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Vaccination for SARS-COV-2 in pregnancy in a referral center in Italy

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Abstract

Objective: The aim of the study was to investigate uptake of COVID-19 vaccination among pregnant women in a referral center in Italy.

Methods: This was an observational retrospective study conducted at ASL NA1 Centro, and at University of Naples Federico II, Italy, among pregnant women. The primary outcome was uptake of COVID-19 vaccination and its determinants.

Results: Data were available for 1,478 pregnant women who were offered COVID-19 vaccination during pregnancy. Of them, 498 (33.7%) rejected the vaccine, while 980 (66.3%) received at least 1 dose of the vaccine before delivery. Out of the 980 women who received vaccination, 357 (36.4%) were vaccinated in the second trimester, 497 (50.7%) in the third trimester, and 126 (12.9%) in the first trimester of pregnancy. 327 (33.3%) women received one dose of the vaccine in pregnancy, and 653 (66.6%) received two doses.

Conclusion: Of pregnant women eligible for COVID-19 vaccination, more than two-third cases accepted COVID-19 vaccination during pregnancy.

Keywords: COVID-19, SARS-COV-2, vaccination, epidemiology

Introduction

Coronaviruses are enveloped, non-segmented positive-sense RNA belonging to the Nidovirales order.[1] In December 2019, a novel Coronavirus spread in China and identified as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) was responsible of a cluster of respiratory disorders, the COVID-19 disease.[2] Pregnant women are at increased risk for severe illness from influenza virus and other respiratory infections due to cardiopulmonary adaptive changes occurring during pregnancy, such as increased heart rate and stroke volume and reduced pulmonary residual capacity, that can increase the risk of hypoxemia and contribute to the increased severity. As well, COVID-19 in pregnancy, is associated with increased risk of maternal and perinatal outcomes.[2-5] Mass vaccination is the best method by which all countries are aiming to control the COVID-19 pandemic;[6] and COVID-19 vaccines are safe for use in pregnancy.[7] Despite this, there is paucity of data regarding the willingness to accept vaccination during pregnancy among pregnant women.[8]

This may question whether the course of COVID-19 in pregnant women can be associated with a higher burden of maternal mortality and morbidity compared to the general population.

Objective

The aim of this study was to investigate uptake of COVID-19 vaccination among pregnant women in a referral center in Italy.

Methods

This was an observational retrospective study conducted at ASL NA1 Centro, and at University of Naples Federico II, Italy, among pregnant women. The primary out-

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come was uptake of COVID-19 vaccination and its determinants. The secondary outcomes were perinatal safety outcomes. Data were collected on COVID-19 vaccination uptake, vaccination type, gestational age at vaccination, maternal characteristics, and perinatal outcomes.

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc., Armonk, NY, USA). Data were shown as means± standard deviation or as number (percentage). Dichotomous data were compared using the chi-square. Comparisons between groups were performed with the use of the T-test to test group means by assuming equal within-group variances. A sample size of 200 women for each group was planned.

Results

Data were available for 1,478 pregnant women who were offered COVID-19 vaccination during pregnancy (Table 1). Of them, 498 (33.7%) rejected the vaccine, while 980 (66.3%) received at least 1 dose of the vaccine before delivery. Out of the 980 women who received vaccination, 357 (36.4%) were vaccinated in the second trimester, 497 (50.7%) in the third trimester, and 126 (12.9%) in the first trimester of pregnancy. 327 (33.3%) women received one dose of the vaccine in pregnancy, and 653 (66.6%) received two doses. There was evidence of reduced vaccine uptake in women younger than 30 years old (<0.01), in smokers (0.02), and in those at risk of preterm birth (<0.01). Women with high-risk pregnancy, including pregnancy-induced hypertension, had increased vaccine uptake (0.02). The rate of adverse pregnancy outcomes in women who received at least one does of the COVID-19 during pregnancy, were similar to those who did not in terms of stillbirth, fetal abnormalities, intrauterine growth restriction, and admission to neonatal intensive care unit. Rate of preterm birth was significantly higher in unvaccinated compared to vaccinated women (0.02) (Table 2).

Table 1. Data on pregnant women who were offered COVID-19 vaccination

	n = 1,478
0 dose	498/1,478 (33.7%)
1 or 2 doses during pregnancy	980/1,478 (66.3%)
Vaccination in the first trimester	126/980 (12.9%)
Vaccination in the second trimester	357/980 (36.4%)
Vaccination in the third trimester	497/980 (50.7%)
1 dose in pregnancy	327/980 (33.3%)
2 doses in pregnancy	653/980 (66.6%)

Data are presented as number with percentage

Table 2. Pregnancy outcomes in vaccinated and unvaccinated patients

	Vaccinated patients n = 980	Unvaccinated patients n = 498	p-value
Miscarriage	13 (1.4%)	10 (2.0%)	NS
Stillbirth (>22 weeks)	2 (0.2%)	1 (0.2%)	NS
Fetal abnormalities	25 (2.6%)	8 (1.6%)	NS
Intrauterine growth restriction	44 (4.5%)	30 (6.0%)	NS
Admission to NICU	102 (10.4%)	51 (10.2%)	NS
Cesarean delivery	298 (30.4%)	167 (33.5%)	NS
PTB <37 weeks	63 (6.4%)	49 (9.8%)	0.02

Data are presented as number with percentage. Boldface data, statistically significant
NICU, neonatal intensive care unit; PTB, preterm birth; NS, non significant

Discussion

Theoretically, COVID-19 vaccines are safe for use in pregnancy, as they do not contain a live attenuated virus. Safety and efficacy have been also shown by data collected by the Centers for Disease Control and Prevention (CDC) V-safe pregnancy registry, and by national and international data.[7] However, pregnant women were excluded from randomized controlled trials (RCTs) testing the safety and efficacy of COVID-19 vaccines, and this have caused debate between patients and providers.[10] In this paper we aimed to investigate the uptake and safety of COVID-19 vaccination among pregnant women. Data from our study shown that of pregnant women eligible for COVID-19 vaccination, more than two-third accepted COVID-19 vaccination during pregnancy. The acceptance rate was lower in younger women, in smokers, and in those with increased risk of preterm delivery, while was higher in patients with pregnancy-induced hypertension.

Conclusion

Of pregnant women eligible for COVID-19 vaccination, more than two-third accepted COVID-19 vaccination during pregnancy, and they experienced similar perinatal outcomes compared with unvaccinated pregnant women.

Conflicts of Interest: No conflicts declared.

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