

# Original Research Article

## Secondary Analysis of Maternal Characteristics and Pregnancy Outcomes of COVID-19 Positive Pregnant Women in Sri Lanka using National COVID-19 Positive Pregnant Women Surveillance

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### ABSTRACT

**Aims:** Limited knowledge exists on pregnancy outcome among COVID-19 positive pregnant women despite relatively better understanding on disease severity in pregnancy. Objective of this assessment is to describe the maternal characteristics and factors associated with disease severity and pregnancy outcome of COVID-19 positive pregnant women in Sri Lanka.

**Study design:** Secondary descriptive analysis was conducted using data reported in the National COVID-19 positive pregnant women surveillance, Sri Lanka.

**Place and Duration of Study:** All pregnant women who were tested positive either by RT-PCR or by Rapid Antigen Test for SARS CoV-2 virus and their pregnancy and neonatal outcomes reported from 1st March 2020 to 31st October 2021 in the National surveillance in Sri Lanka, were included in the study.

**Methodology:** Sri Lankan country-level pregnant women characteristics were compared with COVID-19 positive pregnant women using Z test. Associated factors for disease severity and pregnancy outcome was calculated using univariate and multivariate Odds ratios.

**Results:** Details of pregnancy and neonatal outcomes were reported for 2493 COVID-19 positive pregnant women. Less cases of severe COVID-19 infection were observed among pregnant women with no co-morbidities compared with women having at least single co-morbidity (AOR=0.508, CI=0.293-0.879, P=0.04). Pregnant women with mild to moderate infection reported better pregnancy outcome compared to women with severe infection (AOR=7.376, CI=3.557-15.292, P<0.001). In contrast, COVID-19 diagnosis in 1st and 2nd trimesters significantly reduced the good pregnancy outcome compared to pregnant women with diagnosis of COVID-19 in 3rd trimester of the pregnancy (AOR=0.009, CI=0.005-0.015, P<0.001 and AOR=0.113, CI=0.072-0.179, P<0.001 respectively).

**Conclusion:** Our study showed poor pregnancy outcome among severe vs mild to moderate infection and diagnosis in 1st and 2nd trimesters vs 3rd trimester among COVID-19 positive women. Further, increased severity of COVID-19 infection among pregnant

women with co-morbidities vs no comorbidities.

*Keywords: COVID-19, Pregnancy, Maternal Outcomes, Sri Lanka*

## **1. INTRODUCTION (ARIAL, BOLD, 11 FONT, LEFT ALIGNED, CAPS)**

The novel coronavirus SARS-CoV-2 which was epi-centred in Hubei Province of People's Republic of China, later spread globally within a short time. On 30th January 2020, the WHO Emergency Committee declared SARS-CoV-2 as a global health emergency and later 11th March 2020 as a pandemic[1].

Worsening of severity in COVID-19 infection in pregnancy was suspected at early stages of the pandemic due to the anatomical, physiological, and immunological changes which takes place during the pregnancy [2]. In recent past, poor maternal outcomes were reported among pregnant women who got infected with MERS-CoV-2 and SARS-CoV infections in the 2nd and 3rd trimesters of their pregnancy. Therefore, many suspected poorer maternal outcomes in present COVID-19 pandemic as well [3]. Though severity of disease seems to differ in pregnant vs non-pregnant, numerous studies have demonstrated that characteristics of COVID-19 disease in pregnant women and non-pregnant women were similar. Analogous to MERS-CoV-2 and SARS-CoV, severe maternal infection was reported from pregnant women with SARS-CoV-2 in later stages of the pregnancy. COVID-19 positive pregnant women in the third trimester were more likely than their non-pregnant counterparts to require intensive care. However, careful interpretation required for increased ICU care because it could also be due to the lower threshold for intervention in pregnant women rather than more serious disease. Although the absolute risk remains low, compared with pregnant women without COVID-19, more pregnant women with symptomatic COVID-19 requiring admission to hospital experienced negative health outcomes, including death. Outcomes of neonates born to women positive for COVID-19 were generally good, though iatrogenic preterm birth was common[4-6].

Most of the studies which reported outcomes on COVID 19 on pregnant women were conducted in institutional cohorts. Population-level data is critical compared to institutional level data as evidence on decision-making on COVID-19 positive pregnant mothers and their new-born. It is expected that the pandemic could have influenced health-seeking behaviour and access to maternity care, leading to potential ascertainment bias if institutional level data are relied on. The possibility of under-representation of asymptomatic and mildly symptomatic patients in the assessment of pregnancy and perinatal outcomes could be a concern in institution level data analysis which could introduce bias as mentioned above [7]. Inclusion of both pregnancy and neonatal data (rather than just one or the other) is critical to assess any disparate effect of the pandemic on competing events (e.g., neonatal death)[7].

Lack of scientific information on maternal COVID-19 disease severity and pregnancy outcome following COVID-19 infection in Sri Lanka is a concern. Therefore, this study was intended to answer 3 main concerns related to COVID-19 infection among pregnant women in Sri Lanka. Number one: Is there any significant difference in socio-demographic, maternal and pregnancy related characteristics of COVID-19 positive women compared to the general population of pregnant women in Sri Lanka? Number two: What are the factors significantly associated with the severity of COVID-19 infection among the pregnant women in Sri Lanka? Number three: What are the factors significantly associated with the pregnancy outcome of COVID-19 pregnant women in Sri Lanka?

Objective of this assessment is to describe the maternal characteristics and factors associated with the disease severity and pregnancy outcome of COVID-19 positive pregnant women in Sri Lanka using data from national COVID-19 positive pregnant women surveillance.

## **2. METHODOLOGY**

National population based observational cohort study was conducted using secondary data from National COVID-19 positive pregnant women surveillance in Sri Lanka.

### **2.1 National COVID-19 positive pregnant women surveillance**

National surveillance was initiated in the year 2021 by the Family Health Bureau of Ministry of Health to monitor the COVID-19 infected pregnant mothers of Sri Lanka. Information on COVID-19 positive pregnant women were reported by the field Public Health Midwife (PHM) using a data extraction form. Close to 94 percent of the pregnant women (93.4%) were registered with field PHMs in Sri Lanka and close to 95% of them received routine domiciliary care by field PHMs during the pregnancy [8]. Later they were transferred to the electronic Reproductive Health Management Information System (eRHMS). eRHMS is the current electronic data management system of Reproductive, Maternal, New-born, Child, Adolescent, and Youth Health (RMNCAYH) programme in Sri Lanka which is built on the DHIS2 platform. The database included data of pregnant women who were tested positive either by RT-PCR or by Rapid Antigen Test for SARS-CoV-2 virus.

Data extraction form consisted of four sections. First section contained basic socio-demographic data, pregnancy related information and co-morbidities of all COVID-19 positive pregnant women. Section two consisted of follow up information at the time of discharge and explored the severity of COVID-19 infection in women during the hospital stay and the status of pregnancy at the time of discharge. PHM followed up the mother and completed the third section of the form at one month postpartum. It contained information on both maternal and neonatal outcome. Fourth section consisted of postnatal assessment of the infant at 6 months. The findings of the 6 months assessment will be disseminated in future.

### **2.2 Study methods**

Data of all COVID-19 positive pregnant women who meets the eligibility criteria (completed sections number one, two and three by 31st of October 2021 in the surveillance) was extracted. The information was extracted to a excel sheet from the database of National COVID-19 positive pregnant women surveillance at Family health Bureau from 1st March 2020 to 31st October 2021.

The data base of National Family Health Programme (eRHMS) at Family Health Bureau receives routine information on pregnancy women in Sri Lanka and their delivery outcomes at the end of each month from over 6000 PHMs in the country. Socio-demographic, pregnancy and its outcome related data of COVID-19 positive pregnant women were compared with the above-mentioned national pregnant women data available at eRHMS of Family Health Bureau. Reviewed national data was only available up-to the 2nd quarter of 2021. Thus, details of the pregnant women reported from 1st of March 2020 until 31st July 2021 was included from the national pregnant women cohort of eRHMS.

Data was initially exported to MS Excel software; they were coded and analysed using Statistical Package for Social Sciences (SPSS) 22 version. Rates were presented as

proportions and their 95% confidence intervals (CI). Statistical significance was calculated based on the Z score and a p value of less than 0.05 was considered as statistically significant. All variables were used to perform the multivariate analysis using logistic regression (enter method) irrespective of their significance in bivariate analysis to identify adjusted ORs and their Confidence Intervals. Ethical clearance was obtained from Ethics Review Committee of Faculty of Medical Sciences, University of Sri Jayawardenepura (COVID 11/21).

### 3. RESULTS AND DISCUSSION

By 31st October 2021, 157 cases were entered in national surveillance in year 2020 with 9905 more cases were reported in 2021. Majority of the cases were corresponding to 4th peak of the pandemic and their delivery outcomes has not been reported at the time of the analysis. Therefore, only in 2493 COVID-19 positive pregnant women, details of pregnancy and neonatal outcomes were reported by 31st October 2021.

Table1: one compares the selected socio-demographic, pregnancy and COVID-19 related data of COVID-19 positive pregnant women with available national pregnant women data from RHMIS. Pregnant women aged 35 years or more (18.2% vs 13.6%,  $z=6.6768$ ,  $p<0.001$ ), pre-pregnancy overweight (35.5% vs 32.0%,  $z=3.674$ ,  $p<0.001$ ) and pre-existing DM (2.5% vs 1.6%,  $z=3.564$ ,  $p<0.001$ ) diagnosed with COVID-19 significantly more than the national pregnant women cohort. No significant difference of neonatal deaths was observed between COVID-19 positive pregnant women vs national pregnant women cohort (0.8% vs 0.57%,  $z=1.507$ ,  $p=0.13$ ).

**Table.1 Selected socio-demographic, pregnancy related variables of COVID-19 positive pregnant women**

		COVID-19 positive pregnant women N (%)	National data of pregnant women N (%)*	Significance
Socio-demographic variables				
Age	35 years or less	2040 (81.8%)	393,761(86.4%)	Z=6.6768, p<0.001
	More than 35 years	453(18.2%)	61,902 (13.6%)	
Ethnicity	Sinhala	1548 (62.1%)	N/A	
	Tamil	482 (19.3%)	N/A	
	Muslim	462(18.5%)	N/A	
	Burgher	1 (0.0%)	N/A	
Sector	Rural	1848(74.1%)	N/A	
	Urban	550(22.1%)	N/A	
	Estate	95(3.8%)	N/A	
Family Income	Less than Rs 16,000/=	602(24.1%)	N/A	
	Rs 16,000/= to Rs 45,000/=	1390(55.8%)	N/A	
	Rs 45,001/= to Rs 65,000/=	344(13.8%)	N/A	
	More than Rs 65,000/=	157(6.3%)	N/A	

Employment	Employer	24(1%)	N/A	
	Self-employed	44(1.8%)	N/A	
	Public sector employee	317(12.7%)	N/A	
	Private sector employee	244(9.8%)	N/A	
	Unpaid family worker	42(1.7%)	N/A	
	Unemployed	1808(72.5%)	N/A	
	Other	14(0.6%)	N/A	
Obstetric variables				
Gravida	One	531(21.3%)	142,859(31.4%)	Z=10.8412, P<0.001
	Two or more	1,962(78.7%)	312,816(68.6%)	
Parity	Nulliparous	600(24.1%)	N/A	
	Multiparous	1893(75.9%)	N/A	
Living Children	Zero	899(36.1%)	N/A	
	One or more	1594(63.9%)	N/A	
Comorbidities	GDM- No	2294(92%)	368,278(92.8%)	Z=1.54
	Yes	199(8%)	28,606(7.2%)	P=0.12
	Pre-existing DM- No	2431(97.5%)	390,635(98.4%)	Z=3.564
	Yes	62(2.5%)	6,249(1.6%)	P<0.001
	PIH- No	2418(97.0%)	382,393(96.3%)	Z=-1.847
	Yes	75(3.0%)	14,491(3.7%)	P=0.06
	Chronic HT- No	2475(99.3%)	395,210(99.6%)	Z=2.36
	Yes	18(0.7%)	1674(0.4%)	P=0.018
	Heart Disease- No	2481(99.5%)	394,892(99.5%)	Z=-0.145
	Yes	12(0.5%)	1992(0.5%)	P=0.89
	Chronic Respiratory Disease	2451(98.3%)	NA	
	No			
	Yes	42(1.7%)	NA	
	Maternal Anaemia	2218(89.0%)	285,639(78.1%)	Z=-18.86
	Yes	275(11.0%)	111,245(28.0%)	P<0.001
	No comorbidities (excluding Anaemia)	2061(82.7%)	N/A	
Single comorbidity	387(15.5%)	N/A		
Multiple comorbidities	45(1.8%)	N/A		
Pre-pregnancy BMI**	Less than 18.5 kg/m <sup>2</sup>	231(9.5%)	52,593(14.3%)	Z=3.674
	18.5kg/m <sup>2</sup> - 25kg/m <sup>2</sup>	1337(55.0%)	196,828(53.7%)	P<0.001
	More than 25kg/m <sup>2</sup>	862(35.5%)	117,291(32.0%)	
COVID-19 variables				
POA at diagnosis	First Trimester	114(4.6%)	-	
	Second Trimester	439(17.6%)	-	
	Third Trimester	1940(77.8%)	-	
Covid-19 vaccination Status***	Not vaccinated	1722(69.1%)	71,274(32.9%)	Z=65.83
	Single dose given	518(20.8%)	44,711(20.6%)	P<0.001
	Two doses given	253(10.1%)	100,632(46.5%)	
Severity of COVID-19	Asymptomatic/ Symptomatic-in ward	2421(97.1%)	-	

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**Table.2 Odds Ratios for associated factors on severity of the infection among COVID-19 positive women: Univariate and Multivariate analysis**

	ICU/ Ventilated/ ECMO	48(1.9%)	-	
	Death	42(1.0%)	-	
Pregnancy outcome****	Live neonate at 28 days	2320(93.1%)	402,237 (87.7%)	Z=1.507
	Neonatal Death	21(0.8%)	2617 (0.57%)	P=0.13
	Stillbirth/ miscarriage	152(6.1%)	53,588 (11.7%)	

\*Period-1<sup>st</sup> of March 2020 to 31<sup>st</sup> July 2021

\*\*Less than 18.5 kg/m<sup>2</sup> and 18.5kg/m<sup>2</sup>- 25kg/m<sup>2</sup> were combined for the significance testing.

\*\*\*Single dose and two doses combined for the significance testing. National data of pregnant women COVID-19 vaccination was available only from 1<sup>st</sup> June 2021.

\*\*\*\*Stillbirth/ miscarriages were excluded from the significance analysis because national data include miscarriages from 1<sup>st</sup> trimester to 3<sup>rd</sup> trimester whereas majority of the COVID-19 positive pregnant women was diagnosed in 3<sup>rd</sup> trimester. Therefore, majority of reported miscarriages were 3<sup>rd</sup> trimester miscarriages.

Table 2 describes the unadjusted and adjusted odds ratios of associated factors on severity of infection among COVID-19 positive women. Absence of comorbidities (excluding maternal anaemia) decreases the risk the of severe COVID-19 infection compared to pregnant women with comorbidities by 49.2% (AOR=0.508, CI=0.293-0.879, P=0.016). Diagnosis of COVID-19 infection in 2nd trimester of pregnancy increases the likelihood of severe infection by 79.7% compared to the COVID-19 diagnosis in 3rd trimester (AOR=1.797, CI=1.027-3.147, P=0.040). Despite unadjusted OR displayed reduced risk of severe infection among pregnant women aged 35 years or less compared to older than 35 years, the observed

reduced risk was not significant in multivariate analysis (unadjusted OR=0.527, CI=0.314-0.886, P=0.016 vs AOR=0.666, CI=0.368-1.204, P=0.178).

Table 3 describes the unadjusted and adjusted odds ratios of associated factors on delivery outcome of COVID-19 positive women. Mild to moderate infection increases the good pregnancy outcome by 637.6% compared to severe infection among the COVID-19 positive pregnant women (AOR=7.376, CI=3.557-15.292, P<0.001). Similarly, Sinhala ethnicity increases the good pregnancy outcome by 138.5% compared to Tamil ethnicity (AOR=2.385, CI=1.394-4.081, P=0.002).

In contrast, COVID-19 diagnosis in 1st and 2nd trimesters reduces the good pregnancy outcome compared to pregnant women with diagnosis of COVID-19 in 3rd trimester of the pregnancy by 99.1% and 88.7% respectively (AOR=0.009, CI=0.005-0.015, P<0.001 and AOR=0.113, CI=0.072-0.179, P<0.001). Similarly, pregnant women having no living children decreases the good pregnancy outcomes by 55.8% compared with women with one or more living children (AOR=0.442, CI=0.243-0.804, P=0.008).

<b>Dependent:</b> <b>Mild to moderate- 0</b> (asymptomatic/ symptomatic with home/ ICC/ ward care only) <sup>a</sup> <b>Severe-1</b> (ICU/ Ventilation/ ECMO/Death)		<b>Severe</b>	<b>Mild to Moderate</b>	<b>OR (univariate)</b>	<b>OR (multivariate)</b>
Age	>35 years	21 (4.6)	432 (95.4)		
	35 years or less	51 (2.5)	1989 (97.5)	0.527 (0.314-0.886, p=0.016)	0.666 (0.368-1.204, p=0.178)
Sector	Urban	22 (4.0)	528 (96.0)		
	Rural	49 (2.7)	1799 (97.3)	0.255 (0.034-1.917, p=0.184)	0.696 (0.401-1.209, p=0.198)
	Estate	1 (1.1)	94 (98.9)	0.654 (0.392-1.091, p=0.104)	0.405 (0.049-3.339, p=0.401)
Ethnicity	Tamil	10 (2.1)	472 (97.9)		
	Muslim	10 (2.2)	452 (97.8)	1.596 (0.978-2.606, p=0.062)	0.926 (0.339-2.529, p=0.881)
	Sinhala*	52 (3.4)	1497 (96.6)	1.492 (1.033-2.155, p=0.033)	1.538 (0.682-3.471, p=0.300)
Family Income (monthly)	> Rs 45,000/=	21 (4.2)	480 (95.8)		
	Rs 16,000/= to 45,000/=	39 (2.8)	1351 (97.2)	0.660 (0.384-1.133, p=0.132)	0.764 (0.416-1.403, p=0.385)
	< Rs 16,000/=	12 (2.0)	590 (98.0)	0.465 (0.226-0.955, p=0.037)	0.682 (0.299-1.556, p=0.363)
Employment Status	Unemployed	53 (2.9)	1769 (97.1)		
	Employed	19 (2.8)	652 (97.2)	0.973 (0.572-1.655, p=0.919)	0.997 (0.629-1.581, p=0.991)
Pre-pregnancy BMI	(18.5-25) kg/m <sup>2</sup>	30 (2.2)	1307 (97.8)		
	<18.5kg/m <sup>2</sup>	3 (1.3)	228 (98.7)	0.573 (0.174-1.894, p=0.361)	0.691 (0.207-2.309, p=0.548)
	>25kg/m <sup>2</sup>	33 (3.8)	829 (96.2)	1.734 (1.050-2.865, p=0.393)	1.581 (0.936-2.672, p=0.087)
Gravida	Two or more	62 (3.2)	1900 (96.8)		
	One	10 (1.9)	521 (98.1)	0.588 (0.300-1.155, p=0.123)	0.504 (0.131-1.936, p=0.318)
Parity	One or more	112 (5.9)	1781 (94.1)		
	Zero	13 (2.2)	587 (97.8)	0.688 (0.375-1.264, p=0.228)	1.023 (0.266-3.943, p=0.973)
Living children	One or more	47 (2.9)	1547 (97.1)		
	None	25 (2.8)	874 (97.2)	0.942 (0.576-1.540, p=0.810)	1.628 (0.785-3.378, p=0.191)
Comorbidities (excluding Anaemia)	One or more	25 (5.8)	407 (94.2)		
	None	47 (2.3)	2014 (97.7)	0.380 (0.231-0.624, p<0.001)	0.508 (0.293-0.879, p=0.016)
	Third	51 (2.6)	1889 (97.4)		
POA at COVID-19 diagnosis	Second	20 (4.6)	419 (95.4)	1.768 (1.043-2.997, p=0.034)	1.797 (1.027-3.147, p=0.040)
	First	1 (0.9)	113 (99.1)	0.328 (0.045-2.394, p=0.272)	0.359 (0.049-2.653, p=0.315)

\*Includes a single participant of Burger ethnicity (mother tongue was Sinhala)

<sup>a</sup>ICC- Intermediate Care Center

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**Table.3 Odds Ratios for associated factors on delivery outcome of COVID-19 positive women: Univariate and Multivariate analysis**

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UNDER PEER REVIEW

<b>Dependent:</b> <b>Good pregnancy outcome- 1</b> (Live Neonate at 28 days)		<b>Poor</b>	<b>Good</b>	<b>OR (univariate)</b>	<b>OR (multivariate)</b>
<b>Poor pregnancy outcome- 0</b> (Neonatal death/ Still Birth/ miscarriage)					
Age	>35 years	40 (8.8)	413 (91.2)		
	35 years or less	133 (6.5)	1097 (93.5)	1.389 (0.960-2.953, p=0.081)	1.223 (0.733-2.039, p=0.441)
Sector	Urban	40 (7.3)	510 (92.7)		
	Rural	125 (6.8)	1723 (93.2)	1.081 (0.747-1.564, p=0.679)	0.967 (0.596-1.570, p=0.893)
	Estate	8 (8.4)	87 (91.6)	0.853 (0.386-1.884, p=0.694)	0.544 (0.194-1.526, p=0.247)
Ethnicity	Tamil	45 (9.3)	437 (90.7)		
	Muslim	28 (6.1)	434 (93.9)	1.596 (0.978-2.606, p=0.062)	1.555 (0.800-3.022, p=0.193)
	Sinhala*	100 (6.5)	1449 (93.5)	1.492 (1.033-2.155, p=0.033)	2.385 (1.394-4.081, p=0.002)
Family Income (monthly)	> Rs 45,000/=	37 (7.4)	464 (92.6)		
	Rs 16,000/= to 45,000/=	93 (6.7)	1297 (93.3)	1.112 (0.749-1.651, p=0.062)	0.864 (0.510-1.463, p=0.586)
	< Rs 16,000/=	43 (7.1)	559 (92.9)	1.037 (0.657-1.636, p=0.877)	0.820 (0.420-1.600, p=0.561)
Employment Status	Unemployed	120 (6.6)	1702 (93.4)		
	Employed	53 (7.9)	618 (92.1)	0.822 (0.587-1.151, p=0.253)	1.080 (0.685-1.701, p=0.741)
Pre-pregnancy BMI	(18.5-25) kg/m <sup>2</sup>	55 (6.4)	807 (93.6)		
	<18.5kg/m <sup>2</sup>	10 (4.3)	1239 (92.7)	1.748 (0.898-3.403, p=0.100)	1.911 (0.865-4.221, p=0.109)
	>25kg/m <sup>2</sup>	98 (7.3)	9 (4.5)	1.161 (0.824-1.634, p=0.393)	1.108 (0.722-1.700, p=0.640)
Gravida	Two or more	48 (9.0)	483 (91.0)		
	One	125 (6.4)	1837 (93.6)	0.685 (0.484-0.969, p=0.033)	2.124 (0.867-5.202, p=0.100)
Parity	One or more	112 (5.9)	1781 (94.1)		
	Zero	61 (10.2)	539 (89.8)	0.556 (0.401- 0.770, p<0.001)	0.544 (0.208-1.423, p=0.215)
Living children	One or more	86 (5.4)	1508 (94.6)		
	None	87 (9.7)	812 (90.3)	0.532 (0.390- 0.726, p<0.001)	0.442 (0.243-0.804, p=0.008)
Comorbidities (excluding Anaemia)	One or more	36 (8.3)	396 (91.7)		
	None	137 (6.6)	1924 (93.4)	1.277 (0.871- 1.872, p=0.211)	1.606 (0.979-2.635, p=0.061)
	Third	39 (2.0)	1901 (98.0)		
POA at COVID-19 diagnosis	Second	60 (13.7)	379 (86.3)	0.130 (0.085- 0.197, p<0.001)	0.113 (0.072-0.179, p<0.001)
	First	74 (64.9)	40 (35.1)	0.011 (0.007- 0.018, p<0.001)	0.009 (0.005-0.015, p<0.001)
Severity of COVID-19	Severe	18 (25.0)	54 (75.0)		
	Mild to Moderate	155 (6.4)	2266 (93.6)	4.873 (2.790- 8.512, p<0.001)	7.376 (3.557-15.292, p<0.001)

\*Includes a single participant of Burger ethnicity (mother tongue was Sinhala)

Our study included information of 2493 COVID-19 positive pregnant women which is one of the largest samples of COVID-19 positive pregnant women cohorts studied in South-east Asia. More pregnant women aged 35 years or above and with pre-existing DM were diagnosed with COVID-19 compared to the national pregnant women cohort. No significant difference in neonatal deaths was observed between COVID-19 positive pregnant women compared to national pregnant women cohort. Absence of comorbidities (excluding maternal anaemia) reduced the risk of severe COVID-19 infection compared to pregnant women with comorbidities. COVID-19 diagnosis in 1st and 2nd trimesters reduced the good pregnancy outcome compared to pregnant women with diagnosis of COVID-19 in 3rd trimester of the pregnancy.

We observed low percentage of miscarriages and stillbirths among the COVID-19 positive pregnant women compared to the national cohort (6.1% vs 11.7%). This reduction could be explained by the time of diagnosis of COVID-19 among the pregnant women. Majority of the COVID-19 positive women was diagnosed in the 3rd trimester (77.8%). Therefore, majority of the 1st and 2nd trimester miscarriages were excluded among the COVID-19 positive pregnant women compared to the national cohort which could have resulted in less proportion of miscarriages and stillbirths among COVID-19 positive women.

Number of COVID-19 infections among pregnant women in Sri Lanka increased significantly in the 2nd and 3rd quarters of 2021. Only 157 cases of COVID-19 was reported in National COVID-19 Positive Pregnant Women Surveillance in the year 2020 whereas 9284 cases have been reported in the year 2021 up to 31st of October with majority of them from the months of August, September and October (6,662) [9]. Therefore, deliveries of these women might not have occurred by 31st of October. There could be cases where the COVID-19 positive pregnant mothers were not reported entirely or the pregnancy and neonatal outcome data in National Surveillance. Close to 95% of pregnant women received routine home-based by PHMs in 2019. Therefore, the number of missed cases could be few though estimation of the absolute number was not possible in the National COVID-19 Positive Pregnant Women Surveillance [8].

Advancing age increases the risk of COVID-19 infection among the pregnant women [10]. Our study cohort included higher proportion of pregnant women aged 35 years or above were diagnosed with COVID-19 compared to the national cohort of pregnant women (18.2% vs 13.6%,  $p < 0.001$ ). Pre-existing DM, pre-existing HT and obesity was identified in higher proportions among COVID-19 positive pregnant women and COVID-19 positivity reported less in primiparity in the national retrospective cohort study in France [10]. Similarly, increased prevalence of pre-existing DM and HT among the COVID-19 positive pregnant women was observed compared to the national pregnant women cohort. Further, increased number of women with pre-pregnancy overweight was reported among the COVID-19 positive pregnant women compared to the national cohort whereas among the primigravida, the COVID-19 positivity rates were lower than the national cohort.

There was no significant difference in neonatal death rates in COVID-19 positive pregnant women compared to national data. Similar findings were reported in other studies with many studies reporting zero neonatal deaths among the COVID-19 positive pregnant women mainly due to the low number of women included. In literature, reported infant mortality rate was less than 3% in systematic reviews and meta-analyses which is comparable to our study finding of 0.8% [11-13].

Indian study by Priyadarshani and others in 2021 revealed that poor pregnancy outcome was associated with the duration of the pregnancy. Increased incidence of poor pregnancy outcome in 1st trimester was observed compared to 2nd and 3rd trimesters. However, the same study revealed no association on presence of comorbidities with the poor pregnancy outcome among 381 COVID-19 positive pregnant women [14]. Though, our study suggested that presence of comorbidities could increase the chances of poor pregnancy outcome, it was not significant. However, similar to the Indian study, our study revealed that poor pregnancy outcome was significantly associated with the trimester of pregnancy with increased likelihood of poor outcome in 1st and 2nd trimesters.

Severe COVID-19 infection in pregnancy was associated with the later stages of the pregnancy and with women with co-morbidities. Though our study findings strengthen the fact of presence of co-morbidities increase the likelihood of severe infection, the increased risk of severe infection in later stages of the pregnancy was not significant (Table 2). Severe maternal COVID-19 infection is associated with poor pregnancy outcome [15-16]. Our study revealed more than 600% increase in good pregnancy outcome if the COVID infection is mild to moderate compared to severe infection in pregnancy.

### **3.1 Limitations**

The data was obtained from the National COVID-19 positive pregnant women surveillance. It didn't identify still births and miscarriages separately. The follow up of the pregnancy was limited to one-month during the post-partum period. In addition, there could be COVID-19 positive pregnant women, whose data might not have entered in the National surveillance entirely or lacked data pertaining to pregnancy and neonatal outcomes (incomplete data).

## **4. CONCLUSION**

In conclusion, our study showed poor pregnancy outcome among severe vs mild to moderate infection, Tamil vs Sinhala ethnicity, and diagnosis in 1st and 2nd trimesters vs 3rd trimester among COVID-19 positive women of Sri Lanka. Further severe COVID-19 infection was observed among pregnant women with co-morbidities vs no comorbidities. Targeted health messages to pregnant women in 1st and 2nd trimesters and with comorbidities could be considered to reduce the number of severe COVID-19 infection in pregnancy and to improve the pregnancy outcome.

## CONSENT

Not applicable as secondary data analysis was carried out using National Surveillance data on COVID-19 positive pregnant women.

## ETHICAL APPROVAL

Ethical clearance was obtained from Ethics Review Committee of Faculty of Medical Sciences, University of Sri Jayawardenepura (ERC Number- COVID 11/21).

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