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Original Article

COVID-19 Vaccination Status and Rational Use of Antibiotics in Women: A Prospective Cross-Sectional Study during the COVID-19 Pandemic in India

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ABSTRACT

Background: Diverse beliefs and perceptions on the use of COVID-19 vaccines and drugs have been affecting the acceptance of COVID-19 vaccination and maternal and child health. Further, inappropriate use of antibiotics induces development and spreads antimicrobial resistance. **Materials and Methods:** A cross-sectional study was conducted to evaluate COVID-19 vaccination status and rational use of drugs in women during the recent pandemic. **Results:** The use of medicines in pregnant (94.1%) and non-pregnant (96.0%) is highly prevalent. Prescription of two drugs (24.2%) and three drugs (23.7%) was seen in non-pregnant and pregnant women, respectively. Only 20.4% of pregnant and 43.7% of non-pregnant women received at least one dose of COVID-19 vaccine either Covishield or Covaxin. In addition, 'Watch' antibiotics were prescribed relatively more than 'Access' antibiotics. The most commonly prescribed 'Access' antibiotics were doxycycline and clindamycin in pregnant and non-pregnant women, respectively, whereas azithromycin was the frequently prescribed 'Watch' antibiotic in both groups. **Conclusion:** Polypharmacy was common, the acceptability of COVID-19 vaccination was less and the prescription of 'Watch' antibiotics was more in both pregnant and non-pregnant women. Importantly, there is scope for improvement in promoting vaccination, education on the WHO AWaRe antibiotics and rational prescribing of antibiotics in women of childbearing age.

Keywords: Antibiotics, AWaRe categories, COVID-19 vaccine, Polypharmacy, Pregnancy, Rational drug use.

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INTRODUCTION

Drugs are quintessential for the prevention, diagnosis, treatment and rehabilitation of patients that improve health and promote well-being. The World Health Organization (WHO) estimates that half of all drugs are irrationally prescribed and dispensed and about half of all patients use them inappropriately.[1] Indeed, a large proportion of diseases among women of reproductive age are related to pregnancy-related complications, which are higher in developing nations.[2] Numerous drug utilization studies reported that the prescription rate of filling at least one prescription medicine goes beyond 70% during pregnancy, though this varied among countries.[1,3,4] Inarguably, rational use of medicines at critical time points during pregnancy is essential and impacts maternal health, the development of the fetus and pregnancy outcomes.[3] Despite this, drug exposure in women of childbearing age and pregnant women is common in the world.[1,3]

Vaccination during pregnancy is common to protect maternal, unborn and newborn children from infectious diseases. Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) that causes Coronavirus Disease 2019 (COVID-19) is more severe in pregnant compared with non-pregnant women, with an increased threat of hospital admission, intensive care unit stay and death.[5] The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine encouraged the US Food and Drug Administration (USFDA) to include pregnant and lactating women in the Emergency Use Authorization (EUA) of COVID-19 vaccine owing to the threat of increased disease severity in this population though evidence about vaccine immunogenicity to guide patient decision making, provider-initiated education and counseling points are lacking.[6] This is further hampered by the attitude, worries and beliefs of women surrounding perinatal COVID-19 vaccination.[7]

In addition, the prevalence of antibiotic use is high in women owing to infections encountered during pregnancy and

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childbirth.[3,8] One of the driving forces for the development and spread of Antimicrobial Resistance (AMR) is the irrational use of antibiotics.[9,10] The WHO Access, Watch and Reserve (AWaRe) framework classified antibiotics according to their antibacterial spectrum and potential to develop resistance to promote their rational use. The 'Access' antibiotics are used in the first- and second-line treatment of infections, the 'Watch' category consists of broad-spectrum antibiotics with a higher potential of developing resistance and the 'Reserve' category contains last-resort antibiotics used for multidrug-resistant infections.[10,11] Despite this, the rise of AMR has been worsened by the recent COVID-19 pandemic, which necessitates monitoring of antibiotic prescribing practices.[12] Therefore, the present study systematically evaluated COVID-19 vaccination status and the rational use of drugs and antibiotics in pregnant and non-pregnant women during the COVID-19 pandemic in India.

MATERIALS AND METHODS

Study design and population

An observational, prospective and cross-sectional study was conducted for eight months from September 2021 to April 2022 in pregnant and non-pregnant women attending the Obstetrics and Gynecology Department of Lavanya Hospital, Hanamkonda, Telangana, India.

Sample size and sampling techniques

The final sample size (n) of 422 was calculated ($n=Z^2pq/d^2$) assuming 50% prevalence and considering a 10% non-response rate. A simple random sampling technique was used to collect at least 422 cases.

Eligibility criteria and ethical permission

The confidentiality of the data was ensured throughout the study. Women aged above 18 years, both pregnant and non-pregnant, were included. Women who visited the hospital for a second opinion, those who were not willing to share the information, those on antimycobacterial and antiretroviral therapy, prescriptions with inadequate information and those not written during the study period were excluded. The study received approval from the Institutional Ethics Committee of Care College of Pharmacy (IECHS/CCP/DOPP/09/10). Permission was obtained from women who consented to participate in the study just before or during their first prenatal care visit to collect the data.

Data collection, processing and quality control

Legible and complete prescriptions were collected from the eligible women. The COVID-19 vaccination status was verified using the CoWIN portal (https://www.cowin.gov.in) if any COVID-19 vaccine was received. If vaccinated, information on the type of vaccine received, either Covishield or Covaxin and the number of doses, either one or two, was collected. A certified healthcare provider was asked for clarification if any data was not clear and made a decision of inclusion or exclusion for each patient.

Statistical analysis

The data were analyzed by descriptive statistics using Microsoft Excel and the results are expressed as averages, frequencies and percentages. All the eligible participants were grouped as pregnant and non-pregnant women. 630 valid prescriptions were analyzed for socio-demographic data and chief complaints. Further, the data were assessed for COVID-19 vaccination status and the prescription pattern of medicines. The AWaRe antibiotics prescribed and the AWaRe index metrics were assessed according to the 2021 WHO AWaRe antibiotic framework to evaluate the prescription pattern and rational use of antibiotics.[11,13]

RESULTS

Socio-demographic characteristics of the study population

A total of 630 women, both pregnant and non-pregnant, who met the inclusion criteria were finally selected to collect the data. Of these 630 women, 456 were pregnant and 174 were non-pregnant. The majority of the pregnant were in the age group 21-25 years, whereas the non-pregnant were 26-30 years. Most of the pregnant and non-pregnant women had completed secondary level education (84.2% and 81.6%), while most of them were unemployed (89% and 58%) and hailed from urban areas (72.2% and 73.6%) (Table 1).

Chief complaints, complications and co-morbidities of the study population

The three widely reported complaints in pregnant women were abdomen discomfort (27.8%), vomiting (19.7%) and pain (18.2%), whereas that in non-pregnant women were pain (22.6%), irregular periods (16.3%) and abdomen discomfort (14.8%). About half of the pregnant (52.2%) and non-pregnant women (57.5%) had no complications. The two frequently reported complications in pregnant women were hypothyroidism (18.0%) and hypertension (3.5%) whereas in non-pregnant women were polycystic ovarian disease (22.9%) and hypothyroidism (10.9%). 6.8% of pregnant women had more than one co-morbid condition (Table 2).

General prescription pattern of medications in the study population

The prescription prevalence of drugs and supplements in pregnant women was 94.1% whereas that in non-pregnant women was 96.0% and 97.7%, respectively. In pregnant and non-pregnant women, prescriptions of three (23.6%) and two (24.1%) drugs, respectively, were frequent. Moreover, 9.8% of pregnant and 12.7% of non-pregnant women were prescribed more than five drugs. In pregnant and non-pregnant women, three (28.9%) and four

(31.0%) supplements, respectively, were commonly prescribed. The oral route of medication administration was mostly preferred in both pregnant (93.6%) and non-pregnant (92.3%) women. The widely prescribed dosage form was tablets for both pregnant (69.5%) and non-pregnant (82.9%) women (Table 3).

COVID-19 vaccination status in the study population

Of 456 pregnant women, 363 (79.6%) were not vaccinated. Of 93 (20.4%) vaccinated pregnant women, the majority received either two doses of Covishield (40.9%) or Covaxin (24.7%). Few pregnant women had received a single dose of Covishield (14.0%) or Covaxin (24.7%). In non-pregnant women, 98 out of 174 were not vaccinated (56.3%). Among 76 (43.7%) vaccinated non-pregnant women, most of them received two doses of either Covishield (48.7%) or Covaxin (27.6%). The remaining non-pregnant women received a single dose of either Covishield (13.2%) or Covaxin (10.5%) (Table 4).

Prescription pattern of antibiotics and the AWaRe Index metrics in the study population based on the WHO AWaRe classification

A total of 156 and 73 antibiotic regimens from 155 pregnant (34.0%) and 71 non-pregnant (41.9%) women, respectively, were systematically classified into the AWaRe antibiotic categories. Notably, 47.4% and 47.9% of antibiotic regimens in pregnant and non-pregnant women, respectively, were 'Access' antibiotics. Most importantly, 52.6% and 52.1% of the antibiotic regimens in pregnant and non-pregnant women, respectively, were 'Watch' antibiotics. Among the AWaRe index metrics, the percentage of 'Access' antibiotics prescribed was 47.4% and 47.9% and the Access-to-Watch index was 0.9 and 0.92 in pregnant and non-pregnant women, respectively (Table 5).

Frequently prescribed antibiotics in the study population based on the WHO AWaRe classification.

Among pregnant women, doxycycline (26.3%), clindamycin (14.1%) and nitrofurantoin (7.1%) were most frequently prescribed 'Access' antibiotics whereas azithromycin (39.1%), cefixime (10.9%) and ofloxacin (2.6%) were widely prescribed 'Watch' antibiotics. In non-pregnant women, 'Access' antibiotics, clindamycin (43.8%) and doxycycline (4.1%) were widely prescribed whereas 'Watch' antibiotics, azithromycin (39.7%) and cefixime (12.3%) were commonly prescribed (Table 6).

Table 1: Sociodemographic characteristics of the study population.

Category	Pregnant (456) n (%)	Non-pregnant (174) n (%)
Age (Years)		
18-20	44 (9.6)	10 (5.7)
21-25	291(63.8)	32 (18.4)
26-30	101 (22.2)	70 (40.3)
31-38	20 (4.4)	62 (35.6)
Religion		
Hindu	391 (85.7)	139 (79.9)
Muslim	45 (9.9)	25 (14.4)
Christian	20 (4.4)	10 (5.7)
Educational status		
Primary	1 (0.2)	1 (0.6)
Secondary	384 (84.2)	142 (81.6)
Higher	71 (15.6)	31 (17.8)
Illiterate	0	0
Occupation		
Employed	46 (11.0)	73 (42.0)
Unemployed	410 (89.0)	101 (58.0)
Residency		
Rural	127 (27.8)	46 (26.4)
Urban	329 (72.2)	(73.6)

Table 2: Chief complaints, complications and co-morbidities of the study population.

Clinical characteristics	Pregnant (456) n (%)	Non-pregnant (174) n (%)
Conditions		
Abdomen discomfort	287 (27.8)	57 (14.8)
Vomiting	203 (19.7)	42 (10.9)
Pain	188 (18.2)	87 (22.6)
Irregular periods	-	63 (16.3)
Complications		
Hypothyroidism	82 (18.0)	19 (10.9)
Hypertension	16 (3.5)	1 (0.6)
Anemia	14 (3.1)	1 (0.6)
Amenorrhea	14 (3.1)	2 (1.1)
Polycystic ovarian disease	9 (2.0)	40 (22.9)
Nil	238 (52.2)	100 (57.6)
Co-morbidities	31 (6.8)	
Hypothyroidism with PIH	9 (2.0)	
GDM with hypothyroidism	4 (0.9)	
GDM with PIH	4 (0.9)	

GDM: Gestational diabetes mellitus; PIH: Pregnancy-induced hypertension.

Table 3: General prescription pattern of medications in the study population.

Prescription pattern	Pregnant (456) n (%)	Non-pregnant (174) n (%)
Number of drugs prescribed		
0	27 (5.9)	7 (4.0)
1	103 (22.6)	35 (20.1)
2	97 (21.3)	42 (24.2)
3	108 (23.7)	40 (23.0)
4	76 (16.7)	28 (16.0)
5	45 (9.8)	22 (12.7)
Number of supplements prescribed		
0	27 (5.9)	4 (2.3)
1	127 (27.8)	38 (21.8)
2	130 (28.5)	45 (26)
3	132 (28.9)	23 (13.2)
4	24 (5.3)	54 (31.0)
5	16 (3.6)	10 (5.7)
Dosage forms		
Solid Oral	1574 (93.6)	592 (92.3)
Tablets	1094 (69.5)	491 (82.9)
Liquid (Syrups)	56 (3.5)	31 (5.2)
Parenteral	81 (4.8)	20 (3.1)
Intramuscular	71 (87.6)	19 (95)
Topical	20 (1.2)	21 (3.3)
Ointments	17 (85)	12 (57.1)
Suppositories	6 (0.4)	8 (1.2)

Table 4: COVID-19 vaccination status in the study population.

COVID-19 vaccination status	Pregnant (456) n (%)	Non-pregnant (174) n (%)
Not vaccinated	363 (79.6)	98 (56.3)
Vaccinated	93 (20.4)	76 (43.7)
Type of vaccine		
Covishield one dose	13 (14.0)	10 (13.2)
Covishield two doses	38 (40.9)	37 (48.7)
Covaxin one dose	19 (20.4)	8 (10.5)
Covaxin one doses	23 (24.7)	21 (27.6)

Table 5: Prescription pattern of antibiotics and the AWaRe Index metrics in the study population based on the WHO AWaRe classification.

WHO AWaRe category	Pregnant (156) n (%)	Non-pregnant (73) n (%)
Access	74 (47.4)	35 (47.9)
Watch	82 (52.6)	38 (52.1)
Reserve	0 (0)	0 (0)
Not recommended	0 (0)	0 (0)
AWaRe Index metrics	**Pregnant**	**Non-pregnant**
Access antibiotics index (Priority value > 60%)	47.4%	47.9%
Access-to-Watch index (Priority value > 1.5)	0.90	0.92

DISCUSSION

With increasing awareness, more women are visiting the gynecology specialty; consequently, prescribing drugs used in gynecology has been rising in India.[3] It has been reported that sociodemographic factors and management of complaints and complications affect the quality of life in pregnant women.[14] Additionally, age and gender have shown an influence on drug prescription and treatment costs in primary healthcare settings.[1] In the present study, young women of reproductive age (18-30 years), both pregnant and non-pregnant, visited the hospital, had completed their secondary education and were not employed. These results are similar to those of previous studies.[3,15] This could be due to adulthood because females attain reproductive maturity about 4 years after the physical changes of puberty and due to society's traditions, women get married mostly in this age group. Moreover, one-fourth of the participants were from rural areas indicating that rural patients depend on primary healthcare centers in their locality.

In this study, many women reported chief complaints, such as abdominal discomfort, vomiting, pain and nausea as well as irregular menstrual cycles in non-pregnant women was reported during their Antenatal Care (ANC) checkups. These results are similar to several other studies that also reported the prevalence of more than one co-morbid condition.[15-17] The overall prevalence of prescription of at least one drug or nutritional supplement among women was more than 90%, which is similar to previous studies,[16,17] but different from other studies.[18,19] As observed in this study, prescribing two or three drugs, particularly tablet dosage forms in women was commonly reported in developing and developed countries with high access to healthcare services.[3,4,17] Further, polypharmacy is also reported in the majority of pregnant women.[3,16,20] In addition, multiple supplements, particularly folic acid, calcium and iron, were commonly prescribed to women to fill nutritional gaps and prevent anemia and developmental abnormalities.[21] Indeed, multiple medications may be required to manage a pre-existing medical condition, to be used prophylactically, or to treat obstetric complications individually,

Table 6: Frequently prescribed antibiotics in the study population based on the WHO AWaRe classification.

Antibiotics	Pregnant (156) n (%)	Non-pregnant (73) n (%)	AWaRe Category
Azithromycin (39.1)	61 (39.1)	29 (39.7)	Watch
Doxycycline (26.3)	41 (26.3)	3 (4.1)	Access
Clindamycin (14.1)	22 (14.1)	32 (43.8)	Access
Cefixime (10.9)	17 (10.9)	9 (12.3)	Watch
Nitrofurantoin (7.1)	11 (7.1)	0	Access
Ofloxacin (2.6)	4 (2.6)	0	Watch

thereby making polypharmacy an inevitable consequence of multimorbidity.

Owing to accelerated development and seamless clinical trials, only two EUA COVID-19 vaccines, namely Covishield and Covaxin, were approved in India at the time of the study.[22] However, there is no established evidence that the virus and COVID-19 vaccine are teratogenic or that the use of COVID-19 vaccines is safe for women of reproductive age. There is a risk of infection associated with women as safety during pregnancy directly correlates to the safety of the fetus.[5,8] It is observed that the majority of pregnant and non-pregnant women were not vaccinated. One possible explanation could be that many of them completed their secondary education and were unaware of vaccine safety during pregnancy. A multinational study reported that vaccine hesitancy was associated with the level of education and status of employment.[23] Further, a few women were from rural backgrounds and a lack of resources for the right information might be the reason for false perceptions and beliefs.[7,24] It is also reported that accessing information from non-credible sources, misinformation from social media and believing rumors contributed to vaccine hesitancy.[25] Studies from Canada, a High-Income Country (HIC) and India, a Low- and Middle-Income Country (LMIC), reported that the greatest barriers to vaccine uptake were accelerated development, EUA of vaccines without including pregnant and lactating women in vaccine trials and unforeseen future effects and risks of vaccines on the fetus and in pregnancy.[7,22,24] It is also noticed that some were not vaccinated based on healthcare providers' opinions due to a lack of evidence-based safety and benefits of COVID-19 vaccination in pregnancy, poor access to vaccines and vaccine interference with current treatment. Moreover, there is no evidence suggesting that there is no risk of infection even after being vaccinated. It was recently reported that vaccine-induced immunogenicity was similar in pregnant, lactating and non-pregnant women and testified the transfer of vaccine-generated antibodies to the newborn through the placenta and breast milk.[26] Of particular note, evidence regarding maternal and fetal benefits, risk potential and effects on pregnancy outcomes should be carefully considered for vaccination in pregnant women.[6,26] Therefore, information focused on safety for pregnant women, fetuses and infants and the spread of infection to family members should be well communicated to address vaccine hesitancy, pregnancy outcomes after vaccination for each trimester and long-term effects in children.

Antibiotics are generally prescribed to treat a wide variety of commonly encountered bacterial infections, such as urinary tract and upper respiratory tract infections, apart from uterine infections during pregnancy.[3,27,28] Notably, doxycycline was the widely prescribed 'Access' antibiotic whereas azithromycin was the commonly prescribed 'Watch' antibiotic in pregnant women. Moreover, clindamycin was the frequently prescribed 'Access' antibiotic followed by azithromycin, a 'Watch' antibiotic, in non-pregnant women. Indeed, the prescribing patterns of antibiotics are highly variable between studies, particularly in HIC and LMIC due to variable income and healthcare services.[3,20,27-29] Maternal intra- and extra-uterine infection and associated microbial dysbiosis and inflammation are significant contributors to pregnancy complications that can occur at any stage of pregnancy.[27,29] In particular, the first trimester is significant for the development of the placental barrier between maternal and fetal tissue.[8,29] Critically, antibiotic use is necessary for women's health as maternal intrauterine Infections or Inflammation (Triple I) induce prematurity, low birth weight and preterm births.[29,30] Although not noticed in the present study, antibiotics are also used to treat secondary bacterial infections, such as pharyngitis and pneumonia, when managing COVID-19, a viral infection.[5,12] Among the AWaRe Index metrics, the 'Watch' antibiotics were more frequently prescribed than the 'Access' antibiotics, as against the WHO priority value of more than 60% for the 'Access' category.[10,12,13] It is noteworthy that the 'Access-to-Watch' index was less than the priority limit, which indicates the lower prescription rate of relatively safer 'Access' antibiotics. Notably, the most salient finding in this study was that 'Reserve' antibiotics were not prescribed, which confirms the highly rational use of 'Reserve' antibiotics. The recently released WHO AWaRe antibiotic book guides the empiric treatment of common bacterial infections in children and adults.[11,13] Thus, it is imperative to promote awareness of the AWaRe classification among healthcare practitioners to improve the optimal selection of antibiotics.

CONCLUSION

In the present study, polypharmacy is high and the COVID-19 vaccination rate is lower in women. The prescription of antibiotics is moderately rational as per the WHO AWaRe metrics. Indeed, this study highlights the need for patient expectations in the decision-making process regarding the use and effectiveness of vaccines. Further, there is scope for improving rational prescribing of drugs and antibiotics, reducing polypharmacy and promoting vaccination in women.

LIMITATIONS

First, this is a hospital-based cross-sectional study, interventions are not possible. Second, this research was conducted at one site, the drug utilization pattern cannot be generalized for the entire region. Third, this is the first study to assess vaccination rates in pregnant women in this area, multicenter studies are to be conducted for a better understanding of vaccination rates and their long-term effects on postpartum maternal and child health.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

AMR: Antimicrobial Resistance; **ANC:** Antenatal Care; **AWaRe:** Access, Watch and Reserve; **COVID-19:** Coronavirus Disease 2019; **EUA:** Emergency Use Authorization; **HIC:** High-Income Country; **LMIC:** Low- and Middle-Income Country; **SARS-CoV-2:** Severe Acute Respiratory Syndrome Coronavirus-2; **USFDA:** US Food and Drug Administration; **WHO:** World Health Organization.

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