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COVID-19 Vaccination in Pregnancy

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Abstract

COVID-19 pandemic has affected human lives globally. The most important measure to control this pandemic is vaccination and to follow public health measures like wearing facemasks, maintaining social distancing, and hygiene. Over the last one-year, numerous vaccines have been formulated under rigorous regulatory rules globally. During the process of vaccine development, antenatal and breastfeeding women were not included in vaccine research trials, even though they were at increased risk of developing severe COVID-19 infection in comparison to non-pregnant women. There is reassuring data that there are no safety concerns in antenatal patients who received mRNA vaccine in the third trimester and no evidence of increased miscarriage rate if taken at less than 20 weeks of pregnancy. In mRNA vaccine immunized pregnant women, antibodies were found in cord blood. The healthcare staff should provide effective counselling and promote immunization in antenatal women in all trimesters and breastfeeding mothers.

Introduction

COVID-19 pandemic has affected human lives, the healthcare system, and economies globally. The most important measure to control this pandemic is vaccination and to follow public health measures like wearing facemasks, maintaining social distancing, and strict personal hygiene. Over the last one-year, numerous vaccines have been formulated under rigorous regulatory rules globally, against the COVID-19. During the process of vaccine development, antenatal and breastfeeding women were not included in COVID-19 vaccine research trials, even though they were at increased risk of developing severe COVID-19 infection in comparison to non-pregnant women [1]. Recent literature reports that antenatal women with COVID-19 have a high chance of hospitalization, ICU care, ventilatory support, and high probability of preterm labour [2]. Studies also report that there is a 2-3% risk of transmission of COVID-19 infection to the baby and that viral RNA may be present in the breast milk of COVID-19 infected women [3]. American College of Obstetricians and Gynecologists (ACOG) and Centers for Disease Control and Prevention (CDC), recommend that all antenatal women should receive COVID-19 vaccination.

Recently, all over the world, it has been realized that there is an urgent need for including antenatal women in all research trials of the COVID-19 vaccine. According to Developmental and Reproductive Toxicity (DART) studies using Pfizer-BioNTech and Moderna vaccines, there are no direct or indirect harmful effects on antenatal or perinatal outcomes. The CDC recommends that all pregnant, lactating women and women who are planning to conceive, should take this vaccine. There is reassuring data on the safety of mRNA COVID-19 vaccine administration in antenatal women [4]. There is no evidence of an increased miscarriage rate in women who took mRNA vaccine before conception or less than 20 weeks of pregnancy [5]. Surveillance of pregnancies is underway, and CDC is following all women who took vaccination in all the three trimesters of pregnancy to analyze the effects on gestation and neonates. Recent literature found that the mRNA COVID-19 vaccine lowered the risk of infection in pregnant women. In mRNA COVID-19 vaccinated pregnant women, antibodies were found in umbilical cord blood, which may protect the neonates against COVID-19. More research is required to assess the mechanism by which these antibodies will protect the neonates [6]. Pharmaceutical companies manufacturing these vaccines are analyzing information from the various clinical trials in women who took the vaccine and became antenatal during the trial.

Effect of the vaccine in Antenatal Women

There are severe outcomes of COVID-19 infection in antenatal patients and even though vaccination is available for non-pregnant women, there is limited research assessing the effect of any COVID-19 vaccine during gestation. Vaccination in antenatal or lactating women has been approved on the basis of various reviews, cohort studies, clinical research trials, and registries,

conducted by joint efforts between the World Health Organization (WHO), CDC, National Institutes of Health (NIH), to assess the vaccine:

(i) safety-no unfavorable effect on maternity outcomes or any possible health hazard to mother or the baby

(ii) efficacy-decrease the incidence of COVID-19 in the antenatal woman or the baby [7].

COVID-19 Vaccine Hesitancy

Even though there is enormous advancement in vaccine development and administration, there is inadequate acceptance for the same, therefore there is a delay in development of herd immunity. For reaching the herd immunity threshold, the immunity at the community level should reach minimum of 75% immunity to halt this pandemic. Even before this pandemic, WHO had classified hesitancy to take the vaccine as one of the top ten hazards to worldwide health [8]. Hence, it is essential to realize the various reasons for this reluctance to take vaccine and address it at the earliest. Through an online survey (Oct-Nov 2020), approximately 50 percent of antenatal women and 70 percent of non-pregnant women had the intention to receive the vaccine [8]. The most common reasons for declining the COVID-19 vaccination during pregnancy were:

i) any risk of exposure of fetus to any possible adverse effects (65 percent)

(ii) vaccine was approved because of government-related reasons (45 percent)

(iii) want to wait and see the studies on the effect of the vaccine in antenatal women

The hesitancy to take the vaccine is a multifaceted problem and variation based on area, race/ ethnicity, gestation, educational level, occupational status, interpersonal and political factors [8]. Healthcare providers need to educate patient on regular basis, to increase the vaccine acceptance rate, especially in antenatal women.

Prior to this pandemic also, immunization during gestation was recommended, which provided immunity to mother and baby from communicable diseases like influenza and pertussis. Presently, several experts recommend that mRNA and adenovirus vector COVID-19 vaccine, will not cause any risk to the fetus or breastfeeding baby [9], although there is no literature on whether there will be trans-placental transfer of intact vaccine particles or not. But the studies done in the past on other lipid nanoparticle-based vaccines suggest that they cannot cross the placenta [9].

Shimabukuro et al. reported the effects of mRNA COVID-19 vaccines, information collected from December 2020 to February 2021, using v-safe surveillance system, 14 percent resulted in pregnancy loss and 86 percent resulted in a live birth, largely immunization was received in the last trimester. They reported preterm birth in ten percent, small for gestational age in three percent, and no newborn mortalities. Proportions of unfavorable maternity and neonatal outcomes in immunized women were similar to incidences in antenatal women before the pandemic. The most common adverse outcome was spontaneous abortion [4]. Many experts have recommended the COVID-19 vaccine as vaccine-induced IgG may be secreted in breast milk and provide additive immunity to the baby against infection . Golan reported there are vaccine-stimulated IgA antibodies in breastmilk 3-4 weeks after vaccination with the mRNA vaccine [10]. They also measured IgA antibody titers in breastmilk and found them to be similar between women who got immunization and COVID-19 infection. A study by Rottenstreich et al. reported efficient placental transfer of anti-spike antibodies after immunization of antenatal women with the Pfizer vaccine [11].

Covaxin recently got WHO approval on 3rd November 2021, after evaluation under the WHO EUL protocol. WHO's expert group recommended two doses, with gap of four weeks between both doses, in all age groups 18 and above. Covaxin vaccine has 78% efficacy against infection of any severity, two weeks after the second dose, and is appropriate for developing countries due to easy storage requirements. More than 1 lakh pregnant women have received Covaxin in India, with no short-term side effects. More studies are planned to see the effect of Covaxin in pregnant women. Various COVID-19 vaccines are still under investigation and because of non-uniformity in population, rules and regulations in all the countries, evaluation of different COVID-19 vaccines is not possible at present.

Conclusions

COVID-19 immunization is the utmost important measure to control the spread of the pandemic. It is essential to protect the antenatal and lactating women and they should be involved in vaccine clinical trials and anti-viral treatment protocols. The doctors, nursing staff and counsellors should provide evidence-based knowledge and effective counselling to the antenatal and breastfeeding women and promote immunization in antenatal women in all trimesters and breastfeeding mothers.

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