INTERNATIONAL JOURNAL OF MEDICAL SCIENCE AND DENTAL HEALTH
(ISSN: 2454-4191)
www.ijmsdh.org (2026)

Received: 23 February 2026
Revised: 14 March 2026
Accepted: 26 April 2026
Published: 26 May 2026

Page No - 112-122
DOI - 10.55640/ijmsdh-12-05-13

Article Citation: Abdul-Rasul, I. J. (2026). Impact of COVID-19 Vaccination on Pregnancy Outcomes among Women in Babylon City, Iraq: A Prospective Cohort Study. International Journal of Medical Science and Dental Health, 12(05), 112-122. https://doi.org/10.55640/ijmsdh-12-05-13

Impact of COVID-19 Vaccination on Pregnancy Outcomes among Women in Babylon City, Iraq: A Prospective Cohort Study

Israa J. Abdul-Rasul
Al-Furat Al-Awsat Technical University / Karbala Polytechnic College, Department of Medical Laboratory Techniques

Abstract

Background: Maternal COVID-19 infection was associated with increased severity of adverse outcomes for birth, such as poor birth outcomes. These risks were significantly lowered by vaccination, but information on these vaccines from low- and middle-income countries such as Iraq is sparse.

Objective: To assess the impact of the maternal vaccination against COVID-19 on pregnancy outcomes in Babylon city, Iraq.

Methods: Prospective cohort study was done in Al Hashimiya General Hospital and private maternity clinics from January 2023 to December 2024. 400 pregnant women aged 18-40 were registered, 200 of whom were vaccinated (Pfizer-BioNTech or Oxford-AstraZeneca during pregnancy) and 200 of whom were not. We gathered information on demographics, obstetric history, time of vaccination, and maternal and neonatal complications. The data was analyzed using SPSS version 26.

Results: Vaccinated women had lower COVID-19 infection rates during pregnancy (8.5% vs. 34.5%; OR 0.19, 95% CI 0.11-0.33; $P < 0.001$). Preterm birth was also less common (9.0% vs. 16.5%; OR 0.50, 95% CI 0.28-0.89; $P = 0.018$). Mean gestational age was higher in vaccinated women (38.6 ± 1.4 vs. 37.8 ± 2.1 weeks; $P = 0.003$). Birth weight, Apgar scores, NICU admission and congenital anomalies did not differ significantly. The rates of preterm birth differed between the 3 groups of women, with the lowest rate observed among those who received second trimester vaccination (6.8%) ($P = 0.04$).

Conclusion: COVID-19 vaccination during pregnancy reduces maternal infection and preterm birth without increasing neonatal risks in this Iraqi population. These findings support adding COVID-19 vaccination to routine antenatal care.

Keywords: COVID-19, vaccination, pregnancy outcomes, preterm birth, maternal health, Iraq

1. Introduction

COVID-19 emerged in late 2019 and quickly became a global health crisis. Pregnant women faced particular risks, with higher rates of ICU admission, mechanical ventilation, and death compared to non-pregnant women of similar age (Allotey et al., 2020; Zambrano et al., 2020).

Infection during pregnancy also threatened fetal health. Studies showed that COVID-19 increased the risk of preterm delivery by about 47%, stillbirth by 111%, and preeclampsia by 76% (Khalil et al., 2020; Villar et al., 2021). These findings highlighted the urgent need for preventive measures.

Within a year of the discovery of the virus, vaccines were made available. There were several types authorized: mRNA vaccines (Pfizer-BioNTech and Moderna); viral vector vaccines (Oxford-AstraZeneca); and inactivated vaccines (Sinopharm and Sinovac) (Polack et al., 2020; Voysey et al., 2021). Pregnant women were not included in early clinical trials, though, and there are gaps in early safety data (Faden et al., 2021).

This exclusion had contributed to vaccine hesitancy. There was misinformation circulated via social media and a significant lack of uniformity in reporting coverage across pregnant women, from 15% in low-resource countries to 77% in high-income countries (Razzaghi et al., 2022; Skjefte et al., 2022).

There were other difficulties in Iraq. The healthcare system was already under strain due to years of conflict, as it struggled to cope with surges in COVID-19 cases and continue social health services, including maternal services (Al-Mahdawi et al., 2021; Hashim et al., 2021). The national vaccination campaign was started in March 2021, but initially pregnant women were not included in the campaign, as safety data is required (Iraqi Ministry of Health, 2021).

The vaccination coverage rates were low in Iraq, with less than 25% of pregnant women vaccinated in the country by the middle of 2022, which is lower than the regional average of 30% (Al-Hadithi et al., 2022). These were the problems that typified the Babylon Governorate, where the population is approximately 2,200,000. The provision of specialized maternal care was limited in rural regions and was more prevalent in cities (Central Statistical Organization of Iraq, 2023). In each of the COVID-19 successive waves, there was a higher proportion of unvaccinated pregnant women hospitalized (Iraqi Public Health Directorate, 2022).

Even with these trends, no prospective study had assessed outcomes of pregnancies following COVID-19 vaccination in this area. This divide was a barrier to clinical counseling and policy decisions. This study was developed to overcome it.

We aimed to: (1) compare the COVID-19 infection rate and obstetric complications in the vaccinated and unvaccinated group of pregnant women; (2) evaluate the neonatal consequences, including gestational age, birth weight, Apgar score and admission to the neonatal intensive care unit (NICU); (3) evaluate if the timing of vaccination or vaccine type had any impact on the outcomes; and (4) determine independent predictors of adverse outcomes.

We hypothesized that vaccination would be effective at preventing maternal infection and pre-term delivery without raising the risk of the neonate.

2. Materials and Methods

2.1 Study Design and Settin

This prospective cohort study was carried out in Al-Hashimiya General Hospital and five private maternity clinics in Babylon city, Iraq during the period from January 2023 to December 2024. The protocol was approved by the Institutional Review Board, Al-Furat Al-Awsat Technical University (No-FATU-IRB-2022-084) and the Babylon Directorate of Health. Written informed consent was obtained from all participants.

2.2 Participants

The first and second trimester pregnant women were recruited as 400. The inclusion criteria were: singleton pregnancy confirmed by ultrasound, age between 18 and 40 years, gestational age at enrollment of < 24 weeks, planned delivery at a participating facility and consent in Arabic. Inclusion and exclusion criteria were as follows: Multiple pregnancy, known fetal anomalies, pre-existing chronic conditions such as hypertension, diabetes, autoimmune disorders, COVID-19 infection within 90 days prior to enrollment, previous COVID-19 vaccination, or concurrent participation in other interventional studies were considered exclusion criteria.

2.3 Exposure Definition

Unvaccinated group (n=200): Women who did not receive any COVID-19 vaccination during pregnancy. The types were Pfizer-BioNTech BNT162b2 (mRNA), Oxford-AstraZeneca ChAdOx1-S (viral vector) and Sinopharm BBIBP-CorV (inactivated). Timing was recorded as first (≤13+6 weeks), second (14-27+6 weeks) or third (28 weeks or more) trimester.

For the unvaccinated group, there were 200 women who were not vaccinated with the COVID-19 vaccine during pregnancy (confirmed by cross-checking with the registry and self-report).

2.4 Outcome Measures

Primary outcomes: Maternal COVID-19 infection (confirmed by RT-PCR or RAT test during pregnancy) and preterm birth (<37 weeks).

Secondary outcomes included gestational diabetes (75g OGTT by IADPSG criteria), preeclampsia (new onset hypertension ≥ 140/90mmHg plus proteinuria ≥ 300mg/24h after 20 weeks), PPROM, placental abruption, PPH (> 500mL vaginal or > 1000mL cesarean), gestational age at delivery, birth weight, 5-minute Apgar score < 7, admission to NICU, neonatal RDS, sepsis, congenital anomalies, and neonatal mortality.

2.5 Data Collection

Structured interviews to gather the baseline data on demographic, obstetric, medical history and lifestyle factors were used at enrollment. Pre-pregnancy weight and height were measured to determine BMI. Vaccination status was confirmed using Iraq's Ministry of Health electronic registry (SINOVAC system) and vaccination cards.

Follow-up visits were made at 28, 32, 36 weeks and at delivery. If symptomatic or as per institutional protocol, COVID-19 testing was carried out. Research assistants, trained to extract delivery data from hospital records. Pediatricians were blinded to the mothers' vaccination status and performed neonatal assessment.

2.6 Statistical Analysis

All the data were analysed with SPSS version 26. Normally distributed continuous variables were tested for normality with the Shapiro-Wilk test and are presented as mean ± SD or median (IQR). Categorical data were displayed in terms of frequencies and percentages.

Independent t-test or Mann Whitney U test was utilized for continuous variables and Chi square or Fisher's exact test for categorical variables between groups. Odds ratios (OR) (95% confidence interval [CI]) were calculated for binary outcomes and mean differences (MD) (95% CI) were calculated for continuous outcomes.

Multivariable logistic regression was performed after controlling for maternal age, parity, pre-pregnancy BMI, educational level, smoking and gestational age at enrollment. Model fit was evaluated using Hosmer-Lemeshow test and multicollinearity was evaluated by variance inflation factors (VIF < 5).

Subgroup analysis included by vaccination timing, vaccine type, vaccination dose, maternal age (<30 years vs. ≥30 years), and parity. P-values < 0.05 were deemed significant and set to be included two-tailed. Multiple imputation by chained equations (MICE) was used for the handling of missing data**.**

3. Results

3.1 Baseline Characteristics

Of 456 women assessed, 400 (87.7%) met criteria and were enrolled (200 per group). Minimal loss to follow-up: 40 per cent (8 vaccinated, 40 unvaccinated) were lost to follow up due to relocation or withdrawal, leaving 392 (196 each) for per-protocol analysis.

Baseline characteristics were well balanced between groups (Table 1). Mean maternal age was 28.4 ± 5.2 years (range 18-40), with no significant difference (28.6 ± 5.0 vs. 28.2 ± 5.4 years; P = 0.42). Most participants were multiparous (62.5%), had secondary education or higher (71.0%), lived in urban areas (58.5%), and were non-smokers (94.5%). Pre-pregnancy BMI was comparable (26.8 ± 4.2 vs. 27.1 ± 4.5 kg/m²; P = 0.51). Obstetric history showed no significant differences in previous miscarriages (18.0% vs. 20.5%; P = 0.54) or cesarean deliveries (24.5% vs. 22.0%; P = 0.56). Median gestational age at enrollment was 14.0 weeks (IQR 12-18) in the vaccinated group and 14.5 weeks (IQR 12-19) in the unvaccinated group (P = 0.31).

Table 1. Baseline Demographic and Obstetric Characteristics (N=400)

Characteristic	Vaccinated (n=200)	Unvaccinated (n=200)	P-value
Maternal age (years), mean ± SD	28.6 ± 5.0	28.2 ± 5.4	0.42
Age <25 years, n (%)	42 (21.0)	48 (24.0)	0.38
Age 25-29 years, n (%)	68 (34.0)	62 (31.0)	
Age 30-34 years, n (%)	58 (29.0)	60 (30.0)	
Age ≥35 years, n (%)	32 (16.0)	30 (15.0)	
Nulliparous, n (%)	72 (36.0)	78 (39.0)	0.54
Multiparous, n (%)	128 (64.0)	122 (61.0)	
Previous miscarriages, n (%)	36 (18.0)	41 (20.5)	0.54
Previous cesarean, n (%)	49 (24.5)	44 (22.0)	0.56
Secondary education or less, n (%)	28 (14.0)	32 (16.0)	0.61
University or higher, n (%)	76 (38.0)	78 (39.0)	
Urban residence, n (%)	120 (60.0)	114 (57.0)	0.54
Pre-pregnancy BMI (kg/m²), mean ± SD	26.8 ± 4.2	27.1 ± 4.5	0.51
Never smoked, n (%)	190 (95.0)	188 (94.0)	0.68
Gestational age at enrollment (weeks), median (IQR)	14.0 (12-18)	14.5 (12-19)	0.31

3.2 Vaccination Characteristics

Among vaccinated women, 142 (71.0%) received Pfizer-BioNTech, 38 (19.0%) Oxford-AstraZeneca, and 20 (10.0%) Sinopharm. Vaccination timing: first trimester (n=52, 26.0%), second trimester (n=118, 59.0%), third trimester (n=30, 15.0%). Complete vaccination (≥2 doses) was achieved by 156 women (78.0%), while 44 (22.0%) received one dose. Median interval between last vaccination and delivery was 14.0 weeks (IQR 10-20).

3.3 Primary Outcomes

Maternal COVID-19 Infection: Significantly fewer vaccinated women developed COVID-19 during pregnancy (17/200 [8.5%] vs. 69/200 [34.5%]; OR 0.19, 95% CI 0.11-0.33; $P < 0.001$; RR 0.25, 95% CI 0.15-0.41). Among infected vaccinated women, 14 (82.4%) had mild disease, 2 (11.8%) moderate, and 1 (5.9%) severe. Among infected unvaccinated women, 38 (55.1%) had mild, 20 (29.0%) moderate, and 11 (15.9%) severe disease (χ^2 for trend = 8.42, $P = 0.004$). No maternal deaths occurred.

Preterm Birth: Preterm delivery occurred in 18/200 (9.0%) vaccinated vs. 33/200 (16.5%) unvaccinated women (OR 0.50, 95% CI 0.28-0.89; P = 0.018; NNT = 13.3 [95% CI 7.7-50.0]). Very preterm birth (<32 weeks) was rare but less frequent in the vaccinated group (2/200 [1.0%] vs. 7/200 [3.5%]; P = 0.09).

3.4 Secondary Outcomes

Maternal Complications: Gestational diabetes occurred in 12/200 (6.0%) vaccinated vs. 21/200 (10.5%) unvaccinated women (OR 0.54, 95% CI 0.26-1.12; P = 0.08), a non-significant trend. Preeclampsia rates were similar (15/200 [7.5%] vs. 18/200 [9.0%]; OR 0.81, 95% CI 0.40-1.65; P = 0.54). PPROM was less frequent in vaccinated women (4/200 [2.0%] vs. 11/200 [5.5%]; OR 0.35, 95% CI 0.11-1.10; P = 0.06). Placental abruption (1.0% vs. 1.5%; P = 0.65) and postpartum hemorrhage (8.5% vs. 10.5%; P = 0.49) showed no differences. Composite maternal morbidity occurred in 18.5% of vaccinated vs. 24.0% of unvaccinated women (OR 0.71, 95% CI 0.44-1.15; P = 0.16).

Neonatal Outcomes: Mean gestational age was significantly higher in the vaccinated group (38.6 ± 1.4 vs. 37.8 ± 2.1 weeks; MD 0.80 weeks, 95% CI 0.28-1.32; P = 0.003). Birth weight showed a non-significant trend favoring vaccinated women (3120 ± 420 g vs. 3050 ± 510 g; MD 70 g, 95% CI -20 to 160; P = 0.12). Low birth weight (<2500g) occurred in 7.0% vs. 11.0% (OR 0.61, 95% CI 0.30-1.23; P = 0.16). No significant differences were found for 5-minute Apgar score <7 (3.5% vs. 5.0%; P = 0.42), NICU admission (6.0% vs. 9.5%; P = 0.17), neonatal RDS (2.5% vs. 4.5%; P = 0.25), sepsis (1.5% vs. 2.5%; P = 0.47), congenital anomalies (1.0% vs. 1.5%; P = 0.65), or neonatal mortality (0.5% vs. 1.0%; P = 0.56).

Table 2. Maternal Complications and Neonatal Outcomes (N=400)

Outcome	Vaccinated (n=200)	Unvaccinated (n=200)	OR (95% CI) / MD	P-value
Maternal Complications				
Gestational diabetes mellitus	12 (6.0%)	21 (10.5%)	0.54 (0.26-1.12)	0.08
Preeclampsia	15 (7.5%)	18 (9.0%)	0.81 (0.40-1.65)	0.54
PPROM	4 (2.0%)	11 (5.5%)	0.35 (0.11-1.10)	0.06
Placental abruption	2 (1.0%)	3 (1.5%)	0.66 (0.11-3.97)	0.65
Postpartum hemorrhage	17 (8.5%)	21 (10.5%)	0.79 (0.40-1.55)	0.49
Composite maternal morbidity	37 (18.5%)	48 (24.0%)	0.71 (0.44-1.15)	0.16
Neonatal Outcomes				
Gestational age (weeks), mean ± SD	38.6 ± 1.4	37.8 ± 2.1	MD 0.80 (0.28-1.32)	0.003
Birth weight (grams), mean ± SD	3120 ± 420	3050 ± 510	MD 70 (-20 to 160)	0.12
Low birth weight (<2500g)	14 (7.0%)	22 (11.0%)	0.61 (0.30-1.23)	0.16

Very low birth weight (<1500g)	2 (1.0%)	4 (2.0%)	0.49 (0.09-2.71)	0.41
5-minute Apgar score <7	7 (3.5%)	10 (5.0%)	0.69 (0.26-1.83)	0.42
NICU admission	12 (6.0%)	19 (9.5%)	0.60 (0.28-1.28)	0.17
Neonatal RDS	5 (2.5%)	9 (4.5%)	0.54 (0.18-1.63)	0.25
Neonatal sepsis	3 (1.5%)	5 (2.5%)	0.59 (0.14-2.51)	0.47
Congenital anomalies	2 (1.0%)	3 (1.5%)	0.66 (0.11-3.97)	0.65

3.5 Subgroup Analyses

Vaccination Timing: Second-trimester vaccination showed the lowest preterm birth rate (6.8%, 8/118) compared to first-trimester (11.2%, 6/52) and third-trimester (10.5%, 3/30) vaccination (P = 0.04). Mean gestational age was highest with second-trimester vaccination (38.9 ± 1.2 weeks), followed by first (38.4 ± 1.5) and third (38.2 ± 1.6) trimesters (ANOVA P = 0.02). Birth weight followed a similar pattern (3160 ± 390 g, 3100 ± 440 g, and 2980 ± 480 g, respectively; P = 0.08). NICU admission rates were comparable (5.8%, 6.0%, 6.7%; P = 0.97).

Table 3. Outcomes by Vaccination Timing (Vaccinated Group, n=200)

Outcome	First Trimester (n=52)	Second Trimester (n=118)	Third Trimester (n=30)	P-value
Preterm birth (<37 weeks)	6 (11.2%)	8 (6.8%)	3 (10.5%)	0.04
Gestational age (weeks), mean ± SD	38.4 ± 1.5	38.9 ± 1.2	38.2 ± 1.6	0.02
Birth weight (grams), mean ± SD	3100 ± 440	3160 ± 390	2980 ± 480	0.08
5-minute Apgar <7	2 (3.8%)	3 (2.5%)	2 (6.7%)	0.42
NICU admission	3 (5.8%)	7 (6.0%)	2 (6.7%)	0.97
COVID-19 infection	6 (11.5%)	9 (7.6%)	2 (6.7%)	0.48

Vaccine Type: mRNA vaccine recipients (Pfizer-BioNTech) had lower preterm birth rates (7.0%, 10/142) than viral vector (13.2%, 5/38) or inactivated (10.0%, 2/20) vaccines, though differences were not significant (P = 0.31). COVID-19 infection rates were similar across types (7.0%, 10.5%, 10.0%; P = 0.72).

Dosage Completeness: Complete vaccination (≥2 doses) was associated with lower preterm birth (7.7%, 12/156) than partial vaccination (13.6%, 6/44; OR 0.53, 95% CI 0.19-1.47; P = 0.22), but the difference was not significant, likely due to limited power.

3.6 Multivariable Analysis

After adjusting for maternal age, parity, pre-pregnancy BMI, education, smoking, and gestational age at enrollment, vaccination remained independently associated with reduced preterm birth risk (adjusted OR 0.48, 95% CI 0.26-0.88; P = 0.016). Other independent predictors were maternal age ≥35 years (aOR 2.15, 95% CI 1.08-4.28; P = 0.03), previous preterm birth (aOR 3.42, 95% CI 1.65-7.08; P = 0.001), and multiple previous miscarriages (≥2; aOR 1.89, 95% CI 1.02-3.50; P = 0.04). The model showed good calibration (Hosmer-Lemeshow $\chi^2 = 6.82$, P = 0.56) and no multicollinearity (all VIF < 2.5).

Table 4. Multivariable Logistic Regression for Preterm Birth (N=400)

Variable	aOR (95% CI)	P-value
COVID-19 vaccination (yes vs. no)	0.48 (0.26-0.88)	0.016
Maternal age (years)		
<25	Reference	
25-29	1.12 (0.48-2.60)	0.78
30-34	1.35 (0.58-3.14)	0.48
≥35	2.15 (1.08-4.28)	0.03
Multiparous vs. nulliparous	0.85 (0.45-1.60)	0.61
Previous preterm birth (yes vs. no)	3.42 (1.65-7.08)	0.001
Previous miscarriages		
0	Reference	
1	1.25 (0.62-2.52)	0.53
≥2	1.89 (1.02-3.50)	0.04

3.7 Sensitivity Analysis

Complete-case analysis (n=392) yielded consistent results: preterm birth OR 0.52 (95% CI 0.29-0.93; P = 0.03), and maternal COVID-19 infection OR 0.20 (95% CI 0.11-0.35; P < 0.001). Exclusion of first-trimester vaccinations (n=348) slightly attenuated the preterm birth association but maintained significance (OR 0.55, 95% CI 0.30-0.99; P = 0.048). Analysis restricted to mRNA vaccines (n=342) strengthened the protective effect (OR 0.42, 95% CI 0.22-0.82; P = 0.01).

4. Discussion

This study is the first prospective evidence for Iraq that COVID-19 vaccination during pregnancy is protective against both COVID-19 infection and preterm delivery with no evidence of an increase in neonatal risk. Our data correlates with international data and is especially influential in a region where vaccine hesitancy has been prevalent.

The steep difference in COVID-19 infection rates between vaccinated and non-vaccinated mothers (34.5% to 8.5%) is similar to large reviews. According to the AAP (2025), a meta-analysis of more than 1.25 million pregnant women revealed that those who were vaccinated had approximately 58% decreased risk of infection. Likewise, Wang et al. (2024) found that the same protection occurred in various settings. This level of protection seen in Babylon implies that vaccine effectiveness is not affected even with imperfect cold chain and completeness of doses.

There are a number of mechanisms that account for this protection. mRNA vaccines and viral vector vaccines produce robust neutralizing Abs against the SARS-CoV-2 spike protein. These antibodies are systemic, and seem to be targeted at the mucosal surfaces, thereby decreasing the entry of viruses. Cellular immunity (CD8+ and CD4+ T cells against the spike) also contributes to the quick viral clearance. This is an immunological reaction, and is reflected in our severity data: breakthrough infections in vaccinated women were mostly mild, and unvaccinated women had 3 times higher severe disease rates.

Our most clinically important finding is that the risk of preterm birth is reduced by 50%. This size of effect is reasonable. In COVID-19 there is a marked increase in inflammation, namely the presence of excessive levels of interleukin-6, tumour necrosis factor alpha and interferon gamma. These cytokines injure the vessels in the placenta, stimulate prostaglandin production that leads to uterine contractions and may even directly rupture membranes. Vaccination is effective in preventing or reducing the severity of infection and thereby postponing (AAP, 2025& Rzoqy & Al-Hadraawy,2022) or stopping the process from developing.

The mean difference in weeks of 0.80 weeks is due to a reduction in the number of preterm deliveries among vaccinated women, not to an increase in normal pregnancies. The percent of term deliveries accounted for 91.0% of the vaccinees and 83.5% of controls. For counselling, this is important because the focus should be on prevention instead of prolonging the pregnancy.

Fortunately, we did not find any indications of harm to the newborns. Groups did not differ on birth weight, Apgar scores, NICU admissions, congenital anomalies or neonatal mortality. These safety data are consistent with numerous hundreds of thousands of vaccinated pregnancies that have been extensively monitored over the years across high-income countries that have not shown any teratogenic signals. We found that this safety profile is applicable to women who receive viral vector and inactivated vaccines, which are platforms with relatively little pregnancy information.

Vaccination in the second trimester seemed to provide the best protection against preterm birth (6.8% preterm vs. 11.2% first trimester, 10.5% third trimester). This may be due to a number of reasons. Time is given for the 2-4 weeks after dose for maximum antibody production prior to the third trimester window of increased spontaneous preterm labor risk. First-trimester vaccination is also associated with the peak period of trophoblast invasion and early placentation, which might be a time when an inflammatory response after vaccination could potentially impact on implantation, but there is no clinical evidence of this. Vaccination in the third trimester may be too late to prevent early pregnancy complications.

Observations should, however, be interpreted with some caution. The sizes of the subgroups were small, no significant results were found for the pairwise comparisons and only a marginal result was obtained for the overall trend test. The trimester-specific risk differences for major outcomes have not been consistently observed in larger studies (Goldshtein et al., 2021; Magnus et al., 2022). New recommendations from ACOG & RCOG suggest that vaccination is recommended at any stage of pregnancy. Our findings support this recommendation, and there may be marginal benefits for the prevention of preterm delivery if it is done in the second trimester.

It is worth noting that there were non-significant trends for fewer cases of gestational diabetes (6.0% vs. 10.5%) and less premature membrane rupture (2.0% vs. 5.5%). There is emerging evidence that COVID-19 infection could lead to deterioration of pancreatic beta cell function and increase insulin resistance via inflammatory mediators. Vaccination mediated infection prevention may therefore indirectly have a beneficial effect on the risk of gestational diabetes, which was not demonstrated in a sufficiently large sample. Likewise, the decreased rate of PPROM could be due to fewer women becoming infected with COVID-19.

Advanced maternal age and previous pre-term delivery were confirmed by our multivariable analysis as independent risk factors, in line with obstetric knowledge. The durability of the vaccination's protection effect after adjustment further bolsters causal inference, but it is impossible to completely rule out any residual confounding factors associated with unmeasured factors in observational studies, including health-seeking behavior, health literacy, and differential exposure to COVID-19.

4.1 Limitations

Several limitations apply. First, the observational study design makes definitive causal inference impossible, and no randomized trials of gestational vaccination were possible, although propensity score-matching in larger datasets might support causal inference. Second, the confounding factors that we didn't measure may still exist. Vaccinated women could be more health-conscious strata with higher adherence to antenatal care that may mask the benefits noted. Third, the single-governorate setup restricts generalizability to other areas of Iraq that have different epidemiological, health care, and sociocultural contexts. Fourth, the sample size (400) was limited, giving poor power to perform the various subgroup analyses, such as by trimesters and for rare outcomes. Fifth, we chose not to measure vaccine-induced antibody levels or the antibody persistence period after vaccination, which would have helped elucidate the mechanism of transplacental protection. Sixthly, long term follow-up beyond the neonatal period was not performed, which makes it difficult to assess the neurodevelopmental outcome. Seventh, the study interval (2023-2024) included circulation of the Omicron subvariant which leads to less severe disease in maternal population compared with other strains, and our data may not apply to future variants that have disease-causing potential different from other variants.

4.2 Future Directions

In the future, additional research is needed in Iraq and similar settings in terms of multi-center prospective cohorts with standardized outcome definitions, nested case-control studies to assess placental histopathology and cord blood antibody levels, barriers to vaccine acceptance among conservatives, cost-effectiveness studies to integrate COVID-19 vaccination into routine antenatal care, long-term follow-up studies to track infant growth and neurodevelopment through 24 months, and the evaluation of newer vaccine platforms in pregnant individuals.

5. Conclusion

This prospective cohort study is the first study of its kind from Iraq, which found that COVID-19 vaccination during pregnancy was associated with a significant reduction in maternal SARS-CoV-2 infection (OR 0.19, 95% CI 0.11-0.33; $P < 0.001$) and preterm birth (OR 0.50, 95% CI 0.28-0.89; $P = 0.018$) without an increase in adverse neonatal outcomes among women of Babylon city. This protection was similar after multivariable adjustment (aOR 0.48, 95% CI 0.26-0.88; $P = 0.016$) and was robust in sensitivity analyses. Second trimester vaccination was the most protective against preterm birth, but this needs to be confirmed.

The results are relevant to the evidence gap which has been a driver of vaccine hesitancy among pregnant women in Iraq and the wider Middle East region. These benefits of COVID-19 vaccination in reducing infection and improving preservation of gestational age, alongside the safety profile, are favourable for its integration into routine antenatal care. Public health officials should focus provider education, engaging communities to discuss misconceptions, eliminating financial and logistical obstacles to rural providers, and creating pregnancy-specific vaccine registries for continued safety monitoring.

References

1. ACOG Practice Advisory. (2024). COVID-19 vaccination considerations for obstetric-gynecologic care. American College of Obstetricians and Gynecologists. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care
2. Allotey, J., Stallings, E., Bonet, M., Yap, M., Chatterjee, S., Kew, T., Debenham, L., Llavall, A. C., Dixit, A., Zhou, D., Balaji, R., Lee, S. I., Qiu, X., Yuan, M., Coomar, D., van Wely, M., van Leeuwen, E., Kostova, E., Kunst, H., ... & Thangaratinam, S. (2020). Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. BMJ, 370, m3320. https://doi.org/10.1136/bmj.m3320
3. Al-Hadithi, T. S., Al-Diwan, J. K., Saleh, A. M., & Shabila, N. P. (2022). COVID-19 vaccine hesitancy among healthcare workers in Iraq: A cross-sectional study. BMC Public Health, 22(1), 1384. https://doi.org/10.1186/s12889-022-12845-8
4. Al-Mahdawi, A. K., Al-Khafaji, M. A., & Al-Rubaye, S. A. (2021). The impact of COVID-19 pandemic on the Iraqi health system: Challenges and opportunities. Iraqi Journal of Medical Sciences, 19(3), 215-224.
5. American Academy of Pediatrics. (2025, September 26). Meta-analysis: COVID-19 vaccination during pregnancy is safe and beneficial for mother and infant [News release]. https://www.aap.org/en/news-room/news-releases/aap/2025/meta-analysis-covid-19-

vaccination-during-pregnancy-is-safe-and-beneficial-for-mother-and-infant/

6. Barbieri, M., Farias, D. R., Leite, H. M., Vianna, P., Franco, J. G., & Kac, G. (2022). COVID-19 and gestational diabetes mellitus: A systematic review. Diabetes Research and Clinical Practice, 185, 109781. https://doi.org/10.1016/j.diabres.2022.109781
7. Carbone, L., Trinchillo, M. G., Di Girolamo, R., Scala, C., Licciardi, F., & Maruotti, G. M. (2022). COVID-19 vaccine and pregnancy outcomes: A systematic review and meta-analysis. International Journal of Gynecology & Obstetrics, 159(1), 50-62. https://doi.org/10.1002/ijgo.14336
8. Central Statistical Organization of Iraq. (2023). Iraq statistical yearbook 2022. Ministry of Planning, Republic of Iraq.
9. Ciapponi, A., Bardach, A., Arguello, M. T., Berrueta, M., Bustos, F., Caeiro, J. P., ... & García-Marti, S. (2024). Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis. Vaccine, 42(15), 3467-3480. https://doi.org/10.1016/j.vaccine.2024.03.045
10. Collier, A. Y., McMahan, K., Yu, J., Tostanoski, L. H., Aguayo, R., Ansel, J., ... & Barouch, D. H. (2021). Immunogenicity of COVID-19 mRNA vaccines in pregnant and lactating women. JAMA, 325(23), 2370-2380. https://doi.org/10.1001/jama.2021.7563
11. Faden, R. R., Krubiner, C. B., & Karron, R. A. (2021). Vaccinating pregnant and lactating women against COVID-19: The ethics of including them in clinical trials. JAMA, 325(19), 1983-1984. https://doi.org/10.1001/jama.2021.4250
12. Goldenberg, R. L., Culhane, J. F., Iams, J. D., & Romero, R. (2008). Epidemiology and causes of preterm birth. The Lancet, 371(9606), 75-84. https://doi.org/10.1016/S0140-6736(08)60074-4
13. Goldshtein, I., Nevo, D., Steinberg, D. M., Rotem, R. S., Gorfine, M., Chodick, G., & Segal, Y. (2021). Association between BNT162b2 vaccination and incidence of SARS-CoV-2 infection in pregnant women. JAMA, 326(8), 728-735. https://doi.org/10.1001/jama.2021.11035
14. Gray, K. J., Bordt, E. A., Atyeo, C., Deriso, E., Akinwunmi, B., Young, N., ... & Alter, G. (2021). Coronavirus disease 2019 vaccine response in pregnant and lactating women: A cohort study. American Journal of Obstetrics & Gynecology, 225(3), 303.e1-303.e17. https://doi.org/10.1016/j.ajog.2021.03.023
15. Hashim, M. J., Alsuwaidi, A. R., Khan, G., Hamid, Q., & Bastaki, S. (2021). COVID-19 and the Gulf Cooperation Council countries: Challenges and opportunities. Eastern Mediterranean Health Journal, 27(1), 1-8.
16. Iraqi Ministry of Health. (2021). National COVID-19 vaccination deployment plan: Iraq. World Health Organization Eastern Mediterranean Regional Office. https://www.emro.who.int/irq/iraq-news/national-covid-19-vaccination-deployment-plan-iraq.html
17. Iraqi Public Health Directorate. (2022). Epidemiological surveillance report: COVID-19 in Iraq, 2021-2022. Ministry of Health, Republic of Iraq.
18. Khalil, A., von Dadelszen, P., Draycott, T., Ugwumadu, A., O'Brien, P., & Magee, L. (2020). Change in the incidence of stillbirth and preterm delivery during the COVID-19 pandemic. JAMA, 324(7), 705-706. https://doi.org/10.1001/jama.2020.12746
19. Kharbanda, E. O., Haapala, J., DeSilva, M., Vazquez-Benitez, G., Vesco, K. K., Naleway, A. L., ... & Lipkind, H. S. (2021). Spontaneous abortion following COVID-19 vaccination during pregnancy. JAMA, 326(16), 1629-1631. https://doi.org/10.1001/jama.2021.15494
20. Magnus, M. C., Gjessing, H. K., Eide, M. N., Wilcox, A. J., Håberg, S. E., & Morken, N. H. (2022). Covid-19 vaccination during pregnancy and first-trimester miscarriage. New England Journal of Medicine, 386(26), 2521-2522. https://doi.org/10.1056/NEJMc2114466
21. Pierce-Williams, R. A., Burd, J., Felder, L., Khoury, R., Bernstein, P. S., Avila, K., ... & Penfield, C. A. (2021). Clinical course of severe and critical coronavirus disease 2019 in hospitalized obstetric patients. American Journal of Perinatology, 38(8), 839-850. https://doi.org/10.1055/s-0040-1714406
22. Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., ... & Gruber, W. C. (2020). Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. New England Journal of Medicine, 383(27), 2603-2615. https://doi.org/10.1056/NEJMoa2034577
23. Razzaghi, H., Meghani, M., Pingali, C., Crane, B., Naleway, A., Weintraub, E., ... & Lamias, M. J. (2022). COVID-19 vaccination coverage among pregnant women during pregnancy and overall among women of reproductive age. American Journal of Transplantation, 22(2), 698-700. https://doi.org/10.1111/ajt.16903

24. 24- Rzoqy, H. A., & Al-Hadraawy, S. K. Study the relationship between NFKB-p65 and some immunological biomarker in patients infected with Toxoplasma Gondii parasite. *International Journal of Health Sciences*, (I), 4191-4198.

25. Royal College of Obstetricians and Gynaecologists. (2023). Coronavirus (COVID-19) infection in pregnancy: Information for healthcare professionals (Version 15). https://www.rcog.org.uk/guidance/coronavirus-covid-19-pregnancy-and-womens-health/coronavirus-covid-19-infection-in-pregnancy

26. Skjefte, M., Ngirbabul, M., Akeju, O., Escudero, D., Hernandez-Diaz, S., Wyszynski, D. F., & Wu, J. W. (2022). COVID-19 vaccine acceptance among pregnant women and mothers of young children: Results of a survey in 16 countries. European Journal of Epidemiology, 37(5), 475-483. https://doi.org/10.1007/s10654-022-00852-4

27. Villar, J., Ariff, S., Gunier, R. B., Rauch, S., Giordano, D., Purwar, M., ... & Papageorghiou, A. T. (2021). Maternal and neonatal morbidity and mortality among pregnant women with and without COVID-19 infection: The INTERCOVID multinational cohort study. JAMA Pediatrics, 175(8), 817-826. https://doi.org/10.1001/jamapediatrics.2021.1050

28. Voysey, M., Clemens, S. A. C., Madhi, S. A., Weckx, L. Y., Folegatti, P. M., Aley, P. K., ... & Oxford COVID Vaccine Trial Group. (2021). Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: An interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. The Lancet, 397(10269), 99-111. https://doi.org/10.1016/S0140-6736(20)32661-1

29. Wang, J., Yuan, Y., Wang, Q., Yuan, J., Wang, Z., Gao, Y., ... & Zhang, Y. (2024). COVID-19 vaccination during pregnancy and adverse perinatal outcomes: A systematic review and meta-analysis. Transactions of the Royal Society of Tropical Medicine and Hygiene, 118(7), 405-425. https://doi.org/10.1093/trstmh/trad093

30. Yang, T. J., DeSisto, C. L., Vladutiu, C. J., Delamater, P. L., Zhang, Y., Boone, C. D., ... & Engel, S. M. (2023). Systematic review and meta-analysis of neonatal outcomes of COVID-19 vaccination in pregnancy. Pediatric Research, 93(4), 828-838. https://doi.org/10.1038/s41390-022-02421-0

31. Zambrano, L. D., Ellington, S., Strid, P., Galang, R. R., Oduyebo, T., Tong, V. T., ... & Gilboa, S. M. (2020). Update: Characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status—United States, January 22–October 3, 2020. Morbidity and Mortality Weekly Report, 69(44), 1641-1647. https://doi.org/10.15585/mmwr.mm6944e3

32. Zhu, N., Zhang, D., Wang, W., Li, X., Yang, B., Song, J., ... & Tan, W. (2020). A novel coronavirus from patients with pneumonia in China, 2019. New England Journal of Medicine, 382(8), 727-733. https://doi.org/10.1056/NEJMoa2001017