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Clinical characteristics & outcome of SARS-CoV-2 infected neonates presenting to paediatric emergency

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***Background & objectives*: Data on neonatal COVID-19 are limited to the immediate postnatal period, with a primary focus on vertical transmission in inborn infants. This study was aimed to assess the characteristics and outcome of COVID-19 in outborn neonates.**

***Methods*: All neonates admitted to the paediatric emergency from August 1 to December 31, 2020, were included in the study. SARS-CoV-2 reverse transcription- (RT)-PCR test was done on oro/nasopharyngeal specimens obtained at admission. The clinical characteristics and outcomes of SARS-CoV-2 positive and negative neonates were compared and the diagnostic accuracy of a selective testing policy was assessed.**

***Results*: A total of 1225 neonates were admitted during the study period, of whom SARS-CoV-2 RT-PCR was performed in 969. The RT-PCR test was positive in 17 (1.8%). Mean (standard deviation) gestation and birth weight of SARS-CoV-2-infected neonates were 35.5 (3.2) wk and 2274 (695) g, respectively. Most neonates (11/17) with confirmed COVID-19 reported in the first two weeks of life. Respiratory distress (14/17) was the predominant manifestation. Five (5/17, 29.4%) SARS-CoV-2 infected neonates died. Neonates with COVID-19 were at a higher risk for all-cause mortality [odds ratio (OR): 3.1; 95% confidence interval (CI): 1.1-8.9, *P*=0.03]; however, mortality did not differ after adjusting for lethal malformation (OR: 2.4; 95% CI: 0.7-8.7). Sensitivity, specificity, accuracy, positive and negative likelihood ratios (95% CI) of selective testing policy for SARS-CoV-2 infection at admission was 52.9 (28.5-76.1), 83.3 (80.7-85.6), 82.8 (80.3-85.1), 3.17 (1.98-5.07), and 0.56 (0.34-0.93) per cent, respectively.**

***Interpretation & conclusions*: SARS-CoV-2 positivity rate among the outborn neonates reporting to the paediatric emergency and tested for COVID-19 was observed to be low. The selective testing policy had poor diagnostic accuracy in distinguishing COVID-19 from non-COVID illness.**

Key words COVID-19 - emergency - neonate - outborn - SARS-CoV-2 - screening

Worldwide, more than 278 million patients have COVID-19, with 5.4 million deaths[1]. As compared to adults, children are less affected and have better prognosis[2,3]. Neonates are at risk for acquiring vertical

and horizontal SARS-CoV-2 infection. The evidence so far suggests that vertical transmission is uncommon, and a more significant proportion of neonates acquire SARS-CoV-2 infection in the postnatal period through horizontal transmission from either infected mothers or immediate caregivers[4,5]. Most neonates remain asymptomatic, and the overall prognosis is good[4,6-11]. Most of the studies on neonatal COVID-19 are limited to inborn neonates and focused on vertical transmission. This study was conducted to assess the positivity rate, characteristics, and outcome of COVID-19 among outborn neonates presenting to the paediatric emergency in a tertiary care centre in north India.

Material & Methods

This retrospective study was done at an outborn neonatal unit of the department of Paediatrics, Postgraduate Institute of Medical Education and Research, Chandigarh, India. All outborn neonates up to 44 wk postmenstrual age are admitted to the newborn unit of paediatric emergency. All neonates consecutively referred to the institute from August 1 to December 31, 2020 were enrolled. The details of all the neonates at admission (day of life, history of fever, cough, respiratory distress, day of life at the onset of respiratory distress, admission diagnosis, respiratory support, previous hospitalization, SARS-CoV-2 real-time RT-PCR test, and outcome) were noted. Ethical clearance, including waiver of consent, was obtained from the institute's ethics committee.

The ICMR national guidelines (*https://www.icmr.gov.in*) for assessing eligibility for testing, sample processing, and discharge[12] were adopted. Oro/nasopharyngeal specimens were obtained using standard technique, and SARS-CoV-2 RT-PCR assay (Cepheid Xpert Xpress SARS-CoV-2 assay, Cepheid India Pvt. Ltd; Rewari, India) was used for COVID-19 testing. COVID-19-positive neonates were managed in a dedicated COVID-19 facility.

During the first three weeks of August 2020, a selective testing policy was adopted in which SARS-CoV-2 RT-PCR testing was limited to those who fulfilled any of the following criteria: (*i*) mother had confirmed COVID-19 within 14 days before delivery, (*ii*) the infant had a history of close contact with confirmed COVID-19 patient in the past 14 days, (*iii*) neonates presenting with severe acute respiratory illness (needing supplemental oxygen or respiratory support to maintain oxygen saturation >90%) with onset at more than 24 h of age with or without cough and fever (>38°C)[12]. Later (from August 20, 2020, onwards), with a rising number of community cases, universal screening policy was adopted in which all symptomatic patients (irrespective of illness) reporting to the emergency underwent COVID-19 testing (as recommended by ICMR)[13]. Neonates who tested negative were cared for in the outborn unit, whereas confirmed COVID-19 cases were transferred to the COVID facility of the hospital. The clinical management of these neonates admitted at both places was the same (irrespective of admission site) and was done as per the standard protocols. The samples of accompanying immediate caregivers of COVID-19 confirmed neonates were also sent for contact tracing, if feasible. Rooming-in, breastfeeding, and Kangaroo Mother Care (KMC) were allowed whenever deemed possible. Repeat COVID-19 testing was limited to the neonates needing further care at the institute.

The change from selective testing to universal COVID-19 testing of all neonates presenting to the hospital was not based on neonatal data but was based on extrapolating from the adults. Therefore, the positivity by selective testing in infants admitted after August 20, 2020 was compared with the universal testing to assess how many additional neonates were identified by universal testing. Also, the overall diagnostic accuracy of the selective testing policy was evaluated.

Statistical analysis: The categorical variables were presented as percentages and continuous variables as mean (standard deviation) or median (1^{st}-3^{rd} quartile). The categorical variables were compared using a chi-square test or Fisher's exact test as appropriate and numerical variables using Mann–Whitney U test. Odds ratios (ORs) were calculated with 95 per cent confidence intervals (CIs) for various outcomes among COVID-19-positive neonates compared to COVID-19-negative neonates. SPSS version 21 (IBM SPSS Statistics, IBM Corp. Chicago, IL, USA) software was used for statistical analysis.

Results & Discussion

A total of 1225 neonates were admitted during the study period. The median (1^{st}-3^{rd} quartile) age at admission was two (1, 7) days. Of the 1225 neonates, 1127 (92%) were referred from the surrounding States, and 875 (71.4%) had respiratory distress at admission. Most of the neonates (486 of 1225) presented on day one of life. Of the 1225 neonates, 192 (15.7%) either died

or left against medical advice. SARS-CoV-2 RT-PCR test was done in 969 of 1225 (79.1%) neonates. The remaining 256 neonates could not be tested for various reasons like not meeting the selective screening criteria in the initial study period, died within four to six hours of admission, or parents not willing for testing/care at our hospital and left against medical advice. Of the 969 neonates tested for SARS-CoV-2 infection, only 17 (1.8%, 95% CI: 1.03-2.79) were positive. Five (29.4%) COVID-19-confirmed neonates died, and none of them left against medical advice.

For this study, only those neonates were analysed whose SARS-CoV-2 testing was done (n=969). The clinical characteristics of COVID-19-positive neonates are presented in Table I. Most of them (11/17) presented in the first two weeks of life, and almost all (14/17) presented with respiratory distress. The median (1^{st}-3^{rd} quartile) hospital stay was five (2-7) days. Five (29.4%) COVID-19-positive neonates died during the hospital stay. Two of them had lethal congenital anomalies (Table I), while the rest three died due to severe sepsis (*Klebsiella pneumonia* - 1, *Candida* spp. - 1, culture-negative sepsis - 1). Only one neonate had clinical and radiological manifestations (bilateral ground-glass opacities in peripheral lung fields) consistent with COVID-19 pneumonia and received methylprednisolone for five days. In the remaining 16 neonates, the clinical features were either not attributed to the COVID-19, or the disease was not severe enough to warrant specific therapy.

The various risk factors/parameters among the COVID-19 positive and negative neonates were compared (Table II). COVID-19 confirmed neonates had respiratory distress onset at a later age (2 *vs*. 1 day) and were admitted at an older postnatal age (11 *vs*. 3 days). Neonates having fever at admission had significantly higher odds of having COVID-19 (OR: 12.5; 95% CI: 3.3-47.9, *P*=0.004). However, there was no difference in cough, respiratory distress, prior hospitalization, or need for mechanical ventilation. Although neonates with confirmed COVID-19 were at higher risk for all-cause mortality (OR: 3.1; 95% CI: 1.1-8.9, *P*=0.03), the difference was not significant after adjusting for lethal congenital anomalies (OR: 2.4; 95% CI: 0.7-8.7, *P*=0.17).

If we had followed the selective testing policy, only 9/17 COVID-19 cases (53%) would have been diagnosed. Therefore, the universal testing policy identified additional eight (47%) cases. The diagnostic accuracy of the selective testing policy was assessed considering SARS-CoV-2 RT-PCR as a gold standard. The sensitivity, specificity, accuracy, positive and negative likelihood ratios were 52.9 (95% CI: 28.5-76.1), 83.3 (80.7-85.6), 82.8 per cent (80.3-85.1), 3.17 (1.98-5.07), and 0.56 (0.34-0.93), respectively. We also attempted to assess the effect of change in the cut-off for the onset of respiratory distress in the selective testing policy. As the cut-offs were increased for the onset of respiratory distress, the sensitivity dropped significantly with marginal improvement in specificity. The sensitivity was 41.2 per cent (18.4-67.1) with 48 h. cut-off and 35.3 per cent (14.2-61.7) with 72 h cut-off, while the specificity was 87.4 per cent (85.1-89.4) at 48 h and 89.4 per cent (87.5-91.3) at 72 h.

As a part of contact tracing, at least one of the parents in 13 neonates (13 mothers and four fathers) could be tested. In five cases mother was COVID-19-positive, whereas in one neonate mother was negative, but the father tested positive. In two cases, both parents were negative, and they were the only caregivers.

In this study, the SARS-CoV-2 positivity rate among the outborn neonates presenting to the emergency and tested was lower (n=17, 1.8%) than older children and adults[14,15]. Though the neonates with COVID-19 were at a higher risk for all-cause mortality, there was no significant difference in the adjusted mortality rate. Though neonates with a positive screen at admission had higher odds of COVID-19, the sensitivity was poor (43% of confirmed COVID cases had a negative screen). These observations support a universal testing screening policy.

Children typically account for 10-12 per cent of laboratory-confirmed SARS-CoV-2 cases, and the hospitalization rates range from 2.5 to 4.1 per cent[16,17]. Neonatal COVID-19 accounts for less than one per cent of all and 5-7 per cent of paediatric COVID-19 cases[18-20]. Previous cohort studies showed that the prevalence of COVID-19 in neonates born to COVID-19 mothers was low, and they were generally asymptomatic[7,21,22]. Therefore, even if the mother is COVID-19 positive, exclusive breastfeeding and KMC with adequate respiratory and hand hygiene are recommended[23,24].

A retrospective study from India, where all outborn neonates presenting to the emergency were screened for SARS-CoV-2 infection, reported a higher positivity rate of 4.25 per cent (18 of 423)[11]. In this

Table I. Characteristics of the SARS-CoV-2 infected neonates (n=17)

ID	Gestation (wks)/ birth weight (g)	DOL on which test was positive	Prior hospital stays (days)	Clinical features	Maximum respiratory support	Caregiver's SARS-CoV-2 report*	Hospital stays (days)	Outcome	Reason for death (if applicable)	Repeat swab (days from first positive)
Neo1	37/2452	15	No	Fever×three days and fast breathing×one day	Short binasal prongs	Mother-positive Father-not done	5	Discharged		Negative on day 3
Neo2	37/2000	2	Yes (1)	Respiratory distress since birth	Mechanical ventilation	Not done	2	Died	Multiple CMF (ARM + renal agenesis + TEF + pulmonary hypoplasia)	Not done
Neo3	37/2000	12	No	Fast breathing×two days	Short binasal prongs	Mother-negative Father-positive	5	Discharged		Not done
Neo4	38/3100	23	Yes (23)	Case of MAS. worsening distress since day 22 of life (COVID pneumonia on chest CT)[#]	CPAP	Mother-positive Father-not done	8	Discharged		Not done
Neo5	37/3000	13	No	Case of omphalocele Fever, cough, fast breathing×one day	CPAP	Mother-positive Father-negative	26	Discharged		Negative on days 19 and 20
Neo6	36/1400	5	Yes (5)	Vomiting, abdominal distension, and fast breathing×two days	Short binasal prongs	Mother-negative Father-negative	7	Discharged		Negative on days 3 and 5
Neo7	37/2600	3	Yes (3)	Respiratory distress since birth	CPAP	Mother-negative Father-not done	7	Discharged		Negative on days 11 and 12
Neo8	33/1600	19	Yes (19)	EONS-was asymptomatic at testing; another neonate in the same cot was positive	None	Mother-negative Father-not done	2	Discharged		Negative on day 2
Neo9	37/3105	20	Yes (5)	Asymptomatic, referred for evaluation of lesion in the liver	None	Mother-negative Father-not done	5	Discharged		Not done

Contd...

ID	Gestation (wks)/ birth weight (g)	DOL on which test was positive	Prior hospital stays (days)	Clinical features	Maximum respiratory support	Caregiver's SARS-CoV-2 report*	Hospital stays (days)	Outcome	Reason for death (if applicable)	Repeat swab (days from first positive)
Neo10	38/2200	3	Yes (2)	Respiratory distress since birth	Mechanical ventilation	Mother-positive Father-not done	3	Died	Multiple CMF (CHAOS, absent bilateral thumbs)	Not done
Neo11	28/1230	1	Yes (6 h)	Respiratory distress since birth	Mechanical ventilation	Mother-negative Father-not done	6	Died	Septic shock, pulmonary hemorrhage	Not done
Neo12	37/2200	8	Yes (3)	Respiratory distress onset at day 5 of life	Mechanical ventilation	Not done	2	Died	Multidrug-resistant *Klebsiella pneumoniae* sepsis	Not done
Neo13	37/3500	10	Yes (10)	Respiratory failure and shock (case of TGA)	Mechanical ventilation	Mother-negative Father-negative	5	Discharged		Negative on days 3 and 5
Neo14	34/2000	11	Yes (11)	Respiratory distress since birth	Mechanical ventilation	Mother-negative Father-not done	18	Died	Fungal sepsis/septic shock	Negative on days 3 and 5
Neo15	39/3000	4	Yes (2)	Abdominal distension and fast breathing×two days (hirschsprung disease)	None	Mother-positive Father-not done	7	Discharged		Not done
Neo16	28/1270	29	Yes (28)	Asymptomatic, APROP, admitted for anti-VEGF therapy	None	Not done	2	Discharged		Not done
Neo17	34/2000	31	Yes (30)	Asymptomatic, APROP, admitted for anti-VEGF therapy	None	Not done	1	Discharged		Not done

*Not done - test could not be done due to non-availability of the caregiver at admission/not consented to the test; [#]Received methylprednisolone for five days. ARM, anorectal malformation; APROP, aggressive posterior retinopathy of prematurity; CHAOS, congenital high airway obstruction syndrome; CPAP, continuous positive airway pressure; CMF, congenital malformation; DOL, day of life; EONS, early-onset neonatal sepsis; MAS, meconium aspiration syndrome; OPD, outpatient department; TEF, tracheoesophageal fistula; VEGF, vascular endothelial growth factor; TGA, transposition of the great arteries; COVID, coronavirus disease

Table II. Clinical characteristics of study participants (n=969)

Parameter	COVID positive (n=17)	COVID negative (n=952)	*P* value	OR (95% CI)
Age at admission (days)		n=948		
Median (1st, 3rd quartile)	11 (3.5, 19.5)	3 (1, 8)	0.001*	-
Fever (≥38°C)	3 (17.6)	16 (1.7)	0.004	12.5 (3.3-47.9)
Cough	0	3 (0.3)	1.0	-
Respiratory distress	15 (88.2)	670 (70.4)	0.2	3.2 (0.7-13.9)
Day of onset of respiratory distress	n=15	n=643		
Median (1st, 3rd quartile)	2 (1, 10)	1 (1, 1)	0.001*	-
Hospitalized prior to admission	14 (82.4)	887 (93.2)	0.083	0.3 (0.1-1.3)
Screen positive at admission	9 (52.9)	159 (16.7)	0.001	5.6 (2.1-14.8)
Respiratory support at admission				
None	3 (17.6)	303 (31.8)	0.5	-
Oxygen alone	4 (23.5)	240 (25.2)		
Continuous positive airway pressure	6 (35.6)	258 (27.1)		
Mechanical ventilation	4 (23.5)	151 (15.9)		
Intubated at admission	4 (23.5)	151 (15.9)	0.4	1.6 (0.5-5.1)
Death during hospital stay	5 (29.4)	114 (12)	0.03	3.1 (1.1-8.9)
Deaths after excluding lethal congenital anomalies†	n=15 3 (20.0)	n=925 87 (9.4)	0.17	2.4 (0.7-8.7)

*Mann-Whitney U-test, for rest Chi-square/Fisher's exact test was used. †Lethal congenital anomalies refer to malformations in the presence of which the survival is unlikely beyond the neonatal/infant age group (*e.g.*, potter's syndrome, renal agenesis, anencephaly, holoprosencephaly, hypoplastic left heart syndrome, trisomy 13 and 18, severe congenital diaphragmatic hernia or tracheaoesophageal fistula where the baby died within few hours, tracheal atresia, *etc*.). Values are presented as n (%) unless specified

study, respiratory distress was the most common clinical presentation, and mortality was 16.6 per cent[11]. In another case series from India, the authors screened 18 symptomatic outborn neonates presenting to the emergency, of whom only one had SARS-CoV-2 infection[9]. In a similar study from Bangladesh, 26 of 83 (31.3%) outborn neonates referred to a tertiary center tested positive for SARS-CoV-2 infection[10]. In their series, most presented in the second week of life, with an unrelated diagnosis. In our study, there was no difference in adjusted mortality rate between COVID and non-COVID cases, inferring that SARS-CoV-2 positivity alone does not increase the risk for mortality[25].The practice of universal testing of all outborn neonates requiring admission was not based on neonatal data but rather an extrapolation from older age groups. This study provides some evidence for this practice though the numbers are not large enough to make conclusive recommendations. However, considering the consequences of missing SARS-CoV-2 infection by selective screening and putting others at risk, continuing universal screening in outborn neonates requiring hospitalization may be suggested. Furthermore, this study indicates the possibility of horizontal transmission from immediate caregivers as well as healthcare facilities. In six COVID-19-confirmed cases, the primary caregivers were SARS-CoV-2-negative, and the infants stayed in a healthcare facility since birth. Therefore, there is a need for strict compliance with the precautionary measures in healthcare facilities to prevent horizontal transmission[6,26]. Many caregivers were asymptomatic and found to have COVID-19 when tested as a part of contact tracing. This observation reinforces the importance of contact tracing.

Being a retrospective single-centre study, it had many limitations. The primary illness, hospital course, and cause of mortality in COVID-19-negative neonates were not recorded, precluding further analysis. Contact tracing could not be done for all COVID-19 confirmed cases. Though most confirmed COVID-19 neonates had respiratory distress at admission, chest tomography was done in two cases only. The other neonates with respiratory distress might have radiological findings of COVID-19 that went undetected on a plain chest radiograph[27,28].

This study enrolled outborn neonates referred to the emergency because of a clinical illness; therefore, results cannot be generalized to inborn neonates. As it was a retrospective study, formal sample size calculation was not done. Considering the low incidence of COVID-19 in neonates, large prospective multicentric cohort studies are desirable.

In conclusion, the SARS-CoV-2 positivity rate among outborn neonates presenting to the emergency was found to be low. As the clinical findings at admission cannot distinguish COVID-19 from non-COVID illness, universal screening of all outborn neonates requiring hospitalization seems reasonable.

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