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Original Article

Effect of pregnancy on COVID-19 severity: A retrospective cohort study in Ethiopia

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Abstract

Background: *There is a scarcity of data on the clinical features, severity of disease and treatment outcomes of COVID-19 during pregnancy in Sub-Saharan Africa. The main purpose of this study was to evaluate illness severity and pregnancy.*

Methods: *Between May 21, 2020 and May 20, 2021, medical records were reviewed as part of this single-center retrospective cohort study. Descriptive statistics, including chi-square tests, two independent sample t-tests, and the Mann-Whitney U test, were used as needed. A Poisson regression was also done to determine the effect of pregnancy on severity independently.*

Results: *There were no differences in the comorbidities between pregnant and non-pregnant groups, except for hypertension, which was more common among non-pregnant women. Pregnant women had a greater number of headaches, myalgia, and anosmia. In the pregnant group, absolute lymphocyte counts below 1000/mm^3, and platelet counts below 150,000/mm^3 were more common. Regarding the severity of the diseases, there were similarities between the groups. There was no difference between the groups in terms of disease severity, in-patient care unit admission, type of treatment given, and mortality. Non-pregnant women, however, have a shorter length of hospital stay. Two (5.0 %) of the 40 patients who gave birth at the study facility had a neonatal outcome of death. In a multivariable regression analysis, there was no association between pregnancy and disease severity.*

Conclusion: *Although some of the symptoms and laboratory factors were more prevalent in pregnant women, pregnancy was not found to affect severity or mortality from COVID-19.*

Keywords*:* COVID-19, Pregnancy, Ethiopia
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Introduction

Pregnancy was reported to be predictive of unfavorable outcomes in severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS) and in 2002 and 2013. Pregnancy-related physiologic and immunologic changes have been linked to a more severe disease course and prognosis in pregnant women. The high risk of maternal death surpasses the possible fetal harm(1, 2). As a result, pregnant women have raised increased concern, as previous experiences have shown that this vulnerable group is prone to serious consequences. Data regarding implications of COVID-19 in pregnancy have been reported mostly in small series of patients from high-income settings (3-5)). Data on the risk of severe illness and in-patient care unit (ICU) admission in pregnant women have been inconsistent, with some studies reporting a higher likelihood for adverse outcomes, and others not. Non-pregnant individuals' test abnormalities were like those reported in pregnant patients(3, 6-11)). COVID-19 is known to induce a variety of effects, including respiratory failure and hypercoagulability, problems that can be exacerbated during pregnancy.

To the best of our knowledge, no research on the outcome and severity of pregnancy with COVID-19 has been conducted in our country, and few data are available from other low-income and middle-income nations. The purpose of this study was to compare the clinical features, treatment, and out-

comes of pregnant and non-pregnant women with COVID-19 and to assess the effect of pregnancy on disease severity among patients treated at Eka Kotebe General Hospital.

Methods

Area and time of study

This study was conducted at Eka Kotebe General Hospital, the first institution in Addis Ababa specifically designed to treat COVID-19. The facility was used as an outpost of the Amanuel General Psychiatric Hospital until April 2020, at which point it was transformed into one of the stand-alone government facilities tasked with caring for COVID-19 patients. Data from May 21, 2020, through May 20, 2021, were used for the study.

Study design

Retrospective cohort analysis of women with COVID -19 disease, both pregnant and not, was done. The clinical course of exposed and non-exposed women who were followed at the Eka Kotebe COVID-19 treatment facility was used to analyze the difference in clinical characteristics and patient outcomes. Two non-exposed patients were selected randomly from consecutive non-pregnant patients for each patient on the exposed arm (pregnant women).

Source/study population

The source population consisted of all pregnant and non-pregnant women admitted to Eka Kotebe Hospital with a laboratory-confirmed diagnosis of COVID-19 infection in the reproductive age group (15–49 years). The source population comprised all women in childbearing age groups admitted to Eka Kotebe Treatment Center with a laboratory-confirmed diagnosis of COVID-19 infection using reverse transcription-polymerase chain reaction at the time of study.

Inclusion and exclusion criteria

Inclusion criteria: Pregnant women between the ages of 15 and 49 who were hospitalized at Eka Kotebe Hospital with a gestational age of at least 20 weeks and a diagnosis of SARS CoV-2 infection that had been confirmed by a laboratory. And non-pregnant women between the ages of 15 and 49 who had a confirmed lab diagnosis of COVID-19 infection and were hospitalized at Eka Kotebe Hospital were included.

Exclusion criteria:

Patients whose primary outcome has not been recorded and patients who have stayed less than 24 hours in the hospital.

Sample size calculation

The sample size was determined for the ratio of two populations using EPI-Info. The study calls for 91 pregnant women and 181 non-pregnant women using the following assumptions: 5% of women will develop a severe form of the disease, a two-sided significance level of 95% confidence level, 80% power, a ratio of non-exposed to exposed of 2, and a three-fold increase in severity among pregnant women (12, 13). The sample size is raised to 100 pregnant women and 200 non-pregnant women by adding 10% for non-response (incomplete data).

Data collection procedures, and quality assurance

A case report format (CRF) that had been modified from the World Health Organization (WHO) was used to collect data about the demographic, obstetric, laboratory, clinical, radiological, and therapeutic characteristics, complications, and clinical outcomes of enrolled patients from their medical records. The data also included the dates of onset, admission, and change in severity, as well as the dates of discharge, death, or transfer. For pregnant patients, obstetric and neonatal outcomes were documented. Phone calls were made using their contact addresses when necessary. Two different researchers carefully examined the data. Disagreements between the reviewers were resolved by discussion or the third researcher. At the Eka Kotebe Hospital, trained physicians gathered data on every factor.

Trained data collectors used the data collection instrument daily to assure consistency and minimize inter- and intra-observation differences in variable measurement. Every day, a supervisor analyzed the gathered data for completeness and consistency. Every day, the designated supervisors and primary investigators supervised and monitored.

Data management and analysis

After data collection, the survey findings were entered into the Epi Info program version 7.2.6 and exported to SPSS version 25.0 for analysis. Frequency and percentages (%) for categorical data were provided, while the median and interquartile range (IQR) for continuous data were reported. The study used the Fisher exact test for predicted frequency less than 5 or the chi-square test for categorical data to compare factors between the pregnant and non-pregnant groups. Depending on the situation, either the Mann-Whitney U test or the two independent sample t-test was used to compare continuous data across the two groups. To determine independent factors associated with the severity of COVID-19, data were analyzed using Poisson regression. In the bivariate analysis, variables with p-value <0.25 were used to identify potential significant factors for the final models. The adjusted relative risk with a 95% confidence interval and a p-value <0.05 was used to determine statistical significance.

Result

The study included 301 COVID-19-positive women of reproductive age, including 103 pregnant and 198 non -pregnant women. There were 193 people (61.4% of the population), whose median age was 30 (interquartile range: 26–37). The overall median age was 30 (IQR: 26-37), and 193 (61.4%) were under the age of 35. Compared to non-pregnant women, pregnant women's median age was lower (30 (26-34) versus 32 (24-40) years, p=0.014), and 22/103 (21.4%) versus 86/198 (43.4%) were ≥35 years (p<0.001). Diabetes mellitus was the most frequent comorbidity, accounting for 18 (6.0 %), followed by hypertension 15 (5.0 %), and cardiovascular disease 12 (4.0 %). Except for hypertension, which was more prevalent in non-pregnant women (0 vs 15, p=0.004), the presence of comorbidities did not vary between the groups. Cough, fever, headache, and dyspnea were the most prevalent clinical symptoms in both groups. Pregnant women had a significantly greater proportion of headache, myalgia, and anosmia than non-pregnant women (P <0.05), with 38.8% vs. 23.2%, 32.0% vs. 19.7%, and 15.5% vs. 6.6%, respectively (Table 1)

Table 1. Comorbidities and symptoms of the study participants, Eka Kotebe General Hospital, 2020-21

Characteristics	All patients	Pregnant (n=103)	Non-pregnant (n=198)	P-value
Age in years (median, IQR)	30(26-37)	30 (26-34)	32 (25-40)	0.014
Age, <35, n(%)	193(61.4)	81 (78.6)	112 (56.6)	0.001
Diabetes, n (%)	18(6.0)	3 (2.9)	15 (7.6)	0.105
Hypertension, n (%)	15 (5.0)	0 (0.0)	15 (7.6)	0.004
Cardiovascular disease, n (%)	12 (4.0)	1 (1.0)	11 (5.6)	0.064
Tuberculosis, n (%)	8 (2.7)	0 (0.0)	8 (4.0)	0.054
Chronic respiratory disease	6 (2.0)	1 (1.0)	5 (2.5)	0.668
Cancer, n (%)	6 (2.0)	0 (0.0)	6 (3.0)	0..098
HIV/AIDS, n (%)	6 (2.0)	1 (1.0)	5 (2.5)	0.668
Cough n (%)	119 (39.5)	46 (44.7)	73 (36.9)	0.19
Fever, n (%)	90 (29.9)	38 (36.9)	52 (26.3)	0.056
Headache, n (%)	86 (28.6)	40 (38.8)	46 (23.2)	0.004
Dyspnea, n (%)	72 (23.9)	24 (23.3)	48 (24.2)	0.856
Myalgia, n (%)	72 (23.9)	33 (32.0)	39 (19.7)	0.017
Anosmia, n (%)	29 (9.6)	16 (15.5)	13 (6.6)	0.012

In comparison to the non-pregnant group, the median length of stay in the hospital was shorter in the pregnant group 12 (8-15) days vs 14 (11-20) days P<0. 001. The percentage of women who required supplemental oxygen, mechanical ventilation, therapeutic anticoagulant, vasopressors, and steroids were similar in both groups. In laboratory findings, absolute lymphocyte count <1000/mm^3 and platelet count <150,000/mm^3 were more frequent in the pregnant vs non-pregnant group (p < 0.05). However, non-pregnant women had a significantly higher proportion of acute kidney injury, with creatinine ≥1.3 (10 (6.6%) vs. 0 (0.0%) p<0.0001) and urea ≥20 (19 (13.4%) Vs 0 (0.0%) P<0.0001) than pregnant women. No significant variations were seen between the groups in terms of ICU admission or illness severity. There was no difference in mortality between the groups; two pregnant women and seven non-pregnant women died. Forty (38.9%) of the 103 pregnant women gave birth in the hospital, and two (5%) of the neonates died (Table 2).

Both neonatal deaths were to mothers who had intrauterine fetal death (IUFD) from the outset. The first mother had a retroviral infection and severe COVID-19. She had a spontaneous vaginal delivery (SVD) but she progressively deteriorated and was admitted to ICU. She passed away from progressive respiratory failure and sepsis. The other lady had IUFD with severe oligohydramnios. She had SVD to a dead neonate and was discharged home alive.

In regression analysis, women's relative risk of developing severe COVID-19 was determined by cough and dyspnea symptoms. Women with cough and dyspnea had a higher relative risk of having severe COVID-19 (RR = 3.18, 95% CI 1.61, 6.27, P-value = 0.001, and RR = 4.14, 95% CI 2.35, 7.30, P-value = 0.000 respectively) (Table 3).

Table 2. Treatment, clinical outcome, and laboratory findings of the participants, Eka Kotebe General Hospital, 2020-21

Characteristics		All patients	Pregnant (n=103)	Non-pregnant (n=198)	P-value
Length of stay (median, IQR)		14(10-18)	12 (8-15)	14 (11-20)	<0.001
Oxygen support, n (%)		75(24.9)	21 (20.4)	54 (27.3)	0.19
Mechanical ventilation, n (%)		5(1.7)	2 (1.9)	3 (1.5)	1
Anticoagulant, n (%)		108 (35.9)	39 (37.9)	69 (34.8)	0.605
Vasopressor use, n (%)		6 (2.0)	4 (3.9)	2 (1.0)	0.186
Steroid, n (%)		87 (28.9)	29 (28.2)	58 (29.3)	0.894
ALC, n (%) (n=264)	<1000	62 (23.5)	33 (33.0)	29 (17.7)	0.004
	≥1000	202 (76.5)	67 (67.0)	135 (82.3)	
AST, n (%) (n=207)	<37	159 (76.8)	57 (80.3)	102 (75.0)	0.393
	≥37	48 (23.2)	14 (29.2)	34 (25.0)	
ALT, n (%) (n=179)	≤63	165 (92.2)	54 (96.4)	111 (90.2)	0.231
	>63	14 (7.8)	2 (3.6)	12 (9.8)	
Platelet, n (%) (n=266)	<150000	227 (85.3)	97 (96.0)	130 (78.9)	<0.001
	≥150000	39 (14.7)	4 (4.0)	35 (21.2)	
Creatinine, n (%) (n=235)	<1.3	225 (95.7)	83 (100.0)	142 (93.4)	0.016
	≥1.3	10 (4.3)	0 (0.0)	10 (6.6)	
Urea, n (%) (n=220)	<20	201 (91.4)	78 (100.0)	123 (86.6)	0.001
	≥20	19 (8.6)	0 (0.0)	19 (13.4)	
Admission, n (%)	ICU	18 (6.0)	6 (5.8)	12 (6.1)	0.935
	Ward	283 (94.0)	97 (94.2)	186 (93.9)	
Severity outcome¸ n (%)	Severe	74 (24.6)	21 (20.4)	53 (26.8)	0.223
	Non-severe	227 (75.4)	82 (79.6)	145 (73.2)	
Outcome, n (%)	Alive	292 (97.0)	101 (98.1)	191 (96.5)	0.723
	Dead	9 (3.0)	2 (1.9)	7 (3.5)	

Discussion

This study showed that the majority of pregnant women with acute COVID-19 experience excellent results in terms of their survival and the survival of their unborn children. A larger proportion of pregnant women had a greater frequency of headache, myalgia, and anosmia compared to non-pregnant women. The prevalence of hypertension was also higher in non-pregnant women. Women of reproductive age who were nonpregnant had longer duration of hospital stay. Pregnant women had lower absolute lymphocyte count, platelets, creatinine, and urea levels. Although there were statistical differences in presenting symptoms and laboratory findings, most of them were not clinically significant. Overall, pregnant women fared similarly to those who were not pregnant. In a multivariable analysis, the presence of cough and dyspnea was found to be significantly associated with severe COVID-19. There was no association between pregnancy and the risk of having severe COVID-19.

Pregnant women were younger than non-pregnant women. This is consistent with the finding in a systematic review and meta-analysis by Khan et al and another study by Ozer et al. (14, 15). Symptoms such as headaches, myalgia, and anosmia were more prevalent in the pregnant group. Similar findings were reported previously as well (14, 16). However, another study revealed that pregnant patients complained more of anosmia and myalgia. This disparity might be explained by the relatively small sample size in our study (408 vs 302) (17, 18).

Hypertension was more common in the non-pregnant group which is supported by Ozer KB et al (15). It could be related to the inclusion of relatively younger pregnant ladies in this study, 78.6% <35 years, which might be translated into less likelihood of pregnancy-related hypertension (16). It might also be due to the existing low threshold to admit pregnant ladies with SARS CoV-2 infection for in-hospital treatment and monitoring. Non-pregnant women are admitted if they have comorbidities that makes them likely to have hypertension compared to their counterpart pregnant ones. The median hospital stay for the pregnant group was significantly shorter

Table 3. Determinants of disease severity among women with COVID-19, Eka Kotebe General Hospital, 2020-21

Characteristics		Unadjusted RR (95% CI)	P-Value	Adjusted RR (95% CI)	P-value
Pregnancy	Pregnant	0.4761 (0.487, 1.189)	0.222	0.692 (0.462, 1.036)	0.074
	Non-pregnant	1		1	
Age	<35	1		1	
	≥35	2.478 (1.666, 3.687)	0.000	1.077 (0.704, 1.648)	0.731
Diabetes	Yes	2.176 (1.308, 3.621)	0.009	0.903 (0.540, 1.510)	0.700
	No	1		1	
Hypertension	Yes	2.64 (1.657, 4.203)	0.001	1.172 (0.665, 2.066)	0.582
	No	1		1	
Cardiovascular disease	Yes	2.919 (1.856, 4.590)	0.000	1.080 (0.653, 1.786)	0.762
	No	1		1	
TB	Yes	1.017 (0.301, 3.435)	0.977		
	No	1			
Chronic respiratory disease	Yes	2.077 (0.910, 4.742)	0.144	0.976 (0.630, 1.512)	0.916
	No	1		1	
Cancer	Yes	1.365 (0.432, 4.310)	0.615		
	No	1			
HIV/AIDS	Yes	0.673 (0.111, 4.075)	0.649		
	No	1			
Cough	Yes	7.901 (4.453, 14.019)	0.000	3.183 (1.614, 6.274)	0.001
	No	1		1	
Fever	Yes	3.251 (2.201, 4.804)	0.000	1.139 (0.818, 1.584)	0.440
	No	1		1	
Headache	Yes	2.125 (1.449, 3.115)	0.000	1.243 (0.887, 1.741)	0.205
	No	1		1	
Dyspnea	Yes	8.587 (5.533, 13.326)	0.000	4.148 (2.357, 7.300)	0.000
	No	1		1	
Myalgia	Yes	3.013 (2.079, 4.366)	0.000	1.204 (0.854, 1.698)	0.288
	No	1		1	
Anosmia	Yes	2.188 (1.412, 3.391)	0.001	1.053 (0.726, 1.527)	0.782
	No	1		1	

than for the non-pregnancy group. Although the days are close (14 vs. 12 days), this has little clinical implication. This result is in line with the related retrospective study done in Wuhan, Hubei, China, USA, and Tehran, Iran (19-21).

There were two pregnant women and seven non-pregnant women who passed away, but there were no appreciable differences in ICU admission, disease severity, or mortality between the two groups. On the other side, a study in the USA, Egypt, and a systematic review discovered that pregnant women had a much higher chance of being admitted to the (ICU), develop severe diseases, and die(12, 14, 18, 22)). This disparity might be attributed to the larger sample size in those studies and the relatively younger age of the pregnant versus non-pregnant women. Lack of difference in mortality of pregnant women versus non-pregnant women was also reported by Bahaa Eldin H et al and Qeadan et al (18, 20).

In our study, pregnant women's lymphocyte counts were lower than those of non-pregnant women. This is inconsistent with previous studies(19, 23) Similarly, lower platelets, creatinine, and urea levels were found among pregnant women which might be due to hemodilution, higher renal flow rate, and pregnancy-related thrombocytopenia, which as reported by Januszewski M et al. (23).

Finally, in multivariable analysis, our study showed that pregnancy has no effect on the severity of COVID-19. This finding is contrary to a retrospective cohort study in Egypt and a systematic review and

meta-analysis by Khan et al., which found that severe illness (ICU admission and need for MV) were significantly higher in pregnant patients (14, 17). Similar to what we found, K. Khoiwal et al. reported that pregnancy has no impact on the severity of COVID-19 (24).

One of the limitations of this study is the retrospective nature of the design associated with difficulty retrieving missed data on some variables like the laboratory parameters. The other is the small sample size in this study which might have affected some outcome variables like ICU admission, disease severity, and mortality. This study included participants who were admitted to the hospital during the first two waves and findings might not be reflected in pregnant ladies who were admitted during the subsequent waves.

Conclusion

Pregnancy did not cause an additional risk of severe disease or mortality. However, pregnant women had frequent headaches, myalgia, and anosmia, a shorter length of hospital stay, and a lower absolute lymphocyte count, platelets, creatinine, and urea levels.
This study was presented on the ATS 2022.

Declaration

Authors have no conflict of interest to declare.

Ethical consideration
The Eka Kotebe Institutional Review Board provided ethical approval (Date August 26, 2021, Ref. No. Eka/150/5/109). Subjects' anonymity was maintained by using their identification numbers throughout the data collection and analysis process.
Conflict of interest
No competing interests to disclose.
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Authors Contributions
AB: inception, proposal draft and organization EKE: data analysis and manuscript write up YG: inception and data collection NM: inception BD: inception and data collection HA: inception and data collection BK: data collection TG: inception and supervision of data collection TS: inception AM: data collection TZ: data collection HYA: proposal draft THG: proposal draft DKH: inception, proposal draft, overall organization of the study and write up.

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