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İnaktif SARS-CoV-2 Aşısı Olan Gebenin Bebeğinin Kord Kanında Antikor Saptanması: Olgu Sunumu

Neonatal Antibodies are Detected in Cord Blood After Vaccination of Pregnant Woman with the Inactivated SARS-CoV-2 Vaccine: A Case Report

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ÖZ

SARS-CoV-2 için şu anda mevcut aşılardan güvenliliğini ve etkinliğini değerlendiren çalışmalar hamile kadınları ve yenidoğanları içermiyor. Gebe kadınları COVID 19 aşısı ile aşılama için güvenli verilere acilen ihtiyaç duyulmaktadır, çünkü aşı savunmasız nüfusu korumanın tek yoludur. 33 yaşındaki kadın hastalıkları ve doğum uzmanı sağlık çalışanı gebeye 29.hafta ve 33.haftada önerilen protokole 28 gün arayla iki doz inaktif SARS-CoV-2 aşısı yapıldı. Hamileliğin geri kalanı sorunsuz geçti ve 38. haftada sağlıklı bir bebek dünyaya getirdi. Yenidoğan ilk değerlendirmesinde sağlıklı olarak izlendi. Doğumdan hemen sonra anne kanı ve yenidoğandan kordon kanı, immüno globulin test yöntemi için alındı. Spike antijeni için COVID-19 IgG ve IgM antikorları maternal 2,04 (reaktif) ve kordon kanı 1,36 (düşük titrasyonda reaktif) olarak rapor edilmiştir. Bu vakada, inaktif aşı ile annenin aşılmasından sonra kordon kanında saptanabilen SARS-CoV 2 IgG ve IgM antikorları olan bir yenidoğan bildiriyoruz.

Anahtar kelimeler: COVID-19, kord kanı, anne, yenidoğan, aşı

ABSTRACT

Studies evaluating the safety and efficacy of currently available vaccines for SARS-CoV-2 do not include pregnant women and newborns. Safety data for vaccinating pregnant women with the COVID-19 vaccine is urgently needed since the vaccine is the only way to protect the vulnerable population.

The 33 years-old pregnant woman, a healthcare worker as an obstetrician and gynecologist, was vaccinated with inactivated SARS-CoV-2 vaccine with two doses within 28 days apart as the recommended protocol, on her 29th week and 33rd week of pregnancy. The rest of the pregnancy was uneventful and she gave birth on the 38th week to a healthy infant. The infant was a healthy boy upon first evaluation. Maternal blood was sampled immediately after birth, cord blood was obtained from a neonate for the immunoglobulin testing method.

COVID-19 IgG and IgM antibodies for spike antigen was reported maternal as 2.04 (reactive) and the cord blood as 1.36 (reactive in a low titration).

In this case we report an infant with SARS-CoV-2 IgG and IgM antibodies detectable in cord blood after maternal vaccination with inactivated vaccine.

Key words: COVID-19; Cord blood; Maternal; Newborn; Vaccination.

INTRODUCTION

The coronavirus (SARS-CoV-2) which was first detected in Wuhan-China in December 2019 has caused a pandemic in a short while (1). Approximately within one year, vaccines against COVID-19 disease were developed. The known vaccine technologies for COVID-19 infection include mRNA vaccine (Pfizer-BioNTech, Moderna), vector vaccine (Johnson & John-

son's Janssen, Oxford-Astra Zeneca), and inactivated vaccine (CoronaVac) up-to-date (2-5). During the COVID-19 pandemic, healthcare workers on the front line were determined as the main risk group. In Turkey, similar to many other countries, healthcare workers were vaccinated first as the access to the vaccine was limited and people were classified according to

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the risk groups for the priority of vaccine access. Pregnant and breastfeeding women in risk groups were recommended COVID-19 vaccine in Turkey voluntarily due to the lack of safety data, by the Turkish Ministry of Health. There is a lack of data for the vaccine among pregnant and breastfeeding women and children and urgent studies are needed to show the safety and efficacy of the vaccine among these vulnerable groups.

In the current report, we would like to report a case, a pregnant physician mother who got two doses of the inactivated COVID-19 vaccine and of whom infant was born with antibodies in the cord blood.

Case Presentation

The 33 years-old pregnant woman, a healthcare worker as an obstetrician and gynecologist, was vaccinated with inactivated SARS-CoV-2 vaccine (CoronaVac/Sinovac, China) with two doses within 28 days apart as the recommended protocol, on her 29th week and 33rd week of pregnancy. The patient was Caucasian, Turkish, 72 kg, and non-smoker. She did not have any other medical conditions or a history of drug use except iron supplementation for pregnancy. The patient gave a written informed consent both before vaccination and before the analysis. The case has a negative COVID-19 reverse transcriptase-polymerase chain reaction (RT-PCR) test on the 13th week of pregnancy and a negative COVID-19 IgM + IgG (<0.005, index: 0-0.9) result on her 25th week of pregnancy. During the pregnancy process, she did not have any other risk of contact or symptoms of COVID-19 infection until birth.

After vaccination, the pregnant woman did not have any symptoms except slight pain in the vaccinated arm, and the headache lasted for one day. The rest of the pregnancy was uneventful and she gave birth on the 38th week to a healthy infant. The infant was a healthy boy upon first evaluation.

Upon hospital admission, maternal blood was sampled from the antecubital vein and immediately after birth, cord blood was obtained from a neonate for the immunoglobulin testing method. Samples were stored capped and upright at 2–8°C upon arrival in the laboratory. COVID-19 IgG and IgM antibodies for spike antigen was reported maternal as 2.04 (reactive) and the cord blood as 1.36 (reactive in a low titration).

The analysis was performed via ADVIA Centaur SARS-CoV-2 Total (COV2T), Siemens, Germany assay kit. The antibody test is highly accurate in identifying SARS-CoV-2 antibodies and is designed to detect the spike protein receptor binding domain (S1RBD) on the surface of the SARS-CoV-2 virus which binds

the virus to cells via a distinct human receptor (ACE2) found in lungs, heart, multiple organs and blood vessels. SARS-CoV-2 Total Antibody Assay is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 virus in human serum and plasma (EDTA, lithium heparin). Time to First Result is 16 minutes. Measuring Interval 0.05–10.00 Index. The system reports ADVIA Centaur COV2T assay results in Index Values and as Nonreactive or Reactive: Nonreactive: < 1.0 Index. These samples are considered negative for SARS-CoV-2 antibodies. Reactive: ≥ 1.0 Index. These samples are considered positive for SARS-CoV-2 antibodies. The assay was designed to have the following precision. Repeatability (Within-Run) ≤ 12.0% CV. Within-Laboratory (Total Precision) ≤ 15.0% CV.

DISCUSSION

Pregnant and lactating women in risk groups such as healthcare workers were recommended vaccination by several authorities advocating that the expected benefit and potential risk that COVID-19 infection would bring is higher than the expected risk of vaccines. American College of Obstetricians and Gynecologists, regarding the higher risk of being infected during pandemic, unknown risk of potential severe infection and knowing the security of vaccine for healthy adults while no other potential harms were expected during pregnancy regarding the knowledge of the mechanism of the vaccine (4).

CoronaVac is a recently developed COVID-19 vaccine that uses an inactivated virus (6, 7). For the CoronaVac inactivated vaccine, the phase 3 trials included healthy adults aged 18 – 59 years and >60 years, however pregnant and breastfeeding women were not included in the trials carried in Brazil (NCT04456595), Turkey (NCT04582344), Chile (NCT04651790), China (NCT04617483), Hong Kong (NCT04800133) and Indonesia (NCT04508075). The vaccination for COVID-19 with the inactivated vaccine CoronaVac was initiated in Turkey, as soon as the phase 3 trials were completed.

There are only limited reports on pregnant women who got the COVID-19 vaccine, and the reports were only of vaccines using mRNA technology. Due to reports with limited participants, a better immune response was detected in pregnant and lactating women, while there was also an antibody transfer to their infants via placenta and breastmilk (8-10). To the best of the authors' knowledge, despite the presence of reports on the presence of COVID-19 antibodies in the cord blood of the neonate with the mRNA vaccine technology, a report on an inactivated

vaccine with CoronaVac has not been published.

Safety data for vaccinating pregnant women with the COVID-19 vaccine is urgently needed since the vaccine is the only way to protect the vulnerable population which would face higher risk if infected with COVID-19 and their infants who are not yet candidates for the vaccine.

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