ORIGINAL ARTICLE

Pregnancy Outcomes in COVID-19 Vaccination During Pregnancy

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Objective: To evaluate the pregnancy outcomes in COVID-19 vaccination during pregnancy

Materials and Methods: The present study was a retrospective cohort study. The data were collected from pregnant women attending antenatal care (ANC) and delivery at Makarak Hospital, Kanchanaburi Province, between September 2021 and April 2022. The studied subjects were categorized into three groups, antepartum factor, intrapartum factor, and postpartum and newborn factor. The relationship of each factor was brought for comparative study in COVID-19 vaccination status as vaccinated or unvaccinated, during pregnancy. Then, multivariable analysis was used to adjust the relationship of the variables in each group.

Results: Five hundred sixteen pregnant women attended ANC and delivered. They were aged 27.5 years on the average. Most of them were gravida 2. The proportion of vaccines received was 19.2%. When comparing between the vaccinated and the unvaccinated groups, it was found that the vaccinated group was significantly increased in diabetes disorder (adjusted OR 3.54, 95% CI 1.67 to 7.50) and significantly decreased in neonatal intensive care unit (NICU) admission (adjusted OR 0.43, 95% CI 0.24 to 0.76). Other adverse outcomes between the two groups were not significantly different. In addition, COVID-19 infection rate during intrapartum period was not different (adjusted OR 2.13, 95% CI 0.87 to 5.22, p=0.09).

Conclusion: Diabetes disorder during pregnancy was significantly higher and risk of NICU admission was significantly lower in the COVID-19 vaccinated group compared with the unvaccinated group. Adverse obstetric outcomes between the vaccinated and unvaccinated groups were not different.

Keywords: Pregnancy outcomes; COVID-19 vaccination; Pregnant women

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COVID-19 infection has caused high morbidity and mortality in high-risk populations[1,2]. The risk groups of severe symptoms include patients aged over 60 years, patients with underlying disease, and pregnant women[3,4]. Particularly, pregnant women have anatomical and physiological changes during pregnancy[5], especially in the cardiovascular and the respiratory systems. They are regarded as a fragile group with a risk of severe illnesses or death if infected[6].

There is a report that pregnant women have a high risk of more severe illness than the general population[6], especially higher rates of intensive care unit (ICU) admission, higher use of respirators, and higher mortality[7]. Likewise, COVID-19 infection during pregnancy possibly causes fetal growth restriction, preterm labor, preterm premature rupture of membrane (PPROM), postpartum hemorrhage, higher rates of cesarean section (CS), and infection in newborns[8,9].

Prevention by vaccination is accepted by the World Health Organization (WHO) and was provided to pregnant women in several countries[10,11]. There have been no significant reports about vaccination complications during pregnancy yet such as abortion or fetal anomalies[12]. Vaccination can also reduce the severity and mortality caused by the COVID-19 infection[13]. However, the available data in Thailand are still limited. Thus, the aim of the present study was to evaluate the pregnancy outcomes in COVID-19 vaccination during pregnancy in Thai pregnant women.

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Materials and Methods

The present study was a retrospective cohort study. The data were collected from pregnant women attending the antenatal care (ANC) and delivering at Makarak Hospital, Kanchanaburi Province, between September 2021 and April 2022. The inclusion criteria were pregnant women that delivered at Makarak Hospital, aged 18 years or older, and a gestational age of 28 weeks or more with medical history of ANC. During those times, the present study hospital provided COVID-19 tests for all pregnant women that delivered or those admitted as patients. The exclusion criteria were those with multifetal pregnancy, and unknown vaccination status.

The data on pregnancy outcomes were categorized into three parts as follows:

Part 1, included data of ANC, such as age, the number of gravida, gestational age, the number of ANC visits, hypertension disorders (including preeclampsia with or without severe features, chronic hypertension, and gestational hypertension), diabetes disorder (including gestational diabetes mellitus and pregestational diabetes mellitus), abnormal amniotic fluid index of less than 5 cm or more than 24 cm, placenta previa, underlying disease, previous CS, and COVID-19 vaccination during pregnancy (at that period, most vaccines given to pregnant women were mRNA vaccines, and the present study only focused on "vaccinated" or "unvaccinated" during pregnancy). The number of vaccines and its immunogenicity were not taken into consideration for the outcomes of the study.

Part 2, included data of the intrapartum period, such as fetal presentation, chorioamnionitis, placental abruption, induction of labor, intrauterine fetal status, delivery route (spontaneous vaginal delivery group and CS or operative vaginal delivery group), preterm delivery, meconium staining, and COVID-19 infection status during the intrapartum period (according to the admission criteria at that time, all patients and pregnant women who would deliver had to take a COVID-19 test before admission).

Part 3, included data of the postpartum and newborn period such as postpartum hemorrhage, blood transfusion, puerperal fever, longer admission than usual (48 hours after vaginal delivery or 72 hours after CS), birth asphyxia, low birth weight, stillborn or dead fetus in utero (DFIU), and newborn transfer to neonatal intensive care unit (NICU).

The main outcomes were pregnancy outcomes in terms of the antepartum, intrapartum, postpartum, and newborn factors. The association between the vaccinated and unvaccinated groups was studied and compared. Other factors affecting pregnancy in the vaccinated and unvaccinated groups were also studied.

Statistical analysis

The sample size was calculated by the infinite population proportion formula[14,15]. The proportion was 0.18, referenced to the study of Magnus et al.[16] who found 18% of vaccinated women during pregnancy when comparing to the total number of pregnant women, determined to an alpha error of 0.05 and power 80%. The sample size was 454. The present study was approved by the Institutional Review Board of Makarak Hospital, number 099. The data analyses were using Stata Statistical Software, version 17 (StataCorp LLC, College Station, TX, USA). Descriptive data were reported in the form of percentage, mean, standard deviation, median, minimum, and maximum. A comparative analysis of the qualitative data for the relationship between the different factors associated with COVID-19 vaccination during pregnancy were performed using the chi-square test or Fisher's exact test. The quantitative data were analyzed using Student's t-test or the Mann-Whitney U test with a p-value less than 0.05 indicating statistical significance. After univariable analysis and the selection of variables with statistical significance, a multivariable analysis was performed using stepwise logistic regression model analysis.

Results

Between September 2021 and April 2022, there were 516 pregnant women that attended ANC and delivered at Makarak Hospital. According to Table 1, the average age was 27.5 years. Most of them were gravida 2. Their gestational age at delivery was 39 weeks, 88.2% of them followed standard ANC, which is four times or more, while 7.1% had hypertension disorders, 8.3% had diabetes disorders, 6.6% had underlying disease, and 7.9% had previous CS. Other conditions found in smaller frequencies included 1.9% abnormal amniotic fluid index and 0.6% placenta previa. In total, 19.2% of pregnant women had received the COVID-19 vaccination.

During the intrapartum period, most fetus showed cephalic presentation at 96.9%, while 4.1% had induction of labor, 5.6% had non-reassuring fetal status or fetal distress, 4.5% had meconium staining, 60.2% had spontaneous vaginal delivery, and 11.4% had preterm delivery. Other conditions found less

Table 1. Baseline characteristics of pregnant women

Characteristics	Total n=516
Antepartum	
Age (years); mean±SD	27.5±6.36
Gravida; median (IQR)	2 (1, 2)
Gestational age (weeks); median (IQR)	39 (38, 40)
Number of ANCs <4; n (%)	61 (11.8)
Hypertensive disorders; n (%)	37 (7.1)
Diabetes disorders; n (%)	43 (8.3)
Abnormal amniotic fluid index; n (%)	10 (1.9)
Placenta previa; n (%)	3 (0.6)
Underlying disease; n (%)	34 (6.6)
Previous cesarean section; n (%)	41 (7.9)
COVID-19 vaccination during pregnancy; n (%)	99 (19.2)
Intrapartum; n (%)	
Cephalic presentation	500 (96.9)
Chorioamnionitis	7 (1.4)
Placenta abruption	1 (0.2)
Induction of labor	21 (4.1)
Non-reassuring fetal status or fetal distress	29 (5.6)
Spontaneous vaginal delivery	311 (60.2)
Preterm delivery	59 (11.4)
Meconium staining	23 (4.5)
COVID-19 infection	30 (5.8)
Postpartum and newborns; n (%)	
Postpartum hemorrhage	7 (1.4)
Received blood transfusion	4 (0.8)
Puerperal fever	6 (1.2)
Extended length of stay	24 (4.6)
Birth asphyxia	29 (5.6)
Low birth weight	45 (8.7)
DFIU or still birth	6 (1.2)
NICU admission	170 (32.9)

ANCs=antenatal care visits; DFIU=dead fetus in utero; NICU=neonatal intensive care; IQR=interquartile range; SD=standard deviation

frequently were 1.4% chorioamnionitis and 0.2% placental abruption, while 5.8% of the pregnant women were infected with COVID-19. The present study also found postpartum hemorrhage at 1.4%, low birth weight at 8.7%, birth asphyxia at 5.6%, and NICU admission at 32.9%.

According to the univariable analysis of the relationship of several factors in pregnant women on COVID-19 vaccination as shown in Table 2 and 3, the diabetes disorder was significantly higher in the vaccinated group (OR 1.96, 95% CI 1.24 to 3.08). No factors were found to be significantly related to vaccination during the intrapartum period. The closest factor was induction of labor (OR 1.79, 95% CI 0.95 to 3.37). During the postpartum period, NICU admission was significantly lower in vaccinated group (OR 0.68, 95% CI 0.45 to 0.98).

After multivariable analysis as shown in Table 4, the diabetes disorder was significantly higher in vaccinated group (adjusted OR 3.54, 95% CI 1.67 to 7.50) and NICU admission was significantly lower in the vaccinated group (adjusted OR 0.43, 95% CI 0.24 to 0.76).

Discussion

According to the present study results, the Thai pregnant women had a same rate of COVID-19 vaccination at 19.2% as the previous studies, which showed a range of vaccination rates of 7% to 40%[16-19]. However, the present study found the factor of underlying disease made no difference in vaccination in both groups. It might be that underlying diseases in pregnant women may not be severe illnesses and are not categorized as high risk[20], such as stroke, ischemic heart disease, or chronic obstructive pulmonary disease (COPD), that were usually found in older adults and were the target for vaccination.

Besides, COVID-19 infection during the intrapartum period was similar in both vaccinated and unvaccinated groups. According to data from WHO, it states that COVID-19 vaccination provided different levels of protection to infection. Although COVID-19 vaccines are very effective at preventing serious illness, they are less effective at protecting against infection and mild disease[21].

During the antepartum period, the present study revealed higher vaccination rates in pregnant women of the diabetes disorder groups, possibly because diabetes diagnosis is intricate and may need venipuncture several times as well as the necessity for insulin to control blood sugar levels[22]. Hence, the awareness would be greater in this group. In addition, this group would intend to undertake ANC and would be aware of their higher risk, resulting in a higher rate of vaccination. On the contrary, the other risk factors such as hypertension disorder, abnormal amniotic fluid index, or placental abruption, were mostly acute onset[23] and could not be known forward like diabetes.

The factors that are usually of concern in vaccination include DFIU, stillbirth, or preterm delivery. The previous studies[7,12] revealed that vaccination did not significantly affect these factors. Similarly, the present study revealed that vaccination was not significantly related to these conditions. Moreover, serious events like chorioamnionitis,

Table 2. Univariable analysis of factors associated with COVID-19 vaccination during pregnancy

Factors	Vaccinated; n (%) 99 (19.2)	Unvaccinated; n (%) 417 (80.8)	OR	95% CI	p-value
Antepartum factors					
Age <35 years	83 (83.8)	356 (85.4)	1.09	0.68 to 1.77	0.70
Number of ANC <4	9 (9.1)	52 (12.4)	0.74	0.39 to 1.40	0.34
Gravida 1	40 (40.4)	167 (40.5)	0.98	0.68 to 1.41	0.94
Hypertensive disorders	6 (6.1)	31 (7.4)	0.81	0.34 to 1.90	0.63
Diabetes disorders	15 (15.2)	28 (6.7)	1.96	1.24 to 3.08	0.01
Abnormal AFI	1 (1.0)	9 (2.2)	0.51	0.07 to 3.34	0.45
Placenta previa	0 (0.0)	3 (0.7)	-	-	0.39
Underlying disease	5 (5.1)	29 (6.9)	0.75	0.32 to 1.72	0.49
Previous CS	6 (6.1)	35 (8.4)	0.74	0.34 to 1.60	0.44
Intrapartum factors					
Cephalic presentation	98 (98.9)	402 (96.4)	0.31	0.04 to 2.14	0.18
Chorioamnionitis	0 (0.0)	7 (1.68)	-	-	0.19
Placental abruption	0 (0.0)	1 (0.2)	-	-	0.62
Induction of labor	7 (7.1)	14 (3.3)	1.79	0.95 to 3.37	0.09
Non-reassuring or fetal distress	7 (7.1)	22 (5.3)	1.27	0.65 to 2.49	0.48
Spontaneous vaginal delivery	63 (63.6)	248 (59.4)	0.86	0.59 to 1.25	0.44
Preterm delivery	13 (13.1)	46 (11.0)	1.17	0.69 to 1.96	0.55
Meconium staining	3 (3.0)	20 (4.8)	0.66	0.22 to 1.95	0.44
COVID-19 infection	8 (8.1)	22 (5.3)	1.42	0.76 to 2.65	0.28
Postpartum and newborn factors					
Postpartum hemorrhage	1 (1.0)	6 (1.4)	0.74	0.11 to 4.59	0.74
Received blood transfusion	0 (0.0)	4 (0.9)	-	-	0.32
Puerperal fever	0 (0.0)	6 (1.4)	-	-	0.22
Extended length of stay	5 (5.1)	19 (4.5)	1.09	0.48 to 2.42	0.83
Birth asphyxia	3 (3.0)	26 (6.2)	0.52	0.17 to 1.55	0.21
Low birth weight	5 (5.1)	40 (9.5)	0.55	0.23 to 1.29	0.14
DFIU or still birth	0 (0.0)	6 (1.4)	-	-	0.22
NICU admission	25 (25.3)	145 (34.7)	0.68	0.45 to 0.98	0.07

ANCs=antenatal care visits; AFI=amniotic fluid index; CS=cesarean section; DFIU=dead fetus in utero; NICU=neonatal intensive care; OR=odds ratio; CI=confidence interval

Table 3. Multivariable analysis of factors associated with COVID-19 vaccination during pregnancy

Factors	COVID-19 vaccination during pregnancy		
	Adjusted OR	95% CI	p-value
Diabetes disorders	3.54	1.67 to 7.50	<0.01
Induction of labor	2.24	0.85 to 5.89	0.10
COVID-19 infection	2.13	0.87 to 5.22	0.09
Non-reassuring or fetal distress	1.93	0.77 to 4.83	0.15
NICU admission	0.43	0.24 to 0.76	<0.01

NICU=neonatal intensive care; OR=odds ratio; CI=confidence interval

placental abruption, or non-reassuring fetal status or fetal distress were not significantly related to vaccination either. These conformed to a number of studies[18,19,24] revealing that vaccination during pregnancy did not cause adverse obstetric outcomes.

In addition, vaccination caused indifference in the prevalence of spontaneous vaginal delivery and CS. This conformed to a meta-analysis[25] study that found that vaginal delivery was not related to worse maternal outcomes when compared with CS. When considering the postpartum period, vaccination did not increase the risks of postpartum hemorrhage, low birth weight, birth asphyxia, or puerperal fever. This also corresponded to other studies[18,19,24] that found that vaccination during pregnancy did not affect these conditions.

Furthermore, vaccination also significantly reduced the risk of NICU admission. One previous study[19] found that vaccination significantly reduced NICU admission. However, some studies[17,18,26] did

not find any relationship in terms of post-neonatal hospitalization. One study[27] suggested that after maternal vaccination, the immune response is induced, and antibodies will undergo transplacental transfer to the fetus within 16 days. In addition, COVID-19 infection could be transmitted through the placenta. This was proven by evidence[28] that revealed that newborns delivered by their infected mothers would have higher immunoglobulin G (IgG) and immunoglobulin M (IgM) levels for the COVID-19 virus. These findings may explain the improved outcomes in NICU admission from vaccinated pregnant women. However, the specific causes of NICU admission in all neonates are unspecified. Thus, limitations of the study could occur.

Although the present study revealed the increased risk of COVID-19 infection in vaccinated group (adjusted OR 2.13, 95% CI 0.87 to 5.22), the data was not significant, probably due to the limitation of the retrospective data that some random error could be occur. Additionally, the data from WHO[21] and the previous systematic review and meta-analysis[29] indicated that COVID-19 vaccine effectiveness against infection decayed over time, but protection remained high against severe disease. Further study of severity in COVID-19 infected pregnant women may help to detect the effect of vaccine. Moreover, a larger sample size could have revealed more apparent differences. Several studies[18,26] revealed that COVID-19 vaccination could reduce the infection rate.

The present study might contain the limitations of a retrospective study. There might also be selection bias. In addition, all data were collected from medical records, possibly causing information bias. The present study was a cohort study, which might indicate more apparent vaccination outcomes than the general cross-sectional studies. Multivariable analysis also helped reduce the influence of confounding factors. Moreover, the present study inclusively focused on the factors throughout ANC to the postpartum periods to detect the possible adverse pregnancy outcomes.

Conclusion

COVID-19 vaccination during pregnancy was significantly increased in the diabetes disorder group and decreased the risk in NICU admission, compared with the unvaccinated group. Other adverse obstetric outcomes in the vaccinated and unvaccinated groups during their pregnancy were not different.

What is already known on this topic?

COVID-19 vaccine is provided for pregnant women as a high-risk group of infection. There have been no significant reports about complications during pregnancy, but data were still limited in long term outcomes and no evidence in Thai pregnant women.

What this study adds?

This study confirms the safety of COVID-19 vaccination during pregnancy and reveals the increase in COVID-19 vaccination in pregnant women of the diabetes disorder groups. Furthermore, the study reveals the advantage of COVID-19 vaccination in term of reducing the risk of NICU admission.

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Conflicts of interest

The authors declare no conflict of interest.

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