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Impact of COVID-19 vaccination among pregnant women requiring hospital admission: prospective observational research

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ABSTRACT

Objective. The aim of this study was to assess the impact and effectiveness of vaccination among the pregnant population on maternal, obstetrical, and foetal outcomes.
Materials and Methods. In this study we included all the parturients tested positive for COVID-19 during pregnancy and who needed hospitalization at any stage of gestation. Then, patients were divided into 2 groups according to their vaccination status: the Vaccinated Group included pregnant women with completed vaccination by receiving 3 doses of mRNA Vaccine or 2 doses on condition that the second dose received within the last 6 months. The Non vaccinated group included pregnant women who had no vaccination against COVID-19.
We collected data about obstetrical and foetal outcomes with 3 months of follow-up.
Results. 145 parturients were admitted for COVID-19 in the maternity of Sfax in Tunisia. The Vaccinated group included 45 patients and the Non vaccinated group included 100 patients. Demographic parameters were comparable in both groups. The vaccination reduced the rate of hospitalization in Intensive care units from 23% to 4.3%; $p < 0.001$. Caesarean section delivery was seen in 56 cases from 76 patients who delivered while infected (73%) *versus* 11 cases from 33 who delivered in the vaccinated group (33.3%) with $p < 0.001$. The vaccination reduced the risk of prematurity from 35% to 6.6% with $p < 0.001$. No cases of vertical transmission were noted in either group.
Conclusions. Pregnant women seem to be protected from severe forms and severe complications of COVID-19. Obstetrical and neonatal outcomes appear to be improved with vaccination.

INTRODUCTION

Pregnant and lactating women are vulnerable to viral infections, particularly to SARS-CoV-2 infection. This may be due to physiological and immunological changes that may increase their susceptibility to severe COVID-19 and may result in heavy maternal morbidity and mortality [1], as well as adverse foetal outcomes [2, 3].

The COVID-19 vaccine was reported as a safe and highly effective strategy for general population [4]. Secondly, it was recommended for pregnant and lactating women population [5, 6, 7] despite their initial exclusion from development trials [8] and showed high rates of efficacy and safety. It was reported that maternal, obstetrical, and neonatal outcomes are influenced by the severity of maternal disease, which may be reduced by vaccination [9]. However, the clinical impact of vaccination on the obstetrical outcomes, the delivery mode, and the foetal outcomes is not yet well known.

The aim of this study was to assess the impact and effectiveness of vaccination among the pregnant population on maternal, obstetrical, and neonatal outcomes in our population.

MATERIALS AND METHODS

After obtaining local ethics committee approval and informed oral consent of the patients, a prospective observational study was conducted. We collected data of parturients who were hospitalized in the COVID-19 Unit of the Gynecology and Obstetrics department in the Hedi Chaker University Hospital in Sfax (Tunisia), from January 2021 to May 2022 with a post COVID-19 follow-up visit one month after.

In this study, we included all pregnant women tested positive for COVID-19 and who needed hospitalization (moderate to severe forms and asymptomatic patients admitted for obstetrical reasons) at any stage of gestation, except those < 18 years of age as well as individuals declining to consent or not able to consent for themselves. We did not include parturients hospitalized for COVID-19 with negative rt-PCR even if their Chest CT Scan was evocative. We did not include parturients who did not need hospitalization (asymptomatic or minor forms). Patients with incomplete vaccination (only 1 dose of Pfizer-BioNTech COVID-19 vaccine or when the second dose of vaccination is older than 6 months) were excluded from the study.

In this study, patients were divided into 2 groups according to their vaccination status:

- the Vaccinated group included patients who had completed vaccination by receiving 3 doses of Pfizer-BioNTech COVID-19 vaccine or 2 doses on condition that the second dose received within the last 6 months;
- the Non vaccinated group (control group) included non-vaccinated pregnant women.

We collected data about:

- Demographic parameters: age, weight, size, body mass index, term of pregnancy, and previous co-morbidities.
- Clinical features: clinical signs and the delay between first signs and hospitalization, as well as radiographic and biological findings.
- Obstetric and anaesthesia outcomes (if the parturient was tested positive while delivery): mode of delivery, anaesthesia management, and neonatal outcomes.
- Follow-up and prognosis: maternal and foetal complications, length of stay in COVID-19 unit or ICU and final outcome (recovery, surviving with post COVID-19 syndrome or death).

For completed pregnancies (pregnancy ending in either foetal loss > 14 WG or live birth), obstetrical outcomes (pregnancy outcome, gestational age at delivery, mode of delivery), and neonatal outcomes (neonatal death, neonatal admission to the ICU (NICU), birth weight, and rates of suspected perinatal SARS-CoV-2) were assessed.

We considered foetal loss as a spontaneous antepartum foetal death > 14 WG, late miscarriage 14-24 WG, and stillbirth foetal demise > 24 WG. Suspected perinatal SARS-CoV-2 transmission was defined as a positive RT-PCR result performed at birth.

All patients enrolled in this study had the same management protocol. In our department, clinical management of COVID-19 adheres to the INAES (Instance nationale de l'évaluation et de l'accréditation en santé) guidelines for COVID-19 patients [10].

All statistical analyses were achieved using the SPSS 23.0 (SPSS, Chicago, IL, USA) statistical package. Continuous variables were presented as means value ± standard deviation in the case of a Gaussian distribution and as medians in the case of a non-Gaussian distribution.

We divided positive pregnant women into two groups based on their vaccination status. The comparison between groups was achieved by Student's t-test and Chi^2 test for continuous variables and categorical variables, respectively. The Fisher

exact test was used when the Chi^2 test was not applicable. The Mann-Whitney U test was used for non-parametric continuous variables. The significance threshold was set at $p < 0.05$.

RESULTS

In this study we included 145 pregnant women with COVID-19. 45 patients were vaccinated, and 100 were not vaccinated. No patient was excluded because of incomplete vaccination against COVID-19. All vaccinated patients received at least 2 doses of RNA vaccine in the last 6 months. All vaccinated patients had the Pfizer-BioNTech COVID-19 vaccine. 34 of them received the vaccine when pregnant, and only 9 patients were vaccinated just before pregnancy. No serious maternal or foetal side effects related to the vaccine were noted.

Demographic parameters concerning age, weight, body mass index, term of pregnancy, and previous co-morbidities were comparable in both groups (**Table 1**). Vaccination reduced the severity of COVID-19 signs. COVID-19 was asymptomatic in 37% of vaccinated patients. The vaccination reduced the incidence of dyspnoea from 38% to 2.2%. The need for oxygen was also reduced from 64% in Non vaccinated group to 6.6% in Vaccinated group (**Table 2**).

In this study, 111 patients were infected at the moment of delivery (completed pregnancies), 33 of them were vaccinated and 78 patients were

Table 1. *Demographic parameters.*

	Group 1 Vaccinated n = 45	Group 2 Non vaccinated n = 100	P-value
Age (year)	31.64 ± 3.4	30.61 ± 2.9	0.231
Age > 35 (n, %)	8 (17.7%)	22 (22%)	0.561
Weight (kg)	78.36 ± 7.8	81.05 ±8.01	0.304
BMI (kg/m^2)	28.7 ± 1.5	29.7± 2.02	0.283
Parity: primiparous/multiparous	11/34	28/ 72	0.655
With comorbidities (n, %)	5 (11.1%)	19 (19%)	0.335
Obesity (BMI > 30 kg/m^2)	2	11	0.102
Hypertensive disorders	2	9	0.359
Diabetes	1	2	-
Respiratory disease	0	2	-
Term of pregnancy	35.78 ± 2.3	34.37 ± 3.8	0.143

Table 2. *Clinical features.*

	Group 1 Vaccinated n = 45	Group 2 Non vaccinated n = 100	P-value
Asymptomatic	17 (37.7%)	4 (4%)	**< 0.001**
Symptomatic	28 (62.2%)	96 (96%)	**< 0.001**
Cough	20 (44.4%)	63 (63%)	**0.035**
Fever	14 (31.1%)	56 (56%)	**0.048**
Headache and asthenia	8 (17.7%)	61 (61%)	**< 0.001**
Dyspnoea	1 (2.2%)	38 (38%)	**< 0.001**
Digestive symptoms	2(4.4 %)	12 (12%)	0.154
Others (sore throat or rhinorrhoea, anosmia and ageusia)	2 (4.4%)	4 (4%)	0.901
O_2 need	3 (6.6%)	64 (64%)	**< 0.001**
Delay between signs and hospitalization (days)	0.96 ± 0.24	3.28 ± 1.8	**< 0.001**
Pre-eclampsia	5 (11.1%)	10 (10%)	0.839
Cytolysis (> 3×)	3 (6.6%)	16 (16%)	0.169
Radiological signs > 20%	1	27	**< 0.001**

not vaccinated. We noted higher rates of caesarean section delivery in Non vaccinated group (74.3%). The main indications for caesarean delivery were foetal distress, severe preeclampsia, maternal saving, and obstetrical indications. However, vaginal delivery was noted in 66.6% of completed pregnancies in the Vaccinated group. The incidence of peripartum obstetrical complications was 10.2% in non-vaccinated population *versus* 6.06% in Vaccinated group with p = 0.435 (**Table 3**). The vaccination reduced the maternal mortality related to COVID-19 from 6% to 2.2%. One morbidly obese patient, having had 2 doses of vaccines in the last 6 months, developed severe preeclampsia complicated by HELLP syndrome and needed emergent caesarean delivery and died with severe ARDS two weeks later in the Vaccinated group.

In this study, we noted no cases of vertical transmission in either group. However, we noted 1 case of congenital cardiac malformation associated with oesophageal atresia in a premature newborn from a non-vaccinated mother with a severe COVID-19 in 26 GW. The incidence of premature birth, intrauterine growth retardation, foetal distress, Lower birth weight, and stillbirth was lower in the Vaccinated group (**Table 4**). Breastfeeding was recommended for all patients (both groups) and was safe with no cases of neonatal infection.

DISCUSSION

In this study, we showed the positive impact of vaccination in the pregnant population as it allowed better maternal and foetal outcomes in spite of the vulnerability of this population to viral infections [11].

The severity of COVID-19 in pregnancy is due to physiological changes leading to immunodepression, hypercoagulation, and high oxygen consumption with higher basal metabolism associated with reduced pulmonary capacity [1]. This may expose the pregnant woman to severe hypoxemia which can affect the foetus. It was reported that there is also a possible risk of vertical transmission [2] associated with placental ischemia by blood clotting in severe forms of COVID-19 that may affect the foetus and can lead to emergent extraction [12]. So, the obstetrical and foetal outcomes are influenced by the severity of maternal disease that may be improved by vaccination [13]. Although the benefit–risk profile of these vaccines was proven to be largely favourable in the general population, evidence in special cohorts initially excluded from the pivotal trials, such as pregnant and breastfeeding women, is still limited. The vaccines and particularly mRNA vaccines used in our population may induce additional cellular or humoral immune regulation, including T helper cell responses and germinal centre responses, and form relevant memory cells, greatly

Table 3. *Obstetrical outcomes.*

	Group 1 Vaccinated n = 45	Group 2 Non vaccinated n = 100	P-value
Mode of delivery			
No delivery during infection	12 (26.6%)	22 (22%)	0.221
Completed pregnancy	33 (73.33%)	78 (78%)	0.221
Caesarean section delivery	11/33 (33.3%)	58/ 78 (74.3%)	**< 0.001**
Vaginal delivery	22/33 (66.6%)	20/78 (25.6%)	**< 0.001**
Indications of caesarean delivery			
Foetal distress	7	19	**0.05**
Severe preeclampsia	1	6	0.564
Maternal saving	1	8	0.622
Obstetrical IND	2	24	**< 0.001**
COVID 19 alone	0	1	-
Peripartum complications	2 (6.06%)	8 (10.2%)	0.435
Bleeding	1	2	-
Respiratory distress	0	3	-
Thrombo-embolic events	0	1	-
Severe preeclampsia	1	2	-

Table 4. *Maternal and foetal outcomes.*

	Group 1 Vaccinated n = 45	Group 2 Non vaccinated n = 100	P-value
Length of hospitalization (days)	4.05 ± 1.05	7.46 ± 3.2	**< 0.001**
Referral to ICU	2 (4.4%)	23 (23%)	**0.008**
COVID 19 Complications			
ARDS	1 (2.2%)	23 (23%)	**< 0.001**
Pulmonary embolism	0	1 (1%)	-
Septic shock	0	2 (2%)	-
HELLP syndrome	1 (2.2%)	2 (2%)	-
Maternal deaths	1 (2.2%)	6 (6%)	0.326
Foetal outcomes	n = 33	n = 78	
Premature birth	3 (9.09%)	35 (44.8%)	**< 0.001**
Intrauterine growth retardation	2 (6.06%)	26 (33.3%)	**< 0.001**
Foetal distress	7 (21.2%)	19 (24.3%)	**0.048**
Lower birth weight	2 (6.06%)	14 (17.8%)	**< 0.001**
Stillbirth	2 (6.06%)	5 (6.41%)	0.258

improving their efficiency [14]. However, in pregnancy, there is a shift in Th1/Th2 that may trouble the immune response after infection [15] and may reduce the efficacy of vaccination [16]. In our population the vaccination was safe and efficient. However, some viral vector or mRNA vaccines have been linked to complications such as thrombocytopenia, thromboembolic events, and myocarditis in the literature, raising concerns about the safety of these COVID-19 vaccines [17,18]. The main outcome of our study is that it allowed us to show the benefits of vaccination even during pregnancy. Even if the majority of pregnant women tested positive recovered within one week, the incidence of complications remains high and may lead to maternal morbidity and mortality [19, 20] and poor foetal outcomes in form of early pregnancy loss, prematurity, oligohydramnios, intrapartum foetal distress, and sometimes foetal demise [21]. To improve maternal and foetal outcomes, COVID-19 vaccination in pregnancy has been endorsed by multiple professional societies, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine and the World Health Organization. It was also recommended for the lactating woman by the Italian scientific societies [22]. The impact of vaccination on perinatal outcomes and particularly the mode of delivery is still controversial. Recent studies showed no difference in the mode of delivery between vaccinated and non-vaccinated pregnant population [23]. However, in our study, vaccination reduced the need for caesarean section delivery after reducing the severity of the disease and allowed more vaginal deliveries, which may reduce the incidence of postpartum haemorrhage and thromboembolic events and may enhance recovery after delivery [24].

Maternal, placental, and foetal immune activation have been observed in maternal SARS-CoV-2 infection during pregnancy and may be the cause of adverse foetal outcomes through a direct injurious effect on the placenta like placentitis and trophoblast necrosis [2, 25]. As a consequence, severe foetal outcomes can be seen, like abortion, stillbirth, neonatal death, and perinatal death [3, 26, 27]. The role of vaccination is to reduce this immune activation and to reduce the risk of placentitis. This may explain the improved foetal outcomes in vaccinated patients in our study.

The maternal mortality in non-vaccinated pregnant women was about 6% in non vaccinated population in our study and was widely higher than the mortality in the general population [28] and also in comparison with vaccinated pregnant women in the same study.

This shows that the benefits of vaccination on the mother and the foetus seem to be higher than risks and should be encouraged by facilitating the access to vaccination particularly in rural regions and by informing parturients about these benefits [29]. In Tunisia, vaccination became mandatory in September 2021, and the vaccinal pass was imposed.

Nevertheless, the limit of our study is that we included pregnant women with COVID-19 from

different waves and we did not have any idea about the variants in each wave in our population [30]. The second limit is that the vaccination started in March, although the study began in January 2021.

CONCLUSIONS

Vaccination against COVID-19 during pregnancy was safe and effective. It allowed a reduction in severe forms and the need for oxygen support. Maternal and obstetrical outcomes depend on the severity of the illness and appear to be improved with vaccination. It allowed a reduction in the incidence of caesarean delivery with better foetal outcomes. So, vaccination should be encouraged in this particular population.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

A.J.: Conceptualization, investigation, methodology, writing - review & editing. M.K.: writing - original draft. S.A.: Data curation, formal analysis, investigation. S.E.: Investigation. F.K.: Investigation, writing - review & editing. K.C., K.K.: Supervision, validation, visualization.

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Study registration

N/A.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

Obtained from the HCUH (Local Ethics Committee).

Informed consent

Obtained from all parturients included in the study.

Data sharing

Data are available under reasonable request to the corresponding author.

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