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RESEARCH ARTICLE

Covid - 19 vaccine hesitancy and concerns of safety from the perspective of pregnant women in a tertiary care centre of Southern Rajasthan

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ABSTRACT

Background: COVID-19 vaccination seems to be the most efficacious way to deal the SARS-Cov-2 pandemic till date, but even then there are concerns and indecisions among pregnant female towards vaccination. In this study we aim at identifying factors for vaccine hesitancy and safety concerns from the perspective of pregnant population, in Southern Rajasthan. **Methods:** This observational study was conducted on 200 pregnant female, using a self - administered questionnaire, in a tertiary care centre of Southern Rajasthan from November 2021 to January 2022. The questionnaire contained questions about socio-demographic characteristics, vaccination history, perception of risk related to the COVID-19 pandemic, acceptance and attitude towards COVID-19 vaccination. Chi-square test was used to compare the categorical variables. Spearman's rho test was used to find the correlation between COVID 19 vaccine acceptance and socio-demographic variables of the study participants. **Results:** Out of 200 pregnant women, 102(54%) had taken one or two doses of available vaccines while 98 (49%) refused to take the vaccine. Common reasons given by participants for covid -19 vaccine refusal were vaccine hesitancy among family members, misinformation about covid -19 and concern over safety of vaccines due to lack of data in pregnant women. Positive correlation was found in covid -19 vaccine acceptance with education and gestational age (p value <0.05). **Conclusion:** In spite of all government efforts to improve knowledge, attitude and practice regarding covid-19 vaccine, lacuna still exists. It is the need of hour, to address these concerns in vaccine resistant pregnant women and their families.

Keywords: Covid-19 vaccine, hesitancy, acceptance, pregnant women.

The SARS-CoV2 pandemic has posed one of the greatest challenges to humans, leading to the longest era of pandemic extending for more than 2 years. Globally, as of 20 January 2022, there have been approximately 330 million cases of COVID-19, including 55 lakhs deaths, reported to WHO[1]. Pregnant women owing to their immune-compromised state and physiological changes during pregnancy are more likely to have any viral infection including covid 19 and can have severe manifestations [2, 3]. Vaccine seems to be the only light at the end of this tunnel, as none of the drug has been found to be curative till date [4, 5]. Research development for vaccine was started immediately after the disease was identified; with time restrain being a major challenge [6]. A total of 9.5 billion vaccine doses have been administered till 18 January 2022 [1]. In India, three vaccines have received approval for use in pregnant women since July 2021, one of them is an inactivated vaccine (Covaxin by Bharat biotech in collaboration with ICMR and NIV) and other two are based on non-replicating viral vector platform (Covishield by AstraZeneca with Serum institute of India and Sputnik V) [6].

Safety of covid vaccine mainly relies on data from phase 1-3 randomised control trials [7, 8]. Accelerated research and development of these vaccines, along with limited follow up time post vaccination for adverse events has aroused great

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concern of safety, especially in pregnant women [9]. It is an important prerequisite to illustrate the great safety concerns with confirmed clinical evidence for mass vaccination [10]. Vaccine hesitancy, which is defined as delay in acceptance or refusal of available vaccination, is a common public problem in application and promotion of various vaccines[11]. WHO has already reported vaccine hesitancy as potential threat to global health earlier in 2019 [12]. The aim of study was to identify factors in vaccine acceptance, hesitancy and concern of safety from perspective of pregnant population, in southern Rajasthan.

Materials and methods

This observational study was conducted on pregnant women coming to antenatal care at the Obstetrics and gynaecology department in a tertiary care centre of southern Rajasthan, between 1st November 2021 and 1st January 2022. All pregnant women, irrespective of gestational age, coming to antenatal care, who gave consent to participate, were included in our study. Women with anaphylactic or allergic reaction to the previous dose of covid-19 vaccine, anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items , active covid-19 infection in pregnancy or recovered from covid-19 in ≤8 weeks, covid-19 infection treated with anti-covid-19 monoclonal antibodies or convalescent plasma were excluded from the study [13].

The applied protocol was approved by the ethical department of the hospital in accordance with ethical standards on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983 (GU/HREC/2021/1997). Written informed consent was obtained from all participants. Data were collected using a self-administered questionnaire which contained questions about socio-demographic characteristics, vaccination history, perception of risk related to the COVID-19 pandemic, and acceptance and attitude towards COVID-19 vaccination. Questionnaire was developed, evaluated independently and validated by faculty members of the department. For the purpose of subset analysis pregnant women were divided in high risk and low risk. Indications of high risk pregnancy included preterm labour, gestational hypertension, gestational diabetes mellitus, foetal structural anomalies, multifetal pregnancy, epilepsy, and placenta previa [14].

Statistical data was analysed using statistical package for the social sciences version 16 (IBM Corp. Released 2012; IBM SPSS statistics for Windows, Armonk, NY). Quantitative variables were presented as mean and standard deviation. Frequency distribution was done for categorical variables and determined as proportions. The Chi-square test was done to compare the categorical variables. Spearman's rho test was used to find the correlation between covid19 vaccine acceptance and socio-demographic variables of the study participants.

Results

Table 1: Sociodemographic characteristics of the participants (n= 200)

Characteristic	Value [presented as Mean ± SD; Frequency (%)]
Age (in years)	28.05 ± 4.7
Residence	
Urban	125 (62.5)
Rural	75 (37.5)
Gravidity	
1	115 (57.5)
2	63 (31.5)
3	22 (11)
Gestational age (in weeks)	31.8 ± 9.1
High risk pregnancy	
Yes	35 (17.5)
No	165 (82.5)
No. of family members	4.6 ± 2.9
No. of school age children in family	1.5 ± 0.79
No. of family members (> 65 years)	1.6 ± 0.68
Socioeconomic status (modified Kuppuswamy classification)	
Social class I	42 (21)
Social class II	137 (68.5)
Social class III	19 (9.5)
Social class IV	2 (1)
Education status	
None	14 (7)
Primary school	5 (2.5)
Middle school	19 (9.5)
High school	20(10)
Senior secondary	91 (45.5)
Graduate	47 (23.5)
Post graduate	4 (2)
Occupation	
Housewife	170 (85)
Unskilled work	3 (1.5)
Semi-skilled work	8 (4)
Agricultural work	2 (1)
Clerical	7 (3.5)
Technician	10 (5)
Education status of husband	
None	4 (2)
Primary school	18 (9)
Middle school	24 (12)
High school	9(4.5)
Senior secondary	102 (51)
Graduate	30 (15)
Post graduate	13 (6.5)
Occupation	
Unemployed	4 (2)
Unskilled work	29 (14.5)
Semi-skilled work	22 (11)
Agricultural work	68 (34)
Clerical	20 (10)
Technician	46 (23)
Professional	11 (5.5)

A total of 200 pregnant women were included, out of which 102(54%) had taken one or two doses of available vaccines and 98(49%) refused to take the vaccine. Among all participants, 35 (17.5%) were high risk pregnancies and 165(82.5%) were low risk pregnancies. Most of the pregnant women, who participated in this study, were housewives (85%). Most of the pregnant women participated in this study were educated till senior secondary (45.5%) and only 7% were illiterate (table 1).

Table 2: COVID 19 vaccine acceptance rates and comparison of answers between high risk and low risk pregnancies

Questions	Answer	vaccinated n= 102	Do not want to be vaccinated n = 98	P value	High risk pregnancy n = 35	Low risk pregnancy n = 165	P value
Have you taken tetanus toxoid in pregnancy?	Yes	84 (82.4)	88 (89.8)	0.13	24 (68.6)	148 (89.6)	0.01
	No	18 (17.6)	10 (10.2)		11 (31.4)	17 (10.3)	
Do you think you have high chances of getting COVID infection at work or home?	Yes	33 (32.4)	46 (46.9)	0.04	15 (42.9)	64 (38.8)	0.66
	No	69 (67.6)	52 (53.1)		20 (57.1)	101 (61.2)	
Have you been exposed to covid positive person during pregnancy?	Yes	36 (35)	31 (32)	0.58	16 (45.7)	51 (30.9)	0.09
	No	66 (65)	67 (68)		19 (54.3)	114(50.3)	
Did you follow hand sanitization during pandemic?	Yes	59 (58)	54 (55.1)	0.69	19 (54.3)	94 (56.9)	0.78
	No	43 (42)	44 (44.9)		16 (45.7)	71 (43.1)	
Did you follow social distancing during pandemic?	Yes	60 (58.8)	51 (52)	0. 33	20 (ee57.1)	91 (55.1)	0.82
	No	42 (41.2)	47 (48)		15 (42.9)	74 (44.9)	
Did you follow wearing masks during the pandemic?	Yes	59 (58)	52 (53)	0.49	22 (62.9)	89 (53.9)	0.33
	No	43 (42)	46 (47)		13 (37.1)	76 (46.1)	
Are you well informed about COVID vaccine?	Yes	43 (42.2)	38 (39)	0.63	17 (48.6)	64 (38.7)	0.28
	No	59 (57.8)	60 (61)		18 (51.4)	101 (61.3)	
Do you think that COVID vaccine can be harmful for babies?	Yes	21 (20.6)	30 (30.6)	0.11	13 (37.1)	38 (23.1)	0.08
	No	81 (79.4)	68 (69.4)		22 (62.9)	127 (76.9)	
Are you vaccinated (COVID vaccine)	Yes	102 (51)			29 (82.9)	73(44.3)	0.01
	No		98 (49)		6 (17.1)	92 (55.7)	

Table 3: Reasons given by participants for refusing the COVID 19 vaccine (n= 98)

Reasons*	Frequency	Percentage (%)
Afraid of injection	36	36.7
Vaccine will be harmful	24	24.4
COVID 19 is not a dangerous disease	49	50
Vaccine is not effective	35	35.7
Family members have vaccine hesitancy	51	52
Vaccine will cause COVID 19 disease	43	43.9
Lack of data about safety of vaccine in pregnant women	47	47.9

*Mutually not exclusive

Among 98 non vaccinated, 92 (55.7%) were low risk and 6 (17.1%) were high risk (p value= 0.01). In this group, 14(14.3%) had covid during present pregnancy as well (p value 0.01) (table 2).

Common reasons given by participants for refusing covid-19 vaccine which contributed to observed declines in intention to be vaccinated were vaccine hesitancy among family members (52%), misinformation about covid -19 that it is not a dangerous disease (50%), concern over safety of vaccines due to lack of data in pregnant women (47.9%) (table 3).

A positive correlation (r value= 0.31) was noted between education and vaccine acceptance (p value 0.01). A positive correlation was seen between gestation age and vaccine acceptance (p value= 0.02) which means women in the second and third trimester had greater willingness for the vaccine. An inverse correlation (r value - 0.15) was observed between gravidity and vaccine acceptance i.e. primigravidae expressed lesser interest in receiving covid-19 vaccine (p value = 0.03) (table 4).

Table 4: The correlation between COVID 19 vaccine acceptance and sociodemographic features

Variables	r value*	P value*
Age	0.02	0.78
Education	0.31	0.01
Gravidity	-0.15	0.03
Gestational age	0.16	0.02
Number of family members	0.05	0.47
Number of school going children	-0.07	0.31
Number of family members (> 65 years)	0.08	0.26
Per capita income	0.02	0.77

* Correlation analyses with Spearman test

Discussion

The introduction of COVID-19 vaccine is a revolutionary step towards reducing the spread of the pandemic and further reducing the associated disease and deaths [15, 16]. A total of 1.62 billion doses (including 1st, 2nd and precautionary dose) have been administered, since its introduction in January 2021[17]. The Ministry of Health and Family Welfare had issued guidelines for vaccination in pregnant women in

July 2021 [18]. To the best of our knowledge, the study of covid vaccine acceptance and hesitancy in pregnant women in India has not been reported yet.

Among 200 pregnant women, 102 (51%) were vaccinated and 98(49%) refused the vaccine which suggests that despite tremendous progress in vaccine development and administration, the current acceptance level of the COVID-19 vaccine still remains inadequate in pregnant females. Before recommendation of covid vaccine in pregnancy, Goncu Ayhan C et al evaluated attitude of pregnant women towards covid-19 vaccine and only 37% pregnant women agreed to get vaccine when recommended [14].

There was a significant difference in vaccine acceptance between low risk and high risk pregnant women. Out of 35 high risk pregnant women, 29 (82.9%) have taken the vaccine and among 165 low risk pregnant women, 77(44.3%) have taken (p value=0.01). As high risk pregnant women are under strict vigilance with their respective obstetrician and are counselled from time to time regarding their health status, which might have reflected higher acceptance for the vaccine. Similarly, Sinaci S et al [19] has shown high anxiety levels in high risk pregnant women, which could also contribute to these results.

A total of 162 (88%) pregnant women had been vaccinated for tetanus toxoid in pregnancy, which shows awareness regarding vaccine protection against infectious diseases. Among 102 vaccinated pregnant women, 84 (82.4%) have taken tetanus toxoid and in non-vaccinated group, 88(89.8%) out of 98 have taken tetanus toxoid. Tetanus toxoid during pregnancy has been a part of nationwide immunization policy since 1983 [20, 21] which also could be the reason for greater tetanus toxoid acceptance in comparison with covid -19 vaccine.

The most common reason given by the participants for vaccine refusal included vaccine hesitancy among family members (52%). In India, there is a culture of close family and social units, so pregnant women tends to discuss their health concerns with them, instead of healthcare workers, which further increase the lacuna of misconceptions and myths. So it is important to underline the risk and benefits of vaccines to pregnant females as well as their family members.

Second common reason for vaccine refusal was a misconception regarding the disease being not severe (50%). Sixty nine (67.6%) of 102 vaccinated pregnant women, think that they have no risk of transmission at work or home. Similarly, 52 (53.1%) of 98 pregnant women who have not been vaccinated think of no such risk. This attitude could be a major barrier in achieving a covid free world. The government of India has published a communication strategy since 2020, in order to alleviate these misbeliefs but still there is lack of awareness for disease severity. Policies need to be reinforced for better understanding of disease severity and covid appropriate behaviour, in such a way that all sections of population get maximum benefit.

Third reason is being, concern regarding vaccine safety (47.9%) which could be due to limited published data, since no vaccine trial has been done on pregnant women. Other reasons given by participants were that Covid-19 vaccine can cause disease itself (43.9%), fear of injection (36.7%), vaccine is not effective (35.7%) and vaccine is harmful for foetus (24.4%).

In this study, better vaccine acceptance was observed in educated pregnant females. Positive correlation (r value=0.31) between education and vaccine acceptance with significant p value (0.01) was noted. Education brings about people’s knowledge, motivation and competence to access and apply health information in order to make decisions concerning health care and disease prevention [22]. Similarly, significant positive correlation (0.16) was found between gestational age and vaccine acceptance, which means pregnant women in their first trimester were more hesitant to take the vaccine. A systematic review and meta-analysis was conducted by C Luo et al [23] regarding vaccine acceptance among health care workers and found only 51% were willing to get vaccinated due to limited safety data [24]. A significant inverse correlation (r value -0.15) between gravidity and vaccine acceptance was observed, which means multigravida had greater vaccine acceptance.

Conclusion

In spite of all government efforts to improve knowledge, attitude and practice regarding covid -19 vaccine, lacuna still exists. In order to improve this, we recommend addressing concerns of vaccine hesitant and resistant pregnant women. We need to expand and intensify health education efforts by orienting credible influencers from local communities to build their trust and acceptance. To achieve a wide reach for the messages and in order to get a greater degree of engagement from all target audiences, a wide variety of trusted sources and communication channels like social media, community media, mass media etc. should be leveraged in both urban and rural areas.

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