ARTICLE

Developmental screening of full-term infants at 16 to 18 months of age after in-utero exposure to maternal SARS-CoV-2 infection

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OBJECTIVE: To screen for neurodevelopmental delays in a cohort of full-term infants born to mothers with SARS-CoV-2.
STUDY DESIGN: This was a prospective, descriptive cohort study of full-term infants born to mothers with SARS-CoV-2 during pregnancy. Subjects underwent neurodevelopmental screening using the Ages and Stages Questionnaires®-Third Edition (ASQ®-3) at 16 to 18 months age.
RESULTS: Of 51 subjects, twelve (24%) were below cutoff, and twenty-seven (53%) were either below or close to the cutoff in at least one developmental domain. Communication (29%), fine motor (31%), and problem-solving (24%) were the most affected domains. There were no differences in outcomes between infants born to asymptomatic and mildly symptomatic mothers.
CONCLUSION: We observed increased risk of neurodevelopmental delays during screening of infants born at full-term to mothers with SARS-CoV-2 at 16 to 18 months age. These results highlight the urgent need for follow-up studies of infants born to mothers with SARS-CoV-2.

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INTRODUCTION

Coronavirus disease 2019 (COVID-19) pandemic caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has resulted in significant morbidity and mortality throughout the world. Pregnant mothers with SARS-CoV-2 infection are more likely to deliver prematurely, require respiratory support and intensive care unit (ICU) admission [1]. Additionally, infants born to mothers with COVID-19 are more likely to have morbidities associated with being born premature and require neonatal intensive care unit (NICU) admission. However, the impact of in-utero exposure to maternal SARS-CoV-2 infection on long-term infant neurodevelopment outcomes is currently unknown.

Studies have shown that the vertical transmission of SARS-CoV-2 occurs rarely. Nevertheless, activation of the maternal immune response could impact the long-term outcomes in children as observed after other maternal viral infections. While some intra-uterine viral infections, such as ToRCH (Toxoplasma, rubella, cytomegalovirus, and herpes), human immunodeficiency virus and Zika, can cause direct effects on neurodevelopmental outcomes of children through invasion of brain tissues [2–4], other viruses, such as influenza, may cause adverse neurodevelopmental effects via maternal and placental immune activation [5, 6]. Recent flu epidemics in the 21st century have indicated that maternal influenza infection might have long-term effects on children even after infancy, necessitating the need for life course studies [7, 8]. Activation of maternal immune response, increased inflammation and altered cytokines expression have been postulated as some of the mechanisms causing long-term effects among infants [9–13]. Prematurity is a known risk factor for neurodevelopmental delays necessitating closer follow-up, but those who are born at full-term after maternal SARS-CoV-2 need to be carefully evaluated to understand if they could be at increased risk as well. Additionally, the differential impact of symptomatic or asymptomatic maternal SARS-CoV-2 infection status as well as maternal illness severity remains unknown. Our institution was at the epicenter of the COVID-19 pandemic in March 2020 in New York City. We studied full-term infants born to mothers with confirmed SARS-CoV-2 at our center and report preliminary findings of developmental screening performed with the Ages and Stages Questionnaires®-Third Edition (ASQ®-3) at 16 to 18 months of age comparing the results to previously reported population norms using ASQ®-3.

METHODS

This was an institutional review board approved, prospective descriptive cohort study of full-term infants (≥37 weeks' gestation age) born to mothers with confirmed SARS-CoV-2 infection from a large academic tertiary care center in New York City. The study included mothers who tested positive for SARS-CoV-2 by real-time reverse transcriptase

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polymerase chain reaction of nasopharyngeal swabs, documented anytime during pregnancy on outpatient or inpatient visits between March 1, 2020, and July 31, 2020. During the study period, maternal testing was initially done based on symptoms and then ultimately via universal screening of all those admitted to labor and delivery unit (started on March 30, 2020) [1, 14]. Infants born premature (<37 weeks gestational age) or those with known major congenital/genetic diagnoses were excluded. Eligible maternal-infant dyads were identified from the hospital electronic medical records using DataCore, which is an institutional resource that provides enterprise-level support in the areas of electronic data capture, storage, and management. Identified subjects were then contacted via telephone with a standardized recruitment script to request study participation. Once consent was obtained, the subjects were asked a series of questions including a brief interim medical history for the infant.

A standardized validated tool, the ASQ®-3, was administered by trained personnel via telephone for screening of neurodevelopment in five domains (communication, fine and gross motor, problem solving, and personal social skills) at 16–18 months age [15]. Each domain was individually scored into three categories, as defined by the ASQ®-3 technical manual: 1) above the cutoff (corresponding to normal development), 2) close to the cutoff (corresponding to between 1 and 2 standard deviations below the mean), and 3) below the cutoff (corresponding to ≥2 standard deviations below the mean) [15, 16]. ASQ®-3 is an effective and easy to administer screening tool for detecting neurodevelopmental delays. It is one of the screening tools recommended by the American Academy of Pediatrics [17]. The sensitivity and specificity of ASQ®-3 ranges from 70-100% with overall agreement of 85%. The concurrent validity of ASQ®-3 as measured by comparing the percentage of agreement between the results of the parent-completed ASQ®-3 questionnaires with the results of professionally administered standardized assessments is about 85% [15–17].

The study team collected data on maternal-newborn hospitalization and demographic information for the included subjects with consent. Maternal data included mother's age, gestation age at delivery, parity, number of newborns, comorbid conditions among mothers, rupture of amniotic membranes, *group B Streptococcus* colonization status of the mother, maternal symptoms, medications received by mother during pregnancy, timing of SARS-CoV-2 infection with respect to delivery, diagnosis of chorioamnionitis, method and reason for delivery. Infant data included anthropometric data at birth (birth weight, length and head circumference), sex, need for resuscitation at delivery, Apgar scores at 1 and 5 min of life, admission to neonatal intensive care unit, appropriate, large or small for gestation age, and presence of any symptoms after birth. Mean, median and percentages were used for descriptive data. Categorical variables between symptomatic [14] and asymptomatic mothers were compared using Fisher's exact test on IBM-SPSS® 24.0. A P value < 0.05 was considered significant.

RESULTS

Seventy-eight families were approached, of whom 51 (65%) provided consent and completed the ASQ®-3. Mean (standard deviation [SD]) maternal age was 30.5 (SD 6.1) years and infant mean gestation age at birth was 39.4 (SD 1.2) weeks. Twenty-one (41%) mothers were symptomatic, of whom ten (20%) reported symptoms ≤14 days prior to their hospitalization for delivery and eleven (22%) reported symptoms >14 days prior to their hospitalization for delivery. None of the mothers required respiratory support or intensive care in this cohort. The most common maternal symptoms included cough, fever, and myalgia. None of the mothers were diagnosed with chorioamnionitis in this cohort. Maternal and neonatal demographic information are described in Table 1. Thirty-six (71%) infants were tested for SARS-CoV-2 after birth, and all were resulted negative. None of the infants in this cohort required rehospitalization within one month after discharge from newborn nursery. Mean age of subjects at ASQ®-3 screening was 17.2 (SD 1) months. Twelve (24%) subjects were below cutoff in at least one domain. Twelve subjects (24%) were below cutoff in at least one domain. Cumulatively, 27 subjects (53%) were either below or close to the cutoff in at least one developmental domain. Of five domains, communication, fine motor, and problem-solving were most affected as either below or close to the cutoff, in 29%, 31% and 24% subjects, respectively (Fig. 1).

Table 1. Baseline maternal and neonatal demographics.

Baseline demographics	***n* = 51**
Gestational age, weeks[a]	39.4 ± 1.2
Maternal age, years[a]	30.5 ± 6.1
Cesarean delivery, %	25
Female, %	53
Apgar score, median	
−1 min	9 (IQR 8–9)
−5 min	9 (IQR 9–9)
Birth weight, g[a]	3343 ± 379
NICU Admission[b]	1 (2%)
AGA/LGA/SGA	49/1/1 (96/2/2%)
Age at ASQ®-3[a]screening, months	17.2 ± 1
Public Insurance, %	47
COVID Symptoms of those symptomatic (cough/fever/loss of smell)	60/50/20%

IQR interquartile range, *NICU* neonatal intensive care unit, *LGA* large for gestation age, *AGA* appropriate for gestation age, *SGA* small for gestation age, *n* number of subjects.
[a]Data expressed in mean ± standard deviation.
[b]one baby was admitted to the NICU for brief observation only.

There were no significant differences between subjects who were either below, and/or close to the cutoff born to asymptomatic and symptomatic mothers regardless of timing of symptoms during pregnancy (Table 2).

DISCUSSION

In this study, we observed about one in four infants born at full-term to mothers with SARS-CoV-2 during pregnancy were at risk for developmental delays determined by having at least one developmental domain below cut-off on ASQ®-3 screening at 16 to 18 months of age. Additionally, we observed no differences in outcomes between infants born to asymptomatic and mildly symptomatic mothers with SARS-CoV-2. These results highlight the urgent need for follow-up studies of infants born to mothers with SARS-CoV-2.

The literature on ASQ®-3 developmental screening of low-risk full-term infants show a positive screen in 12.6–13.6% children in at least one developmental domain [15, 18]. In our study cohort, we observed that 24% of subjects were 'below cutoff' in at least one developmental domain and an additional 29% were 'close to the cutoff' in at least one domain, significantly more than what would be expected for a medically low-risk cohort of full-term infants without any genetic or congenital anomalies. These results are similar to preliminary evidence from other emerging epidemiological studies suggesting association of maternal SARS-CoV-2 with neurodevelopmental sequelae in some offspring [19]. Edlow et al. observed greater rate of neurodevelopmental diagnoses in 222 infants born to SARS-CoV-2 positive mothers at 12 months of age after adjusting for multiple confounding factors including prematurity (adjusted OR 1.86, CI 1.03–3.36, $P = 0.04$), particularly during third-trimester maternal infection [19]. However, their study relied on *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* diagnostic codes, which may lead to misclassification and lacks the sensitivity of a prospective neurodevelopmental screening such as in our study. Shuffrey and colleagues concluded in their study that birth during the pandemic and not in-utero exposure to

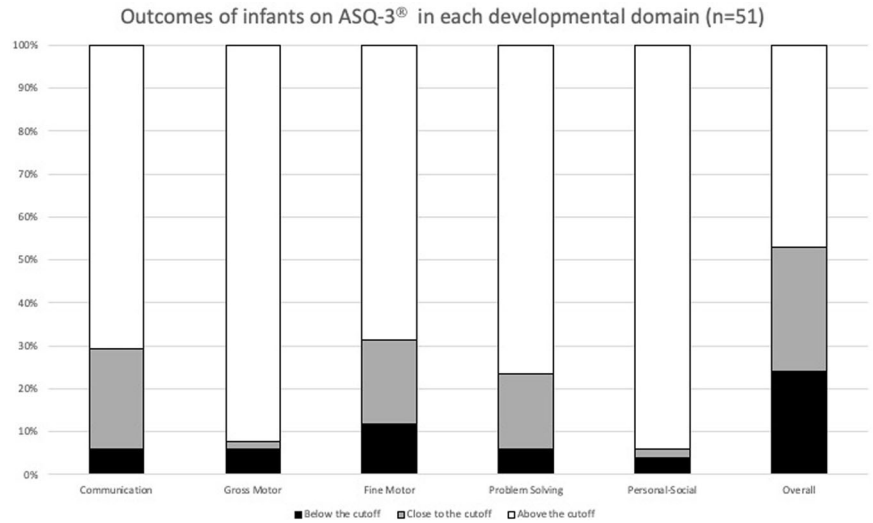

Fig. 1 Outcomes of infants on ASQ®-3 in five developmental domains (communication, gross motor, fine motor, problem-solving, and personal-social) among all subjects as well as for overall cohort. Each domain is scored into three categories: 1) above the cutoff (corresponding to normal development within or above age expectations), 2) close to the cutoff (corresponding to between 1 and 2 standard deviations from the mean), and 3) below the cutoff (corresponding to ≥ 2 standard deviations from the mean). *x*-axis shows five individual developmental domains and overall cohort development, *y*-axis represents percentages of subjects under three categories (n = number of subjects).

Table 2. Comparison of neurodevelopmental screening between children born to asymptomatic or symptomatic mothers with SARS-CoV-2 infection.

	All patients, $n = 51$	Asymptomatic (reference group), $n = 30$	Symptomatic ≤ 14 days, $n = 10$	*P* value	Symptomatic anytime during third trimester, $n = 21$	*P* value
Below cutoff, *n* (%)	12 (24)	5 (17)	1 (10)	0.99	7 (33)	0.20
Only close to cutoff, *n* (%)	15 (29)	8 (27)	5 (50)	0.24	7 (33)	0.76
Either below *or* close to cutoff, *n* (%)	27 (53)	13 (43)	6 (60)	0.47	14 (67)	0.15

Symptomatic mothers are further subdivided into those who had symptoms ≤14 days or any time before delivery (n = number of subjects).

maternal SARS-CoV-2 infection was associated with differences in neurodevelopment at 6 months of age [20]. Both these studies had limited duration of follow-up until maximum one year of age, which may not yet identify risk in subjects on developmental screening assessment when compared to 16 to 18 months of age as performed in our study.

Similar to prior studies, we observed increased concerns in communication, fine motor, and problem-solving neurodevelopmental domains [20–22]. Other than possibility of these preliminary findings being related to the effects on fetus from maternal immune response after SARS-CoV-2 infection, it could also possibly reflect societal and behavioral changes or stressors that occurred during COVID-19 pandemic including reduced play activities among children during this pandemic [22–26]. The precise causes of phenotypic variability after any prenatal maternal viral infection are currently unknown [27]. Therefore, it would be important to differentiate impact of maternal immune activation to those from pandemic related effects on infant neurodevelopment in future studies.

In this cohort of mothers with asymptomatic or mild symptomatic infection, there was no difference in outcomes of their children due to symptomatic maternal status. Most symptomatic mothers with SARS-CoV-2 requiring respiratory support or intensive care delivered prematurely and therefore excluded from this study. However, national data suggests that vast majority of mothers with SARS-CoV-2 deliver at full-term and have asymptomatic or mild infection [28]. At the beginning of COVID-19 pandemic in early 2020, about one in four women aged 15–49 years who had a COVID-19 associated hospitalization was pregnant, based on a *Morbidity and Mortality Weekly Report* from the CDC [29]. It is important to follow infants born to mothers with SARS-CoV-2 during this particularly vulnerable pre-vaccine era. Therefore, it is important to screen these infants in studies like ours from an epidemiological and public health perspective.

Our study has limitations. It has a small sample size from a single center. The maternal subjects in this cohort had mild symptomatology so we did not have the ability to compare outcomes of those infants whose mothers had severe symptoms versus those who were asymptomatic. We do not know if those maternal subjects who declined to participate had more severe symptoms. There is a possibility of ascertainment bias due to likelihood that parents who had concerns for development of their child were more likely to participate in the study, although standardized information was presented to parents while obtaining consent. There is absence of ideal comparable cohort of full-term, medically low risk infants who were born to mothers with negative SARS-CoV-2 testing during similar timeframe of pandemic accounting for psycho-social, economic and biologic exposure variables as opposed to standardized ASQ®-3 historical averages. The added stressors during the pandemic of inconsistent childcare, food insecurity, job and housing losses could confound the risk of having further developmental delays [22–25].

Our study was limited in that we do not have broad socioeconomic data about this cohort, which we understand can have a large impact to infant development. Finally, while ASQ®-3 is a validated questionnaire that can be administered virtually, however, it would be important to have follow up with in-person assessments to further identify degree of developmental delays.

Despite these limitations, it is clear that further research is warranted to study long-term effects on infants born to mothers with SARS-CoV-2 during pregnancy. Findings of this study add to the evidence of possible risk for neurodevelopmental delays in infants due to maternal COVID infection. Additionally, study such as ours are important in contributing to a sample size calculation for a future multicenter study. While infants of mothers more severely affected and delivered prematurely are likely to be at increased risk for adverse neurodevelopmental outcomes, this study shows that the monitoring of infants whose mothers were asymptomatic or mildly symptomatic with SARS-CoV-2 infection and progressed to full-term for delivery is warranted as well. Studies which follow these children will be important to document longer term neurodevelopmental problems in full-term infants [30, 31]. We plan to continue following this cohort of infants longitudinally and perform additional assessments in future to see if there are any long-term implications in these infants. The landscape of COVID-19 pandemic has been rapidly evolving with new variants, effective vaccinations, and COVID-specific therapies [32]. The impact of maternal infection with other variants and timing of infection with respect to delivery [33] would need to be studied as well. Lastly, there is little to no understanding about how maternal immunization may play role in immune response among those with symptomatic or asymptomatic infections.

In conclusion, we observed increased risk of neurodevelopmental delays during screening of infants born at full term to mothers with SARS-CoV-2 at 16 to 18 months of age when compared to historical population norms using ASQ®-3. Additionally, we observed no difference in outcomes between infants born to asymptomatic and mildly symptomatic mothers with SARS-CoV-2. These results highlight the urgent need for follow up studies of infants born to mothers with SARS-CoV-2.

DATA AVAILABILITY

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

AVS, HBH, and SV conceptualized and designed the study, collected data, coordinated and supervised data collection, carried out analysis, drafted the initial manuscript, and reviewed and revised the manuscript. SHK conceptualized and designed the study, designed the data collection instruments, and critically reviewed and revised the manuscript. MZ, FES, TG, PM conceptualized and designed the study, performed acquisition of data, and critically reviewed and revised the manuscript for important intellectual content. BD conceptualized the study, helped with interpretation of data, critically reviewed, and revised the manuscript for important intellectual content.

COMPETING INTERESTS

The authors declare no competing interests.

ETHICAL APPROVAL

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

ADDITIONAL INFORMATION

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