

A Prospective Observational Study on the Clinical Characteristics of Pregnant Women Post COVID-19 Vaccines

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Abstract

Background: The use of mydriatic and cycloplegic eye drops is a common practice in ophthalmology for various diagnostic and therapeutic procedures like for estimation of refractive error and for thorough fundus examination. The combination of Tropicamide and Phenylephrine has been a subject of debate among ophthalmologists regarding its efficacy and side effects.

Aims and Objectives: The aim of this study was to evaluate the efficacy and safety of 1% Tropicamide alone versus a combination of 0.8% Tropicamide and 5% Phenylephrine for mydriasis and cycloplegia. The objectives were to compare the rate of mydriasis and maximal mydriasis after instilling a single drop of each solution and to measure the degree of cycloplegia and amount of residual accommodation at 25 minutes after instillation of the drops.

Methods: This was a hospital-based, analytic cross-sectional study conducted on 100 patients between 15 and 35 years of age presenting to the Department of Ophthalmology, Government Medical College and Associated Group of Hospitals, Kota for refraction or fundus examination. Patients were randomly assigned to either the Tropicamide group or the Tropicamide-Phenylephrine group. The study measured the rate of mydriasis, maximal mydriasis after eye drop instillation. Study also measured the degree of cycloplegia and amount of residual accommodation at 25 minutes after instillation of the drop.

Results: The combination of Tropicamide and Phenylephrine resulted in a higher rate of mydriasis and maximal mydriasis than Tropicamide alone. Tropicamide alone uncovered significantly higher mean latent error of refraction and had higher cycloplegic effect as compared to combination group. The study also found that increasing age lead to increased cycloplegia and decreased residual accommodation in both groups. It was also found that both groups had a similar safety profile, with no significant adverse effects observed except significant increase in pulse rate after instillation of combination eye drop.

Conclusion: The combination of Tropicamide and Phenylephrine is more effective than Tropicamide alone for inducing mydriasis with a similar safety profile except significant change in pulse rate. While Tropicamide alone had better cycloplegic effect.

Keywords: Tropicamide, Phenylephrine, Mydriasis, Cycloplegia, Efficacy, Safety.

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Introduction

Pregnancy increases the chance for extreme COVID-19 illness, and COVID-19 for the duration of pregnancy is related to improved hazards regarding preterm birth yet can also be associated with accelerated risk because of vile damaging maternal or neonatal outcomes. Pregnant yet lactating women have been not included between vaccines that are out of danger because of uses in pregnancy, as much as those enslaved people now do not comprise a stay attenuated virus, enceinte woman. The COVID-19 pandemic has caused ruin initial coronavirus sickness 2019 (COVID-19) gloss trials. However, the first vaccine examination started of lifestyles then poorer fitness outcomes, outdoors or in pregnancy, notwithstanding global Invasive common health measures after limiting the spread. Mass vaccination is an authorisation approach by nations aiming to control the pandemic. COVID-19 vaccines are out of danger because of their uses in pregnancy, as those enslaved people now do not comprise a stay-attenuated virus.

Pregnant women have generally been excluded from clinical trials of novel drugs and vaccinations due to worries about fetal consequences, as has been the case with COVID-19 vaccines thus far. Yet, in recent years, federal agencies have acknowledged the difficulties associated with this method. The National Institute of Allergy and Infectious Diseases of the National Institutes of Health convened an expert group in 2013 to provide guidelines for protocol design and safety evaluation for clinical studies, including pregnant women. [1] Although acknowledging the need to include pregnant women in clinical trials, the speed with which the COVID-19 vaccines were developed and studies were done prohibited the inclusion of pregnant women. [2]

Because the COVID-19 vaccinations used in the UK program do not contain live SARS-CoV-2 virus, they cannot infect a pregnant

woman or her unborn child. While pregnant women were excluded from the original COVID-19 vaccination studies, as is usual in drug trials, there is growing experience and proof of the safe and successful use of mRNA vaccines in pregnant women. [3] There is evidence that COVID-19 immunization provides comparable protection against SARS-CoV-2 infection in pregnant, breastfeeding, and non-pregnant women and that vaccination causes greater antibody levels than the illness. [4] The adverse effects of the vaccination appear to be the same in pregnant and non-pregnant people. [5]

Pregnancy can be affected by multiple physiological changes, including respiratory viral infections, low birth weight, premature birth, and high fever. [6] COVID-19 is a capsulated single-stranded RNA virus. Like other viruses, the immunological response to COVID-19 depends on a functioning immune system. COVID-19 infection can cause moderate illness, in which the immune system easily clears the virus or severe sickness with significant fatality rates. The place of pregnant women in this range is unknown. The immune system adjusts during pregnancy to allow for the formation of a semi-allogenic fetus, leading to a changed immune response to illnesses during pregnancy. [7] SARS-CoV-2 is spread through respiratory droplets, direct contact with fomites, close person-to-person contact, and aerosols. It infects pulmonary cells through ACE2 and TMPRSS2, followed by viral multiplication and release, resulting in host cell pyroptosis. [8]

COVID-19 is a disease that can affect people of all ages and genders, including pregnant women and babies. It is caused by damage-associated molecular patterns (DAMPs), which release an inflammatory response in neighbouring cells, resulting in excessive inflammation and lung damage, leading to infection with other host bacteria. [9] COVID-19 has been associated with mild to severe

upper respiratory tract symptoms such as dry cough and chest tightness, as well as other less usually noticed symptoms such as high fever, tiredness, dyspnea, diarrhoea, and headache in pregnant women. [9,10] Chest computed tomography (CT images) typically confirm

severe upper respiratory tract infections. Varied phases of pregnancy and individual immunological responses in each case may influence the presenting symptoms of COVID-19 in pregnant women. [11] (Figure 1)

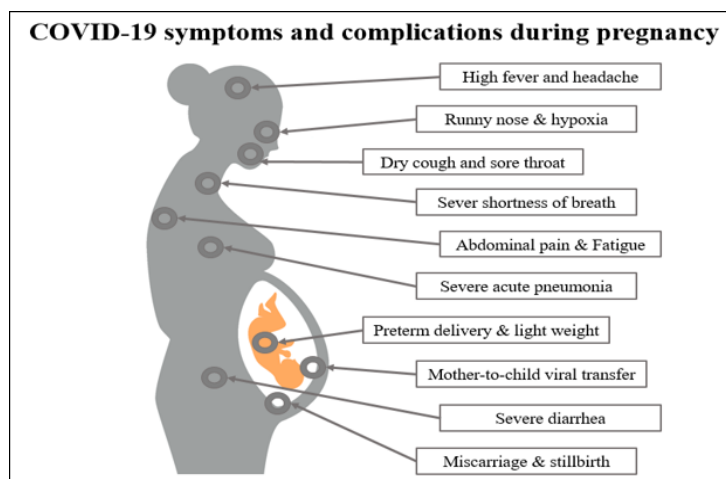


Figure 1: Summarises the symptoms and potential complications in COVID-19-infected pregnant women.

Vaccines are biological products that give active adaptive immunity to certain illnesses. Vaccine development involves employing microorganisms that cause the disease, either in dead or attenuated form or exploiting toxins or surface proteins. The mouth injection administration uses vaccines or nasal routes to stimulate the immune system's response to foreign bodies. The body develops antibodies against specific bacteria throughout the immune development process, which generates the defence mechanism. In response to the antigens of the microorganisms, either protect the person against the sickness caused by the pathogen or lessen the severity of the disease. [12] Vaccination during pregnancy increases maternal immunity to vaccine-preventable diseases and facilitates vaccine-specific antibody transfer to the baby. Pregnant women do not appear more or less prone than the general population to getting the infection. According to the INTERCOVID international trial of unvaccinated women, pregnant women with diabetes, obesity, or gestational diabetes

on insulin had a considerably higher risk of getting SARS-CoV-2 infection than pregnant women without these co-morbidities. [13]

Women with diabetes had a nearly doubled risk of SARS-CoV-2 infection (RR 1.94, 95% CI 1.55-2.42), those who were overweight or obese had a 20% increased risk (RR 1.20, 95% CI 1.06-1.37), and women who developed insulin-dependent gestational diabetes mellitus had an increased risk (RR 1.79, 95% CI 1.06-3.01). [12] Most affected women have just mild to severe cold/flu-like symptoms. Therefore, the main objective is to study the clinical presentation of pregnant women vaccinated against COVID-19 and the incidence of COVID-19 during pregnancy post-COVID-19 vaccination.

Materials and Methods

This prospective observational study was conducted at the outpatient department, a private hospital at Villupuram, Tamilnadu, for nine months. After the institutional ethics committee (IEC) and VISTAS approval and

obtaining written informed consent forms from the participants, the study will include one hundred eight pregnant women receiving covid-19 vaccine shots at a private hospital in Villupuram based on the inclusion and exclusion criteria.

Inclusion criteria: Eligible participants, identified as female, aged between 18-40 years, were included.

They were administered with a self-developed questionnaire for data collection. Patient demographic details like patient's age, op number, body weight, height, chief complaints, medical history, medication history, surgical history, gynaecological history like last menstrual period, number of days of menstruation, number of missed pregnancy, gestational age during pregnancy, the menstrual cycle were collected.

Data about the patient's clinical signs and symptoms after vaccination were collected by phone call for five days post-vaccination as a follow-up during the first and second doses of the vaccine. Study participants were educated about managing post-COVID-19 vaccination effects and precautions to prevent the active COVID-19 disease. The patient was followed

up throughout pregnancy by periodic phone calls to learn about their health and COVID-19 disease, if any. The collected data were entered into a Microsoft Excel spreadsheet for statistical analysis. All categorical variables, including respondents of sociodemographic details and signs and symptoms of participants after taking COVID shots, will be expressed as percentages and frequencies.

Results

Around 108 pregnant women agreed to participate in this study. During the age between 18 to 40 years old pregnant women were participants in this study. Based on age, 19% of the pregnant women were between 18 to 20 years old, 68% of pregnant women between 21 to 30 years and 14% of pregnant women between 31 to 40 years and no one can participate above the age of 41 years.

Types of vaccination, Covishield or Covaxin, are included in this study. Most pregnant women take covishield (77%), and few take covaxin (25%). Among 51% of pregnant women taking 1st dose shorts of COVID vaccination. 41% of pregnant women taking 2nd dose shots of vaccination (Covishield or Covaxin).

Table 1: Participants based on signs and symptoms of 1st and 2nd doses of Covishield and Covaxin

Signs and symptoms	1 st dose of Covishield	2 nd dose of Covishield	1 st dose of Covaxin	2 nd dose of Covaxin
Fever	96%	60%	76%	75%
Chills	80%	30%	46%	25%
Mild headache	76%	54%	38%	41%
Fatigue	60%	30%	38%	5%
Pain at the injection site	92%	90%	92%	91%
Body pain	60%	69%	76%	66%
Swelling	90%	87%	84%	91%
Dizziness	56%	57%	46%	41%
Nausea & Vomiting	12%	15%	0.70%	1%
Tiredness	60%	48%	53%	66%
Muscle pain	72%	57%	69%	75%
Dysentery	0.60%	0.90%	0.70%	0.80%

Table 2: Participants based on signs and symptoms of Covishield (DAY 1-5)

Signs and symptoms	DAY-1	DAY-2	DAY-3	DAY-4	DAY-5
Fever	95%	72%	66%	12%	0.60%
Chills	72%	38%	24%	12%	0.60%
Mild headache	60%	27%	24%	12%	0.60%
Fatigue	48%	43%	36%	0.30%	0.30%
Pain at the injection site	98%	84%	76%	50.00%	30.00%
Body pain	80%	65%	41%	0.60%	0.60%
Swelling	96%	90%	69%	0.20%	0.20%
Dizziness	53%	36%	34%	0.70%	0.70%
Nausea & Vomiting	7%	0.30%	2%	0.10%	0.10%
Tiredness	54%	39%	27%	0.60%	0.60%
Muscle pain	92%	77%	58%	0.20%	0.20%
Dysentery	6%	0.30%	2%	0.10%	0.10%

Table 3: Participants based on signs and symptoms of Covaxin (DAY 1-5)

Signs and symptoms	DAY-1	DAY-2	DAY-3	DAY-4	DAY-5
Fever	92%	72%	48%	40%	24%
Chills	60%	48%	36%	28%	20%
Mild headache	64%	44%	32%	16%	16%
Fatigue	68%	40%	32%	20%	24%
Pain at the injection site	96%	72%	20%	44%	32%
Body pain	48%	36%	20%	16%	12%
Swelling	80%	72%	64%	60%	44%
Dizziness	40%	36%	28%	20%	20%
Nausea & Vomiting	40%	24%	24%	60%	12%
Tiredness	64%	56%	40%	36%	20%
Muscle pain	72%	60%	40%	32%	20%
Dysentery	24%	16%	16%	12%	0.40%

The results revealed the overall signs and symptoms of 108 pregnant women between the ages of 18 to 40 were involved. In this study, most pregnant women were taking both 1st dose and 2nd dose. The signs and symptoms of the Covishield vaccine are lesser than Covaxin.

The most common symptoms of Covishield and Covaxin are fever (90%), mild headache (83%) and pain at the injection site (96%) (Table 1, 2, and 3).

Discussion

Our study aimed at the clinical signs and symptoms of pregnant women who received the COVID-19 vaccine. The study population consists of 108 individuals. The grading of signs and symptoms was done based on participants. They were categorized into fever, chills, mild headache, fatigue, pain at the injection site, body pain, swelling, dizziness,

nausea and vomiting, tiredness, muscle pain and dysentery.

This study demonstrated the efficacy of the Covishield and Covaxin vaccines for preventing future SAR-S-CoV-2 infection in pregnant women. After taking the vaccination for 12 hours, fever and chills developed, requiring the Tablet Paracetamol to resolve.

On the second day, mild headache, swelling, and pain at the injection site persisted. On the third day, fatigue and tiredness continued. The Government of India started what is widely regarded as the country's greatest immunization campaign, relying heavily on two vaccinations made by Indian vaccine manufacturers. [14]

Our result reveals that the difference between the averages of all groups is not big enough to be statistically significant. In addition, India is committed to training healthcare practitioners across economies in safe and effective vaccine delivery. [14]

Following vaccination with Covishield and Covaxin, most pregnant women had pain and muscle pain at the injection site. COVID-19 vaccine effectiveness is high in pregnant people, similar to the general population. [15] Since COVID-19 vaccine-derived maternal antibodies penetrate the placenta, immunization during pregnancy may protect neonates in the first few months of life, comparable to the well-established advantages of influenza and pertussis vaccination during pregnancy [16].

A recent study conducted in 16 nations worldwide, which analyzed the vaccination preferences of pregnant and non-pregnant women, found that only 52.0% of pregnant women expressed willingness to receive the COVID-19 vaccine, compared to 73.4% of non-pregnant women. The study also revealed no significant difference between pregnant and non-pregnant women's post-vaccination adverse effects. Based on clinical research on vaccine safety in pregnant women, which was stratified by the number of doses received during pregnancy or vaccination trimester (second or third trimester) [17-19]. It has been established that pregnant women have no higher risk of COVID-19 infection than the general population. Yet, it has been shown that pregnant women who get the virus may develop more severe COVID-19 illnesses [20].

Conclusion

Our study shows women who received COVID-19 vaccines (Covishield or Covaxin) during pregnancy. Most pregnant women have received the vaccination, either first or second.

The signs and symptoms of COVID-19 vaccines (Covishield) the first dose has a high effect on fever, pain at the injection site, swelling and muscle, and the second dose has mild effects. Simultaneously, the signs and symptoms of the COVID-19 vaccine (Covaxin), both the first and second doses, have mild signs and symptoms.

Our study includes during 1st, 2nd and 3rd trimesters of pregnant women taking the COVID-19 vaccine. Pregnant women taking the COVID-19 vaccine, Covishield or Covaxin, have no side effects.

This study concludes COVID-19 vaccines (Covishield and Covaxin) can reduce the risk of future SARS-CoV-2 infections and are also used to counsel and reassure pregnant patients facing this decision.

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