender and received AstraZeneca vaccine.

These findings have important implications for the ongoing COVID-19 vaccination campaign in Thailand. First, healthcare providers should be aware of the increased risk of AEFI in certain populations, such as females, individuals with no underlying disease, and those who are younger group (18-59 years old). Second, the study's findings suggest that individuals who receive the AstraZeneca vaccine may be more likely to experience AEFI than those who receive the Sinovac and Pfizer vaccine. This highlights the need for ongoing surveillance and monitoring of AEFI in vaccinated individuals to ensure that any safety concerns are promptly identified and addressed.

Overall, this study provides important insights into the factors that may contribute to AEFI following the first dose of COVID-19 immunization in Thailand. Continued monitoring of AEFI, along with targeted efforts to minimize the risk of adverse events, will be essential to ensure the success of Thailand's COVID-19 vaccination campaign.

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