The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has infected over 15 million individuals in India [1]. The SARS-CoV-2 infects both children and adults but has higher fatality in the elderly and individuals with co-morbidities [2]. SARS-CoV-2 infects pregnant women as much as other reproductive-age women [3]. The knowledge about the epidemiology, clinical characteristics, prevention, and treatment of SARS-CoV-2 infection is continually evolving. Currently available data on the consequences of SARS-CoV-2 infection in pregnancy, fetus, and the neonate is mostly from case reports, small case series, retrospective cohort or cross-sectional studies, compiled in a recent systematic review [4]. There is limited data on perinatal SARS-CoV-2 infection from the developing world. We report analysis from a large neonatal coronavirus disease 2019 (COVID-19) registry under the National Neonatology Forum (NNF) of India, on the incidence of perinatal transmission and the factors associated with it, and the clinical features of SARS-CoV-2 positive neonates.

METHODS

In this prospective cohort study, data were collected from various hospitals voluntarily enrolled in the NNF COVID-19 registry, which was initiated in April, 2020. Neonates born to women with SARS-CoV-2 infection within two weeks prior to or two days after delivery and neonates with confirmed SARS-CoV-2 infection within 28 days of life were eligible for enrolment in the study. COVID status of mothers and neonates was assessed by nasopharyngeal RT-PCR in all participating hospitals.

SARS-CoV-2 infected neonates were defined as those with a positive SARS-CoV-2 quantitative RT-PCR test in nasopharyngeal swab within 28 days of birth [5]. SARS-CoV-2 infected mothers were defined as those with a positive SARS-CoV-2 quantitative RT-PCR test in the nasopharyngeal swab.
nasopharyngeal sample during the peripartum period [5]. Perinatal transmission was defined as positive nasopharyngeal RT-PCR in a neonate in the first 72 hours after birth [6,7]. This included intraterine and intrapartum transmission. Testing was avoided in the first 12 hours to minimize false positives due to superficial colonization. Horizontal transmission was considered in a neonate with negative RT-PCR within the first 72 hours who subsequently tested positive any time after 72 hours of birth irrespective of the mother’s SARS-CoV-2 status [6,7].

Mothers were either tested at admission or referred for admission because of the SARS-CoV-2 positive reports. Testing and management were as per the Indian Council for Medical Research (ICMR) and NNF guidelines, and local standard operating procedures [8,9]. SARS-CoV-2 status of the neonate was tested as per NNF guidelines and local institutional protocols, which in most centres was done within the first 72 hours after birth or when the neonate was symptomatic and admitted to the neonatal unit [8]. All neonates were monitored for clinical symptoms for the first seven days after birth and for as long as the mother was admitted to the hospital. Data on mothers and neonates was available till disposition from the hospital.

Data collection: Data was prospectively submitted to the registry by the participating hospitals in a web-based secure platform (https://inncl.org/covid). All the registered hospitals received a short message alert every week on the number of enrolled cases and data completeness. Twenty percent of the enrolled cases from each participating centre were randomly cross-checked for data quality. A closed group of clinical leads from participating hospitals was formalized for secure, encrypted communication. This group managed the updates to the database, day-to-day problems in data management, the progress of the registry, and sharing of education and communication. Any inconsistency in data was highlighted to the respective hospital lead for verification.

The data included baseline characteristics of the mothers, mode of delivery, type of feeding, rooming-in with mother or isolation from mother, clinical features, diagnosis, and neonatal outcomes. The clinical status of patients was classified as per guidelines from the Ministry of Health and Family Welfare, Government of India [10].

The primary outcomes of the study were: (i) the incidence of perinatal transmission; (ii) the rates of SARS-CoV-2 virus positivity in the neonates in association with risk factors of transmission such as mode of delivery, type of feeding and care practices, and (iii) comparisons between intramural and extramural, SARS-CoV-2 positive and SARS-CoV-2 negative neonates born to SARS-CoV-2 positive mothers. The secondary outcomes were respiratory morbidities, the need for respiratory support, and mortality in these infants.

Statistical analyses: Descriptive statistics were used, and comparisons were made using the chi-square test for categorical variables and the Student t-test or Mann-Whitney U test as appropriate for continuous variables. A P-value of <0.05 was considered significant.

RESULTS

The web-based COVID-19 registry received a total of 1733 entries for mothers and their neonates. Almost all (1730/1733) of the enrolled mother-infant dyads were from tertiary care hospitals, 1649 (95%) from public sector hospitals, and 82 (5%) from private hospitals. We excluded 22 entries where both mothers and neonates were negative but were referred because of suspicion of SARS-CoV-2 infection, and 1711 mother-infant dyads were enrolled in this study. Most of the mothers (94.5%) were asymptomatic, and only 1% were critically ill. Cesarean section was the mode of delivery in 68%.

Of the 1711 enrolled neonates, 1589 were intramural, while 122 were extramural births. The extramural infants were referred to the participating hospitals for either symptomatic status or for SARS-CoV-2 positive status of the mother. Figure 1 gives a study flow for intramural neonates enrolled in the registry. Out of 1589 intramural infants, SARS-CoV-2 testing was either not done or not reported in 259, so we excluded them from the analysis. Amongst 1330 tested neonates, 143 (10.8%) were SARS-CoV-2 positive. Of these, 68 (5.1%) tested positive on day one (Fig. 1 and 2). Amongst the intramural newborn infants, 106 (8%) were positive for SARS-CoV-2 within 72 hours (perinatal transmission) and 21 (1.5%) beyond 72 hours (horizontal transmission) of birth. The risk of transmission was not associated with the mode of delivery or type of feeding. The risk of transmission of SARS-CoV-2 from mother to neonate was marginally higher if the baby was roomed-in with the mother (RR 1.16, 95% CI 1.1-2.4; P=0.01). Tables I and II compare the SARS-CoV-2 positive and negative infants born to SARS-CoV-2 positive mothers. The demographic parameters in both the groups were not different except for the prematurity rate, which was higher in SARS-CoV-2 positive group. SARS-CoV-2 positive neonates were five times more likely to be symptomatic and twice more likely to need resuscitation. They had significantly higher probability of having sepsis and septic shock. SARS-CoV-2 positive neonates were more likely to have abnormal radiological findings and need respiratory support. They were also more likely to have received surfactant, steroids and inotropes. The risk of

\[ \text{SARS-CoV-2 and Neonates} \]
mortality was however not significantly different between the two groups. No significant association was noted between mother’s symptomatic status and baby’s SARS-CoV-2 positivity, need for resuscitation, and symptoms.

Fig. 2 depicts the study flow for extramural neonates. Extramural SARS-CoV-2 infected neonates were more likely to present with pneumonia, seizures, and septic shock, and were more likely to present after the first 72 hours of birth (Tables III and IV). This cohort of neonates was generally symptomatic. Like intramural neonates, extramural SARS-CoV-2 infected neonates tended to have more respiratory symptoms, radiological abnormalities, and needed more respiratory support.

There were 17 neonates in the registry, who were positive for SARS-CoV-2, but their mothers were reported negative. Five of these neonates were positive within 72 hours of life, and the remaining tested positive beyond 72 hours of birth. In this sub-group, 3 (17.6%) needed resuscitation at birth, 3 (17.6%) had pneumonia, 5 (29%) had respiratory distress, and 4 (23.5%) had sepsis. One (5.9%) infant had encephalopathy, and 3 (17.6%) had seizures.
Table I  Demographics and Risk Factors in SARS-CoV-2 Positive and Negative Intramural Neonates

| Parameters                        | SARS-CoV-2 | RR (95% CI) |
|----------------------------------|------------|-------------|
|                                  | Positive   | Negative    |
|                                  | (n=143)    | (n=1187)    |
| Male gender                      | 81 (57)    | 581 (49.2)  | 1.1 (0.9-1.3) |
| Weight, g                        | 2746 (618) | 3024 (170)  |
| Gestation, wk                    | 37.5 (2.1) | 37.7 (1.5)  |
| Prematurity reported in          | 130 (90.9) | 1142 (96.2) |
| 34-36 wk                         | 21 (16.1)  | 106 (8.9)   | 1.6 (1.2-2.5) |
| <34 wk                           | 6 (4.6)    | 15 (1.3)    | 3.3 (1.3-8.4) |
| <37 wk                           | 27 (20.7)  | 121 (10.2)  | 1.8 (1.2-2.7) |
| Caesarean delivery               | 88 (61.5)  | 821 (69.7)  | 0.8 (0.7-1)   |
| Mother positive                  | 135 (94.4) | 1167 (98.3) |
| Roomed-in with mother            | 111 (77.6) | 800 (67.4)  | 1.16 (1.1-2.4) |
| Breastfeeding                    | 119 (83.2) | 998 (84.1)  | 0.97 (0.6-1.5) |

Values in no. (%) or mean (SD). bRR(95%CI)=0.7 (0.4-0.9); P=0.05; dRT-PCR for SARS-CoV-2.

DISCUSSION

In this large registry of neonates born to SARS-CoV-2 positive mothers, we report the incidence of neonatal infection, type of symptoms, and neonatal outcomes. Neonates acquired infection most commonly in the first 72 h after birth. The 5.1% neonates who tested positive on day one may have acquired the infection intrauterine or intrapartum. Those neonates who tested positive on days two or three may also have been due to intrauterine transmission but could have acquired the infection postnatally from mother, other family members, or healthcare providers. In the absence of serial testing and testing of various body fluids from mother, it is not possible to pinpoint the timing of acquisition. It is also to be noted that many neonates were tested for the first time on day three as per the local protocols, and the absence of testing on the first day after birth could have led to misclassification of the type of infection. We found a significantly higher incidence of perinatal transmission than that reported in a recent review [10].

This study highlights that SARS-CoV-2 positive neonates are more likely to be symptomatic, more likely to have respiratory symptoms, and other neonatal morbidities. However, the mortality is not increased significantly. In a systematic review by Raschetti, et al. [4], the median age at diagnosis was five days, and 53% of neonates were symptomatic [4]. Common symptoms reported include respiratory distress, fever, and those related to gastrointestinal illness. Most of the infected

Table II Clinical Features and Management of SARS-CoV-2 Infection in Intramural Neonates at Birth

| Parameters                        | SARS-CoV-2 | RR (95% CI) |
|----------------------------------|------------|-------------|
|                                  | Positive   | Negative    |
|                                  | (n=143)    | (n=1187)    |
| Resuscitation                    | 15 (10.4)  | 26 (2.1)    | 4.4 (2.4-8.2) |
| Symptomatic                      | 30 (21)    | 49 (4.1)    | 5 (3.3-7.7)   |
| RDS                              | 13 (9)     | 12 (1.1)    | 7.5 (3.4-16.8)|
| Pneumonia                        | 10 (7)     | 1 (0.08)    | 83 (10.7-643) |
| Sepsis                           | 5 (3.5)    | 1 (0.08)    | 41.5 (4.8-352)|
| Seizures                         | 5 (3.5)    | 6 (0.5)     | 6.9 (2.1-22.3) |
| Septic Shock                     | 6 (4.2)    | 6 (0.5)     | 8.3 (2.7-25.3) |
| DIC                              | 4 (2.8)    | 4 (0.3)     | 8.3 (2-32)    |
| Encephalopathy                   | 3 (2.1)    | 7 (0.6)     | 3.5 (0.93-13.6)|
| Jaundice                         | 6 (4.2)    | 6 (0.5)     | 8.3 (2.7-25.4) |
| Other morbidities                | 28 (19)    | 43 (4.5)    | 5.4 (3-8.4)   |
| Abnormal CXR                     | 16 (11.2)  | 7 (0.6)     | 18.9 (7.9-45.3)|
| Oxygen therapy                   | 11 (7.7)   | 27 (2.3)    | 3.3 (1.7-6.6) |
| CPAP                             | 7 (4.9)    | 13 (1)      | 4.5 (1.8-11)  |
| Ventilation                      | 8 (5.6)    | 14 (1.2)    | 4.7 (2-11.1)  |
| Surfactant                       | 5 (3.5)    | 7 (0.6)     | 5.9 (1.9-18.4)|
| Inotropes                        | 8 (5.6)    | 10 (0.8)    | 6.6 (2.6-16.5) |
| Corticosteroids                  | 4 (2.8)    | 2 (0.2)     | 16.6 (3-89.8) |
| IVIG                             | 0          | 1 (0.08)    | –             |
| Oseltamivir                      | 2 (1.4)    | 0           | –             |
| Mortality                        | 2 (1.4)    | 4 (0.3)     | 4.1 (0.76-22.4)|

Values in no. (%) or mean (SD). bRR(95%CI)=0.7 (0.6-0.9); P<0.01; cRR(95%CI)=0.7 (0.4-0.9); P=0.05; dRT-PCR for SARS-CoV-2.

Table III Demographics and Risk Factors in SARS-CoV-2 Positive and Negative Extramural Neonates

| Parameters                        | SARS-CoV-2 |
|----------------------------------|------------|
|                                  | Positive   | Negative    |
|                                  | (n=39)     | (n=65)      |
| Male gender                      | 22 (57)    | 32 (49.2)   |
| Weight, g                        | 2572 (600) | 2822 (582)  |
| Gestation (wk)                   | 36.9 (2.2) | 37.3 (1.7)  |
| Prematurity                      | 27         | 35          |
| 34-36 weeks                      | 4 (14.8)   | 2 (5.7)     |
| <34 weeks                        | 3 (4.6)    | 4 (1.3)     |
| Total <37 wk                     | 7 (19.4)   | 6 (7%)      |
| Caesarean delivery               | 17 (43.6)  | 43 (66.1)   |
| Mother positive                  | 26 (76.5)  | 62 (95.4)   |
| Roomed-in with mother            | 17 (43.6)  | 23 (35.9)   |
| Breastfeeding                    | 18 (48.6)  | 45 (70.3)   |

Values in no. (%) or mean (SD). bRR(95%CI)=0.7 (0.6-0.9); P<0.01; cRR(95%CI)=0.7 (0.4-0.9); P=0.05; dRT-PCR for SARS-CoV-2.
Symptomatic 13/27 (48) 6/36 (16.6) 2.9 (1.2-6.6)
RDS 13 (33.3) 8 (12.2) 2.7 (1.2-5.9)
Pneumonia 6 (15.4) 1 (1.5) 10.1 (1.2-81)
Seizures 4 (10.2) 1 (1.5) 6.6 (0.7-57)
Septic Shock 6 (15.4) 1 (1.5) 10 (1.2-80)
DIC 7 (17.9) 1 (1.5) 11.6 (1.5-91)
Encephalopathy 1 (2.6) 1 (1.5) 1.6 (0.1-25.8)
Diarrhoea 2 (5.1) 2 (3.1) 1.6 (0.2-11.3)
Other morbidities 11 (28) 2 (3.1) 9.1 (2.1-39)
Abnormal CXR 16 (11.2) 7 (0.6) 18.9 (7.9-45.3)
Oxygen therapy 10 (25.6) 4 (6.1) 4.1 (1.4-12.3)
CPAP 3 (7.7) 3 (4.6) 1.7 (0.3-8.2)
Ventilation 7 (17.9) 1 (1.5) 11.6 (1.5-91)
Inotropes 5 (12.8) 1 (1.5) 7.7 (0.9-64)
Corticosteroids 2 (5.1) 0 8.2 (0.4-167)
IVIG 2 (5.1) 0 8.2 (0.4-167)
Mortality 1 (2.6) 1 (1.5) 1.6 (0.1-25.8)

CXR: chest X-ray; IVIG: intravenous immunoglobulin; CPAP: continuous positive airway pressure; RDS: respiratory distress syndrome; DIC: disseminated intravascular coagulation. *P<0.001; **P=0.001; ***P<0.01; ****P<0.05; +Not significant.

Another important finding in our cohort is that SARS-CoV-2 infected neonates were significantly more likely to need resuscitation, be symptomatic, need NICU admis-
This large registry was created for the new COVID-19 disease within a short span of time after the WHO’s announcement of the pandemic and data was contributed by 20 hospitals on a voluntary basis across the country. The most important limitation, as highlighted above, was non-uniformity in age at testing of neonates born to SARS-CoV-2 positive mothers. As this was a registry-based study, testing of other biological sources like amniotic fluid, placenta, blood, or breastmilk was not pursued. We also did not test for the presence of specific antibodies in the neonatal blood to look for intrauterine infection as suggested by a recent guideline to classify the type of neonatal infection [7]. We did not capture data for neonates with the possibility of multi-system inflammatory syndrome in children (MIS-C) following SARS-CoV-2 infection, which is recently being reported [21].

In conclusion, our study provides important data on neonatal infection, clinical features, and outcomes in neonates born to SARS-CoV-2 positive women. This information can be used to make informed decisions and policies on neonatal SARS-CoV-2 testing, healthcare organization for neonates born to SARS-CoV-2 positive women, and counseling of families regarding various management options.

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Contributors: KM: initiated and wrote the proposal for the registry and created a data collection form, analyzed the data, and finalized the first draft of the manuscript; BT, SM and PK: facilitated the creation of the data registry on web-portal hosted by the Indian Neonatal Collaborative (INCC), India; BT: coordinated data collection and helped to extract relevant data from the portal; SM: wrote the introduction and methods sections, helped in biostatistics and approved the final draft of the manuscript; DC: reviewed the analysis, results section and wrote an interpretation of data and discussion; AD: approved the proposal, encouraged and coordinated hospitals’ participation through National Neonatology Forum, India and reviewed the final draft of the manuscript; PK: approved the proposal, created a registry on the portal, encouraged hospitals’ participation and approved the final draft of the manuscript. All the remaining Collaborators contributed significantly towards data collection and sharing from their respective institutes, and also reviewed and approved the final draft of the manuscript.

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ANNEXURE

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