

Comparison of feto-maternal outcomes during the two ways of COVID-19 in a tertiary care hospital of Karnataka

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Abstract:

Background: Several countries witnessed a two-wave pattern during coronavirus disease-19 (COVID-19) pandemic, with India being no exception. This epidemic had markedly affected pregnant women also. **Objectives:** This study aimed to compare fetomaternal outcomes during the first and second waves of COVID-19 in North India. **Methods:** This retrospective observational comparative study included patients admitted during COVID-19 first wave and second wave in a tertiary care hospital. The inclusion criteria were confirmed RT-PCR or ground glass opacities on HRCT for COVID-19. From the records, the details of demographic characteristics, obstetric history, COVID-19 severity, and investigations were recorded. The maternal outcomes assessed were mode of delivery, ICU admission and mortality. The fetal outcomes assessed were mortality, preterm births, Apgar score, vertical transmission, and other complications. P value <0.05 was considered statistically significant. **Results:** The patients were in the age group of 30s in both COVID-19 first wave and second wave (P=0.333), with an equivalent obstetric history of parity and gestational age. COVID-19 second wave had significantly higher patients with COVID-19 pneumonia (58.33% vs. 3.70%, P<0.0001), significantly lesser patients with hypertension (2.08% vs. 18.52%, P=0.021), significantly more severity category 2 (41.67% vs. 0.00%, P<0.0001), and significantly more deranged LDH (29.17% vs. 3.70%, P=0.007). First and second waves had similar cesarean section rates (66.67% vs. 63.16%). ICU admissions were required more in COVID-19 second wave but statistically no difference was found (26.32% vs. 16.67%, P=0.514). Maternal mortality was seen only in a single case of COVID-19 first wave and two cases of COVID-19 second wave. Compared to COVID-19 first wave, COVID-19 second wave had comparable preterm births, Apgar score, ARDS, vertical transmission, fever, cough, cyanosis, feed intolerance, and tachypnea (P>0.05). **Conclusion:** The second wave of the COVID-19 pandemic caused more severe disease among pregnant as well as peripartum women compared to the first wave. This necessitates our preparation for the third wave to control fetomaternal complications.

Keywords: COVID-19, coronavirus, fetomaternal outcomes, pandemic, pregnancy.

The deadly “severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)” virus continues to damage life around the world since it was declared as a pandemic on March 11, 2020 by WHO. Since then, two waves of covid-19 pandemic have occurred in India and as of October 13, 2021, the second wave of the COVID-19 pandemic in India resulted in more than 34 million cases and nearly 0.45 million deaths ¹.

Earlier, the focus of covid-19 mortality and effects were for the general population but since the pandemic continued for long, there has been increasing interest to know its effects on the feto maternal outcomes and the vertical transmission of covid-19 virus from mother to the baby.

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Systemic impacts of physiologic or immunologic changes during pregnancy may predispose women to complications from respiratory infections resulting in maternal as well as fetal mortality and morbidity^{1,2}. However, the clinical characteristics of pregnant women infected with COVID-19 appear to be similar to that of non-pregnant women, while the majority of expecting moms infected with SARS-CoV-2 have only mild or no symptoms¹. As a result, maternal and perinatal outcomes appear to be good, particularly in asymptomatic or mildly presenting women¹. Despite this, it is reported that in SARS-CoV-2-infected women of reproductive age, pregnancy may be a risk factor for death, pneumonia, and ICU hospitalization¹. Furthermore, the existence of comorbidities, such as advanced age, diabetes, hypertension, and obesity, is a substantial risk factor for a negative outcome in COVID-19 patients¹.

The first wave passed without much uproar of the effects of covid-19 on pregnancy but it is observed that the second wave had a much severe effect on the pregnancy and its outcomes in various countries³⁻¹⁰. Sparse studies have been conducted in India⁸ which compared the fetomaternal outcomes between the two waves of covid-19. This present study thus aimed to compare the first and second wave of the COVID-19 pandemic in India in terms of clinical presentation, comorbidities, pregnancy complications, and outcomes among women with COVID-19.

Methods

A retrospective observational comparative study was done between patients admitted during COVID-19 first wave (July to October 2020) and patients admitted during COVID-19 second wave (April to June 2021) in our tertiary care hospital. Being retrospective in nature informed consent was waived off from the patients. Institutional ethical clearance was obtained before reporting the study. The inclusion criteria were confirmed RT-PCR or ground glass opacities on HRCT for COVID-19 among patients present to the gynecology department with pregnancy. The exclusion criteria was women <18 years of age.

Sample size - The study of Mahajan et al⁸ observed that maternal mortality ratio in 1st wave was 10.2 and in 2nd wave was 83.3 with odds ratio of mortality as 8.96 in 2nd wave. Taking these values as reference, the minimum required sample size with 95% power of study and 5% level of significance is 58 patients. To reduce margin of error, total sample size taken is 75 with at least 25 in each group.

From the records the demographic characteristics like age, obstetric history like gestational age and comorbidities was recorded. The severity of COVID-19 during both the waves among the patients was recorded as per the ICMR guidelines. The details of the investigations done for the patients like CRP, D-dimer, ferritin, LDH, procalcitonin, and HRCT was obtained.

The maternal outcomes assessed were mode of delivery, ICU admission and mortality. The fetal outcomes assessed were mortality, preterm births, Apgar score, vertical transmission, and other complications.

Statistical analysis - The presentation of the categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data with normal distribution were presented as the means \pm SD and the data with non-normal distribution as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results:

1. The comparison of the variables which were quantitative and not normally distributed in nature like gestational age were analyzed using Mann-Whitney Test (for two groups) and independent t test was used for comparison of normally distributed data like age between two groups.
2. The comparison of the variables which were qualitative in nature like obstetric score, PROM, low birth weight, deranged ferritin, IV antibiotics were analyzed using chi-square test. If any cell had an expected value of less than 5 like co-morbidities, severity, mode of delivery, maternal outcome except PROM, perinatal outcome except low birth weight, investigations except deranged ferritin, treatment except IV antibiotics then Fisher's exact test was used.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0. For statistical significance, P-value of less than 0.05 was considered statistically significant.

Results

In our study, 27 cases were admitted during covid first wave and 48 cases were admitted during covid second wave. Among them, 9 cases were lost to follow-up in COVID first wave and 10 cases were lost to follow up in covid second wave. So maternal and fetal outcome could be determined only for 18 cases in covid first wave in 38 cases in covid second wave.

Demographic characteristics	Covid 1st wave (N=27)	Covid 2nd wave (N=48)	Total	P value
Age(years)	27.11 ± 4.5	26.1 ± 4.18	26.47 ± 4.3	0.333*
Obstetric history				
Primi	13 (48.15%)	20 (41.67%)	33 (44%)	0.587 [§]
Multi	14 (51.85%)	28 (58.33%)	42 (56%)	
Gestational age(weeks)	37.29(34.5-38.071)	36(32.75-38)	37(33.429-38)	0.187 [†]

* Independent t test, [†] Mann Whitney test, [§] Chi square test

The patients were in the age group of 30s in both COVID first wave and second wave (P=0.333), with an equivalent obstetric history of primi (48.15% vs. 41.67%) and multi (51.85% vs. 58.33%) (P=0.587), with the mean gestational age of 37 weeks with no significant difference in the two COVID waves (table 1). The comorbidities encountered among the study population were ARDS, HIV, COVID pneumonia, hypertension, hypothyroidism, diabetes mellitus, SLE, Apla, rupture uterus, RHD, HELLP syndrome, and PPH. Compared to COVID first wave, COVID second wave had significantly higher patients with COVID pneumonia (58.33% vs. 3.70%, P<0.0001), while COVID first wave had significantly higher patients with hypertension (18.52% vs. 2.08%, P=0.021) (table 2).

Co-morbidities	Covid 1st wave (N=27)	Covid 2nd wave (N=48)	Total	P value
ARDS	0 (0%)	3 (6.25%)	3 (4%)	0.549 [‡]
Covid pneumonia	1 (3.70%)	28 (58.33%)	29 (38.67%)	<.0001 [‡]
HIV	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]
Hypertension	5 (18.52%)	1 (2.08%)	6 (8%)	0.021 [‡]
Hypothyroidism	2 (7.41%)	0 (0%)	2 (2.67%)	0.126 [‡]
Diabetes mellitus	0 (0%)	2 (4.17%)	2 (2.67%)	0.533 [‡]
SLE	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]
APLA	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]
Ruptura uterus	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]
RHD	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]
HELLP syndrome	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]
PPH	0 (0%)	1 (2.08%)	1 (1.33%)	1 [‡]

[‡] Fisher's exact test

Compared to COVID first wave, COVID second wave had significantly more deranged LDH (29.17% vs. 3.70%, P=0.007), comparable maternal CRP (mg/L) positive (91.67% vs. 85.19%, P=0.448), lesser deranged D dimer (mcg/L) (87.50% vs. 100%, P=0.082), lesser deranged ferritin (mcg/L) (62.50% vs. 70.37%, P=0.492), more deranged procalcitonin (10.42% vs. 0%, P=0.153), more deranged neutrophil/lymphocyte ratio (6.25% vs. 0%, P=0.549), and more HRCT bilateral infiltrates positive (22.92% vs. 14.81%, P=0.551) however statistically no significant difference was reported (table 3).

Table 3: Comparison of investigations between covid 1st and 2nd wave

Investigations	Covid 1st wave (N=27)	Covid 2nd wave (N=48)	Total	P value
Maternal CRP(mg/L)(Positive)	23 (85.19%)	44 (91.67%)	67 (89.33%)	0.448 [‡]
Deranged D dimer (mcg/L)	27 (100%)	42 (87.50%)	69 (92.00%)	0.082 [‡]
Deranged Ferritin (mcg/L)	19 (70.37%)	30 (62.50%)	49 (65.33%)	0.492 [§]
Deranged LDH	1 (3.70%)	14 (29.17%)	15 (20.00%)	0.007 [‡]
Deranged Procalcitonin	0 (0%)	5 (10.42%)	5 (6.67%)	0.153 [‡]
Deranged neutrophil/lymphocyte ratio	0 (0%)	3 (6.25%)	3 (4%)	0.549 [‡]
HRCT bilateral infiltrates (Positive)	4 (14.81%)	11 (22.92%)	15 (20.00%)	0.551 [‡]

[‡] Fisher's exact test, [§] Chi square test

Severity wise, covid second wave had higher cases of category 2 (41.67% vs. 0.00%, $P < 0.0001$) and category 3 severity (12.50% vs. 3.70%, $P = 0.41$) as compared to COVID first wave (figure 1).

Table 4: Comparison of treatment between covid 1st and 2nd wave

Treatment	Covid 1st wave(N=27)	Covid 2nd wave (N=48)	Total	P value
Home isolation	21 (77.78%)	22 (45.83%)	43 (57.33%)	0.007 [§]
O2 supplementation	1 (3.70%)	17 (35.42%)	18 (24%)	0.0002 [‡]
PCT, Anti tussive	26 (96.30%)	39 (81.25%)	65 (86.67%)	0.084 [‡]
IV antibiotics	7 (25.93%)	40 (83.33%)	47 (62.67%)	<.0001 [§]
Steroid-budesonide	1 (3.70%)	10 (20.83%)	11 (14.67%)	0.085 [‡]
Methyl prednisolone	0 (0%)	6 (12.50%)	6 (8%)	0.082 [‡]
Dexamethasone	0 (0%)	9 (18.75%)	9 (12%)	0.022 [‡]
Anticoagulants	1 (3.70%)	34 (70.83%)	35 (46.67%)	<.0001 [‡]
Remdesivir	0 (0%)	9 (18.75%)	9 (12%)	0.022 [‡]
Tofacitinib	0 (0%)	5 (10.42%)	5 (6.67%)	0.153 [‡]
Ivermectin	0 (0%)	0 (0%)	0 (0%)	No p value
Azithromycin	26 (96.30%)	5 (10.42%)	31 (41.33%)	<.0001 [‡]
Oseltamivir	0 (0%)	6 (12.50%)	6 (8%)	0.082 [‡]
Multivitamins	27 (100%)	46 (95.83%)	73 (97.33%)	0.533 [‡]

[‡] Fisher's exact test, [§] Chi square test

The treatment given to the patients were home isolation, O2 supplementation, paracetamol 650 mg (dolo), anti-tussive, IV antibiotics (taxim 1.5gm), steroid-budesonide 800 ug BD, methyl prednisolone (orally 40mg OD for 10 days or 1mg/kg IV), dexamethasone (6mg 12 hourly, 4 doses) anticoagulants (low molecular weight heparin-LMWH 40mg SC), remdesivir (200mg IV day 1 followed by 100mg IV for 4 days), tofacitinib (5mg), azithromycin (500mg 3 tablets), oseltamivir (75mg), and multivitamins as shown in table 4. Compared to COVID first wave, COVID second wave patients were advised less home isolation, while more cases required oxygen supplementation, IV antibiotics, anticoagulants, remdesivir, while in the first wave more patients were put on oral antibiotics like azithromycin.

Table 5: Comparison of maternal outcome between covid 1st and 2nd wave

Maternal outcome	Covid 1st wave (N=18)	Covid 2nd wave (N=38)	Total	P value
Mode of delivery				
Normal delivery	6 (33.33%)	14 (36.84%)	20 (35.71%)	0.798 [§]
LSCS	12 (66.67%)	24 (63.16%)	36 (64.29%)	
ICU admission	3 (16.67%)	10 (26.32%)	13 (23.21%)	0.514 [‡]
Maternal mortality	1 (5.56%)	2 (5.26%)	3 (5.36%)	1 [‡]

[‡] Fisher's exact test, [§] Chi square test

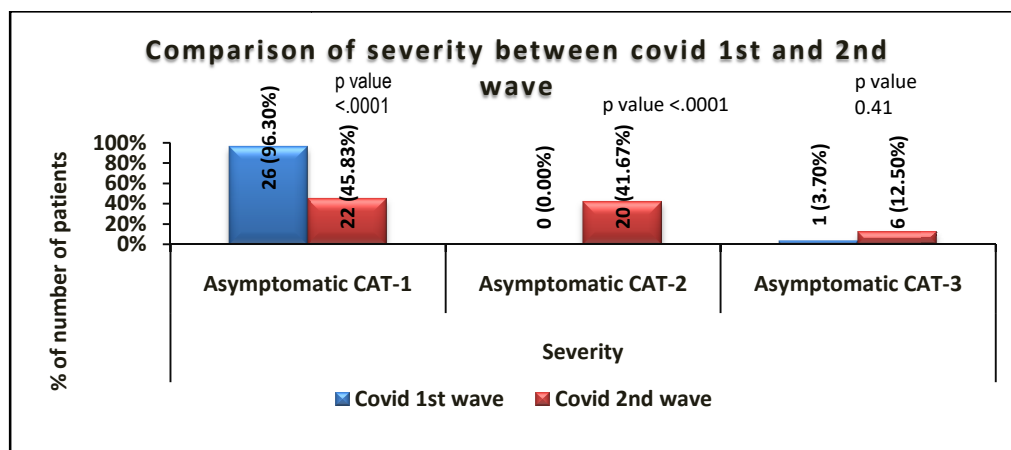


Figure 1: Comparison of severity between covid 1st and 2nd wave

Among the maternal outcomes, the mode of delivery was cesarean in majority of the cases in both first wave and second wave (66.67% vs. 63.16%), while normal delivery was done only in 6 cases of COVID first wave and 14 cases of COVID second wave ($P=0.798$). ICU admissions were required more in COVID second wave than COVID first wave (26.32% vs. 16.67%), however statistically there was no significant difference ($P=0.514$). Maternal mortality was seen only in a single case of COVID first wave and two cases of COVID second wave ($p=1$) as shown in table 5.

Table 6: Comparison of perinatal outcome between covid 1st and 2nd wave				
Perinatal outcome	Covid 1st wave	Covid 2nd wave	Total	P value
Baby-live/death				
IUD	1 (5.56%)	7 (18.42%)	8 (14.29%)	0.414 [‡]
Live	17 (94.44%)	31 (81.58%)	48 (85.71%)	
Term/preterm (remove IUD)				
Preterm	4 (23.53%)	12 (38.71%)	16 (33.33%)	0.350 [‡]
Term	13 (76.47%)	19 (61.29%)	32 (66.67%)	
APGAR score (remove IUD)				
Normal	15 (88.24%)	27 (87.10%)	42 (87.50%)	1 [‡]
Low	2 (11.76%)	4 (12.90%)	6 (12.50%)	
IUGR	3 (17.65%)	5 (16.13%)	8 (16.67%)	1 [‡]
Low birth weight	7 (41.18%)	6 (19.35%)	13 (27.08%)	0.104 [§]
ARDS	0 (0%)	2 (6.45%)	2 (4.17%)	0.533 [‡]
Vertical transmission	0 (0.00%)	4 (12.90%)	4(8.33%)	0.282 [‡]
Respiratory distress	3 (17.65%)	4 (12.90%)	7(14.58%)	0.686 [‡]
Neonatal asphyxia	2 (11.76%)	2 (6.45%)	4(8.33%)	0.607 [‡]
Fever	0 (0.00%)	2 (6.45%)	2(4.17%)	0.533 [‡]
Cough	0 (0.00%)	1 (3.23%)	1(2.08%)	1 [‡]
Cynosis	0 (0.00%)	1 (3.23%)	1(2.08%)	1 [‡]
Feed intolerance	0 (0.00%)	4 (12.90%)	4(8.33%)	0.282 [‡]
Tachypnoea	1 (5.88%)	4 (12.90%)	5(10.42%)	0.643 [‡]
* Fisher's exact test, § Chi square test				

[‡] Fisher's exact test, [§] Chi square test

Compared to COVID first wave, COVID second wave had lower live births (81.58% vs. 94.44%, $p=0.414$), higher preterm (38.71% vs. 23.53%, $P=0.350$), low APGAR score (12.90% vs. 11.76%, $P=1$), lesser IUGR (16.13% vs. 17.65%, $P=1$), lesser low birth weight (19.35% vs. 41.18%, $P=0.104$), more ARDS (6.45% vs. 0%, $P=0.533$), more vertical transmission (12.90% vs. 0.00%, $P=0.282$), lesser respiratory distress (12.90% vs. 17.65%, $P=0.686$), lesser neonatal asphyxia (6.45% vs. 11.76%, $P=0.607$), more fever (6.45% vs. 0.00%, $P=0.533$), more cough (3.23% vs.

0.00%, $P=1$), more cyanosis (3.23% vs. 0.00%, $P=1$), more feed intolerance (12.90% vs. 0.00%, $P=0.282$), and more tachypnea (12.90% vs. 5.88%, $P=0.643$) however statistically no significant difference was reported (table 6).

Discussion

We found more patients to be admitted in second wave which could be possibly due to surge in COVID-19 cases in the second wave, leading to more pregnant women being infected⁹. The second wave patients were affected more by COVID pneumonia; however, there were more hypertensives in first wave. In a similar study from India, Mahajan et al⁸ reported similar occurrence of comorbidities like cardiovascular diseases, gestational diabetes mellitus, and gestational hypertension; however, more second wave patients had anemia (52.3% vs. 41.4%, $P=0.002$). In study conducted at Spain, Cuñarro-López et al¹⁰ found more old age patients to be affected in the first wave than second wave (33.3 vs. 31.7, $P<0.001$), similar to that found in another study,¹¹ had more comorbidities (like chronic hypertension or diabetes), along with obstetric morbidities like preeclampsia.

The present study found second COVID-19 wave to be more severe than first wave, with less favorable maternal outcomes. In both first and second wave, there were more cesarean deliveries (66.67% vs. 63.16%, $P=0.798$) with more ICU admissions in second wave (26.32% vs. 16.67%, $P=0.514$). Severity wise also Covid second wave patients were found to be more in the category 2 and category 3 as compared to covid first wave. This is consistent with the findings by Mahajan et al,⁸ who also found more severity in second wave, as there were more ICU or high-dependency unit admissions (11.6% vs. 2.4%, $P<0.001$), more severe COVID-19 cases (8.5% vs. 1.7%, $P<0.001$) and more maternal deaths (83.3% vs. 10.2%, $P<0.001$). On the contrary, Ifimie S et al¹² reported that second wave of COVID-19 was less severe in Spain. In another study from Spain, Cuñarro-López et al¹⁰ also reported less severity of second wave, which is in contrast to what happened in India. Significantly more caesarean deliveries occurred in the first wave (30.1% vs. 24.1, $P=0.022$), which was explained by the fact that there was no knowledge about the effect of COVID-19 infection on the mother and baby. Also, there was more requirement of oxygen therapy in first wave (7.1% vs. 2.9%, $P=0.001$) and mechanical ventilation (1.8% vs. 0.5%, $P=0.029$). However, no significant difference was found in maternal mortality (42.4% vs. 41.7%, $P=0.617$) or requirement of ICU admission (3.0% vs. 2.5%, $p=0.595$) for mother between the first and second waves.

In the present study, COVID-19 second wave had higher number of preterm births and infants with low Apgar scores and tachypnea; however, the difference failed to reach statistical significance. The infants with ARDS, vertical transmission, fever, cough, cyanosis, and feed intolerance were seen only in second wave group. In accordance with this, Mahajan et al,⁸ who also found higher preterm birth rate (per 1,000 births) (128.7 vs. 93.2, $P=0.09$) and stillbirth rate (per 1,000 births) (34.1 vs. 15.3, $P=0.06$) in second wave; however, they also found no significant difference in findings. The reason for comparable findings was small sample size. On the contrary, Cuñarro-López et al¹⁰ also found no differences in the requirement of ICU admission of the neonate or fetal mortality, however, more preterm birth occurred in first wave (12.4% vs. 8.7%, $P=0.039$). Previous research by Allotey J et al¹³ and Knight M et al¹⁴ reported that pregnancy outcomes are affected by the COVID-19 infection during pregnancy. They found increase in the occurrence of preterm births and caesarean section because of either maternal or fetal compromise, or both. However, the rate of neonatal deaths was not increased. There is still a controversy in the association between COVID-19 and stillbirth. Khalil et al¹⁵ reported increase in number of stillbirths in a London hospital.

Furthermore, as suggested in the study by Raschetti R et al,¹⁶ there is vertical transmission of SARS-CoV-2, which is common route of transmission in COVID-19 infected neonates immediately following birth. Infants were found to be exposed to COVID-19 infection mainly due to postnatal exposure (70.5%); however, some infections were congenital (5.7%). However, this was not quite observant in the present study. Thus there is a need for development of a consensus for the laboratory diagnosis of congenital infection, and mechanism for transmission need to be exactly known.

Pregnancy is reported as a potential risk factor for morbidity–mortality events. Pregnancy has been identified as a possible risk factor for morbidity and mortality. SARS CoV-2 may enter cells through the ACE2 receptor, which is elevated in normal pregnancy because of increased ACE2 expression. Furthermore, due to changes in the immunological and cardiopulmonary systems that occur during pregnancy, pregnant women may be more susceptible to experiencing more severe symptoms following a respiratory virus infection. The differences in the

morbidity events among neonates can be explained by the knowledge related to management of infection and the different behavior of the pandemic.

Although the precise causes of the rise in severity and mortality are still not clear, it is considered that there is a role of a highly virulent variant of concern (B.1.617–10), which is now attributed for the second wave in India. However, because genome sequencing data demonstrating a direct link between B.1.617 and negative outcomes is not available, concrete evidence about the effect of the B.1.617 variant cannot be drawn.^{8,17} Furthermore, our data is restricted to a single center and further studies in India are warranted to determine a definite conclusion of effects of covid-19 on pregnancy.

The increased viral burden in the second wave occurred possible due to widespread disregard to the “COVID Appropriate Behaviors”, i.e. less use of masks, poor compliance with social distancing, more mobility, social gatherings, etc. This was associated with the risk of development of more severe COVID-19 disease during the second wave in India. Besides, factors that resulted in higher risk of adverse fetomaternal outcomes included increased exposure to the virus, lack of diagnostic tests for detecting asymptomatic and patients with mild symptoms, which caused delayed identification and subsequently isolation. In addition, the lack of knowledge about the pathophysiology as well as management of COVID-19, and the advantages of the earlier usage of corticosteroids were also not well known.

Limitations of the study: The present study had some limitations. One limitation was the lack of power in the study due to limited number of pregnant women in each group, which does not provided definite conclusions in terms of the fetomaternal outcomes of COVID-19 disease in pregnant women. Another limitation was that this study was conducted at single center, thus its results cannot be generalized.

Conclusion

To conclude, findings indicates that the second wave of the COVID-19 pandemic caused more severe disease among pregnant as well as peripartum women compared to the first wave. There were more cesarean sections and ICU admissions in COVID-19 second wave with comparable fetal outcomes. More research is needed to determine whether the introduction of novel variants is linked to this trend and whether public health policies should be changed to better safeguard pregnant women as a protective measure for third wave of COVID-19. However, during the ongoing COVID-19 pandemic, present findings imply that giving vaccine to pregnant and nursing women is critical for a better outcome.

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