

COVID-19 positivity and clinical outcome in COVID positive neonates of COVID-19 mothers at a tertiary care COVID treatment centre in South India

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Abstract

Background: With increasing number of COVID infections, more and more pregnant women were affected and hence more vertical transmissions to newborns were reported. There was scarcity of dedicated studies in newborns related to clinical profile and outcome in COVID. This study was aimed at estimating the prevalence of COVID-19 positive babies born of COVID-19 infected Mothers and to describe the early clinical outcome in their COVID positive babies.

Methods: The study was done as a cross sectional study conducted at a tertiary care dedicated COVID treatment Centre in a sample of 388 babies of COVID positive mothers. Along with the prevalence of COVID positive babies, the early clinical outcome at 48 hours after birth was also evaluated.

Results: A total of 388 COVID positive mothers were studied and among them 85 babies were found to be COVID positive. The COVID positivity rate was 21.9% (95% CI 17.83 -25.97). Out of 85 babies 34(40%) babies were male and 51(60) babies were female. The proportion of LBW was 13(15.2%), proportion of preterm babies was 13 (15.3%) and only 19(22%) babies required NICU admission. Among the maternal variables of COVID positive babies, 38 (44.7%) were primi gravida and 46(54%) mothers had vaginal delivery. Regarding the COVID clinical status, 70(82.4%) mothers were asymptomatic and 15(17.6%) were symptomatic. After the subgroup analysis, 22(25.8%) babies were symptomatic and 63(74.1%) babies were asymptomatic. Out of 22 symptomatic babies 13(59.1%) were male and 9(40.9%) female babies (P value 0.03). The mean birth weight in symptomatic and asymptomatic babies was 2.96 kg and 2.98kg respectively (P value 0.687).

Conclusion: The newborn COVID positivity rate was found to be around 22% and majority had good early clinical outcome. The findings from this study helped to assess the burden of COVID pandemic in newborn babies and would help in the higher level of analytical research.

Keywords: COVID 19 positivity, clinical outcome, burden, symptomatic COVID

Introduction

The COVID 19 pandemic emerged as one of the most rapidly spreading infection worldwide. It was caused by Virus, currently referred as Severe Acute Respiratory syndrome corona virus 2 (SARSCoV2) by the International committee of Taxonomy ^[1]. The virus was mainly transmitted by respiratory route and likely to infect people in all ages. The symptomatology of COVID infection was categorized into mild, moderate and severe but asymptomatic infections make up a large proportion which add the fuel to its infectivity and transmission ^[2]. Many studies have reported that COVID infections were getting more in pregnant women along with reports of vertical transmission to newborns ^[3]. Initial reports showed that infection with SARS-CoV-2 result in adverse pregnancy outcomes with no clinical signs of illness in newborn. Later some studies described evidence of SARS-CoV-2 infection in newborn, but with favorable neonatal outcomes and no major morbidities and the cause could be horizontal transmission than vertical transmission. Most recently there were reports indicating the possibility of vertical transmission and there were evidence of reports of prematurity, hypoglycemia, respiratory distress, necrotizing enterocolitis etc. in COVID positive newborns ^[4].

COVID related studies have been published in large numbers since the first wave of COVID pandemic. The majority of available studies were on clinical outcome of pregnant mothers during early phase of pandemic with limitations like less sample size ^[5]. Studies in COVID positive babies born to COVID positive mother were limited and lacked evidence in neonatal variables like prematurity, clinical spectrum, NICU admissions etc. Moreover the COVID research data in babies of COVID positive mothers belonging to the regional study settings were limited. In this background, the present study was planned to estimate the prevalence and clinical outcome of COVID-19 positive babies born to COVID-19 confirmed mothers at a tertiary care dedicated COVID treatment Centre.

Objectives

To estimate the prevalence of COVID-19 positive babies born of COVID-19 confirmed Mothers at a tertiary care dedicated COVID treatment Centre.

To describe the early clinical outcome at 48 hours of life in COVID positive babies born of COVID-19 infected mothers.

Materials and Methods

Study design: Cross sectional study by chart review.

Study setting: The study was conducted in a government run dedicated COVID treatment hospital. This institution was the only tertiary care level treatment center in the district. For pregnant mothers and neonates, the hospital provides primary and secondary care treatment. There was a Level 1 Neonatal Intensive Care unit and dedicated postnatal wards for COVID patients. The babies born would be initially assessed by pediatrician for any need of NICU admission. Stable babies would be shifted mother side in COVID postnatal ward.

Study period: The case records were taken from March 2020 and study done after getting ethical approval.

Sample size: A total of 392 COVID positive mothers and their babies are studied. Among them 4 case records were excluded due to incomplete data and finally 388 case records were analyzed.

Study population: The study data was taken from the records of in the babies born to COVID-19 infected mothers by vaginal delivery or caesarian delivery at the study centre. The study was approved by Institutional Human Ethics Committee (No. IEC.NO.3/EC-4/2021/GMCKLM Dated 15th July 2021).

Inclusion criteria

1. Babies born of COVID positive mothers
2. Babies of mothers who were positive within 14 days before the day of delivery

Exclusion criteria

Mothers not willing to give consent for investigations during the hospital admission.

Sampling procedure: Sampling was done by consecutive method till the required samples were obtained. The COVID positive records of COVID positive mothers and their babies were taken for the study for data extraction. The epidemiological data was collected by telephonic interview after getting audio recorded informed consent.

Study variables: The neonatal baseline data include gravidarum, maternal morbidity, gestational age at delivery, mode of delivery, birth weight and related variables. The study variables include immediate outcomes like COVID positive babies requiring active resuscitation, APGAR score, NICU admission and events like Hypoglycemia, respiratory distress etc. in babies within 48 hours of life.

Study Instrument: A structured Data Extraction Proforma was used to minimize bias. The baseline characteristics of mother and baby, indication for NICU admission for baby, early clinical outcomes, COVID swab test details and home discharge or referral details were included in the proforma.

Data collection procedure: Based on the eligibility criteria, data collection done from the COVID positive records of COVID positive mothers and their babies after their discharge.

Operational definitions

COVID positive newborn: Babies who were born to COVID positive mothers and becomes positive within 48 hours of life by COVID-19 RTPCR test

COVID positive mother: Mothers who become COVID-19 positive within 14 days before the date of delivery or those mothers who become COVID positive within 7 days after delivery by RTPCR test or True Nat test/Antigen test. The mothers who were RTPCR positive within 14 days of delivery who later becoming antigen negative just before delivery will also be taken as a COVID Positive Mother as per WHO and NNF guidelines^[6].

COVID-testing Plan: For all babies born of COVID positive mothers, COVID RTPCR test was done within 24-48 hours. If positive, repeat tests done after day 10 by antigen test. If again positive on day 10 repeat tests were done every 48 hours apart till negative result obtained. This was done as per State and NNF guidelines^[6].

Early neonatal clinical outcome: The early clinical outcome was defined for the group of babies who needed only routine care in resuscitation, do not require any referral to level 2 NICU, do not require any NICU admission for respiratory distress, jaundice, hypoglycemia episode or any other post-natal events within 48 hours of life.

Data Analysis and Statistics

Data obtained by a structured 'Data Collection Proforma, and filled by the investigator after examining the COVID positive records. The data entry was done using Microsoft Excel. The statistical analysis was done by Microsoft Excel Statistical Package and Epi Info v.7.

The prevalence of COVID positivity in babies of COVID positive mothers was estimated in total and after subgrouping of mothers and babies in various epidemiological and clinical parameters. The categorical variables were summarized as percentages and quantitative variables were summarized as mean with SD or median according to distribution of the variable. A P value of <0.05 was taken as statistically significant.

Results

A total of 388 COVID positive mothers were studied and 85 babies were found to be COVID positive. The COVID positivity rate was 21.9% (95% CI 17.83 to 25.97).

The proportion of maternal parameters in COVID positive babies were assessed. Out of 85 mothers, 38 (44.7%) were primi gravida and 47(55.3%) were multi gravida mothers. Apart from COVID symptoms, 38(44.7) mothers had morbidities like GDM or PIH and 47 (55.3%) with no complications. Clinically mothers were categorized in to asymptomatic 70(82.4%) and symptomatic 15(17.6%), symptomatic mothers were again sub classified in to Mild 12(14.1%), Moderate 2(2.4%) and Severe 1(1.2%). The baseline maternal variables is given in Table 1.

Table 1: Descriptive characteristics of baseline maternal parameters in COVID positive babies

Parameters	Summary [n=85] (%)
Mode of delivery	
▪ Vaginal	46(54.1)
▪ Caesarian	39(45.9)
Maternal Morbidity	
▪ Yes	38(44.7)
▪ No	47(55.3)
COVID Clinical category mother	
▪ Asymptomatic	70(82.4)
▪ Mild	12(14.1)
▪ Moderate	2(2.4)
▪ Severe	1(1.2)
Parity of Mother	
▪ Primi	38(44.7)
▪ Multi	47(55.3)
Indication for Caesarian	
▪ Elective	15(17.6)
▪ Emergency	22(25.9)

The baseline neonatal variables in COVID positive babies were assessed. Out of 85 babies 34(40%) babies were male and 51(60) babies were female. Out of 85 babies, 13(15.3%) were preterm and 72(84.7%) were term babies. About the gender, 34(40%) were male and 51(60%) female babies. The proportion of LBW (<2.5kg) among 85 babies was 13 (15.2%), 72 (84.7%) babies had normal birth weight (>2.5kg). 11(12.9%) babies fall under SGA group out of 85 babies. After birth, 10 (11.8%) babies required active resuscitation, whereas 75 (88.2%) received only routine care. Only 2(3.5%) babies had Apgar score < 7 at 5 minute, where 82 (96.5%) babies with score of 7 and above. Clinical conditions were assessed and by indication, 19(22.4%) babies required NICU admission. Post-natal complications were assessed, 9(10.6%) got hypoglycemic attack within 48 hours of life and 20(23.5%) babies got respiratory distress. The baseline neonatal variables are given in Table 2.

Table 2: Descriptive characteristics of baseline neonatal parameters in COVID positive babies

Parameters	Summary [n=85] (%)
Birth Weight-baby	
▪ Low Birth Weight (<2.5 kg)	13(15.3)
▪ Not Low Birth weight	72(84.7)
Gestational Age	
▪ Small for Gestation(SGA)	11(12.9)
▪ Not SGA	74(87.1)
Gender	
▪ Male	34(40)
▪ Female	51(60)
Gestation	
▪ Preterm	13(15.3)
▪ Term	72(84.7)
Active Resuscitation	
▪ Yes	10(11.8)
▪ No	75(88.2)
APGAR Score	
▪ Less than 7	2(3.5)
▪ ≥ 7	83(96.5)
NICU Admission (within 48 hours)	
▪ Yes	19(22.4)
▪ No	66(77.6)
Hypoglycemia within 48 hours	
▪ Yes	9(10.6)
▪ No	76(89.4)
Respiratory distress	
▪ Yes	20(23.5)
▪ No	65(76.5)

Subgroup analysis of symptomatic and asymptomatic COVID positive babies

Among the 85 COVID positive babies, 22(25.8%) babies were symptomatic and 63(74.1%) babies were asymptomatic. Out of 22 symptomatic babies 13(59.1%) were male and 9(40.9%) were female babies showing a male preponderance (P value was 0.03, OR: 2.89, 95% CI: 1.06-7.84) and it was statistically significant. The mean birth weight in symptomatic babies was 2.96 kg and asymptomatic babies was 2.98kg. Independent sample t test showed P value as 0.687, which was statistically not significant. Mean mothers age in Symptomatic and asymptomatic babies were 25.3 and 25.52 respectively. Independent sample t test (P value) 0.82, and statistically it was not significant.

The inferential statistics of birth weight and maternal age is given in Table 3.

Table 3: Mean Birth weight and maternal age in Symptomatic and Asymptomatic babies

Group	Variable	Mean	SD	SE	Independent sample t test (P value)
Symptomatic (n=22)	Birth weight (kg)	2.93	0.44	0.09	0.687
Asymptomatic (n=63)		2.98	0.45	0.05	
Symptomatic (n=22)	Maternal age (yr)	25.3	3.9	0.84	0.82
Asymptomatic (n=63)		25.52	3.7	0.47	

While comparing clinical outcomes with parity, among 38 babies born to primi gravida mothers 11 (50%) were symptomatic and among 47 babies of multi gravida mothers 11(50%) were symptomatic. The P value was 0.56, OR: 1.3, 95% CI: 0.5-3.5, which was statistically not significant. Among 85 babies, 46 babies delivered by normal vaginal delivery and 39 babies by LSCS. Among them, 14(63.6%) babies born by normal vaginal delivery were symptomatic, whereas in those born by LSCS, 8(36.4%) babies were symptomatic (P value was 0.289, OR: 1.7, 95% CI: 0.6-4.6). Among the babies born to mothers with maternal morbidities like GDM, PIH, 10 (45.5%) babies were symptomatic and 28 (44.4%) babies were asymptomatic. P value was 0.935, OR: 0.93, 95% CI: 0.39-2.7, which was statistically not significant. Out of 85 babies, only 13(15.3) babies were LBW and 72(84.7) babies were normal birth weight. Among 13 LBW babies, 6 (27.3%) babies were symptomatic and 16 (72.7%) babies were symptomatic with normal birth weight. P value was 0.07, OR: 3, 95% CI: 0.8-10.2 which was statistically not significant. The inferential statistics is given in Table 4.

Table 4: Inferential Statistics of Asymptomatic and Symptomatic COVID Positive Newborn

Variable	Symptomatic N= 22(25.8%)	Asymptomatic N=63 (74.1%)	X ² value	P value	OR 95% CI
Gender of Baby					
Male (n=34)	13 (59.1)	21 (33.3)	4.5	0.03	2.89 1.06-7.84
Female (n=51)	9 (40.9)	42 (66.7)			
Mode of Delivery					
Vaginal	14(63.6)	32(50.8)	1.08	0.289	1.7 0.6-4.6
LSCS	8(36.4)	31(49.2)			
Maternal Morbidity					
Yes (n=38)	10(45.5)	28(44.4)	0.007	0.935	1.04 0.39-2.7
No (n=47)	12(54.5)	35(55.6)			
LBW	6(27.3)	7(11.1)	3.2	0.07	3 0.8-10.2
Not	16(72.7)	56(88.9)			
Parity of mother					
Primi	11(50)	27(42.9)	0.33	0.56	1.3 0.5-3.5
Multi	11(50)	36(57.1)			

Discussion

This study was done to evaluate the prevalence of newborn COVID positivity in newborns born to COVID positive mothers. The COVID positivity rate was 21.9% (95% CI 17.83 to 25.97). In the study done by Ajith *et al.*, the prevalence was 14.5% which was lower than the present study with almost similar sample size. In another study done on outcomes of pregnant women suspected of COVID infection, majority of women were asymptomatic and none of the babies were COVID positive [7]. In the systematic review by Alvaro *et al.*, among the newborns born to confirmed mothers, only 2% were diagnosed with COVID-19 infection [5]. But in contrast, the study done by Wu *et al.*, in China showed a considerable number of babies born to infected mothers (16%) were COVID positive [8]. The proportion of asymptomatic patients with pregnancy also reported to be higher than that of general population as per the systematic review done by Chen *et al.*, [9].

Parity was another important factor studied in COVID infection during pregnancy. In the present study, multipara mothers were 10% more compared to primi mothers. In a population registry based study done in Norway, multi para mothers had more risk of neonatal COVID positivity compared to primi mothers [10]. But in the study done by Allotey *et al.*, parity showed no association [4]. Similarly in the study done by Yang *et al.*, parity was not related with COVID positivity [11].

Among COVID studies in pregnant mothers, association between mode of delivery and COVID transmission to neonate has been evaluated in many studies and it showed variable observations. In the present study, only 9 percent more babies were born of vaginal delivery than caesarian section. In the study done by Ajith *et al.*, risk was more in vaginal delivery group (17%) compared to caesarean delivery^[12]. But in another systematic review done by Walker *et al.*, the risk was almost same in vaginal and caesarean deliveries^[13]. But contrasting finding was reported in the INTERCOVID multinational cohort study in which caesarean delivery was significantly associated with neonatal COVID positivity^[14].

In the present study, only 15% of babies were low birth weight. In a retrospective cohort study done by Anita *et al.*, in 200 COVID positive mothers, significantly increased proportion of COVID positive babies were seen with low birth weight^[15]. In the initial phase of pandemic, the proportion of low birth weight babies and preterm deliveries in COVID positive mothers was observed to be surprisingly less in a study done by Graf *et al.*,^[16]. In another study done by Chen *et al.*, gestational age was unaffected by COVID 19 infection^[17]. Similarly in the systematic review done by Wei *et al.*, low birth weight was significantly associated with COVID positive babies (OR 1.89, 95% CI 1.14 to 3.12)^[18]. In another systematic review involving 19 studies, higher pooled proportion of preterm births was reported^[19].

In the present study, only 13% babies were small for gestational age. In the study done by Mullins *et al.*, fewer than 10% of babies who were COVID positive were small for gestational age and did not change the expected distribution of birth weight Z scores^[20]. In the study done by Lopes *et al.*, only 6 % babies were low birth weight^[5]. But In another systematic review and meta-analysis done by de Melo *et al.*, with 38 studies, the level of evidence was low in relation to low birth weight in COVID positive babies^[21].

In the present study, only 25% of COVID positive neonates were symptomatic. In the study done by Uday *et al.*, among the total babies born of COVID positive mothers, 15% needed NICU admission and 4% were preterm^[3]. In the study done by Chen *et al.*, neonates of COVID positive mothers had more risk of NICU admissions but none of them were in serious clinical stage^[22]. In the case control study done by Hashmi *et al.*, the babies of COVID positive mothers had increased risk of fetal distress and significantly higher proportion of lower APGAR score^[23].

Limitations

The present study had its limitations. The study was done in a tertiary care centre which may lead to some amount of referral bias. As it was a cross sectional study, the incidence of clinical outcomes could not be ascertained and there was no control group. This was a chart review done on the case records which could contribute to information bias. But the record review helped to reduce recall bias to some extent. Another study with large sample size and a comparative group would help to generate more valid findings and to prove the present study observations.

Conclusion

The newborn COVID positivity rate was found to be around 22% and majority had good early clinical outcome. Majority of COVID positive babies had normal birth weight and only a small percentage required NICU admission. Though there was statistical significance in gender difference for symptomatic babies but other parameters were similar. The findings from this study helped to assess the burden of COVID pandemic in newborn babies and would help in the next higher level of analytical research.

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Ethical statement: Approval obtained from Institutional Research Committee and Institutional Ethics Committee.

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